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

* Required

Your name *

First Last

Shawn Chiang

Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

George Washington University, Washingto

Your e-mail address *

abc@gmail.com

c6chiang@gmail.com

Title of your manuscript *

Provide the (draft) title of your manuscript.

A Motion-Activated Video Game for Prevention of Substance Use Disorder Relapse in Youth: Pilot Randomized Trial

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

Recovery Warrior

Evaluated Version (if any)

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

2.0

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.

http://recoverywarrior.com/

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)"

Substance Use Disorder Relapse

Primary	Outcomes	measured	in tria	*
---------	----------	----------	---------	---

comma-separated list of primary outcomes reported in the trial

Opioid and Marijuana use in the past 7 and

Secondary/other outcomes

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

Your answer

D		_11 1	ID II	4
RACO	mmen	nen .	'Dose"	~
11666		ucu		

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

•	Approximately Daily
0	Approximately Weekly
0	Approximately Monthly
0	Approximately Yearly

"as needed"

Other:

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

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

Overall, was the app/intervention effective? *
yes: all primary outcomes were significantly better in intervention group vs control
o partly: SOME primary outcomes were significantly better in intervention group vs control
on statistically significant difference between control and intervention
o potentially harmful: control was significantly better than intervention in one or more outcomes
inconclusive: more research is needed
Other:
Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form)
,
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) Onot 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) not submitted yet - in early draft status not submitted yet - in late draft status, just before submission submitted to a journal but not reviewed yet submitted to a journal and after receiving initial reviewer comments submitted to a journal and accepted, but not published yet

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? *
Pilot/feasibility
C 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)
on ms number (yet) / not (yet) submitted to / published in JMIR
Other: 11716

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")

	0+1
()	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	\bigcirc	\circ	\circ	\circ		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

A Motion-Activated Video Game for Prevention of Substance Use Disorder Relapse in Youth: Pilot Randomized Trial

1a-ii) Non-web-based components or important co-interventions in title

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

1 subitem not at essential all important

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

Your answer

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

5 1 subitem not at essential all important

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

A Motion-Activated Video Game for Prevention of Substance Use Disorder Relapse in Youth: Pilot Randomized Trial

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 subitem not at essential all important

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

Background: Body motion-activated video games are a promising strategy for promoting engagement in and adherence to addiction treatment among youth.

Objective: This pilot randomized trial (N=80) investigated the feasibility of a body motion-activated video game prototype,

Recovery Warrior 2.0, targeting relapse prevention in the context of a community inpatient care program for youth.

Methods: Participants aged 15-25 years were recruited from an inpatient drug treatment program and randomized to receive

treatment as usual (control) or game play with treatment as usual (intervention).

Assessments were conducted at baseline, prior

to discharge, and at 4 and 8 weeks postdischarge.

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	•	\circ	\circ	\circ	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

Your answer

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

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

	1	2	3	4	5	
subitem not at all important	\bigcirc	\circ	\circ	\circ		essential

Does your paper address subitem 1b-iii?

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

Methods: Participants aged 15-25 years were recruited from an inpatient drug treatment program and randomized to receive treatment as usual (control) or game play with treatment as usual (intervention). Assessments were conducted at baseline, prior to discharge, and at 4 and 8 weeks postdischarge.

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	•	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

Results: The provision of the game play intervention was found to be feasible in the inpatient setting. On an average, participants

in the intervention group played for 36.6 minutes and on 3.6 different days.

Participants in the intervention group mostly agreed

that they would use the refusal skills taught by the game. Participants in the intervention group reported attending more outpatient

counseling sessions than those in the control group (10.8 versus 4.8), but the difference was not significant (P=.32). The game

had no effect on drug use at 4 or 8 weeks postdischarge, with the exception of a benefit reported at the 4-week follow-up among

participants receiving treatment for marijuana addiction (P=.04).

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	\circ	\circ	\circ		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

Conclusions: Preliminary evidence indicates that a motion-activated video game for addiction recovery appears to be feasible and acceptable for youth within the context of inpatient treatment, but not outpatient treatment. With further development, such games hold promise as a tool for the treatment of youth substance use disorder.



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 standalone 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	\circ	\circ	\circ		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

Drug use is recognized as a serious public health problem among adolescents and young adults. In 2015, 37.5% of young adults aged 18-25 years and 17.5% of adolescents aged 12-17 years in the United States reported the use of illicit drugs in that year [1]. Adolescent and young adult substance use disorders (SUDs) are associated with numerous negative outcomes including overdose, HIV transmission, school failure, criminal behavior, and other social problems.

