GAMIFICATION FOR ACTIVATION MOTIVATION AND ENGAGEMENT

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DECLARATION

This dissertation is the result of my own work and includes nothing, which is the outcome of work done in collaboration except where specifically indicated in the text. It has not been previously submitted, in part or whole, to any university of institution for any degree, diploma, or other qualification.

Signed: _____  _____

Date:_____08/08/2019_____

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ABSTRACT

Up to 20% of adults annually seek healthcare for musculoskeletal problems. The prevalence of shoulder problems in this population is approximately 2.5%. Musculoskeletal problems are managed with different modalities of treatment including pharmacological interventions, physiotherapy and surgery. Physiotherapy is applied either in isolation or in conjunction with the other methods. Studies have shown that physiotherapy outcome is dependent on patient engagement. Patient's engagement and motivation plays an important role in determining the outcome of therapy and it is estimated that up to 65% of patients are either non or partially adherent to their rehabilitation program.

Objectives

Physiotherapy exergames were created using a combination of commercially available hardware, the Microsoft Kinect, and bespoke software incorporating games which are based on expertise from specialist clinicians. The exergames were mapped to physiotherapy goals and apply principles of gamification to them.

Methods

This study was a randomised prospective controlled trial which investigated the use of exergames for patients with Shoulder Impingement Syndrome (SIS) who have undergone Arthroscopic Subacromial Decompression. The intervention group [n = 10] received physiotherapy aided by automated sensor-based technology which helped them perform exergames and track their rehabilitation progress. The control group [n = 10] were treated by standard physiotherapy protocols. The two groups were compared using patient reported outcome measures and assessment of shoulder range of movement pre and post operatively. Data were collected on patient engagement with the rehabilitation

process and the usability of exergames. This guided development of methods to quantify patient engagement.

Results

The results from the study show that there was an improvement in the range of movement in both the control and the intervention groups. There was no difference in the intergroup comparisons percentage changes from 6 weeks postoperative and 12 weeks post-operative for external rotation, forward flexion and abduction. The results for the Patient Reported Outcome Measures, Oxford Shoulder Score results show that shows there was a significant change for the control group at 12 weeks to pre – operative ($p= 0.02$), although there was no significant change for the intervention group $p=0.193$. The results for the DASH scoring tool shows that there was no significant change for the control group (t test $p=0.01$) compared to the intervention group (t test $p = 0.088$). The results using the T-test for the EQ5D score show that there was no difference in the intervention group $p=0.135$ compared to the control group 0.171.

Conclusion

Results suggest that in both the control and intervention groups there was an improvement in the range of movement and patient reported outcome measures at 12 weeks compared to pre-operative assessment.

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1 INTRODUCTION

BACKGROUND

Musculoskeletal disorders are one of the most common reasons for seeking medical advice in England, with estimates of up to 20% of adults annually consulting their general practitioner (GP) in primary care (Jordon et al, 2010). Further to this, in 2016-2017 there were over 7.7 million outpatient appointments for trauma and orthopedics in secondary care in England. This accounted for 9.3% of all outpatient attendances, 4 million of which were follow-up appointments after an initial consultation (Hospital Episode Statistics). The average tariff for the initial orthopaedic outpatient appointment in 2018/2019 is £151 with further follow-up appointments costing £59.

Total health expenditure is the sum of public and private health expenditure, including a provision of health services both preventative and curative such as nutrition activities, emergency care, and family planning. Countries spend between 1.3% (World bank, 2013) and 17.1%, (US) of total health expenditure. In 2011 – 2015, the United Kingdom health

expenditure calculated to 9.1%. With an expanding population and an increase in the cost of medical care in combination with a reduced health expenditure, the NHS is constantly looking at ways and means of reducing the number of outpatient appointments and the length of time for which a patient required follow-up.

The prevalence of shoulder problems in the population is approximately 2.5% (Jordon, et al. 2010). Common shoulder presenting complaints include shoulder pain and mobility problems including muscle weakness or stiffness. Vitd et al. (2016) suggest that around 44-65% of all shoulder complaints referred to the GP, are patients diagnosed and further treated for Shoulder Impingement Syndrome (SIS). SIS occurs due to rotator cuff tendinopathy, which in turn is caused due to multiple factors. If the loads applied on the rotator cuff tendons exceed the physiological capacity, reactive tendinopathy results. This may then progress to tendon disrepair and finally tears unless treatment is instituted to prevent the progression of the disease.

Management of SIS usually involves non-invasive treatment modalities which are successful in the vast majority of cases. The rehabilitation programme must be individualised for the patient and will consist of avoidance of provocative actions and manoeuvers as well as physiotherapy exercises to achieve specific physiotherapy goals such as improve range of movement, improve strength and pattern etc. There is good evidence that expert physiotherapy with appropriate protocols is beneficial for these patients.

A major factor determining success of physiotherapy protocols is patient engagement that results in good compliance with the rehabilitation regime. There is significant evidence to show that this can be lacking in some patients.

Therefore improving rehabilitation protocols and patient adherence to such regimes can increase efficiency and effectiveness of rehabilitation regimes that in turn may reduce healthcare costs for this clinical problem.

In addition, technology solutions may allow these protocols to be more effective and efficient by reducing the need for specialist physiotherapist intervention with these patients. This may free up this valuable resource which can be directed towards more complex clinical requirements.

Within the NHS, there have been numerous attempts to motivate patients and engage in their care, decision making and to assist in the improvement of the healthcare system. Engaging and motivating patients in the research process is feasible yet crucial to the delivery of research. However, research is lacking and is needed to identify the best methods to gain an in-depth knowledge of patient engagement and how this is to be implemented into the healthcare system. Gamification is a new method of engaging and motivating patients in healthcare. Exergames are a combination of exercise and gamification which was used to enhance standard physiotherapy protocols.

1.1 Overview of Shoulder Impingement Syndrome

Shoulder Impingement Syndrome is a common shoulder disorder referring to the symptoms of pain and dysfunction that results from any pathology which decreases the size of the subacromial space or increases the size of its contents (Olley et al., 2008).

Neer et al. (1983), suggests that the subacromial space is between the under-surface of the acromion of the shoulder and the superior aspect of the humeral head. The space between these two structures is usually small around 1.0 to 1.5 cm (Masood, 2012). When the arm is abducted i.e. moved in an arc away from the body, the subacromial space narrows. This movement, along with any other pathology that narrows the space further, can cause the clinical symptoms of SIS and when the arm is abducted, this can be exacerbated. Any condition which narrows this space further can cause SIS.

1.1.1 Causes

There are many causes of SIS, including the mechanisms of the rotator cuff tendinopathy, which can be classically described as extrinsic, intrinsic impingement or a combination of both (Masood., 2012).

Michener (2003), believes that intrinsic factors are usually partial or full thickness tendon tears which may be a result of the degeneration process. On the other hand, Extrinsic Impingement includes the mechanisms of the rotator cuff which may lead to symptoms of compression, resulting in anatomical factors, biomechanical factors or combination of both.

Anatomical factors include the variations of the structure and the shape of the acromion, which consists of the slope/angle or prominent osseous changes to the inferior aspect of the acromion – clavicular joint (AC Joint). Anatomical factors also include alterations in scapular kinematics, postural abnormalities decreased extendibility of the pectoralis minor which may cause SIS (Seitz, 2011). Often, the anatomical factors, decrease the suprahumeral space which could potentially require surgery.

Biomechanical factors include altered orientation of the scapular and the clavicle during movement or increased humeral head translations, this may occur with a tight Glenohumeral capsule (Kisner, 2012). There are several classification systems which are used with SIS. Neer (1972), first introduced SIS to the literature.

Neer, (1972) classifies 3 stages impingement:

- Stage one which commonly effects young individuals under 25 years old, which is caused by acute inflammation, edema and hemorrhage in the rotator cuff, this in turn, may be the result of excessive overhead use in sports or at work. This stage usually requires conservative treatment.
- Stage two usually effects patients aged 25 to 40 years of age, which is a continuum from stage one. With repeated episodes of mechanical inflammation, the bursa may become thickened which may exacerbate the symptoms of SIS.
- Stage three commonly effects patients over 40 years of age often impacts the mechanical disruption of the rotator cuff tendon, which may lead to partial or complete tears of the rotator cuff.

Stage	Age	Diagnosis	Treatment
Stage I Edema and Hemorrhage	< 25	Subluxation AC Arthritis	Conservative
Stage II Fibrosis and Tendonitis	>25 < 40	Frozen shoulder Calcium	Conservative +/- surgery
Stage III Bone Spurs and Tendon Rupture	➢ 40	Impingement on the rotator cuff	Conservative +/- surgery

Table 1 The three stages of Impingement (Neer, 1972).

1.1.2 SYMPTOMS

Pain, weakness and loss of motion are amongst the most common symptoms reported with SIS (Allen, 1998). Pain may occur from overuse or a traumatic incident, however, this pain may worsen over a period of weeks or even months (Koester, 2005). Pain is typically located on the antelateral acromion which often radiates to the humerus. Some patients complain of pain when lying on the affected shoulder, and when it is raised above the head at night. Symptoms may also be exacerbated when completing overhead tasks, this often causes a popping or grinding sensation during the movement of the shoulder, and therefore a loss of strength will develop.

Shoulder pain can have a substantial impact on the biopsychosocial aspects of an individual's daily life. SIS may develop individual risk factors including depressive symptoms and biomechanical constraints. Cools et al. (2010) found that pain associated with SIS confirms the psychological symptoms which may be reported. Therefore, it is fundamental that the correct diagnosis and treatment are confirmed (Koester, 2005).

1.1.3 DIAGNOSIS

To successfully diagnose a patient with SIS a careful history and thorough clinical examination is obtained, this usually involves an examination of the shoulder and the neck, including an assessment of strength. There are many clinical tests which are used to assist in the clarification of decision making.

One clinical test used widely is The Neer's Impingement Test, which is widely used in orthopaedic examinations to diagnose SIS. Dr. Neer developed a test based upon his findings when operating, which he believed that the focus should be on the supraspinatus tendon,

anterior infraspinatus and occasionally the long head of the biceps. The test movement involves the examiner to internally rotate the patients arm, and forcefully move the arm through the full range of forward flexion. Neer (1972) describes a positive test to be considered if pain is reported in the anterior – lateral aspect of the shoulder.

Another widely used test to diagnose SIS is The Hawkins – Kennedy test, (Hawkins test). The Hawkins test was first described in the 1980's and was founded by Drs. R. Hawkins and J. Kennedy. A positive Hawkins test is an indicator to suggest a diagnosis of SIS. The impinged structures assessed are the rotator cuff, supraspinatus muscle and the infraspinatus muscle. The patient is examined in a sitting position with their arm flexed to 90 degrees and their elbow flexed to 90 degrees with support from the examiner. The examiner then grasps the proximal wrist, the patient and the examiner then internally rotate the arm, (Hawkins, 1995).

Pain which is located below the acromioclavicular joint with internal rotation is a positive test.

Calis et al. (1999), found that the most sensitive test was the Hawkins test at 92.1%, with the Neer tests resulting in a sensitivity of 88.7%. In the same way, Macdonald et al. (2000) found that the Hawkins test produced a sensitivity of 92% compared with the Neer test which shows a sensitivity of 75%. However, Hegedus (2007), found that the sensitivity for both the Neer and Hawkins test was 79%, thus there is a need for further studies to be conducted to determine the accuracy of these clinical diagnostic tests, and further diagnostic tests may be required such as Magnetic Resonance Imaging (MRI). Roberts et al. (2002), used MRI to measure the changes in the anatomic structures whilst performing the Hawkins and Neer test manoeuvers, it was found that the Hawkins test is clinically consistent with SIS .The

diagnosis of SIS is typically made clinically, however, imaging has a role in assisting clinicians to make decisions for treatment.

An MRI scan will allow the clinician to identify and characterize the cause of SIS, (Radiol et al., 2009). Likewise, Segar et al. (2009) states that a MRI can be used to depict the abnormalities that have been clinically described in SIS. However, Myers et al. (2006) suggests that MR Arthrograms are sometimes used in clinical practice.

An ultrasound scan of the shoulder can also be a useful tool in the assessment and diagnosis of SIS. Sonerbend (2008) found that ultrasound was reliable in the diagnosis of full thickness rotator cuff tears yet a few false positives were produced. Read et al. (1998) found that dynamic ultrasound can assist to confirm, but not exclude, a diagnosis of SIS.
Once SIS has been diagnosed a treatment plan regime will commence.

1.1.4 TREATMENT

SIS is usually treated conservatively, (Taziehm, 2005); Conservative treatment usually consists of pain management in combination with physiotherapy and if required, surgical intervention.

Physiotherapy for SIS usually focuses on maintaining the range of movement whilst strengthening the shoulder muscles and reducing pain. It is tailored to each individual patient and supervised by specialist physiotherapist or self-directed by the patient via patient exercise worksheets.

Physiotherapy aims to reduce functional improvement by enhancing posture, muscle strength, scapular stability, scapula humeral rhythm, (Kibler et al., 2001). Systematic reviews in the literature state that physiotherapy aims to reduce pain and dysfunction, however, most of these trials focused on short term effects (Hanratty et al., 2012). The initial goals with physiotherapy is to relieve pain and inflammation, prevent muscle atrophy, and establish a range of movement. Range of movement exercises include pendulum exercise and active assistive range of movement. Strengthening exercises may focus on external rotators, internal rotators, biceps, deltoid, and scapular stabilizers. Patient education is vital regarding pathology, activity and lifting, which in turn will aim to improve range of movement and reduce pain.

Pain management usually begins with non-steroidal anti-inflammatory drugs (NSAIDs), and ice packs for instant relief, however, this is not always found to be an effective method of treatment and further intervention is needed, (Chen et al., 2003).

Therapeutic injections of corticosteroid and local anesthetic may be used for persistent pain with SIS. Once the injection is administered, the patient may experience instant pain relief, however due to the possible side effects of this form of treatment, injections are typically restricted to three injections, and the treatment/ management plan is reviewed (Chen et al., 2003). Blair et al. (1996), found that the use of corticosteroid injections can substantially decrease pain and increase range of movement in the shoulder. In the same way, Akgun (2004) states that corticosteroids show short-term pain relief, in combination with non-steroidal anti-inflammatory drugs without any complication. However, Thomas et al. (2015) state that a recent Cochrane review concluded that there is insignificant evidence to recommend injections for SIS.

Thomas et al. (2015) state that 60-90% of patients with SIS are successfully treated with conservative treatment, likewise Garofalo et al. (2011) states that conservative management resolves in 70-90% of patients. Supporting this, Khan et al. (2013), suggests that conservative treatment including the use of NSAIDs and physiotherapy with or without the use of steroid injections is a well-established method of practice and these conservative treatments should be closely monitored prior to a surgical decision. However, conservative treatment needs to be monitored for a longer period in patients who are over fifty years of age, (Khan et al., 2013). Often, conservative treatments are unsuccessful and surgical intervention is required.

There are two operative surgical techniques which may be used which includes an open or arthroscopic technique. Clinical and patient outcomes following surgery have been similar for the arthroscopic method when compared to the open technique. However, the arthroscopic technique allows quicker rehabilitation less scarring and less deltoid morbidity, (Johansen, 1997). Arthroscopic procedures often tend to be more favourable option than other treatments, this is usually due to the advantages of the arthroscopic technique when compared to the open procedure. Surgical decisions are particularly important when treating the younger/ athletic cohort of patients, (Khan et al., 2013).

Arthroscopic Subacrominal Decompression (ASD) surgery is a procedure which is used to treat SIS. ASD is a method of performing anterior acromioplasty utilizing the arthroscopic technique. An ASD procedure uses a keyhole intervention technique typically performed as a day case. An arthroscope is inserted through the skin and the deltoid muscle, the surgeon is

then able to identify and inspect the structures including the ligaments, muscles and tendons. Two structures which are typically focused on is the acromion and the rotator cuff itself.

Often, findings during the ASD procedure typically include an impingement lesion which present frayed tissue and abnormal contact between the bursal surface and the undersurface the acromion. Throughout the operation, this is removed and cleared.

One week post-operative it is usually expected that the patient can resume to usually activities of daily living. Ketold et al. (2009), found that there was no evidence to suggest that surgery provides additional value to treatment, when compared to conservative treatment.

1.1.5 Rehabilitation

Following surgery, a physiotherapy rehabilitation program is commenced. Patient progression is dependent on patient engagement and compliance with the rehabilitation program, this may consist of specific exercises which are required to be performed regularly.

Rehabilitation is a process which requires patience, engagement and willingness to make adjustments. Rehabilitation programmes are dependent on the surgery which has been performed. Protocols should be initiated in a sequential and organised structure, which is divided into several phases. Each phase builds on the previous stage and should consist of specific goals, exercises and precautions.

Prior to designing a postsurgical rehabilitation programme, there are four rehabilitation phases which ought to be applied (Donatelli, 2011).

Phase one comprises of the immediate post-surgical phase. Phase one would typically occur within 0-1 week following the ASD procedure. The aim is to protect the surgery and prevent

excessive scarring, whilst considering the rate at which the tissues are likely to heal to bone. This phase is designed to protect the surgical intervention but prevent negative side effects of immobilisation, a sling generally used for the first 48 hours following the ASD surgical procedure. One of the most significant challenges following shoulder surgery is empowering early tissue healing whilst restoring strength, motion and function (Klintberg et al 2008).

Mechanical and biologic factors should be considered such as patient's immobilisation position. The position must induce maximum blood flow to the surgical repair, activities such as exercising the opposite limb may improve circulation and cold therapy may be useful to reduce swelling (Donatelli, 2011).

Depending on the surgical intervention and current tissue state will determine the permitted range of motion, (ROM). Motion is used in a protected and restricted arc, early motion assists in decreasing the patient pain through neuromuscular modulation, (Salter, 1984). ROM will gradually increase in the internal and external rotation, this is particularly important for overhead athletes.

During this phase joint stabilization exercises are performed, and the physiotherapist will initiate gentle isometric contraction, alternating the plane of resistance. Exercises at this stage may include active finger, wrist and elbow exercises, shoulder dumps, weight bearing through upper limbs, active assisted ROM, table slides and passive stretches, (see appendix 1).

Corrected thoracic posture combined with retracted and a depressed scapula restores shoulder function and reduced pain (Greenfield 1995). In the same way, Lewis, (2005) analysed the effect of changing posture in patients who have had ASD and found that pain free ROM improved significantly. Therefore, the scapular setting to improve the shoulder position is essential at phase one to improve shoulder function.

Loss of function can be due to pain (Rahme et al. 1998), positive results of active ROM shows reduction in pain, allowing a patients recovery to progress more quickly, (Klintberg. 2009).

Phase two of the rehabilitation process for the ASD surgical procedure will progress at week 1-3 post-operative. Prior to progressing to the second phase of the rehabilitation process, there are several criteria which must be met such as diminishing the pain, inflammation and developing adequate muscle control (Donatelli, 2011).

Within this phase, the advancement of shoulder ROM is emphasized. The patient's ROM is gradually increased through active assisted and passive ROM exercises, such as stretching and joint mobilization techniques. Guidelines for ROM progress is usually based on the patient's tissue scarring and the physiotherapist's assessment.

Goals at phase two also include improving muscle strength and scapular control. The rhomboids, trapezius, serratus anterior, latissimus dorsi, pectorals, levator scapulae are the muscles which assist to control the scapula. Scapular exercises are introduced at this phase, focusing on the control and normal movement exercises. Scapular control includes the elevation, depression, upward rotation, downward rotation, and protraction and retraction exercises through range including exercises such as table slides and wall slides Donatelli, (2011).

Tate et al, (2008) found that scapular exercises which are initiated in phase one of the rehabilitation process leads to improved clinical outcome and a faster recovery of shoulder function. However, limitations of this study suggest that a larger randomised control trial is required to confirm these results.

Phase three is typically commenced at 3-6 weeks following the ASD procedure, this is the advanced strengthening phase, enhancing strength, power, endurance and proprioception

training (Lephart, 1994). Strengthening of rotator cuff includes static supported through range or if unsupported through range, gravity resisted this is assessed as pain and quality of movement allows. Training drills are designed to increase ROM and gradually increase the functional stress in the shoulder joint. Strengthening of the rotator cuff includes the use of theraband and free weights, however, this decision is the judgement of the physiotherapist.

Phase four usually occurs 6 weeks post-surgical intervention of the ASD procedure. This phase requires the patient to return to their usually activities. For this to occur, full ROM and satisfactory muscle strength with endurance, and a satisfactory clinical examination is essential. Once these have been fulfilled the patient is ready to return to full, unrestricted sports or daily activities..

Activities of daily living such as working should be commenced at 6 week post-operative, however, this is dependent on the type of work but this should be discussed with the physiotherapy and or clinician. Activities such as swimming including breast stroke and racquet sports should be returned at 12 weeks following surgical intervention of ASD. It is the role of the physiotherapist and or clinician to advise on strategies which may increase stress on the shoulder joint, (Conti, 2009).

Evidence has suggested that successful physiotherapy is dependent on patient engagement and motivation in their rehabilitation programme.

1.1.6 ENGAGEMENT

Patient engagement is a term which can be used to describe any interaction which the patient has with the healthcare system however, terminology such as ‘patient involvement’ ‘patient interaction’ and ‘patient participation’ is used in the literature when acknowledging patient engagement, therefore this suggests that the understanding of terminology has not yet been theoretically underpinned.

In the NHS today, the importance of patient engagement is focused on and considered to be the cornerstone of the healthcare system (Danzer, 2013).

Factors affecting patient engagement within the process of healthcare delivery include patient attributes such as patient age, sex, education as well as, patient's ethnicity, (Arora, 2000). Emotional experiences and coping strategies can also have an impact on engagement, 'bad experiences' can lead to negative interpretations and perceptions of the healthcare system, therefore, resulting in lack of patient engagement and motivation. Healthcare professionals can influence and advocate the importance of patient engagement. The way in which a healthcare professional interacts with a patient can affect the patient's participation in healthcare. Patient engagement can be increased by health care professionals who respond positively to the patient's needs, (Little et al 2004). Likewise, Coulter et al. (2007) focused on patient engagement for physiotherapy regime post-surgical intervention and found that the patient's treatment was meditated and motivated by the relationship between the physiotherapist and the patient.

The recent focus on patient engagement acknowledges that patients have an imperative role to play in their own care, patient involvement, engagement and motivation are major factors which can influence patient outcomes (Meichenbaum et al., 1987). Similarly, Carmen et al. (2013) suggests patient satisfaction and quality outcomes have been proven to increase when patients are actively engaged in their own care. Therefore, to engage patients in their own care and make them 'active players', may also assist in the reduction of healthcare finances, the length of hospitalizations and poor clinical outcomes.

Within the NHS, there have been numerous attempts to motivate patients to engage in their care, decision making and to assist in the improvement of the healthcare system. Engaging and motivating patients in the research process is feasible yet crucial to the delivery of research. However, research is lacking and is needed to identify the best methods to gain an

in depth knowledge of patient engagement and how this is to be implemented into the healthcare system. Motivation can determine the outcome of rehabilitation therapy (Hoelscher et al., 1984). Over half of patients are non-compliant to their home exercise program and over 10% fail to complete their prescribed course of physiotherapy (King et al., 2013). Traditionally, the rehabilitation program consists of patients completing home exercise diaries, however, studies have suggested that these are often completed retrospectively and patients tend to exaggerate the amount of activity performance.

1.1.7 GAMIFICATION

Gamification is defined as the use of game design elements in non-game context to improve user experience and engagement (Deterding et al., 2011). It is a system in which players engage in an artificial conflict, defined by rules that results in quantifiable outcome focusing on engagement, motivation and behavioral change via games, (Katie Salen and Eric Zimmermann. Gamification incorporates the following prinicples:

Incorporating the eight individual elements to a game allows the principles of gamification. To apply gamification developers need to use the elements of gamification, integrating their specific intervention. Gamification incorporates serious games which is a term used to describe the development of games which are specifically designed to achieve some change in the player.

Gamification used in health is recognizing and providing personalized interventions focusing on the needs of the patient with the intension to improve and change outcomes. In the healthcare system, there is an increasing need for the use of games and game based approaches with the aim to encourage patient engagement and motivation. The gamification approach in healthcare seeks to improve the health and wellbeing of patients, thus allowing them to become more engaged, to take control and responsibility for their health decisions.

A review of the literature suggests that gamification is currently being used for a range of specialties in healthcare, from weight control, exercise physiotherapy programs and falls prevention. Games have been used in many areas of healthcare such as exergaming. The Games for Health project provides a way of categorizing these different types of games used in healthcare.

1.1.8 EXERGAMING

Exergaming is a portmanteau of 'exercise' and 'gaming' which is widely used form of gaming used in healthcare today. Exergaming is the use of videogames in an exercise activity, combining exercise with gameplay, with the aim to improve health status (Sinclair et al., 2007). Exergames have also been proven to enhance psychosocial and cognitive issues, gaining an increase of self-esteem, engagement, motivation and social interaction.

Exergames may generate more physical activity and energy expenditure, however, there are mixed opinions in the literature to suggest whether Exergames can engage levels of activity which is consistent with public health recommendations for receiving health benefits (Daley., 2009).

