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Psychotherapy Methodological Issues: Choice of Comparison Group

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Psychotherapy Comparison Groups

- Gold (1954) developed placebo controlled studies in the US to establish that the benefits observed with medications were due to their chemical properties rather than to patients' expectations, hopes, or other psychological processes
- Rosenthal and Frank (1956) suggested that placebo designs be applied to psychotherapy research as well, to rule out factors that are incidental to the active "ingredients" specified by the treatment protocol
- Unlike placebo vs. active medication trials, psychotherapy trials cannot use placebo controlled designs in which all factors except the therapy's active ingredient are held constant—challenge to control all non-specific factors

Psychotherapy vs. Medication RCTs

- Patient and providers are not blinded to treatment ("solution"= blinded raters)
- Impact of patient provider interactions on outcome (provider skill / impacts drop out)
- Provider & patient adherence to protocol
- Manualization/standardization of treatment
- Timing of outcome/symptom measures different

Psychotherapy RCTs

- Select designs based on the state of the knowledge about a given treatment
- Four Stages of Psychotherapy Designs:
  - Stage 1: Randomized wait list (currently being challenged)
  - Stage 2: Nonspecific comparison
  - Stage 3: Dismantling, additive, parametric designs
  - Stage 4: Direct comparisons of two treatments

Stage 1: Randomized Wait List Control

Does the treatment have benefit?

- Proponents characterize WLC as…
  - Uses an untreated comparison group assessed at the same intervals as the treatment group
    (CPT w/ Veterans - Monson et al 2006)
  - WLC provided with therapy at end of waiting period
  - Controls for many threats to internal validity
    (Maturation, testing, instrumentation, regression, selection, etc.)
  - Can conclude benefits observed are from treatment

Borkovek 2003; Schnurr 2007

Stage 1: Randomized Wait List Control

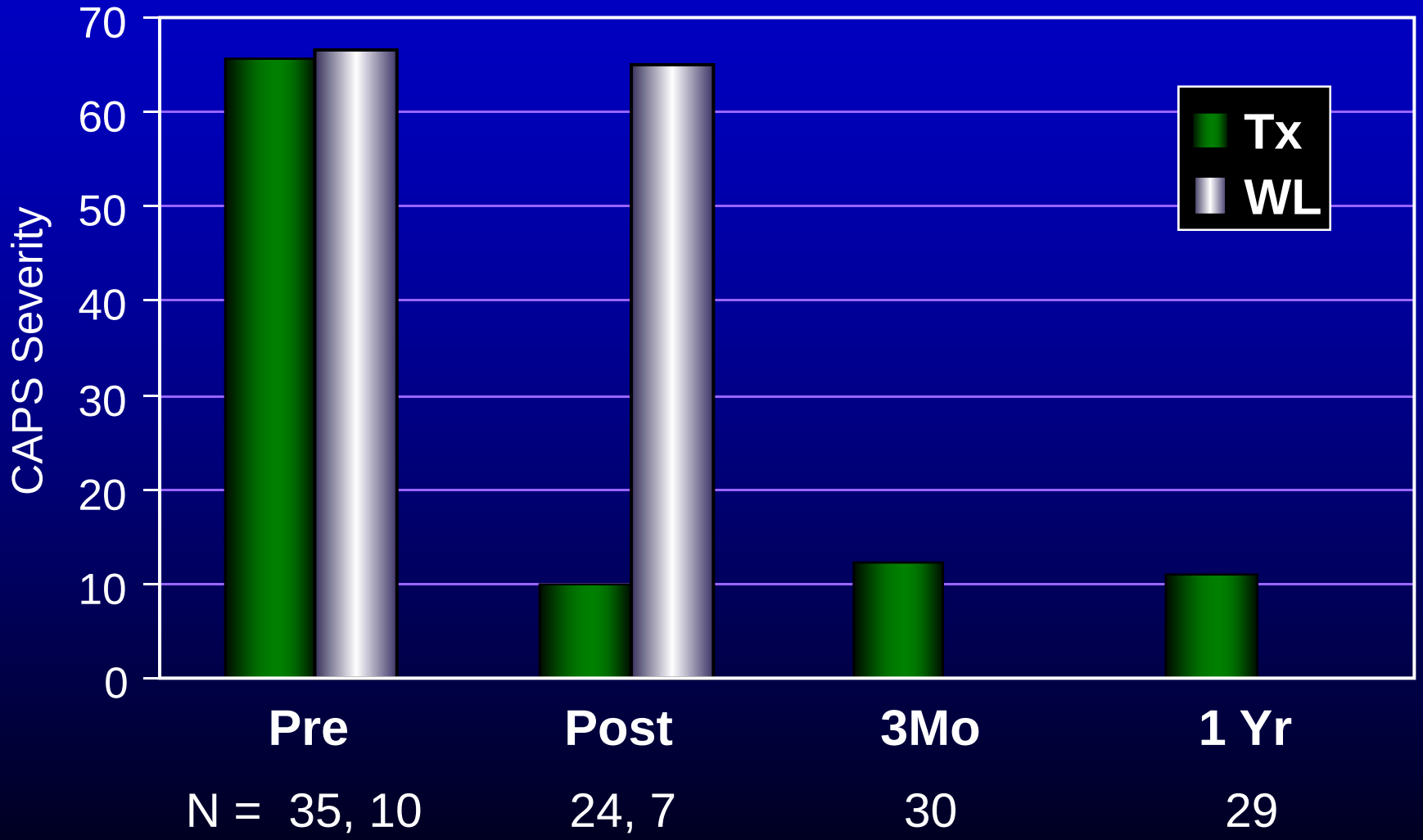
- Disadvantages
  - Don’t rule out possibility that other treatment would be as effective or better
  - Ethical issues (Borkovek 2003)
    - Must monitor participants to assure they are not getting worse. if they are, remove from protocol and offer treatment immediately
    - Must justify use of wait list based on knowledge of nature, course, severity of disorder and length of waiting period

