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Effectiveness of a multifaceted program to improve interpersonal skills of physicians in medical consultations – a randomised controlled trial (EPISIC)

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Short title: Factors associated with interpersonal skills

Abstract

Introduction — Interpersonal skills, encompassing communication and empathy, are key components of effective medical consultations. Many organisations have therefore implemented structured training programs to improve physician communication skills. Yet limited evidence exists on the effectiveness of these programs. The study evaluates the efficacy of a standardised multifaceted interpersonal skills development program for hospital physicians.

Methods and analysis — Our study is a prospective, randomised (with a 1:1 allocation ratio), controlled, open-label, two parallel arms, superiority interventional trial in a university hospital. The unit of randomisation is the physician. Randomisation will be performed by minimisation, taking into account the status (incumbent versus non-incumbent) and specialty (medical versus surgical) of the physician. The primary outcome measure is the overall 4-HCS scale score. This score is computed by summing ratings for the 4-HCS individual items, ranging from 23 (i.e., less effective) to 115 (i.e., more effective). The secondary outcomes are the assessment of patient satisfaction, therapeutic alliance, self-actualisation for physicians and the duration of the medical consultations.

Ethics and dissemination — Study ethics approval was obtained on 21 October 2020 (CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, IRB 5891). Written informed consent of the participants will be obligatory. The results of this study will be published in a medical journal, regardless of whether they confirm or deny the research hypothesis.

Trial registration number — NCT04703816; Pre-results

Keywords: interpersonal skills; doctor–patient relationship; education program; evaluation

Strengths and limitations of this study

- The subject of the study (interpersonal skills) is important for improving the quality of care.
- The impact of interpersonal skills training is studied from both the patient's perspective (therapeutic alliance) and the doctor's perspective (consultation duration).
- The study design (randomised controlled trial) is the most robust methodology to assess the effectiveness of educational program.
- Participating physicians cannot be blinded to study intervention in this open-label trial.
- Recruitment of physicians and patients is difficult when video recording the consultation.

INTRODUCTION

Background

The doctor–patient relationship is central to medical practice and its quality can have a direct impact on the patient [1]. The quality of the interaction between physician and patient during a consultation is a major determinant of patient satisfaction, for example, and of adherence to the care plan. Interpersonal skills, such as communication and empathy, are of considerable importance in establishing the unique relationship between doctor and patient, at a time when medical practice is increasingly focused on the technical act of care. Communication is recognised as an essential skill for effective medicine [2]. According to Candib, interpersonal skills are defined by the presence of effective verbal and nonverbal behaviors in the context of individual interactions with patients or families [3].

However, despite the importance of these nontechnical skills, both a decline in communication skills among physicians over the course of their careers [4] and, in recent years, a decline in empathy have been described [5].

Interpersonal skills education program

Numerous studies have shown how to evaluate these interpersonal skills using standardised scales [2,6]. Subsequently, thanks to these means of evaluation, programs to improve the interpersonal skills of consulting physicians have been developed on a large scale in several countries with different methods [7]. However, these studies were too often descriptive, and a review of the recent literature points to the methodological weaknesses of some and to the need for studies with a higher level of evidence to determine the effectiveness of such programs [8]. Strategies to be adopted in particular for continuing education have been discussed [4].

One of the most successful multifaceted programs for improving interpersonal skills is the one developed in an American care structure: Kaiser Permanente. Using the standardised Four Habits Coding Scheme (4-HCS) evaluation scale [9] with strong psychometric properties [10], Kaiser Permanente has evaluated the skills of its practitioners and developed an original institutional educational program on a large scale [11]. This program was then exported, notably to Norway. However, the American study was essentially descriptive and therefore did not have a sufficient level of evidence to demonstrate effectiveness.

In addition to the difficulty in demonstrating the effectiveness of these programs on physician skills, another shortcoming pointed out by a recent review is the difficulty in demonstrating a transfer of acquired competencies to the patient [12]. Few studies have shown an impact on

the patient or only on satisfaction [11,13] and even less so those that were interested in the impact on the physician. Thus, the most successful Norwegian study in terms of methodology [13] focused only on patient satisfaction, without measuring the therapeutic alliance, which is a final indicator of the quality of care demonstrated to be correlated with the quality of doctor–patient communication [14]. The American study [11] was aimed at improving working conditions in a difficult environment without demonstrating it. However, the effect on long-term interpersonal skills through the multifaceted program inspired by Kaiser Permanente seems to show satisfactory results [15].

Finally, these studies did not investigate the impact of the training programs on consultation duration, an important factor in today's hospital settings.

Thus, to our knowledge, to date no study of this type and with a high level of evidence has been carried out to evaluate the ability to improve doctor–patient interpersonal skills and the impact on both the patient and the doctor.

Research hypothesis

We hypothesise that a multifaceted program will improve the communication and interpersonal skills of hospital physicians, without significantly altering the duration of the consultation. We will also examine whether changes in interpersonal medical skills in consultation are associated with (1) changes in patients' satisfaction and their attitude toward the care project (therapeutic alliance) and (2) changes in clinicians' professional fulfilment.

Objectives

We propose to conduct an experimental study with the highest level of scientific evidence (randomised controlled trial) to determine whether a multifaceted program improves physicians' interpersonal skills with a positive impact on the patient. The evaluated intervention would be based on the American dedicated curriculum [11,16]. This multifaceted intervention will combine theoretical and practical training sessions with the use of video-recorded medical consultations.

The main objective of the study is to determine the effect that a standardised multifaceted interpersonal skills development program for hospital physicians has on their communication and interpersonal skills in consultations compared with a control group not benefiting from this program.

The secondary objectives of the study are to determine whether this education program is associated with an improvement in patient satisfaction, in the therapeutic alliance for patients

seen in consultation, in personal achievement for hospital doctors and in the duration of the consultation.

METHODS

Trial design

To ensure a high level of evidence, we opted for a prospective superiority randomised controlled intervention trial. Given the proposed educational intervention, this trial could only be clustered and open-label; however, physicians will be randomised into the two arms of the study and both the patients and the interpersonal skills assessors will be blinded to the physician allocation group.

Study settings

Recruitment of clinicians

All the doctors and surgeons of the Grenoble Alpes University Hospital will be contacted via their professional e-mail in order to present the study to them and to call for volunteers to participate by simply replying to the investigator's e-mail. Posters will also be printed in the common areas frequented by the doctors as complementary material. It will then be verified that each participant meets the eligibility criteria. The physicians will be reminded of the main information regarding the study and consent will be obtained before inclusion.

Patient recruitment

Each physician will recruit eight consecutive eligible patients from their scheduled consultations (four in the pre-intervention phase and four in the post-intervention phase). The recruitment period will extend to the physician's inclusion of four patients in the pre-intervention phase and four patients in the post-intervention phase. If the physician leaves the study before the intervention, he or she will be excluded from the study. If the physician leaves the study after the intervention, the data acquired so far will be retained unless the physician objects.

In order to quantify the likelihood of possible bias in patient selection, a list of consultations during the recruitment period will be established for each participating clinician. This list will include the patient's age and gender, as well as the reason for exclusion.

Eligibility criteria

Inclusion criteria

- Physicians:
  - Hospital physicians or surgeons in Grenoble Alpes University Hospital
  - Information and collection of consent
- Patients:
  - Scheduled consultation in the public sector at Grenoble Alpes University Hospital
  - Patient treated in the participating physician's department
  - First consultation with the patient
  - Age ≥18 years old

Exclusion criteria

- Physicians:
  - Problems expressing or understanding the French language
- Patients:
  - Patient with difficulties in understanding, expressing, or reading the French language
  - Vulnerable patient or patient with impaired cognitive abilities (dementia, confusion)
  - Patient subject to a legal protection measure or unable to express their objection

Interventions

Inclusion visit

During the inclusion visit, the volunteer physician is asked to meet with one of the study investigators to obtain consent, as well as to state his or her discipline (medicine or surgery) and status (incumbent or non-incumbent).

At the time of the medical appointment, the patient will receive information by way of a display in the department concerned. A generic notice on internal data search will be displayed. The research team member, when she or he welcomes the patient, will verify the absence of any objection. Consent in relation to the patient's image and voice rights will also be obtained by having the patient sign the form in question. The patient will then be invited to fill in a questionnaire in order to collect their main sociodemographic and medical

characteristics. The patient will then be able to go to the filmed consultation with the physician.

Pre-intervention study period

Video-recording equipment will be provided to participating physicians. The physician will start the video recording using a miniaturised recording device placed on the desk, before picking up the patient in the waiting room, by simply pressing the recording button. The physician will end the recording in the same way at the end of the medical consultation. The video recording will therefore be centered on the desk making the doctor and the patient visible, with the notable exception of the clinical examination table.

Practitioners are invited to videotape four medical consultations with consecutive eligible outpatients over a 3-month period. At the end of each consultation, the questionnaires will be given to the participating patient with a stamped return envelope in order to collect the questionnaires on satisfaction and therapeutic alliance. The participating physician will be invited by mail to fill in the personal achievement questionnaire.

Training workshops

The physicians of the intervention arm will receive the multifaceted training program. Physicians in the control group will not receive any specific intervention. The theoretical model of the intervention is based on Philip Price's benchmark of the attributes of being a good doctor [17] and on the skills associated with the patient-centered relationship [18]. For the conceptual framework of the intervention, we will focus on training in interpersonal skills including communication and ethics based on the extensive experience of Kaiser Permanente and the Bayer Institute for Healthcare Communication [11,16] with whom we are in contact. We have adopted the Cochrane Effective Practice and Organisation of Care (EPOC) group typology to present our program. In detail, the intervention consists of training by an expert in the field of communication and interpersonal skills with experience in the hospital medical field. This expert will be accompanied by a physician with experience in the evaluation of interpersonal skills for co-animation. The training will comprise 2 days with a 1-month interval in-between. Prior to the first workshop, a questionnaire will be sent to each doctor to identify the profile of the practices of the different professionals and to adapt the discourse and the workshops. The first day of training will thus include a review of the skills needed to establish a patient-centered relationship, using in particular the various essential points assessed by the 4-HCS scale [10]. An introduction to active listening and Process Communication techniques will also be

provided with the dissemination of educational and interactive materials. Then, the second half-day of training will consist of working on interpersonal skills in relation to the communication techniques developed in the first workshop, putting them into practice through role-playing, and debriefing of consultation videos (feedback). Finally, difficult, emotionally charged consultations and reactions under stress will be addressed, with specific techniques for dealing with them. These different workshops are inspired by Kaiser Permanente's experience of more than 20 years in the United States [11] and by Norwegian hospital teams [15].

Post-intervention study period

At the end of the second workshop, the participating physicians in the two study arms will be invited to videotape medical consultations with at least four consecutive patients (consenting to the research) over a 3-month period. Personalised feedback will then be given on the acquisition of skills of the physicians in the intervention arm.

At the end-of-study visit, one of the study investigators who assessed the interpersonal skills will provide personalised feedback to the participating physician and will note any changes in these skills during the consultations, particularly for the intervention arm.

The physicians of the control arm will benefit from intervention at the end of the trial, and if they wish, from the two workshops.

Outcomes

Primary outcome measure

The main outcome will be the synthetic score produced by the French-language cross-cultural adaptation of the 4-HCS scale [10]. The score will be evaluated by two independent evaluators based on the video recording of the consultations and blinded to the randomisation group. The experts will then randomly distribute all the videos. Thus, all the videos will be analysed during the same time interval after they have been recorded. The evaluators will proceed to the evaluation of the interpersonal skills via a form of the 4-HCS scale validated in the French language.

Secondary outcome measure

The secondary outcomes are as follows:

- For patients: assessment of patient satisfaction with the consultation using the French cross-cultural adaptation of the American Board of Internal Medicine Patient Satisfaction Rating Scale [19] and evaluation of the therapeutic alliance using a cross-

cultural adaptation in the French language: Inventory of the Therapeutic Alliance [20]. The questionnaires will be self-administered and delivered at the end of the consultation with a postage-paid return envelope.

- For physicians: assessment of the score produced by each of the four dimensions of cross-cultural adaptation in the 4-HCS [10], assessment of self-actualisation using the French-language cross-cultural adaptation of the Maslach Burnout Inventory multidimensional scale [21] and duration of the medical consultation measured from the video recording.

Sample size

A sample of 56 patients included by 14 physicians (average number of patients/physician: 4 patients/physician) in each arm (i.e., 112 patients/28 physicians) would confer a power greater than 80% to show an average difference of 7.5 points in the 4-HCS score (alpha risk of 0.05 in bilateral situations). This power was calculated under the hypothesis of a standard deviation of the score equal to 10 [9] and an intra-cluster correlation coefficient equal to 0.30.
Each arm of the trial will include 56 pre-intervention and 56 post-intervention patients, for a total of 224 patients. This number makes it possible to objectify an interaction term between the trial arm and the period equal to 0.30, with a power greater than 80% and an inflation coefficient equal to 1.9 (corresponding to an intra-cluster correlation coefficient equal to 0.3). In cases of early exit from the trial, it will be possible to perform an imputation of the missing data via a multiple imputation technique.

