Spotlight on Women Cyberseminar Series

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Methodological Issues in Psychotherapy (and Other Nonpharmacological) Treatment Research

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ADVANCING SCIENCE AND PROMOTING UNDERSTANDING OF TRAUMATIC STRESS

Context

- **Growing number of women Veterans**
  - ***% among VA users is growing too***
- **Few studies of psychotherapy and other non-drug interventions in women Veterans**
  - ***Few studies in samples that permit male vs. female comparisons either***
- **Principles of studying psychotherapy apply broadly, e.g., surgery, physical therapy, education**

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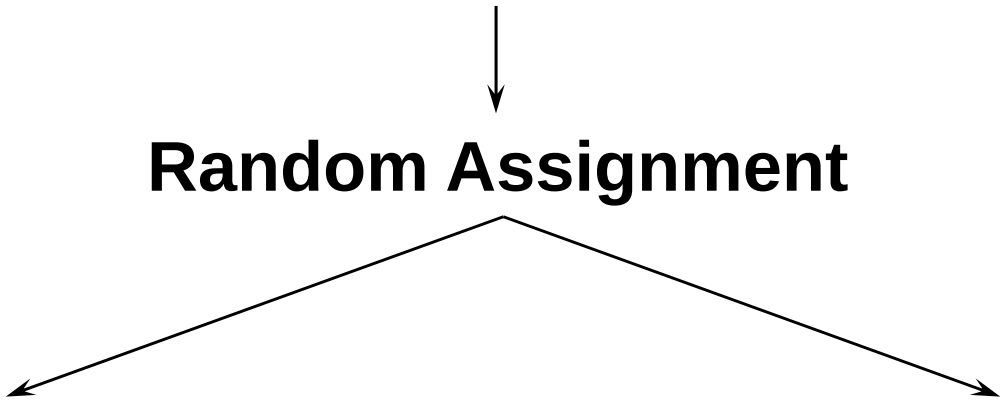
CSP #494: CBT for PTSD in Women

Question: *Are the benefits of Prolonged Exposure greater than the benefits of good therapy?*

284 Female Veterans and Active-Duty Personnel w/PTSD



Random Assignment

141 Total
Prolonged Exposure (PE)
Trauma Focused
Exposure Therapy

143 Total
Comparison Therapy
Present Centered
Therapy (PCT)

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It’s all about control…

“The fundamental goal of any between-group experimental design and its associated methodology is to hold all factors consistent other than the one variable about which cause-and-effect conclusions are to be drawn.”

–Tom Borkovec, 1993

We Have “Control Issues”

- **e.g., choosing a comparison condition**
  - ***No placebos and many options***
- **e.g., equating a comparison condition**
  - ***Many factors to control, or not***
- **e.g., assigning therapists to conditions**
  - ***Need to control therapist effects***

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Characteristics of Psychotherapy and Drug Interventions

	Psychotherapy	Drug
Treatment involves collaboration between participants & providers	+++	+
Blinding patients & providers is virtually impossible	+++	(+)
Provider expertise can influence results	+++	+
Therapist (provider) adherence must be assessed	+++	+
Control conditions often have active elements	+++	(+)

