Cover Page

Official Title: Feasibility and safety validation study of a rehabilitation program and platform using digital devices for Recovery of Bedridden Patients **NCT Number:** NCT06849765 **Document Date:** 2026.01.08.

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:** Many hospitalized patients remain bedridden after surgery, leading to muscle weakness and complications like pneumonia. Current rehabilitation is limited by cost and manpower. Digital therapeutics offer a solution to overcome time, space, and economic limitations.
- **Objective:** To verify the feasibility and safety of a rehabilitation program and platform (MORA application) for the recovery of bedridden patients and to analyze their physical functional characteristics.
- **Study Design:** Prospective cohort clinical study (Pilot Study).
- **Study Duration:** From IRB approval date to December 31, 2025.

2. Participants

- **Target Sample Size:** 28 participants (calculated considering dropout rates for a pilot study).
- **Inclusion Criteria:**
    - Adult patients aged 19 years or older admitted to Asan Medical Center.
    - Patients in a bedridden state with a Functional Ambulatory Category (FAC) score of 3 or less.
    - Note: FAC 3 indicates a state requiring a guardian for supervision without physical contact during ambulation.
- **Exclusion Criteria:**
    - Unable to follow app movements due to cognitive decline.
    - Pain or limited range of motion in upper/lower limbs preventing participation.
    - Biomechanically unstable patients.
    - Difficulty cooperating due to vision or hearing impairment.

3. Interventions (Methods)

- **Rehabilitation Tool:** MORA Application.
- **Protocol:**
    - **Frequency:** Twice a day (morning, afternoon), 20 sessions total over 2 weeks.
    - **Duration:** Within 20 minutes per session (10-15 movements per session).
    - **Supervision:** A researcher visits for the first 5 days to guide app execution and movements. Afterwards, patients perform exercises autonomously with push notifications/reminders.
    - **Customization:** Exercise programs are prescribed based on the patient's functional capability evaluated at enrollment.

4. Outcome Measures

Assessments are conducted at baseline (Screening/Visit 1), 1 week (Visit 7), and 2 weeks/completion (Visit 13).

- **Clinical Assessments:**
    - Manual Muscle Test (MMT), Medical Research Council Sum Score (MRC-SS).
    - ASAN Mobility Score, ICU Mobility Scale, FAC.
    - Sit to Stand test, Single Leg Raise (SLR) (5-second hold capability), Bridge capability.
    - Hand Grip Strength, Knee Extensor Test.
    - 10-Meter Walk Test (10MWT).
    - Mini-Mental State Examination (MMSE), Numeric Rating Scale (NRS) for pain.
- **Video Data:**
    - Exercise performance is recorded and anonymized for analysis.
- **Patient-Reported Outcomes (PROs):**
    - Satisfaction with MORA app, acceptance, difficulty, understanding.
    - Mood, Quality of Life, subjective health status.
- **Safety & Adherence:**

- Adverse events (falls, dizziness, etc.).
- Participation rate, reasons for discontinuation, heart rate monitoring (Polar).

5. Statistical Analysis Plan

- **Software:** SPSS and R programs will be used.
- **Significance Level:** $p < 0.05$.
- **Descriptive Statistics:** Patient compliance, severity, and assistance levels will be described descriptively.
- **Normality Test:** Shapiro-Wilk test.
- **Categorical Variables:** Analyzed using Chi-square test and Logistic regression.
- **Continuous Variables:**
  - Analyzed using Mann-Whitney U test, Wilcoxon signed-rank test (for pre-post comparison), Friedman test, Kruskal Walli's test, and Spearman correlation.

Informed Consent Form Information

1. Study Title and Investigators

- **Title:** Feasibility and safety validation study of a rehabilitation program and platform using digital devices for Recovery of Bedridden Patients.
- **Principal Investigator:** Won Kim (Dept. of Rehabilitation Medicine).

2. Purpose of the Study

- This study explores the possibility of in-bed rehabilitation using the MORA application.
- It aims to verify the feasibility and safety of the rehabilitation program for bedridden patients.

3. Study Procedures

Participation involves the following visits and evaluations:

- **Screening:** Review of inclusion/exclusion criteria, demographics, and medical history.
- **Visit 1 (Baseline Evaluation):** Physical function tests (MMT, FAC, Grip strength, etc.), cognition (MMSE), and pain (NRS) assessments.
- **Visit 2-6 (Supervised Intervention):** A researcher visits to conduct the exercise intervention using the MORA app. Video data is collected on Visit 2 and Visit 6.
- **Visit 7 (Interim Evaluation):** Re-assessment of physical functions and surveys.
- **Visit 8-11 (Autonomous Intervention):** Patient performs exercises autonomously using the app.
- **Visit 12 (Check-up):** Researcher visit for intervention and video data collection.
- **Visit 13 (Final Evaluation):** Final physical assessments, Quality of Life survey (EQ-5D), and satisfaction survey.

4. Risks and Discomforts

- Potential risks include temporary dyspnea, tachycardia, blood pressure changes, falls, or dislodgement of therapeutic devices.
- However, the risk is considered very low as the exercises are low-intensity and performed while lying down or sitting.
- If adverse events occur requiring hospitalization due to the study, the research team will cover the costs.

5. Benefits and Costs

- **Benefits:** Personalized exercise prescription and the ability to perform rehabilitation without a therapist's constant presence.
- **Costs:** There is no cost to the participant for the rehabilitation treatment and evaluations conducted for the study.
- **Compensation: 100,000 KRW** will be provided upon completion of all study procedures. If participation stops due to unavoidable reasons (e.g., discharge), the amount is paid at the

last visit.

6. Confidentiality

- Collected data (age, diagnosis, functional level, video data) will be stored on a computer.
- Data will be encrypted and shared only with authorized researchers (including EverEx researchers) via a secure link (Asan Works Drive) to prevent leakage.
- All data will be stored for 3 years after study completion and then destroyed.

7. Voluntary Participation and Withdrawal

- Participation is voluntary. You may refuse or withdraw at any time without penalty or impact on your standard treatment.