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When waitlists are not feasible, nothing is a thing that does not need to be done.

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Abstract

Clinical psychology practices initially grew through the use of case studies, uncontrolled trials, and eventually through randomised controlled trials (RCTs). The use of a waitlist, control group is standard practice in such trials of treatment regimens for psychopathological conditions. However, as knowledge advances regarding the successful treatment of such conditions, best practice guidelines are being developed. These guidelines have predominantly been based upon the results of RCTs and utilise aggregating mechanisms, such as meta-analysis, to derive their conclusions. We argue here for statistical methods that allow for comparisons to existing data from waitlist controls where the continued use of waitlist conditions has become problematic. Using Post Traumatic Stress Disorder as an example, this article proposes various methods for obviating the need for a waitlist control under such circumstances. After conducting separate meta-analyses for both treatment and control conditions, we find that waitlist conditions do provide some benefit to participants with PTSD, but current best practice treatment conditions elicit far superior effect sizes. The various methods for evaluating a study without a waitlist control are proposed and demonstrated.

Without the use of waiting list / no treatment controls many interventions would not have been found as efficacious and some treatments would not have been found as noxious – both important findings in disease prevention and treatment. The use of no treatment, or waitlist controls, is a challenging ethical and practical question confronting clinical researchers in treatment trials of psychiatric disorders. Before exploring this question, using Post Traumatic Stress Disorder (PTSD) as an example, we will outline the background principals which inform this practice as articulated in the World Medical Association (WMA) Declaration Of Helsinki (1964). This was revised in 2000 (the Edinburgh Revision) and affirmed in 2004 (the Washington Clarification) and makes specific statements regarding the use of non-active treatments in clinical trials where an effective treatment is available. The relevant section now reads: "The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists" (Paragraph 29, WMA, 2000). In effect, where we already have an effective treatment, new treatments should be compared against the extant approach rather than a waitlist or placebo condition. The Washington Clarification, however, argued that "*a placebo-controlled trial may be ethically acceptable, even if proven therapy is available … when …a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm*" (Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002). Of course, the Declaration of Helsinki has no legal authority in any country (Evans, 2003), but many countries have their own sets of procedures, legislation and / or bureaucratic pressures. Whichever the case, the Declaration has been discussed in the

scientific literature in relation to many disorders / issues (e.g., Carpenter, Appelbaum, & Levine, 2003; Weijer & Glass 2002).

While placebos attempt to provide a 'zero-dose' of an intervention and control for non-specifics, waitlists attempt to control for the passage of time and assessment in the population of interest. Without getting into a lengthy debate regarding the different types of waitlists and placebos, a review which would require a treatise in it's own right, the application of such a Clarification requires systematic inspection of the risks involved with disorders and, should the risks be seen as serious, and effective treatments are available, then a method of comparing treatment groups to an already known placebo or waitlist effect size needs to be available. If it is possible to calculate these effect sizes, this process is an important step in obviating the need and justification for the use of placebo or waitlists in future treatment studies. This manuscript aims to provide such an analysis for waitlist controls, using Post Traumatic Stress Disorder (PTSD) as the example disorder and psychotherapy as the example intervention. Psychotherapy trials for PTSD frequently utilise waitlist controls, yet until now there has never been a systematic investigation regarding the effectiveness of waitlists and whether participants are at increased risk of serious harm. We do not see a valid argument as to why psychotherapy trials should be held to a lower standard than pharmaceutical trials.

The Example of PTSD

The background issue of whether effective treatment exists is extensively addressed in recent treatment guidelines for Acute Stress Disorder (ASD) and PTSD. A number of systematic examinations of this question have advised that trauma focused Cognitive Behavioural Therapy (CBT) reaches the highest grade of evidence for efficacy (e.g., American Psychiatric Association, 2004; Australian Centre for Posttraumatic Mental Health, 2007; National Institute for Clinical

Excellence, 2005) or that exposure therapy only (a trauma focused therapy) is effective for veterans with PTSD (Institute of Medicine, 2007). In the most recent meta-analysis (Australian Centre for Posttraumatic Mental Health, 2007), CBT demonstrated a large superior effect, at post-treatment, for PTSD symptom severity against waitlist controls (n =14, *g* = 1.21, 95%CI: 0.8, 1.62). This has led to "key recommendations [indicating] the use of trauma-focused psychological therapy … as the most effective treatment for ASD and PTSD" (p. 637, Forbes, Creamer, Phelps, Bryant, McFarlane, Devilly, Matthews, Raphael, Doran, Merlin, & Newton, 2007).

Authored meta-analytic studies have agreed with these organisational guidelines. For example, Van Etten and Taylor (1998) conducted a meta-analysis on 61 treatment outcome trials for PTSD. For studies that included behavioural treatment (*n* = 13) they found large to very large effect sizes (self-report measures of Cohen's *d* = 1.27; 95%CI: 0.80, 1.74; and observer ratings of Cohen's *d* = 1.89; 95%CI: 1.66, 2.12). Further, Bradley, Greene, Russ, Dutra and Westen (2005) presented a multi-dimensional meta-analysis of studies published between 1980 and 2003 on psychotherapy for PTSD. For exposure therapy (*n*=13 studies), they reported an effect size of 1.57 (95%CI: 1.11, 2.04). A large to very large effect size was also found for general CBT (*n*=5 studies; Cohen's *d* = 1.65; 95%CI: 0.96, 2.35) and exposure plus cognitive therapy (*n* = 9 studies; Cohen's *d* = 1.66; 95%CI: 1.18, 2.14).

Against the background of a large treatment superiority effect size, the question arises as to whether waitlist or placebo controls are still ethical and of any practical value. This matter should be resolved in the light of a secondary question: is the allocation of participants to no treatment likely to introduce the risk of "serious" or "irreversible" harm in comparison to immediate, gold standard treatment? In allocating people to a waitlist control condition are we,

for example, denying people their legal and humanitarian rights? And is the use of wait list controls institutionally feasible?

In psychiatric disorders, the issue of harm should be addressed along a series of dimensions that include the risk of suicide and the presence of comorbid disorders, including the emergence of patterns of substance abuse which may represent a pattern of self-medication, (Jacobsen, Southwick, & Kosten, 2001; McFarlane, 1998). A further theoretical argument is the potential for a delay in the commencement of treatment leading to a decreased probability of a positive treatment outcome (Harrigan , McGorry, & Krstev, 2003) or an increase in the attrition rate leading to no active treatment in the long-term for those people. Such outcomes should also include the measurement of financial costs to the individual and support services, including negative effects on employment opportunities, and the consequences on social and personal relationships. In the case of PTSD, this material is not readily available.

While the natural tendency for post trauma disequilibria is towards eventual resolution (e.g., van Emmerik, Kamphuis, Hulsbosch, & Emmelkamp, 2002), and we caution against the pathologising of expected and short term discomfort (Gist & Devilly, 2002), treatment seeking patients with PTSD tend to demonstrate chronicity, developing comorbidity and financial burden. Davidson et al's (1991) North Carolina subset of the Epidemiological Catchment Area (ECA) study would suggest that those with untreated PTSD are at an increased risk of serious harm. They concluded that of those with a lifetime history of PTSD, 19.8% had attempted suicide. This compares poorly to people with other DSM III diagnoses (3.9%) and the greater general population (0.8%). In fact, after controlling for comorbid depression, those with PTSD were 8.2 times more likely to attempt suicide than those with other disorders. In the 1997 Australian National Mental Health and Wellbeing Survey the disorder with the second highest odds ratio for

suicidal ideation over the previous 12 months was PTSD (OR = 22.8; OR for depression = 29.9; McFarlane, 2004).

Such risk of death is compounded by comorbidity issues. Research has consistently found that traumatic experiences and PTSD diagnoses are accompanied with a high risk of psychiatric morbidity, mainly depressive and anxiety disorders (Bleich, Koslowsky, Dolev, & Lerer, 1997; Cloitre, 1997; Creamer et al., 2001; Kessler et al., 1995; Kulka et al., 1990). The US National Comorbidity Study (NCS; Kessler et al. 1995) reported that 88% of males and 79% of females with lifetime PTSD met criteria for at least one other psychiatric diagnosis. In fact, PTSD was associated with a higher prevalence of all disorders studied: Major Depression, Dysthymia, Mania, Generalised Anxiety Disorder, Panic Disorder, Simple Phobia, Social Phobia, Agoraphobia, Alcohol Abuse/Dependence and Drug Abuse/Dependence. Major Depression was the most common comorbid diagnosis, occurring in just under half of males and females with PTSD. Comorbid conditions such as anxiety and depression may introduce secondary attempts at self-medication, further adding to the complexity of the presentation, decreased efficacy of treatment when it is obtained, and increased functional disability with consequences on stability of employment and relationships. As concluded by Wang et al. (2005) following the US National Comorbidity replication study of first onset mental disorders, “interventions to speed initial treatment contact are likely to reduce the burdens and hazards of untreated mental disorder.” (p.603).

