Original Paper

Virtual Reality–Based 360° Clinic Walk-Through to Reduce Examination Distress in Preschool Children: Randomized Controlled Trial

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Abstract

Background: Routine outpatient examinations can be distressing for preschool children because of unfamiliar clinical environments, physical contact, and uncertainty about what will happen. Virtual reality (VR) may provide developmentally appropriate preexposure to clinical settings, but pediatric VR studies have mainly focused on invasive or high-stress procedures.

Objective: This randomized controlled trial aimed to determine whether a brief, clinic-specific 360° VR clinic walk-through delivered before pediatric outpatient examination reduced behavioral distress and facilitated physician-rated examination ease in children aged 3 to 5.5 years.

Methods: This parallel-group randomized controlled trial was conducted in a tertiary pediatric outpatient clinic. A total of 100 children aged 3 to 5.5 years were randomly assigned 1:1 to the VR group (n=50) or control group (n=50). Children in the VR group viewed an approximately 3-minute 360° video of the actual clinic environment from a child's eye level using a smartphone-based head-mounted display; controls underwent routine waiting. The examining physician, outcome assessor, and data analyst were blinded. The primary outcome was behavioral distress during examination assessed using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale. Secondary outcomes included crying duration, change in the unweighted modified Yale Preoperative Anxiety Scale (mYPAS) raw total, physiological responses, Wong-Baker FACES Pain Rating Scale (WBS) score, parent satisfaction, physician-rated examination ease, and VR-related adverse effects.

Results: Baseline characteristics and mYPAS raw totals were comparable between groups. The change in the mYPAS raw total did not differ significantly (mean 0.6, SD 0.5 vs 0.4, SD 0.5; *P*=.12). During examination, the VR group had lower FLACC scores than controls (median 3, IQR 1-4 vs median 5, IQR 3-8; *P*<.001) and shorter crying duration (mean 11, SD 3 vs 28, SD 9 seconds; *P*<.001). Mean heart rate (101.7, SD 10.4 vs 124.9, SD 18.8 beats/min; *P*<.001) and respiratory rate (24.1, SD 2.2 vs 29.7, SD 3.4 breaths/min; *P*<.001) were also lower during examination. Postexamination WBS scores were lower (mean 3.1, SD 1.1 vs 6.6, SD 2.0; *P*<.001), whereas parent satisfaction (mean 4.2, SD 1.0 vs 2.2, SD 0.8; *P*<.001) and physician-rated examination ease (mean 8.8, SD 1.1 vs 6.1, SD 0.9; *P*<.001) were higher. No serious VR-related adverse effects or session discontinuations occurred.

Conclusions: Compared with routine waiting, the brief, staff-assisted VR preparation approach was associated with lower examination distress and greater physician-rated examination ease in preschool children. The independent contribution of the

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clinic walk-through content could not be distinguished from headset novelty, immersive engagement, or additional researcher attention. Larger trials with attention- and technology-matched comparators are warranted.

Trial Registration: ClinicalTrials.gov NCT07255365; https://clinicaltrials.gov/study/NCT07255365

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KEYWORDS

ambulatory care; anxiety; child; preschool; pain measurement; patient satisfaction; physical examination; randomized controlled trial; virtual reality

Introduction

Background

Childhood outpatient examinations, particularly in the preschool period, are frequently accompanied by marked anxiety and behavioral resistance due to the unfamiliar environment, presence of medical staff in white coats, physical contact, and uncertainty about what will happen [1,2]. Elevated anxiety may prolong the examination, compromise the quality of physical assessment, increase unnecessary diagnostic testing, and lead to tension within the child-parent–health care professional triad, as well as avoidance of health care encounters in later years [1,2]. Despite this, structured, brief, evidence-based preparatory interventions tailored specifically for routine pediatric outpatient visits have been only sparsely integrated into daily practice.

In recent years, virtual reality (VR) applications have emerged as both a distraction tool and an educational medium that allows children to experience medical procedures in advance. Systematic reviews and meta-analyses in pediatric populations show that VR interventions can significantly reduce pain and anxiety and improve procedural cooperation across various interventions [3-6]. The feasibility of delivering low-cost, portable VR content without disrupting clinical workflow further increases the appeal of this approach.

Beyond simple distraction, VR can offer a “near-real” preexposure to the clinical environment, thereby reducing uncertainty and anticipatory distress. Studies in preoperative preparation, venipuncture, imaging, and other medical procedures suggest that VR-based preparation may alleviate anxiety in both children and parents, lower pain scores, and lessen perceived procedural difficulty for health care professionals [4-8]. However, the existing literature has predominantly focused on high-stress or invasive settings such as operating rooms, needle procedures, or magnetic resonance imaging suites. To our knowledge, no randomized, blinded trial has specifically evaluated a brief, 360° VR “through the child’s eyes” clinic walk-through immediately before a routine pediatric outpatient examination while simultaneously assessing multidimensional outcomes, including anxiety, pain, behavioral cooperation, parent satisfaction, and physician-reported examination ease.

Study Objectives

In this study, we aimed to evaluate whether an approximately 3-minute, clinic-specific 360° VR preexamination walk-through delivered via a smartphone-based head-mounted display immediately before the visit could reduce behavioral distress during examination (Face, Legs, Activity, Cry, and Consolability [FLACC] scale and crying duration), attenuate physiological stress responses (heart rate [HR] and respiratory rate [RR]), and enhance physician-rated examination ease in children aged 3 to 5.5 years. The preexamination anxiety assessed using the unweighted modified Yale Preoperative Anxiety Scale (mYPAS) raw total was evaluated as a secondary or exploratory outcome.

