

Free-range reindeer consumption improves protein metabolism in humans

Submission date 24/04/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/05/2020	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Alaska's Indigenous people are growing in number, especially the elderly sector. These groups experience greater functional disabilities throughout life than other populations. In Alaska, the reasons for the disability gap are complicated. Limited economic competition, higher profit margins, expensive medical frameworks, and unique environmental, social, and demographic elements all contribute to the difficulties. Such problems create the most extreme healthcare costs in the United States, 2.5 times the national average. Instead of addressing these challenges after individuals reach the older stages of life, planning for healthy aging over a lifetime is needed to offset the risks of muscle loss, disability, and rising healthcare costs. Taking a critical look at traditional food intake is becoming more important as an attempt to hold off increasing health risks in Indigenous populations.

It is not known how free-range wild game of the Alaska Native traditional foods might affect sarcopenia, which is the age-related loss of lean tissue mass, strength, and function. Muscle, made up of proteins, is in a constant state of turnover; building up and breaking down. Whole-body protein synthesis (PS) and protein breakdown (PB) are always occurring. A healthy, steady state of lean tissue mass is a result of adequate diet and/or physical activity. Both have declined dramatically and quickly in the Alaska Indigenous population, while migration from traditional lifestyles and food consumption has also taken place. For PS to occur as a result of nutrient intake, essential amino acids (EAA's) must be present in sufficient amounts. The wild game of the Alaska Native traditional diet provides proteins with EAA's that are necessary for PS to be greater than PB, and create a higher net balance of protein (NB).

Hypothesis: NB will be higher in FR compared to CB; due to existing differences in the total amount of protein in FR.

Study Aim #1: to compare the feeding-induced response of equivalent amounts of free-range reindeer (FR) and commercial beef (CB) on protein metabolism using stable isotope methodology.

Who can participate?

Males and females of any ethnic background, between the ages of 20 and 70 years with a BMI of

20-28 were considered. Volunteers with a pacemaker, diabetes, or chronic inflammatory condition will not be accepted. Volunteers taking any type of medication or supplement could affect glucose metabolism cannot participate. Those with active cancer, taking corticosteroids by mouth, injection, or trans-dermally are not eligible. If the study physician recognizes any other disease that would place them at increased risk, those volunteers would not be accepted.

What does the study involve?

What are the possible benefits and risks of participating?

Study participants acquire knowledge about their health, including body composition, lipid profiles, and protein responses to reindeer and ground beef.

Where is the study run from?

Clinical Research and Imaging Facility, Alaska (USA)

When is the study starting and how long is it expected to run for?

May 2017 to June 2019

Who is funding the study?

The National Institute of General Medical Sciences of the National Institutes of Health (NIH) under award numbers UL1GM118991, TL4GM118992, or RL5GM118990 and an Institutional Development Award under grant number P20GM130443

Who is the main contact?

Dr Robert Coker, rcoker@alaska.edu

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

IRBnet 749396

Study information

Scientific Title

Ingestion of free-range reindeer promotes higher net protein balance compared to commercial beef

Acronym

FRCB

Study objectives

Ingestion of 2 ounces of free-range reindeer will promote greater whole-body protein net balance than 2 ounces of commercial beef.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 05/04/2017, University of Alaska Fairbanks Institutional Review Board (PO Box 757270, Fairbanks, AK 99775-7270;), ref: #749396

Study design

Interventional randomized cross over trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

School

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Healthy Individuals

Interventions

The acute response to ingestion of 2 oz of free-range reindeer meat compared to 2 oz of commercial beef was evaluated using a randomized, crossover experimental design and stable isotope methodology in healthy male and female participants.

Participants ingested reindeer or commercial beef in conjunction with isotopic tracer infusions of phenylalanine and tyrosine. Whole-body protein synthesis, protein breakdown and net protein balance were determined using the isotopic enrichments of phenylalanine and tyrosine as measured by gas chromatography-mass spectrometry. Amino acid concentrations were measured by liquid chromatography-electrospray ionization-mass spectrometry.

Intervention Type

Other

Primary outcome measure

Whole-body protein synthesis, protein breakdown and protein balance measured using the isotopic enrichments of phenylalanine and tyrosine as measured by gas chromatography-mass spectrometry over a seven-hour period

Secondary outcome measures

Plasma essential amino acids concentration measured using by liquid chromatography-electrospray ionization-mass spectrometry over a seven-hour period

Overall study start date

04/05/2017

Completion date

04/06/2019

Eligibility

Key inclusion criteria

1. Aged 20 - 70 years
2. BMI range of 20-38 kg/m²

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

Maximum number of 15; target of at least 6

Total final enrolment

8

Key exclusion criteria

1. Have a pacemaker
2. Previously diagnosed diabetes
3. Chronic inflammatory condition
4. Taking any type of medication or supplement that may affect glucose metabolism
5. Active cancer or malignancy
6. Taking corticosteroids by mouth, injection or trans-dermally
7. Females who test positively for pregnancy
8. Any other disease that would place them at increased risk of harm if they were to participate, at the discretion of the study physician

Date of first enrolment

04/05/2017

Date of final enrolment

11/05/2018

Locations

Countries of recruitment

United States of America

Study participating centre**Clinical Research and Imaging Facility**

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2140 Koyukuk Drive
Fairbanks
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Sponsor information

Organisation

National Institutes of Health

Sponsor details

9000 Rockville Pike
Bethesda
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20892
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info@nigms.nih.gov

Sponsor type

University/education

Website

<http://www.nih.gov/>

ROR

<https://ror.org/01cwqze88>

Funder(s)

Funder type

Government

Funder Name

National Institutes of Health

Alternative Name(s)

Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

06/01/2020

Individual participant data (IPD) sharing plan

The datasets during and/or analyzed during the current study are/will be available upon request for a period of at least 5 years. Please contact Robert Coker at rcoker@alaska.edu and /or 907 474-6701 for electronic data and data analysis and/or information regarding participant consent and institutional review board documentation.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	27/04/2020	Yes	No

