FIGURE 5

PRAGMATIC TRIAL DESIGN

PLANNING

- Start early and ensure sufficient time for protocol development.
- Collaborate or consult with experts in pragmatic trials.
- Engage stakeholders (e.g., patients, family members/caregivers, healthcare professionals, and hospital managers).
- Co-design with patients and other stakeholders.
- Define research questions that are relevant to stakeholders.
- Determine the population who would most benefit from the intervention. Avoid suboptimal eligibility criteria.
- Define care settings where the intervention will be executed. Assess readiness for trial implementation.
- Define simple, robust, and relevant outcomes.
- Determine recruitment and consent strategies and use of health records for screening
- Check the PRECIS-2*.
- Obtain ethical and regulatory approvals from appropriate research ethics board(s), including permits to access electronic medical records and care facilities.
- Train clinical staff for intervention delivery and outcome assessment.
- Secure clinical space and nutrition care staff for additional assessments.

EXECUTION

- Begin trial, recruitment, and data collection.
- Monitor intervention delivery and data collection.
- Be flexible in terms of intervention delivery and adherence (e.g., deliver core elements of the intervention and modify those elements not affecting the effectiveness analysis).

ANALYSIS & DISSEMINATION

- Disseminate results using transparent reporting of results. Check the CONSORT Extension† for pragmatic trials.
- Engage stakeholders in trial analysis and results dissemination.

Implementation

- Improved care that can be readily implemented in the clinical setting.