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The effect of vitamin D supplementation on muscle strength and function in UK South Asian women

Submission date
28/02/2019

Recruitment status
No longer recruiting

Registration date
04/03/2019

Overall study status
Completed

Last Edited
13/07/2020

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vitamin D is known to play a role in bone health and there is increasing evidence that vitamin D is important to muscle strength and function in ageing. Several studies have shown that South Asians living in the UK have a low vitamin D status and this could be due to limited sun exposure. Some studies have reported improvement in muscle strength and function in response to vitamin D supplementation, however, these studies have been largely confined to the Caucasian population. In this study, we will investigate whether vitamin D supplementation in a population of UK South Asian post-menopausal women with low vitamin D status will improve muscle strength and function.

We hypothesize that vitamin D supplementation improved vitamin D status will have a beneficial effect on muscle strength and function in UK South Asian women.

The aim of this study is to investigate the effect of improving vitamin D status on muscle strength and function in UK South Asian post-menopausal women.

Who can participate?
South Asian women living in the UK, aged 60-75 years.

What does the study involve?
A variety of methods will be used to advertise the study to potential volunteers. Leaflets prepared in Urdu and English language will be distributed to relevant organizations. South Asians community centres, church and Indian temples (Gurdwara) will be approached and information sessions will be arranged. Participant information sheets will be distributed among interested and eligible participants at the end of the session.

Followed a face to face information session at community centres (as detailed above), contact details will be requested from potential participants. These will be followed by a telephone call

with interested participants to ask if they had read the participant information sheet and decided to take part in a study. A one to one appointment will be arranged with potential participants at one of the above places or any place for their convenience.

There will be a total of three meetings with the researcher.

In visit one i.e., about 50-60 minutes, participant's eligibility for this study will be checked and they will be asked to sign a written consent form before starting the study procedure. Finger prick blood spot for vitamin D measurement will be taken and sent to Sandwell and West Birmingham Hospital NHS Trust on the same day and used to measure the vitamin D status. The assessments for muscle strength and function will be performed at visit one.
This will be the screening stage and we aim to recruit approximately 100 participants at visit one in order to get 70 participants to enter on to intervention study. Only vitamin D supplements non- users will be eligible for inclusion. The participants who have low vitamin D levels (below 50nmol/L) will be entered onto intervention study (visit two). Any participant found to have an adequate vitamin D level (equal or above than 50nmol/L) will be excluded and will not enter onto intervention study.

In visit two i.e., within 2 weeks of visit one and last about 10-15 minutes. All eligible participants will be randomized into two equal groups to receive either 3000IU vitamin D oral spray or placebo oral spray once on daily basis for 12 weeks. Neither the participant nor the researcher will know which participant taking oral vitamin D or placebo oral spray.

During visit three (50-60 minutes) i.e., after 12 weeks of being on the supplement or placebo, participants will be invited back at the community centre or temple for their 3rd and final meeting with the researcher. They will be asked for a finger prick blood spot so we can check their vitamin D status and we will repeat the muscle strength and function assessments we made at the 1st visit.

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

What are the possible benefits and risks of participating?
At the end of the study participants will be told their blood vitamin D level and muscle strength (strength in both hands and legs) and physical function level that might not come into the routine assessment. All deficient participants will be supplied with free vitamin D oral spray at the end of the study.

Participants will be asked to use oral vitamin D or placebo spray once on daily basis for 12 weeks. It is unlikely to have an adverse effect from the dose and duration the supplement will be used as participants will be deficient at baseline. They will be asked not to use any other vitamin D supplement during this period, any multivitamin that contains vitamin D, liver cod oil or omega-3 capsules. Finger-prick method of taking blood spot for checking vitamin D may cause little pain but it would be temporary and they may perform it themselves. Physical function assessments may cause some exertion however these are safe and easy to perform and the researcher will be with them for any assistance.

Where is the study run from?
The study is run from the Department of Oncology and Metabolism, The University of Sheffield, UK. This is the only site.

When is the study starting and how long is it expected to run?
The study is starting on 4th March 2019 and is expected to run until Feb 2020. Volunteers will be enrolled in the study for approximately 14 weeks from visit 1 to visit 3.

Who is funding the study?
The study is funded by the University of Sheffield (through the provision of staff and use of PhD fees). The supplement and placebo have been supplied by Better You Ltd, Barnsley, UK. Better You Ltd have had no involvement in the design or delivery of the study and will have no involvement in the analysis or interpretation of the results.

