Trials

GoPerio - Impact of a personalized video and an automated two-way text-messaging system in oral hygiene motivation: study protocol for a randomized controlled trial

--Manuscript Draft--

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Full Title:	GoPerio - Impact of a personalized video and an automated two-way text-messaging system in oral hygiene motivation: study protocol for a randomized controlled trial
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Abstract:	Background Oral hygiene is of paramount importance for the preservation of oral health, and for patients affected by periodontal disease establishing an effective oral hygiene routine is the first step of therapy. Several clinical frameworks have been developed to foster behavior change, such as motivation interviewing. However, two obstacles can be identified. First, patients tend to forget the advice they were given during the consultation. Second, it is hard to maintain motivation in the long-term, thus leading to relapse. An innovative eHealth solution was designed with the aim to tackle both obstacles and supplement the current clinical standard of care. The primary objective is to compare at 8 weeks of follow-up the full mouth plaque scores of study groups (eHealth plus standard of care vs. standard of care only). The main secondary objective is to compare at 8 weeks of follow-up the full mouth bleeding score. Methods/Design The “GoPerio” study is a multicenter, randomized, controlled trial assessing the impact of a novel eHealth concept for oral hygiene motivation (personalized video of oral hygiene routine available for the patient via a cloud server plus interactive text messages) in addition to the current standard of care (motivational interviewing plus tooth scaling and polishing). The minimum sample size required is 86 patients. Randomization will be performed (allocation ratio 1:1): test group (eHealth plus standard of care) vs. control group (standard of care only). The primary outcome is oral hygiene as measured by the full mouth (6 sites per tooth) plaque control record (PCR) index. The main secondary outcome is gingival inflammation as measured by the full mouth (6 sites per tooth) bleeding on probing (BOP) index. Both the primary and the main secondary outcomes are evaluated at 8 weeks of follow-up by blinded and calibrated examiners. The other secondary outcomes are patient satisfaction and patient behavior change and motivation. Discussion The study will investigate the value of an innovative eHealth approach to strengthen patient motivation for oral hygiene. If proven effective, such an approach would supplement the current clinical standard of care, resulting in improved clinical outcomes with negligible impact on productivity of a dental practice. Trial registration ClinicalTrials.gov Identifier NCT03109808 (registered in April 2017) Sponsor Hospices Civils de Lyon. BP 2251, 3 quai des Célestins, 69229 Lyon cedex 02. Protocol version 1.0 as of September 21, 2016.
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Response to Reviewers:	Dear colleagues, We would like to thank both reviewers for their work and for the relevant criticism they raised. The questions of reviewer 1 regarding the content of format of the text messages reminders highlighted the need for clarification in the manuscript. As such, a paragraph dedicated to the text message reminders was added to the manuscript from line 299 to line 320. We hope this brings the much needed information regarding the system we investigate. We also addressed reviewer 2's question regarding the technical platform for the video and whether they are available through a specific app or if a particular operating system is needed by adding the requested information to the manuscript (line 288 to line 292). Reviewer 2's concern regarding the inclusion criteria, especially the age of participants are relevant. When it comes to adoption of technology, age can be a very relevant factor. Aged patients may experience more difficulties. To encourage adoption in the elderly, we streamlined the user experience as much as possible, notably through the use of a web portal, rather than a dedicated application to view videos ; and the text reminders sent to patients contain a direct link to their video. This much needed clarification has been added to the manuscript in the Discussion section (lines 463 to 474) Reviewer 2 raised a valid point concerning the evaluation period. The 8-weeks follow-up considered in our protocol aims to evaluate the added value of our eHealth solution for the acquisition of a satisfactory oral hygiene routine, notably preliminary to initial periodontal therapy. This evaluation period is too short to allow the exploration of the long-term maintenance of this oral hygiene routine, a much needed element when considering maintenance of periodontally compromised patients after treatment of periodontitis. To address reviewer's concerns, we further clarified these elements in the discussion through additions lines 521 to 524 and lines 528 to 533. The rationale for choosing electric toothbrushes require further clarification, as highlighted by reviewer 2's comment. Our study focuses on the comparison between video + SMS and no video + no SMS so choosing one model of toothbrush for all patients was preferred, in order to reduce bias linked to the tool. Electric toothbrush were considered over manual toothbrushes as they have proven to be more efficient for plaque removal, and one can consider electric toothbrushes to be less technique sensitive than manual toothbrushes. We have brought more details to the manuscript and emphasized the need for further studies in that area. Revisions are appear lines 506 and 509-517. To answer reviewer 2's concern regarding the sample size, the sample size was calculated by biostatisticians who co-authored the manuscript. The relevant paragraph is located lines 190-198. We remain available to answer any additional question and

	provide all details between the sample size calculation and its underlying hypotheses if deemed relevant. We are thankful to reviewer 2 for spotting a mistake in the inclusion periods. We corrected that to take into account the actual start date of the recruitment (March 2017) and the projected end date for the end of inclusions (December 2019). Inclusion period had to be extended to meet the sample size. Corrections appear in the manuscript line 156. The question from reviewer 2 regarding other oral conditions that might be diagnosed during the course of the trial led us to provide further clarification. Modifications were made to the manuscript lines 226 and 228-232. We hope this addresses reviewer 2's concerns. Reviewer 2 raised points concerning the use of adjunctive chemical plaque control agents. Unfortunately, most guidelines available in the literature give a lot of lee-way for clinicians to adapt to the individual clinical situation (Tonetti MS, Eickholz P, Loos BG, Papapanou P, van der Velden U, Armitage G, et al. Principles in prevention of periodontal diseases. J Clin Periodontol. 2015;42:S5–11. doi:10.1111/jcpe.12368.). This situation is problematic for clinical trials as it may induce biases. We tried to clarify the way we would use antimicrobial agents in the course of the trial and also acknowledge the fact that the use of chemical agents should be recorded in the eCRF. Additions were made to the manuscript lines 242-245. A very important point regarding continuity of routine and care was raised by reviewer 2 when discussing if patients will have the financial conditions to follow the protocol taught to them. We have clarified that patients will be able to keep all the materials that were given to them during the study and that refills or replacement products are easily available in the market. Modifications to the manuscript appear lines 253-257. Regarding a possible follow-up visit a 1 year, reviewer 2 rightfully recommended for such visit to be conducted by researchers to standardize protocol. Unfortunately, due to French law, we cannot prevent the patient from requesting a follow-up visit at 1 year with an other care provider. If patient would choose another care provider for the 1 year check-up, they would automatically qualify as lost to follow-up for our study. However, should they accept to have a 1 year follow-up visit within the framework of our study, this examination would be conducted by the researchers with the same protocol. We tried to balance the ethical and legal aspects with the research and methodological considerations as best as we could. Further clarification was brought to the manuscript lines 357-359 and lines 531-533. Reviewer 2 highlighted the need to include the the Dental Visit Satisfaction Scale (DVSS) in supplementary material. We included the DVSS in the Supplementary File 1 and acknowledge that this inclusion will help readers to go in more details of our study. For the sake of harmonization, we have also added the behavioral questionnaire used in visit 3 in Supplementary File 2. Reviewer 2 requested further information regarding warnings / notifications about videos in the smartphones. This relevant information was clarified in the manuscript lines 291-292. Finally, we would like to thank both reviewers for the extensive work. We believe their comments and criticisms have helped improve the manuscript, both regarding the methodology and the clarity. We hope our answer fulfill their expectations and brought all necessary details. We remain available for further exchange and improvements. Best regards, Valentin GARYGA et al.
Additional Information:	
Question	**Response**
Covering letter concerning your	Dear Editor,

