

Appendix 2: Randomized controlled trials (RCTs) of psychotherapy (Table A1) and pharmacotherapy (Table A2) for the treatment of borderline personality disorder (BPD) published since 2005

Table A1 (part 1 of 4): RCTs of psychotherapy					
Trial	Study arms and no. of participants	Duration	Outcome measures in addition to clinical data	No. of completers	Treatment results
Linehan et al. (1)	DBT: 52 CTBE: 49	1 year treatment and 1 year follow-up	HAM-D RFLI SASII THI	DBT: 42 CTBE: 28	Greater reductions in suicide attempts, use of crisis services or hospitalization with DBT Higher retention rates with DBT No differences in self-injury or depressive symptoms
McMain et al.(2)	DBT: 90 GPM: 90	1 year treatment	BDI EQ-5D IIP SASII SCL-90-R STAXI ZAN-BPD THI	DBT: 55 GPM: 56	No differences between groups, but both improved
Soler et al. (3)	DBT-ST: 29 SGT: 30	13 weeks treatment	BDHI BIS BPRS CGI-BPD HAM-A HAM-D SCL-90-R	DBT-ST: 19 SGT: 11	Greater reductions in depression, anxiety, general psychiatric symptoms, irritability, anger, and affective instability in the DBT-ST group
Bateman & Fonagy (4)	MBT: 71 SCM: 63	18 months treatment	BDI GAF IIP SAS-SR SCL-90-R	MBT: 52 SCM: 47	Great reductions in suicidal behaviours, self-harm, and days hospitalized in the MBT group Significantly larger improvements in global functioning, depressive symptoms, and social and interpersonal functioning in the MBT group
Giesen-Bloo et al. (5)	SFT: 45 TFP: 43	3 years treatment	BPDSI BPDC DSQ EQT IPO MSGD PDBQ-BPD RSES SCL-90-R WHOQOL YSQ	SFT: 33 TFP: 21	Greater reductions in BPD symptoms in the SFT group Greater improvements in aggregate psycho- and personality factor score in the SFT group No differences in quality of life measures between groups at end point

Table A1 (part 2 of 4): RCTs of psychotherapy					
Trial	Study arms and no. of participants	Duration	Outcome measures in addition to clinical data	No. of completers	Treatment results
Clarkin et al. (6)	TFP: 30 DBT: 30 ST: 30	1 year treatment	AIAQ BDI BIS BSI GAF OAS-M SAS-SR	Unknown completers TFP: 23 continued past 9 months DBT: 17 continued past 9 months ST: 22 continued past 9 months	Improvements in depression, anxiety, global functioning, and social adjustment for all treatments Reductions in anger with TFP and ST Improvements in different forms of impulsivity with TFP and ST Greater reductions in suicidality with TFP and DBT compared to ST
Doering et al. (7)	TFP: 52 ETC: 52	1 year treatment	BDI BSI CRTHI CISSEB GAF SCID-I SCID-II STAI STIPO	TFP: 32 ETC: 17	Greater reductions in BPD symptoms, BPD diagnosis, psychosocial functioning, personality organisation, suicide attempts, and hospitalizations in TFP group
Blum et al. (8)	STEPPS + TAU: 93 TAU: 72	20 weeks treatment and 1 year follow-up	BDI BESOT BIS CGI PANAS SAS-SR SCL-90-R ZAN-BPD	STEPPS + usual treatment: 45 TAU: 51	Faster rate of improvement in BPD severity, social functioning, overall functioning, impulsivity, negative affective, and depression in the STEPPS+TAU group Comparison of total change over treatment by group not reported No significant declines in outcomes from end of treatment to 1 year follow-up No differences in suicide attempts, self-harm, or hospitalizations between groups
Bos et al. (9)	STEPPS-M: 42 TAU: 37	18 weeks treatment and 6 month follow-up	BPD-40 BPDSI SCL-90-R WHOQOL	STEPPS-M: 33 TAU: 33	Greater improvements in overall symptoms, BPD symptoms, and overall quality of life in the STEPPS-M group No differences in parasuicidal behaviours between groups
Farrell et al. (10)	Group SFT+TAU: 16 TAU: 16	8 month treatment and 6 month follow-up	BSI2 DIB-R GAF SCL-90-R	Group SFT+TAU: 16 TAU: 12	Greater improvements in BPD symptoms, overall psychiatric symptoms, and functioning in the group SFT treatment Benefits of group-SFT were maintained or increased at follow-up

Table A1 (part 3 of 4): RCTs of psychotherapy					
Trial	Study arms and no. of participants	Duration	Outcome measures in addition to clinical data	No. of completers	Treatment results
Davidson et al.(11)	CBT+TAU: 54 TAU: 52	1 year treatment and 1 year follow-up	ADSHI BSI DBI EQ-5D IIP SFQ STAI YSQ	CBT+TAU: 52 TAU: 48	Greater decrease in the number of suicidal acts in the CBT+TAU group over 2 year period Greater reduction in anxiety and positive symptoms in the CBT+TAU group over 2 year period No change in hospitalization, crisis usage, self-harm or functioning between groups Some gains retained at 6 year follow-up (12)
Cottraux et al. (13)	CT: 33 RST: 32	1 year treatment and 1 year follow-up	BAI BDI BHS CGI HAM-D IVE MSAS SHBCL TRES YSQ	CT: 20 RST: 18	No significant difference in proportions improved at any time point No significant differences between measures at end of treatment Significantly better overall symptom ratings and lower depression, anxiety, and cognitive scores in subset of participants who completed 1 year follow-up
Chanen et al. (14)	CAT: 41 adolescents GCC: 37 adolescents	6 months treatment and 18 months follow-up	SCID-II SOFAS YASR YSR	CAT: 19 GCC: 16	Both groups improved with no endpoint differences between groups Faster improvement in internalizing and externalizing with CAT Faster improvement in general functioning with GCC
Weinberg et al. (15)	MACT+TAU: 15 Usual treatment: 15	6-8 weeks treatment and 6 months follow-up	PAI PHI SBQ SPS TUI-FA	MACT+TAU: 15 TAU: 13	Greater reduction in self-harm frequency and severity in MACT+TAU group No differences between groups in suicidal ideation
Morey et al. (16)	MACT-TA: 8 MACT: 8	6 sessions		MACT-TA: 3 MACT: 4	Both groups improved on BPD symptoms and suicidal ideation There were no differences between treatments

Table A1 (part 4 of 4): RCTs of psychotherapy

Trial	Study arms and no. of participants	Duration	Outcome measures in addition to clinical data	No. of completers	Treatment results
Zanarini & Frankenburg (17)	Psychoeducation: 30 Wait-list control: 20	1 session psychoeducation and 12 week follow-up	SDS ZAN-BPD	Psychoeducation: 30 Wait-list control: 20	Greater reduction in impulsivity and relationship difficulties in the psychoeducation group Both groups demonstrated reductions in overall BPD symptoms

Note: ADSHI = Acts of Deliberate Self-Harm Inventory, AIAQ = Anger, Irritability, and Assault Questionnaire, BAI = Beck Anxiety Inventory, BDHI = Buss-Durkee Hostility Inventory, BDI = Beck Depression Inventory, BESOT = Borderline Evaluation of Severity Over Time, BHS = Beck Hopelessness Scale, BIS = Barratt Impulsiveness Scale, BPD-40 = Borderline Personality Disorder Checklist-40, BPDC = Borderline Personality Disorder Checklist, BPDSI = Borderline Personality Disorder Severity Index, BPRS = Brief Psychiatric Rating Scale, BSI = Brief Symptom Inventory, BSI2 = Borderline Syndrome Index, CAT = cognitive analytic therapy, CBT = cognitive behavioural therapy, CGI = Clinical Global Impression Scale, CGI-BPD = Clinical Global Impressions Scale – Borderline Personality Disorder, CISSB = Cornell Interview for Suicidal and Self-Harming Behavior, CRTHI = Cornell Revised Treatment History Interview, CT = cognitive therapy, CTBE = community treatment by experts, DBT = dialectical behaviour therapy, DBT-ST = dialectical behaviour therapy skills-training group, DIB-R = Diagnostic Interview for Borderline Personality Disorder – Revised, DSQ = Defense Style Questionnaire, EQ-5D = EuroQol-5D, EQT = EuroQol Thermometer, ETC = experienced therapists in the community, GAF = Global Assessment of Functioning Scale, GCC = manualized good clinical care, GPM = general psychiatric management, HAM-D = Hamilton Rating Scale for Depression, IIP = Inventory of Interpersonal Problems, IPO = Inventory of Personality Organization, IVE = Eysenck Impulsivity Venturesomeness Empathy Inventory, MACT = manual assisted cognitive treatment, MBT = mentalization-based treatment, MSGD = Miskimins Self-Goal (Other) Discrepancy Scale, PAI = Personality Assessment Inventory, PANAS = Positive and Negative Affect Schedule, PDBQ-BPD = Personality Disorder Belief Questionnaire – BPD Section, PHI = Parasuicide History Interview, RSES = Rosenberg Self-Esteem Scale, RST = Rogerian supportive therapy, SAS = Marks Social Adjustment Scale, SASII = Suicide Attempt Self-Injury Interview, SAS-SR = Social Adjustment Scale – Self Report, SBQ = Suicide Behaviors Questionnaire, SCID-II = structured clinical interview for DSM-IV axis I disorders, SCM = structured clinical management, SDS = Sheehan Disability Scale, SFQ = Social Functioning Questionnaire, SFT = schema-focused therapy, SGT = standard group therapy, SHBCL = Self-Harming Behaviors Checklist, SOFAS = Social and Occupational Functioning Assessment Scale, SPS = Suicide Probability Scale, ST = supportive treatment, STAI = State-Trait Anxiety Inventory, STAXI = State-Trait Anger Expression Inventory, STEPPS = Systems Training for Emotional Predictability and Problem Solving, STEPPS-M = Dutch version of STEPPS with individual therapy every 2 weeks, STIPO = Structured Interview of Personality Organization, TAU = treatment as usual, TFP = transference-focused therapy, THI = Treatment History Interview, TRES = Therapeutic Relationship Evaluation Scale, TUI-FA = Treatment Utilization Interview, Follow-Along Version, WHOQOL = World Health Organization Quality of Life Assessment, YASR = young adult self-report, YSQ = Young Schema Questionnaire, YSR = youth self-report, ZAN-BPD = Zanarini Rating Scale for Borderline Personality Disorder.

Table A2 (part 1 of 2): RCTs of pharmacotherapy						
Trial	Study arms and no. of participants*	Treatment duration and dose	Outcome measures	No. of completers	Results	Comments
Soler et al. (18)	Olanzapine+DBT: 30 Placebo+DBT: 30	12 weeks Mean dose 8.83mg olanzapine	CGI HAM-A HAM-D	Treatment: 22 Control: 20	Greater improvements in depression, anxiety and impulsive behaviours in olanzapine group; more weight gain in olanzapine group	Industry funded
Linehan et al. (19)	Olanzapine+DBT: 12 Placebo+DBT: 12	21 weeks Mean dose 4.46mg olanzapine	HAM-D OAS-M	Treatment: 8 Control: 8	No differences in outcomes between groups; faster decline in irritability in olanzapine group	Industry funded; selected only women with high level of irritability
Schulz et al.(20)	Olanzapine: 155 Placebo: 159	12 weeks Mean dose 7.09mg olanzapine	GAF MADRS OAS-M SCL-90-R SDI ZAN-BPD	Treatment: 77 Control: 92	No difference in improvement on ZAN-BPD between groups; greater improvement on irritability, family life and hostility subscales with olanzapine; greater increases in weight gain, cholesterol and prolactin with olanzapine	Industry funded
Shafti & Shahveisi(21)	Olanzapine: 14 Haloperidol: 14	8 weeks Mean dose 7.08mg olanzapine Mean dose 6.83mg haloperidol	CGI BDHI BPRS	Olanzapine: 14 Haloperidol: 14	No differences in improvement between groups	Funding unknown; inpatients only
Zanarini et al. (22)	Low-dose olanzapine: 150 Mid-dose olanzapine: 148 Placebo: 153	12 weeks Fixed low dose olanzapine group – 2.5mg Mean mid dose olanzapine group – 6.7mg	GAF MADRS OAS-M SCL-90-R SDI ZAN-BPD	Low-dose treatment: 97 Mid-dose treatment: 103 Control: 94	No difference at end point in BPD symptom severity; greater improvements in irritability, suicidality and family life in both olanzapine groups; greater improvement in social life with low-dose olanzapine; greater improvement in work/school and total symptoms with mid-dose olanzapine; olanzapine groups had more weight gain, metabolic changes and prolactin increases	Industry funded; sample overlaps with Schulz et al. (3)
Nickel et al. (23)	Aripiprazole: 26 Placebo: 26	8 weeks Fixed dose 15mg aripiprazole	HAM-A HAM-D SCL-90-R STAXI	Treatment: 26 Control: 26	Greater improvements in all measures and all subscales, except somatization, for aripiprazole group	Unfunded; follow-up found continued benefits (24)

