INTERNATIONAL JOURNAL OF HEALTH & MEDICAL RESEARCH

ISSN(print): 2833-213X, ISSN(online): 2833-2148

Volume 03 Issue 08 August 2024

DOI : 10.58806/ijhmr.2024.v3i08n14

Page No. 615-623

Evaluating The Effect of the Use of Virtual Reality Headset in School Vaccinations on Children's Fear and Anxiety Levels: A Randomized Controlled Trial

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ABSTRACT:

Aim: The study aims to evaluate the use of virtual reality during school vaccination and its impact on children's fears and anxiety.

Methods: The study was carried out as a randomized controlled study in primary schools located in a city centre. The study was completed with 169 (experimental group=84, control group=85) students. Child and Parent Information Form, Children's Fear Scale and Children's Anxiety Scale-State Scale were used to collect the data. Data were analysed using SPSS version (SPSS 25.0 SPSS, Chicago, IL). Independent samples t-test was used to compare independent data with normal distribution, and dependent samples t-test was used to compare dependent data. Data with normal distribution were presented as mean ± standard deviation. Chi-square test was used to compare categorical data, which were presented as frequency (percentage).

Results: While the mean score of Children's Fear Scale post-vaccination was 0.64 in the experimental group, it was 2.16 in the control group. Post-vaccination mean score of Children's Anxiety Scale-State was 2.14 in the experimental group; however, it was 6.06 in the control group. The Children's Fear Scale and Children's Anxiety Scale-State scores were higher in the control group compared to the experimental group.

Conclusion: This study is the first study of virtual reality to reduce fear and anxiety during vaccine administration. Study results have demonstrated its effectiveness and will fill a knowledge gap in the literature.

KEYWORDS: Anxiety, Child, Fear, Nursing, Vaccine, Virtual reality

1. INTRODUCTION

Interventions performed to protect health or achieve recovery in case of illnesses significantly affect the psychological state and social adaptation of children. Children are scared of the healthcare personnel, the equipment used, and the procedures and interventions to be performed [1, 2]. These fears of children are traumatic [1], may reduce their participation in healthcare practices and prevent them from being protected from diseases [1, 3].

Vaccinations are among the most beneficial life-saving interventions in modern medicine [4, 5]. However, fear of vaccination is common, especially in childhood [6-8]. The fear and anxiety caused by school vaccinations can affect the treatment and care experiences of children later in life, possibly leading to avoidance [9-11], Therefore, healthcare providers should be aware of these issues and use methods to reduce anxiety and fear during vaccination as an action that can promote compliance with the vaccination program.

Management of fear and anxiety using a timely and effective method during stressful medical procedures applied to the child would increase tolerance to fear and anxiety in later treatments [12, 13]. Nurses should successfully manage these procedures that are frightening to children to reduce the long-term negative effects of fear and anxiety in children [14]. A method most frequently preferred by nurses to control children's fear and anxiety during medical procedures is distraction [15]. Various methods are used for this purpose. These methods include talking about things unrelated to the intervention, making the children blow up balloons, playing music, creating bubbles by blowing foam, playing games, showing cartoons, showing kaleidoscopes, and using virtual reality (VR) headsets [12, 15-17]. Researchers have used VR to reduce pain, anxiety, fear and stress during interventional procedures in children [1, 12, 18, 19]. Interventions designed to actively engage the child possibly improve the vaccination process in children as they are effective in managing anxiety and fear [20].

Evidence-based strategies have been reported and should be implemented for the management of fear and anxiety during vaccination [10, 11, 21-23]. This procedure, which is repeated in early childhood without management of fear and anxiety, is an

important risk factor for developing high levels of fear of needles [8]. Fear of needles can lead to negative experiences and may cause fear, anxiety, and avoidance during subsequent procedures such as vaccination [13]. Therefore, nurses should be aware of these problems and use methods to manage fear and anxiety during vaccination as an action that can promote compliance with the vaccination program [8].

This study will fill a knowledge gap in the literature due to the limited number of studies using VR distraction in vaccines and will support increasing the quality of evidence regarding the effectiveness of distraction methods across different populations and cultures. It will also improve and increase the evidence on the effectiveness of these methods. This study was conducted as a randomized controlled trial. The aim of the research is to evaluate the effect of VR use on children's fears and anxiety during school vaccination.

