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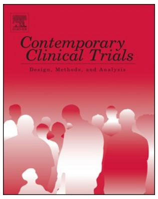

# Improving communication toward ICU families to facilitate understanding and reduce stress. Protocol for a multicenter randomized and controlled Italian study[☆]

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## ARTICLE INFO

**140 characters essential gist:** A family brochure, posters and website to improve ICU experience for families: a nationwide, randomized trial to boost human relationships.

*Keywords:*
Professional-family relations
Intensive care units
Communication
Caregivers
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Information dissemination

## ABSTRACT

*Objective:* Families of ICU patients have a pressing need for information: they find themselves suddenly in a complex technical environment often because of a life-threatening illness of a loved one. Some evidence suggests that specific communication tools (like websites or brochures) could improve the experience of ICU families.
*Design:* Randomized, multicenter, stepped wedge trial for large-scale assessment of the effectiveness of a multitasking intervention to improve communication with families of critically ill patients. Main outcome: correct understanding of the prognosis. Secondary outcomes: correct understanding of medical treatments, prevalence of anxiety, depression and post-traumatic stress symptoms in the first ICU week. Prevalence of PTSD 6 months from ICU discharge. Empathy and burnout among ICU staff. Prevalence of refusals for tissues/organ donation, and medical claims.
*Subjects:* 2100 ICU relatives of critically ill patients.
*Interventions:* The intervention employs specific tools especially designed to raise the correctness of information and to improve the quality of communication: a website presenting the ICU world and justifying the relatives' emotions, with a webpage specifically dedicated to each participating ICU; a standard brochure; eight posters for the families' waiting room and a signboard for the ICU door.
*Measurements and main results:* The study plans to assess these materials in up to 300 Italian ICUs that will participate, according to a five waves program, each one with randomized starting order. This way the effect of the intervention will be evaluated simultaneously.
*Conclusion:* This is an *educational study*, aiming to spread good medical practices, while also verifying their real effectiveness in a large number of ICUs.

Trial registration number: NCT03438175.

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## 1. Introduction

### 1.1. The challenge of communicating in the intensive care unit (ICU)

The admission into the harsh ICU environment [1] exposes both patients and families to an abnormal environment with various physical and psychological stressors [2,3]; it has been reported as an experience very unpleasant for relatives [4]. They have an extremely pressing need for clarity, completeness, and consistency in clinical and technical information [5]; they expect emotional support, respect, and compassion [6].

Patients and relatives have high risk of developing the burden of symptoms of post-traumatic stress disorder (PTSD) [7]. This risk can reach 53% among relatives of critically ill patients [8,9] or even more when ICU patient dies [10,11]. When the PTSD [12] occurs, it can lead to significant impairment in daily life and generate feelings of fear and despair, even becoming a threat to life and physical integrity for patients and relatives after the ICU stay [13,14].

Family members reported as a primary problem the scant understanding of medical information, leading to discordant expectations [15,16], and 70% showed symptoms of anxiety [17] and depression [2,5]. The relationship with families of ICU patients presents several challenges for health care providers: [1,3,15] 1. understanding care essentials (diagnosis, prognosis about illness severity, interventions done); 2. trust in ICU staff; 3. management of their emotions (anxiety, fear, depression); 4. PTSD due to concerns about the life-threatening conditions of their relative [2,14].

### 1.2. The Italian milieu

In Italy, the presence of family members and visitors is generally viewed by ICU staff as interference and is therefore strictly limited [18–20]. Though there have been some cultural and practical changes [19], this point is still highly debated [21].

Despite authoritative recommendations [22], a national law was proposed but never approved; a correlation between open ICU policies and burnout in staff members [21], and a positive role of family-centered care on their satisfaction and perceived stress [23] were highlighted. It is widely believed that relatives should be fully informed about the conditions and prognosis of their relative [24], but this information is not often as complete as it should be.

Italian ICU staff recognize that they have clear responsibility for adequate communication [25,26] and for protection against preventable psychopathologies among family members [27,28]. This need is felt: communication with relatives is recognized as a challenge [29], with ample room to improve important outcomes [30]. In 2012, a project [15] to ease the communication and to improve the correctness of prognosis comprehension was made, also highlighting a post-traumatic stress symptoms reduction.

### 1.3. Need for research and main outcome

The present study was designed to reach a large number of Italian ICUs with some tools to improve communication with ICU patients' relatives. While introducing them, a pragmatic verify is made, to enhance their prognosis comprehension and psychological wellbeing, together with a scientific confirm of their validity [31]. Moreover some *educational experiences* are also offered to ICU staff [32]. From the pilot study [15] described above, the present project can also be a more *educational study*: the ICU staff have an opportunity to take part in online courses, with access to the international literature on these topics.

## 2. Methods

The Intensiva 2.0 Project is a randomized, controlled, multicenter, before and after study with 3 years' total enrolment, from January 2018 to December 2020.

### 2.1. Study population

Relatives of ICU patients, together with the ICU staff members. A certain amount of observational data will be gathered from patients, too.

Enrollment criteria for the closest relatives are: 1) age over 18 years, 2) relative of an ICU patient with duration of mechanical ventilation > 48 h. Exclusion criteria are: 1) refusal to participate, 2) inability to understand Italian, 3) any previously diagnosed and not compensated psychiatric condition, 4) no visiting relatives for the first four ICU days.

All the available ICU physicians, nurses, residents, students, and auxiliary workers will be invited to participate, completing a couple of questionnaires, at the ends of the *before* and *after* phases. Enrollment criteria for the healthy population are: 1) staff physicians dedicated to giving information to relatives, and 2) nurses or other staff who daily collaborate with doctors to create a relationship with relatives.

### 2.2. Study outcomes

The main outcome of the study is the improvement in correct understanding of the patient's life-long prognosis during the family meetings for medical information. The questionnaire used is the *Comprehension Assessment Interview* (CAI).

Secondary outcomes are:

1) Correct understanding about medical treatment. The same questionnaire is used (CAI) [5,33].
2) The burden of the traumatic experience (ICU admission of a relative) on families, in both the short term [34] and the longer term, 6 months after ICU discharge. Questionnaires used: *Short Screening Scale for PTSD (SSS-PTSD)* and *PTSD check list for Diagnostic Statistical Manual of Mental Disorders (DSM) V – civilian version* (PCL-5) [21,35].
3) The degree of anxiety and depression in family members. Questionnaire used: *Hospital Anxiety and Depression Scale* (HADS) [36].
4) The effects of participating in the present study for staff members, their burnout and empathy toward families. Questionnaires used: *Maslasch burnout inventory (MBI)* [37] and *Jefferson Scale for Physician Empathy (JSPE)* [38,39].

Correct understanding of the diagnosis regarding organ dysfunction will be gathered too, but it is not an outcome of the present study, because it is the sole responsibility of physician/nurses in charge. For a complete description of the test used, see the Electronic Supplementary Material (ESM).

### 2.3. Study intervention

The main (and mandatory) intervention is the introduction of support tools (Intensiva 2.0 materials, fully described in the ESM) in the communication process between the ICU staff and the relatives. The tools are: the website, the brochure and the posters. The secondary (and optional) intervention is educational support dedicated to ICU staff members. Since an important component of this study is to assess the correctness and completeness of strategy implementation and to describe the real “dose” of the intervention administered, a specific questionnaire has been developed to systematically measure the work effectively done in the participating ICUs.

