#### MODEL, ARCHITECTURE AND APPLICATION OF CROSS-PLATFORM JUST-IN-TIME ADAPTIVE INTERVENTION (JITAI): AN IMPLEMENTATION IN BEHAVIORAL SLEEP INTERVENTION

by

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University of Pittsburgh, 2016

Cognitive-behavioral therapies (CBT) are common types of non-pharmacological therapy used in treating mental illnesses and behavioral disorders. Smartphone-based interventions have the potential for improving the delivery of traditional CBT with such novel features as personalization and context awareness. Assessments and interventions are best delivered when they are personalized to fit each individual's needs and conditions. Just in Time Adaptive Intervention (JITAI) combines this personalized and adaptive intervention with the use of mobile technology.

An increasing number of studies have been conducted to assess the effect of JITAI on regulating human health behavior; however, there has been no published theoretical model underlying the use of smartphones and mobile devices in relation to JITAI. Therefore, this work aimed to provide 1) a behavioral model and application architecture for JITAI, 2) implementation of the JITAI model and application architecture on behavioral sleep intervention, 3) clinical and usability outcomes of the implementation, and 4) an evaluation of the model and its clinical feasibility. The JITAI model, architecture and application were designed to accommodate various adaptive health/behavioral interventions. Nevertheless, in this dissertation, sleep intervention was chosen as the case study because 1) sleep is a universal and recurrent

behavior, and 2) behavioral sleep treatments are "adaptive" treatment, highly manualized and with well-defined outcome measurements. This cross-platform implementation of JITAI architecture for sleep intervention is named interactive Resilience Enhancing Sleep Tactics (iREST).

The JITAI model, architecture and application were evaluated based on the results of a usability and feasibility study of the iREST system (n=22). The results suggest that the system was highly usable with a mean SUS (System Usability Scale) score of 85.74. Rate of treatment response (84.21%) and remission (68.42%) were greater than those reported in previous traditional (in-person) behavioral sleep intervention trials. This finding suggests that the JITAI model and architecture are feasible tools for designing and implementing adaptive health behavior intervention through mobile health (mHealth).

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## LIST OF ABBREVIATIONS

AES-256	$\rightarrow$	Advanced Encryption Standard with 256-bit key length
ADSM	$\rightarrow$	Active Duty Service Members
ANOVA	$\rightarrow$	Analysis of variance
API	$\rightarrow$	Application Program Interface
ARA	$\rightarrow$	Allergic rhinitis asthma
BBTI	$\rightarrow$	Brief Behavioral Therapy for Insomnia
BBTI-MV	$\rightarrow$	BBTI – Military Version
BHI	$\rightarrow$	Biomedical Health Informatics
BYOD	$\rightarrow$	Bring Your Own Device
BZRA	$\rightarrow$	Benzodiazepine receptor agonist
CAPS	$\rightarrow$	Clinician administered PTSD Scale – Part 1
CBT	$\rightarrow$	Cognitive Behavioral Therapy
CBT-I	$\rightarrow$	Cognitive Behavioral Therapy for Insomnia
CGI	$\rightarrow$	Clinical Global Impression scale
CI	$\rightarrow$	Confident interval
CMS	$\rightarrow$	Center for Medicare and Medicaid Service
CSS	$\rightarrow$	Cascading Style Sheets
СТ	$\rightarrow$	Control Theory
DBMS	$\rightarrow$	Database Management System
df	$\rightarrow$	Degree of Freedom
DSM	$\rightarrow$	Diagnostic and Statistical Manual of Mental Disorders
DSM-IV	$\rightarrow$	Diagnostic and Statistical Manual of Mental Disorders – 4th Edition
ECDH	$\rightarrow$	Elliptic curve Diffie-Hellman
EHR	$\rightarrow$	Electronic health records

EMA	$\rightarrow$	Ecological Momentary Assessment
EMI	$\rightarrow$	Ecological Momentary Intervention
EMR	$\rightarrow$	Electronic medical records, see EHR
ESS	$\rightarrow$	Epworth Sleepiness Scale
GAD2	$\rightarrow$	Generalized Anxiety Disorder scale 2-items
GAD7	$\rightarrow$	Generalized Anxiety Disorder scale 7-items
GMT	$\rightarrow$	Good Morning Time
GNT	$\rightarrow$	Good Night Time
GPS	$\rightarrow$	Global Positioning System
GUI	$\rightarrow$	Graphical user interface
HaRI	$\rightarrow$	The Health and Rehabilitation Informatics Lab
HBM	$\rightarrow$	The Health Belief Model
HCI	$\rightarrow$	Human-Computer Interaction
HIPAA	$\rightarrow$	Health Insurance Portability and Accountability Act
HLM	$\rightarrow$	Hierarchical Linear Model
HTTP	$\rightarrow$	Hypertext Transfer Protocol
HTTPS	$\rightarrow$	HTTP Secure
HTML	$\rightarrow$	Hypertext Markup Language
ICC	$\rightarrow$	Intra-class correlation
ICT	$\rightarrow$	Information and communications technology
IID	$\rightarrow$	Iterative and Incremental Development
IMB	$\rightarrow$	Information-Motivation-Behavioral Skills Model
IoT	$\rightarrow$	Internet of Things
ISI	$\rightarrow$	Insomnia Severity Index
iREST	$\rightarrow$	interactive Resilience Enhancing Sleep Tactics
JITAI	$\rightarrow$	Just in Time Adaptive Intervention
KPI	$\rightarrow$	Key performance indicator
M-STARRT	$\rightarrow$	The Military Sleep Tactics & Resilience Research Team
MVC	$\rightarrow$	Model-View-Controller
MVVC	$\rightarrow$	Model-View-ViewModel
OEM	$\rightarrow$	Original equipment manufacturers

OLS	$\rightarrow$	Ordinary least squares
OOP	$\rightarrow$	Object oriented programming
OS	$\rightarrow$	Operating system
POI	$\rightarrow$	Point of Input
PTSD	$\rightarrow$	Post-traumatic Stress Disorder
PCL-C	$\rightarrow$	PTSD Checklist – Civilian version
PGI	$\rightarrow$	Patient Global Impression of Improvement
PHQ2	$\rightarrow$	Patient Health Questionnaire 2-items
PHQ9	$\rightarrow$	Patient Health Questionnaire 9-items
PSQI	$\rightarrow$	Pittsburgh Sleep Quality Index
PSQI-A	$\rightarrow$	PSQI Addendum for PTSD
RBAC	$\rightarrow$	Roles Based Access Control
RERC	$\rightarrow$	Rehabilitation Engineering Research Center
REST	$\rightarrow$	Representational State Transfer
SCID-NP	$\rightarrow$	Structured Clinical Interview for DSM-IV, non-patient version
SCT	$\rightarrow$	Social Cognitive Theory
SD	$\rightarrow$	Standard Deviation
SDK	$\rightarrow$	Software developer kit
SDLC	$\rightarrow$	Software Development Lifecycle
SE	$\rightarrow$	Sleep Efficiency
SMS	$\rightarrow$	Short Message Service
SOA	$\rightarrow$	Service Oriented Architecture
SOAP	$\rightarrow$	Simple Object Access Protocol
SoC	$\rightarrow$	Separation of Concerns
SUS	$\rightarrow$	System Usability Scale
TAP	$\rightarrow$	Think-aloud Protocols
TBI	$\rightarrow$	Traumatic Brain Injury
TIB	$\rightarrow$	Time in Bed
TLS	$\rightarrow$	Transport Layer Security
TPB	$\rightarrow$	Theory of Planned Behavior
TRA	$\rightarrow$	Theory of Reasoned Action

$\rightarrow$	Total Sleep Time
$\rightarrow$	Telerehabilitation Usability Questionnaire
$\rightarrow$	User interface
$\rightarrow$	Wakeup After Sleep Onset
$\rightarrow$	Web based real time communication
	$\rightarrow$ $\rightarrow$ $\rightarrow$

#### PREFACE

I would like to express my gratitude to everyone who has supported me throughout this PhD journey. I must admit, it was not an easy journey, but I am fortunate to have received continuous encouragements from so many wonderful people around me.

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#### **1.0 INTRODUCTION – RESEARCH PROPOSAL**

#### **1.1 BACKGROUND**

Cognitive-behavioral therapies (CBT) are the most common types of evidence-based psychotherapy used in treating mental disorders, including mood and anxiety disorders, eating disorders, sleep disorders, and alcohol and use disorders. CBT is based on the notions that: (1) cognitions affect behavior; (2) cognitions and behaviors may be monitored and altered; (3) desired behavioral changes can be effected through cognitive changes (Dobson & Dozois, 2010). When applied to mental disorders, CBT attempts to change maladaptive thinking to bring about alterations in affect and behavior to achieve the desired consequences. This is done by challenging the individual's way of thinking (i.e., interpreting internal and external cues) as well as his or her habitual emotional and behavioral reactions to a variety of situations. CBT has six distinct phases: (1) assessment, (2) collaborative reconceptualization of the patient's views of antecedents, behaviors, and consequences of the index problematic behaviors, (3) skill acquisition, (4) skills consolidation and application training, (5) generalization and maintenance, and (6) post-treatment assessment and follow up (Mcmahon, Koltzenburg, Tracey, & Turk, 2013).

In each of the aforementioned phases, assessment is an important part of tracking the problematic cognitive behaviors as well as the desired behaviors or consequences. Traditional clinical assessments typically rely on retrospective and prospective self-reports collected during clinic visits, which are prone to recall bias and are not well-suited for observing what triggers and maintains problematic behaviors, or how behavior changes over time and across contexts (Stone, Shiffman, Atienza, & Nebeling, 2007). Ecological momentary assessment (EMA) involves repeated sampling of subjects' current experiences in real-time, and in subjects' natural environments. EMA aims to minimize recall bias, maximizing ecological validity, and allowing dynamic temporal association between environment and behaviors to be observed over multiple repeated measurements. EMA studies assess a particular event in subjects' lives or assess subjects at periodic sampling intervals that can be fixed or random (Shiffman, Stone, & Hufford, 2008). Thus, EMA can increase the temporal resolution of clinical assessments while limiting self-reports' retrospective biases. Furthermore, the same methodology can be used to deliver intervention and training which is suitable to address phase 2–5 of CBT's phases above. This type of intervention is referred to as ecological momentary intervention (EMI). Incorporating EMA/I into CBT has the potential to improve overall intervention results (Heron & Smyth, 2010; Pramana & Parmanto, 2014).

EMA/I studies utilize technologies ranging from written diaries to more recent smartphones and physiological sensors. Mobile phones particularly smartphones, have become the next evolution, or revolution, of technology for conducting EMA/I. Mobile phones have achieved rapid and high penetration, with more than 79.1% of the 378 million wireless subscribers in the USA using smartphones (comScore, 2016), and more than 7.2 billion (comparable to 99.4% of world population) cellphone subscriptions globally (ITU, 2016). Despite this huge potential, the smartphone market is and will likely be divided between a few mutually incompatible operating systems. Currently in the United States, two players dominate

mobile operating systems: Google Android and Apple iOS, who own 52.8% and 43.6% of the market share, respectively. The Android platform is further fragmented into various original equipment manufacturers (OEMs), e.g., Samsung, LG, Motorola and HTC (comScore, 2016). Development of smartphone-based EMA/I typically requires development of mobile apps for each and every operating system and device that an individual owns. This proposition is costly and not scalable. Alternatively, development of a cross-platform mobile architecture can provide a remedy for this divided market. Such architecture would allow a single mobile application to run on multiple platforms with minimal development effort.

Smartphone-based interventions have the potential to improve the delivery of traditional CBT with such novel features as personalization and context awareness. Assessments and interventions are best delivered when they are personalized to fit each individual's needs and conditions. Tailoring intervention to individual needs is not new in behavioral intervention studies, and many health behavior models such as the Theory of Planned Behavior, the Health Belief Model, the Social Cognitive Model, and Self-Determination Theory have shown how interventions can be tailored to the individual's baseline assessment (Webb, Joseph, Yardley, & Michie, 2010). However, current mobile technologies can further tailor the intervention by dynamically adapting the intervention (both the assessment and intervention), e.g., changing the dose or interval over time in response to the participant's current needs and contexts. This requires personalization of the intervention not only at the beginning of the episode of care, but also frequent iterative adjustments during the course of care. When we combine this adaptive intervention with the EMA/I approach, we have what is called the Just in Time Adaptive Intervention (JITAI) (Collins, Murphy, & Bierman, 2004).

JITAIs are gaining popularity among behavioral scientists for supporting health and behavior changes. An increasing number of studies have been conducted to assess the effect of JITAI on regulating human health behavior (Consolvo & McDonald, 2008; King et al., 2013; Witkiewitz et al., 2014). The use of mobile technology, including smartphones and wearable devices, fits well with JITAI. However, there have been no published theoretical models that underlay the use of smartphones and mobile devices in relation with JITAI. The few models that have been published (Lei, Tewari, & Murphy, 2014; Riley et al., 2011; Riley, Cesar, & Rivera, 2014) only focus on the adaptive mechanism part of JITAI. The JITAI field needs a theoretical model to help: (1) describe and explain how behaviors change and participants' conditions improve through JITAI; (2) guide assessment and intervention program development; (3) describe the important roles mobile technology plays; (4) facilitate testing of the intervention; (5) increase intervention generalization; and (6) support the establishment of the JITAI method of treatment with a theoretical foundation.

Sleep is a universal and recurrent behavior. Hence, sleep intervention is an appropriate case study to evaluate the validity and generalizability of the proposed JITAI model and architecture for the following reasons: 1) the treatment is highly manualized, making translations into other methods of delivery (e.g., mobile technology) more straightforward; 2) healthy sleep needs to happen every day – a recurrent behavior – so there is a need for repeated in-vivo treatment and/or enforcement (e.g., through JITAI); 3) quantifiable metrics of behavior and progress, and a sufficient amount of objective and subjective measurement of sleep quality and disturbances have been developed and validated.

Consolidated, restorative, and sufficient sleep is an essential component of the Armed Forces readiness and fitness (The Army Medical Department, 2014; Troxel, Germain, & Buysse, 2012). However, insomnia, which affects between 40% and 70% of SMs and Veterans, is a robust risk factor for poor psychological health outcomes as well as poor physical health, e.g., increased risk for cardiovascular and metabolic diseases (Livingston et al., 2015). Insomnia can also compromise performance by impairing critical cognitive and moral reasoning abilities and increasing the risk of injuries and costly mishaps due to the resulting fatigue (Rupp, Wesensten, & Balkin, 2010).

#### **1.2 STUDY AIMS**

The goal of this dissertation is to develop and evaluate a behavior model, application architecture, and cross platform mobile application for JITAI with a case study in behavioral intervention for insomnia for a military population. The following specific aims are designed to achieve the research goal:

#### 1.2.1 Specific Aim 1

To develop a model of JITAI based on health behavioral theories.

#### Aim 1.1. To construct a behavior intervention model for JITAI

The proposed JITAI behavior intervention model will help to guide future JITAI developments and may explain behavior changes and symptom improvements produced by this intervention. The model also informs the position of each JITAI characteristic in the context of

health intervention strategies, features and limitations of currently available technologies, including the need for cross-platform design.

#### Aim 1.2. To construct an adaptive intervention model

At the heart of the "adaptive" JITAI is the adaptive intervention. This mechanism includes: (1) identification of adaptive components and related tailoring variables, (2) measurement of tailoring variables, (3) derivation of decision rules, and (4) implementation of decision rules(Collins et al., 2004). Based on the literature review, results from previous studies and expert opinion, a model of adaptive intervention will be built for the study case in this dissertation.

#### **1.2.2** Specific Aim 2

To construct a ready-to-use application architecture for JITAI based on the JITAI model and implement the architecture into a mobile health application system for behavioral sleep intervention.

#### Aim 2.1. To develop application architecture for JITAI

The JITAI application architecture is a generalizable technical implementation<sup>1</sup> of the proposed JITAI health behavior model. To address the current segmentation of the mobile operating system market, the JITAI application architecture is designed as a cross-platform system. This architecture includes ready-to-use, cross-platform and reusable components, such as

<sup>&</sup>lt;sup>1</sup> Technical implementation refers to technology/software implementation which includes: mobile apps, clinician web portal, and two-way communication between the two.

libraries, communication platforms, sensor integration, database, and logical infrastructure. The proposed architecture will allow application developers to customize the architecture to support a variety of health behavioral change interventions without having to build the system from scratch.

# Aim 2.2. To develop a cross-platform JITAI application for delivering behavioral sleep intervention

To test the applicability of JITAI application architecture, a JITAI system will be developed based on the needs of a behavioral sleep intervention study. In the study, the participants will bring their own device (BYOD), which requires the mobile application (app) to be able to run on the two most popular mobile operating systems (e.g., Android and iOS). This can be achieved by customizing the JITAI application architecture with the specific contexts of the behavioral sleep intervention into a cross-platform app for sleep intervention.

#### 1.2.3 Specific Aim 3

To conduct a usability and clinical feasibility study evaluating the JITAI health behavior model, architecture and application in behavioral sleep intervention.

#### Aim 3.1. To evaluate the usability of the cross-platform JITAI application

A pilot study will be conducted to assess the usability of the JITAI application for a behavioral sleep intervention. The evaluation will be conducted pre- and post-intervention, then the results will be used as bases for improvement for subsequent designs.

Hypothesis: Participants rate the JITAI application as highly usable.

*H*<sub>0</sub>: Average SUS score ( $\mu_{SUS}$ )  $\leq 66^2$ 

*H*<sub>1</sub>: Average SUS score (
$$\mu_{SUS}$$
) > 66

In order to prove the stated hypothesis, null hypothesis  $(H_0)$  needs to be rejected.

#### Aim 3.2. Clinical case study in Sleep Intervention

A pilot clinical feasibility study will be performed to evaluate the impact of a novel JITAI tool to deliver behavioral intervention for insomnia in a military population (details on sleep and sleep problems are discussed in **Chapter 4**). The outcomes of this study will be compared with previous traditional (in-person) behavioral intervention, controlling for demographics and initial sleep conditions (insomnia severity index, sleep quality index).

*Hypothesis*: There are no significant differences (non-inferiority) in clinical outcome measures between the JITAI and a traditional<sup>3</sup> behavioral sleep intervention.

 $H_0$ : Symptoms Improvement <sub>iREST</sub> < Symptoms Improvement <sub>Traditional BBTI</sub>  $H_1$ : Symptoms Improvement <sub>iREST</sub>  $\geq$  Symptoms Improvement <sub>Traditional BBTI</sub> In order to prove the stated hypothesis, null hypothesis ( $H_0$ ) needs to be rejected.

#### Aim 3.3. Evaluate the JITAI model and architecture

Based on the clinical outcomes from the case study, the constructed behavioral model and architecture are evaluated. The evaluation is mainly on whether the JITAI health behavior model accurately explains behavior changes and symptom improvement produced by this intervention.

<sup>&</sup>lt;sup>2</sup> The average total score for the System Usability Scale (SUS) on mobile interfaces is 65.9 (Bangor et al., 2009), in order to be considered highly usable, the SUS total score for JITAI application need to be above average (rounded up to 66)

<sup>&</sup>lt;sup>3</sup> Traditional refers to the in-person brief behavioral treatment for insomnia (BBTI) (Germain et al., 2014).

#### **1.3 SIGNIFICANCE**

Mobile technologies are rapidly evolving as a method for delivering health behavior interventions that can be tailored to the individual throughout the intervention. To date, however, many of these interventions have not been grounded in theory or developed from behavior change models, and no overarching model to explain behavior change in Internet interventions has yet been published. The purpose of JITAI health behavior model development is to propose a model to help guide future JITAI intervention development, as well as mobile health intervention in general, and to predict and explain behavior changes and symptom improvement produced by these interventions.

In terms of technology, the proposed JITAI application architecture provides intervention developers with a stepping-stone to develop a cross-platform mobile health application. In addition, a cross-platform application is not only beneficial in providing scalability for the intervention but can also accommodate a "bring-your-own-device" (BYOD) alternative, which could potentially reduce the cost and minimize logistic overhead of a mobile health intervention.

Furthermore, the study has important clinical implications for behavioral sleep treatments. Behavioral sleep treatments have been shown to be safe, effective, and are associated with durable improvements. However, the use of evidence-based, resilience-focused, behavioral treatments to promote healthy sleep pre-deployment and to treat sleep disturbances postdeployment remains scarce among active duty service members (ADSM), Veterans, and the clinicians who serve them. JITAI has the potential to increase access to these behavioral treatments and to improve their effectiveness by tailoring and adapting sleep interventions based on each individual's momentary needs.

#### **1.4 DISSERTATION OUTLINE**

This report begins with an introduction (Chapter 1). It is followed by a literature review of fundamental theories referred to in this dissertation proposal (Chapter 2). The literature review ends with an analysis of correlations between health behavioral models, cognitive behavioral therapy, adaptive intervention and mobile technology in health intervention. It is followed by an analysis of the other related studies that may provide insight and leverage for the proposed study (Chapter 3). Chapter 4 then discusses the case study used in this proposal as an implementation of the JITAI model and application architecture: a behavioral intervention for people with insomnia. Chapters 5, 6 and 7 describe research design and methodology for each of the study aims. Based on the study findings, the proposed JITAI model and architecture are evaluated in Chapter 8. Last, Chapter 9 summarizes the overall conclusions of this research, which are followed by the contributions of this research and opportunities for future work.

#### 2.0 THEORETICAL FRAMEWORK

#### 2.1 THEORIES OF HUMAN BEHAVIOR

Theories of human behavior have typically provided a conceptual framework for examining interrelationships between determinants and behaviors or health outcomes. They provide an estimation of the relative impact of the various inputs that can guide further intervention and research. Importantly, theory can guide development of interventions by delineating factors to be studied, identifying facilitating situations and relevant processes, guiding timing and sequencing, and indicating possible methods of intervention and evaluation. However, no single theory is all-encompassing, often making it necessary to use multiple theories to demonstrate how to promote specific behavior change. These theories can address factors on the individual level (individual theories), or on the community/population level (community-based/multi-level models) (Pbert, 2013).

Since the proposed study focuses on individual-level intervention, this section only discusses "individual theories" of human behavior, in particular, those that are commonly used in health behavior interventions. These include, but are not limited to: social cognitive theory, the health belief model, theory of reasonable action, theory of planned action, and the information-motivation-behavioral skill model. Although not exclusively categorized as the human behavior

model, control theory is also included in this section due to its increasing use in heath behavioral interventions.

#### 2.1.1 Social Cognitive Theory

The social cognitive theory (SCT) was proposed by Bandura (1986). The underlying concept in SCT is the reciprocal nature of influences that produce behavior. Personal factors, existing behaviors, and environments (social and physical) all interact and as a result, their reciprocal influences shape new behavior (shown in Figure 1). According to Bandura (1997), behavior change and maintenance of behavior are mainly a function of (a) expectations about the outcomes that will result from engaging in behavior ("outcome expectations") and (b) expectations about one's ability to engage in the behavior ("efficacy expectations"). Both outcome and efficacy expectations reflect an individual's beliefs about capabilities and the connections between behavior and outcomes. These beliefs may not necessarily be "true" capabilities. In addition, beliefs about capabilities of performing specific behaviors in particular situations are related to the concept of **self-efficacy**. Self-efficacy does not refer to personality characteristics or to a global trait that operates independently of contextual factors (Bandura, 1986, 1997). Thus, an individual's efficacy expectations will vary greatly depending on the particular task and context that confront his or her.

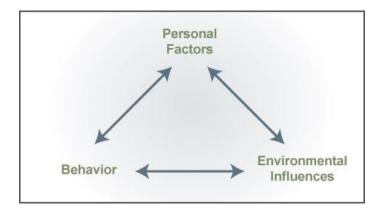


Figure 1. Social Cognitive Theory

Self-efficacy affects all aspects of behavior, including the acquisition of new behaviors, inhibition of existing behavior, and disinhibition of behaviors (Bandura, 1997). For example, individuals with low self-efficacy about a particular task may focus on their personal deficiencies rather than thinking about attending to the task at hand; this would impede successful performance of the task. According to Bandura (1986, 1997), efficacy expectations are learned from four major sources: performance accomplishments, vicarious experience, verbal persuasion, and physiological state. "Performance accomplishment" refers to learning through personal experiences where one gains an increase in self-efficacy by mastering difficult or previously feared tasks. "Vicarious experience" includes learning that occurs through observation of others. "Verbal persuasion" usually comes from clinicians or healthcare workers who motivate patients to persevere in their efforts to change behavior. Finally, an individual's "physiological state" provides information that can influence efficacy expectation. For example, someone who is just beginning an exercise program may experience fatigue and mild aches, which may be mistakenly interpreted as a sign of physical inefficacy rather than the expected "natural" intervening states.

Because SCT is based on understanding an individual's reality construct, it is especially useful when applied to interventions aimed at personality development, behavior pathology, and health promotion. Furthermore, SCT provides not only a way to predict behavior change but also explains how one comes to have certain beliefs or develops readiness for change.

#### 2.1.2 The Health Belief Model

The Health Belief Model (HBM), originally developed by a group of social psychologists at the U.S. Public Health Service in the 1950s, was first inspired by the widespread failure of people to use a screening test for the early detection of asymptomatic diseases, but in more recent years, the model has been used to predict more general health behaviors. The HBM emphasizes personal belief over the wider factors accounted for in SCT. It hypothesizes that behavior depends mainly upon two variables: (1) the value placed by an individual on a particular goal and (2) the individual's estimate of the likelihood that a given action will achieve that goal (Maiman & Becker, 1974).

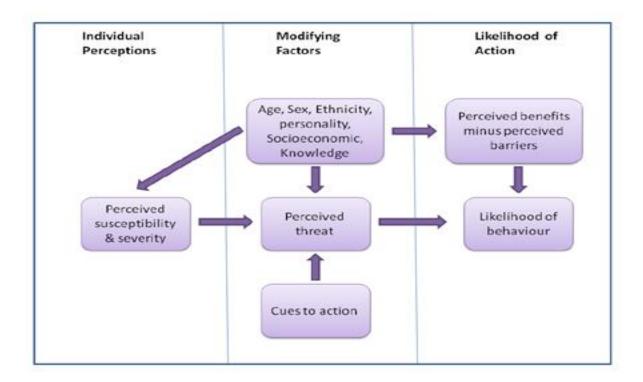


Figure 2. The Health Belief Model (Becker, Drachman, & Kirscht, 1974)

Specifically, HBM consists of the following dimensions: 1) perceived severity, 2) perceived susceptibility, 3) perceived benefits, and 4) perceived barriers. "Perceived severity" is defined as an individual's assessment of the seriousness of the condition and its potential consequences; "perceived susceptibility" is defined as an individual's assessment of their risk of getting the condition; "perceived benefits" refer to an individual's assessment of the positive consequences of adopting the new behavior; and "perceived barriers" refer to an individual's assessment of the influences that facilitate or discourage adoption of the promoted behavior.

Although each HBM dimension was found to be significantly associated with the health related behavior, it has provided limited explanations of variance in findings across studies. Attempts have been made to boost the effect of HBM by combining constructs from SCT, specifically self-efficacy. However, the relative contribution of each construct is not yet clear. The HBM is based on the premise that health is a highly valued concern for most people and that "cues to action" are highly prevalent. When these conditions are not met, the model may not be relevant in predicting behavior.

#### 2.1.3 Theory of Planned Behavior

Ajzen's Theory of Planned Behavior (TPB) (1991) and its predecessor, the Theory of Reasoned Action (TRA) (1985), focus on the prediction of behavioral intentions as the direct antecedent to behavior itself. According to these models, predictors of behavior intention are: (1) an individual's "attitudes" toward the behavior, which are influenced by his and her beliefs about the likelihood and desirability of outcomes resulting from the behavior; (2) the "subjective norm" toward the behavior, which is determined by perceived expectations of important others about the behavior and motivation to comply with these perceived expectations. A recent

refinement of the model included "descriptive norms" as part of the normative beliefs component. Descriptive norms are what an individual perceives as others' actual performance of a particular behavior. The TPB also incorporates a concept similar to Bandura's construct of selfefficacy, namely control beliefs.

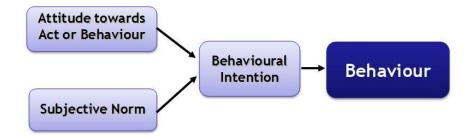


Figure 3. The Theory of Reasoned Action, predecessor of the TPB

Figure 3 shows the two types of beliefs that determine an individual's intention to perform certain behavior. When attitudes and subjective norms are favorable, and perceived behavior control is high, an individual should have a strong intention to perform the behavior. However, these predictors do not solely explain the ultimate execution of the behavior, as actual behavioral control plays an important role as well. Perceived behavioral control can serve as a proxy for actual control over a behavior; as such, it may contribute to the prediction of actual behavior. In sum, successful performance of the behavior will be a result of both intention and sufficient control over the internal and external factors that influence such performance.

The TRA and TPB explain a large proportion of the variance in behavioral intention and predict a number of different behaviors, including health behavior. Specifically for the TPB, a meta-analysis by McEachan and colleagues (McEachan, Conner, Taylor, & Lawton, 2011) shows that the TPB explained 19.3% of the variance in behavior and 44.3% of the variance in intervention across studies. Furthermore, the study found that the TPB more successfully predicted behavior in the shorter term than behavior in the longer term.

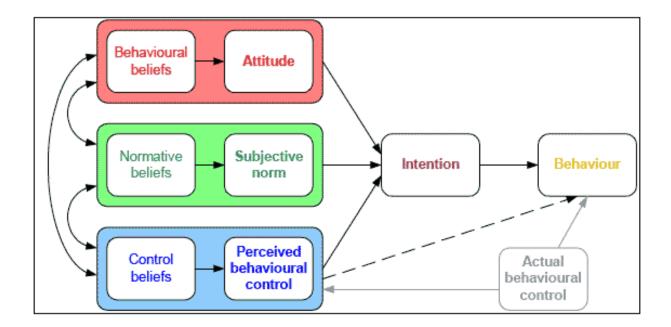


Figure 4. Theory of Planned Behavior (Ajzen, 2015)

## 2.1.4 Information-Motivation-Behavioral Skills Model

The Information-Motivation-Behavioral skill model (IMB) borrowed elements from earlier work to construct a conceptually-based, generalizable, and simple model to guide thinking about complex health behaviors. The IMB constructs include the following: (1) information is the basic knowledge about a medical condition, which might include how the disease develops, its expected course and effective strategies for its management; (2) motivation encompasses personal attitudes towards the adherence behavior, perceived social support for such behavior, and the individual's subjective norms or perceptions of how others with this medical condition might behave; (3) behavioral skills include the specific behavioral tools or strategies necessary to perform the behavior, such as enlisting social support and other self-regulation strategies.

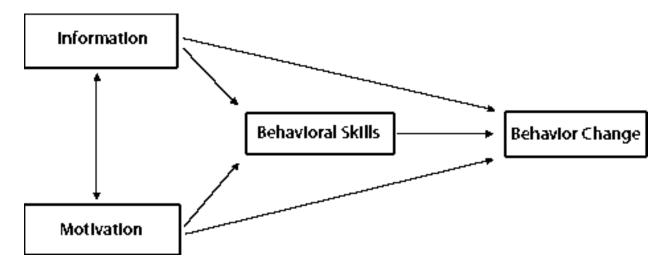


Figure 5. Information-Motivation-Behavioral Skills Model

The IMB model demonstrates that information is a prerequisite for changing behavior but in itself is insufficient to achieve this change. Motivation and behavioral skills are critical determinants and are independent of behavior change. Information and motivation work largely through behavioral skills to affect behavior; however, when the behavioral skills are familiar or uncomplicated, information and motivation can have direct effects on behavior (Figure 5). The relationship between the information and motivation constructs is weak. In other words, a highly motivated person may have little information, or a highly informed person may have low motivation. However, in the IMB model, the presence of both information and motivation increase the likelihood of behavior change.

Interventions based on this model have been effective in influencing behavioral change across a variety of clinical applications, such as changing risky behavior (Jeffrey D Fisher, Fisher, Bryan, & Misovich, 2002), adherence to medication regiments (Starace, Massa, Amico, & Fisher, 2006), and diabetes self-care (Osborn & Egede, 2010). In both prospective and correlational studies, the information, motivation and behavioral skills constructs have accounted for an average of 33% of the variance in behavior change (J D Fisher, Fisher, Misovich, Kimble, & Malloy, 1996).

# 2.1.5 Control Theory

Control theory (CT) is a general approach to understanding the behaviors of dynamic systems with inputs and how behavior is modified by feedback. The usual objective of control theory is to control a system so that its output follows a desired output reference. The difference between actual and desired output, called the error signal, is applied as feedback to the input of the system in order to bring the actual output closer to the reference, as illustrated in Figure 6.

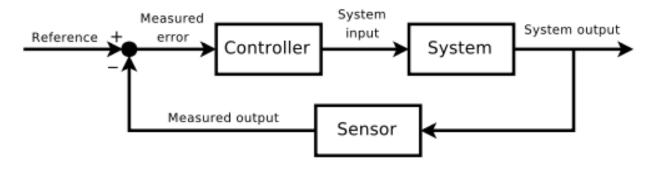


Figure 6. The concept of feedback loop in control theory

In 1982, Carver and Scheier recommended the use of CT as a model of human functioning (Carver & Scheier, 1982). They used a basic unit of cybernetic control that consists of:

- a) Input function, the sensing of present conditions
- b) Comparator, comparing perception (result from input function) with reference value
- c) Output function, where a behavior is performed if a discrepancy is perceived between present state and the reference value
- d) Impact on environment, where the behavior from output function does not encounter the discrepancy directly but by having an impact on the system's environment, which in turn creates a change on present condition, leading to

different perceptions. Other than the behavior, external disturbance may also affect the impact. External disturbance influences the present state separately from the system's own action. For example, a government-mandated tax increase on tobacco influences the outcome of smoking cessation intervention; however, it was not part of the intervention system.

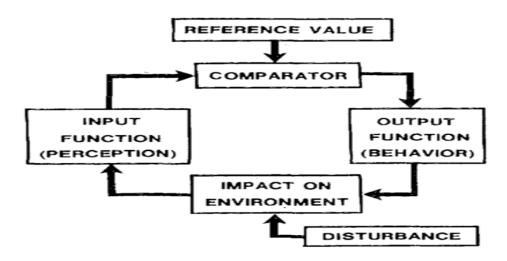


Figure 7. The basic unit of cybernetic control (Carver & Scheier, 1982)

#### 2.1.6 Taxonomy of Behavior Change Technique

A standardized definition of techniques used in behavior change interventions is important to show the generalizability of those interventions, without which it would be difficult to replicate effective interventions. Furthermore, without a standardized definition, it would be hard to identify techniques contributing to effectiveness across interventions. After reviewing 195 published descriptions of behavioral health interventions, Abraham and Michie (2008) proposed taxonomy of behavior change techniques (BCT) as a way to standardize various theoretical frameworks available for health behavior interventions Table 1).

 Table 1. Definitions of 26 behavior change theories (BCT) and illustrative theoretical frameworks (Abraham & Michie, 2008)

Technique		Theoretical Framework	Definition
1.	Provide information about behavior link	IMB	General information about behavioral risk
2.	Provide information on consequences	TRA, TPB, SCT, IMB	Information about the benefits and costs of action or inaction
3.	Provide information about others' approval	TRA, TPB, IMB	Information about what others think about the person's behavior and whether others will approve or disapprove of any proposed behavior change
4.	Prompt intention formation	TRA, TPB, SCT, IMB	Encouraging the person to decide to act or set a general goal
5.	Prompt barrier identification	SCT	Identifying barriers to performing the behavior and plan ways to overcome them
6.	Provide general encouragement	SCT	Praising or rewarding the person for effort or performance without its being contingent on specified behaviors or standards of performance
7.	Set graded tasks	SCT	Setting easy tasks, and increase difficulty until target behavior is performed
8.	Provide instruction	SCT	Telling the person how to perform a behavior and/or preparatory behaviors
9.	Model or demonstrate the behavior	SCT	An expert's showing the person how to correctly perform a behavior
10.	Prompt specific goal setting	СТ	Detailed planning of what the person will do, including a definition of the behavior that specifies frequency, intensity, or duration as well as at least one context, i.e., where, when, how, or with whom

# Table 1 (continued)

Technique	Theoretical Framework	Definition
11. Prompt review of behavioral goals	СТ	Review and/or reconsideration of previously-set goals or intentions
12. Prompt self- monitoring of behavior	СТ	Record-keeping of specified behavior(s), e.g., in a diary
13. Provide feedback on performance	СТ	Providing data about recorded behavior or evaluating performance in relation to a set standard or others' performance
14. Provide contingent rewards	OC	Praise, encouragements, or material rewards that are explicitly linked to the achievement of specified behaviors
15. Teach to use prompts or cues	OC	Teaching the person to identify environmental cues that can be used to remind them to perform a behavior, including times of day or elements of contexts
16. Agree on behavioral contract	OC	Agreement of contract specifying behavior to be performed so that there is a written record of the person's resolution witnessed by another
17. Prompt practice	OC	Prompting the person to rehearse and repeat the behavior or preparatory behavior
18. Use follow-up prompt		Contacting the person again after the main part of the intervention is complete
19. Provide opportunities for social comparison	SCT	Facilitating observation of non-expert others' performance
20. Plan social support or social change	Social support theories	Prompting consideration of how others could change their behavior to offer the person help or social support, including the "buddy" system

# Table 1 (continued)

Technique	Theoretical Framework	Definition
21. Prompt identification as a role model		Indicating how the person may be an example to others and providing opportunities for the person to set a good example
22. Prompt self-talk		Encouraging use of self-instruction and self- encouragement (aloud or silently) to support action
23. Relapse prevention	Relapse prevention therapy	Following initial change, helping identify situations likely to result in re-adopting risk behaviors or failure to maintain new behavior and helping the person plan to avoid or manage these situations
24. Stress management	Stress theories	A variety of possible specific techniques that do not target the behavior but seek to reduce anxiety and stress related to that behavior
25. Motivational interviewing		Prompting the person to provide self-monitoring statements and evaluation of their own behavior to minimize resistance to change
26. Time management		Helping the person make time for behavior, e.g., to fit into a daily schedule

*IMB: information-motivation-behavioral skills model; TRA: theory of reasoned action; TPB: theory of planned behavior; SCT: social-cognitive theory; CT : control theory; OC: operant conditioning.* 

# 2.2 COGNITIVE BEHAVIORAL THERAPY (CBT)

The precursors of CBT can be traced to the development of behavior therapy in the early 20th century. One of the most well-known behaviorally-centered therapeutic approach is proposed by B. F. Skinner, which latter known as *operant conditioning* (Skinner, 1953). In operant conditioning, the strength of a behavior is modified by behavioral reinforcements, which can either positively or negatively modify the behavior. Also, the behavior is controlled by discriminative stimuli which come to signal the behavior's consequences. Skinner's philosophy of behavioral science is considered radical behaviorism, which assumes that behavior is a consequence of environmental histories of reinforcement; private events such as thinking, cognitions, perceptions, and unobservable emotions are not considered as causes of a behavior. This emphasis on behavioral factors constituted the "first wave" of CBT.

Soon after Skinner, Aaron Beck developed a form of psychotherapy to treat depression that he originally called "cognitive therapy" in the 1960s. Beck's cognitive therapy consists of a structured, short-term, present-oriented psychotherapy for depression, directed toward solving current problem and modifying dysfunctional thinking and behavior (Beck, 1964). Overtime, Beck and others have successfully adapted this type of therapy to a diverse set of populations with a wide range of behavioral health diagnoses. The focus techniques and the length of treatment in each adaptation may vary; however, the theoretical assumptions themselves have remained constant. Cognitive therapy is considered as the "second wave" of CBT. Subsequently, CBT is considered as the merge between these two, behavior therapy and cognitive therapy.

The central notion of CBT is the idea that an individual's behavioral and emotional responses are influenced by that person's cognition, which determines how they perceive things. For example, people are only angry or sad if they think that they have reason to be angry or sad.

It is not the situation *per se*, but rather our perceptions, interpretations, and expectations of events that are responsible for the emotions. Dobson and Dozois (2010) expanded this notion into three fundamental propositions of CBT:

- 1) Cognitions affect behavior
- 2) Cognitions may be monitored and altered
- Desired behavioral changes can be effected through cognitive changes and behavioral experiments

The first CBT proposition, that cognitions or cognitive activities affect behavior, is based on the basic mediation model (Mahoney, 1977). There is now overwhelming evidence to support the proposition that cognitive appraisal of events can affect the response to those events, and there is clinical value in modifying the content of these appraisals (Dobson & Dozois, 2010; Granvold, 1994; Hollon & Beck, 1994). The second CBT proposition states that cognitive activity may be monitored and altered, assuming that we may gain access to cognitive activity and that cognitions are knowable and assessable. However, access to cognitions may not be perfect, and people may report cognitive activities on the basis of their likelihood of occurrence rather than actual occurrence. Thus, there is reason to believe that in some cases, there are biases in cognitive reports, and that further validation of cognitive reports is required. The third proposition states that desired behavior change may be achieved through cognitive change. This is a direct result of the adoption of the cognitive mediation model mentioned in the first CBT proposition.

CBT-based interventions are probably the most extensively researched form of psychological intervention. The effects of CBT have been studied for a wide variety of disorders and health problems, ranging from mental health disorders, such as anxiety disorders

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(Cartwright-Hatton, Roberts, Chitsabesan, Fothergill, & Harrington, 2004; Pramana & Parmanto, 2014), depression (Hollon et al., 2002), to health conditions, such as sleep problems (Charles M. Morin, Culbert, & Schwartz, 1994), chronic pain (Gatchel & Rollings, 2008; Turk, 2003) and many others. Almost all of these studies report that CBT has positive effects on each health condition that they intend to treat.

Despite the effectiveness of the treatment and overall low cost relative to other treatments, the majority of people with behavioral and psychological problems do not have easy access to CBT services. Unlike that involved with psychiatric medications, there is no sizable industry promoting CBT due to the limited availability of expert clinicians needed to perform the treatments (Hofmann, 2011).

# 2.3 ECOLOGICAL MOMENTARY ASSESSMENT/INTERVENTION

Ecological Momentary Assessment (EMA) is defined by the repeated collection of real-time data on participants' momentary states in the natural environment (Shiffman et al., 2008). EMA involves repeated assessment of individuals in real time, over time, in their natural environment and across different contexts, enabling a more comprehensive understanding of the frequency, intensity, and duration of both physical and emotional symptoms. EMA may circumvent recall bias, and the method also has the potential to improve insight, as data collection focuses on current symptoms and involves multiple assessments taken over time. As a result, EMA, unlike retrospective reporting, captures fluctuations in emotions from day to day, which may be more informative than retrospective reporting for understanding overall mood. EMA is not a single research method, but rather a framework that encompasses a range of pre-existing methods, including: diary, behavioral observation, self-monitoring, time budget studies, experience sampling method (ESM), and ambulatory monitoring (Stone et al., 2007). Stone et al. (2007) also suggest that EMA is more effective for those willing to use technology. EMA may not suitable for assessing experiences or symptoms that are rare.

Ecological Momentary Intervention (EMI) is an intervention that is delivered using the same principle as EMA, e.g., on participants' momentary states and in their natural environment. EMI can be delivered in many forms ranging from unstructured clinical recommendations (e.g., information about relaxation techniques to patients with anxiety) to more structured interventions (e.g., a person participating in a smoking cessation intervention receives tips on their smartphone app for dealing with cravings during a time when they typically smoke a cigarette). EMI can be incorporated into existing interventions or ongoing treatments (medical or psychological), or it can be implemented on its own.

EMI has several benefits compared to standard in-clinic intervention. First, EMI extends interventions beyond the standard treatment context by providing support in patients' everyday lives, as compared to being delivered only during office visits, for example. Second, EMI provides an opportunity for patients to apply new skills and behaviors that they learned from the intervention to their actual experiences. Therefore, EMI can reinforce the systematic use of treatment components in real-world settings, thus generalizing the intervention program's impact (Heron & Smyth, 2010).

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## 2.4 JUST-IN-TIME ADAPTIVE INTERVENTION

In most research-based interventions intended for promoting and maintaining a behavior change, a single composition, type or dosage of treatment has been offered to all program participants within an intervention group. Although it is recognized that individuals may have different intervention needs, an intervention is generally assumed to work with the same efficacy across participants; even if it may have fewer, or even no, relevant components for that individual.

Recognizing the above limitations, *adaptive* interventions have emerged as a new alternative perspective on research-based health behavior interventions. In contrast to traditional *fixed* intervention, an adaptive intervention assigns different dosages of certain program components across individuals, and/or within individuals across time. Dosage varies based on the individual's needs, and there are decision rules linking characteristics of the individual with specific dosage and types of program components. Different types of program components may be assigned to different individuals, and there may be individuals who do not receive certain components at all (zero dosage). Conceptually, this personalization of treatments resembles standard clinical practice; however, the decision rules in adaptive intervention need to be explicitly defined in order to maintain replicability.

In an adaptive intervention, the assignment of a particular level of dosage and/or type of treatment is based on the individual's values on variables that are expected to moderate the effect of the treatment component. These variables are referred to as *tailoring variables*. In reality, the number of potential tailoring variables can be very large and depend on the researchers to select a manageable number of them to include in the study. Common types of tailoring variables include demographic characteristics or context characteristics representing factors that influence the efficacy of various types or dosages of intervention. The logic is that the level or type of

intervention required to address the needs of individuals varies according to these tailoring variables. For example, individuals who have a higher particular risk factor may require more intensive intervention, whereas less intensive interventions will be sufficient for individuals who have less or none of this risk factor. The intervention can also be adapted over time; in this case, tailoring variables are assessed periodically so that the intervention can be adjusted on an ongoing basis according to individual changes in the tailoring variable. The tailoring variable might reflect a proximal outcome, with dose adjusted based upon each participant's progress toward predefined thresholds. For example, in sleep intervention, these thresholds can be sleep efficiency, total minutes in bed, or total minutes of wakefulness after sleep onset. Based on these thresholds, prescribed sleep time is then adjusted.

