

# Effects of an LCHF/ketogenic diet on symptoms, anxiety, depression, and QoL in Parkinson's disease

<b>Submission date</b> 06/03/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/08/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Current plain English summary as of 09/09/2020:

### Background and study aims

Since the initial identification of the Parkinson's Disease (PD) diagnosis, treatments have been isolated to pharmacological interventions which prove to often have more side effects than benefits. The side effects of PD medications often interfere with daily life functioning causing these patients to further isolate themselves with a subsequent decline in cognitive function and independence.

Due to increased healthcare costs for chronic conditions, research has begun to focus on non-pharmacologic treatments for neurodegenerative diseases (NDDs) to assess the potential improvements in daily functioning and to improve the quality of life for patients with NDDs. Little is known about the effects of a ketogenic diet on symptoms of PD, or depression and anxiety in PD. There are more studies on these diets and general health for general populations. This study aims to investigate the effects of a nutritional approach to the treatment for people with PD on symptoms of PD, metabolic health, and symptoms of depression and anxiety. The results of this study could add to the growing body of research on the use of nutritional approaches to improve symptoms of NDDs and in this case PD.

### Who can participate?

People aged 50 to 85 with mild to severe (Hoehn and Yahr stage 1 to 4) Parkinson's Disease and a BMI of over 18.5

### What does the study involve?

Eligible participants will be scheduled for a 2 hour, individual, face-to-face interview with the research team and will be given paperwork in order to obtain a blood test for metabolic markers in the blood before their first session. The participants will be expected to bring written blood work results to the pre-study interview. At the pre-study appointment participants will receive:

1. A presentation of the study and diet plans and will give their consent to participate if they wish to continue with the study
2. Education/training on the use of the dietary plan, and the use of a Keto Mojo weekly Blood

Glucose/Ketone meter

3. A survey on demographic, medical, and social history intake and measurement of body mass index (BMI) by taking height and weight

4. Questionnaires to assess symptoms of PD, anxiety, and depression and an interview consisting of 4 questions about quality of life which will be audio recorded for analysis

Next, all study participants will be provided with the information to voluntarily sign up for the use of the Myfitnesspal.com application for food tracking during the study. The option for completing written food logs instead of the use of the smartphone/web-based application will also be provided. Participants can enlist the assistance of their caregiver or family member to assist with food log access to the smartphone/web-based application. Private communication between participants and research team members will be conducted via phone or confidential, password-protected email at participant request.

Participants will be enrolled in the study for 12 weeks, and during this time participants will monitor their food intake using either a written food log or Myfitnesspal.com, follow the educational materials provided for the diet, and test their blood glucose/ketones daily using the keto mojo blood meter.

After 12 weeks, post-study interviews will be scheduled. As with the pre-study interviews, these will be conducted in a 2 hour, individual, Zoom online visit. Participants will again be provided with post-study blood work requests prior to the appointments, which they should provide the written results for during the post-study interview. The questionnaires to assess symptoms of PD, anxiety, and depression, and the audio-recorded interview consisting of 4 questions about quality of life will be repeated at the post-study appointment.

What are the possible benefits and risks of participating?

Although blood work for health monitoring is a routine standard of care in adult medicine, it can cause brief pain and bruising. Two research-specific blood tests will be conducted as part of this study.

This study uses routine changes that participants might use in their daily lives such as nutritional /dietary choices. The survey tools and interviews will be conducted in person and pose minimal risk as they ask questions that are commonly used in assessing Parkinson's disease, depression and anxiety.

Since no names will be used for data collection, there is minimal risk of study participants' protected health information (PHI) being breached. There is minimal risk associated with use of a password-protected smartphone or web-based application. The sign-up for and utilization of the Myfitnesspal either smartphone or web-based application is totally voluntary and participants can opt-out of this participation by filling out written food logs instead.

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 2020 to September 2021

Who is funding the study?

Colorado Parkinson Foundation (USA)

Who is the main contact?

Dr Melanie Tidman

melanietidman@gmail.com

Previous plain English summary:

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Colorado Parkinson Foundation (UK)

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

January 2020 to September 2021

Who is funding the study?

Colorado Parkinson Foundation (UK)

Who is the main contact?

