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Effectiveness of patients' involvement in a medical and nursing pain education programme: a protocol for an open-label randomised controlled trial including qualitative data

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ABSTRACT

Introduction Pain is a multidimensional experience that varies among individuals and has a significant impact on their health. A biopsychosocial approach is recommended for effective pain management; however, health professionals' education is weak on this issue. Patient involvement is a promising didactic methodology in developing a more holistic perspective, however there is a lack of reliable evidence on this topic. The aim of the present study is to evaluate the effectiveness of patient involvement in pain education in undergraduate medicine and nursing students.

Methods and analysis An open-label randomised controlled trial including qualitative data will be conducted. After an introductory lesson, each student will be randomly assigned to the intervention group, which includes an educational session conducted by a patient–partner along with an educator, or to the control group in which the session is exclusively conducted by an educator. Both sessions will be carried out according to the Case-Based Learning approach. Primary outcomes will be students' knowledge, attitudes, opinions and beliefs about pain management, whereas the secondary outcome will be students' satisfaction. The Pain Knowledge and Attitudes (PAK) and Chronic Pain Myth Scale (CPMS) will be administered preintervention and postintervention to measure primary outcomes. Students' satisfaction will be measured by a questionnaire at the end of the session. Two focus groups will be conducted to evaluate non-quantifiable aspects of learning.

Ethics and dissemination The protocol of this study was approved by the independent Area Vasta Emilia Nord ethics committee.

Adherence to The Declaration of Helsinki and Good Clinical Practice will ensure that the rights, safety and well-being of the participants in the study are safeguarded, as well as data reliability. The results will be disseminated through scientific publications and used to improve the educational offer. A version of the anonymised data set will be released for public access.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first randomised controlled trial that evaluates the involvement of the patient–partner in pain management training on a sample of students across different health professions.
⇒ The use of Case-Based Learning methodology in both arms allows to assess the contribution of patients' involvement in pain education programme.
⇒ The involvement of patients concerns all the stages of the research process and not only the implementation of the intervention.
⇒ The study is single centre and will be conducted on a small number of students limiting the generalisability of the data.

Trial registration Trial was not registered on ClinicalTrials.gov as the interventions being compared only concern educational programmes and the outcomes considered do not refer to any clinical dimension.

INTRODUCTION

The experience of pain is very common in the general population, and it is one of the most frequent reasons for seeking medical assistance, especially in primary care.[1] It is also well known that acute and chronic pain has a significant impact on quality of life.[2 3]

Several studies have reported that healthcare professionals' knowledge, attitudes and beliefs towards pain as well as patient's sociodemographic factors such as gender[4] and ethnicity[5] influence the management of patients with pain.[6] Authors conclude that these aspects often explain: (a) ineffective interventions,[7] such as the use of lower or disproportionate analgesic doses compared

with the actual need of the patient; (b) discrepancies in the judgement of the patient's pain intensity between healthcare providers and the patient themselves, and/or the caregivers.[8] Healthcare professionals often put the focus on the biomedical causes of pain, especially chronic pain, neglecting psychological and environmental determinants and the impact that pain has on the life of the person as a whole.[9] In other words, despite recommendations in the guidelines,[10] pain assessment and treatment are rarely characterised by a bio-psycho-social approach.[11]

The lack of attention to this aspect in health professionals' undergraduate education on pain management has been pointed out to account for these aspects.[12] A recent systematic review about pain medicine content, teaching and assessment in medical school curricula, at international level,[13] concluded that medical education was insufficient to meet the health needs of the population on this topic. The didactic methodologies used in health professionals pain education are mostly based on traditional lectures or seminars, while innovative didactic methodologies, such as Case-Based-Learning (CBL), small group teaching and Problem-Based-Learning (PBL) have been rarely used.[13] In this regard, patients' involvement in medical undergraduate courses is still anecdotal.[14] A study found that involving patients, who experienced pain, in the course faculty may help students to adopt a more biopsychosocial approach in the treatment of chronic pain.[15] Another study highlighted an improvement in the students' skills and self-confidence in the collection of anamnesis when patients are involved as partners.[16] The involvement of patients in health professionals' undergraduate education is advocated by the scientific and medical community and it is already adopted in several universities.[17] The patient's involvement in education can take place in different ways (patient witness, expert–patient and patient–partner) and for different educational objectives, such as patient-centred care.[1 4 8] It has been shown to be effective in improving health professionals' awareness of the importance of communication, listening, empathy[18] and respect in the relationship with patients and in developing a more holistic perspective on care.[19] Listening to patient stories can influence clinical and research decisions regarding their pain management, as them and their families have personal experiences to share that can help educators, students and researchers understand more accurately how pain affects their lives.[20]

The patient's involvement in the care team and the adoption of a more biopsychosocial care perspective on pain management should be considered priorities in medical practice and these achievements can be reached starting from improving the education at university.[21 22] However, patients' involvement in health-education practice is still not well established and its impact on pain management skills has not been completely evaluated.

Theoretical perspective

In this training context, patient involvement in health-education practice, CBL, small group teaching and PBL are new teaching and learning methods that follow the theoretical perspective of sociocultural learning theory.[23] Sociocultural theory conceives learning as 'distributed' and emerging from interactions, differing from the current medical learning/teaching, which often risks of taking an individualist perspective.[24] As to this protocol, in particular, connecting patients (their biographical experiences and narratives) with medical and nursing students means offering the opportunities to examine how learning occurs at the level of the environment in which medicine/nursing is learnt and will be practiced in the future.[25 26] As Torre and colleagues pointed out, applications of sociocultural learning theory to medical education include collaborative/cooperative learning, and teaching with case studies. The idea behind this study comes from the sociocultural learning perspective mentioned above.[27] By listening to the experiences of others, namely patient–partners, trainees may develop a cognitive representation of the observed/heard experience in a learning process, which is defined as an interaction with, and observation of, others in a social context.[27]

Aims

The overall aim of this study is to evaluate whether the involvement of a patient–partner in a pain education intervention directed to undergraduate students of medicine and nursing could improve students' knowledge, attitudes, opinions and beliefs on pain management and student's satisfaction.

Specifically, primary outcome measures are students' knowledge and attitudes (P1), their opinions and beliefs (P2) on pain management. The secondary outcome is student's satisfaction with the educational intervention (S1). To have a broader understanding of the phenomenon, information on perceptions and experiences of medical and nursing students will be collected.

METHODS AND ANALYSIS

Study design and setting

An open-label, single-centre, randomised controlled trial and a nested qualitative study will be conducted. The study will be carried out at the University of Modena and Reggio Emilia, as part of the activities promoted by the EduCare Laboratory, which is an interdepartmental laboratory for promoting patient's involvement within the University and in healthcare facilities. The Laboratory team is composed by professionals, patients, caregivers and researchers. Further information can be obtained on the website: https://www.educare.unimore.it/. A full diagram of the study's structure and participant's flow is shown in figure 1.

Medical and nursing courses in Italy

In Italy, both the Degree programmes of Medicine and Nursing are organised by the Faculty of Medicine and Surgery and they are taught separately.