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	\circ	\circ	\circ		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

The standard of care for youth with SUDs includes detoxification as needed, followed by traditional psychosocial treatments [2-4]. Psychosocial treatments typically consist of individual and group counseling and may focus on developing skills related to abstinence, such as problem solving, coping, and refusal skills [5]. Although such programs are associated with positive outcomes for youth [5], dropout from treatment remains a major barrier to success [6]. There is a need to develop innovative strategies to improve retention among youth and increase the rates of abstinence.

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

This study is a pilot randomized trial

(N=80) of a revised body motion—activated game, Recovery Warrior 2.0, targeting relapse prevention in the context of a community treatment program for SUD among youth. Of interest was the feasibility of the game in the inpatient and outpatient settings, participant ratings of the game, the effect of the game on the mediators of relapse, treatment adherence and retention, and drug use outcomes.

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

Once consent was obtained, the participants were given a baseline survey and randomized to receive Recovery Warrior game play with treatment as usual or to receive treatment alone. In addition to the baseline survey, all participants were given an in-person survey prior to inpatient discharge (discharge survey) and another survey by phone at 4 weeks and 8 weeks after discharge from inpatient treatment. Participants were given a US \$20 gift card for each survey, plus a bonus gift card of US \$10 at 4 weeks and US \$20 at 8 weeks. This resulted in a maximum incentive of US \$110 for assessments. Phone calls, text messages, Facebook messages, and subject interception at MMTC outpatient treatment were used to remind participants of their upcoming follow-up surveys. For the 4- and 8-week surveys, up to 15 contact attempts were made per survey before considering the case as a missed follow-up.

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

Once consent was obtained, the participants were given a baseline survey and randomized to receive Recovery Warrior game play with treatment as usual or to receive treatment alone. In addition to the baseline survey, all participants were given an in-person survey prior to inpatient discharge (discharge survey) and another survey by phone at 4 weeks and 8 weeks after discharge from inpatient treatment. Participants were given a US \$20 gift card for each survey, plus a bonus gift card of US \$10 at 4 weeks and US \$20 at 8 weeks. This resulted in a maximum incentive of US \$110 for assessments. Phone calls, text messages, Facebook messages, and subject interception at MMTC outpatient treatment were used to remind participants of their upcoming follow-up surveys. For the 4- and 8-week surveys, up to 15 contact attempts were made per survey before considering the case as a missed follow-up.

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		\circ	\circ	\circ	\circ	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

Inclusion criteria were as follows: age of 15-25 years, attending the MMTC inpatient program for primarily opioid or marijuana use disorder treatment, ability to speak English, absence of a comorbid psychiatric condition that would make participation unsafe (eg, acute suicidality or unstable psychosis), and no pregnancy (because of the physical exertion required to play the game).

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	•	\circ	\circ	\circ	\circ	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

Your answer

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.

	1	2	3	4	5	
subitem not at all important	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

Once consent was obtained, the participants were given a baseline survey and randomized to receive Recovery Warrior game play with treatment as usual or to receive treatment alone. In addition to the baseline survey, all participants were given an in-person survey prior to inpatient discharge (discharge survey) and another survey by phone at 4 weeks and 8 weeks after discharge from inpatient treatment. Participants were given a US \$20 gift card for each survey, plus a bonus gift card of US \$10 at 4 weeks and US \$20 at 8 weeks. This resulted in a maximum incentive of US \$110 for assessments. Phone calls, text messages, Facebook messages, and subject interception at MMTC outpatient treatment were used to remind participants of their upcoming follow-up surveys. For the 4- and 8-week surveys, up to 15 contact attempts were made per survey before considering the case as a missed follow-up.

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	\bigcirc	\circ	\circ	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

Patients were approached by MMTC research staff about participating in the study within their first few days of inpatient admission, allowing some time for adjustment to the environment and resolution of the most acute phase of withdrawal distress. Interested individuals were assessed for eligibility and, if eligible, provided written consent. For patients under the age of 18 years, assent and parental consent were obtained.

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

In addition to the baseline survey, all participants were given an in-person survey prior to inpatient discharge (discharge survey) and another survey by phone at 4 weeks and 8 weeks after discharge from inpatient treatment.

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

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

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ		essential

Does your paper address subitem 4b-i? *

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

In addition to the baseline survey, all participants were given an in-person survey prior to inpatient discharge (discharge survey) and another survey by phone at 4 weeks and 8 weeks after discharge from inpatient treatment.

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)

	1	2	3	4	5	
subitem not at all important		\circ	\circ	\circ	\circ	essentia

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	\circ	\circ	\circ	\circ	\circ	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

Your answer

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.

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ	\circ	essential

Does your paper address subitem 5-ii?

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

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).

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

Does your paper address subitem 5-iii?

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

Your answer

5-iv) Quality assurance methods

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

1 subitem not at essential all important

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	\bigcirc	\circ	\circ	\circ	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

Your answer

5-vi) Digital preservation

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

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

In addition to their usual care, participants randomized to game play were given the opportunity to participate in a game play session 3 times/week for the length of their stay in the residential (inpatient) program. Typical inpatient stays at MMTC are for 9 days, and thus, it was expected that participants would have 4 game play sessions over the course of their inpatient stay. Participants in the intervention group who transitioned to outpatient care at MMTC were given an additional weekly opportunity to play the game for 4 weeks. The goal was for each game play session to last 1 hour and include 3-5 participants, with each participant playing for at least 10 minutes and no more than 15 minutes per session. Players would take turns, with each player playing one at a time and the others watching and encouraging him/her. Each 1-hour session included an introduction to the game by the counselor (2 min), game play, and an informal debriefing by the counselor about lessons learned in the game (8-10 mins). In the first session, the participants were directed to play each game, so that they would have an experience of each of the games. Subsequently, participants could choose to play any of the games. Sessions were offered in a dedicated room at the MMTC.

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 computermediated 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	\circ	\circ	\bigcirc	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

Recovery Warrior 2.0 [16] was developed for use with Microsoft Kinect running on a Windows personal computer. The 2.0 version was improved from an initial version that was previously pilot tested [17] and consisted of a suite of several games. All games made use of whole-body motion detection and the same voice-recognition feature. Body motions included a variety of arm, leg, and whole-body movements to physically enact the motions of destroying or evading images of drugs and drug paraphernalia. Voice features consisted of recognition of the refusal phrase "I'm Clean" Players could say or shout "I'm Clean" in order to gain additional strength for their game play avatar. All game art was created in a hyperrealistic, idealized, heroic style, which is the preferred style choice as per a focus group in an earlier work [17]. Across games, players were given a choice of several distinct hyperrealistic avatars. The counselor set up the game, so that the drug images would correspond to the drug being treated for (eg, opioid patients would see syringes, spoons, pill bottles, and pills as part of game play, while marijuana patients were exposed to marijuana cigarettes, baggies of marijuana, and bongs).

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	\circ	\circ	\circ	\circ	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

Your answer

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).

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

Does your paper address subitem 5-x?

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

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	\circ	\circ	0	0	\circ	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

In addition to their usual care, participants randomized to game play were given the opportunity to participate in a game play session 3 times/week for the length of their stay in the residential (inpatient) program. Typical inpatient stays at MMTC are for 9 days, and thus, it was expected that participants would have 4 game play sessions over the course of their inpatient stay. Participants in the intervention group who transitioned to outpatient care at MMTC were given an additional weekly opportunity to play the game for 4 weeks. The goal was for each game play session to last 1 hour and include 3-5 participants, with each participant playing for at least 10 minutes and no more than 15 minutes per session. Players would take turns, with each player playing one at a time and the others watching and encouraging him/her. Each 1-hour session included an introduction to the game by the counselor (2 min), game play, and an informal debriefing by the counselor about lessons learned in the game (8-10 mins). In the first session, the participants were directed to play each game, so that they would have an experience of each of the games. Subsequently, participants could choose to play any of the games. Sessions were offered in a dedicated room at the MMTC.

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 standalone 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.

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

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

Treatment as usual at the MMTC consisted of individual and group counseling as well as pharmacotherapy, where recommended. MMTC is a Joint Commission-accredited community treatment program for SUDs and co-occurring mental health conditions. Typically, patients stay in the inpatient program for 1-2 weeks and then transition to the outpatient program at the MMTC or another treatment center

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

The baseline survey included measures of the demographic characteristics of participants, video game use, and history of drug use of participants. Participants were asked about the primary drug that they were in treatment for. Opioid and marijuana use at follow-up was ascertained by self-report of any use in the past 7 and 30 days, using the Time Line Follow Back tool, as well as the date of last use.

