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

*Obligatoire

Your name *
First Last
Louis-Baptiste Jaunay

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

Your e-mail address *
abc@gmail.com
drjaunay@gmail.com

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

Development and Evaluation of a New Serious Game for Continuing Medical Education of General Practitioners (Hygie): Double-Blinded Randomized Controlled 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.

Hygie

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

V1

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

French

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://hygie-jeu.fr

URL of an image/screenshot (optional)

Votre réponse
| **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 |
| - Autre : |

| **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)" |
| General Practice |

| **Primary Outcomes measured in trial** * |
|----------------------------------------|
| comma-separated list of primary outcomes reported in the trial |
| (1) mean final knowledge score noted on |

| **Secondary/other outcomes** |
|-----------------------------|
| Are there any other outcomes the intervention is expected to affect? |
| transfer of knowledge learned to practice, satisfaction, and time spent playing. |
Recommended "Dose" *

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

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- "as needed"
- Autre :

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%
- Autre :
Overall, was the app/intervention effective? *

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

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

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

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

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

- Pilot/feasibility
- Fully powered

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

- no ms number (yet) / not (yet) submitted to / published in JMIR
- Autre: 12669
1a) Does your paper address CONSORT item 1a? *

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

- yes
- Autre :

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

1 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

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

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

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| subitem not at all important | 〇 | 〇 | 〇 | 〇 | 〇 |
| essential                   | 〇 |    |    |    |    |

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.

not applicable: no co-intervention

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

Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes") Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial.

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| subitem not at all important | 〇 | 〇 | 〇 | 〇 | 〇 |
| essential                   | 〇 |    |    |    |    |

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.

"general practitioners"
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)

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

"We produced a prototype video game called Hygie on the 5 most common reasons of consultation in general practice using 9 articles from independent evidence-based medicine journals (reviews from Prescrire and Minerva). We created 51 clinical cases."
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)

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

"Participants were GPs involved as resident supervisors in 14 French university departments of family practice"

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

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use “blinded” or “unblinded” to indicated the level of blinding instead of “open”, as “open” in web-based trials usually refers to “open access” (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)
Does your paper address subitem 1b-iii?
Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"recruited by email"

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

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| subitem not at all important | | | | | | 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

"269 GPs agreed to participate in the study."

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials
Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used; discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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| subitem not at all important | | | | | | 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

not applicable: not negative trial

INTRODUCTION

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

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

subitem not at all important

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Does your paper address subitem 2a-i? *

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

"General practitioners (GPs) update their medical knowledge throughout their professional life to maintain knowledge acquired during their initial studies and to be abreast of the latest scientific advances. Continuing medical education, however, can be tedious and sporadic because a considerable amount of new medical data and new literature are being continuously released, varying in quality and accessibility. The busy practitioner has limited time to consult this information."

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

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropriate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

| subitem not at all important | 1 | 2 | 3 | 4 | 5 | essential |
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"New teaching materials called "serious games" are efficient (6,7) and easily disseminated methods for education (8). Indeed, they offer the possibility of combining learning activities such as testing (9), feedback (10), spaced repetition (11), problem-based learning (12,13) with a positive experience. Learning challenges can be provided by these games (14,15) in a risk-free environment (16). Therefore, serious games give active participation and autonomy to the learner, both of which are crucial qualities in adult education (17).

Few serious games have been developed with the goal of facilitating continuous medical education for health professionals (18) and general (19,20). To our knowledge, no existing game covers topics related to family medicine."

