Study on application of smartphone cognitive behavioral therapy to promote mental health and well-being in the workplace: a randomized controlled trial

Clinical research protocol

This clinical research protocol was prepared in accordance with the Japanese "Ethical Guidelines for Life Sciences and Medical Research Involving Human Subjects" [1] and its guidance [2] and the SPIRIT 2013 Statement [3] [4].

**Administrative Information**

<table>
<thead>
<tr>
<th>Research Title</th>
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<tr>
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<td>Cognitive behavioral therapy</td>
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<tr>
<td>ICBT</td>
<td>Internet cognitive behavioral therapy</td>
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<tr>
<td>RCT</td>
<td>Randomized controlled trials</td>
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<td>PE</td>
<td>Psychological Education</td>
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<td>SM</td>
<td>Self-monitoring</td>
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<td>CR</td>
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<td>PHQ-9</td>
<td>Patient Health Questionnaire-9</td>
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<td>GAD-7</td>
<td>Generalized Anxiety Disorder-7</td>
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<td>WHO-HPQ</td>
<td>WHO Health and Work Performance Questionnaire</td>
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<td>SWLS</td>
<td>The Satisfaction with life Scale</td>
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<tr>
<td>WSAS</td>
<td>Work and Social Adjustment Scale</td>
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<tr>
<td>UWES</td>
<td>Utrecht Work Engagement Scale</td>
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<td>SSL</td>
<td>Secure Socket Layer</td>
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<td>2022/4/6</td>
<td>1.0.1</td>
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<td>2022/8/30</td>
<td>1.0.2</td>
<td>Addition of UMIN study ID, addition of researchers, change of research structure, and addition of consultation information</td>
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Introduction

Background and reasoning

*Mental health of working adults (workplaces)*

Mood disorders and depression are common mental disorders that affect 264 million people worldwide, and maintaining and improving mental health (wellbeing) is a major social issue in order to reduce the burden of these mental disorders. According to the Ministry of Health, Labour and Welfare's 2017 Patient Survey, the number of patients with mood disorders in Japan is approximately 1.3 million, while there are a large number of untreated patients (the treatment rate is said to be around 20%). It is also said that there are many people in the reserve group who have mental health problems below the diagnostic threshold (1 in 4 adults have mental health problems in the United States) and there are over 5 million potential patients. And one in two workers has low wellbeing, according to recent research, which increases their risk of mental illness such as depression and anxiety disorders. Some studies have shown that as many as 60% of people have increased stress and worries, especially under new coronavirus infection [5]. Furthermore, the direct medical cost for mood disorders alone in Japan is around 250 billion yen, but since the working population (20s to 50s) is affected, the social cost due to disease burden is estimated to be as high as 3 trillion yen per year for mood disorders alone. There are thus many challenges and challenges of social cost.

*Strengths of smartphone CBT*

For many mental health disorders, including mood disorders, medication is the first choice, but cognitive behavioral therapy (Cognitive Behavioral Therapy; CBT) and other psychotherapeutic treatments have accumulated evidence. In recent years, Internet CBT (Internet CBT; ICBT) and smartphone CBT are starting to be used mainly in Europe and the United States. In addition to diagnosed patients, there has also been an expansion of efforts to promote mental health (mental health) by offering a broader cognitive behavioral therapy approach, such as mindfulness, to prevention and to a wider range of healthy individuals, and the effectiveness of this approach is being tested.

*Application persistence rates for general mental health*

On the other hand, there are also challenges in terms of continued use compared to human intervention. A meta-analysis of randomized controlled trials using ICBT in patients with mood disorders reported dropout rates of 25% for guided ICBT and 29% for unguided ICBT [6]. A meta-analysis also reported that smartphone app dropout rates in mood disorders can be as high as 48% [7]. Discontinuation of treatment due to dropouts is not only thought to result in a poor response to treatment, but is also thought to result in a greater loss in terms of relapses that return to pre-treatment conditions.

*Support via chatbots*

Therefore, in this study, in order to continue using a ICBT app, which is an existing ICBT that has applications in non-disease area students, an intervention using a chatbot to encourage non-disease area research subjects to continue using the app is conducted (detailed in a later section), and the difference in the completion rate of a ICBT app between a continuation support group and a control group who are not encouraged to continue using the app is examined. It also explores the effects on wellbeing indicators. In this field, ICBT using conversational agents using AI has also been conducted as prior research [8], but it is thought that a continuity
initiative using a general-purpose technology that can be incorporated into existing ICBT applications will provide new insights.

**Purpose**

A randomized controlled trial (RCT) will be conducted in which research subjects who are volunteers of Sony Group workers will be asked to use the five components (Assertion, self-monitoring, cognitive restructuring, problem-solving, behavioral activation) of a smartphone cognitive behavioral therapy app (Resilience Training! SE App), which aims to promote mental health and wellbeing. To improving continuity, research subjects will be randomly assigned to either a group that supports continuity (a continuation support group) or a group that does not support continuity (a control group) with a chatbot technology that combines cognitive behavioral therapy lessons with Sony's chatbot technology to generate additional dialogue. If significant differences are found in this study, we will aim to apply smartphone cognitive-behavioral therapy and chatbot continuity technology to service solutions aimed at preventing illness and improving mental health and wellbeing in the workplace, insurance subscribers and other mental health areas. It is also expected to be applicable to the continuation of medical treatment for patients, since the use of the smartphone cognitive behavioral therapy app, which has been shown to be useful for mood disorders, will continue. Here are some of the specific research methods:

1) To compare and test the hypothesis that the difference in completion rates of ICBT app in 2 groups of 150 research subjects (volunteers of Sony Group Corp. and Sony Corp’s full-time employees), who were stratified by pre-assessment PHQ-9 scores (4 points or less, 5 points or more) and randomly assigned to a group that supports continuity with a chatbot (Sony Group Corp.) (continued support group) and a group that does not (control group), would be higher in the continued support group than in the control group. The chatbot dialogue provides scenario-based dialogue control and calls out as a pacemaker for the completion of a smartphone cognitive behavioral therapy app. Chatbots will use characters to provide a natural response based on character. It also memorizes a user’s history of using a smartphone cognitive behavioral therapy app and preference for how often to speak to them, and applies it to dialogue. Furthermore, the user analyzes the meaning of the message content in response to the chatbot, and automatically selects the appropriate response from the prepared response text.

