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Research protocol

Effect of virtual reality and conventional physiotherapy on rehabilitation of distal radius fracture

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ABSTRACT

Rehabilitation sometimes may be an uncomfortable and tiring method that incorporates multiple activities and sets of exercises which patients require to perform to achieve good prognosis, for a significant period of time. Unfortunately, most of times the patients frequently become not willing, aggravated, and need inspiration and feel exhausted which makes recovery from the condition will less proficient. Use of the Virtual Reality have been broadly executing into rehabilitation program intends to make the process of recovery more energizing, invigorating and engaging for patients. Within this protocol, we propose to utilization of head wearing gadget name Oculus Quest for patient's wrist recovery after Colle's fracture. After receiving Institutional Ethical committee approval, we will include 40 Colle's fracture patients, and randomly divide them in two groups. Further group A will receive conventional physiotherapy treatment and group B will receive treatment from Virtual reality as well as conventional treatment for 4 weeks. Pre and post treatment for Pain, Range of motion and functional parameters will be evaluated. The primary aim study is to check the impact of virtual reality and conventional physiotherapy after Colle's Fracture. This exploration will help in distinguishing quick and longterm impacts of Virtual reality in DRF patients. The investigation results would assist in forming the newly planned strategies with better prognosis in rehabilitation of patients with Colle's fracture.

Keywords: Clinical protocol, Colle's fracture, Immersive virtual reality, Rehabilitation, Oculus Quest.

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INTRODUCTION

Colle's fracture is the most common injury in any age, appearing around 15%-20% of all fracture oversaw in emergency services ^[1]. The rate of Colle's has a bimodal incidence during the life expectancy, the children are more prone than the adults, but again the frequency increases from adult to elderly ^[2]. Various literatures have shown a more prominent frequency in older individuals who are more than 60 years old. It is the second most occurring fracture type in this age after hip fracture almost multiple times more found in females when contrasted with males ^[3]. The typical reasons for Colle's fracture incorporate various playing activities as well as road traffic accidental injuries in adolescence and adult age groups. Alternately, the most widely recognized injury cause in elderly is a low-energy injury because of fall from a height. It is normal that the patients are generally encouraged for physiotherapy exercises for improving joint range of motion, pain and muscle strength also to perseverance and reestablish functional parameters ^[4]. Close reduction and internal fixation with plaster cast is commonly used conservative treatment for colle's

fracture ^[5]. This remedial methodology attempted to support and decrease the further complications such as nonunion or malunion almost about of 50% of cases. Secondary fractures and delayed in healing of fracture is more significant complication faced by the elderly people. Regardless, the most recent literature exploration shows that increment in functional parameters with early starting of rehabilitation work in old age patients of this type of fracture ^[6].

Reduce range of motion, joint stiffness, compartment syndrome, muscular weakness are some possible short term or long term disabilities post distal radius fracture. These disabilities can lead to temporary or permanent loss of functional parameters. To regain the complete range of motion and reduce the risk of all the complications are consider to be the primary goals of the physiotherapist after colle's fracture. Active and passive physiotherapy are primary categories of physical therapy intervention In order to accomplish these objectives. Patient counseling and the strategies in which patient gives his or her active participation in the form of positive attitude or exercises are said



to be the Active therapy. Passive range of motion exercises as well as joint mobilization technique throughout the rehabilitation, where the patient have more of passive role are said to be the Passive therapy ^[7]. Tailored made exercise prescription using strategic thinking and considering the strengths and limitation of individual should include in the rehabilitation program ^[8].

To enhance the functional outcomes and speed up the recovery after Colle's fracture, Home Exercise Program (HEP) and Physical therapy is advised to the patients. Albeit the objectives of Physical therapy are clear, the treatments can shift tremendously. Such treatment incorporate from modalities like Ultrasound therapy, functional electrical stimulation, continuous passive movements, biofeedback measures, different forms of exercises, uses of proper braces and patient education. Physiotherapeutic rehabilitation post distal radial fracture is considered to be a standard treatment following fracture of the distal radius, for e.g. a study conducted in 2001 found that physiotherapeutic exercises was prescribed after Colle's fracture to somewhere around 80% to 85% of patients going through recovery. There is an extensive need of physical therapy throughout the rehabilitation program as over number of months most of patients experience of wrist tightness and loss of grip strength. Physical therapy is suggested for limiting pain, reestablishing range of motion, improving strength of muscle and function parameters ^[9].