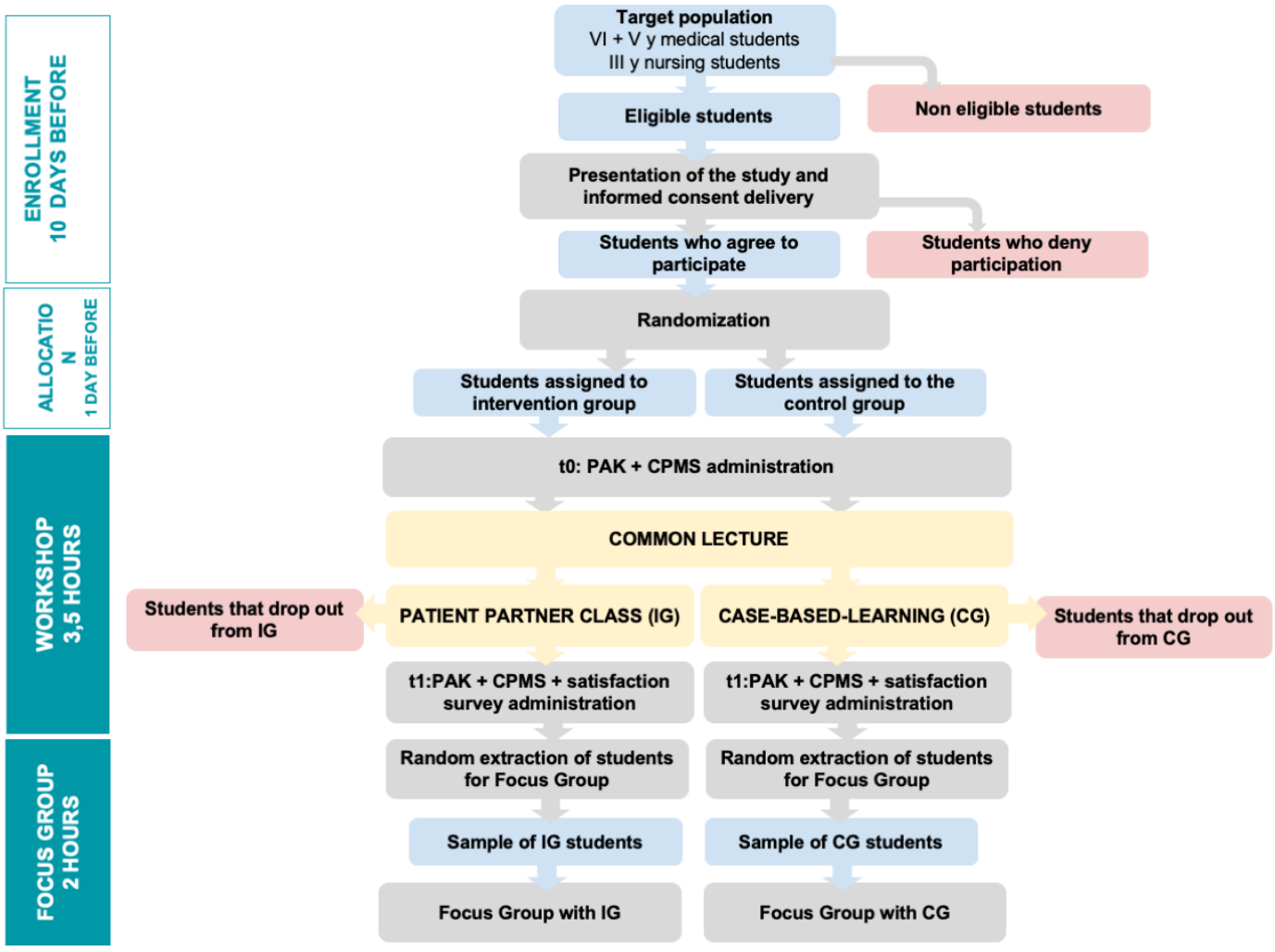

Figure 1 The study's diagram and participants' timeline: since the enrolment of eligible students (15–10 days before the Workshop) to the timeframe of the Workshop and of the administration of both quantitative (questionnaires) and qualitative (Focus Group) data collection methods. CG, control group; IG, intervention group; CPMS, Chronic Pain Myth Scale; PAK, Pain Knowledge and Attitudes.

The Degree programme in Medicine and Surgery is divided into 6 years. During the first 2 years, the basic sciences are mainly addressed. Starting from the third year, all clinical disciplines, medical, surgical, diagnostic and laboratory specialities, disciplines of public health, legal medicine and occupational medicine are taught. Parallel to the lectures, students attend professional training activities at University Hospital, affiliated care facilities and primary care setting.

The Degree Programme in Nursing is divided into 3 years; first year is aimed at providing basic biomedical, hygienic-preventive knowledge and the foundations of the professional discipline. The second year aims at deepening pathophysiological, clinical pharmacological and welfare knowledge to address the most common health problems in medical and surgical fields. The third year is dedicated to the nursing disciplinary study, the acquisition of knowledge and methodologies relating to professional practice, the development of the ability to work in teams and in complex organisational contexts. The relevance assigned to internship experiences increases over the 3 years in which students experience autonomy and acquire responsibility under the supervision of expert health professionals.

Pain education in the Faculty of Medicine at the University of Modena and Reggio Emilia

Currently, pain education within the degree programmes of Medicine and Surgery and of Nursing is structured as follows:

A specific teaching module is active in the Nursing Degree Course, called 'Pain Nursing and Palliative Care', which is part of Nursing in Oncology teaching (four credits, corresponding to 100 hours of study and training). In the Degree Programme of Medicine and Surgery, pain education is taught in the fourth year, as part of Psychology and Neurophysiology teaching. In this course, some lessons about nociception and pain are present. Pain education is also provided in another module called 'Pain Therapy', which is part of the Anesthesiology and Emergency course.

Furthermore, in both Degree Programmes the topic is addressed transversally in various clinical teachings.

Eligibility criteria

Students

An invitation to participate in the study will be issued to medicine and nursing students. The eligibility criteria for students will be the following:

- Regular enrolment in the fifth and sixth years of Bachelor Course in Medicine and Surgery and in the third year of Bachelor Course in Nursing.
- ge ≥18 years.
- Having passed the curricular English examination.

Patients–partners

Patients–partners will be selected among those already involved in the EduCare Laboratory activities.

The eligibility criteria for PP will be the following:

- Having experienced acute or chronic pain during their history of illness or caregiving.
- Expressing the consent to narrate/ describe their own experience of pain or the experience of the person they are caring for.
- Expressing the desire and willingness to participate in the preparation, implementation and evaluation of the teaching sessions with students.
- Being active members of the EduCare Laboratory.

Educators of the intervention group (IG)

IG educators will be selected among the academic or professional staff of the EduCare Laboratory.

The eligibility criteria will be the following:

- Being a member of the EduCare Laboratory.,
- Past experience in education with patient–partner.
- Expressing the desire and willingness to participate in the preparation, implementation and evaluation of the teaching sessions with students.

Educators of the control group (CG)

Educators of the CG will be selected among the academic staff and the collaborators of the Course of Family Medicine at the University of Modena and Reggio Emilia.

The eligibility criteria will be the following:

- Being a health professional.
- Expressing the desire and willingness to participate in the preparation, implementation and evaluation of the teaching sessions with students.
- Past experience of tutorship.

Intervention

Structure of the Workshop

The overall structure of the Pain Management Workshop will be the following:

- egistration procedures and informed consent's collection (30 min).
- ntroductory lecture, common to IG and CG (1 hour).
- Small group sessions: in IG they will be conducted by a patient–partner and an educator; in CG by an educator alone (2 hours).
- Debriefing plenary session, separately for IG and CG (30 min)

Description of the introductory lecture

The first part of the seminar is represented by an introductory lecture, common both to the intervention and the CG. In the medical student Workshop, the lecture will be taught by general practitioners, as part of the teaching of family medicine and primary care course, while in the nursing student Workshop, it will be held by nurse members of the Faculty, according to the indications for basic training of IASP Core Curriculum (IASP).

Preparation of the intervention Workshop

In the weeks prior to the workshop, patients, caregivers and professionals who are members of the EduCare Laboratory will be asked to narrate an experience of pain (acute, chronic, their own or that of a patient or person they are caring for), according to the guidelines developed and consolidated by the EduCare Laboratory.[28 29] The narratives will be analysed by a team composed of: healthcare professionals with experience in qualitative research, experts in philosophy of language applied to care contexts and patients or caregivers partners with an interest in research. After the analysis, brief feedback will be provided to the authors during a 2 day (8 hours in total) educational module that will be organised for patients–partners and educators to jointly define the contents of the Workshop. During this educational module, the dyads patient–partners and health professionals will simulate the conduction of the Workshop with peers. Feedback and advice to improve the Workshop will be provided from the research team and pedagogy experts.

