Just-in-time Delivery of Cognitive Behavior Therapy Based Exercises: A Single Case Experimental Design with Random Multiple Baselines

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Abstract

Background: Just-in-time adaptive interventions (JITAIs) are a promising approach in mental health care. Typically, a smartphone application (app) is programmed to assess users' psychological states in daily life; when a particular state is detected, the app prompts users to engage in specific behaviors. JITAIs are thought to be a promising approach – yet, scarce evidence is available in the literature.

Objective: We implemented this scheme as an online intervention for daily stress management, based on cognitive behavioral therapy (CBT), and evaluated its feasibility and efficacy using a single-case experimental design.

Methods: Eight Japanese adults (community sample: four women; mean age = 37.6 years, SD = 13.1) were recruited. An AB phase design with multiple random baselines was used. Throughout the study period (28 days), participants were prompted to indicate their momentary levels of stress using a smartphone thrice a day. The length of the baseline phase was randomly permuted across participants (7-14 days), and the remaining period was used as the intervention phase (14-21 days), where CBT-based exercises (e.g., breath control, mindfulness, and relaxation) were offered depending on the reported levels of stress.

Results: Approximately 70 % of the participants perceived the intervention to be useful and helpful. A randomization test detected a statistically significant decrease in the reported levels of stress after the onset of the intervention (P=0.004), although this effect was marginal when tested separately for each participant. Multilevel model analysis detected a significant acute reduction in the momentary level of stress right after completing an CBT-based exercise (P=0.03, Cohen's dz=0.58). Also, a significant reduction in depressive rumination was observed in the postintervention assessment (P=0.01, Cohen's dz = 1.17).

Conclusions: The intervention was feasible and effective in reducing subjective stress (and rumination) in the study sample, although more evidence should be collected to draw robust conclusions. Clinical Trial: OSF: https://osf.io/3b5tp/?view_only=822e6357a8f442409285921e4b15e060

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The authors have no conflict of interest to declare concerning this study.

Abstract

Background: Just-in-time adaptive interventions (JITAIs) are a promising approach in mental health care. Typically, a smartphone application (app) is programmed to assess users' psychological states in daily life; when a particular state is detected, the app prompts users to engage in specific behaviors. JITAIs are thought to be a promising approach – yet, scarce evidence is available in the literature.

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Methods: Eight Japanese adults (community sample: four women; mean age = 37.6 years, SD = 13.1) were recruited. An AB phase design with multiple random baselines was used. Throughout the study period (28 days), participants were prompted to indicate their momentary levels of stress using a smartphone thrice a day. The length of the baseline phase was randomly permuted across participants (7-14 days), and the remaining period was used as the intervention phase (14-21 days), where CBT-based exercises (e.g., breath control, mindfulness, and relaxation) were offered depending on the reported levels of stress.

Results: Approximately 70 % of the participants perceived the intervention to be useful and helpful. A randomization test detected a statistically significant decrease in the reported levels of stress after the onset of the intervention (P=0.004), although this effect was marginal when tested separately for each participant. Multilevel model analysis detected a significant acute reduction in the momentary level of stress right after completing an CBT-based exercise (P=0.03, Cohen's *dz*=0.58). Also, a significant reduction in depressive rumination was observed in the postintervention assessment (P=0.01, Cohen's *dz* = 1.17).

Conclusions: The intervention was feasible and effective in reducing subjective stress (and rumination) in the study sample, although more evidence should be collected to draw robust conclusions.

Keywords: ecological momentary assessment; just-in-time adaptive intervention; stress; rumination; cognitive behavior therapy; mindfulness

Introduction

Background

Digital technologies have become familiar not only in daily life, but also in clinical practice for mental health. The electronic and mobile implementation of psychological interventions allows for the remote and ubiquitous delivery of evidence-based care, which is of particular importance to people who have limited access to clinics due to financial or physical constraints [1]. The COVID-19 pandemic has been a turning point [2], that has accelerated the R&D of digital healthcare services. These services can be delivered in various formats and platforms, such as computer- or Internet-based interventions, via chat systems or naïve smartphone applications (apps), with or without human therapeutic guidance. Stakeholders appear to see mobile implementations as one of the most promising directions, given the number of apps available in the market and the huge amount of investment in recent years [3].

