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

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

Sign in to Google to save your progress. Learn more

* Indicates required question

Your name *

First Last

Sylvia Badon

Primary Affiliation (short), City, Country * University of Toronto, Toronto, Canada

Kaiser Permanente Northern California Divisio

Your e-mail address *

abc@gmail.com

sylvia.e.badon@kp.org

Title of your manuscript *

Provide the (draft) title of your manuscript.

Effect of a Tailored eHealth Physical Activity Intervention on Physical Activity and Depression during Postpartum: The POstpartum Wellness Study (POW), a Randomized Controlled Trial

R

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.

MomZing

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 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	
Other:	
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)"	
Postpartum depression	
Primary Outcomes measured in trial * comma-separated list of primary outcomes reported in the trial Depressive symptoms	
Primary Outcomes measured in trial * comma-separated list of primary outcomes reported in the trial	

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: Not specified
Approx. Percentage of Users (starters) still using the app as recommended after * 3 months
unknown / not evaluated
O -10%
O 11-20%
21-30%
31-40%
O 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
o no statistically significant difference between control and intervention
outcomes potentially harmful: control was significantly better than intervention in one or more
inconclusive: more research is needed
Other:
Article Preparation Status/Stage *
Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form)
At which stage in your article preparation are you currently (at the time you fill in this form)
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
At which stage in your article preparation are you currently (at the time you fill in this form) onot submitted yet - in early draft status not submitted yet - in late draft status, just before submission
At which stage in your article preparation are you currently (at the time you fill in this form) onot submitted yet - in early draft status not submitted yet - in late draft status, just before submission submitted to a journal but not reviewed yet
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
At which stage in your article preparation are you currently (at the time you fill in this form) onot 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

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")
onot 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? *
Is this a full powered effectiveness trial or a pilot/feasibility trial? * Pilot/feasibility
O Pilot/feasibility
O Pilot/feasibility
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

43	PM CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form
	TITLE AND ABSTRACT
	1a) TITLE: Identification as a randomized trial in the title
	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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subitem not at all important 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

"Effect of a Tailored eHealth Physical Activity Intervention on Physical Activity and Depression during Postpartum: The POstpartum Wellness Study (POW), a Randomized Controlled Trial among Individuals at High Risk of Postpartum Depression"

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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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

NA- no non-web-based components

1a-iii) Primary	condition /	or target	aroup	in the	title
1 4 111	, i i i i i i i i i i i i i i i i i i i	, oonantion	or target	group		CICIC

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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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

"among Individuals at High Risk of Postpartum Depression"

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)

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Does your paper address subitem 1b-i? *

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

"individuals 2-6 months postpartum at high risk for PPD were randomized to an eHealth PA intervention (n=50) or usual care (n=49). The eHealth PA intervention group received access to an online library of 98 10-minute workout videos developed for postpartum individuals, including interaction with their infants."

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

"an online library of 98 10-minute workout videos"

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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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

"We conducted a remote randomized controlled trial within the Kaiser Permanente Northern California health care delivery system."

"At baseline, 3 months, and 6 months post-randomization, surveys were used to assess depressive symptoms, PA, sleep quality, anxiety symptoms, perceived stress, and mother-infant bonding. PA was also measured using a wrist-worn accelerometer for 7 days at each timepoint."

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)

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Does your paper address subitem 1b-iv?

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

"From November 2020 to September 2022, individuals 2-6 months postpartum at high risk for PPD were randomized to an eHealth PA intervention (n=50) or usual care (n=49)."

