The Methodology Center

Just-in-Time Adaptive Interventions (JITAIs): An Organizing Framework for Ongoing Health Behavior Support

Inbal Nahum-Shani[1]
Shawna N. Smith[1]
Ambuj Tewari[1]
Katie Witkiewitz[2]
Linda M. Collins[3]
Bonnie Spring
Susan A. Murphy[1]
[1]The University of Michigan; [2]The University of New Mexico;
[3]The Pennsylvania State University; [4]Northwestern University

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Please send questions and comments to Inbal Nahum-Shani, 2450 Institute for Social Research, 426 Thompson St., Ann Arbor, MI, 48104-2321; inbal@umich.edu

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Abstract

An emerging mobile phone intervention design, called the just-in-time adaptive intervention (JITAI), holds enormous potential for adapting mobile phone-delivered interventions to the dynamics of an individual's emotional, social, physical and contextual state, so as to prevent negative health outcomes and promote the adoption and maintenance of healthy behaviors. A JITAI is an intervention design aiming to address the dynamically changing needs of individuals via the provision of the type/amount of support needed, at the right time, and only when needed. Despite the increasing use and the practical and conceptual appeal of JITAIs, a comprehensive organizing scientific framework to guide the construction of efficacious evidence-based JITAIs has yet to be provided. To bridge this gap, the current manuscript provides an organizing scientific framework to guide the construction of JITAIs. The key components of a JITAI are described and illustrated using examples of JITAIs from various domains of psychological and health behavior research. Design principles are discussed, as well as practical and theoretical challenges that require consideration in the process of constructing efficacious JITAIs.

KEYWORDS: Just-in-time adaptive interventions, health behavior, support, mobile devices

Introduction

An emerging mobile phone intervention design, called the just-in-time adaptive intervention (JITAI; Spruijt-Metz & Nilsen, 2014), holds enormous potential for adapting mobile phone delivered interventions to the dynamics of an individual's emotional, social, physical and contextual state, so as to prevent negative health outcomes and promote the adoption and maintenance of healthy behaviors. A JITAI is an intervention designed to address the dynamically changing needs of individuals via the provision of the type/amount of support needed, at the right time, and only when needed. The availability of increasingly powerful mobile and sensing technologies underpin this intervention design (Spruijt-Metz & Nilsen, 2014; Mascolo et al., 2011) as these technologies enable the monitoring of the temporal dynamics of an individual's state in real time. As such, mobile technologies can be used to provide interventions whenever and wherever needed (Patrick, Intille, & Zabinski, 2005). These technologies can help overcome barriers to obtaining and receiving sufficient treatment, including cost, availability of therapists, logistics of scheduling and traveling to appointments, stigma, and lack of therapist training in evidence-based treatments (see Azfar et al., 2014; Cartreine et al., 2010; Esterson et al., 2014; Boydell et al., 2014). However the term "adaptive" in the JITAI emphasizes the provision of "personalized, localized, and on-demand interventions in ways previously unimaginable" (Kumar et al., 2013b: p.228).

JITAIs are increasingly being developed and used to support health behavior change in physical activity (Consolvo et al. 2008; King et al. 2013), eating disorders (Bauer et al. 2010), alcohol use (Gustafson et al., 2014; Suffoletto et al. 2013; Witkiewitz et al., 2014;), mental illness (Ben-Zeev et al., 2013b; Depp et al., 2010), smoking cessation (Riley et al., 2008), obesity/weight management (Patrick et al., 2009) and other chronic disorders (Granholm et al., 2012; Kristjánsdóttir et al., 2013). However, despite the increasing use and the practical and conceptual appeal of JITAIs, a comprehensive organizing scientific framework has yet to be provided to guide the construction of efficacious evidence-based JITAIs (Heron & Smyth, 2010; Kennedy et al., 2012; Kumar et al., 2013b). As noted by Dennison et al. (2013), "although there has been much enthusiasm for delivering interventions through smartphone apps, academic research on the development and evaluation of such apps is in the early stages" (p. 4). To bridge

the gap between the growing technological capabilities for delivering JITAIs and academic research, it is critical that behavioral scientists play a leading role (Evans, Abroms, Poropatich, Nielsen, & Wallace, 2012; Hekler, Klasnja, Froehlich, & Buman, 2013).

An organizing scientific framework to guide the development of JITAIs is necessary for several reasons. First, the development of a JITAI requires a multidisciplinary effort, involving clinicians, behavioral scientists, methodologists, computer scientists and human-computer interface specialists. A common framework that defines the key elements that are needed to construct such an intervention can serve as a bridge between diverse scientific perspectives and facilitate better collaboration towards building efficacious JITAIs (Spruijt-Metz & Nilsen, 2014). Second, as we discuss below, because a JITAI is a multi-component intervention, it is important to clearly define the components that comprise the intervention, so that investigators can attend to the utility of each component. Determining which component is effective, and how well different components work together, is an important step in the process of optimizing a multi-component intervention (Collins et al., 2007). Third, a unified framework can anchor the integration of the varied psychological, psychosocial, sociological and health behavior theories that can inform the development of a JITAI. Finally, from a methodological perspective, an organizing framework for JITAIs provides a foundation for the development of new intervention designs, experimental approaches, algorithmic and data analytic methods that will enable the optimization and evaluation of these interventions.

This article provides an organizing framework to guide the construction of a JITAI. We use examples of JITAIs from different domains of psychological and health behavior research to illustrate these ideas. We then discuss design principles, as well as practical and theoretical challenges that require consideration in constructing an effective JITAI. Finally, we discuss directions for future research.

Just-in-Time Adaptive Interventions

JITAIs are designed to provide support at the right time. Such timely provision of support is captured by the term *just-in-time* (Intille, 2004; Intille et al., 2003; Muench et al., 2013). Moreover, in a JITAI the type, the amount or the timing of support may be individualized repeatedly using ongoing

information from the individual, so as to achieve and maintain the desired health outcome, while maximizing engagement and minimizing burden (Kumar, Nilsen, Pavel, & Srivastava, 2013a; Kumar et al., 2013b). This type of individualization is captured by the term *adaptive*. Various scientific fields have used different terms to describe JITAIs, including dynamic tailoring (Kennedy et al., 2012), intelligent real-time therapy (Kelly et al., 2012), and dynamically and individually-tailored ecological momentary interventions (Cafazzo et al., 2012; Heron, 2011; Heron & Smyth, 2010; Wenze & Miller, 2010).