An increasing number of efficacy and effectiveness trials have been published in recent decades, and the results have been synthesized from different aspects. For example, a meta-analysis of digital interventions in general showed a moderate effect on improving depression [4]. Another meta-analysis, with a particular focus on app-based mobile health interventions [5] found small effects on anxiety and depression. A meta-analysis of app-based interventions for moderate to severe depression reported a larger, moderate-sized effect [6]. Overall, the evidence has been mixed, which may be attributed to heterogeneity in the intervention designs and how each intervention (or technique) is delivered.

The rapid development of mobile technologies has expanded the degrees of freedom in implementing care and interventions offered digitally and automatically. Ecological momentary interventions (EMIs) are a general scheme for delivering psychological interventions in daily life, typically for which an app is programmed to obtain information from users and prompt them to engage in specific behaviors at opportunistic times [7–9]. Many EMIs are designed to be just-in-time adaptive interventions (JITAIs), which deliver interventions remotely that are personally tailored and implemented on the basis of an individual’s context (e.g., with the GPS in a mobile device), psychophysiology, or responses to questions. As such, a JITAI provides right treatment (i.e., "adaptive") at the right moment (i.e., "just-in-time") [10].

Decision rules, which define what interventions to deliver and when [10], are the core of EMI and make its shapes heterogeneous. A variety of interventions are offered in EMIs, such as cognitive behavior therapy (CBT), acceptance and commitment therapy, mindfulness, behavioral activation, and relaxation (for a review, see [11]). Furthermore, different trials have used different logic to define delivery interventions. For example, a JITAI trial assessed participants’ experiences of stressful events and related ruminative thinking several times a day, which were then used to determine which messages and CBT-based support needed to be delivered [12].

Objectives

However, EMI and JITAI are still in their infancy, and to the best of our knowledge, there are no established designs (particularly decision rules) that promise the success of an intervention. It is pivotal to accumulate exemplars with different implementations and test various decision rules, as there are a number of parameters to optimize when designing a JITAI. What interventions or techniques should the system offer in its pool? What psychological and behavioral states should be monitored, and how? What conditions should be implemented to trigger or inhibit an intervention? Apropos this, the current study was designed as a pilot example of JITAI, implementing decision rules to offer different CBT techniques for stress management, depending on the momentary states of app users.

Specifically, we aimed to evaluate the feasibility and efficacy of an app-based intervention with just-in-time prompts using CBT-based exercises for stress reduction. The key idea was to provide an opportunity to engage in CBT exercises (including relaxation, body scans, self-compassion, distancing, and cognitive restructuring) when needed, that is, when elevated stress levels are detected. We were interested in the feasibility (e.g., adherence, acceptability, and usability) of this approach as well as its efficacy in reducing stress over a 2–3-week intervention. We regarded this study as a pilot, proof-of-concept trial and used a single-case experimental (AB phase) design with random multiple baselines (baseline for 7-14 days vs. intervention for 14-21 days) to test the hypothesis that participants would show significant decreases in subjective stress.

Methods

Participants

Eight adults (mean age = 37.6 years, SD = 13.1; 4 women) were recruited from among inhabitants of Ibaraki Prefecture and its environs (middle-north regions in Japan) early in 2024. The study was advertised online (e.g., via portal sites and emails), and those interested were invited to an online eligibility assessment. Participants were assessed for their current levels of subjective stress by responding to an item from the perceived stress scale (*In the last week, how often have you felt nervous and stressed?*) [13] by indicating the most applicable of the five response options: 0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often, and 4 = very often. Those who scored 3 or 4 were eligible to participate in the study. Other inclusion criteria were as follows: aged 20-64 years; expecting no major life changes right before or during the study participation; not pregnant or lactating; being in good health with no history of dysautonomia, depression, mania, bipolar disorder, or facial paralysis; no medication with tranquilizers or antihypertensive agents; not under hormone replacement therapy; no oral contraceptives; and no habit of physical activity and exercise (this criterion was used for an overarching study). Recruitment continued until the planned sample size was achieved. The sample size was determined pragmatically (considering the resources of the recruiting institution) due to the pilot nature of this study. Yet, a simulation study [14] suggested that a sample size of N = 6-10 would be sufficient to detect an effect of Cohen's d = 0.60- 1.0 with a sufficient power (0.80).

