The Process of Developing Evidence-Based Psychosocial Treatments (EBTs)

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Linear Model for Development and Dissemination of EBTs

Stage 0: Basic science

Stage 1, 2 & 3: Efficacy Studies

Basic research on mechanisms of the psychopathology in question

Experts develop and test treatment efficacy using RCTs in research setting; these treatments are then tested in community setting

Testing the ability of community clinicians to deliver the treatments successfully in typical clinical settings, sacrificing some internal validity

Stage 4: Effectiveness paradigms

Stage 5: Dissemination

Making treatment widely available, cost-effective, useful in mass disasters
Process of Treatment Development
and Refinement
Example of the Development and Dissemination of Prolonged Exposure Treatment

- Basic Science
- Theory of Psychopathology
- Treatment Mechanisms
- Efficacy Research
- Dissemination
- Effectiveness
Theoritical Model: Emotional Processing Theory
(Foa & Kozak, 1985, 1986; Foa & Cahill, 2001)

• Anxiety disorders reflect the presence of pathological cognitive fear (emotional) structures
• Recovery entails correction of the pathological associations, i.e., emotional processing
• The mechanisms involved in recovery are:
  • Activation of the pathological structure
  • Presence of information that disconfirms the pathological associations
• Indicators of emotional processing are:
  • Emotional engagement
  • Habituation within and between sessions
  • Change in erroneous perceptions of self and world
The Trauma Memory

- A trauma memory is a specific fear structure that includes representations of:
  - Stimuli present during and after the trauma
  - Physiological and behavioral responses that occurred during and after the trauma
  - Meanings associated with these stimuli and responses

Associations among stimulus, response, and meaning representations may be realistic (functional) or unrealistic (dysfunctional)
Schematic Model of a Memory in a Patient With PTSD Post Rape

Confused

Incompetent

I - Me

Afraid

Say “I love you”

Freeze

Scream

PTSD Symptoms

Uncontrollable

Rape

Man

Shoot

Gun

Tall

Bald

Dangerous

Home

Suburbs

Alone

PTSD Symptoms
Dysfunctional, Negative Cognitions Underlying PTSD

• The world is extremely dangerous
  • People are untrustworthy
  • No place is safe

• I (the survivor) am extremely incompetent
  • PTSD symptoms are a sign of weakness
  • Other people would have prevented the trauma
Severity of Negative Cognitions and PTSD

- Negative Thoughts About Self
- Negative Thoughts About World
- Self-Blame

Bar chart showing:
- No Trauma
- Trauma/No PTSD
- PTSD

Negative Cognitions Severity

Values:
- No Trauma: Negative Thoughts About Self, Negative Thoughts About World, Self-Blame
- Trauma/No PTSD: Negative Thoughts About Self, Negative Thoughts About World, Self-Blame
- PTSD: Negative Thoughts About Self, Negative Thoughts About World, Self-Blame
Prolonged Exposure for PTSD: Treatment Procedures

- Prolonged, imaginal exposure to the trauma memory (revisiting, recounting, and processing)
- Repeated *in vivo* exposure to safe situations that are avoided because of trauma-related fear
- Psychoeducation: Education about common reactions to trauma

Treatment consists of an average of 8-15 90-minute sessions
Comparison of PE and Waitlist With Female Assault Survivors: An Efficacy Study

Foa et al., 1999
Parallel Processes of Treatment
Refinement and Dissemination

Established Efficacy

Enhanced Efficacy and Refinement

Effectiveness and Dissemination
Ways to Enhance Treatment Efficacy

1. A theoretical approach that assumes additivity of treatment effects

2. Revisiting the theory and testing hypotheses about treatment mechanisms

3. Revisiting basic science and translating relevant findings to treatment
Ways to Enhance Treatment Efficacy

1. Atheoretical approach that assumes additivity of treatment effects: e.g., PE+SIT or PE+CR will be superior to PE alone
Comparison of PE, PE/CR, and Waitlist With Female Assault Survivors: Efficacy Stage 2-3

Foa et al., 2005
2. Revisiting the theory and testing hypotheses about treatment mechanisms: e.g., Is emotional activation necessary? Is habituation within and between sessions necessary?
Fear Facial Expression (Activation) and Improvement During PE

Emotional Engagement

Facial Expression of Fear During First Recounting Session

Post-treatment

Percent Improvement (PTSD + Phobic + General Anxiety)

.77
Activation Promotes Fear Extinction in Humans

- Amygdala activation is present during extinction (LaBar et al., 1998)

- Greater amygdala activity during extinction predicts greater degree of extinguished fear (Phelps et al., 2004)
## Relationship Between Habituation and PTSD Outcome in PE

<table>
<thead>
<tr>
<th></th>
<th>Posttreatment</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-session habituation</td>
<td>-.05</td>
<td>-.13</td>
</tr>
<tr>
<td>Between-session habituation</td>
<td>-.30**</td>
<td>-.26*</td>
</tr>
</tbody>
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Habituation between, but not within, was related to outcome

* * < .05 ** * < .01  Van Minnen & Foa, 2006
Conclusions From the Data

• The rationale for extending imaginal exposure to 60 minutes was derived from the hypothesis that habituation within sessions is an indicator of the recovery process.

• If habituation within session is unrelated to outcome, perhaps the length of imaginal exposure can be reduced.

• The next step was to test this hypothesis.
Shortened Imaginal Exposure

- Van Minnen and Foa (2006) compared 60- and 30-minute imaginal exposure; no difference in outcome was found.

![Graph showing PSS-SR Scores over Sessions for 60 and 30 minutes of exposure.](image)
Ways to Enhance Treatment Efficacy

3. Revisiting basic science and translating relevant findings to treatment, e.g., paradigms that enhance extinction, in light of viewing fear reduction during treatment as extinction process:

- Methylene blue
- DCS
- Cortisol
- Yohimbine
- Reconsolidation update
Process of Treatment Dissemination
“Cultural” Barriers

- Mental health professionals
  - Prefer individualized to manualized treatments
  - Do not follow expert guidelines

  Why?

- Many graduate training programs do not teach EBTs
- Many graduate trainers
  - Challenge the validity and relevance of findings from RCTs (e.g., rarified samples)
  - Question the specificity of EBTs
PE Effectiveness for PE Experts and Community Therapists in Female Assault Survivors in Philadelphia: Stage 2 & 3

Foa et al., 2005

[Bar chart showing PSS-I Total scores for Expert and Community groups pre and post treatment]
Dissemination of PE in the US VA: Stage 5
A Top Down Approach

- The PE dissemination throughout the VA was initiated by the central office of the Veterans Health Administration, reflecting strong institutional commitment to implement EBTs.
- The goal was to create permanent capacity in the VA system to train and supervise their mental health practitioners in conducting PE.
PE Training Model

Certified PE Clinicians
  • Completed a 4-day workshop followed by weekly individual supervision on two cases

Certified PE Consultants (supervisors)
  • Selected certified clinicians participated in 5-day supervisors’ workshop

Certified PE Trainers (“Train-the-Trainer”)
  • Selected certified consultants participated in a 3-day trainers’ workshop
Numbers Trained

- Total # Clinicians Trained: 1540
- Consultants: 70
- Trainers: 16

88% of therapists completed 2 cases under supervision