Information sheet 1

Project title: FORMSPC-Realvi: Training of caregivers in virtual reality management of psycho-behavioral symptoms of patients with neurocognitive pathologies: Feasibility study, caregiver satisfaction and training effectiveness.

Institution: Broca Hospital - EA 4468 University of Paris

Scientific Lead: Dr. Hermine Lenoir

Madam, Sir,

We propose you to participate in a scientific research project entitled *"FORMSPC-Realvi*: Training of caregivers in the management of psycho-behavioral symptoms of patients suffering from neurocognitive pathologies by virtual reality,: Study of feasibility, caregiver satisfaction and effectiveness of training". This study uses a virtual reality headset that allows participants to work in a 3D environment, with virtual patients and caregivers.

It is important that you read this briefing note carefully before making your decision to participate in this study. Feel free to ask for explanations and freely ask all your questions.

If you choose to participate in this research, you will be asked for written consent.

I. PROJECT OBJECTIVES

The purpose of this study is to evaluate a virtual reality training tool for healthcare professionals, in order to strengthen their knowledge and skills in non-verbal verbal communication and in the management of patients suffering from disturbing behavior disorders (opposition, refusal of care, aggression, agitation, etc...) due to cognitive/dementia diseases (Alzheimer's disease or related diseases).

It is a virtual reality headset, and it makes it possible to project scenarios reconstituting care environments such as a hospital department or an EHPAD (Accommodation for Dependent Elderly People) in which a virtual patient, played by an actor, and a virtual caregiver (or virtual caregivers) are operating in a 3D environment. Different aspects of verbal and non-verbal communication between the caregiver and the virtual patient (e.g. speech, facial expressions or voice intonation) are combined in order to produce either a positive impact (improvement of the caregiver-patient relationship) or a negative impact (worsening of the bad interaction) on the evolution of the clinical situation.

By agreeing to participate in this study, you will be invited to participate in a focus group to express through a questionnaire your training needs in verbal and non-verbal communication for the non-drug care of patients suffering from cognitive diseases (Alzheimer's disease and related diseases) and to participate in a co-design work of 2 short scenarios representing two clinical care situations involving a fictitious patient and a fictitious caregiver and in the design of an evaluation grid.

Your participation is completely voluntary and will not be paid. You may decide to refuse or stop your participation at any time without prejudice, consequence or justification. If you wish, the results of the research can be communicated to you by contacting Dr. Hermine Lenoir at hermine.lenoir@aphp.fr

II. PROTOCOLE SEQUENCE

Experimentation is for you to participate in a composed *focus group* (working group) 10 participants from Broca Hospital's healthcare staff, to give you a questionnaire on your training needs in verbal and non-verbal communication with patients with neurocognitive pathology suffering from disturbing psycho-behavioral symptoms such as anxiety, aggression, opposition, agitation.

You will then be asked to read two scenarios written by the researchers, each describing a clinical context (in hospital or in the EHPAD) between a virtual patient suffering from disturbing psycho-behavioral disorders (aggression, opposition, agitation, and/or anxiety) due to cognitive disorders (e.g. due to Alzheimer's disease) and a virtual caregiver.

Each scenario describes situations where conflict is likely to arise because of the virtual patient's non-cooperative behavior in response to the demands of the virtual caregiver (e.g., toilet or blood test to be performed, medication to be administered but patient opposes/aggressive or agitated). On the basis of your own professional experience/knowledge, you will be asked to give your opinion, to clarify or correct this working document and to modify or supplement if necessary the dialogs and the gestures described by the fictional characters, so as to implement in the text the attitudes/words of the virtual carer(s) likely to aggravate the conflict or on the contrary to appease the patient(s) so as to accede to his/her requests (if they are relevant) while ensuring him/her the care he/she would need. Finally, you will be asked to help design a total score based on the virtual caregiver's good and bad attitudes/words in the conflicted or difficult situation.

The total duration of this *focus group* workshop will not exceed 2 hours.

III. RISKS AND DISADVANTAGES

There are no foreseeable or expected risks in this research.