Study Design

An AB design with random baselines was used. The entire study period was 28 days (four weeks) for each participant. The length of the baseline phase was randomly permuted across participants, ranging from 7 to 14 days, and the remaining period was used as the intervention phase (14-21 days). Throughout the 28-day study period, participants received three signals each day at fixed times (1100, 1600, and 2100hrs) on their smartphones. These momentary cues prompted participants to indicate their current levels of subjective stress using a 0-100 slider (0 = *not at all*, 100 = *very much*). The exact prompt states were as follows: *We would like to ask you about your current stress level. Please rate your current stress using the slider below.*

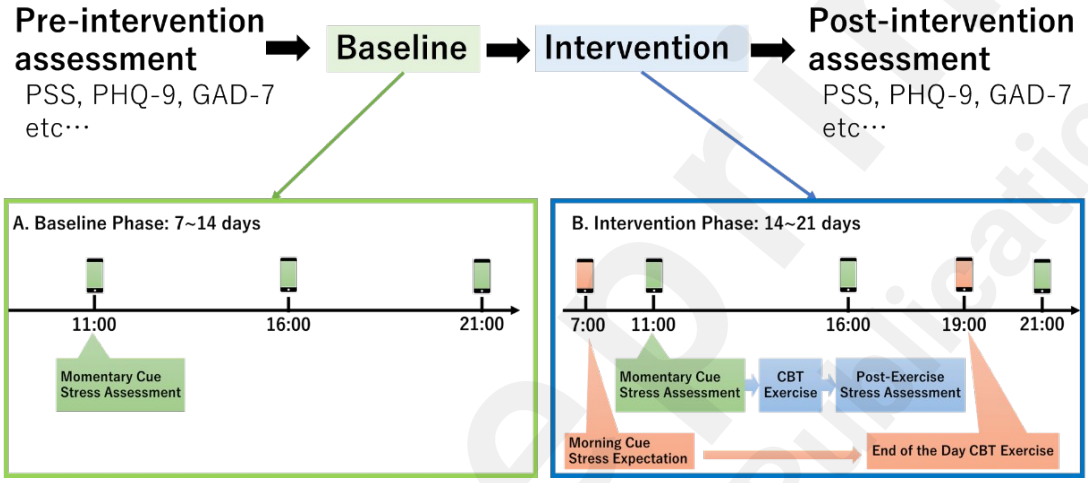
During the intervention phase, participants received in-app guidance for CBT exercises (see the next section) depending on the reported momentary levels of subjective stress. For example, if participants indicated 80 or above on the stress slider, they received a recommendation for muscle relaxation, guided by a tutorial video (3-9 min long each). Participants were allowed to engage in an exercise that was not recommended at this moment (e.g., performing breath control instead of or in addition to muscle relaxation) or skip the opportunity if they were too busy. In addition, if participants indicated low levels of stress (i.e., < 40 on the slider), they received no specific recommendation for exercise.

At the end of the exercises, participants were asked to specify the exercises in which they actually

engaged (this prompt appeared even when no recommendation was presented). Specifically, they indicated any applicability from the list of exercises (i.e., breath control, mindfulness, progressive muscle relaxation, compassionate self-talk, cognitive defusion, and cognitive restructuring) with *other* and *skipped (too busy)* response options. Subsequently, participants rated their current stress levels again using a 0-100 slider. Post-exercise stress levels were subjected to randomization tests as the primary outcome.

In addition to the momentary cues, participants were prompted each morning to estimate how busy they would be today; depending on the estimated levels, they received another in-app guidance for CBT exercise at 1900hrs, on the day. The morning cue stated: *How busy do you expect to be today? Use the slider below to indicate how busy you expect to be today.* We asked how busy they would be instead of how stressful the day would be because we were not sure how accurately participants could estimate the stress level of the day; instead, estimating the extent of busyness was deemed more reliable and easier for participants as they could refer to, for example, their schedules.

Figure 1. Schematic flow of the study



CBT Exercises

Different CBT exercises were prompted depending on the reported levels of stress in response to the momentary and morning cues. Table 1 summarizes the individual exercises and decision rules. Among the techniques used in CBT and related programs [15,16], we implemented the following six exercises into the current program: breath control [17]; mindfulness [18]; progressive muscle relaxation [19]; compassionate self-talk [20]; leaves on a stream exercises [21]; and cognitive restructuring [16]. These techniques are deemed to suit the mobile implementations, which can be packaged as stand-alone exercises requiring no in-person support or interactions with professionals (i.e., each instructed via videos for 3.5 – 9.0 min).

