| 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: Topiramate25 to 500 mg/day (sensitive patients started at 12.5mg/day)G2: Placebo | NR | G1: 2G2: 3 | NR | NR | NR | NR | NR | NR | NR |
| Bartzokis et al., 2005[86](#_ENREF_86) | G1: Risperidone1 to 3 mg/day G2: Placebo | NR | G1: 3G2: 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 300mgG2: Placebo | G1: 12 (85.7%)G2: 13 (81.3%)NS  | NR | G1: 0G2: 1 due to myocardial infarction (judged to be unrelated to study)NS | Suicidal ideationG1: 0G2: 1 (hospitalized for suicidal ideation)NS | NR | NR | SleepinessG1: 36%G2: 13%NS | NR | Loss appetiteG1: 29%G2: 38%Change in sense of tasteG1: 21%G2: 31%ItchingG1: 21%G2: 6%DiarrheaG1: 29%G2: 19%Abnormal visionG1: 21%G2: 19%Serious AEsG1: 0G2: 6NS5 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: Bupropion100 to 300 mg/dayG2: Placebo | NR | G1: 1G2: NR | NR | NR | NR | NR | NR | NR | G1 & G2a: Heart pounding, concentration problems, problem achieving orgasm, & erecticle dysfunctionG1:ability to achieve orgasm (positive & negative direction) & 1 reported rashG2: 30% reported increased appetite |
| Boden et al., 2012[58](#_ENREF_58) | G1: Seeking Safety and TAUG2: 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-PTSDG2: TAU-WL | NR | NR | NR | Suicide AttemptsG1: 0 (0)G2: 0 (0) | NR | NR | NR | NR | Worsening PTSD SymptomsG1: 0 (0)G2: 6 (15.8)) |
| Brady et al., 2000[66](#_ENREF_66) | G1: Sertraline25 to 200 mg/dayG2: Placebo | NR | G1: 5G2: 5 | NR | NR | InsomniaaG1: 16.0%G2: 4.3%p=0.01 | NR | NR | Change, Mean kgG1: -1.3G2: -0.3p=0.01 | HeadacheaG1: 20.2%G2: 28.3%DiarrheaaG1: 23.4%G2: 19.6%MalaiseaG1: 17.0%G2: 15.2%NauseaaG1: 16.0%G2: 12.0%DrowsinessaG1: 12.8%G2: 9.8%Dry MouthaG1: 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: Sertraline150 mg/dayG2: Placebo | NR | G1: 0G2: 0 | NR | NR | NR | NR | NR | NR | NR |
| Butterfield et al., 2001[82](#_ENREF_82)  | G1: Olanzapine5 to 20mg/dayG2: Placebo | G1: 45G2: 3 | NR | NR | NR | NR | NR | NR | G1: 6G2: 0 | Dry mouthG1: 3G2: 0DrowsinessG1: 3G2: 1ConstipationG1: 3G2: 1Increased appetite G1: 3G2: 0DiarrheaG1: 2G2: 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) |   |   |   |   |   |   |   |   |   | TinglingG1: 2G2: 0UnsteadinessG1: 2G2: 0Forgetfulness G1: 3G2: 0Frequent urinationG1: 4G2: 1UncomforTable D-urge to moveG1: 4G2: 0ThirstG1: 6G2: 0SwellingG1: 4G2: 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 10mgG2: Placebo | NR | G1: 1 (due to severe sedation)G2: 0 | NR | NR | InsomniaG1: 3 (20%)G2: 2 (13%)p=0.564 |   | OverallG1: 11G2: 5P, NRMildG1: 5 (73%)G2: 4 (33%)p=0.014ModerateG1: 5 G2: 1 P, NRSevereG1: 1G2: 0P, NR | Weight gain at 8 weeksG1: 14 (100%)G2: 5 (33%)p= 0.001MeanG1: 5.6 (2.6) kgG2: -0.3 (3.9) kgp=0.000 | Serious AEsG1: 0G2: 0Increased AnxietyG1: 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 therapyCPT-SAG2: WL  | NR | NR | NR | NR | NR | NR | NR | NR | No participants reported that their symptoms hadbecome 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: 