Recruitment

A member of research team working at the Clinical Investigation Center (Grenoble Alpes University Hospital) will recruit study participants.

Randomisation

The unit of randomisation is the physician. A balanced randomisation by minimisation will be constituted taking into account the status (incumbent versus non-incumbent) and specialty (medical versus surgical) of the participating physicians. The method of generating the allocation sequence is a computer-generated random numbers. The randomisation will be centralised at the Clinical Investigation Centre of Grenoble Alpes University Hospital.
The moment of randomisation will take place at the end of the inclusion visit.

Allocation and blinding

Participating physicians cannot be blinded to study intervention in this open-label trial. However, the raters evaluating video-recorded consultations will be blinded to the study arm. The statistician in charge of analysis will also be blinded to the study arm. Only the biostatistician who generated randomisation sequence will be able to determine at the end of the analysis the correspondence between the anonymity number and the allocation group with the arm of the study. Similarly, the patient will be blinded to the physician's allocation arm. Indeed, the physician will be explicitly asked not to disclose to the patient whether or not he or she benefits from the intervention.

Data collection, data management and confidentiality

An electronic case report form (CRF) will be created for the study. Trial data management will be carried out in accordance with on-site Standard Operating Procedures (SOP). A data management plan will be developed by the data manager and approved by the principal investigator, the scientific coordinator, and the study statistician. Different approaches will be implemented to optimise data quality and identified in a Data Validation Plan including scheduling of inconsistencies in double data entries, execution of computerize programs for the detection of inconsistencies, follow-up at regular intervals of requests for corrections and final review of the data before the database frozen. The collected data will be stored in areas with limited access. Confidentiality of data, including the personal data and video recording, will be maintained.

Statistical methods

A statistical analysis plan (SAP) will be developed prior to database lock, reviewed by the principal investigator and an independent statistician, and approved by the steering committee. Any post-hoc or unplanned analyses not specified in the SAP will be clearly identified as such in the final statistical report and manuscripts for publication. No formal interim analysis is planned.

The intention-to-treat (ITT) population will consist of all observations for participating physicians who have been randomised. Patients and physicians will be analysed in the study arm assigned by randomisation. The per-protocol (PP) population will consist of all observations for randomised physicians without any major deviation from the protocol (non-compliance with the multifaceted training program) and evaluable. The numbers of patients and physicians in ITT and PP populations will be presented by study arm throughout a flow-

chart extension for cluster randomised trials. Baseline and demographic characteristics will be summarised for both ITT and PP populations. Baseline patient and physician characteristics will be compared between the two study arms.

The primary outcome analysis (i.e., 4-HCS overall score) will be conducted within the ITT population and, for sensitivity reason, repeated within the PP population. For this purpose, we will use a difference-in-differences approach, with a two-sided alpha level of 0.05. To account for patient clustering within participating physicians, we will analyse 4-HCS overall score using random-intercept linear regression model for continuous dependent variable.

The analysis of secondary outcomes will be exploratory in nature. Inferential comparisons for participating physicians between study arms will be performed using the *t* test or Wilcoxon rank-sum test for unpaired data for continuous outcome variables. To account for patient clustering within participating physicians, we will analyse secondary outcome measures using random-intercept linear regression model for continuous dependent variable. All tests of secondary outcome analyses will be performed on both ITT and PP populations at a two-sided alpha level of 0.05.

The completeness of study data will be reported for baseline characteristics and outcome variables. We will perform multivariate imputation using chained equations for replacing missing primary and secondary outcome values

Data monitoring

The establishment of the Data Monitoring Committee or auditing was not considered in the study design. The sponsor (Grenoble Alpes University Hospital) is authorised to inspect and control the study documentation.

Patients and public involvement statement

Patients and the public were not involved in the study commencement, design, recruitment, conduction, or dissemination.

Research checklist

The present protocol complies with the *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) 2013 statement [22].

ETHICS AND DISSEMINATION

Research ethics approval

Study ethics approval was obtained on 21 October 2020 (CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, IRB 5891). Written informed consent of the participants will be obligatory.

Protocol amendments

Any modifications to the protocol which may affect the conduct of the study, a potential benefit for the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects will require a formal amendment to the protocol, reported to the platform ClinicalTrials.gov.

Consent or assent

Before recruiting a participant into the trial, all the information about the study, including the study's objective, design, methodology, possible risks and benefits of taking part in the study, will be presented to the patient's caregiver by a trained member of research team. The participant will receive an information sheet, including the investigator's contact information. The informed written consent and the consent form for image and voice right will be collected.

Dissemination policy

The results of this study will be published in a medical journal, regardless of whether they confirm or deny the research hypothesis.

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Contributors:

All authors initiated the study design and its implementation, wrote the protocol, and have contributed to and approved the final manuscript. JL, AP and PC initially conceptualised the study. AB and ZP conducted the study. AB and JL provided statistical expertise and analysed the data with blinded statistician supervision.

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Effectiveness of a multifaceted intervention to improve interpersonal skills of physicians in medical consultations (EPECREM): Protocol for a randomised controlled trial.

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Short title: Physician interpersonal skills in consultations

Abstract

Introduction — Interpersonal skills, encompassing communication and empathy, are key components of effective medical consultations. Although many organisations have implemented structured training programs, limited evidence exists on their effectiveness in improving physician interpersonal skills. This study aims to evaluate the effectiveness of a standardised, multifaceted, interpersonal skills development program for hospital physicians.

Methods and analysis — This study is a prospective, randomised (with a 1:1 allocation ratio), controlled, open-label, two parallel arm, superiority trial conducted at a single university hospital. Physicians will be randomised to receive either a multifaceted training program or no intervention. The experimental intervention combines two one-day training sessions, dissemination of interactive educational materials, review of video-recorded consultations, and individual feedback. The primary outcome measure is the overall 4- Habits Coding Scheme (HCS) score assessed by two independent raters blinded to the study arm, based on video-recorded consultations, before and after intervention. The secondary outcomes include patient satisfaction, therapeutic alliance, physician self-actualisation, and the length of medical consultation.

Ethics and dissemination — The study protocol was approved on 21st October 2020 by the CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, France (IRB 5891). All participants will provide written informed consent. Efforts will be made to release the primary results within 6 to 9 months of study completion, regardless of whether they confirm or deny the research hypothesis.

Trial registration number — NCT04703816; Pre-results

Keywords: interpersonal skills; physician–patient relationship; education program; evaluation

Strengths and limitations of this study

- Physician interpersonal skills is a major determinant of patient satisfaction with medical consultation and compliance with plan of care.
- The impact of interpersonal skill training will be studied from both the patient's and the physician's perspective.
- Our study is designed as a randomised controlled trial in order to provide the highest level of evidence on the effectiveness of interpersonal skill training program.
- Participating physicians cannot be blinded to study intervention in this open-label trial.
- Video recording of medical consultations may hamper physician and patient participation in the trial.

INTRODUCTION

Background

The doctor–patient relationship is central to medical practice and its quality can have a direct impact on patient outcomes [1]. The quality of the interaction between physician and patient during a consultation is a major determinant of patient satisfaction and adherence to the plan of care. Interpersonal skills, such as patient-centered communication and empathy, are of considerable importance in establishing the unique relationship between doctor and patient, at a time when medical practice is increasingly focused on the technical act of care.

Communication is recognised as an essential skill for effective medicine [2–4]. Interpersonal skills are defined by the presence of effective verbal and nonverbal behaviors in the context of individual interactions with patients or families [5].

However, a decline in communication skills among physicians over the course of their careers [6] and a decline in empathy [7] have been reported, despite the importance of these non-technical skills.

Interpersonal skill training program

Many organisations have implemented training programs and routinely assess physicians' communication skills using standardised scales [2,8]. However, limited evidence exists on the effectiveness of these programs in improving physician interpersonal skills. Indeed, the vast majority of published reports are descriptive in design, lack adequate control groups, enrolled medical students, or had methodological weaknesses [9,10]. Less than 2% of published studies are randomized controlled trials [10] and the best strategy for improving physician interpersonal skills remains to be determined [6].

Evidence is currently lacking on the effectiveness of training program in altering patient outcomes [11]. Few studies have shown an impact of improved physician interpersonal skills on patient satisfaction [12,13] and even fewer investigated the effect on therapeutic alliance, which is correlated with the quality of doctor–patient communication [14].

The "Four Habits Model" is a training program addressing basic medical interview tasks that was developed within the US Kaiser Permanente Health Maintenance Organization. This training program has been implemented for teaching effective communication skills in various organisations in the US and Norway [12].Previous reports suggest that training programs based on the Four Habits Model may improve physicians' communication self-efficacy in the long term[15] and patient satisfaction with medical consultation [12].

Finally, physician interpersonal skills might be improved at the price of longer medical consultations. Substantial heterogeneity exists in the length of medical consultation across countries, ranging from less than 10 minutes in the UK to more than 20 minutes in the USA, with an intermediate value of 16 minutes in France [16]. Longer medical consultations generate extra costs and the length of consultation has been shown to relate to the economic expenditure per capita of the country [16]. Yet, it remains uncertain whether the length of consultation is associated with physician performance and patient satisfaction [17].

Research hypothesis

The primary hypothesis guiding the project is that a multifaceted structured training program may improve the communication and interpersonal skills of hospital physicians, without altering the length of consultation. A multifaceted program combines two or more components. Although speculative, multifaceted interventions may be more effective than single-component interventions in changing physician interpersonal skills. Our experimental multifaceted intervention will combine learning techniques for continuing medical education, role plays for pratice, and feedback on individual performance. Our secondary hypotheses are that improved physician interpersonal skills are paralleled by 1) increased levels of patient satisfaction with medical consultation and therapeutic alliance and 2) changes in physician professional fulfilment and self-actualisation.

Objectives

We propose to conduct an experimental study with the highest level of scientific evidence (randomised controlled trial) to determine whether a multifaceted training program improves physician interpersonal skills with a positive impact on patient outcomes. The Four Habits Model forms the framework of the experimental intervention [12,18]. This multifaceted intervention will combine theoretical and practical training sessions with the use of video-recorded medical consultations and personalised feedback on individual performance during medical consultations.

The primary objective of the study is to determine whether a multifaceted training program is effective in improving physician interpersonal skills as rated with the 4-Habits Coding Scheme (HCS) relative to baseline measure in comparison with a control group receiving no intervention.

The secondary objectives of the study are to compare patient satisfaction, patient therapeutic alliance, physician personal achievement, and the length of consultation between the experimental and control groups.

METHODS

Trial design

To ensure a high level of evidence, we designed a prospective superiority randomised controlled intervention trial. To prevent unintentional spill-over of intervention effect from experimental to control arm, the unit of randomization will be physicians. Given the educational nature of the intervention, physicians cannot be blinded to the study group; however, the patients, the raters in charge of coding the 4-HCS based on video-recorded consultations, and the statistician in charge of the primary and secondary outcome analysis will be blinded to study group.

Study settings

The project is conducted at a single university-affiliated public acute care hospital in France.

Recruitment of clinicians

Each physician board-certified in medical, surgical, or gynaecology-obstetrics specialty at Grenoble Alpes University Hospital was invited to participate in the study. Physicians were contacted by electronic mails send by the principal investigator (AB). Contact information was retrieved from the hospital database of professional electronic addresses. Correspondence enclosed a cover and the study protocol. A reminder was e-mailed to non-respondents one month later. Posters calling for volunteers were also displayed in areas frequented by physicians in the hospital. The principal investigator has no power relationship with the physicians participating in the study.

Physicians volunteering to participate are required to meet the inclusion and exclusion criteria. Prior to enrollment, all participating physicians will be asked to provide written informed consent.

Patient recruitment

Consecutive adult outpatients will be screened for eligibility if they consult with a physician participating in the study. To be eligible, patients will be required to meet all four inclusion

criteria and none of the exclusion criteria. Participating physician will be required to recruit eight consecutive eligible patients from their scheduled consultations. The recruitment period will extend to the physician's inclusion of four patients in the pre-intervention period and four patients in the post-intervention period, respectively. If the physician leaves the study before the intervention is implemented, he or she will be excluded from the study. If the physician leaves the study after the intervention is implemented, the data acquired so far will be retained unless the physician objects.

In order to quantify the likelihood of possible bias in patient selection, a list of consultations during the recruitment period will be established for each participating physician. This list will include the patient's age and gender, as well as the reason for exclusion.