"The aim of this work was to develop a prototype of a new serious game called Hygie for continuing medical education for the general practitioner and to assess its efficiency and user acceptance as compared with a traditional activity (article reading) in a randomized trial."
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

"They were randomized using the rand function of PHP language (allocation ratio 1:1), to either the intervention group (access online to Hygie for one week) or to the control group (access online to the 9 articles)"

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

Not applicable : no change

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].
Does your paper address subitem 3b-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not applicable: bugs were fixed using a pilot study

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

"We asked all 35 French University departments of general practice to contact GPs involved as resident supervisors by email"

4a-i) Computer / Internet literacy
Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

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Does your paper address subitem 4a-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

not relevant: recruitment by email
4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

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

Does your paper address subitem 4a-ii? *

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

"We asked all 35 French University departments of general practice to contact GPs involved as resident supervisors by e-mail to participate in a real-life experience learning where they would have access to an e-learning support for seven days, without mentioning the nature of the educational support. […] After agreeing to participate, GPs accessed the study website where they completed […] Participants did not know if they were assigned to the intervention or control group and did not know which intervention was performed in the other group. " 
4a-iii) Information giving during recruitment

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

1 2 3 4 5

subitem not at all important

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

"Information was delivered to participants about the purpose, the duration, the time to devote to the study, and anonymization of results."

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

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

"Data were collected on a Structured Query Language database."
4b-i) Report if outcomes were (self-)assessed through online questionnaires
Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

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

"After 3 weeks without access to the teaching materials, participants received a final, 20-item knowledge questionnaire"

4b-ii) Report how institutional affiliations are displayed
Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention.(Not a required item – describe only if this may bias results)

Does your paper address subitem 4b-ii?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Institutional affiliations of the investigators were indicated at the end of the email."
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).

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

“Louis-Baptiste Jaunay is the owner of hygie-jeu.fr website. No other COI declared.”

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.

""
Design and Development of Hygie
We produced a prototype video game called Hygie in which the player is a GP in the process of treating several patients. We defined topics for this prototype based on the 5 most frequent reasons for consultation in France [21]: hypertension, health check and prevention, dyslipidemia, acute fever, and rhinopharyngitis.
For these 5 topics, we reviewed 9 articles in 2 French evidence-based journals: 6 from Prescrire and 3 from Minerva [22-30]. We selected these 2 journals because they provide robust evidence-based recommendations and are strictly independent from industrial and institutional influences. From these 9 articles, we created 51 short clinical cases, each having 1 question that could be answered either by multiple choice or free text.
The game was coded using HTML 5, Cascading Style Sheets 3, JavaScript (ECMAScript 2015), and Hypertext Preprocessor (PHP) 7. Graphics were created using Adobe Illustrator and Adobe Photoshop (Figure 1).
Learning methods incorporated into the game included statement of educational objectives, immersion in a general medical consultation setting, problem-based learning with active restitution of knowledge, spaced recall, stimulation of intrinsic motivation by earning points, and having goals and levels with a “final boss” for each level. Humoristic elements such as puns in patients’ names were included to maximize engagement.
A preliminary test phase was conducted with 11 GPs and 9 residents in general practice. The preliminary test allowed us to detect and solve bugs, clarify questions, and sort questions into 5 levels of difficulty.
5-iii) Revisions and updating

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

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subitem not at all important  ○ ○ ☐ ○ ○ ○ essential

Does your paper address subitem 5-iii?

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

"A preliminary test phase was conducted with 11 GPs and 9 residents in general practice. The preliminary test allowed us to detect and solve bugs, clarify questions, and sort questions into 5 levels of difficulty."

5-iv) Quality assurance methods

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

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subitem not at all important  ○ ○ ○ ☐ ○ ○ essential
"For these 5 topics, we reviewed 9 articles in 2 French evidence-based journals: 6 from Prescrire and 3 from Minerva [22-30]. We selected these 2 journals because they provide robust evidence-based recommendations and are strictly independent from industrial and institutional influences."

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

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

Does your paper address subitem 5-v?

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

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

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| subitem not at all important | essential |

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

"The prototype of the game is freely accessible on the Web [31]."

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

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| subitem not at all important | essential |
Does your paper address subitem 5-vii? *

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

"After agreeing to participate, GPs accessed the study website where they completed a demographic questionnaire, a knowledge pretest of 5 questions on each of the 5 reasons for consultation. They were randomized using the rand function of PHP language (allocation ratio 1:1) to either the intervention group (Web access to Hygie for 1 week) or to the control group (access online to the 9 articles). Participants had an individual login, allowing them to access only the teaching material assigned to them. They did not know if they were assigned to the intervention or control group and did not know which intervention was performed in the other group."

