Randomized controlled trial of a Cognitive-Behavioural Therapy Mobile Application (INTELLECT) in alleviating anxiety and depressive symptoms among Japanese employees with depressive symptoms

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Abstract

Background: In Japan, the prevalence of anxiety and depressive symptoms within the working population have risen. This has been accentuated by the economic repercussions of the COVID-19 pandemic and the social isolation resulting from remote work setups. Mobile health (mHealth) applications, particularly those incorporating Cognitive Behavioral Therapy (CBT) features, have shown potential in addressing these symptoms. These self-guided CBT interventions hold promise in alleviating the heightened depressive and anxiety symptoms often observed among Japanese employees.

Objective: Using a randomized controlled trial (RCT), we compared the efficacy of the “INTELLECT” app against a no-treatment control group in improving depressive symptoms and CBT skills among Japanese full-time employees at post-intervention and at 2-month follow-up.

Methods: A total of 123 full-time Japanese employees were randomly allocated to either the intervention group (INTELLECT), where they engaged with self-help CBT features, or to a control group receiving no treatment. Intervention participants were required to engage with these features for at least 20 minutes per week over a span of 4 weeks.. Weekly self-reported assessments were collected from all participants starting from baseline and continuing until the end of the 4-week intervention period. Subsequent assessments were conducted at 1-month and 2-month follow-up intervals. Linear mixed models (LMMs) were used to evaluate any effects of the self-guided intervention on depressive symptoms, as measured by the Patient Health Questionnaire-4 (PHQ-4), and cognitive behavioral skills, as measured by the Cognitive Behavioral Therapy Skills Scale (CBTSS). Feasibility, usability, and acceptability ratings of the app were also examined using the Implementation Outcome Scales for Digital Mental Health (iOSDMH).

Results: The final sample (n=73) consisted of 46 (63.0%) female participants, 23 (31.5%) male participants, and 4 (5.5%) participants identifying as other genders, with a mean age of 40.4 (SD=10.7) years. Significant time x group interactions were found at post-intervention and 2-month follow-up, with the intervention group (n=34) reporting significantly lower depressive symptoms than the control group (n=38) at post-intervention (Cohen’s d=-0.57 [-1.07, -0.06]) and 2-month follow-up (Cohen’s d=-0.85 [-1.38, -0.32]). In addition, intervention participants reported significantly greater improvements in self-monitoring cognitive skills than control participants at post-intervention (Cohen’s d=0.68 [0.17, 1.18]) but not follow-up (Cohen’s d=0.50 [-0.05, 1.02]).

Conclusions: This study provides evidence that CBT features on the INTELLECT app are effective in improving depressive symptoms and self-monitoring cognitive skills. Clinical Trial: This RCT was registered with the University hospital Medical Information Network (UMIN) Center (Registration number: UMIN000051354).

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Introduction

Depressive and anxiety disorders wield substantial global influence. The Global Burden of Diseases, Injuries, and Risk Factors Study, for instance, identified depression and anxiety disorders as two of the most disabling mental disorders, ranking among the top 25 leading causes of global burden in 2019 (GBD 2019 Disease Injuries Collaborators, 2020). The COVID-19 pandemic has also seen a notable surge of 27.6% in major depressive disorder cases and a 25.6% increase in anxiety disorder cases in 2020 (COVID-19 Mental Disorders Collaborators, 2021). Similar figures were reported in Japan, where Midorikawa et al. (2021) conducted a nationwide survey of over 8,000 Japanese citizens and found that approximately one-fifth of respondents experienced clinically severe anxiety and depressive symptoms. Numerous studies also found that significant changes in the economic and working conditions caused by the pandemic contributed to a marked increase in symptoms of anxiety and depression among Japanese employees (Miyake et al., 2022; Ueda et al., 2022; Matsubayashi et al., 2022) .

Despite the increasing prevalence of these symptoms, many Japanese employees primarily rely on informal counseling with family members or non-evidence-based self-management strategies for coping (AIG Institute, 2019). Concurrently, there is a growing demand for alternative, accessible mental health care options. Mobile health (mHealth) applications hold significant promise in delivering cost-effective, evidence-based solutions for mental disorders and in facilitating outcome monitoring. These services are especially valuable for socially disadvantaged groups, such as individuals who face barriers in accessing face-to-face clinical services (Ritterband et al., 2003). Such services are also timely given the increasing ownership of mobile devices (IQVIA, 2017, 2021), which has facilitated access to mental healthcare in daily life, overcoming geographical and temporal limitations (Byambasuren et al., 2018; Huguet et al., 2016; Shen et al., 2015). The increase in mental health applications in

Japan is evident from a systematic review conducted between June 4 and June 11, 2021, which identified 172 mental health apps available on Japan's Google Play Store and Apple App Store (Yamamoto et al., 2022). By September 2022, 53% of Japanese smartphone users were engaging with healthcare applications, indicating a remarkable 21 percentage point increase from September 2019 (Fuller, Inc., 2022). The popularity of digital healthcare solutions seems to offer the potential for digital interventions to alleviate the declining mental health of Japanese employees.

Indeed, Linardon et al. (2019) found significantly larger effect sizes for self-help interventions involving Cognitive Behavioral Therapy (CBT) principles in improving anxiety and depression levels compared to no-treatment control groups. In some studies, these self-help CBT features even demonstrated comparable effectiveness and adherence rates to traditional face-to-face therapy (Carlbring et al., 2018; van Ballegooijen et al., 2014). Additionally, these features have reduced depressive symptoms in Japanese adults (Karyotaki et al., 2017). Despite some evidence of these CBT self-help features, little is known about their effectiveness for clinically at-risk working adults with depressive and anxiety symptoms in Asia.

Current study

The primary objective of the study is to examine whether self-help CBT-based features can improve depressive and anxiety symptoms among Japanese full-time employees experiencing mild, moderate, or severe levels of these symptoms. In selecting evidence-based features, the study utilizes "INTELLECT", a mental health application that provides free access to a variety of evidence-based self-help features aimed at enhancing mental well-being for employees and consumers across Asia-Pacific countries. The efficacies for some of these features have been demonstrated in previous randomized-controlled trials (RCT) (Kosasih et al., 2023; Ong et al., 2022; Toh et al., 2022) and longitudinal studies (Toh et al., 2023a; Toh et

al., 2023b). In particular, the CBT-based features within INTELLECT have shown significant improvements in positive (i.e., psychological resilience, body image perceptions, self-compassion) (Ong et al., 2022; Toh et al., 2023) and negative mental well-being (i.e., symptoms of anxiety and stress) (Toh et al., 2022; Kosasih et al., 2023) when compared to active control groups among working adults. However, no studies to our knowledge have tested the effectiveness of these features in clinically at-risk working populations. In an RCT setting, our primary hypothesis posits that the CBT features within the INTELLECT app will demonstrate greater efficacy in reducing symptoms of anxiety and depression among Japanese employees experiencing mild, moderate, or severe levels of these symptoms, compared to a waitlist control group. Our secondary objectives encompass evaluating whether these features also lead to improvements in cognitive behavioral therapy skills and assessing the acceptability, feasibility, and satisfaction levels among its users.

Methods

Trail Design

This study was a RCT with two groups: (1) a group engaging with self-help CBT features on an intellect app for three weeks (intervention group) and (2) a group receiving no treatment and assessment- only group (control group).

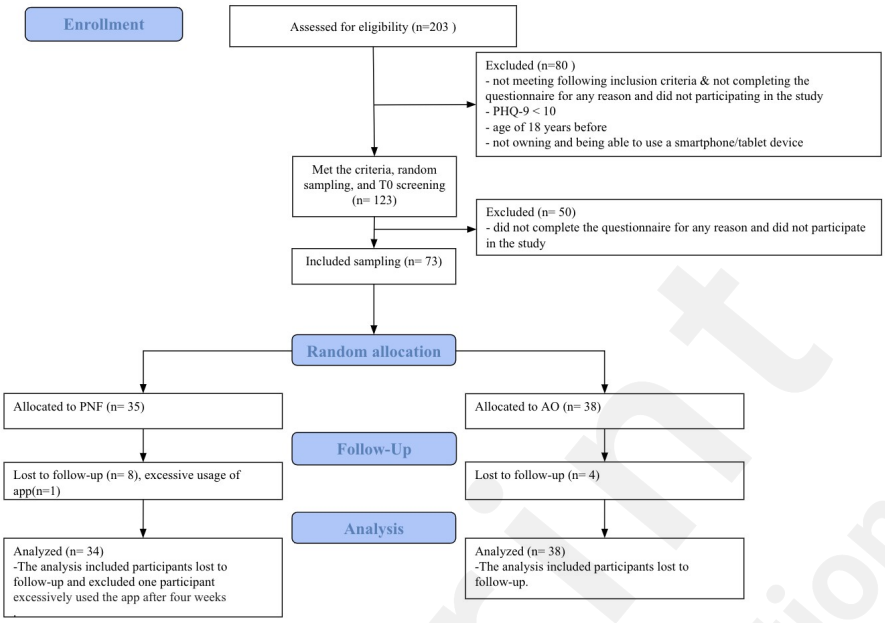
Outcome measures were assessed from baseline and continued until the end of the 4-week intervention period, with subsequent assessments conducted at 1-month and 2-month follow-up intervals. The primary dependent variable measured was depression level while secondary dependent variables included cognitive behavioral skills. Feasibility, usability, and acceptability ratings of the app were also assessed using the Implementation Outcome Scales for Digital Mental Health (iOSDMH).

Participants and Recruitment

A total of 203 participants initially responded to online advertisements for recruitment. Of

these, 130 were excluded from the study due to various reasons, including voluntary withdrawal, failure to complete the questionnaire, or not meeting the study's inclusion criteria (Figure 1). The final sample included 43 female participants (63.0%), 23 male participants (31.5%), and 4 participants identifying as other genders (5.5%). The participants had a mean age of 40.4 years (SD = 10.7) and were all full-time Japanese employees who owned a smartphone. Participants received monetary reimbursement for their participation.

Figure 1 CONSORT 2010 Flow Diagram in this study



Procedure

Participants were initially introduced to the study through online advertisements disseminated from June 16th 2023 to October 31st 2023. These advertisements directed potential participants to recruitment sites where participation information sheets and informed consent were provided. Subsequently, participants followed a link to a secured Google Survey, where participants completed baseline measures on the severity of depression (PHQ-9), various psychiatric symptoms (CCS), and demographic information such as gender, age, occupation, education level, annual income, marital status, types of smartphones owned, and history of treatment for depression and structured psychotherapy for mental disorders to establish baseline ratings. Only full-time Japanese employees aged 18-65 with over mild levels of depressive symptoms (N=121) were then automatically randomized to one of two conditions —intervention (N=59) or active wait-list control (N=62)—using a computer-generated random sequence. Upon consenting to participate in the study, participants completed the primary outcome measure on the severity of depression (PHQ-4) and secondary outcome

measures on the skills related to cognitive behavioural therapy (CBTSS). In this study, they were not informed about the conditions they were allocated to and the real nature of the study. Instead, they were informed that the study would examine the efficacy of the mHealth app (Intellect) in promoting well-being.

Participants in the intervention group were then directed to download the Intellect mHealth application and provided with a unique code to register and access a research version of the app containing only the assigned program. This step was taken to ensure that any observed treatment effects were solely attributable to the program, rather than other features available in the application. It was verified whether participants had downloaded and registered the app through the backend system. Intervention group participants engaged with the "Intellect" application for a minimum of 20 minutes per week over a 4-week period, while active wait-list control group participants accessed the application once the intervention participants had completed the 4-week intervention. Engagement of the app for the intervention group was monitored on a weekly basis and participants were informed when the app engagement was low. Five participants dropped out of the research, either due to low engagement with the app or loss of contact. Additionally, one participant's data will not be included in the analysis due to excessive use of the app after four weeks.

Both intervention and control participants completed a series of self-report measures at seven timepoints: baseline (PHQ-4, CBT-SS), Week 1 (PHQ-4), Week 2 (PHQ-4), Week 3 (PHQ-4), post-intervention (PHQ-4, CBT-SS, iOSDMH), 1-month (PHQ-4), and 2-month follow-up (PHQ-4, CBT-SS). Upon full participation, each participant received 9000 Japanese yen (approximately USD 58) in Amazon Gift Cards as a token of appreciation. Reimbursements were distributed at three different timepoints: Baseline: 1000 Japanese yen (approximately USD 6) Amazon Gift Card, Post-intervention: 3000 Japanese yen (approximately USD 18) Amazon Gift Card, 2-month follow-up: 3000 Japanese yen (approximately USD 18) Amazon

Gift Card.

Intervention

Intellect is a consumer-based mental health application that offers users access to a variety of self-guided, evidence-based features, some of which have been validated in previous randomized controlled trials (Kosasih et al., 2023; Ong et al., 2022; Toh et al., 2022) and longitudinal studies (Toh et al., 2023a; Toh et al., 2023b). The app's 'Home' tab provides access to four main self-care features: 'Learning Paths', 'Rescue Sessions', 'Wellbeing Check-in', and 'Guided Journals'. ‘'Learning Paths' are designed to educate participants using evidence-based content to deepen their understanding and improve their self-management of mental health. For example, the 'Feeling Depressed Learning Path' offers psychoeducation on cognitive distortions linked to low mood and depression, helping users learn how to reframe their thoughts. In other studies, this intervention has been shown to effectively aid users in altering their negative thoughts and emotions. 'Rescue Sessions' are self-guided interventions that focus on addressing specific themes of adversity commonly faced by individuals. These themes include 'overthinking', 'motivation', 'stress management', 'burnout', and 'relationships'. Each session provides targeted support using CBT-based strategies to overcome these challenges. The interventions are firmly rooted in CBT principles to identify and change negative thought patterns and behaviors. 'Rescue Sessions' provide a comprehensive toolkit that enables individuals to strengthen their mental resilience and well-being by selecting the session most relevant to their current struggles. mindfulness, self-compassion, and cognitive behavioral therapy The 'Wellbeing Check-in' feature allows users to evaluate their feelings and stress levels by selecting emojis that best represent their current state. This daily self-monitoring tool encourages participants to track their emotions, fostering greater self-awareness and providing opportunities to manage negative emotions. 'Guided Journals' offer

various themes such as 'reflection', 'problem-solving', 'goal-setting', 'sleep', or 'self-esteem'. Each journal prompts participants to write entries related to these themes, aiding in the identification and restructuring of cognitive patterns. For example, the 'gratitude' journal encourages users to identify and record positive instances of the day, challenging momentary negative thought patterns and promoting cognitive restructuring skills. This practice helps foster a habit of considering alternative perspectives . . Images of these self-care features can be found in Appendix A.