Furthermore, "intervention" in adaptive intervention constitutes not only the treatment components but also the entire system for assigning and adapting dosage. In other words, the intervention itself includes (1) identification of adaptive components and related tailoring variables, (2) measurement of tailoring variables, (3) derivation of decision rules, and (4) implementation of decision rules (Collins et al., 2004).

The aforementioned dosage adjustment can occur at intervention initiation (i.e., tailored or personalized based on initial assessment), during the course of the intervention, or both (Riley et al., 2011). The concept of "just-in-time" is used to characterize interventions that adjust based on data obtained during the course of the intervention (Intille, Kukla, Farzanfar, & Bakr, 2003). With the increasing availability of mobile technology, this concept has been expanded into a new framework called Just-In-Time Adaptive Intervention (JITAI). JITAI is defined as adaptive intervention delivered via a mobile device, anytime, anywhere (Peres, 2013). Delivering the intervention via mobile devices allows the assessment of the tailoring variable and adjustment of

the treatment conducted *in-vivo* during patients' daily lives, where most of the needs for intervention occur.

## 2.5 SOFTWARE DEVELOPMENT LIFE CYCLE (SDLC)

The systems development life cycle (SDLC) is a framework used in project management that describes the stages involved in a system's development, from an initial feasibility study through maintenance of the completed system. A wide variety of SDLC methodologies have been developed to guide the processes involved, including the waterfall model; rapid application development (RAD); prototyping; the fountain model; the spiral model; build and fix; synchronize-and-stabilize; and Iterative and Incremental Development (IID). Each method has its own recognized strengths and weaknesses. A summary of various SDLC methodologies and their characteristics (advantages and disadvantages) has been published by the Center for Medicare and Medicaid Service (CMS) Office of Information Service (CMS, 2008).

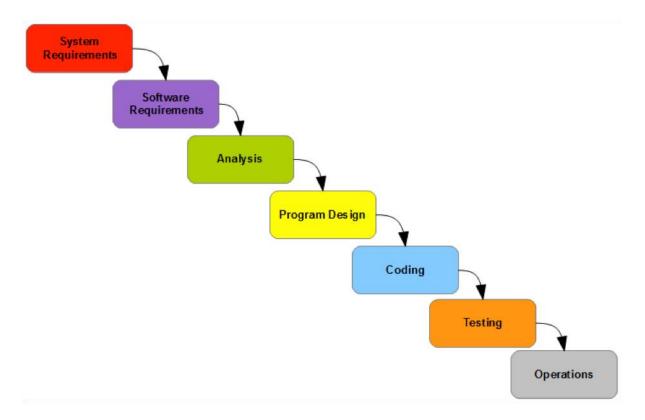


Figure 8. Software Engineering Waterfall Model

The waterfall model gives a fundamental description of distinguishable and sequential (perhaps iterative) steps in system development. The first formal description of the waterfall model was cited in an article by Winston W. Royce (1970), though Royce did not use the term "waterfall" in his article. It describes the system development as a sequential design process in which progress is seen as flowing steadily downwards, like a waterfall, through the phases of *Conception, Initiation, Analysis, Design, Construction, Testing, Production (Implementation), and Maintenance.* 

These sequential phases are described in the following list:

1. *Requirements specification:* identify the problems that a new system is supposed to solve, its operational capabilities and its desired performance characteristics

- Design: define the interconnection and resource interfaces between system subsystems, components and modules in ways suitable for their detailed design and overall configuration management
- 3. *Construction (or implementation or coding):* codify the preceding specifications into operational source code implementations and validate their basic operation
- 4. *Testing and Verification:* affirm and sustain the overall integrity of the software system architectural configuration through verifying the consistency and completeness of implemented modules, verifying the resource interfaces and interconnections against their specifications, and validating the performance of the system and subsystems against their requirements
- 5. Installation: provide directions for installing the delivered software into the local computing environment, configuring operating systems parameters and user access privileges, and running diagnostic test cases to ensure the viability of basic system operation
- 6. *Maintenance*: sustain the useful operation of a system in its host/target environment by providing requested functional enhancements, repairs, performance improvements, and conversions

The simplicity of the step-by-step approach of the waterfall model theoretically makes it easier to measure progress, to ensure the quality of each step and to conserve resources. However, waterfall model provides little room for iteration. In this dissertation, the software development part required incremental phases, with several iterative processes within each phase, e.g., the JITAI application architecture development phase, the clinician portal development phase, and the cross-platform mobile app development phase. For that reason, the SDLC methodology used is Iterative and Incremental Development (IID), which includes the steps described in the waterfall methodology; however, the IID proposes that instead of having steps which flow steadily downward, development processes develop a system feature-by-feature during self-contained cycles of analysis, design, development and testing. Ultimately, it is expected that the IID will produce a stable, fully-integrated and tested, partially-complete system that incorporates all of the features of all previous iterations (Figure 9).

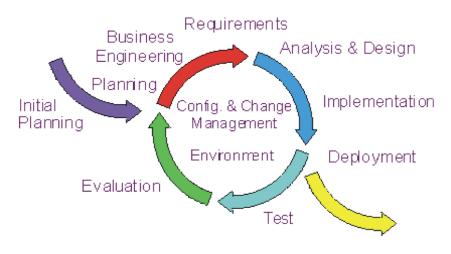


Figure 9. Iterative and Incremental Development

## 2.6 USABILITY EVALUATION

Usability testing is a technique used in user-centered interaction design to evaluate a product by testing it on real/intended users (Nielsen, 1994). Usability itself is not a one-dimensional property of a user interface; it has multiple components that are traditionally associated with these five usability dimensions, casually known as the 5Es:

1. *Easy to Learn*: The system should be easy to learn so that the user can rapidly start getting some work done with the system.

- 2. *Efficiency*: The system should be efficient to use so that once the user has learned the system, a high level of productivity is possible.
- 3. *Effective*: The system should be able to completely and accurately perform its intended functions.
- 4. *Error Tolerant*: The system should have a low error rate so that users make few errors during the use of the system and so that if they do make errors, they can easily recover from them; furthermore, catastrophic errors must not occur.
- 5. *Engaging*: The system should be pleasant to use so that users are subjectively satisfied when using it; i.e., they should like it.

To evaluate the five dimensions of usability, the formative usability assessment typically utilizes the following three protocols: 1) think-aloud assessment, 2) post-study questionnaire, and 3) in-depth semi-structured interview.

First, think-aloud assessment (or think-aloud protocols, or TAP; also talk-aloud protocol) is a method used to gather data in usability testing in product design and development. This protocol was first introduced in the usability field by C. Lewis (1982) and subsequently explained in more detail in another work (C Lewis & Rieman, 1993).

Second, the post-study questionnaire was designed to quantitatively evaluate the five usability factors. In this dissertation, the questionnaires that will be used are System Usability Scale (SUS) (Brooke, 1996) and a modified version of Telerehabilitation Usability Questionnaire (TUQ). The SUS is a simple, ten-item scale giving a global view of subjective assessments of usability. The TUQ, which is currently undergoing validation, measures several usability factors, including usefulness, ease of use, effectiveness, reliability, and satisfaction. Twenty-one questions were derived from previously validated questionnaires, including the Technology Acceptance Model, Perceived Usefulness/Ease of Use, the Telemedicine Satisfaction Questionnaire, and the Post-Study System Usability Questionnaire/Computer System Usability Questionnaire (Davis, 1993; J. R. Lewis, 1995). However, since the TUQ was originally designed for video-conferencing-based telerehabilitation sessions, some of the items on TUQ are not applicable to this study.

Finally, in-depth semi-structured interviews were used to clarify and to elicit more elaborative explanations on any usability problems or improvements found in the first method (think-aloud) or second method (post-study questionnaire).

## 3.0 RELATED WORKS

# 3.1 INTERNET INTERVENTION MODEL

Ritterband et. al. (2009) have proposed a behavioral intervention model through the use of the Internet. The model combines multiple sources of information: theories of motivation, other psychological models, social marketing/advertising strategies, Web-based design/development techniques, information about architecture and design, models of knowledge transfer and behavior change, and general research and clinical experience.

The model was built based on the hypothesis that effective Internet intervention programs produce change in behaviors and reduce unwanted symptoms (as well as maintain improvement) via the following steps: the *user*, influenced by *environmental* factors, affects *website* use and adherence, which is influenced by support and website characteristics. Website use leads to behavior change via different mechanisms of change. Behavior change impacts physiology and target behaviors to bring about symptom improvement, and treatment maintenance helps users maintain these gains.

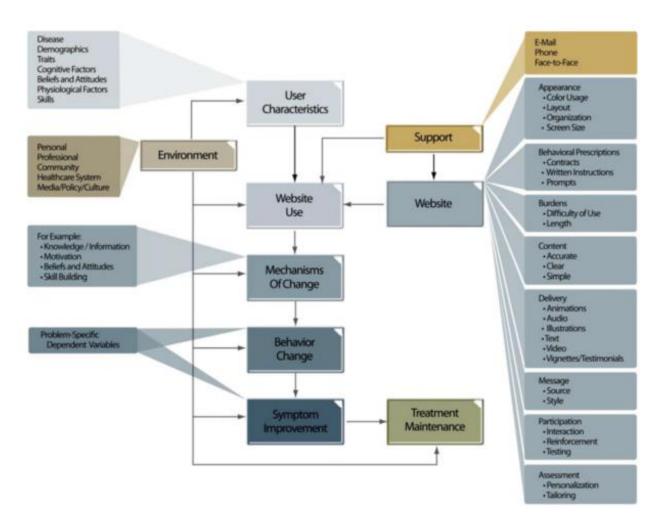


Figure 10. Internet Intervention Model (*Ritterband et al.*, 2009)

The JITAI behavior model and Ritterband's Internet intervention model tackle different domain of intervention: mobile app-based versus web-based. Mobile app-based interventions are different than web based interventions, because mobile devices/smartphones allow richer interaction modality. For example, smartphones allow the deliverance of real-time notification/reminder into the patient. Smartphones may also support automatic behavioral, environmental, and context assessment using various sensors that available in the devices.

Also, the JITAI behavior model is a dynamic model, while the Internet behavior change model is a traditional, static, step-by-step model.

# 3.2 CROSS-PLATFORM MOBILE APPLICATION FOR HEALTH INTERVENTION

Published articles on the use of cross-platform mobile applications in health intervention are still very limited. For example, Zhuang et al. (2013) have developed a hybrid (native application and web/HTML5-based application) cross-platform solution for mobile assistive technology. They found that system-level concerns, such as the performance and efficiency of data storage, became a major roadblock to their implementation. As a remedy, they suggest using as much remote data storage and processing as possible. However, problems of synchronization, data transfer security, and connectivity requirements arise if opting for the remote-processing approach.

 Table 2. Performance Comparison (Zhuang et al., 2013)
 Co

	Local Database	Remote Database
Application Size	39.21 MB	1.29 MB
Require Network	No	Yes
Copy Database	6737 ms	0 ms
Open Database	100 ms	0 ms
Get Geolocation	4 ms	5 ms
Database Query	3262 ms	1483 ms
Total Time	10103 ms	1488 ms

Burnay et al. (2013) also developed a cross-platform mobile application using a similar technological approach as Zhuang et al., albeit targeting allergic rhinitis asthma (ARA) patients. They named the mobile app m.Carat. In m.Carat, an ARA patient may save their daily symptoms and fill out a questionnaire to assess whether their asthma has been under control in the past 4 weeks. If the patient has an exacerbation, they may record the date and time, what triggered it, and the relief medication used. The patients must also record hospital admission events related to their ARA conditions.

m.Carat architecture is based on a client-server model, so one system server provides services to multiple clients' apps. m.Carat uses both local and remote (server-side) databases, and a synchronization algorithm keeps both databases consistent. To achieve this goal, they implemented the synchronization algorithm shown in Figure 11.

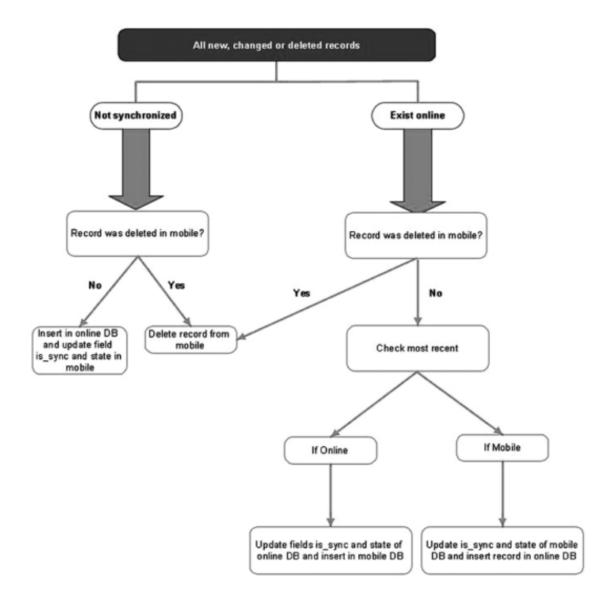


Figure 11. Synchronization algorithm (Burnay et al., 2013)

In relation to the current study, Zhuang's study alerted us to the challenges of developing and implementing a cross-platform mobile application, while Burnay's findings provided ideas on local and remote database synchronization process. A modified version of Burnay's synchronization has been implemented in this dissertation.

## 4.0 SLEEP PROBLEMS AND INTERVENTION: CASE STUDY

## 4.1 INTRODUCTION

Sleep is a fundamental component of physical and brain health. Sleep is essential for survival and sustaining homeostasis, which has effects on a wide range of body functions, including learning and memory, thinking ability, attention and concentration, mood and emotion regulation (Daniel J Buysse et al., 2008), brain functions, cardiovascular and respiratory functions (Cappuccio et al., 2007), immune functions (Cohen, Doyle, Alper, Janicki-Deverts, & Turner, 2009), weight and blood sugar (M. H. Hall et al., 2008), and tissue growth and repair (Ohayon, 2002). Sleep can adapt to unusual or extreme demands and conditions. However, prolonged sleep deficiency can compromise mental and physical health and lead to severe and chronic organ damage and failure (Germain, 2014).

One prominent sleep problem is insomnia. Insomnia is defined as difficulty in falling asleep, difficulty staying asleep, and non-restorative sleep (AASM, 2005). This contributes to waking symptoms such as fatigue, impaired concentration, and mood disturbance (Roth, 2007). Approximately 30% of adults in the United States have at least one of the symptoms of insomnia (Ancoli-Israel & Roth, 1999). Rates of insomnia itself, based on criteria from the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)*, are approximately 5% to 20%

in the general adult population (Ohayon, 2002) and 20% to 30% in primary care medical settings (Shochat, Umphress, Israel, & Ancoli-Israel, 1999; Simon & VonKorff, 1997).

Generally, there are two types of treatment for insomnia: pharmacological and behavioral. Hypnotic agents such as benzodiazepine receptor agonist (BZRA) drugs, are widely available, easy to use, and have rapid and sustained efficacy (Krystal, Erman, Zammit, Soubrane, & Roth, 2008). However, BZRA and other pharmacological treatment may lead to dependence and substance abuse (Goodwin & Hasin, 2002). Behavioral treatments such as Cognitive Behavioral Therapy for Insomnia (CBT-I) (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001) have been found to be as effective as pharmacological treatments (Smith et al., 2002). Furthermore, these behavioral treatments are often preferred by patients (C M Morin, Gaulier, Barry, & Kowatch, 1992) and have been shown to have both short-term and long-term efficacy (Irwin, Cole, & Nicassio, 2006; Webb et al., 2010) with few apparent adverse effects.

## 4.2 COGNITIVE BEHAVIORAL THERAPY FOR INSOMNIA

As mentioned earlier, Cognitive Behavioral Therapy for Insomnia (CBT-I) is the most common non-pharmacological treatment for insomnia. Like other types of cognitive behavioral therapy, CBT-I aims to identify and modify the thoughts and behaviors that are causing problems, in this case to improve sleep.

The first step in treating insomnia with CBT-I is to identify the underlying causes of the insomnia. At the beginning of the treatment, sleep patterns and factors that may be affecting the person's ability to sleep are assessed. This involves keeping a sleep diary for a couple of weeks. The journal helps to identify habits of thought or behavior (e.g., thinking in bed, caffeine

consumption right before bed, and daytime napping) that could be contributing to the person's insomnia. After identifying the possible underlying causes and factors contributing to the insomnia, the person is prescribed with appropriate steps toward better sleep. In CBT-I, these steps may include sleep restriction, stimulus control, healthy sleep practices, relaxation training, and cognitive restructuring with behavioral experiments (Harvey, 2002).

#### 4.2.1 Sleep Restriction

Increasing the amount of wakefulness increases the homeostatic sleep drive and thereby the propensity to fall asleep during the upcoming night. Sleep restriction treatment (Spielman, Saskin, & Thorpy, 1987) involves controlling time in bed (TIB) based upon the person's sleep efficiency. Sleep Efficiency (SE) is the measure of reported Total Sleep Time (TST), the actual amount of time the patient is usually able to sleep, compared with his or her TIB.

#### Sleep Efficiency = (Total Sleep Time / Time In Bed) x 100%

First, a patient's TIB is restricted to TST + 30 minutes, with a minimum of 4 hours and 30 minutes for the military population (Germain et al., 2014) (the minimum limit is 6 hours in older adults (Daniel J Buysse, Germain, et al., 2011)). Based on the patient's sleep diaries, sleep restriction is adjusted for the entire length of treatment (8 weeks). SE in a 5-day window is calculated, and changes are made to TIB according the following rules (Troxel et al., 2012):

- If SE is > 90% (85% in seniors), TIB is increased by 15 minutes
- If SE is < 85% (80% in seniors), TIB is decreased to the average TST
- No changes are made if SE is between 85% and 90%
- Patients are not permitted to lie down or nap at times other than the assigned TIB.

Daytime sleepiness is a side effect during the early phase of treatment; the sleep restriction process is adjustable to optimize patient safety especially in this early phase.

## 4.2.2 Stimulus Control

The concept of stimulus control therapy (SCT) for the treatment of insomnia was first proposed by Bootzin (1973). Stimulus control therapy for insomnia is based on a learning analysis of sleep in which falling asleep is conceptualized as an instrumental act performed to produce reinforcement sleep. External and internal cues to the individual that are associated with the onset and maintenance of sleep become discriminative stimuli for the occurrence of this reinforcement. Consequently, difficulty in falling asleep may be due to inadequate stimulus control: stimuli for sleep may not have been established or stimuli for activities that interfere with sleep may be present.

In SCT, a person with insomnia is guided to do the following:

- Go to bed only when sleepy
- Do not use bed for anything other than sleep. Sexual activity is the only exception to this rule.
- Get up and move to another room if sleep-onset does not occur "immediately" (within 20 minutes)
- Set alarm and wake up at the same time every morning irrespective of how much sleep is accumulated during the night
- Do not nap during the day

## 4.2.3 Healthy Sleep Practices

Healthy sleep practices education (Gehrman, 2011) aims to provide information about environmental factors (light, noise, temperature) and behaviors (diet, exercise, substance use) that may interfere with or promote better sleep. Sleep hygiene may include general sleepfacilitating recommendations, such as not going to bed hungry, not consuming caffeinated drinks in the evening, and allowing time to relax before bedtime.

#### 4.2.4 Relaxation

Relaxation is commonly used as a form of therapy for disorders in which cognitive and physiological arousal plays an important role. As a treatment for insomnia, relaxation works to diminish somatic and cognitive arousal that delays and/or disrupts sleep. Techniques include progressive muscle relaxation (PMR), autogenic training, meditation, guided imagery, and biofeedback.

## 4.2.5 Cognitive Therapy

Cognitive therapy aims to alter sleep-related cognitions that are presumed to contribute to the maintenance and exacerbation of insomnia. The basic premise is that appraisal of a given situation (e.g., sleeplessness) can trigger negative emotions (e.g., fear and anxiety) that are incompatible with sleep. Specific treatment targets include:

- Unrealistic expectations about sleep requirements
- Incorrect attributions about the cause of insomnia

- Excessive worry about sleep loss and its consequences
- Misconceptions about healthy sleep practices

During a therapy session, cognitive therapists (1) identify these automatic thoughts and dysfunctional beliefs about sleep; (2) point out the connection between cognitions, emotions, and behaviors; (3) arrange a situation for the individual to test these flawed beliefs (i.e., behavioral experiments); (4) substitute more realistic interpretations for these biased cognitions (Belanger, Savard, & Morin, 2006).

### 4.3 BRIEF BEHAVIORAL THERAPY FOR INSOMNIA (BBTI)

BBTI was developed to address common challenges encountered in the dissemination of evidence-based CBT-I. The first challenge relates to access to the service; the majority of patients with insomnia seek care at their primary care clinics, which usually are not designed for clinical sleep interventions (Germain et al., 2006). While CBT-I requires weekly visits to a sleep clinic over a period of 8 weeks, BBTI requires only two in-person visits over a period of 4 weeks; this offers a more feasible format for delivering behavioral sleep interventions in primary care clinic settings. A second challenge relates to the qualifications of the provider offering the treatments. CBT-I requires doctoral-level clinicians with extensive training in behavioral sleep medicine to manage and deliver the treatment. These types of sleep specialists are rarely available in primary care settings. In contrast, BBTI can be delivered by Master's-level clinicians, such as nurses or social workers with minimal supervision (Daniel J Buysse, Germain, et al., 2006). BBTI may offer a first-line intervention for the majority of

patients seen in primary care settings, whereas CBT-I may be best for those who require more specialized treatments.

Similar to standard CBT-I, brief behavioral therapy for insomnia (BBTI) combines and emphasizes the implementation of stimulus control and sleep restriction principles. Education about healthy sleep practices and behaviors that affect sleep quality is also provided in BBTI in a way that is comparable to CBT-I. However, BBTI differs from standard CBT-I in terms of number of visits and intervention length; BBTI uses a reduced number of in-person visits (two in-person visits compared to six to eight in CBT-I) and has a shorter intervention length (4 weeks instead of 8 weeks in CBT-I). In addition, BBTI does not systematically address erroneous beliefs about sleep (cognitive therapy) as in CBT-I.

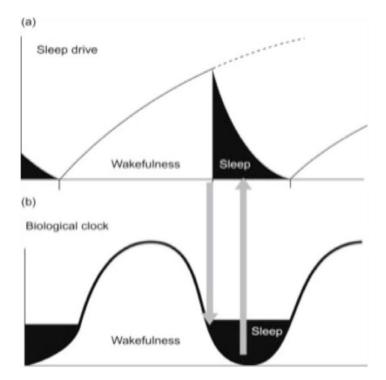


Figure 12. The two-process model of sleep regulation (Borbély, 1982)

Figure 12 shows two major physiological mechanisms that regulate sleep: the homeostatic and circadian drives. The homeostatic sleep drive refers to the propensity for sleep. Duration of wakefulness promotes a higher homeostatic sleep drive. The circadian drive refers to

the variations in brain and body biological processes that are regulated by the biological clock. Our body promotes sleep during darkness, coinciding with the peak of melatonin release from the pineal gland and the decrease of core body temperature. The peak of sleep drive needs to be as closely aligned with the start of biological processes promoting sleep to achieve optimal sleep. When individuals sleep at a suboptimal circadian time, sleep is perceived to be of poorer quality, lighter and prone to more disruptions. Waking behaviors can directly impact these two physiological mechanisms. BBTI aims to modify waking behaviors that increase and regulate the duration of wakefulness (homeostatic drive), and prescribes an individualized sleep and wake time that is consistent with the circadian process. BBTI aims to align the homeostatic and circadian drives by changing waking behaviors to promote restorative sleep and daytime alertness.

## 4.3.1 Step-by-Step Description

As mentioned earlier, BBTI is delivered over four consecutive weeks and includes two individual in-person visits on Week 1 and 3, and telephone appointments on Week 2 and 4. The duration of the first in-person visit is 45 minutes, and the follow-up visit on Week 3 generally lasts no more than 30 minutes. Telephone sessions are conducted to address any question of difficulties that may have arisen in the previous week, to encourage adherence to the prescribed sleep schedule, or to modify the sleep prescription if necessary. These telephone sessions are brief and last no longer than 20 minutes.

The first in-person session aims to provide accurate background information about the individual's mechanisms of sleep regulation and general information about behaviors that influence sleep. This component provides the rationale for both stimulus control and sleep

restriction. The stimulus control intervention in BBTI is similar to that in CBT-I. The formula for sleep restriction, however, is different: BBTI's sleep restriction aims at limiting the number of hours in bed (TIB) to match the actual number of hours spent asleep (TST), plus 30 minutes to allow for normal time to fall asleep and nocturnal awakenings. The prescribed sleep-wake schedule is derived from sleep diary data collected over the previous 7-14 days. In the absence of a sleep diary, retrospective estimates of recent sleep-wake pattern can be used. The prescription process starts with selecting the rise time with the patient and then working backward to establish bedtime. The prescribed sleep-wake schedule should be realistic and accommodate the patient's living conditions and responsibilities. The first session also includes the temporary nature of the prescribed sleep schedule, that time allowed in bed can be increased over time when sleep onset latency (SOL) and wake after sleep onset (WASO) are less than 30 minutes per night on most nights. At the end of the first session, the patient receives the prescribed sleep-wake schedule and also a sleep diary to monitor improvements in sleep, as well as to monitor adherence to the prescribed schedule.

The second in-person visit serves three main purposes: (1) to address possible difficulties regarding the application of the prescribed sleep goals encountered during the previous week; (2) to continue monitoring and reinforcing adherence to treatment recommendations; and (3) to provide education on how to expand time allowed in bed. Based on information collected with sleep diaries, TIB is increased by 15 minutes if sleep latency and WASO are less than 30 minutes on most nights. The patient is then instructed to maintain the new time in bed for one week. If sleep latency and WASO both remain under 30 minutes, then the patient is allowed to add another additional 15 minutes in bed for a week. If sleep latency and WASO exceed 30 minutes on most nights, then the patient is instructed to decrease TIB by 15 minutes. In contrast to

standard CBT-I, modification to TIB in BBTI is determined by maintaining sleep latency and WASO below the 30-minute threshold, rather than based on sleep efficiency under 85%.

#### 4.3.2 Supporting Data/Evidence Base

A clinical trial in the older adult population (Daniel J Buysse, Germain, et al., 2011) corroborated clinically meaningful improvement in sleep (based on self-report questionnaires and sleep diaries) in participants who received BBTI, compared to an information control (IC) group. The study found that the BBTI group had a significantly greater reduction in actigraphybased WASO and sleep latency and a significantly greater increase in sleep efficiency compared with the IC group using mixed models. The BBTI group also had a significantly greater reduction in actigraphically measured TST from pre-treatment to post-treatment. Effect sizes for sleep latency (d = 0.80), WASO (d = 0.67) and sleep efficiency (d = 0.64) were comparable to effect sizes reported in CBT-I trials (Germain & Buysse, 2011). Improvements were maintained at 6 months after the intervention (Daniel J Buysse, Germain, et al., 2011).

In the military population, a randomized controlled trial evaluated the effect of a military version of BBTI (BBTI-MV) compared to an information-only control in combat-exposed Veterans with insomnia (Germain et al., 2014). The study found that both groups experienced significant clinical improvement in insomnia, although the magnitude was greater in the BBTI-MV group. The BBTI-MV group also had a higher response rate (77%) and remission rate (53%). The study suggested that both approaches might provide applicable options in the treatment of insomnia in the military population.

## 4.4 RELATION TO BEHAVIORAL THEORIES

Behavioral sleep treatment by definition requires modifications of malbehaviors that are bad for sleep into behaviors that contribute to healthy sleep. In other words, in order for behavioral sleep treatments to work as intended, behavioral change is warranted. As in any other interventions that require behavioral alteration (i.e., smoking cessation, weight management, and physical activity), behavioral theories can be useful in explaining the outcomes (e.g., observed behavioral changes) of behavioral sleep interventions and, even before that, in designing the intervention (Kerlinger, 1986).

The next question to answer is which behavioral theories are appropriate for behavioral sleep treatments? Mapping the characteristics of behavioral sleep treatments (explained in Section 4.2 and 4.3.1) with the taxonomy of available health behavior theories summarized in Table 1 (Section 2.1.6) may provide the answer. Table 3 lists matching behavioral change techniques and related behavioral theories that correspond to the characteristic of behavioral sleep interventions.

	Technique	Behavioral Theories	Reason for inclusion
1.	Provide information		
	about behavior link	IMB	General information about sleep and its importance
2.	Provide information	TRA, TPB,	Stimulus control, healthy sleep practices, and cognitive
	on consequences	SCT, IMB	therapy contain information on consequences
3.	Prompt intention	TRA, TPB,	Sleep restriction prompt the person to set a restricted sleep
	formation	SCT, IMB	schedule

Table 3. Behavior change technique versus behavioral sleep intervention characteristics

#### Table 3 (continued)

	Technique	Behavioral Theories	Reason for inclusion
4.	Prompt barrier identification	SCT	Stimulus control, healthy sleep practices, and cognitive therapy involve barriers identification and how to overcome them
5.	Provide instruction	SCT	Each part of behavioral sleep intervention provides some type of instructions
6.	Prompt review of behavioral goals	СТ	Part of the adaptive intervention
7.	Prompt self- monitoring of behavior	СТ	The person is asked to keep a sleep diary
8.	Provide feedback on performance	СТ	Feedback about current performance is provided throughout the course of the intervention

*IMB: information-motivation-behavioral skills model; TRA: theory of reasoned action; TPB: theory of planned behavior; SCT: social cognitive theory; CT: control theory.* 

# 4.5 THE NEED FOR MOBILE INTERVENTION AND JITAI

Behavioral sleep treatments have been shown to be safe, effective, and associated with durable improvement (Daniel J Buysse, Germain, et al., 2011; Edinger et al., 2001; Irwin et al., 2006). However, the use of behavioral sleep treatments is still minimal. The pharmaceutical approach (hypnotics) remains the most common sleep treatment despite concerns regarding safety, side effects and potential abuse.

BBTI, with its shorter and less complicated procedures, has the potential to increase dissemination of behavioral sleep interventions and to overcome barriers associated with behavioral interventions. However, the number of clinicians providing the treatment as well as the limited location of clinics that provide the service remains a challenge. With the increasing availability of smartphone technology, a mobile health (mHealth) intervention conducted using smartphone technology has the potential to address this barrier. With the "Bring Your Own Device" (BYOD) approach, this mHealth solution is more economical and has the potential for scalability treatment intervention in large, geographically distributed populations.

Furthermore, BBTI is well-suited to JITAI. A sleep prescription process in BBTI is algorithmically defined with clear rules and decision points, which makes it readily adaptable to computerized applications (in this case, a mobile application or "app"). JITAI eliminates the need for clinicians to calculate treatment parameters manually because the calculation is already programmed within the mobile app and clinician portal. Digitally time-stamping the sleep diary entry also allows more objective monitoring of adherence to the treatment; for example, participants can no longer "cheat" by filling in several days' worth of sleep diary at once.

Adaptiveness of the intervention is the main reason for choosing JITAI as an intervention paradigm. BBTI is an adaptive intervention. For example, a sleep prescription (i.e., sleep restriction schedules, specific sleep education materials, sleep assessments) is tailored for each individual's needs and conditions. This prescription is adjusted when these parameters change. Adaptiveness of the intervention can expand into accommodating the environment and social situation. This is especially true in the military population, where training or deployment may not be compatible with the prescribed sleep treatments.

# 5.0 THE JITAI BEHAVIOR MODEL

# 5.1 CONSTRUCTING BEHAVIOR INTERVENTION MODEL FOR JITAI

The development of health behavioral theories has taken a predominantly intuition-based approach; for example, an expert in a given intervention field first postulated a set of concepts, definitions, and propositions meant to explain behavior by assuming relationships between variables. These postulated theories were then empirically tested one part at a time, commonly using pre- and post-intervention. Hence, most of the current theories of human behavior are largely based on data that provides static snapshots of behavior.

However, with recent developments in mobile and sensing technology, data acquisition is no longer restricted to infrequent (pre- and post-) questionnaires or clinical tests. Nowadays, mobile technologies such as wearable sensors and smartphones can provide a rich stream of continuous data revealing human behavior on a momentary, dynamic, temporally dense, contextualized, and longitudinal basis. These data provide opportunities to understand behavior dynamically in context and in real time, such as understanding behavioral changes in JITAI. In short, the current health behavior theories might not be "up to the task" to answer these new opportunities (Riley et al., 2011).

Furthermore, available theories in human behavior for health interventions may provide useful insights on how behavior-related components of interventions work. However, these theories are not readily implementable for designing and evaluating technology used to deliver this intervention. None of these theories provides technical guidelines to link their components to the potential of currently available technologies in supporting health behavior changes.

Thus, towards this specific aim, the JITAI behavior model is proposed. This model combines characteristic health behavior theories, characteristics of JITAI, and technological characteristics in mHealth. The model should be dynamic, momentary, personalizable, contextualized, and adaptable. The model is conceptually seeded from several health behavior theories, yet data driven, modular and testable.

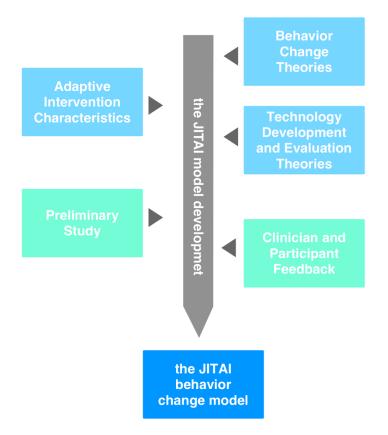


Figure 13. The JITAI behavior model development

#### 5.1.1 Methods

The characteristics of the JITAI behavior model are distilled from the research literatures on fundamental theories and models related to health behavior change (SCT, HBM, TRA, TPB, IMB, CT, see Section 2.1 and Section 4.4), research literatures on JITAI or adaptive interventions using mobile technology (Collins et al., 2004; Intille et al., 2003; Lei et al., 2014; Riley et al., 2011, 2014; Spruijt-Metz & Nilsen, 2014), published systematic review on mobile health interventions (Free, Phillips, Galli, et al., 2013; Free, Phillips, Watson, et al., 2013; A. K. Hall, Cole-Lewis, & Bernhardt, 2015), information architecture and design, preliminary study results, feedback from clinicians and participants during the study, as well as empirical findings and clinical experience.

## 5.1.2 Characteristics

As suggested in Figure 13, the identification of characteristics of the JITAI model started from the existing behavioral models. Social cognitive theory (SCT) provides the simplest explanation about behavior change mechanisms. According to SCT, there are three important factors that influence behavior change: **personal factors**, **environment**, and **the behavior** itself (Bandura, 1986). In addition, Bandura also introduced the importance of **self-efficacy**, one's belief in one's ability to succeed in performing a certain task in a given situation (Bandura, 1997, 1999).

The Health Belief Model (HBM) put greater emphasis on personal factors of behavioral change. According to the HBM, the likelihood of behavior is determined by individual perceptions (self-efficacy), which are moderated by personal factors (such as, age, sex, ethnicity, personality and socioeconomic status). The HBM also includes "**cue to action**" as a factor that

modifies the likelihood of behavior (Becker et al., 1974; Maiman & Becker, 1974). The Theory of Reasoned Action (TRA) and the Theory of Planned Behavior (TPB) added the dimension of **subjective norms** (Ajzen, 1991) in addition to self-efficacy. Subjective norms toward a behavior are determined by how an individual perceives his/her important others' expectations about the behavior. According to Information Motivation Behavior (IMB), **information** is a prerequisite for changing behavior, although in itself, it is not enough (Jeffrey D Fisher & Fisher, 2002). In other words, information can positively influence one's self-efficacy toward performing an intended behavior.

The above-mentioned behavior theories and models are based on describing betweenperson differences, although they lack the ability to account for within-person differences. Therefore, these theories and models have shown considerable success in tailoring health behavior interventions based on pre-intervention factors. However, in adaptive intervention, the tailoring variables are monitored throughout the course of the intervention and adjustments are made whenever necessary – hence the need for within-person descriptions. These adjustments are not limited to the "content" of the interventions but also the timing of the intervention. For example, some individuals may receive frequent cues to perform certain behaviors throughout the course of intervention, while others who are doing well on their own may get only a few or even no cues. The current available behavioral theories and models lack the ability to represent the more within-person **dynamic regulatory** process that JITAI demands (Riley et al., 2011).

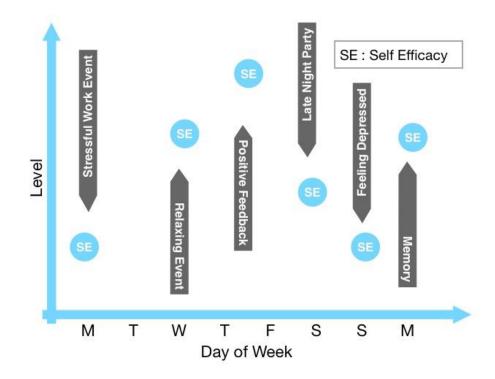


Figure 14. Adaptation of the SCT to represent self-efficacy dynamic over time

The linear and fixed natures of current health behavior theories and models appear to be incompatible with the need for the intra-individual dynamic of JITAI. Bandura acknowledged this paradigm shift toward a dynamic system, pointing out that the SCT is an explicitly dynamic model (Bandura, 2001). However, describing these multifaceted interactions between personal factors, environments, behaviors and an additional time dimension proved to be difficult. Figure 14 illustrates how cumbersome it is to use the SCT as is to represent dynamic processes. The figure shows the self-efficacy level of an individual student towards working on a student paper over a one-week time frame. Therefore, a dynamic system model is needed to supplement, not to replace, the current theories and models.

Control theory (CT) may provide the missing link needed by our current health behavior theories to accommodate the dynamic nature of JITAI. At the core of the CT is the **feedback regulatory process**; the difference between actual output and expected output is applied continuously as feedback to the input of the system. This principle fits well with the concept of adaptive intervention, especially when factoring in the rich real-time longitudinal data that mobile technologies produce in JITAI. The dynamic part of the JITAI model, adaptive intervention, is explained in the next section (5.2).

As explained in Section 1.1, the use of mobile technology has the potential to improve efficacy and access to health behavior interventions. However, a factor that is usually missed in health behavior interventions is that technology itself can provide a barrier to the interventions when the users lack the perceived ability to use the technology. This self-efficacy toward **the use of technology** adds an additional dimension to the JITAI model. Factors that influence this selfefficacy can be explained by human computer interaction theories and software development practices

First, individuals would more likely use a technology product when they perceive the product as "easy to use." A measure of how easy it is to use a product to perform prescribed tasks is called **usability** (Nielsen, 1994). Inclusion of **accessibility** features has also been found to contribute to overall system usability (Yu, Parmanto, Dicianno, & Pramana, 2015). Furthermore, JITAI applications most likely assess, transfer and store sensitive personal health data, therefore raising the concern of **privacy and security** (Luxton, Kayl, & Mishkind, 2012; Watzlaf, Moeini, Matusow, & Firouzan, 2011). Appropriate measures need to be put in place to address privacy and security concerns, including compliance with the federal Health Insurance Portability and Accountability Act (HIPAA). Other technological dimensions of the JITAI application

<sup>&</sup>lt;sup>4</sup> In terms of how easy it is to download/install the mobile application; not to be confused with "accessibility," mentioned earlier.

would promote the use of the application. Personalization involves giving users the ability to customize their interaction experience with a product. Personalization allows users to exercise their preferences, which generally increases their likeability toward the product. Although people tend to like highly usable products, often likeability has less to do with usability than with individual preferences (Microsoft, 2000).

Based on the preliminary study and clinicians' inputs, we confirmed that JITAI is not intended to undermine the importance of **clinicians' roles** in delivering interventions. Rather, JITAI is intended to increase the efficacy and effectiveness of clinicians' supported interventions with the use of mobile technologies. Likewise, the JITAI model needs to take into account the roles of **social supports** (i.e., significant others, care givers, and colleagues).

## 5.1.3 Model Components

In light of the characteristics discussed above, there are eight components to the JITAI model. Each component contains observable and evaluable areas.

## 1. Individual characteristics

Individual (i.e., patients, study participants) characteristics are derived directly from the personal factors of the SCT. These characteristics include mostly fixed demographics, such as age, gender, race, and socioeconomic status (SES). In addition to 1) *demographics*, there are three areas of individual characteristics: 2) *health/behavior disorder*, the primary interest of the intervention, including the severity of the disorder; 3) *comorbidity*, the presence of other diseases or disorders and their severity; 4) *skill*, the familiarity in using mobile technologies; and 5) *self-efficacy*, initial readiness to change

towards treatment behavior. Although demographic variables are mostly fixed variables, other areas are modified to benefit the intervention (e.g., self-efficacy, comorbid disorders, skill).

## 2. Environment

Environmental influences are another component derived from the SCT. A person's environment is composed of a diverse set of variables, including employment/school, the health care system, and societal-level factors such as policy and culture. The environmental factors included in the JITAI model can be physical and/or societal factors, and can either support or inhibit behavior modification.

#### 3. Social Network Structure (SNS)

Several studies have shown that a person's social network structure influences their attitude and beliefs toward behavioral change (Krause, Croft, & James, 2007; Sih, Hanser, & McHugh, 2009). The social network structure (SNS) is part of an individual's social environment. However, in the JITAI model, SNS is treated as a separate component from "environment" due to its inter-personal nature. Several health behavioral theories and models support this argument, including the TPB, TRA, and SCT. SNS variables include, family, significant others, care givers, friends, clinicians, and care providers.

# 4. mHealth Technology

The technological component of mHealth interventions is mobile technology, by which the treatment is delivered, e.g., mobile applications ("apps"), wearable sensors, and smartphones. The mobile technology component needs to accommodate the health behavioral intervention in order to deliver and promote its use. Therefore, the mobile technology component includes issues such as usability, accessibility, burden, contents, content delivery, messaging/communication, and security measures.

# 5. mHealth Uses

The mobile technology use is the actual utilization of the mHealth system. This component includes adherence, amount of usage time, and usage frequency.

# 6. Supports

Scalability is one potential benefit that JTAI provides. In order to achieve effective widescale dissemination, JITAI needs a support mechanism to maintain continuous system utilization. Distribution channels, training programs, reward systems, and clinicians' consultation time (via messaging, phone, or face-to-face) are included among the support components.

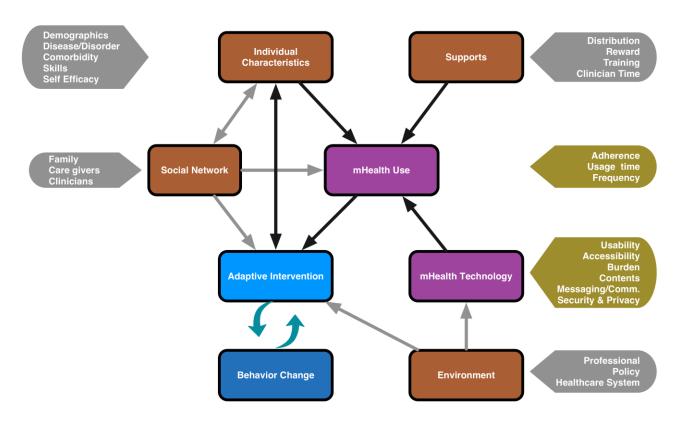
## 7. Adaptive Intervention

Adaptive intervention is the dynamic, adaptive facet of the JITAI model, mainly derived from the CT. Details on the adaptive intervention model are discussed in **Section 5.2**.

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## 8. Behavior Change

The goal of a JITAI intervention is to negate or decrease severity of the health/behavior disorder. Typically, behavior change is necessary to achieve this goal. The behavior change variables will vary between types of intervention (e.g., smoking cessation, weight management, physical activity, insomnia treatment). For example, in insomnia treatment, variables such as time in bed, wake up after sleep onset, sleep efficiency, and sleep practices are targeted for change. The same variables, however, may not hold true for physical activity interventions. Researchers need to identify which behaviors are associated with achieving positive outcomes.



# 5.1.4 The JITAI Model

Figure 15. The JITAI behavior intervention model

The JITAI behavior model (Figure 15) hypothesizes that effective JITAI programs will reduce health/behavioral disorders by the following interactions among the eight components of the model. The *individual's* readiness-to-change (self-efficacy), influenced by *social network* factors (e.g., clinicians, family members), affects the *mHealth use*. The mHealth use is also influenced by *mHealth technological factors* and available *support*. mHealth technology implementations need to take into account the environmental factors (e.g., policy and work arrangement). The *adaptive intervention* directly affects and also receives feedback from *behavior change*. The adaptive intervention is influenced by individual characteristics, mHealth use, environmental factors, and social network structures. As a result of behavior change produced by adaptive intervention, the health/behavioral disorder severity is reduced (symptoms improvements).

# 5.2 ADAPTIVE INTERVENTION MODEL

At the heart of JITAI is the adaptive intervention itself. A model representing adaptive intervention encompasses its four main components: (1) identification of adaptive components and related tailoring variables, (2) measurement of tailoring variables, (3) derivation of decision rules, and (4) implementation of decision (Collins et al., 2004). This adaptive intervention model is also part of the larger JITAI behavioral model as shown in Figure 15.