IV. EXPECTED BENEFITS AND PERPECTIVES

By participating in the *FORMSPC-Realvi* research project, you are contributing to research on the development of technological and digital means for the training of professionals in the health and medico-social sectors in geriatrics. The data collected during this study will be used to create an interactive tool suitable for the training of professionals working with people with Alzheimer's disease or related diseases. Their exploitation will contribute to the training of health workers working with people affected by these diseases.

V. RESPECT FOR PRIVACY AND CONFIDENTIALITY

The data collected is anonymous and confidential. The information processed during the data analysis will appear in the reports but in such a way that no identification of the persons, source of the information, will be possible. The results of this research may be published in scientific journals, presented at clinical information meetings, always respecting the anonymity of the participants. Your agreement to the use of this information is valid until the end of the project, unless you wish to terminate it before. When recruiting health care workers, participation in the study is voluntary and will not depend on the hierarchy of the hospital. Caregivers are thus free to choose whether or not to participate in the experimental protocol. In the event that you wish to exercise your right to withdraw from the research project, your data will no longer be processed, but it would not be possible to modify existing documents.

In accordance with the law "Informatique et Libertés" of January 6, 1978, you have the right to access and rectify the information that concerns you. If you wish to exercise this right and obtain information about yourself, please contact the investigators:

Dr Hermine LENOIR
Responsible for the study
Broca Hospital
Tél: 01 44 08 35 03
Broca Hospital: 54-56, rue Pascal, 75013 PARIS
Email: Hermine.lenoir@aphp.fr

VI. CONTACT PERSON

For further information about your rights as a research participant please contact:

Maribel PINO
Director of the Broca Living Lab
Tél: 01 44 08 35 03
Broca Hospital: 54-56 Pascal Street,
75013 PARIS Bâtiment Bleu - Broca Living Lab
Email: Maribel.pino@aphp.fr

VII. CONFIRMATION

If you agree to participate in the research after reading this information note, please sign and date the following informed consent form (2 copies)

Consent Form 1

I, the undersigned, Madam, Sir [delete as appropriate]

(Surname, Surname)

.....

.....

freely agrees to participate in the research entitled: FORMSPC-Realvi: “Training of caregivers in the management of psycho-behavioral symptoms of patients suffering from neurocognitive pathologies by virtual reality: Study of feasibility, caregiver satisfaction and training effectiveness” organized by the Lusage *Living Lab* of the Broca Hospital (APHP) and EA 4468 University of Paris, under the scientific responsibility of Hermine Lenoir.

I have read the information note explaining the purpose of this research, how it will be carried out and what my participation will entail.

I have become aware that the tool does not replace a real situation.

I understand that during this study I will be asked to participate in a focus group to:

1- express through an anonymised questionnaire my training needs on verbal and non-verbal communication for the non-drug care of patients with cognitive diseases (Alzheimer's disease and related diseases) and

2- participate in a co-design of 2 scenarios representing two clinical care situations involving a fictitious patient and a fictitious caregiver and its evaluation grid.

I understand that my replies to the questionnaire will not be communicated to my hierarchy under any circumstances.

- I will keep a copy of the briefing note and consent.

I received appropriate answers to all my questions before signing this consent.

I have had sufficient time to make my decision to participate.

I have understood that my participation is free and that I will be able to terminate it at any time, without justification and without any consequences.

- I understood my rights in terms of using the data that was collected in that study.
- I have been informed that I can request the deletion of my data in case I wish to leave the study.
- I understand that my data can be kept for 10 years after the end of the project.

I have been informed that I can, if I wish, contact the study leader at any time if I have questions about the conduct of the study and/or the results of the research, research (at hermine.lenoir@aphp.fr) and that these can be communicated to me.

Participant	**Investigator**
LAST NAME First name:	LAST NAME First name:
Date:	Date:
Signature: (preceded by the words "Read and approved")	Signature:

Information sheet 2

Project title: FORMSPC-Realvi: Training of caregivers in virtual reality management of psycho-behavioral symptoms of patients with neurocognitive pathologies: Feasibility study, caregiver satisfaction and training effectiveness.

