ISRCTN69678101 https://doi.org/10.1186/ISRCTN69678101

Vitamin D supplementation and improvement of insomnia symptoms among vitamin D deficient Malaysian women

Submission date
01/07/2024

Recruitment status
No longer recruiting

Registration date
01/10/2024

Overall study status
Completed

Last Edited
31/10/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Vitamin D deficiency (VDD) is implicated in a range of important health issues that affecting women, and several studies have found that VDD is associated with insomnia. The purpose of this study is to analyse the effect of 9 weeks' Vitamin D3 supplementation in women who had insomnia symptoms and low serum 25(OH)D level.

Who can participate?
The study participants are women aged 19 to 50 years old who are having insomnia symptoms, willing to involve in the study and are currently residing in Ipoh, Perak, Malaysia.

What does the study involve?
The intervention will compare the improvement of sleep parameters between a study group given vitamin D3 supplement and a study group given with placebo capsule.
Participants will receive the same treatment except for the intervention product, either placebo or vitamin D3 supplement.
At the beginning and end of study, all participants will be measured for some parameters, including:
i) Sleep quality
ii) Sleepiness severity;
iii) Subjective daytime sleepiness;
iv) Sleep-related quality of life
v) Vitamin D level from a blood test
Participants also will receive an actigraph (a device worn on the wrist to measure and record sleep patterns at home), to objectively measure sleep parameters. The measurements will be taken at week-0 and week-9 of the study.

What are the possible benefits and risks of participating?
You will get a measurement of your Vitamin D level (worth RM200) twice, at the beginning and end of study. Your sleep pattern will be analysed using actigraph so that you can see the difference between before and after participating in the study.

If you are in the intervention group, you will take vitamin D3 supplement. However, if you are assigned in the placebo group, Vitamin D3 will be provided at the end of the study (a total of 9 capsule of Vitamin D3, 1 capsule per week should be taken for 9 week). Vitamin D3 supplementation will raise your vitamin D levels, which may benefit your overall health. Participation in this study will have no substantial adverse effects on your health, and the risk is zero or negligible. High dose of Vitamin D3 supplement rarely give significant adverse effects. Some possible mild adverse effects are stomach discomfort, frequent urination, dehydration, recurrent vomiting, and abdominal pain. If the participant report any adverse event(s), they will be referred to general practitioner and the blood sample will be taken to check some parameters that can indicate the need for study discontinuation.
As a token of appreciation for your contribution to the study, you will be entitled to an honorarium of RM50.

Where is the study run from?
The institution managing this study is Universiti Kuala Lumpur, Royal College of Medicine Perak (Malysia)

When is the study starting and how long is it expected to run for?
January 2022 to December 2025

Who is funding the study?
Universiti Kuala Lumpur (Malaysia)

Who is the main contact?
Rara Merinda Puspitasari, raramerinda@unikl.edu.my

Contact information

Type(s)
Public, Principal investigator

Contact name
Miss Rara Merinda Puspitasari

ORCID ID
https://orcid.org/0000-0002-3907-6243

Contact details
Permai Lake View Apartment, Block A01
Perak
Malaysia
30150
+60 1139796985
raramerinda@unikl.edu.my

Type(s)
Scientific

Contact name
Dr Zaswiza Mohamad Noor

Contact details
Faculty of Pharmacy and Health Sciences Universiti Kuala Lumpur
Royal College of Medicine Perak
No 3, Jalan Greentown
Perak
Malaysia
30450
+60 175993403
zaswiza@unikl.edu.my

Additional identifiers

Protocol serial number
VDSI01

Study information

Scientific Title
Vitamin D supplementation and improvement of insomnia symptoms among vitamin D deficient Malaysian women: a double-blind randomised controlled trial

Acronym
VDSI

Study objectives
1. The Pittsburgh Sleep Quality Index (PSQI) mean score of the intervention group is significantly decreased at week 9 follow-up compared to the placebo group
2. The insomnia severity index (ISI) mean score of the intervention group is significantly decreased at week 9 follow-up compared to the placebo group
3. The daytime sleepiness mean score is significantly decreased at week 9 follow-up compared to the placebo group
4. The sleep quality percentage of the intervention group is significantly increased at week 9 follow-up compared to the placebo group
5. The Functional Outcomes of Sleep Questionnaire (FOSQ-10) mean scores are significantly increased at week 9 follow-up compared to the placebo group

