TITLE: Non-technical skills training and checklists versus standard training with checklists in boarding school students to reduce simulation crisis medical error, randomized controlled clinical trial.

TECRISIS study

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I. Administrative information

1. Title: Training in non-technical skills and checklists versus standard training with checklists in boarding school students to reduce simulation crisis medical error, randomized controlled clinical trial.

2. Protocol Record
   2. a Protocol registration: will be done in Clinical Trial once completed
   2. b Data record according to recommendations of the World Health Organization in Table 1.

Table 1. WHO data record

Fact	**information**
Registration and identification number	Pending
Registration date	Pending
Secondary registration number	Pending
Sources of funding	University of Antioquia
Primary Sponsor	University of Antioquia
Secondary Sponsor	None
Contact for public inquiries	Zamudio Mario email: mario.zamudio@udea.edu.co
Contact for scientific inquiries	Zamudio Mario email: mario.zamudio@udea.edu.co
Public Title	TECRISIS study
Scientific Title	Non-technical skills training and checklists versus standard training with checklists in boarding school students to reduce simulation crisis medical error, randomized controlled clinical trial.
Recruitment Country	Colombia
Problem Studied	Medical error: omission of management steps in medical crises
Interventions	Intervention: training in non-technical skills and checklists
	Control: standard training with checklists
Inclusion and exclusion criteria	Inclusion: over 18 years. Final semester student of medicine at the University of Antioquia. Have passed the theoretical knowledge exam for handling crisis events with a score of 100%. On-site availability on training days
	Exclusion: having received training in a specific crisis resource management course. Refusing to participate
Type of study	Intervention

	Superiority
Recruitment Start Date	Pending
Target sample size	56 participants
Study status	Elaboration of protocol
Primary outcome	Proportion of omissions of treatment steps per group.
Secondary outcomes	Crisis resolution time
	Time in detection and discrimination of the crisis
	Overall score of non-technical skills
	Discriminated score between dimensions of non-technical skills
	Student satisfaction
	Incidence of inadequate crisis management

3. Table 2. Protocol Version:

Version	**Date**	**Modifications**	
one	November 03, 2020		Mario Andrés Zamudio

4. Financing: simulation center of the Faculty of Medicine, University of Antioquia and Authors.

5. Table 3. Research roles

Name	**Assignment**	**Contributions**
Mario Andrés Zamudio Burbano	Principal investigator	Preparation of protocol, collection of patients, statistical analysis, dissemination of results.
Fabian David Casas Arroyabe	Director of research	Protocol review.
Juan Pablo Zapata	Co-investigator	Protocol review, patient collection.

II. Introduction

6a. Background

Medical Error

Medical error defined as an "unintentional act of omission or commission that does not result in the intended result, lack of planning, use of improper plan, or deviation from the plan of care that may or may not harm a patient"(one)it is a big public health problem. For 2013, it was estimated that medical error was the third leading cause of death in the United States.(2); and in Latin America the preventable adverse event and the injury secondary to medical error(3), has a prevalence of 10.5% (95% CI 9.91 to 11.04) of health care (4). A 2008 prospective multicenter cohort in Colombia described a cumulative incidence of 4.6% (95% CI 4.1 to 5.1) for preventable adverse events, with underreporting estimated by the authors of 20 to 40% (5), with similar incidents described in intensive care units(6)(7).

Medical error has been described in several contexts: skipping treatment steps in critical situations(8)medication error(9), diagnostic error(10), among others. Depending on the context, the encoding of such errors can include more than 400 types(eleven). Dovey et al. Propose a taxonomy of medical error in the following way: administrative failures; research failures, understood as the clinical and paraclinical search for a medical pathology; treatment failures; communication errors; failure in treatment decision; and diagnostic error(12).

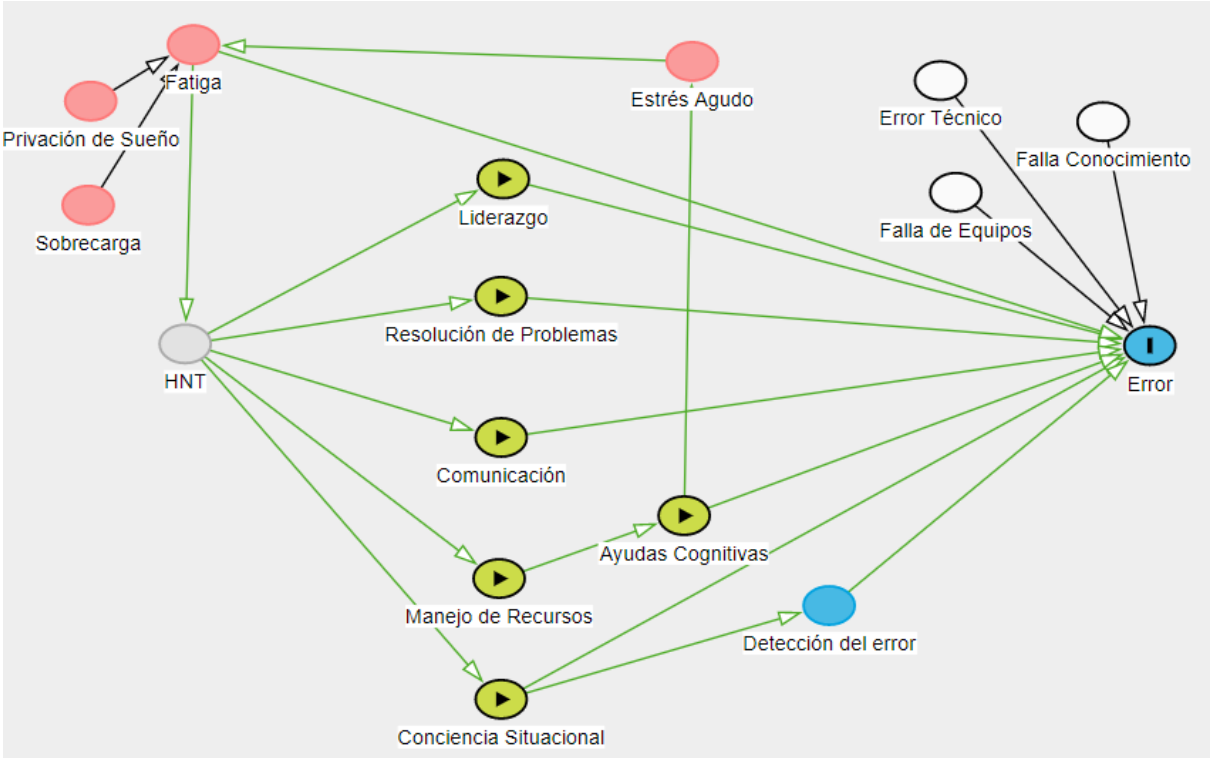
However, from a cognitive point of view, medical error can be classified into two categories: slip, as that incorrect execution of a correct sequence of action; and error, such as the correct execution of an incorrect action sequence, each category in turn can be directed to treatment or diagnosis(13).

The omission of treatment steps in medical crises, that is, medical error in cardiac arrest or those code situations, is of special relevance given the severity of the context and the risk of mortality or serious adverse events, and due to the high incidence reported for this context, which is between 26 and 50%(8); with similar incidents for trained and training personnel(14).

Among the types of medical errors, those due to omission of treatment steps in code crises, that is, life-threatening situations such as acute pulmonary thromboembolism, acute heart failure, unstable arrhythmias, among others; they are the ones that can have the greatest impact on serious complications and mortality. In a retrospective review of over a million medical errors, those related to code situations, represented a large increase in the probability of patient harm and death with an OR of 39 (95% CI 28.6 to 51.4) for adverse event and OR of 51 (95% CI 16.4 to 124.6) for death compared to medical errors not related to acute situations(fifteen).

Although it is a controversial topic, among the potential causes of medical error are: lack of knowledge, cognitive biases, failure in technical ability, failure in non-technical ability such as (communication failure, fatigue, stress management, sleep disorders , failures in situational awareness), severity of the patient's disease, factors external to the doctor-patient relationship, among others(10). Figure 1 shows a potential causal diagram of this phenomenon made with the dagitty tool.(16).

Figure 1. Potential causal diagram.



HNT: non-technical skills

Source: Authors

Despite the causal complexity of medical error, a large part of these possible causal factors have been grouped into what are known as non-technical skills, highlighting their importance in the development of this clinical event. In a Japanese study analyzing cases of medical errors leading to mortality, 55% were explained by failures in non-technical skills, 45% by disease severity and only 5% by failure of technical ability.(17). In the National Audit Poject NAP 4 study, a UK national audit that in 2011 analyzed 286 incident cases of difficult airway complications in anesthesia, critical care and emergency unit at 307 hospitals, described 40% of serious complications are explained by failures in non-technical skills(18). In a database study of reports of adverse events in orthopedics, an association with medical

error of mortality and non-technical skills was found in 65% of cases.(19). Several studies have associated performance in technical and non-technical skills.(twenty)(twenty-one).

