CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

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
Behaviour change text messages for home exercise adherence in knee osteoarthritis: A randomised trial
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.

Behaviour change theory-informed, automated

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

Your answer

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

English

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.

Your answer

URL of an image/screenshot (optional)

Your answer
Accessibility *
Can an end user access the intervention presently?

- access is free and open
- access only for special user groups, not open
- access is open to everyone, but requires payment/subscription/in-app purchases
- app/intervention no longer accessible
- Other: only study participants could access the intervention

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)"

Knee osteoarthritis

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

Self-reported home exercise adherence at 24 v

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

Secondary outcomes included self-rated adherence (numeric rating scale), knee pain, physical function, quality-of-life, global change, physical activity, self-efficacy, pain catastrophising and kinesiophobia.
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"
- Other:

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%
- Other:
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
- Other:

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
- Other:
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
- Other:

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
- Other: 21749
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
- [ ] Other:

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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- [x] 5

subitem not at all important

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

"Behaviour change text messages for home exercise adherence in knee osteoarthritis: A randomised trial"
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").

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subitem not at all important     essential
Clear selection

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

"Behaviour change text messages for home exercise adherence in knee osteoarthritis: A randomised trial"

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
Clear selection
"Both groups were asked to continue their home exercise program unsupervised three times/week for 24-weeks and were randomly allocated to a behaviour change theory-informed, automated, semi-interactive SMS intervention addressing exercise barriers and facilitators or to control (no SMS)."
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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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

"Both groups were asked to continue their home exercise program unsupervised three times/week for 24-weeks and were randomly allocated to a behaviour change theory-informed, automated, semi-interactive SMS intervention addressing exercise barriers and facilitators or to control (no SMS)."

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)

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Clear selection
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.

"A two group, superiority randomized controlled trial in a community setting was performed. Participants were 110 people aged ≥50 years with knee OA and body mass index ≥30 kg/m² who had undertaken a 12-week physiotherapist-supervised exercise program as part of a preceding clinical trial. Both groups were asked to continue their home exercise program unsupervised three times/week for 24-weeks and were randomly allocated to a behaviour change theory-informed, automated, semi-interactive SMS intervention addressing exercise barriers and facilitators or to control (no SMS)."

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)

"110 participants (56 SMS group; 54 No SMS) were enrolled and 99 (90%) completed both primary outcomes (48 (86%) SMS group; 51 (94%) No SMS)."
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

N/A - the trial had a positive finding.

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)

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Clear selection

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

"Exercise programs often involve initial supervision by a clinician followed by unsupervised home exercise. Ideally, regular participation in exercise should be one of the long-term goals of self-management. Unfortunately, adherence to home exercise is often poor,[5] particularly once clinician input ceases.[6] Numerous barriers can impact adherence such as pain, negative beliefs about OA and exercise, and poor self-efficacy.[7, 8] This decline in exercise adherence is typically mirrored by a gradual loss of initial clinical benefits.[6, 9] Thus, scalable strategies to improve adherence to structured home exercise are thought to be important for better longer-term patient outcomes.[10]"
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

"There is uncertainty about how best to help people with knee OA adhere to exercise. Interventions that show promise include ‘booster’ or ‘refresher’ sessions with a physiotherapist and behavioural graded exercise, involving gradual increases in physical activity plus ‘booster’ sessions.[11] However, ongoing clinician involvement may be unfeasible or impractical for many patients due to access challenges and/or cost. Instead, the use of digital communications such as Short Messaging Services (SMS), email or apps may be inexpensive and accessible options to help promote exercise adherence. As patients with knee OA tend to be older, SMS may have advantages over other forms of digital communication due to its widespread use, familiarity and potential to overcome barriers relating to device ownership (not owing a smart phone) and access to and availability of wifi cellular data. The effectiveness of SMS-based interventions to promote healthy behaviours relevant to OA such as physical activity, diet, and/or weight loss has also been demonstrated in various settings and other conditions.[12-14] To date, the use of SMS to improve adherence to home exercise or physical activity in people with knee OA has only been evaluated in three pilot/feasibility studies.[15-17]"
The primary aim of the ADHERE randomised controlled trial (RCT) was to evaluate the effects of a theoretically-informed 24-week SMS program[18] on self-reported adherence to a prescribed unsupervised structured home exercise program, undertaken after an initial 12-week period of physiotherapist supervision. We hypothesized that the SMS intervention would lead to greater exercise adherence than no SMS contact.

