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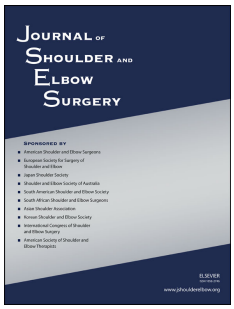

A multi-center randomized control trial, comparing gamification with remote monitoring against standard rehabilitation for patients after arthroscopic shoulder surgery.

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A multi-center randomized control trial, comparing gamification with remote monitoring against standard rehabilitation for patients after arthroscopic shoulder surgery.

Running Title: Gamification vs physio in shoulder surgery

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Connficts of interest

Mr. Bibhas Roy has been a clinical advisor to MIRA rehab since 2013. He has not received any financial remuneration from MIRA rehab. The other authors, their immediate families, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

Full ethical approval for this study was granted by the North West - Greater Manchester East Research Ethics Committee on 17/12/2015 (15/NW/0807).

A multi-center randomized control trial comparing gamification with remote monitoring against standard rehabilitation for patients after arthroscopic shoulder surgery

Abstract

Background: Gamification has become increasingly popular in rehabilitation and is viewed as a tool to improve patient activation, motivation and engagement. The aim of this study was to compare the efficacy of validated Exergames played through a system using 'depth sensor' and bespoke software against standard physiotherapy in patients treated with arthroscopic shoulder surgery. This included the following common conditions; subacromial impingement syndrome, calcific tendinopathy and rotator cuff tears.

Methods: Following arthroscopic shoulder surgery patients were randomized into one of two groups:

1. Standard rehabilitation. Patients were followed up for 12 weeks post-surgery with standard postoperative physiotherapy and had electronic measurements of their active range of movement (ROM).

2. Postoperative regime of exergames using the principles of gamification with physiotherapy support. Patients were given an Exergames schedule prescribed by their therapist on Medical Interactive Recovery Assistant (MIRA) software (MIRA Rehab Ltd., London, UK) paired with a Microsoft Kinect sensor (Microsoft Corp., Redmond, WA, USA).

The primary outcome was active ROM objectively measured by MIRA + Kinect. Secondary outcome measures included The Oxford Shoulder Score (OSS), the Disabilities of the Arm, Shoulder and Hand (DASH) Score and EQ-VAS at 12 weeks post-surgery.

Results: 71 patients were recruited to the study. 7 Patients were excluded due to intra-operative findings. 33 patients were treated with Exergames and 31 patients had conventional physiotherapy. There was no significant difference between the two groups in baseline ROM. Postoperatively there was no significant difference in any of the cardinal planes of movement (Forward flexion (P= 0.64), abduction (p=0.33), external rotation (P=0.75)). The mean OSS in the control group improved from 29.25 to 38.2 (p=0.001) and from 27.1 to 35.1 (p=0.01) in the trial group. There was no significant difference between the groups at 12 weeks (p=.246). The mean DASH improved from 38.13 to 16.98 (p=0.001) in the control group and from 42.3 to 22.54 (p=0.007) in the trial group- there was no significant difference between the two groups (p=.328). There was no significant difference in EQ-VAS in either group at any timepoint (p= 0.5866).

Conclusion: This randomized controlled trial demonstrates that Exergames can be used effectively in the rehabilitation of patients following arthroscopic shoulder surgery. Outcomes, judged by range of movement and patient reported outcome measures, are equivalent to conventional physiotherapy rehab protocols. This healthcare innovation has the potential to relieve some of the heavy burden placed on physiotherapy departments for 'routine' postoperative care in shoulder surgery.

Level of Evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: gamification, exergames, rehabilitation, physiotherapy, shoulders, arthroscopy

Shoulder pain remains a significant burden within the United Kingdom (UK) National Health Service. The overall prevalence of shoulder problems is estimated at 2.4%[18] and as high as 26% in the elderly population[23]. Subacromial pain, including pain from the rotator cuff is

attributable to over 70% of all cases[5,29]. Whilst it is commonly acceptable that the first line of treatment is conservative management, in the last two decades there has been a considerable upward trend in shoulder arthroscopy globally[13,19,33].