II. METHODS

A. Study Design

The research was carried out as a randomized controlled study in primary schools located in a city center in the north of Türkiye. The population of the study consisted of 7-year-old students attending first grade in primary schools located in the city center. Taking the alpha error as 0.05 and the effect size as 0.5, the sample size was determined to be 128 (64 students each in the experimental and control groups) with 80% power in the calculations performed using G*Power 3.1 analysis software [24]. There are 37 primary schools in the city centre. There are 1-8 classes in schools and 30-40 students in each class. Schools were numbered from 1 to 37 and 6 schools and 6 alternative schools were selected using a computerized random number generator. First, detailed information about the study was given to the school administration and teachers. Parents and children were informed about the study through the school administration and teachers. "Informed Consent Form" and "Child and Parent Information Form" were sent to the parents by the school administration between 15 September 2019 and 15 October 2019. Consent was obtained through the "Informed Consent Form" and it was ensured that the "Child and Parent Information Form" was filled in. At this stage, the parents were informed that the students would be asked about their favourite cartoons and VR headsets would be used to watch these cartoons in the study, and their consent was obtained. Parents who agreed to have their children participate in the study filled in the consent form and the Child and Parent Information Form and submitted them to the school administration through the teachers. Parents who did not agree to have their children participate in the study indicated it in the consent form and submitted the forms to the school administration. Inclusion and exclusion criteria were applied to the students whose parental consent was given to participate in the study. Students who consented to participate in the study and did not have exclusion criteria were included in the study.

Exclusion criteria for the study:

- Any chronic disease
- Any disease that causes acute or chronic pain
- Having used any analgesic drug within the last 24 hours
- Any mental or neurological disabilities
- Any barriers to communication
- Any sight or eye problems

  Then, students in each class included in the study were randomized to the experimental and control groups with a random number generator. This study was blinded to the statistician.

B. Study Procedure

Data collection tools

Child and Parent Information Form: It is a tool for collecting sample demographics and personal characteristics.

Children's Fear Scale (CFS): CFS evaluates the level of fear in children. It was developed by McMurtry et al. (2011) [9]. In CFS, drawings of five facial expressions, ranging from a neutral expression (0 = no anxiety) to a frightened face (4 = severe anxiety), are shown to the children. Evaluations are made in the range of 0–4. The scale is meant for children aged 5–10 years and can be used to evaluate their fear levels before and during the procedure. CFS was created based on the Faces Anxiety Scale developed by McKinley et al. (2003) [25]. For CFS, the total size of the Faces Anxiety Scale was reduced to match the size of the Child Anxiety and Pain Scale, but the drawings remained unchanged. The instructions of the Faces Anxiety Scale were changed developmentally in CFS as per the children's vocabulary of fear-related words (McMurtry et al., 2011) [9]. The Turkish validity and reliability study of the scale was conducted by Gerçeker et al. in 2018 [26]. In the scale,

- "Zero" refers to neutral expression (no anxiety)
- "One" refers to very little fear (very little anxiety)
- "Two" refers to some fear (some anxiety)
- "Three" refers to a high level of fear (high level of anxiety)

- "Four" refers to the highest level of fear possible (severe anxiety).

Children's Anxiety Scale-State (CAS-S): CAS-S resembles a thermometer with a bulb at the bottom and horizontal lines at intervals going upwards. It is used to measure the state anxiety level of children aged 4-10 years [27]. CAS-S score can range from 0 to 10 [28]. The Turkish validity and reliability study of the scale was conducted by Gerçeker et al. in 2018 [26].

APPLICATION AND DATA COLLECTION STAGE

The study was conducted during the 2019-2020 academic year during school vaccinations. A pilot application was conducted with 20 students (10 students each in the experimental and control groups) at the first school visited by the vaccination team. Pilot application data were not included in the study.

The application and data collection were performed in between October and December, 2019. The schools were contacted beforehand and were asked to allocate a separate room on the vaccination day. The rooms allocated by the schools for the vaccination days were usually similar and had windows and daylight; their inside was not visible from the outside and they were usually located on the upper floors. There was a table and two armchairs in the rooms. On the vaccination day, first the students in the control group and then those in the experimental group were admitted one by one in the room allocated to prevent the students from being influenced by each other. The room door was kept closed during vaccination. The vaccinated student could not be seen by other students. Vaccinated students were taken to the garden, gym, and conference room. The students could see each other only after all vaccinations were finished.