Rosenberg (2010) studied the use of Exergames in patients diagnosed with Subsyndromal Depression, eighty six percent of patients completed a 12 week intervention and found a significant improvement in mental health quality of life (QoL) and cognitive performance. However, there was no improvement in physical quality of Life. Alternatively Staiano et al. (2012) used Exergames to encourage weight loss and physical activities in adolescents. Results show that the experimental group were more engaged in the physical activity regime and a mean loss of 1.65kg when compared to the control arm of the study, which did not lose weight. It is recognised that Exergames may provide an enjoyable experience, this may be a

key factor in engaging and motivating patients to actively be involved in their physiotherapy regime.

To summarize, from a review of the literature there are no studies using exergames for shoulder rehabilitation. Therefore, a randomized control trial will be delivered on NHS patients using Exergames for shoulder rehab.

The aim of this study:

- To implement a multicenter randomized controlled study using the exergames to understand if exergames are safe and effective in this patient population.
- To work with the clinical team to develop a physiotherapy exergame protocol specifically for this study.
- To understand if there is a difference in post-operative rehabilitation using the Mira software in the intervention group compared to the control group.
- To understand if there is a difference in engagement, clinical outcome and Patient Reported Outcome Measures in the intervention group compared to the control group.

1.2 Literature review

A literature review was performed to identify Randomised Control Trials which evaluate the use of Exergames for physiotherapy.

1.2.1 Aims

This literature review aims to:

1) Provide an overview of Shoulder Impingement Syndrome.

2) To discuss gamification and how this is used in the healthcare setting.

3) Discuss the use of technology to improve patient engagement.

4) Conduct a literature review to identify studies which include gamification in

healthcare.

1.2.2 METHODS

An electronic database search was carried out on the following databases from the dates 01 January 2010 until 31 December 2016.

1) Pub Med

2) CINAHL

The terms which were used in the searches for key criteria included, Gamification, Games, Gaming, Exergames, Orthopaedic, Physiotherapy, Musculoskeletal, and Rehabilitation. This concluded in a high volume of studies, therefore terms were used in combination; Exergames and Physiotherapy, Exergames and Rehabilitation, Exergames and Musculoskeletal, Exergames and Orthopaedics, Exergames and Range of Movement (ROM), Games and Physiotherapy, Games and Rehabilitation, Games and Musculoskeletal, Games and Orthopaedics, Games and Range Of Movement.

During the pre-screening phase, the search included human subjects and only Randomised Control Trials (RCTs) with a date restriction of > 01/01/2012 were encompassed.

	Pubmed	**Pubmed RCT** + DATE >01/01/2012	**CINAHL**	**CINAHL RCT** + DATE >01/01/2012
Gamification	109		25	
Game	19099		9360	
Gaming	1782		494	
Exergames	150		80	
Orthopaedic	105569		32554	
Physiotherapy	142532		9444	
Musculoskeletal	60107		14958	
Rehabilitation	421768		106317	
Exergames+ physiotherapy	27	5	3	0
Exergames+ rehabilitation	39	5	33	3
Exergames+ musculoskeletal	1	1	1	0
Exergames+ orthopaedics	0	0	1	0
Exergames+ ROM	6	0	0	0
Games+ Physiotherapy	488	90	55	3
Games+ rehabilitation	1275	125	602	29
Games+ musculoskeletal	102	2	59	0
Games+ orthopaedics	90	0	41	0
Games+ ROM	35	10	5	0
	2072	236	800	35
Total Studies				271

Table *2*: THE KEYWORDS USED TO SEARCH THE DATABASE AND THE TOTAL NUMBER OF STUDIES ASSOCIATED WITH THESE KEYWORDS.

A total of 271 studies were identified following the initial search. PubMed identified 236 studies and CINAHL 35 studies. An inclusion and exclusion criteria was formulated to identify specific findings relating to the research. The studies were screened by the author using an inclusion / exclusion criteria.

Inclusion

Patients using Exergames, Stroke, MSK, Parkinson's, MS, Geriatrics, Falls prevention, PROMs, RCT.

Exclusion

Patients using Exergames but not for physiotherapy. Patients under the age of 18

The abstracts for the 271 identified studies were screened (level 1) by the researcher, according to the inclusion/ exclusion criteria. The eligible full text articles were screened again using the same inclusion/exclusion criteria (level 2 screening).

1.2.3 Results

A total of 271 studies were eligible for level 1 screening. From reviewing the abstracts following the inclusion / exclusion criteria, 83 studies were suitable for level 2 screening. At level 2 screening, 39 of the studies were excluded as they were duplicates and 16 studies were omitted as no full text publication was made available. Following the screening period a total of 27 studies were include.

1.2.4 Study Selection Process

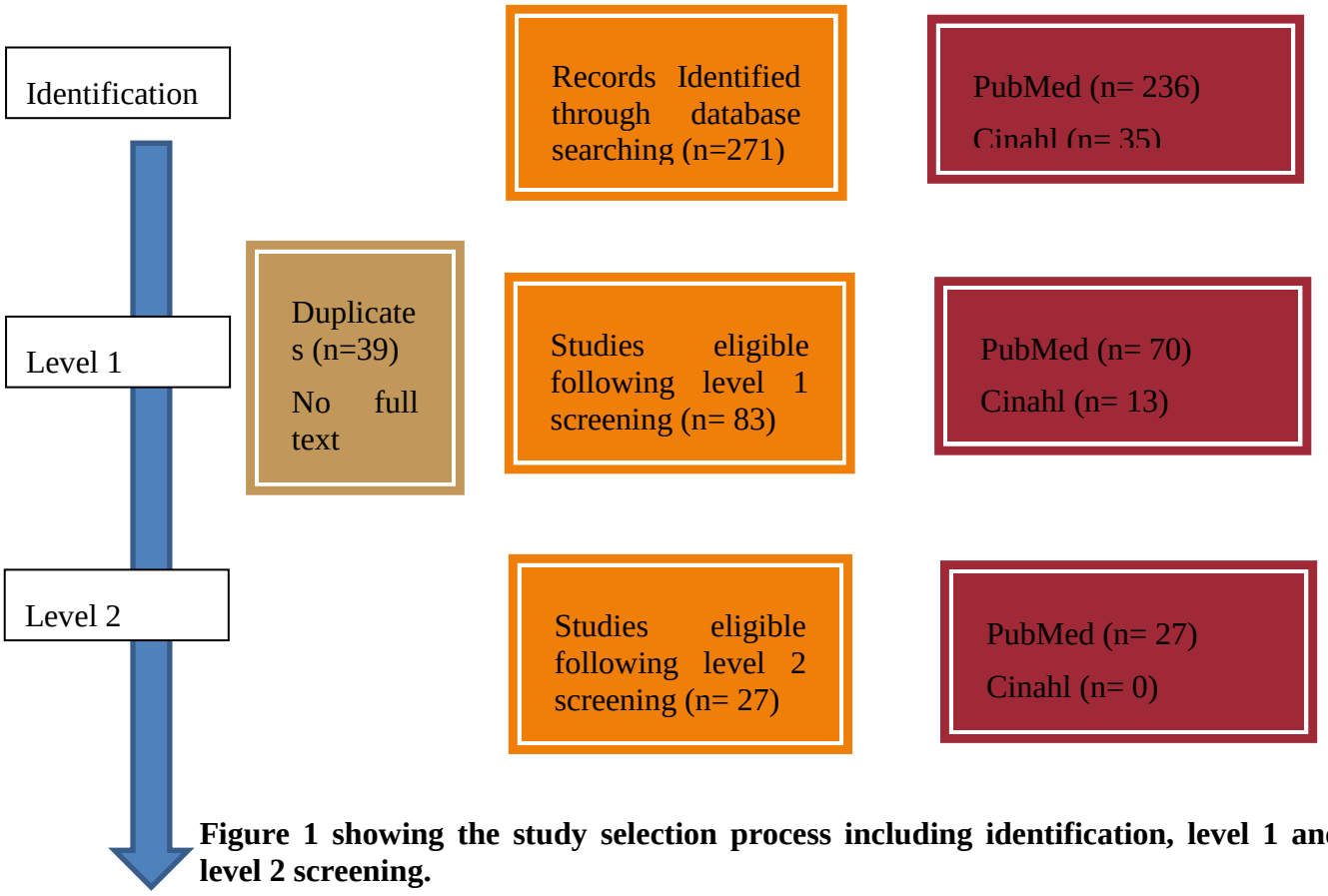

Figure 1 showing the study selection process including identification, level 1 and level 2 screening.

1.1.9 Overview of Results

Within the 27 included studies a number of emerging themes were extracted.

These themes were categorized into patient engagement and clinical improvement which were then classified further.

Clinical Improvement

i) Patient Reported Outcome Measures (validated scores)

ii) Function

iii) Strength

iv) Balance

Patient Engagement

i) Diaries

ii) Engagement/ motivation Questionnaires

Clinical Improvement	No of studies
Strength	3
Balance	13
Function	17
PROMs	23

Table 2 Keywords for clinical improvement which were used to search the database as well as the number of studies associated with these key words

Clinical Improvement (table 3) has been categorized into 4 significant areas which include strength, balance, PROMs and function. Of the 27 included studies, 63% (n=17) focused on the functional aspect of clinical improvement. Remarkably, only 11% concentrated on strength. Additionally, only 4% (n=1) incorporated all four common themes (strength, balance PROMs and function.

Patient Reported Outcome Measure	Number of studies
BERG Balance SCALE	6
Barthel Index (MMSE)	1
Falls Efficacy Scale-International for fear of falling assessment	2
International Physical Activity Questionnaire-Long Version (IPAQ-L)	1
Disability Arm Shoulder and Hand (DASH)	1
Unified Parkinson's Disease Rating Scale-II (UPDRS-II)	1
Lower Extremity Functional Scale (LEFS)	1
Generic Health Related Quality of Life	
European Quality of Life – 5 Dimensions (EQ-5D)	11
Short Form Health Survey (SF-36)	7

Table 3 Keywords for Patient Reported Outcome Measures which were used to search the database as well as the number of studies associated with these key words

Within the 27 included studies, 23 involved the use of PROMs (table 4). The PROMs were then categorized further into, condition specific PROMs and Generic Health Related quality of life PROMs. The PROM (condition specific) which is most frequently used in the BERG balance scale accounting for 26 % (n=6) of the questionnaires used. Additionally, the health related quality of life PROM which is most frequently used is the widely known, EuroQol five dimensions questionnaire (EQ-5D), accounting for 48% (n=11) of questionnaires used. Furthermore, 48% (n=11) of the included studies opted to incorporate both condition specific and health related quality of life PROMs.

Function	No of studies
Device	5
PROMs	13
ROM	1
Physical assessments	6

Table 4 Keywords for function which were used to search the database as well as the number of studies associated with these key words.

Function

Devices were only used in 18% (n=5) of the included studies, with only 4% (n=1) study using ROM to measure function(table 5). The use of device and PROMs were most frequently used in combination, accounting for 11% (n=3) of the selected studies. Functional physical assessments and PROMs were prevalent in 22% (n=6) of the included studies. Physical assessments included a 6 and 10 meter walk test and stepping reaction time.

Balance	No of studies
Physical Assessments	9
Device	12

Table 5 Keywords for balance which were used to search the database as well as the number of studies associated with these key words.

Physical assessments accounted for 33% (n=9) of the included studies, with devices being used for balance in 44% (n=12). Physical assessments in combination with the use of devices were used in 25% (n=7) of the studies. Additionally, from the 27 included studies 25% (n=7) used the Time up and Go Test (TUG) and 7% (n=2) used the 10 meters walk test to assess balance.

Patient Engagement	No of studies
Questionnaires	10
Diaries	6

Table 6 Keywords for patient engagement which used in the search and the number of studies associated with the selected key words.

In comparison, patient engagement (table 7) is measured in 44% (n= 12) of the included studies, of which 37% (n=10) used questionnaires and 22% (n=6) used diaries. Questionnaires and diaries were used in combination in 11% (n=3) of the included studies.

The aim of this study:

- To implement a multicenter randomized controlled study using the exergames to understand if exergames are safe and effective in this patient population.
- To work with the clinical team to develop a physiotherapy exergame protocol specifically for this study.
- To understand if there is a difference in post-operative rehabilitation using the Mira software in the intervention group compared to the control group.
- To understand if there is a difference in engagement, clinical outcome and Patient Reported Outcome Measures in the intervention group compared to the control group.

2 METHODOLOGY

INTRODUCTION

Exergaming is a portmanteau of ‘exercise’ and ‘gaming’ which is a widely used form of gaming used in healthcare today. Exergaming is the use of videogames in an exercise activity, combining exercise with gameplay, with the aim to improve health status. Exergames have also been proven to enhance psychosocial and cognitive issues, gaining an increase of self-esteem, engagement, motivation and social interaction.

Range of Movement (ROM) is an assessment which is widely used by Orthopaedic surgeons and physiotherapists to measure the potential movement in a joint. However, range of movement measurements have not yet been introduced in combination with gamification for patients undergoing shoulder surgery.

The research involved complementing rehabilitation following Arthroscopic Subacrominal Decompression surgery, using Exergames and ROM measurements using software in combination with the Microsoft Kinect sensor. The Exergames used for this study is

software which have been developed by Mira Rehab. Mira Rehab is a company based in London, England who have developed software designed for the rehabilitation for a range of medical conditions.

2.1 Study Design

Patients were recruited to a three-month rehabilitation programme following a standard Arthroscopic Subacromial Decompression for Shoulder Impingement Syndrome. Patients were enrolled onto the study between 29/3/2016 and 1/3/2017. Each patient recruited was randomised into one of two groups:

1. Standard post-operative physiotherapy (Treatment as usual Group). Patients were followed up for 12 weeks post surgery with the researcher measuring their engagement and range of movement on a weekly basis.

2. Post-operative regime of physiotherapy plus exergames using the principles of gamification (Treatment as usual plus Exergames). Patients were given the exergames to take home and were followed up by the researcher for 12 weeks post surgery.

2.1.1 Setting

This was a prospective, multicentre, randomised, controlled study. Central Manchester Foundation Trust (the sponsor) and the lead recruitment site with several research sites which were set up to assist with the recruitment of patients. The additional research sites included Salford Royal Foundation Trust, Bolton Royal Hospital and Wrightington Wigan and Leigh Foundation Trust . Within each research site, a designated principal investigator and lead research nurse were assigned to assist with the setup, delivery, recruitment and retention of study patients. Patients, who were recruited from the additional sites, continued in the study and commenced their post-operative physiotherapy sessions with the research physiotherapist

based at Trafford General Hospital. It was decided that Trafford General Hospital due to room availability and this is where all of the core research team were based .

2.1.2 Ethical Approval

Milestones

- 28/09/2015 - Documentation was submitted to the Regional Ethics Committee (REC) by the researcher. The submission included the Integrated Research Application Submission (IRAS) form, as well as essential documentation such as a study protocol and patient information sheets (PIS). REC invited the team to a committee meeting
- 21/10/2015. REC committee meeting. The team which included the researcher attended this meeting included, the Chief Investigator Bibhas Roy, Usman Butt Principle Investigator for Salford Royal Foundation Trust, James Wilson Principle Investigator for Bolton Royal Hospital. Following the meeting, amendments were made as suggested.
- 17/12/2015 REC approval was granted on. REC Number – 179371.

  Central Manchester Foundation Trust (CMFT) agreed to sponsor the study and local research and development approval was granted on 15/3/2016.

  Ethical approval from The University of Salford was granted on 24/3/2016.

2.1.3 Patient population

Inclusion Criteria:

1. A diagnosis of impingement syndrome based upon history, clinical examination and radiological findings that require arthroscopic subacromial decompression.

2. Patient access to the internet to allow for the remote monitoring element of the intervention.

3. The patient needs to be able to use the sensor-based technology safely, as judged by the research team.

4. The patient is willing to consent to follow-up over a twelve-month period.

5. The patient has capacity to consent to the study.

Exclusion Criteria:

1. Aged less than 18 or greater than 70
2. Patients who are unwilling or unable to consent
3. Previous arthroscopic shoulder surgery
4. Patients undergoing radiotherapy
5. Patients with type 1 or type 2 diabetes
6. Patients not fit for general anaesthetic
7. Patients with significant cardiac dysfunction
8. Uncontrolled hypertension
9. Acute illness
10. History of stroke / neuromuscular conditions preventing the use of Exergames
11. Patient is currently enrolled in another clinical trial.

2.1.4 CONSENT

Patients were referred from their General Practitioner into the orthopedic outpatient

department where they are examined and listed in clinic for surgical intervention. At this appointment the patient was required to complete a consent to contact form (Appendix 1) and a Patient Information Sheet (Appendix 2) was given to patient for their consideration. Prior to their surgery date, the patient was contacted by a member of the research team, to see if they would like to participate in the study. On the date of their surgery, the study doctor reviewed the inclusion/exclusion criteria. Eligible patients were asked to consent to the study (Appendix 3), and patients were then randomised to either treatment group following their surgical intervention.

2.1.5 RANDOMISATION

As the surgical procedure can be altered dependent on the clinical findings, patients were randomised following their surgery.

Participants were given a unique computer-generated identification number that was allocated randomly, using block randomization. Envelopes were used by the researcher to identify each patient into either the control or intervention group.

Patients were randomised on a patient-by-patient basis using a randomised block design to minimise potential confounding variables.

2.1.6 TREATMENT AS USUAL GROUP

Patients attended physiotherapy on a weekly basis for twelve weeks for assessment (standard physiotherapy). The patients within this group were assessed for progression and were provided with a standardised home exercise program. The research physiotherapist recorded the patients shoulder Range of motion, measuring three cardinal planes, on a weekly basis, using the Mira Rehab technology. Patients were required to complete an exercise diary documenting the exercises performed as well as duration and frequency.

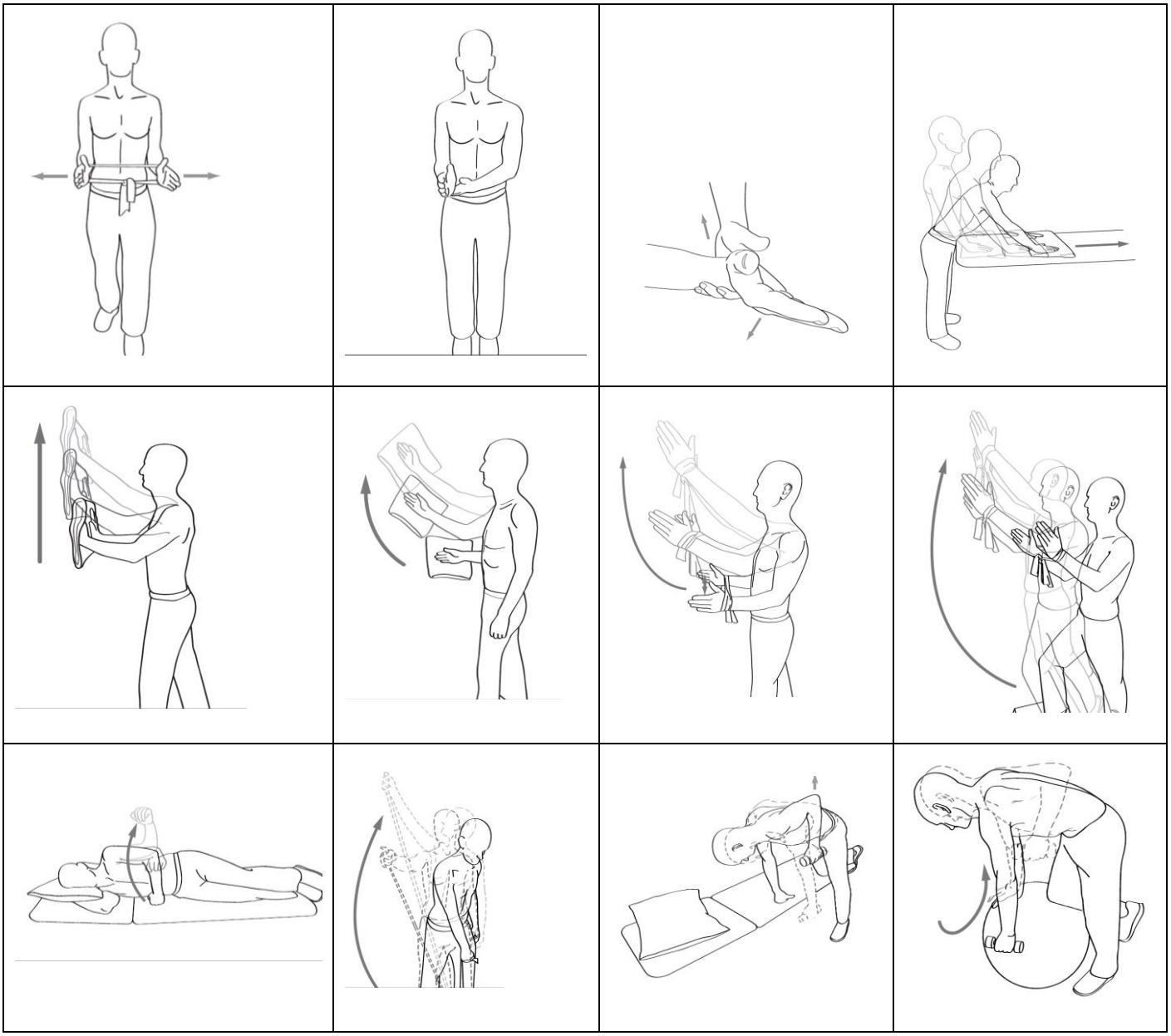

Figure 2 Home exercise programme for the control (standard of care) group.

2.1.7 TREATMENT AS USUAL PLUS EXERGAMES GROUP:

The Mira software together with the appropriate hardware was given to the patient on their first physiotherapy appointment, one week following their surgery. This group of patients required access to the system. To enable access, patient credentials which includes patient usernames and passwords were generated post randomisation. A laptop in combination with the Kinect sensor was given to the patient and Exergames were assigned according to the

physiotherapy protocol.

A full demonstration and training of the laptop / Kinect and Mira Rehab system was given to the patient including:

1) Set up and logging into the laptop and Mira Rehab
2) Instructions on “How to play the games”.
3) Contact details should the patient need to contact team.

Following set up of the system patients were required to attend physiotherapy on a weekly basis as well as partaking in a set of tailored Exergames to play in the home system. The Mira Rehab software recorded the patient engagement with the Exergames including number of sessions and duration of play. These were reviewed regularly.

All data collected was transferred via secured networks and this has appropriate Information Governance approval at Central Manchester Foundation Trust.

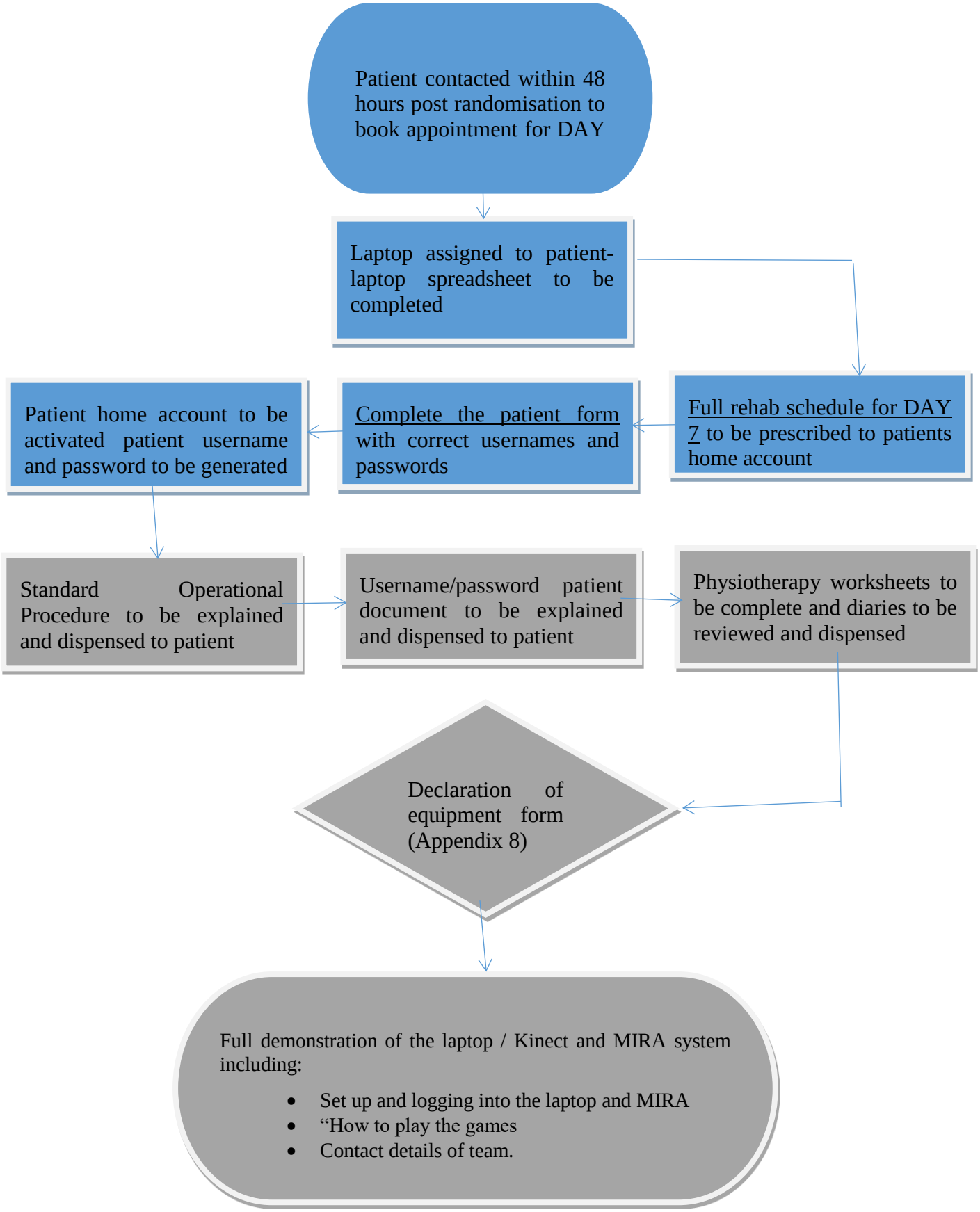

Figure 3 Flow chart showing the operational set up and process for Exergames patients

2.1.8 ASSESSMENTS

The researcher carried out baseline assessments on all patients prior to randomization (Table 9). Post-operative, the research physiotherapist assessed each individual patient on a weekly basis. The collection of patient data included:

1)Sociodemographic data- this included the patients date of birth, address and gender.

