

## Lenire Study Results Comparison Table

Measure	Neuromod Results	Calculation	Tinnitus Hub Results	Calculation
Sample size	326	As reported in the STM article, includes all participants who were enrolled in the trial	43	Includes all participants who took part in our Lenire User Experience Group study
% with ANY improvement in TFI score out of those who completed the 12-week program	81%	As reported in Fig. 6 B of the STM article; out of 256 participants who completed the 12-week program and provided before/after TFI data	69%	Out of 29 participants who completed the 12-week program AND filled in the before/after TFI survey, 20 participants experienced some improvement
% with clinically significant improvement in TFI score out of those who completed the 12-week program	Not reported	N/A	48%	Out of 29 participants who completed the 12-week program AND filled in the before/after TFI survey, 14 participants experienced a clinically significant improvement
% with clinically significant improvement in TFI score out of those who completed the 12-week program OR dropped out due to potential adverse events	Not reported	N/A	40%	Out of 29 participants who completed the 12-week program AND filled in the before/after TFI survey PLUS 6 dropouts due to adverse events = 35, 14 participants experienced a clinically significant improvement
% who experienced potential adverse events that entailed a worsening of tinnitus symptoms	11%	See Table 2 in STM article; we added up the # events of “moderate” increase in tinnitus symptoms that were “probably” or “possibly” device related, divided by the total number (326) enrolled in the trial.  <i>NB: This pertains to # events, not # unique individuals, so the actual % might be slightly lower</i>	8%	Out of 36 participants whom we were able to follow up with until the 12-week mark, 3 people experienced a moderate to severe worsening of their tinnitus symptoms, which caused them to abandon the treatment; we cannot be sure to what degree these events were directly attributable to the treatment  <i>NB: We were only able to record adverse events when a participant dropped out; it is possible that other unrecorded adverse events occurred</i>

<p>% who experienced potential adverse events not related to tinnitus</p>	<p>6%</p>	<p>See Table 2 in STM article; we added up the # events of “moderate” severity that were “probably” or “possibly” device related, divided by the total number (326) enrolled in the trial.</p> <p><i>NB: This pertains to # events, not # unique individuals, so the actual % might be slightly lower</i></p>	<p>8%</p>	<p>Out of 36 participants whom we were able to follow up with until the 12-week mark, 3 people experienced a non-tinnitus related adverse event (ear spasms, trigeminal neuralgia, and severe discomfort during treatment), which caused them to abandon the treatment; we cannot be sure to what degree these events were directly attributable to the treatment</p> <p><i>NB: We were only able to record adverse events when a participant dropped out; it is possible that other unrecorded adverse events occurred</i></p>
<p>Average change in TFI score among those who completed the 12-week program</p>	<p>-13.6</p>	<p>As reported in the STM article, page 6</p>	<p>-13.9</p>	<p>Average TFI change out of the 29 participants who finished the 12-week program AND filled in the before/after TFI survey</p> <p><i>NB: If we include only the 22 participants for whom we were able to verify their identity and/or their Lenire ownership, the average TFI change is only -10.4</i></p>
<p>Patient group most likely to benefit</p>	<p>Not reported</p>	<p>N/A</p>	<p>Hyperacusis + good hearing</p>	<p>See “Section 6: Statistical Analysis” of Tinnitus Hub’s full results report</p>