manuscript	We wish to submit a new manuscript entitled “GoPerio - Impact of a personalized video and an automated two-way text-messaging system in oral hygiene motivation: study protocol for a randomized controlled trial” for consideration by Trials. We confirm that this work is original and has not been published nor is currently under consideration for publication elsewhere. In this paper, we present the protocol for a multicenter randomized controlled trial evaluating an innovative approach for oral hygiene motivation. This trial is currently ongoing in France and Belgium. During the consultation, the dentist records a personalized video for each patient thanks to a miniature camera mounted on the dental loupes. This video depicts all procedures for oral hygiene and is tailored to the patient’s needs, tools, and skills. The video is sent to the patient on his smartphone or tablet via a cloud system. Additionally, personalized motivational text messages are automatically sent to the patient to increase adherence to their new oral hygiene routine. The novelty of our concept resides in the use of personalized videos, coming on top of a motivational interview with the patient. This solution is unique for each patient and as we make it available for them on their smartphones or tablets they can access reliable information anywhere, anytime. The use of text messages has proved beneficial to increase adherence to therapy in other chronic diseases. We wanted to investigate this technology for oral health too. We would like to share this protocol with the scientific community to be fully transparent and hopefully benefit from our peers’ opinions to further improve our work. As specified in the authors instructions we would like to propose the following potential reviewers: -Dr. Olivier HUCK, Université de Strasbourg, Strasbourg, France (huck.olivier@gmail.com - https://bit.ly/2CSF611) -Dr. Marjolaine GOSSET, Université Paris Descartes, Paris, France (marjolaine.gosset@parisdescartes.fr - https://bit.ly/2SvqzgY) As for competing interests, we declare that no authors or investigators received funding from industrial partners. However, both centers involved in the present research protocol received free-of-charge materials (electric toothbrushes, toothpastes, interdental brushes, dental floss, professional prophylaxis materials) and devices (video cameras). The industrial partners providing materials are listed in the manuscript. Nevertheless, the industrial partners did not have any involvement in the study design or in the analysis, collection and interpretation of the data, or in drafting of the manuscript. No other relationships or activities could appear to have influenced the submitted work. We confirm that all authors have approved the manuscript for submission and authorship complies by ICJME standards. Thank you for your consideration of this manuscript. Sincerely, Valentin Garyga
Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’.	Yes
We require registration of all clinical trials that are reported in manuscripts submitted to the journal. More information about trial registration, including the trial	NCT03109808

registries that currently meet all of the ICMJE guidelines, can be found in the FAQ section of “About ICMJE” at http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/. Please provide the following information where prompted: <hr> Enter the Trial Registration Number: as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’."	
Enter the name of the registry: as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’."	clinicaltrials.gov
Enter the URL of the trial registry record: as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’."	https://clinicaltrials.gov/ct2/show/NCT03109808?term=goperio&rank=1
Enter the date that you registered your trial (in mm/dd/yyyy format): as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’."	04-12-2017
Enter the date of enrolment of the first participant to the trial (in mm/dd/yyyy format): as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’."	04-12-2017
Was your trial registered before the first participant was enrolled? (i.e.	Yes

prospectively registered) as follow-up to "Is this study a clinical trial?<hr>A clinical trial is defined by the Word Health Organisation as ‘any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes’."	
Within your manuscript, have you also included details of your trial registration at the end of your abstract? - Name of the registry - Trial registration number - Date of registration - URL of trial registry record Example: Trial registration: ISRCTN, ISRCTN12345678. Registered 28 September 2014, http://www.isrctn.com/ISRCTN12345678 as follow-up to "Was your trial registered before the first participant was enrolled? (i.e. prospectively registered) "	I confirm I have provided trial registration details at the end of the abstract
Does your study have ethical approval?	Yes, and I have included the relevant documentation as an additional file
Has your study received funding?	Yes, the funding is internal or industry funded, and I have included the relevant documentation as an additional file
Is your study protocol reported in accordance with the SPIRIT Guidelines?	Yes, and I have included a populated SPIRIT checklist as an additional file and the SPIRIT figure is included in the main body of the manuscript
What stage of participant recruitment is your study at?	Participant recruitment is in progress

GoPerio - Impact of a personalized video and an automated two-way text-messaging system in oral hygiene motivation: study protocol for a randomized controlled trial

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ABSTRACT

Background: Oral hygiene is of paramount importance for the preservation of oral health, and for patients affected by periodontal disease establishing an effective oral hygiene routine is the first step of therapy. Several clinical frameworks have been developed to foster behavior change, such as motivation interviewing. However, two obstacles can be identified. First, patients tend to forget the advice they were given during the consultation. Second, it is hard to maintain motivation in the long-term, thus leading to relapse. An innovative eHealth solution was designed with the aim to tackle both obstacles and supplement the current clinical standard

of care. The primary objective is to compare at 8 weeks of follow-up the full mouth plaque scores of study groups (eHealth plus standard of care vs. standard of care only). The main secondary objective is to compare at 8 weeks of follow-up the full mouth bleeding score.

Methods/Design: The "GoPerio" study is a multicenter, randomized, controlled trial assessing the impact of a novel eHealth concept for oral hygiene motivation (personalized video of oral hygiene routine available for the patient via a cloud server plus interactive text messages) in addition to the current standard of care (motivational interviewing plus tooth scaling and polishing). The minimum sample size required is 86 patients. Randomization will be performed (allocation ratio 1:1): test group (eHealth plus standard of care) vs. control group (standard of care only). The primary outcome is oral hygiene as measured by the full mouth (6 sites per tooth) plaque control record (PCR) index. The main secondary outcome is gingival inflammation as measured by the full mouth (6 sites per tooth) bleeding on probing (BOP) index. Both the primary and the main secondary outcomes are evaluated at 8 weeks of follow-up by blinded and calibrated examiners. The other secondary outcomes are patient satisfaction and patient behavior change and motivation.

Discussion: The study will investigate the value of an innovative eHealth approach to strengthen patient motivation for oral hygiene. If proven effective, such an approach would supplement the current clinical standard of care, resulting in improved clinical outcomes with negligible impact on productivity of a dental practice.

Trial registration: ClinicalTrials.gov Identifier NCT03109808 (registered in April 2017)

Sponsor: Hospices Civils de Lyon. BP 2251, 3 quai des Célestins, 69229 Lyon cedex 02.

Protocol version: 1.0 as of September 21, 2016.

Keywords: Oral hygiene; Motivational Interviewing; Patient Education as Topic; Patient Compliance; Video; Text Messaging; Periodontal Diseases; Dental Plaque; Telemedicine; eHealth

BACKGROUND (592 mots)

Dental plaque is a bacterial biofilm that is responsible for most periodontal diseases when there is dysbiosis of the oral ecosystem, often due to a lack of oral hygiene [1]. The two main periodontal conditions are gingivitis and periodontitis [2]. In the experimental model of gingivitis, if oral hygiene is reinstated, inflammation is reduced and tissues heal *ad integrum* [3]. If left untreated and compounded by other factors (genetic, environmental, local, etc.), gingivitis evolves to periodontitis in susceptible people [4–6]. In addition to gum inflammation, periodontitis leads to a deeper destructive process targeting the tooth-supporting tissue such as the alveolar bone. Ultimately, this irreversible tissue destruction can lead to the loss of teeth [7]. Other well documented risk factors for periodontitis include smoking and diabetes [5, 8–10].

