Is providing mobile interventions "just-in-time" helpful? An experimental proof of concept study of just-in-time intervention for stress management

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Abstract— **Although there is growing interest in using mHealth approaches to provide just-in-time [JIT] intervention elements tailored to current emotional states in real time, critical evidentiary questions remain unanswered. This study was a 'proof of concept' evaluation to see if, in the context of a manualized stress management program, adding JIT intervention reminders via mobile technology would enhance outcomes more than the provision of random (untailored) reminders (both also relative to a measurement only active control condition). Individuals participated in a stress management course and carried a palmtop computer for 11 days (2 days acclimation and assessment, 1 week intervention, and 2 days post-treatment assessment). For the intervention week participants were assigned to one of three groups and either: (a) only completed self-report assessments multiple times each data (using ecological momentary assessment [EMA]; (b) completed EMA and received random reminders to use stress management skills; (c) completed EMA and received JIT tailored reminders to use stress management intervention elements when high stress or negative affect were reported. Individuals receiving JIT reminders reported stressful events less frequently, lower stress severity, less negative affect, lower levels of a stress biomarker (cortisol), less frequent eating, less alcohol consumption, less smoking and better sleep quality than the other two groups at post-treatment assessment. Tailored mHealth interventions designed in conjunction with ambulatory assessment protocols to provide JIT intervention elements can improve the efficacy of a standard stress intervention above and beyond any effects of simple reminders or over the intervention training. Implications for mHealth and JIT interventions are discussed.**

I. Introduction

Developments in the sophistication and affordability of mobile technologies – including mobile phones, smartphones, and wearable or environmental sensors – have contributed to the growing mobile health (mHealth) field, which uses mobile and wireless technologies to assess status and deliver physical or behavioral health-related services. The use of mobile devices to quantify experiential aspects of daily life is not new in behavioral health fields, with formalized experience sampling and ecological momentary assessment (EMA) methods being commonly used to collect self-report data in natural settings as early as the late 1980s (1;2). Although originating from more 'low-tech' roots (e.g., paper diaries), studies using EMA approaches over the last two decades have often utilized custom-programmed mobile electronic devices to collect self-report data from individuals as they go about their normal daily life. Typically this has been accomplished by programing electronic devices to signal individuals to complete assessments on a predetermined schedule (e.g., at semi-random times throughout the day), asking individuals to self-initiate assessments at particular times (e.g., breakfast, lunch, dinner), and/or in response to specific events (e.g., interpersonal conflict, stressful events, cigarette craving) (2). Somewhat more recently, wearable sensors that are smaller, have greater measurement fidelity, and longer battery capacity have allowed for the concurrent assessment of a wide and growing range of physiological and behavioral parameters as well. This approach of collecting reports from daily life is advantageous because it increases real-world (ecological) generalizability. Furthermore, because EMA and related approaches allow people to report on current or recent states and experiences – particularly for constructs such as emotions and thoughts that cannot yet be automatically or passively measured – this limits memory errors associated with lengthy recall periods and/or global summaries and judgments that are typical for other assessment techniques (see 2;3;4).

In addition to using mobile technology to assess ongoing and dynamic states in natural settings, it is also possible to use such time-varying information to deliver interventions. For example, mobile phones can be used to send text message reminders or intervention content (5;6) and smartphone apps have more recently been used to collect information and provide intervention components (e.g., 7;8). Although there are potentially many benefits of using mHealth approaches to deliver health interventions (9), one of the most widely cited advantages is the opportunity to make treatments available during times and in places or situations when patients may be most in need of intervention. Put simply, this approach assumes that matching the timing of the provision of intervention or intervention components (e.g., reminders) should enhance treatment outcomes. Such mHeath intervention approaches that are informed by, and delivered to, individuals in daily life have come to be known as ecological momentary interventions (EMI) (10;11) or, more recently, just-in-time (JIT) interventions. These approaches are designed to provide intervention content at appropriate moments or contexts. More recently, this has been further extended to include just-in-time adaptive interventions (JITAI) that allow these explicit decision rules

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about when to apply intervention elements to change or adapt over time (12;13). With these approaches, by using mobile technology and EMA to assess current cognitive, affective, behavioral, and/or physiological states, environmentally responsive interventions can be tailored to patients' needs at that moment and administered in real time on the mobile device, thereby creating an interactive and dynamic treatment strategy for use in everyday life.

