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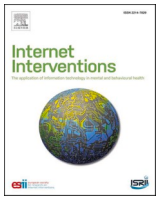

Effectiveness of an online text-based stress management program for employees who work in micro- and small-sized enterprises: A randomized controlled trial

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ABSTRACT

Background: Internet psychoeducational interventions improve employees' mental health. However, implementing them for employees in micro- and small-sized enterprises (MSEs) is challenging.
Objectives: This randomized controlled trial examined the effectiveness of a fully automated text-based stress management program, "WellBe-LINE," in improving mental health and job-related outcomes for employees in workplaces with fewer than 50 employees.
Methods: The program was developed based on stakeholder interviews and surveys of 1000 employees at MSEs. Adult full-time employees at an enterprise with fewer than 50 employees were recruited from registered members of a web survey company in Japan. Participants were randomly allocated to the intervention or control group (1:1). Participants in the intervention group were invited to register for the program using the LINE app. Psychological distress measured by Kessler 6 (K6) was a primary outcome, with self-administrated questionnaires at baseline, 2-month (post), and 6-month follow-ups. A mixed model for repeated measures conditional growth model analysis was conducted using a group * time interaction as an intervention effect. Implementation outcomes were measured through implementation outcome scales for digital mental health (iOSDMH).
Results: 1021 employees were included in this study. No significant effects were shown in any outcome. The reported implementation outcomes were positively evaluated, with 80 % acceptability, 86 % appropriateness, and feasibility (ease of understanding the contents [88 %], frequency [86 %], and length of content [86 %]).
Conclusions: A simple text-message program for employees at MESs was acceptable, appropriate, and feasible; however, it did not result in improved mental health or job-related outcomes.
Trial registration: UMIN clinical trial registration: UMIN000050624 (registration date: March 18, 2023).

1. Introduction

The mental health of employees at micro, small, and medium enterprises (MSEs) is an important occupational health issue (Engels et al., 2022; Hogg et al., 2021). Work-stress-related mental health deterioration leads to a significant burden for both employees and employers. Employees with mental illness often have to navigate long-term treatment and are not always able to work. (Harvey et al., 2009) In addition,

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mental health issues can lead to low work performance (Lu et al., 2022; Kessler et al., 2006; Stewart et al., 2003), decreased safety awareness, (Haslam et al., 2005) and early retirement (Karpansalo et al., 2005). Although effective mental health measures at workplace have been available on guideline (World Health Organization, 2022); however, MSEs have not fully addressed these consequences of mental health deterioration and have not yet implemented evidence-based interventions.

MSEs are a particularly challenging sector for mental health promotion interventions (Martin et al., 2015) due to several limitations, including lack of resources (time, money), employers' low literacy and competency about mental health, and stigma (Martin et al., 2015; Benning et al., 2022; Hannon et al., 2012; Hughes et al., 2009; Masi and Cagno, 2015; McCoy et al., 2014; Saito et al., 2022; Taylor et al., 2016). Web-based platforms or mobile phones are promising options for increasing the accessibility of mental health care (Lattie et al., 2022). However, employees at MSEs may be reluctant to discuss their mental health with their employers (Martin et al., 2015), particularly when compared to employees in larger enterprises (Lai et al., 2015). Therefore, there is a need to develop and assess the effectiveness and implementation of interventions that target the needs of MSEs. A systematic review which examined the effectiveness of workplace interventions to reduce depression and anxiety in small and medium-sized enterprises included seven studies with the interventions such as face-to-face psychoeducation and telephone counseling, and reported five of them showed significant effectiveness (Hogg et al., 2021). However, the paper concluded that high heterogeneity of interventions and outcomes, high attrition and lack of rigorous randomized controlled trial (RCT) reflected the challenges in implementing the programs in MSEs.

Internet-based stress management programs effectively reduce symptoms of depression, leading to the prevention of workplace mental health issues (Donker et al., 2015; Zhou et al., 2016; Carolan et al., 2017). Internet-delivered psychosocial interventions are feasible, cost-effective, accessible, (Carolan et al., 2017; Stratton et al., 2017) and ensure anonymity and reduce stigma. (Moe-Byrne et al., 2022) Internet-based program shows no difference in effectiveness in improving mental health compared to in-person sessions (Hedman-Lagerlöf et al., 2023). Even web-based text messaging is useful in mental health programs (Berrouiguet et al., 2016). Internet-based mental health programs are potentially a good fit for MSE employees. Still, no study has developed an internet-based mental health program and assessed its effectiveness and implementation outcomes in MSEs (Hogg et al., 2021). Moreover, in the nearly 25 years of research efforts with digital interventions, the implementation of effective programs has not always been successfully documented, (Andersson et al., 2019; Andersson and Carlbring, 2022) including in occupational health settings (Bernard et al., 2022). For example, the "Business in Mind" Project targeting small enterprises in Australia reported difficulty taking mental health interventions into the business community (Martin et al., 2015). The "Mental Health at Work" in England provides useful tools to improve mental health at MSEs (Mind, 2021), but the social impact has not been well documented. The "H-WORK Project" and "MENTUPP," which are composed of multi-level interventions, are proposed for MSE employees (Arensman et al., 2023; De Angelis et al., 2020), but not focus on implementation of the self-care. Thus, the authors developed a digital mental health program to implement self-care in Japanese MSEs (Sasaki et al., 2024). The delivery and content of the program were adapted to MSE contexts based on the findings of repeated interviews with stakeholders (i.e., employers, licensed social insurance consultants, and staff at the Tokyo Chamber of Commerce and Industry). Finally, the program was developed in a fully automated/text-based simply formatted stress management program with materials that are easy to understand with low intensity.

This RCT aimed to examine the effectiveness of a fully automated text-based stress management program, "WellBe-LINE," on mental health and work-related outcomes for employees working at a workplace with fewer than 50 employees and to evaluate perceptions of its acceptability, appropriateness, and feasibility.

2. Methods

2.1. Trial design

This study was an RCT. The allocation ratio of the intervention to the control was 1:1. The study protocol was registered before starting the recruitment process (UMIN000050624). This paper was reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Supplementary file 1).

2.2. Ethical approval

The Research Ethics Review Board of the Graduate School of Medicine and Faculty of Medicine, University of Tokyo, approved the study procedures (No.2021190NI-(2)).

2.3. Participants

To recruit large number of participants to meet the target sample size efficiently, participants in this study were recruited from registered members of a web survey company in Japan (Cross Marketing. Inc.), which has approximately 5 million panel members. From the panel, candidates were selected by screening items. Participants' names and emails were provided to researchers at The University of Tokyo.