0G2: 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=0.02G1 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: 0G2: 5 | NR  | NR  | NR  | NR  | NR  | NR  | Worsening of symptomsG1:0 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: Sertraline50 to 200 mg/dayG2: Placebo | NR | G1: 9G2: 5 | NR | NR | InsomniaG1: 35%G2: 22%p=0.04Vivid DreamsG1: 10%G2: 4%p=0.10 | NR | NR | NR | HeadacheG1: 33%G2: 24%, p=0.17DiarrheaG1: 28%G2: 11%, p=0.003NauseaG1: 23%G2: 11%, p=0.03DrowsinessG1: 17%G2: 11%, p=0.24NervousnessG1: 14%G2: 8%, p=0.27FatigueG1: 13%G2: 5%, p=0.05Decreased AppetiteG1: 12%G2: 1%, p=0.001Dry MouthG1: 10%G2: 7%, p=0.45 |
| Davidson et al., 2003[184](#_ENREF_184) | G1: Mirtazapine15 to 45 mg/dayG2: Placebo | G1: 3G2: 3 | G1: 3G2: 3 | NR | NR | NR | NR | NR | G1: 3 G2: 1  | PalpitationsG1: 0G2: 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: Venlafaxine75 to 300mg/dayG2: Sertraline50 to 200mg/dayG3: Placebo | NR | G1: 17, 9.5%G2: 22, 12.7%G3: 19, 10.6% | None related to study med | NR | InsomniaaG1: 24, 13%G2: 18, 10%G3: 16, 9% | NR | FatigueaG1: 19, 11%G2: 24, 14%G3: 17, 9%SomnolenceaG1: 21, 12% G2: 18, 10%G3: 24, 13% | KgaG1 -.5G2: -.3 G3: +.9 G1 vs G3: p=0.00064G2 vs G3: p=0.0242 | HeadacheaG1: 53, 29%G2: 57, 32%G3: 55, 29%NauseaaG1 45, 24%G2: 39, 23%G3: 27, 14%DiarrheaaG1: 22, 12% G2: 47, 26%G3: 25, 13%Dry MouthaG1: 34, 18%G2: 26, 15%G3: 27, 15%DizzinessaG1: 24, 13%G2: 21, 10%G3: 14, 8%ConstipationaG1: 21, 12%G2: 12, 7%G3: 18, 10%Appetite DecreaseaG1: 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: Venlafaxine37.5 to 300 mg/dayG2: Placebo | NR | G1: 15G2: 9 | NR | NR | G1: 12G2: 17 | NR | SomnolenceG1: 9G2: 9 | Weight Change of 7% or greaterG1: 20G2: 12 | Reported by at Least 5% of patientsHeadacheG1: 46G2: 44NauseaG1: 35G2: 19DizzinessG1: 29G2: 19Dry MouthG1: 21G2: 8ConstipationG1: 20G2: 5FatigueG1: 13G2: 6InsomniaG1: 12G2: 17Decreased libidoG1: 8G2: 6NasopharyngitisG1: 8G2: 11Increased SweatingG1: 21G2: 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: Tiagabine4 to16mg/dayG2: Placebo | G1: NRG2: NR | G1: 8%G2: 8% | NR | NR | NR | NR | Somno-lenceG1: 20%G2: 10% | NR | VomitingG1: 11G2: 4TremorG1: 10G2: 6DizzinessG1: 32%G2: 13%HeadacheG1: 25%G2: 27%NauseaG1: 18%G2: 20%Serious Adverse Event G1:1G2:0One 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: Divalproex1000 to 3000 mg/dayG2: Placebo | NR (reported AEs greater than 6% in each group) | G1: 3G2: 1 | NR  | NR  | NR  | NR  | G1: 12G2: <6 | NR | SAE unrelated to studyG1: 1G2: 0Lack of Efficacy:G1:0G2:1Dizziness:G1: 24G2: <6Nausea:G1: 14G2: <6GI tract upset:G1: 12G2: <6Diarrhea:G1: 12G2: <6Increased urinary frequency:G1: 10G2: <6Headache:G1: 10G2: <6Memory Deficit:G1: 10G2: <6Abnormal vision:G1: 7G2: <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: <6G2: 7 |