Non-technical skills

Non-technical skills can be defined as the set of psychosocial skills that complement technical skills, an concept extrapolated from aviation. Flin and collaborators in 2004 described 4 categories: leadership, leadership skills, cooperation, situational awareness, and decision making; based on studies in the field of aviation(22). The following categories have recently been described in the field of medicine:

Leadership and resource management: it is understood as the ability to remain calm to lead a medical team and distribute assignments according to the skills and needs of each team member, within the resources both human talent and technological, technical and cognitive aids such as checklists(2. 3).

Assertive communication: manifests itself as the effective transmission of information and shared interpretation of the situation. Non-assertive communication is associated with both medical and nursing errors, for example, in the safe administration of medications.(24).

*Situational awareness:*It is a cognitive ability that manifests itself by identifying the relevant information in a setting in order to evaluate strategies and imagine possible results of these, taking the best possible result. Association has been found between situational awareness and procedural error in surgery(25).

Clinical decision making and problem solving: The ability to evaluate possible decisions, compare the results, choose and execute the action that best suits the context is considered. Clinical decision-making has been of special interest since there are two described types of reasoning: type 1 uses a fast or heuristic path and type 2 uses a hypothetical deductive path that requires more cognitive resources; when a heuristic leads to an inappropriate decision it has been called cognitive bias(10).

Since teamwork can be simulated(26)There is an interest in training non-technical skills in order to improve patient safety. The most important studies on interventions in non-technical skills, resource management in crisis and standard training, regarding medical error or performance in crisis are summarized in Table 4.

Table 4. Previous studies on non-technical skills or medical error.

Reference	Intervention	Control	Outcome	Observation	Type of study
Müller MP and Cols.(27)	1 Day Resource Management in MRC Crisis	1 day of simulation in crisis	Stress and performance	Performance measured with checklists and HNT with ANTS scale improved in both groups without differences between arms.	Clinical trial

Khoo EM and Cols.(28)	Educational package of methods and processes.	Conventional management before intervention	Diagnostic and treatment errors	Decrease of medical error 54.0% (CI 49.9-58.0) to 36.6% (CI 30.2-43.1)	Clinical trial
Starmer and Cols. (29)	Handoff training program focused on organizational culture and communication	Conventional management before intervention	Medical error and adverse event in a pediatric hospital	Reduction of incidence of medical error 24.5 vs 18.8 per 100 admissions P <0.001	Study Before and after
Wetmore et al.(30)	Use of anesthesia reinduction checklist	Simulation training without a checklist	Performance measured as skipping preparation steps	Improvement of 7.8 points out of 22 possible.	Simulated controlled clinical trial
Duclos and Cols. (31)	Crisis resource management course plus checklists	Checklists	Serious adverse events 30 days after surgery	8·8 to 5·5% (OR 0·57, 95% CI 0·48 to 0·68 versus 7·9 to 5·4% in control (OR 0·64, 0·50 to 0·81 ROR 0.67 to 1.21.	Controlled clinical trial
Doumouras and Cols.(32)	Non-technical skills training	Out of control	Crisis resolution time	Each point on the ANTS scale decreased the crisis resolution time by 53 seconds	Prospective cohort
Arriaga and Cols. (33)	Training with checklists	Conventional training	Errors in omitting treatment steps in crisis	Absolute risk reduction: 17% Relative risk of 0.28. IC0.18 to 0.42; P <0.001	Simulated controlled clinical trial

HNT: Non-technical skills, MRC: resource management in crisis. ANTS: Non-technical Skills Scale for Anesthesiologists.

The problems with the studies carried out up to the moment of carrying out this protocol, in relation to medical error and non-technical skills, are varied. In the pilot study by Müller et al.(27), in which no sample size was calculated, a training day in resource management in CRM crisis was compared, a course that includes some dimensions of non-technical skills: leadership, assertive communication, situational awareness versus conventional medical management training in two scenarios in simulation; hemorrhagic shock and simulation non-intubation non-oxygenation situation; In both groups, performance measured with a checklist of treatment actions and non-technical skills measured with the Non-Technical Skills Scale for ANTS anesthesiologists was improved; without differences between both arms. However, no inference can be made from the population since this study has not been completed so far.

In the Khoo and Collaborators essay(28)An educational intervention was conducted to fill gaps in medical knowledge and aid in decision-making with decision algorithms in outpatient institutions, that is, only one dimension of the HNT, in primary care institutions. The results are not applicable to medical crises since it was carried out in a different context and also the way of measuring the outcome, review of medical records, is aimed at detecting an adverse event, that is, the potential damage derived from the care of health and not medical error.

In the study by Khan et al.(3. 4), only two specific dimensions of non-technical skills are included: assertive communication and teamwork; it was not possible to determine an overall reduction in medical error but a reduction in the risk of medical error with potential harm, a relative risk of 0.69 (95% CI 0.53 to 0.91) and an absolute risk reduction of 2% (95 CI). % 1 to 4).

The most important study on the reduction of medical error in crisis is that of Arriaga and Collaborators.(33) in which the use of checklists reduced the omission of simulation treatment steps with an absolute risk reduction of 17 and relative risk of 0.28 (95% CI). 0.18 to 0.42). These checklists impact one dimension of the HNT: resource management.

Later, in the study by Duclos et al.(31), no differences were found between MRC plus checklists versus checklists. This can be explained since the intervention, training in non-technical skills, was carried out with two half-day days of discussion of CRM in crisis in the hospitals of this group, without using high-fidelity simulation, which is the standardized method for training.

Therefore, there is uncertainty if training in non-technical skills can have an additional effect to checklists to decrease the incidence of medical error.

Justification

Although there are a wide variety of scenarios in which medical error occurs, the omission of treatment steps in medical crises is chosen as the outcome; firstly, due to the possible impact on mortality that its presence may have and; secondly, due to the high incidence of these errors in situations of very short time for decision-making.

It has been described that, in the crisis scenario, the high cognitive and emotional load influences the correct decision making; on the other hand, the vulnerability of the patient in these situations limits the possibility of randomized clinical studies. Due to the ethical conflict that a study in medical crises has in real patients, the high-fidelity simulation scenario is chosen for this specific study.

In addition to the ethical conflict, the high-fidelity simulation scenario is an ideal setting for measuring medical error due to the omission of treatment steps in medical crises. This due to the low frequency of these situations in real clinical scenarios, the possibility of making high-quality recordings of the scenarios; and that most non-technical skill measurement scales were designed and validated in high fidelity simulation(35). Additionally, it has been described that the perception of emotional charge in complex situations in simulation is similar to what happens in a real patient, even elevation of alpha amylase has been detected as a marker of stress in people subjected to high fidelity simulation.(36).

Yuqi and collaborators in 2017 estimated in a controlled clinical trial that simulation training even in low fidelity, after a day of training in medical crises, increases the global score of non-technical skills measured with the Ottawa scale with mean differences between the

Baseline and post-assessment value of 2.6 (95% CI, 1 to 4.3), with no differences between residency students and graduate professionals(37).

Finally, as it is an educational strategy, the population that a priori benefits the most from these interventions is the personnel in training. In the case of the Faculty of Medicine of the University of Antioquia, the training of non-technical skills is not included in the micro curriculum of critical patient care, therefore, the results of the present study could be used to define modification or confirmation of the micro curriculum for critical patient care in the last semester of medicine.

6b. Comparison justification.

Until now, the use of checklists is the intervention that has the most empirical support in reducing medical error due to omission of steps in surgery (38). Arriaga et al. Found that the use of checklists reduces simulation crisis medical error with an absolute risk reduction of 17% and relative risk of 0.28. IC0.18 to 0.42; P <0.001(27). Finally, in the clinical trial by Duclos et al., In which checklists versus MRC training plus checklists were compared, a decrease in adverse event was shown in the two groups without differences between them, 8·8 to 5·5% (OR 0.57, 95% CI 0·48 to 0.68) versus 7.9 to 5.4% in control (OR 0.64, 0.50 to 0.81) (ROR 0.67 to 1.21)(31); the authors attribute the decrease in the probability of an adverse event to the application of checklists.

In light of this, the checklist is the best strategy to prevent medical error in omitting steps in crisis, which is why the World Health Organization WHO recommends the use of checklists to reduce medical error in surgery. and medication error; and further recommends them as a primary educational component in patient safety competencies.

Research question

In the last semester medical students at the University of Antioquia, does training in non-technical skills and checklists reduce simulation crisis medical error, compared to training with checklists?

7. Objectives and Hypotheses

Hypothesis

In the last semester of medicine students at the University of Antioquia, training of non-technical skills and checklists is superior compared to conventional training with checklists to decrease at least 10% omission of steps in crisis management medical in high fidelity simulation.

Primary objective

To determine if the training of non-technical skills and checklists in final semester students of medicine at the University of Antioquia is superior to conventional training with checklists

to decrease at least 10% of omission of steps in the management of medical crisis in high fidelity simulation.

Secondary Objectives

Determine if there are differences between intervention and control strategies in the following results:

Crisis resolution time

Time in detection and discrimination of the crisis

Overall score of non-technical skills

Discriminated score between dimensions of non-technical skills

Student satisfaction

Incidence of inadequate crisis management

8. Study design:

TECRISIS is a study designed as a controlled clinical trial of superiority with parallel groups, random allocation and blinding of investigators who measure outcome.

III Methods: participants, interventions and outcomes

9. Description of the study characteristics

Reference population: medical students

Study population: final semester students of medicine at the University of Antioquia. This study will be carried out in Medellín Colombia, in a single center, the University of Antioquia. This center is chosen since it has a high fidelity simulation center, teachers with simulation experience and also has more than 100 medical students per semester. The community of students of the last semester of medicine is chosen since they are the population to which the possible results of the present study may have better application. Additionally, these interventions are educational strategies and could be adjusted or included in the institution's undergraduate medical curriculum program.

10. Eligibility criteria

10a. Inclusion criteria

- Older than 18 years-old.

- Final semester student of medicine at the University of Antioquia.
- Have passed the theoretical knowledge exam for handling crisis events with a score of 100%
- On-site availability for training days

10b. Exclusion criteria

- Have received training in a specific crisis resource management course.
- Refusal to participate in the clinical study.

11a. Interventions

For all study participants:

In order to increase homogeneity in the technical concepts prior to the interventions, all the participants will take a theoretical knowledge test to manage the events of the following crises: anaphylaxis, unstable bradycardia, cardiac arrest with defibrillable and non-defibrillable rhythms, airway management failure, bronchospasm, severe bleeding, low blood pressure, hypoxia, and unstable tachycardia.

The theoretical exam, with no limit of attempts, must be 100% passed. This will be designed by the main researchers and approved by a teacher external to the study.

Protocol for the simulation sessions: based on the strategy of directed reflection, debriefing with good judgment, described by Maestre and collaborators(38); A safe container will be made, that is, the explanation of a series of agreements to generate confidence in the high-fidelity simulation, by a teacher trained in directed reflection in all the simulation days, with ample and sufficient explanation to ensure the greatest student participation based on three principles.

Denomination principle 1: fiction; both the researchers and the participants will commit to the best of their abilities to carry out the diagnoses and interventions as if it were a real patient; the simulation scenario will have physical fidelity, that is, spaces and sizes similar to real life. Emotional and psychological fidelity, that is, the same roles will be presented as in real practice; for example, treating doctor, nursing assistant and head of nursing to ensure that the perception of the situation is as close as possible to real life.

Denomination principle 2: confidentiality; All the actions carried out in the simulation sessions, both training and outcome measurement, will only be discussed in the reflection space directed at the end of each simulation among the participants and will not be commented on in other scenarios.

Denomination principle 3: basic principle; It will be verbally expressed that all the participants in the level of training in which they are considered to be competent, intelligent, who want to carry out the best actions to treat their patients and improve.

After the agreement of the safe container, that is, the explanation of the three previous principles will proceed with the description of the clinical scenario of two of the crises described at random. After that, the reflection will be carried out to checklists or training of non-technical skills according to the group.

Protocol for directed and structured reflection: directed reflection after the simulated crisis will last for a minimum of 30 minutes and a maximum of one hour, will consist of the following moments or phases:

Phase 1: context description; After the simulation is finished, the participants will be transferred to the reflection room, a suitable and comfortable space different from the simulation. In this scenario, the phases of reflection will be described.

Phase 2: emotional discharge; Participants will be asked about the emotions experienced in the simulation of the crisis, in order to reduce the emotional burden that may arise and in addition to using the possible mental models described to direct the reflection.

Phase 3: discussion of reflection objectives: the objectives of the reflection will be described and agreed according to the intervention group, non-technical skills or checklists.

Phase 4: discussion about mental models, conclusions and learning from the session; It will be done through the use of the "molecule" (38) as an investigation strategy in the reflection with good judgment in order to clarify the actions, concepts and mental models related to the assigned group.

The exploration of mental models through the "molecule" strategy consists of the teacher or instructor, who uses the simulation with good judgment, carry out a directed dialogue to obtain an explanation by the student of an action committed in the simulation. This may be an error or a correct action, said explanation allows clarification or confirmation, by the teacher, of the concepts issued by the student.

The "molecule" is an interrogation strategy that, based on trust between the student and the teacher, allows the search for the reasons why a particular action was carried out(38).

<u>For the intervention group</u>

Since the effectiveness of a single day of intervention to improve non-technical skills in work teams is controversial (39)(40), the specific training in non-technical skills with guided reflection structured in a 10-hour program is proposed. Two hours on the teleeducation platform that includes a description of non-technical skills and checklists, reflection exercises, a pre-test and a test at the end of the platform's content; and 8 face-to-face hours in high-fidelity simulation divided into two four-hour days with a minimum of three days apart, which will emphasize directed and structured reflection (structured debriefing) to mental models that are related to non-technical skills according to the previously described simulation protocol.

The training will be carried out with four random crises from the list of the pathologies described, two in each session, this in order to avoid cognitive continuity bias.

To achieve the adequate training of non-technical skills and that the participants acquire specific behaviors according to each dimension of the same, the directed and structured reflection will be carried out taking into account the following aspects:

Leadership

- Remain calm throughout the crisis
- Make fast and safe decisions
- Maintain global perspective by not focusing on specific skill and moving away from the crisis.

Problem resolution

- Fully and quickly apply systematic patient assessment
- Always handle concurrently or simultaneously life-threatening problems
- Aloud consider more likely alternatives during the crisis

Situational awareness

- Avoid cognitive bias of fixation technique
- Reassess the situation by asking your team for information
- Anticipate probable events constantly manifested as the request for resources that anticipate the evolution of the crisis

Resource management

- Prioritize tasks and assign them to your team
- Ask for help early
- Using checklists and other cognitive aids

Communication

- Always communicate clearly and concisely with the work team
- Stimulate feedback of orders or cross check
- Use directed verbal and nonverbal language

That is, in each high-fidelity simulation, a constructive dialogue will be carried out with the structured debriefing protocol, to fulfill the actions directed at each dimension of non-technical skills.

To achieve the correct use of the checklist in crisis, directed and structured reflection will be carried out so that the participants acquire the following behaviors

- Choosing the right list for the stage
- Assignment of a specific participant using the checklist

- Feedback to the work team on each action suggested in the checklist

For the present protocol, the checklists in Spanish of the Colombian Society of Anesthesiology SCARE that are freely available will be used during the development of simulation crises.(41).

For the control

10 hour program; two hours on the teleeducation platform that includes a description of the checklists to be used, reflection exercises with a previous test and a test at the end of the contents of the platform focused on checklists; and 8 face-to-face hours in high-fidelity simulation divided into two four-hour days with a minimum of three days of difference between them, in which directed and structured reflection (structured debriefing) will be emphasized to the mental models that are related to the checklists. In crisis.

The training will be carried out with four random crises from the list of the pathologies described, two in each session, this in order to avoid cognitive continuity bias.

To achieve the correct use of the checklist in crisis, directed and structured reflection will be carried out so that the participants acquire the following behaviors

- Choosing the right list for the stage
- Assignment of a specific participant using the checklist
- Feedback to the work team on each action suggested in the checklist

For the present protocol, the checklists in Spanish of the Colombian Society of Anesthesiology SCARE that are freely available will be used during the development of simulation crises.(41).

Recording for measurement of outcomes:

The measurement of the outcomes described in section 18, will be carried out after completing the training, on a day different from the last simulation session. To guarantee the homogeneity of the treatment teams, each participant will be evaluated separately in a group of four people where three are resident doctors trained in non-technical skills and checklists blinded to the intervention, since they do not participate in the training sessions. , who will assume the roles of two nursing assistants and a circulator.

Three crises will be carried out at random, different from those used in training to avoid cognitive continuity bias and will be recorded in the same simulation center for all participants with a Logitech® brand HD camera reference Pro stream C922 using a Jabra brand microphone ® reference Speak 510Ms.

For all cases after recording for outcome measurement:

As the intervention and control are about educational strategies of problem solving skills in medical crises, in simulated environments in students from the same year of training, from

a single center, in which it is not possible to blind the participant, there may be communication between treatment and control groups.

This possible communication can lead to biases that affect the internal validity of the study. First, compensatory rivalry bias, if the control group, in this case checklists, knows the outcome, they could behave differently to try to lessen the effect of the outcome on their group, responding to social competition.

Second, demoralization bias, for the control group knowing that they would not receive the intervention training.

To avoid these two possible biases, after recording the three crises to measure the outcome, all participants will undergo training corresponding to the other intervention arm to which they were initially assigned by means of protocol-directed reflection on non-skills. techniques for the control case or checklists for the intervention group case. Additionally, the platform of the arm opposed to the intervention will be left open to each participant.

11b. Modification of the intervention

As these are two educational strategies, no need for changes in the interventions is expected.

11c. Strategies to improve adherence

Various strategies will be used to improve adherence to the study protocol.

Firstly, participants who agree to participate in the study will be explained the importance of fully complying with the intervention and control protocol, and the voluntary nature of participation will be emphasized.

In addition, clinical internship rotations will be sought to ensure attendance at the three face-to-face sessions, two for training, one for outcome measurement, especially the course for critical patient care and the elective rotation for anesthesia for the last semester of medicine. It will seek support from the teachers who coordinate these rotations to achieve this goal.

On the other hand, the virtual platform will have an easily developed content, which meets the objectives of standardizing the technical knowledge necessary for learning to carry out the intervention and control activities. The platform will be closely watched by one of the researchers to confirm the use of it by the participants. Lastly, the simulation center of the Faculty of Medicine of the University of Antioquia will be requested the appropriate spaces for interventions and recordings to measure the outcome, seeking to be separated from other training stations and thus ensure the comfort of the participants. .

11d. Concomitant interventions

As the teaching-learning relationship is bidirectional, other educational interventions on technical skills related to the scenarios and the resolution of questions and doubts about the technical concepts related to the platform will be allowed for both groups.

No training will be conducted in either group on non-technical skills other than those contained in the training in this protocol.

12. Outcomes

12.1 Primary outcome:

Difference of proportions of omission of steps to treatment by group, the measurement of this outcome will be made by reviewing the recordings of three random medical crises different from those used for training in each group of participants. The evaluation will be done by an independent collaborator blinded to the intervention group and previously trained in the detection of errors by one of the authors. Failure to apply the specific actions defined in each pathology, chosen by the authors according to Annex 1, will be considered as omission of the treatment step, this includes the maximum time determined for each action, the choice of appropriate medications with their respective doses, among others. Each evaluation is independent, each crisis will be evaluated in seven steps,

12.2 Secondary outcomes:

12.2a 1Difference of crisis resolution time averages in seconds between both groups, measured in the recording, taking as the beginning of the crisis the moment of calling the treatment team and the end when all the effective treatment of each crisis is completed , according to the treatment steps described in Annex 1. In the event that the treatment steps are not fully completed, the time will be measured until the end of the simulation.

12.2b Difference of time averages in detection and discrimination of the crisis in seconds between both groups, taking as the beginning of the crisis the moment of calling the treatment team and the end the moment of explicitly requesting the specific checklist for the crisis or verbalize the diagnosis of the code situation. If the specific list is not requested or the diagnosis is not verbalized, the time until the end of the simulation will be counted.

12.2c Mean difference between the global non-technical skills score measured with the Ottawa global scale based on video recording by an independent evaluator.

12.2d Mean difference between the discriminated score between dimensions of the non-technical skills of the two groups, measured with the Ottawa global scale based on video recording by an independent evaluator.

Ottawa Global Scale Overview: this scale is free to use for research, it has a validation study in our environment, completed in the publication phase, its psychometric characteristics are summarized in Table 5 (42), the Spanish version can be seen in Annex 6.

Table 5 Ottawa scale psychometric characteristics for HNT

Dimension or item	Internal consistency	Reliability between ICC evaluators	Reliability re-test	Construct validity
Overall evaluation	reference	0.641	0.761	
Leadership Skill	0.902	0.634	0.808	0,776
Problem resolution	0.915	0.628	0,779	0.692
Situational awareness	0.930	0.627	0.708	0.576
Use of resources	0.863	0.696	0.70	0.578
Communication skills	0.893	0.597	0.7407	0.872

12.2e Student satisfaction:

This exploratory outcome is chosen because of the importance of the perception of the participants that hypotheses could generate for future research. A search was made of validated and free scales for use without finding any that meets these requirements for high-fidelity simulation, therefore, the training satisfaction assessment format of the simulation center of the Faculty of Medicine of the University of Antioquia, format F-025-08 (see annex 7).

12.2f Incidence of inadequate crisis management:

Difference in incidence of inappropriate management rating, this dichotomous rating will be performed by the blind evaluator of the outcomes, taking into account the treatment actions considered minimal by the researchers based on the different clinical practice guidelines, these are those specific to management by crisis, it will be classified as adequate management if it is met, inadequate management otherwise, according to table 6.

Table 6. Minimum treatment actions for crisis resolution.

Air embolism	1. Stop the air intake site by applying irrigation 2. Start dobutamine or norepinephrine if hypotension in less than 2 minutes 3. Position in lateral decubitus on the affected side before 10 minutes
Anaphylaxis	1. Stop infusions 2. Apply Adrenaline IM or IV in less than 2 minutes 3. Apply infusion epinephrine in case of non-response of 1 to 4 micrograms / minute
Unstable Bradycardia	1. Apply atropine 0.5mg IV repeat up to 3mg total dose 2. If bradycardia persists use transcutaneous pacemaker

Cardiac arrest / Asystole (hypoxemia)	1. Start cardiac massage in less than a minute 2. Apply 1mg adrenaline every 3 to 5 minutes 3. Use of advanced airway device in less than 5 min
Cardiac Arrest / Ventricular Tachycardia	1. Start cardiac massage in less than 1 minute 2. Rhythm detection every 2 minutes 3. Application of electric shock with 200J bipolar in less than 3 minutes
Unanticipated difficult airway	1. Apply FiO2 100% 2. Perform minimum 3 laryngoscopies maximum 4 3. Use second-generation supraglottic after laryngoscopy failure
Hypovolemic shock from open trauma	1. Verify the patency of 2 peripheral veins 2. Administer 20ml / kilo bolus of crystalloids in less than 5 minutes 3. Request Mass Transfusion Package
Distributional shock hypotension	1. Apply 20ml / kilo crystalloid bolus in the first 5 minutes 2. Start norepinephrine at a dose of 0.05ug / k / min in less than 5 minutes
Malignant hyperthermia	1. Apply Dantrolene at a dose of mg / kg in less than 5 minutes 2. Suspend possible triggers of the crisis
Foreign body airway obstruction	1. Apply FiO2 100% 2. Apply support with positive pressure ventilation in less than 4 minutes 3. Manual removal of foreign body in less than 5 minutes
Unstable ventricular tachycardia	1. Cardiovert in synchronous mode with 100 Joules in the first 3 minutes 2. Perform second cardioversion with 150 Joules in the first 5 minutes