The inclusion criteria of this study were:

1. Adults (18 years old or older).
2. Full-time employees who are employed at an enterprise with fewer than 50 employees.
3. Those who use the LINE app and are willing to register as a friend with the account for the research.

There were no exclusion criteria.

2.4. Procedures

Screened eligible participants received a webpage URL that included detailed information about the study and were asked to click the Agree button to show their consent to participate; then, they proceeded to the baseline questionnaire page. After completing the baseline questionnaire, the participants who met the eligibility criteria were randomly allocated to the intervention group or control group. The researchers sent an email to the participants in the intervention group containing the QR code to start the program (i.e., friend registration with WellBe-LINE). Those in the control group received the program after the six-month follow-up. The participants were asked to answer the questionnaire at baseline, 2-month follow-up (just after the 8-week intervention), and 6-month follow-up. Participants received a 500 Japanese yen Amazon gift as a reward for answering each questionnaire.

2.5. Randomization

Participants were stratified into two strata according to the score of psychological distress measured by Kessler 6 (4 or less, or 5 or more) on the baseline survey. An independent biostatistician created a stratified permuted-block random table using a computer-generated random allocation sequence. The block size was fixed at 4. The stratified permuted-block random table was created by a researcher outside the research team and password-protected. Random allocation was conducted by another researcher outside the research team, and the allocation results were shared with the research team. These processes were blinded to all authors.

2.6. Intervention group

Participants in the intervention group received the fully automated text-based 8-week stress management program "WellBe-LINE," which was customized for employees in MSEs, was set in the LINE app (a commonly used SNS chat tool in Asian countries) based on evidence-based psychological content.

2.6.1. Intervention

The intervention was developed by involving six stakeholders (e.g., employers, licensed social insurance consultants, staff at the Tokyo Chamber of Commerce and Industry), stakeholder interviews ($n = 12$), and quantitative data analysis of employees at MSEs (online survey; $n = 1000$). Through repeated interviews and discussions with involved partners referring to the results of interviews and surveys, the delivery and content of the evidence-based stress management program were adapted to MSEs to provide simple and easy-to-understand materials with low intensity. In details, the prioritized factors were "evidence-based," "useful in daily life," and "read within three minutes." The LINE app was mostly preferred by employees, compared to other tools (e.g., email). The contents were tailored to 16 scenario patterns according to sex x age x psychological distress. The included content was selected based on the employees' preference in each category. The data for this trial was obtained beforehand from the online survey. To provide a tailored program that addresses individual needs, we broadly adopted major psychological interventions with demonstrated effectiveness in previous studies. These interventions included cognitive behavioral techniques, including problem-solving, acceptance and commitment therapy, self-compassion, sleep hygiene, and physical activity. One text message was sent per week, which included a website link (URL) for more information. The psychoeducational website (https://wellbeing-kokoro.com/) contained >100 mental health articles, and some were introduced through the messages. Most pages on the website included limited text, with fewer than 1000 Japanese words per page. The LINE messages were somewhat more concise than the websites. The program was personalized by information about gender, age category, and high or low psychological distress, which was obtained through a screening check when participants started the program. We provided 16 scenarios according to the screening results. Messages for each scenario were sent in order of rank, with preferred content for that persona based on pre online survey. The program screen capture is shown in Fig. 1. No interactive function was available in the program, but a menu list to link to the website was always available if participants wanted to seek more psychoeducational information. More details are available elsewhere (Sasaki et al., 2024).

2.7. Control group

Participants in the control group received this program after the six-month follow-up. The program was not provided to the control program during the study period. The participants in the intervention and control groups could seek any mental health treatment as usual (TAU-Minimal) (Goldberg et al., 2023), such as stress management education or medical care, throughout the research period. Participants in the control group did not receive the detailed information about the psychoeducational website (https://wellbeing-kokoro.com/), but it was available in public and they would have access with active searching.

2.8. Outcome measures

All outcomes were assessed via an online self-report questionnaire at baseline, 2-month follow-up (post-intervention), and 6-month follow-up. The process evaluation outcomes were assessed only in the intervention group at the 2-month follow-up. Primary outcome was psychological distress. Secondary outcomes were euthymia, psychological well-being, work engagement, and work performance.

2.9. Primary outcome

2.9.1. Psychological distress

Psychological distress was evaluated using the Japanese version of the Kessler 6 (K6) (Kessler et al., 2003a; Furukawa et al., 2008). The K6 is a widely used self-rating scale assessing nonspecific distress during the prior 30 days. Each item of the K6 was scored on a Likert scale ranging from never (0) to all the time (4). The total score of the K6 ranged from 0 to 24, with higher scores indicating more severe psychological distress. A score of 13 or more and between 5 and 12 on the K6 were considered severe and moderate psychological distress, respectively (Furukawa et al., 2008; Prochaska et al., 2012). The reliability and validity of the Japanese version of the K6 have been found to be satisfactory.

