PROTOCOL TITLE:
Feasibility of Brief Intervention for HIV+ Adults 50+ in Primary Care Settings

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Statistical Analysis Plan

Aim 1 (Feasibility): The model will be considered feasible if 80% of the target population has been reached.

Primary Outcome

Feasibility Calculation. Feasibility is defined as the extent to which the intervention can be successfully used or carried out within the UF Health Infectious Disease-Medical Specialties Clinic. Therefore, we will calculate feasibility using the following steps (see link to method for calculation below):

- **Step 1:** Enumerating all potential participants in target population. The target population will be defined as all patients seen by Dr. Janelle seen during study period.
- **Step 2:** Quantify Exclusions. List reasons for and number of exclusions.
- **Step 3:** Quantify missed cases. List number of lost cases or missed due to lack of staff resources, etc.
- **Step 4:** Quantify Eligible Participants. List number of known eligible participants who were offered participation.
- **Step 5:** Quantify number of Patients Reached. Divide number of participants enrolled to determine percent participation.
- **Step 6:** Report most common reasons for declining participation.

http://re-aim.org/resources-and-tools/calculations/calculating-and-reporting-on-reach/

Acceptability Questionnaire. This 10-item questionnaire (1 = not acceptable to 5 = highly acceptable) queries the participant on the acceptability of the program. Item content includes the following:

1. Program was a good use of my time
2. Program was helpful
3. Program will be useful in my daily
4. Likeability of interventionist
5. Clinical skill of interventionist
6. Likeability of assessor
7. Ease of participation in assessments
8. Ease of participation in intervention
9. Interactions with program staff
10. Overall rating.

To examine ratings of acceptability, we will use the overall acceptability score and percentage of acceptability. Overall acceptability will be assessed by summing ratings from the 10-item questionnaire to provide a total intervention acceptability score for the intervention, such that acceptability scores for the intervention could range from 10 (low acceptability) to 50 (high acceptability). The intervention will be considered to have acceptability if 80% of the participants rank the intervention as acceptable (i.e., 4 or higher) on 80% or more of the scale items. We will then examine each question of the Acceptability Questionnaire separately to determine strengths and weaknesses of the intervention.

Aim 2a and 2b (Acceptability): Acceptability scores will be calculated for all participants as listed above to determine overall acceptability of the SBIRT model. Sub analyses will be conducted for disease type and HIV x age using calculations listed above. Acceptability will be examined by disease type HIV vs. non-HIV. Acceptability will also be examined for HIV only by younger ($\leq$49) versus older $\geq$50).

Aim 3: We will clean the data, examine variable distributions, compute descriptive statistics, examine outliers, and examine the effectiveness of randomization prior to analyses of specific aims to ensure the underlying assumptions of normality and equal variance have not been violated. Before testing each secondary outcome, we will examine whether intervention and control group participants differ on potential confounding variables at study entry. We will control for a variable if it differs by condition on the outcome variable being tested in that analysis at $p <$ .05. Using chi-square (or t-test for continuous variables) we will examine the associations between the dependent variables and relevant demographic variables. All analyses will employ an intent-to-treat approach.

Our first step will be to see if the intervention influenced formal engagement in substance use treatment. Using chi-square analyses we will examine group difference on engagement in formal treatment (0=no treatment/1=treatment confirmed). To test the remainder of the hypothesis, analyses will rely on mixed model repeated measures ANOVA since the relatively small sample size is likely to prohibit more sophisticated statistical modeling. Hypotheses testing rely on inspection of F values and associated p values. A mixed model ANOVA is used to test for differences between two or more independent groups while subjecting participants to repeated measures. In the current analyses the fixed effect will be group condition (SBIRT-PN or TAU) and the random effect will be number of drug use days in the past 3 and 6 months.