PROTECT

PARTICIPANT INFORMATION SHEET

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VitaMIND: A randomised controlled trial of Vitamin D to improve cognition in people at risk of dementia

Invitation to take part in a research study

We would like to invite you to take part in our research study, VitaMIND, which is part of the PROTECT study portfolio. We have contacted you because you are already taking part in the PROTECT study and we think you fulfil some of the eligibility criteria. If you take part in VitaMIND your involvement will be part of your PROTECT study journey. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully and discuss it with family or friends if you wish. We recognise that there is a lot of information contained within this document. If you have any further questions about this study, please contact a member of the study team (details are on the last page of this information sheet and on the PROTECT study website).

It is important that you understand that you do not have to take part in the study, and that if you do take part you are free to withdraw at any time. If you decide to take part, we will ask you to read and sign the declaration on the next page of the website.

What is the purpose of the study?

VitaMIND is a three-year clinical trial. It aims to determine whether taking Vitamin D supplements improves brain function in older

adults who may be at risk of cognitive decline in later life.

It is being led by the University of Exeter Medical School, in partnership with the Royal Devon & Exeter NHS Trust and Devon Partnership NHS Trust.

Why are we doing the study?

As we get older our brains also begin to age, resulting in a 'slowing down' of abilities such as memory or reasoning. These mental processes are collectively known as ‘cognition’. In some people, cognition declines further, leading to cognitive impairment or dementia, which affects 800,000 people in the UK. There is a growing body of evidence that indicates that people may be able to reduce their risk of dementia through certain lifestyle habits or activities. This is particularly true for people who are at higher risk due to their current cognitive abilities, lifestyle or overall health.

One promising avenue for reducing risk of dementia is through dietary supplementation of Vitamin D. Vitamin D is produced by the body when exposed to sunlight during summer months and is available in some foods such as fish and eggs. However, a large proportion of older adults do not receive enough Vitamin D and few people take regular dietary supplements despite recommendations from the National Institute of Clinical Excellence for older adults. Vitamin D is known to play an important role in brain health and cognition, and research has shown that Vitamin D deficiency is linked to a risk of cognitive decline and dementia.

The VitaMIND study will provide valuable new information about whether Vitamin D supplements should be used by older adults to reduce their risk of cognitive decline and dementia.

Why have I been invited?

All the adults invited to take part in this study are already part of the Platform for Research Online to investigate Cognition and

Genetics in Ageing (PROTECT). Over the next six months we will be looking for 548 people to join the VitaMIND study for a period of three years. In order to participate you will also need to have the ability to use a computer or a device like a smartphone or tablet with internet access.

We are inviting adults aged 50 and over who are at increased risk of cognitive decline from across the UK to take part in this study. You have been invited to take part because we believe that you may be eligible due to your previous scores in the cognitive tests on the PROTECT study which show a slightly lower score than we would expect for someone of your age. For this study eligible participants will need to fulfil the following additional criteria:

1. Not already taking Vitamin D supplements

2. At risk of Vitamin D deficiency. This will be checked when you register using a questionnaire. You should not take part if you have been advised not to take vitamin D supplements due to an existing medical condition, or are taking the drug Digoxin.

If you wish to ask us any questions please use our contact details at the end of this information sheet.

Do I have to take part?

It is entirely up to you to decide whether or not to join the study. The purpose of this information sheet is to describe the study in detail and help you make your decision.

If you do wish to participate, you will need to read and sign a consent form on the PROTECT website. Please note that if you do participate, you will be free to withdraw at any time without giving a reason. Withdrawing will not affect the standard of care you receive through your own GP or local NHS services, or your legal rights. This study does not replace those services and if you feel less well during the time you are part of this study it is important that you seek help from your doctor or local health professionals in the usual way.

If you do not wish to participate this will not change your treatment or rights in any way, nor affect your participation in PROTECT or other studies currently affiliated with PROTECT. Please note the vitamin D supplement used in this study is not suitable for vegans.

What will happen if I take part?

If you decide to take part the following steps will take place:

1. You will be directed to the trial section on the PROTECT site where all instructions, assessments and study information can be found.
2. You will be asked to register with the study and confirm that you have read this Participant Information Sheet. A downloadable copy of this is available at the bottom of this page.
3. You will be asked to complete a series of questions to confirm your eligibility. This will include checking whether you are taking certain medications or existing supplements and completing a short questionnaire to establish your current risk of vitamin D deficiency.
4. Provided you are eligible, you will be asked to read and sign the consent form to ensure you understand what the study involves and that you are happy to participate in the study.
5. Once you have completed your registration the website will randomly allocate you to receive vitamin D supplements or a placebo (dummy). The placebo is an identical tablet that does not contain any vitamin D or other active substance. There will be a 50:50 chance of receiving either Vitamin D or placebo and neither yourself nor the research team will know which study arm you are allocated to.
6. Depending on which arm of the study you are allocated to, you will be provided with a unique kit number to receive your tablets. A study welcome pack will be sent to you in the post which will include:
   - Information about the study including instructions for taking your tablets
   - Fridge magnet as a reminder to take your tablets
   - Your first batch of tablets. Tablets will be in blister packs of 28 tablets, with days of the week printed on each tablet space. You will receive three packs (12 weeks supply)
7. When you have received your welcome pack you can log into the PROTECT site and activate your study page by ticking a box to let us know you have received your pack. You will then be asked to complete your baseline study assessment. The assessments will be:
   a. A set of tests to measure brain function (called a cognitive test battery), which need to be completed in full once at each assessment date
   b. A questionnaire called the Instrumental Activities of Daily Living questionnaire, which measures your day-to-day activities
   c. A Quality of Life questionnaire

d. A questionnaire called the Mild Behaviour Impairment scale, which measures your behaviour

