

	Sequence Generation		Allocation concealment		Blinding of participants, personnel, and outcome assessors		Incomplete outcome data		Selective outcome reporting		Other sources of bias		OVERALL risk of bias for study as a whole
Author Year	Describe method	Was it adequate? Yes/No/Unclear	Describe method	Was it adequate? Yes/No/Unclear	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention participant received. Provide any information relating to whether intended blinding was effective.	Was knowledge of allocated intervention adequately prevented during study? Yes/No/Unclear	Describe completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by review authors.	Were incomplete outcome data adequately addressed? Yes/No/Unclear	State how possibility of selective outcome reporting was examined by review authors, and what was found.	Are reports of study free of suggestion of selective outcome reporting? Yes/No/Unclear	State any important concerns about bias not addressed in other domains in tool. If particular questions/entries were pre-specified in review's protocol, responses should be provided for each question/entry.	Was study apparently free of other problems that could put it at high risk of bias? Yes/No/Unclear	Low/Unclear/High
Bateman 2008 ¹⁷	No information provided other than stating that patients were randomized following the initial assessment.	Unclear	No information provided.	Unclear	Not described, does not appear to be blinded.	No	Attritions and exclusions adequately documented; subject flowchart included in article. Analyzed 36/44 (82%). 3 patients in control group crossed over to treatment group after suicide attempts; 3 patients dropped out of treatment. These were not included in analysis. At 8-year follow-up: results on 41 patients.	No	Methods published prior to results.	Yes	Reports baseline characteristics only on those included in analysis (36 of 44 randomized).	No	High
Bateman 2009 ³⁷	"Randomization followed consent, enrollment, and baseline assessment... Treatment allocation was made offsite via telephone randomization using a stochastic minimization program (MINIM) balancing for age, gender, and presence of antisocial personality disorder."	Yes	"Treatment allocation was made offsite via telephone randomization."	Yes	"A study psychiatrist informed participants of their assignment." "Assessors were blind to treatment group." The study was designed to compare to a well-matched alternative treatment provided in similar contexts by similarly trained therapists and, therefore, even though patients may have been aware of the type of treatment they were receiving, both treatments were likely perceived as effective treatment methods.	Assessors: Yes; Participants: No	Attritions and exclusions adequately documented; subject flowchart included in article. 134/134 analyzed.	Yes	No omissions of any expected suicide-related outcomes; authors state that primary outcomes were declared prior to beginning the study.	Yes	Those who declined participation were more likely to have history of alcohol abuse (N=12); reported rape at baseline was more common in MBT group. No information is provided re: possible nesting (e.g., therapist effects).	Unclear-may have been other unmeasured differences at baseline.	Unclear

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Blum 2008 ³⁹	Coin toss.	Yes	Coin toss occurred following inclusion in study; therefore, allocation was unknown when determining treatment condition.	Yes	No information provided. Because the comparison group (TAU) could likely be identified as such by participants, lack of participant blinding could introduce significant bias.	Unclear	Missing data, attritions, and exclusions adequately reported. Those with at least one post-baseline assessment included in analysis: 124/165.	No	No omissions of any expected suicide-related outcomes.	Yes	Reports baseline characteristics on 124/165 randomized (those who received the intervention); avoidant personality disorder more frequent in treatment as usual alone group (P=0.016). Because it is unclear whether or not the two treatment therapists conducted the groups together or separately, these nesting effects may not have been adequately addressed.	No	High
Comtois 2011 ⁴⁷	"Minimization algorithm matching for gender, history of suicide attempt, pre-existing use of psychotropic medications, and history of substance abuse."	Yes	No information provided.	Unclear	"Primary outcome variables... were assessed by a licensed clinician blind to treatment condition." No information on provider or patient blinding.	Yes for assessors, unclear for participants.	Attritions and exclusions documented; however, 12/16 (75%) of treatment and 10/16 (62.5%) of control participants did not complete study.	No	No omissions of any expected suicide-related outcomes.	Yes	Two "severe and complex" patients removed from treatment condition; one control participant removed due to being court-ordered into an alternative treatment. No demographic or outcome data reported for completers vs. non-completers.	Yes	High

