Protocol for Almond Butter and Fasting Glucose Study

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Brief Title: Almond Butter and Fasting Glucose
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**Inclusion Criteria**

- Individuals 18 to 75 years of age
- Individuals with diagnosed type 2 diabetes
- HgbA1c: <9%
- Not on insulin therapy
- On stable does of oral antihyperglycemic agent (no dose change for 6
- months) or no oral antihyperglycemic agents
- Willing and able to adhere to study protocol

**Exclusion Criteria**

- Individuals with type 1 diabetes, cardiovascular disease, kidney disease, liver
- disease, cancer or inflammatory conditions (e.g. GI disorders, rheumatoid
- arthritis)
- Women who are pregnant, breastfeeding, or have been pregnant within the
- last 6 months or breastfeeding within the last 6 weeks
- Individuals who smoke or use tobacco products
- Use of insulin therapy or sulfonylurea medications
- Almond allergy
- Allergy to Dexcom CGM adhesive

**Recruitment**

Advertisements will be placed in campus buildings and facilities as well as the surrounding area (gyms, churches, supermarkets, coffee shops etc.) to identify potential subjects residing in and around the State College area. We will also provide flyers to local physician offices and recruit through our Facebook page and department website.

Study staff will contact those individuals who have responded to ads (email, newspaper, website, fliers) and have left their name and phone numbers on the recruiting line or email.

Recruitment flyers will be posted in local physician offices. Cardstock fliers may also be distributed to patients or displayed in the waiting room of the office. Websites (http://clinicaltrials.gov/, https://studyfinder.psu.edu/, Facebook, Craig's List), PSU listserv (Health and Human Development Dept listserv; Food Science listserv; post-doc etc.) will also be utilized. Participants will be asked to complete a brief phone screening to confirm eligibility.

**Consent Process and Documentation**

Once interested participants have contacted study staff and have undergone a phone screening, an appointment will be set at the General Clinical Research

Center (GCRC) where study staff will review the consent documents with participants. At this appointment, before any procedures take place, potential participants will be given the informed consent document. Following standard protocol procedure, a trained staff person will review the information in detail, make sure the individual understands the study and answers any questions they may have. If the participant is still interested in enrolling in the study, both the participant and the staff member will sign and date the document. A copy of the signed document will be provided to the participant prior to leaving the screening appointment. If consent is obtained, the study protocol will reviewed, the Dexcom monitor will be placed, and the subject will begin the study that day. Subjects will be made aware that their participation in this study is voluntary, they may drop out of the study at any time, and that there is no penalty for not participating. Consent will be confirmed in writing.

**Protocol**

After completion of the phone screening, an appointment will be set for a baseline visit at the GCRC to obtain informed consent and place the continuous glucose monitor. If the participant consents to the research, the researcher will play a brief video detailing how to use place a Dexcom Continuous Glucose Monitor (CGM), and participants will will then place the monitor on themselves, under the supervision of study staff. Participants will be taught to use the CGM properly and will wear it for 3-7 days. The CGM can be worn for up to 7 days, according to manufacturers' instruction, but in some individuals, the adhesive does not stay in place for the full week. We will plan for study participants to wear the CGM for 7 days, but we will accept a minimum of 3 days of data.

The Continuous Glucose Monitor data receiver will be set to blinded mode and participants will not be able to see their glucose data for the duration of participation (they will still monitor their blood glucose as instructed by their physician, they just will not be able to see it on the CGM). Participants will wear the CGM for 3-7 days, return to the clinic for removal and replacement, and then begin the second study period. They will also be provided with the study food, almond butter, and be asked to consume the almond butter that we provide to them as a bedtime snack for the 3-7 nights of the study. The order of their treatment (control then almond butter or almond butter then control) will be randomly assigned. We will also ask participants to keep a record of what they eat for dinner, what time they eat breakfast, lunch and snacks, and any changes in medication or physical activity on those days. Participants will receive individual packets of 2 tbsp of natural almond butter and be given instructions to eat the almond butter as an evening snack, or to eat nothing after dinner during the no-snack control period. Blood glucose levels will be measured using continuous glucose monitoring (CGM), which will be provided free of charge to participants through a donation from Dexcom. At Visit 3, participants will have the CGM removed and will receive a printout of their CGM data when they return the Dexcom equipment to the office.

**Visit 1**

The study will be explained, questions will be answered and consent forms will be reviewed and signed. Participants providing consent will watch a brief video on use and placement of CGM, and then place their CGM in the office, supervised by study staff. They will be taught to use the CGM, be provided with the study food, food record sheets and randomized. They will also have an appointment set for 6-14 days later.

**Visit 2**

At the second visit, participants will remove and replace their CGM monitor. They will be reminded of all data entry requests.

**Visit 3**

At the third visit, participants will return their CGM equipment and their data will be downloaded. They will receive their CGM data and be entered into a drawing to win a gift card for their participation. They will receive the $100 incentive for participation approximately two weeks later.

**Duration of Participation**

Participants will first complete a phone screening. If they are deemed eligible, they will participate in the study for 2 weeks, including 3 visits to the clinic. Visit 1 lasts approximately 1 hour, visits 2 and 3 last approximately 15 minutes.

**Intervention Food (Almond Butter)**

The almond butter will be packaged into 7 single serving containers to be consumed during the intervention week. Participants will be given individual containers as dictated by the study design, 1 per day, for the duration of the intervention, at their first visit. There are no special requirements for storage by the participants.

**Subject Numbers and Statistical Plan**

Ten participants were recruited for this study. All data collected, including CGM and dietary data, will be identified with a code. None of the collected data will include patient identifiers. Only the PI and study personnel will have access to study data. Linear mixed effect models in R statistical software (The R Project for Statistical Computing) will be used to analyze the data.