

The sun exposure and vitamin D study

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Abstract. Sun exposure has both risks and benefits for human health; finding a balance for optimal sun exposure is challenging due to the lack of evidence. In particular, there are still questions around what an optimal vitamin D level is, whether sun exposure has beneficial effects other than vitamin D and whether sun exposure advice can be used to safely manage vitamin D deficiency. Here we introduce the Sun Exposure and Vitamin D Supplementation Study that seeks to answer these questions. We discuss the methodology used in the study, the public health significance and challenges in study conduct.

Introduction

The Sun Exposure and Vitamin D Supplementation Study (SEDS Study) is a clinical trial that aims to 1) determine the effectiveness of sun exposure compared to vitamin D supplementation for the management of vitamin D insufficiency and 2) determine whether sun exposure and vitamin D supplementation differentially affect markers of immune and metabolic function.



Figure 1. SEDS study medication, sent out to participants once they have returned their questionnaires and informed consent and had their first blood test taken.

Methods

The SEDS Study is recruiting nearly 1000 participants across Australia, with the following inclusion criteria:

- vitamin D test in the past month with a result between 40 -60 nmol/L
- 18-4 years old
- Not currently taking vitamin D supplements
- Low risk of skin cancer

The SEDS Study team determine whether participants are eligible for the study via a screening questionnaire conducted through a phone interview. Participants are then sent out the first pack, which contains a set of questionnaires, a blood request form and a consent form.

Once the participants return all of the documents, they are randomised to one of four arms, and receive their first set of study medication (See Figure 1).

The four arms of the study are:

1. Active vitamin D₃ 2000IU/day orally with meals and standard sun exposure advice
2. Active vitamin D₃ 600IU/day orally with meals and standard sun exposure advice
3. Placebo vitamin D and standard sun exposure advice
4. Placebo vitamin D, enhanced sun exposure advice.

All communication with participants is done via telephone, email or SMS. Data collection is in the form of questionnaires, blood tests and UV dosimeters. We collect information about the participant's lifestyle, including exercise, medications and diet, and also their sun habits.

In order to get as accurate a picture as possible of the participant's sun habits we ask them to fill in two separate questionnaires and wear a UV Dosimeter every 3 months. Participants are either sent a Polysulphone Dosimeter (see Figure 2a) or an Electronic Dosimeter (see Figure 2b). The polysulphone dosimeter is a single-use dosimeter and is worn for one day. Participants get sent 3 dosimeters and are asked to wear one on a working day and one on a non-working day (with one dosimeter spare). The electronic dosimeter is worn for 7 consecutive days while filling in the sun diary.

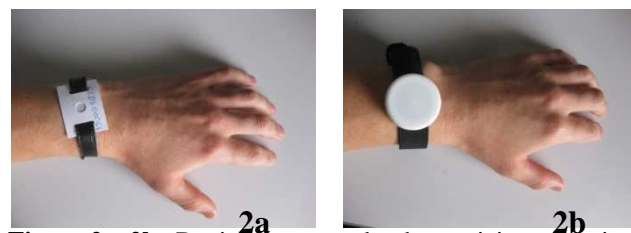


Figure 2a, 2b. Dosimeters worn by the participants during the study. The dosimeter on the left is a polysulphone dosimeter and the dosimeter on the right is the electronic dosimeter.

While wearing the dosimeter, participants fill in the Sun Diary questionnaire which is a detailed record of sun habits over the course of the week. The other questionnaire asks for less detail, but covers the previous 3-month period.

Using these two questionnaires and the dosimeters we will piece together an estimate of how much time the participant spends outdoors, what times of day they are outdoors, approximately how much UV they receive throughout the year and how much vitamin D we would expect them to make through sun exposure throughout the year.

Compliance with study treatment is encouraged via a weekly SMS, and the sun exposure guidelines are also printed on a colourful, easy-to-read fridge magnet. The idea is to make the advice obvious and accessible. Note that participants never meet any of the study team face-to-face, so all of the study materials must be easy to understand.



Figure 3. SEDS promotional flyers which are given to potentially eligible participants, and are also on display in participating blood collection centres and GP clinics.

Challenges

Participants are recruited through referral from General Practitioners (GPs) when routine vitamin D testing shows mild vitamin D insufficiency. When a patient comes to see the GP and they have a blood test result between 40-60 nmol/L the GP then asks if they can pass on the patient's contact details to the SEDS Study team and gives the patient a flyer, as picture in Figure 3.

Most participants who have been referred through this method have been eligible for the study, but many choose not to take part because of the time commitment, or because they would prefer to take vitamin D tablets. An additional challenge is in maintaining GP interest in, and engagement with, the study. To do this we provide regular newsletters and updates to GPs, and have a special section of our website where the abstracts of recent publications of interest are posted.

We have recently added self-referral as a recruitment pathway, and have promoted this through publicity and media coverage. There have already been several articles published around Australia and New Zealand about the SEDS study, with more on the way. A promotional photo was taken of the SEDS study team for use by the media, as seen in Figure 4.

Participants who self-refer are often very interested in the study, but are not eligible because they have either not had a recent vitamin D test or are taking a vitamin D supplement. Some of these potential participants choose to stop taking supplements and are re-tested after 3 months in order to become eligible.



Figure 4. Promotional photo of the SEDS Study team, taken by Stuart Hay, ANU Media. From left to right, the ANU-based research team is Robyn Lucas, Mica Hartley, Laura King, Sam Hoare and Fiona Lithander.

Discussion

The study is innovative but challenging, and the outcomes could have large implications for public health. Australian research shows that both doctors (Bonevski 2012) and the public (Youl 2009) are confused about vitamin D and sun exposure. It is not clear whether mild vitamin D insufficiency can be managed with sun exposure advice, or if vitamin D supplementation is necessary.

If the study were to find that all the benefits of sun exposure are through vitamin D alone, then the correct sun exposure advice may be to avoid the sun and take a vitamin D supplement. However, if the SEDS Study finds benefits of sun exposure which are not linked to vitamin D, then the correct public health message would be to get safe sun exposure similar to the SEDS Study enhanced sun exposure advice.

References

- Bonevski, B. 2012. Prescribing sunshine: A cross-sectional survey of 500 Australian general practitioners' practices and attitudes about vitamin D. *International Journal of Cancer* 130(9): 2138-2145.
- Youl, P. 2009. Vitamin D and sun protection: The impact of mixed public health messages in Australia. *International Journal of Cancer* 124(8): 1963-1970.