The effect of a structured, home-based interview with a patient with a chronic illness on first-year medical students' patient-centredness: protocol for a randomised controlled trial.

19th October 2018

NCT03722810

Michael Harris, Anna-Lea Camenzind, Rita Fankhauser, Sven Streit, Roman Hari

Protocol v2b (English language only)

Abstract

Background

Doctors are regarded as professionals, and specific teaching on professional behaviour is considered important in many countries. For medical students, early patient contact experiences were found to be an important way of learning about professionalism, and learning activities promoting critical reflection were particularly effective. Medical students consider that patient-centredness is one of the most important aspects of medical professionalism, and the PPOS questionnaire has been used extensively in measuring the attitudes of medical students towards patient-centredness. The PPOS-D12 questionnaire is a validated German version of that questionnaire.

The study aim is to assess how a structured, in-depth, home-based interview with a patient with a chronic illness affects first-year medical students' patient-centredness.

Methods

In this randomised controlled trial, medical students who are in the first year of their studies at the University of Bern will be randomised to either seeing a patient with a chronic illness for a structured, in-depth interview in their own home (the intervention), or to reading an educational document that gives information about consultation skills (the sham comparator).

Students will complete the PPOS-D12 survey before and after the interventions, so that changes in their scores can be calculated, and the mean scores of the two groups compared. Secondary outcomes will be the effect of students' gender and prior exposure to chronic illness in the participant or her/his close relatives and friends on their PPOS-D12 scores. A nested study will measure the strength of association between the GP teachers' own levels of patient/doctor-centredness and changes in their students' levels over the year.

Discussion

This research will consider the effect of an in-depth, structured interview with a patient with a chronic illness on changes in first-year medical students' levels of patient-centredness. There is existing evidence that medical students' levels of patient-centredness reduce over their student years, and this study will contribute to an understanding of how this reduction can be minimised or reversed.

Background

Doctors are regarded as "professionals" both by the public and by their peers [1]. They are the most trusted profession among the public, and this has been the case for many years. Medical professionalism is not a new concept and has been present in the history of medicine in the form of a Hippocratic Oath taken by physicians [2]. However, medical professionalism is difficult to define and remains poorly understood [3]. While professionalism has become a widely emphasised subject in medical education and medical practice, there is still a lack of common understanding about the meaning of the concept. Discussions on the subject have thus been unsystematic, as the word "professionalism" has multiple meanings, complexities, and subtle differences [2].

Professional healthcare groups have their own set of norms (codes) which guide members of that profession in terms of how they should behave professionally. [4] These are designed and implemented by the profession's regulatory body, so differ according to different healthcare professions and countries. Over one hundred different dimensions of professionalism have

been identified. Swick [5] proposes that medical professionalism consists of specific behaviours (Table 1).

Table 1: Specific behaviours that constitute medical professionalism [5]
Physicians preferring others' interests over their own.
Physicians adhering to high ethical standards.
Physicians responding to social needs and their behaviours, reflecting a social contract to serve the community.
Physicians representing basic human values, including trustworthiness and honesty, compassion and sympathy, altruism and empathy, respect for others and trust.
Physicians being accountable for their own and their colleagues' actions.
Physicians being committed to excellence.
Physicians being committed to conducting research and updating their knowledge and using these in their professional field.
Physicians dealing with high levels of complexity and uncertainty.
Physicians reflecting on their actions and decisions.

Concerns about professionalism in medicine have made the explicit teaching and learning of ethics, professionalism and personal development necessary. The General Medical Council in the UK, and other professional bodies in both Europe and the Americas, have emphasised the need to enhance the teaching and learning of professionalism in medical schools, particularly the development of good attitudes, appropriate and competent skills, and the inculcation of a value system that reflects the principles of professionalism in medicine [6].

A study investigating tutors' and students' perspectives of the delivery of professionalism in the early years of Glasgow's learner-centred, problem-based learning (PBL) medical curriculum found that [7]: early patient contact experiences were found to be particularly important, and that learning activities promoting critical reflection were most effective. However, a systematic review found no unifying theoretical or practical model to integrate the teaching of professionalism into the medical curriculum [8]. There is no consensus about how best to teach professionalism [9], and few studies have explored the effectiveness of different teaching and learning methods for professionalism [4].

Research on students' understandings of professionalism identified 19 dimensions [4]. Of these, patient-centredness was the second most discussed dimension (after 'professionalism as rules'). Students' ideas of patient-centred professionalism came from a variety of sources: formal lectures on ethics, informal learning through role models, and from formal assessments. In the patient-centred clinical method, both the physician's and the patient's agendas are addressed by the physician and any conflict between them dealt with by negotiation [10]. This means that the physician aims to gain an understanding of the patient as well as the disease, and it is in contrast to the disease-centred method in which only the doctor's agenda is addressed. Summarising patient-centeredness elegantly, McWhinney describes the patient-centred approach as one where the "physician tries to enter the patient's world, to see the illness through the patient's eyes" [11]. Evidence suggests that patient-centred care is associated with a number of favourable biomedical, psychological and social outcomes [12], and it has been recognised as an important aspect of quality in health care [13].

There have been more than 900 papers published that measure patient-centred care or one of its components [14]. However, only two measurement instruments for attitudes towards patient-centredness in undergraduate medical students have been identified: the Doctor Orientation Scale and the Patient-Practitioner Orientation Scale (PPOS); of these two, the PPOS has been used much more extensively [15]. The PPOS was developed in 1999 to measure the attitudes of medical students towards patient-centredness [16]. It differentiates between patient-centred versus doctor-centred or disease-centred orientation, measuring attitudes along 2 dimensions: 'sharing' and 'caring' [17]. It has been used to assess attitude changes towards patient-centredness in medical student cohorts as they progress through the clinical curriculum.

The PPOS is available in 13 languages. It has been translated into German and the degree of medical students' patient-centeredness assessed in 2 student samples in Freiburg, Germany and in Basel, Switzerland [18]. Construct validity was tested using factor analysis. Based on factor analysis and tests of internal consistency, a shortened version with 6 items for each of the 2 subscales "sharing" and "caring" was generated (PPOS-D12). PPOS-D12 (see English-language version at Appendix 1) was found to be a reliable instrument to assess patient-centeredness among medical students in German-speaking countries.

In a longitudinal survey of medical students' attitudes toward patient-centred care in Greece, students' attitudes were significantly less patient-centred at the end of their studies compared to the beginning of their clinical curricula (mean score in year 4: 3.96; mean score in year 6: 3.81; $P < 0.001$) [17]. In a South African study, medical students from all undergraduate six years took the PPOS survey. There was a decrease in mean scores (from 2.65 in first-year students to 2.25 in final-year students), with the most pronounced decrease in the first two years of study [15]. [19]. In a year-long study of resident physicians at a university hospital in Tokyo, PPOS scores reduced significantly over the year (mean score at start of year: 4.5, SD 0.48; mean score at end of year: 4.39, SD 0.51; change: -0.11, SD 0.42) [20].

We have only identified one study that assessed the effect of an intervention on students' levels of patient-centredness. In this uncontrolled UK study, first-year dental undergraduates were given an attitudinal questionnaire to complete before and after their behavioural science course. No significant difference was found between their mean pre- and post-course PPOS scores (pre-course mean scores: 3.44 SD 0.33; post-course mean score: 3.37, SD 0.19; $P > 0.05$). We have found no controlled trials that test the effect of interventions on medical students' levels of patient-centredness, and no trials that look at the effect of early patient contact in the form of an unaccompanied visit to a patient in their home.

Aim of the study

The aim of this study is to assess how a structured, in-depth, home-based interview with a patient with a chronic illness affects first-year medical students' patient-centredness.

A nested study will assess whether the GP's level of patient/doctor-centredness affects changes in their student's level over the year.

Methods

Study setting

The study will take place in the Berner Institut für Hausarztmedizin (BIHAM) at the University of Bern, Switzerland, and a subset of the >700 General Practitioner (GP) teaching practices that are affiliated to it.

Study participants

The population will be medical students who are in the first year of their studies (their first Bachelor year) at the University of Bern, during their longitudinal placements in primary care. The GP teachers are family doctors that are accredited by BIHAM to take medical students.

