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Study protocol for the ETMED-L project: Longitudinal study of medical students' interpersonal competence and mental health

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11 **Study protocol for the ETMED-L project: Longitudinal study of medical students' interpersonal**
12 **competence and mental health**
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ABSTRACT

Introduction. Physician interpersonal competence is crucial for patient care. How interpersonal competence develops during undergraduate medical education is thus a key issue. Past literature on the topic consists predominantly of studies on empathy showing a trend of decline over the course of medical school. However, most existing studies have focused on narrow measures of empathy. The first aim of this project is to study medical students' interpersonal competences with a comprehensive framework of empathy that includes self-reported cognitive and affective empathy, performance-based assessments of emotion recognition accuracy, and a behavioural dimension of empathy. The second aim of the present project is to investigate the evolution of mental health during medical school and its putative link to the studied components of interpersonal competence. Indeed, studies documented a high prevalence of mental health issues among medical students that could potentially impact their interpersonal competence. Finally, this project will enable to test the impact of mental health and interpersonal competence on clinical skills as evaluated by experts and simulated patients.

Methods and analysis. This project consists of an observational longitudinal study with an open cohort design. Each year during the four consecutive years of the project, every medical student (curriculum year 1 to 6) of the University of Lausanne in Switzerland will be asked to complete an online questionnaire including several interpersonal competence and mental health measures. Clinical skills assessments from examinations and evaluations by simulated patients will also be included. Linear mixed models will be used to explore the longitudinal evolutions of the studied components of interpersonal competence and mental health as well as their reciprocal relationship and their link to clinical skills.

Ethics and dissemination. The project has received ethical approval from the competent authorities. Findings will be disseminated through internal, regional, national, and international conferences, news, and peer-reviewed journals.

KEYWORDS: Medical Students, Mental Health, Empathy, Longitudinal Study

STRENGTHS AND LIMITATIONS OF THIS PROJECT

- The longitudinal data collection across the six curriculum years provides an overview of the evolution of interpersonal competence and mental health during medical school.
- To tackle past research gaps, the present project investigates medical students' interpersonal competence with a comprehensive framework of empathy (cognitive and affective empathy, ERA, and behavioural adaptability) and different assessment techniques (self-reported questionnaire, performance-based test, and behavioural task).
- This project is one of the first investigating the relationship between interpersonal competence, mental health, and clinical skills of medical students in an open cohort design allowing both cross-sectional and longitudinal analyses.
- Data on medical students' mental health and interpersonal competence are lacking in the Swiss context and this project will compile a dataset available for comparison at the national and international level.
- Non-response and dropout biases will be inevitable even though the financial compensation for participation should reduce them.

Word count: 3922

1 INTRODUCTION

Physicians' interpersonal competence includes core elements of patient care such as being able to develop common therapeutic goals, sharing power and responsibility, considering the patient as a whole person, and being aware of the influence of the subjectivity and personal qualities of the physician on the practice of medicine.[1–3] The literature on the topic consists predominantly of studies on empathy and the present project thus focuses primarily on this specific component of physicians' interpersonal competences. Empathy has been shown to have a beneficial effect for both the patient and the physician. It is seen as an essential feature of professionalism in medicine and as one of the values of patient-centred care.[3–5] Empathy has been associated with better patient outcomes in terms of satisfaction,[6–8] self-efficacy,[7] enablement,[8,9] trust,[6] anxiety,[8] distress,[7,8] compliance,[6,10] shared decision-making,[7,8] and even clinical outcomes.[11] On the physician side, practitioners who show empathy make better clinical decisions[12,13] and receive fewer malpractice claims.[14] Moreover, physicians' empathy has been shown to be related to their mental health and well-being. More empathic physicians have indeed greater professional satisfaction,[13] better health,[15] increased psychological well-being,[15] and lower burnout incidence.[16]

1.1 Development of interpersonal competence during medical school

There is a longstanding and still growing body of literature on the trajectory of interpersonal competence during medical school. A study dating back to 1958 reported a tendency toward increased cynicism and decreased humanitarianism during medical school.[17] Many studies focussing on empathy followed, such as the often-cited longitudinal one by Hojat et al. showing a significant decline in empathy in the third year of medical school, namely when the curriculum is shifting toward clinical care activities.[18] They attributed this empathy decline to several factors, such as a demanding curriculum, time pressure, environmental factors, or the promotion of emotional detachment in modern medical education. Their results also suggested that there are “at-risk medical students” more vulnerable to losing their sense of empathy. Indeed, students with lower empathy scores at the beginning of medical school (men and students interested in technology-oriented specialties) show a steeper decrease of empathy during medical school than students with relatively higher empathy scores at the baseline.[18]

While several studies confirmed such erosion of empathy in medical students,[19–21] others have demonstrated no change or an increase in empathy.[22–25] In this regard, a 2015 review of literature concluded that empathy does not decline over time, or at least not significantly.[26,27] Some also suggested that a focus on an overall trend may mask different or opposing trajectories displayed, for instance, by gender subgroups [4]. Lastly, for other authors, the measures of empathy used in the existing research is also questionable. Authors indeed stressed the importance of approaching empathy as a complex socio-emotional construct [15,26,28] and a review of studies using the Jefferson Scale of Physician Empathy-Student version (JSPE-S) concluded that “more refined understandings of the nature of empathy [...]” are needed.[27]

1.2 Towards a comprehensive framework of empathy

Empathy is a multidimensional concept encompassing different dimensions. Two widely recognized dimensions are cognitive and affective empathy (for a review see [29]). Cognitive empathy refers to the correct understanding of another person's feelings (emotion recognition) and perspective (perspective taking). Affective or emotional empathy refers to the experience of prosocial and sympathetic feelings towards another person in distress (empathic concern),[30] or feeling the same emotion as another person (emotion contagion).[31]

1
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3 As acknowledged by several authors, a comprehensive understanding of empathy should include the
4 ability to understand others (cognitive empathy) and to share others' feelings (affective empathy),
5 but also the provision of a communicative response that conveys this understanding and sharing of
6 another's perspective and emotions.[32] This empathic communicative response can be provided
7 through behavioural adaptability, which is the ability to adjust one's interaction style to the
8 individual needs, desires, and preferences of a an interactional partner.[33,34] In the clinical context,
9 this implies that there is not one physician interaction style that is the best, but that physicians
10 should adapt to each specific situation based on an empathic understanding of the patient [33,35,36]
11 and studies confirmed that this physician's behavioural adaptability is indeed related to higher
12 patient satisfaction and trust in the physician.[36,37]
13
14

15
16 So far, research on empathy change over the course of medical school mostly relied on self-report
17 measures of cognitive empathy. However, one can also rely on performance task-based tests to
18 measure the ability to understand others. Indeed, several tests assessing emotion recognition ability
19 (ERA) have been developed and validated.[38] These ERA tests consist of pictures or short videos of
20 individuals portraying an emotion through facial, vocal, and bodily expressions. Individuals' ERA is
21 then measured as the number of emotions correctly recognized. Empirical research supports that
22 ERA is an important interpersonal competence for clinicians.[39] Practitioners with high ERA scores
23 show more patient-centred behaviours,[40,41] make more accurate diagnoses,[42] and have less
24 distressed,[41] more satisfied,[43] and more compliant patients.[44]
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26