"Participants were 4 months postpartum at baseline with moderately severe depressive symptoms (mean PHQ-8 score=12.6), on average. Intent-to-treat analyses indicated no association between the intervention and change in depressive symptoms (mean difference= -0.7; 95%CI: -4.0, 2.5), dm-MVPA per day (mean difference= -4.3 minutes; 95%CI: -31.0, 22.0), or sr-MVPA per week (mean difference= 3.5 MET-hours; 95%CI: -5.0, 12.0) at 3 months post-randomization or 6 months post-randomization (depressive symptoms: mean difference= -0.2; 95%CI: -3.4, 3.1; dm-MVPA: mean difference= -11.0 minutes; 95%CI: -44.0, 22.0; sr-MVPA: mean difference= -1.6 MET-hours; 95%CI: -11.0, 8.2). Engagement with the intervention was suboptimal; although 52% (n=26) of participants allocated to the intervention group logged on to the intervention website and watched at least one video, the median minutes watched per week peaked at 10 minutes two weeks post-randomization, then fell to zero for the rest of the follow-up period."

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)

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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

"An eHealth PA intervention tailored to postpartum individuals did not affect depressive symptoms or PA among those at high risk for PPD, likely due to suboptimal engagement."

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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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

"Technology-based electronic health (eHealth) interventions may address common barriers to being physically active in the postpartum period, and as such are a promising approach to increasing PA levels in postpartum individuals at high risk for PPD. eHealth PA interventions have demonstrated effectiveness in increasing PA in the general adult population [24, 25]. In contrast, most previous PA interventions for postpartum individuals have relied on in-person supervised exercise sessions alone or in combination with individual health coaching [10, 26, 27]."

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.

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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 strong evidence that physical activity (PA) can reduce postpartum depression symptoms [8-12]. The PA Guidelines for Americans [13], the American College of Sports Medicine [14], and the American College of Obstetricians and Gynecologists [15] recommend participation in regular PA (at least 150 minutes of moderate to vigorous intensity PA per week) during the postpartum period for physical and mental health benefits. Despite these recommendations, PA levels remain low in postpartum individuals [16]. Common barriers include lack of time and prioritization of other responsibilities, including parenting and household responsibilities, lack of child care, lack of motivation or social support, and difficulty finding accessible and affordable PA programs or classes [17-23]."

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

"The objective of this study, the POstpartum Wellness study (POW), was to test the effectiveness of an eHealth PA intervention for increasing PA and decreasing depressive symptoms in individuals at high risk for PPD."

METHODS

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

"We conducted a two-arm, parallel group randomized controlled trial"

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

"Below we summarize key aspects of the POW study protocol, which has been previously published [28]." Changes to methods are described in detail in the protocol paper referenced at the beginning of the Methods section.

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].

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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

We did not change the content of the intervention during the trial.

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

"From November 2020 through September 2022, 12,269 postpartum individuals who met the following inclusion criteria in the EHR were invited to participate in the study via letter and email invitations: 2-6 months postpartum, no current depression diagnosis, and at high risk for PPD (identified using PPD screening PHQ-9 score 10-19 or PHQ-2 score ≥3, or history of depression diagnosis and antidepressant medication prescription prior to delivery date). Additional eligibility criteria (including re-assessment of depression symptoms using a PHQ-8 screener) were assessed using online questionnaires prior to the baseline survey. See Table S1 for detailed inclusion and exclusion criteria."

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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Does your paper address subitem 4a-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

Exclusion criteria include "Does not own a smartphone, computer, or TV with internet access"

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.

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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

"postpartum individuals who met the following inclusion criteria in the EHR were invited to participate in the study via letter and email invitations"

After survey completion, participants were mailed an accelerometer and were asked to wear the accelerometer for 7 consecutive days, 24 hours per day, then mail it back."

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.

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Does your paper address subitem 4a-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

"Eligible participants completed informed consent documents and baseline surveys online through REDCap."

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

"members of Kaiser Permanente Northern California (KPNC), an integrated health care delivery system that provides care for over 66,000 pregnant and postpartum individuals annually. PPD screening is part of standard postpartum care at KPNC [29, 30] and also occurs at each pediatric well-baby visit. Results of all PPD screening and diagnosis are captured in KPNC's comprehensive electronic health record (EHR) database."

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	0	0	0	0	0	essential					
Does your paper address subitem 4b-i? *											
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											
"Eligible participants completed informed consent documents and baseline surveys online through REDCap." "Follow-up surveys were sent via email at 3- and 6- months post-randomization. After completion of each survey participants were mailed an accelerometer and were asked to wear the accelerometer for 7 consecutive days, 24 hours per day, then mail it back. An additional assessment occurred when the participant's child was 12 months old."											
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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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

All recruitment materials and consent clearly noted that the research was based at Kaiser Permanente Northern California.

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).

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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

"participants randomized to the intervention group received access to MomZing (Klein Buendel, Lakewood CO)"

"CLA designed the eHealth intervention (MomZing)"

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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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

"MomZing (Klein Buendel, Lakewood CO), an eHealth PA intervention tailored to postpartum individuals [32]. MomZing is an online library of 98 10-minute exercise videos that was developed with and for postpartum individuals. The exercise videos on MomZing instructed postpartum individuals how to safely exercise with their baby based on the infant's weight and developmental stage, did not require exercise equipment, and featured postpartum individuals (who were not fitness instructors) exercising with their own infant."

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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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 intervention did not undergo any changes during 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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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 conducted quality assurance checking during the data cleaning process.

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

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

As we did not develop the intervention, we do not have the source code. The intervention has already gone offline so we are not able to access the intervention any longer.

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.

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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

The intervention required login so cannot be archived.

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).

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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 randomized to the intervention group received individual login information for the MomZing website via email" 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].

subitem not at all important O O O o essential

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

"an eHealth PA intervention tailored to postpartum individuals [32]" Detailed description of the intervention features has been published in the referenced protocol paper.

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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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

No instructions regarding use parameters were given to the user.

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).

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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

"MomZing is an online library of 98 10-minute exercise videos"

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).

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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

"up to 6 reminders (text and email per each participant's preference) to log into the MomZing website (73% text and 27% email)"

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

No co-interventions were used.

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

"Primary outcomes were depressive symptoms and device-measured moderate/vigorous intensity PA (dm-MVPA), measured at 3 months post-randomization. Depressive symptoms were assessed using the validated 8-item Patient Health Questionnaire (PHQ-8) screener [33, 34], with higher scores indicating greater symptom severity (range: 0-24). dm-MVPA was measured using the ActiGraph GT3X+ accelerometer (ActiGraph, Pensacola FL), worn on the non-dominant wrist. Raw accelerometer data was downloaded using ActiLife software (ActiGraph, Pensacola FL) and counts were summarized for each 1-second and 60-second epoch. Wear time was identified using the Choi algorithm [35-37], and wake (non-bedrest) was identified using the Tracy algorithm [38]. Individuals with at least 4 days (including at least one weekend day) of at least 10 hours of waking accelerometer wear were considered to have sufficient accelerometer data for analyses [39]. Waking wear time was categorized into intensity categories using the Hibbing two-regression model, which was developed for wrist-worn accelerometer data [40]. Average dm-MVPA duration was calculated across valid days."

"Secondary outcomes included self-reported moderate/vigorous intensity PA (sr-MVPA) at 3- and 6-months post-randomization, and depressive symptoms and dm-MVPA at 6 months post-randomization. sr-MVPA duration was assessed using the sports/exercise domain of the Pregnancy Physical Activity Questionnaire [41]. In addition, we created a subscale of the sports/exercise domain of the Pregnancy Physical Activity Questionnaire (sr-MVPA-MomZing) limited to activities included in MomZing videos: dancing; yoga/Pilates/stretching/core strengthening exercises, exercise videos, or computer games; aerobic exercise videos or computer games; weightlifting/resistance exercises (i.e., MomZing included workouts where the infant was lifted or carried)."

