



Nursing students' experience and training in healthcare aid during the Covid-19 pandemic in Spain

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Manuscripts

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Background:

During the Covid-19 pandemic health crisis, in some countries such as Spain, nursing students have offered to provide health assistance, but the role they have played, their degree of preparedness to face the situation, and what must be improved in their training to be ready for these situations is unknown.

Objective:

Describe the experience and perceptions of students of the Nursing university degree during their participation as health support in the Covid19 health crisis in Spain.

Design: We conducted a cross-sectional observational study.

Data: 503 students enrolled in the 4th course of the Nursing degree in Spain during the months of March and April 2020. An online questionnaire was developed, based on a pilot study and distributed through the Nursing Association, students' unions, and students' associations. Variables were used to describe their participation, degree of preparedness, and training needs to determine how to improve training, as well as non-parametric tests to analyse the relationship between training and degree of preparedness.

Results:

73.2% (368) of students offered to participate in healthcare aid, of which 225 were actively involved. 27.8% developed nursing tasks without supervision, and 47.7% assisted Covid-19 patients as other nurse. Only 3.4% felt very prepared to work in the field of intensive care, and this degree of perceived preparedness statistically relates to prior training in personal protective equipment and mechanical ventilation ($p < 0.005$). The highest scores for training activities that may improve their preparedness were simulations to improve levels of anxiety and stress when managing critical patients, simulation in ventilatory support, and mandatory practices in services where ventilators are used.

Conclusions:

Although three out of four students were willing to provide health assistance, they recognise that they are not specially prepared in the field of intensive care and demand training with simulation.

Relevance to clinical practice: Students have been vital resources for our health system and society when they have been needed. It is now up to us, both teachers and health authorities, to share their efforts by implementing the necessary improvements in training

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3 and safety measures not only because these affects the health and safety of the patient,
4 but because they will be essential parts in future pandemics.
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9 **Keywords:** Covid-19; Students, Nursing; Simulation training
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13 **What does this paper contribute to the wider global clinical community?**
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- After the declaration of the Alarm status in Spain caused by the Covid-19 Pandemic, and the collapse of the health system, the government of Spain issued a ministerial order for the incorporation of medical and nursing students as health support.
 - However, this collaboration has gone beyond what had been planned and has placed students with little experience on the front line of battle. There is currently no publication describing the role of nursing students during this pandemic.
 - This manuscript describes the experience of nursing students in Spain in their participation as a healthcare aid during the Covid-19 Pandemic. The relationship between the degree of preparedness received in different areas of care and their prior training, as well as the main suggestions to improve their training in the face of new pandemics or outbreaks, is studied.
 - Although three out of four students were willing to provide healthcare assistance, they recognise not feeling specially prepared in the field of intensive care and demand training with simulation in this field.

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52 **INTRODUCTION**

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54 Following the declaration by the World Health Organization (WHO) of Coronavirus
55 Disease Pandemic (COVID-19) on 11 March 2020, much of the world has faced one of
56 its biggest health challenges (World Health Organization, n.d.).
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3 In Spain, as of 6 June 2020, a total of 27135 deaths have been recorded, 11604 persons
4 admitted to intensive care units, and 124302 hospital admissions (Ministerio de Sanidad
5 España. Centro de Coordinación de alertas y emergencias sanitarias, 2020). The Carlos III
6 Institute of Health (ISCIII) through the National Epidemiological Surveillance Network
7 (RENAVE), publishes the report on the situation of COVID-19 among health staff in
8 Spain weekly. As of May 29, 2020, 40961 cases and 52 deaths were of health workers,
9 accounting for 24.1% of all confirmed cases of Covid-19, considering health workers as
10 a heterogeneous group of hospital, health centres and/or social-health centres workers
11 (Instituto de Salud Carlos III, 2020).
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19 **BACKGROUND**