13. Figure 2: Participants timeline

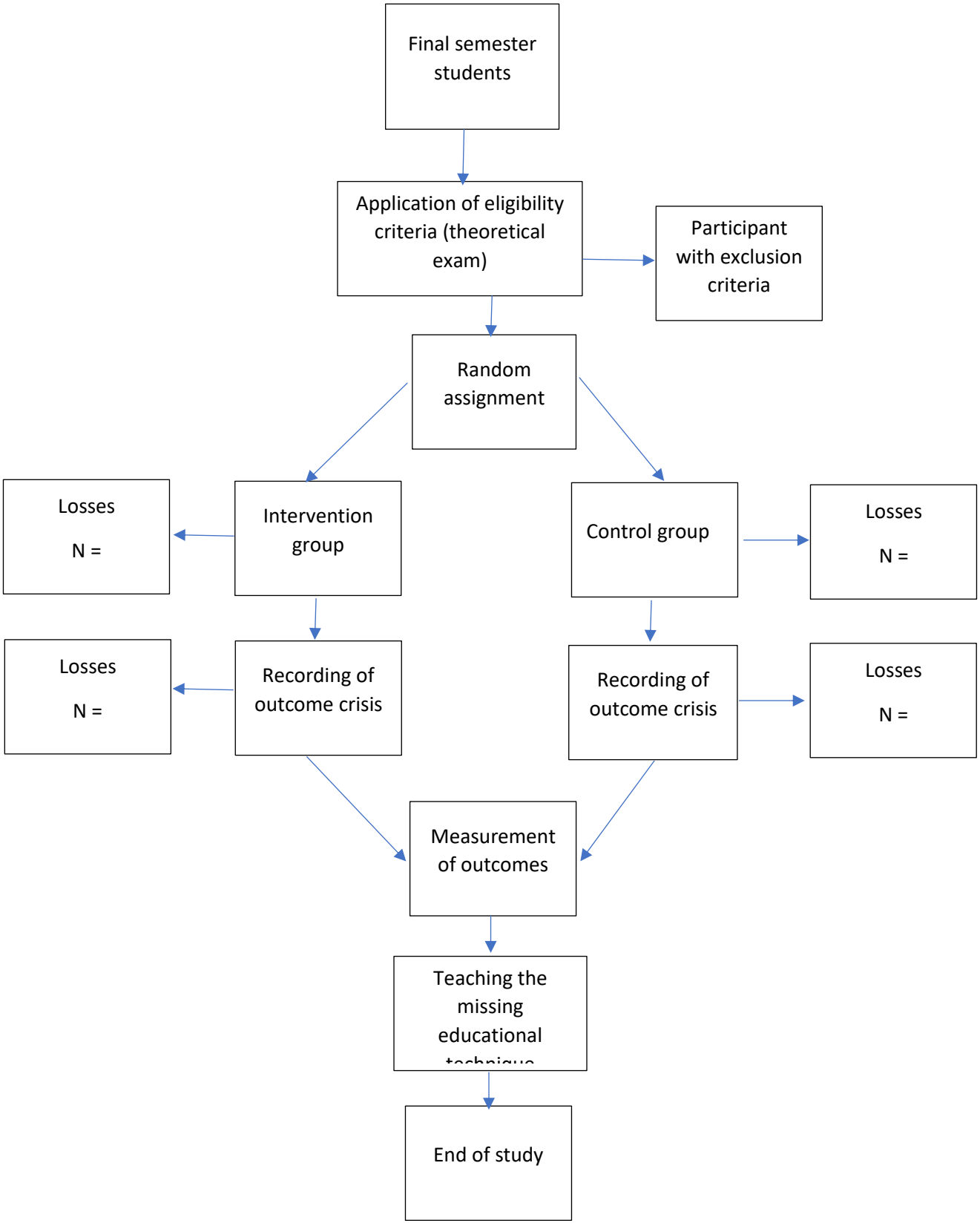


Table 7. Follow-up program and procedures

	Reclu	Assign	Post-allocation stage													Closing	
Time in days	one	one	2	3	4	5	6	7	8	9	1	eleve	1	1	1	fiftee	1
Exercise																	
Assignment																	
Allocation screening																	
Theoretical knowledge test																	
Informed consent																	
Assignment																	
Intervention																	
Post-test virtual platform																	
HNT and LC training																	
LC training																	
Evaluations																	
Baseline measurement																	
Recording of outcome crisis																	
Outcome measurement																	
Measurement of secondary outcomes																	

Reclu: Recruitment, Assig: Assignment.

14. Sample Size

The proportion of treatment steps and not the incidence of medical error is taken as the unit of analysis, the reason for this is the high incidence of medical error that can even manifest itself with more than one error due to crisis, therefore, if used the incidence of the event would decrease the sample size.

Based on the study by Arraiga et al., The proportion of missed treatment steps in the expected control group is 26% and we consider a further 10% reduction in the intervention group to be clinically important. A minimum of 10% additional reduction in omitting treatment steps is decided because it is the approximate effect size of the other dimensions of non-technical skills other than resource management, a dimension that includes the use of checklists. It also establishes power of 90% and alpha of 0.05.

The sample calculation is then carried out in the analysis unit omitting treatment steps according to the formula:

$$n = \frac{\left[Z_{\alpha} * \sqrt{2p(1-p)} + Z_{\beta} * \sqrt{p_1(1-p_1) + p_2(1-p_2)}\right]^2}{(p_1 - p_2)}$$

With the statistical program R version 4.0.0 epiR statistical package, with the following code:

> library (epiR)

> epi.propsize (treat = 0.16, control = 0.26, n = NA, power = 0.9, design = 1, sided.test = 2, conf.level = 0.95)

We found a sample size of 492 treatment actions per arm, which corresponds to 984 in total, and with an estimate of student losses of 20%, we found the total of 1,180 treatment actions; Since 21 treatment steps are evaluated in each team, we obtain a total of 56 final semester medical students, 28 in each arm.

15. Recruitment

In order to complete the calculated sample size, the following recruitment strategies will be carried out:

- Explanation of the project at least once per internship cohort with the whole group.
- Request for participation on day 1 of the anesthesiology rotation in boarding school and the care rotation of the critically ill patient.

Table 8. Monthly evaluation of the monitoring status

Recruitment month	one	2	3	4	5	6	7	8
Current current income								
Income to date								
Income goal to date								
Real less projected								
Success ratio								
Projected final income								
Final deficit or excess								

IV Methods: allocation of interventions

16a. Method to generate random sequence: with the statistical program R 4.0.0, a random sequence will be generated for both groups by blocks of 2 and 4 participants that will have a blind number for the researchers, in a 1: 1 ratio and without strata. The number of participants per block and the detailed randomization strategy will be carried out by an external research collaborator and will be kept hidden from the researchers.

16b. Mechanism to hide the random sequence: the randomization mechanism will be kept hidden by opaque envelopes numbered consecutively and in the possession of an administrative assistant from the simulation center of the Faculty of Medicine of the University of Antioquia and only the group assigned to one will be revealed. of the researchers after signing the informed consent of the participant to place him in the respective group.

16c. Implementation of the random sequence: an external collaborator will be in charge of generating the sequence and preparing the envelopes, researchers MZ and JPZ will be in charge of collecting the participants, revealing the opaque envelope in a row and assigning the participant to their respective group.

17a. Masking.

As these are two educational strategies that require verbalization as part of the training model based on feedback with good judgment, it is not possible or consistent to mask the intervention, both for the participants and for the researchers who apply the interventions. However, since it is a low-risk investigation, it is possible to mask the outcome to the participants.

Trial participants: Tecrisis study participants will be aware of the interventions but will be blinded to the primary outcome, omission of treatment steps. This will be ensured with two strategies; first, modification of the title of the clinical trial taking into account only the secondary outcome of student satisfaction; Second, the directed reflections will focus on learning strategies and not on medical error.

Intervention providers: the researchers who apply the intervention will not be blinded to it since they need to know the educational strategy to use.

Outcome assessors: the collaborator who evaluates the outcomes will be blind to the interventions. At no time will the assigned group be revealed to him.

Analysis of data: Researchers analyzing the data will not be blinded to interventions or outcomes and will not participate in outcome measurement.

Data will not be presented masked to the external data monitoring committee.

17b. Circumstances to reveal masking.

It will be considered to reveal the masking of the outcome in the event that any of the participants present at the time of recording for the measurement of the outcome great psychological or emotional affectation by the simulation and the safe container described in the simulation methodology is not enough.

V Methods: data collection, management and analysis.

18. Baseline and outcome data collection plan

Baseline characteristics: the following baseline characteristics of the participants in the first simulation session will be collected: age, sex, personal history of sleep disorders, personal history of mood disorders, hours of weekly care rotation, hours of daily sleep on average, reported simulation training hours, weekly work hours if applicable. On the day of the outcome measurement, the variable hours of sleep the day before the outcome measurement will be recorded. The variables to be registered are discriminated in Annex 5.

These data will be filled out in physical form and will be transcribed in a database in Google documents.

The outcome variables will be carried out electronically and are summarized in Table 8.

Table 8 measurement of outcome variables

Outcome	Measurement	Responsable
Primary		
Skipping treatment steps	Electronic format in Google based on video recording.	Blind collaborator to the intervention
Secondary		
Crisis resolution time	Electronic format in Google based on video recording.	Blind collaborator to the intervention
Time in detection and discrimination of the crisis	Electronic format in Google based on video recording.	Blind collaborator to the intervention
Overall score of non-technical skills	Electronic format in Google based on video recording.	Blind collaborator to the intervention
Discriminated score between dimensions of non-technical skills	Electronic format in Google based on video recording.	Blind collaborator to the intervention
Student satisfaction	Electronic version of Format F-025-08 of the Simulation Center, Faculty of Medicine, University of Antioquia	Self completed by the Student in an anonymous format.
Incidence of inadequate crisis management	Electronic format in Google based on video recording.	Blind collaborator to the intervention

18b. Plan to promote retention and complete follow-up

The participation, retention and follow-up of the study will be voluntary, based on the explanation of the potential benefits in the participation of the study, such as training in high-fidelity simulation of both interventions, no financial remuneration will be used as a retention strategy.

Since a minimum of three sessions participation on different days is required for high-fidelity simulation training and outcome measurement, a possible participant loss of 20% is considered, which was included in the sample size calculation.

The participant can withdraw from the study at any time they wish, even after randomization, this will be clarified from the beginning of the intervention and follow-up period, in addition it will not have repercussions on any qualification in any of the internship courses to be attended by the competitor.

It will be carried out independently of the possible withdrawals from the study, analysis by intention to treat.

19. Data handling:

After completing the manual forms in their entirety, they will be subjected to quality control during the days of administration of the interventions, avoiding loss of data from the start of the study. After that, the central office of the present investigation located in the Faculty of Medicine of the University of Antioquia will be taken in an opaque and sealed envelope, where an administrative assistant with experience in electronic data management and investigation will enter the information from the formats. manuals to an electronic database that will have two backup copies and to which said assistant will only have access during data collection. Subsequently, they will be presented blinded to the researcher who will carry out the statistical analyzes described in the analysis plan.

