The Effect of Virtual Reality on Pain, Physical Function, and Health-Related Quality of Life in Children with Sickle Cell Disease: A Randomized Controlled Trial

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STUDY PROTOCOL

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Title: The effect of virtual reality on pain, physical function, and health-related quality of life in children with sickle cell disease: A randomized controlled trial

Significance or rationale of the study:

Virtual reality (VR) is a promising non-pharmacological pain management tool. It enhances motor function by promoting cortical reorganization and neuroplasticity. Its multimodal biofeedback engages sensory and cognitive functions, making therapy interactive, motivating, and easy to understand. With strong rehabilitation potential, VR helps patients adapt to real-world movements (Laver, 2020). Initially used for procedural pain management, VR is now expanding into chronic pain rehabilitation by encouraging engagement with difficult or avoided movements (Griffin et al., 2020). Additionally, VR offers a dynamic alternative to traditional exercises, improving adherence and outcomes. Integrating entertainment into therapy can motivate children, enhancing their physical and psychological well-being. Recently, a few studies revealed an improvement in vaso-occlusive episodes (VOE) after VR treatment (Agrawal et al., 2019). However, efficacy studies are needed to assess VR's potential benefits. Additionally, data regarding VR's efficacy on daily pain, functional mobility, and HRQOL as complementary therapy are limited

The objectives: This study aimed to assess the impact of VR on daily pain, functional mobility, and HQOL

Methods: In this single-blind Randomized Controlled Trial (RCT), 42 children aged 8 to 13 with SCD were included. They were divided into an intervention group (group I, n=21) and a control group (group II, n=21). Group I received one session of fully immersive VR for 15 minutes during hospitalization (Phase One). After discharge (Phase Two), Group I participants received fully immersive VR for 40 minutes twice /week over three weeks (six sessions) besides

medications. Yet, Group II received the prescribed drugs. Pain intensity was measured using the Numeric Rating Scale (NRS), and functional mobility was assessed with the Time UP and GO TUG test. The PedsQLTM 3.0 SCD module was used to measure the PedsQL.

Outcomes: Investigate VR's effect on reducing daily pain in children with SCD and evaluate its impact on improving functional mobility in these children.

Examine the changes in PedsQL in children with SCD after engaging in VR experiences. 5- To evaluate the safety and satisfaction of fully immersive VR therapy in children with SCD.

Statistics: Data were analyzed using IBM SPSS Statistics Version 29.0. Descriptive statistics (means, standard deviations, frequencies, and percentages) were calculated to summarize demographic and baseline characteristics. The normality of continuous variables was assessed using the Kolmogorov-Smirnov test.

Due to the non-normal data distribution, the Mann-WhitneyU test was used to compare pain intensity scores measured by the Numeric Rating Scale (NRS) between intervention and control groups. Within-group comparisons of pre- and post-intervention scores were also conducted.

Safety outcomes from the Simulator Sickness Questionnaire were analyzed using the Chi-square test to detect any significant changes in symptoms pre- and post-intervention.

Satisfaction scores from the VR Satisfaction Likert survey were analyzed descriptively, and the Mann-Whitney U test was applied to compare satisfaction across age groups.

A significance level of $p < 0.05$ was used for all inferential statistical tests.