Workshop:
Getting SMART about Developing Individualized Sequences of Health Interventions

Using SMART Design Technology to Develop an Adaptive Reinforcement-based Treatment Strategy for Pregnant Drug Abusers

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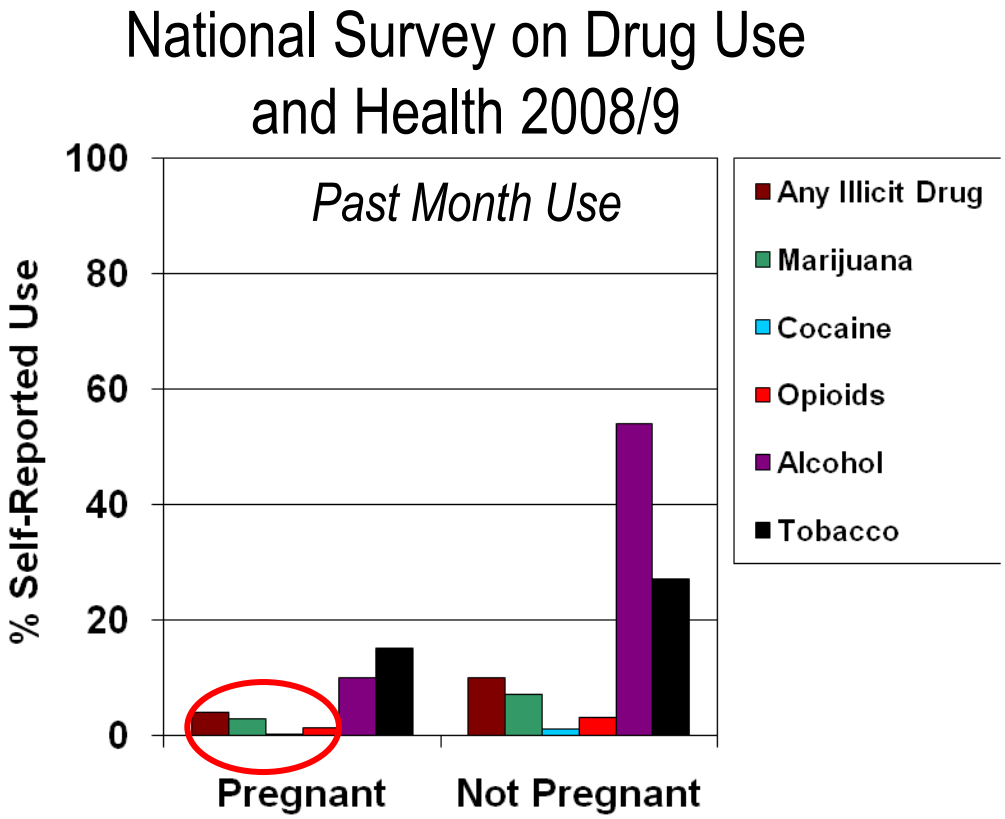
Outline

1. Complexities of the Problem
2. Clinical Setting
3. Role of Behavioral Treatment
4. HOME II Study

1. Complexities of the Problem



- **Although pregnant women use illicit drugs less frequently than alcohol and tobacco, the women who use illicit drugs receive extraordinary scrutiny by society**
- **Drug addiction almost always begins before pregnancy and in the context of past and current exposure to factors that lead to increased vulnerability**

1. Complexities of the Problem

TREATMENT

Pregnancy can be a promising time to evaluate behavior change

1. Complexities of the Problem

Issues Facing Pregnant Drug Users and Their Children

- Exposure to violence and trauma
- Generational drug use
- Lack of formal education
- Lack of job acquisition/maintenance skills
- Gender inequality/male-focused society
- Legal involvement
- Multiple drug exposure
- Limited parenting skills and resources
- History of child abuse and neglect
- Multiple psychiatric issues
- Unstable housing
- Lack of positive/supportive relationships
- Food insecurity/lack of nutrition

2. Clinical Setting

Center for Addiction and Pregnancy

Mission Statement

- Address Barriers to Care
- Improve maternal and infant outcomes
- Conduct clinical research to generate new knowledge to improve maternal *and* neonatal outcomes

2. Clinical Setting

Comprehensive Care

- **Interdisciplinary approach**
  - Psychiatry
  - Psychology
  - Obstetrics
  - Pediatrics
  - Nursing
  - Social Work
- **Multiple modalities**
  - Medically-assisted withdrawal and aftercare
  - Methadone with behavioral treatment

CAP Efficacy

2. Clinical Setting

Clinical measure:	CAP (*n*=100)	No Treatment (*n*=46)
Prenatal visits	8	4
EGA (mean week)	39	35
% positive at delivery	37	63
Infant birth weight (grams)	2934	2539
Apgar scores (1 minute)	8	7
% NICU use	10	26
Length of hospital stay (days)	7	39

All group comparisons are significant: $p \leq .05$

(Data adapted from Svikis et al., 1997)

- Investing **$6,639** in prenatal drug treatment services resulted in *net* savings of **$4,644** in NICU costs.
- Although CAP is cost-effective, many women continue to drop out of treatment prematurely and/or do not respond to treatment

3. Role of Behavioral Treatment

Reinforcement-Based TREATMENT:

A Novel Approach to Treating Substance Abuse During Pregnancy

By Michelle Tuten, MSW, LCSW-C, Hendree Jones, PhD, Jennifer Ertel, MS, Judith Jakubowski, MA and Joan Sperlein, BS

Drug use during pregnancy is associated with adverse prenatal and post-natal consequences. Despite these complications, an alarming number of women are unable to cease drug use once they become pregnant. This population has a number of medical, obstetrical, psychosocial and psychological needs that challenge the skill of providers and the resources available to the treatment community. Novel approaches are needed to effectively treat drug abuse during pregnancy and to prevent postpartum relapse. This article reviews the prevalence of substance use during pregnancy; presents barriers that impede treatment access and retention for pregnant women; and presents a novel behavioral intervention, Reinforcement-Based Treatment (RBT), for initiating abstinence and preventing relapse in this vulnerable population.

