Journal of Critical Reviews

ISSN- 2394-5125 Vol 7, Issue 9, 2020

IMPACT OF IMMERSIVE VIRTUAL REALITY-BASED REHABILITATION ON FUNCTIONAL INDEPENDENCE AND HEALTH RELATED QUALITY OF LIFE AFTER DISTAL RADIUS FRACTURE: A STUDY PROTOCOL FOR A SINGLE BLINDED RANDOMIZED CONTROL TRIAL.

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Received: 24.03.2020 *Revised: 14.04.2020* *Accepted: 22.05.2020*

Abstract:
Background: Physiotherapy techniques are often used to optimize recovery following a distal radial fracture. This the most common upper limb fracture in all age groups. Around 1 in 1000 men and 4 in 1000 women fracture their distal radius. To date, however, work on immersive virtual reality -based rehabilitation of patients with distal radius fracture is limited. This research aims to assess the efficacy of immersive virtual reality in patients with DRF.
Methods: In a single-blinded RCT, subjects (n = 40) with DRF will be recruited. The participants will be enrolled into either experimental or control group with 1:1 allocation ratio. Participants in experimental group will receive both immersive virtual reality and conventional therapy over a period of 6-week immediately following baseline assessments and randomization. Participants in conventional group would undergo only conventional therapy. Throughout the treatement duration and following 6 weeks, daily living activity performance, the hand function and mental status will be assessed in the form of questionnaires.
Discussion: The goal of this clinical trial is to examine the impact of immersive virtual reality after DRF on functional independence and health related quality of life. To conclude, this research seeks to examine the rapid and long term effects of virtual reality in DRF patients. The study findings would help prospective patients with DRF, which may include a newly designed method of rehabilitation.

Keywords: Clinical protocol, Immersive virtual reality training, Distal radius fracture, Rehabilitation.

DOI: http://dx.doi.org/10.31838/jcr.07.09.111

INTRODUCTION

Distal radius fracture (DRF) is a frequent injury at wrist joint which continues to increase incidence worldwide(Gutiérrez-Espinoza et al., 2017). A DRF is typically described by fracture at a junction of the cortical bone where it is thinner and trabecular bone network is reinforced approximately 2cm above the distal articular surface of the radius(MacIntyre & Dewan, 2016). This is most often the result of a falling on an extended hand(Filipova et al., 2015). Given the characteristics of the injury, distal radius fracture may be classified into Colles, Smith, Barton , Monteggia, Galeazzi.

DRF is the most prevalent fracture in the adult people, accounting for nearly majority of all fractures in the emergency department(4). In younger injured people, sports events and traffic accidents most frequently result in a fall. An approximately steady rise in incidence in people between the ages of 20 and 80 was noted. Among females the incidence is significantly greater than males. After menopause it starts to rise and reach peak between the ages of 60 and 70(Gutiérrez-Espinoza et al., 2017). This is due osteoporosis associated with reduced bone density.

DRF'S are typically treated conservatively in patients with a closed reduction and immobilization in plaster cast(Chung et al., 2009) . But, in more than 50 percent of cases, this treatement strategy continued to fail to support reduction and recorded redisplacementandmalunion.Aging is one of the most importa nt risk factors for reduction failure and secondary fracture dis placement.Nonetheless, the latest evidence indicates that the i ncrease in function in older patients is independent of the resi dual deformity(Bruder et al., 2013).Management and outcomes after DRF are affected by inj ury factors and patient factors. Within 3-6 months patients generally recover to maximum range of motion, strength and function , regardless of whether the injury is managed conservatively or surgically.

