

Mobile Physical Activity for Type 1 Diabetes

NCT04204733

March 23, 2021

Statistical Analysis plan

Data will be exported from the Web API, Actilife, and REDCap and merged into an SPSS 24.0 (Armonk, NY) database for analysis. Each variable will be described with frequency distributions and appropriate summary statistics for central tendency and variability; these univariate analyses will help to assess assumptions underlying the statistical tests used in the analysis.

**Primary Aim 1a. To examine the feasibility of a mobile diabetes self-management application and tools to promote physical activity (PA) in patients with type 1 diabetes (T1D).** Feasibility of the mobile intervention will be evaluated according to standards set by previous in-person T1D self-management interventions:

- a) **Enrollment**, defined as proportion of eligible patients who are approached that complete the consent process and baseline assessments. Standard is 50%<sup>1,2</sup>.
- b) **Retention**, defined as the proportion of patients completing the baseline assessments that also complete the follow-up assessments. Standard is 90%<sup>1,2</sup>.
- c) **Biosensor adherence**. For CGM, this is defined as the proportion of possible readings obtained assuming a sampling every 5min. Standard is 98%<sup>3</sup>. For accelerometry, this is defined as the proportion of subjects wearing the device  $\geq 4$  days  $\geq 10$ hr/day. Standard is 92%<sup>4</sup>.

In addition, mobile product usability will be evaluated based upon the System Usability Scale where a score  $\geq 70$  is considered acceptable<sup>5</sup>.

**Primary Aim 1b. To estimate the probable magnitude of the pre-post effect on PA and clinical and mental health outcomes that may be improved by PA.** Pre-post effect on each outcome will be estimated using Cohen's formula (0.20 considered small, 0.50 medium, 0.80 large).

**Secondary Aim. To evaluate predictors and mechanisms of PA behavior change.** This aim will be analyzed by a mixed methods approach. The quantitative dependent variable will be momentary classification of PA status based upon accelerometry, mobile diaries, and timeline followback (TLFB) according to intensity (sedentary, light, moderate, or vigorous) and type (aerobic, resistance, neuromotor, flexibility). Analysis will focus on three primary objectives: 1) To develop a machine learning model<sup>6</sup> that will classify PA status with at least 80% accuracy, 2) To determine the appropriate duration of observation needed to build a model with at least 80% accuracy in predicting future PA, and 3) To determine the classification accuracy of the model trained on group-level data and tested on individual-level data. Modeling frameworks we will apply include: elastic net penalized cox proportional hazards regression<sup>7</sup>, logistic time-varying effect models<sup>8</sup>, and Bayesian multistate Markov models with interval-censored data<sup>9</sup>. Demographics (e.g., age, sex, race/ethnicity), baseline health profile (e.g., body composition, depression), momentary usage of each intervention component, and momentary values of other external (e.g., location, time of day) and internal (e.g., blood glucose, insulin on board, fear of hypoglycemia (FOH)) will be evaluated as potential predictors. Possibilities of time-lagged prediction will be tested (e.g., afternoon PA could be influenced by a morning teleconsultation), particularly for FOH which is only assessed twice daily. These quantitative results will be combined with qualitative results from exit interviews by a mixed methods approach according to Sekhon's theoretical framework for acceptability<sup>10</sup> to determine intervention components that are most helpful and influential regarding PA behavior change.

**Data Sharing.** Individual deidentified participant data (including data dictionaries) will be shared. This includes individual participant data that underlie the results reported in any aspect of a published article (text, tables, figures, and appendices). Other documents that will be

available include the study protocol, statistical analysis plan, informed consent form, analytic code. The data will be available immediately following publication with no end date. Data will be shared with researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Proposals should be directed to Dr. Garrett Ash at Yale University ([garrett.ash@yale.edu](mailto:garrett.ash@yale.edu)). To gain access, data requesters will need to sign a data access agreement.

## **References**

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