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# Protein intake at meal and snack occasions

**Submission date**
11/03/2020

**Recruitment status**
No longer recruiting

**Registration date**
08/04/2020

**Overall study status**
Completed

**Last Edited**
28/10/2022

**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
Greater protein intakes are associated with lower body weight, body mass index, waist circumference and increased HDL-cholesterol concentrations. However, the relationship between protein intake during specific eating occasions and cardio metabolic health is not well described. This study measured protein intake at meals (breakfast, lunch, dinner) and combined snacking occasions and evaluated associations between protein intake at meals or snacking occasions and markers of cardio metabolic health in US adults.
The purpose of this study was to characterize dietary protein intake at meal (breakfast, lunch, or dinner) and combined snacking occasions, evaluate the associations between protein intake at specific eating occasions and markers of cardio metabolic health, and estimate protein intakes at specific eating occasions that benefit cardio metabolic health in U.S. adults.

Who can participate?
Data will be provided by the National Health and Nutrition Examination Survey (NHANES) database.

What does the study involve?
Data were extracted from a pre-existing 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.

What are the possible benefits and risks of participating?
None

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

When is the study starting and how long is it expected to run for?
January 2013 to December 2014

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

Who is the main contact?
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# Contact information

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Scientific

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number
R11-01

# Study information

### Scientific Title
Relationship between protein intake at specific meal and snacking occasions and cardiometabolic health outcomes in US adults

### Study objectives
Is the amount of dietary protein consumed at a specific eating occasion associated with markers of cardiometabolic health and the optimal protein quantity needed during those eating occasions to improve health?
The purpose of this study was to characterize dietary protein intake at meal (breakfast, lunch, or dinner) and combined snacking occasions, evaluate the associations between protein intake at specific eating occasions and markers of cardiometabolic health, and estimate protein intakes at specific eating occasions that benefit cardiometabolic health in U.S. adults.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
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
Cross-sectional epidemiological

### Primary study design
Observational

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Protein intake at meal and snack occasions

### 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.

Deciles of individual usual intake (IUI) for protein at meals and combined snacking occasions were calculated using NHANES 2013-2016 data (n=10,112; ≥ 19 y). Regression analysis was used to determine decile and linear trends for cardiometabolic risk factors by IUI for protein at specific meals (breakfast, lunch, or dinner) and combined snacking occasions. Both models 1 and 2 included age, age*2, sex, race or ethnicity (Hispanic, white, black, Asian, other), physical activity level, poverty income ratio, and protein IUI at other eating occasions throughout the day as model covariates. Model 1 also included total energy IUI at the eating occasion being analyzed as an additional covariate. Model 2 also included carbohydrate and fat IUI at the eating occasion being analyzed and BMI (non-weight-related variables) as additional covariates. Cardiometabolic variables were regressed by decile of IUI protein intake greater than or equal to a given decile to help determine amounts of protein associated with changes in cardiometabolic factors. The regressions were done one protein intake decile at a time. For example, decile 1 is compared to all others, then deciles 1 and 2 with all others, and so on. Independent t-tests were used to evaluate differences between decile groups. Data are interpreted with Bonferroni-corrected $P < 0.0042$ (0.05/12 variables) considered significant.

### Intervention Type
Other

### Primary outcome(s)
Data extracted from the National Health and Nutrition Examination Survey (2013-2016):
1. Protein intake at specific eating occasions
2. Markers of cardiometabolic health:
2.1 Body mass index kg/m²
2.2 Waist circumference (cm)
2.3 Systolic and diastolic blood pressure (mmHg)
2.4 Fasting triglycerides
2.5 Total cholesterol
2.6 LDL-cholesterol
2.7 HDL-cholesterol
2.8 Glucose and insulin concentrations
2.9 Homeostatic model assessment of insulin resistance (HOMA-IR)
2.10 Cardiovascular disease (CVD) risk score

### Key secondary outcome(s))
None

### Completion date
08/11/2019

## Eligibility

### Key inclusion criteria

All data 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).

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
10112

### Key exclusion criteria
1. Less than 20 years old
2. Pregnant or lactating
3. Fasted

### Date of first enrolment
01/01/2013

### 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**
10 General Greene Avenue
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## Sponsor information

**Organisation**
US Army Research Institute of Environmental Medicine

**ROR**
https://ror.org/00rg6zq05

# Funder(s)

**Funder type**
Government

**Funder Name**
United States Army Medical Research and Development Command

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

# Results and Publications

**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 publicly available repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 23/01/2021 | 28/10/2022 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |