**Evidence Table 10. Harms**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Author,  Year,  Trial Name | Overall Adverse Events | Withdrawals Due to Adverse Events | Low Adherence Due to Adverse Events | Mortality | Suicidality |
| Ahrens, 20021  NA | NR | NR | NR | NR | NR |
| Berger, 20072  OTT | NR | NR | NR | NR | NR |
| Berger, 20093  ES-SL | NR | NR | NR | NR | NR |
| Berkowitz,a. 20114  NA | NR | NR | NR | NR | NR |
| Catani, 20095  NA | NR | NR | NR | NR | NR |
| Ford, 20126  TARGET | NR | NR | NR | NR | NR |
| Gelkopf, 20097  ERASE-Stress | NR | NR | NR | NR | NR |
| Goenjian, 1997; 20058, 9  NA; NA | NR | NR | NR | NR | NR |
| Jaycox, 200910  SSET | NR | NR | NR | NR | NR |
| Kemp, 201011  NA | NR | NR | NR | NR | NR |
| Layne,b. 200812  TGCT | NR | NR | NR | NR | NR |
| Nugent, 201013  NA | NRc. | NR | G1: 5 G2: 4 | NA | NR |
| Robb,d. 201014  NA | G1: 51, RR 1.00 G2: 47 | G1: 5 G2: 2 | NR | G1: 0 G2: 0 | G1: 6 reported increased ratings, 1 reported active suicidality G2: 4 reported increased ratings, 0 reported active suicidality |
| Robert, 199915  NA | NR | NR | NR | NR | NR |
| Robert,e. 200816  NA | NR | NR | NR | NR | NR |
| Salloum,f. 200817  NA | NR | NR | NR | NR | NR |

**Evidence Table 10. Harms (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Author,  Year,  Trial Name | Overall Adverse Events | Withdrawals Due to Adverse Events | Low Adherence Due to Adverse Events | Mortality | Suicidality |
| Salloum, 201218 NA | NR | NR | NR | NR | NR |
| Smith, 200719  NA | NR | NR | NR | NR | NR |
| Stallard,g. 200625  NA | NR | NR | NR | NR | NR |
| Stein,h. 200320  NA | NR | NR | NR | NR | NR |
| Tol, 2008; 201021, 22  NA; NA | NR | NR | NR | NR | NR |
| Tol, 201223  NA | NR | NR | NR | NR | NR |
| Zehnder, 201024  NA | NR | NR | NR | NR | NR |

a. The study did not discuss harms but avoidance is stated as a potential reason for dropout; 15 participants did not return after the baseline session, 5 did not attend the final session, and 3 did not participate in the follow-up.

b. 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.

c. Harms were not actually reported specifically, higher symptoms in Girls may be harm with Propranolol, 2 in G1 were lost at 6-week follow-up and 1 in G2 were lost at 6-week follow-up.

d. 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.

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

f. 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).

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

h. 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; NR = not reported; OTT = Overshadowing the Threat of Terrorism; SSET = Support for Students Exposed to Trauma; TARGET = Trauma Affect Regulation: Guide for Education and Therapy.