The Acceptability and Efficacy of Wearable Devices in Digital Mental Health

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ABSTRACT

Rapid advancements in technology through the early twenty-first century have led to the emergence of a new paradigm in mental health, in which digital platforms could become a fundamental part of mental healthcare delivery. Wearable devices, which are computational devices worn on the body, might form an important element of these new approaches by capturing and interpreting physiological data associated with psychological states. This thesis presents a series of studies investigating the range of wearable devices for the treatment of mental health problems, the perceived acceptability of these devices, and the evidence for one specific device modality, aided meditation.

In Study 1, a literature review was conducted to identify wearable devices that could be used in the treatment of anxiety-related symptoms, determine what supporting evidence existed for each device modality, and explore potential clinical implications of using those devices. The review identified early-stage evidence for the use of heart rate variability biofeedback devices, but limited research on other modalities, indicating a need for further high-quality research.

Study 2 surveyed a community sample of 427 adults to investigate perceived acceptability of wearable devices for treating mental health problems. Interest in using wearable devices as adjuncts to conventional therapy was strong, with acceptability closely linked to perceived device effectiveness (β = 0.28-0.30). Wearable devices also appeared to have greater acceptability in the presence of negative attitudes toward conventional therapies, suggesting they might help reduce barriers to treatment.

Studies 3 and 4 focused on evaluating one particular device: the Muse electroencephalogram (EEG) meditation headband. In these studies, 68 adult participants

used the device during a series of lab-based meditation tasks, with a subset (*n* = 29) also completing 14 days of home practice. Study 3 investigated the potential of the headband measures to assess state mindfulness, a process variable linked to psychological benefits resulting from meditation practice. The primary headband measure showed sensitivity to both within-participants (*d* = 0.56) and between-participants (*r* = -0.50) differences on a task measure of state mindfulness. Aggregate measures over 14 days' practice explained around 30% of variance in self-reported trait mindfulness and related constructs. EEG biomarkers thus appear to have potential as a novel objective method of mindfulness measurement.

Study 4 used a crossover trial design (auditory feedback of the primary headband measure vs no feedback) to examine the effect of receiving feedback. The feedback condition resulted in a higher level of state mindfulness (*RR* = 1.15), a lower level of the primary headband measure (*d* = -0.22), and differences in subjective experience of meditation. These results suggest that with appropriate guidance, feedback may be an effective adjunct to meditation.

Together, these studies support the notion that wearable devices could be effective and engaging adjunctive digital mental health interventions. The results support the use of synchronous feedback of practice quality data to enhance the therapeutic benefits of meditation practice, and were consistent with the mechanisms through which neurofeedback is theorised to function. Continuing engagement with wearable devices by both researchers and clinicians is recommended.

DECLARATION

I certify that this work contains no material which has been accepted for the award of any other degree or diploma in my name, in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint-award of this degree. I acknowledge that copyright of published works contained within this thesis resides with the copyright holder(s) of those works. I also give permission for the digital version of my thesis to be made available on the web, via the University's digital research repository, the Library Search and also through web search engines, unless permission has been granted by the University to restrict access for a period of time. I acknowledge the support I have received for my research through the provision of an Australian Government Research Training Program Scholarship.

Published Works

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CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

This thesis considers an emerging group of digital mental health technologies known as wearable devices, and their potential use in the treatment of mental health problems. Wearable devices, which are computational devices worn on the body, are an emerging class of digital mental health interventions that typically work by capturing and interpreting the physiological data associated with psychological states. The present introductory chapter provides a review of related research on wearable devices. Chapter 2 consists of an exegesis detailing the reasoning underpinning the four studies that constitute this thesis. Chapters 3 and 4 present the first two studies, which take a broad focus on wearable devices of any modality. The final two studies evaluate the use of a specific device modality, EEG neurofeedback-assisted meditation, and these are presented in Chapters 5 and 6. Finally, Chapter 7 completes this thesis by summarising the results and discussing relevant implications, strengths, limitations, and future research directions.

This introductory chapter will describe what wearable devices are and explain the rationale for using them to address current challenges in mental health. The Muse EEG meditation headband is then introduced, along with a review of empirical and theoretical research into neurofeedback-assisted meditation within the context of the meditation and mindfulness literature. Next, this introduction reviews some of the research about the acceptability of wearable devices and digital mental health interventions more generally. The chapter concludes with a brief summary of the literature and how it informs the broad purpose and approach of the present thesis.

1.1 Current Challenges in Mental Health

Common mental health disorders such as depression and anxiety rank as some of the most burdensome non-communicable diseases globally, with the burden falling disproportionately on those of lower socioeconomic status (Abajobir et al., 2017; Rehm & Shield, 2019; Vigo et al., 2016). There is a significant global "treatment gap" between those who need access to evidence-based mental health treatments and those who can access them (Alonso et al., 2018; Demyttenaere et al., 2004; Thornicroft et al., 2017). This gap is attributed to attitudinal factors such as a desire to handle one's own problems and help-seeking stigma, as well as structural factors like financial barriers and a lack of available services (Andrade et al., 2014; Corrigan et al., 2014). The treatment gap has persisted in countries such as Australia, Canada, the United Kingdom, and the United States despite increases in the provision of treatment over the last three decades (Jorm et al., 2017; Meadows & Burgess, 2009). Given the need to bridge this gap, there is a recognised need for scalable treatments that can increase access to evidence based interventions (Bower & Gilbody, 2005; Kazdin, 2019). The development of new intervention approaches using latest technology has been identified as an important research direction in addressing the treatment gap (Fairburn & Patel, 2017; Wykes et al., 2015).

1.2 Wearable Devices

Wearable devices are an emerging new class of digital mental health interventions which can perhaps most simply be described as computational devices worn on the body. There appears to be no agreement on a common definition for these devices but important features described in the literature are summarised in Table 1. Perhaps the most studied application of wearable devices is in the area of healthcare (Erdmier et al., 2016; Wu & Luo, 2019) although they have also been leveraged for a wide range of other applications (Park et al., 2014) including occupational health and safety (Mardonova & Choi, 2018), high performance sport (Kos & Kramberger, 2017), cognitive assistance (Chen et al., 2015), entertainment (Mann et al., 2007), and augmenting workforce capabilities (Kumar et al., 2018). The apparent focus on healthcare can be ascribed to the growing availability and consumer interest in wearable devices, as well as their ability to collect large amounts of physiological and behavioural data in a minimally invasive way (Erdmier et al., 2016). Examples of data measured from wearables include levels of physical activity and mobility, falls, posture, gait, respiration rate, heart rate, blood glucose level, blood pressure, blood oxygen saturation, muscular response (electromyography), neural activity (electroencephalography), body or skin temperature, and galvanic skin response (Chen et al., 2015; Izmailova et al., 2018; Wu & Luo, 2019). Some wearable devices are designed specifically for consumer use, while others are developed to be used by clinicians (Wu & Luo, 2019).

Table 1
Key features of wearable devices described in the literature

Feature	Source(s)
Provides computing functionality to the user	Buenaflor & Kim, 2012
Context awareness	Buenaflor & Kim, 2012
May be continuously worn or always-on	Buenaflor & Kim, 2012
Continuously monitors the user's physiology and/or behaviour	Chan et al., 2012; Coffey & Coffey, 2016; Gao et al., 2016
Form factor that does not restrict the physical movement of the user	Gao et al., 2016; Park et al., 2014
Can be used anywhere (mobility) and anytime (availability)	Kim & Shin, 2015
Low cost	Chan et al., 2012
Low power consumption	Chan et al., 2012

1.2.1 Mental Health Applications

Although the majority of wearable devices available today are used with the aim of improving physical health, wearable devices also have potential to enhance mental health assessment and intervention. Firstly, wearable devices could help the user to recognise and change physiological responses that are associated with psychological problems (Schoenberg & David, 2014). The interconnection between mental states and bodily experiences is well-acknowledged in contemporary models of health, such as the biopsychosocial model (Engel, 1977). This link is also evident in current mental healthcare frameworks: for example, a commonly used cross-sectional case formulation model in cognitive behavioural therapy views physical sensations as being in constant interaction with cognitions, affect, and behaviour (Padesky & Mooney, 1990). Changing maladaptive physiological responses might therefore promote more adaptive thoughts, feelings, and actions.

A second way in which wearable devices might be relevant is by detecting the wearer's mental state or behaviours. Using machine learning, data from wearable device sensors such as respiration rate, heart rate, and electrodermal activity can be used to infer internal states like emotions (Ihmig et al., 2020; Vallejo & El Saddik, 2019). Other information, such as accelerometer, gyroscope and location data, could be used to derive behavioural markers such as stress, fatigue, or social avoidance (Mohr, Zhang, et al., 2017). This information is then fed back to the wearer to support their ability to recognise psychological states and behaviours, enabling interventions to be delivered on demand to promote healthy self-regulation. In short, the physiological metrics which can be measured by wearable devices may be important treatment targets themselves whilst also providing valuable information about underlying cognitive, affective, and behavioural processes, complementing conventional assessment and intervention techniques that rely upon self-report measures.

1.2.2 Biofeedback and Neurofeedback

Many wearable devices appear to be based upon biofeedback and neurofeedback techniques. Biofeedback is a type of self-tracking developed in the late 1950s (Schwartz et al., 2016). It involves the precision measurement of physiological activity such as breathing, muscle activity, or heart function (Association of Applied Psychophysiology and Biofeedback, 2021). This physiological information is then provided as feedback to the user, typically through visual or auditory cues, which serve to reward the attainment of a desired physiological state. For example, an auditory cue could be presented whenever a trainee's respiration rate is below eight breaths per minute. A central mechanism through which biofeedback is thought to function is operant learning: by rewarding the trainee, their efforts toward the goal state are reinforced (McKee, 2008; Weerdmeester et al., 2020). Other potential mechanisms of biofeedback include the modulation of attention, self-efficacy, locus of control, and threat appraisal (Weerdmeester et al., 2020). Biofeedback approaches have been used to treat a wide variety of presenting problems, including a range of psychosomatic complaints as well as other pathological states such as anxiety (Gilbert & Moss, 2012; Schoenberg & David, 2014).

Neurofeedback is a distinct type of biofeedback in which the training is based upon a neural signal, such as EEG (Schwartz et al., 2016). The EEG, which represents the postsynaptic potentials of neurons in the cortex (Read & Innis, 2017), can be electronically filtered in order to determine the amplitude within specific frequency bands including delta (1-4hz), alpha (8-12hz), and beta (13-21hz; Demos, 2005). Higher amplitudes within certain bands have been empirically associated with particular types of neural activities: for example, delta amplitudes tend to be higher during sleep, while higher beta amplitudes are associated with thinking and focusing (Demos, 2005). Clinical applications of neurofeedback have generally aimed to enhance specific frequency bands, or to increase coherence between different cortical regions (Demos, 2005; La Vaque, 2012; Schwartz et al., 2016). Two fundamental assumptions of neurofeedback are, firstly, that trainees are able to change neural dynamics in the desired direction, and secondly, that these changes in neural dynamics in turn bring about functional change, or in other words, address a particular neurological or psychiatric condition (Papo, 2019; Thibault & Raz, 2017). There is some evidence for the use of neurofeedback in managing epileptic seizures and treating attention deficit hyperactivity disorder (ADHD), with ongoing research to evaluate other potential applications for conditions such as anxiety, depression, and substance use problems (La Vaque, 2012).

The availability of wearable devices utilising biofeedback and neurofeedback is expanding in the consumer marketplace. For example, the HeartMath range of products provides biofeedback of heart rate variability (HeartMath, 2022). Neurofeedback devices on the market include the Muse (InteraXon Inc., 2020b), MindWave (NeuroSky Inc., 2022), and Insight (Emotiv Inc., 2022) devices which are limited-channel EEG headbands with associated smart device applications that can facilitate neural training. Wearable devices such as these could increase the accessibility of evidence-based biofeedback- and neurofeedback-based interventions, although it is unclear whether results obtained using clinical-grade measurement devices can be reliably reproduced with consumer-grade devices.

1.2.3 Wearables in Clinical Practice

Given the potential mental health applications of wearable devices, an important question is how they might effectively be utilised in clinical practice. The market for wearables is expected to continue to grow strongly over the near term (International Data Corporation, 2020), suggesting that there will be increasing availability of these devices and interest in using them. However, it is currently unclear how this growing range of wearables could be incorporated adjunctively into treatment and what implications would arise from this. The broader literature on digital mental health interventions suggests a range of potential benefits such as reduced clinician involvement for lower intensity treatments, real time risk monitoring, just-in-time adaptive interventions, skills generalisation in ecologically valid settings, and increased engagement with homework (Lui et al., 2017; Mohr, Zhang, et al., 2017; Naslund et al., 2017; Torous et al., 2015). However, these are largely hypothetical advantages which are yet to be widely realised. Furthermore, digital mental health interventions such as wearables could have associated disadvantages or risks such as attitudinal or practical barriers to uptake, increased social isolation, low engagement, poor data security, and poorer skills development (Aboujaoude & Gega, 2020; Clarke & Yarborough, 2013; Garrido et al., 2019; Mrazek et al., 2019; Rudd & Beidas, 2020). This suggests that significant care must be taken if wearable devices are to be effectively utilised in clinical practice.

The limited use of wearable devices in clinical practice to date may be attributed to several factors. Wearables have generally been marketed as enhancing wellbeing rather than addressing clinical problems, perhaps due to the regulatory burden associated with developing a medical device (Erdmier et al., 2016). Devices are therefore less likely to have features designed for clinical use, such as clinician access portals. The lack of information on how to incorporate these devices into practice may also limit uptake. Possibly the biggest barrier, however, is that scientific knowledge remains scant in regard to the range of available devices, the modalities through which they claim to work, and the evidence supporting them (Piwek et al., 2016; Torous & Gualtieri, 2016). A greater evidence base is therefore needed to help clinicians navigate this growing range of wearable interventions for mental health.

1.3 Supporting Meditation with Wearable Devices

One potential way that wearable devices might be leveraged in digital mental health treatments is as an aid to meditation. The term "meditation" encompasses a collection of contemplative practices, some of which have been shown to have therapeutic benefits for common mental health problems like anxiety and depression (Creswell, 2017; Goldberg et al., 2018). However, there appear to be a number of barriers to successful meditation practice, such as a perceived lack of intrinsic reward, a poor understanding of the aim of meditation, and difficulty knowing whether one is practicing this behaviour effectively (Banerjee et al., 2017; Hunt et al., 2020; Moss et al., 2008; Russell et al., 2018).

This section now introduces the Muse EEG meditation headband, which is a commercially-available wearable device developed to provide neurofeedback-based guidance during meditation. It then describes the concept of meditation in greater detail and reviews the theoretical and empirical basis of neurofeedback-assisted meditation. The final part of this section discusses the construct of mindfulness and explains why mindfulness may be an important factor in deriving benefits from meditation.

1.3.1 Muse EEG Meditation Headband

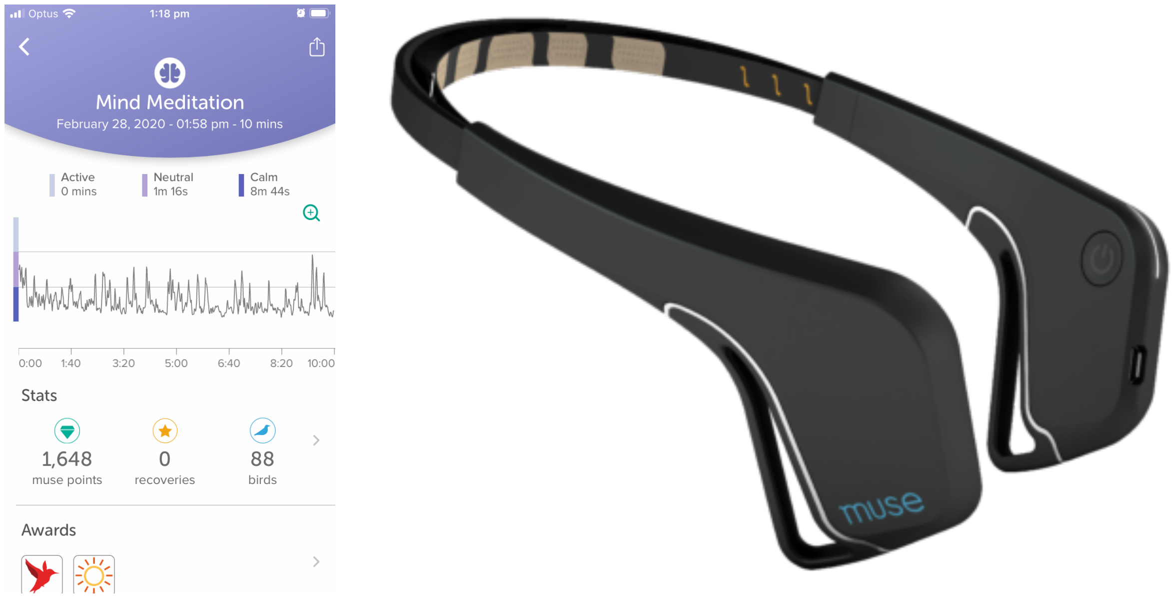
Muse is a series of consumer-grade EEG headbands and associated smart device apps that have been developed to support meditation through neurofeedback. The headbands feature a dry electrode design, avoiding the need for bulky electrode caps or conductive gel typically used with clinical-grade EEG devices. Figure 1 presents the 2016 variant of Muse (InteraXon Inc., 2017) used in the studies herein, which is fitted across the forehead and rests behind the ears. This version features four electrodes approximating the TP9, AF7, AF8, and TP10 standard montage positions, as well as a reference electrode at Fpz. The frontal positions utilise silver electrodes while the temporal electrodes consist of conductive silicon-rubber. The headband has a sampling rate of 256hz, at 12 bits per sample. Current models of Muse with similar features to the device described here can be purchased for between $249-399 USD.[1]

The Muse app utilises a proprietary algorithm to putatively monitor attentional fluctuations during meditation, which are classified into three bands: active, neutral, and calm (Interaxon Inc., 2020). Synchronous neurofeedback is provided to meditators during their

[1] At time of writing, January 2022.

Figure 1

Muse app and EEG headband



meditation, through a dynamically changing soundscape that reflects the measured degree of attention. For example, in the "beach" soundscape, focused attention is represented by gentle waves lapping and light winds while wandering attention results in heavy crashing waves and strong winds. When meditators achieve a prolonged period of focused attention, they are rewarded by the sound of birds tweeting. In addition to synchronous feedback, meditators receive asynchronous feedback through a summary report after each meditation, logging their attentional focus at each moment, and tracking the number of birds and "recoveries" from periods of wandering attention. The app includes several other gamification features, such as a system of levelled challenges, milestones, weekly goals, and "Muse points" (earned from focused attention, birds, and recoveries during each meditation session). An online clinician platform is also available, which allows clinicians to monitor the meditation progress of participating clients.

1.3.1.1 Validity of Muse EEG Measurement. Several studies have been conducted to evaluate the validity and utility of the raw EEG data obtained from Muse. Ratti et al.

(2017) compared Muse with two medical-grade EEG devices. They found that Muse was more prone to artifacts from eye blinks and muscle movement, and tended to have increased power spectral densities relative to the medical-grade devices. Muse also had the poorest test-retest reliability of the devices, perhaps due to inconsistencies positioning the headband and in obtaining good scalp connectivity with dry electrodes. The authors concluded that Muse has limitations but may still provide useful data for some purposes. The issue of artifacts may be somewhat ameliorated using appropriate correction algorithms. Furthermore, although the limitations found by Ratti et al. may compromise the ability to capture good quality absolute EEG data, these issues may not affect the ability to accurately detect relative changes in power spectral density throughout a session. This point is well demonstrated by two further studies using Muse. The first paper demonstrated that it was possible to use Muse to reliably measure three commonly-studied event-related potentials (N200, P300, and reward positivity; Krigolson et al., 2017). Although Muse was somewhat less reliable than research-grade equipment, the authors determined that comparable results could be achieved with only a small increase in the number of samples. In another study, Karydis et al. (2015) showed that Muse could be used to reliably distinguish pain states using machine learning. These studies together suggest that, although EEG data derived from Muse has poorer validity and reliability than high-grade EEG devices, it may nonetheless be appropriate for some applications.

1.3.1.2 Efficacy of Muse. A separate body of research has evaluated the effects of meditating with Muse neurofeedback on outcomes related to mental health. Balconi et al. (2018) conducted a randomised trial over four weeks, in which healthy participants were asked to perform breath-focused meditation for 10 minutes per day, increasing to 20 minutes per day by the end of the study. The experimental group used Muse, while an active control group practiced with a similar, but not dynamic, auditory stimulus (i.e., without neurofeedback). Participants in the experimental group had significantly greater reductions in subjective measures of stress, state anxiety, and fatigue than those in the control group. Furthermore, there was a significant increase in heart rate variability in the experimental group relative to control, both at rest and during a Stroop-like stressor task. A subset of participants completed psychophysiological and task-based outcomes, which were reported in a separate paper (Crivelli et al., 2019). The experimental group demonstrated greater performance than the active control group on a complex response time task. A significantly higher frontal alpha-beta ratio in the experimental group was interpreted as an indicator of improved relaxation skills, while significantly higher alpha blocking in the frontal and central areas was thought to represent an increase in global neural responsiveness. Strengths of this study are the use of a range of subjective, task-based, and neurophysiological outcomes, as well as the choice of an active control condition that closely mirrors the experimental condition in structure. Limitations include a lack of detailed reporting on the intervention, group sizes, and adherence. Moreover, information about the study provided elsewhere (Balconi et al., 2017) suggests that participants completed a large test battery, but not all outcomes were reported, possibly indicating that the reported results were selected based upon their statistical and/or clinical significance.

In another trial, Bhayee et al. (2016) randomised healthy participants to a Muse-assisted meditation group or an active control group that undertook online maths training exercises over a six week period. Both groups spent 10 minutes per day on their respective interventions. Participants in the experimental group showed large improvements in Stroop task response time that were significantly greater than those in the control group. They also had a significantly greater improvement on the somatic subscale of the Brief Symptom Inventory, with a large effect, but no effect on the depression or anxiety subscales. A strength of this study was the experimental design which matched conditions on intervention duration and cognitive demand. However, an important limitation was that it could not be determined whether neurofeedback augmented the benefits of meditation alone, since the control condition did not involve meditation. Furthermore, the small number of analysed participants in the study (n = 26) severely limited statistical power and the ability to detect more modest effects.

1.3.2 Meditation

Neurofeedback-assisted meditation wearables such as Muse aim to leverage an existing evidence-based treatment approach, meditation, to support psychological wellbeing. Meditation is a collection of contemplative practices originating from Eastern religious traditions (Wielgosz et al., 2019). It is a central element of evidence-based psychological treatments such as mindfulness-based stress reduction (MBSR; Kabat-Zinn, 1990) and mindfulness-based cognitive therapy (MBCT; Segal et al., 2002), but may also be used as a standalone treatment or adjunct to other treatments. Meditation practices encompass a range of styles based upon traditional methods, such as the focused attention meditation style supported by Muse. Although there is little agreement on how to classify these different styles (Brandmeyer et al., 2019), most forms of meditation appear to share some common features (Lutz et al., 2015). Firstly, they often involve assuming a particular physical posture, such as sitting with a straight back and a relaxed body. Secondly, the meditator strives to maintain an accepting attitude toward thoughts and feelings that are experienced during the meditation. Thirdly, the meditation is driven by implicitly or explicitly expressed values, such as the reduction of suffering. Lastly, the task set (i.e., instructions for how to practice) must be retained by the meditator throughout the meditation.

1.3.2.1 Clinical Benefits. Meditation-based interventions have been shown to have benefits for a variety of clinical psychological problems. A recent systematic review and meta-analysis showed that manualised interventions, such as MBCT, were equally as efficacious as existing evidence-based treatments for anxiety and depressive symptoms (Goldberg et al., 2018). For pain and substance use problems, meditation-based interventions were equivalent or superior to active controls. A separate meta-analytic review of stand-alone meditation-based interventions (i.e., those delivered ouside of a broader therapeutic framework) found small-to-medium improvements in depression and anxiety symptoms relative to no-treatment controls (Blanck et al., 2018). Meditation-based treatments delivered by smartphone app have been similarly evaluated, with a recent meta-analysis finding small-to-medium improvements in symptoms of stress, anxiety, and depression relative to mostly waitlist controls (Gál et al., 2021). In another meta-analytic review, meditation-based interventions were shown to attenuate physiological markers of stress, including blood pressure, heart rate, triglycerides, and cortisol (Pascoe et al., 2017). Together, these results suggest that meditation-based interventions can help to address the symptoms of common mental health problems such as anxiety, depression, and stress, even when used outside of broader treatment frameworks and delivered digitally.

1.3.2.2 Theorised Mechanisms. There are many theorised mechanisms of action that could explain the beneficial effects of meditation. Cognitive mechanisms that appear to be well-supported include increased meta-awareness, as well as the ability to detect and disengage from attention capture by task-unrelated thought (Gu et al., 2015; Wielgosz et al., 2019). Important affective mechanisms are likely to include an increased ability to distinguish emotional states, reduced emotional reactivity, and altered reward processing (Gu et al., 2015; Wielgosz et al., 2019). These mechanisms appear to be underpinned by structural and functional changes in the brain regions concerned with attention regulation, emotion, and self-awareness (Tang et al., 2015). Because different styles of meditation may each train a distinct subset of skills, the mechanisms through which salutary effects occur may differ according to meditation style (Travis & Shear, 2010).

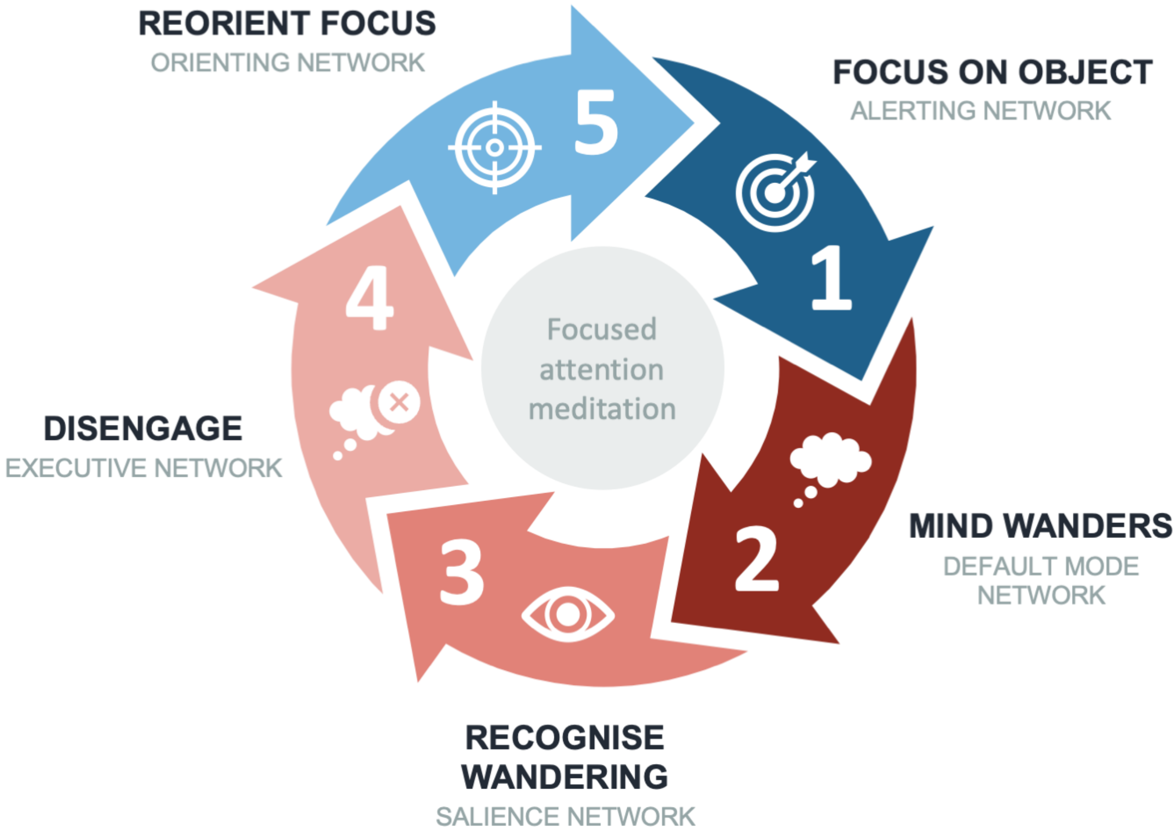
1.3.2.3 Focused Attention Meditation. Focused attention meditation is a style of meditation that is supported by devices like Muse. This style is often used by beginners in order to develop basic skills, after which meditators sometimes transition to other styles such as open monitoring meditation (Lutz et al., 2015; Malinowski, 2013). In focused attention meditation, meditators attempt to maintain focus on a designated object, such as the breath moving in and out of the abdomen (Lutz et al., 2008). When attention inevitably wanders away from the target object, meditators are asked to notice this, and to non-judgementally return their focus to the target. As shown in Figure 2, focused attention meditation can be thought of as a continuous cycle of attending, becoming distracted, and returning attention to the target, with each stage of this cycle linked with heightened activity in specific brain networks (Hasenkamp et al., 2012; Malinowski, 2013). Focused attention meditation is considered to train three key skills: the ability to monitor and be alert to distractions, the ability to disengage attention from a distraction, and the ability to reorient attention to the focal object (Lutz et al., 2008). These abilities have clear relevance in supporting the awareness of, and disengagement from, maladaptive psychological processes such as rumination and worry (Wielgosz et al., 2019).

1.3.3 Neurofeedback-Assisted Meditation

A small body of scientific literature has established the theoretical and empirical basis for neurofeedback-assisted meditation, which is implemented by the Muse EEG headband. Brandmeyer and Delorme (2013) initially proposed the use of neural information to alert meditators to mind wandering episodes, supporting them to reorient to a focused state. This strategy is founded upon the understanding that the cognitive states experienced in meditation (i.e., sustained focus, mind wandering without awareness, awareness of mind wandering, and

Figure 2

Theorised stages of focused attention meditation and their corresponding brain networks, after Malinowski (2013)



attention shifting; Figure 2) are associated with distinct neural states that can be detected using measurement tools such as EEG and fMRI (see, e.g., Braboszcz & Delorme, 2011; Hasenkamp et al., 2012; Malinowski, 2013). Providing meditators with information about their degree of focused attention in real time could thus help them learn to recognise their own attentional states and attain improvements in sustained attention, supporting more effective practice.

There is some empirical support for using neural indicators of mind wandering to support meditation. Garrison et al. (2013) conducted a series of experiments in which novice and experienced meditators undertook focused attention meditation while receiving visual feedback on changes in the fMRI blood oxygenation level-dependent (BOLD) signal change in the posterior cingulate cortex (PCC). The PCC is one part of the default mode network, which appears to become more active when the mind wanders (Hasenkamp et al., 2012). When asked to exert control over the feedback signal, experienced meditators showed a significant decrease in PCC activation, whereas novice meditators were unable to modulate PCC activation. In another study, van Lutterveld et al. (2017) trained novice and experienced meditators in effortless awareness meditation, a style that aims to achieve undistracted awareness. In this experiment, the feedback signal was derived from a spatially filtered EEG measure of PCC activity in the 40-57hz frequency band, a part of the gamma band. Both novice and experienced meditators were able to move the feedback signal in the direction of effortless awareness (i.e., decreased PCC activity), but could not shift it in the opposite direction. These studies suggest that it is possible to modify the neural dynamics associated with mind wandering during meditation when information about these dynamics is provided as feedback. Early evidence therefore supports the theory of neurofeedback-assisted meditation, although these studies have generally involved lab-grade EEG systems rather than consumer-grade wearable devices.

