SilentCloud - First insights from a digital therapeutic for tinnitus

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Background

- Tinnitus is a common symptom that is experienced by about 10-15% of the population[1]
- About 20% need clinical support to cope with their tinnitus[2]
- International clinical guidelines recommend cognitive-behavioral therapy (CBT) and certain sound therapies[2,3]
- Internet-based CBT showed a similar benefit to group CBT[4]
- Tonal therapy based on the acoustic-coordinated reset approach can provide a reduction of tinnitus burden[5]
- Sonova and Aureliym co-developed the SilentCloud app for tinnitus management[6]

About the SilentCloud (SC) app:
- Medical app Class IIa
- Structured self-paced management program
- Assessment of tinnitus characteristics using standardized questionnaires, pitch matching and minimum masking level testing
- Combination of education & counseling with individually tailored sound therapies and app-based CBT for tinnitus

Methods

- Pseudonymized data collected from SC users in Belgium, Italy, Netherlands, Ireland, US, and Switzerland (01/2023 to 08/2024) were analyzed
- Focus 1: treatment efficacy:
  - **Tinnitus burden reduces after completing iCBT (based on THI)**
- Focus 2: user insights:
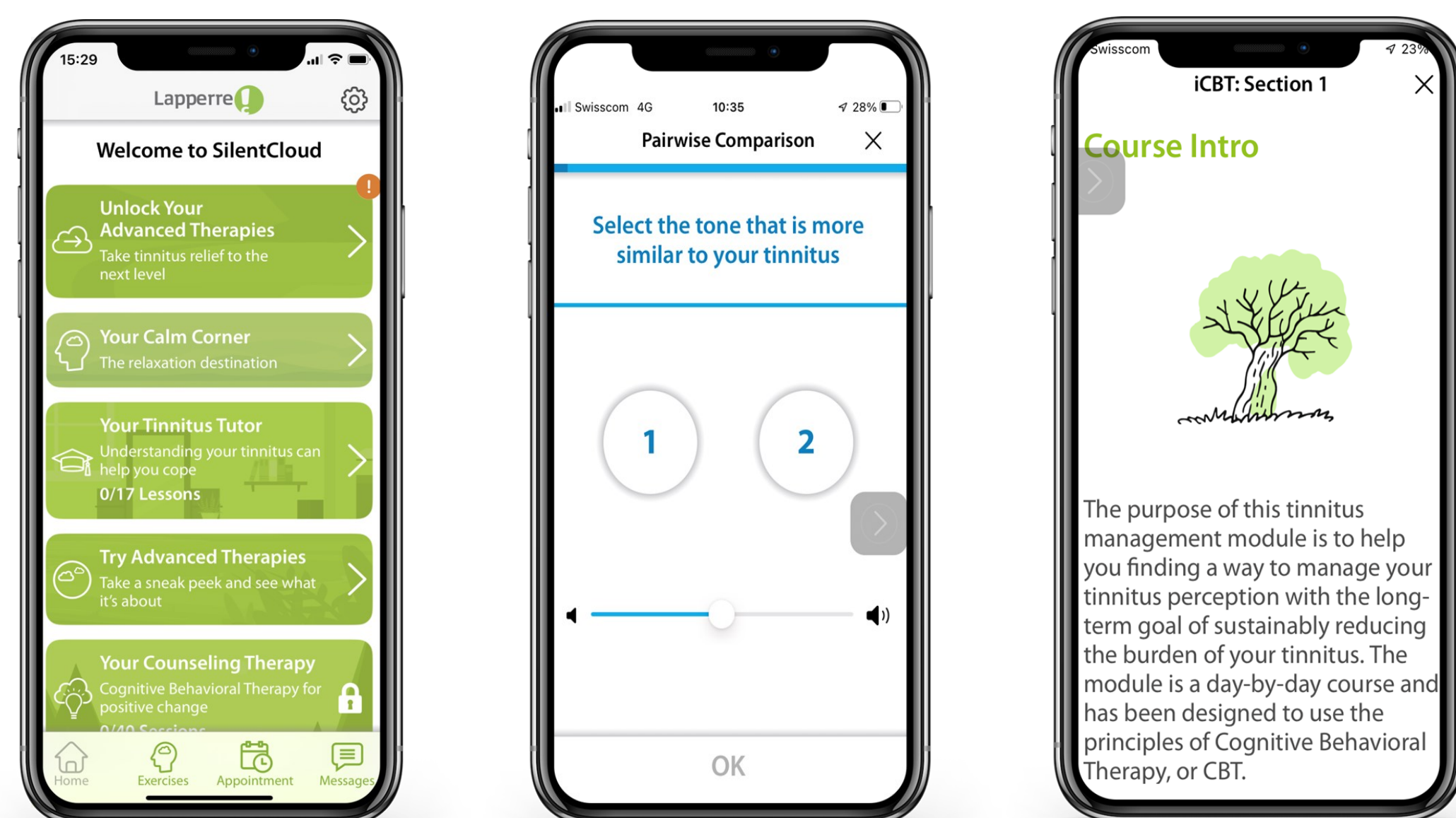 - **Can we identify patient profiles of those that complete iCBT?**

