



UNIVERSITY of LIMERICK
 OLLSCOIL LUIMNIGH

Statistical Plan

An evaluation of a Milk-Based Nutritional Supplement to Effect a Positive Change in Bone Health in Post-Menopausal Women at Risk of Osteoporosis.

Research Question or hypothesis:

Ho: Compared to a placebo control, ingestion of a milk protein-based supplement will not affect the temporal acute (0-4h) and diurnal (24h) rates of bone turnover in post-menopausal women with osteopenia.

Brief Background: In a novel approach to the timing of nutrient ingestion, the proposed nutrient intervention seeks to modify (reduce) the rate of bone resorption and promote the rate of bone formation to the benefit of bone health in post-menopausal women aged 50 to 70y diagnosed with osteopenia.

Study Design: A block randomised, crossover design

Participants: 16 post-menopausal women aged 50 to 70y diagnosed with osteopenia.

Statistical Analysis: ANOVA(R)

Independent variables:

TIME [6]
 0, 1, 2 3 4 and 24h

TEST PRUDUCT [2]
 Placebo, MBPS

MODEL: Mixed model analysis of variance

Dependent variables

Bone Turnover [3]
Blood CTX (bone resorption)
Blood N1PD(bone formation)
Urine DPD/Creatinine (bone resorption)

- a. Within-subject factor, **TIME (6)**
- b. Within-subject factor, **TEST PRODUCT (2)**
- c. Bonferroni corrected post-hoc comparisons

- i. Violation to normality (Shapiro – Wilk) data will be transformed by rank for analysis
- ii. Violation to homogeneity of variance-covariance matrices (Mauchly’s W), e correction factors (Green-House Geisser, Huynh-Feld) will be applied
- iii. Violation to homogeneity of variance for post-hoc analysis (Levene’s or Brown-Forsythe Test), Welsch-Satterthwaite corrections will be applied.

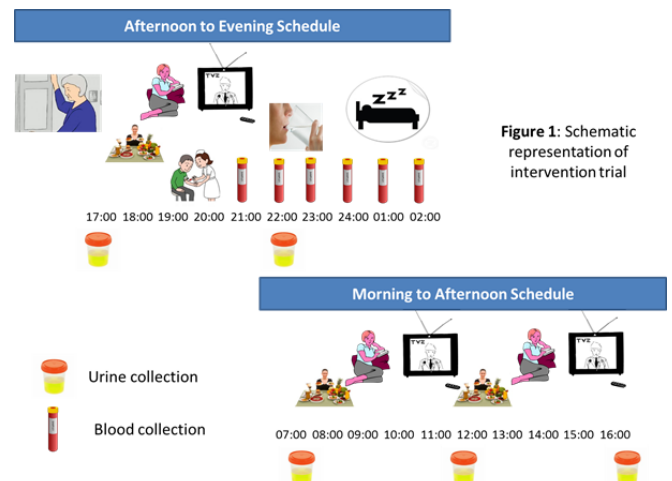


Figure 1: Schematic representation of intervention trial

