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Subjective-Objective Discrepancies Among Patients with Sleep Complaints in the Patient-Centered Medical Home

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SUBJECTIVE-OBJECTIVE DISCREPANCIES AMONG PATIENTS WITH SLEEP COMPLAINTS IN THE PATIENT-CENTERED MEDICAL HOME

by

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ABSTRACT

Sleep misperception – the discrepancy between objective and subjective measures of sleep – has been shown to be prevalent among patients with insomnia and may be a promising target for sleep intervention. This study examined sleep misperception in a diverse outpatient medical sample using consumer-grade wearable actigraphs (i.e., Fitbit Charge HR™). Forty-four self-identified problem sleepers aged 20 to 79 participated in the study. Participants completed sleep diaries for one week while also tracking their sleep using the Fitbit Charge HR™. After receiving a personalized sleep report based on these data, participants repeated another week of sleep assessment. Sleep misperception was observed for both total sleep time and sleep onset latency during the first week, such that participants underestimated their total amount of sleep per night and overestimated the amount of time it took them to fall asleep. Pre-post changes in self-reported sleep, mood, and health were examined as a secondary aim in this study. Objectively measured sleep remained relatively unchanged from baseline to follow-up. Despite this lack of change in actual sleep, participants perceived themselves to be sleeping more hours per night, falling asleep more quickly, and sleeping better overall at one-week follow-up. Statistically significant improvements in depression, anxiety, mental health functioning, and insomnia symptom severity were also observed at follow-up. Overall, findings showed that sleep misperception is prevalent among problem sleepers and that sleep discrepancy can be reduced through the use of corrective sleep feedback.

To my mentor, Dr. Cerissa Blaney, who pushed me when I was stuck, believed in me when my confidence waivered, and supported me when I was not sure that I could make it through. You are an inspiration as a psychologist, a mother, and a woman. Though words will never fully convey my gratitude, I dedicate this dissertation to you in thanks and appreciation.

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INTRODUCTION

Sleep problems are ubiquitous in the modern world and present a significant public health concern (Matricciani et al., 2017; Pallesen et al., 2014). Self-reported sleep problems are associated with higher stress levels, lower life satisfaction, and worse health outcomes (NSF, 2014). More than one-third of U.S. adults sleep less than the 7 hour per night minimum recommended by the National Sleep Foundation (CDC, 2011), consequences of which are well-documented (Itani et al., 2017). Acute sleep insufficiency has been linked to inflammation (Irwin, Olmstead, & Carroll, 2016), decreased insulin sensitivity (Czeisler, 2015; van Cauter et al., 2007), and immunosuppression (Cohen et al., 2009; Prather et al., 2015), whereas, chronic insufficient sleep has been associated with increased risk for cardiovascular disease (Bhaskar, Hemavathy, & Prasad, 2016; Taylor et al., 2007), coronary heart disease (Itani et al., 2017), hypertension (Bathgate et al., 2016), diabetes mellitus (Shan et al., 2015), and obesity (Itani et al., 2017).

Also associated with short duration sleep are impairments in executive functioning (Kuula et al., 2017), memory consolidation (Gildner et al., 2014; Prince & Abel, 2013), and attention (Ahmad & Bashir, 2017; Perez-Lloret et al., 2013). Sleep insufficiency is also associated with increased risk for mild cognitive impairment (MCI), dementia (Chen et al., 2016), and cognitive decline in older adults (Lo et al., 2014). Much research has been done on the impact of sleep disturbance and insufficiency on mood and affective functioning, finding it to contribute to depression and anxiety as well as more global emotion dysregulation (Coulombe et al., 2011; Pasch et al., 2010; Watling et al., 2017).

Taken together, it is clear that sleep impairment has a significant negative impact on health and wellbeing. It is important to note that this relationship is bi-directional, such that those with poor health (medical and psychosocial functioning) are also more likely to develop sleep problems (Mai & Buysse, 2008). Given this reciprocity between sleep and health, it is no surprise that sleep complaints are prevalent in medical settings. Sleep problems are often first identified by primary care providers (Edinger & Sampson, 2003; Qaseem et al., 2016; van der Zweerde et al., 2016). An estimated 20-50% of primary care patients meet full diagnostic criteria for insomnia (Bjorvatn, Meland, Flo, & Mildestvedt, 2017; Trauer, Qian, Doyle, Rajaratnam, & Cunningham, 2015; Troxel & Buysse, 2013) and as many as 55% of those without clinical insomnia report subthreshold sleep problems (Bjorvatn, Meland, Flo, & Mildestvedt, 2017). Overall, findings suggest that a large majority of adults experience some degree of sleep difficulty or impairment, with as few as 10% reporting no sleep problems (Bjorvatn, Meland, Flo, & Mildestvedt, 2017). Further, the rate of sleep problems has increased significantly over the past two decades and continues to rise, according to epidemiological studies (Calem et al., 2012; Pallesen et al., 2014).

With mounting evidence for its' pervasive impact on health, sleep has garnered both empirical and clinical attention in recent years. In fact, the importance of sleep is so widely recognized that the National Sleep Foundation (NSF) recommends including it as a vital sign in routine medical care (Grandner & Malhotra, 2015; Ojile, 2017). To date, researchers have extensively explored sleep disorders and related problems, including development and maintenance factors (e.g., biological, psychological, social, behavioral), assessment and measurement (e.g., polysomnography, actigraphy), current intervention and treatment (e.g., pharmacological, cognitive and behavioral), and other potential treatment targets (i.e., sleep

misperception). The following literature review will describe the research within each of the listed domains broadly then will explore areas relevant to the present study in greater depth. Specifically, the concept of sleep misperception will be introduced and discussed in relation to sleep impairment and health. The present study, which examined sleep misperception as a clinical symptom and as an intervention target among medical patients, will then be presented and results discussed.

LITERATURE REVIEW

Diagnosis

Insomnia is the most common sleep disorder, with prevalence estimates ranging broadly from 10% to more than 50% worldwide (Bjorvatn et al., 2017; Ohayon & Reynolds, 2009; Pallesen et al., 2014; Terzano et al., 2004). This observed discrepancy in prevalence rates is largely believed to be the result of variability in diagnostic criteria across the three major classification systems used to diagnose insomnia: International Classification of Sleep Disorders – Third Edition (ICSD-3; AASM, 2014), International Statistical Classification of Diseases and Related Health Problems – Tenth Revision (ICD-10; World Health Organization, 1992), and Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition (DSM-5; APA, 2013). See Table 1.

In order to diagnose insomnia, all three diagnostic manuals require: (1) self-reported sleep disturbance or difficulty, (2) which causes some form of functional impairment or distress, (3) despite adequate opportunity and circumstances for sleep. Despite these commonalities, the minimum frequency and duration of symptoms required for an insomnia diagnosis varies across each of the classification systems. This is problematic in terms of estimating prevalence rates and interpreting research in the sleep field, as these findings are based on disparate diagnostic criteria. Moreover, recent updates to these manuals and their respective classification systems further compound this diagnostic problem. These diagnostic inconsistencies have sparked debate amongst sleep researchers, many of whom argue that insomnia may be better understood as dimensional rather than categorical (Ohayon & Reynolds, 2009). Much of the research included in this literature review has relied on a clinical diagnosis of insomnia as categorized by one of

the aforementioned diagnostic manuals; therefore, the term "insomnia" will be used inclusively for all three classification systems for simplicity.

Table 1. Insomnia diagnostic criteria

	ICSD-3 (AASM, 2014)	DSM-5 (APA, 2013)	ICD-10 (WHO, 1992)
Sleep disturbance/ complaint	Difficulty initiating sleep, maintaining sleep (frequent awakenings or difficulty returning to sleep after awakenings), waking up earlier than desired with an inability to return to sleep		Difficulty initiating or maintaining sleep, or nonrestorative sleep
Consequence(s)	One or more of the following related to the nighttime sleep difficulty: 1. Fatigue/malaise 2. Attention, concentration, or memory impairment 3. Impaired social, family, occupational, or academic performance 4. Mood disturbance, irritability 5. Daytime sleepiness 6. Behavioral problems (e.g., hyperactivity, impulsivity, aggression) 7. Reduced motivation, energy, initiative 8. Proneness for errors, accidents 9. Concerns about or dissatisfaction with sleep	Clinically significant distress or impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning	
Frequency	Sleep disturbance occurs at least 3 times per week		No minimum
Duration	≥ 3 months (Chronic) < 3 months (Short-Term)	At least 3 months	At least 1 month
Opportunity	Sleep disturbance must occur in the presence of adequate opportunity and circumstances for sleep		
Differential diagnosis	Sleep difficulties are not better explained by another sleep disorder, psychological disorder, or medical condition and are not attributed to the physiologic effects of a substance		

Development and Course

Spielman's 3P Model of Insomnia (Table 2) is one of the most widely recognized models for the development and maintenance of insomnia, offering an integrated explanation and framework for insomnia and its' multiple determinants (Spielman, 1986; Williams, Roth, Vatthauer, & McCrae, 2013). Briefly, this model asserts that individuals who develop insomnia possess predisposing factor(s) that make them susceptible to the disorder (i.e., biological or psychological characteristics that increase one's vulnerability for developing sleep problems). When exposed to a precipitating event, such as an illness or life stressor, these individuals are at

increased risk for developing acute insomnia symptoms. For some, these symptoms will be time-limited and will remit when the stressor is removed, whereas others will develop maladaptive responses such as problematic behaviors, thoughts, or beliefs about sleep which will serve as the perpetuating mechanisms that maintain the sleep disturbance and lead to chronic or more severe sleep problems.

Table 2. Spielman's 3P Model of Insomnia

	Definition	**Examples**
Predisposing factors	Biological and psychological factors that increase risk of developing a sleep disorder	Age (>60), anxiety, hyperactive arousal system
Precipitating events	Situational, medical, psychosocial, and environmental triggers for sleep problems	Deadlines, illness, travel, stressful life events
Perpetuating mechanisms	Behaviors and thoughts or beliefs that exacerbate or perpetuate sleep problems	alcohol use, naps, extending time in bed, worry about ability to sleep, fear of sleeplessness

Spielman's model aptly illustrates the negative cascade of events that leads to the development of more complex and severe sleep problems. Notably, these factors are largely modifiable. As such, early identification of patients with sleep problems offers a golden opportunity for prevention and may allow for early intervention to minimize the negative impact of acute sleep disturbance and prevent the development of chronic sleep problems.

Sleep Measurement

Polysomnography (PSG) is the current gold standard measure in sleep assessment (Kapur et al., 2017). Broadly, PSG provides a measure of sleep architecture, including sleep continuity, neural activity, and time spent in each stage of sleep (Kapur et al., 2017; Togeiro & Smith, 2005). It is typically conducted in a sleep laboratory for a period of one night. PSG is used

primarily to diagnose breathing-related sleep conditions, such as Obstructive Sleep Apnea (OSA; Kapur et al., 2017; Ong, Arnedt, & Gehrman, 2017). Though PSG is the gold standard, it is costly and impractical as a tool for assessing insomnia in routine clinical settings. A major limitation of traditional PSG is that patients are required to complete an overnight sleep study in a laboratory setting. Not only is this often aversive to patients but sleep patterns are also likely to be influenced by the lab environment itself and may not be representative of a patient's typical sleep patterns at home (Nissen et al., 2015).

One alternative to the traditional lab-based sleep study is ambulatory (or portable) PSG. A major benefit of ambulatory PSG is that it can be completed independently in the home, thereby reducing patient burden and the risk of environmental influence on sleep recordings (Kapur et al., 2017). Patients are provided a portable monitor which records blood oxygenation levels, airflow, and respiratory effort, at minimum. Sleep is recorded for one or more nights and data is extracted by a sleep technician or specialist for interpretation. The Portable Monitoring Task Force of the American Academy of Sleep Medicine recommends that it be used when moderate to severe OSA is suspected and no other sleep disorders are present or suspected (Collop et al., 2007). Though ambulatory PSG addresses some of the limitations of traditional PSG, it is not a viable option for insomnia assessment in routine clinical practice.

Actigraphy is a more economical and accessible option that can be more readily integrated into clinical practice to objectively evaluate sleep problems. Actigraphy uses accelerometer technology to measure bodily movement. Specifically, triaxial accelerometry measures movement on three planes which is interpreted as a proxy for sleep disturbance. Actigraphs may be worn on the wrist or ankle and are typically the approximate size of a wristwatch. Research- and medical-grade actigraphy has been found to have good agreement

(90%) with PSG and high sensitivity (90- 95%; Sadeh, 2011; Rupp & Balkin, 2011) for detecting a sleep state, though specificity is lower (50-65%) for detecting awakenings (Rupp & Balkin, 2011). Though it is not a replacement for PSG, actigraphy can be used to characterize sleep and circadian patterns and to evaluate response to treatment (Buysse et al., 2010; Kay et al., 2015). In fact, actigraphy (research/medical grade) is now listed in the Federal Register as an approved method of assessment for patients with insomnia symptoms (minimum of 72 hours to 14 consecutive days of recording). It is recommended that patients complete a sleep log in conjunction with actigraphy to provide a more comprehensive clinical picture (sleep diary entry examples: lights off, lights on, out of bed, actigraph off for shower, estimated TST, sleep latency) (Federal Register).

Commercially available actigraphs have also increased in popularity over the past several years and produce enormous amounts of patient-generated health data (PGHD). Despite their widespread use, these devices and their resultant PGHD are not widely used in clinical practice. Though many healthcare providers are eager to incorporate this data into assessment and treatment planning, no guidelines currently exist. Research is burgeoning in this area but is largely still in its' infancy. Recent research has examined the concordance of sleep data derived from various consumer activity monitors compared to research- and medical-grade actigraphs and PSG (de Zambotti, Baker, & Colrain, 2015; de Zambotti et al., 2016; Mantua, Gravel, & Spencer, 2016).