Stage 1: Randomized Wait List Control

- Disadvantages & Concerns of WLC – The Other Views
  - WLC is problematic as a fair comparison—it should be analogous to a placebo in which the following are accounted for:
    - Passage of time
    - Increased attention
    - Expectation of therapeutic intervention
    - Psychological consequences of legitimized sick role (Klerman 1986)
  - WLC accounts for **time**, but not for *attention* or *expectation* of getting better (Leon 2008)
    - Could be perceived as insulting or detrimental
    - Could exacerbate symptom severity (ethical issue)
    - Not a credible comparator
    - May contribute to attrition

CPT-SA v Waitlist on CAPS

Chard 2005



Stage 2: Non-specific Comparison

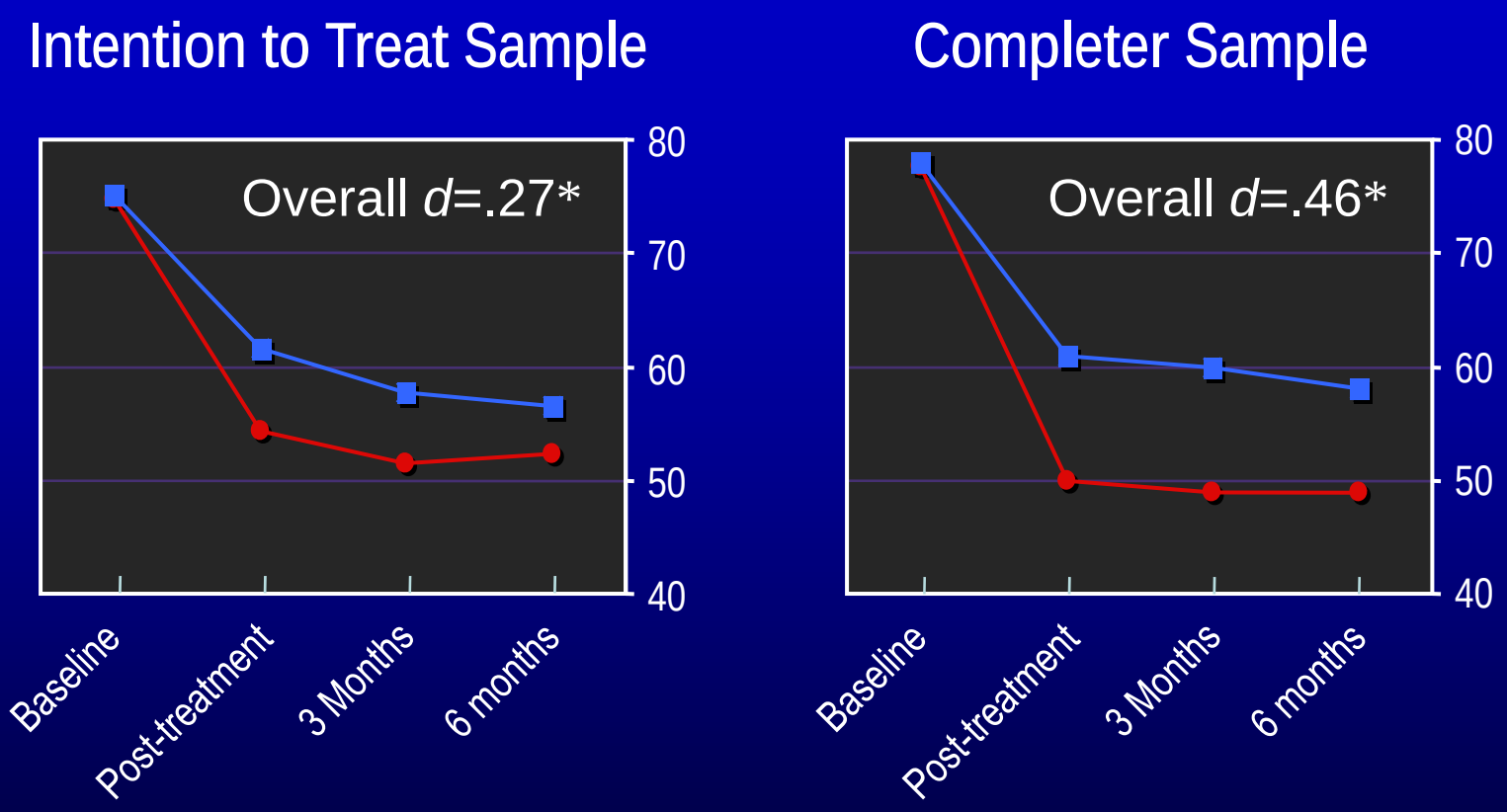
Is the effect greater than the effect of simply going to therapy or getting usual care?

- Non-specific comparison that controls for the effect of receiving a treatment
  ("active ingredient" not included in comparison; CSP 494 - Schnurr et al 2007)
- Randomized to target treatment or one that controls for non-specific benefits of treatment so can make inferences about additional benefits of target treatment
- Can be used with multiple target treatments (PE vs. CPT vs. PCT)
  - Supportive counseling, relaxation training, Present Centered Therapy (PCT), Treatment as Usual (some are more well standarized/ manualized while others are not)

Common Ingredients of Psychotherapy & Non-Specific Comparison

- Contact with therapist
- Attention to problem
- Suggestions for change
- Generation of:
  - Faith
  - Hope
  - Expectancy for improvement

