ClinicalTrials.gov ID: NCT03258723

Title: Diabetes Prevention with Lifestyle Intervention and Metformin Escalation (LIME)

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Document: SAP

Statistical Analysis Plan

Protocol Title: Diabetes Prevention with Lifestyle Intervention and Metformin Escalation (LIME).

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Initial Plan:
Study design: **pre-post study design with non-equivalent control**
Sample Size:
The primary outcome of the LIME pilot study is reducing the proportion of individuals with elevated HbA1c. Sample size calculation was estimated using a two-sample, paired t-test approach.

The estimated total sample size of 200 participants (control and intervention) is required to provide an 80% power to detect a ≥20% difference in proportion of individuals with HbA1c below the high risk range of 6-6.4%. This sample size takes into account a ≤ 10% loss to follow-up.

Survey measures:
Table 3. Proposed areas of LIME baseline and follow-up data collection

Self-Reported Measures	Clinical Assessment	Sociodemographic Characteristics
Fruit and vegetable intake	Weight/Height/BMI	Gender/Sex
Sugar-sweetened beverage intake	Blood pressure	Age
Physical activity	Waist & Hip Circumference	Marital/partner status
Self-efficacy score	Neck Circumference	Self-identified race/ethnicity
Medical history	Hemoglobin A1c	Occupation/occupational history
Family history	Cholesterol	Education
Medication adherence	Creatinine	Wealth
Social desirability scale		Insurance status

Analysis:
We will use the chi-squared test to compare the proportion of individuals who reduce their HbA1c below 6% over the 12-month period in the intervention and control groups as the primary outcome. Differences between the intervention and control groups in the secondary outcomes of average change in HbA1c, weight, BMI, systolic blood pressure, cholesterol, self-efficacy score, and quality of life will be compared using Student's t-tests. Within the intervention arm, we will use chi-squared and t-tests to identify any patient-related factors that are associated with the primary outcome of HbA1c reduction below 6%.

Statistical analysis plan Changes resulting from COVID-19 and inability to recruit a control arm:

Study Design: pre-post study design was used
Statistical analysis: t-test was used to compare the change in primary outcome HbA1c, and secondary outcomes (weight, blood pressure, added sugar intake, fruit and vegetable intake, physical activity) at baseline with 6-months and 12-months post intervention.

Physical activity was measured using the World Health Organization Global Physical Activity Questionnaire. Metabolic equivalents were used to classify level of physical activity as low, medium, or high.[1]

Nutritional assessment was done using the Dietary Screening Questionnaire and established guidelines for the analysis of fruit and vegetable intake (servings) and added sugar intake (teaspoons). [2]

REFERENCES

1. Chu A.H., Ng S.H., Koh D., Muller-Riemenschneider F. Reliability and validity of the self- and interviewer-administered versions of the Global Physical Activity Questionnaire (GPAQ) *PLos One.* 2015;10(9) [PMC free article] [PubMed] [Google Scholar]

2. Thompson F.E., Midthune D., Kahle L., Dodd K.W. Development and evaluation of the National Cancer Institute's Dietary Screener Questionnaire Scoring Algorithms. *J. Nutr.* 2017;147(6):1226–1233. [PMC free article] [PubMed] [Google Scholar] [Ref list]