In 2019/20 there were over 4.6 million trauma and orthopedic outpatient follow-up appointments at an average cost of £76 per visit[42]. The cost of a course of physiotherapy for unilateral shoulder pain has been estimated at £114-175[16,38]. At a time when the NHS is under considerable financial burden there is a drive to reduce costs as well as unnecessary follow-up.

Non-compliance with physiotherapy has been widely reported in the literature and can be as high as 65% for home exercise programs[9,26]. Other studies have shown that 7.9% of patients fail to attend outpatient physio appointments[37]. Rehabilitation professionals have long suspected that a lack of engagement with rehabilitation protocols may play an important role in determining the outcome of therapy[24].

'Gamification' involves the incorporation of game mechanics in a non-game setting using a tailored user interface which may encourage engagement[12]. Reward systems, competition and immediate feedback may improve user experience and these techniques have been implemented in healthcare-related fields[22].

Medical Interactive Recovery Assistant (MIRA™, MIRA Ltd, UK) is a digital platform that has been designed to gamify physical therapy. It can be accessed on a computer and when paired with the Kinect™ sensor (Microsoft Corp., Redmond, WA, USA) it allows users to interact with the system by tracking body movement in 3-D. This combination has been

shown to be more accurate at measuring range of motion in the shoulder than trained observers[40].

In the current study we tested the null hypotheses that:

1.There will be no significant difference in post-surgical range of shoulder movement (ROM) when physiotherapy is performed with exergames using automated sensor-based technology compared to standard physiotherapy protocols.

2. There will be no significant clinical difference in post-surgical results measured by patient reported outcome measures (PROMs) when physiotherapy is performed with exergames using automated sensor-based technology compared to standard physiotherapy protocols.

Materials and Methods

We performed a multi-center, randomized, pragmatic, parallel two-group trial. Three hospital sites (with three surgeons recruiting) were utilized. The study conformed to the CONSORT statement[1]. U.K. National Health Service ethical approval was received from the North West - Greater Manchester East Research Ethics Committee on 17/12/2015. The study is registered at clinicaltrials.gov study number NCT02705521. All patients gave written informed consent before participating in the study. Recruitment was designed initially to only include patients undergoing subacromial decompression for subacromial impingement. However, with the impending publication of the CSAW trial[4], further ethical approval was gained to recruit patients undergoing other arthroscopic shoulder surgery, such as rotator cuff repair (25/05/2017).

All patients were recruited from specialist shoulder clinics across the three sites. Eligible patients were aged 18 and over with a diagnosis of subacromial impingement, rotator cuff

tears or calcific tendinopathy. All patients had failed a suitable course of non-operative management. Patients were assessed as per the inclusion/exclusion criteria (table 1) following listing for surgery. This process was adapted to include those patients with rotator cuff tears in May 2017. Surgery was carried out across two sites- Trafford General Hospital, Manchester Foundation NHS trust, U.K, and The Royal Bolton Hospital, Bolton NHS Foundation Trust U.K. All surgery was performed by experienced, fellowship trained shoulder surgeons. Timely recruitment to the study was limited by the duration of follow-up and the available number of laptops/Kinect sensors.

Randomization

Patients who were eligible for inclusion in the study were randomized to one of two groups on the day of their surgery. The randomization sequence was generated using https://www.sealedenvelope.com/simple-randomiser/v1/lists with a 1:1 allocation using random block sizes of 2, 4, and 6. Blinding was not possible as patients had to interact with the software which had to be set up by the research team.

Interventions

In the first group 'standard physiotherapy'- patients attended physiotherapy on a weekly basis for twelve weeks. The patients within this group were assessed for progression and were provided with a standardized home exercise program. All patients received detailed instructions, an information leaflet and had each exercise demonstrated by the therapist. Patients from all sites attended two physiotherapists at Trafford Hospital to standardize care. A brief outline of the rehabilitation protocol is included in table 2.