2) Shoulder range of movement which was measured by the Mira rehab system and assessed for full return of motion in three cardinal planes:

- Forward Flexion
- Abduction
- External Rotation

3)Clinical status / history of present and past comorbidities.

4) Shoulder function, this was measured using two scoring tools:

- The Oxford Shoulder Score (OSS) (Appendix 5) which is a twelve-item PROM which is condition specific and focuses on assessing outcomes for shoulder surgery. The OSS 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.
- The Disabilities of the Arm, Shoulder and Hand (DASH) (Appendix 6.. This is a thirty item questionnaire which measures the patients ability to complete tasks absorb forces and severity of their symptoms.

5) Pain was measured using the Visual analogue Scale for pain (VAS) (Appendix 4).

6) Health outcome and quality of life was measured using The European Quality of Life 5 Dimensions (EQ5D) (Appendix 4). This is generic yet standardized tool which is widely used

to assess the measure of quality of life. EQ5D focuses on five different dimensions which include, mobility, selfcare, usual activities, pain and discomfort and anxiety and depression.

7) Diaries were used in each arm of the study to measure patient engagement and adherence to their rehabilitation programme (Appendix 7). Diary data such as, time exercised (minutes) and scale was used to measure exercise exertion. For those patients randomised to the 'Exergames' arm of the study, their diaries were compared to the engagement data which is logged within the Mira system and includes data such as, length of duration logged into the system.

2.1.9 Study Assessments

Study Task	Pre-operative	Day 85
Informed Consent	X	
OSS Shoulder Function	X	X
DASH Shoulder Function	X	X
EQ5D Quality of Life	X	X
VAS Pain	X	X
ROM	X	X
Inclusion/ Exclusion Criteria	X	
Medical History Reviewed	X	
Demographics	X	
Diary dispensed		
Diary Reviewed		X

Table 7 Patient assessments and the schedule of events

2.1.10 Equipment

The equipment used for this study was a combination of hardware and software. The software

incorporates the gamification platform which has been developed to work in combination with a standard windows computer and Microsoft Kinect Senor. The rationale for using the following equipment:

1) Microsoft Sensor – At the time of Exergames development, this was the only optical sensor on the market which would allow body tracking, plus Mira Rehab had already been previously working with this sensor.
2) Laptop – it was required for visual feedback for patients when completing the games but also needed to provide to the patients to take home and play the games.

2.1.10.1 MICROSOFT KINECT SENSOR

The Microsoft Kinect Sensor (Figure 3) is a motion sensor input device which has been designed by Microsoft for the Xbox 360. It features a RGB camera, depth sensor and multi-array microphone running propriety software (Titilo, 2010). The device provides facial and voice recognition as well as 3D motion capture. The Kinect is based around a webcam style and allows the user to interact without the need for a game controller and is commonly available for capturing and analysing whole body patterns. The Kinect was used to capture patient range of movement which includes forward flexion, abduction and external rotation.

Figure 3 Microsoft Kinect Sensor

2.1.10.2 LAPTOP

The laptop used for this study was the Lenovo Idea pad Z50-70. This was a standard laptop which was used for the patients randomised to the treatment as usual plus Exergies group and also to measure the range of movement in all patients. This laptop includes nVidia graphics card which enhanced game play. The software which incorporates the exergames was downloaded onto the laptop and dispensed to the patients.

2.1.10.3 MIRA REHAB

Mira Rehab focuses on engaging and motivating patients towards their physiotherapy regime using gamification. Games are built based upon the best clinical practice and expertise from specialist clinicians. The Mira Rehab programme enables patients to progress through different levels within the games and visually track their progress, whilst engaging in their rehabilitation programme (Figure 4 and 5). These games are prescribed by the research physiotherapist and Mira rehab allows the research team to visually track patient progression and compliance. Additionally, throughout the patient's rehabilitation programme the Mira system provides random photographs to confirm patient engagement.

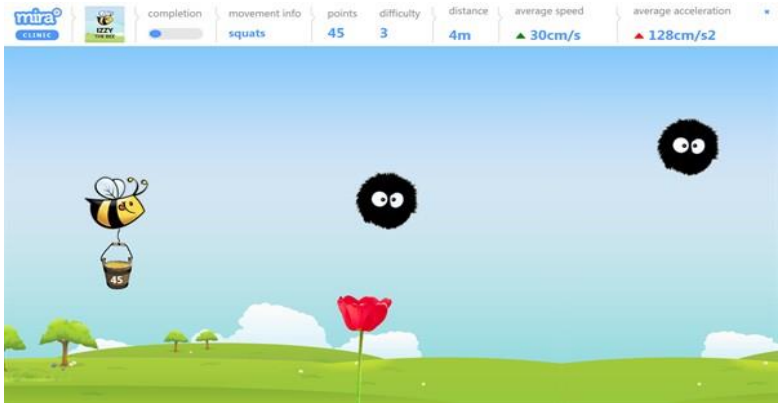

Figure 4 Mira Rehab Exergames "Izzy the Bee"

Izzy the Bee is one of the games which are used to improve shoulder range of movement.

The aim of the game:

The user is Izzy the Bee. The objective is for the Izzy the Bee to collect the pollen from the flowers, using the bucket, whilst avoiding the black circular object. The duration of the time playing the game and the amount of pollen collected will increase the number of points gained by the player.

This game is played using general shoulder movements on the affected arm, which the patient has had previous shoulder surgery.

Figure 5 The Mira Rehab Exergames visual feedback which is generated following playing the game

Mira is being used in over 30 institutions worldwide. Among its UK clients are clinical institutions like Central Manchester University Hospitals NHS Foundation Trust, Guy's ad St. Thomas' NHS Foundation Trust, Derby Teaching Hospitals NHS Foundation Trust, National Star College, with additional clients in Romania, Malaysia, Pakistan and prospects in Spain, Portugal, Germany, U.S.A., Canada, Australia and Brazil. Mira Rehab had previously been used in a study conducted at Manchester University using Exergames for falls prevention, therefore the researcher wished to explore using these games in a different patient population.

2.1.10.4 MEASUREMENT OF RANGE OF MOVEMENT

All patients completed their shoulder range of motion, measured by the Mira technology to exclude researcher bias.

Pre – operatively, each patient was taken into a private area within the surgical ward where their shoulder Range of Movement was completed using the system. The system, with the installed Mira Rehab software, in combination with the Microsoft Kinect Sensor was previously set up with the patient's details which were added including demographics as well as the procedure and their affected side.

Visual and audio communication from the Mira system allowed the patient to follow instruction for shoulder range of movement. The range of movement is completed on both the affected side and the non-effected side.

The patient followed the instructions from the software and should hold the position for 5 seconds until completion whilst the system analysis the patients range of movement measurements (Figure 6).

Completion bar to turn blue once measurements have been taken.

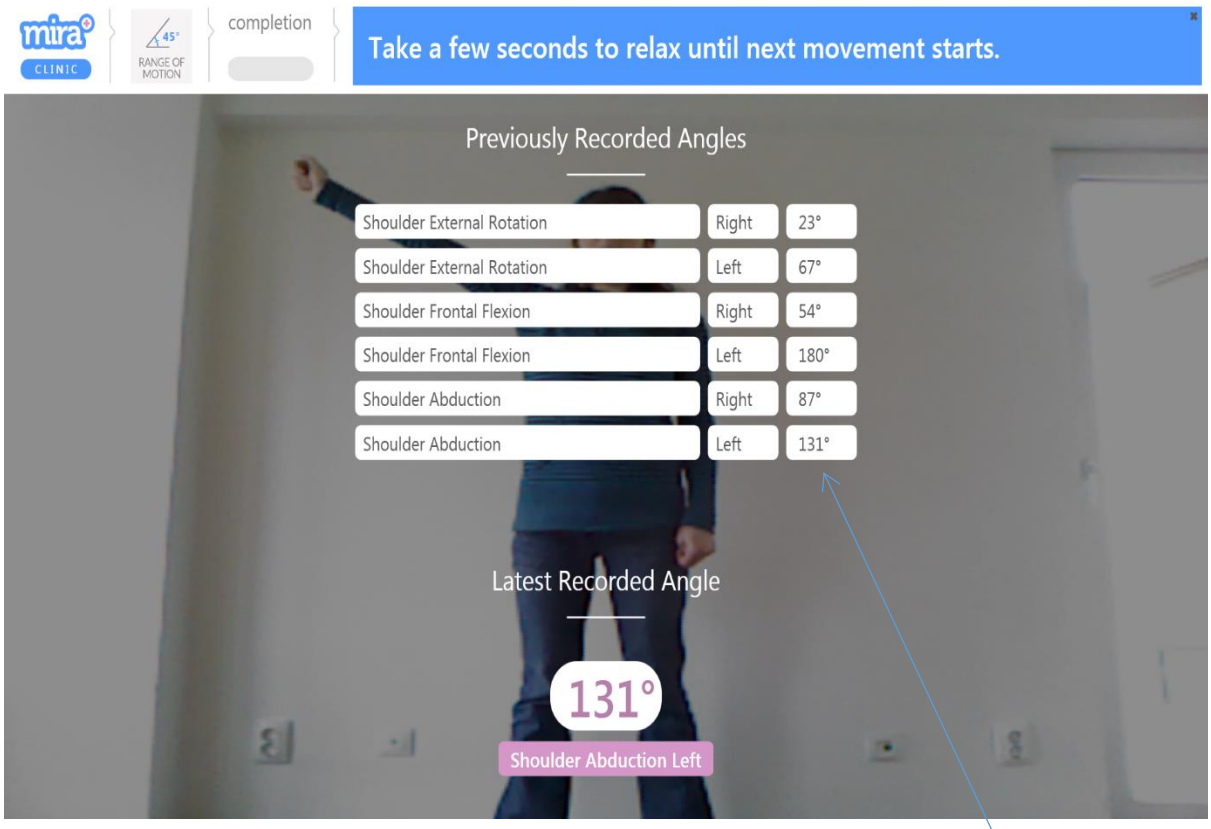

Figure 6 Showing the interface which a subject will see when using the system.

Visual feedback for the range of movement measured in angles.

2.1.10.5 MIRA ASSESSMENT AND VALIDATION OF RANGE OF MOVEMENT

To use this system for the study, the hardware in combination with the Mira rehab platform required validation.

A previous research study using the system was conducted at Manchester Metropolitan University. The aim of the research was to test the accuracy of measuring the shoulder range of movement, using the Mira system against full motion capture laboratory equipment (MoCap) and to compare this with the accuracy of specialist physiotherapist and surgeons measuring the same range of movement. Infrared markers were placed on the thorax and upper limbs of the 49 volunteer participants to allow the motion capture facility to measure the shoulder movements. Movements were then measured by the Mira software and the trained observer.

During validation 1670 measurements were available for analysis. Results showed that there was a good correlation between mocap and the Mira software. The results from this study found that using the MoCap as the standard, Mira Rehab measurement of all cardinal shoulder movements were significantly more consistent than trained observer measurements.

This validation study proves that the Mira software and the hardware are safe and effective in healthy volunteers for range of movement in the shoulder. The next step was to introduce the system to patients whom had previous shoulder problems and complete a feasibility study of the system. The researcher and Chief investigator for this study, completed this feasibility study prior to the main protocol development, which included 10 focus groups with a total of 70 patients who had previously had a shoulder operation (appendix 9). This allowed patients to provide feedback on the usability of the system therefore, at this point it was decided to complete a multicentre randomised controlled study.

2.1.11 MAPPING THE EXERGAMES TO PHYSIOTHERAPY AIMS

Delivering the Exergames through physiotherapy was the next task and it was essential that the Exergames were aligned with physiotherapy goals to enable a physiotherapy protocol using the Exergames to be developed.

A Delphi process was designed by the research team (orthopaedic shoulder surgeon, the researcher and physiotherapist) with an expert focus group composed of the multidisciplinary team in identifying the key objectives of physiotherapy. Significant themes identified included patient education, pain relief, improved Range of Movement and exercise. The movement and exercise category were further divided into five key domains which included the following physiotherapy goals:

1) Range of movement

2) Control

3) Speed

4) Activation of kinetic chain

5) Strength

The physiotherapy goals were then used to understand the aims of the Exergames. Seven Exergames were selected, played by experienced physiotherapists, and weighted for the variables, ROM, Control and Speed. This was then and analysed (table 10). The Exergames were subsequently mapped with their relative weighting in their ability to deliver each of the physiotherapy goals.

Exergames	ROM	Control	Speed
Catch	70%	0%	30%
Firefly	40%	60%	0%
Follow	10%	90%	0%
Izzy the bee	30%	70%	0%
Move	10%	90%	0%
Frog	30%	50%	20%
Atlantis	50%	50%	0%

Table 8 Distribution assigned to the Exergames

The Exergames were then associated to specific timeframes in the rehabilitation programme which were also in line with physiotherapy aims (table 11). This enabled the researcher to formalise the Exergames physiotherapy protocol.

	ROM	Control	Activation of Kinetic chain	Speed	Strength
Timeframe	0-2 weeks	2-4 weeks	2- 4 weeks	6 weeks+	6 weeks +
Appropriate Exergames	Catch Atlantis	Firefly Follow Izzy the bee Move Frog Atlantis	Catch Firefly Follow Izzy the bee Move Frog	Catch Frog	Catch Firefly Follow Izzy the bee Move Frog

Table 9 The Exergames assigned to the appropriate timeframe.

This exercise enabled the researchers to identify the games which were suitable depending on rehabilitation progression. For the patients who were randomised to the experimental arm of the study, a rehabilitation protocol was designed. This was to standardise the games which were prescribed to the patient, although patients were only progressed through their rehabilitation programme once clinically examined and assessed by the research physiotherapist.

2.1.11.1 REHABILITATION PROTOCOL

Week: 1-3

Games: Catch and Atlantis

Level: Easy

Full Schedule - Catch was played by the patient for two minutes using their affect arm. There was a break for 30 seconds, and then Atlantis was played for a further two minutes. Following the full schedule Range of Movement measurements were recorded resulting in a further two minutes.

Week: 3-5

Games: Catch, Firefly, Follow, Izzy the Bee, Move and frog.

Level: Medium

Full Schedule - Izzy the bee was played by the patient for two minutes. There was a scheduled break for thirty second seconds. Fire fly was then played for a further two minutes. Range of Movement measurements were recorded resulting in a further two minutes.

Catch was played by the patient for two minutes. There was a scheduled break for thirty second seconds. Move was then being played for a further two minutes. Range of Movement measurements were recorded resulting in a further two minutes.

Frog was played by the patient for two minutes. There was a scheduled break for thirty second seconds. Izzy the Bee was then played for a further two minutes. Range of Movement measurements are recorded resulting in a further two minutes. Range of movement was set up and prescribed by the research physiotherapist.

Week: 5-7

Games: Catch, Firefly, Follow, Izzy the Bee, Move, Atlantis and frog.

Level: Medium

Full Schedule - Catch was played by the patient for two minutes using a 1-kilogram weight. There was a scheduled break for thirty second seconds. Izzy the Bee was then played for a further two minutes. Range of Movement measurements were recorded resulting in a further two minutes.

Catch was played by the patient for two minutes using 1-kilogram weight. There was a scheduled break for thirty seconds. Atlantis was then being played for a further two minutes. Range of Movement measurements were recorded resulting in a further two minutes.

Frog is to be played by the patient for two minutes. There will be a scheduled break for thirty second seconds. Move using a 1-kilogram weight will then be played for a further two minutes. Range of Movement measurements are recorded resulting in a further two minutes.

Week: 7-9

Games: Catch, Firefly, Follow, Izzy the Bee, Move, Atlantis and frog.

Level: Medium

Full Schedule – Izzy the Bee was played by the patient for two minutes with the patient standing on one leg. There was a scheduled break for thirty second seconds. Firefly using 1-kilogram weight was then played for a further two minutes. Range of Movement measurements were recorded resulting in a further two minutes.

Frog was played by the patient for two minutes. There was a scheduled break for thirty second seconds. Atlantis was then being played for a further two minutes using 1-kilogram weight. Range of Movement measurements were recorded resulting in a further two minutes.

Catch was played by the patient for two minutes. There will be a scheduled break for thirty seconds. Move was then being played for a further two minutes. Range of Movement measurements are recorded resulting in a further two minutes.

Week: 9-12

Games: Catch, Firefly, Follow, Izzy the Bee, Move, Atlantis and frog.

Level: Hard

Full Schedule – Catch was played by the patient for two minutes with the patient standing on one leg. There was a scheduled break for thirty second seconds. Izzy the Bee was then played for a further two minutes. Range of Movement measurements were recorded resulting in a further two minutes.

Catch using 1-kilogram weight was played by the patient for two minutes. There was a scheduled break for thirty second seconds. Atlantis played for a further two minutes standing on one leg. Range of Movement measurements were recorded resulting in a further two

minutes.

Frog with 1-kilogram weight is to be played by the patient for two minutes. There was a scheduled break for thirty second seconds. Move was then being played for a further two minutes. Range of Movement measurements are recorded resulting in a further two minutes.

2.1.12 OUTCOMES

The study outcomes included quality of life, health outcome and patient engagement data. To evaluate these outcomes in the study, the following assessment tools were used to quantify this data:

1) Pain –assessed using the EQ5D Visual Analogue Scale (appendix 4). The EQ5D incorporates measurements specific to pain. This is the patient's perception of their own pain. Patients were required to choose a statement which best describes their pain today:

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

This statement was completed pre-operatively, 3 months and again at 12 months.

2) Quality of Life - the EQ5D (appendix 4) which is a generic questionnaire was used to measure the patients quality of life. The EQ5D is divided into 5 specific domains with an aim to capture the patients perception of their own health on the following:

- Mobility
- Self- Care
- Usual Activities

- Pain

- Anxiety and Depression

Within the tool the patient completed a Visual Analogue Scale which allows the patient (VAS) to provide a score on their health status. The EQ5D which includes VAS was required to be completed by the patient preoperatively, 3 months and 12 months.

3) Health Outcome – assessed using a combination of two validated scoring tools, the Oxford Shoulder Score (appendix 5) and the Disability Arm Shoulder and Hand (appendix 6). Both tools were required to be completed by the patient pre-operatively and again at 3 months and 12 months.

Health outcome was also measured using Range of movement data. This enabled the researcher to identify if a significant difference in post-surgical improvement in range of movement when physiotherapy is aided by Exergames.

4) Engagement – patient engagement was collected using a combination of the diaries and also the Mira software. Patients engagement data from the physiotherapy plus exergames group included:

Identifying the number of minutes each patient played the games, compared to the number of minutes for each session which was prescribed by the research physiotherapist. This data was reviewed over the 12-week rehabilitation programme.

2.1.13 DATA EXTRACTION

Patient data which is stored within Mira was extracted into a Microsoft Excel spreadsheet.

Data extracted from the Mira system for all patients includes the following Range of Movement data which is measured in degrees:

- External Rotation

- Frontal flexion
- Abduction

The above Range of Movement data was extracted for patients at the following time points:

- **Pre-operatively –** this was completed for all patients on the day of surgery, before their surgical procedure.
- **The standard physiotherapy group**- Range of Movement using the hardware and software, was completed postoperatively once every 2 weeks, when the patient attended the research clinic for their scheduled physiotherapy appointments.
- **The standard physiotherapy plus exergames group**- Range of movement was completed at the end of each prescribed rehabilitation session, the patient was prescribed a session to play the games daily.

Additional engagement data was collected for patients randomised into the standard physiotherapy plus the Exergames group, this includes:

- **Total days of activity.** This is defined as the total number of days which the patient has logged into the Mira software (n=84).
- **Total time active in all sessions.** This includes the total number of minutes the patient has been active, defined as logged into the Mira software and playing the games. This data was focusing on all prescribed rehabilitation sessions over the 12-week post-operative period.
- **Average involvement in all sessions.** Time involved in each of the prescribed sessions. This was averaged over the 12-week rehabilitation programme and presented as a percentage.
- **Total time moving whilst exercising**. The total time a patient is actively moving whilst playing the games. This was defined by capturing wrist movement data

and identifying the following for each patient:

1) Wrist speed - this an average measured in cm/s.

2) Wrist acceleration- measured in cm/s2 (an average)

3) Wrist Distance – total distance over the 12 week rehabilitation program, measured in cm.

2.1.14 DATA ANALYSIS

Patient Reported Outcome Measures were completed by each patient at the relevant time frames (pre -operatively, 3 months and 12 months). Differences in the Patient Reported Outcome Measures (OSS, DASH EQ5D and VAS) will be compared using independent samples T tests (two tailed) using SPSS 22 software. Each patient pre-operative score was compared against the 3 month score.

Range of Movement was completed by each patient at the relevant time frames dependant on the group the patient was assigned to. Differences in the Range of Movement between both groups will be compared. Pre-operative Range of Movement measurement and 3 month measurements will be analysed. These metrics will be compared using independent samples T tests (two tailed) using SPSS 22 software.

Patient Engagement data will be analysed looking at correlations between the ROM and the wrist data. The following will be compared:

1. Range of movement and wrist speed
2. Range of movement and wrist acceleration
3. Range of movement and wrist distance.

3 RESULTS

INTRODUCTION

Twenty subjects were analyzed from a larger study over a nine-month period from 01/04/2016 until 06/01/2017. Thirteen of the subjects were female and seven males, all located within the Greater Manchester region. Fourteen of the twenty subjects had surgery to their left shoulder and six subjects to their right. Nineteen subjects were recruited from the main center, Manchester Foundation Trust and one subject was recruited from Bolton Royal NHS Foundation Trust. Complete set of data was collected for all twenty subjects, control group (n= 10) and experimental group (n= 10).

Subject	Age	Location	Trust (recruitment)	Sex	Side
C1	39	Manchester	Manchester Foundation Trust	Female	Left
C2	52	Manchester	Manchester Foundation Trust	Female	Left
C3	65	Manchester	Manchester Foundation Trust	Female	Right
C4	69	Manchester	Manchester Foundation Trust	Male	Right
C5	58	Manchester	Manchester Foundation Trust	Female	Left
C6	66	Manchester	Manchester Foundation Trust	Female	Left
C7	67	Manchester	Manchester Foundation Trust	Female	Left
C8	70	Manchester	Manchester Foundation Trust	Male	Left
C9	40	Manchester	Manchester Foundation Trust	Male	Left
C10	65	Manchester	Manchester Foundation Trust	Male	Left
T1	27	Manchester	Manchester Foundation Trust	Male	Right
T2	52	Manchester	Manchester Foundation Trust	Female	Left
T3	42	Manchester	Manchester Foundation Trust	Female	Right
T4	57	Manchester	Manchester Foundation Trust	Female	Left
T5	51	Manchester	Manchester Foundation Trust	Male	Right
T6	42	Bolton	Bolton NHS Foundation Trust	Female	Left
T7	58	Manchester	Manchester Foundation Trust	Female	Left
T8	48	Manchester	Manchester Foundation Trust	Male	Right
T9	44	Manchester	Manchester Foundation Trust	Female	Left
T10	44	Manchester	Manchester Foundation Trust	Female	Left

Table 10 Subject demographics including; Date of Birth, location, side, sex and Trust where subject was recruited. Subjects listed C1-C10 have been randomised to the control arm of the study and listed T1-T10 are test subjects.

3.1 Range of Movement

Range of movement measurements (external rotation, forward flexion and abduction) were completed for each subject pre-operatively, 6 weeks and 12 weeks post-operative. Both the range of movement and the change in the range of movement, between the two groups, were compared. An ANOVA (single factor) was conducted for each of the measurements of movement for each group separately to test the hypothesis that there were no differences between assessment points (pre-operatively, 6 weeks and 12 weeks post-operative).

Then a Wilcoxon rank test was used to compare specific changes (for each of the measurements for each group):

- Pre-operative assessment to 6 weeks
- Pre-operative assessment to 12 weeks
- 12 weeks to 6 weeks assessments

Percentage change, at week 6 and week 12, to the pre-operative values for all movements were also calculated. The Mann Whitney U Test was used for between group comparisons.

3.1.1 External Rotation Results

Figure 7 shows the external rotation at all time points for all subjects in both groups. Figure 8 shows the percentage change from 6 weeks to pre-operative and 12 weeks to pre-operative assessment for all subjects in both groups.

Table 13 shows the values for the external rotation for the intervention subjects at all time points for all subjects with descriptive statistics. Table 14 shows the external rotation results for the control subjects. Also results are shown for the statistical test comparing results between time points.

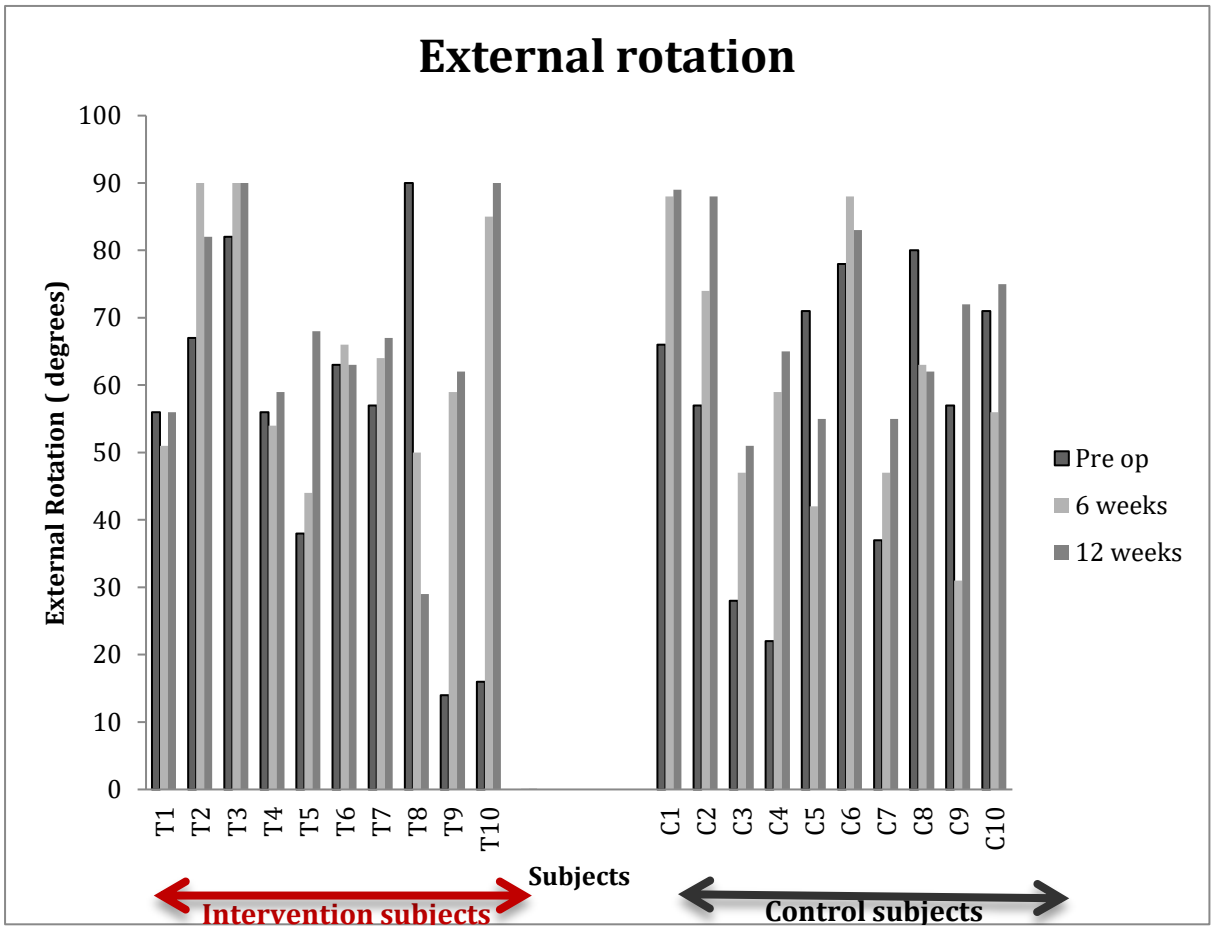

Figure 7 External shoulder rotation for pre-operative, 6 weeks and 12 weeks for all subjects in both the intervention (subjects T1 to T10) and control group (C11-C20).

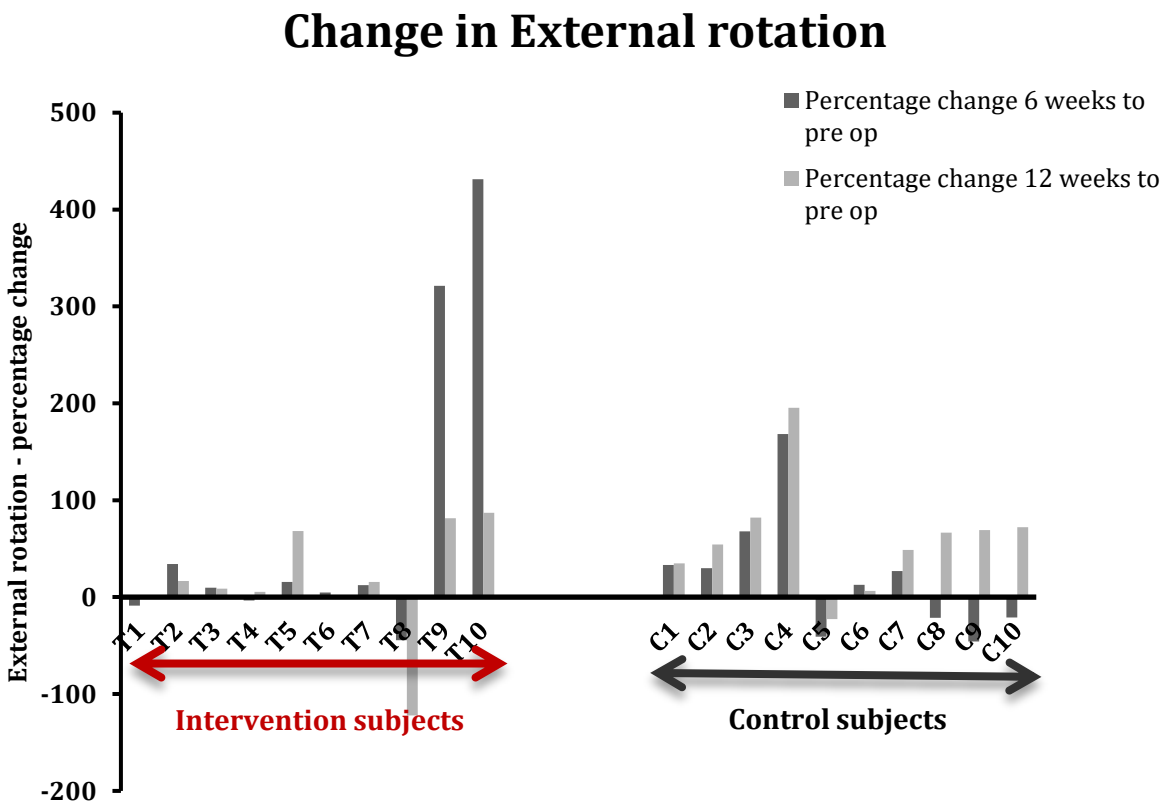

Figure 8 External shoulder rotation percentage change at 6 weeks to pre-operative and 12 weeks to pre -operative assessments, for all subjects in both the intervention (subjects 1 to 10) and control groups (11-20).

Intervention Group:

Subject	Pre-op (degrees)	6 weeks (Degrees)	12 weeks (Degrees)	Percentage Change 6 weeks – pre-op	Percentage Change 12 weeks – pre-op
T1	56	51	56	-8.9%	0.0%
T2	67	90	82	34.3%	16.7%
T3	82	90	90	9.8%	8.9%
T4	56	54	59	-3.6%	5.6%
T5	38	44	68	15.8%	68.2%
T6	63	66	63	4.8%	0.0%
T7	57	64	67	12.3%	15.6%
T8	90	50	29	-44.4%	-122.0%
T9	14	59	62	321.4%	81.4%
T10	16	85	90	431.3%	87.1%
Mean	53.9	65.3	66.6		
Standard Dev	25.0	17.2	18.1		
Minimum	14.0	44.0	29.0		
Maximum	90.0	90.0	90.0		

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	*976.4667*	*2*	*488.2333*	*1.169743*	***0.325688***	*3.354131*
Within Groups	*11269.4*	*27*	*417.3852*			
Total	*12245.87*	*29*				

Table 11 : External Rotation results for intervention group at pre-operative assessment, 6 weeks and 12 weeks post- operative with results for ANOVA

ANOVA showed no significant difference between assessment points for external rotation for the interventi

The Wilcoxon paired statistical test was used to compare mean difference for the intervention group at 6 weeks to pre-operative.

At 6 weeks to pre-operative the mean difference was 11.4 p= 0.114. At 12 weeks to 6 weeks

Mean difference was 1.3 p= 0.512 and 12 weeks to pre-operative mean difference 12.7 p=0.123.

Control Group

Subject	Pre-op (Degrees)	6 weeks (Degrees)	12 weeks (Degrees)	Percentage Change 6 weeks < pre-op	Percentage Change 12 weeks < pre-op
C1	66	88	89	33.3%	34.8%
C2	57	74	88	29.8%	54.4%
C3	28	47	51	67.9%	82.1%
C4	22	59	65	168.2%	195.5%
C5	71	42	55	-40.8%	-22.5%
C6	78	88	83	12.8%	6.4%
C7	37	47	55	27.0%	48.6%
C8	80	63	62	-21.3%	-22.5%
C9	57	31	72	-45.6%	26.3%
C10	71	5	75	-21.1%	5.6%
Mean	56.7	59.0	69.5		
StandardDev	20.8	19.1	14.1		
Minimum	22.0	31.0	51.0		
Maximum	80.0	88.0	89.0		

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	905.6	2	452.8	1.361562	***0.27329***	3.354131
Within Groups	8979.1	27	332.5593			

Total	9884.7	29

Table 12 External Rotation descriptive statistics results and the results from Wilcoxon paired statistical test for the control group at pre-operative, 6 weeks and 12 weeks post-operative, also Including mean, standard deviation.

ANOVA showed no significant difference between assessment points for external rotation for the control gr

The Wilcoxon paired statistical test was used to compare mean difference for the control group at 6 weeks pre-operative. At 6 weeks to pre-operative the mean difference was 2.8 p= 0.759. At 12 weeks to 6 weeks

Mean difference was 10.0 p= 0.025 and 12 weeks to pre-operative mean difference 12.8 p=0.066.

The mean value at pre-operative for the control group was 61.5 degrees and intervention group were 56.5 degrees. There was no difference at 6 weeks post- operative to baseline in the control group (mean difference 2.8, p= 0.759) compared to the intervention group (mean difference 11.4 p =0.114). There was a trend showing an improvement at 12 weeks post-operative compared to baseline in both the control group (mean difference 12.8 degrees, p=0.066) and intervention group (mean difference of 12.7 degrees, p =0.123).

3.1.1.1 Intergroup Comparison – Pre- operative

Comparison between the Intervention and Control Group at pre – operative assessment was performed using the Mann Whitney U Test.

At pre-op there was there was no difference between the control group, who had an external rotation of 56.7, and the intervention group who had 53.9 ($p < 0.653$; Mann-Whitney U Test) (figure 9).

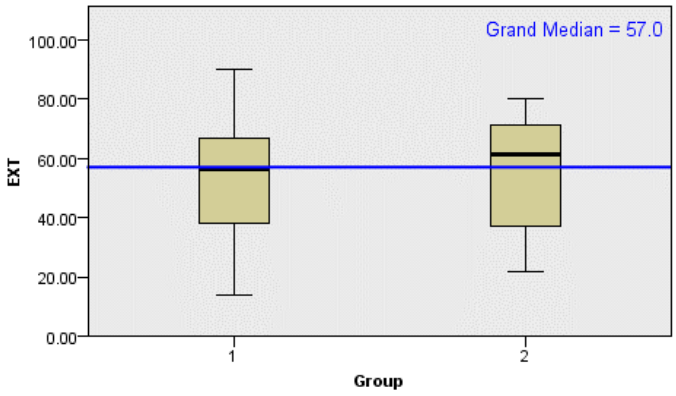

Figure 9 Comparison of external rotation between the Intervention and Control Group at pre – operative assessment was performed using the Mann Whitney U Test.

3.1.1.2 Intergroup Comparison – 6 Weeks Post-Operative

Comparison between the Intervention and Control Group at post – operative assessment using the Mann Whitney U Test.

At 6 weeks post-operative there was no difference between the control group, external rotation of 59.5, and the intervention group 65.3 ($p < 0.653$; Mann-Whitney U Test) (figure 10).

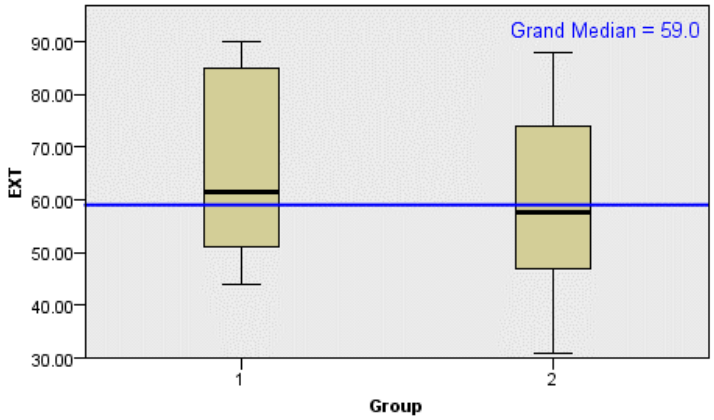

Figure 10 Comparison of external rotation between the median for both the Intervention and control group at 6 weeks post-operative.

3.1.1.3 Intergroup Comparison –12 Weeks Post-Operative

Comparison between the Intervention and Control Group at 12 weeks post – operative assessment using the Mann Whitney U Test.

At 12 weeks post-operative there was no difference between the control group for external rotation of 69.5, and the intervention group 66.6 ($p < 0.971$; Mann-Whitney U Test) (figure 11).

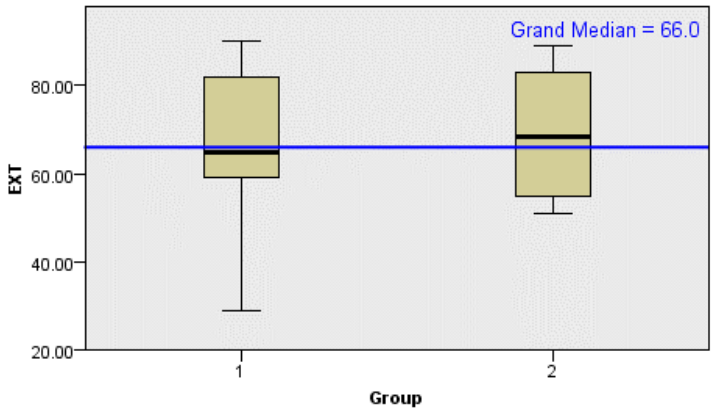

Figure 11 Comparison of external rotation between the median for both the Intervention and control group at 12 weeks post-operative.

3.1.1.4 Intergroup Comparison – Percentage changes 6 Weeks to pre-operative

Comparison between the percentage change for the Intervention and Control Group at 6 weeks to pre– operative assessment was made using the Mann Whitney U Test.

At 6 weeks to pre-operative there was no difference between the control group, percentage change of 21%, and the intervention group 77% ($p < -0.350$; Mann-Whitney U Test) (figure 12).

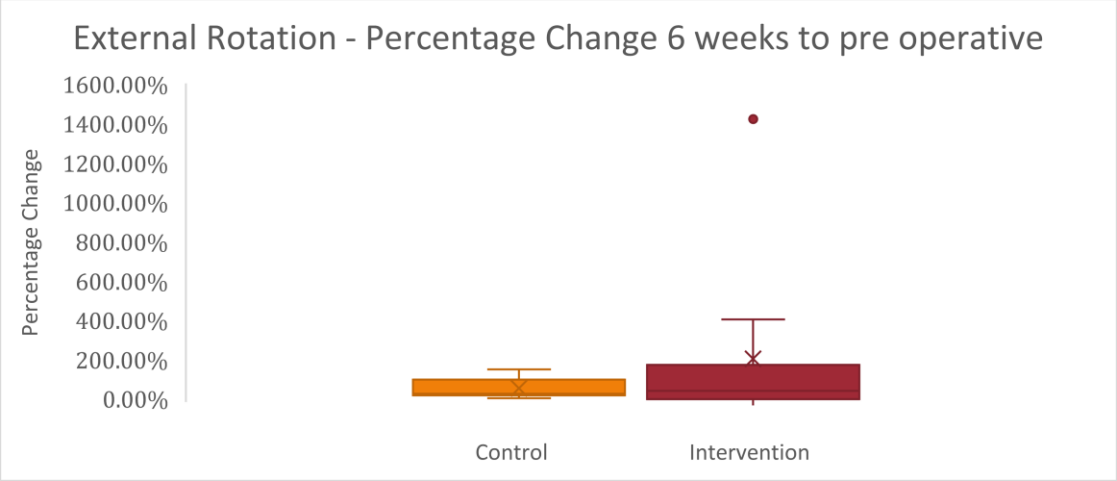

Figure 12 Comparison between the percentage change for both the Intervention and control group at 6 weeks to pre- operative

3.1.1.5 Intergroup Comparison – Percentage changes 12 Weeks to pre-operative

Comparison between the percentage change for the Intervention and Control Group at 12 weeks to pre– operative assessment using the Mann Whitney U Test.

At 12 weeks to pre-operative there was no difference between the control group, who percentage change of 40 %, and the intervention group 16% ($p < -0.433$; Mann-Whitney U Test) (figure 13).

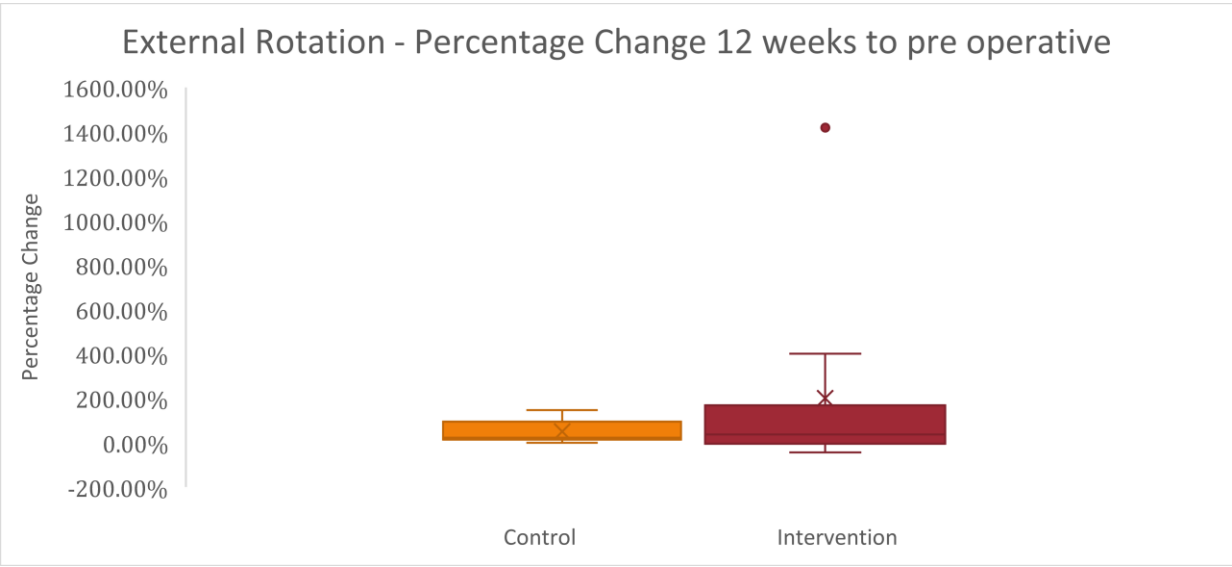

Figure 13 Comparison between the percentage change for both the Intervention and control group at 12 weeks to pre- operative.

3.1.2 Forward Flexion Results

Figure 14 shows the external rotation results for all subjects and figure 15 shows the percentage change from 6 weeks to pre-operative and 12 weeks to pre-operative assessment. Table shows the external rotation results for the intervention subjects. Table 18 shows the external rotation results for the control subjects.

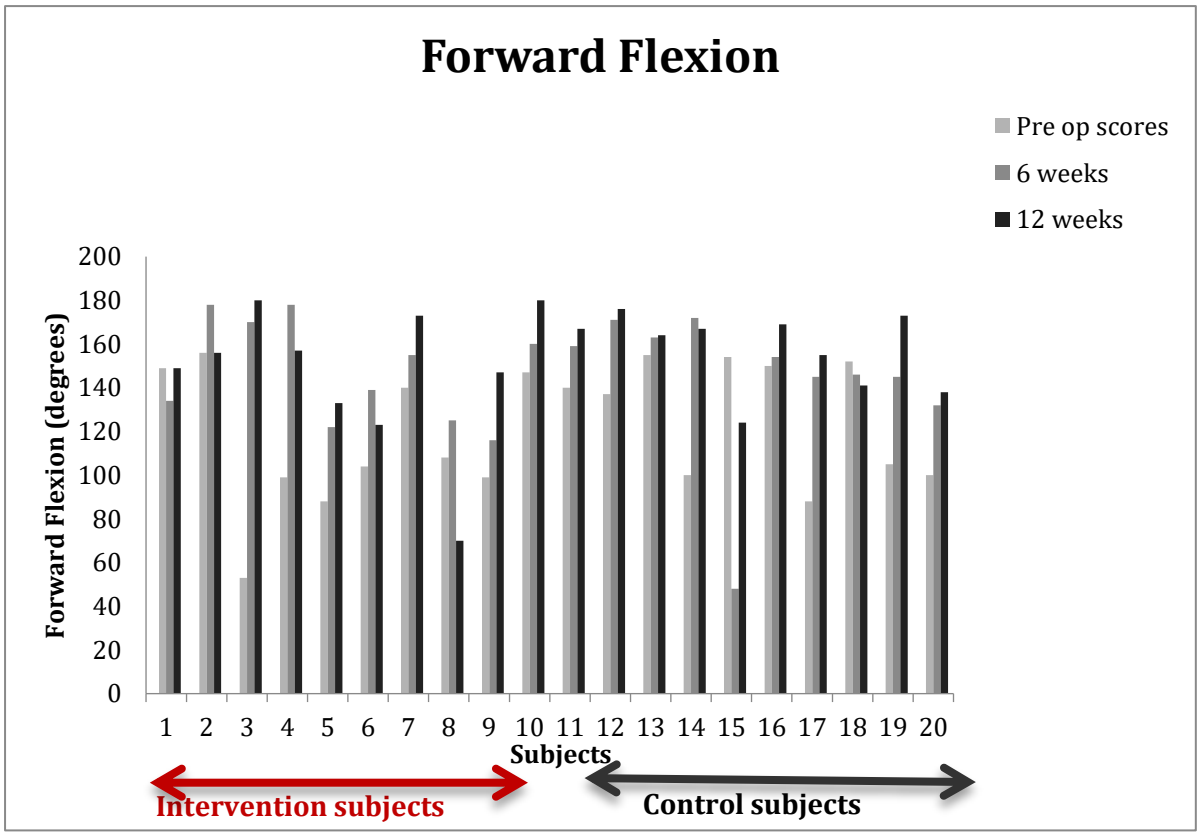

Figure 14: Forward flexion for all subjects in both the intervention (subjects T1 to T10) and control groups (C11-C20) at pre-op, 6 weeks and 12 weeks.

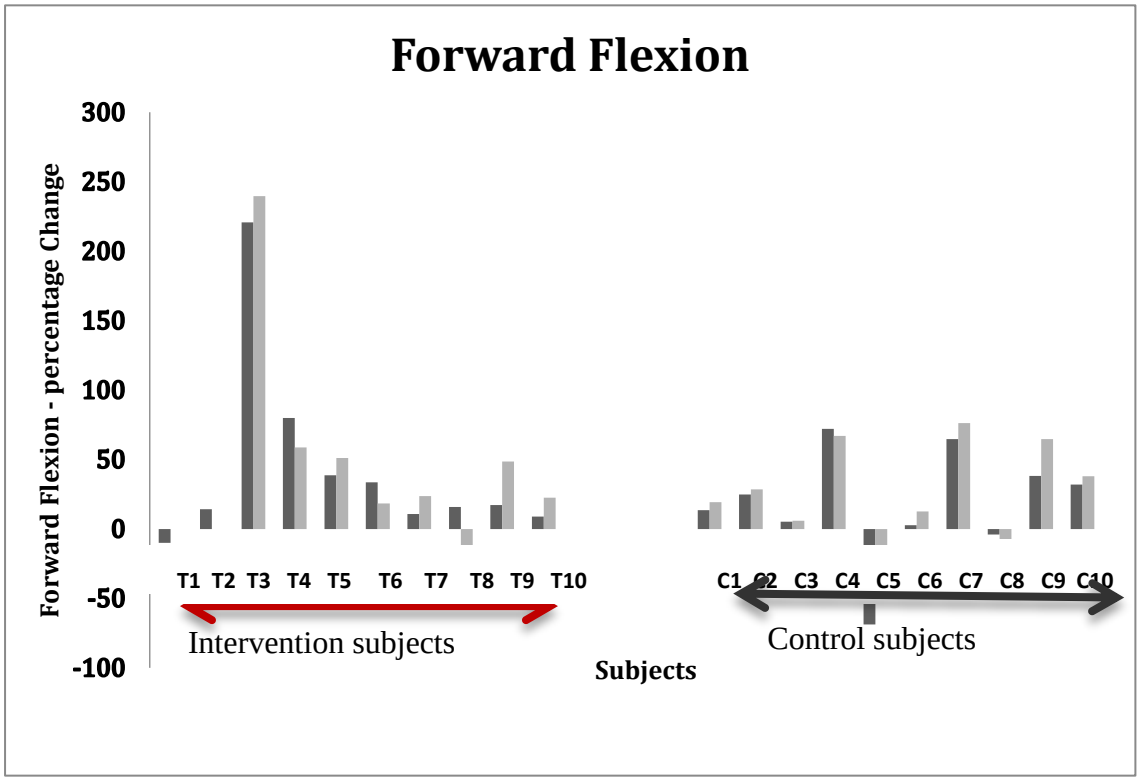

Figure 15: Forward flexion percentage change at 6 weeks to pre-operative and 12 weeks to pre -operative assessments, for all subjects in both the intervention (subjects 1 to 10) and control groups (11-20).

