

# Do we need a confederate in full-scale medical simulation? A randomized controlled trial.

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## Research Article

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# Abstract

**Background:** During simulation training, the confederate is a member of the pedagogical team. Its role is to facilitate the interaction between participants and the environment, and is thought to increase realism and immersion. Its influence on participants' performance in full-scale simulation remains however unknown. The purpose of this study was to explore the effect of the presence of a confederate on the participants' performance during full-scale simulation of crisis medical situations.

**Methods:** This was a prospective, randomized study comparing 2 parallel groups. Participants were emergency medicine residents engaging in a simulation session, with or without confederates. Participants were then evaluated on their Crisis Resource Management performance (CRM). The overall performance score on the Ottawa Global Rating Scale was assessed as primary outcome and the 5 non-technical CRM skills as secondary outcomes.

**Results:** A total of 63 simulation sessions, including 63 residents, were included for statistical analysis (n= 32 for Control group and 31 for Confederate group). The mean Overall Performance score was  $3.9 \pm 0.8$  in the Control group and  $4.0 \pm 1.1$  in the Confederate group, 95% confidence interval of the difference [-0.6; 0.4],  $p=0.60$ . No significant differences between the two groups were observed on each CRM items (leadership, situational awareness, communication, problem solving, resource utilization)

**Conclusion:** In this randomized and controlled study, the presence of confederates during full-scale simulated practice of crisis medical situations does not seem to improve the CRM skills performance of Emergency medicine residents.

**Trial registration:** this study does not need to be registered on Clintrial as it doesn't report a health care intervention on human participants.

## Background

A fundamental assumption of simulation is that learning is enhanced when the environment seems realistic. Full-scale simulation attempts to recreate every elements of a real-life situation in order to persuade the participants to accept the "fiction contract" and to become fully engaged in the simulation experience [1–3]. Perceived realism is linked to the interactions between the participant and the environment. The use of a confederate in a full-scale simulation is of common practice to facilitate these interactions and enhance the immersion of the participant in the environment. The confederate is not a learner, but a member of the pedagogical team with a scripted role during the simulated practice phase [4]. He aims to provide realism, challenges or information when they cannot be transcribed by the simulator [5–6]. The confederate is used to improve the of realism by limiting the biases induced by the simulated environment.

Experts suggest using full-scale simulation to enhance interprofessional teamwork and to deepen Crisis Resource Management (CRM) skills, as leadership, communication, problem solving, resources

management and situational awareness [7]. The lack of CRM skills in the management of critical situations has been proven to be associated with adverse events and malpractice cases [8–9]. Learning CRM skills leads to better safety in patient outcomes, including a decrease in mortality [10].

The main limitation to the implementation of full-scale simulation in medical education programs is human resources [11]. Appropriate and justified supervision is therefore essential [12–14]. The influence and role of each member of the pedagogical team should be argued, considering the performance of the participants as the main outcome. To our knowledge, the effects of confederate presence on the performance of participants in a full-scale simulation has not been addressed in proper quality studies.

The purpose of this study was to explore the effect of the presence of a confederate on the participants' performance during full-scale simulation of crisis medical situations.

## **Methods**

### **Study Design**

This randomized controlled study took place in a French university medical simulation center from December 2018 to February 2020.

According to the French ethic and regulatory law, article R1121-1 of the public health code, ethical approval for the study was waived by the national ethical committee (CPP, Comité de Protection des Personnes).

It was registered at the register of epidemiologic studies of Toulouse University Hospital (RnIPH 2019-53) and has also been declared to National Commission of Informatics and Liberty (CNIL number: 2206723 v0). The University Hospital signed a commitment of compliance to the reference methodology MR-004.

All participants provided written informed consent to participate.

### **Participants**

Participants were residents within the 2nd year, 3rd year or 4th year post-graduate of Emergency Medicine at Toulouse University.

In the curriculum of a resident in Emergency Medicine in Toulouse University, a 2nd year participates to 2 simulation of crisis medical situation within the year, 4 sessions for a 3rd year and a 4th year.

The criterion for non-inclusion was the resident's refusal to participate in the study.

### **Study protocol**

The planning of the simulation sessions was fully integrated into the curriculum of the Emergency Medicine residents according to a simulation training program [15]. Each session was developed in accordance with the French National Health Authority (Haute Autorité de Santé).

The session was led by one simulation instructor and one medical expert. The instructors belong to a group of 9 instructors (7 from a University Hospital and 2 from a General Hospital, including 2 nurses and 7 physicians) with a university degree in simulation training. The medical experts are emergency physicians (n = 15) with at least 5-year experience and specific knowledge in pediatrics, advanced life support, obstetrics, resuscitation, and airway management. The overall purpose of these sessions was to learn communication skills, knowledge of respective roles (leadership/fellowship), involvement in shared decision-making and team coordination.

A simulation session was intended for a complete medical team composed of an emergency physician (resident), a nurse and a medical support worker.

Each simulation session lasted 1 hour and was divided into 3 parts: briefing (15 minutes), simulated practice (15 minutes) and debriefing (30 minutes). The briefing prepared the team for the simulated practice, created a positive learning environment, encouraged the emotional security and introduced the clinical situation. Debriefing was conducted by the instructor and the medical expert according to the RUST model and the good-judgement practice [16].

In the simulation, participants' performance was based on the assessment of CRM skills, a set of non-technical skills required to manage medical emergencies [17].

This assessment was carried out immediately after the debriefing by the simulation instructor and the expert physician who conducted the debriefing and were trained in the use of this assessment grid.

Participant demographics were collected using a paper questionnaire to be completed before the simulation session.

This data was then transferred to an anonymized Excel file.

In the *Confederate group*, two confederates playing the role of a nurse and a medical support worker were part of the session.

They were asked to take no initiatives and to wait for the participant instructions without guidance. In the *Control group*, there was no confederate. An interprofessional group composed of a nurse and a medical support worker from the Emergency Department which were operating during the simulated practice but unfamiliar with the scenarios beforehand. They were asked to act as health professionals just as they would in a real-life situation.

### **Scenarios used in the study**

The scenarios were created by the different pedagogical managers of the simulation centers, in collaboration with the medical and paramedical trainers of each discipline. Each scenario was validated by the research team according to a standardized grid (Appendix A). It made it possible to evaluate the authenticity through the characteristics of a "complex problem" and the relevance of the professional situation described to promote learning to manage a critical situation in an interprofessional team.

Their design took into account the possibility of adapting the scenario on certain aspects related to environmental specificities linked to the learners' working conditions (emergency room, pre-hospital environment, ward...). Several professional situations were modelled in order to expose teams to various crisis situations such as cardiac arrest, difficult airway management, traumatic shock (Appendix B). The scenarios have been designed to avoid participants being confronted with the unexpected death of a patient. Indeed, this type of experience did not show any significant benefit in terms of learning and would have interfere with an environment that learners can trust to be grounded with honesty and safety [18].

## Confederates

Confederates were health professionals of the Emergency Department of the University Hospital. They have all benefited from a training-course in medical education. This is a five-day training course in order to master active teaching techniques, to integrate the specificities of the professional context into the practice of emergency care and to harmonize evaluation techniques. Within this framework, they were also trained in the use of full-scale simulation and specifically in the role of confederate during a three-day training course.

Thirteen confederates participated in the study out of 24 trainers available at the Emergency department (Table 1).

They were selected on a voluntary basis and according to their availability.

Table 1  
Confederates' demographic characteristics (Confederate group)

Demographic Characteristics	Confederates (n = 13)
Mean age $\pm$ SD	44.7 $\pm$ 4.2
Gender, n (%) Female	7 (54)
Professional Category, n (%)	6 (46)
Medical support worker	7 (54)
Nurse	
Years of work experience, mean $\pm$ SD	18.8 $\pm$ 4.3
Years of experience as a trainer, mean $\pm$ SD	6.5 $\pm$ 3.7
Number of simulation sessions/year/trainer, mean $\pm$ SD	27.7 $\pm$ 24.2
Number with more than 25 simulation sessions/year, n (%)	5 (38)

## Rating Scale

At the end of the simulation session, the resident was assessed on CRM performance according to the Ottawa Global Rating Scale (OGRS), composed of the assessment of 5 CRM skills (leadership, communication, problem solving, resource use, situational awareness) scored between 1 and 7, and the assessment of Overall Performance scored between 1 and 7: the score of 1 corresponding to the novice level where all CRM skills require significant improvement, and the score of 7 corresponding to an advanced level where improvement in CRM skills (if any) remains minimal (Appendix C) [19]. The inter-rater measurement difference in this evaluation grid is very small (Intraclass Correlation Coefficient > 0.6 interpreted as good according to Cicchetti) [20].

