The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be:

a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED). Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and
Mobile Health Interventions
J Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829

Your name *
First Last
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Primary Affiliation (short), City, Country *
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University of Occupational and Environmental

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tomomi-a@med.uoeh-u.ac.jp

Title of your manuscript *
Provide the (draft) title of your manuscript.

The Effects of a Digital Health Program Using Chatbot Through a Mobile Messaging App on Musculoskeletal Problems: Randomized Controlled Trial of the Self-Management Program in Workers with Neck/Shoulder Pain/Stiffness and Low Back Pain
Name of your App/Software/Intervention *
If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

secaide (Artificial Intelligence (AI)-assisted he

Evaluated Version (if any)
e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Ver. 0.9

Language(s) *
What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

Japanese

URL of your Intervention Website or App
e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

https://www.secaide.me/

URL of an image/screenshot (optional)

回答を入力
Accessibility *
Can an enduser access the intervention presently?

- access is free and open
- access only for special usergroups, not open
- access is open to everyone, but requires payment/subscription/in-app purchases
- app/intervention no longer accessible
- その他:

Primary Medical Indication/Disease/Condition *
e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Low back pain, Neck and shoulder pain/stiffness

Primary Outcomes measured in trial *
comma-separated list of primary outcomes reported in the trial

A subjective assessment of the degree of low back pain, neck/shoulder pain/stiffness

Secondary/other outcomes
Are there any other outcomes the intervention is expected to affect?

A subjective assessment of whether there was an improvement in low back pain, neck/shoulder pain/stiffness
Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- "as needed"
- その他:

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- unknown / not evaluated
- 0-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71%-80%
- 81-90%
- 91-100%
- その他:
Overall, was the app/intervention effective? *

- yes: all primary outcomes were significantly better in intervention group vs control
- partly: SOME primary outcomes were significantly better in intervention group vs control
- no statistically significant difference between control and intervention
- potentially harmful: control was significantly better than intervention in one or more outcomes
- inconclusive: more research is needed
- その他:

Article Preparation Status/Stage *
At which stage in your article preparation are you currently (at the time you fill in this form)

- not submitted yet - in early draft status
- not submitted yet - in late draft status, just before submission
- submitted to a journal but not reviewed yet
- submitted to a journal and after receiving initial reviewer comments
- submitted to a journal and accepted, but not published yet
- published
- その他:
Journal *
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- not submitted yet / unclear where I will submit this
- Journal of Medical Internet Research (JMIR)
- JMIR mHealth and UHealth
- JMIR Serious Games
- JMIR Mental Health
- JMIR Public Health
- JMIR Formative Research
- Other JMIR sister journal
- その他:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- Pilot/feasibility
- Fully powered

Manuscript tracking number *
If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- no ms number (yet) / not (yet) submitted to / published in JMIR
- その他:  ms#27535
1a) Does your paper address CONSORT item 1a? *

I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- [ ] yes
- [ ] その他:

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if Intervention includes non-web-based Internet components (e.g. email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.

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| [ ] | [ ] | [ ] | [ ] | [ ] | essential |

Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the title, "Using Chatbot Through a Mobile Messaging App".
1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., “with telephone support”).

1 2 3 4 5

subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 1a-ii?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

No. We did not mention it in the Title as we did not use any non-web-based components.

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., “for children with Type I Diabetes”)

Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

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subitem not at all important ☐ ☐ ☐ ☐ ☒ essential
Does your paper address subitem 1a-iii? *
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Title, "Workers with Neck/Shoulder Pain/Stiffness and Low Back Pain".

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions
NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT
Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

subitem not at all important  ⃝  ⃝  ⃝  ⃝  ⃝  essential

Yes. We described it in the Methods of the Abstract: "the AI-assisted health program, in which the chatbot sent messages to users with the exercise instructions at a fixed time every day through the smart phone's chatting app (LINE) for 12 weeks."
1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Abstract: “The program is fully automated.”

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use “blinded” or “unblinded” to indicated the level of blinding instead of “open”, as "open" in web-based trials usually refers to “open access” (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential
Does your paper address subitem 1b-iii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. We described it in the Methods of the Abstract: “We recruited participants with these symptoms through email notifications.”, and “We assessed the subjective severity of the neck and shoulder pain/stiffness and low back pain of participants using a scoring scale of 1 to 5 for both the intervention and the control group at baseline and after 12 weeks of intervention using an online form.”