The adaptive intervention is a dynamic system, and the use of control theory to model this type of system has been suggested by Carver and Scheier (1982). Furthermore, several recent studies have suggested a similar approach (Lei et al., 2014; Riley et al., 2011, 2014; Spruijt-Metz & Nilsen, 2014). Therefore, the current study used adaptation of control theory in a fluid flow analogy to model this mechanism of change. The model provides improvements to previously-published dynamic behavioral models by making them more generalizable, i.e., not specific for certain intervention fields (Riley et al., 2014), and by including contributing factors from the individual's environment and social supports as well as the use of mobile technologies, as described in the JITAI model.

## 5.2.1 Characteristics

As mentioned in **Section 5.1**, the adaptive intervention model is intended to specifically describe the dynamic nature of adaptive intervention. Therefore, several areas of the JITAI model are included as components of the adaptive intervention model: self-efficacy, mHealth use, utilization supports (including "cue-to-action"), social circle supports (social network), and environmental context. Generally, the components are categorized as outputs and inputs: outputs are components/variables that are generated as a result of variation of stimuli (inputs); inputs are variables that act as stimuli that affect the components either positively (promote) or negatively (relegate). Output components include:

- 1. *mHealth utilization skills*, which involve fluencies in using, and adherence to the prescriptions included in the intervention mHealth platform
- 2. *Self-efficacy*, an essential factor that influences realization of a behavior and part of modifiable area of individual characteristics in the JITAI model
- 3. *Behavior*, a certain action or activity targeted by the intervention, such as sleep parameters (e.g., total time in bed, wake up after sleep onset, sleep efficiency), and healthy sleep practices
- 4. *Outcome*, direct and indirect results of the behavior. For example, in sleep intervention, direct outcomes could be reduction in the insomnia severity scale and improvement in

sleep quality; indirect outcomes could be improvement in professional productivity and better wake functions.

The following are the input components of the adaptive intervention model:

- 1. *mHealth use*, the metric of mHealth platform usage, the main input of mHealth utilization skills
- 2. *Utilization supports*, a support component in the larger JITAI model that includes activities that help to increase the utilization of mHealth, such as training, hints, gamifications and reminders
- 3. *Perceived social circle support*, i.e., the area influenced by the social network component in the JITAI model, including the availability of significant others to motivate behavior change, peer competition to achieve better results, and family support for maintaining acquired skills.
- 4. *Perceived barriers*, i.e., external conditions that the individual views as inhibitors for performing the behavior, such as workload, noise, and non-optimal temperature (too cold or too hot)
- 5. *Positive and negative affectivities*, an array of intrapersonal individual mental and emotional states which either improve self-efficacy (e.g., happiness, elated mood) or deplete it (e.g., bothersome thoughts, sadness)
- 6. *Cues to action*, i.e., strategies to activate "readiness" to perform the behavior, part of the support component of the JITAI model, including providing how-to information, promoting awareness and sending reminders
- 7. *Environmental context*, i.e., the context in which the behavior occurs, which is hypothesized to directly influence behavioral outcomes

# 5.2.2 The Adaptive Intervention Model

Figure 16 shows how the input and output components of the adaptive intervention relate with one another. A control-engineering model of the conservation of mass is used to describe this relation over time. The time granularity of the model can be determined by the nature of the individual intervention. For example, a daily time frame would be appropriate for most behavioral interventions such as sleep, physical activity, weight management and smoke cessation. Each output component is treated as an inventory, while input components are represented as inflow or outflow.

In the model, utilization skills are depicted as a fluid inventory that constantly drains to maintain self-efficacy, which is in turn maintained by the inflow of mHealth usage and utilization supports. Self-efficacy can be seen in both the adjustment model and the general JITAI model as part of an individual's characteristics. This is intentional because self-efficacy can vary between persons (the general model) and also fluctuates dynamically within one person based on dynamic inputs represented in the adaptive intervention model, including the following causes and effects: 1) utilization skill increases self-efficacy; 2) perceived barriers decrease self-efficacy; 3) positive affectivities increase the inventory; 4) negative affectivities deplete the inventory; social circle supports promote self-efficacy; 5) feedback from successful execution of the behavior provides perceived control, which positively influences self-efficacy.

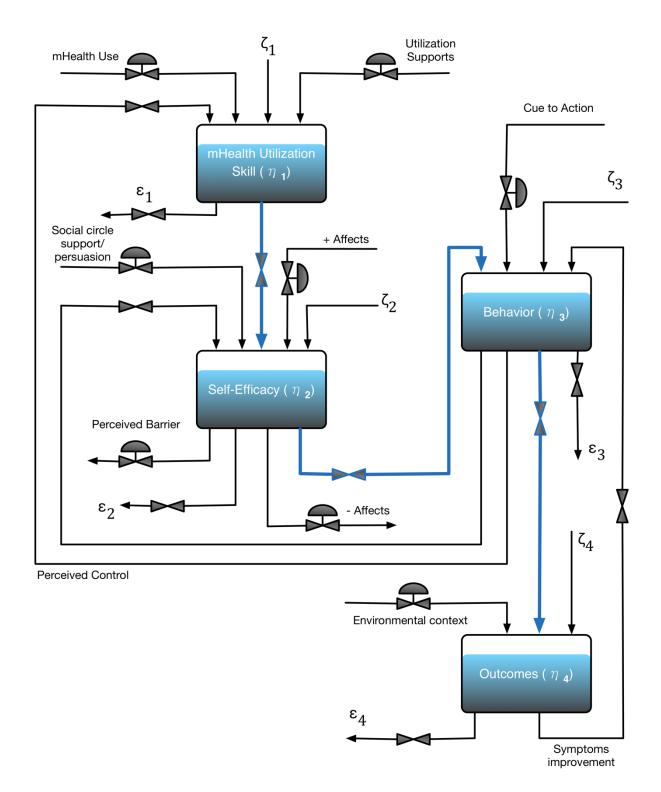


Figure 16. The JITAI adaptive intervention model

The model hypothesizes that a behavior's duration and/or frequency will increase over time as self-efficacy toward that behavior increases. There are also cues to actions, i.e., activities that are intended to "trigger" activation of the behavior. Cues to action, when placed optimally, will increase activation of the behavior, and it is the behavior itself that is the main concern of the intervention; presumably successful execution of the behavior is followed by positive and/or negative consequences. For example, the successful execution of sleep restriction in the short term may positively improve an individual's sleep efficiency, and over the long term, overall sleep quality and insomnia symptoms. However, sleep restriction also has temporary negative side effects, such as daytime sleepiness and decreased awareness, and may contribute to a loss in productivity. These behavior consequences are also influenced by the environmental context of the individual. For example, while others may always view improvement in the disorder symptoms positively, the temporary side effects of the behavior may be viewed negatively by the patient. These consequences create a feedback loop to the self-efficacy and utilization skills.

Finally, the model also represents unmeasured or unexplained disturbances that influence each inventory. Unmeasured inflows are denoted by  $\zeta_1$ , ...,  $\zeta_4$ , and unmeasured outflows are presented by  $\varepsilon_1$ , ...,  $\varepsilon_4$ . We expect the values of these variables to be considerably low. A complete mathematical representation of the adaptive intervention model will be discussed in Chapter 8.0 Simulations on this mathematical model using scenarios based on the case study are also provided.

# 6.0 CROSS-PLATFORM JITAI APPLICATION ARCHITECTURE AND IREST MHEALTH SYSTEM

# 6.1 APPLICATION ARCHITECTURE FOR JITAI

The purpose of this specific aim is to develop the JITAI application architecture. The JITAI application architecture is a generalizable technical implementation of the JITAI health behavior model. This architecture includes ready-to-use and reusable components, such as libraries, communication platforms, sensor integration, databases, and logical infrastructure. The proposed architecture will allow application developers to customize the architecture to support a variety of health behavioral change interventions without having to build the system from scratch. These include but are not limited to addressing the current segmentation of the mobile operating system market since the JITAI application architecture is designed as a cross-platform system.

# 6.1.1 Methods

The development of the JITAI application architecture follows the Iterative and Incremental Development (IID) software development model (See 2.5 Software Development Life Cycle). The JITAI application architecture is the first group of iterations of IID which later on will be followed by the second group of iterations for specific aim 2.1, customizing the architecture to

implement sleep intervention (the case study). In each of the iterations of the development of the JITAI application architecture, the following conceptual stages are followed:

1. Identify functional<sup>5</sup> and non-functional<sup>6</sup> requirements derived from the JITAI health behavior model and the adjustment model characteristics.

The JITAI behavior model and adaptive intervention model provide conceptual components and interactions between those components. This first stage focuses on translating those components and interactions into software requirements.

2. Analyze the requirements and design the JITAI application architecture based on the requirements.

In this second stage, the requirements are mapped onto the available technologies. The mapping consists of information on the technology and how it addresses the needs of corresponding requirements. In addition, the interaction or communication between technologies, and types of data required in each technology is also discussed in the mapping. This mapping dictates the selection of technologies. The result of this stage is an integrated design both for hardware and logical architecture.

3. Develop actual systems.

<sup>&</sup>lt;sup>5</sup> Describe what the system shall do; for example, the system shall deliver electronic format of an assessment tool to patient smartphone.

<sup>&</sup>lt;sup>6</sup> Describe what the system shall be; for example, the system shall be secure so that any data transfers are protected by an encryption layer.

In this stage, the architectural designs are implemented into actual system features. Features derived from non-functional requirements, such as accessibility, usability criteria, reliability, security and privacy, are also implemented into the system. At the end of this stage, a complete JITAI application architecture with all the corresponding features will be ready to be used and tested.

# 4. Conduct testing to refine the system

In this stage, testing scenarios are used to simulate the use of each feature of the JITAI application architecture. Based on the test results, each feature will either go through refining processes (i.e., another cycle of IID for bug fixing, alteration, or removal) or be released to production.

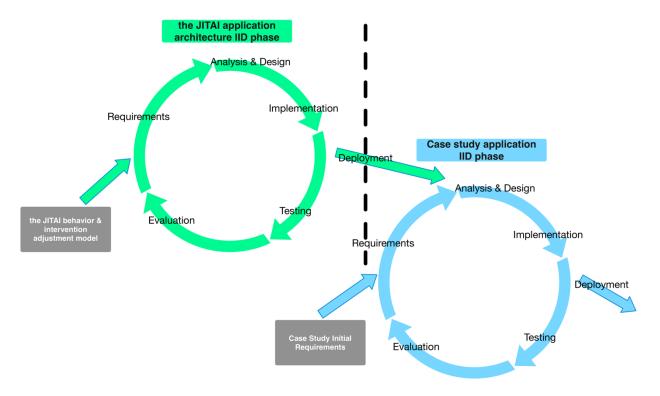


Figure 17. Overall IID diagram

# 6.1.2 Functional Requirements

The requirements for the JITAI application architecture are based on the major characteristics of the system (See **5.1**. The JITAI Behavior Model) and the needs of the intervention adaptive intervention model (See **5.2** Adaptive Intervention Model). The first step of this identification is to recognize the functional requirements demanded by the models. The following are the highlights<sup>7</sup> of such requirements:

#### 1. Separation between roles or role based access (RBAC)

From the JITAI model, several types of users of the system<sup>8</sup> are expected, such as patients, clinicians, case managers, family members and care givers. Each user type may interact in a different way with the system and may also have different access to the system. Therefore, there is a need (requirement) that the system should provide role-based-access and a different user interface/experience appropriate for each user type/role they fall into. For example, one's clinician may be granted access to one's electronic health record available in the system, but not one's friend who also uses the system.

## 2. Self-administered measurement

In order to populate the values of areas mentioned in the JITAI model and the adaptive intervention model, the system need to be able to deliver and collect answers for measurement tools used for that particular area (e.g., in the form of electronic

<sup>&</sup>lt;sup>7</sup> This is not an extensive list of detailed functional requirements.

<sup>&</sup>lt;sup>8</sup> In this section (5.1), "the system" refers to "the JITAI application architecture."

questionnaires or surveys). In most cases, this measurement tools are traditional pen-andpaper questionnaire that transformed into electronic format.

## 3. Reminder and notification

The "support" component of the JITAI model requires the system to be able to send reminder and notification to increase or maintain the use of mHealth system. Furthermore, these features are also important for the intervention itself, as they can act as "cues to action."

## 4. Multimedia education and information delivery

Education and information are also part of the "support" component and are an important way to increase mHealth utilization skills in the adaptive intervention model, which in turn can increase self-efficacy in performing the behavior. The information-motivationbehavior model (IMB) also highlights the importance of information regarding certain behaviors in elevating self-efficacy toward the aforementioned behavior (Jeffrey D Fisher & Fisher, 2002). Hence, the system is required to support multimedia education modules and information delivery.

## 5. Real-time communication channel

The "just-in-time" characteristic demands that the system provide real-time communication between the system components. The system allows patients to receive behavioral prescription, support, feedback and information from the clinician in an immediate manner, and vice versa: clinicians can monitor patients' status and prescribe treatment in real-time. This requirement is also important for providing various real-time communication modalities within the system, such as messaging, audio calling, and video conferencing.

#### 6. Automatic data collection

As the JITAI model suggests, patient burden influences the mHealth utilization. Automatic data collection minimizes this burden by collecting data through objective sensors with minimal to no manual input. Automatic data collection also provides better accuracy and reduces recall bias. As the popularity of wearable sensible technologies continues to increase by double-digit growth in recent years (e.g., a 61.3% expected increase for 2016 in the U.S.) (eMarketer, 2015), incorporating automatic data collection from these wearable technologies has become an important feature in a JITAI system.

# 6.1.3 Non-functional Requirements

The following are highlights of non-functional requirements of the JITAI application architecture:

#### 1. Privacy and security

The system handles personal health records and potentially personal identifiable data. As also suggested in the JITAI model, the policy requirements (one of the environmental factors) influence the mHealth technology implementation. For example, HIPAA mandates privacy and security in handling such data. Therefore, the system must place premium importance on the security and privacy of health record data, especially since perceptions of privacy and security have been found to influence the acceptance of mHealth technologies (Wilkowska & Ziefle, 2011).

#### 2. Cross platform

The smartphone market is and will likely continue to be divided between a few mutually incompatible operating systems (Figure 18). Smartphone-based applications typically need to be specifically developed for each mobile operating system that the intervention plans to support; this process is costly and is not scalable. A cross-platform mobile architecture would allow a single mobile application to run on multiple platforms with minimal development effort and would enable individuals to use their own smartphone, with which they are already presumably familiar. In addition, taking advantage of the familiarity an individual has with their own phone may be particularly meaningful, as it requires no additional training for use of the smartphone itself.

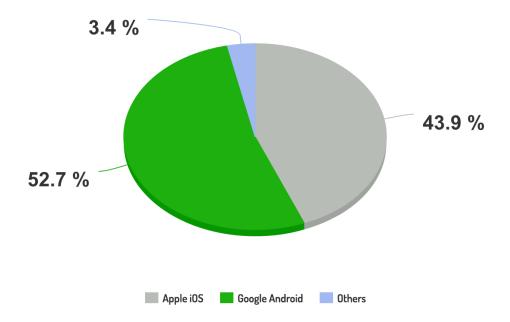


Figure 18. Smartphone Market Share (comScore, 2016)

#### 3. Access and distribution

In relation to the smartphone market segregation mentioned above, the same can be applied to their app distribution channels. There are many methods available for mobile app distribution; however, the simplest and easiest method from the user's perspective is through each vendor's official distribution channel (e.g., Google Play<sup>™</sup> for Android and App Store<sup>™</sup> for iOS). Therefore, the system needs to comply with the requirements and regulations mandated by these distribution channels.

# 4. Availability and reliability

Availability and reliability requirements may vary across the JITAI application architecture implementation; for example, twice daily assessments (e.g., bedtime and wake up time) of a behavioral sleep intervention may not require round-the-clock availability. However, the system should be designed to accommodate such a requirement if deemed necessary by a certain type of intervention.

## 5. Separation of concerns:

In software engineering, separation of concern is a design principle for separating software into distinct sections, such that each section addresses a separate concern. A concern is a set of bits of information that affects the code of a software program. An example of a concern could be handling specific hardware integration, optimizing time and date entry in sleep log form, and securing the communication between the patient app and the clinician server.

The value of separation of concerns is in simplifying development and maintenance of applications/programs. When concerns are well-separated, individual sections can not only be reused but developed and updated independently. Of special value is the ability to later improve or modify one section of code without having to know the details of other sections, and without having to make corresponding changes to those sections. All of these advantages are important for the JITAI application architecture because the architecture is designed to support rapid implementation to a wide variety of health behavior interventions. Typically, each implementation will require a different set of GUI styling. Not only in terms of unique branding or the "look-and-feel"<sup>9</sup> of each application, but also due to the different needs of each population; for example, in terms of accessibility (e.g., different button sizes, color schemes, spacing between objects) and usability (e.g., shortcuts, different color themes based on age or individual preferences). The same assessment (e.g., the Generalized Anxiety Disorder scale 2-items/GAD-2 (K Kroenke, Spitzer, & Williams, 2007) questionnaire) may be presented by GUIs in different interventions or populations. The opposite may also be true, i.e., the same GUIs look-and-feel/style can be used to deliver different behavioral information to different individuals. Because of this, there was a need to separate view layer (GUI) from the business logic (data model) to provide more efficient implementation in various intervention settings.

<sup>&</sup>lt;sup>9</sup> Within aspects of GUI design, the "look" refers to elements such as fonts/typefaces, colors, layouts, while the "feel" refers to behavior of dynamic elements such as buttons, sliders, boxes, and menus.

With regard to interactions between front-end and back-end, the JITAI application architecture was intended to be a service-oriented architecture (SOA), a software architecture style for creating systems built from autonomous "services" delivered over a network using a communication protocol. SOA allows a functionality (e.g., patient information from the clinician portal) to be accessed remotely, acted upon, and updated independently (e.g., from the mobile application/front-end).

Other non-functional requirements such as usability and accessibility have been discussed in detail in **Section 2.6** and **Section 5.1.2**.

## 6.1.4 Requirements to Technologies Mapping and Technology Selection Rationales

In JITAI, mobile applications are typically the primary point of input (POI). Therefore, this section starts with mobile application development. Mobile application development is a multifaceted process which includes mobile front-ends (user interfaces), mobile back-ends, real-time data transfer protocols and a security layer.

## 6.1.4.1 Mobile Front-End

The first step in development was to review available technology platforms to develop the mobile front-end part of the JITAI architecture. Based on non-functional requirements mentioned in Section 6.1.3, only samples of technologies that support cross-platform deployment were included (Table 4).

From the technology options provided in Table 4, Appcelarator uses JavaScript as the language for user interface, data model and interaction between the two. Although separation of

concerns is still possible using the JavaScript-only approach, the approaches using HTML+CSS for user interface and JavaScript for the data model and interaction (view-model) were preferred due to cleaner codes and allowing delegation of expertise (e.g., graphic designers can work on HTML+CSS while programmers work on application logic using JavaScript). Cordova, Sencha Touch and Telerik use this approach; however, the latter two require paid licenses for the purpose intended by the JITAI application architecture. Furthermore, both development platforms support less mobile operating system deployment as compared to Cordova. Hence, Cordova was chosen for the JITAI application architecture's mobile front-end development.

Name	Programming Language	Cross-platform deployment	License/Cost
Appcelerator	JavaScript	Android, iOS, Tizen, BlackBerry	open-sourced Apache 2.0 licensed, paid licenses are available for commercial and enterprise use
Cordova or PhoneGap	HTML, CSS, JavaScript	Android, iOS, Windows Phone, Tizen, BlackBerry, Symbian, Palm, Bada	Apache 2.0
Sencha Touch	HTML, CSS, JavaScript	Android, iOS, Kindle, BlackBerry, Bada	GPL v3, free for commercial use; however, paid license is required for OEM <sup>10</sup>
Telerik	HTML, CSS, JavaScript	Android, iOS, Windows Phone	paid licenses are available for commercial and enterprise use

 Table 4. Mobile front-end development tools

<sup>&</sup>lt;sup>10</sup> Sencha (Redwood City, CA) defines OEM-use as using the product to create a software developer kit (SDK) or an application builder.

# 6.1.4.2 Back-End Server

The back-end of the JITAI application architecture is a secure server that provide functionalities such as:

- 1. storing and managing patients' health records
- 2. performing intervention logic and calculations, for example, calculating sleep efficiency from sleep diary entry, notifying clinicians when patients exhibit suicidality, calculating sleep restriction schedules (i.e., when to go to bed and when to wake up)
- providing services that can be invoked remotely by client applications (e.g., web and/or mobile) in relation to the intervention
- 4. sending push notifications to client applications
- 5. ensuring privacy and security

In the current study, the back-end server was built using Microsoft (Redmond, WA) ASP.NET WebAPI<sup>™</sup> platform due to author familiarity with the platform. However, the JITAI back-end application architecture can be developed using other web server development platforms as long as they can support development for the functionalities listed above.

## 6.1.4.3 Web Service

As a service-oriented architecture, the JITAI application architecture uses web services as the main method of communication between client applications and back-end servers over the Internet. Specifically, the architecture uses the Representational State Transfer (REST) protocol. There are other forms of web service, such as Simple Object Access Protocol (SOAP). However, the REST architecture style was preferred because of its better performance, scalability, simplicity, portability (Fielding, 2000), and most importantly, because it fits the "separation of concerns" required by the JITAI model.

#### 6.1.4.4 Real-time Communication Protocol

One functional requirement that has not been addressed is the need for real-time communication channels. As mentioned above, the JITAI application architecture uses the RESTful (the implementation of REST architecture style) web service as the main method of communication between client applications and the back-end server. The RESTful web service is layered on top of the Hypertext Transfer Protocol (HTTP) and is designed for request-and-response (e.g., the same nature as web browsing over the Internet) communications. However, when used for continuous real-time communication, REST has drawbacks because it lacks the following:

- 1. *Bi-directional protocol*: REST has a one-directional protocol. A request is always initiated by client applications, and a server then processes the request and responds, at which point the response is then consumed by the client application. Clients can only request, and servers can only respond; neither can send a message to the other party outside this pre-defined method.
- 2. *Full duplex*: in REST at any given time, either a client can talk to the server (request), or the other way around (response), but not both. The protocol prohibits the client and server from talking independent of each other.
- 3. *Single connection*: for each REST request, a new connection is initiated and then terminated after the response is received. In real-time communication, however, a single connection for the lifecycle of the communication is preferred. Single connection reduces overhead associated with connection initiation and termination; more importantly, the client application and back-end server have a dedicated channel to exchange messages throughout the communication lifecycle.

To address the REST protocol's drawbacks, the JITAI application architecture used the WebSocket protocol (Hickson, 2010) for real-time communication. WebSocket provides all the features listed above and produces smaller package overhead when compared to REST. In JITAI application architecture, WebSocket was not intended as a replacement for REST, but instead as a supplement. For all of its advantages, WebSocket is not yet supported by all web browser and mobile platforms. Furthermore, the REST protocol has become widely adopted as the standard for interoperability across web-based services (e.g., for importing data from third-party sensor data providers).

In this study, Microsoft (Redmond, CA) SignalR<sup>™</sup> is used as WebSocket implementation. This decision was based on author familiarity and also synergism with the ASP.NET WebAPI chosen earlier.

# 6.1.5 Hardware Architecture

The hardware architecture of the JITAI application architecture was based on the requirements to the technology mapping above. The following are the components of the hardware architecture as depicted in Figure 19:

## 1. Patient Mobile Devices

The patient's mobile devices (smartphones and tablets) are considered as the personal gateway/hub into participating in the JITAI system. The personal gateway is connected

to the back-end server through the HTTP Secure<sup>11</sup> (HTTPS) protocol; therefore, the personal gateway must have Internet connection service such as 3G, 4G, or Wi-Fi to achieve real-time synchronization. In the event of connection loss, the mobile application within the personal gateway switches to stand-alone/offline mode and will automatically perform synchronization as soon as the connection is restored. While this could lead to privacy and security concerns about the temporary data that are stored on patient smartphones to accommodate this offline usage of the application, these concerns will be addressed on the conceptual design of the JITAI architecture.

## 2. Wearable Sensor

To support automatic objective data collection, the hardware architecture includes the use of wearable sensors. Wearable sensory technology is expanding rapidly and encompasses a wide variety of objective measurements of biofeedback and phenomena; these can be used to record physical phenomena (e.g., accelerometer, gyroscope, and magnetometer) or contextual/environmental data (e.g., GPS and weather sensors). In a typical scenario, these sensory devices are paired with the personal gateway via wireless connection (e.g., Bluetooth, ANT). The vendor mobile app then transmits the sensor-collected data to the vendor server, where the sensory data are analyzed and stored. Type-wearable sensors used are tailored to the needs of the individual intervention; for example, accelerometerbased sensors are used in sleep interventions to approximate sleep onset and sleep stages.

<sup>&</sup>lt;sup>11</sup> HTTPS allows encryption of HTTP connection over the Internet, providing protection of the privacy and integrity of the exchanged data.

## 3. Clinician Devices

The clinicians interact with the system through a web portal. Hence, clinician devices could be a desktop computer, laptop computer, tablet or smartphone, as long as it has web-browsing capability. The system will not store any patient information (including electronic health records) on clinician devices. In order to use the system, clinician devices need to have an Internet connection. The data exchanges between the clinician devices and back-end server are performed through the same secure channel using HTTPS.

# 4. Back-End Server

The back-end server performs most of the heavy lifting of the system, such as those already mentioned in **Section 6.1.4.2**. The back-end server is currently a dedicated server placed behind a firewall. A regular back-up mechanism is in place to protect the server and the interventions it serves from catastrophic failure.

#### 5. Wearable Sensor Vendor Server

Typical off-the-shelf wearable sensor products store their data in their online server. In order to import those data into the intervention system, a request needs to be made from the back-end server using a given authentication protocol. After authentication, the backend server can retrieve the sensory data by calling the vendor's Application Program Interface (API). The detailed request-and-response mechanism between the JITAI backend server and the sensory technology vendor server will be discussed as part of the integration design.

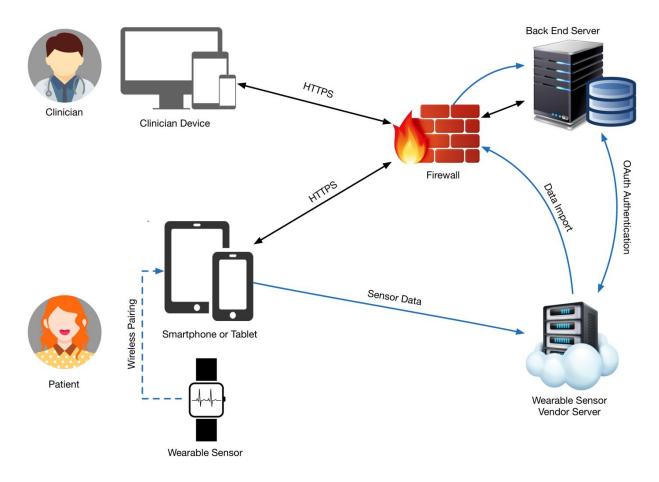


Figure 19. The JITAI Hardware Architecture

# 6.1.6 Mobile Logical Architecture

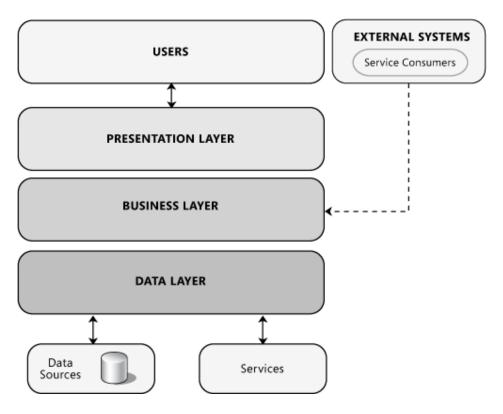


Figure 20. Logical architecture as a layered system (Microsoft, 2016)

The logical architecture decomposes the design into logical groupings of software components called layers. A typical logical architecture (as portrayed in Figure 20) consists of a presentation layer, business layer (heretofore referred to as <u>"intervention" layer</u>), and data layer. In this section, the logical architecture of the mobile application used in the JITAI system is explained. The clinician's portal logical architecture will be discussed in a later section.

As mentioned above, Figure 20 shows a common implementation of a logical architecture on a single platform. However, the JITAI architecture is intended to be cross-platform. Therefore, before we move to the description of each individual layer, we must discuss the method that allows this logical architecture to work across multiple platforms, as depicted in Figure 21.

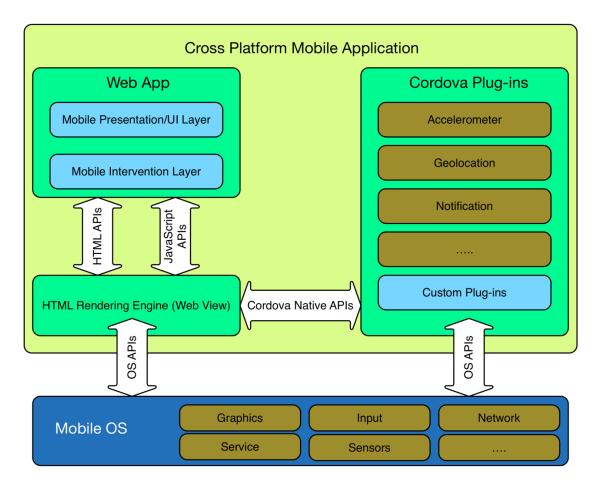


Figure 21. The cross-platform design

The mobile logical architecture is encapsulated in the web app component of the Cordova cross-platform framework. The web app interacts with the rest of the Cordova framework through a series of HTML and JavaScript API calls. In order to use mobile operating system (OS) native capabilities (e.g., sensors), the implementation can include a wide variety of plug-ins that are readily available from the Cordova library. If there is a need for a special type of native OS interaction not covered by the Cordova plug-ins library, a custom plug-in can be developed into the implementation.

## **6.1.6.1 Mobile Presentation Layer**

As mentioned above, the presentation layers discussed here only cover the mobile application portion of the system. The presentation layer consists of user-oriented functionality to accommodate user interaction with the system. In other words, the presentation layer is the user interface (UI) layer. Conceptually, the UI has two main parts: an input/action part and a viewing/feedback part (Figure 22). The input part is designed to accommodate both manual (i.e., by user) data entry and automatic data entry. In the implementation, standard psychological/behavioral traditionally paper-based questionnaires (e.g., the Epworth Sleepiness Scale (ESS) (Johns, 1991), Pittsburgh Sleep Quality Index (PSQI) (D J Buysse, Reynolds, Monk, Berman, & Kupfer, 1989), Insomnia Severity Index (ISI)(Bastien, Vallières, & Morin, 2001)) are translated toward a more concise and touch-friendly electronic version; these questionnaires usually provide subjective and qualitative data. In addition, as much physical phenomena and contextual data are captured as automatically and intelligently as possible using the smartphone's sensors or wearable sensors. These sensory data are objective and quantitative in nature. If automatic input is not possible, e.g., because of technology or procedural limitations, a manual method is provided. For example, in behavioral sleep intervention, sleep patterns are captured automatically using a wristband sensor, whereas sleep quality is captured using an electronic form on a mobile app. Some system functionalities, for example, will unavoidably require manual entry: 1) setting a goal, 2) setting up user information and preferences, and 3) communicating and interacting with others or their clinician.

The viewing/feedback part plays important roles, such as 1) providing status/progress feedback to the user, and 2) delivering education materials or other intervention multimedia materials to the user. The app has a "dashboard" where a summarization of important statuses

and feedbacks are displayed, to provide at-a-glance information to users of their current condition and/or progress.

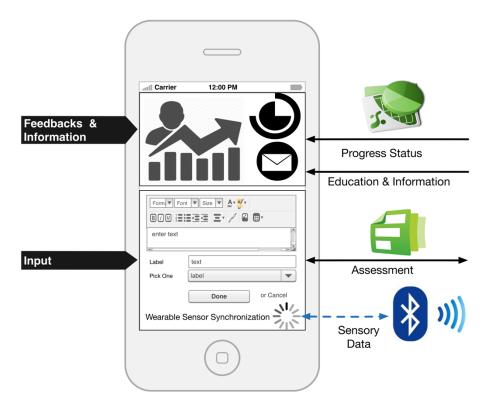


Figure 22. The mobile User Interface (UI) concept design

## 6.1.6.2 Mobile Intervention Layer

The intervention layer implements the core functionalities of the app; it encapsulates the clientside intervention logics (e.g., treatment decision logic, response interpretation algorithms). In the JITAI application architecture, most of the intervention logics are handled by the back-end server (the clinician portal); therefore, these client-side logics are minimal but sufficient to support the app in case the connection to the clinician portal is interrupted. These client-side logics are compiled into application controllers in three main interfaces: 1) to the presentation layers; 2) to the back-end server, in real time as a SignalR client and asynchronously as a RESTful client; 3) to the mobile OS via Cordova plug-ins. The mobile intervention layer is depicted by Figure 23.

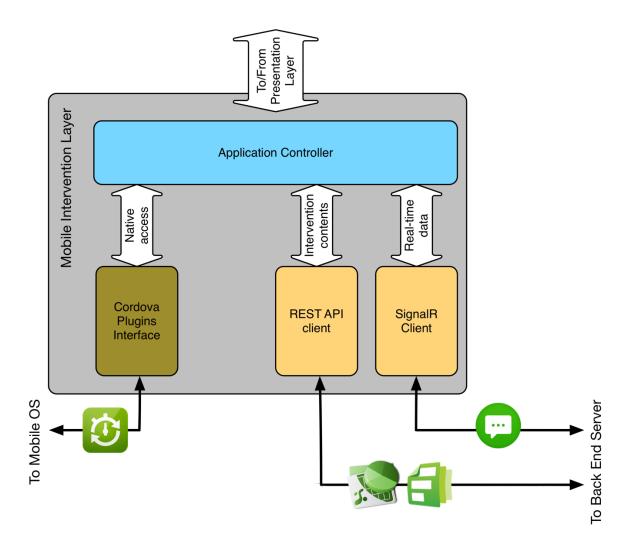


Figure 23. The mobile intervention layer

## 6.1.7 Clinician Portal Logical Architecture

The clinician portal consists of a presentation layer, an application logic layer, and a persistence layer (Figure 24). The <u>presentation layer</u> provides user interfaces for clinicians to complete tasks, such as setting up assessment schedules, monitoring responses, and viewing assessment results. The presentation layer has two main components:

- 1. UI components: visual elements used to display information and to accept user input.
- Presentation logics: implementation-independent (i.e., separation of concerns) logical behavior of the UI (for example, a logic that describes what happens if the user presses the submit button). This logic can be implemented across different styles of UI components, maintaining the same description.

The <u>intervention logic layer</u> provides services for data access and data synchronization connecting both the portal's presentation layer and the mobile application. As the name suggests, this layer is concerned with application of intervention rules; the retrieval, processing, transformation, and management of intervention data; and ensuring data consistency and validity. The intervention logic consists of two components:

1. Clinical practice guidelines: the implementation of adaptive interventions from the JITAI behavior model. Adaptive intervention involves multiple steps that must be performed in the correct order, at the most opportune time, and which may interact with each other through orchestration. Clinical practice guideline components define and coordinate these multistep intervention processes. They work with intervention entities to initiate intervention delivery to the mobile app or to respond to the requests from the mobile app or the portal's presentation layer.

2. *Intervention entities*: the encapsulation of data necessary to represent real-world intervention elements, such as assessments, education materials, clinician feedback and behavior-specific information.

The <u>data layer</u> provides access to persistent data hosted within the boundaries of the system and data exposed by other systems, typically, over web services. This layer consists of relational database software that stores clinical data, medical health records and user management data. In addition, the data layer might need to manage the semantics of communicating with that particular service providing data required for the intervention, e.g., sensory data from a wearable sensor vendor web service.

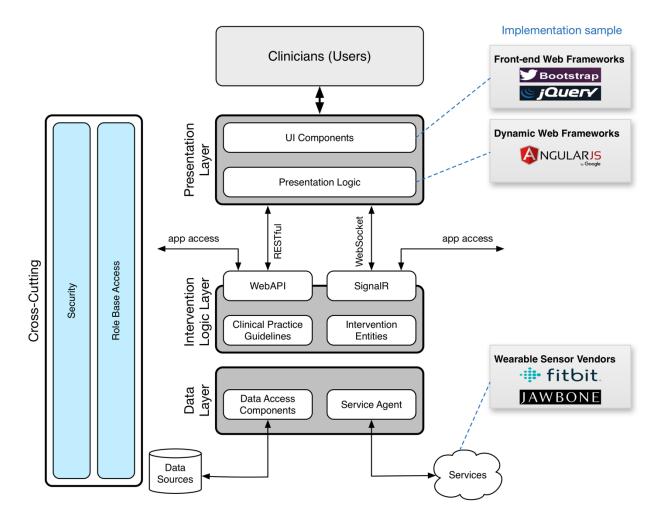


Figure 24. Clinician portal logical architecture

Security and role-based access controls are implemented throughout the hierarchical layers. Both are used to protect the portal and the health records by:

- a) requiring clinicians to use authentication (user name and password) and patients to register their device
- b) conducting communication between the clinician portal and the patient app through HTTPS
- c) only accessing sensitive resources such as electronic health records (EHR) using short-lived access tokens obtained after the authentication process
- d) encoding into cypher text (i.e., an unrecognizable/unreadable string of characters) additional protection of sensitive data such as access tokens and account information
- e) physically locating the back-end server in a locked room inside a secure building
- f) not storing identifiable data in the mobile app

## 6.1.8 Integration Architecture

The purpose of integration architecture is to describe how to integrate current advanced technologies such as sensing technology, smartphone, and portal technology into an integrated JITAI application architecture. This integration allows health and behavior data to be dynamically and securely exchanged among these various technologies. Figure 25 describes an example of the integration between the clinician portal with a wearable sensor vendor service.

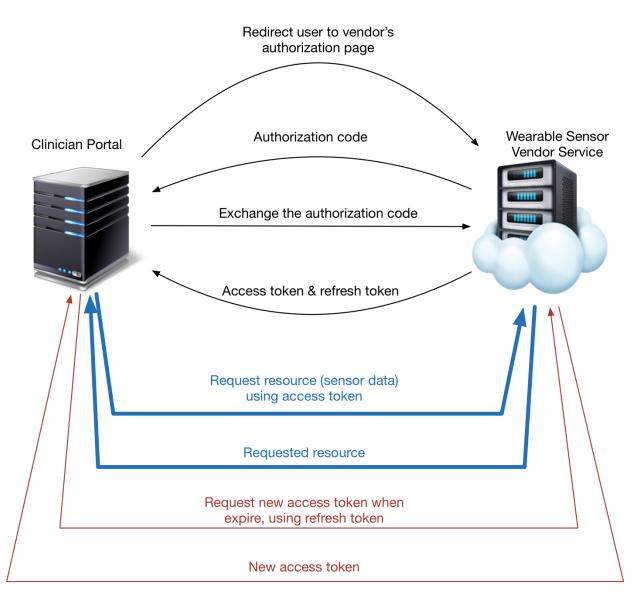


Figure 25. Integration with wearable sensor vendor services

# 6.2 IREST: CROSS-PLATFORM JITAI APPLICATION FOR SUPPORTING SLEEP INTERVENTION

The JITAI application platform is designed to be a general platform that can work on many health-intervention and rehabilitation cases using JITAI as the main strategy. From a technological perspective, the difference between those cases is mainly in the content and context of data collection, information presentation, and data collection methods (sensible devices used); however, the communication infrastructure and the service-oriented architecture remain the same for all types of cases. To test the applicability of the JITAI application architecture, a JITAI system was developed based on the needs of a behavioral sleep intervention study (see details on the case study in **Chapter 4.0**).

## 6.2.1 Clinical Background

Sleep disturbances such as insomnia and nightmares are among the most prevalent complaints reported by ADSM and Veterans (Epstein, Babcock-parziale, Haynes, & Herb, 2012; Hoge, Terhakopian, Castro, Messer, & Engel, 2007; Ocasio-Tascón, Alicea-Colón, Torres-Palacios, & Rodríguez-Cintrón, 2006). Pre- and post-deployment sleep disturbances are robust risk factors for poor psychological health, including Post Traumatic Syndrome Disorder (PTSD), major depressive disorder, suicidality, hazardous alcohol use, and addictive disorders (Chakravorty et al., 2014; Maher, Rego, & Asnis, 2006; Raskind et al., 2007). Sleep disturbances also impede response to treatment for those conditions and increase the risk of onset or recurrence (Gironda et al., 2009). Finally, sleep disturbances in ADSM compromise mission effectiveness by

impairing critical cognitive abilities, moral reasoning skills, and increasing the risks of accidents or injuries due to sleepiness or fatigue (HASLAM, 1982).

Cognitive behavioral therapies for insomnia (CBTI) are associated with marked improvements in sleep, alertness, and psychological health, as well as with better treatment outcomes and reduced risk of relapse (Irwin et al., 2006; Smith et al., 2002). Despite evidence that sleep disturbances are a modifiable threat to psychological resilience and operational readiness, the use of evidence-based behavioral sleep treatments in military or other care settings remains limited. Rather, due to the time required to enact behavioral treatments, pharmacological agents remain the most widely used interventions for sleep disturbances in military samples (Barlas, Higgins, Pflieger, & Diecker, 2013; Mysliwiec & Roth, 2013).

CBTI typically lasts for eight sessions conducted by a licensed psychologist trained in behavioral sleep medicine (Edinger et al., 2001). Our preliminary work suggests that even briefer behavioral interventions of four-week sessions can effectively improve sleep and psychological symptoms in ADSM and Veterans (Germain et al., 2014). The brief behavioral therapy for insomnia (BBTI) may be more easily disseminated to ADSM and Veterans seeking help for insomnia.

Additionally, there is a critical shortage of clinicians trained in evaluating and effectively treating sleep disturbances using behavioral strategies. The ongoing VA rollout of CBTI includes training of a significant number of clinicians (Trockel, Karlin, Taylor, & Manber, 2014) and the use of a standalone mobile app (CBT-i Coach) (Kuhn et al., 2016). This rollout attempts to address the shortage of clinicians, but this effort will not reach ADSM pre- or post-deployment, and the number of clinicians may still not be sufficient to address the needs of the estimated 2.4M troops who have served in Afghanistan or Iraq since 2001.

To address the existing barriers to evidence-based behavioral interventions, we developed an app called interactive Resilience Enhancing Sleep Tactics (iREST), an interactive mobile health tool that provides support for self-management of sleep disturbances. iREST draws directly from existing BBTI interventions that have been found to be effective in ADSM and Veterans.

#### 6.2.2 Methods

Requirement analysis was based on the case study's description, workflow and needs, clinician inputs, as well as a previous BBTI military study (Germain et al., 2014) and previous implementation of the JITAI architecture (Juengst et al., 2015). As mentioned in the development of the JITAI application architecture, the development of iREST was based on the IID software development model. The development of the iREST system was the second group of iterations of the overall IID phases.

## 6.2.3 Requirements Identification and Analysis

When implementing the JITAI application architecture into a specific adaptive intervention such as behavioral intervention for insomnia, the process was focused on determining the "context" and "contents" of the system. The structural and architectural design of the system were provided by the JITAI application architecture. Therefore, in the requirements identification and analysis, the focus is on mapping the functional and non-functional requirements mentioned in the JITAI application architecture onto the context of adaptive behavioral intervention for insomnia (Table 5).

# The JITAI

#### architectural features

#### The BBTI contexts/contents

### Functional Requirements

- Separation between Patients, clinicians, administrator staffs have different access rights roles to the system
- 2. Self-administered For the intervention, patients need to be able to fill out: 1) an electronic sleep log (based on Pittsburgh Sleep Diary (Monk et al., 1994)); 2) a weekly assessment regimen which contains the Generalized Anxiety Disorder scale 2-items (GAD-2) (K Kroenke et al., 2007); 3) the Patient Health Questionnaire 2 items (PHQ-2) (Kurt Kroenke, Spitzer, & Williams, 2003); 4) the Asberg Rating Scale for Side Effects (Asberg, Cronholm, Sjöqvist, & Tuck, 1970); and 5) the Patient Global Impression of Improvement (PGI-I) (Yalcin & Bump, 2003).
  Clinicians also need to be able to fill out the Clinical Global Impression scale (CGI) (Busner & Targum, 2007) weekly to report
- 3. Reminders and The system allows clinicians to send reminders to the patients' notifications mobile app to remind them about filling out assessments/logs, adhering to the sleep restriction schedule, reading prescribed condition-related information/education, etc.

their impressions of the patients' clinical improvement.

The mobile application shows notifications when there are events such as new messages from clinicians, new assessments available, successful submission of assessments/logs, loss of Internet connection. Clinicians, on the other hand, are notified when there are new messages from patients and adverse effect endorsements.

99

Table 5 (continued)

4. Multimedia education	The system allows clinicians to send condition-specific education
and information	and information materials to patients' mobile app. In addition, the
delivery	mobile app contains general information about insomnia, sleep, and
	a quick guide on how to use the education module.
5. Real-time	The system provides a live-chat capability that allows clinicians and
communication	patients to exchange messages in real-time.
6. Automatic data	The iREST system uses a Fitbit wristband to collect the patients'
collection	sleep patterns. Fitbit is preferred due to an open API, relatively
	affordable price and its leading the market of commercial wearables
	(IDC, 2016) compared to other vendors.

# Non Functional Requirements

1.	Privacy and Security	The system provides encryption throughout the data exchange and					
		managements processes. The system does not store any identifiable					
		data on the patients' smartphone.					
2.	Cross-platform	The intervention uses BYOD approach; therefore, the system needs					
		to be cross-platform.					
3.	Access and	The patients' mobile app is available at Google Play and the Apple					
	Distribution	App Store.					
4.	Availability and	The system aims to be available throughout the intervention period.					
	Reliability	A recovery procedure is in place in the event of service disruption					
		in order to minimize down time.					
5.	Separation of	The system is designed on the separation of concern concept, as					
	concerns	shown in Figure 26.					