CAPS PTSD Scores Lower in PE



*p<.05

- Schnurr et al 2007

Stage 3: Combination of Active Elements

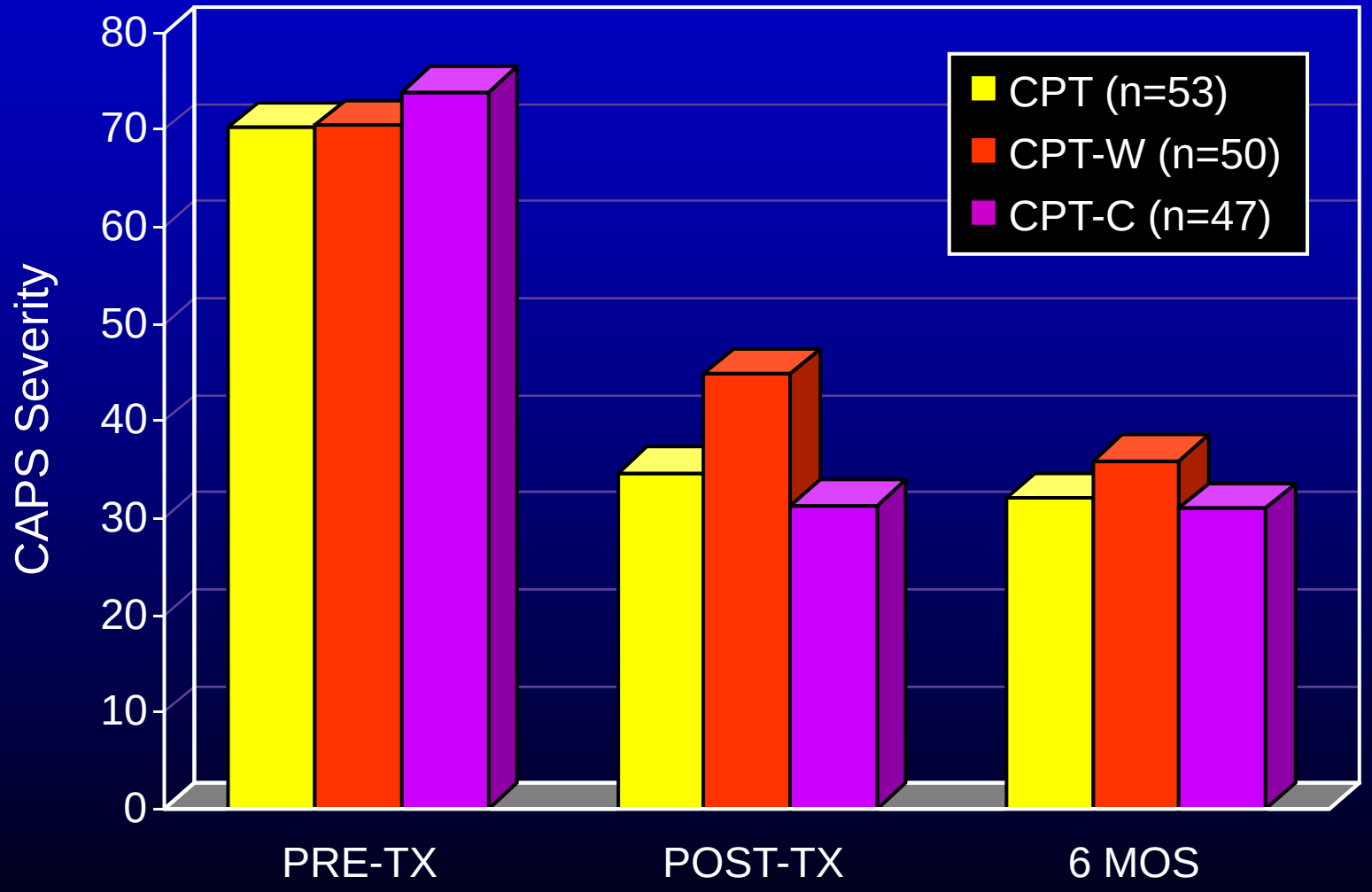
Why does the treatment work?
What are the active ingredients?

- Dismantling Designs: systematically manipulate elements thought to be active ingredients
  (CPT classic vs. CPT-C vs. CPT-W - Resick et al 2008)
- Additive Design: techniques shown to work in isolation are combined and compared to separate techniques
  (PE with and without cognitive restructuring - Foa et al 2005)
- Parametric Design: amount of active treatment is varied from less to greater (ex: length of exposure)

Intent to Treat CAPS Severity

(no difference btw groups)

