

## Supplemental Data

Supplement to: Johan H. Vlake, Jasper van Bommel, Evert-Jan Wils, Tim I.M. Korevaar, Merel E. Hellemons, Eva Klijn, Anna F.C. Schut, Joost A.M. Labout, Marten P. van Bavel, Margo M.C. van Mol, Diederik Gommers, Michel E. van Genderen. Virtual reality for relatives of ICU patients to improve psychological sequelae: study protocol for a multicentre, randomized controlled trial.

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**Supplementary data 1.** Translation of the video script for the ICU-VR-F intervention.

**Scene 1.** Introduction by an ICU physician and a nurse.

*Setting: The ICU physician and nurse are placed in front of the ICU.*

**ICU physician:** Hello, welcome to this virtual environment. My name is '**name physician**', one of the physicians in this ICU.

**ICU nurse:** Hello, I am '**name nurse**', one of the nurses in this ICU.

**ICU physician:** You receive this information because your relative has been admitted to the ICU. In this virtual environment, you will experience different facets of an ICU treatment, and receive explanation about the treatment in an Intensive Care Unit.

**ICU nurse:** We will join you during this experience, but we will first lay you down on an ICU bed.

*Setting: The relative will be virtually installed on an ICU bed during a fade in-fade out.*

**ICU nurse:** We will now bring you to an ICU room.

*Setting: The ICU physician and ICU nurse will bring the relative to one of the ICU rooms while walking over the intensive care department.*

**Voice-over:** Intensive care means intensive and special care for critically ill patients, where the most important vital functions, such as the respiratory rate, oxygen saturation, and heart rate, can be monitored and supported, if needed. Therefore, this department is different from other departments. The intensive care department consists of several one-patient ICU rooms and a post for nurses located in the middle of the department. In an ICU room, circumstances and materials are available to offer critically ill patients the optimal treatment. Moreover, the chances of hospital acquired infections and medication failures are minimal, and a quiet environment is provided. If you look around, you'll see the intensive care department. At the nurse post, nurses are present throughout the day, as are monitors. Nurses can also monitor patients physically through the windows of the room, which allows nurses to be able to continuously keep an eye on your relative.

*Setting: The relative arrives at the ICU room, and the ICU physician and ICU nurse place the relative on the bed in the ICU room.*

**ICU physician:** We are now entering an ICU room. Here, you'll receive an explanation about intensive care treatment. We will first explain the devices in the room, which are placed next to you. We will now leave the room and will come back after the explanation.

*Setting: The ICU physician and ICU nurse will leave the room.*

**Scene 2.** Explanation of the devices and alarm noises.

**Voice-over:** There are several devices next to you, such as a monitor, medication pumps and a mechanical ventilator; look around you. These devices are needed to monitor your relative. Each device has its own functions and alarm noise. We will now explain these to you.

*Setting: The surveillance monitor is outlined.*

**Voice-over:** When you look to your left, you'll see the surveillance monitor.

*Setting: A white arrow appears that points from the surveillance monitor to an explanation window in front of the relative, where the surveillance monitor is animated.*

**Voice-over:** When you look forward again, we will explain the function of the surveillance monitor. The surveillance monitor monitors your relative's heart rate, blood pressure, respiratory rate, and oxygen saturation. If, for instance, your relative's blood pressure is too low, the following alarm signal is produced.

<ALARM SIGNAL SURVEILLANCE MONITOR>

*Setting: The explanation window in front of the relative disappears. The medication pumps are outlined.*

**Voice-over:** If you look to your right, you'll see the medication pumps.

*Setting: A white arrow appears that points from the medication pumps to an explanation window in front of the relative, where the medication pumps are animated.*

**Voice-over:** These pumps are used to give medication. When you hear the following sound,  
<ALARM SIGNAL MEDICATION PUMPS>  
the nurse is warned that your relative's medication is almost empty.

*Setting: The explanation about medication pumps disappears, and an animation appears in the explanation window explaining intubation and mechanical ventilation.*

**Voice-over:** Because your relative was critically ill, we can decide to support your relative's breathing. This was done to maintain the appropriate amount of oxygen in your relative's body. To support the breathing, we inserted a tracheal tube through the mouth into the trachea. Because this procedure is often uncomfortable, your relative will be sedated during the insertion of the tube. At the end of the tube, there is a small air balloon, which is filled with air. This balloon prevents the leakage of oxygen and the contents of the stomach from entering the lungs. Due to the placement of the tube between the vocal cords, patients cannot talk when they are intubated. When the lungs have sufficiently recovered, the tracheal tube can be removed. The tracheal tube is frequently cleaned by suctioning the tube. Hereby, mucus will be removed to prevent infections. Sometimes, it will be enough to do this once, but this has to be repeated often.

*Setting: The explanation window disappears. The mechanical ventilator is outlined.*

**Voice-over:** If you look to your left, you'll see the mechanical ventilator.

*Setting: A white arrow appears that points from the mechanical ventilator to an explanation window in front of the relative, where the mechanical ventilated is animated.*

**Voice-over:** When you look in front of you, we will give you a further explanation about the mechanical ventilator. The mechanical ventilator supports your relative's breathing. If you hear the following sound,  
<ALARM SIGNAL MECHANICAL VENTILATOR>  
the nurse is warned.