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

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

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subitem not at all important 1 2 3 4 5 essential
"Learning methods incorporated into the game included statement of educational objectives, immersion in a general medical consultation setting, problem-based learning with active restitution of knowledge, spaced recall, stimulation of intrinsic motivation by earning points, and having goals and levels with a “final boss” for each level. Humoristic elements such as puns in patients' names were included to maximize engagement."

"After 1 week of free access to their respective teaching material (serious game Hygie vs articles), access was terminated."
5-x) Clarify the level of human involvement

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

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subitem not at all important

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

not applicable: no human involvement

5-xi) Report any prompts/reminders used

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

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subitem not at all important

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

"Reminders were sent to the 2 groups within 3 and 6 days of access to teaching material"

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

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

not appicable: no cointervention

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

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
Primary outcomes were (1) dynamic and (2) static knowledge assessed by questionnaires:

1. A Dynamic Questionnaire-5 (DQ-5) with 5 items compared individual change of score between pretest (before intervention) and post-test (3-5 weeks after intervention). It was a 5-item questionnaire with each of the 5 questions weighted by a scale ranging from 1 to 3 according to its importance for practice and a global score from 0 to 14. The goal of this questionnaire was to assess progression of each participant. For a simpler interpretation, we scaled the DQ-5 score to be out of 10 rather than 14.

2. A Static Questionnaire-20 (SQ-20) measured mean final score 3 to 5 weeks after intervention. It was a 20-item questionnaire (5 of the dynamic questionnaire plus 15 other questions), with each of the 20 questions weighted by a scale ranging from 1 to 3 according to its importance for practice and a global score from 0 to 58. The goal of this questionnaire was to compare groups, minimizing the potential carryover effects induced by the pretest questionnaire. Like for the DQ-5, for interpretation, we rescaled the SQ-20 to a 0 to 10 scale (rather than 0-58).

Here is an example of a knowledge question that appears in both dynamic and static questionnaires and the scoring method:

Question: Which cholesterol-lowering drugs have shown a decrease in mortality and morbidity?
Expected answers (free text): pravastatin, simvastatin.
Scoring method: It was rated 3 points out of 14:
If the 2 right molecules (pravastatin and simvastatin) are mentioned: 3 points
If 1 good molecule among pravastatin and simvastatin is mentioned: 1 point
In all other cases: 0 points.

The 2 knowledge questionnaires and their scale were written from the source articles by 3 experienced physicians who had no information about the game content, with instructions to identify practice-relevant issues in the articles. Participants’ questionnaires were scored blindly by a physician not involved in the other stages of the study.

Secondary outcomes were (1) the use in medical practice of the knowledge acquired through the teaching material assessed at the time of the final questionnaire (participants answered the question "In the course of your practice, did you use the knowledge you learned through the teaching material?"), (2) time spent playing by participants assigned to Hygie, and (3) a satisfaction questionnaire. The satisfaction questionnaire, composed of 8 questions and completed at the end of the 1-week learning period, included quantitative and qualitative data about participant satisfaction, time reported as spent on the materials,
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].

subitem not at all important 1 2 3 4 5 essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

“The 2 knowledge questionnaires and their scale were written from the source articles by 3 experienced physicians who had no information about the game content, with instructions to identify practice-relevant issues in the articles. Participants’ questionnaires were scored blindly by a physician not involved in the other stages of the study.”

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

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

subitem not at all important 1 2 3 4 5 essential
Does your paper address subitem 6a-ii?
Copy and paste relevant sections from manuscript text

"The average total time spent on the Hygie game was measured via server usage data. Average total time spent on the articles was not collected because participants could download the articles and read it offline."

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

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essential

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

"The satisfaction questionnaire, composed of 8 questions and completed at the end of the 1-week learning period, included quantitative and qualitative data about participant satisfaction, time reported as spent on the materials, and additional demographic data (eg, workplace and usual training materials for continuing education). Qualitative data were analyzed by content for themes related to effective learning as well as to illuminate potential strengths and weaknesses of Hygie."

