

# Protein intake trends and conformance with the Dietary Reference Intakes in the United States

<b>Submission date</b> 26/12/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/06/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Protein intake patterns provide information to inform both policy guidelines and nutrition counseling for various groups in the US population. Dietary protein has gained considerable popularity over the past two decades. Protein has been shown to promote weight loss and maintenance while preserving muscle mass. Furthermore, increased protein intake is associated with lower body weight, BMI and waist circumference, and higher HDL-cholesterol levels. Whether widespread awareness of the advantages of dietary protein and increased availability of protein-containing food products have influenced dietary protein intake trends in the US population is unknown. This study looks at protein intake trends over the past 14 years (2001-2014) and assesses recent (2011-2014) conformance with recommended protein intake according to age, sex, and race and ethnicity in the US population.

### Who can participate?

Individuals aged 2+ years, excluding pregnant and lactating women and fasted individuals, are included in the analysis

### What does the study involve?

Previously collected data are extracted from the NHANES public database. NHANES is a large ongoing dietary survey of a nationally representative sample of the non-institutionalized US population. Usual protein intakes and trends during 2-year cycles of NHANES 2001–2014 are calculated. Sex, race and ethnicity differences are determined for protein intake and percentage of the population below the recommended protein intake.

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

This study will provide data related to protein intake trends over the past 14 years (2001-2014) and recent (2011-2014) conformance with recommended protein intake in the US population according to age, sex, and race/ethnicity, which may allow the identification of groups at risk of low protein intake. There are no risks associated with this study.

### 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?

January 2001 to December 2014

Who is funding the study?

1. 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 Stefan Pasiakos

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Stefan Pasiakos

**Contact details**

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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**

Protein intake trends and conformance with the Dietary Reference Intakes in the United States: analysis of the National Health and Nutrition Examination Survey, 2001–2014

**Study objectives**

Systematic analysis of dietary protein intake may identify demographic groups within the American population not meeting the Dietary Reference Intakes (DRIs). The objective of this study was to analyze protein intake trends (2001-2014) and evaluate recent conformance to the DRIs (2011-2014) according to age, sex, and race and ethnicity in the US population.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

All participants or proxies provided written informed consent and the Research Ethics Review Board at the National Center for Health Statistics approved the survey protocol.

On 13/10/2010, the USARIEM Human Use Review Committee determined obtaining unidentifiable information does not constitute human subjects research and, therefore, does not require full human use review for this protocol. Additional information regarding the National Center for Health Statistics Ethics Review Board Approval for NHANES can be found here: <https://www.cdc.gov/nchs/nhanes/irba98.htm>

**Study design**

Observational epidemiological study

**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**

Protein intake

**Interventions**

Data were extracted from a preexisting public database – a nationally representative survey of the US population, NHANES. NHANES is a large ongoing dietary survey of a nationally representative sample of the non-institutionalized US population. The data are collected and released by the National Center for Health Statistics of the Centers for Disease Control and Prevention (National Health and Nutrition Examination Survey; <http://cdc.gov/NCHS/nhanes.htm>) every 2 years. All data used have previously been collected. The database is accessible to the public (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 were employed, including multiple regression modeling.

Usual protein intakes and trends during 2-year cycles of NHANES 2001–2014 (n=57,980; 2+ y) were calculated as absolute (g/d), relative (g/kg ideal body weight/d) intakes, and as a percentage of total energy. Sex, race and ethnicity (Asian, Hispanic, non-Hispanic Black, and non-Hispanic White) differences were determined for protein intake and percent of the population below the Estimated Average Requirement, Recommended Dietary Allowance, and above and below the Acceptable Macronutrient Distribution Range.

**Intervention Type**

Other

**Primary outcome measure**

Protein intake trends over the past 14 years (2001-2014) in the US civilian population, extracted from the National Health and Nutrition Examination Survey

**Secondary outcome measures**

Recent (2011-2014) conformance with protein-specific DRIs according to age, sex, and race and ethnicity in the US civilian population, extracted from the National Health and Nutrition Examination Survey

**Overall study start date**

01/01/2001

**Completion date**

31/12/2014

## Eligibility

**Key inclusion criteria**

All data to be used have previously been collected and are 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.

Individuals aged 2+ years, excluding pregnant and lactating women and fasted individuals, will be included in the analysis.

**Participant type(s)**

Healthy volunteer

**Age group**

All

**Sex**

Both

**Target number of participants**

Females and males (n = 57,980, 2+ y) from NHANES 2001-2014 will be included in the analysis

**Key exclusion criteria**

1. Less than 2 years old
2. Pregnant or lactating
3. Fasted

**Date of first enrolment**

01/01/2001

**Date of final enrolment**

31/12/2014

# Locations

## Countries of recruitment

United States of America

## Study participating centre

US Army Research Institute of Environmental Medicine

United States of America

01760

# Sponsor information

## Organisation

US Army Research Institute of Environmental Medicine

## Sponsor details

10 General Greene Avenue, Building 42

Natick

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 in a publically available repository (National Health and Nutrition Examination Survey; <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>	results	01/08/2018		Yes	No