The Official Title of the study:

The Effectiveness of AI-assisted Masticatory Muscle Training on Oral Hygiene, Masticating, and Swallowing in Patients with Schizophrenia

Date of the document: 2025/8/26

Study Design

This study will adopt a randomized controlled experimental design with parallel groups. Participants will be recruited from two hospitals and randomly assigned in a 1:1 ratio to either the experimental group or the control group.

Participants

Eligible participants will be adults meeting the study inclusion criteria (to be specified separately). A total of 100 participants will be enrolled, with 50 assigned to each group.

Randomization and Allocation

Random assignment will be performed using a computer-generated randomization sequence. Allocation concealment will be ensured through sealed opaque envelopes prepared by a research assistant not involved in recruitment or assessment.

Interventions

- **Experimental Group (n = 50):** Participants will receive *AI-assisted Masticatory Muscle Training* sessions lasting 20 minutes each, administered before each of their three daily meals.
- **Control Group (n = 50):** Participants will continue with their routine scheduled daycare activities without any additional intervention.

Outcome Measures

Assessments will be conducted at baseline (T0), 3 months (T1), and 6 months (T2). The following variables will be measured:

1. Plaque Index
2. Winkle Tongue-Coating Index
3. Dry Mouth Status
4. Repetitive Saliva Swallowing Test (RSST)
5. Saliva Flow Rate

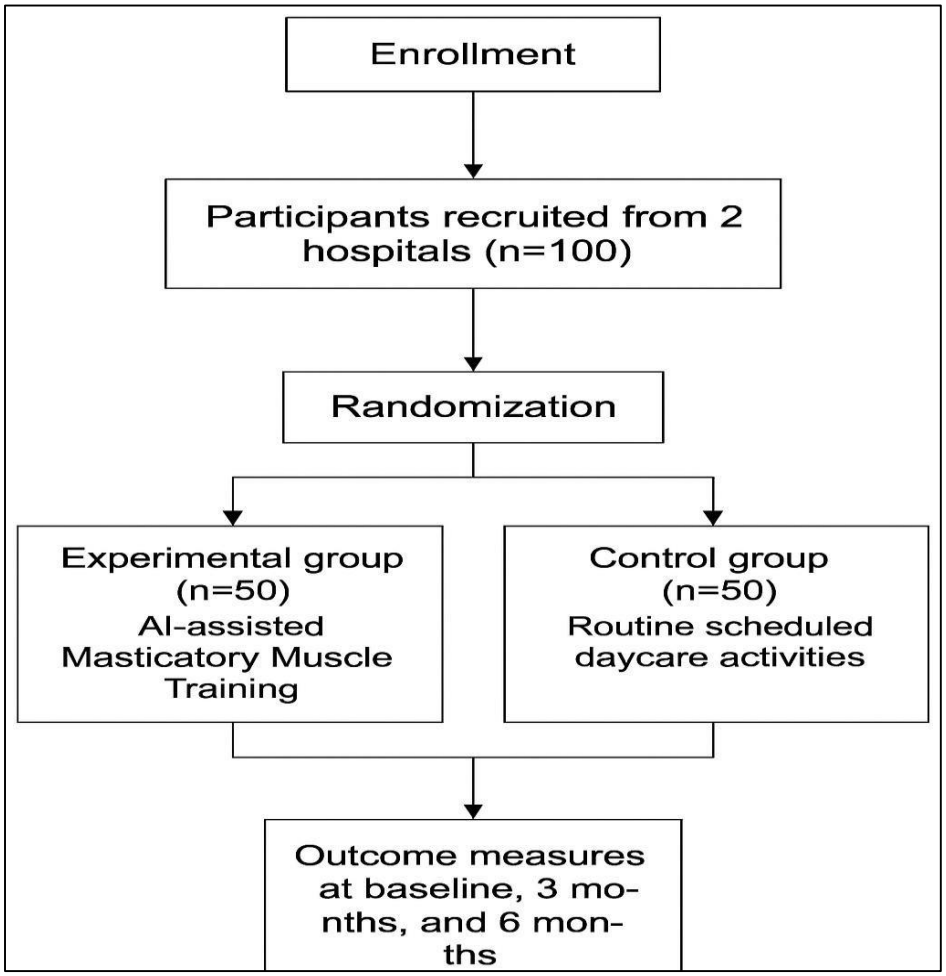
6. Biting Force
7. Tongue Pressure
8. Oral Frailty Assessment
9. Oral Diadochokinesis (DDK)
10. Oral Care Behaviors

Data Collection and Management

Data will be collected by trained assessors blinded to group allocation. All data will be recorded in a secure electronic database with access restricted to the research team.

Statistical Analysis

Descriptive statistics will be used to summarize participant characteristics. Generalized Estimating Equations (GEE) will be employed to examine the effects of the intervention over time, accounting for repeated measures and potential covariates. Statistical significance will be set at $p < 0.05$.



Flow Chart