





BMJ Open 'connEcted caesarean section': creating a virtual link between MOthers and their infanTs to ImprOve maternal childbirth experieNce - study protocol for a PILOT trial (e-motion-pilot)

Fiona Corbaz ¹, Emilie Boussac,² Karine Lepigeon,¹ Diana Gomes Dias,¹ Sandra Marcadent ³, David Desseauve ¹, Antje Horsch ^{1,4}

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DD and AH contributed equally.

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¹Woman-Mother-Child, Lausanne University Hospital, Lausanne, Switzerland

²Anesthesiology, Lausanne University Hospital, Lausanne, Switzerland

³Signal Processing Laboratory 5, EPFL, Lausanne, Switzerland

⁴Institute of Higher Education and Research in Healthcare, University of Lausanne, Lausanne, Switzerland

Correspondence to

Fiona Corbaz;
fiona.corbaz@chuv.ch

ABSTRACT

Introduction One-third of mothers rate their childbirth as traumatic. The prevalence of childbirth-related post-traumatic stress disorder (CB-PTSD) is 4.7%. Skin-to-skin contact is a protective factor against CB-PTSD. However, during a caesarean section (CS), skin-to-skin contact is not always feasible and mothers and infants are often separated. In those cases, there is no validated and available solution to substitute this unique protective factor. Based on the results of studies using virtual reality and head-mounted displays (HMDs) and studies on childbirth experience, we hypothesise that enabling the mother to have a visual and auditory contact with her baby could improve her childbirth experience while she and her baby are separated. To facilitate this connection, we will use a two-dimensional 360° camera filming the baby linked securely to an HMD that the mother can wear during the end of the surgery.

Methods and analysis This study protocol describes a monocentric open-label controlled pilot trial with minimal risk testing the effects of a visual and auditory contact via an HMD worn by the mother airing a live video of her newborn compared with treatment-as-usual in 70 women after CS. The first 35 consecutive participants will be the control group and will receive the standard care. The next 35 consecutive participants will have the intervention. The primary outcome will be differences in maternal childbirth experience (Childbirth Experience Questionnaire 2) at 1-week postpartum between the intervention and control groups. Secondary outcomes will be CB-PTSD symptoms, birth satisfaction, mother-infant bonding, perceived pain and stress during childbirth, maternal anxiety and depression symptoms, anaesthesiological data and acceptability of the procedure.

Ethics and dissemination Ethics approval was granted by the Human Research Ethics Committee of the Canton de Vaud (study number 2022-00215). Dissemination of results will occur via national and international conferences, peer-reviewed journals, public conferences and social media.

Trial registration number NCT05319665.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This monocentric superiority controlled pilot trial is the first trial testing an early intervention with a head-mounted display to improve the maternal childbirth experience.
- ⇒ The study will use internationally validated questionnaires.
- ⇒ Methodological rigour, including a control group, regular monitoring and prospective trial registration limits risks of bias.
- ⇒ There will be no blinding in this open-label study.
- ⇒ This study is a controlled pilot trial without randomisation of the participants.

INTRODUCTION

Although births are common and major life events which are socially considered positive, one-third of mothers rate their childbirth as traumatic.¹⁻³ In some cases, a negative childbirth experience can lead to childbirth-related post-traumatic stress disorder (CB-PTSD).⁴ According to the fifth edition of the diagnostic and statistical manual of mental disorders (DSM-5), PTSD is characterised by the apparition of intrusion symptoms (unwanted upsetting memories, nightmares, flashbacks), avoidance, negative alterations in cognitions and mood and alterations in arousal and reactivity following a stressor event, such as exposure to actual or threatened death, serious injury or sexual violation.⁵ Childbirth can meet the diagnostic criteria for a traumatic event if the woman perceived their life and/or the life of their baby to be in danger.^{5,6} In case of the presence of clinically noteworthy CB-PTSD symptoms which are not fulfilling the whole set of PTSD diagnostic criteria, the term 'childbirth-related post-traumatic stress symptoms (CB-PTSS)' is used.⁷