### 2.4. The criteria used to build website, brochure, and posters

To develop the website, the brochure, and the posters, the Intensiva 2.0 investigators reached agreement on the text, with the following basic rules: sentences had to be short and language very straightforward, understandable even to people with limited education. The ICU rules were changed from prohibitions ("do not touch", "do not speak loudly", "do not give food, beverages or drugs") to positive explanations ("to avoid accidents", "to ensure tranquility", "to reduce infections"); the term "patients" was replaced when possible with "people in hospital". Black and white photos were used as they realistically illustrate the situations, at the same time giving the impression of a solid, safe distance. To make the photos look less gloomy, they were placed against colorful backgrounds. The cover picture was specifically intended to be reassuring and to represent the relatives' ICU path (a country road leading home), focusing on the long-term goal (two children of different ages walking hand-in-hand, representing the patient-relative, patient-staff, and relative-staff relationships). The website http://www.intensiva.it was built to meet relatives' cognitive and emotional needs, and comprised six domains.

1) ABOUT US, to clearly state who guarantees the website's scientific content.
2) KNOWLEDGE, to describe the place, equipment, and organization.
3) TREATMENT, to explain why a person needs intensive care, and how a family member can help by cooperating with healthcare professionals.
4) STARTING OVER, to illustrate what happens after discharge from ICU, together with emotional validation.
5) YOU ARE NOT ALONE, to present stories of former ICU patients or relatives, and offer the opportunity to leave one's own story.
6) DONATIONS, to describe the different donations a patient or relatives may decide to make (blood, time, money, organs, tissues). A simplified glossary of medical terms was supplied too. Since some of the centers were already using their own brochures, it was stated during a TLIS meeting that an editable file of the brochure was freely provided, in order to enable brochures to be prepared containing the study material together with the logo of the hospital or regional healthcare system.

### 2.5. Readability indexes

All the texts used in the brochure, posters, and website were assessed for readability, using specific software for the Italian language (Expert Systems SpA, Modena, Italy). The texts were subsequently improved, by changing long words to the shortest and most commonly used ones, and using short sentences, and the present tense. These rules make a text understandable even for people with limited schooling.

The authors and reviewers tried hard to use straightforward language, but depending on the topics treated readability indexes differed widely. It was unavoidable to have a landmark target of people with fair reading ability, because the very specific topics sometimes made it difficult to convey the message in simple, direct terms, while respecting full technical and scientific accuracy.

It is clear that plain behavior rules (Fig. 1, Poster A) may be understood by someone with a much lower level of education (5 years of school) than text describing the technical instruments commonly used in the ICU, like mechanical ventilator, multi-parameter monitoring, syringe pump, and so forth, which probably need up to 9 years of school to be properly understood (Fig. 1, Poster C). The final text as a whole should be adequate for 60% of the Italian population.

There is a specific menu in the website, to introduce each participating ICUs. From the homepage, the family members can search directly for information about the ICU where their relative has been admitted. Each ICU is free to use locally developed materials, as long as they are coherent with the style of the project, and show the Intensiva 2.0 Project logo (see Figure "Home page" on ESM).

### 2.6. Ethics committee approval

The study was approved by the Ethics Committee of the coordinating center (Ospedale San Paolo, Milano): Comitato Etico Area A, protocol number 35410/2017 on October 30, 2017. Each participating ICU can then decide – according to their local rules – whether they need obtain specific authorization, or if the national one is enough, considering that the study involves the frail – but not hospitalized – population of relatives, and a healthy population of ICU staff. In any case, written informed consent is gathered before completion of all questionnaires. When it is not possible to obtain valid informed consent from the patients in a prospective study, the responsibility for the scientific research falls on three subjects [40]: first, the principal investigator who designed the study; second, the ethics committee, that guarantees the best balance between the possible harms and benefits of patients and the community; third, the local investigator, who guarantees that the patient fulfills the inclusion/exclusion criteria [41].

### 2.7. Randomization: pairing centers according to their characteristics

The characteristics of each participating ICU are collected before the study begins. ICUs are then paired, choosing the most similar ones by a process of minimization, in order to create two similar groups (Alpha and Beta) and to proceed with a "stepped wedge design" with randomization of matched pairs of ICUs to immediate intervention versus delayed intervention. A random criterion based on national batch extractions is used to assign each ICU to one of the two study groups: Alpha, who starts first, and Beta, who starts later (Fig. 2). The ICU assigned to group Alpha (ICU-Alpha) immediately starts collecting data for the *before* phase. Once all these data have been collected, all Intensiva 2.0 materials are introduced into the ICU-Alpha daily practice. At the same time as the ICU-Alpha data collection or in its *after* phase, the coupled ICU assigned to group Beta (ICU-Beta) collects its *before* phase data (Fig. 2).

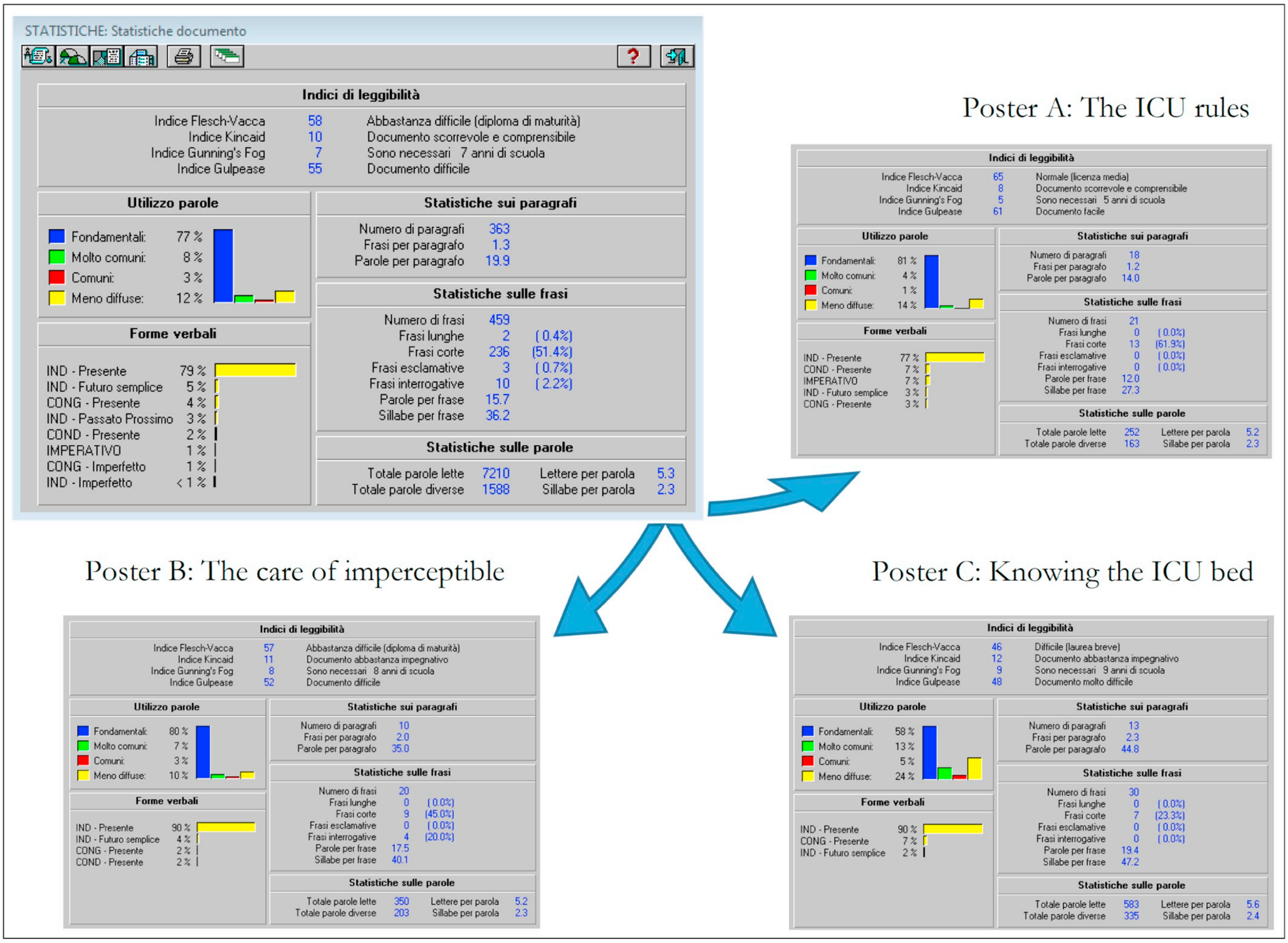
This scheme will permit simultaneous randomized data collection in similar centers, comparing those who have already introduced the proposed tools and those who have yet to introduce them; it will also be possible to make a before-and-after comparison within each ICU.

