**Evidence Table 11. Harms**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Author, Year, Trial Name  | Re-Traumatization | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| Ahrens, 20021NA | NR | NR | NR | NR | NR | NR |
| Berger, 20072OTT | NR | NR | NR | NR | NR | NR |
| Berger, 20093ES-SL | NR | NR | NR | NR | NR | NR |
| Berkowitz, 20114NA | NR | NR | NR | NR | NR | NR |
| Catani, 20095NA | NR | NR | NR | NR | NR | NR |
| Ford, 20126TARGET | NR | NR | NR | NR | NR | NR |
| Gelkopf, 20097ERASE-Stress | NR | NR | NR | NR | NR | NR |
| Goenjian, 1997; 20058, 9NA; NA | NR | NR | NR | NR | NR | NR |
| Jaycox, 200910SSET | NR | NR | NR | NR | NR | NR |
| Kemp, 201011NA | NR | NR | NR | NR | NR | NR |
| Layne,a. 200812TGCT  | NR | NR | NR | NR | NR | NR |
| Nugent, 201013NA | NR | NR | NR | NR | NR | NR |

Evidence Table 11. Harms (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Author, Year, Trial Name  | Re-Traumatization | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| Robb,b. 201014NA | NR | G1: 7, RR 0.81G2: 8 | G1: 4, RR 1.85G2: 2 | NR | Median weight did not change on Sertraline but increased 0.53 kg on placebo | HeadacheG1: 17, RR 1.31G2: 12Abdominal PainG1: 10, RR 0.71G2: 13NauseaG1: 9, RR 1.39G2: 6PharyngitisG1: 7, RR 1.08G2: 6VomitingG1: 9, RR 2.78G2:3 Accidental injuryG1: 6, RR 0.93G2: 6Respiratory Tract InfectionG1: 6, RR 1.39G2: 4DiarrheaG1: 6, RR 1.85G2: 3DizzinessG1: 3, RR 0.56G2: 5HyperkinesisG1: 7, RR 6.48G2: 1RhinitisG1: 5, RR 4.63G2: 1Dry MouthG1: 5G2: 0DysmenorrheaG1: 0G2: 2 |

Evidence Table 11. Harms (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Author, Year, Trial Name  | Re-Traumatization | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
|  |  |  |  |  |  | Any severe adverse eventG1: 5G2: 0Any serious adverse eventc. G1: 2G2: 0 |
| Robert, 199915NA | NR | NR | NR | NR | NR | NR |
| Robert,d. 200816NA | NR | NR | NR | NR | NR | NR |
| Salloum,e. 200817NA | NR | NR | NR | NR | NR | NR |
| Salloum, 201218 NA | NR | NR | NR | NR | NR | NR |
| Smith, 200719NA | NR | NR | NR | NR | NR | NR |
| Stallard,f. 200625NA | NR | NR | NR | NR | NR | NR |
| Stein,g. 200320NA | NR | NR | NR | NR | NR | NR |
| Tol, 2008; 201021, 22NA; NA | NR | NR | NR | NR | NR | NR |
| Tol, 201223 NA | NR | NR | NR | NR | NR | NR |
| Zehnder, 201024NA | NR | NR | NR | NR | NR | NR |

a. This intervention calculated the Reliable Change Index (RCI) for four measures (posttraumatic stress, depression, traumatic grief, and existential grief). No significant differences in proportion with deterioration in intervention versus comparison group.

b. Only 70.1% (n=47) of patients completed treatment for all causes with Sertraline vs. 82.3% (n=51) with Placebo completed treatment. Discontinuation was higher in children (35.9% sertraline vs. 20.0% placebo) than adolescents (21.4% sertraline vs. 14.8% placebo). Most frequent reason for discontinuation among patients with sertraline was miscellaneous - not related to study drug (lost to follow-up, withdrew consent, etc.). However, it might be too much of a leap to say that it was not due to study drug.

c. Hospitalization for agitation and hyperactivity; 12 year old with herpes zoster with hysterical reaction and suicidal ideation.

d. Authors reported no adverse events during the study. 2 dropped out - 1 due to change of guardians, 1 due to change of psych rater.

e. Withdrawals per group: G1: 5, G2: 6. Completers did not differ significantly from non-completers in reported posttraumatic stress (p=0.787) or depression (p=0.286).

f. Authors reported no adverse events during the study. However, participation rate was low at 42% of patients screened.

g. No adverse events noted other than withdrawals. G1: 5 withdrew & did not receive intervention and in G2: 0 withdrew.

Abbreviations: ERASE-Stress – Enhancing Resilience among Students Experiencing Stress; ES-SL = ERASE Stress Sri Lanka; G = Group; kg = kilogram; NR = not reported; OTT = Overshadowing the Threat of Terrorism; RR = risk ratio; SSET = Support for Students Exposed to Trauma; TARGET = Trauma Affect Regulation: Guide for Education and Therapy; TGCT = Trauma and Grief Component Therapy.