CB-PTSD or a traumatic birth experience can have long-term negative repercussions on many aspects of women's lives including lower self-esteem, impact mother–infant bonding, decrease breastfeeding rates and alter the couple relationship satisfaction.^{8–10}

According to the newest meta-analysis on the subject, the overall prevalences of CB-PTSD and CB-PTSS are of 4.7% and 12.3% respectively.⁷ The prevalence of CB-PTSS can reach 21.1% in specific subgroups, such as women having had an emergency caesarean section (CS), a traumatic birth experience or a premature birth.⁷ When comparing different modes of childbirth, it is not surprising to find that women who had an unplanned CS are at a higher risk of having CB-PTSD symptoms than those who had a vaginal birth.^{11 12}

There may be many reasons for that. One of them could be a negative childbirth experience due to the unwanted separation of the mother and her infant after the operative birth.¹³ Usually during childbirth, if the mother's and the newborn's health allow it, maternity healthcare providers promote laying the baby down on his/her mother's chest directly after the birth.¹⁴ This first contact called 'skin-to-skin' has multiple benefits: it helps stabilise the newborn's haemodynamic parameters, encourages the start of breastfeeding and its continuation in the long term and strengthens the mother–baby bonding.¹⁴ However, during all CS, and especially an unplanned CS, its realisation is more difficult than after a vaginal birth due to the relatively low room temperature in the operating theatre, the need to have a dedicated midwife to monitor the newborn, the uncomfortable position of the mother on the operating table, the complicated position of the newborn on the mother's chest, the anaesthesiological parameters or the urgency to give birth.^{15–17}

If skin-to-skin contact is not possible or has to be interrupted, the infant is taken to another room with his/her mother's partner/co-parent and the midwife to receive the first care and have a moment of skin-to-skin contact with the mother's partner/co-parent. During this time, the mother is still in the operating theatre, alone, for the suturing part of the CS. This may trigger negative emotions, which have been identified to be risk factors for a negative or traumatic subjective birth experience.^{18 19} These negative emotions can be concerns for one's own and/or the baby's life,^{19 20} fear and anxiety^{13 18} or feelings of failure, self-blame and reduced self-esteem during and after the birth.^{13 18 21}

Having had a negative childbirth experience is one of the most important risk factors for CB-PTSD.²² Enabling a positive childbirth experience may therefore protect against the development of CB-PTSD and other related mental health disorders. Skin-to-skin contact between the mother and her newborn is a protective factor against a traumatic birth experience²³ and can weaken the association between CS and CB-PTSD symptoms, as it reduces feelings of fear and guilt.¹⁸ Given that prolonged skin-to-skin contact is difficult in the context of a CS for the reasons described above, other avenues to facilitate an

early contact between the mother and her newborn need to be explored and tested to propose an alternative in case of separation. Evidence shows that mothers want to be connected to their baby and experience skin-to-skin contact.²⁴ However, when the physical contact is not possible, it may be possible to enable a contact via a live visual and auditory connection.

One such solution may be based on the use of telemedicine, via technologies such as virtual reality (VR) and head-mounted displays (HMD).²⁵ VR is defined as an environment produced by a computer that seems almost real to the user. It is often used via a headset worn by a participant, showing him/her three-dimensional videos in order to immerse him/her into the environment created.²⁶ The VR equipment, which is usually an HMD, is used in various ways in medicine: in medical education, to previsualise surgical interventions, or in a wide range of therapeutic interventions.^{25 27}

Immersive VR can act as a non-pharmacological analgesic via modulation of the sensory and the emotional aspects of pain processing.²⁸ Essentially, the more the user's attention is drawn into the virtual environment, the less pain he/she experiences.²⁸ A very important advantage of VR is that it is without any serious side effects and well tolerated, unlike pharmacological therapies.^{29–32}

In the field of gynaecology and obstetrics, two studies found that the use of VR during the suture of an episiotomy led to a significant decrease of anxiety and pain symptoms.^{33 34} Another study showed that projecting echographic images of the baby obtained during pregnancy to the mother in labour via a VR headset was associated with a significant decrease of pain and anxiety symptoms.²⁹ A further study revealed that using immersive VR during early labour not only improved patients' pain score but was also associated with a higher patient satisfaction with the overall childbirth experience.³⁵ A recent study described that the use of FaceTime to connect mothers and babies after childbirth may have a positive effect on mother–infant bonding but further research is needed assessing a wider range of outcomes.³⁶

Aims of the present study

The goal of this study is to test the effect of an HMD ('connected caesarean section') on the childbirth experience of mothers undergoing a CS.

Based on the results observed in studies using VR and HMDs and studies on childbirth experience, we hypothesise that enabling the mother to have a visual and auditory contact with her baby may improve her childbirth experience when she and her baby are physically separated.

METHODS AND ANALYSIS

Study design

This study is a monocentric superiority open-label controlled pilot trial with minimal risk, which will take place on the maternity ward of a Swiss University Hospital. In the intervention group, we will use the technology of an

HMD to stream live images filmed by a two-dimensional (2D) 360° camera to enable the participant to have a visual and auditory contact with her baby when they are physically separated during the end of the CS. The HMD will be worn by the mother in the operating room, and the 2D 360° camera will be in the adjacent room where the baby, the mother's partner/co-parent and the midwife are. The camera will film the baby and broadcast the live video to the HMD. The mother will be able to witness the first care of her baby, see him/her being weighed and measured and watch the skin-to-skin contact between the baby and the mother's partner/co-parent. In order to enhance the mother's immersion and active participation, she will have a 360° vision and will be able to change the viewing angle by moving her head from one side to another or up and down. The HMD will only be worn by the mother if the skin-to-skin contact with her newborn is not possible (anymore), for any reason. However, if the skin-to-skin contact between the mother and her baby is possible, it will always be the preferred option to benefit both the mother and the newborn, physically and psychologically.

For ethical reasons, and in accordance with the local ethics committee, we decided against a randomised controlled trial design. Belonging to the control group could possibly induce frustration and disappointment, potentially leading to a worse childbirth experience, which could bias the results. Furthermore, we expect a high acceptability of the intervention even if the procedure is new and no data is known on the subject. However, knowing that this is an open-label study, we would expect a high drop-out rate in the control group if the groups were to be randomised, as the control group is not going to directly gain anything from taking part in the study. Additionally, as it is a pilot study and a new and innovative procedure without previous data on the subject is being tested, one of the goals of the study is to evaluate acceptability and feasibility of the procedure. The acceptability could be modified if participants knew they only had 50% chance of being in the intervention group.

Instead, there will be two consecutive study phases. During the first phase, consecutive participants will be the control group and will receive the standard care. During the second phase, consecutive participants will form the intervention group.

This study is a pilot study before the main study. The goal of the pilot is to elaborate hypothesis on the effect of the intervention on the childbirth experience in order to estimate the number of participants to include in a definitive study. The other goals of this study are to assess and to evaluate the feasibility and acceptability of the procedure in the clinical setting.

Sample size calculation

The study population will consist of 70 pregnant women giving birth via CS. They will be divided into two groups of 35 participants each (see below for a detailed explanation). Given the lack of previous research on which this pilot trial could have been based, the sample size for

the current trial was calculated according to common conventions that apply to the context of a pilot trial.³⁷

Study population, recruitment and group allocation

Inclusion criteria

- ▶ Women aged 18 years old or older.
- ▶ Planned or unplanned CS at ≥ 34 weeks gestation.
- ▶ Gave birth to a healthy baby according to paediatric evaluation (APGAR score ≥ 7 at 5 min).
- ▶ Gave oral consent followed by a written confirmation of consent.
- ▶ Skin-to-skin contact is not possible or was prematurely interrupted.
- ▶ Speaks French well enough to participate in study assessments.
- ▶ Eligibility confirmed by an independent physician for the intervention group.
- ▶ Partner/co-parent gave oral consent to be filmed for the intervention group.

Exclusion criteria

- ▶ Has an established intellectual disability or psychotic illness.
- ▶ Has photosensitive epilepsy.
- ▶ CS under general anaesthesia.