*Setting: The animation of the mechanical ventilator disappears, and the explanation about prone positioning is animated in the explanation window.*

**Voice-over:** As a consequence of several diseases, including coronavirus, the alveoli and pulmonary vessels can partially close, resulting in the body being unable to absorb sufficient oxygen. There are relatively more alveoli in the back of the lungs. In the occasion mechanical ventilation in a normal position is no longer effective, it can be decided to ventilate patients in the prone position or laying on their stomach. The alveoli and pulmonary vessels in the back of the lungs are thereby better ventilated, hopefully resulting in better absorption of oxygen. Often, there is an immediate improvement in the mechanical ventilation conditions after prone positioning. To prevent pressure marks on the face, the eyes are protected and the head is placed in a position to the side. Over time, the positive effect of this prone position diminishes, and the patient is again placed on their back. Therefore, it is often decided to ventilate in prone positioning for several hours and thereafter again on the back for several hours. Because prone positioning can be uncomfortable, patients are sedated.

**Scene 3.** Explanation concerning the drips, infusions and gastric tube.

*Setting: The explanation window disappears, and the ICU physician appears.*

**ICU physician:** The different devices, the mechanical ventilator and the alarm signals have just been explained to you. Now, you will receive an explanation concerning the drips, infusions and gastric tube.

*Setting: The ICU physician disappears.*

**Voice-over:** IV drips and lines are necessary not only to administer medication and fluids but also to continuously monitor the blood pressure.

*Setting: The explanation window appears, and the function of a peripheral drip is explained using an animation.*

**Voice-over:** This is an 'ordinary' IV drip, also called a peripheral IV drip. This is usually inserted into a vessel in the forearm, but sometimes, it is placed in the foot. The nurse can administer medication or fluid through this drip. Because these peripheral vessels are thin, not every medication can be administered through the veins.

*Setting: Explanation of a central line is explained using an animation.*

**Voice-over:** Here, you see a central line. This is a thick IV drip that is inserted into a large blood vessel, often in the neck or groin. The insertion of such a line will be performed in a sterile manner; therefore, a blue cloth is stretched over your relative's head. Working in a sterile field minimises the risk of infection. The main reason to insert a central line is to administer medications that cannot be administered through ordinary IV drips. Nutrition can also be directly administered to the blood stream through a central line.

*Setting: Explanation of an arterial line is explained using an animation.*

**Voice-over:** This is an arterial line. This is an IV drip that is placed directly into an artery, so blood pressure can continuously be monitored. It is also used to take blood samples. Without such a line, blood samples may have to be taken too often.

*Setting: Explanation about a gastric tube is given using an animation.*

**Voice-over:** A gastric tube is a tube that is placed through the nose or mouth through the oesophagus into the stomach. The tube is usually to administer tube feedings. It can also be used to administer medications.

*Setting: The tracheotomy procedure is explained using an animation.*

**Voice-over:**

When patients are mechanically ventilated for a prolonged period of time, they sometimes receive a tracheotomy. During a tracheotomy procedure, a tube, also known as a cannula, is placed in the trachea through the neck. This cannula replaces the ventilation tube, which is inserted through the mouth. There are several reasons to perform a tracheotomy, but the most important one is long-term mechanical ventilation. The patient must be slowly and gradually weaned off mechanical ventilation. Tracheotomy placement is often conducted in the ICU. The cannula is inserted just above the sternum through an incision in the trachea. The end of the tube can be inflated to prevent air leakage. Because the air flows through the cannula to the lungs and no air passes the vocal cords, patients initially cannot speak when they have a tracheotomy. However, the tracheal cannula can be closed using a speaking valve, whereby the end of the cannula is deflated; as a result, air will flow through the vocal cords making it possible to speak. The tracheostomy will be removed when a patient has sufficient strength to breath on their own and can cough up sputum properly.



**Scene 4.** Explanation about the treatment team and their responsibilities.

*Setting: The explanation window disappears, and an ICU physician, nurse and resident enter the room.*

**Voice-over:** In the ICU, your relative is treated 24 hours per day by a treatment team. Therefore, there are many people working in the ICU. The medical treatment team that is primarily responsible for your relative's treatment includes the ICU physician, the ICU resident and the ICU nurse.

**ICU physician:** My fellow ICU physicians and I, the intensivists, are specialised in the treatment of critically ill patients. Every morning, afternoon and evening, there is a meeting with the treatment team taking care of your relative to discuss how you are doing. This will take place in your relative's room.

**ICU resident:** Hello, my name is '**name resident**', I am a resident in the ICU. This means I am being trained to become an ICU physician. Together with my fellow residents, I am responsible for the daily medical care for your relative. Hereby, we are always supported by the ICU physicians.

**ICU nurse:** My fellow ICU nurses and I will look after your relative, monitor your relative continuously and are trained to operate the devices for your treatment. Your relative will be taken care of by the same nurse every shift.

*Setting: The treatment team leaves the room.*

**Scene 5. Outro**

*Setting: The explanation window disappears and the ICU physician and nurse re-enter the room.*

**ICU physician:** We hope you now have a better understanding of the treatment your relative received in the ICU. This is the end of this video, you can remove the VR glasses.

## Supplementary Data 2. Translation of the information for participants and informed consent form.

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## Participant information about participation in medical research.

### Virtual Reality for family members / relatives of patients admitted to the ICU.

*Official title: Intensive Care Unit specific Virtual Reality for family members (ICU-VR-F) of patients in the ICU.*

#### Introduction

Dear sir, madam,

Using this letter, we would like to inquire whether you are interested in participation in medical research. Participation is on a voluntary basis. You have received this letter because your family member or relative has been admitted to the Intensive Care Unit (ICU) of the Erasmus MC, Franciscus Gasthuis & Vlietland, Ikazia hospital or Maasstad hospital.

In this letter, we will inform you about the nature of the study, what participation means, and what the benefits and disadvantages are of participation. Would you like to carefully read the entire letter prior to deciding whether you want to participate? If you are willing to participate, you can fill in and sign the informed consent form, which can be found on the last page of this letter.

#### Ask questions

You can use the information provided in this letter to make your decision. Besides, we would like to encourage you to:

- Ask questions to the investigator who has provided you with this information.
- Talk about participation in this study with your partner, family, or friends.
- Ask questions to the independent expert, [REDACTED]
- Read the information provided on [www.rijksoverheid.nl/mensenonderzoek](http://www.rijksoverheid.nl/mensenonderzoek).

#### 1. General information

This study was initiated by the Erasmus MC. We will refer to the Erasmus MC as the sponsor. Investigators, which can be personified by doctors, nurses and student-researchers, conduct the study in several hospitals, namely the Erasmus MC, the Franciscus Gasthuis & Vlietland, the Ikazia hospital, and the Maasstad hospital, all in Rotterdam.

For this research, we have a required sample size of 160 participants. The medical ethics committee of the Erasmus MC has approved this study.

#### 2. Objectives of the study.

In the current study, we want to study whether information provision using an Intensive Care Unit-specific Virtual Reality intervention for Family Members, ICU-VR-F, can effectively mitigate psychological impairments after ICU treatment of a loved one. Additionally, we will study whether ICU-VR-F helps family members/relatives understand the environment and treatment in the ICU, and whether ICU-VR-F can attribute to the quality of life of relatives of former ICU patients.

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To study this, we will compare family members/relatives who do not receive ICU-VR-F, the control group, with family members/relatives who do receive ICU-VR-F, the intervention group.

ICU-VR-F is an information film about the Intensive Care Unit which can be watched using virtual reality. Virtual reality, or VR, represents a virtual or apparent reality. ICU-VR-F lasts approximately 14 minutes. During ICU-VR-F, you are given explanation about several facets of the ICU environment and treatment. During this explanation, you will be laid down in an ICU bed. You can always interrupt ICU-VR-F. In the latter case, you may decide to continue watching ICU-VR-F later on, or to not continue watching ICU-VR-F.

### 3. Background of the study

An Intensive Care Unit treatment of a family member or relative in the ICU can be a stressful experience. It has been demonstrated that a considerable part of the family members/relatives of ICU patients develop psychological impairments in the period after the patient's ICU treatment. These impairments can comprise symptoms of a post-traumatic stress disorder (PTSD), anxiety disorder, or a depression. Additionally, family members/relative can experience a complicated grief in the unfortunate event of a patient deceasing in the ICU. It is known that proper information provision can help reducing or preventing the development of such complaints.

### 4. Progress of the study

*How long will participation last?*

Are you participating in this study? Participation will last until six months after your family member's/relative's discharge from the ICU.

*Step 1: Are you suitable for participation?*

We will first examine whether you are suitable for participation. All family members/relatives of patient admitted to ICU, of whom the doctors expect that they will be treated there for at least 72 hours, are eligible for participation. Because the explanation in ICU-VR-F is given in Dutch, and because the questionnaires for this study are written in Dutch, it is important that you have sufficient understanding of the Dutch language. You will also need to be in possession of a smartphone, tablet, or laptop which is compatible to use the VR function in YouTube, as you are given the opportunity to watch the intervention at home as well.

In the unfortunate event of your family member/relative deceasing in the ICU, we will ask you to reconsider participation. We will, of course, understand if you no longer wish to participate.

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### *Step 2: Informed Consent*

Within two days after your family member's/relative's ICU admission, the investigator has given information about the study, either by telephone or in person, and has sent you this letter. We ask you to carefully and thoroughly read this letter, and consider participation.

If you decide to participate in this study, you can sign the informed consent form which can be found on the last page of this letter. By signing the informed consent form, you confirm that you have been given enough information about the study, that you have been given the opportunity to ask questions, and, based on this information, wish to participate in the study.

### *Step 3: Randomization*

Participants in this study will be randomly assigned to **two groups**. This randomization, comparable with a lottery, decides to which group you are assigned. The investigator or doctor **does not have any influence** on the outcome of the randomization.

The two groups are as following:

- 1) The control group. Participants assigned to this group will not receive ICU-VR during the study period.
- 2) The intervention group. Participants assigned to this group will receive ICU-VR-F once in the hospital and will be provided with an access link and cardboard VR glasses, making them able to watch ICU-VR-F at home as many times as wanted. If you are not allowed to visit the hospital due to COVID-19 regulations, you will only receive an access link and the cardboard VR glasses to watch ICU-VR-F at home.

Randomization will be conducted immediately after your decision to participate in the study.

### *Step 4a. Participants in the control group*

Participants, who are assigned to the control group, will receive 'care as usual'. This means that nothing will change with regard to how family members/relatives are normally treated in the ICU.

We will however ask you to fill out several questionnaires. You will receive the first one at the time you decide to participate in the study. With this first questionnaire, we aim to determine your psychological state and quality of life prior to the hospitalization of your family member/relative and how you have experienced the ICU admission of your family member/relative. Completing this questionnaire will take approximately **30 minutes**.

### *Step 4b. Participants in the intervention group*

Participants, who are assigned to the intervention group, will receive ICU-VR-F once within the hospital, if they are allowed to visit the hospital with regard to COVID-19 regulations. This will take place as soon as possible after you have decided to participate. To offer ICU-VR-F, we will use our virtual reality glasses. In **Figure 1** you will find a picture of the VR glasses on the left, and a person using the VR glasses on the right. Before you will receive ICU-VR-F, you will be explained how to use the VR glasses, and how to behave in the virtual environment. After you have received ICU-VR-F once with our VR glasses, you

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will receive an access link and cardboard VR glasses. Using these, you can use ICU-VR-F again at home, as many times as wanted. You are also free to offer ICU-VR-F to friends or family. Family members/relatives, who are due to COVID-19 regulations not allowed to visit the hospital, will only receive the access link and cardboard VR glasses to watch ICU-VR-F at home.

Also, you will be asked to fill out several questionnaires. You will receive the first one at the time you decide to participate in the study. With this first questionnaire, we aim to determine your psychological state and quality of life prior to the hospitalization of your family member/relative and how you have experienced the ICU admission of your family member/relative. Completing this questionnaire will take approximately **30 minutes**.



**Figure 1.** Picture of the VR glasses and its controller which will be used when offering ICU-VR-F in the hospital (left). On the right, you see a person using the VR glasses. VR glasses use light that is safe for your eyes. You can keep your own glasses on when using these VR glasses.

*Step 5. After your family member's/relative's discharge from the ICU.*

After your family member/relative has been discharged from the ICU, we will send the second questionnaire. Follow-up questionnaires will thereafter be sent after 1 month, 3 months and 6 months. Using these questionnaires, we will measure your psychological state and quality of life. Completing these questionnaires will take approximately **30 minutes** per time.

After you have completed the last questionnaire, which will be sent six months after your family member's/relative's ICU discharge, you will be finished with the study.

## 5. Which commitments do you make when participating?

We would like this study to be conducted as intended. Therefore, we ask you to honour the following commitments:

- You watch ICU-VR-F for the first time in the hospital in the way the investigator has explained, if you are allowed to visit the hospital.
- If you are not allowed to visit the hospital, you will watch ICU-VR-F at least once at home using the access link and cardboard VR glasses.
- You cannot participate in another medical study, unless the investigator has granted you permission. Permission can only be given if the other study will not confound the outcomes of this study.

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- You complete the questionnaire at the described time-points. If you are unable to fill out the questionnaire by yourself, you may ask a family member or friend to help. If there are no family members or friends available, you may ask the investigator to complete the questionnaire by telephone.
- You contact the investigator in the following situations:
  - You no longer wish to participate in the study
  - Your phone number, home address, or e-mail address changes

## 6. Safety considerations

In previous studies, we have demonstrated the use of an Intensive Care Unit-specific Virtual Reality intervention is safe in healthy volunteers and in patients. Virtual reality can however cause short-term complaints, such as nausea, dizziness, or a spinning feeling during its use. These complaints are commonly mild or nature, lasts for several minutes, and will resolve spontaneously. If the complaints do not resolve, you can contact the investigator. You will find his phone number on page 9 of this letter.

## 7. Benefits and disadvantages of participation

Participation in this study can have benefits and disadvantages. We will describe these here. Consider these when considering participation, and talk about them with others.

A possible benefit of participation in this study is that receiving ICU-VR-F may improve understanding of the ICU and thereby reduce psychological complaints and improve quality of life after your relative's/family member's ICU treatment. This is however **not certain and will be studied in this study**.

The most important disadvantage of participation in this study, it that completing the questionnaire will take a considerable amount of time. Also, you have to honour the commitments as described in paragraph 5, and you may experience short-lasting complaints during ICU-VR-F, as described in paragraph 6.

*If you don't want to participate?*

You are the one to decide whether or not you want to participate. Do you not want to participate? This is no problem, and nothing will change with regard to how you or your family member/relative is treated in the ICU.



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## 8. End of the study.

The investigator will inform you when there is new information about the study, which is important for you as participant. The investigator will then ask you if you want to continue your participation.

