COVID-19 AND ("Intensive Care Unit" OR ICU) AND psychol* AND (implicat* OR intervent*) PubMed 30-9-2022 → 214 results + ClinicalTrials.gov Disease: COVID-19 AND Other terms: intensive care unit AND psychological 30-9-2022 → 41 results

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215	Psychological Impact of Medical Evacuations on Families of Patients Admitted to Intensive Care Unit for Severe COVID-19 (IPES-CoV). ClinicalTrials.gov Identifier: NCT05421182. Principal Investigator: Vincent Peigne, CH Metropole Savoie. Completed	No data
216	Ethical and Psychological Support for Health Care Professions in Intensive Care Units in the COVID19 Pandemic Context: Adequacy With Needs and Psychological Impact Crisis and Post-crisis (PsyCOVID). ClinicalTrials.gov Identifier: NCT04441476. Centre Hospitalier Universitaire Dijon. Completed	No data
217	Evaluation of Psychological Impact of Group Therapy for Patients Who Have Been Hospitalized in Intensive Care During COVID-19 Pandemic: Exploratory Study (GPR COVID). ClinicalTrials.gov Identifier: NCT04747405. Study director: Romain Percot, Cebtre Hospitalier Metropole Savoie. Active, not recruiting	No data
218	Psychological Impact of COVID-19 Outbreak on Caregivers (PSY-CO-ICU). ClinicalTrials.gov Identifier: NCT04511780. Principal Investigator: Jean Yves Lefrant, Centre Hospitalier Universitaire de Nîmes. Not yet recruiting	No data
219	Copeptin and Psychological Stress of Medic During COVID-19 Pandemic (COVID-19). Contact: Hala Mourad Demerdash, Alexandria University, Egypt, Completed	No data
220	Psychological Symptoms and Families of COVID-19 Patients (Relieving the Burden of Psychological Symptoms Among Families of Critically Ill Patients With COVID-19). ClinicalTrials.gov Identifier: NCT04501445. Rush University Medical Center, Central Michigan University, Completed	No data
221	Burnout Among Caregivers Facing COVID-19 Health Crisis at a Non-conventional Intensive Care Unit Compared to a Conventional Intensive Care Unit. ClinicalTrials.gov Identifier: NCT04346810. Responsible: Hakim Harkouk, Hôpital Raymond Poincaré, status Unknown	No data
222	Follow-up of Patients with COVID-19. (TeleRea'nCo). ClinicalTrials.gov Identifier: NCT04609839. Resp. Eric Demonsant, Principal Investigator: Laurence Kessler, Hopitaux Universitaires de Strasbourg, Recruiting	No data
223	Tele-based Psychological Emotional Support for Informal CARegivers of COVID-19 Patients in Intensive Care (CO-CarES). ClinicalTrials.gov Identifier: NCT04409821. Principal Investigator: Annika von Heymann, Department of Oncology, Rigshospitalet, Denmark, Recruiting	No data
224	Chronic Pain in COVID-19 Patients Discharged From Intensive Care Unit. ClinicalTrials.gov Identifier: NCT04940208. Resp.; Mikhail Dziadzko, Hôpital de la Croix-Rousse, Completed	No data

225	Mental Health of Professionals Working in Pediatric Intensive Care Units During the COVID-19 Pandemic. ClinicalTrials.gov Identifier: NCT04846907. Principal Investigator: Fernanda L Setta, D'Or Institute for Research and Education, Rio De Janeiro, Brazil, Active, not recruiting	No data
226	Stress Biomarkers Leading to Professional Burnout Among People Involved in a Mobile Intensive Care Unit During the COVID-19 Pandemic (AUTONOMIC). ClinicalTrials.gov Identifier: NCT04365335. Direction Centrale du Service de Santé des Armées, Completed	No data
227	Social and Psychological Impacts of SARS-Cov-2 Pandemic Period in the Obese Population. (OBIMPACOV). ClinicalTrials.gov Identifier: NCT04910607. Arnaud Alessandrin; Blandine Gatta-Cherifi, University Hospital, Bordeaux-Région Nouvelle Aquitaine. Recruiting	No data
228	Stress Related Disorders in Family Members of COVID-19 Patients Admitted to the ICU. ClinicalTrials.gov Identifier: NCT04476914. Completed	No data
229	Psychological and Ethical Support for Hospital Professionals During the COVID-19 Pandemic: Suitability and Post-crisis Implications for the Experience of All Professionals (PsyCOVID All P). ClinicalTrials.gov Identifier: NCT04944394. Centre Hospitalier Universitaire Dijon, Completed	No data
230	Groenveld T, Achttien R, Smits M, de Vries M, van Heerde R, Staal B, van Goor H; COVID Rehab Group. Feasibility of Virtual Reality Exercises at Home for Post-COVID-19 Condition: Cohort Study. JMIR Rehabil Assist Technol. 2022;9(3):e36836. doi: 10.2196/36836.	**Included**
231	French Cohort of COVID-19 Patients With Post-intensive Care Syndrome (COREADOM). ClinicalTrials.gov Identifier: NCT04590170. Marie-Martine Marie-Martine, Marie Benhammani-Godard, Hôpitaux de Paris. Recruiting	No data
232	Post-intensive Care Follow-up of Patients Hospitalized for an Acute Respiratory Distress Syndrome Caused by COVID-19 (RE-CoV-ERY). ClinicalTrials.gov Identifier: NCT04619368. Principal Investigator: Fanny Bounes, University Hospital, Toulouse, Recruiting	No data
233	One-year Outcomes in Survivors of the Severe COVID-19 Pneumonia (CO-Qo-ICU) (CO-Qo-ICU). ClinicalTrials.gov Identifier: NCT04401111. Contacts: Clément Saccheri, Jean Dellamonica, Centre Hospitalier Universitaire de Nice, Status Unknown	No data
234	Anxiety and Burnout in Anesthetists and Intensive Care Unit Nurses During Covid-19 Pandemic. ClinicalTrials.gov Identifier: NCT04604119. Contact: Sultan Acar Sevinç, Sisli Hamidiye Etfal Education and Training Hospital, Completed	No data
235	Prioritising Prevention of COVID-19 in Persons With Cancer in the French West Indies (RESILIENCE). ClinicalTrials.gov Identifier: NCT04768153. CHU Martinique, Fort-de-France, Martinique, Active, not recruiting	No data
236	Nursing Perspective on Burnout and Medical Errors in the Intensive Care Unit During Covid-19 Pandemic. ClinicalTrials.gov Identifier: NCT04371302. Responsible: Samuel E H Tsan, Sungai Buloh Hospital-University of Malaya. Terminated (Logistical problems, administrative issues)	No data
237	Follow-up of Patients With Previous SARS-CoV-2 Infection: Long-term Damage Assessment. ClinicalTrials.gov Identifier: NCT05359159. Clara Balsano, University of L'Aquila, Recruiting	No data
238	Cohort Follow-up of Survivors of Hospitalization for COVID-19 During the 2nd Wave of the Epidemic in France (COMEBAC 2). ClinicalTrials.gov Identifier: NCT04934202, Tai Pham, Hôpitaux de Paris, Recruiting	No data
239	Impact and Sequelae of High Ventilatory Drive in Critically Ill COVID-19 Patients. ClinicalTrials.gov Identifier: NCT05363332. Candelaria de Haro, Corporacion Parc Tauli, Recruiting	No data
240	Anxiety and Work Resilience Among Tertiary University Hospital Workers During the COVID-19 Outbreak: An Online Survey (PSY_CO_CHU). ClinicalTrials.gov Identifier: NCT04358640, Centre Hospitalier Universitaire de Nīmes, Completed	No data
241	Post ICU Follow up in Patients With Severe SARS-CoV-2 Infection (Covid-19). ClinicalTrials.gov Identifier: NCT04491214. Locations France Hôpitaux Universitaires de Strasbourg (Nouvel Hôpital Civil), Completed	No data
242	Amsalem D, Lazarov A, Markowitz JC, Gorman D, Dixon LB, Neria Y. Increasing treatment-seeking intentions of US veterans in the Covid-19 era: A randomized controlled trial. Depress Anxiety. 2021;38(6):639-647. doi: 10.1002/da.23149. Epub 2021 Mar 18.	Outcome
243	Psychological Impact, Mental Health and Sleep Disorder Among Patients Hospitalized and Health Care Workers During the 2019 Coronavirus Outbreak (COVID-19). ClinicalTrials.gov Identifier: NCT04497246. Principal Investigator: Sophie Levy, CHU Brugmann, Brussels, BE. Completed	No data
244	Sarcopenia and Related Factors in Coronavirus Disease 2019 (COVID-19) Following Intensive Care. ClinicalTrials.gov Identifier: NCT05474157, Principal Investigator: Ozden Ozyemisci Taskiran, Prof Koç University School of Medicine, Istanbul, Turkey, Terminated (technical reasons)	No data
245	Impact of COVID-19 on Mental Health of Health Care Workers (COVID-Impact). ClinicalTrials.gov Identifier: NCT04382196. Study Director: Gilbert Lemmens, University Hospital, Ghent, Active, not recruiting	No data
246	Sociodemographic, Clinical, Quality of Life and Health Care Conditions in COVID-19 Survivors. ClinicalTrials.gov Identifier: NCT05185674. Principal Investigator: Javier Eslava, Professor, Universidad Nacional de Colombia, Active, not recruiting	No data
247	Sociodemographic, Clinical, Quality of Life and Health Care Conditions in COVID-19 Survivors. ClinicalTrials.gov Identifier: NCT05185674. Sponsor: Javier Eslava, Universidad Nacional de Colombia; Principal Investigator: Laura C Loaiza-Fernandez, MD,MSc, Universidad Nacional de Colombia, Active, not recruiting	No data
248	Perceived Stress Among ICU Medical Staff During COVID-19 Crisis (ICUcovid). ClinicalTrials.gov Identifier: NCT04604769. Principal Investigator: Anne-Sophie Nyssen, Université de Liège, Completed	No data
249	Early Care Program for the Management of Post-ICU Syndrome and Chronic Pain After COVID-19 Infection. (PAIN-COVID). ClinicalTrials.gov Identifier: NCT04394169, Tomas Miguel Cuñat Lopez, Hospital Clinic of Barcelona, Principal Investigator: Antonio José Ojeda Niño, MD Pain unit physician, Completed	No data
250	Resilience Evaluation of Caregivers During the SARS-CoV2 Epidemic Period: Prospective Cohort. (Resi-CoV). ClinicalTrials.gov Identifier: NCT04349163. Principal Investigator: Delphine Douillet, UH Angers , Completed	No data
251	COVID-19 Follow up Intensive Care Studies (COFICS), ClinicalTrials.gov Identifier: NCT04460170, Willem Dieperink, PhD, University Medical Center Groningen, Status Unknown	No data
252	COVID-19 and the Brain. ClinicalTrials.gov Identifier: NCT04726176. Kevin De Pauw, Vrije Universiteit Brussel, Universitair Ziekenhuis Brussel. Completed	No data
253	A Brief GAmeplay Intervention for NHS ICU Staff Affected by COVID-19 Trauma (GAINS Study) (GAINS). ClinicalTrials.gov Identifier: NCT04992390. Principal Investigator: Emily Holmes, Uppsala University, Active, not recruiting	No data
254	Silva-Jose C, Sánchez-Polán M, Diaz-Blanco Á, Coterón J, Barakat R, Refoyo I. Effectiveness of a Virtual Exercise Program During COVID-19 Confinement on Blood Pressure Control in Healthy Pregnant Women. Front Physiol. 2021;12:645136. doi: 10.3389/fphys.2021.645136.	Outcome

255	Silva-Jose C, Sánchez-Polán M, Díaz-Blanco Á, Pérez-Medina T, Carrero Martínez V, Alzola I, Barakat R, Refoyo I, Mottola MF. Influence of a Virtual Exercise Program throughout Pregnancy during the COVID-19 Pandemic on Perineal Tears and Episiotomy Rates: A Randomized Clinical Trial. J Clin Med. 2021;10(22):5250. doi: 10.3390/jcm10225250.	Outcome
256	Silva-Jose C, Sánchez-Polán M, Barakat R, Díaz-Blanco Á, Carrero Martínez V, García Benasach F, Alzola I, Mottola MF, Refoyo I. Exercise throughout Pregnancy Prevents Excessive Maternal Weight Gain during the COVID-19 Pandemic: A Randomized Clinical Trial. J Clin Med. 2022;11(12):3392. doi: 10.3390/jcm11123392.	Outcome
257	Silva-Jose C, Sánchez-Polán M, Barakat R, Díaz-Blanco Á, Mottola MF, Refoyo I. A Virtual Exercise Program throughout Pregnancy during the COVID-19 Pandemic Modifies Maternal Weight Gain, Smoking Habits and Birth Weight-Randomized Clinical Trial. J Clin Med. 2022;11(14):4045. doi: 10.3390/jcm11144045.	Outcome
258	Published Tiete J, Guatteri M, Lachaux A, Matossian A, Hougardy JM, Loas G, Rotsaert M. Mental Health Outcomes in Healthcare Workers in COVID-19 and Non-COVID-19 Care Units: A Cross-Sectional Survey in Belgium. Front Psychol. 2021;11:612241. doi: 10.3389/fpsyg.2020.612241.	Lumping
259	Reducing Post-traumatic Stress Disorder After ICU Discharge With the IPREA3 Program (PTSD-REA). ClinicalTrials.gov Identifier: NCT03991611. Principal Investigator: Pierre Kalfon, MD PhD, Centre Hospitalier of Chartres, Active, not recruiting	No data

Included N=65
Excluded N=194
- Outcome N=52
- No data N=38
- Reviews N=25
- Protocol N=17
- Opinion N=16
- Inadequate N=16
- Unfocused N=12
- Lumping N=6
- Case N=5
- Unrelated N=5
- Overlap N=1
- No COVID-19 N=1
- Post mortem N=0
- Animal N=0
- Duplicates N=0

ClinicalTrials.gov September 30 2022, Condition or disease: Covid-19; Other terms: intensive care unit AND psychological → 41 results

N°	Status	Study	Condition	Intervention	
1	Completed	**Psychological** Impact of Medical Evacuations on Families of Patients Admitted to **Intensive Care Unit** for Severe **COVID-19**	**COVID-19** Stress Disorders, Post-Traumatic	Other: Revised Impact of Event Scale Other: Hospital Anxiety and Depression scale Other: 36-Item Short Form Survey (and 3 more...)	CH Metropole Savoie Chambéry, France
2	Completed	Ethical and **Psychological** Support for Health **Care** Professions in **Intensive Care Units** in the **COVID19** Pandemic Context: Adequacy With Needs and **Psychological** Impact Crisis and Post-crisis	**Psychological** Strain	Other: Questionnaires Other: **psychological** and sociological interviews	Chu Dijon Bourgogne Dijon, France
3	Active, not recruiting	Evaluation of **Psychological** Impact of Group Therapy for Patients Who Have Been Hospitalized in **Intensive Care** During **COVID-19** Pandemic: Exploratory Study	**Intensive Care Unit** Syndrome **Covid19** Anxiety Depression	Other: therapy group	CH Métropole Savoie Chambéry, France
4	Not yet recruiting	**Psychological** Impact of **COVID-19** Outbreak on Caregivers	Critical Illness **Covid19** Stress Disorders, Post-Traumatic	Other: questionnaire filling	**Intensive Care Unit**, CHU d'Amiens, **Intensive Care Unit**, CHU d'Angers, CHU de Besançon, France (+ 48...)
5	Completed	Copeptin and **Psychological** Stress of Medic During **COVID-19** Pandemic	**Psychological** Stress Hemostatic Disorder		Alexandria University Faculty of Medicine, Alexandria, Egypt
6	Unknown †	Burnout Among Caregivers Facing **COVID-19** Health Crisis at a Non-conventional **Intensive Care Unit** Compared to a Conventional **Intensive Care Unit**	**COVID-19** Burnout, Caregiver **Intensive Care Unit** Stress, **Psychological**	Other: Patient management suffering of coronavirus infection	Hôpital Raymond Poincaré, 92380 Garches, France
7	Completed	**Psychological** Symptoms and Families of **COVID-19** Patients	Family Members Post **Intensive Care Unit** Syndrome Post Traumatic Stress Disorder	Behavioral: Written Summary of Rounds	Rush University Medical Center Chicago, Illinois, United States
8	Recruiting	FOLLOW-UP OF PATIENTS WITH **COVID-19.**	Patient Admitted to **Intensive Care Unit** for **COVID-19**	Other: Follow-up of patients with COVID-19	Hopitaux Universitaires de Strasbourg, France
9	Recruiting	Tele-based **Psychological** Emotional Support for Informal CARegivers of **COVID-19** Patients in **Intensive Care**	Posttraumatic Stress Disorder Prolonged Grief Disorder COVID	Behavioral: Tele-delivered **psychological** intervention	Skejby Hospital, Aarhus; Rigshospitalet Copenhagen; Hospitalsenheden Vest, Horsens Horsens, Denmark (+3...)
10	Completed	Chronic Pain in **COVID-19** Patients Discharged From **Intensive Care Unit**	**COVID-19** Pandemic ICU Pain, Chronic (and 2 more...)	Other: Pain and neuropsychological questionnaires Diagnostic Test: Quantitative Sensory testing	Hôpital Raymond Poincare - AP-HP, Garches, Hauts-de-Seine; Hôpital Bicêtre AP-HP, Le Kremlin-Bicêtre; Hopital de la Croix Rousse-Hospices Civils de Lyon, France
11	Active, not recruiting	Mental Health of Professionals Working in Pediatric **Intensive Care Units** During the **COVID-19** Pandemic	**Covid19** Burnout, Professional Stress Disorders, Post-Traumatic (+3..)	Other: Web-based survey	D'Or Institute for Research and Education, Rio De Janeiro, Brazil

12	Recruiting	Social and **Psychological** Impacts of SARS-Cov-2 Pandemic Period in the Obese Population.	Obesity **Covid19**	Other: Questionnaire Other: Interview	CHU de Limoges; Hôpital Haut-Lévêque, Pessac; CHU de Poitiers, France
13	Completed	Stress Biomarkers Leading to Professional Burnout Among People Involved in a Mobile **Intensive Care Unit** During the **COVID-19** Pandemic	Occupational Stress	Behavioral: Assessment of work-related stress Biological: Saliva sample collection Other: Cardiac and electrodermal recordings Behavioral: Assessment of behavioral response to emotional stimulation	Elément Militaire de Réanimation (EMR), Mulhouse, France
14	Completed	Stress Related Disorders in Family Members of **COVID-19** Patients Admitted to the ICU	Respiratory Failure SARS-CoV 2 Corona Virus Infection (and 5 more...)		Eastern Colorado Veterans Affairs Health **Care** System, University of Colorado, Aurora; University of Colorado Hospital, Aurora, Colorado; Tulane Medical Center, New Orleans, Louisiana, US (+6...)
15	Completed	**Psychological** and Ethical Support for Hospital Professionals During the **COVID-19** Pandemic: Suitability and Post-crisis Implications for the Experience of All Professionals	**Psychological** Stress	Other: online questionnaire Other: questionnaire survey	Chu Dijon Bourogne, Dijon, France
16	Completed	The Usability, Feasibility, and Tolerability of Virtual Reality for Rehabilitation From **COVID-19**	Coronavirus Post **Intensive Care Unit** Syndrome	Device: Virtual Reality	Radboud university medical center, Nijmegen, Gelderland, Netherlands
17	Recruiting	French Cohort of **COVID-19** Patients With Post-**intensive Care** Syndrome	**Covid19**	Behavioral: Post-**intensive Care unit** syndrome	Department of Physical Medicine and Rehabilitation, Issy-les-Moulineaux; Department of Rehabilitation, Institute of Rheumatology Cochin, Paris, France
18	Completed	Anxiety and Burnout in Anesthetists and **Intensive Care Unit** Nurses During **Covid-19** Pandemic	Sars-CoV2 Anxiety Burnout		Sisli Hamidiye Etfal Education and Training Hospital, Istanbul, Turkey
19	Recruiting	Post-**intensive Care** Follow-up of Patients Hospitalized for an Acute Respiratory Distress Syndrome Caused by **COVID-19**	Human ARDS Coronavirus Infection	Other: Follow up calls	University Hospital of Toulouse, France
20	Unknown †	One-year Outcomes in Survivors of the Severe **COVID-19** Pneumonia (CO-Qo-ICU)	COVID ARDS Quality of Life		CHU de Nice, France
21	Terminated	Nursing Perspective on Burnout and Medical Errors in the **Intensive Care Unit** During **Covid-19** Pandemic	Burnout, Professional Medical Errors Depression	Diagnostic Test: Questionnaire	Sungai Buloh Hospital, Kuala Lumpur, Malaysia
22	Active, not recruiting	Prioritising Prevention of **COVID-19** in Persons With Cancer in the French West Indies	Cancer	Biological: Serology	CHU Martinique, Fort-de-France, Martinique FR
23	Recruiting	Follow-up of Patients With Previous SARS-CoV-2 Infection: Long-term Damage Assessment	**COVID-19**	Other: Data collection	Clara Balsano, L'Aquila; University of L'Aquila, Italy
24	Recruiting	Impact and Sequelae of High Ventilatory Drive in Critically Ill **COVID-19** Patients	**COVID-19** Critical Illness Hypoxemic Respiratory Failure (+2...)		Candelaria De Haro, Sabadell, Barcelona; Fundació Althaia Manresa; Hospital Universitario Central de Asturias, Oviedo E

25	Recruiting	Cohort Follow-up of Survivors of Hospitalization for **COVID-19** During the 2nd Wave of the Epidemic in France	Sequelae Fibrosis Post-COVID Syndrome Post-traumatic Stress Disorder	Other: Teleconsultation Other: Outpatient clinic	Bicetre hospital, Le Kremlin-Bicêtre, France
26	Completed	Post ICU Follow up in Patients With Severe SARS-CoV-2 Infection (**Covid-19**)	**Covid19** Follow up Rehabilitation	Other: quality of live assessment	Hôpitaux Universitaires de Strasbourg (Nouvel Hôpital Civil), Strasbourg, France
27	Completed	**Psychological** Impact, Mental Health and Sleep Disorder Among Patients Hospitalized and Health **Care** Workers During the 2019 Coronavirus Outbreak (**COVID-19**)	**Covid19**	Other: Questionnaire	CHU Brugmann, Brussels, Belgium
28	Completed	Anxiety and Work Resilience Among Tertiary University Hospital Workers During the **COVID-19** Outbreak: An Online Survey	Critical Illness Sars-CoV2 SARS Pneumonia (and 2 more...)		**Intensive care unit** CHU Nîmes, France
29	Completed Has Results	Addressing **COVID-19** Mental Health Problems Among US Veterans	Brief Video-based Intervention Vignette Based Intervention Non Intervention Control Arm	Other: A short video intervention Other: A vignette intervention	New York State Psychiatric Institute, New York, NY, US
30	Terminated	Sarcopenia and Related Factors in Coronavirus Disease 2019 (**COVID-19**) Following **Intensive Care**	Sarcopenia **Covid19** **Intensive Care Unit** Acquired Weakness	Other: Standard **care** treatment for COVID-19 in **Intensive Care Unit**	Koc University School of Medicine, Istanbul, Turkey
31	Active, not recruiting	Impact of **COVID-19** on Mental Health of Health **Care** Workers	Mental Health Quality of Life	Other: Online survey	Ghent University Hospital, Ghent, Belgium
32	Active, not recruiting	Sociodemographic, Clinical, Quality of Life and Health **Care** Conditions in **COVID-19** Survivors.	Post-acute **COVID-19** Syndrome Long-COVID **COVID-19** (and 2 more...)	Other: Exposure: Coronavirus disease 2019 (COVID-19)	Hospital Universitario Nacional de Colombia, Bogotá, Colombia
33	Completed	Perceived Stress Among ICU Medical Staff During **COVID-19** Crisis	Coronavirus Nurse's Role Professional Stress		University of Liège, Liège, Province De Liège, Belgium
34	Completed	Early **Care** Program for the Management of Post-ICU Syndrome and Chronic Pain After **COVID-19** Infection.	Post ICU Syndrome Chronic Pain **Covid-19**	Behavioral: Intervention program	Tomás Cuñat, Barcelona, Spain
35	Completed	Resilience Evaluation of Caregivers During the SARS-CoV2 Epidemic Period : Prospective Cohort.	**Psychological**	Other: Questionnaire	CHU, Angers, France
36	Unknown †	**COVID-19** Follow up **Intensive Care** Studies	Quality of Life **COVID-19**		University Medical Center Groningen, Netherlands
37	Completed	**COVID-19** and the Brain	**Covid19** Brain Neurocognition fMRI	Biological: Exposure to COVID-19	Vrije Universiteit Brussel, Brussels, Belgium

38	Active, not recruiting	A Brief GAmeplay Intervention for NHS ICU Staff Affected by COVID-19 Trauma (GAINS Study)	Intrusive Memories of Traumatic Event(s)	Behavioral: Brief digital imagery-competing task intervention	P1vital Products Limited, Wallingford, Oxfordshire, UK
39	Recruiting	Active Pregnancy Against COVID-19	Pregnancy Complications Pregnancy, High Risk Pregnancy Induced Hypertension (+5)	Other: Exercise program Other: Healthy lifestyle advise	Facultad de Ciencias de la Actividad Física y el Deporte (INEF), Madrid, Spain
40	Completed	Exhaustion and Needs in Frontline COVID-19 Healthcare Workers: Cross-sectional Study in a Belgian Population	COVID-19		Hôpital de Warquignies, Boussu, Hainaut; Hôpital de Jolimont Haine-Saint-Paul, Hainaut; Hôpital de Lobbes, Hainaut, Belgium (+2...)
41	Active, not recruiting	Reducing Post-traumatic Stress Disorder After ICU Discharge With the IPREA3 Program	Critical Illness	Other: Administration of the IPREA3 questionnaire Other: Immediate feedback through electronic reminder messages Other: Targeted interventions in each ICU to reduce discomforts (and 2 more...)	CHU Angers; CH d'Auxerre Auxerre, France (+30...)

Psychological Impact of Medical Evacuations on Families of Patients Admitted to Intensive Care Unit for Severe COVID-19 (IPES-CoV)

ClinicalTrials.gov Identifier: NCT05421182

Recruitment Status : Completed
First Posted : June 16, 2022
Last Update Posted : June 22, 2022

Sponsor:
Centre Hospitalier Metropole Savoie
Information provided by (Responsible Party):
Centre Hospitalier Metropole Savoie

Study Description

Go to

Brief Summary:

At the "Métropole Savoie" hospital, to deal with the daily influx of severe patients during the second wave of COVID-19, 23 patients had to be transferred away from their home city and far from their families as part of a medical evacuation (EVASAN).

The purpose of the study is to investigate whether there is an association between medical evacuations and the occurrence of **psychological** disorders such as post-traumatic stress, anxiety or depression occurring within 6 to 10 months in families of evacuated patients.

The investigators want to compare the prevalence of **psychological** disorders in the families of patients evacuated for a serious form of COVID-19 (cases) compared to that of families of patients not evacuated (controls) hospitalized for a serious form of COVID-19.

Condition or disease	Intervention/treatment	Phase

COVID-19 Stress Disorders, Post-Traumatic	Other: Revised Impact of Event ScaleOther: Hospital Anxiety and Depression scale: 36-Item Short Form SurveyOther: satisfaction survey: semi-directed interview with trusted person on the general experience of the patient's medical evacuation: semi-directed interview with trusted person on the general experience of hospitalization in **intensive care**	Not Applicable

Detailed Description:
The case group is trusted person of evacuated patient. The control group is trusted person of not evacuated patient.
The trusted person of the group control will be matched to trusted patient of the case group on :
their relationship with the patient (spouse/ascendant/descendant/other) and on criteria specific to the patient: sex, age range (<75 years or ≥ 75 years), invasive ventilation and becoming at 3 months post COVID-19 (survivor / non survivor)

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	30 participants
Allocation:	Non-Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Case-Control Study
Masking:	None (Open Label)
Primary Purpose:	Other
Official Title:	**Psychological** Impact of Medical Evacuations on Families of Patients Admitted to **Intensive Care Unit** for Severe **COVID-19**
Actual Study Start Date :	June 30, 2021
Actual Primary Completion Date :	February 14, 2022
Actual Study Completion Date :	February 14, 2022

Resource links provided by the National Library of Medicine
MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019) Family Issues Post-Traumatic Stress Disorder U.S. FDA Resources

Arms and Interventions

Arm	Intervention/treatment
Interview of the trusted person of evacuated patient The interview of the trusted person of evacuated patient will be done 8 months (+/-2 months) after the medical evacuation. The interview will be carried out by a psychologist or by a doctor from the ICU	Other: Revised Impact of Event Scale to measure the affect of routine life stress,everyday traumas and acute stress Other Name: IES-R Other: Hospital Anxiety and Depression scale to measure anxiety and depression Other Name: HADS Other: 36-Item Short Form Survey SF-36 is a set of generic, coherent, and easily administered quality-of-life measures. Other Name: SF-36 Other: satisfaction survey satisfaction survey of the trusted person about the communication with ICU personal Other: semi-directed interview with trusted person on the general experience of the patient's medical evacuation interview of the trusted person about the medical evacuation : evacuation announcement;organization of the medical evacuation,; concerns related to evacuations;reception and information by the center admitting the evacuated patient; arrangements of visit, patient repatriated
Interview of the trusted person of the not evacuated patient The interview of the trusted person of the not evacuated patient will be done 8 months (+/-2months) after the ICU admission The interview will be carried out by a psychologist or by a doctor from the ICU.	Other: Revised Impact of Event Scale to measure the affect of routine life stress,everyday traumas and acute stress Other Name: IES-R Other: Hospital Anxiety and Depression scale to measure anxiety and depression Other Name: HADS Other: 36-Item Short Form Survey SF-36 is a set of generic, coherent, and easily administered quality-of-life measures. Other Name: SF-36

Arm	Intervention/treatment
	Other: satisfaction survey satisfaction survey of the trusted person about the communication with ICU personal Other: semi-directed interview with trusted person on the general experience of hospitalization in **intensive care** interview of the trusted person about ICU hospitalization: reception in ICU; ICU organization; concerns related to ICU hospitalization, information and communication with ICU staff, arrangements of visit, context of ICU discharge

Outcome Measures

Primary Outcome Measures :

1. Comparison of the prevalence of post-traumatic stress disorder, among families of patients with severe COVID-19 evacuated to another region (case) compared to families of matched patients with severe COVID-19 not evacuated to another region (controls). [Time Frame: at 8months (+/-2 months) after medical evacuations for the case group, and at 8 months (+/-2 months) after ICU admission for the control group]
   the post-traumatic stress disorder of the trusted person is assessed by the Impact of Event Scale - Revised (IES-R), at 8months (+/-2 months) after medical evacuations for the case group, and at 8 months (+/-2 months) after **Intensive Care Unit** (ICU) admission for the control group

Secondary Outcome Measures :

1. Prevalence of anxiety and/or depression symptoms questionnaire in families of patients hospitalized with severe COVID-19. [Time Frame: at 8 months (+/- 2months) in families of patients hospitalized in intensive care for a serious form of COVID-19.]
   Association between medical evacuations and the occurrence of symptoms of anxiety and/or depression at 8 months in families of patients hospitalized in **intensive care** for a serious form of COVID19. anxiety and/or depression symptoms assessed by the Hospital Anxiety and Depresion Scale (HADS)
2. Quality of Life in families of patients with severe COVID-19 [Time Frame: at 8 months (+/- 2months) in families of patients hospitalized in intensive care for a serious form of COVID-19.]
   Quality of Life assessed by Medical Outcomes Study Short Form 36 (SF-36)
3. Satisfaction with the communication between the health **care** team and the family of the patient hospitalized with severe form of COVID19 [Time Frame: at 8 months (+/- 2months) in families of patients hospitalized in intensive care for a serious form of COVID-19.]
   satisfaction is measured using a simple digital scale,
4. Qualitative analysis by a psychologist of a semi-structured interview of the testimony and specific experience of families at 8 months. [Time Frame: at 8 months (+/- 2months) in families of patients hospitalized in intensive care for a serious form of COVID-19.]
   semi-structured interview

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

Trusted person of patients admitted to the Adult Intensive Care Unit (ICU) of the "Metropole Savoie"hospital

- during the second wave of COVID-19 in France
- for a serious form of COVID-19
- hospitalized more than 72 hours in ICU

the case group is trusted person of evacuated patient. the control group is trusted person of not evacuated patient.

Non -inclusion criteria :

Trusted Person Refusing patient Medical Evacuation

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT05421182***

Location: France

CH Metropole Savoie
Chambéry, France, 73000

Sponsors and Collaborators
Centre Hospitalier Metropole Savoie
Investigators

Principal Investigator: Vincent Peigne CH Metropole Savoie

More Information

Responsible Party:	Centre Hospitalier Metropole Savoie
ClinicalTrials.gov Identifier:	NCT05421182 History of Changes
Other Study ID Numbers:	CHMS21004
First Posted:	June 16, 2022 Key Record Dates
Last Update Posted:	June 22, 2022
Last Verified:	June 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	The individual participant data (IPD) collected in this study, will not be available to other researchers

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Coronaviridae Infections
Stress Disorders, Post-Traumatic	Nidovirales Infections
Respiratory Tract Infections	RNA Virus Infections
Infections	Lung Diseases
Pneumonia, Viral	Respiratory Tract Diseases
Pneumonia	Stress Disorders, Traumatic
Virus Diseases	Trauma and Stressor Related Disorders
Coronavirus Infections	Mental Disorders

Trial record **2 of 41** for: intensive care unit AND psychological | Covid-19

Ethical and Psychological Support for Health Care Professions in Intensive Care Units in the COVID19 Pandemic Context: Adequacy With Needs and Psychological Impact Crisis and Post-crisis (PsyCOVID)

ClinicalTrials.gov Identifier: NCT04441476

Recruitment Status : Completed
First Posted : June 22, 2020
Last Update Posted : March 30, 2021

Sponsor:
Centre Hospitalier Universitaire Dijon
Information provided by (Responsible Party):
Centre Hospitalier Universitaire Dijon

Study Details No Results Posted
Study Description
Brief Summary:
The **intensive care unit** occupies a particular place in our health **care** system. The urgency of the clinical situations, the proportion of deaths encountered, and the daily workload is likely to generate suffering among staff. The health crisis linked to SARS-COV-2 is unprecedented and has leads to the unprecedented mobilisation of **care** providers, particularly in the ICU. Faced with the massive and growing influx of patients, human, therapeutic and material resources are overwhelmed and the teams are faced with an unusually heavy workload in a context of extreme tension. These professionals are thus exposed to a risk of over-investment, in a context of acute and repetitive stress, over an indeterminate period of time combining workload, emotional intensity with specific ethical issues, simultaneously affecting the professional sphere but also the personal and family sphere (confinement, risk of contamination). Now more than ever, the mental health of caregivers is an important concern, as highlighted by the CCNE. Mental health is understood in the way in which the individual responds specifically to work-related suffering by developing individual and collective defensive strategies. Thus, the issue of mental health in the ICU cannot be considered without taking into account the strategies that professionals put in place to combat stress and to contribute or not to the construction and stabilization of the work collective (collaboration, support). Ethical and/or **psychological** support systems have been set up in most of the establishments involved in the **care** of Covid-19 patients. However, the adequacy of these systems relative to the needs of professionals during and after the crisis is not yet known. We hypothesize that

the **psychological** and social repercussions of this pandemic as well as the individual and collective strategies deployed by ICU **care** providers to deal with it will evolve in view of the progression of the crisis but also of the various types of support, particularly **psychological** and/or ethical, available to them.

Condition or disease	Intervention/treatment
Psychological Strain	Other: QuestionnairesOther: **psychological** and sociological interviews

Study Design

Study Type :	Observational
Actual Enrollment :	3080 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Ethical and **Psychological** Support for Health **Care** Professions in **Intensive Care Units** in the **COVID19** Pandemic Context: Adequacy With Needs and **Psychological** Impact Crisis and Post-crisis
Actual Study Start Date :	April 21, 2020
Actual Primary Completion Date :	December 21, 2020
Actual Study Completion Date :	December 21, 2020

Groups and Cohorts

Group/Cohort	Intervention/treatment
ICU staff	Other: Questionnaires An online questionnaire (Limesurvey platform) will be made available at 4 different times (M0, M1, M2 and M6). The first questionnaires (M0 and M1) will include a component for professional characterization. Generic and specific stress factors related to ICU and the current pandemic and collective and individual defensive strategies will also be collected in M0 and M1. At M2 and M6, the traumatic impact of the crisis, burnout, signs of depression and recourse to internal or external support in the department (occupational medicine, support **unit**) will be collected. Other: **psychological** and sociological interviews conducting semi-directive **psychological** interviews (40 interviews in M2, 40 interviews in M6). sociological interviews: 40 (20 in M1-M2 then 20 in M6) in order to understand the consequences of the epidemic on daily life, both intra-family and micro-social.

Outcome Measures

Primary Outcome Measures :

1. PS-ICU Scale Score [Time Frame: Through study completion, an average of 6 months after the epidemic peak]
   This scale integrates generic stressors as well as factors specific to **intensive care** and crises.

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Probability Sample

Study Population

nursing staff in French hospitals

Criteria

Inclusion Criteria:

- The study population is the entire ICU staff of the participating centres, whether they are permanently or transiently assigned to these units and/or the institution, whether they are students or not.

Professionals involved in psychological and ethical support structures may also be interviewed to provide the information necessary to describe and evaluate the organisations and their evolution.

Exclusion Criteria:

- NA

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04441476***

Locations France

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Dijon, France, 21000

Sponsors and Collaborators
Centre Hospitalier Universitaire Dijon

Responsible Party:	Centre Hospitalier Universitaire Dijon
ClinicalTrials.gov Identifier:	NCT04441476 History of Changes
Other Study ID Numbers:	QUENOT SERI 2020
First Posted:	June 22, 2020 Key Record Dates
Last Update Posted:	March 30, 2021
Last Verified:	June 2020
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Trial record **3 of 41** for: intensive care unit AND psychological | Covid-19

Evaluation of Psychological Impact of Group Therapy for Patients Who Have Been Hospitalized in Intensive Care During COVID-19 Pandemic: Exploratory Study (GPR COVID)

ClinicalTrials.gov Identifier: NCT04747405

Recruitment Status : Active, not recruiting
First Posted : February 10, 2021
Last Update Posted : July 11, 2022

Sponsor:
Centre Hospitalier Metropole Savoie
Information provided by (Responsible Party):
Centre Hospitalier Metropole Savoie

Study Details

No Results Posted

Study Description
Brief Summary:
Psychological impact of **intensive care** hospitalization for patients has been demonstrated during the last few years: anxiety, depression and post traumatic stress disorder. Hospitalizations during COVID-19 pandemic have been marked by factors such as confinement forbidding family members visits, stress on **intensive care unit** ...Those factors may have a **psychological** impact added to factors of long hospitalization and prolonged mechanical ventilation.
For all these reasons the investigators fear that patients hospitalized in **intensive care** during COVID-19 pandemic develop **psychological** trouble with an increased risk for those who experienced COVID-19 infection. The hypothesis therapy group added to standard **care** might have a positive impact on **psychological** troubles such as anxiety, depression and post traumatic stress disorder for patients who have been hospitalized in **intensive care** during COVID-19 pandemic.
The investigators will compare two groups:

- group receiving standard of **care**
- group receiving standard of **care** and therapy group

Condition or disease	Intervention/treatment	Phase
Intensive Care Unit Syndrome**Covid19**AnxietyDepression	Other: therapy group	Not Applicable

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	100 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Other
Official Title:	Evaluation of **Psychological** Impact of Group Therapy for Patients Who Have Been Hospitalized in **Intensive Care** During **COVID-19** Pandemi
Actual Study Start Date :	February 22, 2021
Estimated Primary Completion Date :	July 22, 2022
Estimated Study Completion Date :	December 22, 2022

Resource links provided by the National Library of Medicine

MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019)

U.S. FDA Resources

Arms and Interventions

Arm	Intervention/treatment
No Intervention: A standard standard of **care**	
Experimental: B therapy group standard of **care** and therapy group	Other: therapy group; therapy group of maximum 8 people repeated twice

Outcome Measures

Primary Outcome Measures :

1. prevalence of post traumatic stress syndrome [Time Frame: 12 months after intensive care hospitalization]
   the aim is to compare the prevalence of post traumatic stress syndrome between both groups 12 months after exiting **intensive care unit**

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- 18 years old and older
- hospitalized at least 72h in intensive care during COVID-19 pandemic crisis
- out of intensive care for at least 2 months and maximum 6 months
- psychological evaluation done according to local practice and standard of care
- speaking french
- patient coming alone to the therapy group
- patient agree to respect confidentiality rules and demonstrating goodwill with others participants
- patient comite to respecting barriers rules against COVID-19
- affiliated to social security system
- no juridic protection engaged

Exclusion Criteria:

- presenting psychological disease
- drug addiction
- participation to other interventional clinical trial

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04747405***

Locations France

CH Métropole Savoie
Chambéry, France, 73000

Sponsors and Collaborators

Centre Hospitalier Metropole Savoie

Investigators

Study Director: Romain PERCOT Cebtre Hospitalier Metropole Savoie

Responsible Party:	Centre Hospitalier Metropole Savoie
ClinicalTrials.gov Identifier:	NCT04747405 History of Changes
Other Study ID Numbers:	CHMS20009
First Posted:	February 10, 2021 Key Record Dates
Last Update Posted:	July 11, 2022
Last Verified:	July 2022
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Additional relevant MeSH terms:	
COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Trial record **4 of 41** for: intensive care unit AND psychological | Covid-19

Psychological Impact of COVID-19 Outbreak on Caregivers (PSY-CO-ICU)

ClinicalTrials.gov Identifier: NCT04511780

Recruitment Status : Not yet recruiting
First Posted : August 13, 2020
Last Update Posted : December 19, 2020
See **Contacts and Locations**

Sponsor:
Centre Hospitalier Universitaire de Nîmes
Information provided by (Responsible Party):
Centre Hospitalier Universitaire de Nîmes

- **Study Details**
- **Tabular View**

- **No Results Posted**

- Disclaimer
- How to Read a Study Record

Study Description

Brief Summary:

Based on the experience of previous pandemics, countries reacted by applying different upgrade strategies to prevent or delay the widespread of the disease. Therefore, measures such as border closure, school closure, restrict social gathering (even shutdown of workplaces), limit population movements, and confinement meaning quarantines at the scale of cities or regions. In public hospitals, several measures have been decided to concentrate the power of **care** on potential wave of admissions of patients with severe forms of Covid-19. In this purpose, the number of available beds in **Intensive Care Units** (ICU) has been increased by two-fold and scheduled non-emergency surgical procedure have been cancelled. That means:

1. For the most severe patients, new personals (physician such as anesthesiologists, nurses of other **units**) have been transferred in ICUs.
2. For the less severe patients, personals of non-busy **units** have been transferred in busier ones.