## **Outcomes**

The primary outcome for assessing the performance of the participants was the average scores obtained by the residents in each group (Control and Confederate) on the OGRS Overall Performance during the simulated practice.

The secondary outcomes for assessing each CRM performance of the residents were the average scores obtained by participants in each group (Control and Confederate) on 5 skills: leadership, communication, problem solving, resource utilization and situational awareness.

## **Randomization**

A planning of the simulation sessions on the study inclusion period had been prepared. The randomization of the sessions was realized by the Clinical Research Unit at Toulouse University Hospital in a 1:1 ratio, into 2 groups: Control group and Confederate group.

The confederates were attributed to each session according to the randomization. No sessions were excluded prior to randomization (Fig. 1).

## **Statistical Analysis**

The number of simulation sessions was determined on the primary assumption that participants in the Confederate group would have a 0.4 point variability on the OGRS Overall Performance, compared to participants in the Control group [19]. Based on Cohen's definition of statistical analyses in behavior science, a standard deviation of 0.5 was used [21]. Given the initial hypothesis, a two-tailed test with a power of 80% was used. With these parameters, the number of simulation sessions required is a minimum of 50 sessions, i.e. two groups of 25 sessions.

Statistical analysis of the anonymized data was performed using BiostaTGV® software. All study variables were analyzed individually, checking for missing data and outliers. No imputation method was used for missing values.

The distribution of the quantitative variables was represented by the mean followed by the standard deviation after checking for normality. The comparative analyses were performed using the Student's test after checking for application criteria (distribution of values according to a Gaussian Normal Law). The

threshold of statistical significance allowing to reject the H0 hypothesis, according to which the means are equal in the two groups, was considered reached when the risk of error was less than 5% (p-value < 0.05).

## Results

### General characteristics of the participants

Sixty-three simulation sessions, including 63 residents, were included for analysis: 32 for Control group and 31 for Confederate group (Table 2). The residents' demographic characteristics were homogeneous between the two groups.

Table 2  
Characteristics of the participating residents

	<b>Control group</b> <b>N = 32</b>	<b>Confederate group</b> <b>N = 31</b>
Age (median ± SD)	26.5 ± 3.25	26.9 ± 2.83
No. Women (%)	19 (59)	19 (61)
Semester of Residency (%)		
No. 3rd semester	15 (48)	20 (64)
No. 5th semester	5 (15)	5 (16)
No. 7th semester	12 (37)	6 (20)
Simulation Theme (%)		
Pediatrics	14 (44)	10 (33)
Cardiac Arrest	7 (22)	12 (38)
Cardiology	6 (19)	4 (13)
Vital Medical Emergencies	5 (15)	5 (16)
No. of Previous Full-Scale Simulation Sessions (%)		
0	17 (53)	17 (55)
1	10 (31)	9 (29)
2	5 (16)	5 (16)

### Primary outcome (Fig. 2, Table 3)

Table 3  
The CRM performance scores of the participants in the Control and Confederate group

	Control group	Confederate group	Difference between groups (IC95%)	p-value*
Overall Performance	3.9 ± 0.8	4.0 ± 1.1	-0.12 [-0.61 ; 0.35]	0.60
Leadership	4.7 ± 0.9	4.2 ± 1.1	0.1 [-0.43 ; 0.63]	0.71
Situational Awareness	4.5 ± 1.0	3.9 ± 1.2	0.54 [-0.02 ; 1.09]	0.059
Communication	4.6 ± 0.7	4.5 ± 1.1	0.08 [-0.38 ; 0.54]	0.73
Problem Solving	4.1 ± 1.1	4.4 ± 1.1	-0.25 [-0.82 ; 0.34]	0.40
Resource Utilization	4.4 ± 0.7	4.3 ± 1.2	0.12 [-0.38 ; 0.61]	0.64
<i>Results are expressed as mean ± SD</i>				
<i>*Results were considered significant if p-value &lt; 0.05 and Confidence Interval excluded 0.</i>				

The mean Overall Performance score was 3.9 in the Control group and 4.0 in the Confederate group, 95% confidence interval of the difference [-0.6; 0.4], p = 0.60.