In the following situations, the study will end for you:

- If you have completed the last questionnaire, which is sent to you six months after your family member's/relative's discharge from the ICU.
- If you decide that you no longer wishes to participate. You can always terminate your participation. We ask you to immediately inform the investigator if you wish to no longer participate. You don't have to give a reason why you wish to no longer participate. Discontinuation of your participation will never have consequences for you or your family member/relative.
- If one of the following organization decide that the study should be terminated:
  - The Erasmus MC (sponsor)
  - The governance
  - The medical ethics committee which approved the study.

*What happens if you decide that you no longer wishes to participate*

The investigators may use your data which is collected until the moment you decide to discontinue your participation. If you want, data that is collected from you can be deleted. You can request this by the investigator.

The entire study will be ended if all participants have completed their last questionnaire.

## 9. After the study.

Approximately 6 months after you have completed your last questionnaire, the investigator will inform you about the most important findings of the study.

## 10. Usage of your data

If you participate in this study, you also consent to collect, use, and store your data.

*Which data do we store?*

We will store the following data:

- Your name
- Your gender
- Your (e-mail) address
- Your date of birth
- Data regarding your psychological well-being, extracted from the questionnaires
- Data which is collected during the study
- Treatment-related characteristics of your family member/relative.

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*Why do we collect, use, and store your data?*

We collect, store, and use your data to answer the research questions of this study and to be able to publish the results.

*How do we protect your privacy?*

To protect your privacy, a code will be assigned to all your data. This code will be the only identifier for your data. The key, which makes it possible to link the code with you, will be stored in a safe place in the Intensive Care Unit where your family member/relative is treated. When we process your data, we will only use this code. In reports or publications about the study, we will ensure no participants can be identified based on the data provided.

*Who have access to you data?*

There are persons can be given permission to access the data without codes. These are persons who monitor whether the study is conducted properly and reliably, and according to all regulations.

Persons who will be given permission are:

- A monitor who is an employee of the Erasmus MC
- National supervisory authorities.

These persons will treat you data confidentially. By consenting to participate in this study, you also give permission that your data can be monitored by these.

*For how long will be store your data?*

We will store your data for 15 years in the hospital.

*Can you withdraw your consent for the use of your data?*

You can always withdraw your consent for the use of you data. However, if you withdraw your consent, and the investigators have already collected data for the study, the investigator is allowed to use the data collected until the consent was withdrawn.

*Would you like to know more about your privacy?*

- Do you want to know more about your rights with regard to the use of your data? You can take a look at [www.autoriteitpersoonsgegevens.nl](http://www.autoriteitpersoonsgegevens.nl).
- Do you have any questions about your right? Or do you have complaints about the use of your data? You may contact the person who is responsible to the collection of your data. For this study, this will be the principle investigator, of whom the contact details can be found on page 9 of this letter.
- If you have complaints about the use of your data, we would recommend to first discuss these with the investigators of the study. You can also contact the Data Protection Officer of the hospital where you relative was treated. Their contact details are stated below. You can also file a complaint by the Authority of Personal Data.

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**Erasmus MC:**

E-mail: [REDACTED]

Phone number: [REDACTED]

**Franciscus Gasthuis & Vlietland**

[REDACTED]

E-mail: [REDACTED]

Phone number: [REDACTED]

**Ikazia hospital:**

E-mail: [REDACTED]

Phone number: [REDACTED]

**Maasstad hospital:**

Legal Affairs Department / Data Protection Officer

Postal address: [REDACTED]

Phone number: [REDACTED]

*Where to find more information about this study?*

You may find more information about this study on [www.TrialRegister.nl](http://www.TrialRegister.nl). When the study has ended, you may find a summary of the results of the study on this site. You can find the study by searching for 'ICU-VR for Family members' (number: NL73670.078.20).

## 11. Financial compensation for participation in this study.

Participation in this study is free of charge. You will neither receive any compensation for participation in this study, also no travel or expense reimbursement.

## 12. Insurance.

The Erasmus MC has taken out an insurance for all participants in this study. The insurance will pay for damage due to participation in the study. This comprises damage during the study, or within 4 years after participation in the study. If you need a reimbursement, you should report damage within 4 years at the insurance company.

Have you suffered damage due to your participation in the study? You should report this to the insurer:

The contact details of the study's insurer are:

Name: [REDACTED]

Address: [REDACTED]  
[REDACTED]

Phone number: [REDACTED]

E-mail: [REDACTED]

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The insurance will cover a maximum of € 650.000 per participant, a maximum of € 5.000.000 for the entire study and € 7.500.000 per year for all studies initiated by the Erasmus MC.

Pay attention: the insurance will not cover the following damage:

- Damage due to a risk about which we informed you in this letter. However, if the damage turns out to be higher than we anticipated, or if the risk was very low, the insurance will cover this damage.
- Damage to your health which would have also developed if you hadn't participated in the study.
- Damage which is a direct consequence of not following given instructions or recommendations of the study team.
- Damage to the health of your children or grandchildren.
- Damage due to a treatment strategy which is already evidence based, or due to a study investigated an evidence-based treatment strategy.

These provisions are set out in the 'Compulsory insurance for medical research involving humans 2015 Decree'. This decision can be found in the Laws of the Government (<https://wetten.overheid.nl>).