Figure 1: Screenshots of the app. Left: Home screen; middle: tinnitus pitch matching; right: iCBT screen.

*We acknowledge the contribution of Louisa Busca Grisoni who left the company in the meanwhile
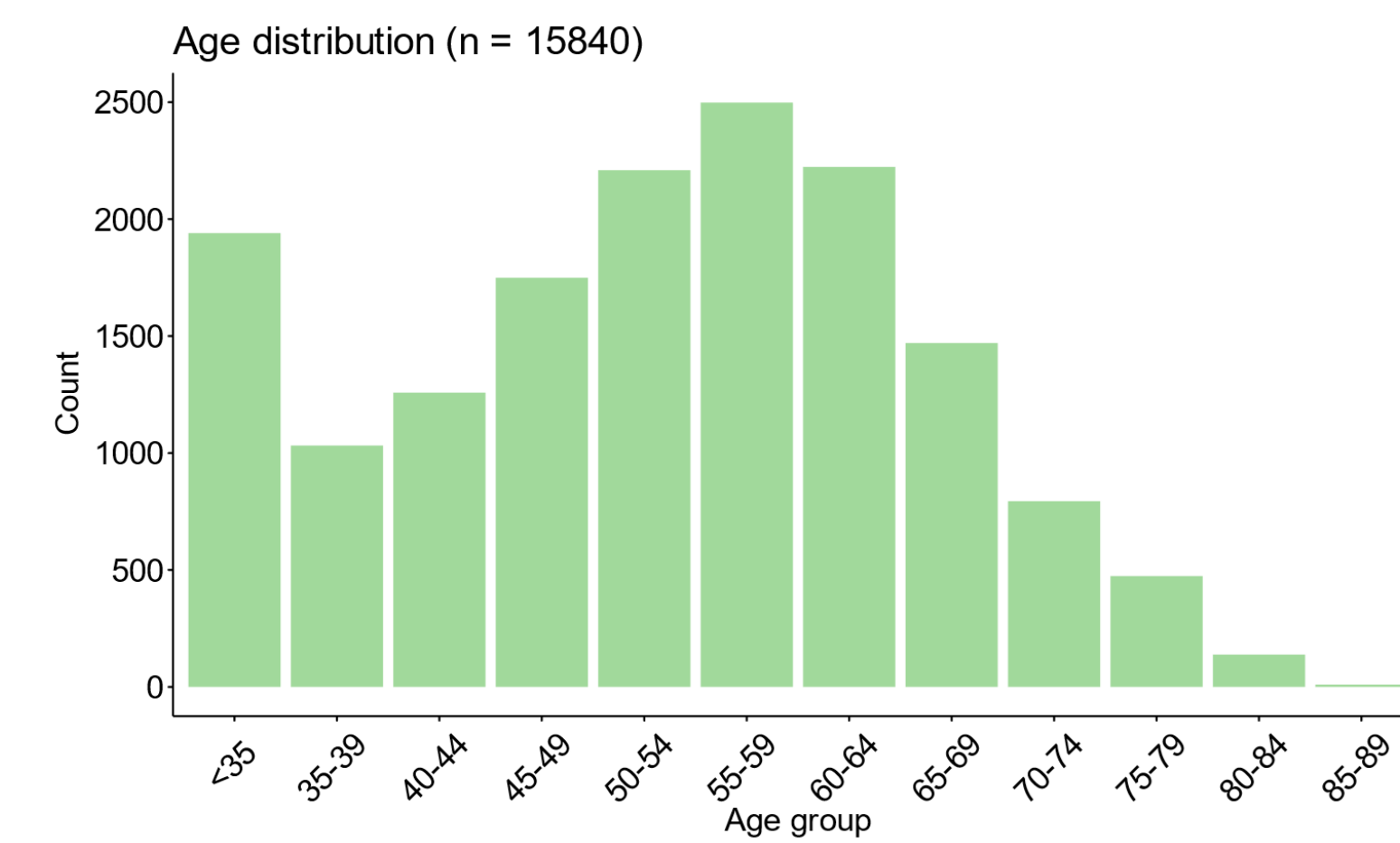
Results - User Insights

Figure 2: Distribution of age groups (n = 15840). The main age group of users is between 50 and 64 years which is slightly younger than traditional hearing impaired patients.
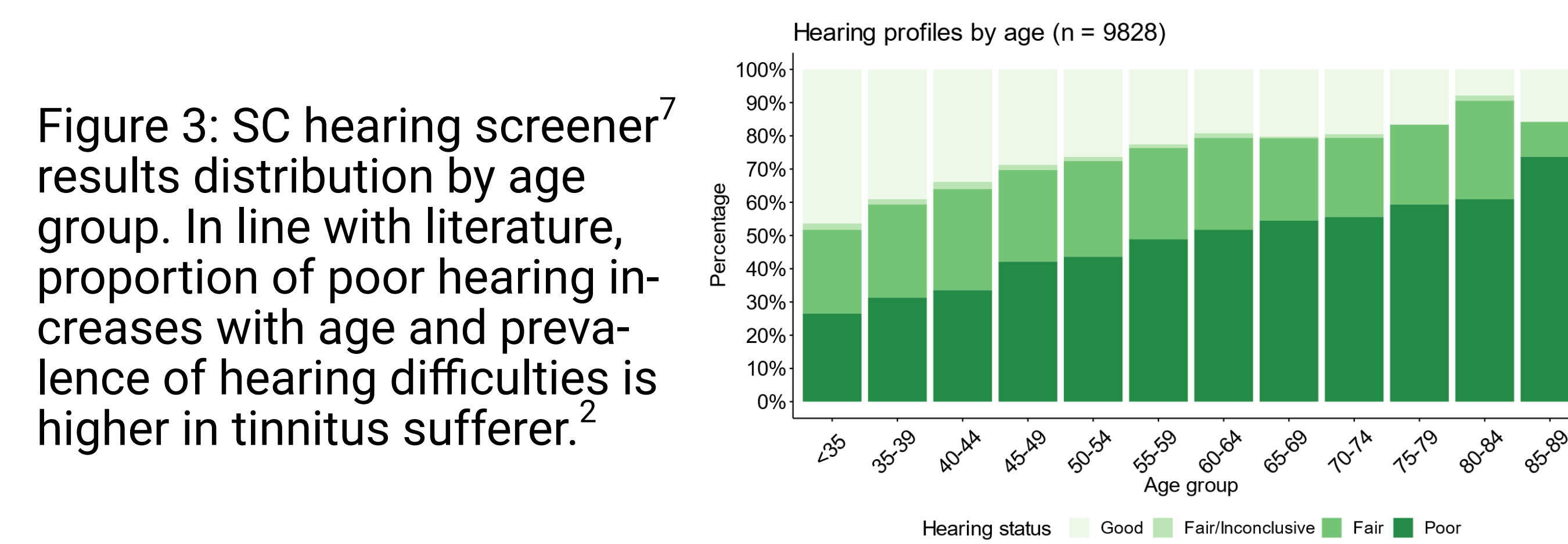

Figure 3: SC hearing screener[7] results distribution by age group. In line with literature, proportion of poor hearing increases with age and prevalence of hearing difficulties is higher in tinnitus sufferer.[2]
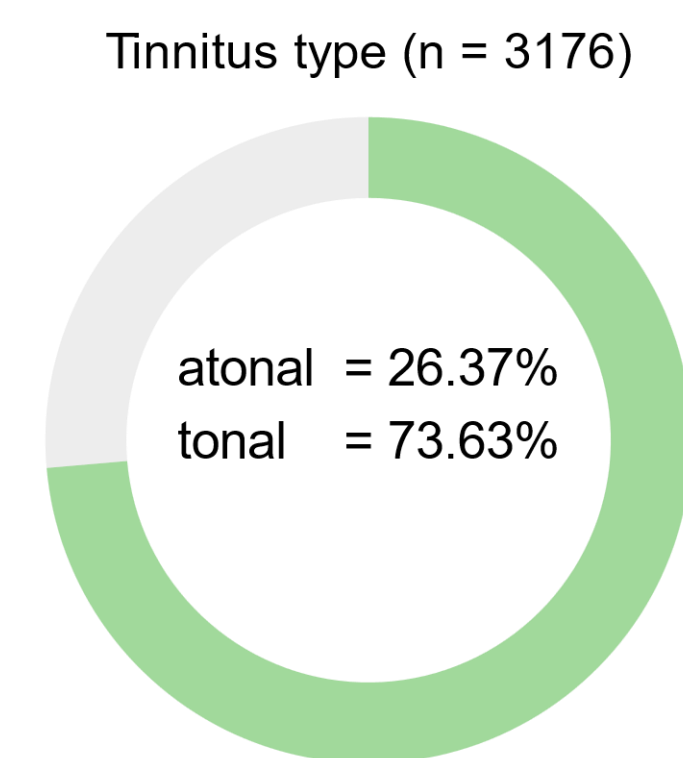

Tinnitus type (n = 3176)
atonal = 26.37%
tonal = 73.63%

Figure 4: Similar to the results from the apple hearing study with focus on tinnitus[9], the majority of SC users rate their tinnitus as tonal. The type of tinnitus defines the personalized sound therapy to be used in SC.

Figure 5: SC app gains high attraction, more than 15k users have registered. A drop-out rate along the funnel was expected but the number of people finishing the CBT program is unexpectedly low. Investigations and adoption of the app flow have been initiated.

Total registrations 15928
TSCHQ complete 12898
THI complete 12487
VAS complete 11490
HA complete 9861
HCP shop selected 6968
ENT selected 5718
EC started 2854
EC complete 674
CBT started 233
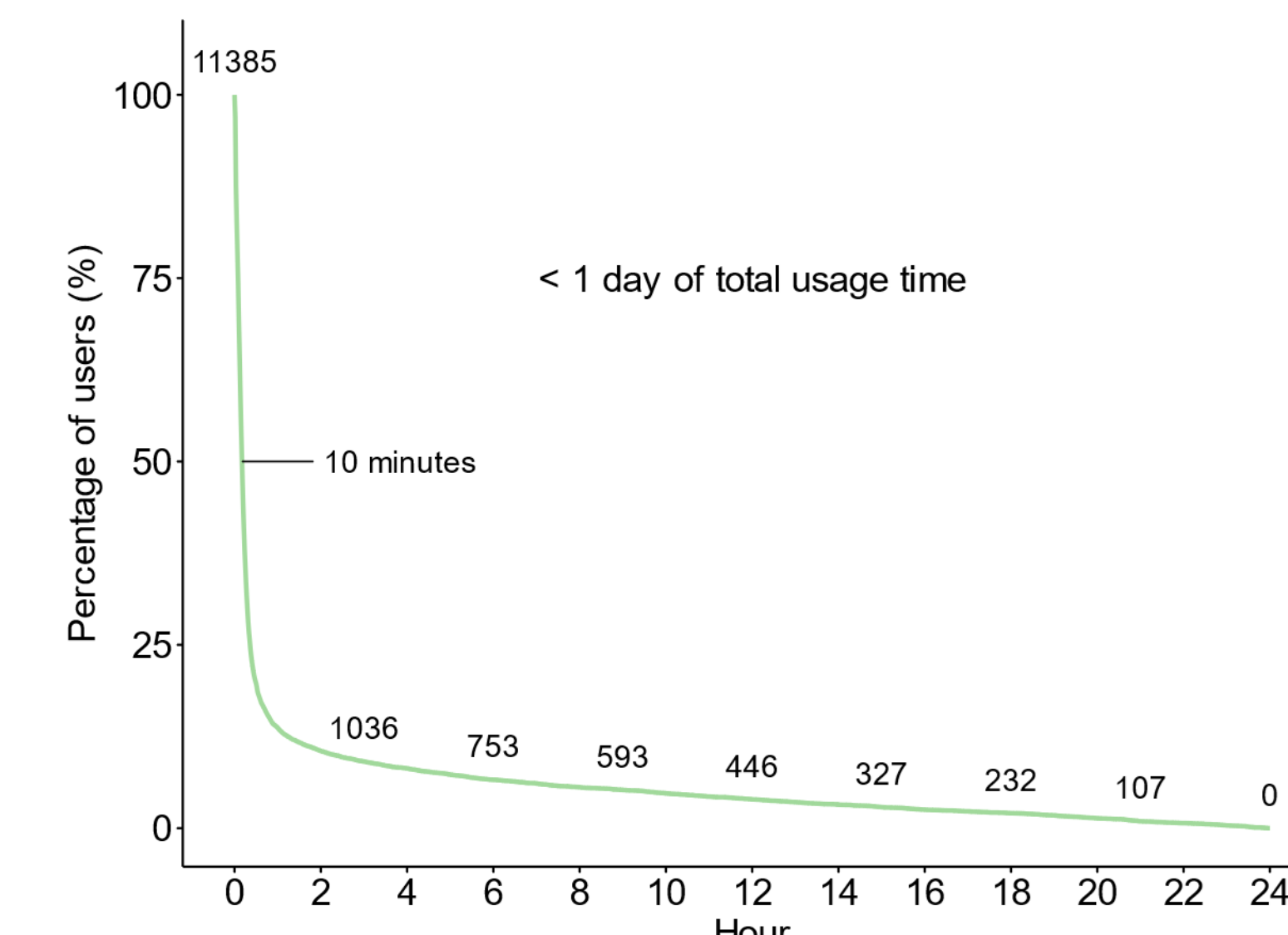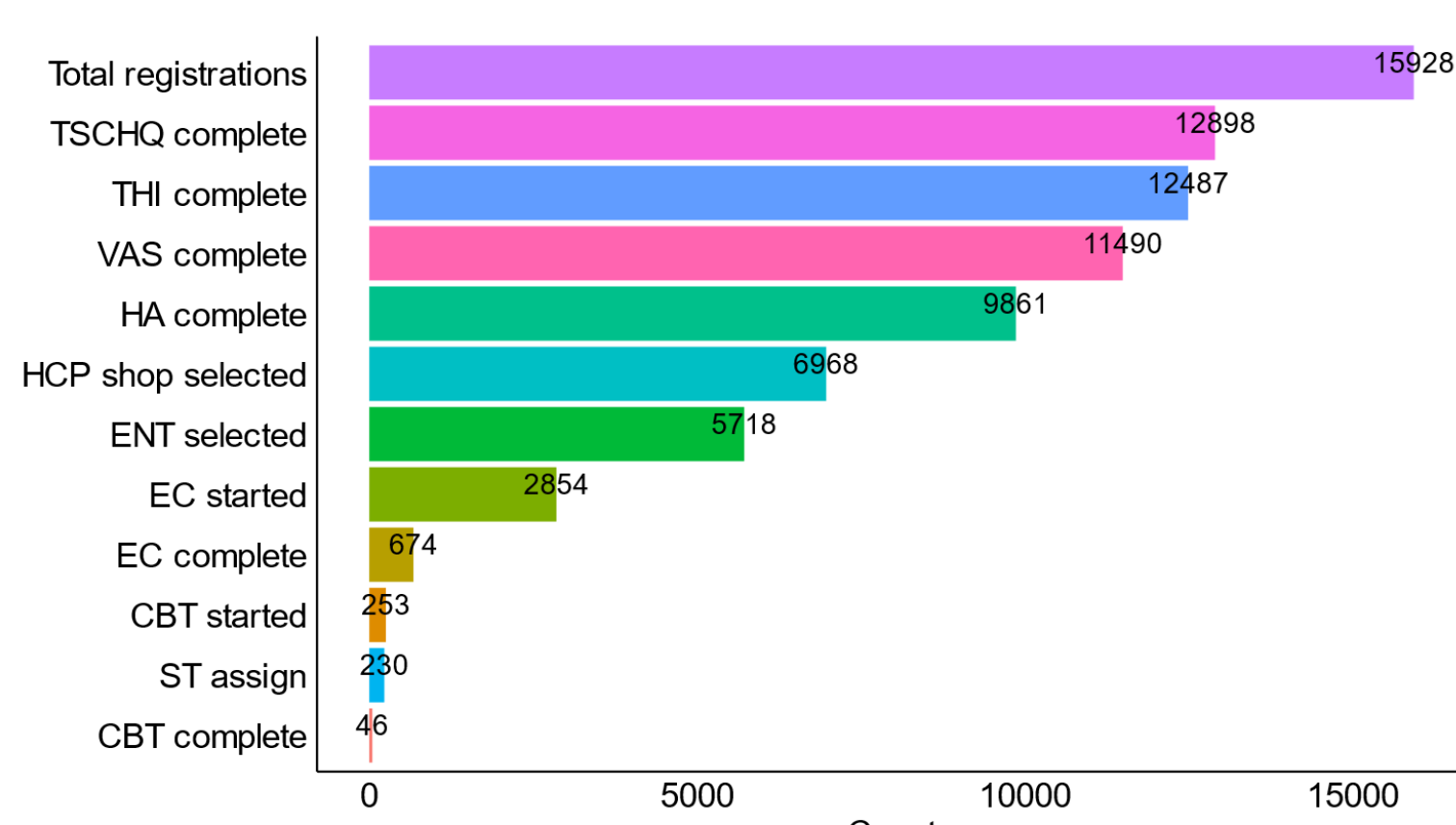ST assign 200
CBT complete 46

Figure 6: The non-adherence group data shows that about 50% of the users that use the app only on the first day are lost after 10min of use. Similar data was found for Germany, where digital health apps are reimbursed by health insurances.[8]

Results - Treatment Efficacy

THI improvement with iCBT (n = 46)
t(45.47) = -3.12, p < 0.003; Raw difference = 16.35 points
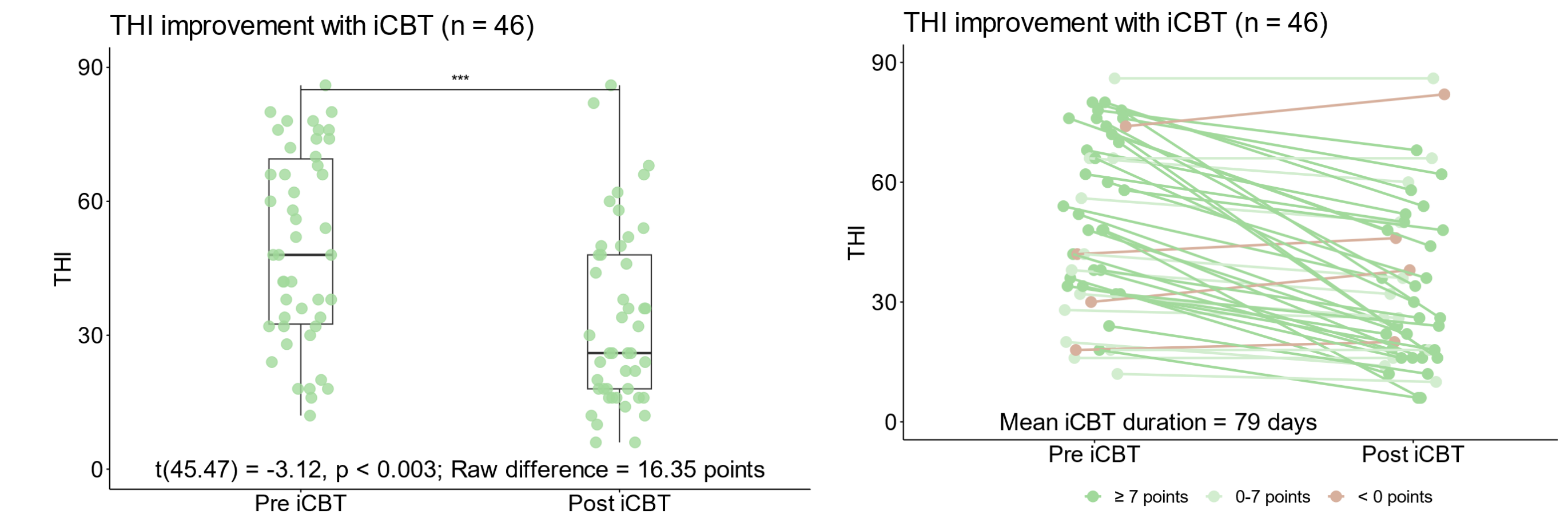Mean iCBT duration = 79 days
≥ 7 points 0-7 points < 0 points

Figure 7: n = 46 SC users completed the iCBT program. Left: the difference in tinnitus burden (THI) pre and post iCBT was significantly reduced. Right: more than half of the users have a clinically meaningful reduction in THI scores (min. 7 pts) after completing iCBT.

