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Study Identification

Unique Protocol ID:	B-2005/612-001
Brief Title:	Rehabilitation Exercise Using Digital Healthcare System in Patients With Rotator Cuff Repair
Official Title:	New Model of Short-term Rehabilitation Exercise Training Using Digital Healthcare System in Patients With Rotator Cuff Repair; Randomized Controlled Study
Secondary IDs:	

Study Status

Record Verification:	January 2022
Overall Status:	Recruiting
Study Start:	July 30, 2020 [Actual]
Primary Completion:	December 31, 2022 [Anticipated]
Study Completion:	March 31, 2023 [Anticipated]

Sponsor/Collaborators

Sponsor:	Seoul National University Bundang Hospital
Responsible Party:	Principal Investigator Investigator: Jae-Young Lim [jlim] Official Title: Professor Affiliation: Seoul National University Bundang Hospital
Collaborators:	Ministry of Health, Republic of Korea

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: B-2005/612-001 Board Name: Institutional Review Board Board Affiliation: Seoul National University Bundang Hospital Phone: +82-031-787-8801 Email: snubhirb@gmail.com Address:

	82, Gumi-ro 173beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do
Data Monitoring:	Yes
FDA Regulated Intervention:	No

Study Description

Brief Summary: The study aims to examine the effect of short-term rehabilitation exercise support using digital healthcare system (Uincare homeplus) in the patients with rotator cuff repair surgery. The study is a two-arm prospective randomized controlled study comparing the effect of rehabilitation exercise digital healthcare system at home with conventional brochure-based home exercise. Simple Shoulder Test (SST), Pain (using Numerical rating scale), shoulder range of motion (ROM), Disability of Arm, Shoulder and Hand (DASH), Shoulder Pain and Disability Index (SPADI), quality of life using EQ-5D will be evaluation on enrollment, 6-weeks, 12-weeks and 24-weeks after enrollment.

Detailed Description: Rotator cuff tear is one of the most common disorders affecting shoulder pain and disabilities of daily life. It is a disorder that can be caused by trauma, overuse, inappropriate usage of shoulder as well as degenerative change, which is increasing due to enlarged geriatric population. Current method of post-operative rehabilitation is home-based self rehabilitation using brochure, combined with one or two times of education at the hospital before discharge. Patients often find difficulty in doing rehabilitation by themselves at home without supervision which resulted in decreased compliance.

With development of technologies using multi-motion sensor and AR(augmented-reality) system, the investigators have developed a digital healthcare system(Uincare Homeplus) which can supplement patients' rehabilitation at home by giving them proper instructions as well as feedback.

In this prospective randomized controlled study, the investigators aimed to compare the efficacy of the newly-developed digital healthcare system with conventional rehabilitation program.

Conditions

Conditions:	Rotator Cuff Tears
Keywords:	Rotator Cuff Repair Post-Operative Rehabilitation Digital Healthcare System

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Single (Outcomes Assessor)
Allocation:	Randomized
Enrollment:	115 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Digital Healthcare System Rehabilitation Rehabilitation using Uincare Homeplus	Device: Rehabilitation using Digital Healthcare System (Uincare Homeplus) Uincare Homeplus is a device using infrared, kinect camera and motion capture technology to track 3D motion of the patients' posture and joint articulations. It also has embedded exercise training software dedicated to rotator cuff repair post-op rehabilitation at home. Home-based self-rehabilitation using brochure for 6 weeks post surgery (same as the active comparator) Home-based self-rehabilitation using digital healthcare system(Uincare Homeplus) for 6 to 12 weeks post surgery. Other Names: • Uincare Homeplus
Active Comparator: Conventional Rehabilitation Rehabilitation using Brochure	Conventional Rehabilitation Home-based self-rehabilitation using brochure for 12 weeks post surgery.

Outcome Measures

Primary Outcome Measure:

1. Change from baseline Simple Shoulder Test (SST) on the affected shoulder
   Simple Shoulder Test is a self-reported shoulder-specific questionnaire that measures functional limitations of the affected shoulder in patients with shoulder dysfunction. The SST consists of 12 questions with dichotomous (yes/ no) response options. score ranges from 0 to 100, higher score meaning better shoulder function.

   [Time Frame: Enrollment, 6-weeks, 12-weeks, 24-weeks]

Secondary Outcome Measure:

2. Numerical Rating Scale (NRS) on the affected shoulder
   Evaluation of pain of the affected shoulder using numerical rating scale (0-10, with score 0 indicating no pain), higher scores mean worse outcome.

   [Time Frame: Enrollment, 6-weeks, 12-weeks, 24-weeks]
3. Range of Motion (ROM) on the affected shoulder
   Evaluation of change of ROM in the affected shoulder from baseline to 24 weeks

   [Time Frame: Enrollment, 6-weeks, 12-weeks, 24-weeks]
4. Manual Muscle Test (MMT) on the affected arm
   Evaluation of change of MMT in the affected arm from baseline to 24 weeks Upper extremities MMT ranges from 0-25, higher scoring meaning better outcome.

   [Time Frame: Enrollment, 6-weeks, 12-weeks, 24-weeks]
5. Disabilities of the Arm, Shoulder and Hand (DASH) on the affected arm
   The DASH is a 30-item self-report questionnaire designed to assess musculoskeletal disorders of the upper limb. The score ranges from 0 (no disability) to 100 (most severe disability) with higher score meaning worse outcome.

   [Time Frame: Enrollment, 6-weeks, 12-weeks, 24-weeks]
6. Shoulder Pain and Disability Index (SPADI) on the affected shoulder
   The Shoulder Pain and Disability Index (SPADI) is a self-administered questionnaire that consists of two dimensions, one for pain and the other for functional activities.

   Overall total scores range from 0 to 130 with higher score indicating more shoulder dysfunction.

[Time Frame: Enrollment, 6-weeks, 12-weeks, 24-weeks]

7. Quality of Life using EQ-5D-5L
   Evaluation of quality of life using EQ-5D-5L. This scale is numbered from -0.066 to 0.904. lower value means worse quality of life.

   [Time Frame: Enrollment, 6-weeks, 12-weeks, 24-weeks]

Eligibility

Minimum Age:	50 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Patient who had rotator cuff repair surgery
- Patient who is discharged to home after surgery

Exclusion Criteria:

- Patient who has previous history of shoulder surgery on the affected shoulder
- Patient who has severe neurological deficit or infection on the affected shoulder
- Patient who has severe comorbidities (Ex: uncontrolled diabetes mellitus or rheumatoid arthritis) that inhibit affected shoulder rehabilitation
- Patient who cannot participate rehabilitation program

Contacts/Locations

Central Contact Person: Jay-Young Lim, M.D., Ph. D
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Central Contact Backup:

Study Officials: NOTE : Study Official is required by the WHO and ICMJE.

Locations: **South Korea**
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[Recruiting]
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Contact: Jae-Young Lim, M.D., Ph.D. +82-10-5390-0373 drlim1@snu.ac.kr
Principal Investigator: Jae-Young Lim, M.D., Ph. D.

IPDSharing

Plan to Share IPD: Undecided
NOTE : Plan to Share IPD must be 'Yes' or 'No' to satisfy ICMJE policy ('Undecided' is not accepted).

References

Citations:

Links:

Available IPD/Information: