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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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ABSTRACT

Introduction Interpersonal skills, encompassing communication and empathy, are key components of effective medical consultations. Although many organisations have implemented structured training programmes, 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 programme 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 programme or no intervention. The experimental intervention combines two 4-hour 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 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 21 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.

Strengths and limitations of this study

- Physician's 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 programme.
- 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-centred 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 non-verbal behaviours 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 programmes and routinely assess

physicians' communication skills using standardised scales.[2 8] However, limited evidence exists on the effectiveness of these programmes 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 randomised 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 programme 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 programme addressing basic medical interview tasks that was developed within the US Kaiser Permanente Health Maintenance Organization. This training programme has been implemented for teaching effective communication skills in various organisations in the USA and Norway.[12]Previous reports suggest that training programmes 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 min in the UK to more than 20 min in the USA, with an intermediate value of 16 min 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 programme may improve the communication and interpersonal skills of hospital physicians, without altering the length of consultation. A multifaceted programme 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 practice 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 programme 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 programme 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 randomisation will be physician. 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 1 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

enrolment, 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 preintervention period and four patients in the postintervention 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 1 July 2021 to 31 October 2021, with an estimated trial end date of 31 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.
  - Patient who is 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 who 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.

Preintervention 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 centred 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 programme

The physicians assigned in the intervention arm will receive the experimental multifaceted training programme. 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-centred relationship.[20] Each of the dimensions of the 4-HCS (ie, '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] The overall effectiveness of the programme 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 programme. 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 coanimation. The training will comprise two 4-hour sessions 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 4-hour session of training will, thus, include a review of the skills needed to establish a patient-centred 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 communication. The workshop provides an understanding of how to enter into a relationship, how to analyse non-verbal behaviour and how to improve patient-centred 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 USA[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 programme 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]

Postintervention 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 postintervention 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 minimise the likelihood of unintentional contamination from experimental to control group, in this parallel-arm cluster randomised 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 subscales. Median average absolute-agreement intraclass correlation coefficient estimates were 0.74 (range, 0.68–0.84) and 0.85 (range, 0.76–0.91) for inter-rater and intrarater 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

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

Brief name	Multifaceted programme 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 programme 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 1-hour theoretical presentation is also given on interpersonal skills, based on the 4-HCS scale and the model developed by Kaiser Permanente organisation. 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 three 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 8–12 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 two 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 programme
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.

HCS, Habits Coding Scheme; TIDieR, Template for Intervention Description and Replication.

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: four patients/physician) in each arm (ie, 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 SD of the 4-HCS score equal to 10[24] and an intracluster correlation coefficient equal to 0.30.

Each arm of the trial will include 56 preintervention and 56 postintervention 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 minimise the likelihood of cross-contamination between study arms. Randomisation will be stratified and balanced by minimisation on the status (incumbent vs non-incumbent) and specialty (medical vs 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 preintervention 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 pre-intervention 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. The correspondence between the anonymity number and the allocation group with the arm of the study can be determined only by the statistician who generates the sequence of randomisation. 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 will be created for the study. Trial data management will be carried out in accordance with on-site standard operating procedures. 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 computerised programmes 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 programme) and evaluable. The numbers of patients and physicians in ITT and PP populations will be presented by study arm throughout a flowchart extension for cluster randomised trials.

Descriptive summary statistics will be used for reporting continuous (arithmetic mean and SD or median and 25th–75th 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 (ie, 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 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 V.16 or higher (Stata Corporation, College Station, Texas) and RStudio V.1.3.959 or higher (PBC, Boston, Massachusetts).

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* 2013 statement.[31]

ETHICS AND DISSEMINATION

Research ethics approval

The study protocol was approved on 21 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

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 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 Consolidated Standards of Reporting Trials extension to cluster randomised trial guidelines, as appropriate.[32] All investigators and subinvestigators 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 (ie, 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 deidentified data set will be available for sharing purpose, on reasonable request to the principal investigator. In accordance with French regulation, study participants will be provided with the overall trial results on request to the principal investigator.

DISCUSSION

This protocol describes the rationale for the EPECREM (Effectiveness of a multifaceted Program to Evaluate the improvement of RElational Competencies in Medical consultation) randomised controlled trial project, explains how the experimental intervention will be implemented, how data collection will be conducted and how the results will be analysed 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 programmes but to demonstrate that a multifaceted training programme 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 enrol 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-actualisation between study arms. To our knowledge, very few standardised 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 conceptualised 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 None declared.

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