Furthermore, the following 2) is also examined or analyzed.

2) The effectiveness of ICBT is examined in volunteers from Sony Group workers by the amount of change from the start to the end of subjective measures of Personal Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7).

3) To examine the effects of ICBT in volunteer Sony Group workers, from the start to the end of subjective measures of resilience (cognitive-behavioral therapy skills), presenteeism (WHO-HPQ presenteeism), well-being (WHO-5, SWLS), work engagement (UWES) and social functioning (WSAS).

4) The purpose of this study is to analyze the relationship between subjective indicators of mental health and subjective indicators of mental health from sensing data using wearable devices (Number of steps taken, distance traveled, how many meters (floor) you climbed, basic metabolism, calories burned, heart rate, time spent exercising and calories burned by exercise, sleep information (bedtime, wake-up time, time of sleep phase, etc.), etc.), and to analyze the correlation between subjective indicators of mental health and sensing data, whether subjective indicators of mental health can be inferred from sensing data, and the extent to which sensing data contributes to subjective indicators of mental health.
Research Design

This study asks all participants to use the five components of a smartphone cognitive behavioral therapy app. Among them, the RCT randomly assigns two groups: one uses only the smartphone cognitive behavioral therapy app (control group), and the other also uses a chatbot that makes appropriate calls based on the usage history of the smartphone cognitive behavioral therapy app (continuous support group). Allocation is by using the stratified substitution block method with scores on the Depression Severity Index (PHQ-9).

Period of study

Date of approval by Sony Bioethics Committee - December 31, 2025
Methods: Participants, interventions, and outcomes

Setting

Recruitment will be made for permanent employees of the Sony Group Corporation and Sony Corporation using the internal mailing list and the internal recruitment website. The study will be conducted at the Sony Satellite Office on the 20th floor of the M & D Tower in Tokyo Medical and Dental University and in the participants' living areas, including their work areas.

Eligibility Criteria

Inclusion criteria for participants

1) Full-time employees of Sony Group Corp. or Sony Corp. (who are not temporary or contract employees)
2) Living in Japan
3) Men and women aged 20 to 60 at the time of enrollment
4) Having own smartphone (iPhone or Android)
5) Those who can obtain electromagnetic or written consent to participate in the study
6) Those who agree to use Resilience Training! SE
7) Agree to the license and use of fitbit, fitabase and LINE

Participant exclusion criteria

1) Those who can't read and write Japanese sentences
2) Those currently receiving specialized treatment for mental problems
3) Those with a score of 15 or more on the PHQ -9 of the Preassessment or 10 or more and 2 or 3 on the 9th item (Suicide ideation).
4) Those who are expected to retire during the participation period (Those who have decided to retire or change jobs)
5) Others that researchers consider inappropriate

Role of secretariat support companies

Secretariat support companies are responsible for:

1) Development of business flow and internal support system
2) Providing an IC (informed consent) tool
3) Recruiting
4) Orientation (Briefing session)
5) Number participants with user IDs, separate them from personal information, and create correspondence tables
6) Follow-up of study participants
   A) Responding to inquiries from applicants and participants (Respond in consultation with researchers in some cases)
   B) Those who fall into the next category will be advised to consult their respective contact points and informed of the freedom to withdraw consent by email (the fact that you can cancel your participation at any time if it seems to be a burden).
Those who receive a PHQ-9 score of 10 or higher every week and 2 or 3 points on the 9th item that asks about suicidal ideation, or those who receive a score of 15 or higher

C) In addition, if the following conditions are met, participants should be advised to consult their contact point before discontinuing their participation in the study. "A weekly PHQ-9 score of 10 or higher and a ninth item for suicidal ideation of 2 or 3, or a score of 15 or higher that the researcher perceived as continuous for 2 weeks or longer"

D) Sending a questionnaire and urging people to respond

E) Post-Study Guidance and Wearable Device Recovery

7) Monitor participant progress
   A) Access data servers and monitor the progress of participants’ apps
   B) Download data on an online server, store it on media, store it in a locked cabinet, or strictly manage it on a server with limited access

8) Regular reporting to researchers
   A) Provide regular reports at regular meetings to monitor the progress of participants during their participation

**Intervention**

*Cognitive behavioral therapy*

The validated and safe cognitive behavioral therapy intervention [9] was based on CBT smartphones for depression, supervised from the perspectives of various occupations involved in mental health care for college students, and modified for content optimized for the unique circumstances of adolescence "Resilience Training!" [10] was also modified and optimized by Sony for content for working adults. To distinguish it from original app that was modified for research conducted by Sony was named "Resilience Training! SE." Under the supervision of external adviser, we reviewed the wording of the application and updated.

"Resilience Training!" refers to Self-Monitoring (SM), Cognitive Restructuring (CR), Behavioral Activation (BA), Assertion Training (AT), Problem Solving (PS). The "Resilience Training! SE" component used in this study also uses all five components implemented in "Resilience Training!". Participants work on each of the above components for 7 to 12 days (up to about 30 minutes per day) and advance to the next component by completing at least one worksheet. The order in which the components are advanced is listed below.

**Psychological Education = > Behavioral Activation = > Self-Monitoring = > Cognitive Restructuring = > Assertion = > Problem Solving = > Epilogue**

(" With regard to the above components from Behavioral Activation to Assertion, the system is such that the next component is not opened until one week after the start, and therefore the five components can not be done in a few days at once. The experience will last at least 29 days.)

The content of each intervention component is described below.

1) PE (Psychoeducation)
   Consists of material on mental stress and the importance of daily maintenance of a healthy psychological state.

2) SM (Self-monitoring)
It consists of psychoeducation of a cognitive-behavioral model using a model of the mechanism of the mind. The subjects learn to monitor their reactions to situations along the lines of their emotions, thoughts, physical reactions, and actions, and to explain them with diagrams of how the mind works. The subjects are asked to fill in at least one diagram of how the mind works in your daily life.