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22 In the 22 to 28 March week, the epidemiological peak of hospital admissions was reached
23 at around 4000 daily admissions, which resulted in the healthcare collapse of many
24 Spanish hospitals (Instituto de Salud Carlos III, n.d.). This same phenomenon was
25 repeated in other parts of the world (WHO, 2020; Xiong & Peng, 2020). The different
26 Spanish hospitals progressively adapted and transformed their units of other specialties
27 into COVID-19 units and created from scratch COVID-19 units to attend to the needs of
28 the high number of patients with this disease. However, as the epidemic progressed in
29 Spain, human resources to care for these patients became insufficient (Instituto de Salud
30 Carlos III, 2020). In view of this unprecedented situation, the Government of Spain
31 published a ministerial order in the Official State Gazette (BOE) of March 15, 2020
32 (Ministerio de Sanidad de España, 2020), providing that students of nursing and medicine
33 degrees could join in to work always as "support or under the supervision of a
34 professional". This also occurred in other countries in a similar way (Jackson et al., 2020;
35 Swift et al., 2020).
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47 However, this student collaboration has gone beyond healthcare support, as the lack of
48 resources has put students with no working experience in the front line. Unions point out
49 that though this is not a widespread practice, there are public and private hospitals with
50 students in emergency services and intensive care units being subject to unnecessary
51 stress and devastating emotional shock (ABC España, 2020; Radio Television Española,
52 2020; Redacción Médica, 2020). On the other hand, other authors have observed that
53 healthcare professionals who treat patients with Covid-19 present an increased risk of
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3 mental health problems such as anxiety, depression, insomnia, and stress (Liu et al.,
4 2020).

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7 There is currently no publication describing the role of nursing and medical students in
8 this pandemic. In Spain, a brief study was conducted on the knowledge and attitudes of
9 102 nursing and medical students on Covid-19 and their potential participation (Cervera-
10 Gasch et al., 2020), where 63.0% said they did not feel prepared.

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13 For this reason, it is considered relevant to describe the experience of Nursing university
14 students during the Covid19 health crisis in Spain, as well as their degree of preparedness
15 and what type of training improvements may be proposed to improve their training in the
16 face of new waves of this pandemic.

17 18 19 20 21 22 23 **METHODS**

24 25 26 *Design and selection of subjects under study*

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28 Cross-sectional observational study on students enrolled in the 4th course of the Nursing
29 Degree in Spain, between April 25 and May 15, 2020. There were no exclusion criteria.

30 31 32 *Sources of information*

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34 For data collection, an anonymous online self-prepared questionnaire was used
35 containing 34 items (4 open questions, 30 closed questions) about sociodemographic
36 characteristics, training characteristics, their participation in healthcare aid, perceived
37 degree of preparedness to carry out their care work, and training needs to improve their
38 professional competence.

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The questionnaire had been previously piloted on a sample of 20 students, from which
the main training needs that were declared to improve professional competence were
extracted. Based on these data, the items and responses of the final questionnaire were
created. This questionnaire was completely anonymous and distributed through the
Nursing Association, students' unions and student organisations of Spain. Before starting
to fill in the questionnaire, students had to read a fact sheet on the study, its objectives,
etc., and give their consent to participate by ticking a box designed for that purpose. An
email address was put at their service to answer all the questions raised during the
completion of the questionnaire.

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11 The following variables were collected:

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13 Sociodemographic variables included age, sex, university to which they belonged, and
14 province. Training variables included: previous clinical rotations in special units (ICU,
15 Resuscitation, Surgical, Emergencies), university and clinical training in personal
16 protective equipment (PPE) and mechanical ventilation. As variables related to the degree
17 of preparedness, 4 Likert-type questions were included for Hospitalisation, Primary Care,
18 Emergencies, and ICU areas. Variables related to their participation included:
19 participation in healthcare aid, reasons for non-participation, service where they
20 participated, work carried out, contact with patients infected by Covid-19, and duration
21 of their care work.
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29 *Statistical analysis used*