1.3.4 Mindfulness

The construct of mindfulness is thought to be important in achieving clinical benefit from meditation (Visted et al., 2015), and could underlie the incremental effectiveness of aided meditation practice relative to conventional approaches. No single definition of mindfulness has been agreed by academics (Van Dam et al., 2018), but most definitions appear to make reference to two dimensions first proposed by Bishop et al. (2004). Firstly, mindfulness involves maintaining attention on the present moment experience, which implies an ability to sustain attention and to switch attention away from distractors. Furthermore, the ability to remain focused on the present moment requires that elaborative thought about that experience, such as rumination, is minimised. The second dimension of mindfulness identified by Bishop et al. is the extent to which experiences are regarded with an attitude of curiosity and acceptance. In other words, mindfulness involves being open to all aspects of the present moment experience without trying to change it. Mindfulness therefore encompasses many of the underlying cognitive abilities that are trained in different styles of meditation.

1.3.4.1 Trait and State Mindfulness. Mindfulness has been conceptualised as both a trait and a state (Brown & Ryan, 2003; Kiken et al., 2015; Lutz et al., 2015; Vago & Silbersweig, 2012). State mindfulness refers to the extent to which attention is openly and non-judgementally directed towards present moment experience at any one moment (Bishop et al., 2004; Lau et al., 2006), while trait mindfulness is theorised as a dispositional tendency to be mindful throughout all parts of daily life (Baer et al., 2006; Brown & Ryan, 2003). Various self-report measures of trait mindfulness have been developed (see, e.g., Baer et al., 2006; Brown & Ryan, 2003), however there is a general lack of consensus about how mindfulness should be defined and operationalised, which is evidenced by inconsistent factor structures and low correlations between different mindfulness measures (Bednar et al., 2020; Davidson & Kaszniak, 2015; Grossman & Van Dam, 2011; Van Dam et al., 2018). Gains in trait mindfulness are not specific to mindfulness-based interventions, and the construct may lack divergent validity with other constructs such as personality, stress, and quality of life (Bishop et al., 2004; Lutz et al., 2015; Visted et al., 2015). Furthermore, self-report mindfulness measures may be vulnerable to social desirability bias, and the interpretation of these measures could differ depending on the respondent's knowledge about mindfulness practices (Lutz et al., 2015; Van Dam et al., 2018). These issues highlight the need for further work on defining and measuring trait mindfulness.

Relative to trait mindfulness, there has been less research on state mindfulness, although there are at least two well-developed measures: the Toronto Mindfulness Scale

(TMS; Lau et al., 2006) and the State Mindfulness Scale (SMS; Tanay & Bernstein, 2013). Although both measures have a two-factor structure, they appear to measure different factors, providing little consensus on what an appropriate factor structure of state mindfulness may be. A recent attempt to develop a state version of a higher-dimensional mindfulness assessment, the Five Factor Mindfulness Questionnaire, was unsuccessful as no items were deemed sufficiently reliable for a state measure (Truong et al., 2020). As with trait mindfulness, more research is needed to better define the state mindfulness construct and to understand how it might best be operationalised.

1.3.4.2 Objective Assessment of Mindfulness. One novel research direction in mindfulness measurement which could resolve some of the outstanding concerns is the use of objective measures (Hadash & Bernstein, 2019). An example of these is the Breath Counting Task (BCT; Levinson et al., 2014). The BCT is a task measure of mindfulness that is administered during focused attention meditation, in which participants track their breaths with keypresses. The premise of the BCT is that lapses of attention will result in either miscounts (i.e., failure to use a separate key to indicate the ninth breath), or resets (i.e., pressing a key to signify losing count).

Initial research appears to support the BCT as a valid measure of mindfulness. Levinson et al. (2014) found that breath counting accuracy had small associations with self-report measures of trait mindfulness, discriminated between novice and experienced meditators, and was sensitive to change. Furthermore, participants with a higher breath counting accuracy spent significantly more time in a brain state that was thought to reflect task readiness, and significantly less time in an “idling” state (Lim et al., 2018). Objective measures such as the BCT may therefore be useful supplements to self-report measures, with benefits such as reduced vulnerability to bias and increased temporal density of data. Although the BCT has been proposed as a measure of trait mindfulness it may in fact more closely measure state mindfulness, given it captures functioning within a fixed period, has a small association with self-reported trait mindfulness, and has only modest test-retest reliability (Levinson et al., 2014).

Novel objective measures of mindfulness could potentially be derived from the EEG-based measures of attentional focus used by devices like Muse. Strong conceptual similarities exist between the Breath Counting Task and these EEG-based measures used to facilitate neurofeedback-aided meditation. Both measures aim to continuously track the degree of sustained attention during meditation, with minimal disruption to the meditative experience. These EEG measures of attentional focus might therefore also serve as objective measures of state mindfulness.

1.3.4.3 State Mindfulness Predicts Clinical Benefits of Meditation. State mindfulness could be an important process variable in relation to meditation and neurofeedback-aided meditation, since regular cultivation of state mindfulness is thought to lead to enhanced trait mindfulness and associated reductions in psychological distress (Garland et al., 2010; Vago & Silbersweig, 2012). Kiken et al. (2015) tested this theory in a group of participants from an 8-week community-based mindfulness program based on MBSR. State mindfulness during the intervention significantly predicted greater improvements in trait mindfulness and psychological distress, even when baseline levels of these outcomes were controlled for. In another study, the level of state mindfulness achieved during a brief focused-attention meditation significantly predicted increases in self-reported cognitive reappraisal, a type of emotion regulation strategy (Garland et al., 2015).

A separate body of research has examined the role of "practice quality" in predicting beneficial outcomes of mindfulness practice, rather than state mindfulness per se (Del Re et al., 2013; Goldberg et al., 2014, 2020). As with state mindfulness, the theory is that adherence to the *manner* of practice, not merely the time spent, may predict the extent of the benefits gained. Del Re et al. (2013) found that increases in practice quality during an 8-week course of MBSR significantly predicted change in psychological distress over the same period, while controlling for baseline trait mindfulness and social desirability. In a later study of an 8-week group mindfulness intervention for smoking cessation, increases in practice quality significantly predicted change in psychological functioning at post-treatment and at 5-month follow-up, controlling for practice time (Goldberg et al., 2014). While empirical data are lacking, there appears to be insufficient divergent validity between the constructs of practice quality and state mindfulness, both conceptually and in the item content of their respective measures. In short, the empirical evidence summarised above suggests that being able to sustain attention on the present with a non-judgemental attitude is central to realising the benefits of mindfulness training, at least for practice types such as focused attention meditation. This suggests an important mechanism by which neurofeedback-aided meditation, which putatively supports sustained attention, could enhance the therapeutic effects of mindfulness practice.

1.4 Acceptability of Wearable Devices

An important consideration in the evaluation of wearable devices is their acceptance by consumers, including both patients and providers. Acceptability concerns the extent to which users and/or clinicians consider an intervention to be appropriate (Sekhon et al., 2017) or to meet expectations (Musiat et al., 2014). There appears to be little agreement in the literature on a theoretical foundation for assessing acceptability. At least two research streams emerge, with one focusing on healthcare intervention acceptability (see, e.g., Sekhon et al., 2017), and the other on the acceptability of technology, usually in organisational contexts (also referred to as acceptance; see, e.g., Arning & Ziefle, 2009; Nadal et al., 2020). In the former stream, acceptability has been construed as a collection of factors that affect engagement with an intervention (Musiat et al., 2014; Sekhon et al., 2017), whereas in the latter stream acceptability appears synonymous with the level of engagement with an intervention (Berry et al., 2016; Nadal et al., 2020). An important distinction that arises within both research streams is that acceptability can relate to different stages of use. In other words, acceptability can be considered prior to use (referred to as prospective, pre-use, or hypothetical acceptability), during use (concurrent or initial use acceptability), or following use (retrospective, sustained use, or actual acceptability; Berry et al., 2016; Nadal et al., 2020; Sekhon et al., 2017). Acceptability across all stages of use is an important consideration in successful implementation of interventions: prospective acceptability is linked to the rate of initial uptake, while concurrent and retrospective acceptability are related to the level of engagement, adherence, and clinical outcomes achieved (Sekhon et al., 2017).

1.4.1 Theoretical Models of Acceptability

A range of existing theories and models may inform important predictors of acceptability of digital healthcare interventions such as wearable devices. In the technology acceptability literature, the technology acceptance model (Davis, 1989) highlights perceived effectiveness and perceived ease-of-use as important high-level predictors of technology uptake, and various extensions of this theory exist (see,. e.g., Venkatesh et al., 2012, 2003). These relatively parsimonious theories tend to focus on higher-level predictors of technology acceptability, but do not typically elaborate on more specific or concrete factors (Arning & Ziefle, 2009; Bagozzi, 2007). Within the health behaviour literature, Ritterband and colleagues (2009) combined a range of existing health behaviour theories with clinical knowledge and empirical findings to develop the Internet interventions model. This is a comprehensive model of behaviour change through Internet interventions which can be readily applied to all kinds of digital health interventions. Although this model does not explicitly consider prospective acceptability, it identifies four domains affecting intervention usage: intervention characteristics, support provided, user characteristics, and environmental factors. Each of these domains is then broken down further, as detailed in Table 2. Many, if not all of these factors have potential relevance to the acceptability of wearable devices.

1.4.2 Empirical Studies of Acceptability

There has been little research into how individual factors influence the acceptability of wearable devices for treatment of mental health problems, however some studies have investigated prospective acceptability of digital mental health interventions more broadly. One branch of research has examined the relative preference for digital mental health treatments compared to conventional treatments (i.e., face-to-face therapy). These studies include samples of the general population (Klein & Cook, 2010; March et al., 2018), university students (Levin et al., 2018; March et al., 2018; Wallin et al., 2018), and attendees at a primary healthcare clinic (Wallin et al., 2018). Stigma regarding mental illness consistently predicted a greater preference for Internet-based treatments (Klein & Cook, 2010; Wallin et al., 2018) or other self-help options (Levin et al., 2018). A greater doctors' locus of control was linked to a greater tendency toward using Internet-based treatments (Klein & Cook, 2010; March et al., 2018). The effect of sociodemographic variables was generally negligible (Klein & Cook, 2010; March et al., 2018) or small (Wallin et al., 2018), as was the effect of psychological distress severity (March et al., 2018; Wallin et al., 2018).

Given that this previous work has focused on other digital mental health interventions, primarily Internet-based treatment, it is unclear how much can be inferred regarding the acceptability of wearable devices. The literature suggests that users' expectations for mental health apps are similar to their expectations for Internet-based interventions (Musiat et al., 2014), but wearable devices were not considered in this research. Digital mental health interventions generally share some common characteristics, such as the use of technology and a potential for reduced clinician contact. However, wearable devices may have unique qualities that affect their acceptability: for example, stigma may be a greater concern due to the visibility of the device, or the therapeutic rationale for using these devices may be less intuitive than that of Internet-based treatments. Research focusing specifically on the acceptability of wearable devices is therefore needed in order to understand which factors might influence the uptake of this distinct class of interventions.

Table 2
Factors that may affect wearable device acceptability, based on the Internet Interventions model (Ritterband et al., 2009)

Domain	Factors
Intervention characteristics	▪ Appearance (*colour usage, layout, organisation, screen size*) ▪ Behavioural prescriptions (*contracts, written instructions, prompts*) ▪ Burdens (*difficulty of use, length*) ▪ Content (*accurate, clear, simple*) ▪ Delivery (*animations, audio, illustrations, text, video, vignettes/testimonials*) ▪ Message (*source, style*) ▪ Participation (*interaction, reinforcement, testing*) ▪ Assessment (*personalisation, tailoring*)
Support provided	▪ Email ▪ Phone ▪ Face to face
User characteristics	▪ Disease ▪ Demographics ▪ Traits ▪ Cognitive factors ▪ Beliefs and attitudes ▪ Physiological factors ▪ Skills
Environmental factors	▪ Personal ▪ Professional ▪ Community ▪ Healthcare system ▪ Media/policy/culture

1.5 Summary

Digital health is expected to be central to the future provision of healthcare, and digital mental health interventions such as wearables could help to overcome the "treatment gap", especially for difficulties that are mild in severity (Labrique et al., 2018; Rodriguez-

Villa, Rauseo-Ricupero, et al., 2020). However, there is presently a lack of knowledge about the available range of wearable devices, how they might be used to address mental health problems, whether any supporting evidence exists, and what clinical implications there might be for their use.

Neurofeedback-supported meditation is one modality of wearable device that is currently available through systems such as the Muse consumer-grade EEG meditation headband (Brandmeyer & Delorme, 2013; InteraXon Inc., 2020b). EEG-based measures of mind wandering, such as those provided by Muse, appear to be conceptually similar to objective measures of state mindfulness. These EEG-based measures might therefore be a novel method of assessing state mindfulness. Furthermore, prior research has shown that higher levels of state mindfulness (and the conceptually similar construct of practice quality) during meditation are thought to be important in enhancing trait mindfulness and reducing psychological distress (Del Re et al., 2013; Garland et al., 2015; Kiken et al., 2015). Hence, providing synchronous feedback of this data to meditators could support learning about how to meditate effectively, reducing barriers to meditation and strengthening the therapeutic effects. Theoretical and empirical research provides some support for neurofeedback-supported meditation (Balconi et al., 2018; Bhayee et al., 2016; Brandmeyer & Delorme, 2013; Crivelli et al., 2019), but existing findings are limited by small samples sizes, choice of comparator conditions, and possible reporting bias.

An important factor in the initial uptake of wearable devices is likely to be their prospective acceptability (Berry et al., 2016; Sekhon et al., 2017). At present, it is not known which individual factors might affect prospective acceptability of wearable devices. Research on other digital mental health interventions, such as Internet-based therapy (see, e.g., Klein & Cook, 2010; March et al., 2018; Wallin et al., 2018), suggests that these interventions may be preferred when there are attitudinal barriers to conventional therapy (such as stigma), when belief in doctors' locus of control is low, and when technology confidence is greater. Research specifically evaluating the acceptability of wearable devices is needed so that devices can be targeted at those most likely to use and benefit from them.

The broad purpose of the present thesis was to advance knowledge about the potential use of wearable devices in treating mental health problems. The first two studies within this thesis (Chapters 3 and 4) investigate the availability and acceptability of wearable devices for mental health across a range of modalities, as well as the clinical implications of their use. The latter two studies (Chapters 5 and 6) evaluate a singular wearable device and modality, EEG neurofeedback-supported meditation using the Muse headband. The following exegesis, in Chapter 2, outlines the rationale, aims, and relevance of each individual study within the thesis.

CHAPTER 2: EXEGESIS

The direction for this thesis developed through several converging factors. I was aware of the Muse EEG meditation headband and was curious about whether the device could help those learning to meditate, or whether it would merely be a well-promoted treatment with no meaningful evidence base to support it. I already had an interest in meditation, and I wanted to learn more about the mechanisms underlying meditative practice. I also recall having some awareness of the challenge to evidence-based practice that was posed by the new frontier of technology-based mental health treatments.

The topic of wearable devices for mental health is indeed broad and Chapter 1 presents an attempt to synthesise relevant research on wearables themselves, as well as approaches to treatment that wearables might leverage such as meditation and mindfulness. Chapter 1 sets the scene for some of the broad but interrelated questions within this general area.

My initial studies kept the focus broad and sought to address two gaps in the literature. Firstly, there was little existing knowledge about the scope of available devices, how they might operate, and what implications there are for using these devices in clinical practice. Secondly, it was unclear whether consumers would want to use such devices for treating mental health problems, and if so, which factors would predict their level of interest relative to conventional treatments. Given the demonstrated need for better evidence of efficacy—drawn from Study 1—and the interest in wearables from consumers (Study 2), the two latter studies in this thesis had a narrower focus on a specific device and modality: the Muse EEG headband, which was developed to support meditation through neurofeedback. The objective of these studies was to build on the limited existing evidence for the Muse headband and the mechanisms through which it was thought to work. In the remainder of this chapter, I provide a rationale for the specific aims and methodology of each of these four studies. The background for each study is then further detailed within the respective chapter.

2.1 Study 1

The purpose of this study was to develop a comprehensive understanding of wearable devices that were commercially available and purportedly targeted mental health problems. Although I had used a Muse EEG meditation headband and a HeartMath heart rate variability device, I did not know the extent of other devices on the market, or which features they offered. Early searches suggested there was little scientific literature for these devices, and so it was necessary to search through grey literature to identify devices that might meet the criteria. Since I knew several devices were already commercially available and being widely used, I felt that it was also important to identify the potential clinical implications of using these devices to help guide their clinical use.

In my early reading of the literature I had not identified any kind of classification paradigm that clearly identified the group of devices that I was interested in studying. Exploratory searches suggested that there were many devices that could monitor and report on physiological features without being oriented around mental health outcomes or actively assisting the wearer to modulate these features. Biofeedback and neurofeedback modalities, which were used in the HeartMath and Muse devices I was aware of, had the critical addition of actively feeding back information to the wearer in real-time. However, I did not want to limit the review to only these modalities in case there were other types of active interventions that would also merit inclusion. One criterion was therefore that the device had to provide some active intervention element: either measuring and feeding back data in real-time, or perhaps actively stimulating some physiological system. Consequently, devices that functioned asynchronously by reporting measures to the user periodically were not considered. Other important inclusion criteria centred upon the issue of availability. The promise of wearable devices rests substantially upon the idea that they can become as easy to access as other consumer electronics such as smartphones (Mrazek et al., 2019; Rodriguez-Villa et al., 2020). For this to occur, devices would need to be available for consumers to purchase, priced at an affordable level, and oriented toward consumer use. Early searches placed most devices around $150-300 USD, and a cutoff of $500 USD was selected as a likely upper limit for many consumers in purchasing a single-purpose device of this type. To further contain the scope of the review, I decided to select only devices that might be used in the treatment of anxiety, since wearable devices generally measure physiological parameters linked to the somatic symptoms seen in many anxiety disorders (Mallorquí-Bagué et al., 2016).

A second issue that arose while developing this review was the complexity and heterogeneity of devices being studied. I expected that there could be numerous potential differences in hardware and software between devices which, on the surface, might appear to work in the same way. The best evidence for a device would therefore be studies that directly test that device in clinical populations. However, such evidence was typically scarce and inconclusive, probably because of the relative short period that the devices had been available. My approach was therefore to present any available evidence from research on individual devices, as well as summarising any systematic reviews of evidence for that device modality.

In summary, the purpose of Study 1 was to identify currently available wearable devices that might be used in the treatment of anxiety, understand the extent of available evidence for these devices or their putative modalities, and review possible clinical considerations when using devices as a part of treatment.

2.2 Study 2

The purpose of the second study was to evaluate the acceptability to consumers of using wearable devices to treat a mental health problem. The acceptability of an intervention is a well-established determinant of its potential clinical utility (American Psychological Association, 2002). Since it has been suggested in the literature that there is a low willingness to utilise digital interventions (Mohr, Lyon, et al., 2017), I felt that it was important to assess whether this was also true specifically for wearable devices. If the acceptability of these devices to consumers was low, they would be unlikely to have widespread clinical utility. I therefore wanted to survey a sample that was broadly representative of the general population.

Careful consideration was needed to select the most appropriate method for measuring the acceptability of wearable devices, and to choose the most relevant comparator treatments. As I wanted to consider wearables as an entire class of devices rather than a specific device, it made sense to evaluate the prospective acceptability, that is the perceived acceptability of such devices without having used them (Berry et al., 2016; Sekhon et al., 2017). I also considered prospective acceptability to be important because it would likely have a strong impact on treatment uptake, regardless of concurrent or retrospective acceptability. Since I predicted that the level of clinician support might affect the acceptability of wearable devices (March et al., 2018; Ritterband et al., 2009), ratings of acceptability were sought for two discrete wearable device use cases: a "blended" use case (i.e., use in conjunction with conventional talk therapies) and a self-help use case. The description of wearable devices shown to participants for these use cases was informed by the characteristics of the devices reviewed in the first study (i.e., device size, purpose, mechanisms, manner of use, and cost; see Appendix A). In order to have some benchmarks of relative acceptability, I decided to also ask participants to rate the acceptability of two other treatment approaches for comparison (conventional talk therapy and the use of self-help material such as an app or book). Prospective acceptability was operationalised as the level of interest in using each treatment in the event of a mental health problem.

As well as evaluating the level of acceptability of devices and other treatments, I thought that it would also be worthwhile to determine whether acceptability was related to participant characteristics. This information could potentially assist clinicians to target wearable device interventions to those who would be most receptive to using them. Literature searching revealed a number of existing studies that had evaluated device-related factors that were associated with wearable device acceptability, but few that focused on the characteristics of the wearer (see, e.g., Kalantari, 2017). Not all possible factors could be measured due to participant burden, and so it was necessary to consider which predictors would likely have the strongest relationship with wearable acceptability. To inform my selection, I looked at which factors had been shown to affect preference for Internet-based treatment relative to conventional face-to-face treatments (e.g., Klein & Cook, 2010; March et al., 2018; Wallin et al., 2018), theorising that these would likely also be relevant in the context of wearable devices.

The purpose of Study 2, then, was to determine the prospective acceptability of wearable devices—or in other words, how willing consumers would be to use such devices with just a basic idea of what they were. This study and its results are fully described in Chapter 4.

2.3 Study 3 and Study 4

Having reviewed a range of wearable devices in Study 1, I thought that the Muse EEG meditation headband warranted further research because it was a relatively mature product that appeared to have a substantial existing user base. Furthermore, given the recent proliferation of mindfulness-based treatments in clinical practice, I expected that there might be significant clinician interest in using Muse. The purpose of these studies, then, was to evaluate the Muse EEG meditation headband as an aid to meditation.

An important consideration in developing these studies was the selection of the most appropriate experimental design. Ultimately, randomised controlled trials in clinical populations are considered to be the gold standard method for establishing treatment efficacy (Chambless & Hollon, 1998). However, as identified in Study 1, aided meditation is a relatively novel and unproven technology. For this reason, I thought that an important initial step would be to develop more evidence for the putative mechanisms underlying Muse, which could be done in a non-clinical population. Identifying mechanisms can help to understand the link between treatment and outcome, optimise therapeutic effects, and identify critical elements, as well as providing support for the efficacy of an intervention (Kazdin, 2007). The mechanisms evaluated in Studies 3 and 4 centred upon two key assumptions. Firstly, the effectiveness of biofeedback interventions is thought to rely upon the reliability and validity of the biological signal being measured (McKee, 2008). For Muse to be effective, it would therefore need to be producing a valid measure of meditation quality (i.e., sustained attention). Secondly, the provision of a biofeedback signal should enhance the ability of the trainee to modulate the signal, gaining some additional control over it (McKee, 2008). Receiving feedback from Muse would therefore be expected to increase the degree of meditation quality, relative to unassisted practice. These assumptions became the research questions underpinning Studies 3 and 4, respectively.

The purpose of Study 3 was to evaluate the reliability and validity of the proprietary measures derived from the Muse headband. Although studies suggest that it is possible to derive meaningful information about meditation state from EEG data (see, e.g., Braboszcz & Delorme, 2011; Hasenkamp et al., 2012), little or no research has demonstrated the same principle using a consumer-grade device with a lower quality EEG signal. The primary Muse measure, which I termed “Muse mind wandering”, ostensibly detects the degree of focused attention on the breath (Interaxon Inc., 2020). It is this measure which is used to provide auditory feedback to meditators. As the Muse mind wandering measure appeared conceptually similar to objective measures of state mindfulness, I wanted to establish its convergent validity with state mindfulness and related measures of trait mindfulness and attention.

The selection of measures to assess concurrently with Muse required some consideration. Although self-report measures of mindfulness have predominantly been used in the literature, they have been criticised on account of insufficient discriminant validity with well-being and biases related to the level of experience of mindfulness practice (Grossman, 2008, 2011; Sauer et al., 2013; Van Dam et al., 2018). I therefore decided to include the Breath Counting Task (Levinson et al., 2014) as an objective measure of state mindfulness. I also selected a well-established experience sampling method (Weinstein, 2018) to assess the subjective level of mind wandering at random intervals during the meditation task. The advantage of these measures was the ability to capture multiple data points with minimal or no disruption to the meditation practice. This yielded a higher density of data, increasing analytic power and providing the opportunity to investigate within-participant as well as between-participant associations.

The purpose of Study 4 was to evaluate the effect of Muse feedback on the quality of meditation practice. According to biofeedback theory, training with feedback should allow the trainee to begin to modulate the physiological signal underpinning that feedback (McKee, 2008). I therefore expected that receiving auditory feedback of the Muse mind wandering measure would result in increased state mindfulness, relative to not receiving any feedback. I chose to test this experimentally using a counterbalanced crossover trial design, giving greater statistical power than a parallel design, and thus reducing the number of participants needed. This design was appropriate as I expected any learning effects accruing from the first condition to the second would not differ substantially based on the order in which the conditions were presented (Senn, 2002). A secondary question was whether participants' experience of meditation differed between conditions. To this end, I chose to administer a questionnaire about meditation experiences after participants completed each condition.

The use of a no-feedback condition as a control condition, rather than a sham feedback condition (i.e., random feedback), was an important methodological consideration in Study 4. Using a sham feedback condition would have ensured that any observed intervention effects could be attributed to the information provided in the feedback, not a result of other factors such as attentional or motivational differences elicited by feedback (Alino, 2016). However, three compelling reasons existed for using a no-feedback condition instead. Firstly, a no-feedback control would best represent a typical unaided meditation, which is a possible alternative clinical treatment, whereas sham feedback would not represent any clinical intervention. Secondly, improvements in attention or motivation resulting from feedback should not necessarily be considered trivial or unimportant, and are perhaps better considered as important mechanisms of the intervention (Lambert, 2013; Weerdmeester et al., 2020). Lastly, the use of a sham feedback condition may compromise participants' perception of control over the signal, risking their motivation or interest in the true feedback condition (Alino, 2016). For these reasons, a no-feedback control was selected as the most appropriate comparator condition for the present work.

In summary, the purpose of Study 3 and Study 4 was to evaluate the potential of the Muse meditation headband as an aid to meditation, by firstly determining whether the measures produced by Muse were related to state mindfulness, and secondly evaluating the effect of Muse neurofeedback on state mindfulness and subjective experiences. These studies are reported in Chapters 5 and 6, respectively.

CHAPTER 3: STUDY 1

Wearable Devices as Adjuncts in the Treatment of Anxiety-Related Symptoms: A Narrative Review of Five Device Modalities and Implications for Clinical Practice

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3.1 Statement of Authorship

Principal Author

Name of Principal Author (Candidate)	Hugh Hunkin		
Contribution to the Paper	Collaboratively developed the research objectives; performed literature searching; wrote initial draft; collaborated on editing of final drafts; acted as corresponding author		
Overall Percentage (%)	80		
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	16 March 2022

Co-author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate in include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution

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3.2 Abstract

Anxiety disorders are a major public health problem, and a range of wearable technological devices for addressing the somatic symptoms of anxiety are increasingly available. This narrative review summarises five distinct modalities underlying wearable devices and investigates clinical implications for managing clients using such devices. The literature suggests potential benefits of HRV biofeedback devices, whilst other modalities (aided meditation, false physiological feedback, electrodermal biofeedback and respiration biofeedback) are less supported. High-quality research on the efficacy of such devices is also lacking, particularly in clinical populations. Wearables could offer potential benefits, but may be contraindicated in some cases. Collaborative use of clinical evaluation tools, such as the American Psychiatric Association's app evaluation model, can aid in shared decision-making about device use.

3.3 Introduction

Anxiety disorders are a major public health concern, with a lifetime prevalence rate estimated to be 16.6% globally (Somers et al., 2006). After depressive disorders, anxiety disorders carry the greatest disease burden of the mental disorders (Abajobir et al., 2017).

Yet despite longstanding recognition of the treatment gap in mental health, and substantial increases in the size of the mental health workforce and related government funding, the evidence suggests that the prevalence of anxiety-related complaints continues to increase, even in developed nations (Jorm et al., 2017). Furthermore, of those who seek help for mood and anxiety disorders, only 26% receive an evidence-based treatment (Jorm et al., 2017). While early technological mental health interventions have shown some promise for scaling up treatments (e.g., O'Connor, Munnelly, Whelan, & McHugh, 2017), a new generation of consumer-targeted wearable electronic solutions that present new possibilities and challenges in addressing anxiety are now becoming available.

Wearables are interactive computing devices, worn either as an item of clothing or as an accessory, and they are an important element of the new frontier of healthcare innovation (Nasir & Yurder, 2015). Wearables, like mobile technologies for health (mHealth), are part of a broader movement to democratise healthcare, potentially enabling ubiquitous, patient-centred health provision. With smartphones acting as an "extension of the self" (Morris & Aguilera, 2012, p. 622), it has been argued that there is promise for improving access, uptake, adherence and engagement with treatments, as well as potentially enabling clients to continually manage their condition outside of treatment, resulting in reduced costs and better outcomes (Clough & Casey, 2015b). Products like smart watches or fitness bands, usually paired with smartphone applications ('apps'), have already been widely adopted in the move towards a "quantified self": increased self-understanding based on personal analytics (Piwek et al., 2016). Now, a first generation of wearable devices for addressing mental wellbeing are moving beyond quantification with the promise of an "augmented self", including EEG headbands to aid meditation, sensors that provide feedback on irregular or adaptive breathing patterns, and heart rate variability monitors that seek to achieve coherence of cardiac and respiratory rhythms.

A common theme across most of these devices is that they provide some form of relaxation training, by giving the wearer an indication of their degree of arousal and guiding them in exercises to achieve calm. Some devices are designed for short session-based use, while others are intended to be worn all day, providing moment-to-moment feedback to the user as required (so-called ecological momentary interventions). It has been proposed that wearable devices could help to reduce various access barriers by avoiding the need to attend a clinic in some cases (Lui et al., 2017), and their deployment on a large scale might even contribute to the collection of field data that can answer difficult research questions, given appropriate user consent (Moraveji, 2012). The use of mHealth platforms may allow for these wearable interventions to be more seamlessly integrated into everyday life, and regular use might be encouraged through gamification (Deterding et al., 2011; Fleming et al., 2016). Technological delivery could also mean that treatments are more consistently applied, compared to provider delivery (Riley, 2017). Of course, many of these potential benefits remain hypothetical for now, since there has been little research on the actual acceptability of wearable devices, while research into other e-mental health interventions suggests that widespread adoption has not yet been achieved, despite there being evidence for the efficacy of some of these treatments (Apolinário-Hagen et al., 2017).