The study population includes women who are 18 years old or more, who have a CS, planned or not, at ≥ 34 weeks gestation, who give birth to a healthy baby according to paediatric evaluation with an APGAR score of ≥ 7 at 5 min, who can not have a continued skin-to-skin contact in the operating room, who speak French and who gave oral and written consent. In the intervention group, the partner/co-parent must give oral consent to be filmed and an independent doctor has to confirm eligibility. The exclusion criteria are having an established disability, psychotic illness or a photosensitive epilepsy and having a CS under general anaesthesia.

It is important to note that if skin-to-skin contact can be started in the operative room and continued until the end of the CS, the mother will not be included in the study, as skin-to-skin contact is the first and preferred option.

As the intervention occurs only in case of an impossible or interrupted skin-to-skin contact and the intervention is low risk, the recruitment will be done in four steps. First, there will be flyers with a QR code leading to a short video in the antenatal clinic of the Lausanne University Hospital waiting room, informing women that such a trial is currently taking place. Secondly, doctors will notify women coming to the pre-anaesthetic consultation for a planned CS or attending their regular antenatal appointment at 36 weeks. Then, a different procedure (with different participant information sheets) will be applied for the control and intervention groups.

Control group

The third step will be the oral consent with oral information on the nature of the study given by the clinical midwife or the study coordinator immediately before

the CS or in the recovery room immediately after the CS. If the woman agrees to participate, they will ask the perceived stress item. The fourth stage will be the written consent and will take place in the recovery or on the post-partum ward and will be done by a study collaborator the same day or the following day.

Intervention group

There is an additional step for the intervention group. As the intervention only takes place in the case of skin-to-skin contact with the newborn not being possible or being interrupted and given that women will not have much time to reflect on their participation in the study, the confirmation of an independent doctor not involved in this study or the direct care of the patient that the best interests of the participant can be guaranteed is needed. This doctor will have sufficient information about the study and will sign the written confirmation. This will be done before the study is briefly explained to the childbearing woman. The third step will be the oral consent obtained by a study collaborator before the HMD is installed. The partner/co-parent will receive the oral information as well and will have to give his oral consent to be filmed. If the partner/co-parent does not give his/her oral consent, there will be no intervention. The written consent of the midwife to be filmed is needed as well. Without it, there will be no intervention. The fourth stage will be the written consent obtained from the participant as soon as possible by a study collaborator in the recovery or hospital room.

For ethical reasons discussed above, the group allocation will take place according to the study phase in which the childbearing woman arrives. During the first study phase, 35 consecutive participants will be included in the control group, and only then, in a second phase, 35 consecutive participants will be allocated to the intervention group. All participant data will be coded to ensure confidentiality.

Withdrawal

Participants will be excluded from the study if they wish to withdraw. They will be replaced until data sets of 70 women at 1 week (assessment of primary outcome) have been collected.

Outcomes

Primary outcome

The primary outcome is the difference in childbirth experience using the Childbirth Experience Questionnaire 2 (CEQ-2) between the intervention and the control group at 1-week post partum.

Secondary outcomes

Secondary outcomes will be evaluated using various validated questionnaires: the City Birth Trauma Scale (City BiTS) evaluating CB-PTSD, the Birth Satisfaction Scale Revised (BSS-R) evaluating the satisfaction of the birth, the Mother–Infant Bonding Scale (MIBS) evaluating the mother–infant bonding, the Hospital Anxiety and Depression Scale (HADS) evaluating symptoms of

depression or anxiety, perceived pain and stress during childbirth using visual analogue scales and anaesthesiological data.

Secondary outcomes will be assessed during and directly after the CS, at 1 week and 4 weeks post partum. Other secondary outcomes include the acceptability of the study by participants.

Data collection

During the CS, routine anaesthesiological data, such as haemodynamic parameters, perioperative shivers, nausea and use of medication will be obtained. Right after the separation of the mother and the infant, the participant's pain level will be assessed using the perceived pain item.

At the end of the CS, the HMD will be removed and the investigator will assess the participant's pain and anxiety level using the perceived stress item and perceived pain item. For the intervention group, the tolerability of the intervention will be assessed as well.