This parallel, 2-arm superiority RCT is reported according to CONSORT,[19] CONSORT-EHEALTH,[20] TIDieR[21] and CERT recommendations.[22]

Participants underwent 1:1 randomisation into either: i) SMS intervention, or ii) Control (no SMS).
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

N/A - no changes to protocol after trial commencement

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].

Does your paper address subitem 3b-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

N/A - no bugs, downtimes or 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

"Inclusion criteria were: i) aged ≥ 50 years; ii) knee pain on most days of the past month; iii) knee pain for ≥3 months; iv) average overall pain severity ≥4 on an 11-point numeric rating scale (NRS); v) tibiofemoral osteophyte(s) on x-ray; vi) obesity (body mass index (BMI) ≥30 kg/m2) and; vii) own a mobile phone with text messaging. Exclusion criteria are found in Appendix Table 1."

4a-i) Computer / Internet literacy

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

The intervention did not use computers or the internet, although for phone use, the following inclusion criteria was used:

"vii) own a mobile phone with text messaging."
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

"The TARGET trial included face-to-face visits with members of the research team at the University of Melbourne. Only those who completed the TARGET trial final 12-week assessment and did not withdraw at this timepoint were enrolled into the ADHERE trial. Participants provided written informed consent to participate at TARGET trial enrolment."

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.
"Participants provided written informed consent to participate at TARGET trial enrolment."

"Participants were blinded to study groups and to the study hypothesis through limited disclosure. They were informed at TARGET trial enrolment that participation was for 9 months, with the initial 3 months comparing two exercise programs and the following 6 months investigating undisclosed adherence strategies, such as a log-book or text messages. To avoid influencing exercise adherence behaviour, participants were not informed that two separate, but related, trials were being conducted or that they were being re-randomised into this trial."

"Outcomes were self-reported and completed electronically (via RedCap™) or on paper."

Does your paper address CONSORT subitem 4b? *

Does your paper address subitem 4a-iii?
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

"Outcomes were self-reported and completed electronically (via RedCap™) or on paper."

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

Clear selection
"The TARGET trial included face-to-face visits with members of the research team at the University of Melbourne. Only those who completed the TARGET trial final 12-week assessment and did not withdraw at this timepoint were enrolled into the ADHERE trial."

"RKN, KLB and RSH developed the SMS intervention."

"The study was funded by the National Health and Medical Research Council Program Grant (#1091302)."
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.

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

"The development of the SMS intervention was based on the Behaviour Change Wheel framework[26] and is described elsewhere.[18] In brief, we identified key barriers/facilitators to exercise adherence in knee/hip OA and mapped these to the Theoretical Domains Framework.[8]"

Development of the SMS intervention is described in reference [18], published in JMIR mHealth and uHealth in 2019.

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).
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.

N/A - no content was changed between final development and commencement of the trial.

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

Clear selection

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.

N/A
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.

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.

"Barrier selection then triggered a message providing a suggestion tailored to address the selected barrier (example shown in Figure 1)."

"Figure 1. Example automated message sequence for a person with low exercise adherence and reporting their main barrier to exercise as 'forgot'."

"Appendix Table 3. Description and frequency of behaviour change messages included in the SMS intervention"

"Appendix Table 4. Description and frequency of logistic and other messages included in the SMS intervention"
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.

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

N/A

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).
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.

"Participants received a 24-week automated, semi-interactive SMS intervention delivered via mobile phone to support adherence to the home exercise program."

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].

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subitem not at all important

Clear selection
"Participants received up to five text messages weekly, with message frequency reducing over the 24-weeks. Appendix Tables 3 and 4 describe all message types and frequencies while Appendix Figure 1 outlines how the automated message sequence functioned. In summary, each week (weeks 1-8) to fortnight (weeks 9-24) participants received a message asking them to self-report the number of home exercise sessions completed in the previous week. Participants who completed ≤2 sessions then received a message prompting them to select their main reason ('barrier') for not performing exercise sessions as prescribed (3 sessions per week) from a predetermined list (forgot, too tired, knee hurts so can’t exercise, worried exercise is causing pain, exercise isn’t helping, boring, lack of time, life stress, and none above apply to me). Barrier selection then triggered a message providing a suggestion tailored to address the selected barrier (example shown in Figure 1). For those who chose the barrier option of none apply received a message encouraging them to continue exercising but the message was not linked to a specific behaviour change technique. Participants who reported being adherent (≥3 exercise session/week) received a positive reinforcement message. Program automation ensured different messages were received each time. All participants, irrespective of their adherence, also received regular motivational SMS (twice weekly initially then once fortnightly by 24-weeks) containing suggestions linked to exercise facilitators. To enhance engagement, participants received special occasion messages (e.g. birthday)."

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.
"Participants received up to five text messages weekly, with message frequency reducing over the 24-weeks. Appendix Tables 3 and 4 describe all message types and frequencies while Appendix Figure 1 outlines how the automated message sequence functioned. In summary, each week (weeks 1-8) to fortnight (weeks 9-24) participants received a message asking them to self-report the number of home exercise sessions completed in the previous week. Participants who completed \(\leq 2\) sessions then received a message prompting them to select their main reason ('barrier') for not performing exercise sessions as prescribed (3 sessions per week) from a predetermined list (forgot, too tired, knee hurts so can’t exercise, worried exercise is causing pain, exercise isn’t helping, boring, lack of time, life stress, and none above apply to me). Barrier selection then triggered a message providing a suggestion tailored to address the selected barrier (example shown in Figure 1). For those who chose the barrier option of none apply received a message encouraging them to continue exercising but the message was not linked to a specific behaviour change technique. Participants who reported being adherent (\(\geq 3\) exercise session/week) received a positive reinforcement message. Program automation ensured different messages were received each time. All participants, irrespective of their adherence, also received regular motivational SMS (twice weekly initially then once fortnightly by 24-weeks) containing suggestions linked to exercise facilitators. To enhance engagement, participants received special occasion messages (e.g. birthday)."
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).

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.

N/A - the intervention did not require any human involvement (care providers or technical 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).
"Participants received up to five text messages weekly, with message frequency reducing over the 24-weeks. Appendix Tables 3 and 4 describe all message types and frequencies while Appendix Figure 1 outlines how the automated message sequence functioned. In summary, each week (weeks 1-8) to fortnight (weeks 9-24) participants received a message asking them to self-report the number of home exercise sessions completed in the previous week. Participants who completed ≤2 sessions then received a message prompting them to select their main reason ('barrier') for not performing exercise sessions as prescribed (3 sessions per week) from a predetermined list (forgot, too tired, knee hurts so can’t exercise, worried exercise is causing pain, exercise isn’t helping, boring, lack of time, life stress, and none above apply to me). Barrier selection then triggered a message providing a suggestion tailored to address the selected barrier (example shown in Figure 1). For those who chose the barrier option of none apply received a message encouraging them to continue exercising but the message was not linked to a specific behaviour change technique. Participants who reported being adherent (≥3 exercise session/week) received a positive reinforcement message. Program automation ensured different messages were received each time. All participants, irrespective of their adherence, also received regular motivational SMS (twice weekly initially then once fortnightly by 24-weeks) containing suggestions linked to exercise facilitators. To enhance engagement, participants received special occasion messages (e.g. birthday)."
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.

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

All participants were asked to continue their allocated TARGET prescribed home exercise program unsupervised for 24 weeks[24] but to reduce the frequency from four times per week to three times per week (Appendix Table 2).