| Ehlers et al., 2014[9](#_ENREF_9) | G1: Intensive CT (standard CT over a much shorter period)G2: Standard CTG3: Supportive TherapyG4: 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: PCTG3: WL | NA | NA | NA | NA | NA | NA | NA | NA | no treatment-related adverse events occurred during the trialWorsening 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 andTherapy (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: Sertraline25 to 200 mg/dayG2: Placebo | G1: NRG2: NR | G1: 11G2: 5 | NR  | NR  | InsomniaaG1: 12G2: 8 | NR | Fatiguea G1: 9G2: 1SomnolenceaG1: 12G2: 7 | NR | DiarrheaaG1: 27G2: 15HeadacheaG1: 23G2: 20NauseaaG1: 18G2: 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: Risperidone1 to 6 mg/dayG2: Placebo | NR | G1: 0G2: 0 | NR | NR | NR | NR | NR | NR | Akathisia, nG1: 1G2: 0Nausea and vomiting, nG1: 1G2: 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 | CommittedG1: 0 (0)G2: 1 (11.1)Rate of any Suicide Attempt (ITT)G1: 37.5%G2: 50.0%Abstinent from Suicidal Behavior during followupG1: 91.7%G2: 100% | NR | NR | NR | NR | Any NSSI (ITT)G1: 68.8%G2: 87.5%Abstinent from NSSI during followupG1: 75%G2: 66.7% |
| Hien et al., 2004[57](#_ENREF_57)  | G1: Seeking SafetyG2: Relapse prevention condition (only substance abuse)G3: Usual care(Non-randomized Standard community Care) | NR | NR | NR | NR | NR | NR | NR | NR | Psychiatric HospitalizationG1: 5%G2: 5%G3: 6% |
| Hien et al., 2009[157](#_ENREF_157)Hien et al., 2012[158](#_ENREF_158) | G1: Seeking SafetyG2: Psychoeducation | NR | NR | NR | NR | NR | NR | NR | NR | no increase in eithertreatment-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; EMDRG2: WL | NR | G1: 1bG2: 0 | NR | NR | NR | NR | NR | NR | NR |
| Hollifield et al., 2007[32](#_ENREF_32) | G1: AcupunctureG2: CBT-mixed (Cognitive restructuring, behavior activation, and coping skills) G3: WL | NR | G1: 1G2: 0G3: NR | NR | NR | NR | NR | NR | NR | Perceived kidney painG1: 1G2: 0G3:0 |
| Ivarsson et al., 2014[24](#_ENREF_24) | G1: Internet based CBTG2: 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: 0G2: 0 | NR | NR | NR | NR | NR | NR | 7 hospitalizations (5medical, 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+TAUG2: 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: 4G2: 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 completefollowup 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 | DeterioratedG1 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: 2G2: 1 | NR | NR | InsomniaG1: 10G2: 7 | NR | DrowsinessG1: 9G2: 5 | NR | NauseaaG1: 12 (33.3)G2: 8 (8 (22.2)HeadacheaG1: 11 (30.6)G2: 6 (16.7)DiarrheaaG1: 5 (13.9)G2: 2 (5.6)Dry MouthaG1: 8 (22.2)G2: 5 (13.9)AsthesniaaG1: 7 (19.4)G2: 4 (11.1)ConstipationaG1: 7 (19.4)G2: 3 (11.1)Decreased appetiteaG1:6 (16.7)G2: 2 (5.6)DiarrheaaG1: 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; Risperidone1 to 4 mg/dayG2: Placebo | Overall: 206G1: 109 G2: 97p= 0.08(Coded using Medical Dictionary for Regulatory Activities) | G1: 1G2: 1 | NR | NR | NR | NR | SomnolenceOverall: 15G1: 13G2: 2p= 0.00FatigueOverall: 18G1: 18G2: 0p=0.00 | Overall: 23G1: 20G2: 3p= 0.00 | Disturbance in attentionOverall: 11G1: 9G2: 2p=0.03Gastrointestinal disordersOverall: 78G1: 41G2: 37p=0.59Salivary hypersecretionOverall: 14G1: 13G2: 1p=0.00Psychiatric disordersOverall:65G1: 42G2: 23p=0.01Decreased LibidoOverall: 8G1:8G2:0p=0.00General disorders and administration site conditions:Overall: 49G1: 31G2: 18p=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 disordersOverall:24G1: 20G2: 4 p=0.00DyspneaOverallG1: 8G2: 0p=0.00Nasal congestionG1: 6G2: 0p=0.01 |
