

Effectiveness of OptraDam Versus Conventional Rubber Dam Isolation on Dental Anxiety in Children: A Randomized Clinical Trial

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Abstract

Background

Effective isolation is essential for successful pediatric dental treatment; however, conventional rubber dam placement may increase discomfort and anxiety because of clamp application. OptraDam, a clamp-free isolation system, has been introduced to improve patient comfort while maintaining adequate moisture control. This study compared the effects of OptraDam and conventional rubber dam on anxiety and physiological stress in children undergoing pulpotomy.

Methods

In this randomized clinical trial, 44 children requiring pulpotomy of primary molars were randomly allocated to treatment with either OptraDam ($n = 22$) or a conventional rubber dam ($n = 22$). Dental anxiety was evaluated using the Venham Anxiety Scale, behavioral response was assessed using the Sound–Eye–Motor (SEM) scale, and physiological stress was measured by heart rate before and after treatment. Baseline demographic characteristics were compared between groups. Independent and paired t-tests and chi-square tests were used for statistical analysis, with the level of significance set at $P < 0.05$.

Results

The two groups were comparable regarding age, sex distribution, baseline Venham anxiety scores, and heart rate. Baseline SEM scores were significantly lower in the OptraDam group. Within the OptraDam group, anxiety and heart rate showed nonsignificant reductions following treatment. In contrast, the conventional rubber dam group demonstrated significant increases in both anxiety and heart rate. After adjustment for baseline values, post-treatment anxiety and heart rate were significantly lower in the OptraDam group than in the conventional rubber dam group.

Conclusions

Compared with the conventional rubber dam, OptraDam was associated with lower post-treatment anxiety and physiological stress in children undergoing pulpotomy. Although within-group reductions in the OptraDam group were not statistically significant, the overall findings suggest that its clamp-free design may provide a more comfortable and child-friendly isolation method while preserving the clinical advantages of rubber dam isolation. Larger multicenter studies are warranted to confirm these findings.

Trial registration

This study was prospectively registered in the Iranian Registry of Clinical Trials (IRCT).

Trial registration

Iranian Registry of Clinical Trials (IRCT), IRCT20250308064976N2, prospectively registered on 27 July 2025.

Introduction

Proper isolation is essential for the success of many dental procedures (1). Isolation of the operative field involves separation from saliva, blood, gingival crevicular fluid, and soft tissues such as the lips, cheeks, gingiva, and tongue. The rubber dam has been available to the dental profession for more than 140 years. Beyond providing effective isolation, a rubber dam offers several clinical advantages, including prevention of aspiration, enhanced visibility and access to the operative field, and protection of the patient's soft tissues. Furthermore, such isolation systems may facilitate longer procedures, particularly in pediatric patients, as children often perceive that the procedure is being performed outside the oral cavity (2). Evidence also suggests that the use of a rubber dam is associated with reduced levels of stress, anxiety, and pain in children (3). Despite this, many practitioners continue to avoid its use, often due to perceptions that it is time-consuming, technically challenging, or poorly accepted by patients (4).

One reason for the reduced use of rubber dams in pediatric dentistry is the pain associated with clamp placement, which may lead to discomfort and subsequent loss of cooperation during treatment. Various approaches have been proposed to address this issue, including the use of newer generations of topical local anesthetics, application of soft clamps, or the use of clamp-free isolation systems, and newer generations of rubber dam systems (4–7).

OptraDam is a relatively new product within the rubber dam family. Due to its increased flexibility, absence of a metal frame, and lack of need for clamp placement, it provides improved ease of use for the clinician and greater acceptance by patients. This system offers additional advantages, such as functioning as a lip and cheek retractor and possessing an anatomical shape that facilitates application without the need for a metal frame, thereby reducing placement time. Its flexible plastic rings enable easy placement in the oral cavity, and its anatomical design improves visibility and access while facilitating complete isolation of both arches. One of the reasons for its limited use is the lack of awareness among dentists regarding newer rubber dam systems (8).

