A prospective randomized controlled monocentric study evaluating the impact of

Virtual Reality Hypnosis during labor

VRH4L

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1. PROTOCOL APPROVAL- Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable European regulations and ICH guidelines.

Study coordinators/Principal investigators

Name and Title	Approval date	Signature
Dr Bosteels Arnaud (AB)	06/08/2020	
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Ms Peeters Fleur (FP)	06/08/2020	

Sponsor

Name and Title	Approval date	Signature
Department of Anesthesia, Clinique Saint-Jean Bruxelles (SJ)	06/08/2020	

2. DOCUMENT HISTORY

Version	Protocol version issue date	Short description of modifications
1	**04/08/2020**	**Original Protocol (Version 1)**
2	**23/02/2021**	**Adapted protocol (Version 2)**

3. SYNOPSIS

<table>
<tr><td>STUDY TITLE</td><td colspan="2">A randomized controlled, single centre, study evaluating the impact of Virtual Reality Hypnosis during labor</td></tr>
<tr><td>SHORT TITLE</td><td colspan="2">VRH4L (Hypnotic Virtual Reality for Labor pain relief)</td></tr>
<tr><td>PROTOCOL NUMBER</td><td colspan="2">2</td></tr>
<tr><td>SPONSOR</td><td colspan="2">Department of Anesthesia, Clinique Saint-Jean Bruxelles (SJ)</td></tr>
<tr><td>STUDY POPULATION</td><td colspan="2">Women during labor</td></tr>
<tr><td>PHASE</td><td colspan="2">Prospective interventional Randomized Controlled Trial (RCT)</td></tr>
<tr><td>STUDY DESIGN</td><td colspan="2">This prospective interventional RCT will evaluate efficacy of Virtual Reality Hypnosis (VRH) in reducing pain during labor. Hypnosis is delivered as a standardized therapeutic intervention through virtual reality, using a digital sedation software. This VRH module is called AQUA© (Oncomfort SA) and is specifically designed for the management of pain and anxiety during labor.

Women who are planning to give birth at the St-Jean Hospital are recruited at prenatal consultation some weeks before the calculated delivery date. Only patients with a planned induced labor can be included.Patients who agree to participate sign an informed consent form.
38 patients will be randomized in two arms (19 patients in each cohort):
• Patients in the intervention groups will receive a session of the AQUA© Digital Sedation module when in active labor (cervical dilatation ≥4 cm, contractions every 5 minutes, NRS pain score ≥4/10) on top of the standard of care
• Patients in the control group will receive standard of care only.

Patients are allowed to discontinue the VRH session at any time. A study staff member is present during the session to explain the intervention and fill in the questionnaires. Furthermore, she/he ensures the patient is receiving appropriate clinical care throughout the duration of the intervention.
Information from patient's report will be collected before the intervention, after the intervention and up to the patient's discharge from the maternity on day after childbirth.
A log will be kept of patients who refuse to participate in the study.</td></tr>
<tr><td rowspan="4">OBJECTIVES AND ENDPOINTS</td><td>Primary objective</td><td>Primary endpoints</td></tr>
<tr><td>To evaluate efficacy of VRH AQUA© module on labor-related pain</td><td>Difference in NRS (Numerial Rating Scale 0 to 10) pain scores before and after the intervention</td></tr>
<tr><td>Secondary objectives</td><td>Secondary endpoints</td></tr>
<tr><td>To compare patient experience in both arms</td><td>Measure of NRS pain after 30 minutes
Measure of satisfaction by Likert Scale (0 to 5)
Measure of nausea by Nausea and Vomiting Score (0 to 3)
Evaluation of comfort during intervention with the CPOT scale (Critical care Patient Observation Tool 0 to 8) and heart rate
Willingness to undergo a potential next labor with VRH
Willingness to recommend VRH to acquaintances</td></tr>
<tr><td>To assess selected safety and efficacy outcomes in both arms</td><td>Progression of labor
Need for epidural</td></tr>
</table>

