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HUMANIZING INTERVENTIONS IN THE ICU FOR PATIENTS AT RISK FOR POST INTENSIVE CARE SYNDROME

PROTOCOL OF A MULTICENTERED, CLINICAL TRIAL

FINAL DEGREE PROJECT

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November 2020
University of Girona
Faculty of Medicine

"After the verb "to love", "to help" is the most beautiful verb in the world"

Bertha Von Suttner

First of all, I would like to thank my family for their unconditional support during these past years.

My mum for inspiring me and my dad for countless afternoons quizzing me.

This long journey would not have been possible if it weren't for them.

I would also like to appreciate my little team in Girona, for sharing with me a new chapter of our life together.

A special thank you to the ICU doctors from Hospital Universitari Doctor Josep Trueta, especially Dra. Patricia Ortiz, Dra. Sara Foradada and Dra. Ariadna Bellès, for allowing me to learn and be moved by the beautiful specialty that is intensive medicine.

And to Dra. Patricia Ortiz and Dr.Rafel Ramos for all their help with this research project.

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ABREVIATIONS

APACHE-II: Acute Physiology and Chronic Health Evaluation II

ARDS: Acute respiratory Distress syndrome

BAI: Beck anxiety inventory

BDI-II: Beck Depression Inventory

CAMICU: Confusion Assessment Method for Intensive Care Unit

CCU: Coronary Critical Unit

CIM: Critical Illness Myopathy

CINM: Critical Illness neuromyopathy

CIP: Critical Illness polyneuropathy

CVP: Central Venous Pressure

DSM-V: Diagnostic and Statistical Manual

DVT: Deep Vein Thrombosis

EKG: Electrocardiogram

ER: Emergency Room

ESCID: Pain Behavioral Scale "escala de conducta intrínseca de dolor"

GI: Gastrointestinal

HUCI: Humanizing Intensive Care

HUDJT: "Hospital Universitari Doctor Josep Trueta"

IADL: Instrumental Activity of Daily Living

ICU: Intensive Care Unit

IES: Impact of Event Scale

LOS: Length of stay

MEC: Mini examen cognoscitivo

Mini-Cog: Mini cognitive test

MMSE: Mini mental State Examination

MoCA: Montreal Cognitive Assessment

MRC-SS: Medical Research Council

NVS: Numerical Verbal Scale

OR: Operating Room

PACU: Post-anaesthesia Care Unit

PaO2: Arterial Oxygen Partial Pressure

PHQ-9: Patient Health Questionnaire-9

PICS-F: Post-Intensive Care Syndrome in Family

PICS: Post-Intensive Care Syndrome

PICU-AW: Post-Intensive Care Unit-Acquired Weakness

PTSD: Post-Traumatic Stress Disorder

PTSS-10: Post-Traumatic Stress Symptoms

RASS: Richmond Agitation-Sedation Scale

SCCM: Society of Critical Care Medicine

SOFA: Sequential Organ Failure Assessment

WHOQOL-BREF: World Health Organization Quality of Life (short version).

ABSTRACT

BACKGROUND

The ICU is an extremely relevant unit in the hospital, its main function is to help patients in a critical situation and to prevent any life-threatening complications.

Patients from the ICU can be planned or unexpected, can come from various places, and can require different treatments depending on their issues. The main pillars for admission in the ICU are hemodynamic instability, pulmonary dysfunction, neurological disease, complicated post-op recovery and polytrauma patients.

Although ICU patients may have serious conditions, 90% of patients survive and move past it. However, the invasive treatments and measures can often affect patients causing mental, physical, and cognitive issues, this is known as the Post-Intensive Care Syndrome (PICS). It was first named as an entity in 2010 by the Society of Critical Care Medicine. And, according to different studies, PICS can affect from 30 to 50%, or more, of patients after ICU.

PICS main symptoms are muscle weakness, myopathy, loss of attention, slow speech, impaired executive functions and finally symptoms of depression, anxiety and Post Traumatic Stress Disorder (PTSD) with flashbacks from the ICU stay. These symptoms can appear a few months after discharge and last up to six years after it, particularly for cognitive symptoms. Affecting patients quality of life after the critical ward.
Similarly, PICS does not only affect patients but family relatives too, this is known as the PICS-F, especially depression, anxiety and possibly even PTSD.

However there have been some measures that have been developed, but they are still in their infancy. This is why the aim of this project is to prove that different humanizing measures can help prevent PICS and therefore improve patients quality of life after ICU discharge.

OBJECTIVES

The objective of this clinical trial is to prove if certain humanizing measures during the ICU stay can improve patients perception of the ICU, benefit patients situations in the critical care unit and reduce PICS. With this, we can also, in the long run, see the benefits of these humanizing

interventions in patients quality of life. While it is of crucial importance to work on the illness, it is also important to have humanizing interventions which are measures that concentrate health care on patient's dignity and general well-being. If it worked hand in hand it would be ideal.

DESIGN

This project is a **multicentre prospective clinical trial.** We will assign 834 patients to either:

- The humanizing interventions program in the ICU (417 subjects)
- Conventional stay in the ICU (417 subjects)

Patients will be randomized depending in the Hospital they are assigned to. The centres participating in the trial are Hospital Universitari Doctor Josep Trueta in Girona (humanizing interventions) and Hospital Germans Trias i Pujol in Badalona (conventional stay).

PARTICIPANTS

Participants in this trial are all patients above 18 years old (admitted in the HUDJT and Germans Trias i Pujol), that spend more than 48 hours on a mechanical ventilator and a minimum of 5 days in the ICU, excluding any patients that have severe mental diseases or cognitive issues which would complicate evaluation and mask true results.

METHODS

Humanizing intervention program

In the intervention program (HUDJT), 5 different interventions will be applied:

- 1 hour of **music therapy** a day.
- **Open visitation** hours allowing patients to be accompanied all day long.
- Access to **natural light**, for as many hours as possible during the day
- **Diary** of a patients events in the ICU, to help patients recover from long memory gaps.
- **Improving sleep patterns** during the night. We can try and achieve this by closing the doors during the night, face mask for light disturbances, ear plugs and avoiding excessive sleep during the afternoon with different activities.

Conventional stay

For the control group, patients will not have any music therapy, limited visitations, the use of artificial light and no specific interventions to improve sleep patterns.

To see if the interventions have had an effect, after patients' discharge, both groups of patients will undergo two follow up check-ups (6 and 12 months after ICU discharge). In these visits, a series of diagnostic scales will be performed on patients to observe the appearance or not of PICS. These tests are: Beck Depression Inventory-II, Beck Anxiety Inventory, Impact Event Scale, Montreal Cognitive Assessment, Medical Research Council-SS, handgrip dynamometry and six minute walk test and WHOQOL-BREF.

Keyword

ICU, Post-intensive care syndrome, humanizing measures,

INTRODUCTION

1. THE INTENSIVE CARE UNIT

The intensive care unit (ICU) is a specialized ward in the hospital that focuses on critically ill patients with life-threatening diseases or injuries.

It is a versatile unit with many facilities and a specialized multitasked team to treat critically ill patients and ensure the best conditions of a recovery for a healthy and positive functional life.

The ICU team consists of physicians (specialized in critical care), physiotherapist, nurses, auxiliary staff, and a firm communication network with respiratory experts, pharmacists, nutrition specialists, etc. Other work profiles in the ICU are social workers, psychologists, and unit administrates(1).

One of the many characteristics of the ICU is the amount of machinery and tubes that are at a single patients room. These devices are required to sustain life support and to maintain the patient stable enough for the body to be able to function on its own again and fully recover in another (less intense) unit (2).

Every hospitals' ICU is different depending on the needs of the area, the funds, the provided equipment, staff, etc… Some medical units like cardiac surgery have their own ICU for the recovery of surgical patients, others have one polyvalent unit. While some ICUs treat a broad spectrum of patients, other ICUs are specialized depending on the type of patient: "Children or paediatric ICUs (PICU), adult cardiac diseases in the coronary care unit (CCU); perioperative care, trauma care and care of multiple organ dysfunction ICU; care of the neurological and neurosurgical patients in the neuroscience ICU" etc. (1)

Lately, the need for ICU wards has been increasing because of the growth in survival, and patients being older and frailer.

Semi-critic unit

There is also a Semi-critical ward, where patients are not in immediate life threatening condition but do require continuous monitoring. In this unit we need to consider patients who

are stable but could experience events that would destabilize them and complicate their condition, so we control them in the semi-critic unit to anticipate possible issues.

Other functions

Finally, the ICU does not only work in the unit but can also operate around the whole hospital if they are required to. There are a number of criteria (loss of consciousness, hypotension, cardiac arrest, etc) that activates the rapid response code where patients are assessed by carers and are transferred, if needed, to the ICU

TYPE OF PATIENTS

Patients in the ICU often require organ support, cardiopulmonary monitoring, continuous medication infusions and a specialized team of multidisciplinary health workers to check continually on them.

These patients are usually patients that are either in a vital situation or that are developing potentially critical issues, and need life support and high-intensity monitoring (1). Some hospitals have a policy of admitting patients in the ICU if their condition has a "high risk of mortality in 30 days".

Patients from the ICU can be unexpected and non-planned for, like for example civilians from an accident with severe injuries, or a grave unexpected illness, etc. These patients (unplanned) have a higher mortality risk (3). However, not all patients in the ICU are un-planned for, some surgical units depend on the ICU for the recovery of their patients. These surgeries can be elective, and their admission to intensive care is scheduled to optimize patients' recovery and avoid any foreseeable complications.

We can classify patients according to the source of their arrival or by type of injury or illness.

1- Arrival

The Medical Intensive Care Unit Guide classifies patients according to the department they come from (1):

- Emergency room: these patients are admitted in the ICU from the ER. They will require several diagnostic tests if the illness is uncertain, monitoring and stabilizing for each specific disease. They can either be medical, if a medical illness has brought on this acute situation; or traumatic. Examples of these patients could be a complicated pneumonia, a septic shock, or a polytrauma patient from a car accident.
- Medical ward: these are patients who are hospitalized and previously stable and in the course of their treatment can develop a serious complication.
- Operating room (OR) or post-anaesthesia care unit (PACU): patients are already in continuous monitoring, the transfer is basically an extension of this care. If all goes as planned, they tend to stay a short time in the ICU, recover and are able to move on to other, less invasive, wards. The situation however can change if any complications appear that could destabilize the patient's recovery (for instance, pneumonia increases average stay in the ICU by 10 days) (4).

  One of the most common surgeries that requires ICU care for an optimum recovery is cardiac surgery. It has many complications such as bleeding, post-operative cardiac arrest, neurologic damage, respiratory distress, kidney failure, infection and venous thromboembolism (5). Another frequent type of surgery which involves recovery in the critical care unit is neurosurgery.

  Some studies have shown that patients coming from the surgical ward and patients that have been operated on, have a shorter length of stay than medical patients without surgery (4).

- Other facilities: some amenities may not have the conditions necessary to treat patients and cannot provide the necessary care. In these cases patients will be transferred to the nearest available ICU.

Therefore, unplanned patients from the ICU are admitted from the emergency room, another ward, general hospitalization, or other facilities. Most planned admissions to the ICU are received from the surgical theatre and the anaesthesia room (1).

2- Critical situations

Respiratory dysfunction: patients who present difficulties with oxygenation or ventilation need to be transferred to the ICU for added respiratory support (1). This support can be invasive and non-invasive and is monitored with blood gas levels and respiratory rate among other parameters.

If patients remain under mechanical intubation for approximately more than 14 days, a tracheostomy will be done to ensure proper respiration functions and to preserve damage to the vocal cords and other obstacles.

Hemodynamic instability: this consists on arrythmias, hypotension or hypertension.

Different reasons for hemodynamic instability could be excessive bleeding, myocardial infarction, aortic injury, pneumothorax, spinal cord injury, anaphylaxis, complicated infections, etc… So as we can see many different situations can lead to it.

To control hypotension the first line of treatment, unless contraindicated, would be the administration of crystalloids or medication like inotropes or vasopressors. If the patients does not respond to the latter treatments, "a pulmonary arterial catheter should be inserted to monitor cardiac output"(1) and decide the better course of treatment acting upon cardiac volumes, heart dysfunction, etc…

Hypertension should be also be treated with continuous medication. And arrythmias with antiarrhythmic medication, electric pacemakers or as a last resource electric cardioversion.

Neurological compromise: loss of consciousness, epileptic status, strokes and other similar diseases can create a critical situation for the patient. These injuries will require close monitoring, reiterated neuro-exams and close attention to intracranial pressures or appearance of other brain complications.

Polytrauma: a polytrauma patient has multiple traumatic injuries and can cause serious morbidity and mortality.

Post-operative: all kind of surgeries can lead to a recovery in the ICU, some are more common, like cardiac surgery, because of the risk for a perioperative mortal complication. However, all

surgeries have detailed issues that may need continuous monitoring and recovery in the ICU, for example, extensive procedures, organ transplantation, vascular surgery, etc… (1)

MONITORING DEVICES USED IN THE ICU

One of the main characteristics of the ICU is to monitor patients closely in order to prevent any serious complications and be able to give adequate treatment.

Regarding hemodynamics we have different machinery that allow us to control and observe if treatments are responding.

- One of the main devices is the ECG leads. This allows us to observe different heart rhythms and be able to treat if any arrythmias appear.
- We also need the arterial line or inflating blood pressure cuff to measure blood pressure.
- Transvenous pacemakers are similarly important, specifically after cardiac surgery, to ensure that if any tissue damage was made during the surgery, we can safeguard a proper rhythm and avoid patient crashing.
- Other more invasive monitoring techniques for hemodynamics are different catheters like the CVP to measure right heart central venous pressure and see volume status or the pulmonary artery catheter to observe cardiac productivity

When monitoring a patient in the ICU it is also essential to monitor ventilation and oxygenation. Ventilation is the action of inspiration (contraction of inspiratory muscle creating negative pressure in the thoracic cavity), and expiration (relaxation of the previous muscles and a positive pressure) that pushes air out of the thoracic cavity.

- This process is measured with the respiratory rate on a screen (1,6,7).

Oxygenation is the process of delivering oxygen to cells and maintain them functioning.

- This gas exchange is measured with oxygen saturation in the monitor and arterial blood gases to check PaO2 (1,8,9) .

Finally, other monitoring devices are Foley catheters to measure urine output and indirectly control kidney function; and neurologic monitoring devices to check intracranial pressures (1,7).

TREATMENT AND PROPHYLACTIC DEVICES

In order to treat patients in the ICU, one of the most important tools is to be able to infuse intravenously medication in patients continuously. These medications are inserted in the patient through a central line, which can also be used to feed patients parenterally if their GI tract is not functional (1,7).

To ensure proper oxygenation and ventilation, we can use mechanical-ventilation which can be invasive (endotracheal tube or tracheostomy) or non-invasive (oxygen mask, nasal cannula) and ensure proper respiratory function. These ventilators can be programmed to assist patients when breathing or to completely take over respiration(7).

Another important prophylactic device in patients in the ICU, who are bed-ridden and have blood disorders, are the sequential compression devices of the lower extremities to avoid deep venous thrombosis (DVT).

In patients with heart or lung surgery, and patients with other lung complications, there may be the need to insert drainage tubes in order to control bleeding, drain fluid, etc…

Nasogastric tubes are also in place and have two main objectives: emptying the stomachs fluids to prevent vomiting and aspiration, and feeding patients when ventilated or unable to eat on their own.

