**A randomised placebo controlled trial to investigate to investigate the effect of vitamin D supplementation on muscle strength and function in UK South Asian post-menopausal women.**

**Study protocol:**

This is 2-arm parallel design double blinded randomized placebo controlled trial to investigate the effect of 12 weeks vitamin D3 supplementation on muscle strength and function in UK South Asian post-menopausal women.

**Study methodology:**

The below study methodology is same for both arms (vitamin D and placebo group). There will be total 70 participants for the intervention with 35 in each arm.

There will be total three meetings with the researcher. At the first visit (lasting 50-60 minutes), participant's eligibility for this study will be checked and they will be asked to sign written consent form before starting study procedure. A finger prick blood spot for vitamin D measurement and assessments for muscle strength and function will be performed. Blood vitamin D level will be performed using vitamin D blood spot kits and report will come after 7-8 days.

This will be the screening stage and we estimate needing to recruit 100 participants at start in order to get 70 participants with low vitamin D status to enter on to intervention study. Only vitamin D supplements non- users will be eligible for inclusion. The participants who will have insufficient vitamin D level (below 50nmol/L) will be entered onto intervention study (second stage). Any participant found to have an adequate vitamin D level (equal or above than 50nmol/L) would be excluded and will not enter onto intervention study.

The second visit (lasting 15-30 minutes) will take place around 2-3 weeks after first visit 1 (allowing for vitamin D analysis). Women with adequate vitamin D will be thanked for their participation, will receive a £10 high street voucher and will leave the study at this point. Women found to have low vitamin D status will be randomized into two groups to receive either 75µg vitamin D oral spray or placebo oral spray once on daily basis for 12 weeks. Neither the participant nor researcher will know which participant taking oral vitamin D or placebo oral spray.

At the third visit (lasting about 50-60 minutes) i.e., after 12 weeks of being on the supplement intervention, participants will be invited back to the community center or temple for their 3rd and final meeting with the researcher. They will be asked for a finger prick blood spot to check their vitamin D status and we will repeat the measurements we made at the 1st visit.

For adherence/compliance to intervention, researcher will make a telephone call to each participant about 6 times during intervention period to make sure that they will be using supplement/placebo as per advised.

Measurements: All assessments will be performed at baseline i.e., visit 1 and end of intervention i.e., visit 3. Vitamin D dried blood spot test kits collected at visit 1 and visit 3 will be posted to Sandwell and West Birmingham Hospital NHS Trust for immediate analysis of vitamin D status (nmol/L) using mass spectrometry. Bloods will not be stored. Single chair stand test (s), repeated chair stand test (s), balance test (s), walking speed (s) and timed up and go test (s) will be performed using a stopwatch at visit 1 and visit 3. Hand-grip strength (kg) of both hands will be noted using Jamar hand-held dynamometer at visit 1 and visit 3. Body composition will be measured using body fat monitor on both occasions. A general interview (demographic and health history) and self-reported physical activity and diet habit interview will be conducted pre and post intervention.

**Treatment and its duration:**

Women found to have low vitamin D status will be randomized into two groups to receive either 75µg vitamin D oral spray or 75µg placebo oral spray once on daily basis for 12 weeks. They will be advised not to take any other supplement, multivitamin or omega-3 capsules during this course.

**Randomisation process:**

Participants will be randomised in a double blinded manner that means neither the participant nor researcher will know which participant taking oral vitamin D or placebo oral spray.

**Follow-up for all study arms:**

After 12 weeks of being on the supplement/placebo intervention, participants will be invited back to the community center or temple for their 3rd and final meeting with the researcher. They will be asked for a finger prick blood spot to check their vitamin D status and we will repeat the muscle strength and function measurements we made at the 1st visit. Below is the flow chart to demonstrate the study timeline.

Participants with vitamin D level equal or above 50nmol/L

**Visit one** (50-60 minutes): at community center or temple

Vitamin D report: after 7-8 days

Vitamin D and muscle strength and function tests

Participants with vitamin D level less than 50nmol/L

**Visit two** (10-15 minutes): enter onto intervention within 2 weeks from visit one

Will not enter onto the intervention

Excluded and thanked with £10 voucher

Randomized to use either 75µg vitamin D or placebo oral spray once daily for 12 weeks

**Visit three** (50-60 minutes): after 12 weeks of using vitamin D supplement/placebo

**End of trial** (approx. 14 weeks):

Thanked all participants with £30 and vitamin D spray given to all deficient participants

Repeat of vitamin D and muscle strength and function tests (same as visit one).

Figure: Study timeline.