Intervention Group:

Subject	pre op	6 week	12 week	Percent change 6 weeks < pre op	Percentage 12 weeks <pre op
T1	149	134	149	-10.1%	0.0%
T2	156	178	156	14.1%	0.0%
T3	53	170	180	220.8%	239.6%
T4	99	178	157	79.8%	58.6%
T5	88	122	133	38.6%	51.1%
T6	104	139	123	33.7%	18.3%
T7	140	155	173	10.7%	23.6%
T8	108	125	70	15.7%	-35.2%
T9	99	116	147	17.2%	48.5%
T10	147	160	180	8.8%	22.4%
Mean	114.3	147.7	146.8		
Standard Dev	32.8	23.5	32.8		
Minimum	53	116	70		
Maximum	156	178	180		

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	7242.067	2	3621.033	3.997412	***0.030155***	3.354131
Within Groups	24457.8	27	905.8444			
Total	31699.87	29				

Table 13 Forward Flexion results for Intervention group at pre-operative assessment, 6 weeks and 12 weeks post- operative, also including percentage changes at 6 weeks and 12 weeks.

ANOVA showed a significant difference between assessment points for forward flexion in

the intervention group.

The Wilcoxon paired statistical test was used to compare mean difference for the intervention group. At 6 weeks to pre pre-operative, 12 weeks to 6 weeks and 12 weeks to pre-operative.

At 6 weeks to pre-operative the mean difference was 33.4 p= 0.011. At 12 weeks to 6 weeks

Mean difference was -0.9 p= 0.878 and 12 weeks to pre-operative mean difference was 32.5 p=0.050.

Control Group:

Subject	Pre op	6 Weeks	12 Weeks	Percentage change 6 weeks < pre op	Percentage change 12 weeks < pre op
C1	140	159	167	13.6%	19.3%
C2	137	171	176	24.8%	28.5%
C3	155	163	164	5.2%	5.8%
C4	100	172	167	72.0%	67.0%
C5	154	48	124	-68.8%	-19.5%
C6	150	154	169	2.7%	12.7%
C7	88	145	155	64.8%	76.1%
C8	152	146	141	-3.9%	-7.2%
C9	105	145	173	38.1%	64.8%
C10	100	132	138	32.0%	38.0%
Mean	128.1	143.5	157.4		
Standard Dev	26.6	35.8	17.3		
Minimum	88	48	124		
Maximum	155	172	176		

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	4296.2	2	2148.1	2.80623	**0.07811**	3.354131
Within Groups	20667.8	27	765.474			
Total	24964	29				

Table 14 Forward flexion results for control group at pre-operative assessment, 6 weeks and 12 weeks post-operative, also including percentage changes at 6 weeks and 12 weeks

ANOVA showed a significant difference between assessment points for forward flexion in the control group.

The Wilcoxon paired statistical test was used to compare mean difference for the control group at 6 weeks to pre pre-operative, 12 weeks to 6 weeks and 12 weeks to pre-operative.

At 6 weeks to pre-operative the mean difference was 15.4 p= 0.114. At 12 weeks to 6 weeks

Mean difference was 13.9 p= 0.028 and 12 weeks to pre-operative mean difference 29.3 p=0.037.

The mean value at pre-operative for the control group is 128.1 degrees and intervention group were 114.3 degrees. There was no change at 6 weeks post- operative to baseline the control group (mean difference 15.4, p= 0.114) compared to the intervention group (mean difference 33.4 p =0.011). There was a significant improvement at 12 weeks post- operative compared to baseline in both the control group (mean difference 29.3 degrees, p=0.03) and intervention group (mean difference of 32.5 degrees, p =0.050).

3.1.2.1 Intergroup Comparison – Pre- operative

Comparison between the Intervention and Control Group at pre – operative assessment using the Mann Whitney U Test.

At pre-op there was there was no difference between the control group, external rotation of 128.1, and the intervention group 114.3 ($p < 0.656$; Mann-Whitney U Test) (figure 15).

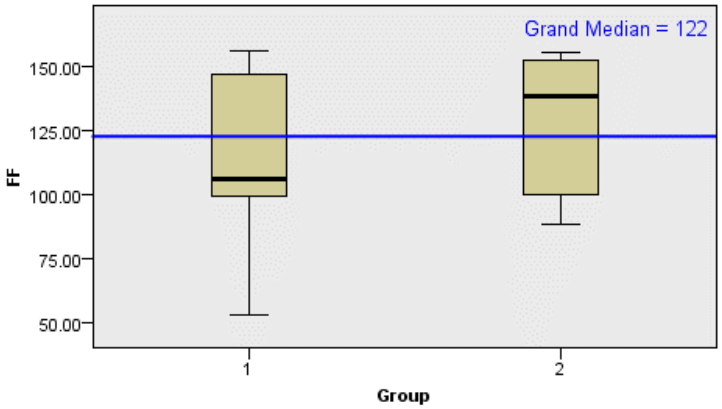

Figure 15: Comparison of forward flexion between the median for both the intervention and control group at pre- operative.

3.1.2.2 Intergroup Comparison – 6 weeks Post- operative

Comparison between the Intervention and Control Group at 6 weeks post – operative assessment using the Mann Whitney U Test.

At 6 weeks post-operative there was there was no difference between the control group, forward flexion of 143, and the intervention group 147 ($p < 0.912$; Mann-Whitney U Test) (figure 16).

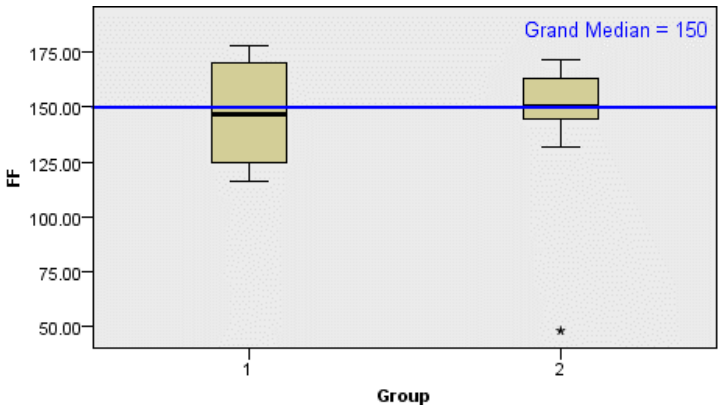

Figure 16 Comparison of external rotation between the median for both the Intervention and control group at 6 weeks post- operative.

3.1.2.3 INTERGROUP COMPARISON – 12 WEEKS POST- OPERATIVE

Comparison between the Intervention and Control Group at 12 weeks post – operative assessment using the Mann Whitney U Test.

At 12 weeks post-operative there was there was no difference between the control group, forward flexion of 157.5, and the intervention group 146.8 (p <0.912; Mann-Whitney U Test) (figure 17).

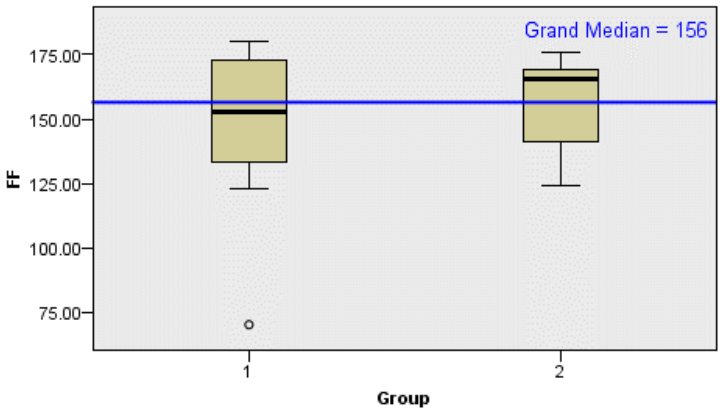

Figure 17 Comparison of forward flexion between the median for both the intervention and control group at 12 weeks post- operative.

3.1.2.4 INTERGROUP COMPARISON – PERCENTAGE CHANGES 6 WEEKS TO PRE-OPERATIVE

Comparison between the percentage change for the Intervention and Control Group at 6 weeks to pre– operative assessment using the Mann Whitney U Test.

At 6 weeks to pre-operative there was no difference between the control group, who percentage change of 18%, and the intervention group 42% (p < -0.350; Mann-Whitney U Test) (figure 18).

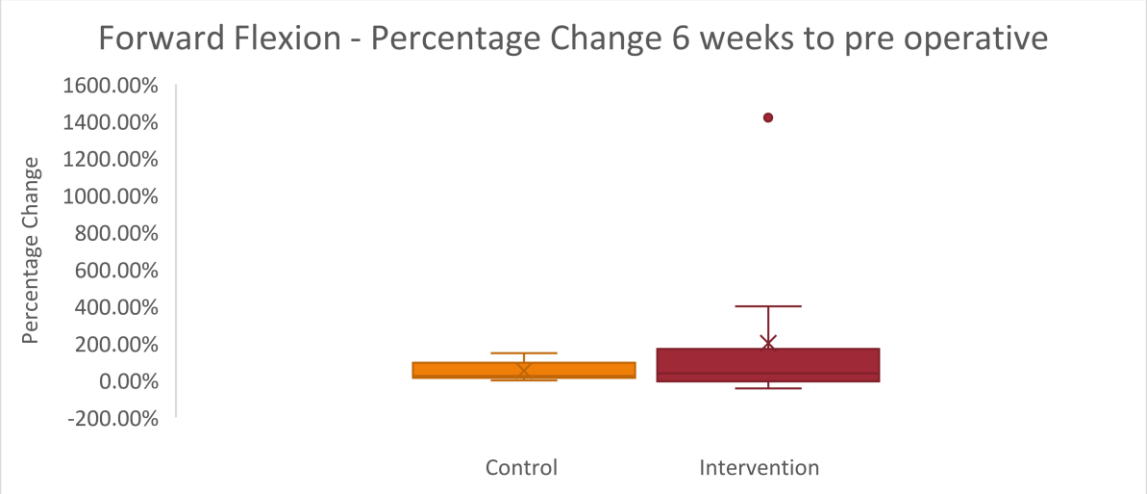

Figure 18 Comparison between the percentage change for both the Intervention and control group at 12 weeks to pre- operative.

3.1.2.5 Intergroup Comparison – Percentage changes 12 Weeks to pre-operative

Comparison between the percentage for the Intervention and Control Group at 12 weeks to pre– operative assessment using the Mann Whitney U Test.

At 12 weeks to pre-operative there was no difference between the control group, percentage change of 28%, and the intervention group 42% ($p < -0.350$; Mann-Whitney U Test) (figure 19).

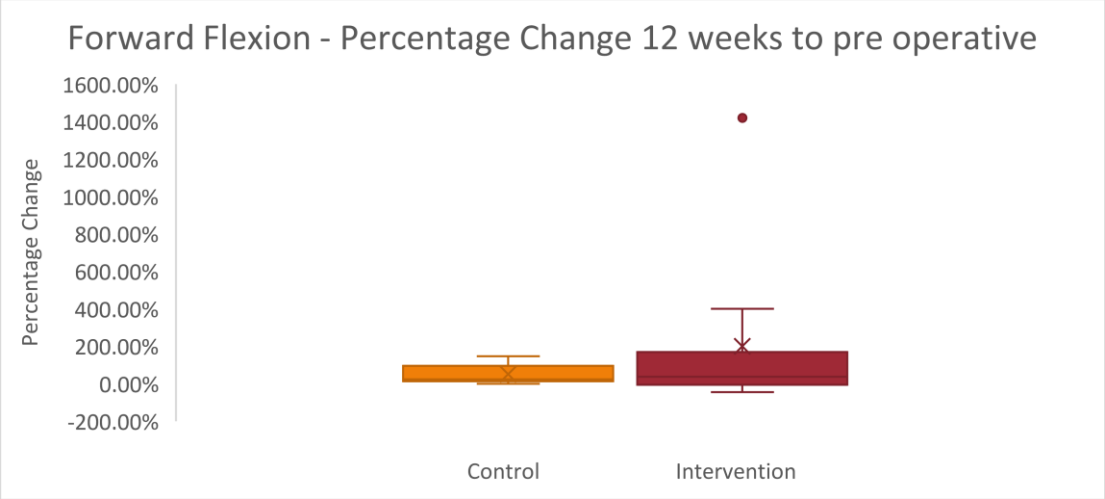

Figure 19 Comparison of forward flexion between the percentage change for both the Intervention and control group at 12 weeks to pre- operative.

3.1.3 Abduction

Figure 20 shows the external rotation results for all subjects and figure 21 shows the percentage change from 6 weeks to pre-operative and 12 weeks to pre-operative assessment. Table 10 shows the external rotation results for the intervention subjects. Table 11 shows the external rotation results for the control subjects.

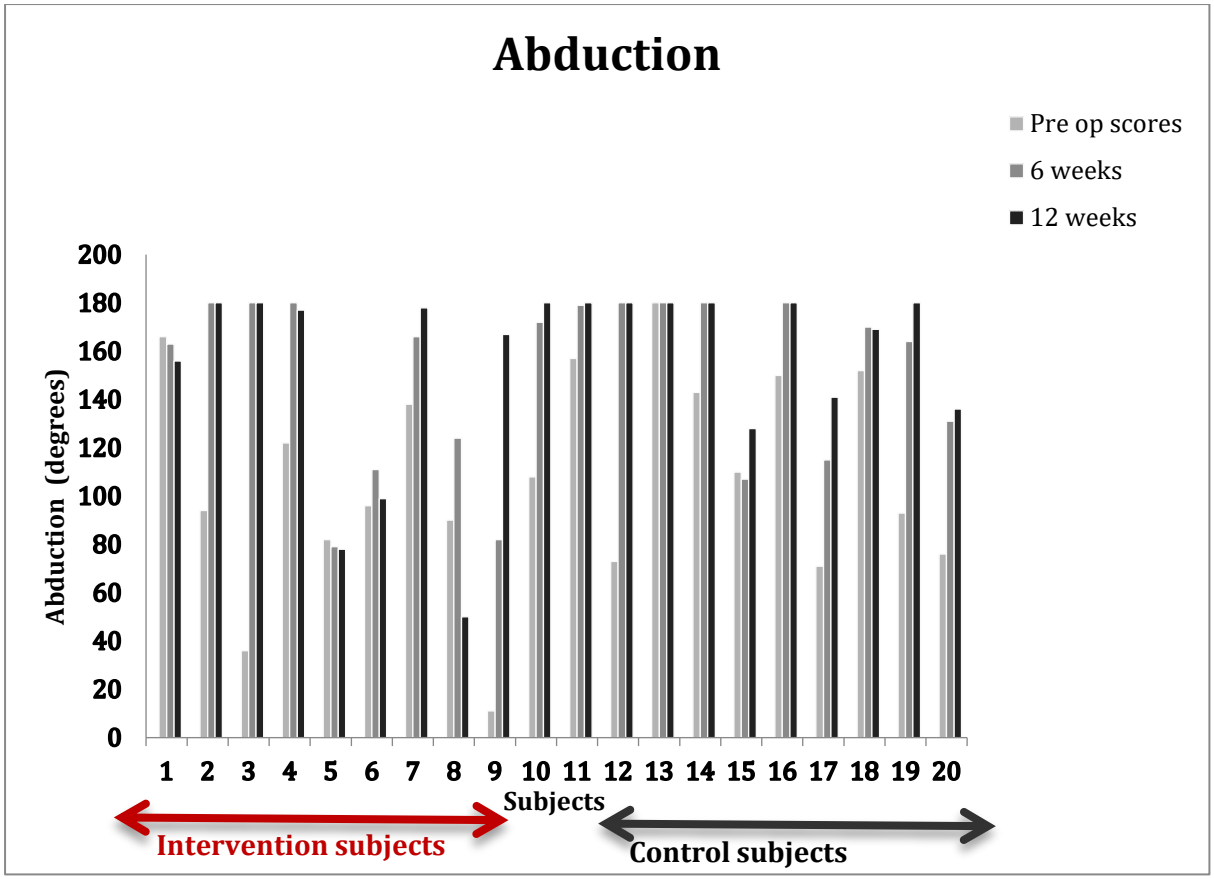

Figure 20 Abduction results for all subjects in both the intervention (subjects T1 to T10) and control groups (C11-C20) at pre-op, 6 weeks and 12 weeks.

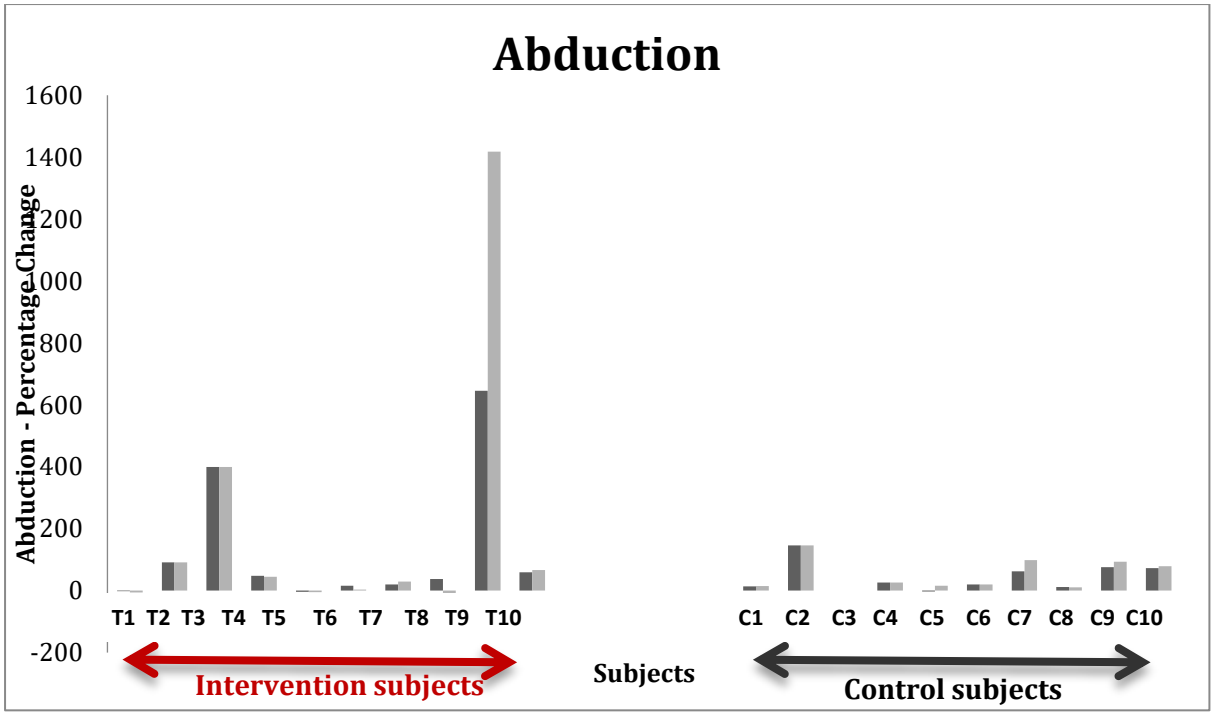

Figure 21 Abduction percentage change at 6 weeks to pre-operative and 12 weeks to pre -operative assessments, for all subjects in both the intervention (subjects 1 to 10) and control groups (11-20).

Intervention Group:

Subject	pre op	6 week	12 week	Percentage change 6 weeks < pre op	Percentage change 12 weeks < pre op
T1	166	163	156	-1.8%	-6.0%
T2	94	180	180	91.5%	91.5%
T3	36	180	180	400.0%	400.0%
T4	122	180	177	47.5%	45.1%
T5	82	79	78	-3.7%	-4.9%
T6	96	111	99	15.6%	3.1%
T7	138	166	178	20.3%	29.0%
T8	90	124	50	37.8%	-44.4%
T9	11	82	167	645.5%	1418.2%
T10	108	172	180	59.3%	66.7%
Mean	94.3	143.7	144.5		
Standard	45.3	40.9	49.4		
Minimum	11	79	50		
Maximum	166	180	180		

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	16536.8	2	8268.4	4.014458	0.029761	3.354131
Within Groups	55610.7	27	2059.656			
Total	72147.5	29				

Table 15 Abduction results for Intervention group at pre-operative assessment, 6 weeks and 12 weeks post- operative, also including percentage changes at 6 weeks and 12 weeks.

ANOVA showed a significant difference between assessment points for abduction in the intervention group.

The Wilcoxon paired statistical test was used to compare mean difference for the intervention group at 6 weeks to pre pre-operative, 12 weeks to 6 weeks and 12 weeks to pre-operative.

At 6 weeks to pre-operative the mean difference was 49.2 p= 0.012. At 12 weeks to 6 weeks

Mean difference was 0.8 p= 0.944 and 12 weeks to pre-operative mean difference 50.2 p=0.066.

Control:

Subject	Pre op	6 week	12 week	Percent Change 6 weeks < pre op	Percent Change 12 weeks < pre op
C1	157	179	180	14.0%	14.6%
C2	73	180	180	146.6%	146.6%
C3	180	180	180	0.0%	0.0%
C4	143	180	180	25.9%	25.9%
C5	110	107	128	-2.7%	16.4%
C6	150	180	180	20.0%	20.0%
C7	71	115	141	62.0%	98.6%
C8	152	170	169	11.8%	11.2%
C9	93	164	180	76.3%	93.5%
C10	76	131	136	72.4%	78.9%
Mean	120.5	158.6	165.4		
StandardDev	40.5	29.3	21.4		
Minimum	71	107	128		
Maximum	180	180	180		

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	11712.87	2	5856.433	5.92727	0.00734	3.354131
Within Groups	26677.3	27	988.0481			
Total	38390.17	29				

Table 16 Abduction results for control group at pre-operative assessment, 6 weeks and 12 weeks post operative, also including percentage changes at 6 weeks and 12 weeks.

ANOVA showed a significant difference between assessment points for abduction in the control group.

The Wilcoxon paired statistical test was used to compare mean difference for the control group at 6 weeks to pre pre-operative, 12 weeks to 6 weeks and 12 weeks to pre-operative.

At 6 weeks to pre-operative the mean difference was 38.1 p= 0.011. At 12 weeks to 6 weeks

Mean difference was 6.8 p= 0.058 and 12 weeks to pre-operative mean difference 44.9 p=0.058

The mean value at pre-operative for the control group is 120 degrees and intervention group were 94 degrees. There was a significant change at 6 weeks post- operative to baseline in both the control group (mean difference 38, p= 0.011) compared to the intervention group (mean difference 49 p =0.012). There was trend in improvement at 12 weeks post- operative compared to baseline in both the control group (mean difference 44 degrees, p=0.058) and intervention group (mean difference of 50 degrees, p =0.058).

3.1.3.1 Intergroup Comparison – Pre- operative

Comparison between the median for the Intervention and Control Group at pre – operative assessment using the Mann Whitney U Test.

At pre-op there was there was no difference between the control group, abduction of 120, and the intervention group 94 ($p < 0.656$; Mann-Whitney U Test) (figure 24).

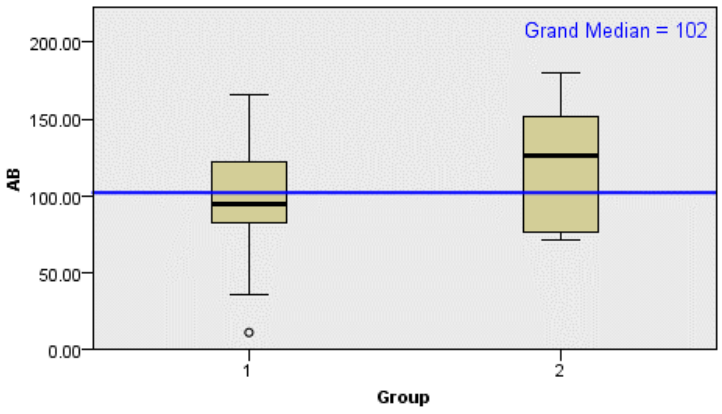

Figure 22 Comparison of abduction between the median for both the intervention and control group at pre-operative

3.1.3.2 Intergroup Comparison – 6 Weeks Post-operative

Comparison between the distribution for the Intervention and Control Group at 6 weeks assessment using the Mann Whitney U Test.

At 6 weeks post-operative there was there was no difference between the control group, abduction of 158, and the intervention group 143 ($p < 0.436$; Mann-Whitney U Test) (figure 25).