| Markowitz et al., 2015[132](#_ENREF_132)Markowitz et al., 2016[261](#_ENREF_261) | G1: PE G2: IPTG3: RT | NR | NR | NR | NR | NR | NR | NR | NR | Worsening DepressionG1: 0G2: 0G3: 2 |
| Marshall et al., 2001[64](#_ENREF_64) | G1: Paroxetine20 mg/day G2: Paroxetine40 mg/dayG3: Placebo | NR | G1: 21G2: 28G3: 18 | NR | NR | NR | NR | NR | NR | Serious Adverse EventsG1 & G2: 9 combinedG3: 0The 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: Fluoxetine20 to 80 mg/dayG2: 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: 3G2: 1 | NR | NR | Martenyi et al., 2002[61](#_ENREF_61)InsomniaG1: 12% G2: 12% Martenyi et al., 2006[173](#_ENREF_173)InsomniaG1: 14.5%G2: 11.8% | NR | NR | NR | Martenyi et al., 2002[61](#_ENREF_61)Most Commonly ReportedHeadacheG1: 16% G2: 15%NauseaG1: 14%G2: 7%Dry Mouth G1: 7%G2: 7%AnxietyG1:G2: 7%Martenyi et al., 2006[173](#_ENREF_173)Most Commonly Reported (>5%)HeadacheG1: 15.5% G2: 11.8%NauseaG1: 12.7%G2: 5.9%VomitingG1: 6.4%G2: 2.9%Dry Mouth: G1: 7.3%G2: 11.8%Abdominal PainG1: 7.3%G2: 2.9%DiarrheaG1: 5.5%G2: 2.9 %Nervousness:G1: 5.5%G2: 0.0% |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Martenyi et al., 2007[62](#_ENREF_62) | G1: Fluoxetine20 mg/dayG2: Fluoxetine40 mg/dayG3: Placebo | G1: 68%G2: 78%G3: 65% | G1: 4.3% G2: 13.1%G3: 8.0% | G1: 0G2: 0G3: 0 | G1: 1G2: 3G3: 0 | NR  | NR  | NR  | NR  | Serious Adverse Events, nG1: 1 (thoughts ofself-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 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Monnelly et al., 2003[167](#_ENREF_167) | G1: Risperidone0.5 to 2.0mg/dayG2: Placebo | G1: 4G2: 3 | G1: 1G2: 0 | NR | NR | NR | NR | NR | NR | Urinary retentionG1:1G2:0Mild Adverse EventsG1: 4 G2: 2. |
| Monson et al., 2006[1](#_ENREF_1) | G1: CBT, cognitive processing therapyG2: WL | NR | NR | NR | NR | NR | NR | NR | NR | no serious adverse eventsin 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 EventG1: 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: 2G2: 0 | NR | NR | NR | NR | NR |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Panahi et al., 2011[71](#_ENREF_71) | G1: Sertraline50 to 200 mg/dayG2: Placebo | NR | NR | NR | NR | InsomniaG1: 10G2: 4 | NR | DrowsinessG1: 5G2: 2 | NR | AE reported by at least 10%HeadacheG1: 10G2: 6NauseaG1: 10G2: 5RestlessnessG1: 8G2: 5DiarrheaG1: 7G2: 4Dry MouthG1: 6G2: 5AstheniaG1: 5G2: 2Decreased appetiteG1: 5G2: 3ConstipationG1: 5G2: 3Decreased libidoG1: 4G2: 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) +PlaceboParticipants 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 + PlaceboParticipants who could not tolerate