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REVIEW ARTICLE

A Protocol for a Systematic Review on Effectiveness of virtual reality distraction on acute pain in cancer children

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Abstract

This study is a systematic review of the literature to identify and describe about the virtual reality distraction that has been studied using rigorous methods and to estimate its effects on acute pain in cancer children. The standard methodology of systematic review and meta-analysis was followed to conduct the study.

Protocol for the systematic review and meta-analysis

I. Background of the condition

Painful medical procedures are an unavoidable aspect of pediatric medical care, such procedures can cause severe worry and anguish in pediatric patients.[1]

Patients and their families are burdened by the pain and distress associated with recurrent procedures.[2] Pain is a common and major issue in children receiving cancer-directed treatment.[3] Needle operations are frequently cited by children with cancer as the most traumatic experience brought on by disease and its treatment[4]. Even when the skin is numbed with a topical anesthetic, the insertion of a needle into a subcutaneous port (SCP) has been demonstrated to be uncomfortable, frightening, and unpleasant to children.[5]

Various potentially painful and/or upsetting needle procedures, such as accessing the central venous access port or bone marrow punctures, are performed on children with cancer. It is becoming widely recognized that children are in danger of long-term consequences as a result of poor pain management during needle operations, such as increased anxiety and non-compliance with care.[6]

Pain should be quantified and controlled with a developmentally appropriate strategy in mind for children. The failure to pay attention to pain management strategies may harm the health of children with cancer.[7] Developmentally appropriate pain evaluation, identification of prospective pain management techniques, and administration of pharmacological and non-pharmacological pain treatments are all responsibilities of pediatric oncology nurses.[8]

II. Description of the intervention and how it will help

Virtual reality has been employed in a variety of settings. This study aims to explore how effective the virtual reality in decreasing the pain intensity during pain-producing treatment procedures. The argument behind how VR works in these situations is that it acts as a sort of distraction, which is defined as purposely diverting attention away from unpleasant feelings.[9] Distraction is a typical coping method adopted by school-aged children and teenagers when confronted with difficult situations.[10]

Distraction therapies work by diverting the child's attention away from the painful stimuli and redirecting it to a more pleasant and positive stimulus (for example, the virtual environment).[11]

Virtual reality interventions are hypothesized to have analgesic benefits through altering pain perception by diverting user focus away from the unpleasant operation, as well as changing how a person interprets incoming

pain signals, resulting in a reduction in pain-related brain activity (as seen on MRI imagery).[12]

By modifying how pain signals are processed in the central nervous system, exposure to virtual reality can design the pain pathways such a way to reduce pain intensity, and discomfort. This is accomplished through a variety of techniques, including attentional diversion, VR imagery conditioning, and pain reduction. VR distraction has been used to help youngsters cope with the anxiety that comes with chemotherapy[13], to lessen the discomfort of children while caring for burning wounds[14], to allow pediatric oncology patients access to intravenous ports[15] for invasive medical procedures such as venipuncture, lumbar puncture, and bone marrow aspirates to reduce discomfort and anxiety[16], to assist adolescents with cerebral palsy who are undergoing physiotherapy[17], employing handheld video games or films to alleviate children's preoperative anxiety.[18]

Distraction, in combination with pharmacological interventions, is regarded to be an effective pain management method because it helps children cope with the unpleasantness of medical treatments by cognitively shifting attention away from pain to a more pleasurable stimulus. Long-term advantages include advantages for later adult life since pain experienced during childhood medical treatments predicts discomfort.[19]

Why it is important to do this review

Virtual reality (VR) is a relatively new technological innovation that has the potential to reduce discomfort in children receiving medical treatment (e.g. intravenous cannulation, lumbar puncture, wound dressings, chemotherapy, bone marrow aspirates). When compared to children who were immersed in a VR intervention, children who had intravenous cannula insertion without distraction experienced a fourfold increase in emotional pain. Furthermore, as compared to children who were not exposed to a VR intervention, children who got a VR intervention were twice as satisfied with their pain management.[20]

When compared to earlier chemotherapy treatments without VR, 82 percent of youngsters said that their VR diversion was better.[21] Parents were also pleased with the usage of virtual reality interventions, believing that they reduced children's suffering and improved compliance during medical treatments.[20] Hoffman (2011) found that when burn patients were immersed in a distracting immersive VR environment, they had a 35 percent to 50 percent reduction in procedural pain.[22] Despite these high ratings and reports of pain alleviation, the effectiveness of VR therapies is still debated.[12]