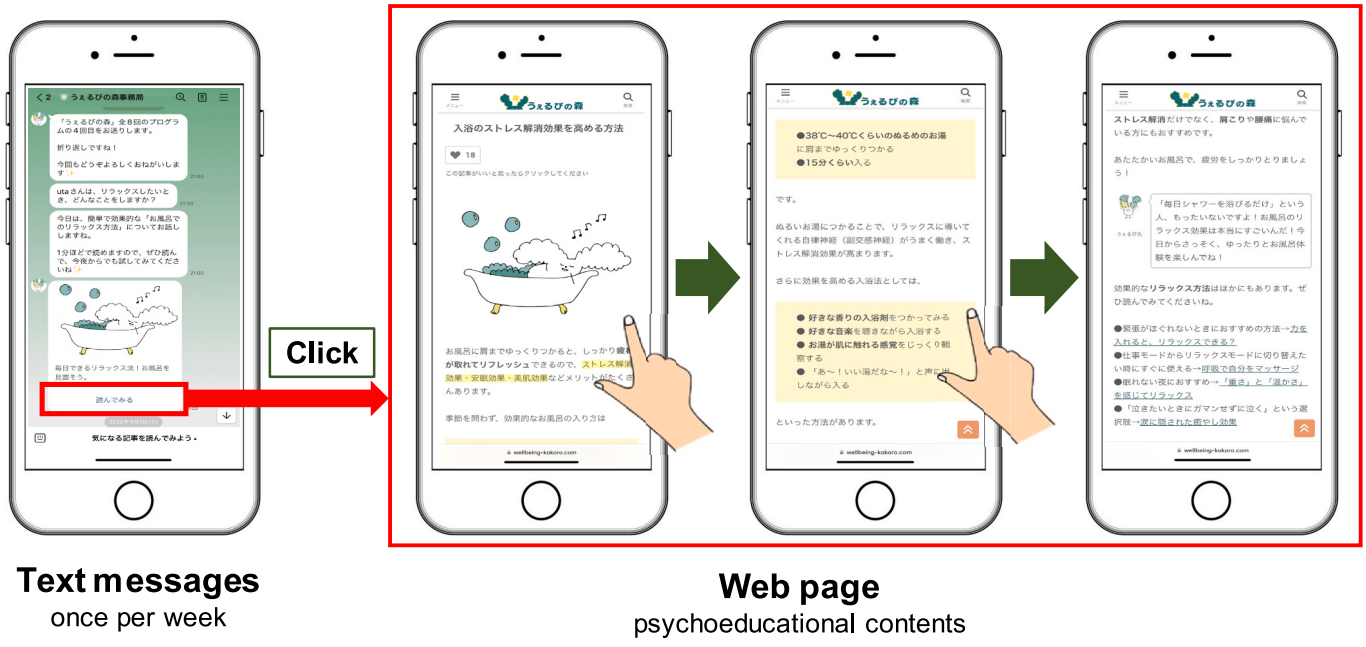

Fig. 1. Outline of WellBe-LINE.

(Furukawa et al., 2008)

2.10. Secondary outcomes

2.10.1. Euthymia

Euthymia, a newly-stated concept by Fava in 2016, is a trans-diagnostic construct for well-being, representing psychological flexibility, a unifying outlook on life, and resistance to stress (i.e., resilience and tolerance to anxiety and frustration) (Fava and Bech, 2016; Guidi and Fava, 2022). The Euthymia scale (ES) (Fava and Bech, 2016) is a 10-item measurement with two dichotomous answer options as False (0) or True (1), resulting in a total score ranging from 0 to 10, with higher scores indicating a better euthymic state. The Japanese version of ES shows high concurrent validity and sensitivity as a clinimetric scale. (Sasaki et al., 2021a; Carrozzino et al., 2022; Sasaki and Nishi, 2023)

2.10.2. Psychological well-being

Psychological well-being was assessed by the Mental Health Continuum-Short Form (MHC-SF) (Lamers et al., 2011), which is widely used as a positive mental health assessment. MHC-SF is constructed by the 3-factor structure in emotional, psychological, and social well-being. The Japanese version of MHC-SF shows high reliability and validity (Ohkata et al., 2021).

2.10.3. Work engagement

Work engagement was assessed by the short form of the Utrecht Work Engagement Scale–9 item (UWES-9) (Schaufeli et al., 2002). The UWES-9 consists of 3 subscales (vigor, dedication, and absorption) that contain 3 items each. The UWES-9 uses a self-report 7-point rating scale from never (0) to every day (6). The three 3 subscale and total scores range from 0 to 6. The Japanese version of the UWES-9 shows high reliability and validity (Shimazu et al., 2010).

2.10.4. Work performance

Work performance was evaluated using one item of the WHO Health and Work Performance Questionnaire (HPQ) (Kessler et al., 2003b). Participants rated their work performance over the prior 4 weeks on an 11-point scale ranging from worst (0) to best (10). Higher scores indicate better work performance. The Japanese version of the HPQ shows high reliability and validity (Kawakami et al., 2020).

2.11. Process evaluation

2.11.1. Completion of the program

As LINE's technical limitations hindered the accurate detection of whether employees read or engaged with messages, we addressed adherence through four questions in the follow-up survey. These questions pertained to how often employees read LINE messages, visited the website, visited other websites upon receiving LINE notifications, read related articles on the website, and took any actions after reading the messages.

2.11.2. Perceptions of the tailoring of the program

The participants in the intervention group were asked about their perceptions of the tailoring of the program at the 8-week follow-up to ensure their awareness of it, although researchers had notified them this program was tailored in the early phase of the intervention. The following questions were used: "This program was tailored by your sex, age, and level of distress. Did you know that?" and "Do you feel that the personalized messages are appropriate for you?"

2.11.3. Contamination of information

To evaluate information contamination among participants, the participants in the control group were asked at the 2-month and 6-month follow-ups: "Have you ever visited the website of 'WellBeLINE?'" The response options were "never," "1 time," "2 – 3 times," and "4 or more times."

2.11.4. Acceptability, appropriateness, feasibility, satisfaction, and uncomfortable experiences

Acceptability, appropriateness, feasibility, satisfaction, and uncomfortable experiences were assessed via 8-week questionnaires in the intervention group by using implementation outcome scales for digital mental health (iOSDMH) (Sasaki et al., 2021b). The scale was developed through a literature review and organized according to Proctor's implementation outcomes (Proctor et al., 2011).

2.12. Demographic characteristics

Demographic data, such as age, sex, marital status (never married, married, divorced, or bereaved), education (high school or lower, some college, undergraduate, graduate school or higher), occupational status (manager, professional, clerical, production, sales, others), and working style (working from home only, both working from home and at the office, working at the office only), were collected in the baseline survey.

2.13. Sample size

The sample size was calculated for psychological distress (K6) to yield an estimated effect size of 0.20 (as a reference of the data of effect size 0.22 in previous meta-analyses (Stratton et al., 2017)) with an α error rate of 0.05 and a β error 0.10. The estimated sample size was about 527 participants in each group. Considering drop-outs, we set 1200 as a target sample size. The statistical power was calculated using the G*Power 3.1 program.

2.14. Statistical methods

We employed a mixed model to analyze conditional growth with repeated measures, utilizing an unstructured covariance matrix. In this analysis, we considered the interaction between two factors: group (intervention and control) and time (baseline, two-month, and six-month follow-ups) as an indicator of the intervention's impact. This served as our primary pooled analysis. Furthermore, we conducted an analogous mixed model for repeated measures employing an analysis of variance (ANOVA) model with an unstructured covariance matrix. We applied maximum likelihood estimation through the MIXED procedure to account for missing data. Our primary analysis adhered to the intention-to-treat (ITT) principle, meaning that participants were retained in their originally randomized groups and analyzed accordingly, irrespective of the interventions they received. Cohen's d effect sizes between groups were calculated at each assessment point among completers at baseline for each follow-up period. Secondary outcomes underwent a similar analysis as the primary outcomes. As an additional analysis, we conducted the same MIXED procedure to adjust the baseline characteristics (sex, age, marital status, education, occupation). As a sub-group analysis, the same analysis was conducted limiting the analysis sample 1) in program completers in the intervention group, 2) in the participants with high psychological distress (K6 $\geq$5), and 3) the non-contaminated participants in the control group. Also, we conducted the sub-group analysis to consider the socio-economic status (SES). The same analysis was conducted separately in the group with less than high school degree and with over, and in the group of managerial level workers and of non-managerial level.