Mahima et al. evaluated anxiety levels in children during the use of rubber dam and OptraDam isolation techniques in a clinical trial involving 27 children aged 6 to 12 years. Analysis revealed that OptraDam produced significantly lower anxiety levels compared to the conventional rubber dam (4).

In contrast, Waheed et al. concluded that, concerning patient comfort, the conventional rubber dam was considered more comfortable than the OptraDam. More effective moisture management was seen in the

conventional rubber dam. Other factors, such as time, convenience of application, and imaging radiography, had statistically insignificant results among both groups (9).

However, to date, there is insufficient strong evidence to confirm its superiority over the conventional rubber dam. The present study aims to evaluate, considering the well-established advantages of the rubber dam in pulp therapy and the reluctance of dentists to use it for the aforementioned reasons, the level of anxiety in children aged 8 to 12 years when treated using two isolation systems: conventional rubber dam and OptraDam.

Material and methods

The study protocol was approved by the Ethics Committee of Isfahan University of Medical Sciences (Approval No. IR.MUI.DHMT.REC.1404.059). The trial was prospectively registered in the Iranian Registry of Clinical Trials (IRCT20250308064976N2; registered on 27 July 2025). Written informed consent was obtained from the parents or legal guardians of all participants before enrollment. This study was a single-blind randomized clinical. The trial was designed and reported in accordance with CONSORT principles for randomized trials. Children aged 8–12 years who attended the Pediatric Dentistry Department of Isfahan Dental School from Sep 2025 to Dec 2025 and required pulpotomy of mandibular primary molar teeth were recruited using convenience sampling. Eligible participants had definitely positive behavior according to the Frankl scale and no previous negative dental experience. Children with systemic disease, psychological disorders, medication use, latex allergy, inability to achieve adequate isolation, lack of indication for pulpotomy, or withdrawal of parental consent were excluded. The procedure was explained to the parents or legal guardians, and written informed consent was obtained before enrollment. The Tell–Show–Do technique was used to prepare the child for treatment and improve cooperation. A total of 50 children were assessed for eligibility. Of these, 6 were excluded (2 did not meet the inclusion criteria and 4 refused to participate). The remaining 44 children were randomly assigned to two groups of 22 participants each. The remaining 44 children were randomly assigned to two groups of 22 participants each using block randomization. Participants were randomly allocated to either the OptraDam group ($n = 22$), which received isolation with OptraDam (Gardent Inc., Chicago, IL, USA), or the conventional rubber dam group ($n = 22$), which received isolation with a conventional rubber dam kit (Supa, Iran). The final sample consisted of 44 randomized participants; a formal sample-size calculation was not reported in the original manuscript.

For both groups, local anesthesia appropriate to the tooth was administered before isolation. In the conventional rubber dam group, a 20% benzocaine topical gel (Doradent, Iran) was applied with a swab for 1 minute according to the manufacturer's instructions. A latex-free powder-free rubber dam sheet (Supa, Iran) was punched according to the tooth number and quadrant. Dental floss was tied to the clamp to prevent aspiration. The clamp was placed with forceps and checked for stability; if needed, it was repositioned. The rubber dam sheet was then stretched over the clamp and adapted to the tooth, the frame was placed, and the seal was checked. Suction was maintained throughout the procedure.

In the OptraDam group, a 20% benzocaine topical gel (Doradent, Iran) was applied for 1 minute. The OptraDam was punched at the appropriate site or sites according to the target tooth and placed according to the manufacturer's instructions. The tooth was passed through the openings using dental floss. Pulpotomy was performed according to the 2020 AAPD guideline. The coronal pulp was removed, bleeding was controlled, and the remaining radicular pulp was treated with a medicament intended to preserve long-term clinical success. The coronal pulp chamber was filled with an appropriate base, and the tooth was restored with a material providing an effective seal against microleakage. Stainless steel crowns were used for multisurface lesions, while amalgam or composite resin could be used when sufficient tooth structure remained, and the expected lifespan of the tooth was 2 years or less.

