

# 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

Florie FILLOL

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Your e-mail address \*

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Title of your manuscript \*

Provide the (draft) title of your manuscript.

Impact of a 12-month web and smartphone-based intervention initiated during spa therapy to improve long-term physical activity of patients with chronic diseases: 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.

THERMACTIVE



**Evaluated Version (if any)**

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

Votre réponse

**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.

Votre réponse

**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)"

Non Communicable Diseases

**Primary Outcomes measured in trial \***

comma-separated list of primary outcomes reported in the trial

Achievement of physical activity guidelines (to

**Secondary/other outcomes**

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

physical activity level, sedentary time, weight, waist circumference, quality of life

**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 : The recommendation of the use of the app was personalised and ada



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 :

## TITLE AND ABSTRACT

### 1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? \*

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

- ☒ yes
- ☐ 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.

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subitem not at all important    ☐    ☐    ☐    ☐    ☒    essential

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**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

"web and smartphone-based intervention"

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

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

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**Does your paper address subitem 1a-ii?**

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

Patient included benefited from a face-to-face session with a physical activity instructor for setting the web and smartphone-based physical activity program. This precision is indicated in the abstract.





**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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**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

"patients with chronic diseases"

**1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions**

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

**1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT**

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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### Does your paper address subitem 1b-i? \*

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

"an intervention combining an individual face-to-face coaching during spa therapy and, when returning home, a web- and smartphone-based PA program including a connected wrist pedometer and a connected weighing scale" "control group who received usual advices about PA"

### 1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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### Does your paper address subitem 1b-ii?

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

"an individual face-to-face coaching during spa therapy"



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

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

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### Does your paper address subitem 1b-iii?

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

"Patients were enrolled during spa therapy" "From the end of spa therapy, PA, body weight, waist circumference, and quality of life of the participants in both groups, were assessed by phone every 2 months until the end of the follow-up."

### 1b-iv) RESULTS section in abstract must contain use data

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

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### Does your paper address subitem 1b-iv?

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

"The mean duration use of the program was 7.1 months (SD 4.5). Attrition rate during the first 2 months of the program was 20.4% (23/113) whereas 39.8% (45/113) of the participants used the program for at least 10 months."

### 1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

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

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### Does your paper address subitem 1b-v?

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

The trial is not negative.

## INTRODUCTION

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



### 2a-i) Problem and the type of system/solution

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

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### Does your paper address subitem 2a-i? \*

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

"Lack of physical activity (PA) and sedentary behaviors are now recognized as leading risk factors for non-communicable diseases (NCD), such as cardiovascular diseases, chronic obstructive pulmonary disease, cancers and type 2 diabetes [...]."

"[...] engaging patients suffering from NCD in long term lifestyle modifications is very challenging."

"To maintain adherence to PA, Information and Communication Technologies (ICT) seem to be promising tools"

"The context and environment of a stay in a spa therapy center has been shown to be conducive to educating patients about their disease and to initiating lifestyle changes, including increasing PA, through a PTEPA program (Patient Therapeutic Education in Physical Activity)."

"We hypothesized that a face-to-face personalized PTEPA during an individual's stay at a thermal spa resort followed by a 12 month web- and smartphone-based PA program would improve long-term PA, compared to usual care, in individuals with chronic NCDs."



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

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

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## Does your paper address subitem 2a-ii? \*

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

"Recent reviews and meta-analyses have found that web-based interventions were effective in increasing PA (physical activity) in the general population in older adults and in NCD (non communicable diseases) patients"

" In 2018, a meta-analysis, gathering data from different target populations (healthy adults, the overweight or inactive, chronically diseased adults, and older age groups), showed that interventions comprising smartphone applications and/or wearable devices had a moderate effect on objectively measured change in PA and a moderate-to-large effect on daily step count"

"Indeed, while many studies have shown the benefits of PA interventions on the health of NCD patients, despite the positive effects of PA experienced by the patients a decrease in PA compliance is frequently observed in the long-term, leading to a loss of the acquired health benefit."

" Furthermore, another systematic review suggested that multi-component interventions combining physical education, provision of physical activity equipment, parental education, and/or face-to-face counselling along with ICT might be more effective than stand-alone ICT interventions."

" The context and environment of a stay in a spa therapy center has been shown to be conducive to educating patients about their disease and to initiating lifestyle changes, including increasing PA, through a PTE program (Patient Therapeutic Education in Physical Activity) "

"Thus, an intervention including face-to-face initiation of physical activity along with a web- and smartphone -based PA program associated with a connected device could gather essential features to increase and maintain the PA level in NCD patients."



**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

"We hypothesized that a face-to-face personalized PTEPA during an individual's stay at a thermal spa resort followed by a 12 month web- and smartphone-based PA program would improve long-term PA, compared to usual care, in individuals with chronic NCDs."

**METHODS****3a) Description of trial design (such as parallel, factorial) including allocation ratio**

Does your paper address CONSORT subitem 3a? \*

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

"This was a 12-month, prospective, parallel-group, open, multicenter randomized controlled trial"

**3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons**

Does your paper address CONSORT subitem 3b? \*

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

There was no important changes to methods after initiation of the trial.



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

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

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### Does your paper address subitem 3b-i?

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

No major bug or change happened during the trial. The program was largely tested before the trial on general population.

### 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

"The volunteers included in the protocol were from 50 to 79 years with a diagnosis of a stabilized chronic disease (cardiovascular disease, obesity, type 2 diabetes, chronic obstructive pulmonary disease, rheumatic conditions, breast cancer), a body mass index between  $19 < \text{BMI} < 35 \text{ kg.m}^2$ , and practiced a PA less than 150 minutes per week."





#### 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

"They (the participants) were required to have access to the Internet and a smartphone connected to the Internet."

#### 4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

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

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### Does your paper address subitem 4a-ii? \*

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

"Patients were recruited through posters and flyers displayed in spa therapy facilities and spa doctors' surgeries. Moreover, a PA instructor (PAI) was allocated in each spa center to pre-screen all potential patients and evaluate their physical fitness and eligibility. Spa physicians participating in the study could also refer their patients to the PAI for pre-screening."

"Eligible volunteers had a medical examination with the spa doctor, who having checked they could safely follow the study protocol, included them in the trial."

### 4a-iii) Information giving during recruitment

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

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### Does your paper address subitem 4a-iii?

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

Participants were first briefed by a spa physical activity instructor during a prescreen and were briefed a second time during an exam performed by a spa doctor.

"Eligible volunteers had a medical examination with the spa doctor, who having checked they could safely follow the study protocol, included them in the trial after the volunteers read and signed an informed consent."

### 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 through an electronic CRF and through the website and the smartphone application of the program.

"Data collected at inclusion and during the follow-up were recorded through an eCRF in a centralized secured management system, RedCap."

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

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

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### Does your paper address subitem 4b-i? \*

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

Outcomes were assessed at inclusion during a face-to-face session and by phone during the 12 months follow-up.

### 4b-ii) Report how institutional affiliations are displayed

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

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### Does your paper address subitem 4b-ii?

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

The logos of the institutional affiliations appeared at the bottom of the posters and the flyers.

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

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

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

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### Does your paper address subitem 5-i?

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

Votre réponse



### 5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

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### Does your paper address subitem 5-ii?

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

The Thermactive application comes from technologies and applications that the company Biomouv has developed since 2010 for the general population. The type of application used for Thermactive had already been used by nearly 10,000 people before the launch of the Thermactive study. The algorithms for generating the appropriate physical activity programs were therefore robust and proven. Only a few adjustments to adapt the volume of daily activity to the situation of patients with chronic disease were necessary.

### 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

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### Does your paper address subitem 5-iii?

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

The application, its functionalities and its content were frozen during the trial.

### 5-iv) Quality assurance methods

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

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subitem not at all important    ☐    ☐    ☐    ☐    ☐    essential

### Does your paper address subitem 5-iv?

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

Votre réponse

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

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

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### 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

For reasons of confidentiality, the algorithms and the source code cannot be communicated. Screenshots are provided in order to better understand the functionalities of the applications made available to patients.

### 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](https://www.webcitation.org), and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

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### Does your paper address subitem 5-vi?

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

Screenshots are provided in order to better understand the functionalities of the applications made available to patients.



