| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Akuchekian et al., 2004[77](#_ENREF_77) | G1: Topiramate  25 to 500 mg/day (sensitive patients started at 12.5mg/day)  G2: Placebo | NR | G1: 2 G2: 3 | NR | NR | NR | NR | NR | NR | NR |
| Bartzokis et al., 2005[86](#_ENREF_86) | G1: Risperidone  1 to 3 mg/day  G2: Placebo | NR | G1: 3 G2: 2 | NR | NR | NR | NR | NR | NS between groups | NS differences on Barnes Akathisia Scale, Columbia Scale, or Abnormal Involuntary Movement Scale |

**Table F-5. Adverse events/harms reported by included randomized controlled trials**

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Batki et al., 2014[165](#_ENREF_165) | G1: Topiramate  25 to 300mg  G2: Placebo | G1: 12 (85.7%)  G2: 13 (81.3%)  NS | NR | G1: 0  G2: 1 due to myocardial infarction (judged to be unrelated to study)  NS | Suicidal ideation  G1: 0  G2: 1 (hospitalized for suicidal ideation)  NS | NR | NR | Sleepiness  G1: 36%  G2: 13%  NS | NR | Loss appetite  G1: 29%  G2: 38%  Change in sense of taste  G1: 21%  G2: 31%  Itching  G1: 21%  G2: 6%  Diarrhea  G1: 29%  G2: 19%  Abnormal vision  G1: 21%  G2: 19%  Serious AEs  G1: 0  G2: 6  NS  5 of 6 SAES possibly related to study.  NS |

| Author Year | | Intervention Groups | Overall AE | | Withdrawal Due to AE | | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Becker et al., 2007[183](#_ENREF_183) | | G1: Bupropion  100 to 300 mg/day  G2: Placebo | NR | | G1: 1  G2: NR | | NR | NR | NR | NR | NR | NR | G1 & G2a: Heart pounding, concentration problems, problem achieving orgasm, & erecticle dysfunction  G1:ability to achieve orgasm (positive & negative direction) & 1 reported rash  G2: 30% reported increased appetite | |
| Boden et al., 2012[58](#_ENREF_58) | | G1: Seeking Safety and TAU  G2: TAU | NR | | NR | | NR | NR | NR | NR | NR | NR | no treatment-related adverse events occurred during the trial | |
| Bohus et al., 2013[23](#_ENREF_23) | G1: DBT-PTSD  G2: TAU-WL | | NR | NR | | NR | | Suicide Attempts  G1: 0 (0)  G2: 0 (0) | NR | NR | NR | NR | Worsening PTSD Symptoms  G1: 0 (0)  G2: 6 (15.8)) |
| Brady et al., 2000[66](#_ENREF_66) | G1: Sertraline  25 to 200 mg/day  G2: Placebo | | NR | G1: 5 G2: 5 | | NR | | NR | Insomniaa G1: 16.0% G2: 4.3%  p=0.01 | NR | NR | Change, Mean kg G1: -1.3 G2: -0.3 p=0.01 | Headachea G1: 20.2% G2: 28.3% Diarrheaa G1: 23.4% G2: 19.6% Malaisea G1: 17.0% G2: 15.2% Nauseaa G1: 16.0% G2: 12.0% Drowsinessa G1: 12.8% G2: 9.8% Dry Moutha G1: 11.7%  G2: 4.3% |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Brady et al., 2005[67](#_ENREF_67) | G1: Sertraline  150 mg/day  G2: Placebo | NR | G1: 0 G2: 0 | NR | NR | NR | NR | NR | NR | NR |
| Butterfield et al., 2001[82](#_ENREF_82) | G1: Olanzapine  5 to 20mg/day  G2: Placebo | G1: 45 G2: 3 | NR | NR | NR | NR | NR | NR | G1: 6  G2: 0 | Dry mouth G1: 3 G2: 0 Drowsiness G1: 3 G2: 1 Constipation G1: 3 G2: 1 Increased appetite  G1: 3 G2: 0 Diarrhea G1: 2 G2: 0 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Butterfield et al., 2001[82](#_ENREF_82) (cont’d) |  |  |  |  |  |  |  |  |  | Tingling G1: 2 G2: 0 Unsteadiness G1: 2 G2: 0 Forgetfulness  G1: 3 G2: 0 Frequent urination G1: 4 G2: 1 UncomforTable D-urge to move G1: 4 G2: 0 Thirst G1: 6 G2: 0  Swelling G1: 4 G2: 0 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Carey et al., 2012[81](#_ENREF_81) | G1: Olanzapine  5 to 10mg  G2: Placebo | NR | G1: 1 (due to severe sedation)  G2: 0 | NR | NR | Insomnia  G1: 3 (20%)  G2: 2 (13%)  p=0.564 |  | Overall  G1: 11  G2: 5  P, NR  Mild  G1: 5 (73%)  G2: 4 (33%)  p=0.014  Moderate  G1: 5  G2: 1  P, NR  