We hypothesized that children exposed to the 360° VR experience would have lower examination distress, shorter crying duration, smaller changes in HR and RR from baseline (T0) to examination (T2), and higher physician-rated examination ease than controls.

Methods

Study Design and Setting

This study was designed as a prospective, parallel-group randomized controlled trial with assessor and analyst blinding in the pediatric outpatient clinic of a tertiary training and research hospital. Participant enrollment was carried out between November 20, 2025, and January 9, 2026. The intervention consisted of a brief 360° VR clinic walk-through integrated into the preexamination waiting period without disrupting routine workflow. Its effects on behavioral pain and distress, anxiety, physiological stress responses, and physician-reported examination ease during the physical examination were evaluated in children aged 3 to 5.5 years.

Participants and Eligibility Criteria

During active recruitment periods, children presenting to the pediatric outpatient clinic for a routine physical examination were screened for eligibility in order of presentation. Recruitment was temporarily suspended during VR sessions and the subsequent examinations to prevent cross-group exposure, as detailed below. The target age range was set at 36 to 66 months (3-5.5 years) considering typical anxiety patterns related to outpatient examinations, recommended screen exposure limitations, and the validity and feasibility of the behavioral scales in this age group.

Inclusion criteria were age of 3 to 5.5 years, clinical stability at presentation, planned standard outpatient physical examination only (no emergency or procedural intervention), adequate cognitive and behavioral capacity to engage with a short audiovisual VR or 360° video, and provision of written informed consent by a parent or legal guardian. When appropriate, age- and developmentally appropriate verbal assent from the child was also sought.

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Exclusion criteria were severe neurodevelopmental delay, marked communication difficulties, autism spectrum disorder, or significant behavioral dysregulation; known epilepsy or history of photosensitivity; relevant visual or hearing impairment; complex chronic disease requiring nonstandard examination; any condition requiring urgent intervention (eg, acute respiratory distress, suspected sepsis, or hypotension); body temperature of 38.0 °C or higher at presentation; prior exposure to VR or 360° clinic simulations; previous participation in the study; concomitant use of sedative medications; or refusal of participation by the parent or guardian or by the child. Children younger than 36 months were not considered for inclusion due to limitations regarding screen exposure recommendations and the validated use of the applied behavioral scales in this age group.

Sample Size and Power Analysis

The sample size was planned based on the primary outcome: FLACC score during examination. Drawing on previous pediatric VR studies [3,5-8], the initial calculation assumed a between-group mean difference of 1 FLACC point, a common SD of 2.0 to 2.5, a 2-sided significance level of .05, and 80% statistical power. A total enrollment target of 100 children (50 per group) was originally established, including an allowance for potential attrition.

Subsequent verification of the sample size calculation revealed that the originally reported estimate of 40 to 45 participants per group was insufficient under these assumptions. Using the normal approximation formula for comparing 2 independent means with equal allocation, $n \approx 2(Z_{1-\alpha}/2 + Z_{1-\beta})^2\sigma^2/\delta^2$, the required sample size was 63 to 99 participants per group after rounding up, depending on the assumed SD of 2.0 to 2.5. A corresponding 2-sided independent-sample *t* test calculation required 64 to 100 participants per group. Under the 2-sided *t* test model, 50 participants per group provided approximately 70% power for an assumed SD of 2.0 and 51% power for an assumed SD of 2.5 to detect a 1-point mean difference. The planning calculation was based on a comparison of means, whereas the primary FLACC outcome was analyzed using the Mann-Whitney *U* test because of its ordinal and discrete nature. No separate distribution-based sample size calculation for the rank-based test was performed. All 100 randomized participants were included in the final analysis.

The design, conduct, and reporting of the trial were guided by the CONSORT (Consolidated Standards of Reporting Trials) 2010 recommendations for parallel-group randomized controlled trials [9]. The completed CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist is provided in Multimedia Appendix 1.

Randomization, Blinding, and Study Roles

An independent researcher who was not involved in participant recruitment or outcome assessment generated the computer-based randomization sequence using variable block sizes and a 1:1 allocation ratio. Group assignments were concealed in sequentially numbered, opaque, sealed envelopes. Researcher 1 performed participant screening, eligibility confirmation, and baseline (T0) assessments before opening the allocation envelope. The envelope was opened only after all T0 measurements had been completed and recorded. Therefore, researcher 1 was unaware of the participants' group assignment during the baseline assessment.

After opening the envelope, researcher 1 became aware of the allocation and implemented the assigned VR intervention or routine waiting procedure. The examining pediatrician (researcher 2) remained blinded to group allocation throughout the examination and independently rated examination ease after completing the assessment. Researcher 3 performed blinded postallocation behavioral assessments, including FLACC and mYPAS evaluations, and recorded the child-reported Wong-Baker FACES Pain Rating Scale (WBS) scores. Data entry and statistical analyses were conducted by researcher 4 using anonymized group codes. Thus, allocation concealment was maintained during baseline assessment, whereas the interventionist necessarily became unblinded only after the allocation envelope was opened.

Complete blinding of families and children was not feasible due to the nature of the intervention. Parents were informed that their child would receive 1 of 2 acceptable preexamination preparation approaches being compared within the study without any implication that one method was superior. They were explicitly instructed not to disclose details of the preparation procedure to the examining physician or observers during the visit. Any suspected unblinding was recorded as a protocol deviation. To prevent cross-group exposure, enrollment of new study participants was temporarily suspended whenever a child was undergoing the VR intervention. Recruitment remained paused until the VR-assigned child had completed the examination and left the clinical area. Enrollment then resumed with the next eligible child presenting thereafter. Researcher 1 remained blinded to the group allocation until completion of the T0 assessment and opening of the sealed randomization envelope. The allocation envelope for each newly enrolled participant was opened only after completion of the T0 assessment. Consequently, children assigned to the control group did not observe other study participants using the VR headset before their examinations.