The first three exercises (breath control, mindfulness, and muscle relaxation) were prompted by momentary cues. These quick-to-go exercises (less cognitive, typically with a particular focus on the body and meditation) were selected because momentary cues were scheduled thrice a day and each exercise should not be too demanding. Another focus was on the levels of stress, and we programmed breath control for low levels of stress, mindfulness for moderate levels, and muscle relaxation for high levels. We expected that the participants (a community sample) would experience low levels of stress most frequently, for which a hands-free light-touch exercise was deemed appropriate. Therefore, the breath-control tutorial video was the shortest (3.8 min) of the three (9.0 and 5.5 min for mindfulness and progressive muscle relaxation, respectively).

The other three exercises (compassionate self-talk, leaves on a stream exercises, and cognitive restructuring) were programmed for morning cues and were to be completed in the evening (at

1900hrs or later). These imaginative or cognitive exercises were performed once a day (which is less frequent than those for the momentary cues), and thus were meant to be more cognitively effortful, and typically required a longer time to complete. Compassionate self-talk was prompted when participants indicated that they would be somewhat busy today, in response to a morning cue. Leaves on a stream exercises and cognitive restructuring were recommended when participants expected that the day would be tougher. These decision rules were determined arbitrarily, but compassionate self-talk was assumed to be less effortful and better fit on the day when light stress was foreseen compared to the other two.

Table 1. Decision rules defining exercises prompted for different levels of stress

Cue / stress level threshold	Exercise	Description / example instruction
Momentary cues		Participants responded to momentary cues thrice a day, and exercise was offered right after each momentary cue.
0-39	No exercise prompted	
40-59	Breath control	Take deep breaths while counting the numbers in your mind.
60-79	Mindfulness (focusing on breath)	Pay attention to your breathing and savor the sensation.
80-100	Progressive muscle relaxation	Reduce stress and anxiety by progressively tensing and then relaxing different muscle groups in the body.
Morning cues		Participants responded to a morning cue each day (0700hrs) and indicated how busy they would be today; exercise was offered at 1900hrs each day.
0-39	No exercise prompted	
40-59	Compassionate self-talk	Repeat in your mind a phrase that is warm and compassionate toward self.
60-79	Leaves on a stream (cognitive defusion)	Imagine leaves flowing down a river and observe the thoughts and feelings that arise.
80-100	Cognitive restructuring	Recall negative events, write down thoughts and feelings, and assess whether your evaluations are accurate.

Measures

We administered two types of assessments: momentary, and pre- and post-intervention assessments. Our primary outcome was the momentary post-exercise levels of subjective stress reported following the momentary cues, which were sent three times daily over the 28-day study period. The pre- and post-intervention assessments included questionnaires on subjective stress (over the past month), psychopathological symptoms and traits, and well-being. The post-intervention assessment also included feasibility measures to clarify how acceptable and appropriate the intervention was for each participant. Note that we did not examine the internal consistency of each measure, given the small sample size. However, all the measures used here have been shown to have good psychometric properties.

Perceived Stress Scale

Subjective stress levels were assessed using the 10-item Perceived Stress Scale (PSS) [13]. The scale asks how respondents felt and thought during the past month (e.g., *how often have you been upset because of something that happened unexpectedly*?). Each item is rated on a 5-point scale (0 = never; 4 = very often), and the total score is calculated. A validation study documented a mean score of 20.3 (SD = 5.4) in a Japanese sample [22], in which a PSS score of 31 or greater (> mean + 2SD) can be interpreted as a high level of subjective stress.

Brief Patient Health Questionnaire

Depressive symptoms were assessed using the brief Patient Health Questionnaire (PHQ-9) [23]. This scale consists of nine items representing depressive symptoms rated using a 4-point scale (0 = not at all; 3 = nearly every day). The sum score was calculated and interpreted with cut-off scores of 5, 10, 15, and 20, indicating mild, moderate, moderately severe, and severe depressive symptoms, respectively.

Seven-item Anxiety Scale

Anxiety and symptoms of generalized anxiety disorder (GAD) were assessed using the 7-item anxiety scale, GAD-7 [24]. Each item represents typical GAD symptoms (e.g., nervousness and excessive worry), rated using a 4-point scale (0 = not at all; 3 = nearly every day). The sum score was calculated and interpreted with cutoff scores of 5, 10, and 15, indicating mild, moderate, and severe levels of anxiety, respectively.

Response Styles Questionnaire

Ruminative response styles to depressed mood were assessed using the Response Style Questionnaire (RSQ) [25,26]. The brooding subscale was the target of our interest, which is known to be predictive of depression and anxiety (e.g., Raes & Hermans, 2008). This subscale has 5 items (e.g., *Think "Why can't I handle things better?"*), and each is rate using a 4-point scale (1 = almost never; 4 = almost always). The sum score was calculated.

Hedonic and Eudaimonic Motives for Activities Scale

Hedonic and eudaimonic conceptions of well-being were assessed using the Hedonic and Eudaimonic Motives for Activities scale (HEMA) [28]. The HEMA has two subscales: hedonic and eudaimonic. The former assesses pleasure and the absence of pain and is subdivided into two factors: seeking relaxation (two items) and seeking pleasure (three items). The eudaimonic subscale consists of four items, reflecting e.g., authenticity and excellence. Each item is rated using a 7-point scale (1 = not at all; 7 = very much), and the sum scores are calculated for the eudaimonic, seeking-relaxation, and seeking-pleasure subscales.

Feasibility

Immediately after the intervention phase, participants rated the feasibility of the intervention online. Specifically, they rated the following aspects using a 7-point scale (1 = not at all; 7 = very much): the intervention was (a) satisfactory, (b) useful, (c) helpful, (d) suited to me, (e) appropriate timing, (f) practical, and (g) I would like to continue using this intervention system (e.g., [29]).

Procedure

Eligible participants were invited to the laboratory individually for a briefing session. They received study instructions and mobile devices (a smartphone and activity tracker) for assessment and intervention. After providing written informed consent, participants completed questionnaires on stress and symptomatology (e.g., the PSS, PHQ-9, etc.). The baseline phase began on the day after the briefing. The randomization sequence for the baseline length was generated prior to recruitment and masked to the participants. Upon completion of the intervention phase, participants completed the post-intervention questionnaires (online) and returned their lab devices in exchange for compensation for study participation. The study protocol was approved by the Ethics Committee of the National Institute of Advanced Industrial Science and Technology (ID: 2022-1240). The registered protocol is available from Open Science Framework [30].

Statistical Analyses

Momentary levels of stress, reported three times daily (for the intervention phase, those reported immediately after the exercises), were aggregated within each day to reduce the proportion of missing values when passing the data to the randomization tests. The aggregated scores were then subjected to randomization tests to establish the effect of the intervention, which was operationalized as the mean difference in the stress score between the baseline and intervention phases. A randomization test permutes the condition assignments of each assessment occasion for a person, which mimics the random assignment used to test a null hypothesis about the treatment effect in a randomized experiment [31]. For example, for a participant who received an assignment sequence of AABBBB for T1-T6 assessment occasions (i.e., the first two occasions were the baseline and the following four were in the intervention phase), the observed test statistic is given by the mean of T1-T2 minus that of T3-T6. Then, a randomization test calculates the test statistics for each possible permuted sequence (e.g., ABBBBB, AAABB, AAAAB) to generate a randomization distribution, on which the observed test statistic (here: T1-T2 minus T4-T6) is located to test the null hypothesis, for example, no treatment effect exists. The p-value is given as the proportion of the observed value equal to or smaller than the values from the permutated sequences. We set the alpha level to 0.05 and generated random permuted sequences 5000 times. Randomization tests were conducted on each participant and group of participants [32]. The R package SCRT [31], was used to conduct the randomization tests.

As an exploratory analysis (not preregistered), a multilevel model was estimated to test whether the momentary level of stress was acutely decreased right after each CBT exercise. The model specified stress as the outcome and time (pre- vs. post-exercise) as the predictor with the random intercept to allow the intercept to vary across participants. Similarly, we tested whether the stress level during the baseline phase would differ from the pre-exercise level during the intervention phase. Multilevel modeling was conducted using lmer4 [33] and lmerTest packages [34].

Results

Demographics and Baseline Characteristics

Eight participants who met the inclusion criteria were enrolled, five of whom were married and had a child/ren. Four participants were unemployed currently. All participants had received higher education, namely, graduated from a two-year college, university, or above. Regarding baseline levels of stress and psychopathology, all participants had experienced high levels of stress, four had mild levels of depressive and anxiety symptoms, and one had moderate levels of symptoms (Table 2).

