Lenire **User Experience Group**

TinnitusHub

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STUDY REPORT #2

Analysis of changes during treatment

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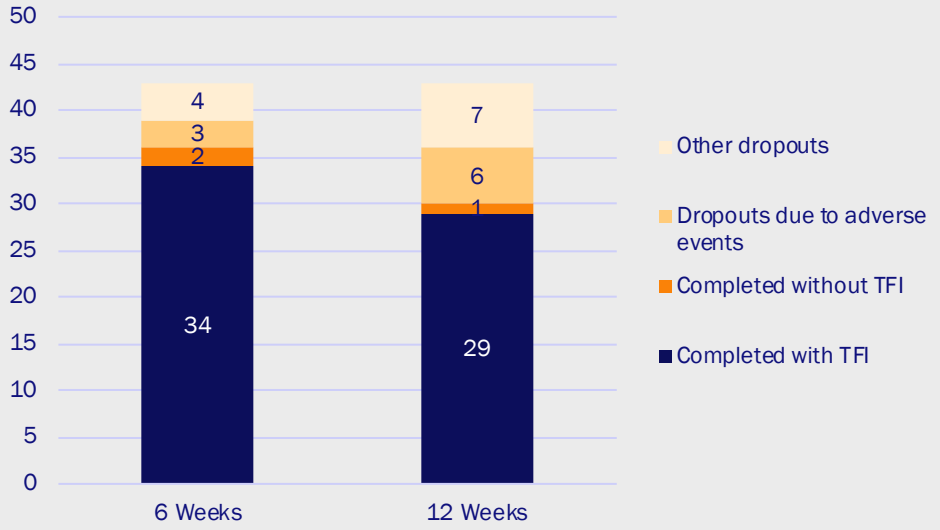
Key Findings

- Amongst those who provided it (29 of 43 patients), Tinnitus Functional Index (TFI) reduced by an **average of 13.9 points** at the 12 week milestone. This was statistically significant (p=0.001).
- **48%** of patients providing TFI experienced a **clinically significant reduction** in TFI.
- Overall, patients experienced statistically significant **improvements in self-assessed severity**.
- 14% (6 out of 43) of patients who signed up **dropped out of the study** due to adverse events. One of these cases was due to the development of trigeminal neuralgia and another was due to tinnitus becoming much worse.
- Differences between groups:
  - Patients **with hyperacusis and no hearing loss** experienced significantly greater reductions in TFI when compared with patients **without hyperacusis with hearing loss** (Delta 29.43, p=0.024).
  - Patients with **moderate hyperacusis** experienced statistically significant reductions in TFI when compared with patients with **no hyperacusis** (Delta 31.75, p=0.02).
  - Patients with **no hearing loss** experienced statistically significant reductions in TFI when compared with patients **with hearing loss** (for best ear, Delta of 17.25, p=0.019).