Institution: Broca Hospital - EA 4468 University of Paris

Scientific Lead: Dr. Hermine Lenoir

Madam, Sir,

We propose you to participate in a scientific research project entitled "FORMSPC-Realvi: Training of caregivers in the management of psycho-behavioral symptoms of patients suffering from neurocognitive pathologies by virtual reality: Study of feasibility, satisfaction and effectiveness of training". This study uses a virtual reality headset that allows participants to work in a 3D environment, with virtual patients and caregivers.

It is important that you read this briefing note carefully before making your decision to participate in this study. Feel free to ask for explanations and freely ask all your questions.

If you choose to participate in this research, you will be asked for written consent.

VIII. PROJECT OBJECTIVES

The purpose of this study is to evaluate a virtual reality training tool for healthcare professionals, in order to strengthen their knowledge and skills in non-verbal verbal communication and in the management of patients suffering from disturbing behavior disorders (opposition, refusal of care, aggression, agitation, etc...) due to cognitive/dementia diseases (Alzheimer's disease or related diseases).

It is a virtual reality headset, which allows to project scenarios reconstructing care environments such as a hospital service or an EHPAD (Accommodation for Dependent Elderly People) in which a virtual patient and a virtual carer are operating in a 3D environment. Different aspects of verbal and non-verbal communication between the virtual caregiver and patient (e.g. speech, facial expressions or voice intonation) are combined to produce either a positive impact (improving the caregiver-patient relationship) or a negative impact (worsening of the wrong interaction) on the evolution of the reproduced clinical situation.

By agreeing to participate in this study, you will be asked to follow and analyze virtual reality clinical situation scenarios in a 3D environment.

The tool that will be presented to you has been created with the aim of testing a new pedagogical approach and does not replace a real situation. Your participation is completely voluntary and will not be paid. You may decide to refuse or stop your participation at any time without prejudice, consequence or justification. If you wish, the results of the research can be communicated to you by contacting Dr. Hermine Lenoir at hermine.lenoir@aphp.fr

IX. PROTOCOL SEQUENCE

- The experiment is for you to wear a virtual reality headset, in a standing position, projecting two successive scenarios, each reproducing a different context of care such as geriatric hospital service or EHPAD reproduced in 3D. It will be for you to identify in real time, inappropriate or

appropriate attitudes or words of the virtual caregiver with the virtual patient in the virtual environment where you, represented by an avatar as care personnel, will evolve. To report these inappropriate and appropriate attitudes/words, depending on your knowledge of verbal and non-verbal communication with people suffering from psycho-behavioral symptoms of neurodegenerative diseases (Alzheimer's or related diseases), you will be asked during viewing to activate a controller with two buttons (one to signify that you approve of the caregiver's action and the other to signify that you disapprove of the way the virtual caregiver acts or speaks with the virtual patient. A score is automatically calculated based on your responses at the end of each scenario. The results are returned to you and discussed with you after the test course.
Each virtual reality film lasts a maximum of 10 minutes. A rest period of 30 minutes is provided between the two 3D scenarii films.

- Then, for you:
    a- Answer a satisfaction questionnaire allowing you to express yourself on the content of the training, its shortcomings, its strengths
    b- Complete a questionnaire on the usability of the proposed tool
    c- Complete two questionnaires on your sense (subjective perception) of competence in similar care situations that you are or might be confronted with in your professional practice as a result of training based on this type of tool.

The information will be collected confidentially, and used exclusively for scientific research, and under no circumstances will it be passed on to your hierarchy.

The total duration of the evaluations will not exceed 1 H30 open days.

X. RISKS AND DISADVANTAGES

According to data from the 2019 ANSES (National Food Safety Agency) survey, exposure to virtual reality can temporarily disturb the sensory system and lead to symptoms such as nausea, dizziness, sweating, paleness, loss of balance... grouped together under the name "cyber-kinetosis". In people who are sensitive to them, these symptoms may appear within minutes of use.

After a session, virtual reality can also temporarily alter sensory, motor, and perceptual skills and thus impair the ability to steer or steer the body.

The possibility of the onset of cyber-kinetics is very dependent on the content (roller coaster ride, or on the contrary calm landscape, ...), the visual field used (the wider it is, the more intense the symptoms may be), the mode of interaction (walking or on the contrary sitting position).

In our study, the scenarios will represent environments with restricted field of view (e.g. hospital room) and no visualization of accelerated or multidimensional movements that typically cause symptoms of cybecinetosis, thus minimizing the risk.

In addition, a rest period of 30 minutes during the viewing and 30 minutes after the screenings are completed is provided in order to minimize this risk.

You may be advised to stop the assessments when using the virtual reality headset if you experience symptoms such as nausea, dizziness, sweating, paleness.

In addition, exposure to time modulation of screen light from virtual reality headsets can trigger seizures in people with favorable terrain. **To avoid these effects, and as recommended by ANSES, you cannot participate in the study if you have epilepsy, are pregnant, have motion sickness, have trouble with balance or are prone to migraines.**

XI. EXPECTED BENEFITS AND PERPECTIVES

By participating in the *FORMSPC-Realvi* research project, you are contributing to research on the development of technological and digital means for the training of professionals in the health and medico-social sectors in geriatrics. The data collected during this study will be used to create an

interactive tool suitable for the training of professionals working with people with Alzheimer's disease or related diseases. Their exploitation will contribute to the training of health workers working with people affected by these diseases.

XII. RESPECT FOR PRIVACY AND CONFIDENTIALITY

The data collected is anonymous and confidential. The information processed during the data analysis will appear in the reports but in such a way that no identification of the persons, source of the information, will be possible. The results of this research may be published in scientific journals, presented at clinical information meetings, always respecting the anonymity of the participants. Your agreement to the use of this information is valid until the end of the project, unless you wish to terminate it before. When recruiting health care workers, participation in the study is voluntary and will not depend on the hierarchy of the hospital. Caregivers are thus free to choose whether or not to participate in the experimental protocol. In the event that you wish to exercise your right to withdraw from the research project, your data will no longer be processed, but it would not be possible to modify existing documents.

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Hermine LENOIR
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Broca Hospital
Tél: 01 44 08 35 03
Broca Hospital: 54-56, rue Pascal, 75013 PARIS
Email: hermine.lenoir@aphp.fr

XIII. CONTACT PERSON

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Maribel PINO

Director of the Broca Living Lab
Tél: 01 44 08 35 03
Broca Hospital: 54-56 Pascal Street,
75013 PARIS Bâtiment Bleu - Broca Living Lab
Email: maribel.pino@aphp.fr

XIV. CONFIRMATION

If you agree to participate in the research after reading this information note, please sign and date the following informed consent form (2 copies)

Consent Form 2

I, the undersigned, Madam, Sir [delete as appropriate]

(Surname, Surname)

.....

.....

freely agrees to participate in the research entitled: FORMSPC-Realvi: "Training of caregivers in the management of psycho-behavioral symptoms of patients suffering from neurocognitive pathologies by virtual reality: Study of feasibility, caregiver satisfaction and training effectiveness" organized by the Lusage *Living Lab* of the Broca Hospital (APHP) and EA 4468 University of Paris, under the scientific responsibility of Hermine Lenoir.

I have read the information note explaining the purpose of this research, how it will be carried out and what my participation will entail.

I have had sufficient time to make my decision to participate.

I have become aware that the tool does not replace a real situation.

I understand that during this study I will be asked to test a virtual reality tool and to view screenplays designed in virtual reality films, to answer questionnaires and evaluations that will be anonymised and that these will under no circumstances be communicated to my hierarchy.

- I will keep a copy of the briefing note and consent.

I received appropriate answers to all my questions before signing this consent.

I have understood that my participation is free and that I will be able to terminate it at any time, without justification and without any consequences.

- I understood my rights in terms of using the data that was collected in that study.
- I have been informed that I can request the deletion of my data in case I wish to leave the study.
- I understand that my data can be kept for 10 years after the end of the project.

I have been informed that I can, if I wish, contact the study leader at any time if I have questions about the conduct of the study and/or the results of the research (at hermine.lenoir@aphp.fr), and that these can be communicated to me.

Participant	**Investigator**
LAST NAME First name:	LAST NAME First name:
Date:	Date:
Signature: (preceded by the words "Read and approved")	Signature: