ADDITION TREATMENT OUTCOME MONITORING STUDY

PROTOCOL AND STATISTICAL ANALYSIS PLAN

Kevin Hallgren, PhD

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MEASURE SCHEDULE

Instrument	Abbrev.	Screen	Baseline	Week 6	Week 12	Week 26
Alcohol Use Disorder Identification Test – Consumption Version	AUDITC	x				
Eligibility criteria, self-report	ELIG	x				
Eligibility criteria, HER	ELIG_EHR	x				
Follow-up cover sheet	FUP		x	x	x	x
Contact information	CONTACT	x	x	x	x	x
Demographics	DEMO		x			
Technology use	TECH		x			
Substances focused on in treatment	SUBSTANCES		x			
Treatment Goal	TXGOAL		x			
Short Inventory of Problems (Lifteime)	SIPL		x			
Weekly check-in (if not completed remotely)	CHECKIN		x	x	x	x
ASI-LITE (alcohol and drug consumption past 30 days)	ASILITE		x	x	x	x
AUD checklist	AUDCHK		x	x	x	x
SUD checklist	SUDCHK		x	x	x	x
Brief Situational Confidence Questionnaire	SEQ_SUBSTANCE		x	x	x	x
Readiness Rulers	RR		x	x	X	x
Penn Alcohol Craving Scale	PACS		x	x	x	x
PHQ-9	PHQ9		x	x	x	x
Service use	SERVICES		x	x	x	x
Usability of check-in survey	USA_SURVEY		x	x	x	x
Self-efficacy for check-in survey	SEQ_SURVEY		x	x	x	x
Working alliance inventory, short form	WAISF		x	x[1]	x[1]	x[1]
Treatment satisfaction	TXSATIS		x	x[1]	x[1]	x[1]
In-session discussion survey	INSESS		x	x[1]	x[1]	x[1]
Audio recording of sessions (if opted in)	AUDIOCONSENT			x		
Qualitative experiences using ATOM tool	ATOM_EXP			x	x	x
Qualitative experiences being in the study	STUDY_EXP				x	x
EHR measures (completed by RA)	EHR					x
Demographics, clinicians	DEMO_CL		x			
In-session discussion survey, clinicians	INSESS_CL			x[1]		
Dashboard usability, clinicians	USA_CL				x	

White background = complete by patients. Gray background = completed by clinician

[1] = Completed only if the patient has attended treatment at HMHAS since the last completed assessment.

STUDY FLOW - CLINICIANS

Recruitment (clinicians)

- **Clinician** participants will be recruited through verbal announcements at staff meetings and by placing letters inviting them to participate in clinicians' mailboxes.
- The research team will make efforts to recruit clinicians prior to recruiting patients.

Screening and Eligibility (clinicians)

- Eligibility will be extended to all clinicians who are employed within the Addictions Clinic or who are identified as harm reduction therapists for patients with substance use disorders within the Harborview Mental Health and Addictions Services (HMHAS) clinic.
- Eligibility criteria will be confirmed by research staff in a private area, typically in the clinician's office or in our research office (which is in the same building as the clinic).
- When a clinician enrolls, they will complete a demographics questionnaire and be informed about the procedures that some of their patients may experience if they enroll in the study.
- We will ask if the clinician wishes to opt-in to audio recording one treatment session with any of their patients who will enroll in the study. Clinicians will be told they can opt out at any time, and that these audio recordings will only be allowed if both the clinician and patient opt-in to audio recording.
- We will offer clinicians brief training on how to use an online dashboard that presents the results of the weekly "check-in" survey that some of their patients may complete in this study.

When a clinician is the primary counselor for a patient who is enrolled in the study:

- If the clinician's patient is in the **green group**, the clinician will receive an information-only email from the study staff notifying them that their patient is in the study and that their weekly check-in results WILL be available for review.
- If the patient is in the **blue group**, the clinician will receive an information-only email from the study staff notifying them that their patient is in the study but their weekly check-in results WILL NOT be available for review.
- For patients in either group, the email will also notify the clinician that we will ask them to complete brief, questionnaires at 6 and 12 weeks, described below.

Brief questionnaire at 6 weeks after a patient enrolls in the study:

- Clinicians will be emailed a REDCap survey invitation. The survey will ask them to describe how much their most recent treatment session with the identified patient was focused on the each of the topics that are measured by the weekly check-in.
- If the patient and clinician both opted-in for audio recordings, research staff will work with the clinician to facilitate audio recording of a one-to-one counseling session near the six-week time point.

Brief questionnaire at 12 weeks after the patient enrolls in the study (green group only):

- Clinicians will be emailed a REDCap survey survey invitation. The survey will ask them to rate the usability of the dashboard used for reviewing patient progress with their patient.

Notification at 24 weeks (green group only):

- Clinicians will be notified via email that their patient has completed the study. The patient will no longer be able to complete weekly check-ins; however, the check-ins they have completed will remain available for clinicians to see for as long as the study is active.

End of study (after clinician's patients have all completed the study)

- Clinicians will be invited to complete a 30-minute qualitative interview with a member of the study team, focusing on providing open-ended feedback about the dashboard (e.g., what they liked about it, what they didn't like about it, what we could do to improve it).

STUDY FLOW - PATIENTS

Recruitment

- **Patient** participants will be recruited through flyers and handouts placed in the clinic (e.g., at check-in desk, in the waiting area, information desk).

Screening

- Patients who are interested in participating will typically be screened via telephone; however, they may occasionally be screened in person in a private research office in the same building as the HMHAS clinic if the patient prefers an in-person screening. Research staff will work to ensure adequate privacy (e.g., conducting screening in research office, asking patients if they are in an area with enough privacy to discuss sensitive questions during telephone interviews).
- During the screening, an RA will provide a brief overview of the study, including that the study duration is up to 6 months long and that participation is completely voluntary.

Eligibility criteria will be assessed in the screening process. Criteria include:

- At least 18 years old.
- Self-reports that they are a patient at HMHAS clinic.
- Self-reports that they are receiving services at HMHAS clinic for an alcohol or drug-related concern.
- Has a smartphone with a working phone number and a mobile plan that allows text messages and internet connection.
- AUDIT-C score indicates past-year hazardous drinking (summed score is at least 3 or 4 for women or men, respectively), or self-reports any drug use for non-medical reasons in the past year.
- Does not anticipate moving away from Seattle within 6 months.
- Does not anticipate becoming incarcerated in next 6 months.
- Able to speak and read English (based on self-report).
- Must be receiving clinical services from an HMHAS clinician who is also participating in the study, which will be evidenced by having attended at least 3 appointments with a participating HMHAS clinician that were either completed within the past three months or are scheduled to occur within the next three months, verified by the electronic health record.
    - The above criterion will only be assessed if the RA is given verbal consent by patient to log into the Harborview/UW electronic health record to confirm this information.
- Eligible patients will be provided more information about the study, including the software we're testing, the duration and scope of involvement, and the expected procedures.
- We will take time to answer any questions.
- We will schedule a three-hour in-person appointment to review informed consent and complete baseline assessments.

Condition Assignment

- Participants will be non-randomly assigned to one of two study conditions: the **blue group (measurement-only)** or the **green group (measurement and feedback)**.
- Assignment to conditions will be determined as follows:
    - The first 20 participants who enter the study will be enrolled in the **blue group** and the rest will be assigned to the **green group**.
    - However, if less than 20 participants have enrolled by the 6th month of recruitment (i.e., due to slow recruitment), participants who are enrolled after the 6th month of recruiting will be assigned to the **blue group** and the **green group** in a balanced order.
- The only difference between these groups is that participants in the **green group** will have their results on the weekly check-in survey shared with their clinicians, whereas participants in the **blue group** will not have the results of the weekly check-in surveys shared.
- Participants and researchers will both have full knowledge of which group the participant is in, as well as the implications of being in either group (i.e., fully transparent, no blinding or deception).
- To ensure that patients understand the implications of the condition they are assigned to, we will complete the following steps during the consent process. Research staff will show the participant a paper form with a description of both conditions (**blue group** and **green group**) and will circle the condition that the participant was assigned to. The participant will then verbally describe their understanding of that condition assignment to the research staff. When the participant's understanding is adequate, the participant will initial the form to indicate their understanding of the study condition they are in. If the participant is unable to adequately describe the group they are in, the RA will re-describe the conditions and will again ask to confirm the participant's understanding. If the participant is still unable to understand adequately, the participant will be compensated for completing the baseline assessment but will not advance further into the study.

Setup and complete first "weekly check-in" survey

- The RA will describe the "weekly check-in" surveys, which will be sent to patient participants via a personalized REDCap link that is emailed or text messaged to patients through REDCap. The research staff will enter the participant's contact information into REDCap which will then send the participant their first weekly check-in via email or text message. The participant will be asked to complete the check-in during the baseline appointment on their smartphone (if possible) or on a computer in the HMHAS clinic. The RA will help instruct the participant as needed on how to open the survey link, complete the questionnaire, and submit their responses.
- The RA will teach participants how to connect to Harborview's WiFi network (designated for visitors and patients) as needed.
- All participants will then complete the remaining baseline assessment measures.

Assessments

- Participants will complete interviews and questionnaires at baseline and 6, 12, and 24 week follow-ups. All baseline assessments will necessarily occur in person to allow fully informed consent and to initiate the study procedures. Follow-up assessments will occur in person whenever possible, but may occur via telephone and/or via web-based REDCap survey if a participant is unable or unwilling to complete follow-up (however, we will attempt to conduct these in person whenever possible).