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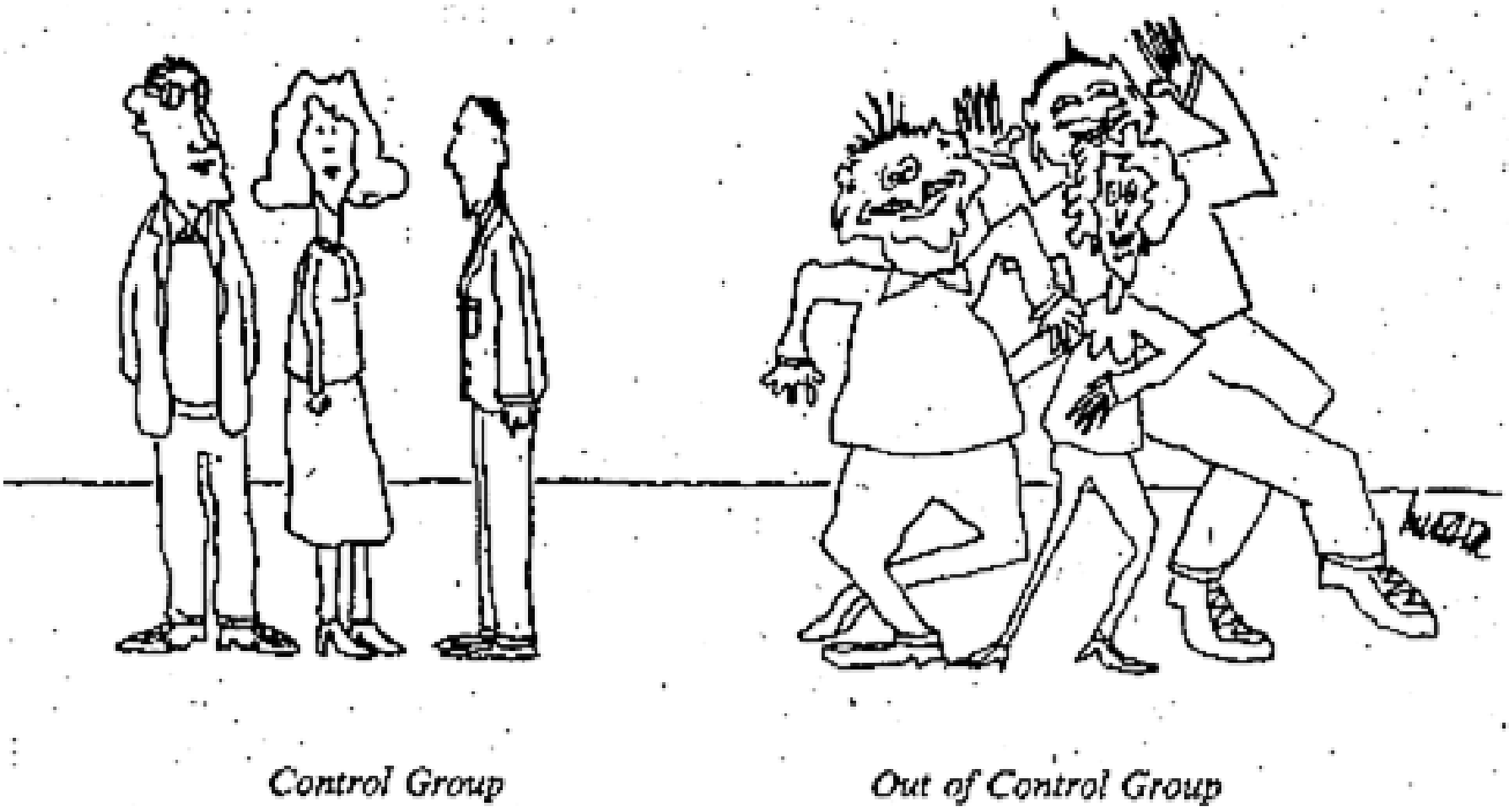
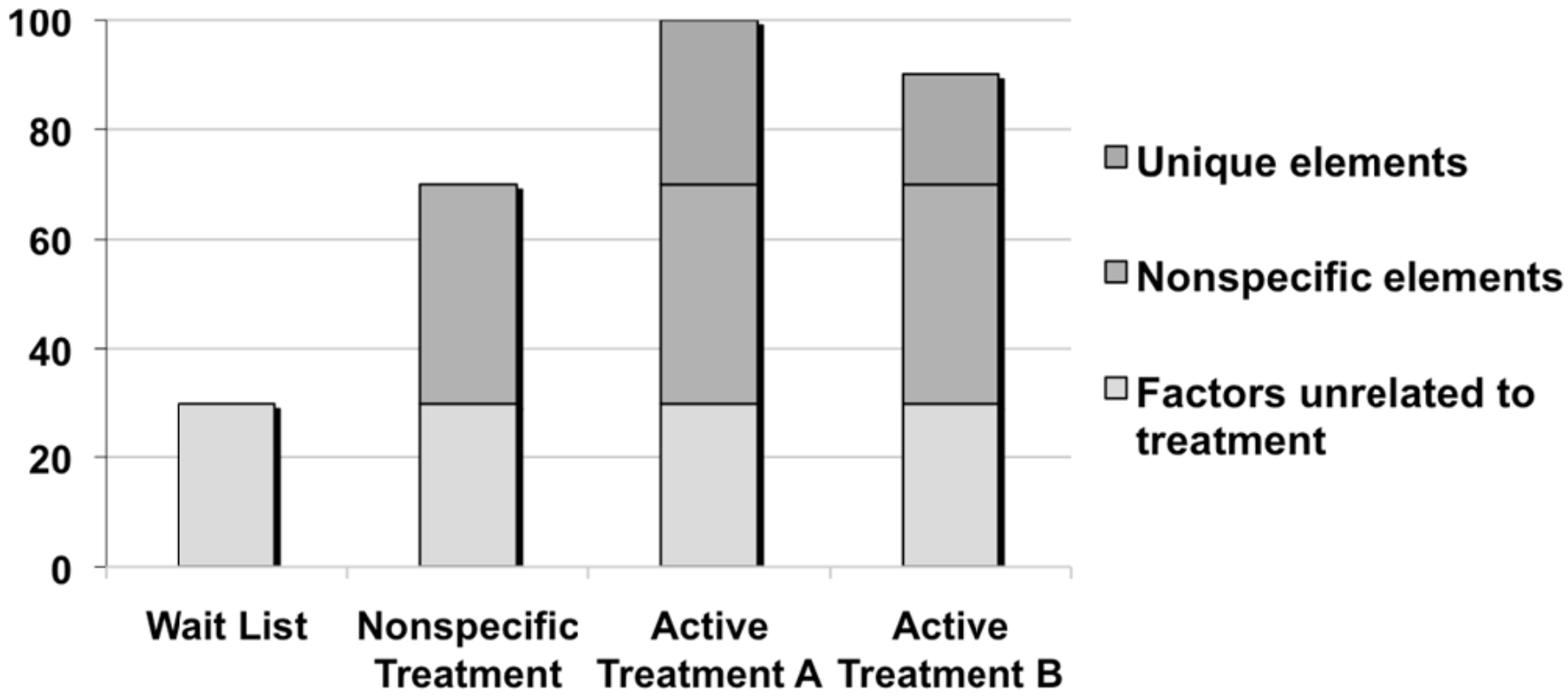
Special Considerations in Psychotherapy Trials