Table 2. Participants' pre-intervention characteristics

ID	Baseline length (day)	Age	Gender	PSS	PHQ-9	GAD-7	RSQ	HEMA Eud	HEMA Ple	HEMA Relx
1	7	52	M	50	7	9	12	21	18	18
2	8	43	M	42	4	1	17	22	18	16
3	9	22	M	54	3	7	14	28	20	18
4	10	23	M	46	9	8	17	19	16	22
5	11	23	W	58	7	4	13	19	18	21
6	12	52	W	31	4	2	7	21	18	24
7	13	39	W	53	13	12	12	22	18	26
8	14	47	W	37	4	6	12	17	17	13
Mean	-	37.6	-	46.4	6.4	6.1	13.0	21.1	17.9	19.8
SD	-	13.1	-	9.2	3.4	3.7	3.2	3.3	1.1	4.3

Note. Gender = self-identified. PSS = Perceived Stress Scale; PHQ-9 = Brief Patient Health Questionnaire; GAD-7 = 7-item anxiety scale; RSQ = Response styles questionnaire, brooding scale; HEMA Eud, Ple, Relax = Hedonic and Eudaimonic Motives for Activities scale: Eudaimonic, Seeking-pleasure, Seeking-relaxation subscales, respectively.

Dropout and dose

All participants completed the pre- and postintervention assessments (no dropouts were observed). One participant (ID 4) showed low compliance (responded to 9 out of 30 momentary cues [30%] during the baseline phase and 2 out of 72 momentary cues [3%] during the intervention phase), whose data were thus excluded from the statistical analyses. The remaining seven participants responded to 75.6 % (range: 44.4-90.5 %) of the momentary cues in the baseline phase and 59.7 % (range: 28.1-79.4 %) in the intervention phase. They showed lower compliance with morning cues: 44.3 % (range: 0-92.9 %). The frequency of recommendations and number of engagements for each type of exercise are shown in Table S1. Breath control and mindfulness were recommended and performed most frequently. in other words, participants hardly experienced the highest (80 or above) levels of stress during the intervention period. Four participants performed breath control more frequently than recommended. Similarly, three participants practiced muscle relaxation spontaneously even when not explicitly recommended.

Feasibility

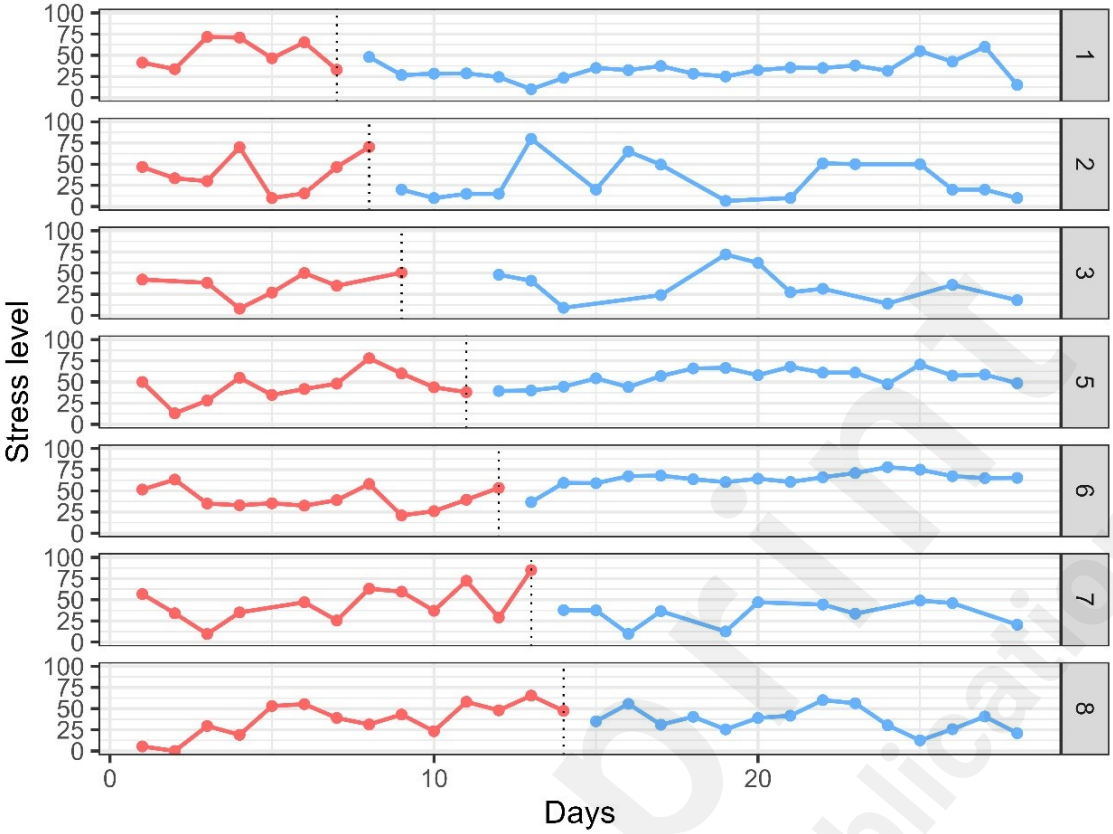
Each aspect of feasibility was rate using a 7-point scale (1 = not at all to 7 = very much), and we counted the number of participants who indicated 4 or higher as an indication of endorsement (Table S2). Most participants perceived the current intervention as satisfactory (63%), useful (75%), helpful (75%), and practical (63%). In addition, most participants reported that they would like to continue the intervention even after the study (75%). However, most participants disagreed that the momentary and morning cues were delivered at appropriate times (88%), which may imply that delivering an intervention at the right timing is still a challenge.