Although a history of a psychiatric disorder is a risk factor for developing PTSD following a traumatic event, PTSD often leads to the development of other psychiatric disorders as well. In the NCS, PTSD was the primary disorder for the majority of females who developed affective and substance-use disorders (Kessler et al., 1995; Schnurr et al., 2002). Creamer and

colleagues (2001) found that 82.5% of males and 79.7% of females with PTSD presented with another Axis I disorder. Furthermore, nearly 50% of females and over 60% of males with PTSD met criteria for two or more additional Axis I disorders.

Kulka et al (1990) has even reported that 99% of Vietnam veterans with chronic PTSD had, at some stage, qualified for another DSM-III-R diagnosis, compared with 41% of those without PTSD. The most prevalent co-morbid disorders were Substance Abuse or Dependence (75%), Generalised Anxiety Disorder (44%) and Major Depression (20%). Likewise, Breslau and colleagues (1991) found that 83% of their young PTSD sample met criteria for at least one other psychiatric disorder compared with 44% of those without PTSD. The most common conditions were Substance Abuse or Dependence (43%), Major Depression (37%) and Agoraphobia (22%). Bleich and colleagues (1997), examining psychiatric morbidity following war-related trauma, found that comorbidity was extensive, with Major Depression the most prevalent (95% lifetime, 50% current), followed by Anxiety Disorders, Affective Disorders and Alcoholism or Drug Abuse.

With such data, we conclude that untreated PTSD leads to increased risk of comorbidity and suicidal ideation and attempts. It is, therefore, reasonable to conclude that PTSD presents a risk which merits inclusion as a disorder which should not be described as “a minor condition”. If that be taken as true, and trauma focussed CBT treatment has been shown to be highly effective, then it behoves us to assess the impact of waitlist control groups in treatment studies. This is particularly important as some researchers have been questioning the ethics of not providing treatment as part of clinically controlled research (Devilly, 2002; Devilly & Spence, 1999).

PTSD treatment-outcome studies often include waitlist control conditions to compare the effects of active treatment (e.g., Foa, 1991; 1999a; Keane et al 1985; Resick & Schnicke, 1992;

Marks et al., 1998; Rothbaum et al., 2005). In their meta-analysis, Van Etten and Taylor found a low to moderate effect size for self-report and observer ratings of PTSD across five studies that included wait-list conditions (self report; Cohen's *d* = 0.44; 95%CI: 0.28, 0.60 and observer ratings, Cohen's *d* = 0.75; 95%CI: 0.67, 0.83). Bradley and colleagues (2005) also found a low effect of no-treatment (waitlist conditions) on PTSD symptoms across 15 randomised control trials (Cohen's *d* = 0.35; 95%CI: 0.19, 0.51) and only a 14.25% rate of diagnostic change (Intent To Treat analysis; ITT) among patients assigned to the waitlist (95%CI: -1.11, 29.61). To place this in perspective: with 95% confidence, being in a waitlist creates minimal symptom improvement and, had people not met full criteria at intake, the chance that a patient met the diagnostic criteria of PTSD by study end could even increase. This compares with very large symptom improvement and an ITT diagnostic change of 55.68% (95%CI: 50.01, 61.20) if a patient were assigned to a treatment condition. A problem here, though, is that to our knowledge there are no data upon which to base how long without treatment (waitlists) increases suicide risk, prolongs distress, increases study attrition rates, or increases vocational, social or financial harm. However, the presence of such effective treatments, and not providing immediate relief, gives us cause for concern when placing people into waiting lists.

Another problem that is particularly relevant for psychological disorders which develop following harrowing events is that people may be legally entitled to be provided prompt and efficacious treatment. In the case of victims of crime in Victoria, Australia, there is legislation that stipulates that a victim of a violent crime has the right to claim financial and emotional compensation. Were one to conduct a RCT involving a waitlist control group with victims of crime who contacted the Victim Support Agency, it would not just be institutionally unfeasible, but likely a breach of the victims' legal rights. So, do we now no longer conduct randomised

(waitlist) controlled treatment trials with victims of crime? Or do we only do so where such laws have not yet been introduced, particularly in countries or states without a strong rule of law? This second option may present a legal loophole, but is hardly a humanitarian loophole. Victims of crime are just one example, returned servicemen, victims of torture, and victims of terrorist attacks all have legal or constitutional rights to receive prompt and effective treatment. Although it may be argued that people were provided with informed consent, this is problematic because people cannot sign away their legal rights in most developed countries and this state of affairs inevitably leads to lawsuits (e.g., see Kovac, 2001) and scientific disarray.

But if waitlist conditions for psychological trauma treatment were to be designated unethical, or just plain unfeasible, it could be argued that we are losing valuable information in studies testing new effects or specific sub-populations and about which we do not have a previously demonstrated effect size. However, Rosenthal & Rubin (1982) have provided us with a method of comparing effect sizes from different specific studies. Were we able to accurately gauge general waitlist effect sizes then we may be able to apply new methods to compare our treatment study against the estimated effect size from a waitlist meta-analysis.

We aim to here provide a meta-analysis of waitlist groups from PTSD treatment studies in order to gauge the effects of being a participant in this condition allocation. We then provide a methodology of comparing the effect size of a treatment study with the meta-analysis of no treatment. In order to make a reasonable assessment of the effect of being part of a treatment study, yet not actually receiving treatment, one needs to keep all other factors constant. For example, assessment strategies would need to be similar in that they stem from generally similar coherent anchor theories. This would make the assessment techniques and micro-skills used to obtain data during the assessment sessions as similar to each other as possible. Further, under a

broadly similar approach to research, the assessment instruments are likely to have equally high validity and be specific to the disorder of interest. Such uniformity of approach by acceptable studies would also increase the likelihood that correspondence between the study researchers and patients were equally impactful and heterogeneity of variance would be less likely to invalidate the meta-analysis.

Method

Procedure

The following procedure was employed to identify studies for the meta-analysis: (1) a manual search through *PsychInfo* was conducted using the key words "PTSD", "trauma", "treatment", "control group" and "wait*" individually and in combination; (2) a review of prior meta-analytic papers was conducted; and (3) contact was made with experts in the field. To keep consistent with the latest treatment guidelines (ACPMH, 2007), studies were included if they were published between 1985 and January 2006. To be included, studies were required to (1) include a wait-list control group examined against a specific, manualised, trauma focussed treatment of PTSD; (2) use validated self-report measures of PTSD symptoms or a validated structured interview; (3) report mean (and standard deviation) symptoms at the start and end of the waitlist period; (4) be reported in English; (5) use adult participants; and (6) examine the treatment of PTSD (rather than acute stress disorder or preventive efforts such as debriefing). It has been argued through qualitative, historical analysis and quantitative, meta-analysis (Devilly, 2002) that EMDR uses similar practices to CBT to the point of indistinct strategies, yet adds inert eye movements. Therefore, both treatment approaches have gained equal standing in many treatment guidelines and will be combined in this meta-analysis. Placebo conditions were not included in this analysis. Our reason for this rests on the unacceptable heterogeneity we believe

that inclusion of such studies would introduce into the analysis. Some studies use a placebo condition for controlling for just one aspect of treatment, some use placebos to control for one or more non-specific factors of therapy, while others use placebos to control for just being included in a study and coming to the hospital / university once a week 'for assessment', which the participant may interpret as treatment. However, waitlist control groups tend to control for assessment by therapists from intake to x weeks later, and the natural passing of time with normal community involvement for people with this disorder. In this respect waitlists in this analysis are assumed to also allow routine care, whether this was specifically mentioned in the original paper or not, as long as this did not include active, trauma-focussed treatment.

The following variables were assessed: number of participants, participant inclusion and exclusion criteria, the waitlist period and the trauma population. Effect sizes for the waitlists were calculated for the time period of the pre- versus post- treatment groups. In cases where both full-scale and subscale scores for a PTSD measure were reported, only the full-scale score was used. Where only subscale scores were reported these were averaged. Only measures of PTSD symptoms were examined. The meta-analysis is limited to studies that examined an active treatment with a trauma focussed component (e.g., imaginal exposure, EMDR, in vivo exposure) against a waitlist control condition. This limitation was made due to the varying nature of assessment protocols (argued above) between different schools of thought possibly having different effects on wait-list conditions.

Effect sizes were calculated for Hedges' *g* (hereafter referred to as *g*) using ClinTools Software (Devilly, 2007). Unlike Cohen's *d*, which systematically overestimates effect when used with small samples, Hedges *g* includes a mathematical adjustment for small sample bias as demonstrated in equation 1.

Equation 1. Hedges' g

$$\left(\frac{Mean\ 1 - Mean\ 2}{\sqrt{((n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2) / (N_{Tot} - 2)}}\right) * \left(1 - \frac{3}{4(n_1 + n_2) - 9}\right)$$

Note: n_x = number of subjects from group x; N_{Tot} = total number of subjects from both groups; SD_x = Standard deviation around mean from group x; Mean x = Mean of group x.

Foa, Keane and Friedman (2000) recommend that Hedges *g* be used to evaluate outcome as it is "based on the standardised difference between two means, typically the mean of a treatment sample minus the mean of a comparison sample divided by the pooled standard deviations of the two samples" (p. 550). It has been argued that this formula when applied to a within subjects design (pre- to post-treatment group) usually overestimates the size of effect, although not to the degree of using an independent t-statistic in computing the results (Dunlap, Cortina, Vaslow, & Burke, 1996). While the alternative formula supplied by these authors does typically change the estimate at the second or third decimal place, which is itself of questionable value, it requires the within subjects *t*-statistic and the correlation coefficient (both pre- to post-treatment for any specific condition) to compute the effect size. Authors do not report these data on a routine basis and the benefit of having extra studies upon which to base our decision making outweighs the small correction the alternative formula would make. Further, and in agreement with van Ettan & Taylor (1998), as the effect sizes will be used comparatively to each other, as long as the same formula is used then the effects of overestimation should be minimal. Therefore, throughout this paper we have used the formula from Equation 1 in computing *g*

In summary, Hedges *g* effect size is reported because this statistic takes account of small sample sizes, uses a pooled standard deviation (sigma), allows for an increased number of studies to be included in meta-analyses and is the gold standard recommended by the International

Society for Traumatic Stress Studies (ISTSS). Effects sizes were calculated for the pre- versus post-waitlist period. Different measures of PTSD symptoms were employed in various studies; therefore, an overall effect size was calculated by aggregating the effect sizes across measures within each study using equation 2. This led to an overall, aggregated, effect size within each study, on measures of PTSD.

Equation 2. Effect Size Aggregate

$$\sqrt{\frac{(\pm)g_1^2 + (\pm)g_2^2 + \ldots (\pm)g_n^2}{n}}$$

Note: g_1 = Hedges' *g* effect size on PTSD measure 1; n = number of PTSD measures; (±) = positive or negative effect size.

Results

Supplemental Table A (APA website) reports the wait-list time period, the exclusion criteria, the number of participants in the waitlist condition and the trauma population for each study. Also reported in Supplemental Table A are the waitlist effect sizes (Hedges *g*) and 95% confidence intervals for each clinical trial. A summary of the results is also included in Table 1 below. Meta-analysing these data (one effect size from each study) was completed both unweighted and with study sample size as a weighting to the importance of the effect size from each study. Standard deviations and 95% confidence intervals were also computed. Twenty studies were included in the meta-analysis, comprising of 418 participants who had acted as a waitlist control in a trauma focussed treatment-outcome study for PTSD. Waitlist time period did not significantly correlate with derived effect size ($r(20) = -0.21$, *ns*), with only 4.38% of the variance of these measures being accounted for by the relationship between effect size and length of waitlist.

Weighted by study sample size, the average effect size (*g*) was 0.336, with a standard deviation of 0.233. There are two methods of computing 95% confidence intervals: by sample size representing the number of studies or the number of participants. With sample size representing the number of studies (20), the confidence intervals around a *g* of 0.336 stretch from 0.23 to 0.44. With sample size representing the number of participants (418), the confidence intervals are even smaller and stretch from 0.31 to 0.36. Either way, it should be kept in mind that the chance that the true weighted effect size is really only zero has the same probability that the true effect size is 0.672 (Rosenthal & Rubin, 1994).

Unweighted, the average effect size (*g*) was 0.358, with a standard deviation of 0.276. With sample size representing the number of studies (20), the confidence intervals around a *g* of 0.358 stretch from 0.24 to 0.48. With sample size representing the number of participants (418), the confidence intervals stretch from 0.33 to 0.39. Either way, it should be kept in mind that the chance that the true unweighted effect size is really only zero has the same probability that the true effect size is 0.716 (Rosenthal & Rubin, 1994).

Using The Meta-analysis To Compare Data from A Treatment Study.

Suppose we wished to see whether our newly run trauma focussed treatment study, which did not include a waiting list control, is better than a waitlist. There are a few possible ways of using the current meta-analysis.

The 1 In 20 Gambit.

The first, and most straightforward, method is to simply place the derived average effect size from the new study into a table of the studies from the meta-analysis in ascending order (see Table 1). This method has the benefit of not assuming a normal distribution of waitlist effect

sizes. In the current example, should the treatment effect size of the new study score greater than $g = 0.969$ then one can say that, as it is greater than the effect sizes of the twenty studies included in the meta-analysis, the effect size is greater than that of waitlist control groups from trauma focussed studies, with a probability of less than 1 in 21 ($p<0.05$). As with all solutions in this manuscript, it should be recognised that this is a 'per study' approach and not an individual patient gambit (i.e., not a 19 in 20 chance of positive outcome).

Not Representative Of A Waitlist (With 95% Confidence)

i). Unlike Waitlists: One could argue that 1.96 standard deviations above the mean (95% confidence interval) would suffice to argue the case that the derived effect size is greater than one would expect from a waitlist. In this case, the new study effect size should be in excess of 0.793 (0.336 + (1.96 * 0.233)) when using the mean effect size weighted by study sample size (0.9 if comparing to the unweighted mean effect size from the meta-analysis (0.358 + (1.96 * 0.276))). This is presented in Figure 1 by point B. Of course, should the effect size be 1.96 standard deviations *below* the mean of the waitlist meta-analysis (point A in Figure 1) then one could argue that the treatment is even worse than would be expected from a waitlist. In the current example this cut-off would equate to -0.121 (0.336 - (1.96 * 0.233)) when using the mean effect size weighted by study sample size (-0.183 if comparing to the unweighted mean effect size from the meta-analysis (0.358 - (1.96 * 0.276))).

ii). Like Treatment Studies: Another possibility is to see whether the new treatment study effect size is more than 1.96 standard deviations below the *treatment* mean effect size of the studies that had been included in the waitlist meta-analysis (point C in Figure 1). If it is not below this level, then one could argue that the study outcome is representative of current best-practice

treatment studies (with 95% confidence)[1]. However, another method of directly comparing individual studies would be to use Rosenthal's (1983, 1984) method of directly comparing the *p* values, *t*-statistics or *z*-statistics of individual studies. This is discussed in more detail below (under *Similarity To A Previous Study*). Of course, if the treatment effect size of the new study is greater than 1.96 standard deviations *above* the mean treatment effect size, then one could argue that the new treatment appears superior to current best practice (point D in Figure 1) and the ground is laid for a direct comparison between treatments (without waitlist controls). This may be used where we only have data from treatment effect sizes or wish to compare only to other treatments. However, in order to conduct either of these comparisons, another meta-analysis is required of the treatment studies from which the waitlist groups were obtained. Following current treatment guidelines regarding best practice (e.g., ACPMH, 2007) trauma focused treatments and stress inoculation practices, when applied individually, have been shown to work with the highest efficacy in the *short* term (i.e., pre- to post treatment). Two studies (Resick et al., 1988; Zlotnick et al., 1997) were, therefore, removed from the meta-analysis for treatment effects as both relied on the delivery of group therapy during the treatment condition. Where more than one trauma focused treatment was administered, effect sizes were aggregated across measures within each treatment condition and then across treatment modalities. Participant numbers were then summed for an overall study size. The results are presented in Supplemental Table B (APA website).