As noted, the utility of these approaches is predicated on the idea that providing interventions "just-in-time" – or only at specific times when patients may be most in need of intervention – will improve the efficacy of treatments. Most studies testing JIT intervention approaches, however, have (in our view) lacked the appropriate comparison conditions (control groups). Although some studies include no control or comparison conditions at all, those that do typically compare JIT intervention to a control group that receives no intervention. Such comparisons, assuming JIT intervention superiority in the treatment effect, demonstrate that the provision of JIT intervention enhances outcomes over doing nothing. Although the intuitive and conceptual appeal of this approach is clear (cf. 14), this design does not provide information regarding the relative contribution of providing interventions "just-in-time" as compared to 'simple' or un-tailored reminders delivered using mobile technology in daily life. To our knowledge, there have been no studies to determine whether tailoring the timing of the delivery of mobile interventions increases their efficacy beyond simple 'random' (or un-timed/tailored) reminders providing the same content – this issue is at the conceptual heart of JIT intervention. The goal of the present study was thus to conduct a very simple proof of concept study to determine if tailoring the timing of intervention delivery improves its efficacy over interventions delivered at randomly scheduled times (each also relative to a measurement only control condition) using a stress management intervention as a reasonable test case.

EMI or JIT intervention are especially useful in fields such as stress management because reporting the occurrence of a stressor represents a discrete event that can be targeted with *real-time* interventions delivered in the *real world*. For this proof of concept demonstration, we chose to implement the study on a very simple palmtop computer device that was not internet connected; this approach had the benefit of stripping away additional potential confounds, such as auxiliary device usage, information searching (e.g., on intervention components), etc., that accompany many commonly used devices (e.g., smart phones). In the present study, all participants completed a highly standardized stress-management intervention and reported their daily stress and other experiences several times daily using EMA. Subsequent to completing the stress management training, one third of participants were randomly assigned to also receive tailored mobile JIT intervention reminding them to use stress management techniques when they reported high levels of stress or negative affect (EMA+Tailored), another third received mobile interventions at random times throughout the day (EMA+Random), and the remaining third only completed the EMA (EMA only; this was to control for any measurement effects of the intensive self-monitoring). It was predicted that for both mood and stress, individuals receiving tailored micro-interventions (i.e., treatment reminder prompts) would experience superior outcomes to both other groups, followed by those who were given random reminders. Exploratory analyses examined the effect on health behaviors with the same general pattern of results expected (i.e., greatest benefit for tailored mobile interventions, least benefit for no mobile interventions).

II. METHODS

A. Participants

A self-selected sample of ninety adult volunteers (58% female) self-identifying as "highly stressed" were recruited via public service announcements to participate in a stress management study. Given these recruitment methods, this sample may be high in terms of 'treatment seeking' and thus evidence greater engagement with the EMA and intervention (e.g., better adherence) than would other samples. Participants ranged in age from 18-58 (mean = 34.7), were mostly married or cohabitating (68%), diverse in income (range <$10,000/year to >$150,000/year family income; median ~$48,000/year), and predominately Caucasian (91%).

B. Materials

Baseline Assessment. A number of psychological self-report measures (e.g., personality characteristics, social support, stress levels) were collected at baseline prior to receiving stress management. These were not used for the current study and are thus not discussed further.