All these measures lead to major daily-life change sets that could be stressful. In the general population, it has been well documented that quarantine or confinement or isolation could lead to the occurrence of Post-Traumatic Stress Disorder (PTSD) syndrome in about 30% overall population. Importantly, high depressive symptoms have been reported in 9% of hospital staff. Numerous symptoms have been reported after quarantine or isolation such as emotional disturbance, depression, stress, low mood, irritability, insomnia, and post-traumatic stress symptoms.

In hospital setting, few studies have been performed for assessing the **psychological** impact of quarantine and isolation. However, two studies reported a high prevalence of burn-out syndrome (BOS) in ICU physician and PTSD syndrome and depression in ICU nurses. As the consequences of all the measures decided and applied during Covid-19 pandemic could be important on caregivers, the present study primarily aims at assessing the prevalence of PTSD syndrome in a large population of caregivers implied or not in **Intensive Care Units**. The secondary objective were 1) to assess the prevalence of severe depression and anxiety and BOS 2) to isolate potential factors associated with PTSD, severe depression, anxiety or BOS.

Condition or disease	Intervention/treatment
Critical Illness**Covid19**Stress Disorders, Post-Traumatic	Other: questionnaire filling

Study Design

Study Type :	Observational
Estimated Enrollment :	5000 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	**Psychological** Impact of **COVID-19** Outbreak on Caregivers Involved in **Intensive Care Unit** Patient Management: Impact on the Occurrence of Post-traumatic Stress Disorder, Anxiety, Depression and Burn Out Syndrome
Estimated Study Start Date :	January 2021
Estimated Primary Completion Date :	September 2022
Estimated Study Completion Date :	September 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
Caregivers • Caregivers (doctors senior and junior, nurses, aid nurses) involved in the staff (permanent or transient, full or partial time) of ICU patients during Covid-19 outbreak	Other: questionnaire filling assessment of post-traumatic stress, anxiety and burn out

Outcome Measures

Primary Outcome Measures :

1. Post-Traumatic Stress Disorder [Time Frame: 3-6 month after the Covid-19 outbreak]
   PCL - 5 (Post-Traumatic Stress Disorder Checklist Scale, version DSM-5)

Secondary Outcome Measures :

1. anxiety and depression [Time Frame: 3-6 month after the Covid-19 outbreak]
   HADS scale (Hospital Anxiety and Depression Scale)

2. Burn out [Time Frame: 3-6 month after the Covid-19 outbreak]
   Score MBI (Burn out syndrome)

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Caregivers (doctors senior and junior, nurses, aid nurses) involved in the staff (permanent or transient, full or partial time) of ICU patients during Covid-19 outbreak

Criteria

Inclusion Criteria:

- Caregivers (doctors senior and junior, nurses, aid nurses) involved in the staff (permanent or transient, full or partial time) of ICU patients during Covid-19 outbreak
- Approved to participate

Exclusion Criteria:

- Participation refusal
- No internet connection for responding to the questionnaire with REDCAP file

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04511780***

Contacts

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Location France

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Centre Hospitalier Universitaire de Nîmes, Principal Investigator: Jean Yves LEFRANT Centre Hospitalier Universitaire de Nîmes

More Information

Responsible Party:	Centre Hospitalier Universitaire de Nîmes
ClinicalTrials.gov Identifier:	NCT04511780 History of Changes
Other Study ID Numbers:	Local/2020/JYL-03
First Posted:	August 13, 2020 Key Record Dates
Last Update Posted:	December 19, 2020
Last Verified:	December 2020

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Coronaviridae Infections
Critical Illness	Nidovirales Infections
Stress Disorders, Traumatic	RNA Virus Infections
Stress Disorders, Post-Traumatic	Lung Diseases
Respiratory Tract Infections	Respiratory Tract Diseases
Infections	Trauma and Stressor Related Disorders
Pneumonia, Viral	Mental Disorders
Pneumonia	Disease Attributes
Virus Diseases	Pathologic Processes
Coronavirus Infections	

Copeptin and Psychological Stress of Medic During COVID-19 Pandemic (COVID-19)

ClinicalTrials.gov Identifier: NCT04757285

Recruitment Status : Completed
First Posted : February 17, 2021
Last Update Posted : February 17, 2021

Sponsor:
Alexandria University
Information provided by (Responsible Party):
hala mourad demerdash, Alexandria University

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
Psychological stress (PSS) is one of the most common problems among healthcare providers during COVID-19 pandemic. PSS influences the homeostatic equilibrium of the body, involving activation of the sympathetic nervous system and hypothalamus pituitary adrenal (HPA) axis. Copeptin; C-terminal portion of Vasopressin (AVP) precursor is stable. Nevertheless, Evidence about influence of PSS on copeptin levels is lacking. The reason we are doing this research is to determine the level of **psychological** stress among healthcare providers exposed to at the time of work in **intensive care unit** (ICU) during COVID-19 pandemic; They will be appraised every assembly for **psychological** stress level; before start of duty shifts (first time), one week after start (second time) and two weeks after departure from shift duties in ICU (third time) for assessment of **psychological** stress level and stress hormones.

Condition or disease
Psychological StressHemostatic Disorder

Detailed Description:
A total of 70 healthcare personnel volunteers participated; 35 physicians and 35 nurses. All healthcare providers' volunteers are in good physical health, Exclusion criteria included hypertension, diabetes mellitus, obesity BMI ≥30, subjects with serum sodium ≤135 or ≥ 145 mmol /L at baseline or females receiving contraceptive pills.
During the research participants will answer a questionnaire as well as three blood samples are taken.

- In the first meeting, evaluation of participant general condition; determining BMI, blood pressure. Then a small amount of blood, equal to about two millimeters, will be taken from participant arm with a syringe. This blood will be tested for serum copeptin, cortisol (fasting morning sample). The investigator will ask participant few questions to evaluate the level of stress (as anxiety, insomnia, fear of infection through questionnaire)
- The second meeting, one week after work in ICU, another blood sample will be taken from participant and determine level of psychological stress.
- The third meeting, two weeks after leave from ICU participant blood sample will be taken from participant to determine stress hormones and determine level of psychological stress.

Duration
The research takes place over six months in total.

Study Design

Study Type :	Observational [Patient Registry]
Actual Enrollment :	90 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Target Follow-Up Duration:	4 Weeks
Official Title:	Evaluation of Serum Copeptin and **Psychological** Stress Level Among Healthcare Providers During **COVID-19** Pandemic
Actual Study Start Date :	May 10, 2020
Actual Primary Completion Date :	October 30, 2020
Actual Study Completion Date :	October 30, 2020

Groups and Cohorts

Group/Cohort
control group 25 healthcare personnel volunteers not working in quarantine hospitals of matched age
healthcare providers worked in **Intensive Care Units** 35 physicians (28 males and 7 females) and 35 nurses (10 males and 25 females). All volunteers were in good physical health Exclusion criteria included hypertension, diabetes mellitus, obesity BMI ≥30, subjects with serum sodium ≤135 or ≥ 145 mmol /L at baseline or females receiving contraceptive pills. Assigned participants were clinically evaluated for as hypertension, DM, dyslipidemia, renal function.

Outcome Measures

Primary Outcome Measures :

1. evaluation of **psychological** stress [Time Frame: four weeks for each participant.]
   - Primarily outcome determination of **psychological** stress among doctors and nurses working in ICU through a questionnaire before duty shifts [first time] and re-evaluate it after one week of work in ICU [second time], and lastly two weeks after departure from shift duties [third time].
2. determine stress hormones in serum cortisol and copeptin [Time Frame: four weeks for each participant..]
   Second to determine stress hormones copeptin and cortisol (possible stress biomarkers) concurrently with questionnaire.

Secondary Outcome Measures :

1. correlation of **psychological** stress with stress hormone copeptin [Time Frame: four weeks for each participant..]
   correlate the level of **psychological** stress calculated from provided questionnaire in the three assemblies with stress biomarkers copeptin and cortisol in the three measurements.

Eligibility Criteria

Ages Eligible for Study:	24 Years to 37 Years (Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Probability Sample

Study Population

Healthcare providers worked in ICU: 35 physicians (28 males and 7 females) and 35 nurses (10 males and 25 females). Age ranged from 24 to 37 years All volunteers were in good physical health Exclusion criteria included hypertension, diabetes mellitus, obesity BMI ≥30, subjects with serum sodium ≤135 or ≥ 145 mmol /L at baseline or females receiving contraceptive pills.

Group Information healthcare providers designated to take duty shifts at ICU in Alexandria quarantine hospitals for two weeks during COVID-19 pandemic. And a control group of healthcare providers not assigned to work in quarantine hospitals.

First assembly one day before enrolling to work in ICU. Second assembly at the end of first week of work, third assembly two weeks after departure from work in ICU

Criteria

Inclusion Criteria:

physicians and nurses under age of 37 years in good health

Exclusion Criteria:

- body mass index above 30
- hypertension
- Diabetes mellitus
- females receiving contraceptive pills

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04757285***

Locations

Egypt

Alexandria University Faculty of Medicine
Alexandria, Egypt, 21311

Sponsors and Collaborators

Alexandria University

More Information

Publications of Results:

McEwen BS. Protective and damaging effects of stress mediators: central role of the brain. Dialogues Clin Neurosci. 2006;8(4):367-81. Review.

Christ-Crain M, Fenske W. Copeptin in the diagnosis of vasopressin-dependent disorders of fluid homeostasis. Nat Rev Endocrinol. 2016 Mar;12(3):168-76. doi: 10.1038/nrendo.2015.224. Epub 2016 Jan 22. Review.

Responsible Party:	hala mourad demerdash, Consultant Clinical Pathology, Alexandria University
ClinicalTrials.gov Identifier:	NCT04757285 History of Changes
Other Study ID Numbers:	0304842
First Posted:	February 17, 2021 Key Record Dates
Last Update Posted:	February 17, 2021
Last Verified:	February 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by hala mourad demerdash, Alexandria University:

psychological stress
copeptin
hormones

Additional relevant MeSH terms:

COVID-19	RNA Virus Infections
Stress, **Psychological**	Lung Diseases
Diabetes Insipidus	Respiratory Tract Diseases
Hemostatic Disorders	Behavioral Symptoms
Blood Coagulation Disorders	Kidney Diseases
Respiratory Tract Infections	Urologic Diseases
Infections	Pituitary Diseases
Pneumonia, Viral	Endocrine System Diseases
Pneumonia	Vascular Diseases
Virus Diseases	Cardiovascular Diseases
Coronavirus Infections	Hemorrhagic Disorders
Coronaviridae Infections	Hematologic Diseases
Nidovirales Infections	

Psychological Symptoms and Families of **COVID-19** Patients (Relieving the Burden of Psychological Symptoms Among Families of Critically Ill Patients With COVID-19)

ClinicalTrials.gov Identifier: NCT04501445

Recruitment Status : Completed
First Posted : August 6, 2020
Last Update Posted : September 16, 2021

Sponsor:
Rush University Medical Center
Collaborator:
Central Michigan University
Information provided by (Responsible Party):
Rush University Medical Center

Study Description

Brief Summary:
Families of patients in **Intensive Care Units** (ICUs) are at increased risk for developing **psychological** symptoms that can last for months after the patient is discharged. These symptoms can have significant impact on both the patient and family member's quality of life.
The investigators have found that families of patients admitted to the Rush University Medical Center ICU during to the COVID-19 pandemic were more likely to develop clinically significant **psychological** symptoms than families of patients admitted prior to the COVID-19 pandemic. The investigators suspect that this finding is due in part to the hospital-wide no visitation policy that altered our standard communication practices and may have prevented families from being active participants in the patient's medical **care**.
The goals of this project are 1) to determine the prevalence of **psychological** disorders among families of COVID-19 patients after ICU discharge 2) to determine the characteristics of ICU **care** that were associated with the development of **psychological** disorders among family members and 3) to pilot a program in which families with **psychological** disorders after ICU discharge receive therapy from mental health professionals.

Condition or disease	Intervention/treatment	Phase
Family MembersPost **Intensive Care Unit** SyndromePost Traumatic Stress Disorder	Behavioral: Written Summary of Rounds	Not Applicable

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	90 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Supportive **Care**
Official Title:	Relieving the Burden of **Psychological** Symptoms Among Families of Critically Ill Patients With **COVID-19**
Actual Study Start Date :	September 14, 2020
Actual Primary Completion Date :	April 8, 2021
Actual Study Completion Date :	July 31, 2021

Arms and Interventions

Arm	Intervention/treatment
Experimental: Rounding Summary Surrogates who were assigned to the intervention group received a written rounding summary every day or every other day that the patient is in the ICU.	Behavioral: Written Summary of Rounds The summary was organized as follows for each of the most important ICU problems: 1) Description of the problem, 2) Ways the ICU team is addressing the problem i.e. consultations, diagnostic tests, and treatments. 3) An assessment of whether the problem is improving or worsening.
No Intervention: Usual **Care**	

Outcome Measures

Primary Outcome Measures :

1. Symptoms of Post-Traumatic Stress Disorder (PTSD) initial [Time Frame: Measured once upon enrollment]
   Score on Impact of Events Scale Revised (IES-R) questionnaire. 22 questions. Score 0-88 with higher scores indicating more stress.
2. Symptoms of Anxiety and Depression initial [Time Frame: Measured once upon enrollment]
   Score on Hospital Anxiety and Depression Scale (HADS). Total score 0-21 for anxiety (7 questions) and 0-21 for depression (7 questions). Higher scores indicate greater symptom burden.

Secondary Outcome Measures :

1. Surrogate Satisfaction with the Patient's ICU **Care**: [Time Frame: Measured once upon enrollment]
   Score on the Critical **Care** Family Needs Inventory (CCFNI) questionnaire. 14 questions. Total score range 14-56 with lower scores indicating better satisfaction.
2. Symptoms of Post-Traumatic Stress Disorder (PTSD) final [Time Frame: Measured before behavioral intervention (6-12 weeks after enrollment)]
   Score on Hospital Anxiety and Depression Scale (HADS). Total score 0-21 for anxiety (7 questions) and 0-21 for depression (7 questions). Higher scores indicate greater symptom burden.
3. Symptoms of Post-Traumatic Stress Disorder (PTSD) final [Time Frame: Measured after behavioral intervention (12-24 weeks after enrollment)]
   Score on Hospital Anxiety and Depression Scale (HADS). Total score 0-21 for anxiety (7 questions) and 0-21 for depression (7 questions). Higher scores indicate greater symptom burden.
4. Symptoms of Anxiety and Depression final [Time Frame: Measured before behavioral intervention (6-12 weeks after enrollment)]
   Score on Hospital Anxiety and Depression Scale (HADS). Total score 0-21 for anxiety (7 questions) and 0-21 for depression (7 questions). Higher scores indicate greater symptom burden.
5. Symptoms of Anxiety and Depression final [Time Frame: Measured after behavioral intervention (12-24 weeks after enrollment)]
   Score on Hospital Anxiety and Depression Scale (HADS). Total score 0-21 for anxiety (7 questions) and 0-21 for depression (7 questions). Higher scores indicate greater symptom burden.
6. Interview initial [Time Frame: Measured once upon enrollment]
   Qualitative analysis of phone interview to determine the presence and reason(s) for **psychological** symptoms
7. Interview final [Time Frame: Measured after behavioral intervention (12-24 weeks after enrollment)]
   Qualitative analysis of phone interview to determine the presence and reason(s) for **psychological** symptoms

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- The patient's surrogate was enrolled in "ICU Rounding Summaries for Families of Critically Ill Patients" (NCT03969810) and the patient had COVID-19
- The patient has been discharged from the hospital

Exclusion Criteria:
- None

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04501445***

Location United States, Illinois, Rush University Medical Center, **Chicago, Illinois, United States, 60612**

Sponsors and Collaborators

Rush University Medical Center
Central Michigan University

More Information

Publications:

Davidson JE, Jones C, Bienvenu OJ. Family response to critical illness: postintensive care syndrome-family. Crit Care Med. 2012 Feb;40(2):618-24. doi: 10.1097/CCM.0b013e318236ebf9. Review.
Nelson JE, Hanson LC, Keller KL, Carson SS, Cox CE, Tulsky JA, White DB, Chai EJ, Weiss SP, Danis M. The Voice of Surrogate Decision-Makers. Family Responses to Prognostic Information in Chronic Critical Illness. Am J Respir Crit Care Med. 2017 Oct 1;196(7):864-872. doi: 10.1164/rccm.201701-0201OC.
Davidson JE, Aslakson RA, Long AC, Puntillo KA, Kross EK, Hart J, Cox CE, Wunsch H, Wickline MA, Nunnally ME, Netzer G, Kentish-Barnes N, Sprung CL, Hartog CS, Coombs M, Gerritsen RT, Hopkins RO, Franck LS, Skrobik Y, Kon AA, Scruth EA, Harvey MA, Lewis-Newby M, White DB, Swoboda SM, Cooke CR, Levy MM, Azoulay E, Curtis JR. Guidelines for Family-Centered Care in the Neonatal, Pediatric, and Adult ICU. Crit Care Med. 2017 Jan;45(1):103-128. Review.

Responsible Party:	Rush University Medical Center
ClinicalTrials.gov Identifier:	NCT04501445 History of Changes
Other Study ID Numbers:	20071101
First Posted:	August 6, 2020 Key Record Dates
Last Update Posted:	September 16, 2021
Last Verified:	September 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Undecided
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	No

Additional relevant MeSH terms:

Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Trauma and Stressor Related Disorders
Mental Disorders

Burnout Among Caregivers Facing COVID-19 Health Crisis at a Non-conventional Intensive Care Unit Compared to a Conventional Intensive Care Unit

ClinicalTrials.gov Identifier: NCT04346810

Recruitment Status : Unknown
Verified April 2020 by HARKOUK Hakim, Hôpital Raymond Poincaré.
Recruitment status was: Not yet recruiting
First Posted : April 15, 2020
Last Update Posted : April 17, 2020

Sponsor:

Hôpital Raymond Poincaré

Collaborators:

Dominique FLETCHER MD-PhD
Guillaume GERI MD-PhD
Clement DURET MD

Information provided by (Responsible Party):

- **Study Details**

- **Tabular View**
- **No Results Posted**

- Disclaimer
- How to Read a Study Record

Study Description

Brief Summary:

The intense health crisis due to COVID-19 led to a profound reorganization of the activities at theatres, recovery rooms and the **intensive care units**. The caregivers are facing several issues and are daily exposed to an intensification of the work. Assessing the stress and the well-being of the caregivers is very important in this context.

Condition or disease	Intervention/treatment
COVID-19 Burnout, Caregiver**Intensive Care Unit**Stress, **Psychological**	Other: Patient management suffering of coronavirus infection

Detailed Description:

The current period of intense and prolonged health crisis has necessitated a profound reorganization of the activities and organizations of the intensive care hospital services in order to be able to cope with it.
Caregivers are at the heart of the management of this crisis and are exposed daily to these situations of repeated emergencies, an intensification of the pace of work and difficulties in care.
In this context, it seemed important to us to try to quantify this pressure of care, in order to be able to offer in second care adapted to caregivers who would like it.
The assessment of the mental state of the caregivers as well as the collection of the feelings and perceptions on the current crisis and its management will be carried out by anonymous and voluntary self-questionnaire in collaboration with the service of professional pathologies and occupational medicine of the hospital structure

Study Design

Study Type :	Observational
Estimated Enrollment :	100 participants
Observational Model:	Ecologic or Community
Time Perspective:	Prospective
Official Title:	Burnout Among Caregivers Facing **COVID-19** Health Crisis at a Non-conventional **Intensive Care Unit** Compared to a Conventional **Intensive**
Estimated Study Start Date :	April 15, 2020
Estimated Primary Completion Date :	August 15, 2020
Estimated Study Completion Date :	September 1, 2020

Groups and Cohorts

Group/Cohort	Intervention/treatment
Recovery room caregivers Caregivers working at a recovery room shifted into an **intensive care unit** for the management of patients suffering from coronavirus infection and needing a resuscitation	Other: Patient management suffering of coronavirus infection Welle-being and stress of the caregivers
Intensive care unit caregivers Caregivers working at a conventional **intensive care unit** for the management of patients suffering from coronavirus infection and needing a resuscitation	Other: Patient management suffering of coronavirus infection Welle-being and stress of the caregivers

Outcome Measures

Primary Outcome Measures

1. Stress in a recovery room transformed into an **intensive care unit** versus a conventional **intensive care unit** [Time Frame: A 3 months period from the starting of the pandemic]
   stress level of caregivers managing patients with coronavirus infection needing airway support or resuscitation. The level of stress will be quantified with the Maslach burnout Inventory.

Eligibility Criteria

Ages Eligible for Study:	Child, Adult, Older Adult
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Sampling Method: Non-Probability Sample

Study Population

Caregivers working in the recovery room shifted into an intensive care unit or in the conventional intensive care unit

Criteria

Inclusion Criteria:

- Consent to participation; caregivers working at recovery room; caregiver working at intensive care unit

Exclusion Criteria:

- refusal of participation

Contacts and Locations

Contacts Hakim Harkouk, M.D. 0033149095422 hakim.harkouk@aphp.fr Dominique Fletcher, MD, PhD 0033149094675 dominique.fletcher@aphp.fr

Sponsors and Collaborators

Hôpital Raymond Poincaré, 104 Bd Raymond Poincaré, 92380 Garches, France
Dominique FLETCHER MD-PhD
Guillaume GERI MD-PhD
Clement DURET MD

More Information

Publications:

Staloff J, Diop M, Matuk R, Riese A, White J. Caring for Caregivers: Burnout and Resources for Caregivers in Rhode Island. R I Med J (2013). 2018 Nov 1;101(9):10-11.
Pastores SM. Burnout Syndrome in ICU Caregivers: Time to Extinguish! Chest. 2016 Jul;150(1):1-2. doi: 10.1016/j.chest.2016.03.024.

Responsible Party:	HARKOUK Hakim, Principal Investigator, Hôpital Raymond Poincaré
ClinicalTrials.gov Identifier:	NCT04346810 History of Changes
Other Study ID Numbers:	CSC19APR
First Posted:	April 15, 2020 Key Record Dates
Last Update Posted:	April 17, 2020
Last Verified:	April 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	No plan to share data with other researchers

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Virus Diseases
Burnout, **Psychological**	Coronavirus Infections
Stress, **Psychological**	Coronaviridae Infections
Caregiver Burden	Nidovirales Infections
Respiratory Tract Infections	RNA Virus Infections
Infections	Lung Diseases
Pneumonia, Viral	Respiratory Tract Diseases
Pneumonia	Behavioral Symptoms

FOLLOW-UP OF PATIENTS WITH COVID-19. (TeleRea'nCo)

ClinicalTrials.gov Identifier: NCT04609839

Recruitment Status : Recruiting
First Posted : October 30, 2020
Last Update Posted : October 30, 2020

Sponsor:

University Hospital, Strasbourg, France

Information provided by (Responsible Party):

University Hospital, Strasbourg, France

- **Study Details**

- **Tabular View**
- **No Results Posted**

- Disclaimer
- How to Read a Study Record

Study Description

Brief Summary:

Some patients admitted to **intensive care** for a severe form of COVID-19 could have respiratory, cardiac, renal and neurological sequelae in the medium or long term.

The results of this research will allow an improvement in the understanding and management of patients in the medium and long term.

Condition or disease	Intervention/treatment
Patient Admitted to **Intensive Care Unit** for **COVID-19**	Other: Follow-up of patients with COVID-19

Study Design

Study Type :	Observational
Estimated Enrollment :	200 participants
Observational Model:	Case-Only
Time Perspective:	Prospective
Official Title:	TeleRea'nCo : FOLLOW-UP OF PATIENTS WITH **COVID-19.**
Estimated Study Start Date :	October 27, 2020
Estimated Primary Completion Date :	April 27, 2023
Estimated Study Completion Date :	April 27, 2023

Groups and Cohorts

Group/Cohort	Intervention/treatment
Patient admitted to **intensive care unit** for COVID-19	Other: Follow-up of patients with COVID-19 The presence of sequelae, number of re-hospitalizations, date of death and cost of health expenditure will be collected. The Quality of life score (SF-36 questionnaire) and the Pittsburgh sleep quality index (PSQI questionnaire) will be completed by patients.

Outcome Measures

Primary Outcome Measures :

1. The presence of respiratory, renal, cardiac, motor, neurological, and **psychological** sequelae will be assessed by specialist doctors during the 12 months following the patient's discharge from **intensive care**. [Time Frame: The primary endpoint will be measured during 12 months following the patient's discharge from intensive care.]

Secondary Outcome Measures :

1. 1) The sequelae by type of impairment will be assessed by specialist doctors at 3, 6 and 12 months [Time Frame: At M3 (+/-15 days) : 3 months after patient inclusion-At M6 (+/-15 days) : 6 months after patient inclusion-At M12 (+/-15 days) : 12 months after patient inclusion]
2. 2) Number of re-hospitalizations at 3, 6 and 12 months [Time Frame: At M3 (+/-15 days) : 3 months after patient inclusion-At M6 (+/-15 days) : 6 months after patient inclusion-At M12 (+/-15 days) : 12 months after patient inclusion]
3. 3) Date of death [Time Frame: Date of death will be collected from inclusion to M12 (12 months after patient inclusion)]
4. 4.1) Quality of life score (SF-36 questionnaire) at 3, 6 and 12 months [Time Frame: At M3 (+/-15 days) : 3 months after patient inclusion-At M6 (+/-15 days) : 6 months after patient inclusion-At M12 (+/-15 days) : 12 months after patient inclusion]
5. 4.2) The Pittsburgh sleep quality index (PSQI questionnaire) at 3, 6 and 12 months [Time Frame: At M3 (+/-15 days) : 3 months after patient inclusion-At M6 (+/-15 days) : 6 months after patient inclusion-At M12 (+/-15 days) : 12 months after patient inclusion]
6. 5) Cost of health expenditure [Time Frame: The cost of health expenditure will be collected from inclusion to M12 (12 months after patient inclusion)]

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Sampling Method: Non-Probability Sample

Study Population
Patient admitted to intensive care unit for COVID-19.

Criteria
Inclusion Criteria:

- Patient admitted to intensive care unit for COVID-19
- Adult patient ≥ 18 years old
- Subject having expressed his non-opposition to the research
- Subject affiliated to a social health insurance protection scheme or beneficiary of such a scheme

Exclusion Criteria:

- Subject under safeguard of justice
- Patient under guardianship or curatorship

Contacts and Locations
Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04609839***
Contacts Eric DEMONSANT +33 3 88 11 54 15 eric.demonsant@chru-strasbourg.fr

Location: France Hopitaux Universitaires de Strasbourg, Strasbourg, France, 67091 Contact: Laurence KESSLER, Pr; Principal Investigator: Laurence KESSLER, Pr **Recruiting**

Sponsors and Collaborators
University Hospital, Strasbourg, France

More Information

Responsible Party:	University Hospital, Strasbourg, France
ClinicalTrials.gov Identifier:	NCT04609839 History of Changes
Other Study ID Numbers:	TeleRea'nCo 7883 (Other Identifier: Hôpitaux Universitaires de Strasborug)
First Posted:	October 30, 2020 Key Record Dates
Last Update Posted:	October 30, 2020
Last Verified:	October 2020
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Additional relevant MeSH terms:	
COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Trial record **9 of 41** for: intensive care unit AND psychological | Covid-19

Tele-based Psychological Emotional Support for Informal CARegivers of COVID-19 Patients in Intensive Care (CO-CarES)

ClinicalTrials.gov Identifier: NCT04409821

Recruitment Status : Recruiting
First Posted : June 1, 2020
Last Update Posted : February 3, 2021

Sponsor:
Rigshospitalet, Denmark
Information provided by (Responsible Party):
Annika von Heymann, Rigshospitalet, Denmark

Study Details

Tabular View
No Results Posted

Study Description

Brief Summary:

The experience of a loved one's stay in a COVID-19 **intensive care unit** (ICU), either intubated or on respiratory support, forces family caregivers (hereafter 'caregivers') to face core existential fears, such as uncertainty and death. It also poses a serious threat to basic human needs for autonomy, competence, and relatedness, as family caregivers have no control over the illness, and limited prior competence in dealing with critical illness. COVID-19 likely aggravates this experience, as social distancing cuts caregivers off from visiting patients in the ICU, from using their usual social supportive network and the threat of infection extends to caregivers themselves, their children and family. Combined, these extreme circumstances put caregivers in emotional turmoil and in need of **psychological** support and assistance in managing difficult emotions. ICU caregivers are at risk of developing clinically relevant symptoms of anxiety or posttraumatic stress. During the patient's ICU stay, caregivers experience peri-traumatic distress, such as helplessness, grief, frustration and anger, that may predict later posttraumatic stress disorder (PTSD). Symptoms of anxiety and PTSD may last for months to years after the patient's discharge. Further, caregivers of patients who die in an ICU may be at greater risk of prolonged grief disorder. Supportive interventions may reduce **psychological** late effects in ICU caregivers, but the primary focus of the majority of interventions has been on communication or surrogate decision making. The CO-**CarES** study aims to develop and test the feasibility of a tele-delivered **psychological** intervention to enable caregivers of ICU patients with COVID-19 to better endure the overwhelming uncertainty and emotional strain and reduce the risk of posttraumatic stress and prolonged grief. The study hypothesizes that providing **psychological** intervention during and after the patients' hospitalization, can decrease peri-traumatic distress during ICU hospitalization and decrease risk of post-traumatic stress, anxiety, depression and perceived stress following discharge, as well as prolonged grief in bereavement. A secondary hypothesis is that changes in emotion regulation mediate effects of the intervention on long-term **psychological** outcomes.

Condition or disease	Intervention/treatment	Phase
Posttraumatic Stress DisorderProlonged Grief DisorderCOVID	Behavioral: Tele-delivered **psychological** intervention	Not Applicable

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	50 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Intervention Model Description:	Feasibility study
Masking:	None (Open Label)
Primary Purpose:	Supportive **Care**
Official Title:	**COVID-19** Caregiver Emotional Support
Actual Study Start Date :	May 29, 2020
Estimated Primary Completion Date :	February 2022
Estimated Study Completion Date :	February 2022

Arms and Interventions

Arm	Intervention/treatment
Experimental: Tele-delivered **psychological** intervention Weekly tele-delivered **psychological** intervention	Behavioral: Tele-delivered **psychological** intervention The intervention consists of two (or one, if preferred by caregivers) weekly tele-sessions during the ICU stay, lasting up to 30 minutes, and two sessions in the month after discharge from or death in the ICU. Sessions will be conducted via phone-calls or video-conferencing. Therapists will 1) validate caregivers' subjective experience, 2) normalize and psychoeducate about emotional reactions, and 3) offer emotion regulation drawing on contemporary cognitive treatment packages of decentering, acceptance and emotion tolerance. Sessions for bereaved caregivers will include psycho-education about grief, assessment of risk for adverse outcomes and information about available support, if needed. The intervention will be performed based on an intervention manual. The content of the intervention will be continually adapted and tailored to the needs of the participating caregivers by involving all caregivers in co-creating the intervention trough brief post-session interviews.

Outcome Measures

Primary Outcome Measures :

1. Recruitment rate [Time Frame: At inclusion]
   Rate of consent among informed eligible participants
2. Completion rate [Time Frame: During and post-intervention (1 month)]
   Rates of completion of intervention sessions among participants

3. Peri-traumatic distress inventory (negative emotions) [Time Frame: Pre-post intervention (1 month after discharge/death)]
   Symptoms of peri-traumatic distress, min. score 0, max score 24, higher score corresponds to worse distress
4. Impact of Events Scale (6 item) [Time Frame: 1 month post intervention]
   Posttraumatic stress, min. score 6, max score 24, higher score corresponds to worse distress
5. Impact of Events Scale (6 item) [Time Frame: 6 months post intervention]
   Posttraumatic stress, min. score 6, max score 24, higher score corresponds to worse distress
6. Impact of Events Scale (6 item) [Time Frame: 12/13 months post intervention]
   Posttraumatic stress, min. score 6, max score 24, higher score corresponds to worse distress

Secondary Outcome Measures :

1. Prolonged Grief-13-scale [Time Frame: 6 and 13 months]
   Prolonged Grief, scored according to diagnostic criteria for prolonged grief disorder
2. PROMIS Depression (8 item scale) [Time Frame: Baseline to 1, 6, and 12/13 months]
   Symptoms of depression, min. score 8, max score 40, higher score corresponds to worse symptoms
3. PROMIS Anxiety (8 item scale) [Time Frame: Baseline to 1, 6, and 12/13 months]
   Symptoms of anxiety, min. score 8, max score 40, higher score corresponds to worse symptoms
4. Perceived Stress Scale (4 item) [Time Frame: Baseline to 1, 6, and 12/13 months]
   Perceived stress, min. score 0, max score 16, higher score corresponds to worse stress

Other Outcome Measures:

1. Short Penn State Worry Questionnaire (3 items) [Time Frame: Baseline to 1, 6, and 12/13 months]
   Worry, min. score 3, max score 15, higher score corresponds to greater worry
2. Brooding subscale of Ruminative Responses Scale [Time Frame: Baseline to 1, 6, and 12/13 months]
   Brooding, min. score 5, max score 20, higher score corresponds to greater brooding/rumination
3. Intolerance of uncertainty Scale (2 item) [Time Frame: Baseline to 1, 6, and 12/13 months]
   Intolerance of uncertainty, min score 2, max score 8, greater score indicates greater uncertainty intolerance

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- close relatives or friends of a patient hospitalized in an intensive care or intermediary care wards with COVID-19
- capable of completing online questionnaires
- speak Danish sufficiently for a therapeutic dialogue
- provide informed consent

Exclusion Criteria:

- suffering from a severe psychiatric disorder (such as schizophrenia) or in ongoing psychotherapeutic treatment for a psychiatric disorder (such as major depression generalized anxiety disorder or others), that cannot be paused
- unable to complete verbal phone- or videoconferencing calls
- unable to complete electronic questionnaires

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04409821***

Contacts

Contact: Annika von Heymann, PhD 0045 35 45 40 90 annika.von.heymann@regionh.dk

Locations Denmark

Skejby Hospital **Recruiting**
Aarhus, Denmark
Contact: Anne Aagaard

Rigshospitalet **Recruiting**
Copenhagen, Denmark, 2100

Contact: Annika von Heymann

Hospitalsenheden Vest, Horsens **Recruiting**
Horsens, Denmark
Contact: Anne H Nielsen

Hvidovre Hospital **Recruiting**
Hvidovre, Denmark
Contact: Klaus T Kristiansen

Sygehus Lillebælt, Kolding **Recruiting**
Kolding, Denmark
Contact: Annika von Heymann

Odense University Hospital **Recruiting**
Odense, Denmark
Contact: Eva Lærkner

Sponsors and Collaborators
Rigshospitalet, Denmark
Investigators

Principal Investigator: Annika von Heymann, PhD Department of Oncology, Rigshospitalet, Denmark

More Information

Responsible Party:	Annika von Heymann, Postdoc, Rigshospitalet, Denmark
ClinicalTrials.gov Identifier:	NCT04409821 History of Changes
Other Study ID Numbers:	P-2020-544 0216-00030B (Other Grant/Funding Number: Independent Research Fund Denmark)
First Posted:	June 1, 2020 Key Record Dates
Last Update Posted:	February 3, 2021
Last Verified:	February 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Annika von Heymann, Rigshospitalet, Denmark:
Informal caregiver
COVID-19

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Disease	Coronaviridae Infections
Stress Disorders, Post-Traumatic	Nidovirales Infections
Pathologic Processes	RNA Virus Infections
Respiratory Tract Infections	Lung Diseases
Infections	Respiratory Tract Diseases
Pneumonia, Viral	Stress Disorders, Traumatic
Pneumonia	Trauma and Stressor Related Disorders
Virus Diseases	Mental Disorders

Chronic Pain in COVID-19 Patients Discharged From Intensive Care Unit

ClinicalTrials.gov Identifier: NCT04940208

Recruitment Status : Completed

First Posted : June 25, 2021
Last Update Posted : February 2, 2022

Sponsor:
Mikhail Dziadzko, MD, PhD
Collaborators:
Hôpital Raymond Poincaré
Bicetre Hospital
Information provided by (Responsible Party):
Mikhail Dziadzko, MD, PhD, Hôpital de la Croix-Rousse

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:
More than six million French were affected by SARS-COV2 epidemic. About 20% of infected peoples were hospitalized, and about 5% were admitted to the **intensive care units** (ICU) for severe SARS-COV2 acute respiratory distress syndrome (ARDS) management.
A spectrum of neuropsychiatric sequelae, specific for the ICU exposure, was already described, including post-**intensive care** syndrome and persistent pain.
A growing body of evidence suggests the impact of SARS-COV2 exposure on the occurrence of neurological disorders and chronic pain syndrome development in COVID-19 patients.
Taking together, one can expect a large number of patients discharged from ICU after severe COVID-19 with high prevalence of persistent pain and **psychological** disorders. To date, no study has evaluated neither the incidence of persistant pains in ICU COVID-19 survivors, nor pain phenotypes.
The knowledge of such data is crucial in order to anticipate the management of such patients by specialized pain team, and to quantify the possible incurred burden of **care**.
Our study aims to evaluate the incidence of pain, pain localization and severity, associated pain-related **psychological** disorders, and to perform quantitative sensory testing in severe COVID-19 patients, admitted to the ICU for more than 48 hours and successfully discharged home during the first French pandemic wave.

Condition or disease	Intervention/treatment
COVID-19 PandemicICUPain, ChronicPost **Intensive Care Unit** SyndromeNeuropathic Pain	Other: Pain and neuropsychological questionnairesDiagnostic Test: Quantitative Sensory testing

Study Design

Study Type :	Observational
Actual Enrollment :	143 participants
Observational Model:	Cohort
Time Perspective:	Cross-Sectional
Official Title:	Chronic Pain in COVID-19 Patients Discharged From **Intensive Care Unit** - a Multicenter Observational Cohort Study
Actual Study Start Date :	January 11, 2021
Actual Primary Completion Date :	January 1, 2022
Actual Study Completion Date :	February 1, 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
post COVID-19 ICU survivors Patients hospitalized to the ICU in the context of severe COVID-19 and discharged alive during the first French COVID-19 pandemic wave	Other: Pain and neuropsychological questionnaires Patient-reported outcomes, listed in the Secondary Outcome Measure Section Diagnostic Test: Quantitative Sensory testing Summation pain threshold test and Heat pain threshold skin test

Outcome Measures

Primary Outcome Measures :

1. Incidence of secondary chronic pain [Time Frame: starting 6 month after discharge]

Secondary chronic pain as defined by International Classification of Disease -11th revision (ICD-11).
Chronic secondary pain is organized into the following six categories:

a. Chronic cancer-related pain (ICD-11 code MG30.1)
b. Chronic postsurgical or post-traumatic pain (ICD-11 code MG30.2)
c. Chronic secondary musculoskeletal pain (ICD-11 code MG30.3)
d. Chronic secondary visceral pain (ICD-11 code MG30.4)
e. Chronic neuropathic pain (ICD-11 code MG30.5)
f. Chronic secondary headache or orofacial pain (ICD-11 code MG30.6)

Any pain detected in the population of interest and fitting in one of 6 categories will be accounted.