A key aspect of periodontal therapy is the instruction and motivation of patients for a satisfactory level of oral hygiene. Once oral hygiene is established, non-surgical and surgical periodontal care can be initiated. In adults, twice daily toothbrushing and daily interdental care (dental floss or interdental brushes) reduces considerably the amount of dental plaque accumulated on teeth [11–13]. Adequate plaque control reduces the prevalence and the severity of periodontal diseases [14]. It reduces the risk of tooth loss both for healthy patients [15] and for those enrolled in supportive periodontal therapy [16].

Several frameworks have been proposed to improve oral hygiene in periodontal patients, among which one can differentiate those that rely mostly on patient education, those that emphasize the use of technology, and those that combine patient education theories and the use of technology. Behavior change techniques can be used by the practitioner to enhance a patient's motivation for durable oral hygiene and healthy habits [17]. One such technique is motivational interviewing (MI), a patient-centered communication technique [18]. MI has been

successfully implemented in patient motivation in periodontology [19–22] as well as in smoking cessation advice [23]. Researchers have also proposed several solutions taking advantage of technology. Videos for oral hygiene instruction have not shown any difference when compared to a clinical consultation [24, 25]. But in these studies, the videos were pre-recorded and generic (i.e. non-personalized). Conversely, having a personalized video, filmed by the dentist or the dental hygienist during the consultation, displaying all steps for a correct oral hygiene routine could be worth exploring as patients may relate more easily with images of their own teeth. Frequent recalls have also been shown to increase long-term adherence in patient motivation for oral hygiene [26, 27], and it is of note that for chronic diseases text messages based recalls improved adherence to medication in several trials [28–32].

It is possible to combine patient motivation techniques and technological aspects to create innovative eHealth solutions. eHealth is defined as an "emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies" [33]. The eHealth concept proposed and evaluated in this randomized controlled trial (RCT) features three key aspects: a consultation taking advantage of MI, personalized oral hygiene videos accessible anytime on a smartphone via a cloud portal, and regular and interactive text messages to enhance patient adherence to the oral hygiene routine. To the best of the authors' knowledge, such a strategy has yet to be evaluated in a RCT.

Objectives and hypotheses

The aim of this randomized trial is to evaluate an eHealth concept for patient motivation for oral hygiene through the combined use of MI, a personalized oral hygiene video, and motivational interactive text messages.

The primary objective is the comparison of the level of oral hygiene as assessed by plaque scores (that range from 0 to 100%) of individuals who benefited from the control versus test patient education strategies at 8 weeks. The main secondary objective is the gingival inflammation as assessed by bleeding on probing (BOP) index (the values of which range from 0 to 100%) of the control and test groups at 8 weeks. Two secondary objectives will be also considered: the satisfaction after 8 weeks, and patient motivation for change after 4 and 8 weeks for each treatment arm. Interventions are further defined below.

The underlying hypothesis is that the eHealth concept for patient motivation for oral hygiene would allow better instruction and motivation for oral hygiene because it gives patients a constant access to a video summarizing their oral hygiene routine, and patients benefit from regular contact via text messages.

METHODS

Trial design

The SPIRIT Statement [34] and SPIRIT-PRO Extension [35] (for patient-reported outcomes) were taken into account for the design of the present clinical trial.

This is a multicenter randomized controlled trial with two parallel arms. For the primary objective and secondary objectives, only outcome examiners and data analysts are blinded to the allocated intervention (control or test patient education strategy). Patient randomization is done at the end of the first consultation so that patients and investigators are not aware of the allocation during the patient education and motivation procedure.

The randomization is performed (allocation ratio 1:1) for the type of patient education strategy (control vs. test) with a stratification based on center of inclusion, patient gender (male vs. female), and tobacco status (currently using tobacco vs. currently not using tobacco).

The flow chart of the study is presented in Figure 1 and the content of each visit is summarized in Figure 2.

Setting and participants

This study is carried out in two teaching hospitals, one located in France and the other in Belgium: the dental teaching hospital of the Lyon university hospitals (Lyon, France) and the department of periodontology of the Liège university hospital (Liège, Belgium). Patients will be included from March 2017 until December 2019.

Eligible patients are informed about the study by dentists and dental students working in the hospital. Then, a study investigator presents the study to patients and gives them information letters before inclusion. Ethical approval was obtained in both countries and patient consent is obtained and recorded in accordance with national regulations.

To be included in this trial patients must be 18 years old and over, be able to receive dental care, be capable to read, write, speak and listen to French language. They must have at least 20 teeth including at least 4 permanent molars and 4 permanent premolars forming premolar-molar interdental sites. They must own an Internet-enabled smartphone or tablet, have an electronic mail address, agree to be registered in the automatic text messages contact system, agree to come to the two follow-up appointments, and be covered under the national health insurance system. Exclusion criteria are : history of periodontal treatment (end of treatment < 1 year), currently enrolled in a periodontal treatment program, last oral hygiene instruction and motivation < 1 year ago, last tooth scaling and polishing < 1 month ago, removable partial or complete dentures, fixed or removable orthodontic appliances, allergy to benzoic acid, under treatment by an antiplatelet or anticoagulant drug, hemophilia, unable to answer questions, unable to perform twice daily toothbrushing, unable to perform daily interdental care, using more than once a week interdental brushes or dental floss, under guardianship, legally deaf or

blind, at risk of infectious endocarditis, planning to relocate to another city during the duration of the study. Non-inclusion criteria have been chosen to reduce loss to follow-up or unreliable results.

Medications taken by the patient less than 8 days before entering the study are recorded in the electronic case report form (e-CRF). History of or current renal condition, head and neck cancer, diabetes, current and past tobacco usage, as well as other current medical conditions must be reported.

No special concomitant care or intervention is prohibited after inclusion in the trial. Patients are specifically instructed to use the material provided for this trial: electric toothbrush (Philips Sonicare, Philips Personal Health France, Suresnes, France); toothpaste (Meridol gum protection, GABA France, Colgate-Palmolive, Bois-Colombes, France); interdental floss (Inava DentoFil Black, Pierre Fabre Oral Care, Castres, France and Meridol expanded dental floss, GABA France, Colgate-Palmolive, Bois-Colombes, France); interdental brushes (Inava Monocompact and Inava Trio Compact, Pierre Fabre Oral Care, Castres, France and Elmex interdental brushes, GABA France, Colgate-Palmolive, Bois-Colombes, France).

Sample size

A literature review found that behavioral interventions, similar to the patient education strategy explored in this trial, allow up to 15% reduction of dental plaque [21, 36–39]. However, at the best of the authors' knowledge, there is no publication examining the eHealth concept for patient motivation for oral hygiene proposed herein. A conservative estimate of 10% reduction in PCR index was therefore chosen for the test group compared to the control group.

A total of 86 patients enables to show a 10% difference PCR index between the 2 groups with 80% power, using a bilateral test with an alpha risk of 5%. At 8 weeks, 15% of patients are expected to be lost to follow-up (calculated by nQuery Advisor 7.0) [40].

To encourage recruitment, the investigators organize regular communications with colleagues of the teaching hospitals, involve student representatives in the process by having them promote the study among their classes, and regularly have the study leaflet as the desktop image of computers in the relevant hospital departments. In addition, students who refer a patient for inclusion in the protocol get extra points for their periodontology practical examination and the patient is referred back to them for the next phases of periodontal therapy.

Randomization

Randomization is performed using a computerized and centralized system via a specific website. A one-stage randomization is conducted stratified on the following potential confounders: investigation center (Lyon vs. Liège), patient gender (male vs. female), and patient current tobacco status (currently a tobacco user vs. not currently a tobacco user).

Because all patient characteristics must be entered in the e-CRF before interventions are assigned, sequence concealment is secured.

Implementation

The stratification algorithm was implemented by statisticians and methodologists independently of investigators. Patients are assigned to intervention arms by the center coordinator.

Intervention

Visit 1

At the first visit (T0), eligibility criteria are verified by an investigator. Information about the study is then given orally and by the means of an information letter to the patient. Patient

consent is sought and registered according to the national regulations. The inclusion is then formalized by the creation of a patient file in the e-CRF

A clinical examination is performed to assess periodontal health and level of oral hygiene. Other oral conditions (such as dental caries, TMJ disorders, failing restorations, etc.) will be further treated by referrals inside the dental teaching hospital according to usual procedures and will not be considered in this study. Whenever clinically and ethically possible, the treatment of such conditions will be delayed for a maximum of 8 weeks until the end of the study in order not to interfere with the evaluation of periodontal parameters (e.g. reducing local plaque retention factors by repairing or replacing a failing filling). If treatment cannot be delayed, it will be recorded in the e-CRF.

Then, a 20-minute MI session is conducted. All investigators apply the same structure of MI to all patients following a dedicated protocol available in the study folder. This MI protocol is arranged around five themes: reason for seeking consultation, dental and medical history, everyday consequences of periodontal or dental problems, current routine of oral hygiene, knowledge of and willingness to get required dental and medical care. Such a framework was previously validated in a RCT and led to better results than patient instruction alone [36]. The patient is instructed and motivated for a tailored regimen of oral hygiene following international recommendations: twice daily electric toothbrushing with a toothpaste containing fluoride agents, the use of dental floss or interdental brushes, and adjunctive chemical plaque control agents if needed [11–13, 41–43]. Adjunctive chemical plaque control agents could be used for instance in case of intense gingivitis to help reduce the total bacterial load. Their use would be limited to as few patients as possible and for the shortest duration achievable [41], to reduce interference with results. If such agents must be used, it will be recorded in the e-CRF.

The use of an electric toothbrush, interdental brushes, dental floss and toothpaste is demonstrated to the patients by investigators. The patient then have to demonstrate use

themselves and reinstruction is performed if needed. This MI session is provided to all patients, irrespective of their allocation (test vs. control). All the required materials, including the electric toothbrush are given to the patient during the MI session in sufficient quantity for the study duration. Patients are specifically instructed to use these tools, and only these, during the study. An electric toothbrush was chosen as these have shown, with a moderate level of evidence, to lead to better plaque control and better gingivitis reduction than manual toothbrushes [43]. After the study, patients can keep all materials to continue using them. Replacement heads for the electric toothbrush, and refills for interdental brushes, floss or toothpaste are easily available for the patients and at a relatively low cost. The end of the study should not prevent them from following the same oral hygiene routine on the long run if they wish to.

After the MI session, an outcome examiner conducts clinical data collection. The clinical data collection for the primary outcome is conducted using a dental plaque disclosing agent, with lip and OptraGate cheek retractors (Ivoclar Vivadent France, Saint-Jorioz, France), and under constant suction.

According to the manufacturer's information, the TriPlaque disclosing agent (GC Europe, Leuven, Belgium) appears as different colors according to biofilm maturation; new plaque appears as pink-red, mature plaque (> 48 hours) as blue-purple, extra high-risk plaque (pH < 4.5) appears as light blue.

For data collection, the PCR index [44] is used with 6 sites per teeth (disto-buccal, buccal, mesio-buccal, mesio-lingual, lingual, disto-lingual). All colors are considered as indicating the presence of plaque and therefore the site is coded "1" by the outcome examiner. If no plaque is present, the site is coded "0". The examination is conducted visually using loupes and a loupe-mounted light emitting diode; during the examination a periodontal probe is used on the tooth surface with an aim to avoid false-positives and false-negatives.

The clinical examination for the secondary outcome is conducted immediately thereafter. A periodontal probe is used to assess the BOP index with six sites per tooth (disto-buccal, buccal, mesio-buccal, mesio-lingual, lingual, and disto-lingual). Criteria for the site to be coded "1" is bleeding within 30 seconds of probing [45], otherwise the site is coded "0".

Then, the investigator records the personalized oral hygiene video. This video is recorded for all patients. The investigator uses a loupe-mounted miniature camera connected to a computer (Futudent Educam, Novocam Medical Innovations Oy, Helsinki, Finland). The video lasts approximately 3 minutes and displays the use of the electric toothbrush the interdental brushes, and the dental floss. It contains audio instructions summarizing what was said to the patient during the consultation, and is to be watched while brushing teeth.

After the video recording, the clinical part of the consultation is finished. Patients are then randomized by the center coordinator. Patients allocated to the control group are not given any further detail beyond their allocation. Patients allocated to the test group are registered in the text messages system and their personalized video is uploaded to the cloud portal by the investigator. The investigator instructs them on how the cloud portal and the text messages system work. Both the cloud portal and the text messages system are secured (see Data management, Ethical considerations, and Discussion sections). The cloud portable is accessible via any smartphone, tablet or computer with a web browser, irrespective of their operating system, and there is no need to install an application in an attempt to maximize technical compatibility. As no application is installed, no notifications will be used to remind the patient about watching the video: only text messages will be used.

The difference between control and test groups is the availability of the personalized oral hygiene video through the cloud server and the registration of the patient in the interactive text messages system. The two follow-up appointments are scheduled, and the visit is brought to

an end. Patients in both groups are not contacted by investigators between visits, except for administrative reasons such as rescheduling an appointment.

Text reminders

All text reminders sent to patients have the same structure : salutation, a piece of information regarding oral hygiene and oral health, a question as to whether the patient is compliant to the oral hygiene regiment that was prescribed, an invitation to view the oral hygiene video and a direct link to it, a recall of the date of the next appointment, greetings, and a link to opt-out of the text reminders service (as required by law). The piece of information regarding oral hygiene and oral health varies across messages, in an attempt to keep patients interested in the messages by avoiding repetitions and providing them with new information. This piece of information is chosen in a randomized fashion, and once it has been used, it cannot be used in further messages.

Twelve messages are automatically sent during over the course of the study based on the following schedule: the day of visit 1 (V1), the day after V1, two days after V1, a week after V1, 2 weeks after V1, 3 weeks after V1, the day before visit 2 (V2), the day of V2, 1 week after V2, 2 weeks after V2, 3 weeks after V2, 1 day before visit 3.

The patient can answer the text messages to tell the investigators if he is or not adherent with the oral hygiene routine that was prescribed to him. To do that, he can reply to the text message he received. The system will register his answer in the database and initiate an automated reply. If the patient is adherent, the reply will include elements of positive reinforcement. If the patient is not adherent, the reply will attempt to play down the situation, reassure the patient and offer to discuss this issue at the next appointment. Enough messages have been written to ensure that they are never repeated. All interactions with the patient through text messages are registered in a database to allow descriptive analysis.

Visit 2

At the second visit (T0 + 4 weeks), patients are first asked to complete a self-administered electronic questionnaire about their motivation and behavior in terms of oral health [46] that is directly linked to the e-CRF and investigators are blinded to answers. Then, a short (<5 minutes) recall about oral hygiene methods is proposed to the patient and conducted by the investigator if needed.