Intervention: 360° VR Preexamination Experience

Children randomized to the intervention group received an approximately 3-minute 360° VR preexamination walk-through before their clinical assessment. A noninteractive MP4 preview of the walk-through is provided in Multimedia Appendix 2, and 2 representative screenshots are provided in Multimedia Appendix 3. The video was recorded from a child's eye level in the actual pediatric outpatient clinic where the study was conducted and featured the pediatrician who would perform the examination. The scenario included transition from the waiting area to the examination room; greeting the physician; and only routine, noninvasive procedures such as cardiac and pulmonary auscultation with a stethoscope, ear-nose-throat inspection, and abdominal examination. The content was intentionally child-friendly and free of frightening or threatening elements; images of injections, blood sampling, intravenous cannulation, painful procedures, or intensive equipment were explicitly

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excluded. Written consent for the use of the video material for scientific publication and educational purposes was obtained from all individuals appearing in the recording, and no identifiable patient data are shown.

The 360° clinic walk-through was delivered in full-screen 360° mode with audio through a smartphone-based head-mounted display using an iPhone 16 (Apple Inc; 6.1-inch organic LED display, 2556 × 1179 pixels, 460 ppi). A single-use disposable face interface was provided for each child, and contact surfaces were cleaned between participants according to the manufacturer's recommendations and institutional infection control procedures [6]. While seated comfortably, each child was fitted with the headset by researcher 1, who adjusted the display and remained nearby with the parent throughout the session to ensure safety. Parents were allowed to stay in physical contact with the child and offer brief verbal reassurance. If the child exhibited marked discomfort, dizziness, nausea, headache, or fear or requested removal of the headset, the intervention was immediately discontinued, and the event was documented in the case report form. Participants who did not complete the VR video were recorded as protocol deviations and excluded from the per-protocol efficacy analysis. These participants were, however, retained in the intention-to-treat analysis.

Control Group and Standard Clinical Approach

Children allocated to the control group did not receive any VR-based or additional structured visual preparation. They waited with their parents in the usual waiting area according to the clinic's standard practice. The waiting time before examination was kept approximately comparable to the VR exposure duration (approximately 2-3 minutes). In both groups, additional toys, television, or digital media were not provided as part of the study, and families were instructed to comfort their children as they normally would but to avoid introducing any extra structured distraction techniques. The control group received routine waiting only and was not provided with any audiovisual material (no videos, cartoons, or visual distractions).

Outcome Measures and Assessment Time Points

All measurements were recorded on a standardized case report form by trained researchers. RR was determined by counting chest movements over a full 60-second interval.

T0 (Baseline, Waiting Area)

Demographic and clinical variables (including age and sex) were recorded. HR was measured using a standard pulse oximeter, and RR was counted by trained staff using visual inspection. Baseline anxiety was assessed using the mYPAS by researcher 1 before the allocation envelope was opened.

T1 (After the intervention or Equivalent Waiting Period, Before the Examination)

After completion of the VR video in the intervention group or the equivalent routine waiting period in the control group, HR, RR, and mYPAS scores were reassessed. This time point was used to evaluate the short-term effect of the preparatory period on preexamination anxiety.

T2 (During the Examination)

The routine physical examination was performed in both groups by the same blinded pediatrician following a standardized protocol. During the examination (T2), researcher 3, who was blinded to group allocation, assessed behavioral distress using the FLACC scale, the primary outcome. HR was measured via pulse oximetry, and RR was determined via visual inspection at a standardized point immediately after initial physician contact during cardiopulmonary auscultation. Crying duration (seconds) was recorded using a stopwatch from the onset of audible crying until sustained cessation for at least 5 seconds.

T3 (Immediately After the Examination)

At the end of the examination, the child's self-reported discomfort or pain was assessed using the WBS. Parents rated their satisfaction with the examination experience using a study-specific 5-point Likert-type item. This single-item measure was not formally validated and was therefore interpreted as an exploratory outcome. Immediately after completing the examination, the examining pediatrician (researcher 2), who remained blinded to group allocation, independently rated the ease of the examination using a study-specific visual analog scale from 0 to 10 (0="extremely difficult"; 10="extremely easy"). This score represented the examining physician's own assessment rather than an observer-assigned rating.

Change Score Definitions

For repeated measures, change (Δ) was defined as the value at the specified time point minus baseline (T0). Accordingly, ΔmYPAS = T1 − T0, whereas physiological change scores were T2 − T0 for both HR and RR.

Intervention Safety Monitoring

Potential intervention-related adverse effects (eg, dizziness, nausea, headache, visual discomfort, marked agitation, or refusal of the headset) were monitored throughout the procedure and documented as separate safety outcomes. In this trial, no child reported or showed dizziness, nausea, headache, or fear requiring headset removal, and no session was discontinued.

Scales, Data Collection, and Quality Control

The scoring and interpretation of the behavioral and self-report scales used in this study are summarized below.