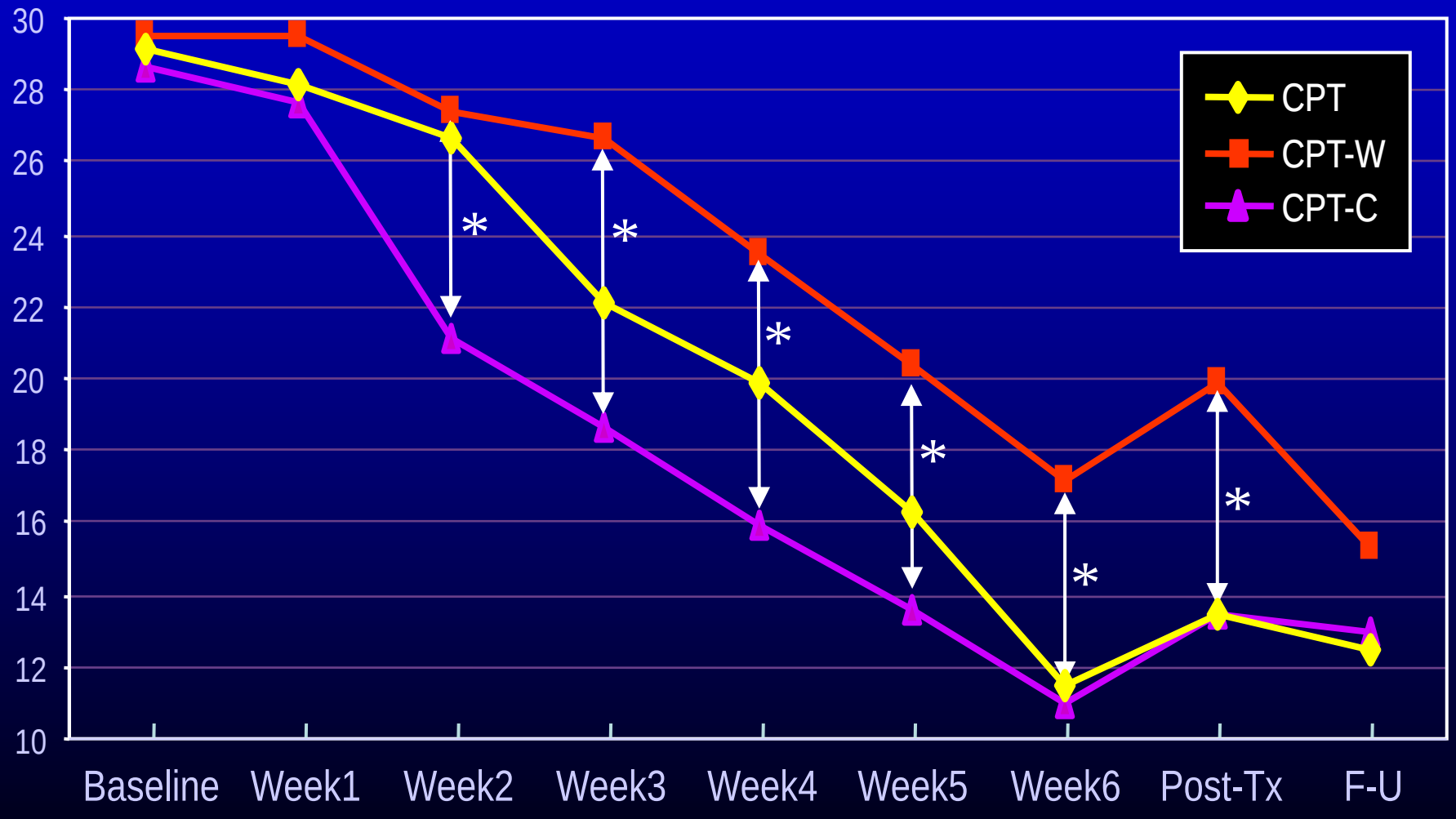
(Resick et al 2008)



Random Regression of PDS

PDS Total with Categorical Assessment Interval

(Resick et al 2008)

