The "Nuts & Bolts" of Behavioral Intervention Development: Using the ORBIT Model to Develop^{trials network} Behavioral Treatments for Chronic Diseases

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IBTN Workshop

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Workshop Goals



- Describe the ORBIT model for behavioral treatment development and its application to health-related interventional research.
- Provide examples of specific study designs and methods applicable at each phase of behavioral intervention development and testing.
 - ORBIT *Health Psych* article (Czajkowski, Powell et al., 2015)
 - Powell and Freedland chapters from Powell, Freedland & Kaufmann book *Behavioral Clinical Trials* (Springer, in press)
- Group Exercise: Using the ORBIT model to design a behavioral intervention.





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Changing unhealthy behaviors is the "single greatest opportunity to reduce premature deaths..."

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Schroeder SA. N Engl J Med 2007;357:1221-1228

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The Challenge: How can we design more effective health-related behavior change interventions?

In biomedical research, a well-defined translational process exists that guides the development of new basic biological discoveries into efficacious therapies

Building better behavioral interventions depends on defining a similar process to accelerate the translation of basic behavioral science research into more effective behavioral interventions



The translational research spectrum applied to health behavior change research



What's the problem?



Many interventions designed according to the ISLAGIATT principle

It Seemed Like A Good Idea At The Time

Patient has changed their behaviour! Intervention worked!

But how did it work? Can we do it again? Can we train others to do the same?

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"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."

Obesity Related Behavioral Intervention Trials (ORBIT) RFA program internationa

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Or

- **Objective**: To translate findings from basic research on human • behavior to develop more effective interventions to reduce obesity & improve obesity-related health behaviors
- **Mechanism:**
 - Trans-NIH U01 (Cooperative agreement)
 - Supported by NHLBI, NCI, NIDDK, NICHD, OBSSR
 - 7 ORBIT research sites & 1 Resource & Coordination Unit (RCU)
- Each research center supports interdisciplinary project teams of basic and applied biological, clinical, behavioral and social scientists who are developing novel obesity-related interventions through formative & experimental research, early phase trials & pilot studies

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ORBIT Projects



- Translating Habituation Research to Interventions for Pediatric Obesity (NIDDK) Leonard H. Epstein, Ph.D. (PI), U at Buffalo, NY
- Interventionist Procedures for Adherence to Weight Loss Recommendations in Black Adolescents (NHLBI & NICHD) Sylvie Naar, Ph.D. & Kai-Lin Catherine Jen, Ph.D. (PI's), Wayne State University, Detroit, MI
- Increasing Sleep Duration: A Novel Approach to Weight Control (NCI) Rena Wing, Ph.D., Miriam Hospital, Providence, R.I
- Habitual & Neurocognitive Processes in Adolescent Obesity Prevention (NHLBI & NICHD) Kim Daniel Reynolds, Ph.D., Claremont Graduate University, CA
- Novel Interventions to Reduce Stress-induced Non-homeostatic Eating (NHLBI) Elissa Epel, Ph.D., Barbara Laraia, Ph.D., Nancy Adler, Ph.D. (PI's), UCSF, CA
- Developing an Intervention to Prevent Visceral Fat in Premenopausal Women (NHLBI) Lynda Powell, Ph.D., Rush University Medical Center, Chicago, IL
- SCALE: Small Changes and Lasting Effects (NHLBI) Mary E. Charlson, M.D., Weill Medical College of Cornell University, NYC
- Resource and Coordination Unit (OBSSR) David Cella, Ph.D., Northwestern University, Chicago, IL
- National Institutes of Health Susan Czajkowski (NHLBI/NCI), Josephine Boyington, Sonia Arteaga, Peter Kaufmann, Kate Stoney, Mario Stylianou (NHLBI); Frank Perna, Linda Nebeling (NCI); Christine Hunter (NIDDK); Deborah Olster, Wendy Smith (OBSSR); Lynne Haverkos, Layla Esposito (NICHD)

ORBIT Behavioral Intervention Development Model: Key Features

- Begin with the "end" in mind
 - Process is guided by "significant clinical questions" from end users trials network patients, providers

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- Progression from basic to more clinical/applied stages
 - Pushes toward the efficacy trial & beyond
- Each phase includes "clinically meaningful" milestones
 - Specify a priori criteria for moving to next phase of the intervention development process
 - Emphasis is on achieving "clinically significant" (not just statistically significant) change in behavioral targets
- Flexibility in terms of:
 - Number & types of studies within phases
 - Duration of each phase
 - Movement from one phase to the next (can "skip" a phase if necessary)
- Flow is *bi-directional*
 - Allows for "failure" & return to earlier phases as needed

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The ORBIT Model for Behavioral Intervention Development



Czajkowski, Powell, Adler, Naar-King, Reynolds, Hunter, Laraia, et al., *Health Psychology*, 2015 Oct; 34(10): 971-982.

