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SYSTEMS-LEVEL QUALITY IMPROVEMENT

Towards a Clinical Trial Protocol to Evaluate Health Information Systems: Evaluation of a Computerized System for Monitoring Tuberculosis from a Patient Perspective in Brazil

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Abstract

Assessment of health information systems consider different aspects of the system itself. They focus or on the professional who will use the software or on its usability or on the software engineering metrics or on financial and managerial issues. The existent approaches are very resources consuming, disconnected, and not standardized. As the software becomes more critical in the health organizations and in patients, becoming used as a medical device or a medicine, there is an urgency to identify tools and methods that can be applied in the development process. The present work is one of the steps of a broader study to identify standardized protocols to evaluate the health information systems as medicines and medical devices are evaluated by clinical trials. The goal of the present work was to evaluate the effect of the introduction of an information system for monitoring tuberculosis treatment (SISTB) in a Brazilian municipality from the patients' perspective. The Patient Satisfaction Questionnaire and the Hospital Consumer Assessment of Healthcare Providers and Systems were answered by the patients before and after the SISTB introduction, for comparison. Patients from an outpatient clinic, formed the control group, that is, at this site was not implanted the SISTB. Descriptive statistics and mixed effects model were used for data analysis. Eighty-eight interviews were conducted in the study. The questionnaire's results presented better averages after the system introduction but were not considered statistically significant. Therefore, it was not possible to associate system implantation with improved patient satisfaction. The HIS evaluation need be complete, the technical and managerial evaluation, the safety, the impact on the professionals and direct and/or indirect impact on patients are important. Developing the right tools and methods that can evaluate the software in its entirety, from the beginning of the development cycle with a normalized scale, are needed.

Keywords Health information system evaluation · Patient satisfaction · Tuberculosis · Patient relationship management

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Introduction

Tuberculosis (TB) is a curable disease, but in 2016 it was among the top 10 causes of death, with 1.3 million deaths and about 10.4 million new cases worldwide [1]. In 2016 Brazil notified 75 thousand new cases and in 2014, registered 72.8% cure rate, 10.5% abandonment and 7.8% death [2]. Brazil follows Directly Observed Treatment, Short-course (DOTS), recommended by the World Health Organization (WHO) [3]. The TB treatment is long. Adherence is one of the main determinants of the success of drug treatment, as it is essential to avoid treatment failure and drug resistance [4]. Technologies such as telemedicine and web portals for physicians and patients can facilitate treatment and improve medical practices [5–10]. The patient should always be aware of his diagnosis and be prepared for a long course of treatment. The patient's satisfaction with the health service and the care provided can positively influence the treatment [11, 12].

Patient Relationship Management (PRM) studies the relationship between health services, user satisfaction, continuous improvement of services provided and improved patient health [13, 14]. The PRM applies the principles of Customer Relationship Management (CRM) [15] to the health sector, aiming the managing relations of a health institution with its users. It is in pursuit of this objective that the PRM proves capable of increasing patient satisfaction, while at the same time it makes possible organizational efficiency and effectiveness gains, as well as the identification of new intervention opportunities.

SISTB is a system to monitor the DOTS, allows the registration and follow-up of TB patients, in which it is possible to register patient identification information, treatment follow-up, diagnostic exams and control exams, communicators, daily supervision of medication and hospitalization. The data should be registered by professionals belonging to the health services that perform the TB treatment. SISTB was developed in two versions, desktop and mobile. The mobile version was developed for health professionals to register and access information about treatment during a home visit to the patient without the need to connect to internet. The system generates reports and charts that can replace paper forms that must be completed routinely.

The goal of the present study was to verify if there is a relationship between the level of TB patients' satisfaction and the use of software by health professionals, namely, evaluating the impact of a software, SISTB, from the TB patients' perspective. The patients are TB patients of the city of Ribeirão Preto, state of São Paulo, Brazil.

