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Virtual Reality in Labor Pain Management: A Randomized Controlled Trial

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ABSTRACT

Background: This study aimed to evaluate the impact of using virtual reality as a non-pharmacological therapeutic method for pain reduction in women during labor.
Methods: A randomized, controlled, single-center clinical trial was conducted in a healthcare unit in northern Portugal, from May 2023 to May 2024. A total of 61 pregnant women participated, with 32 in the intervention group and 29 in the control group.
Results: The results indicated a significant reduction in pain intensity in the intervention group compared to the control group during the application of virtual reality. However, this pain reduction was not significantly sustained 30 minutes after the intervention ended.
Conclusion: Virtual reality proved to be an effective intervention for reducing pain during labor, with beneficial effects during its use. However, these effects were not sustained in the long term. The study highlights the potential of virtual reality as a non-pharmacological and safe approach to pain management in obstetric contexts, emphasizing the need for technological advancements in the development of tailored resources for this target population.

Pregnancy and childbirth are among the most significant experiences in a woman's life (Konieczka et al., 2024). While childbirth is a natural event, it is a transformative process often regarded as physically and emotionally demanding, which women endure(Nori et al., 2023; Marucci et al., 2007). Thus, pregnancy and childbirth represent a period of stress in a woman's life, where the quality of experiences during labor and delivery can significantly influence physical and emotional health (Alizadeh-Dibazari, et al., 2023; Kiruthiga, 2017). Pain is acknowledged as an inherent part of childbirth, although approaches to its management have evolved over time (Nori et al., 2023).

Despite being a physiological process, labor pain, when intense, triggers neuroendocrine, metabolic, and inflammatory responses that can adversely affect maternal-fetal well-being (Nori et al., 2023; Marucci et al., 2007). Pain management during labor presents a significant challenge for both obstetricians and expectant mothers (Nori et al., 2023). Although pharmacological pain management remains the gold standard, it still poses risks for the mother, including hypotension, nausea, vomiting, pruritus, reduced mobility, and, in rare cases, respiratory depression and allergic reactions (Smith et al., 2018; Callahan et al., 2023; Thomson et al., 2019). For the newborn, potential adverse effects include respiratory depression, sedation, decreased alertness, and difficulties initiating breastfeeding, such as delayed onset of the first feed (Smith et al., 2018; Callahan et al., 2023; Thomson et al., 2019).

Over the past decades, there has been a growing interest in non-pharmacological pain management (NPPM) as a safe and effective option to alleviate labor pain (Nori et al., 2023; Domínguez-Solís et al., 2021; Hu et al., 2021). This shift is driven by a confluence of factors, including increasing evidence of the side effects and risks associated with pharmacological interventions (Nori et al., 2023; Zipursky et al., 2023;

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Siyoum & Mekonnen, 2019). Additionally, there is a broader societal transition towards more person-centered and holistic care, emphasizing personal autonomy, shared decision-making, and alternative interventions (Beigi et al., 2019; Alizadeh-Dibazari et al., 2024).

Recently, several non-pharmacological interventions have been applied to manage labor pain, demonstrating positive effects. These include acupressure, aromatherapy, and massage therapy (Hu et al., 2021), as well as distraction and relaxation techniques (Alizadeh-Dibazari et al., 2024; Weschenfelder et al., 2024), hydrotherapy through warm showers, perineal exercises with a birthing ball, yoga, and acupressure (Domínguez-Solís et al., 2021; Hu et al., 2021).Thus, utilizing methods capable of alleviating pain during the different phases of labor can transform labor and delivery into a more satisfying experience (Ebrahimian & Biland, 2021).

Recent literature highlights the successful use of virtual reality (VR) in various healthcare settings (Boussac et al. 2021; Carus et al., 2022; Rousseaux et al., 2022; Wang et al., 2020; Melillo et al., 2024). Virtual reality (VR) is a technology that enables users to immerse themselves in a computer-generated three-dimensional environment, allowing realistic interaction with simulated settings, typically through the use of a headset and headphones, thus providing interactive and immersive experiences (Carus et al., 2022; Rousseaux et al., 2022).

Virtual reality has been employed as a distraction tool to overcome discomfort associated with clinical procedures or as a non-pharmacological therapy for managing pain and associated symptoms (Son et al. 2022). Currently, this technology is applied for various purposes in the training of healthcare professionals (such as surgical simulation and emergency simulation), as well as in pain management during procedures, rehabilitation, relaxation, and anxiety reduction among hospitalized or oncology patients (Carus et al., 2022; Lie et al., 2023; Melillo et al., 2024; Rousseaux et al., 2022; Wang et al., 2020.) Virtual Reality has emerged as a novel non-pharmacological analgesic therapy, demonstrating effectiveness in reducing pain and anxiety, thereby enhancing patient comfort (Rousseaux et al., 2022). In this context, virtual reality can alleviate pain through distraction during the latent phase of labor and improve patient satisfaction, an important quality indicator in labor and delivery care (Carus et al., 2022).This non-pharmacological option is increasingly proposed as a primary, complementary, multimodal analgesic, or anxiolytic management strategy (Boussac et al. 2021; Rousseaux et al., 2022; Son et al. 2022; Wang et al., 2020). When appropriately utilized, this technique can enhance the childbirth experience (Baradwan et al. 2022; Boussac et al. 2021;). Aware of these potentials, this study aims to evaluate the impact of virtual reality as a non-pharmacological therapeutic method for reducing pain in women during labor. Therefore, the research question that guided our study was: “Does the use of virtual reality significantly reduce pain intensity in primiparous women during labor compared to standard care?” This question was based on the underlying hypothesis that virtual reality would result in a significant reduction in pain intensity during labor.

Methods

Study design

The present study was a single-center, prospective, randomized, parallel-group investigation using pre- and post-tests. The study was registered (https://osf.io/5ZEYF) and reported following the CONSORT guidelines (Schulz et al., 2010). It was conducted at a Local Health Unit in Northern Portugal from May 1, 2023, to May 1, 2024. This randomized clinical trial consisted of two parallel groups: the control group, which received standard of care, and the intervention group, which underwent an innovative program using virtual reality during labor induction, providing an additional approach to the standard of care treatment. Randomization was performed by one of the investigators who was not involved in participant recruitment or data collection.

Participants

The participants included in the study were pregnant women admitted for labor induction at a Local Health Unit in Northern Portugal, between May 1, 2023, and May 1, 2024. The following inclusion criteria were established for patient recruitment: participants had to be aged 18 years or older, between 37 and 41 weeks of gestation, with a singleton pregnancy and cephalic fetal presentation. Additionally, participants needed to be receiving care at the mentioned health unit, speak Portuguese, report a pain level between 4 and 7 on the VAS scale, and not have received any form of pharmacological or epidural analgesia (Ferreira-Valente et al., 2011)

Exclusion criteria included the following: preeclampsia/eclampsia, psychiatric disorders, visual or auditory impairment, epilepsy, light sensitivity, predisposition to nausea, migraines, dizziness, pain outside the 4–7 range on the analog scale, use of analgesic medication (oral, intravenous, intramuscular, or epidural), and discomfort with using the equipment.

Randomization

Consecutive sampling was employed, including all eligible primiparous women admitted for labor induction during the study period, until the required sample size was achieved. To estimate the sample size with a power (1-β) of 80%, a significance level (α) of 0.05, and an allocation ratio of 1, a sample size of 17 women per group was calculated to detect the desired difference. To account for potential dropouts, we decided to include up to 35 women in each group (Faul et al., 2007). In the end, 32 women participated in the intervention group, and 29 women participated in the control group.

Randomization was performed at the time of admission, dividing participants into two groups based on the scheduled induction date. Women whose inductions were scheduled on even-numbered days (e.g., March 2) were allocated to the control group, while those scheduled on odd-numbered days (e.g., March 3) were allocated to the intervention group. Both groups were treated identically in all aspects, except for the intervention (Figure 1).

Neither the participants, the nurses responsible for administering the intervention, nor the outcome assessors were blinded to group allocation due to the visible nature of the intervention.

Intervention

There are several options for implementing virtual reality in clinical settings to reduce anxiety and pain. In this study, we chose to use Digital Sedation™ (Sedakit™, Vygon, 2020), a non-pharmacological therapeutic intervention designed to reduce patient pain and anxiety before, during, and after clinical procedures. This intervention is based on the use of a medical device (Oncomfort), which includes a headset and headphones that deliver immersive auditory and visual experiences, helping to shield pregnant women from environmental stimuli. The Oncomfort Virtual Reality technology is, user-friendly, portable, and implemented throughout the clinical procedure (Vygon, 2020). This digital therapy offers an alternative to both pharmacological and non-pharmacological analgesia, with potential positive impacts