### 2.8. Procedure for pairing the participating ICUs

The pairing procedure among ICUs willing to participate in each specific study period is planned to be repeated every 6 months (Fig. 3). The procedure is led by the coordinating center (IRCCS - Fondazione Policlinico Universitario A. Gemelli - Rome), which takes the final responsibility. The ICUs are "paired" by identifying the most similar ones on the basis of their structure and organization. They are then randomly split into two groups, to create the closest possible similarity between them. The criteria are structured in three levels of importance, and this decision was shared inside the Tavolo di Lavoro Inter Societario (TLIS), the study inspirer and controller.

First level: opening times for the families and supply of a local brochure for use before the beginning of the study. Second level: type of ICU (general/surgical/medical/trauma/transplantation/pediatric/other) and estimated workload (nurse/patient ratio). Third level: number of beds and continuity in communication with family members (the same physician during weekdays).

The pair of ICUs will gather data simultaneously through this strategy. Once each ICU in the Alpha group reports the end of the *before* phase to the coordinating center, the paired ICU assigned to the Beta group is contacted: whilst the ICU-Alpha group begins its *after* phase, the ICU-Beta starts its *before* phase (Fig. 3).



STATISTICHE: Statistiche documento

**Indici di leggibilità**

Indice Flesch-Vacca 58 Abbastanza difficile (diploma di maturità)
Indice Kincaid 10 Documento scorrevole e comprensibile
Indice Gunning's Fog 7 Sono necessari 7 anni di scuola
Indice Gulpease 55 Documento difficile

**Utilizzo parole**

Fondamentali: 77 %
Molto comuni: 8 %
Comuni: 3 %
Meno diffuse: 12 %

**Statistiche sui paragrafi**

Numero di paragrafi 363
Frasi per paragrafo 1.3
Parole per paragrafo 19.9

**Statistiche sulle frasi**

Numero di frasi 459
Frasi lunghe 2 ( 0.4%)
Frasi corte 236 (51.4%)
Frasi esclamative 3 ( 0.7%)
Frasi interrogative 10 ( 2.2%)
Parole per frase 15.7
Sillabe per frase 36.2

**Forme verbali**

IND - Presente 79 %
IND - Futuro semplice 5 %
CONG - Presente 4 %
IND - Passato Prossimo 3 %
COND - Presente 2 %
IMPERATIVO 1 %
CONG - Imperfetto 1 %
IND - Imperfetto < 1 %

**Statistiche sulle parole**

Totale parole lette 7210 Lettere per parola 5.3
Totale parole diverse 1588 Sillabe per parola 2.3

Poster A: The ICU rules

**Indici di leggibilità**

Indice Flesch-Vacca 65 Normale (licenza media)
Indice Kincaid 8 Documento scorrevole e comprensibile
Indice Gunning's Fog 5 Sono necessari 5 anni di scuola
Indice Gulpease 61 Documento facile

**Utilizzo parole**

Fondamentali: 81 %
Molto comuni: 4 %
Comuni: 1 %
Meno diffuse: 14 %

**Statistiche sui paragrafi**

Numero di paragrafi 18
Frasi per paragrafo 1.2
Parole per paragrafo 14.0

**Statistiche sulle frasi**

Numero di frasi 21
Frasi lunghe 0 ( 0.0%)
Frasi corte 13 (61.9%)
Frasi esclamative 0 ( 0.0%)
Frasi interrogative 0 ( 0.0%)
Parole per frase 12.0
Sillabe per frase 27.3

**Forme verbali**

IND - Presente 77 %
COND - Presente 7 %
IMPERATIVO 7 %
IND - Futuro semplice 3 %
CONG - Presente 3 %

**Statistiche sulle parole**

Totale parole lette 252 Lettere per parola 5.2
Totale parole diverse 163 Sillabe per parola 2.3

Poster B: The care of imperceptible

**Indici di leggibilità**

Indice Flesch-Vacca 57 Abbastanza difficile (diploma di maturità)
Indice Kincaid 11 Documento abbastanza impegnativo
Indice Gunning's Fog 8 Sono necessari 8 anni di scuola
Indice Gulpease 52 Documento difficile

**Utilizzo parole**

Fondamentali: 80 %
Molto comuni: 7 %
Comuni: 3 %
Meno diffuse: 10 %

**Statistiche sui paragrafi**

Numero di paragrafi 10
Frasi per paragrafo 2.0
Parole per paragrafo 35.0

**Statistiche sulle frasi**

Numero di frasi 20
Frasi lunghe 0 ( 0.0%)
Frasi corte 9 (45.0%)
Frasi esclamative 0 ( 0.0%)
Frasi interrogative 4 (20.0%)
Parole per frase 17.5
Sillabe per frase 40.1

**Forme verbali**

IND - Presente 90 %
IND - Futuro semplice 4 %
CONG - Presente 2 %
COND - Presente 2 %

**Statistiche sulle parole**

Totale parole lette 350 Lettere per parola 5.2
Totale parole diverse 203 Sillabe per parola 2.3

Poster C: Knowing the ICU bed

**Indici di leggibilità**

Indice Flesch-Vacca 46 Difficile (laurea breve)
Indice Kincaid 12 Documento abbastanza impegnativo
Indice Gunning's Fog 9 Sono necessari 9 anni di scuola
Indice Gulpease 48 Documento molto difficile

**Utilizzo parole**

Fondamentali: 58 %
Molto comuni: 13 %
Comuni: 5 %
Meno diffuse: 24 %

**Statistiche sui paragrafi**

Numero di paragrafi 13
Frasi per paragrafo 2.3
Parole per paragrafo 44.8

**Statistiche sulle frasi**

Numero di frasi 30
Frasi lunghe 0 ( 0.0%)
Frasi corte 7 (23.3%)
Frasi esclamative 0 ( 0.0%)
Frasi interrogative 0 ( 0.0%)
Parole per frase 19.4
Sillabe per frase 47.2

**Forme verbali**

IND - Presente 90 %
CONG - Presente 7 %
IND - Futuro semplice 2 %

**Statistiche sulle parole**

Totale parole lette 583 Lettere per parola 5.6
Totale parole diverse 335 Sillabe per parola 2.4

**Fig. 1.** Output data after analysis of readability indexes. Considering together the whole number of texts produced (brochure, posters, and main menu of website), 7 years of school are sufficient to comprehend them. They appear overall moderately simple (Kincaid index: good comprehensibility and fluidity), but highly inhomogeneous, notwithstanding the continuous effort toward simplicity. As examples, three analyses are here shown. ICU rules presentation is very simple to be read (Poster A), being comprehensible even after 5 school years, while increasing difficult are shown in Intensiva spirit presentation (Poster B, 8 years) and in ICU bed and technological tools presentation (Poster C, 9 years).