Stress Management Training. Trained doctoral level psychology students conducted a standardized two-hour stress management course with participants in groups of 2-6. This intervention consisted of empirically supported components addressing stressor appraisal and relaxation training. The stressor appraisal portion used cognitive-behavioral strategies to help participants become aware of thoughts and feelings regarding stressful experiences through various exercises (e.g., cognitive restructuring, reappraisal). The relaxation-training component involved teaching and practicing diaphragmatic breathing and discussing the benefits of using this technique during stressful experiences. This course was developed based on a manualized stress management intervention that has been shown to reduce stress in community and patient populations (e.g., 15).

EMA Survey. Mood was assessed with adjective-checklist measures adapted for EMA timescales to determine to what extent participants felt each of a number of emotions at the time of the prompt. Negative mood was assessed using the adjectives depressed, unhappy, angry, frustrated, and worried; positive mood using happy, joyful, enjoyment, and pleased. All items were on a scale from 0 (*not at all*) to 6 (*extremely*) and were summed (within positive and negative) to create composite scores. Participants next indicated if they had experienced a stressful event since the last assessment (*yes/no*; used to compute stress frequency) and if they responded affirmatively, they reported the stress severity (0=*not at all stressful*, 6=*extremely stressful*). Items regarding several health behaviors were next presented, and participants reported eating, smoking, and alcohol consumption. After completing the EMA survey, participants received a reminder to take a saliva sample using a provided sterile collection device. Participants later returned the saliva sample, which

was used to assay for cortisol, a naturally occurring hormone that increases in response to stress and is a sensitive indicator of biological stress responses in daily life (16). Additionally, participants were asked to report on their sleep quantity (in hrs/min) and sleep quality (how well did you sleep, on scale of 0=*not at all* to 6=*extremely*) at waking each day.

C. Micro-interventions

As appropriate to their randomly assigned group condition, some participants received what we termed 'micro-interventions', consisting of reminder prompts to implement the stress management skills that were delivered on the mobile device screen. A total of 27 unique prompts existed, 16 corresponding to stress appraisal components (e.g., "You learned about the potentially negative effects of catastrophizing; take a moment and evaluate if your worries or other thoughts are out of proportion to the situation.") and 11 corresponding to relaxation components (e.g., "Recall that even a few diaphragmatic breaths can reduce stress; if your current context allows for it, take 5 mindful breaths."). To enhance engagement, within each class of prompts (appraisal/relaxation), reminders were delivered in random order and did not repeat until the set had been depleted.

Participants assigned to the EMA+Random group received three daily reminders at semi-random times (distributed so that it was likely to receive one each in the morning, afternoon, evening, although specific times varied) immediately after completing the EMA survey and again 10-20 minutes later. Of note, the provision of these reminders, as well as which content type they received (appraisal or relaxation), were unrelated to the content of EMA reports (i.e., were not JIT intervention, but rather mere reminders). In contrast, individuals in the EMA+Tailored group were given micro-interventions whenever their EMA reports of stress or negative affect were moderately high or high (operationalized in this simple proof of concept study as being ≥ 1 SD above the person-centered mean on the relevant construct, either stress or negative mood). The micro-interventions were administered immediately after completing the EMA survey and again 10-20 minutes later. Thus, for this group, the timing of the delivery was contingent upon high stress or negative mood, and thus reflected JIT intervention logic.

Finally, participants in both of the micro-intervention groups (i.e., the EMA+Random and EMA+Tailored) could review synopses of the stress management appraisal skills and the relaxation training strategies on the provided device if they had forgotten the skills associated with a micro-intervention reminder. This option was not available to the EMA only (measurement control) group.