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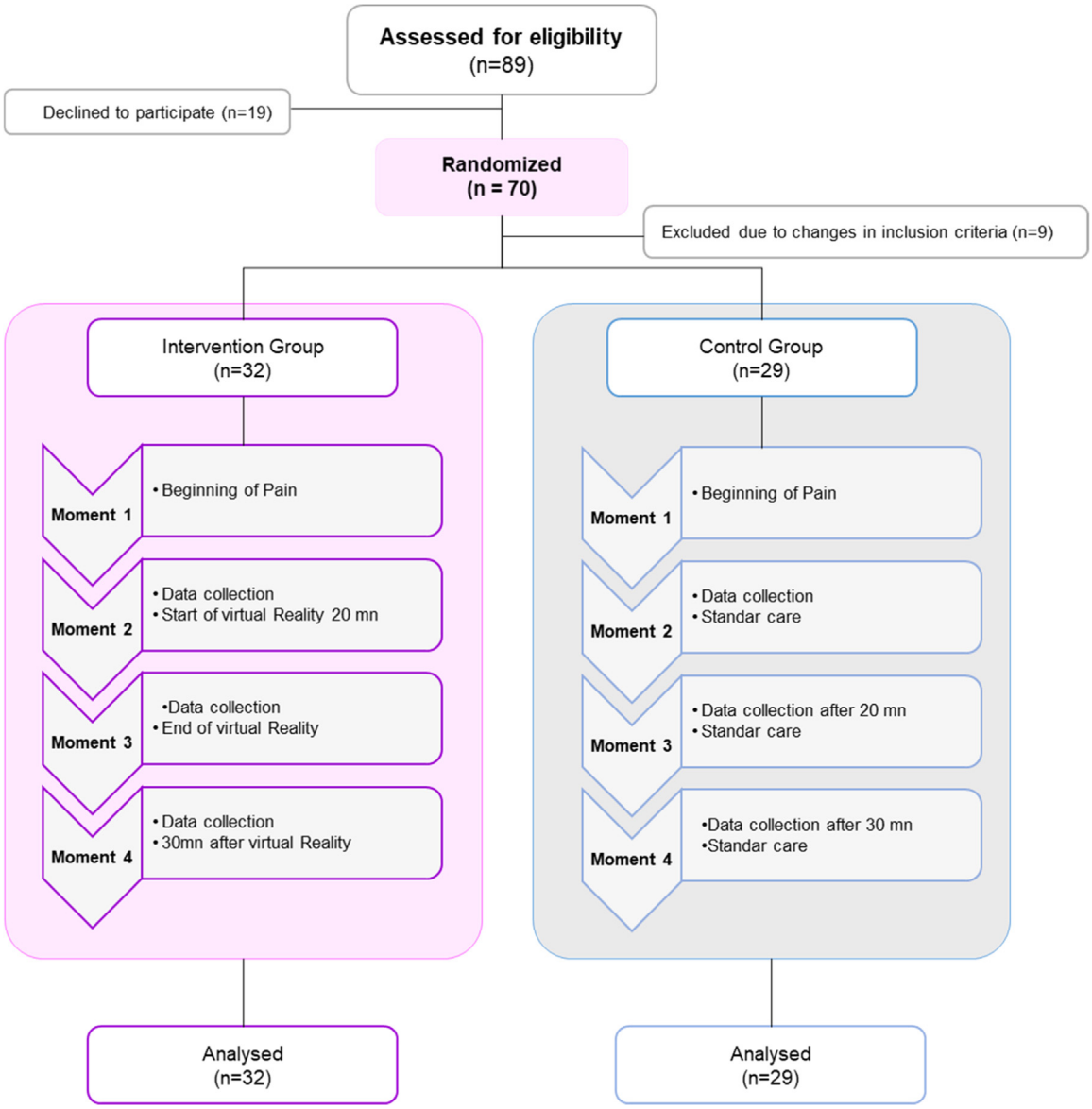

Figure 1. Design flow diagram.

on patient comfort, as well as on anxiety and pain reduction (Joo et al., 2021; Rousseaux et al., 2022; Gullo et al., 2023).

During the intervention, the virtual reality headset delivers an immersive experience with suggestions of positive bodily sensations. Participants are invited to observe the sunrise and a beautiful landscape while relaxing on a chair made of white clouds.

We used the module "SILVA", which creates a virtual countryside environment associated with seasonal variations, with a three-dimensional landscape featuring a mountain cabin by a lake at sunrise, followed by a calming moment among the clouds. Various distraction effects, such as sounds and animals, are also presented throughout the module. The intervention lasts for 20 minutes. In this study, each participant used the VR intervention only once during labor.The intervention process followed the steps identified in Figure 1.

Instruments

During the pre-intervention assessment, when participants reported a pain level between 3 and 6 on the Visual Analogue Scale (VAS), sociodemographic (gender, date of birth, marital status, years of education, and profession) and clinical data (diagnosis, comorbidities, habitual medication, smoking, and alcohol consumption habits) were collected using a form specifically designed for this study. The range of 3 to 6 on the Visual Analogue Scale (VAS) was selected to ensure a moderate level of pain intensity and to support baseline homogeneity between groups.

Additionally, various biometric data (blood pressure, heart rate, and pain level) were monitored and recorded at three time points: before exposure to virtual reality, immediately after its conclusion, and 30 minutes later. These procedures are described and organized as presented in Figure 1.

To assess pain, the Visual Analogue Scale (VAS) was used. The VAS is widely employed to evaluate pain intensity in clinical and research contexts, offering a continuous scale where patients indicate their perceived pain level, ranging from "*no pain*" to "*the worst pain imaginable*." (Ferreira-Valente et al., 2011). The Visual Analogue Scale (VAS) demonstrates high reliability for pain assessment, with a reported Cronbach's alpha coefficient of 0.94 (Ferreira-Valente et al., 2011).

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Table 1
Participants Characteristics.

Category	Control Group CG	Intervention Group IG	*p*-value
Age (years)	Mean: 30.48; SD: 4.911; Range: 18-41	Mean: 31.20; SD: 5.385; Range: 18-40	>.05
Marital status	Most Frequent: Married/Civil Union	Most Frequent: Married/Civil Union	>.05
Education	Most Frequent: High School, Bachelor's Degree	Most Frequent: High School, Bachelor's Degree	>.05
Weeks of gestation	Mean: 39.35; SD: 0.538; Range: 38-41	Mean: 39.12; SD: 0.589; Range: 38-41	>.05
Number of pregnancy	Mean: 1.55; SD: 0.783; Range: 1-4; Most Frequent: First Pregnancy	Mean: 1.77; SD: 1.104; Range: 1-5; Most Frequent: First Pregnancy	>.05
Number of births	Mean: 0.41; SD: 0.780; Range: 0-3; Most Frequent: 0	Mean: 0.47; SD: 0.629; Range: 0-2; Most Frequent: 0	>.05

CG = control group; IG = intervention group, *p*-value; VR = virtual reality; SD = standard deviation.

To ensure comparability between groups, pain in the control group was assessed at the same standardized time points as in the intervention group: at the onset of moderate pain (VAS 3–6), 20 minutes later, after an additional 20 minutes, and again 30 minutes thereafter.

The administration of assessment instruments was carried out by a small team consisting of two nurses and three midwives, all of whom had received prior training in the standardized use of the study's measurement instruments and in the implementation of the virtual reality resource. Additionally, a pre-test was conducted with three pregnant women to validate the study procedures.

Statistical analysis

Statistical analysis was performed using SPSS, version 26. Homogeneity tests were applied to assess the comparability of the groups. Baseline characteristics for each group were presented as frequencies, percentages, means, and standard deviations. Primary outcomes were analyzed by comparing groups regarding the impact of the exergame, using the Mann-Whitney test or the chi-square test for repeated measures. Results were considered significant at a 95% confidence level ($p < .05$), with both parametric and non-parametric analyses applied.

Ethics statement

This study received approval from the ethics committee (Code: CES. 124/CES/JAS), as well as written consent from the institution's administrative board and the data protection committee. All participants were fully informed about the details of the research before providing their written consent to participate. Participation was voluntary, and the confidentiality and anonymity of the participants were ensured throughout the study. The virtual reality intervention was supervised by the healthcare team, and participants were allowed to discontinue their participation at any time in the event of discomfort or adverse effects. No financial or material incentives were offered to participants for their participation in this study.

Results

Participants characteristics

The sociodemographic and clinical characteristics of the study sample, which included an intervention group and a control group, are presented in Table 1. The intervention group comprised 32 participants with a mean age of 31.2 years (SD = 5.385). Most participants were married or in a de facto union. Regarding education level, the majority had completed high school (12th grade). The mean gestational age was 39.12 weeks (SD = 0.589). Obstetrically, most participants were in their first pregnancy (Gesta I, mean = 1.77; SD = 1.104) and had not experienced any previous deliveries (Para 0, mean = 0.47; SD = 0.629). The primary support during labor was reported to be the husband, boyfriend, or partner.