27
28 To the best of our knowledge, Smith et al.[28] were the only ones adding performance task-based
29 measures (emotion recognition task and facial expression sensitivity test) to the generally used self-
30 reported questionnaires of empathy. Their results replicated the decline usually observed in the
31 JSPE-S scores, but the scores of the Questionnaire of Cognitive and Affective Empathy (QCAE) and
32 performance task-based tests showed an increase over time.[28] This indicates that different
33 dimensions of medical students' empathy might evolve differently during medical school. Smith et
34 al.'s study was limited to the first three years of medical school and did not investigate empathic
35 communicative responses of medical students. Thus, more longitudinal studies including a
36 behavioural dimension of empathy such as behavioural adaptability are needed to achieve a more
37 comprehensive understanding of the evolution of empathy during medical school. Moreover, there is
38 a lack of research on the potential impact of students' interpersonal competence on their mental
39 health and clinical skills.
40
41

42 **1.3 Mental health of medical students**

43
44 A 2016 meta-analysis,[45] estimated a prevalence of 27.2% for depression and 11.1% for suicidal
45 ideation among medical students. Furthermore, the prevalence of burnout and other forms of
46 distress in medical students, residents/fellows, and early career physicians was shown to be much
47 higher compared to similarly aged college graduates pursuing other careers.[46] A few longitudinal
48 studies explored mental health problems,[47] burnout and suicidal ideation,[48,49]
49 depression,[50,51] or life satisfaction in medical students,[52,53] but none has concurrently
50 investigated the longitudinal evolution of both interpersonal competence and mental health of
51 medical students. Cross-sectional studies provide evidence that more empathic physicians have
52 greater professional satisfaction,[13] higher well-being,[15] and lower burnout incidence.[16] The
53 link between empathy and mental health might even be bidirectional as studies showed that medical
54 students' mental health and well-being impact their empathy [54] with stress being related to
55 burnout and, in turn, to a deterioration of empathy toward patients.[55] Thus, longitudinal
56 exploration of the relationship between medical students' interpersonal competence and mental
57 health is needed to understand how and when one influences the other.
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1.4 Aims

This project aims to explore the longitudinal evolution of interpersonal competence and mental health during medical school. To tackle past research gaps, interpersonal competence will be investigated with a comprehensive framework of empathy (cognitive and affective empathy, ERA, and behavioural adaptability) and different assessment techniques (self-reported questionnaire, performance-based test, and behavioural task). We will also investigate several indicators of mental health, which may be related to the medical students' empathy. Additionally, we will explore how the studied components of interpersonal competence and mental health can predict clinical skills evaluated during training courses or examinations with simulated patients. Four primary research questions will thus be addressed:

- RQ1.** How differently do cognitive and affective empathy, ERA, and behavioural adaptability evolve over the course of medical school?
- RQ2.** How does mental health evolve over the course of medical school?
- RQ3.** How do the studied components of interpersonal competence (see RQ1) and mental health relate to each other?
- RQ4.** How do the studied components of interpersonal competence (see RQ1) and mental health relate to clinical skills?

2 METHODS AND ANALYSIS

2.1 Design and population

This project consist of an observational study with an open cohort design, which will allow for both cross-sectional and longitudinal analyses. Every medical student in the curriculum years 1 to 6 at the University of Lausanne (Switzerland) will be eligible for participation, except foreign students who are in the University as part of an academic exchange for one or two semesters. The eligible population size is estimated to be 1500 each year.

2.2 Procedure

During the four years of the project (2020-2024), four waves of online questionnaires will be administered during an exam-free month. At each wave, in the beginning of the data collection month, eligible students will be invited by email to fill in an online questionnaire and data collection will be open for 30 days. Participants will receive a financial compensation of 50 Swiss Francs (\approx 50 USD) for each online questionnaire completion. Two electronic reminders will be sent during the month of data collection.

On top of the online questionnaire, clinical skills evaluations will be included. The evaluations collected will be the Objective Structured Clinical Examination (OSCE) scores (for each student providing specific informed consent for this in the online questionnaire) and the ratings by simulated patients when students practice their clinical skills during specific training courses.

2.3 Measures

Besides sociodemographic, medical studies, and health related information, three categories of measures will be collected: interpersonal competence, mental health, and clinical skills (see Table 1 for a complete list of instruments, sample items and scales). The choice of instruments was based on previous research in the field, psychometric qualities, and comparability to existing cross-sectional or cohort studies.

2.3.1 Sociodemographic, medical studies, and health related information

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3 The participants' sociodemographic, medical studies, and health related information collected
4 through the yearly online questionnaire will include age, sex, native language, level of education of
5 parents, relationship status, living arrangements, hours spend in paid job, financial resources,
6 education before medical studies, hours spent on medical studies per week, dropout thoughts,
7 professional perspectives, professional identity,[56] experience of sexism or sexual harassment,
8 health satisfaction, hours of physical activity per week, weight, height, hours of sleep, satisfaction
9 with sleep, and psychiatric/psychotherapeutic past consultation.
10
11

12 **2.3.2 Interpersonal competence**

14 Regarding interpersonal competence, medical students' empathy in terms of cognitive and affective
15 empathy, ERA, and behavioural adaptability will be measured through the yearly questionnaire.
16

17 **Cognitive and affective empathy** will be measured with two often used self-reported instruments:
18 the JSPE-S and the QCAE. The JSPE-S was developed to assess medical students' orientations or
19 attitudes toward empathic relationships in the context of patient care [57] and was thus meant to
20 measure the cognitive dimension of empathy. It is maybe the most researched and widely used
21 empathy instrument in medical education [58] and benefits from solid psychometric foundations.[27]
22
23

24 The QCAE was validated in a large sample of university students and both the English and the French
25 version have been shown to reliably assess the two main dimensions of empathy (cognitive and
26 affective) and 5 correlated subdimensions (perspective taking, online simulation, emotion contagion,
27 peripheral responsivity, and proximal responsivity).[59,60]
28

29 **ERA** will be assessed with a performance-based test: The Geneva Emotion Recognition Test short
30 version (GERT-S).[61] The test consists of 42 short videos (about 3 seconds each) of actors portraying
31 one out of 14 different emotions (e.g., fear, despair, surprise, disgust, anger). The ERA score is then
32 computed as the percent of correctly recognized portrayals. The GERT-S is a multimodal and dynamic
33 ERA test as the actors express emotions through their face, body, and voice. A recent meta-analysis
34 showed that the GERT-S has the highest average reliability among interpersonal accuracy tests and
35 yields the highest average correlation with other ERA tests.[38] Several studies also support the
36 construct and predictive validity of this test.[38,62]
37
38

39 **Behavioural adaptability** will be assessed with the Ability to Modify Self-Presentation Scale (AMSP).
40 The AMSP is a dimension of self-monitoring (i.e. the extent to which people regulate and control
41 their self-presentation) measured in the Lennox and Wolfe revised self-monitoring scale. This scale
42 shows better psychometric and construct validity than the original version proposed by Snyder [63]
43 and several factorial analyses confirmed the general structure of the scale [64,65] including two
44 dimensions: the Sensitivity to Expressive Behaviour of Other and the AMSP. The AMSP assesses one's
45 ability to adapt expressive behaviours in different social situations [63] and was thus chosen as a self-
46 reported measure of behavioural adaptability. The validated French version of the AMSP, which
47 showed good internal consistency and test-retest reliability in a sample of French students,[66] will
48 be used in the present project.
49
50
51

52 In addition to the self-reported AMSP, we will develop a behavioural adaptability task-based
53 assessment that will be proposed to a subsample of volunteer medical students. The goal will be to
54 measure actual displays of behavioural adaptability by coding the extent to which participants adapt
55 their interaction styles to different interactional partners or situations. This has been done in a past
56 study conducted by one of the present project's co-investigators in which participants performed a
57 task with two interactional partners having different needs and preferences.[67]
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2.3.3 Mental health

Depressive symptoms, suicidal ideation, anxiety, stress, burnout, coping strategies, and psychoactive substance use will be investigated in the yearly online questionnaire. Importantly, the choice of instruments will allow a comparison with data of a previous cross-sectional study of Lausanne medical students' mental health (2018 unpublished Master thesis by Mayor, B: Mental health of the Lausanne medical students) as well as with the general population, taking advantage from a large population-based study ongoing in the city of Lausanne over the past 15 years (CoLaus|PsyCoLaus).[68] The cohort of offspring of the CoLaus|PsyCoLaus participants is indeed in the same age range as the students of the present project.