Severe  G1: 1  G2: 0  P, NR | Weight gain at 8 weeks  G1: 14 (100%)  G2: 5 (33%)  p= 0.001  Mean  G1: 5.6 (2.6) kg  G2: -0.3 (3.9) kg  p=0.000 | Serious AEs  G1: 0  G2: 0  Increased Anxiety  G1: 1 (7%)  G2: 2 (13%)  p=0.584 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | | Mortality | | Suicidality | Disturbed Sleep | | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Chard et al., 2005[2](#_ENREF_2) | G1: CBT, cognitive processing therapy  CPT-SA  G2: WL | NR | NR | | NR | | NR | NR | | NR | NR | NR | No participants reported that their symptoms had  become worse from pre- to posttreatment |
| Church et al., 2013[155](#_ENREF_155) | G1: EFT, Emotional Freedom Techniques (brief exposure therapy combining cognitive and somatic elements, on PTSD and psychological distress symptoms in veterans) G2: WL | G1: 0  G2: 0 | NR | | NR | | NR | NR | | NR | NR | NR | No adverse events or increase in subject distress was reported. |
| Cloitre et al., 2010[148](#_ENREF_148) | G1: CBT, exposure-based therapy(STAIR)  G2: WL | NR | NR | | NR | | NR | NR | | NR | NR | NR | CAPS, Symptom worsening  posttreatment:  G1: 1 (3.6)  G2: 3 (7.4)  G3: 5 (15) p=NS  posttreatment to 6-mth fu  G1: 0 (0)  G2: 5 (22.7)  G3: 5 (31.3)  G1 vs. G2, p=0.02  G1 vs. G3, p=0.006 |
| Cottraux, 2008[31](#_ENREF_31) | G1: CBT-mixed  (Exposure in imagination or in vivo and cognitive therapy)  G2: Supportive Control | NR | | G1: 0 G2: 5 | | NR | NR | | NR | NR | NR | NR | Worsening of symptoms G1:0  G2: 5 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Davidson et al., 2001[68](#_ENREF_68) | G1: Sertraline  50 to 200 mg/day  G2: Placebo | NR | G1: 9 G2: 5 | NR | NR | Insomnia G1: 35% G2: 22% p=0.04  Vivid Dreams G1: 10% G2: 4%  p=0.10 | NR | NR | NR | Headache G1: 33% G2: 24%, p=0.17  Diarrhea G1: 28% G2: 11%, p=0.003 Nausea G1: 23% G2: 11%, p=0.03 Drowsiness G1: 17% G2: 11%, p=0.24 Nervousness G1: 14% G2: 8%, p=0.27 Fatigue G1: 13% G2: 5%, p=0.05 Decreased Appetite G1: 12% G2: 1%, p=0.001 Dry Mouth G1: 10% G2: 7%, p=0.45 |
| Davidson et al., 2003[184](#_ENREF_184) | G1: Mirtazapine  15 to 45 mg/day  G2: Placebo | G1: 3 G2: 3 | G1: 3 G2: 3 | NR | NR | NR | NR | NR | G1: 3  G2: 1 | Palpitations G1: 0 G2: 3 (33.3%) Increased appetite: G1: 6 (35.3%) G2: 1 (11.1%) |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Davidson et al., 2006[69](#_ENREF_69) | G1: Venlafaxine  75 to 300mg/day  G2: Sertraline  50 to 200mg/day  G3: Placebo | NR | G1: 17, 9.5% G2: 22, 12.7% G3: 19, 10.6% | None related to study med | NR | Insomniaa G1: 24, 13% G2: 18, 10% G3: 16, 9% | NR | Fatiguea G1: 19, 11% G2: 24, 14% G3: 17, 9%  Somnolencea G1: 21, 12%  G2: 18, 10% G3: 24, 13% | Kga  G1 -.5  G2: -.3  G3: +.9  G1 vs G3: p=0.00064 G2 vs G3: p=0.0242 | Headachea G1: 53, 29% G2: 57, 32% G3: 55, 29%  Nauseaa G1 45, 24% G2: 39, 23% G3: 27, 14%  Diarrheaa G1: 22, 12%  G2: 47, 26% G3: 25, 13%  Dry Moutha G1: 34, 18% G2: 26, 15% G3: 27, 15%  Dizzinessa G1: 24, 13% G2: 21, 10% G3: 14, 8%  Constipationa G1: 21, 12% G2: 12, 7% G3: 18, 10%  Appetite Decreasea G1: 21, 12% G2: 13, 8% G3: 11, 6% | |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Davidson et al., 2006[73](#_ENREF_73) | G1: Venlafaxine  37.5 to 300 mg/day  G2: Placebo | NR | G1: 15 G2: 9 | NR | NR | G1: 12 G2: 17 | NR | Somnolence G1: 9 G2: 9 | Weight Change of 7% or greater G1: 20 G2: 12 | Reported by at Least 5% of patients Headache G1: 46 G2: 44  Nausea G1: 35 G2: 19  Dizziness G1: 29 G2: 19  Dry Mouth G1: 21 G2: 8  Constipation G1: 20 G2: 5  Fatigue G1: 13 G2: 6  Insomnia G1: 12 G2: 17  Decreased libido G1: 8 G2: 6  Nasopharyngitis