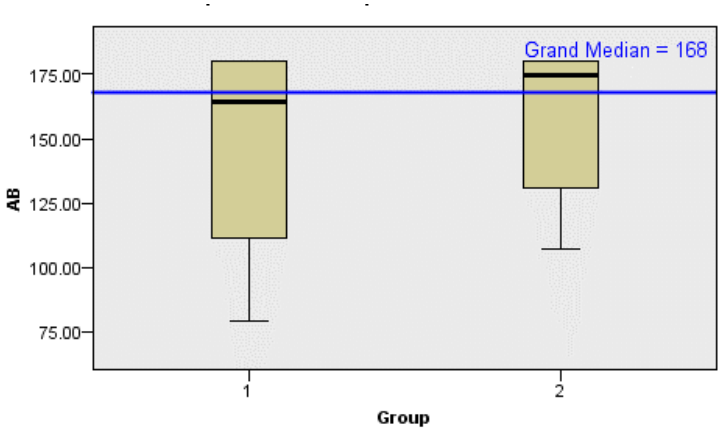

Figure 23 Comparison of abduction between the median for both the Intervention and control group at 6 weeks post -operative.

3.1.3.3 Intergroup Comparison – 12 Weeks Post-operative

Comparison between the Intervention and Control Group at 12 weeks post – operative assessment using the Mann Whitney U Test.

At 12 weeks post-operative assessment there was there was no difference between the control group, abduction of 165, and the intervention group who had 144 ($p < 0.656$; Mann-Whitney U Test) (figure 26).

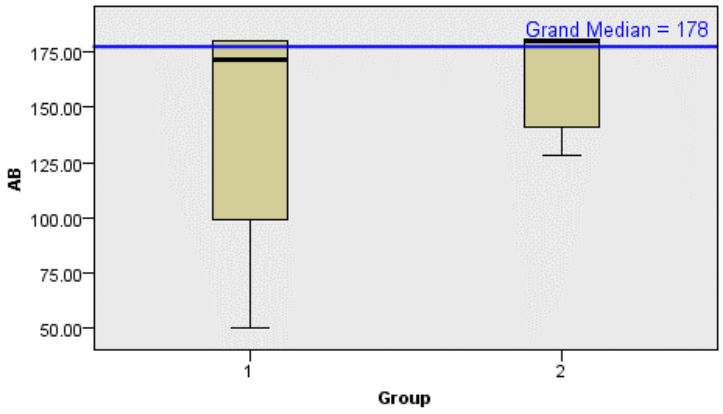

Figure 24 Comparison of abduction between the median for both the intervention and control group at 12 weeks post-operative.

3.1.3.3 Intergroup Comparison – Percentage changes 6 Weeks to pre-operative

Comparison between the percentage for the Intervention and Control Group at 6 weeks to pre– operative assessment using the Mann Whitney U Test.

At 6 weeks to pre-operative there was no difference between the control group, who percentage change of 42%, and the intervention group who had 131% ($p < -0.350$; Mann-Whitney U Test) (figure 27).

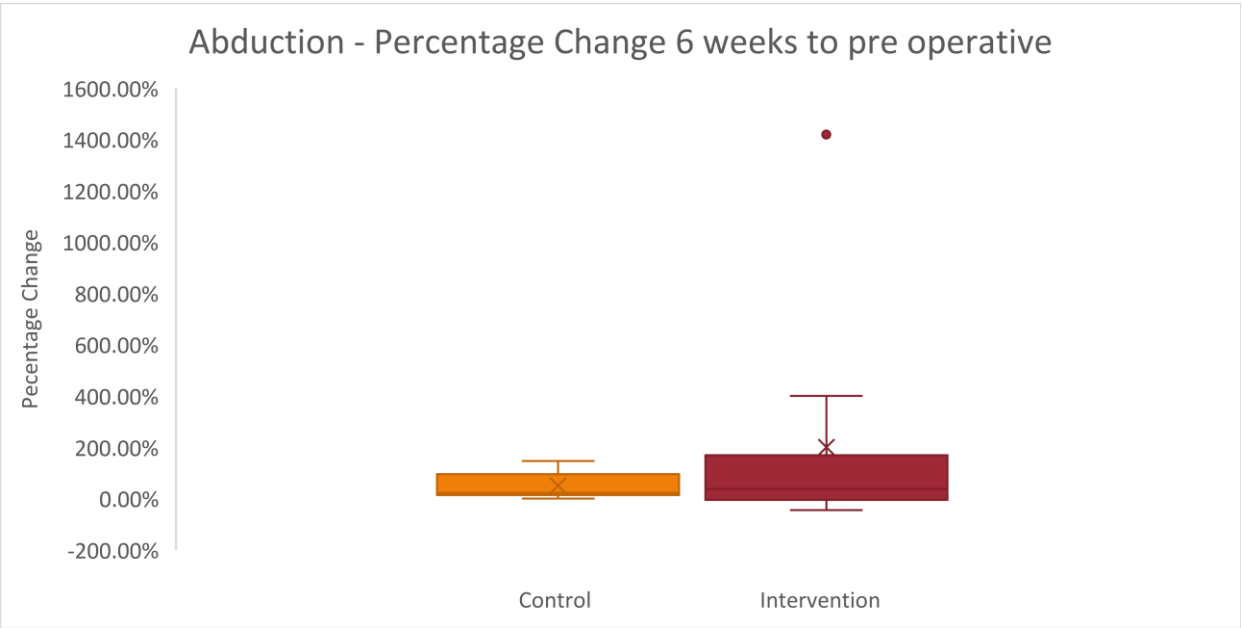

Figure 22 Comparison of abduction between the percentage change for both the

Intervention and control group at 12 weeks to pre- operative.

3.1.3.4 Intergroup Comparison – Percentage changes 12 Weeks to pre-operative

Comparison between the percentage for the Intervention and Control Group at 12 weeks to pre– operative assessment using the Mann Whitney U Test.

At 12 weeks to pre-operative there was no difference between the control group, who percentage change of 50%, and the intervention group who had a mean of 199% ($p < -0.350$; Mann-Whitney U Test) (figure 28).

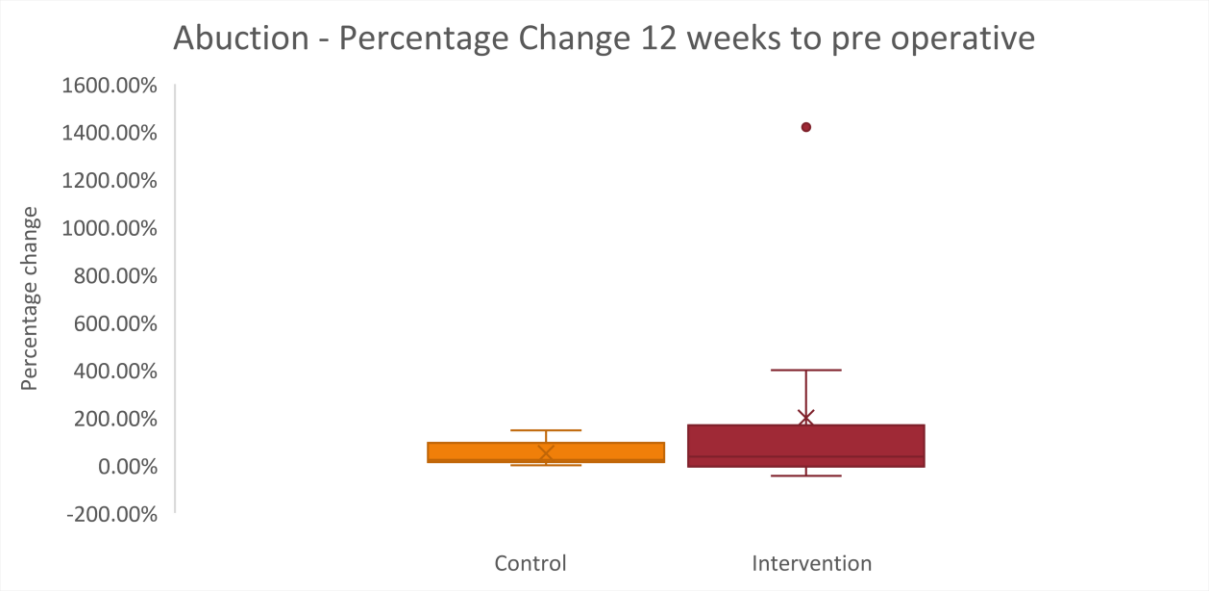

Figure 23 Comparison of abduction between the percentage change for both the Intervention and control group at 12 weeks to pre- operative.

3.2 Patient Reported Outcome Measures

The following Patient Reported Outcome Measures were collected at pre-operative and 12 weeks post-operative assessment by all patients.

1) The Oxford Shoulder Score (OSS) (Appendix 5) which is a twelve-item PROM which is condition specific and focuses on assessing outcomes for shoulder surgery.

The OSS 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. The OSS is a twelve itemed score with each question scoring zero to four, with four being the best.

2) The Disabilities of the Arm, Shoulder and Hand (DASH) (Appendix 6). This is a thirty item questionnaire which measures the patients ability to complete tasks absorb forces and severity of their symptoms. DASH is scored by each individual score to be transformed to a score out of one hundred by subtracting one and then multiplying by twenty five. A higher score indicates a greater disability.

3) Health outcome and quality of life was measured using The European Quality of Life 5 Dimensions (EQ5D) (Appendix 4). This is generic yet standardized tool which is widely used to assess the measure of quality of life. EQ5D focuses on five different dimensions which include, mobility, self care, usual activities, pain and discomfort and anxiety and depression. These five dimensions are divided into five levels with level one indicating no problem.

3.2.1 OXFORD SHOULDER SCORE

Subject	Pre-operative	12weeks Postoperative	Change	Percentage Change
T1	11	13	2	18.1%
T2	37	45	8	21.6%
T3	24	48	24	100%
T4	24	37	13	54.1%
T5	13	18	5	38.4%
T6	44	44	0	100%
T7	39	45	6	15.3%
T8	21	11	-10	-47.6%
T9	0	48	48	100%
T10	0	48	48	100%
MEAN	26.6	35.7	9.1	34.2%
Std.Deviation	14.6	12.2		

Table 17 Oxford Shoulder Score results for intervention group at pre-operative and 12 weeks post-operative assessment, also including absolute and percentage change.

T Test Results

Sig. (2 tailed)	.193

Table 18 T Test results of the Oxford Shoulder Score 12 weeks to pre-operative for the intervention group.

The results for the intervention group shows that there is not a significant difference in the Oxford Shoulder Score for the intervention group $p = 0.193$. There is also a mean change of 9.1 and standard deviation of 12.2 at 12 weeks.

Control Group:

Subject	Pre-operative	12 weeks Postoperative	Change	Percentage Change
C1	31	46	15	48.3%
C2	16	46	30	187.5%
C3	41	0	-41	-100%
C4	39	0	-39	-100%
C5	33	34	1	3.03%
C6	33	31	-2	6.06%
C7	31	45	14	45.1%
C8	38	42	4	10.5%
C9	12	31	19	158.3%
C10	20	45	25	125%
MEAN	29.4	40	10.6	36%
Std.deviation	10	17.9		

Table 19 Oxford Shoulder Score results for the control group at pre-operative and 12 weeks post-operative assessment, also including absolute and percentage change

T Test Results

Sig. (2 tailed)	0.02

Table 20 T Test results of the Oxford Shoulder Score 12 weeks to pre-operative for the control group.

The results for the Oxford Shoulder Score shows there is a significant change for the control group at 12 weeks to pre – operative (p= 0.02), although there is no significant change for the intervention group p=0.193. For subject T8 (intervention group), there is a decline in the OSS from pre-operative (n= 21) to post-operative (n=11), this is because the subject developed post-operative stiffness therefore this resulted in pain and reduced range of movement.

Intergroup Comparison – Percentage change

The results show that the mean percentage change at 12 weeks post-operative is 34.2% for the intervention group and 36% for the control group. Intergroup comparison of the control group and the intervention group at 12 weeks to pre-operative using the Mann Whitney U Test p = 0.42.

3.2.2 DASH RESULTS

Intervention Group:

Subject	Pre-operative	12 weeks Postoperative	Change	Percentage Change
T1	90	73	17	18.8%
T2	31	0	31	100%
T3	43	2	41	95.3%
T4	61	53	8	13.1%
T5	74	15	59	79.7%
T6	0	11	-11	100%
T7	0	0	0	0%
T8	65	0	65	100%
T9	0	0	0	0%
T10	0	0	0	0%
MEAN	60.6	30.8	21	49.1%
Std. Dev	35	26		

Table 21 DASH results for intervention group at pre-operative and 12 weeks post-operative assessment also including absolute and percentage change

T Test Result

Sig. (2-tailed)	.088

Table 22 T Test results of the DASH 12 weeks to pre-operative for the intervention

group.

The results for the intervention group shows that there is no significant difference in the DASH score for the intervention group p = 0.08.

Control Group:

	Pre-operative	12weeks Postoperative	Change	Percentage Change
C1	32.5	0.83	31.6	-97.44%
C2	63.3	10.83	52.5	-82.89%
C3	18.3	No data	No data	No data
C4	20.8	No data	No data	No data
C5	29.1	32.50	-3.3	11.6%
C6	35.0	29.46	5.5	-15.82%
C7	44.1	No data	No data	No data
C8	14.2	15.83	-1.5	11.47%
C9	62.5	0.83	31.6	-98.67%
C10	47.5	10.83	52.5	-77.2%
MEAN	36.7	14.4	22.3	60.7%
Std. Dev	21.3	27.0		

Table 23 DASH results for control group at pre-operative and 12 weeks post-operative assessment, including absolute and percentage chan*ge.*

T Test Results

Sig. (2-tailed)	.001

Table 24 Test results of the DASH 12 weeks to pre-operative for the control group.

The results for the DASH scoring tool shows that there is no significant change for the control group (t test p=0.01) compared to the intervention group (t test p = 0.088).

Intergroup comparison – Percentage Change

The results show that the mean percentage change at 12 weeks post-operative is 49.1% for the intervention group and 60.7% for the control group.

3.2.3 EQ5D RESULTS

Intervention Group

Subject	Pre-operative	12weeks Postoperative	Change	Percentage Change
T1	20	30	10	50%
T2	100	100	0	0%
T3	70	98	28	40%
T4	50	90	40	80%
T5	51	70	19	37.25%
T6	0	90	90	100%
T7	80	85	5	6.25%
T8	75	50	-25	-33.33%
T9	0	100	100	100%
T10	0	100	100	100%
MEAN	63.7	81.3	17.6	27.6%
Std. Dev	37.3	21.6		

Table 25 EQ5D results for intervention group at pre-operative and 12 weeks post-operative assessment, also including absolute and percentage change.

T Test Results

Sig. (2-tailed)	.171

Table 26 T Test results of the EQ5D 12 weeks to pre-operative for the intervention group.

The results for the intervention group shows that there is not significant difference in the EQ5D score for the intervention group p = 0.171. There is also a mean difference of 39.2 and standard deviation of 21.6 at 12 weeks.

Control Group:

Subject	Pre-operative	12 weeks Postoperative	Change	Percentage Change
C1	100	95	-5	-5%
C2	50	90	40	80%
C3	80	0	-80	-100%
C4	70	0	-70	-100%
C5	70	75	5	7.14%
C6	60	80	20	33.33%
C7	60	70	10	16.67%
C8	100	95	-5	5%
C9	80	100	20	44.44%
C10	80	0	-80	-100%
MEAN	75	86.4	11.4	15.2%
Std. Dev	16.4	42.9		

Table 27 EQ5D results for control group at pre-operative and 12 weeks post-operative assessment, including absolute and percentage change.

T Test Results

Sig. (2-tailed)	.135

Table 28 T Test results of the EQ5D 12 weeks to pre-operative for the control group.

The results using the T-test for the EQ5D score show that there is no difference in the

intervention group p=0.135 compared to the control group 0.171.

Intergroup Comparison – Percentage change

The results show that the mean percentage change at 12 weeks post-operative is 27.6% for the intervention group and 15.2% for the control group intergroup comparison of the control group and the intervention group at 12 weeks to pre-operative using the Mann Whitney U Test p = 0.395.

3.3 ENGAGEMENT

Compliance with the prescribed Exergames were measured for the subjects randomised to the intervention group. The following metrics were collected:

1) Time played – the duration of time (n-minutes) which the subject was logged into the system and actively playing the Exergames.

2) Prescribed Physiotherapy – the overall number of minutes of game play which the subject was prescribed by the research physiotherapist.

3) Percentage Played – the number of minutes played by the subject versus the number of minutes prescribed by the research physiotherapist.

3.3.1 TIME PLAYED IN EXERGAMES (INTERVENTION GROUP):

Subject	Time played (n=minutes)	Prescribed physio (n-minutes)	Percentage Played
T1	0	0	0.0%
T2	1917	2200	87.2%
T3	82.1	594	13.8%
T4	93.6	1467	6.4%
T5	2.0	210	1.0%
T6	4.0	210	1.9%
T7	145	1506	9.6%
T8	48	210	23.1%
T9	107	409	26.1%
T10	107	1413	7.6%
MEAN	250	822	17.67%

Table 29 Time played in Exergames for all subjects (T1-T10) from the intervention group.

Each of the patients from the intervention group was provided with the software and hardware to play the Exergames at home. Each patient was prescribed physiotherapy exergames from their therapist and the intensity of the exergames prescribed was assessed on an individual basis.

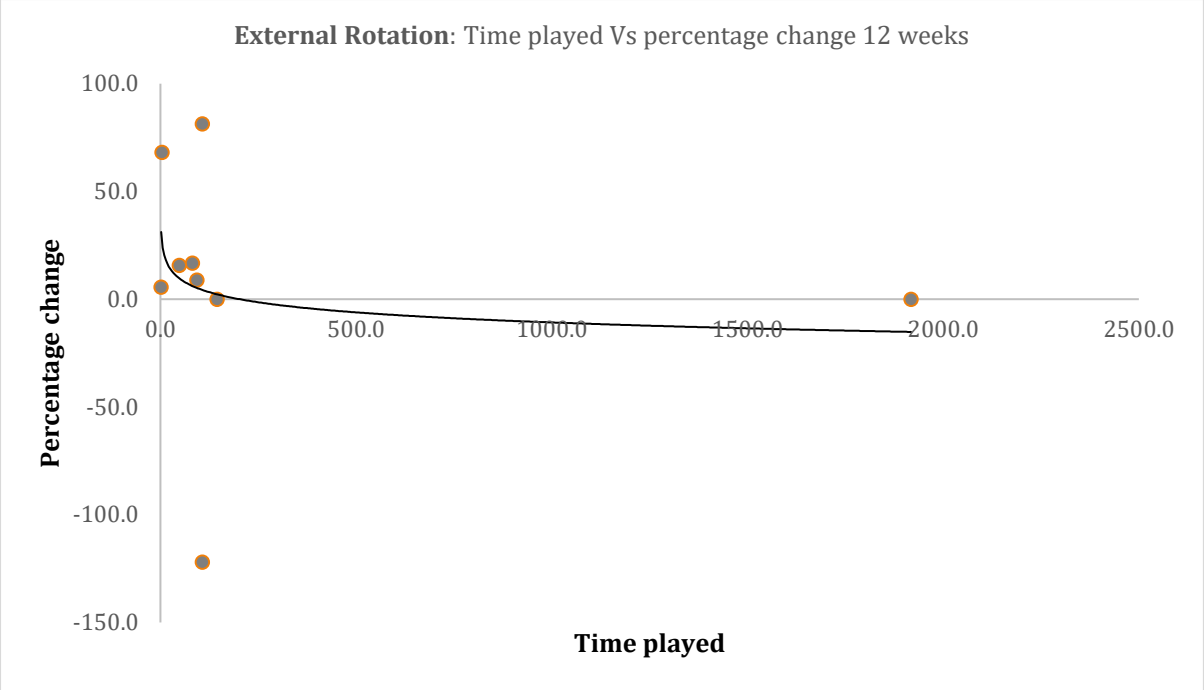

Figure 24 External Rotation - Time played Vs percentage change 12 weeks for the intervention group.

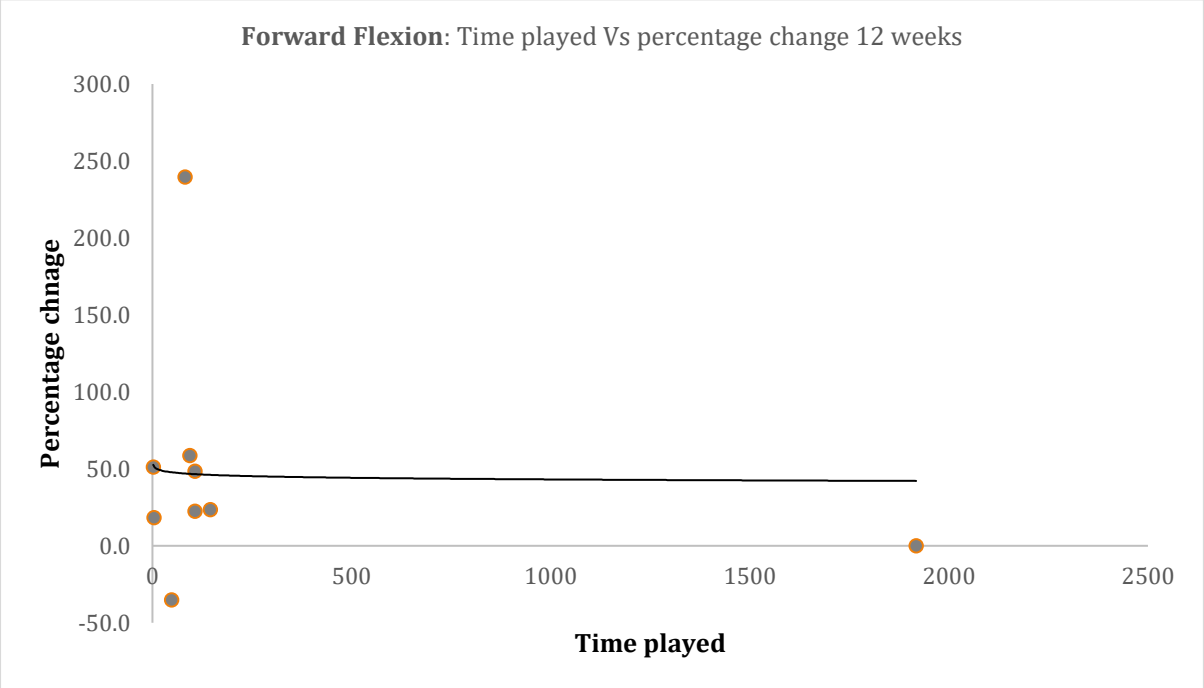

Figure 25 Forward flexion-Time played Vs percentage change 12 weeks for the intervention group.

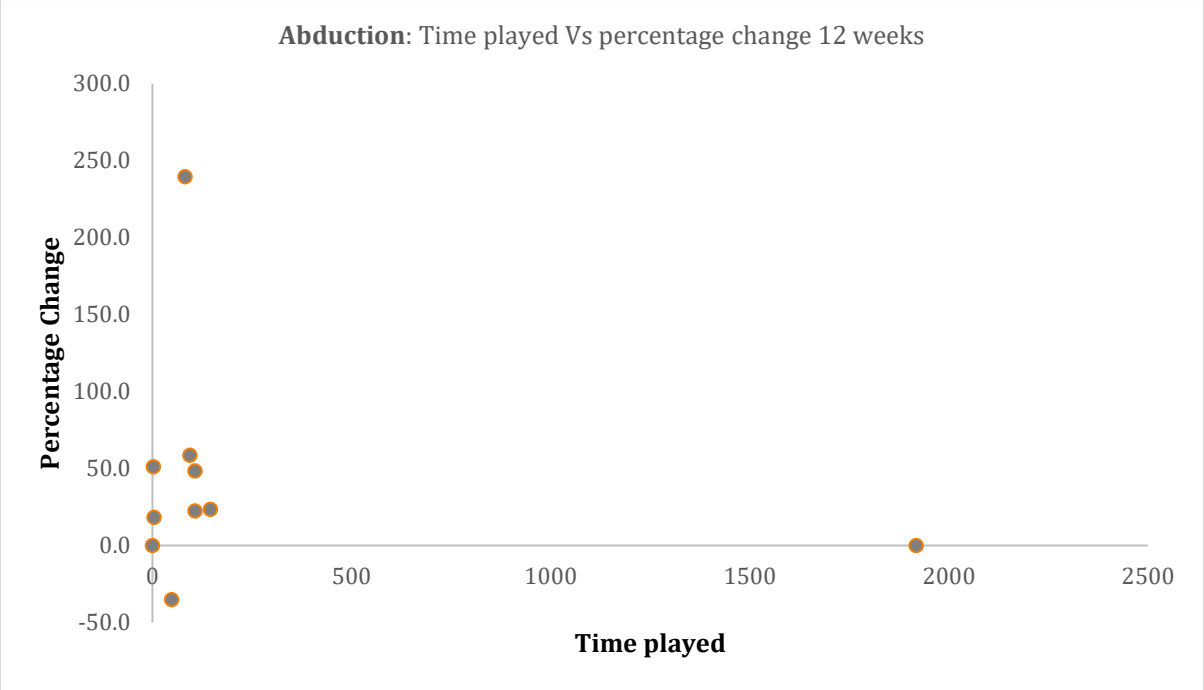

Figure 26 Abduction - Time played Vs percentage change 12 weeks for the intervention group.

3.3.2 DIARIES – INTERVENTION SUBJECTS

Subjects were required to complete their diaries on a weekly basis. This consisted of the amount of time played (n=minutes) which is reported by the subjects.

This will be compared to the total amount of time exercised (n = minutes), extracted from the software.

