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Advanced Rehabilitation Strategies for Post-Operative Breast Cancer: A Study on the Effectiveness of Training using Virtual Reality

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Abstract

Background: Surgical treatment of breast cancer may be associated with physical and psychological side effects. Exercises especially those aided by virtual reality can improve both physical and psychological dysfunction.

Objective: To explore the effects of exercises using Virtual Reality technology (Pablo games) on Function, grip strength, wrist ROM , Fatigue, Pain, Activities of daily living(ADLs) ,and Anxiety on status post-operative breast cancer females.

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Results: There was a decline in pain, function, fatigue, and improvement in ADLs, grip strength, and ROM at post-intervention and at two months follow-up in both groups ($P < .001$). Meanwhile, PG only demonstrated statistically significant improvement in PG. Between-groups Comparison demonstrated statistically significant decrease in pain, disability, anxiety, fatigue, and improvement in ADLs, grip strength and ROM in favor of the PG compared to both at post-treatment and at follow-up ($P < .001$).

Conclusions: Adding Virtual Reality using Pablo Game Training instrument to the standard rehabilitation of post-surgical breast cancer can further improve function, Hand grip, wrist ROM, Fatigue, Pain, and ADLs. Clinical Trial: https://www.clinicaltrials.gov/ website with a registration number: NCT06058936.

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Key words: Tumor, surgery, Pablo, physical training.

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Introduction

Cancer is a global medical concern with a substantial impact on both morbidity and mortality. In 2018, Saudi Arabia reported more than 24 thousand new cancer cases, resulting in 10,518 deaths. These rates have been attributed to diverse risk factors such as genetics, hormonal imbalances, lifestyle choices, obesity, and environmental influences [1,2]. Globally, breast cancer (BC) is considered the most common disease among females. Thanks for the recent advances in diagnosis and treatment technology, growing number of females received early diagnosis and treatment. Hence, the survival rates are rising dramatically[3] .

The fundamental treatment options of BC include surgery, chemotherapy, radiotherapy, and hormone therapy. Despite being effective, these treatments have number of side effects. Limited range of motion (ROM), muscle weakness, fatigue, lymph edema, decreased functional activity, and depression were reported in previous studies [4]. These adverse consequences significantly impede patients' ability to adhere to treatment regimens, perform daily tasks independently, and maintain a high quality of life [5].

Physical Rehabilitation is considered one of the valuable therapeutic tools that addressing multiple side effects linked to BC. Evidence of improvements in physical capacity, muscle power, and psychological well-being were previously reported [6,7]. In order to further augmenting the benefits of physical rehabilitation, recent trends of

using video gaming and virtual reality (VR) have been introduced to the field of exercise rehabilitation [5]. VR can be described as a form of artificial intelligence (AI) that was originally introduced in the 1960s and gradually developed throughout the 20th century [8]. The huge technological development that was evident in recent year make the use of AI applications in medical filed accessible with many variations [9,10].

In virtual reality, users can experience a more immersive experience through the use of various senses (vision, hearing, touch, etc.) by combining computer systems and sensor technology with three-dimensional graphics[11]. This type of therapeutic intervention has the advantage of being highly motivate to a wide variety of patients[12,13].The Pablo is a type of the VR applications, it is a game-based rehabilitation system consists of a handheld device, multi-ball, and multi-board system with sensors. It trains the visuomotor system to help the patient to learn motor skills. Additionally, it can be used to measure the ROM of the wrist joint and hand grip strength [14,15].

Recent studies reported promising results when VR was introduced to the rehabilitation of BC. For example, a recent pilot study reported the reduction of depressive symptoms and improved psychological wellness, however, no between group differences were reported regarding the physical activity level [16]. Another study conducted by Chirico and colleagues assessed the efficacy of interactive VR on relieving chemotherapy-related psychological symptoms in female survived after BC. Symptoms such as fatigue and anxiety demonstrated better values in patients received VR rehabilitation protocol [17]. In a trial done by Feyzioğlu and colleagues, improvements in pain, muscle strength, ROM, and function were evident in BC patients who used VR during the early post-operative phase [18].

According to a recent systematic review, there is an obvious lack of well-designed trials as most of the available literature was limited in number with small sample size which resulted in a low quality of evidence and in ability to reach a conclusive opinion

about the effectiveness of VR in the rehabilitation of patients having BC [13]. This study seeks to address this gap by investigating the effect of VR using the Pablo game on function, hand grip, ROM, fatigue, pain, activity levels, and anxiety in post-operative breast cancer patients.

Methods

This double-blinded randomized control trial design that was conducted between September 2023 to march 2024 in a specialized rehabilitation center for cancer patients, Al Qassim, Saudi Arabia. This study followed the guidelines of the Helsinki declaration and reported according to the CONSORT statement for reporting of randomized controlled trials. The ethical clearance was granted from the institutional review board, University of Ha'il, Saudi Arabia (NO: H-2023-366). Informed consent was signed by each participant before to the start of the trail.

Participants

The inclusion criteria were Females (aged 20 to 60 years) who underwent surgical treatment of breast cancer, have a performance status score of ≤ 2 on the Eastern Cooperative Oncology Group.

The exclusion criteria were anemia (Hb ≤ 8 g/dL), severe unstable cardiovascular disorders, uncontrolled diabetes, neuromuscular disorders , chronic obstructive pulmonary diseases, extensive brain or bone metastases, any contraindications given by the physician.

Sample size

The sample size was calculated in advance using G*POWER software (3.1.9.7; Heinrich-Heine-Universität Dusseldorf, Dusseldorf, Germany). The DASH score was used for the calculation where the mean and SD were retrieved from previous study [18]. Power = 0.80, α = 0.05, effect size = 0.30 suggested a sample size of 50 (25 each group) for this study.

Interventions

All participants received exercise therapy plus intermittent compression. PG received

additional exercises using Pablo training system. The intervention program was conducted three times per week for eight weeks.

Exercises

Five exercises were performed for 15 minutes, 2 set X 15 repetitions for each exercise were performed each session. Exercises were stopped if thee desired repetitions were reached or signs of fatigue were evident (decreased performance, weakness, jerky movement). The exercises used in this study were pumping exercises for upper limbs, Pendulum exercises anterior–posterior, medial–lateral, Shoulder range of motion (ROM) exercises, Arms up and down with clasped hands, wrist ROM exercises in all directions (flexion and extension exercises, ulnar and radial deviation).

Intermittent Compression

Electronic intermittent compression therapy unit (Care Pump Expert 8, Poland) was used to apply pneumatic compression to the affected upper limb. Pressure of 60 mmHg, direction Distal to proximal (sequential mode), for 15 minutes were the parameters selected in this study. Similar parameters were used in previous work [19]

Pablo© Handle training

Single-dimensional games using handheld peace were performed. Five different games (Recycle, Firefighters, Shooting Cans, Balloon, and Apple Hunter) were played each session. The time was 3 min for each game with a 15 minutes total training time [14].

Outcome measures

This study has three main outcome measures which were function, handgrip strength, wrist ROM and three secondary outcomes which were fatigue, pain intensity, activity of daily living (ADLs), and anxiety. Outcomes were obtained at three time points; baseline, post-intervention, and at two months follow up. Initial, post-intervention, and follow-up (two months) assessments were conducted by an experienced physical therapist blinded to group allocation.

Function of Upper limb

The assessment of upper extremity function was assessed using a validated Arabic version of the Disability of the Arm, Shoulder, and Hand (DASH) questionnaire [20]. This scale consists of thirty items, each item is assigned a number between 1 (no difficulty) and 5 (inability). Higher cumulative scores indicate higher level of functional impairment. The cumulative score runs from 0 to 100 points [21].

Hand grip and wrist ROM

Pablo (Tyromotion GmbH, Austria) was used to assess the handgrip strength and wrist joint ROM. The patient assumed sitting position with the elbow flexed 90 degrees and the forearm neutrally positioned [14].

