

**Vitamin D Supplementation Trial**  
**Baseline CRF 1<sup>st</sup> Visit**

Date of 1<sup>st</sup> visit

Please answer the questions below. If you have any queries please ask a member of the study team.

### Ethnicity

**1. Which ethnic group do you belong to? (please select from the card provided)**

**2. Which country were you born in?**

**3. If you were born outside of the UK, when did you move to UK?**

**4. Marital status (please tick one)**

Married or living as married

Never married

Divorced

Widowed

Separated

### Education

**5. Do you have any of the following qualifications? (please tick all that are applicable)**

School Leaving certificate	<input type="checkbox"/>	A Level, AS Level, Highers	<input type="checkbox"/>
CSE	<input type="checkbox"/>	Technical College Exams, City & Guilds	<input type="checkbox"/>
GCE O Level, GCSE	<input type="checkbox"/>	HND, GNVQ	<input type="checkbox"/>
Matriculation	<input type="checkbox"/>	Completed Apprenticeship	<input type="checkbox"/>
Secretarial College Exams	<input type="checkbox"/>	Teaching Diploma, HNC, NVQ	<input type="checkbox"/>
University Degree	<input type="checkbox"/>	Trade Certificates	<input type="checkbox"/>
Other (please describe)		None	<input type="checkbox"/>

**6. At what age did you finish full time education (years)?**

### Betel Nut Use

**7. Please indicate your current betel nut use**

Current chewer

Non chewer

Ex-chewer

Quantity chewed (quids/day)

**Housing**

**8. Please indicate which of the following best describes your current housing status? (please tick one)**

Owner  Council rent  Private rent  Living with family or friends

**9. Skin Type**

**Fitzpatrick classification (please select your skin type from the card provided)** I  II  III  IV  V  VI

**Smoking and Alcohol**

**10. Do you currently smoke?** Yes  No

10a. If yes, when did you start smoking (age in years)?

10b. If yes, how many cigarettes a day?

**11. Are you an ex-smoker?** Yes  No

11a. If yes, when did you start smoking? If yes, when did you stop smoking?

11b. If yes, how many cigarettes did you smoke a day before giving up?

**12. Have you consumed alcohol in the past year?** Yes  No

12a. If yes, how often do you consume alcohol?

12b. If yes, how many units do you consume in a typical week (where one unit is 1/2 pint of beer, or 1 glass of wine, or 1 single measure of spirits, or 1 glass of sherry) ?

Beer, lager, and / or cider	<input type="checkbox"/>
Wine	<input type="checkbox"/>
Spirits	<input type="checkbox"/>
Fortified wine (e.g. Sherry, Cinzano)	<input type="checkbox"/>

**Travel outside of the UK**

**13. Have you recently (in the past 12 months) travelled abroad (if yes, when, where and for how long)**

**Usual sun exposure**

**14. In the summer, on average, how long are you outside per day between 10am & 4pm on WEEKDAYS?**

<=30 mins  31-60 mins  1 to 2 hours  3 to 4 hours  4 hours or more

**15. In the summer, on average, how long are you outside per day between 10am & 4pm at the**

**WEEKEND?**

<=30 mins   
 31-60 mins   
 1 to 2 hours   
 3 to 4 hours   
 4 hours or more   

**16. In the past 12 months, how many times did you have a red or painful sunburn that lasted a day or more? (please tick one)**

0   
 1   
 2   
 3   
 4   
 5 or more   

**During the summer, when you are outside on a warm sunny day how often do you (please tick)**

	Never	Rarely	Sometimes	Often	Always
<b>17a. wear sunscreen?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>17b. wear a shirt with sleeves that cover your shoulders?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>17c. wear a hat?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>17d. stay in the shade or under an umbrella?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>17e. wear sunglasses?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>17f. spend time in the sun in order to get a tan?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**18. In the past 12 months, have you used a sun-bed or sun-lamp? (please tick one)**

Yes, more than 6 times   
 Yes, between 1-6 times   
 No   

**Illnesses/diseases**

**19. Please list all illnesses/diseases and recent operations (past 5 years)**

	Description	Dates of onset and completion (if not ongoing)	Any additional information
a)			
b)			
c)			
d)			
e)			
f)			

CONTINUE AT END IF NECESSARY

**Current medication****20. Please list all medication – prescribed and over the counter**

	Name of medication	BNF Code	Dose	Number of times a day
a)				
b)				
c)				
d)				
e)				
f)				

CONTINUE AT END IF NECESSARY

**Employment****21. Please define your current work status (please tick one)**

In work – full time (>30 hours per week)	<input type="checkbox"/>
In work – part time (<30 hours per week)	<input type="checkbox"/>
Keeping house	<input type="checkbox"/>
Wholly retired from work	<input type="checkbox"/>
Waiting to start a new job already obtained	<input type="checkbox"/>
Employed and looking for work	<input type="checkbox"/>
Out of work as temporarily sick	<input type="checkbox"/>
Permanently sick or disabled	<input type="checkbox"/>
Other, please specify:	

**22. Please tick one answer to show which best describes the sort of work you do.**

(If you are not working now, please tick an answer to show what you did in your last job).