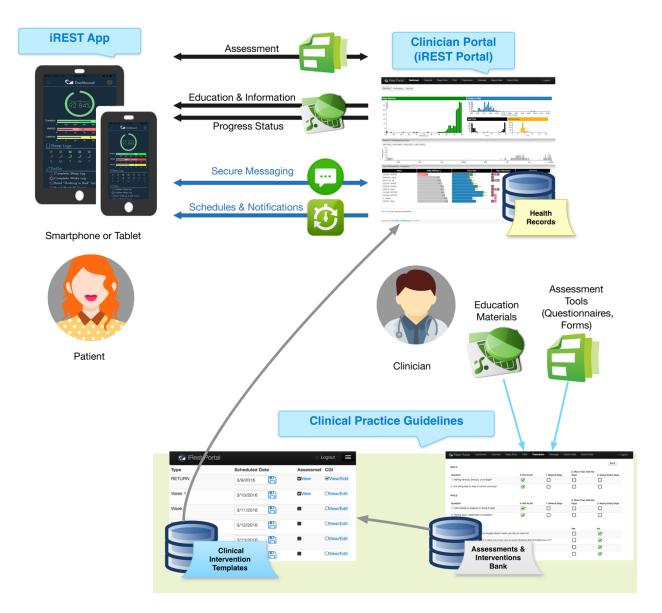


Figure 26. "Separation of concerns" in iREST system

## 6.2.4 Results

As a result of fitting the JITAI application architecture to address the BBTI for Veteran and ADSM, the iREST mHealth system was developed. The system, illustrated in Figure 27, consists of cross-platform smartphone apps, a clinician portal, and secure 2-way communications connecting the app and the portal.

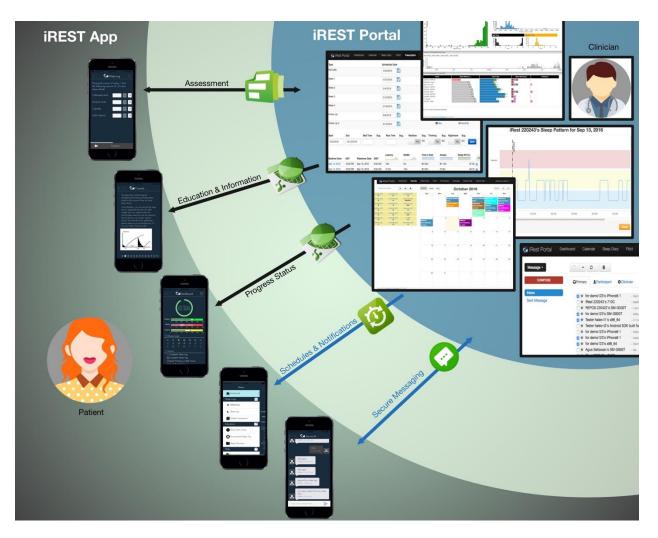


Figure 27. iREST app and portal interaction

# 6.2.4.1 The iREST Patient App

The iREST mobile app is an implementation of mobile logical architecture (see Section 6.1.6) of the JITAI application architecture based on BBTI requirements (described in Section 6.2.3 above). The following are functionalities available on the app (screenshots of each functionality provided in Figure 28):

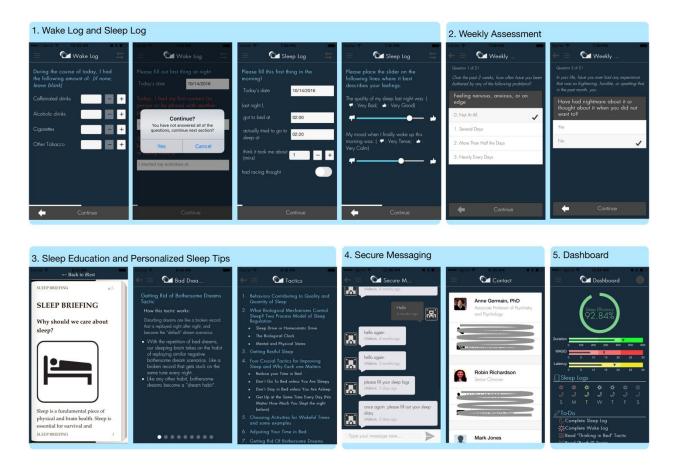


Figure 28. iREST app screenshots

## 1. Wake Log and Sleep Log

The wake log and sleep log of the iREST app is an electronic adaptation of the Pittsburgh Sleep Diary. The wake log records patients' awake/daytime activities that may relate to healthy sleep practices (e.g., caffeine and alcohol consumption, number and duration of daytime naps, and exercise events. It is intended to be filled out right before the patients go to bed. The sleep log tracks patients' sleep parameters (e.g., sleep latency, number and duration of wake-up after sleep onset episodes, go to bed time, and wake up time), dreams and nightmares, and perceived sleep quality. Patients need to fill out the sleep log immediately upon awakening to reduce recall bias.

For both sleep and wake logs, the app records time-stamps of the start and the completion of each entry. The logs also implement validation checking; for example, while the user is filling the logs out, they can know immediately if they've made any mistakes or missed any fields. Furthermore, the previous entry is used as a default value for each new entry in order to reduce time and patient burden in filling out the logs.

## 2. Weekly Assessment

As the name suggests, the weekly assessment is a regimen of assessment that is administered to the patients every week. It consists of GAD-2, PHQ-2, PGI, and Asberg side effect questionnaires (see Table 5) to measure patients' weekly progress and potential side effects. This assessment is only available for the patient when the clinician schedules it.

#### 3. Sleep Education and Personalized Sleep Tips

Sleep education contains information about sleep, insomnia, brain mechanisms that control sleep, and healthy sleep practices. These educational materials are always available on the iREST app. Personalized sleep tips are specific information on how to address or overcome certain behaviors, cognitions, or events (e.g., nightmare episodes) that may be perceived as barriers to healthy sleep. Clinicians can prescribe these sleep tips based on the report from patients' sleep/wake logs. For example, if a patient reports having a nightmare on a previous night, the clinician can prescribe "Getting rid of bothersome dreams" tips to the patient's iREST app.

#### 4. Secure Messaging

Secure messaging allows real-time message exchange between clinicians and patients while maintaining high privacy and security, which are lacking on regular text messaging/short message services (SMS). Multiple security measures are implemented in the secure massaging feature, including:

- a strong protocol for communication between the iREST app and server using Transport Layer Security (TLS) (Blake-Wilson, Nystrom, Hopwood, Mikkelsen, & Wright, 2003)
- a secure encryption key exchange using Elliptic curve Diffie-Hellman (ECDH) anonymous key agreement protocol (Blake-Wilson, S., 2006)
- a secure encoding/enciphering of messages using Advanced Encryption Standard (Daemen, Rijmen, & Leuven, 1999) with 256-bit key length (AES-256) encryption and Base16 encoder (Josefsson, 2006)

The secure messaging feature allows patients and clinicians to exchange information that may not be readily available on the app's other functionalities. For example, using secure messaging, a patient may request additional information on certain sleep problems they are having after reading the personalized sleep tips prescribed by the clinician. The clinician can then reply with links to additional resources.

#### 5. Dashboard

The iREST app's dashboard provides at-a-glance views of key performance indicators (KPI) on individual treatment progress. In sleep interventions, these indicators can be sleep parameters such as sleep efficiency, latency, wake up after sleep onset and total

sleep time. The dashboard also contains indicators of logs and assessment completion. In addition, the dashboard provides visual notification for new messages and new tips that are received from the clinician portal.

## 6.2.4.2 The iREST Clinician Portal

Similar to the iREST mobile app, the clinician portal is an implementation of portal logical architecture (Section 6.1.7) of the JITAI application architecture, based on the requirements described in Section 6.2.3. Figure 29 highlights functionalities available on the iREST clinician portal.

## 1. Calendar and Scheduling

Calendar views allow clinicians to quickly assess the current statuses of scheduled intervention components such as prescribed wake time and assessment schedules. This page also provides patients' mobile device status (active, idle, inactive) and shortcuts for creating new schedules for sending secure messages to the patients.

## 2. Intervention Prescription

Intervention prescription is the main feature for managing and prescribing intervention components. It provides patients' daily sleep logs and weekly progress summaries; based on these summaries, the portal suggests appropriate sleep prescriptions. The clinicians then make judgments on which course of action to take or which intervention components to actually prescribe to the patients' mobile app.

#### 3. Wearable Sensor Integration

On the current implementation of the clinician portal, only integration with Fitbit is supported. The integration functionality provides interfaces to perform sleep data imports from the Fitbit server. The mechanism of this data import has been discussed in Section 6.1.8 on Integration Architecture.

## 4. Secure Messaging

Secure messaging on the portal side is the other side of the real-time secure messaging service mentioned earlier on the app side. In addition, the portal version allows message exchange with other clinicians. Clinicians can also opt to receive notifications through their email whenever there is a new message on the portal intended for them.

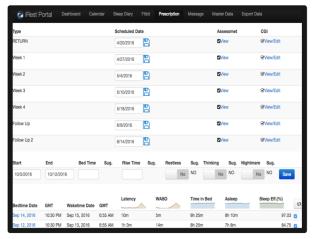
## 5. Clinician Dashboard

The iREST portal's dashboard provides data visualization of patients' progress in the intervention, the intervention status as whole, and also general views of the mHealth utilization. It allows clinicians to make priorities on resource allocation based on the severity of their patients' conditions. For example, patients who frequently express sleep problems (e.g., nightmares, thinking in bed) will have more clinician time than patients whose interventions are going well.

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## 2. Intervention Prescription

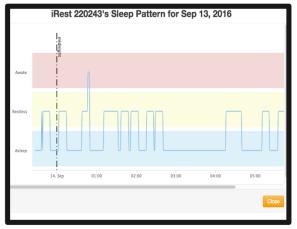


#### 4. Secure Messaging

Dashboard Calendar

iRest Portal

## 3. Wearable Sensor Integration



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#### 5. Clinician Dashboard



Figure 29. iREST portal screenshots

# 7.0 EVALUATION OF THE JITAI HEALTH BEHAVIORAL MODEL AND APPLICATION

To evaluate the usability and clinical feasibility of the iREST mHealth tool, a pilot study was conducted. The purpose of the usability study was to reveal how real patients and clinicians interact with the iREST system and to improve the system based on the results. The purpose of the clinical feasibility study was to evaluate the impact of this novel JITAI tool to deliver and support behavioral intervention on insomnia and sleep disturbances, symptom improvement, overall sleep quality, response to treatment, and remission rates. The outcomes were then compared with previous traditional (paper-and-pencil, in-person visits) BBTI for the same military population (Germain et al., 2014).

## 7.1 THE PILOT STUDY OVERVIEW

#### 7.1.1 Participants

The University's Institutional Review Board approved the present study. Participant recruitment and screening were conducted by the University of Pittsburgh Military Sleep Tactics & Resilience Research Team (M-STARRT). ADSM and Veterans between the ages of 18 and 60 were recruited through postcard, flyer, study website, social media/Facebook (San Francisco, CA) and public television. Since the study is a Bring Your Own Device (BYOD) study, in order to be eligible, ADSM and Veterans had to own a smartphone and necessary Internet access, and be fluent in the use of a smartphone. Other eligibility criteria: 1) endorsing significant sleep complaints as determined by a baseline score higher than 5 on the Pittsburgh Sleep Quality Index (PSQI) (D J Buysse et al., 1989); 2) having a baseline score greater than 10 on the Insomnia Severity Index (ISI) (Bastien et al., 2001); and 3) having sleep complaints for at least 1 month. Exclusion criteria included: 1) past or current history of psychotic disorder or bipolar disorder; 2) suspected or previous diagnosis of sleep apnea narcolepsy or other sleep disorder requiring further evaluation and treatment; 3) severe or untreated psychiatric disorder associated with marked impairments in functioning; 4) current pregnancy or lactation; and 5) scheduled/imminent military deployment during the course of the study.

## 7.1.2 Screening Procedures

With the person's verbal consent, a telephone screen was conducted to assess eligibility prior to the first in-person visit. Screening questions were related to the current use of a smartphone, past and current psychiatric and physical health, and presence of suspected or diagnosis of sleep apnea or other physiological sleep disorders.

After obtaining written, informed consent, participants underwent a 2-part diagnostic evaluation: 1) diagnostic interview and 2) screening questionnaires. The diagnostic interview focused on assessing insomnia, the presence and severity of trauma history, alcohol/substance use disorders, other psychiatric disorders, and current physical health. A weekly consensus meeting was held to review diagnostic information and establish final inclusion or exclusion in

the study. Self-report screening questionnaires (Table 6) were completed after obtaining written

consent during the diagnostic interview.

Table 6. List of assessment tools/questionnaires used for participant screening procedure

Structured Clinical Interview for DSM-IV, non-patient version (SCID-NP)(First, Spitzer, Gibbon,

& Williams, 2002)

was used to assess past and current psychiatric history.

## **DSM Sleep Disorder**

was developed in-house (M-STARRT) to assess the presence, frequency, and severity of symptoms for each DSM sleep disorder.

Clinician administered PTSD Scale – Part 1 (CAPS) (Blake et al., 1995),

considered the gold standard post-traumatic stress disorder (PTSD) diagnostic instrument, was used to evaluate the presence and severity of past and current PTSD symptom.

**PTSD Checklist – Civilian version (PCL-C)** (Weathers, F.W., Litz, B.T., Huska, J.A., & Keane, 1994) was used to measure PTSD symptoms, only participants with PCL-C under 51 were included in the study.

STOP-BANG (Chung et al., 2008),

a set of eight yes/no questions, was performed to assess risk for sleep apnea.

Insomnia Severity Index (ISI)(Bastien et al., 2001)

was used to assess subjective severity of insomnia symptoms.

Pittsburgh Sleep Quality Index (PSQI) (D J Buysse et al., 1989)

was administered to assess different component of sleep quality, with a cut-off of 5 differentiating between good and bad sleepers.

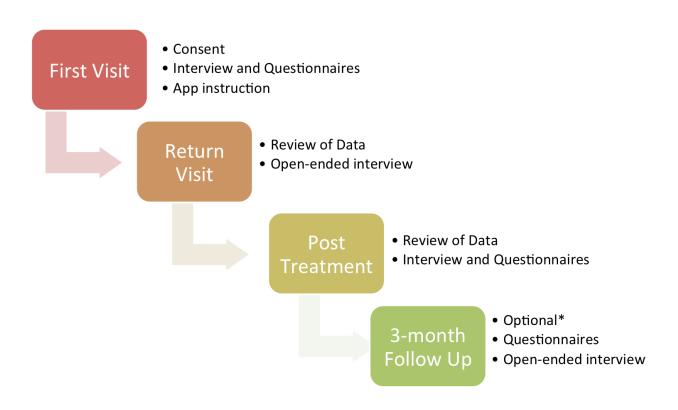
**PSQI Addendum for PTSD (PSQI-A)** (Germain, Hall, Krakow, Katherine Shear, & Buysse, 2005; Insana, Hall, Buysse, & Germain, 2013)

was performed to assess the frequency of disruptive nocturnal behaviors commonly endorsed by traumaexposed individuals.

## Epworth Sleepiness Scale (ESS) (Johns, 1991)

was used to assess daytime sleepiness, with higher scores indicating greater sleepiness.

## 7.1.3 Treatment Conditions



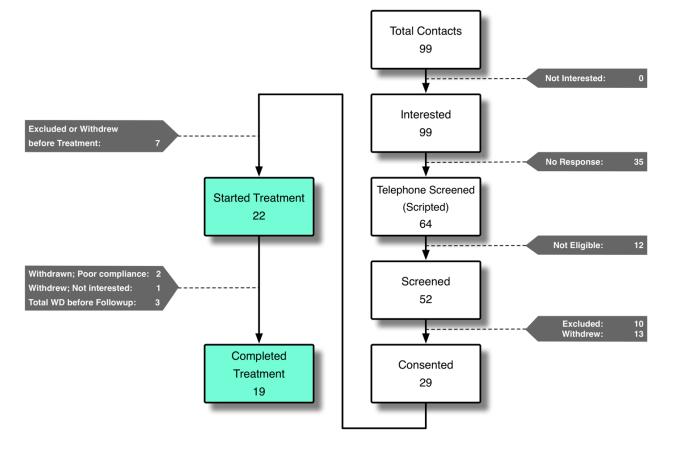
#### Figure 30. The iREST study flow

Figure 30 shows the study's overall workflow. After obtaining written informed consent, participants were issued a six-digit ID and completed a series of self-report questionnaires to assess military history and demographic variables, sleep quality, current sleep habits and behaviors, psychological well-being, and perceived physical health. They also completed a diagnostic interview to assess the presence of psychological disorders. They then received information on how to use the iREST app for the next 7 to 10 consecutive days. This visit required approximately 90 minutes.

Participants then returned to the research office after 7 to 10 days of using the app. This period allows for scheduling flexibility to accommodate participants' schedules. Participants' sleep information was reviewed by the clinicians; the clinicians then recommended a course of behavioral treatment to address the sleep problems reported. This process required less than a one-hour office visit. Participants then used the app and followed the BBTI intervention through the iREST app for 4-6 weeks. Participants who continued to experience significant sleep complaints were offered up to four in-person sleep consults with the clinicians or/and referral to a sleep clinic or mental health services.

We also collected pilot data on the use of Fitbit to track sleep patterns. Seven Fitbit Charge<sup>TM</sup> wristbands were randomly assigned to participants. Participants assigned with Fitbit bands were required to wear the band to measure their sleep patterns in addition to filling out the in-app sleep diary.

## 7.1.4 Participants Flows



#### Participant Flow for IREST Study

Figure 31. Participants Flow

As shown in Figure 31, a total of 99 individuals contacted the research program to inquire about the study, all expressing interest in participating. During the scripted telephone screening, 35 (35.6%) individuals did not respond after several attempts to contact them. Twelve individuals (18.75%) were found not eligible after telephone screening. ADSM and Veterans who passed the telephone screening attended the in-office diagnostic evaluation; ten individuals (19.23%) were excluded in this phase. Twenty-nine ADSM and Veterans provided written informed consent; however, seven of them (24.14%) withdrew from the study before the intervention. Out of 22 who started the intervention, nineteen (19) participants (86.36%) completed post-

treatment/follow-up assessment and were included in the follow-up analysis; Six (31.58%) participants used an iPhone/iOS device, and the other 13 (68.42%) used an Android device.

## 7.1.5 Demographics

 Table 7. Demographic and clinical information at baseline compared with previous BBTI for military population

 study (Germain et al., 2014)

	Current Study (N=22)	Prev. Study (N=20)	Statistical Comparison
Male (%)	18 (81.8)	19 (95)	$\chi^2 = 1.74$ n.s.
Caucasian (%)	17 (77.3)	14 (70)	$\chi^2 = 0.29$ n.s.
Mean Age (SD)	38.7 (9.7)	40.9 (12)	t(40) = -0.67 n.s.
Army (%)	14 (63.6)	16 (80)	$\chi^2 = 1.37$ n.s.
Current PTSD	8 (36.4)	5 (25)	$\chi^2 = 0.63$ n.s.
Using Psychotropic (%)	4 (18.2)	5 (25)	$\chi^2 = 0.29$ n.s.
Current Mood/Anxiety Disorder (%)	8 (36.4)	2 (10)	$\chi^2 = 4.01$ , ns
Baseline Sleep Assessment (SD)			
Mean Epworth Sleepiness Scale	7.4 (4.6)	7.3 (4.4)	t(40) < 0.01 n.s.
Mean Insomnia Severity Index	17.4 (4.0)	16.3(3.9)	t(40) = 0.90 n.s.
Mean PSQI	11.9 (3.9)	11.3(3.5)	t(40) = 0.52 n.s.

Descriptive statistics were performed to describe the demographic characteristics of the study participants using frequencies for categorical variables and means and standard deviations (SDs) for continuously measured demographic variables. Each demographic variable was compared with the same variable from the in-person BBTI trial to compare and to determine if there were statistically significant differences between the distribution in the current study sample and the previous one (using a Chi-squared test for categorical variables and Student t-test for continuous variables).

Demographic information obtained at baseline is provided in Table 7. There were no statistically significant demographic differences between participants in the current study (iREST) and the traditional BBTI study.

## 7.2 USABILITY

To evaluate the usability of the newly-developed iREST system, a usability study was conducted. The purpose of the study was to assess how easy and pleasant to use the iREST system was. Furthermore, the study collected users' feedback on which features were most suitable, their advantages and disadvantages and how to mitigate the disadvantages, and what kind of interface was most effective/preferable. This information was then used to refine the iREST system.

## 7.2.1 Measurement

At the first office visit, participants gave informed consent, completed baseline questionnaires and interview, and given a tutorial on how to use the iREST app. This visit required approximately 90 minutes. After the first visit, participants were allowed to try the app for 7-10 days. After that period, participants returned to the office to fill out the "first impression" usability questionnaires and to provide feedback about the app. Participants then continued to use the app for the following 4-6 weeks of the BBTI, after which they returned to the research office to review progress. Another open-ended interview was performed at this time to obtain feedback on the usability, design, content, and usefulness of the iREST app. Participants were required to complete post-study usability questionnaires: the SUS and TUQ (descriptions of the SUS and TUQ were given in Section 2.6 Usability Evaluation).

App usage adherence was calculated by the number of logs entered by the participants divided by twice (because there are two logs each day: wake log and sleep log) the total number of day participants used the app in the study. Completion time for each log was calculated by measuring time lapse between the time participants accessed the sleep/wake log screen and the time they hit the save button (i.e., completed the logs). The calculation was done automatically by the iREST system.

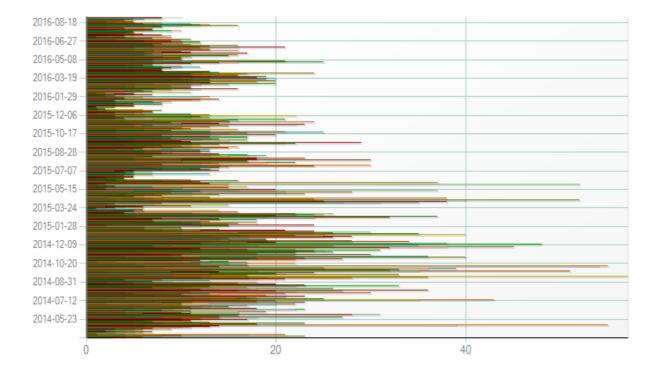
## 7.2.2 Statistical Analysis

IBM (Armonk, NY) SPSS Statistics software version 24.0 was used for data analysis.

<u>Usage characteristics</u>: Descriptive statistics was performed to describe the application usage characteristics using frequencies for categorical variables and means and standard deviations (SDs) for continuously measured demographic variables.

<u>Usability</u>: The Usability Questionnaires results were analyzed using descriptive statistics, including mean and frequency distribution. Furthermore, the SUS mean score was compared to the standardized SUS score (Bangor, Kortum, & Miller, 2009, 2008). A Paired Student t-test was performed to compare the SUS and the TUQ scores, pre- and post-study. In addition to formative usability questionnaires, participants were also asked to provide quantitative feedback or comments about the use of the iREST app.

## 7.2.3 Results



## 7.2.3.1 Usage

Figure 32. Daily Unique Device Access to iREST Portal

One way to describe the overall usage of the system is by calculating the number of unique device accessing the iREST portal per day (Figure 32). Based on the iREST server's log, on average there were at least 12 (mean=12.23, SD=8.96) unique devices accessing the portal daily for more than two years since the iREST study started. On the app side, according to the Apple App Store and Google Play statistics from September 2016, the app was downloaded and installed 247 times (182 on Android devices, 65 on iOS devices). The app is currently active on 53 devices, 47 Android and 6 iOS. In addition to the current study, the iREST mHealth system was also used to support at least two other sleep intervention studies.

During the course of the study, our online server experienced an unplanned outage resulting in no data collection over a three-day period for two participants. This unexpected problem was subsequently fixed by making the system capable of handling server and connection outages. On average, participants completed 91.11% of the required twice-a-day sleep diary entries; each participant on average only missed filling out less than 3 days' worth of sleep dairies throughout the course of the study. It took them an average of less than two minutes (108.53 seconds, SD=26.19) to complete each assessment.

## 7.2.3.2 Usability

In the post-intervention follow-up visit, 17 out of 19 participants finished the post-study questionnaires (the SUS and the TUQ). The sample size is considered appropriate according to the Problem Discovery Rate Model, which is widely used to serve in formative usability evaluations (C Lewis & Rieman, 1993; Nielsen & Landauer, 1993). According to the model, 85% of usability problems were revealed using five participants, and almost 100% of problems using 14 participants (J. R. Lewis, 2006). The participants rated the app as highly usable with a mean SUS score of 85.74 (SD =12.37), which translates to adjective ratings of "Excellent" (Bangor et al., 2009). On the TUQ, participants were satisfied with the iREST app and would consider using it in the future (average score of 4.31 out of 5, SD=0.63). They also gave high scores on "ease of use and learnability" with an average score of 4.33 (SD=0.65). In assessing room for improvement, the sections for "interface quality" and "reliability" received slightly lower scores, although still above average, with a mean score of 4.05 (SD=0.85) and 3.88 (SD=0.70), respectively. Server outage may have contributed to lower scores on reliability, while the lower interface quality score shows the need for more meaningful data visualization and better overall user-interface design.

Variable	Before	After	Pre- to post- mean score change (post-pre)			
	treatment	treatment	Estimates(SE)	t-statistics	p-value	
	(SD)	(SD)		(df)		
SUS	78.04 (13.66)	85.74 (12.37)	6.61 (3.65)	1.81 (13)	n.s.	
TUQ						
Ease of use	4.15 (0.55)	4.33 (0.65)	0.14 (0.18)	0.76 (10)	n.s.	
Interface Quality	3.65 (0.65)	4.05 (0.85)	0.55 (0.17)	3.25 (10)	0.009	
Interaction Quality	3.77 (0.76)	3.95 (0.78)	0.20 (0.14)	1.11 (10)	n.s.	
Reliability	3.58 (0.53)	3.88 (0.70)	0.45 (0.22)	2.09 (10)	n.s.	
Overall Satisfaction	3.96 (0.80)	4.31 (0.63)	0.36 (0.22)	1.62 (10)	n.s.	

 Table 8. Paired T-Test Comparison on Usability Questionnaires Score (SUS and TUQ) between pre- and post-treatment

When compared with pre-treatment scores, both SUS and TUQ post-treatment scores were higher. The results show that participants continued to rate the iREST app as highly usable even as they became more familiar with the system; in other words, rather than *contempt*, in this case, *familiarity breeds content*-ment. Furthermore, the improvement in interface quality score on the TUQ was statistically significant (Table 8), and a noticeable score increase was observed on Reliability (mean increase of 0.45). Continued user-centered improvements (e.g., incorporating users' feedback and addressing UI interaction problems) in user interface and system reliability most likely contributed to the noticeable increase in TUQ scores for those two areas.

In addition to completing usability questionnaires, participants were asked to provide individual comments and feedback about the app. Responses were generally categorized into five types: 1) general comments about the app; 2) comments about the graphical user interface and navigation; 3) comments about the sleep logging process; 4) comments about sleep education features; and 5) questions and problem reporting. Participants expressed liking the application generally with reported comments such as: 'Likes the front page a lot, finds it useful and attractive'; 'Very easy to navigate, found that the data uploaded quickly'; 'Likes the morning reminder to fill out wake time diary' Participants also pointed out issues and made suggestions, such as: 'Time input was tedious, needs improvement'; 'Frustrated by text overlap when device is held horizontally'; 'Have the SE% graphic replaced by something, e.g. tracking how many logs were entered on time.' **Appendix G** contains a portion of the reported feedback and comments. These feedbacks were used to iteratively improve the iREST app reported in this dissertation and were also used as input for future developments.

## 7.3 CLINICAL FEASIBILITY

A clinical feasibility study will be conducted to evaluate the impact of a novel JITAI tool to support self-management for sleep disturbances on sleep quality, consolidation, and psychological health. The study outcomes will then be compared with a previous sleep intervention using the traditional approach.

## 7.3.1 Hypothesis

There are no significant differences (i.e., non inferiority) in clinical outcome measures between the JITAI sleep intervention and a traditional sleep intervention.

> *H*<sub>0</sub>: Symptoms Improvement  $_{iREST} <$  Symptoms Improvement  $_{Traditional BBTI}$ *H*<sub>1</sub>: Symptoms Improvement  $_{iREST} \ge$  Symptoms Improvement  $_{Traditional BBTI}$

In order to prove the stated hypothesis, null hypothesis ( $H_0$ ) needs to be rejected.

## 7.3.2 Outcome Measures

In this feasibility study, the Insomnia Severity Index (ISI) (Bastien et al., 2001) was used as the primary sleep outcome measure. The ISI is a 7-item self-administered questionnaire that subjectively assesses the severity of insomnia symptoms, level of satisfaction with sleep, noticeability and extent of daytime impairment, and concerns caused by sleep problems. Each ISI's item is on a scale of 0 to 4; a total score greater or equal to 14 reflects clinically significant insomnia. In addition, daytime sleepiness was assessed using the Epworth Sleepiness Scale (ESS) (Johns, 1991). The ESS is an 8-item self-report questionnaire on which respondents are asked to rate on a scale of 0 to 3 their usual chances of dozing off or falling asleep while engaged in eight different activities. The ESS score can range from 0 to 24; the higher the score, the higher the severity of 'daytime sleepiness.'

Overall sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI) (D J Buysse et al., 1989) and the PSQI Addendum for PTSD (PSQIA) (Germain et al., 2005; Insana et al., 2013). The PSQI is an 18-item self-administered questionnaire that assesses different components of sleep quality. The PSQI score ranges from 0 to 21, with higher scores reflecting poorer sleep quality. The PSQI-A is a 7-item (with a conditional 3 additional items) self-report measure that assesses the severity of seven disruptive nocturnal behaviors commonly endorsed by trauma-exposed individuals (Germain et al., 2005). Scores range from 1 to 21, similar to PSQI, with higher scores indicating more severe disturbances. Participants also completed the PTSD Checklist – Civilian version (PCL-C) (Weathers, F.W., Litz, B.T., Huska, J.A., & Keane, 1994), given the relationship between sleep problems and symptoms of PTSD in military samples (Bramoweth & Germain, 2013). In addition, the Combat Exposure Scale (CES) (Keane et al., 1989) was also administered. The CES is a 7-item questionnaire with scores ranging from 0 to 42; 0 - 8 is considered 'light' exposure; 9 - 16 is 'light moderate'; 17 - 24 is 'moderate'; 25 - 32 is 'moderate – high'; and 33 - 42 is 'high.'

Treatment response was defined as a reduction of 8 points or more on the ISI (Charles M Morin, Belleville, Bélanger, & Ivers, 2011). Remission was defined as 1) meeting treatment response criteria, and 2) a post-treatment ISI score below the clinical threshold of 7.

## 7.3.3 Statistical Analysis

IBM (Armonk, NY) SPSS Statistics software version 24.0 was used for data analysis for sleep outcomes. Hierarchical linear model (HLM) analysis was conducted using the SSI (Skokie, IL) HLM Student version 7.01 software package.

<u>Sleep Outcomes</u>: Treatment response rate and remission rate were assessed posttreatment. We followed the intention-to-treat principle: all participants who completed the outcomes of interest for at least one of the time points were included in the analyses. The results were then compared using the Chi-squared test with previous traditional (i.e., without mobile health system) BBTI for the military population study (Germain et al., 2014).

Longitudinal Sleep Parameters: The longitudinal view of sleep parameters (day-to-day) was analyzed using a hierarchical linear model (HLM). This special analytic technique is needed to accommodate the nested structure of the data, which includes repeated measures within individual (level-1) and between-person variables (level-2). HLM employs an iterative process to estimate regression equations for level-2 data (i.e., individuals) as a step toward arriving at the best regression equation for the entire set of sampling moments (Raudenbush & Bryk, 1992).

Furthermore, HLM has the important advantage of remaining unbiased in the presence of unequal numbers of observations across individuals and unequally spaced sampling moments.

### 7.3.4 Results

As mentioned earlier, nineteen participant finished the full length of the BBTI, out of 22 who started. There were no significant differences between those who finished and those who did not, as shown in Table 9.

 Table 9. Demographic comparison between the 19 participants who finished and 3 participants who did not finish

 the intervention

	Finished (N=19)	Drop out (N=3)	Statistical Comparison
Male (%)	16 (84.2)	2 (66.7)	$\chi^2 = 0.54$ n.s.
Caucasian (%)	15 (78.9)	2 (66.7)	$\chi^2 = 0.22$ n.s.
Mean Age (SD)	38.7 (10.2)	38.6 (7.1)	t(20) = 0.02 n.s.
Army (%)	12 (63.2)	2(66.7)	$\chi^2 = 0.01$ n.s.
Current PTSD	7 (36.8)	1 (33.3)	$\chi^2 = 0.01$ n.s.
Using Psychotropic (%)	3 (15.8)	1 (33.3)	$\chi^2 = 0.54$ n.s.
Current Mood/Anxiety Disorder (%)	7 (36.8)	1 (33.3)	$\chi^2 = 0.01$ , ns

#### 7.3.4.1 Response and Remission Rate

Post treatment, sixteen of the 19 ADSM and Veterans (84.21%) who completed BBTI through iREST app met criteria for treatment response. The remission rate was 68.42%, or 13 out of 19 participants. The response rate in the traditional/face-to-face BBTI trial was 76.47%, with a

remission rate of 52.94%. There was no significant difference between the rates in the current trial and the previous BBTI-MV study,  $\chi^2 = 0.34$ , p>0.05 and  $\chi^2 < 0.91$ , p>0.05 for response and remission, respectively.

## 7.3.4.2 Changes in Sleep and Daily Symptoms

The pre- and post-intervention tests show statistically significant improvement in primary and secondary outcomes in, for example, insomnia severity, mean reduction on the ISI = 10.16, t(18) = 7.40, p < 0.01; improvement in sleep quality, mean reduction on the PSQI = 6.32, t(18) = 5.66, p < 0.01; decrease in daytime sleepiness, mean reduction on the ESS = 2.11, t(18) = 2.38, p = 0.03. Details on these improvements can be seen in Table 10 bellow.

Variable	Mean Baseline	Mean Post Treatment	Mean Change (SE)	t-statistics (df)	p-value
ISI	17.11	6.95	10.16 (1.37)	7.40 (18)	<0.001
ESS	8.00	5.89	2.11 (0.89)	2.38 (18)	0.029
PSQI	12.16	5.84	6.32 (1.12)	5.67 (18)	< 0.001
PSQI-A	5.11	2.89	2.21 (0.92)	2.40 (18)	0.028
PCL-C <sup>a, b</sup>	41.16	30.05	11.11 (2.37)	4.86 (18)	<0.001

Table 10. Mean scores change pre- and post- intervention

<sup>a</sup> *PCL* scores were not normally distributed, and a natural log (ln) transformation was used in the analyses; <sup>b</sup> Raw scores are presented

Compared with the previous study, a mixed model ANOVA with time as a within-subject repeated measure (pre- and post-treatment) on the primary clinical outcome (the ISI) showed no significant Group x Time interaction (F(1,34) = 0.61, p = 0.44) and no main effect of group (iREST vs. BBTI-MV; F(1,34) = 0.01, p = 0.94). Only a main effect of time was detected

(F(1,34) = 87.39, p < 0.01). This suggests that iREST may be as effective as, or non-inferior to the in-person BBTI-MV.

Mixed model ANOVAs were also performed within-group (in the current study only) to determine whether the improvement in outcomes was different between comorbidity diagnoses (e.g., PTSD, mood and anxiety, and level of combat exposure). After controlling the ISI scores based on whether or not the participants were diagnosed with PTDS, mood and anxiety disorders, and level of their combat exposure, the only significant effect was in terms of time (pre- to post-), but no significant effect of comorbidity conditions (with PTSD vs. without PTSD; with mood and anxiety vs. without; and light vs. light-moderate vs. moderate vs. moderate-heavy vs. heavy combat exposure) were observed; nor was there significant interaction between time and these conditions.

Grouping Variable	Effect	F	p-value
	Time	53.48	< 0.001
PTSD Diagnose	Group	0.16	n.s.
	Time X Group	0.74	n.s.
Mood and Anxiety Diagnose	Time	47.04	< 0.001
	Group	3.60	n.s.
	Time X Group	0.23	n.s.
Combat Exposure (CES)	Time	41.66	<0.001
	Group	0.91	n.s.
	Time X Group	1.39	n.s.

Table 11. Insomnia improvement grouped by comorbidity diagnoses

## 7.3.4.3 Longitudinal Sleep Parameters

By the time the 19 participants finished the study, they were required to fill out the logs (wake and sleep) for a total of 1,035 days, or more than 54 days per person. The adherence to completing the logs was very high (as reported in Section 7.2.3.1 Usage); together the participants finished 904 sleep logs and 982 wake logs, or a total of 1,886 log entries. Figure 33 illustrates first 35 nights snippet of SE values as reported on participant sleep logs. The snippet suggests that the night-to-night variability in sleep parameters was not the same across participants. All 19 participants received the same iREST/BBTI treatment and were in the same group; therefore, there may have been between-person variables which explain these differences.

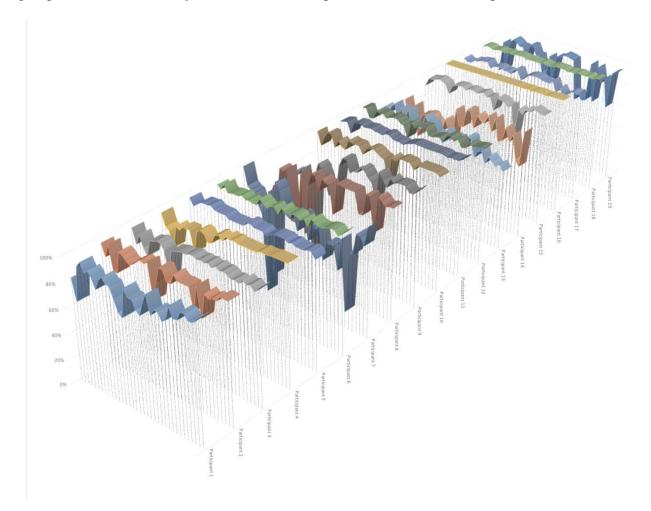


Figure 33. First 35-Night Snippet of Nightly Sleep Efficiency Calculated from Participant Sleep Logs

Although minimal, missing logs were consistent across participants. Also, the total number of completed entries varied between participants. Hence, we cannot use a traditional mixed model ANOVA to analyze these data to determine between-person variables that may explain the differences in day-to-day sleep parameters as shown in Figure 33. This nested data structure requires multi-level analysis, such as hierarchical linear model (HLM) analysis.

During the construction of the HLM, time was considered as a primary independent variable for the model's level-1 (within-subject). The following sleep parameters were considered as the outcomes of the model: SOL, WASO, TIB, TST, and SE. As for level-2 (between-subject), the potential predictor variables included: race, age, military branch, use of psychotropic, mood and anxiety diagnosis, baseline ESS score, baseline Generalized Anxiety Disorder scale 7-items (GAD7) score, baseline ISI score, PTSD diagnose, baseline PCL score, baseline Patient Health Questionnaire 9-items (PHQ9) score, baseline PSQI and PSQI-A score.

#### Model 1: Unconditional Means Model

An unconditional means model of HLM is equal to a one-way random effect ANOVA and is the simplest possible random effect linear model. The motivation for this model was to determine amount of variance in individuals' mean sleep parameters (SOL, WASO, TST, TIB, and SE). In terms of equations, the following emerged, where  $e_{ti} \sim N(0, \sigma^2)$  and  $r_{0i} \sim N(0, \tau^2)$ :

SLEEP PARAMETER<sub>ti</sub> = 
$$\pi_{0i} + e_{ti}$$
  
 $\pi_{0i} = \beta_{00} + r_{0i}$ 

or, in a single equation

SLEEP PARAMETER<sub>ti</sub> = 
$$\beta_{00} + r_{0i} + e_{ti}$$

where:

SLEEP PARAMETER<sub>ti</sub> = sleep parameter measured for participant i (level-2) at time t (level-1);

- $\pi_{0i}$  = mean sleep parameter for participant *i*;
- $\beta_{00}$  = grand mean sleep parameter across participants;

$$e_{ti}$$
 = random error associated with estimation of sleep parameter  
on time *t* for participant *i*;

 $r_{0i}$  = random error associated with estimation of mean for participant *i*;

Variance(
$$e_{ti}$$
) =  $\sigma^2$  = within individual variance in sleep parameter;

Variance $(r_{0i}) = \tau^2$  = between individual variance in sleep parameter.

Table 12 shows the results of fittings Model 1 to sleep logs data for each sleep parameters. The estimated between-subject variance,  $\tau^2$ , corresponds to estimation of variance for random effect  $r_0$ , while the estimated within-subject variance,  $\sigma^2$ , corresponds to estimation of variance for level-1 random effect e. The magnitude of the variation among participants in their means is demonstrated by the *plausible value range* ( $\beta_{00} - 1.96\sqrt{\tau^2}$ ,  $\beta_{00} + 1.96\sqrt{\tau^2}$ ) for these means, which is confident interval (CI) for  $\pi_0$ . Based on the covariance estimates, a chi-squares test for the between-subject variance ( $\tau^2$ ) to be zero were performed; significant result indicates significant variation among individual means of corresponding sleep parameter remains to be explained. In addition, the intra-class correlation (ICC) can be determined by calculating  $\tau^2/(\tau^2 + \sigma^2)$ . This ICC estimate tells us the portion of the total variance that occurs between participants. The reliability measures the overall reliability of the ordinary least squares (OLS) estimates for each of the intercepts,  $\pi_0$ .

For the unconditional model, we first examined the chi-square test. If the test turned significant for certain sleep parameter, it indicates that there was significant variance between subject, therefore further HLM analyses are required for that sleep parameter. The test turned significance for all sleep parameters, so further HLM analyses are justified for all of the parameters. As an additional step, the ICC determine which percentage of the variance in each sleep parameter is attributable to between-individual and which percentage is at within-individual. For example, 41% of variance in sleep efficiency (SE) is between participants, and 59% is within.

Table 12. Unconditional Means Model Results

Sleep	ß	$\tau^2$	$\sigma^2$	ICC	Plausible values	$\chi^2$ (p-value)	Reliability
Parameter	$\beta_{00}$	L	0	ice	range	χ (p-value)	Kenaoliity
SOL <sup>(1)</sup>	20.04	448.04	962.82	0.32	(0, 61.53)	395.42 (p<0.01)	0.955
WASO <sup>(1)</sup>	20.01	349.19	659.04	0.35	(0, 56.63)	477.59 (p<0.01)	0.960
TIB	439.74	2279.81	5487.37	0.29	(346.16, 533.33)	374.16 (p<0.01)	0.950
TST	399.71	3017.62	6370.22	0.32	(292.04, 507.38)	434.43 (p<0.01)	0.956
SE <sup>(2),(3)</sup>	0.9077	0.0056	0.0083	0.41	(0.7608, 1.00)	607.15 (p<0.01)	0.969

Notes: <sup>(1)</sup>The lower end of plausible values range was limited at 0 minutes; <sup>(2)</sup>Additional decimal digits were added for SE estimations because the SE value is represented as a percentage; <sup>(3)</sup>The upper end of plausible values range was limited at 100% (1.00)

## Model 2: Including Effects of Time Predictor

Time is within subject predictor (level-1). Including time into the model will produce a random-coefficient model (Raudenbush & Bryk, 1992). This would be similar to running a regression of a sleep parameter on time (represented as a night-index variable) for each individual, in other words, running 19 linear regressions. This random-coefficient model will answer such questions as:

1. What would be the average of the 19 regression equations (both intercept and slope)?

- 2. How much do the regression equations vary from individual to individual?
- 3. Is the increase/decrease (slope) on sleep parameters across time statistically significant?

The equation for this random-coefficient model is:

SLEEP PARAMETER<sub>ti</sub> = 
$$\pi_{0i} + \pi_{1i}(INDEX_{ti}) + e_{ti}$$
  
 $\pi_{0i} = \beta_{00} + r_{0i}$   
 $\pi_{1i} = \beta_{10} + r_{1i}$ 

or, in a single equation

SLEEP PARAMETER<sub>ti</sub> = 
$$\beta_{00} + \beta_{10}(INDEX_{ti}) + r_{0i} + r_{1i}(INDEX_{ti}) + e_{ti}$$

where:

SLEEP PARAMETER <sub>ti</sub>	=	sleep parameter measured for participant <i>i</i> at time <i>t</i> ;
$\pi_{0i}$	=	regression intercept for participant <i>i</i> ;
$\pi_{1i}$	=	regression coefficient for participant <i>i</i> ;
$\beta_{00}$	=	overall mean intercept across participants;
$\beta_{10}$	=	overall regression coefficient across participants;
e <sub>ti</sub>	=	random error associated with estimation of sleep parameter
		on time <i>t</i> for participant <i>i</i> ;
r <sub>oi</sub>	=	random effect on the intercept for participant <i>i</i> ;
$r_{1i}$	=	random effect on the slope for participant <i>i</i> ;
Variance( $e_{ti}$ ) = $\sigma^2$	=	within individual variance in sleep parameter;
Variance( $r_{0i}$ ) = $\tau^2$	=	between individual variance in intercept;
Variance( $r_{1i}$ ) = $\tau^2$	=	between individual variance in regression coefficient.