Completed Surveys and Dropouts

Completed Surveys at 6 and 12 Weeks



Completion Code

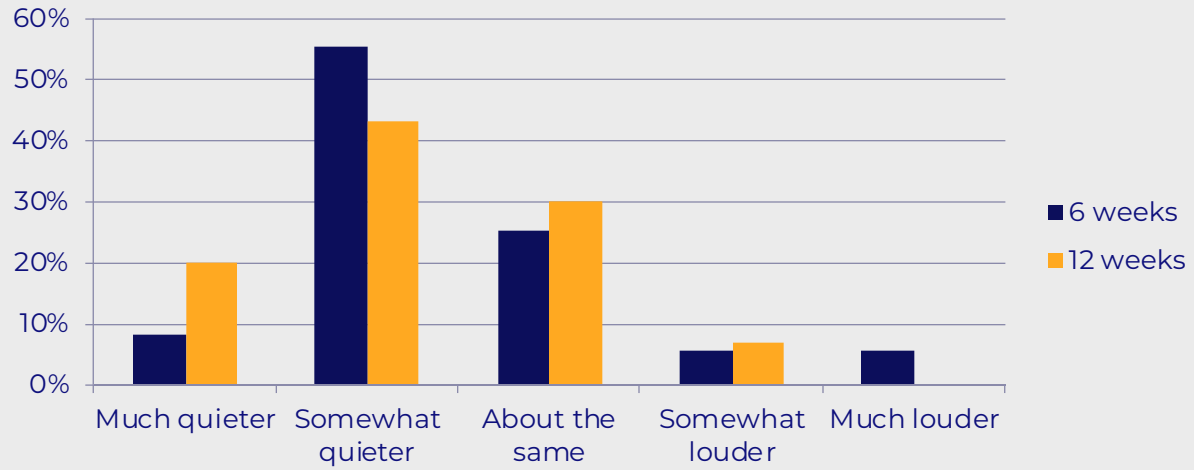
Completed successfully	30
Purchased the device, but did not proceed with treatment	1
Failed to respond at 6 week survey	3
Failed to respond at 12 week survey	1
Dropped out prior to 12 week survey due to adverse outcomes	3
Dropped out prior to 6 week survey due to adverse outcomes	3
Device failed after 6 weeks and unable to replace	1
Delayed treatment commencement, unable to complete in time	1
Totals	**43**

Symptoms (adverse outcome dropouts)	Prior to	Hyperacusis	Hearing Loss (Right)	Hearing Loss (Left)
Got a new tinnitus tone in left ear, a pulsating hiss; quit after 9 days	6 weeks	No	Mild hearing loss	Mild hearing loss
Each 30 minute session is torture so not going to use it anymore	12 weeks	Mildly	Mild hearing loss	Mild hearing loss
Developed trigeminal neuralgia and stopped using	6 weeks	Moderately	No hearing loss	No hearing loss
Stopped as tinnitus got louder; not happy with it	12 weeks	No	Mild hearing loss	Mild hearing loss
Stopped due to ear spasms	6 weeks	Mildly	No hearing loss	No hearing loss
Tinnitus got a lot worse; had to suspend treatment	12 weeks	Mildly	Mild hearing loss	Mild hearing loss

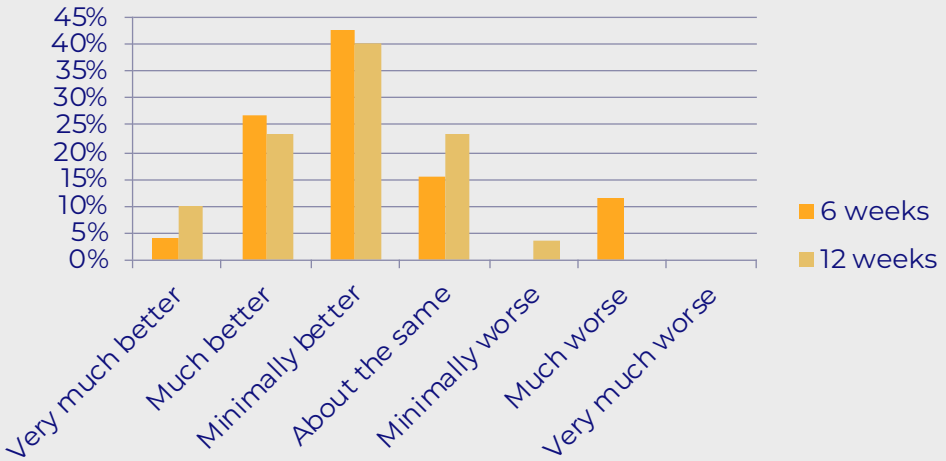
Changes in Severity, Loudness and Bothersomeness

Change in Severity at 12 weeks

Change in Loudness



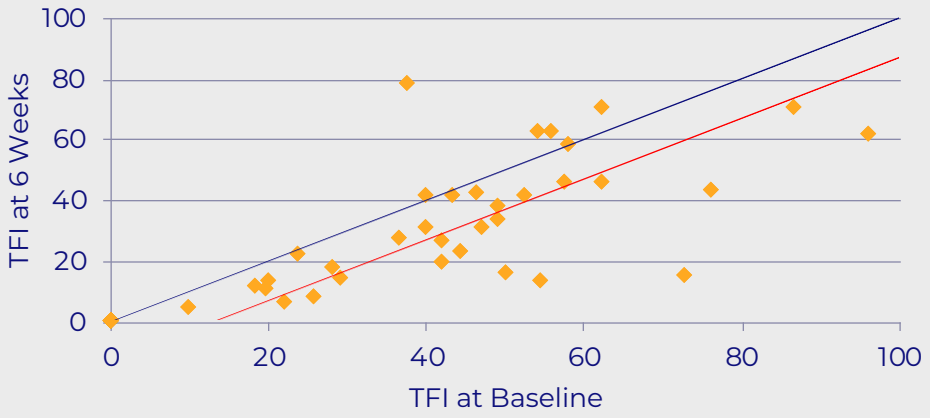
Change in Bothersomeness



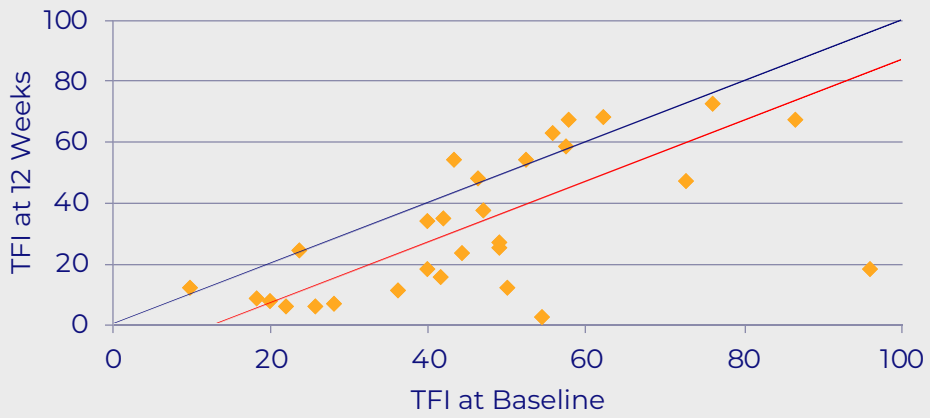
- Changes in severity 0 to 12 weeks = highly significant
  - Wilcoxon Signed Rank, p=0.001
  - Chi-Square, p=0.036

Changes in Tinnitus Functional Index (TFI)

TFI Change from 0 to 6 Weeks*

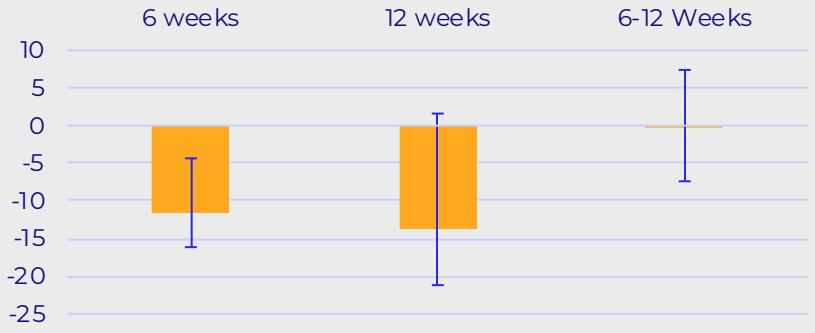


TFI Change from 0 to 12 Weeks*



**The blue diagonal line is the line of no change. The red diagonal line is the line of minimally clinically significant change. Patients below the red line have experienced a clinically significant change.*

TFI Change (All Responders)

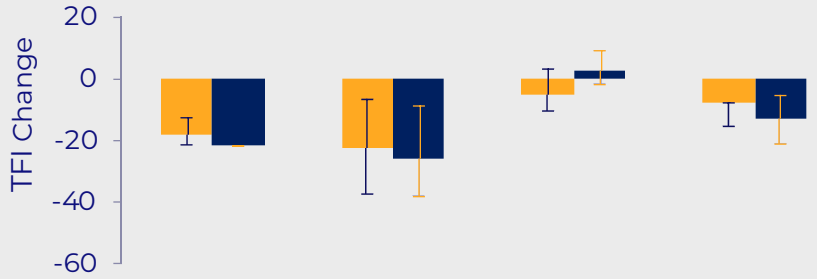


	6 Weeks	12 Weeks	6-12 Weeks
Average TFI Change	-11,52	-13,86	-0,03
Sample Size (N)	34	29	29

- TFI changes 0 to 12 weeks = highly significant
  - Student t-test: p=0.001, Delta -13.9, 95% CI [-6.5,-21.2]
- **48%** of patients providing TFI at 12 weeks experienced a **clinically significant improvement**

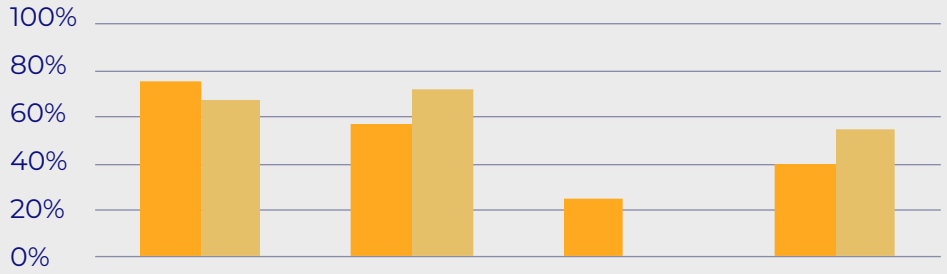
How Hyperacusis and Hearing Loss Factor Into TFI Change

Average TFI Change by Hearing Loss and Hyperacusis



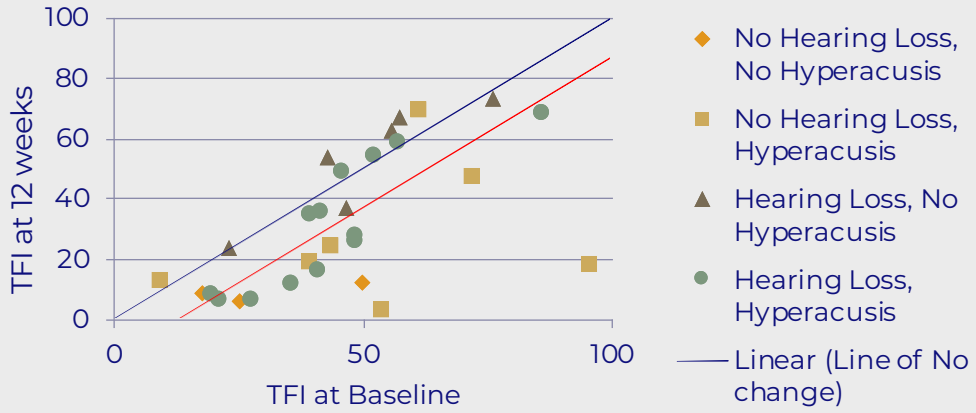
	NoHLNoHy	HyNoHL	NoHyHL	HyHL
6 Week	-18,0	-22,4	-5,2	-8,0
12 Week	-21,8	-26,5	2,8	-12,8
6 Week N	4	7	8	15
12 Week N	3	7	6	13

% With Significant Improvement by Hearing Loss and Hyperacusis



	NoHLNoHy	HyNoHL	NoHyHL	HyHL
6 Weeks	75%	57%	25%	40%
12 Weeks	67%	71%	0%	54%
6 Week N	4	7	8	15
12 Week N	3	7	6	13

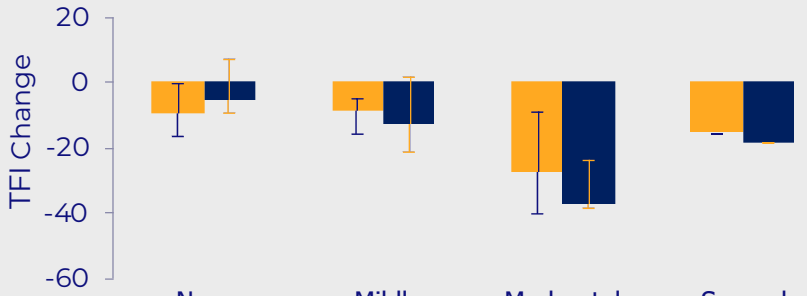
TFI Change versus Hearing Loss and Hyperacusis at 12 weeks



- Significant TFI differences between:
  - people **with hyperacusis without hearing loss (HyNoHL)**
  - versus people **without hyperacusis with hearing loss (NoHyHL)**
  - p=0.024, Delta of 29.43, 95% CI [3.18, 55.68]

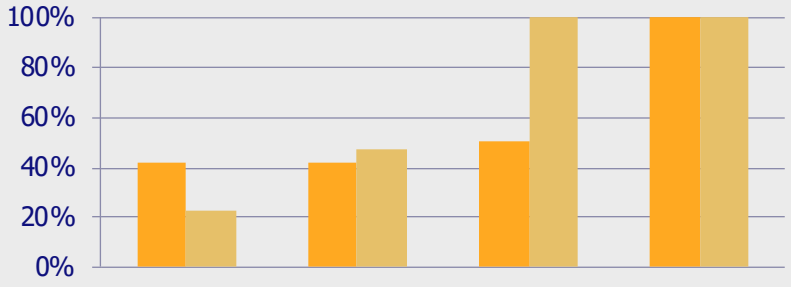
Separate Hyperacusis and Hearing Loss

Average TFI Change by Degree of Hyperacusis



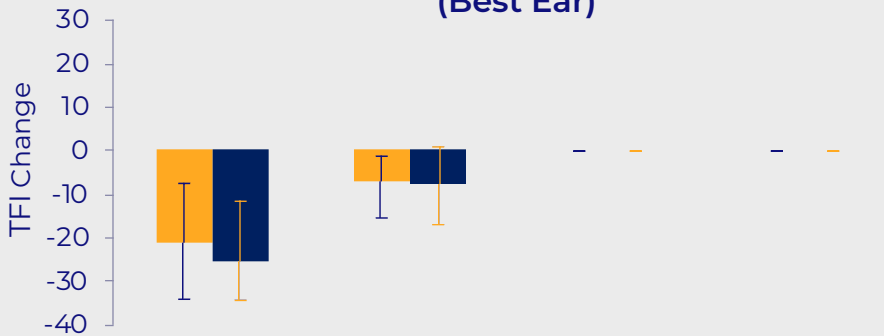
	None	Mildly	Moderately	Severely
6 Weeks	-9,5	-9,0	-27,2	-15,5
12 Weeks	-5,4	-12,4	-37,1	-18,3
6 Week N	12	17	4	1
12 Week N	9	15	4	1

% With Significant Improvement by Degree of Hyperacusis



	None	Mildly	Moderately	Severely
6 Weeks	42%	41%	50%	100%
12 Weeks	22%	47%	100%	100%
6 Week N	12	17	4	1
12 Week N	9	15	4	1

Average TFI Change versus Hearing Loss (Best Ear)



	No HL	Mild HL	Moderate HL	Severe HL
6 Weeks	-20,8	-7,0	0	0
12 Weeks	-25,1	-7,9	0	0
6 Week N	11	23	0	0
12 Week N	10	19	0	0

- Significant TFI differences between people **without hyperacusis** versus people **with moderate hyperacusis**
  - p=0.02, Delta 31.75, 95% CI [3.10, 60.39]
- Significant differences between people **without hearing loss** versus people with **mild hearing loss** (in their best ear)
  - p=0.019, Delta 17.25, 95% CI [3.08, 31.40]

Study Limitations

- Our sample size of 43 is very small. It is difficult to reach sound conclusions with the sample size.
- We had no control arm, or an arm with an alternative treatment. The placebo effect can be very strong for tinnitus sufferers, and we have not been able to control for this effect during the study.