One week after birth, participants will receive a link to online questionnaires via email. The questionnaires will take about 10 min to complete and will assess the participant's experience and satisfaction of the birth, the perceived pain during childbirth, as well as symptoms of anxiety/depression and stress, and the mother–infant bonding (Childbirth Experience Questionnaire, Birth Satisfaction Scale, Mother-Infant Bonding Scale, Hospital Anxiety and Depression Scale). The intervention group will have an additional questionnaire, which evaluates their satisfaction of the intervention.

One month after the birth, participants will be asked to complete questionnaires evaluating their anxiety and depression, and birth-related trauma symptoms (Hospital Anxiety and Depression Scale, City Birth Trauma Scale). The questionnaires will take about 10 min to complete.

Participants will be contacted via telephone if the questionnaires have not been completed within a week after the date of reception of the link.

Figure 1 summarises study procedures.

Measures

Anaesthesiological data

Haemodynamic parameters, perioperative shivers, nausea and use of medication will be extracted from the routine anaesthesiological data in the patient's file and from a perioperative study sheet.

Perceived stress item

A Visual Analogue Scale (VAS) from 0=*no stress at all* to 10=*worst stress imaginable* will be shown to the participant and she will be asked to evaluate her current stress level on that scale.

Perceived pain item

A VAS from 0=*no pain at all* to 10=*worst pain imaginable* will be shown to the participant and she will be asked to evaluate her current pain level on that scale.