The control group included 29 participants with a mean age of 30.5 years (SD = 4.911). Similar to the intervention group, most participants were married or in a de facto union, and the predominant education level was high school (12th grade). The mean gestational age was 39.3 weeks (SD = 0.538). Likewise, most participants were in their first pregnancy (Gesta I, mean = 1.55; SD = 0.783) with no previous deliveries (Para 0, mean = 0.41; SD = 0.780). In this group, the primary support during labor was also reported to be the husband, boyfriend, or partner.

In both groups, all participants attended childbirth preparation classes and indicated that they had received information about childbirth. There were no statistically significant differences between the groups ($p > .05$), indicating a homogeneous sample across the groups and providing a suitable foundation for analyzing the effects of the studied intervention.

Virtual intervention and pain outcomes

All participants in the intervention group (100%) opted to use the virtual reality (VR) headset for the entire duration of the procedure. No adverse events or side effects were reported during the use of the VR headset.

The data presented in Table 2 provide a detailed analysis of pain intensity measured at four distinct time points for both the control and intervention groups.

At **Moment 1**, corresponding to the onset of pain, both groups exhibited similar pain levels, with a mean of 3.21 (SD = 0.620) in the control group and 3.23 (SD = 0.679) in the intervention group. This lack of significant variation was confirmed by the Mann-Whitney test ($U = 422$, $Z = -0.220$, $p = .826$), indicating that the groups were homogeneous at this initial point.

At **Moment 2**, the intervention group began the use of VR. After 20 minutes of VR use, at Moment 3, a marked reduction in pain was observed in the intervention group (mean = 3.43, SD = 0.709) compared to the control group (mean = 4.48, SD = 1.755). The Mann-Whitney test ($U = 279$, $Z = -2.494$, $p = .013$) confirmed a statistically significant difference between the groups, demonstrating that VR was more effective in reducing pain immediately.

At **Moment 4**, 30 minutes after the conclusion of the VR intervention, pain levels in both groups became similar again, with

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Table 2
Detailed Pain Analysis With Statistical Indicators By Moment.

Moment	Control Group (Mean/SD/Median)	Intervention Group (Mean/SD/Median)	*p*-value	Interpretation
Moment 1 (Start of Pain)	3.21 / 0.620 / 3	3.23 / 0.679 / 3	$U = 422$, $Z = -0.220$, $p = .826$	No significant difference, similar pain levels between groups
Moment 2 (Start of Virtual Reality)	4.21 / 0.412 / 4	4.67 / 0.884 / 4	$U = 310$, $Z = -2.279$, $p = .023$	Significant difference, variable VR impact
Moment 3 (End of Virtual Reality)	4.48 / 0.709 / 4	3.43 / 1.755 / 4	$U = 279$, $Z = -2.494$, $p = .013$	Significant difference, VR reduces pain more in control group
Moment 4 (30 min after VR)	4.48 / 0.509 / 4	4.50 / 1.697 / 4.50	$U = 423.5$, $Z = -0.186$, $p = .853$	No significant difference, VR effect not long-lasting

CG = control group; IG = intervention group, p-value, VR = virtual reality; SD = standard deviation.

a mean of 4.48 (SD = 0.620) in the control group and 4.50 (SD = 1.697) in the intervention group. The Mann-Whitney test ($U = 423.5$, $Z = -0.186$, $p = .853$) revealed no statistically significant differences, indicating that the effect of VR in reducing pain was not sustained over the longer term.

Discussion

The present study explored the impact of using virtual reality (VR) as a non-pharmacological therapeutic method and distraction tool on pain parameters in women during labor. Despite the growing popularity of these resources, published reports discussing the effectiveness of VR in this specific context remain scarce (Nori et al., 2023; Hu et al., 2021; Melillo et al., 2024). The distracting effect of VR during potentially painful procedures, particularly its influence, has already been extensively investigated (Rousseaux et al., 2022; Wang et al., 2020; Joo et al., 2021; Gullo et al., 2023).