III. PROCEDURE

The university Institutional Review Board approved this protocol and all participants provided informed consent prior to beginning the study. Participants first completed a baseline assessment of psychological and personality variables that were potential moderators of treatment response (these are not used in this report) and then took part in a two-hour stress management course. Participants were then provided with custom programmed (Satellite Forms, Intellisync/Thacker, Alberta, Canada) palmtop computers (m105, Palm Inc., Sunnyvale, CA) that were not capable of connecting to the internet and were stripped of all other non-study functions and applications. Participants also were given a tutorial on general care and use of the devices and detailed instructions and training on how to complete the EMA assessments. Subsequent to stress management and EMA training (to maintain investigator blinding and reduce potential bias), participants were randomly assigned to one of the three experimental groups: EMA assessments only, EMA plus random micro-interventions (EMA+Random), or EMA plus tailored JIT intervention (EMA+Tailored). Participants carried the devices for 11 consecutive days following a specific sequence. The first 2 days were considered an acclimation and baseline period and consisted of EMA reports at waking and 5 times daily in response to audible signals for all participants regardless of condition. For the following week, EMA reports continued at waking and 5 times daily; additionally, those in the micro-intervention conditions (EMA+Random or EMA+Tailored) received reminders as described above (i.e., at random or JIT intervention tailored times, respectively). Following this 'active' week, micro-interventions ceased for all groups and participants completed a final 2 days of post-treatment assessment (again at waking and EMA 5 times daily). Given random assignment to intervention arms, the data from this final 2 day interval were used in all group comparisons. After all study procedures were completed, participants returned the palmtop computers to the laboratory and were provided $60 compensation for their time and return of study equipment (Fig. 1).

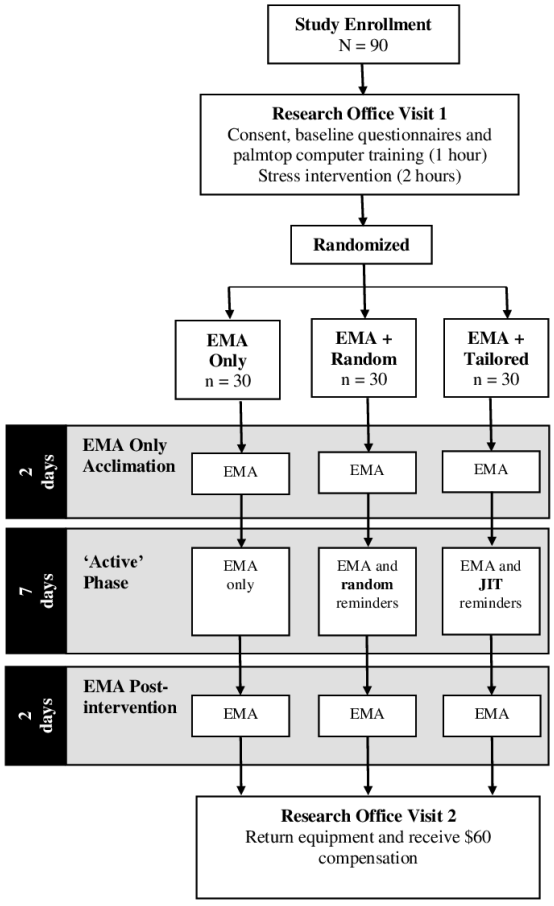

Figure 1. Study procedures.

IV. RESULTS

Multi-level random effect models in PROC MIXED in the SAS statistical software package were used to account for the nested data structure (e.g., assessments are nested within days, days within people) and partial missing data (i.e., missed reports) inherent in EMA data. Models were fit with random intercepts (as individuals differ in average levels) and unstructured covariance structure (to account for the unequal time intervals between EMA assessments). We used $p>.05$ to determine statistical significance for all inferential tests. The effect of experimental group on the average EMA reports of mood, stress, salivary cortisol and health behaviors in the final 2 day evaluation period (when all micro-intervention had ceased) was tested and, when significant, followed by planned contrasts between the three groups. We predicted that the EMA+Tailored group would report lower stressor frequency, stress severity, NA, and cortisol, and higher PA than the other two groups. We also hypothesized that the EMA+Random group would fare better than the EMA only group on all of the above variables. More exploratory secondary analyses examined the effect of experimental group on more distal (relative to stress) EMA reported health behaviors (e.g., eating, smoking, alcohol use, sleep quantity and quality), and the same pattern of results was expected (EMA+Tailored group would have best outcomes).