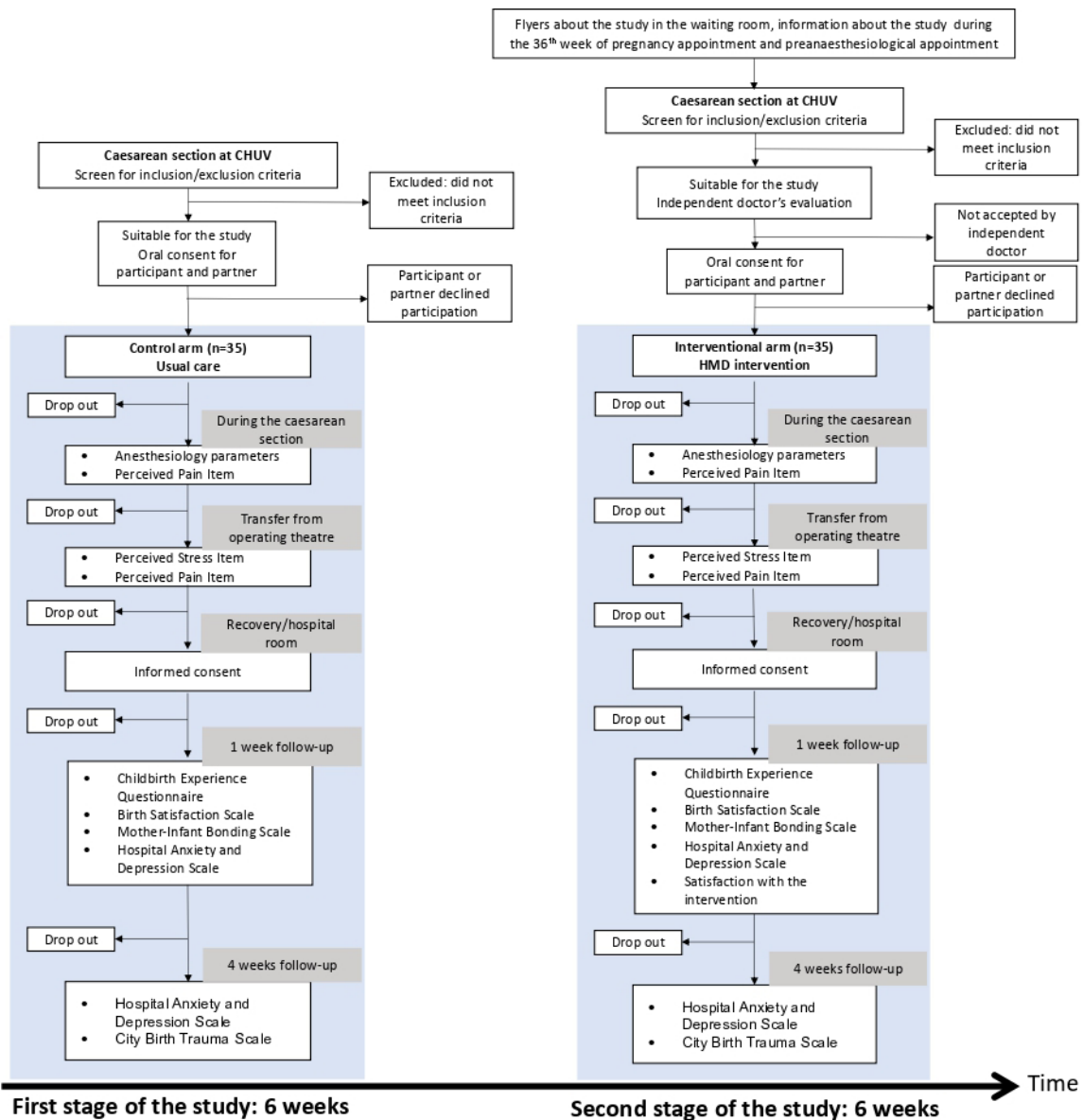


Figure 1 Flowchart of study procedures. HMD, head-mounted display.

Childbirth Experience Questionnaire-2 (CEQ-2)

This self-report questionnaire measures the maternal childbirth experience on four different subscales: *own capacity*, *perceived safety*, *professional support* and *participation*.³⁸ There are 19 items rated on a 4-point Likert scale ranging from 1=*totally disagree* to 4=*totally agree* and 3 items rated on a VAS from 1 to 100,³⁸ 1=*worst imaginable pain/no control/not at all secure* and 100=*no pain/complete control/completely secure*. Rating of negatively worded statements are reversed. Higher scores indicate a better childbirth experience. The word ‘labour’ was put in brackets as some participants will give birth via a planned CS and therefore will have no labour. This questionnaire has good psychometrics and has been validated in English.^{39–41} In the absence of a French version at the time of the study, a forward–backward method to realise a translation and a cultural adaptation was carried out.⁴²

Birth Satisfaction Scale (BSS-R)

The BSS-R is a 10-item self-report questionnaire assessing the perceptions of the birth in order to determine women’s satisfaction of their birth experience.^{43 44} It consists of one higher-order factor, *experience of childbearing*, containing three lower-order factors: *quality of care provision*, *women’s personal attributes* and *stress experienced during labour*.^{43–45} The items are evaluated on a 5-point Likert-type scale that requests participants to rate their level of agreement with each item (from 1=*strongly disagree* to 5=*strongly agree*). Four of the items are reverse-coded. Higher score denotes a greater satisfaction of the birth. The word ‘labour’ was put in brackets as some participants will give birth via a planned CS and therefore will have no labour. This score questionnaire has good psychometrics and was validated in English.^{44 46} In the



absence of a French version at the time of the study, a forward–backward method to realise a translation and a cultural adaptation was executed.⁴²

Mother-Infant Bonding Scale (MIBS)

This eight-item self-report questionnaire assesses the mother's feelings towards her newborn in the first week after birth.⁴⁷ The eight items are statements describing an emotional response and are rated on a 4-point Likert scale (from 0=*very much* to 3=*not at all*). A higher score denotes worse bonding. This score has shown good psychometrics⁴⁸ and has been validated in French.⁴⁹

Hospital Anxiety and Depression Scale (HADS)

This self-report questionnaire measures the severity of anxiety and depression symptoms during the week before replying to the questions.⁵⁰ There are two subscales measuring anxiety or depression symptoms. Each of them consists of seven items scored on a 4-point Likert scale (from 0=*never* to 3=*most of the time*). A higher score reflects greater symptom severity. Good psychometric properties have been reported in both English and French versions.^{51 52}

City Birth Trauma Scale (City BITS)