Depressive symptoms will be assessed with The Center for Epidemiological Studies-Depression (CES-D). Participants rate how often over the past week they experienced symptoms associated with depression.[69] The validated French version of the CES-D showed good internal consistency as well as adequate structural and construct validity.[70] It also provides cut-off scores with good sensitivity and specificity.[70]

Suicidal ideation will be evaluated using 2 questions of the Beck Depression Inventory (BDI).[71,72] The BDI is well validated and has been shown to accurately distinguish individuals at risk of suicidal attempts (based on past and present suicidal behaviour) from other individuals.[73] In the present project, the validated French version of two items belonging to the same higher construct of "Negative attitude" will be used.[74]

Anxiety will be assessed with the trait subscale of the State-Trait Anxiety Inventory (STAI), which measures the level of anxiety participants "generally feel".[75] Considerable evidence attests to the construct and concurrent validity of the scale.[76] Studies also have shown that it is a sensitive predictor of caregiver distress over time, and that it can vary with changes in support systems, health, and other individual characteristics.[77,78]

Furthermore, we created an adaptation of the STAI measuring the level of anxiety "during this COVID-19 pandemic" that will be added to the questionnaire because the first data collection wave will take place during the pandemic (March 2021).

Stress will be measured with one item assessing the general level of stress and six items assessing stress sources (family life, financial situation, paid activity, sentimental life, studies, and work/life balance). These items were used in a previous cross-sectional study of Lausanne medical students (2018 unpublished Master thesis by Mayor, B: Mental health of the Lausanne medical students) and integrated to the questionnaire for comparability purpose.

Burnout will be measured with the Maslach Burnout Inventory Student-Survey (MBI-SS). This scale designed to measure the burnout level of students evaluates the dimensions of Emotional Exhaustion (5 items), Cynicism (4 items), and Academic Efficacy (6 items, reversed dimension). A French version of the MBI-SS was validated and indicated good internal consistency and adequate structural validity.[79]

Coping strategies will be assessed using the French version of the coping section of the Euronet questionnaire validated in a random community sample in Lausanne.[80] Confirmatory factor analysis supported a three-dimension structure with Emotion-focused coping (9 items), Help-seeking (4 items), and Problem-focused coping (4 items).

1
2
3 **Psychoactive substance use** will be measured using the World health Organization's Alcohol,
4 Smoking and Substance Involvement Screening Test [81] and the C-SURF cohort's questionnaire of
5 neuroenhancement drugs use.[82]
6

7 **2.3.4 Clinical skills**

9 At the University of Lausanne, OSCE are carried out to assess medical student's clinical skills. During
10 an OSCE, the students perform a variety of clinical tasks in a simulated context, while being rated by
11 experts using evaluation checklists. Communication skills are systematically assessed in clinical
12 stations with simulated patients. The ratings will be retrieved for students giving formal consent to
13 share this data.
14

15
16 Moreover, communication training courses with simulated patients are conducted from the 2nd to
17 the 5th curriculum year on different topics (e.g., history taking, breaking bad news[83–85], and
18 motivational interview[86]). As part of this project, simulated patients will be asked to evaluate
19 students' communication and interactional skills using a short grid based on the OSCE checklist.
20

21 **2.4 Data analysis**

22
23 Due to the longitudinal nature of the project, Linear Mixed Models (LMMs) will be used to describe
24 the evolution of continuous variables during the course of medical school, adjusting for socio-
25 demographic variables and potential covariates.[87] LMMs combine fixed-effects and random-effects
26 in the same model simultaneously. The fixed effects part combines the effect of fixed variables (in
27 this case age, gender, etc.) on the response. The random part, on the other hand, allows adjusting
28 the model for interdependence among observations (e.g., repeated measures from the same
29 individuals are likely to be correlated; measures from students of the same curriculum year are likely
30 to be correlated). To model the longitudinal evolution of dichotomous variables, Generalized Linear
31 Mixed Models (GLMMs) which are generalized counterparts of LMMs will be used. In the GLMMs
32 predictors are related to the outcome using a link function (usually the *logit link* function, as in the
33 logistic regression) with a random part allowing the analysis of inter-correlated observations. There
34 are several approaches available to fit GLMMs; penalized quasi-likelihood will be used to
35 approximate and maximize the likelihood for GLMMs, which provides certain optimality
36 characteristics for estimated parameters.[88]
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38

39
40 Apart from adjusting the models for potential covariates, current and lagged observations of mental
41 health variables (from previous time points) can also be included to study the effect of current and
42 previous mental health status on the studied components of interpersonal competence and vice-
43 versa. The same will be done to assess the potential influence of interpersonal dimensions and
44 mental health on clinical skills. Ordinary dimension-reduction techniques such as model selection
45 (based on Akaike Information Criterion, etc.) will be used to ensure that models present an
46 acceptable goodness of fit and avoid over-adjustment in the models.
47
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49
50 Students who respond at least on two waves of questionnaires will be included in the longitudinal
51 analyses. The advantage of using LMMs and GLMMs is that cases with missing data will still
52 contribute to the models with all their other observed data (e.g. a participant having missed one
53 wave of annual assessment will contribute all the other measured waves). Multivariate Imputation
54 by Chained Equations will also be used to remedy the presence of potential missing values, in order
55 to reduce the potential bias.[89]
56
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58 **2.5 Sample size calculation**

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2
3 Apart from the curriculum year 1, which brings together more than 750 medical students, there is an
4 average of 240 medical students per curriculum year in the University of Lausanne Medical School,
5 which means more than 1500 eligible participants each year. Past studies with medical students
6 report yearly response rates varying from 32% to 91%^[4,28,48,49,51,52,90–94] and response rates
7 across several years from 20% to 74%.^[47,48,51,52,90] Given the participation compensation, we
8 expect to achieve a response rate of 35%. We used the Monte Carlo method to estimate the
9 potential statistical power of the LMMs to detect a small (as small as 1% which is a very conservative
10 projection) change in response per year. Even in a pessimistic situation where participation rate is
11 just 25% and large error variance in responses, we can still expect a 77% power in detecting the
12 effect size as small as 1% change per year. We have even higher power in detecting the effect of a
13 potential covariate (over 93%) on the response.
14
15

16 17 **2.6 Patient and public involvement**

18
19 This project and its research questions are very much driven by a growing interest and worry
20 regarding young adults' mental health. The online questionnaire was pretested by medical students
21 to evaluate the burden of the participation and medical students' delegates were involved in the
22 advertisement of the project. Moreover, an online newsfeed will be available to inform on the
23 project's progress.
24