One validation study compared a commercially available actigraph (Jawbone UP™) to PSG in a sample of 65 healthy individuals between the ages of 12 and 22 (de Zambotti, Baker, & Colrain, 2015). This study found good agreement between measures for total sleep time (85% within range) and wake after sleep onset (89% within range), based on a priori determined limits,

but found the Jawbone UP™ to overestimate sleep efficiency and underestimate wake after sleep onset (de Zambotti, Baker, & Colrain). Similar results were found for four other commercially available actigraphs (Basis Health Tracker, Misfit Shine, Fitbit Flex, Withings Pulse O2) when compared to the Actiwatch Spectrum research-grade actigraph and PSG among a sample of 40 healthy young adults (Mantua, Gravel, & Spencer, 2016). This study found strong correlations between PSG and all actigraph devices for TST ($r=0.84$-0.97, $p<0.05$), with the Fitbit Flex ($r=0.97$) being most strongly correlated with PSG (Mantua, Gravel, & Spencer, 2016). In a validation study of the Fitbit Charge HR™ researchers employed a third-party research platform (Fitabase™) for data collection, which allowed them to examine sleep data in 60-second epochs, similar to research-grade actigraph output (de Zambotti et al., 2016). The Fitbit Charge HR™ was found to have high overall agreement with PSG (91% within range) and high sensitivity (97%) for detecting sleep. Similar to validation studies with research-grade actigraphs, specificity for detecting wake (42%) was found to be low for the Fitbit Charge HR™ (de Zambotti et al., 2016).

Findings to date indicate that many commercially available actigraphs have good agreement with PSG for TST and have similar sensitivity and specificity to research- and medical-grade actigraph devices (Baron et al., 2018). Taken together, these findings suggest that commercial actigraphs may be a promising tool in sleep assessment and warrant further exploration, both for evaluative and intervention purposes.

Treatment

Cognitive Behavioral Therapy for Insomnia (CBT-I) is the current gold-standard treatment recommended by the American Academy of Sleep Medicine (AASM) for patients with

insomnia and related sleep problems (Morgenthaler, Kramer, Alessi, Boehlecke, & Brown, 2006; Qaseem et al., 2016). CBT-I is a multicomponent treatment that addresses the perpetuating mechanisms implicated in the development and maintenance of insomnia (Williams et al., 2013). Specifically, CBT-I targets the behaviors, cognitions, and beliefs that negatively impact sleep (Perlis, Jungquist, Smith, & Posner, 2006; Riemann & Perlis, 2009). CBT-I treatment components are detailed in Table 3.

Table 3. CBT-I Treatment Components

	Description
Stimulus Control	Behavioral intervention to strengthen association between bed and sleep and undermine conditioned response of wakefulness in bed
Sleep Hygiene	Guidelines for developing healthy habits to promote sleep, such as eliminating caffeine later in the day, reducing alcohol consumption, developing a relaxing bedtime routine, and creating a positive sleep environment
Sleep Restriction	Behavioral intervention aimed at increasing sleep drive and improving sleep efficiency (SE) by reducing time in bed to match the patient's current perceived TST and adjusting over time to achieve >85% SE
Relaxation Training	Techniques to promote relaxation, reduce cognitive arousal, and ease muscle tension to facilitate sleep
Cognitive Restructuring	Cognitive intervention aimed at identifying, challenging, and replacing dysfunctional beliefs and attitudes about sleep, such as unrealistic sleep expectations, overestimated consequences of disturbed sleep, and fear of sleep loss

Despite substantial evidence (see meta-analysis by Trauer et al., 2015) and guidelines recommending CBT-I (e.g., AASM, American College of Physicians, Agency for Healthcare Research and Quality), it is rarely implemented outside of specialty sleep medicine practices (Edinger & Sampson, 2003; Espie MacMahon, Kelly, Broomfield, Douglas, Engleman et al., 2007). Often, CBT-I is unavailable due to geographic restrictions limiting access to trained providers. Many patients are also ambivalent about seeking specialty sleep medicine services which may be burdensome to them due to the time commitment (CBT-I requires ~4-8 sessions), insurance co-payments, out of pocket fees, and lost wages. Despite empirical support and

endorsement for the widespread use of CBT-I, limitations in healthcare workforce training restrict access to treatment and for those who do have access to behavioral sleep medicine specialists trained in CBT-I, treatment duration and cost can be barriers.

Given these limitations, it is not surprising that pharmacological intervention is the most common first-line treatment used in clinical practice. Prescription sleep aids are widely used in primary care (van der Zweerde et al., 2016; Edinger & Sampson, 2003), with benzodiazepines (e.g., flurazepam, temazepam) and non-benzodiazepine receptor agonists (e.g., zolpidem, eszopiclone, zaleplon) being prescribed most frequently (Hoebert, Souverein, Mantel-Teeuwisse, Leufkens, & van Dijk, 2012). Approximately 60% of primary care patients with insomnia symptoms are prescribed benzodiazepine-related medication (van der Zweerde et al., 2016).

Consequences of these medications are notable, including unwanted side effects (e.g., headaches, dizziness, daytime fatigue), rebound insomnia, and high potential for abuse and dependence (Qaseem, Kansagara, Forciea, Cooke, & Denberg, 2016; Pigeon, Bishop, & Marcus, 2014). Though pharmacological treatment can be effective for short-term sleep management, it is not supported for long-term treatment (Qaseem et al., 2016). Similarly, over-the-counter (OTC) sleep aids (e.g., diphenhydramine) provide short-term relief due to their sedating effects (Pigeon, Bishop, & Marcus, 2014). However, patients tend to habituate rapidly and may develop a tolerance within as few as 4 days (Pigeon, Bishop, & Marcus, 2014); therefore, OTC sleep aids are not indicated for long-term management of sleep problems either. Moreover, prescription and OTC sleep aids are often contraindicated for patients with multiple morbidities, cardiac or respiratory illness, cognitive impairment, and for older adults (Williams et al., 2013). Given the current limitations of both medication sleep aids and non-pharmacological treatments,

researchers have continued to explore alternative modalities and mechanisms to target in sleep treatment.

Sleep Misperception

Sleep misperception, also known as sleep discrepancy, has been identified as a potential treatment target. Sleep misperception – discrepancy between subjective reports and objective measures (e.g., polysomnography, actigraphy) of sleep disturbance – is a widely observed phenomenon among problem sleepers and insomniacs (Moon, Song, & Cho, 2015; Harvey & Tang, 2012; Means, Edinger, Glenn, & Fins, 2003). Extreme sleep discrepancy constitutes an insomnia subtype known as *paradoxical insomnia* (AASM, 2014; WHO, 1992). Paradoxical insomnia (also known as *sleep state misperception* or *subjective insomnia*), involves a subjective complaint of insomnia symptoms without objective evidence of short duration sleep (AASM, 2014). Specifically, paradoxical insomnia requires total sleep time greater than 6.5 hours as measured by polysomnography (PSG), 85% sleep efficiency (ratio of total sleep time to time in bed), and less impairment in daytime functioning than would be expected given the severity of subjective sleep complaints (Research Diagnostic Criteria; Edinger et al., 2004). Patients with paradoxical insomnia often misperceive sleep duration and sleep onset latency, significantly underestimating the total amount of time they are asleep and overestimating the amount of time it takes them to fall asleep (Vanable, Aikens, Tadimeti, Caruana-Montaldo, & Mendelson, 2000; Tang & Harvey, 2004, 2006; Van den Berg et al., 2008). Despite self-reports of severe sleep deficits, these individuals do not exhibit daytime sleepiness that would be expected to accompany sleep insufficiency (Rezaie, Fobian, McCall, & Khazaie, 2018). In contrast to paradoxical insomnia, *psychophysiologic insomnia* (also known as *objective insomnia*) is a

subtype diagnosed in patients who have objective evidence of insufficient sleep (<6.5 hours) congruent with self-reported sleep deficits (AASM, 2014).

Sleep Misperception: Patient Characteristics

A key distinction between these two subtypes is the degree of patient accuracy in self-reported sleep compared to objective measures of sleep. Those with psychophysiologic insomnia have more accurate perceptions about their sleep, whereas those with paradoxical type exhibit greater sleep discrepancy, overestimating the degree of sleep impairment. Moreover, individuals who accurately perceive true sleep deficits (psychophysiologic type) are more likely to have personality profiles consistent with those seen in medical patient populations and have comorbid medical problems (Fernandez-Mendoza, Calhoun, Bixler, Karataraki, Liao, Vela-Bueno, Ramos-Platon, et al., 2011; Vgontzas et al., 2013).

In contrast, those who overestimate their sleep impairment (paradoxical type) are more likely than accurate perceivers to exhibit elevations in the domains of depression and anxiety (Fernandez-Mendoza et al., 2011). Similarly, patients with both insomnia and depression have been found to be more likely to exhibit greater sleep discrepancy (Bliwise, Friedman, & Yesavage, 1993; Edinger & Fins, 1995). It has been suggested that this observed relationship may be the result of increased psychological distress associated with the perception that one is not receiving adequate sleep (Harvey & Tang, 2012). Research has found a direct relationship between anxiety and sleep misperception, such that individuals with higher levels of worry have been observed to exhibit greater sleep discrepancy (Harvey, 2005).

Identifying the extent to which patients who report sleep difficulties also have sleep misperceptions and associated clinical characteristics may be important to inform clinical

decision-making. Vgontzas and colleagues (2013) suggest that patients who accurately perceive true sleep deficiencies may respond better to biological interventions; therefore, these patients may directly benefit from immediate initiation of pharmacological treatment to address short duration sleep. In contrast, patients overestimate sleep impairment may benefit from interventions that address cognitive, behavioral, or psychological factors before initiating pharmacological treatment (Moon, Song, & Cho, 2015; Vgontzas et al., 2013).

While sleep misperception is prevalent among problem sleepers, this phenomenon is not observed among those with good sleep (Manconi et al., 2010). For those who do evidence sleep misperception, the degree of discrepancy between self-report and objectively measured sleep varies widely and most do not meet criteria for paradoxical insomnia (Edinger & Fins, 1995; Harvey & Tang, 2012). Given the ubiquity of sleep misperception among problem sleepers, its' relative absence among good sleepers, and the variability of discrepancy among misperceivers, it has been suggested that misperception may be better characterized as dimensional, rather than categorical (Fernandez-Mendoza et al., 2012; Vgontzas, Fernandez-Mendoza, Liao, & Bixler, 2013). Within this framework, paradoxical insomnia would represent the extreme end of the misperception continuum (Fernandez-Mendoza et al., 2012; Vgontzas, Fernandez-Mendoza, Liao, & Bixler, 2013).

Even in the presence of sleep misperception, patients may experience insufficient sleep. Thus, sleep discrepancy should not be taken as an indication that no sleep disturbance exists but rather may indicate that an individual perceives her/his sleep to be impaired above and beyond the true sleep deficit. For instance, a patient with sleep complaints may report sleeping three hours per night on average, whereas objective testing may reveal that the patient is sleeping five hours per night. Despite the inaccuracy of the patient's subjective report, he/she is clearly still

experiencing a sleep deficit. In contrast, many sleep under-estimators do achieve sufficient sleep (Harvey & Tang, 2012). This group may be at elevated risk for developing true sleep deficits, due to increased anxiety and worry about sleep, associated distress, and heightened vigilance and arousal that may impair actual sleep (Harvey, 2002; Harvey & Tang, 2012).

Correcting Sleep Misperceptions

Research has explored the possibility of reversing or correcting sleep misperceptions as a means of improving sleep. In one lab-based polysomnographic study, researchers corrected misperceptions among participants with paradoxical insomnia by training them to differentiate sleep from wake during various sleep stages (Downey & Bonnet, 1992). Following the training, participants were better able to discriminate between sleep and wake and reduced sleep onset latency (Downey & Bonnet, 1992). Mercer, Lack, and Bootzin (2005) expanded this line of research using immediate and retrospective feedback during wake periods and following scheduled awakenings during various sleep stages. Both forms of feedback reduced sleep misperception and improved sleep in paradoxical insomniacs (Mercer, Lack, & Bootzin, 2005).

These previous studies were limited by small sample sizes and reliance on expensive equipment (i.e., polysomnography) and specialized technicians. Tang and Harvey (2004) addressed these limitations in their study, which evaluated a behavioral intervention to correct sleep misperceptions using wrist actigraphy. The behavioral intervention consisted of an instruction period in which participants learned to interpret their own actigraphic sleep data (Tang & Harvey, 2004). Three days post-intervention, those who received the behavioral intervention reported more accurate sleep perceptions (total sleep time, sleep onset latency), improved subjective sleep quality (PSQI), and less sleep-related anxiety and preoccupation

compared to control participants (Tang & Harvey, 2004). Tang and Harvey (2006) extended this research to include an additional comparison group who received a verbal feedback-only intervention, without the behavioral or visual components. Similar to the original study, improvements in self-reported sleep, insomnia symptoms, and sleep-related anxiety and distress were observed for both intervention conditions, though larger effects were found in the behavioral intervention group compared to the verbal feedback-only group (Tang & Harvey, 2006). Results of this study were consistent with previous findings that brief corrective feedback can be effective in reducing sleep discrepancy and improving self-reported sleep. Further, these results support corrective feedback as a method for reducing cognitive distortions related to sleep, thereby addressing a characteristic factor known to perpetuate sleep problems (Harvey, 2002).

Quintiliani and colleagues (2017) expanded on Harvey and Tang's work to examine a single-session psychoeducational sleep intervention with medical patients diagnosed with chronic insomnia. In this study, sleep data were collected using wrist actigraphs and sleep diaries for a total of two weeks. After one week of recording, participants in the treatment group received a brief feedback intervention during which trained clinicians reviewed actigraphic and sleep diary results with each individual, emphasizing any sleep discrepancies. Sleep data were collected from the control group after one week as well but no intervention was provided. All participants then completed a second week of recording before returning to the clinic to complete final assessment measures. Consistent with previous studies, improvements in sleep misperception, sleep-related psychological distress, and subjective sleep quality were observed in the treatment group (Quintiliani et al., 2017).