Background

Evaluation of existing Health Information Systems (HIS) use software engineering concepts to measure quality. They are concerned with the characteristics of the software's itself, managerial benefits and the relationship with the user is measured mainly by attributes such execution time and usability, [16–18] which evaluates only the user's interaction with the system. By measuring quality attributes such as usability, accuracy and performance, it is assumed that this is sufficient to ensure the quality of the software. Despite the evidence that HIS may benefit patients [19], the quality of HIS and its impacts are rarely measured from the patient's point of view [20, 21]. There are studies on patients' perspectives regarding the use of information systems by health professionals, the results showed that, in general, patients had a positive perception regarding the systems, and trust in the doctor-patient relationship was maintained [22–24]. The HIS evaluation needs to be nuanced and multidimensional to ensure good results [25, 26]. In order to bring a more comprehensive approach to the HIS evaluate model, particularly HIS for DOT, a protocol has been proposed [27], where the patients perspective is one of the key factors in the evaluation of health software, along with the professional perspective and software engineering techniques.

Furthermore, the steps proposed in the protocol along with PRM principles were followed to evaluate the SISTB implantation, from the patients' perspective. Specifically, we used questionnaires about satisfaction with the service offered and medication adherence.

Next section details the method used. The following section, the third, present the achieved results. The fourth section analyzes and offers a discussion of the results. The paper ends with a summary of findings and future research.

Method

The SISTB evaluation follows the protocol proposed by Rijo et al. [27]. The protocol is a interventional, observational, descriptive, longitudinal, and case-control study. The protocol consists of five steps. It starts with the definition of the sample (Step 1) and the adjustment of the instruments (Step 2), followed by their validity (Step 3). The next step is the application of the instruments (Step 4). The analysis of the results and expected outcomes is the fifth step (Step 5) [27].

Step 1- **Definition of the sample**

The protocol first step is to define the sample and the control group.

For the sample, were considered all TB patients who were being treated at the time of the study, in the four TB reference outpatient clinics, in the Ribeirão Preto city. The inclusion criteria for the patients were: a) to be an adult, over the age of 18; b) have TB. The exclusion criteria were: a) cognitive impairment; b) hearing impairment; c) to belong the prison system. The criteria were defined based on the patient's ability

to understand the questions. Patients in deprivation of liberty were excluded because they do not do the DOT in reference outpatient clinics. Participants were interviewed when attending medical appointments related to TB treatment at the time of data collection, i.e. they were interviewed the largest possible number of patients who were able to respond to the questionnaires. As a control group patients were chosen from one of the TB reference outpatient clinics in the city, that is, the SISTB was not implanted at the site. To maintain the anonymity of outpatient clinics, they will be designated as ROC1, ROC2, ROC3 (control group) and ROC4 throughout the article. In one of the outpatient clinics (ROC4), the SISTB was already in use, in this case, the protocol was applied partially, i.e., only the post-implantation analysis.

Step 2- **Adjustment of the instruments**

To evaluate the SISTB introduction through patient satisfaction, i.e., using PRM, two questionnaires were used: Patient Satisfaction Questionnaire Short-Form (PSQ18) and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). The adoption of the instruments followed the criteria: (a) instruments must be based on studies demonstrating their fundamentals of validity; (2) instruments used in several other studies published in renown publications; (3) the instruments must assess patient satisfaction, and the impact on healthcare professionals and on the TB services.

The PSQ-18 [28] has been validated for use in different contexts and can also be applied to compare interventions [29]. The questions cover general satisfaction, technical quality, interpersonal manner, communication, financial aspects, time spent with doctor and accessibility and convenience. The HCAHPS [30] measures the patients' perspectives of the health care services. Translation and back translation (retro-translation) procedure was performed to adjust the PSQ-18. It was translated from English to Portuguese of Brazil (Pt-Br) and retro-translation was also done to reduce the bias involved in translation. The HCAHPS already had a Portuguese version. In addition, HCAHPS has several domains about hospital admission and discharge. As most TB patients do not need hospitalization, and consequently, are not discharged, these domains have been removed from the analysis.

Step 3- **Validity of the instruments**

Three series of pre-tests were performed. The patients were selected based on the similarity of the demographic characteristics of the sample, but without being TB patient. The decision to test the instruments in patients without TB was due to two reasons: a) instruments to assess user satisfaction are not specific to TB patients; b) be able to approach as much as possible the population of the study for the work after the adjustment of the instruments. In the third step, the validation of the adjustments made in the instrument was performed, the analysis are presented in the results section. Reliability can be assessed by Cronbach's alpha internal consistency reliability coefficients. Values greater than 0.6 are considered generally satisfactory, and those greater than 0.8 indicate high internal consistency [31].