Weighted by study sample size, the average effect size (*g*) was a large 1.499, with a standard deviation of 0.47. With sample size representing the number of studies (18), the 95% confidence intervals around a *g* of 1.499 stretch from 1.28 to 1.72. With sample size representing the number of participants (576), the confidence intervals are much smaller and stretch from 1.46

[1] Of course, authors may wish to select different confidence intervals for their tests, such as 1 standard deviation (68.26%).

to 1.54. With an effect size of treatment equalling 1.499, it would take at least 63 studies of zero effect size to have not been published (file draw problem) to reduce this effect to the waitlist effect size of 0.336 (Orwin, 1983).

Unweighted, the average effect size (*g*) was 1.466, with a standard deviation of 0.583. With sample size representing the number of studies (18), the 95% confidence intervals stretch from 1.2 to 1.74. With sample size representing the number of participants (576), these confidence intervals shrink to between 1.42 and 1.51. With an effect size of treatment equalling 1.466, it would take over 56 studies of zero effect size to have not been published (file draw problem) to reduce this effect to the waitlist effect size of 0.358 (Orwin, 1983).

iia). Similar To Best Practice Treatment Study. As mentioned above, one could argue that 1.96 standard deviations below the derived mean would suffice to begin arguing the case that the derived effect size is less than one would expect from a best practice treatment (with 95% confidence). In this case, and to qualify as being representative of best practice treatment studies, the new study effect size should be in excess of 0.58 (Point C in Figure 1; 1.499-(1.96*0.47)), when using the mean treatment effect size weighted by the number of participants (0.323, if comparing to the unweighted mean effect size from the meta-analysis).

iib). Better Than Best Practice Treatment Study. Extended from the rationale above, one could argue that the new treatment is better than the current best practice treatments if the derived effect size is greater than 1.96 standard deviations above the mean treatment effect size from the meta-analysis. In this case, the new study effect size should be in excess of 2.42 (Point D in Figure 1; 1.499+(1.96*0.477)), when using the mean treatment effect size weighted by the number of participants (2.609, if comparing to the unweighted mean effect size from the meta-analysis). Either way, in the case of PTSD treatments, this is likely to be a hard task. It

seems to us that if such a treatment were to be tested then one would conduct a head-to-head study between the two treatments (using one of the methods here instead of a waitlist control) or conduct an 'add-on' trial where the new treatment is added to 'treatment as usual' (Evans, 2003) to assess any incremental gains over already existing treatments."

iii). Compromise (Intersection) Point: Jacobson & Truax (1991) have suggested a method for computing a compromise point where two normal distributions intersect. This is most commonly used in the generation of a reliable and clinical change index for individuals. However, with Hedges' *g* and Cohen's *d* being normally distributed (e.g., Chinn, 2000), we can apply the method to our effect sizes and treat the studies as *individual* studies. The intersection of the waitlist effect size distribution and the treatment effect size distribution may be a reasonable selection point as a cut-off for a compromise delineation (point I in Figure 1). The formula suggested for this, when standard deviations are different for the two distributions, is outlined under equation 3.

Equation 3.Waitlist and Treatment Effect Size Intersection

$$I = \frac{M_1 SD_2 + M_2 SD_1}{SD_1 + SD_2}$$

Note: M_1 = Waitlist Mean; M_2 = Treatment Mean; SD_1 = Waitlist Effect Size Standard Deviation; SD_2 = Treatment Effect Size Standard Deviation.

Using the weighted derived effect sizes from the two meta-analyses, the point at which these two curves intersect is approximately 0.722 (0.714 for unweighted means). Therefore, it could be argued that a study with a treatment effect size of less than 0.722 is more similar to a waitlist control group than a best-practice treatment group. An effect size above 0.722 would allow one to argue that the effect size is more similar to a best practice treatment effect size than a waitlist condition.

Similarity To A Previous Study

The last possibility addresses one of the shortcomings of meta-analysis. The main problem with a meta-analysis is that we sometimes don't have a high quality representative mix of studies to include in the analysis. Indeed, we may find that we have heterogeneous outcomes with some studies showing high effects and some studies showing low effects, which may or may not be mediated by quality factors. In such a case the meta-analysis would output a middle-road result (Hedges, 1982). However, it could be argued that rather than using the meta-analysis, one could compare a new treatment group to the waitlist group of a similar, previous study. For example, suppose one wished to compare a new treatment, 'Sudotherapy', to a waitlist control where the subjects were war veterans who were receiving routine, non trauma focused, care about 25 years after the war. If the sample were in the USA one might see Carlson et al (1998) as the most appropriate comparator, while if the sample were Australian then one might chose Devilly et al (1998) to compare.

One possible way of testing these studies is to see whether they are significantly heterogeneous. In other words, are they so alike in result (the new treatment and the old waitlist control group) that one would combine them in a meta-analysis as the same thing (waitlist). Rosenthal (1983, 1984) has suggested a method where two studies can be compared by use of the standard normal deviates *z*. The formula for this is given in equation 3. The individual z-test scores are obtained by converting the one-tailed p value of the published result into a z-score.

Equation 3. Similarity / Difference Of Specific Studies

$$z = \frac{z_1 - z_2}{\sqrt{2}}$$

Where z_1 = z-score of waitlist in study 1 and z_2 = z-score of treatment group in study 2.

As an example, suppose the 'Sudotherapy' treatment was for Australian veterans who were also receiving routine care (and had been for many years), and we wish to compare it to Devilly et al's (1998) waiting list control group. Contacting all authors we find out that Devilly et al obtain a one-tailed *p* value for their waitlist control (pre- to post-treatment) of 0.46 (and in the direction of worsening!). This equates to a *z* score of -0.11. It turns out that 'Sudotherapy' obtains treatment effects remarkably similar to prolonged imaginal exposure and obtains a one tailed *p* value of 0.01, which translates to a *z*-score of 2.33. This is leads to the computation in equation 4:

Equation 4. Working Example Of Sudotherapy Compared To Devilly et al (1998).

$$z = \frac{-0.11 - 2.33}{\sqrt{2}}$$

$$z = -2.44$$

p (one-tailed) = 0.007

One could now argue that the Sudotherapy treatment group derived such a significantly better outcome than the Devilly et al (1998) waitlist controls that one could not see them as being representative of the same population (*p*=.007). There are other methods for comparing the differences / similarities between other values such as *r*-values and *g* statistics, but we mention this as just one method for demonstration purposes. Likewise, one could directly compare treatment outcomes between studies using variants. However, although allowing for a comparison of sorts, we caution of using this method due to the peccadilloes of individual studies, the vagaries of selecting which study to compare to and our greater confidence in meta-analytic results.

Summary Of Approaches

In summary, using only the waitlist data, if the new treatment study scored less than point A in Figure 1 (1.96 standard deviations below the waitlist meta-analysis mean effect size; -0.121), then one could argue that the new treatment is even less effective than a waitlist control. If the new treatment scored 1.96 standard deviations above the mean of the waitlist control (point B; 0.793) one could argue that the new treatment produces an effect size greater than would be expected for a waitlist control, with 95% confidence. Point C could be used if we were to only use treatment studies for our guide. Deriving an effect size greater than 0.58 would suggest that the new study derived a result which is more representative of the main body of effective treatments (with 95% confidence). Scoring greater than point D (1.96 standard deviations above the treatment meta-analysis mean effect size; 2.42) would suggest that the new therapy appears to be better than current 'best practice' for PTSD treatment in the short-term. Point I in Figure 1 represents the compromise point where treatment and waitlist distributions intersect. Using this cut-off, obtaining an effect size above 0.722 would argue that the new treatment is more representational of best practice treatment than a waitlist control condition. Finally, one could compare the treatment group of the new study to a similar type of study where we have data for the waitlist group and see whether the our new study treatment group gets better or worse at a similar rate to the waitlist group in the comparison study.

Discussion

This paper provides methods for evaluating new treatments for disorders, where the use of a waitlist condition and the withholding of current best practice introduces increased risk of harm to the patient in comparison to immediate treatment or impinges upon their legal rights to immediate and effective interventions. Using the example of Post Traumatic Stress Disorder, a meta-analysis of waitlist conditions displayed a small to moderate effect size (g=0.34). However,

treatment conditions using stress and trauma focussed treatments delivered very large effect sizes on average (g=1.5). More than 60 studies with a treatment effect size of zero would need to have been left unpublished to bring the average treatment effect size down to the same level as the average waitlist effect size. Different strategies were offered for detecting whether the result of a treatment condition in a new trial is more representative of a waitlist or a treatment effect. Using these methods one could also argue whether the new treatment is better than one would expect from current best practice and whether any therapy is worse than one would expect from a waitlist control.