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Davidson 2006 ⁴⁰	Randomization schedules "generated by the study data center".	Yes	Blinded researcher contacted trial coordinator by phone to initiate a randomization.	Yes	Research assistants carried out all assessments and were blind to treatment group allocation; they requested that patients did not mention any details of any psychological treatment they were receiving.	Yes	Attritions and exclusions adequately documented. Follow-up data reported on 102/106 (96%).	Yes	Methods published prior to results.	Yes	The study appears to be free of other sources of bias.	Yes	Low
Diamond 2010 ⁴⁶	Adaptive or "urn" randomization procedure, with four stratification variables: age, gender, past suicide attempt, and family conflict	Yes	Randomization described as "maintained by statistician", but no information about allocation	Unclear	Study participants, personnel and outcome assessors were all unblinded.	No	ITT; attrition reasonable overall (14%) and balanced between groups, but reasons not reported	Unclear	Protocol available at clinicaltrials.gov and primary outcomes are consistent. No omissions of any expected suicide-related outcomes.	Yes	The study appears to be free of other sources of bias.	Yes	Unclear
De Leo 2007 ⁴⁵	Method not described ("randomization numbers")	Unclear	Sealed envelopes	Yes	Patients and case managers not blinded; no information on blinding of outcome assessors	No	High and differential attrition: 22/60 completed 12 months of treatment; 14/30 in intervention group vs 8/30 in treatment as usual group (47% vs 27%)	No	No indication of publication bias; outcomes described in methods are reported in results	Unclear	None noted	Yes	High

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Donaldson 2005 ⁴⁸	No information provided other than stating that patients were randomized following the initial assessment.	Unclear	No information provided.	Unclear	The same 6 therapists administered two types of treatments and, therefore, were not blinded. No information on assessor blinding.	No	Demographic comparisons of completers and non-completers; ITT analysis. 31/39 (79%) randomized completed treatment and included in analysis.	No	No omissions of any expected suicide-related outcomes.	Yes	Baseline characteristics reported only for 31 who completed treatment; compared those who remained to those who dropped out and found no differences, but might have been differences between groups at baseline. The same therapists provided both treatments. No statistical techniques were used to account for nested data (e.g., therapist effects).	No	High
Green 2011 ⁴⁴	Allocation was by minimization controlling for factors chosen as likely to predict treatment response	Unclear (sequence generation method not reported)	Randomization by remote telephone to trial center	Yes	Participants were not blinded (therapy study) Outcome assessors were blinded	Yes (for outcome assessors)	High and differential attrition: 37% in routine care group and 21% in therapy group did not receive intervention. But ITT analysis: 359/366 included in ITT analysis (98%); reasons for attrition reported adequately.	Yes	Results for stated primary outcomes are reported	Yes	None noted	Yes	Unclear
Hatcher 2011 ³⁸	Computer-generated random numbers.	Yes	Independent statistician, sealed envelopes.	Yes	Patients blinded due to Zelen design; no therapist blinding for PST intervention and unclear for TAU providers; no information on blinding related to health record outcomes.	Yes for patients; unclear for providers; unclear for raters.	Significant loss to follow-up in consented patients, though 100% follow-up of hospital representation outcome because this was obtained for both consenting and non-consenting patients.	Yes	Outcomes and subgroup analyses determined <i>a priori</i> .	Yes	Patients receiving DBT were excluded from the study, and this could potentially result in a biased sample of patients.	Unclear	Low

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Hazell 2009 ⁴⁹	No information provided other than stating that patients were randomized.	Unclear	Assigned by distant site coordinator	Yes	No patient and therapist blinding. Outcome assessor blinding attempted, but at end of follow-up, raters correctly identified the treatment allocation for 54% of participants: 65% in routine care group vs. 43% in experimental treatment group; $p=0.06$.	No for patient and therapist. Unclear for raters.	Data missing for 3% in experimental group and 8% in routine care group. Reasons not reported.	Yes	Prospectively-registered protocol not available. But, no omissions of any expected suicide-related outcomes	Yes	The study appears to be free of other sources of bias.	Yes	Unclear
Linehan, 2006 ³⁸	"Using a computerized adaptive minimization randomization procedure, eligible subjects were matched to treatment condition on 5 primary diagnostic variables."	Yes	"The participant coordinator, who was not blinded to treatment condition, executed the randomization program and collected all the data related to treatment."	Unclear	"The participant coordinator, who was not blinded to treatment condition, executed the randomization program and collected all the data related to treatment." "Assessments were conducted by blinded independent clinical assessors." "Initial assessments were done before informing subjects of treatment assignment." Notably, the study was designed to compare to a well-matched alternative treatment provided in similar contexts by similarly trained therapists and, therefore, even though patients may have been aware of the type of treatment they were receiving, both treatments were likely perceived as effective treatment methods.	Assessors: yes; participants: no; providers: no.	"To assess the potential effect of missing data..., a pattern-mixture analysis was implemented using 2-tailed tests." Found no evidence that results were biased by these differences (data not reported). Attritions and exclusions clearly documented and accounted for in analyses; subject flowchart included in article.	Yes	No omissions of any expected suicide-related outcomes.	Yes	Differences in amount of therapy received in the different groups (DBT received more than CTBE due to weekly group sessions and greater treatment retention). Statistical techniques adequately accounted for nested data structures.	Unclear	Unclear

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McMain 2009 ⁴²	Pre-generated random block sequence enclosed in envelopes. "Developed by a statistician," but unclear how.	Unclear	Scheme was held by statistician, who prepared 45 sealed envelopes, each containing the group allocations in random order for 4 participants; but no information about whether envelopes were sequentially numbered. Also concerned about potential clinical importance of ≥ 10% higher rates of lifetime anxiety and eating disorders, and current PTSD and substance use in DBT group.	Unclear	Described as single blind. Explicit statements that assessors were blinded. When assessors were asked to guess treatment assignment, they were incorrect for 86% of cases, "suggesting blinding was largely maintained." Notably, the study was designed to compare to a well-matched alternative treatment provided in similar contexts by similarly trained therapists and, therefore, even though patients may have been aware of the type of treatment they were receiving, both treatments were likely perceived as effective treatment methods.	Assessors: yes; participants: no; providers: no.	ITT was conducted, but no information about imputation method. Attrition: 38% (DBT=39% vs. GPM=38%). Most common reasons for discontinuation of treatment were "individual sessions were not helpful (42%), scheduling problems (32%), transportation problems (32%), group sessions not helpful (29%), and that problems improved (24%)".	Unclear	No omissions of any expected suicide-related outcomes.	Yes	The study appears to be free of other sources of bias. No information is provided re: possible nested (e.g., therapist effects).	Yes	Unclear
Stewart 2009 ⁵⁰	Method not described	Unclear	Method not described	Unclear	No information on blinding	Unclear	High and differential attrition: 34.4%, 37.5%, and 26.1% completed CBT, PST, and TAU interventions. Number included is given as 32. Number analyzed is not clear; one outlier was eliminated before data analysis.	No	No information to judge; "outcome measures included..."	Unclear	None noted	Yes	High

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Tamier 2006 ⁵¹	No information provided other than stating that patients were randomized.	Unclear	"The interventions were carried out independently of assessors who were kept unaware of treatment allocation." Study personnel assigning treatment/ control condition were unaware of allocation.	Yes	The same 5 therapists administered 2 types of treatments and, therefore, were not blinded. Assessors were blinded to treatment allocation; deaths determined by review of hospital records.	Assessors: yes; participants: no; providers: no.	Attritions and exclusions adequately documented and subject flowchart included in article. For suicidal behavior, 71% follow-up at 18 months (218/278); for deaths, appears to be complete information.	No	No omissions of any expected suicide-related outcomes.	Yes	The same therapists provided both treatments. No statistical techniques were used to account for nested data (e.g., therapist or facility effects). In addition to suicides, 2 deaths were classified as accidental by the coroner and 2 deaths by natural causes (but possible to do calculations using this information).	No	High
Unutzer 2006 ⁵²	No information provided other than general statement of randomization.	Unclear	No information provided.	Unclear	Telephone survey team blinded to intervention status (surveys measured suicidal ideation); for deaths, unclear if blinded.	Unclear	Unclear if missing data for deaths.	Unclear	No omissions of any expected suicide-related outcomes.	Yes	Primary outcome was suicidal thoughts; 117 patients died during follow-up: "to the authors' knowledge there were no suicides." No information on how this was determined or if data are complete.	No	Unclear
Winter 2007 ⁵³	Not randomized: total randomization of the allocation to conditions was not possible... participants were allocated to the psychotherapy condition if there was a vacancy or to the normal clinical practice condition if not.	No	Not concealed.	No	Does not appear to be blinded (medical records were monitored for repeat episodes of self-harm).	No	Very high and differential attrition: 64 allocated, 45% control and 92% intervention completed post-treatment assessment; 28% and 54% completed 6-month assessment. However, information on repetition of self-harm behavior was traced in all participants over 3 years.	No	No omissions of any expected suicide-related outcomes.	Yes	Differences at baseline in 2 of 10 personal construct categories of self-harm.	No	High