3) CR (Cognitive restructuring)
   It consists of a psychoeducation of cognitive restructuring skills and a worksheet to look for other ideas for recent stress situations. To help broaden your thinking, cognitive restructuring provides three tools to guide other thoughts through your interactions with the character.

4) BA (Behavioral activation)
   Psychoeducation on the importance of engaging in pleasurable activities based on the principle that “movement changes your mood” will be provided, along with a worksheet of individual experiments to evaluate new activities and a gamified “action marathon” to promote individual experiments.

5) AT (Assertion training)
   Psychoeducation to develop assertive rather than aggressive or passive communication teaches subjects how to express their true feelings and wishes without hurting the other person or sacrificing themselves.

6) PS (Structured problem solving)
   Structured problem solving involves learning how to break down problems into smaller, specific achievable goals, brainstorm solutions, compare the pros and cons of solutions, and ultimately choose the activities you want to try. Worksheets are provided to guide the process.

Figure 1 shows screenshot of “Resilience Training!” app.

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Policies to encourage adherence to and monitor progress on cognitive behavioral therapy lessons

Automatic encouragement messages via LINE chatbots

In this study, participants are divided into two groups: those who use only “Resilience Training! SE” (control group) and those who also use an additional chatbot that makes appropriate calls based on the history of using “Resilience Training! SE” (continuous support group). Participants assigned to the Continuing Support group are asked to use a LINE chatbot to encourage them to make progress each day, morning and night. At a given time, it takes participants’ lesson progress on an online server and compares it to a database of chatbot voice-over messages to implement automated voice-over tailored to each participant’s progress. It also asks how often the chatbot should call you during the process, and adjusts how often it sends messages based on participants’ responses. The types of messages to be sent and their purpose are as follows, which are sent by individual participants with modified message contents.

A notice message for the lesson that will be held on the day ➞ Prepared for the lesson
Call for self-check implementation ↔ Reminder
A message of praise if it can be implemented without delay ↔ Increase motivation

For example, it captures your app usage history, such as “how many days you’ve been using the app,” “you haven’t used the app for more than a certain number of days,” or “the app is moving forward at the pace the research team expects,” and automatically changes the content of each message you speak to. Others interact with participants through semi-open questions to increase engagement and encourage continued use of the app. Based on his role as an escort, the message to the participants was carefully examined under the supervision of external adviser to ensure that the message itself did not become an intervention.

Wearing a wearable device

All participants will be given Fitbit LLC.’s fitbit charge 4 (model number: FB 417 BKBK-FRCJK) and encouraged to wear it all day during the intervention (except for times when they need to be removed, such as bathing) during the study description. It takes data on heart rate, (number and height of stair climbs), sleep duration, sleep phase, calories burned and steps taken to explore and analyze objective indicators of mental health. To encourage people to continue wearing them, include tips on how to view and use wearable life log data in emails or voice messages. The fitbit charge 4 is a widely and commonly sold and used device and safety information is provided below.


In addition, the equipment has been tested for compliance with safety certification according to the specifications of the following EN standards.
There is. The credentials are:

EN 62368 -1: 2014 + A 11: 2017 Adapted
**Combination therapy**

Those currently receiving specialized treatment for mental problems at the time of application are excluded because they are included in the exclusion criteria, but there are no restrictions regarding subsequent combination therapy. Participants can voluntarily receive mental health services such as doctors and clinical psychologists. Use of psychotropic drugs and psychotherapy/counseling is documented using a post-intervention questionnaire.

**Criteria for stopping or changing intervention**

Discontinue intervention for an individual participant if the participant meets any of the following withdrawal criteria: Record the date of cancellation and the reason for cancellation. If the intervention was discontinued because of an adverse event, the investigator will review the situation and determine an appropriate response based on the reason for discontinuation of the intervention. After the intervention is stopped, the assessment will continue if the individual consents.

1) When a participant offers to decline or withdraws consent to participate in a study
2) A weekly PHQ-9 score of 10 or higher and a ninth item for suicidal ideation of 2 or 3, or a score of 15 or higher that the researcher perceived as continuous for 2 weeks or longer
3) When continuation of the study is difficult due to serious adverse events
4) When the entire study is stopped
5) If, for any other reason, the researcher deems it appropriate to discontinue the research.

**Anticipated risks and benefits**

anticipated benefits

1) The results of this research are expected to contribute to the development of evidence-based service solutions that have been validated for their medical value in preventing disease and improving mental health and wellbeing in the mental health field, including the workplace and insurance subscribers.
2) They can participate in the study and learn how to improve their stress resilience by using ICBT.
3) During the time they participate, they can check their activity and sleep with a wearable device.

Expected risks and disadvantages

1) It’s hard to say that continuing to wear a fitbit isn’t without the risk of skin irritation, pain, and more. If any skin abnormalities are felt, immediately stop wearing the product and, at the participant’s discretion, seek medical attention. In addition, they are advised in advance to contact the research consultation center operated by Clinical Porter Corp.
2) Because of the randomization process, participants can not decide for themselves which program they are assigned to.
3) The intervention was conducted by self-help on the participants’ own smartphones and consisted of various psychological education and practicing cognitive behavioral skills to reduce depressive symptoms. Therefore, while the psychological and time burden of programming and answering questions can occur, no other serious health consequences are expected. Rather, an Internet-based meta-analysis of self-help cognitive behavioral therapy has shown that depressive symptoms worsen less in the intervention group than in the control group [11]. Therefore, in this study, the risk of health hazards associated with research is not considered to increase compared to activities in general daily life, situations in which people engage in
conversation, and situations in which people operate smartphones. Such burdens will be fully disclosed and explained, and only those who consent will participate in the study.

However, the possibility of unexpected mental deterioration and unpredictable health consequences cannot be completely eliminated. If, by any chance, the research team recognizes a situation in which a health hazard may occur during participation in this study, the following actions should be taken: Tell the participants to consult a health consultation service (Health Development Department (Industrial Health Website), Sony Health Insurance Society Consultation Desk, Mental and Physical Health Consultation Desk, etc.) immediately, or cancel participation in the study.