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32 First, a descriptive analysis was performed using absolute and relative frequencies for
33 categorical variables, mean with standard deviation (SD) for the quantitative variables
34 with normal distribution, and median (Md) with interquartile range (IQR) for ordinal
35 variables. Then, a bivariate analysis was performed using the Kruskal Wallis
36 nonparametric test between prior PPE training and mechanical ventilation and the degree
37 of preparedness to assist Covid-19 patients. All calculations were performed using the
38 spSS 24.0 programme.
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45 *Research Ethics*

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48 This study was approved by the Ethics Committee of the General Nursing Council.

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50 The study methods were compliant with the STROBE checklist.

51 **RESULTS**

52 *Characteristics of the study sample*

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55 A total of 503 nursing students from all over Spain participated. The mean age was 22.7
56 years (SD = 3.18), with 89.4% (433) of women. 49.3% (248) had performed clinical
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3 practices in intensive care units, 58.4% (294) had not received training in PPE at
4 university, and 63.4% (319) had received it in their hospitals of residency. As for training
5 in mechanical ventilation, 17.5% (88) had not received any training at university, and
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7 39.5% (199) had not received it in their hospitals of residency either. The training
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9 characteristics are presented in more detail in Table 1. The distribution of students by
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11 university and province can be found in supplementary tables 1 and 2.
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14 *Degree of preparedness and participation in healthcare during the pandemic*

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17 Students were then asked about their degree of preparedness for caring for Covid-19
18 patients in different fields. The area in which students felt least prepared was critical care,
19 where only 3.4% (17) expressed feeling very prepared, followed by emergency services'
20 nurses, with 4.6% (23), primary care with 8.7% (44), and finally hospitalisation wards
21 with 12.5% (63). Likert-type responses can be found in Table 2.
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27 As for their participation, 73.8% of students who completed the questionnaire offered to
28 participate in healthcare aid, and 44.7% finally participated in it (225). The most common
29 support destination was hospitalisation wards in 54.7% (123) of cases, followed by UCIs
30 with 20.4% (46). The mean duration of the aid was 42.1 days (SD = 13.7), during which
31 27.8% stated to have performed usual nursing tasks (medication administration,
32 peripheral pathway channelling, etc.) without supervision from another professional, and
33 47.7% (98) cared for patients with Covid-19 without supervision as any other nurse.
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35 Finally, 51.9% (122) stated not to be satisfied with the economic and safety conditions
36 during their work (Table 2).
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43 *Relationship between training and degree of preparedness*

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45 The next step was to determine whether the students' perceived degree of preparedness
46 was related to the training they had received in terms of PPE and mechanical ventilation
47 for the different areas of care. In this regard, a statistically significant association was
48 observed between training received at the hospital level and the degree of preparedness
49 in all areas. On the other hand, the area where the most correlation between training and
50 preparedness is observed is in the field of intensive care, where the median scores of
51 training carried out with simulations are higher than scores for theoretical training in all
52 cases (Table 3).
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Areas of improvement

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3 Finally, students were asked, based on their responses during the pilot study, to indicate
4 the degree of importance of enhancing certain teaching actions to improve students'
5 training in the face of a new possible wave of the pandemic. These stated, with the highest
6 median scores (5 points, very important), that simulations should be improved or
7 enhanced to improve anxiety and stress levels in the management of critical patients; also
8 simulation in ventilatory support; and the realisation of mandatory practices in services
9 where ventilators exist (Table 4).
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15 16 **DISCUSSION**

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18 In order to describe the participation of nursing students and their training needs during
19 the Covid-19 pandemic in Spain, an online questionnaire was published that was
20 answered by 503 students of the 4th course of the Nursing degree.
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24 In our sample, almost 2/3 parts of the students offered to participate during the health
25 emergency, and almost half of them participated in direct care. Regarding this last point,
26 there are currently no official volunteering participation figures. However, in a study
27 performed on nursing students where they were involved in participating in a potential
28 influenza pandemic, 67.9% stated they would participate as volunteers, and so, the
29 authors were alerting to the need to create recruitment protocols already in 2010 (Yonge
30 et al., 2010).
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37 Although students' participation in this pandemic was designed to be under the
38 supervision of another professional, a high percentage of them worked as any other nurse
39 and in direct contact with infected patients. It is therefore necessary to recognise and value
40 nursing students' aid in these moments and to be aware of the risks they have faced
41 without having a consolidated degree or training, as also happens with medical
42 students (Representatives of the STARSurg Collaborative, EuroSurg Collaborative, 2020)
43 and residents without having completed their specialty (Legido-Quigley et al., 2020). This
44 experience may also have an impact on their mental health as has happened in other
45 pandemics, among which we may highlight Severe Acute Respiratory Syndrome (SARS)
46 and Middle East Respiratory Syndrome (MERS), where health workers suffered from
47 high stress related to the high risk of infection, stigmatisation, lack of staff, and
48 uncertainty (Lee et al., 2018; Maunder et al., 2003; Swift et al., 2020). In fact, during this
49 pandemic, Chinese students who were outside their country have already suffered
50 isolation and stigmatisation for being considered potential carriers (Zhai & Du, 2020). All
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3 this is joined by the low salary these students have received, that is between 900 euros
4 and 1200 euros depending on whether they were Nursing and/or Medical students, with
5 precarious contracts that do not assure them whether they will be renewed or how long
6 they will continue working (El Español, 2020).
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11 On the other hand, students who had participated in training experiences for the
12 management of PPE and mechanical ventilation felt more prepared to assist patients with
13 Covid-19, especially in the area of critical care. In addition, simulation training presented
14 better scores with respect to the degree of preparedness than exclusively theoretical
15 training. These results are in line with several meta-analyses of clinical trials conducted
16 in both nursing students (Cant & Cooper, 2017; La Cerra et al., 2019) and medical
17 students (Beal et al., 2017), where simulation training has been observed to be one of the
18 best teaching methodologies, especially for skills acquisition.
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26 This result goes in line with the suggestions proposed by students to improve training in
27 the management of patients with Covid-19. Among the areas of teaching improvements
28 proposed by students, simulations to improve anxiety and stress in the management of
29 critical patients, simulation in ventilatory support, and the realisation of mandatory
30 practices in services where there are ventilators were highlighted. In this way, students
31 also bring to light the need to better train them in the field of critical care. In Spain, there
32 is no specialist nurse in critical care (Cubel, 2006), and training in this field is carried out
33 by each centre, as well as self-training and the professional experience acquired over the
34 years. During this pandemic, the need to improve this area of care has been highlighted
35 as, although there may be sufficient material resources such as ventilators, their
36 management is highly complex and requires qualified staff that cannot be trained in just
37 days. For this reason, if this apprenticeship were enhanced during the training degree by
38 including mandatory practices and specific simulation workshops, students could be
39 better prepared for new situations alike.
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51 Among the study limitations, a selection bias is possible since this was an online
52 questionnaire and participation might be conditioned by factors other from the study
53 which are difficult to control. Another limitation also attributable to the online part
54 system is that some students did not participate due to lack of media disposition, although
55 it is considered unlikely nowadays. With all, the distribution by sex and age is
56 representative of the nursing students' population.
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3 Among the strength of the study, it stands out for being the first remarkable one to
4 describe the experience of nursing students during the Covid-19 pandemic which may
5 serve to guide teaching leaders on the urgent need to adopt students' training suggestions.
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9 **CONCLUSIONS**

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11 Students have been vital resources for our health system and society when they have been
12 needed. It is now up to us, both teachers and health authorities, to share their efforts by
13 implementing the necessary improvements in training and safety measures not only
14 because their health may become affected as well as patient's safety, but also because
15 they will be essential parts in future pandemics.
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20 **RELEVANCE TO CLINICAL PRACTICE**

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22 Three out of four students were willing to provide healthcare assistance, they recognise
23 not feeling specially prepared in the field of intensive care and demand training with
24 simulation in this field.
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30 Students have been vital resources for our health system and society when they have been
31 needed. It is now up to us both teachers and health authorities, to share their efforts by
32 implementing the necessary improvements in training and safety measures not only
33 because these affects the health and safety of the patient, but because they will be essential
34 parts in future pandemics.
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For Peer Review

Table 1: Characteristics of the study subjects


Variable	n (%)
	n=503
Age years (Mean ± SD)	22.7 (3.18)
Sex	
Male	70 (13.9)
Female	433 (89.4)
Previous clinical rotations	
Intensive Care Unit	248 (49.3)
Resuscitation Service	151 (30.0)
Surgery Service	281 (55.9)
Emergency Service	293 (58.3)
PPE training at university	
No	294 (58.4)
Yes, but only theoretical	161 (32.0)
Yes, and with simulation	48 (9.5)
PPE training in the hospital of residency	
No	319 (63.4)
Yes, but only theoretical	85 (16.9)
Yes, and with simulation	99 (19.7)
Mechanical ventilation training at university	
No	88 (17.5)
Yes, but only theoretical	260 (51.7)
Yes, and with simulation	155 (30.8)
Mechanical ventilation training in the hospital of residency	
No	199 (39.6)
Yes, but only theoretical	87 (17.3)
Yes, and with simulation 	217 (43.1)

Table 2. Degree of preparedness and healthcare aid participation among Nursing students

Variable	n (%)
You feel prepared to work with Covid-19 patients in the field of critical care	n=503
Not at all	114 (22.7)
Little	165 (32.8)
Somehow	139 (27.6)
Quite	68 (13.5)
Very	17 (3.4)
You feel prepared to work with Covid-19 patients in the field of hospitalization	n=503
Not at all	19 (3.8)
Little	41 (8.2)
Somehow	160 (31.8)
Quite	220 (43.7)
Very	63 (12.5)
You feel prepared to work with Covid-19 patients in the field of emergencies	n=503
Not at all	83 (16.5)
Little	126 (25.0)
Somehow	152 (30.2)
Quite	119 (23.7)
Very	23 (4.6)
You feel prepared to work with Covid-19 patients in the field of Primary Care	n=503
Not at all	22 (4.4)
Little	54 (10.7)
Somehow	161 (32.0)
Quite	222 (44.1)
Very	44 (8.7)
During the crisis, you have offered for healthcare aid	n=503
Yes	368 (73.2)

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3	No	135 (26.8)
4		
5	Reason for not participating (multiple answer)	n=135
6		
7	Fear of getting infected	17 (12.5)
8		
9	Fear of infecting the family	56 (41.5)
10		
11	I don't feel prepared	46 (34.1)
12		
13	Other reasons	69 (51.1)
14	Service in which healthcare has been offered	n=225
15		
16	Resuscitation	6 (11.1)
17		
18	Emergencies	25 (5.0)
19		
20	Hospitalisation	123 (54.7)
21		
22	Nursing homes	22 (9.8)
23		
24	Primary care	3 (1.3)
25		
26	ICU	46 (20.4)
27		
28	During healthcare aid, you have carried out nursing tasks	
29	(medication administration, peripheral pathway channelling,	n=261
30	catheterisation, etc)	
31		
32	No	24 (4.8)
33		
34	Yes, but under the supervision of a professional	78 (15.5)
35		
36	Yes, and without supervision, as any other nurse	140 (27.8)
37		
38	During healthcare aid, you have assisted Covid-19 patients	n=263
39		
40	No	82 (16.3)
41		
42	Yes, but under the supervision of a professional	60 (25.0)
43		
44	Yes, and without supervision, as any other nurse	98 (47.7)
45		
46	Satisfaction with the working conditions (both safety and	n=235
47	economical) of the healthcare aid contract	
48		
49	No	122 (51.9)
50		
51	Yes	113 (48.1)
52		
53	Duration of healthcare aid; days (mean \pm SD)	42.1 (13.7)
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Table 3: Relationship between PPE and mechanical ventilation training and perceived degree of preparedness to work with Covid-19 patients