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8. On the same day that you complete your baseline assessment recording you can take your first tablet at a time convenient to you. You will then be required to take one tablet daily for the study period of three years. Tablets will be sent to you every 12 weeks in blister packs. Please take one tablet each day. It is important that you do not take any multivitamin supplement containing vitamin D during the course of this trial.

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9. One week after you start taking your tablets you will receive a telephone call from our study team to check you are happy with the process and to answer any questions that you may have

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10. You will be asked to complete the same set of tests as mentioned above after six months, and again at one year, two years and three years. These can all be found on your PROTECT homepage. We will send you an email reminder when your assessments are due.

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11. You will also be asked to complete a report every three months to let us know how many tablets you have taken during that time. You will receive a reminder email to complete this activity. When you receive the reminder email we will ask you to log onto your study homepage and enter the tablet information into the relevant sections.

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12. As we would like to have a record of any ill health you experience during the course of the study, you will be asked to answer a set of simple questions related to your health each time you complete a tablet compliance check. This should take no longer than 3-5 minutes of your time depending on your answer. If you do experience a serious health problem, we may contact you and / or your General Practitioner, with your permission, for further information. We also recommend that if you experience any ill health you contact your usual healthcare provider (usually your GP) for advice.

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13. You may also receive a finger prick test kit to send a blood test to your laboratory so we can check your Vitamin D levels. This will be sent to 10% of participants. If you are selected, we will contact you by post and provide you with a finger prick test to be completed at home at the beginning of the study. You will also receive a test to be completed at the end of the study. The test is simple and relatively painless and is accompanied by full instructions. We will ask you to perform the test and send it in a postage paid envelope to our laboratory for analysis of Vitamin D levels in your blood. The laboratory will send the results back to us. They will not receive any of your personal information as your sample will be identified using an ID code. All data will be anonymous to the laboratory. The samples will be destroyed and not used in any other research

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14. At the end of the study we will ask you to complete a survey and provide us with suggestions and feedback on your experience from the study. We will also make the findings of the research available through the study website and newsletter.

All the information we collect will be secure and confidential. Analysis will only use anonymous data. We will keep all data for 10 years after the study has finished and then it will be securely destroyed.

What will happen to the data I provide?

The University of Exeter is the sponsor for this study based in the

United Kingdom. We will be using information from you in order to undertake this study and will act as data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Exeter will keep identifiable information about you for three years after the study has finished. Anonymised information, such as your trial results data, may be kept indefinitely and up until the study objectives have been achieved.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at www.exeter.ac.uk/dataprotection or by emailing dataprotection@exeter.ac.uk.

The University of Exeter will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Exeter and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS sites involved in the research (Royal Devon & Exeter, Devon Partnership Trust) will pass these details to the University of Exeter along with the information collected from you and your medical records. The only people in the University of Exeter who will have access to information that identifies you will be people who need to contact you to discuss issues directly relating to the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. The research

sites will keep identifiable information about you from this study for 10 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

What are the possible benefits and risks of taking part?

By taking part in this research you will also help move forward our understanding of how Vitamin D could play a role in maintaining cognition as we age. In addition to the potential benefit to brain health, findings from previous studies suggest that Vitamin D promotes good health including improved bone and tooth health, immune system and cardiovascular health. We are unable to guarantee that you will have the same benefit because taking part in the study means you will have a fifty percent chance of receiving Vitamin D. The other 50% of participants will receive a placebo containing no Vitamin D. Neither you nor the study team will know whether you are receiving vitamin D or placebo.

There are no known risks associated with taking Vitamin D. However, taking excessive amounts of Vitamin D can lead to symptoms such as fatigue, vomiting and poor appetite. Although

this would only happen if you were to take very large amounts, it is still important to follow the trial tablet course (regimen) and not take any additional Vitamin D supplements.

This study does not replace National Health services and if you feel less well during the time you are part of this study it is important that you seek help from your doctor or local health professionals in the usual way.

What will happen if I don't want to carry on with the study?

You have the right to withdraw from the VitaMIND study at any time and without giving us a reason. You can do this through the 'I wish to withdraw' link on the website or by contacting us on the study helpline. You may withdraw at any point up until the end of this study. We will contact you to let you know when the study has ended. If you do decide to withdraw from the VitaMIND study we will not collect any further data from you for the purposes of this study. However, all anonymised data collected up until you withdraw will be kept and stored for analysis and regulatory purposes. Withdrawing from this study will not affect your participation in PROTECT or other studies currently affiliated with PROTECT.