- Choosing a comparison condition
- Equating a comparison condition
- Assigning therapists to conditions
- Manualization
- Training, supervision, and monitoring
- Additional treatment
- Group-based treatments

Choosing a Comparison Condition



Elements of Pre-Post Change as a Function of Treatment Group



Control for Elements of Change in Psychotherapy Designs

Wait-list: controls for factors unrelated to treatment (most threats to internal validity); provides no information about mechanism

Nonspecific/treatment as usual: also controls for nonspecific therapeutic elements

Component control: also controls for non-specific elements; isolates active ingredients

Other active treatment: control varies; tells you whether treatments differ but not why

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What to Choose?
What's the Question?

<u>Wait list</u>: does the treatment have benefit?

- ***Not for effectiveness questions***

<u>Nonspecific comparison/usual care</u>: is the effect greater than the effect of simply going to therapy or getting usual treatment?

<u>Component control</u>: why does it work? What are the active ingredients?

<u>Other active treatment</u>: is tx A better or more efficient or cost-effective than tx B?

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Choosing a Comparison Treatment in CSP #494

- **Chose a <u>nonspecific</u>, <u>present-centered comparison</u> group because:**
  - **PE shown to work in wait-list studies; limited evidence from nonspecific designs**
  - **many VA patients seek help for current problems; present focus enhances clinical validity and similarity to VA treatment**
  - **Possible to manualize and to equate with PE on # of sessions, format, some content, and homework**
  - **Possible to exclude active ingredients of PE**

