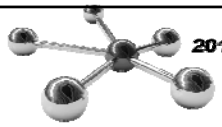

2011 Web Seminar Series

Strategies to Improve Treatment Adherence in CTN Research Protocols

Presented on **June 1, 2011** by:

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Produced by Liz Buttrey, NIDA CTN CCC Training Office

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Training Objectives

- Define adherence
- Identify ways in which adherence problems become evident
- Identify factors affecting adherence
- Identify adverse effects of poor adherence on research, participant, family and caregiver
- Describe strategies for improving adherence including motivational interviewing concepts

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Adherence

- The extent to which the research participant attends the required sessions of the protocol this includes:
  - Assessment sessions
  - Medication visits
  - Treatment sessions
  - Follow up visits

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Treatment Adherence
in Research Protocols

- Treatment Adherence Goals:
  - Desired dose is received by a maximum number of participants as possible
  - Adhere to the protocol as closely as possible
- Treatment entry & engagement
- Session attendance
- Treatment completion
- Task fulfillment (assignments)
- Goal achievement

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Benefits of Good Adherence

- Data
- Flags and triggers
- Adhering to the sessions
  - Better substance use clinical outcomes
  - Better mental health clinical outcomes
- Improvement in psychosocial functioning
- Lower rates of high-risk behaviors
- Lower relapse rates
- Lower readmission rates (psychiatric hospital, detox, rehab)

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Identifying Adherence Problems

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Proactive Identification and Management

- Participants must understand expectations of them during the study
  - Screening and consenting is invaluable
  - Proactive adherence protection is needed
    - Clarify possible issues that may present adherence conflict

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What are the ways you gather information to identify probable adherence barriers?

Researcher: "You'll be required to be at the clinic 3 times a week. We're open from 6am-2pm. Are you going to be able to get the clinic? So how would you be getting the clinic? Will it take you long?"

Researcher

Possible Participant: "Well I don't have issues with 3 times a week but I have a court date in July."

Possible Participant

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Prepare for a Marathon Not a Race

- Early (recruitment/screening)
  - Preparation of participants includes
    - Ensuring participants understand study and what is expected of them
- Initiation
  - Protocol induction and implementation
- Maintenance (*Sheppard them through*)
  - Participant engaged in experiment or control
  - Preserve treatment adherence
  - Good treatment exposure
  - Usher & Sheppard
  - Personalized based scheduling and planning

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Ways In Which Poor Adherence Shows

- Delay in seeking or entering treatment
- Non-compliance with study procedures
  - Urine testing
  - Being prompt to allow time for procedures
- Late or missed appointments
- Early dropout from the study
- Medication use and misuse
- Other

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Adherence Challenges
It Differs by Trial

Medication trial retention	Behavioral trial retention
• Logistical Considerations • Participant expectation of the drug • Subjective experiences varies and may impact adherence o ie; Buprenorphine vs. Methadone	■ Logistical Considerations ■ Number of weekly sessions ■ Length/type of sessions ■ Types of intervention • Group • Individual • Family

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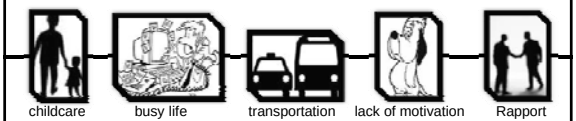
Factors Affecting Adherence



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Factors Affecting Adherence

- Client variables
  - Eg: motivation, symptoms, severity
- Relationship and social variables
  - Eg: support system
- Treatment and system variables
  - Eg: access to treatment

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Why Focus on Adherence (Engagement & Retention)

- In clinical practice outcome is generally associated with adherence to treatment in research there is no guarantee
- In research protocols you have more data for the analyses when participants adhere/retained to the study protocol
- Participants who adhere may do better
- Co-occurring clients have greater problems with adherence

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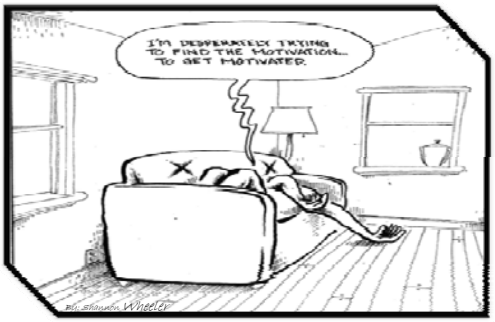
Why focus on adherence motivation?



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Motivation Variation

- Participants motivation to participate in research trials varies greatly and changes over time
  - Variation correlates with treatment adherence and retention
    - Participating for the money
    - Participating to stop drug use
    - Participant participation & completion varies
    - Participant participation due to lack of resources
- Understanding the participant is vital to managing participant motivations

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Motivation to Change

- There are two aspects of motivation
  - Problem acceptance: readiness to change
  - Treatment acceptance: readiness for help
- Co-occurring clients may have difficulty in either or both of these areas
- Who among us hasn't struggled with motivation to change at sometime?

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Relationship is Key

- Relationship between research staff and participants is **vital**
  - Assuring adherence
  - Data collection
  - Relationship value is critical
    - Study Participants value must convey
    - Participants valuing research staff
- Everyone involved has an impact

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Adverse Effects of Poor Adherence

- Participant
  - Less likely to benefit from the intervention
  - May be removed from the study
  - Negative effects of the addiction are likely to continue
- Protocol
  - Difficult to make statements with minimal data
  - Return on investment in the protocol
  - Uses staff and CTP resources
    - Locating participants

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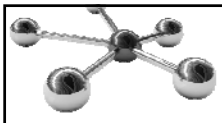

Adherence Improvement Strategies

Successful adherence and retention in research studies is a shared responsibility between research staff and study participants.

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Strategies to Improve Adherence - 1

- Be flexible in working with the participant
- Identify stage of readiness of participant
- Accept resistance and ambivalence as normal (normalize resistance)
- Anticipate non-adherence at various phases of treatment (especially early phase of treatment)

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Strategies to Improve Adherence - 2

- Help client anticipate personal roadblocks to completing the study
- Initial appointment: Write a "user friendly" letter or call the participant to remind him/her of appointment
- Talk to the participant
  - Research staff are more than data collectors
  - Personal rapport has great impact

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Strategies to Improve Adherence - 3

- Use outreach letters or phone calls to re-engage clients who miss appointments or drop-out
- Encourage study drop-outs to feel free to return for services if they change their mind in the future
- Make follow-up call to participants referred to other services

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Strategies to Improve Adherence - 4

- Continuously address adherence issues
  - Reasons for missed appointments
- Convey concern and empathy
- Be respectful and accepting of "reluctant" clients

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Strategies To Improve Adherence - 5

- Maintenance of staff / participant relationship
- Encourage client to discuss any concerns about the study
  - Address concerns about, and perception of, using study medications
  - Adjust medication dosage within protocol guidelines
- Talk to the participant *(the person)*

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Strategies to Improve Adherence - 6

- Provide education on the protocol
- Explore expectations, hope, and goals for the study
- Don't internalize adherence problems
- Incorporate motivational strategies
- Conduct a quick intervention to assess the issue(s)

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Strategies to Improve Adherence - 7

- Be participant oriented
  - Adapt to their needs vs. having them adapt to your needs
  - Be user friendly!
- Facilitate the use of other services or community resources
  - Transportation issues
  - Specialized medical care
  - Social services

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Motivational Interviewing

- Client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence (Miller & Rollnick, 2002)
- Used with many clinical populations
  - Substance use disorders
  - Psychiatric disorders
  - Medical disorders

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What would you do in this situation?

Participant :
"I'm thinking about dropping' out of the study. It's getting' to be a hassle here. Maybe I'll look for treatment somewhere else."

Researcher:
"Sounds like there are something going on. Let's a few minutes to talk about it."

Participant

Researcher

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Conclusions

- Adherence problems show in many ways
- Many factors affecting adherence
- Poor adherence has consequences
- Strategies for improving adherence
  - Benefiting research
  - Benefiting participants

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Take Home Message!

- Successful adherence and retention in research studies is a shared responsibility between research staff and study participants.

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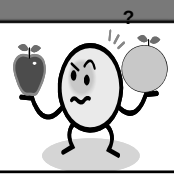
Questions or Comments?



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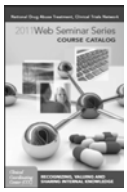
Mark Your Calendar



- **July 20**
  - Relapse Prevention
- **August 10**
  - Certificate of Confidentiality
- **September 14**
  - Integrated Treatment of Co-Occurring Disorders
- **October 12**
  - Informed Consent
- **December 7**
  - A New Look at Manual of Procedure (MOP) Development

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