For the intervention group at the 4-week follow-up, participants were asked about their perceptions of the most helpful game among the games played and the mode of game play that was seen as most helpful (eg, destroy drugs, avoid drugs, and collect goodies). Computer records of game play were also used to measure minutes of game play for each participant and days of game play. Measures of user engagement in Recovery Warrior were collected through a retrospective review of the computer records from game play. The system recorded each time a user played the game in minutes of game play. For each participant, the number of total minutes of game play was calculated across the intervention period.

Additionally, the 4-week follow-up survey assessed refusal skills taught by the game. Refusal skills were measured by asking participants if they agreed that they would use the phrase "I'm Clean" to refuse drugs (1=not agree to 5=highly agree), if they had used the phrase "I'm Clean" since discharge to refuse drugs, and if the phrase "I'm Clean" still rings in their head (not at all, less than once per week, a few times a week, or more often).

For both groups, psychosocial mediators of recovery, self-efficacy, and cravings were measured. Self-efficacy for refusal of drugs was measured using the Marijuana Resistance Self-Efficacy scale at baseline, discharge, and follow-up surveys [23,24]. It used a 4-item, 4-point scale (1=very easy to 4=very hard) that asked participants how easy or hard it would be to refuse the drug if offered and explain why they did not want it, why they wanted to avoid the situation in the first place, and why they wanted to leave the situation. It was adapted so that

there was a similar version for opioid use. Participants were only asked about the primary drug for which they enrolled in treatment (ie, marijuana or opioids).

For cravings, the 5-item Penn Alcohol Craving Scale [25] was included at baseline, discharge, and postdischarge follow-up surveys, but modified to apply to marijuana and opioid use. It assessed the intensity of a participant's cravings (0=none at all to 6=very strong; sum of a maximum total of 30 points).

Treatment rating was measured in three ways. First, it was measured with the Counselor Alliance Scale, which was taken from the Working Alliance Inventory [26-28], and used to measure treatment progress with the counselor at discharge, 4 weeks, and 8 weeks. The Counselor Alliance Scale uses 7-items and 7-points to measure how well participants believe counselors are working with them to improve their situation (1=never to 7=always). The treatment rating was also measured by asking participants about their satisfaction with inpatient care at the time of discharge and satisfaction with outpatient care at the 4-week and 8-week follow-up surveys.

Treatment use was measured by self-report of the use of outpatient services including meeting a doctor, meeting a counselor, attending group sessions, taking medications, and other services. The total number of services used was summed up for each participant. Participants were also asked at the 4-week and 8-week follow-ups about the number of outpatient counseling sessions attended in the past 30 days. Drug use outcomes were measured by asking participants at the 4-week and 8-week surveys if they had used the drug for which they received treatment (eg, opiates or marijuana), over the past 7 and 30 days

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 subitem not at essential all important

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Your answer

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 essential all important

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).

subitem not at essential all important

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

No changes was made to trial outcomes after trial commenced.

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 subitem not at essential all important

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

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

It's simple randomization using a random number generator

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

It's a two group (control vs intervention) simple randomization

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned



Does your paper address CONSORT subitem 9? *

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

random allocation sequence generator was used

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

Clinical Staff in Mountain Manor Treatment Center (MMTC) conducted the baseline survey, enrolled the participant, used the random allocation sequence generator to randomize participants into either control or intervention group.

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).

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

Participant were blinded, the clinical staff was not.

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	\circ	\circ	\circ	\circ	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

Not applicable

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

Means and SDs or percentages were calculated for key variables and compared between intervention and control groups. Chi-squared tests were used for categorical variables, and two-tailed t tests were used for continuous variables. Outcome analyses were conducted both with collected data alone and with missing values imputed as positive for drug use. In addition to the combined analyses, outcome analyses were conducted separately for marijuana and opioid patients.

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]).

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

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

Means and SDs or percentages were calculated for key variables and compared between intervention and control groups. Chi-squared tests were used for categorical variables, and two-tailed t tests were used for continuous variables. Outcome analyses were conducted both with collected data alone and with missing values imputed as positive for drug use. In addition to the combined analyses, outcome analyses were conducted separately for marijuana and opioid patients.