20 a. Analysis methods for primary and secondary outcomes.

The baseline characteristics of the participants in both groups will be summarized with measures of frequency and proportions for the qualitative variables. In the case of quantitative variables, measures of central tendency and dispersion, mean and standard deviation or median and interquartile range will be used after performing the Shapiro Wilk normality test.

The analysis of each variable is explained in Table 9, prior to the use of parametric tests, the necessary assumptions will be verified including probability distribution tests, independence of the data and equality of variances according to the case. For the ratio of proportions and mean differences of the groups, in case of non-compliance, non-parametric statistical inference will be made.

To compare the intervention arm: training with non-technical skills and checklists with the control group: training with checklists, the proportion of omission of treatment steps per group will be used as the primary outcome variable.

Alternate hypothesis: the difference in the proportion of omission of treatment steps between the control and intervention group is greater than 10%.

Null hypothesis: the difference in the proportion of omission of treatment steps between the control and intervention group is 10% or less.

Table 9 analysis plan by variable

Outcome	Outcome measure	Statistical hypothesis	Estimator	Analysis method
Primary outcome: Medical error	Ratio of omission of treatment steps to total steps per group.	Ha: $P_{control} - P_{intervention} > 10\%$ Ho: $P_{control} - Intervention = 10\%$	Difference in proportions (95% CI)	Chi square test
Overall score on non-technical skills scale	Average Interval per group between 1 to 45	He has: $\mu intervention > \mu control$ Ho: $\mu interventions \leq \mu control$	Mean difference (95% CI)	T Student test.
Ottawa Leadership on Scale	Average Interval per group between 1 and 7	He has: $\mu intervention > \mu control$ Ho: $\mu interventions \leq \mu control$	Mean difference (95% CI)	T Student test.
Ottawa scale problem solving	Average Interval per group between 1 and 7	Average Interval per group between 1 and 7	Mean difference (95% CI)	T Student test.
Situational awareness on the Ottawa scale	Average Interval per group between 1 and 7	He has: $\mu intervention > \mu control$ Ho: $\mu interventions \leq \mu control$	Mean difference (95% CI)	T Student test.
Utilization of Ottawa scale resources	Average Interval per group between 1 and 7	He has: $\mu intervention > \mu control$ Ho: $\mu interventions \leq \mu control$	Mean difference (95% CI)	T Student test.
Ottawa Scale Communication	Average Interval per group between 1 and 7	He has: $\mu intervention > \mu control$ Ho: $\mu interventions \leq \mu control$	Mean difference (95% CI)	T Student test.
Crisis resolution time	Average time in minutes per group	He has: $\mu intervention < \mu control$ Ho: $\mu intervention \geq \mu control$	Mean difference (95% CI)	T Student test.
Time in detection and discrimination of the crisis	Average time in minutes per group	He has: $\mu intervention < \mu control$ Ho: $\mu intervention \geq \mu control$	Mean difference (95% CI)	T Student test.
Student satisfaction	Difference of excellent assessment proportions in the categories of the format F-025-08	Ha: Pintervencion> Pcontrol Ho: Pintervencion = Pcontrol	Difference of proportions. (95% CI)	Fisher's Exact Test.

Incidence of improper handling	Relative risk inadequate management intervention / control	Ha: RR ≠ 1 Ho: RR = 1	Relative Risk (95% CI)	Chi square test.

20b. Additional analysis methods

Other analyzes by subgroups or adjustment of analysis by other variables will not be considered.

20c. Methods for analysis of censored or missing data

In case of censored or lost data, multiple imputation method will be carried out (43).

VI Methods: data monitoring

21a. Composition of the data monitoring committee

The Tecrisis study will have a data monitoring committee external to the research group, which will be made up of the coordinator of the simulation center of the Faculty of Medicine of the University of Antioquia, a clinical simulation teacher from outside the study, and a researcher from the research group. GRIMPA Research in Perioperative Medicine.

21b. Interim Analysis Description

An interim analysis will be carried out with 50% of the participants collected, blind and foreign to the research group, only for adverse events in the case suggested by the data monitoring committee.

22. Damage

Given that it is an educational study that uses the same strategies that are usually used in the training of participants, no adverse events are expected other than a possible emotional affectation due to the high fidelity simulation. The report and management of this will be done according to the institutional protocol of the simulation center of the Faculty of Medicine of the University of Antioquia. However, this study is low risk since the participants are constantly exposed to simulation as a teaching tool and reaching an adequate degree of stress can improve learning even in this scenario.

Other unforeseeable adverse events within this protocol will be reported in case of presenting to the simulation center of the Faculty of Medicine of the University of Antioquia and to the ethics committee of the same institution.

Any non serious adverse event will be recorded and evaluated according to the following characteristics: expected / unexpected, severity, possible cause, management and outcome.

23. Audit

An audit of adherence to the protocol is proposed by the data monitoring committee once a semester, regardless of the percentage of the sample collected.

VII Ethics and dissemination

24. Approval by ethics committee

This protocol and informed consent will be evaluated and submitted for approval by the ethics committee of the Faculty of Medicine of the University of Antioquia.

We consider that it complies with the seven recommendations of the American Medicine Association(44).

1. Social or scientific value: this section is fulfilled since a clinical study is proposed that can improve health results and possibly provide tools or confirm existing tools to reduce medical error due to the omission of treatment crises. In addition to increasing knowledge of non-technical skills and checklists that could improve the satisfaction of students in the medicine program at the University of Antioquia.

2. Scientific validity: the principles and methods including statistical analyzes are proposed based on the recommendations of the Master of Clinical Epidemiology of the University of Antioquia with the aim of resulting in valid and reproducible data.

3. Fair selection of subjects: the selection of the participants does not generate any vulnerability, on the contrary, they could contribute to the training process as medical professionals. Participation in this study does not lead to risks of social stigmatization. In addition, as a matter of justice, it is proposed after recording for the outcome measurement to carry out the two intervention and control training sessions for the two groups.

4. Adequate risk-benefit ratio: given the simulation methodology as a tool for the administration of the intervention and control, based on good judgment, the risks of adverse events are minimized, which are similar to those of any simulation teaching scenario. Among the potential benefits is increasing exposure to medical crisis resolution training with the goal of reducing medical error.

5. Independent review: This protocol has two independent and blind review times. A first moment by two professors of the Master of Clinical Epidemiology at the University of Antioquia and a second moment with two independent pairs.

6. Informed consent: ample and sufficient information will be provided for informed consent in which the interventions, the potential risks, benefits and alternatives are explained.

7. Respect for potential and enrolled participants: this recommendation is met since participants can withdraw at any time from the study without any summative or formative retaliation, privacy of all participants is protected, participants will be informed in case of new information and a constant monitoring of adherence to the protocol will be carried

out. In addition, it is a low-risk study that complies with the recommendations of the World Health Organization for clinical studies in humans.(Four. Five) and with the ethical principles of respect for people, justice and charity manifested in the Declaration of Helsinki and the Belmont Report.

It also complies with the recommendations of the ministry of social protection in Colombia expressed in resolutions 8430 of 1993(46) and 2778 of 2008 of good clinical practices(47).

25. Modifications to the protocol

In the event that there is any modification to this protocol that impacts the conduct of the study, for example, the potential benefit of the interventions in the participants, the objectives, the design, the population or the sample size, a formal correction will be made of the protocol, will be presented to the ethics committee of the University of Antioquia and will be implemented after its approval. For administrative corrections that do not generate changes in the conduct of the study, notification will be made to the ethics committee without formal protocol change.

26. Informed Consent

Informed consent will be obtained from the participants eligible for the present study, from one of the researchers who does not participate in the summative evaluation of the clinical rotations, this in order not to generate possible pressure on the participants, the potential benefits of the two educational interventions and the expected results. A benefit of participating in the study is that it includes three simulation days in addition to the standard undergraduate curriculum training. Possible adverse effects such as emotional impairment will be explained and authorization will also be requested for the use of the data generated from this research in other research protocols. Informed consent can be seen in its entirety in Annex 2.

27. Confidentiality

All the information on paper related to the study will be protected in the simulation center of the Faculty of Medicine of the University of Antioquia, the digital information will be protected in a computer with a password and also one of the researchers will have a backup hard disk with all the information that will also have a login password.

The forms filled out on the Google Docs platform will be protected by institutional mail with a password known by the administrative assistant who files them and the researcher who will analyze them.

The videos made for the outcome measurement will be stored on a computer with a password and also one of the researchers will have a backup hard disk with all the information that will also have a login password, the collaborators who measure the outcome will have access to said videos at the time of such measurement.

28. Declaration of conflict of interest

The present principal investigators do not have any conflict of interest regarding the two interventions that will be carried out.

29. Access to data

During the clinical trial, the collaborators who perform the outcomes will not have access to the data, the main researchers will not have access to the database until the end of the study to avoid loss of blinding.

Researchers will have access to the complete database only at the time of results analysis.

Participants will have access to the personal data of the study once their analysis has been completed, and the database will also be restricted to avoid any information that would allow the patient to be identified.

30. Post-study care

Study participants will continue with their clinical internship rotation with the same academic, evaluative and hourly intensity as students who do not participate in the study, no financial compensation will be made for participation in this clinical trial, nor will pharmacological interventions be performed. or that differ from traditional exposure to the high fidelity simulation, low risk of the presence of adverse effects derived from the intervention is expected.

31. Dissemination policy

31a. Communication plan of the results: it is intended to communicate the results of the present study in different media:

Publication of the main article: the results of this study will be taken to an indexed and homologated journal by Colciencias, even in case of no differences between the groups, there are also no limitations on the part of the financing entities of this study for publication.

Publication of minor article: possible secondary articles derived from this study will be submitted to publication in journals indexed and approved by Colciencias, the authors will be those who design new research questions that can be answered with the possible assembled basis of this study.

31b. Authorship Plan: the authors of the possible publications of this study will be those who meet the criteria required by the different scientific journals, this includes, but is not limited to: patient collection, protocol design, data analysis and final writing . It is not intended to hire professional writers for possible publications, although it is possible for style editing.

31b. Public Protocol Access Plan: the protocol will be published on clinicaltrials.gov and in its full version it will be published on the anesthesiology platform of the University of Antioquia on the teleeducacionmedicina.udea.edu.co page.

VIII Annexes

Annex 1: List of medical crises with their corresponding treatment steps.

Air Embolism	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Stop the air intake site by applying irrigation 5. Request echocardiography 6. Start dobutamine or norepinephrine if hypotension in less than 2 minutes 7. Position in lateral decubitus on the affected side before 10 minutes
Anaphylaxis	1. Declare the crisis 2. Request help in less than 1 minute 3. Apply FiO2 100% 4. Stop infusions 5. Apply IM or IV adrenaline in less than 2 minutes 6. Apply infusion epinephrine in case of non-response of 1 to 4 micrograms / minute 7. Apply Hydrocortisone 100-200mg IV within 10 minutes
Unstable Bradycardia	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Apply atropine 0.5mg IV repeat up to 3mg total dose

	5. Use adrenaline 2ugr / min after atropine failure until capture of transcutaneous pacemaker 6. If bradycardia persists use transcutaneous pacemaker 7. Increase 10mA until presence of pulse
Cardiac arrest / Asystole (hypoxemia)	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Start cardiac massage in less than 1 minute 5. Apply 1mg adrenaline every 3 to 5 minutes 6. Rhythm detection every 2 minutes 7. Placement of advanced airway device less than 5 minutes
Cardiac Arrest / Ventricular Tachycardia	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Start cardiac massage in less than 1 minute 5. Apply 1mg adrenaline every 3 to 5 minutes 6. Rhythm detection every 2 minutes 7. Application of electric shock with 200J bipolar in less than 3 minutes
Unanticipated difficult airway	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Perform minimum 3 laryngoscopies maximum 4 5. Use second-generation supraglottic after laryngoscopy failure 6. Stop airway interventions after rescue with supraglottic 7. Application of neuromuscular relaxant at full dose (rocuronium 1.2 mg / kg dose or succinylcholine at 1.5mg IV)
Hypovolemic shock from open trauma	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Verify the patency of 2 peripheral veins

	5. Administer 20ml / kilo bolus of crystalloids in less than 5 minutes 6. Request bulk transfer package 7. Repeat 20ml liquid bolus / crystalloid thread
Distributional shock hypotension	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Apply 20ml / kilo crystalloid bolus in the first 5 minutes 5. Start norepinephrine at a dose of 0.05ug / k / min in less than 5 minutes 6. Request vital signs monitoring every 5 minutes 7. Verify patency of 2 venous accesses
Malignant hyperthermia	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Apply Dantrolene at a dose of mg / kg in less than 5 minutes 5. Increase ventilatory minute volume to 10L / min 6. Suspend possible triggers of the crisis 7. Apply topical cooling measures
Foreign body airway obstruction	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Apply support with positive pressure ventilation in less than 4 minutes 5. Manual removal of foreign body in less than 5 minutes 6. Indicate safety position in right lateral decubitus after removal of foreign body 7. Assess consciousness using the Glasgow scale application.
Unstable ventricular tachycardia	1. Declare the crisis 2. Request Help in less than 1 minute 3. Apply FiO2 100% 4. Request stop car in less than 1 minute 5. Cardiovert in synchronous mode with 100 Joules in the first 3 minutes 6. Perform second cardioversion with 150 Joules in the first 5 minutes

	7. Request control electrocardiogram after return to sinus rhythm

Annex 2 Informed consent form

INFORMED CONSENT FOR PARTICIPATION IN CLINICAL RESEARCH PROTOCOLS FACULTY OF MEDICINE UNIVERSIDAD DE ANTIOQUIA

Project title: Non-technical skills training and checklists versus standard training with checklists in boarding school students, randomized controlled clinical trial.

Name: Mario Andrés Zamudio Burbano

Address: Calle 64 # 51D 154

Telephones: 5167469 - 44441333 ext. 3326

Email: mario.zamudio@udea.edu.co

Place of work: Anesthesia Service - University of Antioquia

Site where the study will be carried out: simulation center, Faculty of Medicine, University of Antioquia.

Entities that support the research: University of Antioquia

Research sponsoring entity: None

Mr. Participant: You are being invited to participate in an investigation into the best simulation educational strategy. Firstly, the use of checklists that are aids for doctors to make decisions in different contexts, are currently considered the best strategy. Secondly, training in checklists and non-technical skills, which also includes communication, leadership, role management, among other strategies.

In principle, the study will not change the training objectives of your rotation of the last semester of medicine, the same planned scenarios are used for your training with the same simulation tools.

What is intended to be evaluated in this study is training on checklists and more training in non-technical skills is superior to training with checklists only, for internship students. In any case, at the end of the study you will receive both trainings.

Study procedures.

After agreeing to participate in the research, you will be randomly assigned to one of the two research groups. Randomly it is like tossing a coin, if it falls heads, you will be assigned to the training group on non-technical skills and checklists, if seal falls you will be assigned to the training group on checklists; In either case, after completing the study you will receive both trainings.

Participation in this research does not carry great risks and uses educational tools similar to those of your scheduled clinical rotation.

Research risks

Your admission to this study is completely voluntary, as well as the option of withdrawal at any time. The data or all the information obtained from you, such as your name, the ID number, the age and what the researchers write down will be hidden from all people who are not involved in the investigation, that is, they will be kept strictly confidentiality. Participation does not mean any additional expense for you other than time.

Study alternatives. If you decide not to participate in the study, this will have no impact on your current rotation, neither training nor evaluation. If you initially decide to participate in the study and eventually decide to withdraw from it, it will not have any repercussions either.

Participant benefits. Your participation in the study will not receive any type of financial compensation, however, it would have the benefit of receiving non-technical skills training and checklists that can benefit your professional practice. Their participation will allow it to be verified if the use of a new educational tool is really useful and effective, which could benefit other students in the same level of training in the future, if it is shown that the new method is superior to the conventional one.

Apart from the inconvenience of the time it takes to read this document and decide voluntarily to participate, there are other additional commitments.

Participant's commitments

1. Participate in all virtual platform activities that takes approximately 2 hours.
2. Participate in all simulation activities that take 8 hours.
3. Inform any of the researchers or the ethics committee of the Faculty of Medicine of any damage or adverse event that may arise.

The researcher assumes the following commitments:

1. Follow up throughout the process.

2. Be pending and solve the problems that arise during the study period.

3. Answer and clarify any questions about the procedures, risks, benefits and other matters related to the investigation.

4. Request the evaluation by the respective specialists or services you need in case of any adverse event.

5. Keep the data of the participants hidden from personnel who are not related to the research, that is, confidentiality.

6. The research is duly approved by the bioethics committee of the Faculty of Medicine of the University of Antioquia. It will also be duly registered in the University Research System of the University of Antioquia and in the International Database of Clinical Trials (Clinicaltrials.gov). The

researchers are medical graduates from certified universities with valid registration to practice the profession and work as teachers at the institution.

7. Disclose the results of the investigation once it is completed.

8. Provide real-time information on the status of the study.

9. Disseminate the results and conclusions among all the participants.

The fact of signing this document does not imply the waiver of the legal rights that may exist.

Expected results

The results will be published in a magazine that reaches teachers or doctors from different parts of the world to achieve a more effective and safe practice and medical education. These results will serve to take advantage of new educational resources in the training of health professionals who can provide greater safety and quality to the care of their patients. The dissemination of the results may lead to the widespread use of these techniques in the population with benefits and reduced risks.