		Need for medication: type and dosages during stay Frequency and type of (severe) adverse events (SAEs) (mother and baby) If the patient removes the headset during the session, motivation is documented.
	To assess gynecologist and nurse satisfaction	Measure of satisfaction of the midwife and obstetrician by the Likert scale (0 to 5) Quality of the therapeutic relationship between the midwife and patient (reported by the midwife in a NRS from 0 to 10)
	Evaluation of vital signs	Oxygen saturation Systolic and diastolic blood pressure Heart rate (during and in between contractions)
NUMBERS OF PARTICIPANTS	38	
INCLUSION CRITERIA	1. Age: ≥ 18 and ≤ 45 years 2. Pregnant with term gestation 3. Willing to adhere to 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. Induced labor	
EXCLUSION CRITERIA	1. Complicated pregnancy (HELLP,…) 2. Scheduled caesarian 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. Schizophrenia 8. Epilepsy 9. Dizziness 10. Non-proficiency in French and/or Dutch (research language)	
MEDICAL DEVICE	The Digital Sedation session used is the AQUA© (module 3.2) delivered through the Sedakit™, both developed by Oncomfort®. According to Annex IX of Directive 93/42 / EEC, the Sedakit™ is classified as a Class I Medical Device, it is a non-invasive device that is in contact only with the skin. The Sedakit™ consists of an audio headset, virtual reality goggles, a mobile phone, AQUA© software and the user's manual. Digital Sedation allows an immersive experience of virtual reality focused on the induction of relaxation. As a solution for non-pharmacological sedation and self-management of pain and anxiety, AQUA© takes the subject into a deep sensory experience and allows her to dive into a soothing environment. The subject will be required to perform simple stress management exercises; helping her to better manage her pain and anxiety. The techniques used is a virtual reality headset combined with an audio recording of psychological interventions, mainly clinical hypnosis.	
STATISTICAL ASPECTS	Inclusion of 38 patients is necessary to ensure statistical significance. Participants are randomized and the investigators are not blinded.	
STUDY MILESTONES	First patient, first visit: March 1, 2021 Last patient, last visit: May 30, 2021	

4. RATIONALE

4.1.CONTEXT AND JUSTIFICATION OF THE STUDY

Labor pain is feared by many women. However some women recall positive feelings about their coping ability with this intense pain. The way they dealt with pain seems more important than the severity of the labor pain. The feeling of being in control, respected and nurtured by caregivers and loved ones is what these women recall mostly.[i]

On the other hand, many women recall feelings of suffering, loneliness and helplessness. These negative feelings make the whole childbirth experience unpleasant. Even a posttraumatic stress disorder can develop after childbirth. The ability to cope with this pain is influenced by experiences that took place before childbirth. It is probably more likely to have dysfunctional coping skills when earlier traumas were never resolved.[i] We believe that Virtual Reality Hypnois (VRH) can improve the way women cope with pain during labor. Through self-hypnosis, the focus is moved from pain to positive feelings, thereby women feel less tensed and have a greater sense of self-control.

Secondly women are increasingly striving for a more natural birth, minimizing medical interventions such as cervical examination, pharmacological analgesia, etc. As such they are looking for nonpharmacological approaches to decrease labor pain.
There are different nonpharmacological (see section 4.1.2 alternatives for standard of care) techniques that can reduce side-effects, increase rates of breast feeding, and eventually increase satisfaction.[ii,iii]
Immersive virtual reality (VR) has been shown to decrease pain in a non-pharmacological way and in a number of different situations.[iv,v] Studies are positive about the use of immersive VR therapy as analgesia during experimental pain in healthy subjects, changing dressings of burn patients and as an analgesic adjunct during physiotherapy.[vi vii viii]

The pain accompanied with childbirth is nor acute nor chronic and thereby a complex unique experience for every woman. Some studies suggest that VR can help controlling the pain during the active stage of labor. Outcomes like anxiety, use of pharmacological analgesia and satisfaction have also been studied.[ix,x,xi]

Could the association of hypnosis with immersive VR have additive positive effects? Based on our internal experience, the use of Virtual Reality Hypnose (VRH) can increase the comfort for women in labor. We decided therefore to organize a trial to measure the benefits and side effects of this new technique. VRH has never been studied before as an analgesic for labor pain.