Two vaccines; Measles–Rubella–Mumps and Adsorbed Diphtheria–Tetanus–Acellular pertussis–Inactive polio were administered to first year primary school students. Each student was first given the Measles–Rubella–Mumps vaccine intramuscularly from the deltoid region of the right arm and then the other vaccine from the deltoid region of the left arm by the same nurse. It took ~2 min to prepare students and prepare and administer vaccines. The students did not know in advance on which day the vaccination would take place. The investigator informed the students of this on the vaccination day.

Experimental and Control Group

Before the vaccination, the student was met, a brief explanation was made and the student's consent was obtained.

Experimental Group

The students were informed about the use of VR and headsets before the procedure. Students were allowed to touch the VR headsets and ask questions. The students were asked whether they wanted to watch cartoons with VR headsets while being vaccinated and if they did, which one they would like to watch. Brief explanations were given to the students in order to prevent risks such as turning away from excitement or curiosity while watching cartoons with VR headsets and to prevent undesirable consequences in vaccine application due to such reasons. The cartoons that the students wanted to watch, and the VR headsets were prepared. While the nurse was preparing the vaccines, the VR headset was put on the student, the distance settings of the lenses were adjusted and the cartoons they chose to watch during the vaccine administration started to be shown. It took ~2 min to administer the vaccine and show the cartoons.

When the vaccination was over, VR headsets were removed; the headsets and lenses were wiped with alcohol-based hygienic wipes. Before and after the procedure, students were asked to mark on the CFS and CAS-S how scared and anxious they were.

Control Group

No intervention was made in the students in the control group during vaccine administration; routine administration was maintained. Before and after the procedure, the student was asked to mark how scared and anxious they were during the procedure on the CFS and CAS-S.

C. Data analysis

Data were analysed using SPSS version (SPSS 25.0 SPSS, Chicago, IL). Normality of distribution was examined with Kolmogorov–Smirnov test. Independent samples t-test was used to compare independent data with normal distribution, and dependent samples t-test was used to compare dependent data. Data with normal distribution were presented as mean ± standard deviation. Chi-square test was used to compare categorical data, which were presented as frequency (percentage). The level of significance was $p<0.050$. In the power analysis, when the effect size was $d=0.5$ before the study, it was predicted that including 64 cases in each group was associated with a test power of 80%.

D. Ethical considerations

Written institutional permissions were obtained from the Directorate of National Education (decision number: 19677617; date: 11.10.2019) and the Health Directorate (decision number: 35335454-799; date: 15.04.2019) to conduct the study. The Institute Ethics Committee approved this study (the decision dated 12.07.2019 and numbered 24237859-532). Before starting the study, parents and students were informed about the purpose, plan, and duration of the study via the Information and Consent Form, and

they were included only if they were willing to participate. This study was performed with the guidance of the CONSORT 2010 statement [29]. The Consolidated Standards of Reporting Trials flow diagram for the study procedure is shown in CONSORT flow diagram (Figure 1).

Moreover, expert opinions were received for the cartoons to be shown and the VR headsets to be used during the procedure. The opinion of a psychologist was obtained about the content of the cartoon to be shown during the study to children through VR headsets, its suitability for the children, and whether or not it contained elements of violence. Upon the recommendation of the psychologist, two cartoons named The Lion King and Squirrel, and Fellow Traveller were shortened and made ready to be watched during vaccine administration. An ophthalmologist's opinion was obtained about whether or not watching short cartoon movies for ~2 min with VR headsets would have harmful effects on the eyes of children. The ophthalmologist's opinion was that it would not have any harmful effects for durations of under 30 min.

III. Results

Of all the included children, 52.7% (n=89) were girls and 47.3% (n=80) were boys. Girls constituted 48.8% (n=41) and boys 51.2% (n=43) of the experimental group. However, 56.5% (n=48) of the control group were girls and 43.5% (n=37) were boys. The gender, family structure, father's education level, mother's education level, father's occupation, mother's occupation, and family's status in terms of scaring the child by saying I'll take you to have an injection when they misbehaved did not differ between the groups (p>0.050) (Table 1).

Father's mean ages (years) in the experimental and control groups were 37.9 and 39.9, respectively, indicating a significant difference (p=0.021). Mother's mean ages (years) in the experimental and control groups were 34.5 and 36.1, respectively, indicating a significant difference (p=0.039). The mean values of other parameters did not differ between the groups (p>0.050) (Table 2).