Intervention Effect

Figure 2 illustrates how the stress levels (for the intervention phase, stress reported immediately after each exercise) changed over time. Participants did not show a clear, acute change in the reported

stress levels; however, three participants (ID 1, 2, and 7) appeared to have experience reductions, whereas two participants (ID 5 and 6) showed slight increases during the intervention phase.

Figure 2. Changes in stress level as a function of time.



Note. Each panel indicates the mean stress levels per day for each participant (ID 1-8, except for ID 4, which was excluded due to low compliance). Red = baseline phase; Blue = intervention phase.

The randomization test for all participants (Table 3) rejected the null hypothesis that the stress level would remain unchanged between the baseline and intervention phases, indicating that subjective stress significantly decreased after the onset of the intervention (p = 0.004). However, randomization tests on each participant failed to detect a significant reduction (all ps > 0.05), which appears to be in line with the visual inspection of individual plots (Figure 2) where no clear tuning points were found. As an exploratory analysis, we tested whether the stress level was acutely decreased from the pre- to post-exercise moments. A multilevel model analysis detected a significant decrease, fixed effect = -5.77, t(4.57) = 3.038, p = 0.032, Cohen's dz = 0.582 (pre-exercise: M = 47.98, SD = 21.65; post-exercise: M = 42.13, SD = 19.88). Another multilevel model revealed no significant change from the baseline phase to the pre-exercise moments during the intervention phase, fixed effect = 1.62, t(6.06) = 0.315, p = 0.763, Cohen's dz = 0.013 (baseline: M = 44.34, SD = 20.46).

Table 3. Results of randomization tests

ID	Baseline phase, M (SD)	Intervention phase, M (SD)	p value
1	51.8 (17.2)	33.0 (11.8)	.254
2	40.3 (22.5)	30.8 (23.0)	.127
3	35.9 (14.8)	34.8 (19.8)	.632
4	-	-	
5	44.5 (17.1)	55.4 (9.90)	.517
6	40.6 (13.1)	64.2 (9.06)	.626
7	46.1 (21.7)	34.0 (13.8)	.134

8	37.0 (19.8)	36.8 (13.9)	.124
All participants	42.3 (5.6)	41.3 (13.0)	.005

Note. p-values were calculated for the test statistics, M(intervention)-M(baseline), with the null hypothesis, M(intervention) = M(baseline). ID4 was not analyzed because of low compliance.

We calculated the means and SDs for each measure administered at the pre- and post-intervention assessments (Table S3). Neither well-being nor psychopathology symptoms showed notable changes (Cohen's $dz < 0.35$, $p > 0.360$), except for rumination, which showed a statistically significant reduction over time (Cohen's $dz = 1.17$, $p = 0.013$). Although this result should be interpreted carefully, given the small sample size, the current intervention may help control depressive cognitive styles.

Discussion

This pilot trial aimed to establish the feasibility and efficacy of the JITAI in reducing subjective stress among eight Japanese adults experiencing high levels of subjective stress at enrolment.

