Questionnaire 2: Informed Consent (ENG)

Title of study: **Prospective randomized controlled monocentric study who investigates the effect of digital sedation during labor. (VRH4L)**
Research sponsor: *Department of Anesthesia Hospital Saint-Jean Brussels(SJ)*
Research organization: /
Ethical committee: *Comité d'éthique Hospitalo-facultaire Saint-Luc-UCLouvain*
Research doctors: *Dr. Bosteels, Dr. Schaub and Dr. Piccart, Department of Anesthesia Hospital Saint-Jean Brussels*
Research nurse: *Fleur Peeters*

I Important information for your participation consent

Introduction

We invite you to be part of a non-pharmacological clinical study that is designed to evaluate the use of hypnosis trough virtual reality during labor.
The sponsor, Department of Anesthesia Saint-Jean Hospital, and research doctor, Dr. Bosteels, are convinced that virtual reality can provide a calming experience by a technique called autohypnosis or digital sedation. This can have advantages for your pain control during childbirth.
This form informs you about the practical implementations, advantages and possible disadvantages that you need to know before you give your 'informed consent'.
You can read this pages and ask all your questions to the research doctor/nurse or the person who represents him/here. There are three parts in this form: essential information before you decide to join the study, your informed consent and extra information.
The document is presented to you during the monitoring session after the gynecologist has decided to confirm the induction date. It will take thirty minutes to read and sign the form.

Important general assumptions:

- This clinical study started after approval of the ethical board of Saint-Luc University Hospital.
- Your participation is **voluntary.** Nobody forces you to join the study and you only join after signing the informed consent. Even after signing up for the study **you can stop** your participation at any time. Your participation or discontinuation will not have any negative influence on the quality of your healthcare or relation with your treating doctors/nurses.
- All your personal information is **confidential**. You are anonym in all times.
- There is an **assurance** in case of any harm linked to the participation of the study.
- **No additional costs** are connected to your participation.
- If you need additional information you can always contact e research doctor or nurse.

Goals and description of the study

You're invited to be part of a clinical investigation of digital sedation (Virtual Reality). The purpose of this research is an evaluation of the effects of digital sedation (helps you to have less pain, fear and stress) during labor (contractions). We propose this technique to all future mothers as an addition to the normal protocol during labor. Digital sedation not instead of a standard treatment but additional to it. Already for a year we receive many positive experiences with the Virtual reality (VR), thereby we want this to confirm with a clinical investigation.

To organize a study, you compare two groups of woman, one with and one without digital sedation (VR). All the information received from their experiences are compared.

Practically there is no change on the maternity ward. Only some extra questions are asked to evaluate your experience.

Everybody will be randomly assigned to a group (with or without virtual reality) to prevent that differences in mentality will influence the results. This is called randomization.

Everyone has access to the standard treatments at any time during labor, the digital sedation is only an addition to this.

Timeline of your participation

The study takes place the two days you're in the hospital for childbirth. You will be guided during labor and the day after.

There are some criteria that need to be checked.

Inclusion criteria

1. Age: ≥ 18 and ≤ 45 years
2. Pregnant with term gestation
3. Willing to accept the rules linked to the use of the VRH headset: turning off mobile phone, visit bathroom in advance, no new visitors and no interference of the partner other than when the woman would ask him so.
4. Provision of written informed consent
5. Planned Induction

Exclusion criteria

1. Complicated pregnancy
2. Scheduled cesarean delivery
3. Receipt of epidural analgesia or opioid painkillers before start active labor phase
4. Low auditory acuity that precludes use of the device
5. Low visual acuity that precludes use of the device
6. Head or face wounds precluding use of the device
7. Epilepsy
8. Schizophrenia
9. Dizziness that precludes use of the device
10. Non-proficiency in French, Dutch or English (languages AQUA)

After signing the informed consent, the coincidence will determine if you are in the group with or without digital sedation. (Randomization)

When your labor starts spontaneously before the induction date, your participation to the study stops. You can always ask after the digital sedation in this stage.

When your induction starts as planned, the study will start when you're in active labor. During this phase we will evaluate your comfort and pain by a numerical scale from 0 to 10. Here 0 stands for 'I don't feel anything' and 10 stands for 'worst feeling ever'. Furthermore, we ask about your experience and your vital signs will be noted.

Group with digital sedation

You can experience the Virtual Reality Hypnosis session.

The standard treatment is available at all times. You can interrupt your digital sedation whenever you want.

Group without digital sedation

The standard treatment is available for you. This is the known standard for every woman in labor.

Advantages
It's possible that you can have profit of the relaxing experience (Virtual reality hypnosis). The information we collect from your experience help us to have better understanding of the use of digital sedation in the future. We would like to scientifically proof the advantages of digital sedation.

