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

Submission date
26/12/2017

Recruitment status
No longer recruiting

Registration date
10/01/2018

Overall study status
Completed

Last Edited
25/06/2018

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
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
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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Observational epidemiological study

Study type(s)
Other

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
All

Sex
All

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

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

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?
Results article	results	01/08/2018		Yes	No