Randomization, Allocation Concealment, and Blinding

Regarding assignment to both participant groups, Intellect Japan's researcher conducted simple randomization using a computer-generated random sequence developed by the researcher. No blocking strategy was employed during the allocation process. Stratification was employed for previous management of depression and structured psychotherapy for mental disorders. To implement the random allocation sequence, a roster of 73 individuals who consented to participate in the study were systematically and alternately assigned to either the INTELLECT or AO groups, commencing from the top of the list. For allocation concealment and blinding, the participants were provided a detailed explanation of the intervention, and the Intellect Japan's researcher created the assignment without reviewing any screening, baseline, or other information about the participants behind previous management for depression and structured psychotherapy for mental disorders.

Measures

Primary Outcome Measure

Patient Health Questionnaire-4 (PHQ-4)

The Japanese version of PHQ-4 is a 4-item self-reported questionnaire for depression symptoms. Items are scored in a 4-point Likert scale (ranging from 0 = "not at all"; 3 = "nearly everyday"), with higher scores indicating more depressive symptoms. In an earlier

study (Doi et al., 2018), this scale demonstrated good internal consistency (alpha=.93) and good convergent validity (correlation coefficient with the Kessler Psychological Distress Scale: r=.81) in a Japanese clinical population.

Secondary Outcome measures

Cognitive Behavioural Therapy Skills Scale (CBTSS)

The CBTSS is a 32 items self-reported questionnaire that assesses the frequency of CBT skills utilization (Sakata et al., 2021). The CBTSS was included in this study to examine whether using the INTELLECT app improves cognitive behavioural therapy skills. Items are scored on a four-point Likert-type scale (ranging from 1= “almost none of the above” to 4,=”quite true”), with higher scores indicating the frequent CBT skills utilization. This scale has a five-factor structure (Cognitive restructuring, Behavioral activation, Assertiveness communication, Self-monitoring, Problem solving). The high reliability and validity of this scale have been reported in previous studies involving Japanese workforce populations (Sakata et al., 2021).

Implementation Outcome Scales for Digital Mental Health (iOSDMH)

The iOSDMH measures the feasibility, appropriateness, and acceptability of digital mental health interventions. This is a 19 items self report measure using a 4-point Likert-type scale (ranging from 1= “disagree” to 4 = “agree”). Internal consistency and validities were confirmed in the scale development study (Sasaki et al., 2021).

Analytic approach

Descriptive statistics were reported as means and standard deviations for continuous variables and frequencies for dichotomous or categorical variables. We used linear mixed modelling (LMM) to analyze the study’s primary outcome measures. LMM was selected because of its strength in accommodating missing data and its ability to incorporate random effects into

analyses. In the primary analysis, the dependent variable was the PHQ-4 score, and the independent variables were assignment (categorical variables: INTELLECT, AO) and time (categorical variables: baseline [T1], and each follow-up [T2–T7]), with the interaction of assignment and time as a fixed-effect variable and participants as a random-effects variable. Secondary outcomes (secondary outcome measures) were analyzed in the same manner as the primary outcome. Moreover, the standardized effect sizes and 95% confidence intervals (95%CI) were estimated. Cohen's d was the effect size reported, whereby 0.20 to 0.49 indicates a small effect, 0.50 to 0.79 indicates a moderate effect, and 0.80 indicates a large effect.

For all analyses, $p < .05$ was considered statistically significant. All statistical analyses were performed using R software (version 4. 0. 2., R Foundation for Statistical Computing, Vienna, Austria). The "lme4" package was used for LMM.

Ethics Approval

Ethics approval was given to the institutional review board of the First author's affiliation. This trial was registered with the University hospital Medical Information Network (UMIN) Center on the 16th of June (Registration number: UMIN000051354).

Data and material availability

Data, materials, and analysis code for this study are not available.

Results

Participant Flow, Characteristics, and Recruitment

Of the 73 participants, 47.94% (n = 35, mean age = 38.91 years, SD = 10.03) and 52.05% (n = 38, mean age = 41.82 years, SD = 10.80) were assigned to INTELLECT and AO groups, respectively. Of the 35 participants allocated to the INTELLECT group, 8 were non-responsive at the 2-month follow-up, as were 4 of the 38 participants in the AO group (Figure

2). The study period spanned between June 16th, 2023 and March 31st, 2024. Tables 1 shows participants' demographic data.