A brief clinical examination is conducted, and the outcome examiner then collects the clinical data. Data collection is conducted following the same protocol as for the first visit. Results are delivered to both the investigator and the patient, and are stored in both the e-CRF and the patient's electronic healthcare records.

The investigator then conducts a full-mouth supra- and juxta-gingival tooth scaling and polishing (Acteon ultrasonic tip number 1 and Newtron LED handpiece, Satelec Acteon, Merignac, France). The investigator ensures thorough removal of calculus but avoids instrumenting the gingival pockets. Following completion of the scaling, patients are invited to rinse with a solution containing 0.12% chlorhexidine digluconate (Paroex, Sunstar France, Levallois Perret, France).

Additional supplies of interdental brushes and floss are given to the patient if required. The next appointment is confirmed, and the second visit is brought to an end.

Visit 3

At the third visit (T0 + 8 weeks), patients are first asked to complete the same questionnaire about their motivation and behaviors for oral health they completed at the second visit. Then, a short (<5 minutes) recall about oral hygiene methods is proposed to the patient and conducted by the investigator if needed.

A brief clinical examination is conducted, and the outcome examiner then collects the clinical data following the same protocol as for the first visit. Results are delivered to both the investigator and the patient, and are stored in both the e-CRF and the patient's electronic health records.

At the end of the appointment, the patient is asked to complete a satisfaction questionnaire specially designed for dental care (Dental Visit Satisfaction Scale [47]). Again, data is directly entered by the patient in the e-CRF and investigators are blinded to answers.

Participation of the patient in the study is complete at the end of the third visit. Should the patient require further treatment, they are referred to the relevant departments following standard hospital protocols. If the patient does not need further treatment, they are informed that they should seek an appointment in 1 year for a check-up, either with the staff of the dental teaching hospital or with another dental care provider. The possibility to consult with another dental care provider is by law an inalienable right of the patient. The Ethics committee emphasized that it should be reminded to the patient.

Various strategies are implemented to improve adherence to intervention protocols: the investigators follow dedicated written protocols to structure the MI (T0), to harmonize the oral hygiene videos (T0), and for recalls about oral hygiene (T0 + 4 weeks and T0 + 8 weeks).

Outcome measures

Data collection is performed at 0, 4, and 8 weeks after patient inclusion by three blinded independent and calibrated outcome examiners.

For the primary objective (oral hygiene) and the main secondary objective (gingival inflammation) the outcome will be the value of indices collected during the third visit (8 weeks of follow-up). Values range from 0 to 100%.

Two additional secondary objectives will be also considered: patient satisfaction after 8 weeks, and patient motivation for change after 4 and 8 weeks for each treatment arm. For the first secondary objective (patient satisfaction after 8 weeks), the Dental Visit Satisfaction Scale questionnaire [47] comprises 10 multiple choice questions (MCQ) scored on a 5-point Likert scale, and explores three aspects of patient satisfaction: information-communication, understanding-acceptance, and technical competence (Supplementary material 1). For the second secondary objective (patient motivation for change after 4 and 8 weeks), a questionnaire featuring 12 questions (MCQ or binary) derived from previous publications is used [46] (Supplementary material 2). Results from this questionnaire would allow a preliminary understanding of psychological factors predictive of patient motivation and readiness to change behavior.

Data collection methods

To promote data quality, investigators and outcome examiners, who will assign scores, are trained in the plaque and gingival inflammation indices by means of group training sessions on live patients. To evaluate calibration on the primary outcome (plaque control), investigators and examiners are trained on a large number of pictures of teeth; inter-rater agreement is measured using the Kappa coefficient. Group training sessions and inter-rater agreement assessment are conducted before the beginning of patient inclusion.

For the primary and the main secondary outcome measures, data collection forms are generated through a public online platform [48]. For the patient-reported outcomes (remaining secondary objectives), patients enter their answers to the questionnaires directly on a dedicated and password-protected page of the e-CRF. No particular reward to promote participant retention and complete follow-up has been instated.

Data management

Data are entered by investigators and outcome examiners to the e-CRF. Fields cannot be left blank. Interactive data controls will be applied for value ranges and presence of impossible values as well as between-form coherence. A patient-operated e-CRF allows for the collection of patient-reported outcomes without intervention of study investigators. Data will be kept anonymous, with high-level security storage, and encryption of all data transfers, in compliance with French regulatory and ECRIN (European Clinical Research Infrastructure Network) requirements [49].

Statistical methods

The statistical unit for analysis will be the patient. All teeth of the patient are considered for data collection but unerupted, impacted, or fractured teeth are excluded (site-related exclusion criteria). Six sites per tooth are examined.

The demographic and clinical characteristics of patients will be described for both the test and control groups with mean and standard deviation or median and interquartile ranges for quantitative variables, and number of subjects and percentages for qualitative variables. The analyses will be performed according to the intention-to-treat principle modified to include only patients with available outcomes.

To respond to the primary objective, the mean plaque score in the test and control groups at 8 weeks will be calculated and compared using the Student's *t*-test for unpaired data. The plaque score at third visit will be modelled using a hierarchical model accounting for the correlation of the measures per patient as well as any possible inter-practitioner heterogeneity. The model will be adjusted on randomization stratification factors (center of inclusion, patient gender, and tobacco status) as well as the baseline value collected at the first visit. If necessary, other

adjustment factors might also be considered. The main secondary objective (bleeding on probing) will be analyzed using the Student's t test (nonparametric test whenever relevant).

In cases of patient non-compliance with follow-up visits, sensitivity analyses will be performed using the last outcome examiner's assessment (last observation carried forward). Additional sensitivity analyses will be performed considering all missing data as equal the test or control group's mean values for the given visit. Candidate factors for subgroup analyses are patient age, patient gender, diabetic status, tobacco status, at least one general medical condition.

Data monitoring, harms, and auditing

The data will be monitored by an independent clinical research assistant who will compare the data entered in the e-CRF with those in the patient's electronic health records. In case of disagreement, the patient's physician will be asked to clarify the data. No interim analysis is planned. Concerning harms monitoring, specific adverse event forms can be accessed in the e-CRF. Trial management may be audited by the Agence Nationale pour la Sécurité du Médicament et des Produits de Santé (ANSM, French medicines agency) at any time; the audit would be independent of investigators and the sponsor.

Dissemination of results

The Consolidated Standards of Reporting Trials (CONSORT [50]) guidelines, CONSORT Extension for Patient-Reported Outcomes in Randomized Trials (CONSORT PRO Extension [51]) and the CONSORT Extension for Electronic and Mobile Health Applications and online Telehealth (CONSORT-EHEALTH [52]) guidelines will be used to report the results of this study and the results will be published in international peer-reviewed journals. Authors of the publications will be those involved in the elaboration of the protocol, the implementation and conduct of the trial, and the drafting of the manuscript and report. The results related to the

main objective will be authored by the coordinator, the methodologists, the investigators, the outcome examiners, and others who will have significantly contributed to the planning of the trial, its implementation, or the drafting of the report.

A summary of the study results will be posted on ClinicalTrials.gov to allow general access to the findings. Study participants will be informed about the study results.