### Secondary outcomes (Table 3)

No significant differences between the two groups were observed on each CRM items (leadership, situational awareness, communication, problem solving, resource utilization).

## Discussion

In this randomized and controlled study, the presence of confederates during full-scale simulated practice of crisis medical situations does not seem to improve the CRM skills performance of Emergency medicine residents.

In the literature, it has been shown that performance and learning depend on the immersion quality into the simulated environment [22]. To ensure participant's immersion, standards of best practice for simulation design expressly require to use confederates who have formal training in simulation-based education. The facilitative approach must also be predetermined during the design phase of the scenario and the level of confederates' involvement must be inversely proportional to the participant's knowledge and experience [23]. Our randomized controlled study suggests that using confederates with formal

training has no added value on the participant's performance. Indeed, situational awareness, problem solving and resource utilization scores showed no significant difference between the two groups. The confederates don't seem to have more effect on residents' CRM performance than nurse and/or medical support worker without formal training in simulation-based education or predetermined facilitative approach. Our results doesn't show that the confederates improve enough resident's immersion and interaction with the simulated environment to influence their performance.

In this study, within the Control group, nurses and medical support workers were not informed beforehand of the outcome of the scenario enabling a spontaneous attitude as a real life. The learning objective were team management in crisis situations. We could think that the interactions between team members is essential for the realism and impact the CRM performance. The nurses and medical support workers have been probably more focus on their role as healthcare professionals and allowed more realistic interactions with the resident.

Research suggests that in a full-scale simulation, participant's behavior is closely linked to his confederate's one so that he comes to imitate their actions [24]. In the case of confederates with very precise scripts often far from reality, deliberately less "helpful" to increase the difficulty of a simulation session, it can be assumed that the simulation session would be locked into a sterile situation without participation or mutual support [25]. In our study, in the Confederate group, confederates were given instructions to act less helpful by taking no initiatives even though they probably would in a real-life situation.

By being part of the pedagogical team and knowing the scenarios outcomes beforehand, it could be hypothesized that their involvement within the simulation was less intense especially with less emotional participation such as doubt or stress and decreased the interaction between the participants and the confederates.

However, the communication skill scores showed no significant differences between the two groups.

Suggesting that the presence of trained confederates has no negative impact on participants' CRM performance.

Nevertheless, the standardization of confederates' behavior in full-scale simulation could prevent some errors of the team during the trained session and prevent them from being addressed during the debriefing. According to our results, confederates do not seem to limit the biases related to the simulated environment that could influence the performance of the participants [23].

The development of training team-based simulation is challenged by the availability of pedagogical staff and by the limited number of learners in each session. We believe that not using confederates could be of major interest in terms of cost-related to the pedagogical staff and could effectively optimize the number of learners.

## Limitations

One of the main limitations of this study is the lack of blinded assessment. Assessment was performed by a group of instructors, involved in the educational training. The use of the OGRS has been shown to have a good reproducibility between observers but the study design did not allow to have a blinded assessment [19].

Another limitation of the study concerns the differences in the participants' semester of residency between the two groups.

Despite randomization, more 7th semester residents were present in the Control group and more 3rd semester residents in Confederate group. This could lead to a difference in performance in favor of control group. Nevertheless, this difference is relatively modest and probably insufficient to impact the CRM performance of either group. Moreover, the experience for simulation tool use was similar between groups. This have been shown to be an import impact on performance [27].

## Conclusion

The presence of confederates during the simulated practice of a full-scale simulation does not have significant impact on the participants' CRM performance.

This study questions the interest of confederates in simulation-based education.

Not using confederates could reduce the pedagogical staff mobilized in full-scale simulation and improve the implementation of interprofessional simulation but still preserve participants' performances.

The impact of confederates' presence during the debriefing phase has not been studied by the present study and should eventually be explored in further studies.

## List Of Abbreviations

CRM: Crisis Resource Management

OGRS: Ottawa Global Rating Scale

## Declarations

### Ethics approval and consent to participate

According to the French ethic and regulatory law, article R1121-1 of the public health code, ethical approval for the study was waived by the national ethical committee (CPP, Comité de Protection des Personnes). It was registered at the register of epidemiologic studies of Toulouse University Hospital (RnIPH 2019-53) and has also been declared to National Commission of Informatics and Liberty (CNIL number: 2206723 v0). The University Hospital signed a commitment of compliance to the reference methodology MR-004. All participants provided written informed consent to participate. No physical,

emotional, psychological or social risks are induced by the study. Participation or refusal to participate will have no impact on any professional or academic evaluations.

### **Consent for publication**

Every participant has agreed for the use of their data in the manuscript. They have given their consent for publication by signing the consent form.

### **Availability of data and materials**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

All authors confirm that all methods were carried out in accordance with relevant guidelines and regulations.

### **Competing interests**

The authors declare that they have no competing interests

### **Fundings**

Authors declare no source of funding for the research

### **Authors' contributions**

CHHC and TG conceived the study and designed the trial. JT and FB supervised the conduct of the trial and data collection. JT, XD and SC undertook recruitment of participating centers and patients and managed the data, including quality control. FB provided statistical advice on study design and analyzed the data. TG drafted the manuscript, and all authors contributed substantially to its revision. JT takes responsibility for the paper as a whole.

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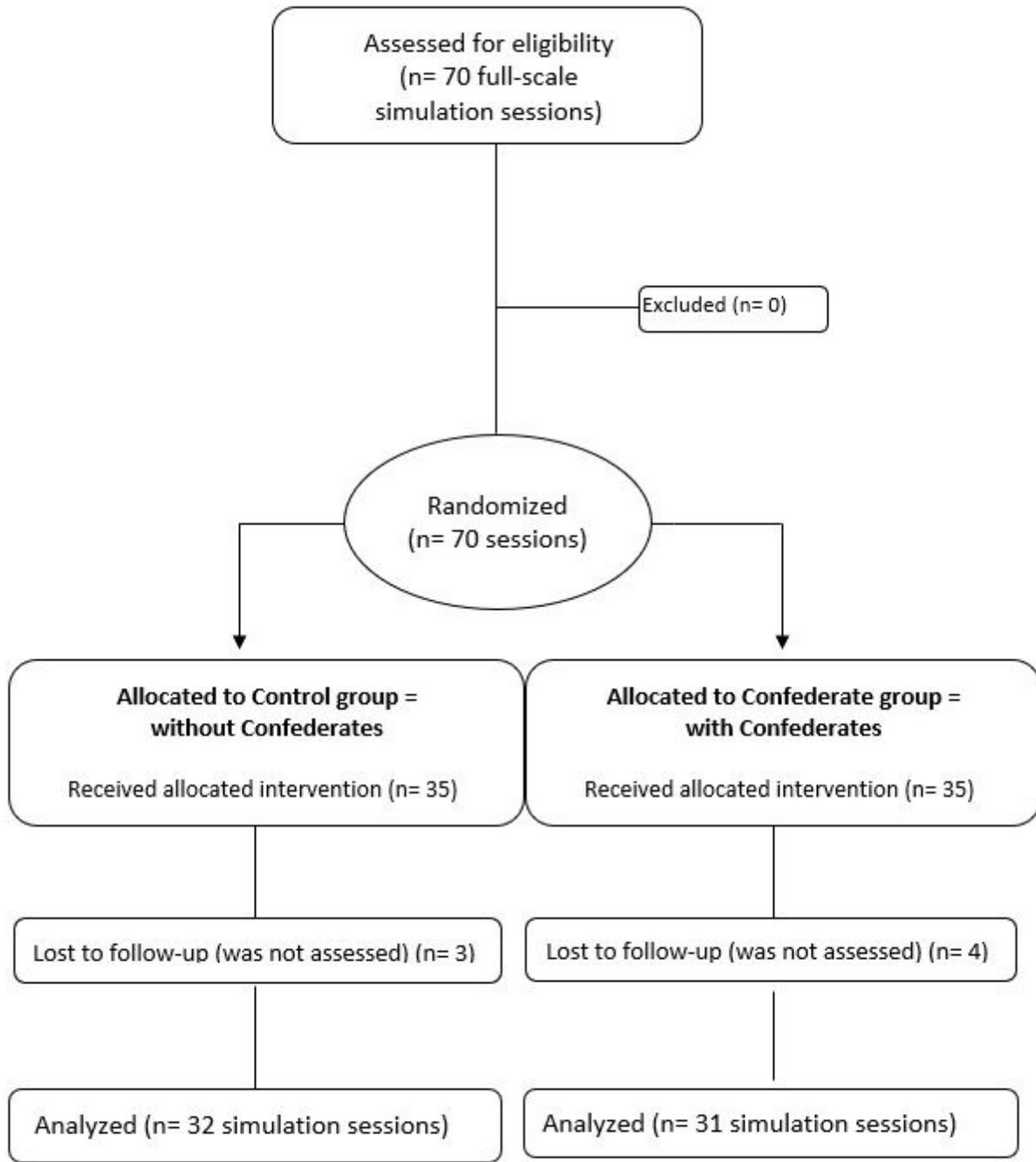
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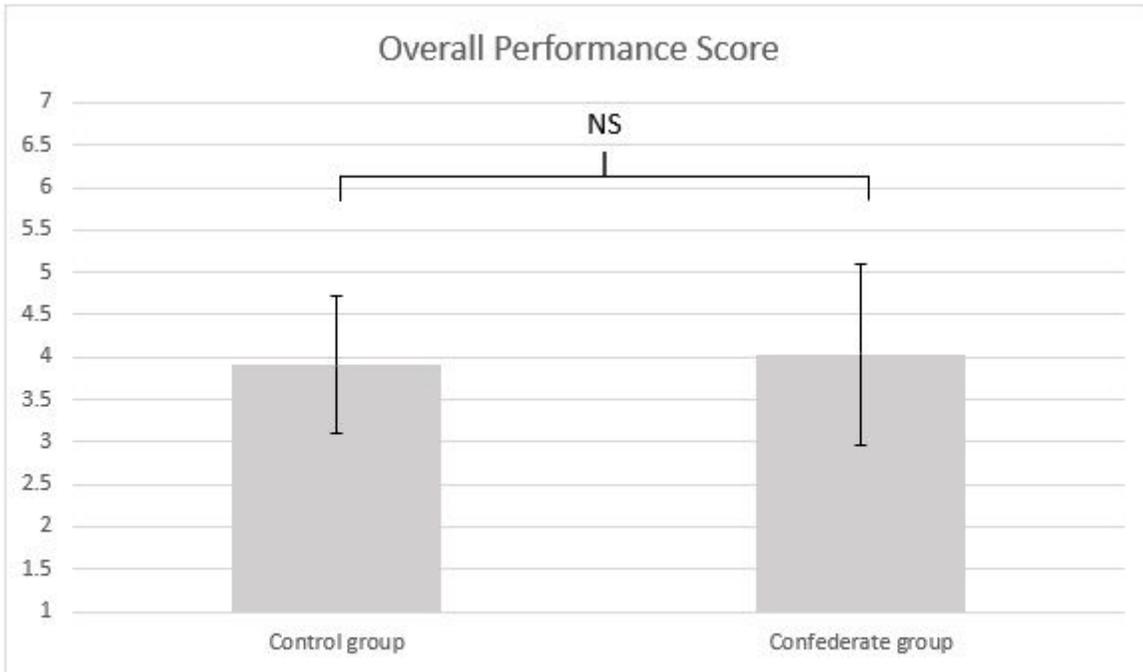
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## Figures



**Figure 1**

Study flow



Overall performance score scored from 1 to 7 in the OGRS (Ottawa Global Rating scale).  
NS = mean difference is Not Significant i.e.,  $p > 0.05$ .

## Figure 2

Mean Overall Performance score in the Control group and the Confederate group

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [AppendixA.docx](#)
- [AppendixB.docx](#)