

Cover Page

Official Title: Use of an Off-the-Shelf Exergame as an In-Bed Gamified Rehabilitation Intervention for Severely Deconditioned Inpatients: A Feasibility Study

NCT Number: NCT06937463 **Document Date:** 2026.05.14.

Principal Investigator: Won Kim, Associate Professor, Department of Rehabilitation Medicine, Asan Medical Center

Study Implementation Institution: Asan Medical Center

Study Protocol and Statistical Analysis Plan

1. Study Overview

- **Background:** Patients often face limited mobility due to Intensive Care Unit Acquired Weakness (ICU-AW) or secondary sarcopenia after acute medical illnesses or surgeries. Traditional rehabilitation is often limited to monotonous movements due to postural restrictions. Exer-gaming (e.g., Nintendo Ring Fit) can increase motivation and improve exercise adherence.
- **Objective:** To explore the feasibility, safety, and adherence of a virtual reality-based rehabilitation program using Nintendo Ring Fit™ for hospitalized patients with limited mobility.
- **Study Design:** Prospective clinical study (Pilot study).
- **Study Duration:** From IRB approval date to October 31, 2025.

2. Participants

- **Target Sample Size:** 28 participants (calculated considering dropout rates for a pilot study).
- **Inclusion Criteria:**
 - Adult patients aged 18 years or older admitted with acute medical/surgical diseases.
 - Patients with limited mobility with a Functional Ambulatory Category (FAC) score of 3 or less.
 - Organ transplant recipients with history of critical care
 - Note: FAC 3 indicates a state requiring one guardian for supervision without physical contact during ambulation.
- **Exclusion Criteria:**
 - Unable to cooperate due to severe cognitive or consciousness impairment.
 - Continuous biomechanical instability.
 - Severe range of motion (ROM) or strength limitations, or amputation, preventing

exercise execution.

- Fractures or skeletal instability requiring movement restrictions.
- Difficulty cooperating due to vision or hearing impairment.

3. Interventions (Methods)

- **Rehabilitation Tool:** Exer-gaming using Nintendo Ring Fit™.
- **Protocol:**
 - **Duration & Frequency:** A total of 10 exercise sessions over 2 weeks (can be extended up to 1 month depending on the patient's condition).
 - **Session Time:** Within 30 minutes per session.
 - **Movements:** The program utilizes movements possible while lying down or sitting (e.g., upper limb, trunk, and lower limb exercises) customized to individual capabilities.

4. Outcome Measures

Assessments are conducted at baseline (Visit 1), interim (Visit 7), and completion (Visit 13), with continuous data collected during intervention sessions.

- **Clinical Assessments:**
 - Manual Muscle Test (MMT), Medical Research Council Sum Score (MRC-SS), Knee Extensor test, Grip strength test.
 - Modified Barthel Index, Mini-Mental State Examination (MMSE), Numeric Rating Scale (NRS) for pain.
 - Mobility/Balance: ASAN Mobility Score, ICU Mobility Scale, FAC, Sit to Stand test, Single Leg Raise (SLR) capability, Bridge capability, 10-Meter Walk Test (10MWT).
- **Engineering Indices (Multi-sensor Data):**
 - Physical measurements (activity level, ROM, speed, distance) utilizing camera-based motion recognition sensors and Inertial Measurement Units (IMU).
 - Built-in Nintendo Ring Fit™ score.

- **Patient-Reported Outcomes (PROs):**
 - Quality of life (EQ-5D), mood, subjective health/functional status.
 - Program satisfaction, acceptance, difficulty, and understanding.
- **Safety & Adherence:**
 - Session participation/discontinuation rates, reasons for dropout.
 - Heart rate monitoring via Polar monitor.
 - Occurrence of adverse events (falls, extubation, altered consciousness).
- **Exercise metrics:**
 - Net exercise time
 - exercise prescription, completion and fail records
 - exercise performance score(calculated by nintendo software) and repetition numbers

5. Statistical Analysis Plan

- **Software:** SPSS and R programs.
- **Significance Level:** $p < 0.05$.
- **Descriptive Statistics:** Baseline participants' demographic and clinical characteristics, compliance, exercise metrics, patient satisfaction, safety measures.
- **Normality Test:** Shapiro-Wilk test.
- **Categorical Variables:** Analyzed using Chi-square test, Fisher's exact test and Logistic regression.
- **Continuous Variables:** Analyzed using Mann-Whitney U test, Kruskal-Wallis test, Wilcoxon signed-rank test and Friedman test. Post hoc pairwise comparisons will be conducted using the Wilcoxon signed-rank test with Bonferroni correction.

Informed Consent Form Information

1. Study Title and Investigators

- **Title:** Feasibility of Exergame-Based Rehabilitation in Patients With Limited Mobility
- **Principal Investigator:** Won Kim (Dept. of Rehabilitation Medicine).

2. Purpose of the Study

- To evaluate the validity, safety, and compliance of a rehabilitation exercise program utilizing Nintendo Ring Fit™ for patients with restricted mobility in bed.

3. Study Procedures

- **Screening:** Review of eligibility, baseline demographics, and medical history.
- **Evaluations (Visits 1, 7, 13):** Comprehensive physical function tests, cognition, and pain assessments.
- **Interventions (Visits 2-6, 8-12):** Execution of the Nintendo Ring Fit™ program. Specific visits include data collection using IMU wearable sensors and camera-based motion recognition.

4. Risks and Discomforts

- Potential risks include temporary dyspnea, tachycardia, blood pressure changes, falls, or dislodgement of therapeutic devices.
- The risk of falling is considered very low as exercises are low-intensity and performed while lying or sitting under 1:1 supervision by medical staff/researchers.
- The research team will cover hospitalization costs if an adverse event requires admission due to the Nintendo Ring Fit™ intervention.

5. Benefits and Costs

- **Benefits:** Patients can perform bed exercises interestingly through gaming, potentially

overcoming boredom. However, as it is for research, direct therapeutic efficacy is not guaranteed.

- **Costs:** There are no additional costs for treatments and evaluations conducted for the study.
- **Compensation:** **100,000 KRW** will be provided upon completion of the study. If participation is interrupted (e.g., due to discharge), the amount will be paid at the last visit.

6. Confidentiality

- Video recordings and sensor data are collected for motion recognition analysis.
- Data will be encrypted and shared securely via restricted-access Asan Works Drive with joint researchers at UNIST (Ulsan National Institute of Science and Technology) to prevent data leakage.
- All research data, including videos, will be securely stored for 3 years post-study and then permanently destroyed.

7. Voluntary Participation and Withdrawal

- Participation is completely voluntary.
- Participants can withdraw at any time without any disadvantage or impact on their standard care.