Wearable devices may be particularly suitable for tackling anxiety because somatic symptoms are a significant feature of various anxiety disorders, and many of these symptoms relate to over-activation of the sympathetic nervous system and corresponding under-activation of the parasympathetic nervous system (Friedman, 2007; Mallorquí-Bagué et al., 2016). Practice with calming technologies might therefore help to increase self-efficacy, reduce aversive interpretations of somatic arousal (Meuret et al., 2004), or even lead to lasting physiological changes (for example, improved baroreflex function; Lehrer et al., 2003). Relaxation techniques already have an established place in the treatment of anxiety disorders (Manzoni et al., 2008), but given the rapid development and commercialisation of wearables, little knowledge has been generated thus far about whether they could facilitate this approach to treatment (Coffey & Coffey, 2016). Nonetheless, despite the lack of existing evidence, numerous online reviews and opinion pieces offer enthusiastic endorsement for the use of these devices in improving wellbeing and addressing clinical disorders such as anxiety. At the same time, strong growth in annual sales of wearable devices is projected to continue over coming years (CCS Insight, 2017). As with the proliferation of smartphone apps, the growing number of wearables presents a challenge for clinicians in terms of being able to provide up-to-date advice to clients who may be eager to use such technologies.

In the present review, we aimed to describe the range of modalities through which wearables ostensibly address anxiety, highlight some of the available evidence for those modalities and for specific devices, and summarise some of the potential implications of using wearables in a clinical context. Importantly, given the broad nature of this issue in terms of the range of technologies available, their mechanisms of action, and the generally limited research material available, a systematic review was not considered appropriate. Instead, we undertook a narrative review to capture the diversity of devices and evidence available in one article (Dijkers, 2009).

In order to determine relevant devices for inclusion herein, literature and broader Internet searches were conducted using search terms such as "wearable device" or the name of specific device modalities once these had been identified. For inclusion, devices needed to (i) be currently available direct to consumers, (ii) cost less than USD $500, (iii) comprise active intervention elements using physiological or neurological signals, and (iv) be oriented toward consumer use rather than research or specialised applications unrelated to anxiety symptoms. A total of 40 devices were identified, with 26 devices being excluded (research/specialised orientation: 11, no active intervention elements: 9, not presently available for purchase: 4, cost: 1, not wearable: 1). The remaining 14 devices (Table 3) were then grouped according to their assumed modalities. Each of these modalities is further described below, and, where available, the results of recent systematic reviews evaluating the evidence for each modality are summarised. Furthermore, where literature that specifically evaluated the identified devices could be found, it is also reviewed here. Following this discussion of different device modalities, the clinical implications of using these devices—including risks and unexpected effects, as well as approaches for clinical evaluation—are considered.

3.4 Device Modalities

3.4.1 Heart Rate Variability Biofeedback

Many of the wearable devices for anxiety identified in this review ostensibly operate through biofeedback. Biofeedback training devices are thought to work by feeding back information about bodily signals to allow trainees to recognise and learn to control those signals. While early biofeedback research tended to focus on parameters such as skin temperature, heart rate and muscle potential, recent devices have been developed around bodily signals that require more sophisticated measurement and/or interpretation, such as heart rate variability, electrodermal activity, respiration and EEG (Schoenberg & David, 2014). Heart rate variability (HRV) is the variation in interval between heartbeats. It is an important signal because it has been shown to be a reliable predictor of physical health as well as an indicator of healthy parasympathetic functioning, which is associated with the ability to self-regulate emotions under stress (Caldwell & Steffen, 2018; Goessl et al., 2017; Jester et al., 2019). It is perhaps unsurprising, then, that reduced HRV has been observed in most types of anxiety disorder (Chalmers et al., 2014). HRV is influenced in large part by respiratory sinus arrhythmia, whereby heart rate accelerates during inhalation and decelerates during exhalation (Goessl et al., 2017). HRV biofeedback aims to maximize HRV by

Table 3
Summary of wearable devices with potential benefit for anxiety symptoms

Modality	Device	Website	Comments	Approx. Cost
EDA	Pip (2014) *Galvanic Ltd*	thepip.com	Held between thumb and forefinger like a guitar plectrum; developer currently in liquidation.	$245 AUD
EEG	Brainlink (2014) *Macrotellect Ltd*	o.macrotellect.com	1 channel dry sensor headband	€149 EUR
	Insight (2015) *Emotiv, Inc.*	emotiv.com	5 channel hybrid sensor headband (requires minimal priming with saline)	$299 USD
	Lowdown Focus (2017) *SmithOptics, Inc.*	smithoptics.com	EEG sunglasses based on Interaxon Muse technology (described below)	$349 USD
	Mindwave (2011) *Neurosky, Inc.*	neurosky.com	1 channel dry sensor headband	$79 USD
	Muse (v2, 2016) *Interaxon, Inc.*	choosemuse.com	4 channel dry sensor headband; primarily offers aided meditation but third-party apps can be used also	$249 USD
	Myndband (2016) *Myndplay Ltd*	myndplay.com	1 channel dry sensor headband	£179 GBP
	SenzeBand (2016) *Neeuro Pte Ltd*	neeuro.com	4 channel dry sensor headband	$299 USD
Entrainment	Doppel (2018) *Team Turquoise Ltd*	feeldoppel.com	Worn on inside of wrist where the pulse is normally felt; provides a regular heartbeat-like tactile sensation	$179 USD
HRV[†]	emWave 2 (2011) *HeartMath, Inc.*	heartmath.com	Standalone feedback device or used with apps on Mac or Windows (no smartphone support)	$199 USD
	Blaze, Charge 2, Ionic, Versa *FitBit, Inc.*	fitbit.com	‘Relax’ app guides breathing based on HRV patterns	$119-$249 USD

Modality	Device	Website	Comments	Approx. Cost
	Inner Balance (2013) *HeartMath, Inc.*	heartmath.com	Bluetooth or wired sensor worn on the earlobe during biofeedback sessions	$159 USD
	Sona (2015) *Caeden, Inc.*	caeden.com	Wristband; monitors HRV through the day and offers HRV biofeedback sessions	$199 USD
Respiration	Stone (2014) *Spire, Inc.*	spire.io	Sensor worn on belt or bra; feedback on elevated and calm states in realtime; also short biofeedback sessions	$149 USD

Note: †The products listed here are integrated software and hardware HRV solutions. However, a range of smartphone apps can also be linked to low-cost generic sensor devices (chest strap, ear clip, finger clip and a limited range of smart watch devices) to provide session-based HRV biofeedback.

guiding trainees in breathing at their "resonance rate"—the number of breaths per minute that produces the largest variability in heart rate, usually around six—through feeding back information about their HRV (Kleen & Reitsma, 2011). The resonance rate causes maximal heart rate oscillation as a result of heart rate becoming in phase with breathing and out of phase with blood pressure oscillations (Lehrer & Gevirtz, 2014).

Individual HRV biofeedback devices may operate in slightly different ways, but they generally work by giving paced breathing cues while also displaying feedback about the level of coherence being achieved between heart rate and breathing. The range of available HRV devices are perhaps the most developed in terms of wearables for mental health. This may be in part because unlike most other wearables, non-proprietary communication protocols used by many HRV sensors mean that apps can connect with a range of different sensors, and vice versa. Perhaps for this reason, some HRV solutions can appear economical when compared to other wearables. Sensors come in multiple forms, from chest straps to optical ear or finger clip sensors. Future apps may even utilise the smartphone camera as a photoplethysmographic heart rate sensor, allowing for HRV to be trained without the use of an additional measuring device, and this technique has been shown to produce valid measurements (Plews et al., 2017). Some of the products on the market are entirely integrated offerings, which function either as standalone devices (e.g. HeartMath emWave 2) or as a paired sensor and smartphone app (e.g. HeartMath Inner Balance). HRV measurement is also incorporated into many recent fitness watch products such as some FitBit and Garmin devices, as well as the Apple Watch. However, these watch implementations are typically not compatible with standard communication protocols, meaning that only proprietary software can be used, and this often does not feature biofeedback options, but is used instead for quantifying fitness levels. Furthermore, the sensors used in wrist-worn devices can be prone to artefacts, and so accurate readings may only be produced when completely still (Baek & Shin, 2017).

3.4.1.1 Support for HRV Biofeedback. A recent meta-analysis of 24 RCTs targeting stress and anxiety in clinical and non-clinical populations revealed large effects for HRV biofeedback overall, both within groups and when compared to a mix of passive and active controls (Goessl et al., 2017). However, the authors of that review identified an unclear risk of study bias (according to Cochrane Handbook guidelines) in the majority of included studies, such that sub-optimal randomisation, blinding, and treatment of missing data may compromise the fidelity of the results. While Goessl et al. attempted to evaluate the impact of study bias with a moderation analysis, the non-significant results of this analysis cannot be interpreted for the intended purpose because only studies with a high or unclear overall risk of bias were included. Schmidt and Martin (2017) carried out a further qualitative systematic review of 21 RCTs using HRV biofeedback for physical and psychological problems, finding that increases in HRV were persistent, and effects on psychological variables like subjective stress were positive but generally not superior to active controls. However, they also note a lack of controlled studies showing effects of HRV biofeedback on psychological outcomes. Both reviews thus demonstrate that potential study bias is a major limitation of the evidence available at present. A second major issue is that few studies identified in these systematic reviews compared HRV biofeedback with active controls in clinical populations. This represents a significant concern for clinicians, who need to know whether a proposed intervention is likely to be at least as effective as current best practices for the treatment of a specific disorder or symptom cluster. Other limitations of existing research include a failure to observe a dose-response relationship in many studies, as well as differences in treatment protocols between studies. Most outcome measures rely on self-report, although physiological and neurological changes have also been observed, indicating that outcomes are not limited to subjective measures (Lehrer et al., 2003; Prinsloo et al., 2013). Lastly, the long-term benefits of treatment, including how measured improvements translate into everyday coping, have not been well explored as yet (Wheat & Larkin, 2010). In summary, while recent systematic reviews suggest that HRV biofeedback could lead to clinically significant improvements for people with anxiety through increased self-awareness and improved physiological and psychological self-regulation, higher quality research, and particularly studies within clinical populations that compare against active control treatments, are needed to further substantiate these claims (Goessl et al., 2017; Schmidt & Martin, 2017). Since much of the research in these reviews was done with research-grade equipment, and given the difficulty in measuring HRV accurately, more evidence is also needed to show that these treatments can be effectively reproduced in consumer-grade wearable technology.

3.4.2 Respiration Biofeedback

Another bodily signal targeted by biofeedback devices is respiration. The dynamic two-way relationship between breathing patterns and affective state has already been well established (Ley, 1999). While stress may lead to hyperventilation—depending on the intensity of the stressor and the learned reactivity to stress—respiratory rate can also be controlled volitionally, and is therefore a potential therapeutic target (Moraveji, 2012). Irregularities in baseline respiratory rate have been observed in some diagnoses of anxiety (Grassi et al., 2014). Furthermore, a decreased baseline respiratory rate has been observed following clinical interventions like meditation (Pascoe et al., 2017). Acknowledging this connection, breathing training has been used as an effective clinical treatment, sometimes aided by feeding back information about respiratory parameters to trainees (Meuret et al., 2004). When combined, respiratory features such as breath rate, inhalation-exhalation ratio and tidal volume can discriminate stress with a similar level of power to ECG features, and closely predict self-reported measures of perceived stress in ecologically valid scenarios

(Plarre et al., 2011). However, consistently monitoring the breath during everyday life is challenging as constant attention is required, and respiratory patterns therefore represent a potential target for intervention with wearable devices.

Perhaps the first mass-market wearable device based on respiratory activity is the Stone (Spire, Inc), a small sensor that is attached to the belt or underwear. This device registers breathing patterns and categorises the user's state as normal, calm, tense, or focused. It can send alerts to the wearer when changes in breath indicate a rise in tension, and gives positive feedback when users achieve an extended period of calm. Guided meditations with respiratory feedback are also available on demand through the app.

3.4.2.1 Support for Respiration Biofeedback. To date, there appears to be little evidence around the effectiveness of respiration biofeedback. A recent systematic review of multiple biofeedback modalities identified only three studies where respiration biofeedback was used, all of which were for treatment of panic disorder, with only one study reporting statistically significant symptomatic change (Schoenberg & David, 2014). However, the treatments used in these studies were fundamentally quite different to that of devices that provide ecological momentary interventions based on respiratory features, such as the Stone, making it difficult to translate any conclusions. Little research evaluating such devices appears to be have been conducted thus far. An unpublished study conducted by Spire in partnership with Stanford University and LinkedIn engaged 225 LinkedIn employees, around half of whom received a Stone device and used it over a one-month period (Moraveji et al., 2017). Compared to the group who did not receive a device, users demonstrated significant decreases in measures of anxiety, negative affect and perceived stress. While the amount of time spent in a 'calm' state (as classified by the device) increased by 37% on average over the course of the study, high variability between participants meant that this change was not statistically significant. The study's conclusions should be considered with caution since it was not subjected to peer review, and the open-label nature of the trial means that expectancy effects were not controlled for. Furthermore, the participants did not represent a well-defined clinical population, and a 41% drop-out rate in the treatment group suggests that uptake of the device among users may be problematic.

3.4.3 Electrodermal Activity Biofeedback

Electrodermal activity (EDA), also known as galvanic skin response, refers to the changes in conductance of the skin due to sweat glands being activated by the sympathetic nervous system (Parnandi & Gutierrez-Osuna, 2017). Changes in EDA are associated both with neural measures of arousal (Critchley et al., 2013) and with psychological stress (Salafi & Kah, 2015; Visnovcova et al., 2016). There are two primary characteristics of EDA: skin conductance level (SCL) is a baseline measure of sympathetic arousal, while skin conductance response (SCR) refers to momentary peaks in the signal which occur in response to episodic stressors such as startle events or affective arousal (Parnandi & Gutierrez-Osuna, 2017). Only one consumer-grade EDA biofeedback device was identified in the present review. The Pip (Galvanic Ltd) is a small device that is held between the thumb and forefinger, and it can be used with a number of included game-based apps in which the user makes progress toward goals by reducing their level of arousal.

3.4.3.1 Support for EDA Biofeedback. Despite research showing the link with objective and subjective measures of arousal, a recent systematic review found a lack of quality evidence for the efficacy of EDA biofeedback for any mental disorder thus far (Schoenberg & David, 2014). Only one study evaluating an EDA-based wearable device could be identified, trialling the Pip in a group of healthy participants using game-based apps following a stress induction two after (Dillon et al., 2016). Compared to the control group who played a game without biofeedback, participants using the Pip reported significantly lower heart rate and perceived stress. However, the observed effect size was small, and longer-term effects were not studied. Further studies therefore appear to be required in order to establish the credibility of this form of treatment, particularly with regard to anxiety disorders.

3.4.4 Neurofeedback and Aided Meditation

Neurofeedback, also known as EEG biofeedback, is a specific form of biofeedback that works by giving users information regarding characteristics of the EEG signal measured over particular cortical regions (Demos, 2005). For some decades, neurofeedback has been used clinically to treat conditions such as attention disorders and epilepsy (Kopřivová et al., 2013). Neurotherapy typically involves taking quantitative EEG data which can be compared to normative data to identify cortical regions that are under- or over-active within specific frequency bands, after which neurofeedback protocols can be developed to reward normalisation of brain activity in these areas (Demos, 2005). Consumer-grade neurofeedback devices operate in a simpler way, often only having active sensors in the prefrontal area where hair does not preclude the use of dry electrodes. These devices typically have a range of manufacturer and/or third-party apps which function in various ways. Some apps simply quantify EEG state, while others attempt to infer associated mental state (e.g. focused, tense, relaxed), or include games where the objective is for the user to perform increasingly difficult tasks while controlling their level of arousal. However, the specific EEG patterns being targeted by these apps are often not disclosed, making it difficult to make any generalisations about the efficacy of treatments using this modality.

One specific way that neurofeedback might be used to improve mental health is through aiding meditation. Meditation-based interventions have been associated with significant reductions in physiological signs of stress, such as cortisol, blood pressure and heart rate (Pascoe et al., 2017). Limited early evidence suggests that mindfulness programs incorporating meditation could be comparable to gold-standard cognitive behavioural interventions when used to treat anxiety disorders (Singh & Gorey, 2018), although more research is needed to comprehensively address this question. Furthermore, stand-alone (i.e., used in isolation from other treatment) mindfulness exercises such as guided breathing meditation have been shown to have small-to-moderate effects on anxiety compared with stand-alone active controls (Blanck et al., 2018). Aided meditation employs algorithms that process EEG signals to detect mind-wandering, which has been associated with gamma power in the posterior cingulate cortex (van Lutterveld et al., 2017) and with theta power globally (Braboszcz & Delorme, 2011). Auditory or visual feedback can then be given to the user, for example by increasing the volume of background sounds to signal the mind becoming distracted. Because meditation can be difficult to learn, neurofeedback may help the learning process by giving objective feedback (van Lutterveld et al., 2017). Moreover, some clients feel they are "doing nothing" during meditation or that the instructions are ambiguous (Kleen & Reitsma, 2011), and real-time feedback based on cortical activity could overcome this problem. It should be noted that current implementations of aided meditation tend to be developed specifically for use with concentrative meditation, such as focusing on the breath, but may not necessarily support other meditative approaches such as mindfully being aware and accepting of all thoughts and feelings.

3.4.4.1 Support for Assisted Meditation. Few studies have assessed the efficacy of neurofeedback-assisted meditation devices, perhaps because of their relatively recent inception. Several recent trials have evaluated the use of the Muse headband relative to similarly structured active controls in short (4-6 week) interventions (Balconi et al., 2017, 2018; Bhayee et al., 2016; Crivelli et al., 2019). The results of this early research suggest that compared to controls, regular use of Muse could lead to significant improvements in outcomes such as somatic symptoms, perceived stress, state anxiety, and mood modulation in healthy or moderately stressed adults. Crivelli et al. (2019) also reported significant changes in objective measures such as a reaction time task, N2 event-related potentials, and associated EEG measures. Preliminary results of another trial involving people with a mild-to-moderate traumatic brain injury suggest improvements in anxiety and depression symptoms, as well as measures of self-efficacy and mindfulness, although full analyses from this study are yet to be reported (Gray, 2017). Importantly, no published studies using participants with anxiety or other psychological disorders were identified and thus, the efficacy of such devices in clinical populations remains entirely unknown.

3.4.5 Entrainment and False Feedback

Another mechanism through which wearable devices can operate is entrainment. Entrainment is the synchronisation of one's brain or body with rhythmic stimuli found in the environment, either voluntarily or involuntarily (Ross & Balasubramaniam, 2014). Unlike biofeedback, entrainment does not rely on learning or even on paying attention to a stimulus, but can occur merely through exposure. For example, heart rate and respiration rate tend to be entrained by music, relative to the tempo (Larsen & Galletly, 2006). In false feedback approaches, a signal is provided which explicitly mimics a natural physiological rhythm, such as heart rate. This type of feedback may alter the perception of emotional arousal, including both positive and negative affect (Crucian et al., 2000). Entrainment and false feedback technologies offer interesting avenues for exploration because they may have the potential to aid emotional regulation with no effort required from the user, reducing problems of compliance, and avoiding the possibility that managing the device itself will become an added stressor for the user (Costa et al., 2016).

3.4.5.1 Support for False Feedback. The entrainment of neural rhythms (brainwave entrainment) has already received much attention from both researchers and consumers, and due to the fact that such devices are not novel, they will not be further explored here. However, recent research has also explored the potential for entraining other physiological characteristics through wearable devices. Costa et al. (2016) developed a prototype wristband device to deliver a heartbeat-like vibration at a consistent low tempo where the pulse is normally felt. Under induced stress, users who were told the device fed back their heart rate had a significantly lower increase in state/trait anxiety relative to the control group, who wore the device switched off. A third group who had the device switched on, but were told only that it created a vibration, did not differ significantly from the control group. These results suggest that the perception of the truthfulness of feedback is important. However, Azevedo et al. (2017) found different effects with the *doppel*—a very similar commercially available device—under comparable conditions. Here, participants who had the device switched on demonstrated an objectively and subjectively reduced stress response, even though they were told that it was simply a measuring instrument. While these early studies show promise, physiological entrainment needs to be researched much more thoroughly in order to answer the outstanding questions and generate sufficient evidence to warrant its use, particularly in clinical populations.

3.5 Clinical Implications

As with many new or alternative therapies there is a growing interest in using wearable devices for mental health, however this has not been matched with adequate supporting evidence. In particular, researchers have not yet investigated whether any of the wearable devices identified in this review are effective for people experiencing clinically significant anxiety symptoms. This is a substantial limitation given that evidence-based approaches emphasise the importance of appropriate evidence being applicable to the specific patient or problem at hand (Gillam & Siriwardena, 2014). Nevertheless, failing to fully engage with clients who intend to use wearables as part of their treatment might lead to those clients seeking help elsewhere, or worse still, not at all (Coffey & Coffey, 2016). If nothing else, the use of wearables as an adjunct to therapy may potentially help through expectancy effects and increased engagement. Several devices also offer online practitioner portals which allow clinicians to monitor the data generated by the client's devices, given their consent—a feature which may be useful in monitoring progress, increasing adherence, and potentially in providing useful diagnostic information.

3.5.1 Risks and Unexpected Effects

Little research has explored the implications of using biofeedback devices as an adjunct to therapy, although potential side effects such as fatigue and dizziness have been identified (Clough & Casey, 2011). For aided meditation, existing contraindications for meditative therapies might be considered, such as a history of trauma, psychosis, mania, suicidality, or seizures (Lustyk et al., 2009). Anxiety about technology could mean that for some clients, attempts to use wearables exacerbates the very issue they try to address (Laxman et al., 2015). It has also been suggested that relaxation techniques may become counterproductive to therapeutic objectives if they begin to be used as a strategy to avoid unpleasant emotions rather than allowing them to be experienced (Allen et al., 2007).

Cuijpers and Schuurmans (2007) report that self-help interventions, including relaxation techniques, are particularly useful in overcoming client barriers such as cost, distance and an anxiety of traditional mental health settings. However, the use of self-help interventions without sufficient professional guidance was a concern due to the possibility of misdiagnosis and the greater likelihood of early dropout. Evidence-based interventions could be iatrogenic if they are poorly implemented technologically, leading to no improvement and thereby reinforcing treatment avoidance (Torous et al., 2017). Concerns have also been expressed about whether the use of technology may compromise the therapeutic alliance, although there is some evidence for the opposite, at least where technology is used appropriately according to client preferences (Richards et al., 2016). Furthermore, the use of mHealth technologies may be unsuited to clients who are at significant safety risk, and may cause unnecessary complications in complex therapeutic cases (Torous & Roberts, 2017b).

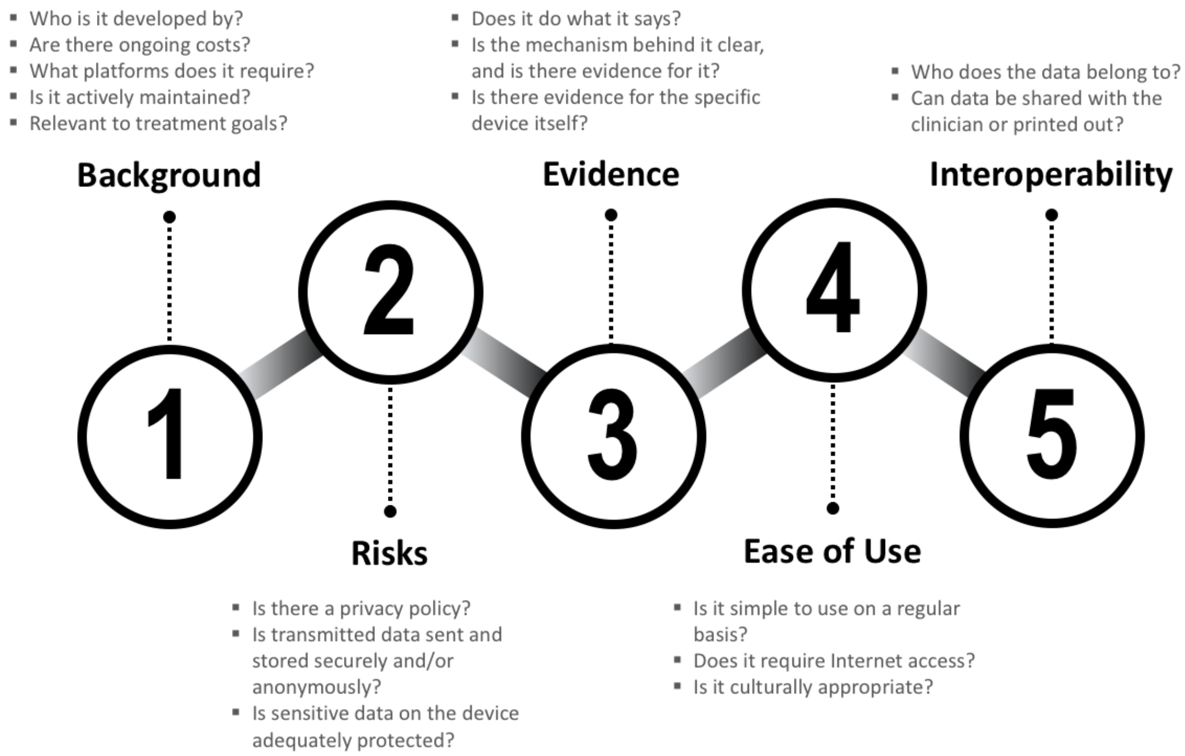
Clinicians can educate clients about the fact that not all treatment approaches are beneficial for every person, and help them to understand the potential risk of iatrogenic effects. For some clients, an over-reliance on the information provided by devices could be a concern: one report indicates that clients may become fixated on wearable device data—which may be limited in accuracy and scope—resulting in the therapeutic relationship being compromised (Baron et al., 2017). It may therefore be important to emphasise to some clients that wearables are only one piece of the larger treatment picture, and to have an open discussion about the limitations to the validity and effectiveness of such devices. On the other hand, perceptions of limited treatment efficacy may increase the risk of premature termination of therapy (Mojtabai et al., 2012), so having an overly negative attitude about wearables may become a self-fulfilling prophesy.

3.5.2 Clinical Evaluation of Devices

While Clough and Casey (2015b) contend that practitioners need to be familiar with mHealth technologies in order to effectively guide clients, Morris and Aguilera (2012) instead see the client as taking ownership, with clinicians guiding the discussion about how devices are being used and adding value to the treatment. Asking the client to demonstrate the use of the device may however be helpful in beginning a dialogue about possible risks and benefits, and about how use of the device might play a role in the treatment (Torous & Roberts, 2017b). Because new wearables are constantly being developed, it may be almost impossible for practitioners to stay abreast of individual devices. Moreover, the information that manufacturers openly provide about the functionality of their devices and their scientific validity is often lacking. Having a basic understanding of the various modalities through which devices operate, as discussed in this review, may aid in navigating this new landscape and in providing guidance to clients. Nonetheless, treatment benefits may vary depending on the fidelity with which the treatment is implemented within each particular device. Much of the supporting evidence for particular modalities (in particular, HRV) is based on the use of research-grade equipment, and this raises questions over whether such treatments can be reproduced in much less robust consumer-grade devices. Furthermore, it is likely that other factors such as device design and usability could have a substantial effect on treatment outcomes.

While no evaluation resources appear to have been developed specifically for wearable devices, there are a number of evaluation frameworks and portals designed to aid clinicians in selecting appropriate mobile apps for mental health (Neary & Schueller, 2018), and these may be adopted for wearables too. Research suggests that apps for anxiety disorders predominantly do not employ evidence-based components and the uptake of apps based directly on academic research is low (Bry et al., 2018; Neary & Schueller, 2018), necessitating proper evaluation of potential interventions. At present, the PsyberGuide website (psyberguide.org) appears to be the only portal to list any wearable devices, with a review of the Muse headband. Another approach is to use evaluation frameworks which provide structured guidelines for the systematic appraisal of mHealth technologies, and these frameworks can readily be applied to devices. While some comprehensive scales have been developed to score technologies on a range of criteria (Baumel et al., 2017; Stoyanov et al., 2015), the American Psychiatric Association's app evaluation model (American Psychiatric Association, 2017; Torous et al., 2018) is a briefer hierarchical framework that may be more suitable for clinical decision making, as it is used to weigh up apps qualitatively according to individual priorities. Under this system, apps are subjected to a five-stage process beginning with the collection of background information, followed by the evaluation of risks, evidence, ease of use, and interoperability in turn (Figure 3). Each stage of the assessment leads to a decision to proceed, to proceed with caution, or not to proceed. This type of rapid evaluation may be useful in helping clinicians and clients orient to pertinent appraisal factors, instead of depending on unreliable information such as app store ratings and user reviews. Where the use of technology is initiated by the clinician, this shared evaluation can also serve to adequately inform the client before consenting to treatment (Torous & Roberts, 2017b).

Figure 3
Wearable device evaluation process, after American Psychiatric Association (2017)



3.6 Conclusion

While there is strong and growing interest in wearable technologies for mental health disorders like anxiety, this interest has not yet catalysed sufficient research into the efficacy and effectiveness of such devices. As with other mental health technologies, the introduction of wearable devices is bound to result in ongoing disruption in the way that treatments are delivered, at least for some. Due to the broad subject of the present review, a narrative review approach was taken, limiting inferences that can be made about levels of evidence.

However, it was nonetheless apparent that overall, little evidence exists to support the use of specific devices for the treatment of anxiety disorders. This is perhaps due to the fact that technology is often superseded before it can be properly evaluated. What evidence for specific devices could be identified here was also largely limited by methodological constraints and narrow or non-clinical samples, making the implications for the treatment of clinically significant anxiety symptoms in real-world clinical settings unclear. Furthermore, general evidence for the modalities through which these devices are presumed to work also appears to be limited, though HRV biofeedback may be an exception to this. Despite this general lack of evidence, it is advantageous for clinicians to be aware of common wearable devices and how they ostensibly function, since it is increasingly likely that clients may independently adopt such technologies. However, the use of these devices as adjuncts should not supplant treatment with appropriate established therapies. Clinicians should be aware that there can be risks and unexpected effects resulting from the use of wearable devices. Using clinical evaluation tools such as the APA app evaluation model to weigh up risks and benefits together with clients can help to identify anticipated problems, ensure both client and practitioner are fully informed, and determine how devices will help work towards therapeutic goals.

CHAPTER 4: STUDY 2

Perceived Acceptability of Wearable Devices for the Treatment of Mental Health Problems

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4.1 Statement of Authorship

Principal Author

Name of Principal Author (Candidate)	Hugh Hunkin		
Contribution to the Paper	Collaboratively developed research objectives and methodology; developed survey materials; managed data collection; performed analyses; wrote initial draft; collaborated on editing of final drafts; acted as corresponding author		
Overall Percentage (%)	80		
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	16 March 2022

Co-author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate in include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution

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Name of Co-Author	Ian Zajac		
Contribution to the Paper	Collaboratively developed research objectives and methods; gave feedback on survey materials and interpretation of data; assisted with thematic analysis; edited drafts; advised on responses to reviewers		
Signature		Date	16 March 2022

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Contribution to the Paper	Collaborated on research design; assisted with thematic analysis; edited drafts; advised on responses to reviewers		
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4.2 Abstract

Objective. This study examined the potential acceptability of wearable devices (e.g. smart headbands, wristbands and watches) aimed at treating mental health disorders, relative to conventional approaches.

Method. A questionnaire assessed perceptions of wearable and non-wearable treatments, along with demographic and psychological information. Respondents (N = 427) were adults from a community sample (M_{age} = 44.6, SD_{age} = 15.3) which included current (30.2%) and former (53.9%) mental health help-seekers.