Disadvantages
There are no healthcare risks connected to the research procedures.
Side effects like nausea and dizziness are rarely noted. Reporting possible side effects is also part of the study. Whenever experiencing one of these you can disrupt the session and remove the headset.

New information
When important new information is available we will always inform you. In this case you will be asked to sign a new informed consent file. When you decide to stop your participation after receiving this new information the research doctors will ensure you receive the best care that's available for you.

Stop participation
Your participation is voluntary. You have always the right to discontinue your participation every moment for any reason. Even without mentioning a reason you can drop out the study but for the research doctors its useful to know the reason of refusal/discontinuation. This helps to improve the use of digital sedation in the future.

Your medical information
We ask you not to hide any information about your health status, current medication or symptoms.
It is advisable to inform your general practitioner about the participation to this study. If you desire not inform other doctors/healthcare workers we will respect this choice.

Contact
When you desire additional information or in case of unsolved worries you can contact a research doctor or a member of the team during office hours.
Dr. Bosteels - 02/2219762
Dr. Piccart – 02/2219543
In case of an emergency you can contact 02/2219100.
Whenever presenting on the emergency department, always mention your participating a clinical study.
Questions about your rights as participant of the clinical study can be addressed to the ombudsman (02/5554491). When desired they can contact the ethical committee for you.

The privacy law is respected during processing your data, see the confidentiality guarantee. Whenever you have any questions contact:

- your research doctor Dr. Bosteels/Piccart
- officer of data protection: privacy-dpo@clstjean.be
- authorities for data protection: Persstraat 35, 1000 Brussel, +32 (0)2 274 48 00, +32 (0)2 274 48 35, contact(at)apd-gba.be

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II Informed consent

Participant

I declare that I'm informed about the nature, duration, advantaged and risks of the study. I read this information document.
I had sufficient time to think through and/or discuss with a family member or general practitioner.
I have asked all my questions and received a clear response.
I understand that the participation to this study is voluntary and that I can dismiss at any time without influencing the therapeutic relation with my caregivers or quality of healthcare.
I understand that during my participation information will be noted about my experience. All the members of the research team guarantee that this data is confidentially according to the Belgian privacy law.
I confirm that I received a copy of the information necessary for the informed consent.

*I *agree/not agree* (erase what's wrong) that the data of this study is collected and processed in the context of the research purpose (improving the knowledge about digital sedation for labor).

*I *agree/not agree* (erase what's wrong) that my general practitioner and other care givers are/will be aware of my participation in this clinical study.

Name, surname, date and signature of the **participant**

_____	_____	_____
Name and surname	Date	Signature

Research member

I r*esearch doctor/nurse* declare that I provided the necessary information orally and that I gave a copy of the information document to the participant.
I confirm that I did not force her to join the study and that I'm willing to answer all her questions.
I confirm that I work according to the ethical principles "Declaration of Helsinki", "Good Clinical Practice" and the Belgian law of 7-5-2004 research with human persons.
Name, surname, date and signature of the **research member:**

_____	_____	_____
Name and surname	Date	Signature

Title of study: **Prospective randomized controlled monocentric study who investigates the effect of digital sedation during labor.**

III Additional information

1 The study product

A smartphone (Samsung Galaxy S 8.0) is inserted in a Virtual Reality Headset to provide a visual medium. A headset is connected to provide an audio support to experience the Virtual Reality Hypnosis.
AQUA® (Oncomfort SA, Wavre, Belgium) is a module designed to treat stress and pain. The script is underwater in the ocean with a voice and a whale who guide you through some auto-hypnoses exercises during +/- 30 minutes.
The combination of Virtual Reality (visual) and Hypnosis (audio) is relatively new for the medical world. The content of the VRH is relaxing and provides a disconnection from the real world (that may be experienced stressful or unpleasant during labor).
You can start and stop the VR experience whenever it suits for you. We will guide you in this.
The standard treatment consists postural exercises, baths, massages and when the labor is sufficiently advanced an epidural analgesia. This is always available for every woman in labor.

2 Risk reporting/prevention

Until now rare cases of dizziness and nausea were noted. With this study we want to explore what possible effects can be experienced.
There is no risk for cyber addiction, violent or disrespectful scenes.

3 Rights study participants

Ethical commission

This study is approved by the ethical commission of the Hospitalo-facultaire Saint-Luc-UCLouvain. An ethical commission protects study participants.
They guard that:

- There is no violation of the rights as patient or study participant
- There is a positive balance between advantages-disadvantages for participants
- The study is scientifically relevant and ethically responsible

Their advice is according the Belgian law of 7-5-2004 about research with human people.

Voluntary participation

Participation is voluntary, nobody forces you to be part of a study. When you refuse, this will not have consequences for your therapeutically relationship with your caregivers or the quality of healthcare.
When you accept being part of the study you and the research doctor/nurse sign the informed consent form. Thereby you declare having sufficient information to join the study and the researchers declare they provides sufficient information to inform you.
You can drop out the study whenever you want, with or without mentioning a reason. Informing a research member is advisable whenever you think about discontinuation.

Costs

The Department of Anesthesia (Clinic Saint-Jean) is principal and only sponsor of this clinical study. They provide compensation for the hours that the research team spent on the study, specific consultations and investigations.
There are no additional costs for participants or the insurance of the participants. All the aspects described on page 2 of this form are provided and funded by the Department of Anesthesia St-Jean.
Medical acts accompanied by childbirth are charged as normal.
Transportation costs (public transport) made extra for the study are funded by the sponsor with a maximum amount of 32 € for one visit. Visits by car are compensated by the official rate of 0,3460 €/km. Evidence of the transport costs is always necessary for a refund. Contact your research member for the practical arrangements.

Confidentiality is guaranteed

During your participation, there will be data collected that is used for research and medical/scientific publications.

You have the right to ask which information is collected from you and where it is used for. This data relates to your current clinical situation, as well as your medical history and the results of study experiments to treat your health according to the applicable standard of care. You have the right to inspect these data and to have corrections made if they are incorrect.[1]

The doctor-investigator is obligated to handle this data confidentially. He/she can never reveal your name in the context of a publication/conference, you remain always anonym. Your identity is replaced by a study code before your information is processed in a database. The research team will be the only people who can connect your identity and the collected data for the study. [2]

The information collected contains no combination of elements whereby your identity can be revealed.[3]

The administrator of the research data cannot identify you on the basis of the transferred data. This person is responsible for the collection of the data collected by all medical researchers participating in the study and for the processing and protection of these data in accordance with the Belgian law on the protection of privacy.

To check the quality of the study, your medical file may be viewed by persons bound by professional secrecy, such as representatives of the ethical committees, the study sponsor or an external audit firm. This can only be done under strict conditions, under the responsibility of the doctor investigators.

The (coded) research data can be passed on to Belgian or other regulatory authorities, to the relevant ethical committees, to other doctors and / or institutions that collaborate with the sponsor.

They can also be passed on to other sites in Belgium and in other countries where the standards regarding the protection of personal data may be different or less strict.[4] This is always done in coded form as explained above.

Your consent to participate in this study therefore also means that you agree that your encrypted medical data will be used for the purposes described in this information form and that it will be transferred to the in this document mentioned persons and / or institutions.

The research team will only use the collected data in the context of the study in which you participate. If you withdraw your consent to participate in the study, the encrypted data already collected before your withdrawal will be retained. This guarantees the validity of the study. No new information will be passed on to the research team.

[1] These rights are guaranteed to you by the law on the protection of natural persons with regard to the processing of personal data of 30 July 2028 in application of regulation 5UE ° 2016/679 (GDPR) with regard to the protection of natural persons with regard to the processing of personal data and the free movement of such data, and patient rights (2002).

[2] For clinical studies, the law requires that the relationship with your file is kept for 20 years. In the case of a study drug for an innovative therapy that uses human tissue material, this period is a minimum of 30 years and a maximum of 50 years in accordance with the Belgian law of 19 December 2008 on the use of human tissue material and the applicable Royal Decrees.

[3] The database of research results therefore does not contain any link with elements such as your initials, your gender and your full date of birth (dd / mm / yyyy).

[4] The research team is responsible to respect the conditions in the European Directives and the Belgian Legislation regarding the protection of privacy.

Insurance

Every participation in a study involves a risk, however small. The mandator is - even if there is no error - liable for the damage incurred by the participant or, in the event of death, his / her rightful claimants and which is directly or indirectly related to his / her participation in the study. You do not have to demonstrate an error for this. The main sponsor has taken out insurance for this liability.[5]

We therefore request that you report any new health problem to the investigator. He / She can provide you with additional information about possible treatments.

If the investigator thinks that a connection with the study is possible (there is no connection with the study in the case of damage due to the natural course of your disease or from known side effects of your standard treatment), he / she will / they inform the sponsor of the study who will initiate the declaration procedure with the insurance. If it deems it necessary, he or she will appoint an expert to assess the relationship between your new health complaints and the study.

For all practical purposes, the contact details of the insurance company MS Amlin Insurance SE, Bld Albert II 37, 1030 Brussels: tel: 02 / 894.70.00. Policy number: LXX089609.

The law provides that the summons of the insurer can take place either in the court of the place where the harmful events occurred, or in the court of your domicile, or in the court of the seat of the insurer.

[5] In accordance with Article 29 of the Belgian Law on experiments on the human person (May 7, 2004)