Summary and Study Aims

Preliminary research supports brief corrective feedback interventions to improve sleep perceptions. Findings to date suggest that brief corrective feedback can be effective in decreasing sleep discrepancy, improving self-reported sleep quality and quantity, and reducing sleep-related distress (Downey & Bonnet, 1992; Mercer, Lack, & Bootzin, 2005; Quintiliani et al., 2017; Tang & Harvey, 2004, 2006). Although such interventions show promise, research has been conducted only with samples meeting diagnostic criteria for insomnia. Further research is needed to allow for greater generalizability to populations other than those with diagnosed insomnia. Specifically, research is needed with problem sleepers more broadly, given the commonality of sleep misperception among this group as well as the potential preventive effects of corrective feedback. To date, studies have also used expensive equipment (i.e., PSG, research-grade actigraphs) for objective sleep measurement. Such equipment is not practical for routine clinical use, therefore, research using more economical measures is needed to expand the ecological validity of these findings to clinical practice.

The present study aimed to extend previous work by investigating, in an outpatient medical setting, the prevalence of sleep misperception among a diverse sample of self-identified problem sleepers using a commercially available actigraph (Fitbit Charge HR™). Specific study aims were to:

1) Determine if sleep misperception is present in a sample of self-identified problem sleepers for total sleep time (TST) and sleep onset latency (SOL).
    a. Hypothesis: Discrepancies will be observed between sleep diary and Fitbit-measures for TST and SOL.

2) Determine if psychological and medical factors are associated with sleep misperception (i.e., TST and SOL).
    a. Hypothesis: Patients with worse medical health (SF-36 Mental Health Composite) will have more accurate sleep perceptions (smaller discrepancies).
    b. Hypothesis: Patients with higher anxiety and depression (GAD-7, PHQ-9) will have less accurate sleep perceptions (greater discrepancies).
3) Examine the impact of a single-session feedback intervention in correcting sleep discrepancies.
    a. Hypothesis: Discrepancies between sleep diary and Fitbit-measured sleep (TST, SOL) will be reduced from baseline to follow-up.
    b. Auxiliary hypotheses: Reductions will be observed from baseline to follow-up for self-reported sleep variables (ISI, sleep diary TST and SOL), medical functioning (SF-36 Physical Health Composite), and psychological functioning (SF-36 Mental Health Composite, PHQ-9, GAD-7).

METHODS

Participants and recruitment

The study was conducted at UCF Health outpatient medical practice. Patients were recruited as a part of standard clinical practice and within the workflow of medical providers at UCF Health as well as through printed recruitment flyers placed in the waiting area and exam rooms and on the UCF Health website. It is well established that sleep problems are often comorbid with other medical and mental health conditions and patients rarely present with sleep problems in isolation; therefore, to maximize the clinical relevance and ecological validity of this study, broad inclusion criteria were used. Patients were invited to participate in the study if they were 18 years or older, endorsed subjective sleep problems, and were interested in receiving a non-pharmacological feedback intervention for sleep. Sleep data were collected using the Fitbit Charge HR™, thus, to be eligible patients had to be willing and able to wear the Fitbit on their non-dominant wrist. Patients with severe psychological conditions (e.g., suicidality, psychosis), acute substance use or dependence, and those with diagnosed obstructive sleep apnea who were not compliant with medical treatment (i.e., use of CPAP) were not eligible for the study. As pregnant women face a unique set of risk factors they were not eligible for the study. Children and incarcerated individuals also were not eligible for the study. Participant recruitment began upon IRB approval in September 2016. All participants were asked to attend three visits at UCF Health, as detailed below. Enrollment for this study was continuous.

Study design and procedures

Visit 1 (Baseline): Individual assessments were conducted in the patient consultation rooms at UCF Health. Each participant met individually with the PI to complete consent

procedures and complete a questionnaire battery consisting of the following measures: Insomnia Severity Index, Dysfunctional Beliefs and Attitudes about Sleep Scale-16, Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, Short Form-36, Generalized Anxiety Disorder-7, Patient Health Questionnaire-9, and the Alcohol Use Disorders Identification Test (described below and in Appendices). Information obtained from participant electronic medical records was reviewed with participants for accuracy (specifically: age, weight, medication list, diagnoses and problem list). Participants then completed an individual sleep assessment with the PI lasting approximately 45 minutes and were fitted with the Fitbit Charge HR™, provided with a sleep diary, and instructed in their use. The instruction period lasted about 15 minutes.

Patients were asked to wear the Fitbit and complete a sleep diary for seven days. Participants returned to UCF Health approximately one week after the initial visit to complete the intervention portion of the study.

Visit 2 (Feedback Intervention): Patients returned after recording sleep for one week and patient sleep data (sleep diary and Fitbit) were reviewed for misperceptions. Each patient completed the Short Form-36 questionnaire (measure of global health and quality of life) at the beginning of the feedback session. The intervention consisted of a single session lasting approximately 30 minutes, during which the participant was provided with written and verbal feedback about their sleep (see Appendix for sample). The feedback report was based on data derived from sleep diaries and actigraphic sleep data from the Fitbit Charge HR™, extracted from Fitabase™, a web-based research platform. All participants received the intervention. After receiving the feedback intervention, participants were asked to wear the Fitbit and complete the daily sleep diary for an additional week.

Visit 3 (Follow-Up): Approximately one week after the feedback session, participants returned to UCF Health to meet with a study clinician, at which time they returned their completed sleep diary and Fitbit device. Participants were asked to complete the initial questionnaire battery again, along with a measure of patient satisfaction (see Appendix J). Participation in the study was then complete. Patients were provided contact information for the behavioral health team and were offered the opportunity to initiate services if desired.

Measures

Insomnia Severity Index (ISI; Morin et al., 2003). The ISI is a 7-item self-report inventory designed to assess the severity of common symptoms of insomnia over the past two weeks. Items are presented on a Likert scale and individual items range from 0 (none) to 4 (very severe) and scores are summed to provide a total score ranging from 0 to 28. Scores are categorized based on the following cutoffs: 0-7 = no clinically significant insomnia; 8-14 = subthreshold insomnia; 15-21 = clinical insomnia (moderate severity); 22-28 = clinical insomnia (severe). The ISI has been shown to detect clinically meaningful treatment response (Morin et al., 2011). Cronbach's alpha in the present sample was 0.74 at baseline and 0.70 at follow-up. See Appendix A.

Dysfunctional Beliefs and Attitudes about Sleep Scale – 16 (DBAS-16; Morin, Vallieres, & Ivers, 2007). The DBAS-16 is a 16-item questionnaire used to assess sleep-disrupting cognitions and beliefs. This measure provides an overall score with higher scores indicating higher levels of dysfunctional beliefs about sleep. Scores are calculated as the mean of all item responses and scores greater than four, or any single item response of 6 or more indicates unrealistic expectations or beliefs about sleep or one's ability to cope with poor sleep.

Cronbach's alpha in the present sample was 0.79 at baseline and 0.88 at follow-up. See Appendix B.

Epworth Sleepiness Scale (ESS). The ESS is an 8-item self-report measure used to assess daytime sleepiness. This measure produces a total score ranging from 0 to 24 with validated cutoffs. A total score of 10 or more or a score of 3 on any item indicates clinically significant symptoms in need of further evaluation. Cronbach's alpha in the present sample was 0.83 at baseline and 0.77 at follow-up. See Appendix C.

Short Form-36: Acute (SF-36; Maruish, 1993, 2011). The SF-36 is a 36-item inventory that measures quality of life across eight domains (physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions). This measure is validated and widely used in medical research. Physical Component Summary and Mental Component Summary scores were derived from this measure. Scores falling between 45 and 55 are considered to be in the average range of functioning. Higher scores indicate better functioning. See Appendix D.

Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a 9-item self-report inventory used to assess the severity of common symptoms of depression over the past two weeks. Items are presented on a Likert scale with item responses from 0 = *Not at all* to 3 = *Nearly every day*. Total scores range from 0 to 27 with the following cutoffs: 5-9 = mild; 10-14 = moderate; 15-19 = moderately severe; ≥20 = severe. The PHQ-9 has been validated for use in medical settings. Cronbach's alpha in the present sample was 0.80 at baseline and 0.81 at follow-up. See Appendix E.

Generalized Anxiety Disorder-7 (GAD-7; Kroenke, Spitzer, Williams, Monahan, & Lowe, 2007; Kroenke, Williams, & Lowe, 2006). The GAD-7 is 7-item self-report inventory designed to assess for the presence and severity of common symptoms of anxiety over the past two weeks. Items are presented on a Likert scale with item responses from 0 = *Not at all* to 3 = *Nearly* e*very day*. Total scores range from 0 to 21 with the following cutoffs: 5-9 = mild; 10-14 = moderate; ≥15 = severe. This measure is validated for use in medical settings (Kroenke et al., 2007). Cronbach's alpha in the present sample was 0.86 at baseline and 0.87 at follow-up. See Appendix F.

Alcohol Use Disorders Identification Test (AUDIT; Babor, de la Fuente, Saunders, & Grant, 1992; Saunders, Aasland, Babor, de la Fuente, & Grant, 1993**)**. The AUDIT is a brief screening tool that is commonly used to assess patients' alcohol use. This measure provides a total score with the following cutoffs for alcohol use risk level: 0-7 = low risk; 8-15 = moderate risk of harm; 16-19 = high risk; ≥20 = likely dependence. Cronbach's alpha in the present sample was 0.85 at baseline and 0.88 at follow-up. See Appendix G.

Sleep Outcomes. Sleep outcomes were derived from sleep diaries and a consumer-grade activity monitor (Fitbit Charge HR™). Data collected from the sleep diary and Fitbit were used to calculate subjective and objective sleep outcomes, respectively. Sleep outcomes were calculated as:

Total sleep time (TST): total time (in minutes) between sleep initiation and final awakening minus WASO (wake after sleep onset).

Sleep onset latency (SOL): amount of time (in minutes) between "lights out" and sleep.

Misperception Index (MI): To assess TST misperception, a Misperception Index (MI; Manconi et al., 2010) was calculated using the following formula. This formula has

been suggested as a useful method for quantifying patient accuracy for total sleep time (Buysse et al., 2006).

$$MI = [(TST_{Fitbit} - TST_{Diary})/TST_{Fitbit}]$$

Negative index scores indicate TST overestimation and positive scores indicate underestimation. Plainly stated, patients with positive scores are sleeping more than they think and patients with negative scores are sleeping less than they think. Scores are presented on a scale from -1.0 to +1.0. Though it is feasible that negative scores could be infinite if a patient were to overestimate TST to such a degree. However, such a report is very unlikely and would represent an extreme outlier. Therefore, consistent with previous research (Manconi et al., 2010), overestimation scores are truncated at -1.0 for practicality and ease of interpretation.

Sleep diaries are the most widely used measure of sleep functioning and provide a subjective report of sleep. The Consensus Sleep Diary (CSD-E; Carney et al., 2012) was used in this study (See Appendix H). Patients were provided written instructions for completing the diary according. Questions about sleep-interfering behaviors (e.g., prescription/OTC sleep medication use, caffeine and alcohol consumption) were answered at night, whereas questions about actual sleep (e.g., awakenings, final wake time) and perceived quality of sleep were completed in the morning.

The Fitbit Charge HR™ (Fitbit Inc., San Francisco, CA, USA) was used to monitor sleep as an objective measure of sleep. This Fitbit model has been established in recent research (de Zambotti et al., 2016). Further, the Fitbit offers an attractive alternative to the gold standards of PSG and research-grade actigraphy, due to its' lower cost, availability, and widespread consumer

use. The device uses tri-axial accelerometer technology to measure gross motor activity continuously while worn. Patients were asked to wear the device on their non-dominant wrist. The data were synced to a web-based research platform (Fitabase™), downloaded to a computer, and analyzed using computer generated algorithms.

Statistical analyses

All data were analyzed using IBM SPSS Version 24.0 (IBM Corp., 2016). Skewness and kurtosis values were calculated for all outcome and predictor variables to assess for normality and all fell within the accepted range (George & Mallery, 2010). Paired samples *t*-tests were used to evaluate sleep discrepancies between Fitbit and sleep diary measures. Linear regression analyses were conducted to examine associations between sleep discrepancy variables and mental and physical health predictor variables. Separate analyses were completed for TST and SOL. Paired samples *t*-tests were performed to assess change in sleep and self-report measures from baseline to follow-up (i.e., one-week post-intervention). Cohen's *d* was calculated to evaluate the magnitude of intervention effects for all pre-post *t*-test analyses. The following cutoffs were used to categorize Cohen's *d* effect sizes (ES): $d = 0.20–0.49$ (small); $d = 0.50–0.79$ (medium); $d \geq 0.80$ (large). In keeping with the guidelines set out by the National Register for actigraphic sleep assessment, participants were required to have a minimum of three days of usable sleep data in order to be included in any analysis of that particular sleep outcome. Those with less than three days were excluded from analyses for that sleep variable.

RESULTS

Sample characteristics

Forty-five participants between the ages of 20 and 79 were enrolled in the study. One participant withdrew less than one week after enrolling due to extenuating personal circumstances (i.e., family emergency requiring extended travel out of the country) and was excluded from all analyses. The majority of participants were female (n=27, 60%), identified as heterosexual (n=44, 98%), and were married (n=25, 56%). Though only 22% of participants had been previously diagnosed with insomnia, most met diagnostic criteria for either chronic or acute insomnia (n=43, 95%) at baseline. Seventy-three percent of participants reported at least a moderate level of insomnia symptoms (ISI ≥ 15) at baseline. Thirty-three percent endorsed moderate or severe depression symptoms (PHQ-9 ≥ 10) and 31% endorsed moderate or severe anxiety symptoms (GAD-7 ≥ 10). Demographic and baseline characteristics are provided in Tables 4 and 5.

