An Ounce of Prevention: Rationale and Design for a Pre-Randomization Discussion to Strengthen Adherence and Retention

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Introduction & Aim

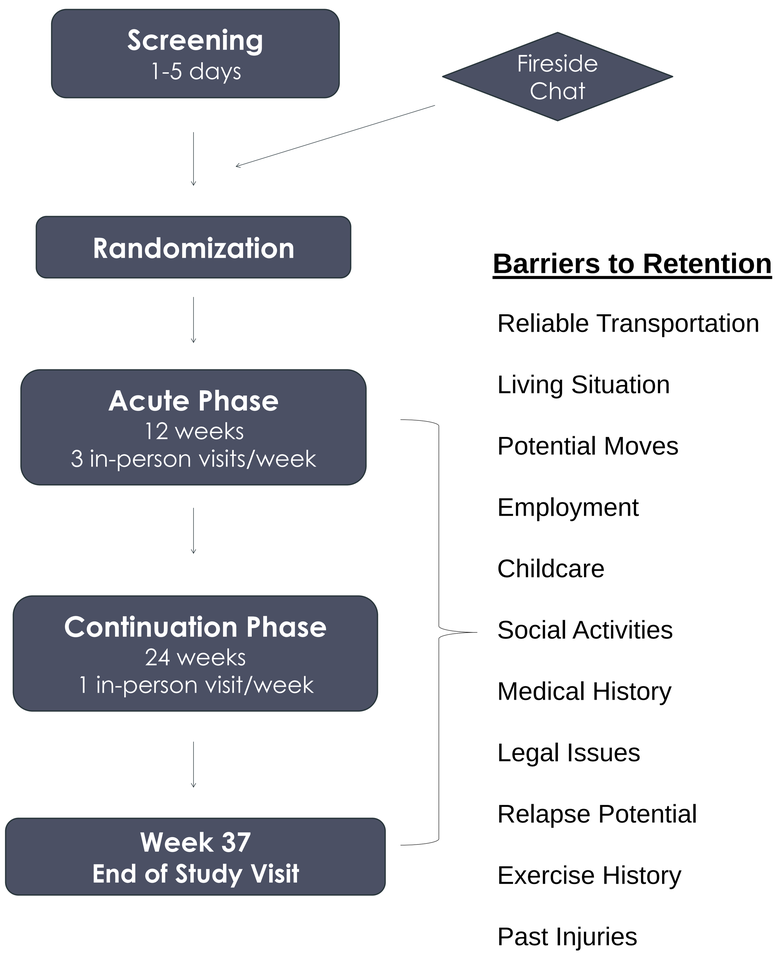
- High retention rates are critical for successful clinical trials.
- Participants in clinical research on stimulant abuse have demonstrated variable attendance at intervention and research visits (Dutra et al., 2008).
- Reasons for decreased attendance and barriers to retention should be addressed *prior* to becoming an issue (Goldberg and Kiernan, 2005).

Aim: Implement an approach to help the study team and study candidate make an informed decision in a relatively short period of time about research participation that spanned 9 months for candidates whose plans were often uncertain. The approach was consistent with our eligibility criteria and focused on proactive identification of barriers to retention and adherence and solutions to these potential difficulties.

Study Background

- The **ST**imulant **R**eduction **I**ntervention using **D**osed **E**xercise (STRIDE; CTN-0037) trial recruited individuals who were abusing stimulants (and not opioid dependent).
- Recruitment and randomization occurred during residential treatment.
- Study participation continued for 9 months, including residential treatment (21-30 days where feasible) and community-based treatment.
- Eligible participants were randomized to dosed-exercise or health education.
- Full details of the protocol and eligibility criteria are published (Trivedi et al., 2011).

Study Design



Barriers to Retention

- Reliable Transportation
- Living Situation
- Potential Moves
- Employment
- Childcare
- Social Activities
- Medical History
- Legal Issues
- Relapse Potential
- Exercise History
- Past Injuries

Methods

The "Fireside Chat"

•Formal discussions about study participation were scheduled between study staff and potential participants prior to randomization.
•The STRIDE approach was nicknamed the "Fireside Chat" to denote the warm, supportive tone of the conversation.
•Topics first addressed during the informed consent were revisited.
•Proactive identification of possible barriers and potential solutions was emphasized.
•"The Chat" was scheduled after a majority or all of the baseline assessments were completed and ideally one day before randomization.
•The collaboration typically lasted 30-45 minutes.
•Study staff paused frequently and participants were encouraged to ask questions throughout the conversation.
•Ideally the Chat was facilitated by a senior researcher and all staff were in attendance.
•The discussion ended by communicating enthusiasm and appreciation for the participant's time and willingness to pursue research involvement.