والمري أور أرو

ihtn The Revised ORBIT Model international behavioural trials network **Basic Behavioral and Social Sciences Research** Significant (a) Clinical (a) (b) (b) (c) Effectiveness Phase II **Efficacy Trial** Proof-ofeasibility Define Refine Question Research Efficacy Concept Pilots Trial Discovery PHASE IV PHASE II PHASE III PHASE I PRELIMINARY EFFICACY **EFFECTIVENESS** DESIGN TESTING **OPTIMIZATION**

Figure 1. The ORBIT Model for Behavioral Treatment Development

Powell LM. Chapter 3: Behavioral Treatment Development. In LM Powell, KE Freedland & PG Kaufmann (Eds) *Behavioral Clinical Trials.* NY: Springer, in press.







Figure 1. The ORBIT Model for Behavioral Treatment Development

Czajkowski, Powell et al., 2015; Powell, Freedland & Kaufmann (in press)

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SIGNIFICANT CLINICAL QUESTION

Objective is to articulate a health need or clinical question requiring a solution "with the precision of a basic science hypothesis" (Coller, 2008) international behavioural trials network

Begin with a health issue that poses a significant problem

- -- A disease that is increasing in numbers, severity, exclusively affects or is increasing in a subgroup
- -- A health problem for which no treatment exists, or treatment is not very effective (could be optimized)
- -- Requires a new approach to improve outcomes
- -- Involves a novel risk factor or new approach to treatment

ومحدودها والمتقالية والمتقالية وتجرب أمرا ومعرجته القابة اللوجي والأقادي

والمستجمعة المتحلط فالمناجع والشريفين والمتحال والمحاط والمحاط والمحاط والمحاط والمحاط والمحاط

How can we identify the important *clinical* & *public health* questions that need to be answered?

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- We can gain insights from clinicians in the field what are the problems they identify & prioritize?
- Public health officials, community leaders & members can identify issues of critical need in their communities
- Evidence reviews (e.g., Cochrane), guideline panel recommendations, NIH Workshop findings & recommendations – all can be sources of "clinically significant" questions that are unresolved or lack sufficient evidence
- The clinical questions we ask also need to take the patient's point of view into account – what are the important questions to patients and their families?

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Czajkowski, Powell et al., 2015; Powell, Freedland & Kaufmann (in press)

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Phases of Behavioral Treatment Development: ORBIT Model

Phase I: Design

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Phase Ia -- *Define* the scientific foundation & basic treatment elements

- Identify behavioral risk factor target & clinically significant milestones
- Provide basic behavioral & social science research basis for treatment components & targets
- Identify candidate intervention components
- Describe pathways through which treatment can affect outcomes

Study Designs & Methods:

- Systematic reviews to determine treatment targets & potential intervention elements
- Laboratory & field experiments to identify behavioral & biological mechanisms of action
- Observational studies to identify key intervention targets & points of "entry"
- Laboratory & field experiments to identify behavioral & biological mechanisms of action
- Qualitative & mixed methods research to assess acceptability of proposed approach to end-users – "user-centered" research

والمستحر المترا والمتكرية والمتناقص الترجيب أعدأ ومحمد وتبالك فالكوي فالأشار

والمستحك والمتعاد المتعالي والمحروقان والمتعالية والمتعادي والمحتك والمتعاد والمتعاد والمتعاد والمتعاد

Phase Ia: Define Essential Features Clinically Significant Milestones:

Physical Activity

150 min/week, moderately vigorous

(Am Coll Sports Medicine)

Weight Loss

3-5% of body weight

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(Am Heart Assoc/Am Coll Cardiol)



Identifying candidate intervention components: The Behaviour Change Wheel

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Small Changes and Lasting Effects Trial (SCALE) Mary Charlson, MD (PI) Weill Cornell Medical College, NY

- Developed and tested a weight loss intervention targeting Black and Hispanic adults, BMI ≥ 25 kg/m^{2,} in Harlem and South Bronx NY based on positive affect/self-affirmation research
- A substudy on Social Network Characteristics Associated with Weight Loss (G. Winston, PI) was conducted in conjunction with SCALE based on Christakis & Fowler's (2007) analysis of BMI trends in Framingham Heart Study participants

Could better understanding of the characteristics, behavior and relationships between social network members help identify which individuals to engage to provide support in a weight loss intervention?

Weight loss by relationship of network members helpful with eating goals



Other family = aunt, uncle, niece, nephew, grandmother, grandfather, in-laws

Weight loss by relationship of network members helpful with exercise







Figure 1. The ORBIT Model for Behavioral Treatment Development



Phases of Behavioral Treatment Develo ORBIT Model internationa Phase I: Design

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Phase Ib – *Refine* the intervention for strength & efficiency

- Identify essential treatment components
- Determine aspects of delivery (mode, frequency, duration, dose, intensity)
- Determine need for tailoring (e.g., for subgroups)

Study Designs & Methods:

- Small-N, case series &/or experimental studies that test effects of varying an intervention's content, timing, frequency, duration, intensity & mode of delivery; dose-finding studies
- Novel methods for developing, testing & refining behavioral interventions such as Multiphase Optimization Strategy (MOST) & adaptive treatment (SMART) designs أترج والمتناكي وتحجو أورا ومحجونا اللابنا

Phase Ib: Dose-finding studies

What is the optimal dose of a behavioral intervention?