Other treatment devices can be dialysis apparatuses to correct electrolytes and metabolic conditions; intra-aortic balloon pumps to help heart contractility, etc. (1,7)

LESS INVASIVE TOOLS

As we have seen, in the ICU there are many invasive tools to asses patients. However, like in all hospital wards, the most important step to treat patients is to know their medical history, make a right anamnesis and complete physical examination.

In the case of patients in the critical care unit, it is of vital importance that physicians communicate with each other, and ICU professionals build a communication network between physicians, family members and patients to make each situation as clear as possible.

Furthermore, there are generic scales or tables to homogenize and diagnose different situations that could be interpreted more or less subjectively.
Some are specific for diseases:

- For example the CAM ICU scale, which assesses delirium in patients in the ICU. The NVS or ESCID scale to evaluate the patient's level of pain, conscious or unconsciously respectively. RASS to evaluate patients level of consciousness and adjust sedatives.

Other tables can helps us asses a patients as a whole:

- APACHE II to assess the patient's severity of injury, SOFA for organ failure, etc..

And finally, we need to take into account that there are other essential less invasive tools and techniques to diagnose and treat patients which are not uniquely of the ICU but are practiced in all hospital wards, like blood drawls, glycaemic controls, taking temperature, imaging tools, etc…

2. POST INTENSIVE CARE SYNDROME

Post Intensive care syndrome is defined as **"a heterogeneous syndrome where new or worsening long term physical, cognitive and emotional impairments appear because of critical care or intensive care unit stay**" (10). The main hallmark being that these symptoms worsen or appear after critical care discharge and can persist for years after discharge, reducing quality of life and limiting many patients.

It is important to understand that PICS is not the same for every patient. The situations leading up to ICU, the subjective experience of it, the baseline lifestyle they were leading before the injury or illness, and every patient's previous perception of health is different, making it difficult to establish one single line of PICS and a single protocol to prevent and treat it.

2.1. EPIDEMIOLOGY

This term was first named after a 2010 conference convened by the Society of Critical Care Medicine where it became aware of this syndrome and established that research and improvements had to be made in order to reduce its prevalence. (11)

PICS is a common disease, it cannot be calculated exactly, but it occurs approximately 30 to 50% or more of patients that have been admitted to the ICU(12).

This syndrome is upcoming and its prevalence is increasing because there has been an improvement in innovative techniques and treatments with the increased demand of the ICU and the worsened conditions of an older population. This has helped around 90% of patients to be discharged but not all of them are completely recovered, leaving them with PICS (13). So, because of medical advances, more patients with worse conditions survive critical care.

To sum up, the short term recovery in ICU patients has improved but long term consequences have been increasing. (14)

2.2. ETIOLOGY

These symptoms are a result of the hospital stay in the Intensive care unit.

There isn't a tangible way to describe the pathogenesis of the symptoms, as a lot of factors are involved in it and it can affect every patient differently.

In the ICU, due to the seriousness of some injuries, the well-being of patients can be unintentionally relegated to a second position, which can increase the odds for PICS (15). Not only is their physical health important, but also their emotional well-being, which can be compromised by the severe vulnerability, loss of autonomy, dependence of machines, etc...

Some studies talk about how the appearance of PICS is related to each patients experience in the ICU plus their individual risk factors.

2.3. RISK FACTORS FOR PICS

Although there is a lot of doubt, and causal relationships have not been established 100%, by analysing each symptom separately we can more or less define risk factors for PICS. Generally we can classify these risk factors according to previous patient state, disease-related risks and ICU factors(10) (Figure 1).

These factors from figure 1 (patient level factors, Disease related exposures and ICU factors) combined with the pathophysiologic states like atrophy, delirium, dysgeusia, encephalopathy, hyperarousal, malnutrition, myopathy, neuropathy and pain can lead to PICS.

Looking at each of the symptoms individually there have been various studies that have linked together risk factors and the appearance of cognitive, physical or psychiatric clinical situations(12).

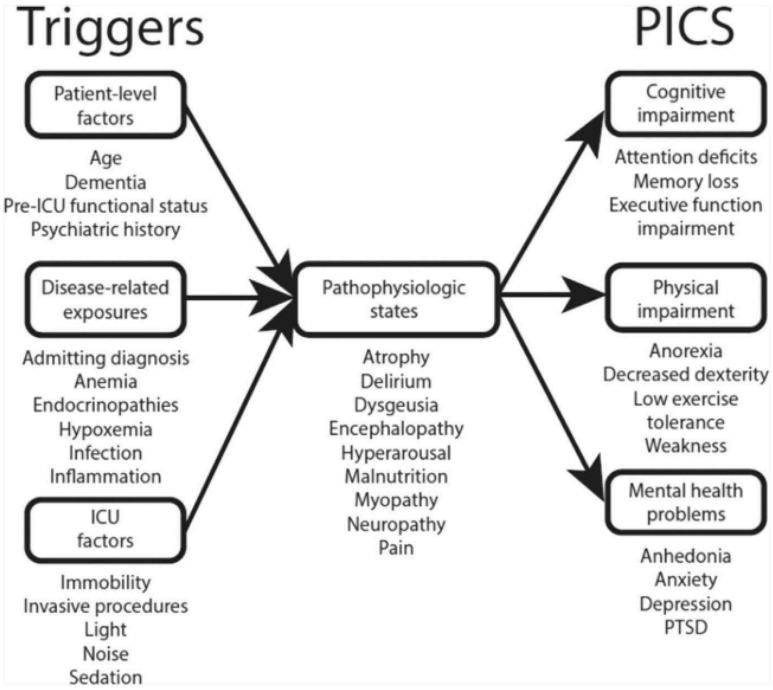

Fig. 1. Conceptual model relating various triggers to pathophysiologic states that are thought to precede the development of PICS.

Figure 1 Summary of triggers and risk factors of Post -Intensive Care Syndrome (9)

Main risks for physical impairment

Risks of PICS-Acquired Muscle Weakness, which will be explained later, is linked with female sex; advanced age; sepsis, catabolic state; multiorgan failure; systemic inflammatory response syndrome; long duration of mechanical ventilation; immobility; hyperglycaemia; pre-existing IADL deficiency; treatment with glucocorticoids; and neuromuscular blocking agents. (12,14,16–18). Being treatment with glucocorticoids one of the most important one.

Risks for cognitive problems

Risk factors for cognitive symptoms have more literature behind them(12).

Studies agree that one of the main risk factor for cognitive impairment, in PICS, is delirium and its duration.

> Delirium is an acute cognitive disorder defined as fluctuations in cognition, conscience and disorganized thoughts. Associated with physical activity, there can be hyperactive and hypoactive delirium, and finally mixed delirium. (19,20).
>
> This delirium can be more or less prevented by the limitation of sedation medication and improving pain relief, however it can appear in any patient in very different ways and it is impossible to generalize a treatment as it can affect each person differently. Nowadays, there are different plans to prevent delirium like the ABDCE bundle explained later on.

Additional risk factors for cognitive problems are sepsis, acute brain dysfunction (stroke, alcoholism), hypoxia (ARDS, cardiac arrest), hypotension, prior cognitive deterioration, sedation, glucose fluctuations and high-stress experiences etc. (10,12,16–18)

Psychiatric risk factor

Risk factors for psychiatric symptoms are similar to cognitive ones (sepsis, ARDS, hyperglycaemia…).

According to Lane, F. *et al* (2019), polytrauma patients admitted to the hospital are particularly vulnerable to developing disorders such as depression, anxiety, and posttraumatic stress disorder unlike other admission reasons(10).

Additionally, there are other specific factors that can trigger depression, anxiety and PTSD.

> Involving the patient: women <50 years old are especially vulnerable to these symptoms. In addition, other similar risk factors for emotional alterations in PICS, are pre-existing conditions like depression, anxiety, PTSD, lower education level and alcohol abuse(10,12).

Referring to PTSD, one of the main risk factors is the inability to recall anything from the ICU, leading to memory gaps that give way to intrusive memories after discharge. Other risk factors are traumatic or delusional memories of the illness or injury. (18)

Some studies that specialized in PTSD after ICU proposed various statements:

Lane F. *et al* (2019) exposed that up to 88% of ICU survivors had unpleasant and disturbing memories from their in-hospital time, proposing continuous sedation to avoid it(10). Nonetheless, this argument would worsen the patient's outcome by increasing mechanical ventilation time, longer weaning, higher risk of infection, longer LOS, increasing other aspects of PICS syndrome, etc. There has to be an equilibrium between sedation and awake time to reduce patients discomfort.

A study by Wade DM, *et al.* (2015) tried to determine the cause that traumatized patients so much; like fear of dying, invasive procedures or hallucinations due to medication. The latter one having the most relationship to intrusive memories and flashbacks(21).

Finally, another very important risk factor when talking about developing PTSD is the length of stay in the ICU (LOS). Patients that suffer through longer LOS are patients that come from the medical or emergency room (as mentioned before, surgical patients spend less time in the ICU). Other factors related to a longer LOS in the ICU were patients with multiple diseases and comorbidities, and decreased kidney function (4).

To sum up mental health affections in the ICU, we must take into account any patient's pre-existing conditions, the nature of the illness or event that has caused the patient to be in the critical care, length of stay in the ICU and finally sedation medication that can lead to delirium and PTSD.

2.4. MAIN SYMPTOMS OF PICS

Cognitive impairment occurs up to 80% of ICU survivors. Psychiatric illnesses appear up to 57% of patients and physical impairment occurs in 25-80% of patients (17).

We need to understand PICS as an "umbrella term that encompasses multiple pathophysiological, psychological and social presses" (13)

Physical altercations

Many patients suffering PICS experience **physical altercations** like muscular weakness, pain, fatigue, dyspnoea, impaired pulmonary function, low exercise tolerance, sexual dysfunction, respiratory failure leading to a reduction of daily activities, anorexia and decreased dexterity(10,22)

Concentrating on muscular issues, skeletal muscle seems disproportionately affected compared to smooth muscle (10). Approximately 30-50% of patients suffer from ICU-Acquired Weakness (ICU-AW) and the incidence is higher if patients have suffered sepsis (23).

Inouse, S *et al*. (2019) explains that the term ICU-AW (acquired weakness) was defined as "muscle weakness of the extremities, in a symmetric pattern" (14), also affecting respirational muscles. Muscle tone is almost always reduced and deep tendon reflexes can be altered (23). This study also details between critical illness polyneuropathy (CIP), with being the most frequent, critical illness myopathy (CIM), critical illness neuromyopathy (CINM), and muscle deconditioning (14).
In addition, unit-acquired weakness contributes in itself to a prolonged mechanical ventilation, increases stay in the ICU (length of stay, LOS) and mortality (10).

- The oropharyngeal muscle groups are frequently affected and along with the duration of the stay, mechanical ventilation and tracheostomy can produce dysphagia leading to anorexia.

So these physical issues are all linked together and it is difficult to pin-point the proper pathophysiology.

Mental health issues

Up to approximately 57% of patients have **mental health effects.** The most common ones being anxiety, depression, posttraumatic stress disorder (PTSD) and sleep disorders.

Depression is a common "mood disorder, where those who suffer from it experience persistent feelings of sadness and hopelessness and lose interest in activities they once enjoyed" along with physical and cognitive alterations (24).

Anxiety defined in DSMV is characterized by "excessive worry and anticipation, difficult to control, with at least 3 of the 6 following symptoms: restlessness, easily fatigued, difficulty concentrating or mind going blank, irritability, muscle tension and sleep disturbance" (24,25). The most frequent symptoms of anxiety being irritability, fatigue and excessive worrying in PICS(12).

Sleep disorders are common in patients that spend a long time in the ICU and are often a result of sleep-wake cycle disruption from the hospital unit. (10)

Lane F, *et al.* (2019) defined PTSD as a "mental health condition that can happen after an actual or perceived event that threatens either life or perception of safety"(10). Main symptoms include flashbacks, invasive unwanted memories, avoidance of triggers, depressive or anxiety mood, extreme physical reaction to reminders of trauma such as nausea, sweating or a pounding heart (12). Another important symptom is sexual dysfunction which has been strongly associated with the presence of PTSD (12).

Cognitive issues

30% to 80% of patients have cognitive issues from experiencing high levels of physical and psychological stress in the ICU, that can lead to months and years of poor quality of life. These include memory loss, difficulty concentrating, slow comprehensive and critical thinking, impaired language, attention, and visual-spatial abilities (14).

The areas most affected in PICS are attention/concentration, memory, mental processing speed, and executive function (12).

Impaired cognition may also contribute to poor communication which can then affect rehabilitation and diagnosis of PICS (12).

Physical weakness	Mental health impairments	Cognitive issues
Fatigue	Depression	Memory loss
Muscular weakness	Anxiety	Speech difficulties
Muscular pain	Nightmares	Decreased attention
Sexual dysfunction	Post-traumatic stress disorder	
Exercise intolerance		

Figure 2: summary of the most important symptoms of PICS, own source.

2.5. PICS-Family

This condition not only affects the patient but also family and caregivers known as PICS-F, where most alterations are effective and emotional (22).

The most important symptoms of PICS-F are depression, anxiety and PTSD. The main causes being the stress of taking care of someone, the fear of the severity of the illness, distancing from social circle and financial strain (10).

2.6. DIAGNOSIS OF PICS

Due to the recent onset of the discovery of the disease, there is still no consensus or clear criteria regarding the diagnosis of this syndrome.

However, if we look at the definition of the disease **"a heterogeneous syndrome where new or worsening long term physical, cognitive and emotional impairments appear because of critical care or intensive care unit stay**" (10), we can establish that any new or worsening symptoms after discharge in these 3 areas can be interpreted as the presence of PICS (in the absence of another event that can produce them).

- If there are any prior conditions to the ICU and they worsen we can say it is PICS.

Any patient with suspected PICS should undergo a clinical assessment and a series of autofill test to identify cognitive, psychological symptoms and physical symptoms.

We should take in account other diseases that can mimic PICS syndrome like cancer, anaemia, B12 deficiency, etc, by realizing other medical tests.

Finally we need to differentiate it from the post hospital syndrome where its main difference is that this latter one is transient compared to PICS, which can last for years (12).

Cognitive and mental health diagnosis

For cognition, there are many tests and evaluations that a patient can undergo to be assessed and evaluated for any cognitive issues. The most useful tests are: the Mini Mental State Examination (Spanish version MEC); Montreal Cognitive Assessment (MoCA), Mini-cognitive , etc…

As for mental health, several tables and scales have been developed to identify symptoms of depression, anxiety, PTSD, etc… nonetheless there is no strict policy in choosing which table or test is better for evaluating post intensive care syndrome. Some o f these examples would be: Beck Depression Inventory, BDI-II (Beck, 2011); Beck Anxiety Inventory, BAI; Impact Event Scale

Mental health complications and cognitive troubles can also be measured with disability time, health care costs, financial strain, reinstatement at work, mortality rates and potential avoidable readmission (10). Along with other psychological scales.

Physical status

All patients at risk for ICU-AW should be evaluated by a physician, a physical therapist and others after ICU discharge to assess any presence of muscle weakness and the effect it can have on daily activities and quality of life.

In definition ICU-AW is acquired muscle weakness after a critical illness, and this temporary sequence is one of the criteria to diagnose it.