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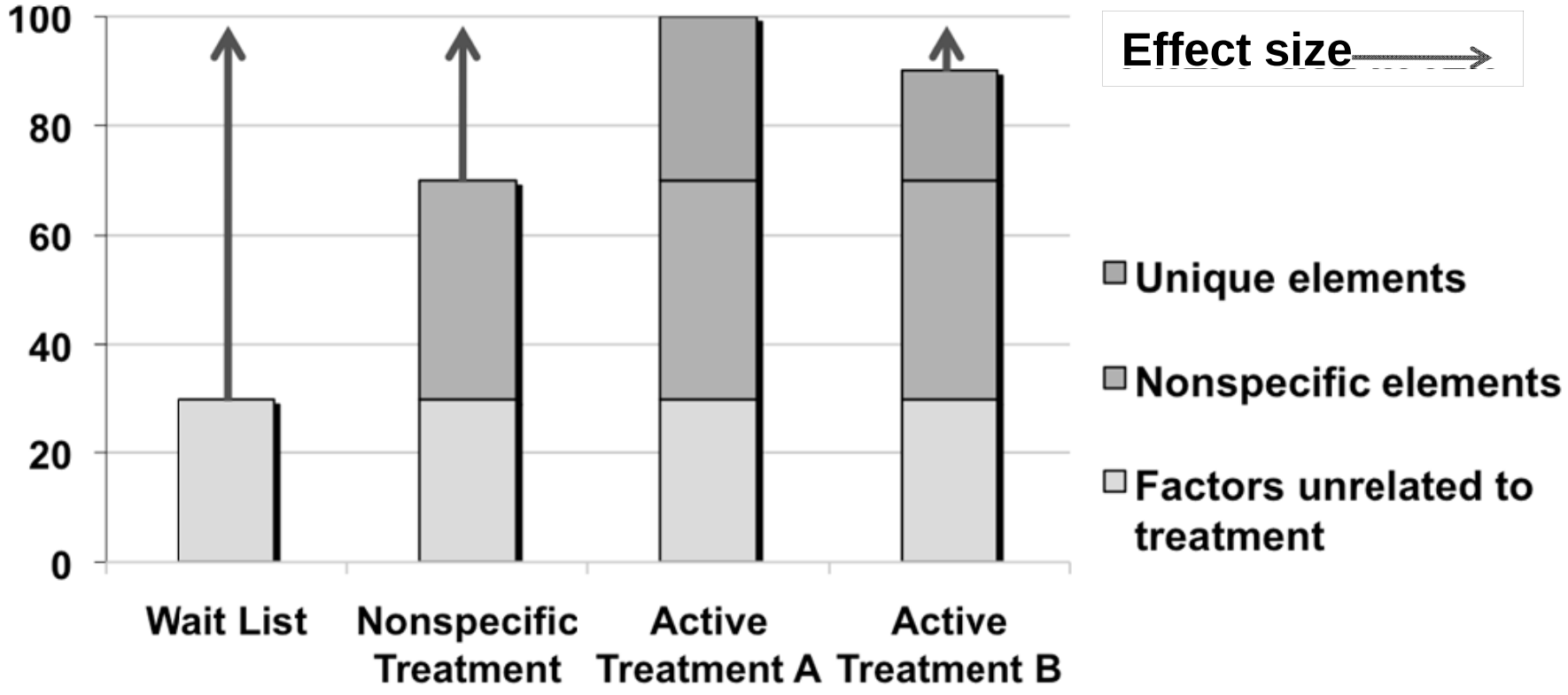
