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Searching for the erosion of empathy in medical undergraduate students: a longitudinal study.

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TITLE PAGE

Title: Searching for the erosion of empathy in medical undergraduate students: a longitudinal study.

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ABSTRACT

Objetive: To analyse the evolution of empathy throughout the degree programme of medicine in a Spanish school of medicine.

Design: Longitudinal, prospective five-year study, between October 2014 and June 2019.

Setting: Students from a Spanish university of Medicine.

Participants: Two voluntary cohorts of undergraduate medical students from two different school years were invited to participate (n=135 and 106 per school year). Finally, a total number of 174 students (102 (C1) and 72 (C2) students respectively) were monitored for five years. Each cohort was divided in two sub-cohorts of paired and unpaired students that were analysed to check possible social desirability bias.

Primary Outcome Measure: The Jefferson Scale of Empathy (JSE).

Results: The cohort of 102 students (C1) monitored between their first and fifth years of study (71.6% females) showed an improvement in JSE scores (global empathy) within paired females by 2.15 points (p=0.01) and in cognitive empathy by 2.39 points (p=0.01); in the unpaired female cohort the increase was of 2.32 points (cogenitive emphaty) (p=0.02). The cohort of 72 students (C2) monitored between their second to sixth years of study (70.8% females) displayed a cognitive empathy increase of 2.32 points (p=0.04) in the paired group of females. There were no decreased in male JSE scores.

Conclusions: The empathy of medical students at our school did not decline along grade years. In fact, it slightly improved in females, due to the cognitive dimension. This paper contributes to enlarge data from the Europe, where longitudinal studies are scarce. It supports the idea that there may be global geo-sociocultural differences; however, more studies comparing different school settings are needed.

Key words: empathy, medical students, medical training.

Key points: We describe the evolution of empathy throughout the degree program in medicine with the implementation of a person-centred medicine project teaching approach. We observed that the empathy of medical students improved over time.

DECLARATIONS

Funding: The research was supported by University Francisco de Vitoria.

Conflicts of interest/Competing interests: Jose Manuel Blanco Canseco, Fernando Caballero Martínez, Mercedes Plans Tena, Santiago Alvarez Montero and Diana Monge Martín declare that they have no conflict of interest.

Ethics approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University Francisco de Vitoria, Madrid. Spain.

Consent to participate: Informed consent was obtained from all individual participants included in the study.

Consent for publication: Not applicable.

Availability of data and material: The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Code availability: Not applicable.

Authors' contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Jose Manuel Blanco Canseco, Diana Monge Martín and Fernando Caballero Martínez. Fernando Caballero Martínez and Santiago Alvarez Montero led our person-centred medical curriculum. Mercedes Plans Tena made substantial contributions to interpretation of data. The first draft of the manuscript was written by Jose Manuel Blanco Canseco and Diana Monge

Martín, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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INTRODUCTION

Empathy is important for a clinical relationship and it is beneficial both for the patient and the healthcare professional. In patients, it has been associated with greater levels of satisfaction^{1,2,3}, greater participation in decision-making and caring for their health⁴, greater adherence to treatment^{1,5,6}, a better quality of life, lower levels of stress¹, and improved health results^{7,8}. Regarding the physician, empathy has been linked to better communication and relationships with the patient⁹, improved clinical skills^{9,10,11}, stronger capacity for inter-professional collaborative work¹², higher level of satisfaction and well-being^{13,14}, lower levels of professional burnout^{15,16,17}, less substance abuse or attempted suicide¹⁸, greater ethical awareness¹⁹ and a reduction in the number of official complaints^{20,21}. Moreover, different authors have reported that medical students with greater empathy have a higher level of well-being²² and experience less burnout²³. Students with greater empathy achieve higher practical work assessment scores from teachers or simulated patients^{24,25}.

Since Hojat et al.'s study in 2009,²⁷ several new studies have pointed out a decline in empathy evolution among schools^{27,28}. A systematic review of qualitative and quantitative studies (1990-2010) supported this observation which was mainly studied from longitudinal designs²⁹. A recent nationwide, multi-institutional, cross-sectional study from the United States comparing preclinical and clinical data found a decline in empathy scores³⁰.

In 2015, Roff warned about the possibility that empathy of medical students could not decline over time, at least, significantly. He conducted a literature review of cohorts of medical students monitored with the Student version of the Jefferson Physician Scale of Empathy (JPSE-S) in Japan, South Korea, China, Kuwait, India, Iran, UD, USA,

Australia, Brazil, Colombia, the Dominican Republic, and Portugal³¹. A subsequent scoping review of English, Spanish, Portuguese and French literature (2009-2016) published in 2017 revealed that the predominant trend in cross-sectional studies was of a significantly higher or of similar empathy scores across years. Nevertheless, most longitudinal studies presented either mixed-results or empathy declines. They concluded that the literature does not offer clear conclusions relative to changes in student empathy³².

In 2019, a meta-analysis was published to synthesize existing evidence examining how empathy changes during undergraduate medical education assessing whether different types of measures produce different results. Spatoula et al³³ discovered that studies showed contradictory results. For example, studies in the US found a significant reduction in empathy, but other countries, such as Portugal and Brazil did not show the same trend, maintaining the empathic disposition throughout medical school. The authors also stated that the JSPE report had higher effect sizes, considering that the decrease in empathy may depend on how empathy is measured³³.

We do not know whether most data that comes from the USA is generalizable and whether empathy evolution could be a global problem or not. It has relevant practical academic consequences. We aimed to ascertain if empathy skills in Spain should be enhanced. More data from certain areas of the world, such as Europe, are needed since geo-sociocultural settings appear to exert an influence^{34.} More longitudinal data may provide a wider perspective about this topic and may help us to make educational decisions³³.

In summary, although empathy is considered a basic skill for medical education and one would expect that medical students would become more empathetic as they progress through their career, results about its evolution are contradictory³³. There are Spanish

studies that have validated versions of JSPE^{35,36,37}. However, these studies are cross-sectional and do not analyse the evolution of empathy throughout time in different student cohorts. Nevertheless, the JSPE seems to be a good resource to derive knowledge about empathy evolution in Spain.

The objective of this study is to measure the evolution of medical students' levels of empathy at a Spanish University. We tracked two different cohorts to obtain a wider sample and checked the consistency of our outcomes by following up two different classes of undergraduates. We also compared the scale results within paired student cohorts to know if voluntary personal identification by means of a numerical code could introduce a social desirability bias.

METHODS

Design:

This was a longitudinal prospective cohort study.

Educational background:

Since its inception, our school has been part of the professional group known as The International Network for Person-Centered Medicine³⁸. One of its objectives is the maintenance and enhancement of levels of student empathy. Our person-centred curriculum has the following four-year educational pillars: a medical humanities pathway (one subject per year, from first to four years, coping with disciplines such as epistemology, anthropology, ethics, deontology and history of medicine), and a standardized-patient simulation program on clinical communication and relationship.

During the first- year and the second-year, students take part in a program of early clinical immersion. It consists of a clinical placement totalling four days at the health centre (primary care) and four days in hospital during the first year. The second year, they attend two days at a palliative care unit, three days in a psychiatric centre, and again, three days in a health centre. It provides students direct experience of the real medical practice in different contexts. Afterwards, they reflect on six principal areas: the patient- physician relationship (professional attitudes and behaviour), communication, the participation of patients and their families in care and decision-making, teamwork, healthcare organization and teaching. The work concludes with their writing a report summarising their reflections. During their clinical years, students approach different clinical simulated scenarios and perform their internship with tasks pointed out and recorded within an electronic portfolio.

Measurement instrument:

The Jefferson Scale of Empathy:

This study used the Jefferson Scale of Empathy, in its professional version (JSE-HP), duly translated, adapted and validated for our environment³⁷. The JSE-HP can be used to assess the empathy of medical students who have already had contact with real or simulated patients (commonly from the third year)^{39,40}. In our case, we decided to use this version because our students take part in the programme of early clinical immersion (see above) which allows them to view themselves from the physician's perspective.

The JSE-HP has 20 items and is scored on a 7-point Likert Scale (1=totally disagree, 7=totally agree). The possible scores range from 20 to 140 points, so the highest scores are associated with a greater degree of empathy. Although there is no time limit for the assessment, it is usually answered in less than five minutes. After the factorial analysis⁴⁰,

three dimensions are: Dimension 1: Patient perspective taking (cognitive aspects of empathy) made up of 10 items; dimension 2: compassionate care (emotional aspects of empathy) consisting of 8 items; dimension 3: standing in the patient's shoes containing 2 items.

Participants

The study took place between October 2014 and June 2019. Two cohorts, cohort 1 (C1) and cohort 2 (C2) of students (Figure 1), respectively from the first and the second years (academic year 2014-2015), were monitored for five years as they were the first cohorts to follow all the person-centred curriculum as it is now. Each student received a call to participate voluntarily, in the study. The degree of empathy within C1 was evaluated at the start of the medical degree and at the end of the second, fourth and fifth years. The C2 completed the JSE-HP at the start of the second year, and at the end of the third, fifth and sixth years.

Statistical analysis

The quantitative variables are presented with their mean and standard deviation (SD). The mean comparison of the JSE results in the paired student cohorts, when the variables showed a non-gaussian distribution in the comparison groups, was made using the Friedman non-parametric test. The mean comparison of the JSE results in unpaired student cohorts was made using the Kruskal-Wallis non-parametric test.

The SPSS 21.0 statistics program was used for statistical analysis, with a significance level of alpha<0.05 in all the analyses.

Ethical approval

All the questionnaires were anonymous, by use of codes, with the aim of adhering to international data protection laws, such as the current Spanish regulation (Organic Law 3/2018, of 5 December, regarding the Protection of Personal Data and guarantee of digital rights, BOE 294 of 6/12/2018). When students voluntarily accept it, some data had a numerical identification code to make possible analysis of paired student cohorts without compromising anonymity. The study received the approval of the Ethics Committee of the Francisco de Vitoria University. Participation was voluntary and independent of students' academic results.

RESULTS

C1 initially had 135 students, and 102 of them (75,5% of this class) were monitored for the five years, from their first year of career until their fifth year. It comprised 73 females (71.6%) and 29 males (28.4%). The C2 students initially account for 106 participants and 72 (67,9% of this class) completed their monitoring from their second year until the end of their sixth year. It comprised 51 females (70.8%) and 21 males (29.2%).

