Study Protocol NCT-05091918

Limited Market Release – MotionSense Clinical Use Evaluation

May 18, 2023

1.1 Study Objectives

1.1.1 Objective Analysis

The primary objectives of this study are to evaluate:

- **OBJ1.1:** Evaluate patient and practice compliance with the MotionSense wearable system
    - Hours of MotionSense use per day in office
    - Number of days use after / prior to surgery
    - Filled out questionnaires
    - Home exercise program
    - Patient onboarding time in surgeon clinic
- **OBJ1.2:** Document home exercise program prescribed to patients throughout their individualized recovery progress by surgeons and physiotherapists

The secondary objectives of this study are:

- **OBJ2.1:** Correlate functional and patient reported outcome metrics
- **OBJ2.2:** Evaluate convenience of using the MotionSense system
    - Number of leg registrations performed (per day)
    - Number of (weekly / daily) patches used
    - Number of wound pictures shared with surgeon office
- **OBJ2.3:** Establish normative recovery data for the primary outcome metrics captured by the MotionSense system
    - Daily VAS pain scores
    - Daily Steps
    - Knee active and weight bearing time
    - Range of Motion
    - Gait quality

1.2 Safety

1.2.1 Safety Parameters

Safety parameters include all adverse events.

1.3 Missing Data

No missing data will be imputed.

1.4 Statistical Methodology

1.4.1 Data Summary

Descriptive statics were computed for demographics parameters and study measures. For continuous data, the N, mean, median, standard deviation, interquartile range, minimum and maximum were computed. For categorical data, the frequency was computed. Correlation was calculated using Spearman's rank correlation coefficient.

Documentation of statistical analyses with Python v3.9.0 will be maintained.

1.4.2 Sample Size Justification

A sample size calculation was not performed for this observational study since the primary goals were to evaluate measures related to the usability of the Motionsense system.

1.4.3 Interim Analyses

No interim analysis is planned.

1.4.4 Analysis Population

The study population will include all non-censored subjects who have received the Motionsense and are available for objective analysis. The objective analyses will be based on the per protocol population.