the highest dose were brought to lower doses. | G1: 2G2: 3G3: 1G4: 3 | G1: 0G2: 0G3: 2G4: 0 | NR | NR | NR | NR | NR | NR | Adverse Effects of Desipramine (G3 or G4)Dizziness or lightheaded: 2Tachycardia: 1Adverse Effects of Paroxetine (G2 only)Experienced a Seizure: 1Side 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: Prazosin2 to 10 mg/dayG2: Placebo | none serious  | NR | NR | NR | NR | NR | NR | NR | Serious Adverse EventsG1: 0G2:0 Mild Orthostatic Hypotension, nG1: 2 (resolved upon dose increase)G2: 0 |

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| Raskind et al., 2007[75](#_ENREF_75) | G1: Prazosin2 to 15 mg at bedtimeG2: Placebo | NR | G1: 3G2: 1 | NR | NR | InsomniaG1: 1G2: 1 | NR | NR | NR | DizzinessG1: 9G2: 6Nasal or sinus CongestionG1: 6 G2:1HeadacheG1: 3G2: 1Dry MouthG1: 2G2:0SweatingG1: 0G2:1DepressionG1: 0G2: 1Lower extremity edemaG1: 0G2: 1Blood 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 doseG2: Placebo | Treatment RelatedG1: 20G2: 18Miscella-neousG1: 16 (50%)G2: 23 (66%) | G1: 2G2: 0NR | NR | G1: 0G2: 2 (1 participant hospital-lized for suicidal ideation; 1 suicide attempt) | NR | NR | DrowsinessG1: 1G2: 3 | NR | DepressionG1: 0G2: 2Lack of EnergyG1: 0G2: 1 |
| Reger et al., 2016[18](#_ENREF_18) | G1: VREG2: PEG3: WL  | NR | Increase in symptom-atologyG1: 3 (6%)G2: 1 (2%)G3: 1 (2%) | NR | NR | NR | NR | NR | NR | NR |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Reich et al., 2004[84](#_ENREF_84) | G1: Risperidone0.5 to 8 mg/dayG2: Placebo | G1: 4G2: 1 | G1: 1G2: 0 | NR | NR | NR | NR | NR | Mean Increase in WeightG1: 2.5 lbG2: 3lb | Reported by Each GroupG1: Sedation, dry mouth, tremor, apathy, and poor concentrationG2: 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 therapyG2: CBT, exposure-based therapy (PE)G3: WL | NR | NR | NR | NR | NR | NR | NR | NR | no adverse events associatedwith the followup assessments. Over time period participants had experienced many adverse events, but none were attributed to the therapy they had received years beforeor 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=nsSuicide 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: 0G2: 4One 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 hospitalizationG1: 4G2: 9 |
| Simon et al., 2008[174](#_ENREF_174) | G1: Paroxetine12.5 to 62.5 mg/day G2: PlaceboPlacebo and 5 additional sessions of prolonged exposure | G1: All reported at least 1G2: All reported at least 1 | G1: 1G2: 1 | NR | G1: 1 G2: 0 | G1: 89%G2: 85% | NR | NR | NR | Concentration and Memory DifficultiesG1: 89% G2: 85%DrowsinessG1: 67%G2: 77% |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sonne et al., 2016[186](#_ENREF_186) | G1: WETG2: WL | NR | 10 overallG1:NRG2: NR | NR | NR | NR | NR | NR | NR | NR |
| Stein et al., 2002[80](#_ENREF_80) | G1: Olanzapine10 to 20 mg G2: Placebo | G1: 3G2: 2 | G1: 3G2: 2 | G1: 0G2: 0 | G1: 0G2: 0 | G1: 0G2: 0 | G1: 0G2: 0 | G1: 2G2: 0 | G1: 13 lbs. mean weight gain G2: NR | G1: 0G2: 0 |