The diagnosis of AW is clinical, and when suspected, the most important tests to confirm the disease are the Medical Research Council scoring (MRC-SS) and handgrip dynamometry(23). We can also dispose of electromyography, muscle biopsy, and nerve conduction. Other substitutes to measure muscle weakness are prolonged mechanical ventilation, tracheostomy placement, exercise tolerance with the six minute walking test or others (10).

2.7. CONSEQUENCES OF PICS

Post intensive care syndrome is a very relevant entity that can have a profound effect on patients and their family members. Most of these alterations take a toll on a patients quality

of life isolating them from their social circle, straining them financially and producing major life style changes.

When talking about the duration of PICS, the longest alterations are normally cognitive, specifically memory impairment and decreased attention, which can last up to 6 years.
PTSD and physical weakness can also persist for several years. However, other symptoms like anxiety and depression decrease over the course of the first year (18).

Financially speaking, Colbenson, G *et al*. (2019) found that 1/3 of post ICU patients could not go back to work, another third could not go back to their previous job title or the same salary. This not only puts a strain on the day to day routine payments, but in the added cost that most patients will need (for a better quality of life) of; physical therapy, rehabilitation of some kind. So, these financial difficulties can further complicate access to healthcare and worsen peoples conditions. (22) Also, the loss of a job can increase depression and lower a patients feeling of self-worth.

Lane F, et al (2019) said that a large amount of patients with long lengths of stay in the ICU were less likely to be discharged home, with a substantial proportion being discharged to facilities providing impatient rehabilitation, skilled nursing, or long-term acute care and increased visits to the emergency room and re-hospitalization(10,22). This fact improves morbidity in sometimes previously healthy individuals.

All of these previous factors result in an overall decrease in quality of life and a negative impact on patients since their hospitalization in the ICU, proving once again that advances in medicine are helping critically ill short term patients, but leaving many patients with long term complications.

2.8. PREVENTION OF PICS

Given as it is a “relatively new” disease, a few institutions have started different programs to prevent PICS and help patients to fully recover.

Some measures already exist and are in place in order to helps patients through their stay.

- One measure to help patients are individual rooms, to ensure patients intimacy (2).
- Other measures are related to improving physician-family and patient communication
    - Nursing care in the ICU is a very important factor, as these professionals are the ones with more direct contact with the patient. The improvement of communication between nursing staff, patients and family members can help create a healthy relationship and proper information exchange.
- There are also psychologists in the ICU specialized in difficult situations that can help the process.

Specifically talking about PICS, different projects were created:

- SCCM developed the term in 2010 and created the THRIVE initiative in the United States but has spread worldwide. This program was created to provide resources and education in order to prevent PICS syndrome, and also to detect it quickly and be able to help patients and physicians suffering from it. One of its main characteristics is the different support groups formed so patients can talk to someone who is or has been in the same situation as them. Also, THRIVE recommends that all patients suffering PICS get in contact with mental health workers, psychiatrists and social workers which may help with different strategies for combating these symptoms (26).
- HUCI initiative is a program created in Spain focused in PICS. It bases itself on patients autonomy and respect and has done numerous projects to help. ÍTACA project was created from it and invites different health work professionals to help research, collect data and improve quality of life of patients and family members after ICU (27,28).
    - This project talks about the importance not only of helping the patient through the illness they are going through, but to also help them with their physical and emotional wellbeing.

The American College of Critical Care Medicine, with the collaboration of the Society of Critical Care Medicine and American Society of Health-System Pharmacists, updated the clinical practice guidelines with management of Pain, Agitation, and Delirium in the ICU (ICU PAD Guidelines) to optimize care and, moreover, target PICS.

The update was the creation of the ABCDE bundle to help professionals optimize ICU care (14,29). It consists of:

- A) Airway management and assessment.
- B) Breathing trials; including daily pauses of mechanical ventilation; spontaneous awakening trials and spontaneous breathing trials. This can reduce days on mechanical ventilation and help wake up patients if they are in the right conditions.
- C) Choice of analgesia and sedation, essential to make patients comfortable in the ICU. Pain should be monitored by talking to the patient if possible or with different scales like ESCID to prevent any avoidable pain.
- D) Delirium prevention and management; can be done by either preventing it with proper medication, light sedation and a proper choice of analgesia. However, if it appears, it is important to be able to screen and detect it as early as possible to try and correct it, for it the CAMICU scale is useful.
- E) Early mobility and exercise when possible. There already is a physical therapist in the ICU to help patients avoid possible physical complications. However, sometimes it is unavoidable if the patient has to be bedridden for a long period of time.

Also added afterwards: FGH F) Family involvement, follow up, referrals and continual reconciliation G) good handoff communication; and H) handout materials on PICS and PICS-F. (14).

Further programs have been designed in order to prevent Post-Intensive Care Syndrome:

- Intensive care unit diaries; written by family or hospital members. Diaries can help prevent PTSD by avoiding memory gaps (17,30).
- Intensive care unit follow-up clinics; they have been developed around Europe to detect PICS and treat the syndrome with professionals like social workers, psychologists, physical therapists, pharmacists… (14,17).
- ICU survivor peer support groups: there are different models like telemedicine, community-based groups, psychologists led sessions, etc. Nontheless, one of the main problems that intercept patients from attending these support groups is the un-identification of these symptoms (17).

However, we must remember that the most important factor to prevent PICS is being able to individualize care for each patient, understanding what is most important for every individual in order to maintain quality of life, dignity, etc… (13).

2.9. TREATMENT OF PICS

If post-intensive care syndrome cannot be prevented and is diagnosed, physicians should try and target every symptom in order to improve patients recovery.

- Cognitive symptoms: therapy should be recommended to all patients suffering from attention, memory loss, executive function disorders, etc…
- Mental health issues can be addressed with pharmaceutical and non-pharmaceutical therapy to reduce anxiety and depression. To target PTSD there are also different techniques, but the combination of pharmaceuticals plus psychological therapy can be a correct approach.
- Physical rehabilitation with a physical therapist can help with ICU-AW. To help with the pain, we can also administer of the counter controlled pain medication.

Finally, it is important to maintain follow-up visits to treat any symptoms and ensure the best care after ICU discharge, individualizing for each patient what may be better for them in order to live in the best possible conditions.

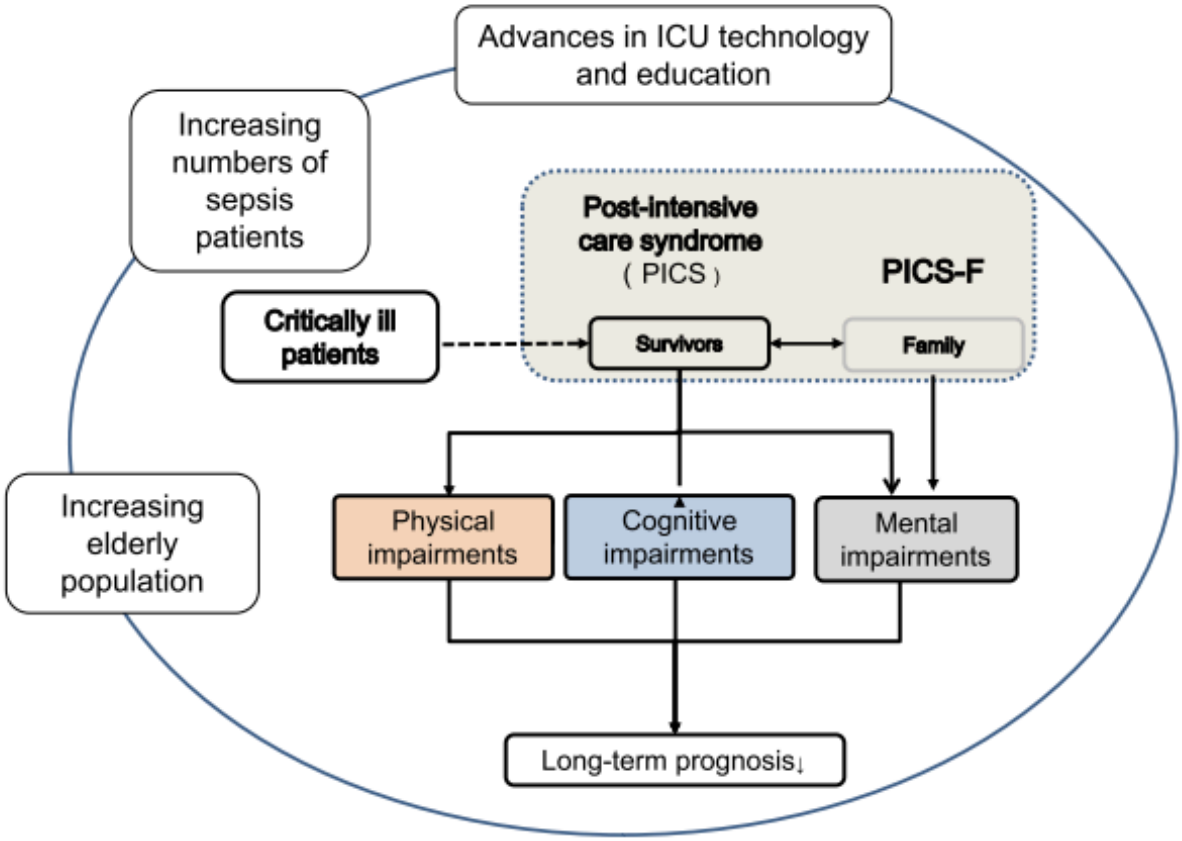

Figure 3:Visual scheme of the Post intensive care syndrome (PICS). ICU, Intensive care unit; PICS-F, PICS-family (13)

JUSTIFICATION

It is clear that the ICU is a vital ward in the hospital. Necessary to help patients in critical situations and to help patients with grave conditions.

Lately, the demand for the ICU has increased, and with it, the upgrading of its facilities and medical advances. Patient survival has also improved.

Admission for patients in the ICU is a traumatic event that can drastically change a patient's life. They can go from being a healthy person to a fragile patient, surrounded by strangers, in an unfamiliar room with many unanswered questions.

Although survival in the ICU is increasing because of better techniques, machinery and treatment plans, we have to take into account how a person's quality of life changes and consider that many patients discharged from a critical care unit can carry many consequences from it. The appearance or worsening physical, cognitive and psychiatric symptoms after ICU is known as the Post-intensive care unit syndrome.

This entity has only recently been acknowledged and even though some strategies have been developed, there is still a lot more to do to ensure the well-being of patients after critical care.

For this reason, we propose a series of interventions that can benefit patients, family members and physicians working in the critical care unit. These interventions are said to be humanizing because they centre the treatment on patient's dignity, contributing to their wellbeing and to the best possible health results; instead of focusing on the disease, it centres on the patient. In order to put the patient first, and when facing very difficult medical decisions, it is important to accept some boundaries, guaranteeing comfort, tranquillity, dignity and respect to their wishes.

We trust that by implementing humanizing non-invasive measures in the ICU we can decrease Post-Intensive Care Syndrome and improve patients' life after discharge.

Moreover, we understand that this study holds enough reason to be with all that has been said up until now, however, the actual situation raises even more the need for it. That is, in the last few months, due to Covid-19, there has been a big increase of patients who have required ICU admission. Long lengths of stay, many days on mechanical ventilation and sedation for stretched periods of time have been one of the protagonists of this pandemic. Linking this with what has been exposed until now, we can predict an increase of PICS in post Covid-19 patients.

PICS is not a simple condition and it's characteristics are very heterogenic between patients. Its complexity requires an implementation of measures to detect, reduce and prevent it whenever is possible. It is our top priority to give back the patient's quality of life, with the best chance at independence, autonomy and comfort after the ICU.

To our knowledge the publications up to date centres on interventions to improve specific symptoms of PICS. Particular symptoms such as PTSD or muscle weakness have been isolated in order to search for more humanizing interventions. However, there seems to be a lack of a view of the PICS as a whole. We would like to consider PICS from a holistic view and propose a multifactorial research project.

HYPOTHESIS

Our main hypothesis is that humanizing interventions (such as music therapy, unlimited visitations hours, natural sunlight, a diary and improving sleep patterns) in patients at risk for Post intensive Care syndrome (PICS), during the ICU stay, can decrease PICS compared to a conventional stay in the critical care unit.

Our second hypothesis is that the appearance of PICS has a significant negative impact on the quality of life of patients.

OBJECTIVES

MAIN OBJECTIVES

Main objectives of the project to corroborate our hypothesis:

- To study the effects of humanizing interventions (such as music therapy, unlimited visitations hours, natural sunlight, a diary and improving sleep patterns) during the ICU stay, in preventing Post-Intensive Care Syndrome.
    - This will be done by applying the interventions and scheduling check-ups six months and a year after critical care discharge to assess the presence of PICS.

- To observe how humanizing interventions can improve quality of life after ICU discharge.

SECONDARY OBJECTIVES

- Observing which component of PICS can be reduced when applying humanizing interventions.
    - Psychiatric symptoms, cognitive issues and or physical difficulties.

- Paying attention to which individual characteristics of critically ill patients respond better to humanizing interventions in order to reduce PICS. The characteristics that should be taken into account are:
    - Age; mobility; days under sedation; days under ventilation; pain medication; others.

METHODOLOGY

1. STUDY DESIGN

This study is a **multicentred, prospective clinical trial** comparing humanizing interventions in patients, compared to a conventional stay in the ICU, in order to decrease post intensive care syndrome.

Centres participating are:

- Hospital Universitari Doctor Josep Trueta (HUDJT), in Girona
- Hospital Germans Trias i Pujol, in Badalona.

2. STUDY POPULATION

All patients above 18 years old hospitalized in the ICU:

⇒ **Inclusion criteria**

- Patients admitted in the ICU (with a critical or life-threatening disease or injury).

⇒ **Exclusion criteria**

- Patients below **18 years old.**
- Patients that are **mechanically ventilated for less than 48h**.
- Patients with a **length of stay of a maximum of 4 days.**
- **Illiterate** patients,
- Patients with a **previous cognitive disorder** that cannot allow us to evaluate the patient properly in follow up check-ups.
- Patients with a **previous severe mental disease** that will condition following diagnosis.

When talking about patients in the ICU, they are not predictable and sometimes we cannot predict how long they are going to be in the critical care unit or if their recovery will be sooner than expected and be discharged sooner than anticipated.

This is why all patients from the two ICUs (who meet inclusion criteria) will be entered in the clinical trial, after themselves or family members have signed a consent form and accepted to participate in it.

- If patients remain in the ICU for more than 5 days and remain intubated for a minimum of 48h their data will be included in the analysis.
- Nonetheless, patients that have signed the consent form but their stay in the ICU is shorter than 5 days and/or ventilation time is less than 48h their data will not be included in the study.
- If researchers want to, they can include all patient criteria and then in the analysis make a double analysis separating patients with 48h ventilated and 5 days minimum in the ICU, and patients with less than 48h ventilated and less than 5 days in the critical care unit.

3. SAMPLING

SAMPLE SIZE

We used the program GRANMO to calculate the size of our sample for the clinical trial.

As we could not know exactly how many patients we needed, we assumed that patients without any interventions would have a prevalence of 45% of appearance of PICS. This is corroborated with different studied that say that between 30-50% or more of patients can have Post-Intensive Care Syndrome (12). We also considered a 10% improvement in patients with the intervention ICU.

Accepting an alpha risk of 0.05 ana beta risk of 0.2 in a two-sided test, **417** subjects are necessary in first group and **417** in the second to fins as statistically significant a proportion difference expected to be 0,45 in group 1 and 0,35 in group 2. It has been anticipated a drop-out rate of 15%. The ARCSINUS approximation.

Taking in account the fact that Post-intensive Care syndrome occurs in approximately 30-50% of patients discharged from the ICU (12).

- Group 1 (control group, with no interventions) with an anticipated prevalence of PICS of 45%
- Group 2 (intervention group with humanizing interventions) with an anticipated prevalence of PICS of 35%.

If we take in account the number or patients that go through the ICU in one year (in our hospitals) we can see that it is possible to get all the patients in one year and analyse in the following year.

SAMPLING METHOD

A non-probabilistic sampling method will be chosen for this study.

The sample will be from patients who are admitted to the two different hospitals (Girona and Badalona) for a year, that meet inclusion criteria and don't meet exclusion criteria.

4. PATIENT INVOLVEMENT

To get the perspective of a patient and a genuine opinion on the project we talked to a patient and his family who had recently been in an ICU.

This patient had a scheduled valve replacement surgery to fix an aortic stenosis. However, things did not go as planned and due to a haemorrhaging complication, the patients un-stabilized and was admitted to the ICU for a total of 42 days.

Speaking to the wife, son and patient when asked about this project and their opinion on a more humanized care in the ICU, they all had the same answer.

- They believed that the professionals in the ICU were honest, kind and respectful and would not change a thing.
- About the surroundings, they agreed on the following aspects:
    - More visitation hours with more family members, and even close friends.
    - They also agreed on the music therapy, as they had already used it on their family member and though to be very important for him.
    - They did not have a specific opinion on the diary, but did say that the patient did not remember anything about the ICU stay and to the day, had not wanted any information about it.

On the other measures they did not specify uniquely but did say that anything that could help humanize this difficult time, they would agree on it.

Other opinions they gave us were how they found themselves overwhelmed with information during the first few days in the ICU and how they didn't expect the recovery at home to be so long and hard for the whole family.

This interview with the family member gives us an idea of how other families would react to this kind of project and gives us further ideas that we could, in the future add to our own project like a recovery leaflet explaining PICS, etc…

5. STUDY VARIABLES AND MEASURING INSTRUMENTS

INDEPENDENT VARIABLE:

- Humanizing interventions in the ICU to avoid PICS.

It is a dichotomous nominal qualitative variable, expressed by yes or no (applying these measures or not).

The measures are series of humanizing interventions, i.e. measures centred on patients dignity and wellbeing.

The following measures should be applied homogeneously for all patients in the "yes category".

- Music therapy: 1 hour of music sessions a day. Any kind of music genre should be chosen according to the patient or family member request during the description of the clinical trial. The sessions should be up to 60 minute long depending on each patients preference. Music should not be heard via headphones or earbuds, instead it is recommended to listen to as background music. At a maximum volume of 75dB, considering 85dB is the maximum safety volume to listen to music before injuring your hearing (31).

  Various studies have proven that noise and music therapy in different situations can alter patients pain and overall situation:

  - Music therapy can be used as a non-pharmaceutical method to decrease pain and keep patients lucid, proven to help anxiety, stress and relief pain. (32) A controlled trial in palliative patients proved that musicotherapy increased the release of oxytocin which decreased anxiety and stress. Another study showed that 30 minute sessions of music during the recovery of surgery proved to decrease patients perception of pain post operatively,

however there wasn't consensus on when this sessions should be applied (pre-operatively, intra-operatively or post-operatively). (33)

- Open visitation hours: with a minimum of 0 and a maximum up to 24 hours a day, exclusively up to each patient. This condition has to be completely up to the patient, because previous relationship with family members is not known and it has to be respected completely.

  It is not the amount of hours, but the patients choice to be visited that determines this variable.

  - If the patient is unconscious, there should be a consensus between family members or close friends, checking in advance if there are any family issues the ICU staff should be aware of.
  - If the patient is conscious, and fully aware of the situation, he or she can choose if he wants visitation around and whenever he prefers to be alone.

- Daily diary: a notebook redacting the day to day of the patient to reduce any intruding memories and memory gaps that can distort patients memories of the stay after discharge. This notebook should be written daily either by professionals attending the patient, by family members visiting the subject or by the patient if awake. Entries should be written in a casual tone and note any patient changes, ICU events or visitation interactions.

- A room with access to natural sunlight. It is proven that natural light instead of artificial lighting in a room can have beneficial effect, specifically morning light, which proved to be better than afternoon lighting. Different studies have proved that patients admitted to a room where they were exposed to natural morning sunlight had a lower LOS in the hospital, also there was a decrease in pain medication, distress and pain while admitted. Other studies proved that light was very effective in depression and affection diseases (32,33). These rooms, should be the same colours (exposed or not exposed), the bed spread and patients gown should also be the same colour to avoid different lighting effects.

- Improving sleep hygiene and preventing sleep in non-sedated patients during the day (entertainment) to improve sleep quality. In order to do that, different measures are:
    - Giving patients a choice of different feasible activities a day, to avoid sleeping during the day.
        - Puzzle
        - Mandala
        - Sudoku
        - Other
    - Increasing sleep hygiene with a fixed routine, noise and light cancelling techniques with facemasks, ear plugs and closed doors to prevent as much as possible any disturbances during the night.
        - Background noise in the ICU has proven to have a negative impact on patients sleep patterns. The use of different noise cancelling systems like ear plugs or noise reduction devices could reduce the development of delirium in the ICU and therefore cognitive PICS syndrome affections(12).
    - Aiming for 8 hours of sleep minimum during the night.

DEPENDENT VARIABLE

PRIMARY OUTCOME

Appearance of post intensive care syndrome after ICU discharge.

This is a dichotomous nominal qualitative variable. It is expressed by appearance of PICS or no appearance of PICS.

In order to calculate the presence of PICS we will have to make routine scheduled check-ups at 6 and 12 months after ICU discharge. The interviewer of this visits will be a psychologist who is external to our study, which we will hire in each of the hospitals. If there is an appearance of physical impairment, psychiatric complications or cognitive issues, and no other event or disease that can justify it, we can confirm that the patient is suffering from PICS.

In order to calculate it we can use different tables and questionnaires that have to be given to all patients during their routine check-ups.

MEASUREMENTS AND INSTRUMENTS FOR THE PRIMARY OUTCOME VARIABLE

All data from both check-ups will be placed in an excel spreadsheet along with the covariables.

Psychiatric status post-ICU

- **Beck Depression Inventory -II (BDI-II)** is a scale that helps determine depression. It is a 21 self-report questionnaire that is able to give us information about the propensity of patients that could suffer depression after ICU. The test should take between 5 to 10 minutes for each patient. Obviously we cannot make a diagnosis with a simple self-questionnaire, but we can suspect which patients are suffering more symptoms with depressive tendencies.(34)
    - The higher the score, the higher the depression diagnosis, considering 17-20 borderline for clinical depression.
- Beck Anxiety Inventory (BAI) is a self-report test to measure anxiety. With 21 items and 4 possible answers (not at all 0/mildly 1/moderately 2/severely 3) we are able to classify patients with or without anxiety, and the degree of it. (35)
    - Score of 0-21 = very low anxiety.
    - Score of 22-35= moderate anxiety.
    - Score of 36 and above = potentially concerning levels of anxiety.
- Impact of Event Scale-Revised (IES-R), is a self-report measure designed to assess distress for any specific life event and see if there are any PTSD symptoms. It consists of 22 items (relating avoidance, hyperactivity and intrusion). All questions are related to a life event (in our case the ICU) and have 4 possible answers (0; not at all, 1; rarely, 3; sometimes and 5 often).
    - The higher the scores, the higher the stressful event impacted patients, and it is the sum of the scores.
    - The sum is the total stress score, being 33 the cut-off point above which we consider there is a high possibility of clinical PTSD.

Cognitive status post ICU

To evaluate cognitive dysfunction we will use the MoCA test (Montreal cognitive Assessment test) because of its sensitivity to diagnose mild cases of cognitive disorder. This test consists of 30 questions that patients can answer in 15 minutes. The aspects the test concentrates on

are orientation (date and place), short term memory, executive functions, language abilities, abstraction, attention, naming animals and finally clock drawing test.

- Punctuation varies from 0 to 30 being 26 the threshold for a normal cognitive capacity and below it cognitive dysfunction, if the score is below 18, a severe cognitive disorder should be suspected.

This test is very useful and although it is not one of the fastest, it has the highest sensitivity because of the evaluation of executive tasks, however interviewers have to be certified. (36,37)

Physical issues

- Handgrip dynamometry is a quick screening tool that helps us assess the isometric muscle strength of the dominant hand, with the cut-off score of <11kg in men and <7kg in women.
    - If this test is normal, ICU-AW can be discarded.
- Muscle strength with the MRC-SS is another test evaluating 12 different muscles around the human body and scoring them from 0 to 5 according to their strength. Grading goes according to the following numbers (38):

    5- normal strength against resistance

    4- reduced strength but active movement against gravity and resistance

    3- active movement only against gravity

    2-Active movement, with gravity eliminated

    1- Flicker or trace of contraction

    0- No contraction

    - The sum up of each muscle strength should be more than 48 out of 60, if below 48 there is a diagnosis of significant weakness, if below 36/60 the diagnosis should be severe weakness.
- Six minute walk test, to calculate if patients can tolerate exercise, ask them to walk for 6 minutes without stopping or resting.
    - Results depend on being able to do it or not (if patients stop, have to catch their breath, need to sit down, etc.)

Depression → Beck Depression Inventory II (BDI-II)
Anxiety → Beck Anxiety Inventory (BAI)
Post-Traumatic Stress Disorder → IES
Cognitive test → Montreal Cognitive Assessment (MoCA)
Muscle weakness → Handgrip dynamometry
Muscle strength → MRC-SS 12
General physical strength →Six minute walking test

Figure 4: summary of test for each symptom, own source

Summary of instruments and measures used to assess presence of PICS:

- Table 1 with a summary of punctuations in order to classify according to the presence or absence of PICS.

TESTS	ABSENCE OF PICS		PRESENCE OF PICS	
BDI	<20		≥20	
BAI	<22		≥22	
IES-R	<33		≥33	
MoCA	≥26		<26	
Handgrip manometry	Women	Men	Women	Men
	>7	>11	<7	<11
MRC-SS	>48		<48	
6' walking test	No need for resting or stopping		Patients' needs to rest or stop.	

Table 1; summary of punctuation, own source.

- If any of these parameters indicate the presence of Post-intensive Care Syndrome, we can establish the patient has PICS.

SECONDARY OUTCOME:
Quality of life and daily activities after ICU discharge.

This variable is a qualitative variable that we can determine with the **WHOQOL-BREF questionnaire**. World Health Organization developed this questionnaire to be able to assess beyond the classic parameters of health (mortality and morbidity) and to appropriately consider patients abilities to continue with their routine and lifestyle after the impact of a disease or a life event.

The WHOQOL-BREF was designed after the WHOQOL-100 was found too extensive to ask patients to answer. This latter table WHOQOL-BREF contains 4 domains (physical health,

psychological, social relationships and environment, related to the 24 facets of WHOQOL-100) plus two aspects of Overall Quality of Life and General Health facet that are written in 26 questions and answered in 5 ordinal response options (39).

To calculate this, we gather all the information and produce a quality of life profile, the higher the score, the better quality of life. Then we can compare it with both groups.

CO-VARIABLES

The interviewer will obtain all of the following data by accessing a **patient's clinical history** after patients have signed the consent form:

About patients:

This data will be collected from patients **medical history**:

- **Age**. It is a discrete numerical or quantitative variable. It will be measured in years. It is important because age can influence the length of stay in the ICU, the severity of the disease and the predisposal to Post-Intensive Care syndrome.
- **Sex**: it is a categorical nominal variable as male, female or other. As seen on different studies, female sex is more predisposed to PICS.
- **Previous history of physical disease:** it is a categorical nominal variable. This can affect patients recovery and can exacerbate any myopathies or other physical disease produced in the ICU. We do not exclude patients with a previous physical condition because PICS also includes cognitive and psychiatric conditions which could appear in a patient independently from their physical health prior to ICU admission.
- **Other diseases before ICU admission**: categorical nominal variable.

Concerning patients ICU stay:

All information regarding patients ICU stay will be found in the patient's **ICU discharge form:**

- **Diagnostics in the ICU:** this is a qualitative or categorical nominal variable with many possibilities, each diagnostic will be written in the ICU discharge form in different codes. In this variable we will include possible diagnostic developed in the ICU (i.e. infection, delirium with their respective codes) and also main reason for admission in the ICU (core pathology that has un-stabilized the patient).

Example: *Acute respiratory failure = J96.0*

- **Treatments and procedures in the ICU:** this is a qualitative nominal variable with again, a multitude of possibilities. It includes all treatments and procedures that the patient has undergone during the stay in the critical unit, written in codes.

Example: *arterial blood-gas = 89.65 / antibiotic infusion = 99.21*

- **Days on bed rest:** It is a quantitative discrete numerical variable. We consider it important because immobility is a risk factor for PICS and can also affect patients psychiatric state.
- **Days on mechanical invasive ventilation**: It is a quantitative or numerical discrete variable. We consider it a covariable because, again, one of the main risk factors for PICS is time on mechanical ventilation. The longer patients remain on mechanical ventilator support, the more risk he is at of developing Post-Intensive Care Syndrome. Also, a long time on mechanical ventilation increases the chances of further complications.
- **Days sedated:** Numerical discrete variable. Time on sedation can influence patients recovery and can be involved in the appearance of PICS.
- **Length of stay in the ICU:** It is a quantitative discrete variable. We include it because it is one of the main risk factors for PICS.
- **Severity of illness**: it is a numerical ordinal variable, calculated with the APACHE II index.

<u>After ICU stay:</u>

This data will be collected from the patient's medical history;

- **Medication:** type of medication. Categorical nominal variable.
- **Hospitalizations:** any hospitalizations that have happened after ICU discharge. This is a binary categorical variable (yes or no).
- **Appearance of other diseases (not including PICS):** categorical nominal variable.
- **Appearance of other symptoms (not including PICS symptom):** categorical nominal variable.
- **Other life-important events:** calculated with yes or no, it is a binary categorical variable.

6. DATA COLLECTION

Information will be collected from the different clinical interviews and medical history, in three different times:

- ICU admission
- 6 months after ICU discharge, during a check-up appointment
- 12 months after ICU discharge, during the last check-up appointment of this trial.

Both check-ups will be done by a hired, external psychologist, blinded to the study.

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	ICU ADMISSION	6 MONTHS AFTER DISCHARGE	12 MONTHS AFTER DISCHARGE
Consent Form	X		
BID-II		X	X
BAI		X	X
IES-R		X	X
MoCA		X	X
Handgrip dynamometry		X	X
MRC-SS		X	X
6' walking test		X	X
WHOQOL-BREF		X	X

Table 2; time table of data collection during clinical trial, own source.

Covariables will be collected from the patients' **medical history** during a 3 month period of time, by another expert blinded to the study.

STATISTICAL ANALYSIS

The statistical analysis will be performed by an statistical analyst (blinded to the study groups) with the Statistical Package for social Sciences (SPSS) software.

Results will be considered as significant if the value of p is <0,05, defining an interval of confidence of 95%.

- P meaning the chances of the results being by chance.

STATISTICAL PLAN:

We will ask the statistical analyst for the following activities:

- To analyse and define the sample with sociodemographic data
- To describe the sample based on the variables collected.
- Analyse the difference in PICS appearance in both groups; with interventions and without interventions.
- Assess whether PICS is affected or not by the con-variables described in the methodology section.
- To describe the results obtained from all data.