**Modern professional occupations** 

such as: teacher - nurse - physiotherapist - social worker - welfare officer - artist - musician - police officer (sergeant or above) - software designer

**Clerical and intermediate occupations** 

such as: secretary - personal assistant - clerical worker - office clerk - call centre agent - nursing auxiliary - nursery nurse

**Senior managers or administrators** 

(usually responsible for planning, organising and co-ordinating work and for finance) such as: finance manager - chief executive

**Technical and craft occupations** 

such as: motor mechanic - fitter - inspector - plumber - printer - tool maker - electrician - gardener - train driver

**Semi-routine manual and service occupations** 

such as: postal worker - machine operative - security guard - caretaker - farm worker - catering assistant - receptionist - sales assistant

**Routine manual and service occupations** 

such as: HGV driver - van driver - cleaner - porter - packer - sewing machinist - messenger - labourer - waiter / waitress - bar staff

**Middle or junior managers** 

such as: office manager - retail manager - bank manager - restaurant manager - warehouse manager - publican

**Traditional professional occupations** 

such as: accountant - solicitor - medical practitioner - scientist - civil / mechanical engineer

**Student** **Never employed or long term (more than 5 years) unemployed**

**Physical Activity****23. Please tick one answer that best corresponds to your activities****Not in employment** 

For example retired, unemployed, or a full-time carer

**Sedentary occupation** 

Spend most of the time sitting (such as in an office)

**Standing occupation** 

Spend most of the time standing or walking. However, the work does not require intense physical effort (e.g. shop assistant, hairdresser, guard etc.)

**Physical work** 

This involves some physical effort including handling of heavy objects and use of tools (e.g. plumber, cleaner, nurse, sports instructor, electrician, carpenter etc.)

**Heavy manual work** 

This involves very vigorous physical activity including handling of very heavy objects (e.g. docker, miner, bricklayer, construction worker etc.)

**In a typical week during the past 12 months, how many hours/minutes did you spend on each of the following activities? (Put 0 for none)**

	In summer (hours per week)	In winter (hours per week)
<b>24a. Walking, including walking to work, shopping and leisure</b>		
<b>24b. Cycling, including cycling to work and during leisure time</b>		
<b>24c. Other physical exercise (such as keep fit, aerobics, swimming, jogging)</b>		

**On average over the last 4 weeks, how much time did you spend on TV or video viewing, and on computer use at home (please tick)**

	Average over the last 4 weeks					
	None	Less than 1 hour a day	1 to 2 hours a day	2 to 3 hours a day	3 to 4 hours a day	More than 4 hours a day
<b>25. Hours of TV or video watched per day</b>						
25a. On a weekday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25b. On a weekend day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>26. Hours of home computer use per day</b>						
26a. On a weekday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26b. On a weekend day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Diet**

Please estimate your average food intake over the past year as best as you can (please put one tick per line)

Food	Never or < once/month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ a day
27a. Margarine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27b. Oily fish *	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27c. Non-oily fish*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27d. Liver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27e. Eggs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27f. Yoghurt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27g. Breakfast cereal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27h. Low-fat fortified milk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\* Oily fish is tuna, sardines, mackerel, eel, salmon, and trout

If you eat or drink yoghurt, breakfast cereal or low-fat milk, please indicate which brands you buy and how often you consume each brand

28a. Yoghurt:

28b. Breakfast cereal:

28c. Low-fat milk:

If you eat fish, please indicate names of fish (e.g. salmon, tuna), whether these are usually farmed or wild, and how often you consume each type

29a. Farmed fish:

29b. Wild fish:

