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Complete List of Authors:	Sasaki, Natsu; The University of Tokyo, Department of Mental Health, Graduate School of Medicine Imamura, Kotaro Nishi, Daisuke; The University of Tokyo, Watanabe, Kazuhiro; The University of Tokyo, Department of Mental Health, Graduate School of Medicine Sekiya, Yuki Tsuno, Kanami Kobayashi, Yuka Kawakami, Norito; The University of Tokyo, Department of Mental Health
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Internet-based Acceptance and Commitment Therapy program "Happiness Mom" for well-being: A protocol for a randomized controlled trial

Natsu Sasaki (MD)[1]
Nasasaki-tky@umin.ac.jp
Kotaro Imamura (PhD)[1]
Kouima-tky@umin.ac.jp
Daisuke Nishi (MD)[1]
d-nishi@m.u-tokyo.ac.jp
Kazuhiro Watanabe (PhD)[1]
Kzwatanabe-tky@umin.ac.jp
Yuki Sekiya (PhD)[1]
syuki-tky@umin.ac.jp
Kanami Tsuno (PhD)[2]
ktsuno-tky@umin.ac.jp
Yuka Kobayashi (PhD)[1]
yukakoba@m.u-tokyo.ac.jp
Norito Kawakami (MD)[1]
nkawakami@m.u-tokyo.ac.jp

1 Department of Mental Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan
2 School of Health Innovation, Kanagawa University of Human Services, Kanagawa, Japan

Corresponding author: Norito Kawakami (M.D.)
Department of Mental Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan
7-3-1, Hongo, Bunkyo-ku, Tokyo, 113-0033, Japan
E-mail: nkawakami@m.u-tokyo.ac.jp
Telephone: +81-3-5841-3364, Fax: +81-3-5841-3392

Abstract

Introduction: This randomized controlled trial (RCT) aims to examine the effects of an internet-delivered Acceptance and Commitment Therapy (iACT) program ("Happiness Mom") for working mothers to improve psychological well-being.

Methods and analysis: The target population of the RCT will be employed mothers with at least one pre-school child. Participants who fulfil the eligibility criteria will be randomly assigned either to an iACT intervention group (n=200) or to a wait-list control group (n=200). Participants in the intervention groups will be asked to complete the programs within 12 weeks of the baseline survey. The intervention program contains eight modules based on ACT. Primary outcomes are six components of psychological well-being, based on Ryff's theory. Secondary outcomes are intention to leave their job, work engagement, work performance, sick leave days, psychological distress, euthymia, positive emotions, job and life satisfaction, social support and parental burnout.

Ethics and dissemination: Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI). If the intervention programs are found to be significantly beneficial, the programs can be made available for all working mothers with pre-school children in Japan.

Trial registration number: UMIN000039918; Pre-results.

Word count: 194 words

Key words: cognitive behavioral therapy, eHealth, positive psychology, smartphone, occupational health, public health

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Article Summary

Strengths and limitations of this study

- The effects of an automated internet-based ACT (iACT) program for working mothers with preschool child(ren) on psychological well-being will be examined.
- "Happiness Mom" program was newly developed through discussion with psychological experts and mothers, which would contribute participants' low dropout and high engagement.
- Multimedia self-help program (e.g., text exercise, audio) can be expected to enhance the intervention effect on ACT and mindfulness.
- A limitation of this study is that all outcomes are self-reported.

Introduction

Working mothers are a vital part of the workforce worldwide [1]. Stable employment for mothers is important in terms of female economic independence and child development [2]. Healthy maternal employment is also highlighted in the United Nation's Sustainable Development Goals (3: promote well-being for all, 5: empower women, and 8: promote productive employment) [3-5]. However, working mothers are often under psychological and physical pressure from their many responsibilities, including domestic activities, childbearing, and paid work [6, 7]. This double burden from work and family life, and work-family conflict make the lives of working mothers difficult [8-11]. In sex-segregated cultures like Japan's, women must shoulder the caretaking responsibilities [12]. As a result, about 47% of Japan's working women give up their job after the birth of their first child [13]. They are required to change their way of living, but some of them may lose their mastery and autonomy as a result.

Poor mental health is a common health-related outcome of the conflicts experienced by working mothers [14-16]. While maternal employment itself is beneficial for mental health [17-19], working mothers' dual burden and poor work-family balance could often lead to depression, anxiety, and burnout [8, 9, 15, 20-22]. In addition, working mothers with conflicts are reported to have poor psychological well-being (PWB) [23]. Women with a young child reported poorer PWB than women with an older child [24]. Moreover, parental task is known to be more challenging to PWB among women than men [33]. PWB presents the potential for people to "live well" (self-realized, fully functioning, purposefully engaged) of people [25, 26] as defined by Ryff [26]. PWB are also shown to be associated with better health outcomes and longer survival [27-35]. Therefore, PWB can be an important mental health outcome, as well as negative emotions and distress. Intervention programs should be developed and established to promote PWB as well as to prevent depression, anxiety, and burnout, of working mothers.

Previous studies showed the effectiveness for several types of interventions in improving PWB,

including well-being therapy [36], third wave cognitive behavioral therapy (CBT) [37] and positive psychology approach [38, 39]. Acceptance and Commitment Therapy (ACT) is one of the third waves of behavioral therapies and involves mindfulness and values-based exercises to help people accept their lives and commit to moving forward in a valued life direction [40-42]. ACT interventions have been found effective in reducing the stress of mothers of children diagnosed with autism [43-49].

Time constraints and busy schedules make it difficult for working mothers to seek mental health support [50]. Internet-delivered psychosocial intervention is feasible, low-cost, effective, and accessible [51, 52]. A comparison of face-to-face and internet interventions revealed no differences in their effectiveness in treating common mental disorders [53, 54]. Web-based intervention thus may be promising for busy working mothers [55]. Several systematic reviews have shown that internet-delivered ACT (iACT) was effective in managing depression and anxiety and improving the quality of life, even with small effect size, in the general and the clinical population [56-58]. In the workplace, one small-scale randomized controlled trial (RCT) investigated the effect of iACT and alleviated depressive symptoms among full-time employed males [59]. The RCT of iACT among community-dwelling people seemed to improve PWB among those who had low PWB [60]. A pre-post-study of group ACT at worksite seemed to improve PWB among university staff [61]. However, no study has investigated the effect of iACT for improving PWB among workers, including working mothers.

The aim of this RCT is to examine the effectiveness of a new and fully automated iACT program on improving psychological well-being at posttreatment and 6-month follow-up among working mothers with at least one pre-school child. In addition, we will examine the acceptability, appropriateness, and feasibility of implementing “Happiness Mom”.

Methods

Trial design

This study will be a two-arm parallel-group non-blinded RCT. Participants will be randomly allocated 1:1 either to the intervention or to the control group after completing a baseline online questionnaire survey. This study's 12-week iACT program will be provided to the participants in the intervention group. Online follow-up surveys will be conducted at three (immediately after the intervention) and six months after the baseline survey. The study protocol was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID = UMIN000039918; trial registration 14th February 2020). This manuscript was written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [62].

Participants

This study is intended for working mothers with at least one pre-school child. The participants will be recruited from several private companies and individual application through internet advertisement in Japan.

All participants must meet to following eligibility criteria:

1. Women over 20 years of age
2. Currently employed for more than 30 hours per week
3. Have at least one preschool-age child
4. Can access the internet via a PC, tablet or smartphone
5. Not on maternity leave at baseline

Recruitment and procedure

A flowchart of how to progress from screening for eligibility to inclusion in the final analysis is given in **Figure 1**. Regarding company-based recruitment, the researchers created the application website for each company. The website will include a description of the study and an application form. The researchers will ask the company's department of human resource or occupational health sector to email the URL of a website to the candidates. The company will provide information for all candidates who

seem to meet the eligibility criteria. For individual-based recruitment, the other website will detect the means of recruitment (which company, or individual) by researchers. The URL of the website for individual recruitment will be spread through social networking service (SNS) advertisement (e.g., Facebook) and personal announcement from the researchers. Candidates will click the URL and read a full explanation of the purpose and procedures of the study on the website. Those who are interested in participating will be asked to mark the consent option and type their name, phone number and their email. This consent information will be sent to the research center and preserved. Workers who are not interested in participating will be asked to leave the website. Subsequently, participants who submitted the consent information will receive an email containing the URL of the baseline survey. They will click the URL and input their baseline information. After completing the baseline questionnaire, the participants will be randomly assigned either to the intervention or to the control group. The researchers will inform the participants of their group assignment via email. To avoid delay between the randomization and the beginning of intervention, the researchers will assign the participants to a group (which automatically set the schedule for opening the new modules) as soon as the baseline survey is completed. The researchers will send an email containing the iACT program's URL and an ID and password to the participants in the intervention group. They will be asked not to share their ID, password, and the iACT program content. Those in the control group will receive the iACT program after the six-month follow-up.

Intervention program

An internet-based, fully automated, eight-module self-help ACT program "Happiness Mom" designed for working women with pre-school children was developed. The first author led and organized the specialist team to develop the program. The researchers (NS, KT and YK), who are working mothers with pre-school children, extracted the essential concerns of working women including their experience in occupational health settings. The first author conducted informal interviews with two working women with pre-school children about their daily stressors, feelings, thoughts, dreams, and ambitions. Citing

the self-help ACT literature [63, 64], the first author made a draft of the program by describing the case to what mothers typically suffer. The ACT specialists (outside the research team) and clinical psychologist (YS) who had experienced to hold a group ACT for mothers revised the program to follow the psychological framework. A psychiatrist (DN) and a clinical psychologist (KI) confirmed the relevance of psychotherapy. The original illustrations were inserted to suit the preferences of the target population and to make it visually easy to understand. In each model, a single working mother case with a two-year-old boy was presented as an example of applying ACT skills to daily life. The eight modules are presented in a fixed order, with one module accessible per week, with four optional reading materials (**Table 1**). Each module will take 15 to 30 minutes to complete. The modules followed the six core processes, "hexaflex," that produce psychological flexibility, [41, 42, 65]. The program modules cover well-being education (module 1), acceptance and willingness (module 2), defusion (module 3), mindfulness and self-compassion (module 4), self-as-context (module 5), value (module 6), committed actions (module 7) and wrap up (module 8). The optional reading materials are (1) parenting skills based on Positive Parenting Program (Triple P) [66]; (2) couple therapy based on assertive communication; (3) relaxation skill; and (4) how to contact mental health services. Thirteen working mothers with small children were recruited by snowball sampling. They sat for a one-hour semi-structured interview conducted by the first author after completing the program. They were asked about its feasibility, usability, adaptability (i.e., timing of reminder, the day of opening the new module) and means of improving the program. Based on the results of the interviews, the researcher modified the program to make it more relevant to working mothers of small children.

Happiness Mom does not have homework and is fully self-guided. The modules are not mediated by a therapist. Although no personalized feedback is provided, the case in the contents is a single working mother with limited support raising her two-year-old son. This scenario should be familiar to the participants.

Well-being education (module 1)

In this module, the six dimensions of Ryff's psychological well-being model are introduced to seek happiness [26]. Besides, the difference of pain (i.e., the discomfort we feel in response to a real-life problem) and suffering (i.e., struggle by expanding negative thoughts or feelings in mind) are illustrated [41, 63]. The exercise "Don't think about your thoughts" is provided [63]. Participants will do three text exercises where they must describe a painful experience, focusing on the reason for it (dysfunctional thoughts), and what they want to do if they do not have dysfunctional thoughts.

Acceptance and willingness (module 2)

In this module, experiential avoidance (attempting to avoid or control internal experiences) does not work [67]. In contrast, acceptance, the adoption of an intentionally open, receptive, flexible, and nonjudgmental posture is introduced as a new strategy. Participants will experience acceptance by following the audio guide and completing a text exercise about their willingness.

Defusion (module 3)

This module introduces the concept of cognitive fusion, or being "stuck" to thoughts and self-evaluations. It encourages the practice of mind watching. Five exercises for defusion are offered: (1) "I think…", (2) leaves on a stream (metaphor), (3) extracting the thoughts from your head and seeing them on the hand, (4) naming the mind, (5) making the endings of your thought funny. Participants will be encouraged to try defusion.

Mindfulness and self-compassion (module 4)

Mindfulness is the process of paying attention on purpose, in the present moment, and nonjudgmentally [68]. Three experiential exercises are introduced here: mindfulness breathing (3 minute audio), mindfulness meditation (5 minute audio), and drinking mindfulness. Self-compassion is presented as a healthy form of self-acceptance to treat ourselves with warmth and understanding [69, 70]. Two writing

exercises, "Be willing to give *words* of comfort and reassurance to yourself as if to a friend who is tired of painful feeling." and "You can also write down some reassuring or relieving *actions* you can take to help yourself" are included. The "self-hug" is introduced with an explanation of oxytocin [71, 72]. Participants will try self-compassion body scan (7 minute audio) to recognize the sense of body and treat themselves with compassion.

Self-as-context (module 5)

The observing self is one facet of what ACT calls "self-as-context." Self-as-context entails taking several perspectives on the self. In this module, conceptualized self and sticking are introduced with the tug-of-war metaphor [63]. Through writing exercises, participants take a bird's eye view of the situation [64]. Participants are encouraged to acquiree the ability to look inside themselves from "now" and "here" [41].

Value (module 6)

ACT defines values as desired global qualities of ongoing action [41]. In this module, the metaphor of passengers on the "your life" bus is explained. Values are the direction of the bus. Two text exercises encourage participants to recognize one's desire: (1) imagine what they would do if they had everything they wanted; (2) write their own epitaph. After that, they write their value in seven important life domains (i.e., work, leaning, parenting, relationship with partner, friends, hobbies, and health) and rank the three values that are most important to them.

Committed actions (module 7)

Committed actions can be large or small moves in the direction of values. The difference between "what you can control" and "what you cannot control" is explained. This module emphasizes the importance of focusing on actions as part of being in control. Participants define several values-based goals, making action plans for each goal, and measures for the internal barriers through text exercises. Some unfamiliar

actions (e.g., wearing different colored socks) for breaking the pattern and expanding variety of actions are introduced for improving psychological flexibility.

Wrap up – Life is a journey. - (module 8)

In this module, Ryff's model of psychological well-being model is reviewed again. The importance of accepting fear, feeling, and thoughts from a perspective of self-as-context with openness and willingness is emphasized. Participants are encouraged to break the cycle of experiential avoidance by taking committed action. After finishing this module, participants receive emails suggesting that they review this program and their personal notepad, and to continue taking the actions that they learned in the program.

Optional sessions

Four articles are the basis of optional essays. Participants can read them at any time during the intervention. These are (1) parenting skills are introduced based on the Positive Parenting Program (Triple P) [73]; (2) the essence of couple therapy based on assertive communication; (3) relaxation skills (i.e., 4-7-8 breathing [74], progressive muscle relaxation [75]) and behavioral activation techniques; and (4) how to contact third-party mental health services.

Additional functions

- *Personal notepad*

Participants' text exercises are stored in their "personal notepad" to review at their convenience. If participants want to repeat an exercise, they can go back from notepad to the exercise and rewrite it.

- *Online forum*

The online forum is set for each module. Participants can use them to share their experiences, ask questions, and talk to staff with specialized knowledge about the program. Participants can post on the

board using their registered nicknames instead of their real names. The first author responds to the comments and questions posted on the board.

Control group

Upon request, participants in the control group will receive the iACT program after the six-month follow-up. The participants in the intervention group and the control group will be able to undergo treatment as usual (TAU), such as stress management education or medical care.

Outcomes

Table 2 summarizes the outcome measures. Only the participants in the intervention group will be assessed regarding the process evaluation outcomes (e.g., usability, satisfactions) at the three-month follow-up. Information contamination will be assessed in the control group at the three- and six-month follow-ups. All data will be collected using web-based self-report questionnaires. At the three- and six-month follow-ups, the research center will send at least two emails reminding non-respondents to complete the questionnaires.

Primary outcome

Psychological well-being (42 items)

Psychological well-being will be evaluated using the 42-item version of Ryff's Psychological Well-being Scales (PWBS). The PWBS originally consisted of six 7-item subscales for the assessment of six factors: 1) autonomy; 2) environmental mastery; 3) personal growth; 4) positive relations with others; 5) purpose in life; and 6) self-acceptance [26, 76]. Response categories for these items are scored along a seven-point Likert scale ranging from *Strongly disagree* (1) to *Strongly agree* (7). The scores of some items will be reversed as recommended in Ryff's original PWBS [26, 76]. The scores for six subscales will be calculated as averages; higher mean scores indicate greater psychological well-being. The reliability and validity of the Japanese version of PWBS have been recently tested [77]. The authors

simplified the Japanese translations of the response options without changing their meaning.

Secondary outcomes

As secondary outcomes, these measurement scales will be used: psychological distress (k6), parental burnout, work engagement, job performance, sick leave days, intention to leave, job and life satisfaction, positive feelings (hedonic well-being), perceived social support from the partner, social support, global fear of COVID-19, and euthymia. The details of these scales are available on **Supplementary 1**.

Process evaluation

Implementation outcomes and adverse effects

For process evaluation, we will track each participant's completion of each module. Authors also will take the 14 items of implementation outcomes for digital health interventions. The measurement was based on three important concepts: acceptability, appropriateness, and feasibility [78]. These concepts were discussed with international specialists in implementation science and internet-based psychotherapy. Adverse effects (i.e., harms) of eHealth interventions, such as physical symptoms (e.g., tired eyes, stiff shoulders), mental symptom (e.g., insomnia), dangerous experiences (e.g., bumping into people while looking at a smartphone), will be covered in five items.

Contamination of information

To evaluate contamination of information among participants in a control group, participants will be asked at follow-up survey: "Have you got to know information on the contents of Happiness Mom from others in an intervention group?"

Demographic characteristics

Demographic data, such as age, marital status, household income, education, years in the workforce, occupations, industry, employment contract, company size, working hours per week, the number of

children, disabled child, age and sex of youngest child, pregnancy, and history of fertility treatments will also be collected.

The impact of COVID-19

Authors collected data about changes in working hours and working styles (e.g., working from home, furlough) to capture the impact of COVID-19 on daily work, as because the target population was recruited during the pandemic. In the three-month follow-up, we will ask the intervention group "Is there anything in the program that you were unable to put into practice because of COVID-19?"

Sample size calculation

Sample size was calculated (total N=398) for the primary outcome to detect an effect size of 0.25 (Cohen's d) with a statistical power of (1 – b)=0.80 in a two-tailed test ($p<0.05$). Estimated effect size was decided based on the subgroup analysis on previous meta-analysis to examine the effect of internet-based CBT for improving well-being (Hedge's g=0.25) [51]. Regarding this calculation, authors set the estimated sample size at N=400.

Randomization

Participants who meet the eligibility criteria will be randomly allocated to the intervention group or control group. Participants will be stratified into two strata according to the score of K6 (4 or less, or 5 or more) and recruitment entry (company-based or individual) on the baseline survey. In addition to the analysis of the whole sample (to examine the universal intervention effect), we will analyze data by prespecified subgroups (to examine the selective intervention effect). Using a computer-generated random allocation sequence, an independent biostatistician created a stratified permuted-block random table. The block size of this RCT will be fixed at 4. The stratified permuted-block random table will be password-protected and blinded to the researcher. Only the research assistant will have access to it

during the work of random allocation.

Duration

This program is scheduled to start recruiting in April 2020 and run until the end of June. The research will end in January 2020 with the follow-up assessment. In March the whole program will be presented to the control group.

Statistical analysis

For the main pooled analysis, a mixed model for repeated measures conditional growth model analysis with an unstructured covariance matrix will be conducted using a group (intervention and control)*time (baseline, 3-month and 6-month follow-ups) interaction as an indicator of intervention effect. The primary analysis will follow the intention to treat (ITT) principle. This means that the participants will remain in the group to which they were randomized and not analyzed according to the interventions actually received. Cohen's d between groups will be calculated at each assessment term. Secondary outcomes will be analyzed in the same way as the primary outcome. The statistical significance for all analyses in this study will be set at 0.05 (two-tailed), and 95% CIs will be calculated.

For sensitivity analysis, a similar mixed model for repeated measures, but using the analysis of variance model, with an unstructured covariance matrix will be conducted. Missing values will be imputed applying the maximum likelihood estimation using the MIXED procedure. We will calculate Cohen's d among participants excluded "not started" subjects, following modified ITT principle.

For subgroup analysis, we will use the stratification factor (i.e., participants who scored 4 or less/5 or more in K6 at the baseline survey or recruitment method [company or individuals]) and analyze the results according to the prespecified subgroups.

SPSS 26.0 (IBM Corp., Armonk, NY, USA) Japanese version will be used.

Monitoring

As we anticipate no potential harms from this intervention, there will be no Data Monitoring Committee, interim analyses or stopping rules.

Data availability

Deidentified individual participant data will be available upon request after the main analysis paper has been published. Please email requests to the corresponding author.

Patient and public involvement (PPI)

The first author had informal discussions with two female workers who are mothers of pre-school children. Based on these conversations, three female researchers (NS, KT, YK), who are working mothers with pre-school children modified the contents to reflect a real situation. One PPI partner reviewed the draft before setting into a web system and suggested clarifying some points that might be difficult for general readers to understand. The second PPI partner enrolled monitors, designed a recruitment poster, introduced the stakeholders (i.e., policy makers) to researchers, and advised on PR strategy for using SNS advertisement. Both women took an interview after using the web system and gave feedback, and took part in the recruitment of participants. Two PPI partners will participate in a discussion of the study findings and in setting up the implementation strategy after finishing RCT. The PPI process will be described based on the PPI handbook and reporting checklists [79, 80].

Ethics and dissemination

Ethical and safety considerations

Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI). Participants will be fully informed that they may withdraw from the trial at any time by contacting the researchers. Any protocol modifications will be communicated to the institutional review board.

Data confidentiality

The collected data will be stored as linkable anonymizing data. The principal investigator will retain access to the final dataset after the trial and assume responsibility for data integrity and the accuracy of analysis.

Dissemination and implementation plan of research findings

The findings of this study will be published in peer-reviewed international journals. They will also be presented at research conferences, academic symposia and seminars. The principal investigator will be listed as the corresponding author, and the authorship eligibility will conform to the International Committee of Medical Journal Editors. If the intervention programs are found to be significantly beneficial, the programs can be made available for all working mothers in Japan with pre-school children.

Word count: 3931 words.

Conflict of interests

The authors declare that they have no conflicts of interest.

Authors' contribution

NK was in charge of this study, of supervising the process and provided his expert opinion. The authors (NS, KI, DN) organized the study design and developed the contents of the intervention. The authors (YS, YK, KT) developed the program. KW led the design of the statistical analyses. NS wrote the first draft of the protocol manuscript. All of the other authors revised the manuscript. All authors approved the final version of this manuscript.

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Competing interests None of the authors report any competing interests related to the submitted work.

Ethics approval Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI).

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Table 1. Contents of the iACT "*Happiness Mom*" program for working mothers with pre-school child(ren).

Module	Key concept	Estimated time	Contents
1	Well-being education	15 min	Defining happiness with psychological well-being m Ineffective coping strategy Don't think about your thoughts (exercise) Difference between "pain" and "suffering" Exploring internal barriers (i.e., thoughts, feelings) a ues-based actions (exercise)
2	Acceptance and Willingness	15 min	Experiential avoidance How to accept negative feelings and thoughts (audi Formulating own willingness (exercise)
3	Defusion	10 min	Fusion with "Mind" Cognitive defusion technique of acknowledging "I am having the thought that … " Leaves on a stream (metaphor)
4	Mindfulness and Self-compassion	30 min	Mindful breathing (audio), meditation (audio), and eating and drinking. Self-compassion "self-hug exercise". Self-compassionate body scan (audio).
5	Self-as-context	15 min	Conceptualized self Tug-of-war (metaphor) Observing communication from the sky (exercise).
6	Value	20 min	Passengers on a bus (metaphor) Think of your own epitaph. (exercise) Defining what values are Clarifying one's values (e.g., epitaph, value in 7 domains) (exercise)

7	Committed actions	30 min	Difference of thigs can be controlled or not Defining effective and values-based goals (exercise) Making action lists and strategies against internal barriers (exercise) Psychological flexibility -break the pattern and expand variety of actions.
8	Wrap up	6 min	Psychological well-being model New strategy to grow yourself up
Optional sessions		5 min/content	Positive parenting program (based on Triple P) and parenting mindfulness. Couple therapy (based on assertive communication) Relaxation skill and behavioral activation technique How to contact to mental health service of 3rd party
Additional functions			Can review what they wrote on exercise in courses (2nd function) Can share their feeling or impression with all participants on forum Can ask questions to researchers on forum

Table 2. Assessment schedule of the outcome measures for the randomized controlled trial for "Happiness Mom".

Measurement	Aim	Baseline (T1)	3-M f/u (T2)	6-M f/u (T3)
Primary outcome				
PWBS-42	Psychological well-being	X	X	X
Secondary outcomes				
K6	Psychological distress	X	X	X
PBA-J	Parental burnout	X	X	X
UWES-9	Work engagement	X	X	X
HPQ	Job performance	X	X	X
Sick leave days	Sick leave days during the past 3 months	X	X	X
Intention to leave	Intention to leave their company/organization	X	X	X
Satisfaction	Job and life satisfaction	X	X	X
Positive feeling	Positive feeling and adjective (hedonic well-being)	X	X	X
VAS	Perceived social support from the partner	X	X	X
MSPSS	Social support	X	X	X
Fear of COVID-19	Global fear and worry about COVID-19	X	X	X
Euthymia	Psychological flexibility and resilience	X	X	X
Process evaluation				
IDMH	Acceptability, appropriateness, feasibility, satisfaction, adverse effect		X	X
Effect of COVID-19	Adverse effects of leaning by COVID-19			
Others				
Demographic data		X		
Contamination	Contamination of information for a control group		X	X

PWBS-42: Psychological well-being scale 42 items version.

K6: Kessler's Psychological Distress Scale.

UWES-9: Utrecht Work Engagement Scale 9 items version.

MSPSS: Multidimensional Scale of Perceived Social Support.

HPQ: WHO Health and Work Performance Questionnaire.

PBA-J: Parental Burnout Assessment Japanese version.

IDMH: Implementation outcome scale for Digital Mental Health.

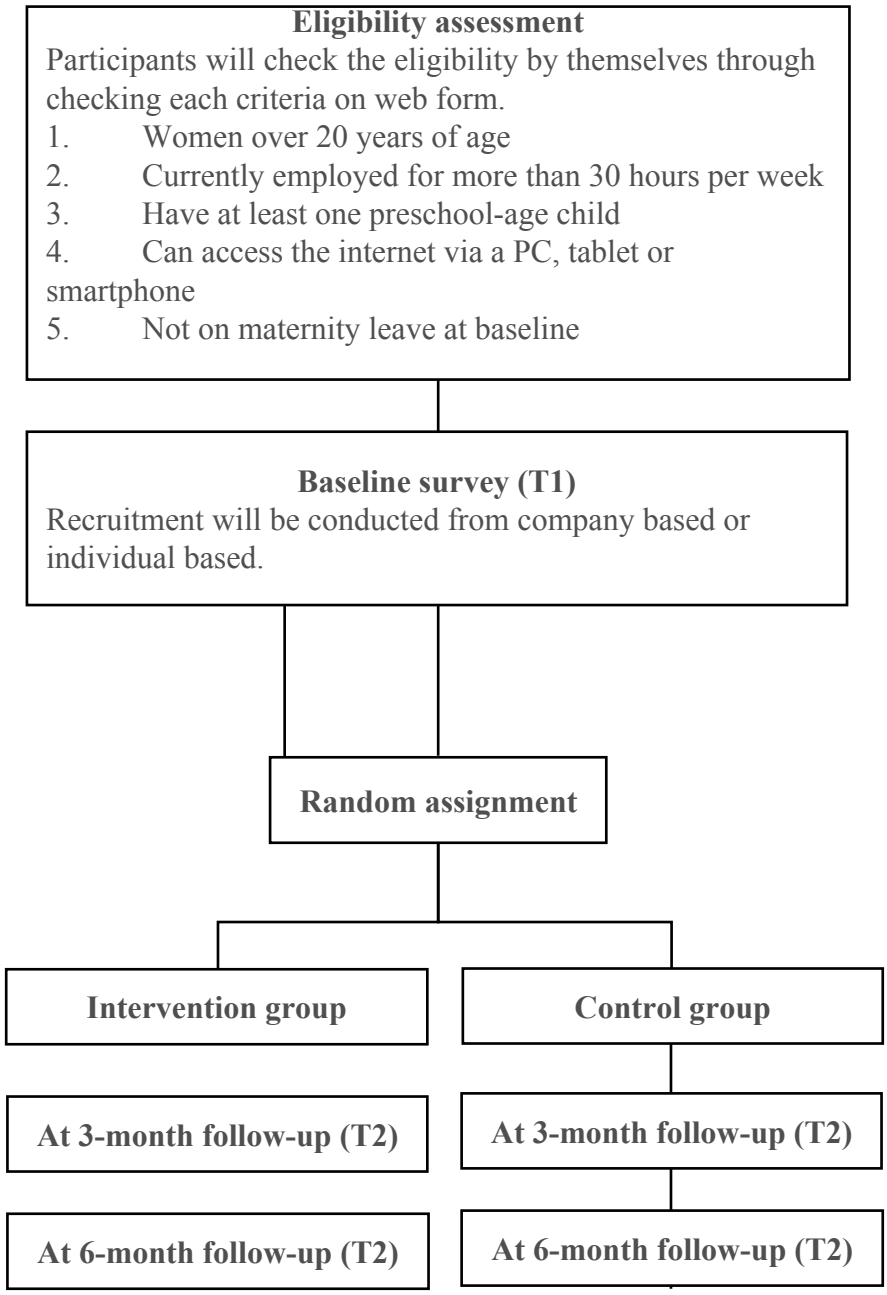

Figure 1. Participants' flow chart

(a) Reading materials (b) Audio (c) Text exercise

Figure 2. Screenshots of Happiness-mom.