Feasibility and adherence

Participants perceived the intervention as satisfactory and helpful; overall, it is appropriate to conclude that the intervention was acceptable. Breath control and mindfulness were the most frequently recommended exercises by the system (because participants typically indicated that they were experiencing low-to-moderate levels of stress in response to momentary cues), and thus were the most frequently performed by participants. Several participants spontaneously performed breath control and relaxation, even when these exercises were not explicitly recommended.
However, the feasibility evaluation revealed a practical issue: participants found that the cues were not sent at the appropriate time. There is an ongoing debate on how to optimize and personalize the intervention timing for an electronic and mobile healthcare system. In general, it is thought that delivering interventions at the right moments (e.g., considering participants' schedules, circadian rhythms, and lifestyles) would increase the likelihood of accepting and adopting the intervention's recommendations, thereby increasing the adherence rate [35,36]. In the current study, one participant failed to respond to most (around 90%) of the momentary cues and therefore missed almost all the opportunities to perform the CBT-based exercises. The remaining seven participants showed good compliance in responding to momentary (sent at 1100hrs, 1600hrs, and 2100hrs each day) and morning cues (at 0700hrs), even though they perceived that these were not the best moments to do so. Participants may have been intrinsically motivated to engage in CBT-based exercises whenever the cues were sent; however, it should be noted that all participants were paid volunteers.

Efficacy

The overall effect of the intervention on momentary subjective stress levels merged across all participants was statistically significant. This result implies that the intervention is effective in reducing subjective stress. However, the randomization tests on individual participants failed to detect significant effects, which may suggest that the size of the effect was too small to be detected with the current design, the statistical power was not sufficient with the number of observations per participant, or both. Another possibility is that the effect of the exercises was short-living – indeed, we found that statistically significant decrease in stress right after completing an CBT exercise, but this decrease did not appear to stay for the entire intervention period. It is also noteworthy that two participants (ID 5 and 6) experienced increases (but did not reach statistical significance) in the intervention phase. We do not have data that readily explain these unexpected increases; both participants received a fair dose, which was comparable to that of other participants (ID 5: breath

control 17 times; ID 6: mindfulness and cognitive defusion 11 times). It is too early to conclude that these exercises had adverse effects on the participants, but the data suggest that they were not responsive to these CBT techniques. Exploring the best prescription of CBT techniques was beyond our scope, but it is important to integrate the P4 health spectrum (predictive, preventive, personalized, and participatory) into a JITAI system to overcome the heterogeneity issue in responsiveness to psychological interventions [37].

Another interesting finding was that participants experienced significant reductions in depressive rumination. This effect was assessed as the difference between the two (pre- vs. post-intervention) time points, and thus, should be interpreted carefully, given the low statistical power. That said, it is fair to say that the current intervention might include a factor that helps reduce cognitive vulnerability (i.e., rumination), such as mindfulness. Mindfulness interventions, even in a brief format or embedded in an EMI, are known to be effective not only in improving symptoms, but also in reducing depressive rumination and repetitive negative thinking [38,39]. We cannot conclude which factors (mindfulness, cognitive restructuring, relaxation, etc.) were the active ingredients, but future research should explore the (combinations of) techniques that should be offered for further optimization (e.g., using a fractional factorial design [40]).

Limitations

This study had some limitations. First, the non-clinical nature of the sample may have limited the clinical implications of the study findings. The mobile implementation of CBT techniques, especially with a just-in-time approach, can guide daily stress management for non-clinical or at-risk individuals. However, it remains necessary to examine whether this approach works in clinical settings as a stand-alone self-help intervention or as an add-on to therapist-guided treatment. Similarly, our sample exclusively consisted of Japanese adults, which may question the generalizability and replicability of our results. Future research should target a wider range of users such as children, adolescents, older adults, and those with different cultural backgrounds. Second, although the single-case design is a powerful tool for investigating the intervention effect in a small sample, it is appropriate to proceed to a larger-scale trial with appropriate controls and long-term follow-ups to establish the efficacy and effectiveness of the intervention. Third, a sampling bias may have affected the results. Overall, we found good compliance, and it is possible that the participants enjoyed the intervention and were intrinsically motivated to participate. However, all participants were paid volunteers and adherence (or user engagement) may not be readily generalized to real-life settings.

Conclusions

The current JITAI implementation of CBT techniques was generally accepted by the participants and was effective in reducing subjective stress and depressive rumination. An important direction for future research is to develop a reliable system to automatically detect psychological distress and stress (e.g., [41]) that can be embedded in the decision rule (i.e., if the sensor detects elevated stress, it triggers a particular intervention). Technological sophistication will improve the usability, adherence, and effectiveness of the intervention.

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Supplementary Files

Multimedia Appendixes

Supplementary tables.
URL: http://asset.jmir.pub/assets/7a7de8516f4aca1c1e379735f2c5818d.docx