### 2.9. *Electronic data gathering*

The main website of the study is dedicated to the family members (www.intensiva.it) and has been freely available online since 2012. In 2017, the section *About us* was completely revised in line with the new study structure, and the website platform has been updated with the latest Joomla version. A specific website was set up for ICU staff (http://dati.intensiva.it), both for data collection and to make all the study materials and the online educational courses immediately available. This second website, built through a WordPress platform, offers a series of freely available documents (study protocol, case report forms, files for ethics committee requests, randomization criteria). An access-level management system guarantees the availability of documents, depending on the type of user: the local principal investigators and ICU staff members, the area administrators, and the whole study administrators.

For simplicity, the questionnaires are supposed to be completed by families and staff on paper. The validated tests chosen for the project offer the best balance between simplicity, feasibility, and validity of the psychologic investigation.

After that, the local Intensiva 2.0 investigators have to transfer onto the electronic system all the data gathered except personal information (name, family name, birth date, phone number); this ensures that all data inserted online and transferred to the central database are completely anonymous. The webpages – containing one electronic form each – are available only after authentication; they permit the user to send the data simultaneously to the database, to an email server available for all area administrators, and to an email address of the compiler. The electronic fields are closed or have pop-down windows, and contain specific data limits to limit transcription errors.

The website for study investigators has a specific menu for the *after phase*, available only after authentication, which offers a series of documents, bibliography, videos, and educational courses to improve the staff's communication skills. Another possibility offered to the ICUs is a weekly music playlist, to offer a sort of music therapy for patients and families. The music has been selected as widely known, to synchronize the circadian rhythm, reduce anxiety in patients, and to create a sort of communication between those inside the ICU and relatives in the waiting room.

### 2.10. *Differences between the before and after phases of the study*

#### 2.10.1. *The "Before" phase*

In the *before* phase of the study, each center collects questionnaires from relatives to describe their understanding and psychological satisfaction with the current state of communication, that may differ

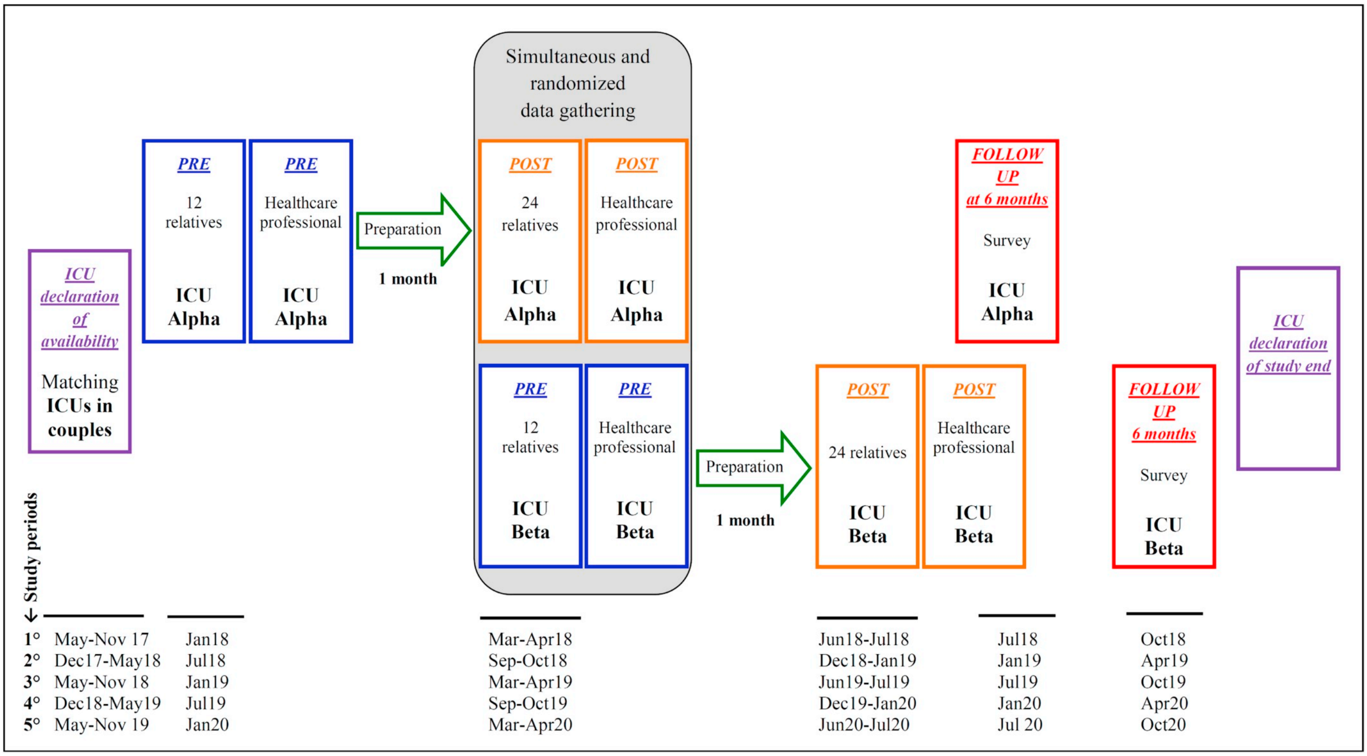


**Fig. 2.** Time schedule for the randomization of ICUs participating to the *Intensiva 2.0 Project*.

among the ICUs. At the end of the *before* phase enrollment, in what we have called the "preparation" month, all ICU staff are invited to complete a questionnaire about their empathy toward families and job satisfaction/susceptibility to burnout. As soon as the *before* phase ends, 100 brochures, eight posters for the waiting room, and a signboard for the ICU main door are delivered to each ICU. At the same time a