The hypnotic virtual reality environments are designed by Oncomfort SA, a Belgian company who's solution has already been extensively researched and published.[xii] The VRH session is a module called AQUA©, a relaxing experience based on clinical hypnosis, respiratory techniques and autogenic muscle relaxation. This hypnotic script will bring the patient in a state of auto-hypnosis. The Head Mounted Display (HMD) is a VR Gear from Samsung-Oculus and the mobile phone used is a Samsung Galaxy S7.

4.1.1.*Standard of care*

The standard treatment (ST) for labor pain as used in our hospital contains massage, aquatherapy and postural exercises. This is always available for any woman in labor. The VR group receives digital sedation and when asked the ST. In comparison to the control group who receives only the ST when asked.
If ST is not sufficient, a patient can receive a pharmacological treatment or an epidural analgesia. However, in this study we will examine the efficacy of VRH before the use of epidural analgesia or pharmacological treatment.

4.1.2.*Alternatives to standard of care*

Audio-analgesia, aromatherapy, biofeedback, acupressure, TENS (Transcutaneous Electric Neurologic Stimulation) and massage are popular methods but are not proven to have a significant effect on labor pain. These are not available in our institution. On the other hand hydrotherapy, acupuncture and hypnosis have a proven significance as a tool for pain management during labor.[xiii] More specifically hypnosis may reduce the overall use of analgesia during labor. [xiv]

4.1.3.*Hypothesis*

Our primary goal is to evaluate the analgesic benefits of Virtual Reality Hypnosis (VRH) compared to the standard of care (ST) solely.

5. STUDY OBJECTIVES

5.1 PRIMARY OUTCOME

The primary endpoint is to compare the differences in NRS pain measured before and after the intervention during labor. (T3 minus T1) The Pain Numerical rating Scale (NRS) is a scale from 0 to 10 well known by the medical staff. [xv] [xvi]

5.2 SECONDARY OUTCOMES

30 min after the end of the intervention the NRS pain is assessed once more. (T4)

During the intervention the comfort of the patient is evaluated. (T2) To do this we use the CPOT (Critical care Pain Observation Tool). CPOT is a comfort scale for (non)-ventilated patients in the intensive care unit. We decided to use this score, because during the VR experience we cannot communicate with the patient, which is similar as in sedated patients. And in our own experience we see that the parameters that we look at to evaluate the comfort of the patient during a VR sedation are very similar to this scale. (Facial expression, body movements, muscle tension and vocalization together make a score of 0 to 8)[xvii] Vital signs like heart rate and blood pressure are parameters that are easily measured during the intervention and considered as objective for evaluating pain during labor. (T1,2,3,4) [xviii]

Nausea is also actively evaluated. Thereforewe use the PONV rating scale from 0 to 3. (T1, T3, T4)

Anxiety is evaluated with the NRS at the same time. (T1, T2, T3) We use the Likert satisfaction scale (from 0 to 5) to explore the satisfaction directly after their experience and the day after delivery. (T3, T6)

Willingness to repeat the intervention and to recommend the intervention can correlate with satisfaction of the overall experience. (T6)

Progression of labor is followed with the degree of the cervix dilatation, therefore we will not perform more cervical examinations than needed but interpret the measurement of the midwives/obstetricians. (T5)

The midwives are asked to evaluate the therapeutic link between themselves and the patient (NRS) after the women return to the maternity ward. (T5)

All the medication received during the stay on the delivery ward, adverse events and interruptions from the intervention is noted. (T3, T5)

6. STUDY DESIGN

The VRH4L trial is an interventional, randomized, controlled, single-center, parallel group trial. Randomization will be done as a block randomization with a 1:1 allocation[xix]

Clinique Saint-Jean Brussels (SJ), where the study takes place, is an academic hospital in the center of Brussels with around than 2000 deliveries per year.

We create two groups: the VRH group and the control group. During the intervention (T1-3) the VRH-group receives a digital sedation in contrary to the control group who will not use the VRH headset.

7. STUDY POPULATION

7.1. INCLUSION CRITERIA

Patients must meet all of the following criteria in order to be eligible for this study:

1. Age: ≥ 18 and ≤ 45 years
2. Pregnant with term gestation
3. Willing to adhere to 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. Induced labor

7.2.EXCLUSION CRITERIA

Patients meeting any ONE of the following criteria are not eligible for this study:

1. Complicated pregnancy (HELLP,…
2. Scheduled caesarian 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. Schizophrenia8. Epilepsy
9. Dizziness
10. Non-proficiency in French and/or Dutch (research language)

7.3.INCLUSION CRITERIA FOR INVESTIGATORS

Every investigator will have to obtain the Oncomfort Academy certificate[xx] and a certificate of Good Clinical Pratice (GCP)[xxi].

8. CONCOMITTANT MEDICATION AND TREATMENT

The standard labor pain management contains massage, aqua therapy and postural exercises. In our institution, opioid patient controlled intravenous infusion (Remifentanil) or N2O inhalation as analgesia in the first stages of active labor is not standard of care. Every women can ask for and receive (if no contra-indications) an epidural. In this study, however, we will only include patients without an epidural. After childbirth we use paracetamol and anti-inflammatory drugs as first line painkillers. When necessary opioids can be added.

9. SCHEDULE OF ASSESMENTS AND PROCEDURES

RCT T	**TO**	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**
Delivery Phase	**Prenat consult**	**Active Labor (study threshold) Day 0**	**Labor**	**Labor**	**Labor**	**End of Delivery**	**Day 1**
		Before the Start AQUA	During AQUA	End AQUA	T3+30 min		
Screening/ ICF	X						
Refusal questionnaire	X						
Patient Quastionaires & Observation							
NRS pain		X		X	X		
Nausea		X		X	X		
Likert satisfaction							X
CPOT (VR comfort scale)			X				
Willingness to repeat (intervention)							X
Recommend (intervention)							X
Practitioner questionnaire							
Monitored contractions (on the CTG during intervention)				X			
Satisfaction midwife						X	
Quality of the therapeutic relationship						X	
Objective criteria							
Vital signs (Saturation)		X	X	X	X		
Medication received							X
Epidural				X	X		
Progression of labor						X	
(Serious) adverse events		X	X	X	X	X	
Stop of digital sedation session				X			

10.SELECTION AND WITHDRAWAL OF SUBJECTS

During the prenatal visit (PNV = T0; some weeks before the due date) the pregnant women receive information about the the study and the use of VRH from the midwife. Each patient will be asked for participation in the study, after verifying the presence of the inclusion criteria and absence of any exclusion criteria. The registration checklist is filled in (questionnaire 1). If patients refuse, their motivation will be noted on the refusal questionnaire(questionnaire 4). All the included patients receive sufficient information and time to decide if they want to participte or not. After signing the informed consent (Questionnaire 2 resp) they will be immediatly randomized using block randomization (with excel). This will assign the pregnant woman to either control group or the VRH group.

On the day of delivery every included patient will receive standard of care. When the women selected in the VR group are in active labor (NRS pain ≥ 4, cervical dilatation ≥4 cm and regular contractions (every five minutes) we present the VRH treatment (T1).
Patients who refuse the VRH treatment (T1) or remove the VRH headset during(T2) will be asked to fill in questionnaire 4 (refusal questionnaire). They will be considered as drop outs.

11.STATISTICAL CONSIDERATIONS AND ANALYTIC PLAN

11.1 SAMPLE SIZE

The sample size of the study is computed on the basis of expectations for the the difference of the pain NRS means between the two arms at final analysis. Based on previous studies (Yildrim 2004 and Harmon 1990), we may expect a difference of the pain NRS means of 2 or more between the two arms, with a standard deviation of the pain NRS of 2 in both arms. For a statistical power of 80%, an alpha error of 5% and a two-sided test, 17 evaluable patients are needed in each group to reach statistical significance (calculation performed with Stata/MP 14.1).
Assuming a potential drop out rate of 10% in each arm, a total of 19 patients need to be randomized to each arm. The total number of patients for the study is 38.

11.2 SEQUENCE GENERERATION

We created a block randomization in excel. This block randomization, has variable block sizes to decrease the chance of deducing the following allocation. The patients will be randomly allocated in either the either the control group or the VRH group in a 1:1 allocation.