UNIVARIATE ANALYSIS

In the univariate analysis, variables will be defined as quantitative or qualitative:

- For quantitative variables and co-variables we will use averages.
- For qualitative variables and covariables, we can express it with percentages or proportions.

BIVARIATE ANALYSIS

For evaluation of quantitative variables, using averages, we will use T student.

When comparing qualitative variables, we will use percentages and analyse it with the Chi-square.

MULTIVARIATE ANALYSIS

A multivariate analysis will be performed to adjust the result of the outcome variable for the covariables, trying to avoid confounders that could modify our results. Talking about or covariables, we need to take in account that patients have been randomized so the groups should be balanced out.

To assess the effect of the intervention (independent variable) on the appearance of Post-Intensive Care Syndrome (dependent variable) we can use logistical regression adjusting with each co-variable.

We can also stratify each result adjusting to each covariable in each group to learn more about our statistics.

WORK PLAN AND CHRONOGRAM

This clinical trial is expected to last a length of 3 years approximately and is divided in 6 stages.

1. PLAN

- First stage: preparation (3 months; January 2021- March 2021)
    - Elaboration of the project and protocol for the clinical trial.
    - Every clinical trial involving patients, their data, or manipulating a course of treatment and other, should be approved by the Ethics Committee of Clinical Investigation.
    - Centre approval, where both hospitals in Girona and Badalona approve the study.
    - Recruitment of a coordinator for each centre involved.

- Second stage: explanation and infrastructure of ICU (2 months; March-April 2021)
    - Explanation to all the staff working around it. These meetings can be done online. The team working on the protocol should be given all the information regarding the clinical trial, the main objectives and interventions performed.
    - Hiring psychologists that will be certified and able to assess patients.
    - Preparation of the infrastructure and making sure both ICUs are equivalently equipped.
        - The trial requires natural sunlight in each individual room, so we need to make sure all rooms have an exterior window. In the group with no interventions, even though they will have artificial lighting, the rooms have to be the same colour, so the lighting effect is as controlled as possible.
        - It also requires a computer with proper functioning sound.
        - Also, one of the interventions is about family visitations, so we will need space for family members to be around and comfortable in the ICU (chairs, a sofa, etc…).

- Third stage: applying the interventions (1 year; May 2021-May 2022)
    - Stage three is about recruiting patients during their admission in the ICU. All patients will be given a written explanation document with all the details of the

interventions. They will participate in it only after themselves or the family members have signed the consent form, patients will be assigned to the trial according to the ICU that corresponds to them by area.

- During this process, we will exclude patients that do not meet the inclusion criteria.

- During their stay in the ICU, patients will either receive a standard care treatment or new humanizing interventions.
  - If patients during their ICU stay meet exclusion criteria, they will be removed from the clinical trial (i.e. interrupt humanizing interventions because early patients discharge).

- Fourth stage: follow up visits (1 year; November 2021-April 2023)
  - Six and 12 months after ICU discharge, patients will have a follow up visit in which they will be evaluated for PICS.

- Fifth stage: analysis of the data (1 month; May 2023)
  - Once all the data is collected, it will be classified, and organized in order to be analysed by a statistical professional.
  - The results will then be presented and discussed by the research team who will be able to make the appropriate assumptions concerning the hypothesis.
  - Analysis and interpretations of the results

- Sixth stage: publication (3 months)
  - Redacting an article with the results found.
  - The article can be published in different journals so different ICU around the world can start implementing their own interventions to help prevent PICS.
  - If patients have required it, they will receive the article with the published results.

2. TEAM

Main investigator: responsible for elaborating the projects protocol talking to the different centres involved, assembling the team and making sure the preparation for the project is ready.

Coordinators: every centre will have a study coordinator to make sure the clinical trial is being done the way the protocol specified. Also, the coordinator will be able to communicate with the main investigator if any doubts arise and if an unexpected situation occurs.

Other professionals from the Intensive Care Unit:

- Different professionals in the ICU. They will be aware of the project and participate whenever they can in in order to help implement the measures as controlled as possible.

Other personnel:

Hired personnel

- A statistical analyst that will evaluate data from the patients results.
- Two psychologists (one for each centre) blinded to the study, in order to evaluate all patients after ICU discharge at 6 and 12 months post-ICU.
- Two junior psychologists (R1), also blinded to the study, in order to add all data from patients history (covariables) to the study.

3. INDIVIDUAL CHRONOGRAM FOR EACH PATIENT

<table>
<tr><th colspan="2">PATIENTS STAY IN THE INTERVENTION ICU</th><th colspan="2">ALL PATIENTS DISCHARGED FROM ICU</th></tr>
<tr><th>SEDATED PATIENT</th><th>NON-SEDATED PATIENT</th><th>6 MONTHS AFTER</th><th>12 MONTHS AFTER</th></tr>
<tr><td colspan="2">Music therapy
Open visitation
Daily diary
Natural sunlight</td><td rowspan="6">Clinical interview
- BDI-II
- BAI
- IES-R
- MoCA
- Handgrip dynamometry
- MRC-SS
- Six minute walk
- WHOQOL-BREF</td><td rowspan="6">Clinical interview
- BDI-II
- BAI
- IES-R
- MoCA
- Handgrip dynamometry
- MRC-SS
- Six minute walk
- WHOQOL-BREF</td></tr>
<tr><td colspan="2">Ensure sleep patterns</td></tr>
<tr><td>- Maintain noise to the minimum *</td><td>- Ear plugs</td></tr>
<tr><td>- Closed doors*</td><td>- Face masks</td></tr>
<tr><td>- Routine*</td><td>- Activities to prevent sleep in the afternoon</td></tr>
</table>

* Activities will be done in sedated and non-sedated patients, patients in the conventional group will not have these measures.

Table 3; Chronogram of the process of each individual patient, in the intervention group

4. CHRONOGRAM OF THE GLOBAL PROJECT

	2021						2022						2023					
DATE	Jan-Feb	Mar-Apr	May-Jun	July-Aug	Sept-Oct	Nov-Dec	Jan-Feb	Mar-Apr	May-Jun	July-Aug	Sept-Oct	Nov-Dec	Jan-Feb	Mar-Apr	May-Jun	July-Aug	Sept-Oct	Nov-Dec
PREPARATION																		
A1; Scientific research and protocol elaboration																		
A2: CEIC evaluation																		
A3: Centre approval																		
A4: Coordination of centres																		
TEAM ASSEMBLY, EXPLANATION AND INFRASTRUCTURE PREPARATION																		
B1Notice to all the staff and information																		
Hiring 2 psychologists																		
Room assembly																		
Purchase of accessories																		
Review																		
RECRUITMENT AND INTERVENTION STAGE																		
Recruitment of patients																		
Applying interventions																		
FOLLOW UP VISITS																		
6 months after discharge																		
12 months post-ICU																		
Data collection (covariables)																		
STATISTICAL ANALYSIS																		
Data analysis																		
Result interpretation																		
PUBLICATION																		
Redacting article with the results																		
ddivulgation.																		

Table 4; Chronogram of the project

DATA COLLECTION

BUDGET

The budget of this study includes all expenses considering personnel expenses, purchases needed for the interventions and other study costs.

PERSONNEL EXPENSES

The personnel we will have to hire additionally for the research project are the statistical analyst, two psychologists (one for each hospital) to do follow up check-ups and others for data collection.

- Calculating 40€ per hour, and a 40hour task for analysing all the data, it would sum up to 1600€.
- 2 psychologists, for approximately 834 interviews each, would be the equivalent of 45.000€.
- 2 junior psychologist, for other data collection (covariables) and input in the database, for 417 patients each, an hour for each medical history, equals 3 months work. The salary for hiring this personnel would be 3600€.

LIABILITY INSURANCE

If the CEIC categorizes this project as invasive, we would need to hire a liability Insurance. However, it is a cost that will be calculated once the project has been assessed by the Ethical Comity of Clinical Investigation.

PREPARATION

Preparation includes revising all the rooms (ICUs from both hospitals and making sure they are both in good conditions).

Also, we need to take in account that the rooms should be the same colour, with the same bedding and pyjamas to ensure there are no differences between infrastructures (except from the ones we are implementing).

- If necessary, we will have to paint rooms the same colour: rooms approximately 3x4m will cost 200€.

Room preparation:

- Control group: curtains, one chair for visitors and a working computer with sound.
- Intervention group: 2 chairs (an extra chair, because there is already one), a diary, an activity of choice, a sleeping face mask, ear plugs and a working computer with sound.

EXECUTION EXPENSES

After the ICU stay, once patients have been discharged, in follow up visits, patients will need to take a total of 8 tests:

- BDI-II, this test has a total cost of 88,50€ (for the manual and 50 response sheets) and an extra 55,50€ for 50 additional answer sheet (40).
- BAI, the manual and 50 response sheets cost 88,50€ and for every additional 50 answer sheets there will be an added cost of 55,50€ (41).
- IES: is a free of charge test.
- MoCA: this test requires the interviewer that administers the test to go through a certification and training period. However, psychologists hired will have the certifications. Also, the test does not require any additional costs.
- Handgrip dynamometer: the dynamometer can be bought with the price of 35€
- MRC-SS: does not require any cost.
- Six minute walking test: it does not need any material or training and is evaluated clinically.
- WHOQOL-BREF is free of charge.

We need to take in account all the printing included in this project.

PUBLICATION EXPENSES

When publishing any results from the study we will assume the costs of edition, preparation and publication will cost approximately 2000€.

The different expenses are summarized in Table 5 below:

TYPE OF COST	UNIT COST	HOURS/UNIT	TOTAL
PREPARATION			
Room preparation			
Chairs	25€	18 (each room in the intervention ICU)	450€
Painting rooms	200€	36 ICU rooms in both hospitals	7200€
EXECUTION EXPENSES			
Facemask	5€	420 (each subject in the ICU)	2100€
Ear plugs	1€	420 (each subject in the ICU)	420€

Mandala book	10€	1	10€
Sudoku book	25€	1	25€
Mandala photocopies	0,03€	210 pages	6,30€
Sudoku photocopies	0,03€	210 pages	6,30€
Puzzle	15€	5	75€
Beck Depression Inventory-II	88,50€ (manual + 50 answer sheets)	1	88,50€
Additional answer sheets	55,50€ (50 units)	33 (1650 answer sheets)	1831,50€
Beck Anxiety Inventory	88,50€ (manual + 50 answer sheets)	1	88,50
Additional answer sheets	55,50€	33 (1650 answer sheets)	1831,50€
Impact Event Scale	No cost	1	0€
IES (1 page per subject)	0,03€	1700pages	51€
Montreal Cognitive Assessment test	No cost	1	0€
MOCA (1 page per subject)	0,03€	1700 pages	51€
CAMRY Digital Hand Dynamometer Grip Strength Measurement Meter Auto Capturing Hand Grip Power	35€	1 unit	35€
WHOQOL-BREF (5 pages per unit)	No cost	1 unit (5 pages)	0€
WHOQOL-BREF copies	0,15€/unit	1700 pages	255€
PERSONNEL EXPENSES			
Statistical analysist	40€	40 hours	1600€
Psychologist	25€/h	2 psychologists, approximately 900h each.	45.000€
Junior psychologist (PIR, R1)	1200€/month	3 months, 2 psychologists	7200€
PUBLICATION EXPENSES			
Article publication			2000€
MISCELANOUS COSTS			
10% of the total amount,			7.032,46€
TOTAL			77.357,06€

Table 5; Budget of the clinical trial, humanizing interventions in the ICU for patients at risk of Post-Intensive Care

FEASIBILITY

This clinical trial will take place in two different ICUs'; Hospital Universitari Doctor Josep Trueta, in Girona, and Hospital Germans Trias i Pujol, in Badalona. These hospitals have been chosen because of the similarity of the two facilities, the number of patients and the polyvalent characteristic that they share. With the size of the sample, we would need a whole year to recruit 834 patients (417 in each group) and another two years to complete it.

Both hospitals will need a preparation stage to make sure they are in the right conditions to start the study, and will need continuous monitorization by the coordinators of each team.
The ICU with the humanizing interventions will be in Girona, whilst the control group will be patients in the ICU of Badalona.

It is a study with many covariables and factors that can be difficult to control. However, to be as accurate as possible, we will notify the whole team in order to continue care work and respect as much as possible the different added measures in place.
There will need to be a lot of collaboration and communication between nurses, doctors, auxiliary staff, physical therapists, etc…

In order to diagnose patients with PICS, both hospitals will need to provide a room for carrying out the different tests at the follow up visits, done by psychologists that are blinded to the project.

Also, two interviewers (one for each hospital) will need to be hired by the research team. The profile of the interviewer should be a psychologist with the knowledge of the different diagnostic scales and certification for the MoCA table. The rest of covariables and data (from a patient's medical history) should be collected and set in a database by other personnel hired, for example two junior psychologists for approximately 3 months' worth of work.

In conclusion, this project is a feasible project which can benefit many patients in the long run.

ETHICAL AND LEGAL CONSIDERATIONS

This clinical trial is conducted according to the requirements expressed in the **Declaration of Helskinki** of ethical Principles for Medical Research Involving Human Subjects reviewed by the World Health Association in October 2013.

We will present this research protocol to the **CEIC** (Comitè Ètica i Investigació Clínica) to evaluate and approve the ethical aspects of the project.

- If there are any suggestions made, modify the study as needed.
- According to the **Law 14/2007 of 3 July 2007** of *Biomedical Investigation of Spain*, the CEIC will decide if the interventions on the clinical trial are classified as invasive or not, in the case of them being invasive, we would need to ask permission to the Autonomy of Catalunya and hire an insurance for possible damage. However, we consider our interventions to be non-invasive and are not associated with possible risks for patients.

Moreover, we will ask for the **approval of both hospitals** involved in the research project in order to participate in it and a coordination team that will want to go through with it.

Considering hospital members and researchers, they will have to sign a statement confirming they will **follow the national and international ethical aspects of research**.

Its participation is voluntary, all patients that enter the study will be fully informed and will be required to sign **a consent form before any involvement** (according *to* **Ley 41/2002** *Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica"*

- If a patient does not want to participate in the clinical trial no interventions will be made to his surroundings and no additional procedures will be made to their stay in the ICU, if another ICU in the building is available he will be admitted in it.
- At any time, if the patient wants to withdraw his consent form and himself from the trial, he is able to without any further a due. If the patient is still in the ICU no additional humanizing interventions will be made and he will continue on as a conventional patient in the ICU. No post-op ICU check-ups will be done unless necessary for the baseline disease.

Finally, regarding patient confidentiality. We will need to follow the EU regulation 2016/679 of the European Parliament and the Council of 27 April 2016 and the respective Ley Orgánica 3/2018, de 5 de Diciembre, de *Protección de Datos personales y Garantia de los Derechos Digitales* in the protection of persons with regard to respect all content related to confidentiality of personal information, anonymity of participants. Also, the right to consult, modify and delete all personal information from the records.

All data used in this study will be anonymous, and only available for the research team. If published, all data will be dissociated from patients in order to maintain participation anonymous.

When publishing, all results will have to be exposed with complete transparency, declaring no conflict of interests.

