Harnessing the Power of Technology: MOMBA for Postpartum Smoking

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Overview: Through a pilot, randomized control trial tested the effectiveness of Momba Live Long (the Momba Live Long application and sensor) on 7-day point prevalence of smoking abstinence rates i) at the end of the trial and ii) at 3-month follow-up as determined by the Timeline Follow Back instrument and number of negative breath tests.
The randomized controlled trial of Momba Live Long utilized a control group which received financial incentives at an in-person office/clinic visit based on expired CO levels obtained through the piCO+™ CO sensor compared to the MoMba Livelong application. We used results from frequently administered assessment instruments over the course of an 3-month period and subsequent 6- and 12-month follow ups to assess outcomes and to examine the reliability and validity of assessment measures, and key methodological parameters, such as effect size, proportion of eligible and willing study participants, attrition rate, time necessary for data collection, and necessary skill sets for CMHAs. The RCT involved an intervention arm (10 women who receive Momba Live Long) and "control" arm (10 women who receive financial incentives delivered in-person in the office). Participants were randomized using a number generation mechanism provided to the CMHAs who are screening and enrolling women.

Intervention Group (Momba Live Long): The intervention group received a smartphone, data plan, Momba Live Long, including the Bluetooth enabled CO sensor, and training from a CMHA on its use. The intervention group did most of its CO tests remotely, outside of a baseline, 3-month end point assessment, and 6-month and 12-month follow-ups. However, participants also came n for the first 5 days of week 1 to be trained on how to use the Sensordrone and Momba Live Long app. As part of this training, we showed the intervention group participants a Demonstration Video and a Powerpoint Presentation about how to use the Momba Live Long Application. Intervention group participants came to the office for a visit in Week 4 and Week 8 to calibrate the Sensordrone and to submit a urine specimen.

Control Group: Control group mothers received traditional, in-office contingency management to prevent smoking relapse. Financial incentives were delivered according to the same schedule at the same frequency as those delivered to mothers on Momba Live Long. The exception was that mothers in Momba Live Long will also receive payment for completing tasks that promote abstinence. Overall, the amount of Contingency Management incentives in the two groups were similar. Thus, we were not directly comparing the effectiveness of contingency management that has already been well established, **but rather we assess the effectiveness of contingency management delivered over a smartphone application vs. traditional contingency management in an office setting.** Women in each condition were provided with the Staying Smoke Free curriculum. Mothers in the control condition completed the same assessment battery and according to the same schedule as participants in the Momba Live Long application group and were compensated similarly. During the first 3 months, control group participants completed assessments with staff during office visits. In months 4-12, surveys were administered via Qualtrics links on personal smartphones, over the phone with research staff, or by mailing the surveys to and from participants' homes. Control group CM breath tests were conducted with the piCO+™, considered as "traditional" Contingency Management. They also completed Sensordrone CO tests for comparison purposes with the Intervention Group. Control participants were also be compensated for attending each scheduled CO test office visit.

Participants: Women who were smoking in the second or third trimester of pregnancy, with no complicating general medical or psychiatric conditions (including other substance use disorder) were eligible. Women were not receiving other smoking cessation medication. Mothers were not eligible to participate if they were planning to move out of the New Haven area in the next 15 months after study enrollment, had medical complications that would interfere with testing the Sensordrone, or were actively suicidal, psychotic or unable to provide informed consent.

Screening and Enrollment: We used rolling enrollment (over a 2-month period) and women were followed up to 15 months after study start date. Following a brief description of the study by the Community Mental Health Ambassadors (**CMHAs**), mothers who live in New Haven and have been trained as research assistants, at a woman's prenatal visit at YNHH or at a community hub visit, women were screened in person or over the phone for smoking status using the Fagerstrom Test for Nicotine Dependence (**FTND**), a six-item self-report form that gives a quantitative measure of the severity of nicotine dependence.(37) The study screening form collected personal contact information and significant other contact information as well as demographics and health history. An abbreviated version of the Mental Test Score (33) was used to determine any cognitive impairment or inability to provide informed consent. The CMHAs performed a brief in-person or phone screening, a more complete in-office screening for those still eligible (including submitting a urine specimen to confirm pregnancy and cotinine and to exclude other drug use), and obtained written informed consent.

