Development of a Weight Loss Intervention Considering Resource Constraints

Angela Fidler Pfammatter, PhD
Northwestern University Feinberg School of Medicine

Angela@northwestern.edu
Twitter: @Apfam
Problems in Obesity Treatment

- Weight loss treatments are often costly and burdensome

Behavioral Programs
- Self-monitoring
- Group sessions
- Feedback
- Goal setting
- Stimulus control
- Social support
- Individual sessions
- Education
- Relapse prevention
Component Selection

Components meet 3 criteria:

a. relative cost/burden is known
b. relative impact on weight loss is unknown
c. can be delivered remotely

1. Coaching Call Levels (weekly vs every 2 weeks)
2. Meal Replacements
3. Progress Report to Physician
4. Train a Buddy to be Supportive
5. Text Messages

Twitter: @Apfam
Setting up a Conceptual Model

Experimental Components

1. Coaching (12 v 24)
2. Text Messages (Y v N)
3. PCP Communication (Y v N)
4. Buddy Training (Y v N)
5. Meal Replacements (Y v N)

Social Cognitive Mechanisms

- Self-Efficacy
- Self-Regulation
- Supportive Accountability
- Facilitation

Adherence

Weight Loss

Core Intervention

- Education
- Goal Setting
- Self-Monitoring
ENLIGHTEN Feasibility Study

- Create messages, test the delivery mechanism, determine preferences for frequency
- Non-randomized, pre-post pilot study
- 9 participants (6/9 Female, 5/9 Black, Mean age 42.4 years, mean BMI 31.8)
- Completers (n=8) lost a range of +.75 – -14.75 lbs
- Preference for 1.8 texts per day on 4.3 days of the week (2-7 texts)

CONCLUSIONS
- We needed to automate the text message delivery
- Participant preference vary wildly; tailoring important

Pfammatter AF, Marchese SH, Pellegrini C, Daly E, Davidson M, Spring B. Using the Preparation Phase of the Multiphase Optimization Strategy to Develop a Messaging Component for Weight Loss: Formative and Pilot Research. JMIR Form Res 2020;4(5):e16297 DOI: 10.2196/16297 PMID: 32347804
Figure 4. Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity Study (Opt-IN) message tailoring: adherence to self-monitoring example.

**Begin: Adherence to Self-Monitoring Text**

- **If No:** Send Text
  - Haven’t recorded your food in the past few days? Not a problem! Today is a new day! Why not get back on track by entering your latest meal right now?

- **If Yes:** Check: Did the participant self-monitor over last 7 days?
  - **If No:** Send Text
    - We see that you’ve been recording your food on some days - try to set recording patterns for yourself so it becomes a habit!
  - **If Yes:** Check: Did the participant record food yesterday or today?
    - **If No:** Send Text
      - Doing an awesome job with recording your food intake! Keep it up!
    - **If Yes:** Send Text
Optimization of a Multicomponent Treatment

The Opt-IN Trial

Design maximally effective and efficient weight loss intervention such that all components are active, feasible for real world implementation, and make lowest possible resource demands.

AIM 1: **Identify which components/component levels**, contribute most to weight loss among adults with overweight and obesity over a 6-month period. 
AIM 2: **Apply results to build** an intervention with only active components that costs less that $500 USD.

Opt-IN Design

N = 562 (81.5% female, BMI 32.2 (3.6) kg/m²)

All participants received CORE intervention and randomized to one of 32 conditions comprised of different combinations of components

Table 2

Full Factorial Design with 32 conditions.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Coaching Sessions</th>
<th>Report to PCP</th>
<th>Text Messages</th>
<th>Meal Replacement Recommendations</th>
<th>Buddy Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>3</td>
<td>12</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>4</td>
<td>12</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>6</td>
<td>12</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>7</td>
<td>12</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>8</td>
<td>12</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>9</td>
<td>24</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>10</td>
<td>24</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>11</td>
<td>24</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>12</td>
<td>24</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>13</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>14</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>15</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>16</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>17</td>
<td>12</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>18</td>
<td>12</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>19</td>
<td>12</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>20</td>
<td>12</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>21</td>
<td>12</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>22</td>
<td>12</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>23</td>
<td>12</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>24</td>
<td>12</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>25</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>26</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>27</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>28</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>29</td>
<td>24</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>30</td>
<td>24</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>31</td>
<td>24</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>32</td>
<td>24</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