Results. Perceived effectiveness of wearables was a strong predictor of interest in using them as adjuncts to talk therapies, or as an alternative to self-help options (e.g., smartphone applications). Devices were more appealing to those with negative evaluations of psychological therapy and less experience in help-seeking.

Conclusions. Interest in using wearable devices was strong, particularly when devices were seen as effective. Clients with negative attitudes to conventional therapies may be more responsive to using wearable devices as a less directive treatment approach.

4.3 Introduction

Untreated psychological disorders are a major global problem. Since the 1990s there has been a growing awareness of the 'treatment gap' between those who require treatment and those who access it (Demyttenaere et al., 2004). However, despite considerable improvements in treatment resources, the gap in industrialized countries does not appear to have shifted over time (Jorm et al., 2017). Improving preventive mental health, as well as targeting therapies to the most severe cases, may be important strategies in reducing the treatment gap (Jorm et al., 2017). However, a range of psychological and structural barriers prevent people from accessing traditional face-to-face mental health services, including stigma, a preference for solving one's own problems, or poor service availability (Mojtabai et al., 2012).

Technological adjuncts to therapy, such as wearable devices, are one proposed strategy for closing the treatment gap (Naslund et al., 2017). A range of wearables—devices worn as an accessory or item of clothing—have recently been developed with the goal of improving mental health (Coffey & Coffey, 2016; Hunkin et al., 2019; Torous & Gualtieri, 2016). Wearable devices typically operate in concert with smartphone applications ('apps') by sensing and relaying physiological signals. For instance, many of these devices work through biofeedback, monitoring bodily signals that reflect arousal state and feeding this information back to the wearer, prompting them to utilize adaptive coping skills. They include EEG headbands for aided meditation, breathing sensors, and heart rate variability monitors. Some are worn throughout the day, while others are used for regular brief sessions of self-administered training. A variety of wearable devices oriented toward mental health are now commercially available and being marketed directly to consumers, with the majority priced between $150-300 US dollars (Hunkin et al., 2019). One example is *Muse* (Interaxon, Inc.), an EEG headband designed to give auditory feedback during focused-attention meditation. While using the headband and accompanying app during meditation sessions, the wearer hears soundscapes that vary from calm to intense, according to their level of focus on the breath. By receiving feedback on what non-judgmental attention feels like, as well as tracking progress, it is theorized that the wearer can more rapidly develop proficiency as a meditator (Balconi et al., 2017).

Like other e-mental health approaches such as apps, evidence-based wearable devices could potentially improve mental health outcomes due to their accessibility, flexibility, and low cost (Nicholas et al., 2017). Recent forecasts for the wearable market (Gartner, 2018) suggest that the number of devices oriented at mental health, as well as their sophistication, will continue to increase. Despite this, many questions remain regarding the use of such devices in clinical practice, such as the extent of potential risks and benefits, principles for the evaluation of devices, and the clinical circumstances in which wearables might be most effective. With the growing use of technology in clinical settings (e.g., smartphone apps, tablets, virtual reality devices), as well as ongoing developments in the consumer device market, clinicians are more likely to encounter wearable devices. However, the potential for these devices to improve therapeutic outcomes, either when used alone or as adjuncts to traditional talk therapies, will depend at least to some extent on their acceptability to clients. Research indicates that consumers' perceived benefits and limitations of e-mental health treatments differ from traditional face-to-face treatment (Musiat et al., 2014), and also that individual interest in these treatments varies (Nicholas et al., 2017). Since there is a demand from clients to receive more personalized treatments (Hollis et al., 2018), and accommodating client preferences results in more positive outcomes and fewer dropouts (Swift et al., 2018), there is a clear need to understand which factors shape the acceptability of wearable devices in order to identify client groups for which they might be efficacious.

Research into the role of individual factors in the acceptability of wearable devices, as opposed to device factors, is limited thus far. Important individual factors are theorized to include aspects such as demographics, traits, cognitive factors, beliefs and attitudes, and disease characteristics (Ritterband et al., 2009). Though knowledge is limited, previous studies have evaluated some individual factors in the broader context of e-mental health treatments, such as Internet-delivered interventions. Several of these studies have focused on the *hypothetical* acceptability of such interventions, referring to the level of interest expressed in an intervention that had not yet been experienced (Berry et al., 2016). This type of acceptability is distinct from the acceptability of interventions which have already been experienced. It is an important target for research because if hypothetical acceptability is low, treatment uptake may be compromised, regardless of the actual quality of the treatment. Furthermore, a generally low willingness to engage with digital interventions has been cited as a major problem in digital mental health research and implementation (Mohr, Lyon, et al., 2017). Klein and Cook (2010) examined the characteristics of 'e-preferers' (i.e. those who had a higher preference for Internet-based mental health assistance compared to face-to-face therapy) and showed they did not differ on demographic factors or previous mental health service usage, but that they had significantly higher stigma regarding mental illness. March et al. (2018) reported similar findings in regard to the absence of demographic differences, but also demonstrated that technology confidence led to a greater preference for online services relative to face-to-face services. Another recent study of university students and primary care patients found that higher help-seeking self-stigma, together with treatment expectancy, predicted a stronger preference for Internet-based approaches compared to face-to-face treatment (Wallin et al., 2018). Taken together, these findings suggest that technological readiness, perceived effectiveness of devices, and barriers to face-to-face therapy (such as stigma) could be important predictors of interest in wearable devices relative to traditional approaches.

Given the need to effectively target wearable devices for mental health to those most likely to use them, we aimed to evaluate how the perceived acceptability of these devices was related to individual factors identified from the e-mental health literature, as well as clinical factors—psychological symptoms, prior mental health diagnoses, previous experience consulting mental health professionals, and satisfaction with previous treatment. Furthermore, because the factors motivating use of mental health wearables in self-help as opposed to clinician-facilitated approaches might differ, these options were considered separately (Arjadi et al., 2018). Given the absence of a research evidence base addressing preference for wearables, we adopted an exploratory approach with the aim of identifying factors that predict a desire to use wearable devices preferentially (either alone or in combination with other treatments).

4.4 Method

4.4.1 Participants

Eligible participants were Australian residents over the age of 18 who considered themselves as fluent in English. A total of 546 participants consented, with two ineligible, 117 partial, and 427 complete responses. Partial responses were discarded as missing items could not be reasonably imputed. Table 4 presents a summary of the characteristics of complete responders.

4.4.2 Measures

4.4.2.1 Demographics. Participants reported their age, gender, relationship status, household income, level of education, Australian postcode, and type of employment (according to the Australian and New Zealand Standard Classification of Occupations). The index of relative socioeconomic disadvantage (IRSD), a measure of socioeconomic status where lower values represent more disadvantageous factors, was computed based on respondent postcodes (Australian Bureau of Statistics, 2016b). Postcodes were used to determine whether respondents resided in major cities or rural/remote areas (Australian Bureau of Statistics, 2016a).

Table 4
Sociodemographic characteristics of participants (N = 427)

	$M \pm SD$ or n (%)
Age	44.63 ± 15.25
18-34	144 (33.7%)
35-54	150 (35.1%)
55+	133 (31.1%)
Gender Male	184 (43.1%)
Education	
Diploma or below	177 (41.5%)
Bachelor degree	178 (41.7%)
Postgraduate degree	72 (16.9%)
Relationship status	
Single/divorced/separated	156 (36.5%)
Married/committed relationship	271 (63.5%)
Household income	
< $35,000	112 (26.2%)
$35,000-$65,000	92 (21.5%)
$65,000-$105,000	103 (24.1%)
> $105,000	120 (28.1%)
Socioeconomic disadvantage	1019.11 ± 56.40
Rural/remote	124 (29.0%)

4.4.2.2 Hypothetical Acceptability of Mental Health Treatments. Participants were asked to report their interest in using each of four specific mental health treatments (*If you were experiencing a mental health problem (e.g. anxiety, depression), how interested would you be in [treatment type] to help your problem?*), scored on a seven-point scale (*Not at all interested – Very interested*). Treatments included (1) *using counselling or talking therapies under the guidance of a mental health professional*, (2) *using wearable devices under the guidance of a mental health professional* (i.e. blended therapy), (3) *using wearable devices* without *professional guidance*, and (4) *using other self-help options* without *professional guidance*.

4.4.2.3 Intention to use a Wearable Device. Participants indicated whether they would "definitely want" or "definitely not want" to use a wearable device if they were experiencing a mental health problem, or whether they would need to find out more before deciding. This categorical response was used to determine the proportion of respondents who made a relatively rapid decision based on the limited information about wearable devices that was provided to them. Those who indicated they required more information were prompted to briefly describe specific details they would need to know in order to decide. The collection of this open-ended data was intended firstly to triangulate the quantitative responses (i.e. to increase confidence in the findings through the use of multiple investigatory methods; Korstjens & Moser, 2018), and secondly to identify any aspects that had not been adequately measured by quantitative items.

4.4.2.4 Other Clinical and Wearable-Oriented Items. Items were developed to assess awareness of wearable devices for mental health (yes/no), intention to use wearables if recommended by a practitioner (yes/no), level of knowledge of wearable devices prior to commencing the survey (seven-point scale, *No knowledge – Expert knowledge*), and perceived effectiveness of wearable devices for mental health problems (seven-point scale, *Not at all effective – Extremely effective*). Use of wearable devices for mental health and well-being, or other purposes (such as fitness) was reported. Participants indicated whether they were currently consulting a mental health professional or had ever done so, as well as any prior mental health diagnosis, whether this diagnosis was still having an impact, and the duration of its impact.

4.4.2.5 Depression, Anxiety and Stress Scales (DASS-21). The DASS-21 (Lovibond & Lovibond, 1995) is an abbreviated self-report measure of the negative affective states of depression, anxiety, and stress. Items represent statements associated with depression, anxiety, or stress, rated in terms of how much they applied over the past week (0 = *Did not apply to me at all,* 1 = *Applied to me to some degree, or some of the time*, 2 = *Applied to me to a considerable degree, or a good part of time,* 3 = *Applied to me very much, or most of the time*). Item scores are summed within each of the three scales and multiplied by two, producing scale scores ranging from 0-42 where higher values represent greater symptom severity. Cronbach's alpha showed good internal consistency (depression = .93, anxiety = .84, stress = .86).

4.4.2.6 Perceived Barriers to Psychological Treatments Scale (PBPT). The PBPT (Mohr et al., 2010) is a multidimensional measure of perceived barriers to face-to-face treatment, comprising nine distinct dimensions. The scale consists of 25 items relating to specific barriers rated by difficulty (1 = *Not difficult at all,* 2 = *Slightly difficult,* 3 = *Moderately difficult,* 4 = *Extremely difficult,* 5 = *Impossible*). Instructions for completion were adapted for readability and the Australian context (*Please rate how difficult these things might make it for you to see a counsellor or psychologist.*) Mean scores are calculated for each of the eight subscales so that each has a score between 1-5, where higher scores represent greater barriers to treatment. The total score is the mean of all 25 items, although notably this over-represents subscales which contain more items (particularly stigma). Internal consistency was generally good (total scale .91; subscales from .75 to .88 except 'availability of services', .59).

4.4.2.7 Technology Readiness Index 2.0 (TRI 2.0). The TRI 2.0 (Parasuraman & Colby, 2015) is a 16-item measure of attitudes toward the use of novel technologies. Four subscales encompass both motivational (optimism, innovativeness) and inhibitory (discomfort, insecurity) aspects, each containing four items which represent statements about technology. Responses indicate level of agreement with each statement (1 = *Strongly* *disagree,* 2 = *Somewhat disagree*, 3 = *Neutral*, 4 = *Somewhat agree*, 5 = *Strongly agree*). Subscales scores are the mean of their constituent items, ranging from 1-5. The total scale score is the mean of the subscales after reversing insecurity and discomfort subscales; higher scores thus represent more positive attitudes to novel technology. Internal consistencies were acceptable, ranging from .64 to .82 for subscales, and .85 overall.

4.4.3 Procedure

After obtaining human ethics approval, the online questionnaire was made active during November and December 2018. To target a broad sociodemographic range, participants were sought via Facebook advertising (n = 378) and convenience sampling (i.e. sharing of the survey through personal and professional networks; n = 53). In order to minimize participation bias, advertisements did not refer to wearable devices but asked potential participants to complete a short survey on "current and future approaches to treating common mental health issues like anxiety and depression", and participation was incentivized with a prize draw of three $150 (Australian dollar) vouchers. Participants were first shown an electronic information sheet describing eligibility requirements, the kind of information they would be asked to provide and how this data would be used, the estimated time to complete the survey, and the potential for experiencing discomfort from some of the questions included in the DASS-21. To continue, participants were required to indicate that they had read and understood this information, and willingly agreed to take part. Following consent, participants completed demographic questions and eligibility checks, and were asked whether they were already aware of wearable devices for mental health. Participants were shown a brief description of wearable devices for mental health, including general information about their typical size, cost, purpose, method of working, and cost (see supplementary material, Appendix A). After viewing this description, participants reported their interest in accessing mental health treatment through four distinct methods, as described above, before completing the remaining measures. Participants who reported ‘moderate’ level or higher depression, anxiety or stress symptoms according to DASS cut-off scores were shown information about some common manifestations of these problems and a range of avenues for seeking help.

4.4.4 Statistical Analyses

Quantitative analyses were conducted using the R statistical software, version 3.5.1 (R Core Team, 2018). Power analysis using G*Power 3.1.9.2 (Faul et al., 2009) indicated that $N = 395$ participants were required to detect small effects ($f^2 = 0.02$) in linear regression models with up to 10 predictor variables, given a 5% Type I error rate and 80% power (Cohen, 1988). Categorical predictor variables were collapsed when groupings appeared to be redundant or contained only a small number of respondents. Since the effects of age on outcome variables appeared linear, age was treated as a continuous variable.

To determine whether treatment preference differed significantly by treatment, a mixed linear model specified with a random intercept for respondent was fitted and post-hoc Tukey comparisons of means were computed. Bivariate analyses were used to examine the association of individual predictors with individual treatment acceptability. Due to non-normal data, Spearman rank correlations were used for continuous predictors; *t*-tests and one-way ANOVAs were considered robust tests for categorical predictors due to the large sample size, the fact that variances were generally homogenous, and distributions did not differ substantially between groups (Fagerland, 2012; Schmider et al., 2010). Given the large number of bivariate tests, Benjamini and Hochberg’s (1995) false discovery rate adjustment was used to correct *p*-values. This procedure is less conservative than family-wise error rate controls such as the Bonferroni correction because it accounts for the number of actual null hypothesis rejections (Streiner, 2015).

To examine predictors of comparative acceptability, three comparisons between specific treatments (as described in the results) were computed as the *Z*-scores of the difference between interest in one treatment and another, thus representing a measure of relative preference for one treatment over the other. Multiple linear regression models were then constructed for each of the three treatment comparisons. While there are a number of limitations to automated stepwise model building approaches (Harrell, 2015), some reduction in predictors was desirable for reasons of interpretability and practicality (Houwelingen & Sauerbrei, 2013). Furthermore, redundancy analysis (Harrell, 2015) did not identify any variables that could be removed prior to modelling, and no particular variables had theoretical primacy. Predictors for each model were therefore selected using backward elimination based on optimizing the Akaike information criterion (Heinze et al., 2018). Reduced models were cross-checked against the corresponding full models for each treatment comparison, to ensure that predictors with sizeable and/or statistically significant effects had been included in the reduced models, and that parameter estimates in the reduced models did not differ wildly from the full models.

For the written responses, thematic analysis from a realist perspective (i.e. assuming responses were a true articulation of participants' experience) was used to explore information respondents desired to know in order to decide whether to use wearable devices (Braun & Clarke, 2006). This process aims to find common patterns of meaning that occur across the data, and normally involves a series of steps consisting of data familiarization, generating codes for features of the data, organizing related codes into overarching themes, and iteratively reviewing and refining themes to fit the data. Data were analyzed using NVivo 12 (QSR International Pty Ltd) taking an inductive approach. The first author developed the coding frame during manual coding of responses, and together with the third author, identified themes that arose from these codes. To establish credibility (Korstjens &

Moser, 2018), the second author assessed 30 randomly selected responses and identified corresponding themes. Differences in thematic associations in this subsample, as well as the categorization of codes into themes overall, were reviewed by the first and second authors in order to reach consensus ('investigator triangulation'; Korstjens & Moser, 2018). The identified themes, along with representative quotes, are presented in Table 7. To promote dependability and confirmability of the analysis, the raw data have been published separately (https://doi.org/10.25909/5d65c816af254).

4.5 Results

Table 4 presents the characteristics of study participants. A similar proportion of males and females over a broad range of ages (18-78) responded, although those over the age of 65 were less represented. Participants were predominantly either professionals (37.9%) or not formally employed (e.g. students, retired, or unpaid caregivers; 35.4%), whereas under 5% reported being sales workers, machinery operators and drivers, or laborers. Mean relative socioeconomic disadvantage was in the seventh decile, signifying somewhat fewer disadvantages than the average Australian. According to DASS cut-off scores, 47.3% of participants had at least a 'mild' level of symptoms for one or more of the depression, anxiety and stress subscales, while 12.9% reported 'moderate', 5.6% 'severe', and 2.8% 'extremely severe' symptoms (Lovibond & Lovibond, 1995). Almost a third (30.2%) of the sample reported that they were presently seeing a mental health professional, while 53.9% had done so previously but were no longer accessing treatment.

Table 5 summarizes clinical and wearable-oriented variables. Around two-fifths (40.7%) of respondents initially reported an awareness of wearable devices for mental health. However, participants later reported relatively low knowledge of the nature of these devices in the context of a description of them during the actual survey. While more than a fifth of respondents indicated that they presently used other types of wearable devices, such as fitness

Table 5
Clinical and wearable-oriented variables

	M ± *SD* or *n* (%)
Pre-existing awareness of wearables for mental health	174 (40.7%)
Previous knowledge	1.75 ± 1.26
Interest in using a wearable device	
Definitely yes	162 (37.9%)
Need to know more	249 (58.3%)
Definitely no	16 (3.7%)
Would use wearable device if recommended by clinician	411 (96.3%)
Wearable devices currently used for mental health/wellbeing[a]	
1 device	7 (1.6%)
2 devices	1 (0.2%)
Use of wearable devices for other reasons	92 (21.5%)
Perceived effectiveness	4.02 ± 1.21
Interest in treatments	
Talk therapies	5.61 ± 1.66
Wearables (blended)	5.28 ± 1.62
Wearables (self-help)	4.01 ± 1.95
Other self-help	4.50 ± 1.74
DASS[b]	
Depression	14.39 ± 11.20
Anxiety	8.78 ± 8.12
Stress	15.37 ± 9.23
Ever consulted a mental health professional	
Yes, and still seeing	129 (30.2%)
Yes, but no longer seeing	230 (53.9%)
No	68 (15.9%)
Ever been diagnosed with a mental health problem	
Yes, and still impacting	239 (56.0%)
Yes, but no longer impacting	70 (16.4%)
No	118 (27.6%)
Satisfaction with prior treatment[c]	4.70 ± 1.70
Years affected by condition[d]	18.57 ± 14.13
Barriers to treatment	1.98 ± 0.60
Stigma	1.85 ± 0.79
Lack of motivation	2.21 ± 1.04
Emotional concerns	1.89 ± 0.90
Negative evaluation of therapy	2.05 ± 0.91
Misfit of therapy to needs	1.84 ± 0.78
Time constraints	2.11 ± 0.96
Participation restrictions	1.59 ± 0.75
Availability of services	2.40 ± 0.95
Cost	3.02 ± 1.13
Technology readiness	3.24 ± 0.63
Optimism	3.65 ± 0.76
Innovation	3.20 ± 0.96
Discomfort	2.68 ± 0.79
Insecurity	3.19 ± 0.88

Note: [a]Devices reported include FitBit 'Relax' app (n = 5), Interaxon Muse headband (n = 2), Sentio Feel wristband (n = 1), and Spire Stone respiration monitor (n = 1). [b]Adjusted for DASS-42 equivalence. [c]For respondents who had previously consulted a mental health professional (n = 359). [d]For those who reported a diagnosed condition and reported duration (n = 234).

wearables, only eight respondents reported that they currently used a wearable device for mental health or well-being. Few respondents indicated they had no interest in using a wearable device, whereas around two-fifths indicated that they would definitely be interested in using such a device.

4.5.1 Acceptability of Treatments

Inspection of hypothesized predictors revealed that older participants tended to have significantly lower depression, anxiety and stress scores, perceived barriers to treatment, and technology readiness, with small-to-moderate effects (Cohen, 1992). Furthermore, greater total perceived barriers to treatment were significantly associated with lower satisfaction with previous treatment (r = -.35) and higher depression, anxiety and stress (r = .38-.39). Greater technology readiness was significantly associated with increased levels of knowledge (r = .19) and greater perceived effectiveness (r = .17) of wearables. Correlations between all study variables are shown in Table A1 (supplementary material, Appendix A). Analysis of variance showed that total DASS scores varied significantly according to whether respondents had ever consulted a mental health professional, $F(2, 424) = 30.89$, $p < .001$, $\eta^2 = .13$, with highest scores for those still seeing a clinician and lowest scores for those who had never visited. However, consulting a mental health professional was not significantly associated with total perceived barriers to treatment, $F(2, 424) = 2.57$, $p = .078$, $\eta^2 = .01$.

Of the four treatment options presented, respondents expressed strongest interest in using talk therapies for treatment of a mental health problem, followed closely by using wearables with the guidance of a mental health professional (i.e. blended therapy). Using wearables without assistance was the least preferred option. A mixed linear effects analysis showed a significant main effect, $F(3, 1278) = 102.24$, $p < .001$, and Tukey post-hoc testing indicated that mean preferences for all treatments were significantly different from one another. The relationships of continuous and categorical predictors with acceptability of the four treatments are provided as supplementary material (Appendix A, Tables A2 and A3).

4.5.2 Multivariable Linear Models of Comparative Treatment Preferences

Multivariable linear models comparing preference for wearable devices relative to other treatment preferences are presented in Table 6. In the model comparing wearables (blended) with talk therapies, six predictors explained 17% of variance in treatment preference. Greater perceived efficacy of wearables, current use of other wearable devices, and negative evaluations of therapy predicted significantly greater interest in accessing treatment using wearable devices in a blended format rather than talk therapies alone. On the other hand, previous or ongoing consultation with a mental health professional predicted a significantly greater preference for talk therapies, as did greater prior knowledge of wearable devices. A second model considering wearables (self-help) vs other self-help incorporated eight predictors and explained 14% of variance in preferred treatment. Greater perceived efficacy of wearables and negative evaluation of therapy predicted a significantly stronger preference for using wearable devices rather than other types of self-help. However, previous or current experience consulting a mental health professional, stigma, and discomfort with technology predicted a significantly greater preference for other self-help options. The last model considered wearables (blended) vs wearables (self-help) and incorporated seven predictors explaining 15% of variance in preferred treatment. Older age and rural/remote location predicted significantly greater preference for using wearables in a blended format rather than for self-help. Furthermore, relative to those in the top two household income quintiles (>\$105,000), being in the second quintile (~\$35,000-65,000) predicted a

Table 6

Linear regression models predicting relative interest in wearable treatments compared with three other specified interventions

Model/predictor	$B \pm SE$	β [95% CI]	p
1. Wearables (blended) vs talk therapies			
Intercept	-1.82 ± 0.41		<.001
Current wearable usage: Yes[a]	0.43 ± 0.18		.016
Ever consulted: Yes (no longer seeing)[a]	-0.51 ± 0.21		.017
Ever consulted: Yes (still seeing)[a]	-1.27 ± 0.23		<.001
Perceived effectiveness	0.39 ± 0.06	0.28 [0.19, 0.37]	<.001
Barrier: Negative evaluation of therapy	0.21 ± 0.08	0.11 [0.02, 0.20]	.014
Barrier: Time	0.14 ± 0.08	0.08 [-0.01,0.17]	.067
Previous knowledge about wearables	-0.13 ± 0.06	-0.10 [-0.18, -0.01]	.033
2. Wearables (self-help) vs other self-help			
Intercept	-1.19 ± 0.55		.030
Current wearable usage: Yes[a]	0.32 ± 0.21		.132
Ever consulted: Yes (no longer seeing)[a]	-0.62 ± 0.25		.014
Ever consulted: Yes (still seeing)[a]	-0.65 ± 0.28		.021
Perceived effectiveness	0.47 ± 0.07	0.30 [0.21, 0.39]	<.001
Barrier: Stigma	-0.52 ± 0.15	-0.22 [-0.34, -0.09]	<.001
Barrier: Negative evaluation of therapy	0.48 ± 0.14	0.22 [0.10, 0.35]	<.001
Barrier: Time	0.14 ± 0.10	0.07 [-0.02, 0.17]	.138
Barrier: Participation restrictions	-0.22 ± 0.13	-0.09 [-0.19, 0.02]	.103
Technology readiness: Discomfort	-0.07 ± 0.03	-0.11 [-0.20, -0.02]	.018
3. Wearables (blended) vs wearables (self-help)			
Intercept	0.56 ± 0.42		.193
Remoteness: Rural/remote[b]	0.43 ± 0.19		.021
Household income: <$35,000[c]	0.03 ± 0.24		.896
Household income: $35,000-65,000[c]	0.56 ± 0.24		.022
Household income: $65,000-105,000[c]	-0.04 ± 0.23		.851
Ever consulted: Yes (no longer seeing)[a]	0.50 ± 0.24		.037
Ever consulted: Yes (still seeing)[a]	1.03 ± 0.26		<.001
Age	0.02 ± 0.01	0.14 [0.05, 0.23]	.018
Barrier: Negative evaluation of therapy	-0.53 ± 0.10	-0.26 [-0.36, -0.16]	<.001
Barrier: Participation restrictions	0.27 ± 0.13	0.11 [0.00, 0.21]	.043
Previous knowledge about wearables	-0.11 ± 0.07	-0.08 [-0.17, 0.01]	.089

Note: Dependent variables in each model are the standardized differences between one treatment and another; positive estimates predict a higher preference for the first treatment described in each model, and vice versa. Predictors were selected using backward elimination to optimize the Akaike information criteria. All three models were significant: (1) Adjusted R^2 = .17, $F(7, 419) = 13.82$, $p < .001$; (2) Adjusted R^2 = .14, $F(9, 417) = 8.89$, $p < .001$; (3) Adjusted R^2 = .15, $F(10, 416) = 8.34$, $p < .001$. Comparison conditions: [a]No, [b]Major cities, [c]>$105,000.

significantly greater preference for using wearables in the blended format, as did the presence of participation restrictions and previous or ongoing consultation with a mental health professional. On the other hand, negative evaluation of therapy was associated with a preference for using wearable devices without clinician assistance. Satisfaction with prior treatment was not included in these models because of incomplete responding. However, bivariate analyses (Appendix A, Table A2) indicated that prior treatment satisfaction was associated with a reduced preference for wearables (blended) relative to talk therapies ($r = -.19$, $p < .001$) and a greater preference for wearables in a blended format relative to self-help format ($r = .15$, $p < .05$).

4.5.3 Written Responses

Around half of study participants (58.3%, $n = 249$) reported an interest in wearables for mental health but indicated that they required further information before deciding whether to use them. Of these, 97.9% ($n = 244$) provided written responses indicating what information they desired in order to inform whether or not to use such devices. Thematic analysis of these responses suggested thirteen distinct themes, which are presented along with representative quotes in Table 7. Around half of the responses were considered to appeal to evidence and efficacy, as well as knowing how devices worked. Privacy was also an important theme for many respondents, particularly in relation to data storage and access control. Further themes concerned discretion, practicality, risks and negative outcomes, positive outcomes, cost, time and effort needed, matching devices to the problem or situation, knowing how devices are used, and the availability of professional support.

4.6 Discussion

This study evaluated predictors of the acceptability of wearable devices for mental health concerns, relative to conventional mental health treatment options. The results indicate that overall, interest in using wearable devices with clinician support was almost as

Table 7

Themes relating to important factors in decision-making about wearable device use

Theme	Description	Excerpts from written responses
Knowing how devices work (n = 112)	How devices work; what devices are measuring; what devices do; how devices help or the theory behind them	*"More detail about how the devices might assist"* (#38) *"What data the device collects, how it would help me in managing my mental health"* (#446)
Evidence and efficacy (n = 100)	Whether devices were efficacious; what evidence or research there was for devices; success rates; reliability	*"Whether it is effective, helpful or a time waster"* (#33) *"A lot of background research and/or reasons for believing they might help."* (#81)
Privacy (n = 45)	Access to data; storage of data; use of data by others (e.g. for monitoring, treatment enforcement, withholding benefits or insurance claims)	*"How the data associated with my use of the wearable device would be gathered, stored and shared; and the particulars of exactly what data would be gathered."* (#127) *"What data was being tracked, if that information was secure, and I'd need to be 100% certain the data could NOT be shared without my consent - and specifically never to insurance or other financial services companies"* (#509)
Discretion (n = 36)	Discreetness, visibility, or obtrusiveness of devices; stigma	*"Having it visible to others would cause me much more anxiety."* (#63) *"…whether I can have it disguised as something else to not single me out as struggling, say a watch or Fitbit for example."* (#493)
Positive outcomes (n = 36)	Potential benefits and advantages; expected effects; helpfulness; positive impact	*"The outcomes that may be expected from the devices."* (#69) *"…how it would benefit in during anxiety and or depressive episodes."* (#357)
Risks and negative outcomes (n = 36)	Side-effects, unexpected effects or potential harm; safety; disadvantages; working counter to therapeutic aims; risks of use without professional support	*"Does it harm the body, any side effects."* (#361) *"I would need reliable evidence regarding the possibility of negative outcomes."* (#342)

Theme	Description	Excerpts from written responses
Cost (n = 31)	Financial cost of purchase and use	*"Is it affordable?"* (#526)
Time and effort needed (n = 29)	Length of treatment; time consumed/required frequency of using; effort involved; ease of use; convenience; time cost vs benefit	*"How long per day and overall duration"* (#50) *"…whether the effort of collecting the data would be worth it."* (#519)
Physical form (n = 25)	Size; type of device/what it is; appearance; design/materials	*"Size/inconvenience."* (#515) *"If it were a watch or similar, I'd wear it. I'd probably not wear a head band or ear clips"* (#356)
Matching devices to problem or situation (n = 21)	Match to problem/situation; whether it is customized for the individual or generic; contraindications	*"I'd want to know if the person or computer knew what my condition was and not just put me in a basket with all other patients."* (#370) *"Would it be specifically tuned for me or offer a generic instruction like go for a walk or have a nap"* (#442)
Practicality (n = 20)	Comfort; durability; intrusiveness/obstructiveness	*"How limiting to normal function it may be."* (#484) *"…practicality when wearing the device, maintenance…"* (#483)
Knowing how devices are used (n = 18)	How to use the devices; how feedback is received, or how to interpret/respond to feedback	*"How to interpret the symptoms that the device is monitoring"* (#230) *"Details of how the sessions proceed"* (#282)
Availability of professional support (n = 15)	Whether support is available; whether devices are recommended by a professional; whether professionals are aware of devices	*"Detailed professional advice from consulting psychologist or psychiatrist well acquainted with my condition to date"* (#113) *"I'd also want to talk to my doctor/psych to gauge how effective they think they are, whether their other patients liked it/had success, that kind of thing."* (#229)

Note: Data based on a subsample of n = 244 responses where respondents indicated they required more information in decision-making about wearable device use.

strong as interest in using talk therapies alone. However, use of mental health wearables appeared to be dependent upon the perceived effectiveness of these devices and knowledge regarding "how they work". Importantly, the use of wearable devices appeared to reduce some barriers to accessing treatment, particularly negative evaluations of therapy, but was contraindicated by higher stigma. Furthermore, prior experience accessing mental health services was associated with a greater preference for treatments involving a higher level of clinician involvement (i.e. talk therapies, followed by wearables in blended format). These findings have several implications for clinical practice and further research with this emerging technology.

The perceived effectiveness of wearable devices was consistently one of the strongest predictors of interest in using wearables over other treatment options. While this is congruent with research into e-mental health treatments more broadly (Gun et al., 2011; Musiat et al., 2014), generating robust evidence for wearable devices is troublesome because devices and apps tend to be updated on short, commercially-oriented timescales, whereas controlled trials are costly and results may become quickly outdated (Kumar et al., 2013). Alternative approaches to evaluation have been proposed (e.g. continuous evaluation systems or rapid research designs; Mohr, Cheung, Schueller, Hendricks Brown, & Duan, 2013; Riley, Glasgow, Etheredge, & Abernethy, 2013), but these new methods have not been widely adopted, and neither is there a consensus view that they supersede existing methods (Torous et al., 2019). Similarly to mental health apps, the current state of evidence for wearables means they may best serve as adjuncts to extend existing evidence-based treatments (e.g. devices such as assisted meditation headbands), while exercising caution (Lui et al., 2017). Brief clinical evaluation frameworks such as the App Evaluation Model (American Psychiatric Association, 2017) can be easily adapted for use with wearable devices (Hunkin et al., 2019), and may provide a pragmatic way to systematically assess the suitability and safety of a given wearable device used adjunctively in a specific clinical situation.

The results of this study provide some insight into factors associated with a desire for clinician guidance when using wearable devices. Respondents' preference for clinician involvement with wearables is consistent with previous work demonstrating that e-mental health interventions are more acceptable and/or helpful when coupled with therapeutic support (Berry et al., 2016; Casey et al., 2013; Klein & Cook, 2010). Research suggests that guided use of e-mental health interventions results in fewer drop-outs (Anton & Jones, 2017) and superior clinical outcomes (Mehrotra et al., 2017) relative to unguided use. Equally, the use of e-mental health interventions as adjuncts to face-to-face interventions may improve compliance with the primary treatment (Lui et al., 2017). However, interrelated factors including negative evaluation of therapy, having no experience consulting mental health professionals, or being less satisfied with prior experiences (and to a lesser extent, younger age) were associated with an increased desire to use wearable devices without clinician support. This is consistent with existing research linking these factors with lower rates of treatment-seeking and treatment continuance, often connected to a desire for managing one's own problems (Mojtabai et al., 2012; Montague et al., 2015; Rickwood, 2015).

Self-help interventions have been viewed as a conduit to accessing higher intensity face-to-face services by increasing mental health literacy and emotional competence (Christensen & Hickie, 2010; Rickwood et al., 2007). However, without clinician guidance as to the suitability of wearable devices, there is a risk that they could be unhelpful, or even iatrogenic (Hunkin et al., 2019). Several strategies can be used by practitioners to overcome these emotional and attitudinal barriers in hesitant clients, including working through harmful effects of self-stigma (Corrigan & Rao, 2012), challenging extreme attitudes about self-reliance (Labouliere et al., 2015), and increasing insight into the severity of one's condition

(Mojtabai et al., 2012). Notably, the present results show that negative evaluation of therapy predicted increased interest in using wearables blended with face-to-face therapy compared with accessing talk therapy alone. This is consistent with evidence that increasing client control over an intervention can reduce resistant behavior linked to emotional barriers (Beutler et al., 2011).

While the standardized effect sizes for some individual predictors of acceptability were substantial, the variance explained by the predictive models in Table 3 was less than 20% in all cases. This large proportion of unexplained variance suggests the existence of various unmeasured factors that modulate interest in wearable devices. One widely cited model of technology acceptance (Venkatesh et al., 2012) implicates a broad range of possible factors, such as attitudes, perceived behavioral control, compatibility (i.e. consistency with needs and values), subjective norm, image (i.e. perceived status enhancement), complexity, perceived ease of use, hedonic motivation, and price value. Participants' written responses, while supporting quantitative findings, also provided insight into some of these other factors. Responses highlighted the importance of perceived efficacy and a desire for clinician support, while a lack of responses concerning issues such as technology readiness or symptom severity was also consistent with quantitative data. Responses also suggested that time and cost, common barriers to more traditional therapy, may remain as substantial barriers to accessing wearable devices. Further themes indicated the presence of other barriers more specific to wearables, such as privacy, discretion, and practicality. These barriers highlight the importance of matching individual needs to devices with specific features (e.g., robust data protection, or a discreet form factor). Lastly, the theme of matching devices to the mental health problems being experienced indicated a desire for devices that can be tailored to meet individual requirements.

The present study has several limitations. These findings may not be generalizable across sociocultural boundaries, since attitudes, barriers, and decision-making processes regarding mental health technology uptake may differ substantially (Bagozzi, 2007; Clough et al., 2019; Rojas-Méndez et al., 2015). Responses were not entirely representative of the broader Australian population in regard to variables such as education level and type of employment. The use of an online survey could also be expected to cause bias toward respondents who are more comfortable with technology. Although these kinds of biases can be expected given the sampling approach used, recruitment via Facebook does compare favorably with traditional methods as far as representativeness (Thornton et al., 2016). Furthermore, the sample did contain sufficient variability to model the impact of various inter-individual differences on treatment preference—including a wide range of scores on technology readiness. Lastly, heterogeneity in devices, individual needs, and mental health conditions means that more specifically targeted wearable interventions may garner stronger interest, as suggested by written responses.

The high proportion of respondents who had experienced mental health conditions and accessed clinical treatments was a strength of this research. Furthermore, we were able to provide some support for the notion that e-mental health may help to improve access to treatment—and perhaps also retention—which has been identified as a priority area for research (Hollis et al., 2018). Given our findings, one direction for future study is to evaluate the factors that influence the perceived effectiveness of wearable devices. Secondly, while hypothetical acceptability should be a good predictor of willingness to engage in specific treatments, future work could determine how this relates to measures of actual acceptability (e.g. ease of use, perceived helpfulness, and satisfaction ratings; Berry et al., 2016), which is likely to moderate the sustained use of wearable devices.

4.6.1 Conclusion

Wearable devices, among other e-mental health approaches, may play a major role in future psychological interventions. Respondents' strong interest in wearables and their general preference for professional guidance highlights the need for clinicians to provide opportunities for integrated approaches for some clients. Furthermore, since augmenting traditional approaches with wearable devices appeared more acceptable for those with negative perceptions of therapy, these adjuncts could be a novel approach to tackling treatment resistance. Although devices need to be seen as effective in order for clients to want to use them, clinicians must also take care to ensure that they adequately inform clients about the evidence base for wearable devices, which is currently limited. These issues notwithstanding, the broad cross-demographic acceptability of wearable devices in the present data suggest strong potential for incorporating these devices into clinical care, providing that risks and benefits are evaluated for each client and treatment scenario.

CHAPTER 5: STUDY 3

Evaluating the Feasibility of a Consumer-Grade Wearable EEG Headband to Aid Assessment of State and Trait Mindfulness

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5.1 Statement of Authorship

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Name of Principal Author (Candidate)	Hugh Hunkin		
Contribution to the Paper	Collaboratively developed the research objectives, methodology and materials; managed data collection; performed analyses; wrote initial draft; collaborated on editing of final drafts; acted as corresponding author		
Overall Percentage (%)	80		
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	16 March 2022

Co-author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate in include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution

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Contribution to the Paper	Collaborated on research design; edited drafts; advised on responses to reviewers		
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5.2 Abstract

Objectives. Measures from wearable devices could be a valuable supplement to mindfulness assessment and intervention. This observational study evaluated measures from a consumer-grade EEG headband (Muse, InteraXon, Inc.) as novel correlates of state mindfulness during focused attention meditation.

Methods. Adult participants ($N = 68$, $M_{age} = 22.66$, $SD_{age} = 7.35$) completed a task-based measure of state mindfulness and thought probe measures of subjective mind wandering while meditating with the EEG headband. A subset completed 14 days of home practice ($n = 29$).

Results. Device measures were sensitive to attention lapses within-participants in the state mindfulness task ($d = 0.56$) and had large between-participants associations for the same task ($r = -0.50$). Mean device metrics from home practice together explained approximately 30% of variance in self-reported trait mindfulness, attentional control, non-attachment and decentering.

Conclusion. EEG biomarkers show potential as correlates of mindfulness with distinct benefits over existing assessment methods.

5.3 Introduction

Wearable devices are an emerging group of technological solutions that are worn on the body and some of these devices are marketed for improved mental health and wellbeing (Hunkin et al., 2019). They typically work by detecting physiological signals that can be fed back to the user in order to train a desired response, such as relaxation, through operant conditioning (i.e., biofeedback; Sergueeva & Shaw, 2017). Wearable devices are becoming increasingly sophisticated and more widely available, and there is substantial consumer interest in their usage (Coffey & Coffey, 2016; Hunkin et al., 2020; Piwek et al., 2016). One important implication of such devices is the large volume of data that is generated through their use (Coffey & Coffey, 2016). However, to date there has been little research to evaluate the theoretical or clinical utility of such measurements (Piwek et al., 2016; Torous & Gualtieri, 2016).

One commercially available device modality is neurofeedback-assisted meditation. These wearable devices aim to support focused attention meditation by distinguishing attentive states from mind wandering states, and feeding back this information to the meditator (Brandmeyer & Delorme, 2013). Sustained attention is a central element of focused attention meditation practice, a meditation style which requires the meditator to maintain focus on an object such as the breath (Malinowski, 2013). Moreover, the degree of sustained attention during this type of meditation has been used as a novel measure of state mindfulness (Frewen et al., 2014; Levinson et al., 2014), a construct that can be described as a non-judgmental awareness of present moment experience (Bishop et al., 2004; Creswell, 2017; Davidson & Kaszniak, 2015). Wearable device measures of sustained attention during meditation might therefore also be closely associated with state mindfulness.

Device-based correlates of state mindfulness during meditation have potential importance for both theory and clinical practice. Whilst mindfulness-based interventions have demonstrated efficacy for addressing a range of clinical problems, there is ongoing scientific debate over how mindfulness itself should be operationalized and measured (Van Dam et al., 2018). Existing self-report mindfulness measures have several limitations, such as poor discriminant validity with well-being scales and the tendency for responses to be biased according to the degree of the mindfulness experience of the respondent (see, e.g., Grossman, 2008, 2011; Sauer et al., 2013; Van Dam et al., 2018). Device-based measures can be recorded continuously and without interruption to the meditator, and they putatively capture mindfulness ability independent of response bias. These measures could also serve as convenient indicators of practice quality and therapeutic progress in clinical work, since state mindfulness during meditation and meditation practice quality are closely related constructs that have been shown to mediate improvements in both trait mindfulness and psychological distress (Del Re et al., 2013; Goldberg et al., 2020; Kiken et al., 2015).

The focus of the present study was an EEG meditation headband (Muse, InteraXon Inc., Toronto). This consumer-grade dry electrode headband was developed to support focused attention meditation practice by providing auditory neurofeedback. The concept for the headband evolved from experiments with "brainwave concerts" in which participants' EEG signals were used to control art installations (Mann et al., 2007). Since then, it has attracted substantial interest from the research community (InteraXon Inc., 2020a). The headband is fitted across the forehead and rests behind the ears, with electrodes approximating standard montage frontal (AF7/AF8) and temporal/parietal (TP9/TP10) placements, as well as a reference electrode (Fpz). The device is arguably affordable ($250-350 US dollars) and ostensibly detects the attentional state of the wearer during meditation using a proprietary algorithm, with data transmitted via Bluetooth to the Muse smartphone application ("app"; available on iOS and Android platforms). While meditating with the app and headband, the wearer hears a soundscape that varies according to their inferred attentional state (e.g., from peaceful lapping waves to an intense storm). Changes in the soundscape thus provide real-time feedback on the wearer's degree of focus, with mind wandering resulting in more intense sounds. Although the quality of Muse data is lower than that of medical grade EEG systems due to the use of dry electrodes (Ratti et al., 2017), data fidelity was sufficient to measure event-related potentials and reliably discern pain states in previous work (Karydis et al., 2015; Krigolson et al., 2017). Muse generates two main proprietary measures, which can be viewed in the Muse app or through an online clinician platform provided by InteraXon. The first measure, here termed "Muse mind wandering", is thought to reflect the degree of attention to the breath from moment to moment within the meditation session. The second measure, "Muse recoveries", putatively represents the number of times during the session that the meditator returned focus to the breath following a mind wandering episode (and thus the total number of such mind wandering episodes).

The present study aimed to evaluate the feasibility of using the Muse EEG headband to support mindfulness assessment. Due to the proprietary nature of the Muse measures, knowledge about their neurophysiological basis could not be used to guide the interpretation. Instead we took a pragmatic approach by assessing the association of Muse measures with state and trait mindfulness, as well as several related constructs. At the within-participants level, we hypothesised that periods of meditation with a greater state mindfulness would be accompanied by a lower Muse mind wandering score. Secondly, it was expected that Muse mind wandering score at any one moment would correspond to the subjective degree of mind wandering at the same moment. At the between-participants level, we anticipated the same relationships between Muse mind wandering, state mindfulness, and subjective mind wandering. Furthermore, we anticipated that mean Muse mind wandering from across the meditation session would be negatively associated with dispositional measures of mindfulness, attention regulation, decentering, and non-attachment. Gains in attention regulation are thought to be central to the development of higher level capacities that result from meditation, such as improved emotional regulation (Isbel & Summers, 2017; Malinowski, 2013). Decentering (taking a detached view of one's thoughts as not defining the self) and non-attachment (perceiving wellbeing as not contingent on specific objects or outcomes) are closely related to trait mindfulness (Fresco et al., 2007; Sahdra et al., 2010; Tran et al., 2014). These constructs have also been implicated as potential mechanisms of mindfulness meditation (Hoge et al., 2015; Tran et al., 2014). Lastly, we explored the utility of the second Muse measure, recoveries, as a predictor of the same trait measures described above, albeit without hypothesising any specific relationships.

5.4 Method

5.4.1 Participants

A total of 68 participants took part, with a mean age of 22.66 (SD = 7.35). Of these, 59% identified as female (the remainder male), and 32% reported having routine meditation experience (i.e. having meditated at least once per week consistently for a month or longer). Of those who did report routine meditation experience, the duration ranged from 3 months to 3 years, except one participant with 19 years of meditation experience.

Participants were required to be at least 18 years old and under 65 years. Those who reported vulnerability to experiencing adverse effects of meditation such as psychosis, seizures or traumatization were excluded to mitigate potential risk (Creswell, 2017); exclusion criteria were a diagnosis of post-traumatic stress disorder, experience of physical or sexual abuse in childhood, a diagnosis or known risk of psychosis, or the regular use of illicit substances (Creswell, 2017; Dobkin et al., 2012; Lustyk et al., 2009). Self-report of any type of neurological disorder or traumatic brain injury, or a lack of English language fluency, were further exclusion criteria. Of those assessed for eligibility ($N = 71$), three participants were excluded for not meeting these criteria ($n = 2$) and technical difficulties ($n = 1$).

5.4.2 Measures

5.4.2.1 Muse. The 2016-model Muse MU-02 EEG headband (firmware version 1.2.13) was used in conjunction with the Muse app (version 19.2.364) running on Apple iPad tablets. During the lab tasks, audio was muted so that participants did not receive feedback normally provided by the app as to the extent of their mind-wandering, but participants heard one of the Muse background soundscapes (calm sounds of waves lapping) throughout all of the exercises. Feedback was suppressed because it could entrain participants' meditative state, confounding the results. Two measures produced by proprietary Muse algorithms were of interest. Firstly, Muse produces a putative measure of momentary attention to the breath, which can be sampled at 1Hz frequency, and with a range of 0-100 where higher values indicate diminished attention to the breath. We termed this "Muse mind wandering". Muse also produces a measure of "recoveries" from each session, i.e. the putative number of times the wearer returns to calm breath focus after an episode of mind wandering. A third measure, "birds", was not included in this analysis as it was very strongly correlated with Muse mind wandering ($r \approx -0.90$).

5.4.2.2 Subjective State Mind Wandering. Thought probe experience sampling (Weinstein, 2018) was used to measure the subjective level of mind wandering during meditation, following Levinson et al. (2014). Participants were asked "when you heard the bell, where was your attention?" (completely with the breath/completely away from the breath), with responses on VAS scales on screen, scored from 0-100. Mean subjective state mind wandering, measured in this way, has previously been shown to have small-to-moderate negative associations with trait mindfulness (Mrazek et al., 2012).

5.4.2.3 State Mindfulness During Meditation. The Breath Counting Task (Levinson et al., 2014) requires participants to undertake a form of breath-focused meditation and to press a key for each breath they register. In each nine-breath cycle, breaths one to eight are registered with the right arrow key, while the ninth breath is registered with the down arrow. If participants notice losing count, they are instructed to press the space bar to 'reset' and begin counting again from one. In the present study, participants were also instructed to reset the count if they noticed counting beyond nine, or if they noticed that they had missed recording more than one breath (rather than retrospectively adding breaths to the count). This was expected to improve the measurement validity of self-caught and uncaught errors, since appropriate responses to these scenarios were otherwise not clearly defined. The main outcome measure of the task is the proportion of accurate count cycles completed. Although the task putatively assesses trait mindfulness, only fair test-retest reliability has been demonstrated (Wong et al., 2018), while moderate-to-large correlations with related state measures have also been observed (Levinson et al., 2014), suggesting some variance in state mindfulness is also being captured.

5.4.2.4 Trait Mindfulness. The Mindful Attention/Awareness Scale—Lapses Only (MAAS-LO) is a 12-item version of the Mindful Attention/Awareness Scale (MAAS; Brown & Ryan, 2003), with the removal of three items to make the measure applicable to university students and more consistent with lapses of attention (Carriere et al., 2008). The MAAS is a widely used mindfulness measure with good psychometric properties, assessing the ability to attend to present moment experience (Osman et al., 2016). Internal consistency for the MAAS-LO was excellent ($\alpha = .86$).

5.4.2.5 Mindfulness-related Trait Measures. Three dispositional measures closely related to trait mindfulness were used. The 5-item Adult Temperament Questionnaire Short Form, Attentional Control subscale (ATQ-SF-ACS; Evans & Rothbart, 2007) is a measure in which higher scores represent greater attentional control. The 7-item Non-Attachment Scale (NAS-7; Sahdra, Ciarrochi, Parker, Marshall, & Heaven, 2015) is a measure of psychological flexibility and nonreactivity such that personal well-being is not predicated upon a fixed set of circumstances or needs. The Experiences Questionnaire, Decentering subscale (EQ-D; Fresco et al., 2007) assesses the capacity to see one's thoughts as momentary mental events, rather than an immutable reflection of the self. Higher scores on these measures indicate greater non-attachment and decentering, respectively. Cronbach's alpha showed good to excellent internal consistency for the ATQ-SF-ACS ($\alpha = .72$), NAS-7 ($\alpha = .78$), and EQ-D ($\alpha = .88$).

5.4.3 Procedure

After gaining ethical approval, participants were recruited through an undergraduate psychology research participation program ($n = 64$) and through promotion via physical and electronic flyers within a university community ($n = 4$). Participants were asked to avoid vigorous exercise or caffeine in the two hours prior to attending, to have eaten at the previous mealtime, and to have had no less sleep than usual on the day. Following informed consent and pre-trial briefing procedures, participants were seated comfortably at a workstation in a quiet, dimly lit space, and the Muse headband was fitted. After the brief calibration performed by the Muse app, the session commenced, with experimental software triggered synchronously.

Lab participation consisted of five experimental phases. Participants were asked to keep their eyes closed, with auditory prompts to open their eyes for thought probe sampling and between phases. The first phase, a focused attention meditation familiarization, guided participants in breath focus (7 minutes, based on existing materials: http://webtasks.keck.waisman.wisc.edu/b/demo). In phase two, participants continued breath-following on their own (10 minutes). During this time, eight thought probes assessed subjective mind wandering (two probes after 10 second delays for familiarization, not analyzed; then six probes after breaks of 60, 90 and 120 seconds, each duration featuring twice in random order). In phase three, participants were familiarized with the Breath

Counting Task (7 minutes), consisting of 270 seconds of guided audio in performing the task, then 150 seconds practice time. During practice, auditory guidance was given if keypress intervals were overly short (< 3 seconds) or long (>30 seconds). Phase four consisted of two self-guided meditations (10 minutes each) while undertaking the Breath Counting Task. In one condition there was no auditory feedback, while in the other Muse auditory mind wandering feedback was enabled (these data are reported separately; see Hunkin et al., 2020a). Conditions were randomly counterbalanced and preceded by a 120 second distractor task (reading from a geological history textbook on screen). Lastly, participants completed a range of self-report measures on screen, were thanked for their time, and received payment (either course credit or a prepaid debit card valued at $20 AUD).

In an optional second stage, participants (n = 29) took a Muse headband home for 14 days, during which they were asked to meditate with eyes closed for 10 minutes with the device at a convenient time each day. Participants were free to use any of the brief guided audio introductions that were available via the app, after which the timed meditation with auditory EEG neurofeedback began. At completion of the home practice stage, participants received a prepaid debit card ($30 AUD).

5.4.4 Statistical Analyses

Statistical analyses were performed using R version 3.6.1 (R Core Team, 2019). Based on simulations with pilot data (Stevens & Brysbaert, 2018), a sample size of 50 participants was selected to provide adequate power to find small effects in the within-participants analyses, which were the primary outcomes. Visual analysis of the data showed no extreme outliers. The internal consistency of Muse mind wandering was estimated by dividing the mind wandering time series during the familiarization phase into eight periods (approximately 52 seconds each), calculating the mean for each period, and computing Cronbach’s alpha as if each period mean represented a scale item (Allen et al., 2004).

For analyses involving the Breath Counting Task, participants were excluded due to technical problems (n = 2) or if data were missing due to headband signal loss during or prior to this phase (n = 22). Those who did not complete at least one breath count in each experimental condition, or failed to achieve at least one correct breath count across both conditions (n = 8), were also excluded because it was unlikely they had attended to and understood the auditory instructions. All remaining cases (n = 35) were analyzed. To determine whether Muse mind wandering was related to Breath Counting Task accuracy within participants, a series of maximum likelihood hierarchical linear models were fitted. The outcome variable for these models was the mean Muse mind wandering score within each breath count in the no-feedback condition of the self-guided meditation task. All models met the assumptions of homogeneity of variance and normality of residuals. An initial model was estimated with only task order as a predictor. Likelihood ratio tests were then used to determine whether changing the correlation structure and adding breath count accuracy as a predictor improved model fit (Pinheiro & Bates, 2000). Because within-participant differences in Muse mind wandering were the focus, a within-participant effect size measure was used (δ_W; Lai & Kwok, 2016). This statistic is calculated by dividing the maximum likelihood estimate of a fixed effect by the residual within-participant standard deviation, and is interpreted as for Cohen's *d*.

Since there were multiple experience sampled mind wandering trials for each participant, the relationship between subjective mind wandering and time-locked Muse-sampled mind wandering may have differed within individuals, compared to across the group (see Simpson's paradox; Kievit et al., 2013). Within- and between-participant correlations (r_w and r_b respectively) were therefore estimated using hierarchical linear models (Lam et al., 1999). Adjusted bootstrap percentile ("BCa") confidence intervals were estimated with 5000 iterations (Hamlett et al., 2003).

Home practice sessions of at least 3 minutes duration were analyzed. To determine test-retest reliability, the absolute intraclass correlation coefficient (ICC) referred to by McGraw and Wong (1996) as ICC(A,1) was calculated for Muse mind wandering and recoveries across home practice sessions (Qin et al., 2019). Lastly, correlations between task summary measures (e.g. mean Muse mind wandering, proportion of correct breath counts) and trait measures were examined.

5.5 Results

Table 8 presents descriptive statistics for study variables, summarised at participant level. Muse data for the thought probe task were complete, but signal loss later in the lab session caused some missing data for the Breath Counting Task (n = 22). In everyday use it would have been possible to adjust the Muse headband and continue the session, however this was not possible within the experimental setting because signal loss caused unrecoverable desynchronisation of timestamps between headband and experimental software. The loss of signal was thought to be related to the duration of use and movements made by participants which compromised the dry electrodes' contact with the scalp, rather than any characteristic of the experimental process or participant. Muse mind wandering exhibited strong internal consistency during the familiarisation phase completed in the lab (α = .95). Some home practice sessions appeared to have scores that were constrained within the upper or lower range, although the mean session range indicated that scores tended to be spread across much of the full 100-point range.

5.5.1 State Mindfulness

Summary statistics for the Breath Counting Task are shown in Table 9. The proportion of correct breaths counts spanned the full range from no correct counts (n = 3) to no errors (n = 1). To determine differences in Muse mind wandering scores between correct,

Table 8

Descriptive data and correlations of between-participant study variables

	M	*SD*	1	2	3	4	5	6	7	8	9	10	11	12
Breath Counting Task[a]														
1. Mean Muse MW	44.46	18.45	–											
2. Muse recoveries	23.31	19.56	.64**	–										
3. BCT Correct counts (%)	0.49	0.32	-.50**	-.48**	–									
4. BCT Miscounts (%)	0.21	0.19	.12	.34*	-.44**	–								
5. BCT Resets (%)	0.30	0.29	.47**	.30†	-.81**	-.18	–							
Probe task														
6. Mean subjective MW	35.76	22.83	.23	.16	-.27	.04	.27	–						
7. Mean Muse MW[b]	45.73	14.79	.86**	.52**	-.39*	.08	.38*	.15	–					
Home practice[a]														
8. Mean Muse MW	38.78	7.38	.23	.44†	-.43	.12	.42	-.24	-.03	–				
9. Mean Muse recoveries	17.23	9.13	-.06	.16	-.49†	-.03	.60*	-.45*	-.22	.76**	–			
Trait measures														
10. Mindfulness	3.61	0.82	-.33†	-.20	.24	-.12	-.18	-.16	-.13	-.25	.15	–		
11. Attentional control	3.44	1.11	.08	.00	.05	.03	-.08	-.20†	-.03	-.18	.18	.53**	–	
12. Non-attachment	4.23	0.84	.00	-.22	.20	-.05	-.18	-.17	-.07	-.23	.11	.59**	.61**	–
13. Decentering	34.97	7.48	-.09	-.22	-.03	.08	-.02	-.08	-.17	-.16	.25	.48**	.56**	.66**

Note: [a]*n* = 67 except in the Breath Counting Task (*n* = 35) and home practice (*n* = 28). [b]Mean of Muse scores sampled at six occasions, time-locked to thought probe sampling. MW = mind wandering. BCT = Breath Counting Task.

† $p < .10$, * $p < .05$, ** $p < .01$

miscounted and reset breath counts, a series of hierarchical models were constructed (Table 10). The first included a random intercept for participant and a fixed effect for taskorder, to control for learning effects. As there was substantial autocorrelation in residuals, an AR(1) correlation structure was added in the second model, with a significant improvement to fit. Including a fixed effect for breath count status (correct, miscounted or reset) gave a further improved fit in the third model. Coefficients for this fixed effect showed that both miscounts, $B = 2.84$, 95% CI [0.96, 4.72], and resets, $B = 4.73$, 95% CI [2.91, 6.55], were associated with significantly higher Muse mind wandering, relative to correct counts, with moderate effect sizes. The difference in Muse mind wandering score between resets and miscounts also approached significance, $B = 1.89$, 95% CI [-0.04, 3.83], $p = .056$.

Table 9
Descriptive statistics for Breath Counting Task correct, miscounted, and reset breath counts

	Correct	Miscount	Reset
Counts	6.46 ± 4.13	2.97 ± 2.73	4.71 ± 5.59
Proportion of total (%)	49.46	21.10	29.44
Participants (*n*)	32	26	30
Duration (s)	47.98 ± 12.69	44.89 ± 14.25	35.07 ± 21.44
Breaths reported	9.00 ± 0.00	7.74 ± 1.39	4.18 ± 2.88
Mean Muse mind wandering	40.12 ± 15.76	44.03 ± 18.72	49.24 ± 20.77

Note: Values represent $M \pm SD$ except where specified. Summary values were first aggregated by participant.

5.5.2 Subjective Mind Wandering

Participants completed a mean of 5.81 thought probes with a mean response time of 10.82 seconds ($SD = 2.52$). Muse mind wandering, sampled at the time of each thought probe, was approximately normally distributed, whereas subjective (probe-caught) mind wandering had the highest frequency on the low bound, meaning that participants often reported their attention being entirely on the breath. Contrary to expectations, the association between Muse-sampled and subjective mind wandering was negligible, both within-participants, r_w = .01, 95% CI [-.07, .12], and between-participants, r_b = .11, 95% CI [-.09, .31].

5.5.3 Home Practice

Participants completed a mean of 11.31 (*SD* = 2.84) meditation sessions at home. Participants with greater meditation experience (i.e. having previously meditated at least once per week for periods totalling six months or more, *n* = 11) had a lower mean Muse mind wandering (*M* = 36.92, *SD* = 8.13) compared to those with less or no meditation experience (*M* = 40.30, *SD* = 6.77), but this difference was not statistically significant, *t*(18) = 1.16, *p* = .262, *d* = 0.45. The ICC(A,1) was .27 (95% CI [.17, .43]) for Muse mind wandering and .17 (95% CI [.09, .30]) for recoveries, indicating low test-retest reliabilities between home practice sessions.

5.5.4 Between-Participant Measures

Table 8 presents the correlations for between-participant measures. Muse mind wandering tended to have small or negligible correlations with mindfulness-related traits that were not statistically significant. The strongest correlation, between trait mindfulness and mean Muse mind wandering during the Breath Counting Task, approached significance, *r*(33) = 0.33, *p* = .053. Mean Muse mind wandering during the Breath Counting Task had a significant negative association with the rate of correct breath count cycles, *r*(33) = -.50, *p* = .002, as well as a significant positive correlation with the rate of reset breath count cycles, *r*(33) = 0.47, *p* = .004. Consistent with the within-session findings, this association indicated that participants who tended to reset their breath counts more frequently also tended to experience more mind wandering according to Muse, while participants who counted more cycles correctly tended to experience less mind wandering according to the device. However, the rate of miscounted breath cycles had a negligible association with mean Muse mind wandering during the task.

A higher rate of recoveries during home practice was associated with more resets in the Breath Counting Task, $r(12) = .60$, $p = .023$, but also with lower subjective mind wandering during the thought probe task, $r(26) = -.45$, $p = .016$. Furthermore, although mean Muse mind wandering and recoveries during home practice were strongly positively correlated, they exhibited opposing associations with trait measures, suggesting that each variable contained uniquely predictive information about these traits. Based on this observation, an unplanned analysis was conducted to determine whether regressing traits on both variables simultaneously could explain additional variance, i.e. an 'enhancement effect' (Lewis & Escobar, 1986). For trait mindfulness and all related trait measures, both mean Muse mind wandering and recoveries were significant predictors, and the four models had significantly better predictive value than corresponding intercept-only models (Table 11). Substantial enhancement effects were observed: individual predictors accounted for under 10% of variance in bivariate associations, whereas together the predictors explained 24-35% of the variance. Semi-partial correlations showed that unique variance in each predictor had large correlations with trait measures ($sr \approx .50$).

5.6 Discussion

The aim of the present study was to evaluate the feasibility of the Muse EEG headband to support mindfulness assessment. Muse mind wandering exhibited a high internal consistency and low test-retest reliability, as expected for a state measure (Zuckerman, 1983). As hypothesised, this measure was significantly associated with a concurrently assessed measure of state mindfulness in both within- and between-participant analyses. However, within-participant associations with subjective mind wandering, and between-participant associations with mindfulness, attention regulation, decentering, and non-attachment were mostly small and none were statistically significant. Participants

Table 10

Hierarchical linear models estimating the effect of correct, miscounted and reset breath counts on Muse mind wandering

	Model 1		Model 2		Model 3		
	Coefficient	*p*	Coefficient	*p*	Coefficient	*p*	*d*[a]
Fixed effects ($B \pm SE$)							
Intercept	41.27 ± 3.62	< .001	41.53 ± 3.59	< .001	39.78 ± 3.50	< .001	
Order: First[b]	11.09 ± 6.47	.096	10.77 ± 6.40	.102	10.08 ± 6.20	.114	1.20
Status: Miscount[c]					2.84 ± 0.96	.003	0.34
Status: Reset[c]					4.73 ± 0.93	< .001	0.56
Random effects (*SD*)							
Participant	17.57		17.17		16.60		
Residual	8.15		8.63		8.42		
Model properties							
AR(1) correlation (ϕ)	—		0.42		0.42		
ICC	.82		.80		.80		
AIC	3628.53		3565.10		3543.09		
Likelihood ratio test[d]			$\chi^2(1) = 65.43$	< .001	$\chi^2(2) = 26.01$	< .001	

Note: [a]The within-participant effect size (δ_W; Lai & Kwok, 2006) was used. [b]Reference level: Second. [c]Reference level: Correct. [d]Relative to the preceding model.

Table 11

Multiple linear regressions of mindfulness, attentional control, non-attachment and decentering traits on mean Muse mind wandering and recoveries during home practice

	Intercept			Mean Muse mind wandering				Mean Muse recoveries				Model fit		
Outcome variable	*B*	*SE*	*p*	*B*	*SE*	*p*	*sr*	*B*	*SE*	*p*	*sr*	R^2	*F*	*p*
Mindfulness	6.19	0.96	.406	-0.11	0.03	.002	.56	0.08	0.03	.004	-.52	.33	6.29	.006
Attentional control	6.07	1.19	< .001	-0.12	0.04	.008	-.49	0.09	0.03	.008	.49	.28	4.80	.017
Non-attachment	6.49	1.00	< .001	-0.09	0.03	.010	-.48	0.07	0.03	.019	.44	.24	4.03	.030
Decentering	53.64	7.86	< .001	-0.86	0.26	.003	-.53	0.74	0.21	.002	.57	.35	6.61	.005

Note: $n = 28$. MW = mind wandering. *sr* = semi-partial correlation (association between predictor and outcome while controlling for the other predictor, interpreted as for Pearson's *r*).

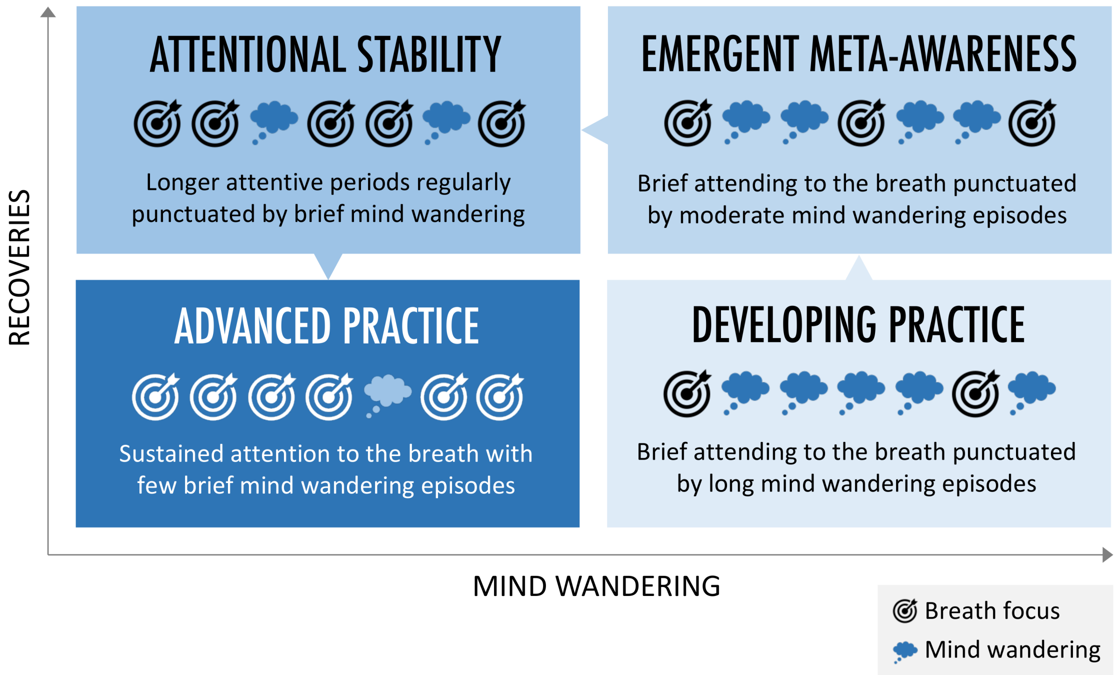
completed over 80% of home sessions, and mean mind wandering and recoveries metrics from these sessions were together strong predictors of mindfulness and related traits.

Given that Muse and task-based state mindfulness measures involved entirely distinct methods, the association between them should be considered exceptionally strong (Patrick et al., 2019). As hypothesized, breath counting miscounts and resets were linked to significantly greater Muse mind wandering relative to correct breath counts. In line with previous findings, breath count resets appeared to represent deeper lapses of attention than miscounts (Wong et al., 2018), with the difference in Muse mind wandering between resets and miscounts approaching significance. Subjective mind wandering was not associated with Muse mind wandering in within-participant analyses, while the small positive between-participants correlation with Muse mind wandering was not statistically significant. The confidence interval for the latter association was not inconsistent with previous work assessing correlations between self-report and task-report measures relating to this construct (Levinson et al., 2014; Mrazek et al., 2012). Greater power may be required to more conclusively test this theorized relationship.

The incremental predictive value of Muse recoveries after accounting for Muse mind wandering was a noteworthy finding, requiring some consideration of the potential reasons. On the one hand, there are conceptual similarities between the recoveries putatively being measured by Muse and the resets being measured in the Breath Counting Task. These similarities were reflected in the strong association between mean recoveries during home practice sessions and breath counting resets during the laboratory session. Since higher rates of resets in the Breath Counting Task index lower mindfulness, recoveries measured by Muse might also be seen as undesirable phenomena. On the other hand, the ability to recover—to catch one's mind wandering and reorient one's attention—is thought to be a central skill in cultivating mindfulness (Isbel & Summers, 2017). Supporting this notion, mean recoveries during home practice were predictive of lower mean subjective mind wandering in the lab. Furthermore, when Muse mind wandering was controlled for, greater recoveries predicted increased mindfulness, attentional control, decentering and non-attachment.

Considering possible permutations of mean mind wandering and recoveries (Figure 4) provides insight into the confounding association between these variables and the reason they might have far greater predictive value when combined, consistent with theory (Malinowski, 2013). For example, a higher rate of recoveries suggests a meditation characterized by

Figure 4
Potential permutations of Muse mean mind wandering and recoveries (icons show representative sequences of focused attention interrupted by mind wandering)



frequent switching between on-task and off-task cognitions. This might reflect a mindful state if mean mind wandering is low, i.e. longer periods of sustained attention predominate, and are interspersed with brief periods of off-task thought that are quickly detected. On the other hand, high mean mind wandering paired with the same level of recoveries would suggest a meditation characterized by brief periods of attention, amongst longer episodes of off-task thought. Because higher levels of mind wandering provide more opportunities to recover focus, the variables are strongly correlated and so the positive role of recoveries can be confounded—and must therefore be controlled for.

Since Muse putatively responds to changes in attention, the mindfulness measures selected for the present study (i.e., MAAS-LO and Breath Counting Task) were also focused on the attentional aspect of mindfulness. Growing evidence suggests that to derive benefits from mindfulness practice, present moment attention must be coupled with an accepting orientation to experience (Curtiss et al., 2017; Lindsay & Creswell, 2019; Rahl et al., 2017). While an acceptance-like factor emerges consistently in self-report measures of trait mindfulness, state mindfulness, and meditation practice quality (Del Re et al., 2013; Lau et al., 2006; Rau & Williams, 2016), it remains unclear to what extent this factor is captured in measures of behavioural performance during meditation. Prior research shows that acceptance training results in incremental improvements in behavioural measures of attention, over and above training in attention monitoring (Rahl et al., 2017). This suggests that such behavioural measures may be measuring some degree of acceptance, consistent with theory that accepting thoughts makes them less distracting (Delorme & Brandmeyer, 2019; Isbel & Summers, 2017). Muse measures may therefore capture both the attention and acceptance qualities of mindfulness, but further research to assess the extent of these relationships using self-report and behavioural measures is needed.

The novel measurement modality and the use of multiple sampling methodologies (EEG, cognitive task, and self-report) were important strengths of the present study. The small size of the sample limited the precision of between-participants estimates, but the findings were strengthened by the use of repeated measures and within-participants analyses. Although the sample was relatively homogenous (i.e., young and well educated) and prone to self-selection bias, we did not expect that these characteristics would substantially affect the measurements obtained with Muse, with age being a possible exception due to neural changes that occur over the lifespan (Dimitriadis & Salis, 2017). The strong associations between Muse measures (jointly) and mindfulness-related traits were limited by the fact that these analyses were unplanned; the enhancement effect observed in the present work should be replicated *a priori*. We did not explicitly test Muse measurements' sensitivity to change during clinical treatment. However, the sensitivity of these measures to within-session variability in the Breath Counting Task does give some confidence in this regard, as the latter measure has been shown to change in response to brief mindfulness training (Rowland et al., 2019). A final important limitation is the use of a non-clinical sample, since common clinical conditions such as depression and anxiety appear to result in changes in some EEG biomarkers (Olbrich & Arns, 2013; Shadli et al., 2015), potentially compromising the validity of the algorithm used by Muse when these conditions are present. Given the proprietary nature of the algorithm, it is difficult to know whether the biomarkers it relies upon could be prone to this issue. It is possible that deficits in trait mindfulness could in fact underlie some of the biomarkers that have previously been linked to psychopathology (e.g. alpha asymmetry; Isbel et al., 2019), which would mitigate this concern. Furthermore, given that our sample was recruited largely from an undergraduate population, we expected a substantial proportion of participants would be experiencing at least mild psychological distress. A final and important limitation of the present work is that it cannot reveal the underlying EEG measures linked with heightened state mindfulness, due to the proprietary algorithm used by the device. Further work will be needed to develop open scientific knowledge regarding EEG-based measures of state mindfulness, however the present results clearly demonstrate the feasibility and potential of this approach.

The practical implications of these findings relate primarily to the interpretation and utility of Muse measures. The considerable associations with state and trait mindfulness measures suggest that Muse does capture substantial variation in these constructs, which have been shown to mediate decreases in psychological symptoms (Kiken et al., 2015; Visted et al., 2015). The sensitivity of Muse to fluctuations in state mindfulness supports the use of the device to enhance learning via neurofeedback during meditation, since gaining a reliable signal of the target state (e.g., a mindful state) is a precondition of effective neurofeedback. Furthermore, the strong internal consistency of Muse mind wandering suggests that valid measurements can be derived even from relatively brief meditation sessions. This provides some confidence in using Muse measures to supplement other assessments. However, a few caveats apply. Firstly, there was low test-retest reliability between sessions during the home practice period, likely due to a combination of state fluctuations and measurement error. This means that sustained trends over weeks or months are most likely to represent true changes, whereas trends over only a few sessions may simply represent noise. Secondly, the interdependence of the mind wandering and recoveries measures means that neither measure can be interpreted in isolation. Increased mindfulness is expected to be characterized by both increased recoveries and decreased mind wandering, at least in early and intermediate stages of practice. It is important to note that these implications for interpretation cannot immediately be generalized to similar devices, because of potential differences in hardware or software. Further discussion of some practical considerations in interpreting Muse scores is provided as supplementary material (Appendix B).

While these results provide preliminary support for Muse measures as correlates of mindfulness, more work is needed to replicate and extend these findings. A higher-powered study would increase confidence in the size of the associations with trait measures of mindfulness and related constructs. Other task-based assessments of mindfulness could also be useful comparative measures (see, e.g., Hadash, Plonsker, Vago, & Bernstein, 2016). Since Muse showed low test-retest reliability, it will be important to quantify how much variability in results represents measurement error as opposed to short term fluctuations in state mindfulness. Future research could also explicitly test the extent of Muse measures' sensitivity to change from mindfulness-based interventions. Lastly, the development of a unitary scoring scheme based on both Muse metrics would simplify its use in practice.

5.6.1 Conclusion

Wearable devices for mental health are increasing in availability and popularity, but the measures they generate remain largely unvalidated. The present results demonstrate the general feasibility of wearable-based EEG measures of mind wandering during meditation as an adjunct assessment tool. Furthermore, they provide preliminary support for Muse measures as correlates of state and trait mindfulness, constructs which are thought to mediate the clinical improvement resulting from meditation. The objectivity of the measures, the high temporal granularity of the data, and the convenience of assessment are all potentially important benefits of this approach. The present findings support further research with this technology, particularly to assess sensitivity to change in clinical treatment groups, and to understand the extent to which Muse captures not only present moment attention but also an accepting orientation to experience. Given the potential to enhance theoretical knowledge and the increasing need to incorporate digital mental health approaches into clinical practice, developing empirical evidence regarding measures produced by Muse and other wearable devices should be a priority.

CHAPTER 6: STUDY 4

EEG Neurofeedback During Focused Attention Meditation:

Effects on State Mindfulness and Meditation Experiences

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6.1 Statement of Authorship

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Name of Principal Author (Candidate)	Hugh Hunkin		
Contribution to the Paper	Collaboratively developed the research objectives, methodology and materials; managed data collection; performed analyses; wrote initial draft; collaborated on editing of final drafts; acted as corresponding author		
Overall Percentage (%)	80		
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	16 March 2022

Co-author Contributions

By signing the Statement of Authorship, each author certifies that:

iv. the candidate's stated contribution to the publication is accurate (as detailed above);
v. permission is granted for the candidate in include the publication in the thesis; and
vi. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution

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6.2 Abstract

Objectives. EEG neurofeedback has potential to increase the effectiveness of mobile meditation applications by providing synchronous performance feedback to meditators. This crossover trial aimed to evaluate the effects of auditory EEG neurofeedback on state mindfulness during focused attention meditation—a putative mediator of mental health benefits—relative to no feedback.

Methods. Adult participants (N = 68, Mage = 22.66, SDage = 7.35) completed a task-based measure of state mindfulness whilst meditating with and without auditory feedback from a consumer-grade EEG headband. Participants rated subjective meditation experiences in each condition. A subgroup (n = 29) completed 14 days of home practice with the device and responded to open-ended questions about their experience.

Results. Auditory feedback was associated with greater state mindfulness (RR = 1.15, 95% CI [1.00, 1.29]). Device-measured mind wandering was lower when feedback was present (d = 0.22 [-0.07, -0.37]), but there was a negligible effect on device-measured recoveries from mind wandering episodes (d = -0.11 [-0.30, 0.08]). Feedback was associated

with quantitative differences in subjective experiences consistent with heightened arousal. Thematic analysis revealed helpful (active, guiding) and unhelpful (stressful, distracting, incongruent with subjective experience) aspects of feedback.

Conclusions. EEG neurofeedback appears to increase state mindfulness in adults during a brief meditation. These results support feedback as an effective adjunct to meditation. Psychoeducation regarding feedback and the meditative experience may help to maximise the beneficial effects. Replication of these findings in clinical populations is warranted.

6.3 Introduction

Meditative practices are an umbrella of methods for cultivating mindfulness, and are central to contemporary evidence-based therapies like mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT; Dimidjian & Linehan, 2008). Growing public interest in meditation has led to the emergence of numerous stand-alone apps that offer guided instruction for meditation practice (Flett et al., 2019). Research and clinical interest in such apps has also increased due to their perceived benefits in complementing existing service delivery in mental health systems. Meditation apps may be used as a low-intensity approach in interventions for mild cases, thereby enabling more resources to be diverted to handling more severe presentations (Bower & Gilbody, 2005; Fairburn & Patel, 2017). App-based interventions might also overcome some traditional barriers to treatment, such as cost, physical distance, stigma, and scalability, thereby increasing access to evidence-based therapies (Kazdin, 2019; Nicholas et al., 2017). The increasing availability and sophistication of digital interventions is expected to increase the scale at which these therapies can be delivered (Cavanagh & Millings, 2013; Mrazek et al., 2019; Muñoz, 2019), and initial evidence for meditation apps supports their continuing development and evaluation (Flett et al., 2019; Linardon, 2020). However, the utility of these apps in clinical practice may be limited by their small effects on common mental health symptoms (Bostock et al., 2019; Flett et al., 2019).

Given the potential advantages of meditation apps, there is a need for research on how their effectiveness can be increased. One proposed approach, EEG neurofeedback, aims to support the development of meditative practice by synchronously providing meditators with objective performance data based on neural indicators (Brandmeyer & Delorme, 2013). Receiving feedback on performance could assist meditators to adopt a higher level of state mindfulness during meditation, which putatively mediates improved emotion regulation and decreased distress (Garland et al., 2015; Kiken et al., 2015). There may also be ancillary benefits of neurofeedback for meditation adherence and uptake. Meditators who consider their performance to be poor during early meditation experiences tend to have a lower intention to continue meditating (Russ et al., 2017), highlighting the importance of providing greater support during initial attempts. The use of feedback could also modify perceptions that meditation involves doing nothing; these perceptions are closely linked to views that meditation has minimal benefit, and form perhaps the most substantial barrier to uptake (Hunt et al., 2020; Russell et al., 2018). However, there is little empirical research to date examining the potential benefits of synchronous neurofeedback during meditation (Hunkin et al., 2019).

Neurofeedback-assisted meditation is available via consumer-grade systems such as the portable headband and app known as Muse (InteraXon, Inc.). Muse supports a form of meditation in which meditators attempt to maintain focused attention on a specific object or sensation, typically one’s breathing (Malinowski, 2013). Practice in this tradition is thought to facilitate increased awareness of mind wandering (i.e., meta-awareness) and an ability to non-judgementally reorient to the object of focus. The Muse app produces a soundscape that ranges from calm (such as gentle rain) to more active (such as thunder, wind and heavy rain), according to the meditator's level of focused attention. By alerting the meditator to attention lapses through these synchronous changes in auditory feedback, Muse purports to support meditation by encouraging a more rapid return to a focused state.

Preliminary research suggests that meditation with Muse may lead to a significant reduction in somatic symptoms along with improvements in attention and cognitive performance, relative to active controls (Bhayee et al., 2016; Crivelli et al., 2019). A recent study found that Muse did not differ from unassisted meditation according to physiological measures of relaxation (Svetlov et al., 2019). However, it is unclear how the degree of relaxation during meditation might be related to concurrent attentional performance and to stress reduction outside of meditation. Furthermore, possible negative effects of neurofeedback are unclear. For example, receiving feedback on errors during a vigilance task has been associated with a renewed focus on the task at hand, but also with reactive mind-wandering that can interfere with immediate task performance (Smallwood et al., 2004). This is consistent with reports of neurofeedback during meditation being distracting, or even anxiety-provoking for some meditators (Marcengo et al., 2017; Sas & Chopra, 2015). Understanding how Muse auditory feedback affects meditation is thus an important research target in evaluating the practical application of these technologies.

The present study used a counterbalanced crossover design to evaluate the effects of Muse feedback (*auditory feedback* condition) on state mindfulness and subjective experience in healthy participants, relative to not receiving feedback (*no feedback* condition). Our primary hypothesis was that, relative to the no feedback group, the auditory feedback group would exhibit an increase in objectively measured state mindfulness. In line with this, Muse data were expected to indicate a lower device-measured mean mind wandering and a greater number of recoveries from a mind wandering state in this condition. Quantitative measures of meditation experiences following both conditions were used to explore how the presence of feedback affected the meditation, from the meditator's perspective. In a second phase, participants used the device over 14 days of home-based practice. Secondary hypotheses predicted a reduction in mean mind wandering and an increase in recoveries according to device measures, as well as an increase in perceived control over device feedback across the home practice period.

6.4 Method

6.4.1 Participants

Participants were university students aged between 18-60 years (N = 68). The majority were aged 20 years or below (M = 22.66, SD = 7.35), with gender identified as female (n = 40) and male (n = 28). Two-thirds of participants (n = 46) reported no habitual meditation experience (defined as any form of meditation at least once per week, over a minimum period of one month). For those who did have meditation experience, the duration ranged from three months to three years, apart from a single participant with a history of 19 years of practice.

Participants at higher risk of adverse effects from meditating were excluded (i.e. risk of psychosis, a previous diagnosis of post-traumatic stress disorder, a history of physical or sexual abuse in childhood, or the regular use of illicit substances; Creswell, 2017; Dobkin et al., 2012; Lustyk et al., 2009). The self-reported presence of a neurological disorder or traumatic brain injury, or poor English fluency, were additional exclusion criteria. Of 71 participants assessed, two were excluded and one could not commence due to technical issues. Further to formal eligibility requirements, participants were asked to avoid caffeine or vigorous exercise during the two hours prior to the initial session, as well as ensuring they had no less sleep than usual and had eaten at the preceding mealtime.

6.4.2 Procedure

Following ethical approval, recruitment took place through an undergraduate psychology research participation program (*n* = 64) and promotional flyers (*n* = 4). Once informed consent, pre-trial screening and briefing were completed, each participant was shown to an individual enclosed lab space, asked to make themselves comfortable at a workstation, and instructed on how to use the Muse headband. The session began with Muse's standard calibration sequence, after which Muse began collecting data, with the experimental software (Inquisit 4) initiated simultaneously. Data from the first two phases were reported elsewhere (Hunkin et al., 2021b) and are not analysed further here. In the first phase, participants were guided in breath-focused meditation, following prior work (http://webtasks.keck.waisman.wisc.edu/b/demo, 7 min duration). The second phase consisted of unguided breath-following (10 min), with eight intermitted thought probes. The third phase consisted of familiarisation with the Breath Counting Task (270 sec) and a brief practice (150 sec). During the practice, participants were reminded of what to do if their keypress intervals were less than 3 seconds or exceeded 30 seconds. Phase four involved two self-guided meditations which were presented in random order. Participants undertook the Breath Counting Task in both conditions; in one condition they heard only a Muse background soundscape (waves lapping) with no auditory feedback, while in the other they heard the same soundscape accompanied by auditory feedback from Muse on their level of attention to the breath. Both conditions were preceded by a 120 second mind wandering induction, which involved reading from a geological history textbook presented on screen (Danckert et al., 2018). Following each meditation, participants completed the MEQ with respect to that session. Finally, a range of self-report measures were completed, and participants were thanked and reimbursed for their time (course credit, or a $20 AUD debit card).

Participants also had the opportunity to take the device home for two weeks of home practice (*n* = 29). During this period they were asked to meditate with Muse for at least 10 minutes per day and complete written responses (Table C1, Appendix C). Participants received a $30 AUD debit card in appreciation of their involvement in the home practice stage.

6.4.3 Measures

6.4.3.1 Muse. The MU-02 ("Original Muse") 2016-model EEG headband (firmware version 1.2.13) was used with the Muse app (version 19.2.364) installed on Apple iPad tablets. Muse is equipped with three silver frontal electrodes (AF7/8 positions, with a reference channel at FPz) and two conductive silicon-rubber temporal electrodes (TP9/10 positions). Raw EEG data are sampled at 256 Hz, while the main proprietary measure of "calm" produced by Muse has a sampling frequency of 1 Hz. A meditation with Muse begins with a calibration phase in which the wearer is asked to let their thoughts flow naturally, followed by a brief auditory instruction in breath-focused meditation. Data collected during the present study provided initial evidence for the internal consistency and validity of two Muse metrics (mean mind wandering and recoveries from mind wandering) as indicators of state mindfulness (Hunkin et al., 2021b).

6.4.3.2 Breath Counting Task. The Breath Counting Task (Levinson et al., 2014) is a task-based objective measure of mindfulness. While following the breath during focused attention meditation, participants are asked to count each breath, starting from one and beginning over again after the ninth breath. Participants pressed the right arrow for each of the first eight breaths, and the down arrow on the ninth breath. If they realised they had lost track of the count, stopped counting, or missed a keypress, the space key could be used to reset the count, after which counting began again from one. The primary outcome of the task is the proportion of correct breath counts to erroneous counts (sum of resets or miscounts).

6.4.3.3 Meditation Experience Questionnaire (MEQ). The MEQ (Frewen et al., 2011) is a thirteen-item self-report questionnaire rating typical experiences encountered during meditation, such as unpleasant thoughts, awareness of one's body, and sleepiness. The questionnaire was developed based on common responses to open-ended questions about experiences during meditation. Each item represents the frequency of a distinct meditation experience, scored on a five-point Likert-type item from *Never* (1) to *Almost constantly* (5). Because each item is interpreted individually, no full-scale scores are derived.

6.4.3.4 Perceived Difficulty of Meditation and Perceived Control over Feedback. A seven-point Likert-type item was used to gauge relative difficulty of maintaining breath focus ("Did you find it easier to keep your attention on the breath in the exercise where you received audio feedback, or the exercise where you only heard wave sounds?"), with endpoint anchors *Easier with audio feedback* (1) and *Easier with just wave sounds* (7), as well as a midpoint anchor (*no difference*). The level of perceived control over the feedback was measured with a second item ("How much control did you feel you had over the audio feedback on your level of attention to the breath, in the exercise where you heard it?"), with anchors of *No control* (1) to *Complete control* (7). A similar item was used at follow-up in relation to perceived control over the most recent home practice session.

6.4.3.5 Written Feedback. Participants were provided a diary during home practice, in which they were asked to respond to open-ended questions regarding their Muse experiences. Diaries included items asking for impressions of using Muse, the auditory feedback, and specific helpful and/or unhelpful aspects of Muse (see Appendix C, Table C1).

6.4.4 Data Analyses

Statistical analyses were performed using R version 3.6.1 (R Core Team, 2019). The planned sample size of 50 was selected to power analyses reported elsewhere (Hunkin et al., 2021b); a priori simulations using pilot data (Stevens & Brysbaert, 2018) showed this would also be sufficient to find small effects in between-group differences in the proportion of correct breath counts. Initial exploration of the data showed no outlying responses attributable to the single participant who had a significant history of meditation, therefore this case was retained. For the main analyses, cases were excluded where Muse signal was lost due to poor headband contact (n = 22), breath count data were deemed invalid (i.e. no correct counts in either condition, n = 9), or technical issues occurred (n = 2), leaving 35 cases. Of these, 24 completed the feedback condition first. Correlations between key study variables are shown in Table C2, Appendix C.

To determine the effect of receiving auditory feedback on the rate of correct and reset breath counts, mean Muse mind wandering and Muse recoveries, four maximum likelihood hierarchical models were constructed with random intercepts for participant and fixed effect predictors for auditory feedback. In the first and second models a binomial distribution was used to compare breath count accuracy between conditions, and relative risk was calculated based on the baseline proportion of correct (Model 1) or reset (Model 2) breath counts in the no feedback condition (Grant, 2014). The third and fourth models used a Gaussian distribution to compare mean Muse mind wandering and recoveries between conditions. To control for learning effects, all four models included a fixed effect predictor for the experimental period (Senn, 2002). One further maximum likelihood hierarchical model was fitted to compute pointwise confidence bands around the difference in mean Muse mind wandering trajectories between conditions. This last model extended the former by adding an interaction term of experimental condition with time and allowing for autocorrelation of residuals. While there was some heterogeneity in the sample with regard to age and experience with meditation, it was not feasible to statistically explore potential moderation effects due to the small sample size and the few participants in the upper end of the age range. Nonetheless, visual inspection of the data did not suggest any marked differences in

EEG or Breath Counting Task outcomes attributable to either age or level of previous meditation experience. Differences in subjective meditation experience were analysed using paired *t*-tests for each individual item, and the false discovery rate adjustment was used to obtain simultaneous *p*-values and confidence intervals (Benjamini et al., 2005; Benjamini & Hochberg, 1995).

The experience of using feedback during meditation, as described in written responses, was explored using thematic analysis from a realist perspective (Braun & Clarke, 2006). This is an inductive technique where data are analysed "bottom up" to derive higher level themes. In the first step, the first and second authors manually coded all of the responses independently of one another. Because responses were broad and did not always focus specifically on auditory feedback, the first author then filtered out codes that bore no relation to feedback before identifying themes in the remaining codes. The first and third authors subsequently reviewed the codes and corresponding themes together in order to establish consensus (i.e. investigator triangulation; Korstjens & Moser, 2018). Lastly, the first author ensured that the themes were consistent with the filtered responses that made up the dataset.

6.5 Results

6.5.1 Effects of Auditory Feedback During Meditation Task

Table 12 presents descriptive data for the Breath Counting Task and Muse measures in each experimental condition. Hierarchical models were constructed to determine whether auditory feedback was associated with significantly increased performance, operationalised as a higher rate of correct breath counts, lower mean Muse mind wandering, and greater Muse recoveries, while controlling for period (Table 13). The first model showed that participants had a 15% higher likelihood of reporting a correct breath count in the auditory feedback condition, compared to the exercise in which they did not hear feedback, with the

Table 12
Descriptive statistics for Breath Counting Task and Muse measures by experimental condition

	No feedback $M \pm SD$	Auditory feedback $M \pm SD$
Breath Counting Task		
Correct (%)	49.46 ± 31.58	52.28 ± 27.34
Miscount (%)	21.10 ± 18.89	26.54 ± 21.52
Reset (%)	29.44 ± 28.79	21.18 ± 18.73
Muse		
Mean mind wandering	44.52 ± 18.51	41.58 ± 16.31
Recoveries	21.46 ± 18.46	19.60 ± 17.92

Note: $n = 35$.

effect approaching statistical significance ($p = .056$). Since there also appeared to be a large difference in the proportion of breath count resets between conditions, a second model was constructed to determine whether this difference was statistically significant. This unplanned supplementary analysis showed that auditory feedback led to a 41% lower likelihood of reset breath counts, relative to miscounts and correct counts. In the third model, auditory feedback predicted a statistically significant 4.15-unit reduction in mean Muse mind wandering; in other words, hearing feedback led to reduced mind wandering as measured by the Muse headband. However, the use of auditory feedback did not predict any significant difference in Muse recoveries (Model 4). Figure 5 shows the trajectory of Muse mind wandering throughout each condition, aggregated across all participants (for key model parameters, see Table C3, Appendix C). Mean mind wandering tended to decrease from an early high in both conditions, with minimal difference between conditions during the first two minutes. After this, a relatively stable mean level of mind wandering was established in both conditions, with a generally lower level in the auditory feedback condition.

Auditory feedback had a large negative effect on self-reported relaxed or calm feelings experienced during meditation, and a moderate negative effect on fatigue or sleepiness (Table 14). Feedback also led to small increases in awareness of difficulty in

Table 13

Hierarchical model estimates of the effect of auditory feedback on correct and reset breath counts, mean Muse scores, and Muse recoveries, relative to no feedback

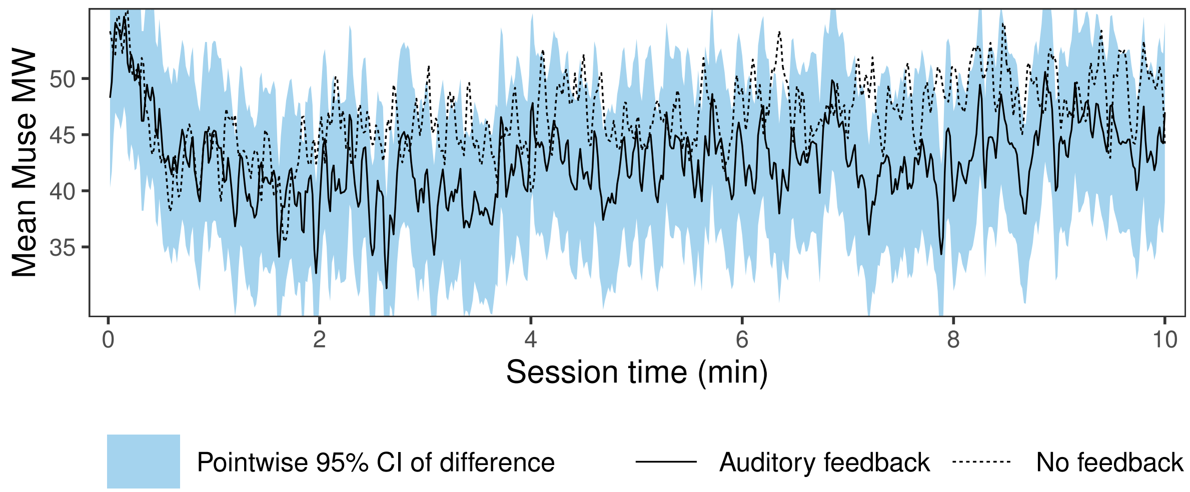
	Coefficient	Std. Error	*p*	*RR*[a]	*d*[b]	95% CI
Model 1: Correct breath counts						
Fixed effects (*B*)						
Intercept	0.00	0.24	.985	1.00		
Auditory feedback	0.30	0.16	.056	1.15		[1.00, 1.29]
Period: First	-0.21	0.16	.195	0.90		[0.75, 1.05]
Random effects (*SD*)						
Participant	1.25					
Model 2: Reset breath counts						
Fixed effects (*B*)						
Intercept	-1.22	0.25	< .001	0.36		
Auditory feedback	-0.67	0.17	< .001	0.59		[0.44, 0.78]
Period: First	0.40	0.17	.022	1.32		[1.04, 1.63]
Random effects (*SD*)						
Participant	1.22					
Model 3: Mean Muse mind wandering						
Fixed effects (*B*)						
Intercept	43.50	2.99	< .001			
Auditory feedback	-4.15	1.41	.006		-0.22	[-0.37, -0.07]
Period: First	3.26	1.41	.027		0.17	[0.03, 0.33]
Random effects (*SD*)						
Participant	16.27					
Residual	5.34					
Model 4: Muse recoveries						
Fixed effects (*B*)						
Intercept	21.34	3.15	< .001			
Auditory feedback	-1.99	1.78	.270		-0.11	[-0.30, 0.08]
Period: First	0.37	1.78	.837		0.02	[-0.17, 0.21]
Random effects (*SD*)						
Participant	16.60					
Residual	6.75					

Note: *n* = 35 participants. [a]Relative risk computed based on the baseline proportion of correct breath counts (49.46%, Model 1) and reset breath counts (29.44%, Model 2). [b]Cohen's *d*, with denominator based on standard deviation of scores in no feedback condition.

maintaining focus on the breath and interest and awareness in the breathing process, although these did not reach significance. There were negligible differences in the frequency of other subjective experiences, such as pleasant/unpleasant thoughts, planning thoughts, or awareness of the body and meditation environment. Participants varied in their rating of whether it was it was more difficult to keep attention on the breath with the auditory feedback or without it, with 11 finding it more difficult without feedback, 21 with feedback, and three neutral (M = 4.89, SD = 1.98). There was a significant tendency toward a higher median perceived difficulty with feedback present, V = 401.5, p = .009, d = 0.45.

Figure 5

Trajectory of mean Muse mind wandering across the session in the no feedback and auditory feedback conditions (MW = mind wandering)



6.5.2 Home Practice

Participants (n = 29) completed a mean of 11.31 (SD = 2.84) out of 14 days of home practice, a mean adherence rate of 81%. Mean Muse mind wandering did not decrease with successive meditation sessions as expected, showing no change statistically (Table 15; see also Appendix C). Muse recoveries were also unchanged across the period. Participants who completed the lab tasks without signal loss and also undertook self-guided practice at home (n = 14) reported a large and statistically significant increase in perceived control over Muse feedback in their final home meditation (M = 5.14, SD = 1.10), relative to the lab session (M = 2.79, SD = 1.67), $t(13)$ = 4.53, p < .001, d = 1.67.

The mean response rate for the open-ended questions during home practice was 75%. Table 16 presents five themes relating to meditation feedback that were extracted from these responses, along with illustrative excerpts. Positive responses concerned the responsivity

Table 14

Differences in meditation experiences with and without auditory feedback from Muse

Experience	Auditory feedback $M \pm SD$	No feedback $M \pm SD$	p_{FDR}	95% CI_{FDR}	d
Reviewing a mental “to do” list (what I have to do)	2.57 ± 1.17	2.54 ± 1.12	.958	[-0.41, 0.47]	0.02
Unpleasant or upsetting thoughts or memories	1.97 ± 0.92	2.03 ± 0.86	.958	[-0.55, 0.43]	-0.06
Pleasant or happy thoughts or memories	2.51 ± 1.01	2.60 ± 1.03	.958	[-0.51, 0.34]	-0.08
Feeling relaxed and calm	3.11 ± 1.16	3.94 ± 0.84	.008	[-1.45, -0.21]	-0.83
Being particularly aware of difficulties maintaining your attention on your breathing (e.g. due to mind wandering)	4.06 ± 0.94	3.74 ± 0.98	.235	[-0.13, 0.76]	0.33
Being particularly aware of the presence of others in the room (e.g., sound of others’ breathing or movements)	1.69 ± 1.11	1.60 ± 0.95	.958	[-0.56, 0.74]	0.08
Being particularly aware of the environment around you (e.g., sounds in the room, the temperature)	2.14 ± 1.06	2.06 ± 0.94	.958	[-0.52, 0.69]	0.09
Being particularly aware of your own body (e.g., posture, heart rate, temperature)	3.23 ± 0.88	3.11 ± 0.96	.958	[-0.39, 0.62]	0.12
Being particularly aware of bodily discomfort (e.g., neck, back, shoulder pain)	2.97 ± 1.34	2.94 ± 0.91	.958	[-0.52, 0.58]	0.03
Thoughts about planning or memories concerning recent social/leisure activities (e.g., what to do tonight/what I did on the past weekend)	2.83 ± 1.07	2.83 ± 1.12	1.000	[-0.54, 0.54]	0.00
Fatigue/sleepiness; began to fall asleep	2.69 ± 1.32	3.31 ± 1.23	.016	[-1.17, -0.08]	-0.49
Being interested in and aware of the process of my breathing	3.54 ± 1.04	3.34 ± 0.87	.831	[-0.29, 0.69]	0.21
Using some type of mantra to focus my attention (e.g., saying to myself “in” and “out,” visualized a scene)	2.86 ± 1.35	2.71 ± 1.25	.958	[-0.31, 0.59]	0.11

Note: n = 35. p-values and confidence intervals were adjusted using the false discovery rate method.

Table 15
Hierarchical linear models estimating change in mean Muse mind wandering and Muse recoveries with successive meditation sessions

	Coefficient	Std. Error	*p*	*d*[a]
Model 1: Mind wandering				
Fixed effects (*B*)				
Intercept	37.24	1.75	< .001	
Session number	0.28	0.17	.099	0.02
Random effects (*SD*)				
Participant	6.58			
Residual	10.91			
Model 2: Recoveries				
Fixed effects (*B*)				
Intercept	15.85	2.47	< .001	
Session number	0.27	0.27	.328	0.02
Random effects (*SD*)				
Participant	7.67			
Residual	17.66			

Note: n = 29 participants, 328 sessions. [a]Cohen's *d*, with denominator based on standard deviation of all participant scores in their first home practice meditation session.

of the feedback (*Active* theme) as well as the helpful nature of the feedback in understanding the current mental state and developing an effective meditation technique (*Guiding*). Participants also reported finding feedback anxiety-provoking, often due to being self-critical of their own meditation performance or feeling like they could not control the feedback (*Stressful*). A fourth theme was the distracting nature of the feedback, which made it more difficult to keep focus on the breath or made participants too conscious of the process (*Distracting*). Lastly, feedback was not always perceived as being representative of participants' subjective level of calm attention to the breath (*Incongruent with subjective experience*). Importantly, positive and negative themes were not mutually exclusive across participants: feedback was often viewed as helpful while causing stress and distraction at the same time.

6.6 Discussion

The aim of the present study was to evaluate the effects of auditory feedback on meditation performance and experience. The results provided preliminary support for the

Table 16

Themes around the experience of receiving feedback while meditating with Muse

Theme	Description	Excerpts from written responses
Active (n = 4)	Sense of responsivity and immediacy; tracking performance in real-time	"Makes meditation feel active and not like a waste of time" (#28) "…it's immediately responsive so I can track how I'm going in the moment" (#7)
Guiding (n = 22)	Helps to stay alert/calm/focused; allows for earlier detection/increased awareness of mind wandering; a reminder to calmly refocus; helps develop meditation technique	"feedback was very helpful to improving and understanding the "correct" headspace" (#8) "the feedback helped me to understand my mind's state better" (#12) "I am able to correct myself and stop my mind from wandering before I would usually notice that it has wandered" (#33)
Stressful (n = 16)	Anxiety-provoking; draws salience to lack of mastery; evokes self-criticism due to desire to succeed; can lead to fixation on controlling feedback; more effort does not always improve performance	"Meditation is supposed to be a calming and relaxing activity, however I rarely felt relaxed, most of the time I felt anxious and agitated." (#29) "…it's stressing as well since [I] want to be good at [calming/focusing thoughts], so sometimes I feel frustrated when I get distracted" (#12)
Distracting (n = 15)	Draws attention away from the breath; disrupts concentration; makes it difficult to focus or be calm; feedback becomes a competing object of focus; overthinking or being too conscious of the process	"I find the sounds distracting and continually filling my mind with thoughts about them" (#11) "When the sounds became more intense (mind was wandering) it became harded to become calm again." (#14) "Became too conscious of controlling the sound as opposed to relaxing" (#21)
Incongruent with subjective experience (n = 7)	Feedback not representative of perceived level of attention to the breath; feedback sensitive to mental state during initial calibration period	"I would also become confused as the sounds would appear when my mind was not wandering…" (#29) "I sometimes think about why the noises change and complain about how it's saying that I'm concentrating when I feel that I actually am" (#32) "Some sessions I was very distracted but because the calibration detected my being more distracted initially, I got a very good score – and the same is true in reverse." (#24)

hypothesis that feedback would improve meditation performance, as evidenced by an increase in state mindfulness—reflected in more accurate breath counting—that closely approached significance. Corroborating this finding, feedback led to significantly reduced mind wandering according to Muse, although recoveries did not differ. Furthermore, participants reported fewer subjective experiences of relaxation and of sleepiness when auditory feedback was present. Home practice led to a large increase in perceived control over feedback, although neither of the Muse metrics showed the hypothesised improvements over the two-week period.

Even with relatively limited time for participants to learn how to modulate the signal, auditory feedback appeared to enhance state mindfulness during meditation. Although the increase in correct breath counts was small in absolute terms and did not quite reach statistical significance (p = .056, two-tailed), supplementary analysis showed a significantly lower rate of breath count resets in the feedback condition. Resets have been linked to more prolonged episodes of mind wandering compared to miscounts, which are thought to reflect briefer deviations of attention (Wong et al., 2018). This suggests that feedback lessened the intensity or duration of mind wandering episodes as well as potentially reducing the incidence of these episodes. The present results also showed that Muse-measured mind wandering was lower when receiving auditory feedback, in contrast to a recent study under very similar conditions (Svetlov et al., 2019). This discrepancy between findings could be due to methodological differences, since those authors used 30% shorter sessions, recalibrated the device between conditions, and dichotomised outcome data according to a pre-defined threshold rather than using raw results.

Subjective ratings of meditation experiences across task conditions provided some context for the objective findings. Ratings showed decreased sleepiness and a reduced sense of calm, which together suggest an increase in subjective arousal when auditory feedback was present. This may at first appear counterintuitive, given a commonly held view that meditation should be a relaxing experience—a notion embedded in the Muse ecosystem itself, where "calm" is explicitly the target state. In the Buddhist tradition, however, meditation has instead been regarded as a kind of relaxed alertness that strikes a balance between under-arousal and over-arousal (Andersen, 2005; Britton et al., 2014). Indeed, evidence suggests that during early training, meditators require substantial mental effort to achieve the meditative state (Lutz et al., 2008; Tang et al., 2012). Furthermore, empirical data from an MBSR cohort showed that reductions in subjective sleepiness were associated with increased self-reported present moment attention and non-judgemental orientation to experience, two abilities thought to characterise the construct of mindfulness (Del Re et al., 2013).

Written responses from home practice gave some additional insight into the experience of feedback during meditation. Responses relating to the *Active* theme suggested feedback increased engagement in meditation, in line with the view of increased arousal. The second theme, *Guiding,* was consistent with the observed trends in quantitative data toward an increased awareness of the process of breathing and with difficulties maintaining attention when auditory feedback was present. The experience of *Stress* due to feedback was, on the one hand, consistent with qualitative reports from users of a similar device prototype (Sas & Chopra, 2015). On the other hand, a recent study found no difference in physiological stress markers (high frequency heart rate variability, electrodermal activity, and salivary α-amylase) when meditating with Muse auditory feedback relative to no feedback (Svetlov et al., 2019). Reports of stress or anxiety due to feedback suggest that the task became onerous or frustrating for some participants, perhaps because of failed attempts to control feedback, performing more poorly than desired, or the need to divide attention between breath focus and feedback monitoring. Auditory feedback on task performance has also been shown to increase physiological indicators of stress when contingency on task performance is low, i.e. feedback is less controllable (Peters et al., 1998). This suggests that as control over feedback increases with practice, the experience should become less stressful. The fourth theme, *Distracting*, was again consistent with open-ended responses from previous work (Marcengo et al., 2017; Sas & Chopra, 2015). Novel stimuli (here auditory feedback) tend to be effective at attention capture, making the task of attending to the breath more difficult (Schmeichel & Baumeister, 2013). The final theme, *Incongruent with subjective experience*, although not endorsed by a large proportion of participants, is in line with previous work showing that subjective mind wandering has only weak or negligible associations with device metrics (Hunkin et al., 2021b).

6.6.1 Limitations and Future Research Directions

A major strength of the present work was the use of multiple measurement and analytic methods, enabling a more comprehensive understanding of the effects of synchronous auditory feedback on meditation. A key limitation is that differences between groups could not be conclusively ascribed to the provision of information about mind wandering, since it is possible that the mere sound of feedback with no neurological basis might also improve meditation performance through demand or expectancy effects, or by increasing attention or task effort due to heightened goal salience. Sham feedback could also produce subjective effects such as less sleepiness and fewer relaxed feelings. However, the no feedback control is a meaningful comparator because it is representative of standard practice (i.e. using a meditation app without feedback). Another limitation was that *a priori* power was not achieved due to high rates of device disconnection during the experiment; higher power may have yielded less ambiguous results regarding state mindfulness, which only approached significance. Lastly, due to time and resource constraints, the present work did not examine EEG performance markers other than Muse mind wandering score.

These findings raise some important directions for future research. The stress experienced by some participants in response to feedback suggests that it may be beneficial to have a training phase where feedback becomes progressively more intrusive as meditators gain skill, in order not to overwhelm their capacity to process it. Advancement through this phase could even be linked to physiological measures of stress, where possible to measure these. We speculate that this could be especially helpful for meditators with an anxious disposition, who may find it particularly difficult to adopt a calm and non-judgemental approach to their own performance. Future research could also evaluate the benefit of providing education regarding feedback, incorporating issues such as the dialectic between relaxation and arousal, the fact that feedback may become easier to control with practice, and the divergence of feedback from subjective mind wandering state. Regarding the methodological limitations discussed previously, evaluating Muse relative to sham feedback may give insight into the importance of the accuracy of feedback, although interpreting the effects of sham feedback also comes with caveats (Alino, 2016; Lambert, 2013). While the present study demonstrated both objective and subjective differences in meditating with Muse relative to no feedback, it is unclear whether these differences persist in long term use, and this would be a worthwhile area for further research. Longitudinal research is also needed to determine whether early meditation experiences with Muse lead to differences in meditation attitudes, intentions, and behaviours, compared to using meditation apps without feedback.

CHAPTER 7: GENERAL DISCUSSION AND RESEARCH CONCLUSIONS

The overall aim of this thesis was to examine how wearable devices might contribute to the treatment of mental health problems. Wearable devices are an emerging group of digital mental health technologies that could play a significant role in overcoming the "treatment gap" between those requiring evidence-based treatments and those who actually receive them (Wilhelm et al., 2020). However, limited knowledge currently exists about the range of devices that are commercially available, how they claim to work, evidence for their efficacy, and the clinical implications of their use. Furthermore, there has been little research examining the acceptability of wearable devices to consumers.

The present research aimed to begin to address these gaps in the literature, which limit greater clinical adoption of wearable technologies. Two studies investigate wearable devices broadly, with the aim of identifying available devices, reviewing potential implications of clinical use, and evaluating acceptability for mental health consumers. A further two studies concern a specific device modality, EEG neurofeedback. This work evaluates the capacity of the Muse EEG meditation headband to measure state mindfulness and related constructs and investigated the effect of receiving EEG neurofeedback from this device during focused attention meditation. The results of these studies build on the limited existing literature on the use of wearable devices for the treatment of mental health problems. The following chapter reviews the key findings of each study and outlines their significance with reference to prior literature. The clinical and theoretical implications of the thesis are then discussed, along with relevant strengths, limitations, and directions for future work.

7.1 Summary and Significance of Key Findings

Study 1 reviews fourteen commercially available wearable devices that could be used as adjuncts in the treatment of anxiety-related symptoms. These devices are thought to work through five distinct modalities: electrodermal activity biofeedback, EEG neurofeedback, entrainment, HRV biofeedback, and respiration biofeedback. The review identifies scant evidence for most modalities in relation to mental health outcomes. There is some evidence for HRV biofeedback, though this tends to be of lower quality and pertains more to sensitive lab-based measurement devices rather than wearable devices. The review reveals a number of risks and unexpected effects that should be anticipated when using these devices. It also proposes a pragmatic clinical evaluation framework, adapted from earlier work, that could be used as a decision aid when considering the use of wearables.

Study 1 addresses a significant gap in the literature on wearable devices for mental health. Since these devices have mostly become available over the past decade, there was little pre-existing research enumerating and classifying devices and their respective modalities. Previous reviews were no longer current (e.g., Clough & Casey, 2011), concerned only with activity and sleep trackers (e.g., Martinez et al., 2016), or examined biofeedback devices within other contexts such as stress (e.g., Subhani et al., 2017). Moreover, these reviews did not comprehensively consider the implications of using wearable devices in clinical practice, such as questions about risks or clinical decision-making regarding device use. The significant contribution of Study 1 is therefore to bring together the most current information regarding available wearable devices, evidence for their use, and relevant clinical considerations in the context of treating anxiety symptoms.

Study 2 specifically focuses on the acceptability of wearable technology, as distinct from other digital mental health technologies. The findings suggest that mental health consumer interest in blended therapies (i.e., wearable device treatments used adjunctively with conventional talk therapies) is strong and only marginally lower than interest in conventional talk therapies. Perceived effectiveness of wearables is a particularly strong predictor of interest in using them, while sociodemographic variables are not predictive of acceptability. These predictors of acceptability are largely consistent with existing studies investigating other digital mental health interventions (see, e.g., Klein & Cook, 2010; March et al., 2018; Wallin et al., 2018). Using wearable devices as adjuncts to treatment appears more appealing for those who have negative attitudes to conventional therapies and less experience in help-seeking. These findings suggest that wearable devices may be a useful engagement tool for those who may typically not seek help via typical mental health channels, consistent with one theorised benefit of digital mental health interventions (Clarke & Yarborough, 2013; Lui et al., 2017).

Study 2 was devised to overcome some significant limitations of existing research into the acceptability of wearable devices and other digital mental health interventions. Firstly, previous research on wearable devices was generally focused on applications other than mental health, with an emphasis on higher-level or device-related characteristics rather than individual-level predictors of acceptability (see, e.g., Kalantari, 2017). Furthermore, some existing work produced an arbitrary measure of acceptability which could not easily be compared to other treatments, or to adjunctive use alongside those treatments (see, e.g., Arjadi et al., 2018; Dorow et al., 2018). Study 2 is thus a significant contribution in two respects. Firstly, it explores the influence of individual factors such as sociodemographic factors, clinical status, and attitudes to therapy. Secondly, acceptability for wearable devices is examined within the context of acceptability for conventional therapies and self-help interventions, so that predictors of differential acceptability between therapies could be examined.

Studies 3 and 4 evaluate the Muse headband, which was developed to support focused attention meditation by providing synchronous neurofeedback. Study 3 identifies significant within- and between-participants associations between device-measured mind wandering and an objective measure of state mindfulness, the Breath Counting Task. These associations are particularly notable due to the entirely distinct methodologies used for each measure (i.e., EEG vs. a cognitive task). Furthermore, mean Muse mind wandering and mean Muse recoveries during a 14-day home practice period jointly explain around 30% of variance in four mindfulness-related trait measures. These findings suggest that Muse has practical value as a measure of state mindfulness during meditation. Study 4 is based upon the same dataset, and the results of this study suggest that receiving neurofeedback during meditation results in a greater level of state mindfulness relative to unaided practice. Feedback also appears linked to differences in the experience of meditation, which are consistent with a heightened sense of arousal. Thematic analysis reveals that participants perceive positive aspects of feedback, specifically making the experience of meditation more active and receiving guidance in how to practice. However, there are negative aspects of feedback too: it could induce stress and distraction, and feedback is not always congruent with subjectively perceived performance.

Although the Muse EEG meditation headband appears to be one of the most-researched wearable devices presently available, Studies 3 and 4 both make significant new contributions to this literature. Previous work typically compared the use of Muse with a control intervention over several weeks, examining the effects on cognitive, psychological and psychophysiological outcomes (see, e.g., Balconi et al., 2018; Bhayee et al., 2016; Crivelli et al., 2019). However, there has been little research to assess whether the measures produced by Muse were valid correlates of enhanced meditation performance. Study 3 is therefore novel in showing that Muse measures are strongly associated with a behavioural measure of state mindfulness. Furthermore, little existing research had compared Muse with a comparable meditation intervention without neurofeedback. This type of comparator is important because the ultimate clinical utility of Muse is for it to have incremental benefits over unaided meditation interventions. Study 4 therefore compares the use of Muse with a no-feedback control condition that is matched in every way except for the presence of feedback. This is an important methodological detail because very little research exists to support the use of EEG neurofeedback as a specific active ingredient that enhances meditation practice relative to unassisted meditation.

These findings add to those of Balconi and colleagues (Balconi et al., 2018; Crivelli et al., 2019) who compared Muse with a closely matched meditation-based active control condition over a four week period. In Study 4, the only difference between experimental conditions is the presence of auditory feedback, whereas in the studies of Balconi and colleagues there were other obvious differences between conditions that participants would have been aware of (the use of a headband and smartphone app, gamification features, asynchronous feedback on performance). The present methodology thus eliminates some possible confounders that were present in previous work. Furthermore, these results suggest a potential mechanism through which the improvements observed by Balconi and colleagues occurred, since higher state mindfulness during meditation has been linked to accumulated decreases in psychological distress (Kiken et al., 2015).

7.2 Clinical and Theoretical Implications

The results of these studies have important implications, both for clinical work and for theory. A recurring clinical implication across all studies is the potential benefit of clinician guidance in the use of wearable devices. The review of the literature in Study 1 highlights that without clinician involvement, there is likely to be a higher risk of misdiagnosis, dropout, overinterpretation of device metrics, or use of devices in unhelpful ways (e.g., as an avoidance strategy). Study 2 shows that wearable devices are far more appealing to most prospective users when coupled with professional support, although the factors driving assisted use may be different to those driving unassisted use (cf. Arjadi et al., 2018). Study 3 demonstrates that Muse EEG headband device metrics contain useful information but that it may need to be interpreted with care, while Study 4 suggests that evidence-based psychoeducation could be critical to reducing misperceptions about the accuracy, controllability, and physiologically arousing nature of neurofeedback during meditation. Together, these findings are consistent with the theory that wearable devices are likely to be more acceptable and effective when clinician guidance is available. This is in line with research findings in other domains of digital mental health, such as apps and Internet interventions (Baumeister et al., 2014; Garrido et al., 2019; Schueller et al., 2017).

The implication of these findings is that clinicians should take an active role in discussing how a wearable device might be therapeutic, how it should be used, what to expect when using it, and what limitations there might be in terms of the beneficial effects or the accuracy of information provided by the device. As with other forms of homework between sessions, clinicians need to devote time to reviewing device data in session regularly or risk clients judging the device to be unimportant (see, e.g., Beck, 2021). There is some disagreement in the literature over the importance of clinicians' personal experience with adjunctive digital mental health interventions (Clough & Casey, 2015b; Morris & Aguilera, 2012). However, experience with wearable devices would arguably be valuable for clinicians, especially when an evidence-based evaluation of the device is not available—as is the case for the vast majority of currently available devices in the marketplace.

While showing that clinician guidance may increase the acceptability of wearable devices, the results of Study 2 also suggest that for some clients, incorporating wearable devices could enhance the acceptability of conventional treatments. Empirical studies and digital mental health models such as the Internet Interventions model (Ritterband et al., 2009) and the Efficiency Model of Support (Schueller et al., 2017) have tended to focus on the additive benefit of the clinician to digital mental health interventions. However, Study 2 further tests this theory by considering whether using wearable devices as adjuncts could increase the prospective acceptability of conventional therapies. The results suggest that incorporating wearables has the potential to increase acceptability, specifically in cases where clients have no previous experience with therapy, have negative evaluations of therapy, or perceive devices to be effective. These findings are consistent with the theory that digital mental health interventions play a role in reducing attitudinal barriers to accessing care (Christensen & Hickie, 2010). Future theoretical and applied research should therefore not only consider the additive benefits of clinician support on digital mental health intervention acceptability, but also the reverse.

The clinical implications for the use of the Muse EEG meditation headband are somewhat less clear. The results of Study 4 suggest demonstrable benefits in using Muse to practice meditation, relative to conventional meditation approaches (represented by the no-feedback condition in Study 4). However, the findings of Study 3 make a less compelling case for using Muse to assess clinical change. As detailed in Section 5.6, the low test-retest reliability of the mind wandering measure is concerning, and may reflect significant measurement error (see Ratti et al., 2017) or calibration effects in addition to the expected fluctuation of a state variable. Study 3 shows that both Muse measures together significantly predict trait mindfulness when they are aggregated over numerous sessions, reducing the noise associated with each measurement occasion. However, comparing a singular session result with a later session is unlikely to produce meaningful information about change, as evidenced by a recent study of Muse measures (Acabchuk et al., 2021). These limits to reliability are likely to be common with consumer-grade wearable devices because of artifacts in the raw physiological measures and the limited accuracy of algorithms in making inferences from the data. This problem underlines the importance of providing appropriate psychoeducation so that clients do not become overly fixated on the meaning of device metrics, as discussed in Section 3.5.1.

A final notable implication relates to the importance of clinical and sociodemographic predictors of the prospective acceptability digital mental health interventions. Previous research has shown mixed findings regarding the importance of sociodemographic predictors in the acceptability of digital mental health interventions, perhaps due to heterogeneity across those interventions (see, e.g., Klein & Cook, 2010; Mackert et al., 2016; Wallin et al., 2018). These predictors, such as age, gender, education, socioeconomic status, and remoteness, tended to not be significant, or demonstrated only small or trivial effect sizes. Likewise, symptom severity had small to negligible effects on preference for e-mental health relative to conventional treatments (March et al., 2018; Wallin et al., 2018). The results of Study 2 are broadly consistent with these existing findings, as differences in symptom severity and sociodemographic factors do not appear to affect the prospective acceptability of wearable devices relative to conventional talk therapies or self-help interventions. The relative lack of influence of sociodemographic factors may run counter to intuition. Although it is known that older age is associated with lower levels of technology acceptability in the broader context of information communications technology, this relationship may not hold within the digital health context due to differences in utilisation context, motives, and user heterogeneity (Arning & Ziefle, 2009). Clinicians should therefore take care not to make assumptions about treatment preferences based solely on symptom severity or sociodemographic factors. Further research in this area may allow for a more nuanced understanding of when symptom severity and sociodemographic factors might be important, and whether concurrent and retrospective acceptability follow a similar pattern.

7.3 Strengths

Wearable devices are rapidly emerging but under-researched technologies, and thus a key strength of this thesis is the novel topic of study and its relevance to current trends in clinical practice. Furthermore, the research program took a multi-faceted approach in line with the Internet Interventions model (Ritterband et al., 2009), which identifies a wide range of factors that would potentially affect the utilisation and effectiveness of e-health interventions such as wearable devices. This resulted in the development of knowledge in multiple areas: from identifying currently available devices and evaluating what evidence existed for using them, to determining individual factors relating to the acceptability of wearable devices and finally, assessing the potential benefits of one specific device.

A particular strength of this thesis is in drawing together the existing literature in the areas of neurofeedback-supported meditation and state mindfulness. Prior theoretical work suggested that detecting mind wandering episodes and feeding this information back to the meditator could facilitate and support the development of effective meditation practice (Brandmeyer & Delorme, 2013). However, existing literature had not acknowledged that the neurological signal being measured might effectively serve as a measure of state mindfulness. The present work thus elucidates a specific mechanism through which neurofeedback-supported meditation could operate, since enhanced state mindfulness during meditation has been linked to superior clinical outcomes (Garland et al., 2015; Kiken et al., 2015). Making the connection between these two separate bodies of literature extends the theoretical basis for neurofeedback-assisted meditation and could stimulate new research in this area.

Another important strength of the present thesis is in demonstrating a novel evaluation paradigm. While clinical trials are the most well-established way to demonstrate the efficacy of new devices, they are costly and time consuming, and more rapid methods of evaluation are needed (Kumar et al., 2013; Mohr, Lyon, et al., 2017; Patrick et al., 2016; Riley et al., 2013). Lab-based evaluation of devices, as Studies 3 and 4 demonstrate, may be a useful middle ground in which potential devices can be assessed in terms of their measurement accuracy and acute effects on relevant process variables. This paradigm is likely to be most appropriate when there are known mediators of the long-term outcomes being studied (in the present work, state mindfulness) and when devices are used intensively for short periods. Other advantages of this approach include the ability to directly compare participants' meditation experience with and without feedback in a relatively controlled environment, without introducing additional confounders such as extended app features like gamification, reminders, and asynchronous feedback on performance, along with the associated digital placebo effect (Torous & Firth, 2016).