G1: 8 G2: 11  Increased Sweating G1: 21 G2: 6 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Davidson et al., 2007[166](#_ENREF_166) | G1: Tiagabine  4 to16mg/day  G2: Placebo | G1: NR G2: NR | G1: 8% G2: 8% | NR | NR | NR | NR | Somno-lence G1: 20% G2: 10% | NR | Vomiting G1: 11 G2: 4  Tremor G1: 10 G2: 6  Dizziness G1: 32% G2: 13%  Headache G1: 25% G2: 27%  Nausea G1: 18% G2: 20%  Serious Adverse Event  G1:1  G2:0  One individual experienced dizziness, loss of consciousness, and nausea |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Davis et al., 2008[164](#_ENREF_164) | G1: Divalproex  1000 to 3000 mg/day  G2: Placebo | NR (reported AEs greater than 6% in each group) | G1: 3 G2: 1 | NR | NR | NR | NR | G1: 12 G2: <6 | NR | SAE unrelated to study G1: 1 G2: 0  Lack of Efficacy: G1:0 G2:1  Dizziness: G1: 24 G2: <6  Nausea: G1: 14 G2: <6  GI tract upset: G1: 12 G2: <6  Diarrhea: G1: 12 G2: <6  Increased urinary frequency: G1: 10 G2: <6  Headache: G1: 10 G2: <6  Memory Deficit: G1: 10 G2: <6  Abnormal vision: G1: 7 G2: <6 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Davis et al., 2008[164](#_ENREF_164) (cont’d) |  |  |  |  |  |  |  |  |  | Muscle weakness/myalgia: G1: <6 G2: 7 |
| Ehlers et al., 2014[9](#_ENREF_9) | G1: Intensive CT (standard CT over a much shorter period)  G2: Standard CT  G3: Supportive Therapy  G4: WL | G1:0 (0%)  G2:0 (0%)  G3:0 (0%)  G4:0 (0%) | NR | NR | NR | NR | NR | NR | NR | No AEs’ were reported in any group (i.e., negative reactions to treatment procedures).  Symptom Deterioration(CAPS), n(%)  G1:0 (0)  G2:1(3.2)  G3: 3 (10.0)  G4: 6 (20.0)  G1 and G2 did not significantly differ from G3 |
| Foa et al., 2005[12](#_ENREF_12) | G1: CBT, exposure-based therapy(PE)  G2: CBT-mixed  (PE plus CR)  G3: WL | NR | Overall: 12 | Overall: 1 | Overall: 4 | NR | NR | NR | NR | NR |
| Forbes et al., 2012[4](#_ENREF_4) | G1: CBT, CPT  G2: TAU | NA | NA | NA | NA | NA | NA | NA | NA | no treatment-related adverse events occurred during the trial |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ford et al., 2011[59](#_ENREF_59) | G1: Trauma Affect Regulation: Guide for Education and Therapy (TARGET)  G2: PCT  G3: WL | NA | NA | NA | NA | NA | NA | NA | NA | no treatment-related adverse events occurred during the trial  Worsening of symptoms:  3 of G1 and 1 of G2 showed evidence of symptom worsening at post-tx; by 6 months all improved from baseline.  From post-tx to 3 month FU:  4 G1 and 3 G1 reported worsened PTSD symptoms; all but two improved at 6-months.  From post-tx to 6 month FU 0 G2 and 3 G1 reported worsened PTSD symptoms. |
| Ford et al., 2013[60](#_ENREF_60) | G1: Trauma Affect Regulation:  Guide for Education and  Therapy (TARGET),  G2: SGT | NR | NR | NR | NR | NR | NR | NR | NR | No instances of serious adverse events involving clinically significant deterioration that required crisis care or intensive treatment.  Symptom Worsen (CAPS >7 points higher than at baseline)  G1: 4 (11%)  G2: 6 (18%)  Between group differences NS |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Friedman et al., 2007[70](#_ENREF_70) | G1: Sertraline  25 to 200 mg/day  G2: Placebo | G1: NR G2: NR | G1: 11 G2: 5 | NR | NR | Insomniaa G1: 12 G2: 8 | NR | Fatiguea  G1: 9 G2: 1  Somnolencea  G1: 12 G2: 7 | NR | Diarrheaa  G1: 27  G2: 15  Headachea  G1: 23  G2: 20  Nauseaa  G1: 18  G2: 8 |
| Galovski et al., 2012[6](#_ENREF_6) | G1: Modified CBT. (potential addition of stressor sessions and variable treatment length)  G2: Delayed treatment symptom monitoring | G1: 0 (0%)  G1: 0 (0%) | NR | NR | NR | NR | NR | NR | NR | Reported no adverse events |
