Title: Use of Virtual Reality Distraction to Reduce Child Pain and Fear during Painful Medical Procedures in Children with Physical Disabilities in Uganda: A feasibility study

Full names and affiliations for all authors, including highest academic degree

Femke Bannink Mbazzi (PhD) [1,2,3], Claire Nimusiima (BSc) [1], Daniella Akellot (MPH) [4], Elizabeth Kawesa (MSc)[1,4], Andrew Abaasa (PhD)[1], Sarah Hodges (DMSc) [4], Janet Seeley (PhD)[1,3], Tine Vervoort (PhD)[2]

[1] Medical Research Council / Uganda Virus Research Institute & London School of Hygiene and Tropical Medicine Uganda Research Unit, Entebbe, Uganda

[2] Faculty of Psychology and Educational Sciences, Ghent University, Ghent, Belgium

[3] London School of Hygiene & Tropical Medicine, Global Health & Development, London, United Kingdom

[4] CoRSU Rehabilitation Hospital, Kisubi, Uganda

Full address corresponding author:

Femke Mbazzi Bannink, PhD

FWO postdoc fellow, Faculty of Psychology and Educational Sciences, Ghent University, Belgium

Assistant Professor, MRC/UVRI & LSHTM Uganda Research Unit, P.O. Box 49, Entebbe, Uganda

Phone +256 772 928011

Email femke.bannink@ugent.be / femke.bannink@mrcuganda.org

Author's contribution

Conceptualization: Femke Bannink Mbazzi, Sarah Hodges, Janet Seeley, Tine Vervoort.

Data analysis and interpretation: Femke Bannink Mbazzi, Claire Nimusiima, Andrew Abaasa.

Funding acquisition: Femke Bannink Mbazzi, Janet Seeley.

Investigation: Femke Bannink Mbazzi, Daniella Akellot, Elizabeth Kawesa, Sarah Hodges.

Methodology: Femke Bannink Mbazzi, Claire Nimusiima, Andrew Abaasa, Sarah Hodges, Tine Vervoort.

Project supervision: Femke Bannink Mbazzi, Daniella Akellot, Claire Nimusiima, Sarah Hodges, Janet Seeley, Tine Vervoort.

Writing – original draft: Femke Bannink Mbazzi

Writing – review & editing: Femke Bannink Mbazzi, Claire Nimusiima, Daniella Akellot, Elizabeth Kawesa, Andrew Abaasa, Sarah Hodges, Janet Seeley, Tine Vervoort.

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Abstract

Objective

This study explored the acceptability and feasibility of the use of low-cost virtual reality (VR) glasses, and the Wong-Baker Faces Pain Scale and Children's Fear Scale scales, for pain and fear reduction in children admitted at the septic ward of CoRSU Rehabilitation Hospital in Uganda.

Methods

In total 79 children aged 4 to 17 years of age were offered to watch cartoons using VR glasses while undergoing painful dressing procedures. Before and after the procedure children were asked to index current pain; children and their caregivers were asked to rate anticipated fear. Focus group discussions with 13 children, 10 caregivers and 9 nurses explored acceptability and feasibility. Quantitative data were analysed using STATA15, NVIVO12 was used for qualitative data analysis.

Results

The VR glasses were accepted by 76 (96%) of the children. Children, caregivers, and nurses mentioned the glasses were helpful in distracting children from the medical procedure, and felt the use of the glasses helped reduce child fear and pain. Nurses felt it made their work easier. The Wong-Baker Faces Pain Scale was an acceptable and feasible method to measure pain, whilst the Children's Fear Scale was more difficult to interpret for our study population as they felt the faces on the scale were hard to read and identify with.

Conclusions

The use of VR glasses may offer an acceptable and effective pain and fear reduction method in resource-constrained settings and should be further explored in a randomized controlled trial.

Introduction

Many children in sub-Saharan Africa have to cope with the general burden of disease, poverty and ineffective care systems, in addition to not receiving basic pain management for disease, surgery or injuries [1]. In South Africa, a recent hospital study showed high prevalence of pain and inadequate pain management in paediatric patients particularly during painful procedures [2]. Pain reduction through the use of analgesic drugs and distraction in sub-Saharan Africa is rare due to limited prescription and availability of drugs and equipment, inadequate training of health care workers, cultural diversity, and language barriers [1-5].

In high income countries, distraction is a common non-pharmacological technique used by health care professionals to manage and attenuate fear and pain during painful procedures in paediatric patients. Both passive and active distraction have been extensively studied and have been found to be associated with decreases in pain and fear [6, 7]. Of various distraction methods available, distraction by means of capitalizing on the power of Virtual Reality is considered a particularly powerful medium as it completely immerses the patient in another world and involves multiple senses [8-10]. Recent studies in high income countries explored using VR with paediatric patients undergoing procedures including dressing of burns, and have shown that VR is effective in reducing the pain and fear patients experience compared with standard care [8]. Little is known about the acceptability and applicability of this method in pain reduction in low income countries. In South Africa, a feasibility study of a low-cost VR system showed promising results in adult burn patients [11]. To the authors' knowledge no other studies have been conducted to explore the effect of VR for pain reduction in resource-constrained countries. Generally access to electronic devices in such settings is still limited [12].
We investigated whether the use of low-cost virtual reality (VR) glasses, playing 3D videos as a passive but immersive distraction method is acceptable and feasible for children undergoing painful medical procedures admitted at Comprehensive Rehabilitation Services Uganda (CoRSU) Rehabilitation Hospital in Uganda. We studied acceptability with children, caregivers, and nurses. Additionally, the cultural acceptability and feasibility of measuring pain using the Wong-Baker Faces Pain Scale (FACES), and fear using the Children's Fear Scale (CFS) were explored. Whilst the Wong-Baker and FACES pain scales (FPS-R) have been validated with children Kenya[13], Cameroon[14], and South Africa [15], no validation studies have been conducted with children undergoing painful (post-operative) procedures in Uganda. Medical staff working in paediatric palliative care in Uganda have said to find the use of various pain scales depicting faces useful, however they have also noted that they seem to measure distress rather than fear[16]. To the authors' knowledge the Child Fear Scale has not been studied in Uganda and other Sub-Saharan Africa countries. To ensure children identify with the faces and use the rating scales to indicate pain and fear well, we studied their acceptability and feasibility.