Motivation for Just-in-Time Adaptation

The motivation for JITAIs is rooted in various conceptual approaches which highlight the importance of providing support when needed, as much as needed, and only when needed, so as to prevent adverse health outcomes and/or promote healthy behaviors. For example, theories focusing on preventing adverse health outcomes, including stress-vulnerability theory (Zubin & Spring, 1977), and relapse prevention theories (Witkiewitz & Marlatt, 2004), suggest that the emergence of a vulnerable state (a period of susceptibility to negative health outcomes, such as an episode of illness, a temporary crisis, or relapse) is a dynamic process in which static and episodic factors interact. Static factors refer to enduring influences, including genetic, developmental, social-psychological, and environmental factors (e.g., personality, neighborhood, socio-economic status). Episodic factors refer to influences that can vary over time, including how the person is feeling (e.g., negative emotions), where he/she is (e.g., risky location) and with whom (e.g., being around people who smoke), as well as changes in these experiences (Witkiewitz & Marlatt, 2004; Zubin & Spring, 1977). In this context, JITAIs are motivated by the need to identify when the individual approaches or enters a state of heightened vulnerability for experiencing adverse health outcomes, so that the type/amount of support needed can immediately be provided to prevent from the vulnerable state from transitioning into an adverse health outcome (Conati & VanLehn, 2001; Diziol, Walker, Rummel, & Koedinger, 2010; Schwonke, Hauser, Nückles, & Renkl, 2006).

Other motivating conceptual approaches include theories that focus on helping individuals adopt and maintain healthy behaviors (see Abraham & Michie, 2008; Webb et al., 2010 for review). This includes health behavior motivation theories, which suggest that in order to attain a long-term health

behavior goal it is important to break it into short-term, specific and achievable sub-goals, monitor for progress, and provide immediate feedback and guidance to support goal attainment (Fahrenwald et al., 2004; Lam, 1991; Strecher et al., 1995). Other examples include learning and cognitive theories, which emphasize the role of "shaping" (i.e., training by identifying and immediately reinforcing successively improving approximations of the target behavior; Krueger & Dayan, 2009; Skinner, 1938) and "teachable moments" (broadly defined as capitalizing on and facilitating natural opportunities for learning and improvement; Lawson & Flocke, 2009; McBride, Emmons & Lipkus, 2003) in the acquisition of a new skill or in the adoption of a new behavior. These theories emphasize the need to identify natural opportunities for improvement and immediately provide only those types of scaffolds and prompts that are needed, and only when they are needed, so as to encourage and motivate the adoption and maintenance of healthy behaviors (S. P. Kaplan, 1991; O'Connell et al., 1998; Panzarine, Slater, & Sharps, 1995; Schwarzer & Leppin, 1991).

Overall, a JITAI is an intervention designed to prevent negative health outcomes and/or promote the adoption and maintenance of healthy behaviors by providing support at the right time and in an adaptive manner. The term *adaptive* in this context captures the provision of the type of support needed, as much as needed, and *only when* needed, so as to effectively address (episodic) states of heightened vulnerability, and/or immediately capitalize on and facilitate natural opportunities to improve health behaviors.

Examples of JITAIs

JITAIs have been implemented and pilot tested in various areas of health behavior change. For example, Ben-Zeev and colleagues (Ben-Zeev et al., 2014) piloted FOCUS, a smartphone behavioral intervention that provides illness management support to individuals with schizophrenia. FOCUS prompts participants three times a day for assessments of difficulties in five target domains (i.e., medicine adherence, mood regulation, sleep, social functioning and coping with persistent auditory hallucinations). When assessments indicate that the participant is experiencing difficulties, FOCUS recommends self-management strategies to ameliorate the type of difficulties the participant endorsed. If the participant

reports no difficulties, FOCUS provides feedback and positive reinforcement. Participants can also access all intervention content "on-demand" whenever and wherever they choose, via the FOCUS home-screen.

Witkiewitz and colleagues (Witkiewitz et al., 2014; Witkiewitz, Desai & Larimer, 2012) piloted Mobile-BASICS, a behavioral intervention that targets heavy drinking and smoking and is delivered via a mobile phone. Mobile-BASICS prompts participants three times a day for assessments of smoking urge, affect, and drinking behaviors. If the participant reports an urge to smoke at an assessment time, an urge-management intervention (called "urge surfing") is delivered immediately via the mobile device.

Free and colleagues (Free et al., 2011) tested the effectiveness of "txt2stop" – an automated smoking cessation program delivered via mobile phone text messaging. In the course of the intervention, the participant could initiate intervention delivery at any time by texting the words "lapse" or "crave." In response, the participant received a series of encouraging text messages addressing either their lapse or their craving.

Finally, SitCoach (Dantzig, Geleijnse, & Halteren, 2013) is an example of a JITAI for office workers in which messages encouraging activity are delivered via a smartphone. Software on the office worker's computer records uninterrupted computer time via mouse and keyboard activity. If 30 minutes of uninterrupted computer time occurs, the smartphone delivers a message to encourage a walking activity.

Components of a JITAI

JITAIs are a special case of Adaptive Interventions (AIs). An AI is a treatment design in which intervention options are adapted to address the unique and changing needs of each participant, with the objective of achieving the best outcome for each participant (Collins et al., 2004; Nahum-Shani et al., 2012). AIs include four key components: (1) decision points (2) intervention options; (3) tailoring variables, and (4) decision rules. Below, we describe each of these elements and how they are employed in the context of a JITAI. We use the four examples of JITAIs provided above to guide the discussion.

Decision points. A decision point is a point in time at which treatment decisions must be made. In a JITAI, the selection and frequency of the decision points are flexible. Table 1 includes examples of

decision points in a JITAI. For example, in Mobile-BASICS treatment decisions were made following the collection of self-report data from the participants. In this case, there was a decision point following any random prompt for self-report.

