Helping People Adhere to Their Varenicline Treatment by Co-creating a Conversational Agent: A Feasibility Study

Statistical Analysis Plan

NCT NumberNCT05997901

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We will calculate descriptive statistics, including means, medians, ranges, and SDs, for the demographic data as well as for the AIM, IAM, and analytics data captured by the health bot internal logs. All scores will be analyzed using the appropriate guidelines provided by Weiner et al [40] (acceptability and appropriateness) and Brooke [42] (usability). Consistent with previous studies, adherence will be defined as taking ≥80% of the prescribed varenicline [45-48]. We will not treat adherence as a continuous variable because it is likely to be strongly bimodal and is not necessarily linearly associated with the cessation outcome. We will calculate the percentage of participants who were adherent at week 12 and who reported not having smoked in the last 7 days. These results will serve as progression criteria to determine whether a full-scale RCT is warranted. Although the sample size will be insufficient for meaningful regression analysis, especially given the potentially nonlinear effects of age, we will also test for differences across age and gender groups using 2-tailed *t* tests and chi-square tests. The power for these comparisons will be low; therefore, this analysis will be an exploratory evaluation of large adherence or outcome differences that may be important to future study design, and interpretation will focus on observed differences and CIs.

Exploring the Feasibility of the Approaches on Recruitment, Retention, and Data Collection

This study, using "stop, amend, and go" progression criteria for pilot studies [51], will help determine if proceeding with an RCT is a logical next step and whether additional adjustments are necessary. We will only conduct a full-scale RCT if none of the criteria outlined in Table 1 meet the "stop" criterion (unless we see that there are contextual issues that can be modified to overcome the identified problems). If 1 or more of the concepts in Table 1 meet the "amend" criterion, the trial will proceed to an RCT only if the issues can be addressed. If all concepts in Table 1 satisfy the "go" criterion, we will proceed with planning an RCT.

Table 1. Criteria to decide if a randomized controlled trial is warranted.

Criteria	Stop	Amend	Go
Patient recruitment	**If <30 patients are recruited within 12 months**	**If 30-40 patients are recruited within 12 months**	**If 40 patients are recruited within 12 months**
Patient retention	**If <25% of patients answer the 12-week survey**	**If 25.1%-79.9% of patients answer the 12-week survey**	**If ≥80% of patients answer the 12-week survey**

Criteria	Stop	Amend	Go
Missing data, medication adherence, or smoking status	If >60% of adherence data and smoking status are missing	If 21%-59% of adherence and smoking status data are missing	If ≤20% of adherence and smoking status data a missing
Acceptability and appropriateness	If mean score for the AIM[a] or IAM[b] is ≤8	If mean score for the AIM or IAM is 9-12	If mean score for the AIM or IAM is ≥13
Usability	If mean SUS[c] score is ≤40	If mean SUS score is 41-67	If mean SUS score is ≥68
Adoption	If mean use is ≤ 20 times	If mean use is 21-79 times	If mean use is ≥80 times

[a]AIM: Acceptability of Intervention Measure.

[b]IAM: Intervention Appropriateness Measure.