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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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
None

Overall study start date
08/11/2018

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

Age group
Adult

Sex
Both

Target number of participants
10,112

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
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Sponsor information

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Sponsor type
Government

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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

Publication and dissemination plan
The results of this study will be published in a peer-reviewed nutrition journal.

Intention to publish date
01/04/2020

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