People to contact for information

Name: Mario Andrés Zamudio Burbano, Address: Calle 64 # 51D 154 Telephones: 5167469 - 44441333 ext. 3326 Email:mario.zamudio@udea.edu.co. Place of work: Anesthesia service - University of Antioquia. Contact Ethics Committee Faculty of Medicine, University of Antioquia.

Acceptance of participation in the Study

I, _____, with citizenship card number _____ of_____, confirm that I have read, the information for the previous study has been explained to me and that I have had the opportunity to ask questions and they have been solved. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any explanation, without my academic training or legal rights being affected. I understand that the study researchers, the institutional ethics committee and the judicial authorities will be the only people who will be able to observe the recordings collected in the study. I agree to the collection, processing,

I agree to participate in the study described above.

Firm: _____

Date:

Principal investigator or who requests consent:

Name:

Firm: _____

Date:

Witness 1

Name:

Relationship with the participant:

Residence address:

Firm: _____

Date:

Witness 2

Name: Relationship with the participant:

Residence address:

Firm: _____

Date:

Annex 3 Schedule of activities

Exercise	Responsable	2019					2020												2021							
		8	9	10	eleven	12	one	2	3	4	5	6	7	8	9	10	eleven	12	one	2	3	4	5	6	7	8
Literature Review	Investigator																									
Preparation and Completion of the research protocol.	Investigator																									
Presentation of the Research Protocol Postgraduate Committee.	Graduate Committee Researcher																									
Presentation and evaluation of the protocol by external peers.	External Peer Investigator																									
Presentation of the institutional ethics committee protocol.	HUSVF Ethics Committee Researcher																									
Suggested protocol modifications	Investigator																									
Sample Collection.	Investigation Group.																									
Data analysis.	Principal investigator																									
Interpretation of results.	Principal investigator																									
Preparation of the text for publication.	Investigate Main																									
Presentation of Results to the Group of	Principal Investigator of the Clinical																									

Clinical Epidemiology.	Epidemiology Group																									
Study evaluation by external peers.	External Pairs																									
Publication process.	Principal investigator																									

Annex 4 Global budget

Heading	Sources		Total
	Simulation Center	Research group	
Personal		250,000,000	250,000,000
Equipment			-
materials	8,850,000		8,850,000
Field trips	-	-	-
Bibliographic material	500,000	500,000	1,000,000
Publications		3,000,000	3,000,000
Technical services	100,000		100,000
Travels			-
buildings	-	-	-
Maintenance	-	-	-
Total			262,950,000

Numbers in colombian pesos

Annex 5: Table of variables

Variable	Operational definition	Nature	Scale	Unit or code
X 1	Age	Continuous quantitative	Reason	Years
X 2	Sex	Qualitative	Nominal	1. woman, 2. man
X 3	Personal history of sleep disorders	Qualitative	Nominal	0. no, 1. yes
X 4	Personal history of mood disorders	Qualitative	Nominal	0. no, 1. yes
X 5	Hours of weekly care rotation	Continuous quantitative	Reason	Hours
X 6	Weekly working hours	Continuous quantitative	Reason	Hours
X 7	Hours of sleep the day before measurement outcome	Continuous quantitative	Reason	Hours
X 8	Average daily sleep hours	Continuous quantitative	Reason	Hours
X 9	Self-reported hours of simulation training	Continuous quantitative	Reason	Hours
X 10	Failure rate of treatment steps	Continuous quantitative	Reason	Percentage
X 11	Overall score on non-technical skills scale	Discrete quantitative	Interval	1 to 7
X 12	Ottawa Leadership on Scale	Discrete quantitative	Interval	1 to 7
X 13	Ottawa scale problem solving	Discrete quantitative	Interval	1 to 7

X 14	Situational awareness on the Ottawa scale	Discrete quantitative	Interval	1 to 7
X 15	Utilization of Ottawa scale resources	Discrete quantitative	Interval	1 to 7
X 16	Ottawa Scale Communication	Discrete quantitative	Interval	1 to 7
X 17	Crisis resolution time	Continuous quantitative	Reason	minutes
X 18	Time in detection and discrimination of the crisis	Continuous quantitative	Reason	Minutes
X 17	Inadequate crisis management	Qualitative	Nominal	0. no, 1. yes
Variables of the satisfaction format				
X 18	Mastery of course topics	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 19	Exhibition security	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 20	Clear and accurate answers to questions	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 21	Ability to arouse interest	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 22	Efficiency in the use of class time	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 23	Order, coherence and clarity in the presentation of the topics	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 24	Punctuality and attendance at class sessions	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 25	Importance of the workshop course in daily practice	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 26	Interest and topicality of the course-workshop content	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good

				3. Excellent
X 27	Achievement of the objectives formulated in the course-workshop	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 28	Practical workshops	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 29	Convenience of Hourly intensity	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 30	Quantity of equipment used	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 31	Quality of the equipment used	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 32	Installations	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 33	Access to the teleeducation platform	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 34	Ease in the use of the tele-education platform	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent
X 35	Contribution to the course of study material located on the tele-education platform	Qualitative	Ordinal	0. Poor 1. Acceptable 2. good 3. Excellent

Annex 6. Ottawa Global Scale Spanish version

DESEMPEÑO GENERAL

1 2	3 4	5 6	7
Novato; todas las habilidades de MRSC requieren mejoras significativas	Novato avanzado; muchas habilidades de MRSC requieren mejoría moderada	Competente; la mayoría de habilidades de MRSC requieren mínima mejoría	Claramente superior; pocas, si acaso algunas, habilidades de MRSC requieren mejoría

I. HABILIDADES DE LIDERAZGO

1 2	3 4	5 6	7
Pierde el control y la calma durante la mayor parte de la crisis; incapaz de tomar decisiones seguras; no mantiene la perspectiva global	Pierde el control y la calma frecuentemente durante la crisis, retarda, inclusive requiriendo indicaciones, la toma de decisiones; rara vez mantiene la perspectiva global	Conserva la calma y el control durante la mayor parte de la crisis; toma decisiones seguras con poco retraso; usualmente mantiene la perspectiva global	Permanece en calma durante toda la crisis; toma decisiones rápidas y seguras; siempre mantiene la perspectiva global

II. RESOLUCIÓN DE PROBLEMAS

1 2	3 4	5 6	7
Incapaz de implementar la evaluación ABC sin indicación directa; utiliza manejo secuencial a pesar de la indicación; no considera ninguna alternativa durante la crisis	Evaluación ABC incompleta o lenta; la mayor parte del tiempo, usa manejo secuencial a menos que reciba indicaciones; considera poco las alternativas	Evaluación ABC satisfactoria; sin indicaciones; la mayoría de las veces usa manejo concurrente con mínimas indicaciones; considera algunas alternativas durante la crisis	Aplica completa y rápidamente el ABC sin indicaciones; siempre usa manejo concurrente; considera las alternativas más probables durante la crisis

III. CONCIENCIA SITUACIONAL

1 2	3 4	5 6	7
Persiste en error de fijación, a pesar de repetitivas indicaciones; no reexamina ni revalua la situación a pesar de repetitivas indicaciones; no logra anticipar probables eventos	Evita el error de fijación solo con indicación; rara vez reexamina y revalúa la situación sin recibir indicaciones; rara vez anticipa probables eventos	Evita errores de fijación con mínimas indicaciones; reexamina y revalúa la situación frecuentemente con mínimas indicaciones; usualmente anticipa probables eventos	Evita cualquier error de fijación; reexamina y revalúa constantemente la situación sin necesidad de indicaciones; anticipa eventos probables constantemente

IV. UTILIZACIÓN DE RECURSOS

1 2	3 4	5 6	7
Incapaz de usar efectivamente los recurso físicos y humanos; no prioriza tareas ni pide ayuda cuando se requiere, a pesar de las indicaciones	Capaz de usar recursos con mínima efectividad; solamente prioriza las tareas o pide ayuda cuando se requiere, con indicaciones	Capaz de usar recursos con moderada efectividad; prioriza tareas y/o pide ayuda cuando se requiere, con mínimas indicaciones	Capaz de utilizar recursos con máxima efectividad; prioriza las tareas y pide ayuda tempranamente y sin indicaciones

V. HABILIDADES DE COMUNICACIÓN

1 2	3 4	5 6	7
No se comunica ni reconoce los aportes del recurso humano; nunca usa comunicación verbal/no verbal direccionada.	Se comunica ocasionalmente con el recurso humano, pero de manera poco clara y vaga; ocasionalmente escucha pero rara vez interactúa con el recurso humano; rara vez usa comunicación verbal/no verbal direccionada	Se comunica la mayoría de veces de manera clara y concisa con el recurso humano; escucha retroalimentación del recurso humano; generalmente utiliza comunicación verbal/no verbal direccionada	Se comunica siempre de manera clara y concisa con el recurso humano; estimula y escucha la retroalimentación del recurso humano; siempre utiliza comunicación verbal/no verbal direccionada

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