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Empathy variation of undergraduate medical students after early clinical contact

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Abstract

Objectives Empathetic education is very important for medical students. There is little research on the influence of early clinical practice on the development of empathy and other professionalism in medical students. The aim of this study is to compare the self-reported empathy levels of the first- and second-year undergraduate medical students before and after their early clinical contact curriculum.

Setting The study was conducted in Shanghai University of Medicine & Health Sciences, Shanghai, China.

Participants 257 undergraduate medical students participated in the study. The 154 first year students were studying in 10 community-based teaching hospitals and the 103-second year students in 3 university-affiliated hospitals.

Primary and secondary outcome measures Primary measures: The Jefferson Scale of Empathy - Students version (JSE-S) was compared between different genders, and students in different academic years before their early clinical contact

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course. Secondary measures: comparisons were made after they finished the curriculum at one month later.

Results 219 out of a total of 257 students responded (85.21% response rate), and 214 answers were effective (135 first year and 79 second year students; 120 females and 94 males). No significant difference in the empathy scores before early clinical contact was observed between gender and different academic years. After early clinical contact, mean JSE-S score of the participants was significantly higher than the mean score at the beginning of the curriculum.

Conclusions Empathy focused training in early clinical contact can improve the empathetic capacity of undergraduate medical students. Fostering empathic attitudes to undergraduate medical students is necessary for their early stage of medical education. Further research is needed on the long-term effects of empathy-focused education in entry-level medical students.

Strengths and limitations of this study:

The results of this study reflect the positive influence of empathy education in early clinical contact training for undergraduate medical students.

There is no gender difference in the empathy scale of the Jefferson Scale of Empathy - Students version, which increased the support for previous related studies.

The interval between two self-reported questionnaires is only three weeks, which may have a certain impact on the result analysis because of recent memory.

Keywords: Empathy; Early clinical contact; Education; Undergraduate medical students

INTRODUCTION

Empathy is the ability to understand and share feelings of another 1, include cognitive, affective, behavioral and moral dimensions². The empathetic capacity of health care professionals plays an important role and empathy has been described as a major factor of professionalism in medicine ^{3,4}. Studies have shown that patients who trust their empathetic doctors tend to communicate well with their doctors and to provide more detailed information favorable for diagnosis and improvement of treatment compliance ^{5,6}. Empathy strengthens interactions between patients and doctors and improves doctor-patient satisfaction ⁷. High levels of empathy in health care professionals are connected to positive clinical prognosis for patients, such as reducing mental stress, improving self-awareness, and reducing anxiety and depression^{8,9}. For tomorrow's doctors, empathy education is as important as enhancing their clinical competence¹⁰. A systematic review showed that educational interventions can be effective in maintaining and enhancing empathy in undergraduate medical students ¹¹. Lim BT and his colleagues introduced a drama training method entitled "how to act-in-role" to enhance the empathetic communication skills of their medical students. This innovative teaching method increased not only students' self-reported empathy but also their competence in consultation skills ¹². Other training methods have also been proposed to enhance medical students' comprehension of empathy and their empathetic capacity, such as "communication skills training" ^{13,14}, "reflective writing"^{15,16} and "motivational" interviewing training" ¹⁷. While some studies showed that the empathy capacity of medical students will decline with the increase in their academic year ¹⁸⁻²⁰, others indicated that the empathy scores of students in their final year were higher as compared with first-year medical students ²¹. In addition to the changes in empathy level of different grade, gender is another very important influencing factor in the empathy ability of undergraduate medical students ²². In terms of gender differences, previous studies had some opposite results, the main reason may be the difference in

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the social-cultural background ²³. Moreover, as empathy level is difficult to measure, the standard approach of enhancing it in medical students remains debatable ²⁴.

Early clinical contact (ECC) for medical students is an important curricular innovation and was found to be particularly crucial for teaching professionalism ²⁵. ECC means real-patient contact in a clinical context that enhances learning of health, illness and/or disease, and the role of the health professional, occurring in the early or preclinical years of undergraduate education^{26,27}. Some studies showed that contact with patients early in medical students' training has a positive elicit emotional response that has the potential to trigger the developments of emotional maturity, relational skill, and patient-centered attitudes, and promote better understanding of health and illness ^{28,29}. However, there is little research on the influence of early clinical contact on the development of empathy or other professional abilities in medical students ³⁰.

In this study, we encourage our first and second-year medical students to focus on empathetic relationships between patients and doctors through our ECC curriculum, and hypothesize that this early empathy focused curriculum can improve their views of empathy and their empathetic capacities. First, we compared the empathy levels between genders and different years of medical students after their ECC course. Secondly, we analyzed the interaction between the two factors of different genders and grades.

METHOD

Patient and Public Involvement

No patient involved

Participants

There were 154 students in the first year and 103 students in the second year that took part in the ECC curriculum at the Shanghai University of Medical & Health Sciences in China in July of 2018. The first-year students were studying in 10 community-based teaching hospitals and the second-year students in 3 of our

Participants

N (%)

78(57.78)

57(42.22)

135(100)

42(53.16)

37(46.84)

79(100)

Response

rates

87.66 %

76.70 %

Hospital

Community

Affiliated

university hospitals, 10-15 students in each group. After informed consent was obtained, 219 medical students completed the measurement of empathy (response rates of 87.66 % of the 1st year and 76.70% of the 2nd year students, respectively), among which 214 returned questionnaires are valid. All of our students are high school graduates, aged between 17 and 21. The basic characteristics of all participants are shown in Table 1.
Table1 Basic characteristics of participants
 Grade Gender All Age students M (SD) N (%) 89(57.80) Females 18.51(0.77) First Males 65(42.20) 18.00(0.73) Total 154(100) 18.38(0.06) Females 18.73(0.13) 55(53.40) Second Males 48(46.60) 19.00(0.15) Total 103(100) 18.85(0.10)

Measurement of Empathy

Jefferson Scale of Empathy - Students version (JSE-S), created by Hoja and colleagues ³¹, was used in this study. It includes 20 items answered on a seven-point Likert-type scale (1 indicating strong disagreement and 7 strong agreement). Ten of the items are positively worded and 10 negatively worded. JSE-S was specifically developed as a self-reporting scale for assessing medical students' attitudes towards empathetic inpatient care. The original JSE-S comprises three components: perspective taking (items 2/4/5/9/10/13/15/16/17/20), compassionate care (items 1/7/8/11/12/14/18/19), and putting yourself in the patient's shoes (items 3/6). The total score was obtained by summing all items (ranging from 20 to 140), with higher scores indicating a higher level of empathy. JSE-S has received international attention from researchers and has been translated into 56 languages including Chinese, French, German, Italian, Korean ^{32,33}.

Procedure

The ECC Curriculum

The ECC curriculum took at the end of the school year and was divided into two

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parts: one week of theoretical lecture about empathy and narrative medicine given by professor and two weeks of clinical practice that included empathy-focused training, patient interviews, and reflective narrative story-writing. We required and guided students to focus on how to care about patients, become patient-centered and make decisions with patients and other contents besides diagnosis and treatment of diseases in clinical work by doctors. In the patient interview, students are required to explore the inner world of patients and the changes in psychological and social adaptability brought by the disease to patients and their families.

Two Pass JSE-S surveys

An initial JSE-S survey was done before the lectures in the first week of our ECC curriculum, the second pass was done at the end of this curriculum three weeks later. The questionnaires were powered by www.wjx.cn and anonymously collected so that students would not feel forced to participate. The platform recorded the time taken to complete the questionnaire, with the average time to complete being 4.2 minutes. If the completed time of a questionnaire was less than 2 minutes or more than 10 minutes, its result was excluded from the statistical analyses, considering that extreme questionnaire completion time will affect the quality of the answers. In this study, five of 219 returned questionnaires were excluded (2 of them were completed in less than 2 minutes and 3 more than 10 minutes).

Data analysis

Statistical analyses were performed using SPSS 19.0 software (SPSS Inc., Chicago, IL, USA). All values are shown as mean \pm standard deviation. Descriptive analyses were performed for all investigated variables and a D'Agostino-Pearson chi-squared test was used for normal distribution ³⁴. The Cronbach's alpha coefficient was calculated to assess the internal consistency aspect of the reliability of the questionnaire. Unpaired t-tests were utilized to compare the differences between two groups, and the analysis of variance (two-way ANOVA) was used for double factor variance analysis. Statistical significance was defined as P < 0.05.

