

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

<b>Submission date</b> 11/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/11/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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  
Natick, MA  
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?
<a href="#">Results article</a>	daily pattern of caffeine intake and demographics	01/01/2019	15/01/2019	Yes	No
<a href="#">Results article</a>	Shift workers	12/03/2020	21/11/2023	Yes	No