Secondary Outcome Measures :

1. Frequency of different secondary chronic pain classes [Time Frame: starting 6 month after discharge]
   as defined by ICD-11 and the International Association for the Study of Pain (IASP)
   Chronic secondary pain is organized into the following six categories:
   a. Chronic cancer-related pain (ICD-11 code MG30.1)
   b. Chronic postsurgical or post-traumatic pain (ICD-11 code MG30.2)
   c. Chronic secondary musculoskeletal pain (ICD-11 code MG30.3)
   d. Chronic secondary visceral pain (ICD-11 code MG30.4)
   e. Chronic neuropathic pain (ICD-11 code MG30.5)
   f. Chronic secondary headache or orofacial pain (ICD-11 code MG30.6)
   For each category of detected pain the frequency will be reported.
2. Pain sensitivity level [Time Frame: starting 6 month after discharge]
   Pain sensitivity level is tested with a Pain sensitivity questionnaire (PSQ). PSQ contains 17 items assessing pain with 11 level scoring from 0 (not at all painful) to 10 (most severe pain imaginable). Maximal summation score is 170, higher score mean worse outcome.
3. Pain localization [Time Frame: starting 6 month after discharge]
   A Michigan Body Map will be used for pain localization inventory. A Michigan Body Map is a self-report measure to assess body areas where chronic pain is experienced.
4. The severity of pain and its impact on functioning [Time Frame: starting 6 month after discharge]
   A Brief Pain Inventory (BPI) will be used to assess the severity of pain and its impact on functioning. The BPI pain scales defines pain as follows: Worst Pain Score: 1 - 4 = Mild Pain. Worst Pain Score: 5 - 6 = Moderate Pain. Worst Pain Score: 7 - 10 = Severe Pain. BPI Interference Items use 0 (less) to 10 (worth) scoring, the arithmetic mean of the interference items is used as a measure of pain interference, higher score mean worse outcome.
5. Neuropathic pain [Time Frame: starting 6 month after discharge]
   A DN4 scale will be used to detect a neuropathic pain. The DN4 (which stands for Douleur Neuropathique 4) is a clinician-administered questionnaire consisting of 10 items. Seven items related to pain quality (i.e. sensory and pain descriptors) are based on an interview with the patient and 3 items based on the clinical examination. Each item has binary value (yes/no), maximal summation score is 10, and the threshold for neuropathic pain is 4.
6. Spiegel Sleep Quality Questionnaire [Time Frame: starting 6 month after discharge]
   Spiegel Sleep Questionnaire is a self-rated questionnaire which assesses the current sleep quality and disturbances. It has six 5 point Likert-like items rated from worst to best value. The total summation score is 30, less score values indicates worth outcome. The threshold of bad sleep is less than 15, and the score 20 indicates a good sleep.
7. Posttraumatic Stress Disorder [Time Frame: starting 6 month after discharge]
   Posttraumatic Stress Disorder Checklist Scale is a 20-item self-report measure that assesses the symptoms of Posttraumatic Stress Disorder. Respondents rate each item from 0 ("not at all") to 4 ("extremely") to indicate the degree to which they have been bothered by that particular symptom over the past month.
   A total symptom severity score is obtained by summing the scores for each of the 20 items. The score superior of 31 is indicative of probable Posttraumatic Stress Disorder.
8. Anxiety and Depression [Time Frame: starting 6 month after discharge]
   Hospital Anxiety Depression scale will be used, it measures anxiety and depression in a general medical population of patients. The questionnaire comprises seven questions for anxiety and seven questions for depression. Greater score values indicates worth outcome.
   For both scales, scores of less than 7 indicate non-cases; 8-10 - mild depression or anxiety; 11-14 - moderate depression or anxiety; and 15-21 - severe depression or anxiety.
9. Pain Catastrophizing Level [Time Frame: starting 6 month after discharge]
   Pain Catastrophizing Scale quantifies an individual's pain experience. It has 13 items rated on 5-point Likert-like scales (0 - not at all to 4 - all the time). A total score is yielded (ranging from 0-52), the threshold above 30 is considered clinically relevant. Higher score indicates higher level of catastrophizing and bad outcome.
10. Perceived Stress Level [Time Frame: starting 6 month after discharge]
    Perceived Stress Scale (PSS-10) is a self stress assessment instrument. It has 10 items rated on 5-point Likert-like scales (0 - never to 4 - very often). Individual scores on the PSS-10 can range from 0 to 40 with higher scores indicating higher perceived stress.
11. Summation pain threshold [Time Frame: starting 6 month after discharge]

Mechanical temporal summation will be evoked using methodology described by Weissman-Fogel, 2008, by Von Frey Filaments, using a 180-gr filament that will be applied to the volar aspect of the dominant forearm. Patients will be exposed to a single stimulus and will be asked to rate the level of pinprick pain intensity using 11 items numeric pain scale. This pain score serve as an index for mechanical suprathreshold pain. Subsequently, 1 Hz repetitive stimuli will be applied within an area of 1 cm in diameter, using the same filament, and subjects will be asked to rate the pain intensity of the last stimulus. The magnitude of mechanical temporal summation will be calculated as the difference between the last and the first pain scores. Higher values indicates worth outcome.

12. Heat pain threshold [Time Frame: starting 6 month after discharge]
    A heat pain threshold will be realized using Thermal Stimulator for Sensory testing (SOMEDIC(R)). A thermode (heating stick) of 7 square centimeters will be applied to the volar aspect of the dominant forearm. Patients will be exposed to 3 repetitive gradual increase in temperature from 32° to 52°C. The skin contact will be withdrawn if an individual is not able to tolerate such stimulation, and the temperature threshold of tolerance will be noted. The final reading will be the median of three measurements, higher values indicate better tolerance.

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

adult patients, infected with SARS COV2 and developed severe COVID, requiring hospitalisation to the ICU during the first French wave of COVID 19, with length of stay > 48 hours, survived and successfully discharged, and approached from 6th month post discharge.

Criteria

Inclusion Criteria:

- adults (>=18 y.o.)
- hospitalized in the ICU for at least 48 hours
- with SARS-Cov2 infection confirmed by Polymerase Chain Reaction (PCR)/serology and/or a suggestive chest Computed Tomography scan
- during the first wave of COVID 19 from March to December 2020 at three investigator sites (2 in Paris and 1 in Lyon)
- discharged alive from the ICU
- at least 6 months after discharge

Exclusion Criteria:

- patient refusal
- inability to communicate or to have in-person appointment
- death in the period from ICU discharge to the first phone call for interview

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04940208***

Locations France: Hôpital Raymond Poincare - AP-HP; Garches, Hauts-de-Seine, France, 92380; Hôpital Bicêtre AP-HP, Le Kremlin-Bicêtre, France, Le Kremlin-Bicêtre; Hopital de la Croix Rousse - Hospices Civils de Lyon, Lyon, France, 69004

Sponsors and Collaborators

Mikhail Dziadzko, MD, PhD, Hôpital Raymond Poincaré, Bicetre Hospital

Publications:

Carfì A, Bernabei R, Landi F; Gemelli Against COVID-19 Post-Acute Care Study Group. Persistent Symptoms in Patients After Acute COVID-19. JAMA. 2020 Aug 11;324(6):603-605. doi: 10.1001/jama.2020.12603.

Needham EJ, Chou SH, Coles AJ, Menon DK. Neurological Implications of COVID-19 Infections. Neurocrit Care. 2020 Jun;32(3):667-671. doi: 10.1007/s12028-020-00978-4.

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Lee AM, Wong JG, McAlonan GM, Cheung V, Cheung C, Sham PC, Chu CM, Wong PC, Tsang KW, Chua SE. Stress and psychological distress among SARS survivors 1 year after the outbreak. Can J Psychiatry. 2007 Apr;52(4):233-40.

Responsible Party:	Mikhail Dziadzko, MD, PhD, Attending Pain Physician, Hôpital de la Croix-Rousse
ClinicalTrials.gov Identifier:	NCT04940208 History of Changes
Other Study ID Numbers:	2020-A02929-30
First Posted:	June 25, 2021 Key Record Dates
Last Update Posted:	February 2, 2022
Last Verified:	February 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	individual participant data are the property of investigator's centers and will not be shared

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No
Keywords provided by Mikhail Dziadzko, MD, PhD, Hôpital de la Croix-Rousse:

- SARS-COV2
- **Intensive care unit**
- critical illness survivors
- chronic pain
- COVID long
- Neuropathic pain
- Quantitative Sensory testing

Additional relevant MeSH terms:

- **COVID-19**
- Neuralgia
- Chronic Pain
- Respiratory Tract Infections
- Infections
- Pneumonia, Viral
- Pneumonia
- Virus Diseases
- Coronavirus Infections
- Coronaviridae Infections
- Nidovirales Infections
- RNA Virus Infections
- Lung Diseases
- Respiratory Tract Diseases
- Pain
- Neurologic Manifestations
- Peripheral Nervous System Diseases
- Neuromuscular Diseases
- Nervous System Diseases

Mental Health of Professionals Working in Pediatric Intensive Care Units During the COVID-19 Pandemic

ClinicalTrials.gov Identifier: NCT04846907

Recruitment Status : Active, not recruiting
First Posted : April 15, 2021
Last Update Posted : January 13, 2022

Sponsor:
D'Or Institute for Research and Education
Collaborator:
Conselho Nacional de Desenvolvimento Científico e Tecnológico
Information provided by (Responsible Party):
D'Or Institute for Research and Education

- **Study Details**
- **No Results Posted**

Study Description
Brief Summary:
Health professionals are extremely exposed to psychosocial risks, as they experience, in general, high levels of stress, anxiety, fatigue and suffering, due to the nature and location of their work. As a result, the health and well being of these professionals can be significantly compromised. In outbreaks of serious infectious diseases and pandemics, these risks become amplified and the health team is at greater risk of falling ill, presenting changes in mental health and **psychological** trauma, while caring for infected patients and becoming potential contaminants in their family and community.
The objective is to study the mental health of professionals who work in Pediatric **Intensive Care Units** (PICUs) in Brazil, during and after the COVID-19 pandemic. The primary outcome will be the prevalence of burnout in the team involved with the **care** of critically ill children. Secondary outcomes such as anxiety, depression, quality of professional life, compassionate fatigue and post-traumatic stress disorder will be measured. Possible associations between demographic, work and coping variables (social support and resilience) with mental and emotional health outcomes will be investigated, in an exploratory character.
It is a multicenter, observational, longitudinal study, with a descriptive and exploratory analytical component. Data collection will be carried out through an electronic survey during and after the COVID-19 pandemic.

Condition or disease
Covid19 Burnout, ProfessionalStress Disorders, Post-TraumaticAnxietyDepressionCompassion Fatigue

Detailed Description:
Health professionals are extremely exposed to psychosocial risks, as they experience, in general, high levels of stress, anxiety, fatigue and suffering, due to the nature and location of their work. As a result, the health and well being of these professionals can be significantly compromised. In outbreaks of serious infectious diseases and pandemics, these risks become amplified and the health team is at greater risk of falling ill, presenting changes in mental health and psychological trauma, while caring for infected patients and becoming potential contaminants in their family and community.

The objective is to study the mental health of professionals who work in Pediatric Intensive Care Units (PICUs) in Brazil, during and after the COVID-19 pandemic. The primary outcome will be the incidence of burnout in the team involved with the care of critically ill children. Secondary outcomes such as anxiety, depression, quality of professional life, compassionate fatigue and post-traumatic stress disorder will be measured. Possible associations between demographic, work and coping variables (social support and resilience) with mental and emotional health outcomes will be investigated, in an exploratory character.
It is a multicenter, observational, longitudinal study, with a descriptive and exploratory analytical component. Data collection will be carried out through an electronic survey during and after the COVID-19 pandemic.

Study Design

Study Type :	Observational
Actual Enrollment :	1148 participants
Observational Model:	Cohort
Time Perspective:	Cross-Sectional
Official Title:	Mental Health and Emotional Aspects of Professionals Working in Pediatric **Intensive Care Units** During the **COVID-19** Pandemic
Actual Study Start Date :	July 1, 2020
Estimated Primary Completion Date :	July 2022
Estimated Study Completion Date :	December 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
Healthcare personnel working in pediatric **intensive care units** during COVID-19 pandemic Physicians, registered nurses, nurse technicians, physical therapists and other professionals; on duty, routine staff or fellow/residents working in participants PICU	Other: Web-based survey Eligible participants received emails or text messages with links to a REDCap-created and managed web-based questionnaire

Outcome Measures

Primary Outcome Measures :

1. Prevalence of burnout as measured by Maslach Burnout Inventory (MBI) [Time Frame: Baseline]
   Proportion of participants positive for Burnout as measured by MBI (Maslach et al), a self-report standardized 22-item questionnaire covering 3 domains: emotional exhaustion (EE), depersonalization (DP) and personal accomplishment (PA). Each subscale includes Likert-scaled questions ranging from 0 (never) to 6 (every day). Higher EE and DP scores and lower PA scores, more severe Burnout. Further analysis will be done to evaluate associations between Burnout presence and severity and demographic and laboral characteristics.

Secondary Outcome Measures :

1. Prevalence of anxiety as measured by Hospital Anxiety and Depression Scale (HADS) [Time Frame: Baseline]
   Proportion of participants positive for anxiety as measured by HADS (Zigmond and Snaith), a self-report standardized 14-item questionnaire covering 1 anxiety 7-question subscale and 1 depression 7-question subscale. Each subscale includes Likert-scaled questions ranging from 0 to 3. Presence of anxiety symptoms when 9 or more points on anxiety subscale. Further analysis will be done to evaluate associations between anxiety presence and severity and demographic and laboral characteristics.

2. Prevalence of depression as measured by Hospital Anxiety and Depression Scale (HADS) [Time Frame: Baseline]
   Proportion of participants positive for depression as measured by HADS (Zigmond and Snaith), a self-report standardized 14-item questionnaire covering 1 anxiety 7-question subscale and 1 depression 7-question subscale. Each subscale includes Likert-scaled questions ranging from 0 to 3. Presence of depression symptoms when 9 or more points on depression subscale. Further analysis will be done to evaluate associations between depression presence and severity and demographic and laboral characteristics.

3. Prevalence of Post-traumatic Stress Disorder (PTSD) as measured by PTSD Checklist DSM-5 (PCL-5) [Time Frame: Baseline]
   Proportion of participants positive for PTSD as measured by PCL-5 (Weathers et al), a self-report standardized 20-item questionnaire covering 4 dimensions of symptoms: intrusions, avoidance, negative alterations in cognitions and mood and alterations in arousal and reactivity. Each subscale includes Likert-scaled questions ranging from 0 (not at all) to 4 (extremely). Presence of PTSD symptoms when 33 or more total points or positivity in each dimension. Further analysis will be done to evaluate associations between PTSD presence and severity and demographic and laboral characteristics.

4. Prevalence of Compassion Fatigue as measured by Professional Quality of Life 5 (ProQOL 5) scale [Time Frame: Baseline]
   Proportion of participants positive for compassion fatigue and satisfaction as measured by ProQOL 5 scale (Stamm), a self-report standardized 30-item questionnaire covering 3 domains: compassion satisfaction (CS), Burnout (BO), secondary traumatic stress (ST). Each subscale includes Likert-scaled questions ranging from 1 (never) to 5 (very often). Scores are scaled between low (22 or less points), moderate (23 to 41) and high (42 or more) levels in each domain. Further analysis will be done to evaluate associations between CS, BO and ST presence and severity and demographic and laboral characteristics.

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

Physicians, registered nurses, nurse technicians, physical therapists and other professionals; on duty, routine staff or fellow/residents working in participants PICU

Criteria

Inclusion Criteria:

- Eligible participants that signed informed consent form

Exclusion Criteria:

- Refused to sign informed consent form

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04846907***

Location Brazil D'Or Institute for Research and Education, Rio De Janeiro, Brazil, 22281-100

Sponsors and Collaborators

D'Or Institute for Research and Education

Conselho Nacional de Desenvolvimento Científico e Tecnológico

Investigators

Principal Investigator: Fernanda L Setta D'Or Institute for Research and Education

More Information

Publications:

Oh N, Hong N, Ryu DH, Bae SG, Kam S, Kim KY. Exploring Nursing Intention, Stress, and Professionalism in Response to Infectious Disease Emergencies: The Experience of Local Public Hospital Nurses During the 2015 MERS Outbreak in South Korea. Asian Nurs Res (Korean Soc Nurs Sci). 2017 Sep;11(3):230-236. doi: 10.1016/j.anr.2017.08.005. Epub 2017 Aug 21.

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Chen Q, Liang M, Li Y, Guo J, Fei D, Wang L, He L, Sheng C, Cai Y, Li X, Wang J, Zhang Z. Mental health care for medical staff in China during the COVID-19 outbreak. Lancet Psychiatry. 2020 Apr;7(4):e15-e16. doi: 10.1016/S2215-0366(20)30078-X. Epub 2020 Feb 19. Erratum in: Lancet Psychiatry. 2020 May;7(5):e27.

Buckley L, Berta W, Cleverley K, Medeiros C, Widger K. What is known about paediatric nurse burnout: a scoping review. Hum Resour Health. 2020 Feb 11;18(1):9. doi: 10.1186/s12960-020-0451-8. Review.

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Wu PE, Styra R, Gold WL. Mitigating the psychological effects of COVID-19 on health care workers. CMAJ. 2020 Apr 27;192(17):E459-E460. doi: 10.1503/cmaj.200519. Epub 2020 Apr 15.

Responsible Party:	D'Or Institute for Research and Education
ClinicalTrials.gov Identifier:	NCT04846907 History of Changes
Other Study ID Numbers:	COVID-EMOTION
First Posted:	April 15, 2021 Key Record Dates
Last Update Posted:	January 13, 2022
Last Verified:	January 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Undecided
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by D'Or Institute for Research and Education:

Covid19	Anxiety
Burnout	Depression
Post-Traumatic Stress Disorder	Compassion Fatigue

Additional relevant MeSH terms:

COVID-19	Virus Diseases
Burnout, **Psychological**	Coronavirus Infections
Stress, **Psychological**	Coronaviridae Infections

Fatigue	Nidovirales Infections
Compassion Fatigue	RNA Virus Infections
Burnout, Professional	Lung Diseases
Depression	Respiratory Tract Diseases
Stress Disorders, Traumatic	Behavioral Symptoms
Stress Disorders, Post-Traumatic	Mental Disorders
Respiratory Tract Infections	Trauma and Stressor Related Disorders
Infections	Occupational Stress
Pneumonia, Viral	Occupational Diseases
Pneumonia	Mental Fatigue

Stress Biomarkers Leading to Professional Burnout Among People Involved in a Mobile Intensive Care Unit During the COVID-19 Pandemic (AUTONOMIC)

ClinicalTrials.gov Identifier: NCT04365335

Recruitment Status : Completed
First Posted : April 28, 2020
Last Update Posted : March 9, 2021

Sponsor:
Direction Centrale du Service de Santé des Armées
Collaborator:
Institut de Recherche Biomedicale des Armees
Information provided by (Responsible Party):
Direction Centrale du Service de Santé des Armées

- **Study Details**
- **Tabular View**
- **No Results Posted**
- Disclaimer
- How to Read a Study Record

Study Description

Brief Summary:

This study is aiming at investigating whether professional burnout in people involved in the mobile **intensive care unit** (in French: Element Mobile de Réanimation, EMR) in Mulhouse (France) can be predicted upstream by a low mindfulness level (as a protective factor) or by a dysregulation of stress pathways with a high level of perceived stress towards an emotional event (**psychological** index of allostatic load), i.e. an early and silent dysfunctional physiological response (measured by the electrophysiological and biological measurements of allostasis load and parasympathetic brake).
It is part of a global approach aiming at identifying levers to prevent the allostatic load of occupational stress related to large-scale health crises.

Condition or disease	Intervention/treatment
Occupational Stress	Behavioral: Assessment of work-related stressBiological: Saliva sample collectionOther: Cardiac and electrodermal recordingsBehavioral: Assessment of behavioral response to emotional stimulation

Study Design

Study Type :	Observational
Actual Enrollment :	50 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Stress Biomarkers Leading to Professional Burnout Among People Involved in a Mobile **Intensive Care Unit** During the **COVID-19** Pandemic
Actual Study Start Date :	April 25, 2020
Actual Primary Completion Date :	June 12, 2020
Actual Study Completion Date :	June 12, 2020

Groups and Cohorts

Intervention Details:

- Behavioral: Assessment of work-related stress

Assessment of burnout, mindfulness, interoceptive awareness, anxiety, post-traumatic stress disorder, coping flexibility and sleep through questionnaires.

- Biological: Saliva sample collection

Saliva sample is collected before and after emotional stimulation in order to measure resting-state allostatic load biomarkers: DHEA, cortisol and chromogranine A levels

- Other: Cardiac and electrodermal recordings

Electrocardiogram and electrodermal activity (tonic and phasic) is collected at rest and after emotional stimulation.

- Behavioral: Assessment of behavioral response to emotional stimulation

Emotional stimulation involves asking the participants to remember a recent event related to the COVID-19 crisis that has been emotionally difficult for them.
Perceived stress, situational awareness and emotions is assessed after emotional stimulation through questionnaires.

Outcome Measures

Primary Outcome Measures :

1. Professional burnout [Time Frame: 21 days after enrollment (Day 21)]
   Professional burnout is measured at D21 by the Burnout Measure Short Version (BMS) questionnaire It is a 10-item questionnaire used to assess burnout regardless of the occupational category.
   Each item is rated from 0 to 6 ("never" to "always"). An average score (sum/10) below 2.4 indicates a very low degree of burnout exposure; a score between 2.5 and 3.4 indicates a low degree of burnout exposure; a score between 3.5 and 4.4 indicates the presence of burnout; a score between 4.5 and 5.4 indicates a high degree of burnout exposure; a score above 5.5 indicates a very high degree of burnout exposure.
2. Mindfulness level [Time Frame: Day 1]
   Mindfulness level is assessed at D0 thanks to the Freiburg Mindfulness Inventory.
   It is a 14 item scale. Each item is rated from 1 to 4 ("almost never" to "almost always"). The total score is between 14 and 56. The mean value in a population of young adults under 36 years of age is 38.5 (+/- 5.1 standard deviation).

Secondary Outcome Measures :

1. Perceived stress level following the emotional stimulation [Time Frame: Day 1]
   Perceived stress level is assessed with the Perceived Stress Scale (PSS). It is a 14 item scale. Each item is rated from 0 to 5 ("never" to "very often"). The total score ranges from 0 to 56 with higher scores indicating greater perceived stress.
2. Parasympathetic flexibility evolution during emotional recall [Time Frame: Day 1]
   Parasympathetic flexibility is assessed through dynamic electro-physiological analysis of cardiac and electrodermal conductance recordings.
   Physiological and cognitive reserve of emotional regulation is assessed through the analysis of the spectral power of the 0.1 Hz frequency band at emotional recall.
3. Sympathetic tone at rest [Time Frame: Day 1]
   The activity of the sympathetic tone is assessed by the measurement of the resting state salivary Chromogranin A.
   Physiological and cognitive reserve of emotional regulation is assessed through the analysis of the spectral power of the 0.1 Hz frequency band at emotional recall.
   The activity of the sympathetic tone is assessed by the measurement of the resting salivary Chromogranin A.
4. Corticotropic activation at rest [Time Frame: Day 1]
   Corticotropic activation at rest is assessed through the DHEA/cortisol level ratio
5. Mood disorders (anxiety / depression) [Time Frame: Day 1]
   The Hospital Anxiety and Depression Scale (HAD-s32) is used to assess mood disorders in the general non-psychiatric population. It is used to discriminate between anxiety and depression. Scores greater than 11 are indicative of charcaterized anxiety/depression.
6. Post-traumatic stress disorder [Time Frame: Day 1]
   Post-traumatic disorder is assessed with the PCL-5. It is a 20-item self-administered questionnaire representing DSM-5 PTSD diagnosis symptoms rated by the subject on a scale from 0 ("not at all") to 4 ("extremely") during the past month. Scores range from 0 to 80. A score greater than of 33 evokes the presence of post-traumatic stress disorder.
7. Sleep quality [Time Frame: Day 1]
   Sleep quality is assesses thanks to the Leeds Sleep Evaluation questionnaire (LEEDS). It consists of ten visual analogue scales assessing four aspects of sleep: (i) quality of falling asleep and degree of drowsiness, (ii) quality of sleep, (iii) quality of wakefulness, and (iv) quality of post-wakefulness and performance.

Biospecimen Retention: Samples Without DNA

Saliva sample

Eligibility Criteria

Ages Eligible for Study:	18 Years to 60 Years (Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

The study population is composed of people who have been deployed to serve at the mobile intensive care unit in Mulhouse (France) during the Covid-19 crisis.

Criteria

Inclusion Criteria:

- Volunteer staff member of the Mulhouse mobile intensive care unit (in French: Elément mobile de réanimation, EMR), including military reservists.

Exclusion Criteria:

- Pregnant or breastfeeding woman,
- Person deprived of liberty by a judicial or administrative decision,
- Person subject to a legal protection measure or unable of giving consent
- Intercurrent pathology with inability to work
- History of psychiatric disorder or cardiac pathology

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04365335***

Sponsors and Collaborators

Direction Centrale du Service de Santé des Armées
Institut de Recherche Biomedicale des Armees

More Information

Responsible Party:	Direction Centrale du Service de Santé des Armées
ClinicalTrials.gov Identifier:	NCT04365335 History of Changes
Other Study ID Numbers:	2020-COVID19-11 2020-A01058-31 (Other Identifier: IDRCB)
First Posted:	April 28, 2020 Key Record Dates
Last Update Posted:	March 9, 2021
Last Verified:	March 2021
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Virus Diseases
Burnout, **Psychological**	Coronavirus Infections
Stress, **Psychological**	Coronaviridae Infections
Occupational Stress	Nidovirales Infections
Burnout, Professional	RNA Virus Infections
Respiratory Tract Infections	Lung Diseases
Infections	Respiratory Tract Diseases
Pneumonia, Viral	Behavioral Symptoms
Pneumonia	Occupational Diseases

Tria record 13 **of 41** for: intensive care unit AND psychological | Covid-19

Social and Psychological Impacts of SARS-Cov-2 Pandemic Period in the Obese Population. (OBIMPACOV)
ClinicalTrials.gov Identifier: NCT04910607

Recruitment Status : Recruiting
First Posted : June 2, 2021
Last Update Posted : March 10, 2022
See **Contacts and Locations**

Sponsor:
University Hospital, Bordeaux
Collaborator:
Région Nouvelle Aquitaine
Information provided by (Responsible Party):
University Hospital, Bordeaux

- **Study Details**

- Tabular View
- No Results Posted

Study Description

Brief Summary:

The population suffering from obesity is particularly at risk during this pandemic period. The Nouvelle Aquitaine region is not spared, since according to the regional epidemiological report of 7 May 2020, carried out by Santé Publique France, 39.2% of cases admitted to the **intensive care unit** in Nouvelle Aquitaine and presenting risk factors are overweight or obese.

Other risk factors, such as social-environmental factors, must be taken into consideration. Socio-demographic surveys in this area highlight the socio-economic and territorial inequalities that interfere with obesity issues. Similarly, the issues of stigmatisation and isolation seem to be at the heart of the question of how to deal with these people.

Condition or disease	Intervention/treatment
Obesity**Covid19**	Other: QuestionnaireOther: Interview

Detailed Description:

This is a prospective multicentre study. Participating patients will be recruited from the Specialised Obesity Centres (CHU and SSR, as well as patient associations) to fill in a questionnaire and take part in an interview (a varied panel representative of the target population in terms of place of residence, socio-professional category, sex and age).

The medical and paramedical staff involved in the partner CSOs and the patients' resources (identified by the patients' associations) will also be asked to participate in a semi-directive interview.

Study Design

Study Type :	Observational
Estimated Enrollment :	310 participants
Observational Model:	Other
Time Perspective:	Prospective
Official Title:	Social and **Psychological** Impacts of SARS-Cov-2 Pandemic Period in the Obese Population.
Actual Study Start Date :	January 21, 2022
Estimated Primary Completion Date :	October 2022
Estimated Study Completion Date :	October 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
Patient Participating patients will be recruited from the Specialised Obesity Centres =CSO (CHU and Follow-up and rehabilitation **care** (SSR), as well as patient associations) to fill in a questionnaire and take part in an interview (varied panel representative of the target population in terms of place of residence, socio-professional category, sex and age).	Other: Questionnaire Questionnaire with 4 axes: sociological, reflexive medical, prospective medical, transversal Other: Interview Interview concerning health pathways, experience of confinement, consequences of confinement on health, representations of obesity.
Professional Medical and paramedical staff involved in the partner CSOs will also be asked to participate in a semi-structured interview.	Other: Interview Interview concerning health pathways, experience of confinement, consequences of confinement on health, representations of obesity.

Outcome Measures

Primary Outcome Measures :

1. Analysed social and **psychological** impacts of containment [Time Frame: 9 months after inclusion day]
   Thanks to sociology questionnaire based on the experience and paths of individuals (not a score).
   The treatments carried out will be limited to cross sorting and flat sorting, factorial analyzes and -previously- the chi-square analysis.
2. Consequences of social distancing during the containment [Time Frame: 9 months after inclusion day]
   Thanks to sociology questionnaire based on the experience and paths of individuals(not a score).
   The treatments carried out will be limited to cross sorting and flat sorting, factorial analyzes and -previously- the chi-square analysis.

Eligibility Criteria

Information from the National Library of Medicine

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All

Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

The obese population is the target population of the study.

Criteria

Inclusion Criteria:

- Patients 18 years of age.
- Be registered in an active file of the 3 partner CSOs.

Exclusion Criteria:

- Patients under 18 years of age.
- Patients under protective measures or deprived of liberty:
  - pregnant or breastfeeding woman,
  - under guardianship,
  - under guardianship,
  - safeguard of justice,
  - incarcerated.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04910607***

Contacts

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Hôpital Haut-Lévêque, Pessac, France, 33604 Contact: Blandine GATTA-CHERIFI, Pr 5 57 65 60 78 ext +33 blandine.gatta-cherifi@chu-bordeaux.fr **Recruiting**
CHU de Poitiers, Poitiers, France, 86000, Contact: Xavier PIGUEL, Dr Xavier.PIGUEL@chu-poitiers.fr **Recruiting**

Sponsors and Collaborators

University Hospital, Bordeaux
Région Nouvelle Aquitaine

Investigators

Study Chair: Arnaud Alessandrin, Dr Universite de Bordeaux

More Information

Responsible Party:	University Hospital, Bordeaux
ClinicalTrials.gov Identifier:	NCT04910607 History of Changes
Other Study ID Numbers:	CHUBX 2020/38
First Posted:	June 2, 2021 Key Record Dates
Last Update Posted:	March 10, 2022
Last Verified:	February 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by University Hospital, Bordeaux:

Obesity
COVID19
semi-directive interview

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections

Infections
Pneumonia, Viral
Pneumonia
Virus Diseases
Nidovirales Infections
RNA Virus Infections
Lung Diseases
Respiratory Tract Diseases

Stress Related Disorders in Family Members of COVID-19 Patients Admitted to the ICU

ClinicalTrials.gov Identifier: NCT04476914

Recruitment Status : Completed
First Posted : July 20, 2020
Last Update Posted : June 22, 2021

Sponsor:
University of Colorado, Denver
Collaborators:
University of Washington
Tulane University
University of Vermont
Penn State University
Columbia University
South Shore Hospital
Evergreen Hospital
Brigham and Women's Hospital
Information provided by (Responsible Party):
University of Colorado, Denver

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
Coronavirus disease 2019 (COVID-19) is a novel infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This syndrome has been associated with high mortality, estimated to be about 1.7% of all infected in the US, though in those who develop acute respiratory distress syndrome (ARDS) in the context of the infection, mortality rates appear to be much higher, perhaps up to 70%. To avoid transmission of the virus, patient isolation has become the standard of **care**, with many hospitals eliminating visitors of any type, and particularly eliminating visitation to patients infected with COVID-19. These necessary, but restrictive, measures add stress to the ICU and particularly to the family members who are not only left with fear, but also many unanswered questions. In contrast to the Society of Critical **Care** Guidelines (SCCM) which recommend family engagement in the ICU and recent data from this study team which suggests engaging families in end-of-life situations reduces symptoms of Post-Traumatic Stress Disorder (PTSD) in family members, family members are now unable to say good-bye and unable to provide support to their loved-one throughout the process of the patients' ICU stay. The study hypothesizes is that these restrictive visiting regulations will increase rates of Post-**intensive care** syndrome- family (PICS-F) which includes symptoms of PTSD, depression, and anxiety and aim to evaluate for factors that either exacerbate these symptoms or protect from them.

Condition or disease
Respiratory FailureSARS-CoV 2Corona Virus InfectionPost **Intensive Care Unit** SyndromeFamily MembersPost Traumatic Stress DisorderAnxietyDepression

Detailed Description:
The study aims to define the prevalence of PICS-F in the study population 3-4 months after ICU admission of patient, specifically symptoms of PTSD as the primary outcome, and symptoms of depression and anxiety as secondary outcomes. The study hypothesizes prevalence will be higher than seen in other studies.
An additional aim is to identify predisposing or mitigating exposures for PICS-F. The study hypothesizes that increased psychological symptoms will be associated less exposure to virtual patient visits (tablet/video conferencing), higher number of patient comorbidities (using the Charleston comorbidity index), preexisting family member psychological conditions.
The study also plans to evaluate the association between family perception of quality of communication or decision-making using items from the validated Family Satisfaction in the ICU (FS-ICU) and psychological symptoms. The study hypothesizes that the quality of communication and decision-making will be associated with lower psychological symptoms.

Finally, the plan is to, using qualitative methods, explore and describe family members' stress, experiences with communication with healthcare providers and their satisfaction with ICU care while being physically distant from their loved ones. The aim is to use qualitative findings about family members' experiences to contextualize and explain results differences in stress, satisfaction and communication quality between low vs high PICS-F scores.

Study Design

Study Type :	Observational
Actual Enrollment :	330 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	**Psychological** Distress Symptoms in Family Members of Patients With **COVID-19** Respiratory Failure in **Intensive Care Units**
Actual Study Start Date :	June 29, 2020
Actual Primary Completion Date :	June 15, 2021
Actual Study Completion Date :	June 15, 2021

Groups and Cohorts

Group/Cohort
Family Member Family members of ICU patients admitted with respiratory failure from COVID-19

Outcome Measures

Primary Outcome Measures :

1. Symptoms of Post-Traumatic Stress Disorder (PTSD) [Time Frame: 90-120 days after admission of patient to the ICU]
   Using Impact of Events Scale-Revised-6 , family members will be screened for symptoms of PTSD. Scale returns scores of 0-24, with higher scores indicating more likely to have symptoms of PTSD

Secondary Outcome Measures :

1. Symptoms of Anxiety [Time Frame: 90-120 days after admission of patient to the ICU]
   Using the Hospital Anxiety and Depression Score, family members will be screened for symptoms of anxiety. The HADS anxiety scale is scored between 0 and 21, with higher scores indicating more likely to have symptoms of anxiety
2. Symptoms of Depression [Time Frame: 90-120 days after admission of patient to the ICU]
   Using the Hospital Anxiety and Depression Score, family members will be screened for symptoms of Depression. The HADS depression scale is scored between 0 and 21, with higher scores indicating more likely to have symptoms of depression
3. Family Satisfaction with Communication and Decision Making [Time Frame: 90-120 days after admission of patient to the ICU]
   Using preselected questions from the Family Satisfaction in the ICU-27 questionnaire, we will survey families to evaluate their satisfaction with communication and decision making. Higher scores will indicate more satisfication

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

The study population will be consenting family members of COVID-19 positive patients who are admitted to the intensive care unit with respiratory failure

Criteria

Inclusion Criteria:

- Family members of COVID-19 positive patients admitted to the Intensive Care Unit with respiratory failure

Exclusion Criteria:

- Family members will be excluded if they: are under 18 or unable to complete the survey's due to language barriers

Contacts and Locations

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT04476914***

Locations United States, Colorado Eastern Colorado Veterans Affairs Health **Care** System, University Of Colorado, Aurora, Colorado, United States, 80045 **Louisiana** Tulane Medical Center New Orleans, Louisiana, United States, 70112 **Massachusetts** Brigham and Women's Medical Center Boston, Massachusetts, United States, 02115 South Shore Medical Center Weymouth, **Massachusetts**, United States, 02910, Columbia Milstein and Allen Hospitals, **New York**, New York, United States, 10034 **Pennsylvania** Penn State Hershey Milton S Hershey Medical Center, Hershey, Pennsylvania, United States, 17033 **Vermont** University of Vermont Medical Center Burlington, Vermont, United States, 05401 **Washington** University of Washington, Seattle, Washington, United States, 98104

Sponsors and Collaborators

University of Colorado, Denver; University of Washington; Tulane University; University of Vermont; Penn State University; Columbia University; South Shore Hospital; Evergreen Hospital; Brigham and Women's Hospital

More Information

Publications:

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Responsible Party:	University of Colorado, Denver
ClinicalTrials.gov Identifier:	NCT04476914 History of Changes
Other Study ID Numbers:	20-1021
First Posted:	July 20, 2020 Key Record Dates
Last Update Posted:	June 22, 2021
Last Verified:	June 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Coronavirus Infections	Respiratory Tract Diseases
Respiratory Insufficiency	Virus Diseases
Stress Disorders, Traumatic	Infections
Stress Disorders, Post-Traumatic	Coronaviridae Infections
Trauma and Stressor Related Disorders	Nidovirales Infections
	RNA Virus Infections

Mental Disorders
Respiration Disorders

Psychological and Ethical Support for Hospital Professionals During the COVID-19 Pandemic: Suitability and Post-crisis Implications for the Experience of All Professionals (PsyCOVID All P)

ClinicalTrials.gov Identifier: NCT04944394

Recruitment Status : Completed
First Posted : June 29, 2021
Last Update Posted : June 29, 2021

Sponsor:
Centre Hospitalier Universitaire Dijon
Information provided by (Responsible Party):
Centre Hospitalier Universitaire Dijon

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

SARS-COV-2 has created an unprecedented health crisis, resulting in unprecedented mobilization of all hospital professionals. The massive influx of patients overwhelmed the human, therapeutic and material resources available, and teams were confronted with an unusually heavy workload in a highly stressful emergency context. These professionals were thus exposed to a risk of over-investment in a context of acute and repetitive stress over an indefinite period of time, combining a heavy workload, emotional challenges and specific ethical issues. These factors simultaneously affected the professional sphere but also the personal and family spheres (lockdown, risk of contamination). In this context, the mental health of hospital staff is considered to be more important than ever, as emphasized on numerous occasions by the Director General of Health and the French Minister for Health and Solidarity. Mental health involves the way in which individuals respond specifically to work-related suffering by developing individual and collective defensive strategies. Thus, the question of the mental health of hospital professionals cannot be considered without taking into account the strategies implmented to combat stress, and the factors that contribute or not to the construction and stabilization of the work environment (collaboration, support).

Condition or disease	Intervention/treatment
Psychological Stress	Other: online questionnaireOther: questionnaire survey

Study Design

Study Type :	Observational
Actual Enrollment :	4522 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Psychological and Ethical Support for Hospital Professionals During the COVID-19 Pandemic: Suitability and Post-crisis Implications for the Experience of All Professionals
Actual Study Start Date :	June 10, 2020
Actual Primary Completion Date :	September 22, 2020
Actual Study Completion Date :	September 22, 202

Groups and Cohorts

Group/Cohort	Intervention/treatment
hospital professionals all professionals working in hospitals in France	Other: online questionnaire Administration of an online questionnaire (Limesurvey platform) at M0 - This questionnaire includes a characterization of the professional (center, profession, usual department and department during the health crisis, family situation). Generic stress factors, the traumatic impact of the crisis and collective and individual coping strategies are also collected. Other: questionnaire survey

Group/Cohort	Intervention/treatment
	A questionnaire survey of the chief physician of the **intensive care unit** of each hospital will make it possible to characterize the support provided by the institution and how it changed over time

Outcome Measures

Primary Outcome Measures :

1. Score assessed by Global Health Questionnaire GHQ-12 [Time Frame: at baseline]

Eligibility Criteria

Information from the National Library of Medicine

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

all professionals working in hospitals

Criteria

Inclusion Criteria:

All professionals working in hospitals Professionals involved in the organization of psychological and ethical support may also be interviewed to provide the information necessary to describe and evaluate the support provided and how it changed over time.

Exclusion Criteria:

None

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04944394***

Locations France, Chu Dijon Bourogne, Dijon, France

Sponsors and Collaborators Centre Hospitalier Universitaire Dijon

More Information

Responsible Party:	Centre Hospitalier Universitaire Dijon
ClinicalTrials.gov Identifier:	NCT04944394 History of Changes
Other Study ID Numbers:	QUENOT 2020-3
First Posted:	June 29, 2021 Key Record Dates
Last Update Posted:	June 29, 2021
Last Verified:	June 2021
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Stress, **Psychological**	Coronaviridae Infections
Respiratory Tract Infections	Nidovirales Infections
Infections	RNA Virus Infections
Pneumonia, Viral	Lung Diseases
Pneumonia	Respiratory Tract Diseases
Virus Diseases	Behavioral Symptoms

Trial record **16 of 41** for: intensive care unit AND psychological | Covid-19

The Usability, Feasibility, and Tolerability of Virtual Reality for Rehabilitation From COVID-19 (COVRehab)

ClinicalTrials.gov Identifier: NCT04505761

Recruitment Status : Completed
First Posted : August 10, 2020
Last Update Posted : April 6, 2021

Sponsor:
Radboud University Medical Center
Information provided by (Responsible Party):
Radboud University Medical Center

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
Patients who receive **intensive care** are known to be at high risk for physical, **psychological**, and cognitive impairments, a constellation known as PICS. COVID-19 patients are expected to have high chances of suffering from PICS (PICS-COV) as they frequently require several weeks of **intensive care** and traditional PICS preventive measures are virtually impossible due to infection control precautions, prone positioning, and deprivation of social contact. To prevent PICS after ICU discharge in COVID-19 patients, physical therapy is recommended. From recent but limited experience it appears that even patients with COVID-19 who have not been admitted to the ICU can suffer from impairments in the same domains and sometimes to a similar degree of severity. Also for these patient group rehabilitation seems warranted.
Yet, the resources needed to provide rehabilitation treatment to COVID-19 patients are inadequate because healthcare systems faced a shortage of high-quality treatment for these impairments already before the COVID-19 crisis emerged. Virtual Reality (VR) provides potential to healthcare practitioners to administer fast, temporary, and tailor-made rehabilitation services at a distance, and offers a solution to address the impending surge of demand for rehabilitation after COVID-19 infection. VR consists of a head mounted display (HMD) that can bring the user by computer-generated visuals into an immersive, realistic multi-sensory environment. Current VR technology is accessible, easy in use for a large audience, and safe in use. There already exist multiple VR applications for providing physical, **psychological**, and cognitive rehabilitation. These applications have been brought together in a VR suite for rehabilitation after COVID-19. Patients visiting a physiotherapist for rehabilitation from COVID-19 will be asked to participate in this study. They receive a VR HMD for training purposes. This study aims to understand the usability, feasibility, and tolerability of VR for rehabilitation after COVID-19, and to pilot the effectiveness of VR improving the physical ability, mental and cognitive status of patients.

Condition or disease	Intervention/treatment	Phase
CoronavirusPost **Intensive Care Unit** Syndrome	Device: Virtual Reality	Not Applicable

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	48 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Intervention Model Description:	Participants are asked to use Virtual Reality as an add-on to standard physiotherapy for revalidation after COVID-19.
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	The Usability, Feasibility, and Tolerability of Virtual Reality for Rehabilitation From **COVID-19**: An Explorative Study
Actual Study Start Date :	August 1, 2020
Actual Primary Completion Date :	February 1, 2021
Actual Study Completion Date :	March 31, 2021

Arms and Interventions

Arm	Intervention/treatment
Experimental: Intervention group Participants will receive Virtual Reality as an add-on to standard physiotherapy after COVID-19.	Device: Virtual Reality Participants will use a Virtual Reality headset with a range of applications applicable for rehabilitation after COVID-19. Applications target physical, **psychological**, and cognitive rehabilitation. VR headset will be used for six weeks first at the physiotherapist's practice, and when possible, at home.

Outcome Measures
Primary Outcome Measures :
1. Semi-structured interview with 15 patients on their experiences of VR for rehabilitation from COVID-19. [Time Frame: Day 42]
   At the end of the study, 15 patients will be interviewed about their experiences using VR for rehabilitation from COVID-19. The interview will be semi-structured, including questions on usability, tolerability and efficacy of VR according to the patients. The interviews will be recorded, written out and coded by means of grounded theory analysis in Atlas.ti. Themes and subthemes will be constructed.

2. Use of VR [Time Frame: Day 42]
   By means of digital tracking in the VR goggles, we aim to understand what games are used most often by the participants.
3. Semi-structured interviews with physiotherapists on their experiences of VR for rehabilitation from COVID-19. [Time Frame: Day 42]
   At the end of the study, 10 physiotherapists will be interviewed about their experiences using VR for rehabilitation from COVID-19. The interview will be semi-structured, including questions on usability, tolerability and efficacy of VR according to the physiotherapists. The interviews will be recorded, written out and coded by means of grounded theory analysis in Atlas.ti. Themes and subthemes will be constructed.

Secondary Outcome Measures :

1. Change in baseline performance test (guidelines KNGF) - Patient specific complaints. [Time Frame: Day 0, day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves physical performance, we use a baseline performance test as constructed by the COVID-19 recommendations (RL 2.0) as issued by the Royal Dutch Society for Physical Therapy (KNGF). Measurements will be done at the start of the intervention period and the end of the intervention period for tracking progress.
   The baseline performance test consists of several items of which the patient specific complaints is the first.
   Patient specific complaints refer to complaints the patients aim to improve by means of physiotherapy. Outcomes are qualitative outcomes.
2. Change in baseline performance test (guidelines KNGF) - 6 minute walk test [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves physical performance, we use a baseline performance test as constructed by the COVID-19 recommendations (RL 2.0) as issued by the Royal Dutch Society for Physical Therapy (KNGF). Measurements will be done at the start of the intervention period and the end of the intervention period for tracking progress.
   The baseline performance test consists of several items of which the 6 minute walk test is the second.
   The 6 minute walk test studies the physical capacity of a patient. We measure at day 0 how many meter a patient can walk in 6 minutes and compare this to the meters a patient is able to walk at day 42.
3. Change in baseline performance test (guidelines KNGF) - one-repetition maximum test [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves physical performance, we use a baseline performance test as constructed by the COVID-19 recommendations (RL 2.0) as issued by the Royal Dutch Society for Physical Therapy (KNGF). Measurements will be done at the start of the intervention period and the end of the intervention period for tracking progress.
   The baseline performance test consists of several items of which hand grip strength is the third.
   The hand grip strength is measured by the One-repetition maximum test which measures the amount of kg's a patient can grip at his peakforce. Measurements are done at day 0 and day 42 and compared.
4. Change in baseline performance test (guidelines KNGF) - 30 sec sit to stand [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves physical performance, we use a baseline performance test as constructed by the COVID-19 recommendations (RL 2.0) as issued by the Royal Dutch Society for Physical Therapy (KNGF). Measurements will be done at the start of the intervention period and the end of the intervention period for tracking progress.
   The baseline performance test consists of several items of which the 30 sec sit to stand test for lower extremities is the fourth.
   The 30 seconds sit to stand test is for testing leg strength and endurance. A patient has to do as many sit to stand exercises in 30 seconds. Measurements are done at day 0 and compared to day 42.
5. Change in baseline performance test (guidelines KNGF) - Borgscale for fatigue [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves physical performance, we use a baseline performance test as constructed by the COVID-19 recommendations (RL 2.0) as issued by the Royal Dutch Society for Physical Therapy (KNGF). Measurements will be done at the start of the intervention period and the end of the intervention period for tracking progress.
   The baseline performance test consists of several items of which the Borgscale for fatigue is the final item.
   The borgscale for fatigue is a numerical scale (1-10) to rate physical exertion and fatigue. Patients fill in the scale at day 0 and day 42. Results are compared.
6. Change in activities of daily life. [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves physical performance, we will as well measure change in activities of Daily Life. This questionnaire (ADL) measures the ease of participating in activities of daily life (ADL) of the patient. The questionnaire consists of 22 questions ranging from 0 (not at all) to 3 (easily autonomous). Maximum score is 63.
7. Change in HADS. [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves **psychological** rehabilitation, we will measure change in HADS. The HADS (Hospital Anxiety and Depression Scale) is used to measure change in **psychological** outcomes before and after the intervention period. Questionnaire consists out of 14 questions with answers ranging from 0 (often) to 3 (almost never). All questions are summed up to a total of 42 points.
8. Change in CFQ. [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves cognitive rehabilitation, we will use the CFQ. The CFQ (Cognitive Failure Questionnaire) is used to measure change in cognitive outcomes before and after the intervention period. Questionnaire consists out 25 questions ranging from 0 to 5. All questions are summed up to a total of 100 points.
9. Change in SF12. [Time Frame: Day 0, Day 42]
   To investigate whether adding VR to rehabilitation (perceivably) improves quality of life, we will use the SF12. The SF12 questionnaire is used to measure change in quality of life before and after the intervention period.
   SF12: SF12 measures via different scaled questions eight concepts: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health. The first four items together form the physical health scale. The latter four items form the mental health scale. The higher the scores, the better the physical and mental health. Highest possible score: 56. Lowest possible score: 12.
10. Change in positive health. [Time Frame: Day 0, Day 42]
    To investigate whether adding VR to rehabilitation (perceivably) improves quality of life, we will as well use the Positive Health questionnaire. The Positive Health questionnaire is used to measure change in quality of life before and after the intervention period.

Positive Health:Positive health consists out of 42 statements separated in 6 categories: bodily functioning, mental functioning, spiritual dimension, quality of life, social participation, daily functioning. Each question should be rated with a 0 (worst) to a 10 (best). The higher the scores, the better the quality of life.

Other Outcome Measures:

1. Patient characteristics related to use of VR [Time Frame: Day 0]
   Age, gender, education, employment, lifestyle, experience with technology - qualitative measures.

Eligibility Criteria

Ages Eligible for Study:	16 Years and older (Child, Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Patient has had COVID-19.
2. Patient has an indication for physical therapy in the context of rehabilitation after COVID-19.
3. At the day of recruitment, the estimated length of the physical therapy is at least 3 weeks after inclusion.
4. Patient is willing and able to comply with the study protocol.
5. Patient is at least 16 years old on the day the informed consent form will be signed.
6. Patient can read and understand the Dutch language.

Exclusion Criteria:

1. The patient is participating in another study interfering with this study.
2. Patient has difficulties to handle virtual reality:
   a. Patient suffers from delirium or acute confusional state.
   b. Patient has (a history of) dementia, seizure, or epilepsy.
   c. Patient has severe hearing/visual impairment not corrected.
   d. The skin of the patient's head or face is not intact (for example head wounds, psoriasis, eczema).
3. Patient has a high risk of contamination with a therapy resistant micro-organism e.g. MRSA.
4. Patients suffers from severe anxiety or depression (HADS≥16).
5. Red flags (see Appendix 1).

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04505761***

Locations Netherlands Radboud university medical center **Nijmegen, Gelderland, Netherlands, 6525 GA**

Sponsors and Collaborators

Radboud University Medical Center

Investigators Principal Investigators: Harry van Goor, MD, PhD **Radboud University Medical Center,** Bart Staal, PT, PhD, Radboud University Medical Center

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Groenveld T, Achttien R, Smits M, de Vries M, van Heerde R, Staal B, van Goor H; COVID Rehab Group. Feasibility of Virtual Reality Exercises at Home for Post-COVID-19 Condition: Cohort Study. JMIR Rehabil Assist Technol. 2022 Aug 15;9(3):e36836. doi: 10.2196/36836.

Responsible Party:	Radboud University Medical Center
ClinicalTrials.gov Identifier:	NCT04505761 History of Changes
Other Study ID Numbers:	COVRehab
First Posted:	August 10, 2020 Key Record Dates
Last Update Posted:	April 6, 2021
Last Verified:	June 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	Only upon asking.

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Radboud University Medical Center:

Virtual Reality
Rehabilitation
Post-**intensive care** syndrome

Additional relevant MeSH terms:

Coronavirus Infections
Syndrome
Disease
Pathologic Processes
Coronaviridae Infections
Nidovirales Infections
RNA Virus Infections
Virus Diseases
Infections

French Cohort of COVID-19 Patients With Post-intensive Care Syndrome (COREADOM)

ClinicalTrials.gov Identifier: NCT04590170

Recruitment Status : Recruiting
First Posted : October 19, 2020
Last Update Posted : January 8, 2021
See **Contacts and Locations**

Sponsor:
Assistance Publique - Hôpitaux de Paris
Information provided by (Responsible Party):
Assistance Publique - Hôpitaux de Paris

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:
The purpose of this study is to describe post-**intensive care** syndrome (PICS) of patients surviving to coronavirus disease 2019 (COVID19) and their rehabilitation and recovery process from hospital to home return

Condition or disease	Intervention/treatment
Covid19	Behavioral: Post-**intensive Care unit** syndrome

Study Design

Study Type :	Observational
Estimated Enrollment :	100 participants
Observational Model:	Cohort
Time Perspective:	Retrospective
Official Title:	French Cohort of **covid19** Patients With Post-**intensive Care** Syndrome : Rehabilitation From **Intensive Care Unit** to Home Return
Actual Study Start Date :	October 30, 2020
Estimated Primary Completion Date :	October 30, 2022
Estimated Study Completion Date :	April 30, 2023

Groups and Cohorts

Intervention Details:

- Behavioral: Post-**intensive Care unit** syndrome
Post-**intensive Care unit** syndrome after an **intensive care unit** stay for the COVID19

Outcome Measures

Primary Outcome Measures :

1. Change on cognitive Impairment: Vigilance (RASS) [Time Frame: Between 10 days and 1 month after ICU's discharge] Used to measure the agitation or sedation level of a person. Range -5 to +4
2. Change on cognitive Impairment: Cooperation [Time Frame: Between 10 days and 1 month after ICU's discharge] Yes/no
3. Change on cognitive Impairment: Communication [Time Frame: Between 10 days and 1 month after ICU's discharge] Yes/no

4. Change on cognitive Impairment: Agitation [Time Frame: Between 10 days and 1 month after ICU's discharge]Yes/no
5. Change on cognitive Impairment: Delirium [Time Frame: Between 10 days and 1 month after ICU's discharge] Yes/no
6. Change on cognitive Impairment : Introduction of neuroleptic [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
7. Change on cognitive Impairment: temporo-spatial disorientation [Time Frame: Between 10 days and 1 month after ICU's discharge] Yes/no
8. Change on physical Impairment : dyspnea [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/No
9. Change on physical Impairment: Modified Borg scale dyspnea score. [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Verbal and numerical scale that asks you to rate the difficulty of your breathing Patients are asked to tick the boxes that reflect their dyspnea perception best range 0-10 lesser is better
10. Change on physical Impairment : cough [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/No
11. Change on physical Impairment : respiratory rate [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Number of breaths/per minute.
12. Change on physical Impairment : ventilation mode [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Tracheotomy/ ambient air / OXYGEN THERAPY Other
13. Change on physical Impairment : Peripheral capillary oxygen saturation (SpO2) at rest [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] measured by pulse oximetry, which provides an indirect measurement of arterial oxygenation (SaO2) based on the differential absorption of light by oxygenated and deoxygenated blood during pulsatile blood flow
14. Change on physical Impairment : respiratory rate on activity [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] respiratory rate breathing rate on activity
15. Change on physical Impairment : Peripheral capillary oxygen saturation (SpO2) on activity [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] measured by pulse oximetry, which provides an indirect measurement of arterial oxygenation (SaO2) based on the differential absorption of light by oxygenated and deoxygenated blood during pulsatile blood flow during activity
16. Change on physical Impairment : orthostatic hypotension [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no drop in blood pressure that occurs when moving from a laying down (supine) position to a standing (upright) position.
17. Change on physical Impairment : electrocardiogram at rest [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] electrocardiogram at rest
18. Change on physical impairment : numeric verbal scales of fatigue [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] self-evaluation numeric verbal scales of fatigue ranges (0-10) lesser is better
19. Change on physical Impairment: numeric verbal scales of pain [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] self-evaluation numeric verbal scales of pain ranges (0-10) lesser is better
20. Change on physical Impairment : stiffness or pain involving joints [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/No small joints (wrists, fingers, toes) and large joints (shoulders, elbows, hips, knees, ankles)
21. Change on physical Impairment : stability of the trunk in siting [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
22. Change on physical Impairment : autonomy for bed-chair transfers [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
Yes/no
23. Change on physical Impairment autonomy for walking [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
24. Change on physical Impairment : sores [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
Yes/no Localisation
25. Change on Imagery cerebral [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
date and result if applicable
26. Change on physical Impairment neurologic exam [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
motor or sensory deficits involving the upper and the lower limbs (yes/no) Anosmia Yes/no taste loss Yes/no
27. Change on physical Impairment Medical Research Council (MRC-SS MRC Sum score) [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
assess muscle strength from Grade 5 (normal) to Grade 0 (no visible contraction).
MRC-SS score was defined as the sum of MRC scores from six muscles in the upper and lower limbs on both sides so that the score ranged from 60 (normal) to 0 (quadriplegic).
28. Change on physical Impairment five times sit to stand test [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
The score is the amount of time (to the nearest decimal in seconds) it takes a patient to transfer from a seated to a standing position and back to sitting five times without use of arms, Equipment • Standard height chair (43-45 cm, 17-18 inches) with a backrest. If the patient cannot perform five stands to complete the test without use of arms, a score of 0 seconds should be documented.
29. Change on cognitive Impairment The Montreal Cognitive Assessment (MoCA) [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
Designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstruction skills, conceptual thinking, calculations, and orientation. Range 0 -30 higher is better
30. Cognitive Impairment Frontal Assessment Battery (FAB) [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
Total score is from a maximum of 18, higher scores indicating better performance.
31. Change on **psychological** Impairment : sadness [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
32. Change on **psychological** Impairment : anxiety [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
33. Change on **psychological** Impairment: Insomnia [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
34. Change on **psychological** Impairment : Apathy [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
35. Change on **psychological** Impairment : sideration [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
36. Change on **psychological** Impairment : Despair [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
37. Change on **psychological** Impairment : Culpability [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]Yes/no

38. Change on **psychological** Impairment : Conduit addictive [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Yes/no
39. Change on **psychological** Impairment : psychiatric or psychologic **care** [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
    Yes/nossess type of psychiatric treatment [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Type
40. Change on **psychological** Impairment : Hospital Anxiety and Depression Scale (HADS) [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
    A 14-item self-report screening scale that was originally developed to indicate the possible presence of anxiety and depressive states It contains two 7-item scales: one for anxiety and one for depression both with a score range of 0-21.
41. Change on **psychological** Impairment : Posttraumatic Stress Disorder Checklist Scale (PCL-S) [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] 20-item questionnaire, corresponding to the Manual of Mental Disorders (DSM-5) symptom criteria for PTSD.
42. assess **psychological** Impairment [Time Frame: Change between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
    Introduction of antidepressant drugs Type
43. assess **psychological** Impairment [Time Frame: change between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Introduction of neuroleptic Type

Secondary Outcome Measures :

1. asses demographics information [Time Frame: Between 10 days and 1 month after ICU's discharge] Age, sex, formal education, marital status, occupation, place of living, socio-professional category
2. assess comorbidities [Time Frame: Between 10 days and 1 month after ICU's discharge] number of comorbidities
3. assess past and current medications [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] Precise
4. assess related symptoms nature of COVID-19 [Time Frame: Between 10 days and 1 month after ICU's discharge]
   duration of COVID-19-related symptoms nature Laboratory-confirmed SARS-CoV-2 infection as determined by PCR, or other commercial or public health assay and/or CT-scan showing typical radiological findings
5. assess characteristics of ongoing hospitalization [Time Frame: Between 10 days and 1 month after ICU's discharge]
   number of characteristics of ongoing hospitalization (invasive ventilation, curare, others treatments)
6. assess medical complications in **intensive care** [Time Frame: Between 10 days and 1 month after ICU's discharge]
   Pneumopathy pulmonary embolism others
7. Descriptive data of the rehabilitation **care** pathway after stay in **intensive care** until return home [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge]
   Number of days to discharge from hospital Service of rehabilitation **care** hospital at home (HAH) return at home
8. Number of new medical qualifying events since last contact [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] complications
9. Social status [Time Frame: Between 10 days and 1 month and 3 months and 6 months after ICU's discharge] professional activity unemployment retirement others
10. Activities of Daily Living (ADL) scale [Time Frame: 3 months and 6 months after ICU's discharge] Related to personal **care** (self-performance) looks at four of these tasks: transfer, bed mobility, toileting and eating. The resident's self- performance and the amount of staff support provided are evaluated for all of these tasks ranges from 0 (independent) to 4 (total dependence)
11. Quality of life Medical outcome study short form 12 items (MOS-SF-12) questionnaire [Time Frame: 3 months and 6 months after ICU's discharge] Self-reported outcome measure assessing the impact of health on an individual's everyday life Patients fill out a 12-question survey which is then scored by a clinician or researcher.
    Questionnaire consisting of 12 questions that measure 8 health domains to assess physical and mental health. Physical health-related domains include General Health (GH), Physical Functioning (PF), Role Physical (RP), and Body Pain (BP). Mental health-related scales include Vitality (VT), Social Functioning (SF), Role Emotional (RE), and Mental Health (MH).
12. Gait analysis 6-minute walk test (6MWT) [Time Frame: 3 months and 6 months after ICU's discharge]
    Sub-maximal exercise test used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity.
13. Balance and Gait analysis [Time Frame: 3 months and 6 months after ICU's discharge]
    Inertial Sensors to Assess Gait Quality

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Sampling Method:	Non-Probability Sample

Study Population

Patients hospitalized in cochin or Corentin-celton hospitals after an intensive care unit stay for a COVID19 infection

Criteria

Inclusion Criteria:

- COVID 19 infection (PCR or CT-scan)
- ICU stay requiring mechanical ventilation
- Age ≥18 years old

Exclusion Criteria:

- Inability to give consent

Contacts and Locations

Contacts

Contact: Marie-Martine Marie-Martine, MD, PhD +33630480893 marie-martine.lefevre-colau@aphp.fr

Contact: Marie Benhammani-Godard +33158411211 marie.godard@aphp.fr

Locations France

Department of Physical Medicine and Rehabilitation **Recruiting**
Issy-les-Moulineaux, France, 92130
Contact: Anita DUMITRACHE alina.dumitrache@aphp.fr

Department of Rehabilitation, Institute of Rheumatology Cochin **Not yet recruiting**
Paris, France, 75014
Contact: Camille Camille, MD +33659064885 camille.daste@aphp.fr

Sponsors and Collaborators

Assistance Publique - Hôpitaux de Paris

Investigators

Principal Investigator: Camille : Camille, MD Study Principal Investigator

More Information

Responsible Party:	Assistance Publique - Hôpitaux de Paris
ClinicalTrials.gov Identifier:	NCT04590170 History of Changes
Other Study ID Numbers:	APHP200812
First Posted:	October 19, 2020 Key Record Dates
Last Update Posted:	January 8, 2021
Last Verified:	December 2020
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	Undecided
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Post-intensive Care Follow-up of Patients Hospitalized for an Acute Respiratory Distress Syndrome Caused by COVID-19 (RE-CoV-ERY)

ClinicalTrials.gov Identifier: NCT04619368

Recruitment Status : Recruiting
First Posted : November 6, 2020
Last Update Posted : June 9, 2022
See **Contacts and Locations**

Sponsor:
University Hospital, Toulouse
Information provided by (Responsible Party):
University Hospital, Toulouse

- **Study Details**

- **Tabular View**
- **No Results Posted**

- Disclaimer
- How to Read a Study Record

Study Description

Brief Summary:

For the last years, studies have described the " Post-**intensive care** Syndrome " (PICS), which consists in alteration of quality of life, cognition, autonomy and **psychological** disorders within the months after **intensive-care**. Patients with COVID-19 in **intensive care units** are at high risks to develop PICS.

The primary objective is to analyse the incidence of the post-traumatic stress disorder at 12 months after **intensive-care** for a COVID-19 Acute Respiratory Distress Syndrome (ARDS).

Condition or disease	Intervention/treatment
Human ARDSCoronavirus Infection	Other: Follow up calls

Many studies have showed that ARDS survivors keep, even a long time after hospitalization, a functional respiratory disability, resulting on one hand from impaired diffusion of carbon monoxide, and on the other hand from a muscular weakness. Indeed, 67% of patients ventilated more than 10 days have a neuromyopathy whose recovery is uncertain.

Beside this, Long-term quality of life is worse than in general population, due in particular to depressive and anxiety disorders such as post-traumatic syndrome disorder with a prevalence around 22% after one year.

The follow-up will consist in phone call with an intensive care doctor. These visits would be the opportunity to screen the complications after intensive-care with, find solutions to cure them or decrease their impact on patient's life to improve quality of life and prevent the post-traumatic syndrome disorder PTSD. A review would be sent to the patients' General Practitioners at the end of each visit.

Study Design

Study Type :	Observational [Patient Registry]
Estimated Enrollment :	100 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Target Follow-Up Duration:	1 Year
Official Title:	Post-**intensive Care** Follow-up of Patients Hospitalized for an Acute Respiratory Distress Syndrome (ARDS) Caused by SARS-CoV-2 (COVID-
Actual Study Start Date :	July 27, 2020
Estimated Primary Completion Date :	July 2022
Estimated Study Completion Date :	July 2022

Resource links provided by the National Library of Medicine

MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019)

Genetic and Rare Diseases Information Center resources: Respiratory Distress Syndrome, Infant Acute Respiratory Distress Syndrome Acute Graft Versus Host Disease

U.S. FDA Resources

Groups and Cohorts

Intervention Details:

- Other: Follow up calls

The follow-up will consist in phone call with an **intensive care** doctor. These visits would be the opportunity to screen the complications after **intensive-care** with, find solutions to cure them or decrease their impact on patient's life to improve quality of life and prevent the post-traumatic syndrome disorder PTSD. A review would be sent to the patients' General Practitioners at the end of each visit.

Outcome Measures

Primary Outcome Measures :

1. Incidence of Post-traumatic Stress Disorder (PTSD) with the Post-traumatic Checklist-5 (PCL-5) 12 months after **intensive-care** [Time Frame: month 12]
   Incidence of Post-traumatic Stress Disorder (PTSD) with the Post-traumatic Checklist-5 (PCL-5) 12 months after **intensive-care**

Secondary Outcome Measures :

1. **psychological** disorders measured by QIDS [Time Frame: Month 3]
   psychological disorders measured by QIDS, Quick Inventory of Depressive Symptomatology. results from 0 to 27; 27 is the higher score of depressive symptoms
2. **psychological** disorders measured by STAI-YA [Time Frame: Month 3]
   psychological disorders measured by STAI-YA, State Trait Inventory Anxiety. Results from 20 to 80. 80 is the higher score of anxiety
3. **psychological** disorders measured by QIDS [Time Frame: Month 6]
   psychological disorders measured by QIDS : Quick Inventory of Depressive Symptomatology. results from 0 to 27; 27 is the higher score of depressive symptoms

4. **psychological** disorders measured by STAI-YA [Time Frame: Month 6]
   psychological disorders measured by STAI-YA, State Trait Inventory Anxiety. Results from 20 to 80. 80 is the higher score of anxiety
5. **psychological** disorders measured by QIDS [Time Frame: Month 12]
   psychological disorders measured by QIDS, Quick Inventory of Depressive Symptomatology. results from 0 to 27; 27 is the higher score of depressive symptoms
6. **psychological** disorders measured by STAI-YA [Time Frame: Month 12]
   psychological disorders measured by STAI-YA, State Trait Inventory Anxiety. Results from 20 to 80. 80 is the higher score of anxiety
7. quality of life by EQL-5 [Time Frame: Month 3]
   Quality of life measured by European Quality of Life -5 scale (overall satisfaction of Europeans concerning different aspects of life) higher score is higher quality of life
8. quality of life by EQL-5 [Time Frame: Month 6]
   Quality of life measured by European Quality of Life -5 scale (overall satisfaction of Europeans concerning different aspects of life), higher score is higher quality of life
9. quality of life by EQL-5 [Time Frame: Month 12]
   Quality of life measured by European Quality of Life -5 scale (overall satisfaction of Europeans concerning different aspects of life), higher score is higher quality of life
10. nutritional status [Time Frame: Month 3]
    nutritional status measured by Nutritional Risk Screening 2002
11. nutritional status [Time Frame: Month 6]
    nutritional status measured by Nutritional Risk Screening 2002
12. nutritional status [Time Frame: Month 12]
    nutritional status measured by Nutritional Risk Screening 2002

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Probability Sample

Study Population

cohort of all COVID patients who went out alive from intensive care

Criteria

Inclusion Criteria:

- adult patient
- hospitalized in intensive care of the CHU anesthesia-intensive care unit (Rangueil, URM, Neurosurgery)
- intubated and ventilated
- supported for an ARDS according to the Berlin criteria (PaO2 / FiO2 ratio <300 mmHg)
- with an rt-PCR positive to SARS-CoV-2
- affiliated to the french social security

Exclusion Criteria:

- minor patient
- patient under protective measure
- ARDS in the pandemic context but rt-PCR negative to SARS-CoV-2

Contacts and Locations

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT04619368***

Contacts

Contact: Fanny BOUNES, PH 05 61 32 23 11 ext +33 Bounes.f@chu-toulouse.fr

Locations France University Hospital of Toulouse Toulouse, France, 31000 Contact: Fanny BOUNES, PH **Recruiting**

Sponsors and Collaborators

University Hospital, Toulouse

Investigators

Principal Investigator: Fanny BOUNES University Hospital, Toulouse

More Information

Responsible Party:	University Hospital, Toulouse
ClinicalTrials.gov Identifier:	NCT04619368 History of Changes
Other Study ID Numbers:	RC31/20/0219
First Posted:	November 6, 2020 Key Record Dates
Last Update Posted:	June 9, 2022
Last Verified:	June 2022
Individual Participant Data (IPD) Sharing Statement:	Undecided
Plan to Share IPD:	
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by University Hospital, Toulouse:

Post-**intensive care** Syndrome	PTSD
Acute Respiratory Distress Syndrome	follow-up after ICU
quality of life	COVID-19
intensive care unit	

Additional relevant MeSH terms:

COVID-19	Pneumonia
Coronavirus Infections	Virus Diseases
Respiratory Distress Syndrome	Coronaviridae Infections
Respiratory Distress Syndrome, Newborn	Nidovirales Infections
Acute Lung Injury	RNA Virus Infections
Syndrome	Lung Diseases
Disease	Respiratory Tract Diseases
Pathologic Processes	Respiration Disorders
Respiratory Tract Infections	Infant, Premature, Diseases
Infections	Infant, Newborn, Diseases
Pneumonia, Viral	Lung Injury

One-year Outcomes in Survivors of the Severe COVID-19 Pneumonia (CO-Qo-ICU) (CO-Qo-ICU)

ClinicalTrials.gov Identifier: NCT04401111

Recruitment Status : Unknown
Verified May 2020 by Centre Hospitalier Universitaire de Nice.
Recruitment status was: Recruiting
First Posted : May 26, 2020
Last Update Posted : September 25, 2020

Sponsor:
Centre Hospitalier Universitaire de Nice
Information provided by (Responsible Party):
Centre Hospitalier Universitaire de Nice

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
Pneumonia caused by infection at SARS-CoV2 may be complicated by an acute respiratory detress syndrome need to take **care** in **intensive care unit** and can lead to mechanical ventilation. COVID-19 is a pandemic disease and lot of patients will survive of severe pneumoniae at SARS-CoV2 treat in ICU. At this time, there is no data about functional prognosis at long term.

This aim of this study is to evaluate the recovery of quality of life, respiratory function, neuromuscular function at long term and incidence of post-traumatic stress disorder. Patients will follow during 1year after out of ICU with 3 consultations at 3month, 6month and 12month. At each consultation patients will be evaluated about respiratory function, effort tolerance via 6minutes walking test, psychologic function with IES-R and HAD score and quality of life with SF36.
The hypothesis is that patients who survived of ARDS post infection at SARS-CoV2 have persistent functional limitation and alteration of quality of life one year after being discharged from the ICU.

Condition or disease
COVIDARDSQuality of Life

Study Design

Study Type :	Observational
Estimated Enrollment :	150 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Multiparametric Evaluation of One-year Outcomes in Survivors of the Severe COVID-19 Pneumonia After **Intensive Care Unit**
Actual Study Start Date :	June 16, 2020
Estimated Primary Completion Date :	June 15, 2021
Estimated Study Completion Date :	June 15, 2021

Groups and Cohorts

Group/Cohort
Survivors of **Intensive care unit** patients Survivors of severe COVID-19 pneumonia after **intensive care unit**

Outcome Measures

Primary Outcome Measures :

1. Evaluation of recovery of quality of life in first year after ICU discharged in patients hospitalised for severe pneumonia at SARS-CoV2 [Time Frame: 1 year]
   The primary outcome is the score SF36 at 3month, 6month, 12 month after discharged of ICU in study population

Secondary Outcome Measures :

1. Evaluation of respiratory function during first year after ICU discharged in population studied [Time Frame: 1 year]
   Evaluation of functional respiratory exploratory
2. Evaluation at 1 year of evolution of functional exercises capacity in population studied [Time Frame: 1 year]
   Mesure of the traveled distance in six-min walk test
3. Evaluation of evolution of renal function during first year after ICU discharged in population studied [Time Frame: 1 year]
   Mesure of creatinine clairance and proteinuria
4. Evaluation of evolution of right and left myocardic function during first year after ICU discharged in population studied [Time Frame: 1 year]
   Sudy of cardiac ultrasonography parameters
5. Evaluation at 1 year of incidence of psychiatric pathology [Time Frame: 1 year]
   Occurence of post-traumatic stress disorder or anxious and depressive disorders in population studied
6. Evaluation at 1 year of consequences in professional activity in population studied [Time Frame: 1 year]
   Rate of return to professional activity

Biospecimen Retention: Samples Without DNA, Whole blood

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Sampling Method:	Non-Probability Sample

Study Population

Patients treated for COVID-19 in Intensive care unit

Criteria

Inclusion Criteria:

All consecutive patients with COVID-19 pneumina with hypoxemia (need >6L/min d'O2) admitted to the ICU and survived of ICU will be included. Patients under 18 years or under guardianship will be excluded

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.
Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04401111***

Contacts

Contact: Clément SACCHERI	0033492035510	saccheri.c@chu-nice.fr
Contact: Jean DELLAMONICA, MD, PhD	0033492035510	dellamonica.j@chu-nice.fr

Locations France CHU de Nice Nice, France, 06200 Contact: Clément SACCHERI saccheri.c@chu-nice.fr Contact: Jean DELLAMONICA dellamonica.j@chu-nice.fr **Recruiting**

Sponsors and Collaborators
Centre Hospitalier Universitaire de Nice

More Information

Responsible Party:	Centre Hospitalier Universitaire de Nice
ClinicalTrials.gov Identifier:	NCT04401111 History of Changes
Other Study ID Numbers:	20reamedcovid04
First Posted:	May 26, 2020 Key Record Dates
Last Update Posted:	September 25, 2020
Last Verified:	May 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	No Data sharing plan has been established
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Centre Hospitalier Universitaire de Nice:
- Long term prognosis
- Six-minute walk test
- Restrictive syndrom

Additional relevant MeSH terms:
- Pneumonia
- Respiratory Tract Infections
- Infections
- Lung Diseases
- Respiratory Tract Diseases

Trial record **20 of 41** for: intensive care unit AND psychological | COVID-19

Anxiety and Burnout in Anesthetists and Intensive Care Unit Nurses During Covid-19 Pandemic

ClinicalTrials.gov Identifier: NCT04604119

Recruitment Status : Completed
First Posted : October 27, 2020
Last Update Posted : October 28, 2020

Sponsor:
Sisli Hamidiye Etfal Training and Research Hospital
Information provided by (Responsible Party):
Sultan Acar Sevinç, Sisli Hamidiye Etfal Training and Research Hospital

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

The aim is to measure anxiety level and burnout frequency of healthcare workers including attending physicians, residents and nurses working at **intensive care unit** during COVID-19 pandemic.

The study protocol had consisted of three parts. The first part was related to demographic details including age, sex, marital status, working position, past medical history.

The second part of the survey was validated Turkish form of Beck anxiety inventory (BAI) It has 21 questions. Every question is a somatic symptom of anxiety. Participants scored them regarding how this symptom bothered them past week. Items have four possible answers: not at all (0 point), mildly (1 point), moderate (2 point), severe (3 point). Total anxiety score can be between 0 and 63. Participants were categorized as no or mild anxiety if the total beck anxiety score was between 0-16, and moderate to severe anxiety if it was more than 16 The last part of the survey was validated Turkish form of Maslach Burnout Inventory (MBI) to evaluate components of BOS

Condition or disease
Sars-CoV2AnxietyBurnout

Detailed Description:

Our institution's ICU has served 31 beds for COVID-19 and 21 beds for other patients during pandemic with 27 attending physicians and 35 residents. Number of night shifts for attending physicians and residents were 3 and 8 per month, respectively. The aim of the study was to evaluate the by measuring anxiety level and burnout frequency of HCWs including attending physicians, residents and nurses in our institution's ICU.

Study Design

Study Type :	Observational [Patient Registry]
Actual Enrollment :	104 participants
Observational Model:	Other
Time Perspective:	Cross-Sectional
Target Follow-Up Duration:	10 Days
Official Title:	Anxiety and Burnout in Anesthetists and **Intensive Care Unit** Nurses During **Covid-19** Pandemic
Actual Study Start Date :	May 1, 2020
Actual Primary Completion Date :	May 30, 2020
Actual Study Completion Date :	June 1, 2020

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Anxiety COVID-19 (Coronavirus Disease 2019)

U.S. FDA Resources

Groups and Cohorts

Outcome Measures

Primary Outcome Measures :

1. Anxiety [Time Frame: 10-25 may]
   Measured by Beck anxiety inventory. Total anxiety score can be between 0 and 63. Participants were categorized as no or mild anxiety if the total beck anxiety score was between 0-16, and moderate to severe anxiety if it was more than 16

Secondary Outcome Measures :

1. Burnout [Time Frame: 10-25 may]
   Measured by Maslach Burnout Inventory. MBI has 7-point 22 Likerd type questions and subdivided into three parts to measure emotional exhaustion (EE) (9 items), depersonalization (DP) (5 items), personal accomplishment (PA) (8 items). High scores on EE and DP subscales and low score on PA subscale imply higher level of burnout

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Attending physicians, resident doctors, nurses working tertiary intensive care units of our institution

Criteria

Inclusion Criteria:

Healthcare workers in our institute's intensive care units

Exclusion Criteria:

None

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04604119***

Locations Turkey Sisli Hamidiye Etfal Education and Training Hospital, Istanbul, Turkey, 34771

Sponsors and Collaborators
Sisli Hamidiye Etfal Training and Research Hospital
More Information

Responsible Party:	Sultan Acar Sevinç, medical doctor, Sisli Hamidiye Etfal Training and Research Hospital
ClinicalTrials.gov Identifier:	NCT04604119 History of Changes
Other Study ID Numbers:	1577
First Posted:	October 27, 2020 Key Record Dates
Last Update Posted:	October 28, 2020
Last Verified:	October 2020
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Sultan Acar Sevinç, Sisli Hamidiye Etfal Training and Research Hospital:

anxiety
burnout
covid 19

Additional relevant MeSH terms:

COVID-19
Burnout, **Psychological**
Stress, **Psychological**
Anxiety Disorders
Respiratory Tract Infections
Infections
Pneumonia, Viral
Pneumonia
Virus Diseases
Coronavirus Infections
Coronaviridae Infections
Nidovirales Infections
RNA Virus Infections
Lung Diseases
Respiratory Tract Diseases
Mental Disorders
Behavioral Symptoms

Prioritising Prevention of COVID-19 in Persons With Cancer in the French West Indies (RESILIENCE)

ClinicalTrials.gov Identifier: NCT04768153

Recruitment Status : Active, not recruiting
First Posted : February 24, 2021
Last Update Posted : August 4, 2022

Sponsor:
University Hospital Center of Martinique
Information provided by (Responsible Party):
University Hospital Center of Martinique

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
The public health council (Haut Conseil de Santé Publique) published a statement on 14 March 2020 relating to the management of patients with severe forms of COVID-19, stipulating specific recommendations for patients with cancer.
The statement notes that patients with cancer at much higher risk (four to five times higher) of several respiratory complications, which develop very rapidly, especially if they had recently undergone surgery or chemotherapy in the previous few weeks, and that this risk could be life-threatening, on top of the cancer-related risk. In addition, the statement noted that:

- COVID-19 appears to be more frequent in patients with cancer than among the general population (1% vs 0.29%)
- Among those infected, the risk of severe respiratory complications requiring admission to the **intensive care unit** (ICU) is higher in patients with cancer than among those without (39% vs 8%, P=0.0003).