Methods

Setting

CoRSU Rehabilitation Hospital (CoRSU) is a not-for-profit organization, established in 2006 in Wakiso district, Central Uganda. CoRSU provides orthopaedic and plastic/reconstructive surgical interventions and rehabilitation services to children with

disabilities. At CoRSU, most children undergo wound dressing and other painful medical procedures as part of their rehabilitation program. The children do not routinely receive any specific distraction method to reduce pain and fear unless the nurse providing the dressing offers play or verbal interaction as distraction, or provides analgesic drugs to reduce pain in case the child has to go through very invasive procedures (personal communication Head of Anaesthetics CoRSU, 2019).

Sample size calculation and selection

We used a convenient sampling method where eligible volunteers were consecutively enrolled into the study until the sample size of 79 children was reached. The main objectives of the study were exploring the acceptability and feasibility of the use of low-cost virtual reality (VR) glasses, and the Wong-Baker Faces Pain Scale and Children's Fear Scale scales, for pain and fear reduction in children. Assuming the acceptability of the intervention in this study was of the order 85%, a sample size of 79 children would allow us determine this proportion with a precision of ±10%.

Participants were consecutively sampled: all 92 children aged 4 to 17 years admitted on the septic ward in CoRSU Hospital undergoing dressing procedures between November 1st 2019 and January 31st 2020 were invited to participate.

Study participants

All children in the study were admitted with a parent or caregiver aged 18 or above as is the practice in Ugandan hospitals. In total, 79 caregivers consented and 69 children aged 8 – 17 years assented. Another 10 children aged 4-7 years who could not assent participated with parental consent.

The 79 children (32% female, 68% male), with a median age of 13 years (4-17 years), were under treatment for osteomyelitis (77%), pressure sores (5%), and other conditions (17%) and hospitalized at CoRSU at different time points between November 2019 and February 2020.

All 16 health workers employed in the septic ward were invited to participate in the study. In total 14 health workers (12 female, 2 male) consented to participate, consisting of 12 nurses, and 2 nursing assistants. The 2 who did not consent usually work at night and did not feel it was feasible to participate as they do not engage in dressing procedures regularly and could not attend the FGD during day time. The health workers provided feedback on the scales and 9 of them participated in a focus group discussion in which acceptability of the intervention was discussed. Whilst all 14 who consented were invited, only 9 could participate in the FGD, as a number of staff had to be on duty to ensure patient care.

VR glasses

Two Oculus Go Standalone Virtual Reality Headsets (2018) with a value of 250 USD were used in this study showing different children's cartoons. This type of headset was chosen as it was a low cost untethered set that was easy to administer and did not use a mobile phone or direct power supply. This was a deliberate choice as hospital budgets are constrained, staff is unfamiliar with the use of VR devices, power outages are common, and mobile phones are prone to theft in Uganda. The child could watch 3D movies as an immersive experience as they could not see the medical procedure. The study team introduced the VR glasses by saying 'Today we have special glasses with which you can watch a cartoon during the dressing, would you like to have a look at the glasses?' After the child had a look at the glasses (when it was not yet playing a movie) the study staff would ask if the child would like to use the glasses during the dressing. When agreed, children were requested to wear the VR glasses watching

selected children's cartoons for the age groups 4-7, 8-13, and 14-17 years while undergoing the painful dressing procedure. The nurse would start the video and help the child to put the glasses on, the children were told they could remove the glasses at any time. If the child did not request for removal, the nurses would prompt the child to take off the glasses when the procedure had been completed and help them to remove it when necessary. The glasses were cleaned thoroughly to ensure they met the hospitals disinfection regulation for use of equipment before offering them to the next child. Children were given a hairnet to wear before the VR glasses to keep the elastic head bands clean.

Stimuli selection

To select the 3D videos that were most appealing for the different age groups (4-7; 8-12; 13-17 years), and thus most capable of effectively distracting children, a group of 30 children admitted at CoRSU watched 10 different children's videos, and were asked to list their top 3 favourite videos. To validate the video content as appropriate for the study population, the initial 10 videos were selected by the CoRSU psychosocial team who are familiar with the children's movies preference, as the hospital has weekly video display afternoons. The selection process consisted of the 6 team members listing the 16 available movies and ranking these based on the ability to immerse and distract children. A top 10 list was derived from the lists of the 6 team members. The lists were then analysed per age group and the most preferred video was selected for use in the study. No gender differences were noted when selecting the movies. In total, a selection of 3 videos (1 per age group) was made. These included excerpts of the Disney movies the 'Ginger Bread man', a little bread man baked by an old lady that comes to life for the 4 - 7 years old children; 'Cars', a movie about talking cars centred around humility, integrity and appreciating others for the 8-12 year old children; and 'Despicable Me' about a villain who wants to steal the moon, highlighting the power of family, friendships and teamwork for the 13 – 17 years old children. The short movie excerpts ranged from 15 to 20 minutes.

Measures

Self-report measures

The Wong-Baker Pain scale (FACES) is a self-report visual measure of pain intensity developed for children aged 3 years and above [17], measuring pain on an 11-point scale from 0 – 10 whereby 0 is no pain, and 10 is the worst pain possible. The scale is easy to administer and requires no equipment except for the photocopied faces. The scale instructions have been translated in over 40 languages including Swahili as an applicable language for this study. It has previously been used in the CHAKA study at the MRC/UVRI & LSHTM Uganda Research Unit and has a Luganda translation [18]. Luganda and English are the most common languages spoken in the Central region where CoRSU is based. Depending on the child's language preference the English or Luganda translation was used. The study team considered the use of the Wong-Baker Pain Scale as well as the FACES Pain scale. In the hospital the Wong-Baker Pain scale had been used earlier and a preference to this scale over the use of the FACES Pain scale was expressed by the study nurses. They felt that the Wong-Baker scale faces were easier to identify with for the children as the faces were rounder and looked less Caucasian than those of the FACES Pain Scale.

The Children's Fear Scale (CFS) is an adaptation of the FACES Pain Scale and measures fear in children undergoing painful medical using a similar ordinal scale, measuring fear an 5-point scale from 0 – 4 whereby 0 is no fear, and 4 is the worst fear possible [19]. Instructions for the CFS scale were translated in Luganda. At the time of designing this study no other visual fear scales for children were known to the authors and no comparison of other tools were made.
As these pain and fear assessment tools have not been used extensively amongst Ugandan populations, children and caregivers were also asked (using open questions) to what extent they felt faces depicted in the FACES and CFS represented pain and fear expressions, respectively.

Focus group discussions

In total, 4 focus group discussions (FGD) were held to understand the acceptability and feasibility of the use of the VR glasses between January 27th and February 6th 2020. Focus groups were chosen over questionnaires as many participants are illiterate and unfamiliar with survey questionnaires. By using focus group discussions, we remained closer to cultural communication which often happens in group settings, and were able to explore more in depth what participants thought about the use of VR. The focus group discussions were held in a meeting room at the hospital. Two focus group discussions were held with 13 children aged 10 to 14 (4 boys and 3 girls in one and 2 boys and 4 girls in another group), 10 caregivers (4 fathers and 6 mothers), and 9 health workers (2 male, 7 female). Figure 1 lists the themes and main questions discussed in the focus groups.

The children's focus group discussions were held with children aged 10 and above to ensure children had the cognitive ability to discuss the use and acceptance of the VR glasses, and the experiences of pain and fear in the hospital. Caregivers of the same children were invited for a parents' focus group discussion. In addition parents of children aged 9 and below were invited to participate in the focus group discussion to ensure we collected data about their perceptions of the glasses too. Children and caregivers were selected based on interest and availability to participate. In the selection of participants, the study team ensured participants of different ages, and socio-economic backgrounds were represented. All nurses working on the septic ward were invited to participate, in total 12 nurses and 2 nursing assistants agreed and 9 were available on the day the FGD was conducted.

The investigators participated in drafting the FGD guides, which consisted of questions around pain experience, pain management, the use and acceptability of VR glasses, and recommendations for its use in future. The questions were based on health care worker experiences, which were shared during monthly team meetings of the nursing and psychosocial teams at CoRSU hospital. A draft FGD guide was shared with the teams for inputs and consensus was reached at the second draft. FGD were moderated by two female Ugandan research team members fluent in English and Luganda, trained and experienced in qualitative data collection in social science studies in the region. FGD moderators were aided by a note taker. Quality checks were conducted by the investigators but none of the investigators participated in FGD to prevent biased responses. On average, FGDs involving caregivers and nurses lasted 90 minutes whereas the children's FGD lasted approximately 60 minutes. All FGD were audio recorded, transcribed verbatim, and translated by the research team.

Procedure

After consenting and assenting basic demographic, and medical information was collected from each child. Children were offered the possibility to use the VR glasses during the medical procedure they had to undergo as part of their planned hospital treatment. The study staff then registered if the child declined, hesitated but accepted after encouragement, or accepted to use the glasses at once. Study staff were instructed to offer the child the glasses before the start of the procedure. In case the child seemed unsure the study staff would ask the child if they would like to hold the glasses and have a peep at the video that was playing. Children who agreed to use the glasses after holding the glasses and peeping at the screen but appeared ambivalent at first, were coded as 'hesitant but accepted after encouragement'. The children were also requested to indicate the pain they were experiencing using the Wong-Baker Faces Pain Scale (FACES) as a pain measurement tool, and fear they had about the procedure using the Children's Fear Scale (CFS) as a fear measurement tool before the dressing procedure indexing current pain and anticipated fear and after the procedure indexing pain and fear at that time. Caregivers of the children were asked about their own procedure-related fear before and after the procedure too. Figure 2 shows a picture of a girl undergoing a painful dressing procedure whilst wearing the VR glasses.

All participant data and responses were captured on paper forms and subsequently entered in REDCap and were stored on the research unit's secure server in a password protected database, only accessible to the study team. Data forms including informed consent and assent forms were filed and stored at the data centre.