Step 4- **Application of the instruments**

The questionnaires application was performed as described in the fourth step of the protocol. At the time SISTB was entered into the service, patients were in different stages of TB treatment, beginning, middle and end. Due to the impossibility of stipulating a fixed scenario for each patient, a variable that can be controlled, that is, the SISTB time of use has been established. Thus, the first moment (M1) of evaluation for all patients regardless of the treatment phase occurred in the first month. After the first moment, the professionals were trained to use the SISTB. Three months after continuous use of the SISTB, it was considered that the professional was adapted to the tool. Month four was the second moment (M2), when the questionnaires were reapplied. One of the outpatient clinics was used as a control group, as proposed in step one. In this place, the 1st evaluation moment and the 2nd evaluation moment were applied, but without introducing the SISTB, in order to detect the existence of an external variable in which it could affect the experiment.

For the data collection, the team attended one clinic at a time, conducting interviews for two months at each clinic. After, it was offered training to use SISTB. Three months after the system was implanted, the team returned to the clinic for the second evaluation, which lasted an average of two months in each clinic. In this way, the data collection took place from July 2015 to May 2017.

Step 5- **Analysis of the results and expected outcomes**

The questionnaires analyses were performed according to specifications proposed by their authors. For the quotation of PSQ18 the average of the items belonging to each dimension is carried out. Each response is transformed into a value ranging from 1 to 5. The higher the value more satisfactory the result. It is possible to perform the calculations for each person or to perform an overall mean for a group of persons. In addition, a mixed effects model was used to analyze the data at different times.

The analysis of HCAHPS responses for each patient was performed using the 'top-box' approach specified by the quotation procedures. The top-box is composed of the most positive answers possible for all HCAHPS questions, so only these answers score. Then the average is calculated for each of the questions and then the average for each section.

Results

The data generated from of the application of the protocol was gathered and analyzed. This section sums up the results of the pre-test phase and the subsequent application of the questionnaires, are presented. A demographic characterization of the interviewees is also presented.

Pre tests

Pre-tests were video recorded – with the consent agreement of the patients – and subsequently analyzed to identify how the questionnaire could be modified for better understanding by patients. The version with the highest alpha value of Cronbach was chosen to be applied in the study.

For PSQ18 adjustment, three pre-tests were also performed, with participation of 8, 15 and 5 patients respectively in each pre-test. The results of the analysis were 0.08 for the first pretest, 0.63 for the second and − 0.68 for the third. The version with value 0.63 was chosen, indicating moderate internal consistency. The negative value could indicate one of the reasons: reverse coding of the questions and multiple factors. The reasons for these results were not explored and the second version, indicating moderate internal consistency, was adopted.

Regarding the HCAHPS, there was already a Portuguese version available on the HCAHPS website, so it was not necessary to perform translation and back translation. Small modifications were made for the Portuguese of Brazil, in view of this, some interviews were carried out to verify the questionnaire understanding by the patients. However, no confidence analysis was calculated.

Interviewees' characterization

Thirty-six patients were interviewed at the moment M1 of the study and 52 patients at the moment M2. The interviewees' demographic characterization can be observed in Table 1.

Some participants answered the questionnaires in the two moments of the study.

Regarding sex, there was a predominance of males in the outpatient clinics, in both moments of the interview, except for ROC2 M2, where the proportion was the same for both sexes. The mean age was between 37 and 44 years old. The brown/mulatto race/color was the most prominent, with the exception of the central outpatient clinic, in which M1 had 44% brown /mulatto and white/caucasian respondents, and in the M2 white/caucasian majority. With respect to schooling, the majority of the patients attended incomplete elementary school. As regards marital status, the single prevailed. When asked what patients thought of their mental / emotional health, most chose the good option, but in the ROC1, also stood out the fair option.

Results per questionnaire

PSQ 18

As observed in Table 2, in the mixed effects model, ROC1 was the only outpatient clinic with statistically relevant differences between the two moments, in terms of technical quality, communication, time spent with the doctor and accessibility, which improved after SISTB implantation.