Compliance with study procedures was generally excellent. No participants dropped out of the stress management training class delivered at study outset and qualitative reports suggested that the intervention was well-received. Random assignment was successful, with no group differences observed on any baseline measures. Compliance with EMA reports was excellent, with 89% of assessments completed (81% within 5 minutes of the signal). There was no significant drop-off in compliance rates over time (by day of study) and the experimental groups did not differ in their overall rates of EMA compliance.

A. Primary Outcomes

The results showed that experimental group predicted the frequency of stressors reported on the EMA during the post-intervention period ($p<.01$). As predicted, the EMA+Tailored group reported that stressful events occurred less frequently than both the other groups (16% of all EMA reports), followed by the EMA+Random group (24% of EMA reports), which reported significantly less frequent stressful events than did the EMA only group (32% of all EMA reports; see Fig. 2). Stress severity during the post-intervention period was also predicted by experimental group ($p<.05$), with both micro-intervention groups reporting lower average stress severity scores than the EMA only group, although the EMA+Tailored and EMA+Random groups were not significantly different from each other (Fig. 3). Mood analyses showed that experimental group predicted negative mood ($p<.01$) during the post-intervention period; the EMA+Tailored group reported the lowest mean level of negative mood (significantly different from both other groups), and the EMA+Random group reported significantly less negative mood than the EMA only groups (Fig. 4). Contrary to predictions, positive mood was not significantly predicted by group ($p=.12$; the pattern of means was in the predicted direction). We next examined if there were reliable group differences in our biomarker of stress, salivary cortisol, over the final 2 assessment days of the study. Results showed experimental group predicted average cortisol levels ($p<.01$). As predicted, this effect followed a step-wise function, with the EMA+Tailored group showing the lowest cortisol levels (significantly lower than the other two groups), followed by the EMA+Random group, which was significantly lower than the EMA only group (Fig. 5).

B. Secondary Outcomes

The effect of experimental group on health behaviors reported on the EMA surveys during the post-intervention period was also examined in a more exploratory fashion. Eating frequency (any eating, including snacking) was predicted by group ($p<.05$), with both micro-intervention groups reporting eating less frequently than the unprompted group. Alcohol consumption was predicted by experimental group ($p<.05$); the EMA+Tailored group reported less alcohol consumption (number of units) than the other two groups (which did not differ from each other). Smoking was analyzed only for participants who reported any smoking behavior ($n=38$), and was significantly predicted by group ($p<.05$); both micro-intervention groups reported smoking fewer cigarettes than the EMA only group. Inconsistent with predictions, sleep quantity was unrelated to group assignment ($p=.42$). Sleep quality, however, was predicted by experimental group ($p<.05$), with the EMA+Tailored group reporting better sleep quality than other two groups (which were not significantly different from one another).