RESULTS

219 of a total of 257 students completed the JSE-S questionnaire (85.21% response rate), and 214 answers were effective (135 1st year and 79 2nd year students; 120 females and 94 males) in both of the two surveys. The JSE-S scores in our study are approximately normally distributed and the internal consistency reliability of the questionnaire had a Cronbach's alpha coefficient of 0.84. No significant difference was observed between gender and different academic years before ECC (P > 0.05; table 2). After finishing the ECC curriculum, all the students showed a significantly higher mean score of empathy measured by the JSE-S than the beginning (Table 2), and students of the different grades showed significant statistical variation (P = 0.001; Table 3), but no interaction effects were found between gender and academic year (P = 0.759; Table 3).

Table 2 G	Table 2 Group comparisons on scores of the JSE-S administered to 214 medical students						
Variable	Subgrou	Number	Before ECC	After ECC	t; df	P-value	
S	р	N (%)	M (SD)	M (SD)		S	
	1 st year						
	Females	78(57.78)	113.2(11.15)ª	115.4(10.48) ^{a,b}	2.95;77	0.015	
Academi			,b				
c year	Males	57(42.22)	110.4(13.14)	114.1(10.73) ^b	2.71;56	0.016	
(Gender)			b				
	Total	135(100)	111.8(11.66)	115.1(11.02) ^b	4.52;134	0.003	
			b				
	2 nd year						
	Females	42(53.16)	113.7(12.60) ^a	115.7(10.32) ^a	4.08;41	0.007	
	Males	37(46.84)	111.6(13.82)	118.7(09.73)	3.89;36	0.009	
	Total	79(100)	113.6(13.14)	118.2(14.00)	2.11;78	0.026	

Note: Values are mean ± SD or number (%). **Abbreviations**: early clinical contact, ECC

P > 0.05 (a: compared between gender; b: compared between different academic years)

Table 3 Two-way ANOVA of grade)	double factor variance	e analysis (gender;	
Source of Variations	Total variation, %	F (DFn, DFd)	P-value
Interaction	0.045	F (1, 206) = 0.095	0.759
Row Factor (Gender)	0.598	F (1, 206) = 1.27	0.261
Column Factor (Grade)	2.240	F (1, 206) = 4.76	0.001

Discussion

Early clinical contact closes the gap between theory and practice. Hence, many medical schools are adjusting their curricula to provide greater vertical integration between basic and clinical subject ²⁸. Clinical scenes can deepen the understanding of medical students on professional quality especially when students face the death of a patient directly³⁵; such scenes have a strong impact on the formation of empathy and other professional qualities³⁶. Hojat defined medical empathy as "a cognitive attribute that mainly includes the understanding of experiences, problems, and perspectives of patients, and the ability to communicate this understanding and an intention to help" ³⁷. Empathy strengthens the relationship between patients and health professionals and improves patient-physician satisfaction ³⁸. Teachers in medical universities must foster the empathetic capacity of future doctors and maintain it at a relatively high level ³⁹. In some studies, self-reported measures have found that empathy declines during undergraduate medical training. A study by Mohammadreza Hojat et al. showed that the empathy scores did not change significantly during the first two years of their students; however, a significant decline was observed at the end of their third-year students⁴⁰. However, Eunice Magalhães, Ulloque MJ and their colleagues' studies showed that the empathy lever of last year students was higher than their freshmen^{21,41}. Several other studies evaluated the levels of empathy among medical students and analyzed the differences by age, gender, and year⁴²⁻⁴⁴. In this study, the Cronbach's alpha coefficient was 0.84; it is similar to some other studies in China ^{45,46}, which indicates that JSPE-S had been

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internally consistent among Chinese medical students. We compared the self-reported empathy levels of two grades of undergraduate medical students before and after their ECC curriculum. The main results of this study are that there were no statistical differences between gender and academic years before the ECC. This is not consistent with other studies that indicated that female students had significantly higher average scores of empathy than the males ¹⁹, but similar to other studies ^{32,47-49}. Gender disparity might be due to "particular factors" unique to European and American medical students. In some Asian countries, there is often no statistical difference, which might be caused by different social-cultural backgrounds ^{48,49}. Our students got directly out of high school after they passed a unified selective examination. Which is essentially different from European and American medical students, who usually major in different subjects in college. Our university has a course of "Introduction to Medicine" in the first year, which helps students to think about ethics, life and death, and the history of medicine. The lack of statistical differences between different gender and academic years before the ECC in our study may result from different cultures and different sources of students addressed above.

After their ECC at the end of the first and second year of study, our students showed a significantly higher mean score of empathy measured by the JSE-S than at the beginning. During the ECC, we emphasized the importance of empathy and students are required to focus on and record real cases of doctor-patient empathy in clinical learning. This suggests that students who attend empathy-focused clinical programs early in their five years of study may establish and strengthen the concept of empathy, which is a key component of medical professionalism. We have unified requirements of patient interviews and reflective writing for both first and second year students. Reflective narratives are a useful and enjoyable way of teaching medical students about empathy issues ⁵⁰. Empathy education should be emphasized as a key part of integrating patient contact early in the curriculum as it plays an important

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role in students' future doctor-patient relationship⁵¹. There is no interaction (p = 0.759) between gender and academy year, it means that there is no dependency between these two factors. This result confirms findings from other study²¹. Future studies should be using multiple forms of measurement in order to better understand the mechanisms involved in empathy changes in medical students⁵².

One limitation of our study is that the valuation of empathy was constructed using only a single subjective self-reported questionnaire among undergraduate medical students. Short observation time is the second limitation, which may introduce a certain bias on the result analysis. The time interval necessary for eliminating bias in the results needs further study, and we will carry out related study in our future research.

Conclusion

Empathy education is very important in undergraduate medical students, in order to promote the quality of the doctor-patient relationship in their future work. Early clinical contact can not only stimulate students' learning enthusiasm, also play a vital role in the formation of vocational ability. This study revealed that empathy-focused training in early clinical contact could improve the empathetic capacity of our undergraduate medical students. Empathy and other professionalism education should be carried out in junior medical students. Further research is needed on the long-term effects to conform to the early empathy education of medical students.

Abbreviations

JSE-S: Jefferson Scale of Empathy - Students version

ECC: Early Clinical Contact

Declarations

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Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to privacy concerns but are available from the corresponding author on reasonable request.

Author contributions

XY and HX contributed to design, data analysis and drafting. HG and XZ contributed to critically revising the paper and agreed to be accountable for all aspects of the work.

Ethics approval and consent to participate

Ethics approval was granted by the Human Research Ethics Committee of Shanghai University of Medicine & Health Sciences, research protocol number 2018/136.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Pag No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the	1
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what	1
		was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of	5
6	-	recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods	5
I		of selection of participants. Describe methods of follow-up	
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and	
		methods of case ascertainment and control selection. Give the rationale for	
		the choice of cases and controls	
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and	
		methods of selection of participants	
		(b) Cohort study—For matched studies, give matching criteria and number	
		of exposed and unexposed	
		<i>Case-control study</i> —For matched studies, give matching criteria and the	
		number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders,	6
		and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If	8
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	6
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	6
		(d) Cohort study—If applicable explain how loss to follow-up was	6
		addressed	
		<i>Case-control study</i> —If applicable, explain how matching of cases and	
		controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking	
		account of sampling strategy	
		(a) Describe any sensitivity analyses	

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Results			
Participants	13*	(a) Report numbers of individuals at each stage of study-eg numbers potentially	4
		eligible, examined for eligibility, confirmed eligible, included in the study, completing	
		follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	4
		(c) Consider use of a flow diagram	
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and	7
data		information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Cohort study-Report numbers of outcome events or summary measures over time	7
		Case-control study—Report numbers in each exposure category, or summary	
		measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and	7
		their precision (eg, 95% confidence interval). Make clear which confounders were	
		adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	
		meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and	8
		sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or	10
		imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	10
		multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	11
		applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Empathy variation of undergraduate medical students after early clinical contact

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Empathy variation of undergraduate medical students after early clinical contact: A cross-sectional study, China

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Abstract

Objectives Empathetic education is very important for medical students. There is little research on the influence of early clinical practice on the development of empathy and other professionalism in medical students. The aim of this study is to compare the self-reported empathy levels of the first- and second-year undergraduate medical students before and after their early clinical contact curriculum.