The study was planned to include patients from 1st July 2021 to 31st October 2021, with an estimated trial end date of 31st December 2021.

Eligibility criteria

Inclusion criteria

- Physicians:
  - Physicians board-certified in medical, surgical, or gynaecology-obstetrics specialty at Grenoble Alpes University Hospital
  - Provision of written informed consent
- Patients:
  - Scheduled consultation in the public sector at Grenoble Alpes University Hospital
  - Patient treated in the participating physician's department
  - Initial consultation for new patient
  - Age ≥18 years old

Exclusion criteria

- Physicians:
  - Problems expressing or understanding the French language for cultural or language reasons
- Patients:
  - Patient with difficulties in understanding, expressing, or reading the French language for cultural or language reasons

- Patients who are unable to provide written informed consent, because of cognitive impairment, altered mental status, or communication impairments for medical reason
- Patient subject to a legal protection measure or unable to express their objection

Interventions

Inclusion visit

During the inclusion visit, the volunteer physician is asked to meet with one of the study investigators to obtain consent and to report his or her specialty (medicine, surgery, or gynaecology-obstetrics) and status (incumbent or non-incumbent).

Prior to the consultation, eligible patients are contacted by phone to be informed about the study protocol and their potential participation. At the time of the medical consultation, the patient receives additional information about the study by a research team member. A generic notice on internal data search is given to the patient. The research team member checks for the absence of any objection. Patient demographics and medical baseline characteristics are collected using a self-administered questionnaire.

Pre-intervention study period

Video-recording equipment will be provided to participating physicians. The physician will start the video recording using a miniaturised recording device placed on the desk, before picking up the patient in the waiting room, by simply pressing the recording button. The physician will end the recording in the same way at the end of the medical consultation. The video recording will therefore be centered on the desk making the doctor and the patient visible, with the notable exception of the clinical examination table.

Practitioners are invited to videotape four medical consultations with consecutive eligible outpatients over a 3-month period. After consultations, satisfaction and therapeutic alliance self-administered questionnaires will be given to the participating patient with a stamped return envelope. A reminder will be made by phone to non-respondents within 15 days of consultation. Questionnaires sent back within 30 days of medical consultations will be included in the analysis. The participating physician will be invited by mail to fill in the personal achievement questionnaire.

Experimental training program

The physicians assigned in the intervention arm will receive the experimental multifaceted training program. Physicians assigned in the control group will not receive any specific intervention. The theoretical model of the intervention is based on Philip Price's benchmark of the attributes of being a good practicing physician [19] and on the skills associated with the patient-centered relationship [20]. Each of the dimensions of the 4-HCS (i.e., "Invest in the beginning," "Elicit Patient's Perspective," "Demonstrate empathy," "Invest in the end") is the subject of specific work during the workshops. For the conceptual framework of the intervention, we will focus on training in interpersonal skills including communication and ethics based on the extensive experience of Kaiser Permanente and the Bayer Institute for Healthcare Communication [12,18] with whom we are in contact. The overall effectiveness of the program has undergone preliminary evaluations but no analysis on a component-by-component has been performed [13,15]. We have adopted the Cochrane Effective Practice and Organisation of Care (EPOC) group typology to present our program. In detail, the intervention consists of training by an expert in the field of communication and interpersonal skills with experience in the hospital medical field. This expert will be accompanied by a physician with experience in the evaluation of interpersonal skills for co-animation. The training will comprise 2 days with a 1-month interval in-between. Prior to the first workshop, a questionnaire will be sent to each doctor to identify the profile of the practices of the different professionals and to adapt the discourse and the workshops. The first day of training will thus include a review of the skills needed to establish a patient-centered relationship, using in particular the various essential points assessed by the 4-HCS scale [21]. An introduction to active listening and Process Communication techniques will also be provided with the dissemination of educational and interactive materials. The Process Communication® model developed by the psychologist Taibi Kahler makes it possible to identify one's own communication profile and that of the patient in order to adapt the communication. The workshop provides an understanding of how to enter into a relationship, how to analyse non-verbal behaviour and how to improve patient-centered communication. Then, the second half-day of training will consist of working on interpersonal skills in relation to the communication techniques developed in the first workshop, putting them into practice through role-playing. Finally, difficult, emotionally charged consultations and reactions under stress will be addressed, with specific techniques for dealing with them. These different workshops are inspired by Kaiser Permanente's experience of more than 20 years in the United States [12] and by Norwegian hospital teams [15]. Participating physicians will then receive individual feedback on their interpersonal skills analysed via the 4-HCS scale [21] on the basis of video-recorded consultations. The complete

description of the educational program is described in Table 1 according to the Template for intervention description and replication checklist [22]. This description follows the taxonomy for delivery characteristics proposed by Schulz et al [23].

Post-intervention study period

At the end of the second workshop, personalised feedback will be given on the acquisition of skills for the physicians assigned in the intervention arm. After the participating physicians in the two study arms will be invited to videotape medical consultations with at least four consecutive eligible patients over a 3-month period.

At the end-of-study visit, one of the study investigators who assessed the interpersonal skills will provide personalised feedback to each participating physician and will note any changes in interpersonal skills during the consultations, for the intervention and control arms.

The physicians assigned in the control arm will benefit from the experimental intervention at the end of the trial, if they wish.

Outcomes

Primary outcome measure

The primary outcome measure is the overall score produced by the cross-cultural adaptation of the 4-HCS scale in French [21]. The 4-HCS was cross-culturally adapted by conducting forward and backward translations with independent translators from the original scale [24], following international guidelines [25]. Cronbach's alpha was 0.94 for the overall 4-HCS, ranging from 0.72 to 0.88 across sub-scales. Median average absolute-agreement intra-class correlation coefficient estimates were 0.74 (range, 0.68–0.84) and 0.85 (range, 0.76–0.91) for inter- and intra-rater reliability of habit subscales, respectively [21].

Two independent raters blinded to study arm assessed physician interpersonal skills based on video-recorded consultations. The raters will be the same as those involved in the cross-cultural adaptation of the 4-HCS in French [21], to ensure a satisfactory level of reliability. The experts will receive all the videos for the period concerned at random. A random list of videos will be produced by experts for the first study period, and then for the second period to allow individual feedback on the interpersonal skills of the physicians in the intervention group (at the end of the first and second periods). Each video-recorded consultation will be analysed within 30 days of acquisition.

Secondary outcome measure

The secondary patient-level outcome measures include patient satisfaction, therapeutic alliance, and the length of consultation. Patient satisfaction with the medical consultation will be assessed with the cross-cultural adaptation of the American Board of Internal Medicine Patient Satisfaction Rating Scale in French [26] Patient therapeutic alliance will be measured using the cross-cultural adaptation of the Inventory of the Therapeutic Alliance in French [27]. The optimal recall period for measuring patient satisfaction with medical consultation is controversial. The criteria that guided our choice of recall period (up to 30 days after the consultation) were 1) patient ability to easily and accurately recall the information requested at home, 2) the potential for maturation bias and 3) the consistency with previous studies [18]. The length of medical consultation will be quantified by the two independent raters based on the video-recording. The physician-level secondary outcome measures include the subscale score for each of the four dimensions of the cross-cultural adaptation of the 4-HCSin French and self-actualisation assessed using the French-language cross-cultural adaptation of the Maslach Burnout Inventory multidimensional scale [28] .

Sample size

A sample of 56 patients included by 14 physicians (average number of patients/physician: 4 patients/physician) in each arm (i.e., 112 patients/28 physicians) would confer a power greater than 80% to show an average difference of 7.5 points in the 4-HCS score (two-sided alpha level of 0.05). This sample size was calculated under the hypothesis of a standard deviation of the 4-HCS score equal to 10 [24] and an intra-cluster correlation coefficient equal to 0.30. Each arm of the trial will include 56 pre-intervention and 56 post-intervention patients, for a total of 224 patients. This number makes it possible to show a significant interaction term between the trial arm and period equal to 0.30, with a power greater than 80% and an inflation coefficient equal to 1.9 (corresponding to an intra-cluster correlation coefficient equal to 0.3).

Recruitment

A member of research team working at the Clinical Investigation Center (Grenoble Alpes University Hospital) will recruit study participants.

Randomisation

The unit of randomisation is the physician, in order to minimize the likelihood of cross-contamination between study arms. Randomisation will be stratified and balanced by minimisation on the status (incumbent versus non-incumbent) and specialty (medical versus

surgical) of the participating physicians. We are anticipating that incumbent versus non-incumbent status and specialty are baseline physician characteristics that may confound the effectiveness of the experimental intervention in improving interpersonal skills. An independent statistician will generate allocation sequence, with a 1:1 ratio using computer-generated random numbers. To ensure concealment, study arm will not be released during the pre-intervention period. The randomisation will be centralised at the Clinical Investigation Centre of Grenoble Alpes University Hospital. The moment of physician randomisation will take place at the end of the first period.

Allocation and blinding

Participating physicians cannot be blinded to study intervention in this open-label trial. However, the patients, the raters evaluating video-recorded consultations and the statistician in charge of the primary and secondary outcome analyses will be blinded to the study arm. Only the statistician who generates the sequence of randomization will be able to determine at the end of the analysis the correspondence between the anonymity number and the allocation group with the arm of the study. The physician will be explicitly asked not to disclose to the patient whether or not he or she is assigned to the experimental intervention.

Data collection, data management and confidentiality

An electronic case report form (CRF) will be created for the study. Trial data management will be carried out in accordance with on-site Standard Operating Procedures (SOP). A data management plan will be developed by the data manager and approved by the principal investigator, the scientific coordinator, and the study statistician. Different approaches will be implemented to optimise data quality and identified in a Data Validation Plan including routine checks (valid values, range checks, and consistency checks) at the time of data entry for specific fields, double data entries, execution of computerized programs for the detection of additional inconsistencies, follow-up at regular intervals of requests for corrections and final review of the data prior to locking the database. The collected data will be stored in areas with limited access. Confidentiality of data, including the personal data and video recording, will be maintained.

Statistical methods

A statistical analysis plan (SAP) will be developed prior to database lock, reviewed by the principal investigator and an independent statistician, and approved by the steering committee. Any post-hoc or unplanned analyses not specified in the SAP will be clearly identified as such in the final statistical report and manuscripts for publication. No formal interim analysis is planned.

The intention-to-treat (ITT) population will consist of all observations for participating physicians who have been randomised. Patients and physicians will be analysed in the study arm assigned by randomisation. The per-protocol (PP) population will consist of all observations for randomised physicians without any major deviation from the protocol (non-compliance with the multifaceted training program) and evaluable. The numbers of patients and physicians in ITT and PP populations will be presented by study arm throughout a flow-chart extension for cluster randomised trials.

Descriptive summary statistics will be used for reporting continuous (arithmetic mean and standard deviation or median and 25^{th} -75^{th} percentiles) and categorical (numbers and percentages) variables. Baseline and demographic characteristics will be summarised for both ITT and PP populations. Baseline patient and physician characteristics will be compared between the two study arms.

The primary outcome analysis (i.e., 4-HCS overall score) will be conducted within the ITT population and, for sensitivity reason, repeated within the PP population. We will use a difference-in-differences approach. To account for patient clustering within participating physicians, we will analyse 4-HCS overall score using random-intercept linear regression model for continuous dependent variable.

The analysis of secondary outcomes will be exploratory in nature. Inferential comparisons for participating physicians between study arms will be performed using the *t* test or Wilcoxon rank-sum test for unpaired data for continuous outcome variables. To account for patient clustering within participating physicians, we will analyse secondary outcome measures using random-intercept linear regression model for continuous dependent variable.

No subgroup analysis is planned for the primary and secondary study outcomes.

For transparency purpose, the completeness of study data will be reported for baseline characteristics and outcome variables. In cases of participating physician withdrawal, we are planning to perform multiple imputation of missing data. To assess the robustness of our findings, we will perform multivariate imputation using chained equations (MICE) for imputing missing primary and secondary outcome values [29].

All primary and secondary outcome analyses will be performed on both ITT and PP populations at a two-sided alpha level of 0.05. All statistical analyses will be performed with Stata Special Edition version 16 or higher (Stata Corporation, College Station, TX, USA) and RStudio version 1.3.959 or higher (PBC, Boston, MA, USA). Additional software may be used for the production of graphics and for statistical methodology not provided by these software packages.

Data monitoring

Monitoring involves onsite periodic reviews of core trial processes and documentation conducted by staff appointed by the sponsor (Grenoble Alpes University Hospital). The sponsor may require an audit in order to obtain independent appraisal of trial data quality and integrity.

Patients and public involvement statement

Patient and the public representatives are not involved in the study design, recruitment, conduct, or dissemination of findings.

Research checklist

The present protocol complies with the *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) 2013 statement [30].

