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Alcohol Use and Chronic Pain among Primary Care Patients

Protocol and Statistical Analysis

PROTOCOL

Design. The study was a block randomized two-group, between-subjects design. Participants were randomized to one of two intervention conditions (i.e., Smartphone Intervention Program vs. Treatment-as-Usual Control) following baseline based on a block randomization schedule stratified by sex at birth and level of heavy drinking (+/- 5 heavy drinking episodes).

Inclusion/Exclusion. Eligible participants were 18 years of age or older, fluent in English, engaged in primary care (i.e., had a primary care physician), experienced chronic non-cancer related pain, and reported heavy drinking. The chronic pain inclusion criterion was pain of moderate severity or greater in the past week that lasted for at least 3 months. Heavy drinking was determined by past month drinking that exceeded NIAAA limits (>7 for women > 14 for men) and/or the occurrence of one or more heavy drinking episodes in the past month. Participants currently using pharmacological approaches for pain or alcohol use were permitted in the study if medication doses were stable for at least two months. Exclusion criteria were: history of bipolar disorder/schizophrenia/ complicated alcohol withdrawal, psychological treatment for pain or alcohol use within the past 3 months, and planned surgery for a pain-related condition in the subsequent six months. Participants were also excluded if they did not have a smartphone.

Recruitment. Recruitment took place within primary clinic waiting rooms in a large urban hospital, through recruitment letters sent to patients from a hospital data base by permission of primary care provider, and social media. Patients from hospital-based recruitment efforts who expressed interest were then screened by phone. Study advertisements delivered through social media were linked to a preliminary, web-based screening form. Individuals who met initial eligibility criteria based on the web-based screening were contacted by a member of the research team for phone screening to determine eligibility.

Assessments

Sample characteristics. Participants completed a series of measures to assess demographic characteristics including race/ethnicity, marital status, education, and employment.

*Pain outcomes***.** The primary pain outcome for the trial was the Pain, Enjoyment of Life, and General Activity (PEG; Krebs et al., 2009). Participants rated the severity of their pain and the degree to which their pain interfered with enjoyment in life and general activity "in the past 7 days" using 0-10 scales. The PEG has excellent reliability and validity and has been widely established with medical populations. Secondary pain outcomes were past week pain severity rated on an 11-point scale and pain interference composite scores from the Brief Pain Inventory-Short Form (BPI)' (Dworkin et al., 2005).

Alcohol outcomes. The primary alcohol outcomes were frequency of heavy drinking episodes (women > 3 per occasion, men > 4 per occasion) in the past 30-days and mean number of drinks per week as assessed by the 30-day alcohol Timeline Follow-Back calendar method (Alcohol TLFB-30) (Sobell et al., 1979). Alcohol-related consequences were assessed with the Short Inventory of Problems-Revised (Kiluk et al., 2013).

Additional outcome assessments. Participants completed additional assessments to examine the transdiagnostic effects of the intervention including depressive symptoms with the PHQ-8 (Kroenke et al., 2009), days of cannabis use in the past 30 days (Rosen et al., 2000) and physical functioning from the PROMIS-29 v2.0 (Hays et al., 2018).

Feasibility, acceptability, health behavior change processes. A series of assessments were taken approximately 8-weeks following baseline to assess participant experiences with the intervention conditions and assess health behavior change. All participants completed indices of intervention satisfaction using a modified version of the *Client Satisfaction Questionnaire-8 (CSQ-8),* an 8-item validated measure of perceived value of treatment services (Kelly et al., 2018; Larsen et al., 1979). In addition, we used study specific Likert-type items based on the *Perceptions of Treatment Questionnaire (PTQ-17),* (Pincus et al., 2010) that provides descriptive

information about perceived comprehensibility and utility of the intervention. Finally, to provide initial data regarding hypothesized mechanisms underlying the intervention, we utilized pain and alcohol specific measures of the Goal Systems Assessment Battery (Karoly and Ruehlman, 1995). Participants rated their self-regulatory processes related to the behavior change goals of "pain management" and "moderating/limiting alcohol use" using 4-point 16-item Likert-scale measures ("not at all" to "very much"). To gather usability and acceptability data on the smartphone intervention itself, we examined rates of completion for the video modules, adherence to health coach instant messaging sessions, and completion of smartphone daily activities to assess intervention acceptability. We also assessed whether participants engaged with the optional skills library. Participants in the smartphone intervention condition also completed 3-items selected from the *Systems Usability Scale* (Brooke, 1996) to provide information about the experience of program use through subjective ratings

Conditions

Smartphone Intervention Program [MCBMAP Intervention (INTV]). The intervention utilized a self-regulation framework (Karoly, 2012) to integrate evidence-based approaches for hazardous drinking and pain including Motivational Interviewing (Miller and Rollnick, 2013) and cognitive-behavioral and self-management training (Morgenstern et al., 2007; Otis, 2007; Ruehlman et al., 2012; Sobell and Sobell, 1996). Participants first met with the health coach, who introduced the program, reviewed participants' experience of pain and prior treatment, provided psychoeducation on the interaction between pain and alcohol use, and presented the program rationale. Participants were then provided access to the smartphone app. Intervention content was delivered through a series of app-based video modules that were supplemented with a brief (15 minute) weekly health coaching session delivered through instant messaging. Each of the eight intervention weeks were conducted through the app and included viewing one or two short video modules, completing two daily check-in and activity surveys. In addition,

participants had access to a Skills Library which contained a brief summary of each of the skills learned throughout the program.