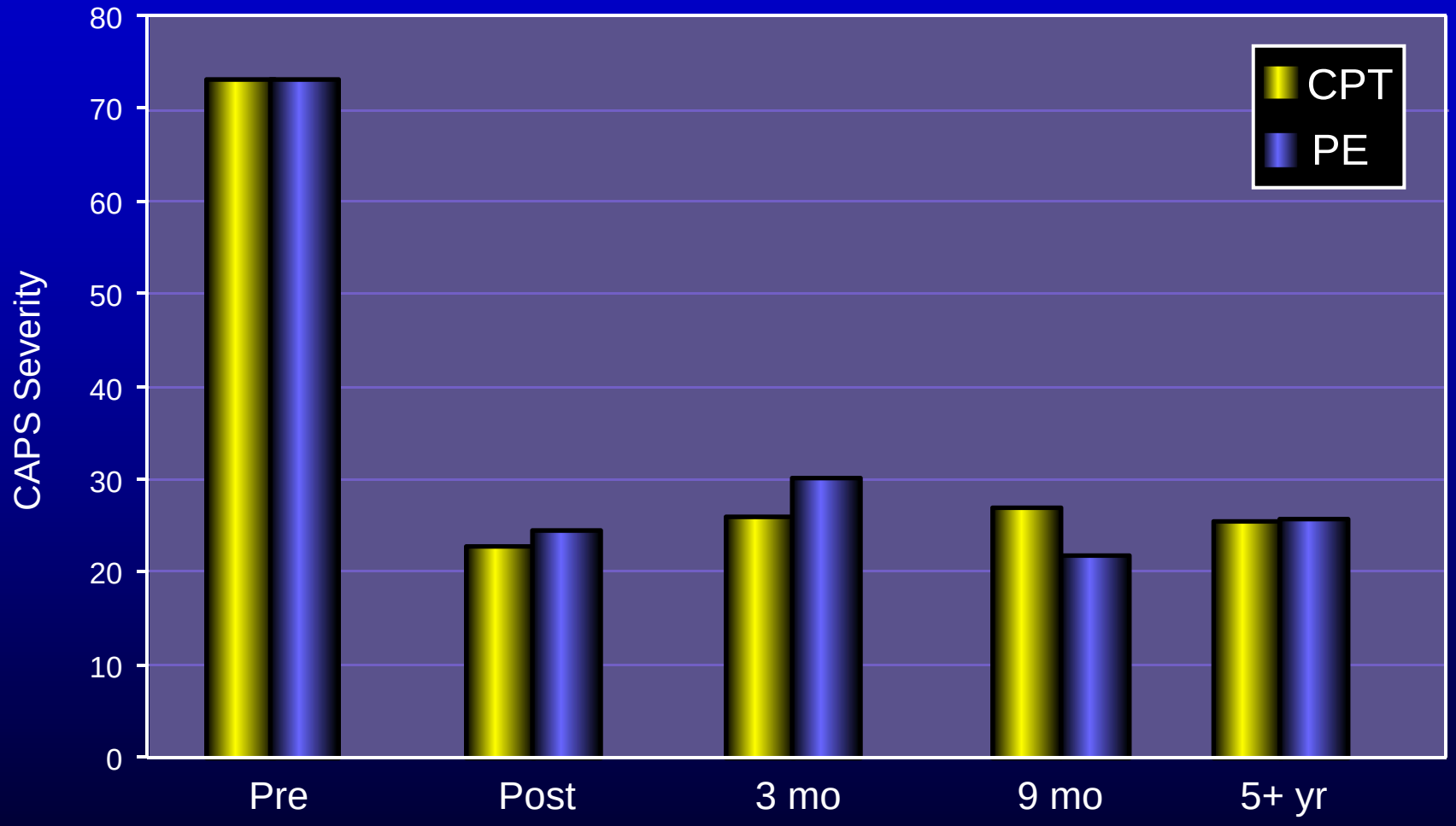


Stage 4: Direct Comparison of Two Efficacious Treatments

Is treatment A better in some way than treatment B?

- Compares two active but different treatments
- Chance of finding differences is slim (Maat et al 2007)
  (CPT compared to PE - Resick et al 2008)
- Often aim is to find no difference and are looking for equivalence or non inferiority (uses different design)
  - Implications for cost, acceptability, etc

CPT vs. PE (intent to treat)