ETHICS AND DISSEMINATION

Research ethics approval

The study protocol was approved on 21st October 2020 by the CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, France (IRB 5891). All participants will provide written informed consent.

Protocol amendments

During the conduct of the study, protocol changes are not desirable and should not be made unless new information strongly suggests that such changes would strengthen the scientific validity of the study. If substantive modifications are necessary that may impact on the study conduct or results, including changes of study objectives, eligibility criteria, data collection methods, variable definitions, or significant administrative aspects, they will require a formal amendment to the protocol. The date, description of changes, and rationale for amendments

will be reported in a tabular format. Minor corrections or clarifications that have no effect on the way the study is to be conducted will be documented in a memorandum.

Protocol registration

The study protocol is registered on www.clinicaltrials.org (NCT04703816). Recorded information will be updated on a regular basis.

Consent or assent

Before participating in the trial, the patient will be informed of all pertinent aspects of the study (including objective, design, methods, constraints, anticipated risks and benefits), be provided with information form, and be given time to ask questions and time to consider the decision to participate. The patient will be informed that the quality of care will not be affected by the decision to participate in or to withdraw from the study. The investigator is responsible for obtaining informed consent for participating in the study and for image and voice right before any study intervention is administered. The acquisition of informed consent will be documented in the patient's medical records, and the informed consent form will be signed and personally dated by the patient and by the investigator.

Dissemination policy

Efforts will be made to reduce the interval between data collection completion and the release of the primary study results. The results of this study will be published, regardless of whether they confirm or deny the research hypothesis. It is expected that 6-9 months will be necessary to compile the primary study results before manuscript submission to an appropriate journal. All publications will comply with the CONSORT extension to cluster randomized trials guidelines, as appropriate [31]. All investigators and sub-investigators that have actively participated in the trial will be listed at the end of all manuscripts if this can be arranged with the publisher. Authors' names will be listed in order of contribution. Assistance for preparing and editing manuscripts (i.e., English language revision) provided by professional medical writers will be acknowledged.

No later than 3 years after final acceptance of the primary study paper, a completely de-identified data set will be available for sharing purpose, upon reasonable request to the principal investigator. In accordance with French regulation, study participants will be provided with the overall trial results upon request to the principal investigator.

DISCUSSION

This protocol describes the rationale for the EPECREM randomized controlled trial project, explains how the experimental intervention will be implemented, how data collection will be conducted, and how the results will be analyzed and interpreted. The potential limitations of this trial deserve mention. First, the control group will not receive any specific intervention. Actually, our trial is not designed to compare the effectiveness of concurrent training programs but to demonstrate that a multifaceted training program improves physician interpersonal skills. Second, physicians might avoid recruiting patients with whom the interaction is perceived as unfavourable. To limit the potential for patient selection bias, participating physicians will be invited to enroll consecutive eligible patients. Only initial consultations for new patients will be eligible. A list of eligible consultations during the recruitment period will be established for each participating physician. Third, the Maslach Burnout Inventory scale was originally developed for assessing burnout and may lack sensitivity to detect clinically significant differences in physician self-actualization between study arms. To our knowledge, very few standardized scales assessing physician's self-actualisation have been published. The Maslach Burnout Inventory, which has been translated and validated in French, includes a self-accomplishment subscale. Fourth, our study is conducted at a single university-afiiliated hospital in France and our findings may not apply to other settings or regions.

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Contributors:

AB conceptualized the study and is the guarantor. AB and PC developed the protocol and drafted the initial manuscript. AB and JL provided statistical expertise. AB, PC, AP, ZP, GC, SC and FP will be involved in the acquisition of data. All authors critically reviewed the protocol and approved submission of the final manuscript.

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Competing interests statement:

None declared

Word counts:

4278

Table 1. Intervention description according to the TIDieR checklist (Template for intervention description and replication)

Brief name	Multifaceted program for interpersonal and communication skills development in medical consultation
Why	Improved doctor-patient interpersonal skills are associated with improved patient satisfaction and quality of care, but there is a lack of evidence in the literature on how to develop these skills.
What	The multifaceted program includes two 4-hour workshops and feedback on the interpersonal skills observed during the doctor's consultation. Before the first workshop, an evaluation questionnaire based on the Process Communication model is sent to each participant. This questionnaire allows us to establish the communication profile of each participant. The first workshop presents the Process Communication theoretical model of communication during 2 hours to explain the profile of each person. A one-hour theoretical presentation is also given on interpersonal skills, based on the 4-HCS scale and the model developed by Kaiser Permanente organization. The last hour consists of a communication approach based on Process-Com and adapted to the doctor-patient relationship, linking the two theoretical models presented. The second workshop includes role-playing situations in groups of 3 people, with an observer, a physician and a patient. An observation grid inspired by the 4-HCS scale is given to each observer to allow a constructive debriefing on interpersonal skills. The participants take turns exchanging roles and a collective debriefing is conducted after each clinical situation. These clinical situations involve different communication profiles in order to apply the knowledge acquired in the first workshop. A detailed written analysis of the interpersonal skills observed during the consultations is finally given to each participant after the workshops. This analysis details strengths and areas for improvement, based on the 4-HCS assessment of the video recorded consultations by the physicians.
Who provided	The workshops are conducted by an expert in the field of communication with 20 years of experience in the hospital medical field. This expert is a professional trainer with a degree in communication and expert in the Process Communication model. The physician who also conducts the training is a physician who has conducted the cross-cultural adaptation of the 4-HCS scale into French, with experience in nearly 1000 consultation assessments using this scale. Interpersonal skills assessments are conducted by another physician with experience of several hundred evaluated consultations with 4-HCS scale.
How	The workshops are conducted in groups of 8 to 12 people with 2 trainers at 1-month intervals. The evaluations of the participants' consultations are sent by e-mail in the form of paragraphs describing the strengths and weaknesses in relation to the interpersonal skills assessed by the 4-HCS scale. Videos are added to the e-mail.
Where	The workshops take place in a classroom located in the hospital. Medical consultations take place in the doctor's usual department.

When and how much	The training includes 2 workshops of 4 hours at 1-month interval, as well as individual feedback on 8 consultations of the participating physician.
Tailoring	The training is adapted to the communication profile of each participant during the first workshop, based on the results of the previously completed Process Communication questionnaires. The feedback during the second workshop is adapted to the content observed during the different role plays.
Modifications	No changes made to the program
How well (planned)	The verification that each workshop participant has completed the communication profile questionnaire is done prior to the training. A monitoring is also done during the second workshop by the trainers to ensure that each participant changes roles systematically during the role-playing session.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	19
Roles and responsibilities: sponsor and funder	#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	19
Roles and responsibilities: committees	#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)	13
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	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	5
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, non-inferiority, exploratory)	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	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	7

		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
Interventions: modifications	#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)	9
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
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	10
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)	8
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	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
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	10

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	12
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection plan	#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	12
Data collection plan: retention	#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	13
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	13
Statistics: outcomes	#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	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13

Statistics: analysis population and missing data	#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)	13
Methods: Monitoring			
Data monitoring: formal committee	#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	13
Data monitoring: interim analysis	#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	13
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	13
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
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)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	14
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect	14

		confidentiality before, during, and after the trial	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
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	14
Dissemination policy: trial results	#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	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	15
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Not applicable
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	Not applicable

BMJ Open

Effectiveness of a multifaceted intervention to improve interpersonal skills of physicians in medical consultations (EPECREM): Protocol for a randomised controlled trial.

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Effectiveness of a multifaceted intervention to improve interpersonal skills of physicians in medical consultations (EPECREM): Protocol for a randomised controlled trial.

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Short title: Physician interpersonal skills in consultations

Abstract

Introduction — Interpersonal skills, encompassing communication and empathy, are key components of effective medical consultations. Although many organisations have implemented structured training programs, limited evidence exists on their effectiveness in improving physician interpersonal skills. This study aims to evaluate the effectiveness of a standardised, multifaceted, interpersonal skills development program for hospital physicians.

Methods and analysis — This study is a prospective, randomised (with a 1:1 allocation ratio), controlled, open-label, two parallel arm, superiority trial conducted at a single university hospital. Physicians will be randomised to receive either a multifaceted training program or no intervention. The experimental intervention combines two one-day training sessions, dissemination of interactive educational materials, review of video-recorded consultations, and individual feedback. The primary outcome measure is the overall 4- Habits Coding Scheme (HCS) score assessed by two independent raters blinded to the study arm, based on video-recorded consultations, before and after intervention. The secondary outcomes include patient satisfaction, therapeutic alliance, physician self-actualisation, and the length of medical consultation.

Ethics and dissemination — The study protocol was approved on 21st October 2020 by the CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, France (IRB 5891). All participants will provide written informed consent. Efforts will be made to release the primary results within 6 to 9 months of study completion, regardless of whether they confirm or deny the research hypothesis.

Trial registration number — NCT04703816; Pre-results

Keywords: interpersonal skills; physician–patient relationship; education program; evaluation

Strengths and limitations of this study

- Physician interpersonal skills is a major determinant of patient satisfaction with medical consultation and compliance with plan of care.
- The impact of interpersonal skill training will be studied from both the patient's and the physician's perspective.
- Our study is designed as a randomised controlled trial in order to provide the highest level of evidence on the effectiveness of interpersonal skill training program.
- Participating physicians cannot be blinded to study intervention in this open-label trial.
- Video recording of medical consultations may hamper physician and patient participation in the trial.

INTRODUCTION

Background

The doctor–patient relationship is central to medical practice and its quality can have a direct impact on patient outcomes [1]. The quality of the interaction between physician and patient during a consultation is a major determinant of patient satisfaction and adherence to the plan of care. Interpersonal skills, such as patient-centered communication and empathy, are of considerable importance in establishing the unique relationship between doctor and patient, at a time when medical practice is increasingly focused on the technical act of care.

Communication is recognised as an essential skill for effective medicine [2–4]. Interpersonal skills are defined by the presence of effective verbal and nonverbal behaviors in the context of individual interactions with patients or families [5].

However, a decline in communication skills among physicians over the course of their careers [6] and a decline in empathy [7] have been reported, despite the importance of these non-technical skills.

Interpersonal skill training program

Many organisations have implemented training programs and routinely assess physicians' communication skills using standardised scales [2,8]. However, limited evidence exists on the effectiveness of these programs in improving physician interpersonal skills. Indeed, the vast majority of published reports are descriptive in design, lack adequate control groups, enrolled medical students, or had methodological weaknesses [9,10]. Less than 2% of published studies are randomized controlled trials [10] and the best strategy for improving physician interpersonal skills remains to be determined [6].

Evidence is currently lacking on the effectiveness of training program in altering patient outcomes [11]. Few studies have shown an impact of improved physician interpersonal skills on patient satisfaction [12,13] and even fewer investigated the effect on therapeutic alliance, which is correlated with the quality of doctor–patient communication [14].

The "Four Habits Model" is a training program addressing basic medical interview tasks that was developed within the US Kaiser Permanente Health Maintenance Organization. This training program has been implemented for teaching effective communication skills in various organisations in the US and Norway [12].Previous reports suggest that training programs based on the Four Habits Model may improve physicians' communication self-efficacy in the long term [15] and patient satisfaction with medical consultation [12].

Finally, physician interpersonal skills might be improved at the price of longer medical consultations. Substantial heterogeneity exists in the length of medical consultation across countries, ranging from less than 10 minutes in the UK to more than 20 minutes in the USA, with an intermediate value of 16 minutes in France [16]. Longer medical consultations generate extra costs and the length of consultation has been shown to relate to the economic expenditure per capita of the country [16]. Yet, it remains uncertain whether the length of consultation is associated with physician performance and patient satisfaction [17].

Research hypothesis

The primary hypothesis guiding the project is that a multifaceted structured training program may improve the communication and interpersonal skills of hospital physicians, without altering the length of consultation. A multifaceted program combines two or more components. Although speculative, multifaceted interventions may be more effective than single-component interventions in changing physician interpersonal skills. Our experimental multifaceted intervention will combine learning techniques for continuing medical education, role plays for pratice, and feedback on individual performance. Our secondary hypotheses are that improved physician interpersonal skills are paralleled by 1) increased levels of patient satisfaction with medical consultation and therapeutic alliance and 2) changes in physician professional fulfilment and self-actualisation.

Objectives

We propose to conduct an experimental study with the highest level of scientific evidence (randomised controlled trial) to determine whether a multifaceted training program improves physician interpersonal skills with a positive impact on patient outcomes. The Four Habits Model forms the framework of the experimental intervention [12,18]. This multifaceted intervention will combine theoretical and practical training sessions with the use of video-recorded medical consultations and personalised feedback on individual performance during medical consultations.

