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

Submission date
06/03/2020

Recruitment status
No longer recruiting

Registration date
05/05/2020

Overall study status
Completed

Last Edited
09/08/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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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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.
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Where is the study run from?
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 HgAIC, 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 (HgA1C, 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 HgA1C, Triglycerides, LDL, CRP, and HDL.

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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 in a private location 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.

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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.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/02/2022	09/08/2022	Yes	No