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A retrospective study of demographic and lifestyle factors associated with caffeine and dietary supplement use

Submission date
11/10/2017

Recruitment status
No longer recruiting

Registration date
20/10/2017

Overall study status
Completed

Last Edited
21/11/2023

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
The relationships between consumption of caffeine or dietary supplements (DS) and health outcomes are controversial. Some studies have associated caffeine intake with negative outcomes such as caffeine dependence and cardiovascular (heart) disease. Other studies have linked caffeine intake with favorable outcomes, such as a reduced risk for Parkinson's disease and beneficial effects on cognitive performance and mood state. Similarly, there is evidence to suggest that particular DS may improve aspects of health and well-being, such as sleep, exercise performance, and bone density. However, consumption of certain DS – particularly those sold for weight loss – has been associated with adverse outcomes, including renal (kidney) failure, myocardial infarction (heart attack) and stroke in military and civilian populations. Potential associations between caffeine or DS usage and health and performance outcomes have public health relevance for military as well as civilian populations. Current data on the characteristics, usage patterns and adverse effects of caffeine and DS on the general US population are not available. The aim of this study is to investigate relationships between caffeine and DS intake and various demographic and lifestyle variables in a representative sample of the US population using a nationally-representative, publicly-available database – the National Health and Nutrition Examination Survey (NHANES). A survey of Army-wide caffeine and DS use is being conducted by the US Army Research Institute of Environmental Medicine. It is essential to have civilian data for comparison and interpretation of Army data.

Who can participate?
Data is extracted from a pre-existing public database – a nationally representative survey of the US population, the National Health and Nutrition Examination Survey (NHANES)

What does the study involve?
Information on the relationship between caffeine and DS intake and various demographic and lifestyle data and adverse outcomes is extracted from the NHANES. The results of this study are compared to previously published survey-based research and to survey data published in the future. The populations studied are selected so that the results can be compared to military populations.

What are the possible benefits and risks of participating?
This study will provide data on the extent and patterns of use of caffeine and DS and possible adverse effects in the civilian population, providing information relevant to the Army and other DoD services including possible risks and benefits of DS or caffeine intake. This information will also provide reference population data for interpreting findings on caffeine and DS use by military personnel.

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

When is the study starting and how long is it expected to run for?
October 2010 to December 2016

Who is funding the study?
1. US Army Medical Research and Materiel Command (USA)
2. Department of Defense Center Alliance for Nutrition and Dietary Supplement Research (USA)

Who is the main contact?
Dr Harris Lieberman

Contact information

Type(s)
Public

Contact name
Dr Harris Lieberman

Contact details
10 General Greene Avenue, Building 42
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United States of America
01760

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R11-01

Study information

Scientific Title
A retrospective study of demographic and lifestyle factors associated with caffeine and dietary supplement use

Study objectives
Current data on the characteristics, usage patterns and adverse effects of caffeine and dietary supplements (DS) on the general US population are not available. This study will provide data on the extent and patterns of use of caffeine and DS and possible adverse effects in the civilian population, providing information relevant to the Army and other DoD services including possible risks and benefits of DS or caffeine intake. This information also will provide reference population data for interpreting findings on caffeine and DS use by military personnel.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The US Army Research Institute of Environmental Medicine (USARIEM) Scientific Review Board approved the research plan on 13/10/2010; the USARIEM Human Use Review Committee determined obtaining unidentifiable information did not constitute human subjects research and therefore did not require full human use review on 13/10/2010; final approval to implement the research protocol was granted by the USARIEM Commander on 13/10/2010.

Study design
Epidemiological retrospective investigation

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Caffeine and dietary supplement intake and various demographic and lifestyle data and adverse outcomes

Interventions
Data will be extracted from a preexisting public database – a nationally representative survey of the US population, the National Health and Nutrition Examination Survey (NHANES) – to obtain information on the relationship between caffeine and DS intake and various demographic and lifestyle data and adverse outcomes. All data to be used have previously been collected. The database is accessible to the public through the Centers for Disease Control website on the World Wide Web (National Health and Nutrition Examination Survey; http://cdc.gov/NCHS

/nhanes.htm) and does not contain any personal identifiers. Standard statistical methods for analysis of weighted population NHANES datasets will be employed, including multiple regression modeling.

Intervention Type
Other

Primary outcome measure
The extent and patterns of use of caffeine and DS and possible adverse effects in the civilian population, extracted from the National Health and Nutrition Examination Survey

Secondary outcome measures
Reference population data for interpreting findings on caffeine and DS use by military personnel, extracted from the National Health and Nutrition Examination Survey

Overall study start date
01/10/2010

Completion date
31/12/2016

Eligibility

Key inclusion criteria
All data to be used have previously been collected and is part of an existing national public database (NHANES) accessible to the public through the Centers for Disease Control website on the World Wide Web (National Health and Nutrition Examination Survey; http://cdc.gov/NCHS /nhanes.htm). This data does not contain any personal identifiers.

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
This is an epidemiological retrospective investigation. Data will be extracted from a pre-existing public database – a nationally representative survey of the US population.

Key exclusion criteria
This is an epidemiological retrospective investigation. Data will be extracted from a preexisting public database – a nationally representative survey of the US population.

Date of first enrolment
13/10/2010

Date of final enrolment

31/12/2016

Locations

Countries of recruitment
United States of America

Study participating centre
US Army Research Institute of Environmental Medicine
Natick
United States of America
01760

Sponsor information

Organisation
US Army Research Institute of Environmental Medicine

Sponsor details
10 General Greene Avenue, building 42
Natick, MA
United States of America
01760

Sponsor type
Government

ROR
https://ror.org/00rg6zq05

Funder(s)

Funder type
Government

Funder Name
Medical Research and Materiel Command

Alternative Name(s)
U.S. Army Medical Research and Materiel Command, US Army Medical Research and Materiel Command, MRMC, USAMRMC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
Department of Defense Center Alliance for Nutrition and Dietary Supplement Research

Results and Publications

Publication and dissemination plan
The results of this study should be published in a high-visibility peer-reviewed nutrition journal by mid-2018.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
De-identified data are available at the participant level for all study participants. These data can be found at: http://cdc.gov/NCHS/nhanes.htm.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	daily pattern of caffeine intake and demographics	01/01/2019	15/01/2019	Yes	No
Results article	Shift workers	12/03/2020	21/11/2023	Yes	No