- <u>Duration</u>: how long individual is exposed to intervention (e.g., weeks, months, years?)
- <u>Frequency</u>: how often contact is made over specified length of time (# of counseling session/week? How many texts or prompts/day or week?)
- <u>Amount:</u> length of each intervention contact (minutes/hours for counseling sessions, phone contact; # of words for texts)



Dose-finding methods for behavioral interventions

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- Identify/narrow doses (Voils et al., 2014)
 - Retrospective analysis of RCT data
 - Surveys/interviews with key stakeholders
 - Prospective/longitudinal/observational studies
- Validate the hypothesized optimal dose (Voils et al., 2014)
 - Early phase non-randomized designs
 - Randomized designs
- Use of dose-finding designs adapted from drug development (E.K. Towner, SBM seminar, 2018)
 - Accelerated Biased Coin Up-And-Down Design (ABCD) stepped-approach used in Phase I dose-finding drug trials (Styliaou et al., 2004)

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Figure 2. Sequential Multiple Assignment Randomization Trial (SMART) design and participant flow. 5 families were removed from the study by the research team and are not included in the numbers shown. MIS = Motivational interviewing and skills (Phase 1); HB-MIS = Home-based motivational interviewing and skills; OB-MIS = Office-based motivational interviewing and skills; RP = Relapse Prevention; CS = Continued Skills; CM = Contingency Management.

Figure adapted from Naar-King et al., J of Clinical Child & Adolescent Psychology, 2015





Figure 1. The ORBIT Model for Behavioral Treatment Development

Czajkowski, Powell et al., 2015; Powell, Freedland & Kaufmann (in press)

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Phases of Behavioral Treatment Develop ORBIT Model internationa

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Phase II: Preliminary Testing

Phase IIa – **Proof-of-Concept Studies**

- Determine if the intervention can achieve a *clinically significant signal* on the relevant behavioral risk factor
- Inexpensive initial test of a fixed protocol

Study Designs & Methods

- Typically non-randomized
- No control group
- Small-N, single-case designs

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Behavioral Control of Overeating ibtn



ومسالحاتها والماسين بالجريين والواقيا بالاستخاصي ورزاما والار

Reversal design



J. Dallery, SBM seminar, 2017

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Multiple-baseline design

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J. Dallery, SBM seminar, 2017





Figure 1. The ORBIT Model for Behavioral Treatment Development

OPTIMIZATION

Czajkowski, Powell et al., 2015; Powell, Freedland & Kaufmann (in press)

Phases of Behavioral Treatment Development: ORBIT Model

Phase II: Preliminary Testing

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Phase IIb -

- Feasibility & Pilot Testing to determine:
 - Whether the intervention is feasible & acceptable
 - Numbers available for screening & recruitment
 - Estimates of yield (screening to enrollment ratio), drop-out rate, crossovers, adherence to treatment
- Study Designs & Methods:
 - Randomized or non-randomized designs
 - Can include qualitative methods to understand patient experiences, acceptability, feasibility

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Phases of Behavioral Treatment Development: ORBIT Model

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Phase IIc –

- **Phase II Efficacy Studies** to determine:
 - whether the intervention has an effect on a behavioral or intermediate outcome of interest (e.g., often an outcome in the mechanistic pathway &/or related to the ultimate clinical or physical health outcome)
- Study Designs & Methods:
 - Typically randomized designs

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Phase IIc: Limiting dietary variety in family-based treatment (Epstein et al, 2015)

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- 24 families, with a child \geq 85th percentile BMI and aged 8 to 12 years
- Randomly assigned to 1 of 2 conditions:
 - Family-Based Treatment (FBT)
 - Traffic Light Diet (1000-1500 kcal/day, < 2 servings/day of RED foods)
 - Developed meal plans
 - <u>></u> 60 min/day of MVPA prescription
 - FBT+Variety
 - Family-based treatment (identical to FBT)
 - Identified two RED foods to consume during the intervention: one dinner entrée and one snack food
 - Developed meal plans that repeated dinner entrees and included leftovers from the dinner entrees and reduced variety of RED foods
- Outcomes:
 - Child percent overweight: FBT+Variety -15.4% vs. FBT 8.9%, p = 0.017
 - Variety of RED foods consumed by family: FBT+Variety = 20.2 to 12.6 vs. FBT = 19.7 to 16.8, p = 0.01

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Epstein et al, 2015

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ORBIT Behavioral Intervention Development Model: Key Features

- Begin with the "end" in mind
 - Process is guided by "significant clinical questions" from end users trials network patients, providers

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- Progression from basic to more clinical/applied stages
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Orbit

Thanks to all my colleagues who participated in ORBIT



Questions?