Given that the personal identification by means of a code was voluntary, both cohorts were subdivided into two sub-cohorts, one consisting of numerical code identified students (paired) and another of unidentified students (unpaired). In C1, 49 students were identified by code (48%): 35 females (71.4%) and 14 males (28.6%). Fifty-three students remained unidentified (52%): 38 females (71.7%) and 15 males (28.3%). In the C2, 53 students were identified by numerical code (73.6%): 36 females (67.9%) and 17 males (32.1%). Nineteen students remained unidentified (26.4%): 15 females (78.9%) and 4 males (21.1%).

In the paired female C1 students, a statistically significant increase in global empathy (JSE-HP total) of 2.15 points (Cohen's d 0.26) was observed from their first to their fifth year (p=0.01). In the same way, the cognitive empathy (dimension 1 JSE-HP) increased 2.39 points (Cohen's d 0.35) when finishing the fifth year compared to the first (p=0.01). See Figure 2; Table 1.

Table 1. JSE-HP results in cohort C1 of medical students at the UFV monitored from the 1st to 5th years (paired and unpaired) \mathbb{F}

YEAR	2014/15 First	2015/16 Second	2017/18 Fourth	2018/19 Fifth	р
Paired females (n, %)	35 (71.4)	33 (70.2)	35 (71.4)	33 (70.2)	
Dim 1	61.4	64.48	60.14	63.79	0.01
Dim 2	48.74	50	48.37	49.33	0.45
Dim 3	12.77	12	11.63	11.94	0.25
JSE TOTAL	122.91	126.48	120.14	125.06	0.01
Paired males (n, %)	14 (28.6)	14 (29.8)	14 (28.6)	14 (29.8)	
Dim 1	64.29	61.86	61.36	61.71	0.75
Dim 2	48.43	48.64	48.43	47.36	0.78
Dim 3	12.36	11.14	11.21	11.57	0.44
JSE_TOTAL	125.07	121.64	121	120.64	0.37
Unpaired females (n, %)	38 (71.7)	38 (71.7)	22 (66.7)	28 (71.8)	
Dim 1	62.82	63.34	59.86	65.14	0.02
Dim 2	49.29	49.89	49.14	50.46	0.61
Dim 3	12.03	12.11	11.55	11.39	0.77
JSE TOTAL	124.13	125.34	120.55	127	0.1
Unpaired males (n, %)	15 (28.3)	15 (28.3)	11 (33.3)	11 (28.2)	
Dim 1	60.07	60.2	57	60.73	0.79
Dim 2	47.33	48.47	45.18	49.55	0.3
Dim 3	12.53	11.73	12.18	11.36	0.31
JSE TOTAL	119.93	120.4	114.36	121.64	0.59

In the unpaired females of this cohort an improvement in cognitive empathy (dimension 1 JSE-HP) was also observed of 2.32 points (Cohen's d 0.48) (p=0,02). Differences found in empathy scores along time and between paired and nonpaired students were not statistically significant (Table 1).

In the paired C2, an increase in cognitive empathy (dimension 1 JSE-HP) was observed in females of 2.33 points (Cohen's d 0.44) (p=0,04). Again, there were no statistical

significative differences along time and between paired versus non-paired students (Figure 3; Table 2).

Table 2. JSE-HP results in cohort of medical students at the UFV monitored from the 2nd to 6th years (paired and unpaired)

4,550-20-20-2	2014/15	2015/16	2017/18	2018/19	
YEAR	Second	Third	Fifth	Sixth	р
Paired females (n, %))	36 (67.9)	36 (67.9)	36 (67.9)	29 (64.4)	0.04
Dim 1	61.81	61.81	63.69	64.14	0.04
Dim 2	49.17	49.94	50.53	50.52	0.09
Dim 3	11.47	12.06	11.81	12.41	0.08
JSE TOTAL	122.44	123.81	126.03	127.07	0.12
Paired males (n, %)	17 (32.1)	17 (32.1)	17 (32.1)	16 (35.6)	
Dim 1	56.94	57.76	60.71	62.06	0.17
Dim 2	44.29	45.35	44.29	47.12	0.31
Dim 3	10	10.06	10.35	10.37	0.1
JSE TOTAL	111.24	113.18	115.35	119.56	0.1
Unpaired females (n, %)	15 (78.9)	15 (78.9)	24 (70.6)	28 (76.7)	
Dim 1	62.27	61.47	62.83	62.86	0.2
Dim 2	50	49.73	47.42	49.29	0.94
Dim 3	11.87	11.67	11.42	12.82	0.29
JSE TOTAL	124.13	122.87	121.67	124.96	0.69
Unpaired males (n, %)	4 (21.1)	4 (21.1)	10 (29.1)	10 (23.3)	
Dim 1	62.5	64.75	60.2	57.5	0.4
Dim 2	46	43	46.1	45.6	0.79
Dim 3	10.5	10	11.3	11.6	0.79
JSE TOTAL	119	117.75	117.6	114.7	0.66

As can be seen in Tables 1 and 2 and Figures 2 and 3, male cohorts showed levels of empathy that did not fall significantly among the preclinical (first and second years) and clinical years (third to sixth years).

DISCUSSION

The current study describes the curricular evolution of empathy in medical students at a university on European setting. The empathy of medical students at the Francisco de Vitoria University did not show a decline of scores on the JSE-HP at the end of their studies compared to their results when they started (preclinical and clinical courses,

respectively). Moreover, it pointed out an increase of empathy evolution in females, as evidenced by a slight improvement of cognitive dimension.

The JSE-HP measures self-perception of empathic attitudes but not empathic behaviour, though different studies have established a link between their results and those observed by the real^{41,42} or simulated patients⁴³. Otherwise, the cognitive empathy (dimension 1 JSE-HP) seems to be the most likely influenced through suitable educational programmes⁴⁴, since emotional empathy appears to be more innate⁴⁴.

The samples correspond to a single non-profit private university in Madrid and may not be representative of the rest of the Schools of Medicine in our environment. The cohorts of identified students behaved in the same way as those who did not wish to be identified, which is similar to the observations made by Hojat et al.²⁶. This fact is interesting as it seems to limit the social desirability bias which may accompany self-administered questionnaires.

In Spain, there are no studies which analyse the degree of empathy of medical students over the long term. The current study provides a prospective monitoring of cohorts for five years. More longitudinal studies are required, as well as the effectiveness of the different programmes which aim to maintain and enhance it. Currently, we are carrying out an investigation which aims to analyse the degree of empathy in students across the eight medical faculties in Madrid (public and private) at three critical times in their training: at the start of the degree, at the end of the third year, and at the end of the sixth. The analysis of this data will provide more evidence regarding the evolution of empathy of Spanish medical students, discovering if differences exist in the empathy of students who take part in different curricular programmes, as well as establishing a proposal for cut-off values of low, medium and high levels of empathy in our environment.

The broader question is what is taking place globally. This study adds some evidence about the situation in Europe, where these kinds of studies are scarce, needed²⁹ and under development⁴⁵. If we take into consideration west European quality studies selected in the Spatoula et al's meta-analysis³³, nine cross-sectional and only three longitudinal, we find that they gathered and analysed data (difference in means and 95% CI) from only two European countries: one university in Portugal (cross-sectional), 5 in another UK university (longitudinal). Also, they analysed 15 universities in the US, 10 universities in Asia and two universities in Africa.

The cross-sectional study in a medical school in Portugal showed that the empathy measures of senior year students were higher than the scores of those from the first year's students. A longitudinal study from the UK showed that neither men nor women showed any change in cognitive empathy during the course. Women were more empathetic than men and men's affective empathy declined slightly, whilst women's affective empathy showed no change. Although statistically significant, the size was low. Neither men nor women appear to become meaningfully less empathetic during their medical education 47.

Our results complement these studies and it seems to support the idea that, at least in the European setting, empathy does not diminish during the medical career. However, a recent study from Switzerland showed that empathy remains stable in most medical students but declines in some students. It suggests that some personality traits (openness) as well as patient-oriented motives for studying medicine were associated with higher and stable empathy⁴⁸.

We cannot establish a cause-effect relationship as our study lacks a control group and all the possible confusion bias factors which may be influencing the results have not been isolated. However, it may help to acquire insight for asking questions and suggesting hypotheses. One question may be what sort of interventions are associated to better empathy outcomes. A second one could be whether the effects of these interventions are maintained in the long term, but actually little is known about it⁴⁹. Katahoka et al.⁵⁰ observed an improvement in the empathy of first-year medical students in Japan after an intervention was developed based on a communicative skills programme. They monitored this cohort of students and observed that the improvement in empathy did not last over time. They concluded that activities to improve empathy are necessary throughout the entire degree programme.

This study stresses the question about what variables are associated with better or worse outcomes. The empathy scores of UFV students are high compared to those reported in other countries^{31,32} and in our environment³⁶, although these populations are not fully comparable to ours. We may ask if it may be due to some of our four-year educational pillars: a medical humanities pathway and a standardized-patient based program on clinical communication and relationship.

Empathy training interventions may be a possible factor among others. Intervention length, scope of empathy measured, or the kind of tool used are important variables⁴⁹. For instance, in two systematic reviews performed by the Best Evidence Medical Education (BEME)⁵¹⁻⁵² the benefits of early clinical immersion at different levels is highlighted. On the affective level, early clinical immersion promotes empathetic attitudes in students towards the patients, reduces stress during clinical appointments, and enhances the awareness of the students' own feelings and reactions. As we have described, our personcentred curriculum has many kinds of interventions to promote empathy since first to last year. The Carnegie Foundation⁵³ established the integration of theoretical knowledge into clinical experience from the start of the degree among its most important lines of work. The General Medical Council of the United Kingdom⁵¹ prefers a vertical integration of

different types of practical experience over time. This idea attempts to break down the traditional division between preclinical and clinical courses (Flexner Academical Model).

Another variable to be considered is the criteria for admission⁵⁴. At our school, 20% of the admission score depends on the results of a personality, intelligence and psychopathological test to which candidates are submitted. Therefore, there is a possible selection bias towards students with a more humanistic and empathic profile. Stern, Frohna and Gruppen⁵⁵ did not find a link between academic performance, used by the medical faculties for student access, and students' future professional behaviour. They believe, however, that certain humanistic personal qualities, such as empathy, could be an influence. In this case, Hojat et al^{44,56,57} maintain that the personality and empathy questionnaires as well as personal interviews could be a useful extra element to consider in the selection process of the best students who wish to study at faculties of medicine. This should undoubtedly be a variable to consider in future studies.

A systematic review explored this question, but only a small number of possible influential factors were investigated in each publication reviewed²⁹. In this review, gender and age did not yield consistent results, but those students who selected patient-oriented specialties had higher empathy scores. Some studies selected in this systematic review found out that distress (for instance, burnout or a low sense of well-being) was associated to a decrease of empathy. Hidden curriculum could play a role: mistreatment, confrontation with clinical reality (illness, suffering, death), social support problems or an excessive workload. It suggests that not only educational interventions may play a role in empathy evolution, but other factors should be taken in mind in order to design future studies.

CONCLUSION

The empathy of medical students at our school did not decline along grade years. In fact, it slightly improved in females, due to the cognitive dimension. Our institution makes a special effort in teaching empathy. This paper contributes to enlarge data from European area, where studies are scarce. It supports the idea that there may be global geosociocultural differences, however more studies comparing different school settings are needed to know what variables are associated with better results.

ARTICLE SUMMARY: STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a longitudinal study of two different cohorts we tracked yearly for 5 years.
- We used a Spanish validated version of JSPE that is widely used for measuring medical empathy.
- We compared the results between paired and unpaired student cohorts to control the social desirability bias.
- Our students follow a person-centred medicine project In addition to their medical technical training.
- Our study includes only one University.

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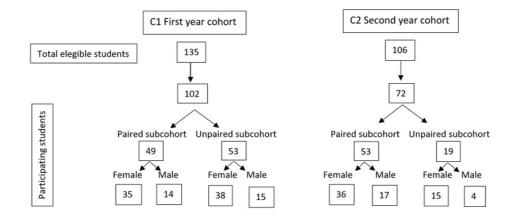
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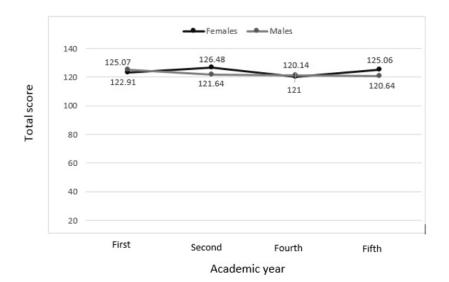
Figure 1.



Cohorts description: sample size of C1 from first year and C2 from second year.

229x121mm (96 x 96 DPI)

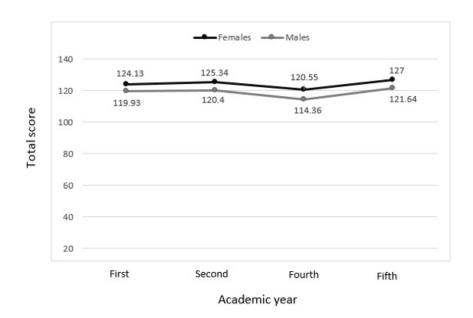
Fig 2.



JSE-HP results in C1 paired cohort of 35 females and 14 males monitored for five years (Start of 1st year - end of 5th year).

197x129mm (96 x 96 DPI)

Fig 3.



JSE-HP results in C2 paired cohort of 36 females and 17 males monitored for five years (Start of 2nd year - end of 6th year).

173x129mm (96 x 96 DPI)

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ABSTRACT

Objetive: To analyse the trajectory of empathy throughout the degree programme of medicine in a Spanish school of medicine.

Design: Longitudinal, prospective five-year study, between October 2014 and June 2019.

Setting: Students from a Spanish university of Medicine.

Participants: Two voluntary cohorts of undergraduate medical students from two different school years were invited to participate (n=135 (cohort 1, C1) and 106 (cohort 2, C2) per school year). Finally, a total number of 174 students (102 (C1, 71.6% females) and 72 (C2, 70.8% females) students respectively) were monitored for five years. Each cohort was divided in two sub-cohorts of paired and unpaired students that were analysed to check possible social desirability bias.

Primary Outcome Measure: The Jefferson Scale of Empathy (JSE).

Results: The cohort of 102 students (C1) monitored between their first and fifth years of study (71.6% females) showed an improvement among paired females of 2.15 points (p=0.01) in total JSE score and 2.39 points (p=0.01) in cognitive empathy; in the unpaired female cohort the increase was of 2.32 points (cognitive emphaty) (p=0.02). The cohort of 72 students (C2) monitored between their second to sixth years of study (70.8% females) displayed a cognitive empathy increase of 2.32 points (p=0.04) in the paired group of females. There were no significant differences between paired and unpaired results for either cohort. There were no decreased in male JSE scores.

Conclusions: The empathy of medical students at our school did not decline along grade years. In fact, it improved slightly, particularly cognitive empathy, among females. This paper contributes to enlarge data from the Europe, where longitudinal studies are scarce. It supports the idea that there may be global geo-sociocultural differences; however, more studies comparing different school settings are needed.

ARTICLE SUMMARY: STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a longitudinal study of two different cohorts we tracked yearly for 5 years.
- We used a Spanish validated version of JSE that is the most widely used for measuring medical empathy.
- We compared the results between paired and unpaired student cohorts to control the social desirability bias.
- Our students follow a person-centred medicine project in addition to their medical technical training.
- Our study includes only one University.

Key words: empathy, medical students, medical training.

Key points: We describe the trajectory of empathy throughout the degree program in medicine with the implementation of a person-centred medicine project teaching approach. We observed that the empathy of medical students improved over time in females.

DECLARATIONS

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Ethics approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University Francisco de

Consent to participate: Informed consent was obtained from all individual participants included in the study.

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Availability of data and material: Data are available upon reasonable request.

Code availability: Not applicable.

Authors' contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Jose Manuel Blanco Canseco, Diana Monge Martín and Fernando Caballero Martínez. Fernando Caballero Martínez and Santiago Alvarez Montero led our person-centred medical curriculum. Mercedes Plans Tena made substantial contributions to interpretation of data. The first draft of the manuscript was written by Jose Manuel Blanco Canseco and Diana Monge Martín, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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INTRODUCTION

Empathy is important for a clinical relationship and it is beneficial both for the patient and the healthcare professional. In patients, it has been associated with greater levels of satisfaction[1,2,3] greater participation in decision-making and caring for their health[4], greater adherence to treatment[1,5,6] a better quality of life, lower levels of stress[1], and improved health results[7,8]. Regarding the physician, empathy has been linked to better communication and relationships with the patient[9], improved clinical skills[9,10,11] stronger capacity for inter-professional collaborative work[12], higher level of satisfaction and well-being [13,14], lower levels of professional burnout [15,16,17], less substance abuse or attempted suicide[18], greater ethical awareness[19] and a reduction in the number of official complaints[20,21]. Moreover, different authors have reported that medical students with greater empathy have a higher level of well-being[22] and experience less burnout[23]. Students with greater empathy achieve higher practical work assessment scores from teachers or simulated patients[24,25].

Since Hojat et al.'s study in 2009[26], several new studies have pointed out a decline in empathy trajectory among schools[27,28]. A systematic review of qualitative and quantitative studies (1990-2010) supported this observation which was mainly studied from longitudinal designs[29]. A recent nationwide, multi-institutional, cross-sectional study from the United States comparing preclinical and clinical data found a decline in empathy scores[30].

In 2015, Roff [31] warned about the possibility that empathy of medical students could not decline over time, at least, significantly. He conducted a literature review of cohorts of medical students monitored with the Student version of the Jefferson Scale of Empathy (JSE-S) in Japan, South Korea, China, Kuwait, India, Iran, UD, USA, Australia, Brazil,

Colombia, the Dominican Republic, and Portugal[31]. A subsequent scoping review of English, Spanish, Portuguese and French literature (2009-2016) published in 2017 revealed that the predominant trend in cross-sectional studies was of a significantly higher or of similar empathy scores across years. Nevertheless, most longitudinal studies presented either mixed-results or empathy declines. They concluded that the literature does not offer clear conclusions relative to changes in student empathy[32].

In 2019, a meta-analysis was published to synthesize existing evidence examining how empathy changes during undergraduate medical education assessing whether different types of measures produce different results. Spatoula et al[33] discovered that studies showed contradictory results. For example, studies in the US found a significant reduction in empathy, but other countries, such as Portugal and Brazil did not show the same trend, maintaining the empathic disposition throughout medical school. The authors also stated that the JSE report had higher effect sizes, considering that the decrease in empathy may depend on how empathy is measured[33].

We do not know whether most data that comes from the USA is generalizable and whether empathy trajectory could be a global problem or not. It has relevant practical academic consequences. We aimed to ascertain if empathy skills in Spain should be enhanced. More data from certain areas of the world, such as Europe, are needed since geo-sociocultural settings appear to exert an influence[34] More longitudinal data may provide a wider perspective about this topic and may help us to make educational decisions[33].

In summary, although empathy is considered a basic skill for medical education and one would expect that medical students would become more empathetic as they progress through their career, results about its trajectory are contradictory[33]. There are Spanish studies that have validated versions of JSE [35,36,37]. However, these studies are cross-

sectional and do not analyse the trajectory of empathy throughout time in different student cohorts. Nevertheless, the JSE seems to be a good resource to derive knowledge about empathy trajectory in Spain.

Another aspect to take into account is the social desirability bias described by Edwards[38] when answering self-completed questionnaires. The authors of the JSE recommend that the questionnaire should be anonymous and applied in non-penalizing situations. Some studies[39,40] have controlled for this effect on JSE scores, not observing substantial changes in them. Nevertheless, the risk of giving fake positive answers and trying to present a socially acceptable image can always be present.

The objective of this study is to measure the trajectory of medical students' levels of empathy at a Spanish University. We tracked two different cohorts to obtain a wider sample and checked the consistency of our outcomes by following up two different classes of undergraduates. We also compared the scale results within paired student cohorts to know if voluntary personal identification by means of a numerical code could introduce a social desirability bias.

METHODS

Design:

This was a longitudinal prospective cohort study.

Educational background:

Since its inception, our school has been part of the professional group known as The International Network for Person-Centered Medicine[41]. One of its objectives is the maintenance and enhancement of levels of student empathy. Our person-centred

curriculum has the following six-year educational pillars: a medical humanities pathway (one subject per year, from first to four years, coping with disciplines such as epistemology, anthropology, ethics, deontology and history of medicine), and a standardized-patient simulation program on clinical communication and relationship.

During the first- year and the second-year, students take part in a program of early clinical immersion. It consists of a clinical placement totalling four days at the health centre (primary care) and four days in hospital during the first year. The second year, they attend two days at a palliative care unit, three days in a psychiatric centre, and again, three days in a health centre. It provides students direct experience of the real medical practice in different contexts. Afterwards, they reflect on six principal areas: the patient- physician relationship (professional attitudes and behaviour), communication, the participation of patients and their families in care and decision-making, teamwork, healthcare organization and teaching. The work concludes with their writing a report summarising their reflections. During their clinical years, from third to sixth year, students approach different clinical simulated scenarios and perform their internship with tasks pointed out and recorded within an electronic portfolio.