- Those who fall into the next category will be urged to consult their respective contact points and informed of the (the fact that you can cancel your participation at any time if it seems to be a burden) regarding the freedom to withdraw consent.
  - "Those who receive a PHQ-9 score of 10 or higher every week and 2 or 3 points on the 9th item that asks about suicidal ideation, or those who receive a score of 15 or higher"

- In addition, if the following conditions are met, participants should be advised to consult their contact point before discontinuing their participation in the study.
  - "A weekly PHQ-9 score of 10 or higher and a ninth item for suicidal ideation of 2 or 3, or a score of 15 or higher that the researcher perceived as continuous for 2 weeks or longer"

4) Data communication is required to use ICBT, fitbit app and LINE. The cost of data communication is borne by the participants themselves. If you are not using a service such as a fixed communication fee, explain beforehand to be careful.

Intervention contamination between employees

Since the participants belong to the same company or group company, there is concern about contamination of intervention among colleagues, superiors and subordinates, and other acquaintances. For example, they may share information about ICBT lessons, chatbots, etc. However, they speculate that such contamination is unlikely because it is difficult for participant intervention to take place on each individual's smartphone or to share the content itself. In order to prevent contamination, at the information session, make sure that participants do not recognize each other by asking them to change the displayed name of the information session (online), and clearly instruct participants not to discuss or exchange the apps assigned to each individual.

Outcome

Primary outcomes

The primary outcome of the study was the completion rate of "Resilience Training! SE." The completion rate is defined as the percentage of participants who completed a lesson of 5 components within 8 weeks (56 days) of the day after PE completion. To "finish to the end" is to finish all the lessons and complete one worksheet for the problem-solving components before the epilogue.

Secondary outcomes

The secondary endpoints were as follows:

1) Change from baseline in PHQ-9 for each week from week 1 to week 8

2) Change from baseline in GAD-7 at Weeks 4 and 8
3) Change from baseline in cognitive behavioral therapy skills at weeks 4 and 8
4) Change from baseline in The Satisfaction with life Scale (SWLS) at Weeks 4 and 8
5) Change from baseline in WHO -5 (mental health status table) at Weeks 4 and 8
6) Change from baseline in Work and Social Adjustment Scale (WSAS) at Weeks 4 and 8
7) Change from baseline in Utrecht Work Engagement Scale (UWES) at Weeks 4 and 8
8) Change from baseline in WHO-HPQ presenteeism at Week 8

Other Outcomes

Other evaluation items are as follows:
1) Start to Week 8 “Resilience Training! SE” Usage History
2) Chatbot usage history from start to 8 weeks
3) Wearable device lifelog from start to 8 weeks
4) Demographic items before start
5) Questionnaire on Research Management at Week 8
6) Questionnaire on “Resilience Training! SE” at Week 8
7) Questionnaire on chatbots at 8 weeks
8) Survey on fitbit at 8 weeks

Each outcome detail

- Clinical features
  - Severity of depressive symptoms: PHQ-9 [12]
  - Severity of anxiety symptoms: GAD-7 [13]
  - Presenteeism: The Presenteeism Scale [14]
  - Life Satisfaction Scale: SWLS [15]
  - Wellbeing: WHO-5 [16] [17] [18]
  - Work and social involvement: WSAS [19]
  - Work Engagement: UWES [20]
  - “Resilience Training! SE” Usage history
    ① Number of terminated sessions
    ② Total access time
    ③ Number of entries on each worksheet
    ④ Date and reason if discontinued
    ⑤ Frequency of use, etc.
- Chatbot usage history
  ① Number of calls to participants
  ② Number of calls from participants
  ③ Dialogue log (messages and speaking times)
  ④ Total number of dialogues
Number of messages sent
Percentage of frequency of sending messages (high, medium, low)

Lifelog with Wearable Devices
- Number of steps
- Travel distance
- Distance (in floors)
- Basic metabolism, calories burned
- Heart rate range time
- Time spent exercising and calories burned by exercise (METs)
- Sleep information (Time for bedtime, wake-up time, and sleep phase)

Combination therapy
- Visiting a mental health professional
- Psychotropic drugs
- Counseling/Psychotherapy

Demographic items
- Age
- Gender
- Company history (years of employment)
- Job Type
- Marital status (unmarried/married or cohabiting/separated/widowed)

Psychosocial items
- Cognitive behavioral therapy skills
  - Self-monitoring (5 items) [21]
  - Cognitive restructuring (6 items) [22]
  - Behavioral Activation for Depression Short-SF (BADS-SF) (8 items) [23] and [24]
  - Assertiveness (7 items) [25]
  - Problem solving (6 items) [26]

Participants’ impressions
- Questionnaire on research management
  Questionnaires will be administered to participants to analyze improvements in the overall research and administration.
- Questionnaire on “Resilience Training! SE”
  A questionnaire will be administered to participants to analyze factors that promote or impede their use of the “Resilience Training! SE” lessons.
- LINE Chatbot Survey
  A questionnaire will be administered to participants to analyze factors that promote or impede the continued use of
“Resilience Training! SE” in relation to messages sent by LINE chatbots.

- Survey on fitbit
  A questionnaire will be administered to participants to analyze factors that promote or hinder the use of fitbit.
**Evaluation schedule for each evaluation item**

The evaluation schedule for each evaluation item is described below.