Dr Melanie Tidman

melanietidman@gmail.com

## Contact information

**Type(s)**

Public

**Contact name**

Dr Melanie Tidman

**Contact details**

521 Vineyard Rd NE

Albuquerque

United States of America

87113

+1 5052593118

melanietidman@gmail.com

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPFPD2020

## **Study information**

**Scientific Title**

Effects of an LCHF/ketogenic diet on symptoms, anxiety, depression, and QoL in Parkinson's disease: a prospective observational study

**Study objectives**

1. What are the effects of an LCHF/Ketogenic dietary intervention on improvement of scores on the MDS-UPDRS Scale (Parts 1-4), and reducing the overall severity of motor and non-motor symptoms in persons with PD?
2. What are the effects of an LCHF/Ketogenic dietary intervention on reducing the severity of symptoms of depression in persons with PD as measured by the CESD-R-20?
3. What are the effects of an LCHF/Ketogenic dietary intervention in reducing the overall severity of anxiety in persons with PD as measured by scores on the Parkinson's Anxiety Scale (PAS)?
4. What are the effects of an LCHF/Ketogenic dietary intervention on blood markers of health including HgA1C, Triglycerides, LDL, CRP, and HDL in persons with PD?
5. How have mental, physical, and social interactions affected Quality of Life (QoL) in PD patients before the dietary intervention?
6. How does QoL in persons with PD affect mental, physical, and social relationships after the LCHF/Ketogenic dietary interventions?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 31/07/2020, AT Still University IRB (AT Still University, 5850 E/ Still Circle, Mesa, Arizona 85206 USA; no telephone number provided; MesaIRB@atsu.edu), ref: 2020-058

**Study design**

Prospective observational study

**Primary study design**

Observational

**Secondary study design**

Epidemiological study

**Study setting(s)**

Community

**Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Parkinson's Disease, Neurodegenerative Diseases

## **Interventions**

Current interventions as of 09/09/2020:

This is prospective, pre-test/post-test, one-group study, with both quantitative and qualitative analysis. The study will investigate the effects of a nutritional approach to the treatment of symptoms of Parkinson's disease. The intervention that participants will receive is an LCHF /Ketogenic Diet

Participants will receive a presentation giving an overview of the study and diet plan. They will also be provided with education and training on the use of the dietary plan, and the use of the Keto Mojo daily Blood Glucose/Ketone meter. Study participants will be provided with the information to either sign up for the use of the Myfitnesspal.com smartphone/web-based application for food tracking during the study or agree to complete written food logs.

During the 12 weeks of the intervention, participants will monitor food intake using either a written Food Log or Myfitnesspal.com, follow the educational materials provided for the diet, and test their Blood Glucose/Ketones daily using the Keto Mojo Blood meter which stores up to 1000 test results for later download by study researchers. The Daily blood Glucose/Ketone levels will be used to track dietary compliance.

Participants will be invited to attend two 2-hour, individual, online Zoom appointments, the first at baseline (which also includes the presentation and training) and the second, post-intervention, at 12 weeks. During the pre- and post-study appointments, the MDS-UPDRS scale, the Parkinson's Anxiety Scale, and the CESD-R-20 depression scales will be administered. Additionally, each participant will have a 15-minute pre-study and post-study interview to answer 4 specific questions related to QoL. Participants will be provided with paperwork to obtain blood tests before both the pre- and post-study appointments to test for blood markers including HgA1C, fasting insulin, triglycerides, LDL, CRP, and HDL.

Qualitative interviews will consist of a 15 minute, audio-recorded interview where participants will answer 4 qualitative questions including:

Pre-study Interview:

1. Please describe your current mental QoL
2. Please describe your current physical QoL
3. Please describe your current social QoL
4. What do you expect to get from this study?

Post-study Interview Questions:

1. Please describe your current mental QoL
2. Please describe your current physical QoL
3. Please describe your current social QoL
4. Please describe if the study met, did not meet, or exceeded your expectations

The recorded interview will be sent to Rev.com for confidential transcription and returned to study researchers. The transcribed interviews will then be hand-coded to saturation to look for themes and sub-themes.

The two appointments will be scheduled using a private, secure, online appointment site (Signup Genius), a password protected appointment website application. Pre and post-study interviews will be conducted on the Zoom online conferencing program to maintain confidentiality.

The interviews will be transcribed by Rev.com, a confidential, online transcription service, which will have signed a confidentiality agreement. Once transcribed, the researcher will go back over the transcription to verify. Finally, member checking will be employed. Some interviews may be transcribed by the researcher, as well. A copy of the document will be emailed to each participant, allowing 7 days for feedback/input. Interviews will be digitally recorded and the audio file will be electronically stored on the researcher's password-protected computer and external hard drive.