Study design

This will be a randomised controlled trial. During their first Bachelor year, each medical student will spend a series of six half-days at the practice of a GP teacher that she/he has been allocated to. Students will be randomly assigned to either the intervention or the sham comparator which will take place during their last half-day in their practices. All students will complete an on-line version of the PPOS-D12 questionnaire at the start of the academic year and once more after the last half-day at their GP teachers' practices.

Intervention

The intervention will be a structured in-depth interview with a patient with a chronic illness that has been chosen by the student's allocated GP teacher. These chronic diseases are the four conditions at the top of a list of diseases with high disability-adjusted life years (DALY) scores in Switzerland: ischemic heart disease, low back pain, major depressive disorder and COPD [21]. GP teachers who only see children are asked to choose a patient who has a chronic cardiac condition, a chronic lung disease, or another chronic illness that has a significant effect on the child's quality of life, the interview to be carried out at the child's home with one or both parents, and the child if she/he is old enough to take part in the interview.

GP teachers and students will be told that the students' intervention interviews need to be unaccompanied and at patients' own homes, but in justified, exceptional cases, and after consultation with a member of the research team, the interview may take place in the GP teacher's practice premises. The interview will be followed by a structured interview with the practice nurse and then a structured debriefing interview with the GP teacher.

Sham comparator

In the sham comparator, the student's the allocated GP teacher will give the student time to read a document that gives information about consultation skills, and asks questions that the student will need to discuss with the GP teacher. The document is designed to have real educational value, and to complement BIHAM's department-based consultation skills teaching. The use of this approach as the sham intervention is based on a study that found that a behavioural science course (including consultation skills teaching) had no effect on students' PPOS scores [19].

Data collection

At the start of the academic year (i.e. before the interventions), students will complete a SurveyMonkey questionnaire that asks for demographic information (gender, history of serious chronic illness in the participant, a friend or close relative, history of training or patient contact other than in medical school) and the PPOS D12 form.

At the end of their GP attachment (i.e. after the interventions), students will complete a SurveyMonkey questionnaire that asks whether they had the intervention or sham comparator or neither (and if neither, why), and the PPOS D12 form. Consent to use these data for research will also be requested.

At the end of their students' attachments, their GP teachers will complete a SurveyMonkey questionnaire that asks them to complete the PPOS D12 form. Consent to use these data for research will also be requested.

Each of these questionnaires will ask for the participant's name, so that pre-intervention, post-intervention, and GP's data can be linked and compared.

Outcome measures

The primary outcome measure will be the change in students' PPOS-D12 scores from baseline (at the start of the academic year) to the end of their year-long primary care attachment.

Secondary outcomes will be the effect of students' gender, previous experience and prior exposure to chronic illness in the participant or her/his close relatives and friends on their PPOS-D12 scores

A nested study will measure the strength of association between the GP teachers' own levels of patient/doctor-centredness and changes in their students' levels over the year.

Development of the intervention

Following a literature review and discussion, RF, A-LC and MH developed a patient interview pro-forma which was designed to identify patients' views on their illnesses, how it affects their lives in physical, psychological and social terms, and how their relationships with their GPs impacts on their lives. The sections of the interview pro-forma map across to Mead and Bower's conceptual framework of patient-centredness given above [22].

Six medical students who had been visiting their GP teachers for eight half-days per year since their first year of study agreed to pilot the intervention in November 2017. The GP teachers were asked to select a patient with a chronic illness for their students, and to organise 2.5-hour interviews, half of the students at the patients' home and in the other half in the teaching practices. Students were asked to use the questionnaire pro-forma. In addition, the students each had a 30-minute interview with a practice nurse to assess their perceptions of the effect of the illnesses on their patients, and finally a one-hour discussion with their GP teacher to reflect on their encounters with the patients, discuss their findings, and talk about any difficulties that may have arisen.

Following this, RF conducted a focus group interview with the participating students. The discussion was recorded and transcribed in full. A-LC and MH analysed parts of each the transcript independently, then independently developed a coding frame. Their coding and thematic analysis was similar. The findings (the experiences, suggestions and criticisms of the piloting students) were used to make improvements in the organisation and in the information sheets for patients, students, MPAs and GPs.