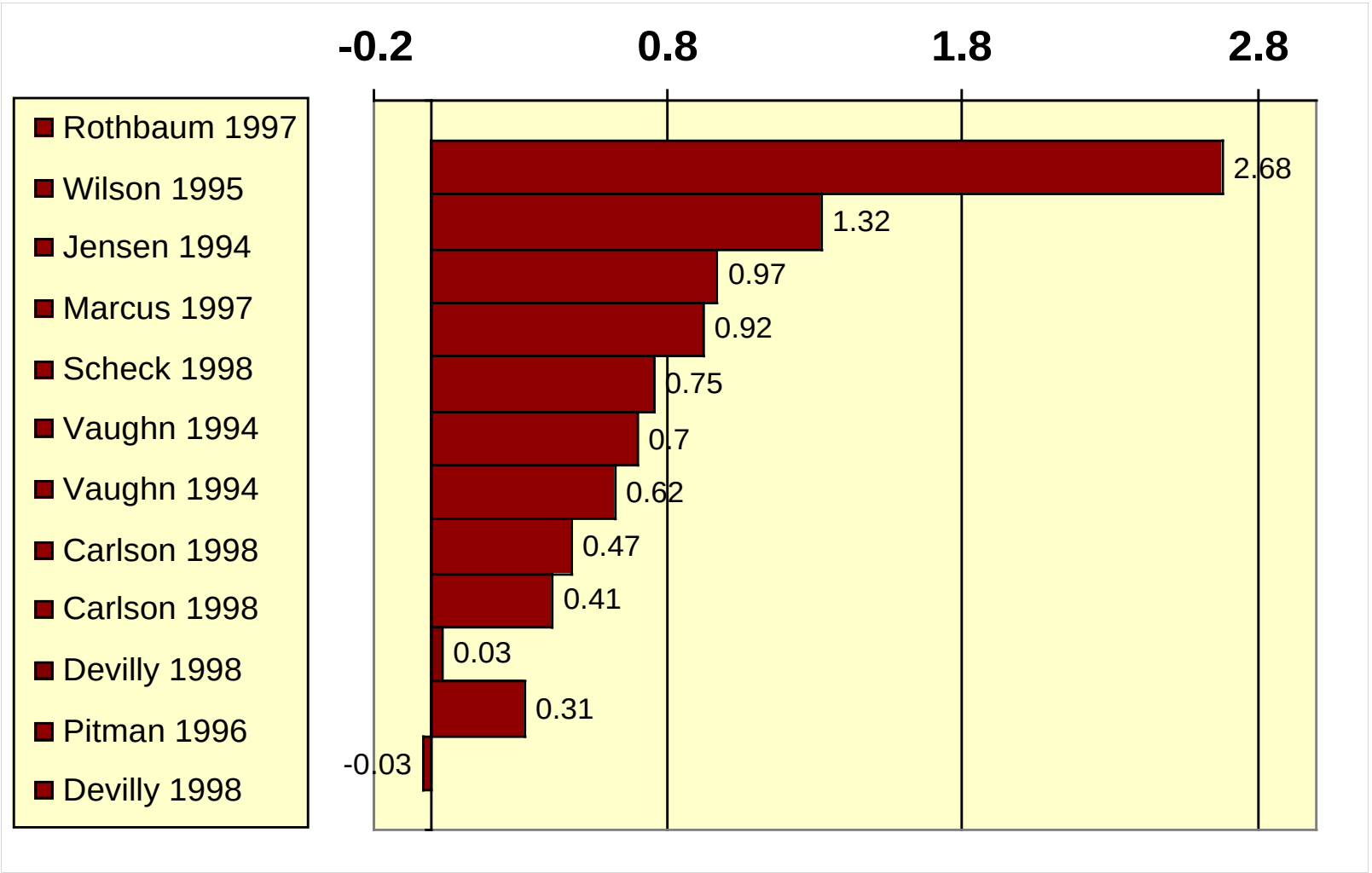
Effect Size as a Function of Comparison Group, e.g., vs. Treatment A