Control (CTL). Those in the CTL condition completed a single videoconferencing session with the health coach which consisted of a brief review of the participant's pain and treatment history, psychoeducation about the interactive effects of pain and alcohol, discussion of resources available for pain and alcohol use, and the option to review information regarding available local and web-based behavioral health and wellness resources to address pain and alcohol use. These procedures are consistent with a treatment-as-usual-strategy to address these conditions in the clinic setting with available resources.

Training, supervision and fidelity assessment. The health coaches were advanced level PhD clinical psychology students who were trained for content related to both conditions. Supervision was provided biweekly and involved individual discussion of ongoing cases. Intervention fidelity assessment was conducted through a checklist of session components (specific to condition) conducted by research assistants based on audio-recordings and instant messaging transcripts.

Procedures

Participants were screened by phone and, if eligible, scheduled for an initial visit conducted through a videoconferencing platform. During the initial visit, participants were consented, completed a 50-minute baseline assessment, and were then randomized to the Control or Intervention condition. Participants then met with a study health coach for approximately 20 minutes through the videoconferencing platform. Those randomized to smartphone intervention program concluded the initial videoconferencing visit by downloading the study smartphone application and learning the procedures for using the app. The post-intervention and primary follow-up assessments were conducted 8 and 16-weeks following baseline respectively by a research assistant who was blind to study condition. All assessments were conducted using a videoconferencing interviewing assessment method supplemented with

on-screen displayed measures. Study data were collected and managed using REDCap electronic data capture tools (Harris et al., 2009). Participants were compensated for their time and effort related to assessments and paid $50 for each assessment session.

Participants in the smartphone intervention condition, completed 8-weekly video-modules to learn new skills through the app and then completed two daily surveys to practice skills and evaluate outcomes over the subsequent week. Brief (approximately 15 minute) weekly health coaching sessions conducted through text messaging were scheduled to reinforce learning, identify barriers, and support program engagement. Participants were provided with technology support via a “troubleshooting” form designed for the program and the study research assistant. Participants were reminded via text message the day before and the day of each weekly instant messaging health coaching session.

STATISTICAL ANALYSES

The goals of this study were to provide information about the feasibility and acceptability of the intervention and preliminary information about the utility of this approach for reducing pain and heavy drinking (primary outcomes). Descriptive analyses provided information about intervention engagement, usability, and satisfaction while effect size estimates were computed to provide preliminary information about intervention efficacy.

Feasibility of methods and procedures were evaluated with descriptive data on the percent of patients screened, percent of eligible patients enrolled, and percent of patients who completed assessments. For those in the Intervention condition, adherence rates for the percent of modules completed and the percent of coaching sessions attended were assessed. Patient satisfaction with the intervention and treatment adherence, mean and median treatment satisfaction ratings were calculated based on measures described above.

Analyses of intervention impact were based on the full sample of participants who completed baseline and were randomized to condition. Lost to follow-up primary and secondary outcomes was defined as missing the 16-week assessment. For the primary analyses (i.e., PEG, heavy drinking, weekly drinking), multiple imputation was used to address missing outcome data and the full randomized sample was included. Completer analyses were conducted as sensitivity analyses for the primary outcomes and for all remaining outcomes. We estimated effect sizes using f^2 calculated from regression analyses, controlling for corresponding baseline values. For pain analyses, we also followed recommendations from the IMMPACT trial (Turk et al., 2008), and examined the percent of participants who exhibited moderate clinical improvement based on reductions of 30% and substantial clinical improvement based on 50% reduction in PEG scores.

Because the primary alcohol outcomes (i.e., number of heavy drinking episodes, number of drinks per week) were skewed, transformations to drinking data were required to provide an effect size estimate to parallel pain outcomes (i.e., f^2). To reduce the effects of extreme values,

one drinking quantity outcome greater than 3 SD was recoded to one greater than the next largest value (Tabachnick and Fidell, 2013). Alcohol outcomes were square root transformed in each analysis. Due to sex differences in consumption, analyses with alcohol outcomes were conducted with sex at birth as a covariate along with the corresponding baseline alcohol variable. Pooled estimates from multiple imputations were used for each of these primary outcomes.

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