Supplementary. Details of secondary outcomes.

Psychological distress (K6)

Psychological distress will be evaluated using the Japanese version of the K6 [1, 2]. The K6 is a widely-used self-rating scale assessing nonspecific distress during the past 30 days. Each item of the K6 is scored on a Likert scale ranging from *never* (0) to *all of the time* (4). The total score of the K6 ranges from 0 to 24, with higher scores indicating more severe psychological distress. A score of 13 or more and between 5 to 12 on the K6 will be considered severe and moderate psychological distress, respectively [3]. The reliability and validity of the Japanese version of the K6 has been found to be satisfactory [1, 4].

Parental burnout

Parental burnout will be assessed by the Parental Burnout Assessment (PBA) [5]. PBA is a 23-item with four dimensions: exhaustion in one's parental role (6 items), contrast with previous parental self (6 items), feelings of being fed up with one's parental role (5 items) and emotional distancing from one's children (3 items). Items are rated on 7-point Likert scales: *never* (0) to *every day* (6). Japanese version of PBA (PBA-J) has showed high reliability and validity [6].

Work engagement

The short form of the Utrecht Work Engagement Scale, 9-items (UWES-9) will be used to assess work engagement [7]. The UWES-9 consists of three subscales (vigor, dedication and absorption) which contain three items each. The UWES-9 is a self-report 7-point rating scale (0 = *never*; 6 = *every day*). The mean scores of the three UWES subscales and the total score are computed by adding the scores and dividing the sum by the number of items in each subscale. Hence, the UWES's three subscale scores and a total score range from 0 to 6. The Japanese version of UWES-9 has showed acceptable reliability and validity [8].

Job performance

Work performance will be evaluated using one item of the WHO Health and Work Performance Questionnaire (HPQ) in Japanese [9, 10]. The HPQ is a self-report measure designed to estimate the workplace costs of health problems. In this study, participants will be asked to rate their overall work performance during the past 4 weeks. Items are scored on an 11-point scale ranging from 0 (worst possible performance) to10(best possible performance). A high score indicates a high degree of work performance. The reliability and validity of Japanese version of HPQ have been tested [10].

Sick leave days

Participants will be asked to report their number of sick leave days during the past 3 months.

Intention to leave

The intention to leave is simply by asking one original item "Are you thinking of quitting your job?". The item is scored on a scale from 0 (*none*) to 4 (*always*). Higher scores indicate greater intention to leave. Reliability and validity of the Japanese version have not yet been determined.

Job and life satisfaction (evaluative well-being)

Job and life satisfaction will be assessed by each one item of the Brief Job Stress Questionnaire (BJSQ) [11-13]. The job and life satisfaction score are estimated on a 4-point Likert-type scale by asking "I am satisfied with my job (family life)".

Positive feelings (hedonic well-being)

Positive adjectives were measured by 10 items (e.g., enthusiastic, strong, inspired, proud, active, interested, excited, alert, determined, attentive) from *The Positive and Negative Affect Schedule (PANAS)* [14], which is a widely used mood measurement and regarded as one of the indicators of hedonic well-being. In addition, positive affect was each measured by six items (i.e., cheerful, in good spirits, extremely happy, calm and peaceful, satisfied, full of life), because such low arousal positive feeling has been reported to have stronger link with health among Japanese people, other than high arousal feelings, measured by PANAS [15]. Other than them, two items (i.e., close to others and confident) were added in terms of cultural affinity. These 18 items were used in the previous large population-based cohort study in Japan [16]. This study used the past 30 days as the time frame. All items were rated on a 5-point Likert-type scale, ranging from 1 "*None of the time*" to 5 "*All of the time*". Scales were constructed by calculating the mean across each set of items. Higher scores indicate greater positive feeling. Positive feeling scales in this questionnaire is well validated elsewhere [15].

Perceived social support from the partner

Perceived social support from the partner was measured in an original visual analogue scale (range: 0 - 100) by asking two questions: "How much emotional support does your partner (e.g. your spouse) provide for you? Please answer on a scale of 0 to 100." and "How much housework and childcare does your partner (e.g. your spouse) provide?". This scale will be shown only for participants who answer they are married.

Social support

Social support was assessed using the Japanese short (7-item) version of the self-rating Multidimensional Scale of Perceived Social Support (MSPSS) [17, 18]. It assesses perceived support

from each of three sources: family (2 items), friends (3 items) and a significant other (2 items). The scale uses a 7-point Likert scale, ranging from *very strongly disagree* (1) to *very strongly agree* (7), with higher scores suggesting greater levels of perceived social support. The mean score of 7 items is used as a total score. Japanese short version of MSPSS has been shown acceptable reliability and validity [19].

Global fear and worry about COVID-19

Global fear and worry about COVID-19 was assessed by a single item [20]: "Do you feel anxiety about COVID-19?" Responses were rated along a 6-point Likert-type scale ranging from 1 "*Not at all*" to 6 "*Feel strongly*."

Euthymia

Euthymia, which is newly stated concept by Fava in 2016, is a transdiagnostic construct for representing a psychological flexibility, a unifying outlook on life, and resistance to stress (i.e., resilience and tolerance to anxiety and frustration) [21, 22]. The Euthymia scale (ES) is a 10-item measurement with two answer options dichotomously as False (0) or True (1), resulting in a total ranging from 0 to 10, with higher scores indicating a better euthymic state. The Japanese version of ES shows high reliability (Cronbach's alpha; 0.832).

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	13
Sample size	7a	How sample size was determined	14
	7b	When applicable, explanation of any interim analyses and stopping guidelines	14
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	15
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	15
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	15
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	15

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	15
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Internet-based Acceptance and Commitment Therapy program "Happiness Mom" for well-being: A protocol for a randomized controlled trial

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Internet-based Acceptance and Commitment Therapy program "Happiness Mom" for well-being: A protocol for a randomized controlled trial

Natsu Sasaki (MD)[1]
Nasasaki-tky@umin.ac.jp
Kotaro Imamura (PhD)[1]
Kouima-tky@umin.ac.jp
Daisuke Nishi (MD)[1]
d-nishi@m.u-tokyo.ac.jp
Kazuhiro Watanabe (PhD)[1]
Kzwatanabe-tky@umin.ac.jp
Yuki Sekiya (PhD)[1]
syuki-tky@umin.ac.jp
Kanami Tsuno (PhD)[2]
ktsuno-tky@umin.ac.jp
Yuka Kobayashi (PhD)[1]
yukakoba@m.u-tokyo.ac.jp
Norito Kawakami (MD)[1]
nkawakami@m.u-tokyo.ac.jp

1 Department of Mental Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan
2 School of Health Innovation, Kanagawa University of Human Services, Kanagawa, Japan

Corresponding author: Norito Kawakami (M.D.)
Department of Mental Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan
7-3-1, Hongo, Bunkyo-ku, Tokyo, 113-0033, Japan
E-mail: nkawakami@m.u-tokyo.ac.jp
Telephone: +81-3-5841-3364, Fax: +81-3-5841-3392

Abstract

Introduction: This randomized controlled trial (RCT) aims to examine the effects of an internet-delivered Acceptance and Commitment Therapy (iACT) program ("Happiness Mom") for working mothers to improve psychological well-being.

Methods and analysis: The target population of the RCT will be employed mothers with at least one pre-school child. Participants who fulfil the eligibility criteria will be randomly assigned either to an iACT intervention group (n=200) or to a wait-list control group (n=200). Participants in the intervention groups will be asked to complete the programs within 12 weeks of the baseline survey. The intervention program contains eight modules based on ACT. Primary outcomes are six components of psychological well-being, based on Ryff's theory. Secondary outcomes are intention to leave their job, work engagement, work performance, sick leave days, psychological distress, euthymia, positive emotions, job and life satisfaction, social support, parental burnout and global fear and worry of COVID-19.

Ethics and dissemination: Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI). If the intervention programs are found to be significantly beneficial, the programs can be made available for all working mothers with pre-school children in Japan.

Discussion: This study will contribute to develop an internet-based self-care program which is effective, feasible, low-cost, and accessible to improve well-being of working mothers.

Trial registration number: UMIN000039918; Pre-results.

Word count: 224 words

Key words: cognitive behavioral therapy, eHealth, positive psychology, smartphone, occupational health, public health

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Article Summary

Strengths and limitations of this study

- The effects of an automated internet-based ACT (iACT) program for working mothers with preschool child(ren) on psychological well-being will be examined.
- "Happiness Mom" program was newly developed through discussion with psychological experts and mothers, which would contribute participants' low dropout and high engagement.
- Multimedia self-help program (e.g., text exercise, audio) can be expected to enhance the intervention effect on ACT and mindfulness.
- A limitation of this study is that all outcomes are self-reported.

Introduction

Working mothers are a vital part of the workforce worldwide [1]. Stable employment for mothers is important in terms of female economic independence and child development [2]. Healthy maternal employment is also highlighted in the United Nation's Sustainable Development Goals (3: promote well-being for all, 5: empower women, and 8: promote productive employment) [3-5]. However, working mothers are often under psychological and physical pressure from their many responsibilities, including domestic activities, childbearing, and paid work [6, 7]. This double burden from work and family life, and work-family conflict make the lives of working mothers difficult [8-11]. In sex-segregated cultures like Japan's, women must shoulder the caretaking responsibilities [12]. As a result, about 47% of Japan's working women give up their job after the birth of their first child [13]. They are required to change their way of living, but some of them may lose their mastery and autonomy as a result.

Poor mental health is a common health-related outcome of the conflicts experienced by working mothers [14-16]. While maternal employment itself is beneficial for mental health [17-19], working mothers' dual burden and poor work-family balance could often lead to depression, anxiety, and burnout [8, 9, 15, 20-22]. In addition, working mothers with conflicts are reported to have poor psychological well-being (PWB) [23]. Women with a young child reported poorer PWB than women with an older child [24]. Moreover, parental task is known to be more challenging to PWB among women than men [33]. PWB presents the potential for people to "live well" (self-realized, fully functioning, purposefully engaged) of people [25, 26] as defined by Ryff [26]. PWB are also shown to be associated with better health outcomes and longer survival [27-35]. Therefore, PWB can be an important mental health outcome, as well as negative emotions and distress. Intervention programs should be developed and established to promote PWB as well as to prevent depression, anxiety, and burnout, of working mothers.

Previous studies showed the effectiveness for several types of interventions in improving PWB, including well-being therapy [36], third wave cognitive behavioral therapy (CBT) [37] and positive psychology approach [38, 39]. Acceptance and Commitment Therapy (ACT) is one of the third waves of behavioral therapies and involves mindfulness and values-based exercises to help people accept their lives and commit to moving forward in a valued life direction [40-42]. ACT interventions have been found effective in reducing the stress of mothers of children diagnosed with autism [43-49].

Time constraints and busy schedules make it difficult for working mothers to seek mental health support [50]. Internet-delivered psychosocial intervention is feasible, low-cost, effective, and accessible [51, 52]. A comparison of face-to-face and internet interventions revealed no differences in their effectiveness in treating common mental disorders [53, 54]. Web-based intervention thus may be promising for busy working mothers [55]. Several systematic reviews have shown that internet-delivered ACT (iACT) was effective in managing depression and anxiety and improving the quality of life, even with small effect size, in the general and the clinical population [56-58]. In the workplace, one small-scale randomized controlled trial (RCT) investigated the effect of iACT and alleviated depressive symptoms among full-time employed males [59]. The RCT of iACT among community-dwelling people seemed to improve PWB among those who had low PWB [60]. A pre-post-study of group ACT at worksite seemed to improve PWB among university staff [61]. However, no study has investigated the effect of iACT for improving PWB among workers, including working mothers.

The aim of this RCT is to examine the effectiveness of a new and fully automated iACT program, named "Happiness Mom", on improving psychological well-being at posttreatment and 6-month follow-up among working mothers with at least one pre-school child. In addition, we will examine the acceptability, appropriateness, and feasibility of implementing "Happiness Mom".

Methods

Trial design

This study will be a two-arm parallel-group non-blinded RCT. Participants will be randomly allocated 1:1 either to the intervention or to the control group after completing a baseline online questionnaire survey. This study's 12-week iACT program will be provided to the participants in the intervention group. Online follow-up surveys will be conducted at three (immediately after the intervention) and six months after the baseline survey. The study protocol was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID = UMIN000039918; trial registration 14th February 2020). This manuscript was written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [62].

Participants

This study is intended for working mothers with at least one pre-school child. The participants will be recruited from several private companies and individual application through internet advertisement in Japan.

All participants must meet to following eligibility criteria:

1. Women over 20 years of age
2. Currently employed for more than 30 hours per week
3. Have at least one preschool-age child
4. Can access the internet via a PC, tablet or smartphone
5. Not on maternity leave at baseline

Recruitment and procedure

A flowchart of how to progress from screening for eligibility to inclusion in the final analysis is given in **Figure 1**. Regarding company-based recruitment, the researchers created the application website for

each company. The website will include a description of the study and an application form. The researchers will ask the company's department of human resource or occupational health sector to email the URL of a website to the candidates. The company will provide information for all candidates who seem to meet the eligibility criteria. For individual-based recruitment, the other website will detect the means of recruitment (which company, or individual) by researchers. The URL of the website for individual recruitment will be spread through social networking service (SNS) advertisement (e.g., Facebook) and personal announcement from the researchers. Candidates will click the URL and read a full explanation of the purpose and procedures of the study on the website. Those who are interested in participating will be asked to mark the consent option and type their name, phone number and their email. This consent information will be sent to the research center and preserved. Workers who are not interested in participating will be asked to leave the website. Subsequently, participants who submitted the consent information will receive an email containing the URL of the baseline survey. They will click the URL and input their baseline information. After completing the baseline questionnaire, the participants will be randomly assigned either to the intervention or to the control group. The researchers will inform the participants of their group assignment via email. To avoid delay between the randomization and the beginning of intervention, the researchers will assign the participants to a group (which automatically set the schedule for opening the new modules) as soon as the baseline survey is completed. The researchers will send an email containing the iACT program's URL and an ID and password to the participants in the intervention group. They will be asked not to share their ID, password, and the iACT program content. Those in the control group will receive the iACT program after the six-month follow-up.

Intervention program

An internet-based, fully automated, eight-module self-help ACT program "Happiness Mom" designed for working women with pre-school children was developed (**Figure 2**). The first author led and

organized the specialist team to develop the program. The researchers (NS, KT and YK), who are working mothers with pre-school children, extracted the essential concerns of working women including their experience in occupational health settings. The first author conducted informal interviews with two working women with pre-school children about their daily stressors, feelings, thoughts, dreams, and ambitions. Citing the self-help ACT literature [63, 64], the first author made a draft of the program by describing the case to what mothers typically suffer. The ACT specialists (outside the research team) and clinical psychologist (YS) who had experienced to hold a group ACT for mothers revised the program to follow the psychological framework. A psychiatrist (DN) and a clinical psychologist (KI) confirmed the relevance of psychotherapy. The original illustrations were inserted to suit the preferences of the target population and to make it visually easy to understand. In each model, a single working mother case with a two-year-old boy was presented as an example of applying ACT skills to daily life. The eight modules are presented in a fixed order, with one module accessible per week, with four optional reading materials (**Table 1**). Each module will take 15 to 30 minutes to complete. The modules followed the six core processes, "hexaflex," that produce psychological flexibility, [41, 42, 65]. The program modules cover well-being education (module 1), acceptance and willingness (module 2), defusion (module 3), mindfulness and self-compassion (module 4), self-as-context (module 5), value (module 6), committed actions (module 7) and wrap up (module 8). The optional reading materials are (1) parenting skills based on Positive Parenting Program (Triple P) [66]; (2) couple therapy based on assertive communication; (3) relaxation skill; and (4) how to contact mental health services.

Thirteen working mothers with small children were recruited by snowball sampling. They sat for a one-hour semi-structured interview conducted by the first author after completing the program. They were asked about its feasibility, usability, adaptability (i.e., timing of reminder, the day of opening the new module) and means of improving the program. Based on the results of the interviews, the researcher modified the program to make it more relevant to working mothers of small children.

Happiness Mom does not have homework and is fully self-guided. The modules are not mediated by a

therapist. Although no personalized feedback is provided, the case in the contents is a single working mother with limited support raising her two-year-old son. This scenario should be familiar to the participants.

Well-being education (module 1)

In this module, the six dimensions of Ryff's psychological well-being model are introduced to seek happiness [26]. Besides, the difference of pain (i.e., the discomfort we feel in response to a real-life problem) and suffering (i.e., struggle by expanding negative thoughts or feelings in mind) are illustrated [41, 63]. The exercise "Don't think about your thoughts" is provided [63]. Participants will do three text exercises where they must describe a painful experience, focusing on the reason for it (dysfunctional thoughts), and what they want to do if they do not have dysfunctional thoughts.

Acceptance and willingness (module 2)

This module introduces that experiential avoidance (attempting to avoid or control internal experiences) does not work [67]. In contrast, acceptance, the adoption of an intentionally open, receptive, flexible, and nonjudgmental posture is introduced as a new strategy. Participants will experience acceptance by following the audio guide and completing a text exercise about their willingness.

Defusion (module 3)

This module introduces the concept of cognitive fusion, or being "stuck" to thoughts and self-evaluations. It encourages the practice of mind watching. Five exercises for defusion are offered: (1) "I think…", (2) leaves on a stream (metaphor), (3) extracting the thoughts from your head and seeing them on the hand, (4) naming the mind, (5) making the endings of your thought funny. Participants will be encouraged to try defusion.

Mindfulness and self-compassion (module 4)

Mindfulness is the process of paying attention on purpose, in the present moment, and nonjudgmentally [68]. Three experiential exercises are introduced here: mindfulness breathing (3 minute audio), mindfulness meditation (5 minute audio), and drinking mindfulness. Self-compassion is presented as a healthy form of self-acceptance to treat ourselves with warmth and understanding [69, 70]. Two writing exercises, "Be willing to give *words* of comfort and reassurance to yourself as if to a friend who is tired of painful feeling." and "You can also write down some reassuring or relieving *actions* you can take to help yourself" are included. The "self-hug" is introduced with an explanation of oxytocin [71, 72]. Participants will try self-compassion body scan (7 minute audio) to recognize the sense of body and treat themselves with compassion.

Self-as-context (module 5)

The observing self is one facet of what ACT calls "self-as-context." Self-as-context entails taking several perspectives on the self. In this module, conceptualized self and sticking are introduced with the tug-of-war metaphor [63]. Through writing exercises, participants take a bird's eye view of the situation [64]. Participants are encouraged to acquiree the ability to look inside themselves from "now" and "here" [41].

Value (module 6)

ACT defines values as desired global qualities of ongoing action [41]. In this module, the metaphor of passengers on the "your life" bus is explained. Values are the direction of the bus. Two text exercises encourage participants to recognize one's desire: (1) imagine what they would do if they had everything they wanted; (2) write their own epitaph. After that, they write their value in seven important life domains (i.e., work, leaning, parenting, relationship with partner, friends, hobbies, and health) and rank the three values that are most important to them.

Committed actions (module 7)

Committed actions can be large or small moves in the direction of values. The difference between "what you can control" and "what you cannot control" is explained. This module emphasizes the importance of focusing on actions as part of being in control. Participants define several values-based goals, makes action plans for each goal, and measures for the internal barriers through text exercises. Some unfamiliar actions (e.g., wearing different colored socks) for breaking the pattern and expanding variety of actions are introduced for improving psychological flexibility.

Wrap up – Life is a journey. - (module 8)

In this module, Ryff's model of psychological well-being model is reviewed again. The importance of accepting fear, feeling, and thoughts from a perspective of self-as-context with openness and willingness is emphasized. Participants are encouraged to break the cycle of experiential avoidance by taking committed action. After finishing this module, participants receive emails suggesting that they review this program and their personal notepad, and to continue taking the actions that they learned in the program.

Optional sessions

Four articles are the basis of optional sessions. Participants can read them at any time during the intervention. These are (1) parenting skills are introduced based on the Positive Parenting Program (Triple P) [73]; (2) the essence of couple therapy based on assertive communication; (3) relaxation skills (i.e., 4-7-8 breathing [74], progressive muscle relaxation [75]) and behavioral activation techniques; and (4) how to contact third-party mental health services.

Additional functions

- *Personal notepad*

Participants' text exercises are stored in their "personal notepad" to review at their convenience. If participants want to repeat an exercise, they can go back from notepad to the exercise and rewrite it.

- *Online forum*

The online forum is set for each module. Participants can use them to share their experiences, ask questions, and talk to staff with specialized knowledge about the program. Participants can post on the board using their registered nicknames instead of their real names. The first author responds to the comments and questions posted on the board.

Control group

Participants in the control group will receive the iACT program after the six-month follow-up. The participants in the intervention group and the control group can seek any mental health treatment as usual (TAU), such as stress management education or medical care, throughout the research period.

Outcomes

Table 2 summarizes the outcome measures. Only the participants in the intervention group will be assessed regarding the process evaluation outcomes (e.g., usability, satisfactions) at the three-month follow-up. Information contamination will be assessed in the control group at the three- and six-month follow-ups. All data will be collected using web-based self-report questionnaires. At the three- and six-month follow-ups, the research center will send at least two emails reminding non-respondents to complete the questionnaires.

Primary outcome

Psychological well-being (42 items)

Psychological well-being will be evaluated using the 42-item version of Ryff's Psychological Well-being Scales (PWBS). The PWBS originally consisted of six 7-item subscales for the assessment of six factors: 1) autonomy; 2) environmental mastery; 3) personal growth; 4) positive relations with others; 5) purpose in life; and 6) self-acceptance [26, 76]. Response categories for these items are scored along a seven-point Likert scale ranging from *Strongly disagree* (1) to *Strongly agree* (7). The scores of some items will be reversed as recommended in Ryff's original PWBS [26, 76]. The scores for six subscales will be calculated as averages; higher mean scores indicate greater psychological well-being. The reliability and validity of the Japanese version of PWBS have been recently tested [77]. The authors simplified the Japanese translations of the response options without changing their meaning.

Secondary outcomes

As secondary outcomes, these measurement scales will be used: psychological distress (K6), parental burnout, work engagement, job performance, sick leave days, intention to leave, job and life satisfaction, positive feelings (hedonic well-being), perceived social support from the partner, social support, global fear of COVID-19, and euthymia. The details of these scales are available on **Supplementary 1**.

Process evaluation

Implementation outcomes and adverse effects

For process evaluation, we will track each participant's completion of each module. Authors also will take the 14 items of implementation outcomes for digital health interventions. The measurement was based on three important concepts: acceptability, appropriateness, and feasibility [78]. These concepts were discussed with international specialists in implementation science and internet-based psychotherapy. Adverse effects (i.e., harms) of eHealth interventions, such as physical symptoms (e.g., tired eyes, stiff shoulders), mental symptom (e.g., insomnia), dangerous experiences (e.g., bumping into people while looking at a smartphone), will be covered in five items.

Contamination of information

To evaluate contamination of information among participants in a control group, participants will be asked at follow-up survey: "Have you got to know information on the contents of Happiness Mom from others in an intervention group?"

Demographic characteristics

Demographic data, such as age, marital status, household income, education, years in the workforce, occupations, industry, employment contract, company size, working hours per week, the number of children, disabled child, age and sex of youngest child, pregnancy, and history of fertility treatments will also be collected.

The impact of COVID-19

Authors collected data about changes in working hours and working styles (e.g., working from home, furlough) to capture the impact of COVID-19 on daily work, as because the target population was recruited during the pandemic. In the three-month follow-up, we will ask the intervention group "Is there anything in the program that you were unable to put into practice because of COVID-19?"

Sample size calculation

Sample size was calculated (total N=398) for the primary outcome to detect an effect size of 0.25 (Cohen's d) with a statistical power of (1 – b)=0.80 in a two-tailed test ($p<0.05$). Estimated effect size was decided based on the subgroup analysis on previous meta-analysis to examine the effect of internet-based CBT for improving well-being (Hedge's g=0.25) [51]. Regarding this calculation, authors set the estimated sample size at N=400.

Randomization

Participants who meet the eligibility criteria will be randomly allocated to the intervention group or control group. Participants will be stratified into two strata according to the score of K6 (4 or less, or 5 or more) and recruitment entry (company-based or individual) on the baseline survey. In addition to the analysis of the whole sample (to examine the universal intervention effect), we will analyze data by prespecified subgroups (to examine the selective intervention effect). Using a computer-generated random allocation sequence, an independent biostatistician created a stratified permuted-block random table. The block size of this RCT will be fixed at 4. The stratified permuted-block random table will be password-protected and blinded to the researcher. Only the research assistant will have access to it during the work of random allocation.

Duration

This program is scheduled to start recruiting in April 2020 and run until the end of June. The research will end in January 2021 with the follow-up assessment. In March 2021 the whole program will be presented to the control group.

Statistical analysis

For the main pooled analysis, a mixed model for repeated measures conditional growth model analysis with an unstructured covariance matrix will be conducted using a group (intervention and control)*time (baseline, 3-month and 6-month follow-ups) interaction as an indicator of intervention effect. The primary analysis will follow the intention to treat (ITT) principle. This means that the participants will remain in the group to which they were randomized and not analyzed according to the interventions actually received. Cohen's d between groups will be calculated at each assessment term. Secondary outcomes will be analyzed in the same way as the primary outcome. The statistical significance for all analyses in this study will be set at 0.05 (two-tailed), and 95% CIs will be calculated.

For sensitivity analysis, a similar mixed model for repeated measures, but using the analysis of variance model, with an unstructured covariance matrix will be conducted. Missing values will be imputed applying the maximum likelihood estimation using the MIXED procedure. We will calculate Cohen's d among participants excluded "not started" subjects, following modified ITT principle.

For subgroup analysis, we will use the stratification factor (i.e., participants who scored 4 or less/5 or more in K6 at the baseline survey or recruitment method [company or individuals]) and analyze the results according to the prespecified subgroups.

SPSS 26.0 (IBM Corp., Armonk, NY, USA) Japanese version will be used.

Monitoring

As we anticipate no potential harms from this intervention, there will be no Data Monitoring Committee, interim analyses or stopping rules.

Data availability

Deidentified individual participant data will be available upon request after the main analysis paper has been published. Please email requests to the corresponding author.

Patient and public involvement (PPI)

The first author had informal discussions with two female workers who are mothers of pre-school children. Based on these conversations, three female researchers (NS, KT, YK), who are working mothers with pre-school children modified the contents to reflect a real situation. One PPI partner reviewed the draft before setting into a web system and suggested clarifying some points that might be difficult for general readers to understand. The second PPI partner enrolled monitors, designed a recruitment poster, introduced the stakeholders (i.e., policy makers) to researchers, and advised on PR strategy for using SNS advertisement. Both women took an interview after using the web system and

gave feedback, and took part in the recruitment of participants. Two PPI partners will participate in a discussion of the study findings and in setting up the implementation strategy after finishing RCT. The PPI process will be described based on the PPI handbook and reporting checklists [79, 80].