Description of the educational intervention in the intervention group

The educational intervention with the patient–partner will last a total of 2.5 hours and will take place in five small groups in which students will be randomly allocated. In each group, the patient–partner will narrate his/her experience of pain and then he or she will promote a discussion on experiences of pain among students. Each group will be asked to produce a synthesis/summary to highlight similarities and differences between experiences and good practices that have emerged from the group discussion. Then, one student for each group will be instructed to share the results during a 30 min plenary session through a short presentation.

Preparation of the control Workshop

The training of the faculty will be structured in two encounters of 2 hours each; in the first, a synopsis of the research project and the overall structure of the protocol will be presented, together with an introduction on CBL prepared by an expert of PBL and CBL methodologies.[30] During this first session, the clinical scenarios (that will be the same episodes of care faced in IG and CG except for the presence of the patient–partner) will be assigned

to the educators with the task of preparing a simulation Workshop for the second encounter. In the second encounter, each educator will simulate the conduction of the Workshop with peers. Feedback and advice to improve the Workshop will be provided from the research team and pedagogy experts.

Description of the educational intervention in the control group

The educational intervention in the CG without the patient–partner will last a total of 2.5 hours and will take place in five small groups in which students will be randomly allocated. It will be conducted using CBL methodology by an educator and will take place in the following way: the clinical scenario will be presented in different steps (clinical presentation, diagnostic hypotheses and treatment and management strategies) by the educator, and for each step the discussion in each group will be prompted using different tools (eg, post-its and polls, discussion in pairs). At the end of the discussion, a healthcare professional educator will draw conclusions. During a 30 min plenary session, one student for each small group will give a short presentation about what emerged from the group discussion.

Outcomes

Primary outcomes

The two primary outcomes, as defined above, are:

- P1, knowledge and attitudes about pain.
- P2, opinions and beliefs on pain.

Both outcomes will be assessed through questionnaires which will be administered in both arms before the educational intervention (T_0) and after it (T_1).

Knowledge and attitudes about pain will be measured through the Pain Knowledge and Attitudes (PAK) questionnaire,[30] while opinions and beliefs on pain will be measured through the Chronic Pain Myths Scale (CPMS)[31] questionnaire in its English version.[32]

A significant improvement in scores' value is expected between T_0 and T_1 in the IG with respect to the CG. In each student, the variation between the scores obtained at T_1 and T_0 will be calculated.

Pain Knowledge and Attitudes Questionnaire (PAK)

The PAK questionnaire[30] aims at measuring the attitudes and knowledge of healthcare professionals regarding pain and it is the only validated tool in Italian. The validation process took place on a large sample of Italian health workers (4961) in a hospital setting.

The PAK questionnaire is composed by 10 items, each of them scores from 1 to 5, where 1 corresponds to a completely wrong answer and 5 to a completely correct one. The final score is the sum of values obtained for each item and it ranges from 10 (all answers are wrong) to 50 (all answers are right). Knowledge and attitude about pain will be analysed as following: for each patient, the difference between the score obtained at T_1 and T_0 (ΔPAK_{T1-T0}) will be calculated. A positive difference will suggest an improvement. In each arm, the mean of ΔPAK_{T1-T0} will be estimated. The means of ΔPAK_{T1-T0} obtained in the IG and in the CG will be compared by using Student's t test or multivariable analysis.

Chronic Pain Myths Scale (CPMS) Questionnaire

It is a scale, originally developed in Canadian French,[31] consisting of 26 items aimed at investigating knowledge, beliefs and attitudes towards (1) people suffering from chronic pain, (2) the biopsychosocial impact of chronic pain and (3) the treatment strategies for chronic pain. It is a scale applicable to both the general population and healthcare professionals. Each element is associated with a 5-point Likert scale ranging from 1 (completely disagree) to 5 (completely agree). Similarly to what followed with PAK score, to assess the presence of an improvement in performance, the $\Delta CPMS_{T1-T0}$ will be calculated and compared between the two groups.

Secondary outcome

The level of satisfaction and appreciation of the training and teaching activity will be considered as a secondary quantitative outcome (S_1) and it will be measured at T_1 by a questionnaire. When compared with the CG, the IG is expected to show, on average, a significantly increased satisfaction score.