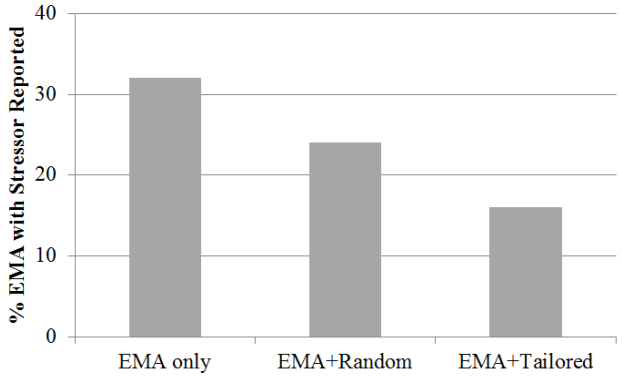

Figure 2. Stressor frequency

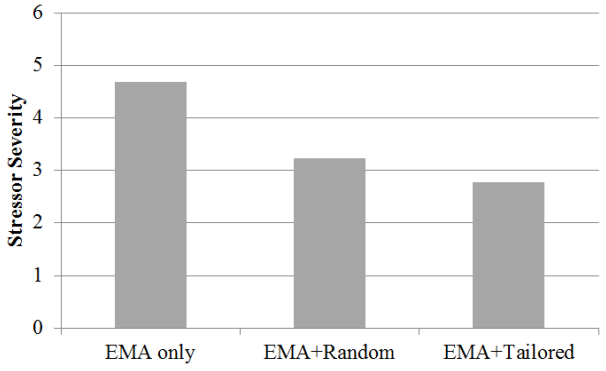

Figure 3. Stressor severity

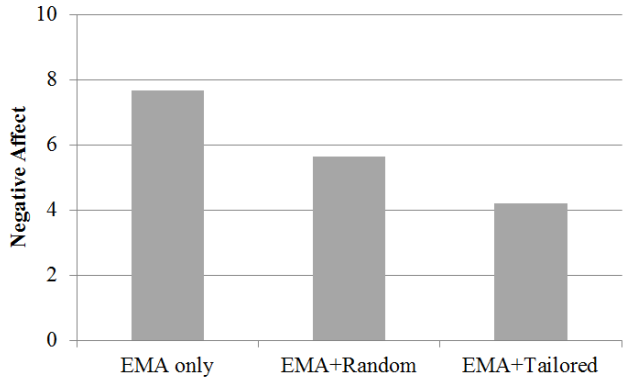

Figure 4. Negative mood

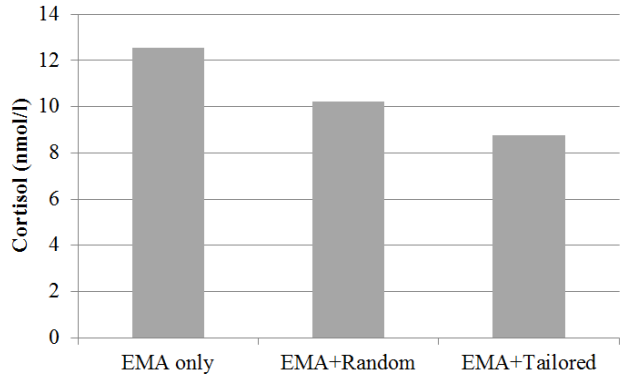

Figure 5. Salivary cortisol

V. Conclusion

Although advances in mobile technologies have greatly increased interest in developing mHealth interventions, there has been relatively little empirical research into some of the fundamental issues underlying such approaches. In this study, we examined if the temporal linking inherent to the logic of JIT intervention (i.e., providing intervention elements at times of need) leads to enhanced outcomes over more stringent comparison conditions; namely, including not only a measurement/reactivity control group, but also a group receiving random/non-tailored intervention reminders that were otherwise matched in content to the JIT intervention condition. To test this proof of concept, this study used an empirically validated stress management intervention and applied simplistic, top-down *a priori* decision rules to test the JIT intervention on devices without connectivity or any other non-study capabilities or features. We predicted that the JIT intervention, providing micro-intervention elements at specific times when people would most likely benefit from using stress management techniques (i.e., when high stress or negative mood were reported via EMA in daily life) would be more effective than both micro-interventions with identical content provided at random times throughout the day or no micro-interventions.

Results showed participants who received JIT intervention (i.e., micro-interventions at times of high stress or negative mood) reported fewer stressors, lower stress severity, less negative affect, lower levels of a stress biomarker (cortisol) and some evidence of more positive health behaviors than those who received micro-interventions at random times (EMA+Random) or not at all (EMA measurement only). Importantly, the present findings provide the first evidence of which we are aware from a randomized trial demonstrating that providing interventions "just-in-time" – that is, at times when people may be most in need of support – offers an added benefit over providing interventions at arbitrary times that are not linked to participants' real-world states or experiences. One other essential element to this proof of concept demonstration is the possibility that JIT intervention may elicit powerful demand characteristics and reporting biases. In other words, the repeated administration of intervention elements, and the associated expectations, may result in study participants altering self-reports and/or behaviors to 'fit' the experimental demands; if this occurs, this may result in overestimating JIT intervention benefits. Our approach mitigated this concern in two ways – the non-tailored (random) reminders should largely produce similar expectancies and we also included a stress biomarker (salivary cortisol) that should be uninfluenced by such reporting or demand characteristics – further strengthening the demonstration that JIT intervention produces benefits beyond expectancies.