Measurement instrument:

The Jefferson Scale of Empathy (JSE):

The most widely used measure of medical empathy is JSE. It is designed specifically to measure self-perceived empathy in doctor-patient relationship, and it is more sensitive to changes than others[42]. The IRI is a generic measure of empathy and, the JSE measures empathy specifically for health care professionals. Both scales measure different but related constructs[43].

This study used the Jefferson Scale of Empathy, in its professional version (JSE-HP), duly translated, adapted and validated for our environment[37]. The JSE-HP can be used to assess the empathy of medical students who have already had contact with real or simulated patients (commonly from the third year)[44][45]. In our case, we decided to use this version because our students take part in the programme of early clinical immersion (see above) which allows them to view themselves from the physician's perspective.

The JSE-HP has 20 items and is scored on a 7-point Likert Scale (1=totally disagree, 7=totally agree). The possible scores range from 20 to 140 points, so the highest scores are associated with a greater degree of empathy. Although there is no time limit for the assessment, it is usually answered in less than five minutes. After the factorial analysis[45], three dimensions are: Dimension 1: Patient perspective taking (cognitive aspects of empathy) made up of 10 items; dimension 2: compassionate care (emotional aspects of empathy) consisting of 8 items; dimension 3: standing in the patient's shoes containing 2 items.

Setting and participants

The study took place between October 2014 and June 2019 in the school of Medicine of Francisco de Vitoria University (UFV). Two cohorts, cohort 1 (C1) and cohort 2 (C2) of students (Figure 1), respectively from the first and the second years (academic year 2014-2015), were monitored for five years as they were the first cohorts to follow all the personcentred curriculum as it is now. Each student received a call to participate voluntarily in the study, at the beginning of the class and fill in the paper questionnaire. The degree of

empathy within C1 was evaluated at the start of the medical degree and at the end of the second, fourth and fifth years. The C2 completed the JSE-HP at the start of the second year, and at the end of the third, fifth and sixth years.

To control the desirability bias, the two cohorts were subdivided into two sub-cohorts, one consisting of numerical code identified students (paired) and another of unidentified students (unpaired). So, the paired cohort could be tracked within subject longitudinally and compared.

Patient and public involvement

No patient involved.

Statistical analysis

The quantitative variables (JSE total, dimension 1, 2 and 3) are presented with their mean and standard deviation (SD). The qualitative variables (sex, code, cohort year) are presented with their frequency and percentage. The mean comparison of the JSE results in the paired student cohorts, when the variables showed a non-gaussian distribution in the comparison groups, was made using the Friedman non-parametric test. The mean comparison of the JSE results in unpaired student cohorts was made using the Kruskal-Wallis non-parametric test.

The SPSS 21.0 statistics program was used for statistical analysis, with a significance level of p<0.05 in all the analyses.

Ethical approval

All the questionnaires were anonymous, by use of codes, with the aim of adhering to international data protection laws, such as the current Spanish regulation (Organic Law 3/2018, of 5 December, regarding the Protection of Personal Data and guarantee of digital

rights, BOE 294 of 6/12/2018). When students voluntarily accept it, some data had a numerical identification code to make possible analysis of paired student cohorts without compromising anonymity. The study received the approval of the Ethics Committee of the Francisco de Vitoria University. Participation was voluntary and independent of students' academic results.

RESULTS

C1 initially had 135 students, and 102 of them (75.5% of this class) were voluntary monitored for the five years, from their first year of career until their fifth year. It comprised 73 females (71.6%) and 29 males (28.4%). The C2 students initially account for 106 participants and 72 (67.9% of this class) completed their voluntary monitoring from their second year until the end of their sixth year. It comprised 51 females (70.8%) and 21 males (29.2%).

Given that the personal identification by means of a code was voluntary, both cohorts were subdivided into two sub-cohorts, one consisting of numerical code identified students (paired) and another of unidentified students (unpaired). In C1, 49 students were identified by code (48%): 35 females (71.4%) and 14 males (28.6%). Fifty-three students remained unidentified (52%): 38 females (71.7%) and 15 males (28.3%). In the C2, 53 students were identified by numerical code (73.6%): 36 females (67.9%) and 17 males (32.1%). Nineteen students remained unidentified (26.4%): 15 females (78.9%) and 4 males (21.1%).

In the first clinical years (4th cohort year) we observe a slight drop in the total JSE score in both cohorts. However, scores at the end of follow-up recover to baseline levels. In cohort 2 they even improve slightly. See Figure 2 and 3.

In the paired female C1 students, a statistically significant increase in global empathy (JSE-HP total) of 2.15 points (Cohen's d 0.26) was observed from their first to their fifth year (p=0.01) (Figure 2). In the same way, the cognitive empathy (dimension 1 JSE-HP) increased 2.39 points (Cohen's d 0.35) when finishing the fifth year compared to the first (p=0.01). See Table 1.

Table 1. JSE-HP results in cohort C1 of medical students at the UFV monitored from the 1st to 5th years (paired and unpaired)

	2014/15	2015/16	2017/18	2018/19	
	First	Second	Fourth	Fifth	
YEAR	(mean, SD)	(mean, SD)	(mean, SD)	(mean, SD)	р
Paired females (n, %)	35 (71.4)	33 (70.2)	35 (71.4)	33 (70.2)	
Dim 1	61.40 (5.19)	64.48 (4.34)	60.14 (7.24)	63.79 (5.28)	0.01
Dim 2	48.74 (4.62)	50.00 (4.51)	48.37 (5.04)	49.33 (4.94)	0.45
Dim 3	12.77 (1.14)	12.00 (1.78)	11.63 (2.22)	11.94 (1.69)	0.25
JSE TOTAL	122.91 (8.29)	126.48 (7.19)	120.14 (9.85)	125.06 (8.40)	0.01
Paired males (n, %)	14 (28.6)	14 (29.8)	14 (28.6)	14 (29.8)	
Dim 1	64.29 (3.20)	61.86 (7.16)	61.36 (7.40)	61.71 (6.59)	0.75
Dim 2	48.43 (4.31)	48.64 (5.55)	48.43 (7.25)	47.36 (8.87)	0.78
Dim 3	12.36 (1.28)	11.14 (2.14)	11.21 (2.81)	11.57 (2.62)	0.44
JSE_TOTAL	125.07 (6.89)	121.64 (12.00)	121.00 (14.57)	120.64 (16.78)	0.37
Unpaired females (n, %)	38 (71.7)	38 (71.7)	22 (66.7)	28 (71.8)	
Dim 1	62.82 (5.69)	63.34 (6.11)	59.86 (6.67)	65.14 (3.90)	0.02
Dim 2	49.29 (5.01)	49.89 (4.67)	49.14 (4.95)	50.46 (4.83)	0.61
Dim 3	12.03 (1.91)	12.11 (1.61)	11.55 (2.28)	11.39 (2.54)	0.77
JSE TOTAL	124.13 (10.70)	125.34 (10.24)	120.55 (11.37)	127.00 (8.58)	0.10
Unpaired males (n, %)	15 (28.3)	15 (28.3)	11 (33.3)	11 (28.2)	
Dim 1	60.07 (6.13)	60.20 (7.28)	57.00 (10.25)	60.73 (6.87)	0.79
Dim 2	47.33 (4.82)	48.47 (5.14)	45.18 (6.43)	49.55 (4.82)	0.30
Dim 3	12.53 (2.20)	11.73 (1.75)	12.18 (1.66)	11.36 (2.73)	0.31
JSE TOTAL	119.93 (10.43)	120.40 (12.03)	114.36 (16.10)	121.64 (11.59)	0.59

In the unpaired females of this cohort an improvement in cognitive empathy (dimension 1 JSE-HP) was also observed of 2.32 points (Cohen's d 0.48) (p=0,02). Differences found

in empathy scores along time and between paired and nonpaired students were not statistically significant (Table 1).

In the paired C2, an increase in cognitive empathy (dimension 1 JSE-HP) was observed in females of 2.33 points (Cohen's d 0.44) (p=0,04). Again, there were no statistical significative differences along time and between paired versus non-paired students (Table 2).

Table 2. JSE-HP results in cohort C2 of medical students at the UFV monitored from the 2nd to 6th years (paired and unpaired)

YEAR	2014/15 Second (mean, SD)	2015/16 Third (mean, SD)	2017/18 Fifth (mean, SD)	2018/19 Sixth (mean, SD)	р
Paired females (n, %))	36 (67.9)	36 (67.9)	36 (67.9)	29 (64.4)	Ρ
Dim 1	61.81 (6.32)	61.81 (5.98)	63.69 (4.90)	64.14 (4.02)	0.04
Dim 2	49.17 (5.27)	49.94 (4.34)	50.53 (4.00)	50.52 (4.59)	0.09
Dim 3	11.47 2.22)	12.06 (2.32)	11.81 (1.95)	12.41 (2.06)	0.08
JSE TOTAL	122.44 (11.33)	123.81 (8.28)	126.03 (6.95)	127.07 (7.63)	0.12
Paired males (n, %)	17 (32.1)	17 (32.1)	17 (32.1)	16 (35.6)	
Dim 1	56.94 (7.10)	57.76 (8.19)	60.71 (8.59)	62.06 (5.01)	0.17
Dim 2	44.29 (4.90)	45.35 (5.95)	44.29 (9.34)	47.12 (4.91)	0.31
Dim 3	10.00 (2.50)	10.06 (2.19)	10.35 (3.08)	10.37 (2.06)	0.10
JSE TOTAL	111.24 (11.13)	113.18 (12.68)	115.35 (17.03)	119.56 (9.16)	0.10
Unpaired females (n, %)	15 (78.9)	15 (78.9)	24 (70.6)	28 (76.7)	
Dim 1	62.27 (4.33)	61.47 (3.52)	62.83 (7.14)	62.86 (7.07)	0.20
Dim 2	50.00 (3.29)	49.73 (4.57)	47.42 (8.68)	49.29 (4.17)	0.94
Dim 3	11.87 (1.96)	11.67 (1.95)	11.42 (3.22)	12.82 (1.02)	0.29
JSE TOTAL	124.13 (7.73)	122.87 (6.58)	121.67 (14.96)	124.96 (9.74)	0.69
Unpaired males (n, %)	4 (21.1)	4 (21.1)	10 (29.1)	10 (23.3)	
Dim 1	62.50 (5.32)	64.75 (3.95)	60.20 (7.57)	57.50 (8.06)	0.40
Dim 2	46.00 (4.00)	43.00 (16.67)	46.10 (7.53)	45.60 (5.38)	0.79
Dim 3	10.50 (1.91)	10.00 (3.91)	11.30 (2.00)	11.60 (0.84)	0.79
JSE TOTAL	119.00 (9.76)	117.75 (24.06)	117.60 (15.00)	114.70 (11.25)	0.66

As can be seen in Tables 1 and 2 and Figures 2 and 3, male cohorts showed levels of empathy that did not fall significantly among the preclinical (first and second years) and clinical years (third to sixth years).