- A history of chemotherapy or surgery in the previous months is an important prognostic factor for the development of severe respiratory complications (odds ratio (OR) = 5.34, P= 0.0026).
- Deterioration of respiratory function occurs more quickly in patients with cancer (13 vs 43 days, hazard ratio (HR) 3.56, 95% confidence interval (CI) [1.65-7.69]).

In addition, COVID-19 may lead to a change in the diagnostic and therapeutic management of patients with cancer, with potential consequences such as use of oral treatments at home, discontinuation of anticancer therapy depending on the context, or prioritization of management according to curative/palliative treatment type, age, and line of therapy.
International studies previously reported the **psychological** repercussions of major epidemics on the emotional state. The impact of COVID-19 on patients with cancer therefore warrants evaluation, among cancer patients in the French West Indies, in the current situation of nationwide lockdown.

Condition or disease	Intervention/treatment
Cancer	Biological: Serology

Study Design

Study Type :	Observational
Estimated Enrollment :	66 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Prioritising Prevention of COVID-19 in Persons With Cancer in the French West Indies: Monitoring **Psychological** Impact to Optimize Healthcare Delivery Strategies in Unique Public Health Circumstances
Actual Study Start Date :	July 15, 2020
Actual Primary Completion Date :	December 31, 2021
Estimated Study Completion Date :	December 31, 2024

Groups and Cohorts

Group/Cohort	Intervention/treatment
Patients	Biological: Serology Serological diagnosis of COVID-19 in patients with cancer from a sample of cancer patients, at 3 and 6 months after implementation of confinement in France

Outcome Measures

Primary Outcome Measures :

1. Evaluation of Psychiatric disorders [Time Frame: 3 months after implementation of confinement in France]
   Evaluation of presence of psychiatric disorders by questionnaire after the initiation of population-level confinement due to the COVID-19 epidemic
2. Evaluation of Psychiatric disorders [Time Frame: 6 months after implementation of confinement in France]
   Evaluation of presence of psychiatric disorders by questionnaire after the initiation of population-level confinement due to the COVID-19 epidemic

Biospecimen Retention: Samples With DNA
Realization of the COVID -19 serological profile of cancer patients

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Probability Sample

Study Population

Cancer patients followed at the Martinique University Hospital

Criteria

Inclusion Criteria:

- Patients aged 18 years or older living in the French West Indies
- Patient with prevalent cancer of the prostate, breast, lung, colon or rectum
- Patients who receive the information leaflet and do not express any opposition to the use of their personal medical data

Exclusion Criteria:

- Patients who are unable to answer the study questionnaires

- Patients who do not speak fluent French
- Persons under legal protection

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04768153***

Locations Martinique CHU Martinique, Fort-de-France, Martinique, 97261

Sponsors and Collaborators

University Hospital Center of Martinique

More Information

Responsible Party:	University Hospital Center of Martinique
ClinicalTrials.gov Identifier:	NCT04768153 History of Changes
Other Study ID Numbers:	20_RIPH3_04
First Posted:	February 24, 2021 Key Record Dates
Last Update Posted:	August 4, 2022
Last Verified:	August 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by University Hospital Center of Martinique:

Psychiatry
Public health

Nursing Perspective on Burnout and Medical Errors in the Intensive Care Unit During Covid-19 Pandemic

ClinicalTrials.gov Identifier: NCT04371302

Recruitment Status : Terminated (Logistical problems, administrative issues)
First Posted : May 1, 2020
Last Update Posted : October 8, 2021

Sponsor:

University of Malaya

Information provided by (Responsible Party):

Samuel E H Tsan, MD, BMedSc, University of Malaya

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

The investigators plan to perform an observational study to evaluate the prevalence of burnout, depression and medical errors in a designated exclusive Covid-19 patients hospital in Malaysia, during the Covid-19 pandemic. In addition, the relationship between burnout and depression with medical errors will be assessed. The population studied will be the nurses working in the **Intensive Care Unit**, who are at higher risk due to the nature of their work at the frontlines of the pandemic.

Condition or disease	Intervention/treatment
Burnout, ProfessionalMedical ErrorsDepression	Diagnostic Test: Questionnaire

Detailed Description:

During this unprecedented Covid-19 pandemic crisis in the whole world, Malaysia is also affected, with more than 5000 patients infected in the whole country as of 20th April, 2020. Many Intensive Care Unit nurses, who are at the frontlines of managing Covid-19 patients, face increased workload, in addition to psychological stress from managing these patients, with stress also coming from being exposed to the risk of cross infection. Hence, they are possibly at high risk of burnout and depression. In such a time of increased stress, the investigators also seek to find out the prevalence of medical errors made by Intensive Care Unit nurses during this pandemic, and whether the medical errors are associated with burnout. Factors associated with burnout, depression and medical errors will also be evaluated.

Study Design

Study Type :	Observational
Actual Enrollment :	145 participants
Observational Model:	Cohort
Time Perspective:	Cross-Sectional
Official Title:	Nursing Perspective on Burnout and Medical Errors in the **Intensive Care Unit** of an Exclusively **Covid-19** Hospital: the Malaysian Experience
Actual Study Start Date :	May 1, 2020
Actual Primary Completion Date :	June 30, 2020
Actual Study Completion Date :	June 30, 2020

Groups and Cohorts

Group/Cohort	Intervention/treatment
Intensive Care Unit nurses Nurses working in the **Intensive care Unit** of an exclusive Covid-19 hospital in Malaysia, during the Covid-19 pandemic	Diagnostic Test: Questionnaire Assessment of demographics, burnout, depression and self-perceived medical errors

Outcome Measures

Primary Outcome Measures :

1. Prevalence of burnout among ICU nurses during Covid-19 [Time Frame: 2 months]
   Prevalence of burnout risk
2. Prevalence of depression among ICU nurses during Covid-19 [Time Frame: 2 months]
   Prevalence of depression risk
3. Prevalence of self-perceived medical errors among ICU nurses during Covid-19 [Time Frame: 2 months]
   Prevalence of self perceived medical errors
4. Association of burnout, depression and medical errors among anaesthesiology clinicians during Covid-19 [Time Frame: 2 months]
   To find out if there exists a relationship between burnout, depression and medical errors

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Sampling Method:	Non-Probability Sample

Study Population

All ICU nurses serving in Sungai Buloh Hospital, a nationally designated exclusive Covid-19 hospital in Malaysia during the Covid-19 pandemic.

Criteria

Inclusion criteria

1. All nurses currently serving in the ICU, Sungai Buloh Hospital

Exclusion criteria

1. Subjects who refuse to participate
2. Subjects working in ICU, Sungai Buloh Hospital, for less than 1 month

Contacts and Locations

Information from the National Library of Medicine

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT04371302***

Locations Malaysia Sungai Buloh Hospital, Kuala Lumpur, Malaysia, 59000

Sponsors and Collaborators

University of Malaya

More Information

Responsible Party:	Samuel E H Tsan, MD, BMedSc, Doctor, University of Malaya
ClinicalTrials.gov Identifier:	NCT04371302 History of Changes
Other Study ID Numbers:	54843
First Posted:	May 1, 2020 Key Record Dates
Last Update Posted:	October 8, 2021
Last Verified:	No
Individual Participant Data (IPD) Sharing Statement:	No
Plan to Share IPD:	No

Studies a U.S. FDA-regulated Drug Product:
Studies a U.S. FDA-regulated Device Product:
Keywords provided by Samuel E H Tsan, MD, BMedSc, University of Malaya:

- Burnout
- Depression
- Medical errors
- **Intensive Care Unit** nurses
- **Covid-19**

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Burnout, **Psychological**	Coronaviridae Infections
Stress, **Psychological**	Nidovirales Infections
Burnout, Professional	RNA Virus Infections
Depression	Lung Diseases
Respiratory Tract Infections	Respiratory Tract Diseases
Infections	Behavioral Symptoms
Pneumonia, Viral	Occupational Stress
Pneumonia	Occupational Diseases
Virus Diseases	

Follow-up of Patients With Previous SARS-CoV-2 Infection: Long-term Damage Assessment

ClinicalTrials.gov Identifier: NCT05359159

Recruitment Status : Recruiting
First Posted : May 3, 2022
Last Update Posted : May 3, 2022
See **Contacts and Locations**

Sponsor:
University of L'Aquila
Information provided by (Responsible Party):
Clara Balsano, University of L'Aquila

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:

People affected by SARS-CoV-2 infection, whether they have developed mild forms or a severe form of the disease, complain of nonspecific and entirely new symptoms or complain about the persistence pf them.We intend to follow over time the post-infectious phase of patients discharged from sub-**intensive care unit**. The aim is to identify symptoms and their frequency of presentation in the SARS-CoV-2 population in the post-acute period.

Condition or disease	Intervention/treatment
COVID-19	Other: Data collection

Study Design

Study Type :	Observational
Estimated Enrollment :	100 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Follow-up of Patients With Previous SARS-CoV-2 Infection: Long-term Damage Assessment
Actual Study Start Date :	February 1, 2021
Actual Primary Completion Date :	February 1, 2022
Estimated Study Completion Date :	February 2023

Resource links provided by the National Library of Medicine

MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019)

U.S. FDA Resources

Groups and Cohorts

Group/Cohort	Intervention/treatment
Post-COVID patients Patients recovered from Sars-CoV2 infection	Other: Data collection Data collection
healthy control patients Patients who did not have Sars-CoV2	Other: Data collection Data collection

Outcome Measures

Primary Outcome Measures :

1. Greater understanding of SARS-CoV-2 disease [Time Frame: 24 months]
   Greater understanding of SARS-CoV-2 disease and its long-term manifestations. To this end, the clinical manifestations, any alterations in laboratory and instrumental parameters will be evaluated to identify organ damages and calculate its prevalence

Secondary Outcome Measures :

1. Sequelae on daily life [Time Frame: 24 months]
   Understanding the impact of the disease and its sequelae on daily life and the impact on the **psychological** aspect of the person;

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Gender Based Eligibility:	Yes
Accepts Healthy Volunteers:	Yes
Sampling Method:	Probability Sample

Study Population

Patients admitted to Ospedale San Salvatore dell'Aquila over 18 years during Sars-CoV2 pandemics, with or without Sars-CoV2 related disease

Criteria

Inclusion Criteria:

- Patients over 18

Exclusion Criteria:

- Patients under 18

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT05359159***

Contacts

Contact: Clara Balsano 00390862434774 clara.balsano@univaq.it

Locations Italy

Clara Balsano **Recruiting**
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Sponsors and Collaborators

University of L'Aquila

More Information

Responsible Party:	Clara Balsano, Full professor, University of L'Aquila
ClinicalTrials.gov Identifier:	NCT05359159 History of Changes
Other Study ID Numbers:	66848
First Posted:	May 3, 2022 Key Record Dates
Last Update Posted:	May 3, 2022
Last Verified:	April 2022
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Clara Balsano, University of L'Aquila:

Long-COVID
post-COVID
SarS-CoV2

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Infections	Coronaviridae Infections
Respiratory Tract Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Cohort Follow-up of Survivors of Hospitalization for COVID-19 During the 2nd Wave of the Epidemic in France (COMEBAC 2)

ClinicalTrials.gov Identifier: NCT04934202

Recruitment Status : Recruiting
First Posted : June 22, 2021
Last Update Posted : June 22, 2021
See **Contacts and Locations**

Sponsor:

Assistance Publique - Hôpitaux de Paris

Information provided by (Responsible Party):

Assistance Publique - Hôpitaux de Paris

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

From July to September 2020, in a first uncontrolled cohort study, 478 patients who were hospitalized at Bicêtre hospital for COVID-19 and who survived were evaluated at 4 months (publication accepted at JAMA). The current project aims to bring together the means to continue this work during the 2nd epidemic wave.

Condition or disease	Intervention/treatment
SequelaeFibrosisPost-COVID SyndromePost-traumatic Stress Disorder	Other: TeleconsultationOther: Outpatient clinic

Detailed Description:

From 15th July to 18th September, 2020, in a first uncontrolled cohort study (Multi-Expertise Consultation of Bicêtre After Covid-19, COMEBAC), we evaluated at four months the surviving patients who were hospitalized at the Bicêtre hospital for COVID-19 during the 1st wave of the epidemic in France and having survived this hospitalization. This cohort included 478 patients. The article resulting from the analysis of the data collected is accepted for publication in JAMA.

This evaluation, the aim of which was both clinical and scientific, was carried out largely thanks to human and material resources then demobilized because of the epidemic and thanks to the investment of doctors and psychologists who carried out the work in addition to their usual work.

The response to the current call for projects aims to bring together the means to continue this monitoring work during the 2nd epidemic wave, while the means and staff are this time completely mobilized by the care of patients with COVID-19 and other. It also aims to raise funds that will allow an in-depth analysis of the residual symptoms presented by the patients.

The current project aims to continue the work started with the COMEBAC "1st wave" cohort with:

- The inclusion of patients hospitalized after the 1st wave.
- An assessment of symptoms according to the SARS-CoV-2 variant.
- A 12-month follow-up of symptomatic patients during the evaluation in COMEBAC "1st wave".

Study Design

Study Type :	Observational
Estimated Enrollment :	500 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Cohort Follow-up at 6-12 Months of Survivors of Hospitalization for COVID-19 During the 2nd Wave of the Epidemic From a University Hospital in France
Actual Study Start Date :	May 5, 2021
Estimated Primary Completion Date :	May 5, 2022
Estimated Study Completion Date :	May 5, 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
Patients from the 1st epidemic wave One year after their discharge from the initial hospitalization, patients who presented symptoms during the evaluation in COMEBAC "1st wave" in summer 2020 will benefit from a telephone assessment on the same schedule as that detailed above. If symptoms persist, they will be called to the day hospital for an assessment similar to the one detailed above.	Other: Teleconsultation Teleconsulting physicians will subject patients to a standardized questionnaire that will look for the following symptoms: General signs: Anorexia, fatigue, new hospitalization, weight loss, Respiratory signs: recent dyspnoea, chest discomfort, chest pain, new cough, abnormal lung CT scan since discharge Neurological signs: headache, paraesthesia, anosmia, limb paralysis Digestive signs: abdominal pain, diarrhoea, constipation, nausea, vomiting Edition 2021 ○ Cognitive signs using the Q3PC questionnaire (10): memory loss, slowness in reasoning, activity planning or problem solving, concentration, attention difficulties Other: Outpatient clinic

Group/Cohort	Intervention/treatment
	During a day hospitalization planned during the teleconsultation, patients will benefit from the following multidisciplinary assessment. General clinical examination Assessment of the state of health Respiratory assessment Pulmonary CT assessment Cognitive evaluation Cardiological evaluation Renal assessment Immunological evaluation
Patients from the 2nd epidemic wave As during the evaluation carried out during the 1st wave, the detection of persistent symptoms will be done in two stages: During a teleconsultation, to which all eligible patients will be invited, systematically looking for general, neurological, cognitive and respiratory symptoms During a hospitalization in an outpatient clinic to which all survivors who have stayed in an **intensive care unit** (ICU) will be invited and, among patients who have not stayed in an ICU, those who have residual symptoms detected during the teleconsultation.	Other: Teleconsultation Teleconsulting physicians will subject patients to a standardized questionnaire that will look for the following symptoms: General signs: Anorexia, fatigue, new hospitalization, weight loss, Respiratory signs: recent dyspnoea, chest discomfort, chest pain, new cough, abnormal lung CT scan since discharge Neurological signs: headache, paraesthesia, anosmia, limb paralysis Digestive signs: abdominal pain, diarrhoea, constipation, nausea, vomiting Edition 2021 ○ Cognitive signs using the Q3PC questionnaire (10): memory loss, slowness in reasoning, activity planning or problem solving, concentration, attention difficulties Other: Outpatient clinic During a day hospitalization planned during the teleconsultation, patients will benefit from the following multidisciplinary assessment. General clinical examination Assessment of the state of health Respiratory assessment Pulmonary CT assessment Cognitive evaluation Cardiological evaluation Renal assessment Immunological evaluation

Outcome Measures

Primary Outcome Measures :

1. Prevalence of respiratory, cognitive and **psychological** symptoms presented at 6 months of hospitalization for COVID-19. [Time Frame: 6 months]
   nature and prevalence of symptoms persisting at 6 months of an episode of COVID-19 requiring hospitalization

Secondary Outcome Measures :

1. Difference between the prevalence of residual symptoms between patients hospitalized during the 1st wave of the epidemic in France (from the COMEBAC "1st wave" study) and those of the current study [Time Frame: 6 months]
   risk factors for the various sequelae of COVID-19
2. Association between patient characteristics and the prevalence of residual symptoms. [Time Frame: 6 months]
   effect of the therapeutic changes that occurred between the 1st and 2nd wave of COVID-19 on these persistent symptoms.
3. Association between residual symptoms and the type of SARS-CoV-2 variant [Time Frame: 6 months]
   residual symptoms of COVID-19 according to the SARS-CoV-2 variants responsible
4. Prevalence of respiratory, neurological, cognitive and **psychological** symptoms presented at 6 months of hospitalization for COVID-19 which occurred during the 1st epidemic wave. [Time Frame: 6 months]
   residual symptoms of COVID-19 one year after COVID-19 that occurred during the 1st epidemic wave

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: All

Accepts Healthy Volunteers: No
Sampling Method: Non-Probability Sample

Study Population

Patients from the 1st epidemic wave Patients from the 2nd epidemic wave

Criteria

For the 6-month evaluation of patients from the 2nd epidemic wave

- Inclusion criteria
  - Age ≥18 years old
  - COVID-19 defined either by a reverse transcriptase-polymerase chain reaction (RT-PCR) or by a combination of clinical signs and compatible lung CT scan
  - Hospitalization for COVID-19 after 1st July 2020
  - Living out of the hospital
- Exclusion criteria
  - Death occurring between index hospitalization and reassessment
  - Patient refusal
  - Discovery of a positive RT-PCR for SARS-CoV-2 during hospitalization for a reason other than COVID-19
  - Nosocomial COVID-19

For the 12-month evaluation of patients from the 1st epidemic wave

- Inclusion criteria
  - Presence of general, cognitive, psychological and respiratory symptoms during the assessment made at 4 months in COMEBAC "1st wave"
- Exclusion criteria
  - Death occurring between the evaluation in COMEBAC "1st wave" and the re-evaluation
  - Patient refusal

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04934202***

Contacts

Contact: Tai PHAM +33145217245 tai.pham@aphp.fr

Locations France Bicetre hospital

Recruiting

Le Kremlin-Bicêtre, France, 94270
Contact: Tai PHAM 0145217245 tai.pham@aphp.fr

Sponsors and Collaborators

Assistance Publique - Hôpitaux de Paris

Investigators

Principal Investigator: Tai PHAM Bicêtre Hospital

More Information

Responsible Party:	Assistance Publique - Hôpitaux de Paris
ClinicalTrials.gov Identifier:	NCT04934202 History of Changes
Other Study ID Numbers:	COMEBAC 2
First Posted:	June 22, 2021 Key Record Dates
Last Update Posted:	June 22, 2021
Last Verified:	June 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic

Impact and Sequelae of High Ventilatory Drive in Critically Ill COVID-19 Patients

ClinicalTrials.gov Identifier: NCT05363332

Recruitment Status : Recruiting
First Posted : May 5, 2022
Last Update Posted : May 5, 2022
See **Contacts and Locations**

Sponsor:
Corporacion Parc Tauli
Collaborators:
Althaia Xarxa Assistencial Universitària de Manresa
Hospital Universitario Central de Asturias
Information provided by (Responsible Party):
Candelaria de Haro, Corporacion Parc Tauli

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

Critically ill COVID-19 patients with acute respiratory failure, in the **intensive care unit** (ICU), often feature high respiratory drive, determining large inspiratory efforts resulting in high pressures and global and regional over-distention, leading to lung injury. SARS-CoV-2 neurotropic-penetration in control centers in medulla oblongata might contribute to dysregulation and to excessively high respiratory drive observed in these patients. These pathophysiological conditions may often lead to the development of patient-ventilator asynchronies in aptients under mechanical ventilation, again leading to high tidal volumes and increased lung injury. These phenomena can contribute to prolonged duration of mechanical ventilation and ICU length of stay, but also can result in long term adverse outcomes like emotional/**psychological** and cognitive sequelae. All them compromising the quality of life of critically ill survivors after ICU discharge.

The investigators will conduct a multicenter study in adult critically ill COVID-19 patients with hypoxemic respiratory failure, aiming to: 1) characterize incidence and clustering of high respiratory drive by developing algorithms, 2) apply artificial intelligence in respiratory signals to identify potentially harmful patient-ventilator interactions, 3) characterize cognitive and emotional sequelae in critically ill COVID-19 survivors after ICU discharge and 4) identify sets of genes and transcriptomic signatures whose quantified expression predisposed to asynchronies and cognitive impairment in critically ill COVID-19 patients.

Condition or disease
COVID-19Critical IllnessHypoxemic Respiratory FailureNeurocognitive DysfunctionMechanical Ventilation Complication

Study Design

Study Type :	Observational
Estimated Enrollment :	126 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Impact and Sequelae of High Ventilatory Drive in Critically Ill COVID-19 Patients With Acute Respiratory Failure Requiring High Flow Oxygen or Mechanical Ventilation: Mechanistic and Genomic Characterization Using Artificial Intelligence
Actual Study Start Date :	November 15, 2021
Estimated Primary Completion Date :	May 15, 2023
Estimated Study Completion Date :	November 15, 2024

Resource links provided by the National Library of Medicine
MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019)
Genetic and Rare Diseases Information Center resources: Acute Graft Versus Host Disease
U.S. FDA Resources

Groups and Cohorts

Group/Cohort
COVID-19 Cohort Patients with a diagnosis of moderate or severe pneumonia or ARDS secondary to COVID-19.
Non COVID-19 Cohort Patients with a diagnosis of moderate or severe pneumonia or ARDS not secondary to COVID-19.

Outcome Measures

Primary Outcome Measures :

1. Respiratory drive [Time Frame: From day 1 at ICU until the day were the criteria of PaFi > 300 is met, up to 30 days]
   To characterize the high respiratory drive phenomena in critically ill COVID-19 patients undergoing mechanical ventilation.

Secondary Outcome Measures :

1. Cluster of high respiratory drive [Time Frame: From day 1 of mechanical ventilation until the day of mechanical ventilation discontinuation, up to 30 days]
   To describe the incidence and clustering of high respiratory drive throughout mechanical ventilation period by the development of specific algorithms.
2. Artificial intelligence algorithms [Time Frame: From day 1 of mechanical ventilation until the day of mechanical ventilation discontinuation, up to 30 days]
   To apply artificial intelligence (machine learning, deep learning, pattern/image recognition and entropy) in physiologic respiratory signals to identify potentially harmful patient-ventilator interactions.
3. Neurocognitive disorders [Time Frame: 1 month after ICU discharge and 1 year after ICU discharge]
   To characterize cognitive and emotional sequelae in critically ill COVID-19 survivors at 1 month and 1 year after ICU discharge.
4. Gene expression [Time Frame: day 1 of ICU admission]
   Application of massive sequencing of gene expression and circulating micro-RNA in blood samples to identify sets of genes and c-miRNA whose quantified expression is related to ventilatory asynchronies and cognitive and emotional impairment in critically ill COVID-19 patients.

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Adult patients admitted to ICU with acure respiratory failure secondary to COVID-19 infection and other etiologies.

Criteria

Inclusion Criteria:

- Adults patients with hypoxemic respiratory failure.
- Admitted to ICU.
- Mechanical ventilation or high flow nasal cannula

Exclusion Criteria:

- Neurologic patients with brainsteam affection.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT05363332***

Locations

Spain Candelaria De Haro **Recruiting**

Sabadell, Barcelona, Spain, 08208
Contact: Candelaria De Haro, MD, PhD 0034937231010 ext 21158 cdeharo@tauli.cat
Principal Investigator: Josefina Lopez-Aguilar, PhD

Fundació Althaia **Recruiting**
Manresa, Spain
Contact: Rafael Fernandez, PhD 938 75 93 00 rfernandez@althaia.cat
Sub-Investigator: Montserrat Batlle, MD, PhD

Hospital Universitario Central de Asturias **Recruiting**
Oviedo, Spain
Contact: Guilermo Muñiz-Albaiceta, PhD 985 10 80 00 gma@cri-lab.org

Sponsors and Collaborators
Corporacion Parc Tauli
Althaia Xarxa Assistencial Universitària de Manresa
Hospital Universitario Central de Asturias

More Information

Responsible Party:	Candelaria de Haro, Medical doctor and Doctor of Philosophy, Corporacion Parc Tauli
ClinicalTrials.gov Identifier:	NCT05363332 History of Changes
Other Study ID Numbers:	HighDrive COVID-19
First Posted:	May 5, 2022 Key Record Dates
Last Update Posted:	May 5, 2022
Last Verified:	May 2022

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided
Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No
Additional relevant MeSH terms:

COVID-19	Nidovirales Infections
Respiratory Insufficiency	RNA Virus Infections
Critical Illness	Lung Diseases
Cognitive Dysfunction	Respiratory Tract Diseases
Respiratory Tract Infections	Disease Attributes
Infections	Pathologic Processes
Pneumonia, Viral	Respiration Disorders
Pneumonia	Cognition Disorders
Virus Diseases	Neurocognitive Disorders
Coronavirus Infections	Mental Disorders
Coronaviridae Infections	

Trial record **26 of 41** for: intensive care unit AND psychological | COVID-19

Anxiety and Work Resilience Among Tertiary University Hospital Workers During the COVID-19 Outbreak: An Online Survey (PSY_CO_CHU)

ClinicalTrials.gov Identifier: NCT04358640

Recruitment Status : Completed
First Posted : April 24, 2020
Last Update Posted : December 19, 2020

Sponsor:
Centre Hospitalier Universitaire de Nīmes
Information provided by (Responsible Party):
Centre Hospitalier Universitaire de Nīmes

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

For limiting COVID-19 spreading, the World Health Organisation (WHO) recommended worldwide confinement on 2010. In France, unessential institutions were closed on March 14th and population confinement was decided on March 17th.

Quarantine and/or confinement could lead to **psychological** effects such as confusion, suicide ideation, post-traumatic stress symptoms or anger COVID-19 outbreak highlighted a considerable proportion of health **care** workers (HCW) with depression, insomnia, anxiety and distress symptoms. In front line, facing the virus with the fear of contracting it and contaminate their closest. During previous outbreaks (H1N1, SARS), HCWs have been shown to experience such negative **psychological** effects of confinement as well as work avoidance behaviour and physical interaction reduction with infected patients (4-7).

In France, Covid 19 outbeak led to increase ICU bed capacity with a full reorganization of the human resources. Some caregivers were reassigned to newly setup **units** admitting or not Covid-19 patients. In the same time, non-caregivers were also encouraged to work at home whenever possible. Thus, every hospital staff member's private and professional life could be altered by the Covid-19 outbreak.

As all these changes in the daily life could induce **psychological** disturbances, the present study was aimed at assessing the acute anxiety level (main objective) of the staff in our Tertiary University Hospital, (6300 employees). Secondarily, the self-reported insomnia, pain, catastrophism and work avoidance behaviour levels were assessed

Condition or disease
Critical IllnessSars-CoV2SARS PneumoniaCoronavirus InfectionStress Disorders, Post-Traumatic

Study Design

Study Type :	Observational
Actual Enrollment :	1784 participants
Observational Model:	Other
Time Perspective:	Prospective
Official Title:	Anxiety and Work Resilience Among Tertiary University Hospital Workers During the COVID-19 Outbreak: An Online Survey
Actual Study Start Date :	April 9, 2020
Actual Primary Completion Date :	April 27, 2020
Actual Study Completion Date :	April 27, 2020

Groups and Cohorts

Group/Cohort
Employees of Nîmes University Hospital (France) Employees of Nîmes University Hospital (France)

Outcome Measures

Primary Outcome Measures :

1. Anxiety [Time Frame: 15 to 45 days after the beginning of the outbreak]
   Mesured by STAY Scale

Secondary Outcome Measures :

1. Insomnia [Time Frame: 15 to 45 days after the beginning of the outbreak]
   Participant suffering of Insomnia
2. Catastrophism [Time Frame: 15 to 45 days after the beginning of the outbreak]
   Participant suffering of catastrophism

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

All employees of ICHU Nîmes participating to the present study will be sent a questionnaire for assessing the potential occurrence of anxiety This evaluation will be performed after the beginning of the outbreak (15 to 45 days)

Criteria

Inclusion Criteria:

- Employees of CHU Nîmes during COVID-19 pandemic
- Approved to participate

Exclusion Criteria:

• Participation refusal

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04358640***

Locations France Intensive care unit CHU Nimes, Nîmes, France, 30029

Sponsors and Collaborators

Centre Hospitalier Universitaire de Nîmes

More Information

Publications:

Brooks SK, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, Rubin GJ. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. Lancet. 2020 Mar 14;395(10227):912-920. doi: 10.1016/S0140-6736(20)30460-8. Epub 2020 Feb 26. Review.

Responsible Party:	Centre Hospitalier Universitaire de Nîmes
ClinicalTrials.gov Identifier:	NCT04358640 History of Changes
Other Study ID Numbers:	LOCAL COVID 2019/JYL-01)
First Posted:	April 24, 2020 Key Record Dates
Last Update Posted:	December 19, 2020
Last Verified:	December 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Coronavirus Infections	Coronaviridae Infections
Critical Illness	Nidovirales Infections
Stress Disorders, Post-Traumatic	RNA Virus Infections
Infections	Virus Diseases
Stress Disorders, Traumatic	Disease Attributes
Trauma and Stressor Related Disorders	Pathologic Processes
Mental Disorders	

Post ICU Follow up in Patients With Severe SARS-CoV-2 Infection (Covid-19)

ClinicalTrials.gov Identifier: NCT04491214

Recruitment Status : Completed
First Posted : July 29, 2020
Last Update Posted : February 12, 2021

Sponsor:

University Hospital, Strasbourg, France

Information provided by (Responsible Party):

University Hospital, Strasbourg, France

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

Patients affected by new coronavirus infectious disease (COVID) were mostly hospitalized in ICU. This infection seems to cause widespread organ injury (i.e acute renal injury, neurological disorders, pulmonary embolism,…). It is therefore necessary to provide a framework for the follow up of patients. Moreover SARS-CoV-2 infection consequences remain unknow at this time. Study hypothesis is that COVID alters determining factors (physical or **psychological**) of quality of life after ICU hospitalisation. The aim of the study is to assess quality of life 3 months after ICU hospitalization.

Secondary purposes of the study are 1) assessment of quality of life 6 months and the evolution between the third and the sixth months after ICU hospitalization 2) description patients **care** after 3 and 6 months ICU left and their clinical status 3) convening and providing a "platform" within several physicians (neurologist, biologist, pneumologist…) will be able to follow up patients and perform complementary investigations according to patients injuries.

Condition or disease	Intervention/treatment
Covid19 Follow upRehabilitation	Other: quality of live assessment

Study Design

Study Type :	Observational
Actual Enrollment :	112 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Post ICU Follow up in Patients With Severe SARS-CoV-2 Infection (**Covid-19**)
Actual Study Start Date :	July 24, 2020
Actual Primary Completion Date :	January 21, 2021
Actual Study Completion Date :	January 21, 2021

Groups and Cohorts

Intervention Details:

- Other: quality of live assessment

quality of live assessment 3 moth and 6 moth after ointensive **care** hospitalisation using SF36.

Outcome Measures

Primary Outcome Measures :

1. assess quality of life after severe COVID infection [Time Frame: measured at 3 months after ICU left.]
   assess different dimensions of quality of life: physical and mentaland social dimensions

Secondary Outcome Measures :

1. Quality of life and Clinical status [Time Frame: measured at 3 and 6 months after ICU left.]
   Clinical status of patients and assessment of quality of life. collects crucial elements of **care** based on doctors' prescriptions

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

Patient with severe SARS-Cov-2 hospitalized in intensive care.

Criteria

Inclusion criteria:

- Subject male or female ≥ 18 years old

- Patient hospitalized in the anesthesia-resuscitation department of the NHC for COVID-19 from March 1, 2020.
- Patient (or his legal representative) having given his consent for the use of his data for the purposes of this research.

Exclusion criteria:

- Subject not hospitalized in intensive care
- Patient's refusal to participate in the study
- Inability to give informed information to the subject (subject in an emergency, difficulty understanding the subject, etc.)
- Subject under low protection

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04491214***

Locations France Hôpitaux Universitaires de Strasbourg (Nouvel Hôpital Civil)

Sponsors and Collaborators

University Hospital, Strasbourg, France

More Information

Responsible Party:	University Hospital, Strasbourg, France
ClinicalTrials.gov Identifier:	NCT04491214 History of Changes
Other Study ID Numbers:	7890
First Posted:	July 29, 2020 Key Record Dates
Last Update Posted:	February 12, 2021
Last Verified:	February 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Undecided
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by University Hospital, Strasbourg, France:

SARS-CoV-2
Follow up
Intensive care unit
Cohort

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Infections	Coronaviridae Infections
Respiratory Tract Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Addressing COVID-19 Mental Health Problems Among US Veterans

ClinicalTrials.gov Identifier: NCT04484207

Recruitment Status : Completed
First Posted : July 23, 2020
Results First Posted : October 28, 2021
Last Update Posted : October 28, 2021

Sponsor:

Research Foundation for Mental Hygiene, Inc.

Information provided by (Responsible Party):

Yuval Y Neria, Research Foundation for Mental Hygiene, Inc.

- **Study Details**

- **Tabular View**
- **Study Results**

Study Description

Brief Summary:

Coronavirus disease 2019 (COVID-19) has widely and rapidly spread around the world, overwhelming **intensive care units** and health **care** capacity. While the physical risk (e.g. pneumonia, respiratory breakdown) is getting the most scientific and clinical attention, this outbreak also has significant mental health risks and extreme **psychological** fear-related responses. Among the general population, there are high-risk groups as elderly people, disabled individuals and people with previous exposure to trauma (e.g., people with military experience). Veterans are among the subgroups who are high risk for PTSD and other mental health problem. The overarching goal of this study is to examine the efficacy of an online, largescale, brief video-based intervention in reducing fear and stress and improving help seeking behavior in relate to COVID-19.

Condition or disease	Intervention/treatment	Phase
Brief Video-based InterventionVignette Based InterventionNon Intervention Control Arm	Other: A short video interventionOther: A vignette intervention	Not Applicable

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	172 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Single (Participant)
Primary Purpose:	Health Services Research
Official Title:	Addressing COVID-19 Mental Health Problems Among US Veterans
Actual Study Start Date :	July 6, 2020
Actual Primary Completion Date :	October 20, 2020
Actual Study Completion Date :	October 26, 2020

Arms and Interventions

Arm	Intervention/treatment
Experimental: Video-based intervention A brief video about coping with COVID-19 stress presented to the participants	Other: A short video intervention Three minutes video of a veteran that shares his personal story
Experimental: vignette intervention A brief vignette about coping with COVID-19 stress presented to the participants	Other: A vignette intervention A written description of the content of the video
No Intervention: Control Only assessment, no intervention arrm	

Outcome Measures

Primary Outcome Measures :

1. Help Seeking Intention [Time Frame: Assessed at baseline and post-intervention (both day 1), first follow-up (day 14), and second follow-up (day 30)]
   Attitudes Toward Seeking Professional Help Scale Minimum value: 3 Maximum value: 12 Higher scores indicate higher help seeking intentions

Secondary Outcome Measures :

1. Help Seeking Intentions Among Veterans Who Reported Anxiety, Depression, or PTSD [Time Frame: Assessed at baseline and post-intervention (both day 1), first follow-up (day 14), and second follow-up (day 30)]
   Attitudes Toward Seeking Professional Help Scale among veterans who reported anxiety, depression, or PTSD Minimum value: 3 Maximum value: 12 Higher scores indicate higher help seeking intentions

Eligibility Criteria

Ages Eligible for Study: 18 Years to 80 Years (Adult, Older Adult)

Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- English speakers, veterans (military experience) aged 18-80, US residents

Exclusion Criteria:

- non-English speakers, age less than 18 or more than 80

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04484207***

Locations United States, New York New York State Psychiatric Institute New York, New York, United States, 10032

Sponsors and Collaborators

Research Foundation for Mental Hygiene, Inc.

Investigators Principal Investigator: Yuval Neria Neria, PhD Columbia University and NYSPI

Study Documents (Full-Text) Documents provided by Yuval Y Neria, Research Foundation for Mental Hygiene, Inc.: Study Protocol and Statistical Analysis Plan [PDF] October 6, 2021

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Amsalem D, Lazarov A, Markowitz JC, Gorman D, Dixon LB, Neria Y. Increasing treatment-seeking intentions of US veterans in the Covid-19 era: A randomized controlled trial. Depress Anxiety. 2021 Jun;38(6):639-647. doi: 10.1002/da.23149. Epub 2021 Mar 18.

Responsible Party:	Yuval Y Neria, Professor of Medical Psychology, Research Foundation for Mental Hygiene, Inc.
ClinicalTrials.gov Identifier:	NCT04484207 History of Changes
Other Study ID Numbers:	8006
First Posted:	July 23, 2020 Key Record Dates
Results First Posted:	October 28, 2021
Last Update Posted:	October 28, 2021
Last Verified:	October 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	Data will be shared as needed with investigators, IRB etc. A plan will be determined in the short future
Supporting Materials:	Study Protocol Statistical Analysis Plan (SAP) Informed Consent Form (ICF)
Time Frame:	two months
Access Criteria:	Co-Is
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Trial record **29 of 41** for: intensive care unit AND psychological | COVID-19

Psychological Impact, Mental Health and Sleep Disorder Among Patients Hospitalized and Health Care Workers During the 2019 Coronavirus Outbreak (COVID-19)

ClinicalTrials.gov Identifier: NCT04497246

Recruitment Status : Completed
First Posted : August 4, 2020
Last Update Posted : April 6, 2022

Sponsor:

Murielle Surquin

Information provided by (Responsible Party):

Murielle Surquin, Brugmann University Hospital

- **Study Details**
- **Tabular View**

- **No Results Posted**

Study Description

Brief Summary:

COVID-19 is an infectious disease caused by the last coronavirus discovered, called SARS-CoV-2. Symptoms encountered in COVID-19 are: cough, breathing difficulties (dyspnea, chest pain, etc.), pyrexia, anosmia (loss of smell) and/or dysgeusia (loss of taste), but also ENT symptoms (rhinitis type, odynophagia), headaches, asthenia, muscle pain, confusion and diarrhea. Infection with SARS-CoV-2 can also be asymptomatic. COVID-19 can be passed from person to person by respiratory droplets expelled when a person speaks, coughs or sneezes. The currently estimated incubation period ranges from 1 to 14 days, and most often this is around 5 days. According to a literature review, there is strong evidence that COVID-19 has an impact on mental health (anxiety being the most common symptom) whether in the general population, healthcare workers or vulnerable populations. The objective of this project is to assess mental health and sleep disorders within two populations: elderly patients and nursing staff.

Condition or disease	Intervention/treatment
Covid19	Other: Questionnaire

Study Design

Study Type :	Observational
Actual Enrollment :	1150 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	**Psychological** Impact, Mental Health and Sleep Disorder Among Patients Hospitalized and Health **Care** Workers During the 2019 Coronavirus Outbreak (COVID-19)
Actual Study Start Date :	May 29, 2020
Actual Primary Completion Date :	August 20, 2021
Actual Study Completion Date :	August 20, 2021

Resource links provided by the National Library of Medicine

MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019) Child Mental Health Mental Health

U.S. FDA Resources

Groups and Cohorts

Group/Cohort	Intervention/treatment
Elderly patients Elderly patients (over 65 years old) hospitalized for COVID-19 within the CHU Brugmann Hospital	Other: Questionnaire Data collection by means of various questionnaires
Health **Care** professionals Health **Care** professionals working within the CHU Brugmann Hospital	Other: Questionnaire Data collection by means of various questionnaires

Outcome Measures

Primary Outcome Measures :

1. Impact Event Scale-Revised (IES-R) [Time Frame: 15 minutes]
   The IES-R is a 22-item self-report measure that assesses subjective distress caused by traumatic events.Items are rated on a 5-point scale ranging from 0 ("not at all") to 4 ("extremely"). The IES-R yields a total score (ranging from 0 to 88) and subscale scores can also be calculated for the Intrusion, Avoidance, and Hyperarousal subscales.
2. Generalised Anxiety Disorder-7 (GAD-7) [Time Frame: 15 minutes]
   Self-administered patient questionnaire used as a screening tool and severity measure for generalised anxiety disorder (GAD).The GAD-7 score is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of 'not at all', 'several days', 'more than half the days', and 'nearly every day', respectively, and adding together the scores for the seven questions. Scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate and severe anxiety, respectively. When used as a screening tool, further evaluation is recommended when the score is 10 or greater.
3. Patient Health Questionnaire-9 (PHQ-9) [Time Frame: 15 minutes]
   The PHQ-9 is the depression module, which scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day). It has been validated for use in primary **care**. It is not a screening tool for depression but it is used to monitor the severity of depression and response to treatment.
4. Insomnia severity index (ISI) [Time Frame: 15 minutes]
   The ISI is a 7-item self-report questionnaire assessing the nature, severity, and impact of insomnia.The dimensions evaluated are: severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. A 5-point Likert scale is used to rate each item (e.g., 0 = no problem; 4 = very severe problem), yielding a total score ranging from 0 to 28. The total score is interpreted as follows: absence of insomnia (0-7); sub-threshold insomnia (8-14); moderate insomnia (15-21); and severe insomnia (22-28).

Secondary Outcome Measures :

1. Demographic data [Time Frame: 1 year]
   Age, gender, familial status, home status (living alone/family support/healthcare support/ retirement home).
2. Hospitalization duration [Time Frame: 1 year]
   Hospitalization duration
3. ICU stay [Time Frame: 1 year]
   Hospitalization within the **intensive care unit** (yes/no) with or without intubation
4. Medical history [Time Frame: 1 year]
   History of chronic diseases
5. Alcohol consumption [Time Frame: 1 year]
   Alcohol consumption : none - stable - increased - diminished
6. Tobacco consumption [Time Frame: 1 year]
   Tobacco consumption : none - stable - increased - diminished

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

- Subjects 65 years of age or older, having been hospitalized for COVID-19 within the CHU Brugmann Hospital
- People aged 18 or over, member of the nursing staff of the CHU Brugmann Hospital, having worked during COVID-19.

Criteria

Inclusion Criteria:

- Subjects 65 years of age or older, having been hospitalized for COVID-19 within the CHU Brugmann Hospital
- People aged 18 or over, member of the nursing staff of the CHU Brugmann Hospital, having worked during COVID-19.

Exclusion Criteria:

- Incoherent patients
- Severe presbycusis
- Oral expression impairment
- Insurmountable language barrier

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04497246***

Locations Belgium CHU Brugmann Brussels, Belgium

Sponsors and Collaborators

Murielle Surquin

Investigators

Principal Investigator: Sophie Levy, MD CHU Brugmann

More Information

Responsible Party:	Murielle Surquin, Head of geriatry department, Brugmann University Hospital
ClinicalTrials.gov Identifier:	NCT04497246 History of Changes
Other Study ID Numbers:	CHU-COVIDIMPACT
First Posted:	August 4, 2020 Key Record Dates
Last Update Posted:	April 6, 2022
Last Verified:	March 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

- COVID-19
- Sleep Wake Disorders
- Parasomnias
- Respiratory Tract Infections
- Infections
- Pneumonia, Viral
- Pneumonia
- Virus Diseases
- Coronavirus Infections
- Coronaviridae Infections
- Nidovirales Infections
- RNA Virus Infections
- Lung Diseases
- Respiratory Tract Diseases
- Nervous System Diseases
- Neurologic Manifestations
- Mental Disorders

Sarcopenia and Related Factors in Coronavirus Disease 2019 (COVID-19) Following Intensive Care

ClinicalTrials.gov Identifier: NCT05474157

Recruitment Status : Terminated (technical reasons)
First Posted : July 26, 2022
Last Update Posted : July 26, 2022

Sponsor:
Koç University
Information provided by (Responsible Party):
Koç University

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

The primary aim of this study is to evaluate the patients who had pneumonia or severe acute respiratory distress syndrome (ARDS) due to COVID-19 in terms of sarcopenia and related factors following **Intensive Care Unit** (ICU).
The patients who had COVID-19 infection in the ICU and the patients who admitted to the 'Physical Medicine and Rehabilitation' clinic for other reasons during the pandemic period will be compared in terms of sarcopenia.

Condition or disease	Intervention/treatment
Sarcopenia**Covid19Intensive Care Unit** Acquired Weakness	Other: Standard **care** treatment for COVID-19 in **Intensive Care Unit**

Detailed Description:

Patients with acute respiratory distress syndrome (ARDS) could develop muscle weakness associated with impairment of physical function defined as intensive care unit acquired weakness. Significant muscle loss occurs in the first week of the Intensive Care Unit (ICU) hospitalizations due to acute respiratory failure. Patients lose 18 percent of their body weight when discharged from the ICU. The presence of sepsis is known as the hypercatabolic process for the muscles. Hypophosphatemia and hypomagnesemia can cause respiratory muscle weakness. Fever and inflammation, use of muscle relaxant or sedatives may also cause muscle loss in intensive care during this period.
COVID-19 is an acute infection with a high risk of enormous cytokine storm exacerbating the clinical condition in acute respiratory distress syndrome and is thought to further increase the risk of muscle weakness.
The patients will be evaluated for hand grip strength, calf circumference measurement, 'Strength, Assistance with walking, Rise from a chair, Climb stairs and Falls' (SARCF), SarQoL, timed up and go test, sit to stand test, and Short form-36.

Study Design

Study Type :	Observational
Actual Enrollment :	30 participants
Observational Model:	Case-Control
Time Perspective:	Prospective
Official Title:	Sarcopenia and Related Factors in COVID-19 Following **Intensive Care**
Actual Study Start Date :	March 1, 2021

Actual Primary Completion Date : January 1, 2022
Actual Study Completion Date : January 1, 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
Study group 15 patients Patients followed in the **Intensive Care Unit** due to COVID-19 infection	Other: Standard **care** treatment for COVID-19 in **Intensive Care Unit** Standard **care** for ARDS patients consisted of respiratory support, intravenous fluid therapy, medical treatment including anticoagulation and sedation, nutrition, change of position every 4 hours and if needed, hemodynamic support
Control group 15 patients Patients who admitted to the 'Physical Medicine and Rehabilitation' clinic for other reasons during the pandemic period	

Outcome Measures

Primary Outcome Measures :

1. Hand grip strength [Time Frame: 12 months]
   Hand grip strength is an indicator of overall muscle strength that predicts mortality in older patients. Hand grip strength was measured using a handheld dynamometer according to the instructions of the American Society of Hand Therapists.Patients were seated placing their arms by their sides with the elbow flexed to 90°, the forearm mid-prone, and the wrist in neutral position. Patients were asked to grip the dynamometer with maximal effort using standard verbal encouragement. Three trials were performed in the dominant hand with a 30 sec rest between trials and the highest value was recorded in kg. The cut-off values of grip strength is 28.6 kg in men and 16.4 kg in women.

Secondary Outcome Measures :

1. Calf circumference measurement [Time Frame: 12 months]
   Calf circumference which positively correlate with appendicular skeletal muscle mass could be used as a surrogate tool of muscle mass for sarcopenia. Adding calf circumference to SARC-F significantly improves the sensitivity and overall diagnostic accuracy of SARC-F in Chinese community dwelling older adults. Calf circumference of the patients was measured while patients in supine position, with left knee raised and calf at right angles to the thigh, using flexible plastic tape at the greatest circumference without compression of the subcutaneous tissue. The measurement were repeated 2 times and average value was recorded. According to 'European Working Group on Sarcopenia in Older People', calf circumference measure on the left leg for right-handed persons in a sitting position with the knee and ankle at a right angle and feet resting on the floor so we measured the left side for sarcopenia.
2. SARC-F (Strength, Assistance with walking, Rise from a chair, Climb stairs and Falls) [Time Frame: 12 months]
   To evaluate sarcopenia SARC-F was applied as a screening questionnaire. It is a self-filled survey questionnaire consisting of five items. The most commonly used criteria for sarcopenia in clinical practice are 'European Working Group on Sarcopenia in Older People' (EWGSOP). EWGSOP recommends using the SARC-F test for risk assessment in patients at risk of sarcopenia. Turkish validation study of the test has been done.
3. Sit to stand test [Time Frame: 12 months]
   Sit to stand test was used to evaluate strength and endurance of lower limbs. Patients are asked to sit on a chair by crossing their hands over their chest. They are asked to sit five times consecutively as fast as possible. The test is started in the sitting position and the test is terminated at the last standing position and the time is recorded. The test is carried out 2 times and the best grade obtained is recorded
4. Timed up and go test [Time Frame: 12 months]
   To assess physical function/performance, timed up and go test was performed. It is an objective, reliable and simple test to evaluate balance and functional movement. The patient is asked to get up from a chair, walk 3 m, turn around, walk back and sit on the chair again. The time is recorded in how many seconds the patient has finished the test. The test is started and ended when the patient sit on the chair with back supported. It predicts mortality
5. Sarcopenia Quality of Life (SarQoL) [Time Frame: 12 months]
   To evaluate the impact of sarcopenia on quality of life SarQoL was administered. This test identifies and predicts sarcopenia complications that can affect the patient's quality of life. It helps to evaluate the patient's perception of their health, physical, **psychological** and social aspects to healthcare professional. SarQoL has been found reliable for use in clinical **care** and research study
6. Short form - 36 [Time Frame: 12 months]
   Short form - 36 measures health related quality of life. It is a self-reported survey that evaluates individual health status with eight parameters consisting of physical function, pain, role limitations attributed to physical problems, role limitations attributed to emotional problems, mental health, social functioning, energy/ vitality, general health perception. There is not a summary score, each section is scored between 0-100, 0 indicates the worst condition, 100 indicates the best.

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes
Sampling Method: Probability Sample

Study Population

30 patients with ARDS or severe pneumonia due to COVID-19 hospitalized in intensive care unit, >18 years Study group: 15 Control group: 15

Criteria

Inclusion Criteria:

- Patients with ARDS or severe pneumonia due to COVID-19 hospitalized in intensive care unit
- > 18 years old
- Age and gender matched patients admitted to the 'Physical Medicine and Rehabilitation' clinic for control group

Exclusion Criteria:

- Other diseases that may cause sarcopenia (cancer, non-respiratory organ failure and heart, liver or kidney failure)
- Neurological diseases that may cause sarcopenia (stroke, spinal cord injury, muscle diseases)

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.
Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT05474157***

Locations Turkey Koc University School of Medicine Istanbul, Turkey, 34010

Sponsors and Collaborators

Koç University

Investigators Principal Investigator: Ozden Ozyemisci Taskiran, Prof Koc University School of Medicine

More Information

Publications of Results:

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Responsible Party:	Koç University
ClinicalTrials.gov Identifier:	NCT05474157 History of Changes
Other Study ID Numbers:	2020.221.IRB1.071
First Posted:	July 26, 2022 Key Record Dates
Last Update Posted:	July 26, 2022

Last Verified:	December 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	It was not planned to share individual participant data
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Koç University:

- Sarcopenia
- **covid19**
- acute respiratory distress syndrome
- **intensive care unit**

Additional relevant MeSH terms:

- COVID-19
- Sarcopenia
- Respiratory Tract Infections
- Infections
- Pneumonia, Viral
- Pneumonia
- Virus Diseases
- Coronavirus Infections
- Coronaviridae Infections
- Nidovirales Infections
- RNA Virus Infections
- Lung Diseases
- Respiratory Tract Diseases
- Muscular Atrophy
- Neuromuscular Manifestations
- Neurologic Manifestations
- Nervous System Diseases
- Atrophy
- Pathological Conditions, Anatomical

Impact of COVID-19 on Mental Health of Health Care Workers (COVID-Impact)

ClinicalTrials.gov Identifier: NCT04382196

Recruitment Status : Active, not recruiting
First Posted : May 11, 2020
Last Update Posted : May 11, 2020

Sponsor:
University Hospital, Ghent
Information provided by (Responsible Party):
University Hospital, Ghent

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:
The impact of the current Covid-19 pandemic on healthcare workers is enormous. This longitudinal study investigates the prevalence of mental health problems and the quality of life of healthcare workers during and after the Covid-19 pandemic. Underlying risk factors are also examined. Health **care** workers of the different Covid-19 cohort and transit wards, as well as the **intensive care unit** and (psychiatric) emergency services of the Ghent university hospital will be included, as well as the health **care** workers of 6 non-Covid-19 wards.

Condition or disease	Intervention/treatment
Mental HealthQuality of Life	Other: Online survey

Detailed Description:
The impact of the current Covid-19 pandemic on healthcare workers is enormous. Previous studies during the SARS outbreak demonstrated a significant burden and increase of mental health problems in health care workers.This longitudinal study aims to investigate the prevalence of mental health problems and the quality of life of health care workers during and after the Covid-19 pandemic. Health care workers of the different Covid-19 cohort and transit wards, as well as the intensive care unit and (psychiatric) emergency services of the Ghent university hospital will be included, as well as the health care workers of 6 non-Covid-19 wards. Participants will receive a monthly online survey during the government issued restrictions. After cessation of the restrictions participants will receive three-monthly surveys for a one-year-period. Sociodemographic data, data regarding employment and previous mental health problems will be collected at the first survey. The Covid-19 status of the health care workers will be inquired at every survey. The Depression, Anxiety and Stress Scale (DASS-21), the Dutch translation of the Covid-19 Peritraumatic Distress Index (CPDI), the WHO Quality of Life-BREF (WHOQOL-BREF), and the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5) and three items measuring social support will be administered at every survey.

Study Design

Study Type :	Observational
Actual Enrollment :	497 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	The Impact of the **COVID-19** Pandemic on Mental Health and Quality of Life of Healthcare Workers in a University Hospital
Actual Study Start Date :	April 17, 2020
Estimated Primary Completion Date :	December 31, 2022
Estimated Study Completion Date :	December 31, 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
Health **care** workers Health **care** workers at university hospital	Other: Online survey An online survey will be administered

Outcome Measures

Primary Outcome Measures :

1. Depressive symptoms at baseline [Time Frame: Baseline]
   Depressive symptoms as measured by the 7-item depression subscale of the self-reported 21-item Depression, Anxiety, and Stress Scale (DASS-21) (DASS-21-Depression). A higher score indicates more depressive symptoms with a minimum score of 0 and a maximum score of 21.
2. Change in depressive symptoms [Time Frame: Baseline, baseline + 30 days, baseline + 90 days, baseline + 180 days, baseline + 270 days, baseline + 360 days, baseline + 540 days, baseline + 900 days]
   Depressive symptoms as measured by the 7-item depression subscale of the self-reported 21-item Depression, Anxiety, and Stress Scale (DASS-21) (DASS-21-Depression). A higher score indicates more depressive symptoms with a minimum score of 0 and a maximum score of 21.
3. Anxiety levels at baseline [Time Frame: Baseline]
   Anxiety as measured by the 7-item anxiety subscale of the self-reported DASS-21 (DASS-21-Anxiety). A higher score indicates higher anxiety levels with a minimum score of 0 and a maximum score of 21.
4. Change in anxiety levels [Time Frame: Baseline, baseline + 30 days, baseline + 90 days, baseline + 180 days, baseline + 270 days, baseline + 360 days, baseline + 540 days, baseline + 900 days]
   Anxiety as measured by the 7-item anxiety subscale of the self-reported DASS-21 (DASS-21-Anxiety). A higher score indicates higher anxiety levels with a minimum score of 0 and a maximum score of 21.
5. Stress levels at baseline [Time Frame: Baseline]
   Stress as measured by the 7-item stress subscale of the self-reported DASS-21 (DASS-21-Stress). A higher score indicates higher stress levels with a minimum score of 0 and a maximum score of 21.
6. Change in stress levels [Time Frame: Baseline, baseline + 30 days, baseline + 90 days, baseline + 180 days, baseline + 270 days, baseline + 360 days, baseline + 540 days, baseline + 900 days]
   Stress as measured by the 7-item stress subscale of the self-reported DASS-21 (DASS-21-Stress). A higher score indicates higher stress levels with a minimum score of 0 and a maximum score of 21.
7. Quality of life at baseline [Time Frame: Baseline]
   Quality of life will be measured by the WHO Quality of Life Bref Questionnaire (WHOQOL-BREF). This self-report questionnaire has a minimum score of 0 and a maximum score of 100 with a higher score indicating higher quality of life. It includes different domains such as physical health, **psychological** health, social relationships and environment as well as two specific questions regarding an individual's overall perception of quality of life and physical health.
8. Change in Quality of life [Time Frame: Baseline, baseline + 30 days, baseline + 90 days, baseline + 180 days, baseline + 270 days, baseline + 360 days, baseline + 540 days, baseline + 900 days]
   Quality of life will be measured by the WHO Quality of Life Bref Questionnaire (WHOQOL-BREF). This self-report questionnaire has a minimum score of 0 and a maximum score of 100 with a higher score indicating higher quality of life. It includes different domains such as physical health, **psychological** health, social relationships and environment as well as two specific questions regarding an individual's overall perception of quality of life and physical health.
9. Covid-19 related **psychological** distress [Time Frame: baseline]
   Specific distress regarding Covd-19 will be measured by the Dutch translation of the COVID-19 Peritraumatic Distress Index (CPDI). This self-reported questionnaire inquires about the frequency of anxiety, depression, specific phobias, cognitive change, avoidance and compulsive behaviour, physical symptoms and loss of social functioning in the past week. The score ranges from 0 to 100, with higher scores indicating more distress.

10. Change in Covid-19 related **psychological** distress [Time Frame: Baseline, baseline + 30 days, baseline + 90 days, baseline + 180 days, baseline + 270 days, baseline + 360 days, baseline + 540 days, baseline + 900 days]
    Specific distress regarding Covd-19 will be measured by the Dutch translation of the COVID-19 Peritraumatic Distress Index (CPDI). This self-reported questionnaire inquires about the frequency of anxiety, depression, specific phobias, cognitive change, avoidance and compulsive behaviour, physical symptoms and loss of social functioning in the past week. The score ranges from 0 to 100, with higher scores indicating more distress.
11. Post traumatic stress symptoms [Time Frame: Baseline]
    The Primary **Care** PTSD Screen for DSM-5 (PC-PTSD-5) is a 5-item screen that was designed for use in primary **care** settings. The measure begins with an item designed to assess whether the respondent has had any exposure to traumatic events. If a respondent denies exposure, the PC-PTSD-5 is complete with a score of 0. However, if a respondent indicates that they have experienced a traumatic event over the course of their life, the respondent is instructed to respond to five additional yes/no questions about how that trauma exposure has affected them over the past month. The minimum score is 0 and the maximum score is 5 with higher scores indicating more PTSD-related symptoms.
12. Change in post traumatic stress symptoms [Time Frame: Baseline, baseline + 30 days, baseline + 90 days, baseline + 180 days, baseline + 270 days, baseline + 360 days, baseline + 540 days, baseline + 900 days]
    The Primary **Care** PTSD Screen for DSM-5 (PC-PTSD-5) is a 5-item screen that was designed for use in primary **care** settings. The measure begins with an item designed to assess whether the respondent has had any exposure to traumatic events. If a respondent denies exposure, the PC-PTSD-5 is complete with a score of 0. However, if a respondent indicates that they have experienced a traumatic event over the course of their life, the respondent is instructed to respond to five additional yes/no questions about how that trauma exposure has affected them over the past month. The minimum score is 0 and the maximum score is 5 with higher scores indicating more PTSD-related symptoms.

Secondary Outcome Measures :

1. Perceived social support at baseline [Time Frame: Baseline]
   Social support (from colleagues and employer) as perceived by participants will be measured by three items as measured on a 5-point Likert scale. For each item the minimum score is 1 and the maximum score is 5.
2. Change in perceived social support [Time Frame: Baseline, baseline + 30 days, baseline + 90 days, baseline + 180 days, baseline + 270 days, baseline + 360 days, baseline + 540 days, baseline + 900 days]
   Social support (from colleagues and employer) as perceived by participants will be measured by three items as measured on a 5-point Likert scale. For each item the minimum score is 1 and the maximum score is 5.

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below.

Ages Eligible for Study:	Child, Adult, Older Adult
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

All personnel of the above specified services of the university hospital involved in direct or indirect care will be eligible for inclusion

Criteria

Inclusion Criteria:

- health care worker
- employed at inclusion at Covid cohort/transit or (psychiatric) emergency services or intensive care unit or 6 specified wards of the Ghent University Hospital

Exclusion Criteria:

- none

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04382196***

Locations Belgium Ghent University Hospital Ghent, Belgium, 9000

Sponsors and Collaborators University Hospital, Ghent **Investigators** Study Director: Gilbert Lemmens, University Hospital, Ghent

More Information

Responsible Party:	University Hospital, Ghent
ClinicalTrials.gov Identifier:	NCT04382196 History of Changes
Other Study ID Numbers:	BC-07564
First Posted:	May 11, 2020 Key Record Dates
Last Update Posted:	May 11, 2020
Last Verified:	May 2020

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided
Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No
Keywords provided by University Hospital, Ghent:
Health **care** workers
Covid-19
Mental health
Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Sociodemographic, Clinical, Quality of Life and Health Care Conditions in COVID-19 Survivors.

ClinicalTrials.gov Identifier: NCT05185674

Recruitment Status : Active, not recruiting
First Posted : January 11, 2022
Last Update Posted : May 19, 2022

Sponsor:
Javier Eslava
Information provided by (Responsible Party):
Javier Eslava, Universidad Nacional de Colombia

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
Sociodemographic, Clinical, Quality of Life, and Health **Care** Conditions After Hospital Discharge in Patients Who Required Admission to the **Intensive Care Unit** for COVID-19 at the Hospital Universitario Nacional Between April 2020 and March 2021. Bogotá, Colombia
The main objective of this study is to characterize the sociodemographic, clinical, quality of life and health **care** conditions in a cohort of patients who have survived a stay in the **Intensive Care Unit** of the National University Hospital of Colombia. Secondarily, associations between these findings and sociodemographic and clinical characteristics will be evaluated.
It is expected to contribute to the scientific literature through the characterization and epidemiology of the problem in a sample of patients from a Latin American country. It is planned to contribute not only with clinical data, but also with data on socioeconomic impacts on patients and notions of the health **care** they are receiving. Through the analyzes to be carried out, associations that will contribute to the evidence for prevention and management of the outcome will be explored.

Condition or disease	Intervention/treatment
Post-acute **COVID-19** SyndromeLong-COVID**COVID-19**Long COVIDPost-acute Sequelae of SARS-CoV-2 Infection	Other: Exposure: Coronavirus disease 2019 (COVID-19)

Detailed Description:

Progressively, the evidence is growing that COVID-19 survivors present persistent or new symptoms and / or alterations in diagnostic studies / functional tests. There is no consensual characterization and denomination for this outcome, proposing names such as "Long-COVID" or "Post-COVID Syndrome", among others. Nor are there homogeneous estimates regarding incidence and prevalence. Most of the population studies and surveys have been conducted in the United States, China, and European countries. It is considered that this problem can have negative effects on the quality of life, the health of patients and a significant burden of disease for the system. Patients may face inequities and barriers in health care.
At the national and global level; it is projected that large numbers of people may present or are exhibiting this "syndrome." Knowing the situation is necessary to formulate and develop responses in terms of prevention, diagnosis, management and rehabilitation.
This study will be carried out with the main purpose of characterizing the sociodemographic, clinical, quality of life and health care conditions in a cohort of patients who have survived a stay in the Intensive Care Unit of the National University Hospital of Colombia. Secondarily, associations between these findings and sociodemographic and clinical characteristics will be evaluated.
The study will be developed with patients who have been admitted to the Intensive Care Unit of the National University Hospital of Colombia for COVID-19. Once the study is explained to the potential participants, doubts are resolved and informed consent is obtained; clinical variables registered in the database will be taken and a remote interview (virtual, telephone) will be carried out with the participant applying the collection instrument that contains questions of own elaboration and validated and recognized scales. No physical, treatment or experimentation interventions will be made. The study period is from April 1, 2020 to March 31, 2021.
A pilot test is included to determine the applicability of the collection instrument, average duration of the interview, feasibility of filling out informed consent by electronic means and disposition of the participants to receive the information and be part of the study.
The data is recorded in REDCap and will be taken to the R-Studio statistical program, through which and with the STATA v16.1 program the analysis will be executed.
As a benefit to patients, a copy of their answers to the instrument's medical questions and a medical guidance will be sent to them. It will be explained to the participants that said orientation does not replace a formal medical consultation nor does it correspond to a teleconsultation and medical orders will not be issued.
This study also corresponds to a Master's thesis in Public Health for the Universidad Nacional de Colombia, within the framework of the "Equidad en Salud" Research Group of the Universidad Nacional de Colombia.

Study Design

Study Type :	Observational
Estimated Enrollment :	312 participants
Observational Model:	Cohort
Time Perspective:	Other
Official Title:	Sociodemographic,Clinical,Quality of Life, and Health **Care** Conditions After Hospital Discharge in Patients Who Required Admission to ICU for **COVID-19** at Hospital Universitario Nacional Between April 2020 and March 2021. Bogotá, Colombia
Actual Study Start Date :	September 10, 2021
Actual Primary Completion Date :	April 29, 2022
Estimated Study Completion Date :	August 2022

Groups and Cohorts

Group/Cohort	Intervention/treatment
COVID-19 survivors subjects All patients discharged from the National University Hospital of Colombia (Bogotá, Colombia) who required admission to the **Intensive Care Unit** of the same institution with a confirmed diagnosis of SARS-CoV-2 disease (COVID-19 disease) between April 1, 2020 and March 31, 2021 Severe Acute Respiratory Syndrome (SARS) Coronavirus (CoV)	Other: Exposure: Coronavirus disease 2019 (COVID-19) Having presented Coronavirus disease 2019 (COVID-19) and stay in the **Intensive Care Unit**

Outcome Measures

Primary Outcome Measures :

1. Number of participants with new or persistent symptoms after COVID-19 Number of participants with new or persistent symptoms after COVID-19 [Time Frame: Baseline (At the time of the interview and application of the collection instrument)]
   Percentage of Participants with one or more new or persistent symptoms. Assessment of the presence or absence of one or more new or persistent symptoms after having COVID-19, reported as yes or no for each symptom.
   If the participant manifests dyspnea, the severity will be evaluated using the Modified Medical Research Council (mMRC) instrument, with scoring options from 0 to 4. The higher score the worse the symptoms.
2. Health-related quality of life before and after presenting COVID-19 [Time Frame: Baseline (At the time of the interview and application of the collection instrument)]
   The instrument 12-Item Short-Form Health Survey (SF-12v2) version in Spanish for Colombia will be applied. The valid questionnaire consists of 12 questions about mental and physical health. Questions will be asked for the current moment and also directed to before having COVID-19. Scores ranging from 0 to 100 with higher score indicating better health.
3. Health **care** conditions after presenting COVID-19 [Time Frame: Baseline (At the time of the interview and application of the collection instrument)]
   The participants will be asked questions designed by the researchers in the collection instrument about medical controls that they have received after medical discharge from COVID-19 and mainly for new or persistent symptoms, reported as yes or no medical control. Frequency of each barrier in access to health services (by default in the collection instrument elaborated by researchers).
4. Socioeconomic impact after presenting COVID-19 [Time Frame: Baseline (At the time of the interview and application of the collection instrument)]
   Frequency of each economic impact like salary decrease or job loss. The participants will be asked questions designed by the researchers in the collection instrument about possible personal socioeconomic impacts of having fallen ill with COVID-19 and being admitted to the **Intensive Care Unit**.

5. Mental health symptoms before and after presenting COVID-19 [Time Frame: Baseline (At the time of the interview and application of the collection instrument)]
   The researchers use the valid instrument Self-Reporting Questionnaire (SRQ-20) version in Spanish. The scale consists of 20 questions to be answered: yes or no. The score ranges from 0-20, each positive answer add 1 point. Higher score indicating greater possibility of **psychological** distress.
6. Functional Independence before and after presenting COVID-19 [Time Frame: Baseline (At the time of the interview and application of the collection instrument)]
   The Barthel Index, Spanish version, will be applied to assessment functional independence. Scores ranges from 0 to 100, when 100 is better outcome (independence) and 0 is worst outcome (total dependence).

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

: Patients admitted to the Intensive Care Unit of the Hospital Universitario Nacional de Colombia (Bogotá, Colombia) between April 1, 2020 and March 31, 2021.

Criteria

Inclusion Criteria:

- Inclusion Criteria
- Living patients, who presented COVID-19 with admission to the Intensive Care Unit of the National University Hospital of Colombia between April 1, 2020 and March 31, 2021.
- Patients 18 years of age and older
- COVID-19 confirmed by polymerase chain reaction (PCR) test positive for SARS-CoV-19.
- Signature of informed consent

Exclusion Criteria:

- Missing data in the database, referring to the variables of interest
- Pregnant patients
- Limitation for communication in Spanish language

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT05185674***

Locations Colombia Hospital Universitario Nacional de Colombia Bogotá, Colombia, 111321

Sponsors and Collaborators Javier Eslava

Investigators

Principal Investigator:	Laura C Loaiza-Fernandez, MD,MSc (c)	Universidad Nacional de Colombia
Principal Investigator:	Jairo A Pérez-Cely, MD, ICU	Hospital Universitario Nacional de Colombia / Universidad Nacional de Colombia
Principal Investigator:	Javier H Eslava-Schamalbach, MD, PhD	Universidad Nacional de Colombia / Hospital Universitario Nacional de Colombia

More Information

Responsible Party:	Javier Eslava, Principal Investigator. Professor, Universidad Nacional de Colombia
ClinicalTrials.gov Identifier:	NCT05185674 History of Changes
Other Study ID Numbers:	53543 (Hermes) CEI-2021-06-01 (Other Identifier: Hospital Universitario Nacional de Colombia)
First Posted:	January 11, 2022 Key Record Dates
Last Update Posted:	May 19, 2022
Last Verified:	May 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	Individual participant data are protected by legislation and by ethical standards for research.

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Javier Eslava, Universidad Nacional de Colombia:

Sequelae	Functional status
Quality of Life	**Intensive Care Unit**
Delivery of Health **Care**	**COVID-19**
Socioeconomic factors	Post-acute **COVID-19** syndrome
Mental health	Long-COVID

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

Perceived Stress Among ICU Medical Staff During COVID-19 Crisis (ICUcovid)

ClinicalTrials.gov Identifier: NCT04604769

Recruitment Status : Completed
First Posted : October 27, 2020
Last Update Posted : October 27, 2020

Sponsor:
University of Liege
Information provided by (Responsible Party):
Audrey Vanhaudenhuyse, University of Liege

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:
The objective of this study is to compare **psychological** distress and needs of nurses in ICU before and during coronavirus pandemic.

Condition or disease
CoronavirusNurse's RoleProfessional Stress

Detailed Description:
Well-being of caregivers and stress management in intensive care units are essential keys to an adequate quality of care, especially during the anxious context of coronavirus pandemic. Taking care of numerous patients, the increasing work and mental charges, facing death, the need of material and changes in work organization are all elements that can influence stress among medical workers. Considering real causes of stress and what are the needs of the medical team is fundamental for developing concrete actions to ease the workloads. A few studies were conducted in China on psychological distress of medical staff during COVID-19. According to these few studies about psychological distress in ICU, investigators think that stress scores during COVID-19 could be increased among nurses during pandemic. The second hypothesis is that causes of stress would be not so different from normal care but could be amplified by the actual situation. One point to take into consideration is that most of the studies were conducted in China and medical policy and hospital organization are different in Belgium. The objective of the study is to compare psychological distress and needs of nurses in ICU before and during coronavirus pandemic.

Study Design

Study Type :	Observational
Actual Enrollment :	60 participants
Observational Model:	Cohort
Time Perspective:	Cross-Sectional
Official Title:	Perceived Stress and Needs Among Medical Staff in ICU During **COVID-19** Crisis

Actual Study Start Date :	June 26, 2019
Actual Primary Completion Date :	September 1, 2020
Actual Study Completion Date :	September 1, 2020

Groups and Cohorts

Group/Cohort
Daily routine, control group ICU medical staff were asked about their stress and causes of stress during their daily professional life.
During Covid-19 ICU medical staff were asked about their stress and causes of stress in their daily professional life during COVID-19 crisis.

Outcome Measures

Primary Outcome Measures :

1. stress at work [Time Frame: change from baseline at one year]
   Job Content Questionnaire (Karasek, 1979)
2. stress in a medical **unit** [Time Frame: change from baseline at one year]
   Nursing Stress Questionnaire (Gray-Toft, 1981)

Secondary Outcome Measures :

1. hobby activities [Time Frame: change from baseline at one year]
   We will ask if they are used to do activities like hypnosis, yoga, mediation, sport, etc. This factor could help us to know if these activities can help and if we have to promote them in the hospital.

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

Nurses and doctors working in intensive care units before and during the COVID pandemic.

Criteria

Inclusion Criteria:

- Adults > 18 years old
- working in ICU for at least November 2019
- working in ICU regularly since March 2020
- Medical and paramedical professionals
- Working in direct contact with COVID patients

Exclusion Criteria:

- Medical professionals from others departments
- Internship students
- External volunteers for COVID
- Non front-line nurses

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04604769***

Locations Belgium University of Liège, Liège, Province De Liège, Belgium, 4000

Sponsors and Collaborators

University of Liege

Investigators Principal Investigator: Anne-Sophie Nyssen, Université de Liège

More Information

Responsible Party:	Audrey Vanhaudenhuyse, PhD, Head of the Sensation and Perception Research Group, GIGA Consciouness, University of Liege
ClinicalTrials.gov Identifier:	NCT04604769 History of Changes
Other Study ID Numbers:	stressICUcovid
First Posted:	October 27, 2020 Key Record Dates

Last Update Posted:	October 27, 2020
Last Verified:	October 2020
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Audrey Vanhaudenhuyse, University of Liege:

- coronavirus
- **covid-19**
- pandemia
- professional stress
- burnout
- nursing
- **intensive care units** (ICU)
- infection
- work organization

Additional relevant MeSH terms:

COVID-19	Virus Diseases
Stress, **Psychological**	Coronaviridae Infections
Coronavirus Infections	Nidovirales Infections
Occupational Stress	RNA Virus Infections
Respiratory Tract Infections	Lung Diseases
Infections	Respiratory Tract Diseases
Pneumonia, Viral	Occupational Diseases
Pneumonia	Behavioral Symptoms

Early Care Program for the Management of Post-ICU Syndrome and Chronic Pain After COVID-19 Infection. (PAIN-COVID)

ClinicalTrials.gov Identifier: NCT04394169

Recruitment Status : Completed
First Posted : May 19, 2020
Last Update Posted : December 14, 2021

Sponsor:
Hospital Clinic of Barcelona
Information provided by (Responsible Party):
TOMAS MIGUEL CUÑAT LOPEZ, Hospital Clinic of Barcelona

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:
COVID-19 (coronavirus 2019) disease has led to a large number of hospital admissions, many of which require admission to **intensive care** (ICU).
Post-**intensive care** syndrome (PICS) is defined as deterioration or worsening of previous deterioration in the mental, physical or cognitive status that appears as a consequence of a critical illness and which persists after acute hospital **care**. Also, there is evidence that patients who survive a critical illness have a high prevalence of moderate to extreme chronic pain.
Patients with COVID-19 disease are an especially susceptible population to develop PICS due to acute respiratory distress syndrome (ARDS) survivors have significant long-term deterioration in mental, cognitive, and functional health.
This study hypothesis is that a specific **care** program based on early therapeutic education and **psychological** intervention improves the quality of life of patients at risk of developing PICS and chronic pain after COVID-19 disease.

Condition or disease	Intervention/treatment	Phase
Post ICU SyndromeChronic Pain**Covid-19**	Behavioral: Intervention program	Not Applicable

Detailed Description:
A randomized, controlled, and single-blind trial will be performed. Patients over 18 years who have been admitted to intensive care units with the diagnosis of COVID-19 disease at risk of presenting PICS will be recruited.
The study subjects will be divided into two arms, and the intervention program will be compared to the standard care clinical practice.

The program will consist of early care (first visit at one month of hospital discharge), therapeutic education on prevention and management of PICS and chronic pain during three medical visits in six months, and psychological treatment in patients at risk for emotional distress.
The main objective is to evaluate the impact of the program on health-related life quality at six months after hospital discharge.
The secondary objectives are:

1. To assess the health-related life quality at three months after hospital discharge.
2. To quantify the incidence of chronic pain, its characteristics, and the degree of functional limitation at three and six months after hospital discharge.
3. To quantify the incidence of anxiety and depression at three and six months after hospital discharge.
4. Quantify the incidence of post-traumatic stress syndrome at 3 and 6 months after hospital discharge.

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	102 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Randomized, controlled, single-blind, and single-center clinical trial that will include patients who have been admitted to intensive care of our hos
Masking:	Single (Investigator)
Masking Description:	Visits 1,2, and 3 will be carried out by an investigator with sufficient training in questionnaires. This investigator will not participate on the interv The intervention will be performed by two researchers (Pain Physician and psychologist). This researcher will not participate in the questionnaire Researchers who analyze the results will not participate in the questionnaire and basal data collection or program intervention.
Primary Purpose:	Prevention
Official Title:	Early **Care**, Therapeutic Education, and **Psychological** Intervention for the Management of Post-**intensive Care** Syndrome and Chronic Pain Aft Randomized Trial.
Actual Study Start Date :	May 25, 2020
Actual Primary Completion Date :	October 15, 2021
Actual Study Completion Date :	October 22, 2021

Arms and Interventions

Arm	Intervention/treatment
Experimental: Intervention arm The intervention is a program that includes early patient **care**, therapeutic education, and **psychological** intervention. It will be performed through three medical visits and a **psychological** intervention that requires seven face-to-face sessions.	Behavioral: Intervention program Medical visits: There will be three medical visits stipulated as follows: Visit 1 Intervention Group, four weeks after hospital discharge. Visit 2 Intervention Group, eight weeks after hospital discharge. Visit 3 Intervention Group, 18 weeks after hospital discharge. Components of visits: Interview and physical examination. Therapeutic education about the **intensive care** syndrome orally and with a specific document that will be delivered at the end of the visit. Therapeutic education around pain. If the patient reports pain, a specific document will be prepared that will be delivered at the end of the visit. **Psychological** intervention: Inclusion criteria for **psychological** intervention: Patients with a score higher than 8 on the HAD (hospital anxiety and depression) test depression subscale. Description : The intervention protocol consists of 7 weekly sessions lasting one hour and a half. The intervention in depression is based on Rehm's model of self-control.
No Intervention: Standard **care** arm Standard medical practice: patient follow-up is carried out by their referring physicians (primary **care** physicians or specialists) who are outside the study.	

Outcome Measures

Primary Outcome Measures :

1. Impact of intervention program on health-related quality of life (VAS) [Time Frame: Six months after discharge]
   Health-related quality of life reported by the patient assessed through the visual analogue scale of the EQoL 5D/5L questionnaire at six months after discharge.
   [European quality of life 5 dimensions/5 levels ; from 0 (the worst imaginable health) to 100 (the best imaginable health)]

Secondary Outcome Measures :

1. Impact of intervention program on health-related quality of life (VAS) [Time Frame: Three months after discharge.]
   Health-related quality of life reported by the patient assessed through the visual analogue scale of the EQoL 5D / 5L questionnaire at three months after discharge.
   [European quality of life 5 dimensions/5 levels ; from 0 (the worst imaginable health) to 100 (the best imaginable health)]
2. Impact of intervention program on health-related quality of life (Index) [Time Frame: Three months after discharge]
   Health-related quality of life reported by the patient assessed through health index of the EQoL 5D/5L questionnaire at three months after discharge.
   [European quality of life 5 dimensions/5 levels ; the questionnaire assesses quality of life in study participants according to 5 domains (mobility, self-**care**, usual activities, pain/discomfort, anxiety/depression) each scored according to a scale of 1 (no problems) to 5 (indicating extreme problems) and generating a 5-digit code corresponding to quality of life]
3. Impact of intervention program on health-related quality of life (Index) [Time Frame: Six months after discharge]
   Health-related quality of life reported by the patient assessed through health index of the EQoL 5D/5L questionnaire at six months after discharge.
   [European quality of life 5 dimensions/5 levels ; the questionnaire assesses quality of life in study participants according to 5 domains (mobility, self-**care**, usual activities, pain/discomfort, anxiety/depression) each scored according to a scale of 1 (no problems) to 5 (indicating extreme problems) and generating a 5-digit code corresponding to quality of life]
4. Impact of intervention program on chronic pain (intensity) [Time Frame: Three and six months after discharge.]
   Chronic pain intensity defined by BPI questionnaire (short version), at three and six months after discharge.
   [Brief pain inventory; A multidimensional questionnaire that evaluates pain intensity in the last 24 hours (worst, lowest, average) and current (right now). The questions are rated on a scale of 0 to 10, with 10 being the worst possible value. Subsequently, the average intensity score (BPI intensity score) is calculated.]
5. Impact of intervention program on chronic pain (limitation of daily activities) [Time Frame: Three and six months after discharge.]
   Limitation of daily activities due to chronic pain, defined by BPI (short version), at three and six months after discharge.
   [Brief pain inventory; Multidimensional questionnaire that assesses the impact of pain on daily activities (general activity, encouragement, work, relationships with other people, sleep, enjoying life and the ability to walk). The questions are rated on a scale of 0 to 10, with 10 being the worst possible value. Subsequently, the mean score of the responses related to pain interference in activities (BPI interference score) is calculated.]
6. Impact of intervention program on chronic pain (Pain catastrophization) [Time Frame: Three and six months after discharge.]
   Pain catastrophization assessed by Pain Catastrophizing Scale at three and six months after hospital discharge.
   [Pain Catastrophizing Scale; Consisting of 13 questions that explore the frequency of thoughts and feelings that the interviewees have in the presence of current or anticipated pain, which are grouped into three scoring subscales (magnification, rumination and defenselessness). Each question is rated on a 5-point scale (0: not at all; 4: all the time). Being the maximum total score of 52 points.]
7. Impact of intervention program on anxiety or depression incidence [Time Frame: Three and six months after discharge.]
   Clinically significant anxiety or depression symptoms prevalence at three and six months, assessed by the HAD test.
   [hospital anxiety and depression test; 14 questions, with two subscales, one for anxiety and the other for depression, with seven items each, the maximum score is 21 for each subscale. The cut-off points from zero to seven imply the absence of clinically relevant anxiety and depression, from eight to ten symptoms that require consideration and from 11 to 21 reports the presence of relevant symptoms, with a very probable diagnosis of anxiety or depression.]
8. Impact of intervention on probable post-traumatic stress syndrome incidence [Time Frame: Three and six months after discharge.]
   Probable post-traumatic stress syndrome prevalence at three and six months after discharge assessed by the DSM (Diagnostic and Statistical Manual of Mental Disorders) V PTSD Checklist questionnaire (PCL-5)
   [PTSD Checklist questionnaire; It contains 20 questions that correspond to the DSM V PTSD (Post Traumatic Stress Disorder) criteria. Participants rated their symptoms on a scale of 0 (not at all), 1 (slightly), 2 (moderately), 3 (quite) to 4 (extremely), with a score ranging from 0 to 80. A total of the severity of the symptoms can be made, adding the score of each question (interval 0-80). The severity of each symptom can be evaluated, adding the score of the questions. The cut-off point to use for a provisional diagnosis of PTSD is 31 points.]

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Admitted to the ICU due to COVID infection19.
- APACHE II score> 14 or ICU stay> 10 days or Duration of mechanical ventilation> 7 days or Acquired weakness in ICU or Delirium during ICU admission.
- Accept to participate in the study and sign informed consent.

Exclusion Criteria:

- Central Nervous System degenerative diseases. Examples: Alzheimer's disease, Amyotrophic lateral sclerosis, Lewy body dementia, Parkinson's disease, among others.

- Terminal illness: Definition according to the palliative care guide, Spanish Society for Palliative Care. "Advanced, progressive, and incurable disease with a lack of reasonable possibilities of specific treatment, with a life prognosis of less than 6 months.
- Insufficient understanding of the Spanish language.
- Patients in whom it would be difficult to complete follow-up.
- Not having informed consent.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04394169***

Locations Spain Tomás Cuñat, Barcelona, Spain, 08036

Sponsors and Collaborators Hospital Clinic of Barcelona

Investigators Principal Investigator: Antonio José Ojeda Niño, MD Pain unit physician

More Information

Publications:

Yang X, Yu Y, Xu J, Shu H, Xia J, Liu H, Wu Y, Zhang L, Yu Z, Fang M, Yu T, Wang Y, Pan S, Zou X, Yuan S, Shang Y. Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: a single-centered, retrospective, observational study. Lancet Respir Med. 2020 May;8(5):475-481. doi: 10.1016/S2213-2600(20)30079-5. Epub 2020 Feb 24. Erratum in: Lancet Respir Med. 2020 Apr;8(4):e26.

Mao L, Jin H, Wang M, Hu Y, Chen S, He Q, Chang J, Hong C, Zhou Y, Wang D, Miao X, Li Y, Hu B. Neurologic Manifestations of Hospitalized Patients With Coronavirus Disease 2019 in Wuhan, China. JAMA Neurol. 2020 Jun 1;77(6):683-690. doi: 10.1001/jamaneurol.2020.1127.

Boldrini P, Bernetti A, Fiore P; SIMFER Executive Committee, SIMFER Committee for International Affairs. Impact of COVID-19 outbreak on rehabilitation services and Physical and Rehabilitation Medicine physicians' activities in Italy. An official document of the Italian PRM Society (SIMFER). Eur J Phys Rehabil Med. 2020 Jun;56(3):316-318. doi: 10.23736/S1973-9087.20.06256-5. Epub 2020 Mar 16.

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Torres J, Carvalho D, Molinos E, Vales C, Ferreira A, Dias CC, Araújo R, Gomes E. The impact of the patient post-intensive care syndrome components upon caregiver burden. Med Intensiva. 2017 Nov;41(8):454-460. doi: 10.1016/j.medin.2016.12.005. Epub 2017 Feb 8. English, Spanish.

Elliott D, Davidson JE, Harvey MA, Bemis-Dougherty A, Hopkins RO, Iwashyna TJ, Wagner J, Weinert C, Wunsch H, Bienvenu OJ, Black G, Brady S, Brodsky MB, Deutschman C, Doepp D, Flatley C, Fosnight S, Gittler M, Gomez BT, Hyzy R, Louis D, Mandel R, Maxwell C, Muldoon SR, Perme CS, Reilly C, Robinson MR, Rubin E, Schmidt DM, Schuller J, Scruth E, Siegal E, Spill GR, Sprenger S, Straumanis JP, Sutton P, Swoboda SM, Twaddle ML, Needham DM. Exploring the scope of post-intensive care syndrome therapy and care: engagement of non-critical care providers and survivors in a second stakeholders meeting. Crit Care Med. 2014 Dec;42(12):2518-26. doi: 10.1097/CCM.0000000000000525.

Hayhurst CJ, Jackson JC, Archer KR, Thompson JL, Chandrasekhar R, Hughes CG. Pain and Its Long-term Interference of Daily Life After Critical Illness. Anesth Analg. 2018 Sep;127(3):690-697. doi: 10.1213/ANE.0000000000003358.

Battle CE, Lovett S, Hutchings H. Chronic pain in survivors of critical illness: a retrospective analysis of incidence and risk factors. Crit Care. 2013 May 29;17(3):R101. doi: 10.1186/cc12746.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Ojeda A, Calvo A, Cuñat T, Mellado-Artigas R, Comino-Trinidad O, Aliaga J, Arias M, Ferrando C, Martinez-Pallí G, Dürsteler C. Characteristics and influence on quality of life of new-onset pain in critical COVID-19 survivors. Eur J Pain. 2022 Mar;26(3):680-694. doi: 10.1002/ejp.1897. Epub 2021 Dec 15.

Ojeda A, Calvo A, Cuñat T, Artigas RM, Comino-Trinidad O, Aliaga J, Arias M, Ahuir M, Ferrando C, Dürsteler C. Rationale and study design of an early care, therapeutic education, and psychological intervention program for the management of post-intensive care syndrome and chronic pain after COVID-19 infection (PAIN-COVID): study protocol for a randomized controlled trial. Trials. 2021 Jul 24;22(1):486. doi: 10.1186/s13063-021-05463-7.

Responsible Party:	TOMAS MIGUEL CUÑAT LOPEZ, Collaborator Investigator, Hospital Clinic of Barcelona
ClinicalTrials.gov Identifier:	NCT04394169 History of Changes
Other Study ID Numbers:	HCB/2020/0549
First Posted:	May 19, 2020 Key Record Dates
Last Update Posted:	December 14, 2021
Last Verified:	December 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by TOMAS MIGUEL CUÑAT LOPEZ, Hospital Clinic of Barcelona:

Covid-19	Post-traumatic Stress Disorder
SARS-COV2	Quality of Life
Critical **Care**	Depressive Disorders
	Anxiety disorders

Post ICU Syndrome
Chronic Pain

Additional relevant MeSH terms:

COVID-19	Virus Diseases
Syndrome	Coronavirus Infections
Chronic Pain	Coronaviridae Infections
Disease	Nidovirales Infections
Pathologic Processes	RNA Virus Infections
Infections	Lung Diseases
Respiratory Tract Infections	Respiratory Tract Diseases
Pneumonia, Viral	Pain
Pneumonia	Neurologic Manifestations

Resilience Evaluation of Caregivers During the SARS-CoV2 Epidemic Period : Prospective Cohort. (Resi-CoV)

ClinicalTrials.gov Identifier: NCT04349163

Recruitment Status : Completed
First Posted : April 16, 2020
Last Update Posted : September 23, 2020

Sponsor:
University Hospital, Angers
Information provided by (Responsible Party):
University Hospital, Angers

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

The outbreak linked to SARS-CoV-2 infection was declared a Public Health Emergency of International Concern on 30 January 2020. In all of the emergency Departments, a major reorganization was necessary, notably with the creation of a specific channel for COVID-19 suspect patients. Thus, all caregivers involved must adapt day by day to new places of exercise, new protocols,...The major influx of patients, the precautions to be taken, the specifics of the pathology and its management have profoundly changed daily practice. This exogenous hospital tension impacts all caregivers and more particularly their resilience capacities. Resilience is defined as an ability to recover from or adjust easily to misfortune or change. The Resi-CoV study aims to assess the level of resilience of caregivers of different specialties and trades in the context of covid-19.

Condition or disease	Intervention/treatment
Psychological	Other: Questionnaire

Detailed Description:

Caregivers will be invited to complete a self-administered questionnaire online via a personalized electronic message. Caregivers will be free to participate. Signed consent will not be requested, but the return of the questionnaire will be considered consent. The questionnaire will be administered using Google form® software. Caregivers will have 2 weeks to respond. A reminder will be made at 7 days. The questionnaire will be anonymized upon receipt by the investigator.

Study Design

Study Type :	Observational
Actual Enrollment :	280 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Resilience Evaluation of Caregivers During the SARS-CoV2 Epidemic Period

Actual Study Start Date : May 10, 2020
Actual Primary Completion Date : June 15, 2020
Actual Study Completion Date : June 25, 2020

Groups and Cohorts

Group/Cohort	Intervention/treatment
Caregivers Physicians and nurses working at the Emergency Department, **Intensive care Unit**, infectious disease Department, Anaesthesiology.	Other: Questionnaire CD-RISC 25 questionnaire

Outcome Measures

Primary Outcome Measures :

1. compare the level of resilience between physicians and caregivers of different specialties and in different workplaces according to the covid-19 epidemic. [Time Frame: 14 days]
   CD-RISC-25 : Connor-Davidson Resilience Scale - 25. This scale contain 25 questions each range from 1 to 5. The total is 100 points which means a very high level of resilience.

Eligibility Criteria

Ages Eligible for Study: Child, Adult, Older Adult
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes
Sampling Method: Non-Probability Sample

Study Population

All caregivers willing to answer.

Criteria

Inclusion Criteria:

- Caregivers (physicians, nurses)
- working in the Emergency Department, Anaesthesiology, Infectious Department, Intensive care Unit.
- Voluntary to answer the questionnaire

Exclusion Criteria:

- Working in another Department

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04349163***

Locations France CHU Angers, France, 49100

Sponsors and Collaborators University Hospital, Angers

Investigators Principal Investigator: Delphine Douillet, UH Angers

More Information

Responsible Party: University Hospital, Angers
ClinicalTrials.gov Identifier: NCT04349163 History of Changes
Other Study ID Numbers: 2020-A00831-39
First Posted: April 16, 2020 Key Record Dates
Last Update Posted: September 23, 2020
Last Verified: May 2020

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No
Keywords provided by University Hospital, Angers:

caregivers
covid-19
resilience
questionnaire
CD-RISC 25

ClinicalTrials.gov Identifier: NCT04460170

Recruitment Status : Unknown
Verified July 2020 by Willem Dieperink, University Medical Center Groningen.
Recruitment status was: Recruiting
First Posted : July 7, 2020
Last Update Posted : July 28, 2020

Sponsor:
University Medical Center Groningen
Collaborator:
Hanze University of Applied Sciences Groningen
Information provided by (Responsible Party):
Willem Dieperink, University Medical Center Groningen

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:
Since the SARS-CoV-2 infection is relatively new, the long term attributable burden related to COVID19 has not been investigated yet. To date, in patients with COVID-19 and their family members, there is little information on the functional status, cognitive ability, pattern of return to work, and health related quality of life after the ICU admission.
This study aims to describe the **psychological** wellbeing, physical - and social functioning of COVID-19 ICU survivors and their family members up to 12 months following ICU discharge.

Condition or disease
Quality of Life**COVID-19**

Detailed Description:
Study design The COVID-19 Follow up Intensive Care Study (COFICS) is a single center, prospective cohort study performed at a University Medical Center in The Netherlands.
Study population The study population consists of all admitted critically ill COVID-19 patients with a > 48 hours ICU admission at the ICU of a University Medical Center and a family member of the patient. Family members in this study can be partners, other family members, or friends who are identified by the patient as important.
Sample size All consecutive patients admitted to the ICU of the University Hospital for respiratory distress due to COVID-19 between March 19th 2020 and September 30th 2020 will be enrolled. With consent of the patient, family member(s) of participating patients will be enrolled.

Study Design

Study Type :	Observational [Patient Registry]
Estimated Enrollment :	100 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Target Follow-Up Duration:	12 Months
Official Title:	**COVID-19** Follow up **Intensive Care** Studies
Actual Study Start Date :	July 1, 2020
Estimated Primary Completion Date :	February 1, 2022
Estimated Study Completion Date :	February 1, 2022

Groups and Cohorts

Outcome Measures

Primary Outcome Measures :

1. General Health [Time Frame: 3 months post ICU discharge]
   MOS Short-Form General Health Survey (SF-20). The SF-20 contains 20 items and has six dimensions; physical functioning (min. score 6, max. score 12) rolefunctioning (min. score 2, max. score 4) social functioning (min. score 1, max. score 6) mental health (min. score 5, max. score 30) general health (min. score 5, max. score 25) pain (min. score 1, max score 5) All endscores will be transformed to a 100 points scale where a higher score means better functioning. Except for pain where a higher score means more pain.
   The five mental health questions will be excluded from our questionnaire because the questions are comparable with the HADS.

2. General Health [Time Frame: 6 months post ICU discharge]
   MOS Short-Form General Health Survey (SF-20). The SF-20 contains 20 items and has six dimensions; physical functioning (min. score 6, max. score 12) rolefunctioning (min. score 2, max. score 4) social functioning (min. score 1, max. score 6) mental health (min. score 5, max. score 30) general health (min. score 5, max. score 25) pain (min. score 1, max score 5) All endscores will be transformed to a 100 points scale where a higher score means better functioning. Except for pain where a higher score means more pain.
   The five mental health questions will be excluded from our questionnaire because the questions are comparable with the HADS.
3. General Health [Time Frame: 12 months post ICU discharge]
   MOS Short-Form General Health Survey (SF-20). The SF-20 contains 20 items and has six dimensions; physical functioning (min. score 6, max. score 12) rolefunctioning (min. score 2, max. score 4) social functioning (min. score 1, max. score 6) mental health (min. score 5, max. score 30) general health (min. score 5, max. score 25) pain (min. score 1, max score 5) All endscores will be transformed to a 100 points scale where a higher score means better functioning. Except for pain where a higher score means more pain.
   The five mental health questions will be excluded from our questionnaire because the questions are comparable with the HADS.
4. Anxiety and Depression [Time Frame: 3 months post ICU discharge]
   Hospital Anxiety and Depression Scale (HADS). The HADS contains two subscale of 7 items each. Minimal score is 0, maximal score 21 for each subscale where a higher score means a higher burden.
5. Anxiety and Depression [Time Frame: 6 months post ICU discharge]
   Hospital Anxiety and Depression Scale (HADS). The HADS contains two subscale of 7 items each. Minimal score is 0, maximal score 21 for each subscale where a higher score means a higher burden.
6. Anxiety and Depression [Time Frame: 12 months post ICU discharge]
   Hospital Anxiety and Depression Scale (HADS). The HADS contains two subscale of 7 items each. Minimal score is 0, maximal score 21 for each subscale where a higher score means a higher burden.
7. Long function [Time Frame: 6 months post ICU discharge (only in patients)]
   Spirometry test
8. Long function [Time Frame: 12 months post ICU discharge (only in patients)]
   Spirometry test
9. Frailty [Time Frame: 3 months post ICU discharge (only in patients)]
   Clinical Frailty Scale with a single outcome measure summarizing the overall level of fitness.
10. Frailty [Time Frame: 6 months post ICU discharge (only in patients)]
    Clinical Frailty Scale with a single outcome measure summarizing the overall level of fitness.
11. Frailty [Time Frame: 12 months post ICU discharge (only in patients)]
    Clinical Frailty Scale with a single outcome measure summarizing the overall level of fitness.
12. Family functioning [Time Frame: 6 months post ICU discharge]
    McMaster Family Assessment Device (FAD-GF6+). The FAD-GF6+ contains 6 items (min. score 6, max. score 24) where a higher scores indicate a lower caregiver burden.
13. Family functioning [Time Frame: 12 months post ICU discharge]
    McMaster Family Assessment Device (FAD-GF6+). The FAD-GF6+ contains 6 items (min. score 6, max. score 24) where a higher scores indicate a lower caregiver burden.
14. Effect of an ICU admission on return to work [Time Frame: 3 months post ICU discharge (only in family members)]
    Return to work knowing; possible job loss, change of work activities and worsening employment status
15. Effect of an ICU admission on return to work [Time Frame: 6 months post ICU discharge]
    Return to work knowing; possible job loss, change of work activities and worsening employment status
16. Effect of an ICU admission on return to work [Time Frame: 12 months post ICU discharge]
    Return to work knowing; possible job loss, change of work activities and worsening employment status

Secondary Outcome Measures :

1. age [Time Frame: 24 hours (patient) / 3 months post ICU discharge (family member)]
   age (years)
2. Gender [Time Frame: 24 hours (patient) / 3 months post ICU discharge (family member)]
   Gender (male/female)
3. Social status [Time Frame: 3 months post ICU discharge]
   Social status (married/living together/ single)
4. APACHE IV [Time Frame: 24 hours (only in patients)]
   Acute Physiology And Chronic Health Evaluation (APACHE IV). It is applied within 24 hours of admission of a patient to an **intensive care unit** (ICU): based on several measurements; higher scores correspond to more severe disease and a higher risk of death
5. Comorbidity [Time Frame: 3 months post ICU discharge (only in patients)]
   Comorbidity (free text)
6. Body mass index [Time Frame: 3 months post ICU discharge (only in patients)]
   Body mass index (kg/m2)
7. ICU stay [Time Frame: hospital discharge, an average of 4 weeks (only in patients)]
   ICU stay (days)

8. Mechanical ventilation [Time Frame: hospital discharge, an average of 4 weeks (only in patients)]
   Mechanical ventilation (days)
9. Delerium [Time Frame: hospital discharge, an average of 4 weeks (only in patients)]
   Delerium (no / yes --> CAM-ICU / DOS score)
10. Hospital stay [Time Frame: hospital discharge, an average of 4 weeks (only in patients)]
    Hospital stay (days)
11. Discharge locationn [Time Frame: hospital discharge, an average of 4 weeks (only in patients)]
    Discharge location (home, other hospital, nursing home, revelidation center)
12. Mortality [Time Frame: 3 months post ICU discharge (only in patients)]
    Mortality (no / yes --> date)
13. Mortality [Time Frame: 6 months post ICU discharge (only in patients)]
    Mortality (no / yes --> date)
14. Mortality [Time Frame: 12 months post ICU discharge (only in patients)]
    Mortality (no / yes --> date)
15. Relationship with the patient [Time Frame: 3 months post ICU discharge (only in family members)]
    Relationship with the patient (Partner, sibling, child, other)
16. Educational level [Time Frame: 3 months post ICU discharge]
    Educational level (low, middle, high)
17. Readmission [Time Frame: 3 months post ICU discharge (only in patients)]
    Readmission (no / yes --> free text)
18. Health **care** consumption [Time Frame: 3 months post ICU discharge]
    Health **care** consumption (general practicionar, home **care**, physiotherapist, lung specialist, psychologist, onther (free text))
19. Health **care** consumption [Time Frame: 6 months post ICU discharge]
    Health **care** consumption (general practicionar, home **care**, physiotherapist, lung specialist, psychologist, onther (free text))
20. Health **care** consumption [Time Frame: 12 months post ICU discharge]
    Health **care** consumption (general practicionar, home **care**, physiotherapist, lung specialist, psychologist, onther (free text))
21. Weight [Time Frame: 3 months post ICU discharge]
    Weight (kg)
22. Weight [Time Frame: 6 months post ICU discharge]
    Weight (kg)
23. Weight [Time Frame: 12 months post ICU discharge]
    Weight (kg)
24. Hypertensive [Time Frame: 3 months post ICU discharge]
    Hypertensive (RR)
25. Hypertensive [Time Frame: 6 months post ICU discharge]
    Hypertensive (RR)
26. Hypertensive [Time Frame: 12 months post ICU discharge]
    Hypertensive (RR)
27. Thrombosis [Time Frame: 3 months post ICU discharge]
    Thrombosis (no / yes --> anticoagulant, DVT or PE)
28. Thrombosis [Time Frame: 6 months post ICU discharge]
    Thrombosis (no / yes --> anticoagulant, DVT or PE)
29. Thrombosis [Time Frame: 12 months post ICU discharge]
    Thrombosis (no / yes --> anticoagulant, DVT or PE)
30. Diabetes [Time Frame: 3 months post ICU discharge]
    Diabetes (no /yes --> current insulin level, metformin/ insulin use)
31. Diabetes [Time Frame: 6 months post ICU discharge]
    Diabetes (no /yes --> current insulin level, metformin/ insulin use)
32. Diabetes [Time Frame: 12 months post ICU discharge]
    Diabetes (no /yes --> current insulin level, metformin/ insulin use)

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

The study population consists of all admitted critically ill COVID-19 patients with a > 48 hours ICU admission at the ICU of a University Medical Center and a family member of the patient. Family members in this study can be partners, other family members, or friends who are identified by the patient as important.

Criteria

Inclusion Criteria:

- ≥ 18 years old
- Ability to speak and write Dutch
- Ability to conduct a telephone call
- Diagnosed with COVID-19 infection (only in patients)
- 48 hours ICU admission (only in patients)

Exclusion Criteria:

- Refuse to participate
- Serious language barrier
- Cognitive impairment
- Severe psychiatric disorder
- Chronic ventilator dependency (only in patients)

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04460170***

Contacts I van der Meulen, PhD +31503615617 i.c.van.der.meulen@pl.hanze.nl

Locations Netherlands, University Medical Center Groningen, Groningen, Netherlands, 9700 RB Recruiting

Sponsors and Collaborators

University Medical Center Groningen
Hanze University of Applied Sciences Groningen

More Information

Responsible Party:	Willem Dieperink, PhD, University Medical Center Groningen
ClinicalTrials.gov Identifier:	NCT04460170 History of Changes
Other Study ID Numbers:	COFICS201800422
First Posted:	July 7, 2020 Key Record Dates
Last Update Posted:	July 28, 2020
Last Verified:	July 2020
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Willem Dieperink, University Medical Center Groningen:

Critical **Care**	Follow-Up Studies
Family Members	Quality of Life
Patients	**COVID-19**

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

COVID-19 and the Brain

ClinicalTrials.gov Identifier: NCT04726176

Recruitment Status : Completed
First Posted : January 27, 2021
Last Update Posted : April 29, 2022

Sponsor:
Vrije Universiteit Brussel
Collaborator:
Universitair Ziekenhuis Brussel
Information provided by (Responsible Party):
Kevin De Pauw, Vrije Universiteit Brussel

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
The main objective of this project is:
1. To assess the impact of COVID-19 on the brain and executive functioning.
Twenty adult subjects of UZ Brussels (volunteers), who needed **intensive care** due to COVID-19 (n=10) or exhibited mild symptoms due to COVID-19 (n=10), will be recruited after hospital discharge. After signing an informed consent the subjects will undergo brain scans (T1, DTI, SWI, DWI, FLAIR MRI and rsfMRI), an emotion regulation task and a neurocognitive test battery. The latter test battery will be performed using an iPad and will test different neurocognitive functions such as memory, abstract thinking, spatial orientation and attention. The duration of the test battery is 18min. The total duration of one trial is estimated at one hour and a half. All tests are planned at the department of Radiology-Magnetic Resonance (UZ Brussel). After three months patients will visit the department of Radiology-Magnetic Resonance a second time for the same experimental trial. Additionally, a matched control group (n = 20; non covid or ICU patients) will be included and undergo the same tests in order to compare the results of the brain scans, emotional regulation task and neurocognitive test battery with results of both Covid-groups. Next to objective data, questionnaires will be filled out, i.e. visual analogue scales of mental and physical fatigue, Profile of Mood States and some additional return to work questions.

Condition or disease	Intervention/treatment
Covid19 BrainNeurocognitionfMRI	Biological: Exposure to COVID-19

Study Design

Study Type :	Observational
Actual Enrollment :	40 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	**COVID-19** and Brain Health
Actual Study Start Date :	January 30, 2021
Actual Primary Completion Date :	December 1, 2021
Actual Study Completion Date :	December 1, 2021

Groups and Cohorts

Group/Cohort	Intervention/treatment
COVID-19 Participants who were admitted to the **intensive care unit** due to COVID-19 or participants who exhibited "mild" symptoms due to COVID-19 but needed to be hospitalized.	Biological: Exposure to COVID-19 To study the exposure of COVID-19 on the brain and executive functioning

Group/Cohort	Intervention/treatment
Healthy control group Healthy matched participants who never had COVID-19.	

Outcome Measures

Primary Outcome Measures :

1. Brain scans [Time Frame: Up to 12 weeks]
   T1, FLAIR MRI, SWI, DWI, DTI, rsfMRI and a task-based functional MRI
2. Neurocognitive test battery [Time Frame: Up to 12 weeks]
   The computerized cognitive test battery "Cognition" will be conducted using an iPad. This cognitive test battery is sensitive to multiple domains at high-level cognitive performance. It consists of the motor praxis test (measure of sensorimotor speed), visual object learning test (measure of spatial learning and memory), abstract matching (measure of abstraction), line orientation test (measure of spatial orientation), digit symbol substitution test (measure of complex scanning and visual tracking), balloon analogue risk test (measure of risk decision making), NBACK (measure of working memory) and psychomotor vigilance test (measure, or vigilant attention) and takes approximately 18 min in total.

Secondary Outcome Measures :

1. Emotion regulation task [Time Frame: Up to 12 weeks]
   During the last brain scan, i.e. the task-based functional fMRI, a short emotion regulation task will be employed. Twenty negatively rated stimuli from the International Affective Picture System balanced on arousal (exciting/calm) will be randomly allocated to one of two blocks, one block per condition (experiential awareness, i.e. switching attention towards the bodily felt affective experience / cognitive reappraisal i.e. cognitively changing how one appraises the situation represented on the negative pictures).
2. Mental fatigue Visual Analogue Scale (M-VAS) [Time Frame: Up to 12 weeks]
   Subjective measure of mental fatigue (0-10cm; 0 = no mental fatigue; 10 = maximal mental fatigue)
3. Physical fatigue Visual Analogue Scale (P-VAS) [Time Frame: Up to 12 weeks]
   Subjective measure of physical fatigue (0-10cm; 0 = no mental fatigue; 10 = maximal mental fatigue)
4. Return to work questionnaire [Time Frame: Up to 12 weeks]
   Questionnaire encompassing the following questions:
   a. When did you restart work duties after hospital discharge?
   b. Did you consider yourself fit to return to work?
   c. What is your general experience of restart working?
   d. Have you been equally as productive, less productive, or more productive than before the COVID-19 infection/since the former consultation?
5. Profile of Mood States (POMS) [Time Frame: Up to 12 weeks]
   The Profile of Mood States (POMS) is a 65 item self-report **psychological** instrument. The POMS measures six different dimensions of mood states over a period of time. These include: Tension or Anxiety, Anger or Hostility, Vigor or Activity, Fatigue or Inertia, Depression or Dejection, Confusion or Bewilderment. These 65 items are rated on a five-point scale ranging from "not at all" to "extremely".

Eligibility Criteria

Ages Eligible for Study:	35 Years to 76 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Sampling Method:	Non-Probability Sample

Study Population

Both the "ICU COVID-19" and "Mild COVID-19" groups will be selected from COVID-19 patients that were admitted to the UZ Brussel hospital.
The "Healthy volunteers" group will be selected through the network of the involved researchers (convenience sampling).

Criteria

Inclusion Criteria:

- Adult patients of UZ Brussels, who left the hospital and needed intensive care
- Adult patients of UZ Brussels, who left the hospital and exhibited mild symptoms
- Healthy volunteers (who never had COVID-19)
- Ability to give informed consent
- Dutch or French speaking

Exclusion Criteria:

- History of neurological diseases

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04726176***

Locations Belgium Vrije Universiteit Brussel, Brussels, Belgium, 1050

Sponsors and Collaborators
Vrije Universiteit Brussel
Universitair Ziekenhuis Brussel

Investigators Principal Investigator: Kevin De Pauw, Prof. Dr., Vrije Universiteit Brussel

More Information

Publications:
Iadecola C, Anrather J, Kamel H. Effects of COVID-19 on the Nervous System. Cell. 2020 Oct 1;183(1):16-27.e1. doi: 10.1016/j.cell.2020.08.028. Epub 2020 Aug 19. Review.

Responsible Party:	Kevin De Pauw, Professor Dr., Vrije Universiteit Brussel
ClinicalTrials.gov Identifier:	NCT04726176 History of Changes
Other Study ID Numbers:	1432020000338
First Posted:	January 27, 2021 Key Record Dates
Last Update Posted:	April 29, 2022
Last Verified:	April 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	Researchers, K De Pauw, R Meeusen, B Tassignon, J De Mey, L Van Liedekerke, H Raeymaekers, F De Ridder, G Nagels, J Van Schependom, M Vandekerckhove, L Van Imschoot, P Lacor, L Seyler, R Mertens, S Allard, AM Van Binst, LCB Fuentes, N Hoornaert, M Naeyaert, A Radwan, P Van Schuerbeek, S Sunaert and E De Waele will have access to IPD. All electronic data is stored on the shared encrypted university drive. All files & written data will be stored in a locked filing cabinet. With only the previously mentioned researchers having access. All data will be anonymized by assigning an exclusive identity code to each participant. The identity of the individual will only be known by the previously stated research team. Anonymized data will be stored for up to four years to allow for publication access, further analyses and auditing. All personal data, including health questionnaires and signed consent forms, will be destroyed within 12 months of study completion.
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases

A Brief GAmeplay Intervention for NHS ICU Staff Affected by COVID-19 Trauma (GAINS Study) (GAINS)

ClinicalTrials.gov Identifier: NCT04992390

Recruitment Status : Active, not recruiting
First Posted : August 5, 2021
Last Update Posted : June 13, 2022

Sponsor:
P1vital Products Limited

Collaborators:
Wellcome Trust
Uppsala University
Intensive Care Society
University of Nottingham

Information provided by (Responsible Party):
P1vital Products Limited

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

Intensive care unit (ICU) staff are frequently exposed to traumatic events at work (e.g., witnessing patients die), amplified by the COVID-19 pandemic. A significant proportion experience intrusive memories of these events that pop suddenly into mind: these imagery-based memories can disrupt functioning and contribute to posttraumatic stress disorder. Previous research has shown that a brief behavioural intervention can reduce the number of intrusive memories after a traumatic event. In this study we aim to optimise a brief digital intervention to help reduce the number of intrusive memories experienced by ICU staff (primary outcome). We will explore if it can improve work functioning and wellbeing (secondary outcomes). We will recruit approximately 150 ICU staff with intrusive memories of events experienced during the COVID-19 pandemic.

The study is funded by the Wellcome Trust (223016/Z/21/Z).

Condition or disease	Intervention/treatment	Phase
Intrusive Memories of Traumatic Event(s)	Behavioral: Brief digital imagery-competing task intervention	Not Applicable

Detailed Description:

A statistical analysis plan will be prepared prior to the first interim analysis for the outcomes that will guide study optimisation, i.e., primarily the primary outcome.

A second statistical analysis plan will be prepared prior to the end of the study, to outline the standard (frequentist) statistical approaches that will be used to analyse the primary, secondary and tertiary data.

Regular monitoring will be performed by P1vital Products to verify that the study is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

Quality assurance representatives from the Sponsor may carry out an audit of the study in compliance with regulatory guidelines and relevant standard operating procedures.

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	106 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Single (Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	A Randomised Optimisation Study of a Brief Digital Imagery-competing Task Intervention to Support NHS ICU Staff Experiencing Intrusive Memories of Traumatic Events From Working in the **COVID-19** Pandemic
Actual Study Start Date :	August 24, 2021
Estimated Primary Completion Date :	June 2022
Estimated Study Completion Date :	July 2022

Arms and Interventions

Arm	Intervention/treatment
Experimental: Immediate intervention arm Immediate access to the brief digital imagery-competing task intervention plus symptom monitoring for 4 weeks including completing a daily count of the number of their intrusive memories in week 4 (primary outcome).	Behavioral: Brief digital imagery-competing task intervention First session guided by a researcher: A memory cue followed by playing the brief digital imagery-competing task with mental rotation instructions. Option to engage in self-administered/guided sessions after the first session and record their intrusive memories (symptom monitoring).
Experimental: Delayed intervention arm Usual **care** for 4 weeks including completing a daily count of the number of their intrusive memories in week 4 (primary outcome),	Behavioral: Brief digital imagery-competing task intervention First session guided by a researcher: A memory cue followed by playing the brief digital imagery-competing task with mental rotation instructions.

Arm	Intervention/treatment
followed by access to the brief digital imagery-competing task intervention plus symptom monitoring for 4 weeks.	Option to engage in self-administered/guided sessions after the first session and record their intrusive memories (symptom monitoring).

Outcome Measures

Primary Outcome Measures :

1. Number of intrusive memories of traumatic event(s) [Time Frame: Week 4 (both arms) and Controlling for Run in week (both arms)]
   Number of intrusive memories of traumatic event(s) recorded by participants in a brief daily online diary for 7 days.

Secondary Outcome Measures :

1. Number of intrusive memories of traumatic event(s) [Time Frame: Run-in week (immediate intervention arm) , week 4 (both arms) and week 8 (delayed intervention arm)]
   Number of intrusive memories of traumatic event(s) recorded by participants in a brief daily online diary for 7 days.
   Total number of intrusive memories reported in Week 4 compared to baseline for the immediate intervention group and Week 8 compared to Week 4 for the delayed intervention group (within-group comparisons).
2. Intrusive memory ratings [Time Frame: Baseline, 4 weeks and 8 weeks]
   The 9-item questionnaire assesses a number of intrusive memories characteristics. These characteristics include frequency (7-point categorical response from 'never' to 'many times a day); distress (0=not at all to 10=extremely); disruption to concentration (0=not at all to 10=extremely); interference with what you were doing (how much (0=not at all to 10=extremely) and for how long (6-point categorical response from '<1min' to '+60mins')); impact on work functioning (0=not at all to 10=extremely) and in what ways (open text response)); impact on functioning in other areas of life (how much (0= not at all to 10 = extremely) and in what ways (open text response)).
3. Impact of Event Scale-Revised (IES-R) [Time Frame: Baseline, 4 weeks and 8 weeks]
   This 22-item questionnaire assesses subjective distress after a traumatic event (with reference to the events for which participants are taking part in the study).
   Items are rated for how distressing they have been during the past 7 days on a 5- point scale ranging from 0 ("not at all") to 4 ("extremely"). Scores are calculated for the intrusion, avoidance and hyperarousal subscales and total score. We will analyse total score (mean of all 22 items) and subscales separately (mean of items in each subscale).
4. PTSD Checklist for DSM-5 (PCL-5) 4-item version [Time Frame: Baseline, 4 weeks and 8 weeks]
   This shortened 4-item version of the PCL-5 assesses symptoms of PTSD over the last month.
   Items are rated on a 5-point scale ranging from 0 ("not at all") to 4 ("extremely"). Total score ranges from 0 to 16 (cut-off for possible PTSD is 10 or above).
5. Sleep Condition Indicator (SCI) [Time Frame: Baseline, 4 weeks and 8 weeks]
   This 8-item scale measures sleep problems against the DSM-5 criteria for insomnia disorder.
   Item responses are each scored 0-4, with scores from 0 to 2 indicating threshold criteria for insomnia disorder. Total score ranges 0-32, with a higher score indicating better sleep (cut-off for possible insomnia disorder is a total score from 0 to 2).
6. Generalised Anxiety Disorder 2-item scale (GAD-2) [Time Frame: Baseline, 4 weeks and 8 weeks]
   Items are rated for how often they have bothered the respondent over the last two weeks, from 0 ("not at all") to 3 ("nearly every day"). Total score is the sum of both items and ranges from 0 to 6 (cut-off for possible GAD is 3 or above).
7. Patient Health Questionnaire 2-item version (PHQ-2) [Time Frame: Baseline, 4 weeks and 8 weeks]
   This 2-item short-form self-report measure assesses symptoms of depression.
   Items are rated for how often they have bothered the respondent over the last two weeks, from 0 ("not at all") to 3 ("nearly every day"). Total score is the sum of both items and ranges from 0 to 6 (cut-off for possible major depressive disorder is 3 or above).
8. **Psychological** Outcome Profiles (PSYCHLOPS) [Time Frame: Baseline, 4 weeks and 8 weeks]
   This measure consists of 4 questions that are scored and designed to assess the impact of a person's intrusive memories.
   Questions 1b, 2b, 3b, and 4 are scored. These have a six-point ordinal scale ranging from 0 to 5 and are summed to generate a total score from 0 to 20. Higher values indicate the person is more severely affected.
9. World Health Organization Disability Assessment Schedule 12-item version (WHODAS 2.0) [Time Frame: Baseline, 4 weeks and 8 weeks]
   The 12-item, self-report version of the WHODAS 2.0 will be used to assess difficulties in relation to the impact of intrusive memories.
   Respondents rate how much difficulty they have had in each area in the past 30 days, from 0 (none) to 4 (extreme or cannot do). The overall score is calculated as a percentage of the maximum possible score (i.e., 48 points).
10. 5-level European Quality of Life 5 Dimension (EQ-5D-5L) [Time Frame: Baseline, 4 weeks and 8 weeks]
    The 5-level version of the EuroQol-5D (EQ-5D-5L) is a brief measure for assessing general quality of life and health status.
    Items assess mobility, self-**care**, usual activities, pain/discomfort and anxiety/depression each on a 5-point scale. 5 items are scored on a 5-point ordinal scale from 'no problem' (1) to 'highest level of problems' (5). Respondents also rate their overall health today from 0 (the worst health you can imagine) to 100 (the best health you can imagine). Scores are analysed separately (not summed).
11. Scale of Work Engagement and Burnout (SWEBO) [Time Frame: Baseline, 4 weeks and 8 weeks]
    This 18-item self-report measure assesses work engagement and burnout.

The work engagement subscale consists of 9 items assessing three dimensions (vigour, attentiveness, dedication). Respondents rate how often they have felt each descriptive in the past two weeks, from 1 (not at all) to 4 (all the time). The mean score is calculated for two subscales: engagement and burnout (9 items each).

12. Sickness absence [Time Frame: Baseline, 4 weeks and 8 weeks]
    Single item assessing self-reported number of sick days taken from work in the last 4 weeks. Total scoring includes total number of sick days.
13. Intention to leave job [Time Frame: Baseline, 4 weeks and 8 weeks]
    This 3 items questionnaire is used to assess participants' intention to leave their job e.g. "I think a lot about leaving the job", each rated from 1 (strongly agree) to 5 (strongly disagree). The total score ranges 3 to 15, with a lower score indicating stronger intention to leave the job.
14. Weekly Work Pattern [Time Frame: Baseline, 4 weeks and 8 weeks]
    Two items asses the number of days worked and number of night shifts worked in the last week (both with responses from 0 to 7). Items are examine separately (not summed).

Other Outcome Measures:

1. Support from managers and from family/friends [Time Frame: Baseline]
   The 2 item questionnaire asks "During the COVID-19 pandemic, how well supported have you been by your supervisors/managers?" and "how well supported have you been by your family and friends?" The response is rated as "not at all", "quite a bit", "moderately", "quite a bit", or "extremely"
2. Changes to health and work [Time Frame: 4 weeks and 8 weeks (both arms)]
   The 6-item questionnaire questionnaire will be used to assess the occurrence of any new traumatic events, any additional stressful life events (e.g. relationship problems, financial problems), new treatments received, social support received, changes to the job, or changes to the number of hours worked per week since the last assessment.
3. Optimisation Assessment [Time Frame: Baseline, 4 weeks and 8 weeks]
   Rates of recruitment, intervention use/adherence, outcome measure completion and participant attrition will be assessed.
4. Feedback questionnaire [Time Frame: Week 4 (immediate intervention arm), Week 8 (delayed intervention arm)]
   The first ten items assess how easy, helpful, distressing, burdensome and acceptable participants found the intervention, how willing they would be to use it in the future, how confident they would be in recommending it to a friend and how much they feel it could be used to support staff within NHS ICUs, each rated from 0 (not at all) to 10 (very). The last two items ask how the intervention could be improved, for any other comments or suggestions about the intervention, and for the occurrence of any adverse events, all with an open response.
5. Optional qualitative interview [Time Frame: Week 5 (immediate intervention arm), Week 9 (delayed intervention arm)]
   Qualitative interview will consist of a number of questions designed to gain an in-depth understanding of participants' experience of using the intervention, including acceptability, improvement suggestions, training/psychoeducation materials, potential barriers/facilitators to recruitment and uptake, and support needed for remote intervention delivery.

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion criteria:

- Aged 18 or above.
- Able to read, write and speak in English.
- Worked in a clinical role in an NHS Intensive Care Unit or equivalent during the COVID-19 pandemic (e.g. as a member of ICU staff or deployed to work in the ICU during the pandemic)
- Experienced at least one traumatic event related to their work during the COVID-19 pandemic, meeting criterion A of the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) criteria for Post-Traumatic Stress Disorder (PTSD): "exposure to actual or threatened death, serious injury, or sexual violence" by "directly experiencing the traumatic event(s)" or "witnessing, in person, the event(s) as it occurred to others"
- Experience intrusive memories of the traumatic event(s).
- Experienced at least three intrusive memories in the week prior to screening.
- Have internet access.
- Willing and able to provide informed consent and complete study procedures (including briefly listing their intrusive memories (without going into any detail), and playing the brief digital imagery-competing task with particular mental rotation instructions, and completing an online intrusive memory diary).
- Willing and able to be contacted by the research team during the study period.

Exclusion criteria:

• Have fewer than three intrusive memories during the run-in week.

We will not exclude those undergoing other treatment for PTSD or its symptoms, so the study is as inclusive as possible to meet the challenges ICU staff are facing during the COVID-19 pandemic.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04992390***

Locations United Kingdom P1vital Products Limited, Wallingford, Oxfordshire, United Kingdom, OX10 8BA

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Uppsala University
Intensive Care Society
University of Nottingham
Investigators Principal Investigator: Emily Holmes, Uppsala University

More Information

Responsible Party:	P1vital Products Limited
ClinicalTrials.gov Identifier:	NCT04992390 History of Changes
Other Study ID Numbers:	P1V-GAINS-IN01
First Posted:	August 5, 2021 Key Record Dates
Last Update Posted:	June 13, 2022
Last Verified:	May 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	An anonymised database of individual participant data, along with a data dictionary, as well as the Clinical Study Report (which will include summarised anonymised participant data), will be shared on the Open Science Framework.
Supporting Materials:	Study Protocol Statistical Analysis Plan (SAP) Clinical Study Report (CSR)
Time Frame:	We aim to share the Study Protocol and Statistical Analysis Plan when the final participant allocated to delayed arm completed the guided intervention. The Clinical Study Report will be shared when available following publication. Supporting information mentioned above will be shared indefinitely and with no end date on Open Science Framework Platform.
Access Criteria:	Anonymised research data will be made available on open science frame work (OSF) indefinitely. OSF is an open source web application that is freely accessible to public and scientific community.

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Active Pregnancy Against COVID-19 (ACPREGCOV)

ClinicalTrials.gov Identifier: NCT04563065

Recruitment Status : Recruiting
First Posted : September 24, 2020
Last Update Posted : July 1, 2022
See **Contacts and Locations**

Sponsor:
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Collaborators:
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Hospital Vall d'Hebron
Hospital Universitario de Torrejón de Ardoz
Clínica Zuatzu de San Sebastián
Information provided by (Responsible Party):
Rubén Barakat Carballo, Universidad Politecnica de Madrid

- **Study Details**

- **Tabular View**
- **No Results Posted**

- Disclaimer
- How to Read a Study Record

Study Description

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Brief Summary:

Historically and traditionally, the recommendations related to physical exercise during pregnancy have been based more on moral or cultural issues than on scientific evidence. During some phases of history, pregnancy has meant a period of seclusion for women (not only physical). One of the adverse consequences has been the common recommendation of rest as a general rule for pregnant women.

Scientific evidence from recent years has achieved a better understanding of the process of pregnancy and childbirth as well as maternal and fetal responses to exercise. Currently, both from a scientific and clinical/obstetric point of view, there is no doubt about the benefits of an active pregnancy for entire body of pregnant woman, and even her child. In fact, risks of a sedentary lifestyle are applicable to the pregnancy situation, even more with important associated complications during pregnancy and postpartum period.

Unfortunately, the impact of COVID-19 has caused an unprecedented global crisis, in this sense the necessary measures taken by the different administrations, especially in terms of confinement causes (from now on) a large number of complications affecting different populations. In summary a complex situation without established prevention strategies exists.

The pregnant population is, due to the nature of the gestation and delivery process, one of the population groups with the highest risk of adverse outcomes and associated complications and whose consequences include the mother, fetus, newborn and even children. According to an important body of scientific literature and based on an epigenetic effect, the intrauterine environment can be a determining factor for the future human being to evolve regardless of complications and pathologies (cardiovascular, metabolic, psychic, emotional). This is demonstrated by numerous recent scientific evidences that confirm the unfortunate association between an adverse intrauterine environment (due to various factors) and observable postnatal pathologies in infants.

In addition, current publications report the large number and variety of alterations that the COVID-19 situation causes in pregnant women and that includes the entire female organism. This complex situation does not only affect aspects of a physical or physiological nature, but also psychic and emotional factors. In summary, a new state of confinement or similar situations in the near future (impossibility of groupings, distance between people), avoid during the daily life of pregnant women one of the important and recent recommendations made by the international scientific community: a pregnancy physically active.

This is especially relevant, due to the dangerous association between complications of a **psychological** or emotional nature during pregnancy with pre, peri and postnatal disorders (low birth weights, perinatal complications, altered and prolonged deliveries, etc.), which affect not only to the mother and can determine the health of the future human being. According to the scientific literature and based on an epigenetic effect, the intrauterine environment can be a determining aspect in the health of the future human being and the prevention of complications and pathologies (cardiovascular, metabolic, psychic, emotional). This is demonstrated by numerous and recent scientific evidences that confirm the unfortunate association between an adverse intrauterine environment (due to various factors) and different pathologies during and after pregnancy.

It is evident the change that COVID-19 and its effects will generate in the lifestyle of the pregnant population and the increased probability of suffering associated pathologies in the next 24-36 months. No preventive actions have yet been planned in Spain and its public hospitals against the impact of COVID-19 on the quality of life of pregnant women. It is urgent to design and perform an adequate strategy of intervention for its possible prevention. From the scientific point of view, the recommendations are clear and concrete, an aerobic exercise program, designed and supervised by professionals from the Sciences of Physical Activity and Sports, is the best option for pregnant women.

In this sense, in the last 30 years, physical exercise has proven to have many benefits for pregnant women, without causing risks or adverse effects on maternal-fetal well-being. This is confirmed by an important body of scientific literature on gestational physical exercise and its effects on pregnancy outcomes.

Condition or disease	Intervention/treatment	Phase
Pregnancy ComplicationsPregnancy, High RiskPregnancy Induced HypertensionNewborn MorbidityFetal Growth RetardationFetus DisorderWeight Gain, MaternalMaternal-Fetal Relations	Other: Exercise programOther: Healthy lifestyle advise	Not Applicable

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	280 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Single (Outcomes Assessor)
Primary Purpose:	Prevention
Official Title:	Active Pregnancy, Prevention Against the Effects of **COVID-19**
Actual Study Start Date :	August 1, 2020
Actual Primary Completion Date :	November 30, 2020
Estimated Study Completion Date :	December 31, 2023

Arms and Interventions

Arm	Intervention/treatment
Experimental: Exercise group The design of the physical exercise program will be supported by the Canadian and Spanish Guidelines for exercise throughout pregnancy (11,13) and published by Barakat model (10). Frequency: The program will consist of three weekly sessions. The duration of every session will be 55-60 minutes. The intensity of the workload will be 55-60% of the maximum maternal Heart Rate, and controlled by Polar monitor (FT60). Likewise, once a week, the Borg Scale of Perceived Effort will be administered to participants, in order to have a more reliable assessment of the intensity of the activities, 12-14 (moderate; out of a 20 point scale) will be the level used. The minimum adherence required for the participants will be 80% of the total sessions (approximately 80 sessions).	Other: Exercise program All sessions will begin with a warm-up of 7-8 minutes composed of mild movements and joint mobility of upper and lower limbs exercises. Then a central part of 35-40 minutes, four types of activities will be included (aerobic work, muscle strengthening, coordination/balance tasks, pelvic floor exercises), finally a section of flexibility, relaxation and final talk (comments and sharing) will be performed (12-15 minutes). Other: Healthy lifestyle advise This intervention consists of providing infographics and videos with advice on healthy habits throughout the pregnancy process. This type of content will be related to daily physical activity, food recommendations and fundamental exercises to perform during pregnancy.
No Intervention: Control group Women randomly assigned to the control group (CG) received general advice from their health **care** provider about the positive effects of physical activity. Participants in the CG had their usual visits with health **care** providers during pregnancy, which were equal to the exercise group. Women were not discouraged from exercising on their own. However, women in the CG were asked about their exercise once each trimester using a "Decision Algorithm" (by telephone).	

Outcome Measures

Primary Outcome Measures :

1. Maternal weight gain [Time Frame: 9 months]
   analyze the increase during pregnancy
2. blood pressure [Time Frame: 9 months]
   analyze how it varies during pregnancy
3. OGTT-O'Sullivan test [Time Frame: 1 month]
   analyze the value and its interrelationship with physical exercise patterns
4. Urinary Incontinence Questionnaire (ICIQ-SF) [Time Frame: 9 months]
   analyze with a questionnaire the value and its interrelationship with physical exercise patterns (different measures in the questionnaire)
5. State-Trait Anxiety Inventory (STAI) [Time Frame: 9 months]
   analyze with a questionnaire the value and its interrelationship with physical exercise patterns (Likert scale 0-3)
6. depression scale (CES-D) [Time Frame: 9 months]
   analyze with a questionnaire the variability during pregnancy (Likert scale 0-3)
7. Behavior of Fetal Heart Rate [Time Frame: 3 months]
   analyze variability during pregnancy
8. gestational age [Time Frame: 9 months]
   analyze the value and its interrelationship with physical exercise patterns
9. type of delivery (Vaginal, instrumental or cesarean) [Time Frame: 1 month]
   analyze whether women have had a vaginal, instrumental or cesarean delivery and its interrelationship with physical exercise patterns
10. duration of labor [Time Frame: 1 month]
    analyze the value and its interrelationship with physical exercise patterns
11. birthweight [Time Frame: 1 month]
    analyze the value and its interrelationship with physical exercise patterns
12. child's weight [Time Frame: 24 months]
    analyze the value and its interrelationship with physical exercise patterns during pregnancy
13. child's height [Time Frame: 24 months]
    analyze the value and its interrelationship with physical exercise patterns during pregnancy
14. mental assessment of the child (depression questionnaire adapted to childhood) [Time Frame: 24 months]
    analyze the value and its interrelationship with physical exercise patterns during pregnancy (Likert scale 0-3)

15. psychomotor behavior of the child [Time Frame: 24 months]
    analyze some variables (sitting, crawling, standing, walking, holding objects...) and its relationship with maternal exercise

Secondary Outcome Measures :

1. Maternal pains during pregnancy (headache, back pain, pelvic pain, paravertebral, scapular, etc.) [Time Frame: 9 months]
   analyze the value and its interrelationship with physical exercise patterns
2. fetal growth and development [Time Frame: 9 months]
   analyze the value and its interrelationship with physical exercise patterns
3. Delivery tears [Time Frame: 1 month]
   analyze the value and its interrelationship with physical exercise patterns
4. performing episiotomy during childbirth [Time Frame: 1 month]
   analyze the appearance (descriptive: yes/no) and its interrelationship with physical exercise patterns
5. Apgar Score [Time Frame: 1 month]
   analyze the value and its interrelationship with physical exercise patterns
6. length [Time Frame: 1 month]
   analyze the value and its interrelationship with physical exercise patterns
7. cranial perimeter [Time Frame: 1 month]
   analyze the value and its interrelationship with physical exercise patterns
8. Landau reflexes test [Time Frame: 1 month]
   analyze the value and its interrelationship with physical exercise patterns
9. neonatal **intensive care unit** (NICU) [Time Frame: 1 month]
   analyze the number of admissions and its interrelationship with physical exercise patterns
10. Postpartum recovery of pre-pregnancy weight [Time Frame: 12 months]
    analyze how it varies during postpartum period
11. Edinburgh Postpartum Depression Scale (EPDS) [Time Frame: 12 months]
    analyze with a questionnaire how it varies during postpartum period (Likert scale 0-3)
12. umbilical cord Ph [Time Frame: 1 month]
    analyze the value and its interrelationship with physical exercise patterns
13. Fetal development [Time Frame: 9 months, once a trimester]
    analyze variables (estimated fetal weight, FCF, DBT, CRL, SNT, uterine arteries...) by ultrasound
14. Carotid intima-media thickness (CIMT) [Time Frame: 9 months]
    Measurement of carotid intima-media thickness (CIMT) with B-mode ultrasound is a noninvasive, sensitive, and reproducible technique for identifying and quantifying subclinical vascular disease and for evaluating CVD risk.
15. Maternal sleep habits [Time Frame: 9 months]
    analyze with Pittsburgh´s sleep quality index
16. maternal body self-perception [Time Frame: 9 months]
    analyze using Ben-Tobim Walker Body Attitude Questionnaire
17. Newborn sleep habits [Time Frame: 24 months]
    analyze using Brief Infant Sleep Questionnaire
18. Placental angiogenic factors [Time Frame: measured at 24-25 weeks and at 34-35 weeks]
    placental growth factor (PIGF)
19. Placental angiogenic factors [Time Frame: measured at 24-25 weeks and at 34-35 weeks]
    soluble fms-like tyrosinekinase-1(sFlt1)
20. Lipidic profile [Time Frame: measured at 24-25 weeks and at 34-35 weeks]
    Total Cholesterol, LDL-Cholesterol, HDL- Cholesterol, Tryglicerids

Other Outcome Measures:

1. Perception of health status - SF36 health scale [Time Frame: 24 months]
   analyze the value and its interrelationship with physical exercise patterns (Likert scale)
2. Recovery of pelvic floor muscles ultrasound [Time Frame: 6 months]
   analyze the diameter and thickness of muscles in the perineal area and its interrelationship with physical exercise patterns
3. Maternal habits of physical activity - Pregnancy Physical Activity Questionnaire (PPAQ) [Time Frame: 12 months]
   analyze with a questionnaire how it varies during and after pregnancy
4. Pregestational maternal patterns [Time Frame: 9 months]

analyze sociodemographic and behavioural habits like (smoking, alcoholism, pervious illness, COVID-19, parity, occupation, previous miscarriage...)

5. Edimburgh postpartum depression scale [Time Frame: 6 months]
   analyze with a questionnaire the variability in the postpartum
6. Covid-19 disease [Time Frame: 9 months]
   analyze the covid-19 condition durign pregnancy and its interrelationship with other variables

Eligibility Criteria

Ages Eligible for Study:	18 Years to 50 Years (Adult)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Pregnant women fulfilling the following criteria: >18 years old, singleton pregnancies and planning management and delivery at the research hospitals and also do not participate in any other program of supervised physical exercise.

Exclusion Criteria:

- Women with absolute contraindications. Women with relative contraindications need permission from obstetric care provider prior to participation(1,2):

Absolute contraindications to exercise:

- Ruptured membranes.
- Premature labour.
- Unexplained persistent vaginal bleeding.
- Placenta praevia after 28 weeks' gestation.
- Pre-eclampsia.
- Incompetent cervix.
- Intrauterine growth restriction.
- High-order multiple pregnancy (eg, triplets).
- Uncontrolled type I diabetes.
- Uncontrolled hypertension.
- Uncontrolled thyroid disease.
- Other serious cardiovascular, respiratory or systemic disorder.

Relative contraindications to exercise:

- Recurrent pregnancy loss.
- Gestational hypertension.
- A history of spontaneous preterm birth.
- Mild/moderate cardiovascular or respiratory disease.
- Symptomatic anaemia.
- Malnutrition.
- Eating disorder.
- Twin pregnancy after the 28th week.
- Other significant medical conditions.

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2. Barakat R, Díaz-Blanco A, Franco E, Rollán-Malmierca A, Brik M, Vargas M, et al. Guías clínicas para el ejercicio físico durante el embarazo/Clinical guidelines for physical exercise during pregnancy. Prog Obstet Ginecol 2019;62(5):464-471. DOI: 10.20960/j.pog.00231.

Contacts and Locations

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Sub-Investigator: Irune Alzola, Dr
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Study Director: Rubén Barakat, Dr Universidad Politécnica de Madrid (UPM)

More Information
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Additional Information:
Reference of the Spanish clinical guidelines of physical exercise for pregnancy

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Responsible Party:	Rubén Barakat Carballo, Dr, Universidad Politecnica de Madrid
ClinicalTrials.gov Identifier:	NCT04563065 History of Changes
Other Study ID Numbers:	UPM-2020-32/33
First Posted:	September 24, 2020 Key Record Dates
Last Update Posted:	July 1, 2022
Last Verified:	June 2022
Individual Participants' Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Additional relevant MeSH terms:	

- Pregnancy Complications
- Fetal Growth Retardation
- Hypertension, Pregnancy-Induced
- Weight Gain
- Gestational Weight Gain
- Hypertension
- Vascular Diseases
- Cardiovascular Diseases
- Body Weight Changes
- Body Weight
- Fetal Diseases
- Growth Disorders
- Pathologic Processes

Exhaustion and Needs in Frontline COVID-19 Healthcare Workers: Cross-sectional Study in a Belgian Population

ClinicalTrials.gov Identifier: NCT04344145

Recruitment Status : Completed
First Posted : April 14, 2020
Last Update Posted : September 9, 2020

Sponsor:
Université Libre de Bruxelles
Information provided by (Responsible Party):
Dr Julien Tiete, Université Libre de Bruxelles

- **Study Details**

- **Tabular View**
- **No Results Posted**

Study Description
Brief Summary:
Background: In the Covid-19 pandemic context, all healthcare teams face clinical, organizational and technical challenges given the contagion, severity and mortality characteristics of the disease. A study reported the negative **psychological** impact on healthcare workers of this new situation, in terms of depression, anxiety and distress. Working in frontline constitutes an independent risk factor for worse mental health outcomes.
Methods: This is a cross-sectional study aiming to compare levels of burnout, emotional distress and needs between frontline Covid-19 and non-Covid-19 healthcare workers. Any physician, nurse and physiotherapist will be recruited from emergency **care units** and Covid-19 **care units** (target group) and from non-Covid-19 **care units** (control group) from different hospitals in Belgium. The participation will occur on a voluntary basis. Participants will be recruited from April 15th 2020 to May 15th 2020. Participants will complete self-reported questionnaires and scales. A mixed-mode data collection will be carried out, either in paper or web-based form. This mixed-mode survey will ensure the highest range of participants, considering the hygiene and organizational requirements for target **care units**. Assessment will provide socio-demographic characteristics and professional information. It will also measure professional fulfillment and burnout with the Stanford Professional Fulfillment Index (PFI), emotional distress with the Depression, Anxiety and Distress Scale-Short Form (DASS-21), sleep disturbance with the Insomnia Severity Index (ISI) and needs with the Needs and Difficulties Inventory (developed for the study).
Hypothesis: This study is based on the hypothesis that higher levels of burnout, depression, anxiety and stress will be found in frontline Covid-19 healthcare workers than in non-Covid-19 healthcare workers. Considering the unprecedented challenges for healthcare workers and organizations, and considering the exploratory nature of the study, no hypothesis is made for the needs of the healthcare workers.
Statistical Analysis: Means and standard deviation will be calculated for the PFI, the DASS-21, the ISI and the NDI. Multivariate Analysis of Variance (MANOVA) will be performed including the PFI, the DASS-21 and the ISI scores to test the effect of group (work position), occupation and the two-way group × occupation interaction effect. Age, gender, profession, sector of activity, job status and job experience will be entered as covariate. Odds ratio will be also provided. All tests are two-tailed and alpha is set at .05. All analyzes will be performed using IBM SPSS®, version 26.

Condition or disease
COVID-19

Study Design

Study Type :	Observational
Actual Enrollment :	693 participants
Observational Model:	Case-Control
Time Perspective:	Cross-Sectional
Official Title:	Burnout, Emotional Distress and Needs in Frontline **COVID-19** Healthcare Workers: Cross-sectional Study in a Belgian Population
Actual Study Start Date :	April 16, 2020
Actual Primary Completion Date :	May 25, 2020
Actual Study Completion Date :	May 29, 2020

Groups and Cohorts

Group/Cohort
Target Group

Group/Cohort
This group includes frontline healthcare workers who are actively involved in the management of the Covid-19 outbreak: from emergency **units**, non-intensive Covid-19 and **intensive** Covid-19 **units**. They will fill self-reported questionnaires and scales upon their inclusion.
Control group This group includes healthcare workers who are actively involved in usual medical **care units**, referred in this study as non-Covid-19 **units**. They will fill same self-reported questionnaires and scales than those filled in the Target group, also upon their inclusion.This group will be the comparator of the Target Group to assess the "frontline Covid-19" condition.

Outcome Measures

Primary Outcome Measures :

1. Burnout [Time Frame: 1 assessment time, at inclusion]
   Measured with the Professional Fulfillment Index (PFI). This is a 16-item scale, divided into 2 sub-scales: professional fulfillment (6 items) and burnout, including professional exhaustion (4 items) and interpersonal disengagement (6 items). Subscales scores are given by the mean of all sub-scale items (professional fulfillment, 0-4; burnout, 0-4). Cut-off scores are set for the fulfillment sub-scale at > 3, significant professional fulfillment and for the burnout sub-scale at > 1.33, significant burnout.
2. Emotional Distress [Time Frame: 1 assessment time, at inclusion]
   Measured with the Depression, Anxiety and Stress Scale-Short Form (DASS-21). This a 21-item scale divided into 3 7-item sub-scales: depression, anxiety and stress. Sub-scales scores are given by the sum of all sub-scale items. The DASS has a 4-point Likert scale. Responses options range from " Never " to " Almost always " (0-3 score range). Only cut-off scores are provided for the original version of the DASS. Sub-scales scores must therefore be multiplied by 2. Cut-off scores for depression are Normal, 0-9; Mild, 10-13; Moderate, 14-20; Severe, 21-27; Extremely severe, 28+. Cut-off scores for anxiety are Normal, 0-7; Mild, 8-9; Moderate, 10-14; Severe, 15-19; Extremely severe, 20+. Cut-off scores for stress are Normal, 0-14; Mild, 15-18; Moderate, 19-25; Severe, 26-33; Extremely severe, 34+.
3. Insomnia [Time Frame: 1 assessment time, at inclusion]
   Measured with the Insomnia Severity Index (ISI). This is a 7-item scale. The ISI has a 5-point Likert scale (0-4 score range). Responses options range from " None " to " Very severe " for items 1a., 1b. and 1c., from " Very satisfied " to " Very dissatisfied " for item 2 and from " None " to " Very much " for items 3,4 and 5. The ISI provides a total score by summing all items scores. Cut-off scores are set for no clinically significant insomnia (0-7), subthreshold insomnia (8-14), moderate clinical insomnia (15-21) and severe clinical insomnia (22-28).

Secondary Outcome Measures :

1. Needs and difficulties in work situations [Time Frame: 1 assessment time, at inclusion]
   Measured with the Needs and Difficulties Inventory (developed for the study). This scale has been set up for this study. This is a 17-item scale, divided into 5 sub-scales: information/communication (3 items), practical (4 items), physical (4 items), emotional (4 items) and ethical (2 items). The NDI has a 4-point Likert scale. Responses options range from " Not at all agree " to " Totally agree " (0-3 score range). The NDI provides 5 sub-scales scores by summing all sub-scales items: information/communication, 0-9; practical, 0-12; physical, 0-12; emotional, 0-12 and ethical, 0-6. As a no-validated scale, scores and their treatment will be taken into account with caution. In order to compare sub-scales with each other, each sub-scale score must be divided by its maximum value, providing a coefficient (0-1).

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

This study targets healthcare workers in Belgian hospital. It targets any physician, nurse or physiotherapist in emergency, non-intensive Covid-19 and intensive Covid-19 care unit (target group) and in usual medical care unit (control group). There is no sampling method. Participation is on voluntary basis.

Criteria

Inclusion Criteria:

- Ability to read, speak and write in French;
- Being professionally active (doctor, nurse or physiotherapist) within a medical care unit;

Exclusion Criteria:

- Having been off work (for medical, professional or personal reasons) for ≥ 3 weeks before first assessment time.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04344145***

Locations Belgium

Hôpital de Warquignies
Boussu, Hainaut, Belgium, 7300

Hôpital de Jolimont
Haine-Saint-Paul, Hainaut, Belgium, 7100

Hôpital de Lobbes
Lobbes, Hainaut, Belgium, 6540

Hôpital de Mons
Mons, Hainaut, Belgium, 7000

Erasme Hospital CUB
Brussels, Belgium, 1070

Sponsors and Collaborators
Université Libre de Bruxelles
Investigators Principal Investigator: Julien Tiete, PhD, Université Libre de Bruxelles

More Information
Publications of Results:

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Lovibond, SH, Lovibond, PF. (1995). Manual for the Depression Anxiety & Stress Scales (2nd Ed.) Sydney: Psychology Foundation.
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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Tiete J, Guatteri M, Lachaux A, Matossian A, Hougardy JM, Loas G, Rotsaert M. Mental Health Outcomes in Healthcare Workers in COVID-19 and Non-COVID-19 Care Units: A Cross-Sectional Survey in Belgium. Front Psychol. 2021 Jan 5;11:612241. doi: 10.3389/fpsyg.2020.612241. eCollection 2020.

Responsible Party:	Dr Julien Tiete, Dr, Université Libre de Bruxelles
ClinicalTrials.gov Identifier:	NCT04344145 History of Changes
Other Study ID Numbers:	PSY-ENCOVID19
First Posted:	April 14, 2020 Key Record Dates

Last Update Posted:	September 9, 2020
Last Verified:	September 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Undecided
Plan Description:	Local Ethics Committee has not yet approved the study. No plan has therefore been done for the IPD sharing.

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Dr Julien Tiete, Université Libre de Bruxelles:

COVID-19
Healthcare workers burn out
Healthcare workers emotional distress
Healthcare workers needs

Additional relevant MeSH terms:

COVID-19
Respiratory Tract Infections
Infections
Pneumonia, Viral
Pneumonia
Virus Diseases
Coronavirus Infections
Coronaviridae Infections
Nidovirales Infections
RNA Virus Infections
Lung Diseases
Respiratory Tract Diseases

Reducing Post-traumatic Stress Disorder After ICU Discharge With the IPREA3 Program (PTSD-REA)

ClinicalTrials.gov Identifier: NCT03991611

Recruitment Status : Active, not recruiting
First Posted : June 19, 2019
Last Update Posted : March 23, 2022

Sponsor:
Centre Hospitalier of Chartres
Information provided by (Responsible Party):
Centre Hospitalier of Chartres

- **Study Details**
- **Tabular View**
- **No Results Posted**

Study Description

Brief Summary:

Reducing discomfort in the **intensive care unit** (ICU) should be beneficial to longterm outcomes. This study assesses whether a tailored multicomponent program for discomfort reduction may be effective in reducing post-traumatic stress disorder (PTSD) symptoms at 1-year in general ICU survivors.

The psychiatric morbidity may be increased by the COVID-19 epidemic and its consequences on the healthcare system (patient **care**, reorganization of French ICUs). The main objective of PTSD-REA_COVID cohort is to assess this psychiatric morbidity 6 months after an ICU stay during the epidemic period.

Condition or disease	Intervention/treatment	Phase
ritical Illness	Other: Administration of the IPREA3 questionnaireOther: Immediate feedback through electronic reminder messagesOther: Targeted interventions in each ICU to reduce discomfortsOther: 6 months follow-up to assess the prevalence of PTSD symptomsOther: 1 year follow-up to assess psychiatric morbidity	Not Applicable

Detailed Description:

After carrying out the cluster-randomized controlled IPREA3 study demonstrating that a tailored multicomponent program based on assessment of self-perceived discomfort, feedback to the healthcare teams, and tailored site-targeted measures was effective to decrease self-perceived overall discomfort, we performed the 1-year follow-up of ICUs survivors included in the IPREA3 study to assess psychiatric morbidity at 1 year. Our tailored multicomponent program was also associated with less PTSD at 1 year after ICU discharge. Based on this positive long-term result, this study confirms the need to implement a new strategy for reducing discomfort in the ICU based on such programs.
PTSD-REA is a stepped wedge cluster randomized trial involving 18 ICUs. The exposure will be the implementation of a tailored multicomponent program consisting of assessment of ICU-related self-perceived discomforts, immediate and monthly feedback to the healthcare team, and site-specific tailored interventions. The eligible patients will be exposed vs. unexposed general adult ICU survivors. The prevalence of substantial posttraumatic stress disorder (PTSD) symptoms at 1 year will be assessed by using diagnostic criteria adapted to the new definition of PTSD according to DSM-5.
The current context of the COVID-19 pandemic has considerably disrupted the ICUs organizations as well as the patients care which may lead to increased psychiatric morbidity. In this context, it seems necessary to assess this phenomenon in order to anticipate the consequences on patients but also on the healthcare system. The objectives of the PTSD-REA_COVID cohort are to assess the prevalence of PTSD symptoms, 6 months after ICU stay during COVID-19 epidemic and to compare the psychiatric morbidity at 1 year after an ICU stay during epidemic period and non epidmic period.

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	3312 participants
Allocation:	Randomized
Intervention Model:	Sequential Assignment
Intervention Model Description:	Stepped wedge cluster randomized trial
Masking:	Single (Participant)
Primary Purpose:	Supportive **Care**
Official Title:	Tailored Multicomponent Program for Discomfort Reduction in Critically il Patients May Decrease Post-traumatic Stress Disorder in General ICU Survivors at One Year
Actual Study Start Date :	November 1, 2019
Estimated Primary Completion Date :	July 31, 2022
Estimated Study Completion Date :	January 1, 2023

Arms and Interventions

Arm	Intervention/treatment
Experimental: IPREA3 program Application of the IPREA 3 program (multicomponent intervention to reduce perceived discomforts in critically ill patients) for at least 5 months	Other: Administration of the IPREA3 questionnaire On the day of the ICU discharge, the bedside nurse administers to the patient the 18-item IPREA questionnaire i.e the nurse asks the patient to rate from 0 to 10 the severity of each discomfort source contained in the IPREA3 questionnaire experienced during the entire stay in the ICU Other: Immediate feedback through electronic reminder messages After the nurse had administered the questionnaire, warning messages are displayed on the screen corresponding to the key points to prevent the three discomforts reported with the highest scores Other: Targeted interventions in each ICU to reduce discomforts These targeted interventions are implemented through the coordination of two local champions. The central coordination IPREA3 team sends each month to the local champions monthly and cumulative discomfort scores of their **unit** (overall score of discomfort and scores for each item) and their ranking relative to other **units** assigned to the interventional arm i.e applying the IPREA3 program. The local champions organize monthly meetings with the **unit** staff to present the results in terms of perceived discomforts measured by the IPREA questionnaire, identify main discomfort sources and actions to be conducted to reduce the discomforts reported with the highest scores in the **unit** and those that are most easily preventable, and assess the efficacy of already applied measures. Other: 1 year follow-up to assess psychiatric morbidity Psychologist will collect the PCL-5, HAD-S, WHOQOL-BREF, LEC-5 and CTQ items during the telephone follow-up, 1 year after ICU discharge
Intermediate group Application of the IPREA 3 program (multicomponent intervention to reduce perceived discomforts in critically ill patients) for less than 5 months	Other: Administration of the IPREA3 questionnaire On the day of the ICU discharge, the bedside nurse administers to the patient the 18-item IPREA questionnaire i.e the nurse asks the patient to rate from 0 to 10 the severity of each discomfort source contained in the IPREA3 questionnaire experienced during the entire stay in the ICU Other: Immediate feedback through electronic reminder messages After the nurse had administered the questionnaire, warning messages are displayed on the screen corresponding to the key points to prevent the three discomforts reported with the highest scores

Arm	Intervention/treatment
	Other: Targeted interventions in each ICU to reduce discomforts These targeted interventions are implemented through the coordination of two local champions. The central coordination IPREA3 team sends each month to the local champions monthly and cumulative discomfort scores of their **unit** (overall score of discomfort and scores for each item) and their ranking relative to other **units** assigned to the interventional arm i.e applying the IPREA3 program. The local champions organize monthly meetings with the **unit** staff to present the results in terms of perceived discomforts measured by the IPREA questionnaire, identify main discomfort sources and actions to be conducted to reduce the discomforts reported with the highest scores in the **unit** and those that are most easily preventable, and assess the efficacy of already applied measures
Active Comparator: Standard **care** Standard **care**	Other: Administration of the IPREA3 questionnaire On the day of the ICU discharge, the bedside nurse administers to the patient the 18-item IPREA questionnaire i.e the nurse asks the patient to rate from 0 to 10 the severity of each discomfort source contained in the IPREA3 questionnaire experienced during the entire stay in the ICU Other: 1 year follow-up to assess psychiatric morbidity Psychologist will collect the PCL-5, HAD-S, WHOQOL-BREF, LEC-5 and CTQ items during the telephone follow-up, 1 year after ICU discharge
PTSD-REA_COVID cohort ICU admission between March 1, 2020 and April 30, 2020.	Other: 6 months follow-up to assess the prevalence of PTSD symptoms Psychologist will collect the PCL-5, HAD-S, WHOQOL-BREF, LEC-5 items during the telephone follow-up, 6 months after ICU discharge Other: 1 year follow-up to assess psychiatric morbidity Psychologist will collect the PCL-5, HAD-S, WHOQOL-BREF, LEC-5 and CTQ items during the telephone follow-up, 1 year after ICU discharge

Outcome Measures

Primary Outcome Measures :

1. Presence of posttraumatic stress disorder (PTSD) symptoms at one year after ICU discharge and 6 months (PTSD-REA_COVID cohort) [Time Frame: One year after ICU discharge]
   PTSD symptoms at one year will be assessed from the PCL-5 which is a 20-item self-report measure that assesses the 20 DSM-5 (Diagnostic and Statistical Manual of Mental Disorders) symptoms of PTSD. Each item is rated from 0 "Not at all" to 4 "Extremely". A total symptom severity score (range - 0-80) can be obtained by summing the scores for each of the 20 items.
   A provisional PTSD diagnosis can be made by treating each item rated as 2 = "Moderately" or higher as a symptom endorsed, then following the DSM-5 diagnostic rule which requires at least: 1 B item (questions 1-5), 1 C item (questions 6-7), 2 D items (questions 8-14), 2 E items (questions 15-20).

Secondary Outcome Measures :

1. ICU stay's duration [Time Frame: The day of ICU discharge]
2. Number of days with mechanical ventilation [Time Frame: The day of ICU discharge]
3. Overall score of discomfort assessed from the IPREA3 questionnaire [Time Frame: The day of ICU discharge]
4. The duration of hospital stay after ICU discharge [Time Frame: 6 months (PTSD-REA_COVID cohort) or 1 year after ICU discharge and]
5. Intrusion Symptom Category B assessed from the PCL-5 (Posttraumatic Stress Disorder Checklist) (Items 1-5) [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
   Recurrent or involuntary distressing dreams, memories, thoughts, or feelings related to the traumatic event(s)
6. Persistent Avoidance Category C assessed from the PCL-5 (Items 6-7) [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
   Avoidance or efforts to avoid internal or external reminders of the traumatic event(s)
7. Negative Alterations in Cognitions and Mood Category D assessed from PCL 5 (Items 8-14) [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
   Persistent and exaggerated negative beliefs about oneself, the world, others, negative mood states, inability to experience positive emotions
8. Alterations in arousal and reactivity Category E assessed from the PCL-5 (Items 15-20) [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
   Marked increase in arousal or reactivity such as irritability, hypervigilance, exaggerated startle response, sleep or concentration problems exaggerated startle response
9. Score of the sub-scale A of the questionnaire HAD-S (Hospital and Anxiety Depression Scale) [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
   Allowing to estimate the presence of anxious symptoms. The scale HAD contains 14 items rated from 0 to 3. The score of Anxiety (total A) is obtained by summing items 1-3-5-7-9-11-13 and the depressive dimension (total D) is obtained by summing items 2-4-6-8-10-12-14. The maximal note for each of them is 21.
   8 points is a minimum threshold for determining whether the anxiety is clinically meaningful
10. Score of the sub-scale D of the questionnaire HAD-S (Hospital and Anxiety Depression Scale) [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
    Allowing to estimate the presence of anxious symptoms. The scale HAD contains 14 items rated from 0 to 3. The score of Anxiety (total A) is obtained by summing items 1-3-5-7-9-11-13 and the depressive dimension (total D) is obtained by summing items 2-4-6-8-10-12-14. The maximal note for each of them is 21.
    8 points is a minimum threshold for determining whether Depression is clinically meaningful
11. Score obtained from The World Health Organization Quality of Life (WHOQOL-BREF) [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
    The WHOQOL-BREF measure the following broad domains: physical health, **psychological** health, social relationships, and environment.

Each item is rated from 0 to 5. The score of each domain is obtained by summing items then standardized on a scale of 0 (worst quality of life related to health in the dimension explored) to 100 (better quality of liferelated to health in the dimension explored).

12. Number of emergency stays [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
    Since ICU discharge
13. Number of hospitalization [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
    Since ICU discharge
14. Number of psychiatric or **psychological** consultation [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
    Since ICU discharge
15. The place of leaving after ICU stay [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
    Evaluated in population of patients living at home before the ICU stay.
16. Presence of professional activity [Time Frame: 6 months (PTSD-REA_COVID cohort) and1 year after ICU discharge]
    Evaluated in population of patients with a professional activity before ICU stay

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients who survived an ICU stay of at least 3 calendar days
- Affiliation to a social security scheme
- First stay in ICU during current short-term hospitalization
- Patient's oral consent to participate in the PTSD-REA_COVID cohort

Exclusion Criteria:

- Deceased during the ICU stay
- Minors
- Under trusteeship
- Without affiliation to a social security scheme
- Transferred to another ICU
- Already hospitalized in ICU during the current short stay
- Already included in the study
- Limitation and cessation of active treatment
- Advance healthcare directive indicating the refusal of ICU stay
- Irreversible state like diminished cognitive capacity based on the investigator's opinion or not understanding French sufficiently to be questioned (language barrier)
- Subject not consenting to participate in the study

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03991611***

Locations

▶ Show 33 study locations

Sponsors and Collaborators

Centre Hospitalier of Chartres

Investigators

Principal Investigator: Pierre KALFON, MD PhD CH Chartres

More Information

Publications of Results:

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Studies a U.S. FDA-regulated Device Product: No
Keywords provided by Centre Hospitalier of Chartres:
Critical **care**
Post-traumatic stress disorder
Discomfort
Tailored program
Patient-reported outcome
ICU
COVID-19
Additional relevant MeSH terms:
Critical Illness
Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Trauma and Stressor Related Disorders
Mental Disorders
Disease Attributes
Pathologic Processes