From our results, a high level of patient participation was observed, with all participants (100%) in the intervention group expressing interest in using the VR headset and choosing to wear it throughout the procedure. Some authors highlight the high satisfaction of participants using VR during labor (Nori et al., 2023; Musters et al., 2023; Xu et al., 2022; Akin et al., 2021). Regarding the type of VR intervention used, the "Digital Sedation™ - Sedakit™ (Vygon, 2020)". was highly appreciated by the participants. This VR hypnosis program was designed to manage anxiety and pain during treatments, employing immersive 360° audio and video to create a virtual scenario that induces physical and emotional comfort, as well as meditation (Joo et al., 2021; Gullo et al., 2023). In a qualitative study examining women's experiences, preferences, and satisfaction with VR during labor, guided meditation emerged as a preferred feature (Musters et al., 2023). VR provides an effective and accessible method for creating simulated scenarios, enabling interaction with virtual environments through immersive multisensory stimuli (Xu et al., 2022; Akin et al., 2021). In the latent phase and early dilation stage (with regular painful contractions and cervical dilation between 3 and 5 cm), women preferred stimuli that offered greater distraction, such as diverse natural scenarios, realistic nature images, and meditative voiceovers to facilitate relaxation (Musters et al., 2023).

In terms of adverse effects, no adverse events or side effects associated with VR use were reported. Using VR during labor is an accessible and practical method that does not produce negative side effects for the mother or fetus (Akin et al., 2021). Although nausea is sometimes reported with VR headset use, a study involving 70 women demonstrated no significant differences in nausea symptoms (Frey et al., 2019). Therefore, VR can be considered a safe, non-invasive analgesic method with minimal side effects and no risk of drug dependency (Musters et al., 2023).

The primary finding of our study centers on pain intensity scores, which were significantly lower during VR use. The reductions in pain scores during labor observed in this study align with findings from previous studies on VR during labor (Musters et al., 2023; Frey et al., 2019; Siyoum et al., 2019), and in other acute pain scenarios outside the labor process (Joo et al., 2021; Gullo et al., 2023). However, at **Moment 4**, 30 minutes after discontinuing VR during labor, no reduction in pain was observed between the groups. This may be attributed to the distraction effect provided by VR, which temporarily diverts attention from pain. Once the exposure to VR ends, the distraction effect diminishes, and pain perception may return to previous levels, indicating that while VR is effective during application, its pain-relieving effects do not persist over time.

In summary, opting for non-pharmacological methods such as VR for pain control during normal labor, which are free of side effects and offer good cost-effectiveness, can improve healthcare quality and patient satisfaction (Baradwan et al., 2022). Therefore, VR holds significant potential as a safe alternative or complement to existing pharmacological analgesia during labor (Musters et al., 2023).

The results of this study highlight several implications for future research and clinical practice. It is recommended that future studies include an assessment of cost-effectiveness and maternal satisfaction. The development and validation of virtual reality resources specifically tailored to this population is also suggested. At the level of health policy, the integration of virtual reality may contribute to more personalized, humanized, and accessible childbirth experiences.

Limitations

Despite the strengths of the study, it had some limitations, notably the sample size. The small number of participants may limit the generalizability of the findings. Another relevant aspect that could have been explored is the measurement of additional outcomes, which would provide a more holistic view of the effects of virtual reality during labor, such as satisfaction, fear, and other factors, as well as post-intervention follow-up.

Another limitation to highlight is that the VR resource used had a duration of only 20 minutes and was not specifically designed for this target population. Future studies may explore the impact of using virtual reality (VR) in multiple sessions during labor. Given that labor can extend over several hours, it would be important to develop and validate resources tailored to this population that could provide a longer-lasting intervention. This would allow for

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the inclusion of extended interventions better suited to the needs of women during labor.

Conclusion

In summary, this study aimed to evaluate the impact of using virtual reality (VR) as a non-pharmacological therapeutic method for reducing pain in women during labor. The results demonstrated a significant impact on pain reduction during the use of this technology. This study highlights the potential of virtual reality (VR) as an effective and accessible non-pharmacological intervention for pain management during labor, without causing side effects.

However, the findings emphasize the need for further research, particularly in the development of virtual reality (VR) resources specifically designed for this target population. Future investigations should focus on creating resources that enable personalized interventions, adapted to the various positions assumed by patients during labor, while facilitating mobility and position changes.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Maria do Carmo Gamboa Correia: Writing – original draft, Methodology, Data curation, Conceptualization. **Carla Maria Ribeiro da Silva Teles:** Writing – review & editing, Formal analysis, Data curation, Conceptualization. **Rosa Maria Pereira Vilarinho Assunção:** Writing – review & editing, Formal analysis, Data curation, Conceptualization. **Bruno Miguel Magalhães:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Carla Sílvia Fernandes:** Writing – original draft, Supervision, Project administration, Formal analysis, Data curation, Conceptualization.

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