Of course, the methods proposed here are only instructive if there is a pool of previous RCTs which used a waitlist. Further, what one author describes as a waitlist may not be what another describes as a waitlist. Such shortcomings are endemic to the topic and require further, specialised attention that exceeds the breadth of the current manuscript. The appropriateness of the current methods can also be questioned when we expect cultural differences between populations. We argue that these differences need to be demonstrated first and, even then, our last presented method of analysis may be of value. However, we do caution against the reliance of one study (particularly when 'hand-picked') over a reliance in many studies, when this option is available.

Factors which affect presentation severity over time include: a natural resolution of symptoms; a commitment to the need for treatment (Wang et al 2005); increased confidence due to 'professional attention'; treatment expectancy effects; and an understanding of one's own presentation due to structured assessments. In the case of PTSD, it is quite clear that the combined effects of expectancy and having a thorough assessment conducted on the disorder have quite a considerable ameliorative outcome in most cases. It appears that, for many patients,

the process of talking about their experience of the traumatic event and feeling understood and supported, which occurs during the intake assessment, will result in some reduction in the severity of PTSD symptoms in the short term. These effects may arise as they have many shared features with the non-specific effects that are well recognised, but seldom articulated, as efficacious elements in the treatment of PTSD (McFarlane, 1994). A waitlist effect size of g = 0.34 is quite remarkable when one considers that PTSD is generally seen as chronic, with a median time to remission of 64 months without treatment, and the "consistent finding that PTSD failed to remit in somewhat more than one third of persons even after many years not only in the subsample of respondents who did not receive professional treatment but also in the … [non specific] … treatment subsample" (p. 1056, Kessler et al., 1995).

However, following symptom targeted interventions with an average treatment effect size of nearly g = 1.5 (more than four times the size of being on a waitlist) and the legal right many trauma victims have for immediate and effective intervention, the arguments for continued use of waitlists in PTSD trials appears tenuous. With a heightened suicide attempt rate and continued functional and vocational impairment (Davidson, et al., 1991; Kessler et al., 1995) the provision of a marginally helpful intervention (assessment and being placed on a waitlist) is eclipsed by the provision of stress and trauma focussed treatment – at least in the short term. Should it be agreed that this is indeed the case for any specific disorder, the current paper goes some way in providing a dialogue for researchers to use a statistical alternative to non-active, control groups.

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Table 1.

Summary of Study Waitlist Effect Sizes (Pre- to Post-treatment) in Ascending Order & Corresponding Treatment Effect Sizes (Pre- to Post-treatment), Using Equation 1.

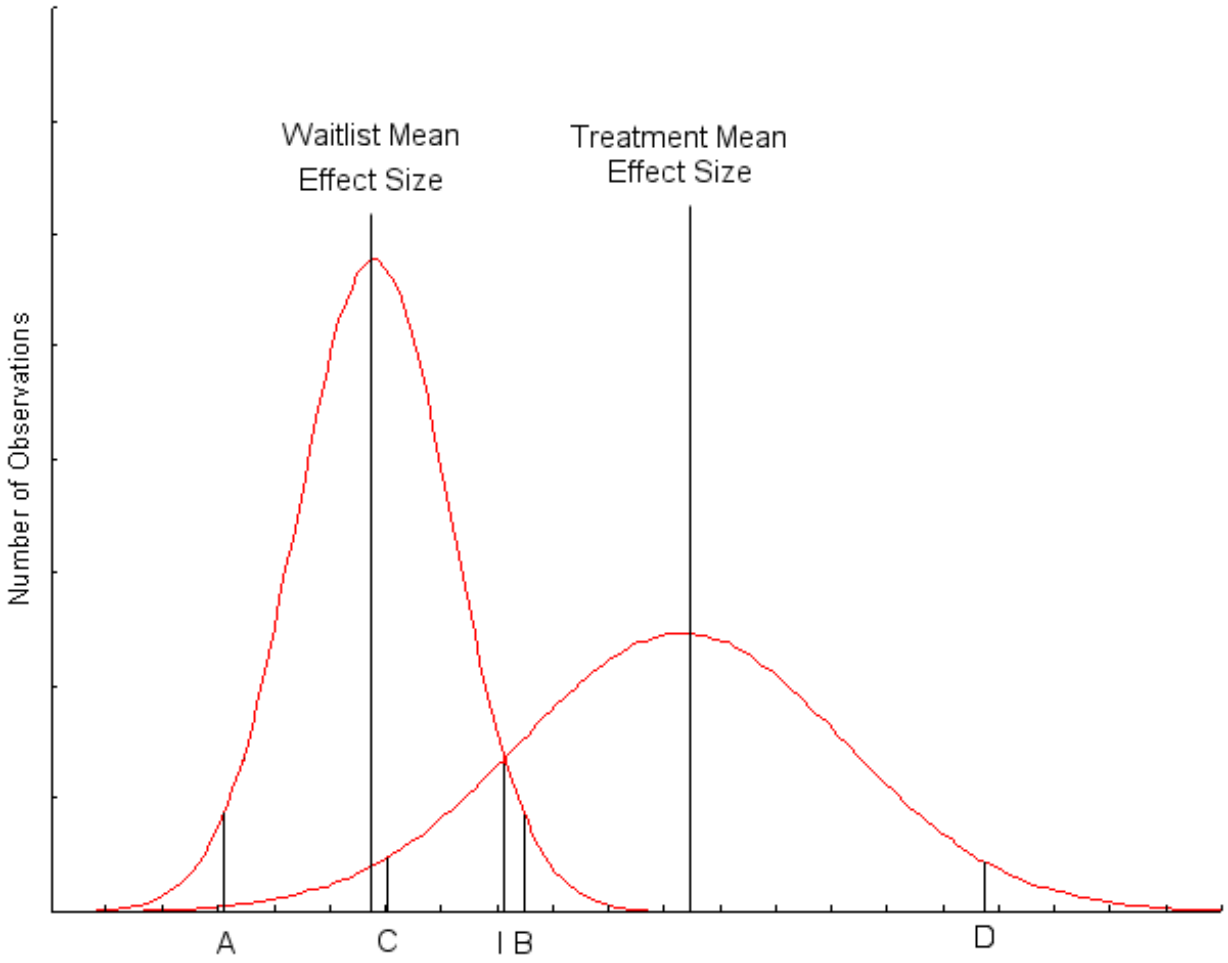
Study Name	Year of Study	Waitlist Period	Waitlist N	Waitlist Hedges' g	Treatment Group Therapy Comparator	Treatment N	Treatment Hedges' g
Zlotnick et al.	1997	16 weeks	17	-0.132	Group Therapy	-	-
Devilly et al.	1998	5 weeks	10	-0.0121	EMDR / REDDR	24 (12/12)	0.293
Resick & Schnick	1992	≥12 weeks	20	0.025	CPT	18	0.887
Resick et al.	2002	6 weeks	47	0.087	CPT / PE	124 (62/62)	1.312
Fecteau & Nicki	1999	4 weeks	10	0.141	CBT (Exposure)	10	1.417
Vaughan et al.	1994	2-3 weeks	17	0.229	IHT / EMDR	25 (12/13)	0.95
Resick et al.	1988	6 weeks	13	0.257	Group Therapy	-	-
Power et al.	2002	10 weeks	24	0.299	EMDR / Exposure + CR	48 (27/21)	2.03
Brom et al.	1989	16 weeks	23	0.308	Exposure	31	1.183
Ehlers et al.	2005	13 weeks	14	0.327	CT + Exposure	14	2.376
Krakow et al.	2001	12-24 weeks	55	0.353	IRT	50[c]	1.325
Rothbaum et al.	2005	4-5 weeks	20	0.364	EMDR / PE	40	1.898
Blanchard et al.	2003	8-12 weeks	24	0.442	CBT (Inc. Exposure)	27	1.789
Keane et al.	1989	16 weeks	31	0.467	Implosive Therapy	11	1.931
Rothbaum	1997	4 weeks	8	0.481	EMDR	10[c]	2.33
Lee et al.	2002	6 weeks	24	0.492	EMDR / PE	24 (12/12)	1.487