Effect Sizes for Eye Movement Desensitization & Reprocessing for PTSD



–Chemtob et al., 2000

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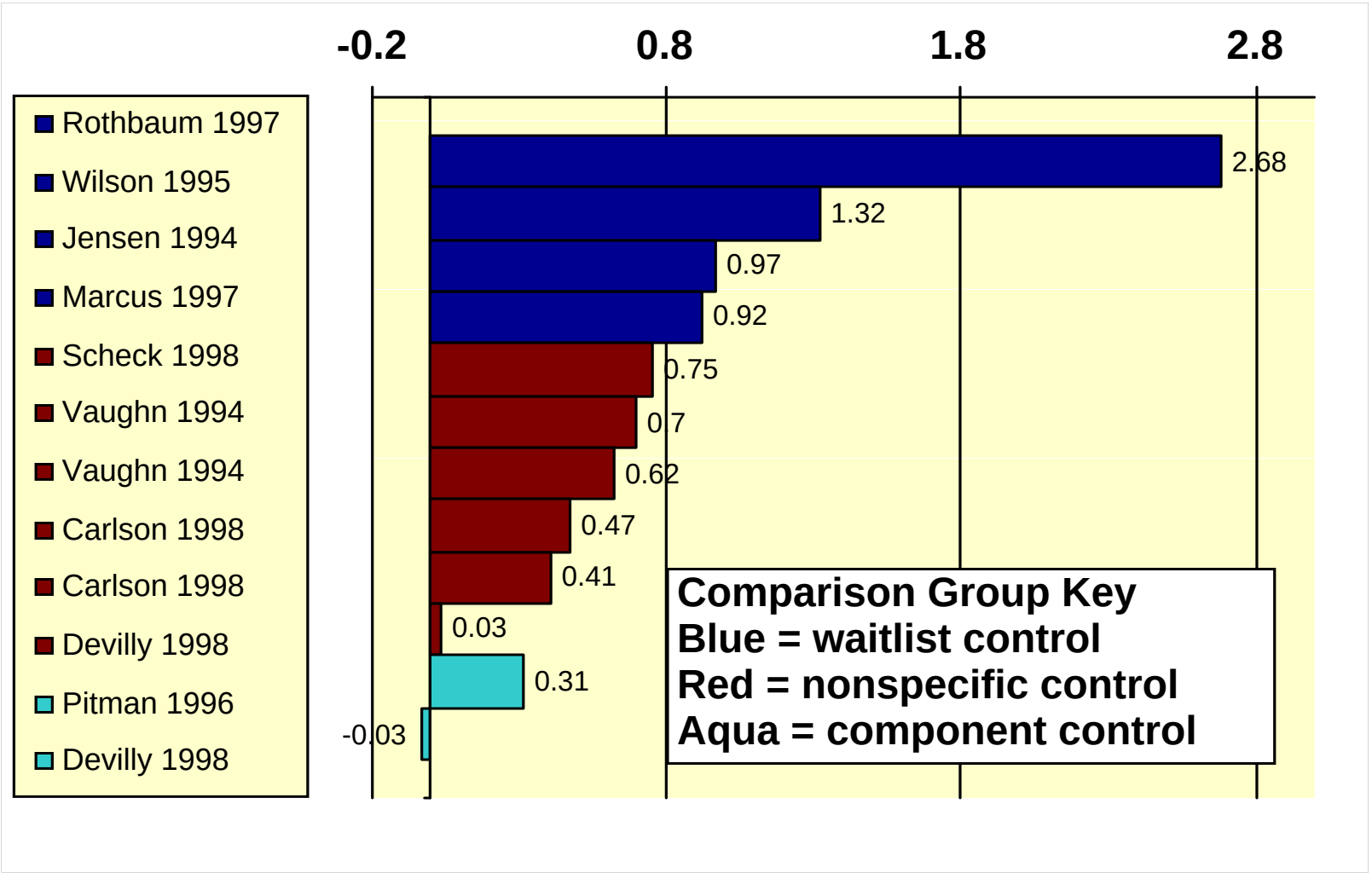

–Chemtob et al., 2000)

Rules of Thumb for Effect Size as a Function of Comparison Group

Comparison Group	Expected Effect Size	N Needed Per Group
Waitlist	Large	26
Nonspecific/ TAU	Medium	64
Component/ Active	Small	393

Estimates for 2-group, 2-tailed t-test, at .80 power, p = .05

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Equating a Comparison Condition

- **Amount of therapy, e.g., number of sessions**
- **Format, e.g., homework, group or individual**
- **Type of therapist, e.g., MD vs. PhD**
- **Rationale/credibility**
- **Treatment overlap/what is “common”**

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Meta-Analysis of Equivalence Effects in Psychotherapy

	# of studies	*d*	95% CI
Inequivalent structure	8	.47	.31-.62
Equivalent structure	13	.15	.06-.29

Inequivalent > equivalent, p = .003

–Baskin et al., 2003

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How Much to Equate?