3. Results

3.1. Participant recruitment

The participant flowchart is shown in Fig. 2. A total of 1021 participants answered the baseline survey. Participants were randomly allocated to an intervention group ($n = 510$) and a control group ($n = 511$).

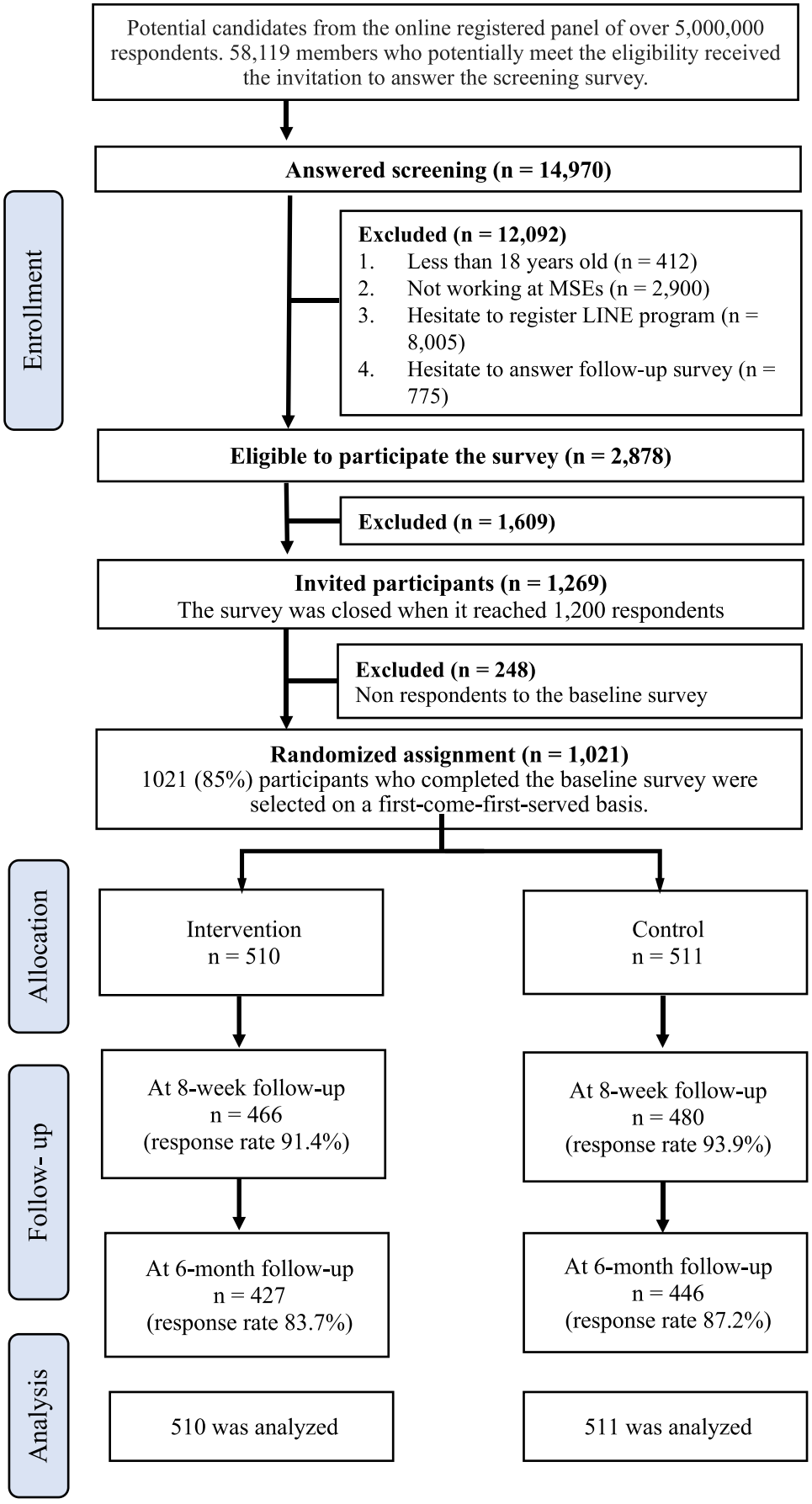

Fig. 2. Participant flowchart.

The percentage of participants with high psychological distress (K6 ≥5) was 37.5 %. The response rate of the follow-ups was 91 % (intervention) and 94 % (control) at 2-month follow-up, and 84 % (intervention) and 87 % (control) at the 6-month follow-up.

The participant's characteristics are presented in Table 1. The majority demographics included those who were men, married, with undergraduate degrees, clerical, and working in an office.

3.2. Effects of the intervention

The mean scores of outcomes in each group are shown in Table 2. The scores of psychological distress increased in both groups at the 2-month follow-ups and decreased only in the control group at 6 months. The intervention group showed no significant effect in improving any outcomes compared to the control group.

Table 3 shows the estimated effects of the "WellBe-LINE" intervention on all outcomes based on mixed model analysis. In ITT analyses, the "WellBe-LINE" intervention showed no significant favorable effect on any outcome. Additional analysis to adjust the baseline characteristics did not either show significant effectiveness on any outcome.

As a sub-group analysis, there was no significant effectiveness found limiting the sample into program completers in the intervention group. The result of the analysis limiting the participants with high psychological distress at baseline ($n = 383$) is presented in Table 4. The total scores of well-being and psychological well-being measured by MHC-SF significantly decreased in intervention group (pooled: $p = 0.021$, $p = 0.049$; respectively). The result of the analysis limiting the non-contaminated participants in the control group showed no significant difference.

A sub-group analysis in the group with less than high school degree showed the significant improvement in social well-being measured by MHC-SF at 2-month follow-ups (Effect = 1.19, SE = 0.53, $t = 2.26$, $p = 0.025$). No significant difference was found in the group with high educational status. A sub-group analysis in the group of manager level workers showed the significant deterioration in emotional well-being measured by MHC-SF (pooled: $p = 0.042$, at 6 month: $p = 0.38$). No significant difference was found in the group of non-managerial level workers. (The data is available upon reasonable request).