Person-centered and prominent effective rehabilitation outcome can achieve by Virtual reality as it is an engaging technology which enables the customized treatment options. It includes an immersive experience of computing world and games which can be look and feel real. People can be engage with a simulated space and functional activities various using custom-made apps^[10]. Incorporating the virtual reality based games with rehabilitation program which include hand held controls, can turn the exercise program and workout sessions into more of entertaining and interactive activity which patient can perform without tiring or exhausting ^[11]. VR therapy can make it easier to customized care, encourage patients, improve their exercises compliance and track their prognosis, this will ultimately reduce the work load causes it require less monitoring.

Oculus Quest is a head-mounted device that cover over the eyes like normal specs and created with immersive simulated world in mind which can be look and feel real, the Oculus quest allows the user six dimension experience. This head-mounted device created to take peripheral vision into account, and isn't the same as watching television. Every possible visual field is covered, every movement of head and eyelid is consider. User can experience of very realistic environment. Oculus quest is found to be the newly device, and applications in it are still being built. Using of virtual reality is not new in the rehabilitation program, but 6D systems like oculus quest are making this type of treatment and learning both fun and exciting. Almost no uses of any forms of wires is much liberating and allow the user for more freedom of activity ^[12].

METHODOLOGY

The primary objective of the Research to evaluate the efficacy of virtual reality program in comparison with conventional physiotherapy in patients with conservatively treated colle's fracture. The research protocol has got approval from the Institutional Ethical Committee with IEC no. RNPC/IEC/2020-21/0010, also register with (CTRI) Clinical Trial Registry India with the no CTRI/2021/05/033496. The protocol was submitted in Nature protocol exchange with DOI - 10.21203/rs.3.pex-1341/v1. The sample size will be drawn and accordingly subjects will be included in the study. All the participants will be told about the goals and standard procedure for operating oculus quest and take informed consent. The pretreatment assessment will be done by universally accepted outcome measures. The selected subjects then randomly assign in group A in which they will receive conventional physiotherapy program and group B where subjects will receive treatment from oculus quest as well as conventional therapy for four weeks for both the groups. Post treatment assessment will be done after the six weeks.

Participants: Inclusion criteria

Subjects age 60 to 75 years or older patients both males and females who have been redirected from the Dept. of Orthopedic or directly come to OPD with Patients diagnosed with an extra articular multi fragmentary DRF type and treated conservatively and closed reduction. The Participants must accept and sign Informed consent and should not have any past history of wrist/ hand fracture, history of arthritis, or a possible upper extremity fracture. No problem with auditory or visual functioning.

Exclusion criteria:

Participants who were treated for DRF reduction and/or fixation with some form of surgical intervention (e.g. external fixation, volar plate, and Kirschner wires). Patients with Mini-Mental score less than 26 points on the examination. After the removal of the immobilization, patients with immediate complications. Patients with past trauma either in arms or hands that had impaired function. Rheumatic and neurological disorder patients were excluded. Symptomatic osteoarthritis of wrist and hand.

Sample size consideration:

This study protocol is an independent two-group study investigating the impact of VR on treatment of subjects with distal radial fracture. 40 subjects will be enrolled in the study by the G Power analysis system. Comparison of the VR therapy over conventional therapy will be done. 5 % of estimated dropout rate will be consider, and we consider that 40 sample subjects will complete the

rehabilitation program of four week. To decrease the dropout rate, we will implement the use of two approaches to keep subjects occupied: first is daily conversation via social media, phone and second one is clinical visits.