The City Birth Trauma Scale is a 29-item questionnaire measuring birth-related post-traumatic stress disorder symptoms according to DSM-5 criteria of (1) stressor criteria, (2) symptoms of re-experiencing, (3) avoidance, (4) negative cognitions and mood, (5) hyperarousal, (6) duration of symptoms, (7) signification distress or impairment and (8) exclusion criteria or other causes.⁵³ Items are evaluated with yes/no/maybe or by frequency of the symptoms. A higher score indicates a higher level of PTSD symptoms.⁵⁴ Good psychometrics properties have been reported for both the English and French version.^{53–55}

Satisfaction with the intervention

Twelve questions will be asked to the participants of the intervention group on their global satisfaction with the intervention, the utility of the intervention, the comfort of the HMD, the quality of the images, sound and camera-HMD connection, as well as the advantages and disadvantages of the HMD. Three questions will be evaluated on a 5-point Likert-scale (from 0=*not at all* to 4=*very much*). Four questions will require a yes–no answer and five questions will be open questions.

Risks and serious adverse events

As mentioned above, this trial has a minimal risk. Studies using VR in obstetrics did not notice any serious side effects and VR was well tolerated.^{29–32} A potential risk of this study is that the mother witnesses her baby needing medical attention. In the case that the mother is wearing the HMD and there is a sudden issue with her child's health, the research team will ask the mother if she wishes to continue to wear the HMD or not. We will offer her the choice, as we think that suddenly removing the HMD could be traumatic as well. In any case, she will be

excluded from the statistical part of the study as her experience will be very different from those of the other study participants.

Only adverse events of interest happening between the start of the surgery until 1 hour after the end of the HMD intervention, such as nausea or headaches, arising from the intervention, the surgery or the anaesthesia will be reported in the electronic case report form by the investigators. All serious adverse events will be reported immediately to the Sponsor-Investigator of the study and if it cannot be excluded that the serious adverse event is attributable to the intervention the Ethics Committee will be alerted.

Benefits and potential risks are written in the informed consent document that the participants receive. They will be informed of the purpose of the intervention, the benefits and possible risks of the study.

PATIENT AND PUBLIC INVOLVEMENT

A questionnaire of satisfaction and tolerability of the intervention will examine the burden of the intervention. After each participant completed the study, a study collaborator will contact them to have a follow-up and to offer to send a list of psychological resources and contacts if needed. Furthermore, as for every childbirth at the Lausanne University Hospital, the mother can have, at her demand, two consultations with a midwife screening for CB-PTSD, one during the hospital stay and the second at 6 weeks post partum. Global results will be disseminated in written form to the participants and distributed to the public via social media and public events. They will also be discussed with professionals involved in this project. No patient was involved in the development or the design of this study.

DATA MANAGEMENT AND STATISTICAL ANALYSES

The questionnaires will be filled out by the participants via REDCap (Research Electronic Data Capture, a secure web application for building and managing online surveys and databases—projectredcap.org). The rest of the data will also be collected using REDCap. The data will be stored on a secured server at Lausanne University Hospital that meets high security standards and performs automatic continuous backups. Access to the full final trial data set will be restricted to the Principal Investigator. The database will be exported from REDCap to the Stata V.17.0 software for the statistical analyses.

For the primary analyses, group differences regarding the mean subscale and total scores of the CEQ-2 at 1-week post partum will be analysed using linear regression analysis.

For the secondary outcomes, the same type of statistical analyses will be conducted as for the primary outcome. The analyses will be performed for differences between groups regarding the different questionnaires at 1 week or 4 weeks postpartum using linear regression analysis.

ETHICS AND DISSEMINATION

Ethics approval was granted by the Human Research Ethics Committee of the Canton de Vaud (study number 2022–00215). Dissemination of results will occur via national and international conferences, peer-reviewed journals, public conferences and social media.

Contributors AH and DD designed the study with input from all coauthors and members of the consortium. SM developed technological solutions for the study. FC, EB, KL and DGD participated in the design of the study. AH, DD and FC drafted the manuscript. All authors critically revised the manuscript and approved its final version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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ORCID iDs

Fiona Corbaz <http://orcid.org/0000-0002-6778-3527>

Sandra Marcadent <http://orcid.org/0000-0002-6470-3974>

David Desseauve <http://orcid.org/0000-0003-1308-7750>

Antje Horsch <http://orcid.org/0000-0002-9950-9661>

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