STUDY PROTOCOL

Management of Vitamin D Deficiency Among the Under-Five Children Residing in Coastal Areas of Karnataka: A Study Protocol

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ABSTRACT

Introduction: Vitamin D deficiency has become the new normalcy due to rapid transition of lifestyles among the people globally. Vitamin D is synthesized in the body due to exposure of skin to sunlight. Correction of vitamin D deficiency poses a major demand due to its action on bone and muscle health. The objective of this study is to assess the effectiveness of sun exposure and Vitamin D supplement and Vitamin D supplements alone on serum vitamin D levels among the under-fives.

Methods: This protocol is a randomized controlled study planned to be carried out among the under-five children with vitamin D deficiency. Children will be randomised into two groups (Group 1 -Vitamin D supplementation only) and (Group 2 - vitamin D supplementation +sun exposure). Both the group will receive intervention for 12 weeks and Serum Vitamin D levels will be tested after 12 weeks. Descriptive and inferential statistics will be used to present the findings of the study.

Conclusion: Identification and treatment of Vitamin D deficiency is vital in children`s bone health. This protocol will provide direction and guidance to optimize utilization of treatments to improve vitamin D deficiency among under five children.

Keywords: Child health, Vitamin D deficiency, sunlight exposure, vitamin D supplements, under-five children, India

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Introduction

Vitamin D also known as sunshine vitamin is synthesized on exposure to sunlight, that yields in photo conversion of 7-dehydrocholestrol in the skin to cholecalciferol. The existing scientific knowledge indicates that vitamin D and calcium has a vital role in the bone health. Globally Vitamin D deficiency affects all the age groups.[1] In Indian subcontinents Vitamin D deficiency prevails 70%–100% among the general population.[2] Hypovitaminosis D was prevalent among 62.2% and 3% of children (6 months to 18 years) had overt rickets in a tertiary care hospital of Chennai.[3] The vitamin D is synthesized endogenously during exposure of the skin to direct sunlight, 7-dehydrocholesterol present in the skin absorbs ultraviolet B radiation and is converted to cholecalciferol which is then converted to vitamin D3 after further metabolic process in the body. The study in Northern part of India has identified that, children with Vitamin D deficiency are more prone to respiratory infections and diarrhoea. The children who are having Vitamin D deficiency had higher chances of lower respiratory tract infections in comparison with children with normal Vitamin D level.[4]

The prevalence of vitamin D deficiency among children vary from 30 to 82% in different parts of India.[3,5-8] A systematic review on prevalence of Vitamin D deficiency among adolescent girls in India reported the prevalence as 25.70%, the study addressed the need for proven public health intervention for tackling Vitamin D deficiency.[9] Low intake of sources rich in vitamin D, high intake of fibre and phytates that reduces absorption of vitamin D levels or reduced exposure of skin to sun light makes Indians prone to Vitamin D deficiency. A study reported significant positive correlation between afternoon sunlight exposure and infant's vitamin D levels, independent of maternal vitamin D status among 132 healthy infants at a tertiary care hospital of Delhi.[10] Breast milk is a best source of nutrients for the infant but will not provide enough Vitamin D. In this study sun exposure and Vitamin D is given to the under-five children to assess its impact on serum Vitamin D level.

In countries with high temperature the studies reported the prevalence of vitamin D deficiency due to limited sunlight exposure and restricted physical activity.[11,12] Even though in the coastal areas of South India natural sunlight is available throughout the year, there is no evidence to suggest the vitamin D levels of children. The high cost of serum vitamin D test is one of the reasons for not having adequate data. As this study provides an opportunity for covering the expenses of the blood test and the medicine, the results could help in adding to the knowledge regarding the vitamin D status of children in the coastal area. Columbia national survey show that the toddlers had the high prevalence of low vitamin D 42.5% ± 1.8%.[13] The available literature in the coastal regions show the high prevalence in different age group: adults of Odissa region (48.2%)[14]; Hence if this study proves to be effective mothers can expose the children to the sunlight without any expense. Vitamin D is relatively cheaper medicine available in all the places and easy to administer to the infants. Vitamin D will be provided to the under-five children as supplementary which will help to maintain normal serum Vitamin D level thus helps in normal growth and development of children.