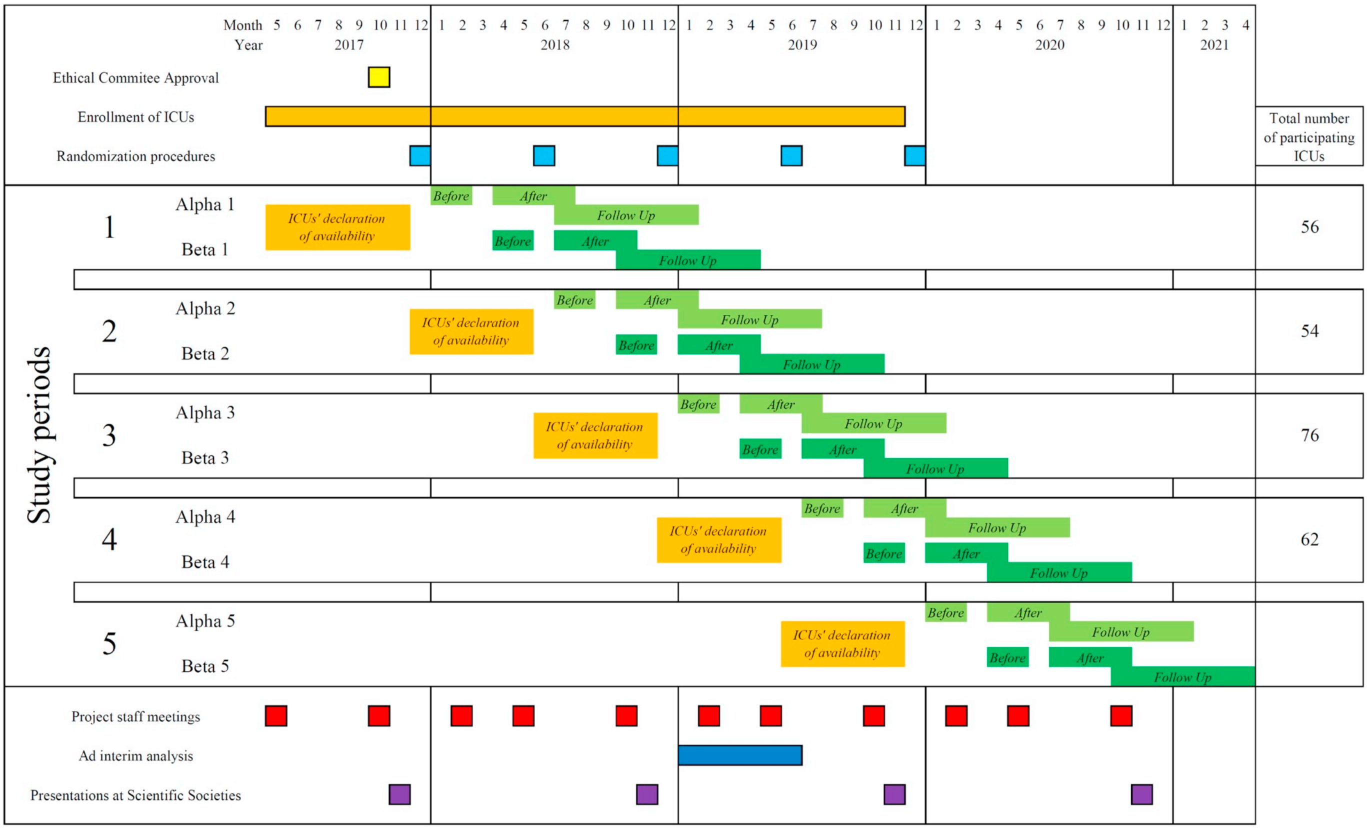


**Fig. 3.** Gantt diagram for the whole *Intensiva 2.0 Project* time schedule.

**Table 1**
The tasks of each ICU during the *after* phase.

| Mandatory actions | Optional actions |
|---|---|
| Distribution of Intensiva.it brochure to all family members at the first clinical meeting | Drafting a brochure specific for each ICU, containing the Intensiva.it project logo |
| Hanging eight posters in the ICU waiting room or in the passage to the entry of the ICU | Presentation of the Intensiva 2.0 project at a dedicated ICU staff meeting |
| Designing and approving the webpage presenting that specific ICU | Training for all the ICU staff members about communication skills (online courses) |
| Sending the "standard" email to all families involved in the study | Use of general music therapy, inside the ICU and in the family waiting room |

Each participating ICU had to accomplish with four mandatory action, characterizing the study intervention. Moreover, four other optional actions are possible to introduce, on the willingness of study local investigators.

dedicated webpage is created for each ICU on the site www.intensiva.it. All these materials are to be used throughout the *after* phase of the study.

During the preparation month, each local principal investigator is expected to organize an ICU staff meeting to present the Intensiva 2.0 Project and all the materials provided. All staff are invited to freely access the online training platform to improve their communication skills: http://dati.intensiva.it/fad/

### 2.10.2. The "After"phase

Only during the *after* period, about the first clinical talk with the ICU staff, a copy of the brochure is given to each family member by the nurse or the physician who had welcomed the family in the ward, together with information about the website. An email presenting the website is sent to the families, and the eight posters are hung up in the waiting room (Table 1).

In the *after* phase the emotional experience of the relatives is investigated as well as their understanding of the medical condition of the hospitalized patient (like in the *before* phase). Two other dimensions are also considered: first, how families assess the informative material (useful/useless); second, from the ICU staff members' point of view, whether they feel the informative materials have made their communication with families easier or more difficult, and how this has influenced their understanding of the clinical situation.

None of the other habits in dealing with families needs to change during the study – for example, making changes as a result of the introduction of the website/brochures/posters – so as to avoid confounding factors as far as possible. At the end of the *after* phase, the survey on staff will be repeated, focusing on empathy and work satisfaction/burnout.

All the family and staff questionnaires will be self-administered. At the beginning and end of the study, the local principal investigators of each ICU has to compile the **Center forms**, to supply information about the structure and organization of each ICU (study beginning) and utility of the tools introduced, together with observations about organ/tissue donation and medical claims (study end).

### 2.11. Study conduction: time frame for interviews of ICU families and staff members

Families are offered the possibility of taking part in this study between the 3rd and the 7th day after ICU admission of their relative, at the end of the clinical talk. After signing a written consent form to participate in the study, the closest relative of each patient is invited to complete a self-assessment questionnaire (Fig. 4). The correctness of how well the clinical condition is understood will be assessed by comparing the questionnaire (**Form A**) filled in by the attending physician with the one filled in by the family member who attended the clinical talk (**Form B**). The Supplemental Digital Content gives a full description of the differences between the before and the after phases.

### 2.12. Statistical analysis

An intention-to-treat statistical analysis is planned both comparing the simultaneous observations from the two randomized ICU groups, Alpha and Beta, and with a before and after approach, within each participating center. Two-tailed tests will be used, with significance $p < .05$. These paired data tests will be applied for the before and after

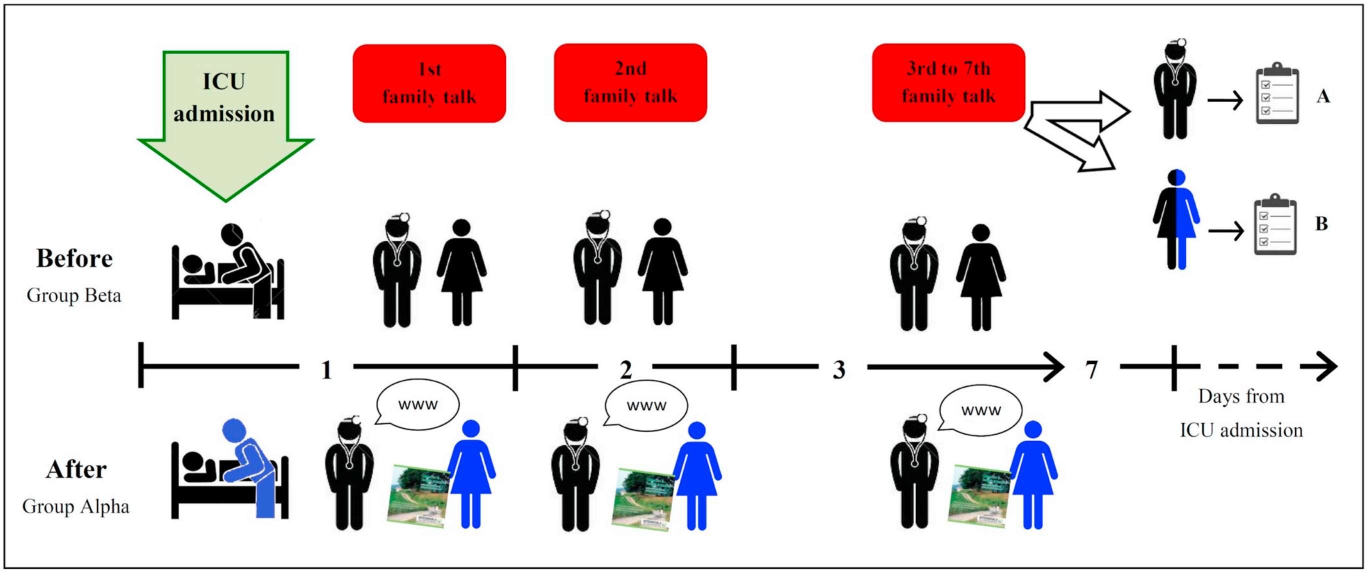


**Fig. 4.** Study timeline: after ICU admission, the families undergo clinical talks as usual. During the *after* phase, families can read the posters in the waiting room, receive the brochure and an email inviting to visit the website. At any time between the 3rd and 7th ICU day, both before (group Beta) and after (group Alpha) the intervention, at the end of the family talk, questionnaire A is filled by doctors (what I said), and questionnaire B by the closest relative (what I understood), to compare the correctness by sender and receiver content of the communication.

observations: Student's *t*-test for normally distributed continuous data, the Wilcoxon rank sum test for non-normally distributed continuous data, the Pearson $\chi^2$ test or Fisher exact test for categorical data, depending on the number of observations. The same tests with unpaired approach will be used for the observations referring to groups Alpha and Beta.

The main outcome (correct understanding of the prognosis between ICU-Alpha *after* phase and ICU-Beta *before* phase) will be analyzed with univariate approach, because this outcome has to be analyzed as an independent datum. Multivariate analysis will be used for all other secondary outcomes, because psychological indicators needs to be evaluated together with other conditions, regarding both the families' and the patients' conditions. These analyses will be done with multivariate Poisson regression models (coefficient of variation and 95% confidence interval).

These planned sub-analyses will be done on all the outcomes, dividing the observations gathered according to the following criteria for the ICUs, in view of the likely heterogeneity of the observations settings. 1) Median opening hours to relatives. 2) Median nurse/patient ratio, as an indicator of workload. 3) Median empathy score in each center during the *before* phase. 4) Information given by the same physician on weekdays. 5) Facilities for family members before the study (meeting room, waiting room, information brochure, availability of a psychologist).

The electronic data forms are especially designed for this study, and do not allow entering questionnaires if not complete regarding all outcomes. Since three questionnaires regarding each enrolled family member (Form A, Form B, Form Follow-Up) are required, it could be possible a significant amount of lacking data, especially about the 6-months follow-up. A sensitivity analysis will therefore be done between cases with complete and incomplete data: epidemiological characteristics and available questionnaires will be compared between families having (or not) all the three forms, to highlight any differences in estimates, and assessing the selection bias.

### 2.13. Sample size and power

The power needed to define the sample size is calculated on the main outcome, regarding the cognitive aspect of correctly understanding the patient's life-long prognosis. Previously collected data indicate that 40% of family members do not give the questionnaire back and 31% do not properly understand the prognosis described by the physicians. The assumption was therefore made that the tools introduced will lead to a 10% gain in understanding, and that 50% of the family members in the *after* phase will see both the brochure and the website. Considering these hypotheses, with a type I error rate of 0.05 and 90% power tone can estimate that 2100 family members will need to be enrolled, 700 during the *before* phase and 1400 during the *after* phase.

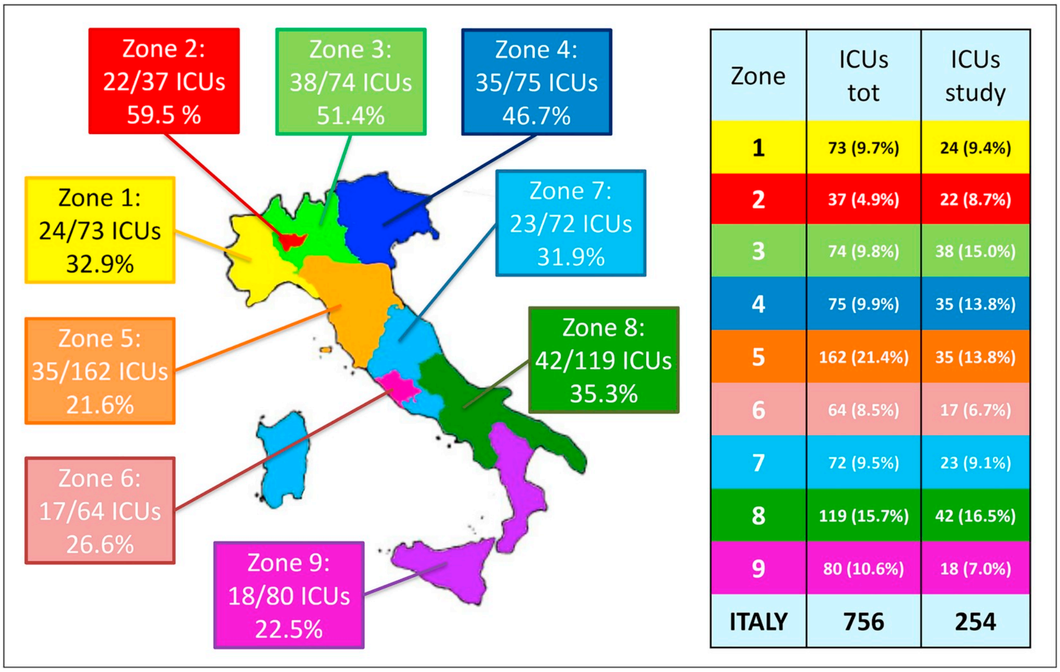
A large number of missing/incomplete data is expected, with as much as 80% of the questionnaires not completed, considering also the difficulties of contacting relatives after 6 months for their diagnosis of PTSD. Assuming, therefore, complete data from 20% of the enrolled family members, and that it will be possible to involve 300 different ICUs in the 3 years of the study, each center has to enroll at least 12 family members in the *before* phase and 24 in the *after* phase. The Supplemental Digital Content gives further explanations of the study head decision about sample size.

### 2.14. The magnitude of cultural changes

The calculations presented in the main text are made on extremely cautious assumptions, and probably the required 2100 questionnaires could be gathered from a much smaller number of ICUs. It must be borne in mind that the calls for participation for the present study attracted many centers not used to doing any kind of scientific research. The study organizers explicitly decided not to exclude anyone, even without requesting some research background from the ICUs, but only the declaration that they were available to participate. This choice is mainly based on awareness of the need for a cultural change: in Italy we think it is still necessary to boost the idea that communication skills are necessary for ICU professionals [42].

ICU staff questionnaires will be distributed at the end of the *before* and *after* phases. They will be considered for the final analysis only if at least 65% of the questionnaires distributed are completed.

One year from the start of data collection (January 2019) an interim analysis is planned, to assess the effectiveness and feasibility of the study, and decide whether the data collection needs to be continued



| Zone | ICUs tot | ICUs study |
|---|---|---|
| **1** | **73 (9.7%)** | **24 (9.4%)** |
| **2** | **37 (4.9%)** | **22 (8.7%)** |
| **3** | **74 (9.8%)** | **38 (15.0%)** |
| **4** | **75 (9.9%)** | **35 (13.8%)** |
| **5** | **162 (21.4%)** | **35 (13.8%)** |
| **6** | **64 (8.5%)** | **17 (6.7%)** |
| **7** | **72 (9.5%)** | **23 (9.1%)** |
| **8** | **119 (15.7%)** | **42 (16.5%)** |
| **9** | **80 (10.6%)** | **18 (7.0%)** |
| **ITALY** | **756** | **254** |

**Fig. 5.** Territorial distribution of Study Zones made according to the telephone area codes and prevalence of the Italian ICUs participating to the *Intensiva 2.0 Project*.

until December 2020, as scheduled. This decision will be made by the "data and safety monitoring board" (DSMB), composed of international experts in intensive care medicine, together with people representing significant roles for the study: a former ICU patient, a relative of an ICU patient, a journalist, and a bioethicist (see Acknowledgements section for the full list).