In general, the decision points in a JITAI may be either ***intervention scientist-specified*** or ***participant-initiated***. Intervention scientist-specified decision points include (a) at every given time interval; for example, the location of a recovering participant is passively monitored every three minutes to detect if/when s/he is approaching a bar or a liquor store (Gustafson et al., 2011); (b) specific time points during the day; for example at night, or at 2pm (King et al., 2008), or specific days during the week (Suffoletto et al., 2012); and (c) following the collection of self-report data; for example after random prompts for self-report as in Mobile-BASICS.

Decision points that are participant initiated include points in time in which the participant requests support, for example, when the participant indicates the need for help as in txt2stop (see also Franklin et al, 2008), or when the participant accesses the intervention options on-demand on a mobile device, as in FOCUS (Ben-Zeev et al., 2014).

Intervention options. Intervention options in JITAIs include types of support (e.g., instrumental, emotional), sources of support (e.g., automated sources, social sources); and modes of support delivery (e.g., support provision and/or support availability). For example, intervention options in SitCoach include 4 types of messages, each using a different persuasive strategy for increasing activity. In a JITAI, intervention options can be delivered at any time they are needed and/or desired (Gustafson et al., 2011; Schroder, 2011; Thinnes & Padilla, 2011; Yank, Stafford, Rosas, & Ma, 2012). The term "ecological momentary intervention" (EMI) is often used to describe intervention options that can be delivered at any time, as people go about their daily lives (cf. Heron & Smyth, 2010; Heron, 2011). In other fields, such as education (Alibali et al., 2013) and organizational behavior (Kelloway, HurrellJr, & Day, 2008; Luthans, Avey, Avolio, Norman, & Combs, 2006), these intervention options are known as "micro-interventions" (also see Smyth, 2005) again to emphasize that the options are relatively brief in duration and are designed to provide in-the-moment support. See Table 2 for further concrete examples.

Tailoring variables. In the context of the AI framework, a tailoring variable is defined as information concerning the participant that is used to make treatment decisions. In the context of a JITAI, the collection of tailoring variables is flexible in terms of the timing of assessments. This flexibility is critical to enable timely individualization of intervention options to a participant's momentary needs. For example in txt2stop, the tailoring variable is the content of the text message ("lapse" or "crave"); in Mobile-BASICS the measure of urge is the tailoring variable; and in FOCUS, measures of illness management difficulties were used as tailoring variables.

Tailoring variables in a JITAI can be obtained via active assessments, passive assessments or both (Wenze & Miller, 2010). ***Active assessments*** are self-reported and hence require engagement on the part of the participant. These assessments are also known as Ecological Momentary Assessments (EMA) (cf. Stone & Shiffman, 1994; Shiffman & Stone, 1998; Schiffman, et al., 2008). Active assessments may be initiated by the participant (e.g., in txt2stop the participant initiates a text message) or by an automated system (e.g., in Mobile-BASICS the mobile device prompts the participant to self-report his/her level of smoking urge). ***Passive assessments*** of tailoring variables are those that require minimal or no engagement on the part of the participant. For example, in SitCoach, the computer passively monitors the participant's mouse and keyboard activity. Recent advances in technologies support new, non-intrusive methods for collecting information about the participant and his/her environmental and social context without user engagement. Passive sensing has been used to detect participant's level of stress (e.g,. AutoSense: Ertin et al., 2011; Shi et al., 2010; Galvanic Skin Response: Bakker, Pechenizkiy & Sidorova, 2011); heavy alcohol use (Secure Continuous Remote Alcohol Monitoring; Barnett, Meade, & Glynn, 2014), smoking (mPuff: Ali et al., 2012) and social interactions (e.g., RIP: Rahman et al., 2011). Passive data can also be used to gauge participant burden and/or engagement with the intervention itself (e.g., the number of prompts ignored by a participant or the amount of time the participant interacted with a mobile-based intervention; Heron & Smyth, 2010).

Decision rules. The decision rules in JITAIs operationalize the individualization by specifying which intervention option to offer, to whom, and when based on the tailoring variables. In other words,

the decision rules link the tailoring variables and intervention options in a systematic way. There is a decision rule for each decision point. Table 1 provides examples of how decision rules can be used to formulate the individualization in a JITAI. For example, in the Mobile-BASICS intervention, one of the decision rules might be of the form:

Decision Rule # 1:

If reported smoking urge $\geq S_0$

Then, intervention option = [recommend an urge-surfing intervention]

Else if reported smoking urge $< S_0$

Then, intervention option = [do not recommend an urge-surfing intervention].

Notice that a decision rule includes the values (levels, thresholds, ranges) of the tailoring variable that determine what intervention option each participant should receive. For example, in Decision Rule # 1, S_0 is the level of self-reported smoking urge (the tailoring variable) that determines who should be offered an urge surfing intervention (those with self-reported smoking urge $\geq S_0$), and who should not (those with self-reported smoking urge $< S_0$).

Summary of JITAIs

JITAIs are intended to offer support in a timely manner so as to address states of heightened vulnerability for an adverse health outcome, and/or help the participant achieve ongoing progress toward adopting and maintaining healthy behaviors. The individualization in a JITAI is intended to address the unique and changing needs of the participant, by providing the kind of support that is needed, as much as needed, and only when needed. It occurs through decision rules that specify which intervention options to offer to which participants, and when, based on the tailoring variables. In a JITAI, the selection and frequency of the decision points, the measurement of the tailoring variables, the decision rules, and the delivery of intervention options are employed in a flexible manner with respect to their timing. Wireless and mobile devices provide such flexibility and thus play an important role in the implementation and dissemination of JITAIs. As is the case with any intervention, careful thought is required in constructing a JITAI. Next we discuss design principles that are important to consider in constructing an effective JITAI.

Design Principles for JITAIs

We discuss design principles and considerations aimed at maximizing the ***effectiveness*** of the JITAI, namely the ability of the JITAI to achieve the desired distal outcome(s) when implemented in a real-world setting. All the design principles discussed below should be considered in the context of a distal outcome targeted by the JITAI. Specifically, the selection of decision points, tailoring variables, intervention options, as well as the formulation of the decision rules should be guided primarily by the ultimate goal the JITAI is intended to achieve.