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

not applicable: no change

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.

| subitem not at all important | 1 | 2 | 3 | 4 | 5 | essential |
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Does your paper address subitem 7a-i?
Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The number of participants required with 80% power (1−beta) and 5% type I error was estimated before the study. A total of 128 participants were needed to detect a difference of 2 points out of 10 between the groups on the final questionnaire, assuming that the participants in the Hygie group had a final score of 8 out of 10 on average."
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: no interim analyses nor stopping guidelines

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

"They were randomized using the rand function of PHP language (allocation ratio 1:1) to either the intervention group (Web access to Hygie for 1 week) or to the control group (access online to the 9 articles)."

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

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

not applicable: no allocation sequence
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).

| Importance | 1 | 2 | 3 | 4 | 5 |
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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

*"They did not know if they were assigned to the intervention or control group and did not know which intervention was performed in the other group [...] Participants’ questionnaires were scored blindly by a physician not involved in the other stages of the study."
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".

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

"They did not know if they were assigned to the intervention or control group and did not know which intervention was performed in the other group."

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

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

"We performed a double-blind randomized controlled trial to assess the effectiveness of Hygie as a method for continuing education for GPs as compared with a traditional article reading activity with the same content."
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

"The answers to the knowledge and satisfaction questionnaires were collected on the framaform website. Statistical analyses were performed using R software (R Foundation for Statistical Computing) [32]. The 2 groups were compared using Fisher exact tests for nominal variables and Welch t tests for quantitative variables. Differences with P<.05 were considered significant."

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

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

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subitem not at all important ○ ○ ○ ● ○ essential

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

not applicable: no imputation techniques to deal with attrition/missing values
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

not applicable : no additional analyses

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

X26-i) Comment on ethics committee approval

Does your paper address subitem X26-i?
Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The study was approved by the Committee for the Evaluation of the Ethics of Research Projects of hospital Robert Debré n° 2017/359.
### x26-ii) Outline informed consent procedures

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

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**subitem not at all important**

**essential**

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### Does your paper address subitem X26-ii?

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

Participation was anonymous and voluntary. Participants began the study by clicking a link to teaching materials.

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### x26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

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**subitem not at all important**

**essential**

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### Does your paper address subitem X26-iii?

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

not applicable : no harm to detect
RESULTS

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

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

13b) For each group, losses and exclusions after randomisation, together with reasons

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

"A total of 3398 GPs were invited to participate in this study by email. Of these, 269 participants (7.9%) accepted to participate in the study. Recruitment occurred between May 31, 2017, and June 27, 2017. A total of 108 participants completed the study and were analyzed."

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

"The inclusion flow diagram according to Consolidated Standards of Reporting Trials recommendations [33] is shown in Figure 3."
13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

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.

"The inclusion flow diagram according to Consolidated Standards of Reporting Trials recommendations [33] is shown in Figure 3."

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.

Recruitment occurred between May 31, 2017, and June 27, 2017.
14a-i) Indicate if critical “secular events” fell into the study period

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

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subitem not at all important  ○  ○  ○  ●  ○  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

not applicable: no secular events

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: not stopped early

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

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

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

"Baseline characteristics of participants in both groups were comparable (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.

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subitem not at all important

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.

"Mean age was 40.9 years, there was a majority of women, and an urban setting was the most common"

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

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

Does your paper address subitem 16-i? *

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

A total of 108 participants completed the study and were analyzed

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).