### 13. Informing the general practitioner

As participation to this study is not expected to have any negative consequences for your health, or the health of your family members/relatives, we will **not** inform you general practitioner about your participation in this study. You are however free to tell your general practitioner yourself, and he/she can contact the study team for questions.

### 14. Do you have questions?

Questions about the study can be asked to the study team. The contact details of the study team are stated below. Would you like to be advised by someone who is not involved in the study team? You can then contact dr. [REDACTED] (e-mail: [REDACTED], phone number: [REDACTED]). He is an independent expert of the study, and has thereby the knowledge to answer your questions and give you advice, but is not involved in the study.

If you have complaints about the study, we would recommend to first discuss these with the investigators of the study or the doctor who is treating your relative. Do you prefer to talk to somebody else? You may contact the complaints officer or complaints committee of your hospital, or the Authority of Personal Data.

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The treatment team involves:

- [REDACTED], executive investigator, primary contact for this study  
E-mail: [REDACTED]  
Phone number: [REDACTED]
- [REDACTED], coordinating investigator  
E-mail: [REDACTED]  
Phone number: [REDACTED]
- [REDACTED], principle investigator Erasmus MC  
E-mail: [REDACTED]  
Phone number: [REDACTED]  
Intensive Care Unit: [REDACTED]  
Hospital: [REDACTED]
- [REDACTED], principle investigator Franciscus Gasthuis & Vlietland  
E-mail: [REDACTED]  
Phone number: [REDACTED]  
Intensive Care Unit: [REDACTED]  
Hospital: [REDACTED]
- [REDACTED], principle investigator Ikazia hospital  
E-mail: [REDACTED]  
Phone number: [REDACTED]  
Intensive Care Unit: [REDACTED]  
Hospital: [REDACTED]
- [REDACTED], principle investigator Maasstad hospital  
E-mail: [REDACTED]  
Phone number: [REDACTED]  
Intensive Care Unit: [REDACTED]  
Hospital: [REDACTED]

## 15. Consent for this study.

You should first think about participating in this study. Therefore, you should tell the investigator whether you have understood the provided information and whether or not you would like to participate. If you want to participate, you will be asked to fill out and sign the informed consent form on the last page of this letter. Both you as the investigator will receive a copy of the signed version of the informed consent form.

Thank you for your time.

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## Informed consent form for participants

Related to: *'Virtual Reality for family members/relatives of patients in the Intensive Care Unit.'*

- I have read the information letter. I have been given the opportunity to ask additional questions, and my questions are answered sufficiently. I have had enough time to consider participation.
- I know that participation is on a voluntary basis. I also know that I can always decide to not participate or to stop participation. I do not have to give any reason if I decide not to participate or to stop participation..
- I give consent to the investigators to collect and use my data. The investigators will only collect and use data to answer the research question of the study.
- I am aware that there are persons who can be granted permission to access my data to monitor the study. I give consent to these persons to access my data.
- I do  / do not  (**please indicate you choice**) give permission to contact me after this study to ask if I am interested to participate in another, related study.
- I want to participate in the study.

My name is (participant): .....

Signature: .....

Date: \_\_ / \_\_ / \_\_

I declare that I have fully informed this participant about the current study.

If new insights will be obtained about the study, which could influence the participant's decision to participate in the current study, I will timely inform the participant.

Name investigator (or its representative):.....

Signature:.....

Date: \_\_ / \_\_ / \_\_

*The participant will receive a complete copy of the information letter, including a (copy of the) signed version of the informed consent form.*

### Supplementary data 3. Translation of the self-composed questionnaires.

**Questionnaire about your experiences in the Intensive Care Unit.**

We would like to know how you have experienced the information provision regarding the ICU admission or your relative.

Therefore, we would like to ask you to answer the following questions as honest as possible.

Are you unsure which of the answers to choose? Choose the answer that applies most to your situation.

- 1) Prior to your relative's current ICU admission, do you have other experiences with an ICU admission?

*Multiple answers can be given.*

- Yes, I have previously been admitted to an ICU myself.  
 Yes, my relative has also been treated in an ICU previously.  
 Yes, one of my other relatives have been treated in an ICU previously.  
 No, I have no other experiences with an ICU admission.

- 2) Was the ICU admission of your relatives unexpected for you?

- Yes  
 No

- 3) What is the current situation of your relative?

- My relative is still hospitalized or in another care institution  
 My relative is at home  
 My relative has passed away  
 Other, namely: \_\_\_\_\_

The following questions are about your experiences with the care and support of relatives in the Intensive Care Unit. When the term "care providers" is used in a question, this refers to all care providers who work in the Intensive Care Unit. Some questions relate to one specific care provider, for example the nurse. In that case, this is mentioned in the question.

***Reception and guidance***

The following questions are about your first visit to your relative in the Intensive Care Unit.

- 4) During your first visit to your relative in the Intensive Care Unit, has there been given attention to you as being a relative?

- No, not at all  
 A little  
 Quite much  
 Yes, very much

- 5) During your first visit to your relative in the Intensive Care Unit, did you receive information about your relative's condition?

- No, not at all  
 A little  
 Quite much  
 Yes, very much

- 6) Did you receive timely information about your relative's condition during your first visit?