Setting The study was conducted in Shanghai University of Medicine & Health Sciences, Shanghai, China.

Participants 257 undergraduate medical students participated in the study. The 154 first year students were studying in 10 community-based teaching hospitals and the 103-second year students in 3 university-affiliated hospitals.

Primary and secondary outcome measures Primary measures: The Jefferson Scale of Empathy - Students version (JSE-S) was compared between different genders, and students in different academic years before their early clinical contact course. Secondary measures: comparisons were made after they finished the curriculum at one month later.

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Results 219 out of a total of 257 students responded (85.21% response rate), and 214 answers were effective (135 first year and 79 second year students; 120 females and 94 males). No significant difference in the empathy scores before early clinical contact was observed between gender and different academic years. After early clinical contact, mean JSE-S score of the participants was significantly higher than the mean score at the beginning of the curriculum.

Conclusions Empathy focused training in early clinical contact can improve the empathetic capacity of undergraduate medical students. Fostering empathic attitudes to undergraduate medical students is necessary for their early stage of medical education. Further research is needed on the long-term effects of empathy-focused education in entry-level medical students.

Strengths and limitations of this study:

• We used the Jefferson Scale of Empathy - Students version as a validated instrument, which with good internal consistency (Cronbach alpha 0.84).

• The results of this study reflect the positive influence of empathy education in early clinical contact training for undergraduate medical students.

• There is no gender difference in the empathy scale of the Jefferson Scale of Empathy -

Students version, which increased the support for previous related studies.

• The interval between two self-reported questionnaires is only three weeks, which may be

have a certain impact on the result analysis because of recent memory.

Keywords: Empathy; Early clinical contact; Education; Undergraduate medical students

INTRODUCTION

Empathy is the ability to understand and share feelings of another ¹ and includes cognitive, affective, behavioral and moral dimensions ². The empathetic capacity of health care professionals plays an important role and empathy has been described as a major factor of professionalism in medicine ^{3,4}. Studies have shown that patients who trust their empathetic doctors tend to communicate well with their doctors and to provide more detailed information favorable for diagnosis and are likely to display improved treatment compliance ^{5,6}. Empathy strengthens interactions between patient and doctor and improves doctors' satisfaction ⁷. High levels of empathy in health care professionals are connected to positive clinical prognosis for patients, such as reducing mental stress, improving self-awareness, and reducing anxiety and depression ^{8,9}.

For tomorrow's doctors, empathy education is as important as enhancing their clinical competence ¹⁰. A systematic review showed that educational interventions can be effective in maintaining and enhancing empathy in undergraduate medical students ¹¹. Lim BT and his colleagues introduced a drama training method entitled "how to act-in-role" to enhance the empathetic communication skills of their medical students. This innovative teaching method increased not only students' self-reported empathy but also their competence in consultation skills ¹². Other training methods have also been proposed to enhance medical students' comprehension of empathy and their empathetic capacity, such as "communication skills training" ^{13,14}, "reflective writing" ^{15,16} and "motivational interviewing training" ¹⁷. While some studies showed that the empathy capacity of medical students decline with increasing academic years ¹⁸⁻²⁰, others indicated that the empathy scores of students in their final year were higher as compared with first-year medical students ²¹. Gender has also been found to influence undergraduate medical students' empathy ²². Conflicting results have been found in respect of gender differences, a reason for this may be social-cultural background²³. Moreover, as empathy level is difficult to measure, standard approach of enhancing it in medical students remains debatable ²⁴.

Early clinical contact (ECC) for medical students is an important curricular innovation

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and was found to be particularly crucial for teaching professionalism ²⁵. ECC means real-patient contact in a clinical context that enhances learning of health, illness and/or disease, and the role of the health professional which occurs in the early or preclinical years of undergraduate education^{26,27}. Some studies showed that contact with patients early in medical students' training elicits a positive emotional response that has the potential to trigger the developments of emotional maturity, relational skill, and patient-centered attitudes, and promote better understanding of health and illness ^{28,29}. However the impact of ECC on the development of empathy or other professional abilities in medical students remains relatively under researched ³⁰.

In this study, we encourage our first and second-year medical students to focus on empathetic relationships between patients and doctors through our ECC curriculum. We sought to investigate whether ECC altered medical students' empathy and whether there were any differences in this respect in terms of gender and or academic year.

METHOD

Participants

There were 154 students in the first year and 103 students in the second year that took part in the ECC curriculum at the Shanghai University of Medical & Health Sciences in China in July of 2018. The first-year students were studying in 10 community-based teaching hospitals and the second-year students in 3 of our university hospitals, 10-15 students in each group. After informed consent was obtained, 219 medical students completed the measurement of empathy (response rates of 87.66 % of the 1st year and 76.70% of the 2nd year students, respectively), among which 214 returned questionnaires were valid. All of our students are high school graduates, aged between 17 and 21. The basic characteristics of all participants are shown in Table 1.

Table1	Table1 Basic characteristics of participants							
Grade	Gender	All students	Age	Participants	Response rates	Hospital		
		N (%)	M (SD)	N (%)				
	Females	89(57.80)	18.51(0.77)	78(57.78)				
First	Males	65(42.20)	18.00(0.73)	57(42.22)	87.66 %	Community		
	Total	154(100)	18.38(0.06)	135(100)				
	Females	55(53.40)	18.73(0.13)	42(53.16)				
Second	Males	48(46.60)	19.00(0.15)	37(46.84)	76.70 %	Affiliated		
	Total	103(100)	18.85(0.10)	79(100)				

Measurement of Empathy

Jefferson Scale of Empathy - Students version (JSE-S), created by Hojat and colleagues ³¹, was used in this study. It includes 20 items answered on a seven-point Likert-type scale (1 indicating strong disagreement and 7 strong agreement). Ten of the items are positively worded and 10 negatively worded. JSE-S was specifically developed as a self-reporting scale for assessing medical students' attitudes towards empathetic inpatient care. The original JSE-S comprises three components: perspective taking (items 2/4/5/9/10/13/15/16/17/20), compassionate care (items 1/7/8/11/12/14/18/19), and putting yourself in the patient's shoes (items 3/6). The total score was obtained by summing all items (ranging from 20 to 140), with higher scores indicating a higher level of empathy. JSE-S has received international attention from researchers and has been translated into 56 languages including Chinese, French, German, Italian, Korean ^{32,33}.

Procedure

The ECC Curriculum

The ECC curriculum took place at the end of the school year and was divided into two parts: one week of theoretical lecture about empathy and narrative medicine given by a professor and two weeks of clinical practice that included empathy-focused training, patient interviews and reflective narrative story-writing. We required and guided students to focus on how to care about patients, become patient-centered and make decisions with patients and other contents besides diagnosis and treatment of diseases in clinical work by doctors. In the patient interview, students are required to explore the inner world of patients and the

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psychological and social changes associated with the illness experienced by the patients and their families. Each student should complete interviews independently with at least 6 patients and write 2 reflective narrative stories in two weeks of clinical exposure. Students just following a doctor everyday and they have no responsible for the patients' diagnosis and treatment.

Two Pass JSE-S surveys

An initial JSE-S survey was done before the lectures in the first week of our ECC curriculum, the second pass was done at the end of this curriculum three weeks later. The questionnaires were powered by www.wjx.cn and anonymously collected so that students would not feel forced to participate. The platform recorded the time taken to complete the questionnaire, with the average time to complete being 4.2 minutes. If the completed time of a questionnaire was less than 2 minutes or more than 10 minutes, its result was excluded from the statistical analyses, considering that extreme questionnaire completion time will affect the quality of the answers. In this study, five of 219 returned questionnaires were excluded (2 of them were completed in less than 2 minutes and 3 more than 10 minutes).

Data analysis

Statistical analyses were performed using SPSS 19.0 software (SPSS Inc., Chicago, IL, USA). All values are shown as mean \pm standard deviation. Descriptive analyses were performed for all investigated variables and a D'Agostino-Pearson chi-squared test was used for normal distribution ³⁴. The Cronbach's alpha coefficient was calculated to assess the internal consistency aspect of the reliability of the questionnaire. Unpaired t-tests were utilized to compare the differences between two groups, and the analysis of variance (two-way ANOVA) was used for double factor variance analysis. Statistical significance was defined as P < 0.05.

Patient and public involvement

No patient involved.