1b-iv) RESULTS section in abstract must contain use data
Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

Yes. We described it in the Results of the Abstract: “We analyzed 48 participants in the intervention group and 46 in the control group. The adherence rate was 93.6% (44/47) during the intervention. The participants in the intervention group showed significant improvements in the severity of the neck/shoulder pain/stiffness and low back pain compared to those in the control group (OR 6.36, P <.001). Based on the subjective assessment of the improvement of the pain/stiffness at 12 weeks, 36 out of 48 participants (75%) in the intervention group and 3 out of 46 (7%) in the control group had improved (improved, slightly improved) (OR 43.00, P <.001).”
1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

We did not obtain negative results in this study.

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in “Methods” under 5)
Does your paper address subitem 2a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Introduction: “One problem with exercise therapy is the low level of adherence to the prescribed exercises. Two systematic reviews reported that up to 70% of participants did not adhere to prescribed exercises [22,23].”, “In Japan, the medical system has not been able to provide sufficient services for such conditions. Some enthusiastic medical professionals, preventive medical services, and occupational health services provide care for people with functional impairments, such as musculoskeletal symptoms. In most other situations, patients need to look for ways to improve their symptoms on their own.”, “Besides, 65% percent of smartphone apps that perform self-monitoring and self-managing of chronic pain have been developed without the involvement of experts and proper supporting evidence [39].”, “Conversely, it has also been suggested that digital interventions may have possibilities to improve adherence in the target population [26].”, and “The aim of this study was to improve neck/shoulder pain/stiffness and low back pain of workers who experienced from those symptoms by continuing to do exercises that included stretching and mindfulness. As a measure of encouraging them to continue the exercises, we provided them with secaide Ver.0.9 [44], an artificial intelligence (AI)-assisted interactive health promotion system using a mobile messaging app (the AI-assisted health program).”

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.
Does your paper address subitem 2a-ii? * 
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it in the Introduction: “Several studies have reported methods to minimize the discomfort from such symptoms—a combination of exercises and psychological approaches seems effective for patients with musculoskeletal symptoms. Moderate to strong evidence suggests that exercise therapy is effective in relieving pain and improving function in musculoskeletal disease.(omitted) “Two systematic reviews reported that up to 70% of participants did not adhere to prescribed exercises. (omitted)”, and “Three systematic reviews that included a plethora of studies with digital interventions, for example, mobile phone apps, websites, and web-based software have been performed involving musculoskeletal symptoms. (omitted) Besides, 65% percent of smartphone apps that perform self-monitoring and self-managing of chronic pain have been developed without the involvement of experts and proper supporting evidence. (omitted) Some studies including digital health interventions have shown enhanced self-management and adherence to medication in patients with asthma, chronic obstructive pulmonary disease, hypertension, and diabetes.”

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? * 
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Introduction: “The aim of this study was to improve neck/shoulder pain/stiffness and low back pain of workers who experienced from those symptoms by continuing to do exercises that included stretching and mindfulness. As a measure of encouraging them to continue the exercises, we provided them with an artificial intelligence (AI)-assisted interactive health promotion system using a mobile messaging app (secaide [44], abbreviated as ‘AI-assisted health service’). We hypothesized that this digital intervention would support participants to continue exercising and enhance their adherence to the exercises, resulting in greater improvement in symptoms. To the best our knowledge, this is the first study to use a chatbot as a health care support measure through a messaging app to improve musculoskeletal symptoms for workers.”
3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Study Design and Randomization of the Methods: "This study was a two-armed, randomized, controlled, and unblinded trial on workers with neck/shoulder pain/stiffness and/or low back pain. We set the intervention and control groups and the participants of the intervention group used the AI-assisted health program for 12 weeks and those of the control group continued their regular exercise routine at workplace.", and "with a 1:1 allocation ratio".

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not change the methods after the trial started.
3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

We have not experienced any bug fixes, downtimes, and content changes.

4a) Eligibility criteria for participants
Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Study Population of the Methods: “We targeted those who answered “frequently” or “almost always” in either of the following questions in the survey: 1. How often do you have a stiff neck and/or shoulders? 1) Almost never, 2) Occasionally, 3) Frequently, 4) Almost always, 2. How often do you have low back pain? 1) Almost never, 2) Occasionally, 3) Frequently, 4) Almost always", and “The inclusion criteria were as follows: employees 1) aged 20 to 64 years, 2) who had their own cell phones and the apps could be installed on the phones, and 3) who understood the purpose and agreed to the publishing of the contents and results of the study. The exclusion criteria were as follows: employees who 1) disagreed with the study, 2) were pregnant or may have been pregnant, 3) had cardiopulmonary diseases, 4) participated in other clinical trials, and 5) had any other obvious disabilities or exercise restrictions.”

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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- subitem not at all important
- essential

We did not clarify the computer/Internet literacy in this study, because the participants were all workers who used computers in their daily work and used their own smartphone in a daily basis. We just have included in the inclusion criteria that “employees who had their own cell phones and the apps could be installed on the phones.”
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. We described it in the Study Population of the Methods: “We conducted this study in a company that develops, designs, and manufactures precision electronic components, which has approximately 2200 employees.”, “The occupational health staff of the company recruited employees with remarkable musculoskeletal symptoms, either or both neck/shoulder stiffness and low back pain.”, and “They recruited applicants by email notification between 3 and 14 September 2018.”

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.
4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Outcomes of the Methods: “All participants answered the questions through an online form.”

4b-i) Report if outcomes were (self-)assessed through online questionnaires

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

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subitem not at all important ○ ○ ○ ○ ● essential
Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. We described it in the Outcomes of the Methods: “All participants answered the questions through an online form.”

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item – describe only if this may bias results)

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subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

No. It is not described in the manuscript. The occupational health staff of the targeted company told the participants that the interventional study was collaborated with the staffs of the university of Tokyo. We are not sure if it affected or biases the results.

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a “Conflict of interest” section or mentioned elsewhere in the manuscript).

1 2 3 4 5
subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We mentioned in the Intervention of the Methods, and in the Conflicts of Interest: “The program we used in this study was named secaide Ver.0.9, which was patented and have been created and developed since June 2017 by Travoss Co., Ltd., and an orthopedist who specialized musculoskeletal disorder.”, and “Ko Matsudaira is a shareholder/adviser of Trunk Solution Co., Ltd., who has a patent for the AI-assisted health program using in this study”.

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

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subitem not at all important ○ ○ ● ○ ○ essential
Does your paper address subitem 5-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We mentioned in the Intervention of the Methods: “The program we used in this study was named secaide Ver.0.9, which was patented and have been created and developed since June 2017 by Travoss Co., Ltd., and an orthopedist who specialized musculoskeletal disorder. Until we performed this interventional study, the program had not been used or evaluated previously.”

5-iii) Revisions and updating
Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

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| subitem not at all important | ○ | ○ | ● | ○ | ○ | essential

Does your paper address subitem 5-iii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The system we used in this study were not revised and updated during the intervention.
5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

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subitem not at all important ○ ○ ● ○ ○ essential

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not adopt and grasp quality assurance methods for the AI-assisted health program.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

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subitem not at all important ○ ○ ● ○ ○ essential
Does your paper address subitem 5-v?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

We provided some screenshots of the screen of the AI-assisted health system in the Figure 1. The system is commercially available. We also provided the reviewers introduction videos of the AI-assisted health system. The flowcharts of the algorithms used in the system has archived at Japan Patent Office.

5-vi) Digital preservation
Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

1 2 3 4 5
subitem not at all important ○ ○ ○ ○ ○ essential

Does your paper address subitem 5-vi?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

In the Reference list of the manuscript, we showed the website of the AI-assisted health program, https://www.secaide.me/. In case the website disappears, an archived page is https://webcache.googleusercontent.com/search?q=cache:QTdPBshGJWQJ:https://www.secaide.me/+&cd=1&hl=ja&ct=clnk&gl=us. If you apply to use the AI-assisted health program, you can get access to the program because it is commercial.
5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained “access to the platform and Internet” [1]. To ensure access for editors/reviewers/readers, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

subitem not at all important  ○ ○ ○ ○ ○ essential

Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it in the Intervention of the Methods: “We also explained to the participants of the intervention group how to install and use the AI-assisted health program on their cell phones to inform them a QR code and a passcode to access the program on September 26 and 27, 2018.”

