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 (nonpharmacologic 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: <u>http://www.jmir.org/2011/4/e126/</u> doi: 10.2196/jmir.1923 PMID: 22209829

* Required

Your name *

First Last

Anish Agarwal

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University of Pennsylvania, Philadelphia, USA

Your e-mail address * abc@gmail.com

anish.agarwal@pennmedicine.upenn.edu

Title of your manuscript *

Provide the (draft) title of your manuscript.

Testing Digital Methods of Patient-Reported Outcomes Data Collection: A prospective, cluster randomized trial to test text messaging and mobile surveys.

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.

Mobiel Surveys

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)

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)"

Opioid Use

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Response Rate, Opioid Use, and Pain Score

Secondary/other outcomes

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



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

$oldsymbol{O}$	unknown / not evaluated
0	0-10%
0	11-20%
0	21-30%
0	31-40%
0	41-50%
0	51-60%
0	61-70%
0	71%-80%
0	81-90%
0	91-100%
0	Other:

Overall, was the app/intervention effective? *
O 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
O potentially harmful: control was significantly better than intervention in one or more outcomes
O inconclusive: more research is needed
O 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
O 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
Uther:

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 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? *



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: 31894

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	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

Testing Digital Methods of Patient-Reported Outcomes Data Collection: A prospective, cluster randomized trial to test text messaging and mobile surveys

1a-ii) Non-web-based components or important co-interventions in title Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").								
	1	2	3	4	5			
subitem not at all important	0	0	0	0	0	essential		

Does your paper address subitem 1a-ii?

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

Testing Digital Methods of Patient-Reported Outcomes Data Collection: A prospective, cluster randomized trial to test text messaging and mobile surveys

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 1a-iii? *

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

Testing Digital Methods of Patient-Reported Outcomes Data Collection: A prospective, cluster randomized trial to test text messaging and mobile surveys

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)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

OBJECTIVES: To prospectively investigate two common methods of remote patient-reported outcomes data collection. The study sought to analyze response and engagement rates through two modalities including bi-directional text messaging or mobile surveys.

METHODS: Prospective, block randomized trial of adult patients undergoing elective sports medicine and orthopedic procedures over 6 weeks. The primary objective was to determine if the method of digital patient engagement would impact response and completion rates. The primary outcome was response rate and total competition of patient reported outcomes questionnaires.

RESULTS: 127 participants were block randomized into either receiving a mobile survey (n=63) delivered as a hyperlink or were asked the same questions through an automated conversational text messaging (n=64). Gender, age, number of comorbidities, number of opioid tablets prescribed were similar across messaging arms. Overall engagement over the immediate post-operative was similar between the messaging arms. Prolonged engagement past post-operative day 4 was higher in the mobile survey arm at day 7 (95% vs. 56%). Patients with more invasive procedures showed a trend toward being responsive at day 4 as compared to non-responders.

CONCLUSIONS: As digital platforms become more commonly used in health care, testing the various options to engage patients to gather data is crucial to inform future care and research. We found that globally bi-directional text messaging and mobile surveys were comparable in response and engagement rates, however mobile surveys may trend toward higher response rates over longer periods of time.

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)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 1b-ii?

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

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CONCLUSIONS: As digital platforms become more commonly used in health care, testing the various options to engage patients to gather data is crucial to inform future care and research. We found that globally bi-directional text messaging and mobile surveys were comparable in response and engagement rates, however mobile surveys may trend toward higher response rates over longer periods of time.

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)



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

Your answer

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)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

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)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

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)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

The purpose of this study was to prospectively investigate a component of digital health patient engagement and PRO data collection. A common clinical scenario, post-operative follow-up, has been a unique area of study for digital health. In response to the opioid epidemic, clinicians seek PRO data on acute pain management to inform quality improvement (QI) efforts and prescribing. Less is known about which types of digital engagement are best suited to engage post-operative patients for continuous QI. The objective of this study was to prospectively investigate and compare two widely used methods of digital interaction and PRO data capture following elective, outpatient surgeries. We compared response and overall completion rates of a post-operative patient engagement delivered through conversational text messaging versus mobile surveys. To our knowledge, this is the first study to compare patient engagement commonly used modalities using two distinct approaches.

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 appropiate), 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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Health care delivery continues to evolve with an effort to create patient-centered care models. Learning health systems are those which engage patients and elicit patient-reported outcomes (PROs) data to continuously improve and drive clinical practice.1 Incorporating PROs into clinical decision making and health management has led to improvements in patients' quality of life, improved patient-provider communication, and reductions in unscheduled acute care such as emergency department visits.2,3 Nonetheless, in real-world contexts, collecting PROs has remained challenging and integration into clinical decisions remains sparse.4,5

A large motivator for change in how health care is delivered, monitored, and researched has been the boom of simple digital technologies. The ubiquity of mobile health devices (cell phones, smart phones, tablets) continues to permeate society and health.6 Indeed, the coronavirus pandemic (COVID-19) has dramatically scaled the use of digital technologies in health care.7 Engaging patients and capturing PROs remotely, in between outpatient visits would provide a robust and deep understanding to support care remotely.5 As digital strategies continue to expand, research has yet to describe the optimal ways to reach patients and capture PROs. Indeed, less is known about the various methods of engaging, collecting and monitoring patient reported data in remote fashions. Testing varying approaches would provide clinicians and researchers critical data and inform the use of effective strategies.

Research in areas of mobile health (mhealth) has grown dramatically in the past decade.8 Health care providers have attempted to use mhealth to track medication adherence9,10, encourage healthy ehaviors11, boost home monitoring12, and institute automated 'hovering' to track chronic disease.13 The rapid growth is likely largely due scalability, accessibility, and lack of large federal regulations. The evidence generated by these studies has not been well defined or characterized.14,15 In today's digital era, what is the best way to interact with patients remotely? How do researchers and providers build systems which efficiently capture meaningful patient-centered data?

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 purpose of this study was to prospectively investigate a component of digital health patient engagement and PRO data collection. A common clinical scenario, post-operative follow-up, has been a unique area of study for digital health. In response to the opioid epidemic, clinicians seek PRO data on acute pain management to inform quality improvement (QI) efforts and prescribing. Less is known about which types of digital engagement are best suited to engage post-operative patients for continuous QI. The objective of this study was to prospectively investigate and compare two widely used methods of digital interaction and PRO data capture following elective, outpatient surgeries. We compared response and overall completion rates of a post-operative patient engagement delivered through conversational text messaging versus mobile surveys. To our knowledge, this is the first study to compare patient engagement commonly used modalities using two distinct approaches.

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

This was a prospective, block randomized trial of adult patients (age 18 or older) undergoing elective sports medicine and orthopedic procedures (clinicaltrails.gov NCT03532256). This study was approved as a quality improvement study by the University of Pennsylvania's Institutional Review Board. The study took place over 6 weeks. The primary objective was to determine if the method of digital patient engagement would impact response and completion rates. The primary outcome was response rate and total competition of patient reported outcomes questionnaires.

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

Eligible patients included all adult patient undergoing an elective, outpatient sports medicine surgeries (including knee, hip, shoulder and elbow) and prescribed an acute opioid for post-operative pain. Acute opioid pain medications included oxycodone, acetaminophen-oxycodone (Percocet), hydromorphone, or hydrocodone. Exclusion criteria included no access to a SMS-capable device or no acute opioid prescription.

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].

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

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

Eligible patients included all adult patient undergoing an elective, outpatient sports medicine surgeries (including knee, hip, shoulder and elbow) and prescribed an acute opioid for post-operative pain. Acute opioid pain medications included oxycodone, acetaminophen-oxycodone (Percocet), hydromorphone, or hydrocodone. Exclusion criteria included no access to a SMS-capable device or no acute opioid prescription.

4a-i) Computer / Internet literacy

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

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 webbased 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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential



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

Prior to this study, the research team had previously worked with the Institution's legal, privacy and patient safety departments in order to obtain remote, text message-based consent for data collection. This was an intentional design of a larger institutional program aimed to understand acute opioid prescribing. The approach allows for remote consent in an attempt to offload clinical providers and improve the scale of engaging eligible patients. Following an elective, outpatient surgery within the Department of Orthopaedics, patients receive a brief initial text message within a two-day period following the procedure. This message informs the patient of 1) safe text messaging data practices; 2) links to further information regarding follow up research study; 3) offers the ability to opt-in or opt-out of further messaging. Patients consent via a simple text response of "yes." Enrolled patients were then sent text messages on post-operative days number 4, 7, 10, and 14. Patients were block randomized to receiving either 1) a hyperlink to a web based mobile survey or 2) automated, chatbot questions in a conversational text messaging fashion. Mobile survey questions and conversational questions were identical and included questions on patientreported pain intensity, use of prescribed pain medications, and ability to control pain. Block randomization was used to achieve balance in the two groups across demographics, procedure date, and dates of mobile engagement.

Importantly, in accordance with institutional approval, individuals who either 1) did not respond, 2) opted-out, or 3) self-reported no further planned use of acute opioid medications were not subsequently messaged. For example, if a participant completed either the mobile survey or conversational messaging on post-operative day 4 and indicated they were no longer planning on using their opioid prescription, no further messaging was sent on day 7, 14, 21 or 28. Participants who did not respond to any messaging, would receive a reminder message within 30 minutes, if that also did not trigger a response then no further messaging was sent.

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

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

This was a prospective, block randomized trial of adult patients (age 18 or older) undergoing elective sports medicine and orthopedic procedures (clinicaltrails.gov NCT03532256). This study was approved as a quality improvement study by the University of Pennsylvania's Institutional Review Board. The study took place over 6 weeks. The primary objective was to determine if the method of digital patient engagement would impact response and completion rates. The primary outcome was response rate and total competition of patient reported outcomes questionnaires.



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

Enrolled patients were then sent text messages on post-operative days number 4, 7, 10, and 14. Patients were block randomized to receiving either 1) a hyperlink to a web based mobile survey or 2) automated, chatbot questions in a conversational text messaging fashion. Mobile survey questions and conversational questions were identical and included questions on patient-reported pain intensity, use of prescribed pain medications, and ability to control pain. Block randomization was used to achieve balance in the two groups across demographics, procedure date, and dates of mobile engagement.

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)



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

Your answer

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and

owners

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 5-i?

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

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

Your answer

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

5-iv) Quality assurance methods

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 5-iv?

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

Your answer

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 5-v?

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

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, <u>webcitation.org</u>, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 5-vi?

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

Your answer

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).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 5-vii? *

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

Enrolled patients were then sent text messages on post-operative days number 4, 7, 10, and 14. Patients were block randomized to receiving either 1) a hyperlink to a web based mobile survey or 2) automated, chatbot questions in a conversational text messaging fashion. Mobile survey questions and conversational questions were identical and included questions on patient-reported pain intensity, use of prescribed pain medications, and ability to control pain. Block randomization was used to achieve balance in the two groups across demographics, procedure date, and dates of mobile engagement.

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].

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	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

Enrolled patients were then sent text messages on post-operative days number 4, 7, 10, and 14. Patients were block randomized to receiving either 1) a hyperlink to a web based mobile survey or 2) automated, chatbot questions in a conversational text messaging fashion. Mobile survey questions and conversational questions were identical and included questions on patient-reported pain intensity, use of prescribed pain medications, and ability to control pain. Block randomization was used to achieve balance in the two groups across demographics, procedure date, and dates of mobile engagement.

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 5-ix?

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

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

Your answer

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).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Enrolled patients were then sent text messages on post-operative days number 4, 7, 10, and 14. Patients were block randomized to receiving either 1) a hyperlink to a web based mobile survey or 2) automated, chatbot questions in a conversational text messaging fashion. Mobile survey questions and conversational questions were identical and included questions on patient-reported pain intensity, use of prescribed pain medications, and ability to control pain. Block randomization was used to achieve balance in the two groups across demographics, procedure date, and dates of mobile engagement.

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

Importantly, in accordance with institutional approval, individuals who either 1) did not respond, 2) opted-out, or 3) self-reported no further planned use of acute opioid medications were not subsequently messaged. For example, if a participant completed either the mobile survey or conversational messaging on post-operative day 4 and indicated they were no longer planning on using their opioid prescription, no further messaging was sent on day 7, 14, 21 or 28. Participants who did not respond to any messaging, would receive a reminder message within 30 minutes, if that also did not trigger a response then no further messaging was sent.

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

Descriptive summary statistics were used to characterize the study population, using mean ± standard deviation for age, and frequencies and percentages for categorical variables including gender, type of surgery, opioid tablet quantity, comorbidities and invasiveness of the procedure. To determine differences in response rate at Day 4, between messaging arms and categorical demographic variables, Fisher's exact test was used. To determine difference in response at day 4 by age, Student's t-test was used. To determine if there were differences in opioid use over time, Kaplan Meier product limit method with a log-rank test was used. All analyses were performed using SAS statistical software (version 9.4, SAS Institute, Cary NC).

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].

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

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.							
	1	2	3	4	5		
subitem not at all important	0	0	0	0	0	essential	

Does your paper address subitem 6a-ii? Copy and paste relevant sections from manuscript text	
Your answer	
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).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Your answer

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

There were no changes needed throughout.

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	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

Your answer

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

Not applicable to this study.

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

This was a prospective, block randomized trial of adult patients (age 18 or older) undergoing elective sports medicine and orthopedic procedures (clinicaltrails.gov NCT03532256). This study was approved as a quality improvement study by the University of Pennsylvania's Institutional Review Board. The study took place over 6 weeks. The primary objective was to determine if the method of digital patient engagement would impact response and completion rates. The primary outcome was response rate and total competition of patient reported outcomes questionnaires.

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

This was a prospective, block randomized trial of adult patients (age 18 or older) undergoing elective sports medicine and orthopedic procedures (clinicaltrails.gov NCT03532256). This study was approved as a quality improvement study by the University of Pennsylvania's Institutional Review Board. The study took place over 6 weeks. The primary objective was to determine if the method of digital patient engagement would impact response and completion rates. The primary outcome was response rate and total competition of patient reported outcomes questionnaires.

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

Not needed for this study.

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

This was a prospective, block randomized trial of adult patients (age 18 or older) undergoing elective sports medicine and orthopedic procedures (clinicaltrails.gov NCT03532256). This study was approved as a quality improvement study by the University of Pennsylvania's Institutional Review Board. The study took place over 6 weeks. The primary objective was to determine if the method of digital patient engagement would impact response and completion rates. The primary outcome was response rate and total competition of patient reported outcomes questionnaires.

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).



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

This was not blinded.

Your answer must have a minimum of 25 characters.

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".

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	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

Your answer

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

Patients were block randomized to receiving either 1) a hyperlink to a web based mobile survey or 2) automated, chatbot questions in a conversational text messaging fashion. Mobile survey questions and conversational questions were identical and included questions on patient-reported pain intensity, use of prescribed pain medications, and ability to control pain. Block randomization was used to achieve balance in the two groups across demographics, procedure date, and dates of mobile engagement.

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

Descriptive summary statistics were used to characterize the study population, using mean ± standard deviation for age, and frequencies and percentages for categorical variables including gender, type of surgery, opioid tablet quantity, comorbidities and invasiveness of the procedure. To determine differences in response rate at Day 4, between messaging arms and categorical demographic variables, Fisher's exact test was used. To determine difference in response at day 4 by age, Student's t-test was used. To determine if there were differences in opioid use over time, Kaplan Meier product limit method with a log-rank test was used. All analyses were performed using SAS statistical software (version 9.4, SAS Institute, Cary NC).

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]).



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

No imputation was needed in this study.

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

Descriptive summary statistics were used to characterize the study population, using mean ± standard deviation for age, and frequencies and percentages for categorical variables including gender, type of surgery, opioid tablet quantity, comorbidities and invasiveness of the procedure. To determine differences in response rate at Day 4, between messaging arms and categorical demographic variables, Fisher's exact test was used. To determine difference in response at day 4 by age, Student's t-test was used. To determine if there were differences in opioid use over time, Kaplan Meier product limit method with a log-rank test was used. All analyses were performed using SAS statistical software (version 9.4, SAS Institute, Cary NC).

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

X26-i) Comment on ethics committee approval								
	1	2	3	4	5			
subitem not at all important	0	0	0	0	0	essential		

Does your paper address subitem X26-i?

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

x26-ii) Outline informed consent procedures

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



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

Your answer

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)

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

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

Over 6 weeks, 127 participants were block randomized into either receiving a mobile survey (n=63) delivered as a hyperlink or were asked the same series of questions through an automated system, chatbot using conversational text messaging (n=64). 57% were male, mean age 38.5 ± 13.9 years, and 73% (n=90) were having a knee procedure. Gender, age, number of comorbidities, number of opioid tablets prescribed were similar across messaging arms (Table 1). Patients receiving the mobile survey were more likely to be having a knee procedure (83% vs 63%, p=.015) but less likely to have an invasive procedure (41% vs 61%, p=.032).

Overall engagement over the immediate post-operative was similar between the messaging arms (Table 2). Using conversational, automated text messaging the response rate was 47% vs. 49% using a hyperlink to a mobile survey. For those patients resuming opioids past 4 days, prolonged engagement past post-operative day 4 was higher in the mobile survey arm at day 7 (95% vs. 56%). Amongst no-responders, the majority of patient drop off occurred at day 4 (76% vs 94% for conversational vs mobile survey respectively). Patients with more invasive or hip procedures showed a trend toward being responsive at day 4 as compared to non-responders (Table 3).

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

Over 6 weeks, 127 participants were block randomized into either receiving a mobile survey (n=63) delivered as a hyperlink or were asked the same series of questions through an automated system, chatbot using conversational text messaging (n=64). 57% were male, mean age 38.5 ± 13.9 years, and 73% (n=90) were having a knee procedure. Gender, age, number of comorbidities, number of opioid tablets prescribed were similar across messaging arms (Table 1). Patients receiving the mobile survey were more likely to be having a knee procedure (83% vs 63%, p=.015) but less likely to have an invasive procedure (41% vs 61%, p=.032).

Overall engagement over the immediate post-operative was similar between the messaging arms (Table 2). Using conversational, automated text messaging the response rate was 47% vs. 49% using a hyperlink to a mobile survey. For those patients resuming opioids past 4 days, prolonged engagement past post-operative day 4 was higher in the mobile survey arm at day 7 (95% vs. 56%). Amongst no-responders, the majority of patient drop off occurred at day 4 (76% vs 94% for conversational vs mobile survey respectively). Patients with more invasive or hip procedures showed a trend toward being responsive at day 4 as compared to non-responders (Table 3).

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

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

This was a prospective, block randomized trial of adult patients (age 18 or older) undergoing elective sports medicine and orthopedic procedures (clinicaltrails.gov NCT03532256). This study was approved as a quality improvement study by the University of Pennsylvania's Institutional Review Board. The study took place over 6 weeks. The primary objective was to determine if the method of digital patient engagement would impact response and completion rates. The primary outcome was response rate and total competition of patient reported outcomes questionnaires.

