Statistical Analysis Plan

Subject Data Confidentiality

Participant confidentiality and privacy will be strictly maintained by the investigators, their staff, and sponsors. Therefore, the study protocol, documentation, data, and all other information generated will be kept confidential. All research activities will be conducted in as private a setting as possible. Representatives of the IRB, regulatory agencies or the study sponsor/funding agency may inspect all documents and records required to be maintained by the investigator for participants in this study. The study site will permit access to these records.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at SPSS. This will not include the participant's contact or identifying information. Only study investigators and staff will have access to the data. Other researchers may request the use of the data collected in this study. At the discretion of the PI and other investigators, data may be shared with outside researchers for research, analysis, and statistical reporting purposes. In such cases, only anonymous information will be provided. No identifying information will ever be sent to researchers using the data in this way.

At the conclusion of the study, all records will be securely maintained within the Second Xiangya Hospital of Central South University network for as long as required by the reviewing IRB, institutional policies, regulatory guidelines, or sponsor/funding agency requirements.

Data Quality Assurance

During a participant’s hospitalization, researchers will proactively engage with the patient and their relatives to understand their condition and establish a positive rapport. Before the investigation, researchers must fully inform

participants about the purpose, methods, and potential benefits of the study and obtain informed consent. All assessments will be conducted when the participant's physical and emotional condition is stable.

The PI will be responsible for data quality and management. All data will be monitored monthly. This monitoring will include audits to ensure completeness. The PI will also audit intervention in experimental group, adhering to an internal standard procedure manual. Well-trained research team members will conduct standardized interventions and administer questionnaires during each survey. A schedule for data collection will be established. The participant will follow up according to this schedule.

Data or Specimen Storage/Security

All data will be stored in a password-protected computer file in the Second Xiangya Hospital of Central South University, and paper records will be stored in a locked filing cabinet.

Study Records

Study records will be maintained by the site PI Tieying Qiu on a secure box folder. These include all IRB documents, an internal standard operating procedure manual, AE forms and confidential data sources (list in section 8.1).

Access to Source

All data and study records (including regulatory documents, protocols, consent forms, case report forms, subject medical records, surveys, etc.) will be restricted to only members of the research team. Research staff making any changes will document the reason for the change and sign their initials. Source documents will be maintained in a neat and legible manner. When making changes or corrections, the initial entry will be crossed out with a single line, initialed, and dated.

Retention of Records

Identifiers and consent forms will be securely retained in a locked folder at the Second Xiangya Hospital of Central South University for 3 years. Following the completion of data collection and anonymous data will be retained indefinitely.

Data and Safety Monitoring Plan

(1) Data monitoring is detailed in section 7.5 and pasted below for reference:

A Data and Safety Monitoring Board (DSMB) will oversee the progress of the study, evaluate the data collected, and ensure the safety of all participants. The PI will have primary responsibility for the ongoing monitoring of AEs and will submit reports in accordance with Section 6.3 and the Institutional Review Board (IRB) guidelines. The research team will review all AEs and provide recommendations as necessary. The PI will assess study progress every two months, which will include metrics on recruitment (number of participants approached, number eligible, number enrolled, and reasons for ineligibility or non-enrollment), retention (percentage of participants completing baseline and follow-up assessments and reasons for dropouts), and adherence (exercise duration and attendance at group sessions).

(2) Safety monitoring is detailed in section 6.3 and pasted below for reference:

Adverse event (AE) refers to any untoward medical occurrence associated with the use of an intervention in humans, regardless of whether considered intervention related. An AE or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it leads to any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of an existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

The Investigator Manual protocol for reporting AEs to the IRB is given below:

Yale IRBs require Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly,probably, or related to study procedures or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities tobe reported to both the IRB and any appropriate funding and regulatory agencies.

The following events may represent UPIRSOs that should be promptly reported:

- Adverse device effects that are unanticipated.
- Adverse events or injuries that are serious, unexpected, *and* related.
- Breaches of confidentiality involving risks.
- Monitoring reports by the PI and study physician altering the risk/benefit profile by identification of increased risks*.
- New information indicating an unexpected increase in risks or decrease in potential benefits(e.g., literature/scientific reports or other published findings).
- Protocol deviations, violations, or other accidental or unintentional changes to the protocol or procedures involving risks or with the potential to recur.
- Unapproved changes made to the research to eliminate an apparent immediate hazard to a subject.
- Other problem or finding (e.g., loss of study data or forms) that an investigator or research staffmember believes could influence the safe conduct of the research.