Table 4. Participant demographics

Variable	**M**	**SD**
Age, years	52.71	17.10
Sex, n (%)		
Female	27 (60%)	-
Male	18 (40%)	-
Race, n (%)		
Caucasian	30 (66.7%)	-
Hispanic	9 (20.0%)	-
African American	5 (11.1%)	-
Other	1 (2.2%)	-
Sexual Orientation, n (%)		
Heterosexual	44 (97.8%)	-
Homosexual	1 (2.2%)	-
Relationship Status, n (%)		
Single, never married	5 (11.1%)	-
In a committed relationship	5 (11.1%)	-
Married	25 (55.6%)	-
Divorced	4 (8.9%)	-
Widowed	6 (13.3%)	-
Employment Status, n (%)		

Variable	M	SD
Employed	22 (48.9%)	-
Unemployed	6 (13.3%)	-
Retired	12 (26.7%)	-
Disabled	3 (6.7%)	-
Student	2 (4.4%)	-
Education, n (%)		
Graduate degree	11 (24.4%)	-
College degree, 4-year	15 (33.3%)	-
College degree, 2-year	7 (15.6%)	-
Some college	8 (17.8%)	-
High school diploma	3 (6.7%)	-
Other	1 (2.2%)	-

Table 5. Participant characteristics at baseline

Variable	M	SD
Sleep related diagnosis, n (%)^		
Insomnia	10 (22.2%)	-
Obstructive Sleep Apnea	4 (8.9%)	-
Restless Leg Syndrome	1 (2.2%)	-
"Sleep difficulties"	4 (8.9%)	-
Meet diagnostic criteria for Insomnia, n (%)	43 (95.6%)	-
Chronic	39 (86.7%)	-
Acute	4 (8.9%)	-
Sleep medication use, n (%)^		
Prescription	15 (33.3%)	-
OTC	4 (8.9%)	-
Melatonin	9 (20.0%)	-
BMI^	29.23	6.77

^per medical record. BMI = Body mass index; OTC = over the counter.

Sleep discrepancy analyses

Mean discrepancies between Fitbit and sleep diary measures are displayed in Table 6. Across outcomes and time points, sleep diary reports overestimated sleep impairment compared to Fitbit measurement. For total sleep time (TST), Fitbit measurements were higher on average by 52.94 minutes at baseline and 24.20 minutes at one-week follow-up, compared to sleep diary estimates. For sleep onset latency (SOL), Fitbit measurements were lower on average by 24.99 minutes at baseline and 14.41 minutes at one-week follow-up. Consistent with hypotheses, sleep misperceptions were observed such that participants underestimated their total amount of sleep per night and overestimated the amount of time it takes them to fall asleep. See Figures 1 and 2.

Table 6. Sleep discrepancies at baseline and one-week follow-up

Sleep Feature	N	Fitbit M (SD)	Sleep diary M (SD)	Mean diff (SE)	*t*
TST, baseline	38	438.34 (66.52)	385.40 (73.74)	52.94 (11.09)	**4.78***
TST, follow-up	37	434.97 (61.35)	410.77 (53.63)	24.20 (5.62)	**4.31***
SOL, baseline	35	11.67 (10.09)	36.66 (30.23)	-24.99 (4.60)	**-5.43^**
SOL, follow-up	35	10.47 (10.21)	24.88 (19.48)	-14.41 (2.71)	**-5.31***

*p<.001; ^p<.01. TST = total sleep time; SOL = sleep onset latency; TST and SOL are reported in minutes.

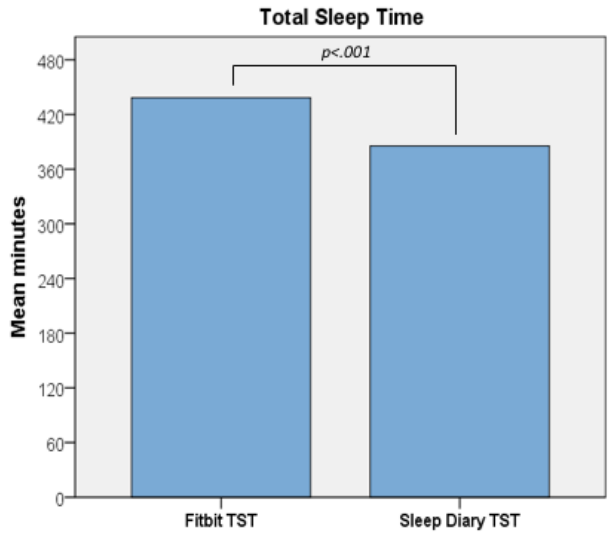


Figure 1. Baseline TST discrepancy

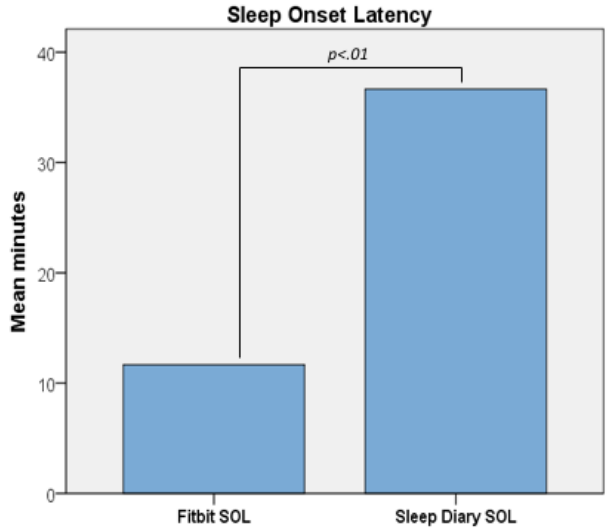


Figure 2. Baseline SOL discrepancy

Regression analyses

Depression scores significantly predicted SOL discrepancy, b = -.37, t(39) = -2.46, p = .018 but not TST discrepancy. Physical health scores were not a significant predictor of sleep discrepancy for SOL or TST. Anxiety scores were not a significant predictor of TST discrepancy or SOL discrepancy. Unstandardized coefficients, standard errors, and *t*-values are displayed in Tables 7 and 8.

Table 7. Unstandardized regression coefficients for predictors of TST Misperception Index

Predictor variable	**N**	**B**	**SE B**	***t***	**p**
Physical health (PCS)	43	.001	.002	.54	.593
Depression (PHQ-9)	43	.001	.005	.27	.789
Anxiety (GAD-7)	43	-.009	.005	-2.01	.051

PCS = Physical Composite Scale of the Short-Form-36; PHQ-9 = Patient Health Questionnaire; GAD-7 = Generalized Anxiety Disorder 7-item scale.

Table 8. Unstandardized regression coefficients for predictors of SOL discrepancy

Predictor variable	**N**	**B**	**SE B**	***t***	**p**
Physical health (PCS)	40	.30	.50	.59	.558
Depression (PHQ-9)	40	**-2.37**	**.96**	**-2.46**	**.018**
Anxiety (GAD-7)	40	-1.26	1.03	-1.22	.228

PCS = Physical Composite Scale of the Short-Form-36; PHQ-9 = Patient Health Questionnaire; GAD-7 = Generalized Anxiety Disorder 7-item scale.

Intervention effects

Paired samples *t*-tests were conducted to evaluate changes pre- to post-treatment. Significant improvements were observed for sleep diary measures of TST and SOL and for TST discrepancy. Self-reported TST increased on average by 19.69 minutes per night from baseline to one-week follow-up. Self-reported SOL decreased from baseline, with participants reporting an average SOL of less than 30 minutes at follow-up. TST discrepancy decreased on average by 31.16 minutes from baseline to follow-up. No significant differences were observed in SOL discrepancy or in Fitbit measures of TST or SOL from baseline to follow-up. Means, standard

deviations, *t*-values, and effect sizes with 95% confidence intervals are displayed in Table 9.

Table 9. Differences in sleep features from baseline to follow-up

Sleep Feature	N	Baseline M (SD)	Follow-up M (SD)	*t*	*d* (95% CI)
Fitbit Charge HR™					
TST, mean	41	441.88 (65.52)	443.34 (66.39)	-.24	0.04 (-0.40, 0.47)
SOL, mean	42	13.66 (19.01)	10.38 (9.92)	1.36	-0.19 (-0.62, 0.24)
Sleep diary					
TST, mean	41	392.39 (78.69)	412.08 (53.14)	**-2.11^**	0.30 (-0.14, 0.73)
SOL, mean	40	39.57 (32.75)	28.32 (26.61)	**4.26***	**-0.65* (-1.10, -0.20)**
Sleep discrepancy					
TST disc, mean	38	52.34 (68.28)	21.18 (32.51)	**3.94***	**-0.65* (-1.11, -0.19)**
TST MI, mean	38	.11 (.15)	.04 (.08)	**4.23***	**-0.64* (-1.10, -0.18)**
SOL disc, mean	37	-24.30 (32.38)	-17.25 (28.38)	-1.91	0.30 (-0.16, 0.76)

*p<.001; ^p<.05. TST = total sleep time; SOL = sleep onset latency; MI = misperception index; disc = discrepancy between Fitbit and sleep diary. TST and SOL are reported in minutes. Follow-up was conducted one-week post-intervention.

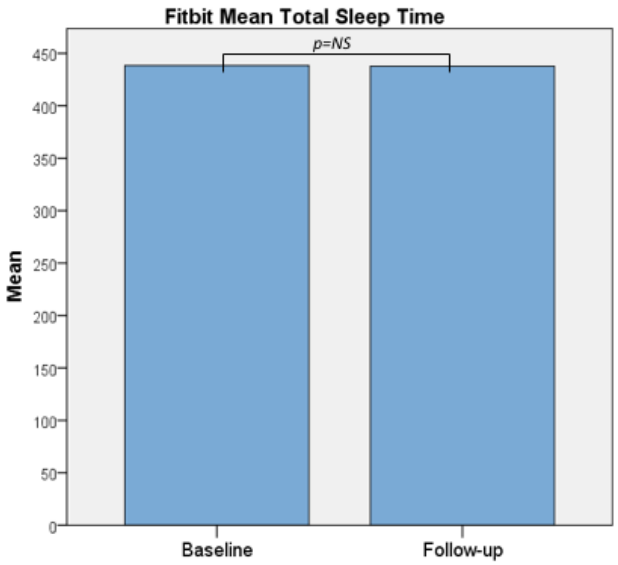


Figure 3. Fitbit Mean TST Pre-Post Intervention

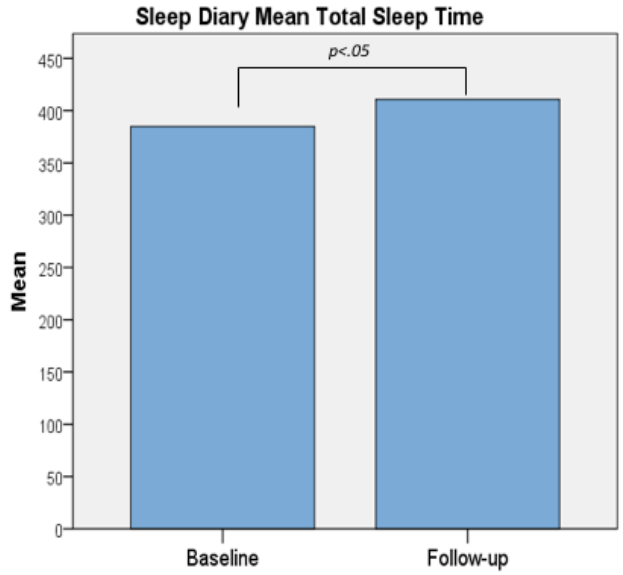


Figure 4. Sleep Diary Mean TST Pre-Post Intervention

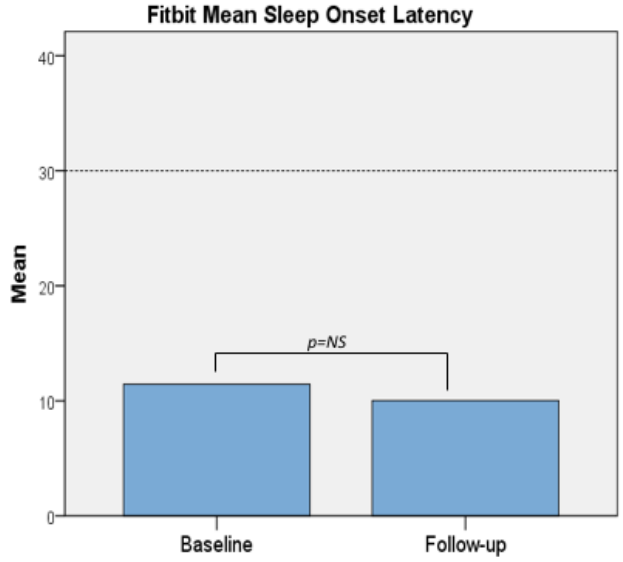


Figure 5. Fitbit Mean SOL Pre-Post Intervention

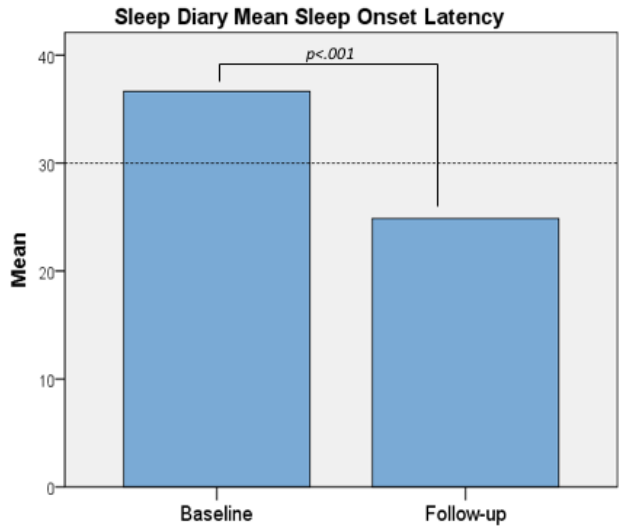


Figure 6. Sleep Diary Mean SOL Pre-Post Intervention

Paired-samples *t*-tests also revealed significant reductions in insomnia (ISI), depression (PHQ-9), and anxiety (GAD-7) symptoms from baseline to one-week follow-up. Insomnia symptom severity decreased from moderately severe to subthreshold insomnia. Depression and anxiety scores remained in the mild range but evidenced statistically significant improvements from baseline to follow-up. Mental health scores (SF-36, MCS) improved significantly, falling within the average range of functioning at follow-up. No significant differences were observed in sleep beliefs (DBAS), daytime sleepiness (ESS), or physical health functioning (SF-36, PCS) from baseline to follow-up. Means, standard deviations, *t*-values, and effect sizes with 95% confidence intervals are displayed in Table 10.