Table 1
Participants' characteristics in the intervention and control groups ($N = 1021$).

	Intervention ($n = 510$)	Control (n = 511)
	n (%)	n (%)
Age (years), mean (SD)	49.3 (10.3)	49.7 (11.0)
Sex		
Men	346 (67.8)	348 (68.1)
Women	164 (32.2)	163 (31.9)
Marital status		
Single	146 (28.6)	147 (28.8)
Married	302 (59.2)	306 (59.9)
Divorced/widows	62 (12.2)	58 (11.3)
Educational attainment		
High school	137 (26.9)	118 (23.1)
Some college	108 (21.2)	99 (19.4)
Undergraduate	243 (47.6)	266 (52.1)
Graduate or over	22 (4.3)	28 (5.4)
Occupation		
Manager	125 (24.5)	131 (25.6)
Professional	104 (20.4)	96 (18.8)
Clerical	152 (29.8)	160 (31.3)
Production	30 (5.9)	28 (5.5)
Sales	60 (11.8)	56 (11.0)
Others	39 (7.6)	40 (7.8)
Working style		
Work from home	23 (4.5)	26 (5.1)
Hybrid working	60 (11.8)	80 (15.7)
Working at office	427 (83.7)	405 (79.2)

SD: standard deviation.

Table 2
Mean of outcome variables at baseline, 2-months and follow-up.

	Intervention		Control		Intervention vs control Effect size
Outcome variables	n (%)	Mean (SD)	n (%)	Mean (SD)	Cohen d (95 % CI)
Psychological distress (K6)					
Baseline	510	4.70 (5.06)	511	4.43 (4.92)	n/a
2-Months	466	4.75 (5.08)	480	4.61 (5.21)	−0.05 (−0.18–0.08)
6-Months	427	4.75 (5.11)	446	4.41 (5.02)	0.03 (−0.10–0.17)
Work engagement (UWES)					
Baseline	510	2.63 (1.15)	511	2.69 (1.20)	n/a
2-Months	466	2.53 (1.18)	480	2.59 (1.20)	0.03 (−0.10–0.15)
6-Months	427	2.55 (1.19)	446	2.65 (1.26)	−0.02 (−0.16–0.11)
Job performance (HPQ)					
Baseline	510	6.31 (1.72)	511	6.32 (1.83)	n/a
2-Months	466	6.17 (1.82)	480	6.06 (1.96)	0.07 (−0.06–0.19)
6-Months	427	6.20 (1.81)	446	6.22 (1.88)	0.03 (−0.11–0.16)
Well-being (MHC-SF total)					
Baseline	510	27.8 (15.2)	511	28.43 (16.25)	n/a
2-Months	466	27.8 (15.8)	480	27.96 (15.86)	0.05 (−0.08–0.18)
6-Months	427	28.1 (15.5)	446	28.50 (16.34)	−0.03 (−0.17–0.10)
Emotional well-being (MHC-SF)					
Baseline	519	6.45 (3.75)	511	6.41 (3.90)	n/a
2-Months	466	6.39 (3.70)	480	6.37 (3.82)	−0.01 (−0.14–0.11)
6-Months	427	6.49 (3.81)	446	6.58 (3.84)	−0.12 (−0.25–0.01)
Social well-being (MHC-SF)					
Baseline	510	8.89 (5.83)	511	9.30 (6.18)	n/a
2-Months	466	9.05 (6.07)	480	9.03 (5.87)	0.11 (−0.02–0.24)
6-Months	427	9.07 (5.98)	446	9.14 (6.14)	0.06 (−0.08–0.19)
Psychological well-being (MHC-SF)					
Baseline	510	12.45 (6.99)	511	12.72 (7.30)	n/a
2-Months	466	12.36 (7.20)	480	12.56 (7.30)	0.01 (−0.12–0.14)
6-Months	427	12.55 (6.98)	446	12.78 (7.43)	−0.05 (−0.18–0.08)
Euthymia (ES-J)					
Baseline	510	6.81 (2.99)	511	6.99 (3.00)	n/a
2-Months	466	6.74 (3.02)	480	6.88 (3.05)	0.04 (−0.09–0.17)
6-Months	427	6.91 (2.99)	446	7.01 (3.05)	0.03 (−0.10–0.16)

CI: confidence interval. ES-J: Japanese version of Euthymia scale. HPQ: WHO Health and Work Performance Questionnaire.K6: Kessler 6. MHC-SF: Mental Health Continuum-Short Form. SD: standard deviation. n/a: not applicable. UWES: Utrecht Work Engagement Scale.
Note. Cohen d values were calculated among participants who answered each follow-up survey.

Table 3
Effects of the WellBe-LINE program on outcomes using intention to treat (ITT) analysis (N = 1021).

	Effect	95 % CI	SE	t value	*p* value
Psychological distress					
2 months[a]	−0.15	−0.53–0.23	0.19	−0.79	0.429
6 months[a]	0.08	−0.37–0.53	0.23	0.34	0.734
Pooled[b]	0.04	−0.17–0.25	0.11	0.35	0.728
Work engagement (UWES)					
2 months[a]	0.01	−0.06–0.09	0.04	0.38	0.705
6 months[a]	−0.03	−0.13–0.07	0.05	−0.65	0.517
Pooled[b]	−0.01	−0.06–0.03	0.02	−0.55	0.585
Job performance (HPQ)					
2 months[a]	0.10	−0.11–0.30	0.10	0.94	0.347
6 months[a]	0.01	−0.21–0.22	0.11	0.06	0.954
Pooled[b]	0.01	−0.10–0.11	0.06	0.11	0.913
Well-being (MHC-SF total)					
2 months[a]	0.48	−0.67–1.62	0.58	0.82	0.414
6 months[a]	−0.18	−1.41–1.04	0.62	−0.29	0.771
Pooled[b]	−0.08	−0.69–0.53	0.31	−0.26	0.797
Emotional well-being (MHC-SF)					
2 months[a]	−0.03	−0.35–0.29	0.16	−0.18	0.856
6 months[a]	−0.25	−0.59–0.09	0.17	−1.45	0.148
Pooled[b]	−0.12	−0.30–0.05	0.09	−1.43	0.154
Social well-being (MHC-SF)					
2 months[a]	0.44	−0.07–0.96	0.26	1.69	0.091
6 months[a]	0.27	−0.26–0.80	0.27	1.01	0.311
Pooled[b]	0.15	−0.13–0.42	0.14	1.05	0.294
Psychological well-being (MHC-SF)					
2 months[a]	0.06	−0.49–0.61	0.28	0.22	0.825
6 months[a]	−0.16	−0.81–0.48	0.33	−0.50	0.619
Pooled[b]	−0.09	−0.40–0.21	0.16	−0.60	0.548
Euthymia (ES-J)					
2 months[a]	0.07	−0.16–0.30	0.12	0.58	0.561
6 months[a]	0.04	−0.21–0.30	0.13	0.34	0.731
Pooled[b]	0.02	−0.10–0.15	0.06	0.35	0.725

CI: confidence interval. SE: standardized error.
[a] Mixed-model with repeated measures analysis of variance model analyses was conducted.
[b] Mixed-model with repeated measures conditional growth model analyses was conducted.

3.3. Process evaluation

The results of adherence are presented in Table 5. Seventy percent of participants in the intervention group completed our program (i.e., reading LINE messages at 8 times). Forty percent of participants visited websites spontaneously without receiving messages. Sixty-one percent took some action at least one time after reading the message.

In the intervention group, 263 (59 %) of the participants recognized that "WellBe-LINE" was tailored to their personal information. The perception was positively evaluated for the personalized and tailored messages: highly suited (n = 75, 17 %) and relatively well suited (n = 264, 59 %), compared to low suited (n = 97, 22 %) and not suited at all (n = 10, 2 %).

Regarding contamination, 136 (28.3 %) of participants in the control group visited the websites more than once at a 2-month follow-up and 154 (34.5 %) at 6-month follow-up.

Table 6 presents the results of acceptability, appropriateness, feasibility, and uncomfortable experiences in the intervention group. A total of 358 participants (80 %) reported the program as acceptable, and 384 (86 %) reported it as appropriate. Regarding the feasibility, easy-to-understand content (n = 394, 88 %), frequency (n = 385, 86 %), and length of content (n = 383, 86 %) were highly positively evaluated. Overall satisfaction was 80 % (n = 356). Uncomfortable experiences were reported as <18 %.

Table 4
Effects of the WellBe-LINE program on outcomes among participants with high psychological distress (K6 ≥5) at baseline (N = 383).

	Effect	95 % CI	SE	t value	p value
Psychological distress					
2 months[a]	−0.26	−1.11–0.59	0.43	−0.61	0.545
6 months[a]	−0.20	−1.10–0.70	0.46	−0.44	0.664
Pooled[b]	−0.09	−0.54–0.36	0.23	−0.39	0.694
Work engagement (UWES)					
2 months[a]	−0.03	−0.17–0.11	0.07	−0.44	0.658
6 months[a]	−0.13	−0.29–0.03	0.08	−1.57	0.117
Pooled[b]	−0.07	−0.15–0.02	0.04	−1.55	0.123
Job performance (HPQ)					
2 months[a]	−0.05	−0.41–0.32	0.19	−0.25	0.800
6 months[a]	−0.05	−0.45–0.36	0.21	−0.23	0.822
Pooled[b]	−0.03	−0.22–0.18	0.10	−0.24	0.808
Well-being (MHC-SF total)					
2 months[a]	−1.78	−3.86 to −0.29	0.89	−2.01	0.045*
6 months[a]	−2.07	−3.86 to −0.29	0.91	−2.23	0.023*
Pooled[b]	−1.06	−1.96 to −0.16	0.46	−2.32	0.021*
Emotional well-being (MHC-SF)					
2 months[a]	−0.41	−0.92–0.10	0.26	−1.57	0.116
6 months[a]	−0.47	−1.01–0.08	0.28	−1.67	0.095
Pooled[b]	−0.24	−0.51–0.04	0.14	−1.70	0.090
Social well-being (MHC-SF)					
2 months[a]	−0.64	−1.39–0.11	0.38	−1.68	0.093
6 months[a]	−0.62	−1.39–0.15	0.39	−1.59	0.112
Pooled[b]	−0.32	−0.70–0.07	0.20	−1.63	0.103
Psychological well-being (MHC-SF)					
2 months[a]	−0.72	−1.62–0.19	0.46	−1.55	0.122
6 months[a]	−0.95	−1.93–0.02	0.50	−1.92	0.056
Pooled[b]	−0.49	−0.97 to −0.002	−0.25	−1.98	0.049*
Euthymia (ES-J)					
2 months[a]	0.26	−0.19–0.70	−0.23	1.14	0.256
6 months[a]	−0.05	−0.53–0.43	0.25	−0.21	0.838
Pooled[b]	−0.02	−0.26–0.22	0.12	−0.16	0.873

CI: confidence interval. SE: standardized error. *$p < 0.05$.
[a] Mixed-model with repeated measures analysis of variance model analyses was conducted.
[b] Mixed-model with repeated measures conditional growth model analyses was conducted.

4. Discussion

This study showed no effect of a fully automated text-based stress management program on mental health and job-related outcomes for employees working at a small workplace. However, self-reported adherence was high (70 %), and users' perceptions were positively evaluated as 76 % reported that the tailored program fit their personal situations and the overall satisfaction with the program was 80 %. Developing the program in a participatory manner and designing for dissemination and sustainment by making the program low-intensity with simple messages resulted in good implementation outcomes (e.g., acceptability, feasibility, appropriateness); however, further improvements are likely necessary to improve mental health outcomes.

The program had no influence on psychological distress, euthymia, psychological well-being, work engagement, or job performance. The results were inconsistent with the previous study showing the effectiveness of mental health interventions at MSEs (Hogg et al., 2021). There are several possible reasons for this finding: (i) the low intensity of the program, (ii) contents that did not directly reduce distress, (iii) preference-based exposure, and (iv) the lack of a systematic approach to

Table 5
The adherence to the programs in the intervention group who answered at 8-week follow-up ($N = 446$).

	n (%)
The times to read the LINE messages	
Never	9 (2.0)
1 time	11 (2.5)
2 times	18 (4.0)
3 times	18 (4.0)
4 times	24 (5.4)
5 times	17 (3.8)
6 times	25 (5.6)
7 times	11 (2.5)
8 times (completion)	313 (70.2)
The times to visit the website through LINE	
Never	25 (5.6)
1 time	24 (5.4)
2 times	25 (5.6)
3 times	28 (6.3)
4 times	36 (8.1)
5 times	28 (6.3)
6 times	33 (7.4)
7 times	16 (3.6)
8 times	231 (51.8)
Visit websites when did not receive notification	
Yes	177 (39.7)
No	269 (60.3)
The times to read the related articles in website	
Never	185 (41.5)
1–2 times	125 (28.0)
3–5 times	90 (20.2)
6–7 times	22 (4.9)
>8 times	24 (5.4)
The times to take any actions after reading the messages	
Never	174 (39.0)
1 time	95 (21.3)
2–3times	149 (33.4)
4 or more times	28 (6.3)

developing the program.