Twitter: @Apfam
### Decision Making

<table>
<thead>
<tr>
<th>Combination</th>
<th>Estimated Effects</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6-mo weight change (kg)</td>
<td>% achieving 5% wt loss</td>
</tr>
<tr>
<td># Calls</td>
<td>Text Message</td>
<td>Meal Replacement</td>
</tr>
<tr>
<td>21</td>
<td>12</td>
<td>No</td>
</tr>
<tr>
<td>1</td>
<td>12</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>No</td>
</tr>
<tr>
<td>17</td>
<td>12</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Combination</th>
<th>Estimated Effects</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>#</td>
<td>Calls</td>
<td>Text Message</td>
</tr>
<tr>
<td>21</td>
<td>12</td>
<td>No</td>
</tr>
<tr>
<td>1</td>
<td>12</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>No</td>
</tr>
<tr>
<td>17</td>
<td>12</td>
<td>No</td>
</tr>
</tbody>
</table>

## Decision Making

<table>
<thead>
<tr>
<th>Combination</th>
<th>Estimated Effects</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6-mo weight change (kg)</td>
<td>% achieving 5% wt loss</td>
</tr>
<tr>
<td># 21</td>
<td>-6.1112</td>
<td>57.13</td>
</tr>
<tr>
<td>1</td>
<td>-3.3966</td>
<td>34.48</td>
</tr>
<tr>
<td>5</td>
<td>-5.0540</td>
<td>46.56</td>
</tr>
<tr>
<td>17</td>
<td>-5.2389</td>
<td>52.95</td>
</tr>
</tbody>
</table>

Continual Optimization Principle

**Preparation**
- **Purpose**: Lay groundwork for optimization
- **Activities**:
  - Derive/revise conceptual model
  - Identify set of candidate components
  - Conduct pilot tests
  - Identify optimization criterion

**Optimization**
- **Purpose**: Build optimized intervention
- **Activities**:
  - Conduct optimization trial(s)
    - Factorial experiment
    - Fractional factorial experiment
    - SMART
    - Micro-randomized trial
    - System identification
    - Other
  - Identify intervention that meets optimization criterion

**Evaluation**
- **Purpose**: Confirm effectiveness of optimized intervention
- **Activity**:
  - Randomized controlled trial

**Flowchart**
- Continual optimization principle
- Optimized intervention expected to be sufficiently effective?
- Yes
  - [Activity]
- No
  - [Activity]

Resource management principle

Moving on to Evaluation


@ibtnetwork  #ibtn2020  Twitter: @Apfam
**Evaluation Trials**

- **Baseline**
- **Randomization**
- **Optimized Package**
  - 12 Biweekly calls – 10 min
  - 6 Month Assessment
  - 12 Month Assessment
- **Gold Standard**
  - 16 in-person sessions – 60 min
  - 6 Month Assessment
  - 12 Month Assessment

**Multi-site**

**Dissemination & Implementation**

**Longer Term Outcome**

---

@ibtnetwork  #ibtn2020  Twitter: @Apfam
R01DK097364 (Spring/Collins); F31DK120151 (Hoffman) through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
UL1TR001422 (Lloyd-Jones) through National Center for Advancing Translational Sciences

-Pfammatter AF, Marchese SH, Pellegrini C, Daly E, Davidson M, Spring B. Using the Preparation Phase of the Multiphase Optimization Strategy to Develop a Messaging Component for Weight Loss: Formative and Pilot Research. JMiR Form Res 2020;4(5):e16297 DOI: 10.2196/16297 PMID: 32347804

@ibtnetwork #ibtn2020 Twitter: @Apfam