Pre-vaccination mean scores of CFS did not differ between the groups (p=0.348), but post-vaccination mean scores of CFS differed (control: 2.16, experimental: 0.64; p<0.001). Mean CFS scores before (1.69) and after (0.64) vaccination showed a statistically significant difference in the experimental group (p<0.001). Mean CFS scores showed a statistically significant difference before (1.46) and after (2.16) vaccination in the control group (p<0.001) (Table 3).

Pre-vaccination mean scores of the CAS-S did not differ between the groups (p=0.543), but post-vaccination mean scores of the CAS-S differed (control: 6.06, experimental: 2.14; p<0.001). Mean CAS-S scores before (4.46) and after (2.14) vaccination showed a statistically significant difference in the experimental group (p<0.001). Mean CAS-S scores before (4.79) and after (6.06) vaccination showed a statistically significant difference in the control group (p<0.001) (Table 3).

Table 1. Comparison of experimental and control groups in terms of identifying characteristics

	Experimental (n = 84)	Control (n = 85)	Total (n = 169)	Test statistic	p
Gender					
Female	41 (48.8) *	48 (56.5)	89 (52.7)	χ^2 = 0.995	0.319
Male	43 (51.2)	37 (43.5)	80 (47.3)		
Family structure					
Nuclear family	72 (85.7)	71 (83.5)	143 (84.6)	χ^2 = 0.251	0.882
Extended family	7 (8.3)	9 (10.6)	16 (9.5)		
Mother and father living separately	5 (6)	5 (5.9)	10 (5.9)		
Education level of the father					
Illiterate	1 (1.2)	0 (0)	1 (0.6)	χ^2 = 3.248	0.517
Literate	0 (0)	2 (2.4)	2 (1.2)		
Primary school graduate	12 (14.3)	12 (14.1)	24 (14.2)		
Secondary school graduate	35 (41.7)	38 (44.7)	73 (43.2)		
University and above	36 (42.9)	33 (38.8)	69 (40.8)		
Education level of the mother					

Illiterate	1 (1.2)	1 (1.2)	2 (1.2)		
Literate	2 (2.4)	2 (2.4)	4 (2.4)		
Primary school graduate	13 (15.5)	14 (16.5)	27 (16)	χ^2 = 0.512	0.972
Secondary school graduate	41 (48.8)	37 (43.5)	78 (46.2)		
University and above	27 (32.1)	31 (36.5)	58 (34.3)		
Father's occupation					
Not working	2 (2.4)	3 (3.5)	5 (3)		
Self-employed	28 (33.3)	37 (43.5)	65 (38.5)		
Public sector employee	26 (31)	26 (30.6)	52 (30.8)	χ^2 = 5.254	0.262
Private sector employee	27 (32.1)	16 (18.8)	43 (25.4)		
Retired	1 (1.2)	3 (3.5)	4 (2.4)		
Mother's occupation					
Not working	49 (58.3)	50 (58.8)	99 (58.6)		
Self-employed	4 (4.8)	1 (1.2)	5 (3)	χ^2 = 3.261	0.353
Public sector employee	19 (22.6)	16 (18.8)	35 (20.7)		
Private sector employee	12 (14.3)	18 (21.2)	30 (17.8)		
The family's status of scaring the child by saying "I'll take you to have an injection."					
Doesn't scare the child	81 (96.4)	83 (97.6)	164 (97)	χ^2 = 0.218	0.640
Scares the child	3 (3.6)	2 (2.4)	5 (3)		

χ^2: Chi-square test statistic * Frequency (percentage)

Table 2. Comparison of experimental and control groups in terms of some characteristics

	Experimental (n = 84)	Control (n = 85)	Test statistic	p
Number of siblings of the child	2 ± 0.9	2.2 ± 1	t = −1.416	0.159
Birth order in the family	1.6 ± 0.7	1.8 ± 0.8	t = −1.878	0.062
Father's age	37.9 ± 5.7	39.9 ± 5.4	t = −2.329	**0.021**
Mother's age	34.5 ± 5.4	36.1 ± 5.1	t = −2.084	**0.039**
How scared of the vaccine needle the child is	4.7 ± 3.4	5.7 ± 3.8	t = −1.924	0.056

t: Independent samples t test * Mean ± Standard deviation

Table 3. Comparison of children's fear and anxiety levels within and between groups

		Experimental	Control	Test statistic	p
CFS	Before vaccination	1.69 ± 1.55	1.46 ± 1.64	t * = 0.942	0.348
	After vaccination	0.64 ± 1.1	2.16 ± 1.58	t = −7.264	**<0.001**
	Test statistic	t ** = 7.398	t = −5.198		
	p	**<0.001**	**<0.001**		
CAS-S	Before vaccination	4.46 ± 3.25	4.79 ± 3.65	t = −0.609	0.543
	After vaccination	2.14 ± 2.59	6.06 ± 3.33	t = −8.530	**<0.001**
	Test statistic	t = 7.335	t = −4.583		
	p	**<0.001**	**<0.001**		

* t: Independent samples t test ** t: Dependent samples t test

IV. DISCUSSION

This study is the first study of the use of VR to reduce fear and anxiety during vaccine administration and study results have demonstrated its effectiveness.