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 "Depressive symptoms were assessed using the validated 8-item Patient Health Questionnaire (PHQ-8) screener [33, 34], with higher scores indicating greater symptom severity (range: 0-24)." 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. subitem not at all important essential Does your paper address subitem 6a-ii? Copy and paste relevant sections from manuscript text "Participants allocated to the intervention group received a feedback survey at 3 months post-randomization that assessed their use of the MomZing website, reasons for not using the website." Additional details about website analytics are provided in the published protocol paper. 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).

subitem not at all important

essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

"Participants allocated to the intervention group received a feedback survey at 3 months post-randomization that assessed their use of the MomZing website, reasons for not using the website, experience and satisfaction with the MomZing intervention, and qualitative feedback about the intervention. The satisfaction questions were adapted from a validated satisfaction questionnaire for web-based health interventions with Likert scale responses, with higher scores indicating higher satisfaction (range: 12-60) [49]."

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

No changes to trial outcomes were made after the trail started.

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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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

"Original sample size calculations were based on a planned sample size of 100 participants per group. With our achieved sample size of 99 participants (50 in the intervention group, 49 in the control group), 80% power, and 5% type I error rate, the minimum detectable difference in means for depressive symptoms and dm-MVPA was 0.57 standard deviation units, which is considered a "medium" effect size [50]."

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 conduct interim analyses.

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

"Participants were randomized by the study project manager into the intervention group or control (usual care) group using minimization, implemented using QMinim [31]. Minimization aims to achieve between-group balance in distributions of pre-specified important factors associated with outcomes of interest."

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

"Participants were randomized by the study project manager into the intervention group or control (usual care) group using minimization, implemented using QMinim [31]. Minimization aims to achieve between-group balance in distributions of pre-specified important factors associated with outcomes of interest. Variables included in the randomization procedure included number of children at home (1, 2+), self-reported race and ethnicity category (Asian/Pacific Islander, Hispanic, non-Hispanic Black, non-Hispanic white, other), baseline PHQ-8 score (10-14, 15-19), and PA level prior to pregnancy (below recommendations, at or above recommendations)."

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

"Participants were randomized by the study project manager into the intervention group or control (usual care) group using minimization, implemented using QMinim [31]."

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

"Participants were randomized by the study project manager into the intervention group or control (usual care) group using minimization, implemented using QMinim [31]."

"Research assistants, who informed participants of their assigned study group, and participants were not blinded."

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).

subitem not at all important O O O O 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

"Investigators and data analysts were blinded to assigned study group. Research assistants, who informed participants of their assigned study group, and participants were not blinded."

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".

subitem not at all important O O O essential

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

Given the nature of the intervention, it was not possible to blind participants.

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

This is not relevant for this eHealth trial.

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

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

"Primary analyses followed an intent-to-treat approach. We used multivariable linear regression models, adjusted for variables used in the randomization procedure (number of children at home, race and ethnicity, baseline PHQ-8 score, pre-pregnancy PA level) and corresponding baseline value of the outcome, to estimate mean differences in each outcome associated with the MomZing intervention."

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 used multiple imputation using chained equations to impute missing outcome and baseline MVPA data with 10 imputations. Variables included in imputation models are shown in Table S2. Regression models were run using each imputed dataset. Results were combined using Rubin's rules [51]."

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

"Secondary analyses followed a modified intent-to-treat approach (mITT). We excluded participants allocated to the intervention group who did not engage with the intervention (did not watch at least one video on the MomZing website during the 3-month period post-randomization)."

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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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

"This study was approved by the KPNC Institutional Review Board and registered with ClinicalTrials.gov on June 1, 2020 (ID: NCT04414696)."

x26-ii) Outline informed consent procedure	x26-ii	ii) Outline	informed	consent	procedure
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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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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

"Eligible participants completed informed consent documents and baseline surveys online through REDCap."

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

"Participants reported injuries or illnesses related to exercise at 3- and 6- months post-randomization." Additional details about privacy and security are in the published protocol paper.

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

Does your paper address CONSORT subitem 13a? *

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

"Of the 99 randomized participants, 27 (54%) and 26 (53%) in the intervention and control groups, respectively, completed all 3-month follow-up activities (online surveys and accelerometer; Figure 1)."