Table 10. Differences in self-report measures from baseline to follow-up

Questionnaire	N	Baseline	Follow-up	*t*	*d* (95% CI)
Insomnia Severity Index	44	17.14 (4.15)	14.00 (4.22)	**6.68***	**-1.02 (-1.46, -0.57)**
Sleep beliefs (DBAS)	43	6.06 (1.56)	5.79 (1.71)	1.58	-0.26 (-0.69, 0.16)
Epworth Sleepiness Scale	44	8.86 (5.11)	8.23 (4.68)	1.43	-0.21 (-0.63, 0.21)
Short Form-36					
Physical health composite (PCS)	43	47.29 (10.29)	46.82 (10.46)	.65	-0.10 (-0.52, 0.32)
Mental health composite (MCS)	43	41.62 (11.30)	47.93 (9.28)	**-6.48***	**0.94 (0.50, 1.39)**
Depression symptoms (PHQ-9)	44	8.59 (4.78)	7.23 (4.87)	**3.17^**	**-0.48 (-0.91, -0.06)**
Anxiety symptoms (GAD-7)	44	7.18 (4.75)	5.61 (4.95)	**2.53^**	-0.39 (-0.81, 0.03)

*p<.001; ^p<.05; *d* = repeated measures using baseline SD. DBAS = Dysfunctional Beliefs and Attitudes about Sleep scale; PHQ-9 = Patient Health Questionnaire; GAD-7 = Generalized Anxiety Disorder 7-item scale.

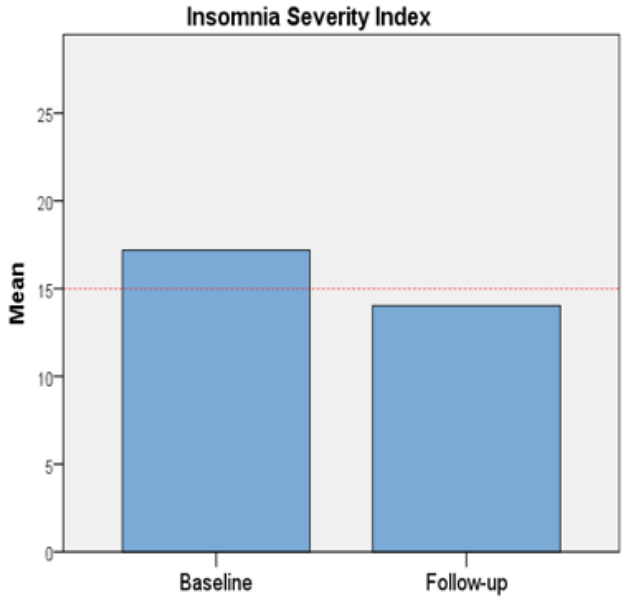


Figure 7. Insomnia Severity Index Pre-Post Intervention

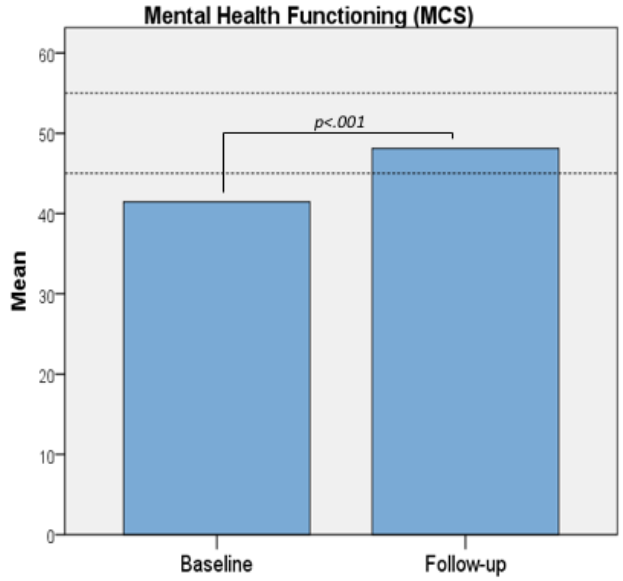


Figure 8. Mental Composite Score (SF-36) Pre-Post Intervention

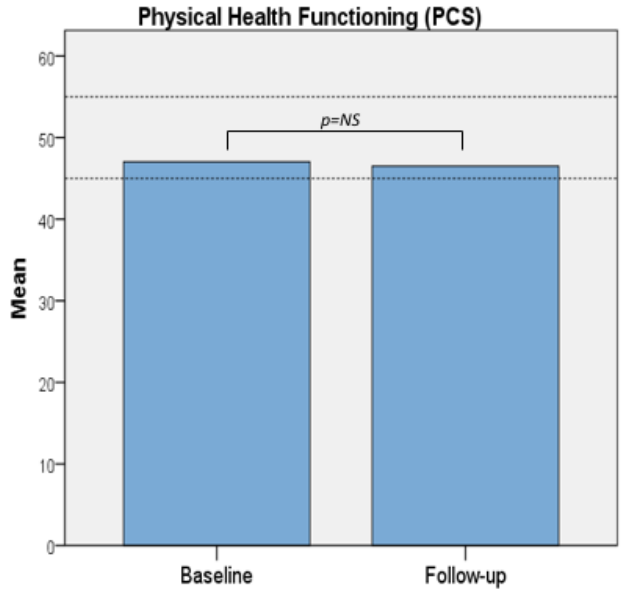


Figure 9. Physical Composite Score (SF-36) Pre-Post Intervention

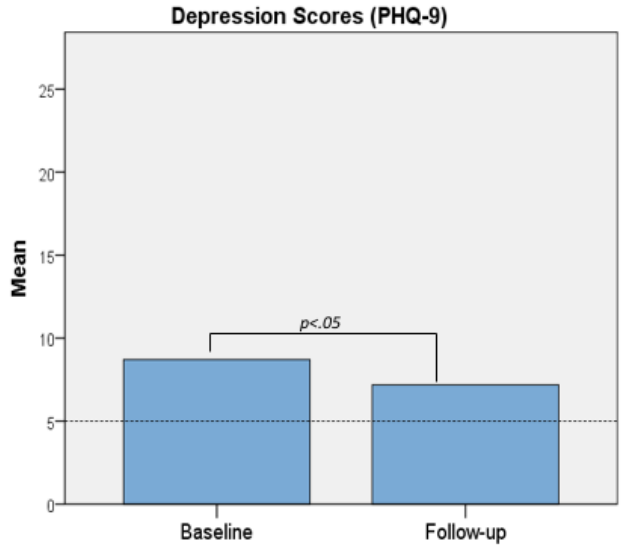


Figure 10. Depression scores (PHQ-9) Pre-Post Intervention

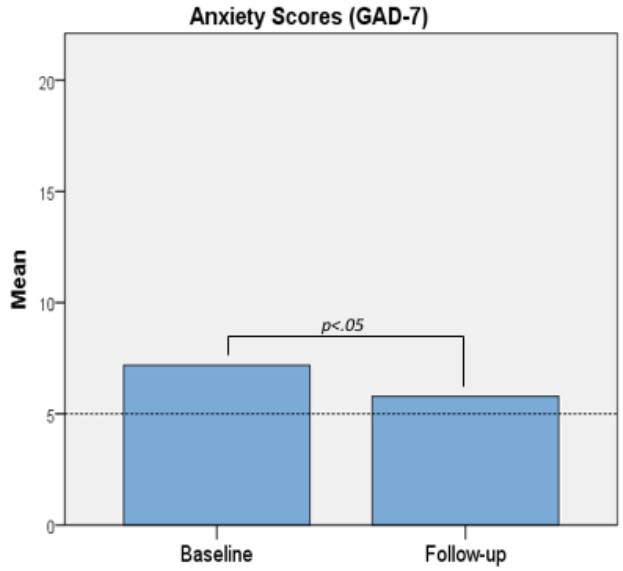


Figure 11. Anxiety scores (GAD-7) Pre-Post Intervention

Patient Perceptions of Intervention

Descriptive statistics were examined for the patient perceptions measure completed at follow-up. Overall, participants reported positive responses and perceptions of the feedback intervention. All participants indicated that the feedback was useful and informative and that

they had a better understanding of their own sleep patterns after receiving the intervention. Eighty percent of participants believed the Fitbit accurately measured their sleep and all participants found the device easy to use. Sixty-five percent reported that they intend to purchase a Fitbit or other sleep monitoring device after completing the study. Lastly, all participants would recommend this study to others and a most (91%) endorsed interest in having consumer technology incorporated into routine clinical care. See Figures 12-19.