The screening consent also included a Release of Information (ROI) from YNHH and other local medical providers to obtain medical records about pregnancy and smoking status, pregnancy complications and medical exclusion criteria. These records were reviewed to confirm medical conditions which may interfere with the results of the Sensordrone. A second Release of Information was completed with the consent to participate requesting information about pregnancy and delivery status.

All women were approached until the target enrollment has been reached.

Delivery of the Momba Live Long Intervention: After completion of screening, consents and intake interview, women were provided with a smartphone and data plan, a carbon monoxide sensor compatible with their phone, access to the Momba Live Long application, and training on its use by the CMHAs. This exchange of equipment and training occured at our office at the end of week 1 of study start date. Testing of CM lasted 12 weeks.

In office monitoring: Women were required to come into the office to perform in-person CO breath tests using the Sensorcon Sensordrone™ and Bedfont piCO+™ in order for us to continue to compare data on the reliability and validity of the Sensordrone. At each office visit women completed additional questionnaires and urine tests to measure cotinine levels to provide additional data on the validity of the Sensordrone™ and other drug use (to see if these other drugs affect how well the Sensordrone performs).

Financial incentives were delivered based on the CO breath test. We followed standard protocols for in office monitoring of smoking abstinence and the delivery of financial incentives in

pregnant and postpartum women. These included the provision to all participants of the Smoke Free curriculum in addition to the financial incentives to promote abstinence. We required women to report to our clinical office for 5 consecutive days for abstinence monitoring the first week of study enrollment. The frequency of in-office abstinence monitoring decreased to twice weekly in week 2. Frequency of visits in weeks 3-12 depended on accuracy of the Sensordrone; at most, in weeks 3-8 it was twice per week and in weeks 9-12 it was once per week. In-office visits for breath tests were not required after week 12.

Administration of Standardized Measures*:* All follow-up measures, with the exception of baseline, post, and 6-month post CM and 12-month post CM follow-ups (administered in-office by research assistants, and mostly on a laptop computer) were administered via the Momba Live Long application. Mothers were prompted by the Momba Live Long application upon login and push notifications, to complete the questionnaires at specified intervals. The outcome measures we assessed were: (1) acceptability of the smartphone application to low-income, pregnant women (as defined by the percentage of women who would recommend the site to a friend); (2) point and 7-day smoking prevalence as determined by the Timeline Follow Back assessment, and # of negative breath tests, (secondary outcome); and (3) correlation coefficients between the piCO+™ and the Sensordrone™ specific to expired CO measurement and verified through urine cotinine levels.

The Phen-X was used to generate diagnoses of depression, anxiety disorders (including trauma and stress disorders), and substance use disorders at baseline and 6-month follow-up. We will collect detailed information about enrolled mothers from the eligibility screening interview and baseline and outcome assessments. Specific instruments utilized and delivered via the Momba Live Long application and the in-person office visits included:
Smoking cessation outcome assessments- In addition to the results of the CO monitor (which only can detect nicotine levels up to 2 to 3 hours after a cigarette), urine will be tested in the office with a qualitative cotinine cassette test from Redwood Toxicology Laboratory and sent to the Dept. Laboratory Medicine, at Yale School of Medicine for confirmation and cotinine levels. Other drugs tested in the office using cassette and dip tests from Redwood Toxicology Laboratory will be for amphetamines, barbiturates, benzodiazepines, cocaine, methadone, Methamphetamine, opiates, PCP, THC and Oxycodone.Self-report of cigarette smoking history was collected with the timeline follow-back (TLFB) for the past 28 days. Measures at post, 6M post CM and 12M post CM included the Fagerstrom Test for Nicotine Dependence, and the self-report of cigarette smoking history using the timeline follow-back (TLFB) for the past 28 days.