The FLACC scale is an observational measure including 5 domains (face, legs, activity, crying, and consolability), each scored from 0 to 2, yielding a total score from 0 to 10, with higher scores indicating greater pain or distress. In this study, a score of 0 was interpreted as calm or comfortable, a score of 1 to 3 was interpreted as mild discomfort, a score of 4 to 6 was interpreted as moderate discomfort, and a score of 7 to 10 was interpreted as severe distress or pain [10]. Preexamination anxiety was assessed at T0 and T1 using the 5-domain mYPAS [11]. The domains were activity, vocalizations, emotional expressivity, state of apparent arousal, and use of parents. Vocalizations were scored from 1 to 6, and the remaining domains were scored from 1 to 4. Analyses used the unweighted sum of the domain scores, yielding a raw total of 5 to 22, with higher scores indicating greater observed anxiety. This raw total differs from the standard weighted mYPAS score. The WBS

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provides a self-report rating from 0 (no pain or discomfort) to 10 (very severe pain or discomfort) using facial expressions; it was administered at T3, and higher scores were interpreted as greater discomfort [12]. Parent satisfaction was rated on a 5-point Likert scale (1=very poor; 5=excellent) [13]. Physician examination ease was assessed using a study-specific visual analog scale from 0 to 10 (0=very difficult; 10=very easy).

Data were recorded on predesigned electronic case report forms and subsequently entered into a secure database using double data entry. Inconsistencies or missing values were checked prior to analysis and resolved, when necessary, by referring back to source forms without revealing group allocation. All physiological measurements were performed using the same brand and model of devices to minimize measurement variability. Before study initiation, the research team completed joint training sessions to standardize the application and scoring of the FLACC scale, mYPAS, and WBS using detailed instructions and example cases. Behavioral assessments at T1 and T2 were performed by researcher 3, who remained blinded to group allocation.

Statistical Analysis

Data were summarized as means and SDs for approximately normally distributed continuous variables, medians and IQRs for nonnormally distributed or ordinal variables, and frequencies and percentages for categorical variables. Normality was assessed using visual inspection and the Shapiro-Wilk test. For between-group comparisons, independent-sample 2-sided *t* tests were used for continuous outcomes when normality assumptions were satisfied; if the Levene test indicated unequal variances, the Welch *t* test was applied. Ordinal or nonnormally distributed outcomes (including the FLACC scale) were analyzed using the Mann-Whitney *U* test. Categorical variables were compared using the chi-square test or Fisher exact test, as appropriate. For outcomes with repeated measurements, within-child change scores (Δ) were computed relative to baseline (T0) as prespecified above.

The primary analysis followed the intention-to-treat principle, including all randomized participants in the groups to which they were assigned. All 100 randomized participants were included in the primary FLACC outcome analysis according to their assigned groups. Two additional exploratory measurements, peripheral oxygen saturation (SpO_2) at T2 and parent-perceived child anxiety at T3, were not included in the comparative analyses because sufficient reliable data were unavailable. Missing values for these measurements were not imputed.

In addition to *P* values, effect sizes with 95% CIs were reported. For outcomes analyzed using 2-sided *t* tests, the Cohen *d* was calculated. For the primary FLACC outcome, rank-biserial correlation and the Hodges-Lehmann estimator, defined as the median of all pairwise between-group differences, were calculated. For the rank-biserial correlation and Hodges-Lehmann estimator of the primary FLACC outcome, 95% bootstrap CIs were obtained using 20,000 resamples within each group. Secondary outcomes were considered exploratory; no adjustment for multiple comparisons was applied, and the findings were interpreted cautiously in light of multiplicity. All tests were 2 sided, with a significance level of α=.05. Analyses were performed using SPSS Statistics (version 28.0; IBM Corp).

Ethical Considerations

The study procedures were explained to all parents or legal guardians in clear and age-appropriate language, including the purpose, scope, voluntary nature of participation, potential benefits, and possible discomforts. Written informed consent was obtained from all parents or guardians prior to enrollment. Children received developmentally appropriate information and were approached in a supportive, noncoercive manner regarding their participation. No financial or nonfinancial compensation was provided to participants or their families. No identifiable images of study participants are included in the manuscript or supplementary materials. The only individuals appearing in the clinic walkthrough video are two study investigators (researchers 2 and 3), who were also coauthors of the manuscript.

The 360° VR video intervention was noninvasive, did not delay the routine examination, and did not replace standard medical care. Participant confidentiality was ensured using anonymized study codes; identifiable data were kept confidential and used solely for research purposes.

This study was conducted in accordance with the principles of the Declaration of Helsinki. Ethics committee approval for this study was obtained from the Health Sciences University, Haseki Training and Research Hospital, Clinical Research Ethics Committee (decision 248-2025; November 19, 2025). Written informed consent was obtained from the parents or legal guardians of all participating children.

The trial registration was submitted to ClinicalTrials.gov on November 20, 2025 (NCT07255365), and was first posted on December 1, 2025, following processing through the Protocol Registration and Results System (PRS).

Results

Participant Flow and Baseline Characteristics

The CONSORT participant flow diagram is shown in Figure 1. Of 120 children assessed for eligibility, 20 were excluded, and 100 were randomized equally to the VR and control groups. The mean age of the cohort was 50.4 (SD 9.4) months, and 52% (52/100) of children were female. Baseline demographic and clinical characteristics, including age, sex, HR, RR, and mYPAS scores, were comparable between the VR and control groups (Table 1).

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Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participant enrollment, allocation, follow-up, and analysis. VR: virtual reality.

