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Repletion of vitamin D levels using an oral spray vs capsule supplement among individuals who are deficient

Submission date
15/11/2024

Recruitment status
No longer recruiting

Registration date
06/12/2024

Overall study status
Completed

Last Edited
15/04/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Vitamin D is an important nutrient for bone health, helping the body to absorb calcium, magnesium, and phosphate. Vitamin D is activated in the liver and kidneys, with 25-hydroxyvitamin D (25(OH)D) being the key form used to assess vitamin D levels in the blood. The risk of vitamin D deficiency (low vitamin D levels) is higher among certain groups of individuals. For example, as people age, their bodies produce and process vitamin D differently. Older adults can often spend more time indoors, which reduces their sun exposure. This makes it harder for them to get the amount of vitamin D they need. Also, those with darker skin naturally produce less vitamin D from sunlight, especially in regions with high latitudes, such as the North East of England. Therefore, supplementation may be required to ensure these individuals have sufficient vitamin D to maintain good health. This study will compare the effectiveness of two vitamin D supplements—one in spray form and one in capsule form—among older people (study 1) and people with darker skin complexion (study 2) who have low vitamin D levels. This research aims to determine how quickly each supplement raises vitamin D levels and how well participants adhere to taking them.

Who can participate?
Otherwise healthy older adults aged 65 years and over (Study 1) and those aged 18 years and over with darker skin complexion (Study 2). Participants must either have sub-optimal (<50 nmol /l) or deficient (<30 nmol/l) vitamin D levels to be eligible and this will be determined via a screening appointment with a researcher.

What does the study involve?
If eligible, participants will be randomly allocated into one of three groups:
Group 1: Participants will be required to take a Vitamin D capsule (one capsule per day) and a placebo spray (one spray per day, orally) for 6 weeks (the placebo spray will have no active properties and is water based).
Group 2: Participants will be required to take a Vitamin D spray (one spray per day, orally) and a placebo capsule (one capsule per day) for 6 weeks (the placebo capsule will have no active properties and is water based).

Group 3: Participants will be required to take a placebo capsule (one capsule per day) and placebo spray (one spray per day, orally) for 6 weeks (the placebo capsule and spray will have no active properties and are water based).
On three occasions (at the beginning of the study, at 2 weeks and at the end of the study period at 6 weeks) participants will attend an appointment with a researcher at the Nutrition Research Facility at Newcastle University, a community-based location or online via MS Teams/Zoom. Vitamin D levels will be measured using a self-administered finger-prick blood spot kit at the baseline appointment – 0 hours (Day 1), and then at 4 and 8 hours (Day 1) followed by alternate days between Day 2 and Day 14. After Day 14, the self-administered finger prick sample will be taken weekly (days 21, 28, 35 and 42) until study completion.

What are the possible benefits and risks of participating?
To express our thanks for the participants' time and effort in taking part in the study, they will receive up to £100 shopping vouchers upon successful completion of the study. It is not intended that participation in this research study will cause any discomfort or harm. Part of this study involves providing a small blood draw via finger-prick sampling on 14 separate occasions across 6 weeks. There is a small risk of developing bruising, fainting or excessive bleeding after the blood sampling. A fully trained researcher will demonstrate how to take the blood samples safely to ensure that any discomfort or risk is minimal.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
October 2024 to July 2025

Who is funding the study?
BetterYou Ltd (UK)

Who is the main contact?
Dr Andrea Fairley, andrea.fairley@newcastle.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NU021205

Study information

Scientific Title
Repletion rate of circulating 25-hydroxyvitamin D following sublingual and capsular vitamin D supplementation among individuals with sub-optimal vitamin D status

Study objectives
The hypothesis is that a 3000 IU vitamin D supplement delivered sublingually will achieve time-to-repletion rates identical to a matched enteric capsule preparation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2024, Newcastle University FMS Ethics Committee (Newcastle University, Newcastle Upon Tyne, NE2 4HH, United Kingdom; +44 (0)191 208 6000; fmsethics@newcastle.ac.uk), ref: 2922/50103

Study design
Double-blind placebo-controlled three-arm parallel-design study in two subgroups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
This study will involve two, double-blind, placebo-controlled trials (6-week duration), each with a three-arm parallel design. Study 1 will target older adults (65 years and above) (n = 75); Study 2 will target adults with darker skin complexion (18 years and above) (n = 75). Each study will follow the same design and will be operationalised concurrently.