In the comparison of the group with intervention and control, in the first and second moments, the average of the dimensions *General Satisfaction*, *Technical Quality*, *Communication*, *Time Spent with doctor*, increased in both groups. *Financial aspects* decreased in both groups. The mean for *Interpersonal Manner* and *Accessibility and Convenience* increased in the intervention group and decreased in control.

HCAHPS

In the ROC1, the dimensions *Communication with Nurses*, *Communication with doctors*,

Treatment Unit Environment – Cleanliness and *General Classification* of the *Treatment Unit* presented better means after the intervention. There was a small decrease in the average *Treatment Unit Environment – Silence* and *Recommendation of the Treatment Unit* after the intervention.

At ROC2, there was an improvement of means in most dimensions, except *Recommendation* of the *Treatment Unit*.

In the control, ROC3, there was an improvement of the averages in all dimensions, and *Treatment Unit Environment – Cleanliness*, remained with the same average of 1 (maximum average).

Results per ambulatory

ROC1

The results of the two questionnaires are aligned. In the mixed effects model, ROC1 was the only clinic with statistically relevant differences between the two moments, in the dimensions: *Technical Quality*, *Communication*, *Time Spent with the doctor* and *Accessibility*, of the PSQ 18 questionnaire. The increase of these averages are in line with the HCAPS, mainly in the dimensions of *Communication with Nurses* and *Communication with Doctors*. In relation to the environment of the health unit, the unit became cleaner but the silence decreased. Despite the high recommendation of the unit, it decreased somewhat in the M2.

ROC2

Regarding the PSQ18 questionnaire, the overall satisfaction dimensions with the care received and communication with

Table 1 Demographic characterization of the interviewees

		ROC1 M1	ROC1 M2	ROC2 M1	ROC2 M2	ROC3 M1	ROC3 M2	ROC4 M2
Sex	**male**	**70%**	**81%**	**56%**	**50%**	**71%**	**75%**	**63%**
	female	30%	19%	44%	**50%**	29%	25%	38%
Mean age		44	40	42	37	37	37	42
Race/color	**white/ caucasian**	25%	25%	**44%**	**42%**	25%	12.5%	19%
	black/ afro descending	10%	31%	11%	17%	11%	0%	13%
	brown/ mulatto	**60%**	**44%**	**44%**	33%	**61%**	**87.5%**	**69%**
	indigenous	5%	0%	0%	8%	3%	0%	0%
Education	uneducated	5%	0%	11%	0%	0%	25%	6%
	incomplete elementary school	**60%**	**56%**	**44%**	33%	**86%**	**37.5%**	**69%**
	complete elementary school	15%	13%	0%	17%	0%	25%	6%
	incomplete high school	5%	19%	0%	0%	0%	0%	0%
	full high school	10%	0%	33%	**42%**	14%	12.5%	19%
	incomplete undergraduate	0%	6%	11%	0%	0%	0%	0%
	complete undergraduate	5%	6%	0%	8%	0%	0%	0%
Marital status	**single**	**40%**	**63%**	**56%**	**67%**	**50%**	**62.5%**	**40%**
	married	25%	25%	11%	25%	0%	12.5%	27%
	divorced	10%	0%	11%	0%	17%	0%	13%
	widower	10%	6%	0%	0%	0%	0%	7%
	stable union	15%	6%	22%	8%	33%	25%	13%
Mental health	excellent	15%	12.5%	11%	8%	14%	0%	0%
	very good	5%	6%	22%	8%	14%	25%	0%
	good	25%	**37.5%**	**56%**	**67%**	**57%**	**50%**	**68.8%**
	fair	**40%**	**37.5%**	11%	17%	0%	25%	18.8%
	poor	15%	6%	0%	0%	14%	0%	12.5%

The entries in bold are highlighting the options that achieved the highest percentage of response among respondents

the doctor also obtained a lower value in M2. However, these values did not fully align with the HCAPS questionnaire, which in terms of communication with nurses and doctors had a higher value in M2, as well as almost all other topics covered in the questionnaire, except for the recommendation of the unit that obtained a lower value in the M2.