Figure 1

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

"Of the 99 randomized participants, 27 (54%) and 26 (53%) in the intervention and control groups, respectively, completed all 3-month follow-up activities (online surveys and accelerometer; Figure 1)."

Figure 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.

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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

"Fifty-two percent (n=26) of participants allocated to the intervention group logged in to the MomZing website and watched at least one video. The median minutes of videos watched per week peaked at 10 minutes two weeks after randomization, then fell to zero for the rest of the follow-up period (Figure 2)."

Figure 2

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

"From November 2020 through September 2022, 12,269 postpartum individuals who met the following inclusion criteria in the EHR were invited to participate in the study."

"Follow-up data collection ended in April 2023."

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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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

". Study recruitment occurred from November 2020 to September 2022, during the COVID-19 pandemic when many stressors and barriers to PA were heightened [58], which may have reduced motivation for and interest in PA. This was also when many other online PA offerings were becoming available, which may have been more attractive to participants, resulting in low engagement with the MomZing intervention and highlighting potential needs for improvement in production value and content of the website. Finally, retention for follow-up assessments was a challenge, likewise potentially due in part to the challenges of the COVID-19 pandemic"

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

F

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

The trial was not ended early.

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

"At baseline, participants were 4 months postpartum, on average, and had moderately severe depressive symptoms (mean PHQ-8=12.6; Table 1). Most participants were members of a minoritized racial or ethnic group (63%), not currently working (74%), married or living with their partner (86%), did not meet PA recommendations prior to pregnancy (61%), had a college education or more (80%), and had two or more children at home (59%). Baseline characteristics were similar between the intervention and control groups."

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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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

At baseline, participants were 4 months postpartum, on average, and had moderately severe depressive symptoms (mean PHQ-8=12.6; Table 1). Most participants were members of a minoritized racial or ethnic group (63%), not currently working (74%), married or living with their partner (86%), did not meet PA recommendations prior to pregnancy (61%), had a college education or more (80%), and had two or more children at home (59%). Baseline characteristics were similar between the intervention and control groups."

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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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

"Secondary analyses followed a modified intent-to-treat approach (mITT). We excluded participants allocated to the intervention group who did not engage with the intervention (did not watch at least one video on the MomZing website during the 3-month period post-randomization)."

Table 2,3,4

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).

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Does your paper address subitem 16-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

"Primary analyses followed an intent-to-treat approach. We used multivariable linear regression models, adjusted for variables used in the randomization procedure (number of children at home, race and ethnicity, baseline PHQ-8 score, pre-pregnancy PA level) and corresponding baseline value of the outcome, to estimate mean differences in each outcome associated with the MomZing intervention.

Secondary analyses followed a modified intent-to-treat approach (mITT). We excluded participants allocated to the intervention group who did not engage with the intervention (did not watch at least one video on the MomZing website during the 3-month period post-randomization)."

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

"Primary outcomes: There was no association between the MomZing intervention and change in depressive symptoms (mean difference=-0.7; 95%CI: -4.0, 2.5) or dm-MVPA per day (mean difference=-4.3 minutes; 95%CI: -31.0, 22.0) at 3 months post-randomization (Table 2).

Secondary outcomes: As shown in Table 3, there were no differences between groups in sr-MVPA or sr-MVPA-MomZing per week at 3 months post-randomization and no differences between groups in change in depressive symptoms, dm-MVPA per day, sr-MVPA or sr-MVPA-MomZing per week at 6 months post-randomization.

Additional outcomes: As shown in Table 4, the MomZing intervention was not associated with change in sleep quality, anxiety symptoms, or perceived stress at 3 or 6 months post-randomization, mother-infant bonding score at 3 months post-randomization, or infant development in any area."

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).

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subitem not at all important O O O essential

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

"Among those who reported using the MomZing website (44%, n=22), mean satisfaction score was 40, indicating moderately high overall satisfaction with the intervention (Table 5). Ninety percent rated MomZing as good or very good/excellent. Over 60% of participants who reported using the MomZing website found it very or moderately helpful for being more physically active. Qualitative feedback also indicated that participants wanted more frequent reminders to use the MomZing website, more intense workouts, and an app that is accessible on multiple devices. The most common reason for not using the MomZing website was lack of time (77%)."

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

Outcomes are continuous.



Your answer must have a minimum of 25 characters.

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

"Findings from modified intent-to-treat analyses were similar to those from intent-to-treat analyses for primary, secondary, and additional outcomes (Tables 2, 3, 4)."

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).

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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

"Findings from modified intent-to-treat analyses were similar to those from intent-to-treat analyses for primary, secondary, and additional outcomes (Tables 2, 3, 4)."

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

"There were no adverse events reported during the study."

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].

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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

There were no privacy breaches.

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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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

"Ninety percent rated MomZing as good or very good/excellent. Over 60% of participants who reported using the MomZing website found it very or moderately helpful for being more physically active. Qualitative feedback also indicated that participants wanted more frequent reminders to use the MomZing website, more intense workouts, and an app that is accessible on multiple devices. The most common reason for not using the MomZing website was lack of time (77%)."

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

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

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subitem not at all important

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Does your paper address subitem 22-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

"In this two-arm, parallel group randomized controlled trial, there were no statistically significant differences in change in depressive symptoms or dm-MVPA over a three-month period associated with the MomZing eHealth PA intervention in postpartum individuals at high risk of PPD. There were also no differences in change in sr-MVPA, sleep quality, anxiety symptoms, perceived stress, mother-infant bonding or infant development at 12 months of age associated with the intervention."

22-ii) Highlight unanswered new questions, suggest future research Highlight unanswered new questions, suggest future research.

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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

"These findings along with our study results highlight the need for additional research to develop effective PA interventions for postpartum individuals at high risk of PPD and for the postpartum population in general."

"Additional research to develop effective and engaging PA interventions for this population is needed to help alleviate PPD symptoms and decrease PPD risk."

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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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 did not meet our recruitment goal, and as a result our study is underpowered for effect sizes smaller than "medium," resulting in imprecise estimates of associations (wide confidence intervals). As discussed previously, engagement with the intervention was low, which can lead to underestimation of intervention effects in intent-to-treat analyses [57] and further reduces sample size and power in modified intent-to-treat analyses. Study recruitment occurred from November 2020 to September 2022, during the COVID-19 pandemic when many stressors and barriers to PA were heightened [58], which may have reduced motivation for and interest in PA. This was also when many other online PA offerings were becoming available, which may have been more attractive to participants, resulting in low engagement with the MomZing intervention and highlighting potential needs for improvement in production value and content of the website. Finally, retention for follow-up assessments was a challenge, likewise potentially due in part to the challenges of the COVID-19 pandemic; however, multiple imputation mitigated this limitation."

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

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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

Results are most relevant to this specific population of individuals identified as high risk of PPD and it is not our goal to generalize to a general population.

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 cointerventions) 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.

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Does your paper address subitem 21-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 intervention would likely be very similar in a routine application setting in the healthcare delivery system.

OTHER INFORMATION

23) Registration number and name of trial registry

R

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

"ClinicalTrials.gov on June 1, 2020 (ID: NCT04414696)"

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

"Below we summarize key aspects of the POW study protocol, which has been previously published [28]."

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 research reported in this publication was supported by the Kaiser Permanente Exercise as Medicine Research Program. The funding organization had no role in the design and conduct of the trial; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication."

X27) Conflicts of Interest (not a C	CONSORT item)
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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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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

"The authors report no conflict of interest."

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
- O no

What were the most important changes you made as a result of using this checklist?
Additional minor details about the remote nature of the trial.
How much time did you spend on going through the checklist INCLUDING making * changes in your manuscript
About half a day
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:
Clear selection

Any other comments or questions on CONSORT EHEALTH

Your answer

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