- Assessment questionnaires may be completed on paper-and-pencil forms or entered directly into REDCap by patients via desktop computers in the research office. The questionnaires will be branded with the UW ATOM Study logo to help identify them as part of the study.
- Research staff will compensate patients with a $50 pre-paid Visa gift card (functionally similar to a debit card) for their participation. We anticipate that most follow-ups will occur in person, allowing the RA to pay participants at the appointment. If a participant completes a follow-up assessment remotely (via telephone or online), we will allow the participant to pick up their gift card in person or offer to mail it via US Postal Service to the participant, with the caveat that we cannot guarantee the gift card will arrive (e.g., it could be stolen if it is delivered to an unsecured location).
- Research staff will give the participant a business card with the name and contact information for their primary point of contact for the study at the end of each in-person assessment.
- Research staff will emphasize that patients may continue to participate in the study even if they discontinue treatment at HMHAS.

Weekly check-in surveys

- Participants will be sent a link to complete weekly check-in surveys once per week up to 24 times after the baseline appointment. Surveys will be sent automatically through REDCap and will use a customized link created by REDCap, which obviates any need to collect identifiers in the longitudinal surveys. Links to weekly check-ins will be sent to participants via text message or email (based on the participant's preference).
- After the 1st and 2nd weekly check-ins, an RA will contact participants via phone, text message, or email to inquire about their experience completing the questionnaire.
    - If the participant completed the questionnaire, the RA will ask about any potential challenges that could be encountered when completing the questionnaires (e.g., was the text large enough to read, were there any questions in the survey that were difficult to understand).
    - If the participant did not complete the questionnaire, the RA will ask about challenges that could have stopped them from completing the questionnaires, and will then attempt to help the participant troubleshoot those problems and encourage completion of the weekly check-in surveys.
- For the first three months of the study, an RA will proactively reach out to patient participants to assist with completing weekly check-ins if there is evidence of non-completion. For example, if participants do not complete weekly check-ins, the RA will contact the patient to inquire if they are receiving the surveys or unable to complete them (e.g., due to changes in phone number or loss of their personal smartphone).
- For months 4-6, we will evaluate the extent to which participants patients sustain their engagement with the survey after proactive outreach from RA's has ended. Automated survey reminders will continue to be sent to patients through REDCap, and patients may contact the study team for assistance or to inform us of changes in their contact information. However, RAs will not proactively reach out to patients to encourage or assist with survey completion. The purpose of this phase is to assess the *sustainability* of the tool when there is minimal involvement by the researchers.

Other activities during research period

- Research staff will periodically contact participants via text message, email, or phone to:
    - Schedule and remind participants of upcoming research appointments
    - Coordinate payments for involvement in the research

    - Check in regarding potential changes in contact information (e.g., if participant does not respond to surveys or messages sent by staff)
- Research staff will periodically review the participant's electronic health record to check for updated contact information and to assist with scheduling follow-ups (e.g., to help schedule follow-up research appointments with their clinical appointments, which will reduce the burden of making extra trips to Harborview to complete the study assessments).
- Throughout the study, all decisions that are made in therapy sessions, including any medications prescribed, will be decided by clinical staff as part of clinical care. The research team will not prescribe, advise, or provide consultation on such decisions.

Counseling Session Recordings

- If the patient and their participating clinician have both opted-in to recording sessions, then research staff will work with the patient and clinician to set-up materials for audio recording near the 6-week follow-up point.
    - Prior to the patient's scheduled counseling session, research staff will give their clinician an envelope with a consent form allowing for permission to audio record, (the form will use large, bold font to indicate that both the patient and clinician must both agree to recording on the date that the recording is made and must sign the form prior to the recording). The envelope will also include a digital audio recorder (with any pre-recorded audio wiped from the device) along with instructions on how to use the recorder. Clinicians will be asked to keep these materials in a drawer or cabinet in their office, which per clinic policy must remain locked at all times.
    - Within 2 business days of the completed session, the research staff will retrieve these materials from the clinician. Signed consent forms will be filed and audio recordings will be removed from the recording devices.

EHR Coding – 6 months after baseline

- Research staff will review patients' UW/Harborview electronic health records (via EPIC) for the six-month period after the participant enrolls. EHR data will never be printed or downloaded; it will only be coded using research forms. Direct identifiers will not be recorded on research forms. Research staff will use EHR coding forms to obtain the study information and will then enter information from these forms into REDCap.

DATA ANALYSIS PLAN

- Descriptive statistics, data visualizations, and multilevel models will be used to characterize measures of acceptability and engagement with the intervention with 95% CI's. Statistics on enrollment (e.g., number of patients and clinicians eligible and willing to participate), measure completion, and dashboard use will be used to assess acceptability and engagement.
- Linear regression models will compare participants in the measurement-only (blue group) vs. measurement and feedback (green group) conditions on in-session discussion topics.
- Multilevel models will generate effect size estimates and 95% CIs to examine whether TABLET sessions have differential degrees of changes in weekly progress and measures. Models will be two-level (repeated measures nested within patients); however, the need for three-level models (patients nested within clinicians) will be tested. Fixed effects for study condition and fixed effects for time will be used to generate growth curve models of change over time in each

TABLET-recorded measure. Growth-curve modeling will allow testing between conditions in the amount of change over time for each construct.