# Vitamin D supplementation on body composition in basketball players

Submission date	Recruitment status	[] Pro
03/11/2020	No longer recruiting	[X] Pro
Registration date 06/11/2020 Last Edited	Overall study status Completed Condition category	[] Sta
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13/08/2021	Musculoskeletal Diseases	

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#### Plain English summary of protocol

Background and study aims

The main purpose of this research study is to see if taking Vitamin D supplements will improve bone health in basketball players. A previous study performed on Oakland University studentathletes showed that basketball players, especially male participants, had the lowest Vitamin D levels compared with other athletes. Thus, this study will follow-up by seeing whether or not giving Vitamin D supplements can improve the physical response to training, especially improving bone mass, and mood state in response to hard summer training.

#### Who can participate?

Members of Oakland University's Men's and Women's Basketball team aged between 18 and 25 years. Participants will not be eligible for this study if they have a history of fainting due to having blood drawn. Also, since the radiation exposure from dual-energy x-ray absorption (DXA) scans (used to assess body composition) can be harmful to a developing fetus (baby), participants who are pregnant or think they may be pregnant will not be allowed to participate in this study.

#### What does the study involve?

This study requires testing twice in the lab. At the beginning of the study, participants will come into the lab and have a teaspoon of blood drawn for analyses of vitamin D levels and then undergo a DXA scan to see how much fat, lean (muscle), and bone mass they have. Then, participants will be given a supplement (either vitamin D or a placebo pill) once a week during 12weeks of summer strength training. After 3-months of summer training is over, they will come into the lab once more to have their blood drawn (for vitamin D levels) and a DXA scan.

#### What are the possible benefits and risks of participating?

The possible benefits to participants from participating in the research study are knowing their Vitamin D levels and determining if taking a Vitamin D supplement can help them (and other basketball players) build more bone mass, improving conditioning gains, and improving their mood state during the off-season training. The results of this investigation could benefit athletes, coaches, trainers, and doctors by providing evidence to support (or not) measurement of blood Vitamin D levels throughout the season. The risks of participating include discomfort and infection from the blood draw and being exposed to small doses of radiation during the DXA scans (equal to a normal days worth of radiation exposure).

Where is the study run from? Oakland University (USA)

When is the study starting and how long is it expected to run for? From October 2016 to December 2019

Who is funding the study? The study is funded by Oakland University's University Research Council (URC) Fellowship award to Tamara Hew-Butler

Who is the main contact? Tamara Hew-Butler tamara.hew-butler@wayne.edu

# **Contact information**

**Type(s)** Scientific

**Contact name** Prof Tamara Hew-Butler

#### **Contact details**

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### Additional identifiers

**EudraCT/CTIS number** Nil known

**IRAS number** 

**ClinicalTrials.gov number** Nil known

**Secondary identifying numbers** Nil known

## Study information

#### Scientific Title

Vitamin D supplementation on bone turnover in NCAA D1 collegiate basketball players: a pilot study

#### **Study objectives**

Modest (4000 IU/week) Vitamin D3 supplementation will augment bone and muscle mass in collegiate basketball players undergoing three months of strength training, over placebo supplementation.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved on 24/07/2017, Oakland University's Institutional Review Board (OU IRB) (The Research Office, Wilson Hall, 371 Wilson Boulevard, Rochester, Michigan 48309-4486 +1 (248) 370-4306; kwydeven@oakland.edu), ref: 922734

#### Study design

Single-blind randomized controlled trial

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** School

**Study type(s)** Treatment

#### Participant information sheet

See additional file ISRCTN14155111\_PIS\_24July2020 (added 02/12/2020)

#### Health condition(s) or problem(s) studied

Increase bone and muscle strength in collegiate basketball players

#### Interventions

Members from a men and women's National Collegiate Athletic Association (NCAA) Division 1 (D1) basketball team will be recruited to participate. All subjects will give informed consent before participating in the study, which will be conducted in accordance with the Declaration of Helsinki. After obtaining written informed consent, all participants will undergo pre-intervention testing which will be conducted prior to summer strength training. Players will then be randomized (single-blind, with participants blinded to the intervention) at a ratio of 1:1 to receive either a Vitamin D (Vitamin D3, 4000IU soft gels, Up&Up™, Greenville, SC) or placebo capsule (Gelatin 1300mg Spring Valley, Bentonville, AR) weekly. The randomization order was odd/even while ensuring that a racial balance between African American and Caucasian players existed between the two supplement groups, during the randomization process.

Supplementation will occur weekly for logistical reasons as the IRB limited the daily dose to 4000IU and the investigators can only access the basketball players once per week. The dosage is based upon current recommendations (600 IU/day or 4200 mg/week with a daily tolerable upper limit of 4000 IU) for healthy young (19-50 years) individuals. Weekly supplementation will be administered by the research team over a 12-week period. Researchers will bring the supplements in (labeled) plastic cups to the weight-training room and dispense them after completion of every Monday's workout.

#### Intervention Type

Supplement

#### Primary outcome measure

Bone mass measured using whole body dual x-ray absorptiometry (DXA) scans performed at baseline and 12 weeks

#### Secondary outcome measures

 Total body lean mass measured using whole body dual x-ray absorptiometry (DXA) scans performed at baseline and 12 weeks
Total body fat mass measured using whole body dual x-ray absorptiometry (DXA) scans performed at baseline and 12 weeks

**Overall study start date** 16/10/2016

**Completion date** 30/12/2019

# Eligibility

#### Key inclusion criteria

1. National Collegiate Athletic Association (NCAA) Division 1 (D1) basketball players currently eligible to play for the upcoming season 2. Aged between 18 and 25 years

#### Participant type(s)

Healthy volunteer

#### **Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

Target number of participants 40

**Total final enrolment** 23

**Key exclusion criteria** 1. History of fainting during blood draw 2. Pregnancy

Date of first enrolment 27/06/2017

Date of final enrolment 30/09/2019

### Locations

**Countries of recruitment** United States of America

**Study participating centre Oakland University** Rochester United States of America 48309

### Sponsor information

**Organisation** Wayne State University

**Sponsor details** 656 West Kirby

Detroit United States of America 48202 +1 313-577-0014 aj4391@wayne.edu

**Sponsor type** University/education

Website https://wayne.edu/

ROR https://ror.org/01070mq45

# Funder(s)

**Funder type** Other

#### Funder Name

Investigator initiated and funded by Oakland University URC Summer Fellowship Award

### **Results and Publications**

#### Publication and dissemination plan

We are in the process of submitting the results of this study for publication.

#### Intention to publish date

31/12/2020

#### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

#### IPD sharing plan summary

Other

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		24/07/2020	02/12/2020	No	Yes
<u>Protocol file</u>		24/07/2020	02/12/2020	No	No
Preprint results		02/03/2021	13/08/2021	No	No