



A Randomized Controlled Trial of STEPPS for Borderline Personality Disorder with a 1-year Follow-up

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STEPPS for BPD

- Background
- Current research
 - RCT
 - Prison study
- Future plans

First, let's review the data supportive of STEPPS...

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- ☞ Three uncontrolled studies
 - Blum et al. (2002)
 - Freije et al. (2002)
 - Black et al. (unpublished)
 - ☞ Two randomized controlled trials (RCTs)
 - Blum et al. (*Am J Psychiatry*, 2008)
 - Van Wel et al. (2007)

Uncontrolled Studies

☞ Blum et al. (2002)

- STEPPS reduced BPD symptoms, reduced negative thoughts and behaviors, and had an antidepressant effect in 52 subjects.

☞ Frije et al. (2002)

- STEPPS (VERS) reduced BPD symptoms and overall severity in 85 subjects.

☞ Black et al. (unpublished)

- STEPPS reduced negative affectivity, depression, and BPD symptoms in 10 incarcerated women offenders.



Now, let's move on to the randomized controlled trial just published in the *American Journal of Psychiatry*.....

RCT: US

- Started in 2002
- Goals:
 - Randomize 160 subjects
 - STEPPS plus TAU v. TAU alone
- 8 cohorts (~20 subjects)
- Assignment by coin toss
- Length of study: 20 weeks with 1 year follow-up
- Completion date: 4/07



Study Design: Treatment Groups

1) STEPPS plus treatment as usual (TAU):

Subjects attend STEPPS program in addition to receiving their usual treatment (e.g., medication, individual therapy, case management).

2) TAU alone:

Subjects receive whatever treatment they desire, but cannot attend a STEPPS group.

Study Design

- 
- ➔ Secondary efficacy measures
- BEST
 - Beck Depression Inventory (BDI)
 - Positive and Negative Affectivity Scale (PANAS)
 - Symptom Checklist – 90-R (SCL-90-R)
 - Social Adjustment Scale (SAS)
 - Clinical Global Impression Scale (CGI)
 - Global Assessment of Functioning (GAS)
 - Interval Treatment Record
 - Hospital days
 - Suicide/self-harm behaviors

Measuring Change with the BEST: A New Rating Scale for BPD

- Self-rated
- 15 items rated on 5-point scale
- Scores range from 12-72
- 3 subscales
- Reliable and valid (Pfohl et al., submitted)

BEST: Borderline Evaluation of Severity Over Time



Borderline Evaluation of Severity over Time (Version 1.7)

ID# _____

Circle the time period you have been asked to rate: Last 7 days, **Last 30 days**, Other: _____

For the first 12 items, the highest rating (5) means that the item caused extreme distress, severe difficulties with relationships, and/or kept you from getting things done. The lowest rating (1) means it caused little or no problems. Rate items 13-15 (positive behaviors) according to frequency.

Circle the number which indicates how much the item in each row has caused distress, relationship problems, or difficulty with getting things done

A. THOUGHTS AND FEELINGS: []

	None/Slight	Mild	Moderate	Severe	Extreme
1. Worrying that someone important in your life is tired of you or is planning to leave you.	1	2	3	4	5
2. Major shifts in your opinions about others such as switching from believing someone is a loyal friend or partner to believing the person is untrustworthy and hurtful.	1	2	3	4	5
3. Extreme changes in how you see yourself. Shifting from feeling confident about who you are to feeling like you are evil, or that you don't even exist.	1	2	3	4	5
4. Severe mood swings several times a day. Minor events cause major shifts in mood.	1	2	3	4	5
5. Feeling paranoid or like you are losing touch with reality.	1	2	3	4	5
6. Feeling angry.	1	2	3	4	5
7. Feelings of emptiness.	1	2	3	4	5
8. Feeling suicidal.	1	2	3	4	5

[] Name: _____ Date: _____

B. BEHAVIORS (Negative): []

	None/Slight	Mild	Moderate	Severe	Extreme
9. Going to extremes to try to keep someone from leaving you.	1	2	3	4	5
10. Purposely doing something to injure yourself or making a suicide attempt.	1	2	3	4	5
11. Problems with impulsive behavior (not counting suicide attempts or injuring yourself on purpose). Examples include: over-spending, risky sexual behavior, substance abuse, reckless driving, binge eating, other _____ (circle those that apply)	1	2	3	4	5
12. Temper outbursts or problems with anger leading to relationship problems, physical fights, or destruction of property.	1	2	3	4	5

Circle the number below which indicates how often you used the following positive behaviors:

C. BEHAVIORS (Positive): []

	Almost always	Most of the time	Half of the time	Sometimes	Almost never
13. Choosing to use a positive activity in circumstances where you felt tempted to do something destructive or self-defeating.	5	4	3	2	1
14. Noticing ahead of time that something could cause you emotional difficulties and taking reasonable steps to avoid/prevent the problem.	5	4	3	2	1
15. Following through with therapy plans to which you agreed (e.g., talk therapy, "homework" assignments, coming to appointments, medications, etc.)	5	4	3	2	1

*The BEST is copyrighted 1997 by Bruce Pföhl, M.D. & Nancee Blum, M.S.W. University of Iowa, Department of Psychiatry, 200 Hawkins Drive, Iowa City, IA 52242.

To the clinician: The total for each section (A, B, & C) should be recorded in the brackets next to the section titles above. At top of page record Composite Score = 15 + A + B + C

Inclusions/Exclusions

- DSM-IV criteria for BPD
- 18 years or older
- Speak English
- Not have a psychotic disorder or a primary neurological condition
- Not have obvious cognitive impairment
- Not have current (past month) substance abuse or dependence
- Have not participated in STEPPS
- Must have a designated MH professional

Recruitment Details

- UIHC inpatient, outpatient, and partial hospital program
- Mental health facilities in eastern Iowa
- Advertising
- Word-of-mouth



GROUP THERAPY STUDY

- ◆ Are your relationships very painful and difficult?
 - ◆ Are you often distrustful of others?
 - ◆ Are you extremely moody?
 - ◆ Do you frequently feel out of control?
-
- If you answered yes to several of these questions, you might qualify for this study
 - We are looking for men and women over the age of 18 for participation in a research study of a new group treatment, utilizing a skills training approach
 - Compensation is provided
 - Please contact Nancee Blum, MSW, for more information at:

319-353-4393

Principal Investigator: Dr. Donald W. Black
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Final Results

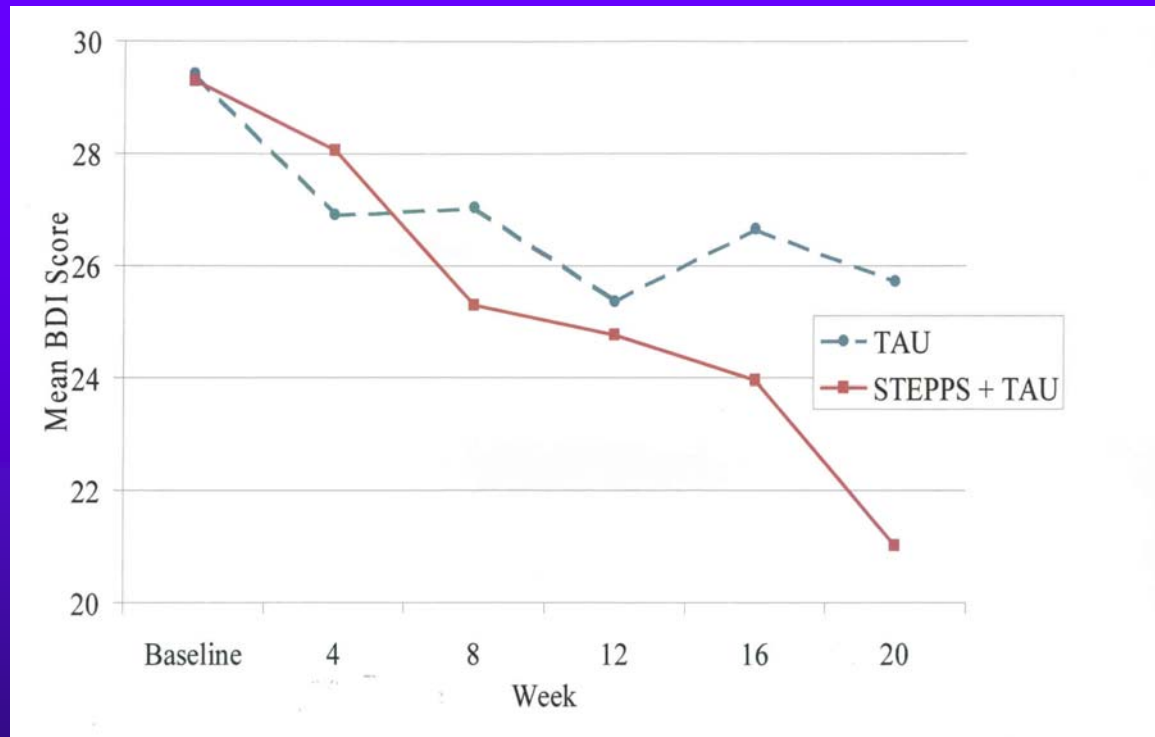
- 172 subjects consented
- 165 randomized
- 125 entered STEPPS plus TAU or TAU alone
 - 83% women
- 124 cases analyzed (1 case removed)
- Groups were well matched
- Linear mixed effects model analysis