Specific Areas Highlighted and Addressed

•Rationale for the Chat due to attrition and missing data in past studies, underscoring the importance of having complete data to answer the research question.
•Detailed review of visit frequency/structure and study length.
•Detailed review of compensation and incentive structure.
•Personal barriers to retention and "fit" of the study in the participant's life.
•Differentiation of research and clinical staff with a focus on confidentiality.
•Detailed review of each study condition.
•Condition preference (if applicable) was acknowledged but 50/50 randomization was underscored.
•Uniqueness of the experience.
•Opportunity to inform treatment for others with substance abuse problems.
•Opportunity to improve treatment for themselves.
NOTE: Participants were asked to revisit this discussion at a later point (e.g., the end of the acute phase or if/when attendance became less reliable).

Questions used By Study Team	Intention of Question
Necessity of the Talk 1) How do you see the study fitting in your day-to-day life? 2) How have you have managed difficult commitments in the past? 3) What would it mean to you to commit to this study for the entire study timeframe (9 months)?	•Help the participant imagine what the real experience would be like. •Gauge the participant's abilities to overcome barriers.
Importance of the Research Question 1) What does it mean to you to be involved with this study? 2) How does it make you feel to think about your study participation potentially shaping treatment for others? 3) What is your most important reason for wanting to participate?	•Foster commitment and enthusiasm for research involvement. •Appeal to the participant's sense of empathy as their data could help/affect others.
Describe the Study from Start to Finish 1) What is your assessment of the time involvement relative to the personal and scientific benefits? 2) To what degree does the compensation affect your decision? 3) What is your preference for visit scheduling? 4) What are other times that you might be available?	•Allow the participant to express possible concerns. •Give the participant the opportunity to think through the visit scheduling.
Specific Barriers 1) What is your current transportation method? 2) How willing are you to use public transportation? 3) Where do you live currently? Thoughts on commute time? 4) What is your past/current occupation and work schedule? 5) What is your chance of moving during the study timeframe? 6) Do you have children? Do you have help with childcare? 7) What vacations are you planning (if any) during the study? 8) Do you have any upcoming surgeries/medical procedures?	•Give the participant the opportunity to enumerate potential barriers, as well as possible solutions to the myriad life events that may affect participation.

Methods (Cont.)

Questions used by Study Team	Intention of Question
Specific Barriers (Continued) 9) What medical ailments might affect study participation? 10) What legal issues have you experienced in the past? What legal issues are pending? 11) What else might come up for you during the study that could interfere with participation?	•Elicit full range of potential conflicts known to affect intervention and study visits.
Description of Interventions/Condition Preference 1) Which condition do you prefer? 2) If you are randomized to your less-preferred condition, how willing would you be to follow through with it (per the protocol)? 3) What factors might affect your ability to comply with (*each intervention)*? 4) In the past what has affected your commitment to similar obligations/commitments?	•Give the participant the chance to think through the specifics involved with *each* study condition. •Help the participant explore any reservations about the specifics of the intervention(s).
Separation from the CTP & Relapse Potential 1) How do you feel about your treatment providers here? 2) How would it feel for you to return here (for study visits) if you were to use drugs? 3) How comfortable do you feel divulging personal information about your drug use patterns to study staff?	•Explore feelings of shame & embarrassment that could make it hard for the participant to return following relapse. •Normalize experience of relapse. •Underscore importance of study participation. regardless of relapse •Emphasize research and clinical staff distinction and confidentiality.
Enthusiasm and Collaboration 1) What reservations do you have about the study? 2) What can we do to help you succeed?	•Express study team's commitment to help them succeed as a participant and foster collaboration.

Results & Discussion

- Anecdotally, one site noted retention improvements after Fireside Chat implementation and participants often expressed appreciation for taking part in the Fireside Chat.
- Any improvements cannot be solely attributed to the Fireside Chat as research teams were also becoming more accustomed to the protocol and participants.
- However, research team members were able to refer back to the Fireside Chat and more easily and openly discuss barriers to continued study participation.
- Clinical research and participants may benefit from a formalized discussion about realistic study expectations and potential barriers prior to randomization.
- Clinical research with ongoing participant contact should consider tailoring this approach to increase retention and future investigation with this approach is advised.

References

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