DISCUSSION

The current study describes the curricular trajectory of empathy in medical students at a university in a European setting. The empathy of medical students at the Francisco de Vitoria University did not show a decline of scores on the JSE-HP at the end of their studies compared to their results when they started (preclinical and clinical courses, respectively). Moreover, it pointed out an increase of empathy trajectory in females, as evidenced by a slight improvement of cognitive dimension.

The JSE-HP measures self-perception of empathic attitudes but not empathic behaviour, though different studies have established a link between their results and those observed by the real[46,47] or simulated patients[48]. Otherwise, the cognitive empathy (dimension 1 JSE-HP) seems to be the most likely influenced through suitable educational programmes[49], since emotional empathy appears to be more innate[49].

The samples correspond to a single non-profit private university in Madrid and may not be representative of the rest of the Schools of Medicine in our environment. The cohorts of identified students behaved in the same way as those who did not wish to be identified, which is similar to the observations made by Hojat et al.[26]. This fact is interesting as it seems to limit the social desirability bias which may accompany self-administered questionnaires.

In Spain, there are no studies which analyse the degree of empathy of medical students over the long term. The current study is the first longitudinal work that provides a

prospective monitoring of cohorts for five years. More longitudinal studies are required, as well as the effectiveness of the different programmes which aim to maintain and enhance it. Currently, we are carrying out an investigation which aims to analyse the degree of empathy in students across the eight medical faculties in Madrid (public and private) at three critical times in their training: at the start of the degree, at the end of the third year, and at the end of the sixth. The analysis of this data will provide more evidence regarding the trajectory of empathy of Spanish medical students, discovering if differences exist in the empathy of students who take part in different curricular programmes, as well as establishing a proposal for cut-off values of low, medium and high levels of empathy in our environment.

The broader question is what is taking place globally. This study adds some evidence about the situation in Europe, where these kinds of studies are scarce, needed[29] and under development[50]. If we take into consideration west European quality studies selected in the Spatoula et al's meta-analysis[33], nine cross-sectional and only three longitudinal, we find that they gathered and analysed data (difference in means and 95% CI) from only two European countries: one university in Portugal (cross-sectional), 5 in another UK university (longitudinal). Also, they analysed 15 universities in the US, 10 universities in Asia and two universities in Africa.

The cross-sectional study in a medical school in Portugal showed that the empathy measures of senior year students were higher than the scores of those from the first year's students.[51] A longitudinal study from the UK showed that neither men nor women showed any change in cognitive empathy during the course. Women were more empathetic than men and men's affective empathy declined slightly, whilst women's affective empathy showed no change. Although statistically significant, the size was low.

Neither men nor women appear to become meaningfully less empathetic during their medical education[52].

Our results complement these studies and it seems to support the idea that, at least in the European setting, empathy does not diminish during the medical career. However, a recent study from Switzerland showed that empathy remains stable in most medical students but declines in some students. It suggests that some personality traits (openness) as well as patient-oriented motives for studying medicine were associated with higher and stable empathy[53].

Besides, results from studies which use different instruments to analyse medical students' empathy, as IRI and JSE, should be compared cautiously. Both scales measure different but related constructs[43]. There might be appropriate to use both instruments or even use other scales that measure empathy from real or simulated patients[46,47,48] in future studies.

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We cannot establish a cause-effect relationship as our study lacks a control group and all the possible confusion bias factors which may be influencing the results have not been isolated. However, it may help to acquire insight for asking questions and suggesting hypotheses. One question may be what sort of interventions are associated to better empathy outcomes. A second one could be whether the effects of these interventions are maintained in the long term, but actually little is known about it[54]. Katahoka et al.[55] observed an improvement in the empathy of first-year medical students in Japan after an intervention was developed based on a communicative skills programme. They monitored this cohort of students and observed that the improvement in empathy did not last over

time. They concluded that activities to improve empathy are necessary throughout the entire degree programme.

This study stresses the question about what variables are associated with better or worse outcomes. The empathy scores of UFV students seems higher than those reported in other countries[31,32] and in our environment[36], although these populations are not fully comparable to ours and we haven't analysed this differences statistically. We may ask if it may be due to some of our four-year educational pillars: a medical humanities pathway and a standardized-patient based program on clinical communication and relationship.

Empathy training interventions may be a possible factor among others. Intervention length, scope of empathy measured, or the kind of tool used are important variables[54]. For instance, in two systematic reviews performed by the Best Evidence Medical Education (BEME) [56,57] the benefits of early clinical immersion at different levels is highlighted. On the affective level, early clinical immersion promotes empathetic attitudes in students towards the patients, reduces stress during clinical appointments, and enhances the awareness of the students' own feelings and reactions. As we have described, our person-centred curriculum has many kinds of interventions to promote empathy since first to last year. The Carnegie Foundation [58] established the integration of theoretical knowledge into clinical experience from the start of the degree among its most important lines of work. The General Medical Council of the United Kingdom[59] prefers a vertical integration of different types of practical experience over time. This idea attempts to break down the traditional division between preclinical and clinical courses (Flexner Academical Model).

Another variable to be considered is the criteria for admission [60]. At our school, 20% of the admission score depends on the results of a personality, intelligence and

psychopathological test to which candidates are submitted. Therefore, there is a possible selection bias towards students with a more humanistic and empathic profile. Stern, Frohna and Gruppen[61] did not find a link between academic performance, used by the medical faculties for student access, and students' future professional behaviour. They believe, however, that certain humanistic personal qualities, such as empathy, could be an influence. In this case, Hojat et al [40,49,62] maintain that the personality and empathy questionnaires as well as personal interviews could be a useful extra element to consider in the selection process of the best students who wish to study at faculties of medicine. This should undoubtedly be a variable to consider in future studies.

A systematic review explored this question, but only a small number of possible influential factors were investigated in each publication reviewed[29]. In this review, gender and age did not yield consistent results, but those students who selected patient-oriented specialties had higher empathy scores. Some studies selected in this systematic review found out that distress (for instance, burnout or a low sense of well-being) was associated to a decrease of empathy. Hidden curriculum could play a role: mistreatment, confrontation with clinical reality (illness, suffering, death), social support problems or an excessive workload. It suggests that not only educational interventions may play a role in empathy trajectory, but other factors should be taken in mind in order to design future studies.

CONCLUSION

The empathy of medical students at our school did not decline along grade years. In fact, it slightly improved in females, due to the cognitive dimension. Our institution makes a special effort in teaching empathy. This paper contributes to enlarge data from European area, where studies are scarce. It supports the idea that there may be global geo-

sociocultural differences, however more studies comparing different school settings are needed to know what variables are associated with better results.



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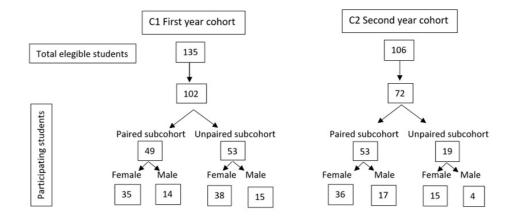
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FIGURES LEGENDS:

- Figure 1. Cohorts description: sample size of C1 from first year and C2 from second year.
- Figure 2: JSE-HP results in C1 paired cohort of 35 females and 14 males monitored for five years (Start of 1st academic year end of 5th year).
- Figure 3: JSE-HP results in C2 paired cohort of 36 females and 17 males monitored for five years (Start of 2nd academic year end of 6th year).

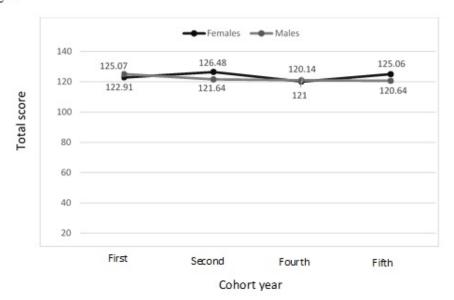
Figure 1.



Cohorts description: sample size of C1 from first year and C2 from second year.

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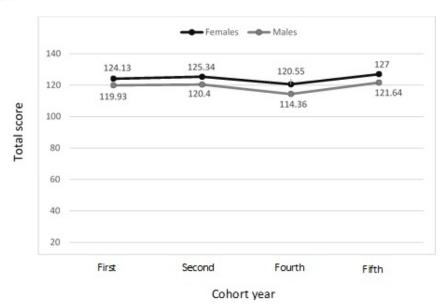
Fig 2:



JSE-HP results in C1 paired cohort of 35 females and 14 males monitored for five years (Start of 1st academic year - end of 5th year).

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JSE-HP results in C2 paired cohort of 36 females and 17 males monitored for five years (Start of 2nd academic year - end of 6th year).

141x96mm (96 x 96 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies **BASED ON pages and lines of "Main document-marked copy"**

	Item No	Recommendation	Pag/line
Title and abstract	1	(a) Indicate the study's design with a commonly used term	Pag1 L2 and
		in the title or the abstract	pag3 L30-31
		(b) Provide in the abstract an informative and balanced	Pag 3 L32-48
		summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pag 7 L113-166
Objectives	3	State specific objectives, including any prespecified hypotheses	Pag 9 L173-178
Methods			
Study design	4	Present key elements of study design early in the paper	Pag 9 L181 and 194-205
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pag 11 L230-239
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—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 Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	Pag 11 L208-214
		(b) Cohort 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	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pag 10 L207-220
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pag 11 L221-228
Bias	9	Describe any efforts to address potential sources of bias	Pag 12 L240-243
Study size	10	Explain how the study size was arrived at	Pag 12 L235-239
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pag 12 L247-248
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Pag 12 L 249-253

(b) Describe any methods used to examine subgroups and	Pag 12 L 251-253	
interactions		
(c) Explain how missing data were addressed	-	
(d) Cohort study—If applicable, explain how loss to follow-	-	
up was 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		
(\underline{e}) Describe any sensitivity analyses		

Continued on next page

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	Pag 13 L269-274
		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	Pag 13 L269 and 272
		(c) Consider use of a flow diagram	Figure 1
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical,	Pag 13 L271-282
data		social) and 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)	Pag 13 L269 and 272
Outcome	15*	Cohort study—Report numbers of outcome events or summary measures	Pag 14 L285-292
data		over time	Table 1 and 2
		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	Pag 14 L288-292
		estimates and their precision (eg, 95% confidence interval). Make clear which	Table 1 and 2
		confounders were adjusted for and why they were included	Pag 15 L299-315
		(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	17	Report other analyses done—eg analyses of subgroups and interactions, and	-
analyses		sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	Pag 16 L317-322
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias	Pag 16-17 L328-348
		or imprecision. Discuss both direction and magnitude of any potential bias	Pag 18 L378-388
Interpretatio	20	Give a cautious overall interpretation of results considering objectives,	Pag 17 L349-371
n		limitations, multiplicity of analyses, results from similar studies, and other	
		relevant evidence	
Generalisabi	21	Discuss the generalisability (external validity) of the study results	Pag 17-20 L349-431
lity			
Other inform	ation		
Funding	22	Give the source of funding and the role of the funders for the present study	Pag 4 L79
-		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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Searching for the erosion of empathy in medical undergraduate students: a longitudinal study.

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TITLE PAGE

Title: Searching for the erosion of empathy in medical undergraduate students: a longitudinal study.

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ABSTRACT

Objetive: To analyse the trajectory of empathy throughout the degree programme of medicine in a Spanish school of medicine.

Design: Longitudinal, prospective five-year study, between October 2014 and June 2019.

Setting: Students from a Spanish university of Medicine.

Participants: Two voluntary cohorts of undergraduate medical students from two different school years were invited to participate (n=135 (cohort 1, C1) and 106 (cohort 2, C2) per school year). Finally, a total number of 174 students (102 (C1, 71.6% females) and 72 (C2, 70.8% females) students respectively) were monitored for five years. Each cohort was divided in two sub-cohorts of paired and unpaired students that were analysed to check possible social desirability bias.

Primary Outcome Measure: The Jefferson Scale of Empathy (JSE).

Results: The cohort of 102 students (C1) monitored between their first and fifth years of study (71.6% females) showed an improvement among paired females of 2.15 points in total JSE score (p=0.01) and 2.39 points in cognitive empathy (p=0.01); in the unpaired female cohort the increase was of 2.32 points (cognitive emphaty) (p=0.02). The cohort of 72 students (C2) monitored between their second to sixth years of study (70.8% females) displayed a cognitive empathy increase of 2.32 points (p=0.04) in the paired group of females. There were no significant differences between paired and unpaired results for either cohort. Empathy scores among males did not decrease.

Conclusions: The empathy of medical students at our school did not decline along grade years. In fact, it improved slightly, particularly cognitive empathy, among females. This paper contributes to enlarge data from the Europe, where longitudinal studies are scarce. It supports the idea that there may be global geo-sociocultural differences; however, more studies comparing different school settings are needed.

ARTICLE SUMMARY: STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a longitudinal study of two different cohorts we tracked yearly for 5 years.
- We used a Spanish validated version of JSE that is the most widely used for measuring medical empathy.
- We compared the results between paired and unpaired student cohorts to control the social desirability bias.
- Our students follow a person-centred medicine project in addition to their medical technical training.
- Our study includes only one University.

Key words: empathy, medical students, medical training.

Key points: We describe the trajectory of empathy throughout the degree program in medicine with the implementation of a person-centred medicine project teaching approach. We observed that the empathy of medical students improved over time in females.

DECLARATIONS

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Vitoria, Madrid. Spain. Number/ID: 09/2017

Conflicts of interest/Competing interests: Jose Manuel Blanco Canseco, Fernando Caballero Martínez, Mercedes Plans Tena, Santiago Alvarez Montero and Diana Monge Martín declare that they have no conflict of interest. Competing interest non declared.

Ethics approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University Francisco de

Consent to participate: Informed consent was obtained from all individual participants included in the study.

Consent for publication: Not applicable.

Availability of data and material: Data are available upon reasonable request.

Code availability: Not applicable.

Authors' contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Jose Manuel Blanco Canseco, Diana Monge Martín and Fernando Caballero Martínez. Fernando Caballero Martínez and Santiago Alvarez Montero led our person-centred medical curriculum. Mercedes Plans Tena made substantial contributions to interpretation of data. The first draft of the manuscript was written by Jose Manuel Blanco Canseco and Diana Monge Martín, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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INTRODUCTION

Empathy is important for a clinical relationship and it is beneficial both for the patient and the healthcare professional. In patients, it has been associated with greater levels of satisfaction[1,2,3] greater participation in decision-making and caring for their health[4], greater adherence to treatment[1,5,6] a better quality of life, lower levels of stress[1], and improved health results[7,8]. Regarding the physician, empathy has been linked to better communication and relationships with the patient[9], improved clinical skills[9,10,11] stronger capacity for inter-professional collaborative work[12], higher level of satisfaction and well-being [13,14], lower levels of professional burnout [15,16,17], less substance abuse or attempted suicide[18], greater ethical awareness[19] and a reduction in the number of official complaints[20,21]. Moreover, different authors have reported that medical students with greater empathy have a higher level of well-being[22] and experience less burnout[23]. Students with greater empathy achieve higher practical work assessment scores from teachers or simulated patients[24,25].

Since Hojat et al.'s study in 2009[26], several new studies have pointed out a decline in empathy trajectory among schools[27,28]. A systematic review of qualitative and quantitative studies (1990-2010) supported this observation which was mainly studied from longitudinal designs[29]. A recent nationwide, multi-institutional, cross-sectional study from the United States comparing preclinical and clinical data found a decline in empathy scores[30].

In 2015, Roff[31] warned about the possibility that empathy of medical students could not decline over time, at least, significantly. She conducted a literature review of cohorts of medical students monitored with the Student version of the Jefferson Scale of Empathy (JSE-S) in Japan, South Korea, China, Kuwait, India, Iran, UD, USA, Australia, Brazil,

Colombia, the Dominican Republic, and Portugal[31]. A subsequent scoping review of English, Spanish, Portuguese and French literature (2009-2016) published in 2017 revealed that the predominant trend in cross-sectional studies was of a significantly higher or of similar empathy scores across years. Nevertheless, most longitudinal studies presented either mixed-results or empathy declines. The authors of this study that the literature does not offer clear conclusions relative to changes in student empathy[32].

In 2019, a meta-analysis was published to synthesize existing evidence examining how empathy changes during undergraduate medical education assessing whether different types of measures produce different results. Spatoula et al[33] discovered that studies showed contradictory results. For example, studies in the US found a significant reduction in empathy, but other countries, such as Portugal and Brazil did not show the same trend, maintaining the empathic disposition throughout medical school. The authors also stated that the JSE report had higher effect sizes, considering that the decrease in empathy may depend on how empathy is measured[33].

We do not know whether most data that comes from the USA is generalizable and whether empathy trajectory could be a global problem or not. It has relevant practical academic consequences. We aimed to ascertain if empathy skills in Spain should be enhanced. More data from certain areas of the world, such as Europe, are needed since geo-sociocultural settings appear to exert an influence[34] More longitudinal data may provide a wider perspective about this topic and may help us to make educational decisions[33].

In summary, although empathy is considered a basic skill for medical education and one would expect that medical students would become more empathetic as they progress through their career, results about its trajectory are contradictory[33]. There are Spanish studies that have validated versions of JSE [35,36,37]. However, these studies are cross-

sectional and do not analyse the trajectory of empathy throughout time in different student cohorts. Nevertheless, the JSE seems to be a good resource to derive knowledge about empathy trajectory in Spain.

Another aspect to take into account is the social desirability bias described by Edwards[38] when answering self-completed questionnaires. The authors of the JSE recommend that the questionnaire should be anonymous and applied in non-penalizing situations. Some studies[39,40] have controlled for this effect on JSE scores, not observing substantial changes in them. Nevertheless, the risk of giving fake positive answers and trying to present a socially acceptable image can always be present.

The objective of this study is to measure the trajectory of medical students' levels of empathy at a Spanish University. We tracked two different cohorts to obtain a wider sample and checked the consistency of our outcomes by following up two different classes of undergraduates. We also compared the scale results within paired student cohorts to know if voluntary personal identification by means of a numerical code could introduce a social desirability bias.

METHODS

Design:

This was a longitudinal prospective cohort study.

Educational background:

Since its inception, our school has been part of the professional group known as The International Network for Person-Centered Medicine[41]. One of its objectives is the maintenance and enhancement of levels of student empathy. Our person-centred

curriculum has the following six-year educational pillars: a medical humanities pathway (one subject per year, from first to four years, coping with disciplines such as epistemology, anthropology, ethics, deontology and history of medicine), and a standardized-patient simulation program on clinical communication and relationship.

During the first- year and the second-year, students take part in a program of early clinical immersion. It consists of a clinical placement totalling four days at the health centre (primary care) and four days in hospital during the first year. The second year, they attend two days at a palliative care unit, three days in a psychiatric centre, and again, three days in a health centre. It provides students direct experience of the real medical practice in different contexts. Afterwards, they reflect on six principal areas: the patient- physician relationship (professional attitudes and behaviour), communication, the participation of patients and their families in care and decision-making, teamwork, healthcare organization and teaching. The work concludes with their writing a report summarising their reflections. During their clinical years, from third to sixth year, students approach different clinical simulated scenarios and perform their internship with tasks pointed out and recorded within an electronic portfolio.

Measurement instrument:

The Jefferson Scale of Empathy (JSE):

The most widely used measure of medical empathy is JSE. It is designed specifically to measure self-perceived empathy in doctor-patient relationship, and it is more sensitive to changes than others[42]. The IRI is a generic measure of empathy and, the JSE measures empathy specifically for health care professionals. Both scales measure different but related constructs[43].

This study used the Jefferson Scale of Empathy, in its professional version (JSE-HP), duly translated, adapted and validated for our environment[37]. The JSE-HP can be used to assess the empathy of medical students who have already had contact with real or simulated patients (commonly from the third year)[44][45]. In our case, we decided to use this version because our students take part in the programme of early clinical immersion (see above) which allows them to view themselves from the physician's perspective.

The JSE-HP has 20 items and is scored on a 7-point Likert Scale (1=totally disagree, 7=totally agree). The possible scores range from 20 to 140 points, so the highest scores are associated with a greater degree of empathy. Although there is no time limit for the assessment, it is usually answered in less than five minutes. After the factorial analysis[45], three dimensions are: Dimension 1: Patient perspective taking (cognitive aspects of empathy) made up of 10 items; dimension 2: compassionate care (emotional aspects of empathy) consisting of 8 items; dimension 3: standing in the patient's shoes containing 2 items.

Setting and participants

The study took place between October 2014 and June 2019 in the school of Medicine of Francisco de Vitoria University (UFV). Two cohorts, cohort 1 (C1) and cohort 2 (C2) of students (Figure 1), respectively from the first and the second years (academic year 2014-2015), were monitored for five years as they were the first cohorts to follow all the personcentred curriculum as it is now. Each student received a call to participate voluntarily in the study, at the beginning of the class and fill in the paper questionnaire. It was

administered in a classroom setting. The degree of empathy within C1 was evaluated at the start of the medical degree and at the end of the second, fourth and fifth years. The C2 completed the JSE-HP at the start of the second year, and at the end of the third, fifth and sixth years.

To control the desirability bias, the two cohorts were subdivided into two sub-cohorts, one consisting of numerical code identified students (paired) and another of unidentified students (unpaired). So, the paired cohort could be tracked within subject longitudinally and compared.

Patient and public involvement

No patient involved.

Statistical analysis

The quantitative variables (JSE total, dimension 1, 2 and 3) are presented with their mean and standard deviation (SD). The qualitative variables (sex, code, cohort year) are presented with their frequency and percentage. The mean comparison of the JSE results in the paired student cohorts, when the variables showed a non-gaussian distribution in the comparison groups, was made using the Friedman non-parametric test. The mean comparison of the JSE results in unpaired student cohorts was made using the Kruskal-Wallis non-parametric test.

The SPSS 21.0 statistics program was used for statistical analysis, with a significance level of p<0.05 in all the analyses.

Ethical approval

All the questionnaires were anonymous, by use of codes, with the aim of adhering to international data protection laws, such as the current Spanish regulation (Organic Law

3/2018, of 5 December, regarding the Protection of Personal Data and guarantee of digital rights, BOE 294 of 6/12/2018). When students voluntarily accept it, some data had a numerical identification code to make possible analysis of paired student cohorts without compromising anonymity. The study received the approval of the Ethics Committee of the Francisco de Vitoria University. Participation was voluntary and independent of students' academic results.

RESULTS

C1 initially had 135 students, and 102 of them (75.5% of this class) were voluntary monitored for the five years, from their first year of career until their fifth year. It comprised 73 females (71.6%) and 29 males (28.4%). The C2 students initially account for 106 participants and 72 (67.9% of this class) completed their voluntary monitoring from their second year until the end of their sixth year. It comprised 51 females (70.8%) and 21 males (29.2%).

Given that the personal identification by means of a code was voluntary, both cohorts were subdivided into two sub-cohorts, one consisting of numerical code identified students (paired) and another of unidentified students (unpaired). In C1, 49 students were identified by code (48%): 35 females (71.4%) and 14 males (28.6%). Fifty-three students remained unidentified (52%): 38 females (71.7%) and 15 males (28.3%). In the C2, 53 students were identified by numerical code (73.6%): 36 females (67.9%) and 17 males (32.1%). Nineteen students remained unidentified (26.4%): 15 females (78.9%) and 4 males (21.1%).

In the first clinical years (4th cohort year) we observe a slight drop in the total JSE score in both cohorts. However, scores at the end of follow-up recover to baseline levels. In cohort 2 they even improve slightly. See Figure 2 and 3.

In the paired female C1 students, a statistically significant increase in global empathy (JSE-HP total) of 2.15 points (Cohen's d 0.26) was observed from their first to their fifth year (p=0.01) (Figure 2). In the same way, the cognitive empathy (dimension 1 JSE-HP) increased 2.39 points (Cohen's d 0.35) when finishing the fifth year compared to the first (p=0.01). See Table 1.

Table 1. JSE-HP results in cohort C1 of medical students at the UFV monitored from the 1st to 5th years (paired and unpaired)

	2014/15 First	2015/16 Second	2017/18 Fourth	2018/19 Fifth	
YEAR	(mean, SD)	(mean, SD)	(mean, SD)	(mean, SD)	р
Paired females (n, %)	35 (71.4)	33 (70.2)	35 (71.4)	33 (70.2)	
Dim 1	61.40 (5.19)	64.48 (4.34)	60.14 (7.24)	63.79 (5.28)	0.01
Dim 2	48.74 (4.62)	50.00 (4.51)	48.37 (5.04)	49.33 (4.94)	0.45
Dim 3	12.77 (1.14)	12.00 (1.78)	11.63 (2.22)	11.94 (1.69)	0.25
JSE TOTAL	122.91 (8.29)	126.48 (7.19)	120.14 (9.85)	125.06 (8.40)	0.01
Paired males (n, %)	14 (28.6)	14 (29.8)	14 (28.6)	14 (29.8)	
Dim 1	64.29 (3.20)	61.86 (7.16)	61.36 (7.40)	61.71 (6.59)	0.75
Dim 2	48.43 (4.31)	48.64 (5.55)	48.43 (7.25)	47.36 (8.87)	0.78
Dim 3	12.36 (1.28)	11.14 (2.14)	11.21 (2.81)	11.57 (2.62)	0.44
JSE_TOTAL	125.07 (6.89)	121.64 (12.00)	121.00 (14.57)	120.64 (16.78)	0.37
Unpaired females (n, %)	38 (71.7)	38 (71.7)	22 (66.7)	28 (71.8)	
Dim 1	62.82 (5.69)	63.34 (6.11)	59.86 (6.67)	65.14 (3.90)	0.02
Dim 2	49.29 (5.01)	49.89 (4.67)	49.14 (4.95)	50.46 (4.83)	0.61
Dim 3	12.03 (1.91)	12.11 (1.61)	11.55 (2.28)	11.39 (2.54)	0.77
JSE TOTAL	124.13 (10.70)	125.34 (10.24)	120.55 (11.37)	127.00 (8.58)	0.10
Unpaired males (n, %)	15 (28.3)	15 (28.3)	11 (33.3)	11 (28.2)	
Dim 1	60.07 (6.13)	60.20 (7.28)	57.00 (10.25)	60.73 (6.87)	0.79
Dim 2	47.33 (4.82)	48.47 (5.14)	45.18 (6.43)	49.55 (4.82)	0.30
Dim 3	12.53 (2.20)	11.73 (1.75)	12.18 (1.66)	11.36 (2.73)	0.31
JSE TOTAL	119.93 (10.43)	120.40 (12.03)	114.36 (16.10)	121.64 (11.59)	0.59

In the unpaired females of this cohort an improvement in cognitive empathy (dimension 1 JSE-HP) was also observed of 2.32 points (Cohen's d 0.48) (p=0,02). Differences found in empathy scores along time and between paired and nonpaired students were not statistically significant (Table 1).

In the paired C2, an increase in cognitive empathy (dimension 1 JSE-HP) was observed in females of 2.33 points (Cohen's d 0.44) (p=0,04). Again, there were no statistical significative differences along time and between paired versus non-paired students (Table 2).

Table 2. JSE-HP results in cohort C2 of medical students at the UFV monitored from the 2nd to 6th years (paired and unpaired)

YEAR	2014/15 Second (mean, SD)	2015/16 Third (mean, SD)	2017/18 Fifth (mean, SD)	2018/19 Sixth (mean, SD)	р
Paired females (n, %))	36 (67.9)	36 (67.9)	36 (67.9)	29 (64.4)	P
Dim 1	61.81 (6.32)	61.81 (5.98)	63.69 (4.90)	64.14 (4.02)	0.04
Dim 2	49.17 (5.27)	49.94 (4.34)	50.53 (4.00)	50.52 (4.59)	0.09
Dim 3	11.47 2.22)	12.06 (2.32)	11.81 (1.95)	12.41 (2.06)	0.08
JSE TOTAL	122.44 (11.33)	123.81 (8.28)	126.03 (6.95)	127.07 (7.63)	0.12
Paired males (n, %)	17 (32.1)	17 (32.1)	17 (32.1)	16 (35.6)	
Dim 1	56.94 (7.10)	57.76 (8.19)	60.71 (8.59)	62.06 (5.01)	0.17
Dim 2	44.29 (4.90)	45.35 (5.95)	44.29 (9.34)	47.12 (4.91)	0.31
Dim 3	10.00 (2.50)	10.06 (2.19)	10.35 (3.08)	10.37 (2.06)	0.10
JSE TOTAL	111.24 (11.13)	113.18 (12.68)	115.35 (17.03)	119.56 (9.16)	0.10
Unpaired females (n, %)	15 (78.9)	15 (78.9)	24 (70.6)	28 (76.7)	
Dim 1	62.27 (4.33)	61.47 (3.52)	62.83 (7.14)	62.86 (7.07)	0.20
Dim 2	50.00 (3.29)	49.73 (4.57)	47.42 (8.68)	49.29 (4.17)	0.94
Dim 3	11.87 (1.96)	11.67 (1.95)	11.42 (3.22)	12.82 (1.02)	0.29
JSE TOTAL	124.13 (7.73)	122.87 (6.58)	121.67 (14.96)	124.96 (9.74)	0.69
Unpaired males (n, %)	4 (21.1)	4 (21.1)	10 (29.1)	10 (23.3)	
Dim 1	62.50 (5.32)	64.75 (3.95)	60.20 (7.57)	57.50 (8.06)	0.40
Dim 2	46.00 (4.00)	43.00 (16.67)	46.10 (7.53)	45.60 (5.38)	0.79
Dim 3	10.50 (1.91)	10.00 (3.91)	11.30 (2.00)	11.60 (0.84)	0.79

JSE TOTAL	119 00 (9 76)	117 75 (24 06)	117.60 (15.00)	11/1 70 (11 25)	0.66
13L TOTAL	113.00 (3.70)	117.73 (24.00)	117.00 (13.00)	114.70 (11.23)	0.00

As can be seen in Tables 1 and 2 and Figures 2 and 3, male cohorts showed levels of empathy that did not fall significantly among the preclinical (first and second years) and clinical years (third to sixth years).

DISCUSSION

The current study describes the curricular trajectory of empathy in medical students at a university in a European setting. The empathy of medical students at the Francisco de Vitoria University did not show a decline of scores on the JSE-HP at the end of their studies compared to their results when they started (preclinical and clinical courses, respectively). Moreover, it pointed out an increase of empathy trajectory in females, as evidenced by a slight improvement of cognitive dimension.

The JSE-HP measures self-perception of empathic attitudes but not empathic behaviour, though different studies have established a link between their results and those observed by the real[46,47] or simulated patients[48]. Otherwise, the cognitive empathy (dimension 1 JSE-HP) seems to be the most likely influenced through suitable educational programmes[49], since emotional empathy appears to be more innate[49].

The samples correspond to a single non-profit private university in Madrid and may not be representative of the rest of the Schools of Medicine in our environment. The cohorts of identified students behaved in the same way as those who did not wish to be identified, which is similar to the observations made by Hojat et al.[26]. This fact is interesting as it seems to limit the social desirability bias which may accompany self-administered questionnaires.