| Taylor et al., 2003[133](#_ENREF_133) | G1: CBT, exposure-based therapyG2: EMDRG3: Relaxation Training | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| ter Heide et al., 2016[43](#_ENREF_43) | G1: EMDRG2: Stabilisation  | NR | G1: 0 (0%)G2: 1 (2%) (symptom increase) | NR | NR | NR | NR | NR | NR | CAPS Severity changeDeterioration (>-10 points)G1: 7/32 (21.9)G2:8/31 (25.8) |
| Tucker et al., 2001[65](#_ENREF_65) | G1: Paroxetine20 to 50mg/dayG2: Placebo | NR | G1: 17.97 (11.9%)G2: 10 (6.4%) | NR | NR | NR | NR | SomnolenceG1: 17.2%G2: 3.8% | NR | NauseaG1: 19.2%G2: 8.3%Dry MouthG1: 13.9%G2: 4.5%AstheniaG1: 13.2%G2: 5.8%Abnormal-ejaculationG1: 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% |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 | InsomniaG1: 13 G2: 6G3: 6 | NR | FatigueG1: 8G2: 6G3: 3 | NR | JitterinessG1: 6G2: 6G3: 2GI distressG1: 3G2: 6G3: 2NauseaG1: 5G2: 8G3: 3VomitingG1: 1G2: 1G3: 0Decreased appetiteG1: 9G2: 8G3: 1Increased appetiteG1: 7G2: 8G3: 5Decreased sexual functionG1: 4G2: 1G3: 0DizzinessG1: 4G2: 4G3: 2Sweating, chillsG1: 3G2: 4G3: 0 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tucker et al., 2007[78](#_ENREF_78) | G1: Topiramate25 to 400mg/day; given 2 times a dayG2: Placebo | G1: 45cG2: 25c | G1: 4G2: 3 | NR  | NR  | G1: 4G2: 3 | NervousnessG1: 4G2: 1 | FatigueG1: 4G2: 0 | Weight gain in each conditionG1: -1.8 (3.3G2: -1.1 (2.6) kgsp=0.434 | HeadacheG1: 7G2: 5SinusitisG1: 5G2: 2Taste PerversionG1: 5G2: 0Language problemsG1: 4 G2: 3DyspepsiaG1: 4 G2: 2ParesthesiaG1: 4G2: 1HypertensionG1: 2 G2: 4Difficulty with concentration/attentionG1:2G2: 4 |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| van den Berg et al., 2015[16](#_ENREF_16) | G1: PEG2: EMDRG3: 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: Fluoxetine20 to 60mg/dayG2: Placebo | NR | NR | NR | NR | NR | NR | NR | NR | Side Effects Reported at p<0.05 level Diarrhea, nG1: 25G2: 16Sweating, nG1: 20G2: 10Headaches, nG1: 10G2: 3 |
| van Emmerik et al., 2008[40](#_ENREF_40) | G1: CBT-Mixed Psychoeducation, prolonged exposure, imaginal exposure, exposure in vivo, cognitive exposureG2: SWT G3: WL | NR  | NR  | NR  | NR  | NR  | NR  | NR  | NR  | NR  |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yeh et al., 2011[79](#_ENREF_79) | G1: Topiramate25 to 200mg/dayG2: Placebo | NR | G1: 1G2: 0 | NR | NR | NR | NR | SomnolenceG1: 23%G2: 35% | NR | InsomniaG1: 23%G2: 7%ParesthiaG1: 17%HeadacheG1: 11%G2: 21%IrritabilityG1: 11%DyspepsiaG1: 17%Difficulty with ConcentrationG1: 11% |

| Author Year | Intervention Groups | Overall AE | Withdrawal Due to AE | Mortality | Suicidality | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Zohar et al., 2002[72](#_ENREF_72) | G1: Sertraline50 to 200 mg/dayG2: Placebo | >10% overall | G1: 3G2: 1 | NR | NR | NR | NR | NR | NR | NauseaG1: 8G2: 4HeadacheG1: 6G2: 3DrowsinessG1: 6G2: 3AstheniaG1: 4G2: 1Increased appetiteG1: 3G2: 2Dry mouthG1: 3G2: 2Decreased appetiteG1: 3G2: 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”?