Fatigue

Fatigue measurement was done by the Multidimensional Fatigue Inventory MFI. It is a self-reported tool consisting of 20 items designed to measure fatigue for cancer patients. To measure the scale, individuals were required to respond to each item based on their perceived fatigue levels. Responses were typically scored ranging from 1 to 5, with 1 indicating "never" experiencing the stated fatigue-related symptom and 5 indicating "very much" or "always" experiencing it. Greater scores referring to more fatigue. The MFI is a valid and reliable instrument for assessing fatigue across different populations and contexts [22,23].

Pain intensity

The intensity of pain was evaluated by Visual Analogue Scale (VAS). This scale is simple, widely recognized, and reliable [24].The VAS includes a 10-centimeter scale (0 being no pain and 10 being the greatest pain), This scale provides clinicians with valuable insights into the subjective experience of pain, allowing for accurate assessment and monitoring of pain intensity over time [25].

Activities of daily living (ADLs):

Barthel Index (BI) was used to assess the ADLs. BI is a valid and reliable tool for measuring an individual's ability to perform basic daily tasks [26]. Scores vary from 0 to 100, where higher scores represent greater performance. There are several domains measured by the BI: feeding, grooming, bathing, dressing, bowel control, bladder

control, toileting, transfers from bed to chair, ambulation, and stair climbing [27].

Anxiety

Anxiety level was assessed using State Anxiety Inventory (SAI), a well-established and widely adopted measure for evaluating anxiety [28]. The SAI consists of 20 items, and a 4-point for each item (1 = almost never, 2 = occasionally, 3 = most of the time, and 4 = almost always). Participants provide responses based on the extent to which they experience feelings of anxiety. the SAI score ranges from 20 to 80, with higher scores demonstrate higher anxiety [29]. This comprehensive instrument provides valuable insights into the current state of anxiety experienced by individuals, allowing healthcare professionals to tailor interventions and support strategies accordingly [30].

Figure 1: study flow chart

Allocation, concealment, and Blinding

Following the baseline assessment, patients had been assigned randomly into two groups; the control group (CG) who received a standard intervention consisted of exercise therapy and intermittent compression, and the Pablo group (PG) who received Pablo games training plus the standard intervention. The allocation procedure was concealed where it was controlled by the senior author (XX) who was not involved in the treatment or assessment. SPSS was used to generate a random number sequence to determine the allocation sequence. A unique identification code number was assigned for each participant. This code was disseminated to the therapist only at the beginning of the study. The assessor and the data analyzers were blind to the allocation.

Statistical analysis

Statistical measures were performed through the Statistical Package for Social Sciences (SPSS) version 25 for Windows. Mean, standard deviation (SD), and percentages were used to express the outcome values. Unpaired t-test was conducted to compare groups characteristics. The normality of data was assessed using Shapiro–

Wilk while the Levene's test was used to assess the equality of variances. Mixed MANOVA was conducted to investigate the effect of treatment on the outcome measures. Multiple post-hoc tests were conducted using the Bonferroni correction. The level of significance was set at $P < .05$.

RESULTS

After screening of 50 females, status post-operative breast cancer, forty-four joined the study. Three females from the CG and one from the PG dropped out due to personal and social issues (Figure 1). Forty women completed the study with 100% commitment to the treatment sessions. No intervention-related adverse effects were reported.

The basic characteristics of the participants were summarized in Table 1. All demographic data were comparable between both groups ($P > .05$). the participants were subjected to either radical or modified radical mastectomy operations. Radiotherapy was performed to 33% of patients, Chemotherapy to 30 % of patients and Radiation with chemotherapy to 37% of patients

Table 1. Characteristics of the participants.