Regarding the qualitative part of the study, the impact of the patient–partner will be explored by means of qualitative interviews conducted through focus groups. Comparing the IG with the CG, the qualitative analysis is expected to offer insights into the following dimensions:

- Perceptions and experiences of medical and nursing students on pain and patients with pain.
- eaning-making and sharing of the pain experience.
- Advantages, challenges and opportunities of the patient's involvement in education.

Sample size

We expect to enrol about 220 students, 50% of them will be students enrolled in the fifth and sixth years of the Bachelor of Medicine and the remaining 50% will be students in the third year of the Bachelor of Nursing. This figure corresponds to about 80% of the students attending both Bachelors.

Setting alpha=0.05 and beta=0.20, this sample size will allow us to detect a statistically significant difference between the means of ΔPAK_{T1-T0} observed in the two groups of at least two points, assuming a SD of ΔPAK_{T1-T0} of 3.

Assignment of interventions

Allocation

The randomization list, stratified by year of course and gender, will be generated through Stata Software that randomly assign the participants to the IG and CG with a ratio of 1:1. Randomisation will be carried out by an independent statistician of the Unit for the Statistical and Methodological Support to Clinical Research of Azienda Ospedaliero-Universitaria di Modena, who will not be involved in the delivery of the educational intervention.

Blinding

Given the nature of the study, it would not be possible to perform any form of blinding for both participants and researchers, who will conduct the focus group and analyse the qualitative data. However, the statistician who will analyse the results of the PAK and CPMS questionnaires will be blinded in this respect, without knowing their belonging to the IG or CG. To avoid contamination between IG and CG, educators of the different groups will be trained separately and will never meet before the day of the Workshop. The small group sessions will be conducted in separate places for the IG and CG to avoid exchange of information between participants.

Data collection, management and analysis

Quantitative data collection

All questionnaires will be administered in an electronic version, by showing a QR code on the SurveyMonkey platform to all participating students. All questionnaires are designed to be quickly completed (15 min).

Qualitative data collection method

For the collection of the qualitative data, two focus groups will be organised at the end of the intervention, one for the IG and one for the CG. Two students from each small group will be asked to participate in the focus groups. Each focus group will be carried out by an expert moderator and an observer, who is part of the research team. The session will be recorded via audio-recorder.

Strategies to promote participation

According to the Declaration of Helsinki and Good Clinical Practice, students' involvement will take place on voluntary basis. The students participating in the study will receive credits for attending optional classes.

Data management

GDPR (General Data Protection Regulation) compliance will be guaranteed through the use of the SurveyMonkey platform for data collection. All data relating to the participants, their informed consent, as well as the original patient narratives and consent to their use will be stored in a password-protected folder on the computer of the EduCare Laboratory for 7 years and will only be accessible to researchers. All information will be confidential and used in accordance with data protection and privacy legislation. The Principal Investigator is responsible for data transmission and ownership (for the purposes of art. 29 of Legislative Decree 196/2003) and she guarantees for the quality of the study.

Quantitative data analysis

The data will be analysed by using the STATA software programme (StataCorp LP, College Station, TX, USA). The Unit for the Statistical and Methodological Support to Clinical Research of Azienda Ospedaliero-Universitaria di Modena will be in charge of the management of data and their analysis. A comprehensive descriptive data analysis will be carried out. For each group, the frequency distribution of the characteristics will be given in absolute and relative numbers, median plus IQR or mean values±SD. The comparison between IG and CG with respect to PAK and CPMS questionnaires will be carried out as follows: for each student, the difference of the values of both scores between T_0 (start of experimentation) and T_1 (end of experimentation), defined as ΔPAK_{T1-T0} and $\Delta CPMS_{T1-T0}$, will be calculated. The obtained Δs in each group will be compared by using Student's t-tests or non-parametric tests, as well as multivariable models. Results will be considered statistically significant if their p-values are less than 0.05. All data will be analysed according to the intention to treat principle.

Qualitative data analysis

Focus groups will be audio-recorded with the consent of the participants. The day following each focus session, the moderator and the observer will produce a written report to highlight the most relevant themes. The thematic analysis procedure described by Braun and Clarke,[33] whose steps are reported below, will be used:

1. ranscription of verbatim recordings and full reading.
2. ubdivision into conversation sequences and definition of the initial labels.
3. The labels will be combined to identify the main themes and sub-themes.
4. omments on the list of issues identified to ensure internal consistency.
5. Description of the main themes
6. riting the first results report.

Data will be presented in a manner that includes measures of the intensity of identified themes, as indicated by the frequency of labels associated with these themes and subthemes. To ensure a comprehensive understanding, the analysis will begin by examining each of the two focus groups separately. Subsequently, a cross-sectional analysis will be conducted to uncover both commonalities and disparities between the two groups. Furthermore, any shifts in meaning, referred to as 'meaning shifts', will be diligently explored.

The chosen approach is an inductive analysis method, primarily intended to be descriptive and exploratory. The primary objective is not to formalise the analysis into a rigid model but rather to offer a rich and nuanced portrayal of the data.

However, considering this exploratory nature, further qualitative inquiry will be relevant for incorporating relevant insights from the literature[34] and modelling what may work, how and why in future programme implementation. Its overarching aim will be to conceptualise and formulate a theory that comprehensively elucidates how the presence of patient–partners shapes and exerts influence on the learning environment of medical students.[35]

Patient and public involvement

The development of the study has seen the involvement of patient–partners and the collaboration of selected patients and caregivers (FR and EB) from EduCare

Laboratory. The formers were involved in several stages of this project including the identification of the research question, the choice of the study design and they will take part in the intervention administration and discussion of the results. The research question addressed in this study was identified through a discussion with members of the EduCare Laboratory.

ETHICS AND DISSEMINATION

This protocol has been written following the Standard Protocol Items: Recommendations for Interventional Trials guidelines.

The protocol of the present study (Version 4, 13 October 2021) was approved by the independent ethics committee Area Vasta Emilia Nord (comitato.etico@pec.aou.mo.it) on 19 October 2021 with protocol AOU 0031533/21.

The Declaration of Helsinki and its revisions are the reference for the ethical aspects of this study. The Principal Investigator is responsible for conducting the study in accordance with the current guidelines of Good Clinical Practice, which represent the international quality standard for the design, conduct and dissemination of studies involving human subjects. Adherence to these standards ensures that the rights, safety and well-being of the subjects involved in the study are safeguarded, and that the data obtained from the study are credible. The results of this research project will be disseminated through scientific publications in peer-reviewed national and international journals and discussed within the EduCare Laboratory Faculty to improve the educational offer. At the conclusion of the study, the authors intend to provide the anonymised data set for public accessibility as supplementary material for the forthcoming manuscripts.

Informed consent

All eligible students will be informed of the nature, purpose and course of the study by the investigators and through an understandable written document provided by them. The student who signs the consent will be informed that participation in the study is voluntary and that they can withdraw their consent to participate at any time and this will not affect their academic progression. A copy of the informed consent will be available on request to the correspondence author.

Access to data

The Principal Investigator will ensure the monitoring, verification and review of the Ethics Committee and the regulatory authorities at every stage of the study, providing direct access to both the data and the original documents. According to the European guidelines, a Data Monitoring Committee (DMC) was not required, as this study is an interventional educational trial, with a relatively small sample size without critical safety concerns. The authors plan to share, at the end of the study, the anonymised data set to guarantee public access to data.

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Contributors AS, MSP, LG and MGR conceived the overall study design. AS and MSP communicated with the Ethic Committee to obtain the approval. AS, MSP, MGR, PF, FL, EB, SA, SC, DF, AC and FR participated in the design and preparation of the educational intervention for IG and CG. RD, PF and AS planned the sampling, allocation and statistical strategy. LG, MSP and MGR provided advice on the qualitative methods. AS wrote the first draft of the manuscript, RCC, VS, MDC and SA provided substantial revisions and all authors provided constructive feedbacks and approved the final version of the manuscript. FR provided language revision. All authors met the authorship eligibility criteria, and no professional writer was employed.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

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