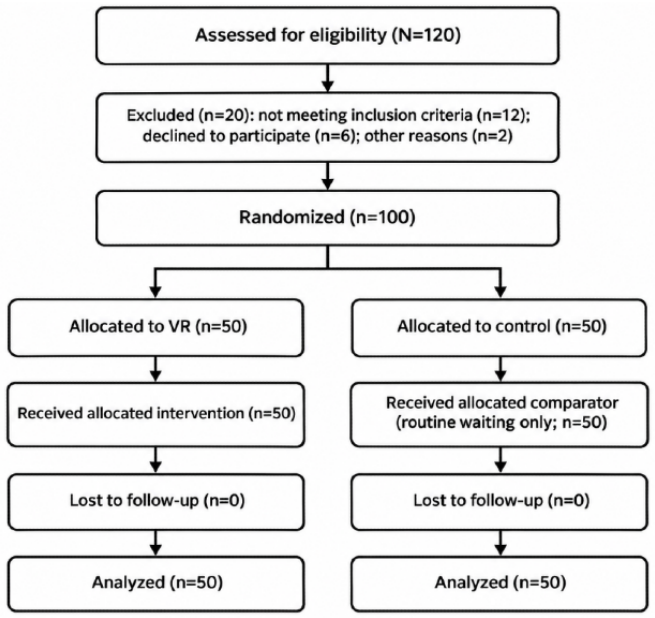

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Table 1. Baseline characteristics, examination outcomes, and changes in the virtual reality (VR) and control groups[a].

Variables	VR (n=50)	Control (n=50)	*P* value
Age (mo), mean (SD)	49.1 (9.0)	51.7 (9.6)	.17
Female sex, n (%)	27 (54)	25 (50)	.69
T0[b] HR[c] (beats/min), mean (SD)	102.8 (12.0)	106.2 (12.0)	.16
T0 RR[d] (breaths/min), mean (SD)	24.5 (2.6)	23.5 (2.8)	.07
T0 mYPAS[e] score (5-22), mean (SD)	6.72 (1.81)	7.26 (2.04)	.16
T1[f] HR (beats/min), mean (SD)	103.6 (10.0)	110.8 (12.3)	.002
T1 RR (breaths/min), mean (SD)	24.3 (2.1)	23.3 (2.0)	.02
T1 mYPAS score (5-22), mean (SD)	7.3 (2.2)	7.7 (2.5)	.40
FLACC[g] score (0-10), median (IQR)	3 (1-4)	5 (3-8)	*<.001* [h]
Crying time (s), mean (SD)	11 (3)	28 (9)	*<.001*
T2[i] HR (beats/min), mean (SD)	101.7 (10.4)	124.9 (18.8)	*<.001*
T2 RR (breaths/min), mean (SD)	24.1 (2.2)	29.7 (3.4)	*<.001*
WBS[j] score (0-10), mean (SD)	3.1 (1.1)	6.6 (2.0)	*<.001*
Parent satisfaction (Likert scale 1-5), mean (SD)	4.2 (1.0)	2.2 (0.8)	*<.001*
Physician ease of examination (0-10), mean (SD)	8.8 (1.1)	6.1 (0.9)	*<.001*
ΔHR (T2 – T0), mean (SD)	−1.1 (1.8)	18.7 (7.1)	*<.001*
ΔRR (T2 – T0), mean (SD)	−0.4 (0.6)	6.2 (1.2)	*<.001*
ΔmYPAS (T1 – T0), mean (SD)	0.6 (0.5)	0.4 (0.5)	.12

[a]*P* values were calculated using the independent-sample 2-sided *t* test (Welch correction applied when variances were unequal) for continuous variables with approximately normal distributions, the Mann-Whitney *U* test for nonnormally distributed variables (Face, Legs, Activity, Cry, and Consolability Scale), and the Pearson chi-square test for categorical variables.

[b]T0: baseline.

[c]HR: heart rate.

[d]RR: respiratory rate.

[e]mYPAS: modified Yale Preoperative Anxiety Scale.

[f]T1: after the intervention and before the examination.

[g]FLACC: Face, Legs, Activity, Cry, and Consolability.

[h]Italicized *P* values indicate nominal statistical significance (2-sided *P*<.05). No adjustment for multiple comparisons was applied to secondary outcomes.

[i]T2: during the examination.

[j]WBS: Wong-Baker FACES Pain Rating Scale.

Primary and Secondary Outcomes

Preexamination anxiety did not differ between groups (mean ΔmYPAS 0.6, SD 0.5 vs 0.4, SD 0.5; *P*=.12). In contrast, examination distress was lower in the VR group (median FLACC score 3, IQR 1-4 vs 5, IQR 3-8; *P*<.001; Figure 2), with shorter crying duration (mean 11, SD 3 vs 28, SD 9 seconds; *P*<.001). Physiological stress responses during examination were attenuated in the VR group (mean T2 HR 101.7, SD 10.4 vs 124.9, SD 18.8 beats/min; mean T2 RR 24.1, SD 2.2 vs 29.7, SD 3.4 breaths/min; *P*<.001 in both cases). In the postexamination period (T3), children in the VR group had lower WBS scores and higher parent satisfaction and physician-rated examination ease scores than those in the control group (*P*<.001 in all cases; Figure 3). From baseline to examination (T2 – T0), mean HR decreased by 1.1 beats/min, and RR decreased by 0.4 breaths/min in the VR group, whereas HR increased by 18.7 beats/min and RR increased by 6.2 breaths/min in the control group. Both between-group differences in change scores were statistically significant (*P*<.001 for each comparison; Table 1).

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Figure 2. Distribution of Face, Legs, Activity, Cry, and Consolability (FLACC) scores during the physical examination (T2) by study group. VR: virtual reality.

