

Partnering with Industry in the Testing and Implementation of Behavioral Interventions: Lessons from the Hopkins-Healthways Collaboration



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Disclosure

- Institutional disclosure with Healthways, Inc, which is developing a commercial weight loss program, Innergy, based on the results of the POWER trial.
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Practice-Based Opportunities for Weight Reduction (POWER)

Background

- ❑ In 2005, NIH issued a request for applications to conduct effectiveness trials on weight loss
 - “Dissemination: A critical feature of this project is the development of interventions with the potential to be incorporated into medical care systems”

Objective of POWER

- ☐ Test two practical behavioral weight loss interventions that could be implemented in routine medical practice in obese patients with cardiovascular risk factors
 - ☐ Remotely-delivered (phone, Web, email)
 - ☐ In-person (group, individual, plus remote)
 - ☐ Self-directed

Academic-Public-Private Partnership

- ❑ JHU School of Medicine (PI: Appel)
 - Designed and implemented trial
- ❑ National Heart, Lung and Blood Institute
 - Sponsored trial
- ❑ Healthways, Inc
 - Developed and managed website
 - Conducted the remote intervention
 - Provided some financial support after trial ended

Background

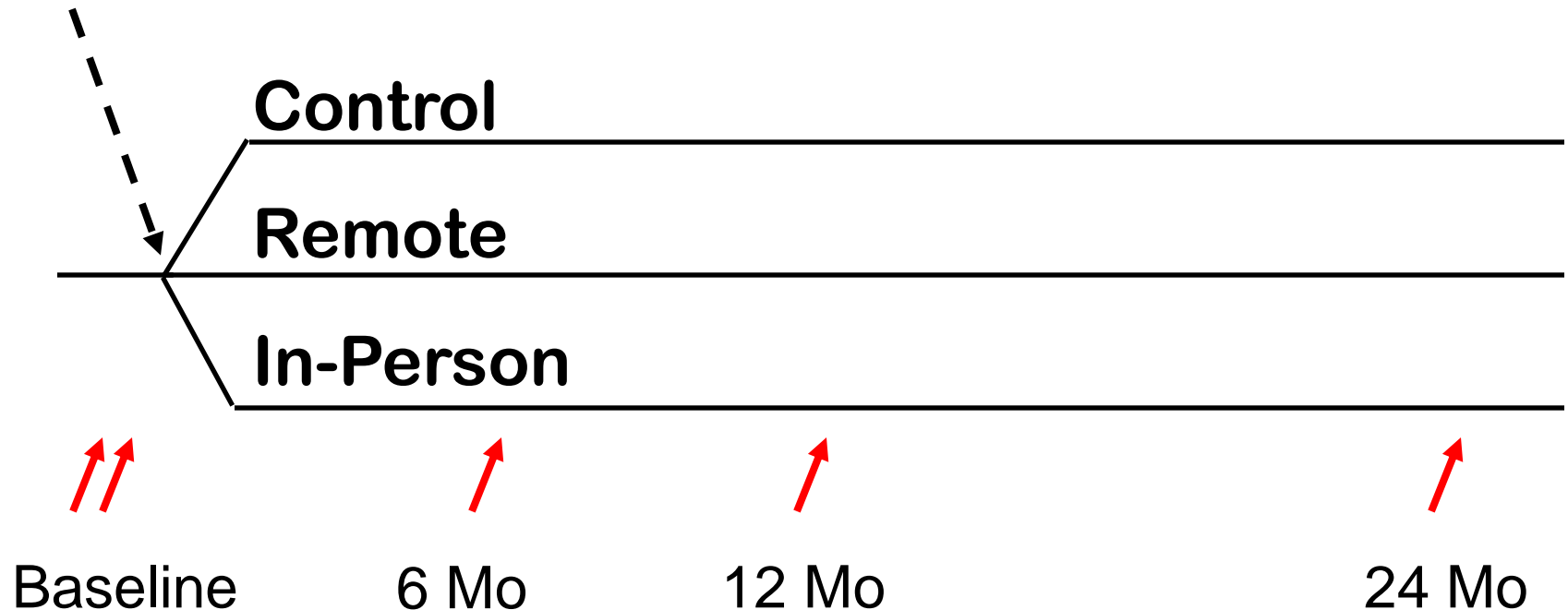
- ❑ Excerpts from the review of our grant
 - the remote intervention should have the advantage of being readily scalable
 - the most innovative aspect of the proposal is the collaboration with Healthways, Inc

