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

Information Sheet for Study Participants

You are being invited to take part in a research study. Before you decide whether you wish to take part it is important that you understand why the research is being done and what it will involve. **Please read this information carefully and discuss it with others if you wish.** Please do not hesitate to contact us if you require more information.

What is the purpose of this study?
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 get older, their bodies produce and process vitamin D differently. Older adults can often spend more time indoors, which reduces their sun exposure. Also, those with darker skin naturally produce less vitamin D from sunlight, especially in regions with high latitude, 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 and people with darker skin pigmentation who have low vitamin D levels. The aim of this research is to determine how quickly each supplement raises vitamin D levels and how well participants adhere to taking them.

Why have I been invited to take part?
We are looking to **recruit people who are either aged 65 years or older (from any background or ethnicity) or adults with darker skin pigmentation (aged 18 years and above)** living in North-East England. You have been invited because you may be eligible for this study.

Do I have to take part?
It is up to you to decide whether to take part. If you do decide to do so, you will be asked to sign a consent form. To take part, you will have to consent to completing all aspects of the study. However, you are free to withdraw at any time and without giving a reason.

What will happen to me if I decide to take part?
If you decide to take part you will meet with a researcher at the Nutrition Research Facility at Newcastle University, or at a community-based location. On this visit, the 'screening' visit, the researcher will complete a screening questionnaire, and to take a self-administered finger-prick blood sample to assess your vitamin D levels. Full training and guidance on how to take this sample will be provided. The visit will last no longer than 50 minutes. Once your blood results are returned from the laboratory, they will be reviewed by our research dietitian who will contact you via letter or email to confirm whether you are eligible to take part in the study.

If you are eligible to take part in the study, you will be randomly assigned to one of three groups. Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People will be placed into these three groups and then compared. The groups are selected by a computer which has no information about the

individual – i.e. by chance. Participants in each group then have a different treatment and these are compared. You will be given a unique study number so that your data remains anonymous to anyone else. The study will last a total of 6 weeks.
The three groups are:

(1) You will be required to take a **Vitamin D capsule** (1 capsule per day) and **placebo spray** (1 spray per day, orally) for six weeks (the placebo spray will have no active properties, and is water based).
(2) You will be required to take a **Vitamin D spray** (1 spray per day, orally) and a **placebo capsule** (1 capsule per day) for six weeks (the placebo capsule will have no active properties, and is water based).
(3) You will be required to take a **placebo capsule** (1 capsule per day) and **placebo spray** (1 spray per day, orally) for six weeks (the placebo capsule and spray will have no active properties, and is water based).

To keep the study as fair as possible, neither you nor the researchers who interact with you will know which group you are in during the study. This is called "blinding". Blinding helps prevent bias, meaning that the results of the study are less likely to be influenced by anyone's expectations or preferences. After the study is completed, the blinding will be removed for analysis. However, you will remain unidentifiable throughout.
For those who are allocated to group 3 (placebo capsule and spray), this will mean you will not receive any vitamin D during the 6-week study. However, you will be provided with an active Vitamin D spray once you have finished taking part in the study.
On three occasions - *at the beginning of the study, at 2 weeks and at the end of the study period i.e. at 6 weeks* - you will attend an appointment with a researcher at the Nutrition Research Facility at Newcastle University, or a community-based location.

Here is an outline of the study procedures:

- **Study Visit 1 (Day 1):** At this appointment, the researcher will ask you to complete a demographic and lifestyle questionnaire, a diet questionnaire and take your weight, height and body fat percentage. The researcher will recap the training on how to self-administer the finger-prick blood sampling kit and support you to complete a self-test blood sample. You will then be given enough sampling kits for the first 14 days of the study. You will also be given the first batch of your allocated nutritional supplements. This appointment will last approximately 45-60 minutes.
- **Days 1-42 (duration of the study):** You should take the stated daily dosage of each supplement. You will be given instructions by the researcher.
- **Day 1:** Following your appointment with the study researcher on Day 1, you should take a further two self-administered finger prick blood samples. You should take one sample at 4 hours and one sample at 8 hours after your appointment. You will receive reminders from the research team.
- **Days 2, 4, 6, 8, 10, 12:** On these days you should complete a self-test finger prick blood sample and return it in the pre-paid envelope provided. You will be given instructions by the researcher.
- **Study Visit 2 (Day 14):** At this appointment, the researcher will ask you to complete a diet questionnaire. You will be asked to bring along your supplements so we can measure compliance. You will self-administer a finger prick blood sample, and the researcher will issue of further test kits for the remainder of the study. This appointment will last approximately 30 minutes.
- **Days 21, 28, and 35:** On these days you should complete a self-test finger prick blood sample and return it in the pre-paid envelope provided. You will be given instructions by the researcher.
- **Study Visit 3 (Day 42):** At this appointment, your final study visit, you will self-administer your final finger-prick blood sample. The researcher will also ask you to complete a diet questionnaire and take your weight, height and body fat percentage. You will be asked to return any remaining supplements and their packaging and complete an exit questionnaire. This appointment will last approximately 45-60 minutes.