25
26 The representative of the medical school of the University of Lausanne and the contact person for
27 issues related to mental health among students at Lausanne medical school are both co-investigators
28 of the present project. Exchanges regarding medical students' needs and medical education
29 strategies are thus ongoing since the beginning of the project drafting and will continue even after
30 the completion of the project. Indeed, this collaboration will enable to translate the clinical
31 implications of the project into educational strategies to implement in our University.
32

33 **3 RELEVANCE AND IMPACT**

34
35 The data collected through the ETMED-L project will be key to a better understanding of the
36 longitudinal development of interpersonal competence and mental health as well as their reciprocal
37 influence over the course of medical studies. By adopting a more comprehensive framework of
38 empathy including different dimensions (cognitive and affective empathy, ability to recognize
39 emotions, and a behavioural counterpart of empathy) and using different measurement methods
40 (self-report and performance-based tests) this project will contribute to fill an important gap in the
41 literature. It will allow a better understanding of the differential evolution of specific dimensions of
42 empathy and will help to improve the curriculum of medical studies, particularly in relation to
43 potential critical periods.
44
45

46
47 There are preliminary data indicating that medical students are at risk of mental health problems and
48 that it may impact their ability to interact with patients, which ultimately may impair their ability to
49 practice medicine. On top of mental health problems, tendency to distancing and loss of empathy
50 have consistently been reported in residents and physicians, highlighting the importance of
51 addressing these issues already during medical studies. This project will contribute to current efforts
52 to understand and promote mental health of students in medical schools. Moreover, dimensions that
53 are usually approached separately – interpersonal competence and mental health – will be analysed
54 concurrently, which makes this project unique. Having a better understanding of the longitudinal
55 course of mental health in relation to interpersonal competence will help to develop prevention
56 strategies and to provide better support and supervision.
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Ethics and dissemination

The project was approved by the Human Research Ethics Committee of the Canton de Vaud (protocol number 2020-02474). The participation poses little to no risk to the participants. However, as the questionnaire includes mental health questions, we will clearly indicate that students experiencing distress can refer to the psychiatric emergency ward of Lausanne University Hospital or (in non-urgent situations) contact the psychotherapeutic consultation for students of the University of Lausanne.

Findings will be disseminated through internal, regional, national, and international conferences, news, and peer-reviewed journals.

Author contributions

Alexandre Berney, Céline Bourquin, and Marianne Schmid Mast designed the project with input from all other authors. Valerie Carrard, Alexandre Berney, and Céline Bourquin drafted the present manuscript. Sylvie Berney, Katja Schlegel, Jacques Gaume, Mehdi Gholam, Pierre-Alexandre Bart, Martin Preisig, and Katarzyna Wac contributed to the establishment and refinement of project procedures and critically revised the manuscript. All authors approved the final version of the manuscript.

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Competing interest statement

None declared.

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Table 1. Measures

	Variables	Instruments	N° of items	Sample item (scale)
Interpersonal Competence	Cognitive empathy	Jefferson Scale of Physician Empathy-Student version	20	"Patients feel better when their physicians understand their feelings." (1 = strongly disagree; 7 = strongly agree)
	Cognitive and affective empathy	Questionnaire of Cognitive and Affective Empathy	31	"I am good at predicting how someone will feel." (1 = strongly disagree; 2 = slightly disagree; 3 = slightly agree; 4 = strongly agree)
	Emotion recognition accuracy (ERA)	Geneva Emotion Recognition Test short version	42	"Among these 14 emotions ^a , indicate which one had been expressed by the actor in the video clip." (0 = emotion not accurately recognized; 1 = emotion correctly recognized)
	Behavioural adaptability	The Ability to Modify Self-Presentation Scale	7	"When I feel that the image I am portraying isn't working, I can readily change it to something that does." (0 = strongly disagree; 1 = disagree; 2 = slightly disagree; 3 = slightly agree; 4 = agree; 5 = strongly agree)
Mental Health	Depressive symptoms	Center for Epidemiological Studies-Depression	20	"I felt sad." (0 = rarely or none of the time (less than 1 day); 1 = some or little of the time (1-2 days); 2 = occasionally or a moderate amount of time (3-4 days); 3 = a lot of the time (5-7 days))
	Suicidal ideation	2 questions of the Beck Depression Inventory	2	"How did you feel during the past 2 weeks?" (0 = I don't have any thoughts of killing myself; 1 = I have thoughts of killing myself, but I would not carry them out; 2 = I would like to kill myself; 3 = I would kill myself if I had the chance)
	Anxiety	Trait subscale of the State-Trait Anxiety Inventory	20	"I feel nervous and restless." (1 = no; 2 = rather no; 3 = rather yes; 4 = yes)
	Anxiety during COVID-19	Adaptation of the Trait subscale of the State-Trait Anxiety Inventory	20	"I feel nervous and restless." (1 = no; 2 = rather no; 3 = rather yes; 4 = yes)
	Stress	General stress item	1	"Globally, how would you evaluate your current stress level on a scale from 1 "none" to 10 "extreme"?"
	Stress sources	Sources of stress items	6	"Indicate to which extent each of the following ^b was a source of stress in your life during the last 12 months on a scale from 1 "none" to 10 "extreme"?"
	Burnout	Maslach Burnout Inventory Student-Survey	15	"I feel emotionally drained by my studies." (1 = never; 2 = rarely; 3 = sometimes, 4 = often, 5 = very often, 6 = always)
	Coping strategies	Coping section of the Euronet questionnaire	17	"I try to calm down." (0 = not at all common for me; 1 = not very common for me; 2 = quite common for me; 3 = very common for me)
	Psychoactive substance use	Alcohol, Smoking and Substance Involvement Screening Test	10 to 64 ^c	"In your life, which of the following substances have you ever used? (non-medical use only)" (0 = no; 3 = yes)
Clinical Skills	Neuroenhancement drugs use	C-SURF cohort's questionnaire	20	"How often did you use Neuroenhancement drugs over the past 12 months?" (0 = never; 1 = once; 2 = 2 to 3 times a year; 3 = 4 to 9 times a year; 4 = 1 to 2 times a month; 5 = 3 to 4 times a month; 6 = 2 to 3 times a week; 7 = 4 times a week or more)
	Clinical examination and simulated patients evaluation	Checklist of the Objective Structured Clinical Examination	21	"Responded to patient feelings and needs" (1 = not at all, 5 = totally)

^aPride, joy, amusement, pleasure, relief, interest, surprise, anxiety, fear, despair, sadness, disgust, irritation, anger

^bFamily, financial situation, paid activity, sentimental life, studies, and work/life balance

^cAcross nine substances: tobacco, alcohol, cannabis, cocaine, amphetamine, inhalants, sedatives, hallucinogens, and opioids; with follow up questions for the substances reported to be used.