The Role of Proximal Outcomes

A proximal outcome is a crucial element in a pathway (a mediator) through which the intervention can impact the distal outcome (Lavori & Dawson, 2014). When constructing a JITAI it is important to select and clearly define the proximal outcomes. The selection of decision points, tailoring variables, intervention options, as well as the formulation of the decision rules are informed by the proximal outcome the JITAI should impact. In this section, we provide examples of proximal outcomes, discuss the importance of including proximal outcomes that capture poor engagement and/or burden, and illustrate the motivation for designing a JITAI that targets multiple proximal outcomes.

Examples of proximal outcomes. JITAIs aiming to prevent adverse health outcomes often target proximal outcomes that mark (i.e., signal the emergence or existence of) a state of heightened vulnerability. Such markers can be in the form of episodic factors (e.g., psychological, psychosocial, physiological and micro-environmental experiences) that precede an adverse health outcome. For example, an intervention scientist constructing a JITAI for smoking cessation might build on dynamic relapse prevention theories (Witkiewitz & Marlatt, 2004), positing that when an individual experiences a momentary urge to smoke, s/he is vulnerable to smoking a cigarette. Hence, smoking cessation (the distal outcome) can be achieved by addressing momentary experiences of smoking urge (the proximal outcome). Similarly, intervention scientists constructing a JITAI for preventing a clinical relapse among individuals with mental illness (e.g., schizophrenia) might build on the stress-vulnerability model (Zubin & Spring, 1977) to posit that when the individual experiences an episode of mild symptoms in response to

stress, s/he is vulnerable to full clinical relapse. Hence, clinical relapse prevention (the distal outcome) can be achieved by ameliorating momentary experiences of stress (the proximal outcome) (Ben-Zeev, et al., 2013b; 2014).

JITAIs aiming to promote the adoption and maintenance of healthy behaviors often target proximal outcomes that capture short-term progress towards adopting and maintaining the targeted behavior. For example, an intervention scientist might build on health behavior goal-setting theories to select daily step-count, or achievement of daily walking goals, as proximal outcomes in a JITAI aimed at increasing physical activity as the distal outcome (Consolvo, Everitt, Smith, & Landay, 2006; Consolvo, Klasnja, McDonald, & Landay, 2009).

Signs of poor engagement and/or burden as proximal outcomes. Poor engagement and burden are likely to hinder intervention effectiveness. Engagement reflects emotional reactions to and cognitive and behavioral investment in the intervention; burden is an indication that intervention requirements exceed the momentary personal resources of the participant. Given the real time and ongoing nature of JITAIs, it is important that intervention scientists constructing a JITAI consider mediators that quantify signs of poor engagement and/or excessive burden as proximal outcomes (Jochems et al., 2012). For example, poor engagement might be in the form of habituation (i.e., when frequent and repeated exposure to the intervention progressively attenuate arousal and investigatory reactions: Pop-Eleches et al., 2011; Stein, 1966; Thompson, 2009), and/or boredom (i.e., "unpleasant transient affective state in which the individual feels a pervasive lack of interest in and difficulty concentrating on the current activity": Fisher, 1993, p. 396). Participant burden might be in the form of high demands on participant's time, and/or cognitive overload (i.e., when new information exceeds the cognitive capacity of the participant, such that the participant feels overwhelmed or confused by the intervention: Chen & Chang, 2011; Yu & Roh, 2002).

Selecting multiple proximal outcomes. In many cases, multiple mediators play an important role in the pathway through which the intervention can impact the distal outcome (Preacher & Hayes, 2008). In such a setting, intervention scientists might select multiple proximal outcomes to be targeted by

the JITAI. For example, consider a JITAI for use in achieving the distal goal of smoking cessation. Suppose this intervention is designed to target three proximal outcomes: (1) momentary smoking urge was selected to mark a state of heightened vulnerability for smoking (Ditre & Brandon, 2008; Strong et al., 2009); (2) reduction in the number of cigarettes smoked per day was selected to capture short-term progress toward smoking cessation (Broms, Korhonen, & Kaprio, 2008); and (3) participant ratings of intervention usefulness was selected to capture the extent of engagement with intervention options (Fjeldsoe, Miller, & Marshall, 2010).

Decision Points

The selection of scientist-specified decision points should be informed by the extent to which the tailoring variables and the proximal outcomes are expected to change systematically over time (Collins, 2006; R. M. Kaplan & Stone, 2013). For example, if the tailoring variable and/or the proximal outcome is likely to change in a meaningful manner every 30 minutes (e.g., mood), then there should be a decision point every 30 minutes; if the tailoring variable and/or the proximal outcome might change every 3 minutes (e.g., location), then there should be a decision point every 3 minutes.

When the tailoring variable is measured via active assessments (i.e., self-report), considerations of assessment burden may lead to less frequent decision points. For example, the selection of decision points in Mobile-BASICS (i.e., at random prompts 3 time/day) was intended to balance empirical evidence and theories suggesting that smoking urge might change frequently during the day with considerations of burden (as well as quality of measurements) that might result from asking the participant to self-report too frequently (Witkiewitz et al., 2014). On the other hand, in iHeal (Boyer et al., 2012) -- a JITAI that uses biosensors to monitor arousal and stress in individuals with histories of substance abuse-- there are decision points at very small intervals in time. The selection of decision points in this case is guided by the notion that arousal and stress (which mark a state of vulnerability to substance abuse) can change very frequently. Given that passive assessments were used to measure the tailoring variable, the selection of decision points in this case is not constrained by considerations pertaining to assessment burden.

Note that the choice of the time interval between decision points can have a dramatic impact on the ability of the adaptation to achieve its short- and long-term goals. If the timing of the decision points is not aligned with the temporal dynamics of the tailoring variable, important opportunities for intervention might be missed. Given that the temporal dynamics of a tailoring variable may vary between people, as well as within a person as s/he progresses through the intervention, intervention scientists may consider the timing of the decision points as possible intervention options. In this case, decision rules would be formulated to specify how the timing of the decision points should be individualized based on participant information. For example, individuals who are classified as higher risk at baseline (e.g., heavy smokers) might experience more frequent changes in the tailoring variable (e.g., urge to smoke) relative to those at low-risk (e.g., light smokers) and hence would require more frequent decision points in order to intervene as soon as changes in the tailoring variable indicate entry into a vulnerable state.

Throughout, a JITAI might accommodate patient-initiated decision points (i.e., points in time in which the participant requests support) in addition to those specified by the intervention scientist. This can facilitate autonomous regulation via participant's control over the decision points, while effectively addressing the real-time needs of individuals in situations where they are unable to identify or act upon their vulnerability or difficulties.

Intervention Options

The type of intervention options included in a JITAI should be theoretically and empirically-driven, guided by the types of proximal outcomes the JITAI is intended to affect. Intervention options targeting markers of state vulnerability or short-term progress as the proximal outcomes often draw on the integration of multiple stress-coping and behavior change theories (see Klein et al., 2011 for a full review). Among the theories most often invoked are social cognitive theory (Bandura, 2001); temporal self-regulation theories (Hall & Fong, 2007); self-determination theory (Deci & Ryan, 2010); the health belief model (Janz & Becker, 1984); the theory of planned behavior (Ajzen, 1985); components of cognitive behavioral therapy (e.g., Bang et al., 2007; Morris et al., 2010); motivational interviewing (e.g., Woolford et al., 2010); relapse prevention model (e.g., Gustafson et al., 2011); and many others. Table 2

includes examples of intervention options that build on a variety of theories to target proximal outcomes that concern markers of vulnerability or short-term progress. Intervention options that target proximal outcomes pertaining to engagement and/or burden draw, less explicitly, on theories concerning strategies for increasing participant engagement and/or reducing participant burden (Jochems, et al., 2012). In this section we focus on design considerations for including intervention options that deal with participant engagement and/or burden.

Managing participant engagement and burden. To maintain engagement, it is important that intervention options in a JITAI involve careful considerations of habituation and boredom. Since intervention options in a JITAI often are offered frequently, intervention scientists might consider presenting and delivering supportive content in a variety of ways to prevent habituation. For example, instead of delivering the same message multiple times (e.g., a message recommending an intervention), the JITAI might draw from a "bank" that includes various messages whenever the participant is in need (as indicated by the decision rule) (Franklin, Waller, Pagliari, & Greene, 2003; Linn, van Weert, Smit, Perry, & van Dijk, 2013; Piette, 1999). Additionally, the JITAI might vary the type of signal (e.g., notifications, alerts, pings) used to prompt and engage the participant in the content (Paterson et al., 2010). In sum, varying the presentation of the same supportive content can be a powerful strategy for reducing and preventing habituation, and hence increasing the efficacy of the JITAI (Mulvaney, Ritterband, & Bosslet, 2011).

Boredom can be prevented by focusing on increasing stimulation (i.e., inspiration and motivation) and connection (i.e., sufficient social interaction or fit with the person's needs and context) (Conrad, 1997). In the context of a JITAI, this can be done by (a) developing and implementing a variety of intervention options, such as various types of messages and/or recommended activities; (b) designing intervention options that maintain an optimal level of challenge, namely one that generates sufficient interest yet prevents persistent frustration and failure (D'Mello, Olney, Williams, & Hays, 2012; Engeser & Rheinberg, 2008); (c) incorporating immediate rewards and feedback (Fukuoka, Kamitani, Bonnet, & Lindgren, 2011); (d) including intervention options that are interactive, such as games (Lee et al., 2010)

and interactive visual displays that represent progress and goal attainment (Consolvo et al., 2008); (e) facilitating user participation and autonomy, for example, by incorporating user preferences and suggestions in intervention options (Boyer et al., 2012; Fukuoka et al., 2012); and (f) encouraging/facilitating social interaction, for example, by harnessing social networks (Marsch & Ben-Zeev, 2012). In sum, the effectiveness of a JITAI can be improved substantially by planning for possible boredom when selecting and developing intervention options.

To reduce burden, intervention options in a JITAI should involve careful considerations of participant cognitive overload, as well as contextual constraints on using the intervention, such as time and location. Interventions delivered in real-time may be particularly sensitive to the effects of cognitive overload given their likely deployment in multiple task settings (e.g., the participant may receive the intervention when performing additional tasks, such as walking, or interacting with others) (Harrison, Flood, & Duce, 2013). One approach to minimizing cognitive overload is presenting intervention options in a way that is short and clear (Kommers & Hooreman, 2009). This is particularly important when the target population is older adults, people with less education, and/or people who are unfamiliar with computerized and mobile devices (Fukuoka, et al., 2011). Other approaches to designing intervention options that minimize cognitive load are summarized in the literature on multimedia and computerized learning (Mayer & Moreno, 2003; Moreno & Mayer, 2000).

In terms of contextual constraints, there are many situations in which the participant cannot view or use the recommended intervention, including when they are driving a car, interacting with others, or in a meeting or class. In such cases, efforts to provide an intervention will not be successful. Other examples might include situations where the participant has recently experienced a large dose of the intervention (e.g., received the urge surfing intervention 3 times/day over past few days). Indeed, empirical evidence (see Shin & Dey, 2013 for review; as well as Lu et al., 2011) and theories (Geser, 2004) suggest that increased usage of mobile devices, and the easy access to smartphones at any time and in any place may lead to increased burden and untimely use of the phone (e.g., while driving). As such, when designing a JITAI, intervention scientists may wish to explicitly include a "*provide nothing*" intervention option,

namely an intervention option that provides no intervention at a decision point. A "*provide nothing*" intervention option can be used in the decision rules to address situations and circumstances where the use of the mobile device in general, or the provision of support in particular, may not be feasible or may even be counterproductive.

Tailoring Variables

In this section, we discuss design considerations pertaining to the selection of tailoring variables in a JITAI; the measurement of the tailoring variables in a JITAI; and missing data on the tailoring variable.

Selection of tailoring variables. The selection of tailoring variables in a JITAI should be guided by theoretical, practical and clinical considerations. This includes theories concerning variables that ***moderate*** the effect of the intervention options on the selected proximal outcomes. The pattern of moderation suggested by these theories and/or empirical evidence should indicate that the tailoring variable is useful for making intervention decisions. By "useful" we mean that the tailoring variable (e.g., smoking urge; social context) can be used to identify specific types of experiences (e.g., high smoking urge) or contexts (e.g., being around people who smoke) under which individuals are likely to benefit from one intervention option (e.g., recommend an urge management intervention) as opposed to another (e.g., provide nothing).