- **Depends on which differences could <u>plausibly</u> (not <u>possibly</u>) bias outcomes**
- **Control to the point of *<u>"reasonableness</u>"***
  - **A reasonable person would accept differences between treatments as true differences**
  - **Treatment integrity is preserved**
- **Consider:**
  - **10 90-minute sessions in target tx vs. 10 60-minute sessions in comparison tx?**
  - **if CBT vs. relaxation, no written homework in relaxation?**

Example:
Equating Treatments in CSP #494

Conditions equated on:

- # and duration of sessions
- Individual format
- Use of manual
- Initial psychoeducation in first sessions
- Rationale (although type differed)
- Homework (although type differed)

Assigning Therapists to Conditions

- **(There should always be > 1 therapist)**
- **Outcomes within therapists are likely to be clustered**
- **Important to control for therapist effects due to differential skill, enthusiasm, warmth**

Meta-Analysis of Therapist Effects

(Crits-Cristoph et al., 1991)

	Simple *r*s	Partial *r*s
CBT (vs. Dynamic)	-.33*	.09
Use of manual	-.45**	-.42**
Therapist experience	-.41**	-.50**
Treatment length	.28	---

Variance due to therapist effects = 8.6%

(range = 0%-48.7%)

***N*=15 studies, 27 treatment conditions, 141 therapists**

***p*<.10 ****p*<.05**

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Approaches to Assigning Therapists

- **Each therapist delivers both/all txs**
- **Different therapists deliver each tx**
  - **Assigned by convenience or expertise**
  - **Randomized**
- **CSP #494: 2 therapists per condition/site**
  - **Not PE experts; few had CBT training**
  - **Therapists randomized**
  - **Sample size and analysis accounted for clustering**
  - **ICC ~.05**

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Each Therapist Delivers Both/All

- **Useful if few therapists (usually small *N*, single-site design)**
- **<u>Problems</u>: therapist delivers treatments with differential skill, enthusiasm, warmth; difficulty separating treatmentss**
- **<u>Remedies</u>: Careful training and supervision; independent fidelity monitoring is essential**

Different Therapists Deliver Each

- **Useful if experts needed or more than few therapists (usually large N, multisite design)**
- **Problems: therapist effects still possible; discordant preferences (if randomized); compensatory strategies**
- **Remedies: Randomization; training, supervision, and fidelity monitoring still important**

Manualization

- **Manuals ensure consistent treatment delivery and permit replication**
- ***Detail*** **is essential**
  - **Session by session guidelines**
  - **Specific prompts and suggestions**
  - **How to address noncompliance, crises, etc.**
- **If treatment can't be manualized, alternative strategies may be needed**
  - **e.g., content analysis of tapes, chart notes, patient reports**

Training vs. Supervision vs. Monitoring

- **Training: teaching therapists how to deliver the treatment**
- **Supervision: providing feedback to therapists during the study**
- **Monitoring: independently checking on fidelity and competence**
  - **checking alliance and process are types of monitoring too**

Study Training and Supervision

- **Training**
  - **Type and amount**
  - **Training cases**
- **Supervision**
  - **Audiotaping/videotaping**
  - **Frequency/type**
- ***Should be more rigorous in efficacy studies***
- **In CSP #494, in-person workshops followed by 1-2 training cases; individual supervision throughout**

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Monitoring Adherence and Competence

- **Format**
  - **Consider video/audiotape, % of sessions monitored, and basis for selecting**
- **Monitor should be independent of training and supervision process**
- **Measures need to capture unique, common, and proscribed elements and allow comparison of treatments**
- **In CSP #494, ~8% of sessions monitored; oversampling of key sessions**

Additional Treatment

- **Many patients entering trials are receiving concurrent therapy**
- **Medications?**
  - **Most psychotherapy studies allow medication**
- **Other treatment for the same disorder?**
  - **Usually contraindicated for scientific or safety reasons**
- **Other psychotherapy?**
  - **Supportive and self-help usually allowed**

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Suggestions for Allowing Additional Treatment

- **In efficacy studies, allow what is necessary for ethical reasons**
- **In effectiveness studies, also allow treatments that do not interfere with treatment**
- **Medications should be stabilized before study**
- **Discourage/disallow concurrent PTSD treatment**
- **Discourage change unless clinically necessary**
- **Measure co-therapy to check for compensatory strategies**

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Group-Based Treatment

- **Group clustering should be accounted for in sample size projection and data analysis, whether randomization is by group or individual**
- **Same principle applies for clustering due to therapists**