DISCUSSION

The inclusion and non-inclusion criteria for this RCT require patients to have at least 20 teeth and 4 premolar-molar interdental sites. Such criteria can lead to the exclusion of patients affected by severe periodontal disease with several lost teeth. The external validity of the study for this particular patient population should be interpreted with caution. Yet, two reasons led to this choice. First, the eHealth concept proposed in this trial is applicable in primary prevention (prior to the onset of any periodontal disease), as well as in secondary prevention (gingivitis) and tertiary prevention (periodontitis). Second, the statistical unit for analysis is the patient. As such, estimates for patients with few remaining teeth could be less reliable and the planned statistical analysis does not allow for weighting results from different patients according to number of teeth. Other inclusion and non-inclusion criteria, as well as the overall study methodology are in line with the recommendations from the Cochrane Oral Health Group [38, 53].

Restricting patients' age to a younger group could be discussed as engagement of patients with eHealth is negatively correlated with age although correlation coefficients are small [54, 55]. But other factors such as educational attainment level [54, 55] and technophilia [56] also influence patient's attitude towards eHealth. As such, researchers and developers should take into consideration these factors and others in order to overcome barriers to eHealth for the public they aim at [57, 58]. Application design and user experience are important

elements in that regard, especially for an elderly population [59]. By keeping the cloud interface as minimal as possible, we aimed to make it as accessible as possible. Also, this influenced the choice for a platform that does not require to download and install an application, as it runs entirely within the web browser. Finally, the inclusion of a direct link to the patient's video in the text reminders further reduces such obstacles as patients only need to click on that link and enter their credentials to consult their video.

The choice of a given plaque index has an impact of the statistical analyses – and likely on the outcomes. Several plaque indices have been developed, with different fields of application [60]. The modified PCR index chosen for this study records presence or absence of plaque (binary outcome) on 6 sites per tooth. Some indices are more research-oriented such as the Turesky modification of the Quigley-Hein Plaque Index that records plaque as an ordinal outcome with 6 levels [61, 62] or the Rustogi/Navy Plaque Index that records plaque still as a binary outcome but on 9 sites per tooth [63]. An ordinal outcome and more sites per tooth dramatically increase the sensitivity of the index, thus allowing the detection of smaller differences between groups [64, 65]. While the original PCR index proposed by O'Leary et al. used 4 sites per tooth [44], it was decided for this RCT to use 6 sites per tooth to achieve a balance between clinical practicability and precision for plaque assessment. Also, using a plaque disclosing agent facilitates the detection of plaque [66] but a number of false positives were detected during the calibration phase of the trial. Taking this finding into consideration, outcome examiners were instructed to use a periodontal probe on the tooth surface when in doubt, to clear any uncertainty about plaque presence or absence.

In terms of internal validity, the sources of bias are limited by the use of centralized randomization (selection bias), strict prospective data record and monitoring (information bias), and blinded outcome examiners (performance and detection bias). However, because of the

nature of the investigation, the patients cannot be blinded. Also, investigators are not blinded but as the randomization is done at the end of the first visit, it ensures that investigators are not biased when performing the MI and recording the video.

A factorial design would have allowed to explore any interaction between the patient education strategy (control vs. test eHealth strategy) and the type of toothbrush recommended during the consultation (electric vs. manual toothbrush). One might consider that correct demonstration is of major importance for manual toothbrushes and that electric toothbrushes are less dependent on a patient's brushing technique. Two reasons led to the choice of a two parallel arm design with electric toothbrushes for all participants. First, the sample size for a full factorial design (including interactions) would have been of 508 patients without taking into account patients lost to follow-up. This was beyond the recruitment capacity of the centers involved so either electric or manual toothbrushes had to be selected for all patients. Second, a Cochrane review established with a moderate level of evidence that electric toothbrushes are more effective than manual toothbrushes for plaque removal by 11% and up to 21% when follow-up is over 3 months [43] so choice was made to favor electric toothbrushes.

To use only one type of toothbrush for all patients also helps to suppress a potential bias due to the variation in cleaning efficacy between different models of toothbrushes, manual or electric. However, to generalize the results to all toothbrush designs and validate the added value of our eHealth solution (video + SMS), further studies would be needed.

While electric toothbrushes are more expensive than manual ones, cost to patients was not an issue for this trial as all oral hygiene materials are provided to them. Lastly, some electric toothbrushes can be connected to smartphones, which sounds a promising area of research for enhanced interaction with the patients and adherence monitoring.

Patient compliance for oral hygiene is of paramount importance for oral health [15, 67], and patient motivation is the first step of periodontal therapy and instrumental care should not be initiated before plaque control is satisfactory. The focus of the present study is to evaluate the added value of a eHealth platform (video + SMS) for the acquisition of an effective oral hygiene routine. As such, an 8-weeks follow-up is acceptable, and fits with the recommendations from the Cochrane Oral Health Group [38, 53].

However, when patients enter supportive periodontal therapy, oral hygiene should be maintained over time in order to entail long-term tooth loss: in a 10-year cohort study, Eickholz et al. found that an increase of 10 points of the PCR index was associated with a risk ratio of 1.57 for tooth loss [16]. As such, should the stability over time for oral hygiene adherence be investigated, a much longer follow-up, for instance 1 year, would be required. A 1-year follow-up visit could be organized after further approval by the Ethics committee. Such possibility has been expressly incorporated in the file submitted to the Ethics committee. If a 1-year visit is scheduled, the calibrated researchers from the original 8-weeks study will be responsible for it, in order to standardize protocol.

The eHealth concept assessed in this RCT aims to take advantage of MI for patient motivation and to create a supportive environment at home through the use of videos and text messages. According to 2016 Eurostat survey, respectively 78% of Belgian and 71% of French residents used their smartphones to access Internet, as often or more often than desktop computers, laptops and tablets [68]. This motivated the choice of a cloud platform compatible with smartphones so that a patient can view his video anytime.

As the video is recorded by a healthcare professional, the information delivered through it is of adequate quality. The burden of recording the video is minimized by the small size of the camera, as it can be kept on the dental loupes all the time. Also, the structure of the

consultation can be optimized by each practitioner according to their wishes. Recording the video requires less than 5 additional minutes for the clinician, which is reasonable as the latest findings suggest that 50% of European periodontal practitioners spend more that 15 minutes for the first phase of patient education before instrumental care [69].

Overall, several barriers and facilitators have been identified for the implementation of eHealth solutions [70]. A recent systematic review indicates that one of the key obstacles is when systems require users to manually enter a lot of data [71]. With the computer framework used in this RCT, while recording and sharing the video is straightforward, the system supporting text messages is more cumbersome. A gateway to the telephone network had to be developed separately from the electronic health records system of the teaching hospital and of the camera software. When registering a new patient in the text messages database, several steps are needed, and the process takes 5-10 minutes. While acceptable in a research environment, these extra steps might affect productivity in a private dental practice. Further integration of such systems into various practice management software could help streamline the process.

The legislative and regulatory environment should also be taken into consideration. For the video recording, it might be required in some settings to seek and record patient consent, as it would be for photographs. Regarding the cloud platform, the solution proposed by the camera manufacturer fully complies with the new European Union General Data Protection Regulation requirements and relies on a certified cloud provider (Microsoft Azure). Similarly, the telephone network gateway is secured, and all communications are encrypted. If this eHealth concept is to be disseminated to private practices, practice owners and service providers should pay great attention to the applicable legal and regulatory requirements, in particular regarding who is responsible for data confidentiality.

The present research focuses on the assessment of a novel eHealth concept linking proven behavior change techniques and mobile technology. After motivation for oral hygiene in the dental office, the proposed concept aims to help keep the link with the patient at home and strengthen their long-term commitment for a good oral hygiene routine. The availability of new data should help make a case for an increased use of eHealth solutions by dental practitioners.

Trial status

The trial is currently in the recruitment phase.

Abbreviations

ANSM: Agence Nationale pour la Sécurité du Médicament et des Produits de Santé (French medicines agency, independent state agency)

BOP: bleeding on probing

CNIL: Commission Nationale de l'Informatique et des Libertés (National Commission for Information Technology and Individual Freedom, independent state agency)

CONSORT: Consolidated Standards Of Reporting Trials

CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth

CONSORT-PRO: Consolidated Standards Of Reporting Trials - Patient-Reported Outcomes

e-CRF: electronic case report form

ECRIN: European Clinical Research Infrastructure Network

MCQ: multiple choice question

MI: motivational interviewing

RCT: randomized controlled trial

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

SPIRIT-PRO: Standard Protocol Items: Recommendations for Interventional Trials – Patient-Reported Outcomes

Ethical considerations

The local ethics committee (Comité de Protection des Personnes Sud-Est IV) in Lyon and the ethics committee of the university hospital of Liège (Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège) have approved the study protocol (registration numbers: 16/065 A 16-381 and B707201731667 2017-56, respectively). The protocol is registered with the ANSM (registration number: 2016-A01549-42) and on ClinicalTrials.gov (registration number: NCT03109808). All amendments to the protocol will be justified, submitted to the scientific board, accepted by the ethics committees, and recorded by the ANSM. Changes and amendments will be also recorded on ClinicalTrials.gov. Informed consent will be obtained from participants after the trial is explained to them by an investigator, examiner or coordinator of the corresponding center. Patients are informed that they have the right to withdraw from the study at any time without giving a reason. Regardless of withdrawal, patients will be provided any treatment in their best interest. Withdrawal will be documented. Procedures for data confidentiality were audited by the Commission Nationale de l'Informatique et des Libertés (CNIL, French data protection authority); last and first names of included patients are not recorded in the database.

No data monitoring committee is needed for the GoPerio trial as no or very few serious adverse events are expected from this study limited to patient education and routine dental prophylaxis. No interim analysis is planned.

Availability of data and material

Access to the full protocol can be granted to anyone upon request. The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interest

Authors and investigators did not receive any funding from the industrial partners. However, all centers involved in the present research protocol received free-of-charge materials (electric toothbrushes, toothpastes, interdental brushes, dental floss, professional prophylaxis materials) and devices (video cameras).

The industrial partners providing materials are:

- Futudent / Novocam Medical Innovations Oy, Helsinki, Finland
- Philips Personal Health France, Suresnes, France
- GC Europe NV, Leuven, Belgium
- Ivoclar Vivadent France, Saint-Jorioz, France
- Pierre Fabre Oral Care, Castres, France
- GABA France, Colgate-Palmolive, Bois-Colombes, France
- Komet France SA, Paris, France

No other relationships or activities could appear to have influenced the submitted work.

The industrial partners did not have any involvement in the study design or in the analysis, collection and interpretation of the data, or in drafting of the manuscript.

Responsibilities

The coordination center as a member of sponsor organization is responsible for overall data management, monitoring, and communication between all sites, and general oversight of the

conduct of the project. The investigator as a member of sponsor organization is responsible for submitting the report for publication.

The coordination center is accredited by the European Clinical Research Infrastructure Network (ECRIN: http://www.ecrin.org).

Authors' contributions

- BG, KG, VG and FP participated in conception of the study and its design. VG was the main author of this manuscript. BG, KG and FP contributed equally to this manuscript.

- DMB participated in the design of the study and is responsible for the sample size calculation and biostatical analysis. She contributed to this manuscript.

- FG and PN supervised the design and coordination of the study. They contributed to this manuscript.

- BG supervised the coordination, in accordance with the international guidelines, for the centers of Lyon and Liège. BG and KG coordinated the Lyon center. FL coordinated the Liège center.

- FP and VG were the operators.

- BT, JS, KG and WA were the outcome examiners.

- All authors read and approved the final manuscript.

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The members of the coordination center are: Halla Djadoudi (coordinator), Hélène Lozano (monitor), Patrick Grivot (data manager), Delphine Maucort-Boulch (Biostatistics), Patrice Nony (methodologist) and François Gueyffier (methodologist).

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Figures

Figure 1, title:

Flow chart

Figure 1, legend:

[1] PCR = plaque control record

[2] BOP = bleeding on probing

[3] DVSS = dental visit satisfaction scale

Figure 2, title:

Content of the study visits

Figure 2, legend:

