

A retrospective study of socio-demographic and lifestyle factors associated with macronutrient intake

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
13/08/2019	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
19/08/2019	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
10/10/2022	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

The optimal macronutrient (e.g. fat, protein, carbohydrate) composition of the diet is a controversial topic and many adults attempt to regulate their intake of specific macronutrients. Popular dietary trends with radical shifts in macronutrient intake emerge from time to time for various perceived health-specific reasons. However, they often lack adequate scientific evidence for their efficacy and do not appear to be successful on a long-term basis due to a variety of factors, including compliance. Additionally, consciously selecting a diet consisting of a specific macronutrient mix is a complex task, since diets usually consist of a variety of foods in which nutrients are present in complex matrices. The aim of this study is to evaluate the relative proportions of macronutrient intake in US adults and how dietary composition is affected by various lifestyle and socio-demographic factors using the National Health Examination Survey (NHANES) 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 macronutrient intake and various socio-demographic and lifestyle factors is extracted from the NHANES. The results of this study are compared to previously published research and will provide information on which to base future comparisons. When appropriate, data from the general population will be compared to data from military populations.

What are the possible benefits and risks of participating?

This study will provide data related to macronutrient intake and help to better understand the biological constraints on dietary constituents. This information may improve formulation of practical guidance regarding optimal macronutrient intake in both civilian and military populations. 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?

December 2016 to December 2018

Who is funding the study?

Medical Research and Development Command (USA)

Who is the main contact?

Dr Harris Lieberman

harris.r.lieberman.civ@mail.mil

Contact information

Type(s)

Public

Contact name

Dr Harris Lieberman

Contact details

10 General Greene Ave.

Building 42

Natick

United States of America

01760

+1 (0)5082334856

harris.r.lieberman.civ@mail.mil

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

17-07-R

Study information

Scientific Title

Use of NHANES data to assess nutrition issues related to the health of DoD personnel

Study objectives

Since macronutrients are acquired from a variety of foods and are typically present in complex food matrices, consciously selecting a diet consisting of a specific macronutrient mix is a complex task. However, with adequate availability of varied foods, the macronutrient

composition of diets may be unconsciously but effectively regulated. The objective of this study is to evaluate relative proportions of macronutrients consumed by US adults and ascertain the impact of various lifestyle and socio-demographic factors on dietary habits using the National Health Examination Survey (NHANES). When applicable, this information will provide reference population data for interpreting findings on the dietary intake of military personnel.

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. Additional information regarding the National Center for Health Statistics Ethics Review Board Approval for NHANES can be found at: <https://www.cdc.gov/nchs/nhanes/irba98.htm>

The US Army Research Institute of Environmental Medicine (USARIEM) Scientific Review Board approved the research plan on 29/12/2016; 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 29/12/2016; final approval to implement the research protocol was granted by the USARIEM Commander on 29/12/2016.

USARIEM Office of Research Quality and Compliance (US Army Research Institute of Environmental Medicine, 10 General Greene Ave., Building 42, Natick, MA 0760-5007, USA; Tel: +1 (0)508 233 5319; Email: usarmy.natick.medcom-usariem.list.usariem-rqc@mail.mil), ref: USARIEM 17-07-R

Study design

Epidemiological retrospective investigation using an existing publicly-available database of anonymized survey data

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Macronutrient intake and various demographic and lifestyle data

Interventions

There will be no controlled experimental intervention in this research. Instead, 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 macronutrient intake and various socio-demographic and lifestyle factors. All data to be used in this research will be obtained from previously-established databases. The database is accessible to the public through the Centers for Disease Control website on the World Wide Web (NHANES; <http://cdc.gov/NCHS/nhanes.htm>) and does not contain any personal identifiers. Standard statistical methods for the analysis of weighted population NHANES datasets will be employed, including multiple regression modeling and other multivariate techniques. United States data will be compared to publically-available data from other countries.

Intervention Type

Other

Primary outcome(s)

Protein, carbohydrate and fat intake ranges by the civilian population subgroups, extracted from the National Health and Nutrition Examination Survey for years 2009 to 2014

Key secondary outcome(s)

Reference population data for interpreting findings on protein, carbohydrate and fat intake ranges by military personnel, extracted from the National Health and Nutrition Examination Survey for years 2009 to 2014

Completion date

31/12/2018

Eligibility

Key inclusion criteria

All data to be used reside in an existing national database (NHANES) accessible to the public through the Centers for Disease Control website on the World Wide Web (NHANES; <http://cdc.gov/NCHS/nhanes.htm>). This data does not contain any personal identifiers.

Participant type(s)

All

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

This is an epidemiological retrospective investigation in which select survey data may be excluded based on the sociodemographic and lifestyle strata of interest at different stages of the investigation. Data will be extracted from a pre-existing public database – a nationally representative survey of the US population.

Date of first enrolment

29/12/2016

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

United States of America

Study participating centre

US Army Research Institute of Environmental Medicine
10 General Greene Ave.
Building 42
Natick
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 Development Command

Results and Publications

Individual participant data (IPD) sharing plan

All data used for this study are publicly available at the NHANES website: <https://www.cdc.gov/nchs/nhanes/Default.aspx>

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	17/04/2020	Yes	No
Protocol file	version 2016	02/11/2016	10/10/2022	No	No