Table 1 Participant demographics and clinical characters (n = 73)

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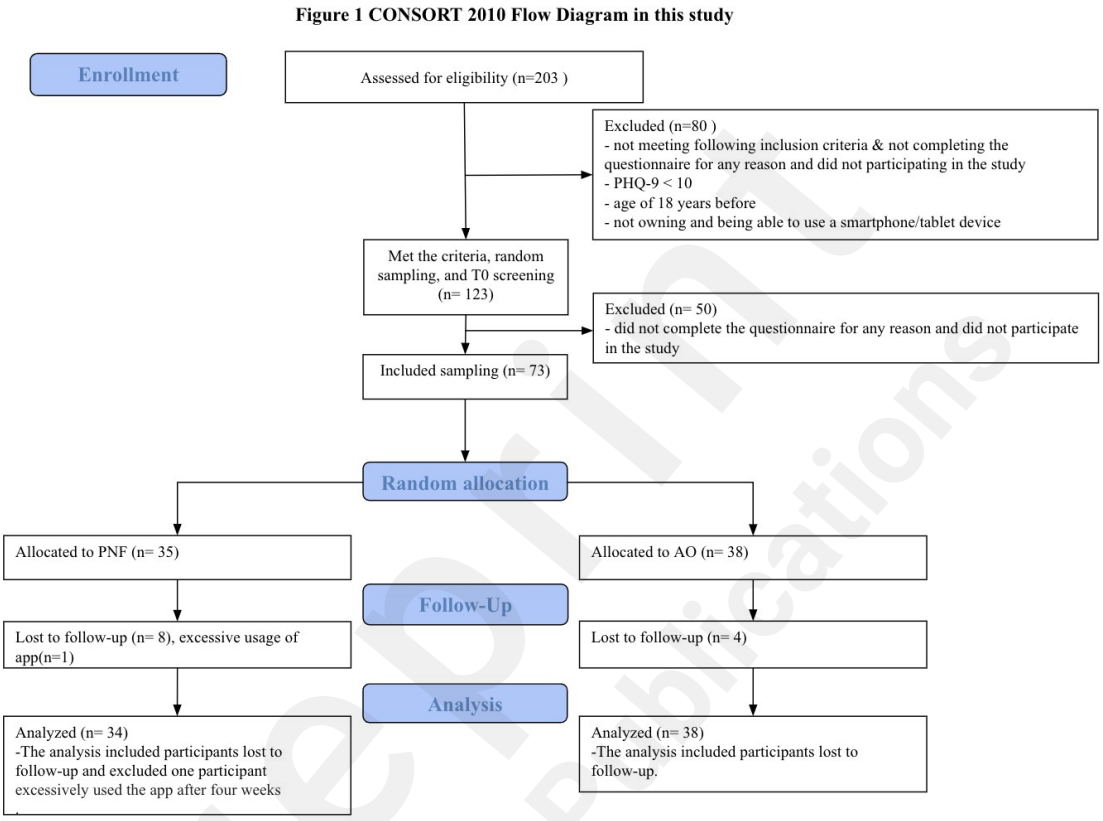
	Total	Intervention group	Control group
	n = 73	n = 35	n = 38
	n (%)	n (%)	n (%)
Gender			
men	23 (31.5)	13 (37.1)	10 (26.3)
women	46 (63.0)	20 (57.1)	26 (68.4)
other	3 (4.1)	1 (2.9)	2 (5.3)
no response	1 (1.4)	1 (2.9)	0 (0.0)
Age	40.42 (10.7)	38.91 (10.03)	41.82 (10.80)
Occupation			
managing post	4 (5.5)	2 (5.7)	2 (5.3)
technical job	16 (21.9)	6 (17.1)	10 (26.3)
clerical worker	11 (15.1)	6 (17.1)	5 (13.2)
sales staff	3 (4.1)	2 (5.7)	1 (2.6)
service industry	15 (20.5)	9 (25.7)	6 (15.8)
security worker	1 (1.4)	1 (2.9)	0 (0.0)
production process worker	1 (1.4)	0 (0.0)	1 (2.6)
transport and machine operation worker	3 (4.1)	1 (2.9)	2 (5.3)
construction and mining woker	3 (4.1)	2 (57.0)	1 (2.6)
carrying, cleaning, packaging, and relate	2 (2.7)	0 (0.0)	2 (5.3)
full-time homemaker	5 (6.8)	2 (5.7)	3 (7.9)
family care/own illness treatment	3 (4.1)	2 (5.7)	1 (2.6)
teporary retirement	5 (6.8)	2 (5.7)	3 (7.9)
others	1 (4.1)	0 (0.0)	1 (2.6)
Education			
elementary and junior high school	7 (9.6)	3 (8.6)	4 (10.5)
high school (equivalent test)	23 (31.5)	10 (28.6)	13 (34.2)
two-year and career college	8 (11.0)	6 (17.1)	2 (5.3)
four-year college	31 (42.5)	13 (37.1)	18 (47.4)
graduate school	4 (5.5)	3 (8.6)	1 (2.6)
Income (monthly)			
< 100,000 JPY	9 (12.3)	4 (11.4)	5 (13.2)
100,000–199,999	11 (15.1)	4 (11.4)	7 (18.4)
200,000–299,999	9 (12.3)	7 (20.0)	2 (5.3)
300,000–399,999	23 (31.5)	10 (28.6)	13 (34.2)
400,000–499,999	7 (9.6)	4 (11.4)	3 (7.9)
500,000–599,999	6 (8.2)	3 (8.6)	3 (7.9)
600,000–699,999	2 (2.7)	1 (2.9)	1 (2.6)
700,000–799,999	3 (4.1)	1 (2.9)	2 (5.3)
800,000–899,999	1 (1.4)	1 (2.9)	0 (0.0)
900,000–999,999	1 (1.4)	0 (0.0)	1 (2.6)
1000,000–1500,000	0 (0.0)	0 (0.0)	0 (0.0)
>1500,000	1 (1.4)	0 (0.0)	1 (2.6)
Marital status			
married	33 (45.2)	15 (42.9)	18 (47.4)
single	30 (41.1)	17 (48.6)	13 (34.2)
divorced	10 (13.7)	3 (8.6)	7 (18.4)
Smartphone they are using			
Android	25 (34.2)	14 (40.0)	11 (28.9)
iPhone	46 (63.0)	20 (57.1)	26 (68.4)
others	2 (2.7)	1 (2.9)	1 (2.6)
Previous management of depression	37 (50.7)	19 (54.3)	18 (47.4)
Previous structured psychotherapy for men	6 (8.2)	3 (8.6)	3 (7.9)
Habitual use of alcohol	8 (11.0)	6 (17.1)	2 (5.3)
Habitual use of tobacco	16 (21.9)	7 (20.0)	9 (23.7)