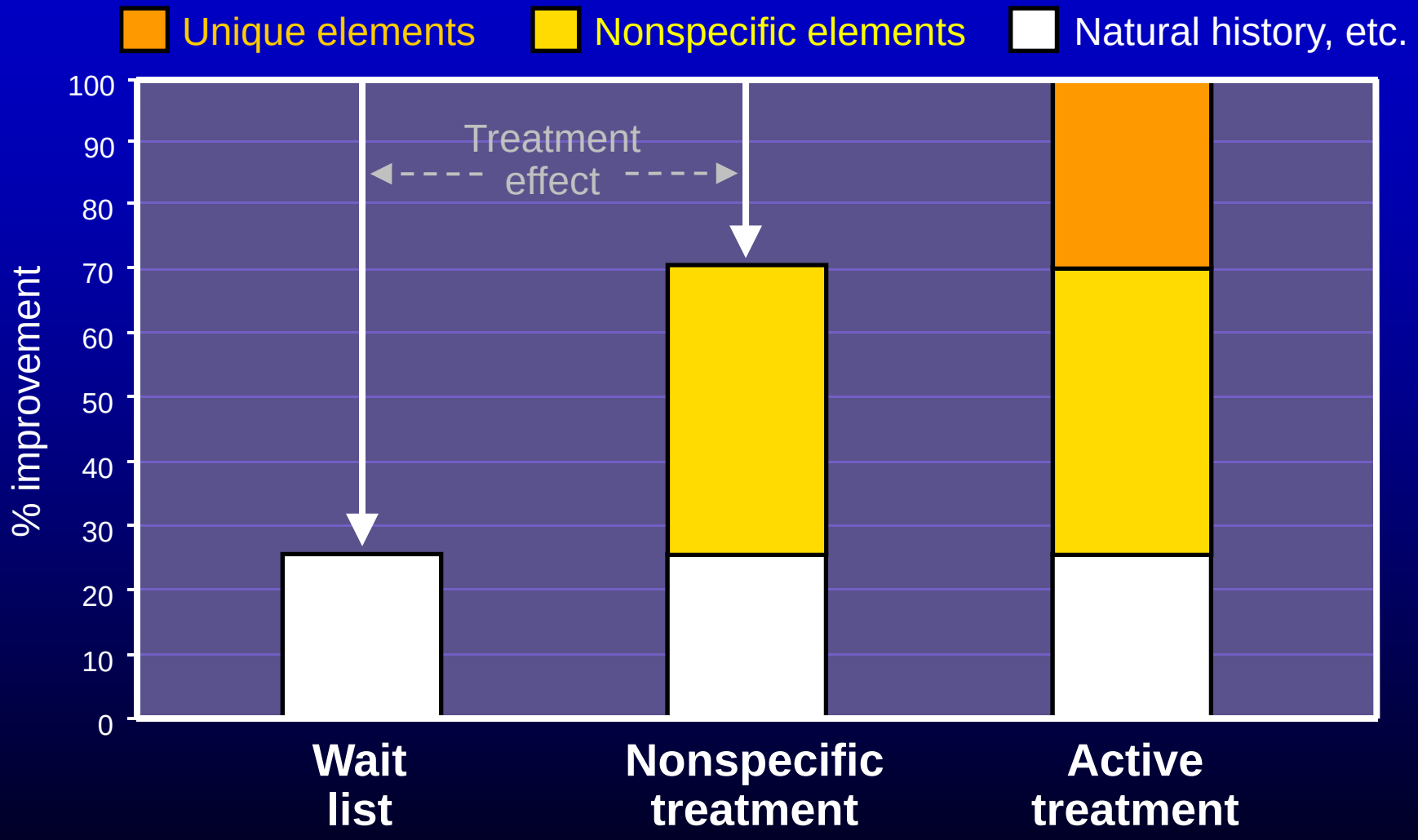
CPT:	N = 83	55	50	41	63
PE:	N = 88	55	51	39	64

Additional Issues

- Regardless of type of design, other factors can impact treatment response
  - Amount of treatment (dose)
  - Therapist expertise
  - Treatment credibility
- Treatment effect is impacted by type of design and how well conditions are equated
  (ex: more active comparison group and greater control for non-specific factors = smaller effect size)
- Not appropriate to compare effect sizes from a study that used wait list with study that used non-specific design

Hypothetical Example of Elements of Change in Wait-list, Nonspecific, and Active Treatments

(Schnurr 2007)



- Vertical arrows indicate effect size observed in wait-list and nonspecific groups relative to active treatment

Other Comparisons

- Three staged approach
  - Feasibility and pilot studies
  - RCT for efficacy (Random assignment, control of non-specific benefits of treatment, manualized treatment, fidelity monitoring, fixed sessions, well defined outcomes, blind raters, exclusion of patients with co-morbidities, fixed assessment intervals)
  - Effectiveness studies to establish benefit in clinical settings (Rounsaville et al 2001)
- Explanatory Trial vs. Practical Clinical Trail
- Explanatory – how and why an intervention works
  - Practical Trial – combines efficacy and effectiveness and answers questions about decisions about healthcare (CSP 494 - Schnurr et al 2007)

Summary

- Medication and psychotherapy RCT vary on multiple factors

  (Comparison group choice, blinding, manualization, fidelity, interactions of provider & patients, adherence to protocol, timing of symptom and outcome measurement)

- Psychotherapy RCT have no true placebo control comparison

- Comparison groups differ depending on questions being addressed

- Effect sizes vary depending on comparison group and how well groups equated