The distal radius fractures, including the Colles fracture, are co mmon occurrences in the community(Dekkers & Søballe, 2004). Patients with distal radius fractures after a duration of immobilisation are often referred for physiotherapy. In the clinical setting physiotherapists use disability assessment, such as range of motion and grip strength, to dete rmine progress as well as outcomes. Hand activityrequires a combination of adequate sensation, pr oprioception, intact neurological control and coordination,appropriate anatomical alignment, , and muscle strength and flexibility.(7)

Physiotherapy interventions are techniques used to improve functional recovery following a distal radial fracture(Bruder et al., 2013). Physical therapy (PT) is of critical importance after the immobilization phase. PT is recommended for reducing pain, increasing range of motion (ROM) and enhancing muscle function and muscle strength. The therapeutic methods applied to attain these goals may be categorized as active or passive methods. Active treatement includes approaches in which patients has to participate actively in their treatment, such as counseling, a home exercise program (HEP), or supervised programme by a physiotherapist(Smith et al., 2004). Passive treatments relate to interventions where the patient plays a passive part during its procedure, such as mobilization of joint (JM), massage and the use of hot pack, TENS and ultrasound(Maciel et al., 2005).

The use of virtual reality (VR) technology in a health – care environment has become increasingly common over the last two decades. This was rooted in clinical practice. The

introduction of VR technology into traditional training has the ability to further increase the outcomes of the training. VR allows users to actively interact in real-time with a simulated environment and offers the opportunity to practice skills learned in the virtual environments to everyday life(Huang et al., 2019). VR-based training has the ability to promote implicit learning, improve variety, and involve the patient actively during the training. Such characteristics are crucial in the optimization of motor learning and could maximize the training impact.

The Leap Motion Controller is an infrared light detector developed as a means of hand gesture recognition. The corresponding software applies algorithms to the sensor data detected from the hands and generates a 3D representation of contour, position and movement. Current applications include gaming, education, maps and navigating the computer desktop. The technology lends itself to monitoring hand movement exercises used for wrist physiotherapy. However, no current research exists that investigates the feasibility and validity of using this technology.

METHODS/DESIGN:

Aim

To assess the impact of virtual reality based rehabilitation on hand function and functional independence after distal radius fracture.

Study design

This study will be carried out in the HumEn research lab of Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha, after approval from Institutional Ethics Committee of Datta Meghe Institute Of Medical Sciences, Deemed to be University. Before inclusion, all the participants will be informed regarding the aim and procedure of research. Those participants who will meet the inclusion criteria must give the written informed consent. In a single blind RCT, those participants (N= 40) diagnosed with distal radius fracture will be enrolled for 6 week's. Fig. 1. Show's the flow chart of the study.

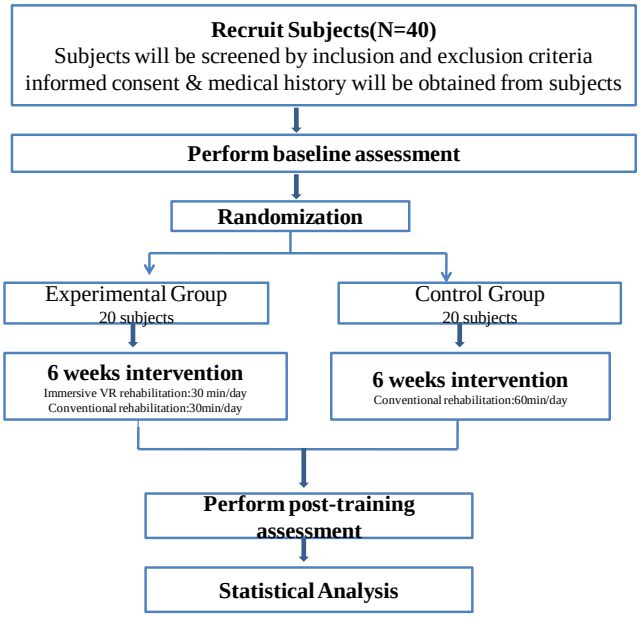

Fig.1

TRIAL DESIGN:

Single blinded randomised control trial study in which the patients will be randomized into two group independent design. Group A will be control group getting the conventional physiotherapy rehabilitation program while Group B will be assigned with experimental group.