Ethics and dissemination

Ethical and safety considerations

Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI). Participants will be fully informed that they may withdraw from the trial at any time by contacting the researchers. Any protocol modifications will be communicated to the institutional review board.

Data confidentiality

The collected data will be stored as linkable anonymizing data. The principal investigator will retain access to the final dataset after the trial and assume responsibility for data integrity and the accuracy of analysis.

Dissemination and implementation plan of research findings

The findings of this study will be published in peer-reviewed international journals. They will also be presented at research conferences, academic symposia and seminars. The principal investigator will be listed as the corresponding author, and the authorship eligibility will conform to the International Committee of Medical Journal Editors. If the intervention programs are found to be significantly beneficial, the programs can be made available for all working mothers in Japan with pre-school children.

Discussion

An internet-based, fully automated, eight-module self-help ACT program “Happiness Mom” designed

for working women with pre-school children was developed to improve psychological well-being. This study is the first randomized controlled trial to examine the effectiveness of iACT for psychological well-being among working population. There are some limitations in the study: first, the program has small-optional essays (e.g., parenting, relaxation skills). The intervention effectiveness will not be identified as the difference between iACT and those essays. The study will examine the effectiveness of the intervention "Happiness Mom" as a whole package. Second, this study will not assess multiple aspects of psychological flexibility using validated scales (e.g., Acceptance and Action Questionnaire-II) to know a psychological process connecting between the intervention and the outcomes. We would not be able to identify what psychological process most important if the intervention is found effective. Finally, all outcome will be assessed by the self-reporting questionnaire. In spite of some limitations, this study will contribute to develop an internet-based self-care program which is effective, feasible, low-cost, and accessible to improve well-being of working mothers. Newly-developed program may provide psychological support for women to pursue their life-career according to their value. Web-based program can be easily available in other countries through translation in the future.

Word count: 4128 words.

Conflict of interests

The authors declare that they have no conflicts of interest.

Authors' contribution

NK was in charge of this study, of supervising the process and provided his expert opinion. The authors (NS, KI, DN) organized the study design and developed the contents of the intervention. The authors (YS, YK, KT) developed the program. KW led the design of the statistical analyses. NS wrote the first draft of the protocol manuscript. All of the other authors revised the manuscript. All authors approved the final version of this manuscript.

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Competing interests None of the authors report any competing interests related to the submitted work.

Ethics approval Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI).

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Table 1. Contents of the iACT "*Happiness Mom*" program for working mothers with pre-school child(ren).

Module	Key concept	Estimated time	Contents
1	Well-being education	15 min	Defining happiness with psychological well-being model Ineffective coping strategy Don't think about your thoughts (exercise) Difference between "pain" and "suffering" Exploring internal barriers (i.e., thoughts, feelings) to values-based actions (exercise)
2	Acceptance and Willingness	15 min	Experiential avoidance How to accept negative feelings and thoughts (audio) Formulating own willingness (exercise)
3	Defusion	10 min	Fusion with "Mind" Cognitive defusion technique of acknowledging "I am having the thought that … " Leaves on a stream (metaphor)
4	Mindfulness and Self-compassion	30 min	Mindful breathing (audio), meditation (audio), and eating and drinking. Self-compassion "self-hug exercise". Self-compassionate body scan (audio).
5	Self-as-context	15 min	Conceptualized self Tug-of-war (metaphor) Observing communication from the sky (exercise).
6	Value	20 min	Passengers on a bus (metaphor) Think of your own epitaph. (exercise) Defining what values are Clarifying one's values (e.g., epitaph, value in 7 domains) (exercise)

7	Committed actions	30 min	Difference of thigs can be controlled or not Defining effective and values-based goals (exercises) Making action lists and strategies against internal barriers (exercise) Psychological flexibility -break the pattern and expand variety of actions.
8	Wrap up	6 min	Psychological well-being model New strategy to grow yourself up
Optional sessions		5 min/content	Positive parenting program (based on Triple P) and promoting mindfulness. Couple therapy (based on assertive communication) Relaxation skill and behavioral activation technique How to contact to mental health service of 3rd party
Additional functions			Can review what they wrote on exercise in courses (2nd function) Can share their feeling or impression with all participants on forum Can ask questions to researchers on forum

Table 2. Assessment schedule of the outcome measures for the randomized controlled trial for "Happiness Mom".

Measurement	Aim	Baseline (T1)	3-M f/u (T2)	6-M f/u (T3)
Primary outcome				
PWBS-42	Psychological well-being	X	X	X
Secondary outcomes				
K6	Psychological distress	X	X	X
PBA-J	Parental burnout	X	X	X
UWES-9	Work engagement	X	X	X
HPQ	Job performance	X	X	X
Sick leave days	Sick leave days during the past 3 months	X	X	X
Intention to leave	Intention to leave their company/organization	X	X	X
Satisfaction	Job and life satisfaction	X	X	X
Positive feeling	Positive feeling and adjective (hedonic well-being)	X	X	X
VAS	Perceived social support from the partner	X	X	X
MSPSS	Social support	X	X	X
Fear of COVID-19	Global fear and worry about COVID-19	X	X	X
Euthymia	Psychological flexibility and resilience	X	X	X
Process evaluation				
IDMH	Acceptability, appropriateness, feasibility, satisfaction, adverse effect		X	X
Effect of COVID-19	Adverse effects of leaning by COVID-19			
Others				
Demographic data		X		

Contamination	Contamination of information for a control group	X	X

PWBS-42: Psychological well-being scale 42 items version.

K6: Kessler's Psychological Distress Scale.

UWES-9: Utrecht Work Engagement Scale 9 items version.

MSPSS: Multidimensional Scale of Perceived Social Support.

HPQ: WHO Health and Work Performance Questionnaire.

PBA-J: Parental Burnout Assessment Japanese version.

IDMH: Implementation outcome scale for Digital Mental Health.

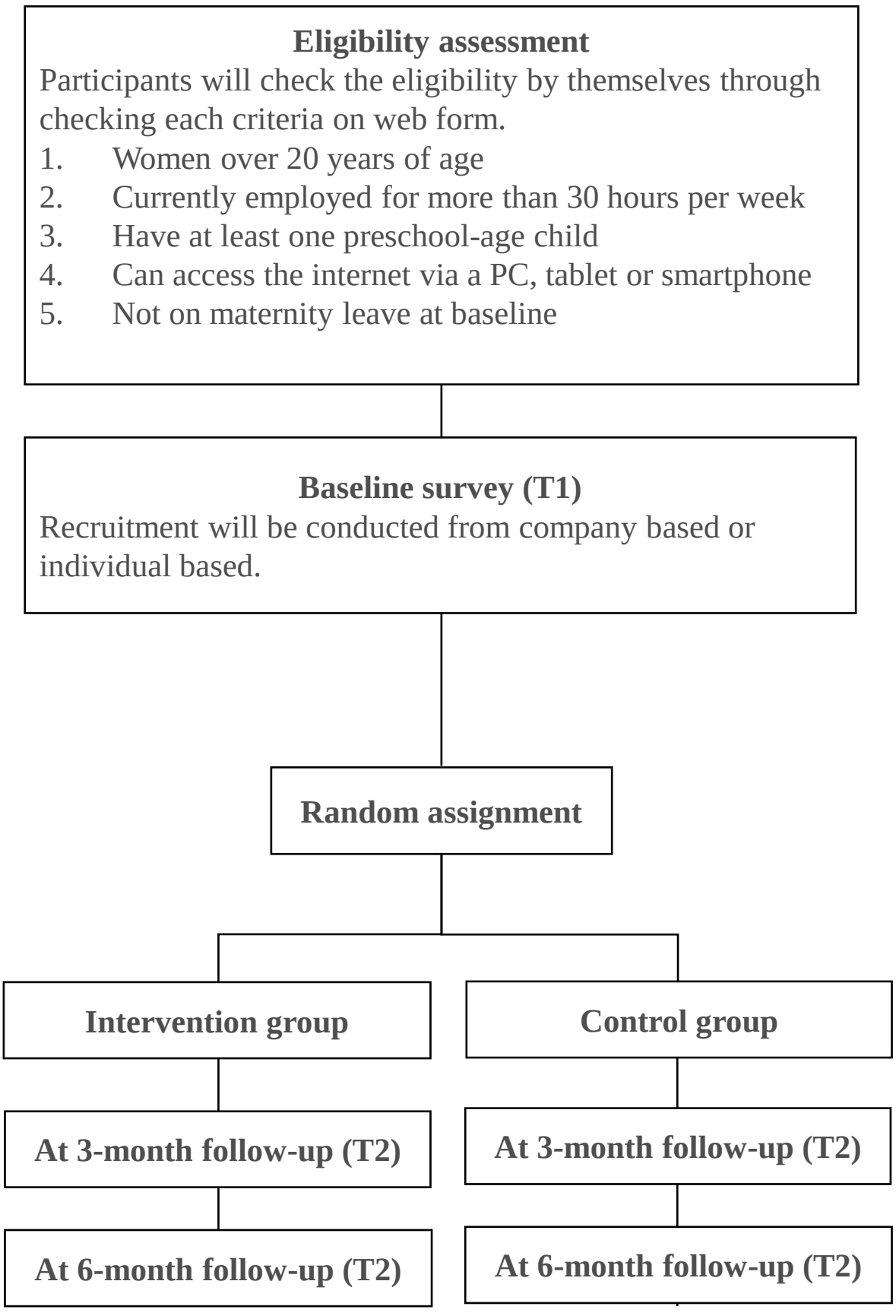

Figure 1. Participants' flow chart

(a) Reading materials (b) Audio (c) Text exercise

Figure 2. Screenshots of Happiness-mom.

Supplementary. Details of secondary outcomes.

Psychological distress (K6)

Psychological distress will be evaluated using the Japanese version of the K6 [1, 2]. The K6 is a widely-used self-rating scale assessing nonspecific distress during the past 30 days. Each item of the K6 is scored on a Likert scale ranging from *never* (0) to *all of the time* (4). The total score of the K6 ranges from 0 to 24, with higher scores indicating more severe psychological distress. A score of 13 or more and between 5 to 12 on the K6 will be considered severe and moderate psychological distress, respectively [3]. The reliability and validity of the Japanese version of the K6 has been found to be satisfactory [1, 4].

Parental burnout

Parental burnout will be assessed by the Parental Burnout Assessment (PBA) [5]. PBA is a 23-item with four dimensions: exhaustion in one's parental role (6 items), contrast with previous parental self (6 items), feelings of being fed up with one's parental role (5 items) and emotional distancing from one's children (3 items). Items are rated on 7-point Likert scales: *never* (0) to *every day* (6). Japanese version of PBA (PBA-J) has showed high reliability and validity [6].

Work engagement

The short form of the Utrecht Work Engagement Scale, 9-items (UWES-9) will be used to assess work engagement [7]. The UWES-9 consists of three subscales (vigor, dedication and absorption) which contain three items each. The UWES-9 is a self-report 7-point rating scale (0 = *never*; 6 = *every day*). The mean scores of the three UWES subscales and the total score are computed by adding the scores and dividing the sum by the number of items in each subscale. Hence, the UWES's three subscale scores and a total score range from 0 to 6. The Japanese version of UWES-9 has showed acceptable reliability and validity [8].

Job performance

Work performance will be evaluated using one item of the WHO Health and Work Performance Questionnaire (HPQ) in Japanese [9, 10]. The HPQ is a self-report measure designed to estimate the workplace costs of health problems. In this study, participants will be asked to rate their overall work performance during the past 4 weeks. Items are scored on an 11-point scale ranging from 0 (worst possible performance) to10(best possible performance). A high score indicates a high degree of work performance. The reliability and validity of Japanese version of HPQ have been tested [10].

Sick leave days

Participants will be asked to report their number of sick leave days during the past 3 months.

Intention to leave

The intention to leave is simply by asking one original item "Are you thinking of quitting your job?". The item is scored on a scale from 0 (*none*) to 4 (*always*). Higher scores indicate greater intention to leave. Reliability and validity of the Japanese version have not yet been determined.

Job and life satisfaction (evaluative well-being)

Job and life satisfaction will be assessed by each one item of the Brief Job Stress Questionnaire (BJSQ) [11-13]. The job and life satisfaction score are estimated on a 4-point Likert-type scale by asking "I am satisfied with my job (family life)".

Positive feelings (hedonic well-being)

Positive adjectives were measured by 10 items (e.g., enthusiastic, strong, inspired, proud, active, interested, excited, alert, determined, attentive) from *The Positive and Negative Affect Schedule (PANAS)* [14], which is a widely used mood measurement and regarded as one of the indicators of hedonic well-being. In addition, positive affect was each measured by six items (i.e., cheerful, in good spirits, extremely happy, calm and peaceful, satisfied, full of life), because such low arousal positive feeling has been reported to have stronger link with health among Japanese people, other than high arousal feelings, measured by PANAS [15]. Other than them, two items (i.e., close to others and confident) were added in terms of cultural affinity. These 18 items were used in the previous large population-based cohort study in Japan [16]. This study used the past 30 days as the time frame. All items were rated on a 5-point Likert-type scale, ranging from 1 "*None of the time*" to 5 "*All of the time*". Scales were constructed by calculating the mean across each set of items. Higher scores indicate greater positive feeling. Positive feeling scales in this questionnaire is well validated elsewhere [15].

Perceived social support from the partner

Perceived social support from the partner was measured in an original visual analogue scale (range: 0 - 100) by asking two questions: "How much emotional support does your partner (e.g. your spouse) provide for you? Please answer on a scale of 0 to 100." and "How much housework and childcare does your partner (e.g. your spouse) provide?". This scale will be shown only for participants who answer they are married.

Social support

Social support was assessed using the Japanese short (7-item) version of the self-rating Multidimensional Scale of Perceived Social Support (MSPSS) [17, 18]. It assesses perceived support

from each of three sources: family (2 items), friends (3 items) and a significant other (2 items). The scale uses a 7-point Likert scale, ranging from *very strongly disagree* (1) to *very strongly agree* (7), with higher scores suggesting greater levels of perceived social support. The mean score of 7 items is used as a total score. Japanese short version of MSPSS has been shown acceptable reliability and validity [19].