### Table 1 Assessment Schedule

<table>
<thead>
<tr>
<th>Tolerance (days)</th>
<th>Applications Form</th>
<th>Briefing session</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
<th>Week 8</th>
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<tbody>
<tr>
<td>Registration</td>
<td>Qualification assessment</td>
<td>● ●</td>
<td>● ●</td>
<td>● ●</td>
<td>● ●</td>
<td>● ●</td>
<td>● ●</td>
<td>● ●</td>
<td>● ●</td>
<td>● ●</td>
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<td>Interventions</td>
<td>Informed consent</td>
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<td>●</td>
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<td>●</td>
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<td>●</td>
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<tr>
<td>CBT intervention</td>
<td>Assignments</td>
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<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
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</tr>
<tr>
<td>Intervention</td>
<td>CBT intervention</td>
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<tr>
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<td>Wearable device wearing</td>
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<tr>
<td>Evaluation</td>
<td>Chatting to chatbots (continued support group only)</td>
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<tr>
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<tr>
<td>Evaluation</td>
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</tr>
<tr>
<td>Evaluation</td>
<td>Work Engagement UWES</td>
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<tr>
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<td>Combination therapy</td>
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<tr>
<td>Evaluation</td>
<td>Usability Questionnaire</td>
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</tr>
</tbody>
</table>

From consent to allocation and setting up the app is done during the briefing. Explain that core lessons (PE) and questionnaires should be given individually during or on the day of the briefing. The questionnaire at this point is considered week 0 (baseline) (other than CBT skills).
Participant Schedule

The participants’ real-life experiences are outlined below in bullet points.

Do the following 1 to 5 for about 2 months.

1) Set up the fitbit and the fitbit app loaded by the researcher, set up the connection between the fitbit account and the data collection server (Use fitbase, a fitbit data acquisition service provided by Small Steps Labs LLC), and wear the fitbit all the time. (except when bathing or other removal is required)

2) After installing and setting up the "Resilience Training SE" app, participants pace the lessons themselves. (30 minutes a day at most)

3) Complete a survey on a regular basis "Resilience Training SE" using the app.

4) After setting up a connection between the LINE account and the data collection server (to about half of those allocated), we ask that you become friends with the official LINE account for this study, and that you receive and send regular messages.

5) Answer a questionnaire that will be emailed to you at (1) participation in the study, (2) one month later, and (3) two months later. (Each can take up to 20 minutes)

*A survey will also be sent out to those who stop using the app along the way.

6) At the end of the study two months after participating in the study, follow the guidance to complete termination procedures, such as collecting fitbit and unlinking LINE and fitbit accounts.

The overall picture of what participants in this study experience is also shown in Figure 2.
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Figure 2 Participants Flow

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Sample size

The primary outcome of the study was the completion rate of "Resilience Training! SE". In estimating the completion rate and designing an appropriate sample size, we referred to the papers described below. There have been reports from RCTs and meta-analyses on continuity challenges, such as failing to continue (complete) a given treatment or psychotherapy such as ICBT until the end and dropping out. For example, review articles report ICBT dropout rates of 32% [27] and meta-analysis articles report 57% [28]. In recent years, ICBT using AI-driven conversation agents has also been developed, and it has been reported that the dropout rate is 9% in the conversation agent group and 30% in the information providing group [8]. It was also reported that the dropout rate of smartphone apps for general patients with depression, including ICBT, was 48% [7] of which the dropout rate of depression apps with feedback was 11.7% and that of apps without feedback was 34%, showing a marked difference in the dropout rate due to the feedback function, and there was no significant difference in the dropout rate between CBT-based apps and other apps, which could be referred to in this study. In this study, we set the number of applicants by considering the following three points, which are different from the research status of apps in general ICBT.

1) With a reminder function (a pop-up function on a smartphone) that prompts users to fill out a form when there is no self-check entry in a cognitive behavioral therapy app, the completeness rate is expected to be higher than in apps with no reminder function at all.
2) Since they volunteer freely for non-disease areas that are not currently being treated, the complete-out rate is expected to be lower than the apps used in prescribing by doctors and in clinical trials.
3) It is expected to have a lower completion rate than the ICBT meta-analysis because it comprises five cognitive behavioral therapy lessons over approximately two months.

Based on the above information, the completion rate of the application in the group using only "Resilience Training! SE" in this study was estimated slightly higher at 70% from the cited paper above. In addition, based on the report of a significant improvement in the dropout rate in the app with feedback in the cited paper above and the fact that the chatbot designed in this study optimizes frequent voice calls according to the progress of each individual's app, we estimated that the completion rate of "Resilience Training! SE" in the group that additionally provides continuous support via LINE to "Resilience Training! SE" (continuous support group) could improve to 90%.

Completion rate, the primary outcome of this study, uses the chi-square test for analysis. We set an effect size of 0.2 for ICBT with continued support by chatbots and estimated that a sample size of 124 people would be needed, 62 people per group, with alpha = 0.05 and beta = 0.20. To secure the power of detection, we assume that 20% of the applicants will drop out before the briefing session and subsequent consent to the briefing, and we assume that about 150 people will be recruited. This estimate was made using the power.prop.test function, which is a standard function of R (version 4.1.1), a statistical analysis software.

Recruitment

A pilot study will be conducted with full-time employees excluding temporary and contract employees of Sony Group Corp. and Sony Corp. in Japan.
Methods: Allocation of interventions

Allocation and its concealment method

Allocations are stratified by pre-assessment PHQ-9 scores (4 points or less, 5 points or more). In the allocation process, researchers not involved in the recruitment of participants in this study generate random allocation sequences in advance using the R (version 4.1.1) blockrand package.

In the briefing session, participants are to explain the contents of the research, access the system through the link of the consent acquisition system distributed in the chat section of the email or online meeting, check the consent check box, enter their email address and send it. Allocation is made after consent is obtained. Since the consent acquisition system provides a time stamp, the allocation is made by the stratified permutation block method in order of the time so that the number of people with a score of 4 or less on the PHQ-9 of the preassessment and those with a score of 5 or more are equally allocated to the 2 groups. The two groups are the group that uses only "Resilience Training! SE" (control group) and the group that also uses an additional chatbot that makes appropriate calls based on the history of using "Resilience Training! SE" (continuous support group).

Implementation

The Secretariat support company will be responsible for the incorporation and allocation of participants.

Masking

This study will be conducted with an open label.

1) Participants

Participants are not masked about intervention conditions. Because the assessment items are self-administered, participants are also not masked in the assessment. Regarding the presence or absence of ongoing support by LINE chatbots, participants can recognize whether they are in the control group or the ongoing support group by the step of becoming friends with or not becoming friends with LINE chatbots and the presence or absence of subsequent support in the setup procedure at the time of the study description.