### *2.15. Enrolling centers: proposals put forward at congresses*

To ensure the widest spread of the proposal to participate in this study, several presentations were made at the most important Italian national congresses from May 2017, with the aim to enroll 300 Italian ICUs. The Call for Centers was directed both to physicians and to nurses, looking for 1–4 multidisciplinary people directly involved in each center. With the endorsement of the three most important Italian societies in the field of Anesthesiology and Intensive Care Medicine (SIAARTI, ANIARTI, AAROI-EMAC), it was possible to reach a very large number of ICUs. Nine zones to organize data gathering and the management of participating ICUs led us to set up a structure among the study investigators, creating nine zones to organize data gathering and the management of participating ICUs. These zones were established according to the national telephone area codes, which reflect comparable numbers of residents.

In each zone, a survey was done of the total number of existing ICUs and the number of ICUs declaring their willingness to participate. This would serve as the basis for seeking new ICUs especially in the less represented zones, to have the most realistic picture of the Italian situation regarding the relationship between ICU staff members and patients' families. (Fig. 5).

### *2.16. Trial status*

As of June 30, 2019, a total of 248 Italian ICUs, evenly spread over the country were interested in participating in the Intensiva 2.0 Project. The first 56 ICUs were matched and randomized in December 2017, and the first 28 started the *before* phase in January 2018. The second randomization process was in June 2018, and 54 ICUs participated, 27 beginning their *before* phase in July 2018. The third randomization process was in November 2018, and 76 ICUs participated, 38 beginning their *before* phase in January 2019. The fourth randomization process was in June 2019, and 62 ICUs participated, 31 beginning their *before* phase in July 2019. These ICUs are described both subdivided in terms of study periods (Supplemental Digital Content – Table S1) and in randomization between the Alpha and Beta groups (Table 2). The group assignment procedure gave two satisfactorily balanced ICU sets.

## 3. Discussion

Compared to other European realities such as Spain or France [43–46], in Italy the need to deal with the communication issue is felt among intensivists, but until now there have been only a few isolated interventions. This study represents the first attempt to involve a substantial number of Italian ICUs in evaluating generalizable materials to improve communication and to set in motion a cultural shift about human relationships in this harsh environment.

After the pilot study in 2012 [15], this larger, randomized controlled trial was designed, to replicate and verify the preliminary results, overcoming some of the limits and testing new strategies to enhance the effects of good communication.

**Table 2**
Description of the two randomized ICU groups.

| Coupling criteria | Characteristic | All randomized ICUs (*N* = 248) | Group Alpha (*N* = 124) | Group Beta (*N* = 124) | *p* value |
|---|---|---|---|---|---|
| | University Hospital – *n* (%) | 65 (26.2) | 29 (23.4) | 36 (29.0) | .386 |
| | Trauma Centre – *n* (%) | 78 (31.5) | 36 (29.0) | 42 (33.9) | .494 |
| 3 | Hospital beds number – median [IQR] | 390 [236–650] | 400 [243–629] | 379 [233–650] | **.968** |
| 2 | ICU type | | | | |
| | General / Mixed ICU – n (%) | 210 (84.7) | 107 (86.3) | 103 (83.1) | **.354** |
| | Post-Operative / Transplantation ICU – *n* (%) | 6 (2.4) | 3 (2.4) | 3 (2.4) | |
| | Neurosurgical ICU – *n* (%) | 13 (5.2) | 3 (2.4) | 10 (8.1) | |
| | Cardiologic ICU – *n* (%) | 9 (3.6) | 5 (4.0) | 4 (3.2) | |
| | Pediatric ICU – *n* (%) | 10 (4.0) | 6 (4.8) | 4 (3.2) | |
| | ICU beds number – *n* [IQR] | 8 [6–10] | 8 [6–10] | 8 [6–11] | .035 |
| | Nurses during night shift – median [IQR] | 4 [3–5] | 3 [3–5] | 4 [3–5] | .298 |
| 2 | Patients / nurse ratio – median [IQR] | 2.3 [2.0–2.6] | 2.2 [2.0–2.5] | 2.3 [2.0–2.7] | **.156** |
| | Physicians during night shift – median [IQR] | 1 [1–1] | 1 [1–1] | 1 [1–2] | .119 |
| | Staff members | | | | |
| | Physicians – median [IQR] | 12 [9–16] | 12 [8–15] | 12 [9–17] | .367 |
| | Medical students and residents – median [IQR] | 0 [0–3] | 0 [0–3] | 0 [0–3] | .590 |
| | Nurses – median [IQR] | 22 [18–30] | 21 [17–30] | 24 [18–30] | .204 |
| | Auxiliary – median [IQR] | 4 [2–6] | 4 [3–5] | 4 [2–6] | .835 |
| | Psychologist in staff – *n* (%) | 30 (12.4) | 13 (10.7) | 17 (14.2) | .712 |
| | Presence of dedicated room for clinical talks with relatives – *n* (%) | 205 (82.7) | 99 (79.8) | 106 (85.5) | .314 |
| | Waiting room – *n* (%) | 203 (81.9) | 95 (76.6) | 108 (87.1) | .047 |
| 1 | Hours of ICU opened to relatives – median [IQR] | 4 [2–7] | 3 [2–7] | 4 [2–8] | **.226** |
| 1 | Use of brochure for relatives – *n* (%) | 136 (54.8) | 72 (58.1) | 64 (51.6) | **.372** |
| 3 | Clinical talks made by the same physician during weekdays – *n* (%) | 108 (43.6) | 55 (44.4) | 53 (42.7) | **.898** |
| | Number of staff members' talking with relatives – median [IQR] | 2 [1–2] | 1 [1–2] | 2 [1–2] | .172 |
| | Physicians talking with relatives – *n* (%) | 233 (100) | 120 (100) | 113 (100) | > .99 |
| | Nurses talking with relatives – *n* (%) | 116 (49.8) | 60 (50.0) | 56 (49.6) | > .99 |
| | Clinical talks made together (physician and nurse) – *n* (%) | 110 (44.5) | 53 (42.7) | 57 (46.3) | .797 |

Comparison between the two randomized groups, regarding the ICUs enrolled during the first three study periods. In the first column, the criteria used to build the couples of ICUs are pointed out, according to their relative importance. In bold, the p values of the comparisons between the criteria used to build groups Alpha and Beta.

### 3.1. The reasons behind the Intensiva 2.0 project

The present study serves to evaluate on a large scale the effectiveness of tools to facilitate communication between health professionals and family members of critical patients. Some innovations were introduced in the light of the findings of the earlier study and the feedback from approximately 30 Italian centers that collaborated on this project between 2013 and 2017. The innovation of communication tools and their effective generalizability will mean they can be proposed on a national scale, and be continuously adapted to the changing needs of patients and their families.