Data analysis

Data analysis of quantitative data were conducted using Stata V 15.0 (Stata Corp, College Station, TX, USA). The participants' characteristics were summarised in descriptive terms such as mean, median, standard deviations (SD) or percentage, as appropriate. Spearman correlations between possible confounding demographic and procedural variables and the fear and pain outcome scores were conducted. We estimated children's mean score for pain at the start and end of procedure and did the same for fear for both children and their parents. We further used a student t-test to compare mean score of the study outcomes between the different children characteristics. To understand if there were possible differences between the pain and fear scores in children undergoing different medical procedures, we created dummy responses from medical procedures variables (only postsequestrectomy, only general wound dressing and both postsequestrectomy & wound dressing) and compared mean fear scores for children, parents and pain scores for children; among these categories using analysis of variance. We further performed a post hoc analysis using bonferroni for multiple comparison. To compare the relationship between parental and children's fear scores, we fitted a negative binomial model regressing children's fear on parental fear at the end of the procedures controlling for both children and parental fear at the start. Analysis of FGD data was managed using Nvivo10 (QSR International, Melbourne, Australia). Data were reviewed following a thematic approach using framework analysis, and a matrix-based system for organizing, reducing, and synthesizing data [20 21]. FGD data was transcribed and imported in Nvivo10, and coded using the codebook themes (Figure 2). The codebook was developed by two investigators and imported into NVIVO10. The thematically organized data were then reviewed and synthesized into meaningful themes and quotes were selected to highlight, explain or describe relevant themes. The data was queried to look at differences in outcomes between the 3 groups: children, parents, and health workers.

Materials were summarized in a framework matrix to easily compare what children, parents, and health workers said about the feasibility of the use of VR glasses, and the acceptability of the FACES and CFS.

Ethical considerations

Ethical approval for this study was obtained from the Uganda Virus Research Institute, Research Ethics Committee (GC/127/19/08/731) and the London School of Hygiene and Tropical Medicine Ethics Committee (Ref 17959). Research clearance was received from Uganda National Council for Science and Technology (HS 2661). LSHTM Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies applied to this trial. No adverse events were reported during the study. Preliminary results of the feasibility study were shared with participants through a CoRSU patient information meeting, and with CoRSU staff in an all staff meeting at the hospital in March 2020. Participants were able to validate findings and ask questions.

Results

Descriptive statistics

Table 1 shows the descriptive characteristics of the children who participated in the study. In total 25 girls and 54 boys participated in the age groups 4-7 (n=10), 8 – 12 (n=27), and 13-17 years (n=42).

The dressing procedures during which the children were exposed to the VR glasses included general wound dressing (35.4%) and wound dressing post sequestrectomy (74.9%); some children underwent both procedures. Less than 4% of the children who participated were offered pethidine IM (2.5%), a ketamine mixture containing paracetamol syrup, diazepam and ketamine (0.9%), paracetamol (0.3%), or diclofenac (0.3%) in addition to the VR glasses by the medical staff. These children had severe burns and very deep wounds. It should be noted the other children who did not receive analgesics had serious wounds too and would most likely have received pain medication in high income countries. The average length of the procedure was 21 minutes (SD=15, range 2 – 129 minutes). On average each child was exposed to using the VR glasses 5 times (SD=4.39, range 1-21) during their admission.

Table 2 shows the means, standard deviation, frequencies, percentages and spearman's correlation coefficients between study outcomes.

Feasibility

In total, 85.9% (79/92) caregivers agreed to participate in the study. The 13 caregivers who declined to participate expressed concerns to the nurses that this new device might cause cancer or infertility. Findings indicated that almost all (96.2%) of the participating children who were exposed to the study for the first time (N=79) immediately accepted and used the VR glasses (with a 95% confidence interval of 89.3 – 99.2). Another 2.53% hesitated but later accepted the use of the glasses. Only 1.27% declined to use the glasses. Of those who accepted to use the glasses 22.1% of the children asked to remove the glasses during the first exposure. There was no clear pattern on request to remove the glasses during the procedures until at least the 10^{th} time of exposure when it reduced to 3.5% from the 22% reported initially.

On average each child was exposed to using the glasses 5.15 times (SD=4.39, range 1-21) during their admission. No adverse events were reported during the pilot study, and no unintended effects were registered.

Qualitative assessment of feasibility

The main themes emerging from the qualitative assessment on feasibility of the use of the glasses were the pain and fear experiences children, parents, and nurses had prior to using the glasses, the first response children, parents, and nurses had to the glasses, the effect the glasses had on the fear and pain children experienced over time, and feasibility of use of the glasses in future. Focus group findings showed that all children, caregivers, and nurses mentioned the glasses distracted children from the medical procedure, and reduced fear, and pain. Children explained to experience high levels of fear about the dressing procedures, as many had undergone these prior to the introduction of the glasses, and found the procedures very painful. Parents confirmed the same, and some said their children start crying and shaking when taken to the dressing room, as they anticipate the pain to come. The nurses mentioned the dressing procedures could be difficult to complete if the child has a lot of fear or would cry a lot.

When introduced to the glasses children and nurses were immediately excited to try these out as they felt the movies were attractive and something 'new' to do whilst having the dressing procedures. A few caregivers wondered what these new glasses were about, and were unsure if they would be beneficial, but over time did feel they were helpful.