2) Staff

Staff (secretariat-supported companies and researchers) are not masked. It can be grasped by the correspondence table in the staff who manage the correspondence table of user ID and allocation. E-mail addresses, user IDs and their progress can also be viewed from the "Resilience Training! SE" management website operated by the secretariat support company.

3) Analyst

Analyzers are not masked in this study. However, anonymized data are received from the secretariat support company, and each data is analyzed in a form that does not identify the individual.
Methods: Data collection, management, and analysis

Data collection method

Data collection form

The data to be acquired in this study will be acquired from the following applications and systems.

1) Questionnaire system (Microsoft Forms or Google Forms or the system of the secretariat support company)
2) Smartphone cognitive behavioral therapy app "Resilience Training! SE"
3) LINE
4) Fitbit and Fitbit apps

Prevent participants from dropping out

If participants drop out of the intervention, they continue to be evaluated unless they withdraw their consent to the follow-up evaluation. If there is no entry in the "self-check", pop-ups will be presented automatically after 24 and 48 hours. If they still don’t fill it out, they send a semi-automated reminder email. No further prompting.

Questionnaires sent to participants at the time of study participation, one month after participation, and two months after participation, with a reminder email sent when no response is received.

It also sends messages from chatbots in the morning and at night to participants assigned to the Continuing Support Group, which sends LINE chatbot messages of encouragement, asking them to proceed with the sequential lessons. The message content can be encouraging, comforting, and contrived to make you feel less like a mechanical voice by using various patterns. The chatbot character will be profiled as a person who is learning CBT with the participant, which will help prevent dropout by sending message content that is close to the participant.

Data management

The data acquisition flow used in this study is described in Figure 3 below.

As the main policy for data acquisition, the secretariat support company handles the handling and anonymization of research subjects, and researchers handle only user-ID data, except for the research director.

Data from surveys, LINE message history, fitbit-derived biometric data, and application logs will be obtained from participants. In terms of fitbit, LINE, and questionnaire systems, these are already widely used by the public.

As for the "Resilience Training! SE" server, it is operated and maintained by Life2Bits Inc., an application development company "Resilience Training! SE". The "Resilience Training! SE" server uses the Administration Web, a program on a password-protected and secure Web server, to schedule and track, evaluate from baseline to follow-up, and provide intervention components. The program automatically verifies the integrity of all assessment data. Security for data transfer from the app to the server is ensured by Secure Socket Layer (SSL).

A system developed by Sony sends messages to participants via the LINE server between the participant and the "Resilience Training! SE" server based on the progress of the participant. Communication between Sony's systems, the LINE server and "Resilience Training! SE" is secured with Secure Socket Layer (SSL).
OAuth2 authorization and the transfer of biometric information between a fitbit server and a Small Steps Lab server is done using Secure Socket Layer (SSL), which secures the data transfer.

The operator of the Secretariat Support Company will use the services of Sony's AWS server, Small Steps Lab's server, and the A server operated by Life2Bits, respectively, to collect data such as user-identified interaction logs for Sony's AWS, user-identified biometric data for Small Steps Lab's server, and the usage history of “Resilience Training! SE” server, and with respect to the “Resilience Training! SE” server, data such as the usage history of “Resilience Training! SE” servers, and the security of these data transfers is ensured by Secure Socket Layer (SSL).
Figure 3 System Overview
Statistical approach

All analyses were performed according to the intention-to-treat (ITT) principle, and the population excluding the following 1-3 participants is defined as the full analysis set (FAS).

1. Participants who did not meet eligibility criteria but were mistakenly assigned
2. Participants who did not install, start, or set up “Resilience Training! SE” or LINE (Continuous Support Group) after allocation
3. Participants who withdrew consent during the assigned day briefing

Basic statistical analysis is performed using statistical software such as R and SAS. Analysis using machine learning in life log data and so on uses software tools such as open source and Prediction One in addition to R and SAS.

Analysis of primary outcomes

1) Completion rate of “Resilience Training! SE”

The completion rate of “Resilience Training! SE” is counted from the day after PE completion and is defined as the percentage of those who complete a lesson consisting of 5 components within 8 weeks (56 days). To “finish to the end” is to finish all the lessons and complete one worksheet for the problem-solving components before the epilogue.

The analysis of the completion rate of “Resilience Training! SE” covers all baseline scores of PHQ-9. Aggregate completion rates for the control and continued support groups, and report 95% confidence intervals. The completion percentage is tested by a one-degree-of-freedom chi-square test. A two-tailed test defines a significance level of 5% as statistical significance.

Analysis of secondary outcomes

1) PHQ-9

In the analysis of PHQ-9, mild-to-moderate participants with a baseline score of 5 or more on PHQ-9 will observe the effect of the use of “Resilience Training! SE” on the decrease in scores, so the analysis subjects will be the participants with a baseline score of 0-4 on PHQ-9 excluded. For PHQ-9 outcomes, we analyze the change from baseline in PHQ-9 for each week from week 1 to week 8. Analyses are performed using a linear mixed-effects model of repeated measures (MMRM; Mixed effect Models for Repeated Measures) to estimate the least-squares mean of the weekly change in PHQ-9 scores from baseline and to compare groups. The model includes participants as a random effect, treatment condition (with or without ongoing support by LINE), time point of evaluation, interaction between treatment and time point of evaluation as fixed effects, and age and recruitment and baseline PHQ-9 scores as covariates. The standard deviation of PHQ-9 at Week 8 is used to calculate the standard mean difference. A two-tailed test with a significance level of 5% is defined as statistically significant.

For 2-8 below, the analysis covers all baseline scores, including participants with a PHQ-9 baseline score of 0-4. It is analyzed by a mixed-effects model (MMRM; Mixed effect Models for Repeated Measures) with repeated measurements as in PHQ-9.

2) GAD-7
3) Cognitive behavioral therapy skills
4) WHO-HPQ Presenteeism
5) SWLS
6) WHO-5
7) WSAS
8) UWES

Analysis of other outcomes

Hereafter, 9 -11 will be analyzed in an exploratory manner. It does not recognize specific tests and significance.

9) “Resilience Training! SE” usage history
10) Chatbot usage history

The purpose of this research is to explore the relationship between the history of chatbot interaction logs and other usage and subjective rating scales obtained by primary and secondary outcomes.

11) Lifelog with Wearable Devices

Using lifelog data and demographic data as explanatory variables, we conduct an exploratory analysis of the contribution ratio of each explanatory variable to objective indicators of mental health based on a machine learning method.

Sensitivity analysis

As with the primary outcome, the analysis subjects are all baseline scores on the PHQ -9, and the completion rate of the “Resilience Training! SE” is subjected to a Cochran-Mantel-Haentzel test with adjustment for the influence of stratification factors as a sensitivity analysis. A two-tailed test with a significance level of 5% is defined as statistically significant. Aggregate completion rates for the control and continued support groups, and report a confidence interval of 95%.

Interim analysis

No particular interim analysis is performed in this study.
Methods: Monitoring

Data Monitoring

The maintenance of the server is determined as follows.

1) Sony AWS servers are commissioned by researchers, and Sony Group Corp.'s R&D Center TL 11 and Sony Digital Network Applications Inc. will conduct maintenance and inspections during the commissioning period, as well as respond to server failures.

2) The AWS server of “Resilience Training! SE” is commissioned by the researcher and will be serviced by Life2bits Inc. during the contract period and will be dealt with in case of server failure.

3) The AWS server for LINE’s chatbot database is commissioned by the researchers, and Sony Group Corp.’s R&D Center TL 15 will conduct maintenance and inspections during the commissioning period, as well as handle server failures.

4) Sony’s AWS servers use security-aware servers that have passed internal cloud review reviews.

Adverse event

If, by any chance, the research team recognizes a situation in which a health hazard may occur during participation in this study, the following actions should be taken: Tell the participants to consult a health consultation service (Health Development Department (Industrial Health Website), Sony Health Insurance Society Consultation Desk, Mental and Physical Health Consultation Desk, etc.) immediately, or cancel participation in the study.

- Those who fall into the next category will be urged to consult their respective contact points and informed of the (the fact that you can cancel your participation at any time if it seems to be a burden) regarding the freedom to withdraw consent.
  "Those who receive a PHQ-9 score of 10 or higher every week and 2 or 3 points on the 9th item that asks about suicidal ideation, or those who receive a score of 15 or higher"

- In addition, if the following conditions are met, participants should be advised to consult their contact point before discontinuing their participation in the study.
  "A weekly PHQ-9 score of 10 or higher and a ninth item for suicidal ideation of 2 or 3, or a score of 15 or higher that the researcher perceived as continuous for 2 weeks or longer"

All serious adverse events (Defined as anything that results in death, is life-threatening, requires hospitalization or prolonged hospitalization for treatment, or results in permanent or significant disability or dysfunction), regardless of their association with the study, should be reported promptly in accordance with rules such as the Sony Bioethics Committee and the participant’s workplace emergency flow.

Audit

We do not plan to audit this study because it is a non-invasive intervention.
Ethics and dissemination

Research ethics approval

Approval of research ethics
This research is conducted in accordance with the Ethical Guidelines for Life Sciences and Medical Research in Human Subjects (effective June 30, 2021) and the Declaration of Helsinki. The research protocol is subject to review by the Sony Bioethics Committee and is conducted with permission from the head of the research institution.

Report to the head of the research institution
Any facts or information that impairs, or is likely to impair, the ethical validity or scientific rationale of a study should be promptly reported on safety information. If facts or information that impairs the appropriateness of the conduct of the study or the reliability of the study results, or information that could impair the reliability of the study results, a report of nonconformity, etc. shall be submitted promptly. Interim reports are required annually for interventional studies and observational studies with invasions (except minor invasions), but only the final report should be submitted if the study is completed before the interim report time because the intervention period is approximately two months and all participants participate in the study at the same time.

Protocol modifications
When changes occur in the study plan and its protocol documents, an application for change is submitted to the Sony Bioethics Committee for approval. After approval, the co-investigators and, if necessary, the research participants are notified of the content.

End of Study
End the study at the end of the planned recruitment and intervention period of 150 participants and at the end of the evaluation. Immediately submit the completion report to the Sony Bioethics Committee.

Suspension of the study
Upon the recommendation or instruction of the Sony Bioethics Committee to discontinue the research, the research shall be discontinued with the agreement of the researchers. The researcher will consider whether to continue the research if the following conditions are met.

1) When critical information about the quality, safety, and efficacy of the treatment is available.

2) When a change to the implementation plan, etc. has been directed by the ethics committee and it has been determined to be difficult to accept it.

Any decision to discontinue or discontinue research shall be promptly reported in writing to the Sony Bioethics Committee along with the reasons for such decision. After the decision to discontinue the study is made, the decision shall be promptly communicated to the relevant research staff and the business director for post-termination processing.
Consent or Ascent

In this study, a two-step consent procedure is performed.

1) Those who are interested after seeing the announcements on the internal public relations mailing list and the contents of the recruitment on the internal website, access the recruitment webpage and read the explanation of the research and the recruitment summary. Those who are willing to participate access the application form (Web questionnaire system) on the recruitment webpage, check the eligibility criteria, and fill out and submit the questionnaire to be invited to the briefing session.

2) Participants who are invited to attend the briefing will attend an online briefing using a web conferencing system and will be briefed on the objectives and means of the study, including: Participants who agree to participate in the study access the system through a link in the consent acquisition system distributed in the chat section of an email or online meeting, check the consent check box, include their email address, and send.

Since this study was conducted with subjects aged 20 years and older, consent and ascent by proxy consenters were not assumed. The following information should be included in the explanatory document in accordance with the format prescribed by the Sony Bioethics Committee.

