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Impact of honey on inflammation and metabolic health

Submission date	Recruitment status	[ ] Prospectively registered
20/01/2026	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/01/2026	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/01/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Dr Weiwen Chai

ORCID ID
https://orcid.org/0000-0002-0769-555X

Contact details
104D Leverton Hall; Department of Nutrition and Health Sciences; University of Nebraska-Lincoln; 1700 N 35th Street
Lincoln
United States of America
68583
+1 (402) 472-3716
wchai2@unl.edu

Additional identifiers

Study information

Scientific Title
Impact of honey on inflammation and metabolic health

Study objectives

1. To determine the feasibility and logistics of conducting a honey supplementation trial.
2. To assess the potential effects of daily consumption of 21 g (1 tablespoon) of Manuka honey for 4 weeks on the inflammatory and metabolic biomarkers and gut microbiota compared to a sugar-matched control (a sugar mixture that matches the primary contents of sugar of 1 dosage of honey) in overweight and obese adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/05/2023, University of Nebraska-Lincoln Institutional Review Board (2200 Vine Street, 278 Prem S. Paul Research Center, Lincoln, 68583, United States of America; +1 (402) 472-6965; irb@unl.edu), ref: 20230522443FB

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Metabolic health in overweight and obese adults

Interventions
Potential participants are screened for eligibility conducted via Qualtrics (online survey) using a pre-screen questionnaire regarding inclusion and exclusion criteria. The study is organized as a randomized, controlled, parallel-arm trial conducted at Nebraska Food for Health Center (NFHC) Research Clinic. The trial lasts approximately 5 weeks with the involvement of two parallel-arm groups (honey vs control) among overweight and obese (BMI>=27 kg/m2) subjects aged 40-75 years. After initial screen process subjects are randomly assigned to two groups as follows:
1. Honey group: Ingestion of 21 g (1 tablespoon) of manuka honey daily for 4 weeks.
2. Control group: Ingestion of a mixture of sugar (which has the equivalent amount of sugar content in 21 g of Manuka honey [0.2 g sucrose, 9 g fructose, 7 g glucose]) daily for 4 weeks.

Both honey and sugar supplements are purchased from commercial providers. Manuka Honey is purchased directly from the Wedderspoon company. For sugar supplement, sucrose (table sugar) is purchased from a grocery store, glucose and fructose are purchased from respective

commercial providers. Thus, honey and sugar supplement used in the study are purchased from the same individual manufacturers for honey and individual sugars (sucrose, glucose and fructose) with the same batch numbers. The purchased honey and sugar are packed in individual containers (one dosage per container) in the food processing lab (food grade). Subjects are enrolled continuously and assigned sequentially to either the honey or control group using a pre-generated computer-based randomization sequence (block size = 10), ensuring approximate balance throughout enrollment.

Three visits are required from each subject. Subjects are consented prior to any study-related procedures. At visit 1, potential subjects are screened for eligibility and provided with a food questionnaire (FFQ), food screener (polyphenol screener), and physical activity screener, and supplies for stool collection (stool kit) before the next visit with instructions. Subjects are asked basic demographic information, anthropometrics, medical and medication history, and other study-relevant questions.
At visit 2 (baseline), each of the subjects provides collected stool samples and completes a food questionnaire (FFQ), food screener (polyphenol screener) and physical activity screener; they also have their blood drawn for Completed Metabolic Panel (CMP), lipid panel and hsCRP after an 8-hour fasting at this visit. Additional plasma samples are collected and stored in -80C freezer for biomarker measures (e.g. insulin, cytokines, leptin, metabolite, etc). Subjects are then provided with honey or sugar mixture (as determined by randomization). They consume their randomly assigned dietary dosage (honey or sugar) every day (one time per day of assigned dosage) for approximately 4 weeks as instructed. They are also instructed to maintain their usual diet and lifestyle upon study enrollment.

At the end of 4 weeks (visit 3) of treatment, subjects return to the lab to provide collected stool samples and completed food questionnaire (FFQ), food screener (polyphenol screener) and physical activity screener. Fasting blood samples (for CMP, lipids and hsCRP) and plasma samples (for biomarkers) are collected from each subject at visit 3. Weight, height and waist circumference are measured at visit 1; weight and waist circumference are also measured at visit 3. During the duration of study subjects are instructed to consume their routine diet but avoid honey (except for the honey provided for subjects in the honey group) and other supplements which may influence the study results. Subjects are asked to complete a daily log noting consumption of the honey/control. Subjects are asked about adverse effects and medication changes throughout the study.

Intervention Type
Supplement

Primary outcome(s)
1. Plasma fasting insulin levels measured using enzyme-linked immunosorbent assays (ELISA) (Crystal Chem, Elk Grove Village, IL) at baseline and 4 weeks (conclusion of the intervention)

2. Fasting glucose measured using analyzed by LabCorp as part of the completed Chemistry panel at baseline and 4 weeks (conclusion of the intervention)

3. Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) measured using HOMA-IR = glucose (mg/dL) x insulin (mU/L) / 405 at baseline and 4 weeks (conclusion of the intervention)

4. High-sensitive C-reactive protein (hs-CRP) measured using immunochemiluminometric assay (ICMA) (LabCorp, Lincoln, NE) at baseline and 4 weeks (conclusion of the intervention)

5. Interleukin 6 (IL-6) measured using enzyme-linked immunosorbent assays (ELISA) (BioLegend, San Diego, CA) at baseline and 4 weeks (conclusion of the intervention)

6. Triglyceride measured using analyzed by LabCorp as part of the Lipid Panel at baseline and 4 weeks (conclusion of the intervention)

7. HDL-cholesterol measured using analyzed by LabCorp as part of the Lipid Panel at baseline and 4 weeks (conclusion of the intervention)

8. LDL-cholesterol measured using analyzed by LabCorp as part of the Lipid Panel at baseline and 4 weeks (conclusion of the intervention)

9. Microbiota community features measured using 16S rRNA gene amplicon sequencing at baseline and 4 weeks (conclusion of the intervention)

10. Body weight measured using a flat surface scale with minimal clothing at baseline and 4 weeks (conclusion of the intervention)

11. Body mass index (BMI) measured using BMI = weight (kg) / height (m)2 at baseline and 4 weeks (conclusion of the intervention)

12. Waist circumference measured using a tape measure at baseline and 4 weeks (conclusion of the intervention)

Key secondary outcome(s)

Completion date
14/06/2024

Eligibility

Key inclusion criteria
1. Aged 40-75 years
2. Body mass index >= (equal or greater than) 27 kg/cm2
3. Participants who read and speak English

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
40 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Allergic or intolerant to honey
2. Frequent honey consumer (habitual honey consumption of more than 2 tbsp per week in the past 6 months)
3. Oral antibiotic use or antibody ingestion in the past 12 weeks
4. History of GI disease or GI surgery (with the exception of hiatal hernia, GERD/reflux, hemorrhoids, GB surgery, or mild GI symptoms)
5. History of type 1 or type 2 diabetes and/or currently taking any medications for either type 1 or type 2 diabetes
6. History of renal diseases
7. Presence of active cancer (basal and squamous cell skin cancer ok)
8. Received cancer treatment in the past 6 months
9. Consumption of supplemental fiber, probiotics and/or prebiotics in the past 4 weeks (yoghurt is ok)
10. Currently consuming a restrictive diet (keto, Palaeolithic, etc)
11. Plan to have a diet habit and/or exercise habit change during the period of study
12. Changed medication in the past 30 days
13. Female participants who are currently pregnant or planning to become pregnant in the 2 months following consent
14. Female participants who are currently breastfeeding
15. Unwillingness to consent to study and study assessments
16. Requires a LAR
17. Any condition per the PI's discretion that could potentially adversely affect the study outcomes or the participant

Date of first enrolment
14/07/2023

Date of final enrolment
10/05/2024

Locations

Countries of recruitment
United States of America

Sponsor information

Organisation
University of Nebraska–Lincoln

ROR
https://ror.org/043mer456

Funder(s)

Funder type

Funder Name
University of Nebraska-Lincoln

Alternative Name(s)
University of Nebraska, Lincoln, University of Nebraska, Nebraska, Universitas Nebraskensis, UNL, NU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available