The second group 'physiotherapy with exergames' had a therapy program prescribed for them on the MIRA system. Patients were reviewed by the physiotherapist one week

postoperatively. A baseline assessment was performed and the Kinect + MIRA system was issued to the patient. To enable access, patient credentials which included patient usernames and passwords were generated post randomization. A full demonstration as well as training on the Kinect + MIRA system was given to the patient including Set up and logging into the software, instructions on "How to play the games" and contact details should the patient need to contact the research team. Each game on the system also had a pre-recorded demonstration of how to perform the games. Games were tailored specifically in terms of duration and difficulty depending on the patient's ability which was determined by their physiotherapist. Individual games are used to target different physiotherapy goals including ROM, control, activation of the kinetic chain, arm velocity and strength. On a weekly basis the patient's performance was reviewed remotely, or face to face if any issue was encountered. At this review the rehabilitation schedule would be altered- including increasing the duration/frequency of games or the addition of games with targeted goals. As the patient progressed through rehabilitation therabands or free weights were added as necessary to improve strength.

Patients received real-time feedback including their ROM and 'points scored' during the game which are displayed in a graph (figure 1a/b). The Mira Rehab software recorded the patient engagement with the Exergames including number of sessions and duration of play. Remote monitoring of the patient's progress was possible through a secure online portal. Consent was included to photograph the patients performing the rehabilitation schedule. This would confirm to the research team that it was the patient using the software. These patients were also booked into physiotherapy slots to ensure that any technical issues they encountered could be resolved. All data collected was transferred via secured networks and this had appropriate information governance approval at Manchester Foundation Trust.

In patient's treated for impingement or calcific tendinopathy an active range of movement was permitted from day 0. Each rotator cuff tear was treated individually, and careful attention was paid to the surgeon's postoperative instructions. Initially, focus was on early wrist and elbow exercises. Patients were allowed to perform passive flexion and external rotation to a range recommended by the surgeon. To protect the integrity of the repair active assisted and active movements were limited before 21 days. To facilitate this in the trial, exergames and monitoring of ROM using the Kinect + MIRA system did not commence until 21-28 days postoperatively.

Outcomes

The primary outcome was change in ROM Between day 0 (morning of surgery) and at 12 weeks. For both groups, ROM was recorded by the Kinect + MIRA system in the cardinal planes of forward flexion, abduction and external rotation. This has been shown to be more accurate than visual estimation[40] and eliminates the potential for observer bias.

The secondary outcome measures were the Oxford Shoulder score (OSS), the Disabilities of the Arm, Shoulder and Hand (DASH) Score and EQ-VAS. These were recorded on the day or surgery and on completion of treatment at 12 weeks. The OSS is a patient reported outcome score designed to assess change in pain and function over time[11]. It has undergone rigorous testing for the reliability, validity and the sensitivity to change and it has been proven as a robust tool for assessing outcomes in shoulder surgery[32]. The DASH is a patient reported outcome measure which can demonstrate treatment effectiveness after surgery for subacromial impingement[15]. The EQ-VAS is a quality-of-life metric that measures a broad underlying construct of health. Visual analogue scales have been shown to have good validity and reliability when compared to multi-item questionnaires[25].

Statistical Analysis

A sample size calculation was performed using OSS sample data collected on patients previously undergoing arthroscopic subacromial decompression[10] (Alpha error set at 0.05, and beta error at 0.8, mean difference of 5 points in the OSS, standard deviation 6.96). Based upon this, a sample size of 32 patients in each group would be required.

All data was tested to determine for normality using the Shapiro-Wilk's calculation. Changes in ROM within the two groups at 0 and 12 weeks was assessed using the Wilcoxon signed-rank test. Differences in ROM between the two groups at 0 and 12 weeks was compared using the Mann Whitney-U Test. Differences in the PROMs (OSS, DASH, EQ-VAS) were compared using independent samples T tests (two tailed). These analyses were performed using IBM SPSS Statistics 26 software (IBM, Armonk, NY, USA). This trial has been registered at clinicaltrials.gov, number NCT02705521.