① Overview of the study
- Name of research institute and research director
- Research objectives
- Study period
- What research participants do (including samples and information and data to be collected)
- Eligibility Criteria
- Data to be collected
- Methods for obtaining and viewing research plans and materials related to research methods

② Voluntariness and freedom to withdraw research cooperation
- The fact that participation in research is voluntary
- The fact that there is no disadvantage from a personnel standpoint
- The fact that there is no benefit from a personnel perspective
- That and how consent may be withdrawn at any time
- Disposal of samples, information, data, etc., and results of examination upon request, or non-disposal in the case of non-consolidation anonymization

③ Protection of Personal Information
- Methods for storage and disposal of collected samples, information and data
- The fact that they are not viewed by their superiors or personnel departments and are not disadvantageous in personnel matters

④ Publication of research results
- Availability of conference presentations and academic journals and databases
- Whether results were reported to participants
- What to do if someone asks for personal results
Consideration of ethical aspects in the event of unexpected outcomes

5 Benefits and disadvantages to research participants
   - Possible benefits to participants
   - Possible disadvantage to participants
   - Consideration in the event of participant abnormalities
   - Patent rights as a result of research

6 Handling policy for samples, information, etc. after completion of research
   - That samples, information, etc. will be used only for this research
   - The fact that it will be disposed of or stored at the end of the study period

7 Outsourcing organization

8 Other
   - The fact that no research costs will be borne by the participants
   - If there is an economic burden or gratuity, a statement to that effect and the details thereof
   - Approval by the Sony Bioethics Committee
   - Institutions and organizations for expenditure
   - Research funding and conflict of interest management, if available
   - Consultation desk information on research when you have an opinion or question
   - Health consultation information

Confidentiality

All participants will be given a user ID and all records will be maintained with this user ID. The transfer of data between each server and between the secretariat support company and each server is secured by SSL, and the data is stored on secure servers. Secretariat support companies download data and store it in media, which is stored in locked cabinets. Once the study is finished, the data on the server is permanently deleted. The secretariat support company anonymizes the data and sends it to the researchers of Sony Group, Corp. and destroys it after a certain period of time from the end of the research. The researchers store the anonymized data on a secure, limited-access server at Sony Group Corp. The anonymized data will be stored for five years after the study ends and then discarded.

Declaration of interest

There is a conflict of interest with Sony Group, Corp. because the research was conducted by Sony Group, Corp. with employees of Sony Group, Corp. and Sony Corp. as research subjects, and the research was conducted by Sony Group, Corp. However, in conducting and reporting research, we will not intentionally guide Sony Group Corp. and Sony Corp. to obtain favorable results, and we will disclose funding and make research transparent when presenting at conferences and publishing articles.

As external advisors for this research, we have signed a contract of service with Professor Toshi A Furukawa (Department of Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine/School of Public Health), Associate Professor Hisashi Noma (The Institute of Statistical Mathematics), and Assistant Professor Masatsugu Sakata (Department of Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine/School of Public Health).
Health Promotion and Human Behavior, Kyoto University Graduate School of Medicine/School of Public Health) to provide academic guidance.

**Accessing data**

Access to data containing personal information such as names, email addresses, and other highly personally identifiable information is restricted to the research director, the secretariat support company, and the system operator, and all researchers except the research director can access anonymized data sets that do not contain them. The correspondence table between the personal identification information and the user ID will be kept strictly as a medium accessible only to the research director and the company supporting the secretariat for five years after the completion of the research. Anonymized data will be kept under lock and key on media or servers accessible only to the researcher, including the research director, for five years after the study ends.

If the entire anonymized data set is to be made available to the public, it will be uploaded to UMIN-ICDR (https://www.umin.ac.jp/icdr/index-j.html) with the approval of the head of the research institution. The UMIN-ICDR data set is accessible only to those approved by the researchers.

**Incidental and post-participation care**

During and after the study, all participants have access to the standard of care provided by Sony's Health Development Department and external medical providers, respectively.

If you would like more information about a clinical study, or if a health hazard has occurred, please contact:

Consultation desk for research
Office of Clinical Porter, Corp. (to 2022/9/30)
Research Director, Sony Group, Corp. (from 2022/10/1)

Health Consultation Desk
1) Sony Health Development Department
   Industrial Health Website Mental and Physical Health Consultation
2) Sony Health Insurance Society
   Mental Health Counseling Service Consultation Office
   Log in to My Page from the URL, dial the dedicated number and consult from the website.
   https://www.sonykenpo.or.jp/member/health/mental.html (accessible externally)
3) Kokoro no mimi (the Ministry of Health, Labour and Welfare)
   Ear consultation for workers
   • “Ear Phone Consultation” for Workers
   • Ear of the mind of workers: SNS consultation
   • An Ear E-mail Consultation for Workers
   Search for national medical institutions
   https://kokoro.mhlw.go.jp/agency/#anc1 (accessible externally)
Policy on dissemination

Publication of clinical studies and research protocols
The clinical study and research protocol of this study will be published in the following media.

1) Set the appropriate scope of publication in the internal document system and publish it after the intervention period for all participants.
2) Registration in the UMIN Clinical Research Registry (UMIN-CTR) (https://www.umin.ac.jp/ctr/index-j.htm) is subject to prior approval by the heads of research institutions of Sony Group, Corp.
3) If this research protocol is to be published in an English-language academic journal, it shall be conducted with prior approval from the heads of research institutions of Sony Group, Corp.

Publication of results
The results of this research will be published in the following media.

1) Set the appropriate scope of publication in the internal documentation system and publish the results after the intervention period for all participants.
2) Registration in the UMIN Case Data Repository (UMIN-ICDR) (https://www.umin.ac.jp/icdr/index-j.html) is made only after obtaining prior approval from the heads of research institutions of Sony Group, Corp.
3) If the results of this research are to be published in an English-language academic journal, approval from the heads of research institutions of Sony Group, Corp. will be obtained in advance.

Intellectual property rights
Intellectual property rights are treated as follows:

Intellectual property rights relating to the ideas arising from this research and the ideas resulting from the results obtained belong to Sony Group Corporation.

Materials on informed consent
Attached are the materials of the prepared explanatory consent form.
Citations