Methodology

Study design: The study uses quantitative research approach with randomized controlled study design. To identify the under-fives with low vitamin D level, survey will be carried out in paediatric OPD of Kasturba Hospital Manipal who are advised for blood investigation by the paediatrician. A total of 120 research participants will be enrolled for the intervention. The design of the study is depicted as consort in Figure 1. The Group 1 and Group 2 will be allotted with 60 research participants each.

Children between the age of 6 months to 5 years will be recruited for the study. *Inclusion criteria* include children belonging to Coastal Karnataka (Uttar Kannada, Dakshina Kannada, and Udupi District) and visiting the paediatric unit (OPD/ward) of Kasturba Hospital Manipal; children who are advised blood test by the paediatrician. *The exclusion criteria* include children suffering from chronic illnesses (chronic kidney disease, chronic liver disease, malabsorption syndrome, endocrine disorders like hyperparathyroidism, neuromuscular disorders), under-five children receiving vitamin D prophylaxis or having intolerance to hot sun light will be excluded.

Ethical considerations: Ethical approval for this project is obtained from the Institutional ethical committee (IEC 1: 157/2022). The protocol is registered under Clinical Trial Registry of India (CTRI) with registration number CTRI/2023/07/054883. A written informed consent will be obtained from all parents who can read and understand Kannda prior to the recruitment. The confidentiality will be maintained throughout the study. The project is funded by Indian Council of Medical Research (ICMR), India, so, the expenses of vitamin D blood test and vitamin D supplementation will be covered from the project. Hence parents need not pay for the test and the treatment. The parents will be informed about consulting the paediatrician in case of any event leading to vitamin D supplementation or sunlight exposure. The research team will identify and address the concerns in consultation with treating paediatrician.

Sample size: The study will include total 120 participants, who will be randomly allocated into intervention (n=60) and control group (n=60). Sample size is calculated based on vitamin D deficiency prevalence rate of 60.92% in the published literature (8). However, the sample size will be recalculated based on the result of the survey.

