A Machine Learning Approach to Alzheimer's Detection from Continuous Blood Glucose Monitoring Data

Brief Title: Alzheimer's and Blood Glucose Levels

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Study ID: BCT_AD_001

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Informed Consent for Participation in the "Alzheimer's and Blood Glucose Levels"

Principal Investigators: Tim Cashion and Amir Hayeri
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This "Informed Consent" document is for participants of the open pilot study, "Alzheimer's and Blood Glucose Levels".

It has two parts:

1. **Information Sheet (to share information about the program with you)**
2. **Certificate of Consent (to be signed if you are willing to participate in this program)**

PART I: Information Sheet

Introduction
Bio Conscious Technologies Inc. has designed an observational study to monitor blood glucose levels of patients recently diagnosed with Mild Cognitive Impairment or Alzheimer's Disease. For this study, we are recruiting individuals to meet a target of 100 participants.

Purpose of the Program
5 million Americans are living with Alzheimer's currently. As you age, your risk of Alzheimer's increases significantly. However, research has shown that early diagnosis, treatment and management of the disease can significantly improve the lives of those at risk. The "Alzheimer's and Blood Glucose Levels" open pilot study is designed to focus on the early detection of Mild Cognitive Impairment and Alzheimer's disease using continuous glucose monitoring.

Participant Selection and Participation
All people who meet the inclusion criteria are invited to participate. The major limitations to participation are participants must be 50 years of age or older, and currently use a continuous glucose monitor. Participation is completely voluntary and if you choose to do so, you can withdraw at any time. For participants with Alzheimer's disease, permission is required from the participant's primary caregiver in addition to the participant. The primary caregiver may also withdraw the participant at any time on behalf of the participant.

Process
Participants in this project will:
* Use a continuous glucose monitor (CGM) for a period of 90 days. Due to this requirement, only participants who are already currently using a continuous glucose monitor will be selected for this study.

* Connect their CGM to the Endobits Companion app for the duration of the study. This app is freely available from the Apple App Store and the Google Play Store. All assistance on using the app is available through the app's support feature.
* All information collected will be viewable by the participant and/or their primary caregiver(s).

Confidentiality
All individual information about a participant in this program will be kept confidential. There will be no names used in any information shared among program team members. To ensure this, each participant will be identified by a number. Confidentiality may be breached if required by law, or an accidental privacy breach outside of the study team's control. However, all data will be stored on a secure and compliant database with restricted access.

The aggregated results of this study may be disseminated in academic journal articles or presentations. No identifying information will be included in these publications, nor in any datasets that may be made publicly available as a result of these publications.

All data will be retained for a period of 3 years after the last approval of a marketing application or academic publication based on these data. After this point, data pertaining to this study will be destroyed. The de-identified data will be by the study team for analyses and development of products relating to the study's aim.

Risks
Normal use of the Endobits Companion app does not provide any additional information and will not lead to participants changing their current diabetes management.

Benefits
There is no expected direct benefit to participants; however, the result may provide knowledge to improve clinical diagnosis of Mild Cognitive Impairment or Alzheimer's Disease.

Compensation
Participants will not be compensated for their participation, and will not be entitled to compensation in the unlikely event of injury during the study.

Voluntary Participation and Withdrawal
Participation in this study is completely voluntary. As such, participants may withdraw from the study at any time with no negative repercussions. If a participant does withdraw, they have the choice of whether their data will be used for the study or if the data will be destroyed at the time of their withdrawal.

Institutional Review Board
This study has been reviewed by Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or the Investigator's responsibilities, you may contact the Manager of Veritas IRB 24 hours per day and 7 days per week at

514-337-0442 or toll-free at 1-866-384-4221. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the subject's rights and welfare in mind. If you have any study related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you need to speak to a person independent from the Investigator and the research staff, and/or if the Investigator and the research staff could not be reached.

PART II: Certificate of Consent.

I have read this information, or it has been read to me and I have had the opportunity to ask questions and these questions have been answered to my satisfaction. I consent voluntarily to participate as a participant in this program.
Print Name of Participant _____
Signature of Participant _____
Date _____
Day/month/year

For participants with Alzheimer's Disease, we ask for an additional signature from the participant's primary caregiver. The primary caregiver may withdraw the participant from the study at any time.

As the primary caregiver for, _____ (print name of participant), I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.
Print name of witness/primary caregiver_____
Signature of witness/primary caregiver _____
Date _____
Day/month/year

If you have any questions, please contact the Study Monitor:
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