Caregivers explained that their child reported to feel less pain during the procedure when using the glasses. A male caregiver said the following:

> *'My daughter used to scream a lot but after they brought the glasses, you could see that she still feels pain but not as much as she used to before the glasses.'*

Caregivers explained that the glasses helped distract the child, and reduced fear in their children. A female caregiver said about her child:

> *'The glasses make her [the child] not focus so much on the dressing, they reduce her fear and keep her calm.'*

Caregivers also narrated that the glasses helped them too, as they now have something to give the child. A mother said:

> *'Glasses have relieved us of the pressure, and I can stay in the room when I am relaxed because I no longer have to worry a lot.*'

Caregivers did not indicate any dislikes with the glasses outside some initial hesitation. One of the caregivers suggested the children and parents could be introduced to the glasses on the ward rather than the dressing room, to familiarize with the tool and feel comfortable with this. They also asked if the glasses could be used in the pre-operation room before children go in for surgery, as they experience a lot of fear then.

Children who participated in the focus group discussion also said that the glasses helped reduce pain and fear:

'*It [the VR glasses] takes away all my fears.'* (15 year old boy).

'*The pain is less compared to previous dressings, I am happy to watch.*' (11 year old girl).

Children explained that the glasses spared them from having to look at their wounds and just wait and sit. At first they found it strange not to see what was happening around them when wearing the glasses, and would take them off if feeling a lot of pain. Later on they could 'trust' the process more and were less inclined to remove the glasses to peep at what was happening to their wounds. This could explain the initial higher request to remove the glasses during the procedure, which reduced over time.

The children said there was nothing they did not like about the glasses itself. They indicated that they would like to use the glasses prior to entering the dressing room, as they are often feel anxious when waiting for the dressing to start. The children also suggested to use the glasses before entering theatre in case of future surgeries, as this too had been fearful moments for many. The children who stayed on ward longer and underwent various dressing procedures using the glasses, asked to have a variety of movies available so that they could watch something new every time.

Nurses felt the glasses made their work less stressful as children tended to cry less and be more calm during the procedure. As one of the nurses said:

There is less crying, it makes my work easier (nurse)A few nurses felt piloting the glasses was a lot of work and delayed their work, one of them said:

The process takes longer than usual, where you would have dressed two patients, you dress one patient now (nurse)

When further explored, the delays mentioned were mostly related to administering the FACES and CFS, registering the scores on the data collection forms, and ensuring the procedures were recorded. The actual administration of the glasses was not seen as time consuming, and was overall rated as positive by the nurses. They felt rating the pain and fear was something particular for the study, they did not feel this was something that would be helpful in their work. The nurses suggested to purchase more glasses so that these could be used in all the hospital wards. They specifically thought of the pre-operation room when preparing children for surgery, as well as physiotherapy. They also requested to have the glasses for both adults and children, and select movies appropriate for the different age groups. Some nurses suggested to have a wider range of movies to choose from, especially for patients who stay at the hospital for longer periods of time.

The nurses expressed a challenge in using the glasses with children who have wounds on their heads, such as burns, and wondered if there were other ways of allowing children with such conditions to watch movies and distract them during the dressing.

Pain and fear scales - reliability

Most participants felt the scales were easy to understand and use, and some said it made them laugh with their children about the anticipated fear on the day.

'It [the scales] was easy, I picked the face that was similar to my feelings.'

'*My son kept talking about the funny faces and he would tell me 'mummy you are like number three yet for me I am at number one' [laughter]*.'

Children and caregivers reported that whilst the pain faces (FACES) clearly depicted painful expressions, the faces depicted in the CFS did not look 'Ugandan' and 'fear' could not be easily be read from the faces. Some nurses felt that the faces should be coloured in African skin colour to make them look more familiar. A few children mentioned to find it difficult to identify the difference between the second, third, and fourth face on the CFC scale, they suggested to make the difference more obvious.

Scores on the pain and fear outcomes

Table 3 shows the FACES and CFC scores at the start and end of the procedure rated by the children and their parents.

Boys had significantly higher self-reported pain scores compared to girls, both before (t=-2.215, p=.027) and after (t=-2.352, p=.0193) the procedure. Self-rated fear scores were also significantly higher for boys compared to girls at the start (t=-3.091, p=.002) but not at the end of the procedure (after exposure to the glasses). Parents reported significantly higher fear for boys compared to girls before (t=-4.352, p<.0001) and after (t==2.910, p=.0004) the procedures. There was no significant difference in diagnosis or procedures that boys and girls went through.

Older children had significantly lower self-rated pain (t=3.912, p<.001) and fear scores (t=4.185, p<.0001) at the end of the procedure compared to younger children. No significant differences were seen between the age groups in parental rated pain and fear scores, or the children's self-rated scores at the start of the procedures.

The average duration of the medical procedures was 20 minutes (SD=15, range 2 – 120 minutes). We noted that the children's self-rated pain scores on the FACES were significantly lower when the procedures were <20 minutes at the start (t=-3.520, p=.001) and end of the procedure (t=-3.522, p<.0001), compared to when the procedure lasted longer than 20 minutes. Similarly, on the CFC, a lower child self-rated fear score was noted at the start (t=-2.052, p=.041) and the end of the procedure (t=-2.497, p=.013) when children underwent a procedure that was under 20 minutes. No parental differences were noted in relation to the duration of procedures.

The results of the mean and mean differences between the different procedures either singularly or in a combination are shown in the Table 4. Other than the mean fear ($\bar{x}$=0.60) and pain ($\bar{x}$=2.47) scores for children between post sequestrectomy wound dressing and general would dressing (fear $\bar{x}$=0.31, pain $\bar{x}$=1.40) that achieved statistical difference, respectively p=0.003 and p=0.049, other mean differences did not achieve statistical significance.

Children's start ($\bar{x}$=1.09) and end fear mean scores ($\bar{x}$=0.84) were higher compared to parental start ($\bar{x}$=0.86) and end ($\bar{x}$=0.61) fear scores. The results of a negative binomial model regressing children's fear on parental fear showed that for each one-score increase on children's fear, the expected log score of the parent's fear increased by 0.61, p<0.001.

Discussion

The current study explored the feasibility of the use of low-cost virtual reality (VR) glasses, the FACES and CFS scales, and the glasses' perceived efficacy in pain and fear reduction in children undergoing a painful dressing procedure in CoRSU Rehabilitation Hospital in Uganda. Overall, our study showed that the use of low cost simple virtual reality (VR) glasses is a feasible and acceptable pain and fear reduction method for children undergoing painful medical procedures in a hospital setting in Uganda.

Acceptability of VR glasses in children was high, and mostly positive reactions were gathered from children, caregivers, and nurses. Whilst some studies have noticed that more immersive and interactive VR methods are more helpful in reducing procedural pain compared to passive distraction [22-24], children in our study seemed sufficiently distracted by the passive display. This is most likely explained by the lack of exposure to virtual reality and movies in general, as most of our study population comes from households with limited resources which often do not have a television or access to internet at home.

Related to the limited exposure to electronic devices in the home, the use of VR distraction methods requires careful introduction to the population. Some participants declined to participate as they feared the device could cause infertility or cancer. Similar fears have been noted in studies in African countries when contraception or HIV prevention methods were introduced [25, 26]. Careful preparation of patients and psycho-education of the use of glasses is important to enhance acceptability and ensure cultural relevance. The private non for profit hospital is located in a semi-urban area, use of the glasses in rural areas, and public hospitals needs to be further explored to establish generalizability of trial methods.

We noted that both boys and girls report relatively 'low' pain and fear scores compared to children in high income countries [17, 19]. Nortjé & Albertyn (2015) earlier described how children are expected to be resilient when feeling pain in South Africa[27]. This was also often heard in our study as parents would tell their children to 'be strong' and may partly explain the low scores. Girls reported significantly lower pain and fear scores compared to boys for similar conditions and procedures, unlike in high income countries where gender differences are rare [28, 29]. This may be related to different gendered patterns of identification and understanding of the rating scale faces and cultural expressions of pain and fear. More research is needed to understand cultural perceptions of fear and parental fear and its effect on the child in low resource settings.

Older children seemed to experience more effect of the use of the glasses in pain and fear reduction in our pilot study compared to younger children, which may be attributed to the type of movies used. Further studies need to look into the choice of VR stimuli and the effect of age on the experience of pain and fear during procedural painful intervention It is likely that there is a cultural difference in what children perceive as distracting or 'funny'. When selecting movies of interest with the children, there is need to offer a variety which include movies from Uganda. Although little is known about movie preferences of children in sub-Saharan Africa, it will be important to be aware of neo-colonial influences and stereotyping [30] and refrain from these when further studying distraction methods. Possibly self-made movies of the children

could equally distract children in our setting. The making and effect of these could be further explored.

When comparing the pain and fear scores at the start and end of each procedure, we noted that children undergoing procedures of short to moderate duration had lower pain and fear scores. This is in line with findings from studies in high income countries where children benefit from the use of VR distraction during immunization, a relatively short procedure [31].

The type of procedure also had an influence on the child's pain and fear ratings in our study population. Pain and fear in general wound dressing was lower than in post-sequesterectomy dressing. VR distraction has earlier been reported to reduce pain in wound dressing of chronic wounds [32]. Those who had undergone sequestrectomy in our study were diagnosed with osteomyelitis. This condition is common in school aged children who have complex fractures and is often severe as caregivers delay to seek and find appropriate health care [33, 34]. The treatment of osteomyelitis involves surgical removal of all infected tissue, including the non-viable bone[35]. Bone grafting is often applied and external fixators to maintain length and stability of the bone may be used [35]. These procedures are extremely painful, which could explain the higher fear and pain scores in children undergoing these procedures. It should be noted that compared to high income countries, the use of pain medication in our study sample was extremely low. Berterame et al (2016) earlier noted that more than 90% of the use of opioid analgesics occurred in high income countries, and mentions lack of training, financial resources, cultural attitudes, and fear of dependence as some of the factors impeding its use in low income countries [36]. The low use of analgesics might have an impact on the distraction effect VR can have on pain and fear in our study population.

Although parental fear was lower than children's fear before and after the medical procedures, parental fear did increase when the child's fear increased. This is in line with other studies that have shown caregivers facing their child in pain are likely to experience distress or fear too [37, 38].

The FACES and CFS scales were easily understood, although more culturally appropriate facial pictures were recommended for the CFS scale. Very little is known about the use of the CFS in sub-Saharan African countries, the faces do seem to resemble Caucasian persons more, and could as participants suggested be changed to look more 'African'.

The FACES face images do not have a particular shape which certain populations may or may not identify with but are closer to cartoonish images which children worldwide might find it easier to identify with. Studies from high income countries show good reliability of and a preference of children to use the FACES over other pain scales [39]. Similarly Young et al showed that in Cameroon the FACES is a culturally relevant pain measure [40]. In Kenya, the FACES with instructions translated in Kiswahili, had good reliability, and was preferred over another pain scale [13]. In Cameroon the FACES was also tested and In South Africa however Yazbek et al (2018) proposed a verbal pain scale as existing visual scales including the FACES pain scale were not well understood in their non English speaking study population [41, 42].