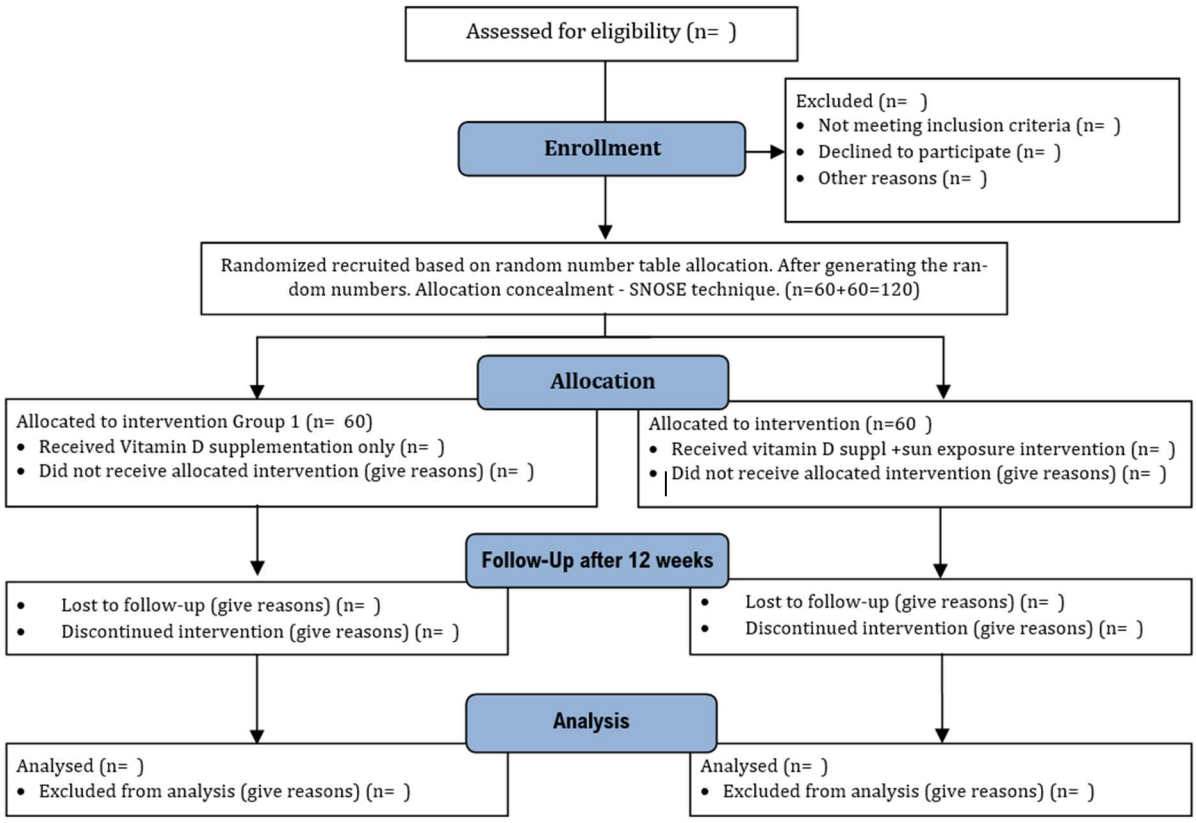

Fig 1: CONSORT flow chart

Randomisation: Under-fives having Insufficiency/ deficiency will be recruited based on random number table allocation. After generating the random numbers, allocation concealment will be done using SNOSE technique. The groups will be prepared in advance and kept in a sealed envelope, and each child will be assigned to the groups (Group 1 and Group 2) randomly. The assessor blinded about the treatment allocation as the assessor is not involved in preparing the SNOSE. Figure 1 represents the study procedure. Outcome assessment is blinded as it involves finding the serum vitamin D level, a laboratory test that may not change the outcome assessment.

Description of the intervention:

Intervention for group 1: Intervention for group 1 is vitamin D supplementation only. Vitamin D supplement for infants between 6 and 12 months will be 60000 IU once a month for 12 weeks and Children between > 1 and 5 years old will receive 60000 IU once every 20 days for 12 weeks. Mothers will be provided with a logbook where the details of Vitamin D supplement need to be documented regularly. Supervisory visits/telephone follow-up will be made to their home to assess the compliance of intervention and motivate the mothers to provide the intervention. In addition, the use of reminders in mobile and/or photos will be used.

Intervention for group 2: Intervention for group 2 include vitamin D supplements + sunlight exposure.

Infants between 6 and12 months will receive 60000 IU, Vitamin D once a month for 12 weeks and children between >1 and 5 years will receive 60000 IU once every 20 days for 12 weeks. In addition to this they will be exposed to sunlight.

Sunlight Exposure**:** The literature was reviewed to identify the suitable timings of sunlight exposure**.** Based on the literature available for sunlight exposure of Delhi and Pune, the timing of sun exposure will be between 11 a.m. – 2 p.m., with 15–40% of the body surface area exposed for 5 days a week. The duration is 17–30 minutes for infants and 30-45 minutes per day for >1–5-year-old children for 5 days for 12 weeks at least 5 times a week during noon (11 am–2 pm).[2,15] In the winter season, the duration of the sun exposure will be 10 minutes longer, that is,17–40 minutes for infants and 30-55 minutes per day for 1–5-year-old children for 5 days for 12 weeks at least 5 times a week during noon (11 am–2 pm). The data collection will be stopped during monsoon, in the month of May or June based on the weather forecast and will restart after rainy season i.e. in September or October. This will be monitored by the research team. The mothers will be given a logbook for maintaining the details ofthe sun's light exposure. The research team will also randomly visit and supervise the intervention. Daily applications of sunscreen/smoothening cream decrease the serum Vitamin D levels and are not recommended for routine use in children.[2] If the mother expresses concern regarding skin darkening because of sun exposure, they will be counselled. If mothers do not agree tothe continuation of the intervention, the intervention for the child will be stopped.

Table 1: Schedule of enrolment, intervention and assessments

Group	Pretest at baseline	Intervention (for 12 weeks)	Posttest at 12 weeks
Group 1	Serum Vitamin D level	**Vitamin D supplement only** Infants between 6 and12 months 60000 IU once a month for 12 weeks Children between >1 and 5 years 60000 IU once every 20 days for 12 weeks Home visit/telephone follow up/photo's/ reminders	Serum Vitamin D level
Group 2	Serum Vitamin D level	Vitamin D supplement+ sunlight exposure Infants between 6 and12 months 60000 IU once a month for 12 weeks Children between >1 and 5 years 60000 IU once every 20 days for 12 weeks +Sun Exposure: for 12 weeks. Home visit/telephone follow up/photo's/reminders	Serum Vitamin D level

Data Collection: The children who are advised by the pediatrician for blood investigations will be contacted for recruitment. Mothers will be explained regarding the study. Written informed consent will be obtained to find the serum Vitamin D level, Demographic data including nutritional status and time spent in outdoor activities will be obtained from the mothers and 0.5 ml of blood will be withdrawn from the under-five children in the laboratory for checking the serum vitamin D level. The vitamin D levels will be documented in clinical parameters for vitamin-D tool. The tools were validated by the experts and translated into local language i.e. Kannada. Under-fives having vitamin D Insufficiency/ deficiency will be recruited based on random number table allocation. After generating the random numbers allocation concealment will be done using SNOSE technique. The groups will be prepared in advance and kept in a sealed envelope, and each child will be assigned to the groups (Group 1 and Group 2) randomly**.** Mothers in both groups 1 and 2 will be educated on the importance of Vitamin D to their children on a one-to-one basis and the intervention will be explained in detail as detailed in table 1. They will be provided with a logbook to enter the date and time of administering vitamin D supplements and sun exposure with specific instructions, which also sensitizes them to the importance of Vitamin D in the body. Supervisory visits/telephone follow-up will be made to their home to assess the compliance of intervention and motivate the mothers to provide the intervention. The mobile reminders requesting photo also may be considered for follow up. The follow-up will be done in 12 weeks, where 0.5 ml of blood will be drawn in the laboratory for the analysis of serum vitamin D level.

Analysis: Data will be managed using Jamovi software. Descriptive and inferential statistical analysis will be carried out in consultation with the statistician. The data will be checked for normality and an appropriate test will be applied. The data on serum vitamin D will be presented as a mean and standard deviation. The categorical data will be presented in terms of frequency and percentage.

STRENGTHS AND LIMITATIONS:

The results of this study will help in deciding on the sunlight exposure in areas with similar geographical conditions. The evidence generated from this research helps strengthen the goal of the SDG 3, as Vitamin D levels in children can contribute to good health. Findings from this study will help in implementing an economical and easily available intervention, i.e., sun exposure. The administration of vitamin D can be strengthened through a universal immunization program.

One of the limitations of this study is that the study is limited to the coastal areas of one state.

Expected outcome of the study:

The outcome of this study is change in serum vitamin D levels, compliance rates to the treatment. The study is going to benefit the children residing in the coastal area and contribute to good health and well-being. The findings of the study will be disseminated through the conferences and will be published in the peer reviewed journals.

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Ethical Approval: Informed consent was obtained from the mothers of under-fives before obtaining the blood sample. This study was approved by IEC 1:157/2022

Individual Authors' Contributions: MSP & RRK: Conception and design; **SCM:** conception and supervision of data collection; **SUK, AD & BBB:** Design; **SMA:** Design

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