The adverse consequences of drug use during pregnancy are well known. Systematic methods for assessing and quantifying drug use during pregnancy do not exist; therefore, the rate of infant drug exposure is unknown. In a survey of pregnant women aged 15 to 44, 18 percent reported smoking cigarettes; 9.8 percent reported drinking alcohol in the past month; and 4 percent reported using one or more illicit drugs in the past month (SAMHSA, 2005). Since many estimates are based exclusively on self-report, these numbers are likely underestimates of the true prevalence of licit and illicit substance use during pregnancy. Prevalence estimates of illicit drug use in cities with large teaching hospitals are much higher, ranging from 11 percent to 40 percent of pregnant patients receiving care at these facilities (Jansson & Velez, 1999). Chasnoff and colleagues (1990) found that 15 percent of women tested for drug use at first prenatal care visit were positive for one of more substance.

Pregnant, drug-dependent women often enter treatment with a complex picture of medical, psychological, and psychosocial needs. They frequently have medical conditions related to drug use or a drug-using lifestyle, including: infectious diseases such as hepatitis B and C and HIV; sexually transmitted diseases; cellulitis; abscesses; and endocarditis (Jansson, et al, 1999). Pregnancy-specific complications of drug use include miscarriage, premature labor, preeclampsia, and infant outcomes such as intrauterine growth retardation, low birth weight, and neonatal abstinence syndrome (Svikis and Higgins, 1996; Finnegan, 1991).

It remains unclear whether adverse maternal and infant outcomes are the result of substance use, the interaction among multiple substances (including nicotine), and whether these interac-

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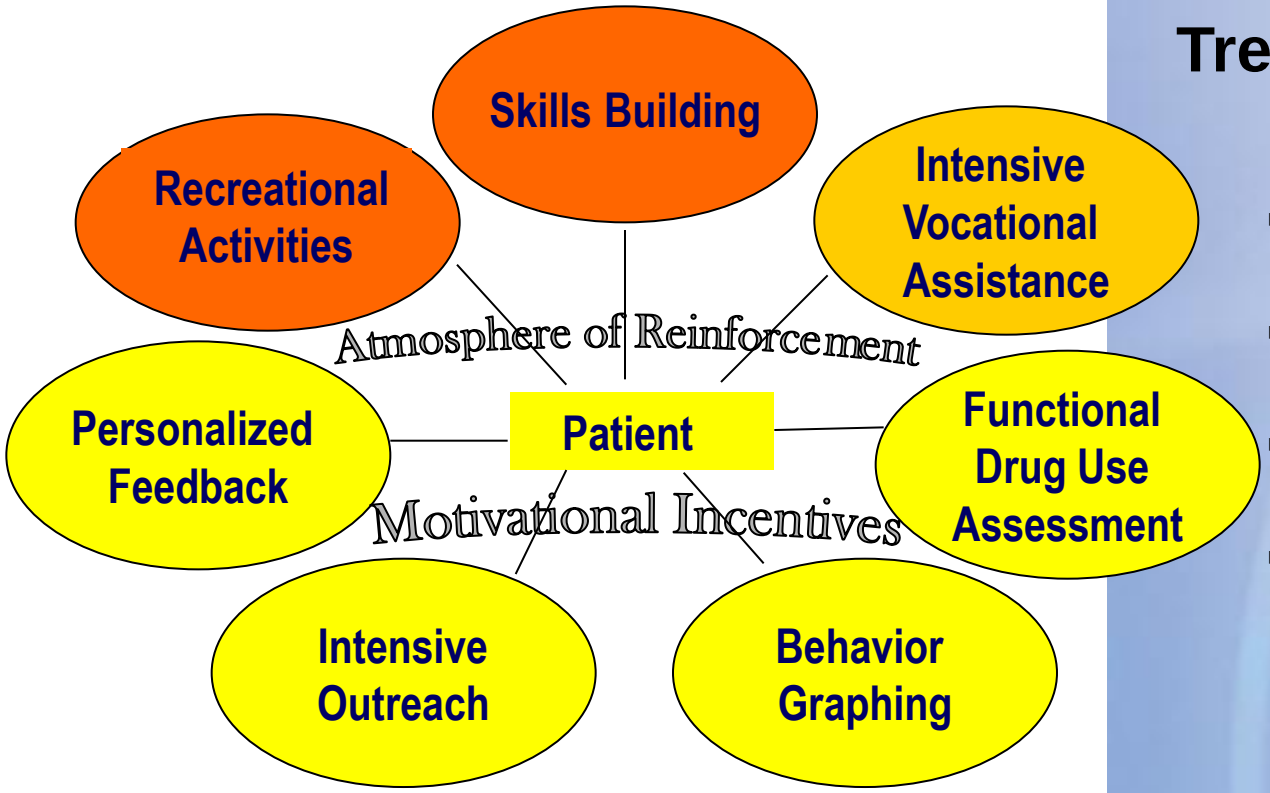
Guiding Principles

- Drug addiction occurs in absence of alternative positive reinforcers
- Drug use behavior can be controlled using operant reinforcement procedures
- A behavior followed by positive consequences is more likely to be repeated
- Eliminate drug use by making other behaviors in a person's environment more appealing

3. Role of Behavioral Treatment

Treatment Elements



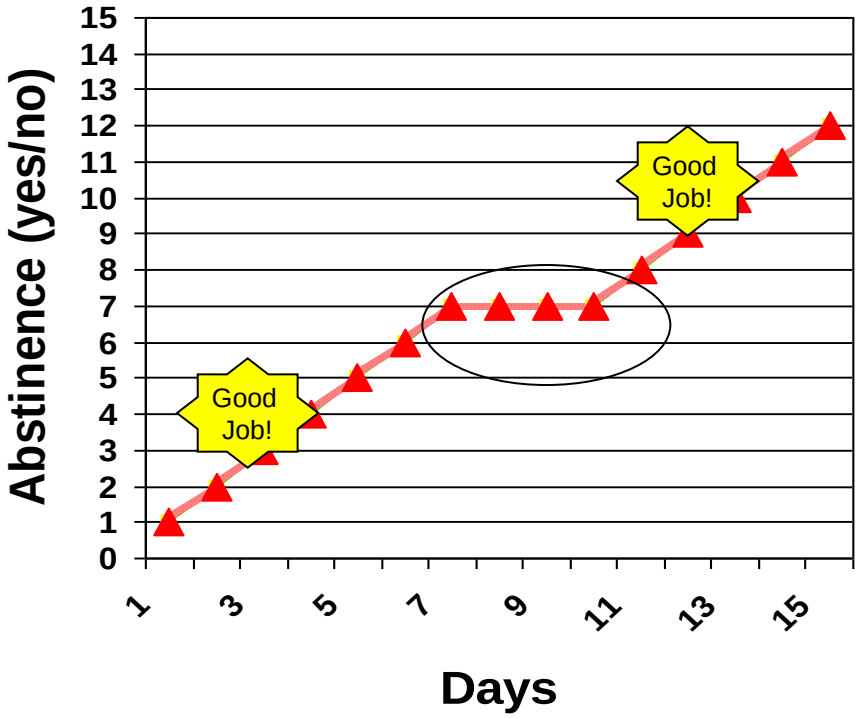
Treatment Objectives

- Drug abstinence
- Purposeful days
- Fulfilling social relationships
- Engagement in recreational activities that compete with drug use

3. Role of Behavioral Treatment

Example of Close Behavioral Observation:

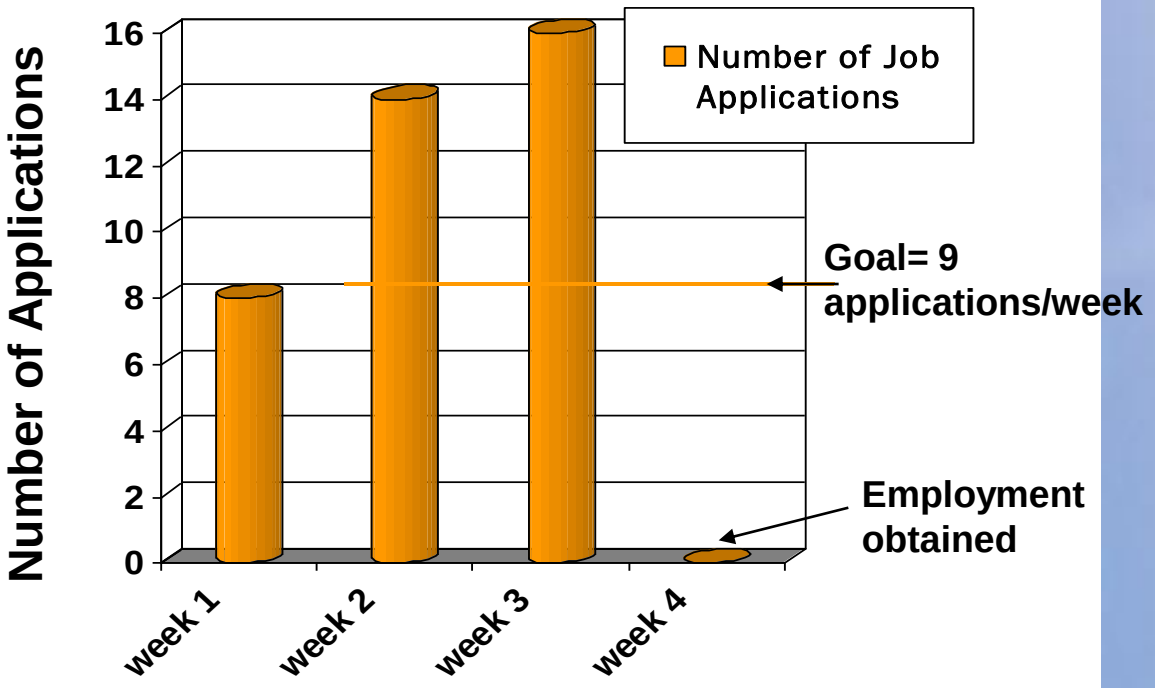
Drug Free Days



- Specific treatment goals are selected based upon counselor and patient discussions
- Larger goals are broken into smaller goals
- Positive reinforcement given for successes