RESULTS

219 of a total of 257 students completed the JSE-S questionnaire (85.21% response rate), and 214 answers were effective (135 1st year and 79 2nd year students; 120 females and 94 males) in both of the two surveys. The JSE-S scores in our study are approximately normally distributed and the internal consistency reliability of the questionnaire had a Cronbach's alpha coefficient of 0.84. No significant difference was observed between gender and different academic years before ECC (P > 0.05; table 2). After finishing the ECC curriculum, all the students showed a significantly higher mean score of empathy measured by the JSE-S than the beginning (Table 2), and students of the different grades showed significant statistical variation (P = 0.001; Table 3), but no interaction effects were found between gender and academic year (P = 0.759; Table 3).

Table 2 Group comparisons on scores of the JSE-S administered to 214 medical students							
Variables	Subgroup	Number	Before ECC	Before ECC After ECC		P-values	
		N (%)	M (SD)	M (SD)			
	1 st year						
	Females	78(57.78)	113.2(11.15) ^{a,b}	115.4(10.48)	2.95; 77	0.015	
Academic	Males	57(42.22)	110.4(13.14) ^b	114.1(10.73)	2.71; 56	0.016	
year	Total	135(100)	111.8(11.66) ^b	115.1(11.02)	4.52; 134	0.003	
(Gender)	2 nd year						
	Females	42(53.16)	113.7(12.60) ^a	115.7(10.32)	4.08; 41	0.007	
	Males	37(46.84)	111.6(13.82)	118.7(09.73)	3.89; 36	0.009	
	Total	79(100)	113.6(13.14)	118.2(14.00)	2.11; 78	0.026	

Note: Values are mean \pm SD or number (%). Abbreviations: early clinical contact, ECC

P > 0.05 (a: compared between gender; b: compared between different academic years)

Table 3 Two-way ANOVA of double factor variance analysis (gender; grade)						
Source of Variations Total variation, % F (DFn, DFd) P-val						
Interaction	0.045	F (1, 206) = 0.095	0.759			
Row Factor (Gender)	0.598	F (1, 206) = 1.27	0.261			
Column Factor (Grade)	2.240	F (1, 206) = 4.76	0.001			

Discussion

Early clinical contact closes the gap between theory and practice. Hence, many medical

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schools are adjusting their curricula to provide greater vertical integration between basic and clinical subject²⁸. Clinical contact can deepen medical students' understanding of professionalism especially when students face the death of a patient directly³⁵; such scenes have a strong impact on the formation of empathy and other professional qualities³⁶. Hojat defined medical empathy as "a cognitive attribute that mainly includes the understanding of experiences, problems, and perspectives of patients, and the ability to communicate this understanding and an intention to help" ³⁷. Empathy strengthens the relationship between patients and health professionals and improves patient-physician satisfaction ³⁸. In some studies, self-reported measures have found that empathy declines during undergraduate medical training. Study by Mohammadreza Hojat et al. showed that the empathy scores did not change significantly during the first two years of their students, but a significant decline was observed at the end of their third-year students³⁹. However, Eunice Magalhães, Ulloque MJ and their colleagues' studies showed that the empathy level of last year students was higher than their freshmen^{21,40}.

In our study, the Cronbach's alpha coefficient was 0.84; it is similar to some other studies in China ^{41,42}, which indicates that JSPE-S had been internally consistent among Chinese medical students. We compared the self-reported empathy levels of two grades of undergraduate medical students before and after their ECC curriculum. The main finding of this study was the improvement in empathy scores in all of our students after the ECC. Our ECC curriculum includes not only empathy focused early clinical exposure of real patients but also the theory instruction of doctor – patient empathy. During the ECC, we emphasized the importance of empathy and students are required to focus on and record real cases of doctor-patient empathy in clinical works. This suggests that students who attend empathy-focused clinical programs early in their five years of study may establish and strengthen the concept of empathy, which is a key component of medical professionalism. We have unified requirements of patient interview and reflective writing for both of first and second year students. Reflective narratives are a useful and enjoyable way to teaching medical students about empathy issues⁴³. Empathy education should be emphasized as a key

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part of integrating patient contact early in curriculum as it plays an important role in students' future doctor-patient relationship⁴⁴. Other interesting results were that there were no statistical differences between gender and academic year, and there was no interaction (p = 0.759) between these two factors. This is not consistent with some studies that indicated that female students had significantly higher average scores of empathy than the males ^{19,45,46}, but similar to other studies ^{32,47-49}. Gender disparity might be due to "particular factors" unique to European and American medical students. In some Asian countries, there is often no statistical difference, which might be caused by different social-cultural backgrounds ^{48,49}. Our students got directly out of high school after they passed a unified selective examination. Which is essentially different from American medical students, who usually major in different subjects in college. Our university has a course of "Introduction to Medicine" in the first year, which helps students to think about ethics, life and death. The lack of statistical differences between different gender and academic years before the ECC in our study may result from different cultures and different sources of students addressed above. Future study should using multiple forms of measurement in order to better understand the mechanisms involved in empathy changes in medical students⁵⁰.

One limitation of our study is that the valuation of empathy was constructed using only a single subjective self-reported questionnaire among undergraduate medical students. The self-reported empathy capacity is not always accurate and often does not correlate to the patients' assessments^{51,52}, future study should consider the patients perspectives. Short observation time is the second limitation, and self-reported scales suffer the influence of socially desirable behavior, which means that after the training, students may become aware of what is the desirable answer in the questionnaire, which may introduce certain bias on the result analysis. The main purpose of this study is to observe the short-term impact of ECC on empathy for medical students, the time interval necessary for eliminating bias in the results needs further study, and we will carry out related study on its long-term effects in our follow-up research.

Conclusion

Empathy education is very important in undergraduate medical students, in order to promote the quality of the doctor-patient relationship in their future work. Early clinical contact can not only stimulate students' learning enthusiasm, also play a vital role in the formation of vocational ability. This study revealed that empathy-focused training in early clinical contact could improve the empathetic capacity of our undergraduate medical students. Empathy and other professionalism education should be carried out in junior medical students. Further research is needed on the long-term effects to conform to the early empathy education of medical students.

Abbreviations

JSE-S: Jefferson Scale of Empathy - Students version

ECC: Early Clinical Contact

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Funding

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Availability of data and materials

The raw datasets generated and/or analyzed during the current study are not publicly available due to privacy concerns but are available from the corresponding author on reasonable request.

Author contributions

XY and HX contributed to design, data analysis and drafting. HG and XZ contributed to critically revising the paper and agreed to be accountable for all aspects of the work.

Ethics approval and consent to participate

Ethics approval was granted by the Human Research Ethics Committee of Shanghai University of Medicine & Health Sciences, research protocol number 2018/136.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the	1
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what	2
		was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of	4
5		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods	4-5
1		of selection of participants. Describe methods of follow-up	
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and	
		methods of case ascertainment and control selection. Give the rationale for	
		the choice of cases and controls	
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and	
		methods of selection of participants	
		(b) Cohort study—For matched studies, give matching criteria and number	
		of exposed and unexposed	
		<i>Case-control study</i> —For matched studies, give matching criteria and the	
		number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders,	5
		and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	5
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If	6
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	6
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	6
		(d) Cohort study—If applicable, explain how loss to follow-up was	6
		addressed	
		<i>Case-control study</i> —If applicable, explain how matching of cases and	
		controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking	
		account of sampling strategy	
		(a) Describe any consistivity engly as	1

Continued on next page

9-10

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially
		eligible, examined for eligibility, confirmed eligible, included in the study, completing
		follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and
data		information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Cohort study-Report numbers of outcome events or summary measures over time
		Case-control study-Report numbers in each exposure category, or summary
		measures of exposure
		Cross-sectional study-Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
		their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and
		sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other informati	on	
Funding	22	Give the source of funding and the role of the funders for the present study and, if
		applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Empathy variation of undergraduate medical students after early clinical contact: A cross-sectional study, China

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Empathy variation of undergraduate medical students after early clinical contact: A cross-sectional study, China

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Abstract

 Objectives Empathetic education is very important for medical students. There is little research on the influence of early clinical practice on the development of empathy and other professionalism in medical students. The aim of this study is to compare the self-reported empathy levels of the first- and second-year undergraduate medical students before and after their early clinical contact curriculum.

Setting The study was conducted in Shanghai University of Medicine & Health Sciences, Shanghai, China.