If you apply to use the AI-assisted health program, you can get access to the program because it is commercial. Users were normally charged the fee. In this study, they were not charged. We also provided the reviewers introduction videos of the AI-assisted health system.
5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Intervention of the Methods: “The AI-assisted chatbot was programmed to send the users messages with the exercise instructions and some tips on what they can do in their daily lives to improve those symptoms. The messages were sent every day at a fixed time through LINE. The notification time could be changed by the users to a time convenient for them. The participants could finish their exercise within 1 minute each day. The program is interactive and the participants can respond to the messages using a simple selection list; the chatbot offers them tailored replies depending on their responses.

The exercise provided by the program had three components: stretching [45–47], maintaining good posture [48,49], and mindfulness [21] (Figure 1). When the participants interrupted the exercise, the chatbot motivated them to continue exercising.”
5-ix) Describe use parameters

Describe use parameters (e.g., intended “doses” and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

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- essential

Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. We described it in the Intervention of the Methods: “The messages were sent every day at a fixed time through LINE. The notification time could be changed by the users to a time convenient for them. The participants could finish their exercise within 1 minute each day.”

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as “type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered”. It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

- subitem not at all important:anine
- essential
Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. We described it in the Intervention of the Methods: “we did not provide any human support”.

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. Although we didn’t send specific reminders in addition to the program, we considered the messages that were sent from the chatbot every day at a fixed time also had reminder function. We mentioned it in the Discussion: “The chatbot sent a message with the exercise instructions and a corresponding illustration at a fixed time every single day, which also functioned as a reminder feature that sent instructions at a fixed time each day.”
5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

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Does your paper address subitem 5-xii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

We did not perform any co-interventions such as training and support.

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it in the Outcomes of the Methods: “In this study, we set two types of outcomes. The first was a subjective assessment of the degree of pain on a scale of 1 to 5; this included subjective ratings of the neck/shoulder stiffness/pain and low back pain at baseline and after 12 weeks. A score of 4 or more was defined as severe pain. The second was a subjective assessment of whether there was an improvement. The participants were asked to subjectively rate whether their pain had improved after 12 weeks; they chose from the following options: improved, slightly improved, unchanged, slightly worse, and worse. Those who responded that their pain had improved or slightly improved were defined as the group that showed subjective improvement. All participants answered the questions through an online form.”

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

We did not validate the questionnaires for online use and apply CHERRIES items.
6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Yes. We described it in the Adherence to the Program of the Methods: “We counted the number of participants who continued to access and reply the chatbot’s messages at least once every 3 days and excluded the participants who did not access and reply for three weeks in a row.”

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).
Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

The owner of the program, Travoss, collected feedbacks from the participants of the program. If they had technical problems, they could ask the inquiry service of the program.

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not change trial outcomes.

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

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subitem not at all important ○ ○ ● ○ ○ essential

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Does your paper address subitem 7a-i?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This intervention was performed as an occupational health activity at a company and all employees who wanted to participate in the study were accepted unless they did not meet the inclusion criteria or they violated the exclusion criteria. Therefore, we did not calculate the sample size or power, nonetheless, the results obtained showed statistically significant differences.

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not perform any analyses during the intervention

8a) Method used to generate the random allocation sequence
NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it in the Randomization of the Methods: “After we confirmed that the applicants met all the inclusion criteria and did not violate any of the exclusion criteria, all 121 participants were randomized to the two groups by generating random numbers on a computer and stratified by 10-year age groups and separated them by the age group with a 1:1 allocation ratio.”
8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We used stratified randomization.

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

Does your paper address CONSORT subitem 9? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it in the Randomization of the Methods: “all 121 participants were randomized to the two groups by generating random numbers on a computer and stratified by 10-year age groups and separated them by the age group with a 1:1 allocation ratio.”