Participants will be randomised into one of three groups:

Study 1: Older adults
1. Active vitamin D capsule (3000 IU, 1 x capsule/day) and 1 x placebo spray (1 x spray orally/day) for 6 weeks (n = 25)
2. Active vitamin D spray (3000 IU, 1 x spray orally/day) and placebo capsule (1 x capsule/day) for 6 weeks (n = 25)
3. Double placebo (1 x spray orally/day & 1 x capsule/day) for 6 weeks (n = 25)

Study 2: Adults with darker skin complexion
1. Active vitamin D capsule (3000 IU, 1 x capsule/day) and 1 x placebo spray (1 x spray orally/day) for 6 weeks (n = 25)
2. Active vitamin D spray (3000 IU, 1x spray orally/day) and placebo capsule (1 x capsule/day) for 6 weeks (n = 25)
3. Double placebo (1 x spray orally/day & 1 x capsule/day) for 6 weeks (n = 25)

A double-blinded method will be applied for both subjects and investigators. The identity of the groups will be disclosed upon completion of the data analysis.

Intervention Type
Supplement

Primary outcome measure
Time from initiation of supplementation to participants meeting the definition of adequate circulating levels of vitamin D [25(OH)D] analysed by liquid chromatography tandem mass spectrometry measured by a self-administered finger prick blood spot at baseline – 0 h (day 1), and then at 4 h and 8 h (day 1), day 2, 4, 6, 8, 10, 12, 14, 21, 28, 35 and 42.

Secondary outcome measures
1. Compliance measured by weighing/counting the spray bottle and capsules at 2 weeks and 6 weeks.
2. Acceptability measured using a questionnaire at 6 weeks

Overall study start date
06/10/2024

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Older adults aged 65 years and over (Study 1)
2. Adults aged 18 years and over with darker skin complexion. This is classified using the Fitzpatrick Classification of Skin Phototype (Phototype IV, V, VI) (Fitzpatrick, 1988) (Study 2)
3. Participants to be screened for sub-optimal 25(OH)D status (<50 nmol/L) or deficient (<30 nmol/L) 25(OH)D status at baseline (both Study 1 and 2)
4. Willing and able to give written informed consent
5. Can understand and speak the English language

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Individuals who report any food supplement use
2. Individuals with a Vitamin D status of ≥50 nmol/L
3. Recent or planned overseas vacation / sunny holiday
4. Pregnant or lactating women
5. History of gastrointestinal disease, liver disease, or renal disease
6. History of bleeding disorders, and/or taking blood thinning medications
7. Skin disorders that would impede finger prick sampling
8. Those living with diabetes
9. Any disability or mental impairment that precludes safe and adequate participation in the study and inability to provide consent
10. Inability to understand written and verbal instructions in English

Date of first enrolment
11/12/2024

Date of final enrolment
20/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Newcastle Upon Tyne
Claremont Road
Newcastle upon Tyne
United Kingdom
NE1 7RU

Sponsor information

Organisation
Newcastle University

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Sponsor type
University/education

Website
https://www.ncl.ac.uk/

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Industry

Funder Name
BetterYou Ltd

Results and Publications

Publication and dissemination plan
Data arising from the study will be considered for dissemination at scientific conferences with a plan for publication in a high-impact peer-reviewed journal.

Intention to publish date
31/10/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	06/11/2024	06/12/2024	No	Yes
Participant information sheet	version 3	06/03/2025	10/03/2025	No	Yes