Participants 257 undergraduate medical students participated in the study. The 154 first year students were studying in 10 community-based teaching hospitals and the 103-second year students in 3 university-affiliated hospitals.

Primary and secondary outcome measures Primary measures: The Jefferson Scale of Empathy - Students version (JSE-S) was compared between different genders, and students in different academic years before their early clinical contact course. Secondary measures: comparisons were made after they finished the curriculum at three weeks later.

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Results 219 out of a total of 257 students responded (85.21% response rate), and 214 answers were effective (135 first year and 79 second year students; 120 females and 94 males). No significant difference in the empathy scores before early clinical contact was observed between gender and different academic years. After early clinical contact, mean JSE-S score of the participants was significantly higher than the mean score at the beginning of the curriculum.

Conclusions Empathy focused training in early clinical contact can improve the empathetic capacity of undergraduate medical students. Fostering empathic attitudes to undergraduate medical students is necessary for their early stage of medical education. Further research is needed on the long-term effects of empathy-focused education in entry-level medical students.

Strengths and limitations of this study:

• We used the Jefferson Scale of Empathy - Students version as a validated instrument, which with good internal consistency (Cronbach alpha 0.84).

• The results of this study reflect the positive influence of empathy education in early clinical contact training for undergraduate medical students.

• There is no gender difference in the empathy scale of the Jefferson Scale of Empathy -

Students version, which increased the support for previous related studies.

• The interval between two self-reported questionnaires is only three weeks, which may be

have a certain impact on the result analysis because of recent memory.

Keywords: Empathy; Early clinical contact; Education; Undergraduate medical students

INTRODUCTION

Empathy is the ability to understand and share feelings of another ¹ and includes cognitive, affective, behavioral and moral dimensions ². The empathetic capacity of health care professionals plays an important role and empathy has been described as a major factor of professionalism in medicine ^{3,4}. Studies have shown that patients who trust their empathetic doctors tend to communicate well with their doctors and to provide more detailed information favorable for diagnosis and are likely to display improved treatment compliance ^{5,6}. Empathy strengthens interactions between patient and doctor and improves doctors' satisfaction ⁷. High levels of empathy in health care professionals are connected to positive clinical prognosis for patients, such as reducing mental stress, improving self-awareness, and reducing anxiety and depression ^{8,9}.

For tomorrow's doctors, empathy education is as important as enhancing their clinical competence ¹⁰. A systematic review showed that educational interventions can be effective in maintaining and enhancing empathy in undergraduate medical students ¹¹. Lim BT and his colleagues introduced a drama training method entitled "how to act-in-role" to enhance the empathetic communication skills of their medical students. This innovative teaching method increased not only students' self-reported empathy but also their competence in consultation skills ¹². Other training methods have also been proposed to enhance medical students' comprehension of empathy and their empathetic capacity, such as "communication skills training" ^{13,14}, "reflective writing" ^{15,16} and "motivational interviewing training" ¹⁷. While some studies showed that the empathy capacity of medical students decline with increasing academic years ¹⁸⁻²⁰, others indicated that the empathy scores of students in their final year were higher as compared with first-year medical students ²¹. Gender has also been found to influence undergraduate medical students' empathy ²². Conflicting results have been found in respect of gender differences, a reason for this may be social-cultural background²³. Moreover, as empathy level is difficult to measure, standard approach of enhancing it in medical students remains debatable ²⁴.

Early clinical contact (ECC) for medical students is an important curricular innovation

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and was found to be particularly crucial for teaching professionalism ²⁵. ECC means real-patient contact in a clinical context that enhances learning of health, illness and/or disease, and the role of the health professional which occurs in the early or preclinical years of undergraduate education^{26,27}. Some studies showed that contact with patients early in medical students' training elicits a positive emotional response that has the potential to trigger the developments of emotional maturity, relational skill, and patient-centered attitudes, and promote better understanding of health and illness ^{28,29}. However the impact of ECC on the development of empathy or other professional abilities in medical students remains relatively under researched ³⁰.

In this study, we encourage our first and second-year medical students to focus on empathetic relationships between patients and doctors through our ECC curriculum. We sought to investigate whether ECC altered medical students' empathy and whether there were any differences in this respect in terms of gender and or academic year.

METHOD

Participants

There were 154 students in the first year and 103 students in the second year that took part in the ECC curriculum at the Shanghai University of Medical & Health Sciences in China in July of 2018. The first-year students were studying in 10 community-based teaching hospitals and the second-year students in 3 of our university hospitals, 10-15 students in each group. After informed consent was obtained, 219 medical students completed the measurement of empathy (response rates of 87.66 % of the 1st year and 76.70% of the 2nd year students, respectively), among which 214 returned questionnaires were valid. All of our students are high school graduates, aged between 17 and 21. The basic characteristics of all participants are shown in Table 1.

Table1 Basic characteristics of participants								
Grade	Gender	All students	Age	Participants	Response rates	Hospital		
		N (%)	M (SD)	N (%)				
	Females	89(57.80)	18.51(0.77)	78(57.78)				
First	Males	65(42.20)	18.00(0.73)	57(42.22)	87.66 %	Community		
	Total	154(100)	18.38(0.06)	135(100)				
	Females	55(53.40)	18.73(0.13)	42(53.16)				
Second	Males	48(46.60)	19.00(0.15)	37(46.84)	76.70 %	Affiliated		
	Total	103(100)	18.85(0.10)	79(100)				

Measurement of Empathy

Jefferson Scale of Empathy - Students version (JSE-S), created by Hojat and colleagues ³¹, was used in this study. It includes 20 items answered on a seven-point Likert-type scale (1 indicating strong disagreement and 7 strong agreement). Ten of the items are positively worded and 10 negatively worded. JSE-S was specifically developed as a self-reporting scale for assessing medical students' attitudes towards empathetic inpatient care. The original JSE-S comprises three components: perspective taking (items 2/4/5/9/10/13/15/16/17/20), compassionate care (items 1/7/8/11/12/14/18/19), and putting yourself in the patient's shoes (items 3/6). The total score was obtained by summing all items (ranging from 20 to 140), with higher scores indicating a higher level of empathy. JSE-S has received international attention from researchers and has been translated into 56 languages including Chinese, French, German, Italian, Korean ^{32,33}.

Procedure

The ECC Curriculum

The ECC curriculum took place at the end of the school year and was divided into two parts: one week of theoretical lecture about empathy and narrative medicine given by a professor and two weeks of clinical practice that included empathy-focused training, patient interviews and reflective narrative story-writing. We required and guided students to focus on how to care about patients, become patient-centered and make decisions with patients and other contents besides diagnosis and treatment of diseases in clinical work by doctors. In the patient interview, students were required to explore the inner world of patients and the

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psychological and social changes associated with the illness experienced by the patients and their families. Each student should complete interviews independently with at least 6 patients and wrote 2 reflective narrative stories in two weeks of clinical exposure. Students shadowed a doctor everyday and they have no responsible for the patients' diagnosis and treatment.

Two Pass JSE-S surveys

An initial JSE-S survey was done before the lectures in the first week of our ECC curriculum, the second pass was done at the end of this curriculum three weeks later. The questionnaires were powered by www.wjx.cn and anonymously collected so that students would not feel forced to participate. The platform recorded the time taken to complete the questionnaire, with the average time to complete being 4.2 minutes. If the completed time of a questionnaire was less than 2 minutes or more than 10 minutes, its result was excluded from the statistical analyses, considering that extreme questionnaire completion time will affect the quality of the answers. In this study, five of 219 returned questionnaires were excluded (2 of them were completed in less than 2 minutes and 3 more than 10 minutes).

Data analysis

Statistical analyses were performed using SPSS 19.0 software (SPSS Inc., Chicago, IL, USA). All values are shown as mean \pm standard deviation. Descriptive analyses were performed for all investigated variables and a D'Agostino-Pearson chi-squared test was used for normal distribution ³⁴. The Cronbach's alpha coefficient was calculated to assess the internal consistency aspect of the reliability of the questionnaire. Unpaired t-tests were utilized to compare the differences between two groups, and the analysis of variance (two-way ANOVA) was used for double factor variance analysis. Statistical significance was defined as P < 0.05.

Patient and public involvement

No patient involved.