ROC3

In relation to PSQ18 the dimensions Interpersonal conduct and accessibility to treatment decreased. The other dimensions increased, as did all of the HCAPS dimensions, aligning the results of these two questionnaires.

ROC4

As only M2 of the patients interview was performed in this clinic, it was not possible to make comparative analyzes between the two moments. Comparing the results of M2 between outpatient clinics, the results were similar for PSQ18, so the overall satisfaction, technical quality, interpersonal manner and communication reached averages greater than 4.

Aggregated results: Intervention vs control group

With the aggregated data from all outpatients that underwent intervention, most of the HCAHPS dimensions increased in both groups, intervention and control, except Environment in the treatment - cleaning unit, which in the control group remained with the same average of 1 (maximum average). In this questionnaire, the results obtained in the intervention group are in line with the results of the control group.

The dimensions Communication with Nurses and Communication with Physicians of the HCAHPS are aligned with the Communication dimension of the PSQ18, in both groups the average increased.

Discussion of results

The differences between outpatient clinics receiving the SISTB can be explained by the way each clinic organizes the service and by the differences of the patients in each location. The ROC1 had only one health professional to perform the DOTS daily while the other outpatient clinics had at least

Table 2 Mixed effects model in the analysis of the PSQ18 questionnaire

	Dimensions	estimated difference	*p* value	confidence interval 95%	
				lower	upper
ROC1	General Satisfaction	−0.4441	0.0739	−1.4866	0.05124
	Technical Quality	−0.7337	0.026	**−1.324**	**−0.1435**
	Interpersonal Manner	−0.6795	0.031	−1.2349	0.1909
	Communication	−0.6025	0.0412	**−1.1659**	**−0.03919**
	Financial Aspects	0.09903	0.6722	−0.5043	0.7024
	Time Spent with Doctor	−1.2125	0.018	**−2.0823**	**−0.3427**
	Accessibility and Convenience	−1.0822	0.0087	**−1.7096**	**−0.4547**
ROC2	General Satisfaction	0.1389	0.6769	−0.7205	0.9983
	Technical Quality	−0.2056	0.5028	−0.9815	0.5704
	Interpersonal Manner	−0.3333	0.3032	−1.1173	0.4506
	Communication	0.06944	0.819	−0.7195	0.8584
	Financial Aspects	0.8194	0.0781	−0.1465	1.7854
	Time Spent with Doctor	−0.4444	0.3412	−15,879	0.699
	Accessibility and Convenience	−0.6944	0.146	−1.0065	1.2468
ROC3	General Satisfaction	−0.2536	0.4843	−1.1681	0.6609
	Technical Quality	−0.1917	0.6054	−1.142	0.7587
	Interpersonal Manner	0.06026	0.868	−0.8843	1.0048
	Communication	−0.1087	0.7629	−1.043	0.8256
	Financial Aspects	0.35	0.4104	−0.7081	1.4082
	Time Spent with Doctor	−0.5208	0.3601	−1.9213	0.8796
	Accessibility and Convenience	0.1202	0.7819	−1.0065	1.2468

The entries in bold are highlighting the results that presented relevant statistical differences

two professionals, and could influence the patient's trust relationship with the professional. Despite the similarity of sociodemographic characteristics among the ambulatories, aspects that were not addressed in the questionnaire were observed during the interviews, such as the number of street dwellers and the number of drug users. Although some outpatient clinics show better results after the intervention, including the control unit itself, it is difficult to conclude that SISTB has improved adherence to the patients' medication. It is far more plausible to justify the results with the human factor or the way the service is organized. According to Palha et al. [11], aspects such as delay in diagnosis, dependence on third parties and means of transportation to access services, deficiency in social support and stigma of the disease, make adherence to treatment difficult.

In the mixed effects model, ROC1 was the only outpatient clinic with statistically relevant differences. Despite the significant result, the SISTB may not have influenced directly in this aspect, since the doctors did not incorporate in its routine the system continuous use. The fact is that not all the doctors have adopted the use of SISTB after training. We highlight two factors that may have influenced this reality: 1) DOTS performed by nursing technicians; 2) resistance to the system use. Although the SISTB offers several functions in the follow-up of TB treatment, it is aimed at the DOTS daily monitoring, which in the municipality of the study is performed by a nursing technician or health agent. Therefore, they were responsible for the DOTS daily registration, making them enjoy more of the system than the doctors. In addition, studies point out that there is resistance in the use of software applications [32, 33]. However, the results found complement the previous results, in which the SISTB usability was evaluated [34]. In the questionnaire answered by the professionals who participated in the training, the scores show good satisfaction with the SISTB usability [34], indicating that was easy to use it.

In relation to the sociodemographic characterization, the information found corroborate with other studies related to TB patient satisfaction [11, 35, 36], where there is predominance of sex among those interviewed, at an economically active age and with low schooling. Particularly Palha et al. [11], who carried out a Ribeirão Preto study, presented the same socio-demographic characteristics. These same studies also showed that the general satisfaction of the TB patient was positive in relation to the service provided.

When evaluating a HIS from a patient's perspective, it is evaluated whether the treatment offered has undergone any modification after the implementation of the system, whether in the way professionals act or in the service organization itself. In this way, the evaluation occurred indirectly, since the patient itself had no interaction with the SISTB. A study

conducted in the United States used secondary data from different sources to evaluate the HIS impact on the care quality offered to the patient [19]. This study showed that the Electronic Health Record (HER) adoption was partially associated with lower re-hospitalization rate but was not associated with patient satisfaction. Another study carried out in Japan evaluated patients' satisfaction at three hospitals, before and after the EHR implantation [20]. The study concluded that after the EHR implantation, the waiting time for the consultations decreased and there was an improvement in the medical explanations. However, it did not improve overall patient satisfaction. In the results presented in the previous section, there was a slight improvement in patient satisfaction, but not statistically significant, after SISTB implantation. There is rare information in the literature about HIS assessment from a patient's perspective. The studies found are mainly focused on the professional's point of view and on the technical and managerial characteristics that are offered [27]. In Brazil, the Brazilian Society of Health Informatics (SBIS), which certifies Electronic Health Registration Systems, only verifies the technical aspects of the software, and according to them, the requirements are founded mainly by the International Organization for Standardization (ISO) [37]. The studies of [19, 20] and the presented results reinforce the concept that patients need to be considered in the HIS development.

Conclusions

A software evaluation was performed from the patients' perspective, through an interview with the support of three questionnaires. Although the positive results, they are not statistically relevant, therefore, we cannot associate the SISTB with an increase of patient satisfaction. It is noteworthy that in both moments of evaluation, M1 and M2 the results were positive.

Another conclusion is that the evaluation of HIS are of the greater importance either by their direct impact on the organizations and professionals or by their indirect impact on patients. In other situations some mobile applications are used to support therapy, as a medical device or medication. This demands a 360 degrees evaluation including not only the technical and managerial evaluation but also the safety, the impact on the professionals and direct and/or indirect impact on patients.

It is also possible to conclude that the existents approaches and the protocol developed are very time consuming and infeasible from the practical point a view. They take too long and consume too many resources. In addition, these approaches analyze the software in the end of the development process, not during the development process. Finally, there are any standards/protocols with normalized scales for comparing the different applications and define levels acceptance.

The present work is part of the development of a more comprehensive model that proposes a new way of evaluating HIS. A model in which the perspective of patients, health professionals, software engineering, security and safety, and managerial issues are equally important to assess the HIS. Developing the right tools and methods that can evaluate the software in its entirety, from the beginning of the development cycle with a normalize scale, are the ultimate goal. Likewise medicines and medical devices, which are subject to clinical trials before its use by the community, software needs also a clinical trial protocol to guarantee its effectiveness, security, safety and operational goals. A type of clinical Trial should be established in the health software construction, with stages of evaluations performed by all who will use it, directly or indirectly.

As a future work, we hope to develop a single instrument that is simple to use and less extensive, but which can cover the most important issues.

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Compliance with ethical standards

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Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

In the work development, all the ethical requirements prescribed by Resolution 466/12 of the Brazil National Health Council and its complementary ones were fulfilled, being approved by the Research Ethics Committee of the Medical School of Ribeirão Preto of the University of São Paulo, Certificate of Presentation for Ethical Assessment 44813815.6.0000.5440 and 69187617.7.0000.5440.

This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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