The selection of the tailoring variables should also be guided by the type of pathways (i.e., proximal outcomes) through which the JITAI is designed to affect the distal outcome. As discussed earlier, the JITAI is often designed to affect the distal outcome by influencing multiple proximal outcomes. In this case, different tailoring variables might be considered for each proximal outcome. For example, assume that an intervention scientist is interested in developing a JITAI that will reduce smoking (i.e., the distal outcome) by reducing momentary negative affect (proximal outcome #1), reducing momentary urge to smoke (proximal outcome #2); reducing the number of cigarettes smoked per day (proximal outcome #3); and minimizing possible burden resulting from the intervention options

(proximal outcome #4). In this case, different information from the participant in the form of different tailoring variables might be needed in order to make decisions that will affect each proximal outcome.

Note that the intervention options required to influence each pathway might differ as well. For example, to reduce negative affect, an emotion-regulation intervention might be recommended depending on the participant's momentary level of negative affect (tailoring variable #1), and to reduce smoking urge, an urge-management intervention might be recommended depending on the participant's momentary level of smoking urge (tailoring variable #2). Additionally, to reduce the number of cigarettes smoked per day, an encouraging message might be offered at the end of each day depending on the number of cigarettes smoked during that day relative to the goal the participant assigned (tailoring variable #3). Finally, to minimize burden, the frequency of intervention options delivered per day might be reduced depending on the number of intervention options the participant received in the prior day (tailoring variable #4), and a "*provide nothing*" intervention option might be used when information from the participant indicates that s/he cannot utilize the emotion-regulation or the urge-management interventions (tailoring variable #5); this includes when the participant is in a meeting, or driving a car. Overall, a JITAI might include multiple tailoring variables, each selected based on the various proximal outcomes the JITAI is intended to achieve.

Notice that in the example above, some of the proximal outcomes are used as tailoring variables. Specifically, in this example the participant's current level of negative affect (tailoring variable #1) is used to individualize the intervention options to attenuate subsequent levels of negative affect (a proximal outcome); and the participant's current level of smoking urge (tailoring variable #2) is used to individualize the intervention options to attenuate subsequent levels of smoking urge (a proximal outcome). In general, the decision rules in a JITAI can use information about previous or current values of a proximal outcome to individualize the intervention options. However, tailoring variables in a JITAI are not limited to proximal outcomes targeted by the intervention. For example, an urge-management intervention might be provided to reduce momentary urge to smoke (proximal outcome) depending on (a) current levels of smoking urge; (b) presence of other smokers; and (c) the location of the participant (e.g.,

in a bar). In this example, one proximal outcome is addressed by intervention options that are individualized based on three tailoring variables. The motivating assumption is that all three variables are useful in identifying individuals for whom providing an urge management intervention, as opposed to providing nothing, will prevent an increase, or facilitate a reduction, in momentary urge to smoke.

Measurement of tailoring variables. When using active assessments to measure tailoring variables, it is helpful to give careful consideration to the dynamic theories that informed the selection of the tailoring variables. Suppose an investigator is constructing a JITAI using urge management options to reduce smoking, and decides to use active assessment of momentary negative affect as a tailoring variable. In this setting, affect is conceptualized as a dynamic construct, with meaning and operationalization that are different from a more static scientific approach in which negative affect is conceptualized as a long-term personality trait (Diener, Smith & Fujita, 1995). Active assessment of a dynamic construct can be challenging; for example, participants may start to skim over or even ignore parts of an instrument that is presented several times a day (Bolger, Davis, & Rafaeli, 2003; Shiffman, 2009), likely reducing measurement reliability and validity. This consideration must be balanced against the need to measure the construct frequently enough to obtain an accurate picture of the dynamic process.

Passive assessment of tailoring variables is becoming more feasible as sensors of various kinds become more sophisticated and cost-effective. Typical modern-day smartphones include a wide range of embedded sensors (e.g., an accelerometer, magnetometer, camera, GPS, microphone, screen proximity sensor, and the touchscreen itself) which can potentially be used to make inference about emotions, stress, physical activity and social interactions (Lathia et al., 2013). Capitalizing on these existing sensors, as well as additional sensors (e.g., wearable accelerometer, temperature and humidity sensors, hand movement sensors, electrocardiogram: ECG, Galvanic Skin Response: GSR: see Sun et al., 2012) has the potential to considerably reduce the burden associated with obtaining information from the individual for use in individualizing the intervention.

Tailoring variables might be constructed from summaries of sensor data (R. M. Kaplan & Stone, 2013; McClernon & Choudhury, 2013; Wu, Dasgupta, Ramirez, Peterson, & Norman, 2012); these

summaries might also incorporate self-reported information (Dunton et al., 2014; Pitta et al., 2006; Tudor-Locke & Myers, 2001). For example, information from a GPS (to capture risky location); ECG (to capture increased heart rate; Gould & Tanapat, 1999), and self-reported urge to smoke might be summarized to form a composite score that marks a state of heightened vulnerability to smoking (i.e., composite risk score). This summary would then be used to identify individuals who would benefit from an urge-management intervention vs. the "provide nothing" option. Constructing summaries that are useful for individualizing intervention options in a JITAI requires an iterative process involving the use of machine learning algorithms and clinical expertise (Boyer et al., 2010; 2012).

Whether assessment of a tailoring variable is active, passive, or both, careful consideration must be given to reliability and validity, because good measurement of tailoring variables is essential for effective JITAIs. Recall that the decision rules in a JITAI provide the link between the tailoring variable and the best intervention option. A highly reliable and valid tailoring variable is required in order for the decision rule to direct the participant to the best intervention option with a high degree of accuracy. In contrast, when the tailoring variable is unreliable, the decision rule will perform little better than randomly assigning individuals to intervention options, and when the tailoring variable is invalid, the decision rule may even direct participants to a counterproductive intervention option. For example, consider a JITAI that uses a sedentary behavior (i.e., sitting for 30 minutes) tailoring variable inferred from sensors in order to intervene by providing a recommendation to walk. Suppose the measurement is not reliable, so that it captures considerable random variability (noise) in addition to the actual sedentary behavior (signal). Consequently, using this assessment tool might result in unsystematic assignment of the recommendation that bears little relation to participant sedentary behavior. Now suppose the measurement is reliable, but invalid; specifically, it produces a high rate of false positives by incorrectly classifying the participant's behavior as sedentary when in fact s/he was active. This bias leads to unnecessary prompts to engage in activity. Both examples illustrate how poor measurement of tailoring variables can undermine the effectiveness of a JITAI.