Three medical students then piloted the re-designed interview pro-forma with one of the researchers (A-LC) role-playing the patient), and they gave feedback with recommendations on how the pro-forma could be further improved. Following this, RF, A-LC and MH reviewed the pro-forma and designed the final version. The interview proforma and instructions on implementation of the intervention will be sent to students and their GP teachers before the students' final visits to their teaching practices.

Development of the sham comparator

MH wrote an English-language 'Communication skills for BIHAM medical students' didactic document, which included sections on 'Why should I learn about communication skills?', 'What do patients want from a doctor?', What information are patients looking for?', What consultation skills should I use when I interview patients?', 'Do good communication skills really matter?', 'How can I learn good interpersonal and consultation skills?', 'How is a good consultation structured?', and 'Questions to discuss with your GP teacher'. This document was translated into German by A-LC. The resulting 1,850-word, 9-page document and instructions on implementation of the intervention will be sent to students and their GP teachers before the students' final visits to their teaching practices.

Randomisation

Participants will be allocated to intervention or sham intervention through random sequences generated in the SPSS statistical package.

Blinding procedures

This study will be partially blinded:

- Screening and enrolment. A person blinded to the purpose of the interventions (i.e. that one is the intervention, the other is a sham comparator) will enrol participants and allocate them to their arm of the study. This person will work separately from the rest of the trial team and all team members will be asked to sign a form stating that they will not disclose the purpose of the interventions to this person.
- Students. In a tailored informed consent procedure, students will be given a 'high-level description' of the study objectives with only superficial information on the study interventions, as accepted by ethics committees in similar studies. They will be informed that they are randomised to one of two study groups, without revealing that one is an intervention and the other is a sham comparator. The aim of this is to minimise performance and other reporting biases.
- GP teachers. A similar approach with be taken with information for the GP teachers, so that they also have only a 'high-level' description of the study objectives.

Statistical analysis

Descriptive statistics will be used to describe the relationships between student demographics and PPOS scores. Mean pre- and post-test PPOS scores will be compared using paired t tests. Differences between PPOS scores in the intervention and control groups will be examined with unpaired t tests. For the nested study, GPs' PPOS scores and changes in their students' PPOS scores will be compared using paired t tests.

The sample size calculation for the primary outcome was based on reported mean reduction of 0.11 in the PPOS score over one year in a group without any intervention [20], and a mean increase of 0.05 in the intervention group. We therefore assumed a mean difference 0.16, with a standard deviation of 0.42. The study was designed with a 5% level of significance and a 90% power to reject the null hypothesis of equivalence between the two groups. To achieve this objective, 220 students would be required (110 for each group). Assuming a 20% drop-out, we therefore aimed to enrol a total of 275 students.

Discussion

This research will consider the effect of an in-depth, structured interview with a patient with a chronic illness on changes in first-year medical students' levels of patient-centredness. There is existing evidence that medical students' levels of patient-centredness reduce over their student years, and this study will contribute to an understanding of how this reduction can be minimised or reversed.

Strengths

To our knowledge, this is the first randomised controlled trial that has been designed to study the effect of an intervention on medical students' levels of patient-centredness. The intervention materials were carefully developed and piloted by GP teachers and medical students, and therefore grounded in their clinical and educational experience.

Limitations

Although the research team will give participants information about the study in a presentation and in correspondence, there is a risk that fewer students than anticipated consent to take part in the study. While the researchers aim to blind participants to the nature of the comparison, i.e. that one intervention is the intervention and the other is a sham comparator, control intervention, participants may guess the researchers' intentions, and this may result in bias in their responses. The power calculations have been based on data from other published studies, but these may not be directly comparable to our own study. Our control intervention has been chosen because of evidence that teaching dental students about communication skills does not affect their levels of patient-centredness, but it is possible that our communication skills intervention will indeed have an effect the levels of our medical students' patient-centredness, and thus not be a truly inactive control.