RESULTS

Column Factor (Grade)

219 of a total of 257 students completed the JSE-S questionnaire (85.21% response rate), and 214 answers were effective (135 1st year and 79 2nd year students; 120 females and 94 males) in both of the two surveys. The JSE-S scores in our study are approximately normally distributed and the internal consistency reliability of the questionnaire had a Cronbach's alpha coefficient of 0.84. No significant difference was observed between gender and different academic years before ECC (P > 0.05; table 2). After finishing the ECC curriculum, all the students showed a significantly higher mean score of empathy measured by the JSE-S than the beginning (Table 2), and students of the different grades showed significant statistical variation (P = 0.001; Table 3), but no interaction effects were found between gender and academic year (P = 0.759; Table 3).

Table 2 Gro	Table 2 Group comparisons on scores of the JSE-S administered to 214 medical students						
Variables	Subgroup Number		Before ECC	After ECC	t; df	P-values	
		N (%)	M (SD)	M (SD)			
	1 st year						
	Females	78(57.78)	113.2(11.15) ^{a,b}	115.4(10.48)	2.95; 77	0.015	
Academic	Males	57(42.22)	110.4(13.14) ^b	114.1(10.73)	2.71; 56	0.016	
year	Total	135(100)	111.8(11.66) ^b	115.1(11.02)	4.52; 134	0.003	
(Gender)	2 nd year						
	Females	42(53.16)	113.7(12.60) ^a	115.7(10.32)	4.08; 41	0.007	
	Males	37(46.84)	111.6(13.82)	118.7(09.73)	3.89; 36	0.009	
	Total	79(100)	113.6(13.14)	118.2(14.00)	2.11; 78	0.026	

Note: Values are mean \pm SD or number (%). Abbreviations: early clinical contact, ECC P > 0.05 (a: compared between gender; b: compared between different academic years)

Table 3 Two-way ANOVA of double factor variance analysis (gender; grade)							
Source of Variations	Total variation, %	F (DFn, DFd)	P-value				
Interaction	0.045	F (1, 206) = 0.095	0.759				
Row Factor (Gender)	0.598	F(1, 206) = 1.27	0.261				

2.240

F(1, 206) = 4.76

0.001

Discussion

Early clinical contact closes the gap between theory and practice. Hence, many medical schools are adjusting their curricula to provide greater vertical integration between basic and clinical subject²⁸. Clinical contact can deepen medical students' understanding of professionalism especially when students face the death of a patient directly³⁵; such scenes have a strong impact on the formation of empathy and other professional qualities³⁶. Hojat defined medical empathy as "a cognitive attribute that mainly includes the understanding of experiences, problems, and perspectives of patients, and the ability to communicate this understanding and an intention to help" ³⁷. Empathy strengthens the relationship between patients and health professionals and improves patient-physician satisfaction ³⁸. In some studies, self-reported measures have found that empathy declines during undergraduate medical training. Study by Mohammadreza Hojat et al. showed that the empathy scores did not change significantly during the first two years of their students, but a significant decline was observed at the end of their third-year students³⁹. However, Eunice Magalhães, Ulloque MJ and their colleagues' studies showed that the empathy level of last year students was higher than their freshmen^{21,40}.

In our study, the Cronbach's alpha coefficient was 0.84; it is similar to some other studies in China ^{41,42}, which indicates that JSPE-S had been internally consistent among Chinese medical students. We compared the self-reported empathy levels of two grades of undergraduate medical students before and after their ECC curriculum. The main finding of this study was the improvement in empathy scores in all of our students after the ECC. Our ECC curriculum includes not only empathy focused early clinical exposure of real patients but also the theory instruction of doctor – patient empathy. During the ECC, we emphasized the importance of empathy and students were required to focus on and record real cases of doctor-patient empathy in clinical works. This suggests that students who attend empathy-focused clinical programs early in their five years of study may establish and strengthen the concept of empathy, which is a key component of medical professionalism. We have unified the requirements of the patient interview and reflective writing for both of

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first and second year students. Reflective narratives are a useful and enjoyable way to teaching medical students about empathy issues⁴³. Empathy education should be emphasized as a key part of integrating patient contact early in curriculum as it plays an important role in students' future doctor-patient relationship⁴⁴. Other interesting results were that there were no statistical differences between gender and academic year, and there was no interaction (p = (0.759) between these two factors. This is not consistent with some studies that indicated that female students had significantly higher average scores of empathy than the males ^{19,45,46}, but similar to other studies ^{32,47-49}. Gender disparity might be due to "particular factors" unique to European and American medical students. In some Asian countries, there is often no statistical difference, which might be caused by different social-cultural backgrounds ^{48,49}. Our students come directly from high school after passing a unified selective examination. Which is essentially different from American medical students, who usually major in different subjects in college. Our university has a course of "Introduction to Medicine" in the first year, which helps students to think about ethics, life and death. The lack of statistical differences between different gender and academic years before the ECC in our study may result from different cultures and different sources of students addressed above. Future research should use multiple forms of measurement in order to better understand the mechanisms involved in empathy changes in medical students⁵⁰.

One limitation of our study is that empathy was constructed using only a single subjective self-reported questionnaire among undergraduate medical students. The self-reported empathy capacity is not always accurate and often does not correlate to the patients' assessments^{51,52}, future research should consider the patients' perspectives as well. Short observation time is the second limitation, and self-reported scales suffer the influence of socially desirable behavior, which means that after the training, students may become aware of what is the desirable answer in the questionnaire, which may introduce certain bias on the result analysis. The main purpose of this study was to observe the short-term impact of the ECC on medical students' empathy, the time interval necessary for eliminating bias in the results needs further study, and we will carry out related study on its long-term effects in our

follow-up research.

Conclusion

Empathy education is very important in undergraduate medical students, in order to promote the quality of the doctor-patient relationship in their future work. Early clinical contact can not only stimulate students' learning enthusiasm, also play a vital role in the formation of vocational ability. This study revealed that empathy-focused training in early clinical contact could improve the empathetic capacity of our undergraduate medical students. Empathy and other professionalism education should be carried out in junior medical students. Further research is needed on the long-term effects to conform to the early empathy education of medical students.

Abbreviations

JSE-S: Jefferson Scale of Empathy - Students version

ECC: Early Clinical Contact

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Availability of data and materials

The raw datasets generated and/or analyzed during the current study are not publicly available due to privacy concerns but are available from the corresponding author on reasonable request.

Author contributions

XY and HX contributed to design, data analysis and drafting. HG and XZ contributed to

critically revising the paper and agreed to be accountable for all aspects of the work.

Ethics approval and consent to participate

Ethics approval was granted by the Human Research Ethics Committee of Shanghai University of Medicine & Health Sciences, research protocol number 2018/136.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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STROBE Statement-checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the	1
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what	2
		was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting locations and relevant dates including periods of	4
Setting	5	recruitment exposure follow-up and data collection	-
Participants	6	(a) Cohort study — Give the eligibility criteria, and the sources and methods	1-5
1 articipants	0	of selection of participants. Describe methods of follow up	4-5
		Case control study. Give the elicibility criteria, and the sources and	
		<i>Cuse-control study</i> —Give the englotity criteria, and the sources and	
		the choice of cases and controls	
		Characteristic of cases and controls	
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and	
		(b) Conort study—For matched studies, give matching criteria and number	
		of exposed and unexposed	
		Case-control study—For matched studies, give matching criteria and the	
		number of controls per case	-
Variables	1	Clearly define all outcomes, exposures, predictors, potential confounders,	5
	0*	and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	3
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	-
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If	6
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	6
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	6
		(d) Cohort study—If applicable, explain how loss to follow-up was	6
		addressed	
		Case-control study—If applicable, explain how matching of cases and	
		controls was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking	
		account of sampling strategy	
		(e) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible examined for eligibility confirmed eligible included in the study completing	,
		follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	,
		(c) Consider use of a flow diagram	
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and	
data		information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Cohort study-Report numbers of outcome events or summary measures over time	
		Case-control study-Report numbers in each exposure category, or summary	
		measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and	
		their precision (eg, 95% confidence interval). Make clear which confounders were	
		adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	
		meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and	
		sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or	
		imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	
		multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	
		applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Empathy variation of undergraduate medical students after early clinical contact: A cross-sectional study in China

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Empathy variation of undergraduate medical students after early clinical contact: A cross-sectional study in China

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Abstract

Objectives Empathy education is very important for medical students. There is little research on the influence of early clinical practice on the development of empathy and other aspects of professionalism in medical students. The aim of this study was to compare the self-reported empathy levels of first- and second-year undergraduate medical students before and after their early clinical contact curriculum.