A. Age comparison — Welch's t-test; $t(45.47) = -3.12, p = 0.003$; No (n = 15749), Yes (n = 46)
B. THI comparison at baseline — Welch's t-test; $t(45.46) = -3.13, p = 0.003$; No (n = 12441), Yes (n = 46)
C. Do you think you have a hearing problem? iCBT completed (n = 46): no = 0.39, yes = 0.61; iCBT not completed (n = 12852): no = 0.58, yes = 0.42; 2-sample proportion test; $\chi^2(1) = 5.70, p = 0.017$
D. How many different tinnitus treatments have you undergone? No (n = 12852), Yes (n = 46); Treatments: none, one, several, many
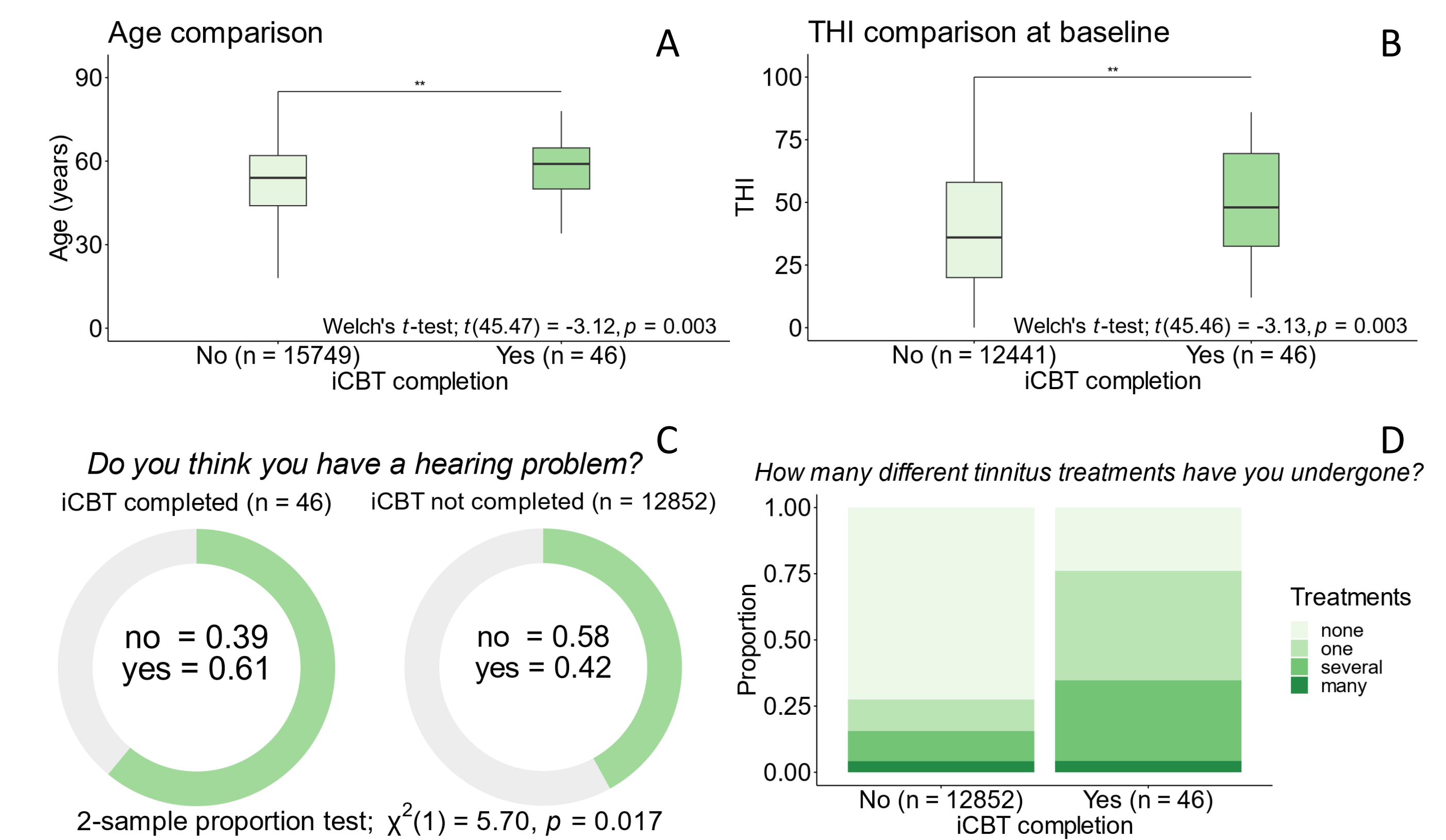
Figure 8: Individuals who complete iCBT differ from others: A) they are slightly older, B) report higher tinnitus-related distress at baseline, and C) more frequently report subjective hearing problems. D) Further explorations suggest that a higher proportion indicate that that they have already undertaken various treatments.

Conclusions

Real-world data suggest that individuals who engage in the training protocol exhibit a significant reduction in tinnitus-related distress. This underscores the potential of SC as a valuable tool in a tinnitus management plan. Nonetheless, the key factors that substantially impact adherence of app users are yet to be identified.

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