| Hamner et al., 2003[83](#_ENREF_83) | G1: Risperidone  1 to 6 mg/day  G2: Placebo | NR | G1: 0 G2: 0 | NR | NR | NR | NR | NR | NR | Akathisia, n  G1: 1  G2: 0  Nausea and vomiting, n  G1: 1  G2: 0 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Harned et al., 2014[144](#_ENREF_144) | G1: DBT plus DBT PE  G2: DBT | NR | NR | NR | Committed  G1: 0 (0)  G2: 1 (11.1)  Rate of any Suicide Attempt (ITT)  G1: 37.5%  G2: 50.0%  Abstinent from Suicidal Behavior during followup  G1: 91.7%  G2: 100% | NR | NR | NR | NR | Any NSSI (ITT)  G1: 68.8%  G2: 87.5%  Abstinent from NSSI during followup  G1: 75%  G2: 66.7% |
| Hien et al., 2004[57](#_ENREF_57) | G1: Seeking Safety  G2: Relapse prevention condition  (only substance abuse)  G3: Usual care  (Non-randomized Standard community Care) | NR | NR | NR | NR | NR | NR | NR | NR | Psychiatric Hospitalization  G1: 5%  G2: 5%  G3: 6% |
| Hien et al., 2009[157](#_ENREF_157)  Hien et al., 2012[158](#_ENREF_158) | G1: Seeking Safety  G2: Psychoeducation | NR | NR | NR | NR | NR | NR | NR | NR | no increase in either  treatment-as-usual dropout or adverse events |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hogberg et al., 2007[48](#_ENREF_48) | G1; EMDR  G2: WL | NR | G1: 1b G2: 0 | NR | NR | NR | NR | NR | NR | NR |
| Hollifield et al., 2007[32](#_ENREF_32) | G1: Acupuncture  G2: CBT-mixed  (Cognitive restructuring, behavior activation, and coping skills)  G3: WL | NR | G1: 1 G2: 0 G3: NR | NR | NR | NR | NR | NR | NR | Perceived kidney pain  G1: 1 G2: 0 G3:0 |
| Ivarsson et al., 2014[24](#_ENREF_24) | G1: Internet based CBT  G2: Delayed treatment attention control | NR | NR | NR | NR | NR | NR | NR | NR | Symptom Deterioration (IES-R)  G1:1 (3.2)  G2:0 (0%)  Symptom Deterioration (CGI-I)  G1: 2 (6.1)  G2: 8 (25.8) |
| Johnson et al., 2011[29](#_ENREF_29) | G1: CBT-mixed  (Psychoeducation and CBT restructuring)  G2: Usual care | NR | G1: 0  G2: 0 | NR | NR | NR | NR | NR | NR | 7 hospitalizations (5  medical, 2 substance related) and 4 life-threatening traumatic experiences (2 abuse-related) reported over the course of the 6-month followup period. |
| Kearney et al., 2013[159](#_ENREF_159) | G1: MBSR+TAU G2: TAU (VHA health system) | G1: 0 (0%)  G2: 0 (0%) | NR | NR | NR | NR | NR | NR | NR | NR |
| Krakow et al., 2001[52](#_ENREF_52) | G1: IRT  G2: WL | NR | G1: 4  G2: NR | NR | NR | NR | NR | NR | NR | 4 patients reported increased negative imagery and eventually withdrew, and 12 of 66 who completed treatment did not complete  followup for unknown reasons. |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Langkaas et al., 2017[142](#_ENREF_142) | G1: PE  G2: IRT | NR | NR | NR | NR | NR | NR | NR | NR | Deteriorated  G1 Post-tx: 0%  G2 Post-tx: 3%  G1 12 mth FU:3%  G2 12 mth FU: 9% |
| Li et al., 2017[172](#_ENREF_172) | G1; Sertraline 135 mg  G2: Placebo | NR | G1: 2  G2: 1 | NR | NR | Insomnia  G1: 10  G2: 7 | NR | Drowsiness  G1: 9  G2: 5 | NR | Nauseaa  G1: 12 (33.3)  G2: 8 (8 (22.2)  Headachea  G1: 11 (30.6)  G2: 6 (16.7)  Diarrheaa  G1: 5 (13.9)  G2: 2 (5.6)  Dry Moutha  G1: 8 (22.2)  G2: 5 (13.9)  Asthesniaa  G1: 7 (19.4)  G2: 4 (11.1)  Constipationa  G1: 7 (19.4)  G2: 3 (11.1)  Decreased appetitea  G1:6 (16.7)  G2: 2 (5.6)  Diarrheaa  G1: 5 (13.9)  G2: 2 (5.6) |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Krystal et al., 2011[85](#_ENREF_85) | G1; Risperidone  1 to 4 mg/day  G2: Placebo | Overall: 206 G1: 109  G2: 97 p= 0.08  (Coded using Medical Dictionary for Regulatory Activities) | G1: 1 G2: 1 | NR | NR | NR | NR | Somnolence Overall: 