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
"The primary outcomes were two measures of adherence, collected at 24 weeks: i) Adherence to prescribed home exercise using the Exercise Adherence Rating Scale (EARS) Section B which has six items, each scored on a 5-point scale with terminal descriptors of ‘strongly agree’ to ‘strongly disagree’. The total score ranges between 0 and 24, with higher scores indicating better adherence. This measure has acceptable internal consistency, high test-retest reliability (intraclass correlation coefficients (ICC) from 0.91 to 0.97) and evidence of construct validity and responsiveness to change;[29-31] ii) Number of days home exercises completed in the past week. Participants were asked “In the past week, how many days did you do your recommended home exercises (maximum of 3 days)?” Response choices range from 0 to 3 days. Our test retest reliability (2-week interval) with such a scale in 54 patients with knee OA is good (ICC (2,1)= 0.79 (95% confidence interval 0.66-0.87)) with fair validity based on agreement with concealed accelerometer-measured session number (spearman correlations from 0.26 to 0.48 over a 12-week period) (method of accelerometer measure reported in Nicolson et al.);[32]

Secondary outcomes measured at baseline and 24 weeks, unless otherwise indicated, included: i) Adherence to home exercise program three times per week (24-weeks only) based on strength of agreement to the statement “I have been doing my exercise sessions 3 times each week as recommended” using an 11-point numeric rating scale (NRS) with terminal descriptors “strongly disagree =0 to “strongly agree”=10;[32] ii) Average overall knee pain in the past week using a NRS [33] with terminal descriptors of ‘no pain’ (score=0) and ‘extreme pain’ (score=10); [33] iii) Pain, other symptoms, function in daily living, function in sport and recreation and knee-related quality-of-life in the last week using the Knee Injury and Osteoarthritis Outcome Score (KOOS) [34], ranging from 0-100 with higher scores indicating better outcomes; iv) Health-related quality-of-life using Assessment of Quality of Life instrument[35] (version AQoL-6D), scores ranging from -0.04 to 1.00 and higher scores indicating better quality-of-life[35]; v) Arthritis Self-Efficacy Scale, scores ranging from 0-10 and higher scores indicating greater self-efficacy[36]; vi) Kinesiophobia using the Brief Fear of Movement Scale for OA, scores ranging from 6-24 and higher scores indicating greater kinesiophobia;[37] vii) Pain Catastrophising Scale, scores ranging from 0-52 and higher scores indicating greater catastrophising;[38] viii) Physical Activity Scale for the Elderly, scores ranging from 0 to >400 and higher scores representing greater physical activity;[39] ix) Participant-reported global overall change using a 7-point scale (terminal
Participant-reported global overall change using a 7-point scale (terminal descriptors 'much worse' to 'much better'). Participants who reported “moderately better” and ‘much better” were classified as improved.[40]"

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].

Clear selection

Does your paper address subitem 6a-i?
Copy and paste relevant sections from manuscript text

No.

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.

Clear selection
Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

"Automatically-collected SMS data included: i) number who opted to cease receiving messages; ii) mean (SD) number of SMS sent per participant; iii) mean (SD) participant reply rate to self-reported exercise sessions; iv) mean (SD) participant reply rate for barrier selection; v) group frequency of barriers selected."

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).

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subitem not at all important ◯ ◯ ◯ ◯ ◯ essential

Does your paper address subitem 6a-iii?
Copy and paste relevant sections from manuscript text

Qualitative feedback was not collected from trial participants.

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

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

"We conservatively estimated that 102 participants (i.e. 80% of n=128 TARGET participants) would be randomised into ADHERE, and of those, 82 (80%) would be retained at week 24."

7b) When applicable, explanation of any interim analyses and stopping guidelines
8a) Method used to generate the random allocation sequence
NPT: When applicable, how care providers were allocated to each trial group

8b) Type of randomisation; details of any restriction (such as blocking and block size)

"Computer-generated randomisation was prepared by the biostatistician (JK) in permuted blocks of sizes 6 to 12, stratified by type of exercise performed in TARGET and by exercise adherence at the final TARGET time-point (0-1 sessions in the past week arbitrarily classified as "lower adherence" and 2-4 sessions "higher adherence")."
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

"Allocation was concealed in a password-protected computer program and accessed by a researcher not involved in enrolment or assessment."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

"Computer-generated randomisation was prepared by the biostatistician (JK)"

"Allocation was concealed in a password-protected computer program and accessed by a researcher not involved in enrolment or assessment."