- No  
 Yes



- 7) Were you prepared for your first confrontation with your relative in the Intensive Care Unit?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 8) Have you received general information about the ICU department (about telephone numbers, visiting hours and work flow in the ICU)?
- No
  - Yes
- 9) Did you receive information about how you could contribute to the care, comfort and well-being of your relative?
- No
  - Yes
- 10) Were you given the opportunity to contribute to the care, comfort and well-being of your relative?
- No
  - Yes
- 11) Were you kept informed of your relative's condition?
- No
  - Yes
- 12) Did you feel heard in decision-making about your relative's medical treatment?
- Never
  - Sometimes
  - Usually
  - Always
- 13) Has there been given attention to your needs?
- No
  - Yes

***Explanation in the Intensive Care Unit***

The following questions are about the information you received in the Intensive Care Unit.

- 14) Have you received explanation about the treatment of your relative in the Intensive Care Unit?
- No, not at all
  - A little
  - Quite much
  - Yes, totally
- 15) Have you received explanation about the different devices in the Intensive Care Unit?
- No, not at all
  - A little
  - Quite much
  - Yes, very much

- 16) Did you receive explanation about the different alarm sounds in the Intensive Care Unit?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 17) Have you received explanation about mechanical ventilation of your relative?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 18) Have you been given explanation about the different IV drips and lines used for your relative and their usefulness?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 19) Were you given explanation of the treatment team that cared for your relative, and their corresponding duties?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 20) Have you received explanation of the different transition times/consultation times of the care providers?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 21) In general, was the information you received relevant/useful?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 22) Are you, in general, satisfied with the completeness of the information you have received?
- No, not at all
  - A little
  - Quite much
  - Yes, very much
- 23) Was the information and explanation you received in general understandable for you?
- No, not at all
  - A little
  - Quite much
  - Yes, very much

**Additional help**

You may have been offered additional help for you as a relative. This concerns practical or emotional support from social workers, spiritual counsellors and/or psychologists. The following questions will ask you about this help.

24) Was there attention to your needs as a relative?

- No, not at all
- A little
- Quite much
- Yes, very much

25) Have you been informed about keeping a diary during the ICU period?

- Yes
- No

If yes; did you keep a diary about your relative's Intensive Care period?

- Yes
- No

26) Have you been informed about social work, spiritual care or psychological help for yourself?

*Multiple answers can be given.*

- No
- Yes, about social work
- Yes, about spiritual care
- Yes, about psychological help

27) Have you been in contact with the social worker, chaplain or psychologist in the hospital?

*Multiple answers can be given.*

- Yes, with the social worker
- Yes, with the spiritual caretaker
- Oh yes, with the psychologist
- No

If yes; was the social worker, spiritual counsellor or psychologist easily accessible for you?

- Yes
- No

If yes; did you experience the contact with the social worker, spiritual counsellor or psychologist as supportive?

- Yes
- No

28) Were you informed about the possibility to talk to a care provider about your experiences, after your relative's discharge from the ICU or the death of your relative in the ICU?

- Yes
- No

29) Did the visiting hours match your needs?

- No, not at all
- A little
- Quite much
- Yes, very much

**Contact with healthcare staff**

30) Were you kept informed of your relative's situation by the same doctor during your relative's Intensive Care Unit admission?

No, often by different doctors

Yes, mostly by the same doctors, but also by other doctors.

Yes, almost always by the same doctor, but sometimes by a different doctor.

Yes, always by the same doctor.

31) Were you kept informed of your relative's situation by the same nurses during your relative's Intensive Care Unit admission?

No, often by different nurses

Yes, mostly by the same nurse, but also by other nurses.

Yes, almost always by the same nurse, but sometimes by a nurse.

Yes, always by the same nurse.

32) How often have you had contact by telephone with a doctor about your nurse's condition?  
 \_\_\_\_ times a week

33) How often have you had contact by telephone with a doctor about your nurse's condition?  
 \_\_\_\_ times a week

34) How often did you have contact in person with a doctor about your relative in person?  
 \_\_\_\_ times a week

35) How often did you have contact in person with a nurse about your relative?  
 \_\_\_\_ times a week

**General judgment**

We would like to ask you to indicate below what rating you would give various aspects of Intensive Care Unit. 0 means that you were very unsatisfied, 10 means that it couldn't be better.

36) What number from 0 to 10 (where 0 is very bad and 10 is very good) do you give for the information you received in the Intensive Care Unit?

0	1	2	3	4	5	6	7	8	9	10
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

37) Which number from 0 to 10 (where 0 is very bad and 10 is very good) do you give for the explanation about the treatment and the environment of the Intensive Care Unit?

0	1	2	3	4	5	6	7	8	9	10
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

38) What number from 0 to 10 (where 0 is very bad and 10 is very good) do you give the doctors in the ICU for their way of communicating?

0	1	2	3	4	5	6	7	8	9	10
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

39) On a scale from 0 to 10 (where 0 is very bad and 10 is very good), what number do you give the nurses in the ICU for their way of communicating?

0	1	2	3	4	5	6	7	8	9	10
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

40) What number from 0 to 10 (where 0 is very bad and 10 is very good) do you give the care and guidance of relatives in the ICU?