LIMITATIONS OF THE STUDY

This study has potential limitations that can affect the results of our study:

- This trial is an **open label trial**, which means that both health workers and participants know the group they are in (it is not double blinded) therefore it is liable to biases.
    - This limitations magnifies the intervention effect in comparison with both groups because patients admitted with the humanizing measures could be more optimistic about their outcome and recovery.
    - However, to minimize this effect, the psychologists hired to interview all patients, 6 and 12 months after ICU discharge, will both be blinded to the study.

- Being a multicentric trial, we need to consider that treatments, protocols and staff care can be different depending on which centre the patient is admitted in, this can produce **variability** between hospitals and physicians. By choosing two similar hospitals, with similar characteristics, we can minimize as possible differences between the two ICUs.

- In a prospective study, we must expect **withdrawals and losses** that can modify our study and produce a selection bias. However we have anticipated a loss of 15% and have been taken in account when calculating the size of our sample.

- Some co-variables are considered in this study. However, talking about PICS as a whole, it is such a subjective and individual disease for each patient, it is very difficult to control all covariables and factors that can involve each patient and can become a **cofounding factor.**

- Another limitation is the **costs** put into the study as it is expensive. However it can change many patients outcomes for the better If results are conclusive.

IMPACT ON THE NATIONAL SYSTEM

Every day, medicine has huge advances that improve the health system and help many patients in need. However, with these technological and pharmaceutical advances, we have to guarantee that we improve all aspects of health and wellbeing.

Currently, and especially with COVID-19, the increase of patients in the ICU has become obvious and therefore the appearance of PICS will also rise in the following years to come.

If this project proves that humanizing interventions in the ICU can decrease Post-Intensive Care syndrome, it can help support ICUs' that want to transition into a more humane unit.

By proving that humanizing interventions can prevent PICS, we could not only improve patients quality of life after ICU but also reduce the workload of the health system by decreasing post-ICU complications that, in the future, may require further assistance and treatments.

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ANNEXES

1. EXPLANATORY DOCUMENT FOR THE PARTICIPANT (Catalan)

Nom de l'estudi: Estudiar l'impacte de mesures humanitzadores, en pacients ingressats a la UCI, per disminuir la incidència del síndrome Post-UCI.

Centre assistencial:

Investigador/a principal:

Benvolgut/da,

Ens adrecem a vostè per agrair-li la seva participació en el següent projecte de recerca:
Humanizing interventions in the ICU to reduce Post-Intensive Care Syndrome.

Introducció i objectiu de l'estudi

Durant l'estada a la UCI, l'objectiu principal de tots és que els pacients es puguin recuperar de la millora manera. Aquesta estada pot requerir mesures invasives i de suport vital que, sumat a la situació de gravetat, poden tenir conseqüències motores, cognitives o emocionals que es manifesten un cop donat d'alta. Aquest conjunt de símptomes formarien el síndrome Post-UCI

Aquest projecte, té com a objectiu principal reduir, mitjançant mesures no-invasives i no-farmacològiques, els efectes adversos que es poden produir en el context d'una unitat de cures intensives.

D'aquesta manera, podem millorar tots els aspectes del tractament de la UCI i en un futur intentar reduir la incidència d'aquest síndrome, optimitzant la qualitat de vida de molts pacients que malauradament han de passar un temps ingressats a la UCI

Descripció de l'estudi

Abans de tot, informar que aquest projecte ha estat aprovat pel Comitè d'Ètica Investigació Clínica (CEIC).

En aquest estudi hi participaran aproximadament uns 840 participants. Llavors, de manera aleatoritzada, segons l'hospital d'ingrés (l'Hospital Germans Trias i Pujol de Badalona i Hospital Universitari Doctor Josep Trueta de Girona), formarem dos grups de les quals es modificarà una mica la seva estada a la UCI

- Un grup, durant l'estada a la Unitat de Cures Intensives, se li aplicaran (de manera addicional sense substituir el tractament estàndard) un seguit de mesures no invasives a l'entorn, a l'habitació i al mateix subjecte.
- L'altre grup tindrà una estada a la Unitat de Cures Intensives de la manera estandarditzada.

De totes maneres, és important aclarir que en cap dels dos grups la recuperació i millora del pacient es veurà repercutida o afectada.

Un cop superada l'estada a la UCI, tots els participants de l'estudi tindran dos visites de seguiment on se'ls hi realitzaran unes exploracions no-invasives i varies escales d'aproximació diagnòstica que ens ajudaran a veure l'efectivitat o no de les mesures aplicades en la fase anterior.

Participants en el projecte

Degut al vostre ingrés a la UCI, és convidat a participar en el projecte:

- De totes maneres, depenent de l'evolució, les dades només quedaran incloses a l'estudi si passa un mínim 48 hores mecànicament intubats i un mínim de 7 dies a la unitat.
    - En aquest cas, es demanarà als participants a fer les visites de seguiment.
- En el cas que l'estada a la UCI sigui menor de 7 dies o 48 hores intubats, els participants quedaran exclosos de les visites de seguiment, i les dades no seran utilitzades en l'anàlisi del resultat.

La participació en l'estudi inclourà dues visites de seguiment d'aproximadament 1h de durada, als 6 i 12 mesos per avaluar diferents aspectes del síndrome post-UCI.

Riscs de l'estudi

Al ser un estudi amb intervencions no-invasives ni farmacològiques, no es preveu cap risc físic pels participants. El potencial risc estaria en relació amb la confidencialitat de les seves dades clíniques, que s'evitarà sent tractades d'acord amb la Llei de Protecció de Dades.

Possibles beneficis de l'estudi

El benefici de tots els participants seria el de l'avanç de la medicina en benefici de la societat i el coneixement de que ha col·laborat en aquest procés.. Si vostè ho desitgés, se li facilitaria un resum dels resultats de l'estudi.

L'investigador no obtindrà remuneració econòmica per realitzar l'assaig clínic.

Confidencialitat

Finalment, a l'acceptar la seva participació, vostè permetria al seu investigador registrar algunes dades de la seva història clínica. Tota informació utilitzada en l'estudi serà codificada, mantenint la dissociació de les seves dades, l'anonimat i tractades segons la Llei de Protecció de Dades 3/2018. No s'utilitzaran noms o dades on es puguin identificar participants, tots els resultats de la resta d'exàmens complementaris i les dades de la història clínica seran tractades amb total confidencialitat.

Tant l'hospital com l'investigador són responsables respectivament del tractament de seves dades i es comprometen a complir amb la normativa de protecció de dades en vigor

Els comitès d'Ètica de la investigació, els representants de l'autoritat sanitària en matèria d'inspecció i el personal autoritzat per l'investigador, únicament podran accedir per comprovar les dades personals, els procediments de l'estudi clínic i el compliment de les normes de bona pràctica clínica (sempre mantenint la confidencialitat de la informació).

D'acord al que estableix la legislació esmentada, vostè pot exercir els drets d'accés, rectificació, oposició i cancel·lació de dades en qualsevol moment. Vostè també pot limitar el tractament de dades que siguin incorrectes, sol·licitar una còpia o que es traslladin a un tercer (portabilitat) les dades que vostè ha facilitat per a l'estudi. Per exercitar els seus drets, pot dirigir-se al metge responsable de l'estudi, o si s'escau a la Agència Espanyola de Protecció de Dades (AEPD).

L'investigador està obligat a conservar les dades recollides per a l'estudi a almenys durant 5 anys després de la seva finalització. Posteriorment, la seva informació personal només es conservaria al centre per a la cura de la seva salut i per l'investigador per a altres fins d'investigació científica si vostè hagués atorgat el seu consentiment per a això, i si així ho permet la llei i els requisits ètics aplicables.

Difusió dels resultats

Un cop s'hagi completat tot l'estudi, es preveu una anàlisi de les dades i una extracció de resultats. Les conclusions del projecte seran sotmesos a publicacions científiques, independentment d'un resultat favorable o desfavorable.
Com comentat anteriorment, sense cap dada que pugui portar a la identificació del subjecte.

Participació i compensació econòmica

La participació en aquest estudi és voluntària. Per tant, si vostè decideix participar no rebrà cap tipus de compensació econòmica. En el cas contrari, tampoc implicarà un canvi a la seva atenció mèdica per part dels diferents especialistes.

Abans de participar, haurà de firmar un consentiment informat on confirma que ha llegit el document explicatiu i està d'acord amb el projecte. En el cas que el pacient vulgui deixar de participar en l'estudi, ho podrà fer mitjançant la revocació del consentiment informat, un document que podrà demanar a qualsevol membre de l'estudi. Igual que participar en l'estudi clínic, sortir de l'estudi és voluntari, sense necessitats de donar explicacions i amb la seguretat que en cap cas comprometrà la seva atenció mèdica ni el curs del seu tractament.

Respecte les vostres dades, vostè pot retirar en qualsevol moment el consentiment sobre el tractament de les seves dades. Així mateix, té dret a dirigir-se a l'AEPD si no quedés satisfet.

- En el cas que el pacient no pugui firmar el consentiment informat, un representant del subjecte pot firmar el consentiment.
- De totes maneres, en el moment d'alta de la UCI, es demanarà al pacient un propi consentiment informat.

Contacte

En cas de qualsevol dubte o pregunta durant la realització d'aquest estudi, podrà posar-se en contacte amb el responsable i coordinador de l'estudi:

2. EXPLANATORY DOCUMENT FOR THE PARTICIPANT (Spanish)

Nombre del estudio: Estudiar el impacto de medidas humanizadoras, en pacientes ingresados en la UCI, para disminuir la incidencia del síndrome Post-UCI.

Centro asistencial:

Investigador/a principal:

Estimado / a,

Nos dirigimos a usted para agradecerle su participación en el siguiente proyecto de investigación:

Humanizing Interventions in the ICU to reduce Post-Intensive Care Síndrome.

Introducción y objetivo del estudio

Durante la estancia en la UCI, el objetivo principal de todos es que los pacientes se puedan recuperar de la mejora manera. Esta estancia puede requerir medidas invasivas y de apoyo vital que, sumado a la situación de gravedad, pueden tener consecuencias motoras, cognitivas o emocionales que se manifiestan una vez dado de alta. Este conjunto de síntomas formarían el síndrome Post-UCI

Este proyecto, tiene como objetivo principal reducir, mediante medidas no-invasivas y no-farmacológicas, los efectos adversos que se pueden producir en el contexto de una unidad de cuidados intensivos.

De este modo, podemos mejorar todos los aspectos del tratamiento de la UCI y en un futuro intentar reducir la incidencia de este síndrome, optimizando la calidad de vida de muchos pacientes que desgraciadamente tienen que pasar un tiempo ingresados en la UCI

Descripción del estudio

Antes de todo, informó que este proyecto ha sido aprobado por el Comité de Ética Investigación Clínica (CEIC).

En este estudio participarán aproximadamente unos 840 participantes. Entonces, de forma aleatorizada, según el hospital de ingreso (el Hospital Germans Trias i Pujol de Badalona y Hospital Universitario Doctor Josep Trueta de Girona), formaremos dos grupos de las que se modificará un poco su estancia en la UCI

- Un grupo, durante su estancia en la Unidad de Cuidados Intensivos, se le aplicarán (de manera adicional sin sustituir el tratamiento estándar) una serie de medidas no invasivas en el entorno, en la habitación y al mismo sujeto.
- El otro grupo tendrá una estancia en la Unidad de Cuidados Intensivos de la manera estandarizada.

De todos modos, es importante aclarar que en ninguno de los dos grupos la recuperación y mejora del paciente se verá repercutida o afectada.

Una vez superada la estancia en la UCI, todos los participantes del estudio tendrán dos visitas de seguimiento donde se les realizarán unas exploraciones no invasivas y varias escalas de aproximación diagnóstica que nos ayudarán a ver la efectividad o no de las medidas aplicadas en la fase anterior.

Participantes en el proyecto

Debido a su ingreso en la UCI, es invitado a participar en el proyecto:

- De todas formas, dependiendo de la evolución, los datos sólo quedarán incluidos en el estudio si pasa un mínimo 48 horas mecánicamente intubados y un mínimo de 7 días a la unidad.
    - En este caso, se pedirá a los participantes a hacer las visitas de seguimiento.
- En caso de que la estancia en la UCI sea menor de 7 días o 48 horas intubados, los participantes quedarán excluidos de las visitas de seguimiento, y los datos no serán utilizados en el análisis del resultado.

La participación en el estudio incluirá dos visitas de seguimiento de aproximadamente 1h de duración, a los 6 y 12 meses para evaluar diferentes aspectos del síndrome post-UCI.

Riesgos del estudio

Al ser un estudio con intervenciones no-invasivas ni farmacológicas, no se prevé ningún riesgo físico para los participantes. El potencial riesgo estaría en relación con la confidencialidad de sus datos clínicos, que se evitará siendo tratados de acuerdo con la Ley de Protección de Datos.

Posibles beneficios del estudio

El beneficio de todos los participantes sería el del avance de la medicina en beneficio de la sociedad y el conocimiento de que ha colaborado en este proceso .. Si usted lo deseara, se le facilitaría un resumen de los resultados del estudio .

El investigador no obtendrá remuneración económica para realizar el ensayo clínico.

Confidencialidad

Finalmente, toda información utilizada en el estudio será codificada, manteniendo la disociación de sus datos, el anonimato y tratados según la Ley de Protección de Datos 3/2018. No se utilizarán nombres o datos donde se puedan identificar participantes, todos los resultados del resto de exámenes complementarios y los datos de la historia clínica serán tratados con total confidencialidad.

Ambos (hospital e investigador) son responsables respectivamente del tratamiento de sus datos y se comprometen a cumplir con la normativa de protección de datos en vigor

Los comités de Ética de la investigación, los representantes de la autoridad sanitaria en materia de inspección y el personal autorizado por el investigador, únicamente podrán acceder para comprobar los datos personales, los procedimientos del estudio clínico y el cumplimiento de las normas de buena práctica clínica (siempre manteniendo la confidencialidad de la información).

De acuerdo a lo establecido en la legislación mencionada, usted puede ejercicio los derechos de acceso, rectificación, oposición y cancelación de datos en cualquier momento. Usted también puede limitar el tratamiento de datos que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado para el estudio. Para

ejercitar sus derechos, puede dirigirse al médico responsable del estudio, o en su caso a la Agència Española de Protección de Datos (AEPD).

El investigador está obligado a conservar los datos recogidos para el estudio a menos durante 5 años después de su finalización. Posteriormente, su información personal sólo se conservaría el centro para el cuidado de su salud y por el investigador para otros fines de investigación científica si usted hubiera otorgado su consentimiento para ello, y si así lo permite la ley y los requisitos éticos aplicables.

Difusión de los resultados

Una vez se haya completado todo el estudio, se prevé un análisis de los datos y una extracción de resultados. Las conclusiones del proyecto serán sometidos a publicaciones científicas, independientemente de un resultado favorable o desfavorable.
Como comentado anteriormente, sin ningún dato que pueda llevar a la identificación del sujeto

Participación y compensación económica

La participación en este estudio es voluntaria. Por lo tanto, si usted decide participar no recibirá ningún tipo de compensación económica. En el caso contrario, tampoco implicará un cambio en su atención médica por parte de los diferentes especialistas.

Antes de participar, deberá firmar un consentimiento informado donde confirma que ha leído el documento explicativo y está de acuerdo con el proyecto. En caso de que el paciente quiera dejar de participar en el estudio, lo podrá hacer mediante la revocación del consentimiento informado, un documento que podrá pedir a cualquier miembro del estudio. Al igual que participar en el estudio clínico, salir del estudio es voluntario, sin necesidades de dar explicaciones y con la seguridad que en ningún caso comprometerá su atención médica ni el curso de su tratamiento.
Respecto sus datos, usted puede retirar en cualquier momento el consentimiento sobre el tratamiento de sus datos. Asimismo, tiene derecho a dirigirse a la AEPD si no quedara satisfecho.