BMJ Open

Study protocol for the ETMED-L project: Longitudinal study of mental health and interpersonal competence of medical students in a Swiss university using a comprehensive framework of empathy

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11 **Study protocol for the ETMED-L project: Longitudinal study of mental health and interpersonal**
12 **competence of medical students in a Swiss university using a comprehensive framework of**
13 **empathy**
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ABSTRACT

Introduction. Physician interpersonal competence is crucial for patient care. How interpersonal competence develops during undergraduate medical education is thus a key issue. Literature on the topic consists predominantly of studies on empathy showing a trend of decline over the course of medical school. However, most existing studies have focused on narrow measures of empathy. The first aim of this project is to study medical students' interpersonal competences with a comprehensive framework of empathy that includes self-reported cognitive and affective empathy, performance-based assessments of emotion recognition accuracy, and a behavioural dimension of empathy. The second aim of the present project is to investigate the evolution of mental health during medical school and its putative link to the studied components of interpersonal competence. Indeed, studies documented a high prevalence of mental health issues among medical students that could potentially impact their interpersonal competence. Finally, this project will enable to test the impact of mental health and interpersonal competence on clinical skills as evaluated by experts and simulated patients.

Methods and analysis. This project consists of an observational longitudinal study with an open cohort design. Each year during the four consecutive years of the project, every medical student (curriculum year 1 to 6) of the University of Lausanne in Switzerland will be asked to complete an online questionnaire including several interpersonal competence and mental health measures. Clinical skills assessments from examinations and training courses with simulated patients will also be included. Linear mixed models will be used to explore the longitudinal evolutions of the studied components of interpersonal competence and mental health as well as their reciprocal relationship and their link to clinical skills.

Ethics and dissemination. The project has received ethical approval from the competent authorities. Findings will be disseminated through internal, regional, national, and international conferences, news, and peer-reviewed journals.

KEYWORDS: Medical Students, Mental Health, Empathy, Longitudinal Study

STRENGTHS AND LIMITATIONS OF THIS PROJECT

- To tackle past research gaps, the present project investigates medical students' interpersonal competence with a comprehensive framework of empathy (cognitive and affective empathy, ERA, and behavioural adaptability) and different assessment techniques (self-reported questionnaire, performance-based test, and behavioural task).
- This project is one of the first investigating the relationship between interpersonal competence, mental health, and clinical skills of medical students in an open cohort design allowing both cross-sectional and longitudinal analyses.
- Data on medical students' mental health and interpersonal competence are lacking in the Swiss context and this project will compile a dataset available for comparison at the national and international level.
- Non-response and dropout biases will be inevitable even though the financial compensation for participation should reduce them.

Word count: 3934

1 INTRODUCTION

Physicians' interpersonal competence includes core elements of patient care such as being able to develop common therapeutic goals, sharing power and responsibility, considering the patient as a whole person, and being aware of the influence of the subjectivity and personal qualities of the physician on the practice of medicine.[1–3] The literature on the topic consists predominantly of studies on empathy and the present project thus focuses primarily on this specific component of physicians' interpersonal competences. Empathy has been shown to have a beneficial effect for both the patient and the physician. It is seen as an essential feature of professionalism in medicine and as one of the values of patient-centred care.[3–5] Empathy has been associated with better patient outcomes in terms of satisfaction,[6–8] self-efficacy,[7] enablement,[8,9] trust,[6] anxiety,[8] distress,[7,8] compliance,[6,10] shared decision-making,[7,8] and even clinical outcomes.[11] On the physician side, practitioners who show empathy make better clinical decisions[12,13] and receive fewer malpractice claims.[14] Moreover, physicians' empathy has been shown to be related to their mental health and well-being. More empathic physicians have indeed greater professional satisfaction,[13] better health,[15] increased psychological well-being,[15] and lower burnout incidence.[16]

1.1 Development of interpersonal competence during medical school

There is a longstanding and still growing body of literature on the trajectory of interpersonal competence during medical school. A study dating back to 1958 reported a tendency toward increased cynicism and decreased humanitarianism during medical school.[17] Many studies focussing on empathy followed, such as the often-cited longitudinal one by Hojat et al. showing a significant decline in empathy in the third year of medical school, namely when the curriculum is shifting toward clinical care activities.[18] They attributed this empathy decline to several factors, such as a demanding curriculum, time pressure, environmental factors, or the promotion of emotional detachment in modern medical education. Their results also suggested that there are “at-risk medical students” more vulnerable to losing their sense of empathy. Indeed, students with lower empathy scores at the beginning of medical school (men and students interested in technology-oriented specialties) show a steeper decrease of empathy during medical school than students with relatively higher empathy scores at the baseline.[18]

While several studies confirmed such erosion of empathy in medical students,[19–21] others have demonstrated no change or an increase in empathy.[22–25] In this regard, a 2015 review of literature concluded that empathy does not decline over time, or at least not significantly.[26,27] Some also suggested that a focus on an overall trend may mask different or opposing trajectories displayed, for instance, by gender subgroups [4]. Lastly, for other authors, the measures of empathy used in the existing research is also questionable. Authors indeed stressed the importance of approaching empathy as a complex socio-emotional construct [15,26,28] and a review of studies using the Jefferson Scale of Physician Empathy-Student version (JSPE-S) concluded that “more refined understandings of the nature of empathy [...]” are needed.[27]

1.2 Towards a comprehensive framework of empathy

Empathy is a multidimensional concept encompassing different dimensions. Two widely recognized dimensions are cognitive and affective empathy (for a review see [29]). Cognitive empathy refers to the correct understanding of another person's feelings (emotion recognition) and perspective (perspective taking). Affective or emotional empathy refers to the experience of prosocial and sympathetic feelings towards another person in distress (empathic concern),[30] or feeling the same emotion as another person (emotion contagion).[31]

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3 As acknowledged by several authors, a comprehensive understanding of empathy should include the
4 ability to understand others (cognitive empathy) and to share others' feelings (affective empathy),
5 but also the provision of a communicative response that conveys this understanding and sharing of
6 another's perspective and emotions.[32] This empathic communicative response can be provided
7 through behavioural adaptability, which is the ability to adjust one's interaction style to the
8 individual needs, desires, and preferences of a an interactional partner.[33,34] In the clinical context,
9 this implies that there is not one physician interaction style that is the best, but that physicians
10 should adapt to each specific situation based on an empathic understanding of the patient [33,35,36]
11 and studies confirmed that this physician's behavioural adaptability is indeed related to higher
12 patient satisfaction and trust in the physician.[36,37]
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16 So far, research on empathy change over the course of medical school mostly relied on self-report
17 measures of cognitive empathy. However, one can also rely on performance task-based tests to
18 measure the ability to understand others. Indeed, several tests assessing emotion recognition ability
19 (ERA) have been developed and validated.[38] These ERA tests consist of pictures or short videos of
20 individuals portraying an emotion through facial, vocal, and bodily expressions. Individuals' ERA is
21 then measured as the number of emotions correctly recognized. Empirical research supports that
22 ERA is an important interpersonal competence for clinicians.[39] Practitioners with high ERA scores
23 show more patient-centred behaviours,[40,41] make more accurate diagnoses,[42] and have less
24 distressed,[41] more satisfied,[43] and more compliant patients.[44]
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28 To the best of our knowledge, Smith et al.[28] were the only ones adding performance task-based
29 measures (emotion recognition task and facial expression sensitivity test) to the generally used self-
30 reported questionnaires of empathy. Their results replicated the decline usually observed in the
31 JSPE-S scores, but the scores of the Questionnaire of Cognitive and Affective Empathy (QCAE) and
32 performance task-based tests showed an increase over time.[28] This indicates that different
33 dimensions of medical students' empathy might evolve differently during medical school. Smith et
34 al.'s study was limited to the first three years of medical school and did not investigate empathic
35 communicative responses of medical students. Thus, more longitudinal studies including a
36 behavioural dimension of empathy such as behavioural adaptability are needed to achieve a more
37 comprehensive understanding of the evolution of empathy during medical school. Moreover, there is
38 a lack of research on the potential impact of students' interpersonal competence on their mental
39 health and clinical skills.
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42 **1.3 Mental health of medical students**