This systematic evaluation is necessary to assess the effectiveness of virtual reality as a distractive device during medical treatment. Because some advanced interventions try to evaluate the effectiveness of modern and newer technologies like virtual reality, this review goes with other Cochrane Reviews that assess the efficacy of distraction-based interventions other than pharmacology methods for reducing pain intensity in children undergoing treatment procedure.[23]

Objectives

To assess the effectiveness of virtual reality distraction vs no distraction for children with cancer (0 to 18 years) with acute pain

III. Methods

Criteria for considering studies for this review:

Types of studies

Randomized controlled trial (RCT) designs, and clinical controlled trials (CCTs), Quasi-experimental, pre-test-post-test designs with the control group, cohort studies (prospective & retrospective) which are made some attempts to address the effectiveness of virtual reality distraction vs no distraction for children with cancer with acute pain.

Type of participants

Children with all types of cancer diagnosis

The studies were conducted on children with cancer during the period 2000 to 2022, aged from birth up to 18 years.

Inclusion criteria

Children diagnosed with cancer and undergoing painful procedures (surgery, chemotherapy, radiation therapy, IV cannulation, lumbar puncture, etc) will be eligible.

The Studies which address virtual reality distraction for children with cancer will be included

Exclusion criteria

Children with end-of-life treatment.

The studies with interventions other than virtual reality distraction.

Types of interventions

Any technology that creates a virtual environment/world, including immersive and/or non-immersive VR of any intensity or duration, to reduce the intensity of acute pain. These interventions can be used with or without

medication. Interventions that used any combination of input and output devices will be included like mouse and shutter glasses; position tracker and head-mounted display. For the intervention to be VR the participant must be actively interacting with the virtual environment which responds to their actions. We will be comparing these interventions were compared to an inactive control intervention, such as a placebo, standard care, or waiting list control: 'a group assigned to a waiting list to receive an intervention after the active treatment group', or to an active control intervention (for example another form of psychological intervention). Studies with multi-interventions will be excluded unless were extractable data.

Types of outcome measures

Primary outcome

Acute pain intensity:

1. During the procedure will be measured using:

   a. Self–report

   b. Observer-report

   c. Behavioral measurements (observer-report)

2. Post-procedure (up to one hour), will be measured using:

   a. Self–report

   b. Observer-report

   c. Behavioral measurements (observer-report)

Search methods for identification of studies

The search strategy for the identification of relevant studies is highlighted below.

• **Electronic Search:** Computerized database searches will be conducted. Search terms and search strategies will be tailored to each database.

The following databases will be searched (along with others that may be added):

1. Pubmed
2. Science direct
3. Cochrane library
4. Ctri (clinical trials registry – india)
5. Conference report or dissertations published in shodhganga
6. Medline
7. PsychINFO

It will include literature published from January 2000 to May 2022. The database search will be conducted using four sets of keywords related to the population, intervention, outcomes, and study design. The keywords in search strings will be tailored to the specific thesaurus of each database. Linking of Keywords will be done with "and"/"or" when searching titles and abstracts. Search terms will also be shortened to account for variations in word endings, spellings, and database indices. Studies in the English language only will be considered.

Keywords:

- "Virtual reality distraction" and "Childhood Cancer"
- "Virtual reality distraction" and "Children with cancer"
- "No distraction" and "Childhood cancer"
- "No distraction" and "Children with Cancer"
- "Acute pain" and "Childhood cancer"
- "Acute pain" and "Children with cancer"
- "Acute pain" and "Virtual reality distraction"
- "Acute pain" and "No distraction"
- "Virtual reality distraction" and "No distraction"
- "Painful procedures" and "Childhood Cancer"
- "Painful procedures" and "Children with cancer"
- "Virtual reality distraction" and "Cancer"
- "Cancer" and "Children"
- "Distraction" and "Children"
- "Distraction" and "Pain"

Keywords as per PICO format

Patient	Intervention	Control	Outcome
Children with cancer Childhood cancer	Virtual reality distraction	No distraction	Reduced pain perception

1V. Data collection and analysis

Selection of studies

- ✓ The screening process will be divided into two stages: the first stage will screen articles based on titles or abstracts, and the second stage will screen full-text articles.
- ✓ Two investigators will screen the titles and abstracts of studies found during the literature search. The

review author will read potentially eligible studies in their entirety to determine whether or not they meet the eligibility criteria. Any clarifications will be discussed with a third author until there is agreement.

- ✓ Excluded studies will be listed in the table 'Characteristics of excluded studies.
- ✓ A PRISMA flow chart will be used to document the study selection process.
- ✓ Articles that have only been published in English will be included.

Data extraction and management

Data will be extracted from all relevant studies using a pretested extraction sheet and entered into the 'Characteristics of included studies' table in RevMan 5.3. (RevMan). Two review authors will independently evaluate all studies. Any disagreements were settled through discussion. The following information will be extracted.

(a) Participants: country of origin, sample size, setting, diagnostic criteria, age, ethnicity, study date

(b) Methods: study design, allocation methods, allocation sequence concealment, blinding, and participant exclusion after randomization, proportion, and reasons for loss at follow-up.

(c) Interventions: intervention type, dose, duration, and frequency (for each intervention and comparison group).

(d) Outcomes: the type of outcome, the assessment instruments, the assessment time point, and the follow-up time point.

Sources of funding were noted in the 'Characteristics of included studies' section if they were mentioned.

In the case of studies with multiple publications, the first publication will be considered the primary reference, but data will be extracted from all of the publications.

Assessment of risk of bias in included studies

Each selected trial will be graded and assessed by two review authors using a simple contingency form that addresses the seven specific domains discussed in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). All authors' evaluations will be compared, and any inconsistencies or disagreements will be resolved through discussion. Each domain will be assigned a judgment based on the likelihood of bias in that domain. The following judgments were used: 'low risk of bias,' 'high risk of bias,' and 'unclear,' which indicated an unclear or unknown risk of bias.

The domains will be:

- Random sequence generation.
- Allocation concealment.
- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Selective outcome reporting.
- Other sources of bias.

Each domain will be rated as either:

- 'low risk of bias if the requirements are met or
- 'high risk of bias if the requirements are not adequately fulfilled
- 'Unclear risk of bias' if insufficient data for a judgment are provided

The risk of bias will be considered when assessing the effectiveness of evidence for each outcome by following the GRADE recommendations.[24]

Measures of treatment effect

According to the Cochrane Handbook for Systematic Reviews of Interventions, chapter 7, section 7.7.325, primary outcomes will be classified as continuous outcomes and expressed as standardized mean differences (SMD) with 95 percent confidence intervals (CI). If the outcome variable is dichotomous (yes/no) we will be using the Risk ratio and if it is the continuous mean difference will be used. For discrepancies in scales, standardized mead differences will be used.

All measures of effect included 95 percent CIs, P values, and the I2 statistic for pooled measures.

Assessment of heterogeneity

The Chi2 test will be used to assess statistical heterogeneity between studies. A P value of 0.10 will be considered significant heterogeneity. In addition, the I2 statistic will be employed.

Assessment of reporting biases

If at least ten studies are included in a meta-analysis, Review Manager Software will generate funnel plots of effect estimates versus standard errors (on a reversed scale). Visual analysis of funnel plots will be used to

assess publication bias, with roughly symmetrical funnel plots indicating low risk and asymmetrical funnel plots indicating high risk.[25] Further efforts will be made to avoid publication bias by searching for unpublished studies in trial registries and conference proceedings.

Duplicate publication bias will be addressed by including studies with multiple publications only once. If there is any doubt about whether multiple publications refer to the same data, the trial authors will be contacted via e-mail.

Data synthesis

A random-effects model will be used to pool data for continuous outcomes (inverse variance method). All analyses will be performed using RevMan 5.3 software. If the studies are found to be homogenous in terms of study designs, participant characteristics, interventions, and outcome the extracted data from such studies will be pooled in a meta-analysis using a random effect model, Revman 5.3. If meta-analysis is not appropriate then the results of the studies will be synthesized narratively

Subgroup and moderator analyses

A small number of independent variables will be subjected to subgroup/moderator analyses. The approach to the moderator analyses will be determined by the data available. If the volume of data allows for multiple factor regression on treatment effect size, meta-regression will be used.

Conflict of interest

None

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