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Does your paper address CONSORT subitem 10? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

One of the authors, Dr. Oka generated the random allocation sequence. We also described it in the Study Population of the Methods and the Results: “The occupational health staff of the company recruited employees with remarkable musculoskeletal symptoms” and “we randomly assigned them to an intervention group (n=61) and control group (n=60)”.

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn’t

Specify who was blinded, and who wasn’t. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

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subitem not at all important ☐ ☐ ☐ ☐ ☐ essential

Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

We described it in the Study Design of the Methods: “This study was a two-armed, randomized, controlled, and unblinded trial on workers with neck/shoulder pain/stiffness and/or low back pain. We set the intervention and control groups “. 
11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

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Does your paper address subitem 11a-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it in the Limitation: “we did not reveal to the intervention group that they were the intervention group”.

11b) If relevant, description of the similarity of interventions
(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it in the Intervention of the Methods: “The control group continued with their regular exercise routine, which included exercising for about 3 minutes during the break time provided by the company every day to prevent stiff shoulders and back pain. We also allowed the control group to use the AI-assisted health program after the 12-week intervention.”
12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

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| Does your paper address CONSORT subitem 12a? * |
|-----------------------------------------------|
| Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study |
|---|
| Yes. We described it in the Statistical Analysis of the Methods: "A linear regression analysis was used to compare the intervention and control groups for subjective pain scores after the program. The odds ratios (OR) of the intervention group to achieve a subjective pain score of less than 3 compared with those of the control group was estimated using the logistic regression model. In addition, the OR of the subjective improvement of the symptoms compared to the intervention and control groups was estimated using the logistic regression model. All analyses were performed using Stata software (version 16, StataCorp LLC, TX, USA)." |

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12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

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Does your paper address subitem 12a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

We analyzed the data with 48 participants in the intervention group and 46 in the control. We had recruited 61 for intervention group and 60 for control group, but we lost 13, and 14 participants, respectively, for each before starting the intervention and we did not collect baseline information except for eligibility. Therefore, we were obliged to perform the study for only 48 participants in the intervention group and 46 in the control.

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

No. We did not perform additional analyses, such as subgroup analyses and adjusted analyses.

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

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subitem not at all important  ○  ○  ○  ○  ○  essential
### Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. We described it in the Study Design if the Methods, “This trial was conducted with the approval of the ethics committee of the University of Tokyo Hospital (ID: 12035) and the ethical review of the target company. The trial was registered at UMIN (ID: 000033894).”

### x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

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Yes. We described it in the Study Design and Intervention of the Methods: “We provided an explanatory document regarding the study to the applicants and obtained informed consent.”, and “We held an initial training session for the applicants to explain the purpose of the study and obtain informed consent.”
X26-iii) Safety and security procedures
Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

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Does your paper address subitem X26-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We mentioned it in the informed consent document.

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center
13b) For each group, losses and exclusions after randomisation, together with reasons

Yes. We described it in the Study Population of the Results: “After we confirmed the eligibility of 121 applicants who wished to participate in the study, we randomly assigned them to an intervention group (n=61) and control group (n=60), because we had to notify the schedule of the initial session during their working hours to the participants. Unfortunately, 13 and 14 allotted in the intervention and control group, respectively, could not participate in the session or answer the baseline survey. Therefore, the intervention started with 48 and 46 participants in the intervention and control groups, respectively.”
13b-i) Attrition diagram
Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

Does your paper address subitem 13b-i?
Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it as the Adherence to the Program of the Results: “Of the 48 participants in the intervention group, 47 started the AI-assisted health program and 44 continued the exercise for the entire intervention period. The adherence rate was 93.6% (44/47) in the study.”

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Study Population and Study Design of the Methods, “They recruited applicants by email notification between 3 and 14 September 2018,”, “the participants of the intervention group used the AI-assisted health program for 12 weeks”, and “We assessed the subjective severity of the neck and shoulder pain/stiffness and low back pain in both the intervention and control groups at baseline and 12 weeks immediately after the intervention.”.
14a-i) Indicate if critical “secular events” fell into the study period

Indicate if critical “secular events” fell into the study period, e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources”

Does your paper address subitem 14a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We have not experienced any critical secular events during the intervention

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

There was no interruption or discontinuance during the intervention.

