

Official Title: Improving Detection and Evidence-based Care of NAFLD in Latinx and Black Patients With Type 2 Diabetes (NAFLD-DM): A Pilot Study

NCT: NCT05844137

IRB Document Date: 5/31/2024

Statistical Design and Power

V: May 31,2024

We expect to enroll 15 participants who self-identify as Black or African American (AA), and 15 participants who self-identify as Hispanic/Latinx.

Our quantitative primary outcomes will be feasibility and acceptability, as below:

Feasibility of system-level NAFLD detection approach	Patients who met criteria for NAFLD after chart review / total number of potentially-eligible patients based on our EHR criteria. We will deem this approach feasible if detection rates are >70%.
Feasibility of patient-level management	We will assess recruitment rates, retention rates and study visit completion rates. We will consider our management approach to be feasible if we can recruit at least 10 Black/AA patients and 10 Hispanic/Latinx patients over 12 weeks (3 months)
Acceptability of intervention by participants	We will calculate the mean and standard deviation of the Treatment Acceptability and Preferences (TAP) measure at 3 months; a score >3 will be deemed acceptable.

Secondary outcomes: Patient-level outcomes will be examined at 12 weeks (3 months), and these include: hemoglobin A1c, alanine aminotransferase level (ALT), and survey measures (i.e., self-efficacy, perceived autonomy support and quality of life). Effect size of the pre-post difference and 95% confidence intervals will be calculated.

This pilot study will not have enough statistical power to establish effectiveness of the intervention for these secondary outcomes. Results of an intervention to improve NAFLD detection and management in Black and/or Hispanic/Latinx persons with T2D has not been previously reported. Therefore, the primary goal of this pilot study is to generate evidence in this area to estimate effect sizes and show feasibility of the intervention to guide future work.