Subject	Reported total minutes exercised	Time played
T1	No data	No data
T2	144	1917.8
T3	No data	82.1
T4	130	93.6
T5	No data	2.0
T6	170	4.0
T7	100	145.0
T8	No data	48.4
T9	366	107.0
T10	97	107.0

Table 30 Showing the reported total minutes exercised and time played for the intervention group.

Results above (table 41) show the total minutes exercised, as reported in the patient diaries, compared to the total minutes exercised on the Mira software. From the data presented, only 60% of the patients completed and returned their diaries, however engagement data with the Mira software shows that 90% of the patients completed their rehabilitation program.

4 DISCUSSION

Effective physiotherapy is essential for treatment of all musculoskeletal problems; this is an effective treatment modality with low risks (Steuri et al, 2017). Subacromial impingement is also effectively treated using physiotherapy, either in isolation or in combination with other interventions (Steuri et al, 2017). This project investigates the use of technology to assist physiotherapy to make it more effective and efficient.

Physiotherapy treatment requires patients to perform a prescribed set of exercises or activities regularly in order to achieve the desired goals. Patient involvement is required to achieve this. However, adherence to physiotherapy is still a problem that has been studied by many authors (Craike et al, 2016). A literature review concluded that poor treatment adherence was associated with low levels of physical activity at baseline or in previous weeks, low in-treatment adherence with exercise, low self-efficacy, depression, anxiety, helplessness, poor social support/activity, and greater perceived number of barriers to exercise and increased pain levels during exercise (Jack et al, 2010*)*. The authors concluded that 'physiotherapists should be concerned about the attitudes, beliefs and barriers facing their patients and act collaboratively with their patients to design realistic treatment plans which are customised to

the patient's life circumstances' (Jack et al, 2010). Demographic factors are also relevant for levels of compliance (Shen et al, 2017).

The realisation that the patient does not always do as the clinician recommends, has meant this area has been researched in an attempt to improve care. Terminology has been even more confused as deviating from a prescribed treatment plan can be seen as patient empowerment, does the clinician always know best? 'Compliance' a word used from the 1950s, has become unpopular due to its judgmental overtones, and alternatives are used. Adherence is used synonymously with compliance, but there is acceptance that non-adherence or non-compliance is a full spectrum, from partial to total. Persistence, is also used, mostly for pharmaceuticals, where prescriptions have to be regularly renewed (Fraser, 2010). Metrics have been developed to measure patient compliance/adherence (Graffigna, 2015).

The creation of an agreement between parties, instead of a mere giving and receiving of instructions, is perhaps the most positive approach. Termed "concordance", this concept has seen an increased usage in the past decade or so to describe a more equal relationship between physician and patient. It describes a change in culture and builds on the idea of a shared responsibility. The emphasis is more on setting out the goals of therapy and not arbitrarily enforcing a treatment regime (Fraser, 2010). Concordance may result in patient activation, it is being appreciated that Value concordance is a critical component of patient-centred care (Winn et al, 2015).

This project attempts to use gamification techniques to create physiotherapist and patient concordance. Gamification in seeing usage in healthcare setting and is predicted to improve health by integrating software design and game mechanics with public health theory and behavioural insights (King et al, 2013). It is now known that players of active video games in a health care setting are motivated to exert themselves to achieve activity goals through game mechanics (Read et al, 2011). Motivating user behaviour, games usually provide conditional

rewards, i.e. points that can improve with more frequently play.

The use of gamification in physiotherapy is through ‘exergames’ a part of the emerging field of ‘serious gaming’. Successful exergames should lead players not only to achieve enough level of energy expenditure but also to engage in the play itself (Lee et al, 2011). This requires attributes such as enjoyment, immersion flow etc. However, research is lacking about the efficacy of exergames to improve musculoskeletal symptoms. A metanalysis found no evince of benefit in relieving pain (Collado-Mateo et al, 2017). There is however evidence that exergames improved executive functions, attentional processing and visuospatial skills (Standmore et al, 2017).

For the purposes of the present project, the physiotherapy goals were mapped and exergames developed to fit with these goals. The exergames were then profiled by physiotherapists, and weighted to the different physiotherapy goals. This created a ‘menu’, from which exergames could be chosen to fit the goals for a specific patient. The schedule was altered dependent on the progress of the individual patients in an attempt to maintain variation and interest. The physiotherapy programme was complemented by the exergames, but did not completely supplement the face to face physiotherapy visits. Each patient underwent 12 weeks of physiotherapy with or without exergames depending on their randomisation schedule.

Throughout the project, Range of Movement was used to assess clinical improvement and included the following measurements:

1) External Rotation

2) Forward flexion

3) Abduction

Patients were required to complete these measurements weekly along side their allocated physiotherapy regime using the Mira software. Patients were able to interact with the system

and receive feedback to track their progress. For the purposes of the project, the range of movement data was extracted for pre- operative assessment, 6 weeks and 12 weeks post op.

As well as clinical assessment, Patient Reported Outcome Measures were used to assess improvement following surgery. The following scores were collected from the patient at pre-operative assessment and 12weeks (end of study).

1) Oxford Shoulder Score

2) EQ5D

3) DASH

A combination of using range of movement and patient reported outcome measures to were used to assess the effectiveness of the exergames.

Early healthcare technology systems were designed primarily for physicians and other healthcare professionals, but there is an increasing interest in reaching consumers and patients directly through technology solutions. Systems aimed at professionals are being adapted for home use. Computer based decision aids are also increasingly being deployed in the community. However, as little research is available on how patients use technology tools at home, the challenge is in producing a system that is easily accessible and usable. Using a technical solution does require technology to be accessible to patients. The risk of creating and widening a gap between patients who use technology solutions and those who do not must be managed.

In this study, all patients were provided with the necessary tools to take part in the study. Hardware and software were both provided, and there was support available for patients while using the device at home. However, there were individuals who still had trouble using the equipment, and failed to do so.

Patient engagement with their physiotherapy regime is often difficult to measure. This study

allowed the study team to remotely measure the patient compliance with their prescribed therapy programme. Within this study, all patients were required to complete a patient diary on a weekly basis, which included the number of minutes that they had exercised.

The results confirm improvement in both groups of patients.

Subacromial decompression is a successful procedure that does require a defined amount of physiotherapy input based on individual patients. This technology allows the physiotherapy to be complemented with the exergames to make the protocols more efficient as well as cost effective, while retaining the initial physiotherapy goals.

The results from this study shows that patients who played the games and the patients who continued with standard physiotherapy had an improvement in the range of movement from pre – operative to 12weeks post operative. Although there was no significant difference between the control and the intervention group. The patient report outcomes showed that there was no significant difference between the control and the intervention group using the EQ5D and the DASH score, although there was a significant difference between the groups with the OSS. Engagement data showed that there was no correlation with the amount of time played versus the time prescribed, as well as no significant difference between both of the groups.

The hardware and software from this study has now been implemented as standard of care across Manchester Foundation Trust. https://www.nihr.ac.uk/news/manchester-hospital-first-in-world-to-introduce-video-game-shoulder-rehab/8574. This is currently being used in the physiotherapy department at Trafford General Hospital for patients following shoulder surgery with scope to role this innovation out into our areas such as inpatient Trauma and Orthopaedics and falls prevention.

Implications for Practice

- Introducing a solution which requires change management, not only for NHS professionals but for patients also.
- The Microsoft Kinect is now obsolete.

Recommendations for future practice using Exergames (Mira):

- To include a condition specific physiotherapy protocol using the Exergames.
- Ensure that all Exergames are validated clinically.
- To ensure that patients have a single point of contact should they need support.
- Ensure that the Exergames are capped and patients are unable to overplay.

5 CONCLUSION

From a review of the literature, this study was the first trial using gamification principles for rehabilitation and shows promising results.

The results from the study show that there was an improvement in the range of movement in both the control and the intervention groups. There was no difference in the intergroup comparisons percentage changes from 6 weeks postoperative and 12 weeks post operative for external rotation, forward flexion and abduction. The results for the Patient Reported Outcome Measures, Oxford Shoulder Score results show that shows there is a significant change for the control group at 12 weeks to pre – operative ($p= 0.02$), although there is no significant change for the intervention group $p=0.193$. The results for the DASH scoring tool shows that there is no significant change for the control group (t test $p=0.01$) compared to the intervention group (t test $p = 0.088$). The results using the T-test for the EQ5D score show that there is no difference in the intervention group $p=0.135$ compared to the control group 0.171.

To conclude, the results shows that this innovative solution has proven to be safe and

effective in this patient population. The hardware and software from this study has now been implemented as standard of care across Manchester Foundation Trust. https://www.nihr.ac.uk/news/manchester-hospital-first-in-world-to-introduce-video-game-shoulder-rehab/8574.

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7 APPENDICES

APPENDIX 1 CONSENT TO CONTACT FORM

Today your surgeon has invited you to consider being a part of the GAME study. You have been provided with a patient information sheet that outlines the principles of the study. Your decisions to participate in the study will in no way affect the treatment you are offered. This form allows our research team, to contact you about the study before your surgery, to provide you with more information.

Please sign the statement if you are happy to be contacted.

Individual's details

Address:

Telephone contact number:

Email address:

Preferred method of contact by:

Post ☐ Telephone ☐ Email ☐

Preferred contact time:

I give consent for the research team to contact me before my surgery regarding the GAME study. I understand the purpose of this contact is to provide further information or answer questions I may have about the study. I understand that this is not consent to partake in the study. I am aware that I can decline any further contact about this study if I wish to
Individuals signature …….. Date …….

APPENDIX 2 PATIENT INFORMATION SHEET

Central Manchester University Hospitals NHS
NHS Foundation Trust

Dear Patient,

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with us if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Why have I been chosen?

You have been invited to take part because you have impingement syndrome and the hospital in which you are being treated, is carrying out this research. Impingement syndrome is a common shoulder condition which is treated effectively with a standard operative procedure. Postoperative rehabilitation consists of physiotherapy with home exercises and outpatient follow up. We would like to investigate a different way for patients to receive their rehabilitation treatment.

What is the purpose of the study?

The purpose of the study is to compare two different methods of delivering rehabilitation treatment following surgery. We want to investigate if there is a difference in surgical outcomes between the two treatment groups.

Group 1 – Treatment as usual Group

Group 1 will receive standard post-operative physiotherapy. This is the current standard treatment for all patients. The treatment will be delivered by experienced physiotherapists following a developed programme which has been used following this type of surgery to maximise patients' recovery.

Group 2 – Treatment as usual plus Exergames Group.

Group 2 will follow a post-operative regime of standard physiotherapy plus 'Exergames'. (Exergames are physiotherapy based games which use sensor based technology in the rehabilitation of post-operative shoulder recovery). The games utilise principles of gamification, which may improve patient engagement and motivation. As well as use of the Exergames we also aim to develop a new shoulder score, through use of the games, which combines 3 elements; patient reported measures (which are being used increasingly within physiotherapy), patients' feedback on their experience of using the games and sensor derived data, which isn't usually available to the physiotherapist. We will call this the 'PKEX Score'

Central Manchester University Hospitals NHS
NHS Foundation Trust

Do I have to take part?

No. You do not have to take part; it is entirely up to you to decide whether or not you do so. If you do decide to take part, you will be given this information sheet to keep and asked to

sign a consent form. Even after you have signed the consent form you are still free to withdraw from taking part in the study at any time without giving a reason, a decision not to take part will not affect the standard of care you receive.

What will happen next?

Prior to your surgery date, you will be contacted by a member of the research team, to see if you would like to participate in the study. If you do decide to participate, on the date of your surgery your doctor may ask you questions to check that you are eligible. You will be asked to give your consent to the study.

What will happen to me if I take part?

Your surgeon will have already outlined the surgical treatment, this will not be altered whether you decide to take part or not. If you do decide to take part, you will be randomly assigned into one of the two groups. Neither you or the research team or surgeon can choose whether you take part in Group 1 or Group 2, this will be decided by a random allocation method.

Before your surgery, you will be asked to complete a consent form with a member of the research team, please ask as many questions as you would like, the research team are there to provide as much information as you need in order to make the right decision for you.

All patients will then be asked to complete five questionnaires and baseline measurements, which will be taken and recorded by the research team.

Group 1 – Standard Physiotherapy

If you are assigned to the standard post-operative physiotherapy group, you will be asked to attend your local outpatient physiotherapy department weekly and complete a range of home exercises, this is usual practice following surgery. Your Physiotherapist will progress your exercises with your improvement and schedule your appointments in line with your recovery. As part of the study, we require you to complete an exercise diary which will be collected and reviewed by your physiotherapist, this is not usually asked for as standard care. Completion of the exercise diaries is an important piece of information for this study.

Group 2 – Standard Physiotherapy plus Exergames

The second group will commence the same standard post-operative physiotherapy regime as Group 1 they will also receive a supplement to the weekly physiotherapy with computer

technology, using a range of games which have been designed to improve the range of motion in your shoulder.

The use of the technology and aim of the games will be explained and demonstrated to you by your Physiotherapist, you will then be lent a games kit for you to take home and continue

with the game exercises at home (more about the games kit and technology is explained in the following section). Like Group 1 we will also ask you to complete an exercise diary

which will be collected and reviewed by your physiotherapist.

The study requires your involvement for a 12-week period. As part of the study, taxis can be provided for transport for study visits to and from the hospital.

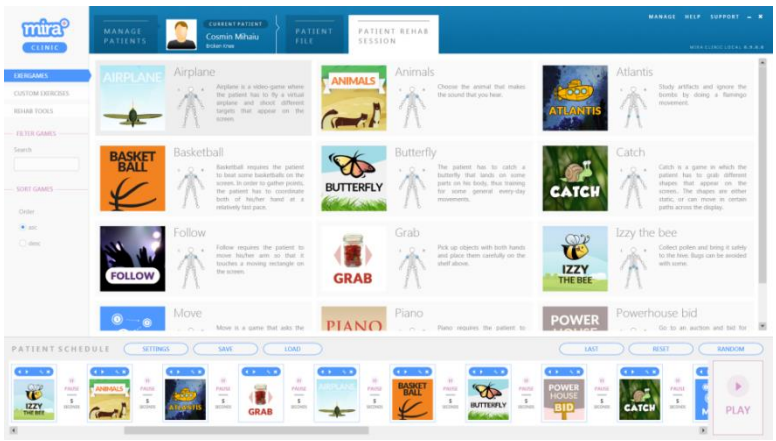
At the end of the study, you will be asked to complete the same measurements and questionnaires which were completed at the beginning of the study. You will also be followed up by a member of the research team 12 months after your surgery, this is to complete further questionnaires.

What is the technology that is being tested?

Mira Rehab is a company which has designed software using Microsoft Kinect technology. The technology will run from a laptop which will be provided to all patients randomised to Group 2. You will log into the gaming portal and will have the range of movement of your shoulder measured and recorded. Following this you will play a set of games that are aimed at improving the range of motion in your shoulder. The Mira programme enables patients to progress through different levels within the games whilst engaging in their rehabilitation programme.

Below is the Kinect sensor which you will be using throughout the study:

The image below is a screen shot of the technology that will used during your rehab:



Support for using the games will be available through your Research Physiotherapist.

What are the possible disadvantages and risks of taking part?

Risks

Any intervention does carry some small risks but these risks are not increased by taking part in this study. We know that some patients are competitive about completing their exercises and that games can increase patient's competitiveness, which may lead to 'overdoing' exercise and could result in shoulder pain. Reminders have been built into the games console to remind patients to stay within safe exercise limits. Your clinician will advise you how often you should undertake both physiotherapy exercises and use of the games.

What are the benefits of taking part?

There is no guarantee that participation in this study will improve your recovery from shoulder surgery, we want to see if there are any differences between the groups. The development of the PKEX score should help surgeons develop a more tailored patient perspective into their rehabilitation.

What if new information becomes available?

We will inform you if any new information becomes available while you are taking part in the study.

What happens when the research study stops?

Your care will continue under standard treatment by the NHS.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain, you can do this by following the NHS complaints procedure, please find the details below:

Elaine Paul

Central Manchester University Hospital

Trafford General

Orthopeadic Unit

Moorside Road

Urmston

M41 5SL

Contact Number- 01617484022

Will my participation in this study be kept confidential?

All information, which is collected, about you during the course of this research will be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

The results of the study will be presented at scientific meetings and in a scientific journal. You will not be identified in any report or publication

Contact for further information.

If you need further information about this research or have any concerns, you should contact the study coordinator:

Gemma Wilde- Research Physiotherapist

Central Manchester University Hospital

Trafford General

Orthopeadic Unit

Moorside Road

Urmston

M41 5SL

Contact Number- 01617462525

APPENDIX 3 INFORMED CONSENT

Central Manchester University Hospitals NHS
NHS Foundation Trust

FULL CONSENT FORM FOR ALL GAME ACTIVITIES

Name of individual (capitals) ……

GAME Study Identification Number

……

Please initial each statement to show your agreement

1) I have read the Participant Information Sheet version 1.2 on the above study and I have been given a copy to keep. I have had the opportunity to ask questions about the study and I am satisfied with the information that I have been given. ☐

2) I give permission for my medical records to be looked at throughout the duration of the study, using my personal details and NHS number by the research team, monitors and authorities. I understand that my personal information will be used in strict confidence by members of the research team (complying with data regulation). ☐

3) I understand that within this study there are two treatment groups, and I may be assigned into either group.

4) I understand that all information which is collected about me, during the course of this study will be kept strictly confidential, and identifiable information will be removed, if the results from this project are published.

5) I understand that participating in the above research project is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical treatment or legal rights being affected.

6) I agree to participate in the above study and I know how to contact the research team should I need to.

7) I agree that my GP can be informed of my participation in the research project and they will be updated on my progress.

Participant's signature …….. Date ……..

I confirm that I have fully explained the nature of this study to the above named

volunteer.

APPENDIX 4 EQ5D

EQ-5D Health Questionnaire

☐ ☐ Client ID New User ☐
☐ Existing User

Date

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐

I have some problems with washing or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Pain / Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety / Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

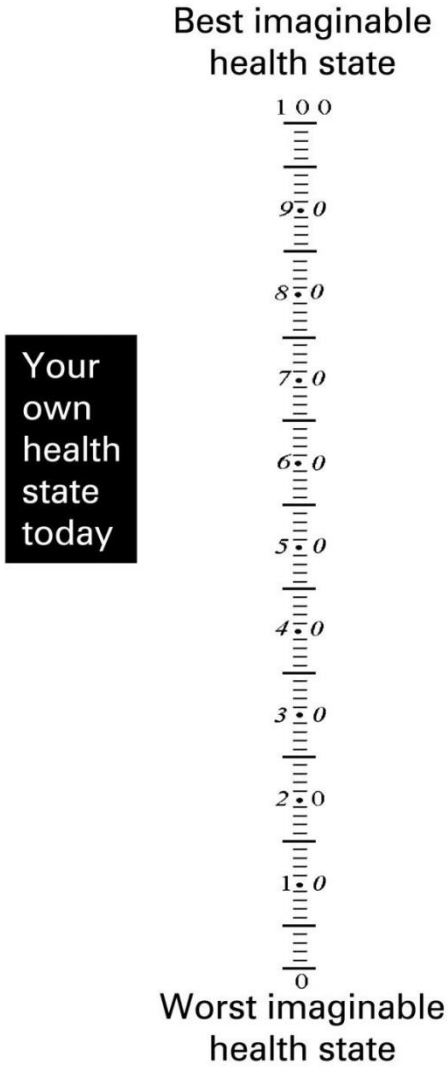
I am extremely anxious or depressed ☐

Visual Analogue Scale

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box to the point on the scale that indicates how good or bad your health state is today.



Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

APPENDIX 5 OXFORD SHOULDER SCORE

PROBLEMSWITHYOURSHOULDER Tick (✓) one box for every question.

1. During the past 4 weeks…

How would you describe the **worst** pain you had from your shoulder?

None ☐ Mild ☐ Moderate ☐ Severe ☐ Unbearable ☐

2. During the past 4 weeks…

Have you had any trouble dressing yourself because of your shoulder?

No trouble ☐ A little bit of trouble ☐ Moderate difficulty ☐ Extreme trouble to do ☐ Impossible at all ☐

3. During the past 4 weeks…

Have you had any trouble getting in and out of transport a car or using public because of your shoulder?

No trouble ☐ A little bit of trouble ☐ Moderate at all trouble ☐ Extreme difficulty ☐ Impossible to do ☐

4. During the past 4 weeks…

Have you been able to use a knife and fork - at the same time?

With

Yes, easily ☐ With little difficulty ☐ moderate difficulty ☐ With extreme difficulty ☐ No, impossible ☐

5. During the past 4 weeks…

Could you do the household shopping on your own?

With

Yes, easily | With little difficulty | moderate difficulty | With extreme difficulty | No, impossible

☐ ☐ ☐ ☐ ☐

6. During the past 4 weeks…

Could you carry a tray containing a plate of food across a room?

Yes, easily | With little difficulty | With moderate difficulty | With extreme difficulty | No, impossible

☐ ☐ ☐ ☐ ☐

7. During the past 4 weeks…

Could you brush/comb your hair with the affected arm?

Yes, easily | With little difficulty | With moderate difficulty | With extreme difficulty | No, impossible

☐ ☐ ☐ ☐ ☐

8. During the past 4 weeks…

How would you describe the pain you usually had from your shoulder?

9. During the past 4 weeks…

Could you hang your clothes up in a wardrobe, using the affected arm?

Yes, easily | With little difficulty | With moderate difficulty | With great difficulty | No, impossible

–

□	□	□	□	□

10. During the past 4 weeks…

Have you been able to wash and dry yourself under both arms?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
□	□	□	□	□

11. During the past 4 weeks…

How much has pain from your shoulder interfered with your usual work (including housework)?

None Very mild Mild Moderate Severe

12. During the past 4 weeks…

Have you been troubled by pain from your shoulder in bed at night?

APPENDIX 6 DASH

1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	**1**	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5

18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NOT AT ALL	SLIGHTLY	MODERATELY	A BIT	EXTREMELY
22. During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?					

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand. **1**		2	3	4	5
27. Weakness in your arm, shoulder or hand. **1**		2	3	4	5
28. Stiffness in your arm, shoulder or hand. **1**		2	3	4	5

NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP

23. During the past week, were you limited in your work or other regular daily activities as a result of your arm,

DASH DISABILITY/SYMPTOM SCORE = [(sum of n responses) - 1] x 25, where n is equal to the number of completed responses. n

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including hom

Please indicate

p I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO	MILD	MODERATE	SEVERE	UNABLE	DI
1. using your usual technique for your work?	**1**	**2**	**3**	**4**	**5**	
2. doing your usual work because of arm, shoulder or hand pain?	**1**	**2**	**3**	**4**	**5**	
3. doing your work as well as you would like?	**1**	**2**	**3**	**4**	**5**	
4. spending your usual amount of time doing your work?	**1**	**2**	**3**	**4**	**5**	

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing your musical instrument or s

Please indicate the sport or instrument. (You may skip this section.)

Please circle the number that best describes your physical ab

	NO	MILD	MODERATE	SEVERE	UNABLE D
1. using your usual technique for playing your instrument or sport?	**1**	**2**	**3**	**4**	**5**
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	**1**	**2**	**3**	**4**	**5**
3. playing your musical instrument or sport as well as you would like?	**1**	**2**	**3**	**4**	**5**
4. spending your usual amount of time practising or playing your instrument or sport?	**1**	**2**	**3**	**4**	**5**

APPENDIX 7 PATIENT DIARIES

To be completed by patient:

Date:

Over the whole day how many minutes have you exercised today? ....

How many times have you exercised today? ....

Please circle how hard you feel you have exerted yourself today:

None   Very very light   Very light   Fairy Light   Somewhat hard

Hard   Very Hard   Very Very Hard

Date:

Over the whole day how many minutes have you exercised today? ....

How many times have you exercised today? ....

Please circle how hard you feel you have exerted yourself today:

None   Very very light   Very light   Fairy Light   Somewhat hard

Hard   Very Hard   Very Very Hard

Date:

Over the whole day how many minutes have you exercised today?.........

How many times have you exercised today? ....

Please circle how hard you feel you have exerted yourself today:

None   Very very light   Very light   Fairy Light   Somewhat hard

Hard   Very Hard   Very Very Hard

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Over the whole day how many minutes have you exercised today? ....

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Hard   Very Hard   Very Very Hard

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None   Very very light   Very light   Fairy Light   Somewhat hard

Hard   Very Hard   Very Very Hard

Date:

Over the whole day how many minutes have you exercised today? ....

How many times have you exercised today? ....

Please circle how hard you feel you have exerted yourself today:

None   Very very light   Very light   Fairy Light   Somewhat hard

Hard   Very Hard   Very Very Hard

G.A.M.E Study Patient Diary

APPENDIX 8 DECLARATION OF EQUIPMENT FORM

Central Manchester University Hospitals NHS
NHS Foundation Trust

Declaration of returning study equipment

Thank you for taking part in the GAME study. As part of your physiotherapy regime, you will be lent a games kit for you to take home and continue with the game exercises. The games kit will consist of a laptop with the charger and a Kinect sensor.

By signing the declaration below, I agree to return the games kit (**which includes the laptop with the charger and Kinect sensor)** at the end of my 12 week physiotherapy treatment.

Please sign the statement to show your agreement

Name of individual (capitals) ……

Individuals signature …….. Date ……

APPENDIX 8 PROTOCOL

G.A.M.E.

Gamification for Activation, Motivation and Engagement

TITLE OF STUDY:

A Multi-Centre, Randomised, Controlled Study comparing Gamification with Remote Monitoring against standard rehabilitation, for Patients after Arthroscopic Subacromial Decompression Surgery.

Research Proposal

This randomised prospective controlled trial will investigate patients with impingement syndrome who undergo arthroscopic subacromial decompression. The intervention group will receive physiotherapy aided by automated sensor-based technology which will help them perform exergames and track their rehabilitation progress. The control group will be treated by standard physiotherapy protocols. The two groups will be compared using patient reported outcome measures and assessment of shoulder range of movement before and after the shoulder surgery.

Data will be collected on patient experience, engagement with the rehabilitation process and the usability of the sensor-based technology through the use exergames. This will guide development of methods to quantify patient activation and engagement.

Objectives and Endpoints

1. There will be a significant clinical difference in post-surgical improvement measured by patient reported outcomes when physiotherapy is aided by automated sensor-based technology to perform Exergames and track progress, compared to standard physiotherapy protocols.
2. There will be a significant difference in post-surgical improvement in range of shoulder movement, measured by patient reported outcomes when physiotherapy is aided by automated sensor-based technology to perform exergames and track progress, compared to standard physiotherapy protocol.

INTRODUCTION

Impingement syndrome refers to the symptoms of pain and dysfunction resulting from any pathology which decreases the size of the subacromial space or increases the size of its contents[1]. Arthroscopic subacromial decompression is one of the most common procedures performed by a shoulder surgeon.

Surgery forms only part of the treatment. Physical therapy is the other key element of the treatment. The results of this physiotherapy are dependent on patients regularly performing specific exercises and following a rehabilitation programme[2].

We propose a prospective, multicentre trial to assess patient reported outcomes and shoulder range of movement in this group of patients. We will investigate if the use of a

physiotherapy regime, harnessing gamification principles, increases patient engagement and improves patient outcomes.

Background:

Musculoskeletal problems are one of the most common reasons for seeking medical advice, with estimates of up to 20% of adults annually consulting their general practitioner. The prevalence of shoulder problems in the population is approximately 2.5% [3]. In 2012/13, there were over 7.1 million outpatient appointments for trauma and orthopaedics in England (accounting for 9.3% of all outpatient attendances) and over 4 million of these visits were follow-up appointments after the initial consultation (Hospital Episode Statistics)[4]. The average cost for each outpatient follow up is £76. At a time when the NHS is under considerable financial burden we are constantly looking at ways and means of reducing the number of outpatient appointments and the length of time for which a patient required follow-up. By improving rehabilitation protocols patients will complete their recovery more rapidly which may reduce clinician-patient face-to-face interactions. This may free up this valuable resource which can be directed towards more complex clinical requirements.

Patient Reported Outcome Measures (PROMs)

In order to judge patient outcomes, validated tools are required. These tools have seen a gradual shift from physician reported measures to patient reported outcome measures. In 2009, PROMs were introduced for assessing the outcome of care in the NHS in England for four elective procedures. This has since been expanded to being part of the NHS Outcomes framework since April 2013.

The most commonly used validated shoulder scores are the Constant Score (CS, 1987) and the Oxford Shoulder Score (OSS, 1996). The OSS has been observed to be a robust tool for the quantitative assessment and tracking of patient outcomes after surgery[5]. The constant score has the benefits of including a pain score, functional assessment, range of motion and strength measures but is not suitable for all shoulder conditions.

Patient Engagement

One of the major factors that influence patient outcomes is their engagement with the rehabilitation program. Rehabilitation professionals have long suspected that a patient's motivation plays an important role in determining the outcome of therapy, despite the lack of a clear definition of the phenomenon[6]. It is estimated that up to 65% of patients are non/partially adherent to their home exercise program[7]. Classically, patients have completed home exercise diaries. However, studies have suggested that these are often completed retrospectively. This may encourage patients to exaggerate the amount of activity performed. Hoelscher at al (1984), timed patients at home performing a relaxation exercise program and compared this to patient reported duration. They found that the latter tended to suggest a higher level of adherence[8].

Patient activation describes the knowledge, skills and confidence a person has in managing their own health and health care. Intervening to increase activation can improve a patient's engagement and health outcomes. This is an important factor in helping patients manage their health[9]. As a part of this study we will quantify patient engagement, develop and validate a new tool to comprehensively measure patient outcomes using four domains. These will be Patient reported pain and function (P), shoulder range of movement i.e. Kinematics (K), patient activation or engagement (E) and patient experience (X). The PKEX shoulder score is the first of its kind that will actively score patients participation in the rehabilitation process.

<u>Gamification:</u>

Traditional evaluation of the patient's range of motion usually occurs in a clinic, often using subjective and informal methods of angle measurement. This has the potential to create discrepancies in findings between clinicians. To reduce the use of healthcare resources,

make the clinical assessment more convenient for the patient, to improve the quality of the information collected and the assessment conducted, electronic measurement has the potential to perform repeatable validated objective results.

If combined with appropriate principles of gamification, these measurements can become a part of the rehabilitation process with potentially faster clinical improvement and comprehensive analysis of patient generated outcomes. In light of this, there has been a wave of support for the implementation of gaming elements in healthcare technologies. 'Gamification' involves the incorporation of game mechanics in a non-game setting and a tailored user interface for better learning which encourages engagement[10]. Reward systems, competition and immediate feedback improve user experience and have been implemented in healthcare-related fields where patients have become a niche target group[11]. These tools are used for directing users towards achieving realistic, tailored short and long-term goals. This may in turn increase patient activation allowing them to manage their own health.

STUDY DESIGN AND METHODOLOGY

Methodology:

90 patients will be recruited to a 3 month rehabilitation programme following a standard subacromial decompression +/- biceps tenotomy for impingement syndrome. Patients will be randomised into two groups:

1. Standard post-operative physiotherapy regime without the use of accessory software (Treatment as usual Group).
2. Post-operative regime of physiotherapy plus exergames utilising principles of gamification.

Power calculation:

A sample size calculation was performed using Oxford Shoulder Score (OSS) sample data collected on patients previously undergoing arthroscopic subacromial decompression. [Alpha error set at 0.05, and beta error at 0.8, mean difference of 5 points[12] in the OSS, standard deviation 6.96] Based upon this, a sample size of 32 patients in each group would be required.

A second sample size calculation was performed based on the disabilities of arm shoulder and hand (DASH) outcome measure. [Alpha error set at 0.05, and beta error at 0.8, mean difference of 15 points in the DASH[13], standard deviation 23[14]] Based upon this, a sample size of 37 patients in each group would be required.

Therefore, a target of 45 patients per group was chosen to allow for some participants withdrawing from the study (20%).

Treatment as usual Group:

Patients will attend physiotherapy on a weekly basis for assessment. They will be assessed for progression and be provided with a home exercise program. Range of motion in their shoulder will be collected on a weekly basis using the Mira technology. Patients will be required to complete an exercise diary documenting the exercises performed as well as duration and frequency.

Treatment as usual plus Exergames Group:

Prior to commencing the study the physiotherapists will set up and initially demonstrate the Exergames to the intervention participants in the home setting. This will ensure the safety of the patients and address any technological issues that may arise. Patients will attend

physiotherapy on a weekly basis as well as partaking in a set of tailored Exergames to play in the home system. The Mira software will record the patient engagement with the system including number of sessions and duration of play. Patients will also be asked to complete an exercise diary.

MIRA

Mira Rehab is a company who has developed software designed for the rehabilitation of medical conditions. Combined with a Microsoft Kinect sensor it accurately traces the range of motion in the shoulder. Mira uses games which are built based upon the best clinical practice and expertise from specialist clinicians. The Mira programme enables patients to progress through different levels within the games whilst engaging in their rehabilitation programme. Figure 1+2 demonstrate a Kinect sensor and a screenshot of theof Mira desktop demonstrating the range of Exergames available.

STUDY CRITERIA

Patient should meet the following criteria prior to enrolment in the study:

INCLUSION CRITERIA :

1. A diagnosis of impingement syndrome based upon history, clinical examination and radiological findings that requires arthroscopic subacromial decompression.

2. The patient has access to the internet to allow for the remote monitoring element of the intervention.
3. The patient needs to be able to use the sensor based technology safely, as judged by the research team.
4. The patient is willing to consent to follow-up over a twelve month period.
5. The patient has capacity to consent to the study.

EXCLUSION CRITERIA:

1. Aged less than 18 or greater than 70
2. Patients who are unwilling or unable to consent
3. Previous arthroscopic shoulder surgery
4. Patients undergoing radiotherapy
5. Patients with type 1 or type 2 diabetes
6. Patients not fit for general anaesthetic
7. Patients with significant cardiac dysfunction
8. Uncontrolled hypertension
9. Acute illness
10. History of stroke / neuromuscular conditions preventing the use of exergames
11. Patient is currently enrolled in another clinical trial.

–

Schedule of Visits Procedure	Clinic consultation	+24hours following Informed Consent	Day 1	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	Day 77	Day 84	Day 85 End of Study
Informed Consent	X															
PKEX SCORE	X	X													X	X
OSS	X														X	
DASH	X														X	
EQ5D	X														X	
VAS	X														X	
ROM	X			X	X	X	X	X	X	X	X	X	X	X	X	
Inclusion/ Exclusion Criteria Met	X															
Medical History Reviewed	X															
Demographics Collected	X															

Diary dispensed			X													
Diary Reviewed				X	X	X	X	X	X	X	X	X	X	X	X	
Physical Examination	X			X			X			X			X		X	
Withdrawal Criteria Met	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

VISIT SUMMARY

Baseline (Clinic Consultation):

Patient's eligibility to participate in the study will be assessed; inclusion/ exclusion criteria must be met. The Patient Information Sheet will be given to the patient when they are listed for surgery. Prior to their surgery date, the patient will be contacted by a member of the research team, to see if they would like to participate in the study. Patient will be asked to give their consent to the study on the day of surgery. Past medical history will be reviewed and patient demographics will be documented.

The following questionnaires will be completed by all patients at baseline:

1. The Oxford Shoulder Score (OSS)

2. The European Quality of Life 5 Dimensions (EQ5D)

3. The Disabilities of the Arm, Shoulder and Hand (DASH)

4. Visual analogue Scale for pain (VAS)

5. PKEX Patient reported outcome measures (These will be repeated at 24 hrs. to allow assessment of validity, reproducibility and test-retest reliability)

All patients will have their range of motion measured by the Mira technology to exclude researcher bias.

Randomisation:

Participants will be given a unique computer-generated identification number that will be allocated randomly, using block randomisation by the researcher to either the control or intervention group.

Patients will be randomised on a patient-by-patient basis using a randomised block design to minimise potential confounding variables.

Sealed Envelope Ltd. 2015. Create a blocked randomisation list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 25 Apr 2015].

+ 24 hours (following baseline assessments)

The patient reported outcome measures questionnaires will be repeated by all patients to allow assessment of validity, reproducibility and test-retest reliability.

Day 1

Patient attends hospital for surgical treatment. Confirmation of study consent must be confirmed. A study diary will be dispensed to patient. Study coordinator will give full explanation regarding completion of the diary.

Day 7,14,21,28,35,42,49,56,63,70,77.

Patient must attend physiotherapy clinic at day 7,14,21,28,35,42,49,56,63,70,77. A scheduled visit window to allow flexibility is +/- 2 days. Patient is to continue with their post-operative physiotherapy regime depending on the treatment group they have been randomised. Range of Movement will be assessed and documented by the research physiotherapist. Each patient diary will be reviewed and assessed.

Day 84 and 365

Patient diary will be reviewed and returned.

On completion of the 12 week programme all patients (N=90) will complete:

1. The Oxford Shoulder Score (OSS)

2. The European Quality of Life 5 Dimensions (EQ5D)

3. The Disabilities of the Arm, Shoulder and Hand (DASH)

4. Visual analogue Scale for pain (VAS)

5. PKEX Patient reported outcome measures

6. Patients randomised to Exergames arm will complete a Systems Usability score for the Mira software.

Range of movement will be assessed and documented by the research physiotherapist.

Assessment of sensor-based system:

The Kinect motion sensor has undergone full evaluation of how well it can measure shoulder movements. During validation 1670 measurements were available for analysis. Mirameasurement of all cardinal shoulder movements were significantly more precise than trained observer measurements. (Orthopaedic surgeon/physiotherapist)

The limits of agreement were (95% confidence interval):

Forward Flexion	Mira +/- 11° (8.7-12.6); trained observer +/- 16° (14.6-17.6)
Abduction	Mira +/- 11° (8.7-12.8); trained observer +/- 15° (13.4-16.2)
External rotation	Mira +/- 10° (8.1-11.9); trained observer +/- 21° (18.7-22.6)
Internal rotation	Mira +/- 9° (7.2-10.4); trained observer +/- 18° (16.0-19.3)

Range of movement will be measured as an integral part of the exergames protocol. Patients will log into the system at home. At the beginning of each session they will have their range of motion in the four planes measured. Following this the patients will complete a series of exercise games - 'exergames'. The patients will complete these as often as dictated by the clinician.

The System Usability Score (SUS) will be used to quantify how easy and acceptable it is for patients to use the system.

Standard Physiotherapy:

Patients will attend routine physiotherapy appointments and perform a set of standard exercises that has been agreed as the post-operative protocol for subacromial decompression.

OUTCOME MEASURES

1. PKEX Score

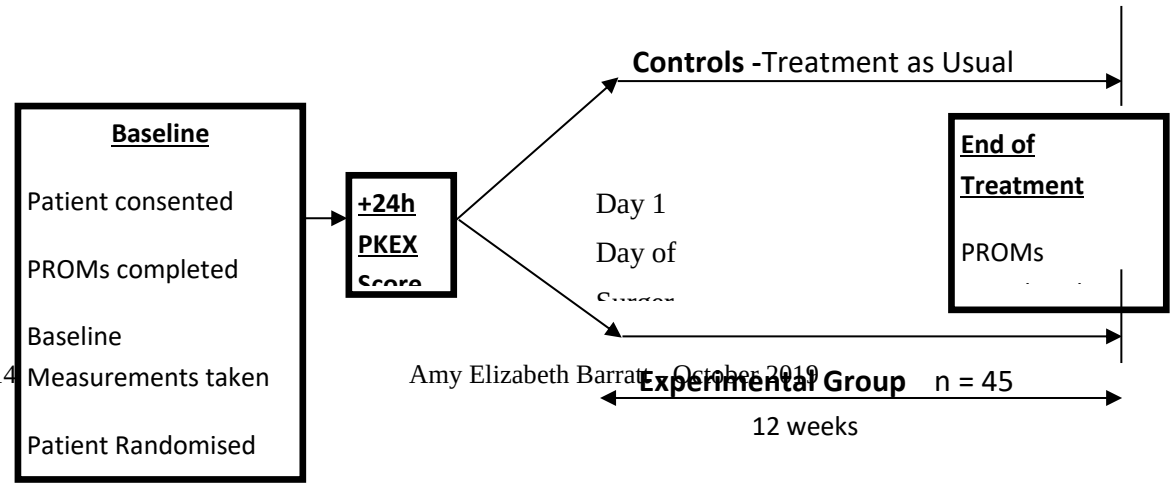
2. Oxford Shoulder score
3. DASH Score
4. EQ5D
5. Visual analogue scale for pain and satisfaction

Data Collection & Management:

The researcher and/or physiotherapist will carry out baseline assessments on all patients prior to randomisation. The research physiotherapist will assess each patient on a weekly basis. Outcome data will be collected at baseline and 12 weeks. Weekly range of motion will be documented to assess for full return of motion. Participant data sheet will record: Sociodemographic data, shoulder range of movement in the four cardinal planes, Clinical status / history of present and past comorbidities. On-going records of recruitment problems specifying reasons for refusal, attrition, etc. will be maintained.

During this period the participants will be asked to complete scoring tools at baseline, and 3 months. At the three month stage, the patients will be clinically assessed and further treatment or intervention arranged if necessary (see schedule of events). The three month results will be considered the primary outcome measure. Further scores will be collected at 12 months to assess the sustainability of any improvement.

During the course of rehabilitation using the exergames software, several parameters will be stored about each patient. These include range of motion, duration of log in time, and the number of times the patient logs into the exergames. This will allow the team to calculate the engagement section of the PKEX score. All data collected will be transferred via secured networks and this has appropriate Information Governance approval at Central Manchester Foundation Trust. If a participant does not respond to two appointment invitations, a telephone enquiry will be made asking if they wish to remain enrolled in the study



STATISTICAL ANALYSIS

Differences in the primary outcome measures (OSS and DASH) will be compared using independent samples T tests (two tailed) using SPSS 22 software.

Elements of the new questionnaire (PKEX) will be tested to see whether it is internally consistent, reproducible, valid and sensitive to clinical change[15]. Internal consistency examines whether the items measure a single underlying concept. Reproducibility is concerned with whether the questionnaire yields the same results on repeated trials under the same conditions. Validity determines whether it measures what it aims to measure; this can be examined by two methods. Content validity shows whether items in a questionnaire cover the intended topics clearly. Construct validity, the extent to which the questionnaire supports predefined hypotheses, is assessed by whether it produces an anticipated set of relationships with other variables such as clinical evidence. Sensitivity to change, or responsiveness, reflects the ability to detect clinically significant changes[16].

Internal consistency will be tested by using Cronbach's alpha[17]. This summarises the internal correlations of all items in a scale. The higher the alpha coefficient (range 0.0 to 1.0) the more consistent is the scale. We will look at the correlations of all items with the overall score and also whether Cronbach's alpha can be improved by removal of any item.

Reproducibility (test-retest reliability) will also be assessed by participants completing a second questionnaire 24 hours after the first. The data will be examined by the coefficient of reliability according to the method described by Bland and Altman[18].

Construct validity will be analysed using Pearson correlation coefficients between the total score of the questionnaire and other related measures obtained at the same assessment. Statistical analysis of the outcome measures recorded will be anaylsed using IBM SPSS Statistics Package as well as independent analysis from a statistician. We consider that the scores for the questionnaire should correlate moderately with the DASH score, OSS, VAS and the EQ5D.

CONSENT

Patients will undergo routine assessment and treatment as per trust protocol. When surgical intervention is indicated suitable patients will be invited to be part of the study. When the patient is initially listed for surgery a Patient Information Sheet will be given to patient for their consideration. Prior to their surgery date, the patient will be contacted by a member of the research team, to see if they would like to participate in the study. Willing participants will give verbal assent to the study. On the date of their surgery, the study doctor will review the inclusion/exclusion criteria. Eligible patients will be asked to consent to the study, and patient will then be randomized to either treatment group.

MONITORING

Central Manchester Foundation Trust is responsible for ensuring proper monitoring of the study is conducted. Study monitoring will be conducted by appropriately trained personnel appointed by Central Manchester Foundation Trust, in accordance with GCP guidelines and applicable regulatory requirements. Monitoring activities will include verifying the accuracy of recorded data against source documentation. Informed consent forms will be checked, and all study site files will be reviewed.

ADVERSE EVENTS MONITORING & REPORTING

Data on adverse events will be monitored and recorded throughout the duration of the study. Should any serious adverse event become apparent during the trial, this will be reviewed and assessed in line with Good Clinical Practice**.**

ETHICS AND HUMAN SUBJECT ISSUES

Full ethical approval will be obtained from the National Research Ethics Committee. Local Information Governance approval has been obtained.

PUBLICATION

Preliminary results of the study will be presented at local, national and international shoulder meetings- e.g. The British Society of Shoulder and Elbow Surgery. The study should provide several publications including data based on:

1. Validation of sensor technology in the measurement of shoulder movements
2. Validation of the PKEX shoulder score.
3. The use of gamification in the rehabilitation of post-operative shoulder patients.

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APPENDIX 9 PHYSIOTHERAPY PROTOCOL USING EXERGAMES

Physiotherapy Game Protocol

Aim: Exergames to incorporate game points and weightage distribution to map physiotherapy goals including:

1) Range of movement
2) Control
3) Speed
4) Activation of kinetic chain
5) Strength

Weightage distribution:

GAME	ROM	Control	Speed
Catch	70%		30%
Firefly	40%	60%	
Follow	10%	90%	
Izzy the bee	30%	70%	
Move	10%	90%	
Frog	30%	50%	20%
Atlantis	50%	50%	

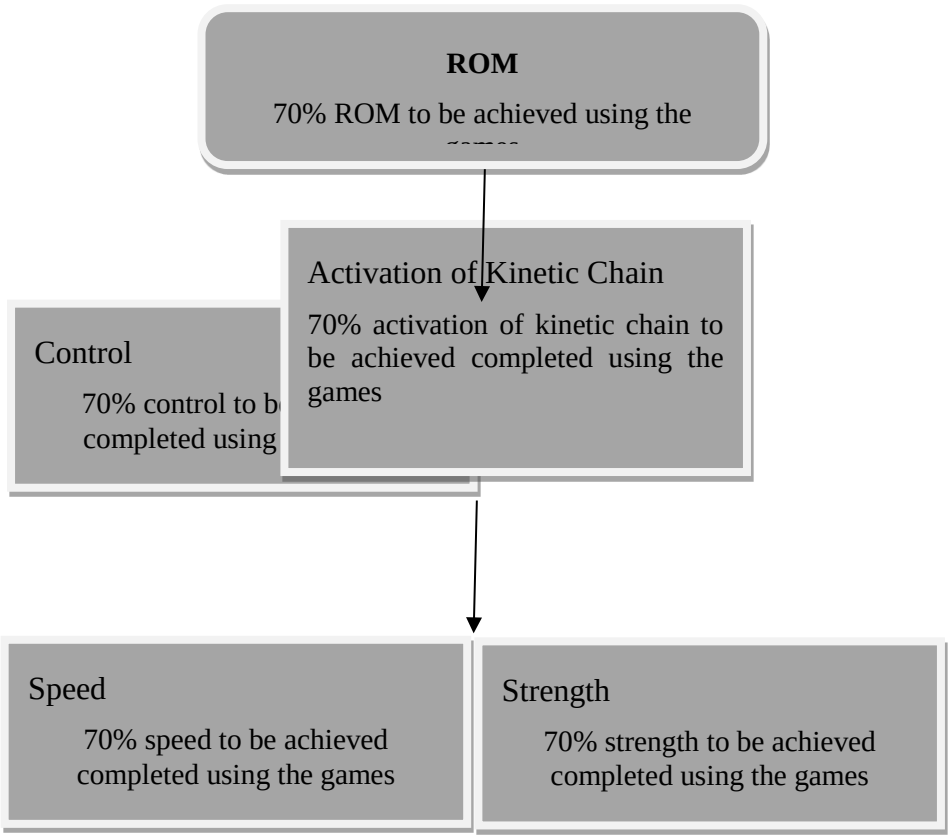
	ROM	Control	Activation of Kinetic chain	Speed	Strength
Timeframe	0-2 weeks	2-4 weeks	2- 4 weeks	+6 weeks	+ 6 weeks
Appropriate Games	Catch Atlantis	Firefly Follow Izzy the bee Move Frog Atlantis	Catch Firefly Follow Izzy the bee Move Frog	Catch	Catch Firefly Follow Izzy the bee Move Frog

Game points

Week 0-2

Week 2-4

Week +6



Games protocol for patients achieving the physiotherapy goals

Timeframe	Games	Level	Full Schedule	Repetition
1-3 weeks	Catch Atlantis	Easy Easy	**1**) Catch for 2 minutes Break for 30 seconds Atlantis 2 minutes ROM	X1 daily
3-5 weeks	Catch Firefly Follow Izzy the bee Move Frog	Medium Medium Medium Medium Easy Medium	**1**)Izzy the bee for 2 minutes Break for 30 seconds Fire fly for 2 mins ROM **2**) Catch for 2 minutes Break for 30 seconds Move for 2 minutes ROM **3**) Frog for 2 minutes Break for 30 seconds Izzy the bee for 2 minutes ROM	X 1 daily
5-7 weeks	Catch Firefly Follow Izzy the bee Move Frog Atlantis	Medium Medium Medium Medium Easy Mediu	**1)**Catch for 2 minutes **using 1 KG Weight** Break for 30 seconds Izzy the be for 30 seconds **2)**Catch for 2 minutes **using 1 KG weight**	X1 daily

		m Mediu m	Break for 30 seconds Atlantis for 2 minutes ROM **3)**Frog for two minutes Break for 30 seconds Move using **1 KG weight** for 2 minutes ROM	
7-9 weeks	Catch Firefly Follow Izzy the bee Move Frog Atlantis	Mediu m Mediu m Hard Mediu m Hard Hard Mediu m	**1)**Izzy the bee **standing on one leg** for 2 minutes Break for 30 seconds Firefly **using 1KG weight** for 2 minutes ROM **2)**Frog for 2 minutes Break for 30 seconds Atlantis **using 1KG weight** for 2 minutes ROM 3)Catch using 1KG weight for 2 minutes Break for 30 seconds Move for 2	X 1 daily

			minutes ROM	
9-12 weeks	Catch Firefly Follow Izzy the bee Move Frog Atlantis	Hard Hard Hard Hard Hard Hard Hard	1)Catch standing on one leg for 2 minutes Break for 30 seconds Izzy the be for 30 seconds **2)**Catch **using 1KG weight** for 2 minutes Break for 30 seconds Atlantis **standing on one leg** for 2 minutes ROM **3)**Frog using **1KG weight** for two minutes Break for 30 seconds Move for 2 minutes ROM	X1 daily