Role of the funding source

The funders of the study had no role in study design, data collection, data interpretation, statistical analysis, or preparation of the manuscript.

Results

Between 29/03/2016 and 13/11/2018 71 patients were recruited to the study; however, 7 patients were subsequently excluded due to the findings at the time of surgery. Reasons for exclusion included rotator cuff tears (n=5, prior to the ethics amendment) and degenerative changes at the time of arthroscopy (n=2). 64 patients were randomized into two groups: standard physiotherapy (n=33) and exergames (n=31). Due to the finite number of Kinect/Laptops recruitment to the study was only possible when the Kinect + MIRA units

were available. Therefore, a total of all patients eligible for recruitment during the study period would not fairly represent the proportion agreeing to participate.

The study groups were well balanced in their baseline characteristics (Table 3.) The primary analysis was intention-to-treat and involved all patients who were randomly assigned. One patient in the control group withdrew from the study and one patient in the trial group was lost to follow-up at 8 weeks, thus data from 62 patients was available for the intention-to-treat analysis.

Range of movement

At baseline assessment there was no significant difference between the two groups in forward flexion ($p=0.179$), abduction ($p=0.104$) or external rotation ($p=0.054$).

Between 0 and 12 weeks there was significant improvement in forward flexion in both groups (standard physiotherapy ($p=0.002$), exergames ($p<0.001$)). There was no significant between the two interventions at 12 weeks ($p=0.805$). Between 0 and 12 weeks there was significant improvement in abduction in both groups (standard physiotherapy ($p=0.004$), exergames ($p<0.001$)). There was no significant between the two interventions at 12 weeks ($p=0.414$). There was no significant difference between 0 and 12 weeks noted in external rotation with standard physiotherapy ($p=0.274$), however there was a significant difference noted in the exergames group ($p=0.005$). This difference did not lead to a statistical difference between the two groups at 12 weeks ($p=0.697$). Statistical results are summarized in table 4.

Patient reported outcomes

There were no significant baseline differences in OSS ($p=0.458$), DASH ($p=0.243$) and EQ-VAS ($p=0.821$). The mean OSS improved from 29.1 to 37.6 in the physio group ($p=0.001$) and from 27.1 to 35.6 in the Exergames group ($p=0.005$). There was no significant difference in the two groups at 12 weeks ($p=0.462$). The mean DASH improved in the physio group

from 38.1 to 17.9 ($p<0.001$) and from 42.9 to 23.7 in the exergames group ($p=0.01$). Again, there was no significant difference between the two groups at 12 weeks ($p=0.315$) There was no significant difference in EQ-VAS in either group at any time point ($p= 0.587$).

No complications were reported as a direct result of using the new technology. One patient in the treatment group developed biceps pain following a subacromial decompression and biceps tenotomy. They were subsequently treated with an injection into the biceps sheath. One patient in the control group developed postoperative pain and stiffness resulting in ongoing treatment with the physiotherapists beyond the end of the trial.

Discussion

This is the first randomized control trial published comparing outcomes of standard physiotherapy and exergames after arthroscopic shoulder surgery. The study showed that shoulder ROM significantly improved in the cardinal planes of flexion, abduction and external rotation in the exergames group but only in flexion and abduction in the physio group. However, there was no difference between the groups at any time-point. There is no obvious explanation for this different as both groups were equally matched in pathology. Both groups had significant improvement in the PROMs at the end of the study. All improvements were above the reported minimally clinical important difference (MCID) of the DASH and OSS[17].

The use of a Microsoft Kinect in rehabilitation for conditions including stroke, neuro-rehabilitation and frozen shoulder is well published in the literature[8,14,21,30]. In a recent meta-analysis Steiner et al[36] concluded that there are limited applications designed for rehabilitation of the shoulder. They found that those available commercially failed to deliver programs tailored to the multiple phases of rehabilitation. Whilst MIRA rehab is designed to facilitate the rehabilitation of multiple musculoskeletal systems it has been shown that this platform is able the deliver the key goals of physiotherapy for shoulder problems[2]. As the

rehabilitation schedule is set by the physiotherapist, different games can be prescribed to target specific goals at different timepoints.

