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Vitamin and mineral deficiencies in the US military

Submission date
10/09/2019

Recruitment status
No longer recruiting

Registration date
13/09/2019

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nutritional deficiencies have occurred in military units throughout history, significantly compromising the health of Service Members (SMs) and the operational effectiveness of military units. For example, scurvy disabled many sailors in the British Royal Navy and during the United States (US) Civil War, a lack of appreciation that vitamin A deficiency resulted in night blindness caused many physicians to ascribe this medical condition to malingering. With improved understanding of the links between nutrition and diseases these and other nutrition-related maladies have been largely ameliorated. Nonetheless, nutritional status remains an important issue for military populations. Deficiencies in critical minerals, vitamins, and other nutritional constituents have been reported among US SMs and these have been shown to affect SM health and performance. For example, iron is a critical micronutrient that is incorporated into proteins and enzymes and is important for physical, cognitive, and immune functioning. In longitudinal studies, markers of iron status were found to decline during deployment among Special Operations Soldiers, as well as during military training among male and female soldiers and this was associated with a decline in aerobic performance. The prevalence of iron deficiency and iron deficiency anemia was documented to be as high as 33% and 21%, respectively, among female personnel during Army Basic Training and in Advanced Individual Training. Another example is vitamin D which is essential for maintaining bone health. Vitamin D sufficiency, measured with 25-hydroxyvitamin D (25(OH)D), was found to decline during Basic Combat Training (BCT) among women. It is well established that stress fracture rates in BCT are higher among women compared to men, and lower levels of 25(OH)D have been associated with increased risk of stress fractures in a number of military investigations. This study will examine clinically-diagnosed vitamin and mineral deficiencies in the entire US military population. The specific aims are to: describe the overall incidence of clinically-diagnosed vitamin and mineral deficiencies in all military services, describe temporal trends in clinically-diagnosed nutritional deficiencies in all military services, and examine associations between the incidence of nutritional deficiencies and demographic characteristics that include sex, age, race and military service.

Who can participate?
All active-duty US military service members (Army, Navy, Air Force, Marines) serving in the inclusive years 1997-2015

What does the study involve?
Compilation and examination of clinically-diagnosed vitamin and mineral deficiencies obtained from the Defense Medical Epidemiology Database (DMED). Vitamin and mineral deficiencies will be identified from specific International Classification of Diseases, Ninth Revision (ICD-9) codes.

What are the possible benefits and risks of participating?
This is an examination of existing de-identified medical data. Thus, the study poses no physical risks to the participants. Benefits include identification of the incidence and longitudinal trends in vitamin and mineral deficiencies. Subpopulations (by sex, age, race and military service) that might be at higher risk will also be identified for each vitamin and mineral deficiency.

Where is the study run from?
The US Army Research Institute of Environmental Medicine (USA)

When is the study starting and how long is it expected to run for?
February 2019 to June 2020

Who is funding the study?
The US Army Research Institute of Environmental Medicine (USA)

Who is the main contact?
Dr Joseph Knapik
joseph.j.knapik.ctr@mail.mil

Contact information

Type(s)
Scientific

Contact name
Dr Joseph Knapik

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinically-diagnosed vitamin and mineral deficiencies in the entire population of the United States military, 1997-2015

Study objectives
Hypothesis 1: The incidence of nutritional deficiencies in SMs will increase during the period examined.
Hypothesis 2: The incidence of nutritional deficiencies in SMs will differ by the demographic characteristics of the military population (e.g., sex, age, race, and military service).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Office of Research Quality and Compliance at the US Army Research Institute of Environmental Medicine (USARIEM) judged that since this study involved a publicly available database and had no personal identifiers the study did not constitute human subjects research and was exempt.
United States Army Research Institute of Environmental Medicine (USARIEM) Office of Research Quality and Compliance (10 General Greene Ave, Natick MA 01760; Tel +1 (0)508 233 5319; Email: usarmy.natick.medcom-usariem.list.usariem-rqc@mail.mil)

Study design
Retrospective cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Clinically-diagnosed vitamin and mineral deficiencies

Interventions
Data will be extracted from a pre-existing database, the Defense Medical Epidemiological Database (DMED) to obtain information on the incidence of vitamin and mineral deficiencies, examine associations with demographic factors (age, sex, race, military service), and examine trends over time. The DMED does not contain any personal identifiers. Standard statistical measures will be employed to analyze the data (descriptive statistics, chi-square, linear regression).

Intervention Type
Other

Primary outcome(s)
Vitamin and mineral deficiencies and disorders extracted from the Defense Medical Epidemiology Database for the years 1997 to 2015

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
13/06/2020

Eligibility

Key inclusion criteria
All active-duty US military service members in the US Army, Navy, Air Force and Marines serving between 1997 and 2015

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1382266

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
04/04/2019

Date of final enrolment
30/08/2019

Locations

Countries of recruitment
United States of America

Study participating centre
US Army Research Institute of Environmental Medicine
10 General Greene Ave

Natick, MA
United States of America
01760

Sponsor information

Organisation
US Army Research Institute of Environmental Medicine

ROR
https://ror.org/00rg6zq05

Funder(s)

Funder type
Government

Funder Name
U.S. Army Research Institute of Environmental Medicine

Alternative Name(s)
US Army Research Institute of Environmental Medicine, United States Army Research Institute of Environmental Medicine, USARIEM

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Joseph Knapik (joseph.j.knapik.ctr@mail.mil).
Type of data:
1. Number of cases for specific ICD-9 codes indicative of clinically diagnosed vitamin and mineral deficiencies and disorders.
2. Population data for each year of the survey.

When data will become available and for how long:
Data should be available by 18/12/2019 for a two year period.
Access criteria data will be shared including with whom, for what types of analyses, and by what mechanism: Data will be shared with any clinical medical care provider or researcher on reasonable request with justification. Each request will be judged individually. Data sharing must be approved by the US Army Research Institute of Environmental Medicine Commander or higher military authority. Data will be sent by postal mail.
Was consent from participants was obtained:
Consent was not obtained because the study was judged by an IRB to be non-human and exempt. This is because data was de-identified and in a publically accessible database.
Data anonymisation:
Data is de-identified.
Ethical or legal restrictions, any other comments.
Any publication, presentation, or any form of publicly available access must be approved by the US Army Research Institute of Environmental Medicine Commander or higher military authority.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/06/2021	26/10/2022	Yes	No
Results article		01/08/2021	26/10/2022	Yes	No