More topically, the provision of the JIT intervention in daily life appeared to greatly enhance the efficacy of a standardized stress management intervention; this is consistent with previous studies demonstrating similar effects for mHealth approaches to other psychological conditions and health behaviors (17;18;19). Early studies delivering ambulatory interventions often either provided intervention content at fixed (e.g., 10:00am, 2:00pm) or random times throughout the day (17;18;19). More recent studies developing JIT intervention (or JITAI) are beginning to tailor the timing of intervention materials based on people's self-reported or objectively measured states or experiences (e.g., 7;8). Previous research has provided promising, although sometimes inconsistent, findings that mobile electronic devices can be effectively used to implement psychological and health behavior interventions (10). One explanation for the inconsistent findings may be that – in many mHealth interventions – treatment is not delivered at specific moments when participants are especially in need of additional support.

We and others have noted that JIT intervention appear to be especially useful in problem domains that have distinct antecedent states (e.g., cravings/urges, experience of negative emotions) or events (e.g., stressors, mealtimes, distressing situation) for which ambulatory assessments and interventions can be developed. As ambulatory assessment devices for physiological, emotional, behavioral, and environmental states (20;21;22;23;24;25;26) become more sophisticated (including native smart phone sensors as well as an ever-expanding suite of wearable devices), people's momentary physiological states and environmental

conditions will also be used to trigger and tailor real time interventions. Although these systems have yet to be carefully evaluated and fully integrated into intervention design, there is great potential to create interactive treatments for use in everyday life that are dynamically and adaptively sensitive to internal and external cues and states.

Our efforts to design a clean and simple proof of concept study also produced several notable limitations. The JIT intervention application in this study was based on a broad heuristic of high stress or negative mood (1 SD above the person mean on each). Although straightforward, this approach has notable problems – for example, it does not fully account for individual differences in levels and distributional characteristics of stress and emotional variability, or changes in variability over time. Next steps in this approach are to utilize more sophisticated within-person dynamical models that capture multiple features of affective experiences (e.g., including level, variability, rates of change, etc., and that adapt and update over time; see also 27;28). Ongoing work also explores alternatives to using self-reported triggers; for example, using objective behavior (e.g., 24), physiological parameters (e.g., 25;26), and exploring mixed-methods that leverage continuous passive/automatic sensing in conjunction with EMA based self-report in order to validate the presence of specific experiential states (e.g., 23). Other groups are exploring a wide range of machine-learning and related discovery informatics approaches at both the between-person and within-person levels (e.g., 29;30; see also 31); we expect each of these methods to provide interesting, and potentially unique, insights. For this initial study we also used a mobile device with very few capabilities; although this provides the advantage of removing a range of potential confounds, it also clearly does not leverage the ever-increasing capacity of current mobile devices that have shown promise in enhancing intervention approaches (e.g., GPS integration; 32). Our current work attempts to integrate a wider range of these capabilities in a variety of intervention contexts and theoretical approaches.

Despite the relative simple implementation of this proof of concept study, this is the first study to experimentally manipulate JIT intervention delivery timing to test if providing interventions "just-in-time" provides an added benefit over providing content-matched reminders at random (non-tailored) moments in everyday life. This is an important and, we believe, essential demonstration of a core principle underlying JIT intervention-based mHealth approaches that we hope stimulates continued research on these fundamental conceptual issues.

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