The primary objective of the study is to determine whether a multifaceted training program is effective in improving physician interpersonal skills as rated with the 4-Habits Coding Scheme (HCS) relative to baseline measure in comparison with a control group receiving no intervention.

The secondary objectives of the study are to compare patient satisfaction, patient therapeutic alliance, physician personal achievement, and the length of consultation between the experimental and control groups.

METHODS

Trial design

To ensure a high level of evidence, we designed a prospective superiority randomised controlled intervention trial. To prevent unintentional spill-over of intervention effect from experimental to control arm, the unit of randomization will be physicians. Given the educational nature of the intervention, physicians cannot be blinded to the study group; however, the patients, the raters in charge of coding the 4-HCS based on video-recorded consultations, and the statistician in charge of the primary and secondary outcome analysis will be blinded to study group.

Study settings

The project is conducted at a single university-affiliated public acute care hospital in France.

Recruitment of clinicians

Each physician board-certified in medical, surgical, or gynaecology-obstetrics specialty at Grenoble Alpes University Hospital was invited to participate in the study. Physicians were contacted by electronic mails send by the principal investigator (AB). Contact information was retrieved from the hospital database of professional electronic addresses. Correspondence enclosed a cover and the study protocol. A reminder was e-mailed to non-respondents one month later. Posters calling for volunteers were also displayed in areas frequented by physicians in the hospital. The principal investigator has no power relationship with the physicians participating in the study.

Physicians volunteering to participate are required to meet the inclusion and exclusion criteria. Prior to enrollment, all participating physicians will be asked to provide written informed consent.

Patient recruitment

Consecutive adult outpatients will be screened for eligibility if they consult with a physician participating in the study. To be eligible, patients will be required to meet all four inclusion

criteria and none of the exclusion criteria. Participating physician will be required to recruit eight consecutive eligible patients from their scheduled consultations. The recruitment period will extend to the physician's inclusion of four patients in the pre-intervention period and four patients in the post-intervention period, respectively. If the physician leaves the study before the intervention is implemented, he or she will be excluded from the study. If the physician leaves the study after the intervention is implemented, the data acquired so far will be retained unless the physician objects.

In order to quantify the likelihood of possible bias in patient selection, a list of consultations during the recruitment period will be established for each participating physician. This list will include the patient's age and gender, as well as the reason for exclusion.

The study was planned to include patients from 1st July 2021 to 31st October 2021, with an estimated trial end date of 31st December 2021.

Eligibility criteria

Inclusion criteria

- Physicians:
  - Physicians board-certified in medical, surgical, or gynaecology-obstetrics specialty at Grenoble Alpes University Hospital
  - Provision of written informed consent
- Patients:
  - Scheduled consultation in the public sector at Grenoble Alpes University Hospital
  - Patient treated in the participating physician's department
  - Initial consultation for new patient
  - Age ≥18 years old

Exclusion criteria

- Physicians:
  - Problems expressing or understanding the French language for cultural or language reasons
- Patients:
  - Patient with difficulties in understanding, expressing, or reading the French language for cultural or language reasons

- Patients who are unable to provide written informed consent, because of cognitive impairment, altered mental status, or communication impairments for medical reason
- Patient subject to a legal protection measure or unable to express their objection

The potential for recruiting physicians into this study was assessed beforehand by interviewing physicians that participated to the activities of the continuing medical education department at Grenoble University Hospital.

Interventions

Inclusion visit

During the inclusion visit, the volunteer physician is asked to meet with one of the study investigators to obtain consent and to report his or her specialty (medicine, surgery, or gynaecology-obstetrics) and status (incumbent or non-incumbent).

Prior to the consultation, eligible patients are contacted by phone to be informed about the study protocol and their potential participation. At the time of the medical consultation, the patient receives additional information about the study by a research team member. A generic notice on internal data search is given to the patient. The research team member checks for the absence of any objection. Patient demographics and medical baseline characteristics are collected using a self-administered questionnaire.

Pre-intervention study period

Video-recording equipment will be provided to participating physicians. The physician will start the video recording using a miniaturised recording device placed on the desk, before picking up the patient in the waiting room, by simply pressing the recording button. The physician will end the recording in the same way at the end of the medical consultation. The video recording will therefore be centered on the desk making the doctor and the patient visible, with the notable exception of the clinical examination table.

Practitioners are invited to videotape four medical consultations with consecutive eligible outpatients over a 3-month period. After consultations, satisfaction and therapeutic alliance self-administered questionnaires will be given to the participating patient with a stamped return envelope. A reminder will be made by phone to non-respondents within 15 days of consultation. Questionnaires sent back within 30 days of medical consultations will be included in the analysis. The participating physician will be invited by mail to fill in the personal achievement questionnaire.

Experimental training program

The physicians assigned in the intervention arm will receive the experimental multifaceted training program. Physicians assigned in the control group will not receive any specific intervention. The theoretical model of the intervention is based on Philip Price's benchmark of the attributes of being a good practicing physician [19] and on the skills associated with the patient-centered relationship [20]. Each of the dimensions of the 4-HCS (i.e., "Invest in the beginning," "Elicit Patient's Perspective," "Demonstrate empathy," "Invest in the end") is the subject of specific work during the workshops. For the conceptual framework of the intervention, we will focus on training in interpersonal skills including communication and ethics based on the extensive experience of Kaiser Permanente and the Bayer Institute for Healthcare Communication [12,18] with whom we are in contact. The overall effectiveness of the program has undergone preliminary evaluations but no analysis on a component-by-component has been performed [13,15]. We have adopted the Cochrane Effective Practice and Organisation of Care (EPOC) group typology to present our program. In detail, the intervention consists of training by an expert in the field of communication and interpersonal skills with experience in the hospital medical field. This expert will be accompanied by a physician with experience in the evaluation of interpersonal skills for co-animation. The training will comprise 2 days with a 1-month interval in-between. Prior to the first workshop, a questionnaire will be sent to each doctor to identify the profile of the practices of the different professionals and to adapt the discourse and the workshops. The first day of training will thus include a review of the skills needed to establish a patient-centered relationship, using in particular the various essential points assessed by the 4-HCS scale [21]. An introduction to active listening and Process Communication techniques will also be provided with the dissemination of educational and interactive materials. The Process Communication® model developed by the psychologist Taibi Kahler makes it possible to identify one's own communication profile and that of the patient in order to adapt the communication. The workshop provides an understanding of how to enter into a relationship, how to analyse non-verbal behaviour and how to improve patient-centered communication. Then, the second half-day of training will consist of working on interpersonal skills in relation to the communication techniques developed in the first workshop, putting them into practice through role-playing. Finally, difficult, emotionally charged consultations and reactions under stress will be addressed, with specific techniques for dealing with them. These different workshops are inspired by Kaiser Permanente's experience of more than 20 years in the United States [12] and by Norwegian hospital teams [15].

Participating physicians will then receive individual feedback on their interpersonal skills analysed via the 4-HCS scale [21] on the basis of video-recorded consultations. The complete description of the educational program is described in Table 1 according to the Template for intervention description and replication checklist [22]. This description follows the taxonomy for delivery characteristics proposed by Schulz et al [23].

Post-intervention study period

At the end of the second workshop, physicians assigned in the intervention arm will be provided with personalised feedback on the acquisition of interpersonal.

Physicians assigned in the control group will not receive any specific training or feedback during the post-intervention study period. Patients enrolled by physicians assigned in the control group will receive usual care. Physicians assigned in the control arm will not be exposed to any component of the multifaceted intervention during the conduct of the study, in order to minimize the likelihood of unintentional contamination from experimental to control group, in this parallel-arm cluster randomized trial. The participating physicians in the two study arms will be invited to videotape medical consultations with at least four consecutive eligible patients over a 3-month period.

At the end-of-study visit, one of the study investigators who assessed the interpersonal skills will provide personalised feedback to each participating physician and will note any changes in interpersonal skills during the consultations, for the intervention and control arms.

The physicians assigned in the control arm will benefit from the experimental intervention at the end of the trial, if they wish.

Outcomes

Primary outcome measure

The primary outcome measure is the overall score produced by the cross-cultural adaptation of the 4-HCS scale in French [21]. The 4-HCS was cross-culturally adapted by conducting forward and backward translations with independent translators from the original scale [24], following international guidelines [25]. Cronbach's alpha was 0.94 for the overall 4-HCS, ranging from 0.72 to 0.88 across sub-scales. Median average absolute-agreement intra-class correlation coefficient estimates were 0.74 (range, 0.68–0.84) and 0.85 (range, 0.76–0.91) for inter- and intra-rater reliability of habit subscales, respectively [21].

Two independent raters blinded to study arm assessed physician interpersonal skills based on video-recorded consultations. The raters will be the same as those involved in the cross-cultural adaptation of the 4-HCS in French [21], to ensure a satisfactory level of reliability. The experts will receive all the videos for the period concerned at random. A random list of videos will be produced by experts for the first study period, and then for the second period to allow individual feedback on the interpersonal skills of the physicians in the intervention group (at the end of the first and second periods). Each video-recorded consultation will be analysed within 30 days of acquisition.

Secondary outcome measure

The secondary patient-level outcome measures include patient satisfaction, therapeutic alliance, and the length of consultation. Patient satisfaction with the medical consultation will be assessed with the cross-cultural adaptation of the American Board of Internal Medicine Patient Satisfaction Rating Scale in French [26] Patient therapeutic alliance will be measured using the cross-cultural adaptation of the Inventory of the Therapeutic Alliance in French [27]. The optimal recall period for measuring patient satisfaction with medical consultation is controversial. The criteria that guided our choice of recall period (up to 30 days after the consultation) were 1) patient ability to easily and accurately recall the information requested at home, 2) the potential for maturation bias and 3) the consistency with previous studies [18]. The length of medical consultation will be quantified by the two independent raters based on the video-recording. The physician-level secondary outcome measures include the subscale score for each of the four dimensions of the cross-cultural adaptation of the 4-HCS in French and self-actualisation assessed using the French-language cross-cultural adaptation of the Maslach Burnout Inventory multidimensional scale [28].

Sample size

A sample of 56 patients included by 14 physicians (average number of patients/physician: 4 patients/physician) in each arm (i.e., 112 patients/28 physicians) would confer a power greater than 80% to show an average difference of 7.5 points in the 4-HCS score (two-sided alpha level of 0.05). This sample size was calculated under the hypothesis of a standard deviation of the 4-HCS score equal to 10 [24] and an intra-cluster correlation coefficient equal to 0.30. Each arm of the trial will include 56 pre-intervention and 56 post-intervention patients, for a total of 224 patients. This number makes it possible to show a significant interaction term

between the trial arm and period equal to 0.30, with a power greater than 80% and an inflation factor equal to 1.9 [29].

Recruitment

A member of research team working at the Clinical Investigation Center (Grenoble Alpes University Hospital) will recruit study participants.

Randomisation

The unit of randomisation is the physician, in order to minimize the likelihood of cross-contamination between study arms. Randomisation will be stratified and balanced by minimisation on the status (incumbent versus non-incumbent) and specialty (medical versus surgical) of the participating physicians. We are anticipating that incumbent versus non-incumbent status and specialty are baseline physician characteristics that may confound the effectiveness of the experimental intervention in improving interpersonal skills. An independent statistician will generate allocation sequence, with a 1:1 ratio using computer-generated random numbers. To ensure concealment, study arm will not be released during the pre-intervention period. The randomisation will be centralised at the Clinical Investigation Centre of Grenoble Alpes University Hospital. The moment of physician randomisation will take place at the end of the first period.

Allocation and blinding

Participating physicians cannot be blinded to study intervention in this open-label trial. However, the patients, the raters evaluating video-recorded consultations and the statistician in charge of the primary and secondary outcome analyses will be blinded to the study arm. Only the statistician who generates the sequence of randomization will be able to determine at the end of the analysis the correspondence between the anonymity number and the allocation group with the arm of the study. The physician will be explicitly asked not to disclose to the patient whether or not he or she is assigned to the experimental intervention.

Data collection, data management and confidentiality

An electronic case report form (CRF) will be created for the study. Trial data management will be carried out in accordance with on-site Standard Operating Procedures (SOP). A data management plan will be developed by the data manager and approved by the principal

investigator, the scientific coordinator, and the study statistician. Different approaches will be implemented to optimise data quality and identified in a Data Validation Plan including routine checks (valid values, range checks, and consistency checks) at the time of data entry for specific fields, double data entries, execution of computerized programs for the detection of additional inconsistencies, follow-up at regular intervals of requests for corrections and final review of the data prior to locking the database. The collected data will be stored in areas with limited access. Confidentiality of data, including the personal data and video recording, will be maintained.