Our study sample only contained of children admitted on one ward of one non for profit hospital, undergoing painful dressing procedures, which limits the

generalizability of this feasibility study. Another limitation was the absence of a (small) control group to understand better if the use of the glasses potentially mediates pain and fear experiences during painful medical procedures. When testing the acceptability of rating scales, we only included the Wong-Baker FACES and CFS in this study, which limited our ability to compare results between rating scales, e.g. the Faces Pain Scale – Revised [17], the Paediatric Pain Fear Scale [43] or the Fear of Pain Questionnaire [44] . Nevertheless we feel that our findings indicate possible benefits to use of VR glasses, and use of the FACES scale to measure pain, in future studies. To prove its effectiveness we recommend designing a RCT.

Conclusions

This study showed that the use of VR glasses may offer an acceptable and effective pain and fear reduction method in low resource setting. We recommend further research into the practical implementation of the use of VR glasses and its effectiveness.

More specifically we recommend to test the acceptability of the relatively new Visual Facial Anxiety Scale [45], as this might be a more culturally appropriate measure for fear in our setting. We would suggest to further study the effect of exposure to different type of movies, including some made locally, to measure which movies have the best potential to distract children and adults in our setting. The movies or video clips used will need to be available offline. We recommend to maintain the passive immerse method of just watching a video as this may be the most uncomplicated and manageable way to implement VR in our setting at this time. Nevertheless in future more interactive VR could be explored, if the cost of the device is affordable and do not require internet connection.

To further explore the effect the VR glasses have a pain and fear reduction intervention, we suggest a randomized control trial in at least two, preferably four hospitals, both private non for profit, and public, in urban and rural areas, in which children exposed to the same procedure in multiple locations are offered to use the VR glasses. Especially in more rural areas the use of VR glasses needs to be explored as exposure to virtual reality is extremely limited, as is the availability of electricity which would be required to charge the VR glasses battery at times. In addition a randomized control trial could look at comparing the pain and fear scores in groups of children exposed to the VR glasses, children exposed to anaesthesia alone, and children exposed to both.

In future studies we also recommend to prepare participants using a longer preparation period. Information about the VR glasses could be shared by the health workers in patient information sessions, at admission, and during ward rounds. The VR glasses could be physically shown to patients admitted in the hospital by the nurses, prior to offering these for use during painful medical procedures. We recommend that both the children and caregivers are offered to try on the glasses to enhance acceptance and reduce fear about possible side effects of the tool.

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References

1. Albertyn R, Rode H, Millar A, Thomas J. Challenges associated with paediatric pain management in Sub Saharan Africa. *International Journal of Surgery*. 2009;7(2):91-93.
2. Cardona CV, Rajah C, Mzoneli YN, et al. An audit of paediatric pain prevalence, intensity, and treatment at a South African tertiary hospital. *Pain Reports*. 2019;4(6):e789.
3. Jagwe J, Merriman A. Uganda: delivering analgesia in rural Africa: opioid availability and nurse prescribing. *Journal of pain and symptom management*. 2007;33(5):547-551.
4. Jitta J, Whyte SR, Nshakira N. The availability of drugs: what does it mean in Ugandan primary care. *Health Policy*. 2003;65(2):167-179.
5. Huang KT, Owino C, Gramelspacher GP, et al. Prevalence and correlates of pain and pain treatment in a western Kenya referral hospital. *Journal of palliative medicine*. 2013;16(10):1260-1267.
6. Chau B. KindVR pilot study demonstrates use of virtual reality for pain reduction in kids. *iMedicalApps*. 2017;
7. Koller D, Goldman RD. Distraction techniques for children undergoing procedures: a critical review of pediatric research. *Journal of pediatric nursing*. 2012;27(6):652-681.
8. Arane K, Behboudi A, Goldman RD. Virtual reality for pain and anxiety management in children. *Canadian Family Physician*. 2017;63(12):932-934.
9. Lange B, Williams M, Fulton I. *Virtual reality distraction during pediatric medical procedures*. Dalhousie University and IWK Health Centre; 2006.
10. Gupta A, Scott K, Dukewich M. Innovative technology using virtual reality in the treatment of pain: Does it reduce pain via distraction, or is there more to it? *Pain Medicine*. 2018;19(1):151-159.
11. Morris LD, Louw QA, Crous LC. Feasibility and potential effect of a low-cost virtual reality system on reducing pain and anxiety in adult burn injury patients during physiotherapy in a developing country. *Burns*. 2010;36(5):659-664.
12. World Bank. *Digital Dividends - world development report*. 2016.
13. Huang KT, Owino C, Vreeman RC, et al. Assessment of the face validity of two pain scales in Kenya: a validation study using cognitive interviewing. *BMC palliative care*. 2012;11(1):5.
14. Naegeli AN, Heath L, Zhou C, Gupta N, Dampier C. Psychometric properties of a modified version of the Faces Pain Scale-Revised (Modified FPS-R) to evaluate worst pain in children and adolescents with sickle cell anemia. *Journal of pediatric hematology/oncology*. 2018;40(7):499-503.
15. Bosenberg A, Thomas J, Lopez T, Kokinsky E, Larsson L. Validation of a six-graded faces scale for evaluation of postoperative pain in children. *Pediatric Anesthesia*. 2003;13(8):708-713.
16. Amery J. *Children's palliative care in Africa*. Oxford University Press, USA; 2009.
17. Hicks CL, von Baeyer CL, Spafford PA, van Korlaar I, Goodenough B. The Faces Pain Scale–Revised: toward a common metric in pediatric pain measurement. *Pain*. 2001;93(2):173-183.
18. Taylor Salisbury T, Kinyanda E, Levin J, et al. Clinical correlates and adverse outcomes of ADHD, disruptive behavior disorder and their co-occurrence among children and adolescents with HIV in Uganda. *AIDS care*. 2020:1-9.