[1] PCR = plaque control record

[2] BOP = bleeding on probing

Figure 1 Flowchart

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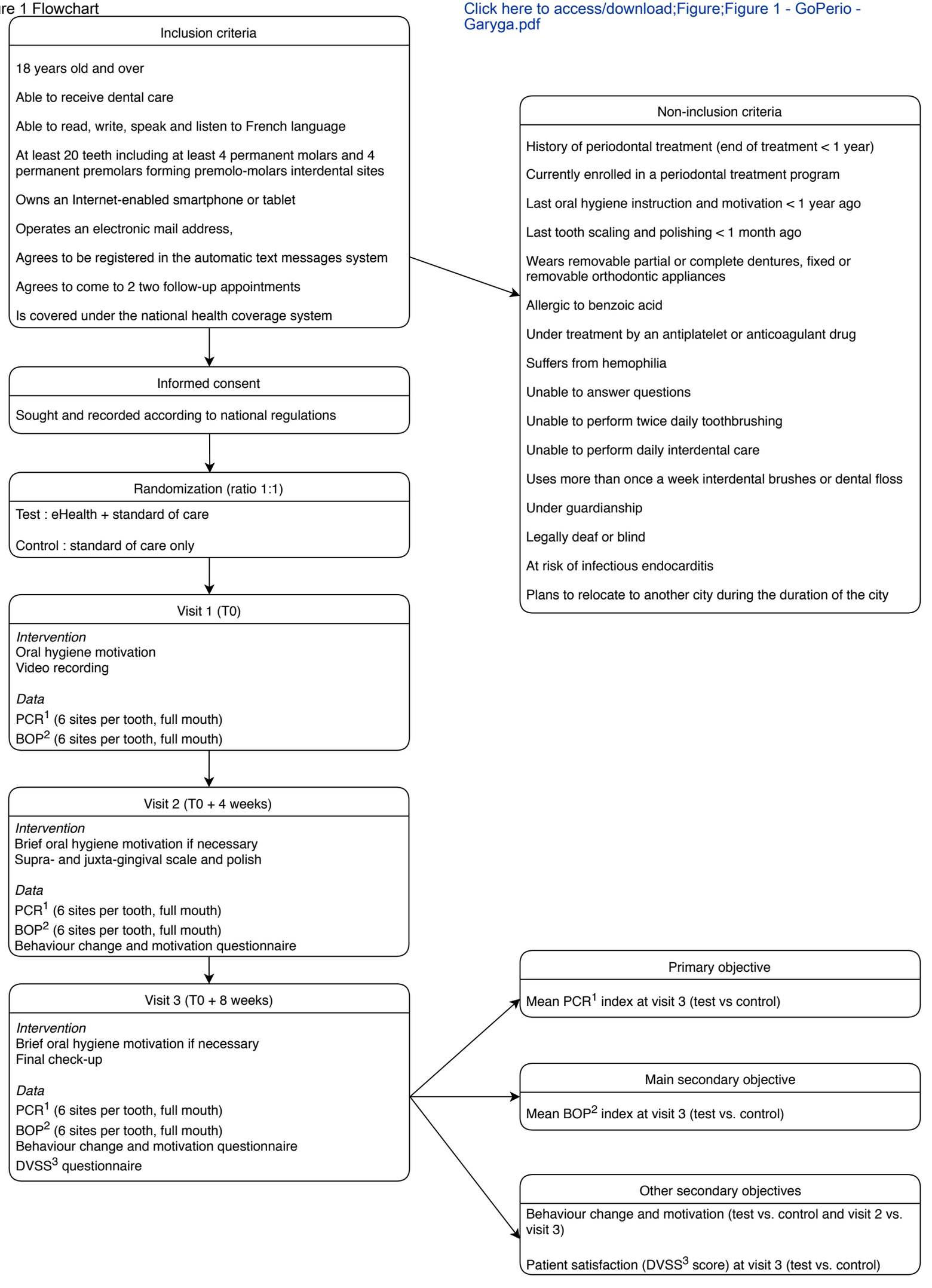
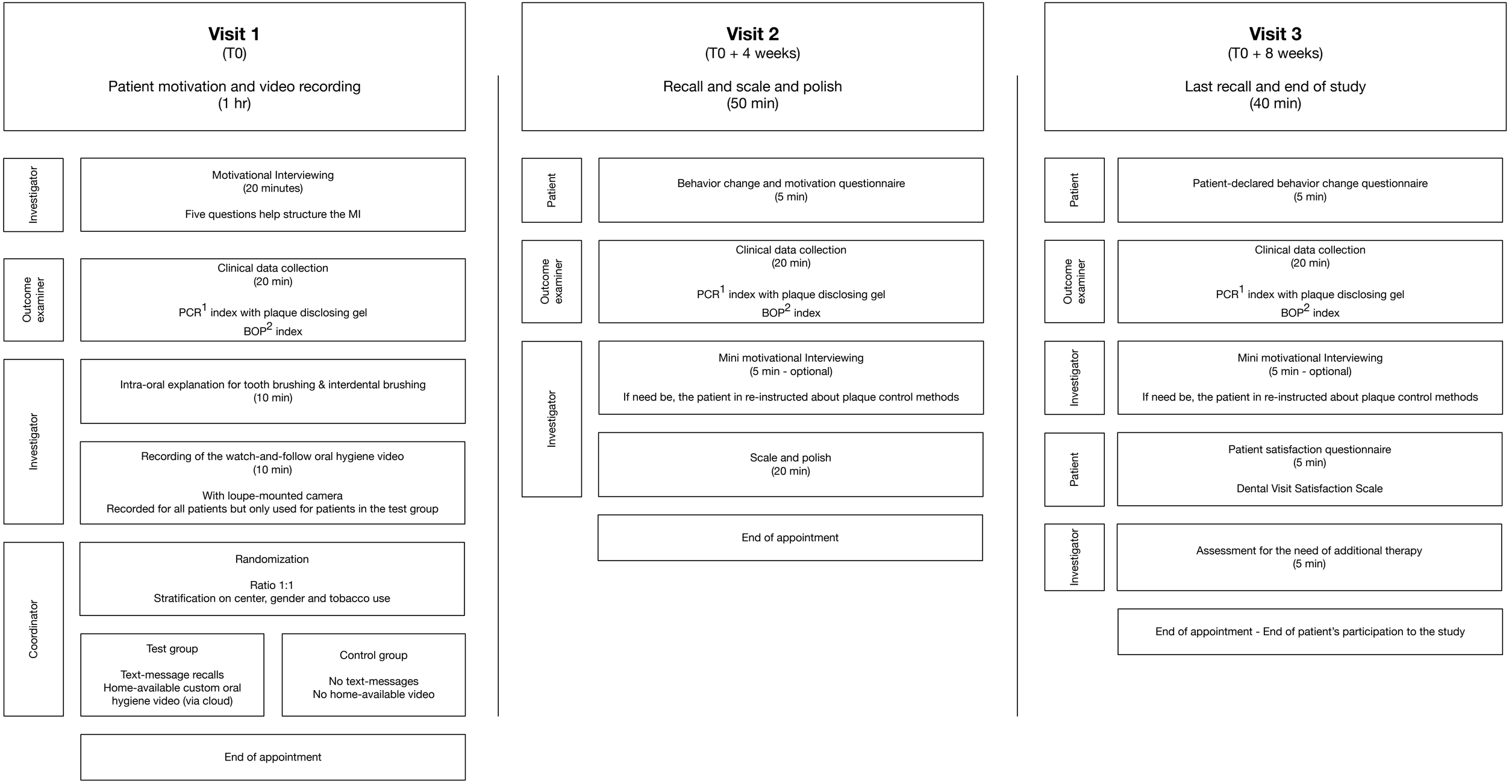


Figure 2: Schedule of enrolment, interventions, and assessments

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		**Close-out**
TIMEPOINT	*Before t_0*	*t_0*	*First visit (t_0)*	*Second visit (t_0 + 4 weeks)*	*Third visit (t_0 + 8 weeks)*
ENROLMENT:					
Eligibility screen	**X**				
Informed consent	**X**				
Registration in eCRF	**X**				
Medical and dental history, ongoing medications	**X**				
Allocation		**X**			
INTERVENTIONS:					
Motivational interviewing			**X**		
Oral Hygiene video recording			**X**		
Test - Video on cloud & text messages			◆—	—	—◆
Control – Video not available & no text messages			◆—	—	—◆
Tooth scaling and polishing				**X**	
Brief motivational interviewing				**X**	**X**
Assessment of the need for additional therapy					**X**
ASSESSMENTS:					
Stratification variables (Center, Gender, Smoking status)		**X**			
Dental plaque (Plaque Control Record)			**X**	**X**	**X**
Gingival inflammation (Bleeding On Probing)			**X**	**X**	**X**
Patient motivation (ad-hoc questionnaire)				**X**	**X**
Patient satisfaction (Dental Visit Satisfaction Scale)					**X**
Clinical time spent with patient (minutes)			**X**	**X**	**X**

Figure 3 Content of visits

Click here to access/download;Figure;Figure 3 - Content of the study visits.pdf



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Yes	No	NA	Page of manuscript
Administrative information						
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	X			1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	X			3
	2b	All items from the World Health Organization Trial Registration Data Set			X	
Protocol version	3	Date and version identifier	X			
Funding	4	Sources and types of financial, material, and other support	X			22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	X			1, 23-25

	5b	Name and contact information for the trial sponsor	X			3
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	X			23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	X			23,24
Introduction						
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	X			4,5
	6b	Explanation for choice of comparators	X			4,5
Objectives	7	Specific objectives or hypotheses	X			5,6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	X			6

Methods: Participants, interventions, and outcomes						
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	X			6,7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	X			7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	X			9-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)			X	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	X			13
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial			X	

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	X			13,14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	X			9-13 and Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	X			8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	X			8

Methods: Assignment of interventions (for controlled trials)						
Allocation:						
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	X			9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	X			9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	X			9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	X			6,12,13

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial			X	
Methods: Data collection, management, and analysis						
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	X			10-12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	X			14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	X			14

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	X			15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	X			15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	X			15
Methods: Monitoring						
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	X			16,17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial			X None are planned	(16

Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	X			16
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	X			16

Ethics and dissemination						
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	X			16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	X			16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	X			21,22
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable			X	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	X			16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	X			22,23

Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	X			17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation			X	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	X			17
	31b	Authorship eligibility guidelines and any intended use of professional writers	X			17
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	X			17
Appendices						
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	X			7 (Available upon request from authors)

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable			X	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.