Intervention design: (Figure 1) Group A:

The carefully monitored physiotherapy program will include 10 to 15 min. of all possible movements of wrist and hand in a whirlpool bath with 32° to 38° temperature. After that Maitland joint mobilization with grade II and III will be performed to the radio carpal joint during the first two weeks at the rate of one cycle for one second for complete one minute ^[13]. Pain will be managed using TENS. Strengthening technique will include exercises such as manual resistance, weights, TheraBand. This treatment will be performed for 45 mins per day for 4 days in the week for continuous 4 weeks.

Group B:

This group, which will be an experimental group, will undergo 30 min VR treatment daily. The subjects have to complete the six activity (shooting gallery, boxing arena, kitchen, fencing hall, playground, basketball court) performing various parts in a immersive world^[14]. The subjects will be using the Oculus Quest HMD with which they can physically turn the head to a limited degree and can be able to look around. This HMD will be give real experience and will give greater engagement (Figure 1).

Outcome measures:

Primary outcome measure:

- Disabilities of the Arm, Shoulder, and Hand Outcome Questionnaire (DASH): This questionnaire consists of 30 items in it. It is used to assess the level of disability, ability to perform activity. This will be used to characterize the functional ability of patients with wrist fractures.
- Range of motion (ROM): ROM will be measured using the goniometer instrument. It will help in measuring wrist movements. Subjects will assess in sitting position with full support to the elbow. During assessment subjects should uncover the forearms and should not have accessories.

Secondary outcome measure:

 Visual Analogue Scale (VAS): VAS will be used for assessing pain. It consists of a scale which is of 10cm. There are left side & right side of scale which shows "no pain" and "severe pain" respectively. The subject will be informed to mark a point on the scale indicating their magnitude of pain experienced. This is recommended to all patients with DRF.



Follow up:

All participants will be followed up at 6 weeks after rehabilitation and follow-up record forms will be completed. The time of the last rehabilitation training session will be recorded. Electronic

follow-up rehabilitation records will be preserved. When patients drop out of the trial, the reasons for withdrawal will be recorded in detail. Comprehensive and supportive patient communication will be

undertaken; patients lost to follow-up because of any reason will be gotten in touch as soon as possible and be followed up within 6 weeks. Data regarding patients withdrawn from the trial will be included in the final analysis, according to the intention-to-treat analysis principle. **Data management:**

Data of the study will be stored in a safe, secured store room with limited access for later review by a biostatistician, a researcher in charge.

Statistical analysis:

The SPSS latest version will be used to perform statistical analyses. To compare the group effect, analysis of variance (ANOVA) will be used. Homogeneity of the two study classes will be tested for individual studies using the Student's t test. Both statistical analyzes should be conducted with a 95% confidence interval (p-value < 0.05) to assess effect of two measures. Mann-Whitney U will be used for comparing Groups at baseline.

DISCUSSION

This Study aims to assess the impact of immersive VR-based treatment in patients after colle's fracture. Past researches have shown that non-immersive VR is safe relative to conventional rehabilitation but not substantially more effective. Immersive VR may have advantageous outcomes in enhancing the patient's hand function after distal radial fracture. as VR system focus on providing synchronize movements of extra spatial transformation of coupled and uncoupled eye–hand activities ^[14]. Outcome obtained from this survey if gives the expected results will support this hypothesis.

To evaluate the difference in treatment time between the two groups, which could require additional variables to clarify the resulting improvement in hand function, the overall treatment period for the two groups is set to be equivalent. In addition, in order to check on the long term results of VR-based treatments in context of functional parameters, post successful completion of 4 weeks intervention, we will ask for the follow up visit to the OPD. In conclusion, this research aims at exploring the longer-term and immediate effects of VR-based therapy in DRF subjects. The outcome of this study, if gives positive result, might helpful to upcoming colle's fracture patients for the best and the newly form improved method of treatment.

Conflict of interest

All the author's contributed equally in this study, with declared no conflict of interest.

Ethical standards statement

Procedures in this study were conducted be in accordance with the Helsinki Declaration of 1975, as reference in 2008.

Informed consent

All the patients included in this study were given prior information about the study, and written consent obtained from them.

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