Guiding Principles

- ❑ Design interventions that could be implemented in a variety of health care delivery settings.
- ❑ Provide the interventions in an efficient manner by using the internet and web to achieve frequent, regular contact.
- ❑ Design interventions that would be applicable when the trial ended in 2011. For this reason, we required access to and use of computers.

Design

Randomization



 = Measured weights and other outcomes

Interventions

	Remote	In-Person
Mode of Delivery	Telephone only	Group meetings Individual meetings Telephone
Coach	Healthways	Hopkins
Coach support	Case management	
Study website	Educational modules Self-monitoring tools Tailored emails	
Physician Roles	Supportive Review weight progress reports	

Intervention Goals and Behaviors

- ❑ Weight loss goal
 - 5% weight loss

- ❑ Behaviors
 - Reduce caloric intake
 - Consume healthy dietary pattern, DASH diet
 - Exercise \geq 180 min/week
 - Self-monitor weight, calorie intake and exercise
 - Log-in study website at least weekly



Participant Self-Monitoring

JOHNS HOPKINS virtual coach



Welcome, [Logout]

Self-Monitoring

Modules

Learning

Links

Appointments

Clinic Surveys

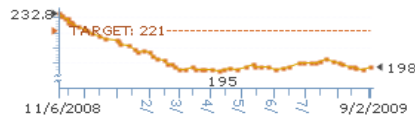
FAQ

Self-Monitoring

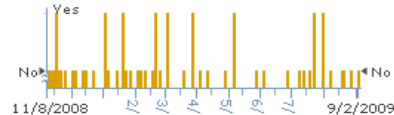
Self monitoring is the key to losing weight and keeping it off.

These graphs show your progress and things you could do improve your weight control. To learn more about what these graphs mean see Module 1, Part 3. Remember, the more data you enter and the more accurate the data are, the more helpful these graphs will be.

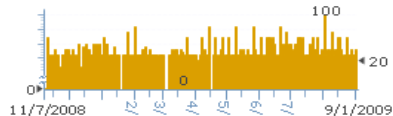
Weight (lbs)



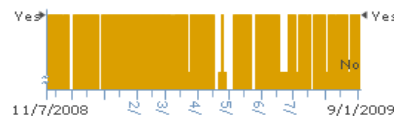
Witnessed Weight?



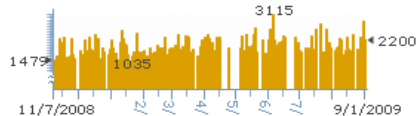
Exercise (minutes)



Daily Tracker?



Calorie Intake



Next Appointment

9/9/2009 - Individual 13

[» Other appointments](#)

You are still below the target weight we set for you at the beginning of the study; however, the weight you just entered is higher than your last online weight.

To make sure it doesn't continue to creep up, remember the reasons you joined the POWER study. Think about the things that have helped you lose weight, try to exercise daily, record everything you eat, and talk to your coach on your next call.