First, the intensity of the program may have been too low, compared to the previous study of in-person components showing the effectiveness (Hogg et al., 2021). The program was developed based on the stakeholders' and end-users' opinions, and we intended for it to be evidence-informed, useful, and simple/easy/short (<5 min per session) (Sasaki et al., 2024). We also considered that employees may be hesitant to participate in a stress management program. However, there is some evidence that more intensive interventions may be necessary. For example, a systematic review (Hogg et al., 2021) examining the effectiveness of psychosocial interventions at SMEs included only seven studies and reported that significant effectiveness was shown in five of the seven, but these effective studies had in-person or telephone components (e.g., 6 hour in-person workshop, unlimited telephone counseling). This review suggested that interventions in a group setting or the addition of telephone support appeared to be beneficial. Our WellBe-LINE, without such an intensive component, may not cause effective and sustained behavioral changes. Once weekly, short messages to click the link and read a short web page are certainly preferable for employees at MSEs, but they are not sufficient to promote well-being. Some increase in intensity combined with an improved user interface may increase the effectiveness of the intervention with minimal loss of acceptability.

Second, the psychoeducational contents did not follow the classical order of cognitive behavioral therapy (CBT) to reduce psychological distress. Our program prioritized and was tailored to the preferences of end-users, but some content was not relevant to reduce distress (e.g., how to increase job performance and efficient communication skills). The systematic review indicated that studies that showed positive effectiveness used skills of CBT. (Hogg et al., 2021) Content revisions to more closely align the program with CBT principles may increase its effectiveness. Previous study also showed that work-focused internet-

Table 6
Acceptability, appropriateness, feasibility, and uncomfortable experience/harms for "WellBe-LINE" among intervention groups at 2-month follow-up (n = 446).

	Disagree	Relatively disagree	Relatively agree	Agree	Preferable responses and harms[a]
	n (%)	n (%)	n (%)	n (%)	%
Acceptability (3 items)					
Advantages outweigh the disadvantages for keeping my mental health	26 (5.8)	74 (16.6)	284 (63.6)	62 (13.9)	77.6
Improves my social image	50 (11.2)	131 (29.4)	233 (52.2)	32 (7.2)	59.4
Acceptable for me	12 (2.7)	76 (17.0)	267 (59.9)	91 (20.4)	80.3
Appropriateness (4 items)					
Appropriate (from my perspective, it is the right thing to do)	14 (3.1)	48 (10.8)	300 (67.3)	84 (18.8)	86.1
Applicable to my health status	16 (3.6)	100 (22.4)	265 (59.4)	65 (14.5)	74.0
Suitable for my social conditions	13 (2.9)	95 (21.3)	277 (62.1)	61 (13.7)	75.8
Fits my living condition	18 (4.0)	95 (21.3)	278 (62.3)	55 (12.3)	74.7
Feasibility (6 items)					
Easy to use	12 (2.7)	79 (17.7)	257 (57.6)	98 (22.0)	79.6
Physical effort*	195 (43.7)	187 (41.9)	54 (12.1)	10 (2.2)	14.3
Total length is implementable	8 (1.8)	63 (14.1)	288 (64.6)	87 (19.5)	84.1
Length of one content is implementable	11 (2.5)	52 (11.7)	278 (62.3)	105 (23.5)	85.9
Frequency is implementable	8 (1.8)	53 (11.9)	278 (62.3)	107 (24.0)	86.3
Easy to understand	6 (1.3)	46 (10.3)	262 (58.7)	132 (29.6)	88.3
Overall satisfaction	19 (4.2)	71 (15.9)	263 (59.0)	93 (20.9)	79.8
Uncomfortable experience/harms (5 items)					
Physical symptoms	245 (54.9)	130 (29.1)	66 (14.8)	5 (1.1)	15.9
Mental symptoms	274 (61.4)	123 (27.6)	44 (9.9)	5 (1.1)	11.0
Induced dangerous experience regarding safety	314 (70.4)	89 (20.0)	39 (8.7)	4 (0.9)	9.6
Time-consuming	234 (52.5)	138 (30.9)	63 (14.1)	11 (2.5)	16.6
Excessive pressure on learning regularly	237 (53.1)	132 (29.6)	66 (14.8)	11 (2.5)	17.3

* Reversed item.
[a] Preferable responses and harms were summed with "Relatively agree" and "agree" responses, except for reversed item of physical effort.

based CBT was effective to improve job-related outcomes as well as health-related (Persson Asplund et al., 2023). Classical case formulation using a scenario at the workplace is one option for future revision of the program.

Third, the content exposures had too much emphasis on end-users' preferences, and the content varied from person to person due to the tailored program. The program automatically sent messages, and employees could choose to what extent they read the message and the website. Additionally, the tailored content that each participant received was slightly different, resulting in the heterogeneity of intervention effects. Content designed to potentially reduce psychological distress (i.e., how to cope with stress) may not be preferred because of stigma and a sense of "not in my business." Exposures may not reach the levels to achieve improvement in mental health. The precise data about time spent reading the content and what content they read was unavailable in this study. Most employees do not have motivation for content that directly addresses mental health (Hogg et al., 2021; Martin et al., 2015; Carolan and de Visser, 2018). The content exposures needed to improve employees' outcomes may be insufficient in this study. Adding basic part of CBT at the beginning of all personalized story and quick knowledge check (quiz) may be an option to ensure exposures to the contents reducing distress.

Finally, no specific framework was used to develop this program. Previous studies suggest that small adaptations in evidence-based interventions may not be trivial since adaptations may harm essential elements (also known as core elements or active ingredients) that make the intervention effective (Sasaki et al., 2021b), alerting a considerable adaptation process. Intervention Mapping (Fernandez et al., 2019) or IM adapt (a simplified version of Intervention Mapping) (Highfield et al., 2015) are options for guides to develop context-specific interventions and increase the interventions' fit with targeted settings while guarding the essential elements. Although we mainly followed the process, conducting needs assessment by interviews of stakeholders ($n = 12$) and surveys for end-users ($n = 1000$), defining the "essential element" and adaptations of it may be lacking.