15 G1: 13 G2: 2 p= 0.00  Fatigue Overall: 18 G1: 18 G2: 0 p=0.00 | Overall: 23 G1: 20 G2: 3 p= 0.00 | Disturbance in attention Overall: 11 G1: 9 G2: 2 p=0.03  Gastrointestinal disorders Overall: 78 G1: 41 G2: 37 p=0.59  Salivary hypersecretion Overall: 14 G1: 13 G2: 1 p=0.00  Psychiatric disorders Overall:65 G1: 42 G2: 23 p=0.01  Decreased Libido Overall: 8 G1:8 G2:0 p=0.00  General disorders and administration site conditions: Overall: 49 G1: 31 G2: 18 p=0.04 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Krystal et al., 2011[85](#_ENREF_85)  (cont’d) |  |  |  |  |  |  |  |  |  | Respiratory, thoracic and mediastinal disorders Overall:24 G1: 20 G2: 4  p=0.00  Dyspnea Overall G1: 8 G2: 0 p=0.00  Nasal congestion G1: 6 G2: 0 p=0.01 |
| Markowitz et al., 2015[132](#_ENREF_132)  Markowitz et al., 2016[261](#_ENREF_261) | G1: PE  G2: IPT  G3: RT | NR | NR | NR | NR | NR | NR | NR | NR | Worsening Depression  G1: 0  G2: 0  G3: 2 |
| Marshall et al., 2001[64](#_ENREF_64) | G1: Paroxetine  20 mg/day  G2: Paroxetine  40 mg/day  G3: Placebo | NR | G1: 21 G2: 28 G3: 18 | NR | NR | NR | NR | NR | NR | Serious Adverse Events G1 & G2: 9 combined G3: 0  The study reports that the most commonly reported AEs associated with paroxetine use (with an incidence of at least 10% and twice that of placebo) were asthenia, diarrhea, abnormal ejaculation, impotence, nausea, and somnolence (data NR)." |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Martenyi et al., 2002[61](#_ENREF_61)  Martenyi et al., 2006[173](#_ENREF_173) | G1: Fluoxetine  20 to 80 mg/day  G2: Placebo | Martenyi et al., 2002[61](#_ENREF_61)  G1: 53% G2: 55% Martenyi et al., 2006[173](#_ENREF_173)  G1: 55.5% G2: 55.9% | Martenyi et al., 2002[61](#_ENREF_61)  G1: 2.7% G2: 4.0% Martenyi et al., 2006[173](#_ENREF_173)  G1: 3 G2: 1 | NR | NR | Martenyi et al., 2002[61](#_ENREF_61)  Insomnia G1: 12%  G2: 12%  Martenyi et al., 2006[173](#_ENREF_173) Insomnia G1: 14.5% G2: 11.8% | NR | NR | NR | Martenyi et al., 2002[61](#_ENREF_61)  Most Commonly Reported Headache G1: 16%  G2: 15% Nausea G1: 14% G2: 7% Dry Mouth  G1: 7% G2: 7% Anxiety G1:  G2: 7% Martenyi et al., 2006[173](#_ENREF_173) Most Commonly Reported (>5%)  Headache G1: 15.5%  G2: 11.8%  Nausea G1: 12.7% G2: 5.9% Vomiting G1: 6.4% G2: 2.9% Dry Mouth:  G1: 7.3% G2: 11.8% Abdominal Pain G1: 7.3% G2: 2.9% Diarrhea G1: 5.5% G2: 2.9 % Nervousness: G1: 5.5% G2: 0.0% |

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| Martenyi et al., 2007[62](#_ENREF_62) | G1: Fluoxetine  20 mg/day  G2: Fluoxetine  40 mg/day  G3: Placebo | G1: 68% G2: 78% G3: 65% | G1: 4.3%  G2: 13.1% G3: 8.0% | G1: 0 G2: 0 G3: 0 | G1: 1 G2: 3 G3: 0 | NR | NR | NR | NR | Serious Adverse Events, n  G1: 1 (thoughts of  self-mutilation)  G2: 5 (2 patients’ anxiety; 1 patient, chest pain; 1 patient, suicidal ideation; and 1 patient, gastritis)  G3: 2 (palpitation, thyroid carcinoma). |
| McGovern et al., 2015[27](#_ENREF_27) | G1: ICBT plus SC, manual-guided therapy focused on PTSD and substance use.  G2: IAC plus SC, (focused exclusively on substance use and recovery) (arm not eligible)  G3: SC (intensive out-patient program services) | G1: 0 (0)  G2: 0 (0) | NR | NR | NR | NR | NR | NR | NR | NR |
| Mills et al., 2012[20](#_ENREF_20) | G1: COPE, a modification of Concurrent Treatment of PTSD and Cocaine Dependence. (motivational enhancement, psychoeducation, in vivo exposure, imaginal exposure, and cognitive therapy)  G2: TAU. | NR | NR | G1: 1 (2%, but patient had a preexisting medical condition) G2: 0 (0%) | G1: 2 (4%) G2: 5 (10%) | NR | NR | NR | NR | NR |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Monnelly et al., 2003[167](#_ENREF_167) | G1: Risperidone  0.5 to 2.0mg/day  G2: Placebo | G1: 4 G2: 3 | G1: 1 G2: 0 | NR | NR | NR | NR | NR | NR | Urinary retention G1:1 G2:0  Mild Adverse Events  G1: 4  G2: 2. |
