ISRCTN13221188 https://doi.org/10.1186/ISRCTN13221188

How a low carb/ketogenic diet affects Parkinson's disease symptoms: a 36-week study

Submission date
27/02/2023

Recruitment status
No longer recruiting

Registration date
08/03/2023

Overall study status
Completed

Last Edited
16/12/2024

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
New evidence suggests that a diet low in carbohydrates but high in healthy fats, called a low carbohydrate/healthy fat/ketogenic diet (LCHF/KD), could help treat symptoms of neurodegenerative diseases like Parkinson's Disease (PD). Common symptoms of PD include problems with thinking, poor sleep quality, and feeling tired all the time. However, there isn't enough information about how changing your diet can help these symptoms.

This research study wants to find out if changing your diet can help people with PD. They will test three different diets over 8 weeks: a normal American diet, an American diet with MCT oil, and a low carbohydrate/healthy fat/ketogenic diet with MCT oil.

MCT stands for medium-chain triglycerides, which are a type of fat found in coconut oil, palm kernel oil, and dairy products. MCT oil is a supplement made by extracting and isolating these medium-chain triglycerides from these sources. It is a popular supplement among people following a low carbohydrate or ketogenic diet, as it is quickly absorbed and converted into ketones, which can provide energy to the body and brain.

The researchers will compare the effects of each diet on how well people can think, how healthy their body is, how well they sleep, and how tired they feel. This study will use a randomized crossover trial design, meaning that each person will try each of the three diets at different times, and the researchers will compare the results.

Who can participate?
Adult patients aged 18 - 35 years with PD.

What does the study involve?
The research will involve a comparison of 8 weeks of a standard American diet (SAD), 8 weeks of a Standard American Diet (SAD-MCT) plus daily MCT oil, and an 8-week ketogenic diet plus daily MCT oil (LCHF/KD-MCT)intervention with a pretest/posttest study design using common blood tests for metabolic biomarkers, and scales for cognition, sleep, and fatigue widely used in assessing symptoms in patients with PD. Baseline and post-intervention testing will investigate the effectiveness of each intervention by repeating the same biomarker blood tests, cognition,

sleep, and fatigue scales and comparing post-study results with the baseline results in adults 30-85 with PD Hoehn and Yahr Stages I-IV. The research will involve a 4-week washout period between dietary interventions.

The study protocol will also require daily blood glucose and ketone testing using a home Glucose /Ketone meter provided at no cost to participants for all interventions, (SAD, SAD + MCT OIl, and LCHF/KD) dietary interventions. The 8 week SAD will be the typical diet based on the 2020 USDA Dietary Guidelines for all Americans. Adherence to the LCHF/KD-MCT nutrition plan will be based on Dr. Eric Westman's (Duke University) Page 4 Food list, For all dietary interventions, data using daily food logs, cognition, sleep quality, and fatigue surveys, with baseline metabolic biomarkers (free of charge) of HgA1C, Triglycerides, HDL, Fasting Insulin, C-Reactive Protein, weight, and waist circumference will be collected.

What are the possible benefits and risks of participating?
Benefits to society include: Research on nutritional interventions has shown positive effects on persons with neurodegenerative diseases like Parkinson’s Disease (PD).
Minimal risk, but the possibility of psychological stress exists. The expected risks from participating in this study are minimal, which means they are equal to the risks the participants would encounter in everyday life. The risks involved in this study include minimal stress from daily finger pricks for glucose/ketone testing, which is customary for patients who need to test blood sugar/ketones daily due to diabetes. To reduce this risk of stress, the study team will supply a trained assistant and/or training videos to educate participants on the proper ways to test blood using the provided KetoMojo Blood Glucose/Ketone meter until they feel comfortable using the meter to test blood

each morning. In addition, participants will have access to training videos on the KetoMojo website, free of charge, that show them exactly how to use the meter to test blood glucose and ketones each morning. In addition, Dr. Tidman is available by email, Live Zoom meeting, or by phone to respond to any questions or concerns participants might have during the course of the study.