0	1	2	3	4	5	6	7	8	9	10
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Questions about your perspectives on the ICU-VR-F intervention.**

We are interested in how you experienced receiving information about the Intensive Care Unit admission and the Intensive Care Unit environment through Virtual Reality. That is why we would like to ask you to answer the questions below as honestly as possible.

1) I liked to receive explanation about the Intensive Care Unit treatment of my relative in this way

- Not at all
- Almost not
- Neutral
- A little
- Very much

2) Virtual Reality is a nice way to obtain information for me.

- Not at all
- Almost not
- Neutral
- A little
- Very much

3) For me, Virtual Reality is a better way of obtaining information than an information folder.

- Not at all
- Almost not
- Neutral
- A little
- Very much

4) For me, Virtual Reality is a better way of obtaining information than a 'normal' video

- Not at all
- Almost not
- Neutral
- A little
- Very much

5) The Virtual Reality information film has ensured that I understand the treatment of my relative in the Intensive Care Unit.

- Not at all
- Almost not
- Neutral
- A little
- Very much

6) The Virtual Reality information film has helped me with processing the Intensive Care Unit admission of my relative.

- Not at all
- Almost not
- Neutral
- A little
- Very much

7) The Virtual Reality information film allows me to empathize with my relative's experience when he/she was in the Intensive Care Unit.

- Not at all
- Almost not
- Neutral
- A little
- Very much

8) I recommend this Virtual Reality information film for other relatives of Intensive Care Unit patients

- Not at all
- Almost not
- Neutral
- A little
- Very much

9) Do you think there was information missing in the Virtual Reality information film that you would have liked to have explained?

- Yes
- No

If yes, what information did you miss?

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10) Have you shown the Virtual Reality information film to others to explain to them about the Intensive Care Unit?

- Oh yes, to my family
- Oh yes, to my friends
- Oh yes, to both my family and my friends
- Yes, to others, namely: \_\_\_\_\_
- No

11) How often have you watched the Virtual Reality information film at home?

- Not at all, only once in the hospital
- 1-3 times
- 4-6 times
- 7-10 times
- More than 10 times

12) How did you watch the information film at home?

- Only through Virtual Reality, with the cardboard VR glasses
- Only in 2D, without the cardboard VR glasses
- Usually through Virtual Reality, with the cardboard VR glasses, but also in 2D, without the cardboard VR glasses
- Usually in 2D, without the cardboard VR glasses, but also through Virtual Reality, with the cardboard VR glasses.
- Just as often by means of Virtual Reality, with the cardboard VR glasses, as in 2D, without the cardboard VR glasses.

### Questions about perceived stress factors during your relative's Intensive Care Unit treatment.

With the questions below we want to investigate which factors caused you concerns during the Intensive Care Unit admission of your relative. The first question asks how many hours per week you spent on the ICU admission of your relative. In the questions that follow, we want to know how much you were concerned about the topics mentioned during the ICU admission of your relative.

- 1) How much time per week did you spend in total on the Intensive Care Unit treatment of your relative, which you would not otherwise have spent on your relative?

*Think of travel time to the hospital, visiting times, tasks in the household that you normally did not do*

Approximately \_\_\_\_\_ hours

- 2) What other activities related to your relative's ICU admission did you spend time on, and how much time did you spend on these activities?

Activity <i>For example, visiting time, travel time, etc.</i>	Time per week (in hours)
1. Visiting time	__ __ hour
2. Travel time	__ __ hour
3.	__ __ hour
4.	__ __ hour
5.	__ __ hour
6.	__ __ hour
7.	__ __ hour
8.	__ __ hour
9.	__ __ hour
10.	__ __ hour

- 3) To what extent were you concerned about your relative's mental health?

- Not at all  
 A little  
 Neutral  
 Pretty much  
 Very much



4) How concerned are you about your relative's cognitive recovery?

*Thinking speed, memory, planning, understanding, etc.*

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

5) How concerned were you about your relative's resumption of work?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

6) How concerned are you about your own mental health?

- Not at all
- A little
- Neutral
- Pretty much
- Very much

7) To what extent were you concerned about being able to carry out your own daily work?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

8) To what extent were you concerned about your financial situation as a result of your relative's Intensive Care Unit admission?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

9) To what extent were you concerned about the travel time spend to visit your relative in the Intensive Care Unit?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

10) To what extent did you find it frightening to visit your relative in the Intensive Care Unit for the first time?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

11) Did you still find it frightening to visit your relative in the Intensive Care Unit?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

12) To what extent were you concerned about supporting your family during your relative's Intensive Care Unit admission?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

13) To what extent were you concerned about the household during your relative's Intensive Care Unit admission?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

14) To what extent were you concerned about the transfer from the Intensive Care Unit to the normal ward?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

15) To what extent were you concerned about the necessary medical care for your relative after hospitalization?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

16) How was your night's sleep during your relative's Intensive Care Unit admission?

- Very bad
- Bad
- Neutral
- Good
- Very good

17) To what extent did you feel responsible for the treatment of your relative?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much

18) To what extent did you feel involved in the treatment of your relative?

- Not at all
- A little
- Neutral (not much, not little)
- Pretty much
- Very much