

# “Real World” Adolescent Intervention Research Meets Randomized Controlled Trial Methodology

## Lessons Learned

DIANA JACOBSON PHD, RN, PPCNP-BC, PMHS, FAANP

BERNADETTE M. MELNYK PHD, RN, CPNP/PMHNP, FAANP, FNAP,  
FAANP, FAAN

STEPHANIE KELLY PHD, RN

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# Objectives

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- 1) The learner will be able to identify detracting and facilitating factors that influence the development and implementation of healthy lifestyle interventions with adolescents within the school setting.
- 2) The learner will be able to discuss techniques to improve intervention fidelity.

# Behavior Change

- Goals of behavior change research
  - COPE TEEN
- Behavior change research is difficult.
  - Increasing knowledge alone does not change behavior
- Theory is necessary in order to guide the design of interventions.
  - Describes the “how” and “why” of behavior change

**Is there such a thing as  
a perfect Randomized  
Controlled Trial?**

# Randomized Controlled Trials

- Assumption by the NIH, FDA and others that RCTs should be the **gold standard\*** for clinical research.
  - Strengths
  - Disadvantages

**\*and now systematic reviews of RCTs**

# Strengths of the RCT

- Decreases spurious causality and bias
- Assumes equal distribution of individual characteristics in both the intervention and control groups
- Internal validity can be viewed as a matter of degree

# Disadvantages of the RCT

- Limitations of external validity
- Expensive endeavor
- Long time delays in publishing results especially with longitudinal designs
- Significance of results does not always indicate clinical meaningfulness
- Some research questions don't permit random assignment to condition

# Fidelity

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- To the principles of randomized controlled trials
- To the theoretical underpinnings guiding the development of the intervention
- To the intervention delivery

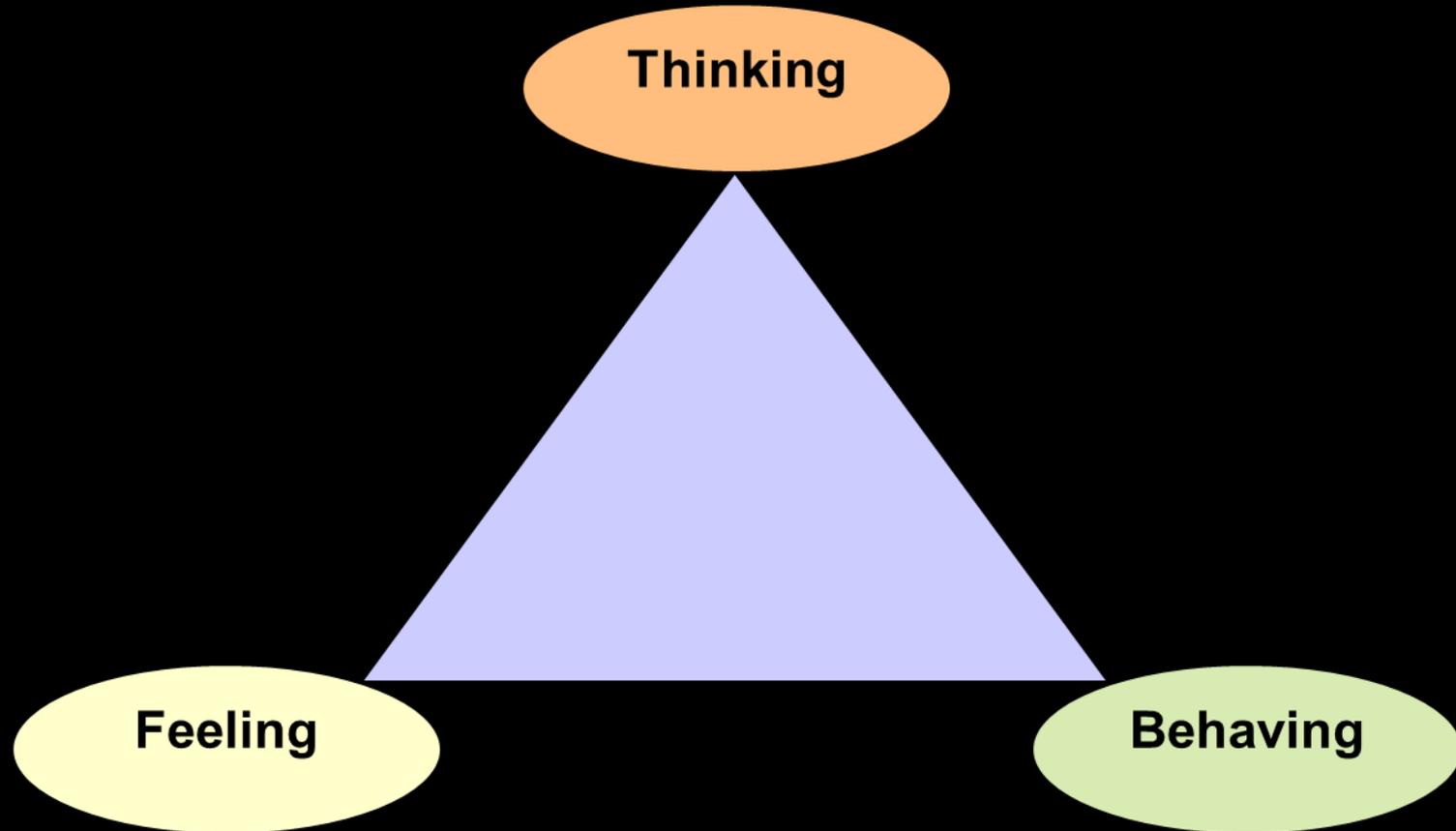
# Fidelity to the Intervention Theory

- Keller, Fleury, Sidani & Ainsworth (2009)
  - Evaluative components of fidelity
    - Conceptualization of the problem
    - Operationalization of the theory
    - Specification of mediating processes
    - Specification of outcome variables