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

not intent-to-treat "A total of 108 participants completed the study and were analyzed"
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

*The final SQ-20 mean score was similar in the 2 groups: Hygie group 4.9 (95% CI 4.6-5.2) and control group 4.6 (95% CI 4.2-4.9; P=.21, not significant).
The final DQ-5 mean score (5-item post-test) was also similar in the 2 groups: Hygie group 5.0 (95% CI 4.6-5.4) and control group 4.7 (95% CI 4.2-5.1; P=.26, not significant).
The mean individual change of DQ-5 score between pre- and post-test was significantly superior to 0 in the Hygie group with a mean gain of 1.6 (95% CI 1.2-2.1; P<.001) and in control group with a mean gain of 0.9 (95% CI 0.5-1.4; P<.001).
For the critical test of our trial, this mean individual change of DQ-5 score between pre- and post-test at 3 to 5 weeks was significantly superior in the Hygie group compared with the reading group, with a difference of 0.7 (95% CI 0.1-1.3; P=.02; Figure 4).
For the question “In the course of your practice, did you use the knowledge that you learned through the teaching material?,” the percentage of participants reporting “yes” was significantly greater in the Hygie group (77% in the Hygie group vs 53% in the reading group; odds ratio 2.9, 95% CI 1.2-7.4; Table 2)."
17a-i) Presentation of process outcomes such as metrics of use and intensity of use

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

Does your paper address subitem 17a-i?

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

"The average total time spent on the Hygie game, measured via server usage data for the included participants, was 43 min. The average time per game session was 10 min and 50 seconds. Participants self-reported the time they spent on learning materials in the satisfaction questionnaire through a discontinuous quantitative variable. The most common responses were “45 to 60 minutes” in the Hygie group and “10 to 20 minutes” in the reading group."

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

"For the question “In the course of your practice, did you use the knowledge that you learned through the teaching material?,” the percentage of participants reporting “yes” was significantly greater in the Hygie group (77% in the Hygie group vs 53% in the reading group; odds ratio 2.9, 95% CI 1.2-7.4;"

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

not applicable no subgroup or adjusted analyses

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

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

not applicable : not done

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

not applicable : no harm

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

subitem not at all important

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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.

not applicable : no technical problem

19-ii) Include qualitative feedback from participants or observations from staff/researchers

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

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subitem not at all important

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.

“The qualitative reasons spontaneously mentioned by the participants also justified Hygie, including the following themes:

• Effective learning: the characteristics of the game (subthemes mentioned the following: speed, simple learning, and effective information assimilation), informative content (key messages, relevance of themes, clarity, and referenced responses), and its mechanisms (repetition of clinical cases promoting memorization, cognitive conflict that allows for better memorization, and allows one to learn test with real-life scenarios).

• An enjoyable experience (subthemes mentioned the following: playful and fun) with stimulating challenges (challenging stimulation and real-time style mimics the clinic): 36% of participants of the Hygie group answered "yes" to the question “Did this session make you want to consult medical journals more regularly or take out a subscription?,” which suggests that gaming encourages players to read journals, considering that 73% of GPs already reported consulting Prescrire regularly and 12% reported consulting Minerva.”

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group.
22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

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

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subitem not at all important  ○  ○  ○  ○  ○

essential
"To our knowledge, Hygie is the first continuing education material of this type; it is the first educational video game developed for and by GPs. Hygie was created without external funding and independently of the pharmaceutical and medical device industries. Moreover, it is based on reliable sources that are helpful to GPs in maintaining and expending their knowledge. Finally, it is unique because of its extensive evaluation among a significant number of GPs from several regions of France. The use of both a double-blinded randomized trial and a satisfaction questionnaire evaluation differentiates Hygie from other serious health games in existence, with a few exceptions such as InsuOnline [20]. Our study shows that it is feasible to create an engaging educational video game, including validation in a randomized trial, without influence of public or private financing.

Our results have shown that giving access to the Hygie game to GPs in "real life" conditions (ie, where learner decided when, where, and how much time he or she wants to spend learning) results in a persistent learning at 3 to 5 weeks. Furthermore, giving access to Hygie resulted in a better improvement in medical knowledge compared with giving access to articles, which is the traditional method. In addition, this knowledge seems to be more easily transferable to medical practice, as shown by the greater proportion of GPs reporting having used the knowledge in their own practices as compared with traditional journal article reading. This result suggests that serious games may engender better transfer of knowledge to real-life situations by actively engaging the learner.

