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And

"Supplement to Prevention Research Center: Parenting Among Women Who are Opioid Users, Project 2"

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DATA MANAGEMENT AND ANALYSIS

Data analyses and management will be supported in collaboration with the Data Science Core of the PWO Prevention Center, and will rely on resources and support from the center to test complex models associated with the specific aims of the project as well as management of data in the context of the larger dataset associated with the Center. Data management systems similar to those used in our other web-based research projects will be used to ensure the integrity of the analytic results. These systems entail the creation of scheduling algorithms and web-based data collection forms for each instrument. The collection system contains backup and protection routines that ensure confidentiality and preservation of the electronic records.

We will use accepted practices for handling missing data when appropriate. Maximum likelihood methods with time as a random variable, such as the mixed-effects regression models described below, allow the use of all available data and reduce bias associated with attrition and increasing power. These procedures can provide unbiased conclusions even with substantial attrition. We anticipate a participation rate through 12-month follow-up of at least 85% based on our previous FCU school-based efficacy trials and our current rate of participation and retention in our FCU Online randomized trial.

We will compare baseline characteristics of participants across conditions to test for significant differences; characteristics that differ across conditions will be used as covariates in subsequent analyses. Logistic regression analyses will be used to examine potential differences by study condition between dropouts and continuing participants on baseline measures. Attrition analyses will provide information about the external validity of the study, and interaction effects between condition and predictors will provide information about potential confounding effects.

AIM 1: WORK WITH COMMUNITY STAKEHOLDERS IN RURAL OREGON TO EXPAND THE FCU ONLINE TO TARGET EARLY CHILDHOOD (AGES 2-5) AND MOTHERS WITH OPIOID USE AND ADDICTION.

Focus groups and usability testing will be conducted and will be audiorecorded for subsequent transcription. Content analysis techniques will be used to analyze the transcript text from open-ended questions. Coding of text will proceed in two stages. First, a topical indexing coding dictionary will be developed to identify the text pertaining to particular topics generated by focus group and usability testing questions. Data management and data reduction will be supported by use of the ATLAS-ti text-analysis software that supports coding, organization, searching, and retrieval of qualitative data. The software is capable of generating text associated with single or multiple codes, and by

participant characteristics. A more-detailed coding scheme will be developed to capture the content, themes, or sentiment of responses within topics. Specific themes (i.e., content codes) within central concepts will be identified by the evaluation team, and all text pertaining to a specific topic will be coded individually by trained coders. Coder reliability for content will be determined through interrater comparisons of at least 20% of the randomly chosen text in major topical categories. This system of coding will enable us to understand the themes, or issues, related to particular topics, such as barriers to program engagement. It will also enable us to retrieve text illustrating the vocabulary used by participants to describe these issues. Analysis of participants' discourse may reveal statements about, for example, the way they describe program engagement or features that may contribute to intervention modifications. This qualitative data will be categorized into general themes, and the proportions responding to each category will then be tabulated. These responses will be used to evaluate strengths and weaknesses of the intervention approach and to guide further program refinement. Dr. Tasia Smith has expertise in qualitative approaches to analyses and will be responsible for this aim and analyses associated with our focus group data.

We will assess participant quantitative ratings during the usability testing phase in which the benchmark for acceptable ratings will be mean ratings of 4 or greater on a 5-point scale for each of the SUS items and an overall SUS rating of 80.3, which represents an "A" score. Program acceptability will also be demonstrated by (a) a high level of program usage (e.g., 80% of participants complete the FCU assessment and feedback sessions), and (b) a high degree of consumer satisfaction (e.g., mean ratings > 4 on a 5-point rating scale across satisfaction domains).

AIM 2. EXAMINE THE EFFICACY OF FCU ONLINE FOR RURAL FAMILIES WITH OPIOID USE: MAIN EFFECTS, MEDIATORS, AND MODERATORS.

RESEARCH HYPOTHESES. The hypotheses tested in this aim are (a) families in the intervention condition will show significant improvements on the primary outcomes (child problem behavior and school readiness) and secondary outcomes (parenting skills, parent self-regulation/executive control, and child self regulation/ executive control), compared with families in the control condition; and (b) the putative intervention mechanisms of parenting skills and child self-regulation will mediate (either partially or fully) the association between study condition and the longitudinal trajectories of the primary outcomes. Though we have no specific hypotheses regarding moderating mechanisms, we will also conduct exploratory analyses to examine potential moderators of intervention effects. See Statistical Design component of this proposal for additional information.

We will test whether change in the putative mediating mechanisms of parenting skills and self-regulation (e.g., baseline to 3 months) mediate the association between study conditions and longitudinal trajectories of the primary child outcomes (e.g., overall trajectories, 3- to 12-month change to establish temporal precedence of mediators). Such mediating effects will be tested using the strategies outlined by MacKinnon and Preacher and Hayes. We will assess the joint significance of the indirect pathways (i.e., the joint significance of the pathways from the predictor to the mediating variable and from the mediating variable to the outcome) using the bias-corrected bootstrap test, as recommended by Fritz and MacKinnon. We will also use the bootstrapping technique to test multiple simultaneous mediators proposed by Preacher and Hayes.

The moderation analyses will follow recommendations by Kraemer and colleaguesand analytic methods of Aiken and West, Jaccard and Turrisi, and Preacher et al. Each of the potential moderating effects (e.g., child biological sex, race/ethnicity, SES, service utilization; and neonatal abstinence syndrome) will be investigated by conducting the above-mentioned mixed-effects analyses for each outcome that incorporate the Moderator × Condition interaction term. We have no specific hypotheses for testing sex as a biological variable that would impact outcomes, but we will include sex as a moderator in these analyses. For example, we will test for individual differences in the effect of intervention response (e.g., child problem behavior trajectories) as a function of the participant's value of baseline moderator. Significant moderating effects will be further probed to understand the nature of the conditional relation using computational tools recommended by Preacher et al.

SAMPLE SIZE AND POWER. Using an intent-to-treat approach for the hypothesis of an overall intervention effect, with 127 participants per condition after accounting for 15% attrition across the 12-month assessment period, alpha set to .025 (to adjust for the two outcome domains), there is sufficient power (>.80) to detect a condition effect of Cohen's d = .30 or larger. Previous FCU efficacy trials have demonstrated medium-to-large effects for antisocial cigarette use, alcohol use, cannabis use, antisocial behavior, and family conflict. As reported in the prior research section, initial analyses of our ongoing efficacy trial of the FCU Online program demonstrated a medium effect size (d = .45) for improvements in child health behaviors, and small-to-medium effect sizes for child social/emotional behavior (d = .35), parenting self-efficacy and confidence (d = .37 – .41). Given that the effect sizes obtained in the previous FCU efficacy research and the FCU Online preliminary analyses are larger than the power estimates, we should be sufficiently powered to detect meaningful differences between study conditions.

AIM 3. EXAMINE FACTORS RELATED TO SUCCESSFUL UPTAKE AND IMPLEMENTATION.

RESEARCH HYPOTHESES. We will assess the feasibility of the FCU as an Internet-delivered intervention in rural communities with high levels of opioid use, including the extent to which participants engaged in the intervention, completed the program, and were satisfied with the program. We hypothesize that the FCU Online intervention will demonstrate feasibility based on benchmark analyses described below. We also hypothesize that website usage (dosage) and coach fidelity will be associated with significantly greater change in the primary and secondary outcomes.

SAMPLE SIZE AND POWER. With a sample size of 127 in the intervention condition (accounting for 15% attrition), with alpha set to .05 (two-tailed), there is sufficient power (>.80) to detect r = .25 (moderate effects) for the process analyses involving treatment acceptability, fidelity, and engagement.

Data Management and Analysis for Supplement Pilot Aim

Data management systems similar to those used in our other web-based research projects will be used to ensure the integrity of the analytic results. These systems entail the creation of scheduling algorithms and web-based data collection forms for each instrument, including backup and protection routines that ensure confidentiality and preservation of the electronic records. We will use accepted practices for handling missing data when appropriate. Maximum likelihood methods with time as a random variable, such as the mixed effects regression models described below, allow the use of all available data and reduce bias associated with attrition and increasing power. These procedures can provide unbiased conclusions even with substantial attrition. We anticipate a participation rate through three months of at least 85% based on our previous FCU school-based efficacy trials and our current rate of participation and retention in our FCU Online RCT (90%).

Aim 1: Adapt the FCU Online for young adult parents with a history of substance misuse using a prevention framework

Feasibility. Focus groups and usability testing will be conducted and will be audiorecorded for subsequent transcription. Content analysis techniques will be used to analyze the transcript text from open-ended questions. Coding of text will proceed in two stages. First, a topical indexing coding dictionary will be developed to identify the text pertaining to particular topics generated by focus group and usability testing questions. Data management and data reduction will be supported by use of the ATLAS-ti text-analysis software that supports coding, organization, searching, and retrieval of qualitative data. The software is capable of generating text associated with single or multiple codes, and by

participant characteristics. A more detailed coding scheme will be developed to capture the content, themes, or sentiment of responses within topics. Specific themes (i.e., content codes) within central concepts will be identified by the evaluation team, and all text pertaining to a specific topic will be coded individually by trained coders. Coder reliability for content will be determined through interrater comparisons of at least 20% of the randomly chosen text in major topical categories. This system of coding will enable us to understand the themes, or issues, related to particular topics, such as barriers to program engagement or adverse reactions to the content. It will also enable us to retrieve text illustrating the vocabulary used by participants to describe these issues. Analysis of participants' discourse may reveal statements about, for example, the way they describe program engagement or features that may contribute to intervention modifications. These qualitative data will be categorized into general themes, and the proportions responding to each category will then be tabulated. These responses will be used to evaluate strengths and weaknesses of the intervention approach and to guide further program refinement.

Usability. We will assess participants' quantitative ratings during the usability testing phase in which the benchmark for acceptable ratings will be mean ratings of 4 or greater on a 5-point scale for each of the System Usability Scale (SUS) items and an overall SUS rating of 80.3, which represents an "A" score. Program acceptability will also be demonstrated by (a) high level of program usage (e.g., 80% of participants complete the FCU assessment and feedback sessions), and (b) high degree of consumer satisfaction (e.g., mean ratings > 4 on a 5-point rating scale across satisfaction domains).

Aim 2: Conduct a pilot test of the efficacy of the adapted FCU Online developed in Aim 1.

Statistical design. Individual participants will be randomized to condition and will therefore be the unit of analysis in tests of condition effects in all statistical models. The pilot study will use a pre-post between-group design to examine differences between conditions in the intervention targets assessed at baseline and postintervention (3-month assessment point). Due to the limited sample size and duration of the pilot study, we do not expect to find differences between conditions for the more distal outcomes of opioid misuse or OUD.

Intervention effects and statistical power. We expect that participants receiving the FCU Online intervention will demonstrate improvements in the intervention targets compared to those assigned to the treatment-as-usual control condition. We will examine descriptive statistics and pre-post data to evaluate trends and outcomes, which will provide us with preliminary data to support further research with this population. Mixed-effects regression models will be used to examine post-test differences in the intervention targets between

the two study conditions controlling for baseline levels. With 100 participants and a two-tailed alpha of .05, the pilot study lacks sufficient power (<.50) to detect clinically meaningful effects (d = .30). As such, we will use the effect size benchmark of d > .30 standard deviation units for evaluating intervention effects rather than conducting formal hypothesis testing using p < .05. We will evaluate consumer satisfaction surveys after the pilot testing to access acceptability of this model to participants. Program acceptability will also be demonstrated by (a) high level of program usage (e.g., 80% of participants complete the FCU assessment and feedback sessions), and (b) high degree of consumer satisfaction (e.g., mean ratings > 4 on a 5-point rating scale across satisfaction domains). After implementation of the pilot study, we will review results with our stakeholders and obtain feedback on the intervention and outcomes, which will enable us to further refine the model for future uptake and dissemination.

Aim 3: Integrate novel passive sensing and active mobile phone data collection methods into the FCU Online to better understand risk for opioid misuse and points of intervention to reduce risk behavior.

Statistic design and analyses. Analysis of outcomes assessed during the one-week bursts of passive or active data collection methods surrounding each assessment time point will involve alternative mixed-effects models appropriate for measurement-burst study designs. Briefly, subjects (Level 3) will undergo three assessment time points (Level 2). Each time point will involve passive and active data collection methods that generate repeated measures of key study variables at Level 1 (e.g., moment-level affective tone, sleep routines, mood state, coping skills, and stress). The corresponding three variances of these mixed-effects models are between-subjects (BS), within-subjects-between-time points (WS-BTP) and within-subjects-within timepoints (WS-WTP). Unconditional models will describe the degree of BS, WS-BTP, and WS-WTP variability in outcomes. Conditional models will be specified to investigate whether study condition predicts variability in outcomes at each of these levels. Models will include random intercept and time effects to account for individual heterogeneity in levels within and trends across time points, as well as random effects for condition to allow heterogeneity across subjects in effects on outcomes. Because the pilot study is underpowered, we will use standard deviation effect sizes (d > .30) as the benchmark for determining clinically meaningful effects.