Degree of preparedness to work with Covid-19 patients (Likert-type scale 1-5) in:

Training	Primary Care		Hospitalisation ward		Emergencies		Intensive Care	
	Md (IQR)	P value	Md (IQR)	P value	Md (IQR)	p value	Md (IQR)	P value
PPE training at university		<0.001		0.164		0.060		0.018
No	3 (1)		4 (1)		3 (2)		2 (2)	
Yes, but only theoretical	4 (1)		4 (1)		3 (2)		2 (1)	
Yes, and with simulation	4 (1)		4 (1)		3 (2)		3 (2)	
PPE training in the hospital of residency		0.002		0.002		0.022		0.003
No	3 (1)		4 (1)		3 (1)		2 (2)	
Yes, but only theoretical	4 (1)		4 (1)		3 (2)		2 (1)	
Yes, and with simulation	4 (1)		4 (1)		3 (2)		3 (2)	
Mechanical ventilation training at university		0.225		0.127		0.140		<0.001
No	3 (1)		3 (1)		3 (1)		2 (2)	
Yes, but only theoretical	4 (1)		4 (1)		3 (2)		2 (1)	
Yes, and with simulation	4 (1)		4 (1)		3 (2)		3 (2)	
Mechanical ventilation training in the hospital of residence		0.009		0.008		0.019		<0.001
No	3 (1)		3 (1)		3 (1)		2 (2)	
Yes, but only theoretical	4 (1)		4 (1)		3 (2)		2 (2)	
Yes, and with simulation	4 (1)		4 (1)		3 (2)		3 (2)	

Table 4: Students' assessment of specific training actions to improve the degree of preparedness to assist Covid_19 patients

Actions	Not at all	Little	Somehow	Quite	Very	Score Md (IQR)
	1	2	3	4	5	
	n (%)	n (%)	n (%)	n (%)	n (%)	
Simulations to improve teamwork and communication between professionals	9 (1.8)	15 (3.0)	111 (22.1)	176 (35.0)	192 (38.2)	4 (2)
Simulations to improve communication with patients and families	6 (1.2)	23 (4.6)	109 (21.7)	163 (32.4)	202 (40.2)	4 (2)
Simulations to improve anxiety and stress in managing critical patients	8 (1.6)	18 (3.2)	94 (18.7)	125 (24.9)	260 (51.7)	5 (1)
Mechanical ventilation simulations	7 (1.4)	8 (1.6)	78 (15.5)	96 (19.1)	314 (62.4)	5 (1)
Training in epidemiology	15 (3.0)	50 (9.9)	171 (34.0)	158 (31.4)	109 (21.7)	4 (1)
Training in palliative care	5 (1.0)	16 (3.2)	91 (18.1)	145 (28.8)	246 (48.9)	4 (1)
Relation of compulsory training in services with ventilators	6 (1.2)	8 (1.6)	86 (17.1)	91 (18.1)	312 (62.0)	5 (1)