In the study, gender, number of siblings, birth order in the family, family structure, father's education level, mother's education level, father's occupation, mother's occupation, how scared of the vaccine needle the child was, and family's status in terms of scaring the child by saying I'll take you to have an injection when they misbehaved did not differ between the groups. Herein, the experimental and control groups were homogeneous in terms of their background characteristics (Tables 1 and 2).

The mean fear score of the experimental group after vaccination was lower than that of the control group. Similar trend was observed for children's anxiety score after vaccination (Table 3). This suggested that VR headsets used in the experimental group distracted the children in this group, leading them to experience less fear and anxiety.

The most common invasive procedure faced by pediatric patients is injection. Since school-age children rarely show fear or discomfort during the procedure, their fear and discomfort can be ignored. A randomized controlled trial was conducted by Chen et al. (2020) to determine whether VR as a distracting intervention could reduce pain and fear in school-aged children who received intravenous injections in the emergency department. In the results of the study, it was found that the pain and fear ratings of the children and the scores perceived by the children's caregivers and nurses were significantly lower in the VR group [18]. Seventeen studies were included in the meta-analysis, which aimed to pool the evidence for the efficacy of VR in reducing pain and anxiety in pediatric patients undergoing medical procedures. In these studies, VR was applied during venous access, dental, burn, or oncological care, and prior to elective surgery under general anesthesia. Research shows that VR is an effective distraction intervention for reducing pain and anxiety in pediatric patients undergoing a wide variety of medical procedures. VR research in pediatrics has focused mainly on distraction [30]. In the study, it was observed that distracting children with VR headsets reduced anxiety and fear during school vaccinations in children. Althumairi et al. (2021) used a VR headset during vaccination with children aged 4-6 years. It was stated that the pain and fear scores of children in the VR group were lower than those in the control group and were found to be statistically significant [31]. Some studies have evaluated whether VR as a distracting intervention reduces anxiety and fear in school-age children undergoing needle procedures. In these randomised controlled studies, it was reported that VR significantly reduced anxiety and fear in children, similar to the findings of the present study [1, 18, 19, 32-35].

In the present study, there was a statistically significant difference in the mean CFS scores before and after vaccination in the experimental group, indicating that the children's fear decreased after vaccination (Table 3). These results are similar to those of a study conducted by Chad et al. (2018), wherein the vaccine was administered while children were wearing VR headsets, and fear decreased in children who were vaccinated [36]. Interventions designed to actively engage the child possibly improve the vaccination process in children as they are effective in managing anxiety or fear that has been reported [20].

In the present study, a statistical difference was found between the groups in terms of the mean scores of fear and anxiety after vaccination. The fear and anxiety levels of the children in the experimental group decreased, but those of the children in the control group increased. This may suggest that the children in the experimental group may have felt better because they received special attention that they had not experienced before. Similar results were obtained in a randomised controlled study conducted to evaluate the effects of two VR methods on procedure-related pain, fear, and anxiety during blood collection in children aged 5–12 years. Participation in VR groups decreased children's fear and anxiety levels, whereas being in the control group increased their fear and anxiety levels [19]. Similar results were obtained in another study. In a study conducted to determine the applicability and acceptability of distraction with VR and to examine its preliminary effects on pain and anxiety, children aged 7–17 years who required venipuncture in the pediatric emergency department were included. Participants were randomised into control (standard care) or intervention (standard care+VR) groups. It was reported that the addition of VR to standard care is applicable and acceptable for managing pain and anxiety during venipuncture in the pediatric emergency department [37]. The study results suggest that VR may be a viable option to add to the arsenal of distracting strategies to consider fear and anxiety reduction in vaccine management.

LIMITATIONS OF THE STUDY

The study was conducted in one province of the country, and this province may not have been representative of other provinces in the country. However, participating schools represent different geographic and socioeconomic regions in the province. This points to the strength of the study. The study had other limitations. Students in the experimental group may have felt better because they received special treatment that they had not experienced before. In addition, a single ethnic age group was included in the study and the research was limited to two different vaccines. Although VR requires very little preparation time (2 minutes), other strategies may not require any preparation time before use. Additionally, the nurse must have access to a VR device to make this a viable option.

V. CONCLUSION

The results obtained in this study show that distraction with VR headsets is effective in managing anxiety and fear during school vaccinations in children. Students who watched cartoons with VR headsets during school vaccinations experienced less anxiety and fear. Based on this particular study, we can say that VR effectively reduces anxiety and fear. However, additional research or replication studies are needed to further confirm these findings. Study results suggest that VR may be a viable option to add to the arsenal of distraction strategies to consider reducing fear and anxiety in vaccine management.

ACKNOWLEDGMENT

This study was produced from the doctoral thesis of the first author under the supervision of the second author.

Trial registration ClinicalTrials.gov NCT04755998. Registered on February 15, 2021.

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Evaluating The Effect of the Use of Virtual Reality Headset in School Vaccinations on Children's Fear and Anxiety Levels: A Randomized Controlled Trial

CONSORT 2010 Flow Diagram

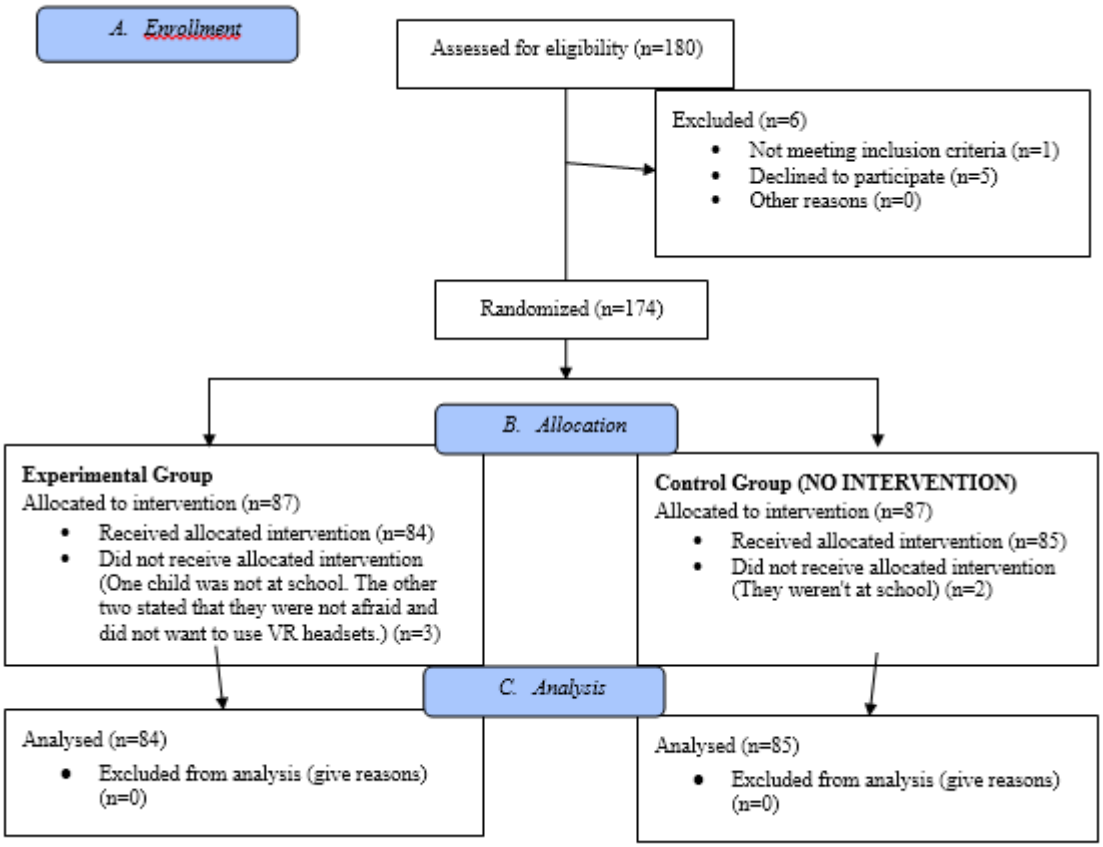

Figure 1. CONSORT flow diagram