Comparisons at Baseline

Variable	TAU alone	STEPPS plus TAU
Age, (Mean)	30.7 (9.5)	31.3 (9.5)
Psych hospitalizations, (Mean)	2.3 (3.8)	2.0 (3.2)
Suicide attempts, (Mean)	2.2 (3.4)	2.7 (4.0)
Medications, (Mean)	2.5 (2.0)	2.8 (2.4)
BEST, (Mean)	39.8 (12.6)	39.0 (9.7)
BDI, (Mean)	29.7 (15.0)	29.0 (11.6)
CGI, Severity, (Mean)	4.9 (0.1)	5.1 (0.1)

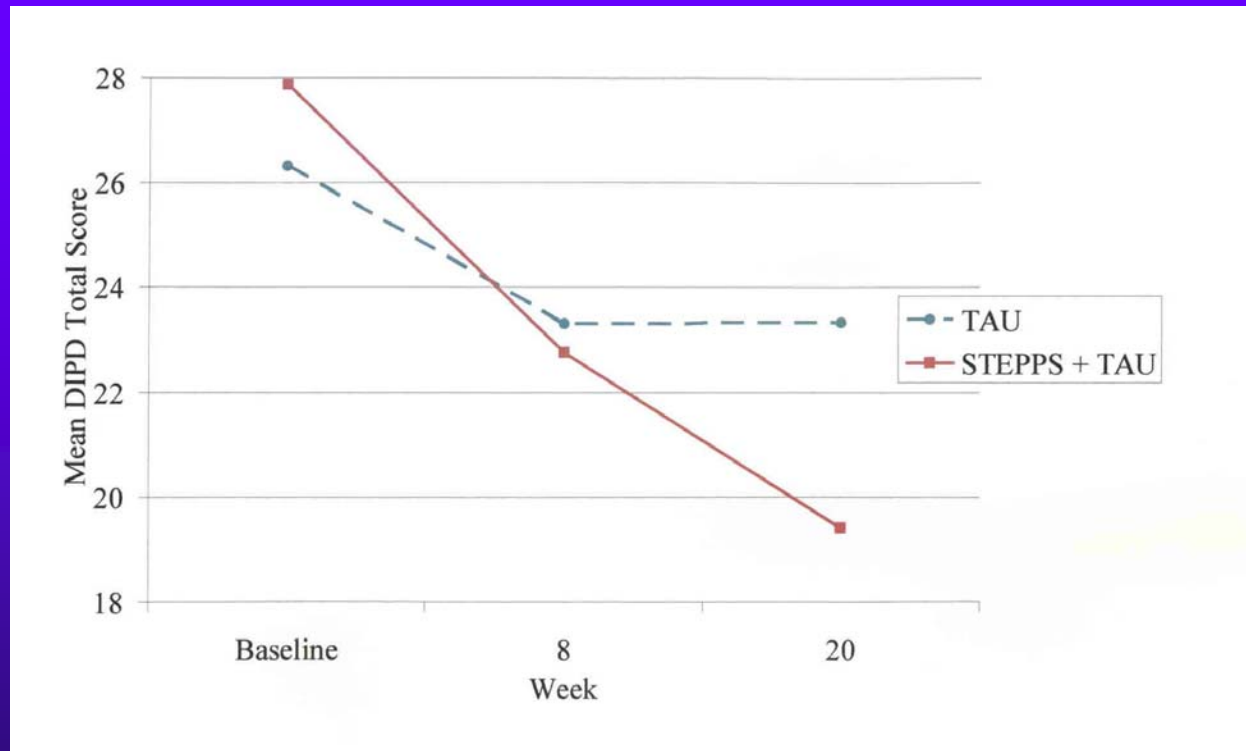
Beck Depression Inventory

$p=.033$. $es=.50$



ZAN-BPD Total p=.001, es=.84

S
T
E
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S



Effect Size Defined (Cohen, 1988)

- Dimensionless measure of treatment effect
- Calculated by taking the difference in mean outcomes between treatment and control groups and divided by the SD of either group
- .2 = small effect; .5 = moderate effect; .8 = large effect

CGI, GAS Data: Week 20

- 40% STEPPS plus TAU group rated “much” or “very much” improved vs. 5.1% TAU alone group ($p < .001$)
- 26.2% of STEPPS plus TAU had GAS \geq 60 vs. 8.5% of TAU alone group ($p < .001$)

Optimal # Sessions

- Post-hoc analysis
- Linear mixed model analysis
- ZAN-BPD, BEST, GAS
- 15 sessions appeared to be a cut-point
 - The slope (rate of change) was >0.5 at 15 or more sessions.

Other Results

☞ Reduces:

- impulsivity ($p=0.004$)
- negative affectivity ($p=0.038$)
- overall SCL-90 severity ($p=0.031$)

☞ Improves:

- social functioning (SAS social/leisure subscale) ($p=0.02$)

☞ Findings not confounded by medication or individual psychotherapy attendance

Other Findings

- ☞ Suicide attempts and self-harm behaviors not reduced
 - Trend towards fewer suicide attempts
- ☞ Hospital days not reduced
 - Trend towards less utilization

Predictors of Outcome/Dropping Out

- Greater baseline severity predicted better outcome
