

**The Effectiveness of Game-Based Virtual Reality Approach in Patients with  
Subacromial Impingement Syndrome**

**Study Protocol and Statistical Analysis Plan (SAP)**

**(Pages 1 - 20)**

**April 8, 2019**

**The Effectiveness of Game-Based Virtual Reality Approach in Patients with  
Subacromial Impingement Syndrome**

**Study Protocol**

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**April 8, 2019**

## **Study Protocol**

Study titled “The Effectiveness of Game-Based Virtual Reality Approach in Patients with Subacromial Impingement Syndrome” was approved by Marmara University Faculty of Health Sciences Ethical Committee at the meeting on 29.11.2018 with approval number: 36 (Annex-1).

The legal representatives of the patients who participated in the study will be informed about the aim, duration and the programs to be applied throughout the study. Volunteer Information Form will be signed and approved in accordance with the standards deemed appropriate by the Ethical Committee of Marmara University Faculty of Health Sciences. The study will be conducted in accordance with the Declaration of Helsinki.

### **Hypothesis of the Study**

H<sub>0</sub>: Addition of game-based virtual reality exercises to the rehabilitation program in patients with subacromial impingement syndrome does not contribute positively in improving the effectiveness of upper extremity for pain, range of motion and disability

H<sub>1</sub>: Addition of game-based virtual reality exercises to the rehabilitation program in patients with subacromial impingement syndrome contribute positively in improving the effectiveness of upper extremity for pain, range of motion and disability.

### **Randomization of the Study Groups**

Individuals with Subacromial Impingement Syndrome applying to Cadde Medical Center for treatment will be invited to participate in the study. Individuals who volunteered to participate and whom met the criteria for participation will be randomized with simple random sampling method and will be divided into two groups. In both groups participants will receive conventional physiotherapy and rehabilitation. In the study group, 10 minutes of exercises with the game-based virtual reality exercises will added to the conventional physiotherapy and rehabilitation methods

### **Inclusion Criteria**

- Volunteered to participate in the study,
- Aged between 18-65 years

### Exclusion Criteria

- Any visual or hearing problem,
- Other neurological, orthopedic or rheumatic problems that may restrict shoulder motion or cause pain,
- Having a physical disability or uncontrolled chronic systemic disease,
- Major trauma,
- Treatment for shoulder problems within the last 6 months,
- History of epilepsy

### Evaluations

A Physiotherapist will applying the following evaluation parameters at the baseline, and at the end of 4-weeks treatment program, the same physiotherapist will be applying evaluation parameters. Primary outcome measures and applied evaluations are shown in Table 1.

**Table 1.** Primary outcome measures and evaluation methods

<b>Primary Outcome Measures</b>	<b>Evaluation Methods</b>
Range of Motion (ROM)	Goniometer
Pain	Visual Analogue Scale (VAS)
Disability	The Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire
Quality of Shoulder Function	Constant-Murley Score
Muscle Strength	Dynamometer
Pain Threshold	Algometer
Proprioception	Marmara Visual Auditory Joint Education Device (MarvaJED)
Kinesiophobia	Tampa Kinesiophobia Scale (TKS)
Satisfaction of the Treatment	Visual Analogue Scale (VAS)

The range of motion will be defined with ‘goniometer’, the pain with ‘Visual Analogue Scale (VAS)’, the disability with ‘The Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire’, the quality of shoulder function with ‘Constant- Murley Score’, the muscle strength with ‘dynamometer’, the pain threshold with algometer, the proprioception with

‘Marmara Visual Auditory Joint Education Device (MarvaJED)’, the kinesiophobia with ‘Tampa Kinesiophobia Scale (TKS), the satisfaction of the treatment with ‘Visual Analog Scale (VAS)’.

### **Treatment Program**

The participants in the study will be rehabilitated in Cadde Medical Center for 5 times a week for 4 weeks, a total of 20 sessions (Duration of one session is 60 minutes).

Group I (Control Group) will receive conventional physiotherapy and rehabilitation treatment program

Group II (Study Group) will receive conventional physiotherapy and rehabilitation treatment program and game-based virtual reality exercises (with a device named USE-IT) (10 minutes).