In Spain, there are no studies which analyse the degree of empathy of medical students over the long term. The current study is the first longitudinal work that provides a prospective monitoring of cohorts for five years. More longitudinal studies are required, as well as the effectiveness of the different programmes which aim to maintain and enhance it. Currently, we are carrying out an investigation which aims to analyse the degree of empathy in students across the eight medical faculties in Madrid (public and private) at three critical times in their training: at the start of the degree, at the end of the third year, and at the end of the sixth. The analysis of this data will provide more evidence regarding the trajectory of empathy of Spanish medical students, discovering if differences exist in the empathy of students who take part in different curricular programmes, as well as establishing a proposal for cut-off values of low, medium and high levels of empathy in our environment.

The broader question is what is taking place globally. This study adds some evidence about the situation in Europe, where these kinds of studies are scarce, needed[29] and under development[50]. If we take into consideration west European quality studies selected in the Spatoula et al's meta-analysis[33], nine cross-sectional and only three longitudinal, we find that they gathered and analysed data (difference in means and 95% CI) from only two European countries: one university in Portugal (cross-sectional), 5 in another UK university (longitudinal). Also, they analysed 15 universities in the US, 10 universities in Asia and two universities in Africa.

The cross-sectional study in a medical school in Portugal showed that the empathy measures of senior year students were higher than the scores of those from the first year's students.[51] A longitudinal study from the UK showed that neither men nor women showed any change in cognitive empathy during the course. Women were more empathetic than men and men's affective empathy declined slightly, whilst women's

affective empathy showed no change. Although statistically significant, the size was low. Neither men nor women appear to become meaningfully less empathetic during their medical education[52].

Our results complement these studies and it seems to support the idea that, at least in the European setting, empathy does not diminish during the medical career. However, a recent study from Switzerland showed that empathy remains stable in most medical students but declines in some students. It suggests that some personality traits (openness) as well as patient-oriented motives for studying medicine were associated with higher and stable empathy[53].

Besides, results from studies which use different instruments to analyse medical students' empathy, as IRI and JSE, should be compared cautiously. Both scales measure different but related constructs[43]. There might be appropriate to use both instruments or even use other scales that measure empathy from real or simulated patients[46,47,48] in future studies.

There might be appropriate to use both instruments or even use other scales that measure empathy from real or simulated patients

We cannot establish a cause-effect relationship as our study lacks a control group and all the possible confusion bias factors which may be influencing the results have not been isolated. However, it may help to acquire insight for asking questions and suggesting hypotheses. One question may be what sort of interventions are associated to better empathy outcomes. A second one could be whether the effects of these interventions are maintained in the long term, but actually little is known about it[54]. Katahoka et al.[55] observed an improvement in the empathy of first-year medical students in Japan after an intervention was developed based on a communicative skills programme. They monitored

this cohort of students and observed that the improvement in empathy did not last over time. They concluded that activities to improve empathy are necessary throughout the entire degree programme.

This study stresses the question about what variables are associated with better or worse outcomes. The empathy scores of UFV students seems higher than those reported in other countries[31,32] and in our environment[36], although these populations are not fully comparable to ours and we haven't analysed this differences statistically. We may ask if it may be due to some of our four-year educational pillars: a medical humanities pathway and a standardized-patient based program on clinical communication and relationship.

Empathy training interventions may be a possible factor among others. Intervention length, scope of empathy measured, or the kind of tool used are important variables[54]. For instance, in two systematic reviews performed by the Best Evidence Medical Education (BEME) [56,57] the benefits of early clinical immersion at different levels is highlighted. On the affective level, early clinical immersion promotes empathetic attitudes in students towards the patients, reduces stress during clinical appointments, and enhances the awareness of the students' own feelings and reactions. As we have described, our person-centred curriculum has many kinds of interventions to promote empathy since first to last year. The Carnegie Foundation [58] established the integration of theoretical knowledge into clinical experience from the start of the degree among its most important lines of work. The General Medical Council of the United Kingdom[59] prefers a vertical integration of different types of practical experience over time. This idea attempts to break down the traditional division between preclinical and clinical courses (Flexner Academical Model).

Another variable to be considered is the criteria for admission [60]. At our school, 20% of the admission score depends on the results of a personality, intelligence and psychopathological test to which candidates are submitted. Therefore, there is a possible selection bias towards students with a more humanistic and empathic profile. Stern, Frohna and Gruppen[61] did not find a link between academic performance, used by the medical faculties for student access, and students' future professional behaviour. They believe, however, that certain humanistic personal qualities, such as empathy, could be an influence. In this case, Hojat et al [40,49,62] maintain that the personality and empathy questionnaires as well as personal interviews could be a useful extra element to consider in the selection process of the best students who wish to study at faculties of medicine. This should undoubtedly be a variable to consider in future studies.

A systematic review explored this question, but only a small number of possible influential factors were investigated in each publication reviewed[29]. In this review, gender and age did not yield consistent results, but those students who selected patient-oriented specialties had higher empathy scores. Some studies selected in this systematic review found out that distress (for instance, burnout or a low sense of well-being) was associated to a decrease of empathy. Hidden curriculum could play a role: mistreatment, confrontation with clinical reality (illness, suffering, death), social support problems or an excessive workload. It suggests that not only educational interventions may play a role in empathy trajectory, but other factors should be taken in mind in order to design future studies.

CONCLUSION

The empathy of medical students at our school did not decline along grade years. In fact, it slightly improved in females, due to the cognitive dimension. Our institution makes a

special effort in teaching empathy. This paper contributes to enlarge data from European area, where studies are scarce. It supports the idea that there may be global geosociocultural differences, however more studies comparing different school settings are needed to know what variables are associated with better results.



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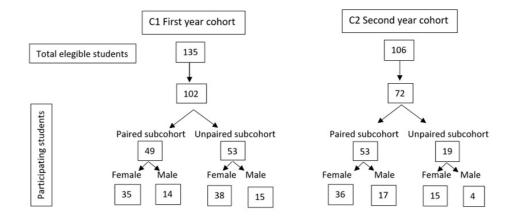
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FIGURES LEGENDS:

- Figure 1. Cohorts description: sample size of C1 from first year and C2 from second year.
- Figure 2: JSE-HP results in C1 paired cohort of 35 females and 14 males monitored for five years (Start of 1st academic year end of 5th year).
- Figure 3: JSE-HP results in C2 paired cohort of 36 females and 17 males monitored for five years (Start of 2nd academic year end of 6th year).

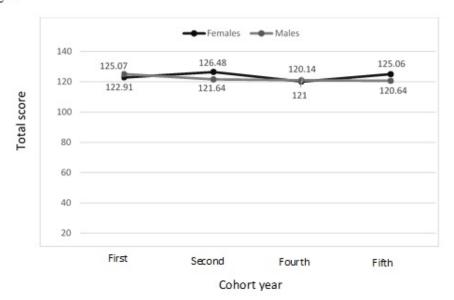
Figure 1.



Cohorts description: sample size of C1 from first year and C2 from second year.

229x121mm (96 x 96 DPI)

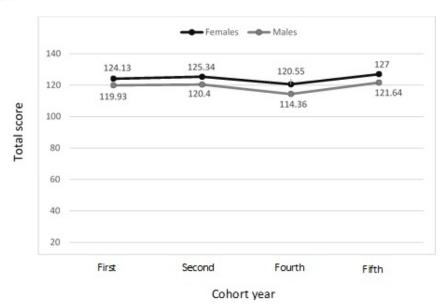
Fig 2:



JSE-HP results in C1 paired cohort of 35 females and 14 males monitored for five years (Start of 1st academic year - end of 5th year).

141x92mm (96 x 96 DPI)





JSE-HP results in C2 paired cohort of 36 females and 17 males monitored for five years (Start of 2nd academic year - end of 6th year).

141x96mm (96 x 96 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies **BASED ON pages and lines of "Main document-marked copy"**

	Item No	Recommendation	Pag/line
Title and abstract	1	(a) Indicate the study's design with a commonly used term	Pag1 L2 and
		in the title or the abstract	pag3 L30-31
		(b) Provide in the abstract an informative and balanced	Pag 3 L32-48
		summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pag 7 L113-166
Objectives	3	State specific objectives, including any prespecified hypotheses	Pag 9 L173-178
Methods			
Study design	4	Present key elements of study design early in the paper	Pag 9 L181 and 194-205
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pag 11 L230-239
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—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 Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	Pag 11 L208-214
		(b) Cohort 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	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pag 10 L207-220
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pag 11 L221-228
Bias	9	Describe any efforts to address potential sources of bias	Pag 12 L240-243
Study size	10	Explain how the study size was arrived at	Pag 12 L235-239
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pag 12 L247-248
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Pag 12 L 249-253

(b) Describe any methods used to examine subgroups and	Pag 12 L 251-253
interactions	
(c) Explain how missing data were addressed	-
(d) Cohort study—If applicable, explain how loss to follow-	-
up was 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

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	Pag 13 L269-274	
Turtionpunts	15	potentially eligible, examined for eligibility, confirmed eligible, included in	146 13 1207 271	
		the study, completing follow-up, and analysed		
		(b) Give reasons for non-participation at each stage	Pag 13 L269 and 272	-
		(c) Consider use of a flow diagram	Figure 1	_
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical,	Pag 13 L271-282	_
data	social) and 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)	Pag 13 L269 and 272	_
Outcome	15*	Cohort study—Report numbers of outcome events or summary measures	Pag 14 L285-292	_
data		over time	Table 1 and 2	
		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	Pag 14 L288-292		
		estimates and their precision (eg, 95% confidence interval). Make clear which	Table 1 and 2	
	confounders were adjusted for and why they were included	Pag 15 L299-315	_	
		(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	17	Report other analyses done—eg analyses of subgroups and interactions, and	-	
analyses		sensitivity analyses		
Discussion				
Key results	18	Summarise key results with reference to study objectives	Pag 16 L317-322	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias	Pag 16-17 L328-348	_
		or imprecision. Discuss both direction and magnitude of any potential bias	Pag 18 L378-388	_
Interpretatio	20	Give a cautious overall interpretation of results considering objectives,	Pag 17 L349-371	_
n		limitations, multiplicity of analyses, results from similar studies, and other		
		relevant evidence		_
Generalisabi	21	Discuss the generalisability (external validity) of the study results	Pag 17-20 L349-431	
lity				
Other inform	ation			
	ation 22	Give the source of funding and the role of the funders for the present study	Pag 4 L79	

^{*}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.