Table A2 (part 2 of 2): RCTs of pharmacotherapy						
Trial	Study arms and no. of participants*	Treatment duration and dose	Outcome measures	No. of completers	Results	Comments
Pascual et al. (25)	Ziprasidone: 30 Placebo: 30	12 weeks Mean dose 84.1mg ziprasidone	BDHI BIS BPRS CGI-BPD HAM-A HAM-D SCL-90-R	Treatment: 13 Control: 16	No differences between groups	Industry funded
Hollander et al. (26)	Divalproex: 20 Placebo: 32	12 weeks Mean modal dose 1325mg divalproex	OAS-M	Unknown	Greater reductions in aggression with divalproex only after controlling for mania and depression symptoms	Industry funded
Nickel et al. (27)	Topiramate: 22 Placebo: 22	8 weeks Titrated up to fixed dose of 250mg topiramate	STAXI	Treatment: 22 Control: 20	Greater reductions in aggression with topiramate; greater weight loss with topiramate	Unfunded; male participants only; follow-up found continued benefits (28)
Loew et al.(29)	Topiramate: 28 Placebo: 28	10 weeks Titrated up to fixed dose of 200mg topiramate	IIP SCL-90-R SF-36	Treatment: 27 Control: 25	Greater improvements in various psychiatric symptoms (including hostility and anxiety), interpersonal functioning and health-related quality of life with topiramate	Unfunded; follow-up found continued benefits (30)
Tritt et al.(31)	Lamotrigine: 18 Placebo: 9	8 weeks Titrated up to fixed dose of 200mg lamotrigine	STAXI	Treatment: 17 Control: 7	Greater reductions in anger with lamotrigine	Unfunded
Reich et al.(32)	Lamotrigine: 15 Placebo: 13	12 weeks Mean dose 106.7mg lamotrigine	ALS ZAN-BPD	Treatment: 9 Control: 8	Greater reductions in affective lability and impulsivity with lamotrigine; no changes in overall BPD severity	Industry funded
Ziegenhorn et al.(33)	Crossover trial with placebo and clonidine: 17	1 week taper and 1 week treatment Clonidine 0.15mg in morning and 0.3mg at night	BDI BSL CAPS-D SCL-90-R	12 completers	Greater improvement in hyperarousal with clonidine, primarily in those with post-traumatic stress disorder; improved sleep with clonidine; no other differences between groups	Unfunded
<p>Note: ALS = Affective Lability Scale, BDHI = Buss-Durkee Hostility Inventory, BDI = Beck Depression Inventory, BIS = Barratt Impulsiveness Scale, BPRS = Brief Psychiatric Rating Scale, BSL = Borderline Symptom List, CAPS-D = Clinician Administered Post-Traumatic Stress Disorder Scale – Hyperarousal subscale, CGI = Clinical Global Impression Scale, CGI-BPD = Clinical Global Impressions Scale – Borderline Personality Disorder, DBT = dialectical behaviour therapy, DIB-R = Revised Diagnostic Interview for Borderlines, GAF = Global Assessment of Functioning Scale, HAMA-A = Hamilton Rating Scale for Anxiety, HAM-D = Hamilton Rating Scale for Depression, HDI = Hamilton Depression Inventory, IIP = Inventory of Interpersonal Problems, MADRS = Montgomery–Asberg Depression Rating Scale, OAS-M = Overt Aggression Scale – Modified, PANSS = Positive and Negative Syndrome Scale, SCID = Structured Clinical Interview for DSM-IV Axis I Disorders, SCL-90-R = Symptom Checklist-90, SDI = Sheehan Disability Scale, SF-36 = Short Form-36 Health Survey, STAXI = State–Trait Anger Expression Inventory, ZAN-BPD = Zanarini Rating Scale for Borderline Personality Disorder.</p> <p>*Unless otherwise noted, all studies conducted primarily or exclusively with female participants.</p>						

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