Effect of Group Format on Sample Size Calculation

The whole is less than the sum of the parts

Variance Inflation Factor to adjust for nonindependence:

$$VIF = 1 + (\#\ group\ members - 1)ICC$$

Examples for groups of 6, assuming desired α = .05 and power = .80 to find an effect of d = .50:

ICC	VIF	Sample needed (per group)
.00	1.00	64
.10	1.50	96
.20	2.00	128
.30	2.50	160

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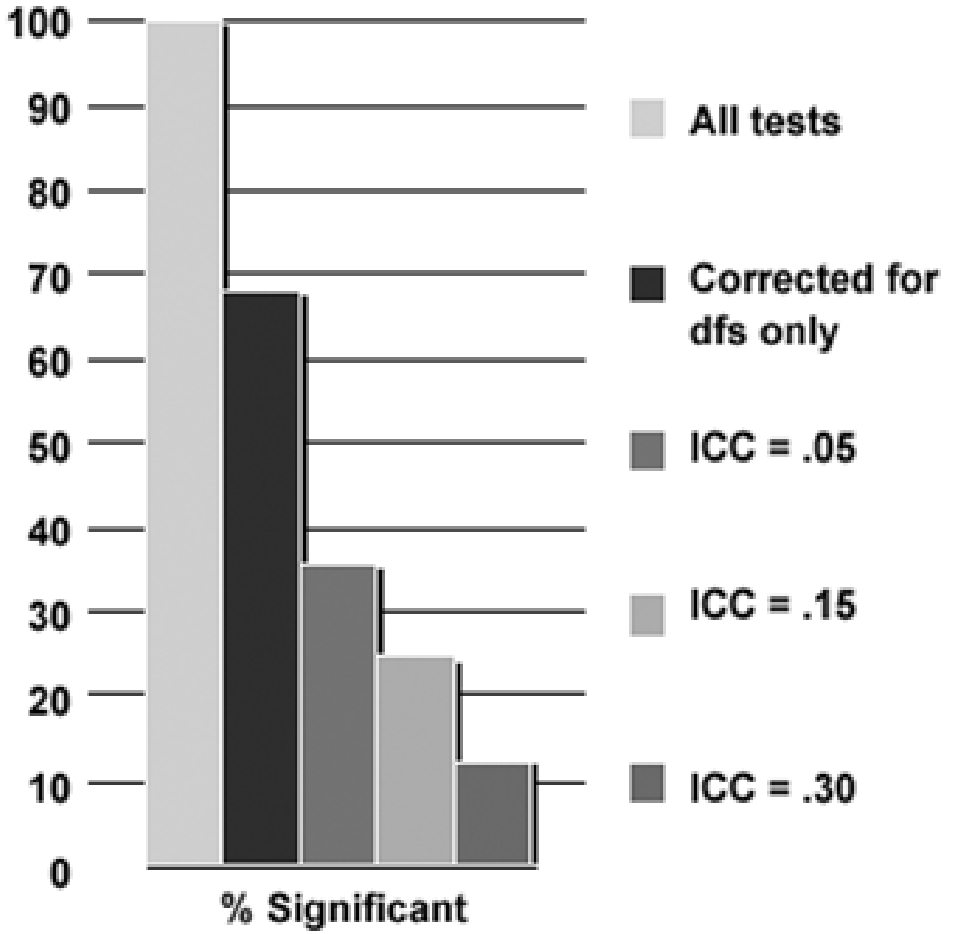
Effects of Corrected Analysis on Results of Group Treatment

- **Baldwin et al. (2006) reanalysis of significant tests for group evidence-based treatments**
  - **Corrected dfs**
  - **Varied ICC assumptions**



Recommendations

1. **Address unique methodological issues in addition to the usual issues in trials:**

   manuals, therapist assignment, additional treatment, training, and supervision

2. **Ensure adequate statistical power and address therapist effects and group clustering in analysis and sample size projections**

3. **Choose the comparison group that is appropriate for your question**

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Questions? Comments?

For more information: Schnurr, P.P. (2007). The rocks and hard places in psychotherapy outcome research. *Journal of Traumatic Stress*, *20*, 779-792.

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