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Opt-IN: <u>Op</u>timization of Remotely Delivered <u>In</u>tensive Lifestyle Treatment for Obesity

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Society of Behavioral Medicine's Annual Meeting
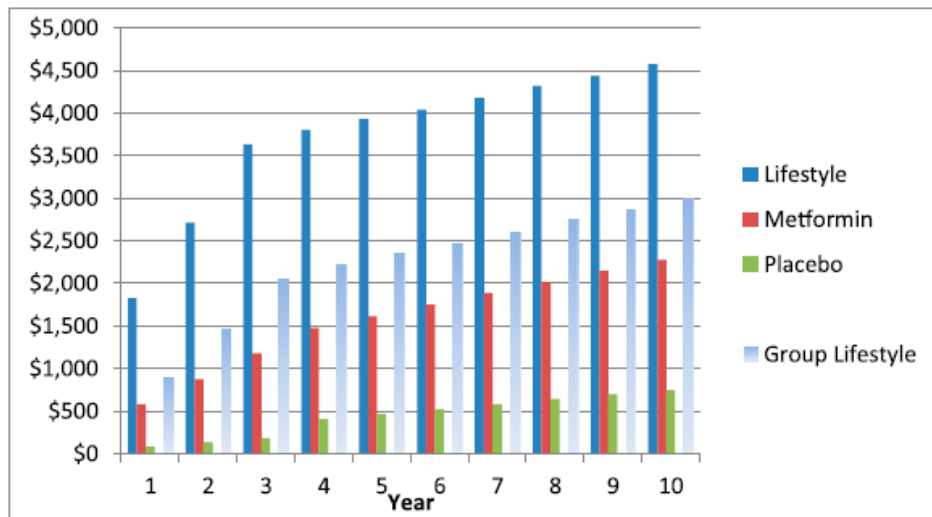
April 1, 2016

Obesity – The Public Health Problem

- **Prevalence**:

    U.S: 30% obese; 69% overweight/obese (CDC, 2008)

    World: 1.4 bill overweight/obese (WHO, 2013)

- **U.S. employer annual cost** of obesity-related medical expense, absenteeism, and presenteeism for full-time workers

    $73.1 billion (Finkelstein et al, 2010)

The Intervention Development Challenge

- **Effective treatment** (intensive lifestyle treatment – e.g., DPP, Look AHEAD) produces 7% sustained weight loss and metabolic improvement but **burdensome** (16-36 sessions) and **costly** ($1800/patient)

Self-monitoring

Group sessions

Feedback

Goal setting

Stimulus control

Behavioral Programs

Social support

Individual sessions

Relapse prevention

Education

Chart legend:
- Lifestyle
- Metformin
- Placebo
- Group Lifestyle

Year 1–10, $0–$5,000

Diabetes Prevention Program, *Diabetes Care*, 2012

What We Don't Know about Intensive Lifestyle Treatments for Obesity

- Which components are making positive contributions

- Whether all components are needed

- Which components' contribution to effect offsets its cost

- How to make intervention more effective and efficient

Primary Aim 1

To **identify which components/component levels**, contribute most prominently to a) **average weight loss** and b) **percent achieving ≥ 7 % weight loss** among overweight and obese adults over a 6-month period.

Five components ➡

1. **Coaching Intensity**
   - 12 v. 24 phone sessions
2. **Text Messaging**
   - No v. Yes
3. **Progress Reports for PCP**
   - No v. Yes
4. **Recommendations to use meal replacements**
   - No v. Yes
5. **Training participants' self selected buddies to be supportive**
   - No v. Yes

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Primary Aim 2

- Apply these results to build an appropriate intervention strategy, and/or implement a 2nd intervention.

  - Made up of the best set of components/component levels based on the results of Aim 1

  - Scalable Intervention < $500 dollars

  - If >$500, we will identify the combination of components/component levels corresponding with greatest treatment effect for <$500

Secondary Aims: Mediation & Moderation

Improve understanding of the 5 intervention components

- Analysis of weight loss mediators
  - Hypothesized
    - Adherence to treatment
  - Exploratory
    - Self-efficacy
    - Self-regulation
    - Supportive accountability
    - Facilitation

- Analysis of subgroup moderators
  - Gender
  - Ethnicity
  - BMI categories
- Latent class analysis to identify latent subgroups and predictors of subgroup membership

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Core Treatment Plan

- Behavioral Coaching and Curriculum
  - Online lessons
  - Phone coaching (12 vs. 24)
- Self-Monitoring Tool
  - Smartphone application
- Dietary Intervention
  - Calorie/fat goals, feedback
- Physical Activity Intervention
  - Moderate intensity (brisk walking) physical activity goal, increasing duration over time

Pellegrini CA, Hoffman SA, Collins LM, Spring B. Optimization of remotely delivered intensive lifestyle treatment for obesity using the multiphase optimization strategy: Opt-in study protocol. *Contemporary clinical trials*. 2014;38:251-259