Where is the study run from?
Colorado Parkinson Foundation (USA)

When is the study starting and how long is it expected to run for?
January 2023 to December 2025

Who is funding the study?
Colorado Parkinson Foundation (USA)

Who is the main contact?
Dr Melanie Tidman, melanietidman@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Melanie Tidman

ORCID ID
https://orcid.org/0000-0002-6333-8514

Contact details
521 Vineyard Rd NE
Albuquerque
United States of America
87113
+1 5052593118
mtidman@liberty.edu

Additional identifiers

Protocol serial number
01-2023-2024

Study information

Scientific Title
Effects of three dietary approaches on biomarkers, cognition, sleep and fatigue in Parkinson’s disease: a 36-week crossover pilot study

Study objectives
This 8-week randomized crossover pilot study will investigate whether an LCHF/KD-MCT approach is a safe and feasible adjunctive treatment approach for improved health biomarkers, cognition, sleep quality, and fatigue with improved scores on commonly used surveys/scales as compared with the SAD and SAD + MCT Oil approaches, and whether an LCHF/KD can be a complementary treatment approach in PD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/02/2023, Liberty University IRB (Green Hall 2845, 1971 University Blvd., Lynchburg, VA 24515, USA; +1 434-582-2000; no email provided), ref: IRB-FY22-23-440

Primary study design
Interventional

Study design
Interventional randomized crossover trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Nutritional interventions for Parkinson's Disease

Interventions

The research will involve a comparison of:
Intervention 1: 8 weeks of consuming a Standard American Diet as defined by the USDA Food Pyramid
Intervention 2: 8 weeks of consuming a Standard American Diet (USDA Food Pyramid) + MCT Oil.
Intervention 3: 8 weeks of consuming a Low Carbohydrate Healthy Fat/Ketogenic Diet (70% Fats, 25% proteins, 5% carbohydrates)

for a total of 36 weeks. Three groups will each progress through each of the 3 interventions for periods of 8 weeks, with a 4-week washout period between each interventional strategy. Randomization will be done using a Simple Randomization method (Dice Throw method with dice containing numbers 1, 2 or 3)

Baseline and post-intervention testing will investigate the effectiveness of each intervention by repeating the same biomarker blood tests, cognition, sleep, and fatigue scales and comparing post-study results with the baseline results in adults 30-85 with PD Hoehn and Yahr Stages I-IV. The research will involve a 4-week washout period between dietary interventions.

The study protocol will also require daily blood glucose and ketone testing using a home Glucose /Ketone meter provided at no cost to participants for all interventions, (SAD, SAD + MCT OIl, and LCHF/KD) dietary interventions. The 8 week SAD will be the typical diet based on the 2020 USDA Dietary Guidelines for all Americans. Adherence to the LCHF/KD-MCT nutrition plan will be based on Dr. Eric Westman's (Duke University) Page 4 Food list, For all dietary interventions, data using daily food logs, cognition, sleep quality, and fatigue surveys, with baseline metabolic biomarkers (free of charge) of HgA1C, Triglycerides, HDL, Fasting Insulin, C-Reactive Protein, weight, and waist circumference will be collected.

Intervention Type
Mixed

Primary outcome(s)
Measured before and after each 8-week diet period:
1. Blood biomarkers measured using blood test:
1.1. Biomarkers HDL
1.2. HgA1C
1.3. Triglycerides
1.4. Fasting Insulin
1.5. hs-C-Reactive Protein
2. Biometrics
2.1. BMI (kg/m²)
2.2. Waist circumference (cm)
3. Parkinson's symptoms
3.1. Cognition using scores on the Parkinson’s Disease Cognitive Rating Scale
3.2. Sleep quality as measured by the Epworth Sleepiness Scale and the Parkinson’s Disease Sleep Scale
3.3. Fatigue scores measured by the Parkinson’s Disease Fatigue Scale
3.4. Scores on Part I of the United Parkinson’s Disease Rating Scale (UPDRS)
3.5.Scores on Part II of the United Parkisnon’s Disease Rating Scale (UPDRS)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Between the ages of 30-85 years
2. Live in the United States
3. Can speak, read and understand English
4. Diagnosis of PD (H-Y Stages I-IV)
5. BMI>18.5 kg/m²
6. Ability to understand and follow an LCHF/KD diet
7. Obtained permission to participate from their Primary Care Provider (PCP) or neurologist
8. Signed the informed consent and the HIPAA Release of Medical Information form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 Years

Upper age limit
85 Years

Sex
All

Key exclusion criteria
1. Does not meet inclusion criteria
2. Persons with PD H-Y Stage V
3. Persons with unstable/uncontrolled type 2 diabetes

Date of first enrolment
04/01/2023

Date of final enrolment
12/01/2023

Locations

Countries of recruitment
United States of America

Study participating centre
Colorado Parkinson Foundation
1155 Kelly Johnson Blvd, Suite 111
Colorado Springs
United States of America
80920

Sponsor information

Organisation
Colorado Parkinson Foundation

Funder(s)

Funder type
Research organisation

Funder Name
Colorado Parkinson Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and may be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date