Supplementary tables 1. Distribution of participants by university

Universities	n	%
Antonio de Nebrija University	2	0.4
Autonomous University of Barcelona	1	0.2
Autonomous University of Madrid	24	4.8
Cardenal Herrera - CEU University	1	0.2
Valencia Catholic University	3	0.6
Complutense University	1	0.2
University of Alcala	19	3.8
University of Alicante	8	1.6
University of Barcelona	9	1.8
University of Cadiz	2	0.4
University of Cantabria	1	0.2
University of Castilla la Mancha	132	26.2
University of Cordoba	3	0.6
University of Extremadura	10	2.0
University of Granada	4	0.8
University of Huelva	2	0.4
University of Jaen	29	5.8
University of La Coruña	15	3.0
University of La Laguna	16	3.2
University of La Rioja	8	1.6
University of the Balearic Islands	13	2.6
University of Lleida	31	6.2
University of Malaga	2	0.4
University of Murcia	20	4.0
University of Navarra	17	3.4
University of Oviedo	6	1.2
University of Salamanca	5	1.0
University of Santiago de Compostela	20	4.0
University of Sevilla	2	0.4
University of Valencia	2	0.4
University of Valladolid	4	0.8
University of Vic - Central University of Catalunya	3	0.6
University of Vigo	1	0.2
University of Zaragoza	13	2.6
Francisco de Vitoria University	18	3.6
International University of Catalunya	1	0.2

Pompeu Fabra University	1	0.2
Pontificia Comillas University	2	0.4
Navarra Public University	3	0.6
Ramon Llull University	1	0.2
Rey Juan Carlos I University	2	0.4
Rovira i Virgili University	7	1.4
San Pablo - CEU University	14	2.8
Not specified university	25	5.0
Total	503	100.0

Supplementary tables 1. Distribution of participants by province of origin

Province	n	%
Alava	1	0.2
Albacete	1	0.2
Alicante	9	1.8
Asturias	7	1.4
Avila	10	2.0
Badajoz	2	0.4
Baleares	13	2.6
Barcelona	17	3.4
Caceres	8	1.6
Cadiz	2	0.4
Cantabria	1	0.2
Ceuta	4	0.8
Ciudad Real	67	13.3
Autonomous Community of Madrid	91	18.1
Cordoba	3	0.6
Cuenca	37	7.4
Huelva	2	0.4
Jaen	29	5.8
La Coruña	35	7.0
La Rioja	8	1.6
Lerida	31	6.2
Malaga	2	0.4
Navarra	21	4.2
Palencia	1	0.2
Region of Murcia	21	4.2
Santa Cruz de Tenerife	16	3.2

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Sevilla	2	0.4
Tarragona	8	1.6
Teruel	13	2.6
Toledo	27	5.4
Valencia	8	1.6
Valladolid	3	0.6
Zamora	3	0.6
Total	503	100.0

For Peer Review

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found PAGES 1
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported PAGE 3,4
Objectives	3	State specific objectives, including any prespecified hypotheses PAGE 4
Methods		
Study design	4	Present key elements of study design early in the paper PAGE 4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection PAGE 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants PAGE 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable PAGE 5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group PAGE 5
Bias	9	Describe any efforts to address potential sources of bias PAGE 5
Study size	10	Explain how the study size was arrived at PAGE 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why PAGE 5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding PAGE 5 (b) Describe any methods used to examine subgroups and interactions PAGE 5 (c) Explain how missing data were addressed PAGE 5 (d) If applicable, describe analytical methods taking account of sampling strategy PAGE 5 (e) Describe any sensitivity analyses PAGE 5
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed PAGE 5,6 (b) Give reasons for non-participation at each stage PAGE 5,6 (c) Consider use of a flow diagram PAGE 5,6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders PAGE 5,6 (b) Indicate number of participants with missing data for each variable of interest PAGE 5,6
Outcome data	15*	Report numbers of outcome events or summary measures PAGE 5,6
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included PAGE 5,6 (b) Report category boundaries when continuous variables were categorized

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **PAGE 5,6**

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses PAGE 5,6
Discussion		
Key results	18	Summarise key results with reference to study objectives PAGE 7,8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias PAGE 8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence PAGE 7,8
Generalisability	21	Discuss the generalisability (external validity) of the study results PAGE 8
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based NO FUNDING

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. Information on the STROBE Initiative is available at www.strobe-statement.org.