### **Game-Based Virtual Reality Exercises**

In addition to the conventional physiotherapy and rehabilitation program, a 10-minute game-based virtual reality exercises will be applied. A game-based virtual reality device named USE-IT will be added to the rehabilitation program. USE-IT is a technological rehabilitation system designed by the Department of Physiotherapy and Rehabilitation at Hacettepe University (Ankara, Turkey). It is a smart gaming device which has been used in patients who suffer from movement loss in their upper extremities due to various neurological and orthopedic reasons.

### **Conventional Physiotherapy and Rehabilitation Program**

The conventional physiotherapy and rehabilitation program includes the application of Transcutaneous Electrical Nerve Stimulation (TENS), cold pack, therapeutic ultrasound, Codman Exercises, Wand exercises, shoulder wheel exercises, finger ladder exercises, strengthening exercises with elastic band and capsule stretching.

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**Statistical Analysis Plan (SAP)**

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## **Statistical Analysis Plan (SAP)**

The statistical program Statistical Package for Social Sciences (SPSS) Version 11.5 (SPSS Inc., Chicago, IL, USA) will be used in the data analysis of the study. The p value of  $p < 0.05$  will be considered to be statistically significant in the data analysis. The initial demographic characteristics (age, boy, body weight) of all patients included in the study will be calculated.

‘Shapiro-Wilks Test’ will be used to investigate the appropriateness of the variables to normal distribution. ‘t-test’ will be used to compare the parameters of normal distribution in order to investigate the efficacy studies before and after the treatment; ‘Wilcoxon Test ‘ will be used to compare the parameters that do not comply with normal distribution.

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**Annex**

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**April 8, 2019**

**Annex 1. Marmara University Faculty of Health Sciences Ethical Committee  
Approval (Approval made at the meeting on 29.11.2018 with number: 36)**



**T.C.  
MARMARA ÜNİVERSİTESİ  
Sağlık Bilimleri Fakültesi  
Girişimsel Olmayan Etik Kurulu**

PROJENİN ADI : "Subakromiyal Sıkışma Sendromlu Olgularda Oyun Temelli Sanal Gerçeklik Yaklaşımının Etkinliği"  
ROJENİN YÜRÜTÜCÜSÜ : Doç. Dr. Zübeyir SARI  
PROJEDEKİ ARAŞTIRICILAR : Berivan Beril KILIÇ, Dilara Merve SARI, Nimet SERMENLİ  
ONAY TARİHİ VE SAYISI : 29.11.2018/36

**Sayın: Doç. Dr. Zübeyir SARI**

"36" protokol numaralı "Subakromiyal Sıkışma Sendromlu Olgularda Oyun Temelli Sanal Gerçeklik Yaklaşımının Etkinliği" isimli projenin Fakültemiz Etik Kurulu tarafından incelenmiş oy birliği ile etik yönden uygun olduğuna karar verilmiştir.

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KARAKOÇ

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**Annex 2. Participants Tracking Form**

**Name-Surname:**

**Date:**

**Tel Number:**

**Birth Date:**

**Age:**

**Sex:**

**Height:**

**Weight:**

**Dominant Side (Mark): Right / Left**

**Effected Side (Mark): Right/ Left**

**How did the problem occur? (Please explain):**

**Did you have any operation? Please write, if you did:**

**Do you have any additional problem?**

**No:**

**Yes/ If yes, What is it?**

**Assessment of Pain - Visual Analogue Scale**

- How severe is your shoulder pain during activity?

0.....5.....10  
(no pain) (worst possible pain)

- How severe is your shoulder pain during rest?

0.....5.....10  
(no pain) (worst possible pain)

### Assessment of Range of Motion and Muscle Strength

	Muscle Strength				Range of Motion						
	R		L		R			L			
	1	2	1	2	1	2	3	1	2	3	
Shoulder Flexion											
Shoulder Extension											
Shoulder Abduction											
Shoulder Adduction											
Shoulder IR											
Shoulder ER											
Elbow Flexion											
Elbow Extension											
Supination											
Pronation											

## Assesment of Disability - Disabilities of the Arm, Shoulder and Hand Questionnaire– DASH

### DISABILITIES OF THE ARM, SHOULDER AND HAND – British English

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

	<i>NO</i>	<i>MILD</i>	<i>MODERATE</i>	<i>SEVERE</i>	<i>UNABLE</i>
	<i>DIFFICULTY</i>	<i>DIFFICULTY</i>	<i>DIFFICULTY</i>	<i>DIFFICULTY</i>	
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 jobs (e.g. wash windows, clean floors)	1	2	3	4	5
8 Garden or outdoor property 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/ 5kgs)	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 jumper	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. card playing, knitting, etc)	1	2	3	4	5
17 Recreational activities which require you to take some force or impact through your arm, shoulder or hand (e.g. golf, hammering, tennis etc)	1	2	3	4	5
18 Recreational activities in which you move your arm freely (e.g. playing Frisbee, badminton etc)	1	2	3	4	5
20 Manage transport needs (getting from one place to another)	1	2	3	4	5
21 Sexual activities	1	2	3	4	5

	<b>NOT AT ALL</b>	<b>SLIGHTLY</b>	<b>MODERATELY</b>	<b>Quite a bit</b>	<b>Extremely</b>
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? (circle number)	1	2	3	4	5

	<b>NOT LIMITED AT ALL</b>	<b>SLIGHTLY LIMITED</b>	<b>MODERATELY LIMITED</b>	<b>VERY LIMITED</b>	<b>UNABLE</b>
23 During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? (circle number)	1	2	3	4	5

<b>Please rate the severity of the following symptoms in the last week (circle number)</b>	<b>NONE</b>	<b>MILD</b>	<b>MODERATE</b>	<b>SEVERE</b>	<b>EXTREME</b>
24 Arm, shoulder or hand pain	1	2	3	4	5
25 Arm, shoulder or hand pain when you do 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

	<b>NO DIFFICULTY</b>	<b>MILD DIFFICULTY</b>	<b>MODERATE DIFFICULTY</b>	<b>SEVERE DIFFICULTY</b>	<b>SO MUCH DIFFICULTY THAT I CAN'T SLEEP</b>
29 During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? (circle number)	1	2	3	4	5

	<b>STRONGLY DISAGREE</b>	<b>DISAGREE</b>	<b>NEITHER AGREE OR DISAGREE</b>	<b>AGREE</b>	<b>STRONGLY AGREE</b>
30 I feel less capable, less confident or less useful because of my arm, shoulder or hand problem (circle number)	1	2	3	4	5

DASH DISABILITY/SYMP TOM SCORE =  $\frac{((\text{sum of n responses})-1)}{n} \times 25$  (where n is the number of completed responses)

A DASH score may not be calculated if there are greater than 3 missing items.

## DISABILITIES OF THE ARM, SHOULDER AND HAND – British English

### WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including home-making if that is your main work role).

Please indicate what your job / work is: \_\_\_\_\_

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 DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Doing your work in your usual way?	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 sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you: \_\_\_\_\_

I do not play a sport or an instrument. (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 DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Playing your instrument or sport in your usual way?	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 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

**Scoring the optional modules:** add up the assigned values for each response;

Divide by 4 (number of items); subtract 1; multiply by 25.

An optional module score may not be calculated if there are any missing items.

# Assessment of Quality of Shoulder Function- Constant Murley Score

## Patient-based Questionnaire

Date: .....

PATIENT'S NAME: ..... PATIENT NUMBER: .....

D.O.B.: ..... SIDE: RIGHT /LEFT

We would be grateful if you could take a few minutes to fill in this questionnaire. It is an essential part of our evaluation of the results of our treatment and surgery. It ultimately improves the quality of service we provide to you. **PLEASE COMPLETE THE FORM BY CIRCLING THE MOST APPROPRIATE RESPONSE.**

### A. PAIN

A1. Do you have pain in your shoulder during **normal** activities? (Please circle the most appropriate response)

1. NO PAIN      2. MILD PAIN      3. MODERATE PAIN      4. SEVERE PAIN

A2. LEVEL OF PAIN

If 0 means no pain and 15 means the worst pain you can have, **please circle the number** which describes your shoulder pain when you are doing **normal** activities:

☺ 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 ☹

NONE      MILD      MODERATE      SEVERE      UNBEARABLE

### B. FUNCTION (please circle the most appropriate response)

B1. Does your shoulder limit your occupation or daily living?

1. NO OR VERY SLIGHTLY      2. MODERATE LIMITATION      3. SEVERE LIMITATION

B2. Are your leisure and recreational activities limited by your shoulder?

1. NO OR VERY SLIGHTLY      2. MODERATE LIMITATION      3. SEVERE LIMITATION

B3. Does your shoulder disturb your night sleep?

1. NO      2. SOMETIMES      3. YES

B4. What level can you use your arm for **reasonable painless** movement?

1. WAIST      2. CHEST      3. NECK      4. EAR      5. ABOVE HEAD

B5. On a scale of 0 to 10, where 0 is **not satisfied** and 10 is **very satisfied**, how satisfied are you with your shoulder? (Circle the correct number)

☹ 0 1 2 3 4 5 6 7 8 9 10 ☺

**C. WHAT IS YOUR OCCUPATION?** .....

C1. How well can you perform your occupation? **(Please circle the most appropriate response)**

1. EASILY      2. WITH LITTLE DIFFICULTY      3. WITH MODERATE DIFFICULTY  
4. WITH EXTREME DIFFICULTY      5. NOT AT ALL

C2. What are your two main sporting/leisure activities?  
.....

C3. How well can you perform these activities? **(Please circle the most appropriate response)**

1. EASILY      2. WITH LITTLE DIFFICULTY      3. WITH MODERATE DIFFICULTY  
4. WITH EXTREME DIFFICULTY      5. NOT AT ALL

=====

**D. POSTOPERATIVE QUESTIONS** - only complete this section if you have had an operation

[Operation: ..... Date of operation:.....]

D1. How do you feel **now**, following your operation?  
**(Please circle the most appropriate response)**

1. MUCH BETTER      2. BETTER      3. SAME      4. WORSE

D2. Have you **now** **(Please circle the most appropriate response)**

1. Returned to the same occupation?  
2. Returned to the same occupation but with decreased level of activity (due to the shoulder)?  
3. Changed occupation due to the shoulder?  
4. Stopped working altogether because of your shoulder?

D3. If you have changed occupation, what job do you do now?:  
.....

D4. Have you **now** **(Please circle the most appropriate response)**

1. Returned to the same level of activity in the same sport?  
2. Returned to a decreased level of activity in the same sport (because of the shoulder)?  
3. Changed sports because of the shoulder?  
4. Stopped playing sports altogether because of the shoulder?

D5. If you have changed sports, what have you changed to?  
.....

**E. Range of Motion**

Copy the movements the model is performing – it may be useful to perform this exercise in front of a mirror.

Starting from left to right in each row

- **Tick the box** (below each photograph) if you are **able to perform the action**
- **Leave the box blank** if you **cannot perform** the action



**F. Strength**

Look at the two photographs below. Try to hold your arm in this position for 3 seconds each time carrying weights in the plastic bag.

Please use as weights within the plastic bag:

- **Bags of sugar**
- and/or
- **Filled plastic bottles of milk** (may be filled with water)
- and/or
- **Whatever is available for you with known weight**

Please record in the spaces below what was **the maximum weight** in kilograms (or pounds) or litres (or pints) that you **were able to hold in this position for 3 seconds** for each arm.



Seen from the front



seen from above

The maximum weight that I was able to hold in this position for 3 seconds:

Right Arm:	<input type="text"/>	Kilograms/Litres	Left Arm:	<input type="text"/>	Kilograms/Litres
Right Arm:	<input type="text"/>	Pounds/Pints	Left Arm:	<input type="text"/>	Pounds/Pints

**G. COMMENTS**

The space below is for any further comments you would like to make.

Thank you for filling in this questionnaire.

## Assessment of Kinesiophobia - Tampa Kinesiophobia Scale (TKS)

### Tampa Scale for Kinesiophobia (Miller , Kori and Todd 1991)

- 1 = strongly disagree  
 2 = disagree  
 3 = agree  
 4 = strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

### Assessment of satisfaction after the treatment

- How satisfied are you with the decrease of pain at the end of treatment?

0.....5.....10  
(Not satisfied at all) (Very satisfied)

- How satisfied are you with your functionality at the end of treatment?

0.....5.....10  
(Not satisfied at all) (Very satisfied)

- How satisfied are you with all of your treatment?

0.....5.....10  
(Not satisfied at all) (Very satisfied)

- How satisfied are you with your physiotherapist?

0.....5.....10  
(Not satisfied at all) (Very satisfied)