Child anxiety was assessed subjectively before and after pulpotomy using the Venham Anxiety Scale (Fig. 1). The scale consists of 8 paired images, each showing an anxious and a non-anxious child; the child selected the image that best represented their feelings. Scores ranged from 0 to 8, and scores of 4 or higher were considered indicative of anxiety.

Heart rate was measured objectively with a pulse oximeter before and after treatment. Pain and anxiety during the pulpotomy were also assessed using the SEM scale (Fig. 2), with scores ranging from 3 to 12; higher scores indicated greater distress.

SEM scoring was performed by a second researcher who was blinded to the study groups and stood approximately 1.5 meters from the dental chair during treatment. The second assessor was trained and calibrated by the primary researcher using video recordings of 10 children undergoing fissure sealant treatment outside the study.

Data were analyzed using SPSS version 25. Repeated-measures ANOVA was used to compare mean anxiety scores and heart rate over time within groups and between groups. One-way ANOVA and ANCOVA were used for between-group comparisons before and after intervention. Statistical significance was set at 5%

Results

Figure 3 represents the CONSORT flow diagram for participant enrollment and allocation. Of the 50 individuals assessed for eligibility, 6 were excluded (2 did not meet the inclusion criteria, 4 refused to participate). The remaining 44 participants were randomly assigned: 22 were allocated to the OptraDam group, and 22 were allocated to the conventional rubber dam group. There were no significant differences in baseline demographic characteristics between the two groups. The distribution of sex was comparable (40.9% boys and 59.1% girls in the OptraDam group versus 54.5% boys and 45.5% girls in the conventional rubber dam group; $P = 0.365$). Likewise, the mean age did not differ significantly between the OptraDam and conventional rubber dam groups (10.05 ± 1.33 vs. 9.64 ± 1.53 years, respectively; $P = 0.349$).

At baseline, no significant differences were observed between the two groups regarding Venham Anxiety Scale scores (1.91 ± 1.95 vs. 2.05 ± 1.36 , $P = 0.789$) or heart rate (94.45 ± 9.42 vs. 92.27 ± 6.24 beats/min, $P = 0.370$).

Within the OptraDam group, the mean Venham Anxiety Scale score decreased from 1.91 ± 1.95 before pulpotomy to 1.23 ± 1.19 after treatment, although this reduction was not statistically significant ($P = 0.065$) (Table 1). Heart rate also decreased from 94.45 ± 9.42 to 90.23 ± 8.92 beats/min, without reaching statistical significance ($P = 0.072$) (Table 2). However, SEM scores were significantly lower in the OptraDam group than in the conventional rubber dam group (3.86 ± 1.25 vs. 6.68 ± 3.01 , $P < 0.001$) (Table 3).

Table 1
Mean anxiety scores before and after pulpotomy.

Group	N	Before Mean $\pm$ SD	After Mean $\pm$ SD	p-value
Optra Dam	22	1.91 ± 1.95	1.23 ± 1.19	0.065
Rubber dam	22	2.05 ± 1.36	3.45 ± 1.84	0.002
p-value		0.789	0.001	
SD: standard deviation				

Table 2
Mean heart rate (bpm) before and after pulpotomy.

Group	N	Before Mean $\pm$ SD	After Mean $\pm$ SD	p-value
Optra Dam	22	94.45 ± 9.41	90.23 ± 8.92	0.072
Rubber dam	22	92.27 ± 6.24	111.18 ± 3.29	> 0.001
p-value		0.371	> 0.001	

Table 3
SEM scores after pulpotomy

Group	N	Mean $\pm$ SD	<i>p</i> -value
Optra Dam	22	3.86 $\pm$ 1.24	< 0.001
Rubber dam	22	6.68 $\pm$ 3.01	

In contrast, children treated with the conventional rubber dam exhibited significantly higher anxiety following the procedure. The mean Venham Anxiety Scale score increased from 2.05 $\pm$ 1.36 to 3.45 $\pm$ 1.85 (P = 0.002), while heart rate increased significantly from 92.27 $\pm$ 6.24 to 111.18 $\pm$ 3.29 beats/min (P < 0.001).