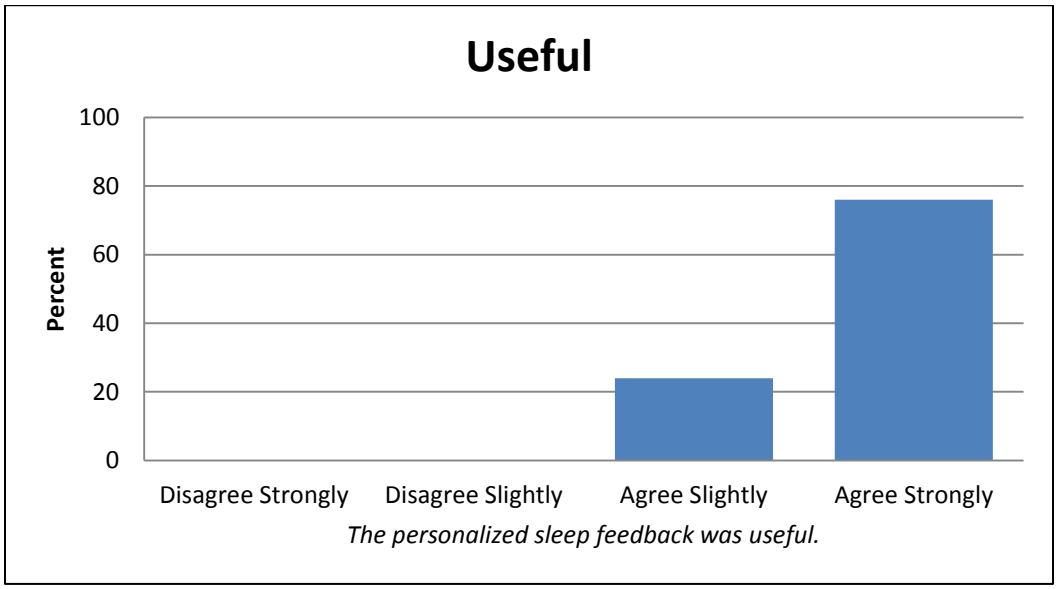


Figure 12. Perception of feedback as useful

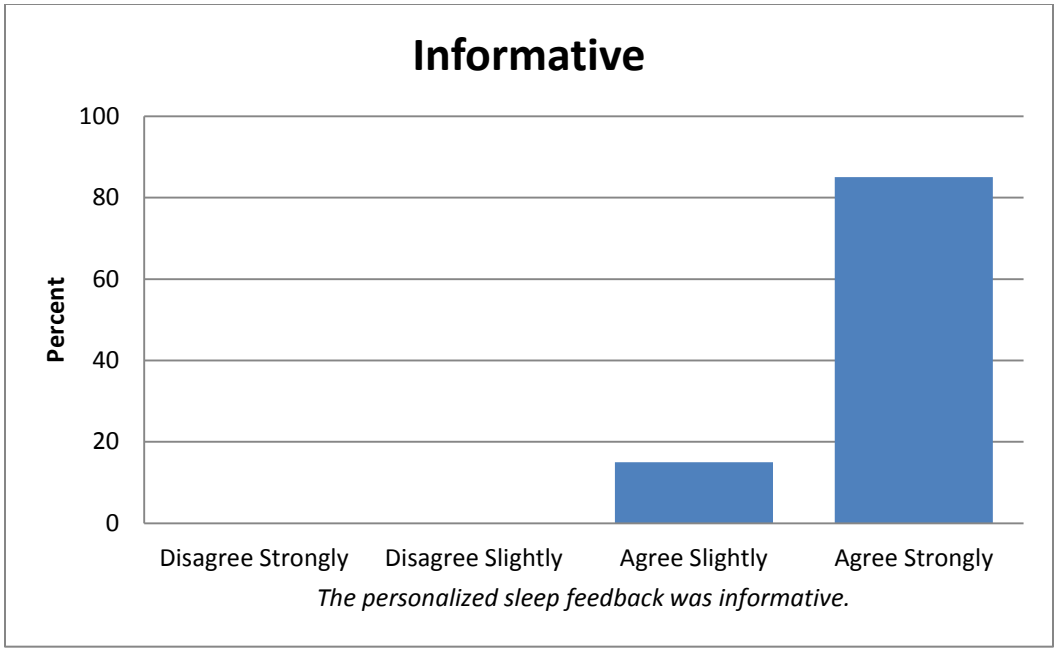


Figure 13. Perception of feedback as informative

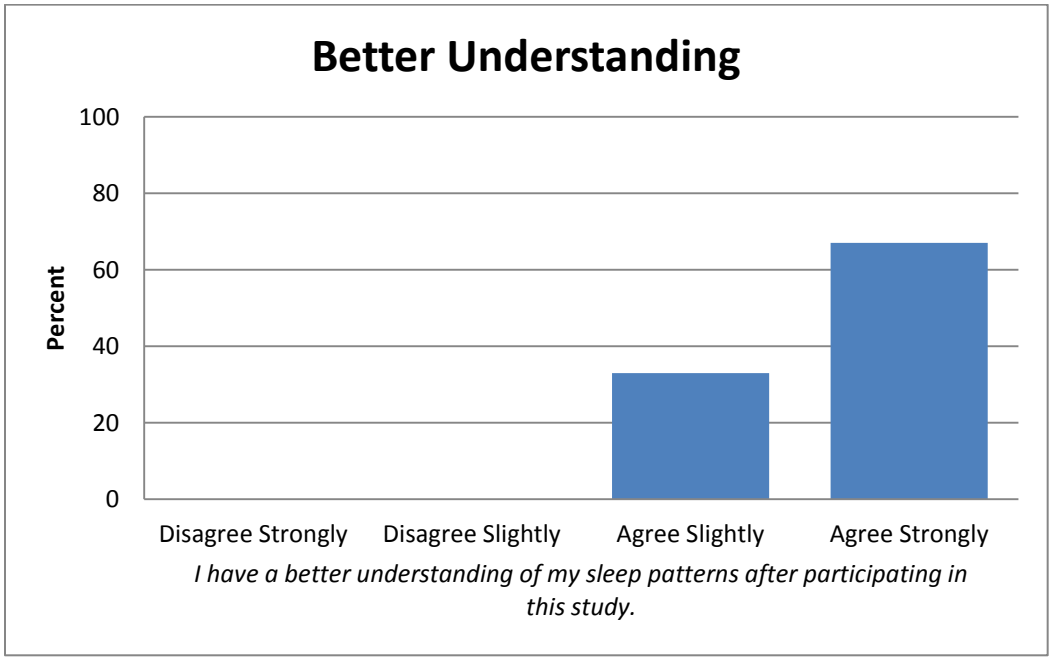


Figure 14. Perception of feedback as helpful in understanding sleep

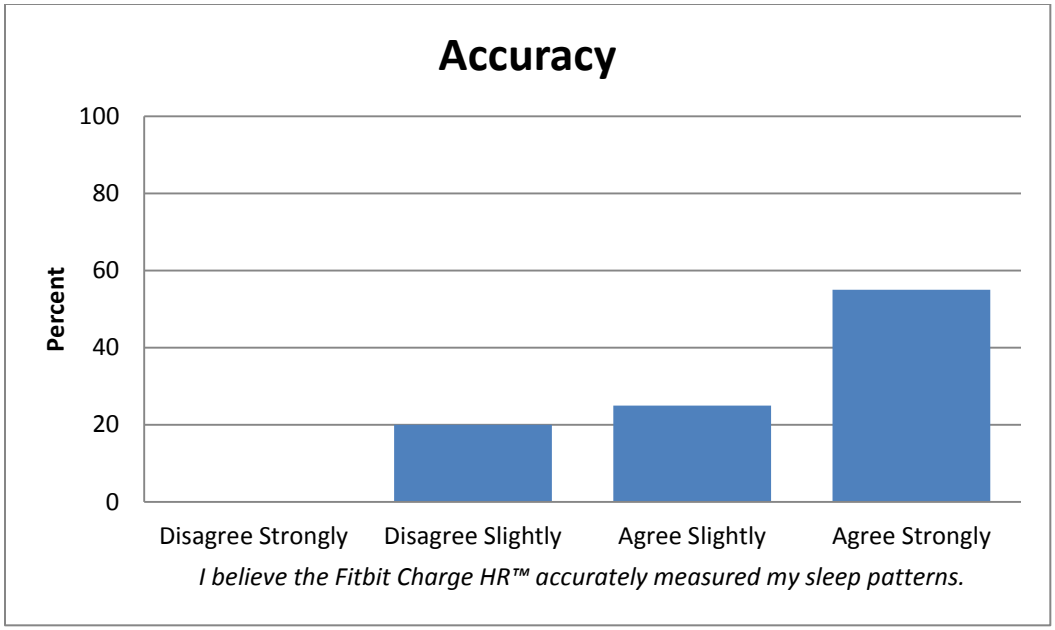


Figure 15. Perception of Fitbit as accurate

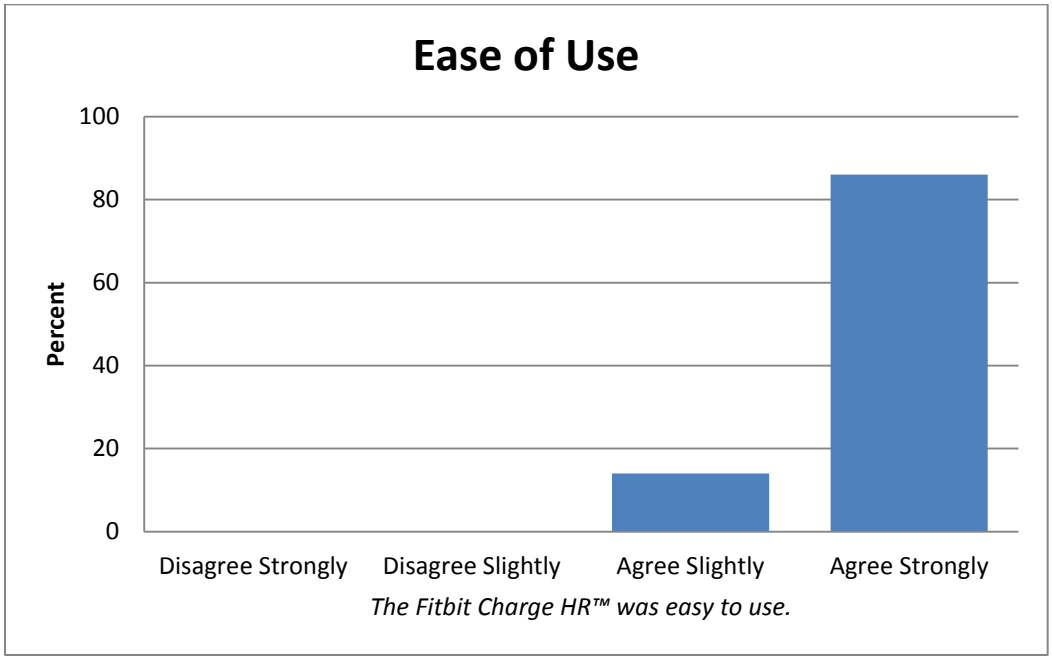


Figure 16. Perception of Fitbit as easy to use

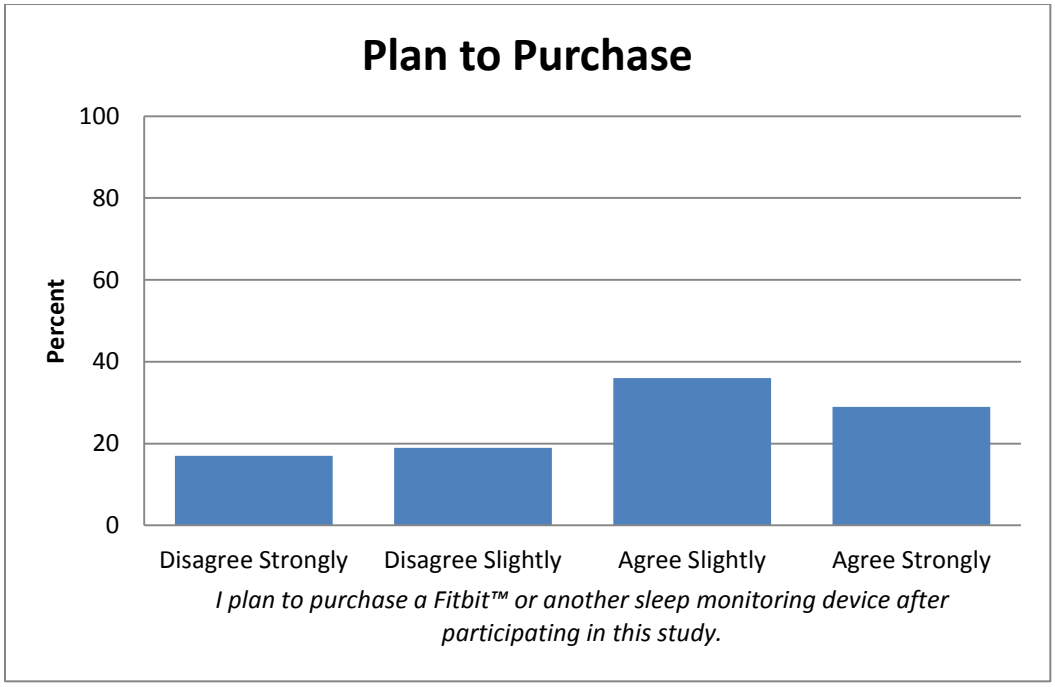


Figure 17. Plan to purchase a Fitbit

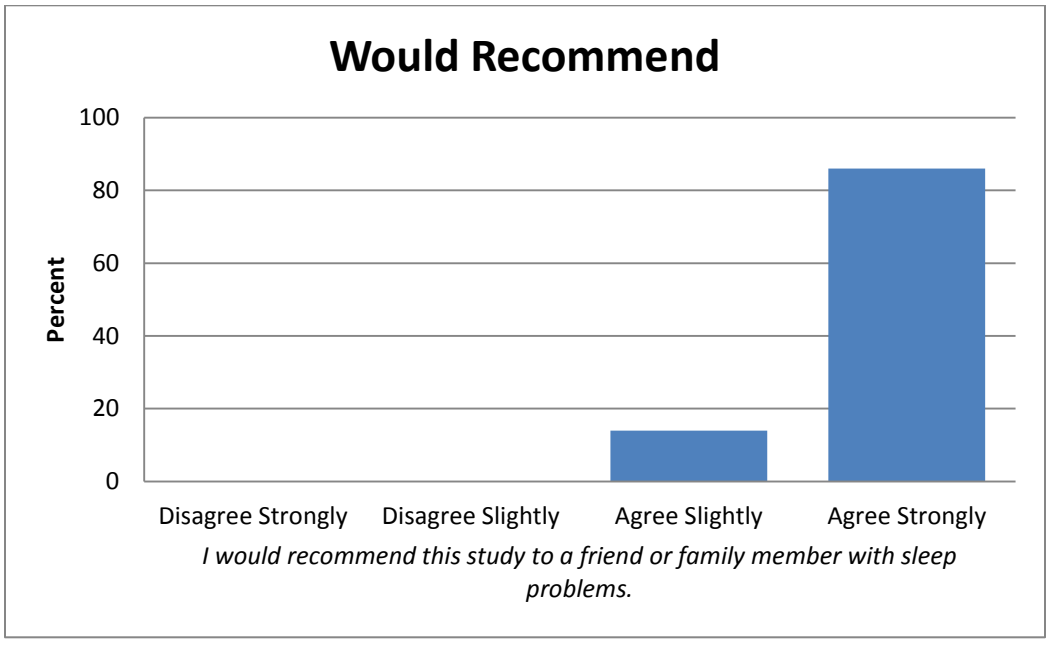


Figure 18. Would recommend study to others

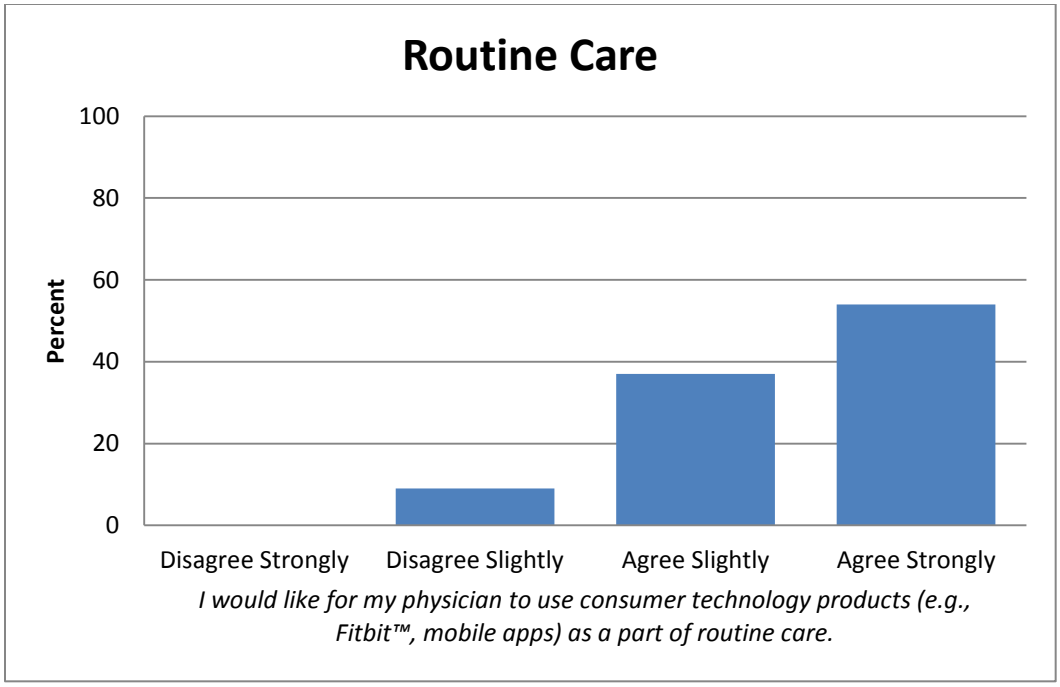


Figure 19. Participants perception of consumer products in routine care

DISCUSSION

Results of the present study are consistent with previous findings, showing that sleep misperception is prevalent among problem sleepers and that sleep discrepancy can be reduced through the use of corrective sleep feedback. This study expands on previous research to examine sleep misperception in a diverse outpatient medical sample of self-identified problem sleepers, using consumer-grade wearable actigraphs.