Setting The study was conducted at Shanghai University of Medicine & Health Sciences, Shanghai, China.

Participants A total of 257 undergraduate medical students participated in the study. The 154 first-year students were studying in 10 community-based teaching hospitals, and the 103 second-year students were studying in 3 university-affiliated hospitals.

Primary and secondary outcome measures Primary measures: The Jefferson Scale of Empathy - Student version (JSE-S) was compared between students of different sexes and in different academic years before their early clinical contact course. Secondary measures: comparisons were made after they finished the curriculum three weeks later.

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Results A total of 219 out of 257 students responded (85.21% response rate), and 214 answers could be analysed (135 first-year and 79 second-year students; 120 females and 94 males). No significant differences in the empathy scores before early clinical contact were observed between students of different sexes and in different academic years. After early clinical contact, the mean JSE-S score of the participants was significantly higher than the mean score at the beginning of the curriculum.

Conclusions Empathy-focused training during early clinical contact can improve the empathetic capacity of undergraduate medical students. Fostering empathetic attitudes among undergraduate medical students is necessary for the early stage of their medical education. Further research is needed on the long-term effects of empathy-focused education in entry-level medical students.

Strengths and limitations of this study:

• We used the Jefferson Scale of Empathy - Student version as a validated instrument, which has good internal consistency (Cronbach alpha 0.84).

- We compared the changes in empathy in undergraduate medical students in different grades after early clinical practice in community hospitals and university-affiliated hospitals.
- The interval between the two self-reported questionnaires was only three weeks, which may have affected the results because of influence of recent memory.

Keywords: Empathy; Early clinical contact; Education; Undergraduate medical students

INTRODUCTION

Empathy is the ability to understand and share feelings of another ¹ and has cognitive, affective, behavioural and moral dimensions ². The empathetic capacity of health care professionals is important to patient' satisfaction and compliance, and empathy has been described as a major aspect of professionalism in medicine ^{3,4}. Studies have shown that patients trust empathetic doctors; tend to communicate well with those doctors; provide more detailed information, facilitating diagnosis; and are likely to display improved treatment compliance ^{5,6}. Empathy strengthens interactions between patients and doctors and improves doctors' satisfaction levels ⁷. High levels of empathy in health care professionals are connected to positive clinical prognoses for patients, by reducing mental stress, improving self-awareness, and reducing anxiety and depression ^{8,9}.

For future doctors, education about empathy is as important as enhancing their clinical competence ¹⁰. A systematic review showed that educational interventions can be effective at maintaining and enhancing empathy in undergraduate medical students ¹¹. Lim et al introduced a drama-based training method entitled "How to Act in a Role" to enhance the empathetic communication skills of their medical students. This innovative teaching method increased not only students' self-reported empathy but also their competency with regard to consultation skills ¹². Other training methods have also been proposed to enhance medical students' comprehension of empathy and their empathetic capacity, such as "communication skills training" ^{13,14}, "reflective writing" ^{15,16} and "motivational interviewing training" ¹⁷. While some studies showed that the empathetic capacity of medical students declined with increasing academic years ¹⁸⁻²⁰, others indicated that the empathy scores of students in their final year were higher than those of first-year medical students ²¹. Sex has also been found to influence undergraduate medical students' empathy ²². Conflicting results have been found with respect to sex-based differences; a reason for this may be the social-cultural background of the students being investigated ²³. Moreover, as empathy level is difficult to measure, the standard approach to enhancing empathy in medical students remains debatable ²⁴.

Early clinical contact (ECC) for medical students is an important curricular innovation

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and has been found to be particularly crucial for teaching professionalism ²⁵. ECC means real-patient contact in a clinical context that enhances the students' understanding of illness and the role of the health professional and that occurs in the early or preclinical years of undergraduate education^{26,27}. Some studies showed that contact with patients early in medical students' training elicits a positive emotional response that has the potential to trigger the development of emotional maturity, relational skills, and patient-centred attitudes and to promote a better understanding of health and illness ^{28,29}. However, the impact of ECC on the development of empathy or other professional abilities in medical students remains relatively under-researched ³⁰.

In this study, we encouraged our first- and second-year medical students to focus on empathetic relationships between patients and doctors through our ECC curriculum. We sought to investigate whether ECC altered medical students' empathy and whether there were any differences in this respect in terms of sex and/or academic year.

METHODS

Participants

There were 154 students in the first year and 103 students in the second year who took part in the ECC curriculum at the Shanghai University of Medical & Health Sciences in China in July 2018. The first-year students were studying in 10 community-based teaching hospitals, and the second-year students were studying in 3 of our university hospitals, with 10-15 students in each group. After informed consent was obtained, 219 medical students completed the measurement of empathy (response rates of 87.66% of the 1st year and 76.70% of the 2nd year students, respectively). In total, 214 returned questionnaires were valid. All of our students are high school graduates, aged between 17 and 21 years. The basic characteristics of all participants are shown in Table 1.

Table 1 Basic characteristics of participants									
Year	Sex	All students	Age	Participants	Response rates	Hospital			
		N (%)	M (SD)	N (%)					
	Females	89(57.80)	18.51(0.77)	78(57.78)					
First	Males	65(42.20)	18.00(0.73)	57(42.22)	87.66%	Community			
	Total	154(100)	18.38(0.06)	135(100)					
	Females	55(53.40)	18.73(0.13)	42(53.16)					
Second	Males	48(46.60)	19.00(0.15)	37(46.84)	76.70%	University-aff			
						iliated			
	Total	103(100)	18.85(0.10)	79(100)					
		· · · · · · · · · · · · · · · · · · ·							

Measurement of empathy

The Jefferson Scale of Empathy - Student version (JSE-S), created by Hojat and colleagues ³¹, was used in this study. It includes 20 items answered on a seven-point Likert-type scale (1 indicating strong disagreement and 7 indicating strong agreement). Ten of the items are positively worded, and 10 are negatively worded. The JSE-S was specifically developed as a self-reporting scale for assessing medical students' attitudes towards empathetic inpatient care. The original JSE-S comprises three components: perspective taking (items 2/4/5/9/10/13/15/16/17/20), compassionate care (items 1/7/8/11/12/14/18/19), and putting yourself in the patient's shoes (items 3/6). The total score was obtained by summing all items (total scores range from 20 to 140), with higher scores indicating a higher degree of empathy. JSE-S has received international attention from researchers and has been translated into 56 languages, including Chinese, French, German, Italian, and Korean ^{32,33}.

Procedure

ECC curriculum

The ECC curriculum was administered at the end of the school year and was divided into two parts: one week of theoretical lectures about empathy and narrative medicine given by a professor and two weeks of clinical practice that included empathy-focused training, patient interviews and reflective narrative story writing. We required and guided students to focus on how to care about patients, become patient-centred and make decisions with consideration given to patients and other aspects beyond the clinical diagnosis and treatment of diseases by doctors. In the patient interview, students were required to explore the inner world of patients

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and the psychological and social changes associated with the illness experienced by the patients and their families. Each student completed interviews independently with at least 6 patients and wrote 2 reflective narrative stories during the two weeks of clinical exposure. Students shadowed a doctor every day, and they were not responsible for the patients' diagnoses and treatments.

Two JSE-S surveys

An initial JSE-S survey was administered before the lectures in the first week of our ECC curriculum, and the second survey was administered at the end of this curriculum three weeks later. The questionnaires were powered by www.wjx.cn and anonymously collected so that students would not feel forced to participate. The platform recorded the time taken to complete the questionnaire, with the average time to complete being 4.2 minutes. If the completion time of a questionnaire was less than 2 minutes or more than 10 minutes, its result was excluded from the statistical analyses, because completion times on either end of the spectrum affect the quality of the answers. In this study, five of 219 returned questionnaires were excluded (2 of them were completed in less than 2 minutes and 3 in more than 10 minutes).

Data analysis

Statistical analyses were performed using SPSS 19.0 software (SPSS Inc., Chicago, IL, USA). All values are shown as the means \pm standard deviations. Descriptive analyses were performed for all investigated variables, and a D'Agostino-Pearson chi-squared test was used for normally distributed variables ³⁴. The Cronbach's alpha was calculated to assess the internal consistency of the questionnaire. Unpaired t-tests were utilized to compare the differences between two groups, and analysis of variance (two-way ANOVA) was used for two-factor variance analysis. Statistical significance was defined as P < 0.05.