Statistical methods

A statistical analysis plan (SAP) will be developed prior to database lock, reviewed by the principal investigator and an independent statistician, and approved by the steering committee. Any post-hoc or unplanned analyses not specified in the SAP will be clearly identified as such in the final statistical report and manuscripts for publication. No formal interim analysis is planned.

The intention-to-treat (ITT) population will consist of all observations for participating physicians who have been randomised. Patients and physicians will be analysed in the study arm assigned by randomisation. The per-protocol (PP) population will consist of all observations for randomised physicians without any major deviation from the protocol (non-compliance with the multifaceted training program) and evaluable. The numbers of patients and physicians in ITT and PP populations will be presented by study arm throughout a flow-chart extension for cluster randomised trials.

Descriptive summary statistics will be used for reporting continuous (arithmetic mean and standard deviation or median and 25^{th} -75^{th} percentiles) and categorical (numbers and percentages) variables. Baseline and demographic characteristics will be summarised for both ITT and PP populations. Baseline patient and physician characteristics will be compared between the two study arms.

The primary outcome analysis (i.e., 4-HCS overall score) will be conducted within the ITT population and, for sensitivity reason, repeated within the PP population. We will use a difference-in-differences approach. To account for patient clustering within participating physicians, we will analyse 4-HCS overall score using random-intercept linear regression model for continuous dependent variable.

The analysis of secondary outcomes will be exploratory in nature. Inferential comparisons for participating physicians between study arms will be performed using the *t* test or Wilcoxon

rank-sum test for unpaired data for continuous outcome variables. To account for patient clustering within participating physicians, we will analyse secondary outcome measures using random-intercept linear regression model for continuous dependent variable.
No subgroup analysis is planned for the primary and secondary study outcomes.
For transparency purpose, the completeness of study data will be reported for baseline characteristics and outcome variables. In cases of participating physician withdrawal, we are planning to perform multiple imputation of missing data. To assess the robustness of our findings, we will perform multivariate imputation using chained equations (MICE) for imputing missing primary and secondary outcome values [30].

All primary and secondary outcome analyses will be performed on both ITT and PP populations at a two-sided alpha level of 0.05. All statistical analyses will be performed with Stata Special Edition version 16 or higher (Stata Corporation, College Station, TX, USA) and RStudio version 1.3.959 or higher (PBC, Boston, MA, USA). Additional software may be used for the production of graphics and for statistical methodology not provided by these software packages.

Data monitoring

Monitoring involves onsite periodic reviews of core trial processes and documentation conducted by staff appointed by the sponsor (Grenoble Alpes University Hospital). The sponsor may require an audit in order to obtain independent appraisal of trial data quality and integrity.

Patients and public involvement statement

Patient and the public representatives are not involved in the study design, recruitment, conduct, or dissemination of findings.

Research checklist

The present protocol complies with the *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) 2013 statement [31].

ETHICS AND DISSEMINATION

Research ethics approval

The study protocol was approved on 21st October 2020 by the CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, France (IRB 5891). All participants will provide written informed consent.

Protocol amendments

During the conduct of the study, protocol changes are not desirable and should not be made unless new information strongly suggests that such changes would strengthen the scientific validity of the study. If substantive modifications are necessary that may impact on the study conduct or results, including changes of study objectives, eligibility criteria, data collection methods, variable definitions, or significant administrative aspects, they will require a formal amendment to the protocol. The date, description of changes, and rationale for amendments will be reported in a tabular format. Minor corrections or clarifications that have no effect on the way the study is to be conducted will be documented in a memorandum.

Protocol registration

The study protocol is registered on (NCT04703816). Recorded information will be updated on a regular basis.

Consent or assent

Before participating in the trial, the patient will be informed of all pertinent aspects of the study (including objective, design, methods, constraints, anticipated risks and benefits), be provided with information form, and be given time to ask questions and time to consider the decision to participate. The patient will be informed that the quality of care will not be affected by the decision to participate in or to withdraw from the study. The investigator is responsible for obtaining informed consent for participating in the study and for image and voice right before any study intervention is administered. The acquisition of informed consent will be documented in the patient's medical records, and the informed consent form will be signed and personally dated by the patient and by the investigator.

Dissemination policy

Efforts will be made to reduce the interval between data collection completion and the release of the primary study results. The results of this study will be published, regardless of whether they confirm or deny the research hypothesis. It is expected that 6-9 months will be necessary to compile the primary study results before manuscript submission to an appropriate journal.

All publications will comply with the CONSORT extension to cluster randomized trials guidelines, as appropriate [32]. All investigators and sub-investigators that have actively participated in the trial will be listed at the end of all manuscripts if this can be arranged with the publisher. Authors' names will be listed in order of contribution. Assistance for preparing and editing manuscripts (i.e., English language revision) provided by professional medical writers will be acknowledged.

No later than 3 years after final acceptance of the primary study paper, a completely de-identified data set will be available for sharing purpose, upon reasonable request to the principal investigator. In accordance with French regulation, study participants will be provided with the overall trial results upon request to the principal investigator.

DISCUSSION

This protocol describes the rationale for the EPECREM randomized controlled trial project, explains how the experimental intervention will be implemented, how data collection will be conducted, and how the results will be analyzed and interpreted. The potential limitations of this trial deserve mention. First, the control group will not receive any specific intervention. Actually, our trial is not designed to compare the effectiveness of concurrent training programs but to demonstrate that a multifaceted training program improves physician interpersonal skills. Second, physicians might avoid recruiting patients with whom the interaction is perceived as unfavourable. To limit the potential for patient selection bias, participating physicians will be invited to enroll consecutive eligible patients. Only initial consultations for new patients will be eligible. A list of eligible consultations during the recruitment period will be established for each participating physician. Third, the Maslach Burnout Inventory scale was originally developed for assessing burnout and may lack sensitivity to detect clinically significant differences in physician self-actualization between study arms. To our knowledge, very few standardized scales assessing physician's self-actualisation have been published. The Maslach Burnout Inventory, which has been translated and validated in French, includes a self-accomplishment subscale. Fourth, our study is conducted at a single university-afiiliated hospital in France and our findings may not apply to other settings or regions.

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Contributors:

AB conceptualized the study and is the guarantor. AB and PC developed the protocol and drafted the initial manuscript. AB and JL provided statistical expertise. AB, PC, AP, ZP, GC, SC and FP will be involved in the acquisition of data. All authors critically reviewed the protocol and approved submission of the final manuscript.

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Competing interests statement:

None declared

Word counts:

4372

Table 1. Intervention description according to the TIDieR checklist (Template for intervention description and replication)

Brief name	Multifaceted program for interpersonal and communication skills development in medical consultation
Why	Improved doctor-patient interpersonal skills are associated with improved patient satisfaction and quality of care, but there is a lack of evidence in the literature on how to develop these skills.
What	The multifaceted program includes two 4-hour workshops and feedback on the interpersonal skills observed during the doctor's consultation. Before the first workshop, an evaluation questionnaire based on the Process Communication model is sent to each participant. This questionnaire allows us to establish the communication profile of each participant. The first workshop presents the Process Communication theoretical model of communication during 2 hours to explain the profile of each person. A one-hour theoretical presentation is also given on interpersonal skills, based on the 4-HCS scale and the model developed by Kaiser Permanente organization. The last hour consists of a communication approach based on Process-Com and adapted to the doctor-patient relationship, linking the two theoretical models presented. The second workshop includes role-playing situations in groups of 3 people, with an observer, a physician and a patient. An observation grid inspired by the 4-HCS scale is given to each observer to allow a constructive debriefing on interpersonal skills. The participants take turns exchanging roles and a collective debriefing is conducted after each clinical situation. These clinical situations involve different communication profiles in order to apply the knowledge acquired in the first workshop. A detailed written analysis of the interpersonal skills observed during the consultations is finally given to each participant after the workshops. This analysis details strengths and areas for improvement, based on the 4-HCS assessment of the video recorded consultations by the physicians.
Who provided	The workshops are conducted by an expert in the field of communication with 20 years of experience in the hospital medical field. This expert is a professional trainer with a degree in communication and expert in the Process Communication model. The physician who also conducts the training is a physician who has conducted the cross-cultural adaptation of the 4-HCS scale into French, with experience in nearly 1000 consultation assessments using this scale. Interpersonal skills assessments are conducted by another physician with experience of several hundred evaluated consultations with 4-HCS scale.
How	The workshops are conducted in groups of 8 to 12 people with 2 trainers at 1-month intervals. The evaluations of the participants' consultations are sent by e-mail in the form of paragraphs describing the strengths and weaknesses in relation to the interpersonal skills assessed by the 4-HCS scale. Videos are added to the e-mail.
Where	The workshops take place in a classroom located in the hospital. Medical consultations take place in the doctor's usual department.

When and how much	The training includes 2 workshops of 4 hours at 1-month interval, as well as individual feedback on 8 consultations of the participating physician.
Tailoring	The training is adapted to the communication profile of each participant during the first workshop, based on the results of the previously completed Process Communication questionnaires. The feedback during the second workshop is adapted to the content observed during the different role plays.
Modifications	No changes made to the program
How well (planned)	The verification that each workshop participant has completed the communication profile questionnaire is done prior to the training. A monitoring is also done during the second workshop by the trainers to ensure that each participant changes roles systematically during the role-playing session.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	19
Roles and responsibilities: sponsor and funder	#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	19
Roles and responsibilities: committees	#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)	13
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	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	5
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, non-inferiority, exploratory)	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	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	7

		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
Interventions: modifications	#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)	9
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
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	10
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)	8
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	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
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	10

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	12
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection plan	#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	12
Data collection plan: retention	#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	13
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	13
Statistics: outcomes	#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	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13

Statistics: analysis population and missing data	#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)	13
Methods: Monitoring			
Data monitoring: formal committee	#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	13
Data monitoring: interim analysis	#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	13
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	13
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
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)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	14
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect	14

		confidentiality before, during, and after the trial	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
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	14
Dissemination policy: trial results	#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	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	15
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Not applicable
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	Not applicable

BMJ Open

Effectiveness of a multifaceted intervention to improve interpersonal skills of physicians in medical consultations (EPECREM): Protocol for a randomised controlled trial.

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Keywords:	GENERAL MEDICINE (see Internal Medicine), MEDICAL ETHICS, MEDICAL EDUCATION & TRAINING

Effectiveness of a multifaceted intervention to improve interpersonal skills of physicians in medical consultations (EPECREM): Protocol for a randomised controlled trial.

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Short title: Physician interpersonal skills in consultations

Abstract

Introduction — Interpersonal skills, encompassing communication and empathy, are key components of effective medical consultations. Although many organisations have implemented structured training programs, limited evidence exists on their effectiveness in improving physician interpersonal skills. This study aims to evaluate the effectiveness of a standardised, multifaceted, interpersonal skills development program for hospital physicians.

Methods and analysis — This study is a prospective, randomised (with a 1:1 allocation ratio), controlled, open-label, two parallel arm, superiority trial conducted at a single university hospital. Physicians will be randomised to receive either a multifaceted training program or no intervention. The experimental intervention combines two one-day training sessions, dissemination of interactive educational materials, review of video-recorded consultations, and individual feedback. The primary outcome measure is the overall 4- Habits Coding Scheme (HCS) score assessed by two independent raters blinded to the study arm, based on video-recorded consultations, before and after intervention. The secondary outcomes include patient satisfaction, therapeutic alliance, physician self-actualisation, and the length of medical consultation.

Ethics and dissemination — The study protocol was approved on 21st October 2020 by the CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, France (IRB 5891). All participants will provide written informed consent. Efforts will be made to release the primary results within 6 to 9 months of study completion, regardless of whether they confirm or deny the research hypothesis.

Trial registration number — NCT04703816; Pre-results

Keywords: interpersonal skills; physician–patient relationship; education program; evaluation

Strengths and limitations of this study

- Physician interpersonal skills is a major determinant of patient satisfaction with medical consultation and compliance with plan of care.
- The impact of interpersonal skill training will be studied from both the patient's and the physician's perspective.
- Our study is designed as a randomised controlled trial in order to provide the highest level of evidence on the effectiveness of interpersonal skill training program.
- Participating physicians cannot be blinded to study intervention in this open-label trial.
- Video recording of medical consultations may hamper physician and patient participation in the trial.

INTRODUCTION

Background

The doctor–patient relationship is central to medical practice and its quality can have a direct impact on patient outcomes [1]. The quality of the interaction between physician and patient during a consultation is a major determinant of patient satisfaction and adherence to the plan of care. Interpersonal skills, such as patient-centered communication and empathy, are of considerable importance in establishing the unique relationship between doctor and patient, at a time when medical practice is increasingly focused on the technical act of care.

Communication is recognised as an essential skill for effective medicine [2–4]. Interpersonal skills are defined by the presence of effective verbal and nonverbal behaviors in the context of individual interactions with patients or families [5].