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44 A 2016 meta-analysis,[45] estimated a prevalence of 27.2% for depression and 11.1% for suicidal
45 ideation among medical students. Furthermore, the prevalence of burnout and other forms of
46 distress in medical students, residents/fellows, and early career physicians was shown to be much
47 higher compared to similarly aged college graduates pursuing other careers.[46] A few longitudinal
48 studies explored mental health problems,[47] burnout and suicidal ideation,[48,49]
49 depression,[50,51] or life satisfaction in medical students,[52,53] but none has concurrently
50 investigated the longitudinal evolution of both interpersonal competence and mental health of
51 medical students. Cross-sectional studies provide evidence that more empathic physicians have
52 greater professional satisfaction,[13] higher well-being,[15] and lower burnout incidence.[16] The
53 link between empathy and mental health might even be bidirectional as studies showed that medical
54 students' mental health and well-being impact their empathy [54] with stress being related to
55 burnout and, in turn, to a deterioration of empathy toward patients.[55] Thus, longitudinal
56 exploration of the relationship between medical students' interpersonal competence and mental
57 health is needed to understand how and when one influences the other.
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1.4 Aims

This project aims to explore the longitudinal evolution of interpersonal competence and mental health during medical school. To tackle past research gaps, interpersonal competence will be investigated with a comprehensive framework of empathy (cognitive and affective empathy, ERA, and behavioural adaptability) and different assessment techniques (self-reported questionnaire, performance-based test, and behavioural task). We will also investigate several indicators of mental health, which may be related to the medical students' empathy. Additionally, we will explore how the studied components of interpersonal competence and mental health can predict clinical skills evaluated during examinations or training courses with simulated patients. Four primary research questions will thus be addressed:

- RQ1.** How differently do cognitive and affective empathy, ERA, and behavioural adaptability evolve over the course of medical school?
- RQ2.** How does mental health evolve over the course of medical school?
- RQ3.** How do the studied components of interpersonal competence (see RQ1) and mental health relate to each other?
- RQ4.** How do the studied components of interpersonal competence (see RQ1) and mental health relate to clinical skills?

2 METHODS AND ANALYSIS

2.1 Design and population

This project consist of a 4-year observational study with an open cohort design, which will allow for both cross-sectional and longitudinal analyses. Each year, every medical student in the curriculum years 1 to 6 at the University of Lausanne (Switzerland) will be eligible for participation, except foreign students who are in the university as part of an academic exchange for one or two semesters. The eligible population size is estimated to be 1500 each year.

2.2 Procedure

During the four years of the project (2020-2024), four waves of online questionnaires will be administered during an exam-free month. At each wave, in the beginning of the data collection month, eligible students will be invited by email to fill in an online questionnaire. Data collection will be open for 30 days and two electronic reminders will be sent during this period. Participants will receive a financial compensation of 50 Swiss Francs (\approx 50 USD) for each online questionnaire completion. Financial compensation likely increases the overall response rate and was deemed fair for the effort and time students take for the study. However, individuals could then participate solely for monetary benefits and be less attentive when filling in the questionnaire. To tackle this issue, two attention questions will be introduced in the questionnaire (e.g., 'In order to check your attention, please answer "Slightly agree" to this question.') and participants giving wrong answers to any of these attention questions will be excluded from the analysis.

On top of the online questionnaire, clinical skills ratings will be included. The ratings collected will be the Objective Structured Clinical Examination (OSCE) scores (for each student providing specific informed consent for this in the online questionnaire) and coding by simulated patients when students practice their clinical skills during specific training courses.

Data will be coded to protect confidentiality. All participants will be assigned an identification code, which will be used throughout the project. A secured correspondence table between participant's codes and participant's personal data will be kept separately from the datasets.

2.3 Measures

Besides sociodemographic, medical studies, and health related information, three categories of measures will be collected: interpersonal competence, mental health, and clinical skills (see Table 1 for a complete list of instruments, sample items and scales). The choice of instruments was based on previous research in the field, psychometric qualities, and comparability to existing cross-sectional or cohort studies.

2.3.1 Sociodemographic, medical studies, and health related information

The participants' sociodemographic, medical studies, and health related information collected through the yearly online questionnaire will include age, gender, native language, level of education of parents, relationship status, living arrangements, hours spend in paid job, financial resources, education before medical studies, hours spent on medical studies per week, dropout thoughts, medical specialisation targeted, professional identity,[56] experience of sexism or sexual harassment, health satisfaction,[57] hours of physical activity per week, weight, height, hours of sleep, satisfaction with sleep, and psychiatric/psychotherapeutic past consultation.

2.3.2 Interpersonal competence

Regarding interpersonal competence, medical students' empathy in terms of cognitive and affective empathy, ERA, and behavioural adaptability will be measured through the yearly questionnaire.

Cognitive and affective empathy will be measured with two often used self-reported instruments: the JSPE-S and the QCAE. The JSPE-S was developed to assess medical students' orientations or attitudes toward empathic relationships in the context of patient care [58] and was thus meant to measure the cognitive dimension of empathy. It is maybe the most researched and widely used empathy instrument in medical education [59] and benefits from solid psychometric foundations.[27] A four-year license will be purchased for the use of the JSPE-S.

The QCAE was validated in a large sample of university students and both the English and the French version have been shown to reliably assess the two main dimensions of empathy (cognitive and affective) and 5 correlated subdimensions (perspective taking, online simulation, emotion contagion, peripheral responsivity, and proximal responsivity).[60,61]

ERA will be assessed with a performance-based test: The Geneva Emotion Recognition Test short version (GERT-S).[62] The test consists of 42 short videos (about 3 seconds each) of actors portraying one out of 14 different emotions (e.g., fear, despair, surprise, disgust, anger). The ERA score is then computed as the percent of correctly recognized portrayals. The GERT-S is a multimodal and dynamic ERA test as the actors express emotions through their face, body, and voice. A recent meta-analysis showed that the GERT-S has the highest average reliability among interpersonal accuracy tests and yields the highest average correlation with other ERA tests.[38] Several studies also support the construct and predictive validity of this test.[38,63]

Behavioural adaptability will be assessed with the Ability to Modify Self-Presentation Scale (AMSP). The AMSP is a dimension of self-monitoring (i.e. the extent to which people regulate and control their self-presentation) measured in the Lennox and Wolfe revised self-monitoring scale. This scale shows better psychometric and construct validity than the original version proposed by Snyder [64] and several factorial analyses confirmed the general structure of the scale [65,66] including two dimensions: the Sensitivity to Expressive Behaviour of Other and the AMSP. The AMSP assesses one's ability to adapt expressive behaviours in different social situations [64] and was thus chosen as a self-reported measure of behavioural adaptability. The validated French version of the AMSP, which

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3 showed good internal consistency and test-retest reliability in a sample of French students,[67] will
4 be used in the present project.
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6 In addition to the self-reported AMSP, we will develop a behavioural adaptability task-based
7 assessment that will be proposed to a subsample of volunteer medical students. The goal will be to
8 measure actual displays of behavioural adaptability by coding the extent to which participants adapt
9 their interaction styles to different interactional partners or situations. This has been done in a past
10 study conducted by one of the present project's co-investigators in which participants performed a
11 task with two interactional partners having different needs and preferences.[68]
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14 **2.3.3 Mental health**

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16 Depressive symptoms, suicidal ideation, anxiety, stress, burnout, coping strategies, and psychoactive
17 substance use will be investigated in the yearly online questionnaire. Importantly, the choice of
18 instruments will allow a comparison with data of a previous cross-sectional study of Lausanne
19 medical students' mental health (2018 unpublished Master thesis by Mayor, B: Mental health of the
20 Lausanne medical students) as well as with the general population, taking advantage from a large
21 population-based study ongoing in the city of Lausanne over the past 15 years
22 (CoLaus|PsyCoLaus).[69] The cohort of offspring of the CoLaus|PsyCoLaus participants is indeed in
23 the same age range as the students of the present project.
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25

26 **Depressive symptoms** will be assessed with The Center for Epidemiological Studies-Depression (CES-
27 D). Participants rate how often over the past week they experienced symptoms associated with
28 depression.[70] The validated French version of the CES-D showed good internal consistency as well
29 as adequate structural and construct validity.[71] It also provides cut-off scores with good sensitivity
30 and specificity.[71]
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33 **Suicidal ideation** will be evaluated using 2 questions of the Beck Depression Inventory (BDI).[72,73]
34 The BDI is well validated and has been shown to accurately distinguish individuals at risk of suicidal
35 attempts (based on past and present suicidal behaviour) from other individuals.[74] In the present
36 project, the validated French version of two items belonging to the same higher construct of
37 "Negative attitude" will be used.[75]
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40 **Anxiety** will be assessed with the trait subscale of the State-Trait Anxiety Inventory (STAI), which
41 measures the level of anxiety participants "generally feel".[76] Considerable evidence attests to the
42 construct and concurrent validity of the scale.[77] Studies also have shown that it is a sensitive
43 predictor of caregiver distress over time, and that it can vary with changes in support systems,
44 health, and other individual characteristics.[78,79]
45

46 Furthermore, we created an adaptation of the STAI measuring the level of anxiety "during this
47 COVID-19 pandemic" that will be added to the questionnaire because the first data collection wave
48 will take place during the pandemic (March 2021).
49

50 **Stress** will be measured with one item assessing the general level of stress and six items assessing
51 stress sources (family life, financial situation, paid activity, sentimental life, studies, and work/life
52 balance). These items were used in a previous cross-sectional study of Lausanne medical students
53 (2018 unpublished Master thesis by Mayor, B: Mental health of the Lausanne medical students) and
54 integrated to the questionnaire for comparability purpose.
55
56

57 **Burnout** will be measured with the Maslach Burnout Inventory Student-Survey (MBI-SS). This scale
58 designed to measure the burnout level of students evaluates the dimensions of Emotional
59 Exhaustion (5 items), Cynicism (4 items), and Academic Efficacy (6 items, reversed dimension). A
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3 French version of the MBI-SS was validated and indicated good internal consistency and adequate
4 structural validity.[80]
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6 **Coping strategies** will be assessed using the French version of the coping section of the Euronet
7 questionnaire validated in a random community sample in Lausanne.[81] Confirmatory factor
8 analysis supported a three-dimension structure with Emotion-focused coping (9 items), Help-seeking
9 (4 items), and Problem-focused coping (4 items).
10

11 **Psychoactive substance use** will be measured using the World health Organization's Alcohol,
12 Smoking and Substance Involvement Screening Test [82] and the C-SURF cohort's questionnaire of
13 neuroenhancement drugs use.[83]
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16 **2.3.4 Clinical skills**

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18 At the University of Lausanne, OSCE are carried out to assess medical students' clinical skills at the
19 end of the 3rd, 5th, and 6th curriculum year. OSCE stations represent clinical situations in which
20 students interact with simulated patients. In some stations, experts systematically assess
21 communication skills using a 5-item checklist (see Table 1 for sample items). These scores will be
22 retrieved for the students giving formal consent to share this data.
23

24 Moreover, communication training courses with simulated patients are conducted from the 2nd to
25 the 5th curriculum year on different topics (e.g., history taking, breaking bad news[84–86], and
26 motivational interview[87]). As part of this project, simulated patients will be asked to fill in a grid at
27 the end of the interviews with students that includes the OSCE communication 5-item checklist as
28 well as the Jefferson Scale of Patient Perceptions of Physician Empathy [88] (see Table 1 for sample
29 items).
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32 **2.4 Data analysis**

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34 Due to the longitudinal nature of the project, Linear Mixed Models (LMMs) will be used to describe
35 the evolution of continuous variables during the course of medical school, adjusting for socio-
36 demographic variables and potential covariates.[89] LMMs combine fixed-effects and random-effects
37 in the same model simultaneously. The fixed effects part combines the effect of fixed variables (in
38 this case age, gender, etc.) on the response. The random part, on the other hand, allows adjusting
39 the model for interdependence among observations (e.g., repeated measures from the same
40 individuals are likely to be correlated; measures from students of the same curriculum year are likely
41 to be correlated). To model the longitudinal evolution of dichotomous variables, Generalized Linear
42 Mixed Models (GLMMs) which are generalized counterparts of LMMs will be used. In the GLMMs
43 predictors are related to the outcome using a link function (usually the *logit link* function, as in the
44 logistic regression) with a random part allowing the analysis of inter-correlated observations. There
45 are several approaches available to fit GLMMs; penalized quasi-likelihood will be used to
46 approximate and maximize the likelihood for GLMMs, which provides certain optimality
47 characteristics for estimated parameters.[90]
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52 Apart from adjusting the models for potential covariates, current and lagged observations of mental
53 health variables (from previous time points) can also be included to study the effect of current and
54 previous mental health status on the studied components of interpersonal competence and vice-
55 versa. The same will be done to assess the potential influence of interpersonal dimensions and
56 mental health on clinical skills. Ordinary dimension-reduction techniques such as model selection
57 (based on Akaike Information Criterion, etc.) will be used to ensure that models present an
58 acceptable goodness of fit and avoid over-adjustment in the models.
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3 Every student who gave consent for participation will be considered for analysis. Students who
4 respond at least on two waves of questionnaires will be included in the longitudinal analyses. The
5 advantage of using LMMs and GLMMs is that cases with missing data will still contribute to the
6 models with all their other observed data (e.g. a participant having missed one wave of annual
7 assessment will contribute all the other measured waves). Multivariate Imputation by Chained
8 Equations will also be used to remedy the presence of potential missing values, in order to reduce
9 the potential bias.[91]
10
11

12 **2.5 Sample size calculation**

13
14 Apart from the curriculum year 1, which brings together more than 750 medical students, there is an
15 average of 240 medical students per curriculum year in the University of Lausanne Medical School,
16 which means more than 1500 eligible participants each year. Past studies with medical students
17 report yearly response rates varying from 32% to 91% [4,28,48,49,51,52,92–96] and response rates
18 across several years from 20% to 74%.[47,48,51,52,92] Given the participation compensation, we
19 expect to achieve a response rate of 35%. We used the Monte Carlo method to estimate the
20 potential statistical power of the LMMs to detect a small change in individuals' response from one
21 year to the other (as small as 1% change per year, which is a very conservative projection). Even in a
22 pessimistic situation where participation rate is just 25% and large error variance in responses, we
23 can still expect a 77% power in detecting the effect size as small as 1% change per year. We have
24 even higher power in detecting the effect of a potential covariate (over 93%) on the response.
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28 **2.6 Patient and public involvement**

29
30 This project and its research questions are very much driven by a growing interest and worry
31 regarding young adults' mental health. The online questionnaire was pretested by medical students
32 to evaluate the burden of the participation and medical students' delegates were involved in the
33 advertisement of the project. Moreover, an online newsfeed will be available to inform on the
34 project's progress.
35

36
37 The representative of the medical school of the University of Lausanne and the contact person for
38 issues related to mental health among students at Lausanne medical school are both co-investigators
39 of the present project. Exchanges regarding medical students' needs and medical education
40 strategies are thus ongoing since the beginning of the project drafting and will continue even after
41 the completion of the project. Indeed, this collaboration will enable to translate the clinical
42 implications of the project into educational strategies to implement in our university.
43
44

45 **3 RELEVANCE AND IMPACT**

46
47 The data collected through the ETMED-L project will be key to a better understanding of the
48 longitudinal development of interpersonal competence and mental health as well as their reciprocal
49 influence over the course of medical studies. By adopting a more comprehensive framework of
50 empathy including different dimensions (cognitive and affective empathy, ability to recognize
51 emotions, and a behavioural counterpart of empathy) and using different measurement methods
52 (self-report and performance-based tests) this project will contribute to fill an important gap in the
53 literature. It will allow a better understanding of the differential evolution of specific dimensions of
54 empathy and will help to improve the curriculum of medical studies, particularly in relation to
55 potential critical periods.
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58 There are preliminary data indicating that medical students are at risk of mental health problems and
59 that it may impact their ability to interact with patients, which ultimately may impair their ability to
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3 practice medicine. On top of mental health problems, tendency to distancing and loss of empathy
4 have consistently been reported in residents and physicians, highlighting the importance of
5 addressing these issues already during medical studies. This project will contribute to current efforts
6 to understand and promote mental health of students in medical schools. Moreover, dimensions that
7 are usually approached separately – interpersonal competence and mental health – will be analysed
8 concurrently, which makes this project unique. Having a better understanding of the longitudinal
9 course of mental health in relation to interpersonal competence will help to develop prevention
10 strategies and to provide better support and supervision.
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For peer review only

Ethics and dissemination

The project was approved by the Human Research Ethics Committee of the Canton de Vaud (protocol number 2020-02474). The participation poses little to no risk to the participants. However, as the questionnaire includes mental health questions, we will clearly indicate that students experiencing distress can refer to the psychiatric emergency ward of Lausanne University Hospital or contact the psychotherapeutic consultation for students of the University of Lausanne, which offers prompt on-site consultations.

Findings will be disseminated through internal, regional, national, and international conferences, news, and peer-reviewed journals.

Author contributions

Alexandre Berney, Céline Bourquin, and Marianne Schmid Mast designed the project with input from all other authors. Valerie Carrard, Alexandre Berney, and Céline Bourquin drafted the present manuscript. Sylvie Berney, Katja Schlegel, Jacques Gaume, Mehdi Gholam, Pierre-Alexandre Bart, Martin Preisig, and Katarzyna Wac contributed to the establishment and refinement of project procedures and critically revised the manuscript. All authors approved the final version of the manuscript.

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Competing interest statement

None declared.

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Table 1. Measures

	Variables	Instruments	N° of items	Sample item (scale)
Interpersonal Competence	Cognitive empathy	Jefferson Scale of Physician Empathy-Student version	20	"Patients feel better when their physicians understand their feelings." (1 = strongly disagree; 7 = strongly agree)
	Cognitive and affective empathy	Questionnaire of Cognitive and Affective Empathy	31	"I am good at predicting how someone will feel." (1 = strongly disagree; 2 = slightly disagree; 3 = slightly agree; 4 = strongly agree)
	Emotion recognition accuracy (ERA)	Geneva Emotion Recognition Test short version	42	"Among these 14 emotions ^a , indicate which one had been expressed by the actor in the video clip." (0 = emotion not accurately recognized; 1 = emotion correctly recognized)
	Behavioural adaptability	The Ability to Modify Self-Presentation Scale	7	"When I feel that the image I am portraying isn't working, I can readily change it to something that does." (0 = strongly disagree; 1 = disagree; 2 = slightly disagree; 3 = slightly agree; 4 = agree; 5 = strongly agree)
Mental Health	Depressive symptoms	Center for Epidemiological Studies-Depression	20	"I felt sad." (0 = rarely or none of the time (less than 1 day); 1 = some or little of the time (1-2 days); 2 = occasionally or a moderate amount of time (3-4 days); 3 = a lot of the time (5-7 days))
	Suicidal ideation	2 questions of the Beck Depression Inventory	2	"How did you feel during the past 2 weeks?" (0 = I don't have any thoughts of killing myself; 1 = I have thoughts of killing myself, but I would not carry them out; 2 = I would like to kill myself; 3 = I would kill myself if I had the chance)
	Anxiety	Trait subscale of the State-Trait Anxiety Inventory	20	"I feel nervous and restless." (1 = no; 2 = rather no; 3 = rather yes; 4 = yes)
	Anxiety during COVID-19	Adaptation of the Trait subscale of the State-Trait Anxiety Inventory	20	"I feel nervous and restless." (1 = no; 2 = rather no; 3 = rather yes; 4 = yes)
	Stress	General stress item	1	"Globally, how would you evaluate your current stress level on a scale from 1 "none" to 10 "extreme"?"
	Stress sources	Sources of stress items	6	"Indicate to which extent each of the following ^b was a source of stress in your life during the last 12 months on a scale from 1 "none" to 10 "extreme"?"
	Burnout	Maslach Burnout Inventory Student-Survey	15	"I feel emotionally drained by my studies." (1 = never; 2 = rarely; 3 = sometimes, 4 = often, 5 = very often, 6 = always)
	Coping strategies	Coping section of the Euronet questionnaire	17	"I try to calm down." (0 = not at all common for me; 1 = not very common for me; 2 = quite common for me; 3 = very common for me)
	Psychoactive substance use	Alcohol, Smoking and Substance Involvement Screening Test	10 to 64 ^c	"In your life, which of the following substances have you ever used? (non-medical use only)" (0 = no; 3 = yes)
Clinical Skills	Neuroenhancement drugs use	C-SURF cohort's questionnaire	20	"How often did you use Neuroenhancement drugs over the past 12 months?" (0 = never; 1 = once; 2 = 2 to 3 times a year; 3 = 4 to 9 times a year; 4 = 1 to 2 times a month; 5 = 3 to 4 times a month; 6 = 2 to 3 times a week; 7 = 4 times a week or more)
	OSCE scores	Checklist of the OSCE	5	"Responded to patient feelings and needs" (1 = not at all, 5 = totally)
	Simulated patient coding	Checklist of the OSCE and Jefferson Scale of Patient Perceptions of Physician Empathy	10	"Responded to patient feelings and needs." (1 = not at all, 5 = totally) "Understands my emotions, feelings, and concerns." (1 = Strongly Disagree, 5 = Strongly Agree)

^aPride, joy, amusement, pleasure, relief, interest, surprise, anxiety, fear, despair, sadness, disgust, irritation, anger.

^bFamily, financial situation, paid activity, sentimental life, studies, and work/life balance.

^cAcross nine substances: tobacco, alcohol, cannabis, cocaine, amphetamine, inhalants, sedatives, hallucinogens, and opioids; with follow up questions for the substances reported to be used.

OSCE = Objective Structured Clinical Examination.