The scientific and cognitive results expected at the end of the Intensiva 2.0 Project are:

1) large-scale evaluation of the effectiveness of communication tools for improving the proper understanding of a prognosis,
2) controlling relatives' anxious-depressive reactions and their post-traumatic stress syndromes,
3) easing the job of ICU workers in the time for communication,
4) creating an Italian network of ICUs to promote *educational research*, not driven by commercial interests, with both a scientific goal of innovation/development, and some educational goals to spread good practice skills; this network – it is hoped – will be maintained beyond the end of the data-collection phase,
5) spreading the habit of contacting critically ill patients and their families even a long time after discharge from the ICU (Outpatient post-ICU follow-up clinic),
6) Evaluation of the prevalence of refusal of tissue/organ donation,
7) A survey about medical claims made by family members,
8) A valuable broad assessment on many aspects of communication between staff members and ICU patients' families, never made before in Italy.

### 3.2. ICU humanization and the aims of educational research

This project aims to exhort ICU personnel to introduce new good habits in their communications with family members. Dissemination of the results in international scientific journals would provide an opportunity to disclose and strengthen communication skills between physicians and intensive care nurses, which has proved essential in health professionals' daily work [42].

The Intensiva 2.0 Project sets out to drive a cultural change in the communicative approach with family members of ICU patients, to create a true partnership – a therapeutic alliance – to foster the appropriate care of patients, correct information, and the psychological wellbeing of family members and healthcare workers. The diffusion of this project will provide an opportunity to spread the *humanization* of intensive care as described in the 'heroic bundle' (www.heroicbundle.org) in many clinical practices.

We believe that the introduction of tools such as web site, brochures, and posters, that explain to family members what the ICU is, how it is structured, and what happens to the patient in this unit, will help them understand better the care provided. Better understanding is probably a protective factor against anxious-depressive reactions and post-traumatic stress syndrome, and can help family members feel less alone and less stressed throughout this highly emotional experience.

Informative material can also be seen as an advantage for health workers: they can convey a better idea of transparency, and inspire confidence in their work. Moreover, many of the most frequently asked questions might find an answer in the Intensiva 2.0 materials, leaving staff to focus on the specific conditions of the patient during their talks, paying more attention to the relationship with the family and their emotional experience. Last, these instruments may boost closer cooperation with families, through their deeper engagement and empowerment. The collected data – together with the shared materials – will be useful in the future as a basis for guidelines for communicating with relatives of critically ill patients.

The new habits acquired during the Intensiva 2.0 Project should be kept up even after the end of the study, in order to maintain the expected benefits. This study would also give all intensivists the chance to create a national-level platform for exchange of ideas; this could have far-reaching consequences for improving the quality of the materials offered. After the evaluation of the effectiveness of these easy, ready to use' tools, they will made freely available for all Italian and worldwide ICUs.

### 3.3. Study limitations

The present study has several important limitations. First, it is essentially based on voluntary participation, since no specific funding was obtained; a small financial contribution from the Italian scientific societies that endorsed the Intensiva 2.0 Project enabled us to print the brochures and posters, and to maintain the server for the two websites (one for families, one for ICU staff and data collection). The study head made a courageous attempt to couple the spread of good clinical practices (which should circulate as widely as possible) with competence on data collection. Many peripheral ICUs have no experience, so can offer no warrantee about the adequacy and timeliness of data gathering. This is why we had to hypothesize completeness of the data in only 20% of the family members enrolled, also bearing mind the difficulties of contacting relatives for the diagnosis of PTSD 6 months after the patient had been discharged from the ICU. This might be an important source of selection bias: mainly the most skilled ICUs for correct and complete data collection may essentially contribute to the results. Moreover, the decision to participate depends on the goodwill of local physicians and nurses. This is an intrinsic study limitation, because they could be more motivated to look for the effectiveness of the intervention.

Second: it was not possible to control the location of the materials and their distribution (posters displayed in the waiting room, or timely dispatch of the emails to present the website), the timing of delivery of the brochures, or the efforts to invite families to visit the website. Third, indications on the topics concerning the study and how to conduct it were formally given to all participating ICUs, but the physicians and nurses did not receive any formal, controlled training. Fourth: the ICU staff members who work and collect data in both phases (*before* and *after*) are the same. They could acquire specific personal skills, extend their expertise, or gain a kind of empowerment with awareness about the study topics during the *before* phase. This unpredictable situation could lead to results not completely due to the planned intervention (brochures/posters/website/email), but due to behavioral changes (training/presentations in the center/customization of brochures).

## 4. Conclusion

The present ongoing Italian randomized, controlled "*educational research*" is designed to test synergistic strategies to foster positive relationships so as to improve communication with family members of critically ill patients, within a series of interventions coming under the heading of the new culture of *ICU humanization*. Results are expected in 2021.

## Availability of data and materials

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

## Funding

The present study did not receive any financial support. The corresponding author, Giovanni Mistraletti, MD, had full access to all the data in the study and had final responsibility for the decision to submit.

He takes responsibility for the integrity of the data and the accuracy of the data analysis.

## Authors' contributions

GM is the principal investigator of the study and responsible for the conception, protocol design, and organization of the study. AM built the electronic system for data gathering. GM, SA, AIM and MGB made the literature search. GM and SDN drafted the figures. GM and GDG designed the posters and revised the brochure for family members. GM, AG and MGB provided statistical guidance, are responsible for calculating the sample size and final statistical analysis. GM and EI are responsible for the website www.intensiva.it changes and contents. GM, EI, and MGB conducted the randomization procedures. MGB, SMP, and GC have final responsibility for ICU pairing and group assignment. GM, SA, MGB wrote the first manuscript draft; AM, DG, EI, SMP, GC revised the draft for important intellectual content. All authors have read and approved the final version and submission of the manuscript to Contemporary Clinical Trials.

## Declaration of competing interest

All the authors and the Intensiva 2.0 investigators declare they have no competing interests.

## Acknowledgements

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## Appendix A. Intensiva 2.0 staff members

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### A.2. Study board members

Massimo Antonelli, Università Cattolica - Policlinico Gemelli, Roma. Davide Chiumello, Università degli Studi di Milano - Ospedale San Paolo, Milano. Giorgio Conti, Università Cattolica - Policlinico Gemelli, Roma. Alberto Giannini, Spedali Civili, Brescia. Massimo Girardis, Università degli Studi di Modena e Reggio - Policlinico di Modena. Gaetano Iapichino, Università degli Studi di Milano – Ospedale San Paolo, Milano. Franco Marinangeli, Università degli Studi dell'Aquila - Ospedale San Salvatore, L'Aquila. Alessandra Palo, Policlinico San Matteo, Pavia. Andrea Pettenazzo, Azienda Ospedaliera - Università di Padova. Luigi Riccioni, Ospedale San Camillo, Roma. Elena Vegni, Università degli Studi di Milano, Ospedale San Paolo, Milano.

### A.3. Data and safety monitoring board

Cristina Ansaloni, wife of an ICU patient, Milano, Italy. Rinaldo Bellomo, University of Melbourne, Australia. Lorenzo Berra, MGH Anesthesia Center for Critical Care Research, Boston, MA, USA. Franco Carli, McGill University, Montreal, QC, Canada. Maurizio Cecconi, Humanitas University, Rozzano (MI), Italy. Lucia Fontanella, former ICU patient, Università degli Studi di Torino, Italy. Roberto Malacrida, Ospedale di Bellinzona, Switzerland. Roberto Satolli, intensivist, cardiologist, and health communication journalist, Milan, Italy.

## Appendix B. Supplementary data

Study materials

- Homepage of www.intensiva.it (1x)
- Brochure (12 pages)
- Posters (8x)
- Signboard for ICU door (1x)
- Homepage of http://dati.intensiva.it (1x)
- Study CRFs (complete Italian version)

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2019.105847.

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