No significant difference was found on the final questionnaire score, which is consistent with a previous study [20] and may suggest that journal article reading can still lead to sufficient knowledge for continuing education but that Hygie is at least noninferior to traditional methods."
20-i) Typical limitations in ehealth trials

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

Does your paper address subitem 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.

"In the future, we could evaluate the appropriation of this tool by GPs and their ability to improve it."

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

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

Highlight unanswered new questions, suggest future research.
Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study.
There were some limitations to our study. Recruitment was limited to GPs who were resident supervisors. This population is representative of the French GP population with some particularities such as a higher proportion of women, an underrepresented 45 to 54 years age group, a majority group practice, and a lower weekly working time [34]. Another bias is that participants were volunteered for the study after reading the email solicitation that offered to try a “new continuing education material.” Thus, it was possible that this population of GPs was especially interested in updating their medical knowledge; this is supported by the proportion of physicians declaring reading the Prescrire journal in our study (70%), which is much higher than the proportion of French GPs subscribing to Prescrire (18.1% of GPs subscribed to Prescrire in 2016) [35].

The GPs’ positive response rate for participating in the study was 7.9% (269 included out of 3398 requested), which is comparable with the average response rate in this population [36] but prevented us from reaching the number of participants suggested by our power analysis. The real response rate cannot be definitively known because it is possible that some emails failed to reach potential GPs and were not read.

Contamination bias between groups is a potential limitation, but limited access to 1 of the 2 teaching materials through the login and individual working environment of French GPs has limited this possibility.

More than half (60%) of the participants did not complete the study, which may have been a consequence of the “real life” conditions of our trial (unconstrained use) and the fact that the study took place during the summer holidays. The similar number of participants who did not complete the study in the 2 groups (58% in the Hygie group and 62% in the control group) suggests that the reasons for not participating are not related to the nature of the teaching material. Similarly, it can be assumed that the influence of reminders during the week of access to teaching materials, compared with routine use, was similar for both groups. However, the final sample size was smaller than the number calculated as required. A lack of power may explain that 1 of the 2 end points did not reach statistical significance.

Knowledge and satisfaction questionnaire have not been previously validated because they have been made to match the content of the teaching materials. The use of customized instruments is strongly recommended for the evaluation of serious games by Moreno-Ger [37], who argues that generic questionnaires are usually not useful for assessing games that can be very different in their objectives, target audiences, and needs. However, GPs experienced in medical pedagogy reviewed and improved these questionnaires, which was then
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 all important | 1 | 2 | 3 | 4 | 5 | essential |

Does your paper address subitem 21-i?

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

"Recruitment was limited to GPs who were resident supervisors. This population is representative of the French GP population with some particularities such as a higher proportion of women, an underrepresented 45 to 54 years age group, a majority group practice, and a lower weekly working time [34]. Another bias is that participants were volunteered for the study after reading the email solicitation that offered to try a “new continuing education material.”"
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] 1
- [2] 2
- [3] 3
- [4] 4
- [5] 5

subitem not at 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.

"Our pragmatic study suggests that under usual conditions with e-learning teaching material, Hygie game can be an effective, pleasant, and engaging method for continuing education of GPs. It can be widely disseminated at low cost. Its modular content allows for future adaptation and improvement, and immersive qualities in a virtual reality where errors are not detrimental to patients render it an exciting next direction for adult learning among GPs and other physicians."

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

"Trial Registration: Clinicaltrials.gov NCT03486275; https://clinicaltrials.gov/ct2/show/NCT03486275."

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

not applicable: not available

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

"Hygie was created without external funding and independently of the pharmaceutical and medical device industries."

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

Although not at all important, it is 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.

“Louis-Baptiste Jaunay is the owner of hygie-jeu.fr website. No other COI declared.”

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

○ yes, major changes

○ yes, minor changes

○ no
What were the most important changes you made as a result of using this checklist?

Votre réponse

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

3 hours

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

- yes
- no
- Autre :

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

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

- yes
- no
- Autre :
Any other comments or questions on CONSORT EHEALTH

Votre réponse

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