Table 13 shows the results of fitting Model 2 to sleep log data for each sleep parameter. The types of estimates reported in the table are similar to the results of the previous model, except for level-1 residual variance ( $\sigma^2$ ) reduction. The reduction is calculated by subtracting the level-1 residual variance in the one-way ANOVA with random effect model (Model 1) from the residual variance in the random-coefficient model (Model 2). Knowing this, we can calculate the proportion of variance explained at level-1 from introducing time as a predictor by ( $R^2_{Model 2}$  =

 $\sigma_{Model\,1}^2 - \sigma_{Model\,2}^2) / \sigma_{Model\,1}^2 \, .$ 

Sleep	$\pi_{\rm o}$ (intercept)			$\pi_1$ (slope)				$\sigma^2$	
Parameter	β <sub>00</sub>	p- value	V(r <sub>0i</sub> )	$\chi^2$ (p-value)	β10	p- value	V(r <sub>1i</sub> )	$\chi^2$ (p-value)	Reduction (R <sup>2</sup> %)
SOL	27.04	<0.01	962.82	223.39 (p<0.01)	-0.27	0.03	0.17	47.56 (p<0.01)	44.54 (5%)
WASO	20.24	<0.01	361.00	157.20 (p<0.01)	-0.03	n.s.	0.48	148.03 (p<0.01)	83.17 (13%)
TIB	451.58	<0.01	4133.13	184.76 (p<0.01)	-0.46	n.s.	0.96	54.71 (p<0.01)	257.89 (5%)
TST	404.47	<0.01	4702.74	187.34 (p<0.01)	-0.18	n.s.	1.69	74.99 (p<0.01)	387.97 (6%)
SE	0.8941	<0.01	0.0077	250.03 (p<0.01)	0.0006	n.s.	<0.0001	132.49 (p<0.01)	0.001 (12%)

Table 13. Random-coefficient Model Results

The slope estimates for WASO, TIB, TST, and SE were not found to be statistically significant. This means that there was no significant fixed effect of time for those variables; the values did not change significantly over time. However, it needs to be noted that the model shows negative slope coefficients for TIB, WASO, and TST, and a small positive slope coefficient for SE. This indicates that as the intervention progressed over time, participants reported a reduction in their TIB, WASO, and TST, which results in a slight increase in their SE. Statistical significance was found for the reduction (negative slope) coefficient of SOL,

indicating that there was a negative fixed effect of time on SOL. All intercept estimates (i.e., the estimate value of sleep parameters when time=0, at the beginning of the intervention) were found to be statistically significant.

### Model 3: Including Level-2 Predictors

There are several ways to include level-2 (between-subject) predictors. The first option is to treat the level-2 variables as controls for the level-1 intercept variability, or an intercepts-as-outcomes model. Second, level-2 variables can be treated as controls for the level-1 slope variability, or a slope-as-outcomes model. Last, we can combine both approaches, an intercept and slope-as-outcomes model (Raudenbush & Bryk, 1992).

To determine which level-2 predictors out of the 13 (race, age, military branch, use of psychotropic, mood and anxiety diagnosis, baseline ESS score, baseline GAD7 score, baseline ISI score, PTSD diagnosis, baseline PCL score, baseline PHQ9 score, baseline PSQI and PSQI-A score) would contribute an improvement to the model, a level-2 exploratory analysis was done using the HLM7 software. The analysis was performed for both intercepts and slopes. The results (please see **Appendix H**) show that only two variables are considered as significant predictors – age for intercept-as-outcome model for TST, and PSQI baseline score for slope-as-outcome model for TIB. A detailed explanations for each model is given below.

# <u>Model 3a: Intercept-as-Outcomes Model: Predicting Across Time Means Differences of</u> <u>TST from Age.</u>

Model 3a assesses whether the significant variance at the intercepts (shown by the Model 2 chi-squared test of intercept variability) is related to a participant's age. It is also known as the

intercepts-as-outcomes model. HLM uses another random regression model to assess whether age is significantly related to the intercept while holding time (INDEX) constant. Adding AGE as a level-2 (between-subject) intercept predictor, resulted in the following equations:

$$TST_{ti} = \pi_{0i} + \pi_{1i}(INDEX_{ti}) + e_{ti}$$
$$\pi_{0i} = \beta_{00} + \beta_{01} (AGE_i) + r_{0i}$$
$$\pi_{1i} = \beta_{10} + r_{1i}$$

or, in a single equation:

$$TST_{ti} = \beta_{00} + \beta_{01} (AGE_i) + \beta_{10} (INDEX_{ti}) + r_{0i} + r_{1i} (INDEX_{ti}) + e_{ti}$$

where:

TST <sub>ti</sub>	= total sleep time (TST) measured for participant $i$ at time $t$ ;
$\pi_{0i}$	= regression intercept for participant <i>i</i> ;
$\pi_{1i}$	= regression coefficient for participant <i>i</i> ;
$\beta_{00}$	= overall mean intercept across participants;
$\beta_{01}$	= regression coefficient associated with participant $i$ 's age
	$(AGE_i)$ relative to level-1 slope;
$\beta_{10}$	= overall regression coefficient across participants;
e <sub>ti</sub>	= random error associated with estimation of total sleep time
	(TST) on time <i>t</i> for participant <i>i</i> ;
<i>r</i> <sub>0<i>i</i></sub>	= random effect on the intercept adjusted for age of participant
	<i>i;</i>
<i>r</i> <sub>1<i>i</i></sub>	= random effect on the slope for participant <i>i</i> ;
Variance( $e_{ti}$ ) = $\sigma^2$	= within individual variance in sleep parameter;
Variance( $r_{0i}$ ) = $\tau^2$	= between individual variance in intercept;

Variance $(r_{1i}) = \tau^2$  = between individual variance in regression coefficient.

Filling in the parameter estimates that we get from the HLM analysis results in:

$$TST_{ti} = 512.47 - 2.79 (AGE_i) - 0.17 (INDEX_{ti}) + r_{0i} + r_{1i} (INDEX_{ti}) + e_{ti}$$

with:

- Residual intercept variance,  $V(r_{0i}) = 3719.63$
- Variance in slopes,  $V(r_{1i}) = 1.71$
- p-value for  $\beta_{01}$  estimation is 0.03 (significant)
- AGE explains 6% of residual (level-1) variability of Model-1.

The intercepts-as-outcomes model is similar to the random coefficient regression model except that it includes AGE as a predictor of the intercepts at level-2. This is a statistical test on whether age is related to TST after controlling for time (INDEX). We cannot accept the null hypothesis (that there was no difference in the level-1 intercepts based on age) because the p-value for the estimate is significant at 0.03. The model above estimates that every year in age difference contributes to 2.79 minutes in individual baseline TST differences. A negative coefficient means that the older the participant, the lower their TST. Based on a reduction of level-1 residual variances compared to Model 1, introducing AGE as a predictor explains 6% of the level-1 variability.

## <u>Model 3b: Slope as Outcomes Model: Predicting Differences in Rate of Changes of TIB</u> from baseline PSQI score.

The Model 3b assesses whether the differences in slopes across individuals is related to baseline PSQI score. This is known as the slopes-as-outcomes model. The following equations are used to determine whether or not a condition is satisfied:

$$TIB_{ti} = \pi_{0i} + \pi_{1i}(INDEX_{ti}) + e_{ti}$$
$$\pi_{0i} = \beta_{00} + r_{0i}$$
$$\pi_{1i} = \beta_{10} + \beta_{10} (PSQI_i) + r_{1i}$$

or, in a single equation:

$$TIB_{ti} = \beta_{00} + \beta_{10}(INDEX_{ti}) + \beta_{11}(PSQI_i)(INDEX_{ti}) + r_{0i} + r_{1i}(INDEX_{ti}) + e_{ti}$$

where:

TIB <sub>ti</sub>	= total time in bed (TIB) measured for participant $i$ at time $t$ ;		
$\pi_{0i}$	= regression intercept for participant <i>i</i> ;		
$\pi_{1i}$	= regression coefficient for participant <i>i</i> ;		
$\beta_{00}$	= overall mean intercept across participants;		
$\beta_{10}$	= overall regression coefficient across participants;		
$\beta_{11}$	= regression coefficient associated with participant $i$ 's baseline		
	PSQI score $(PSQI_i)$ relative to level-1 slope;		
e <sub>ti</sub>	= random error associated with estimation of total time in bed		
	(TIB) on time <i>t</i> for participant <i>i</i> ;		
<i>r</i> <sub>0<i>i</i></sub>	= random effect on the intercept for participant <i>i</i> ;		
<i>r</i> <sub>1<i>i</i></sub>	= random effect on the slope adjusted for baseline PSQI of		
	participant <i>i</i> ;		
Variance( $e_{ti}$ ) = $\sigma^2$	= within individual variance in sleep parameter;		
Variance( $r_{0i}$ ) = $\tau^2$	= between individual variance in intercept;		
Variance( $r_{1i}$ ) = $\tau^2$	= between individual variance in regression coefficient.		
Filling in the parameter estimates that we get from the HLM analysis results in:			

$$TIB_{ti} = 451.14 + 0.97(INDEX_{ti}) - 0.11(PSQI_i)(INDEX_{ti}) + r_{0i} + r_{1i}(INDEX_{ti}) + e_{ti}$$

with:

- Residual intercept variance,  $V(r_{0i}) = 4089.36$
- Residual slope variance,  $V(r_{1i}) = 0.58$
- p-value for  $\beta_{10}$  estimation is 0.03 (significant)
- PSQI explains 5% of residual (level-1) variability of Model-1.

The slopes-as-outcomes model allows testing for the hypothesis that baseline PSQI is related to variability in slopes coefficient observed across individuals, after controlling for intercepts. Based on the t-test on  $\beta_{10}$  estimation, we confirmed that this was the case. Based on the reduction of level-1 residual variances compared to Model 1, introducing PSQI as a predictor explains 5% of the level-1 residual variance.

Figure 34 illustrates the differences in average regression and level-1 regressions before and after introduction of baseline PSQI as a level-2 predictor. The without PSQI model (on the left) assumes that there was only one grand mean of slope coefficient, while introducing PSQI (on the right) allows the slope coefficients to vary based on each individual's baseline PSQI score. The negative slope of TIB over time was steeper for individuals with higher baseline PSQI score. In other words, individuals with worse baseline sleep quality had their TIB shorten faster than individuals with better baseline sleep quality. These differences might be a result of significant reduction in WASO and SOL by the intervention; as TIB is the accumulation of TST, WASO and SOL.

Without PSQI as Level 2 Predictor

With PSQI as Level 2 Predictor

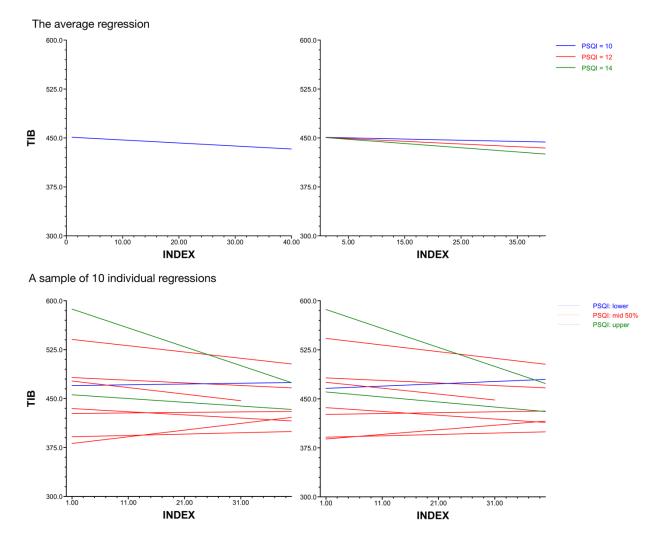


Figure 34. With and without PSQI as a level-2 predictor comparison

## 7.4 FITBIT VS IREST SLEEP DIARY

In addition to usability and clinical analyses, sleep diary and Fitbit-reported sleep data were compared. Wearable sensors such as Fitbit bands can potentially reduce participants' burden in manually inputting a wide range of sleep parameters data. Therefore, it is important to understand the level of agreement between these two measurements.

#### 7.4.1 Statistical Analysis

IBM (Armonk, NY) SPSS Statistics software version 24.0 was used for data analysis for Fitbit vs. sleep diary comparison, while GraphPad (La Jolla, CA) Prism version 7 was used to build Bland-Altman plots.

Sleep diary and Fitbit-reported sleep data were compared. First, intra-class correlation coefficients (ICC<sub>2,1</sub>) were used to examine agreement between sleep parameters taken from the Fitbit and sleep diary data. An ICC  $\geq$ 0.75 was considered excellent, 0.60–0.74 good, 0.40–0.59 fair and<0.40 poor (Hallgren, 2012). A Bland-Altman plot (Martin Bland & Altman, 1986) was used to visualize any systematic difference between values reported by the two measurements.

#### 7.4.2 Results

Seven participants were assigned with Fitbit Charge<sup>TM</sup> throughout the course of study. In total, 202 paired (Fitbit vs. sleep diary) nights were acquired. We used the automatic sleep detection feature available on the Charge model, in which the wristband automatically detects when the wearer falls asleep and wakes up without manual input (e.g., pressing a button). This feature, although convenient for the participants, greatly underestimated latency to the onset of the first sleep epoch (SOL). As a result, Fitbit only reported one instance of SOL (SOL > 0 minute) out of 202-recorded nights. Due to limitations in statistical analysis packages, variables representing clock time, such as Good Night Time (GNT) and Good Morning Time (GMT) are translated into

minutes distant from midnight (12:00 AM). For example, 11:00 PM on GNT was translated into -60 (60 minutes before midnight), and 5:15 AM in GMT was translated into 315 (315 minutes after midnight).

Variables	Means $\pm$ SD		Mean difference $\pm$	Intra-class correlation,	
	Fitbit	iREST Diary	standard error (two tailed)	ICC <sub>2,1</sub> (range)	
SOL	$0.38\pm0.38$	$18.60 \pm 1.63$	18.23±1.66 ( <i>p</i> <0.01)	0.15 (-0.123 – 0.153)	
WASO	$5.64\pm0.58$	$20.19 \pm 1.97$	14.54±1.86 ( <i>p</i> <0.01)	0.174 (0.038 - 0.305)	
TIB	422.9±6.48	430.9±6.00	8.08±4.80 ( <i>p</i> =0.09)	0.705 (0.628 - 0.768)	
TST	$416\pm 6.39$	392.14±6.82	-24.69±4.79 ( <i>p</i> <0.01)	0.737 (0.667 – 0.794)	
SE	98.59±0.16	90.53±0.74	-8.06±0.70 ( <i>p</i> <0.01)	0.144 (0.006 - 0.276)	
GNT	-17.8±5.55	-32.9±5.35	-15.10±3.95( <i>p</i> <0.01)	0.738 (0.668 - 0.795)	
GMT	405.0±6.87	398.00±6.25	-7.03±4.39( <i>p</i> =0.11)	0.777 (0.715 – 0.826)	

Table 14. Fitbit versus iREST Sleep Diary

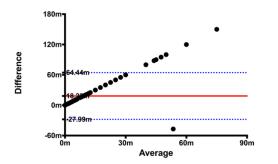
WASO, wakefulness after sleep onset (in minutes); SOL, sleep onset latency (in minutes); TIB, total in bed (in minutes); TST, total sleep time (in minutes); SE, sleep efficiency (%); GNT, good night time or fall asleep time (distance to midnight in minutes); GMT, good morning time or awake time (distance to previous midnight in minutes)

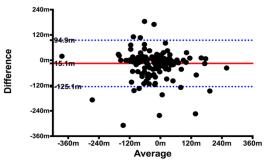
As shown in Table 14 above, significant statistical differences were found for the following variables recorded between Fitbit and sleep diaries, with diaries recording longer mean of latency (SOL), longer mean of WASO, shorter mean of TST, earlier GNT and smaller average SE. However, no significant differences were found on TIB (longer in sleep diary) and GMT (earlier in sleep diary). Furthermore, good intra-class correlations were observed for TST (ICC<sub>2,1</sub>=0.737, p<0.01), GNT (ICC<sub>2,1</sub>=0.738, p<0.01), and TIB (ICC<sub>2,1</sub>=0.705, p<0.01). There was excellent agreement on GMT between Fitbit and sleep diary, with ICC<sub>2,1</sub>=0.777, p<0.01

Bland and Altman difference plots (Figure 35) for these sleep parameters showed no statistically significant agreement between Fitbit and sleep diaries. As demonstrated in ICC analysis, the plots also show a higher level of disagreement between Fitbit and diaries for SOL, WASO and SE. Furthermore, proportional bias was observed for these three variables, and the disagreement between measurement modalities increased: 1) as the average value of SOL increased, 2) as the average value of WASO increased, and 3) as the average value of SE decreased from 100. Furthermore, the higher individual day-to-day sleep pattern variability, the worse the level of agreement was observed for that individual when compared with the group mean. For example, a participant whose WASO changed significantly from night to night (e.g., from 0 on the first day, to 45 on the second day, and back to 15 on the third, and so on) is likely to have worse agreement on the Fitbit vs. sleep diary WASO when compared with the rest of the sample.



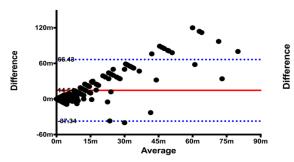
Difference vs. average: Fall Asleep Time of Sleep Diary - Fitbit

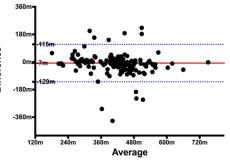




Difference vs. average: WASO of Sleep Diary - Fitbit

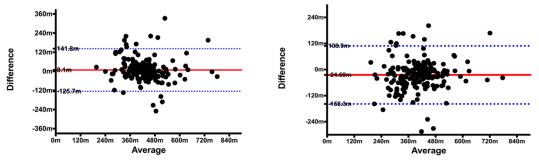
Difference vs. average: Wake Up Time of Sleep Diary - Fitbit





Difference vs. average: Time in Bed of Sleep Diary - Fitbit

Difference vs. average: TST of Sleep Diary - Fitbit



Difference vs. average: SE of Sleep Diary - Fitbit

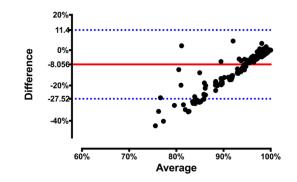


Figure 35. Bland-Altman plots of Sleep Diary vs. Fitbit

## 7.5 DISCUSSION ON THE PILOT STUDY RESULTS

This pilot usability study of the iREST system demonstrated that not only is the IREST app applicable to implementing BBTI in a military population, but is also usable and well received. Overall, participants were satisfied with the iREST application, finding it easy to use. All nineteen participants used the app daily to record their sleep with very few missed entries (on average less than 3) over the course of the 4-to-6-week intervention. The iREST app's sleep/wake logs were optimized for touch-based input, which reduced fill-out time and participants' burden.

Consistent with previous studies conducted on the use of a movement-based sensor (e.g., Fitbit, actigraphy) for measuring sleep (Daniel J Buysse, Cheng, et al., 2011; Lockley, Skene, & Arendt, 1999; Mccall & Mccall, 2012), there was poor agreement between Fitbit and participants' reported sleep diaries. This low level of agreement presents a challenge for the goal of collecting accurate sleep data while reducing participant bias and burden. As a possible solution, in the next iteration of the iREST system, we plan to use a hybrid approach between the two modalities. The hybrid approach will let participants modify Fitbit-reported data. Each modification will then be fed into a machine-learning algorithm, so the longer an individual uses the system, the less modification will be needed and the more accurate the data will be.

The iREST mHealth intervention was associated with slightly higher rates of response and remission compared to our previous in-person BBTI (Germain et al., 2014). Significant improvements in sleep quality and decreases in daytime sleepiness after treatment were observed. These improvements may be attributed to the use of the smartphone app and clinician web portal, which allows real-time monitoring and delivery of personalized treatment prescription (e.g., bedtime reminder, wake-up alarm, appropriate bibliotherapy, and additional assessments) matching the need of each individual. These results show the mHealth application's potential in delivering evidence-based behavioral treatment for insomnia in the military population. However, results from this preliminary study should nevertheless be interpreted with caution. Larger confirmatory trials are needed in order to fully understand the efficacy and effectiveness of the mHealth-based BBTI among the military population and, ultimately, the general civilian population.

# 8.0 REVISITING THE JITAI HEALTH BEHAVIORAL MODEL AND APPLICATION ARCHITECTURE

The constructed behavioral model was evaluated based on the clinical outcomes from the case study. The evaluation mainly focuses on whether or not the JITAI health behavior model accurately explains behavior changes and symptom improvement produced by this intervention.

## 8.1 **REVISITING THE APPLICATION ARCHITECTURE OF JITAI**

The application architecture of the JITAI was successfully implemented into the iREST system: iREST mobile app, iREST clinician portal, and iREST integration layer. This was possible because the JITAI application architecture follows the concept of "separation of concerns" (SoC). The SoC principle was applied to all layers of the JITAI architecture, from selection of programming paradigm, to architectural style, to architectural design pattern. For the programming paradigm, object oriented programming (OOP) was used. OOP is a programming paradigm with the main purpose of making a system with modular and reusable components. Modularity and reusability are enabled by encapsulating system components as "objects." Objects can independently contain data, procedures and object interfaces. "Object interface" allows objects to interact with other objects. Each object can be viewed as an independent "machine" with a distinct role or responsibility. In OOP, systems consist of objects and the interactions among them. Following the object oriented paradigm, the JITAI architecture is divided into four large groups of computer codes: System Presentation/User Interface (UI), Intervention Logic, Data Management, and Integration Layer (For a more detailed explanation, see Sections 6.1.6 and 6.1.7). This design and programing approach allows the programming libraries and codes available on the JITAI architecture to independently and easily use multiple times in multiple scenarios of JITAIs.

In terms of architecture style, the JITAI application architecture is a service-oriented architecture. While the object-oriented paradigm shows how different components of the system are assigned into different objects/entities, the SOA is more concerned with the interactions among these entities throughout a network (e.g., the Internet). One of the fundamental principles in SOA is allowing "services" to be delivered and consumed, independent of products, vendors, and technologies. A service is a discrete unit of functionality that 1) logically represents an activity with a certain outcome; 2) is self-contained; and 3) is a black box to its consumers. This principle exactly matches the needs of JITAI; it allows "cross-platformness," i.e., adoption and implementation to wide variety of technologies (e.g., mobile, web, desktop), form factors (e.g., smartphone, tablet, desktop computer), and platforms/operating systems (e.g., Android, iOS, Windows). Furthermore, it allows for potential integrations to perform synergy with other systems, such as a hospital's electronic medical records (EMR), billing systems, and other thirdparty systems. These integrations would maintain the high level of security warranted by the JITAI, due to the black-box nature of the services. SOA also allows the JITAI application to consume third-party services, such as that provided by Fitbit in the iREST implementation.

The SoC principle was also implemented on the presentation/user interface (UI) level, using architectural design patterns such as Model-View-Controller (MVC)<sup>12</sup> on the portal side and Model-View-ViewModel<sup>13</sup> (MVVM) on the app side. These separations between Models and Views allow modification on a View (i.e., a UI for certain functionality) to be performed independently from the Model that the View represents. For example, in addressing a usability concern about time input in the sleep log screen, a UI designer can replace the time input component with a more usable one without having to worry about the propagation effect it may cause to the sleep log's app logic (i.e., the Model). The opposite also proved to be beneficial as well: this design pattern supports collaboration among different disciplines or professionals involved in the development of JITAI, e.g., clinicians, application programmers and UI designers.

The promising results from the iREST usability study show that the JITAI application architecture was able to support a real JITAI. It also accommodates iteration of improvements made to the iREST clinician portal and mobile application. As a case example, the development of the iREST app's dashboard yielded the following improvement scenario:

- An early version of the iREST app did not contain any dashboard or feedback on patients' progress.
- Based on input from the study participants and clinicians, the dashboard feature was added to the app.

<sup>&</sup>lt;sup>12</sup> Models are the data and logics of an application; Views are the representation (UI) of the models; Controllers accept users' input and convert it to modify the models and/or to update the views.

<sup>&</sup>lt;sup>13</sup> A ViewModel is an abstract representation of the View and does not convey the concrete UI; it also wraps the Model in a way so that it can be displayed as desired.

- Participants' feedback indicated that some of the fields on the dashboard were either incorrect or not helpful/necessary.
- Modifications to the dashboard UI and logic were made to address participants' feedback.

The ability to customize certain components of the mHealth system while maintaining reusability is important in supporting the rapid deployment of the JITAI architecture to various JITAIs; each intervention will use largely the same reusable components (e.g., RESTful web service, real-time communication channels, persistent data management, UI design patterns) of the JITAI application architecture, albeit with some customization to address the unique context and content of a given intervention.

#### 8.2 **REVISITING THE ADAPTIVE INTERVENTION MODEL OF JITAI**

## 8.2.1 Variables Mapping

In evaluating a temporal dynamic model, it is important to choose a time granularity (e.g., dayto-day/daily, week-by-week, month-by-month) in which to view the state of the model. The adaptive intervention model is adaptable to various time granularities based on the nature of the intervention. However, for this study, a daily time frame was used since sleep is after all a dayto-day activity.

Figure 36 shows the mapping of the iREST study variables onto the adaptive intervention model. Based on the adaptive intervention model, mHealth utilization skills are influenced by usage and utilization support. The iREST app usage is recoded automatically by

the app, allowing for the calculation of frequency and duration of use. These two variables are then fed into the model. In this study, utilization supports were not explicitly measured. However, the sum of the number of reminders sent by clinicians to the app within a weekly time frame may be used to estimate utilization supports.

In the model, self-efficacy is represented as a fluid inventory that is influenced by perceived barriers, social support, inter-personal affectivities, and mHealth utilization skills. In the study, negative affectivities were measured by the GAD-2 and PHQ-2; both were administered weekly as part of iREST's weekly assessment. Barriers to healthy sleep included nightmares, restlessness and thinking (awake) in bed. The number of occurrences of each event was fed into the model as input. In the iREST study, social supports from clinicians were measured. These supports include clinicians prescribed behavioral sleep tips/treatment information based on the type of barriers endorsed by the patients. Clinicians also provided support in the form of messaging and face-to-face sessions.

The target behavior in the iREST study is high efficiency sleep that leads to healthy sleep; during treatment, however, sleep restriction might initially result in high SE. Behaviors inherently produce positive and/or negative perceived outcomes. For example, sleep restriction has been proven to reduce insomnia symptoms and to improve overall sleep quality; however, for a short time, it may cause temporary disruptions in daytime functions (e.g., sleepiness). Patients' environmental context could influence their view of the outcomes (as negative or positive). These views then affect the reutilization of the behavior.

Lastly, behavior is directly influenced by cues to action. In real life, cue to action events can include someone reminding the patient to sleep, alarm sounds, wake-up calls, weather events, and lights-out events. In the iREST study, the cue to action was wake-up alarms sent by clinicians from the portal as part of the sleep restriction. The number of these alarms within a weekly time-frame is used as model input:

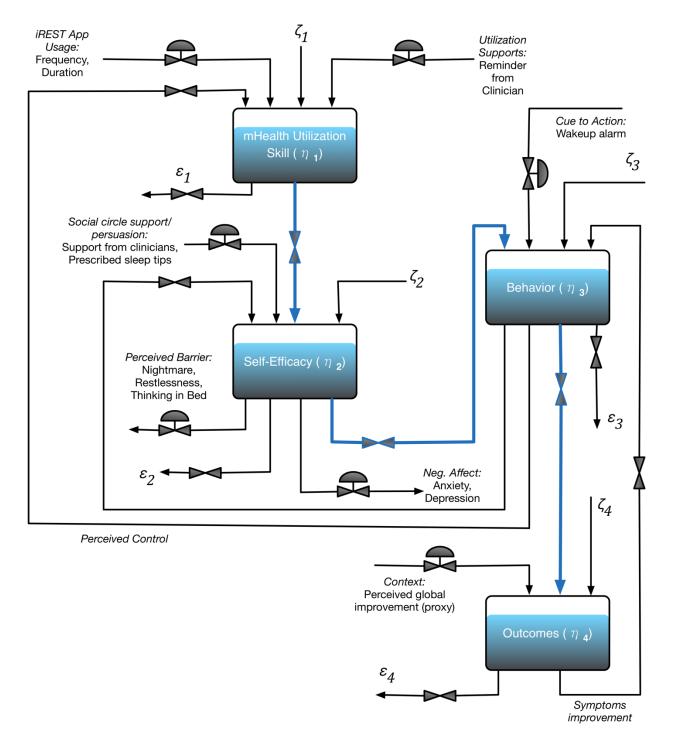


Figure 36. The iREST adaptive intervention model

This mapping of direct and complete variables shows that the JITAI adaptive intervention model is representative of dynamic processes in JITAI implementation. The successful implementation of the iREST mHealth system also supports the hypothesis that the model can be used as a guide for designing and implementing intervention adaptiveness in a JITAI treatment; the iREST mHealth system was based on the JITAI application architecture, which was in part based on the adaptive intervention model.

### 8.2.2 Mathematical Model

In addition to demonstrating that the adaptive intervention model represents adaptive health behavior intervention characteristics (e.g., variable mapping), it is important to construct a mathematical representation of the model. The mathematical model allows for model simulations. These simulations are crucial, not simply for describing how variables in the current study influence each other but also for providing insights for further improvements to the intervention. As previously stated, a mechanistic modeling framework relying on a fluid analogy will be used for this purpose.

The adaptive intervention model has four inventories represented by the variable  $\eta_1$ , ...,  $\eta_4$ . For each inventory, there is an assumption of inflow resistances represented by the coefficients  $\mu_{11}$ , ...,  $\mu_{47}$  and outflow resistances represented by the coefficients  $\beta_{21}$ , ...,  $\beta_{43}$ . These resistance coefficients can be viewed as the fraction of each inventory or input that feeds into the next inventory. Still related to inflow and outflow processes, the model acknowledges that in reality, an outflow from one inventory/input does not instantly reach the next inventory as an inflow; there are time delays ( $\theta_1$ , ...,  $\theta_{14}$ ) for each flow. Lastly, the time constants  $\tau_1$ , ...,  $\tau_4$  were introduced; the constants allow for exponential growth or decay of the inventory.

The model has six exogenous inputs that are represented by  $\xi_1, ..., \xi_8$ . The model also represents unmeasured or unexplained disturbances that influence each inventory. Unmeasured inflows are denoted by  $\zeta_1, ..., \zeta_4$  and unmeasured outflows are represented by  $\varepsilon_1, ..., \varepsilon_4$ .

## 8.2.2.1 Inflow and outflow equation representation

The following are equation representations of each inflow or outflow shown in the model:

i. mHealth usage inflow to utilization skills ( $\delta_{a1}$ ):

$$\delta_{11}(t) = \mu_{11}\xi_1(t - \theta_1)$$

ii. Utilization supports inflow to utilization skills ( $\delta_{12}$ ):

$$\delta_{12}(t) = \mu_{12}\xi_2(t - \theta_2)$$

iii. Social network supports inflow to self-efficacy ( $\delta_{23}$ ):

$$\delta_{23}(t) = \mu_{23}\xi_3(t-\theta_3)$$

iv. Positive affectivities inflow to self-efficacy ( $\delta_{24}$ ):

$$\delta_{24}(t) = \mu_{24}\xi_4(t-\theta_4)$$

v. Negative affectivities outflow from self-efficacy ( $\delta_{25}$ ):

$$\delta_{25}(t) = \mu_{25}\xi_5(t-\theta_5)$$

vi. Perceived barriers outflow from self-efficacy ( $\delta_{26}$ ):

$$\delta_{26}(t) = \mu_{26}\xi_6(t - \theta_6)$$

vii. Cue to action inflow to behavior  $(\delta_{36})$ :

$$\delta_{37}(t) = \mu_{37}\xi_7(t - \theta_7)$$

viii. Environmental context inflow to outcomes ( $\delta_{36}$ ):

$$\delta_{48}(t) = \mu_{48}\xi_8(t - \theta_8)$$

ix. Utilization skills to self-efficacy flow ( $\sigma_{21}$ ):

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$$\sigma_{21}(t) = \beta_{21}\eta_1(t-\theta_9)$$

x. Self-efficacy to behavior flow ( $\sigma_{32}$ ):

$$\sigma_{32}(t) = \beta_{32}\eta_2(t - \theta_{10})$$

xi. Behavior to self-efficacy flow ( $\sigma_{23}$ ):

$$\sigma_{23}(t) = \beta_{23}\eta_3(t - \theta_{11})$$

xii. Behavior to utilization skills flow ( $\sigma_{13}$ ):

$$\sigma_{13}(t) = \beta_{13}\eta_3(t - \theta_{12})$$

xiii. Behavior to outcome flow ( $\sigma_{43}$ ):

$$\sigma_{43}(t) = \beta_{43}\eta_3(t - \theta_{13})$$

xiv. Outcome to behavior flow ( $\sigma_{34}$ ):

$$\sigma_{34}(t) = \beta_{34}\eta_4(t - \theta_{14})$$

Based on the above equations, equation representation of  $\varepsilon_1$ , ...,  $\varepsilon_4$  were derived as the following:

xv. 
$$\varepsilon_1 = (1 - \beta_{21})\eta_1$$
  
xvi.  $\varepsilon_2 = (1 - \beta_{32})\eta_2$   
xvii.  $\varepsilon_3 = (1 - \beta_{43} - \beta_{23} - \beta_{13})\eta_3$   
xviii.  $\varepsilon_4 = (1 - \beta_{34})\eta_4$ 

## 8.2.2.2 Inventory level equation representation

The level of each inventory (i.e., the accumulation of liquid) is equal to the time constant  $\tau$  times the rate of fluid change. The model uses the assumption of conservation of mass principle, such that the sum of all inflows deducted by the sum of all outflows results in this accumulation. Therefore, the following differential equation determines the level of each inventory:

$$\tau_1 \frac{d\eta_1}{dt} = \delta_{11}(t) + \delta_{12}(t) + \sigma_{13}(t) - \sigma_{21}(t) - \varepsilon_1(t) + \zeta_1(t)$$
$$= \mu_{11}\xi_1(t - \theta_1) + \mu_{12}\xi_2(t - \theta_2) + \beta_{13}\eta_3(t - \theta_{12}) - \eta_1(t) + \zeta_1(t)$$
(1)

$$\tau_{2} \frac{d\eta_{2}}{dt} = \delta_{23}(t) + \delta_{24}(t) + \sigma_{23}(t) + \sigma_{21}(t) - \delta_{25}(t) - \delta_{26}(t) - \sigma_{32}(t) - \varepsilon_{2}(t) + \zeta_{2}(t) = \mu_{23}\xi_{3}(t - \theta_{3}) + \mu_{24}\xi_{4}(t - \theta_{4}) + \beta_{23}\eta_{3}(t - \theta_{11}) + \beta_{21}\eta_{1}(t - \theta_{11}) - \mu_{25}\xi_{5}(t - \theta_{5}) - \mu_{26}\xi_{6}(t - \theta_{6}) - \eta_{2}(t) + \zeta_{2}(t)$$
(2)

$$\tau_{3} \frac{d\eta_{3}}{dt} = \delta_{37}(t) + \sigma_{32}(t) + \sigma_{34}(t) - \sigma_{43}(t) - \sigma_{23}(t) - \sigma_{13}(t) - \varepsilon_{3}(t) + \zeta_{3}(t)$$
$$= \mu_{37}\xi_{7}(t - \theta_{7}) + \beta_{32}\eta_{2}(t - \theta_{10}) + \beta_{34}\eta_{4}(t - \theta_{14}) - \eta_{3}(t) + \zeta_{3}(t)$$
(3)

$$\tau_4 \frac{d\eta_4}{dt} = \delta_{48}(t) + \sigma_{43}(t) - \sigma_{34}(t) - \varepsilon_4(t) + \zeta_4(t)$$
$$= \mu_{48}\xi_8(t - \theta_8) + \beta_{43}\eta_3(t - \theta_{13}) - \eta_4(t) + \zeta_4(t)$$
(4)

As shown above, the model is represented in first-order differential equations. Therefore, the model assumes that the effects of self-regulatory processes within each inventory are minimal, hence, negligible. An example of these self-regulatory effects is damping effects (e.g., overdamped, critically damped, or underdamped). A second-order model would be required to represent such effects, which would greatly increase the complexity of the model. As the model uses the assumption of conservation of mass, the sum of all outflows for each inventory must be equal to or lower than the value of that respective inventory. Hence, the following constraints are introduced:

$$\beta_{21} \le 1$$
  $\beta_{32} \le 1$   $\beta_{13} + \beta_{23} + \beta_{43} \le 1$   $\beta_{34} \le 1$ 

## 8.2.2.3 Simulation

To evaluate dynamic regulatory processes represented by the adaptive intervention model, a simulation was performed. The simulation was based on scenarios encountered in the iREST clinical feasibility study (Section 7.3 above). The simulation represents a 5-week period; the first week was data initiation followed by a 4-week intervention for which the following assumptions were made:

- To simplify the results, all time delays were considered to be zero.
- The level of each inventory was only allowed to fluctuate within 0 and 100%.
- The initial levels of the inventories were the solutions of corresponding differential equations at a steady state.
- Unexplainable disturbances ( $\zeta_1, ..., \zeta_4$ ) were considered as a zero mean stochastic signal.
- The values of the following parameters were selected based on the data from the iREST study:

$$\begin{aligned} \tau_1 &= \tau_2 = \tau_3 = \tau_4 = 1 \\ \mu_{11} &= 0.88, \mu_{25} = 0.1, \mu_{23} = 0.4, \mu_{26} = 0.4, \mu_{37} = 0.1 \\ \beta_{13} &= 0.1, \beta_{21} = 0.8, \beta_{23} = 0.4, \beta_{32} = 0.9, \beta_{34} = 0.3, \beta_{43} = 0.5 \end{aligned}$$

There were three scenarios in the simulation, the first two of which were based on the current treatment protocol (in iREST study) and the third of which was a just-in-time model that

exemplifying potential improvement to the existing treatment by reducing the response time between intervention prescription and occurrences of symptoms/barriers. The first scenario illustrated the effect of personalized sleep tips in addressing reported sleep disturbances. Based on iREST study findings, negative affectivities were held at a constant high level ( $\xi_5 = 4$ ), as PTSD and mood disorders are highly prevalent in ADSMs and Veterans. Positive affectivities and environmental context were considered as negligible ( $\xi_4 \approx 0, \xi_8 \approx 0$ ). As a barrier ( $\xi_6$ ), nightmares were occurred: 4 times during the first week (night 1, 2, 5, and 6), 3 times during the second week (night 8, 10, and 11), and 1 time during the third week (night 19). In response, the clinicians prescribed personalized sleep tips for nightmares ( $\xi_3$ ), at the start of the second week, third week and fourth weeks (each lasting for 2 days). The mHealth utilization skill was determined mainly by utilization adherences, whose value was set at 91% based on average adherence reported by the iREST usability study (Section 7.2.3).

In the second scenario, a daily wake-up alarm was added as part of the intervention. Other parameters were kept the same as in the first scenario. The alarm acts as cue to action  $(\xi_7)$  for the healthy sleep behavior of always waking up at the same time every day. Cues to action directly affect the initiation of the behavior; however, they also improve the levels of other inventories. The MathWorks (Natick, MA) MATLAB software version R2016a was used to run the simulation. The results and contrasts of these two scenarios can be viewed in Figure 37 below.

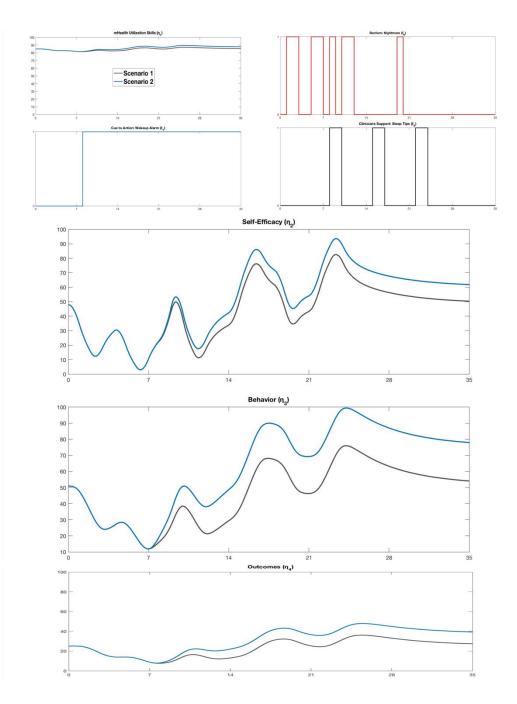


Figure 37. Simulation results: Scenario 1 and 2

The third scenario demonstrates the just-in-time approach of JITAI. It improved the first and second scenarios by allowing the personalized sleep tips to be delivered as soon as an individual mentioned having nightmares (or other sleep problems). This process can be done automatically by the app, the portal, or with the approval of clinicians. Figure 38 shows the comparison of the day-by-day level of behavior inventory between the third and the second scenarios. By delivering the intervention as close as possible to the triggering events (i.e., at the opportune moment), the simulation shows that the third scenario has less day-by-day fluctuation/variability of the level of behavior initiations and higher total behavior initiations.

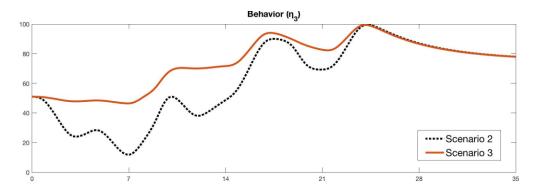


Figure 38. Comparison of the behavior inventory between Scenario 3 and Scenario 2

## 8.2.2.4 Limitations

During the construction of this mathematical model, a balance was considered between complexity (in which higher complexity reduces practicality) and wholeness (in which the more variables to be considered, the more accurately the model represents the system). In light of the compromise between these two, the following are limitations of the current model:

- It does not account for self-regulatory processes within each inventory, such as those represented using second-order differential equations in the Navarro-Barrientos et al. study (Navarro-Barrientos, Rivera, & Collins, 2011).
- It does not consider the nonlinear dynamics of habituation. According to the behavioral characteristics of habituation (Rankin et al., 2009), a repeated application of a stimulus will result in a progressively decreased response, leading to a negative exponential curve of stimulus effectiveness over time. In the current model, inflows and outflows are

considered to be linear. To address habituation, a more complex model would need to be obtained to modify flow resistances, such as  $\mu_{37}$  for cue of action. An example of such a habituation model has been proposed using first-order derivatives in the realm of machine learning (Marsland, 2009).

- It does not yet account for the between-person modifiers that derive from the encompassing JITAI behavior model. Similar to habituation, these modifiers influence flow resistances.
- Response delay, although mentioned in the model, was not included in the simulations.
- It was optimized for a daily timeframe. Changing the timeframe to broader granularity (e.g., weekly) may require additional inventories to be added to the model.

## 8.3 **REVISITING THE BEHAVIOR MODEL OF JITAI**

Figure 39 illustrates the implementation of the JITAI behavior model in the iREST intervention. According to the JITAI model (see Section 5.1.3 for details on model components), individual characteristics are described by 5 types of variables: 1) demographics, 2) primary health/behavior disorder, 3) comorbidity, 4) self-efficacy, and 5) technology utilization skills. Variables such as sex, race, age and military branch are considered as demographics. The severity of the primary disorder (insomnia) was measured by the ISI, PSQI and ESS scores. Comorbidity variables include PTSD diagnosis and severity, mood/anxiety disorder diagnosis and severity, and psychotropic use. The iREST study lacked a formal measurement tool for assessing self-efficacy toward healthy sleep. However, the baseline ISI score may be used to estimate the initial self-efficacy (Rutledge, Guardia, & Bluestein, 2013). Familiarity with smartphones was used as a predictor for technology utilization skill. These individual characteristics directly influence the adaptive intervention and mHealth use. Hence, they may explain between-person variability in the intervention outcomes and may need to be controlled as covariates during statistical analysis of the outcomes.

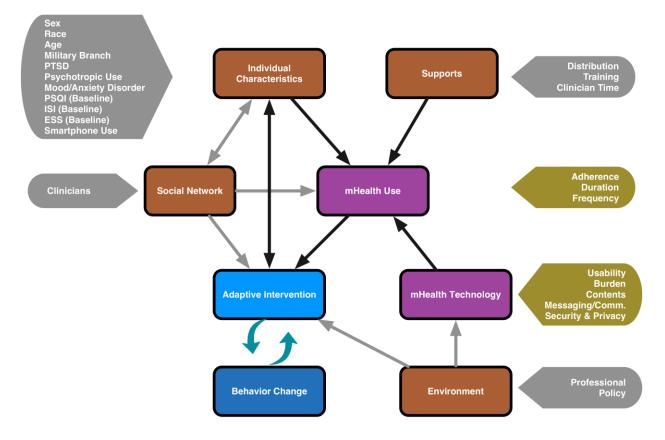


Figure 39. The JITAI behavior model for the iREST study

In the study, two environmental factors were considered: the working/professional environment of the participants, and the broader privacy and security policy that influences mHealth interventions (e.g., HIPAA). HIPAA requirements directly affect the design of the mHealth technology (e.g., iREST mHealth system) used in the intervention. The professional environment was included in the adaptive intervention model as a contributing factor in the context influencing the interpretation of behavior outcomes (e.g., feeling sleepy at work due to sleep restriction may negatively influence a participant's view of the intervention efficacy). In

the iREST study, the clinicians were considered as part of the participants' social network structure (SNS). Based on quantitative feedback, participants mentioned that the availability of clinicians to support the intervention (rather than stand-alone mHealth, without clinician support) was important and necessary. These types of social support also affect the adaptive intervention.

The mHealth technology component is made up of the following areas: the usability of the mHealth system, the burden of using the mHealth system (e.g., average time required to fill out a sleep log in the app), the content or actual treatment information, the availability and quality of messaging and communication channels, and security and privacy implementation. These characteristics affect the utilization of the mHealth system; for example, better usability resulted in higher utilization. mHealth utilization was measured by participants' adherence, utilization frequency, and duration. Utilization was also influenced by support components, including software distribution/access (e.g., perceived ease of access may be different between Apple App Store and Google Play Store), whether and how much training was provided, and the availability of clinician time to monitor the mHealth usage.