Similar to previous studies (Morin & Benca, 2012; Quintilliani et al., 2017), objectively measured TST and SOL remained relatively unchanged from baseline to follow-up. Despite this lack of change in actual sleep, participants perceived themselves to be sleeping more hours per night, falling asleep more quickly, and sleeping better overall at one-week follow-up. Perceived sleep impairment has been shown to cause sleep-related anxiety and distress and can result in objective sleep impairment, even among those without true impairment previously (Harvey & Tang, 2012; Mercer, Bootzin, & Lack, 2002). In the present study, nearly 70% of participants were sleeping the recommended minimum of seven hours per night on average at baseline, whereas only 31% believed they were sleeping at least seven hours. This population of misperceivers may be at risk for developing objective sleep impairment. This finding has important clinical implications. Given the malleability of sleep misperception, it is feasible that corrective sleep feedback could disrupt the cycle of insomnia by reducing sleep discrepancy and subsequently reducing sleep-related anxiety and distress (Quintiliani et al., 2017; Semler & Harvey, 2005).

The present study also sought to explore predictors of sleep misperception. As hypothesized, depression was found to predict SOL discrepancy, such that those with elevated depression scores were more likely to report larger overestimations of SOL. However, contrary

to previous research (Fernandez-Mendoza et al., 2011; Vgontzas et al., 2013), TST misperception was not associated with elevations in depression or anxiety nor did poor physical health predict lower levels of sleep discrepancy in the present study. Previous work in support of these relationships was conducted primarily with paradoxical or psychophysiologic insomnia samples and represent extreme ends on a continuum of sleep misperception (Fernandez-Mendoza et al., 2011; Vgontzas et al., 2013). As such, it is possible that mental and physical health may predict sleep misperception only among the most severe cases which were not represented in the Primary Care patient sample of the present study.

Pre-post changes in self-reported sleep, mood, and health were examined as a secondary aim in this study. Statistically significant improvements in depression, anxiety, mental health functioning, and insomnia symptom severity were observed at one-week follow-up. Daytime sleepiness and physical health functioning both remained relatively unchanged, falling within a normal range at baseline and follow-up. Dysfunctional sleep beliefs did not change significantly from baseline to follow-up. Overall, these findings suggest that a single-session corrective sleep feedback intervention is associated with improvements in self-reported sleep, mood, anxiety, and mental health functioning.

Limitations. The present study has some notable limitations. This study did not include a control group to compare response to intervention, as such, improvements in secondary outcomes of depression, anxiety, and mental health functioning should be interpreted with caution as they may just represent the passage of time. Further, findings are restricted to short-term follow-up in this study. Longitudinal studies are needed to evaluate intermediate and long-term effects of corrective feedback on sleep perception, sleep-related distress, and objectively measured sleep. Longer-term follow up would also provide an opportunity to explore the

potential preventive impact of corrective feedback, examining if there may be a buffering effect on a population health level within medical practices. Such effects have been reported for corrective feedback when applied to other health behaviors (Dotson, Bowers, & Dunn, 2015). A relatively small sample was included in this study, limiting statistical power. Future research should be conducted with larger samples.

Challenges in using technology were also evident in the present study. Early in the study it was apparent that there was a seemingly systematic error with the Fitbits which resulted in the first night of data not being recorded for most participants. This issue was not able to be resolved during the course of the study and, though the majority of participants were able to successfully record at least five nights of data, this highlights the continued challenges of conducting research using consumer devices.

Moreover, consumer actigraphs are limited in measurement precision, however, they provide greater ecological validity in evaluating the utility of patient-generated health data (PGHD) in clinical practice. It is important to note that future research and clinical practice should seriously consider this and employ such consumer-grade products within the context of this limitation. Systemic issues and limitations should also be considered as the field continues to develop and explore the clinical utility of consumer devices and PGHD. Probably most important is the question of standardization.

Future Directions. Though participants were instructed to wear the Fitbit a minimum of one hour before bed until one hour after waking, they were encouraged to wear the device throughout the day if they were so inclined. It would be interesting to explore differences between those who elected to wear the Fitbit all day to track steps, activity, or heart rate and those who wore it only during required periods, as this may elucidate differences in engagement

and may offer insight into the target users who may benefit from technology-driven interventions for multiple health behavior change. Researchers should consider evaluating overall engagement with consumer devices in future studies, as participants who are more invested may be more likely to engage in self-management and take a more active role in their own health and wellbeing.

Research should not only explore the viability of consumer devices for assessing and intervening on sleep pathology but should also examine their potential as a tool for promoting and maintaining sleep health. This framework is particularly attractive from a population and public health perspective. Moreover, given the typical developmental course from acute to chronic sleep disturbance and insomnia, a health promotion approach seems to be a promising prevention effort worth further consideration.

APPENDIX A: ISI

The Insomnia Severity Index

Please rate the current (i.e., last 2 weeks) severity of your insomnia problem(s).

		None	Mild	Moderate	Severe	Very
a.	Difficulty falling asleep:	0	1	2	3	4
b.	Difficulty staying asleep:	0	1	2	3	4
c.	Problem waking up too early:	0	1	2	3	4

How satisfied/dissatisfied are you with your current sleep pattern?

Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied
0	1	2	3	4

To what extent do you consider your sleep problem to interfere with your daily functioning (e.g., daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.)?

Not at all interfering	A little	Somewhat	Much	Very much interfering
0	1	2	3	4

How noticeable to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all noticeable	A little	Somewhat	Much	Very much noticeable
0	1	2	3	4

How worried/distressed are you about your current sleep problem?

Not at all worried	A little	Somewhat	Much	Very much worried
0	1	2	3	4

APPENDIX B: DBAS-16

Beliefs About Sleep

Several statements reflecting people's beliefs and attitudes about sleep are listed below. Please indicate (by circling the number) to what extent you personally agree or disagree with each statement. There is no right or wrong answer. For each statement, **circle a number that best reflects your personal experience**. Consider the whole scale, rather than only the extremes of the continuum.

1. I need 8 hours of sleep to feel refreshed and function well during the day.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
2. When I do not get proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night by sleeping longer.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
3. I am concerned that chronic insomnia may have serious consequences for my physical health.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
4. I am worried that I may lose control over my abilities to sleep.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
5. After a poor night's sleep, I know that it will interfere with my daily activities on the next day.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
6. In order to be alert and function well during the day, I am better off taking a sleeping pill rather than having a poor night's sleep.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
7. When I feel irritable, depressed, or anxious during the day, it is mostly because I did not sleep well the night before.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
8. When I sleep poorly on one night, I know that it will disturb my sleep schedule for the whole week.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
9. Without an adequate night's sleep, I can hardly function the next day.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
10. I can't ever predict whether I will have a good or poor night's sleep.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
11. I have little ability to manage the negative consequences of disturbed sleep.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
12. When I feel tired, have no energy, or just	*Strongly*												*Strongly*

seem not to function well during the day, it is generally because I did not sleep well the night before.	*Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Agree*
13. I believe that insomnia is essentially a result of a chemical imbalance.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
14. I feel that insomnia is ruining my ability to enjoy life and prevents me from doing what I want.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
15. Medication is probably the only solution to sleeplessness.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*
16. I avoid or cancel obligations (social, family, occupational) after a poor night's sleep.	*Strongly Disagree*	0	1	2	3	4	5	6	7	8	9	10	*Strongly Agree*

APPENDIX C: ESS

Epworth Sleepiness Scale

ID #: _____ Today's date: _____

Your age (Yrs): _____ Your sex (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

0 = would **never** doze
1 = **slight chance** of dozing
2 = **moderate chance** of dozing
3 = **high chance** of dozing

It is important that you answer each question as best you can.

Situation	**Chance of Dozing (0-3)**
Sitting and reading	
Watching TV	
Sitting, inactive in a public place (e.g. a theatre or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	

THANK YOU FOR YOUR COOPERATION

APPENDIX D: SF-36

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one week ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one week ago	Somewhat better now than one week ago	About the same as one week ago	Somewhat worse now than one week ago	Much worse now than one week ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a mile	☐ 1	☐ 2	☐ 3
h Walking several hundred yards	☐ 1	☐ 2	☐ 3
i Walking one hundred yards	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

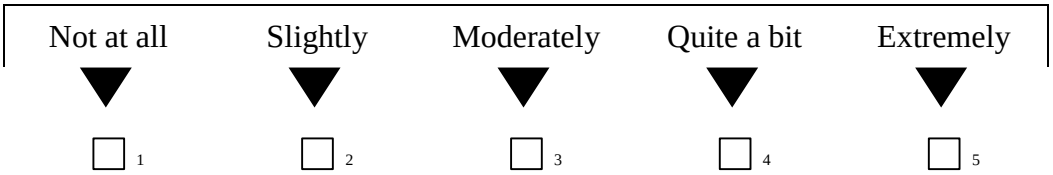
4. During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

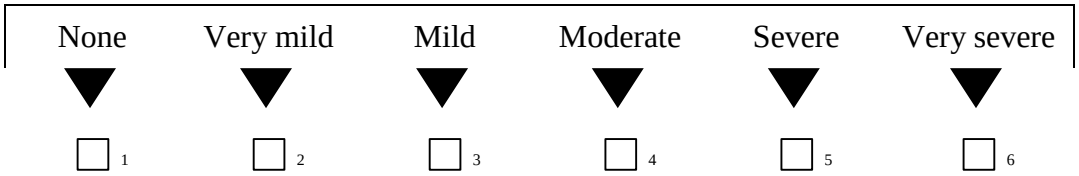
5. During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

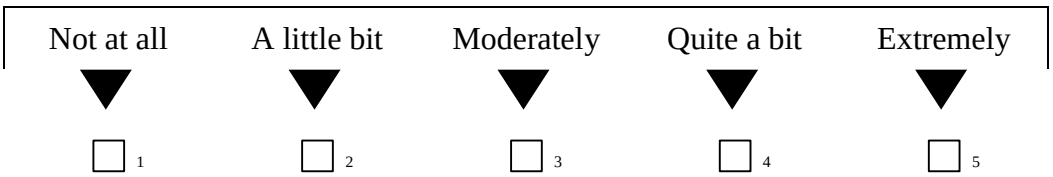
6. During the <u>past week</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?



7. How much <u>bodily</u> pain have you had during the <u>past week</u>?



8. During the <u>past week</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?



9. These questions are about how you feel and how things have been with you <u>during the past week</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past week</u>…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the <u>past week</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

APPENDIX E: PHQ-9

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

APPENDIX F: GAD-7

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

(For office coding: Total Score T____ = ____ + ____ + ____)

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APPENDIX G: AUDIT

Drinking alcohol can affect your health. This is especially important if you take certain medications. We want to help you stay healthy and lower your risk for the problems that can be caused by drinking.
These questions are about your drinking habits. We've listed the serving size of one drink below.

Please circle your answer	0	1	2	3	4
How often do you have one drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4+ times per week
How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
How often do you have four or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the ***last year*** have you……					
…found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
…failed to do what was normally expected from you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
…needed a first drink in the morning to get yourself going after heavy drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
…had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
…been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
	0		2		4
Have you or someone else been injured as a result of your drinking?	No	Yes, but not in the last year			Yes, during the last year
Has a relative, friend, doctor or other health worker been concerned about your drinking or suggested you cut down?	No	Yes, but not in the last year			Yes, during the last year
(8)					
				Total:	

Standard serving of one drink:

12 ounces of beer or wine cooler
1.5 ounces of 80 proof liquor
5 ounces of wine
4 ounces of brandy, liqueur or aperitif

APPENDIX H: CDS-E

Sleep Diary Instructions (CSD-E)

General Instructions

What is a Sleep Diary? A sleep diary is designed to gather information about your daily sleep pattern.

How often and when do I fill out the sleep diary? It is necessary for you to complete your sleep diary every day. If possible, the sleep diary should be completed within one hour of getting out of bed in the morning. The Nighttime Sleep Diary questions can be completed before you go to bed at night.

What should I do if I miss a day? If you forget to fill in the diary or are unable to finish it, leave the diary blank for that day.

What if something unusual affects my sleep or how I feel in the daytime? If your sleep or daytime functioning is affected by some unusual event (such as an illness, or an emergency) you may make brief notes on your diary.

What do the words "bed" and "day" mean on the diary? This diary can be used for people who are awake or asleep at unusual times. In the sleep diary, the word "day" is the time when you choose or are required to be awake. The term "bed" means the place where you usually sleep.

Will answering these questions about my sleep keep me awake? This is not usually a problem. You should not worry about giving exact times, and you should not watch the clock. Just give your best estimate.

Morning Sleep Diary Item Instructions

Use the guide below to clarify what is being asked for each item of the Sleep Diary.

Date: Write the date of the morning you are filling out the diary.

1. What time did you get into bed? Write the time that you got into bed. This may not be the time you began "trying" to fall asleep.

2. What time did you try to go to sleep? Record the time that you began "trying" to fall asleep.

3. How long did it take you to fall asleep? Beginning at the time you wrote in question 2, how long did it take you to fall asleep.

4. How many times did you wake up, not counting your final awakening? How many times did you wake up between the time you first fell asleep and your final awakening?