There is a very small chance that people taking part in this study may develop cognitive impairment or dementia over the three-year period. This will be monitored as usual for the PROTECT study, through your regular assessments. In the unlikely event we detect a clinically significant drop in your performance in the study tests we will contact your GP to recommend they arrange an appointment with you to carry out further tests. This follows the same process as the PROTECT study. If you are concerned about your cognition we recommend you contact your GP to discuss your concerns. You can also follow the links on the PROTECT website to talk to trained advisers at Alzheimer's Society UK.

If you receive a diagnosis of dementia or your cognitive performance is deemed to fulfil criteria for a loss of capacity, unfortunately you will need to withdraw from this study and PROTECT. If this happens we would retain all anonymous data collected up until this point. We would like to keep any personal information (email address, home address, GP details, NHS number) that you have provided up until that date. However, if you would prefer for personal data collected up to this date to be removed from the study you can indicate this on the consent form. If you decide that you would like us to destroy your personal information please note that we will retain your name and participant ID to ensure we have a record of your consent when you registered for regulatory purposes.

You can change your mind about your preferences for data at any time by following the link on the website or by contacting the study helpline.

Who is organising and funding the research?

The study is supported by the JP Moulton Foundation and is Sponsored by the University of Exeter. You will not receive payment for participating in this study.

Who has reviewed and approved this study?

The study has been reviewed by an independent NHS ethics committee Wales Research Ethics Committee 3), and the Health Research Authority who are the regulatory authority for clinical studies.

Will my taking part in this study be kept confidential?

Research data will be collected online through the PROTECT website over the three-year period, and is subject to the privacy terms of the PROTECT study [https://www.protect-exeter.org.uk/Home/PrivacyPolicy]. All data will be stored securely

according to the General Data Protection Regulation 2018 and the security procedures in place at the University of Exeter. The research will also be covered by normal insurance policies at the University of Exeter.

Only members of the PROTECT research team will have access to your name for this study. The study database will not include your name, just a study number. Your data may be used by other researchers in the future, however your data will only be accessible in a completely anonymised format and it will not be possible to identify you. We will ask for your permission for this as part of the informed consent process

All the data we collect will be stored confidentially, according to the law. Data will be analysed anonymously so no participant can be identified.

All study data will be stored securely according to Data Protection Laws* and the security procedures in place at the University of Exeter, Royal Devon & Exeter NHS Foundation Trust and Devon Partnership NHS Trust.

For further information on how your personal information will be processed please visit our privacy policy on the study website.

*Data Protection Laws means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a Party is subject, including the Data Protection Act 1998 ("DPA") and EC Directive 95/46/EC (the "DP Directive") (up to and including 24 May 2018) and on and from 25 May 2018, the GDPR and all legislation enacted in the UK in respect of the protection of personal data; and (b) any code of practice or guidance published by the ICO (or equivalent regulatory body)

from time to time.

What will happen at the end of the study?

At the end of the study you will complete your final tests for the Vitamin D study on the PROTECT website. We will then contact you to let you know the study has ended and to thank you for your contribution. The results of the study may be published in a scientific journal. We will provide you with a lay summary of our findings in the form of a newsletter which is sent to all PROTECT participants and is available on the website. The findings will also be available on the PROTECT website. The information collected will be totally confidential and no individuals will be identified in any reports/publications or presentations. A description of this clinical study will be available at https://www.clinicaltrialsregister.eu, and at http://www.ClinicalTrials.gov.

What if there is a problem?

If you have a concern or complaint about any aspect of this study, information and Frequently Asked Questions are available on the study website. If this does not answer your query you can contact the research team by calling 01392 725010.

For independent advice and information you can contact the PALS Service at the Royal Devon & Exeter or Devon Partnership NHS Trusts.

Patient Advice and Liaison Service (PALS)

Royal Devon & Exeter NHS Trust PALS:

Telephone: 01392 402093

Email: rde-tr.PALS@nhs.net

Devon Partnership NHS Trust PALS:

Telephone: 0800 073 0741

Email: dpn-tr.pals@nhs.net

Additional contacts relating to this research

Research Team Contact (study Helpline)

Tel: 01392 725010

Email: VitaMIND@exeter.ac.uk

VitaMIND Trial Co-ordinator

Mrs Ellie Pickering

Tel: 01392 726046

Email: e.pickering@exeter.ac.uk

Sponsor Contact

Mrs Pam Baxter

Tel: 01392 723588

Email: P.R.Baxter2@exeter.ac.uk

Further Information

Thank you for taking the time to read the information about this study. If you would like to take part, please register for the study through the PROTECT website at www.protect-study.org.uk. If you would like more information about the study before you decide whether or not to take part, you can contact a member of the study team by ringing the study help and information line 01392 725010.

Please note that this helpline is for general information and support for the study. It will connect you to a member of the study team who will be able to talk about the study but will not be able to provide medical advice. Please also note that we are not able to give out information about your personal performance or progress

in the study.

Thank you for your interest in taking part.