## 9.0 SUMMARY AND OPPORTUNITIES FOR FUTURE WORKS

## 9.1 SUMMARY OF WORK

JITAIs are gaining popularity as a new paradigm to deliver health and behavioral interventions. The widespread use of mobile technology, including smartphones and wearable devices, has led to an increasing number of research studies and implementations of JITAI. However, until now, no theoretical model that describes the characteristics of JITAI and their interactions has been published. From the technology side, the growth and ever-changing scenery of mobile technologies requires the rapid development and deployment of the mHealth solutions (e.g., smartphone apps, wearable sensors, security protocols, and their interactions/integrations) used in JITAIs. Furthermore, the smartphone market is and will likely continue to be divided between a few mutually incompatible operating systems. The need to specifically develop mHealth solutions for each mobile operating system is costly and is not scalable. Therefore, a ready-to-implement, cross-platform JITAI application architecture will provide the leverage needed to support rapid deployment of mHealth solutions.

This dissertation has provided a theoretical behavioral model and a cross-platform application architecture for JITAI. It began in Chapter 1 by describing the background and significance of the JITAI behavior model and application architecture to support and deliver health behavior interventions. It also explained that behavioral sleep interventions are an appropriate case study to evaluate the JITAI model and application architecture since sleep is a universal and recurrent behavior, insomnia and sleep disturbances are highly prevalent and because sleep problems may lead to other health problems.

In Chapter 2, brief overviews of the behavior theories and models referred to in this dissertation were provided, including The Social Cognitive Theory, The Health Belief Model, The Theory of Planned Behavior, The Information-Motivation-Behavioral Skills Model and The Control Theory of Behavior Change. These theories and models provide understanding in what to consider in designing a behavioral model. They also helped to drive the design of the JITAI behavioral and adaptive intervention model. In addition to behavioral theories and models, design considerations for the JITAI model were also derived from intervention paradigms such as Cognitive Behavioral Therapy (CBT), Ecological Momentary Assessment/Intervention, and the Just-in-Time Adaptive Intervention itself. Chapter 2 also provided an overview of technological theories that were used in the development and evaluation of the JITAI application architecture and the consequence application in sleep intervention (iREST). In Chapter 3, several published studies that either contribute or related to this dissertation are briefly discussed.

An overview on sleep, sleep problems, and behavioral sleep intervention were provided in Chapter 4. The chapter began with the importance of sleep, then continued with insomnia and sleep problems, as well as examining the different behavioral intervention strategies that are available to address insomnia and sleep disturbances. As the iREST system used this intervention method, emphasis was given to the brief behavioral treatment for insomnia (BBTI). A brief summary of previous studies and the rationale for including JITAI on BBTI were also provided.

Chapters 5 - 8 further discussed specific aims of this dissertation. Chapter 5 described the process of building the JITAI behavioral and adaptive intervention model, which is the solution

for Specific Aim 1. The first model describes the fundamental and preferred characteristics of the JITAI, which also includes interactions among these characteristics. The second model, the adaptive intervention model, depicts the temporal and within-person dynamics of a JITAI. These models incorporate the theories described in Chapter 2.

Specific Aim 2 is discussed in detail in Chapter 6. It includes the design, analysis and development of the JITAI application architecture. It follows the Iterative and Incremental Development (IID) of software development theory mentioned in Section 2.5. It described how the architecture was then implemented in the case study (i.e., behavioral sleep intervention) as an mHealth system called iREST.

Chapter 7 discussed the pilot study, which was conducted to assess the usability and clinical feasibility of the iREST system. In the study, the evidence-based BBTI was delivered and supported through the iREST mHealth system for treating insomnia in a military sample (i.e., active duty service members and Veterans). The usability study assessed the utilization, usability rating, and feedback from the iREST app, while the clinical feasibility study highlighted the response and remission rates, sleep quality and symptoms improvements, longitudinal data trends, and agreements between subjective and objective sleep parameters measurement.

Based on the results from the aforementioned study (Chapter 7), evaluations on the JITAI behavioral model, the JITAI adaptive intervention model and the JITAI application architecture were performed, as shown in Chapter 8. It began with reviewing the JITAI architecture implementation in the iREST system. The ease of this implementation process and direct variables mapping indicate readiness and completeness of the architecture in supporting health behavioral JITAIs. Emphasis was given to the evaluation of the adaptive intervention model

since adaptive intervention is the core of JITAIs. The evolution of this model includes variables mapping, which determines whether characteristics mentioned in the model represent real world characteristics of behavioral sleep intervention. Based on the evaluation, a mathematical model was constructed. Simulations on this mathematical model were used to show how the adaptive intervention works in temporal dynamic scenarios. Lastly, a review of the JITAI behavior model and how the model fit the actual JITAI were discussed.

## 9.2 CONTRIBUTIONS

This dissertation has made several contributions and suggested opportunities for future work primarily for the field of Just-In-Time Adaptive Intervention (JITA), but also for the broader fields of Behavioral Sleep/Insomnia Intervention, Human-Computer Interaction (HCI), mHealth, Biomedical Health Informatics (BHI), Software Engineering, Telemedicine, and Telerehabilitation. These contributions include:

1) A JITAI behavior model as a guideline for developing just-in-time adaptive health/behavioral interventions

The JITAI behavior model can help to identify the various components of a JITAI and describe the relationships among the various components. This model was intended to explain and predict behavior changes and symptom improvements across JITAIs. By synthesizing previously established behavior change theories and models, features of mHealth and mobile technologies, as well as dynamic characteristics of adaptive intervention, the JITAI model enables us to conceptualize, identify, and measure the factors likely to contribute to behavior change in JITAIs.

## 2) A complete model for designing and optimizing adaptive intervention in JITAIs

Treatment adjustment is a dynamic process that defines an adaptive intervention. The adaptive intervention model for JITAI has been proposed to illustrate how various intervention components dynamically and longitudinally interact, resulting in actualizations of the intended behavior. By relying on control systems engineering principles, the model also provides a potentially useful framework for designing and optimizing adaptive mechanisms in current and future JITAIs. Researchers and intervention scientists can optimally decide on aspects of adaptive treatments, such as the ordering and strength of prescriptions, by evaluating the effects of these intervention components on outcomes of interest over time through model simulations. In addition, the mathematical form of the adaptive intervention can provide better predictions on the between- and within-individual variability that will be reflected in the outcomes.

## *3)* A cross-platform and integrated application architecture

The JITAI application architecture gives leverage for intervention scientists in implementing mobile app solutions for JITAIs. By analyzing the technical needs of the JITAI behavior and adjustment models, the architecture provides a wide variety of functionalities, design patterns, and guidelines that are readily implemented in various JITAI mobile app solutions. Also, the JITAI application architecture is cross-platform; therefore, it allows rapid deployment to various mutually incompatible mobile operating systems, and it opens the possibility for a bring-your-own-device (BYOD) approach, which greatly increases the scalability of and access to the interventions.

## 4) An innovative off-the-shelf wearable product integration

Automatic data collection minimizes user burden by collecting data through objective sensors with minimal to no manual input. Automatic data collection also provides better accuracy and reduces recall bias. Furthermore, the popularity of wearable sensible technologies has continued to increase in recent years (eMarketer, 2015), making them a suitable candidate for automatic data collection tools. An integration layer has been developed specifically for this purpose in the JITAI application architecture. This integration layer provides a key communication protocol for retrieving resources collected by off-the-shelf wearable products that are used by patients. The market for wearable sensors is segregated, similar to the smartphone market; however, most wearable product vendors provide online access to the collected data using the same resource access protocol. The JITAI application architecture includes this resource access protocol.

# 5) A usable and feasible implementation of the JITAI mHealth system for supporting behavioral sleep interventions in a military population

Consolidated, restorative, and sufficient sleep is an essential component of Armed Forces readiness and fitness (The Army Medical Department, 2014; Troxel, Wendy M., Regina A. Shih, Eric R. Pedersen, Lily Geyer, Michael P. Fisher, Beth Ann Griffin, Ann C. Haas, 2015). However, insomnia, which affects between 40% and 70% of ADSMs and Veterans, is a robust risk factor for poor psychological health outcomes as well as poor physical health (e.g., increased

risk for cardiovascular and metabolic diseases) (Livingston et al., 2015). Insomnia can also compromise performance by impairing critical cognitive and moral reasoning abilities and increasing the risk of injuries due to the resulting fatigue (Rupp, Wesensten, & Balkin, 2010).

Though recommended as the first choice of treatment (NIH, 2005), evidence-based behavioral treatments for insomnia remain under-utilized and often unavailable in care settings where ADSMs and Veterans seek help. Hence, hypnotics remain the most common insomnia treatment, despite the substantial concerns regarding their safety, side effects, and potential for abuse. Several factors contribute to the gap between the high prevalence of insomnia in military samples and low use of evidence-based, military-relevant, non-pharmacological treatments of insomnia: (1) shortage of trained clinicians; (2) treatment restricted to mental health clinics; (3) the persistent but erroneous belief that insomnia is "only" a symptom of another disorder; (4) barriers to attending appointments, such as distance to travel, work schedule, childcare; and (5) treatment duration and delivery method (6-8-hour-long sessions for CBTI). The iREST mHealth system developed in this dissertation was aimed at overcoming these barriers.

The pilot usability and feasibility study (see Chapter 7.0) demonstrated that not only was the IREST app applicable to implementing BBTI in a military population, but was also well received. The iREST app was rated excellent in usability and as clinically capable as if not better than the traditional BBTI.

# 6) A demonstration on the use of hierarchical linear model analysis to estimate between and within effects in longitudinal health/behavioral improvements.

JITAI relies on longitudinal repeated measures for adjusting treatment based on current patient conditions. This sampling method resulted in hierarchical levels of grouped data, as data collected at different times and under different conditions are nested within each study participant (Raudenbush & Bryk, 1992). Analysis of hierarchical data is best performed using statistical techniques that account for the hierarchy, such as Hierarchical Linear Modeling (HLM) (for detailed explanations, see Section 7.3.3). In this dissertation, the longitudinal sleep pattern data were analyzed using the HLM. In addition to elaborating on the clinical significance and feasibility of the iREST/BBTI intervention, the analysis also provides a practical example of running an HLM on JITAI's longitudinal outcomes. Therefore, Section 7.3.4.3 Longitudinal Sleep Parameters also emphasized a straightforward overview of the basic principles of HLM in analyzing within-individual (e.g., time variable) and between-individual factors contributing to the outcomes.

## 9.3 LIMITATIONS

One of the limitations of this dissertation is the relatively small sample size used in the usability and feasibility study. Although the number of participants was more than sufficient to assess the usability of the mHealth system (as explained in Section 7.2.3.2), it may not be sufficient to determine the generalizability of the clinical findings. The determination of the sample size for this pilot study was influenced by the size of the intervention group in a previous BBTI-MV study (Germain et al., 2014), with which the outcomes of this study were compared. Related to this comparison, the exclusion criteria were also similar; i.e., both studies excluded individuals with severe psychiatric disorders and sleep apnea. The high rate of exclusion based on this criteria in both studies (the current and (Germain et al., 2014)) highlights the fact that these disorders are highly comorbid with insomnia and hence limit the generalizability of the findings reported in the present study to the more severely affected population. Furthermore, the small number of participants also hinders the possibility of definitely assessing the effectiveness of the iREST/BBTI in improvements observed in symptoms of common comorbidity in a military population, such as PTSD, depression, and alcohol or substance use. Lastly, the current study used a military sample, but whether the findings are extendable to the general population requires further investigation.

The present study was highly focused on patients' improvements and experiences in using the iREST system. However, equally important are perspectives from the clinicians' side. As mentioned before, the highly manualized BBTI supported by the easy-to-use iREST system is likely to facilitate the delivery of this treatment by mid-level (non-doctoral) clinicians; however, the present study has not provided a sufficient level of heterogeneity in a clinician sample to determine whether a comparable magnitude of improvement would also be observed with less experienced therapists; In the current study, the intervention was administered by two clinicians with extensive experience in behavioral sleep treatments. Also, this dissertation performed usability testing and utilization analysis on the iREST patient app. However, no usability on the clinician portal was explicitly reported.

One of the limitations of the JITAI application architecture is that the wearable integration currently only supports Fitbit devices. A comparison of preliminary statistics of sleep parameters measured by the Fitbit vs. sleep diary shows poor agreement; however, clinically, the Fitbit data may be sufficient to be used as a consideration for BBTI sleep prescriptions<sup>14</sup>. Nevertheless, improvements need to be made to the architecture to increase the sensitivity of

<sup>&</sup>lt;sup>14</sup> Mean differences for sleep parameters between Fitbit and sleep diary are below the clinically significant threshold of 30 minutes

Fitbit measurements of sleep parameters. In addition, the architecture does not yet support background services (i.e., running *behind the scenes* and without user intervention), which would allow the app to keep running after the smartphone screen is locked and the app minimized. This feature is important for real-time communication such as initiation of video or audio calls.

The limitations of the adaptive intervention model were discussed briefly in Section 8.2.2.4. In addition to the aforementioned limitations, the model currently also lacks comparison with the real data generated in the iREST feasibility study. Although based on observation of scenarios in the iREST study, the parameters used in the model simulations were not estimated from "real" data. Furthermore, the "self-efficacy" component of the model did not have a direct measurement tool. Rutledge et al. (2013) suggest that the ISI score can be one predictor of self-efficacy for sleep; however, this was found to be not viable because the ISI was also the primary outcome measurement. The JITAI behavior model also shares the same limitation. Both models are designed to encourage understanding and to facilitate use; therefore, both models may oversimplify how the JITAI produces behavior change and symptom improvement. As George Box famously said, "All models are wrong but some are useful" (Box, 1979); likewise, the JITAI behavior and adaptive intervention model strives for practicality and usefulness over impractical precision.

## 9.4 FUTURE WORK

## 9.4.1 Overcoming the Limitations of the Study

Future studies with more varied behavioral health intervention contexts and more heterogeneous and larger samples are required to fully elucidate the potential benefits of the JITAI behavioral models and application architecture. Testing in various health behavior intervention contexts would allow for the determination of the acceptance, adaptability and generalizability of the models and architecture. In addition to behavioral sleep interventions, JITAI can be applied to health contexts such as chronic illness management (e.g., asthma and allergies (Burnay et al., 2013)), diabetes (Osborn & Egede, 2010), mental health (De Joode, Van Heugten, Verhey, & Van Boxtel, 2013; Donker et al., 2013; Husky et al., 2014; Javelot et al., 2014; Walz, Nauta, & Aan Het Rot, 2014), health promotion and disease prevention programs (e.g., smoking cessation (Dunbar, Scharf, Kirchner, & Shiffman, 2010; Witkiewitz et al., 2014)), physical activity promotion (Ferguson, Rowlands, Olds, & Maher, 2015; King et al., 2013; Riley et al., 2014), and weight management programs (Navarro-Barrientos et al., 2011; Rabbi, Aung, Zhang, & Choudhury, 2015). Larger and more heterogeneous samples would include wider demographics (e.g., civilian, elderly, people with disabilities), as well as social and cultural contexts which were not included in the present study. More heterogeneous samples would allow for the evaluation of every component of the JITAI models. The current study, for example, did not assess social interactions between participants and their social networks, which may promote or hinder their sleep improvement.

Clinicians and providers play important roles in JITAIs. Additional studies are needed to assess clinicians' acceptance of this new intervention paradigm and to quantify the "real" cost and potential cost savings of such interventions. In order to promote widespread adoption and dissemination of the JITAI, it is necessary to prove not only that it works but also that it is more cost-effective than other alternatives. Usability also plays an important role in system acceptance; therefore, further investigation is needed to assess clinicians' perspectives and preferences on the system interface (notably, the clinician portal).

The usability study of the iREST app identified a number of potential improvements and additional features suggested by the participants. Most critical suggestions (e.g., application "bugs") were already addressed and incorporated into the app during the development iterations; however, some remain to be addressed in future developments, including:

1) informative, concise but customizable data visualization on the app's dashboard ("Finds the downloaded actigraphy data to be most compelling argument for maintaining consistent schedule. Would like to see graphical representation of his own sleep data on app"; "Show times of sunrise and sunset on app"; "Have the SE% + graphic replaced by something tracking how many logs were entered on time, etc.;, "Would like to see more than past week for the front page to be able to compare all of his data to current week")

2) smart data input, in which the app learns from previously-entered data about each participant's usual sleep habits to reduce participant burden

("Automating answers to the many questions each morning and night would make the system far more convenient and enjoyable to use"; "Requirement to be cognizant of total minutes awake during night disturbed efforts to resume sleep")

3) general UI components

("Slide bars defective on iOS platform. Very difficult to 'slide' because of iPhone 'highlight' function"; "Screen moved upward when trying to enter total WASO, was still able to enter the minutes")

### 4) better notifications and reminders

("Continues to get pop-up notification for GMT at odd times intermittent"; "Sleep Rx gave same GMT/GNT daily, but can't respond rapidly to change in schedule"; "Possibly integrating a calendar or alarm clock option, i.e., calendar to quickly get to a specific date on sleep diary and alarm clock quick for resetting alarm")

5) streamline Fitbit integration

("It would be nice to have the Fitbit talk directly with the app and factor in 'went to bed' time w/sleep on Fitbit"; "Discrepancy between data being entered on app and the data that is downloaded from Fitbit is problematic, causing participant to question utility and/or validity of the data"; "Would like to have app include some graphics-finds the downloaded actigraphy data to be most compelling argument for maintaining consistent schedule. Would like to see graphical representation of his own sleep data on app")

The promising findings in the iREST preliminary feasibility study warrant further investigation. To increase the internal and external validity of the findings, future studies should consider the following:

1. a larger sample size and more heterogeneous participants, such as including civilian population and those with severe comorbidities (Randomized control trials with intervention control (IC) arm are preferred, instead of using previous study as control)

- including all components of the JITAI behavior model, especially the social network and environmental components, such as support from significant other in the intervention and variety of working shifts
- 3. supporting more wearable devices (even inclusion of the broader Internet of Things/IoT<sup>15</sup>), extending the BYOD policy to wearables, and better analytics to determine whether the data collected by these wearable devices are clinically acceptable

Future work on the JITAI models include fitting both models into the study data. For the adaptive intervention model, this can be done by using non parametric fitting, such as a grey box analysis (Box, 1979; Kroll, 2000), while factor analysis may be more appropriate for the JITAI behavior model fitting.

## 9.4.2 Further Improvements

With the advances in hybrid (cross-platform) mobile app frameworks such as adoption of webbased real-time communication (Web RTC), the JITAI application architecture support for realtime interaction can include audio/video conferencing. This would allow richer modality in patient-clinician remote interactions. In-app audio/video conferencing is also a more secure and HIPAA compliance alternative than over-the-phone or third-party software approaches.

Future implementations of the JITAI architecture need to consider how to promote and maintain utilization of the system. Without maintenance effort, system utilization tends to decrease over time. As the JITAI model suggests, effective treatment is highly influenced by

<sup>&</sup>lt;sup>15</sup> "a global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies" (International Telecommunication Union, 2012)

mHealth utilization. Therefore, utilization support such as smart reminders and gamifications should be included in the JITAI architecture. The adaptive intervention model should then include these additional utilization supports, which can be viewed as counter measures for the habituation effects.

Ultimately, the JITAI model and application architecture demonstrate that adaptive intervention works effectively with current mobile technology. Furthermore, the models and architecture are flexible enough to accommodate expected rapid advances in the field of mobile and wearable technology, the Internet of things, big data and health informatics in general.

## **APPENDIX** A

# CONSENT TO ACT AS PARTICIPANT IN A RESEARCH STUDY

# University of Pittsburgh

Clinical and Translational Science Institute Neuroscience Clinical and Translational Research Center

Sterling Plaza 201 N. Craig Street Pittsburgh, PA 15213 412-383-2168 Fax 412-383-5412

#### CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY TITLE: Feasibility and refinement of the interactive Resilience Enhancing Sleep Tactics (iREST) mobile app

#### PRINCIPAL INVESTIGATOR:

Anne Germain, Ph.D. Associate Professor of Psychiatry and Psychology University of Pittsburgh School of Medicine 201 N. Craig Street, #239 Pittsburgh, PA 15213 Telephone: 412-383-2150

**CO-INVESTIGATORS:** 

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Hassen Khan, BS Database Analyst University of Pittsburgh Tel: 412-383-2137

Wayan Pulantara, MS Graduate Student Biomedical Informatics

SOURCE OF SUPPORT: None

#### Why is this research being done?

Sleep disturbances are prevalent among Active Duty Service Members (ADSM) and Veterans, and threaten psychological health, resilience, and the military mission. Medications remain the most common sleep treatments among ADSMs and Veterans, despite substantial concerns regarding their safety (particularly in operational settings), side effects, and potential for abuse. Behavioral sleep treatments have been shown to be safe, effective, and are associated with durable improvements. However, the use of

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evidence-based, resilience-focused, behavioral treatments to promote healthy sleep pre-deployment and to treat sleep disturbances post-deployment remain scarce among ADSM, Veterans, and the clinicians who serve them. You are being asked to participate in this research study because you are an ADSM or Military Veteran, you own a smartphone, and you experience symptoms of insomnia. Insomnia refers to difficulties falling or staying asleep, or non-refreshing sleep. The purpose of this pilot study is to assess the feasibility, usability, and acceptability of the newly developed interactive Resilience Enhancing Sleep Tactics (iREST) mobile application (app) in military service members and veterans with chronic sleep disturbances in order to to support ADSMs' and Veterans' self-help efforts to improve sleep. Your feedback will be used to further refine the app.

We will also explore whether using the iREST app over a period of 4-6 weeks improves sleep related behaviors and sleep quality. The data obtained from this pilot study will provide preliminary data for funding proposals to NIMH and/or the DoD. In this research study, we will evaluate the use and impacts of the iREST mobile app as a tool to support the use of self-management strategies to improve sleep pre- or post-deployment. iREST draws directly from existing interventions that have been found to be effective in ADSMs and Veterans. The iREST system consists of a smartphone app, a clinician portal, and secure, 2-way communications connecting the two. You will be able to receive personalized feedback from a trained sleep coach ("coach in a pocket"). Our clinicians will be able to monitor and assess sleep based on the sleep data sent from the app. The focus will be on exploring changes and improvements to your insomnia and daytime functioning using the app for 4-6 weeks, including a 3-month follow-up with you.

#### Who is being asked to take part in this research study?

People invited to participate in this study must be ADSMs or Military Veterans (men and women) 18 to 60 years old. This phase of the study will include a total of 12 individuals to participate in the intervention procedures.

#### What procedures will be performed for research purposes?

If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical care:

1. Telephone Screening

You have already completed one of this study's screening procedures. Since that brief telephone interview indicated that you may have sleep disturbances consistent with insomnia, you are being asked to participate in the other screening procedures to determine if you will be eligible for this study.

2. In-person questionnaires, interview, and iREST app instruction

These interviews and questionnaires focus on assessing the presence and severity of sleep disturbances and disorders, psychiatric symptoms, and your current physical health. They also inquire about military history and demographic variables, sleep quality, current sleep habits and behaviors, psychological well-being, , the use of alcohol and drugs, and other activities. You may refuse to disclose information regarding your health or health habits (e.g., alcohol or drug use) for any reason. Furthermore, you are not required to answer the first question on the Clinician Administered PTSD Scale. If you judge that answering this question will trigger psychological distress, you can move on with the remaining questions on the instrument. However, because your refusal will prevent the investigators from fully assessing whether you can safely participate in this research study, they may decide to withdraw your participation. If this evaluation reveals the presence of a current, severe, untreated, or inadequately treated major depression, sleep apnea, or restless leg syndrome, you will be referred to your primary care physician for further assessment and intervention.

All contact visits will be held at the Military Sleep Tactics and Resilience Research Team office space at Sterling Plaza. One of the study investigators will meet with you to review information about your physical and mental health, and to resolve any questions you may have. In addition, your information will be reviewed during staff consensus conferences held weekly with the study coordinator



and the study investigators to verify your eligibility as well as to ensure your safety.

If you are eligible for the study, you will then receive information on how to use the iREST app throughout the duration of the study. Adherence to study procedures will be monitored through the clinician's portal by the study coordinator and/or a trained staff member and the PI. In the case of non-adherence, The portal allows the investigators to send secure messages to each participant. You will use the app for 7-10 days and at the same time, you will be asked to wear an activity monitor, such as a Fitbit or Actiwatch. An activity monitor is a non-intrusive watch-like bracelet, worn on the wrist opposite your writing hand, that monitors activity level (derived from wrist movements) over a series of 24-hour periods in your natural environment. This will allow the investigators to monitor your sleep schedule and to evaluate your sleep quality.

This visit will require approximately 100 to 210 minutes and may be broken into two shorter visits if you desire.

3. Return visit for review of sleep data and interview

You will then return to the research office after 7 to 10 days of using the app. This period allows for scheduling flexibility to accommodate your schedule. Sleep-related information from the app will be reviewed with study staff. The accuracy of recommendations from the app based on 7-0 days of use will be examined. We will also ask you to complete some short self-report questionnaires on your current mood and daytime functioning and to assess any side effects that you may be experiencing. An open ended interview will also occur at this time to obtain your feedback of the usability, design, content, and usefulness of the iREST app. This will be conducted by the research coordinator or a staff member, and will require less than 1 hour.

4. 4-6 week use of iREST app

You will continue to use the app and activity monitor for the following 4-6 weeks. During this time, you will be asked to complete several short self-report questionnaires weekly to assess side effects, daytime functioning and mood and anxiety symptoms. You may wish to contact your sleep coach to ask questions about your recommended sleep schedule and habits, at points during the 4-6 weeks of app usage, and are welcome to do so, either via the 2-way messaging system in the app or via phone. If more informatin or guidance is needed, you may come to the office to have an in-person meeting with your sleep coach. At the completion of the 4-6 weeks of app usage, you will return to the research office to review progress. The open-ended interview will be completed again at this time to obtain feedback of the usability, design, content, and usefulness of the iREST app and to have you complete self-report questionnaires. This visit will require less than 1 hour.

5. Follow up meeting and 3-month follow-up contact

If you continue to experience significant sleep disturbances, you will be offered up to 4 in-person sleep consults with the PI or a clinically trained staff member, and/or referral to a sleep clinic or mental health services will be facilitated as needed.

We will contact you again three months after you complete the active part of the study. We will ask you to enter your sleep information into the app's sleep diary for one week. We will alsoask you about mood and anxiety symptoms, daytime functioning and side effects that you may be experiencing, such as increased daytime sleepiness.

#### Monitoring Procedures:

Procedures performed to evaluate the effectiveness and safety of the experimental procedures are called "monitoring" procedures. During the program, we will have weekly contacts to address any questions or challenges you may be experiencing with the techniques and information discussed to improve your sleep. You will also have the contact information of the clinician and study investigator in case you would have any questions between scheduled contacts.

#### What are the possible risks, side effects, and discomforts of this research study?

The possible risks of this research study may be caused by completing the in-person interviews and questionnaires that include selfdisclosure of illegal activities, following recomendations for better sleep, a breach of confidentiality, or use of a smartphone

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<u>Risks from the in-person evaluation and assessment:</u> Some people feel uncomfortable answering questions of a personal nature, such as questions about mood, and you may self-disclose illegal activities. You can refuse to answer any questions or questionnaires that make you uncomfortable. Psychological discomfort related to interviews and questionnaires infrequently occurs (in less than 10% or less than 10 out of 100 participants).

Risks from the recomendations for better sleep (i.e., changes in sleep schedule, sleep restriction, sleep hygiene): Modifications to your sleep schedule recommended during the behavioral intervention may be associated with increased sleepiness. Sleepiness or drowsiness related to sleep restriction could increase your risk of accidents while driving or at work. Risk for increased daytime sleepiness is common (occurs in 10-25% or 10 to 25 out of 100 participants). Some people may also experience increased distress associated with the mild sleep deprivation. You may report side effects to your clinician at any time. If you find the side effects are unbearable, you can discontinue the program at any time, and we will help you to find alternative treatment approaches that may be helpful to you based on the information from your baseline assessments.

<u>Breach of confidentiality:</u> It is possible that information regarding the participants' psychological health or the content of audiotaped treatment sessions will be discovered by individuals outside of study personnel, despite careful steps to protect confidentiality. Breach of confidentiality rarely occurs (in less than 1% or less than 1 out of 100 participants). Maintaining strict security of the information that you provide will minimize these risks. Study data will be kept strictly confidential and participants' identities will not be revealed in any publication. All participants have subject numbers that will be used on forms and for data storage purposes. The PI will have locked files linking participants' names and identification numbers. No results will be released to employers, ensuring no impact on future insurability or employability. All information and assessments will be kept in locked files and access to these materials will be limited to study personnel and those involved in the clinical care of participants. Computer databases are protected by several procedures, including password protection of subject data and a firewall around the entire Research Computing Network in the Neuroscience Clinical and Translational Research Center (N-CTRC) at the University of Pittsburgh. The only party outside of the study staff that will have access to identifiable information (names and social security numbers) will be the WePay system of UPMC.

The activity monitors will be set up by a research staff member through the developer's website using a general program account including a generic username and password not linked to participants in anyway. No identifiable information will be used to set up the account such as DOB, gender or age and subject numbers will be used to store and retrieve participant sleep data only. Activity monitoring data will only be downloaded using a secure network computer.

Activity monitoring companies may use de-identified data to inform the health community about trends; for marketing and promotional use; or may sell it to interested audiences.

If communicating by email or text for scheduling purposes be aware that although every reasonable effort may be taken, confidentiality during internet communication and text messaging activities cannot be guaranteed and it is possible that information may be intercepted and used by others not associated with this study.

<u>Risks specific to the use of smartphones:</u> Security and confidentiality in a mobile health application is of paramount importance. We will use layered security measures to protect the privacy and confidentiality of the data, including: (1) the use of a forced PIN/password to access the apps; (2) a strong authentication procedure that combines a PIN/password, the phone number of the device, and the device's unique International Mobile Equipment Identity (IMEI) number; (3) encryption of all communication between the smartphone and the server using the AES (Advanced Encryption Standard) 192-bit key; (4) A novel security method that allows clinicians to disable the app and to erase records from the device in the event of a lost smartphone while preserving the records on the secure server; (5) a secure messaging system between the portal and smartphone will be used in the place of SMS/text messaging, and lastly, (6) a secure server behind a firewall with security policy in place that includes a dedicated server, regular back-up of data, a monitored network with active security measures, and a well-defined, role-based, access to the database.

Risk from wearing activity monitor. (Rare: occur in less than 1% of participants or less than 1 out of 100 people): A side effect that you might experience is related to parts of the activity monitor (e.g. FitBit, Actiwatch) that are in direct contact with your skin and is



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limited to mild skin irritaiton from extended periods of wear.

#### What are possible benefits from taking part in this study?

There is no certain benefit to research subjects from study participation. Data from the clinical assessments may lead to additional and more accurate information regarding current psychiatric symptoms, allowing for appropriate referrals for further evaluation and treatment. Participation in the behavioral program for insomnia or the information condition may provide some relief of symptoms from insomnia.

#### What treatments or procedures are available if I decide not to take part in this research study?

If you decide not to take part in this research study you can ask your doctor about other treatments for insomnia. These may include behavioral treatment from a psychologist, which usually involves meeting several times to review your sleep habits and recommend changes. Your doctor can also prescribe medication for insomnia. Several medications are effective and available for the treatment of insomnia, including sleeping pills.

# If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the course of this research study, any new information develops which may cause you to reconsider your participation.

#### Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

None of the services and/or procedures you receive during this research study, such as the diagnostic interviews and questionnaires, will be billed to you or your health insurance. If you receive a bill, or believe that your health insurance has been billed for something that is part of the research study, notify a member of the research team or UPMC Patient Billing Services.

#### Will I be paid if I take part in this research study?

Parking in the garage beneath Sterling Plaza will be provided at no cost to all participants.

Participants will receive:

\$10 for completing self-report questionnaires at baseline and again after 4 weeks of using the iREST app (total \$20)

\$25 for completion of the assessments

\$15 per week for using the iREST app, for a maximum of 6 weeks (total \$90).

\$25 for completion of the 3-month follow-up procedures (one week app completion, telephone contact and self-report questionnaires), each participant will receive \$25.

If a participant does not complete the entire study, partial compensation is provided for procedures completed.

In total, participants may receive up to \$160 for participating in the study.

#### Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers and their associates who provide services at University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact the PI immediately or contact one of the co-investigators listed on the first page of this form.

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Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You, however, do not waive any legal rights by signing this form.

#### Who will know about my participation in this research study?

The investigators of this study are currently conducting several other sleep studies. If you decide that you are interested in participating in one of these other studies at any point, your screening and assessment data will be provided to the personnel on the second study so that you do not have to repeat certain procedures, such as the physical exam and structured psychiatric assessment. You can request that your data not be transferred and choose to repeat the procedures again, if you so desire. None of your data will ever be communicated to personnel working on another study without your signed consent.

The People/Organizations Who May Use or Disclose the Information: Your information will be used only as specified above and under the direction of Dr. Germain and her research team.

The People/Organizations Who Will Receive the Information: It has been explained to you that every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study:

It has also been explained to you that medical information may be shared with your healthcare provider(s) with your consent, and possibly, without your consent if permissible under federal laws and regulations, such as in the case where the investigators learn that you or someone with whom you are involved is in serious danger or potential harm. Finally, you consent to the publication of the study results so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

The investigators involved in the conduct of this research study may receive funding to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your participation in the study.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders made by the investigators for hospital and health care services (e.g., laboratory tests) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e., quality assurance).

#### Additional confidentiality (privacy) protections that are provided by a federal Confidentiality Certificate.

Although disclosing personal information about yourself could violate the Military Code of Conduct, to help us protect your privacy, the investigators will obtain a Certificate of Confidentiality from the National Institutes of Mental Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for



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information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that your family or yourself must actively protect your privacy. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The fact that you are participating in a research study and that you are undergoing certain research procedures (but not the results of the procedures) may also be made known to individuals involved in other administrative activities associated with the conduct of the study. Study personnel have signed confidentiality statements indicating that they may not disclose information acquired in conjunction with this research study to anyone without your consent.

Finally, you should understand that a Certificate of Confidentiality does not prevent researchers from taking steps, including reporting to authorities, to prevent harm to you or others.

#### For how long will the investigators be permitted to use and disclose identifiable information related to my participation?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study indefinitely. It is a University of Pittsburgh policy that all research records must be maintained for at least 7 years following final reporting or publication of a project.

#### May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdraw your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

#### If I agree to participate in this research study, can I be removed from the study without my consent?

You may also be withdrawn from the study by the investigators if they feel that it is necessary because of specific medical or psychiatric problems that are discovered. In this case, you would be referred for appropriate treatment. You may also be withdrawn if after several attempts study investigators are unable to establish contact with you or ascertain that study procedures are being completed safely and fully. If you decide to no longer participate in the study, we ask that you inform us of your decision in a timely manner.



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**VOLUNTARY CONSENT:** All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions that I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh, **1-866-212-2668**.

By signing this form, I agree to participate in this research study and I agree to allow the information I have provided in the questionnaires to be used to determine my eligibility for this research study. A copy of this consent form will be given to me.

Participant's Printed Name

Participant's Signature

Date

**CERTIFICATION of INFORMED CONSENT**: I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits of study participation. Any question the individual has about this study has been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

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# **APPENDIX B**

# THE PITTSBURGH SLEEP QUALITY INDEX (PSQI)

				Pa	age 1 of 4
Subjec	ct's Initials	ID#	Da	ate	AN _TimePN
		PITTSBURGH S	LEEP QUALITY I	NDEX	
The f		relate to your usual sl accurate reply for the ons.			
1.	During the past m	onth, what time have	you usually gone	to bed at night?	
		BED TIM	IE		
2.	During the past me	onth, how long (in min	utes) has it usuall	y taken you to fall asl	eep each night?
		NUMBER OF M	IINUTES		
3.	During the past m	onth, what time have	you usually gotter	up in the morning?	
		GETTING UF	P TIME		
4.	During the past m different than the	nonth, how many hou number of hours you	rs of <u>actual</u> <u>sleep</u> spent in bed.)	did you get at night	? (This may be
		HOURS OF SLEEP	PER NIGHT		
For ea	ch of the remainin	g questions, check t	he one best resp	onse. Please answe	er <u>all</u> questions
5.	During the past m	onth, how often have	you had trouble sl	eeping because you	5 2012/01-1
a)	Cannot get to slee	ep within 30 minutes			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week	
b)	Wake up in the m	iddle of the night or e	arly morning		
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week	
c)	Have to get up to	use the bathroom			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week	_ ·

d) Cannot breathe comfortably

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
e)	Cough or snore lo	udly		
		Less than once a week	Once or twice a week	Three or more times a week
f)	Feel too cold			
		Less than once a week		Three or more times a week
g)	Feel too hot			
		Less than once a week	Once or twice a week	Three or more times a week
h)	Had bad dreams			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
i)	Have pain			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
j)	Other reason(s), p	lease describe		

How often during the past month have you had trouble sleeping because of this?

Not during the	Less than	Once or twice	Three or more
past month	once a week	a week	times a week

6. During the past month, how would you rate your sleep quality overall?

Very good	
Fairly good	3
Fairly bad	·
Very bad	3

#### Page 3 of 4

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

 
 Not during the past month\_\_\_\_\_
 Less than once a week\_\_\_\_
 Once or twice a week\_\_\_\_
 Three or more times a week\_\_\_\_

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the	Less than	Once or twice	Three or more
past month	once a week	a week	times a week

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

	No problem at all	
	Only a very slight problem	
	Somewhat of a problem	
	A very big problem	
10.	Do you have a bed partner or room mate?	
	No bed partner or room mate	

No bed partner of room mate	
Partner/room mate in other room	

Partner in same room, but not same bed

Partner in same bed

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
b)	Long pauses betw	veen breaths while as	leep	
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
c)	Legs twitching or j	erking while you slee	р	
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week

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d) Episodes of disorientation or confusion during sleep

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
e)	Other restlessness	s while you sleep; plea	se describe	
	ni			
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week

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Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: Psychiatry Research, 28:193-213, 1989.

# **APPENDIX C**

# THE INSOMNIA SEVERITY INDEX (ISI)

For each question, please CIRCLE the number that best describes your answer.

Please rate the CURRENT (i	e. LAST 2 WEEKS)	SEVERITY of your	insomnia problem(s).

Insomnia Problem		None	Mil	d Mode	erate	Severe	Very Severe	
1. Difficulty	1. Difficulty falling asleep			1	2		3	4
2. Difficulty	staying asleep		0	1	2		3	4
3. Problems	waking up too ear	ly	0	1	2		3	4
	SFIED/DISSATIS Very Satisfied 0	Satisfied 1	Moderately Sa 2	atisfied	Dissatisfied 3		ery Dissatisf 4	
5. How NOTI	CEABLE to othe Not at all	rs do you think	your sleep probl	em is in t	terms of impa	iring tl	he quality of	your life?
	Noticeable 0	A Little 1	Somewhat 2	Much 3	Very	Much 4	Noticeable	
6. How WOR	RIED/DISTRESS Not at all	ED are you abo	out your current	sleep pro	blem?			
	Worried 0	A Little 1	Somewhat 2	Much 3	Very	Much 4	Worried	
	tent do you consid , ability to functio Not at all							
	Interfering 0	A Little 1	Somewhat 2	Much 3	Very	Much 4	Interfering	

# **APPENDIX D**

# THE EPWORTH SLEEPINESS SCALE (ESS)

NAME	ID#:				1	9	3		/			/			
						Y	'ear			Mon	ith		Da	У	
8		 	 	 				 							

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired. They refer to your usual way of life in recent times. Even if you have not 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

#### SITUATION

1. Sitting and Reading	00	<b>○1</b>	02	് 3
2. Watching TV	0 0	<u>ୀ</u>	02	് 3
<ol> <li>Sitting, inactive in a public place (i.e., a theater or meeting)</li> </ol>	O <b>0</b>	01	ି 2	ි 3
4. As a passenger in a car for an hour without a break	0 0	<u>ୀ</u>	02	് 3
<ol><li>Lying down to rest in the afternoon when circumstances permit</li></ol>	୦ <b>୦</b>	○ 1	ି 2	ි 3
6. Sitting and talking to someone	0 0	<b>ୀ</b>	02	ි 3
7. Sitting quietly after a lunch without alcohol	് 0	<u>ୀ</u>	02	ି 3
8. In a car, while stopped for a few minutes in the traffic	00	<b>1</b>	<u>ି</u> 2	03

# **APPENDIX E**

# THE SYSTEM USABILITY SCALE (SUS)

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	Strongly disagree				Strongly agree
1. I think that I would like to		-			
use this system frequently	1	2	3	4	5
<ol><li>I found the system unnecessarily complex</li></ol>				0	
	1	2	3	4	5
<ol><li>I thought the system was easy to use</li></ol>		-		-	
	1	2	3	4	5
<ol> <li>I think that I would need the support of a technical person to</li> </ol>					
be able to use this system	1	2	3	4	5
5. I found the various functions in					
this system were well integrated	1	2	3	4	5
<ol><li>I thought there was too much inconsistency in this system</li></ol>			8		
inconsistency in this system	1	2	3	4	5
7. I would imagine that most people					1
would learn to use this system very quickly	1	2	3	4	5
8. I found the system very					
cumbersome to use	1	2	3	4	5
9. I felt very confident using the				-	
system	1	2	3	4	5
10. I needed to learn a lot of					
things before I could get going with this system	1	2	3	4	5

- 3
- 5

- things before I could get going with this system

# **APPENDIX F**

# THE TELEHEALTH USABILITY QUESTIONNAIRE (TUQ)

#### \*Modified from TUQ for iREST study

		N/A		1	2	3	4	5	
1.	mHealth improves my access to healthcare services.		DISAGREE						AGREE
2.	mHealth saves me time traveling to a hospital or specialist clinic.		DISAGREE						AGREE
3.	mHealth provides for my healthcare need.		DISAGREE						AGREE
4.	It was simple to use this system.		DISAGREE						AGREE
5.	It was easy to learn to use the system.		DISAGREE						AGREE
6.	I believe I could become productive quickly using this system.		DISAGREE						AGREE
7.	The way I interact with this system is pleasant.		DISAGREE						AGREE
8.	I like using the system.		DISAGREE						AGREE
9.	The system is simple and easy to understand.		DISAGREE						AGREE
10.	This system is able to do everything I would want it to be able to do.		DISAGREE						AGREE
11.	I can easily update my health status with the clinician using the mHealth system.		DISAGREE						AGREE
12.	I can-easily manage my condition(s) using the mHealth system.		DISAGREE						AGREE
13.	I felt I was able to express myself effectively.		DISAGREE						AGREE
14.	Using reminders from mHealth system, it is easy to manage my self-care activities.		DISAGREE						AGREE
15.	I think the visits provided over the telehealth system are the same as in person visits.	₽	DISAGREE	₽	₽	₽	₽	₽	AGREE
16.	Whenever I made a mistake using the system, I could recover easily and quickly.		DISAGREE						AGREE

17.	The system gave error messages that clearly told me how to fix problems.	DISAGREE			AGREE
18.	I feel comfortable communicating with the clinician using the mHealth system.	DISAGREE			AGREE
19.	mHealth is an acceptable way to receive healthcare services.	DISAGREE			AGREE
20.	I would use mHealth services again.	DISAGREE			AGREE
21.	Overall, I am satisfied with this mHealth system.	DISAGREE			AGREE

# Please provide comments about the mHealth system:

••••••••••••••••••	 	
•••••••••••••••••	 	
••••••••••••••••••••••••••••••••••••	 ••••••••••••••••••••••••••••••••••••	••••••
•••••••••••••••••••••••••••••••••••	 ••••••••••••••••••••••••••••••••••••	

# **APPENDIX G**

# PARTICIPANTS FEEDBACKS AND COMMENTS ON IREST APP

APPCOMMENTS	DATAENTRY	FEATURES	GENERAL
	BUTTONS INSTEAD OF SLIDING SCALES FOR CERTAIN QUESTIONS. APP CYCLES TO NEXT ENTRY WHEN "SUBMIT" IS PRESSED	FIELDS TO INPUT SPEC	
SOMEWHAT FRUSTRATED BY APP SENDING HIM "GIBBERISH" SLEEP PRESCRIPTIONS DAILY IN FLUCTUATING GMT AND GNT	COULD NOT GO BACK AND FIX THE INCORRECT TIME ENTERED FOR 'TIME 1 ACTUALLY TRIED TO GO TO SLEEP'	SLEEPTACTICS PAGES VISIBLE SOME DAYS, GONE OTHER DAYS	SERVER FAILURE OVER WEEKEND?
ALL OF THE "SLEEP BRIEFING INFO" IS ONLY VISIBLE INTERMITTENTLY. "SLEEP SUGGESTIONS" PAGE GONE. CONTINUES TO RECEIVE DIFFERENT SLEEP RX DAILY (IN FORM OF ALARM/ALERTS) BUT NOT IN FORM OF MESSAGES-GETS THESE AS ALERTS	SLIDE BARS DEFECTIVE ON IOS PLATFORM. VERY DIFFICULT TO 'SLIDE' BECAUSE OF IPHONE 'HIGHLIGHT' FUNCTION	CONTINUES TO GET POP-UP NOTIFICATION FOR GMT AT ODD TIMES (I.E. 1150 TODAY), INTERMITTENT	
1. FINDING IT PLUS EXPERIENCE TO USE APP TO TRACK SLEEP 2. LIKES THE MORNING REMINDER TO FILL OUT WAKETIME DIARY -> IS THIS THE MORNING ALARM? 3. RECEIVED PRESCRITION BY APP, BUT IGNORED IT	FINDS THAT THE UP/DOWN ARROWS ON ANDROID ONE TIME-CONSUMING FOR SETTING TIME	ADD REMINDER(OPTIO NS) FOR BEDTIME DIARY COMPLETION	
SLEEP RX GAVE SAME GMT/GNT DAILY, BUT CAN'T RESPOND RAPIDLY TO CHANGE IN SCHEDULE	11/28/2014-TRIED TO SUBMIT WAKETIME DIARY AND DID NOT GET "SAVED" MSG.	ALARM-GOES OFF REPEATEDLY EVEN AFTER HE HAS ENTERED HIS WAKETIME DIARY	
GOT NEW PHONE, APP MOVED OVER BY PHONE DEALER, HE WAS 'UNCONFIRMED' ON NEW PHONE, BUT COULD STILL ENTER DATA ON OLD PHONE (EXCEPT FOR DAY IMMEDIATELY AFTER PHONE UPGRADE)			

	LIKES ADDED "TIME WHEEL" FUNCTION FOR ANDROID	ALARM GOING OFF ONLY 1X NOW FOR GMT	
WOULD LIKE TO HAVE APP INCLUDE SOME GRAPHICS-FINDS THE DOWNLOADED ACTIGRAPHY DATA TO BE MOST COMPELLING ARGUMENT FOR MAINTAINING CONSISTENT SCHEDULE. WOULD LIKE TO SEE GRAPHICAL REPRESENTTION OF HIS OWN SLEEP DATA ON APP		WOULD PREFER A MORE USEFUL/CONSISTE NT "WAKE UP" REMINDER TO ENTER DATA - OCCASIONALLY FOUIND HIMSELF FORGETTING	STOPPED EXPERIENCING ALARM GOING OFF AT NIGHT. FEELS THAT USING THE APP EVERY DAY HAS CREATED SENSE OF ACCOUNTABILITY
	ОК	"FIRST CONTACT" INFO SHOULD BE COMPLETED IN MORNING. WOULD BE USEFUL TO ENTER DATA AS IT HAPPENS	
SHOW TIMES OF SUNRISE AND SUNSET ON AP?	FINE	WORKS WELL	CONTACT INFO FOR CLINICIAN
POSSIBLY INTERGRATING A CALENDER OR ALARM CLOCK OPTION. IE CALENDER TO QUICKLY GET TO A SPECIFIC DATE ON SLEEP DIARY AND ALARM CLOCK QUICK FOR RESETTING ALARM			
I HAD AN ANDROID PHONE AT FIRST, THAT ONE BROKE, AND I SWITCHED TO THE IPHONE. TESTFLIGHT WORKED FOR A WHILE, BUT AFTER IT UPDATED IT STOPPED. I COULDN'T GET INTO ANYTHING & IT KEPT GLITCHING			
	VERY EASY TO NAVIGATE, FOUND THAT THE DATA UPLOADED QUICKLY, NO DELAY WITH THE UPLOAD OF DATA	HAVE THE SE% + GRAPHIC REPLACED BY SOMETHING TRACKING HOW MANY LOGS WERE ENTERED ON TIME, ETC.	LIKES THE FRONT PAGE A LOT, FINDS IT USEFUL AND ATTRACTIVE
SERVER POWERED OFF OVER WEEKEND. PARTICIPANTS WERE UNABLE TO ENTER DATA OVER THAT PERIOD OF TIME + IT WAS NOT CACHED ON THEIR DEVICES-LOST DATA. ALSO, AFTER SERVER PROBLEMS, THE SLEEP BRIEFING MATERIALS UPLOADED WITH MISSING OR REPETITIVE SECTIONS			
	WOULD LIKE TO BE ABLE TO SEE	LINE MAY OR MAY NOT CROSS OUT ITEMS ON TO DO LIST	
	EASY, QUICK-NO SUGGESTIONS		

	DROP-DOWN MENUS CONTINUE TO DEFAULT TO A DIFFERENT CHOICE THEN THE ONE THAT PARTICIPANT CHOICES ON 1ST EFFOFT- HAS TO CHOOSE AGAIN TO GET THE ITEM TO 'STAY'		
		WOULD LIKE TO SEE MORE THAN PAST WEEK FOR THE "FRONT PAGE" TO BE ABLE TO COMPARE ALL OF HIS DATA TO CURRENT WEEK	
SIMPLE, EASY TO USE. HAS NOT YET READ SLEEP TACTICS	EASY TO MAKE RESPONSES. UNABLE TO ADD ADDITIONAL INFO(I.E. NOTES)		
	SHOULD HAVE A WRITE-IN SPACE FOR WASO REASONS (PRIMARY REASON FOR WAKING AT NIGHT IS NOT IN DROP-DOWN MENU)		
	DISCOVERED THAT HE CAN ALTER COMPLETED SLEEP LOGS BY[DID NOT FINISH]		
DID READ SLEEP TACTICS. FOUN THE LEVEL OF DETAIL TO BE USEFUL. USED THE SHORT BULLET POINTS FOR TROUBLE-SHOOTING AND THE DETAIL FOR MORE BACKGROUND	SIMPLE, CUT, AND DRY		
SUBJECT REPORTED NO COMMENTS OR SUGESSTIONS			
	SCREEN MOVED UPWARD WHEN TRYING TO ENTER TOTAL WASO, WAS STILL ABLE TO ENTER THE MINUTES		
WE REVIEWED THE MATERIAL FIRST IN- SESSION, THEN HE USED APP AS REVIEW			STEP 4:(SUDDEN APPEARANCE OF STRANGE/FOREIGN LANGUAGE) ON SAMSUNG(PLATFO RM)-LET WAYAN KNOWN ABOUT CHARACTERS AND WORDS IN FOREIGN LANGUAGE
	PROVIDE OPTION TO SELECT FINAL WAKE UP FROM BATHROOM BREAK		
HAVING TO ENTER DATA CUMBERSTOME. DIDN'T WANT TO HAVE TO LOOK AT CLOCK			

		1	
WOULD LIKE IF UNIT COULD DETERMINE TIME AWAKE AT NIGHT AND RETURN TO SLEEP			
	REQUIREMENT TO BE COGNIZANT OF TOTAL MINUTES AWAKE DURING NIGHT DISTURBED EFFORTS TO RESUME SLEEP	ADD ABILITY FOR SYSTEM TO RECOGNIZE AND CALCULATE PERIODS OF SLEEP AND WAKE DURING THE NIGHT!!!	AUTOMATING ANSWERS TO THE MANY QUESTIONS EACH MORNING AND NIGHT WOULD MAKE THE SYSTEM FAR MORE CONVENIENT AND ENJOYABLE TO USE.
DISCREPANCY BETWEEN DATA BEING ENTERED ON APP AND THE DATA THAT IS DOWNLOADED FROM FITBIT IS PROBLEMATIC, CAUSING PARTICIPANT TO QUESTION UTILITY AND/OR VALIDITY OF THE DATA			
IF IT WORKED BETTER WITH COMMUNICATION WITH FITBIT AND IREST WOULD BE GOOD			
	2 OR 3 DAYS IN A ROW WOULDN'T LET ME INPUT DATA, AND IT KEPT THE FIELDS POPULATED WITH THE LAST DATA ENTERED	IT WOULD BE NICE TO HAVE THE FITBIT TALK DIRECTLY WITH THE APP AND FACTOR IN "WENT TO BED" TIME W/SLEEP ON FITBIT	
THE APP NEEDS NO IMPROVEMENTS	WORKS FINE	WORKS FINE	WORKS FINE
IT'S A WONDERFUL APP AND WOULD BE HELPFUL FOR ANYONE			
GREAT SYSTEM EASY TO USE AND MONITOR SLEEP EASY	REAL EASY TO USE. VERY SIMPLE. BELIEVE ALL PEOPLE OF ALMOST ALL AGES CAN LEARN TO USE IT NO PROBLEM.	THINK IT WOULD HELP IF THERE WAS A SEPARATE JOURNAL TO WRITE ABOUT YOUR SLEEP IN YOUR OWN WORDS.	
EASY TO USE			
BUG: SLEEP DISTURBANCES DROP DOWN MENU -OFTEN HAVE TO ENTER "TIMES USED BATHROOM" ATTEMPTS >3X	SEE ABOVE		

## **APPENDIX H**

## LEVEL-2 PREDICTORS EXPLORATORY ANALYSIS RESULTS

Level-1 Coefficient			Potenti	al Level-2 Predic	ctors	
INTRCPT1, $\pi_0$						
	RACE	AGE	MBRANCH	PSYCHMED	MOOD	ESS
Coefficient	0.010	-0.002	0.008	0.077	0.032	0.004
Standard Error	0.030	0.002	0.020	0.051	0.041	0.004
t-value	0.329	-0.898	0.384	1.503	0.799	0.863
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INTRCPT1, $\pi_0$						
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA
Coefficient	-0.002	-0.004	-0.038	-0.001	-0.004	-0.004/0.000
Standard Error	0.004	0.005	0.040	0.001	0.004	0.006/0.005
t-value	-0.583	-0.822	-0.930	-0.392	-1.000	-0.760/0.042
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INDEX, $\pi_1$						
	RACE	AGE	MBRANCH	PSYCHMED	MOOD	ESS
Coefficient	0.001	-0.000	0.000	-0.001	-0.000	-0.000
Standard Error	0.001	0.000	0.000	0.001	0.001	0.000
t-value	0.844	-0.374	0.105	-0.629	-0.104	-0.200
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INDEX, $\pi_1$						
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA
Coefficient	-0.000	-0.000	0.000	-0.000	-0.000	-0.000/0.000
Standard Error	0.000	0.000	0.001	0.000	0.000	0.000/0.000
t-value	-0.067	-0.258	0.151	-0.243	-0.327	-0.326/0.017
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
n.s. = not significant						

Sleep Efficiency as outcome (HLM 7 level-2 exploratory analysis output):

Latency as outcome:

Level-1 Coefficient			Potenti	al Level-2 Predi	ictors	
INTRCPT1, $\pi_0$						
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS
Coefficient	-9.167	-0.060	-7.921	-17.608	-7.099	-0.831
Standard Error	10.688	0.718	6.982	19.081	14.680	1.565
t-value	-0.858	-0.084	-1.134	-0.923	-0.484	-0.531
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INTRCPT1, $\pi_0$						
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA
Coefficient	2.351	2.620	21.791	0.523	2.105	2.074/1.191
Standard Error	1.182	1.782	13.804	0.462	1.333	2.082/1.676
t-value	1.988	1.470	1.579	1.132	1.579	0.996/0.711
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INDEX, $\pi_1$						
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS
Coefficient	0.103	0.001	0.096	0.254	0.095	0.010
Standard Error	0.140	0.009	0.091	0.246	0.191	0.020
t-value	0.740	0.086	1.050	1.032	0.499	0.496
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INDEX, $\pi_1$						
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA
Coefficient	-0.030	-0.036	-0.278	-0.007	-0.029	-0.027/-0.017
Standard Error	0.015	0.023	0.180	0.006	0.017	0.027/0.022
t-value	-1.976	-1.551	-1.548	-1.167	-1.669	-1.013/-0.782
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

## WASO as outcome:

Level-1 Coefficient	Potential Level-2 Predictors						
INTRCPT1, $\pi_0$							
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS	
Coefficient	-2.540	0.185	0.924	-11.527	-9.088	-1.238	
Standard Error	6.417	0.422	4.271	11.204	8.446	0.882	
t-value	-0.396	0.439	0.216	-1.029	-1.076	-1.404	
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	
INTRCPT1, $\pi_0$							
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA	
Coefficient	-0.273	-0.414	1.894	-0.023	0.084	1.051/-0.610	
Standard Error	0.772	1.113	8.717	0.283	0.843	1.239/0.994	
t-value	-0.353	-0.372	0.217	-0.083	0.100	0.848/-0.614	
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	

Level-1 Coefficient			Pote	ntial Level-2 Pro	edictors	
INDEX, $\pi_1$						
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS
Coefficient	-0.106	0.016	-0.046	-0.011	-0.107	0.007
Standard Error	0.233	0.015	0.155	0.421	0.317	0.034
t-value	-0.454	1.070	-0.293	-0.025	-0.337	0.192
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INDEX, $\pi_1$						
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA
Coefficient	0.012	0.045	-0.041	0.005	0.038	0.021/0.007
Standard Error	0.028	0.039	0.318	0.010	0.029	0.046/0.037
t-value	0.429	1.134	-0.129	0.466	1.280	0.449/0.188
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

Total time in bed (TIB) as outcome:

Level-1 Coefficient			Poten	tial Level-2 Prec	lictors	
INTRCPT1, $\pi_0$						
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS
Coefficient	-14.282	-2.911	-13.127	31.113	-12.835	-2.694
Standard Error	22.025	1.286	14.443	39.216	30.028	3.156
t-value	-0.648	-2.264	-0.909	0.793	-0.427	-0.854
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INTRCPT1, $\pi_0$						
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA
Coefficient	4.605	2.415	4.947	0.911	3.651	5.424/1.976
Standard Error	2.437	3.820	30.165	0.953	2.778	4.172/3.441
t-value	1.890	0.632	0.164	0.956	1.314	1.300/0.574
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INDEX, $\pi_1$						
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS
Coefficient	0.086	0.028	0.172	-0.145	-0.091	0.057
Standard Error	0.294	0.018	0.191	0.527	0.399	0.040
t-value	0.293	1.559	0.899	-0.276	-0.229	1.401
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
INDEX, $\pi_1$						
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA
Coefficient	-0.051	-0.055	-0.367	-0.014	-0.048	<u>-0.130</u> /-0.036
Standard Error	0.033	0.049	0.389	0.012	0.037	<u>0.049</u> /0.045
t-value	-1.549	-1.124	-0.942	-1.148	-1.316	<u>-2.665</u> /-0.804
	n.s.	n.s.	n.s.	n.s.	n.s.	<u>0.03 (sig)</u> /n.s.
*PSQI is a significar	it level-2 p	oredictor	for regression	coefficient		

Level-1 Coefficient	Potential Level-2 Predictors						
INTRCPT1, $\pi_0$							
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS	
Coefficient	-4.690	-3.138	-7.535	60.952	6.684	-0.870	
Standard Error	23.652	1.360	15.600	39.754	32.021	3.416	
t-value	-0.198	-2.308	-0.483	1.533	0.209	-0.255	
	n.s.	<u>0.03</u> (sig)	n.s.	n.s.	n.s.	n.s.	
INTRCPT1, $\pi_0$							
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA	
Coefficient	2.652	0.096	-13.919	0.427	1.230	2.642/1.382	
Standard Error	2.774	4.104	31.883	1.033	3.082	4.602/3.675	
t-value	0.956	0.023	-0.437	0.413	0.399	0.574/0.376	
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	
INDEX, $\pi_1$							
	RACE	AGE	MBRANCH	PSYCHMED	MOODANXD	ESS	
Coefficient	0.205	0.018	0.188	-0.404	-0.215	0.055	
Standard Error	0.402	0.026	0.265	0.719	0.546	0.057	
t-value	0.510	0.688	0.708	-0.562	-0.393	0.968	
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	
INDEX, $\pi_1$							
	GAD7	ISI	PTSDDX	PCL	PHQ9	PSQI/PSQIA	
Coefficient	-0.038	-0.054	-0.255	-0.012	-0.044	-0.140/-0.02	
Standard Error	0.048	0.069	0.545	0.018	0.052	0.072/0.063	
t-value	-0.788	-0.779	-0.469	-0.687	-0.851	-1.953/-0.35	
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	

Total sleep time (TST) as outcome:

## **BIBLIOGRAPHY**

- AASM. (2005). The International Classification of Sleep Disorders: Diagnostic and Coding Manual. Neurology. doi: 10.1212/WNL.41.1.160
- Abraham, C., & Michie, S. (2008). A taxonomy of behavior change techniques used in interventions. *Health Psychology : Official Journal of the Division of Health Psychology, American Psychological Association*, 27(3), 379–387. doi: 10.1037/0278-6133.27.3.379
- Ajzen, I. (1991). The theory of planned behavior. Orgnizational Behavior and Human Decision Processes, 50, 179–211. doi: 10.1016/0749-5978(91)90020-T
- Ajzen, I. (2015). Theory of Planned Behavior Diagram. Retrieved March 20, 2015, from http://people.umass.edu/aizen/tpb.diag.html
- Ajzen, I., & Madden, T. J. (1985). Ajzen\_Madden.Goal directed.JESP 1986.pdf. Journal of Experimental Social Psychology, 22, 453–474.
- Ancoli-Israel, S., & Roth, T. (1999). Characteristics of insomnia in the United States: results of the 1991 National Sleep Foundation Survey. I. Sleep, 22 Suppl 2, S347-53.
- Asberg, M., Cronholm, B., Sjöqvist, F., & Tuck, D. (1970). Correlation of subjective side effects with plasma concentrations of nortriptyline. *British Medical Journal*, 4(5726), 18–21.
- Bandura, A. (1986). Social foundations of thought and action: A social cognitive theory.
- Bandura, A. (1997). Self-efficacy: The Exercise of Control. W. H. Freeman. New York, New York, USA. doi: 10.1002/9780470479216.corpsy0836
- Bandura, A. (1999). Social cognitive theory of self-regulation. Organizational Behavior and Human Decision Processes, 50, 248–287. doi: 10.1016/0749-5978(91)90022-L
- Bandura, A. (2001). S OCIAL C OGNITIVE T HEORY: An Agentic Perspective. Annual Review of Psychology, 52(1), 1–26. doi: 10.1146/annurev.psych.52.1.1
- Bangor, A., Kortum, P., & Miller, J. (2009). Determining what individual SUS scores mean: Adding an adjective rating scale. *Journal of Usability Studies*, 4(3), 114–123. doi: 66.39.39.113

- Bangor, A., Kortum, P. T., & Miller, J. T. (2008). An Empirical Evaluation of the System Usability Scale. *International Journal of Human-Computer Interaction*, 24(6), 574–594. doi: 10.1080/10447310802205776
- Barlas, F. M., Higgins, W. B., Pflieger, J. C., & Diecker, K. (2013). 2011 Health related behaviors survey of active duty military personnel.
- Bastien, C. H., Vallières, A., & Morin, C. M. (2001). Validation of the insomnia severity index as an outcome measure for insomnia research. *Sleep Medicine*, 2(4), 297–307. doi: 10.1016/S1389-9457(00)00065-4
- Beck, A. T. (1964). Thinking and depression: II. Theory and therapy. Archives of General *Psychiatry*, 10(6), 561–571.
- Becker, M. H., Drachman, R. H., & Kirscht, J. P. (1974). A new approach to explaining sick-role behavior in low-income populations. *American Journal of Public Health*, 64, 205–216. doi: 10.2105/AJPH.64.3.205
- Belanger, L., Savard, J., & Morin, C. M. (2006). Clinical management of insomnia using cognitive therapy. *Behavioral Sleep Medicine*, 4(3), 179–202.
- Blake-Wilson, S., et. al. (2006). [ECC] Elliptic Curve Cryptography (ECC) Cipher Suites for Transport Layer Security (TLS) [RFC 4492]. *RFC* 4492, 1–36.
- Blake-Wilson, S., Nystrom, M., Hopwood, D., Mikkelsen, J., & Wright, T. (2003). Transport Layer Security (TLS) Extensions. *RFC 3546*.
- Blake, D. D., Weathers, F. W., Nagy, L. M., Kaloupek, D. G., Gusman, F. D., Charney, D. S., & Keane, T. M. (1995). The development of a clinician-administered PTSD scale. *Journal of Traumatic Stress*, 8(1), 75–90.
- Bootzin, R. R. (1973). Stimulus control treatment for insomnia. In APA 80th Annual Convention, Honolulu, HI, September 2-8, 1972.
- Borbély, A. A. (1982). A two process model of sleep regulation. *Human Neurobiology*, 1(3), 195–204. doi: 10.1111/jsr.12371
- Box, G. E. P. (1979). Robustness in the strategy of scientific model building. *Robustness in Statistics*, 1, 201–236.
- Bramoweth, A. D., & Germain, A. (2013). Deployment-related insomnia in military personnel and veterans topical collection on sleep disorders. *Current Psychiatry Reports*, 15(10).
- Brooke, J. (1996). SUS-A quick and dirty usability scale. Usability Evaluation in Industry, 189, 194. doi: 10.1002/hbm.20701
- Burnay, E., Cruz-Correia, R., Jacinto, T., Sousa, A. S., & Fonseca, J. (2013). Challenges of a mobile application for asthma and allergic rhinitis patient enablement-interface and

synchronization. *Telemedicine Journal and E-Health : The Official Journal of the American Telemedicine Association*, 19(1), 13–8. doi: 10.1089/tmj.2012.0020

- Busner, J., & Targum, S. D. (2007). The clinical global impressions scale: applying a research tool in clinical practice. *Psychiatry (Edgmont (Pa. : Township))*, 4(7), 28–37.
- Buysse, D. J., Angst, J., Gamma, A., Ajdacic, V., Eich, D., & Rössler, W. (2008). Prevalence, course, and comorbidity of insomnia and depression in young adults. *Sleep*, *31*(4), 473–80.
- Buysse, D. J., Cheng, Y., Ph, D., Germain, A., Moul, D. E., Franzen, P. L., ... Monk, T. H. (2011). Night-to-Night Sleep Variability in Older Adults with and Without Chronic Insomnia. *Sleep Medicine Reviews*, 11(1), 1–16. doi: 10.1016/j.sleep.2009.02.010.Night-to-Night
- Buysse, D. J., Germain, A., Moul, D. E., Franzen, P. L., Brar, L. K., Fletcher, M. E., ... Monk, T. H. (2011). Efficacy of brief behavioral treatment for chronic insomnia in older adults. *Archives of Internal Medicine*, 171(10), 887–95. doi: 10.1001/archinternmed.2010.535
- Buysse, D. J., Reynolds, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Research*, 28(2), 193–213.
- Cappuccio, F. P., Stranges, S., Kandala, N.-B., Miller, M. a, Taggart, F. M., Kumari, M., ... Marmot, M. G. (2007). Gender-specific associations of short sleep duration with prevalent and incident hypertension: the Whitehall II Study. *Hypertension*, 50(4), 693–700. doi: 10.1161/HYPERTENSIONAHA.107.095471
- Cartwright-Hatton, S., Roberts, C., Chitsabesan, P., Fothergill, C., & Harrington, R. (2004). Systematic review of the efficacy of cognitive behaviour therapies for childhood and adolescent anxiety disorders. *The British Journal of Clinical Psychology*, 43, 421–436. doi: 10.1348/0144665042388928
- Carver, C. S., & Scheier, M. F. (1982). Control theory: a useful conceptual framework for personality-social, clinical, and health psychology. *Psychological Bulletin*, 92(1), 111–135. doi: 10.1037/0033-2909.92.1.111
- Chakravorty, S., Grandner, M. a., Mavandadi, S., Perlis, M. L., Sturgis, E. B., & Oslin, D. W. (2014). Suicidal ideation in Veterans misusing alcohol: Relationships with insomnia symptoms and sleep duration. *Addictive Behaviors*, 39(2), 399–405. doi: 10.1016/j.addbeh.2013.09.022
- Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., ... Shapiro, C. M. (2008). STOP Questionnaire: A Tool to Screen Patients for Obstructive Sleep Apnea. *Anesthesiology*, 108(5), 812–821 10.1097/ALN.0b013e31816d83e4.
- CMS. (2008). Selecting a Develoment Approach. Retrieved January 20, 2015, from https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/XLC/Downloads/SelectingDevelopmentApproach.pdf

- Cohen, S., Doyle, W. J., Alper, C. M., Janicki-Deverts, D., & Turner, R. B. (2009). Sleep habits and susceptibility to the common cold. *Archives of Internal Medicine*, *169*(1), 62–7. doi: 10.1001/archinternmed.2008.505
- Collins, L. M., Murphy, S. a, & Bierman, K. L. (2004). A conceptual framework for adaptive preventive interventions. *Prevention Science : The Official Journal of the Society for Prevention Research*, 5(3), 185–96.
- comScore. (2016). comScore Reports February 2016 U.S. Smartphone Subscriber Market Share
   comScore, Inc. Retrieved from http://www.comscore.com/Insights/Rankings/comScore-Reports-February-2016-US-Smartphone-Subscriber-Market-Share
- Consolvo, S., & McDonald, D. (2008). Activity sensing in the wild: a field trial of ubifit garden. *Proceedings of the ...*, 1797–1806.
- Daemen, J., Rijmen, V., & Leuven, K. U. (1999). AES Proposal : Rijndael. Complexity, 1-45.
- Davis, F. D. (1993). User acceptance of information technology: system characteristics, user perceptions and behavioral impacts. *International Journal of Man-Machine Studies*, 38(3), 475–487. doi: 10.1006/imms.1993.1022
- De Joode, E. A., Van Heugten, C. M., Verhey, F. R. J., & Van Boxtel, M. P. J. (2013). Effectiveness of an electronic cognitive aid in patients with acquired brain injury: a multicentre randomised parallel-group study. *Neuropsychological Rehabilitation*, 23(1), 133–156. doi: 10.1080/09602011.2012.726632
- Dobson, K. s., & Dozois, D. J. A. (2010). Historical and Philosophical Bases of the Cognitive-Behavioral Therapies. In *Handbook of Cognitive-Behavioral Therapies*.
- Donker, T., Petrie, K., Proudfoot, J., Clarke, J., Birch, M.-R., & Christensen, H. (2013). Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review. *Journal of Medical Internet Research*, 15(11). doi: 10.2196/jmir.2791
- Dunbar, M. S., Scharf, D., Kirchner, T., & Shiffman, S. (2010). Do smokers crave cigarettes in some smoking situations more than others? Situational correlates of craving when smoking. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, 12(3), 226–234. doi: 10.1093/ntr/ntp198
- Edinger, J. D., Wohlgemuth, W. K., Radtke, R. A., Marsh, G. R., & Quillian, R. E. (2001). Cognitive Behavioral Therapy for Treatment of Chronic Primary Insomnia. *JAMA*, 285(14), 1856. doi: 10.1001/jama.285.14.1856
- eMarketer. (2015). Wearable Usage Will Grow by Nearly 60% This Year eMarketer. Retrieved August 12, 2016, from http://www.emarketer.com/Article/Wearable-Usage-Will-Grow-by-Nearly-60-This-Year/1013159
- Epstein, D. R., Babcock-parziale, J. L., Haynes, P. L., & Herb, C. A. (2012). Insomnia treatment acceptability and preferences of male Iraq and Afghanistan combat Veterans and their

healthcare providers. Journal of Rehabilitation Research & Development, 49(6), 867.

- Ferguson, T., Rowlands, A. V, Olds, T., & Maher, C. (2015). The validity of consumer-level, activity monitors in healthy adults worn in free-living conditions: a cross-sectional study. *The International Journal of Behavioral Nutrition and Physical Activity*, 12. doi: 10.1186/s12966-015-0201-9
- Fielding, R. T. (2000). CHAPTER 5 Representational State Transfer (REST). *Style DeKalb IL*, 76–106.
- First, M. B. et, Spitzer, R. L., Gibbon, M., & Williams, J. B. W. (2002). Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Non-patient Edition. for DSMIV.
- Fisher, J. D., & Fisher, W. A. (2002). The information-motivation-behavioral skills model. In R. J. DiClemente, R. A. Crosby, & M. C. Kegler (Eds.), *Emerging theories in health promotion practice and research: Strategies for improving public health* (pp. 40–70). John Wiley & Sons.
- Fisher, J. D., Fisher, W. a, Bryan, A. D., & Misovich, S. J. (2002). Information-Motivation-Behavioral Skills Model-Based HIV Risk Behavior Change Intervention for Inner-City High School Youth. *Health Psychology*, 21(2), 177–86. doi: 10.1037/0278-6133.21.2.177
- Fisher, J. D., Fisher, W. a, Misovich, S. J., Kimble, D. L., & Malloy, T. E. (1996). Changing AIDS risk behavior: effects of an intervention emphasizing AIDS risk reduction information, motivation, and behavioral skills in a college student population. *Health Psychology: Official Journal of the Division of Health Psychology, American Psychological Association*, 15(2), 114–123. doi: 10.1037/0278-6133.15.2.114
- Free, C., Phillips, G., Galli, L., Watson, L., Felix, L., Edwards, P., ... Haines, A. (2013). The Effectiveness of Mobile-Health Technology-Based Health Behaviour Change or Disease Management Interventions for Health Care Consumers: A Systematic Review. *PLoS Medicine*, 10(1). doi: 10.1371/journal.pmed.1001362
- Free, C., Phillips, G., Watson, L., Galli, L., Felix, L., Edwards, P., ... Haines, A. (2013). The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis. *PLoS Medicine*, 10(1). doi: 10.1371/journal.pmed.1001363
- Gatchel, R. J., & Rollings, K. H. (2008). Evidence-informed management of chronic low back pain with cognitive behavioral therapy. *The Spine Journal : Official Journal of the North American Spine Society*, 8(1), 40–4. doi: 10.1016/j.spinee.2007.10.007
- Gehrman, P. R. (2011). Sleep Hygiene. In *Behavioral treatments for sleep disorders: a comprehensive primer of behavioral sleep medicine interventions* (pp. 31–43). Boston: Academic.
- Germain, A. (2014). Sleep and Dreams as Pathways to Resilience Following Trauma. In

Abstracts of the 31th Annual Conference of the International Association for the Study of Dreams (p. 1). Berkeley.

- Germain, A., & Buysse, D. J. (2011). Brief Behavioral Treatment of Insomnia. In *Behavioral treatments for sleep disorders: a comprehensive primer of behavioral sleep medicine interventions* (pp. 143–150). Boston: Academic. doi: 10.1016/B978-0-12-381522-4.00015-8
- Germain, A., Hall, M., Krakow, B., Katherine Shear, M., & Buysse, D. J. (2005). A brief Sleep Scale for Posttraumatic Stress Disorder: Pittsburgh Sleep Quality Index Addendum for PTSD. *Journal of Anxiety Disorders*, 19(2), 233–244.
- Germain, A., Moul, D. E., Franzen, P. L., Miewald, J. M., Reynolds, C. F., Monk, T. H., & Buysse, D. J. (2006). Effects of a brief behavioral treatment for late-life insomnia: Preliminary findings. *Journal of Clinical Sleep Medicine*, 2(4), 403–406.
- Germain, A., Richardson, R., Stocker, R., Mammen, O., Hall, M., Bramoweth, A. D., ... Buysse, D. J. (2014). Behaviour Research and Therapy Treatment for insomnia in combat-exposed OEF / OIF / OND Military Veterans : Preliminary randomized controlled trial. *Behaviour Research and Therapy*, *61*, 78–88. doi: 10.1016/j.brat.2014.07.016
- Gironda, R. J., Clark, M. E., Ruff, R. L., Chait, S., Craine, M., Walker, R., & Scholten, J. (2009). Traumatic brain injury, polytrauma, and pain: challenges and treatment strategies for the polytrauma rehabilitation. *Rehabilitation Psychology*, 54(3), 247–258. doi: 10.1037/a0016906
- Goodwin, R. D., & Hasin, D. S. (2002). Sedative use and misuse in the United States. *Addiction* (*Abingdon, England*), 97(5), 555–62.
- Granvold, D. K. (1994). *Cognitive and behavioral treatment: methods and application*. Cengage Learning.
- Hall, A. K., Cole-Lewis, H., & Bernhardt, J. M. (2015). Mobile Text Messaging for Health: A Systematic Review of Reviews. *Annual Review of Public Health*, *36*, 393–415. doi: 10.1146/annurev-publhealth-031914-122855
- Hall, M. H., Muldoon, M. F., Jennings, J. R., Buysse, D. J., Flory, J. D., & Manuck, S. B. (2008). Self-reported sleep duration is associated with the metabolic syndrome in midlife adults. *Sleep*, 31(5), 635–43.
- Hallgren, K. A. (2012). Computing Inter-Rater Reliability for Observational Data: An Overview and Tutorial. *Tutorials in Quantitative Methods for Psychology*, 8(1), 23–34. doi: 10.1016/j.biotechadv.2011.08.021.Secreted
- Harvey, A. G. (2002). A cognitive model of insomnia. *Behaviour Research and Therapy*, 40(8), 869–893.
- HASLAM, B. D. R. (1982). Sleep loss, recovery sleep, and military performance. *Ergonomics*, 25(2), 163–178.

- Heron, K. E., & Smyth, J. M. (2010). Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments. *British Journal of Health Psychology*, 15(Pt 1), 1–39. doi: 10.1348/135910709X466063
- Hickson, I. (2010). The websocket api. W3C, Editor's Draft.
- Hofmann, S. G. (2011). An introduction to modern CBT: Psychological solutions to mental health problems. John Wiley & Sons.
- Hoge, C. W., Terhakopian, A., Castro, C. a, Messer, S. C., & Engel, C. C. (2007). Association of posttraumatic stress disorder with somatic symptoms, health care visits, and absenteeism among Iraq war veterans. *The American Journal of Psychiatry*, 164(1), 150–153. doi: 10.1176/appi.ajp.164.1.150
- Hollon, S. D., & Beck, A. T. (1994). Cognitive and cognitive-behavioral therapies.
- Hollon, S. D., Muñoz, R. F., Barlow, D. H., Beardslee, W. R., Bell, C. C., Bernal, G., ... Sommers, D. (2002). Psychosocial intervention development for the prevention and treatment of depression: promoting innovation and increasing access. *Biological Psychiatry*, 52(6), 610–630. doi: 10.1016/S0006-3223(02)01384-7
- Husky, M., Olié, E., Guillaume, S., Genty, C., Swendsen, J., & Courtet, P. (2014). Feasibility and validity of ecological momentary assessment in the investigation of suicide risk. *Psychiatry Research*, 220(1), 564–570. doi: 10.1016/j.psychres.2014.08.019
- IDC. (2016). Worldwide Wearables Market Increases 67.2% Amid Seasonal Retrenchment, According to IDC - prUS41284516. Retrieved October 3, 2016, from http://www.idc.com/getdoc.jsp?containerId=prUS41284516
- Insana, S. P., Hall, M., Buysse, D. J., & Germain, A. (2013). Validation of the Pittsburgh Sleep Quality Index Addendum for Posttraumatic Stress Disorder (PSQI-A) in U.S. Male Military Veterans. *Journal of Traumatic Stress*, 26(2), 192–200.
- Intille, S. S., Kukla, C., Farzanfar, R., & Bakr, W. (2003). Just-in-time technology to encourage incremental, dietary behavior change. AMIA ... Annual Symposium Proceedings / AMIA Symposium. AMIA Symposium, 42(5), 874.
- Irwin, M. R., Cole, J. C., & Nicassio, P. M. (2006). Comparative meta-analysis of behavioral interventions for insomnia and their efficacy in middle-aged adults and in older adults 55+ years of age. *Health Psychology : Official Journal of the Division of Health Psychology, American Psychological Association*, 25(1), 3–14. doi: 10.1037/0278-6133.25.1.3
- ITU. (2012). Overview of the Internet of things. Recommendation ITU-T Y.2060.
- ITU. (2016). Global ICT Developments. Retrieved from http://www.itu.int/en/ITU-D/Statistics/Pages/stat/default.aspx
- Javelot, H., Spadazzi, A., Weiner, L., Garcia, S., Gentili, C., Kosel, M., & Bertschy, G. (2014).

Telemonitoring with respect to mood disorders and information and communication technologies: overview and presentation of the PSYCHE project. *BioMed Research International*, 2014, 104658. doi: 10.1155/2014/104658

- Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep*, *14*(6), 540–545. doi: 10.1016/j.sleep.2007.08.004
- Josefsson, S. (2006). RFC 4648 The Base16, Base32, and Base64 Data Encodings. *IETF*, 1–18. doi: 10.17487/rfc4648
- Juengst, S. B., Graham, K. M., Pulantara, I. W., McCue, M., Whyte, E. M., Dicianno, B. E., ... Wagner, A. K. (2015). Pilot feasibility of an mHealth system for conducting ecological momentary assessment of mood-related symptoms following traumatic brain injury. *Brain Injury*, 29(11), 1351–61. doi: 10.3109/02699052.2015.1045031
- Keane, T. M., Fairbank, J. A., Caddell, J. M., Zimering, R. T., Taylor, K. L., & Mora, C. A. (1989). Clinical evaluation of a measure to assess combat exposure. *Psychological Assessment: A Journal of Consulting and Clinical Psychology*, 1(1), 53–55.
- Kerlinger, F. N. (1986). Foundations of behavioural research. Holt Rinehart Winston London (Vol. Hoit, Rine).
- King, A. C., Hekler, E. B., Grieco, L. a, Winter, S. J., Sheats, J. L., Buman, M. P., ... Cirimele, J. (2013). Harnessing different motivational frames via mobile phones to promote daily physical activity and reduce sedentary behavior in aging adults. *PloS One*, 8(4), e62613. doi: 10.1371/journal.pone.0062613
- Krause, J., Croft, D. P., & James, R. (2007). Social network theory in the behavioural sciences: Potential applications. *Behavioral Ecology and Sociobiology*, 62(1), 15–27. doi: 10.1007/s00265-007-0445-8
- Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2003). The Patient Health Questionnaire-2. *Medical Care*, 41(11), 1284–1292. doi: 10.1097/01.MLR.0000093487.78664.3C
- Kroenke, K., Spitzer, R., & Williams, J. (2007). The 2-item Generalized Anxiety Disorder scale had high sensitivity and specificity for detecting GAD in primary care. *Annals of Internal Medicine*, 146(October), 317–325. doi: 10.1136/ebm.12.5.149
- Kroll, A. (2000). Grey-box models: Concepts and application. *New Frontiers In Computational Intelligence and Its Applications*, 57, 42–51.
- Krystal, A. D., Erman, M., Zammit, G. K., Soubrane, C., & Roth, T. (2008). Long-term efficacy and safety of zolpidem extended-release 12.5 mg, administered 3 to 7 nights per week for 24 weeks, in patients with chronic primary insomnia: a 6-month, randomized, double-blind, placebo-controlled, parallel-group, multicenter study. *Sleep*, 31(1), 79–90.
- Kuhn, E., Weiss, B. J., Taylor, K. L., Hoffman, J. E., Ramsey, K. M., Manber, R., ... Trockel, M. (2016). CBT-I coach: A description and clinician perceptions of a mobile app for

cognitive behavioral therapy for insomnia. *Journal of Clinical Sleep Medicine*, 12(4), 597–606.

- Lei, H., Tewari, A., & Murphy, S. (2014). An Actor-Critic Contextual Bandit Algorithm for Personalized Interventions using Mobile Devices. In NIPS 2014 Workshop: Personalization: Methods and Applications (pp. 1–9).
- Lewis, C., & Mack, R. (1982). Learning to use a text processing system: Evidence from "thinking aloud" protocols. In *Proceedings of the 1982 conference on Human factors in* computing systems (pp. 387–392).
- Lewis, C., & Rieman, J. (1993). Testing The Design With Users. In *Task-centered user interface* design: A Practical Introduction.
- Lewis, J. R. (1995). IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use. *International Journal of Human-Computer Interaction*, 7(1), 57–78. doi: 10.1080/10447319509526110
- Lewis, J. R. (2006). Sample sizes for usability tests. *Interactions*, 13(6), 29.
- Livingston, W. S., Rusch, H. L., Nersesian, P. V, Baxter, T., Mysliwiec, V., & Gill, J. M. (2015). Improved Sleep in Military Personnel is Associated with Changes in the Expression of Inflammatory Genes and Improvement in Depression Symptoms. *Frontiers in Psychiatry*, 6(April), 59. doi: 10.3389/fpsyt.2015.00059
- Lockley, S. W., Skene, D. J., & Arendt, J. (1999). Comparison between subjective and actigraphic measurement of sleep and sleep rhythms. *Journal of Sleep Research*, 8(3), 175–183. doi: 10.1046/j.1365-2869.1999.00155.x
- Luxton, D. D., Kayl, R. a., & Mishkind, M. C. (2012). mHealth Data Security: The Need for HIPAA-Compliant Standardization. *Telemedicine and E-Health*, 18(4), 284–288. doi: 10.1089/tmj.2011.0180
- Maher, M. J., Rego, S. A., & Asnis, G. M. (2006). Sleep disturbances in patients with posttraumatic stress disorder: epidemiology, impact and approaches to management. CNS Drugs, (20), 567–590.
- Mahoney, M. J. (1977). Personal science: A cognitive learning therapy. Handbook of Rational-Emotive Therapy. New York: Springer.
- Maiman, L. A., & Becker, M. H. (1974). The health belief model: Origins and correlates in psychological theory.
- Marsland, S. (2009). Using habituation in machine learning. *Neurobiology of Learning and Memory*, 92(2), 260–266. doi: 10.1016/j.nlm.2008.05.014
- Martin Bland, J., & Altman, D. (1986). STATISTICAL METHODS FOR ASSESSING AGREEMENT BETWEEN TWO METHODS OF CLINICAL MEASUREMENT. *The*

Lancet, 327(8476), 307-310. doi: 10.1016/S0140-6736(86)90837-8

- Mccall, C., & Mccall, W. V. (2012). Comparison of actigraphy with polysomnography and sleep logs in depressed insomniacs. *Journal of Sleep Research*, 21(1), 122–127. doi: 10.1111/j.1365-2869.2011.00917.x
- McEachan, R. R. C., Conner, M., Taylor, N. J., & Lawton, R. J. (2011). Prospective prediction of health-related behaviours with the Theory of Planned Behaviour: a meta-analysis. *Health Psychology Review*, 5, 97–144. doi: 10.1080/17437199.2010.521684
- Mcmahon, S. B., Koltzenburg, M., Tracey, I., & Turk, D. C. (2013). The Cognitive Behavioral Approach to Pain Management. In *Wall and Melzack's textbook of pain* (pp. 592–602).
- Microsoft. (2000). Usability in Software Design. Retrieved August 12, 2016, from https://msdn.microsoft.com/en-us/library/ms997577.aspx?f=255&MSPPError=-2147217396
- Microsoft. (2016). Chapter 5: Layered Application Guidelines. Retrieved August 15, 2016, from https://msdn.microsoft.com/en-us/library/ee658109.aspx
- Monk, T. H., Reynolds, C. F., Kupfer, D. J., Buysse, D. J., Coble, P. A., Hayes, A. J., ... Ritenour, A. M. (1994). The Pittsburgh Sleep Diary. *Journal of Sleep Research*, 3(2), 111– 120. doi: jsr003002111 [pii]
- Morin, C. M., Belleville, G., Bélanger, L., & Ivers, H. (2011). The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep*, 34(5), 601–8.
- Morin, C. M., Culbert, J. P., & Schwartz, S. M. (1994). Nonpharmacological interventions for insomnia: A meta-analysis of treatment efficacy. *American Journal of Psychiatry*, 151(8), 1172–1180.
- Morin, C. M., Gaulier, B., Barry, T., & Kowatch, R. A. (1992). Patients' acceptance of psychological and pharmacological therapies for insomnia. *Sleep*, *15*(4), 302–5.
- Mysliwiec, V., & Roth, B. (2013, February). Pharmacotherapy refractory insomnia in soldiers with traumatic brain injury. *Chest*. United States. doi: 10.1378/chest.12-2269
- Navarro-Barrientos, J.-E., Rivera, D. E., & Collins, L. M. (2011). A dynamical model for describing behavioural interventions for weight loss and body composition change. *Mathematical and Computer Modelling of Dynamical Systems*, 17(2), 183–203. doi: 10.1080/13873954.2010.520409
- Nielsen, J. (1994). Usability engineering. Elsevier.
- Nielsen, J., & Landauer, T. K. (1993). A mathematical model of the finding of usability problems. *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems CHI '93*, 206–213. doi: 10.1145/169059.169166

- NIH. (2005). NIH State-of-the-Science Conference Statement on manifestations and management of chronic insomnia in adults. *Sleep*, 22(2), 1–30.
- Ocasio-Tascón, M. E., Alicea-Colón, E., Torres-Palacios, A., & Rodríguez-Cintrón, W. (2006). The veteran population: One at high risk for sleep-disordered breathing. *Sleep and Breathing*, *10*(2), 70–75. doi: 10.1007/s11325-005-0043-9
- Ohayon, M. M. (2002). Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Medicine Reviews*, 6(2), 97–111.
- Osborn, C. Y., & Egede, L. E. (2010). Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC). *Patient Education and Counseling*, 79(1), 49–54.
- Pbert, L. (2013). The handbook of health behavior change. Springer Publishing Company.
- Peres, S. (2013). What are JITAIs? Retrieved January 2, 2015, from https://community.isr.umich.edu/public/Portals/11/Docs/201308\_session1.pdf
- Pramana, G., & Parmanto, B. (2014). The SmartCAT: An m-Health Platform for Ecological Momentary Intervention in Child Anxiety Treatment. *Telemedicine and E-Health*.
- Rabbi, M., Aung, M. H., Zhang, M., & Choudhury, T. (2015). MyBehavior: automatic personalized health feedback from user behaviors and preferences using smartphones. *Ubicomp* '15, September 7–11, 2015, Osaka, Japan. doi: 10.1145/2750858.2805840
- Rankin, C. H., Abrams, T., Barry, R. J., Bhatnagar, S., Clayton, D. F., Colombo, J., ... Thompson, R. F. (2009). Habituation revisited: An updated and revised description of the behavioral characteristics of habituation. *Neurobiology of Learning and Memory*, 92(2), 135–138.
- Raskind, M. a., Peskind, E. R., Hoff, D. J., Hart, K. L., Holmes, H. a., Warren, D., ... others. (2007). A Parallel Group Placebo Controlled Study of Prazosin for Trauma Nightmares and Sleep Disturbance in Combat Veterans with Post-Traumatic Stress Disorder. *Biological Psychiatry*, 61(8), 928–934. doi: 10.1016/j.biopsych.2006.06.032
- Raudenbush, S. W., & Bryk, A. S. (1992). *Hierarchical linear models: Applications and data analysis methods* (Vol. 1). Sage.
- Riley, W. T., Cesar, a., & Rivera, D. E. (2014). The importance of behavior theory in control system modeling of physical activity sensor data. 2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 6880–6883. doi: 10.1109/EMBC.2014.6945209
- Riley, W. T., Rivera, D. E., Atienza, A. A., Nilsen, W., Allison, S. M., & Mermelstein, R. (2011). Health behavior models in the age of mobile interventions: are our theories up to the task? *Translational Behavioral Medicine*, 1(1), 53–71. doi: 10.1007/s13142-011-0021-7

- Ritterband, L. M., Thorndike, F. P., Cox, D. J., Kovatchev, B. P., & Gonder-Frederick, L. A. (2009). A behavior change model for internet interventions. *Annals of Behavioral Medicine : A Publication of the Society of Behavioral Medicine*, 38(1), 18–27. doi: 10.1007/s12160-009-9133-4
- Roth, T. (2007). Insomnia: definition, prevalence, etiology, and consequences. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine*, 3(5 Suppl), S7-10.
- Royce, W. W. (1970). Managing the development of large software systems. In *proceedings of IEEE WESCON* (Vol. 26).
- Rupp, T. L., Wesensten, N. J., & Balkin, T. J. (2010). Sleep history affects task acquisition during subsequent sleep restriction and recovery. *Journal of Sleep Research*, 19(2), 289– 297.
- Rutledge, C. M., Guardia, A. C. La, & Bluestein, D. (2013). Predictors of self-efficacy for sleep in primary care. *Journal of Clinical Nursing*, 22(9–10), 1254–1261. doi: 10.1111/jocn.12005
- Shiffman, S., Stone, A. A., & Hufford, M. R. (2008). Ecological momentary assessment. *Annual Review of Clinical Psychology*, *4*, 1–32.
- Shochat, T., Umphress, J., Israel, A. G., & Ancoli-Israel, S. (1999). Insomnia in primary care patients. *Sleep: Journal of Sleep Research & Sleep Medicine*.
- Sih, A., Hanser, S. F., & McHugh, K. A. (2009). Social network theory: New insights and issues for behavioral ecologists. *Behavioral Ecology and Sociobiology*, 63(7), 975–988. doi: 10.1007/s00265-009-0725-6
- Simon, G. E., & VonKorff, M. (1997). Prevalence, burden, and treatment of insomnia in primary care. *Am J Psychiatry*, *154*, 1417–1423.
- Skinner, B. F. (1953). Operant behavior. *Science and Human Behavior*, 59–90. doi: 10.3390/ijerph8093528
- Smith, M. T., Perlis, M. L., Park, A., Smith, M. S., Pennington, J., Giles, D. E., & Buysse, D. J. (2002). Comparative meta-analysis of pharmacotherapy and behavior therapy for persistent insomnia. *The American Journal of Psychiatry*, 159(1), 5–11.
- Spielman, A. J., Saskin, P., & Thorpy, M. J. (1987). Treatment of chronic insomnia by restriction of time in bed. *Sleep: Journal of Sleep Research & Sleep Medicine*.
- Spruijt-Metz, D., & Nilsen, W. (2014). Dynamic models of behavior for just-in-time adaptive interventions. *IEEE Pervasive Computing*, 13, 13–17. doi: 10.1109/MPRV.2014.46
- Starace, F., Massa, A., Amico, K. R., & Fisher, J. D. (2006). Adherence to antiretroviral therapy: an empirical test of the information-motivation-behavioral skills model. *Health*

*Psychology*: Official Journal of the Division of Health Psychology, American Psychological Association, 25(2), 153–162.

- Stone, A. A. (2007). Historical Roots and Rationale of Ecological Momentary Assessment (EMA). In *The Science of Real-time Data Capture* (pp. 3–10).
- Stone, A. A., Shiffman, S., Atienza, A. A., & Nebeling, L. (2007). Historical Roots ad Rationale of Ecoogical Mementary Assessment (EMA). In *The Science of Real-time Data Capture* (pp. 3–10). Oxford, England: Oxford University Press.
- The Army Medical Department. (2014). Army Medicine's Performance Triad. Retrieved October 18, 2015, from http://armymedicine.mil/Pages/performance-triad.aspx
- Trockel, M., Karlin, B. E., Taylor, C. B., & Manber, R. (2014). Cognitive behavioral therapy for insomnia with veterans: evaluation of effectiveness and correlates of treatment outcomes. *Behaviour Research and Therapy*, 53, 41–46.
- Troxel, Wendy M., Regina A. Shih, Eric R. Pedersen, Lily Geyer, Michael P. Fisher, Beth Ann Griffin, Ann C. Haas, J. K. and P. S. S. (2015). *Sleep in the Military: Promoting Healthy Sleep Among U.S. Servicemembers*. RAND Corporation.
- Troxel, W. M., Germain, A., & Buysse, D. J. (2012). Clinical management of insomnia with brief behavioral treatment (BBTI). *Behavioral Sleep Medicine*, 10(4), 266–279.
- Turk, D. (2003). Cognitive-behavioral approach to the treatment of chronic pain patients. *Regional Anesthesia and Pain Medicine*, 28(6), 573–579. doi: 10.1016/S1098-7339(03)00392-4
- Walz, L. C., Nauta, M. H., & Aan Het Rot, M. (2014). Experience sampling and ecological momentary assessment for studying the daily lives of patients with anxiety disorders: A systematic review. *Journal of Anxiety Disorders*, 28(8), 925–937. doi: 10.1016/j.janxdis.2014.09.022
- Watzlaf, V. J. M., Moeini, S., Matusow, L., & Firouzan, P. (2011). VOIP for Telerehabilitation: A Risk Analysis for Privacy, Security and HIPAA Compliance: Part II. *International Journal of Telerehabilitation*, 3(1), 3–10. doi: 10.5195/ijt.2011.6070
- Weathers, F.W., Litz, B.T., Huska, J.A., & Keane, T. M. (1994). PTSD Checklist—Civilian version. Boston: National Center for PTSD, Behavioral Science Division. doi: 10.1037/t02622-000
- Webb, T. L., Joseph, J., Yardley, L., & Michie, S. (2010). Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *Journal of Medical Internet Research*, 12(1), e4. doi: 10.2196/jmir.1376
- Wilkowska, W., & Ziefle, M. (2011). Perception of privacy and security for acceptance of Ehealth technologies: Exploratory analysis for diverse user groups. In *International*

*Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth) and Workshops* (pp. 593–600).

- Witkiewitz, K., Desai, S. a, Bowen, S., Leigh, B. C., Kirouac, M., & Larimer, M. E. (2014). Development and evaluation of a mobile intervention for heavy drinking and smoking among college students. *Psychology of Addictive Behaviors : Journal of the Society of Psychologists in Addictive Behaviors*, 28(3), 639–50. doi: 10.1037/a0034747
- Yalcin, I., & Bump, R. C. (2003). Validation of two global impression questionnaires for incontinence. American Journal of Obstetrics and Gynecology, 189(1), 98–101. doi: 10.1067/mob.2003.379
- Yu, D. X., Parmanto, B., Dicianno, B. E., & Pramana, G. (2015). Accessibility of mHealth Self-Care Apps for Individuals with Spina Bifida. *Perspectives in Health Information Management / AHIMA, American Health Information Management Association*, 12(Spring), 1h.
- Zhuang, Y., Baldwin, J., Antuña, L., Yazir, Y. O., Ganti, S., & Coady, Y. (2013). Tradeoffs in cross platform solutions for mobile assistive technology. *IEEE Pacific RIM Conference on Communications, Computers, and Signal Processing - Proceedings*, 330–335. doi: 10.1109/PACRIM.2013.6625498
- AASM. (2005). The International Classification of Sleep Disorders: Diagnostic and Coding Manual. Neurology. doi: 10.1212/WNL.41.1.160
- Abraham, C., & Michie, S. (2008). A taxonomy of behavior change techniques used in interventions. *Health Psychology : Official Journal of the Division of Health Psychology, American Psychological Association*, 27(3), 379–387. doi: 10.1037/0278-6133.27.3.379
- Ajzen, I. (1991). The theory of planned behavior. Orgnizational Behavior and Human Decision Processes, 50, 179–211. doi: 10.1016/0749-5978(91)90020-T
- Ajzen, I. (2015). Theory of Planned Behavior Diagram. Retrieved March 20, 2015, from http://people.umass.edu/aizen/tpb.diag.html
- Ajzen, I., & Madden, T. J. (1985). Ajzen\_Madden.Goal directed.JESP 1986.pdf. Journal of Experimental Social Psychology, 22, 453–474.
- Ancoli-Israel, S., & Roth, T. (1999). Characteristics of insomnia in the United States: results of the 1991 National Sleep Foundation Survey. I. Sleep, 22 Suppl 2, S347-53.
- Asberg, M., Cronholm, B., Sjöqvist, F., & Tuck, D. (1970). Correlation of subjective side effects with plasma concentrations of nortriptyline. *British Medical Journal*, 4(5726), 18–21.
- Bandura, A. (1986). Social foundations of thought and action: A social cognitive theory.
- Bandura, A. (1997). Self-efficacy: The Exercise of Control. W. H. Freeman. New York, New York, USA. doi: 10.1002/9780470479216.corpsy0836

- Bandura, A. (1999). Social cognitive theory of self-regulation. Organizational Behavior and Human Decision Processes, 50, 248–287. doi: 10.1016/0749-5978(91)90022-L
- Bandura, A. (2001). S OCIAL C OGNITIVE T HEORY: An Agentic Perspective. Annual Review of Psychology, 52(1), 1–26. doi: 10.1146/annurev.psych.52.1.1
- Bangor, A., Kortum, P., & Miller, J. (2009). Determining what individual SUS scores mean: Adding an adjective rating scale. *Journal of Usability Studies*, 4(3), 114–123. doi: 66.39.39.113
- Bangor, A., Kortum, P. T., & Miller, J. T. (2008). An Empirical Evaluation of the System Usability Scale. *International Journal of Human-Computer Interaction*, 24(6), 574–594. doi: 10.1080/10447310802205776
- Barlas, F. M., Higgins, W. B., Pflieger, J. C., & Diecker, K. (2013). 2011 Health related behaviors survey of active duty military personnel.
- Bastien, C. H., Vallières, A., & Morin, C. M. (2001). Validation of the insomnia severity index as an outcome measure for insomnia research. *Sleep Medicine*, 2(4), 297–307. doi: 10.1016/S1389-9457(00)00065-4
- Beck, A. T. (1964). Thinking and depression: II. Theory and therapy. Archives of General *Psychiatry*, 10(6), 561–571.
- Becker, M. H., Drachman, R. H., & Kirscht, J. P. (1974). A new approach to explaining sick-role behavior in low-income populations. *American Journal of Public Health*, 64, 205–216. doi: 10.2105/AJPH.64.3.205
- Belanger, L., Savard, J., & Morin, C. M. (2006). Clinical management of insomnia using cognitive therapy. *Behavioral Sleep Medicine*, 4(3), 179–202.
- Blake-Wilson, S., et. al. (2006). [ECC] Elliptic Curve Cryptography (ECC) Cipher Suites for Transport Layer Security (TLS) [RFC 4492]. *RFC* 4492, 1–36.
- Blake-Wilson, S., Nystrom, M., Hopwood, D., Mikkelsen, J., & Wright, T. (2003). Transport Layer Security (TLS) Extensions. *RFC 3546*.
- Blake, D. D., Weathers, F. W., Nagy, L. M., Kaloupek, D. G., Gusman, F. D., Charney, D. S., & Keane, T. M. (1995). The development of a clinician-administered PTSD scale. *Journal of Traumatic Stress*, 8(1), 75–90.
- Bootzin, R. R. (1973). Stimulus control treatment for insomnia. In APA 80th Annual Convention, Honolulu, HI, September 2-8, 1972.
- Borbély, A. A. (1982). A two process model of sleep regulation. *Human Neurobiology*, 1(3), 195–204. doi: 10.1111/jsr.12371
- Box, G. E. P. (1979). Robustness in the strategy of scientific model building. Robustness in

*Statistics*, *1*, 201–236.

- Bramoweth, A. D., & Germain, A. (2013). Deployment-related insomnia in military personnel and veterans topical collection on sleep disorders. *Current Psychiatry Reports*, 15(10).
- Brooke, J. (1996). SUS-A quick and dirty usability scale. Usability Evaluation in Industry, 189, 194. doi: 10.1002/hbm.20701
- Burnay, E., Cruz-Correia, R., Jacinto, T., Sousa, A. S., & Fonseca, J. (2013). Challenges of a mobile application for asthma and allergic rhinitis patient enablement-interface and synchronization. *Telemedicine Journal and E-Health : The Official Journal of the American Telemedicine Association*, 19(1), 13–8. doi: 10.1089/tmj.2012.0020
- Busner, J., & Targum, S. D. (2007). The clinical global impressions scale: applying a research tool in clinical practice. *Psychiatry (Edgmont (Pa. : Township))*, 4(7), 28–37.
- Buysse, D. J., Angst, J., Gamma, A., Ajdacic, V., Eich, D., & Rössler, W. (2008). Prevalence, course, and comorbidity of insomnia and depression in young adults. *Sleep*, *31*(4), 473–80.
- Buysse, D. J., Cheng, Y., Ph, D., Germain, A., Moul, D. E., Franzen, P. L., ... Monk, T. H. (2011). Night-to-Night Sleep Variability in Older Adults with and Without Chronic Insomnia. *Sleep Medicine Reviews*, 11(1), 1–16. doi: 10.1016/j.sleep.2009.02.010.Night-to-Night
- Buysse, D. J., Germain, A., Moul, D. E., Franzen, P. L., Brar, L. K., Fletcher, M. E., ... Monk, T. H. (2011). Efficacy of brief behavioral treatment for chronic insomnia in older adults. *Archives of Internal Medicine*, 171(10), 887–95. doi: 10.1001/archinternmed.2010.535
- Buysse, D. J., Reynolds, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Research*, 28(2), 193–213.
- Cappuccio, F. P., Stranges, S., Kandala, N.-B., Miller, M. a, Taggart, F. M., Kumari, M., ... Marmot, M. G. (2007). Gender-specific associations of short sleep duration with prevalent and incident hypertension: the Whitehall II Study. *Hypertension*, 50(4), 693–700. doi: 10.1161/HYPERTENSIONAHA.107.095471
- Cartwright-Hatton, S., Roberts, C., Chitsabesan, P., Fothergill, C., & Harrington, R. (2004). Systematic review of the efficacy of cognitive behaviour therapies for childhood and adolescent anxiety disorders. *The British Journal of Clinical Psychology*, 43, 421–436. doi: 10.1348/0144665042388928
- Carver, C. S., & Scheier, M. F. (1982). Control theory: a useful conceptual framework for personality-social, clinical, and health psychology. *Psychological Bulletin*, 92(1), 111–135. doi: 10.1037/0033-2909.92.1.111
- Chakravorty, S., Grandner, M. a., Mavandadi, S., Perlis, M. L., Sturgis, E. B., & Oslin, D. W. (2014). Suicidal ideation in Veterans misusing alcohol: Relationships with insomnia

symptoms and sleep duration. *Addictive Behaviors*, 39(2), 399–405. doi: 10.1016/j.addbeh.2013.09.022

- Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., ... Shapiro, C. M. (2008). STOP Questionnaire: A Tool to Screen Patients for Obstructive Sleep Apnea. *Anesthesiology*, 108(5), 812–821 10.1097/ALN.0b013e31816d83e4.
- CMS. (2008). Selecting a Develoment Approach. Retrieved January 20, 2015, from https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/XLC/Downloads/SelectingDevelopmentApproach.pdf
- Cohen, S., Doyle, W. J., Alper, C. M., Janicki-Deverts, D., & Turner, R. B. (2009). Sleep habits and susceptibility to the common cold. *Archives of Internal Medicine*, *169*(1), 62–7. doi: 10.1001/archinternmed.2008.505
- Collins, L. M., Murphy, S. a, & Bierman, K. L. (2004). A conceptual framework for adaptive preventive interventions. *Prevention Science : The Official Journal of the Society for Prevention Research*, 5(3), 185–96.
- comScore. (2016). comScore Reports February 2016 U.S. Smartphone Subscriber Market Share
   comScore, Inc. Retrieved from http://www.comscore.com/Insights/Rankings/comScore-Reports-February-2016-US-Smartphone-Subscriber-Market-Share
- Consolvo, S., & McDonald, D. (2008). Activity sensing in the wild: a field trial of ubifit garden. *Proceedings of the ...*, 1797–1806.
- Daemen, J., Rijmen, V., & Leuven, K. U. (1999). AES Proposal : Rijndael. Complexity, 1-45.
- Davis, F. D. (1993). User acceptance of information technology: system characteristics, user perceptions and behavioral impacts. *International Journal of Man-Machine Studies*, 38(3), 475–487. doi: 10.1006/imms.1993.1022
- De Joode, E. A., Van Heugten, C. M., Verhey, F. R. J., & Van Boxtel, M. P. J. (2013). Effectiveness of an electronic cognitive aid in patients with acquired brain injury: a multicentre randomised parallel-group study. *Neuropsychological Rehabilitation*, 23(1), 133–156. doi: 10.1080/09602011.2012.726632
- Dobson, K. s., & Dozois, D. J. A. (2010). Historical and Philosophical Bases of the Cognitive-Behavioral Therapies. In *Handbook of Cognitive-Behavioral Therapies*.
- Donker, T., Petrie, K., Proudfoot, J., Clarke, J., Birch, M.-R., & Christensen, H. (2013). Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review. *Journal of Medical Internet Research*, 15(11). doi: 10.2196/jmir.2791
- Dunbar, M. S., Scharf, D., Kirchner, T., & Shiffman, S. (2010). Do smokers crave cigarettes in some smoking situations more than others? Situational correlates of craving when smoking. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, 12(3), 226–234. doi: 10.1093/ntr/ntp198

- Edinger, J. D., Wohlgemuth, W. K., Radtke, R. A., Marsh, G. R., & Quillian, R. E. (2001). Cognitive Behavioral Therapy for Treatment of Chronic Primary Insomnia. *JAMA*, 285(14), 1856. doi: 10.1001/jama.285.14.1856
- eMarketer. (2015). Wearable Usage Will Grow by Nearly 60% This Year eMarketer. Retrieved August 12, 2016, from http://www.emarketer.com/Article/Wearable-Usage-Will-Grow-by-Nearly-60-This-Year/1013159
- Epstein, D. R., Babcock-parziale, J. L., Haynes, P. L., & Herb, C. A. (2012). Insomnia treatment acceptability and preferences of male Iraq and Afghanistan combat Veterans and their healthcare providers. *Journal of Rehabilitation Research & Development*, *49*(6), 867.
- Ferguson, T., Rowlands, A. V, Olds, T., & Maher, C. (2015). The validity of consumer-level, activity monitors in healthy adults worn in free-living conditions: a cross-sectional study. *The International Journal of Behavioral Nutrition and Physical Activity*, 12. doi: 10.1186/s12966-015-0201-9
- Fielding, R. T. (2000). CHAPTER 5 Representational State Transfer (REST). *Style DeKalb IL*, 76–106.
- First, M. B. et, Spitzer, R. L., Gibbon, M., & Williams, J. B. W. (2002). Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Non-patient Edition. for DSMIV.
- Fisher, J. D., & Fisher, W. A. (2002). The information-motivation-behavioral skills model. In R. J. DiClemente, R. A. Crosby, & M. C. Kegler (Eds.), *Emerging theories in health promotion practice and research: Strategies for improving public health* (pp. 40–70). John Wiley & Sons.
- Fisher, J. D., Fisher, W. a, Bryan, A. D., & Misovich, S. J. (2002). Information-Motivation-Behavioral Skills Model-Based HIV Risk Behavior Change Intervention for Inner-City High School Youth. *Health Psychology*, 21(2), 177–86. doi: 10.1037/0278-6133.21.2.177
- Fisher, J. D., Fisher, W. a, Misovich, S. J., Kimble, D. L., & Malloy, T. E. (1996). Changing AIDS risk behavior: effects of an intervention emphasizing AIDS risk reduction information, motivation, and behavioral skills in a college student population. *Health Psychology : Official Journal of the Division of Health Psychology, American Psychological Association*, 15(2), 114–123. doi: 10.1037/0278-6133.15.2.114
- Free, C., Phillips, G., Galli, L., Watson, L., Felix, L., Edwards, P., ... Haines, A. (2013). The Effectiveness of Mobile-Health Technology-Based Health Behaviour Change or Disease Management Interventions for Health Care Consumers: A Systematic Review. *PLoS Medicine*, 10(1). doi: 10.1371/journal.pmed.1001362
- Free, C., Phillips, G., Watson, L., Galli, L., Felix, L., Edwards, P., ... Haines, A. (2013). The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis. *PLoS Medicine*, 10(1). doi: 10.1371/journal.pmed.1001363

- Gatchel, R. J., & Rollings, K. H. (2008). Evidence-informed management of chronic low back pain with cognitive behavioral therapy. *The Spine Journal : Official Journal of the North American Spine Society*, 8(1), 40–4. doi: 10.1016/j.spinee.2007.10.007
- Gehrman, P. R. (2011). Sleep Hygiene. In *Behavioral treatments for sleep disorders: a comprehensive primer of behavioral sleep medicine interventions* (pp. 31–43). Boston: Academic.
- Germain, A. (2014). Sleep and Dreams as Pathways to Resilience Following Trauma. In *Abstracts of the 31th Annual Conference of the International Association for the Study of Dreams* (p. 1). Berkeley.
- Germain, A., & Buysse, D. J. (2011). Brief Behavioral Treatment of Insomnia. In *Behavioral treatments for sleep disorders: a comprehensive primer of behavioral sleep medicine interventions* (pp. 143–150). Boston: Academic. doi: 10.1016/B978-0-12-381522-4.00015-8
- Germain, A., Hall, M., Krakow, B., Katherine Shear, M., & Buysse, D. J. (2005). A brief Sleep Scale for Posttraumatic Stress Disorder: Pittsburgh Sleep Quality Index Addendum for PTSD. *Journal of Anxiety Disorders*, 19(2), 233–244.
- Germain, A., Moul, D. E., Franzen, P. L., Miewald, J. M., Reynolds, C. F., Monk, T. H., & Buysse, D. J. (2006). Effects of a brief behavioral treatment for late-life insomnia: Preliminary findings. *Journal of Clinical Sleep Medicine*, 2(4), 403–406.
- Germain, A., Richardson, R., Stocker, R., Mammen, O., Hall, M., Bramoweth, A. D., ... Buysse, D. J. (2014). Behaviour Research and Therapy Treatment for insomnia in combat-exposed OEF / OIF / OND Military Veterans : Preliminary randomized controlled trial. *Behaviour Research and Therapy*, *61*, 78–88. doi: 10.1016/j.brat.2014.07.016
- Gironda, R. J., Clark, M. E., Ruff, R. L., Chait, S., Craine, M., Walker, R., & Scholten, J. (2009). Traumatic brain injury, polytrauma, and pain: challenges and treatment strategies for the polytrauma rehabilitation. *Rehabilitation Psychology*, 54(3), 247–258. doi: 10.1037/a0016906
- Goodwin, R. D., & Hasin, D. S. (2002). Sedative use and misuse in the United States. *Addiction* (*Abingdon, England*), 97(5), 555–62.
- Granvold, D. K. (1994). *Cognitive and behavioral treatment: methods and application*. Cengage Learning.
- Hall, A. K., Cole-Lewis, H., & Bernhardt, J. M. (2015). Mobile Text Messaging for Health: A Systematic Review of Reviews. Annual Review of Public Health, 36, 393–415. doi: 10.1146/annurev-publhealth-031914-122855
- Hall, M. H., Muldoon, M. F., Jennings, J. R., Buysse, D. J., Flory, J. D., & Manuck, S. B. (2008). Self-reported sleep duration is associated with the metabolic syndrome in midlife adults. *Sleep*, 31(5), 635–43.

- Hallgren, K. A. (2012). Computing Inter-Rater Reliability for Observational Data: An Overview and Tutorial. *Tutorials in Quantitative Methods for Psychology*, 8(1), 23–34. doi: 10.1016/j.biotechadv.2011.08.021.Secreted
- Harvey, A. G. (2002). A cognitive model of insomnia. *Behaviour Research and Therapy*, 40(8), 869–893.
- HASLAM, B. D. R. (1982). Sleep loss, recovery sleep, and military performance. *Ergonomics*, 25(2), 163–178.
- Heron, K. E., & Smyth, J. M. (2010). Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments. *British Journal of Health Psychology*, *15*(Pt 1), 1–39. doi: 10.1348/135910709X466063
- Hickson, I. (2010). The websocket api. W3C, Editor's Draft.
- Hofmann, S. G. (2011). An introduction to modern CBT: Psychological solutions to mental health problems. John Wiley & Sons.
- Hoge, C. W., Terhakopian, A., Castro, C. a, Messer, S. C., & Engel, C. C. (2007). Association of posttraumatic stress disorder with somatic symptoms, health care visits, and absenteeism among Iraq war veterans. *The American Journal of Psychiatry*, 164(1), 150–153. doi: 10.1176/appi.ajp.164.1.150
- Hollon, S. D., & Beck, A. T. (1994). Cognitive and cognitive-behavioral therapies.
- Hollon, S. D., Muñoz, R. F., Barlow, D. H., Beardslee, W. R., Bell, C. C., Bernal, G., ... Sommers, D. (2002). Psychosocial intervention development for the prevention and treatment of depression: promoting innovation and increasing access. *Biological Psychiatry*, 52(6), 610–630. doi: 10.1016/S0006-3223(02)01384-7
- Husky, M., Olié, E., Guillaume, S., Genty, C., Swendsen, J., & Courtet, P. (2014). Feasibility and validity of ecological momentary assessment in the investigation of suicide risk. *Psychiatry Research*, 220(1), 564–570. doi: 10.1016/j.psychres.2014.08.019
- IDC. (2016). Worldwide Wearables Market Increases 67.2% Amid Seasonal Retrenchment, According to IDC - prUS41284516. Retrieved October 3, 2016, from http://www.idc.com/getdoc.jsp?containerId=prUS41284516
- Insana, S. P., Hall, M., Buysse, D. J., & Germain, A. (2013). Validation of the Pittsburgh Sleep Quality Index Addendum for Posttraumatic Stress Disorder (PSQI-A) in U.S. Male Military Veterans. *Journal of Traumatic Stress*, 26(2), 192–200.
- Intille, S. S., Kukla, C., Farzanfar, R., & Bakr, W. (2003). Just-in-time technology to encourage incremental, dietary behavior change. AMIA ... Annual Symposium Proceedings / AMIA Symposium. AMIA Symposium, 42(5), 874.
- Irwin, M. R., Cole, J. C., & Nicassio, P. M. (2006). Comparative meta-analysis of behavioral

interventions for insomnia and their efficacy in middle-aged adults and in older adults 55+ years of age. *Health Psychology : Official Journal of the Division of Health Psychology, American Psychological Association*, 25(1), 3–14. doi: 10.1037/0278-6133.25.1.3

- ITU. (2012). Overview of the Internet of things. Recommendation ITU-T Y.2060.
- ITU. (2016). Global ICT Developments. Retrieved from http://www.itu.int/en/ITU-D/Statistics/Pages/stat/default.aspx
- Javelot, H., Spadazzi, A., Weiner, L., Garcia, S., Gentili, C., Kosel, M., & Bertschy, G. (2014). Telemonitoring with respect to mood disorders and information and communication technologies: overview and presentation of the PSYCHE project. *BioMed Research International*, 2014, 104658. doi: 10.1155/2014/104658
- Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep*, *14*(6), 540–545. doi: 10.1016/j.sleep.2007.08.004
- Josefsson, S. (2006). RFC 4648 The Base16, Base32, and Base64 Data Encodings. *IETF*, 1–18. doi: 10.17487/rfc4648
- Juengst, S. B., Graham, K. M., Pulantara, I. W., McCue, M., Whyte, E. M., Dicianno, B. E., ... Wagner, A. K. (2015). Pilot feasibility of an mHealth system for conducting ecological momentary assessment of mood-related symptoms following traumatic brain injury. *Brain Injury*, 29(11), 1351–61. doi: 10.3109/02699052.2015.1045031
- Keane, T. M., Fairbank, J. A., Caddell, J. M., Zimering, R. T., Taylor, K. L., & Mora, C. A. (1989). Clinical evaluation of a measure to assess combat exposure. *Psychological Assessment: A Journal of Consulting and Clinical Psychology*, 1(1), 53–55.
- Kerlinger, F. N. (1986). Foundations of behavioural research. Holt Rinehart Winston London (Vol. Hoit, Rine).
- King, A. C., Hekler, E. B., Grieco, L. a, Winter, S. J., Sheats, J. L., Buman, M. P., ... Cirimele, J. (2013). Harnessing different motivational frames via mobile phones to promote daily physical activity and reduce sedentary behavior in aging adults. *PloS One*, 8(4), e62613. doi: 10.1371/journal.pone.0062613
- Krause, J., Croft, D. P., & James, R. (2007). Social network theory in the behavioural sciences: Potential applications. *Behavioral Ecology and Sociobiology*, 62(1), 15–27. doi: 10.1007/s00265-007-0445-8
- Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2003). The Patient Health Questionnaire-2. *Medical Care*, 41(11), 1284–1292. doi: 10.1097/01.MLR.0000093487.78664.3C
- Kroenke, K., Spitzer, R., & Williams, J. (2007). The 2-item Generalized Anxiety Disorder scale had high sensitivity and specificity for detecting GAD in primary care. *Annals of Internal Medicine*, 146(October), 317–325. doi: 10.1136/ebm.12.5.149

- Kroll, A. (2000). Grey-box models: Concepts and application. *New Frontiers In Computational Intelligence and Its Applications*, 57, 42–51.
- Krystal, A. D., Erman, M., Zammit, G. K., Soubrane, C., & Roth, T. (2008). Long-term efficacy and safety of zolpidem extended-release 12.5 mg, administered 3 to 7 nights per week for 24 weeks, in patients with chronic primary insomnia: a 6-month, randomized, double-blind, placebo-controlled, parallel-group, multicenter study. *Sleep*, 31(1), 79–90.
- Kuhn, E., Weiss, B. J., Taylor, K. L., Hoffman, J. E., Ramsey, K. M., Manber, R., ... Trockel, M. (2016). CBT-I coach: A description and clinician perceptions of a mobile app for cognitive behavioral therapy for insomnia. *Journal of Clinical Sleep Medicine*, 12(4), 597– 606.
- Lei, H., Tewari, A., & Murphy, S. (2014). An Actor-Critic Contextual Bandit Algorithm for Personalized Interventions using Mobile Devices. In NIPS 2014 Workshop: Personalization: Methods and Applications (pp. 1–9).
- Lewis, C., & Mack, R. (1982). Learning to use a text processing system: Evidence from "thinking aloud" protocols. In *Proceedings of the 1982 conference on Human factors in computing systems* (pp. 387–392).
- Lewis, C., & Rieman, J. (1993). Testing The Design With Users. In *Task-centered user interface* design: A Practical Introduction.
- Lewis, J. R. (1995). IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use. *International Journal of Human-Computer Interaction*, 7(1), 57–78. doi: 10.1080/10447319509526110
- Lewis, J. R. (2006). Sample sizes for usability tests. Interactions, 13(6), 29.
- Livingston, W. S., Rusch, H. L., Nersesian, P. V, Baxter, T., Mysliwiec, V., & Gill, J. M. (2015). Improved Sleep in Military Personnel is Associated with Changes in the Expression of Inflammatory Genes and Improvement in Depression Symptoms. *Frontiers in Psychiatry*, 6(April), 59. doi: 10.3389/fpsyt.2015.00059
- Lockley, S. W., Skene, D. J., & Arendt, J. (1999). Comparison between subjective and actigraphic measurement of sleep and sleep rhythms. *Journal of Sleep Research*, 8(3), 175– 183. doi: 10.1046/j.1365-2869.1999.00155.x
- Luxton, D. D., Kayl, R. a., & Mishkind, M. C. (2012). mHealth Data Security: The Need for HIPAA-Compliant Standardization. *Telemedicine and E-Health*, 18(4), 284–288. doi: 10.1089/tmj.2011.0180
- Maher, M. J., Rego, S. A., & Asnis, G. M. (2006). Sleep disturbances in patients with posttraumatic stress disorder: epidemiology, impact and approaches to management. *CNS Drugs*, (20), 567–590.

Mahoney, M. J. (1977). Personal science: A cognitive learning therapy. Handbook of Rational-

Emotive Therapy. New York: Springer.

- Maiman, L. A., & Becker, M. H. (1974). The health belief model: Origins and correlates in psychological theory.
- Marsland, S. (2009). Using habituation in machine learning. *Neurobiology of Learning and Memory*, 92(2), 260–266. doi: 10.1016/j.nlm.2008.05.014
- Martin Bland, J., & Altman, D. (1986). STATISTICAL METHODS FOR ASSESSING AGREEMENT BETWEEN TWO METHODS OF CLINICAL MEASUREMENT. *The Lancet*, 327(8476), 307–310. doi: 10.1016/S0140-6736(86)90837-8
- Mccall, C., & Mccall, W. V. (2012). Comparison of actigraphy with polysomnography and sleep logs in depressed insomniacs. *Journal of Sleep Research*, 21(1), 122–127. doi: 10.1111/j.1365-2869.2011.00917.x
- McEachan, R. R. C., Conner, M., Taylor, N. J., & Lawton, R. J. (2011). Prospective prediction of health-related behaviours with the Theory of Planned Behaviour: a meta-analysis. *Health Psychology Review*, 5, 97–144. doi: 10.1080/17437199.2010.521684
- Mcmahon, S. B., Koltzenburg, M., Tracey, I., & Turk, D. C. (2013). The Cognitive Behavioral Approach to Pain Management. In *Wall and Melzack's textbook of pain* (pp. 592–602).
- Microsoft. (2000). Usability in Software Design. Retrieved August 12, 2016, from https://msdn.microsoft.com/en-us/library/ms997577.aspx?f=255&MSPPError=-2147217396
- Microsoft. (2016). Chapter 5: Layered Application Guidelines. Retrieved August 15, 2016, from https://msdn.microsoft.com/en-us/library/ee658109.aspx
- Monk, T. H., Reynolds, C. F., Kupfer, D. J., Buysse, D. J., Coble, P. A., Hayes, A. J., ... Ritenour, A. M. (1994). The Pittsburgh Sleep Diary. *Journal of Sleep Research*, 3(2), 111– 120. doi: jsr003002111 [pii]
- Morin, C. M., Belleville, G., Bélanger, L., & Ivers, H. (2011). The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep*, *34*(5), 601–8.
- Morin, C. M., Culbert, J. P., & Schwartz, S. M. (1994). Nonpharmacological interventions for insomnia: A meta-analysis of treatment efficacy. *American Journal of Psychiatry*, 151(8), 1172–1180.
- Morin, C. M., Gaulier, B., Barry, T., & Kowatch, R. A. (1992). Patients' acceptance of psychological and pharmacological therapies for insomnia. *Sleep*, *15*(4), 302–5.
- Mysliwiec, V., & Roth, B. (2013, February). Pharmacotherapy refractory insomnia in soldiers with traumatic brain injury. *Chest*. United States. doi: 10.1378/chest.12-2269

- Navarro-Barrientos, J.-E., Rivera, D. E., & Collins, L. M. (2011). A dynamical model for describing behavioural interventions for weight loss and body composition change. *Mathematical and Computer Modelling of Dynamical Systems*, 17(2), 183–203. doi: 10.1080/13873954.2010.520409
- Nielsen, J. (1994). Usability engineering. Elsevier.
- Nielsen, J., & Landauer, T. K. (1993). A mathematical model of the finding of usability problems. *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems CHI '93*, 206–213. doi: 10.1145/169059.169166
- NIH. (2005). NIH State-of-the-Science Conference Statement on manifestations and management of chronic insomnia in adults. *Sleep*, 22(2), 1–30.
- Ocasio-Tascón, M. E., Alicea-Colón, E., Torres-Palacios, A., & Rodríguez-Cintrón, W. (2006). The veteran population: One at high risk for sleep-disordered breathing. *Sleep and Breathing*, *10*(2), 70–75. doi: 10.1007/s11325-005-0043-9
- Ohayon, M. M. (2002). Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Medicine Reviews*, 6(2), 97–111.
- Osborn, C. Y., & Egede, L. E. (2010). Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC). *Patient Education and Counseling*, 79(1), 49–54.
- Pbert, L. (2013). The handbook of health behavior change. Springer Publishing Company.
- Peres, S. (2013). What are JITAIs? Retrieved January 2, 2015, from https://community.isr.umich.edu/public/Portals/11/Docs/201308\_session1.pdf
- Pramana, G., & Parmanto, B. (2014). The SmartCAT: An m-Health Platform for Ecological Momentary Intervention in Child Anxiety Treatment. *Telemedicine and E-Health*.
- Rabbi, M., Aung, M. H., Zhang, M., & Choudhury, T. (2015). MyBehavior: automatic personalized health feedback from user behaviors and preferences using smartphones. *Ubicomp '15, September 7–11, 2015, Osaka, Japan.* doi: 10.1145/2750858.2805840
- Rankin, C. H., Abrams, T., Barry, R. J., Bhatnagar, S., Clayton, D. F., Colombo, J., ... Thompson, R. F. (2009). Habituation revisited: An updated and revised description of the behavioral characteristics of habituation. *Neurobiology of Learning and Memory*, 92(2), 135–138.
- Raskind, M. a., Peskind, E. R., Hoff, D. J., Hart, K. L., Holmes, H. a., Warren, D., ... others. (2007). A Parallel Group Placebo Controlled Study of Prazosin for Trauma Nightmares and Sleep Disturbance in Combat Veterans with Post-Traumatic Stress Disorder. *Biological Psychiatry*, 61(8), 928–934. doi: 10.1016/j.biopsych.2006.06.032

Raudenbush, S. W., & Bryk, A. S. (1992). Hierarchical linear models: Applications and data

analysis methods (Vol. 1). Sage.

- Riley, W. T., Cesar, a., & Rivera, D. E. (2014). The importance of behavior theory in control system modeling of physical activity sensor data. 2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 6880–6883. doi: 10.1109/EMBC.2014.6945209
- Riley, W. T., Rivera, D. E., Atienza, A. A., Nilsen, W., Allison, S. M., & Mermelstein, R. (2011). Health behavior models in the age of mobile interventions: are our theories up to the task? *Translational Behavioral Medicine*, 1(1), 53–71. doi: 10.1007/s13142-011-0021-7
- Ritterband, L. M., Thorndike, F. P., Cox, D. J., Kovatchev, B. P., & Gonder-Frederick, L. A. (2009). A behavior change model for internet interventions. *Annals of Behavioral Medicine : A Publication of the Society of Behavioral Medicine*, 38(1), 18–27. doi: 10.1007/s12160-009-9133-4
- Roth, T. (2007). Insomnia: definition, prevalence, etiology, and consequences. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine*, 3(5 Suppl), S7-10.
- Royce, W. W. (1970). Managing the development of large software systems. In *proceedings of IEEE WESCON* (Vol. 26).
- Rupp, T. L., Wesensten, N. J., & Balkin, T. J. (2010). Sleep history affects task acquisition during subsequent sleep restriction and recovery. *Journal of Sleep Research*, 19(2), 289– 297.
- Rutledge, C. M., Guardia, A. C. La, & Bluestein, D. (2013). Predictors of self-efficacy for sleep in primary care. *Journal of Clinical Nursing*, 22(9–10), 1254–1261. doi: 10.1111/jocn.12005
- Shiffman, S., Stone, A. A., & Hufford, M. R. (2008). Ecological momentary assessment. *Annual Review of Clinical Psychology*, *4*, 1–32.
- Shochat, T., Umphress, J., Israel, A. G., & Ancoli-Israel, S. (1999). Insomnia in primary care patients. *Sleep: Journal of Sleep Research & Sleep Medicine*.
- Sih, A., Hanser, S. F., & McHugh, K. A. (2009). Social network theory: New insights and issues for behavioral ecologists. *Behavioral Ecology and Sociobiology*, 63(7), 975–988. doi: 10.1007/s00265-009-0725-6
- Simon, G. E., & VonKorff, M. (1997). Prevalence, burden, and treatment of insomnia in primary care. *Am J Psychiatry*, *154*, 1417–1423.
- Skinner, B. F. (1953). Operant behavior. *Science and Human Behavior*, 59–90. doi: 10.3390/ijerph8093528
- Smith, M. T., Perlis, M. L., Park, A., Smith, M. S., Pennington, J., Giles, D. E., & Buysse, D. J.

(2002). Comparative meta-analysis of pharmacotherapy and behavior therapy for persistent insomnia. *The American Journal of Psychiatry*, 159(1), 5–11.

- Spielman, A. J., Saskin, P., & Thorpy, M. J. (1987). Treatment of chronic insomnia by restriction of time in bed. *Sleep: Journal of Sleep Research & Sleep Medicine*.
- Spruijt-Metz, D., & Nilsen, W. (2014). Dynamic models of behavior for just-in-time adaptive interventions. *IEEE Pervasive Computing*, *13*, 13–17. doi: 10.1109/MPRV.2014.46
- Starace, F., Massa, A., Amico, K. R., & Fisher, J. D. (2006). Adherence to antiretroviral therapy: an empirical test of the information-motivation-behavioral skills model. *Health Psychology : Official Journal of the Division of Health Psychology, American Psychological Association*, 25(2), 153–162.
- Stone, A. A. (2007). Historical Roots and Rationale of Ecological Momentary Assessment (EMA). In *The Science of Real-time Data Capture* (pp. 3–10).
- Stone, A. A., Shiffman, S., Atienza, A. A., & Nebeling, L. (2007). Historical Roots ad Rationale of Ecoogical Mementary Assessment (EMA). In *The Science of Real-time Data Capture* (pp. 3–10). Oxford, England: Oxford University Press.
- The Army Medical Department. (2014). Army Medicine's Performance Triad. Retrieved October 18, 2015, from http://armymedicine.mil/Pages/performance-triad.aspx
- Trockel, M., Karlin, B. E., Taylor, C. B., & Manber, R. (2014). Cognitive behavioral therapy for insomnia with veterans: evaluation of effectiveness and correlates of treatment outcomes. *Behaviour Research and Therapy*, 53, 41–46.
- Troxel, Wendy M., Regina A. Shih, Eric R. Pedersen, Lily Geyer, Michael P. Fisher, Beth Ann Griffin, Ann C. Haas, J. K. and P. S. S. (2015). *Sleep in the Military: Promoting Healthy Sleep Among U.S. Servicemembers*. RAND Corporation.
- Troxel, W. M., Germain, A., & Buysse, D. J. (2012). Clinical management of insomnia with brief behavioral treatment (BBTI). *Behavioral Sleep Medicine*, 10(4), 266–279.
- Turk, D. (2003). Cognitive-behavioral approach to the treatment of chronic pain patients. *Regional Anesthesia and Pain Medicine*, 28(6), 573–579. doi: 10.1016/S1098-7339(03)00392-4
- Walz, L. C., Nauta, M. H., & Aan Het Rot, M. (2014). Experience sampling and ecological momentary assessment for studying the daily lives of patients with anxiety disorders: A systematic review. *Journal of Anxiety Disorders*, 28(8), 925–937. doi: 10.1016/j.janxdis.2014.09.022
- Watzlaf, V. J. M., Moeini, S., Matusow, L., & Firouzan, P. (2011). VOIP for Telerehabilitation: A Risk Analysis for Privacy, Security and HIPAA Compliance: Part II. *International Journal of Telerehabilitation*, 3(1), 3–10. doi: 10.5195/ijt.2011.6070

- Weathers, F.W., Litz, B.T., Huska, J.A., & Keane, T. M. (1994). PTSD Checklist—Civilian version. Boston: National Center for PTSD, Behavioral Science Division. doi: 10.1037/t02622-000
- Webb, T. L., Joseph, J., Yardley, L., & Michie, S. (2010). Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *Journal of Medical Internet Research*, 12(1), e4. doi: 10.2196/jmir.1376
- Wilkowska, W., & Ziefle, M. (2011). Perception of privacy and security for acceptance of Ehealth technologies: Exploratory analysis for diverse user groups. In *International Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth) and Workshops* (pp. 593–600).
- Witkiewitz, K., Desai, S. a, Bowen, S., Leigh, B. C., Kirouac, M., & Larimer, M. E. (2014). Development and evaluation of a mobile intervention for heavy drinking and smoking among college students. *Psychology of Addictive Behaviors : Journal of the Society of Psychologists in Addictive Behaviors*, 28(3), 639–50. doi: 10.1037/a0034747
- Yalcin, I., & Bump, R. C. (2003). Validation of two global impression questionnaires for incontinence. American Journal of Obstetrics and Gynecology, 189(1), 98–101. doi: 10.1067/mob.2003.379
- Yu, D. X., Parmanto, B., Dicianno, B. E., & Pramana, G. (2015). Accessibility of mHealth Self-Care Apps for Individuals with Spina Bifida. *Perspectives in Health Information Management / AHIMA, American Health Information Management Association*, 12(Spring), 1h.
- Zhuang, Y., Baldwin, J., Antuña, L., Yazir, Y. O., Ganti, S., & Coady, Y. (2013). Tradeoffs in cross platform solutions for mobile assistive technology. *IEEE Pacific RIM Conference on Communications, Computers, and Signal Processing - Proceedings*, 330–335. doi: 10.1109/PACRIM.2013.6625498