BestFIT: A Sequential Multiple Assignment Randomized Trial for Obesity Treatment

A weight loss study that focuses on FIT
“Finding Individualized Treatments”

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Supported by the National Cancer Institute R01 CA 188892
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BestFIT Study Background

- State-of-the art behavioral weight loss program participation leads to clinically meaningful weight loss for many; however, about half of obese adults are unable to meet this goal.
- Despite this heterogeneity, a “one size fits all” approach is the norm
- To increase the number of people who experience clinically significant weight loss, we need to develop strategies that
  1) address the adherence challenges facing suboptimal responders AND
  2) are offered when suboptimal responders are most likely to benefit
BestFIT Study Background

• This gap in weight loss intervention science calls for an adaptive intervention approach.
• Adaptive interventions individualize treatment through empirically-supported decision rules that advise when and how treatments unfold over time to maximize effectiveness.
• Sequential Multiple Assignment Randomized Trials (SMART) use experimental design principles to build optimal adaptive interventions
BestFIT Study Goals: Optimal therapeutic approach for addressing suboptimal response

• Therapeutic choice should be informed by the reasons people struggle with weight loss initiation; self-regulation difficulties have been identified as a major adherence barrier.

• Two attractive options to meet this challenge
  – 1) augmenting behavioral treatment with Portion-Controlled Meals which reduce the need for self-regulation; and
  – 2) switching therapeutic approaches by providing training in acceptance and commitment skills (Acceptance-Based Treatment) which boost capacity for self-regulation.
BestFIT Study Goals: Optimal timing for addressing suboptimal response

- Waiting too long may be detrimental as people may experience a sense of futility regarding success.
- Augmenting or switching too early may not allow enough time for the initial treatment to be effective.
- Based on empirical decision support & the previous stepped care literature, we propose to evaluate two time points:

  **Week 3 versus Week 7**
Study Timeline

Orientation

Weight Loss Program
(20 Weekly Sessions)

Intake Visit
6-month Visit
$25 gift card

6 months

18-month Visit
$50 gift card

18 months
Participants and coaches are blind to their randomly assigned response assessment time to reduce the impact of treatment assignment knowledge on early treatment performance.
**Primary Aim**

- **Baseline** → 3 Weeks → 7 Weeks

**SBT for 3 weeks (N=250)**

- Responder
  - Continue SBT
  - Augment SBT: SBT + Portion-Controlled Meals
  - Switch from SBT: Acceptance-Based Treatment

**SBT for 7 weeks (N=250)**

- Responder
  - Continue SBT
  - Augment SBT: SBT + Portion-Controlled Meals
  - Switch from SBT: Acceptance-Based Treatment

*Participants and coaches are blind to their randomly assigned response assessment time to reduce the impact of treatment assignment knowledge on early treatment performance.*
Secondary Aim

Participants and coaches are blind to their randomly assigned response assessment time to reduce the impact of treatment assignment knowledge on early treatment performance.
BestFIT Exploratory Aim

• To make further progress toward building an individually-tailored adaptive intervention:
  
  – Does responsiveness to different sequences of treatment vary as a function of participant characteristics?
BestFIT Study Measures

- Measured Height & Weight
- “Eating Specific” Self-Regulation
  - Eating Disorder Examination-Binge Eating Module
  - Binge Eating Scale
  - Power of Food Scale
- “General” Self-Regulation/Executive Functioning
  - Stop Signal Task
  - Tower Task
  - BART
  - NIH Toolbox Working Memory Sorting Task
## BestFIT Implementation Challenges & Solutions

<table>
<thead>
<tr>
<th>Category</th>
<th>Challenges</th>
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<tbody>
<tr>
<td><strong>Design decisions</strong></td>
<td>• Individual versus Group Treatment</td>
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<tr>
<td></td>
<td>• No re-randomization to “treatment as usual”</td>
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<tr>
<td><strong>Recruitment</strong></td>
<td>• Explaining study design to participants</td>
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<tr>
<td></td>
<td>• No treatment as usual</td>
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<tr>
<td><strong>Managing Re-Randomization</strong></td>
<td>• Developing timing</td>
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<td></td>
<td>• Extensive programming/database work algorithm</td>
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BestFIT Implementation Challenges & Solutions

Therapist training & Fidelity Monitoring

- Same therapist after switch
- Finessing the switch
- Learning & implementing 5 different sequences of treatment
- Monitoring contamination
Questions?

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Extra Slides
BestFIT Recruitment

- Potential participants hear about BestFIT at the workplace, study website, radio ads, print ads and a variety of other places
- BestFIT staff conducts a phone screen to provide more information and determine pre-eligibility
- Potential participants attends a BestFIT study orientation at the Institute
- BestFIT staff conducts follow-up phone call to answer questions and ensure study fit for each potential participant
Eligibility

- Between the ages of 21 and 70
- BMI between 30 and 45 kg/m²
- Able to walk at least 2 blocks without stopping
- No food allergies or food sensitivities
- Able and willing to attend up to 20 sessions with weight loss coach at the Institute and to attend 6 month and 18 month measurement visits
## BestFIT Current Status & Goals

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<tr>
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<th>CURRENT STATUS</th>
<th>GOAL</th>
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<tr>
<td>Recruitment</td>
<td>N=134</td>
<td>N=500</td>
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<tr>
<td>Intervention</td>
<td>1559 Sessions</td>
<td>10,000 Sessions</td>
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<tr>
<td>6 Month Measurement</td>
<td>N=40</td>
<td>N=500</td>
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<tr>
<td>Visit</td>
<td>N=0</td>
<td>N=500</td>
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<tr>
<td>18 Month Measurement</td>
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<tr>
<td>Visit</td>
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