- En caso de que el paciente no pueda firmar el consentimiento informado, un representante del sujeto puede firmar el consentimiento.

- De todas formas, en el momento de alta de la UCI, se pedirá al paciente un propio consentimiento informado.

Contacto

En caso de cualquier duda o pregunta durante la realización de este estudio, podrá ponerse en contacto con el responsable y coordinador del estudio:

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3. CONSENT FORM (Catalan)

DOCUMENT DE CONSENTIMENT INFORMAT DEL PACIENT

L'investigador d'aquest estudi li donarà informació personalitzada sobre el mateix. Preneu-vos el temps, llegiu atentament aquest document i faci-li a el metge o al personal de l'estudi totes les preguntes que tingueu.

No signi aquest document fins que entengui tota la informació i s'hagin respost a la seva satisfacció totes les seves preguntes sobre l'estudi.

Nom de l'investigador :_____

DNI/NIF: _____

Jo, _____amb document d'identificació personal (DNI/NIE): _____ afirmo que:

- He rebut una còpia del consentiment informat pel pacient.
- He rebut, he entès i estic d'acord amb tota la informació que hi ha en el document explicatiu sobre l'assaig clínic
- Se'm ha respost tots els dubtes i preguntes que podien sorgir respecte el projecte.
- Reconec els risc i beneficis que hi ha participant en l'assaig clínic.
- Accepto que investigadors utilitzin les meves dades i accedeixin a la meva història clínica, sempre respectant la Llei de Protecció de Dades, respectant l'anonimat i confidencialitat.
- He entès que la participació és voluntària, no remunerada i en qualsevol moment puc revocar el consentiment informat
    - Sense cap explicació necessària, sense repercussió de la meva assistència mèdica.

Firma del pacient Firma de l'investigador

Lloc i data _____, _____ de _____ de l'any _____.

DOCUMENT DE CONSENTIMENT INFORMAT DEL PACIENT PER PART DEL REPRESENTANT

L'investigador d'aquest estudi li donarà informació personalitzada sobre el mateix. Preneu-vos el temps, llegiu atentament aquest document i faci-li a el metge o al personal de l'estudi totes les preguntes que tingueu.

No signi aquest document fins que entengui tota la informació i s'hagin respost a la seva satisfacció totes les seves preguntes sobre l'estudi.

Nom de l'investigador :_____

DNI/NIF: _____

Jo, _____representant de _____amb document d'identificació personal (DNI/NIE): _____ afirmo que:

- He rebut una còpia del consentiment informat.
- He rebut, he entès i estic d'acord amb tota la informació que hi ha en el document explicatiu sobre l'assaig clínic
- Se'm ha respost tots els dubtes i preguntes que podien sorgir respecte el projecte.
- Reconec els risc i beneficis que hi ha participant en l'assaig clínic.
- Accepto que investigadors utilitzin les dades i accedeixin a la història clínica de _____, sempre respectant la Llei de Protecció de Dades, respectant l'anonimat i confidencialitat.
- He entès que la participació és voluntària, no remunerada i en qualsevol moment puc revocar el consentiment informat
    - Sense cap explicació necessària, sense repercussió de l'assistència mèdica de _____.

Firma del representant Firma de l'investigador

Lloc i data _____, _____ de _____ de l'any _____.

4. CONSENT FORM (Spanish)

DOCUMENTO DE CONSENTIMIENTO INFORMADO DEL PACIENTE

El investigador de este estudio le dará información personalizada sobre el mismo. Tómese su tiempo, lea atentamente este documento y hágale a el médico o al personal del estudio todas las preguntas que tenga.

No firme este documento hasta que entienda toda la información y hayan respondido a su satisfacción todas sus preguntas sobre el estudio.

Nombre del investigador :_____

DNI/NIF: _____

Yo, _____con documento de identificación personal (DNI/NIE): _____ declaro que:

- He recibido una copia del consentimiento informado por el paciente.
- He recibido, he entendido y estoy de acuerdo con toda la información que hay en el documento explicativo sobre el ensayo clínico
- Se me ha respondido todas las dudas y preguntas que podían surgir respecto al proyecto.
- Reconozco los riesgo y beneficios que hay participando en el ensayo clínico.
- Acepto que investigadores utilicen mis datos y accedan a mi historia clínica, siempre respetando la Ley de Protección de Datos, respetando el anonimato y confidencialidad.
- He entendido que la participación es voluntaria, no remunerada y en cualquier momento puedo revocar el consentimiento informado
    - Sin ninguna explicación necesaria, sin repercusión de mi asistencia médica.

Firma del paciente Firma del investigador

Lugar y fecha _____, _____ de _____ del año _____.

DOCUMENTO DE CONSENTIMIENTO INFORMADO DEL PACIENTE POR PARTE DEL REPRESENTANTE

El investigador de este estudio le dará información personalizada sobre el mismo. Tómese su tiempo, lea atentamente este documento y hágale a el médico o al personal del estudio todas las preguntas que tenga.

No firme este documento hasta que entienda toda la información y hayan respondido a su satisfacción todas sus preguntas sobre el estudio.

Nombre de investigador/a :_____

DNI/NIF: _____

Yo, _____representante de _____con documento de identificación personal (DNI/NIE): _____ declaro que:

- He recibido una copia del consentimiento informado.
- He recibido, he entendido y estoy de acuerdo con toda la información que hay en el documento explicativo sobre el ensayo clínico
- Se me ha respondido todas las dudas y preguntas que podían surgir respecto al proyecto.
- Reconozco los riesgo y beneficios que hay participando en el ensayo clínico.
- Acepto que investigadores utilicen los datos y accedan a la historia clínica de _____, siempre respetando la Ley de Protección de Datos, respetando el anonimato y confidencialidad.
- He entendido que la participación es voluntaria, no remunerada y en cualquier momento puedo revocar el consentimiento informado
    - Sin ninguna explicación necesaria, sin repercusión de la asistencia médica de _____.

Firma del representante Firma del investigador

Lugar y fecha _____, _____ de _____ del año _____.

5. PATIENT INTERVIEW

This patient had a scheduled valve replacement surgery to fix an aortic stenosis. However, things did not go as planned and due to a haemorrhaging complication, the patients un-stabilized and was admitted to the ICU for a total of 42 days.

Initially his state was very severe and many measures were taken to help resuscitate the patient, mechanical ventilation, sedation, morphine drip, pacemakers, an aortic counter-pulsion balloon pump and many catheters.

His first week in the ICU was very severe with an APACHE II score of 26 (35-55% chance of death), he required extremely high doses of vasoactive drugs and different platelet and plasma transfusions. Due to his unstable situation, the patient also developed renal failure for which he needed haemodialysis and a gut paralysis due to liver failure.

His second week in the ICU was better, he slowly recovered his blood pressure so the vasoactive drugs were slowly but surely removed. His renal function improved to the point that the haemodialysis filter was detached. He also developed a pneumothorax but was quickly resolved with a pleural drainage tube. And his orotracheal mechanical ventilator is changed for a tracheostomy.

On his third week the patients was critical, but not unstable, and he was in a stagnation phase, he did not improve, but didn't worsen either.

The rest of the stay in the ICU, the patients started to improve and day by day little changes could be made to slowly unlink him from all the support and allow the patient to function on his own. He had further tests to determine neurological damage which were not definite but did talk about possible damage to his left side of the body.

Finally 42 days later, the patient was able to move to another ward in order to continue his neurological recovery but was no longer in a critical situation requiring life support.

In total, the patient spent 42 days in the ICU, plus 3 weeks more hospitalized in internal medicine and after that he still underwent several weeks of rehabilitation.
He was sedated for 8 days, mechanically ventilated for 30 days, on intravenous antibiotics for 27 days and on several other pain killers and drugs for a minimum of 20 days. He had one main diagnostic: haemorrhagic and cardiogenic shock which led him to complications with his kidneys, respiration, liver, brain and blood circulation.
He had a total of 22 different procedures and treatments, some of them repeated daily, some sporadically.

With all these listings, what we mean to say is that even though the ICU saved this patients life, all the trauma the body goes through can manifestate itself after discharge and reduce patients quality of life.

When speaking to the patients family they defined this time as the worst time of their life, they didn't describe symptoms or diseases, they just explained how the patient could not breathe, or would not wake up, etc…

Family members also said that they only wanted positiveness around the patient, even when he was sedated and apparently unaware of the situation.

They would play him his favourite music on their phones, broadcast football games and send him audionotes from his grandchildren.

They also talked about how much time and effort It took to get back to their day to day reality and lifetime routine.

- The patient needed a lot of physical rehabilitation (due to myopathy and neurological damage)
- Initially the patient would be very fatigued and worn out.
- The wife also talked about her own extreme fatigue and anxiety triggered when watching the news about hospitals and ICUs.

And how finally, after nearly two years, they have managed to more or less return tot heir normality and leave behind this episode of their life.

When asked about this project and their opinion on a more humanized care in the ICU, they all had the same answer.

- They believed that the professionals in the ICU were honest, kind and respectful and would not change a thing.
- About the surroundings, they agreed on the following aspects:
    - More visitation hours with more family members, and even close friends.
    - They also agreed on the music therapy, as they had already used it on their family member and though to be very important for him.
    - They did not have a specific opinion on the diary, but did say that the patient did not remember anything about the ICU stay and to the day, has not wanted any information about it.

On the other measures they did not specify uniquely but did say that anything that could help humanize this difficult time, they would agree on it.

Other opinions they gave us were how they found themselves overwhelmed with information and their own questions during the first few days in the ICU and how they didn't expect the recovery at home to be so long and hard for the whole family.

This interview with the family member gives us an idea of how other families would react to this kind of project and gives us further ideas that we could, in the future add to our own project like a recovery leaflet explaining PICS, etc…

6. DIAGNOSTIC TESTS

IMPACT OF EVENTS SCALE-Revised (IES-R)

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to _____ _____(event) that occurred on _____(date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it	0	1	2	3	4
2. I had trouble staying asleep	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3	4
6. I thought about it when I didn't mean to	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders of it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on-guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

Total IES-R Score:_____

INT: 1, 2, 3, 6, 9, 14, 16, 20
AVD: 5, 7, 8, 11, 12, 13, 17, 22
HYP: 4, 10, 15, 18, 19, 21

Weiss, D.S. (2007). The Impact of Event Scale-Revised. In J.P. Wilson, & T.M. Keane (Eds.)
Assessing psychological trauma and PTSD: a practitioner's handbook (2nd ed., pp. 168-189). New York: Guilford Press.

AETR2N 22 1/13/2012

Revised Impact of Event Scale (22 questions):

The revised version of the Impact of Event Scale (IES-r) has seven additional questions and a scoring range of 0 to 88.

On this test, scores that exceed 24 can be quite meaningful. High scores have the following associations.

Score (IES-r) **Consequence**

24 or more	PTSD is a clinical concern.[6] Those with scores this high who do not have full PTSD will have partial PTSD or at least some of the symptoms.
33 and above	This represents the best cutoff for a probable diagnosis of PTSD.[7]
37 or more	**This is high enough to suppress your immune system's functioning** (even 10 years after an impact event).[8]

The IES-R is very helpful in measuring the affect of routine life stress, everyday traumas and acute stress

References:

1. Horowitz, M. Wilner, N. & Alvarez, W. (1979). Impact of Event Scale: A measure of subjective stress. Psychosomatic Medicine, 41, 209-218.
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3. Hutchins, E. & Devilly, G.J. (2005). Impact of Events Scale. Victim's Web Site. http://www.swin.edu.au/victims/resources/assessment/ptsd/ies.html
4. Coffey, S.F. & Berglind, G. (2006). Screening for PTSD in motor vehicle accident survivors using PSS-SR and IES. Journal of Traumatic Stress. 19 (1): 119-128.
5. Neal, L.A., Walter, B., Rollins, J., et al. (1994). Convergent Validity of Measures of Post-Traumatic Stress Disorder in a Mixed Military and Civilian Population. Journal of Traumatic Stress. 7 (3): 447-455.
6. Asukai, N. Kato, H. et al. (2002). Reliability and validity of the Japanese-language version of the Impact of event scale-revised (IES-R-J). Journal of Nervous and Mental Disease. 190 (3): 175- 182.
7. Creamer, M. Bell, R. & Falilla, S. (2002). Psychometric properties of the Impact of Event Scale- Revised. Behaviour Research and Therapy. 41: 1489-1496.
8. Kawamura, N. Yoshiharu, K. & Nozomu, A. (2001) Suppression of Cellular Immunity in Men with a Past History of Post Traumatic Stress Disorder. American Journal of Psychiatry. 158: 484- 486

Great Plains Health
Behavioral Health

Beck Anxiety Inventory (BAI)

About: This scale is a self-report measure of anxiety.

Items: 21

Reliability:

Internal consistency for the BAI = (Cronbach's a=0.92)
Test-retest reliability (1 week) for the BAI = 0.75 (Beck, Epstein, Brown, & Steer, 1988)

Validity:

The BAI was moderately correlated with the revised Hamilton Anxiety Rating Scale (.51), and mildly correlated with the Hamilton Depression Rating Scale (.25) (Beck et al., 1988).

Scoring:

	Not at all	Mildly, but it didn't bother me much	Moderately – it wasn't pleasant at times	Severely – it bothered me a lot
All questions	0	1	2	3

The total score is calculated by finding the sum of the 21 items. Score of 0-21 = low anxiety
Score of 22-35 = moderate anxiety
Score of 36 and above = potentially concerning levels of anxiety

References: Beck, A.T., Epstein, N., Brown, G., & Steer, R.A. (1988). An inventory for measuring clinical anxiety: Psychometric properties. *Journal of Consulting and Clinical Psychology*, 56, 893-897.

Beck Anxiety Inventory (BAI)

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by circling the number in the corresponding space in the column next to each symptom.

	Not at all	Mildly, but it didn't bother me much	Moderately – it wasn't pleasant at times	Severely – it bothered me a lot

Numbness or tingling	0	1	2	3
Feeling hot	0	1	2	3
Wobbliness in legs	0	1	2	3
Unable to relax	0	1	2	3
Fear of worst happening	0	1	2	3
Dizzy or lightheaded	0	1	2	3
Heart pounding / racing	0	1	2	3
Unsteady	0	1	2	3
Terrified or afraid	0	1	2	3
Nervous	0	1	2	3
Feeling of choking	0	1	2	3
Hands trembling	0	1	2	3
Shaky / unsteady	0	1	2	3
Fear of losing control	0	1	2	3
Difficulty in breathing	0	1	2	3
Fear of dying	0	1	2	3
Scared	0	1	2	3
Indigestion	0	1	2	3
Faint / lightheaded	0	1	2	3
Face flushed	0	1	2	3
Hot / cold sweats	0	1	2	3

BDI - II

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully. And then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness
   0. I do not feel sad.
   1. I feel sad much of the time.
   2. I am sad all the time.
   3. I am so sad or unhappy that I can't stand it.

2. Pessimism
   0. I am not discouraged about my future.
   1. I feel more discouraged about my future than I used to.
   2. I do not expect things to work out for me.
   3. I feel my future is hopeless and will only get worse.