September 2009						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	1	2	3
4	5	6	7	8	9	10

Thursday, September 03, 2009

- ➔ Weight (lbs):
- ➔ Witnessed Weight?: ☐ Yes ☐ No
- ➔ Exercise (minutes):
- ➔ Daily Tracker?: ☐ Yes ☐ No
- ➔ Calorie Intake:

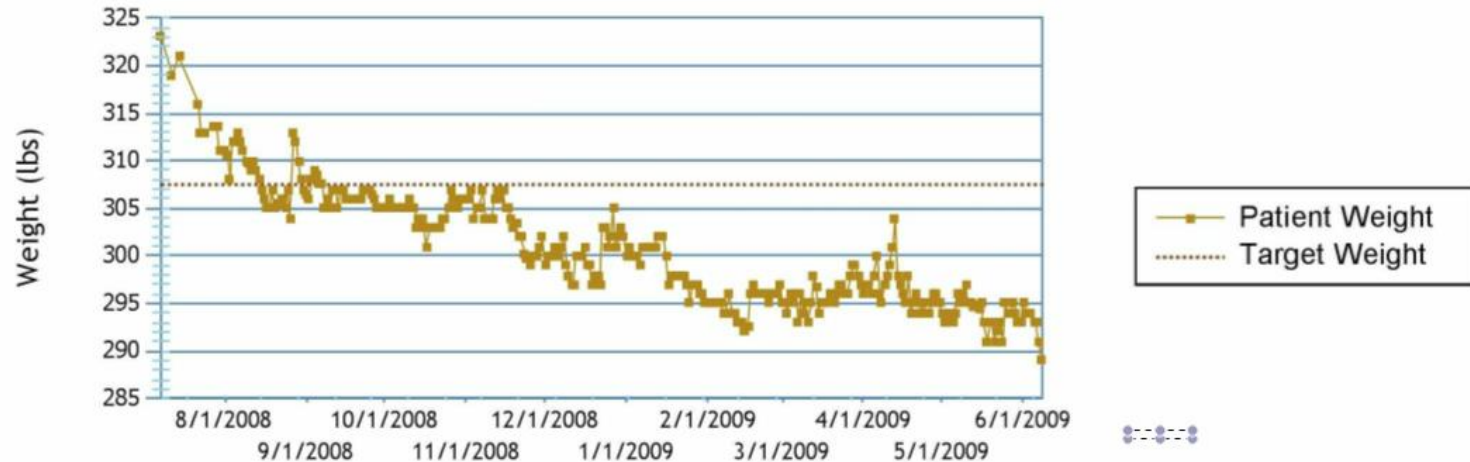
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Primary Care Physician Involvement

- ☐ Promote participation in interventions
 - ☐ Review Weight Progress Report at routine visits
 - ☐ Send reengagement letters for inactive participants
-

Weight Progress Report



Comments to participant

Comments to patient:

Basic (HELP):

- * Help by acknowledging that losing weight is challenging.
- * Encourage keeping scheduled contacts with coach, logging in to record weight, exercise, food.
- * Let patient know program is based on scientifically verified (tried and true) principles.
- * Point out individual benefits of weight loss (e.g. BP, glucose control). Even a small weight loss will help your.

Additional (if time allows):

- * Comment on weight change (e.g. It's great that you have been losing weight, or It's great that you are sticking with the program).
- * Reinforce tracking: The more you track your behavior and log in the more likely you are to achieve weight loss success.