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

Although the differences were not significant in the combined marijuana and opioid analysis, the patients were analyzed separately. For analyses with drug use values imputed for the missing values, at 4 weeks after the intervention, 13 of the marijuana patients in the intervention group (72.22%) reported that they did not use drugs in the past 7 days compared with 6 people in the control group (37.50%; P=.04). Other results for marijuana patients (past 30 days at 4 weeks and past 7 and 30 days at 8 weeks) were not found to be significant (P=.81). No differences were observed for opioid patients

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	\bigcirc	\circ	\circ	\circ	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

The study was approved by the MaGil Institutional Review Board. Participants were recruited from the short-term inpatient program at the Mountain Manor Treatment Center (MMTC) in Baltimore, MD, between February 5, 2016, and June 21, 2016.

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.

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ	\circ	essential

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	\circ	\circ	\circ	\circ	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



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

Eighty participants were recruited, of which 36 were randomized to the intervention group and 44 were randomized to the control group. Of the 80 participants, 64 completed the discharge interview (80.0%), 48 completed the 4-week follow-up interview (60.0%), and 46 completed the 8-week follow-up interview (57.5%). There were no significant differences between groups in terms of survey completion

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

In multimedia appendix.

Eighty participants were recruited, of which 36 were randomized to the intervention group and 44 were randomized to the control group. Of the 80 participants, 64 completed the discharge interview (80.0%), 48 completed the 4-week follow-up interview (60.0%), and 46 completed the 8-week follow-up interview (57.5%). There were no significant differences between groups in terms of survey completion

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	\circ	\circ	\circ	\circ	\circ	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

In Multimedia appendix.

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

Participants were recruited from the short-term inpatient program at the Mountain Manor Treatment Center (MMTC) in Baltimore, MD, between February 5, 2016, and June 21, 2016.

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	\bigcirc	\circ	0	0	\circ	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

Not applicable

15) A table showing baseline demographic and clinical characteristics for each group



NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

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

Table 1

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.

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ	\circ	essential

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

Overall, there were no significant differences in the demographic items between the intervention and control groups, with the exception of gender: The intervention group was more likely to have male patients than female patients (P=.03) Participants who completed the 4-week survey were similar to noncompleters in all demographic variables. As expected, there were some differences in the demographic characteristics of marijuana and opioid users; the opioid users were more likely to be older (P<.001) and not in school (P<.001).

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 subitem not at essential all important

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

Loss to follow up is reported.

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 subitem not at essential all important

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

Table 4

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).

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ	\circ	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

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

Table 4

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

Although the differences were not significant in the combined marijuana and opioid analysis, the patients were analyzed separately. For analyses with drug use values imputed for the missing values, at 4 weeks after the intervention, 13 of the marijuana patients in the intervention group (72.22%) reported that they did not use drugs in the past 7 days compared with 6 people in the control group (37.50%; P=.04). Other results for marijuana patients (past 30 days at 4 weeks and past 7 and 30 days at 8 weeks) were not found to be significant (P=.81). No differences were observed for opioid patients.

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	\circ	\circ	\circ	\circ	\circ	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 unintended harms reported

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].

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ	\circ	essential

Does your paper address subitem 19-i?

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

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	\circ	\circ	\circ	\circ	\circ	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

Your answer



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	\circ	\circ	\circ	\circ	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 represents the first randomized trial of a body motion-activated game targeting drug-relapse prevention for patients who were enrolled in an inpatient treatment programand the first trial of a motion-activated video game aimed at the treatment of addiction in youth in any setting. The program was found to be feasible, primarily in the inpatient setting. Participants in the intervention group played for 3.6 days on an average, which was close to the 4 days of game play target set by the study protocol for inpatient care. Those randomized to the game play group mostly agreed that they would use the refusal skills taught by the game, and a near majority reported that they used those skills 4 weeks after discharge. There was a trend for those in the intervention group to report attending more outpatient counseling sessions than the control group, but the differences were not significant. There was a trend for an effect of the game on past 7- and 30-day drug use at 4 weeks postdischarge, with a significant benefit for a subgroup of participants who were in treatment for marijuana use disorder. No evidence was found that the game worked by differentially improving self-efficacy for drug refusal or reducing cravings. Overall, the dose of game play was small, limiting the potential for demonstration of effect. Contrary to the intended protocol, most intervention participants never received any game play after discharge from inpatient treatment. Thus, as designed, this study could not address the question of the effects of continued exposure to game play in the outpatient setting. Difficulties encountered for outpatient treatment were largely due to characteristics of the trial. Only about half of the intervention participants came to the MMTC for outpatient care. For the few who did come, game play could only be offered in the outpatient setting on an individual basis, as there were too few trial participants at any given time to form a group. Participants expressed that they did not want to leave their outpatient group counseling sessions for individual game play and therefore declined to play in this setting. Future tests of the game may benefit from careful consideration of group dynamics, and where

possible, deliver the game in a group, social format rather than in an individual game format. Furthermore, if patients are unlikely to get access to the game in their outpatient treatment setting, additional opportunities should be developed for game play in other settings, perhaps using home-based play on a computer or smartphone. This may have the potential to make the effects of the game last longer and should be investigated further.

We found some effect of the game for marijuana participants but not opioid participants; this may indicate that the game is more promising for the former subgroup. It is possible that these patients are younger, with lower addiction severity and chronicity, and more likely to respond to a behavioral intervention. A game may also be more consistent with younger patients' preferences for less "serious" and more experiential treatments. It may be that higher doses of game play are needed for more entrenched physiological addiction such as that for opiates.

Although originally hypothesized as mediators of the effect of the game, the game play did not appear to increase the levels of self-efficacy for drug refusal, as self-efficacy remained constant. It is possible that the game does not operate as hypothesized through drug refusal self-efficacy. It also appears that the game does not differentially decrease cravings. Other mechanisms such as repetition priming can be explored as mechanisms in future studies of the game.

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

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ	\circ	essential

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.

	1	2	3	4	5	
subitem not at all important	\circ	\circ	\circ	\circ	\circ	essential

Does your paper address subitem 20-i? *

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

The study experienced significant loss to follow-up, as about 40% of participants were not available for the 4-week and the 8-week follow-up interviews. Although this is a high level of attrition, this level is not unusual for youth attending drug-treatment facilities, as participants following discharge are at high risk for dropout, relapse, incarceration, or readmission to inpatient treatment. Additionally, marijuana and opioid patients were found to have different demographic characteristics and possibly different responses to the game. In addition, treatment adherence in the intervention group was low in the postdischarge period, and few participants experienced game play after leaving the inpatient setting. It should also be noted that while current video game use was captured in this study, the use of Microsoft Kinect specifically was not captured and may have implications for the dose and fidelity of the intervention. Another limitation is that the intervention group was not balanced with the control group for gender, as there were fewer female patients in the intervention group than in the control group, although we did not find different effects of the game by gender. Finally, the drug use outcome measures in this study relied on self-report only and because of social desirability, they may represent undercounts of relapse rates. Future studies should use drug testing to verify abstinence.

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

subitem not at essential all important

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

Your answer

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

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

1 subitem not at essential all important

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

The trial will be retroactively registered.

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

The full protocol is not publicly available, but can be requested through corresponding author.

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

This study was supported by contract HHSN271201300006C under grant N43DA-13-4419 (SBIR Topic #150) from the National Institute of Drug Abuse to Media Rez LLC (to Principal Investigator DG).

X27) Conflicts of Interest (not a CONSORT item)



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

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

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

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

DG is the President of Media Rez LLC. Media Rez is planning to sell Recovery Warrior as a commercial venture. LA has the

potential to benefit financially from the sale of Recovery Warrior. MF is the Medical **Director of Mountain Manor Treatment**

Center (MMTC), where patients were enrolled in this study. MF is also a part-time faculty member of the Johns Hopkins University

and a beneficiary of the trust that owns MMTC. In addition, MF serves on the governing board of the trust and the Board of

Directors of MMTC. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its

conflict of interest policies. SC, LR, MR, VS, and HV declare no conflicts of interest.

About the CONSORT EHEALTH checklist



As a result of using this ch manuscript? *	necklist, did you make changes in your
yes, major changes	
yes, minor changes	
no	
What were the most imporusing this checklist?	rtant changes you made as a result of
Your answer	
How much time did you sp INCLUDING making chang 3 hour	pend on going through the checklist les in your manuscript *
As a result of using this chimproved? *	necklist, do you think your manuscript has
O 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

ves

Other:

Any other comments or questions on CONSORT EHEALTH

Your answer

STOP - Save this form as PDF before you click submit



To generate a record that you filled in this form, we recommend to generate a PDF of this page (on a Mac, simply select "print" and then select "print as PDF") before you submit it.

When you submit your (revised) paper to JMIR, please upload the PDF as supplementary file.

Don't worry if some text in the textboxes is cut off, as we still have the complete information in our database. Thank you!

Final step: Click submit!



Click submit so we have your answers in our database!

SUBMIT

Never submit passwords through Google Forms.

This content is neither created nor endorsed by Google. Report Abuse - Terms of Service



Google Forms