3. Past Failure
   0. I do not feel like a failure.
   1. I have failed more than I should have.
   2. As I look back, I see a lot of failures.
   3. I feel I am a total failure as a person.

8. Self-Criticalness

4. Loss of Pleasure
   0. I get as much pleasure as I ever did from the things I enjoy.
   1. I don't enjoy things as much as I used to.
   2. I get very little pleasure from the things I used to enjoy.
   3. I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings
   0. I don't feel particularly guilty.
   1. I feel guilty over many things I have done or should have done.
   2. I feel quite guilty most of the time.
   3. I feel guilty all of the time.

6. Punishment Feelings
   0. I don't feel I am being punished.
   1. I feel I may be punished.
   2. I expect to be punished.
   3. I feel I am being punished.

7. Self-Dislike
   0. I feel the same about myself as ever.
   1. I have lost confidence in myself.
   2. I am disappointed in myself.
   3. I dislike myself.

   0. I don't criticize or blame myself more than usual.

1. I am more critical of myself than I used to be.
2. I criticize myself for all of my faults.
3. I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes
0. I don't have any thoughts of killing myself.
1. I have thoughts of killing myself, but I would not carry them out.
2. I would like to kill myself.
3. I would kill myself if I had the chance.

10. Crying
0. I don't cry anymore than I used to.
1. I cry more than I used to.
2. I cry over every little thing.
3. I feel like crying, but I can't.

11. Agitation
0. I am no more restless or wound up than usual.
1. I feel more restless or wound up than usual.
2. I am so restless or agitated, it's hard to stay still.
3. I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest
0. I have not lost interest in other people or activities.
1. I am less interested in other people or things than before.
2. I have lost most of my interest in other people or things.
3. It's hard to get interested in anything.

13. Indecisiveness
0. I make decisions about as well as ever.
1. I find it more difficult to make decisions than usual.
2. I have much greater difficulty in making decisions than I used to.
3. I have trouble making any decisions.

14. Worthlessness
0. I do not feel I am worthless.
1. I don't consider myself as worthwhile and useful as I used to.
2. I feel more worthless as compared to others.
3. I feel utterly worthless.

15. Loss of Energy
0. I have as much energy as ever.
1. I have less energy than I used to have.
2. I don't have enough energy to do very much.
3. I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0. I have not experienced any change in my sleeping. 1a I sleep somewhat more than usual.
1b I sleep somewhat less than usual. 2A I sleep a lot more than usual.
2B I sleep a lot less than usual. 3a I sleep most of the day.
3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

0. I am not more irritable than usual.
1. I am more irritable than usual.
2. I am much more irritable than usual.
3. I am irritable all the time.

18. Changes in Appetite

0. I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual. 2A My appetite is much less than before.
2B My appetite is much greater than usual. 3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

1. I can concentrate as well as ever.
2. I can't concentrate as well as usual.
3. It's hard to keep my mind on anything for very long.
4. I find I can't concentrate on anything.

20. Tiredness or Fatigue

5. I am no more tired or fatigued than usual.
6. I get more tired or fatigued more easily than usual.
7. I am too tired or fatigued to do a lot of the things I used to do.
8. I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

9. I have not noticed any recent change in my interest in sex.
10. I am less interested in sex than I used to be.
11. I am much less interested in sex now.
12. I have lost interest in sex completely.

Total Score:

THE PSYCHOLOGICAL CORPORATION
Harcourt Brace & Company

MINI MENTAL STATE EXAMINATION (MMSE)

Basado en Folstein et al. (1975), Lobo et al. (1979)

Nombre: Varón [ ] Mujer [ ]
Fecha: F. nacimiento: Edad:
Estudios/Profesión: Núm. Historia:
Observaciones:

¿En qué año estamos? 0-1 ¿En qué estación? 0-1 ¿En qué día (fecha)? 0-1 ¿En qué mes? 0-1 ¿En qué día de la semana? 0-1	**ORIENTACIÓN TEMPORAL** (máx. 5)	
¿En qué hospital (o lugar) estamos? 0-1 ¿En qué piso (o planta, sala, servicio)? 0-1 ¿En qué pueblo (ciudad)? 0-1 ¿En qué provincia estamos? 0-1 ¿En qué país (o nación, autonomía)? 0-1	**ORIENTACIÓN ESPACIAL** (máx. 5)	
Nombre tres palabras peseta-caballo-manzana (o balón-bandera-árbol) a razón de 1 por segundo. Luego se pide al paciente que las repita. Esta primera repetición otorga la puntuación. Otorgue 1 punto por cada palabra correcta, pero continúe diciéndolas hasta que el sujeto repita las 3, hasta un máximo de 6 veces. Peseta 0-1 Caballo 0-1 Manzana 0-1 (Balón 0-1 Bandera 0-1 Árbol 0-1)	Núm. de repeticiones necesarias **FIJACIÓN RECUERDO** inmediato (máx. 3)	
Si tiene 30 euros y me va dando de tres en tres, ¿Cuántos le van quedando?. Detenga la prueba tras 5 sustracciones. Si el sujeto no puede realizar esta prueba, pídale que deletree la palabra MUNDO al revés. 30 0-1 27 0-1 24 0-1 21 0-1 18 0-1 (O 0-1 D 0-1 N 0-1 U 0-1 M 0-1)	**ATENCIÓN CÁLCULO** (máx. 5)	
Preguntar por las tres palabras mencionadas anteriormente. Peseta 0-1 Caballo 0-1 Manzana 0-1 (Balón 0-1 Bandera 0-1 Árbol 0-1)	**RECUERDO DIFERIDO** (máx. 3)	
DENOMINACIÓN. Mostrarle un lápiz o un bolígrafo y preguntar ¿qué es esto?. Hacer lo mismo con un reloj de pulsera, lápiz 0-1, reloj 0-1. **REPETICIÓN.** Pedirle que repita la frase: "ni sí, ni no, ni pero" (o "en un trigal había 5 perros") 0-1. **ÓRDENES.** Pedirle que siga la orden: "coja un papel con la mano derecha, dóblelo por la mitad, y póngalo en el suelo". Coge con la mano derecha 0-1 dobla por la mitad 0-1 pone en suelo 0-1. **LECTURA.** Escriba legiblemente en un papel "cierre los ojos". Pídale que lo lea y haga lo que dice la frase 0-1. **ESCRITURA.** Que escriba una frase (con sujeto y predicado) 0-1. **COPIA.** Dibuje 2 pentágonos intersectados y pida al sujeto que los copie tal cual. Para otorgar un punto deben estar presentes los 10 ángulos y la intersección 0-1.	**LENGUAJE** (máx. 9)	
Puntuaciones de referencia: 27 ó más: normal 24 ó menos: sospecha patológica 12-24: deterioro 9-12: demencia	**PUNTUACIÓN TOTAL** (máx. 30 puntos)	

a.e.g.(1999)

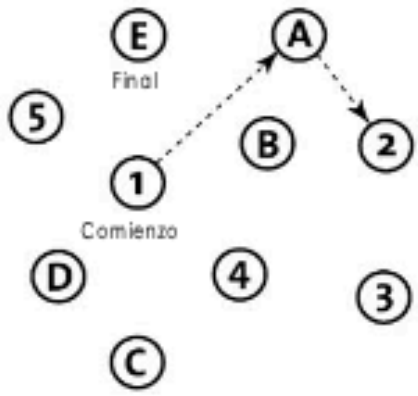
MONTREAL COGNITIVE ASSESSMENT (MOCA)

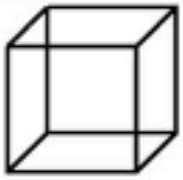
(EVALUACIÓN COGNITIVA MONTREAL)

NOMBRE:
Nivel de estudios:
Sexo:

Fecha de nacimiento:
FECHA:

VISUOESPACIAL / EJECUTIVA





Copiar el cubo

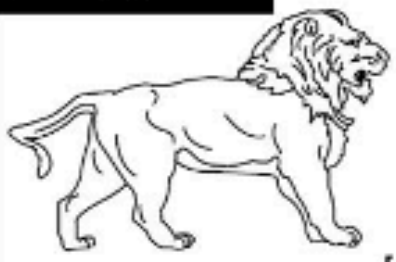
[ ] [ ]

Dibujar un reloj (Once y diez)
(3 puntos)

[ ] Contorno [ ] Números [ ] Agujas

Puntos ___/5

IDENTIFICACIÓN



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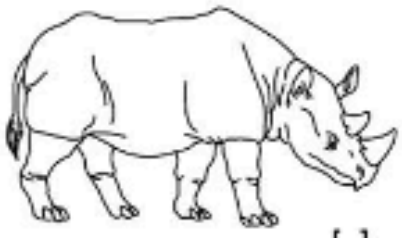

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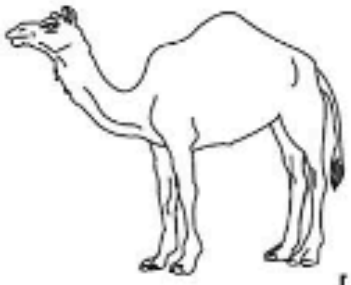

[ ]

___/3

MEMORIA

Lea la lista de palabras, el paciente debe repetirlas. Haga dos intentos. Recuérdeselas 5 minutos más tarde.

	ROSTRO	SEDA	IGLESIA	CLAVEL	ROJO
1er intento					
2º intento					

Sin puntos

ATENCIÓN

Lea la serie de números (1 número/seg.) El paciente debe repetirla. [ ] 2 1 8 5 4

El paciente debe repetirla a la inversa. [ ] 7 4 2 ___/2

Lea la serie de letras. El paciente debe dar un golpecito con la mano cada vez que se diga la letra A. No se asignan puntos si ≥ 2 errores. ___/1

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

Restar de 7 en 7 empezando desde 100. [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65 ___/3

4 o 5 sustracciones correctas: **3 puntos**, 2 o 3 correctas: **2 puntos**, 1 correcta: **1 punto**, 0 correctas: **0 puntos**

LENGUAJE

Repetir: El gato se esconde bajo el sofá cuando los perros entran en la sala. [ ] Espero que él le entregue el mensaje una vez que ella se lo pida. ___/2

Fluidez del lenguaje. Decir el mayor número posible de palabras que comiencen por la letra "P" en 1 min. [ ] _____ (N ≥ 11 palabras) ___/1

ABSTRACCIÓN

Similitud entre p. ej. manzana-naranja = fruta [ ] tren-bicicleta [ ] reloj-regla ___/2

RECUERDO DIFERIDO

	ROSTRO	SEDA	IGLESIA	CLAVEL	ROJO	
Debe acordarse de las palabras SIN PISTAS	[ ]	[ ]	[ ]	[ ]	[ ]	Puntos por recuerdos SIN PISTAS únicamente
Opcional: Pista de categoría						
Opcional: Pista elección múltiple						

___/5

ORIENTACIÓN

[ ] Día del mes (fecha) [ ] Mes [ ] Año [ ] Día de la semana [ ] Lugar [ ] Localidad ___/6

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www.mocatest.org

Normal ≥ 26 / 30

TOTAL ___/30
Añadir 1 punto si tiene ≤ 12 años de estudios

QÜESTIONARI WHOQOL-BREF: sobre qualitat de vida

Aquest qüestionari serveix per conèixer la seva opinió sobre la seva qualitat de vida, la seva salut i altres àrees de la seva vida. Si us plau, contesti a totes les preguntes. Si no sabeu quina resposta donar a una pregunta, trïi la que li sembli més apropiada. De vegades, aquesta pot ser la seva primera resposta.

Tingui present la seva manera de viure, expectatives, plaers i preocupacions. Li demanem que pensi en la seva vida durant les últimes dues setmanes.

Si us plau llegiu cada pregunta, valori seus sentiments i faci un cercle en el nombre de l'escala de cada pregunta que sigui la seva millor resposta.

1. Com puntuaria la seva qualitat de vida?
    1. Molt malament.
    2. Poc.
    3. El normal.
    4. Bastant bé.
    5. Molt bé.

2.Quant satisfet està amb la seva salut?
    1. Molt insatisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

Les següents preguntes fan referència a quant ha experimentat certs fets en les últimes dues setmanes.

3.Fins quin punt pensa que el dolor (físic) li impedeix fer el que necessita?
    1. Res.
    2. Una mica.
    3. El normal.
    4. Bastant.
    5. Extremadament.

4.Quant necessita de qualsevol tractament mèdic per a funcionar en la seva vida diària?
    1. Res.
    2. Una mica.
    3. El normal.
    4. Bastant.
    5. Extremadament.

5.Quánto gaudeix de la vida?
    1. Res.
    2. Una mica.

3. El normal.
4. Bastant.
5. Extremadament.

6.Fins quin punt sent que la seva vida té sentit?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

7.Quina és la seva capacitat de concentració?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

8. Quanta seguretat sent en la seva vida diària?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

9. Com de saludable és l'ambient físic al seu voltant?
1. Res.
2. Una mica.
3. El normal.
4. Bastant.
5. Extremadament.

Les següents preguntes fan referència a "quant totalment" vostè experimenta o va ser capaç de fer certes coses en les últimes dues setmanes.

10. Té energia suficient per a la seva vida diària?
1. Res.
2. Una mica.
3. Moderat
4. Bastant.
5. Totalment.

11. És capaç d'acceptar la seva aparença física?
1. Res.
2. Una mica.
3. Moderat
4. Bastant.
5. Totalment.

12. Té prou diners per cobrir les seves necessitats?
    1. Res.
    2. Una mica.
    3. Moderat
    4. Bastant.
    5. Totalment.

13. Què disponible té la informació que necessita en la seva vida diària?
    1. Res.
    2. Una mica.
    3. Moderat
    4. Bastant.
    5. Totalment.

14. Fins a quin punt té oportunitat per realitzar activitats de lleure?
    1. Res.
    2. Una mica.
    3. Moderat
    4. Bastant.
    5. Totalment.

15. És capaç de desplaçar-se d'un lloc a un altre?
    1. Res.
    2. Una mica.
    3. El normal.
    4. Bastant.
    5. Extremadament.

Les següents preguntes fan referència a "quant satisfeta o bé" s'ha sentit en diversos aspectes de la seva vida en les últimes dues setmanes.

16. Com de satisfeta està amb el seu somni?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

17. Com de satisfeta està amb la seva habilitat per realitzar les seves activitats de la vida diària?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

18. Com de satisfeta està amb la seva capacitat de treball?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.

4. Bastant satisfeta.
5. Molt satisfeta.

19. Com de satisfeta està de si mateixa?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

20. Com de satisfeta està amb les seves relacions personals?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

21. Com de satisfeta està amb la seva vida sexual?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

22. Com de satisfeta està amb el suport que obté dels seus amics?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

23. Com de satisfeta està de les condicions del lloc on viu?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

24. Com de satisfeta està amb l'accés que té als serveis sanitaris?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.
    5. Molt satisfeta.

25. Com de satisfeta està amb el seu transport?
    1. Res satisfeta.
    2. Poc satisfeta.
    3. El normal.
    4. Bastant satisfeta.

5. Molt satisfeta.

La següent pregunta fa referència a la freqüència amb que vostè ha sentit o experimentat certs sentiments en les últimes dues setmanes.

26. Amb quina freqüència té sentiments negatius, com ara tristesa, desesperança, ansietat, depressió?

14. Mai.
15. Rarament.
16. Mitjanament.
17. Freqüentment.
18. Sempre.