We should note that the result of sub-group analysis among participants with high distress did not show favorable effect on distress, rather negative effect on well-being. This was inconsistent with the previous study, which stated that tailored digital interventions seemed more effective in employees with higher levels of distress, presenteeism or absenteeism than in the general working population (Moe-Byrne et al., 2022). It is conceivable that this intervention, not being CBT, was not fully effective in improving psychological stress reactions. Moreover, it may have been burdensome for individuals with high psychological stress, potentially reducing their well-being. In the analysis considering SES, a positive effect in well-being was observed for the less educated group, while a negative effect was noted for the higher occupational class (i.e., managerial group). This contradicted previous studies, which reported that populations with low SES were less likely to benefit from digital interventions (Western et al., 2021). The program of "WellBe-LINE" with contents easy to understand may potentially provide benefits for less educated population. On the other hand, the contents were developed to target non-managerial workers, and it may cause some burden for managers to be exposed to the contents despite its low intensity.

The present findings showed a positive evaluation of implementation outcomes. The completion rate achieved 70 %, suggesting high adherence compared to previous reports (mean rate 45 %) (Carolan et al., 2017). The perceived implementation outcomes (i.e., acceptability, appropriateness, feasibility) (Proctor et al., 2023) showed high user evaluations compared to other studies using the same scale (Obikane et al., 2022). While participants may not have had a strong need to receive the program given the nature of this preventive trial, the intervention was perceived favorably, with 76 % reporting the tailored program fit their personal situations and 80 % reporting that the program was acceptable. Mismatch with individual preferences and expectations has been reported as one of the significant barriers to digital mental health interventions (Vis et al., 2018). Our automatic semi-tailoring program seemed to contribute to high acceptability. Engaging stakeholders in the early stages of decision-making in developing the program surely helped to increase its acceptance (Persson Asplund et al., 2023) and address the concerns of end users at MSEs (Lyon and Koerner, 2016; Ramanadhan et al., 2023). Overall, these findings suggest the promise of implementing mental health promotion programs in MSEs.

4.1. Limitations

This study has several limitations. First, the study participants were recruited from the registered panel of an online survey company. Most participants were men, married, with undergraduate degrees, clerical, and working in an office. Other samples at MSEs may provide different results. The generalizability of this study should be viewed with caution. Findings from participants outside of the context of the workplace in this study may make it difficult to estimate the effectiveness if it is implemented in the MSEs. Implementation at an enterprise level may decrease perceived implementation outcomes and reduce effectiveness, influenced by evaluations of the organization and a sense of "being made to do it." It is necessary to improve the program based on the present study findings. Second, completion of the program was self-reported and website access logs by users were not collected. The actual time of exposure to the program was unclear. Time spent on the program may be moderated by its effectiveness. Third, a high contamination rate (35 %) possibly underestimated the program's effectiveness. The website is naturally open-access to the public, so the participants in the control group can search the word of the program name and easily find the website. Fourth, it is possible that the follow-up period was not appropriate to detect the effectiveness of our interventions. Very short-term or long-term improvement was unmeasured in this study. Fifth, all outcomes were measured by self-report, which may be affected by the perceptions of the participants or by situational factors at work. This kind of psychosocial intervention cannot be blinded, so personal factors, including social preference, can easily influence the self-reporting measurement. Sixth, the data about industry of the company which participants were employed was not available, leading a certain difficulty to assess the representatives of the study sample. In addition, it is possible that some participants worked the same company and it caused high contamination. In this study, it was unsure that the influence of participating together/not together with employees at the workplace on effectiveness. Engaging the program together with colleagues may increase the effectiveness.

4.2. Future directions and practical implications

The question of which aspects to prioritize in implementation and to what extent is a very complex issue; a program that stakeholders and recipients feel is acceptable is sometimes too low intensive to make the intervention effective. We "cannot have it all." Evidence that needs to be prioritized can differ by context. In MSE settings in Japan, this low-intensity once-a-week program was desirable and the format should be retained to the extent possible. Yet, we may improve the content to integrate CBT-based principles or to focus on more effective components. A recent systematic review showed behavioral activation is the most effective component in internet-based CBT (Furukawa et al., 2021). Changing the content of "WellBe-LINE" is one way to enhance the program's efficacy without making it high-intensity. In future studies, it is advisable to incorporate evidence, theory, and stakeholder preferences into the design or adaptation of these programs. Besides, more discussion is needed about the core components of preventive internet-based interventions in disadvantaged occupational health settings.

4.3. Conclusion

Overall, we did not find significant effects of a fully automated text-based stress management program, "WellBe-LINE," on any of mental health and work-related outcomes for employees working at a workplace with fewer than 50 employees. Developing the program collaboratively and making it low-intensity with simple messages led to positive implementation outcomes, such as acceptability, feasibility, and appropriateness. Future studies should integrate evidence, theory, and stakeholder preferences into program design, retaining the low-intensity format where suitable, such as in MSE settings in Japan, while potentially enhancing efficacy by incorporating effective components like CBT principles, particularly behavioral activation, and engaging in discussions about core elements of preventive internet-based interventions in disadvantaged occupational health settings.

Approval of the research protocol

Ethics approval and consent to participate: This study protocol was approved by the Research Ethics Committee of the Graduate School of Medicine/Faculty of Medicine, The University of Tokyo, No.2021190NI-(2).

Informed consent

Online informed consent was obtained from all participants with full disclosure and explanation of the purpose and procedures of this study. The panelists had the option not to respond to any part of the questionnaire and the option to discontinue participation in the survey at any point.

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Registry and registration number of the study/trial

The study protocol was registered in UMIN clinical trial registration before starting recruitments: UMIN000050624 (registration date: March 18, 2023) https://center6.umin.ac.jp/cgi-bin/ctr/ctr_view_reg.cgi?recptno=R000057552

Animal studies

N/A.

CRediT authorship contribution statement

KI was in charge of this study, supervised the process, and provided his expert opinion. AT provided expert suggestions regarding the study concept as a supervisor. NS and KI organized the study design. SO and US supported the study management. NS and KI wrote the first draft of the manuscript, and all the other authors critically revised the manuscript. All the authors approved the final version of the manuscript.

Patient and public involvement statement

Not applicable.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Kotaro Imamura reports a relationship with Department of Digital Mental Health that includes: employment. Natsu Sasaki reports a relationship with Medilio Inc. that includes: employment. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data related to the present study are available from the corresponding author, KI, upon reasonable request.

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