Intervention Components
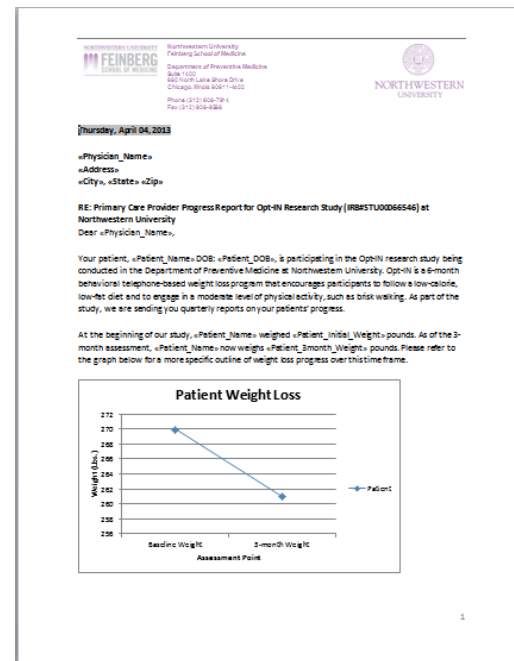
1. **Coaching Calls over 6 Months**

   - 12 calls

   - 24 calls

2. **Progress Report Mailed to Primary Care Physician**

   - Report mailed at 3- and 6-months to participant and Provider

   - Outlines weight loss progress, behavioral recommendations

3. **Text Messages**

   - Encouraging words, personalized feedback based on self-monitoring

   - Automated messages in real-time

Intervention Components (continued)

4. <u>**Meal Replacement Recommendations**</u>

- Provided with one week's supply at randomization session
- Recommendations to continue use made by coach throughout intervention

5. <u>**Buddy Training**</u>

- One telephone training session
- Four 30-45 minute online webinar sessions
- Buddies receive $5 for each session complete and additional $20 for completing 3 out of 4 webinars

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Implemented Design

Condition	Coaching Sessions	PCP Report	Texts	Meal Replacement Recommendations	Buddy Training
1	12	Yes	No	No	No
2	12	Yes	No	Yes	Yes
3	12	Yes	Yes	No	Yes
4	12	Yes	Yes	Yes	No
5	12	No	No	No	Yes
6	12	No	No	Yes	No
7	12	No	Yes	No	No
8	12	No	Yes	Yes	Yes
9	24	Yes	No	No	No
10	24	Yes	No	Yes	Yes
11	24	Yes	Yes	No	Yes
12	24	Yes	Yes	Yes	No
13	24	No	No	No	Yes
14	24	No	No	Yes	No
15	24	No	Yes	No	No
16	24	No	Yes	Yes	Yes

Challenges Along the Way…

How to Explain to Participants?

- Ensure they know the 5 components

- Show them the 16 different conditions

- Highlight:
  - No control group
  - Everyone gets something

- Study staff & coaches have no idea which conditions/components have greatest weight loss

Condition	Opt-IN Study Components	Buddy Training
1		No
2		Yes
3		Yes
4		No
5		Yes
6		No
7		No
8		Yes
9		No
10		Yes
11		Yes
12		No
13		Yes
14		No
15		No
16		Yes

Opt-IN Study Components

Opt·In

- You *will* receive:
  - Personalized weight, calorie, and physical activity goals to promote weight loss
  - Online handouts and lessons on diet, physical activity, and behavioral strategies
  - Opt-IN study smartphone application to monitor your diet, activity, and weight daily
  - Coaching calls (12 or 24 total) over the 6 month program

- Additionally, you MAY receive a combination of these weight loss components:
  - Text Messaging
  - Progress Reports to PCP
  - Meal Replacement *Recommendations*
  - Buddy Support

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How to Implement a Study with 16 Conditions?

Checks, double checks, and triple checks!

17) (12)
18) (12) ● ●
19) (12) ● ●
20) (12) ● ●
21) (12) ● ●
22) (12) ● ●
23) (12) ● ●
24) (12) ● ● ● ●

25) (24)
26) (24) ● ●
27) (24) ● ●
28) (24) ● ●
29) (24) ● ●
30) (24) ● ●
31) (24) ● ●
32) (24) ● ● ● ●

● # of Coaching Calls
● PCP Reports
● Text Messages
● Meal Replacements
● Buddy Training

12

☐ PCP 3- or 6-month report time?

    ☐ Yes   ☐ No

    ☐ Participant informed report has or will be sent

_____

_____

24

☐ Review use of meal replacements over the last 2 weeks:

    ☐ Number of meal replacements _____   ☐ Using no meal replacements

_____

_____

☐ Confirm that participant received text messages over last week from coach:

_____

_____

☐ Inquire about buddy support:

    ☐ Buddy providing support   ☐ Buddy not providing support

_____

_____

Can Mistakes Happen?

- Clerical error – intended design did not match implemented design

- Enrollment almost halfway completed when error discovered

- Solution: expand the design to a complete 2^5 factorial with 32 experimental conditions

  - Eliminates aliasing of effects among experimental factors and enables us to examine all five components

- Does not require randomization of additional subjects

Table 2
Full Factorial Design with 32 conditions.

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

Pellegrini CA, Hoffman SA, Collins LM, Spring B. Corrigendum to optimization of remotely delivered intensive lifestyle treatment for obesity using the multiphase optimization strategy: Opt-in study protocol; *Contemporary clinical trials*. 2015;45:468-469

Approaching the Finish Line

- Current Progress:
  - Randomized 405 participants since October 2013

- Goal = 560 participants by December 2016

- Design a little more challenging to implement but not impossible!

- Error highlights flexibility & ability to move from fractional factorial to full factorial

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