Patient and public involvement

No patients were involved.

RESULTS

A total of 219 of the 257 students completed the JSE-S questionnaire (85.21% response rate), and 214 answers were analysed (135 1st year and 79 2nd year students; 120 females and 94 males) for both surveys. The JSE-S scores in our study were approximately normally distributed, and the Cronbach's alpha of the questionnaire was 0.84. No significant differences were observed between students of different sexes and in different academic years before the ECC curriculum (P > 0.05; Table 2). After finishing the ECC curriculum, all the students showed a significantly higher mean empathy score as measured by the JSE-S than the score for the whole sample population before the course (Table 2). There was a significant difference between students in different grades (P = 0.001; Table 3), but there was no interaction effect between sex and academic year (P = 0.759; Table 3).

Table 2 Group comparisons of scores on the JSE-S administered to 214 medical students								
Variables	Subgroup	Number	Before ECC	After ECC	t; df	P-values		
		N (%)	M (SD)	M (SD)				
	1 st year							
	Females	78(57.78)	113.2(11.15) ^{a,b}	115.4(10.48)	2.95; 77	0.015		
Academic	Males	57(42.22)	110.4(13.14) ^b	114.1(10.73)	2.71; 56	0.016		
year (sex)	Total	135(100)	111.8(11.66) ^b	115.1(11.02)	4.52; 134	0.003		
	2 nd year							
	Females	42(53.16)	113.7(12.60) ^a	115.7(10.32)	4.08; 41	0.007		
	Males	37(46.84)	111.6(13.82)	118.7(09.73)	3.89; 36	0.009		
	Total	79(100)	113.6(13.14)	118.2(14.00)	2.11; 78	0.026		

Note: Values are the mean \pm SD or number (%). Abbreviations: early clinical contact, ECC P > 0.05 (a: compared between sexes; b: compared between different academic years)

Table 3 Two-way ANOVA of two-factor variance analysis (sex; grade)							
Source of variation	Total variation, %	F (DFn, DFd)	P-value				
Interaction	0.045	F (1, 206) = 0.095	0.759				
Row factor (sex)	0.598	F (1, 206) = 1.27	0.261				
Column factor (grade)	2.240	F (1, 206) = 4.76	0.001				

Discussion

ECC closes the gap between theory and practice. Hence, many medical schools are adjusting their curricula to provide greater vertical integration between basic and clinical subjects²⁸. Clinical contact can deepen medical students' understanding of professionalism, especially when students face the death of a patient directly³⁵; such scenes have a strong impact on the formation of empathy and other professional qualities³⁶. Hojat defined medical empathy as "a cognitive attribute that mainly includes the understanding of experiences, problems, and perspectives of patients, and the ability to communicate this understanding and an intention to help" ³⁷. Empathy strengthens the relationship between patients and health professionals and improves patient-physician satisfaction ³⁸. In some studies, self-reported measures have found that empathy declines during undergraduate medical training. A study by Hojat et al. showed that the empathy scores did not change significantly during the first two years among their students, but a significant decline was observed at the end of their third year³⁹. However, studies by Eunice and Ulloque et al. showed that the empathy level of last-year students was higher than that of freshmen^{21,40}.

In our study, the Cronbach's alpha was 0.84, which is similar to the findings in some other studies in China ^{41,42} and indicates that the JSPE-S is internally consistent among Chinese medical students. We compared the self-reported empathy levels of two grades of undergraduate medical students before and after the ECC curriculum. The main finding of this study was the improvement in empathy scores in all of our students after ECC. Our ECC curriculum includes not only empathy-focused early clinical exposure to real patients but also theoretical instruction regarding doctor-patient empathy. During ECC, we emphasize the importance of empathy, and students are required to focus on and record real cases of doctor-patient empathy in clinical practice. This suggests that students who attend empathy-focused clinical programmes early in their five years of study may establish and strengthen their empathy, which is a key component of medical professionalism. We have unified the requirements for the patient interview and reflective writing for both first- and second-year students. Reflective narratives are a useful and enjoyable way to teach medical

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students about issues pertaining to empathy⁴³. Empathy education should be emphasized as a key part of the early integration of patient contact into the curriculum, as it plays an important role in students' future doctor-patient relationships⁴⁴. Other interesting results were that there were no significant differences between students of different sexes and in different academic years, and there was no interaction (p = 0.759) between these two factors. This is not consistent with the findings of some studies that indicated that female students had significantly higher average empathy scores than males ^{19,45,46} but similar to the results of other studies ^{32,47-49}. The sex-based disparity might be due to "particular factors" unique to European and American medical students. In some Asian countries, there is often no significant difference, which might be caused by the different social-cultural background ^{48,49}. Our students come directly from high school after passing a unified selective examination. This is essentially different from American medical students, who usually major in different subjects in college. Our university has a course called "Introduction to Medicine" in the first year, which helps students think about ethics, life and death. The lack of significant differences between different sexes and academic years before ECC in our study may result from different cultures and different sources of students, as addressed above. Future research should use multiple forms of measurement to better understand the mechanisms involved in empathy changes in medical students⁵⁰.

One limitation of our study is that empathy was constructed using only a single subjective self-reported questionnaire among undergraduate medical students. Self-reported empathetic capacity is not always accurate and often does not correlate with the patients' assessments^{51,52}; future research should consider the patients' perspectives as well. A short observation time is the second limitation, and self-reported scales are influenced by the perception of socially desirable behaviour, which means that after the training, students may have become aware of what were the desirable answers on the questionnaire, which may have introduced bias. The main purpose of this study was to observe the short-term impact of ECC on medical students' empathy. The time interval necessary for eliminating bias in the results needs further study, and we will carry out related studies on the long-term effects in our
follow-up research.

Conclusion

Empathy education is very important for undergraduate medical students to promote the quality of the doctor-patient relationship in their future work. ECC can not only stimulate students' enthusiasm for learning but also play a vital role in the formation of vocational ability. This study revealed that empathy-focused training during ECC could improve the empathetic capacity of our undergraduate medical students. Empathy and other aspects of professionalism should be taught to junior medical students. Further research is needed on the long-term effects of early empathy education in medical students.

Abbreviations

JSE-S: Jefferson Scale of Empathy - Student version

ECC: Early clinical contact

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Availability of data and materials

The raw datasets generated and/or analysed during the current study are not publicly available due to privacy concerns but are available from the corresponding author upon reasonable request.

Author contributions

XY and HX contributed to the design, data analysis and drafting of the study. HG and XZ contributed to critically revising the paper and agreed to be accountable for all aspects of

the work.

Ethics approval and consent to participate

Ethics approval was granted by the Human Research Ethics Committee of Shanghai University of Medicine & Health Sciences, research protocol number 2018/136.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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 STROBE Statement-checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the	, 1
		abstract	2
		(b) Provide in the abstract an informative and balanced summary of what	2
		was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of	4
6		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods	4-5
1		of selection of participants. Describe methods of follow-up	
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and	
		methods of case ascertainment and control selection. Give the rationale for	
		the choice of cases and controls	
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and	
		methods of selection of participants	
		(b) Cohort study—For matched studies, give matching criteria and number	<u> </u>
		of exposed and unexposed	
		<i>Case-control study</i> —For matched studies, give matching criteria and the	
		number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders.	5
		and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	5
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	6
Ouantitative variables	11	Explain how quantitative variables were handled in the analyses. If	6
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	6
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	6 6 6
		(d) Cohort study—If applicable explain how loss to follow-up was	
		addressed	
		<i>Case-control study</i> —If applicable explain how matching of cases and	
		controls was addressed	
		Cross-sectional study—If applicable describe analytical methods taking	
		account of sampling strategy	
		(a) Describe any sensitivity analyses	
		(<u>c)</u> Describe any sensitivity analyses	1

Continued on next page

Results			_
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible examined for eligibility confirmed eligible included in the study completing	,
		follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	,
		(c) Consider use of a flow diagram	
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and	
data		information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Cohort study-Report numbers of outcome events or summary measures over time	
		Case-control study-Report numbers in each exposure category, or summary	
		measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and	
		their precision (eg, 95% confidence interval). Make clear which confounders were	
		adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	
		meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and	
		sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or	
		imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	
		multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other informati	ion		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	
		applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.