What are the possible benefits of taking part?
To express our thanks for giving your time and effort, you will receive a £10 voucher following completion of your screening appointment. If deemed eligible and enrolled in the study, each participant will receive a £10 voucher after 2 weeks (after study visit 2), with a final £80 voucher paid upon successful completion of the study (after study visit 3 at week 6).

Will my participation involve any physical discomfort?
It is not intended that your participation in this research study will cause any discomfort or harm to you. 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. If you are concerned about providing finger prick blood samples, please discuss this with the researcher so they can support you.

Will my taking part in this study be kept confidential?
Yes. All information that is collected about you during this research will be kept strictly confidential. You will be allocated a unique code which will be used in all data sets so any information collected, cannot be linked to you by anyone outside of the research team. The consent form you signed will be stored separately from your other data.

Who will have access to the information that I provide?
Any information and data gathered during this research study will only be available to the research team and commercial partner identified in the information sheet. Should the research be presented or published in any form, anonymised data will be generalised (i.e. your personal information or data will not be identifiable). Only members of the research team will have access to your personal information.

During the study you will be asked to fill out some questionnaires at various points using an application called Trialflare. The service allows you to login to a trial as a participant, however they do not ask for or collect personal data relating to you as part of usual operation. When you login to a trial, they collect a participant ID and trial code for the purposes of granting you access to the trial, however your participant ID should not contain any personally identifiable information.

If you are a participant and make use of the additional "eConsent" feature when joining a trial, you have the option of providing an email address and/or a phone number. We collect this data to complete the eConsent verification process.

How will my information be stored / used in the future?
Personal information linked to the personal code number will be stored in a locked filling cabinet or a password protected computer. The information gathered during the project which links the participant's code to the personal information will be kept separately in a locked cabinet. Anonymised data will be stored for a minimum of 10 years under the responsibility of the principal investigator. Anonymised project data which is transferred to a third party will be their responsibility. This data will include your responses to the questionnaires but cannot be linked to you in any way.

Can I withdraw from the study?
Yes, you can stop being part of the study at any time, without giving a reason. If you decide to withdraw during the conversation itself, you can inform the researcher you are talking to. If you wish to withdraw after the conversation, you will need to email or phone the research team (contact details below). We wouldn't ask you to provide a reason, rather, we would respect your wishes to withdraw. We will keep any data that you have provided, up until the point at which you withdraw and use it in our analyses unless you explicitly ask us not too; if you make this request, and it is not possible at that stage as the data has already been anonymised, we will inform you.

Who is the sponsor and data controller for this research?
Better You Ltd. is the funder and Newcastle University is the data controller for this study. This means that Newcastle University is responsible for looking after your information and using it properly.

Has ethical approval been granted?
This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This Committee includes members who are internal to the faculty. This study was reviewed by members of the Committee, who must provide impartial advice and avoid significant conflicts of interests.

What is the legal basis for processing personal data?
Under the General Data Protection Regulation (GDPR), the legal basis for processing personal data is Article 6(1) e: "processing is necessary for the performance of a task carried out in the public interest". GDPR categorises some of data as 'sensitive' personal data. This includes information on your ethnicity and health. The legal basis for processing this type of personal data is Article 9 (2)(j) "processing is necessary for scientific and historical research purposes".

How can I find out more about how my information is used?
You can view our Data Protection Policy, available at: https://www.ncl.ac.uk/data.protection/dataprotectionpolicy/. Alternatively, you could ask a member of the research team, or contact the Data Protection Officer at Newcastle University: rec-man@ncl.ac.uk.

Who should I contact to file a complaint?
If you wish to raise a complaint on how your personal data is handled, you can contact the Data Protection Officer, Maureen Wilkinson, who will investigate the matter: rec-man@ncl.ac.uk. If you are not satisfied with their response, you can complain to the Information Commissioner's Office (ICO): https://ico.org.uk/

Contact for further information
If you have any further questions, then please contact Andrea Fairley:
Dr Andrea Fairley (Principal Investigator / Dietitian)
Email: vitdstudy@ncl.ac.uk
Mobile: 07350 439361

And finally…
Thank you for taking the time to read this information sheet and for your interest in this study.