

# Issues in studying behavioral and pharmacological interventions

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# Issues in studying behavioral and pharmacological interventions

- Common placebo controlled design
  - Drug versus placebo (vehicle)
  - Double-blind
  - Post-hoc evaluation of drug/placebo assignment
  - Attribute differences to active pharmacological agent, controlling for non-specific aspects of drug administration

# Strengths of placebo-controlled trials

- Can attribute between group differences to pharmacological agent
- Compare effect sizes between drugs based on a common control

# Weaknesses of placebo-controlled trials

- Minimal test of treatment efficacy
- No information on comparative treatment efficacy

# Testing behavioral and pharmacological interventions

- Variations of behavioral/pharmacological studies
  - Are there differences in outcome between behavioral versus pharmacological interventions?
  - Are there additive effects such that the combination of behavioral + pharmacological interventions are superior to either alone

# Groups for behavioral versus pharmacological comparisons

- Behavioral
- Pharmacological
- Control for behavioral
- Control for pharmacological
- Control for any intervention

# Groups for additive behavioral plus pharmacological comparisons

- Behavioral
- Pharmacological
- Behavioral plus pharmacological
- Behavioral plus pharmacological placebo
- Pharmacological plus behavioral placebo
- Control for behavioral
- Control for pharmacological
- Control for any intervention

# Tailoring behavioral interventions in combined trials

- Use common behavioral intervention and add it to drug treatment
- Develop behavioral intervention that is designed to take advantage of pharmacological effects:
  - Examples
    - Orlistat
    - Zyban

# Drug-behavioral attributions

- How they can influence treatment
  - If people who are provided drugs during behavioral treatment and they attribute effects to drugs, then when drugs are removed, the treatment effects may be lost
- Example
  - Insomnia (Davidson et al)

# State-dependent effects

- Drug effects can be conditioned to environmental stimuli
- Behaviors learned during pharmacological treatments that have psychoactive effects may not demonstrate behaviors when drugs are withdrawn

# Main effect of compliance

	Drug	Placebo	
Compliant	A	B	$A + B$
Non-compliant	C	D	$C + D$
	$A + C$	$B + D$	

- In studies that contrast drug and placebo interventions, patients who comply to the placebo often show the same treatment effects as those who comply to the active drug ( $A + B = C + D$ )
- Epstein, 1984; Horwitz, 1993