Missing data on the tailoring variable. When designing a JITAI, intervention scientists should anticipate and plan the functioning of the decision rule when the tailoring variable is missing. Missing data can occur for various reasons (see Eagle & Pentland, 2006; as well as Scherr et al., 2006), including: (a) data corruption (e.g., loss of data due to technical problems associated with how the data is stored); (b) device detection failures: this is relevant in passive data collection where the sensing device fails because of technical limitations (e.g., temporarily poor or absent mobile phone reception), (c) human error, including errors resulting from the phone being shut off or separated from the user, or errors resulting from misunderstandings in correctly using the device or self-monitoring; (d) poor compliance with the intervention (e.g., participants who do not adhere to a weight loss program are less likely to self-report food intake); and (e) burden associated with self-monitoring (e.g., participants not providing self-monitoring information because self-monitoring is too burdensome). In the case of (d) and (e), indicators of missingness may be used as tailoring variables that are indicative of poor engagement and/or high burden. In all cases, it is important to anticipate situations that may lead to missing data on the tailoring variable(s) and ensure that there are decision rules that cover these situations.

Characteristics of Good Decision Rules in a JITAI

Good decision rules in a JITAI are based on an accurate and comprehensive model of the relations between the tailoring variables, the intervention options, the various proximal outcomes and the distal outcome. This includes a clear understanding of how the effect of a particular intervention option (as compared to another option) on the proximal outcome is expected to differ across values of a tailoring variable, at a specific decision point. This means that for every decision point and for each value of the tailoring variable, the investigator should be able to articulate which of the intervention options will have the greatest impact on the proximal outcome. An example of such a model can be found in the early work of Zubin and Spring (1977) which builds on the idea that challenges experienced by individuals will lead to adverse health outcomes depending on the level of stress elicited by these events and the capacity of the individual to tolerate it. This model is useful for guiding the construction of decision rules in a JITAI as it articulates the situations and circumstances in which a person might be vulnerable and hence would

benefit from receiving support (vs. no support), compared to other situations in which the person might not need support (Ben-Zeev, et al., 2013b; 2014).

The more comprehensive and accurate the model is, the greater the potential for achieving efficacious intervention. A comprehensive model often requires the integration of prior empirical evidence, scientific theory in the area, and prior clinical or prevention experience. It also requires assembling a multi-disciplinary team, involving behavioral scientists, clinicians, computer scientists, engineers and human-computer interface specialists for thinking through the various implications of specific decision rules, while taking into account technical constraints. Such a multi-disciplinary team should carefully think through and discuss questions such as, "If at [a specific decision point], we were to offer [this intervention option] to individuals with [this value of the tailoring variable], what treatment effect would be expected in the short term on [the proximal outcome]?"

Challenges and Directions for Future Research

The major gap that hinders the development of efficacious JITAIs concerns the lack of specificity of behavioral theories and the static nature of these theories (Riley et al., 2011). As discussed earlier, the development of efficacious JITAIs can be guided by a scientific model that integrates theories concerning the emergence and abatement of a vulnerable state, theories that focus on temporal progress and setbacks in the process of adopting and maintaining health behaviors, and theories that concern engagement and burden resulting from the provision of real-time interventions. However, most existing theories are not dynamic, treating mechanisms pertaining to vulnerability, progress, and engagement/burden as relatively stable features, which at most vary as a function of baseline variables, such as personal characteristics (e.g., age, gender) and baseline symptom severity. Moreover, existing theories that do conceptualize mechanisms pertaining to vulnerability, progress, and engagement/burden as dynamic, are often limited in that they do not articulate (a) how frequently and to what extent these mechanisms might change over time; (b) how and why their temporal nature might vary between people and within a person; and (c) when and what kind of support should be offered to immediately address these mechanisms.

For example, consider emotional distress, which is a well-known marker of an emerging state of vulnerability (Zubin & Spring, 1977). Although existing theories acknowledge that emotional distress is a dynamic construct that changes over time, and hence needs to be regularly monitored and addressed (Cooper, Cartwright, Payne, & Cooper, 2001; Segerstrom & O'Connor, 2012), current theories and models do not specify its temporal dynamics, namely how frequently emotional distress might change over the course of a day or a week (Segerstrom & O'Connor, 2012). Moreover, emotional distress is known to be experienced more frequently among individuals with specific characteristics (e.g., occupation or personality traits), and at specific times (e.g., at work) (Affleck, Tennen, Urrows, & Higgins, 1994). Yet, to guide the development of a JITAI that aims to ameliorate temporal experiences of emotional distress as a proximal outcome, a comprehensive model that articulates more specifically how temporal experiences of emotional distress might vary as a function of the interplay between stable and dynamic personal, social and environmental features is needed. Finally, although various types of evidence-based supportive interventions exist to ameliorate emotional distress, their translation and effective application in a just-in-time setting, if feasible, requires the integration of dynamic engagement and burden theories that guide the timing and form of support provision. This can be challenging given that dynamic and comprehensive models of engagement and burden are rare and incomplete (Marlatt & Donovan, 2005; Simpson & Joe, 2004).

In the absence of theory, choices concerning decision points and the form of individualization in a JITAI should be made in a more exploratory manner, namely via exploratory studies and secondary data analyses. To enable such systematic exploration, new experimental design and data analysis methods are needed. These data analysis methods would enable investigators to utilize empirical evidence in selecting and refining the different components of JITAIs, thus informing the development of more efficacious JITAIs. New methodologies are also needed to test and inform the development of dynamic health behavior models that can guide the development of efficacious JITAIs.

Conclusion

This article provides an organizing scientific framework to guide the construction of interventions that use mobile devices to offer support in a timely and adaptive manner. As we enter a new era of technological capacity for individualizing and delivering just-in-time interventions, it is critical that academic research catch up via the development of sophisticated and nuanced psychological and health behavior theories capable of guiding the construction of such interventions.