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"							
	1	2	3	4	5		
subitem not at all important	0	0	0	0	0	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

Your answer

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

This was not stopped 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

Yes this is included in table 1.

15-i) Report demographics associated with digital divide issues

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



Does your paper address subitem 15-i?*

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

Not applicable in this study.

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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, this is included throughout the paper.

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).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

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

Analytic section included in results and reported in tables.

essential

17a-i) Presentation of process use	outcom	ies such	as met	rics of u	se and intensity of
In addition to primary/secondary (clinic metrics of use and intensity of use (dos not only refer to metrics of attrition (13 metrics such as "average session lengt metric like a "session" is defined (e.g., t	cal) outcon se, exposu -b) (often h". These i imeout aft	nes, the pr re) and the a binary va must be ae ter idle tim	resentation eir operati ariable), bu ccompanio ne) [1] (rep	n of proces onal defini ut also to r ed by a tec ort under i	ss outcomes such as tions is critical. This does nore continuous exposure hnical description how a item 6a).
	1	2	3	4	5

Does your paper address subitem 17a-i?

subitem not at all important

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

 \bigcirc

Your answer

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

This is included in analysis, results, and tables.

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

Included in the results section.

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).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 18-i?

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

Your answer

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

No harms or unintended effects.

19-i) Include privacy breaches, technical problems

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



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

Your answer

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.

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

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).

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

This study has two key findings within the context of mobile patient engagement and data capture. First, immediate post-operative digital patient engagement and research consent are feasible. We deployed a prospective, direct-to-patient approach in obtaining mobile consent for longitudinal capture of patient-reported outcomes for post-operative pain and pain management. A key element is that no identifiable patient health information (PHI) was sent over text messaging or through surveys. Prior studies, aiming to understand patients' pain and use of pain medications following surgeries have been limited by retrospective design, telephone or paper surveys, and recall bias. We worked collaboratively within the health system to develop an approach which offloads busy clinical providers from obtaining additional written consent during pre-operative visits and reaches out to patients 4 days following their procedure. Patients in this study were verbally notified of post-operative mobile engagement, and then received the first message on post-operative day 4 prompting them for consent. This mobile consent process may be further studied to decrease inperson time, allow for researchers to link important research and other patient information, and offer patients the ability to opt-out at any through a simple text message.



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

Your answer

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.



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

This study has limitations. It represents an approach and data collected from a single division of Sports Medicine at a single academic medical center and thus is not generalizable. Furthermore, the completion rates represent selection bias in patients who have a mobile device and opt-in to completing either mobile survey or the bi-directional text messaging. Those patients receiving a mobile link to a survey must have had a smartphone and thus may represent a select population. Patients also were undergoing elective, outpatient procedures and may represent a population that is healthier, younger, and were 'primed' during their pre-operative appointment that they will receive this message.

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

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

	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

Does your paper address subitem 21-i?

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

21-ii) Discuss if there were ele routine application setting	ements	in the R	CT that	would k	be differ	ent in a
Discuss if there were elements in the prompts/reminders, more human invo impact the omission of these element applied outside of a RCT setting.	RCT that olvement, ts could h	would be o training se ave on uso	different ir essions or e, adoptior	n a routine other co-i n, or outco	applicatio nterventior mes if the	n setting (e.g., ıs) and what intervention is
	1	2	3	4	5	
subitem not at all important	0	0	0	0	0	essential

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

Your answer

OTHER INFORMATION

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

This was a prospective, block randomized trial of adult patients (age 18 or older) undergoing elective sports medicine and orthopedic procedures (clinicaltrails.gov NCT03532256).

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

Appendix attached.

Your answer must have a minimum of 25 characters.

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

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

Yes, funding is included.

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluatedIn 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.12345subitem not at all importantOOOOessential

Does your	paper	address	subitem	X27-i?
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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

Your answer

About the CONSORT EHEALTH checklist

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

yes, major 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 *

60 minutes in total

(!) Your answer must have a minimum of 25 characters.

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