

Biobehavioral Effects of Tai Chi Qigong for Male Cancer Survivors with Fatigue (HERO)

NCT03345563

October 25, 2025

Project HERO Statistical Analysis Plan

Project HERO is a three-arm randomized controlled trial (RCT) evaluating the effects of Tai Chi Qigong (TCQ) on cancer-related fatigue among older male cancer survivors.

Participants are randomized to one of three groups: Body–Mind Training (TCQ), an exercise intensity–matched Body Training (EIM) control, or Usual Care (UC). The intervention lasts 12 weeks, with assessments at baseline, 6 weeks (mid-intervention), 13 weeks (1-week post-intervention), 3 months post-intervention, and 12 months post-intervention.

The primary objective: To determine whether BMT produces greater reductions in cancer-related fatigue, measured by the FACIT-Fatigue scale, compared with EIM and UC from baseline to 13 weeks.

Secondary objectives include the following:

- Assess intervention effects on inflammatory biomarkers, psychosocial outcomes, and physical function.
- Explore potential moderators and mediators such as age, BMI, and treatment-related factors.

Analyses will be conducted under an intent-to-treat framework. Continuous outcomes will be analyzed using mixed-effects models for repeated measures with fixed effects for group, time, and group-by-time interaction, a random effect for participant, and adjustment for baseline values. Binary or ordinal outcomes will be analyzed using generalized mixed models. Primary contrasts will evaluate group differences in change from baseline to 3 months post-intervention, comparing TCQ vs EIM and TCQ vs UC. Secondary outcomes will be adjusted using a false discovery rate (FDR) approach. Missing data will be handled under the Missing at Random (MAR) assumption using mixed models, with multiple imputation sensitivity analyses conducted to assess robustness.

Exploratory analyses will examine the durability of effects, adherence, and dose-response relationships. Prespecified subgroup analyses (e.g., age, cancer type, hormonal therapy) will be interpreted as exploratory. Feasibility, adherence, and acceptability will be summarized descriptively. Any qualitative or process feedback collected will be reviewed to inform implementation and future intervention refinement.