Cloitre et al.	2002	12 weeks	24	0.497	CBT (Inc. Exposure)	22	1.742
Foa et al.	1991	5 weeks	10	0.781	SIT / PE	24 (14/10)	1.874
Foa et al.	1999	5 weeks	15	0.788	PE / SIT / PE+SIT	64 (23/19/22)	1.931
Carlson et al.	1998	6 weeks	12	0.969	EMDR	10	1.004
Aggregate Effect Size Weighted By Study Sample Size			**20** **418**	**0.336 (0.23 to 0.44)[a]** **0.336 (0.31 to 0.36)[b]** **sd = 0.233**		**18** **576**	**1.499 (1.28 to 1.72)[a]** **1.499 (1.46 to 1.54)[b]** **sd = 0.47**
Aggregate Unweighted Effect Size			**20** **418**	**0.358 (0.24 to 0.48)[a]** **0.358 (0.33 to 0.39)[b]** **sd = 0.276**		**18** **576**	**1.466 (1.20 to 1.74)[a]** **1.466 (1.42 to 1.51)[b]** **sd = 0.583**

Note: [a] = 95% confidence intervals based on number of studies; [b] = 95% confidence intervals based on total number of participants; [c] = Weighted Average Of Those Completing Different Questionnaires And Rounded Up To Whole Person; CBT = Cognitive Behavior Therapy; CPT = Cognitive Processing Therapy; CR = Cognitive Restructuring; CT = Cognitive Therapy; EMDR = Eye Movement Desensitization & Reprocessing; IHT = Image Habituation Training; IRT = Imagery Rehearsal Therapy; PE = Prolonged Exposure; REDDR = Rapid Eye Dilation Desensitization & Reprocessing; SIT = Stress Inoculation Training.

Figure 1.

Summary Graph of Two Meta-Analyses, Where Points A, B, C, D And I Represent The Clinical Cut-Offs That Can Be Used To Judge The Relative Efficacy Of A New Treatment For Post Traumatic Stress Disorder When A Waitlist Control Has Not Been Used. Using the example in the text (weighted g): Waitlist Mean Effect Size = 0.336; Treatment Mean Effect Size = 1.499; A (1.96sd Below Waitlist Mean) = -0.121: B (1.96sd Above Waitlist Mean) = 0.793; C (1.96sd Below Treatment Mean) = 0.58; D (1.96sd Above Treatment Mean) = 2.42; I (Intersection: Compromise Point Between Waitlist And Treatment Conditions) = 0.722.


Waitlist Mean
Effect Size
Treatment Mean
Effect Size
Number of Observations
A
C
I B
D

SUPPLEMENTAL MATERIAL FOR JOURNAL WEBSITE

Supplemental Material - Table A

Studies included in a Meta-Analysis of No Treatment for PTSD: Study Summary, Pre- to Post-Waitlist Scores and Improvement Effect Sizes (Using Equation 1) Across Measures of PTSD.

Study	Treatment Conditions	Waitlist Period	Trauma	Exclusion Criteria	PTSD Measure	N	Pre-Waitlist		Post-Waitlist		Effect Size	
							Mean	SD	Mean	SD	Hedges *g*	95% CI
Blanchard et al (2003)	• CBT[k] (including in vivo & reading aloud) • Supportive psychotherapy • Waitlist	2-3 months	Motor Vehicle Accidents	• Comorbid diagnoses	CAPS[a]	24	65.8	26.6	54.0	25.9	**0.442**	-0.131 to 1.015
Brom et al (1989)	• Trauma desensitisation (in vivo & imaginal exposure) • Hypnotherapy • Psychodynamic therapy Waitlist	4 months	Mixed	• Trauma no more than 5 years prior	IES[b]	23	51.1	14.1	46.5	15.2	**0.308**	-0.273 to 0.890

Carlson et al (1998)	• EMDR[m] • Biofeedback-assisted relaxation • Routine clinical care (Waitlist)	6 weeks	Veterans	• Not stated	IES[b]	12	52.8	11.5	38.7	16.2	**0.969**	0.123 to 1.815
Cloitre et (2002)	• 2 phase CBT[k] (skills training followed by PE[n])	12 weeks	Childhood abuse	• Substance-dependence • Borderline PD • Recent hospitalisation • Thought disorder	PSS-SR[c] (modified) CAPS[a] Average ES	24	73 69	18.66 16.6	58 62	28.6 22.7	0.612 0.346 **0.497**	0.0327 to 1.191 -0.224 to 0.916
Devilly et al (1998)	• EMDR[m] • Equivalent procedure without eye movements • Psychiatric support control condition (Waitlist)	5 weeks	Veterans	• Medico-legal claim • Depression & suicidal ideation • Current psychosis • Previously received EMDR[m]	M-PTSD[f]	10	110.9	22.54	111.2	24.77	**-0.0121**	-0.864 to 0.889
Ehlers et al (2005)	• Cognitive Therapy (including in vivo and imaginal	13 weeks	Mixed trauma	• Unconscious >15 mins/no memory of trauma • History of psychosis	PDS[c] Original Distress Average ES	14	 31.2 34.4	 6.3 7.1	 29.8 30.5	 8.4 9.3	 0.183 0.458 0.349	 -0.559 to 0.925 -0.293 to 1.208

	• Waitlist			• Alcohol/drug dependence • Borderline PD Severe Depression	CAPS[a] Frequency Intensity Average ES Average ES CAPS[a] & PDS[c]		31.6 29.0	8.4 8.5	35.5 30.9	11.4 9.6	0.378 0.203 0.303 **0.327**	-0.369 to 1.126 -0.539 to 0.946
Fecteau & Nicki (1999)	• CBT[k] (including in vivo and imaginal exposure) • Waitlist	1 month	Motor vehicle accident	• Moderate to severe head injury • Alcohol/Substance abuse • Severe pre-injury mental health problems	CAPS[a] IES[b] Intrusion Avoidance Average ES Average ES CAPS[a] & IES[b]	10	77.3 24.8 26.5	22.7 8.0 10.5	74.6 24.4 24.4	24.7 8.4 6.3	0.109 0.047 0.232 0.167 **0.141**	-0.768 to 0.986 -0.830 to 0.923 -0.647 to 1.112
Foa et al (1991)	• SIT[o] • PE[n] (including	5 weeks	Female rape	• Organic mental disorder, psychosis	PSS-I[d]	10	24.43	4.64	19.50	7.18	**0.781**	-0.128 to 1.690

	• Supportive Counselling • Waitlist		victims	• Depression • Bipolar disorder • Alcohol/drug abuse In relationship with assailant								
Foa et al (1999a)	• PE[n] (including in vivo & imaginal) • SIT[o] Combined treatment (SIT[o]&PE[n]) Waitlist	5 weeks	Female assault victims	• Schizophrenia • Bipolar disorder • Organic mental disorder • Substance dependence • Suicidal ideation • relationship with assailant	PSS-I[d]	15	32.93	5.89	26.93	8.47	**0.788**	-0.122 to 1.698
Keane et al (1989)	• Implosive (flooding) therapy • WL	4 months	Vietnam veterans	• Not noted	MMPI-PTSD scale[g]	31	36.5	6.7	31.9	12.0	**0.467**	-0.037 to 0.972
Krakow et al (2001)	• Imagery rehearsal therapy (for nightmares) • Waitlist	3 month for PSS-SR, 6 months for	Adult sexual assault, childhood sexual	• Acute intoxication • Acute withdrawal • Psychosis	CAPS[a] PSS-SR[c] Average ES	52 58 55	79.26 28.48	24.37 11.73	68.37 25.26	27.26 11.78	0.418 0.272 **0.353**	0.030 to 0.807 -0.094 to 0.638

		CAPS	abuse		CAPS[a] & PSS-SR[c]							
Lee et al (2002)	• SIT[o]&PE[n] • EMDR[m] • Waitlist	6 weeks	Mixed trauma	• Alcohol/drug dependency • Psychosis • Cluster B Personality Disorder	IES[b]	24	55.33	8.49	50.50	10.70	**0.492**	-0.082 to 1.066
Power et al (2002)	• EMDR[m] • Exposure + CR[l] • Waitlist	10 weeks	Mixed trauma	• Depressive illness • Psychosis • Alcohol/drug abuse • Suicidal ideation • Clinically significant Physical illness	IES[b] SI-PTSD[e] Average ES IES[b] & SI-PTSD[e]	24	32.6 47.9	6.6 10.0	29.6 45.5	8.6 16.1	0.385 0.176 **0.299**	-0.186 to 0.956 -0.391 to 0.743
Resick et al (1988)	Group Therapy: • SIT[o] • Assertion training • Supportive psychotherapy • Waitlist	6 weeks	Rape victims	• Not listed	IES[b] Avoidance Intrusion Average ES IES[b]	13	 15.43 14.27	 8.90 5.00	 19.09 13.34	 11.76 8.55	 0.340 0.129 **0.257**	 -0.434 to 1.114 -0.641 to 0.898
Resick & Schnick	• Cognitive processing	At least 12 weeks	Sexual assault	• Incest victims • Severe competing	SCL-90-R PTSD[h]	20	1.37	0.80	1.35	0.78	**0.025**	-0.595 to 0.645

(1992)	therapy • Waitlist		victims	pathology								
Resick et al (2002)	• Cognitive Processing Therapy • Exposure • Waitlist	6 weeks	Adult sexual assault, childhood sexual abuse	• Psychosis • Developmental disabilities • Suicidal intent • Para-suicidal behavior • Drug/alcohol dependence • Illiteracy	CAPS[a] PSS-SR[c] Average ES CAPS[a] & PSS-SR[c]	47	69.85 28.70	19.57 7.33	69.26 27.77	18.55 8.12	0.031 0.119 **0.087**	-0.374 to 0.435 -0.285 to 0.524
Rothbaum (1997)	• EMDR[m] • Waitlist	4 weeks	Adult sexual assault	• Alcohol/drug dependence	PSS-I[c] IES[b] Average ES PSS-I[c] & IES[b]	8	39.0 48.9	8.2 8.9	35.0 45.4	5.9 6.4	0.529 0.427 **0.481**	-0.468 to 1.526 -0.564 to 1.418
Rothbaum et al (2005)	• EMDR[m] • PE[n] • Waitlist	4-5 weeks	Female adult rape victims	• Psychosis • Suicide risk • Substance abuse • Eye disorders	CAPS[a] PSS-SR[c] IES-R[j] Average ES CAPS[a],	20	75.75 26.75 41.20	18.08 7.89 15.36	64.55 25.70 36.95	19.87 10.47 20.89	0.578 0.111 0.227 **0.364**	-0.055 to 1.211 -0.51 to 0.731 -0.395 to 0.849

					PSS-SR[c] & IES-R[j]							
Vaughan et al (1994)	• Imaginal exposure (image habituation training – IHT) • Applied muscle relaxation (AMR) • EMDR[m] • Waitlist	2-3 weeks	Mixed trauma	• Personality disorder Schizophrenia	SI-PTSD[e]	17	30.44	7.7	28.5	8.9	**0.229**	-0.393 to 0.85
Zlotnick et al (1997)	• Affect-management treatment (AM) • Waitlist	16 weeks	Childhood sexual abuse	• Psychosis • Substance abuse • Dissociative identity disorder	CR-PTSD[h] DTS[i] Average ES CR-PTSD[h] & DTS[i]	17	46.88 74.69	21.16 25.83	51.43 73.06	24.19 29.86	-0.196 0.058 **-0.132**	-0.869 to 0.478 -0.822 to 0.939
Aggregate Effect Size Weighted by study sample size						20 418					**0.336** sd = 0.233	0.23 to 0.44 0.31 to 0.36
Aggregate Unweighted Effect Size						20 418					**0.358** sd = 0.276	0.24 to 0.48 0.33 to 0.39

Note: Bold used for study effect size in meta-analysis; Measure Acronyms: [a]CAPS (Clinician-Administered PTSD scale, Blake et al., 1995); [b]IES (Impact of Event Scale, Horowitz et al., 1979); [c]PSS/PDS (Posttraumatic stress scale/Posttraumatic diagnosis scale; I = Interview, SR = Self Response; Foa, 1995); [d]PTSD severity based on structured interview of symptoms; [e]SI-PTSD (structured interview for PTSD, based on DSM-III-R critieria, Davidson, Smith, & Kudler, 1989); [f]M-PTSD (The Mississippi Scale for combat

related PTSD Keane, Caddell, & Taylor, 1988); [g]MMPI-PTSD scale (PTSD scale of the Minnesota; Multiphasic Personality Inventory, Keane, Malloy, & Fairbank, 1984); [h]SCL-90-R PTSD scale/CR-PTSD (Symptom Checklist 90 - Revised, PTSD subscale, Saunders, Arata, & Kilpatrick, 1990); [i]DTS (Davidson Trauma Scale, Davidson et al., 1997); [J] Impact of Events Scale- Revised (Weiss & Marmar, 1997); Treatment Acronyms: [k]CBT = Cognitive Behaviour Therapy; [l]CR = Cognitive Restructuring; [m]EMDR = Eye Movement Desensitization & Reprocessing; [n]PE = Prolonged Exposure; [o]SIT = Stress Inoculation Training.

Supplemental Material Table B

Studies included in a Meta-Analysis of Individual Trauma-Focussed Treatment for PTSD: Pre- to Post-Treatment Scores and Effect Sizes (Using Equation 1) Across Measures of PTSD.

Study	Treatment Conditions	Treatment Period	Trauma	Exclusion Criteria	Therapy & PTSD Measure	N	Pre-Treat		Post-Treat		Effect Size	
							Mean	SD	Mean	SD	Hedges *g*	95% CI
Blanchard et al (2003)	• CBT[k] (including in vivo & reading aloud) • Supportive psychotherapy • Waitlist	2-3 months	Motor Vehicle Accidents	• Comorbid diagnoses	*CBT*[k] CAPS[a]	27	68.2	22.7	23.7	26.2	**1.789**	1.16 to 2.42
Brom et al (1989)	• Trauma desensitisation (in vivo & imaginal exposure) • Hypnotherapy	4 months	Mixed	• Trauma no more than 5 years prior	*Trauma desensitization* IES[b]	31	47.4	12	28	19.5	**1.183**	0.644 to 1.723

	• Psychodynamic therapy Waitlist											
Carlson et al (1998)	• EMDR[m] • Biofeedback-assisted relaxation (BART) • Routine clinical care (Waitlist)	6 weeks	Veterans	• Not stated	*EMDR[m]* IES[b]	10	52.9	9	35.2	22	**1.004**	.07 to 1.93
Cloitre et al (2002)	• 2 phase CBT[k] (skills training followed by PE[n])	12 weeks	Childhood abuse	• Substance-dependence • Borderline PD • Recent hospitalisation • Thought disorder	*CBT[k]* PSS-SR[c] (modified) CAPS[a] Average ES	22 22	69.0 69.0	16.6 16.3	29.0 31.0	27.6 25.2	1.725 1.758 **1.742**	1.03 to 2.42 1.06 to 2.45
Devilly et al (1998)	• EMDR[m] • Equivalent procedure without eye movements	5 weeks	Veterans	• Medico-legal claim • Depression & suicidal ideation • Current	*EMDR[m]* M-PTSD[f] *REDDR[p]*	12	120.42	26.48	110.42	27.72	0.356	-0.45 to 1.163

	• Normal psychiatric support control condition (Waitlist)			• Previously received EMDR[m]	M-PTSD[f] Average ES	12 24	123.17	18.93	118.58	22.64	0.212 **0.293**	-0.59 to 1.015
Ehlers et al (2005)	• Cognitive Therapy (including in vivo and imaginal exposure) • Waitlist	13 weeks	Mixed trauma	• Unconscious >15 mins/no memory of trauma • History of psychosis • Alcohol/drug dependence • Borderline PD Severe Depression	*CT* PDS[c] Original Distress Average PDS[c] ES CAPS[a] Frequency Intensity Average CAPS[a] ES Average ES	14	 32.4 33.8 42.0 36.5 	 6.5 7.1 8.5 9.4 	 10.3 9.7 16.0 13.7 	 8.9 10.1 15.3 13.4 	 2.753 2.68 2.717 2.04 1.913 1.978 **2.376**	 1.72 to 3.79 1.66 to 3.70 1.13 to 2.95 1.018 to 2.807
Fecteau &	• CBT[k]	One month	Motor	• Moderate to	*CBT[k]*	10						