	Pablo G	Control G	MD	t- value	p-value
	Mean ± SD	Mean ± SD			
Age (years)	47.71 ± 3.94	48.47 ± 4.60	-0.76	-0.56	.57
Weight (kg)	69.67 ± 4.73	72.32 ± 6.68	-2.65	-1.45	.15
Height (cm)	157.95 ± 5.61	158.53 ± 4.11	-0.58	-0.36	.71
BMI (kg/m²)	28.05 ± 3.04	28.80 ± 2.84	-0.75	-0.81	.42
	Type of surgery n (%)				
Radical Mastectomy	8(38%)	5(26%)		Total (33%)	
Modified radical mastectomy	13(62%)	14(74%)		Total (67%)	
	Adjuvant therapy n (%)				
Radiation	7(33%)	6(32%)		Total (33%)	
Chemotherapy	4(19%)	8(42%)		Total (30%)	

Radiation chemotherapy	+	10(48%)	5(26%)	Total (37%)

SD, standard deviation**; MD,** mean difference**; *p*-value,** level of significance**; G,** group.

There was a statistically significant interaction treatments*time (F = 25.58, *P* =.001, ηp2 = 0.94). There was a statistically significant main effect of time (F = 211.99, p = 0.001, ηp2= 0.99) and treatment (F = 24.35, *P* = 0.001, ηp2= 0.86).

Within group comparison

There were statistically significant differences in pain, disability, fatigue, ADLs, and grip strength at post-intervention and at two-months follow-up compared to baseline values (*P* <.001) and at follow-up compared with that at post-treatment (*P* <.01).

In the PG, there was a statistically significant decrease in participants' anxiety level post treatment and follow up compared to baseline and at follow up compared to post treatment values (*P* <.001). Regarding the CG, there was no statistically significantly difference in the anxiety level post treatment (*P* =.25), while statistically significant difference was observed at two months follow-up compared to the baseline and to the post-treatment values (*P* <.001)

The wrist ROM demonstrated statistically significantly differences post treatment and at two months follow up compared to the baseline in both groups (*P* < .001) while in PG, statistically significantly difference was evident upon comparing the follow up values to the post treatment ones (*P* < .001) (Table 2-3).

Between group comparison

There was a statistically significantly difference in pain, disability, anxiety, fatigue, ADLs, and grip strength between both groups at post treatment and at follow up period (*P* <.001). At two months follow up, there was a statistically significantly difference

between both groups in Wrist ROM (P <.05) (Table 2-3).

Table 2. ***Mean values of pain, disability, anxiety, fatigue and daily activity at pre and post treatment, and at two months follow up of both groups.***

	Pre treatment	Post treatment	2 months follow up	*P*-value*		
	mean ± SD	mean ± SD	mean ± SD	Pre vs Post ttt	Pre vs follow up	Post ttt vs Follow up
VAS						
Pablo G	6.95 ± 1.07	4.33 ± 0.91	2.71 ± 1.01	.001	.001	.001
Control G	6.79 ± 1.23	5.26 ± 1.20	4.42 ± 0.96	.001	.001	.001
MD	0.16 ***P = .65***	-0.93 ***P = .008***	-1.71 ***P = .001***			
DASH						
Pablo G	59.29 ± 5.62	38.10 ± 4.16	29.05 ± 4.49	.001	.001	.001
Control G	57.42 ± 3.58	49.16 ± 3.72	46.26 ± 3.43	.001	.001	.001
MD	1.87 ***P = 0.22***	-11.06 ***P = .001***	-17.21 ***p = 0.001***			
SAI						
Pablo G	37.05 ± 4.62	30.48 ± 4.49	25.81 ± 3.54	.001	.001	.001
Control G	35.26 ± 5.36	33.84 ± 5.07	30.89 ± 4.70	.25	.001	.001
MD	1.79 ***P = .26***	-3.36 ***P = .03***	-5.08 ***P = .001***			
MFI						
Pablo G	51.81 ± 7.09	40.24 ± 4.83	29.48 ± 4.80	.001	.001	.001
Control G	52.26 ± 7.50	46.42 ± 7.14	41.53 ± 6.65	.001	.001	.001
MD	-0.45 ***P = .84***	-6.18 ***P = 0.003***	-12.05 ***P = .001***			
Barthel index						
Pablo G	61.43 ± 5.73	79.76 ± 6.22	86.19 ± 4.98	.001	.001	.001
Control G	62.89 ± 8.05	72.63 ± 7.52	75 ± 6.87	.001	.001	.01
MD	-1.46 ***P = .51***	7.13 ***P = .002***	11.19 ***P= .001***			