3. Role of Behavioral Treatment

Example of Behavior Tracking

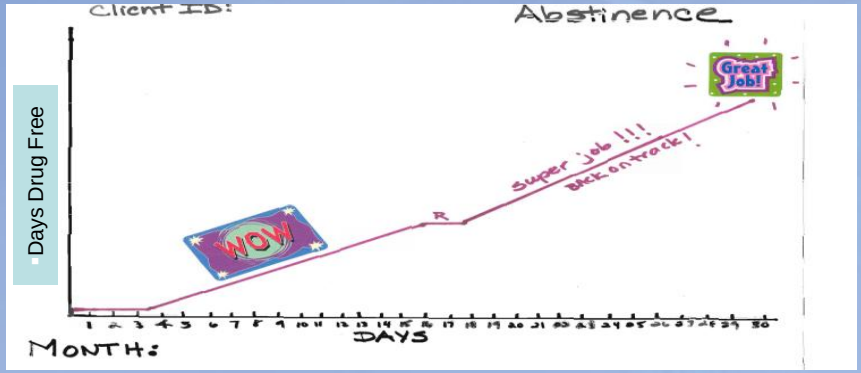


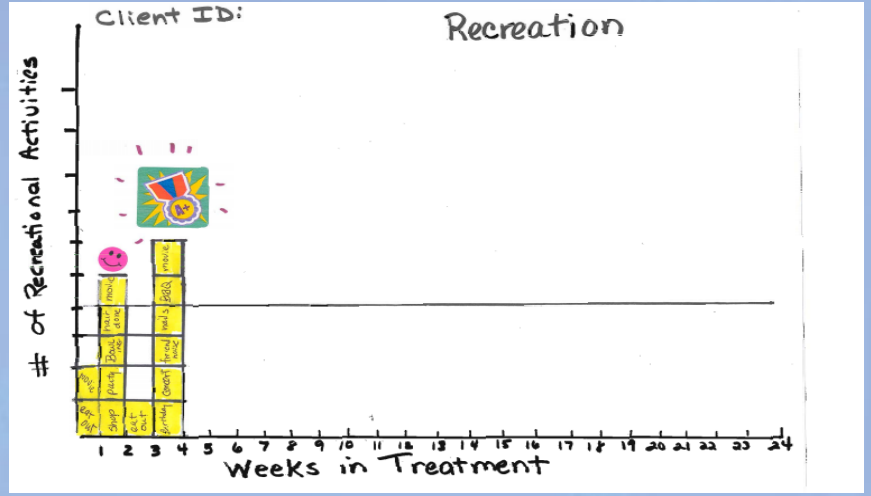
Manualized method

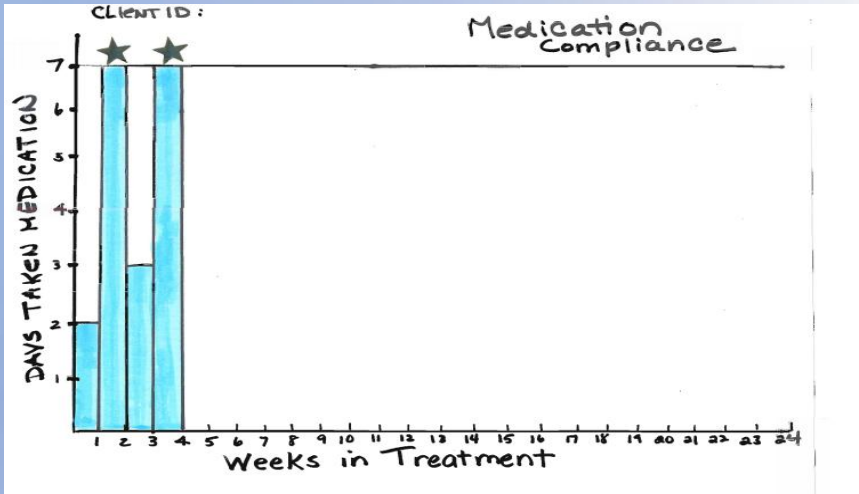
- Helping patients identify job interests
- Look for jobs
- Develop resume
- Practice Interviewing
- Complete applications

3. Role of Behavioral Treatment

Examples: Sally Summer's Treatment Progress







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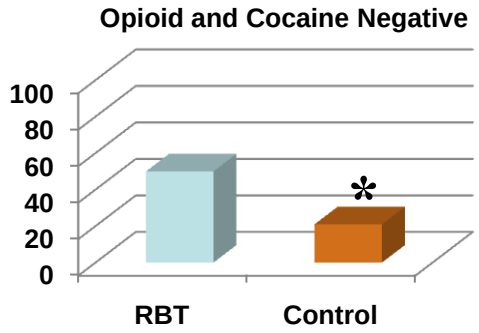
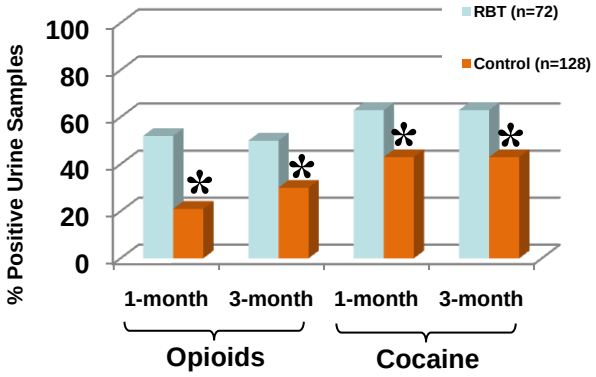
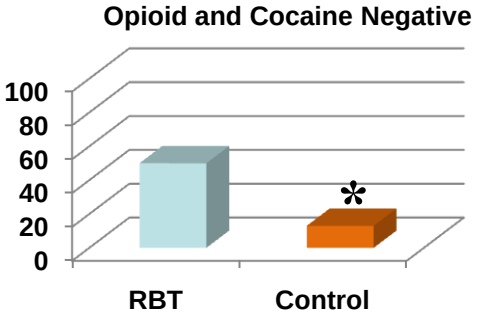
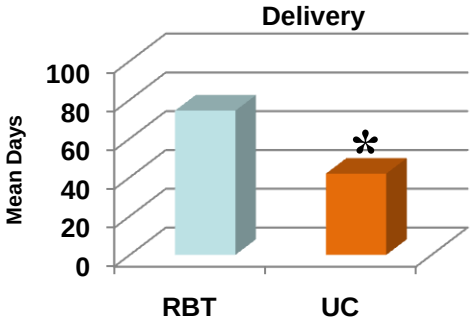
3. Role of Behavioral Treatment









(Gruber et al., 2000; Jones et al., 2005; Jones 2011; Tuten et al., under review)

- 3 randomized trials showing RBT's efficacy in nonpregnant patients
- 1RBT adaptation and test in pregnant patients
- As with any intervention, not all RBT-treated participants attended treatment or reduced drug use, suggesting that further modifications to RBT are needed to improve patient response

* All treatment condition comparisons are significant at $p \leq .05$

3. Role of Behavioral Treatment

An adaptive intervention trial would answer two questions:

- Would variants of RBT that differed in terms of their intensity and scope be effective?
- Would patients who differed in terms of their treatment compliance be differentially responsive to these variants of RBT?

4. A *SMART* Trial at HOME

HOME II

Inclusion Criteria:

- Evidence of cocaine and/or opiate use
- Treatment entry at or before 32 weeks EGA with singleton fetus
- Completion of the eight-day residential detoxification stay

Exclusion Criteria:

- Age 17 or younger
- Geographical Constraints
- Severe medical or psychiatric concomitant condition interfering with treatment or needing hospitalization

4. A *SMART* Trial at HOME

Primary Outcomes- *Maternal*:

- Treatment Completion (Delivery)
- Heroin Use
- Cocaine Use

Secondary Outcomes- *Neonatal* :

- Neurobehavioral Functioning
- Birth weight
- Head Circumference
- Length of Hospital Stay
- Urine Toxicology at Delivery
- Physical Birth Parameters
- Neonatal Complications

4. A *SMART* Trial at HOME

Challenges in Designing the Trial:

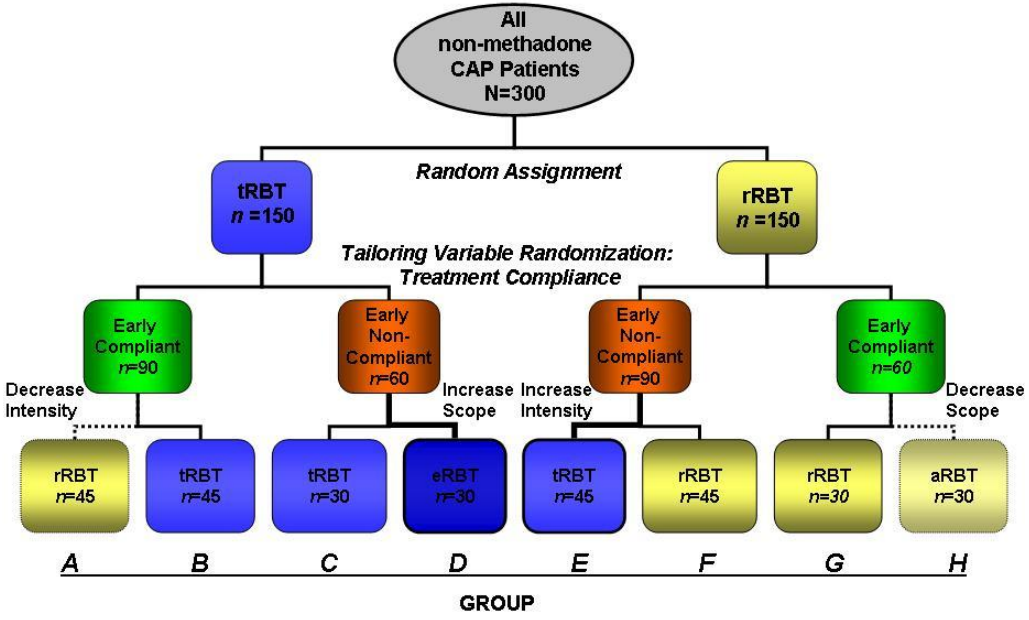
- **How to choose a design structure that would best answer questions of interest**
  - Initial randomization conditions?
  - Second randomization to what combination of treatment conditions?
- **Which patient characteristic to focus on that**
  - Was strongly related to outcome?
  - Would allow reasonable tailoring?
- **Length of time to allow for assessment of the tailoring variable – Pregnancy time-limited window**

Solutions:

- **Initial Randomization:** Compare RBT to an alternate, potentially more cost effective RBT intervention rather than some other behavioral intervention
- **Treatment Compliance as the tailoring variable:** Failure to comply with treatment soon after treatment entry the biggest reason for failure to complete treatment
- **Assess compliance during the first two weeks following treatment entry**

4. A *SMART* Trial at HOME

Planned Sample Size

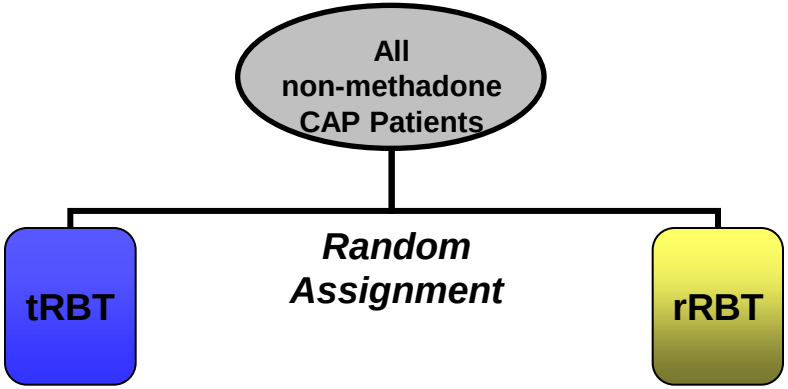


tRBT = treatment-as-usual RBT rRBT = reduced RBT eRBT = enhanced RBT aRBT = abbreviated RBT

Early compliance response rate of 60% based on preliminary studies

- **HOME II** uses a dynamic treatment regimen that adjusts in intensity or scope following patients' initial treatment compliance or non-compliance.
- It is expected that providing RBT in an adaptive intervention format will optimize both maternal treatment and birth outcome benefits for both early compliant and early non-compliant participants by matching treatment services to patient needs.

4. A *SMART* Trial at HOME



- 5X/week: Individual sessions
- 3X/week: Recreation
- 3X/week: Job Club

- 3X/week: Individual sessions
- 1X/week: Recreation
- 1X/week: Job Club

tRBT: Treatment-as-usual RBT

rRBT: reduced RBT

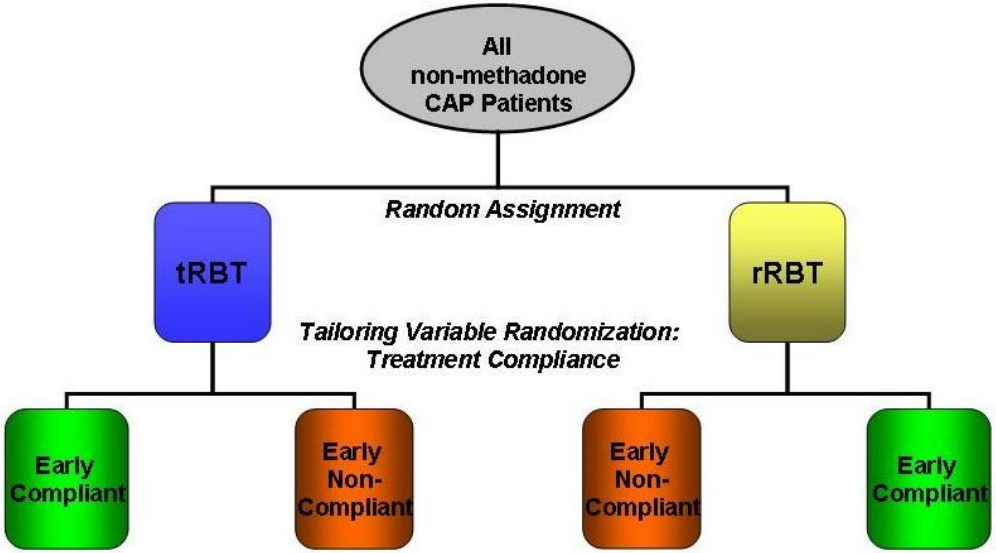
- All elements of treatment-as-usual RBT

– Several key RBT elements are provided at a reduced scope in order to examine a version of RBT that might be more in line with competing demands on time and resources a community therapist might face in treating his/her patients

– Less frequent individual sessions

– Recreation and job club reduced to one a week

4. A *SMART* Trial at HOME



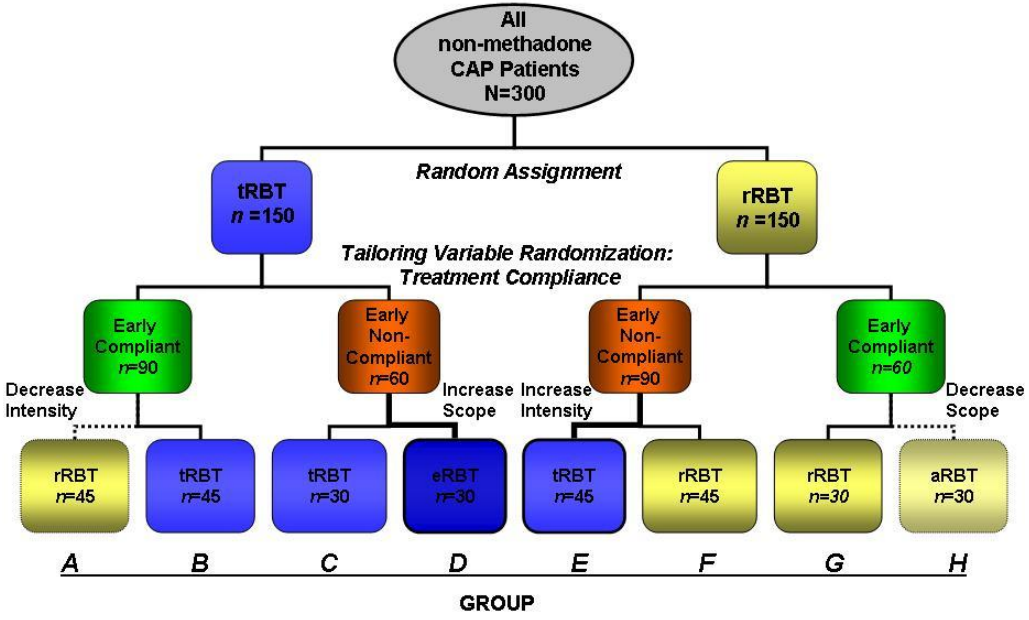
Early treatment non-compliance:
(a) a missed unexcused treatment day,
(b) a positive opioid or cocaine urine specimen,
(c) or self-report of use of either drug.

Tailored Treatment Randomization

Two-week window for treatment response

- **Early compliant** participants randomized to either the same intensity of treatment or a decreased intensity or scope of RBT treatment
- **Early non-compliant** participants randomized to receive either the same treatment or a greater intensity or scope of RBT

4. A *SMART* Trial at HOME



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Early compliance response rate of 60% based on preliminary studies

eRBT: Enhanced RBT

All tRBT elements, plus:

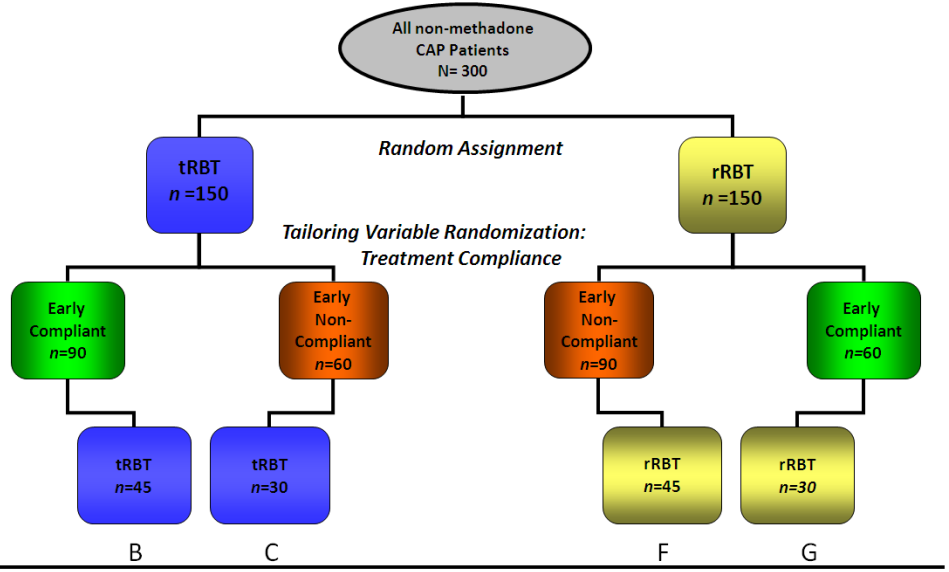
- **Therapists visit the participant in the community to perform urine drug screening. If positive:**
  - **Therapy sessions that include a functional analysis will be provided**
  - **Immediate re-admission to the residential unit to "time out" from drug use and to once again achieve abstinence**

aRBT: Abbreviated RBT

Most reduced version of RBT:

- **Graphing only drug abstinence**
- **No tangible reinforcers**
- **Outreach performed less proactively**
- **Individual therapy sessions once a week**
- **Recreation and social club once a month**

4. A *SMART* Trial at HOME



GROUP

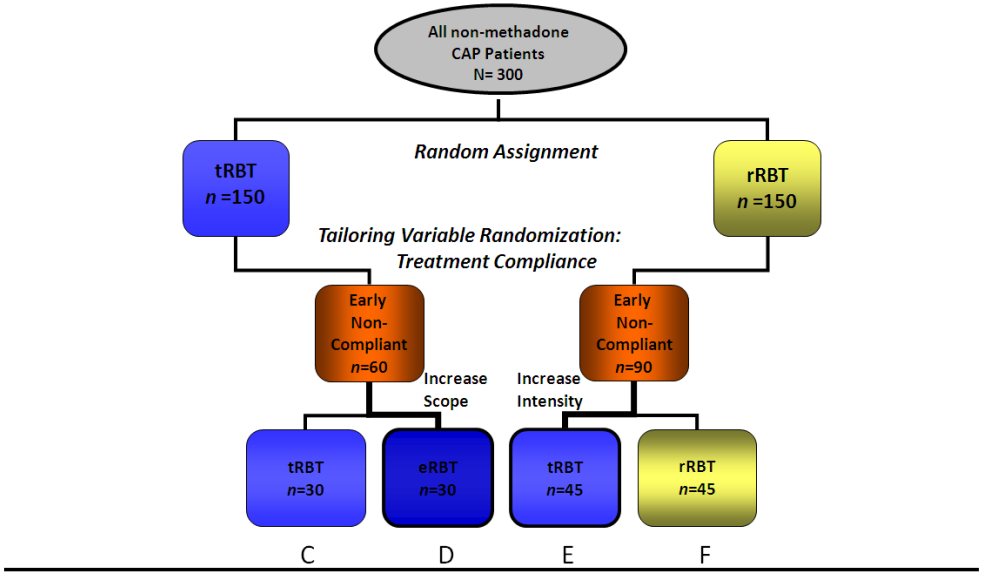
tRBT=treatment-as-usual RBT rRBT=reduced RBT eRBT=enhanced RBT aRTB=abbreviated RBT
Early compliance response rate of 60% based on preliminary studies

Hypothesis 1: B+C v. F+G

- Relative efficacy of providing continued treatment-as-usual RBT in comparison to continued reduced RBT to both early-compilers and early non-compliers throughout the trial.

► Therefore, this hypothesis addresses the question of whether it is necessary to provide treatment-as-usual RBT, or if it is possible to successfully treat patients with reduced RBT, regardless of the patient's level of compliance.

4. A *SMART* Trial at HOME



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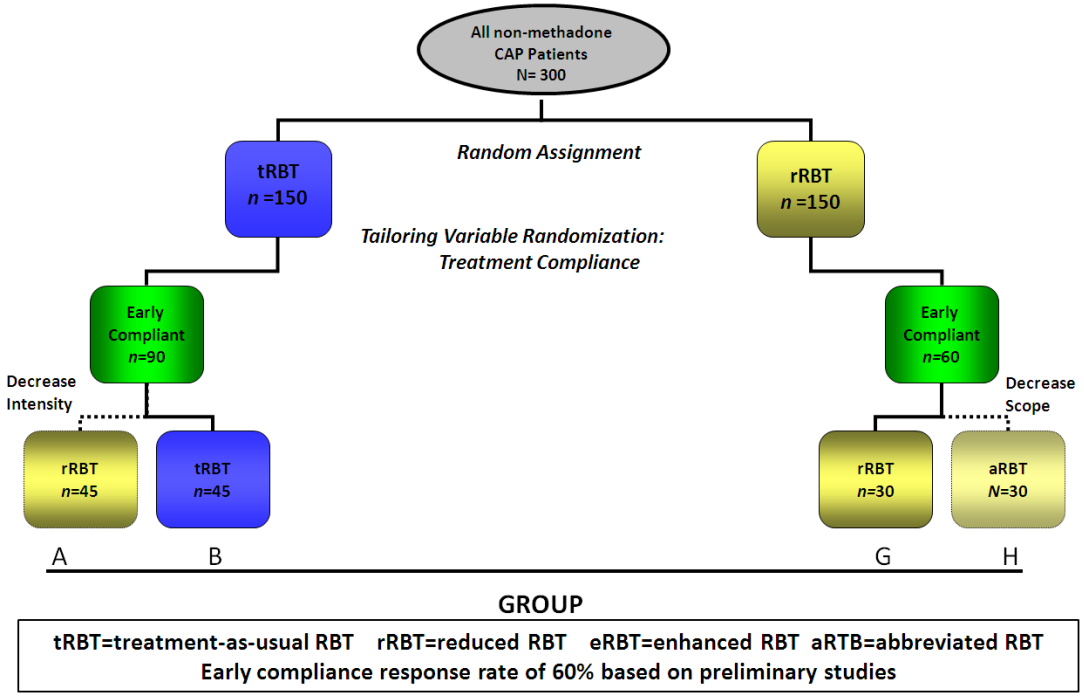
Early compliance response rate of 60% based on preliminary studies

Hypothesis 2A: C v. D
Hypothesis 2B: E v. F

- Relative efficacy of transitioning to a more intensive level of treatment for early-non-compliers within the initial treatment-as-usual RBT and reduced RBT treatment conditions, respectively.

► Therefore, this pair of hypotheses answers questions regarding the relative importance of the initial level of care in determining the efficacy of transitioning to a higher level of care for early-non compliers.

