**Evidence Table 11. Harms**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Author,  Year,  Trial Name | Re-Traumatization | Disturbed Sleep | Agitation | Sedation | Weight Gain | Other Adverse Effects |
| Ahrens, 20021  NA | NR | NR | NR | NR | NR | NR |
| Berger, 20072  OTT | NR | NR | NR | NR | NR | NR |
| Berger, 20093  ES-SL | NR | NR | NR | NR | NR | NR |
| Berkowitz, 20114  NA | NR | NR | NR | NR | NR | NR |
| Catani, 20095  NA | NR | NR | NR | NR | NR | NR |
| Ford, 20126  TARGET | NR | NR | NR | NR | NR | NR |
| Gelkopf, 20097  ERASE-Stress | NR | NR | NR | NR | NR | NR |
| Goenjian, 1997; 20058, 9  NA; NA | NR | NR | NR | NR | NR | NR |
| Jaycox, 200910  SSET | NR | NR | NR | NR | NR | NR |
| Kemp, 201011  NA | NR | NR | NR | NR | NR | NR |
| Layne,a. 200812  TGCT | NR | NR | NR | NR | NR | NR |
| Nugent, 201013  NA | 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. 201014  NA | NR | G1: 7, RR 0.81 G2: 8 | G1: 4, RR 1.85 G2: 2 | NR | Median weight did not change on Sertraline but increased 0.53 kg on placebo | Headache G1: 17, RR 1.31 G2: 12 Abdominal Pain G1: 10, RR 0.71 G2: 13 Nausea G1: 9, RR 1.39 G2: 6 Pharyngitis G1: 7, RR 1.08 G2: 6 Vomiting G1: 9, RR 2.78 G2:3  Accidental injury G1: 6, RR 0.93 G2: 6 Respiratory Tract Infection G1: 6, RR 1.39 G2: 4 Diarrhea G1: 6, RR 1.85 G2: 3 Dizziness G1: 3, RR 0.56 G2: 5 Hyperkinesis G1: 7, RR 6.48 G2: 1 Rhinitis G1: 5, RR 4.63 G2: 1 Dry Mouth G1: 5 G2: 0 Dysmenorrhea G1: 0 G2: 2 |

Evidence Table 11. Harms (continued)

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