### 5-vii) Access

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

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### Does your paper address subitem 5-vii? \*

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

Access to the web and mobile application were opened to patients during the spa stay, during the training workshop on physical activity. These accesses were opened free of charge for the subjects included in the study. They were equipped with a connected wristband and scale free of charge. The applications are no longer online. But screenshots make it possible to understand the functionalities of the applications used by the patients during the trial

"The intervention consisted of a one-hour individual consultation with a PAI during the 3-week spa therapy stay in one of the eight spa care facilities and then access to the automated mobile-based PA program and associated connected devices during the 12 months following the end of the spa therapy. [...] Then the PAI presented the automated web and mobile-phone-based PA program (THERMACTIVE) together with the use of the connected devices (weighing scales, wrist pedometer) (supplementary files). The PAI downloaded the mobile application onto the patient's smartphone and showed him/her how to login to the mobile application and connect and use the weighing scale. The PAI also explained access to the website and showed the participant the main functionalities of the program. The patients were registered in the program by the PAI who completed a web-based questionnaire to determine the patient's PA profile: age, weight, height, physical fitness (endurance, strength, flexibility and balance measured by the PAI), PA, joint disabilities, pathology, availability for PA sessions, PA preferences and sports material. Participants in the intervention group followed the "web and mobile-based" PA program for 12 months from the end of their stay in the spa therapy





### 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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**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

"The automated "web and mobile-based" PA program aimed to help patients achieve recommended levels of PA in 2 ways: by proposing a series of specific exercises in each session and by increasing daily PA (number of steps). PA sessions were automatically generated based on the patient's profile. To generate personalized sessions, an algorithm was developed to select and associate exercises from a database of more of 1500 different exercises. Each exercise was classified according to its nature (aerobic, strengthening, balance), the part of the body concerned (leg, arm, trunk), exercise intensity and duration. The algorithm selected exercises appropriate to the patient's physical capacities and availability, and constructed a session adapted to the patient. Each session comprised three phases: a 5 minute warm-up period; either 10 to 35 minutes of exercises developing muscle strength and flexibility, or 10 to 50 minutes of endurance during walking or cycling (mixing continuous and/or intermittent effort); and lastly a 5-minute recovery phase consisting of stretching and relaxation , or a return to calm after walking sessions. The structured PA sessions were either automatically compiled videos or pdf files. The program of PA sessions followed the international guidelines regarding the number of sessions by week, resting periods, type of exercise (resistance, endurance), duration and the intensity of each exercise [1, 2]. For each participant their PA sessions evolved during the course of the intervention taking into account the number of sessions completed (recorded by the patient) and any difficulty perceived at the end of the sessions (collected using a Borg scale). To increase daily PA, the program generated a daily goal of number of steps to achieve based on data from the pedometer over 7 consecutive days. The achievement of these goals determined the subsequent goals and everyday participants received a notification on their mobile application about the achievement of their personal goal. They also received emails about new sessions of PA available on the website and/or reminding them if a session had not been carried out and inviting them to do it when possible. Participants had the possibility to record or add activities on the mobile application which were not planned in the program such as walking, cycling, swimming or fitness sessions. The website and the mobile application also allowed participants to record their daily PA and amount of sedentary time in order to visualize the evolution over the time. Patients allocated to the control group received the usual advice on PA and a booklet giving advice and examples of PA suited to their pathology. At the end of the 12-month-follow-up period, the patients included in the control group received the free connected devices and access to the THERMACTIVE program for 12 months."



### 5-ix) Describe use parameters

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

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### Does your paper address subitem 5-ix?

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

Votre réponse

### 5-x) Clarify the level of human involvement

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

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### Does your paper address subitem 5-x?

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

"The intervention consisted of a one-hour individual consultation with a PAI during the 3-week spa therapy stay in one of the eight spa care facilities and then access to the automated mobile-based PA program and associated connected devices during the 12 months following the end of the spa therapy. All PAIs had received the same training and used the same material. The first part of the consultation aimed to introduce or remind the participant of the benefits of PA for health and disease management. The PAI gave advice on how to reach the recommended level of PA and examples of PA adapted to the patient's particular condition. Then the PAI presented the automated web and mobile-phone-based PA program (THERMACTIVE) together with the use of the connected devices (weighing scales, wrist pedometer) (supplementary files). The PAI downloaded the mobile application onto the patient's smartphone and showed him/her how to login to the mobile application and connect and use the weighing scale. The PAI also explained access to the website and showed the participant the main functionalities of the program. The patients were registered in the program by the PAI who completed a web-based questionnaire to determine the patient's PA profile: age, weight, height, physical fitness (endurance, strength, flexibility and balance measured by the PAI), PA, joint disabilities, pathology, availability for PA sessions, PA preferences and sports material."

