

Digital Health for Medication Adherence Among African Americans with Hypertension
Phase 1
NCT05009004
October 14 2022

Analysis plan:

Measures: Primary: HTN med adherence will be assessed by the Adherence to Refills and Medication Scale (ARMS), a well-validated self-report measure used widely in studies with minority patients and/or those with low literacy (Buis et al., 2019; Kripalani et al., 2009; McNaughton et al., 2014). We will also use Segural et al. (2010) 3-item adherence measure, as in our prior research (Pagan-Ortiz et al., 2019). (NB: The team revised the adherence measure approach to use a single measure, namely the Wilson et al. (2016) Self-Report Medication Adherence scale.) **Secondary:** Adherence self-efficacy will be assessed with the HTN med adherence self-efficacy scale (MASSES) new (Ogedegbe et al. 2003). Stress burden will be assessed using Perceived Stress Scale (Cohen et al., 1983). HTN knowledge will be assessed using the NHLBI HTN Knowledge Scale (Carter-Edwards et al., 2002). **Primary Hypothesis:** Participants will show greater HTN med adherence at 6 wks compared to baseline. **Secondary Hypothesis:** Participants will show greater HTN adherence self-efficacy, greater HTN knowledge, and lower stress burden at 6 wks compared to baseline.

Data analyses: We will conduct one-tailed paired t-tests at the .05 level for primary hypotheses. Data from our Phase 1 evaluation of short-term effectiveness will be used to determine the sample size necessary for an adequately-powered Phase 2 RCT.