However, a decline in communication skills among physicians over the course of their careers [6] and a decline in empathy [7] have been reported, despite the importance of these non-technical skills.

Interpersonal skill training program

Many organisations have implemented training programs and routinely assess physicians' communication skills using standardised scales [2,8]. However, limited evidence exists on the effectiveness of these programs in improving physician interpersonal skills. Indeed, the vast majority of published reports are descriptive in design, lack adequate control groups, enrolled medical students, or had methodological weaknesses [9,10]. Less than 2% of published studies are randomized controlled trials [10] and the best strategy for improving physician interpersonal skills remains to be determined [6].

Evidence is currently lacking on the effectiveness of training program in altering patient outcomes [11]. Few studies have shown an impact of improved physician interpersonal skills on patient satisfaction [12,13] and even fewer investigated the effect on therapeutic alliance, which is correlated with the quality of doctor–patient communication [14].

The "Four Habits Model" is a training program addressing basic medical interview tasks that was developed within the US Kaiser Permanente Health Maintenance Organization. This training program has been implemented for teaching effective communication skills in various organisations in the US and Norway [12].Previous reports suggest that training programs based on the Four Habits Model may improve physicians' communication self-efficacy in the long term [15] and patient satisfaction with medical consultation [12].

Finally, physician interpersonal skills might be improved at the price of longer medical consultations. Substantial heterogeneity exists in the length of medical consultation across countries, ranging from less than 10 minutes in the UK to more than 20 minutes in the USA, with an intermediate value of 16 minutes in France [16]. Longer medical consultations generate extra costs and the length of consultation has been shown to relate to the economic expenditure per capita of the country [16]. Yet, it remains uncertain whether the length of consultation is associated with physician performance and patient satisfaction [17].

Research hypothesis

The primary hypothesis guiding the project is that a multifaceted structured training program may improve the communication and interpersonal skills of hospital physicians, without altering the length of consultation. A multifaceted program combines two or more components. Although speculative, multifaceted interventions may be more effective than single-component interventions in changing physician interpersonal skills. Our experimental multifaceted intervention will combine learning techniques for continuing medical education, role plays for pratice, and feedback on individual performance. Our secondary hypotheses are that improved physician interpersonal skills are paralleled by 1) increased levels of patient satisfaction with medical consultation and therapeutic alliance and 2) changes in physician professional fulfilment and self-actualisation.

Objectives

We propose to conduct an experimental study with the highest level of scientific evidence (randomised controlled trial) to determine whether a multifaceted training program improves physician interpersonal skills with a positive impact on patient outcomes. The Four Habits Model forms the framework of the experimental intervention [12,18]. This multifaceted intervention will combine theoretical and practical training sessions with the use of video-recorded medical consultations and personalised feedback on individual performance during medical consultations.

The primary objective of the study is to determine whether a multifaceted training program is effective in improving physician interpersonal skills as rated with the 4-Habits Coding Scheme (HCS) relative to baseline measure in comparison with a control group receiving no intervention.

The secondary objectives of the study are to compare patient satisfaction, patient therapeutic alliance, physician personal achievement, and the length of consultation between the experimental and control groups.

METHODS

Trial design

To ensure a high level of evidence, we designed a prospective superiority randomised controlled intervention trial. To prevent unintentional spill-over of intervention effect from experimental to control arm, the unit of randomization will be physicians. Given the educational nature of the intervention, physicians cannot be blinded to the study group; however, the patients, the raters in charge of coding the 4-HCS based on video-recorded consultations, and the statistician in charge of the primary and secondary outcome analysis will be blinded to study group.

Study settings

The project is conducted at a single university-affiliated public acute care hospital in France.

Recruitment of clinicians

Each physician board-certified in medical, surgical, or gynaecology-obstetrics specialty at Grenoble Alpes University Hospital was invited to participate in the study. Physicians were contacted by electronic mails send by the principal investigator (AB). Contact information was retrieved from the hospital database of professional electronic addresses. Correspondence enclosed a cover and the study protocol. A reminder was e-mailed to non-respondents one month later. Posters calling for volunteers were also displayed in areas frequented by physicians in the hospital. The principal investigator has no power relationship with the physicians participating in the study. Of 839 physicians contacted by electronic mail, 37 volunteered to participate, and 28 were recruited.

Physicians volunteering to participate are required to meet the inclusion and exclusion criteria. Prior to enrollment, all participating physicians will be asked to provide written informed consent.

Patient recruitment

Consecutive adult outpatients will be screened for eligibility if they consult with a physician participating in the study. To be eligible, patients will be required to meet all four inclusion criteria and none of the exclusion criteria. Participating physician will be required to recruit eight consecutive eligible patients from their scheduled consultations. The recruitment period will extend to the physician's inclusion of four patients in the pre-intervention period and four patients in the post-intervention period, respectively. If the physician leaves the study before the intervention is implemented, he or she will be excluded from the study. If the physician leaves the study after the intervention is implemented, the data acquired so far will be retained unless the physician objects.

In order to quantify the likelihood of possible bias in patient selection, a list of consultations during the recruitment period will be established for each participating physician. This list will include the patient's age and gender, as well as the reason for exclusion.

The study was planned to include patients from 1st July 2021 to 31st October 2021, with an estimated trial end date of 31st December 2021.

Eligibility criteria

Inclusion criteria

- Physicians:
  - Physicians board-certified in medical, surgical, or gynaecology-obstetrics specialty at Grenoble Alpes University Hospital
  - Provision of written informed consent
- Patients:
  - Scheduled consultation in the public sector at Grenoble Alpes University Hospital
  - Patient treated in the participating physician's department
  - Initial consultation for new patient
  - Age ≥18 years old

Exclusion criteria

- Physicians:
  - Problems expressing or understanding the French language for cultural or language reasons
- Patients:

- Patient with difficulties in understanding, expressing, or reading the French language for cultural or language reasons
- Patients who are unable to provide written informed consent, because of cognitive impairment, altered mental status, or communication impairments for medical reason
- Patient subject to a legal protection measure or unable to express their objection

The potential for recruiting physicians into this study was assessed beforehand by interviewing physicians that participated to the activities of the continuing medical education department at Grenoble University Hospital.

Interventions

Inclusion visit

During the inclusion visit, the volunteer physician is asked to meet with one of the study investigators to obtain consent and to report his or her specialty (medicine, surgery, or gynaecology-obstetrics) and status (incumbent or non-incumbent).

Prior to the consultation, eligible patients are contacted by phone to be informed about the study protocol and their potential participation. At the time of the medical consultation, the patient receives additional information about the study by a research team member. A generic notice on internal data search is given to the patient. The research team member checks for the absence of any objection. Patient demographics and medical baseline characteristics are collected using a self-administered questionnaire.

Pre-intervention study period

Video-recording equipment will be provided to participating physicians. The physician will start the video recording using a miniaturised recording device placed on the desk, before picking up the patient in the waiting room, by simply pressing the recording button. The physician will end the recording in the same way at the end of the medical consultation. The video recording will therefore be centered on the desk making the doctor and the patient visible, with the notable exception of the clinical examination table.

Practitioners are invited to videotape four medical consultations with consecutive eligible outpatients over a 3-month period. After consultations, satisfaction and therapeutic alliance self-administered questionnaires will be given to the participating patient with a stamped return envelope. A reminder will be made by phone to non-respondents within 15 days of consultation. Questionnaires sent back within 30 days of medical consultations will be included in the

analysis. The participating physician will be invited by mail to fill in the personal achievement questionnaire.

Experimental training program

The physicians assigned in the intervention arm will receive the experimental multifaceted training program. Physicians assigned in the control group will not receive any specific intervention. The theoretical model of the intervention is based on Philip Price's benchmark of the attributes of being a good practicing physician [19] and on the skills associated with the patient-centered relationship [20]. Each of the dimensions of the 4-HCS (i.e., "Invest in the beginning," "Elicit Patient's Perspective," "Demonstrate empathy," "Invest in the end") is the subject of specific work during the workshops. For the conceptual framework of the intervention, we will focus on training in interpersonal skills including communication and ethics based on the extensive experience of Kaiser Permanente and the Bayer Institute for Healthcare Communication [12,18] with whom we are in contact. The overall effectiveness of the program has undergone preliminary evaluations but no analysis on a component-by-component has been performed [13,15]. We have adopted the Cochrane Effective Practice and Organisation of Care (EPOC) group typology to present our program. In detail, the intervention consists of training by an expert in the field of communication and interpersonal skills with experience in the hospital medical field. This expert will be accompanied by a physician with experience in the evaluation of interpersonal skills for co-animation. The training will comprise 2 days with a 1-month interval in-between. Prior to the first workshop, a questionnaire will be sent to each doctor to identify the profile of the practices of the different professionals and to adapt the discourse and the workshops. The first day of training will thus include a review of the skills needed to establish a patient-centered relationship, using in particular the various essential points assessed by the 4-HCS scale [21]. An introduction to active listening and Process Communication techniques will also be provided with the dissemination of educational and interactive materials. The Process Communication® model developed by the psychologist Taibi Kahler makes it possible to identify one's own communication profile and that of the patient in order to adapt the communication. The workshop provides an understanding of how to enter into a relationship, how to analyse non-verbal behaviour and how to improve patient-centered communication. Then, the second half-day of training will consist of working on interpersonal skills in relation to the communication techniques developed in the first workshop, putting them into practice through role-playing. Finally, difficult, emotionally charged consultations and reactions under stress will be addressed, with specific techniques for

dealing with them. These different workshops are inspired by Kaiser Permanente's experience of more than 20 years in the United States [12] and by Norwegian hospital teams [15]. Participating physicians will then receive individual feedback on their interpersonal skills analysed via the 4-HCS scale [21] on the basis of video-recorded consultations. The complete description of the educational program is described in Table 1 according to the Template for intervention description and replication checklist [22]. This description follows the taxonomy for delivery characteristics proposed by Schulz et al [23].

Post-intervention study period

At the end of the second workshop, physicians assigned in the intervention arm will be provided with personalised feedback on the acquisition of interpersonal.

Physicians assigned in the control group will not receive any specific training or feedback during the post-intervention study period. Patients enrolled by physicians assigned in the control group will receive usual care. Physicians assigned in the control arm will not be exposed to any component of the multifaceted intervention during the conduct of the study, in order to minimize the likelihood of unintentional contamination from experimental to control group, in this parallel-arm cluster randomized trial. The participating physicians in the two study arms will be invited to videotape medical consultations with at least four consecutive eligible patients over a 3-month period.

At the end-of-study visit, one of the study investigators who assessed the interpersonal skills will provide personalised feedback to each participating physician and will note any changes in interpersonal skills during the consultations, for the intervention and control arms.

The physicians assigned in the control arm will benefit from the experimental intervention at the end of the trial, if they wish.

Outcomes

Primary outcome measure

The primary outcome measure is the overall score produced by the cross-cultural adaptation of the 4-HCS scale in French [21]. The 4-HCS was cross-culturally adapted by conducting forward and backward translations with independent translators from the original scale [24], following international guidelines [25]. Cronbach's alpha was 0.94 for the overall 4-HCS, ranging from 0.72 to 0.88 across sub-scales. Median average absolute-agreement intra-class

correlation coefficient estimates were 0.74 (range, 0.68–0.84) and 0.85 (range, 0.76–0.91) for inter- and intra-rater reliability of habit subscales, respectively [21].

Two independent raters blinded to study arm assessed physician interpersonal skills based on video-recorded consultations. The raters will be the same as those involved in the cross-cultural adaptation of the 4-HCS in French [21], to ensure a satisfactory level of reliability. The experts will receive all the videos for the period concerned at random. A random list of videos will be produced by experts for the first study period, and then for the second period to allow individual feedback on the interpersonal skills of the physicians in the intervention group (at the end of the first and second periods). Each video-recorded consultation will be analysed within 30 days of acquisition.

Secondary outcome measure

The secondary patient-level outcome measures include patient satisfaction, therapeutic alliance, and the length of consultation. Patient satisfaction with the medical consultation will be assessed with the cross-cultural adaptation of the American Board of Internal Medicine Patient Satisfaction Rating Scale in French [26] Patient therapeutic alliance will be measured using the cross-cultural adaptation of the Inventory of the Therapeutic Alliance in French [27]. The optimal recall period for measuring patient satisfaction with medical consultation is controversial. The criteria that guided our choice of recall period (up to 30 days after the consultation) were 1) patient ability to easily and accurately recall the information requested at home, 2) the potential for maturation bias and 3) the consistency with previous studies [18]. The length of medical consultation will be quantified by the two independent raters based on the video-recording. The physician-level secondary outcome measures include the subscale score for each of the four dimensions of the cross-cultural adaptation of the 4-HCS in French and self-actualisation assessed using the French-language cross-cultural adaptation of the Maslach Burnout Inventory multidimensional scale [28].

Sample size

A sample of 56 patients included by 14 physicians (average number of patients/physician: 4 patients/physician) in each arm (i.e., 112 patients/28 physicians) would confer a power greater than 80% to show an average difference of 7.5 points in the 4-HCS score (two-sided alpha level of 0.05). This sample size was calculated under the hypothesis of a standard deviation of the 4-HCS score equal to 10 [24] and an intra-cluster correlation coefficient equal to 0.30.

Each arm of the trial will include 56 pre-intervention and 56 post-intervention patients, for a total of 224 patients. This number makes it possible to show a significant interaction term between the trial arm and period equal to 0.30, with a power greater than 80% and an inflation factor equal to 1.9 [29].

Recruitment

A member of research team working at the Clinical Investigation Center (Grenoble Alpes University Hospital) will recruit study participants.

Randomisation

The unit of randomisation is the physician, in order to minimize the likelihood of cross-contamination between study arms. Randomisation will be stratified and balanced by minimisation on the status (incumbent versus non-incumbent) and specialty (medical versus surgical) of the participating physicians. We are anticipating that incumbent versus non-incumbent status and specialty are baseline physician characteristics that may confound the effectiveness of the experimental intervention in improving interpersonal skills. An independent statistician will generate allocation sequence, with a 1:1 ratio using computer-generated random numbers. To ensure concealment, study arm will not be released during the pre-intervention period. The randomisation will be centralised at the Clinical Investigation Centre of Grenoble Alpes University Hospital. The moment of physician randomisation will take place at the end of the first period.

Allocation and blinding

Participating physicians cannot be blinded to study intervention in this open-label trial. However, the patients, the raters evaluating video-recorded consultations and the statistician in charge of the primary and secondary outcome analyses will be blinded to the study arm. Only the statistician who generates the sequence of randomization will be able to determine at the end of the analysis the correspondence between the anonymity number and the allocation group with the arm of the study. The physician will be explicitly asked not to disclose to the patient whether or not he or she is assigned to the experimental intervention.

Data collection, data management and confidentiality

An electronic case report form (CRF) will be created for the study. Trial data management will be carried out in accordance with on-site Standard Operating Procedures (SOP). A data management plan will be developed by the data manager and approved by the principal investigator, the scientific coordinator, and the study statistician. Different approaches will be implemented to optimise data quality and identified in a Data Validation Plan including routine checks (valid values, range checks, and consistency checks) at the time of data entry for specific fields, double data entries, execution of computerized programs for the detection of additional inconsistencies, follow-up at regular intervals of requests for corrections and final review of the data prior to locking the database. The collected data will be stored in areas with limited access. Confidentiality of data, including the personal data and video recording, will be maintained.

Statistical methods

A statistical analysis plan (SAP) will be developed prior to database lock, reviewed by the principal investigator and an independent statistician, and approved by the steering committee. Any post-hoc or unplanned analyses not specified in the SAP will be clearly identified as such in the final statistical report and manuscripts for publication. No formal interim analysis is planned.

The intention-to-treat (ITT) population will consist of all observations for participating physicians who have been randomised. Patients and physicians will be analysed in the study arm assigned by randomisation. The per-protocol (PP) population will consist of all observations for randomised physicians without any major deviation from the protocol (non-compliance with the multifaceted training program) and evaluable. The numbers of patients and physicians in ITT and PP populations will be presented by study arm throughout a flow-chart extension for cluster randomised trials.

Descriptive summary statistics will be used for reporting continuous (arithmetic mean and standard deviation or median and 25^{th} -75^{th} percentiles) and categorical (numbers and percentages) variables. Baseline and demographic characteristics will be summarised for both ITT and PP populations. Baseline patient and physician characteristics will be compared between the two study arms.

The primary outcome analysis (i.e., 4-HCS overall score) will be conducted within the ITT population and, for sensitivity reason, repeated within the PP population. We will use a difference-in-differences approach. To account for patient clustering within participating

physicians, we will analyse 4-HCS overall score using random-intercept linear regression model for continuous dependent variable.

The analysis of secondary outcomes will be exploratory in nature. Inferential comparisons for participating physicians between study arms will be performed using the *t* test or Wilcoxon rank-sum test for unpaired data for continuous outcome variables. To account for patient clustering within participating physicians, we will analyse secondary outcome measures using random-intercept linear regression model for continuous dependent variable.

No subgroup analysis is planned for the primary and secondary study outcomes.

For transparency purpose, the completeness of study data will be reported for baseline characteristics and outcome variables. In cases of participating physician withdrawal, we are planning to perform multiple imputation of missing data. To assess the robustness of our findings, we will perform multivariate imputation using chained equations (MICE) for imputing missing primary and secondary outcome values [30].

All primary and secondary outcome analyses will be performed on both ITT and PP populations at a two-sided alpha level of 0.05. All statistical analyses will be performed with Stata Special Edition version 16 or higher (Stata Corporation, College Station, TX, USA) and RStudio version 1.3.959 or higher (PBC, Boston, MA, USA). Additional software may be used for the production of graphics and for statistical methodology not provided by these software packages.

Data monitoring

Monitoring involves onsite periodic reviews of core trial processes and documentation conducted by staff appointed by the sponsor (Grenoble Alpes University Hospital). The sponsor may require an audit in order to obtain independent appraisal of trial data quality and integrity.

Patients and public involvement statement

Patient and the public representatives are not involved in the study design, recruitment, conduct, or dissemination of findings.

Research checklist

The present protocol complies with the *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) 2013 statement [31].

ETHICS AND DISSEMINATION

Research ethics approval

The study protocol was approved on 21st October 2020 by the CECIC Rhône-Alpes Auvergne, Clermont-Ferrand, France (IRB 5891). All participants will provide written informed consent.

Protocol amendments

During the conduct of the study, protocol changes are not desirable and should not be made unless new information strongly suggests that such changes would strengthen the scientific validity of the study. If substantive modifications are necessary that may impact on the study conduct or results, including changes of study objectives, eligibility criteria, data collection methods, variable definitions, or significant administrative aspects, they will require a formal amendment to the protocol. The date, description of changes, and rationale for amendments will be reported in a tabular format. Minor corrections or clarifications that have no effect on the way the study is to be conducted will be documented in a memorandum.

Protocol registration

The study protocol is registered on (NCT04703816). Recorded information will be updated on a regular basis.

Consent or assent

Before participating in the trial, the patient will be informed of all pertinent aspects of the study (including objective, design, methods, constraints, anticipated risks and benefits), be provided with information form, and be given time to ask questions and time to consider the decision to participate. The patient will be informed that the quality of care will not be affected by the decision to participate in or to withdraw from the study. The investigator is responsible for obtaining informed consent for participating in the study and for image and voice right before any study intervention is administered. The acquisition of informed consent will be documented in the patient's medical records, and the informed consent form will be signed and personally dated by the patient and by the investigator.

Dissemination policy

Efforts will be made to reduce the interval between data collection completion and the release of the primary study results. The results of this study will be published, regardless of whether they confirm or deny the research hypothesis. It is expected that 6-9 months will be necessary to compile the primary study results before manuscript submission to an appropriate journal. All publications will comply with the CONSORT extension to cluster randomized trials guidelines, as appropriate [32]. All investigators and sub-investigators that have actively participated in the trial will be listed at the end of all manuscripts if this can be arranged with the publisher. Authors' names will be listed in order of contribution. Assistance for preparing and editing manuscripts (i.e., English language revision) provided by professional medical writers will be acknowledged.

No later than 3 years after final acceptance of the primary study paper, a completely de-identified data set will be available for sharing purpose, upon reasonable request to the principal investigator. In accordance with French regulation, study participants will be provided with the overall trial results upon request to the principal investigator.

DISCUSSION

This protocol describes the rationale for the EPECREM randomized controlled trial project, explains how the experimental intervention will be implemented, how data collection will be conducted, and how the results will be analyzed and interpreted. The potential limitations of this trial deserve mention. First, the control group will not receive any specific intervention. Actually, our trial is not designed to compare the effectiveness of concurrent training programs but to demonstrate that a multifaceted training program improves physician interpersonal skills. Second, physicians might avoid recruiting patients with whom the interaction is perceived as unfavourable. To limit the potential for patient selection bias, participating physicians will be invited to enroll consecutive eligible patients. Only initial consultations for new patients will be eligible. A list of eligible consultations during the recruitment period will be established for each participating physician. Third, the Maslach Burnout Inventory scale was originally developed for assessing burnout and may lack sensitivity to detect clinically significant differences in physician self-actualization between study arms. To our knowledge, very few standardized scales assessing physician's self-actualisation have been published. The Maslach Burnout Inventory, which has been translated and validated in French, includes a self-accomplishment subscale. Fourth, our study is conducted at a single university-affiliated hospital in France and our findings may not apply to other settings or regions.

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Contributors:

AB conceptualized the study and is the guarantor. AB and PC developed the protocol and drafted the initial manuscript. AB and JL provided statistical expertise. AB, PC, AP, ZP, GC, SC and FP will be involved in the acquisition of data. All authors critically reviewed the protocol and approved submission of the final manuscript.

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Competing interests statement:

None declared

Word counts:

4372

Table 1. Intervention description according to the TIDieR checklist (Template for intervention description and replication)

Brief name	Multifaceted program for interpersonal and communication skills development in medical consultation
Why	Improved doctor-patient interpersonal skills are associated with improved patient satisfaction and quality of care, but there is a lack of evidence in the literature on how to develop these skills.
What	The multifaceted program includes two 4-hour workshops and feedback on the interpersonal skills observed during the doctor's consultation. Before the first workshop, an evaluation questionnaire based on the Process Communication model is sent to each participant. This questionnaire allows us to establish the communication profile of each participant. The first workshop presents the Process Communication theoretical model of communication during 2 hours to explain the profile of each person. A one-hour theoretical presentation is also given on interpersonal skills, based on the 4-HCS scale and the model developed by Kaiser Permanente organization. The last hour consists of a communication approach based on Process-Com and adapted to the doctor-patient relationship, linking the two theoretical models presented. The second workshop includes role-playing situations in groups of 3 people, with an observer, a physician and a patient. An observation grid inspired by the 4-HCS scale is given to each observer to allow a constructive debriefing on interpersonal skills. The participants take turns exchanging roles and a collective debriefing is conducted after each clinical situation. These clinical situations involve different communication profiles in order to apply the knowledge acquired in the first workshop. A detailed written analysis of the interpersonal skills observed during the consultations is finally given to each participant after the workshops. This analysis details strengths and areas for improvement, based on the 4-HCS assessment of the video recorded consultations by the physicians.
Who provided	The workshops are conducted by an expert in the field of communication with 20 years of experience in the hospital medical field. This expert is a professional trainer with a degree in communication and expert in the Process Communication model. The physician who also conducts the training is a physician who has conducted the cross-cultural adaptation of the 4-HCS scale into French, with experience in nearly 1000 consultation assessments using this scale. Interpersonal skills assessments are conducted by another physician with experience of several hundred evaluated consultations with 4-HCS scale.
How	The workshops are conducted in groups of 8 to 12 people with 2 trainers at 1-month intervals. The evaluations of the participants' consultations are sent by e-mail in the form of paragraphs describing the strengths and weaknesses in relation to the interpersonal skills assessed by the 4-HCS scale. Videos are added to the e-mail.
Where	The workshops take place in a classroom located in the hospital. Medical consultations take place in the doctor's usual department.

When and how much	The training includes 2 workshops of 4 hours at 1-month interval, as well as individual feedback on 8 consultations of the participating physician.
Tailoring	The training is adapted to the communication profile of each participant during the first workshop, based on the results of the previously completed Process Communication questionnaires. The feedback during the second workshop is adapted to the content observed during the different role plays.
Modifications	No changes made to the program
How well (planned)	The verification that each workshop participant has completed the communication profile questionnaire is done prior to the training. A monitoring is also done during the second workshop by the trainers to ensure that each participant changes roles systematically during the role-playing session.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	19
Roles and responsibilities: sponsor and funder	#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	19
Roles and responsibilities: committees	#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)	13
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	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	5
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, non-inferiority, exploratory)	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	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	7

		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8
Interventions: modifications	#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)	9
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
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	10
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)	8
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	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
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	10

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	12
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection plan	#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	12
Data collection plan: retention	#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	13
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	13
Statistics: outcomes	#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	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13

Statistics: analysis population and missing data	#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)	13
Methods: Monitoring			
Data monitoring: formal committee	#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	13
Data monitoring: interim analysis	#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	13
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	13
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
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)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	14
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect	14

		confidentiality before, during, and after the trial	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
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	14
Dissemination policy: trial results	#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	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	15
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Not applicable
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	Not applicable