4. A *SMART* Trial at HOME

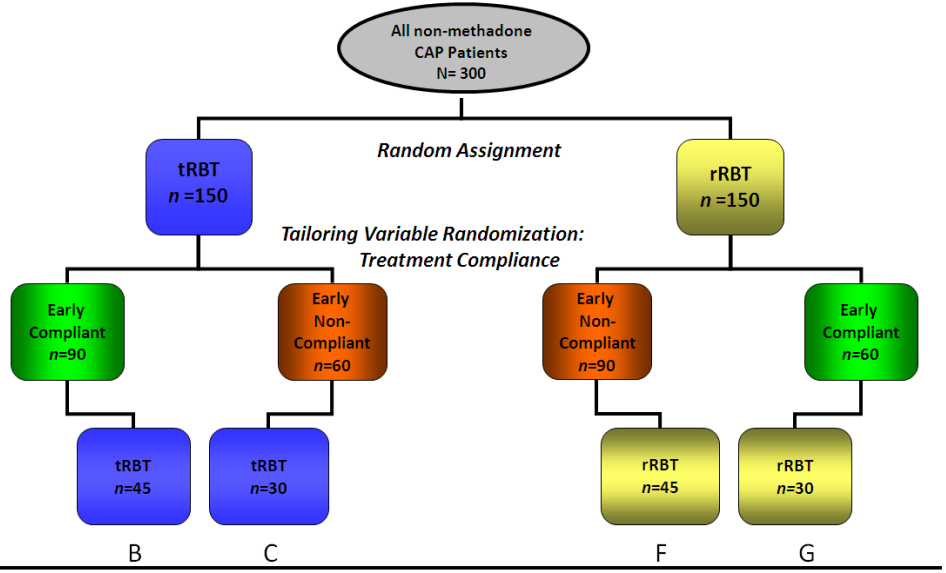


Hypothesis 3A: A v. B
Hypothesis 3B: G v. H

- Relative efficacy of transitioning to a less intense level of treatment for early-compliers within the initial treatment-as-usual RBT and reduced RBT treatment conditions, respectively.

► Therefore, this pair of hypotheses answers questions about the importance of the initial level of RBT treatment in determining success in subsequently reducing the level of RBT treatment in early-compliers.

4. A *SMART* Trial at HOME



GROUP

tRBT=treatment-as-usual RBT rRBT=reduced RBT eRBT=enhanced RBT aRTB=abbreviated RBT
Early compliance response rate of 60% based on preliminary studies

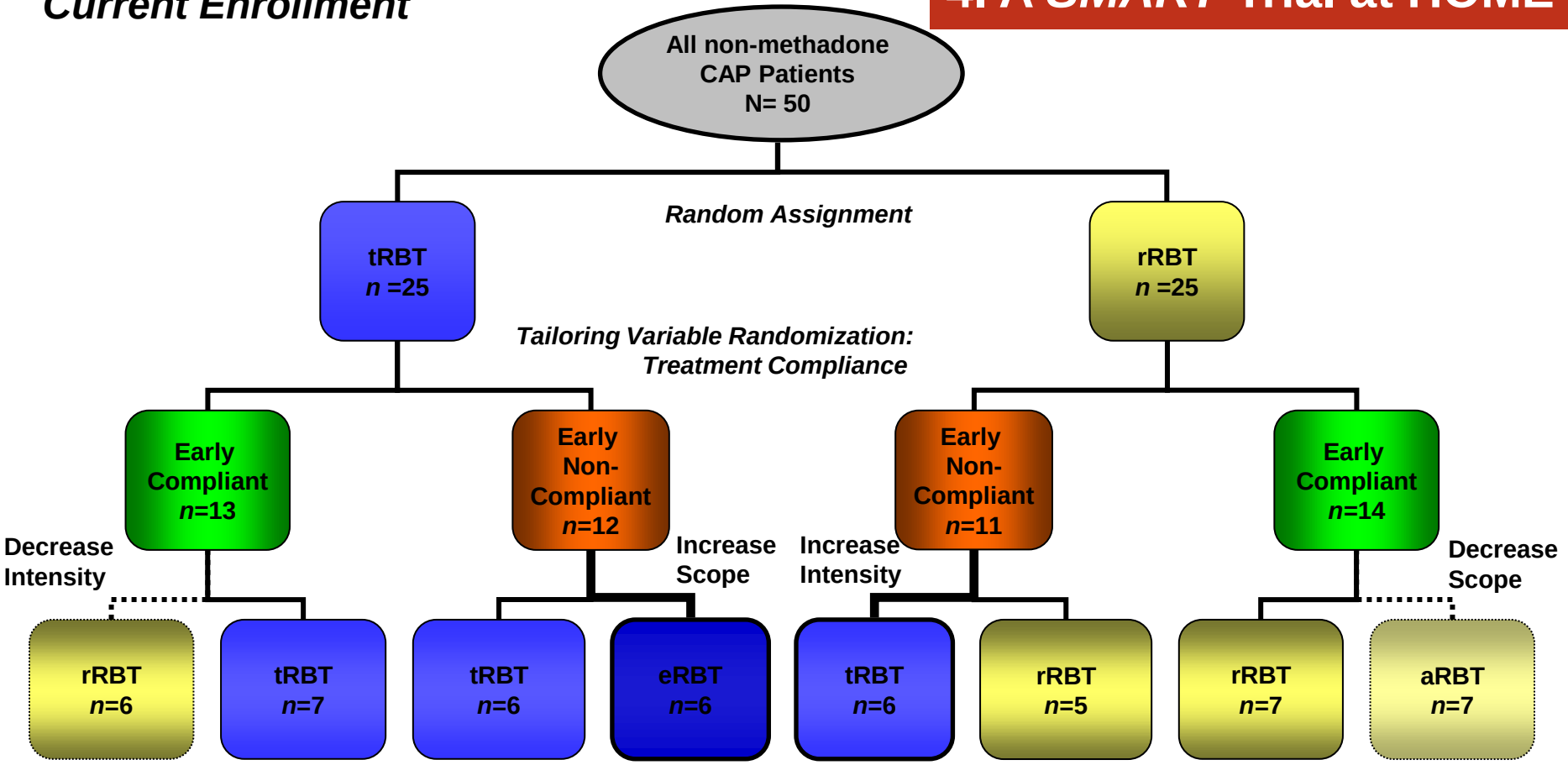
Hypothesis 4A: B v. C
Hypothesis 4B: F v. G

- Relative efficacy for early-complier and early-non-compliers who begin and continue in treatment-as-usual RBT or who begin and continue in reduced RBT, respectively.

► Therefore, these two hypotheses answer the question about the relative decrement in treatment success that occurs as a result of an early failure to comply with the initial demands of treatment.

4. A *SMART* Trial at HOME

Current Enrollment



4. A *SMART* Trial at HOME

Challenges in Conducting the Trial

- Recruitment
- Adherence of the clinical staff to the protocol
- Changing clinical context

New Insights Resulting from the Trial

- Patient acceptance of the tailoring treatment randomization
- Better-than-expected distribution of patients into tailoring treatment randomization

For More Information

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A complete reference list for the presentation is available upon request