Who is the main contact?
The main person to contact regarding this study is Dr Elizabeth Williams, Senior Lecturer in Human Nutrition, Department of Oncology and Metabolism, The University of Sheffield, e.a.williams@sheffield.ac.uk

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
N/A

Protocol serial number
022981

Study information

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

Acronym
VITD trial

Study objectives
Muscle strength and function will improve in vitamin D deficient women upon repletion with vitamin D.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/02/2019, the Ethics committee at the University of Sheffield (Beech Hill Road, Sheffield, S10 2RX; medschoolethics@sheffield.ac.uk; +44 (0) 114 215 9058), ref: 022981.

Study design
Two arm parallel design double-blinded randomized placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vitamin D deficiency

Interventions
This is a double blinded randomised (added 13/07/2020) placebo controlled trial. Both treatment arms will be treated identically.

Postmenopausal South Asian women (aged 60-75) will be recruited and consented. There are 3 visits associated with the study. At visit 1: A fingerprick blood sample will be collected for the analysis of vitamin D status. Muscle strength and function will be measured using functional performance measures. Demographic details will be collected. Physical activity level and diet habits will be self-reported. At visit 2: participants found to have a vitamin D status greater then or equal to 50nmol/L will be excluded. The remaining participants will be randomized to placebo or vitamin D supplement (75microg/d Vitamin D3) that they will be asked to take daily for 12 weeks. At visit 3: A final fingerprick blood sample will be collected for the analysis of vitamin D status. Muscle strength and function will be measured using a functional performance measures. There will be no further follow up of participants.

Total duration of intervention: 12 weeks

Total duration participant is involved in the study: 14 weeks

Randomisation process: This is a double blind placebo control trial. Volunteers will be randomly allocated to treatment or placebo using a block randomisation schedule in blocks of 4. The randomisation code has been generated using a randomisation generator and will be held by a 3rd party until analysis is complete.

Intervention Type
Supplement

Primary outcome(s)
Single chair stand as an indicator of lower limb muscle strength assessed using a stopwatch at baseline and following 12 weeks of vitamin D supplementation.

Key secondary outcome(s))
1. Circulating vitamin D level (nmol/L) will be measured at entry to determine vitamin D status and after 12 weeks supplementation to assess the ability of the supplement to replete vitamin D status. Measured using mass spectrometry.
2. Short physical performance battery (SPPB) [repeated chair stand test (s), balance test (s) and timed up and go test (s)] will be performed at baseline and at 12 weeks of vitamin D supplementation as parameter of muscle strength and function. Measured using a stopwatch.
3. Hand-grip strength (kg) of both hands will be performed at baseline and at 12 weeks as an indicator of upper limb muscle strength. Measured using Jamar hand dynamometry.
4. Walking speed test (s) will be performed at baseline and at 12 weeks as parameter of muscle

function. Measured using a stopwatch.
5. Body fat and muscle mass will be measured at baseline and at 12 weeks as parameter of body composition. Measured using Bioelectrical Impedance.
6. General interview (demographic, anthropometric and health history etc) will be conducted at start and exist.
7. Pre and post course self-reported physical activity interview by using international physical activity questionnaire (IPAQ) - short form.
8. Diet and nutrition knowledge interview will be conducted once during the study.

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. South Asian women (Indians and Pakistanis)
2. Aged 60-75 years
3. Able to walk without assistance

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Current exclusion criteria as of 13/07/2020:
1. vitamin D supplement user
2. Multi-vitamin user, cod liver oil user
3. Found to have vitamin D status equal or above than 50nmol/L at baseline/screening stage
4. Impaired cognition

Previous exclusion criteria:
1. vitamin D supplement user
2. Multi-vitamin user, cod liver oil user
3. Found to have vitamin D status equal or above than 50nmol/L at baseline screening
4. Impaired cognition

Date of first enrolment
04/03/2019

Date of final enrolment
28/11/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Sheffield
Department of Oncology and Metabolism
The Medical School
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Sponsor information

Organisation
The University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
University/education

Funder Name
University of Sheffield

Alternative Name(s)
The University of Sheffield, Sheffield University, sheffielduni, University of Sheffield UK, theuniversityofsheffield, University of Sheffield in United Kingdom, University of Sheffield, UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Ethical approval has been given on the following condition: 'The data collected will be used only by the research team (Sabeen Zahra, supervisors Dr Elizabeth Williams and Dr Bernard Corfe) for analysis purposes only. Participant identifiers will be destroyed at the end of the postgraduate research and all data destroyed 10 years after completion of the PhD'. Deviation from this would therefore require ethical approval. Data could be made available to researchers with a relevant research question on the condition that ethical approval is acquired. This would need to happen after publication between (12-36 months after the trial being published). Beyond that time, it is unknown whether investigators would have the resources/capacity to make data available to others.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		04/03/2019	08/03/2019	No	No