| Monson et al., 2006[1](#_ENREF_1) | G1: CBT, cognitive processing therapy  G2: WL | NR | NR | NR | NR | NR | NR | NR | NR | no serious adverse events  in either condition |
| Monson et al., 2012[22](#_ENREF_22) | G1: CBCT, manualized cognitive-behavioral conjoint therapy for PTSD delivered in a couple therapy format  G2: WL | NR | G1: 1 (severe intimate aggression)  G2: 0 | NR | NR | NR | NR | NR | NR | Serious Adverse Event  G1: 1 (severe intimate aggression)  G2: 0 |
| Mueser et al., 2008[7](#_ENREF_7) | G1: CBT-mixed  (CBT for PTSD)  G2: Usual care | NR | G1: 2 withdrawals due to "other psychiatric symptoms"  G2: NR | NR | NR | NR | NR | NR | NR | NR |
| Neuner et al., 2010[53](#_ENREF_53) | G1: CBT, exposure based (NET)  G2: UC | NR | NR | NR | G1: 2 G2: 0 | NR | NR | NR | NR | NR |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Panahi et al., 2011[71](#_ENREF_71) | G1: Sertraline  50 to 200 mg/day  G2: Placebo | NR | NR | NR | NR | Insomnia  G1: 10  G2: 4 | NR | Drowsiness  G1: 5  G2: 2 | NR | AE reported by at least 10%  Headache  G1: 10  G2: 6  Nausea  G1: 10  G2: 5  Restlessness  G1: 8  G2: 5  Diarrhea  G1: 7  G2: 4  Dry Mouth  G1: 6  G2: 5  Asthenia  G1: 5  G2: 2  Decreased appetite  G1: 5  G2: 3  Constipation  G1: 5  G2: 3  Decreased libido  G1: 4  G2: 2 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Petrakis et al., 2012[185](#_ENREF_185) | G1: Paroxetine (40 mg/day) + Naltrexone (50 mg/day)  Participants who could not tolerate the highest dose were brought to lower doses.  G2: Paroxetine (40 mg/day) +Placebo  Participants who could not tolerate the highest dose were brought to lower doses.  G3: Desipramine (200 mg/day) + Naltrexone (50 mg/day)  Participants who could not tolerate the highest dose were brought to lower doses.  G4: Desipramine (200 mg/day + Placebo  Participants who could not tolerate the highest dose were brought to lower doses. | G1: 2 G2: 3 G3: 1 G4: 3 | G1: 0 G2: 0 G3: 2 G4: 0 | NR | NR | NR | NR | NR | NR | Adverse Effects of Desipramine (G3 or G4) Dizziness or lightheaded: 2  Tachycardia: 1  Adverse Effects of Paroxetine (G2 only) Experienced a Seizure: 1  Side Effects of Desipramine: reported significantly more gastrointestinal symptoms (abdominal pain, nausea, vomiting, loss of appetite, constipation, diarrhea, dry mouth, coughing up blood, vomiting, black/blood/light stool, yellow eyes, weight gain, and increased thirst than paroxetine treated subjects (F = 7.67, p=0.007) |
| Raskind et al., 2003[74](#_ENREF_74) | G1: Prazosin  2 to 10 mg/day  G2: Placebo | none serious | NR | NR | NR | NR | NR | NR | NR | Serious Adverse Events  G1: 0  G2:0  Mild Orthostatic Hypotension, n  G1: 2 (resolved upon dose increase)  G2: 0 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Raskind et al., 2007[75](#_ENREF_75) | G1: Prazosin  2 to 15 mg at bedtime  G2: Placebo | NR | G1: 3 G2: 1 | NR | NR | Insomnia G1: 1 G2: 1 | NR | NR | NR | Dizziness G1: 9 G2: 6 Nasal or sinus Congestion G1: 6  G2:1 Headache G1: 3 G2: 1 Dry Mouth G1: 2 G2:0 Sweating G1: 0 G2:1 Depression G1: 0 G2: 1 Lower extremity edema G1: 0 G2: 1 Blood Pressure: No significant difference |
| Raskind et al., 2013[76](#_ENREF_76) | G1: Prazosin 1 to 5 mg/day morning dose, 1 to 20mg/day bedtime dose  G2: Placebo | Treatment Related  G1: 20  G2: 18  Miscella-neous  G1: 16 (50%)  G2: 23 (66%) | G1: 2  G2: 0NR | NR | G1: 0  G2: 2 (1 participant hospital-lized for suicidal ideation; 1 suicide attempt) | NR | NR | Drowsiness  G1: 1  G2: 3 | NR | Depression  G1: 0  G2: 2  Lack of Energy  G1: 0  G2: 1 |
| Reger et al., 2016[18](#_ENREF_18) | G1: VRE  G2: PE  G3: WL | NR | Increase in symptom-atology  G1: 3 (6%)  G2: 1 (2%)  G3: 1 (2%) | NR | NR | NR | NR | NR | NR | NR |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Reich et al., 2004[84](#_ENREF_84) | G1: Risperidone  0.5 to 8 mg/day  G2: Placebo | G1: 4 G2: 1 | G1: 1 G2: 0 | NR | NR | NR | NR | NR | Mean Increase in Weight G1: 2.5 lb G2: 3lb | Reported by Each Group G1: Sedation, dry mouth, tremor, apathy, and poor concentration G2: Sedation  # or % not reported for specific adverse events |
| Resick et al., 2002[3](#_ENREF_3)  Resick et al., 2003[125](#_ENREF_125)  Resick et al., 2012[126](#_ENREF_126) | G1: CBT, cognitive processing therapy  G2: CBT, exposure-based therapy (PE)  G3: WL | NR | NR | NR | NR | NR | NR | NR | NR | no adverse events associated  with the followup assessments. Over time period participants had experienced many adverse events, but none were attributed to the therapy they had received years before  or to the LTFU assessment itself. |
| Resick et al., 2015[127](#_ENREF_127), [128](#_ENREF_128) | G1: CPT-C (only cognitive component)  G2: PCT | During treatment: G1: 20 (38%) G2: 21 (42%)  During treatment related to study procedures:  G1: 10 (19%)  G2: 3 (6%)  During followup:  G1: 13 (24.7%) G2: 15 (30%) | NR | NR | Ideation During treatment: G1: 2 (3.8%) G2: 3 (6%)  F[1, 613] = .21, p = .647)  Ideation During followup:  G1: 1 (1.9%) G2: 2 (4%) p=ns  Suicide attempt during follow up.  G1: 1 (1.9%)  G2: 0 (0%) | NR | NR | NR | NR | Increased PTSD During treatment: G1: 11 (20.9%) G2: 6 (12%) Increased PTSD During followup:  G1: 1 (1.9%) G2: 1 (2%) |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sannibale et al. 2013[146](#_ENREF_146) | G1: IT (Integrated CBT for PTSD and AUD)  G2: AS, (CBT for AUD plus SC) | G1: 1 (3.0)  G2: 1 (3.4) | NR | NR | NR | NR | NR | NR | NR | NR |
| Schnurr et al., 2003[139](#_ENREF_139) | G1: Exposure-based, trauma-focused group therapy  G2: Present-centered group Therapy | NR | NR | G1: 0 G2: 4  One death in G2 was suicide. The other 3 deaths in the G2 group were of "natural causes" | NR | NR | NR | NR | NR | NR |
| Schnurr et al., 2007[138](#_ENREF_138) | G1: CBT, exposure-based therapy (PE)  G2: PCT | G1: 5  G2: 14 | G1: NR  G2: NR | G1: 0  G2: 2 (non-suicide) | G1: 1  G2: 3 | NR | NR | NR | NR | Psychiatric hospitalization G1: 4 G2: 9 |
| Simon et al., 2008[174](#_ENREF_174) | G1: Paroxetine  12.5 to 62.5 mg/day  G2: Placebo  Placebo and 5 additional sessions of prolonged exposure | G1: All reported at least 1 G2: All reported at least 1 | G1: 1 G2: 1 | NR | G1: 1  G2: 0 | G1: 89% G2: 85% | NR | NR | NR | Concentration and Memory Difficulties G1: 89%  G2: 85% Drowsiness G1: 67% G2: 77% |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sonne et al., 2016[186](#_ENREF_186) | G1: WET  G2: WL | NR | 10 overall  G1:NR  G2: NR | NR | NR | NR | NR | NR | NR | NR |
| Stein et al., 2002[80](#_ENREF_80) | G1: Olanzapine  10 to 20 mg  G2: Placebo | G1: 3 G2: 2 | G1: 3 G2: 2 | G1: 0 G2: 0 | G1: 0 G2: 0 | G1: 0 G2: 0 | G1: 0 G2: 0 | G1: 2 G2: 0 | G1: 13 lbs. mean weight gain  G2: NR | G1: 0 G2: 0 |
| Taylor et al., 2003[133](#_ENREF_133) | G1: CBT, exposure-based therapy  G2: EMDR  G3: Relaxation Training | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| ter Heide et al., 2016[43](#_ENREF_43) | G1: EMDR  G2: Stabilisation | NR | G1: 0 (0%)  G2: 1 (2%) (symptom increase) | NR | NR | NR | NR | NR | NR | CAPS Severity change  Deterioration (>-10 points)  G1: 7/32 (21.9)  G2:8/31 (25.8) |
| Tucker et al., 2001[65](#_ENREF_65) | G1: Paroxetine  20 to 50mg/day  G2: Placebo | NR | G1: 17.97 (11.9%) G2: 10 (6.4%) | NR | NR | NR | NR | Somnolence G1: 17.2% G2: 3.8% | NR | Nausea G1: 19.2% G2: 8.3% Dry Mouth G1: 13.9% G2: 4.5% Asthenia G1: 13.2% G2: 5.8% Abnormal-ejaculation G1: 11.8% G2: 3.7% Incidence of non-ejaculation-related sexual adverse events (decreased libido, impotence, female genital disorders) G1: 7.3% G2: 2.6% |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tucker et al., 2003[175](#_ENREF_175)  Tucker et al., 2004[176](#_ENREF_176) |  | Overall NR (just specific) | 2 overall; group not specified | NR | NR | Insomnia G1: 13  G2: 6 G3: 6 | NR | Fatigue G1: 8 G2: 6 G3: 3 | NR | Jitteriness G1: 6 G2: 6 G3: 2 GI distress G1: 3 G2: 6 G3: 2 Nausea G1: 5 G2: 8 G3: 3 Vomiting G1: 1 G2: 1 G3: 0 Decreased appetite G1: 9 G2: 8 G3: 1 Increased appetite G1: 7 G2: 8 G3: 5 Decreased sexual function G1: 4 G2: 1 G3: 0 Dizziness G1: 4 G2: 4 G3: 2 Sweating, chills G1: 3 G2: 4 G3: 0 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tucker et al., 2007[78](#_ENREF_78) | G1: Topiramate  25 to 400mg/day; given 2 times a day  G2: Placebo | G1: 45c G2: 25c | G1: 4 G2: 3 | NR | NR | G1: 4 G2: 3 | Nervousness  G1: 4 G2: 1 | Fatigue  G1: 4 G2: 0 | Weight gain in each condition  G1: -1.8 (3.3 G2: -1.1 (2.6) kgs  p=0.434 | Headache  G1: 7  G2: 5  Sinusitis  G1: 5  G2: 2  Taste Perversion  G1: 5  G2: 0  Language problems  G1: 4  G2: 3  Dyspepsia  G1: 4  G2: 2  Paresthesia  G1: 4  G2: 1  Hypertension  G1: 2  G2: 4  Difficulty with concentration/attention  G1:2  G2: 4 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| van den Berg et al., 2015[16](#_ENREF_16) | G1: PE  G2: EMDR  G3: WL | NR | NR | NR | NR | NR | NR | NR | NR | Serious AEs (none judged to be related to the study)  G1: 2 (4%)  G2: 1 (2%)  G3: 4 (8%) |
| van der Kolk et al., 1994[63](#_ENREF_63) | G1: Fluoxetine  20 to 60mg/day  G2: Placebo | NR | NR | NR | NR | NR | NR | NR | NR | Side Effects Reported at p<0.05 level  Diarrhea, n G1: 25 G2: 16 Sweating, n G1: 20 G2: 10 Headaches, n G1: 10 G2: 3 |
| van Emmerik et al., 2008[40](#_ENREF_40) | G1: CBT-Mixed  Psychoeducation, prolonged exposure, imaginal exposure, exposure in vivo, cognitive exposure  G2: SWT  G3: WL | NR | NR | NR | NR | NR | NR | NR | NR | NR |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yeh et al., 2011[79](#_ENREF_79) | G1: Topiramate  25 to 200mg/day  G2: Placebo | NR | G1: 1 G2: 0 | NR | NR | NR | NR | Somnolence G1: 23% G2: 35% | NR | Insomnia G1: 23% G2: 7% Paresthia G1: 17% Headache G1: 11% G2: 21% Irritability G1: 11% Dyspepsia G1: 17% Difficulty with Concentration G1: 11% |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Zohar et al., 2002[72](#_ENREF_72) | G1: Sertraline  50 to 200 mg/day  G2: Placebo | >10% overall | G1: 3 G2: 1 | NR | NR | NR | NR | NR | NR | Nausea G1: 8 G2: 4 Headache G1: 6 G2: 3 Drowsiness G1: 6 G2: 3 Asthenia G1: 4 G2: 1 Increased appetite G1: 3 G2: 2 Dry mouth G1: 3 G2: 2  Decreased appetite G1: 3 G2: 1 |

a Reported by at least 10 percent of patients

b Adverse event was an adverse reaction during the provocation and somatic investigation using SPECT.

c Number of adverse events occurring in > 20 percent of subjects.

Abbreviations: AE = adverse events; kg = kilogram; NA = not applicable; NR= not reported; NS = not significant; SAE = serious adverse events.

EPC: Should this be “harms”?