|  | **Intervention 1 (N₁=29)** | | | **Control (N₂=32)** | | | **Treatment Effect Estimate (IRR)** | **95% CI** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| At least one event | Number of events | | At least one event | Number of events | |
| Body system class | N (%) | n (IR) | Mean number of events per participant (SD) | N (%) | n (IR) | Mean number of events per participant (SD) |
| Allergies | 7 (24.1%) | 14 (4.2%) | 2 (1.8) | 6 (18.8%) | 15 (5.2%) | 2.5 (2) | 0.750 | (0.356, 1.58) |
| Dermatological | 23 (79.3%) | 68 (6.1%) | 3 (1.1) | 31 (96.9%) | 89 (6.1%) | 2.9 (1.9) | 1.010 | (0.733, 1.38) |
| Eyes, ear, nose, throat | 1 (3.4%) | 1 (2.1%) | 1 (NA) | 5 (15.6%) | 6 (2.4%) | 1.2 (0.4) |  |  |
| Gastro-intestinal | 6 (20.7%) | 13 (4.5%) | 2.2 (1.5) | 7 (21.9%) | 8 (2.4%) | 1.1 (0.4) | 1.910 | (0.722, 5.06) |
| Genito-urinary | 1 (3.4%) | 1 (2.1%) | 1 (NA) | 1 (3.1%) | 1 (2.1%) | 1 (NA) |  |  |
| Haematological | 3 (10.3%) | 3 (2.0%) | 1 (0) | 3 (9.4%) | 3 (2.1%) | 1 (0) |  |  |
| Hepatic |  |  |  | 1 (3.1%) | 1 (2.1%) | 1 (NA) |  |  |
| Immunological | 1 (3.4%) | 1 (2.1%) | 1 (NA) | 1 (3.1%) | 1 (2.1%) | 1 (NA) |  |  |
| Musculo-skeletal | 1 (3.4%) | 2 (4.2%) | 2 (NA) | 4 (12.5%) | 6 (3.1%) | 1.5 (1) |  |  |
| Neurological | 4 (13.8%) | 10 (5.2%) | 2.5 (2.4) | 3 (9.4%) | 4 (2.8%) | 1.3 (0.6) |  |  |
| Other | 16 (55.2%) | 22 (2.8%) | 1.4 (0.6) | 9 (28.1%) | 12 (2.7%) | 1.3 (0.5) |  |  |
| Respiratory | 15 (51.7%) | 26 (3.5%) | 1.7 (0.8) | 25 (78.1%) | 63 (5.2%) | 2.5 (1.6) | 0.668 | (0.423, 1.06) |