UNIVERSITY of LIMERICK
OLLSCOIL LUIMNIGH

Statistical Plan

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 habitual dietary intake, ingestion of a milk protein-based supplement in the evening each day for a period of 24 weeks will not affect site specific bone mineral densityof post-menopausal women with osteopenia

Ho: Compared to habitual dietary intake, ingestion of a milk protein-based supplement in the evening each day for a period of 24 weeks will not affect fasting serum 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 design with a TREATMENT group maintaining habitual dietary intake with evening MBPS and a CONTROL group maintaining habitual dietary intake only.

Participants: 60 post-menopausal women aged 50 to 70y diagnosed with osteopenia.

Previous studies conducted by the research team (Norton et al. 2016 Journal of Nutrition, 146(1),65–69) required a sample of 30 per group to give statistical power of >80 % at alpha 0.05 with delta change in BMD of 0.017 gcm^2 compared to a control group for period of 6 months.

Statistical Analysis: ANOVA(R)

Independent variables:	**Dependent variables:**
Group [2]	**Bone Mineral Density (BMD)**
TREATMENT (MBPM) and CONTROL	
TIME [2]	**Serum CTX (bone resorption)**
Pre and Post 24 week intervention	**Serum N1PD(bone formation)**
	Urine DPD/Creatinine (bone resorption)
	Urine NTX/Creatinine (bone resorption)

Significance of effect on bone remodeling will be analysed by 2 Factor ANOVA(R)

Notes:

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), 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.
iv. Bonferroni corrected post-hoc comparisons