A 3-month Pilot Trial of the Ketogenic Diet for People with PD: Program Design, Implementation, and Maintenance

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introduction

- The classic ketogenic diet (KD; 80% fat, 15% protein, and 5%carbohydrate) is intensive and requires substantial engagement and collaboration between participants, families, and providers.
- Several academic medical institutions have KD centers that provide inpatient dietary initiation for pediatric clinical populations.
- Few outpatient programs have been described for clinical research with adults.

objective

- To safely initiate, monitor, and maintain a 3-month KD in a clinical trial setting

methods

study design

- Uncontrolled, pre-post pilot trial (n=13)
- Two-week educational run-in
- KD for 12 weeks
- Outcomes assessed at baseline, 4-, 8-, and 12-weeks off PD meds for ≥ 12 hours

clinical outcome measures

- Unified PD Rating Scale Total
- Mini-BESTest
- 360◦ Turn in Place
- Freezing of Gait & QOL Questionnaires

safety and fidelity measures

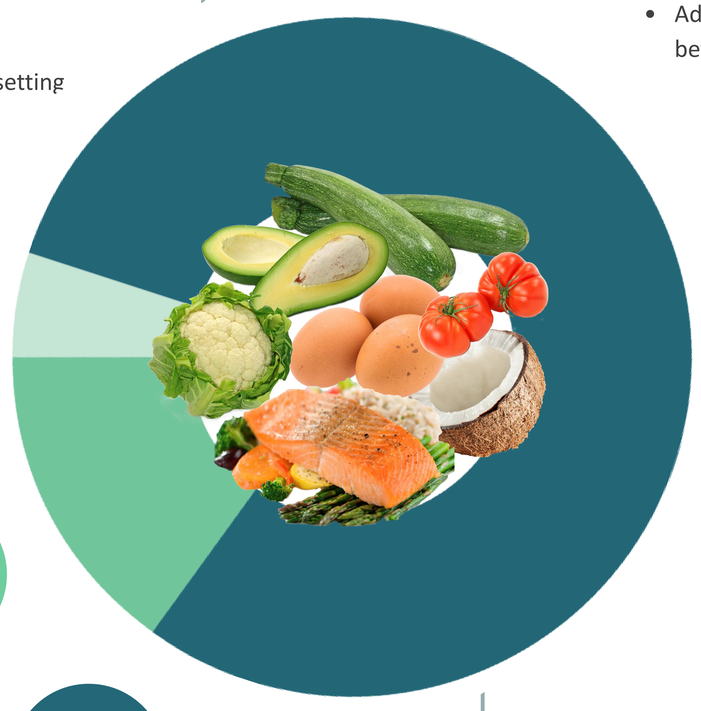
- daily finger stick glucose & ketones
- daily diet diary: MyFitnessPal
- monthly CBC/chem panel, urinalysis with ca^{2+} & creatinine

inclusion criteria

- 21 to 70 years old
- PD Hahn & Yarh stage 2.0 – 3.0
- Stable on medications for ≥ 3 months

exclusion criteria

- hyperlipidemia
- CAD
- congestive heart failure
- diabetes
- cancer
- kidney or gall stones
- inborn error of metabolism
- pregnancy



program design

- Participants who were not the primary preparer of food in their home brought a study partner.
- Participants/study partners were paired with nutrition graduate students for one-on-one support.
- A pre-diet nutritional interview assessed potential psychosocial barriers to dietary change.
- 2-week run in: 4 hours of education, history of the diet, menu plans, expectations and potential side effects.
- Diet focused on whole-food preparation: coconut, avocado, olive oil, fish, green beans, cauliflower…
    - Weekly study visits included individual check-in with participant-student pairs, as well as facilitated group meetings with the entire cohort for peer support.
        - Adherence was tracked via MyFitnessPal diet diaries and confirmed by serum beta-hydroxybutyrate levels.

results

- Thirteen participants and 6 study partners (three cohorts) participated in the program.
- One participant worsened and terminated the diet after 4 weeks; 12 participants completed the trial.
- Data from diet diaries were 95.74% complete and reflected beta-hydroxybutyrate levels.
- On average, participants consumed 76% fat, 15% protein, 5% net carb.
- Adverse symptoms included cramps, fatigue, constipation, nausea, worsening arrhythmias and were safely managed.
- Participants shared challenges and solutions in group meetings, which established community and reinforced motivation. .

conclusion

- This program successfully initiated and safely monitored an outpatient ketogenic diet, achieving excellent participant adherence to a challenging protocol.
- Key components included education, one-on-one clinical support, community building and peer engagement.

acknowledgements

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