Expected impact

One of the aims of BIHAM's clerkships in primary care is to shift the medical students' focus towards 'professionalism', and patient-centredness is an important aspect of professionalism. This study will assess whether a single in-depth structured interview with a patient, followed by a de-briefing interview with the patient's GP, can contribute to achieving this aim.

Quality assurance

The study may be monitored or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

Confidentiality

The research team will ensure that the participants' anonymity is maintained. As soon as each student's pre- and post-intervention questionnaires have been matched with each other and those of their GP teachers, each participant will be identified only by a participant ID number on all study documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. Under no circumstances will the identifiers be made available to individuals outside the research team.

Dissemination

Results will be published in peer-reviewed scientific journals as well as by conference presentations. The researchers will publicise the project findings within their university and the Swiss health system, for example in newsletters, websites, meetings and local journal publications.

Funding

This research receives no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Availability of data and materials

Only the research team at the University of Bern will have access to the data during the study. The datasets analysed during this study will be available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The research proposal was presented to the regional ethics committee (Kantonale Ethikkommission für die Forschung, Gesundheits- und Fürsorgedirektion des Kantons Bern) and a waiver was issued on Jan 24th 2018 stating that the study does not fall under the Swiss Human Research Act (BASEC-Nr. Req-2018-00059).

Students and GP teachers will be sent an email with a link to the online survey, where they will be given information about the project, an assurance that their answers are confidential, and a request for their agreement to allow their data to be used in the study. Clicking on the 'agreement' button will be considered as consent to participate in the study. Student and their GP teachers, as well as the selected patients in the intervention group, will be given information sheets about the study.

Competing interests

The authors declare that they have no competing interests.

Timetable

	Sep-Dec 17	Jan 18	Feb 18	Mar-May 18	Jun 18	Jul 18	Aug 18	Sep 18	Oct 18-May 19	May-July 19	Aug-Sept 19
Pilot 1	■										
Ethics application		■	■								
Pilot 1 analysis			■	■	■						
Protocol					■	■					
Pilot 2 and analysis						■	■				
Finalise materials						■	■	■			
Data collection								■	■		
Write report										■	
Write paper										■	■

References

1. Medical Protection Society. Medical Professionalism - What do we mean? London2017 [31 October 2017]. Available from: http://www.medicalprotection.org/uk/advice-booklets/professionalism-an-mps-guide/chapter-1-medical-professionalism-what-do-we-mean

2. Seif-Farshad M, Bazmi S, Amiri F, et al. Knowledge of medical professionalism in medical students and physicians at Shahid Beheshti University of Medical Sciences and affiliated hospitals—Iran. Medicine. 2016;95(45):e5380. doi: 10.1097/MD.0000000000005380. PubMed PMID: PMC5106075.

3. Riley S, Kumar N. Teaching medical professionalism. Clin Med (Lond). 2012 Feb;12(1):9-11. PubMed PMID: 22372211; eng.

4. Monrouxe V, Rees C. Healthcare Professionalism: Improving Practice through Reflections on Workplace Dilemmas. Wiley-Blackwell; 2017.

5. Swick HM. Toward a normative definition of medical professionalism. Acad Med. 2000 Jun;75(6):612-6. PubMed PMID: 10875505; eng.

6. Sivalingam N. Teaching and learning of professionalism in medical schools. Ann Acad Med Singapore. 2004 Nov;33(6):706-10. PubMed PMID: 15608822; eng.

7. Goldie J, Dowie A, Cotton P, et al. Teaching professionalism in the early years of a medical curriculum: a qualitative study. Med Educ. 2007 Jun;41(6):610-7. doi: 10.1111/j.1365-2923.2007.02772.x. PubMed PMID: 17518842; eng.

8. Birden H, Glass N, Wilson I, et al. Teaching professionalism in medical education: a Best Evidence Medical Education (BEME) systematic review. BEME Guide No. 25. Med Teach. 2013 Jul;35(7):e1252-66. doi: 10.3109/0142159x.2013.789132. PubMed PMID: 23829342; eng.

9. Stockley AJ, Forbes K. Medical professionalism in the formal curriculum: 5th year medical students' experiences. BMC Med Educ. 2014 Nov 30;14:259. doi: 10.1186/s12909-014-0259-0. PubMed PMID: 25433816; PubMed Central PMCID: PMCPMC4261576. eng.

10. Levenstein JH, McCracken EC, McWhinney IR, et al. The patient-centred clinical method. 1. A model for the doctor-patient interaction in family medicine. Fam Pract. 1986 Mar;3(1):24-30. PubMed PMID: 3956899; eng.

11. McWhinney IR. The need for a transformed clinical method. In: Stuart M, Roter D, editors. Communicasting with medical patients. London: Sage; 1989.

12. Bauman AE, Fardy HJ, Harris PG. Getting it right: why bother with patient-centred care? Med J Aust. 2003 Sep 1;179(5):253-6. PubMed PMID: 12924973; eng.

13. Institute of Medicine Committee on Quality of Health Care in A. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington (DC): National Academies Press (US); 2001.

14. de Silva D. Helping measure person-centred care. In: The Health Foundation, editor. London2014.

15. Archer E, Bezuidenhout J, Kidd MR, et al. Making use of an existing questionnaire to measure patient-centred attitudes in undergraduate medical students: A case study. AJHPE. 2014;6(2):150-154.

16. Krupat E, Hiam CM, Fleming MZ, et al. Patient-centeredness and its correlates among first year medical students. Int J Psychiatry Med. 1999;29(3):347-56. doi: 10.2190/dvcq-4lc8-nt7h-ke0l. PubMed PMID: 10642908; eng.

17. Tsimtsiou Z, Kerasidou O, Efstathiou N, et al. Medical students' attitudes toward patient-centred care: a longitudinal survey. Med Educ. 2007 Feb;41(2):146-53. doi: 10.1111/j.1365-2929.2006.02668.x. PubMed PMID: 17269947; eng.

18. Kiessling C, Fabry G, Rudolf Fischer M, et al. [German translation and construct validation of the Patient-Provider-Orientation Scale (PPOS-D12)]. Psychother Psychosom Med Psychol. 2014 Mar;64(3-4):122-7. doi: 10.1055/s-0033-1341455. PubMed PMID: 23606403; ger.

19. Beattie A, Durham J, Harvey J, et al. Does empathy change in first-year dental students? Eur J Dent Educ. 2012 Feb;16(1):e111-6. doi: 10.1111/j.1600-0579.2011.00683.x. PubMed PMID: 22251333; eng.

20. Ishikawa H, Son D, Eto M, et al. Changes in patient-centered attitude and confidence in communicating with patients: a longitudinal study of resident physicians. BMC Medical Education. 2018;18:20. doi: 10.1186/s12909-018-1129-y. PubMed PMID: PMC5785873.

21. Institute for Health Metrics and Evaluation. Global burden of diseases, injuries, and risk factors study 2010, Switzerland. University of Washington, USA; 2012.

22. Mead N, Bower P. Patient-centredness: a conceptual framework and review of the empirical literature. Soc Sci Med. 2000 Oct;51(7):1087-110. PubMed PMID: 11005395; eng.

Appendix 1. PPOS-D12 English translation

Possible Likert-scale responses: 'I completely agree'; 'I agree'; 'I agree slightly'; 'I disagree slightly'; 'I disagree'; 'I completely disagree'.

1. Although treating patients today is not so personal anymore, it is ultimately a small price for medical advancement.

2. The most important part of the normal visit is the physical examination.

3. Patients should rely on the knowledge of their doctors and not try to inform themselves about their condition.

4. When doctors ask a lot of questions about a patient's personal situation, they are too involved in private matters.

5. When doctors are really good at diagnosis and therapy, their treatment of patients is not so important.

6. Many patients keep asking questions without really learning anything new.

7. Patients tend to want to hear that everything is good, rather than real information about their health.

8. When doctors first try to be open and make a warm-hearted impression, they will not be so terribly successful.

9. If patients disagree with their doctors, it shows that they disrespect their doctors and do not trust them.

10. The patient must always be aware that the doctor is responsible.

11. It is not so important to know the cultural background of a patient and his life situation in order to treat his illness.

12. When patients get their own medical information, it often confuses them more than it helps them.