19. McMurtry CM, Noel M, Chambers CT, McGrath PJ. Children's fear during procedural pain: preliminary investigation of the Children's Fear Scale. *Health psychology*. 2011;30(6):780.
20. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative research in psychology*. 2006;3(2):77-101.
21. Flick U. *The SAGE handbook of qualitative data analysis*. Sage; 2013.
22. Nilsson S, Enskär K, Hallqvist C, Kokinsky E. Active and passive distraction in children undergoing wound dressings. *Journal of Pediatric Nursing*. 2013;28(2):158-166.
23. Trost Z, France C, Anam M, Shum C. Virtual reality approaches to pain: toward a state of the science. *Pain*. 2020;
24. Indovina P, Barone D, Gallo L, Chirico A, De Pietro G, Giordano A. Virtual reality as a distraction intervention to relieve pain and distress during medical procedures. *The Clinical journal of pain*. 2018;34(9):858-877.
25. Boivin J, Carrier J, Zulu JM, Edwards D. A rapid scoping review of fear of infertility in Africa. *Reproductive health*. 2020;17(1):1-13.
26. Chitukuta M, Duby Z, Katz A, et al. Negative rumours about a vaginal ring for HIV-1 prevention in sub-Saharan Africa. *Culture, Health & Sexuality*. 2019;21(11):1209-1224.
27. Nortjé N, Albertyn R. The cultural language of pain: a South African study. *South African Family Practice*. 2015;57(1):24-27.
28. Goodenough B, Thomas W, Champion GD, et al. Unravelling age effects and sex differences in needle pain: ratings of sensory intensity and unpleasantness of venipuncture pain by children and their parents. *Pain*. 1999;80(1-2):179-190.
29. Knutsson J, Tibbelin A, Von Unge M. Postoperative pain after paediatric adenoidectomy and differences between the pain scores made by the recovery room staff, the parent and the child. *Acta Oto-Laryngologica*. 2006/01/01 2006;126(10):1079-1083. doi:10.1080/00016480600606715
30. Yenika-Agbaw V. 18 Images of West Africa in Children's Books: Replacing Old Stereo-types with New Ones? *DOCUMENT RESUME ED 480 339 CS 512 399*. 2003:231.
31. DeMore M, Cohen LL. Distraction for pediatric immunization pain: A critical review. *Journal of Clinical Psychology in Medical Settings*. 2005;12(4):281-291.
32. Hua Y, Qiu R, Yao W-y, Zhang Q, Chen X-l. The effect of virtual reality distraction on pain relief during dressing changes in children with chronic wounds on lower limbs. *Pain Management Nursing*. 2015;16(5):685-691.
33. Ibingira C. Chronic osteomyelitis in a Ugandan rural setting. *East African medical journal*. 2003;80(5):242-246.
34. Stanley CM, Rutherford GW, Morshed S, Coughlin RR, Beyeza T. Estimating the healthcare burden of osteomyelitis in Uganda. *Transactions of the Royal Society of Tropical Medicine and Hygiene*. 2010;104(2):139-142.
35. Spiegel DA, Penny JN. Chronic osteomyelitis in children. *Techniques in Orthopaedics*. 2005;20(2):142-152.
36. Berterame S, Erthal J, Thomas J, et al. Use of and barriers to access to opioid analgesics: a worldwide, regional, and national study. *The Lancet*. 2016;387(10028):1644-1656.
37. Caes L, Goubert L, Devos P, Verlooy J, Benoit Y, Vervoort T. Personal distress and sympathy differentially influence health care professional and parents' estimation of child procedure-related pain. *Pain Medicine*. 2017;18(2):275-282.

38. Vervoort T, Trost Z. Examining affective-motivational dynamics and behavioral implications within the interpersonal context of pain. *The Journal of Pain*. 2017;18(10):1174-1183.
39. Tomlinson D, von Baeyer CL, Stinson JN, Sung L. A systematic review of faces scales for the self-report of pain intensity in children. *Pediatrics*. 2010;126(5):e1168-e1198.
40. Young JR, Sih C, Hogg MM, Anderson-Montoya BL, Fasano HT. Qualitative Assessment of Face Validity and Cross-Cultural Acceptability of the Faces Pain Scale:“Revised” in Cameroon. *Qualitative health research*. 2018;28(5):832-843.
41. Yazbek M, Stewart A, Becker P. Tswana speaking South Africans' understanding of pain scales. *South African Journal of Physiotherapy*. 2009;65(1):28-34.
42. Yazbek M, Stewart AV, Bentley A. A verbal descriptor incremental pain scale developed by South African Tswana-speaking patients with low back pain. *The South African journal of physiotherapy*. 2018;74(1)
43. Huguet A, McGrath PJ, Pardos J. Development and preliminary testing of a scale to assess pain-related fear in children and adolescents. *The Journal of Pain*. 2011;12(8):840-848.
44. Simons LE, Sieberg CB, Carpino E, Logan D, Berde C. The Fear of Pain Questionnaire (FOPQ): assessment of pain-related fear among children and adolescents with chronic pain. *The Journal of Pain*. 2011;12(6):677-686.
45. Cao X, Yumul R, Elvir Lazo OL, et al. A novel visual facial anxiety scale for assessing preoperative anxiety. *PloS one*. 2017;12(2):e0171233. doi:10.1371/journal.pone.0171233