### 5-xi) Report any prompts/reminders used

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

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### Does your paper address subitem 5-xi? \*

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

" To increase daily PA, the program generated a daily goal of number of steps to achieve based on data from the pedometer over 7 consecutive days. The achievement of these goals determined the subsequent goals and everyday participants received a notification on their mobile application about the achievement of their personal goal. They also received emails about new sessions of PA available on the website and/or reminding them if a session had not been carried out and inviting them to do it when possible."

### 5-xii) Describe any co-interventions (incl. training/support)

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

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**Does your paper address subitem 5-xii? \***

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

"The intervention consisted of a one-hour individual consultation with a PAI during the 3-week spa therapy stay in one of the eight spa care facilities and then access to the automated mobile-based PA program and associated connected devices during the 12 months following the end of the spa therapy. All PAIs had received the same training and used the same material. The first part of the consultation aimed to introduce or remind the participant of the benefits of PA for health and disease management. The PAI gave advice on how to reach the recommended level of PA and examples of PA adapted to the patient's particular condition. Then the PAI presented the automated web and mobile-phone-based PA program (THERMACTIVE) together with the use of the connected devices (weighing scales, wrist pedometer) (supplementary files). The PAI downloaded the mobile application onto the patient's smartphone and showed him/her how to login to the mobile application and connect and use the weighing scale. The PAI also explained access to the website and showed the participant the main functionalities of the program. The patients were registered in the program by the PAI who completed a web-based questionnaire to determine the patient's PA profile: age, weight, height, physical fitness (endurance, strength, flexibility and balance measured by the PAI), PA, joint disabilities, pathology, availability for PA sessions, PA preferences

**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

"Participants' [...] weight, waist circumference, [...] PA, and quality of life were collected at baseline (M0) by the PAI. PA was assessed using the validated International Physical Activity Questionnaire (IPAQ), short version." (PAI : Physical Activity Instructor)

"From the end of spa therapy, PA, body weight, waist circumference, and quality of life of the participants in both groups, were assessed at months 2 (M2), 4 (M4), 6 (M6), 8 (M8), 10 (M10) and 12 (M12) by interviewers masked to the participant's randomization group by phone. "



6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

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subitem not at all important	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential
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Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

No online questionnaires were used to assess outcomes.

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.

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Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Votre réponse



### 6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	essential

### Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Votre réponse

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

### Does your paper address CONSORT subitem 6b? \*

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

No changes to trial outcomes happened after the 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.

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subitem not at all important      ☐      ☐      ☐      ☐      ☐      essential

### Does your paper address subitem 7a-i?

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

Votre réponse

### 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

No interim analyses were done.

### 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

"Randomization of the participants to the intervention or control group was stratified by gender and center (thermal spa resort) and performed by the spa PAI using a centralized secured management system, RedCap"

**8b) Type of randomisation; details of any restriction (such as blocking and block size)****Does your paper address CONSORT subitem 8b? \***

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

"Participants were randomized 1:1 either to the intervention group or to the control group."  
 "Randomization of the participants to the intervention or control group was stratified by gender and center (thermal spa resort) and performed by the spa PAI using a centralized secured management system, RedCap"

**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

Once the patient was included by the spa doctor, the random allocation of the patient in intervention or control group was done by the spa physical activity instructor using a centralized secured management system, RedCap, which automatically allocated the patient in a group. This system was available to each physical activity instructor thanks to a secured website.



## 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

The allocation sequence was generated by a centralized secured management system, RedCap. The spa physical activity instructor pre-screened the patients. Eligible volunteers were included by a spa doctor and then assigned to intervention or control group by the spa physical activity instructor.

"Eligible volunteers had a medical examination with the spa doctor, who having checked they could safely follow the study protocol, included them in the trial after the volunteers read and signed an informed consent."

"Randomization of the participants to the intervention or control group was stratified by gender and center (thermal spa resort) and performed by the spa PAI using a centralized secured management system, RedCap".

## 11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

### 11a-i) Specify who was blinded, and who wasn't

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

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**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

"From the end of spa therapy, PA, body weight, waist circumference, and quality of life of the participants in both groups, were assessed at months 2 (M2), 4 (M4), 6 (M6), 8 (M8), 10 (M10) and 12 (M12) by interviewers masked to the participant's randomization group by phone."

**11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"**

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse

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

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

**Does your paper address CONSORT subitem 11b? \***

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

This item is not relevant for our trial.



## 12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

### Does your paper address CONSORT subitem 12a? \*

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

"To compare between-group differences from baseline for repeated outcomes, a constrained longitudinal data analysis (CLDA) was used. This mixed model is a constrained full-likelihood approach, whereby both the baseline and post-baseline values are modeled as dependent variables (the constrained model assumes that both the baseline and post-baseline measurements are jointly multivariate and normally distributed because the baseline value is treated as part of response vector), and the true baseline values are constrained to be the same for the 2 treatment groups."

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

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

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### Does your paper address subitem 12a-i? \*

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

"Such methods (i.e. CLDA models) based on maximum likelihood are consistent under the "missing at random" assumption. This model allows the inclusion of patients for whom either the baseline or post-baseline measurements are missing, thereby increasing efficiency."



## 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

" this analysis (i.e. CLDA model) provides an adjustment for the observed baseline difference in estimating the intervention effects. [...] In addition to adjusting for baseline covariates, the analysis model also adjusted for the intervention, time, sex and interaction of time and intervention. Random effects at the patient level and center were added."

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

X26-i) Comment on ethics committee approval

subitem not at all important      1      2      3      4      5      essential

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Does your paper address subitem X26-i?

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

"The trial, funded by AFRETH (Grant N° 2015-02) a non-profit independent organization, was approved by the ANSM (National Agency for the Safety of Medicine and Health products) and the Regional Ethics Committee (Comité de Protection des Personnes Sud-Est N° 6. Ref. CPP: AU1196; ref. ID.RCB: 2015-A00855-44) and registered in ClinicalTrials.gov (NCT02694796) before beginning enrolment of the participants."



**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse

**RESULTS**

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

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

**Does your paper address CONSORT subitem 13a? \***

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

"Among the 304 patients screened, 230 were enrolled and randomly assigned to the control group (n=114) or intervention group (n=116) (Figure 1). After randomization, 2 patients (one in each group) withdrew their participation. A total of 228 patients were included in the analyses."

**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

This item is addressed in the CONSORT flow chart (Figure 1 in the manuscript).

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse

### 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 was from September 2015 to December 2016."

The patients were followed for 12 months after the end of spa therapy.

#### 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse



## 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

The recruitment was stopped before achieving the number of patients required by the sample size calculation.

"Despite an extension of the period of recruitment to the trial it was impossible to enroll the number of patients required by the sample size calculation. In part because it appeared that a lot of patients with a web connection and a smartphone were already meeting PAG. "

## 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

The table 1 in the manuscript show baseline demographic and clinical characteristics for each group.

### 15-i) Report demographics associated with digital divide issues

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

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subitem not at all important    ☐    ☐    ☐    ☒    ☐    essential

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### Does your paper address subitem 15-i? \*

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

"Participants' demographic variables including sex, age, weight, waist circumference, highest level of formal education (high school or less, higher education), occupation (retired, not-working (unemployed, homemaker, on disability pension, on long-term leave), artisan/trader/manager, senior executive/intellectual profession, intermediate occupation, employee, laborer), [...] were collected at baseline (M0) by the PAI (Physical Activity Instructor)."

"The characteristics of the patients are presented in Table 1."

### 16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

#### 16-i) Report multiple "denominators" and provide definitions

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

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subitem not at all important    ☐    ☐    ☐    ☒    ☐    essential

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### Does your paper address subitem 16-i? \*

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

The number of participants in each group included in the analyses are presented in figure 1 of the manuscript.



**16-ii) Primary analysis should be intent-to-treat**

Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	essential
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**Does your paper address subitem 16-ii?**

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

"To test effectiveness, data were analyzed using intention-to-treat principles."

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

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

Primary outcome : "At 12 months, the proportion of patients achieving PAG was significantly higher in the intervention group compared to the control group (81% vs 67% respectively, figure 2), OR=2.34 (95% CI 1.02-5.38; P=.045) (table 2)."

Secondary outcomes :

"At 6 months of follow-up, the achievement of PAG was not different between the intervention and control groups (69% and 70% of patients reached the PAG, respectively, figure 2), OR=0.95 (95%CI 0.45-2.01; P=.89) (table 2)."

The Quality of life assessment showed that the physical component subscale (PCS) score was significantly higher at M12 in the intervention group compared to the control group (figure 6): mean difference at M12 4.1 (95% CI: 1.9- 6.3; P<.001). At M6, the PCS score tended to be higher in the intervention group compared to the control group (PCS score = 2.1, 95%CI: 0.0-4.3; P=.055).

For the other secondary outcomes, if not statistically significant, the figures not stated in the text of the manuscript, they are presented on graphs.



### 17a-i) Presentation of process outcomes such as metrics of use and intensity of use

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

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subitem not at all important    ☐    ☐    ☐    ☐    ☐    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

Votre réponse

### 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

In the manuscript the effect sizes of binary outcomes are presented as follow : "At 12 months, the proportion of patients achieving PAG was significantly higher in the intervention group compared to the control group (81% vs 67% respectively, figure 2), OR=2.34 (95% CI 1.02-5.38; P=.045) "

"At 6 months of follow-up, the achievement of PAG was not different between the intervention and control groups (69% and 70% of patients reached the PAG, respectively, figure 2), OR=0.95 (95%CI 0.45-2.01; P=.89)."

### 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

The following 2 analyses were exploratory analyses :

"Nevertheless, time spent in front of a screen (computer or television) decreased significantly over the follow-up in the 2 groups both during weekdays and week-ends (table 3). "

"However, the mean waist circumference for the 2 groups had significantly decreased at 6 months by 1.9 cm (95%CI: -3.0 cm; -0.8 cm) and at 12 months by 2.4 cm (95%CI: -3.5 cm; -1.3 cm),  $P=.001$  and  $P<.001$  respectively."

**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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse

**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

"All serious adverse events (SAEs) were recorded and notified to the French clinical trials pharmacovigilance system."

"Safety

Adverse events recorded during the study are presented in table 5. None of the severe AE was attributed to the intervention. One patient reported an aggravation of a lymphedema in the left arm due to wearing a wrist pedometer. This adverse effect was solved thanks to physiotherapy."

### 19-i) Include privacy breaches, technical problems

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse

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

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

	1	2	3	4	5	
subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

Votre réponse

**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

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**Does your paper address subitem 22-i? \***

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

"This randomized controlled trial aimed to assess the long-term effectiveness of a program including an initial face-to-face coaching during spa therapy and web-and mobile-based coaching (adapted to the particular situation of the patients) in PA to meet PAG among older adults with chronic conditions. The results showed significantly more participants meeting PAG at one year in the intervention group compared to controls."





**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 ☐ ☐ ☐ ☐ ☐ 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

Votre réponse

**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 ☐ ☐ ☐ ☒ ☐ essential

Effacer la sélection



**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 relevance of a digital program of PA coaching needs to be considered in view of the difficulties of enlistment in the program. Despite an extension of the period of recruitment to the trial it was impossible to enroll the number of patients required by the sample size calculation. In part because it appeared that a lot of patients with a web connection and a smartphone were already meeting PAG."

"A greater number of patients were assessed at M12 in the control group (91/113) than in the intervention group (79/115) (figure 1). It is possible that patients of the intervention group had recognized by M2 the benefits of the program on their personal PA level and were prone to neglect responding to follow-up messages while controls persisted so as to have free access to the program after M12."

"The regular calls to participants in both groups (every two months), probably reinforced their personal involvement."

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

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

**21-i) Generalizability to other populations**

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

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subitem not at all important    ☐    ☐    ☐    ☐    ☐    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

Votre réponse



## 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.

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subitem not at all important    ☐    ☐    ☐    ☐    ☐    essential

## Does your paper address subitem 21-ii?

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

Votre réponse

## 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

ClinicalTrials.gov : NCT02694796

## 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 available on request from the principal investigator.

**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

"funded by AFRETH (Grant N° 2015-02) a non-profit independent organization"

AFRETH : French Association for spa research

The funder participated in the steering committee of the trial.

**X27) Conflicts of Interest (not a CONSORT item)****X27-i) State the relation of the study team towards the system being evaluated**

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

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subitem not at all important	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	essential

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### Does your paper address subitem X27-i?

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

Florie FILLLOL was employee of BIOMOUV and Sébastien PASCAL was CEO of BIOMOUV who provided the web and smartphone-based physical activity program.  
Christian-François ROQUES who is President of the Association Française pour la Recherche Thermale (AFRETH) Scientific Committee.

### About the CONSORT EHEALTH checklist

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

- ☐ yes, major changes
- ☒ yes, minor changes
- ☐ no

What were the most important changes you made as a result of using this checklist?

Votre réponse

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

Fullfill this formular including changes made in the manuscript took around 2 days



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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