Discussion

The choice of isolation technique may influence not only procedural success but also the child's behavioral and physiological response. In pediatric patients, salivary flow is often higher than in adults, and excessive tongue movement is common, both of which may compromise visibility and operator performance (10, 11). Undoubtedly, the use of a rubber dam provides significant benefits, including enhanced infection control and improved patient safety (12). Nevertheless, studies have shown that approximately 64 to 80 percent of children report pain and discomfort associated with rubber dam clamp placement, which may lead to increased dental anxiety, reduced treatment acceptance, and additional challenges for clinicians in managing patient behavior (7).

Based on available evidence, patients often prefer simpler isolation methods, which do not provoke pain from clamp placement and are less time-consuming. In response to these concerns, newer generations of rubber dam systems have been introduced, including OptraDam and OptiDam (4). The present findings indicate that the conventional rubber dam was associated with higher anxiety, greater physiological stress, and more observable distress than OptraDam. This pattern is clinically plausible, as clamp placement, soft-tissue pressure, and movement restriction may be perceived by children as threatening. Prior studies have similarly reported that rubber dam placement can increase discomfort and stress-related responses in pediatric patients, especially when topical anesthesia or other comfort measures are not used(7). By contrast, OptraDam appears to offer a more child-friendly experience due to its clamp-free design, flexibility, and easier placement.

The present study used the Venham Anxiety Scale to assess subjective anxiety in children and measured heart rate as an objective physiological marker of stress, reflecting autonomic arousal. The two groups were comparable with respect to baseline Venham anxiety scores and heart rate, indicating similar preoperative anxiety and physiological status. However, baseline SEM scores were significantly lower in the OptraDam group than in the conventional rubber dam group. This difference may reflect variability in

children's observable behavioral responses before treatment rather than differences in subjective anxiety. OptraDam® does not require a clamp or a separate frame. Its innovative inner ring, high flexibility, and anatomical shape allow placement without a clamp or frame. It is also considered more efficient in terms of time and cost compared to conventional rubber dam systems and is available in regular and small sizes. Its soft, flexible material enables patients to maintain full jaw mobility and experience greater comfort during treatment (1).

Within the OptraDam group, Venham anxiety scores showed a decreasing trend after treatment; however, this reduction did not reach statistical significance. In contrast, anxiety increased significantly in the conventional rubber dam group. Post-treatment anxiety remained significantly lower in the OptraDam group, suggesting that OptraDam was associated with a more favorable psychological response during treatment. This may reflect psychological mechanisms involved in pediatric dental anxiety. Dental anxiety in children is strongly influenced by unfamiliar instruments, perceived invasiveness, and restriction of oral movement. Conventional rubber dam placement usually requires clamp application, which may produce transient pain or pressure on the gingival tissues and create a feeling of confinement. Such sensory stimuli can activate the sympathetic nervous system, resulting in increased heart rate and heightened behavioral distress. In contrast, the soft, anatomical design of OptraDam allows greater mandibular mobility and reduces tissue compression, potentially improving the child's sense of comfort and control throughout treatment. The lower post-treatment anxiety and physiological stress observed in the present study are therefore biologically plausible and consistent with current concepts of pediatric behavior management, which emphasize minimizing threatening stimuli to improve cooperation and treatment acceptance(13).

Although anxiety and heart rate tended to decrease in the OptraDam group, these within-group changes were not statistically significant. Nevertheless, compared with the conventional rubber dam group, children treated with OptraDam demonstrated significantly lower post-treatment anxiety and heart rate after adjustment for baseline values. This is consistent with earlier evidence showing better acceptance and comfort for newer isolation systems compared with conventional rubber dams. Mahima et al. reported that children experienced significantly lower anxiety with OptraDam than with a conventional rubber dam (14).

