

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

Submission date 01/07/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/10/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/10/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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 (Malaysia)

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

Study website

<https://vdinsomniastudy.wordpress.com>

Contact information

Type(s)

Public, Principal Investigator

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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: UNIKL REC/2022/0017

Study design

Single centre interventional double-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Community, Internet/virtual, Pharmacy, Retail/food outlet, University/medical school/dental school, Workplace

Study type(s)

Quality of life, Efficacy

Participant information sheet

<https://vdinsomniastudy.wordpress.com>

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 measure

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)

Secondary outcome measures

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

Overall study start date

01/01/2022

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

Age group

Adult

Lower age limit

19 Years

Upper age limit

50 Years

Sex

Female

Target number of participants

82

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

Sponsor details

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Sponsor type

University/education

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<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

Publication and dissemination plan

Planned publication in a peer-reviewed journal that is indexed in scopus or others.

Intention to publish date

31/12/2026

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