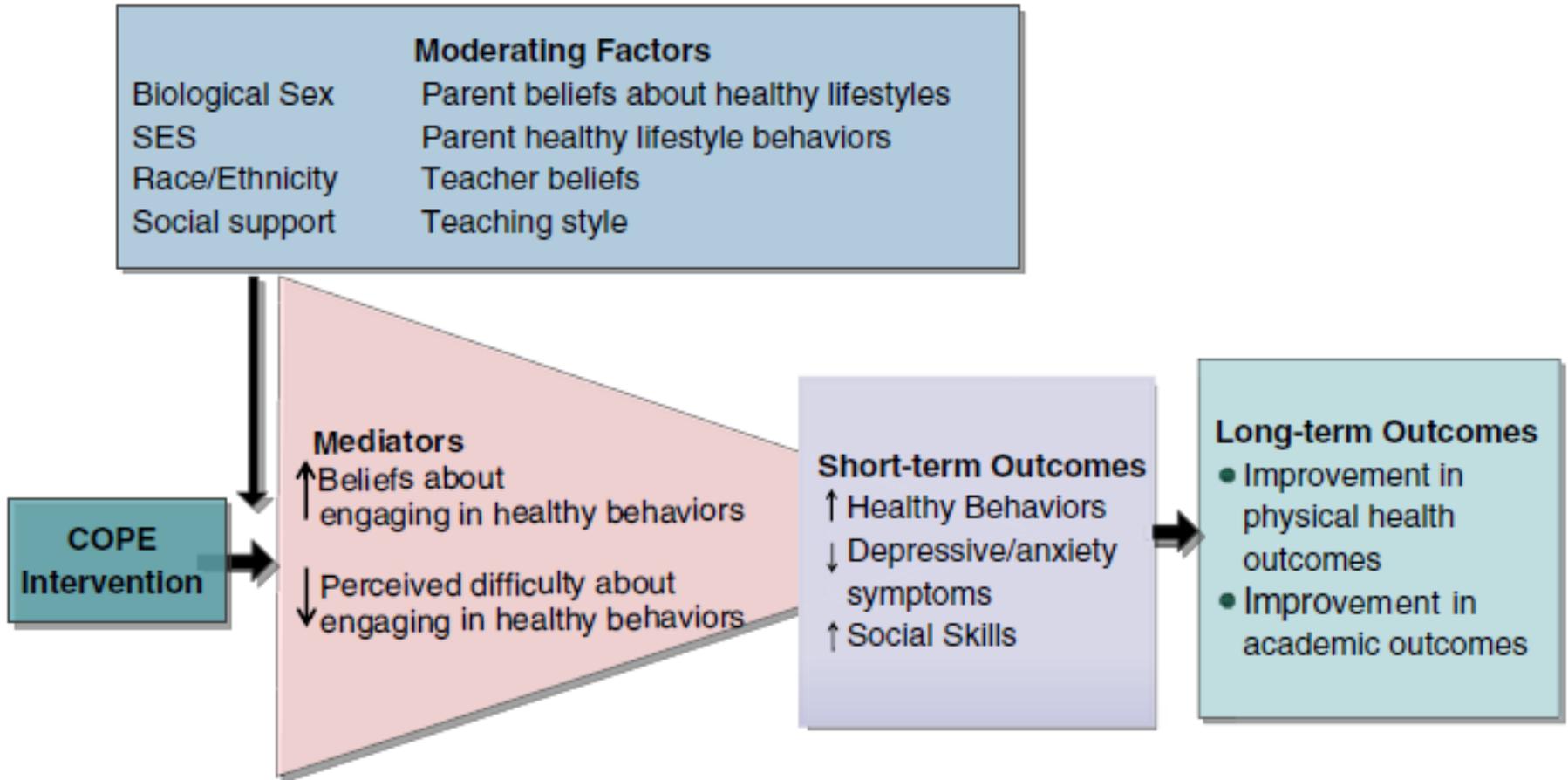
# Fidelity to the Intervention Theory

“Intervention theory offers explanations of the problem amenable to treatment, critical inputs of the intervention, mediating processes, and expected outcomes of the intervention, thus providing a basis for explaining how an intervention exerts its influence on desired outcomes, and furthering understanding of what interventions work, for whom, and under what conditions, thus strengthening causal inferences.” (Keller et al. p. 291)

# Fidelity to the Intervention Theory



# COPE Conceptual Model



# Fidelity to Intervention Delivery

- Gearing, R. E. et al. (2011) and Bellg, A. J. et al. (2004) have developed fidelity guides for intervention delivery.



# Fidelity to Intervention Delivery

- **Bellg et al. (2004)**
  - 1. Study design
  - 2. Provider training
  - 3. Treatment delivery
  - 4. Treatment receipt
  - 5. Enactment of treatment skills
- **Gearing et al. (2011)**
  - 1. Intervention design
  - 2. Intervention training
  - 3. Monitoring the intervention
  - 4. Monitoring the intervention receipt

# Fidelity to Intervention Delivery

- COPE TEEN Challenges
  - Teacher training
  - Session observation and rating by team members
  - Teacher delivery of intervention without “drift” or adaptation
  - Teen receipt and practice of core elements
  - No corrective protocol in place



# Steps to Fidelity Improvement

- 1. specify the essential ingredients
- 2. **collaborate** with change agents in field settings
- 3. obtain commitment to intervention
- 4. train and **retrain** change agents
- 5. provide ongoing supervision and **remediation**
- 6. be ready for challenges
- 7. do pilot work
- 8. designate staff to **carry out fidelity checks**

# Fidelity to Intervention Delivery

- Despite more fidelity issues in the COPE TEEN vs the Healthy Teen teachers, important outcome differences were found between groups at 6 and 12 months post intervention
  - > # of steps/day
  - Less BMI
  - Less depression in students who were severely depressed
  - Lower alcohol use
  - Higher social skills



**Thank you!**

**Questions?**

**DIANA.JACOBSON@ASU.EDU**

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