15) A table showing baseline demographic and clinical characteristics for each group
NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group
Does your paper address CONSORT subitem 15? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described it in the Table 1, Baseline characteristics of participants.

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

Does your paper address subitem 15-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described age and gender in the Table 1. We also described computer/Internet literacy in the Discussion: "They were usually engaged in jobs that required the use of computers and were accustomed to using smartphones on a daily basis. In other words, they had high computer/internet literacy."

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
16-i) Report multiple “denominators” and provide definitions

Report multiple “denominators” and provide definitions: Report N's (and effect sizes) “across a range of study participation [and use] thresholds” [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants “used” the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define “use” of the intervention.

Does your paper address subitem 16-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks “like this” to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We described all denominators in the manuscript, the figures, and tables.

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only “users”, with the appropriate caveats that this is no longer a randomized sample (see 18-i).
We performed intention to treat analyses for 48 participants in the intervention group and 46 in the control that we could collect data of the baseline survey.

We described outcomes with 95% confidence interval in the Outcomes of the Results: "We performed logistic regression analyses to evaluate the differences in symptoms (neck/shoulder, back) between the baseline and at 12 weeks after adjusting for age and sex.; the result was −1.12 (95% CI −1.53 to −0.70, P<.001) (Table 3). We also examined the OR of the outcomes (Table 3). The OR of the worst pain score at 12 weeks between the intervention and control groups was 6.36 (95%CI 2.57 to 15.73, P<.001). The OR of the subjective improvement in symptoms at 12 weeks was 43.00 (95%CI 11.25 to 164.28, P<.001)."
17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as “average session length”. These must be accompanied by a technical description how a metric like a “session” is defined (e.g., timeout after idle time) [1] (report under item 6a).

Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We described it as the Adherence to the Program of the Results: "Of the 48 participants in the intervention group, 47 started the AI-assisted health program and 44 continued the exercise for the entire intervention period. The adherence rate was 93.6% (44/47) in the study."

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not use binary outcomes for a questionnaire. However, we analyzed the outcomes by dividing the answers into two categories depending on whether symptoms were severe (a score of 4 or more) or not (a score of 3 or less) at 12 weeks.
18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not perform any other analyses such as subgroup analyses and adjusted analyses.

18-i) Subgroup analysis of comparing only users
A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

Subitem not at all important: ○ ○ ○ ○ ○ essential

Does your paper address subitem 18-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not perform a subgroup analysis of comparing only users.

19) All important harms or unintended effects in each group
(for specific guidance see CONSORT for harms)
Does your paper address CONSORT subitem 19? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not have any or unintended effects.

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical “harm” to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. “Unintended effects” also includes unintended positive effects [2].

We did not have privacy breaches, technical problems during the intervention.
19-ii) Include qualitative feedback from participants or observations from staff/researchers
Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

Does your paper address subitem 19-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We did not have specific problems during the innervation.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
We described it in the Discussion: "This RCT showed that the 12-week use of an AI-assisted health program that provides one short exercise routine per day significantly improved (1) subjective symptoms of both neck and shoulder pain/stiffness and low back pain after 12 weeks compared to those at baseline, and (2) the subjective assessment of improvement following the 12-week intervention in the intervention group compared to the control group. In this study, the intervention group showed a high adherence of 93.6% (44/47) for the whole intervention period as we hypothesized that this digital intervention would support participants to continue exercising and enhance their adherence to the exercises, resulting in greater improvement in symptoms."
Does your paper address subitem 22-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We stated in the Discussion: "We are not sure which elements of this intervention, including the exercises themselves, were clearly effective."

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials
Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

subitem not at all important  ○   ○   ○   ○   ●  essential

Does your paper address subitem 20-i? *
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We stated it in the Limitation: "Fourth, this study was unblinded because of the characteristics of the intervention. The influence of the Hawthorne effect should be considered. Although we also provided the AI-assisted health program to the control group after completing the intervention for the intervention group and we did not reveal to the intervention group that they were the intervention group, it cannot be denied that the population of the intervention group could infer that they had been selected and should be able to improve because they were doing the exercises every day."
21) Generalisability (external validity, applicability) of the trial findings
NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations
Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ● essential

Does your paper address subitem 21-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

We stated it in the Discussion: "Although we used a specific program in this study, apps or Internet services with similar functions, such as sending easy and simple instructions every day at a fixed time, may be effective in relieving musculoskeletal symptoms."

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting
Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

1 2 3 4 5

subitem not at all important ○ ● ○ ○ ○ essential
The Ai-assisted health program was fully automated and we did not provide any additional human support except for inquiries about changes in their physical condition and the technical problems during the intervention.

Does your paper address CONSORT subitem 23? *

Yes. We mentioned in the Registration of the Abstract: “Trial Registration: University hospital Medical Information Network-Clinical Trials Registry (UMIN-CTR) 000033894; https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000038307.

Does your paper address CONSORT subitem 24? *

All the protocol of this study were written on the manuscript.
25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes. We wrote it in the Funding information of the Acknowledgements: "This study was supported by a grant from the Ministry of Health, Labor, and Welfare (No. H30-rodo-ippan-008) and the 2018 Japan Full Happ Survey Research (Public Interest Incorporated Foundation Japan Small and Medium Enterprise Welfare Business Foundation). The funding agencies had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript."

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

1 2 3 4 5

subitem not at all important ○ ○ ○ ○ ◆ essential

選択を解除
Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.

Yes. We wrote it in the Conflicts of Interest: "The authors declare the following potential conflicts of interest: Ko Matsudaira is a shareholder/adviser of Trunk Solution Co., Ltd., who has a patent for the AI-assisted health program using in this study and received the following support: a research grant from the Ministry of Health, Labor and Welfare for the submitted work; grant support from Sumitomo Dainippon Pharma Co., Ltd., and Okamura Corporation; grant support, including lecture fees from AYUMI Pharmaceutical Corporation, Nippon Zoki Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd., Eli Lilly Japan K.K., Astellas Pharma Inc., TOTO LTD., and Eisai Co., Ltd.; lecture fees from Pfizer Japan Inc., Hisamitsu Pharmaceutical Co., Inc., Janssen Pharmaceutical K.K., Kaken Pharmaceutical Co., LTD., and Teijin Pharma Limited; and lecture fees and advisory fees from Shionogi & Co., Ltd., MTG Co., Ltd., Sompo Holdings, Inc., NUVASIVE Japan, Murata Manufacturing Co., Ltd.; grants and personal fees from The Association for Preventive Medicine of Japan., Shionogi & Co., Ltd., Nippon Zoki Pharmaceutical Co., Ltd., Ono Pharmaceutical Co. Ltd., AYUMI Pharmaceutical Corporation; grants from DeNA, Murata Manufacturing Co., Ltd., Chugai Pharmaceutical Co., Ltd., Sompo Holdings, Inc, MS&AD InterRisk Research & Consulting, Inc, NUVASIVE Japan, Medical Data Scientist and Medical AI Device Development Organization, Inotech Co., Ltd., personal fees from Eli Lilly Japan K.K, Pfizer Japan Inc, and Hisamitsu Pharmaceutical Co., Inc., outside of the submitted work. Hiroyuki Oka reports personal fees received from AYUMI Pharmaceutical Corporation, Nippon Zoki Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd., Sompo Holdings, Inc., NuVasive Japan, Inc., Promotion of Practical Use of AI Medical Diagnosis Support Equipment, MS&AD InterRisk Research & Consulting, Inc., Inotech Corporation, Chugai Pharmaceutical CO., LTD, The Association for Preventive Medicine of Japan, Shionogi & Co., Ltd., MTG Co., Ltd.; grants from Pfizer Inc., outside of the submitted work."

As a result of using this checklist, did you make changes in your manuscript? *

- [ ] yes, major changes
- [ ] yes, minor changes
- [ ] no
What were the most important changes you made as a result of using this checklist?

This checklist helped us improve our manuscript better than before in terms of clarity.

How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

It took about 5-6 hours to fill out all of the question above and change the manuscript.

As a result of using this checklist, do you think your manuscript has improved? *

- yes
- no
- その他:

Would you like to become involved in the CONSORT EHEALTH group?

This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- yes
- no
- その他: I need more experiences to become a CONSORT EHEALTH group me
Any other comments or questions on CONSORT EHEALTH

回答を入力

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