Proposed Analytic Plan: The goal of the proposed analysis is to determine the feasibility of the web-based intervention and acceptability and perceived value of the Momba Live Long smartphone-based system. We will evaluate progress toward these goals looking specifically at: (1) ensuring a process exists to assess best practices and participant opinion and integrate them into Momba Live Long and (2) ensuring procedures exist to support and monitor intervention delivery and dissemination.

We will develop Momba Live Long**,** test it, observe the results, and provide feedback, tracking relevant process measures and repeatedly assessing:

- time burden, sensor functionality (including the establishment of validity of the reading with the traditional expired CO monitor), integration into daily lifestyle, requirements for additional training for women on the hardware (phone and sensor) and smartphone application, women's reactions to Momba Live Long's immediate incentive system, and unexpected or potentially adverse events (including loss/sale of equipment);
- number of women approached, consented, and # of logins to the application, time of logon, modules visited, time per module, time per sensor challenge, # of training sessions delivered by the CMHAs, # of contacts made by women to the CMHAs;

To quantitatively evaluate the *feasibility* and *acceptability* of Momba Live Long to postpartum women we will begin by calculating the number of women screened and eligible and enrolled. We will collect data on reasons women are not enrolled. We will consider a participation rate of $\geq$ 60% for eligible women between screening and enrollment as supportive of feasibility. We will evaluate retention and set a threshold of 80% for the Momba Live Long group. Since feasibility also depends upon compliance to the challenges or office visits through which contingency management is delivered, we will use challenge completion and in-office visit attendance to assess compliance. Mixed-effects regression models will be conducted as outlined above for group comparisons. Because number of visits attended is a count variable, random effects regression with a negative binomial model will be used which is appropriate for count data.(45) Additional procedures to evaluate abstinence from smoking are described below.

Data Analysis for Pilot RCT: Descriptive statistics will summarize the data on all screened and randomized subjects. Baseline demographic and clinical characteristics for the randomized groups will be compared using chi-square tests for categorical variables and analysis of variance for continuous variables. All continuous variables will be examined for adherence to the normal distribution using normal probability plots and Kolmogorov-Smirnov tests. Dropouts and completers will also be compared on baseline characteristics using the same approach. Data analyses will be conducted using the intent-to-treat principle. We will use mixed-effects regression models to compare the two groups (Momba Live Long vs. in-office contingency management) using SAS PROC MIXED version 9.3. These models allow for different numbers of observations per subject, use all available data on each subject, and are unaffected by randomly missing data. They are flexible in modeling the correlation structure of the data. In each model, we will include fixed effects of time, group (Momba vs. in-office) and time by group, and random subject effects. If there are concerns of informative dropout and/or informative intermittent missing data, we will use pattern mixture models to perform sensitivity analyses to our main analyses.

For the RCT dependent variables are the 7-day point prevalence of smoking abstinence rates i) at the end of the trial and ii) at 3-month follow-up. We will also compare 2-week continuous smoking abstinence rates at these time points. Smokers are considered abstinent based on self-reported smoking abstinence verified by CO levels <6 ppm and self-report abstinence based on the Timeline Follow Back. (50) Because abstinence is categorical, a binary random effects logit model will be used. (51) As a secondary analysis, we will add an indicator variable for intensity of utilization for Momba Live Long application to the model in order to determine if it contributes significantly to response. Given that this is a pilot, we are not powered

to detect a significant difference on our outcomes. However, we will develop effect sizes to estimate power for a larger study and we will evaluate the direction and consistency of effects. We use guidelines for Stage 1b studies, which suggest 15-30 participants per cell. (52) For the outcome of 7-day point prevalence for smoking abstinence at the end of the trial, and 15 subjects per condition, a 2-tailed alpha of .05 we will have power of 90% if we have the same effect size found in other studies of contingency management with perinatal women smokers. (34) In all likelihood, the effect will be smaller for the 3-month outcomes. However, these results will provide a reasonable estimate with which to power a larger study.