Private communication between participants and research team members will be conducted via phone, confidential, password-protected email, or Zoom online format at participant request.

The study analysis will be conducted with the assistance of the statistical staff at the AT Still University and will utilize the Wilcoxon signed-rank test for within-group comparisons for pre-study and post-study assessments of the MDS\_UPDRS scale (parts 1-4), the PAS, the CESD-R-20, and bloodwork (HbA1C, Triglycerides, LDL, HDL, and CRP). All data will be stored and analyzed using the RedCap database management system.

If an adequate number of participants are enrolled and complete the study ( $n > 30$ ), data analysis will involve a t-test to compare pre and post-study results.

#### Previous interventions:

This is prospective, pre-test/post-test, one-group study, with both quantitative and qualitative analysis. The study will investigate the effects of a nutritional approach to the treatment of symptoms of Parkinson's disease. The intervention that participants will receive is an LCHF /Ketogenic Diet

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Participants will be invited to attend two 2-hour, individual, face-to-face appointments, the first at baseline (which also includes the presentation and training) and the second, post-intervention, at 12 weeks. During the pre- and post-study appointments, the MDS-UPDRS scale, the Parkinson's Anxiety Scale, and the CESD-R-20 depression scales will be administered. Additionally, each participant will have a 15-minute pre-study and post-study interview to answer 4 specific questions related to QoL. Participants will be provided with paperwork to obtain blood tests before both the pre- and post-study appointments to test for blood markers including HbA1C, Triglycerides, LDL, CRP, and HDL.

Qualitative interviews will consist of a 15 minute, audio-recorded interview where participants will answer 4 qualitative questions including:

Pre-study Interview:

1. Please describe your current mental QoL
2. Please describe your current physical QoL
3. Please describe your current social QoL
4. What do you expect to get from this study?

Post-study Interview Questions:

1. Please describe your current mental QoL
2. Please describe your current physical QoL
3. Please describe your current social QoL
4. Please describe if the study met, did not meet, or exceeded your expectations

The recorded interview will be sent to Rev.com for confidential transcription and returned to study researchers. The transcribed interviews will then be hand-coded to saturation to look for themes and sub-themes.

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If an adequate number of participants are enrolled and complete the study ( $n > 30$ ), data analysis will involve a t-test to compare pre and post-study results.

## **Intervention Type**

Other

## **Primary outcome measure**

1. The course of Parkinson's disease measured using the Unified Parkinson's Disease Rating Scale (UPDRS) Parts 1 to 4 at baseline and 12 weeks
2. Anxiety measured using the Parkinson's Anxiety Scale (PAS) at baseline and 12 weeks
3. Depression measured using the Center for Epidemiologic Studies Depression Scale-Revised (CESD-R-20) at baseline and 12 weeks
4. Lipid profile assessed through blood markers including HgA1C, Triglycerides, LDL, CRP, and HDL taken at baseline and 12 weeks

## **Secondary outcome measures**



Mental, physical, and social quality of life assessed through qualitative analysis of these themes from audio-recorded structured interviews at baseline and 12 weeks

**Overall study start date**

01/01/2020

**Completion date**

30/09/2021

## **Eligibility**

**Key inclusion criteria**

1. BMI >18.5
2. Hoehn-Yahr Stages I-IV
3. Aged 50 to 85 years
4. Have received permission from their Primary Care Provider to participate in the study and, if diabetic, have received a written Insulin Sliding Scale to be used during the study
5. Are cognitively able to follow the dietary plan
6. Are able to read, speak, and understand English
7. Provide written informed consent to participate in the trial

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

None

**Date of first enrolment**

15/09/2020

**Date of final enrolment**

01/01/2021

## **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

**Sponsor details**  
1155 Kelly Johnson Blvd  
Suite 111  
Colorado Springs  
United States of America  
80920  
+1 (719) 884-0103  
jedpfarrer@outlook.com

**Sponsor type**  
Charity

**Website**  
<https://co-parkinson.org/>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Colorado Parkinson Foundation

## **Results and Publications**

**Publication and dissemination plan**  
Planned to submission to Neurodegenerative Disease Management

## Intention to publish date

12/01/2021

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from [melanietidman@gmail.com](mailto:melanietidman@gmail.com).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/02/2022	09/08/2022	Yes	No