Table 1

Examples of Decision Rules in JITAIs

Examples	Decision rule	Decision point	Tailoring variables	Intervention options
Substance abuse intervention based on composite risk assessment	*At random EMA prompt* *If composite substance abuse risk ≥ R_0* *Then, IO = [recommend intervention]* *Else if composite substance abuse risk < R_0* *Then, IO = [encouraging message]*	Random prompt	Composite risk	Recommend intervention *OR* Encouraging message
Participant does not access intervention within M minutes	*At M minutes following a random EMA prompt* *If composite risk ≥ R_0 and intervention access in past M minutes= NO* *Then, IO = [message encouraging intervention use]* *Else if risk < R_0 or intervention access in past M minutes= YES* *Then, IO= [provide nothing]*	*M* minutes following random prompt	Composite risk; Intervention access in past M minutes	Message encouraging intervention use *OR* Provide nothing
Physical activity intervention using passive assessments of step-count	*At 4pm* *If current accumulated step-count < P_0* *Then, IO= [recommend exercise]* *Else if current accumulated step-count ≥ P_0* *Then, IO = [encouraging message]*	4pm	Current accumulated step count	Recommend exercise *OR* Encouraging message
Responding to participant request using active assessments of stress	*At participant-initiated help request* *If self-report stress ≥ S_0* *Then, IO= [recommend relaxation]* *Else if self-report stress < S_0* *Then, IO = [recommend one of other interventions]*	Participant request for help	Self-reported Stress	Recommend relaxation *OR* Recommend one of other interventions
Responding to passively assessed risky location, using active assessments of urge	*Every 3 minutes,* *If location = close to a liquor store,* *Then,* *If self-report urge ≥ U_0* *Then, IO= [send alert to sponsor]* *Else, self-report urge < U_0* *Then, IO = [recommend an intervention]* *Else, if location = not close to a liquor store* *Then, IO = [provide nothing]*	Every 3 minutes	Passively assessed location; self-reported urge	Alert sponsor *OR* Recommend an intervention *OR* Provide nothing
Participant ignores request for assessment	*At M minutes following a random prompt* *If EMA completion = NO* *Then, IO = [TXT encourage EMA completion]* *Else if EMA completion = YES* *Then, IO = [provide nothing]*	*M* minutes following random prompt	EMA completion	Text encouraging EMA completion *OR* Provide nothing

Note. IO=Intervention option.

Table 2
Examples of Intervention Options in JITAI

Type of support	***Instrumental.*** Intervention options that offer tangible resources for problem solving	***Emotional.*** Intervention options aiming to encourage and enhance one's self-worth
Examples	• Recommending and/or training the participant to use coping strategies, either behavioral (e.g., exercising or playing a game; Patrick et al., 2009; setting goals or modify previously set goals: King et al., 2013; Pelligrini et al., 2012), or cognitive (e.g., reframing and relaxation techniques: Vidrine et al., 2006); • Motivational messages to help the participant reflect on his/her reasons and/or barriers for changing their unhealthy behavior(s) (Riley et al. 2008) • Feedback (often visual) about progress to encourage self-reflection and aid in the behavior modification process (Consolvo et al., 2008; King et al., 2013; Lin et al., 2006) • Reminders to perform particular tasks, such as taking medication (Gerber, Stolley, Thompson, Sharp, & Fitzgibbon, 2009). • Prompts to self-monitor specific behaviors, such as physical activity or food intake (Patrick et al., 2009). • Educational information to improve participant understanding of specific health conditions, consequences and mechanisms for change (Granholm et al., 2012; Suffoletto et al., 2013).	• Content that acknowledges, encourages and praises tangible achievement (Dennison et al., 2013) and/or progress towards goals (Riley et al., 2008). • Content that expresses care, concern, acceptance and empathy (Lin, 2011).
Source of support	***Automated.*** Intervention options that are fully automated, provided by a computerized system without involving, facilitating or encouraging social interactions.	***Social.*** Intervention options that facilitate and/or encourage the provision of support from other people.
Examples	• Automated goal-setting and tailored feedback on progress (Achterkamp, Cabrita, Hermens, & Vollenbroek-Hutten, 2013; Richardson et al., 2007) • Automated promotes/reminders (Bauer, de Niet, Timman, & Kordy, 2010; Fry & Neff, 2009; Lieberman & Naylor, 2012) • Automated tailored motivational, and/or self-management messages (Free et al., 2011; Quinn et al., 2011).	• Reporting tangible achievement to peers and/or family members (Rotheram-Borus et al., 2012) • Enabling social sharing, social comparison and/or competition among individuals working toward similar goals (e.g., participants using the same mobile health application or participating in the same face-to-face intervention program) (Rotheram-Borus, et al., 2012; Toscos, Faber, Connelly, & Upoma, 2008) • Encourage people with similar goals to provide tips and advice (Rotheram-Borus, et al., 2012) • Initiate contact with family members, sponsors or health professionals when participant is in need (Dennison et al., 2013).

Mode of delivery?	***Support Provision.*** Intervention options that provide support without requiring the participant to initiate or seek help.	***Support Availability.*** Intervention options that the participant can access and use regardless of location and timing (Matthews et al., 2008).
Examples	• Prompts or reminders (e.g., to self-monitor, or take medication) (Cole-Lewis & Kershaw, 2010). • Delivering recommendations (e.g., to use a specific type of intervention: Bock et al., 2013; Heron, 2011) via text messages, emails, or phone calls (Holtz & Whitten, 2009; Kim & Kim, 2008). • Sending alerts to health care providers, sponsors or family members to inform them that the patient is at-risk and facilitate social contact (Nundy et al., 2012). • Triggering (i.e., activating) specific types of interventions (Witkiewitz et al., 2014).	• Making specific content (e.g., intervention modules, useful websites, videos, tips and feedback) accessible to participants, so they can use it when needed (Gerber et al., 2009; Morris et al., 2009, 2010; Przeworski & Newman, 2004) • Allowing the participant to seek help from family-members, friends, sponsors or health care provides (e.g., via a "help-seeking" button that the participant can press in times of need, and that will send an alert to a family member) (Franklin, et al., 2003; 2008).

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