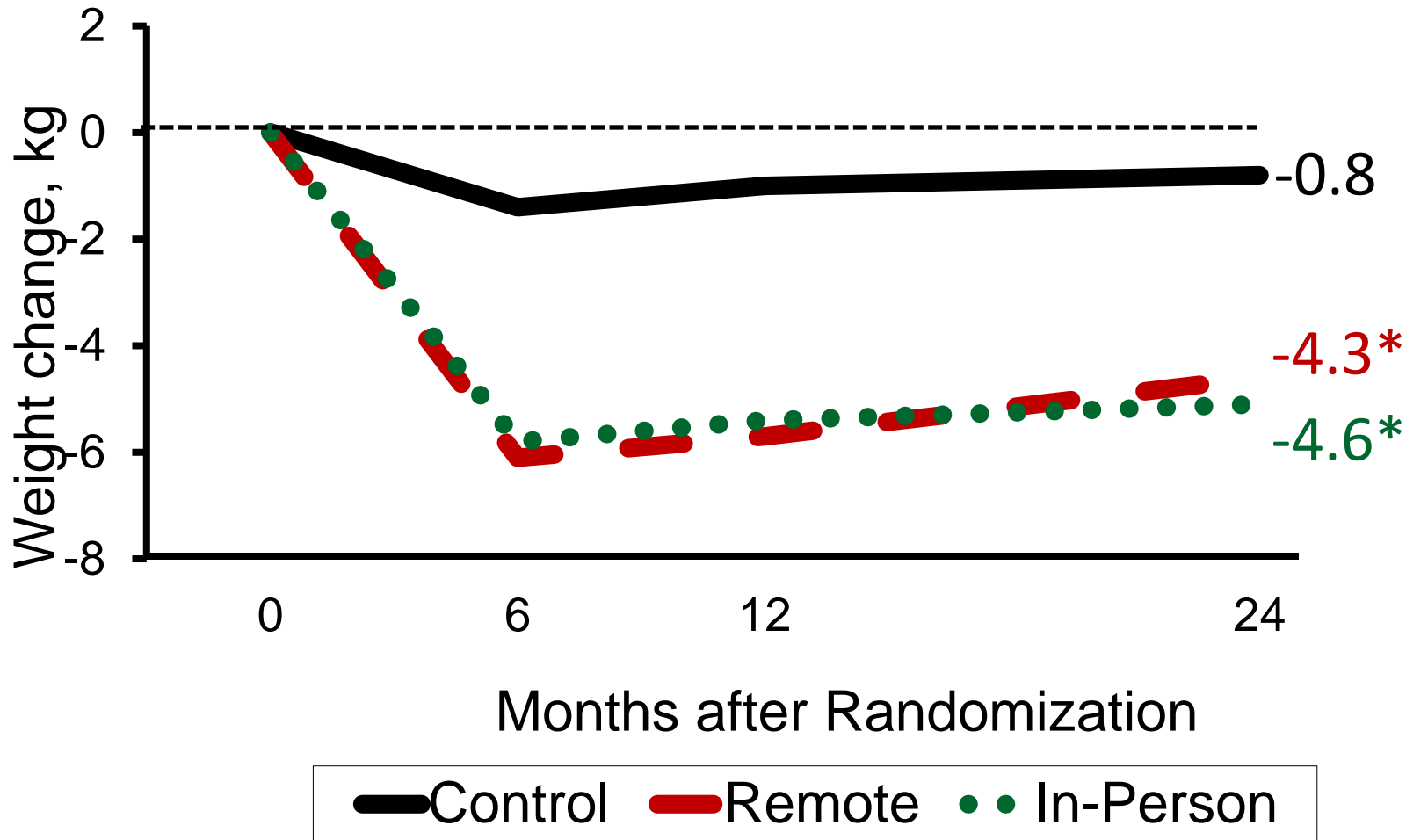
Participants

- ❑ Obese individuals ($\text{BMI} \geq 30 \text{ kg/m}^2$) with hypertension, hypercholesterolemia, or diabetes
- ❑ Other major inclusion criteria
 - Patient at one of six primary care practices
 - Internet access at least 4 days per week
 - Ability to use internet and email
- ❑ Approach to enrollment
 - Minimize barriers and exclusion criteria to increase generalizability

Characteristics (n=415)

Age	54 yrs
Women	64%
White	56%
Black	41%
Weight	103 kg
Body Mass Index	37 kg/m ²
Hypertension	76%
Hypercholesterolemia	68%
Diabetes	23%
Metabolic Syndrome	33%

Mean Weight Change (kg) by Randomized Group



Percent of Participants at Various Weight Thresholds at 24 months

	Control	Remote	In-Person
\leq Baseline weight	52%	77%**	74%**
\geq 5% Weight loss (goal)	19%	38%**	41%**
\geq 10% Weight loss	9%	18%*	20%*

*P <0.05 (vs control), **P <0.001 (vs control)

Intervention Drop-Outs*

	6 Months	24 Months
Remote	5%	13%
In-Person	9%	16%

*No contact with coach and no use of study website in prior 2 months

Conclusions

- ❑ Two behavioral interventions achieved and sustained clinically significant weight loss over 24 months in obese medical patients
- ❑ The *Remote* and *In-Person* interventions were similarly effective

? Reasons for Successful Weight Loss

- A. Skilled coaches
- B. Case management
- C. Motivated patients
- D. Interactive website
- E. Ongoing reinforcement with semi-tailored emails
- F. Team approach including physician
- G. All of the above

Previous Interventions

‘Die on the Vine’



Next Phase.....

- ❑ Dissemination/translation was intent of initial RFA and also a substantial interest of the investigators

- For-profit company, headquarters in Nashville, TN and call-centers throughout the US
- Healthcare ‘wellness’ solutions delivered to clients which are large employers and insurance companies
 - Disease management
 - Health coaching
- 2001 – Hopkins develops institutional consulting arrangement with Healthways
- 2006 – Healthways agrees to core design of POWER and provide letter of support
- 2011 – Healthways develops Innergy, based on POWER

innerGY™

healthier weight

*from Healthways, in collaboration
with Johns Hopkins Medicine*



*from Healthways, in collaboration
with Johns Hopkins Medicine*

Johns Hopkins Medicine provides

- Branding and endorsement
- Coach training, measurement of Innergy Coach skill proficiency for MI, mentoring for call quality and case management
 - **Movement to Train the trainer model**
- Collaboration for Innergy product development
- Innergy outcomes analysis

Healthways provides

- Market Access and Expertise
- Global delivery infrastructure
- Product design, development and promotion
- Website design and maintenance
- Innergy Health coaching, Management, Quality Review

Translation of the POWER Trial to Innergy™

Comparative Coaching Call Cadence – Initial 2-Year Program Enrollment

Time Period (Months)	POWER trial	Innergy™
1-3	12	12
4-6	3	3
7-12	6	6
Year 1 Total	21	21
12-24	12	7
Year 2 Total	12	7
Program Total	33	28

Welcome back, Sally-Anne!

My Progress
Week 1
Wed Sept 22, 2012
[View Overall Progress](#)

Your Weight
STARTING: 200 POUNDS
CURRENT: 200 POUNDS
LAST WEEK: 0 MINUTES
TOTAL MIN: 20 MINUTES

Your Activity
LAST WEEK: 0 MINUTES
TOTAL MIN: 20 MINUTES

Track Your Food, Weight and Activity
It's important to stay on track!
[Track Now](#)

Learning Center – Week 1
A Healthier You

Your success at weight loss improves when you build a balance between eating well, moving more and mastering a positive mindset. And healthy habits in these three areas of your life will also contribute to lifelong weight management and improve your well-being. The Innergy Well-Being Guidelines can help you shape that balance. They aren't intended to be done all at once. Like a map, they can guide you toward healthy choices and keep you headed in the right direction as you begin your journey to a healthier you.

Each week, a new Learning Focus will help you learn how to apply well-tested strategies that will allow you to meet your goals.

[Read More](#)

Your Coach
Tamara Lake
Registered Dietician
[View Coach Profile](#)

COACH MESSAGES
2 new unread messages
[See All](#)

NEXT COACHING SESSION
Sunday, September 25, 7:00pm
[See All](#)

Your Inspiration
[Edit](#)

What matters most to me in my life is my family. I don't want to disappoint them.

Innergy™
Make Today Matter

Home Learn Track Calendar Community

Track Your Food, Weight & Activity

Thursday September 22, 2012

WHAT DID YOU EAT & DRINK TODAY?

TODAY'S TARGET: 1400 CALORIES
CURRENT: 0 CALORIES
REMAINING: 1400 CALORIES

TRACK YOUR WEIGHT

STARTING: 180 POUNDS
CURRENT: 176 POUNDS
YOUR TARGET: 170 POUNDS

Today is your Weigh-in Day!

TODAY'S ACTIVITY

Let's try 30 mins per day

WEEK'S TARGET: 200 MINUTES
CURRENT: 0 MINUTES
REMAINING: 170 MINUTES

Visual Portion Guide
Here's a visual guide to help you understand healthy portion sizes for common foods.

Food Tracker

Thursday September 22, 2012

Daily Target: 1600 CALORIES
Current: 360 CALORIES
Remaining: 1240 CALORIES

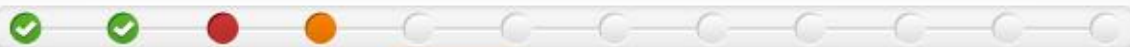
Breakfast
Banana, Fresh - Medium
1 each
Cereal, Frosted Flakes
1 cup

Lunch
Cereal, Frosted Flakes
1 cup

Totals: Fat 1g, Fiber 0g, Protein 2.3g, Sugar 26g, Sodium 151mg

My Progress

Week 4: September 22, 2012



Phase 1

Phase 2

Phase 3

Weekly

Monthly

Program

< September 18 – September 24 >



My Weight



○ = Reported Dates

Next Reward
Weight Buster
100%

STARTING
(LBS)

174

CURRENT
(LBS)

169

Track Now

Your Coach


Tamara Lake

Registered Dietician

[View Coach Profile](#)

✉ COACH MESSAGES

2

2 new unread messages

[See All](#)

📅 NEXT COACHING SESSION

Sunday, September 25, 7:00pm

[See All](#)

Your Inspiration

[Edit](#)


“ What matters most to me in my life is my family. I don't want to disappoint them. ”



Next Reward

PCP Engagement

- Currently under continued development:
 - Client reports to share with PCPs
 - Coaches to encourage PCP engagement
- Future capabilities:
 - Communication between PCP and coach
 - EMR integration to facilitate direct PCP referral to InnergyTM

Comments on Hopkins-Healthways Collaboration

- Collegial, based on > 10 years of collaboration
- Innergy required high level approval (JHU leadership, then Board)
- New processes and organizational structure; Massively different size and scope
 - POWER – tightly integrated unit with continuity of ~15 staff and investigators through whole project for trial with n=415
 - Innergy –
 - Deployment, potentially involving 1000's
 - Separate Healthways units responsible for:
 - Development
 - Training
 - Quality
 - Research

Conflict of Interest Safeguards: External Advisory Board

- Three obesity experts unaffiliated with the Department of Medicine and the Welch Center
 - Ben Caballero
 - Tim Moran
 - Tom Wadden
- Meet every 6 months
- Role – determine whether Innergy processes and outcomes align sufficiently with POWER to continue affiliation of Hopkins and Healthways
 - What outcomes should be considered?
 - What types of additional research can be funded?
 - Can results of translation/dissemination be published?

Lessons Learned – Translating Research into Practice

- What component(s) of interventions worked? What to “push” for? How to make it work?
- Interventions evolve (how much is permissible)
 - Content
 - Delivery channels
 - Number of contacts
 - Entry criteria
 - Modifications not made in original trial

Conclusions

- More work is needed that focuses on translation/dissemination/implementation
- Preferably at low cost
- Industry offers an exciting opportunity for partnerships
- Mentorship and strong models are needed to provide guidance
- Standards are needed for commercializing
- Much more work is needed to:
 - integrate obesity treatment into primary care
 - make this a reimbursable/billable service
- Thank you!