Lastly, the use of multiple investigative methods is a strength of all three empirical studies within this thesis. Study 2 includes qualitative responses, which captured important aspects of wearable device acceptability that were not part of the quantitative scales. Studies 3 and 4 utilise a task-based assessment as well as a quantitative and qualitative measures of the experience of meditating with Muse, in addition to the device measures. These measures reveal important aspects of the meditation experience, such as heightened arousal, stress, and distraction related to feedback, which are not evident from the quantitative measures. Utilising multiple methods has thus allowed for a more rigorous and nuanced investigation across each of the three empirical studies.

7.4 Limitations

A considerable limitation affecting Studies 1 and 2 concerns the heterogeneity of wearable devices. As identified in Study 1, at least five modalities of device may be used for the treatment of mental health problems, and there are varying levels of evidence for these modalities. Device factors such as the physical profile of each device modality and the way it is used could be major factors in whether it is acceptable to clients, as discussed in Study 2.

However, even within each modality there is likely to be substantial heterogeneity in aspects such as device build quality, proprietary algorithms, software usability, measurement fidelity, and user appeal (see, e.g., Nelson et al., 2020). Heterogeneity could also result from device and software development evolution over time (Clough & Casey, 2015a). For example, while the EEG headband evaluated in Studies 3 and 4 was a current model at the commencement of this thesis, two newer models of the same device are now available, and numerous software updates have been made. It is typically not evident to clinicians and clients whether the intervention being delivered by these newer devices or newer software differs substantially from earlier versions. Given these factors, it may be difficult to develop general rules about the efficacy of any one specific modality—thus limiting the external validity of the present findings.

Although this thesis takes a broad approach to the use of wearable devices in the mental health context, it was not possible to include all of the potentially important aspects. For example, while Study 2 investigates the perceived acceptability of wearables to clients, the factors involved in clinician decision making were not examined. Clinician barriers are thought to be critical to achieving broader implementation of digital mental health services, and may include issues such as cost, privacy concerns, a lack of awareness or training, and resistance to change (Batterham et al., 2015; Ramsey et al., 2016). The significance of clinician attitudes was reinforced in Study 2, where over 96% of respondents said that they would use a wearable device if their clinician recommended doing so. A further limit to the scope of the present work concerns the theorised benefits of digital mental health interventions. Study 2 suggests that there is a high level of prospective acceptability for wearable devices amongst potential clients. However, the present work does not quantify the level of retrospective acceptability following use of such devices in a wearable-based intervention, or the degree of adherence and retention achieved in such an intervention.

An important limitation of Studies 3 and 4 is the sample size, which fell short of the planned number due to data loss. This led to relatively wide confidence intervals, which limit the certainty that the results could be replicated in future. The first main source of data loss, due to a poor headband signal, is unlikely to have affected the results, other than to reduce the effective sample size. Nonetheless, recurrent experiences of losing headband connection may limit the clinical utility of the device for some meditators, and indeed appeared to be a source of significant frustration in verbal feedback to the researcher. The second main source of data loss, invalid breath count data, could have potentially biased the results. However, the lack of information about why breath count data loss occurred (i.e., why participants failed to complete at least one correct breath count cycle) means that it is difficult to know the extent of any possible bias. Investigating this problem further will be important to confirm the validity of the task as an objective measure of mindfulness.

Another limitation concerns the non-clinical nature of the sample used in Studies 3 and 4. Due to the evaluation paradigm used in these studies (outlined earlier in this section), the objective was to assess state and trait mindfulness and the effect of neurofeedback on these process variables, rather than on psychological symptoms directly. For this reason, it was possible to use a non-clinical sample (albeit sampled from a population known to have a high proportion of individuals with elevated mental health symptoms). This approach was beneficial in terms of ease of participant recruitment and was appropriate given the little existing research with the device. However, the use of non-clinical samples represents a common limitation in digital mental health research (Lau et al., 2020). In the present context, it is possible that higher levels of psychopathology may somehow invalidate the EEG algorithms used, leading to less accurate feedback being provided. Perhaps more conceivably, heightened psychopathology could affect the ability of the meditator to utilise feedback in order to achieve a heightened state of mindfulness. These limitations highlight the importance of working toward trials within clinical populations, to ensure that the beneficial effects of the device are invariant to psychopathology.

One final limitation relates to the assumptions made about the purpose of meditation and the underlying mechanisms that bring about therapeutic benefits. The present thesis considers meditation as a clinical treatment for the purpose of symptom reduction, however Eastern meditation traditions may have a different goal—usually, the experience of particular subjective state (Reddy & Roy, 2019). The utility of neurofeedback support may therefore vary depending on what the meditator is aiming to achieve through their practice. Furthermore, as described in Section 1.3.2, there are many different styles of meditation, and each style may train different cognitive and affective skills, or even produce salutary effects via other mechanisms such as increasing self-compassion (Wielgosz et al., 2019). The present thesis emphasises the skills thought to be trained in focused attention meditation: the ability to monitor for distractions, disengage from them, and reorient attention (Lutz et al., 2008). The findings are thus most relevant in the context of focused attention meditation, but at the same time may not consider all of the important mechanisms of symptom reduction associated with this style of meditation.

7.5 Future Research Directions

Considering the issue of device heterogeneity, a significant contribution to the scientific literature would involve the development of an explicit classification framework of wearable devices for mental health, building on the work of Study 1. The key purposes of such a framework would be to identify important dimensions across which wearable devices differ, and to consider the implications of these differences for clinical and research work. For example, devices like Muse are used primarily for brief practice sessions, whereas other devices are designed to be worn throughout the entire day and/or night. This characteristic is likely to have implications for device evaluation, because while lab-based evaluation may be appropriate for the former type, the latter is likely to require the use of field data. A classification framework would aid future work in the area by providing a common language for researchers, reducing terminological differences and redundancy.

Given the need to broaden the empirical evidence for wearable devices, an important future research direction is in developing the most economical and rapid methods of evaluating wearables. Digital mental health interventions like apps and wearable devices typically have a short lifespan before being superseded (Clough & Casey, 2015a). Furthermore, as shown in Study 1, a large number of wearable devices targeting mental health and wellbeing are already available, with this number likely to grow significantly in coming years. This constant turnover and short lifespan make evaluation difficult because devices may be outdated before evaluation is completed. Future research will need to establish evaluation paradigms that can overcome these challenges, and there are several avenues of enquiry that could contribute to this end. Firstly, given limited research capacity, one target might be to formalise the process of determining which devices are most likely to prove efficacious based on a rapid device assessment. This would allow evaluation resources to be targeted more efficiently. A second strategy is to develop research methods that might yield more rapid results. Randomised controlled trials are considered a gold standard, yet there is thought to be a time lag of around seven years from grant application to the dissemination of results in these trials (Ioannidis, 1998). The use of alternative methods such as multiple baseline designs has been proposed (Bucci et al., 2019; Clough & Casey, 2015a; Kumar et al., 2013), but to date there are few examples to demonstrate the theorised benefits of these approaches.

The final proposed strategy is to develop a greater theoretical understanding of the active ingredients in different types of wearable device interventions, and the factors that might moderate the effect of those mechanisms. Theory development can help to understand possible explanations for the effects under study, as opposed to merely quantifying those effects (Borghi & Fini, 2019). Developing theory would thus help to inform the development of more effective devices, but also allow provide some objective guidelines for evaluating devices (potentially augmenting the first strategy described above). Furthermore, theoretical models might suggest which factors could moderate the effectiveness of any given intervention, helping to gauge whether changes to wearable software and hardware are likely to have an impact upon intervention effectiveness.

In regard to the Muse EEG meditation headband, an important avenue for future research will be evaluation in clinical populations. One objective of this work would be to determine whether the presence of psychopathology affects the efficacy of the device, as mentioned in the discussion of limitations. A recent systematic review found that stand-alone mindfulness exercises have small-to-medium effect sizes for symptoms of both anxiety (g = 0.39) and depression (g = 0.41; Blanck et al., 2018). The results of Study 4 suggest that neurofeedback during meditation could amplify these effects, however it is possible that these additional benefits of neurofeedback could be moderated by the presence of clinical symptoms. It would therefore be valuable to test whether the device has specific efficacy in the presence of anxiety or depression symptoms, which are common mental health problems. Device efficacy could also be differentially affected by the presence of common neurodevelopmental disorders, such as Autism Spectrum Disorder or Attention Deficit Hyperactivity Disorder.

Another important question regarding assisted meditation is whether it may have the potential to be unhelpful or even harmful for some meditators. It is theorised that monitoring for distractions is one of the key skills trained in focused-attention meditation (Lutz et al., 2008). While supporting this ability with feedback may aid the meditation process in the short term, there may be a point at which this aid becomes an unhelpful crutch if it substitutes for the meditator developing their own monitoring skills. Furthermore, iatrogenic effects have been observed in connection with both neurofeedback and meditation, although these effects are not well understood at present (Hammond & Kirk, 2008; Van Dam et al., 2018). Future work should consider whether the level of meditation experience or the presence of particular risk factors might contraindicate aided meditation. Researchers should also collect data about adverse events in order to better understand possible harms.

Clinical trials could consider a range of secondary questions that are pertinent to wearable devices. Digital mental health interventions are theorised to enhance engagement (Lui et al., 2017; Naslund et al., 2017), which is pertinent since there are some common barriers to engaging with meditation (Hunt et al., 2020; Russell et al., 2018). It would therefore be worthwhile to determine whether the use of a meditation aid such as Muse led to increased adherence and retention in therapy relative to a comparable meditation intervention that was unassisted. These behavioural data form one measure of retrospective acceptability, but should also be complemented with self-report data in order to achieve a more comprehensive evaluation (Sekhon et al., 2017). Furthermore, evaluating the prospective acceptability of devices used in clinical trials may give insight as to device-level factors such as specific modalities or features that influence the likelihood of using particular devices. This data could complement the individual-level predictors of prospective acceptability that were reported in Study 2.

Further research into the use of feedback during meditation could help to determine how the quality and source of the feedback signal might moderate the benefits to meditation practice. For example, a newer version of the Muse EEG meditation headband, Muse 2, also collects data from a gyroscope, accelerometer, and pulse oximeter, which can be used to provide feedback on the basis of body movement, breath, and heart rate during meditation (InteraXon Inc., 2021). It is possible that these data could have incremental validity in predicting mindfulness during meditation, increasing the accuracy of feedback. It is not clear whether any increase in accuracy would further enhance the effect of neurofeedback during meditation on state mindfulness. However, one potential benefit of increased signal accuracy may be greater convergence of device feedback with subjective meditation experience, increasing the face validity of the technology and potentially enhancing device acceptability.

A related research question is whether degradation of the neurofeedback signal accuracy substantially reduces the benefits of feedback on meditation. It is presumed that accurate feedback is a necessary element of biofeedback (McKee, 2008), although other mechanisms affecting attention, motivation, self-efficacy, and locus of control may play a significant role (Alino, 2016; Thibault & Raz, 2017; Weerdmeester et al., 2020). The effect of degradation of other signal characteristics, such as feedback frequency, is another theoretical question. A recent study by Patsenko et al. (2019) tested a mindfulness training paradigm similar to Muse, in which feedback was provided during a mindfulness-based game app. Feedback was based upon tapping the screen with each breath, similarly to the Breath Counting Task; the correct response was a single tap for the first four breaths, and a double tap for the fifth breath. Since participants only received feedback with each tap, the frequency of the feedback signal would be around six times per minute (a typical paced breathing rate), whereas the measure of mind wandering produced by Muse is sampled at 1 Hz (i.e., once per second). Patsenko et al. found that two weeks' practice with the app led to significant changes in connectivity in fronto-parietal areas thought to be involved in attention regulation, relative to a control group who played an attentionally demanding game. However, it is unclear from this work whether feedback of this type has incremental benefits over meditation practice without feedback. Future research might therefore compare this type of mindfulness game to a conventional app-based mindfulness intervention, or to other forms of feedback such as Muse. If feedback based on behavioural data such as breath counting is comparable to that from neural data, this could obviate the need for wearable devices, thus increasing access to meditation-supporting technologies.

7.6 Conclusion

Wearable devices are one part of a broader move toward the digitalisation of mental healthcare, and have potential for enhancing the accessibility, acceptability, and effectiveness of psychological interventions. The present thesis adds to a growing body of evidence for the use of wearable devices in treating mental health problems. Overall, the results of the present research program are consistent with research in the wider digital mental health field. A diverse range of innovative therapeutic interventions are increasingly available (Study 1; cf. Mohr, Burns, et al., 2013). These interventions show broad appeal with clients and hold promise in reaching those who may not use or respond to conventional therapies (Study 2; cf. Klein & Cook, 2010; March et al., 2018). The results of the present thesis therefore support the notion that wearable devices are an emerging category of digital mental health interventions that may have distinct benefits for engaging consumers.

Generating an evidence base for the effectiveness of digital health interventions remains one of the most difficult problems in the field, given their vast number and rapid turnover (Coffey & Coffey, 2016; Torous & Roberts, 2017a). The present thesis used a process-oriented approach, novel relative to other work in this area, to contribute new knowledge about neurofeedback-assisted meditation. The results provide preliminary support for the use of synchronous feedback to enhance the therapeutic benefits of meditation practice. Moreover, the observed data were consistent with the mechanisms through which neurofeedback is theorised to function. This work thus complements existing theoretical and empirical studies in the area.

Wearable devices will continue to evolve and are likely to be influenced by innovation in areas like digital phenotyping, the use of smart devices to track observable markers of mental health. Future directions could include greater integration with social media, or with virtual and augmented reality systems. These developments undoubtedly represent new and demanding challenges for the field. Given the potential importance of wearable devices in future mental healthcare systems, continuing clinician and researcher engagement with the development and evaluation of these devices is essential.

APPENDIX A: STUDY 2 SUPPLEMENTARY MATERIAL

Description of wearable devices shown to participants

Wearable devices for mental health:

- are small devices like headbands, clips which attach to the ear or finger, or wristbands/watches
- might be used to improve general wellbeing or to treat mental health problems detect body signals like breathing, heart rate, skin dryness or level of brain activity generally work through relaxation training and give the user feedback about signals of relaxation or stress in the body
- may be worn either all day or for brief periods of time
- are low cost - around the same as one session with a psychologist, or less

Table A1

Spearman correlations between all study variables

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1. Age	—	-.11[c]	-.13[c]	-.04	.10	-.20[a]	-.26[a]	-.24[a]	-.27[a]	-.19[a]	.10[d]	.07	-.14[b]	-.10[d]	-.01	-.08	.18[a]
2. Socioeconomic disadvantage	-.11[c]	—	.03	-.03	.09	-.10[d]	-.05	-.04	-.01	.02	-.03	-.08	-.01	-.03	-.03	.02	-.04
3. Previous knowledge	-.13[b]	.03	—	.16[b]	.00	-.02	.04	.00	.00	.19[a]	.05	.05	.12[c]	.07	.00	.04	-.08
4. Perceived effectiveness	-.04	-.03	.16[a]	—	.15[c]	.02	.13[c]	.13[c]	-.01	.17[b]	.23[a]	.51[a]	.46[a]	.20[a]	.24[a]	.26[a]	-.04
5. Satisfaction with prior treatment[e]	.10[d]	.09[d]	.00	.15[b]	—	-.20[a]	-.12[d]	-.11[d]	-.35[a]	.12[d]	.30[a]	.09	-.06	.01	-.19[a]	-.08	.15[c]
6. Depression	-.20[a]	-.10[c]	-.02	.02	-.20[a]	—	.60[a]	.61[a]	.39[a]	-.01	.06	.02	.02	.12[c]	-.04	-.05	-.02
7. Anxiety	-.26[a]	-.05	.04	.13[b]	-.12[c]	.60[a]	—	.71[a]	.39[a]	-.04	.13[c]	.10[d]	.10[d]	.15[b]	-.04	.00	-.04
8. Stress	-.24[a]	-.04	.00	.13[b]	-.11[c]	.61[a]	.71[a]	—	.38[a]	-.02	.14[c]	.14[b]	.12[c]	.16[b]	-.01	-.01	-.04
9. Barriers to treatment (total)	-.27[a]	-.01	.00	-.01	-.35[a]	.39[a]	.39[a]	.38[a]	—	-.13[c]	-.21[a]	-.08	.10[d]	.17[b]	.10[d]	-.01	-.18[a]
10. Technological readiness	-.19[a]	.02	.19[a]	.17[a]	.12[c]	-.01	-.04	-.02	-.13[b]	—	.06	.10[d]	.11[d]	-.07	.04	.15[b]	.01
11. TT	.10[c]	-.03	.05	.23[a]	.30[a]	.06	.13[b]	.14[b]	-.21[a]	.06	—	.44[a]	.01	.04	-.54[a]	-.06	.34[a]
12. WB	.07	-.08[d]	.05	.51[a]	.09[d]	.02	.10[c]	.14[b]	-.08[d]	.10[c]	.44[a]	—	.47[a]	.19[a]	.45[a]	.29[a]	.29[a]
13. WS	-.14[b]	-.01	.12[c]	.46[a]	-.06	.02	.10[c]	.12[c]	.10[c]	.11[c]	.01	.47[a]	—	.46[a]	.43[a]	.59[a]	-.65[a]
14. OS	-.10[c]	-.03	.07	.20[a]	.01	.12[c]	.15[b]	.16[b]	.17[a]	-.07	.04	.19[a]	.46[a]	—	.12[c]	-.39[a]	-.36[a]
15. WB v TT	-.01	-.03	.00	.24[a]	-.19[a]	-.04	-.04	-.01	.10[c]	.04	-.54[a]	.45[a]	.43[a]	.12[c]	—	.34[a]	-.09
16. WS v OS	-.08	.02	.04	.26[a]	-.08	-.05	.00	-.01	-.01	.15[b]	-.06	.29[a]	.59[a]	-.39[a]	.34[a]	—	-.35[a]
17. WB v WS	.18[a]	-.04	-.08[d]	-.04	.15[b]	-.02	-.04	-.04	-.18[a]	.01	.34[a]	.29[a]	-.65[a]	-.36[a]	-.09[d]	-.35[a]	—

Note: $N = 427$. Significance values shown in the upper right triangle are adjusted using the false discovery rate method. TT = talk therapies, WB = wearables (blended), WS = wearables (self-help), OS = other self-help.

[a]$p < .001$, [b]$p < .01$, [c]$p < .05$, [d]$p < .10$

[e]For respondents who had previously consulted a mental health professional ($n = 359$).

Table A2

Spearman correlations of continuous predictors with hypothetical acceptability of four mental health treatments

	TT	WB	WS	OS
Age	.10^	.07	-.14**	-.10^
Socioeconomic disadvantage	-.03	-.08	-.01	-.03
Previous knowledge	.05	.05	.12*	.07
Perceived effectiveness	.23***	.51***	.46***	.20***
Satisfaction with prior treatment[a]	.30***	.09	-.06	.01
Years affected by condition[b]	-.03	.01	-.12	-.14^
DASS				
Depression	.06	.02	.02	.12*
Anxiety	.13*	.10^	.10^	.15**
Stress	.14*	.14**	.12*	.16**
Barriers to treatment (total score)	-.21***	-.08	.10^	.17**
Stigma	-.24***	-.12*	.11^	.22***
Lack of motivation	.00	.07	.09	.13*
Emotional concerns	-.18***	-.06	.11*	.18***
Neg. evaluation of therapy	-.29***	-.18***	.05	.05
Misfit of therapy to needs	-.33***	-.17**	.08	.13*
Time constraints	-.11*	.02	.19***	.11*
Participation restriction	.06	.00	.01	.04
Availability of services	-.04	.04	.08	.09
Cost	.05	.02	-.02	.08
Technology readiness (total score)	.06	.10^	.11^	-.07
Optimism	.13*	.20***	.13*	-.01
Innovativeness	.02	.04	.10^	.00
Discomfort	-.03	-.02	-.04	.13*
Insecurity	-.01	-.04	-.02	.12*

Note: TT = talk therapies, WB = wearables (blended), WS = wearables (self-help), OS = other self-help.

[a]For respondents who had previously consulted a mental health professional (n = 359).

[b]For those who reported a diagnosed condition and reported duration (n = 234).

^ $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$ (adjusted using the false discovery rate method).

Table A3

Categorical predictors of hypothetical acceptability of four mental health treatments (M ± SD)

	TT	WB	WS	OS
Gender				
Female	5.71 ± 1.61	5.37 ± 1.53	4.00 ± 2.01	4.56 ± 1.72
Male	5.47 ± 1.71	5.17 ± 1.74	4.01 ± 1.88	4.41 ± 1.77
d	.14	.12	.00	.08
p_{FDR}	.322	.483	.971	.632
Relationship status				
Single/divorced/separated	5.65 ± 1.61	5.14 ± 1.75	3.90 ± 1.97	4.40 ± 1.85
Married/committed relationship	5.58 ± 1.68	5.37 ± 1.54	4.07 ± 1.94	4.55 ± 1.67
d	.04	-.13	-.08	-.08
p_{FDR}	.829	.392	.632	.632
Remoteness				
Major cities	5.64 ± 1.61	5.28 ± 1.57	4.19 ± 1.97	4.58 ± 1.75
Rural/remote	5.53 ± 1.76	5.30 ± 1.76	3.56 ± 1.82	4.29 ± 1.72
d	.06	-.01	.34	.17
p_{FDR}	.742	.947	.011	.278
Current wearable usage				
No	5.58 ± 1.69	5.14 ± 1.70	3.84 ± 1.91	4.46 ± 1.75
Yes	5.71 ± 1.53	5.78 ± 1.20	4.58 ± 1.98	4.62 ± 1.70
d	-.07	-.49	-.41	-.13
p_{FDR}	.742	<.001	.005	.519
Education				
Diploma or below	5.44 ± 1.76	5.22 ± 1.71	3.91 ± 2.01	4.47 ± 1.86
Bachelor degree	5.66 ± 1.66	5.25 ± 1.61	4.07 ± 1.95	4.48 ± 1.72
Postgraduate degree	5.92 ± 1.32	5.51 ± 1.43	4.08 ± 1.81	4.60 ± 1.48
η^2	.01	.00	.00	.00
p_{FDR}	.252[a]	.632	.823	.941
Household income				
< $35,000	5.56 ± 1.70	5.25 ± 1.75	4.00 ± 2.02	4.56 ± 1.88
$35,000-$65,000	5.64 ± 1.63	5.22 ± 1.73	3.43 ± 1.93	4.04 ± 1.83
$65,000-$105,000	5.54 ± 1.66	5.15 ± 1.56	4.10 ± 1.88	4.51 ± 1.57
> $105,000	5.68 ± 1.66	5.48 ± 1.47	4.38 ± 1.87	4.77 ± 1.62
η^2	.00	.01	.03	.02
p_{FDR}	.950	.632	.026	.079
Consulted a professional				
No	4.79 ± 1.75	5.26 ± 1.62	4.65 ± 1.76	4.50 ± 1.82
Yes (no longer seeing)	5.42 ± 1.72	5.20 ± 1.68	3.96 ± 1.91	4.55 ± 1.63
Yes (still seeing)	6.37 ± 1.12	5.45 ± 1.52	3.75 ± 2.05	4.40 ± 1.90
η^2	.11	.00	.02	.00
p_{FDR}	<.001[a]	.632	.033	.871
Mental health diagnosis				
No	5.08 ± 1.70	5.18 ± 1.71	4.26 ± 1.86	4.58 ± 1.71
Yes (no longer impacting)	5.51 ± 1.89	5.16 ± 1.66	3.69 ± 1.86	4.14 ± 1.67
Yes (still impacting)	5.90 ± 1.50	5.37 ± 1.57	3.97 ± 2.00	4.56 ± 1.77
η^2	.05	.00	.01	.01
p_{FDR}	<.001	.632	.312	.380

Note: TT = talk therapies, WB = wearables (blended), WS = wearables (self-help), OS = other self-help. *t*-tests used to infer significance of two-group variables and ANOVA for more than two groups. *p*-values adjusted using the false discovery rate method. [a]Levene's test indicates non-homogenous variance; interpret *p*-values with caution..

APPENDIX B: STUDY 3 SUPPLEMENTARY MATERIAL

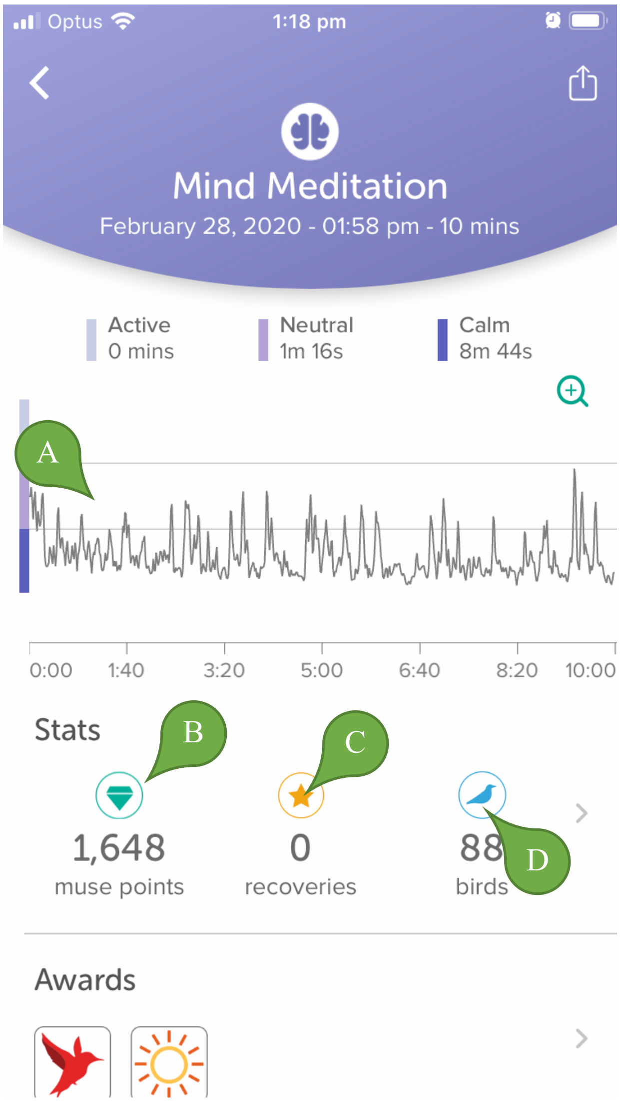
Interpretation of Muse Scores

Additional to the discussion in the accompanying paper, the following issues require consideration when interpreting the measures produced by Muse:

1. The measure used in the accompanying paper, Muse mind wandering, is not directly reported by the Muse app or clinical platform. The score found there, “Muse points”, is calculated by apportioning 0, 1, or 3 points for each second of meditation spent within the active, neutral, and calm bands, which represent the three tertiles of the scoring range. The measure used in the paper, Muse mind wandering, is calculated by extracting the raw score (ranging from 0-100) for each second of meditation, and taking the mean of these scores. It can therefore be estimated by viewing the charted session progress, as shown in Figure 1 (overleaf).
2. The measurements produced by Muse are dependent on the calibration process that occurs at the beginning of each session. During this calibration, the wearer is asked to just let their thoughts flow naturally. If the wearer purposefully attends to the breath during the calibration, then the device will tend to show poorer performance during the meditation. Conversely, if the wearer purposefully adopts a “busy mind” during the calibration, the device will tend to report better performance during the meditation. It is therefore important to ensure that any improvements observed are not due to the calibration process being “gamed”.

Figure B1

Screenshot of a session summary shown in the Muse app, with description of measures



A. Plot of mind wandering score throughout the session. The upper extreme represents a score of 100 and the lower extreme a score of 0.

B. "Muse points" – a score derived by apportioning 3 points per second in the "Calm" band and 1 point per second in the "Neutral" band. Not analysed in the accompanying paper, as the raw mind wandering score was expected to contain more information.

C. Count of recoveries within the session, as used within the accompanying paper.

D. Count of "birds", which are heard when mind wandering is low for extended periods. Not analysed in the accompanying paper, due to its extremely high correlation with mind wandering score.

APPENDIX C: STUDY 4 SUPPLEMENTARY MATERIAL

Table C1

Written feedback items

Day	Item
2	Why did you decide to try meditation in this trial?
2	What are your initial impressions of meditation as practiced with the Muse app and headband?
5	During today's meditation session, how did you feel when you heard the sounds indicating that your mind was wandering?
5	Do you think these sounds helped or hindered your meditation practice? Why?
8	What aspects of using the Muse app and headband (if any) are you finding most helpful to your meditation practice?
8	What aspects of the Muse app and headband (if any) are you finding distracting or stopping you from meditating effectively?
14	Have your feelings about meditation changed throughout this trial? If so, how have they changed, and why do you think this is?
14	If you were going to meditate again in future, would you prefer to do so using the Muse app and headband, or without this assistance? Why?

Table C2

Correlations between key study variables

Variable	n^a	*M*	*SD*	1	2	3	4	5	6	7	8	9	10	11	12
No feedback condition															
1. Mean Muse mind wandering	35	44.52	18.51												
2. Muse recoveries	35	21.46	18.46	.65**											
3. BCT proportion correct	35	0.49	0.32	-.50**	-.48**										
4. BCT proportion reset	35	0.30	0.29	.47**	.30	-.81**									
Auditory feedback condition															
5. Mean Muse mind wandering	35	41.58	16.31	.90**	.62**	-.34*	.28								
6. Muse recoveries	35	19.60	17.92	.66**	.86**	-.44**	.27	.74**							
7. BCT proportion correct	35	0.52	0.27	-.28	-.35*	.61**	-.37*	-.27	-.37*						
8. BCT proportion reset	35	0.22	0.19	.31	.20	-.59**	.62**	.30	.23	-.63**					
Other lab responses															
9. Easier condition	35	4.89	1.98	.06	.12	.17	-.09	.14	.15	.01	.03				
10. Control over feedback (lab)	35	2.97	1.48	-.08	-.24	-.05	.12	-.12	-.22	.33*	-.11	-.46**			
Home practice															
11. Control over feedback (home)	29	4.38	1.61	.28	.07	-.09	-.06	.28	.06	.08	.14	-.24	.06		
12. Mean Muse mind wandering	29	39.02	7.36	.23	.41	-.43	.42	.53*	.53	-.18	.21	.15	-.01	-.26	
13. Muse recoveries	29	17.53	9.11	-.06	.22	-.49	.60*	.23	.32	-.30	.46	.23	.02	-.24	.77**

Note: BCT = Breath Counting Task. [a]The intersection of lab (n = 35) and home (n = 29) data was n = 14 cases.

Table C3

Hierarchical linear model of trajectory of mean Muse mind wandering between no feedback and auditory feedback conditions

	Coefficient	Std. Error	*p*
Fixed effects (*B*)			
Intercept	51.97	4.05	< .001
Period: First	3.26	0.62	< .001
(1199 parameter estimates follow – as per Figure 5)			
Random effects (*SD*)			
Participant	16.55		
Residual	16.87		
AR(1) correlation (ϕ)	0.85		

Note: n = 42 000.

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