Global fear and worry about COVID-19

Global fear and worry about COVID-19 was assessed by a single item [20]: "Do you feel anxiety about COVID-19?" Responses were rated along a 6-point Likert-type scale ranging from 1 "*Not at all*" to 6 "*Feel strongly*."

Euthymia

Euthymia, which is newly stated concept by Fava in 2016, is a transdiagnostic construct for representing a psychological flexibility, a unifying outlook on life, and resistance to stress (i.e., resilience and tolerance to anxiety and frustration) [21, 22]. The Euthymia scale (ES) is a 10-item measurement with two answer options dichotomously as False (0) or True (1), resulting in a total ranging from 0 to 10, with higher scores indicating a better euthymic state. The Japanese version of ES shows high reliability (Cronbach's alpha; 0.832).

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

Section/item	Item No	Description	Reported page on No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	19
	5b	Name and contact information for the trial sponsor	19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16, 19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	7
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	15
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	15
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	15
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	15
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	15

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	15
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	19
	31c	Plans, if any, for granting public access to the full protocol, participant-level data, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Internet-based acceptance and commitment therapy programme "Happiness Mom" for well-being: A protocol for a randomized controlled trial

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Revised manuscript (submitted 24/01/2021)

Internet-based acceptance and commitment therapy programme "Happiness Mom" for well-being: A protocol for a randomized controlled trial

Natsu Sasaki (MD)[1]
Nasasaki-tky@umin.ac.jp
Kotaro Imamura (PhD)[1]
Kouima-tky@umin.ac.jp
Daisuke Nishi (MD)[1]
d-nishi@m.u-tokyo.ac.jp
Kazuhiro Watanabe (PhD)[1]
Kzwatanabe-tky@umin.ac.jp
Yuki Sekiya (PhD)[1]
syuki-tky@umin.ac.jp
Kanami Tsuno (PhD)[2]
ktsuno-tky@umin.ac.jp
Yuka Kobayashi (PhD)[1]
yukakoba@m.u-tokyo.ac.jp
Norito Kawakami (MD)[1]
nkawakami@m.u-tokyo.ac.jp

1 Department of Mental Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan
2 School of Health Innovation, Kanagawa University of Human Services, Kanagawa, Japan

Corresponding author: Norito Kawakami (M.D.)
Department of Mental Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan
7-3-1, Hongo, Bunkyo-ku, Tokyo, 113-0033, Japan
E-mail: nkawakami@m.u-tokyo.ac.jp
Telephone: +81-3-5841-3364, Fax: +81-3-5841-3392

Abstract

Introduction: This randomized controlled trial (RCT) aims to examine the effects of an internet-delivered acceptance and commitment therapy (iACT) program ("Happiness Mom") on the psychological well-being of working mothers.

Methods and analysis: The target population of the RCT will be employed mothers with at least one pre-school child. Participants who fulfil the study's eligibility criteria will be randomly assigned either to an iACT intervention group (n = 200) or to a wait-list control group (n = 200). Participants in the intervention groups will be asked to complete the programme within 12 weeks of the baseline survey. The intervention programme contains eight modules based on ACT. Primary outcomes are six components of psychological well-being, based on Ryff's theory. Secondary outcomes are intention to leave their job, work engagement, work performance, sick leave days, psychological distress, euthymia, positive emotions, job and life satisfaction, social support, and parental burnout.

Ethics and dissemination: Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI). If the intervention programmes are found to be significantly beneficial, the programmes can be made available for all working mothers with pre-school children in Japan.

Discussion: This study will contribute to the development of an internet-based self-care programme that is effective, feasible, low-cost, and accessible to improve the well-being of working mothers.

Trial registration number: UMIN000039918; Pre-results.

Word count: 231 words

Key words: cognitive behavioural therapy, eHealth, positive psychology, smartphone, occupational health, public health

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Article Summary

Strengths and limitations of this study

- The effects of an automated internet-based ACT (iACT) programme on the psychological well-being of working mothers with preschool children will be examined.
- The "Happiness Mom" programme is a newly developed programme that involves discussion with psychology experts and mothers, designed to contribute to participants' low dropout and high engagement in the trial.
- Multimedia self-help programmes (e.g., text exercise, audio) are expected to enhance the intervention effect on ACT and mindfulness.
- A limitation of this study is that all outcomes will be self-reported.

Introduction

Working mothers are a vital part of the workforce worldwide [1]. Stable employment for mothers is important in terms of female economic independence and child development [2]. Healthy maternal employment is also highlighted in the United Nation's Sustainable Development Goals (3: promote well-being for all, 5: empower women, and 8: promote productive employment) [3-5]. However, working mothers are often under psychological and physical pressure from their many responsibilities, including domestic activities, childbearing, and paid work [6, 7]. This double burden from work and family life and work-family conflict make the lives of working mothers difficult [8-11]. In sex-segregated cultures like Japan's, women must shoulder their caretaking responsibilities [12]. As a result, about 47% of Japan's working women give up their jobs after the birth of their first child [13]. They are required to change their way of living, with some losing their mastery and autonomy as a result.

Poor mental health is a common health-related outcome of the conflicts experienced by working mothers [14-16]. Although maternal employment itself is beneficial for mental health [17-19], working mothers' dual burden and poor work-family balance could often lead to depression, anxiety, and burnout [8, 9, 15, 20-22]. Working mothers with conflicts reportedly have poor psychological well-being (PWB) [23]. Women with young children reported poorer PWB than women with older children [24]. Moreover,

parental tasks are known to be more challenging to PWB among women than men [24]. PWB presents the potential for people to "live well" (self-realised, fully functioning, purposefully engaged) as defined by Ryff [25, 26]. PWB has also been associated with better health outcomes and longer survival [27-35]. Therefore, PWB can be an important mental health outcome, as well as negative emotions and distress. Intervention programmes should be developed and established to promote PWB as well as to prevent depression, anxiety, and burnout among working mothers.

Previous studies showed the effectiveness of several types of interventions in improving PWB, including well-being therapy [36], third wave cognitive behavioural therapy (CBT) [37] and positive psychology approaches [38, 39]. Acceptance and commitment therapy (ACT) is one of the third waves of behavioural therapies and involves mindfulness and values-based exercises to help people accept their lives and commit to moving forward in a valued life direction [40-42]. ACT interventions have been found effective in reducing the stress of mothers of children diagnosed with autism [43-49].

Time constraints and busy schedules make it difficult for working mothers to seek mental health support [50]. Internet-delivered psychosocial intervention is feasible, low-cost, effective, and accessible [51, 52]. A comparison of face-to-face and internet interventions revealed no differences in their effectiveness in treating common mental disorders [53, 54]. Web-based intervention may thus be promising for busy working mothers [55]. Several systematic reviews showed that internet-delivered ACT (iACT) has been effective in managing depression and anxiety and improving the quality of life, even with a small effect size, in the general and clinical population [56-58]. For the working population, randomized-controlled trials (RCTs) showed the effectiveness of ACT-based intervention (combined iACT and face-to-face group sessions) for improving negative mood outcomes (e.g., depression, burnout) among employees with psychological symptoms [59-62]. One RCT showed the significant effectiveness of improving Ryff's PWB at post- follow-up (Cohend's $d = 0.32$, $p<0.01$), but not at 6- or 12-month follow-up [60, 63]. A pre-post-study of group ACT at worksite also showed the improvement of PWB among university

staff [64]. The RCT of iACT among community-dwelling people seemed to improve PWB among those who had low PWB [65]. However, no study has investigated the effect of fully automated iACT without face-to-face sessions for improving PWB among workers regardless of psychological symptoms.

The aim of this RCT is to examine the effectiveness of a new and fully automated iACT programme on improving psychological well-being at posttreatment and 6-month follow-up among working mothers with at least one pre-school child. We also examine the acceptability, appropriateness, and feasibility of implementing "Happiness Mom".

Methods

Trial design

This study is a two-arm parallel-group non-blinded RCT. Participants will be randomly allocated 1:1 either to the intervention or to the control group after completing a baseline online questionnaire survey. This study's 12-week iACT programme was provided to the participants in the intervention group. Online follow-up surveys will be conducted at three (immediately after the intervention) and six months after the baseline survey. The study protocol was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID = UMIN000039918; trial registration 14th February 2020). This protocol has been written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [66]. Data generated by this research that supports the main findings will be made available as soon as possible, wherever legally and ethically possible. The data from this trial will be made available upon reasonable request.

Participants

This study is intended for working mothers with at least one pre-school child. The participants will be recruited from several private companies and individual applications through internet advertisements in

Japan.

All participants must meet the following eligibility criteria:

1. Women over 20 years of age
2. Currently employed for more than 30 hours per week
3. Have at least one preschool-age child
4. Can access the internet via a PC, tablet, or smartphone
5. Not on maternity leave at baseline

This study is "a universal prevention programme"; thus, the participants will be recruited regardless of psychological symptoms or current regular psychotherapeutic treatment.

Recruitment and procedure

A flowchart of how to progress from screening for eligibility to inclusion in the final analysis is given in **Figure 1**. Regarding company-based recruitment, the researchers have created the application website for each company. The website will include a description of the study and an application form. The researchers will ask the company's department of human resources or occupational health sector to email the URL of a website to the candidates. The company will provide information for all candidates who seem to meet the eligibility criteria. For individual-based recruitment, the other website will detect the means of recruitment (which company or individual) by researchers. The URL of the website for individual recruitment will be spread through social networking service (SNS) advertisements (e.g., Facebook) and personal announcements from the researchers. Candidates will click on the URL and read a full explanation of the purpose and procedures of the study on the website. Those who are interested in participating will be asked to mark the consent option and type their name, phone number, and email. This consent information will be sent to the research centre and preserved. Workers who are not interested in participating will be asked to leave the website. Subsequently, participants who submitted the consent information will receive an email containing the URL of the baseline survey.

They will be required to click the URL and input their baseline information. After completing the baseline questionnaire, the participants will be randomly assigned either to the intervention or to the control group. The researchers will inform the participants of their group assignment via email. To avoid delay between the randomization and the beginning of intervention, the researchers will assign the participants to a group (which automatically sets the schedule for opening the new modules) as soon as the baseline survey is completed. The researchers will email the iACT programme's URL and an ID and password to the participants in the intervention group. They will be asked not to share their ID, password, and the iACT programme content. Those in the control group will receive the iACT programme after the six-month follow-up.

Intervention programme

An internet-based, fully automated, eight-module self-help ACT programme "Happiness Mom" designed for working women with pre-school children was developed (**Figure 2**). The first author led and organized the specialist team to develop the programme. The researchers (NS, KT and YK), who are working mothers with pre-school children, have extracted the essential concerns of the working women, including their experience in occupational health settings. Informal interviews were conducted with two working women with pre-school children about their daily stressors, feelings, thoughts, dreams, and ambitions. Based on the self-help ACT literature [67, 68], the programme has been drafted by using a typical case experienced by mothers. The ACT specialists (outside the research team) and clinical psychologist (YS) who had experienced holding a group ACT for mothers have revised the programme to follow the psychological framework of ACT. A psychiatrist (DN) and a clinical psychologist (KI) confirmed the relevance of the psychotherapy. Original illustrations have been inserted to suit the preferences of the target population and to make it visually easy to understand. In each model, a single working mother case with a two-year-old boy (fictitious) is presented as an example of applying ACT skills to daily life. The eight modules are presented in a fixed order; one module is accessible per week,

with four optional reading materials (**Table 1**). Each module will take 15 to 30 minutes to complete. The modules followed the six core processes, "hexaflex," which produces psychological flexibility [41, 42, 69]. The programme modules cover well-being education (module 1), acceptance and willingness (module 2), defusion (module 3), mindfulness and self-compassion (module 4), self-as-context (module 5), value (module 6), committed actions (module 7), and wrap up (module 8). The optional reading materials address (1) parenting skills based on Positive Parenting Programme (Triple P) [70]; (2) couple therapy based on assertive communication; (3) relaxation skills; and (4) how to contact mental health services. Thirteen working mothers with small children were recruited by snowball sampling. They attended a one-hour semi-structured interview conducted by the first author after completing the programme. The participants were asked about its feasibility, usability, adaptability (i.e., timing of reminder, the day of opening the new module), and suggestions for improving the programme. Based on the results of the interviews, the researcher modified the programme to make it more relevant to working mothers of small children.

Happiness Mom does not have homework and is fully self-guided. The modules are not mediated by a therapist. Although no personalized feedback is provided, the case in the contents is about a single working mother with limited support for raising her two-year-old son, a scenario expected to be familiar to the participants.

Well-being education (module 1)

In this module, the six dimensions of Ryff's psychological well-being model are introduced to seek happiness [26]. The differences between pain (i.e., the discomfort we feel in response to a real-life problem) and suffering (i.e., struggle by expanding negative thoughts or feelings in mind) are illustrated [41, 67]. The exercise "Don't think about your thoughts" is provided [67]. Participants will perform three text exercises, in which they have to describe a painful experience, focusing on the reason for it (dysfunctional thoughts) and how to avoid such dysfunctional thoughts.

Acceptance and willingness (module 2)

In this module, experiential avoidance (attempting to avoid or control internal experiences) does not work [71]. By contrast, acceptance, the adoption of an intentionally open, receptive, flexible, and non-judgmental posture, is introduced as a new strategy. Participants will experience acceptance by following the audio guide and completing a text exercise about their willingness.

Defusion (module 3)

This module introduces the concept of cognitive fusion, or being "stuck" to thoughts and self-evaluations. It encourages the practice of mind watching. Five exercises for defusion are offered: (1) "I think…", (2) leaves on a stream (metaphor), (3) extracting the thoughts from your head and seeing them on the hand, (4) naming the mind, and (5) making the endings of your thought funny. Participants will be encouraged to try defusion.

Mindfulness and self-compassion (module 4)

Mindfulness is the process of paying attention on purpose, in the present moment, and nonjudgmentally [72]. Three experiential exercises are introduced here: mindfulness breathing (3-minute audio), mindfulness meditation (5-minute audio), and drinking mindfulness. Self-compassion is presented as a healthy form of self-acceptance to treat oneself with warmth and understanding [73, 74]. Two writing exercises, "Be willing to give *words* of comfort and reassurance to yourself as if to a friend who is tired of painful feeling" and "You can also write down some reassuring or relieving *actions* you can take to help yourself" are included. The "self-hug" is introduced with an explanation of oxytocin [75, 76]. Participants will try a self-compassion body scan (7-minute audio) to recognize their sense of body and treat themselves with compassion.

Self-as-context (module 5)

The observing self is one facet of what ACT calls "self-as-context." Self-as-context entails taking several perspectives on the self. In this module, conceptualized self and sticking are introduced with the tug-of-war metaphor [67]. Through writing exercises, participants will take a bird's eye view of the situation [68]. Participants will be encouraged to acquire the ability to look inside themselves from "now" and "here" [41].

Value (module 6)

ACT defines values as desired global qualities of ongoing action [41]. In this module, the metaphor of passengers on the "your life" bus is explained. Values are the direction of the bus. Two text exercises encouraged participants to recognize one's desire: (1) imagine what they would do if they had everything they wanted; (2) write their own epitaph. Thereafter, participants will write their values in seven important life domains (i.e., work, leaning, parenting, relationship with partner, friends, hobbies, and health) and rank the three values that are most important to them.

Committed actions (module 7)

Committed actions can be large or small moves in the direction of values. The difference between "what you can control" and "what you cannot control" is explained. This module emphasizes the importance of focusing on actions as part of being in control. Participants will define several values-based goals, making action plans for each goal and measures for the internal barriers through text exercises. Some unfamiliar actions (e.g., wearing different coloured socks) for breaking a pattern and expanding the variety of actions are introduced to improve psychological flexibility.

Wrap up – Life is a journey - (module 8)

In this module, Ryff's model of psychological well-being is reviewed again. The importance of

accepting fear, feeling, and thoughts from a perspective of self-as-context with openness and willingness is emphasized. Participants are encouraged to break the cycle of experiential avoidance by taking committed action. After finishing this module, participants receive emails suggesting that they review the programme and their personal notes, and to continue taking the actions that they learned in the programme.

Optional sessions

Four articles form the basis of optional sessions. Participants may read them at any time during the intervention. These articles address (1) parenting skills based on the Positive Parenting Programme (Triple P) [77]; (2) the essence of couple therapy based on assertive communication; (3) relaxation skills (i.e., 4-7-8 breathing [78], progressive muscle relaxation [79]) and behavioural activation techniques; and (4) how to contact third-party mental health services.

Additional functions

- *Personal notepad*

Participants' text exercises will be stored in their "personal notepad" for review at their convenience. If participants want to repeat an exercise, they can go from their notepad to find the exercise and rewrite it.

- *Online forum*

The online forum is set for each module. Participants can use the forum to share their experiences, ask questions, and talk to staff with specialized knowledge about the programme. Participants can post on the board using their registered nicknames instead of their real names. The first author will respond to the comments and questions posted on the board.

Control group

Participants in the control group will receive the iACT programme after the six-month follow-up. The participants in the intervention group and the control group can seek any mental health treatment as usual (TAU), such as stress management education or medical care, throughout the research period.

Outcomes

Table 2 summarizes the outcome measures. Only the participants in the intervention group will be assessed regarding the process evaluation outcomes (e.g., usability, satisfaction) at the three-month follow-up. Information contamination will be assessed in the control group at the three- and six-month follow-ups. All data will be collected using web-based self-report questionnaires. At the three- and six-month follow-ups, the research centre will send at least two emails reminding non-respondents to complete the questionnaires.

Primary outcome

Psychological well-being (42 items)

Psychological well-being will be evaluated using the 42-item version of Ryff's Psychological Well-being Scales (PWBS). The PWBS originally consisted of six 7-item subscales for the assessment of six factors: 1) autonomy; 2) environmental mastery; 3) personal growth; 4) positive relations with others; 5) purpose in life; and 6) self-acceptance [26, 80]. Response categories for these items are scored along a seven-point Likert scale ranging from *Strongly disagree* (1) to *Strongly agree* (7). The scores of some items will be reversed as recommended in Ryff's original PWBS [26, 80]. The scores for six subscales will be calculated as averages; higher mean scores indicate greater psychological well-being. The reliability and validity of the Japanese version of PWBS have been recently tested [81]. The authors simplified the Japanese translations of the response options without changing their meaning.

Secondary outcomes

As secondary outcomes, these measurement scales will be used: psychological distress (K6), parental burnout, work engagement, job performance, sick leave days, intention to leave, job and life satisfaction, positive feelings (hedonic well-being), perceived social support from the partner, social support, global fear of COVID-19, and euthymia. The details of these scales are available in **Supplementary 1**.

Process evaluation

Implementation outcomes and adverse effects

For process evaluation, we will track each participant's completion of each module. The researcher will take the 14 items of implementation outcomes for digital health interventions. This measurement is based on three important concepts: acceptability, appropriateness, and feasibility [82]. These concepts have been discussed with international specialists in implementation science and internet-based psychotherapy. Adverse effects (i.e., harms) of eHealth interventions, such as physical symptoms (e.g., tired eyes, stiff shoulders), mental symptoms (e.g., insomnia), and dangerous experiences (e.g., bumping into people while looking at a smartphone), will be covered in five items.

Contamination of information

To evaluate contamination of information among participants in a control group, participants will be asked at follow-up survey: "Have you got to know information on the contents of Happiness Mom from others in an intervention group?"

Demographic characteristics

Demographic data, such as age, marital status, household income, education, years in the workforce, occupations, industry, employment contract, company size, working hours per week, the number of children, disabled child, age and sex of the youngest child, pregnancy, and history of fertility treatments will also be collected.

The impact of COVID-19

The researchers collected data about changes in working hours and working styles (e.g., working from home, furlough) to capture the impact of COVID-19 on daily work, as the target population was recruited during the pandemic. In the three-month follow-up, we will ask the intervention group, "Is there anything in the programme that you were unable to put into practice because of COVID-19?"

Sample size calculation

Sample size was calculated (total N = 398) for the primary outcome to detect an effect size of 0.25 (Cohen's d) with a statistical power of (1 – b) = 0.80 in a two-tailed test ($p < 0.05$). Estimated effect size was decided based on the subgroup analysis of a previous meta-analysis that examined the effect of internet-based CBT for improving well-being (Hedge's g = 0.25) [51]. Regarding this calculation, the researchers set the estimated sample size as N = 400.

Randomization

Participants who meet the eligibility criteria will be randomly allocated to the intervention group or control group. Participants will be stratified into two groups according to the score of K6 (4 or less, or 5 or more) and recruitment entry (company-based or individual) on the baseline survey. In addition to the analysis of the whole sample (to examine the universal intervention effect), we will analyze data by prespecified subgroups (to examine the selective intervention effect). Using a computer-generated random allocation sequence, an independent biostatistician has created a stratified permuted-block random table. The block size of this RCT will be fixed at 4. The stratified permuted-block random table will be password protected and blinded to the researchers. Only the research assistant will have access to it during random allocation.

Duration

This programme is scheduled to start recruiting in April 2020 and will run until the end of June. The research will end in January 2021 with a follow-up assessment. In March 2021, the whole programme will be presented to the control group.

Statistical analysis

For the main pooled analysis, a mixed model for repeated measures conditional growth model analysis with an unstructured covariance matrix will be conducted using a group (intervention and control)*time (baseline, 3-month and 6-month follow-ups) interaction as an indicator of intervention effect. The primary analysis will follow the intention to treat (ITT) principle. This means that the participants will remain in the group to which they were randomized and not analyzed according to the interventions actually received. Cohen's d between groups will be calculated at each assessment term. Secondary outcomes will be analyzed in the same way as the primary outcome. The statistical significance for all analyses in this study will be set as 0.05 (two-tailed), and 95% CIs will be calculated.

For sensitivity analysis, a similar mixed model for repeated measures, but using the analysis of variance model, with an unstructured covariance matrix will be conducted. Missing values will be imputed by applying the maximum likelihood estimation using the MIXED procedure. We will calculate Cohen's *d* among participants excluded "not started" subjects, following the modified intention to treat (ITT) principle.

For subgroup analysis, we will use the stratification factor (i.e., participants who scored 4 or less/5 or more in K6 at the baseline survey or recruitment method [company or individuals]) and analyze the results according to the prespecified subgroups. The Japanese version of SPSS 26.0 (IBM Corp., Armonk, NY, USA) will be used.

Monitoring

As we anticipate no potential harm from this intervention, there will be no data monitoring committee, interim analyses, or stopping rules.

Data availability

Deidentified individual participant data will be available upon request after the main analysis paper has been published. Please email requests to the corresponding author.

Ethics and dissemination

Ethical and safety considerations

Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI). Participants will be fully informed that they may withdraw from the trial at any time by contacting the researchers. Any protocol modifications will be communicated to the institutional review board.

Data confidentiality

The collected data will be stored as linkable anonymizing data. The principal investigator will retain access to the final dataset after the trial and assume responsibility for data integrity and the accuracy of analysis.

Dissemination and implementation plan of research findings

The findings of this study will be published in peer-reviewed international journals. They will also be presented at research conferences, academic symposia, and seminars. The principal investigator will be listed as the corresponding author, and the authorship eligibility will conform to the International Committee of Medical Journal Editors. If the intervention programmes are found to be significantly beneficial, the programmes can be made available for all working mothers in Japan with pre-school

children.

Patient and public involvement (PPI)

The first author had informal discussions with two female workers who were mothers of pre-school children. Based on these conversations, three female researchers (NS, KT, YK), who were working mothers with pre-school children, modified the contents to reflect a real situation. One PPI partner reviewed the draft of the programme before setting it into a web system and suggested clarifying some points that might be difficult for general readers to understand. The second PPI partner enrolled monitors of a one-hour semi-structured interview, designed a recruitment poster, introduced the stakeholders (i.e., policy makers) to researchers, and advised on PR strategy for using SNS advertisement. Both women participated in an interview after using the web system, provided feedback, and took part in the recruitment of participants. Two PPI partners will participate in a discussion of the study findings and in setting up the implementation strategy after finishing RCT. The PPI process will be described based on the PPI handbook and reporting checklists [83, 84].

Discussion

An internet-based, fully automated, eight-module self-help ACT programme "Happiness Mom" designed for working women with pre-school children was developed to improve their psychological well-being. This study is the first randomized controlled trial to examine the effectiveness of a fully automated iACT without face-to-face sessions for the psychological well-being of a working population regardless of psychological symptoms. Some limitations of the study include the small size of the optional sessions of the programme (e.g., parenting, relaxation skills). The intervention effectiveness will not be identified as the difference between iACT and those sessions. The study will examine the effectiveness of the intervention "Happiness Mom" as a whole package. Second, this study will not assess multiple aspects of psychological flexibility using validated scales (e.g., Acceptance and Action

Questionnaire-II) to determine psychological processes connecting the intervention and the outcomes. We will not be able to identify what psychological process is most important if the intervention is found effective. Lastly, all the outcomes in this study will be assessed by the self-reporting questionnaire. In spite of these limitations, this study will contribute to the development of an internet-based self-care programme that is effective, feasible, low-cost, and accessible for improving the well-being of working mothers. This newly developed programme may provide psychological support for women to pursue their life careers according to their values. The web-based programme can be easily made available in other countries through translation in the future.

Word count: 4234 words.

Figure legends.

Table1. Contents of the iACT "Happiness Mom" program for working mothers with pre-school child(ren).

Table2. Assessment schedule of the outcome measures for the randomized controlled trial for "Happiness Mom".

Figure 1. Participants' flow chart

Figure 2. Screenshots of Happiness mom.

Authors' contribution

NK was in charge of this study, of supervising the process and provided his expert opinion. The authors (NS, KI, DN) organized the study design and developed the contents of the intervention. The authors (YS, YK, KT) developed the program. KW led the design of the statistical analyses. NS wrote the first draft of the protocol manuscript. All of the other authors revised the manuscript. All authors approved the final version of this manuscript.

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Competing interests None of the authors report any competing interests related to the submitted work.

Ethics approval Ethical approval for this study has been obtained from the Research Ethics Review Board of Graduate School of Medicine, the University of Tokyo (No. 2019134NI).

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The authors appreciated Masao Tsuchiya and Satoshi Tajima, specialists in occupational psychology for contributing to the improvement of the iACT contents. The artist Ami Kito (amikitosketch Inc), created the wonderful illustrations for Happiness Mom. Junko Tashiro and Toyoko Adachi, close friends of the first author and mothers of preschoolers, helped with developing the program and recruiting the participants. We also extend great thanks to our research assistant Keiko Miyake for building a web site and leaning system. The authors wish to thank the members of the Department of Psychiatric Nursing and Mental Health at The University of Tokyo for their advice in developing program.

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673 **Table 1. Contents of the iACT "*Happiness Mom*" program for working mothers with pre-school child(ren).**

Module	Key concept	Estimated time	Contents
1	Well-being education	15 min	Defining happiness with psychological well-being model
			Ineffective coping strategy
			Don't think about your thoughts (exercise)
			Difference between "pain" and "suffering"
			Exploring internal barriers (i.e., thoughts, feelings) to values-based actions (exercise)
2	Acceptance and Willingness	15 min	Experiential avoidance
			How to accept negative feelings and thoughts (audio)
			Formulating own willingness (exercise)
3	Defusion	10 min	Fusion with "Mind"
			Cognitive defusion technique of acknowledging "I am having the thought that … "
			Leaves on a stream (metaphor)
4	Mindfulness and Self-compassion	30 min	Mindful breathing (audio), meditation (audio), and eating and drinking.
			Self-compassion "self-hug exercise".
			Self-compassionate body scan (audio).
5	Self-as-context	15 min	Conceptualized self
			Tug-of-war (metaphor)
			Observing communication from the sky (exercise)
6	Value	20 min	Passengers on a bus (metaphor)
			Think of your own epitaph. (exercise)
			Defining what values are
			Clarifying one's values (e.g., epitaph, value in 7 domains) (exercise)

7	Committed actions	30 min	Difference of thigs can be controlled or not Defining effective and values-based goals (exercise) Making action lists and strategies against internal barriers (exercise) Psychological flexibility -break the pattern and explore variety of actions.
8	Wrap up	6 min	Psychological well-being model New strategy to grow yourself up
Optional sessions		5 min/content	Positive parenting program (based on Triple P) and parenting mindfulness. Couple therapy (based on assertive communication) Relaxation skill and behavioral activation techniques. How to contact to mental health service of 3rd party
Additional functions			Can review what they wrote on exercise in course (Note function) Can share their feeling or impression with all participants on forum Can ask questions to researchers on forum

677 **Table 2. Assessment schedule of the outcome measures for the randomized controlled trial for "Happiness Mom".**

Measurement	Aim	Baseline (T1)	3-M f/u (T2)	6-M f/u (T3)
Primary outcome				
PWBS-42	Psychological well-being	X	X	X
Secondary outcomes				
K6	Psychological distress	X	X	X
PBA-J	Parental burnout	X	X	X
UWES-9	Work engagement	X	X	X
HPQ	Job performance	X	X	X
Sick leave days	Sick leave days during the past 3 months	X	X	X
Intention to leave	Intention to leave their company/organization	X	X	X
Satisfaction	Job and life satisfaction	X	X	X
Positive feeling	Positive feeling and adjective (hedonic well-being)	X	X	X
VAS	Perceived social support from the partner	X	X	X
MSPSS	Social support	X	X	X
Fear of COVID-19	Global fear and worry about COVID-19	X	X	X
Euthymia	Psychological flexibility and resilience	X	X	X
Process evaluation				
IDMH	Acceptability, appropriateness, feasibility, satisfaction, adverse effect		X	X
Effect of COVID-19	Adverse effects of leaning by COVID-19			
Others				
Demographic data		X		

Contamination	Contamination of information for a control group	X	X

PWBS-42: Psychological well-being scale 42 items version.

K6: Kessler's Psychological Distress Scale.

UWES-9: Utrecht Work Engagement Scale 9 items version.

MSPSS: Multidimensional Scale of Perceived Social Support.

HPQ: WHO Health and Work Performance Questionnaire.

PBA-J: Parental Burnout Assessment Japanese version.

IDMH: Implementation outcome scale for Digital Mental Health.

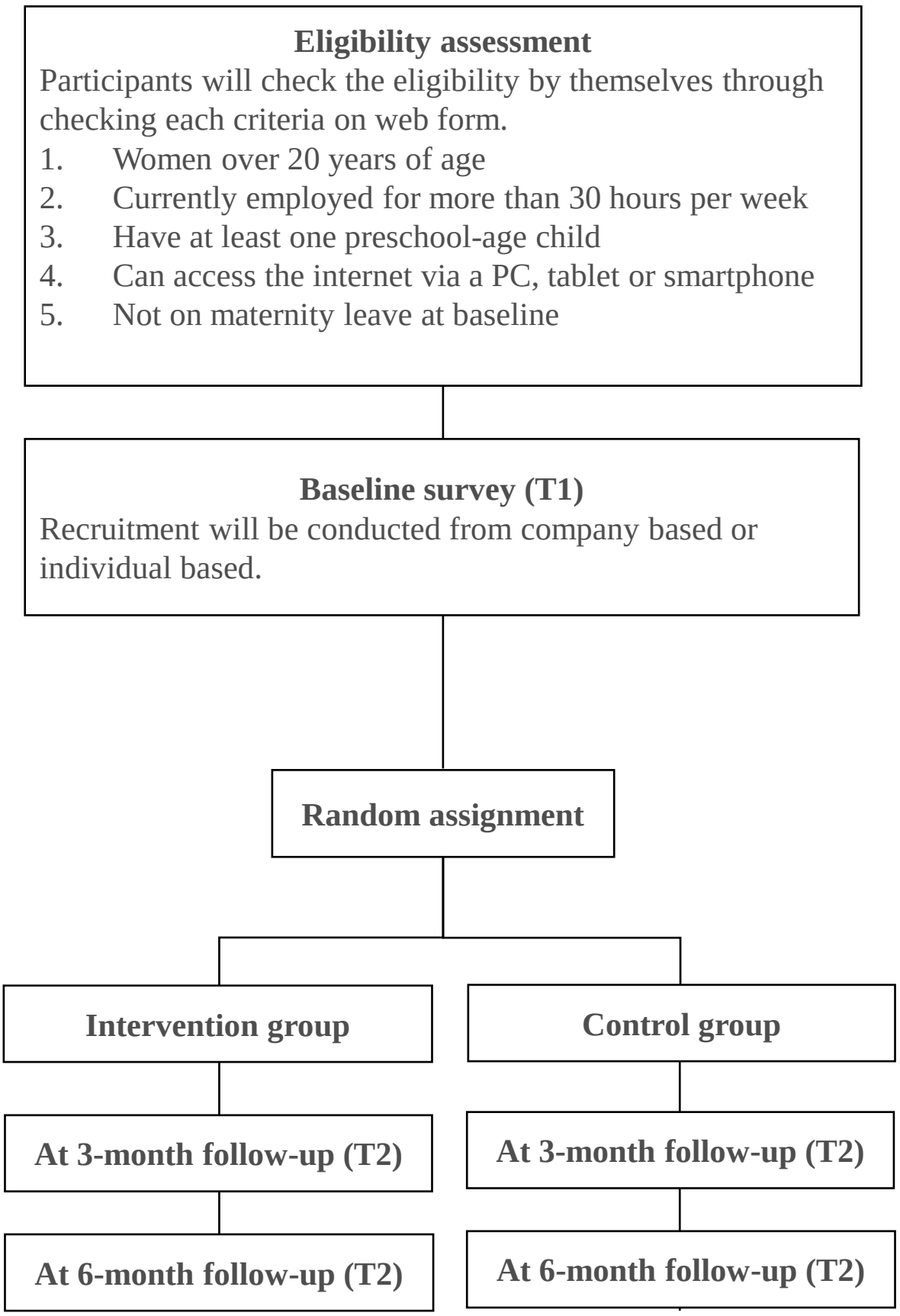
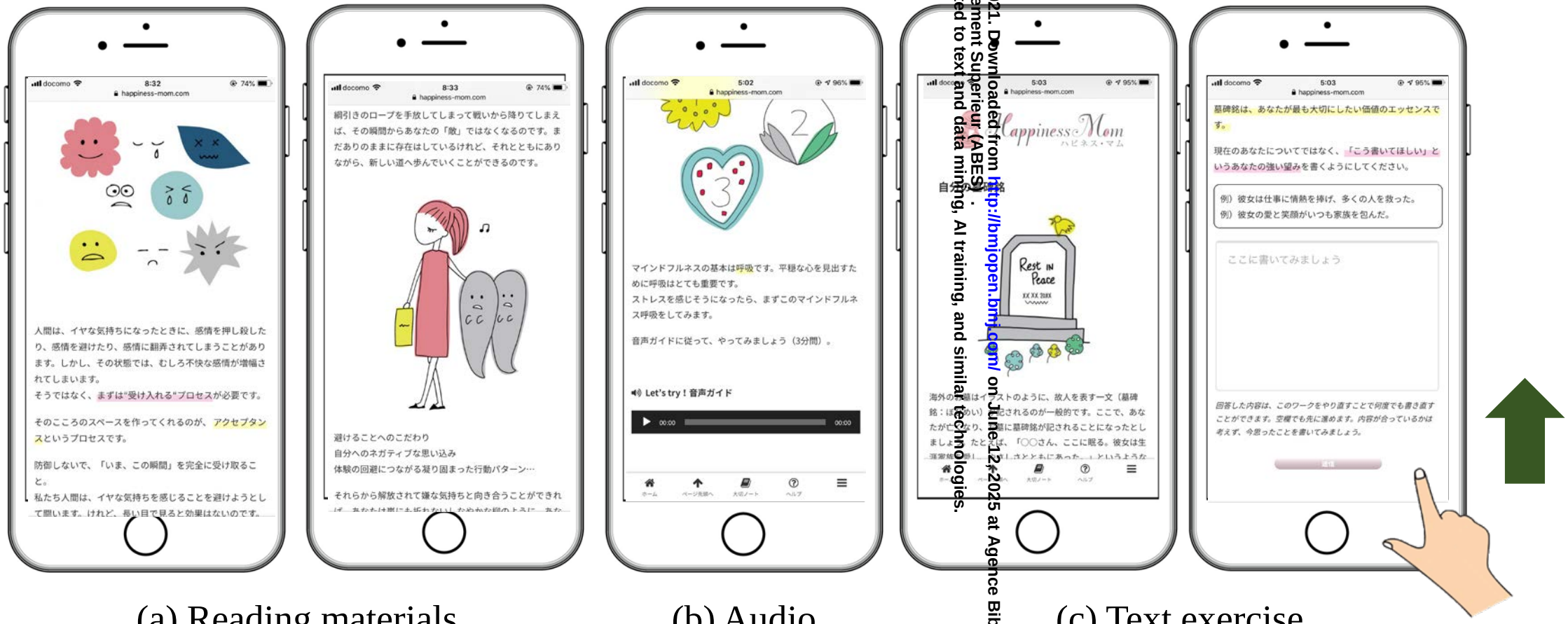


Figure 1. Participants' flow chart



(a) Reading materials (b) Audio (c) Text exercise

Figure 2. Screenshots of Happiness-mom.

Supplementary. Details of secondary outcomes.

Psychological distress (K6)

Psychological distress will be evaluated using the Japanese version of the K6 [1, 2]. The K6 is a widely-used self-rating scale assessing nonspecific distress during the past 30 days. Each item of the K6 is scored on a Likert scale ranging from *never* (0) to *all of the time* (4). The total score of the K6 ranges from 0 to 24, with higher scores indicating more severe psychological distress. A score of 13 or more and between 5 to 12 on the K6 will be considered severe and moderate psychological distress, respectively [3]. The reliability and validity of the Japanese version of the K6 has been found to be satisfactory [1, 4].

Parental burnout

Parental burnout will be assessed by the Parental Burnout Assessment (PBA) [5]. PBA is a 23-item with four dimensions: exhaustion in one's parental role (6 items), contrast with previous parental self (6 items), feelings of being fed up with one's parental role (5 items) and emotional distancing from one's children (3 items). Items are rated on 7-point Likert scales: *never* (0) to *every day* (6). Japanese version of PBA (PBA-J) has showed high reliability and validity [6].

Work engagement

The short form of the Utrecht Work Engagement Scale, 9-items (UWES-9) will be used to assess work engagement [7]. The UWES-9 consists of three subscales (vigor, dedication and absorption) which contain three items each. The UWES-9 is a self-report 7-point rating scale (0 = *never*; 6 = *every day*). The mean scores of the three UWES subscales and the total score are computed by adding the scores and dividing the sum by the number of items in each subscale. Hence, the UWES's three subscale scores and a total score range from 0 to 6. The Japanese version of UWES-9 has showed acceptable reliability and validity [8].

Job performance

Work performance will be evaluated using one item of the WHO Health and Work Performance Questionnaire (HPQ) in Japanese [9, 10]. The HPQ is a self-report measure designed to estimate the workplace costs of health problems. In this study, participants will be asked to rate their overall work performance during the past 4 weeks. Items are scored on an 11-point scale ranging from 0 (worst possible performance) to10(best possible performance). A high score indicates a high degree of work performance. The reliability and validity of Japanese version of HPQ have been tested [10].

Sick leave days

Participants will be asked to report their number of sick leave days during the past 3 months.

Intention to leave

The intention to leave is simply by asking one original item "Are you thinking of quitting your job?". The item is scored on a scale from 0 (*none*) to 4 (*always*). Higher scores indicate greater intention to leave. Reliability and validity of the Japanese version have not yet been determined.

Job and life satisfaction (evaluative well-being)

Job and life satisfaction will be assessed by each one item of the Brief Job Stress Questionnaire (BJSQ) [11-13]. The job and life satisfaction score are estimated on a 4-point Likert-type scale by asking "I am satisfied with my job (family life)".

Positive feelings (hedonic well-being)

Positive adjectives were measured by 10 items (e.g., enthusiastic, strong, inspired, proud, active, interested, excited, alert, determined, attentive) from *The Positive and Negative Affect Schedule (PANAS)* [14], which is a widely used mood measurement and regarded as one of the indicators of hedonic well-being. In addition, positive affect was each measured by six items (i.e., cheerful, in good spirits, extremely happy, calm and peaceful, satisfied, full of life), because such low arousal positive feeling has been reported to have stronger link with health among Japanese people, other than high arousal feelings, measured by PANAS [15]. Other than them, two items (i.e., close to others and confident) were added in terms of cultural affinity. These 18 items were used in the previous large population-based cohort study in Japan [16]. This study used the past 30 days as the time frame. All items were rated on a 5-point Likert-type scale, ranging from 1 "*None of the time*" to 5 "*All of the time*". Scales were constructed by calculating the mean across each set of items. Higher scores indicate greater positive feeling. Positive feeling scales in this questionnaire is well validated elsewhere [15].

Perceived social support from the partner

Perceived social support from the partner was measured in an original visual analogue scale (range: 0 - 100) by asking two questions: "How much emotional support does your partner (e.g. your spouse) provide for you? Please answer on a scale of 0 to 100." and "How much housework and childcare does your partner (e.g. your spouse) provide?". This scale will be shown only for participants who answer they are married.

Social support

Social support was assessed using the Japanese short (7-item) version of the self-rating Multidimensional Scale of Perceived Social Support (MSPSS) [17, 18]. It assesses perceived support

from each of three sources: family (2 items), friends (3 items) and a significant other (2 items). The scale uses a 7-point Likert scale, ranging from *very strongly disagree* (1) to *very strongly agree* (7), with higher scores suggesting greater levels of perceived social support. The mean score of 7 items is used as a total score. Japanese short version of MSPSS has been shown acceptable reliability and validity [19].

Global fear and worry about COVID-19

Global fear and worry about COVID-19 was assessed by a single item [20]: "Do you feel anxiety about COVID-19?" Responses were rated along a 6-point Likert-type scale ranging from 1 "*Not at all*" to 6 "*Feel strongly*."

Euthymia

Euthymia, which is newly stated concept by Fava in 2016, is a transdiagnostic construct for representing a psychological flexibility, a unifying outlook on life, and resistance to stress (i.e., resilience and tolerance to anxiety and frustration) [21, 22]. The Euthymia scale (ES) is a 10-item measurement with two answer options dichotomously as False (0) or True (1), resulting in a total ranging from 0 to 10, with higher scores indicating a better euthymic state. The Japanese version of ES shows high reliability (Cronbach's alpha; 0.832).

Reference on Supplementary

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

Section/item	Item No	Description	Reported page on No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	19
	5b	Name and contact information for the trial sponsor	19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16, 19

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	7
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	15
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	15
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	15
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	15
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	15

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	15
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	19
	31c	Plans, if any, for granting public access to the full protocol, participant-level data, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.