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Can an app support a healthy vitamin D level in healthy volunteers?

Submission date
16/04/2021

Recruitment status
No longer recruiting

Registration date
07/05/2021

Overall study status
Completed

Last Edited
02/12/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
This small scale pilot trial seeks to determine whether the app Sun4Health (provided by siHealth Ltd) can be effective in supporting its users to maintain a 'healthy' vitamin D level whilst making sure they manage a safe level of exposure to the sun.

Who can participate?
Healthy volunteers aged between 20 and 60

What does the study involve?
Participation will involve the use of an app that will model vitamin D blood level by satellite-based monitoring of their sun exposure, then providing recommendations for supporting better health. It will require participants to use the app on a smartphone connected to the internet and with GPS localization active; regularly check if the app correctly detects if they are indoors or outdoors (adjusting when needed); set in the app their sunscreen use and clothes (e.g. summer wear, winter wear) throughout the day; provide diary data through the app (e.g. food and supplements intake). In addition, participants will be asked to provide a regular monthly or fortnightly blood spot test for vitamin D (D3 and D2).

What are the potential benefits and risks of participating?
The potential benefits are learning more about personal management of exposure to sunlight whilst obtaining maximum benefit of Vitamin D from that sunlight. The only risk is doing the finger prick blood spot on a regular basis - this may involve a very low level of pain.

Where is the study run from?
NHS Highland (UK)

When is the study starting and how long is it expected to run for?
August 2020 to January 2022

Who is funding the study?
siHealth Ltd (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V4.2

Study information

Scientific Title
Can an app support a healthy vitamin D level in healthy volunteers? The Sun4Health-Vitamin D randomized controlled trial

Acronym
VitD App

Study objectives
The aim of this pilot study is to identify and evaluate the effects on healthy volunteers of an app designed to provide information and recommendations to improve the health of individuals in relation to vitamin D.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require ethics approval. The researchers have checked with the NHS REC and as it is a healthy volunteer study it was judged to not require REC approval.
Approved 31/03/2021, NHS Highland Research, Development & Innovation Office (NHS Highland RD&I Office, Centre for Health Science, Old Perth Road, Inverness, IV2 3JH, UK; Tel: not provided; beth.sage@nhs.scot), ref: HIGHLAND 1737

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Management of access to sunlight/amount of Vitamin D from sunlight in healthy volunteers

Interventions
Randomisation is carried out following the recruitment of the participants and stratification of skin phototype. Randomisation is a simple 1:1, using Excel.

Participation will involve the use of an app that will model vitamin D blood level by satellite-based monitoring of their sun exposure, then providing recommendations for supporting better health. It will require participants to use the app on a smartphone connected to the internet and with GPS localization active; regularly check if the app correctly detects if they are indoor or outdoor (adjusting when needed); set in the app their sunscreen use and clothes (e.g. summer wear, winter wear) throughout the day; provide diary data through the app (e.g. food and supplements intake). In addition, participants will be asked to provide a regular monthly or fortnightly blood spot test for vitamin D (D3 and D2).

The control group receives access to the Sun4Health app with a diary but no access to the Sun4Health information and recommendations about sun exposure.

All participants are expected to use the app for 8 months in total. The study will be completed at the end of month 9.

Intervention Type
Behavioural

Primary outcome measure
Accuracy of the siHealth proprietary model for vitamin D levels in the blood using data collected from the app through its use by participants. Vitamin D2 and 3 levels are measured using blood spot samples at baseline (T0), T0 + 1 month, T0 + 1 months and 15 days, T0 + 2 months, T0 + 2 months and 15 days, T0 + 3 months, T0 + 3 months and 15 days, T0 + 4 months, T0 + 5 months, T0 + 6 months, T0 + 7 months, T0 + 8 months (final)

Secondary outcome measures
Food intake, satisfaction with use of the app, deviations in data entered (e.g. inaccurate exposure times, inaccurate supplement recording) and any adverse events related to sun exposure (e.g. sunburn) measured using a fortnightly app-based questionnaire for the duration of the study (8 months)

Overall study start date
10/08/2020

Completion date
31/01/2022

Eligibility

Key inclusion criteria
Between ages of 20 and 60 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
80

Total final enrolment
106

Key exclusion criteria
1. Under 20 years old
2. Over 60 years old
3. Unable to provide written informed consent or not able to understand the Participant Information Sheet
4. Vulnerable people deemed inappropriate to approach e.g. children or prisoners
5. Persons who have been told by a clinician that medication they are currently taking may increase the risk of photosensitivity
6. People with a previous or current medical history of skin cancer as exposure to the sun is of greater risk in this population.
7. People who are undergoing medical phototherapy
8. People who are pregnant
9. People who report that they have the following conditions: Crohn’s disease, cystic fibrosis, celiac disease
10. People who use sunbeds more than once every 6 months on average
11. Not owning a smartphone suitable for accessing the app

Date of first enrolment
01/04/2021

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Highlands Scotland (NHS Highland)
Assynt House
Beechwood Park
Old Perth Road
Inverness
United Kingdom
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Sponsor information

Organisation
NHS Highland

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Sponsor type
Hospital/treatment centre

Website
https://www.nhshighland.scot.nhs.uk/

ROR
https://ror.org/010ypq317

Funder(s)

Funder type
Industry

Funder Name
siHealth Ltd

Results and Publications

Publication and dissemination plan
At the current time the funder does not want the protocol to be made available for commercially confidentiality reasons.

There is an Agreement between the funder and NHS Highland to cover all aspects including publications. siHealth Ltd will be responsible for the majority of publications in relation to the evaluation of their Sun4Health App, and NHS Highland will develop two publications with permission from siHealth looking at the challenges of remote delivery of research studies and general use of apps for preventative health management.

Intention to publish date

01/04/2023

Individual participant data (IPD) sharing plan

As this pilot trial is being undertaken for a commercial organisation to evaluate their product (App) they currently do not want to make this dataset available. However, they may consider this more appropriate at the end of the trial.

IPD sharing plan summary

Not expected to be made available