**TO BE COMPLETED BY RESEARCHER****Medical screening / history**

<b>Does the participant have a known history of any of the following exclusion criteria for the trial?</b>	<b>Yes / No</b>	<b>Further details if required</b>
30a. T2D or use of oral hypoglycaemic agents		
30b. Hypercalcaemia (serum calcium >2.65 mmol/l)		
30c. Intolerance to vitamin D2 or D3 or currently taking vitamin D supplements		
30d. Stage 4 or worse chronic kidney disease (eGFR (estimated glomerular filtration rate) < 30 ml/min)		
30e. Significant liver disease (AST (aspartate aminotransferase) >3 x upper limit of normal (ULN) or ALT (Alanine aminotransferase) >3 x upper limit of normal (ULN) or serum bilirubin > 2.5 x ULN)*		
30f. Renal stones		
30g. Hyperparathyroidism		
30h. Active sarcoidosis, tuberculosis or malignancy		
30i. Current anaemia of <11g% or known haemoglobinopathy such as sickle cell anaemia and beta or alpha thalassemia		
<b>Is the participant:</b>		
30j. Taking cardiac glycosides, thiazide diuretics or corticosteroids? (or has the participant taken these in the past one month?)		
30k. Breast feeding, pregnant or planning a pregnancy?		
30l. Unavailable to attend for follow-up visits		
<b>Researcher signature / ID</b>		<b>Date</b>

If 'yes' has been answered to any of the above, the participant is **NOT ELIGIBLE** for this trial.

**General health**

**31. Please summary the participant's general health, mentioning any on-going health concerns**

**Researcher signature / ID**

**Date**



## Body measurements

**32. Urine pregnancy test result (only in women with childbearing potential; test must be negative before proceeding to subsequent tests) (please tick)**

Positive  Negative  Not applicable

**33. Height**

cm

**34. Weight**

kg

**35. BMI**

**36. Body fat, Tanita**

%

**37. Waist circumference (If the first two differ by >3cms complete a 3<sup>rd</sup> measure)**

1.  cm 2.  cm 3.  cm

**38. BP (take 3 times)**

1<sup>st</sup>

Systolic  mmHg

Diastolic  mmHg

Pulse Rate

2<sup>nd</sup>

Systolic  mmHg

Diastolic  mmHg

Pulse Rate

3<sup>rd</sup>

Systolic  mmHg

Diastolic  mmHg

Pulse Rate

Researcher's signature and ID

Date

## iSTAT results

**39. POC ionised calcium (mmol/l)\*\***

1<sup>st</sup>

2<sup>nd</sup> – if required

3<sup>rd</sup> – if required

**40. POC Random blood glucose (mmol/l)\*\***

1<sup>st</sup>

2<sup>nd</sup> – if measured

3<sup>rd</sup> – if measured

Researcher's signature and ID

Date

**41. Other study bloods**

Collected? Yes  No

Site of procedure (e.g. left arm)

**42. Urine sample (for ca:cr ratio)**

Collected? Yes  No

Researcher's signature and ID

Date

**43. Is the participant's ionised calcium from this visit within the acceptable range?\***

Yes  No

Researcher's signature and ID

Date

## Observation only

**44. Is the participant wearing a "hijab" (Islamic headscarf)?** Yes  No

Researcher's signature and ID

Date

**Prescribing of study medication.**

45. Participant's randomisation code

**Researcher's signature and ID****Date**

To the prescribing clinician – in signing this and the prescription you are agreeing that you have reviewed the participant's medical screening summary and baseline tests and are happy for the participant to receive any of the trial IMPs at this current time.

**Prescribing clinician's signature and ID****Date**

**46. Date and time of administration of study medication** (please ensure negative pregnancy test (as appropriate) and acceptable safety readings before administering).

**Researcher's signature and ID****Date****47. Any comments / actions taken?****Researcher signature / ID****Date****Additional notes**

\*All participants invited to participate in this trial had a serum Bilirubin measurement of <2.5xULN when this was measured as part of the Fenland Study. Ensure the participants have no known history of significant liver disease subsequent to their participation in the Fenland Study.

\*\*Ensure the iSTAT measurements are within the acceptable ranges before proceeding with this visit (ionised calcium <1.3mmol/l and random blood glucose <11mmol/l)

If the iSTAT measurements are found not to be acceptable repeat the measurements. If the second measurement is within the acceptable range, take a third measure. If two of three measurements are normal proceed with this visit. If two of three measurements fall outside of the acceptable ranges do not proceed with this visit. If the second test is unacceptable, as well as the first, do not carry out a third test. The participant cannot proceed in the trial.

If the participant cannot continue in the trial, collect a blood sample for each measure that was found to be abnormal when using the iSTAT (i.e. calcium or glucose or both of these) to enable laboratory analysis of these measures for reporting to the participant's GP as appropriate. There is no need to collect the other trial bloods.