Figure 1

CONSORT flow diagram



Group differences for the Primary Outcome Variable

72 participants were included in the analysis. The results showed that participants' PHQ-4 scores significantly decreased from baseline at both post-intervention and 2-month follow-up. There was a significant interaction between group and time at post-intervention (t (364.7426) = -2.243, $p < .05$) and 2-month follow-up (t (364.6948) = -3.284, $p < .05$). As shown in Table 2, the effect sizes were moderate and large at post-intervention and follow-up respectively ((Cohen's d = -.57, 95% CI = -1.07 to -0.06)) at post-intervention; (Cohen's d = -.85, 95% CI = -1.38 to -0.32) at 2-month follow-up).

Table 2 Results of depressive symptoms

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	Group	*N*	*Mean*	*SD*	*Cohens' d [95 % CI]*
Time 1	Intervention	34	8.18	3.19	-0.07 [-0.53 , 0.39]
	Control	38	8.39	2.97	
Time 2	Intervention	30	7.23	3.35	-0.19 [-0.69 , 0.31]
	Control	33	8.00	2.73	
Time 3	Intervention	26	6.15	3.71	-0.30 [-0.81 , 0.22]
	Control	34	7.53	3.09	
Time 4	Intervention	27	6.52	3.65	-0.14 [-0.64 , 0.37]
	Control	34	6.97	2.97	
Time 5	Intervention	29	5.62	3.53	-0.57 [-1.07 , -0.06]
	Control	34	7.74	3.12	
Time 6	Intervention	26	4.62	3.71	-0.57 [-1.09 , -0.04]
	Control	33	6.91	3.39	
Time 7	Intervention	26	4.35	2.37	-0.85 [-1.38 , -0.32]
	Control	35	7.03	3.55	

Group differences for the Secondary Variable

As shown in Table 3, the results showed that participants' CBTSS scores increased post-intervention and follow-up. The intervention group showed a significant improvement in CBTSS's self-monitoring score only at post-intervention compared to the control group ($t(120.7526) = 2.672$, $p < .05$). The effect size at post-intervention was moderate (Cohen's d = 0.68, 95% Cl = 0.17 to 1.18).