Nicki (1999)	• Waitlist		vehicle accident	• Alcohol/Substance abuse • Severe pre-injury mental health problems	CAPS[a] IES[b] Intrusion Avoidance Average IES Average ES	 10	70.9 20.4 24.7	16.2 8.7 8.2	37.5 8.3 7.2	30.4 8.9 11.4	1.313 1.317 1.688 1.514 **1.417**	0.35 to 2.28 0.35 to 2.28 0.67 to 2.71
Foa et al (1991)	• SIT[o] • PE[n] (including in vivo & imaginal) • Supportive Counselling • Waitlist	5 weeks	Female rape victims	• Organic mental disorder, psychosis • Depression • Bipolar disorder • Alcohol/drug abuse • In relationship with assailant	SIT[o] PSS-I[d] PE[n] PSS-I[d] Average ES	14 10 24	24.48 25.78	6.62 5.01	11.07 15.40	3.97 11.09	2.385 1.155 **1.874**	1.42 to 3.35 0.21 to 2.1
Foa et al (1999a)	• PE[n] (including in vivo & imaginal) • SIT[o] • PE[n]+SIT[o] Combined	5 weeks	Female assault victims	• Schizophrenia • Bipolar disorder • Organic mental disorder • Substance dependence • Suicidal ideation	PE[n] PSS-I[d] SIT[o] PSS-I[d] PE[n]+ SIT[o]	23 19 22	29.48 29.42	9.94 8.69	11.70 12.89	7.32 8.96	2.002 1.834	1.29 to 2.71 1.08 to 2.59

	• Waitlist			• relationship with assailant	PSS-I[d] Average ES	 64	29.95	6.97	13.55	9.35	1.953 **1.931**	1.23 to 2.67
Keane et al (1989)	• Implosive (flooding) therapy (IT) • WL	4 months	Vietnam veterans	• Not noted	*IT* MMPI-PTSD scale[g]	11	36.4	10.6	28.8	15.0	**0.563**	-0.29 to 1.42
Krakow et al (2001)	• Imagery rehearsal therapy (for nightmares; IRT) • Waitlist	3 month for PSS-SR, 6 months for CAPS	Adult sexual assault, childhood sexual abuse	• Acute intoxication • Acute withdrawal • Psychosis	*IRT* CAPS[a] PSS-SR[c] Average ES	 45 54 99	 81.88 28.29	 16.96 10.37	 49.58 17.19	 23.96 10.39	 1.543 1.062 **1.325**	 1.07 to 2.01 0.66 to 1.47
Lee et al (2002)	• PE[n]+SIT[o] • EMDR[m] • Waitlist	6 weeks	Mixed trauma	• Alcohol/drug dependency • Psychosis • Cluster B Personality Disorder	EMDR[m] or PE[n]+SIT[o] IES[b]	24	50.50	10.70	26.71	19.51	**1.487**	0.85 to 2.13
Power et al (2002)	• EMDR[m] • Exposure plus CR[l]	10 weeks	Mixed trauma	• Depressive illness • Psychosis	*EMDR[m]* IES[b] SI-PTSD[e]	27	 35.1 50.6	 4.4 8.4	 11.8 16.8	 12 17.2	 2.541 2.461	 1.824 to 3.258 1.754 to 3.168

	• Waitlist			• Alcohol/drug abuse • Suicidal ideation • Clinically significant Physical illness	EMDR[m] ES *E+CR* IES[b] SI-PTSD[e] E+CR ES Average ES	 21 48	 32.7 46.6 	 5 9.9 	 19.2 25.9 	 12.3 17.9 	2.501 1.411 1.404 1.408 **2.03**	 0.735 to 2.087 0.729 to 2.079
Resick & Schnick (1992)	• Cognitive processing therapy • Waitlist	At least 12 weeks	Sexual assault victims	• Incest victims • Severe competing pathology	*CPT*[q] SCL-90-R[h] PTSD[h]	18	1.56	0.84	0.93	0.51	**0.887**	0.2 to 1.57
Resick et al (2002)	• Cognitive Processing Therapy • Exposure • Waitlist	6 weeks	Adult sexual assault, childhood sexual abuse	• Psychosis • Developmental disabilities • Suicidal intent • Para-suicidal behavior • Drug/alcohol dependence • Illiteracy	*CPT*[q] CAPS[a] PSS-SR[c] CPT[q] ES PE[n] CAPS[a] PSS-SR[c] PE[n] ES	62 62	 74.76 29.55 76.60 30.09	 18.77 8.62 19.72 9.18	 39.08 13.66 44.89 17.99	 31.12 11.05 33.52 13.17	 1.38 1.594 1.491 1.146 1.06 1.104	 0.99 to 1.78 1.19 to 2.00 0.77 to 1.53 0.68 to 1.44

					Average ES	124					**1.312**	
Rothbaum (1997)	• EMDR[m] • Waitlist	4 weeks	Adult sexual assault	• Alcohol/drug dependence	*EMDR[m]* PSS-I[c] IES[b] Average ES	 9 10 10	 33.3 47.4 	 8.7 15 	 14.3 12.4 	 8.4 11.2 	 2.116 2.532 **2.333**	 0.962 to 3.27 1.356 to 3.709
Rothbaum et al (2005)	• EMDR[m] • PE[n] • Waitlist	4-5 weeks	Female adult rape victims	• Psychosis • Suicide risk • Substance abuse • Eye disorders	*EMDR[m]* CAPS[a] PSS-SR[c] IES-R[J] EMDR[m] ES PE[n] CAPS[a] PSS-SR[c] IES-R[J] PE[n] ES Average ES	20 20 40	 80.1 29.25 49.10 62.15 25.35 41.45 	 20.24 11.05 21.82 17.71 9.04 19.62 	 31.65 10.75 15.5 21.25 6.9 8.7 	 25.27 10.61 17.12 22.5 9.40 11.87 	 2.074 1.674 1.679 1.819 1.98 1.961 1.98 1.974 **1.898**	 1.306 to 2.843 0.954 to 2.394 0.959 to 2.4 1.223 to 2.737 1.207 to 2.715 1.223 to 2.736
Vaughan et al (1994)	• Imaginal exposure (image	2-3 weeks	Mixed trauma	• Personality disorder Schizophrenia	*IHT* SI-PTSD[e]	13 	 28.5	 8.9	 20.5	 11.3	 0.762	 -0.034 to 1.558

	habituation training – IHT) • Applied muscle relaxation (AMR) • EMDR[m] • Waitlist				*EMDR*[m] SI-PTSD[e] Average ES	12 25	27.9	9.5	16.8	6.2	1.336 **0.95**	0.451 to 2.221
Aggregate Effect Size Weighted by study sample size						18 576					**1.499** (sd = 0.47)	1.28 to 1.72 1.46 to 1.54
Aggregate Unweighted Effect Size						18 576					**1.466** (sd = 0.583)	1.20 to 1.74 1.42 to 1.51

Note: Measure Acronyms: [a]CAPS (Clinician-Administered PTSD scale, Blake et al., 1995); [b]IES (Impact of Event Scale, Horowitz et al., 1979); [c]PSS/PDS (Posttraumatic stress scale/Posttraumatic diagnosis scale; I = Interview, SR = Self Response; Foa, 1995); [d]PTSD severity based on structured interview of symptoms; [e]SI-PTSD (structured interview for PTSD, based on DSM-III-R critieria, Davidson, Smith, & Kudler, 1989); [f]M-PTSD (The Mississippi Scale for combat related PTSD Keane, Caddell, & Taylor, 1988); [g]MMPI-PTSD scale (PTSD scale of the Minnesota; Multiphasic Personality Inventory, Keane, Malloy, & Fairbank, 1984); [h]SCL-90-R PTSD scale/CR-PTSD (Symptom Checklist 90 - Revised, PTSD subscale, Saunders, Arata, & Kilpatrick, 1990); [i]DTS (Davidson Trauma Scale, Davidson et al., 1997); [J] Impact of Events Scale- Revised (Weiss & Marmar, 1997); Treatment Acronyms: [k]CBT = Cognitive Behaviour Therapy; [l]CR = Cognitive Restructuring; [m]EMDR = Eye Movement Desensitization & Reprocessing; [n]PE = Prolonged Exposure; [o]SIT = Stress Inoculation Training; [p]REDDR = Rapid Eye Dilation Desensitization & Reprocessing; [q]CPT = Cognitive Processing Therapy.