11.3 CONCEALMENT MECHANISM AND IMPLEMENTATION

On the prenatal visit an investigator randomizes incuded patients (after they signed the IC) and gives them a study number as described in section ‘13.4 confidentiality and access to data’. A pop up in their electronic file and all the 4 questionnaires are kept together in one plastic sheet (one folder with 4 questionnaires per patient: registration checklist, informed consent, data collection form and refusal questionnaire) in a closet of the prenatal visit. Every day all folders of incuded patients are moved from the prenatal visit to the maternity ward (by the study nurse) where there is also a predetermined closed closet to store all the forms.

When the patient arrives on the labor ward to give birth (due day) the midwifes are aware of their participation in the study thanks to the pop up in their electronic file. On this day, we explain again the study to the patient and give them the possibility to drop out. The reason why is always noted on Questionnaire 4 (refusal questionnaire).

The investigators (AB, LP, IS , FP) will not be blinded to the allocation because they can see if patients have the VRH experience or not during measurements.

11.4 ANALYSIS

First descriptive analysis will be performed. Qualitative data will be described by frequency and percentage. Quantitative data will be described by mean, standard deviation, median, minimum, and maximum numbers.
Regarding the primary outcome, NRS pain score before and after the intervention will be compared using paired t-test or Mann-Whitney test, depending of data distribution. 95% confidence intervals will be provided.
Regarding secondary outcomes, chi-squared tests will be used to compare frequencies and rates between groups. In case of small cell sizes, we will alternatively use the Fisher's exact test. T-Test or Mann-Whitney test will be used to determine if there is a significant difference between means of the two groups. T-Test or Mann-Whitney test will be also used for all continuous data normally distributed or not such as NRS, Likert scale and physiologic data. Repeated measurements such as Anxiety and Nausea will be handled with appropriate techniques such as paired tests.
Safety variables include the incidence of Serious Adverse Events (SAEs), discomfort and the quality of immediate and distant labor pain analgesia. These data will be tabulated by treatment groups and overall, in contingency table for percentages or in descriptive univariate analyzes for continuous variables.

The Intent-to-Treat (ITT) population will be used for all efficacy and safety analyzes unless otherwise specified. This ITT analysis will include all randomized patients, according to their allocation group.
The Per-Protocol (PP) population will be used to validate the effectiveness of the studied intervention, as specified by the primary outcome. This PP analysis will include all patients in the ITT population who do not have a major violation of the protocol. The list of major violations includes at least:
• Non-administered medication
• Failure to meet an inclusion or exclusion criterion
Patients identified as having major violations will be screened to determine their final exclusion from the PP population, prior to the freezing of the database.

12.QUALITY CONTROL AND QUALITY ASSURANCE

Increased adherence to the protocol is acquired by multiple information sessions about the study for the midwives. Furthermore, a reminder poster will be displayed in their office. Adherence to the protocol by the participants will be monitored daily by a non-blinded investigator (LP) by looking at the daily reports of the study.

Patients will be well informed in advance about the study and the intervention on the prenatal visit. The informed consent must be signed to be included.

We refer to the section data handling to remind that we have attention for the privacy of the patient and their data. They will remain anonym participants.

Furthermore, we use standard forms with standard questions who are the same for every patient. (Questionnaire 1-4) Suggestive questions and subjective evaluations are not accepted. Also, the standard of care is a standardized protocol for every woman in active labor.

Important protocol modifications wille be communicated to relevant parties. See appendix 'Clinical study agreement' Article 3 'Clinical study – Changes or modifications'.

13.ETHICAL ASPECTS

13.1 HARMS

On every form used to collect data there is a possibility to report important information concerning possible harms during the study. This information will be analyzed and discussed by the investigators and reported in the study. See appendix 'Clinical study agreement' Article 3 'Clinical study-Safety reports'.

13.2 RESEARCH ETHICS APPROVALS

The central ethical committee (EC) is the Comité d'éthique Hospitalo-facultaire Saint-Luc-UCLouvain. They will evaluate the research proposition, check the scientific relevance and make sure the patient's rights are respected. Approval granted on February 23, 2021 (study number: 2020/11AOU/403, Eudra-CT nr: 2020-003935-95)

The EC of Saint-Jean (OM 072) will check if the local investigator is able to and if the local conditions are met to participate in this study accord according to the law of May the 7th 2004. Approval granted on ###

13.3 CONSENT OR ASSENT

Every investigator will be taking part in the recruitment of the patients.
Each includable patient will be approached on the prenatal visit and asked for participation in the study, after verifying the inclusion criteria and the absence of the exclusion criteria.
The investigators will present the study to the patients, using a patient oriented explicatory form, after which they will look at the informed consent together with the patient.
They will receive the following information:

- The aim of this research
- The duration of their participation in this research
- Their participatrion has to be based solelyon their own free choice
- Profits that may result from the research
- Demonstrates how medical care will be continued at the end of the research, in case of premature termination of the research and in case of exclusion from the research, where applicable
- Confidentiality of data and the possibility to withdraw from the research at any time.

If necessary they will give the patient some time to reflect and come back to sign and collect, or not, the informed consent. After signing by the patient and the investigating physician, a copy of this document will be given to the individual research participant. The investigator must keep a second copy of the signed inormed consent in the archives for a minimum of 15 years.
See appendix 17.1 'Informed consent'.

13.4 CONFIDENTIALITY AND ACCESS TO DATA

Every patient gets a code to anonymize her. The code will be a tree number code following VRH4L (VRH4L XXX) Information leading to their identity will be kept in the protected database file.
This database is only accessible to the lead investigators. (requiring a password)
The IC forms and data forms will be kept in a closet with very limited access.
See appendix 'Clinical study agreement' Article 9 'Data privacy' and Article 5 'Confidentialy'.

13.4 DECLARATION OF INTERESTS

There is no potential conflict of interest for any investigator. The Principal investigator (AB) is member of the clinical advisory board of Oncomfort SA. There is only a financial compensation for expences related to participacion of scientific meetings.

14.DATA HANDLING AND RECORD KEEPING

14.1 DATA COLLECTION METHODS AND RETENTION

There are four paper forms per patient that are used to collect the data that we put together in one plastic sheet (folder). Questionnaire 1 is the registration checklist where inclusion and exclusion criteria are checked, the study number and randomization group is noted. Questionnaire 2 is the informed consent signed by the patient and the investigator. Questionnaire 3 is the data collection form used by the investigators to note all the outcomes previously described. Questionnaire 4 is a refusal questionnaire where all reasons of refusal or interruption of the VRH can be assessed standardized.

The investigators earned the Oncomfort Academy certificate and a Good Clinical Practice certificate. Midwives on the ward have already a year of experience with the VRH therapy for labor pain.

14.2 DATA MANAGEMENT

The investigators are responsible for the forms and for the database. They will collect all the forms on the first working day after the delivery (Day after delivery = D+1). They will put all the data anonymously in a protected database after every investigator verifies the entry of the data previously collected by him.

15.PUBLICATION POLICY

15.1 TRIAL RESULTS AN REPRODUCIBLE RESEARCH

The investigators are intended to publish the results, even if not significant, so other investigators can be aware of this study.
Information about publication of the results are mentioned in appendix 'Clinical study agreement' Article 11 'publication'.

15.2 AUTHORSHIP

Every investigator will be named as an author if he meets the criteria for authorship defined by the International Committee of Medical Journal Committee of Medical Journal Editors[xxii].

16.FINANCE AND INSURANCE

16.1 SPONSOR

The primary sponsor is the Department of Anesthesia, Clinique Saint-Jean (SJ).
Oncomfort SA provides the headsets that are needed to perform the study.

16.2 INSURANCE

The primary sponsor, the department of Anaesthesia, Clinique Saint-Jean, provides an adapted contract.

17.ABBREVIATIONS

DiS: Digital Sedation
DD: Delivery Day
HMD: Head Mounted Display (headset)
IASP: International Association for the Study of Pain
PNV: Prenatal Visit
D+1: Post-Partum Day 1
SJ: Clinique Saint-Jean Brussels
ST: Standard Treatment
NRS: Numerical Rating Scale
VR: Virtual Reality
VRH: Virtual Reality Hypnosis
WHO: World Health Organisation
TAP: Transversus Abdominal Plane Block
PP: Per-Protocol (patient population)
EC: Ethical committee
VRCAS: VR comfort assessment scale
GCP: Good Clinical Practice
IC: Informed Consent

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