Similar to other commercially available systems, MIRA asks the user to perform simple tasks like catching moving items or moving objects across the screen[8,20]. Stanmore et al[27] identified that when patients used MIRA as part of a falls prevention program, they were intrinsically motivated to participate in the exergames because of the enjoyment they experienced. The same authors showed that MIRA + Kinect improved balance, pain and fear of falling and was a cost-effective fall prevention strategy in care homes[35]. Exergames may have added benefits beyond improved motivation and engagement. A meta-analysis has inferred it may help to improve cognitive function including attentional processing and visuospatial skills[34]. Having a software platform that has multiple rehabilitation options for different conditions may confer financial benefits to departments looking to implement new technologies.

As a result of the COVID-19 pandemic physiotherapy departments have turned to alternative methods of follow-up to cope with the outpatient backlog[31]. It has been postulated that the pandemic represents a chance to embrace innovation and move away from traditional outpatient clinic review with formal physiotherapy sessions[28]. The clinician dashboard available on MIRA rehab allows remote review of a patient's progress. ROM, adherence to treatment and progress over time can be monitored. This has the potential to free up both outpatient clinic and physio sessions at a time when capacity is reduced by as much as 60%[3].

One major issue with the implementation of new technology is the rate at which scientific advances occur compared with the research process. During recruitment to this study the Microsoft Kinect v2™ was subsequently released. This has been shown to have good test-retest reliability and can accurately measure range of movement in the shoulder [6,41]. In 2019 the Azure Kinect ™ was commercially released but is yet to be validated for rehabilitation purposes. The Development of 'wearable technologies' represents a rapidly expanding

market. These may allow collection of newer kinematic components including the range of angular velocity and moment score[7]. These scores may provide greater quantitative feedback for both patient and clinician. However, these technologies do face several issues including cost and the 'wearability' of the technology[39].They also lack the 'gamification' aspect that is provided by systems like MIRA.

The strength of this study is in its randomized controlled design. Baseline assessments were undertaken prior to randomization to prevent bias. The use of a validated objective ROM assessment using MIRA at set time points ensured no bias and more accurate assessment of ROM. All PROMs scores used in the study had previously been validated in patients treated with arthroscopic shoulder surgery.

Recruitment to the study fulfilled the requirements of the power calculation based on a clinically significant difference in the OSS. Results between the two groups did not come close to a clinically or statistically significant difference, therefore we feel that this study was of sufficient magnitude to reliably show equivalence between the two groups.

This study does have its limitations. As part of the CONSORT process, we cannot provide a true number of 'eligible' patients for the study as patients were recruited on an availability basis due to the number of laptops and sensors available. This may also result in a degree of recruiter bias as not all eligible patients could be considered for the study. In planning the implementation of a new system careful consideration would have to be given to the number of available units within a department. Following commencement of the trial, the CSAW trial showed no benefit of decompression over arthroscopy in impingement syndrome[4]. As a result, ethical approval was granted to include patients with rotator cuff tears. Due to low numbers in each group, sub-group analysis has not been performed. It may be that there is a difference in those with rotator cuff tears that this study did not identify. Further research is required to assess the efficacy of MIRA+ Kinect and patient engagement with rehabilitation.

Conclusion

To our knowledge this is the first randomized control trial comparing Exergames with standard physiotherapy in patients undergoing arthroscopic shoulder surgery. This study shows that a progressive schedule of exergames prescribed by, and remotely monitored by a physiotherapist provide an effective rehabilitation program for patients post shoulder surgery. This has the potential to relieve some of the heavy burden placed on physiotherapy departments for 'routine' face to face postoperative care and better facilitate remote rehabilitation.

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Legends

Figure 1A

During each rehabilitation session patients get real time feedback as to how much movement they have in their shoulder.

