Krill Oil for Pain and Physical Function in Older Adults

NCT06580912

03/05/2025

Statistical Analysis Plan

Feasibility and acceptability will be determined as (1) recruitment of at least 80% of the target sample (n=32), (2) attrition rate ≤20%, and (3) adherence rate ≥70% (based on capsule counts and intake diaries). Changes in fatty acid profile (i.e., omega-3 index) will be analyzed using mixed-effects linear regression models with fixed effects for treatment group, time (as categorical), and a group-by-time interaction. While there is currently no guidance on what may constitute a minimal clinically meaningful change in plasma ω-3 index, current evidence supports that an ω-3 index ≥8% may be protective against cardiovascular disease, whereas an index of ≤4% indicates increased risk[88]. Given the pilot nature of the trial, analyses will emphasize estimation of between-group differences and corresponding 95% confidence intervals rather than formal hypothesis testing. Estimates of variability and feasibility metrics will be used to inform outcome selection and design considerations for future trials. Changes in pain intensity, pain interference, and physical function will be analyzed using mixed-effects linear regression models, with fixed effects for treatment group, time (as categorical), and a group-by-time interaction, adjusting for age, sex, and BMI. A random intercept will be included for each participant, assuming an independent covariance structure. A 20% pain reduction on a 0-10 numeric rating scale is considered a clinically significant pain reduction.[1] A 1-point change in the SPPB and a 50-m increase in the 6MWT are considered clinically meaningful changes for older adults.[2] All analyses will follow an intent-to-treat approach, including all randomized participants in the groups to which they were assigned, regardless of adherence. A per-protocol analysis may also be conducted as a sensitivity analysis, including only participants with ≥70% adherence. Missing data will be addressed using maximum likelihood estimation within the mixed-effects models, which accommodates data missing at random. Sensitivity analyses may be conducted using multiple imputation if warranted.

References

1. Smith SM, Dworkin RH, Turk DC et al. (2020) Interpretation of chronic pain clinical trial outcomes: IMMPACT recommended considerations. Pain. 161, 2446–2461. doi: 10.1097/j.pain.0000000000001952.

2. Perera S, Mody SH, Woodman RC et al. (2006) Meaningful change and responsiveness in common physical performance measures in older adults. J Am Geriatr Soc. 54, 743–749. doi: 10.1111/j.1532-5415.2006.00701.x.