5. In total, how long did these awakenings last? What was the total time you were awake between the time you first fell asleep and your final awakening. For example, if you woke 3 times for 20 minutes, 35 minutes, and 15 minutes, add them all up (20+35+15= 70 min or 1 hr and 10 min).

6a. What time was your final awakening? Record the last time you woke up in the morning.

6b. After your final awakening, how long did you spend in bed trying to sleep? After the last time you woke-up (Item #6a), how many minutes did you spend in bed trying to sleep? For example, if you woke up at 8 am but continued to try and sleep until 9 am, record 1 hour.

6c. Did you wake up earlier than you planned? If you woke up or were awakened earlier than you planned, check yes. If you woke up at your planned time, check no.

6d. If yes, how much earlier? If you answered "yes" to question 6c, write the number of minutes you woke up earlier than you had planned on waking up. For example, if you woke up 15 minutes before the alarm went off, record 15 minutes here.

7. What time did you get out of bed for the day? What time did you get out of bed with no further attempt at sleeping? This may be different from your final awakening time (e.g. you may have woken up at 6:35 a.m. but did not get out of bed to start your day until 7:20 a.m.)

8. In total, how long did you sleep? This should just be your best estimate, based on when you went to bed and woke up, how long it took you to fall asleep, and how long you were awake. You do not need to calculate this by adding and subtracting; just give your best estimate.

9. How would you rate the quality of your sleep? "Sleep Quality" is your sense of whether your sleep was good or poor.

10. How restful or refreshed did you feel when you woke up for the day? This refers to how you felt after you were done sleeping for the night, during the first few minutes that you were awake.

Nighttime Sleep Diary Item Instructions

Please complete the following items before you go to bed.

Date: Write the date of the evening you are filling out the diary.

11a. How many times did you nap or doze? A nap is a time you decided to sleep during the day, whether in bed or not in bed. "Dozing" is a time you may have nodded off for a few minutes, without meaning to, such as while watching TV. Count all the times you napped or dozed at any time from when you first got out of bed in the morning until you got into bed again at night.

11b. In total, how long did you nap or doze? Estimate the total amount of time you spent napping or dozing, in hours and minutes. For instance, if you napped twice, once for 30 minutes and once for 60 minutes, and dozed for 10 minutes, you would answer "1 hour 40 minutes." If you did not nap or doze, write "N/A" (not applicable).

12a. How many drinks containing alcohol did you have? Enter the number of alcoholic drinks you had where 1 drink is defined as one 12 oz beer (can), 5 oz wine, or 1.5 oz liquor (one shot).

12b. What time was your last drink? If you had an alcoholic drink yesterday, enter the time of day in hours and minutes of your last drink. If you did not have a drink, write "N/A" (not applicable).

13a. How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have? Enter the number of caffeinated drinks (coffee, tea, soda, energy drinks) you had where for coffee and tea, one drink = 6-8 oz; while for caffeinated soda one drink = 12 oz.

13b. What time was your last drink? If you had a caffeinated drink, enter the time of day in hours and minutes of your last drink. If you did not have a caffeinated drink, write "N/A" (not applicable).

14. Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken: List the medication name, how much and when you took EACH different medication you took tonight to help you sleep. Include medication available over the counter, prescription medications, and herbals (example: "Sleepwell 50 mg 11 pm"). If every night is the same, write "same" after the first day

15. Comments If you have anything that you would like to say that is relevant to your sleep feel free to write it here.

Consensus Sleep Diary - E (Please Complete Upon Awakening) **ID/NAME: ____________________**

Sample

Today's Date	4/5/08							
1. What time did you get into bed?	10:15 p.m.							
2. What time did you try to go to sleep?	11:30 p.m.							
3. How long did it take you to fall asleep?	55 min.							
4. How many times did you wake up, not counting your final awakening?	6 times							
5. In total, how long did these awakenings last?	2 hours 5 min.							
6a. What time was your final awakening?	6:35 a.m.							
6b. After your final awakening, how long did you spend in bed trying to sleep?	45 min.							
6c. Did you wake up earlier than you planned?	☑ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
6d. If yes, how much earlier?	1 hour							
7. What time did you get out of bed for the day?	7:20 a.m.							
8. In total, how long did you sleep?	4 hours 10 min.							
9. How would you rate the quality of your sleep?	☐ Very poor ☑ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good
10. How rested or refreshed did you feel when you woke-up for the day?	☐ Not at all rested ☑ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested	☐ Not at all rested ☐ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested	☐ Not at all rested ☐ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested	☐ Not at all rested ☐ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested	☐ Not at all rested ☐ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested	☐ Not at all rested ☐ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested	☐ Not at all rested ☐ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested	☐ Not at all rested ☐ Slightly rested ☐ Somewhat rested ☐ Well-rested ☐ Very well-rested

Consensus Sleep Diary - E (Please Complete Before Bed) **ID/NAME: _____**

	Sample							
Today's Date	4/5/10							
11a. How many times did you nap or doze? 11b. In total, how long did you nap or doze?	2 times 1 hour 10 min.							
12a. How many drinks containing alcohol did you have? 12b. What time was your last drink?	3 drinks 9 :20 p.m.							
13a. How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have? 13b. What time was your last drink?	2 drinks 3 :00 p.m.							
14. Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken	☑ Yes ☐ No Medication(s): Relaxo-Herb Dose: 50 mg Time(s) taken: 11 pm	☐Yes ☐No Medication(s): Dose: Time(s) taken:	☐Yes ☐No Medication(s): Dose: Time(s) taken:	☐Yes ☐No Medication(s): Dose: Time(s) taken:	☐Yes ☐No Medication(s): Dose: Time(s) taken:	☐Yes ☐No Medication(s): Dose: Time(s) taken:	☐Yes ☐No Medication(s): Dose: Time(s) taken:	☐Yes ☐No Medication(s): Dose: Time(s) taken:
15. Comments (if applicable)	I have a cold							

APPENDIX I: PATIENT SATISFACTION QUESTIONNAIRE

For each of the following questions, please mark an X in the box that best describes your answer.

		Disagree Strongly	Disagree Slightly	Agree Slightly	Agree Strongly
1	I believe the Fitbit Charge HR™ accurately measured my sleep patterns.				
2	The Fitbit Charge HR™ was easy to use.				
3	I plan to purchase a Fitbit™ or another sleep monitoring device after participating in this study.				
4	I have a better understanding of my sleep patterns after participating in this study.				
5	The personalized sleep feedback was informative.				
6	The personalized sleep feedback was useful.				
7	I would recommend this study to a friend or family member with sleep problems.				
8	I would like for my physician to use consumer technology products (e.g., Fitbit™, mobile apps) as a part of routine care.				

Please provide any comments or feedback that you may have for the researcher in the space below:

APPENDIX J: SAMPLE FEEDBACK REPORT

Sleep Feedback Report

The following feedback report is based on behavioral sleep measurement data collected from the Fitbit Charge HR over the course of one week. This device uses accelerometer technology to detect your movement and activity level during sleep. Your sleep data was extracted and analyzed in 60-second increments using a specialized research platform to provide a reliable estimate of your sleep pattern. Below is a summary and a graphic illustration of your sleep data.

During the nights when you wore the Fitbit, the average time you fell asleep was 11:31 PM and your average total sleep duration was 6 hours and 38 minutes, with total sleep time ranging from 6 hours and 15 minutes to 7 hours and 1 minute. In contrast, during your initial visit (xx/xx/xx) you estimated that you sleep approximately 4 hours and 30 minutes per night, on average. Based on your sleep diary, you reported sleeping an average of 5 hours and 36 minutes per night during the past week. Taken together these results indicate that, on average you slept 56 minutes more per night than you thought during the past week (based on sleep diary) and approximately 2 hours and 8 minutes more per night than you estimated at your initial visit. The National Sleep Foundation recommends that adults sleep at least 7 hours per night and based on this standard your sleep results indicate that you are generally getting slightly less than adequate sleep.

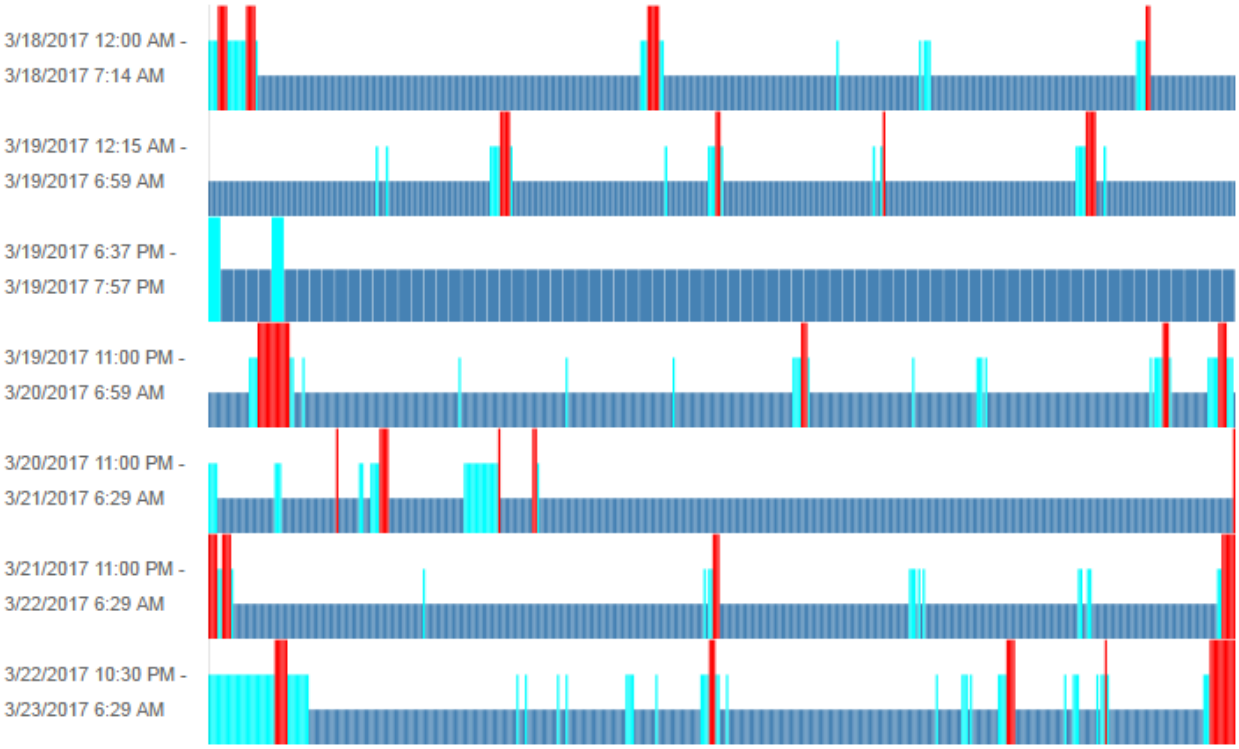
When taking into consideration all 6 nights of recording, the total amount of time you spent awake after initially falling asleep was 1 hour and 43 minutes and this amount ranged from 9 minutes to 26 minutes per night. Results also indicated that you were quite restless, with an average of 34 restless minutes per night and a total of 3 hours and 24 minutes of restlessness across all 6 nights.

Overall, results of your sleep assessment suggest that you sleep more hours per night than you expected and that you are receiving an inadequate amount of sleep on average. Also, your sleep is very fragmented and restless throughout the night.

Keri Dotson, M.S.
Doctoral Candidate, Clinical Psychology

Sleep

Sleep / Day **Minute-by-Minute**



3/18/2017 - 3/23/2017

Average

Minutes Asleep: **412**

High

Minutes Asleep: **454** **(3/19/2017)**

Low

Minutes Asleep: **377** **(3/23/2017)**

Date	Mins Asleep	Mins In Bed	Mins To Fall Asleep	Awake Mins	Restless Mins	Awake Count	Restless Count	Efficiency	Is Main Sleep
3/18/2017	393	435	21	15	27	4	9	95	true
3/19/2017	375	405	0	11	19	4	11	93	true
3/19/2017	79	81	0	0	2	0	2	98	false
3/19/2017	421	480	0	25	34	4	16	88	true
3/20/2017	412	450	4	9	29	5	6	93	true
3/21/2017	415	450	11	17	18	4	11	96	true
3/22/2017	377	480	47	26	77	5	21	90	true

Showing 1 to 7 of 7 entries

Disclaimer: The data presented herein were collected using the Fitbit Charge HR™ as part of a research study for which you volunteered to participate. The Fitbit Charge HR™ is not a medical device and has not been evaluated by the FDA for this purpose. This report aims to provide an exploratory interpretation based on data collected from the Fitbit™ for research purposes. The information provided in this report does not constitute a medical diagnosis or medical advice and is not intended to be a substitute for professional medical treatment. Do not disregard professional medical advice or delay seeking advice or treatment because of something you have read here.

APPENDIX K: IRB APPROVAL LETTER

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Keri B. Dotson** and Co-PIs: **Jeffrey E. Cassisi & Maria Louise Cannarozzi**

Date: **September 15, 2016**

Dear Researcher:

On 09/15/2016 the IRB approved the following human participant research until 09/14/2017 inclusive:

Type of Review:	UCF Initial Review Submission Form Expedited Review
Project Title:	Evaluating the Use of a Consumer Activity Monitor to Assess Sleep in the Patient Centered Medical Home: Feasibility and Pilot Study
Investigator:	Keri B. Dotson
IRB Number:	SBE-16-12361
Funding Agency:	
Grant Title:	
Research ID:	N/A

The scientific merit of the research was considered during the IRB review. The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

If continuing review approval is not granted before the expiration date of 09/14/2017, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

Use of the approved, stamped consent document(s) is required. The new form supersedes all previous versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Participants or their representatives must receive a signed and dated copy of the consent form(s).

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

Signature applied by Kamille Chaparro on 09/15/2016 09:55:47 AM EDT

IRB Coordinator

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