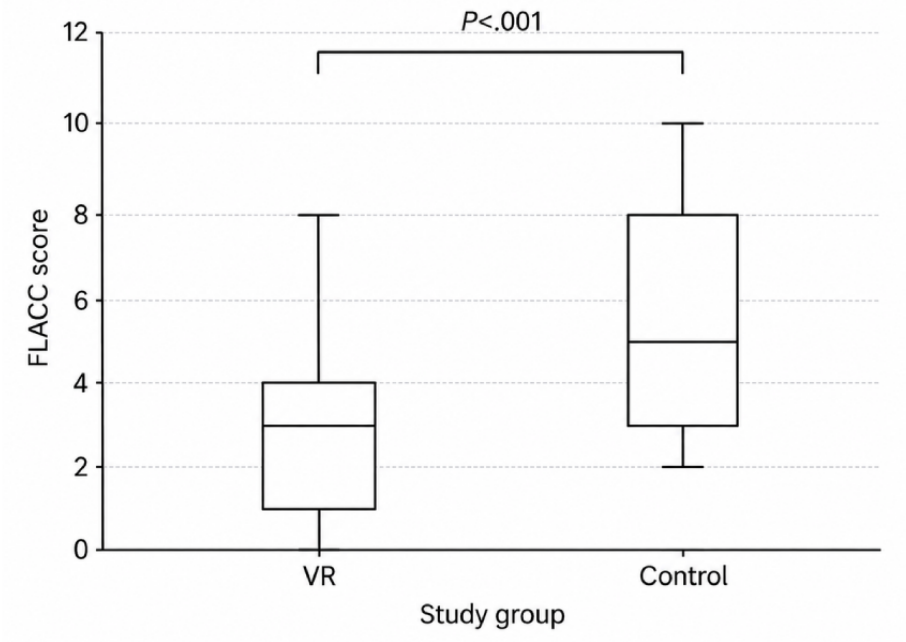
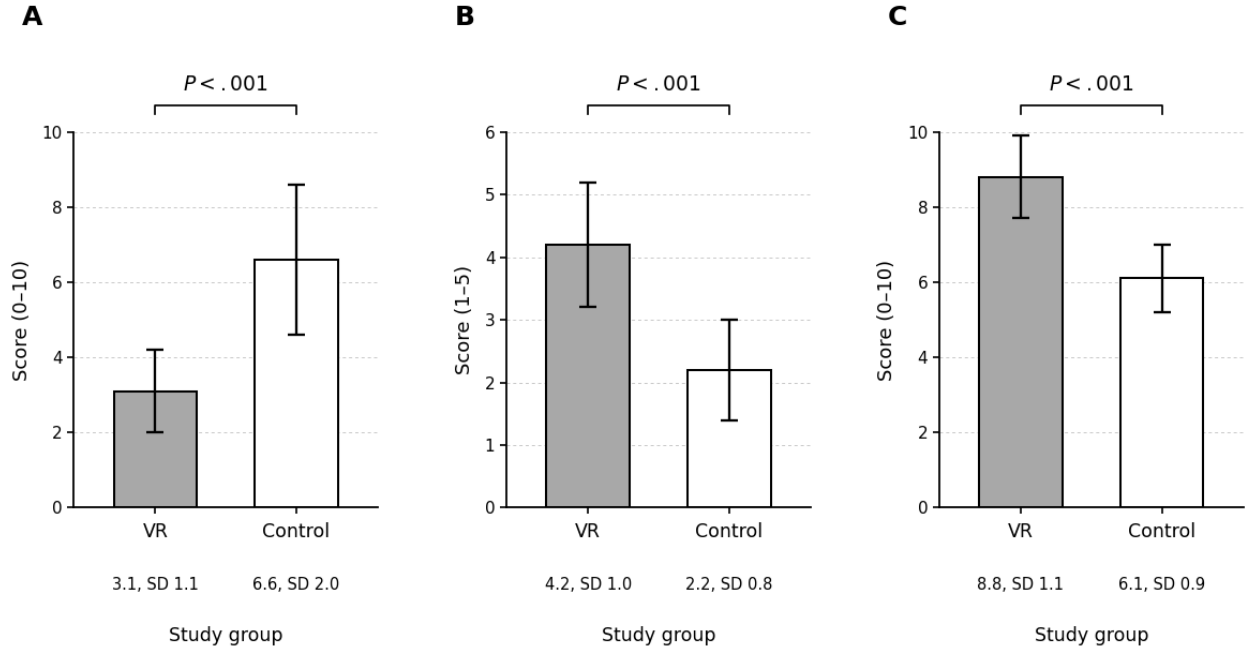


Figure 3. Postexamination (T3) outcomes in the virtual reality (VR) and control groups (n=50 per group): (A) Wong-Baker FACES Pain Rating Scale, (B) parent satisfaction, and (C) physician-rated examination ease. Bars show means, and error bars indicate SDs. Values below the groups are means and SDs.



For the primary FLACC outcome, the Mann-Whitney *U* statistic was 558 (*P*<.001). The rank-biserial correlation (VR vs control) was −0.554 (95% bootstrap CI −0.717 to −0.369), and the Hodges-Lehmann estimator of pairwise between-group differences was −3 points (95% bootstrap CI −4 to −2).

No serious VR-related adverse effects were observed. Usable SpO_2 measurements at T2 were available for 44% (22/50) of the children in the VR group and 34% (17/50) of the children in the control group. Parent-perceived child anxiety ratings at T3 were obtained from 36% (18/50) of the caregivers in the VR group and 38% (19/50) of the caregivers in the control group as some caregivers were unable to remain for the additional assessment after the examination. Given the substantial missingness and incomplete measurement reliability, these 2 planned exploratory outcomes were excluded from comparative analyses.

Effect Size Estimates

Effect size estimates indicated large standardized between-group differences across several secondary outcomes. Crying time showed a very large reduction in the VR group (Cohen *d*=−2.53, 95% CI −3.06 to −2.01). Physiological stress responses during examination were also markedly attenuated (T2 HR: Cohen

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d=−1.53, 95% CI −1.97 to −1.08; T2 RR: Cohen *d*=−1.96, 95% CI −2.43 to −1.48). Postexamination distress (WBS) was substantially lower with VR (Cohen *d*=−2.17, 95% CI −2.66 to −1.67), while parent satisfaction (Cohen *d*=2.21, 95% CI 1.71-2.71) and physician-rated ease of examination (Cohen *d*=2.69, 95% CI 2.14-3.23) were higher in the VR group.

Discussion

Principal Findings

In this randomized trial with a blinded examining physician, outcome assessor, and data analyst, the combined 360° VR preparation approach yielded lower examination distress and physiological stress responses, shorter crying duration, and higher parent satisfaction and physician-rated examination ease than routine waiting. This study was not designed to determine whether these differences were specifically caused by the clinic walk-through content rather than nonspecific aspects of VR exposure or researcher interaction. Although the median FLACC score was 2 points lower in the VR group, no minimum clinically important difference was prespecified for this outcome. The accompanying reductions in crying duration and higher physician-rated examination ease suggest potential practical relevance. However, changes in clinical management, examination completeness, or diagnostic accuracy were not directly assessed. Therefore, the clinical importance of the observed differences requires further evaluation.

Comparison With Prior Work

In the existing literature, VR has predominantly been evaluated as a distraction or preparatory tool during invasive or painful procedures, with multiple trials and meta-analyses showing significant reductions in pediatric pain, anxiety, and procedural distress and supporting VR as a feasible and safe intervention [2,3,6,14-24]. However, these studies largely focus on settings such as venipuncture, intravenous cannulation, burn dressing changes, vaccination, or magnetic resonance imaging and often use generic or entertainment-based VR content. To our knowledge, no previous randomized, blinded study has assessed a clinic-specific, 360° VR scenario that faithfully replicates the real outpatient clinic environment for routine pediatric physical examination while concurrently evaluating anxiety, pain, behavioral cooperation, physiological responses, parent satisfaction, and physician examination ease. By targeting a low-intensity but highly prevalent clinical context, this study addresses a clear gap in the literature and provides early evidence for extending VR-based preparation beyond classically "high-stress" procedures [2,3,6,14,21,23].

A key finding is the significantly lower examination distress (FLACC), shorter crying duration, and attenuated physiological stress responses (HR and RR elevations) observed in the VR group. In contrast, preexamination anxiety assessed using the mYPAS did not show a differential change between groups. These results are consistent with randomized trials in which VR reduced pain, fear, and behavioral distress during venipuncture and intravenous procedures [15-19]. Unlike distraction-only approaches, our VR protocol provided a realistic, developmentally appropriate preview of the actual waiting area, examination room, physician interaction, and routine noninvasive steps. The lower examination distress observed in the VR group may reflect greater familiarity with the clinic environment; however, this mechanism was not directly assessed, and whether these short-term improvements persist across subsequent health care encounters remains unknown. Although the same 5-domain mYPAS instrument was used in our previous inhaler trial [6], this does not establish the sensitivity of the unweighted raw total in routine outpatient examinations. The absence of a significant between-group difference in preexamination anxiety may reflect relatively low baseline scores, limited measurement sensitivity, or a genuine lack of effect on anticipatory anxiety. Similarly, a recent randomized pediatric outpatient trial by Ciolini et al [25] found that VR significantly reduced procedural pain but not preprocedural anxiety, with maternal anxiety identified as an important predictor of child anxiety. These findings suggest that improvements in behavioral distress during examination may not necessarily be accompanied by measurable reductions in anticipatory anxiety.

The attenuation of physiological stress responses in the VR group further strengthens this interpretation. HR and RR showed small mean decreases from baseline to examination in the VR group, whereas both parameters increased in the control group. The between-group differences in these physiological change scores were statistically significant, consistent with the pattern observed for behavioral distress. Previous studies of procedural VR have reported similar convergence of subjective and physiological markers as well as reduced procedure time and improved staff experience [6,14,18,21,24]. Our data indicate that these benefits are not limited to painful interventions but can also be achieved in brief, noninvasive outpatient examinations when VR is designed as a targeted preparatory tool.

Parent satisfaction scores were significantly higher in the VR group, indicating more favorable caregiver evaluations of the examination experience. However, satisfaction was assessed using a study-specific single-item measure, and no formal qualitative interviews were conducted. Therefore, the specific reasons underlying these ratings and any potential effects on parent-clinician communication could not be determined.

Physician-rated examination ease was significantly higher in the VR group based on a subjective assessment provided by the examining pediatrician while blinded to group allocation. This finding suggests that the VR preparation approach may facilitate the perceived ease of routine physical examination. However, examination duration, completeness, diagnostic accuracy, and subsequent diagnostic testing were not directly measured. Therefore, improvements in clinical efficiency or diagnostic quality cannot be established from the present findings.

Strengths

This study has several notable strengths. It used a randomized prospective design with a blinded examining physician, blinded outcome assessment, and blinded statistical analysis in a clearly defined and homogeneous age group (3-5.5 years). The 360° VR content was specifically created in the real clinic where the examinations took place, closely mirroring the actual environment; staff; and sequence of routine, noninvasive

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procedures. This clinic-specific and developmentally tailored design distinguishes our approach from that of many previous studies that have relied on generic VR games or noncontextualized content and underscores the importance of ecological validity when using VR in pediatric care. Furthermore, the use of multiple complementary outcomes—behavioral scales, physiological parameters, crying duration, parent satisfaction, and physician examination ease—provides a robust and multidimensional assessment of the intervention's impact and offers a realistic, scalable model for future implementations.