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

"Participants were blinded to study groups and to the study hypothesis through limited disclosure."

"Outcome assessment was therefore blinded as the participants were deemed ‘assessors’ in this RCT given outcomes were participant-reported. The statisticians were blinded to group allocation."

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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subitem not at all important   essential

Clear selection
"They were informed at TARGET trial enrolment that participation was for 9 months, with the initial 3 months comparing two exercise programs and the following 6 months investigating undisclosed adherence strategies, such as a logbook or text messages. To avoid influencing exercise adherence behaviour, participants were not informed that two separate, but related, trials were being conducted or that they were being re-randomised into this trial."

"All participants were asked to continue their allocated TARGET prescribed home exercise program unsupervised for 24 weeks[24]"

"Participants in the control group did not receive any SMS contact."
"For the primary outcome of exercise adherence EARS Section B, the mean between-group difference at week 24 was estimated using a linear regression model adjusted for baseline measures and the stratifying variables of TARGET exercise group and dichotomised baseline adherence. For the primary outcome of number of days home exercises completed in past week, and the secondary outcome of adherence to home exercise, the mean between-group difference at week 24 was estimated using linear regression models, adjusted only for the stratifying variables. For the continuous secondary outcomes, the mean between-group difference in change (baseline minus follow-up) at week 24 was estimated using linear regression models adjusted for baseline measures and stratifying variables. The proportion of participants with self-perceived improvement overall was compared between groups using a logistic regression model adjusted for stratifying variables, with results presented as odds ratios and risk ratios. Complete-case analyses were also conducted."

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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subitem not at all important  ○  ○  ○  ●  ○ essential
"Missing outcomes were imputed using chained equations with predictive mean matching and five nearest neighbours for continuous outcomes and logistic regression imputation models for binary improvement outcomes. Data were imputed for each group separately. Imputation models for continuous outcomes at 24 weeks included all baseline and outcome variables where appropriate. Imputation models for binary variables omitted all outcome variables due to the potential for perfect prediction, including only baseline variables. Estimates from 20 imputed datasets were combined using Rubin’s rules.[45] Standard diagnostic plots assessed validity of model assumptions and imputed datasets."

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

N/A

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)
X26-i) Comment on ethics committee approval

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

"Ethics approval was obtained from the Human Research Ethics Committee of University of Melbourne (HREC No. 1544919)."

X26-ii) Outline informed consent procedures

x26-ii) 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.

Does your paper address subitem X26-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

"Participants provided written informed consent to participate at TARGET trial enrolment."
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

"We randomised 110 participants (56 SMS group; 54 No SMS), with 99 (90%) completing both primary outcome measures at week 24 (48 (86%) SMS group; 51 (94%) No SMS), Figure 2."
13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? *(NOTE: Preferably, this is shown in a CONSORT flow diagram)*

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

Figure 2: SMS intervention: "Did not return messages (n = 7); chose to withdraw (n=1)"

Figure 2: No SMS intervention: "Did not return messages (n = 2); chose to withdraw (n=1)"

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

No.
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

"TARGET trial participants were recruited from the community in Melbourne, Australia between September 2017 and May 2019"

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”

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subitem not at all important ○ ○ 3 ○ ○ essential

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

N/A

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

N/A

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

"Table 1. Baseline characteristics of participants, by group, reported as mean (standard deviation) unless otherwise stated"

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.

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subitem not at all important ○ ○ ¤ ○ ○ essential

Clear selection
Table 1 includes age, gender and employment status.

Inclusion criteria for the trial included "own a mobile phone with text messaging."

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.

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subitem not at all important   ○   ○   ○   ○   ●    essential

Clear selection
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. N values are given in flow charts and tables. Exception to stated N values are provided in table footnotes where relevant. Eg Table 2:

"a n=48 for both primary outcomes, n=45 for all secondary outcomes
b n=49 for both primary outcomes, n=45 for Sport and Recreation (KOOS), AQoL BFOMS and PASE, n=46 for all other secondary outcomes"

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).

"Analyses were performed by biostatisticians (JK and SJCC) using Stata (v16) software and intention-to-treat."

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
Does your paper address CONSORT subitem 17a? *

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

"Table 3: Mean (SD) scores at week 24, or mean (SD) change within groups from baseline to week 24, and mean (95% confidence interval) difference between groups (adjusted for baseline value of outcome, TARGET exercise group and dichotomised baseline adherence), for continuous outcomes, using multiply imputed data"

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

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory analyses.
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.

"Appendix Table 7: Means (SD) at week 24 or mean (SD) change within groups, from baseline to week 24, and mean (95% confidence interval) difference between groups (adjusted for baseline value of outcome, TARGET exercise group and dichotomised baseline adherence), for continuous outcomes, using complete case data"

"Appendix Table 8: Number (percentage) of participants reporting global improvement (adjusted for TARGET exercise group and dichotomised baseline adherence), using complete case data."

Both of the above are pre-specified.

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).

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.

N/A
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

"Seventeen participants reported adverse events (none serious), mostly increased knee pain or pain elsewhere (Appendix Table 6)."

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].

subitem not at all important  ○  ○  ○  ○  ○  essential

Does your paper address subitem 19-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

N/A
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.

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Clear selection

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

N/A

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 found that an automated behaviour change theory-informed, semi-interactive SMS intervention improved self-reported adherence to a prescribed unsupervised home-based exercise program over 24-weeks, evidenced by both primary outcomes, when compared to no SMS contact in people with knee OA and obesity."
"Further research into modification of the program and its implementation is warranted to optimise exercise behaviour change and impact clinical outcomes. This could include messages that better address each person's unique exercise barriers, use of the program at more distal time points when adherence substantially declines and symptomatic benefits are reduced and testing the program in a pragmatic setting where patients as less motivated to exercise at the outset. Our results also highlight the need for further research to better understand the nature of the relationship between exercise adherence and clinical outcomes."

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.

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Clear selection
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

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

"There are some limitations. First, accurate measurement of exercise adherence is challenging[54] and there is no gold standard."

"Second, only those who completed the preceding TARGET study were enrolled as participants. This may have introduced selection bias, particularly by increasing the likelihood that a more adherent group was enrolled, which could make it more difficult to detect an effect of the SMS program on exercise adherence."

"Third, we do not know whether the improved exercise adherence is sustainable over time once SMS contact is ceased nor whether our findings can be generalised to a home exercise program that is unsupervised from its outset, to patients who may be less motivated than research volunteers or to those without obesity."

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

Clear selection
"Nonetheless, the characteristics of our sample broadly reflect those of the general knee OA patient population which includes greater proportion of females, overweight and obesity and older age.[55]"

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.

Does your paper address subitem 21-ii?

No

23) Registration number and name of trial registry
Does your paper address CONSORT subitem 23? *

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

"It was prospectively registered (Australian New Zealand Clinical Trials Registry #12617001243303)"

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

Cite a Multimedia Appendix, other reference, or 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, available in the Multimedia Appendix.

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

"The study was funded by the National Health and Medical Research Council Program Grant (#1091302). The funder played no role in study design, data collection, analysis or interpretation or manuscript preparation."

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.

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subitem not at all important ○ ○ ○ ○ ○ essential

Clear selection

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

"RKN, KLB and RSH developed the SMS intervention."

"The authors declare that they have no competing interests."

About the CONSORT EHEALTH checklist

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?

Your answer

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

6 hours

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

- yes
- no
- Other:

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
- Other:
Any other comments or questions on CONSORT EHEALTH

Your answer

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Bennell, K; Nelligan, RK; Schwartz, S; Kasza, J; Kimp, A; Crofts, SJC; Hinman, RS

Title: 
Behavior Change Text Messages for Home Exercise Adherence in Knee Osteoarthritis: Randomized Trial

Date: 
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