PARTICIPANTS:

Inclusion criteria are as follows:

1) Patient willing to participate.
2) Distal radius fracture patients with visible X-ray displacement.
3) 18 years of age or older.
4) Conservatively managed in a cast. The k-wires used under a cast was permitted, as this method of immobilization is commonly used.
5) No previous history of wrist/ hand fracture, history of inflammatory arthritis, or any possible upper limb fracture.
6) Ability to recognize and obey basic verbal instructions(Lyngcoln et al., 2005).

Exclusion criteria are as follows:

1. Not willing to participate.
2. Patients with bilateral fracture.
3. Patients with past trauma either in arms or hands that had impaired function.
4. Rheumatic and neurological disorder patients were excluded.
5. Malignant conditions.
6. Symptomatic osteoarthritis of wrist and hand.

SAMPLE SIZE CONSIDERATION:

This single blinded randomized controlled trial is an experimental two-group design that examines the effect of virtual reality in distal radius fracture rehabilitation. 40 participants will be enrolled to the control group or experimental group and will be randomized (Maciel et al., 2005).

INTERVENTION DESIGN:

Group A: Those Subjects in control group should undergo conventional training for 60 mins a day, 5 days a week for 6 weeks. This group will receive conventional physiotherapy program consisting of Whirlpool, Joint mobilisation (Maitland <grade 2 or 3> , Kalternborn 1 gliding, grip strength exercises, scapular retraction exercises, HEP). Some of the most common therapeutic approaches used to optimize the

patient's functional recovery are physical pain management strategies such as TENS, heat therapy, manual aids and occupational/ home assessment . The range of motion (ROM) exercises would include passive mobilization of forearm and wrist, active exercises and active-assisted exercises for forearm, wrist, and fingers. The PT strengthening plan includes exercises to strengthen wrist and finger flexors and extensors, forearm supinators and pronators (against therapist's manual resistance and/ or elastic bands), and gripping activities (using several soft balls). Conventional therapy will be structured to replicate the skills needed in the immersive VR environment, with comparable intensity and complexity. Study researchers would encourage and supervise participants to ensure the consistency of the study.

Group B: Those subjects in experimental group will be expected to complete the six activities during the regular 30-min virtual reality intervention (basketball court, shooting gallery, fencing hall, playground, kitchen, boxing arena) playing various roles in a virtual environment(Huang et al., 2019). The patient will be able to look around using the oculus quest HMD by simply turning the head to a limited degree. It is similar to a realistic simulation and offers an high level of immersion.

Leap Motion - With the Leap, the participants will be asked to actively move their fingers from initial resting position and execute maximally the following five movements with their wrist and hand: fingers flexion and extension, flexion and extension of the thumb, wrist radial and ulnar deviation, forearm pronation and supination and wrist flexion and extension(Meijer et al., 2019). Rehabilitation games such as **Rhythm game**: This game is aimed at helping patients perform flexion exercises for wrist joint. The buttons fall from above as music plays in the background, and must be pushed at the right time by the player. **Flappy Bird Clone:** This game is designed for wrist flexion and wrist extension both. The player controls a bird that flying over a series of tubes before the track ends. **Skiing Game:** This game requires wrist extension/flexion and wrist radial/ulnar deviation. A skier who comes down a slalom track is guided by the player and must cross the gates.(Corona et al., 2018)

OUTCOME MEASURES:

Primary outcome measure:

1) **Patient-Rated Wrist Evaluation (PRWE)**: The PRWE is a 0–100-point scale that evaluates pain, range of motion, grip strength, daily activities and specific activity of t wrist joint. Higher scores indicate more severe joint pain and dysfunction (Magnus et al., 2013).
2) **Disabilities of the Arm, Shoulder, and Hand Outcome Questionnaire (DASH):** The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire is a 30-item questionnaire that looks at the ability of a patient to perform certain upper extremity activities.
3) **Michigan hand outcomes questionnaire:** The validity and responsiveness of the MHQ has been proven for a variety of common hand conditions and it is currently being used as the primary outcome in the trial.
4) **Functional independance measure:** Functional independence measure (FIM) will be used to determine the patient independence during ADL's.

Secondary outcome measure:

1)Grip strength : To check grip strength a jamar dynamometer will be used. The participants would be tested in sitting position, with their arm placed to the side of the body; their shoulders in neutral position, elbow in 90 degrees of flexion, and forearm in neutral(Tremayne et al., 2002). Then, subjects will be asked with all their strength to make tight fists to maintain that position for 4 seconds and then rest for 30 seconds. First, the unaffected side will be tested and then affected side will be tested. The maximum value obtained from 3 trials will be recorded.

2)VAS: The visual analogue scale is a measurement scale for pain, consisting straight line of 10-cm, the left edge shows "no pain"(0) and the far right edge shows the "worst pain imaginable" (10). The subjects will be asked to draw a straight line illustrating the severity of the pain felt during the assessment.

3)ROM: Active flexion and extension of the wrist will be measured by a goniometer. Participants will be assessed to expose their arms in a seated position and to remove any accessories(Tremayne et al., 2002).

4) DASS 21: To assess the emotional states of depression, anxiety and stress, the scale of depression, anxiety and stress - 21 (DASS-21) will be used.

Follow up:

All patients 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 from the trial will be kept in a secure, locked storage area with limited access for later review by a biostatistician, a researcher in charge.

Power analysis:

A PRWE score will be used as the primary outcome measure in the study. In PRWE the minimal clinically important difference (MCID) is 11 points and standard deviation (SD) is 14 points(Walenkamp et al., 2015). In power calculations, we calculated the sample size required per group to be 20 patients with 95% confidence interval, power of 0.95 and SD of 14. Therefore 20 patients in both groups have to complete 6 weeks of follow-up to have adequate statistical power.

STATISTICAL ANALYSIS:

The SPSS latest version will be used to perform statistical analyses. To compare the group effect, two-way repeated measures analysis of variance (ANOVA) will be used. If subjects are lost to follow up, an intention-to-treat analysis will be carried out. When ANOVA reveals a significant difference, student's t test will be used to compare the changes within the group. Statistical significance is determined by a two-sided p value of less than 0.05. Mann-Whitney U, t-test or Fisher's exact test will be used for comparing Groups at baseline. Mann-Whitney U test will be used to compare primary and secondary outcomes between the groups at 6 weeks.

DISCUSSION:

The goal of this clinical trial is to evaluate the impact of immersive virtual reality after DRF on functional independence and health related quality of life. Nonetheless, it was proposed that immersive virtual reality may have more positive effects in enhancing patient's hand function and quality of life after distal radius fracture, because these virtual reality programs provides a improved motion control, combination of extra spatial transformation of uncoupled eye–hand movements, and more patient entertainment to encourage motion learning. The findings of this research may or may not provide evidence supporting this hypothesis.

To conclude, this research seeks to examine the rapid and long term effects of immersive virtual reality in DRF patients. The study findings would help prospective patients with DRF, which may include a newly designed method of rehabilitation. A number of related articles in this region were

reviewed.(Belekar, 2017; Karia et al., 2017; Khanam et al., 2019; Kumar et al., 2019)

RECRUITMENT: ETHICS AND DISSEMINATION:

Figure. Example template of recommended content for the schedule of enrolment, interventions, and assessments. *

	STUDY PERIOD							
	Enrolment	**Allocation**	**Post-allocation**					**Close-out**
TIMEPOINT**	$-t_1$	**0**	t_1	t_2	t_3	t_4	***etc.***	t_x
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
[List other procedures]	X							
Allocation		X						
INTERVENTIONS:								
[Conventional]			♦—	—	—	—♦		
[Virtual reality]			X		X			
[List other study groups]			♦—	—	—	—	—♦	
ASSESSMENTS:								
[PRWE]	X	X						
[DASH]				X		X	etc.	X
[MHQ]			X	X	X	X	etc.	X

RESEARCH ETHICS APPROVAL:

The trial will be performed in accordance with the Declaration of Helsinki.

FUNDING:

There will be no direct support for this research from public and private organizations. The
Department of Physiotherapy, at Datta Meghe Institute Of Medical Sciences, Deemed to be
University will provide material needed for research.

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