- Gender and age were not predictive of outcome
- High impulsivity ratings predicted early discontinuation

1-Year Follow-up

- Subjects followed at 1, 3, 6, 9, 12 months
- Gains were maintained, but not enhanced.
- Suicide attempts, self-harm, and hospital days were not reduced.
- ER visits reduced ($p=0.04$)


Limitations

- Drop out rate was high (31% for STEPPS+TAU, 17% for TAU alone)
- Clinician ratings were not blind
- TAU is not an active comparator
- Few men and minorities

Patient Comments

- ☞ STEPPS gives me the tools to work through my emotions and understand them.”
- ☞ “I feel my improvement can be attributed to the skills I am learning.”
- ☞ “The STEPPS program has helped me gain control over myself.”


STEPPS in Prison

- 
- ☞ Pilot study just completed at the women's unit at Mt. Pleasant, IA
- STEPPS manual used “as-is”
 - High therapist fidelity to the model
- 12 women entered, 10 completed
- Mean age 35 years
- Improvement in
- Depression ($p=0.003$)
 - Negative affectivity ($p=0.021$)
 - BPD symptoms ($p=0.009$)
- (Black et al., submitted)

Conclusions

- Three uncontrolled studies are supportive of STEPPS.
- US RCT supportive of STEPPS.
- STEPPS reduces global severity, BPD symptoms, depression, and ER visits.
- Gains are maintained over 1-year follow-up.
- STEPPS works well in prison.
- STEPPS now joins other evidence-based treatments for BPD.

Future Plans

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- STEPPS RCT in prison
 - Effectiveness study of STEPPS
 - 3 sites (Iowa, Massachusetts, Minnesota)
 - 5 mental health centers
 - “real world” setting to show transportability

References

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Thank you!



Questions?