Figure 1B

On the patient's individual 'dashboard' the therapist can track how many sessions the patient has participated in the exergames. The patient can see how many 'points' they scored in a rehab schedule- giving them a target to beat in their next session.

Table 1

Inclusion and exclusion criteria. *An amendment was granted from the regional ethics committee to include rotator cuff tears.

Table 2

Overview of rehabilitation schedule for control group (non-rotator cuff)

Table 3

460 Data represents number in each group (%), mean patient reported outcome measures (SD).
461 Oxford shoulder score range: 0-48. Disabilities of the Arm, Shoulder and Hand Score range:
462 0-100. EQ-VAS range: 0-100.

463 Table 4

464 Mean ROM in both groups comparing baseline and 12 weeks post-surgery. P values
465 represent statistical significance between baseline and 12-week assessment

INCLUSION CRITERIA
Age 18-70
A diagnosis of impingement syndrome based upon history, clinical examination and radiological findings that requires arthroscopic subacromial decompression **OR** A diagnosis of calcific tendinopathy **OR** A diagnosis of rotator cuff tear on ultrasound/MRI*
Failed conservative management
Patient access to the internet to allow for the remote monitoring element of the intervention
The patient needs to be able to use the sensor-based technology safely, as judged by the research team
The patient is willing to consent to follow-up over a twelve-month period
The patient has capacity to consent to the study
EXCLUSION CRITERIA
Patients who are unwilling or unable to consent
Previous arthroscopic shoulder surgery
Patients undergoing radiotherapy
Patients not fit for general anaesthetic
Patients with type 1 or type 2 diabetes
Patients with significant cardiac dysfunction
Uncontrolled hypertension
Acute illness
History of stroke / neuromuscular conditions preventing the use of Exergames
Patient is currently enrolled in another clinical trial
Irreparable rotator cuff tear
Subscapularis tear
Patients in whom a 'water-tight' non tensioned rotator cuff repair cannot be performed

Rehabilitation protocol for patients in the control arm of trial (Non cuff)	
Week 0-1	Remove of sling within 0-48 hrs, regular analgesia to allow activities of daily living
	Active finger, wrist and elbow exercises, shoulder dumps, weight-bearing through upper limbs, active assisted ROM (if required): FF/ER, table slides and passive stretches
Week 1-3	Increase range of movement, focus on good scapular control
	Include strengthening of rotator cuff depending on patient progression
	Soft tissue work including: scar / portal massage as required, release of anterior (pecs) and posterior structures (post. cuff) to improve internal and external rotation
	Avoid repetitive overhead work in first 6 weeks as can lead to prolonged pain.
Week 4-6	Assess active ROM and quality of movement
	Aim for full ROM by 6 weeks
	Progress scapula control by increasing resistance
	If full ROM, progress strengthening of rotator cuff (theraband resisted/free weights)
Week 6+	Sports/function specific rehab including overhead work

	(n=33)	
Female	20 (61%)	18 (58%)
Age	54.4 (36-70)	52.9 (26-68)
Subacromial impingement	18 (54.5%)	15(48.4%)
Cuff Tear	12 (36.4%)	13 (41.9%)
Calcific tendinopathy	3 (9.1%)	3 (9.7%)
OSS	29.1 (10.6)	27.1 (10.3)
DASH	38.1(18.1)	42.86 (23.6)
EQ-VAS	74.7 (17.5)	72.8 (21.4)

	Mean range pre-op	Mean range postop	P value
FF physio	119 (103-134)	151.4 (88-180)	0.002
Abd. physio	120 (101.5-138.4)	157 (71-180)	0.004
ER physio	54.2 (47.6-60.7)	58.1 (25-70)	0.724
FF Exergames	103.5 (85.7-121.3)	149 (40-180)	<0.001
Abd. Exergames	98.3 (80.8-115.9)	148.3 (50-180)	<0.001
ER Exergames	46 (39.1-52.8)	57.3 (18-70)	0.05