Limitations

This study has several limitations. First, the single-center design, modest sample size, and specific sociocultural setting may limit the generalizability of the findings. Reassessment of the original sample size assumptions indicated that 50 children per group did not provide the planned 80% power to detect a 1-point mean difference in FLACC scores. Furthermore, sample size planning was based on a comparison of means, whereas the primary FLACC outcome was analyzed using the Mann-Whitney *U* test. These aspects should be taken into account when interpreting smaller effects and the precision of the estimates. No minimum clinically important difference was prespecified for FLACC, and changes in clinical management, examination completeness, or diagnostic accuracy were not directly assessed.

Second, complete blinding of children and parents was not feasible, and the control condition was not matched for researcher attention or technology exposure. Although the examining pediatrician and outcome assessor were blinded, the observed differences may partly reflect headset novelty, immersive engagement, participant expectations, or additional researcher attention rather than the specific clinic walk-through content alone. Therefore, the 2-arm design cannot distinguish the independent effects of these components. Recruitment was temporarily suspended during VR sessions and the subsequent examinations to prevent cross-group exposure; however, this approach may have influenced recruitment patterns and introduced potential selection bias.

Third, the assessment of preexamination anxiety was based on an instrument originating from perioperative settings, and its sensitivity in routine, low-acuity pediatric outpatient examinations remains uncertain. The psychometric properties of the unweighted mYPAS raw total were not established in the present study. Anxiety findings were therefore interpreted as exploratory and cannot be directly compared with published standard-score thresholds. Relatively low baseline anxiety scores raise the possibility of a floor effect, although this was not formally evaluated. Alternatively, the absence of a significant difference may reflect a genuine lack of effect on anticipatory anxiety. The WBS relies on child self-report, which may be less reliable among younger preschool children, particularly those aged 3 to 4 years. Parent satisfaction was assessed using a nonvalidated, study-specific single-item measure, while physician-rated examination ease was also a subjective, study-specific assessment. Additionally, substantial missing or unreliable data prevented comparative analyses of SpO_2 at T2 and parent-perceived child anxiety at T3. Only immediate outcomes were assessed, and the possible longer-term effects of VR preparation remain unknown. The clinic-specific content and hardware procedures may also require adaptation in other settings. Future multicenter trials incorporating attention- and technology-matched comparators, age-appropriate anxiety measures, and longer follow-up are warranted.

Conclusions

In this single-center randomized trial, a brief 360° VR clinic walk-through delivered before routine outpatient examination was associated with lower behavioral distress and crying duration, more favorable physiological responses, and higher parent satisfaction and physician-rated examination ease than routine waiting among preschool children. However, because the control condition was not attention or technology matched, the independent contribution of the clinic-specific video content remains uncertain. Larger studies with attention-matched and alternative VR comparators are needed to establish which components drive the observed effects and whether they generalize to other clinical settings.

Data Availability

Deidentified participant-level data are available from the corresponding author on reasonable request after publication subject to institutional approval and a data sharing agreement because the raw data contain pediatric clinical information that may not be fully anonymizable.

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Generative AI Use

OpenAI ChatGPT (GPT-6 Astra), Anthropic Claude (Opus 5.5), Google Gemini (3.1 Pro), and Julius AI (1.5 Max) were used as assistive tools during manuscript preparation and revision for English-language drafting, translation, proofreading, stylistic editing, literature and reference checks, methodological and statistical reporting verification, and preparation and refinement of data visualizations based on author-provided results. OpenAI's generative image technology was also used to create the table-of-contents illustration, which was subsequently reviewed and modified by the authors. This conceptual illustration does not depict actual study participants and is separate from the original 360° clinic walkthrough video used in the trial. All AI-assisted outputs were critically reviewed, verified, and revised by the authors. The authors retained full responsibility for the research methodology,

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clinical data, statistical findings, interpretation, and final manuscript content. Generative AI was not used to create participant-level research data or to deliver the clinical intervention.

Authors' Contributions

Conceptualization: ZÜO, BO, TA, CTA, KŞ, ME
Data curation: ZÜO, BO, TA, CTA, KŞ, ME
Formal analysis: ZÜO, BO, TA, CTA, KŞ, ME
Methodology: ZÜO, BO, TA, CTA
Investigation: ZÜO, BO, TA, CTA
Writing—original draft: ZÜO, BO, TA, CTA
Writing—review and editing: ZÜO, BO, TA, CTA, KŞ, ME

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH V1.6.1 checklist.
[PDF File (Adobe PDF File), 1202 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Noninteractive 2D MP4 preview of the 360° virtual reality clinic walk-through used in the intervention (duration: 2 minutes, 38 seconds).
[MP4 File (MP4 Video), 9178 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Representative screenshots from the 360° virtual reality clinic walk-through: (A) pediatrician demonstrating a routine examination from the child's perspective and (B) pediatric outpatient examination room viewed from the child's perspective.
[PNG File , 1080 KB-Multimedia Appendix 3]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
FLACC: Face, Legs, Activity, Cry, and Consolability
HR: heart rate
mYPAS: modified Yale Preoperative Anxiety Scale
RR: respiratory rate
SpO2: peripheral oxygen saturation
VR: virtual reality
WBS: Wong-Baker FACES Pain Rating Scale

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