SD, standard deviation**; MD,** mean difference**; p-value,** level of significance**; G,** group**; VAS**, visual analog scale; **DASH**, Disabilities of the Arm, Shoulder and Hand; **SAI**, State Anxiety Inventory; **MFI**, Multidimensional Fatigue Inventory; ttt, treatment

*** Significant at P value ≤ .017 (adjusted p value)**

Table 3. ***Mean wrist flexion and extension and grip strength at pre and post treatment, and post*** **follow up** ***of both groups.***

	Pre treatment	**Post treatment**	**Two months follow up**	***P*-value***		
	mean ± SD	**mean ± SD**	**mean ± SD**	**Pre vs Post ttt**	**Pre vs follow up**	**Post ttt vs follow up**
Flexion ROM						
Pablo G	77.67 ± 2.56	84.43 ± 2.18	87.43 ± 1.75	.001	.001	.001
Control G	78.79 ± 2.25	84.47 ± 2.29	83.74 ± 2.26	.001	.001	.46
MD	-1.12 ***P = .15***	-0.04 ***P = .95***	3.69 ***P = .001***			
Extension ROM						
Pablo G	72.19 ± 2.96	79.14 ± 3.99	81.05 ± 3.11	.001	.001	.001
Control G	73.16 ± 3.15	78.42 ± 2.79	78.79 ± 2.87	.001	.001	.87
MD	-0.97 ***P = .32***	0.72 ***P = .51***	2.26 ***P = .02***			
Grip strength						
Pablo G	13.90 ± 1.73	21.62 ± 2.27	23.71 ± 2	.001	.001	.001
Control G	13.21 ± 1.13	17.89 ± 1.49	18.89 ± 1.41	.001	.001	.001
MD	0.69 ***P= .15***	3.73 ***P = .001***	4.82 ***P= .001***			

SD, standard deviation**; MD,** mean difference**; p-value,** level of significance**; G,** group**; ROM,** range of motion; ttt, treatment

*** Significant at P value ≤ .017 (adjusted p value)**

DISCUSSION

This study was conducted to investigate the additional benefits that might be gained when VR training games were added to the standard physical therapy care for patients underwent surgical treatment of BC. The current study found that using VR game-based rehabilitation added more significant effects when compared to the standard physical therapy care in favor of Function, grip strength, wrist ROM, Fatigue, Pain, Activities level, and Anxiety

The use of VR application for the rehabilitation of patients having BC is quite limited. Additionally, due to the wide variations in the VR based interventions limited evidence has been reported in favor of each VR application. In the current study, the Pablo (Tyro-motion) device was used to conduct the VR training games. This device VR device can be used for both training and assessment. The training can be performed through interactive games while this device can assess different outcomes such as handgrip strength, pinch force, and ROM for all upper limb joints [31,32].

The current study is considered the first randomized controlled that used Pablo games rehabilitation in the rehabilitation of BC patients. Previously, different types of VR application have been used. Kinect-based VR [33], head-mounted glasses (VuzixWrap 1200VR) with a head motion tracking system [17], Nintendo Wii® video game [34] were used in previous related studies.

Function

Five recent studies investigated the function after using VR in patients having BC [16,33–36]. No between groups significant differences were reported in two studies [16,33] where both the VR and the comparator groups demonstrated similar improvement. The study conducted by House and colleagues did not conduct between group comparisons, only within group comparisons were reported where the VR and the standard treatment groups demonstrated significant changes in the upper limb function as indicated by the UEFI-20 scale [36]. Similarly, Atif et al [34] reported no significant difference between the VR and proprioceptive neuromuscular facilitation (PNF) technique on improving function. However, the detailed evaluation of the date might be promising because the mean difference of the reported median values pre and post treatment in the VR groups was higher than in the PNF group (MD= 15.5 and 11, respectively). These findings were further supported by Chan's work [35] where the function measured by Quick-DASH scale were not significant after 2 or 6 weeks of intervention. The current study findings were on contrary to those reported in previous studies where the patients in the VR group demonstrated better functional scores in contrast to the control group.

Handgrip strength and ROM

As previously reported with the function, muscular strength and ROM were not after treatment or in comparison to the control group. In Feyzioglu study [33], muscle and handgrip strength using handheld dynamometer and ROM using electrical goniometer were assessed before and after standard physiotherapy or VR. Although there were significant improvements reported after treatment, there was no significant difference between groups regarding muscle strength, ROM, and function. In the other study that was performed by Chan and colleagues, no between groups comparison yet there was significant improvement in shoulder abduction and flexion active ROM after VR training [35].

Fatigue

Fatigue was one of the outcomes measures in a single previous study [17]. A comparison with music therapy and standard treatment revealed that VR was better than any of them as a distracting therapy that significantly improved the resistance to fatigue in BC patients receiving chemotherapy. This finding was per our results. However, our intervention was not performed at the same time of receiving chemotherapy as did by Chirico et al.

Pain intensity

Pain intensity was assessed in four studies; house et al found a trend toward a decline in pain intensity. However, one of six patients demonstrated statistically significant reduction in pain measures [36]. In another study that conducted on 80 patients with BC, statistical significant improvement in pain scores were evident when VR training was added to morphine medication [30]. On the other hand, Feyzioglue et al [33] could not report any additional benefits regarding pain scores after application of VR in comparison to standard treatment.

Activities of daily living

A single previous study [36] assessed the ADLs on a single group of post-surgical BC patients. This study reported indirectly the ability of the patients to use the upper extremities in various ADLs by using the UEFI-20. Unfortunately, no control group

was implemented. Yet, there was statistically significant improvement after application of VR to the experimental group which supports out findings.

Anxiety

In a previous study, the anxiety showed significant improvement after using VR compared to music or standard care. VR, music therapy, and standard care were introduced to three groups of BC patients receiving chemotherapy [17]. Another study found that immersion VR plus morphine was superior to morphine alone in alleviating anxiety after a single session that was applied during the chemotherapy session [30]. Recently, Buche et al continued a previously conducted study where the impact of different kinds of virtual stimulation – namely Greener Gamer's Nature Treks OR relaxation application- was examined on a single group of patients. Better anxiety score indicated by the STAI-YA scale was evident after VR compared to other situation where the music was used [37].

Observations on the related literature

Few studies are available related to the use of the VR in the treatment of patients having BC. Of these studies, Pablo was not used in any of them. These studies encounter several limitations such as the small sample size such as Czech et al [16] where 16 patient were included. Less number of participants (n=6) was included in another study [36]. Weak design that lack a control group was also implemented in many occasions [16,35–37]. Finally, short duration of intervention was evident in many studies where it ranged from single session [30] to two weeks [16] while other researchers applied the interventions during the chemotherapy session [17,37]. Compared to previous studies, our study included relatively acceptable sample size that was previously calculated, randomized controlled trials were not extensively performed in previous work, the relatively long intervention duration, using the Pablo system for training and assessment, and the implementation of follow up design were unique features in the current study. These variations could explain the difference in the reported findings between our work and previous research.

The clinical Implication of our trial, Pablo system was used to measure wrist range of

motion and grip strength in post-operative breast cancer women, our study offered a novel viewpoint on Pablo-based game-based therapy, which incorporates accurate evaluation and engaging training techniques for breast cancer patient in regards to pain, function, fatigue, anxiety, and daily activity level.

This study has certain limitations, including lack of long-term follow-up and of dropout participants during randomization, future research is needed to provide an in-depth qualitative analysis of patients' experiences during the Pablo game rehabilitation sessions, additionally, research should be applied to measure the effectiveness of Pablo's game rehabilitation along with other diagnoses and to compare Pablo's game rehabilitation with other physical therapy techniques

Conclusion

In women undergoing breast cancer surgery adding of Pablo games to rehabilitation program significantly improved pain, function, strength, anxiety, fatigue, and daily activity, The utilization of Pablo gaming technology for therapeutic delivery resulted in a new organizational concept.

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Declaration of conflict of interest:

The authors report there are no competing interests to declare.

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Flow Diagram.