Another noteworthy finding was the significant increase in both anxiety and heart rate within the conventional rubber dam group. This observation suggests that although the conventional rubber dam remains the gold standard for moisture control, its application may represent an additional stressor for some pediatric patients. Increased heart rate is a well-recognized physiological marker of sympathetic activation during stressful dental procedures and has frequently been used alongside behavioral scales to objectively assess dental anxiety in children. Therefore, the concurrent increase in both subjective (Venham) and physiological (heart rate) measures strengthens the validity of the present findings and indicates that the children's emotional responses were not limited to behavioral observations alone. Because successful pediatric dental care depends not only on technical quality but also on maintaining

patient cooperation, reducing treatment-related stress may improve the overall clinical experience for both the child and the operator (15, 16).

The Sound–Eye–Motor (SEM) scale was employed as an objective behavioral assessment tool to evaluate children’s anxiety-related responses during dental treatment. Unlike self-reported measures, SEM is based on direct observation of vocal, ocular, and motor reactions, making it particularly suitable for pediatric populations who may have limited ability to accurately communicate their emotional experiences. In the present study, the use of SEM enabled a standardized and reliable assessment of behavioral manifestations of dental anxiety during isolation procedures. Therefore, the observed differences in SEM scores between the OptraDam and conventional rubber dam groups may reflect genuine variations in children’s comfort and anxiety levels during treatment. The incorporation of SEM strengthens the validity of the findings by providing an objective measure of anxiety-related behavior in addition to subjective assessments(17). The lower SEM scores also indicate improved behavioral cooperation, which is especially valuable in pediatric dentistry, where treatment success depends heavily on patient compliance. Taken together, these findings support the view that minimizing the perceived invasiveness of isolation may improve the overall treatment experience.

From a clinical standpoint, the results suggest that OptraDam may be a suitable alternative for pulpotomy in children who are anxious or poorly tolerant of conventional isolation. Although the rubber dam remains the standard for moisture control and safety, its behavioral burden should not be overlooked in pediatric practice. A more comfortable isolation method may facilitate treatment without sacrificing the essential advantages of field control.

The main limitation of this study is the relatively small sample size, which may limit generalizability. In addition, the study was conducted in a single center, and operator-related factors may have influenced child responses. Larger multicenter trials are needed to confirm these findings. In this study, variables such as the child’s personality traits were not systematically controlled or analyzed. These factors may influence a child’s anxiety level and could therefore affect the study outcomes. Although validated instruments such as the Venham Anxiety Scale, SEM, and heart rate measurement were used, biochemical markers such as salivary cortisol were not assessed. As a result, the evaluation of anxiety was based primarily on simple behavioral and physiological indicators, and a more comprehensive picture of the child’s biological response could not be obtained.

Conclusion

The findings of this study demonstrated that OptraDam provides a more comfortable and child-friendly isolation method for pediatric pulpotomy while maintaining the advantages of rubber dam isolation. Further multicenter studies with larger sample sizes are recommended to confirm these findings.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Isfahan University of Medical Sciences (Approval No. IR.MUI.DHMT.REC.1404.059). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from the parents or legal guardians of all participants prior to enrollment.

Authors' contributions

RF conceived and designed the study. MJT contributed to the study design, developed the methodology, and performed the statistical analyses. AG and NN drafted the manuscript, coordinated the manuscript preparation and submission process, and contributed to data interpretation. MR and AGh performed the clinical procedures and participated in data collection. All authors critically revised the manuscript, read, and approved the final manuscript.

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Availability of data and materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Trial registration

This study was prospectively registered in the Iranian Registry of Clinical Trials (IRCT).

Registration number: IRCT20250308064976N2. Registration date: 27 July 2025. Registration timing: Prospective.

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Figures



Figure 1

Venham Anxiety Scale (0–8), with lower scores indicating less anxiety and scores ≥ 4 indicating clinically significant anxiety.

Parameters	Comfort (Score 1)	Mild discomfort (Score 2)	Moderate discomfort (Score 3)	Painful (Score 4)
Sound	No sound	Non-specific sound	Verbal complaint, louder sound	Verbal complaint shouting, crying
Eye	No sign	Dilated eye without tears (anxiety sign)	Tears, sudden eye movements	Crying, tars all over the face
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defense, turning the head the opposite site

Figure 2

SEM (Sound, Eye, Motor) scale (3–12), with higher scores indicating greater pain and anxiety.

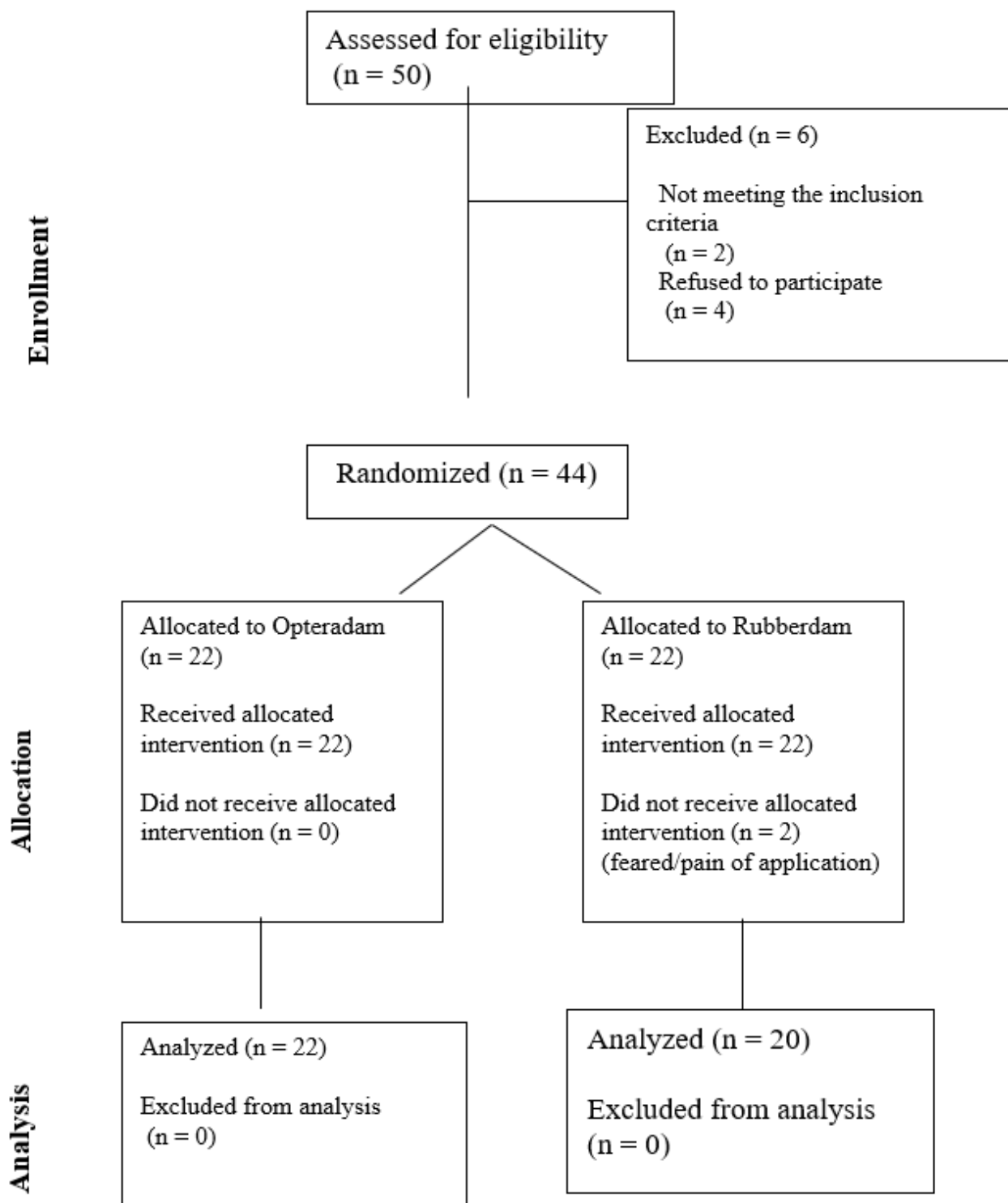


Figure 3

CONSORT flow diagram indicating participant enrollment and allocation

Supplementary Files

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