Table 3 Results of Cognitive Behavioral Therapy Skills Scale's score

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Group	Time 1				Time 2				Time 3			
	N	*Mean*	*SD*	*Cohens' d [95 % CI]*	*N*	*Mean*	*SD*	*Cohens' d [95 % CI*	*N*	*Mean*	*SD*	*Cohens' d [95 % CI]*
Cognitive restructuring												
Intervention	34	6.18	4.37	-0.08 [-0.54 , 0.38]	29	8.79	4.69	0.42 [-0.08 , 0.92]	26	8.92	4.22	0.42 [-0.09 , 0.93]
Control	38	6.50	3.52		34	7.26	4.21		35	7.43	4.19	
Behavioral activation												
Intervention	34	4.85	3.17	0.08 [-0.39 , 0.54]	29	7.07	3.70	0.49 [-0.02 , 0.99]	26	7.69	3.67	0.32 [-0.19 , 0.83]
Control	38	4.58	3.75		34	4.71	3.91		35	6.09	4.28	
Assertiveness communication												
Intervention	34	9.15	3.65	0.09 [-0.37 , 0.55]	29	10.21	3.52	0.23 [-0.27 , 0.72]	26	10.92	3.38	0.25 [-0.26 , 0.76]
Control	38	8.84	3.37		34	9.35	3.61		35	9.80	3.01	
Self-monitoring												
Intervention	34	7.35	4.55	-0.13 [-0.59 , 0.34]	29	11.97	4.85	0.68 [0.17 , 1.18]	26	11.81	4.17	0.50 [-0.05 , 1.02]
Control	38	7.89	4.09		34	8.76	4.06		35	9.51	5.06	
Problem solving												
Intervention	34	6.65	3.99	0.24 [-0.23 , 0.70]	29	8.83	3.86	0.34 [-0.16 , 0.83]	26	9.81	4.25	0.48 [-0.03 , 1.00]
Control	38	5.76	3.50		34	6.56	3.74		35	6.86	4.07	

App engagement among the intervention group

As shown in Table 4, the average degree of satisfaction measured by the iOSDMH among users of the Intellect application was notably high. Around 16-24 (55.2%-82.8%) of the 29 intervention participants answered “agree” or “relatively agree” on each item of acceptability (n=16-24, 55.2%-82.8%), appropriateness (n=19-24, 65.5%-82.8%), feasibility (n=7-23, 24.1%-79.3%). The highest proportions of positive responses in each of the 3 aspects were “ this program is acceptable for me”(n=24, 82.8%) in acceptability, “the content of the program is appropriate” (n=24, 82.8%) in appropriateness, and “the length of 1 content is implementable; the program is easy to understand” (n=23, 79.3) in feasibility, respectively. Regarding overall satisfaction with Intellect app, 23 (79.3%) participants answered “agree” or “relatively agree”. Regarding harms, 2-8 (6.8%-27.5.4%) participants answered “agree” or “relatively agree”, except for “excessive pressure on learning this program regularly” (n=12, 41.4%). An examination of the engagement with individual components over a four-week period revealed that the 'Wellbeing Check-in' module was the most frequently utilized, followed in descending order of usage by the 'Rescue Sessions,' and 'Guided Journals'. Notably, the 'Learning Path' component required the most significant investment of time from users. This substantial time requirement for the 'Learning Path' is likely the reason for the observed discrepancy between the number of initial engagements with the component and the lower rate of completions.

Table 4 Results of app engagement

Table 4 Results of app engagement (n = 29)

	Mean	SD	Zeroth quartile	First quartile	Median	Third quartile	Forthq uartile
iOSDMH							
Acceptability	8.59	2.40	3.00	6.50	9.00	10.00	12.00
Appropriateness	11.59	2.61	4.00	10.50	12.00	13.00	16.00
Feasibility	16.52	2.85	10.00	15.00	17.00	18.00	21.00
Satisfaction	2.86	0.74	1.00	3.00	3.00	3.00	4.00
Harms	8.52	3.30	5.00	6.00	8.00	10.00	18.00
used componets							
Starting learning paths	5.19	3.03	2	3	4	5	13
Completed learning paths	3.63	2.72	1	2	3	4	11
Resucue Sessions	7.67	5.28	0	4	6	11	20
Wellbeing Check-in	15.11	8.31	1	9	15	21	33
Guided Journals	7.19	5.68	1	2	6	11	22

Discussion

Principal Results

The primary aim of this study was to compare the efficacy of INTELLECT's CBT-based features in improving anxiety and depressive symptoms among Japanese employees experiencing mild, moderate, or severe levels of these symptoms, compared to a waitlist control group. In addition, the study examined whether these features resulted in significant improvements in CBT-related life skills and assessed the acceptability, feasibility, and satisfaction levels among users.

Our primary hypothesis was supported, with the intervention group showing significantly greater improvements in depression and anxiety levels at post-intervention and 2-month follow-up. Effect sizes of these improvements at each timepoint were considerably larger than those reported in similar studies reviewed by a recent meta-analysis (Firth et al., 2017). These findings add to the scant literature by showing that self-guided CBT features can be highly effective in reducing anxiety and depressive symptoms among clinically at-risk working adults in Japan. This aligns with previous research showing comparable efficacy of

brief CBT-based mobile features, or computerized CBT in alleviating depressive symptoms among university students experiencing baseline depressive symptoms in Western societies (Mantani et al., 2017; Bruhns et al., 2021; Six et al., 2022).

Our secondary hypothesis was partially supported. The self-guided CBT features also demonstrated significantly greater improvements in the self-monitoring aspect of cognitive behavioural skills than the waitlist control group, as assessed through the CBTSS. The effect size of this improvement at post-intervention was moderate (Cohen's d = .68, 95% CI = 0.17 to 1.18). Self-monitoring questions are prominently featured throughout INTELLECT's self-guided features. For example, thought records are embedded within all of INTELLECT's "Learning Paths" "Rescue Sessions" and "Guided Journals," consistently prompting each participant to analyze their own thought patterns. It is probable that the decrease in anxiety and depressive symptoms among our participants was related to the increase in self-monitoring. This technique alone has previously shown efficacy in alleviating anxiety and depressive symptoms in adults (Rickard et al., 2016; Bakker and Rickard, 2018) and youths diagnosed with major depression (Hetrick et al., 2018). However, our study did not conduct longitudinal mediation analyses to confirm this hypothesis. Future research could utilize more rigorous statistical methods, such as multilevel mediation analyses to support this claim. In contrast, for other skills assessed by the CBTSS (i.e., Behavioral Activation, Assertiveness Communication, Problem Solving), only specific self-guided features within INTELLECT were tailored to enhance these skills. For example, within INTELLECT's suite of Learning Paths, approximately half of them concentrate on modifying behavioral patterns, while only three focus on modifying communication styles. Researchers have also proposed that the anticipated type of improvements resulting from the interventions correlate with the type of content offered within the intervention (Morrison et al. (2012)). Future researchers are encouraged to isolate various types of self-guided interventions and assess the efficacy of

each intervention using a similar RCT design to ours.. In comparison to the control group, the intervention group also did not exhibit significantly greater improvements in the cognitive restructuring aspect of CBT skills. There are a couple of possible reasons. Firstly, cognitive restructuring has been identified as one of the most challenging CBT skills to impart, even among trained counselors and psychotherapists with many years of experience (Stark et al., 2011). Furthermore, cognitive restructuring is widely recognized as a difficult skill to master independently, both within and outside of therapeutic contexts (Willner et al., 2005; Neal-Barnett et al., 2019). Further research is needed to explore suitable methodologies for effectively teaching cognitive restructuring skills within self-help modalities, enabling users to learn autonomously. Finally, it is important to note that participants in both the intervention and control group demonstrated significant improvements in the CBT skills across time (see Table 3). This particular control group may have masked the intervention effects on CBT skills. Future researchers can more effectively assess the efficacy of INTELLECT's self-guided CBT interventions by employing a three-armed randomized controlled trial (RCT), wherein the efficacy of these CBT features is compared against those of an active control group and a waitlist control group.

Finally, it is noteworthy that a sizable percentage of our participants expressed satisfaction with using INTELLECT, rating it highly in terms of acceptability, appropriateness for improving mental health, and ease of understanding. The self-help features of INTELLECT, which utilize plain language, illustrations, videos, and audio narration to explain evidence-based content, may contribute to these positive implementation outcomes. Given the substantial effect sizes and user-friendly design of this application, we recommend broader dissemination of the INTELLECT app to alleviate anxiety and depressive symptoms among employees in need.

Limitation

This study has three limitations. Firstly, although INTELLECT's self-help interventions significantly reduced depressive symptoms during the study period and at the 2-month follow-up, it is uncertain if these improvements would persist beyond two months. Previous research on similar internet-based CBT interventions suggests a potential decline in efficacy over extended durations. Hence, it is important for future studies to evaluate the longitudinal effects of mobile-based CBT interventions. Secondly, this intervention study primarily focused on assessing improvements in depressive symptoms and user engagement with the application, overlooking potential adverse effects associated with its use. A thorough examination of post-intervention side effects is essential to ensure the app's safety across diverse user demographics. Lastly, while the INTELLECT app effectively enhanced self-monitoring capabilities, it did not significantly influence the development of other crucial CBT-related skills, such as cognitive restructuring, behavioral activation, communication, or problem-solving. Future studies may explore strategies for enhancing the application to facilitate a more comprehensive development of these skills, which could augment INTELLECT's efficacy in addressing anxiety and depressive symptoms.

Conclusion

This study provides the first evidence of the efficacy of the INTELLECT app including all components in reducing depressive symptoms among Japanese adult workers. The utilization of the INTELLECT app significantly enhanced self-monitoring skills, a key component of the observed improvement. However, the absence of post-intervention effects on other cognitive-behavioural therapy skills underscores the necessity for further investigation in these areas.

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Authors' Contributions

All of the authors contributed substantially to the conceptualisation of this study. KY and RO led the data collection procedures, data analysis, and wrote the initial draft of the manuscript. SHYT revised all sections of the manuscript and finalized the draft with the approval of KY. OS supervised the study's procedures.

Conflicts of Interest

The study was fully funded by Intellect Pte Ltd. The study design, data management, interpretation, analysis, reporting, and decision to publish of the study are entirely independent of Intellect Pte Ltd.

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