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/02/2022, UNIKL Research Ethics Committee (Universiti Kuala Lumpur, 1016, Jalan Sultan Ismail, Kuala Lumpur, 50250, Malaysia; +60 321754000; enquiries@unikl.edu.my), ref: UNKIL REC/2022/0017

Primary study design
Interventional

Study design
Single centre interventional double-blinded randomized controlled trial

Study type(s)
Quality of life, Efficacy

Health condition(s) or problem(s) studied
Improvement of insomnia symptoms among vitamin D deficient Malaysian women

Interventions
This study is a double-blind, randomised, placebo-controlled trial, employs one intervention group and one control group, designed in a parallel group. This superiority trial aims to demonstrate that the response to the investigational product (vitamin D3) is superior to that of a placebo.

Randomisation and Blinding: Study participants will be randomised into two study groups: the placebo group (PG) and intervention group (IG). A double-blinding method will be applied for both subjects and investigators. The placebo and intervention group will be labelled as either group A or B. A third party (an appointed pharmacist) will draw lots using a coin to determine which group will belong to IG or PG. The result will be enclosed in a sealed envelope and stored by the third party in a locked cabinet. The identity of the intervention group, either participants in group A or B, will be disclosed upon completion of the data analysis.

Intervention: Participants in intervention group will be instructed to take 50,000 IU of vitamin D3 (9 capsules) once weekly for 9 weeks, whereas those in the placebo group will take the placebo capsule (9 capsule) for the same duration. Subjects will be instructed to take the product with food in the morning or after breakfast.

Intervention Type
Supplement

Primary outcome(s)
1. Participant’s Vitamin D level status is measured using biochemistry test (Radioimmunoassay) at baseline and at the end of study (end of week 10)
2. Changes in sleepiness severity is measured using Insomnia Severity Index (ISI) questionnaire at baseline, week 5 and end of week 10
3. Sleep quality is measured using Pittsburgh Sleep Quality Index (PSQI) questionnaire at baseline, week 5 and end of week 10
4. Subjective daytime sleepiness is measured using The Epworth Sleepiness Scale (ESS) questionnaire at baseline, week 5 and end of week 10
5. Sleep pattern and sleep efficiency is measured using Actigraph (ActiTrust-2) at baseline and at the end of study (end of week 10)

Key secondary outcome(s)
Daytime function is measured using Functional Outcomes of Sleep Questionnaire (FOSQ-10) questionnaire at baseline, week 5 and end of week 10

Completion date
30/12/2025

Eligibility

Key inclusion criteria

1. Woman
2. Aged 19 - 50 years old.
3. Serum 25(OH)D level of <20 ng/mL (50 nmol/L)
4. PSQI score of ≥5
5. Not pregnant or lactating
6. Not sleeping with infant (< 2 years)
7. Currently (consider from the past 3 months) is not taking vitamin D or any supplements containing vitamin D
8. Not a smoker and/or alcoholic

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
82

Key exclusion criteria
Participants are excluded based on whether they have the following causes or risk factors that may contribute to insomnia:
1. Currently having the following conditions:
1.1. Malabsorption
1.2. Chronic diseases (diabetes, hypertension, cardiovascular disease etc).
1.3. Osteoporosis and/or other bone diseases
1.4. Malignancy
1.5. Hypo-or hyperthyroidism
1.6. Psychological-related illness (such as depression and anxiety)
2. Taking the following medications:
2.1. Corticosteroids
2.2. Anticonvulsant
2.3. Narcotics and psychotropics (such as antidepressants and antipsychotics).
2.4. Antiretroviral drugs
2.5. Cytotoxic agents
2.6. Antihistamines

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
Ipoh, Perak, Malaysia
Ipoh
Perak
Malaysia
30450

Sponsor information

Organisation
University of Kuala Lumpur

ROR
https://ror.org/026wwrx19

Funder(s)

Funder type
University/education

Funder Name
Universiti Kuala Lumpur

Alternative Name(s)
University of Kuala Lumpur

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Malaysia

Results and Publications

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	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes