Continuous improvement of chronic tinnitus by a 9 months smartphone-based cognitive behavioral therapy: randomized controlled trial

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Uso Walter[1]; Stefan Pennig[2] Dr; Lothar Bleckmann[3]; Kristina Röschmann-Doose[4]; Thomas Wittig[4]; Jörn Thomsen[4]; Winfried Schlee[5, 6]

[1]ENT Practice Walter & Zander Duisburg DE
[2]context Essen-Kettwig DE
[3]ENT Practice Dr. med. Bleckmann Kleve DE
[4]G. Pohl-Boskamp GmbH & Co. KG Hohenlockstedt DE
[5]Eastern Switzerland University of Applied Sciences St. Gallen CH
[6]Clinic and Polyclinic for Psychiatry and Psychotherapy, University of Regensburg Regensburg DE

Corresponding Author:
Jörn Thomsen
G. Pohl-Boskamp GmbH & Co. KG
Kieler Straße 11
Hohenlockstedt
DE

Abstract

Background: Tinnitus is the perception of sound without an external auditive stimulus and can be a severe burden for affected patients. Cognitive Behavioral Therapy (CBT) is recommended by medical guidelines and effectively improves tinnitus related distress and anxiety.

Objective: The study investigated the outcome of a 9 months smartphone-based CBT in patients suffering from tinnitus.

Methods: The present randomized controlled clinical trial investigated the efficacy of a smartphone-based CBT in 187 patients suffering from chronic tinnitus over a 9-months treatment period. In the initial 3 months a waiting-list design was applied and in the subsequent study phase data of both treatment groups were collectively analyzed. Tinnitus Questionnaire (TQ), Patients Health Questionnaire (PHQ9), Self-Efficacy-Optimism-Pessimism (SWOP-K9), and Perceived-Stress-Questionnaire (PSQ20) were assessed as endpoints after 3 and 9 months of treatment.

Results: Following the app-based CBT, the TQ sum scores were significantly reduced, indicating a significant decrease of tinnitus-related distress. The calculated Cohen's d was 1.38 and the observed improvement also exceeded the minimal clinically important difference.
Similarly, all other parameters PSQ20 (-9.14 points), PHQ9 (-2.47 points) and SWOP-K9 (0.17 points) were significantly improved at the end of therapy with corresponding intermediate effect sizes after 9 months. The study revealed a significant reduction of tinnitus burden in patients who received a smartphone-based CBT. TQ was reduced by 12.49 ± 1.44 and 18.48 ± 1.85 points after 3 and 9 months, respectively, whereby the improvement was clinically important.

Conclusions: The data provide evidence of a substantial and continuous benefit of CBT in patients suffering from chronic tinnitus. Clinical Trial: DRKS-ID: DRKS00022973

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Author Summary

[1]Uso Walter, [2]Dr. Stefan Pennig, [3]Lothar Bleckmann, [4]Kristina Röschmann-Doose, [4]Thomas Wittig, [4]Jörn Thomsen, [5,6]Winfried Schlee

[1]ENT Practice Walter & Zander, Duisburg, and mynoise GmbH, Duisburg, Germany, [2]context, Essen-Kettwig, Germany, [3]ENT Practice Dr. med. Bleckmann, Kleve, Germany, [4]G. Pohl-Boskamp GmbH & Co. KG, Hohenlockstedt, Germany, [5]Eastern Switzerland University of Applied Sciences, St. Gallen, Switzerland, [6]Clinic and Polyclinic for Psychiatry and Psychotherapy, University of Regensburg, Germany

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Conclusion:

The data provide evidence of a substantial and continuous benefit of CBT in patients suffering from chronic tinnitus.

Introduction

Subjective tinnitus is the perception of sound without an external stimulus. Its total prevalence

among adults is about 14 % which is independent of sex but increases with age and is considered severe in about 2.3 % of affected patients (1). How the burden is perceived differs substantially depending on the characteristics and severity of tinnitus or accompanying co-morbidities and may affect the quality of life substantially. The multifaceted nature of tinnitus and its purely subjective valuation and accompanying co-morbidities make the treatment challenging. Highly diverse treatment options have been developed which may, however, be effective only in a certain subset of patients (2). Treatment may also target not tinnitus itself but co-morbidities (e.g. hearing loss, depression) with secondary beneficial effects on the patients' tinnitus (3, 4).

In patients with tinnitus resulting from hearing impairment, cochlear implants and hearing aids can significantly improve tinnitus although variable methodologies applied in clinical trials complicate comparisons between the studies (5, 6).
Despite short-term benefits from e.g. intravenous application of lidocaine in some patients, no superiority compared to placebo was observed for commonly prescribed drugs like betahistine or dexamethasone and currently no medicinal products are approved for treatment of chronic tinnitus (3, 7). In contrast, pharmacological treatment may be required for co-morbidities like depressions or anxieties.
A number of therapeutic options have been developed for symptomatic treatment in patients without causative organic dysfunction or unsuccessful treatment. However, clinical evidence for treatments like transcranial electric or vagus nerve stimulation, sound therapy or tinnitus retraining therapy is scarce and evaluation of the efficacy in guidelines is ambiguous (5).
Among current symptomatic treatment options cognitive behavioral therapy (CBT) has the highest clinical evidence compared to other treatment approaches. Its validity has been confirmed in several studies and clinical guidelines recommend CBT for symptomatic treatment (8, 9). Whereby it does not target the tinnitus characteristics (e.g. loudness) it focuses on perception and acceptance by the patients and thereby improves their quality of life and co-morbidities.
In recent years, app- or internet-based telemedicine has become a promising treatment alternative to conventional therapies. Application of CBT both guided or non-guided by a psychologist or audiologist is predestinated for remote therapy and its efficacy to reduce the distress resulting from tinnitus has been proven over the years (10, 11). Nevertheless, more clinical trials are needed to strengthening the clinical evidence and research continues (11).

The present randomized controlled clinical trial investigated the long-term efficacy of an app-based CBT. The primary endpoint was the difference of the tinnitus questionnaire (TQ) between patients who started CBT treatment without delay (group 1) and a waiting list control group (group 2) after 3 months and the results have been previously published (12). The baseline score of patients of group 1 using the app improved from 39.7 by 13.4 points but remained largely unchanged (0.6 score points) in group 2. Following the 3-months waiting period, patients of group 2 received the CBT-app as well and patients of both groups continued treatment for a total duration of 9 months when final assessments of tinnitus severity (TQ score) as well as stress perception (PSQ20), depression (PHQ9), and self-efficacy (SWOP K9) were performed. This publication presents the long-term results of the full 9-months treatment period from patients of both groups.

Material and Methods

The present longitudinal analysis represents the outcome of the full 9-month treatment period using a CBT app, marketed under the name Kalmeda. The outcome of the initial 3-months period has been previously published (12).

Legal framework and patients

The clinical investigation plan was prospectively approved by the Ethics Committee Nordrhein, Germany on May 20, 2020 (case number 2020026), followed the ISO 14155 norm (Clinical investigation of medical devices for human subjects — Good clinical practice) the study was registered in the German Clinical Trials Register (DRKS-ID: DRKS00022973) and conducted in two ENT centers in North Rhine Westphalia, Germany. Recruitment lasted from August 2020 to March 2021.

All patients fulfilled the inclusion criteria age ≥ 18 and chronic subjective tinnitus of more than 3 months' duration and not the exclusion criterium diagnosed acute or chronic mental illness. All patients signed an informed consent from prior to randomization to one of the treatment arms. The intervention group started using the app immediately after inclusion for a total of 9 months, while in the control group treatment commenced after a 3-months waiting period.

Kalmeda Tinnitus app, associated regulations and study design

The present study investigated the efficacy of the Kalmeda app in treatment of tinnitus. The app follows principles of cognitive behavioral therapy (CBT), a self-help format following the Zürcher Ressourcen Modell ZRM (motivational psychology) and acceptance and commitment therapy (ACT) for tinnitus (13). The Kalmeda app was developed by the mynoise GmbH and is a CE marketed medical device since 2019 (DIMDI registration number: DE/CA20/mynoise_01/18). During the study software version 1.5.1 was used.

The app has 5 levels with 9 steps each. The first two levels of the behavioral therapy are typically accomplished within 3 months and the subsequent levels in not less than 7 months.

Efficacy was assessed in a randomized control clinical trial applying a waiting group design.

Patients were randomized to the two trial arms in blocks of 6 in order of their appearance. While the patients of group 1 started CBT immediately following randomization at T0 individuals of group 2 postponed treatment and began with the 3 months waiting period (Figure 1). In both groups efficacy of CBT was assessed after 3 and 9 months of treatment in comparison to baseline. Thus, the total study duration of patients of group 1 and 2 was 9 and 12 months, respectively. Efficacy endpoints were the changes of tinnitus severity (tinnitus questionnaire (TQ) sum score, (14), and depression (PHQ9, (15)), stress perception (PSQ20, (16) and self-efficacy (SWOP K9, (17)) using validated questionnaires. The severity of tinnitus is evaluated according to four categorizes (<30, 31-46, 47-59 and 60-84) from mild to very severe whereby it is considered as uncompensated for TQ scores ≥47 (14).

Once the 3-months waiting period of the control group ended and CBT was initiated, TQ sum scores significantly improved in individuals of the control group to a similar extend when compared to intervention group. As data from baseline and after 3 and 9 months of treatment did not differ significantly between groups, the data for all patients using the app were pooled for the current

analysis for further analysis and evaluated collectively, independent from initial randomization into group 1 or 2.

Statistical analysis

Sample size calculation were based on an effect size of 0.5 and a power of 0.8 using a two-sided t-test with α-level of .05. This agreed to a sample size of 64 per group or 128 patients in total. Considering a drop-out rate of 15% a total of at least 150 patients needed to be enrolled. All statistical analyses were performed with SAS 9.4.

The primary statistical analysis was performed applying analysis of covariance (ANCOVA). Missing data were imputed using reference based multiple imputations. Robustness was verified with a sensitivity analysis using a completer data set which encompassed only individuals without any missing answers in particular questionnaires over the whole period, thus the numbers of completers vary between the different endpoints (TQ: n = 88; PHQ9: n = 86; PSQ20: n = 86; SWOP K9: n = 91). The outcomes were analyzed in comparison to baseline using t-test.

Distribution of demographic and clinical characteristics of both groups at baseline were tested using nonparametric (Mann-Whitney test, Chi^2) or parametric analyses (t-test).

Frequency changes of tinnitus severity categories was analyzed using Chi^2-tests.

Values in the text are mean ± 95% confidence interval.

Results

Patient demographics and disposition

A total of 187 patients were randomized in blocks of 6 to group 1 or 2 (Table 1). Group 1 started using the app immediately after randomization whereas patients in group 2 were assigned to a 3-months waiting period before treatment commenced. In group 1, 53 patients completed the treatment. In group 2, 42 patients completed the treatment. Thus, a total of 95 patients completed the study after 9 treatment months, respectively (Figure 2).

At baseline groups 1 and 2 did not differ with regard to mean age (48.2 ± 12.5 years), sex ratio (97 males (51.9 %), 90 females (48.1 %) and mean duration of tinnitus (6.57 ± 6.93 years).

The mean duration of app-based therapy was comparable in both study arms and was 99.3 ± 14.4 and 288.1 ± 29.0 days for the 3- and 9-months treatment period, respectively.

Table 1: Demographic and clinical characteristics of the participants at baseline. Tinnitus distress was measured with the Tinnitus Questionnaire (TQ) as primary outcome. Secondary outcomes were measured with the Perceived Stress Score (PSQ29), Patient Health Score (PHQ9), and Self-Efficacy-Optimism-Pessimism (SWOP-K9) questionnaires.

	Group 1	**Group 2**	**Statistical Test**
Participants [n]	94	93	
Males [n (%)]	45 (47.9%)	52 (55.9%)	Chi^2-test: $P = 0.2711$
Females [n (%)]	49 (52.1%)	41 (44.1%)	

	Group 1	Group 2	Statistical Test
Age mean ± SD (range)	48.1 ± 12.8 (22-72)	48.4 ± 12.2 (21-74)	t-test: *P* = .86
Tinnitus Duration in years mean ± SD (range)	6.21 ± 6.62 (0.33-28)	6.94 ± 7.25 (0.25-31)	U-test: *P* = .79
TQ sum score: mean ± SD; (range)	39.65 ± 15.08 (12-73)	38.30 ± 15.10 (9-76)	t-test: *P* = .54
PSQ20 mean ± SD (range)	46.9 ± 17.6 (11.7-95)	45.1 ± 18.9 (11.7-83.3)	t-test: *P* = .51
PHQ9 score mean ± SD (range)	8.31 ± 3.89 (2-19)	7.53 ± 4.21 (0-21)	t-test: *P* = .19
SWO9 K9 mean ± SD (range)	2.76 ± 0.45 (1.8-4)	32.75 ± 0.52 (1.4-3.8)	t-test: *P* = .92

App-based CBT significantly improved the subjective tinnitus burden as assessed by TQ sum scores in patients of both study arms after 3- and 9-months treatment whereas the TQ score of patients of group 2 did not improve during waiting period (Table 2, Figure 3). During treatment, TQ sum scores of completers declined significantly from 37.27 ± 2.86 at baseline to 23.99 ± 2.86 (t-test: 10.8, *P* <.001) and 18.73 ± 2.43 (t-test: 13.0, *P* <.001) after 3 and 9 months of treatment, respectively. In agreement, imputation of missing data using MI, resulted in initial TQ sum scores of 38.46 ± 2.30 which improved to 25.97 ± 2.09 after 3 months and to 19.98 ± 1.39 after 9 months of CBT in the analysis of completed courses corresponding to a total improvement of 12.49 ± 1.44 (*P* <.001) after 3 months and 18.48 ± 1.85 (*P* <.001) after 9 months score points during therapy for all patients (Table 3). Thus, the prolonged treatment period of another 6 months resulted in a further and significant decrease of TQ.

Table 2: TQ sum score of completers at begin of the waiting period (group 2 only), begin of treatment and after 3 and 9 months of treatment Mean ± 95% confidence interval.

Time point of assessments	group 1 N = 51	group 2 N = 37
Begin of waiting period		37.8 ± 4.7
Begin of treatment	37.1 ± 3.7	37.5 ± 4.8
3 Months	23.4 ± 3.3	24.8 ± 5.2
9 Months	17.6 ± 2.9	20.3 ± 4.3

Table 3: ANCOVA of treatment difference compared to baseline of TQ sum score after multiple imputation 3 and 9 months after begin of treatment

Parameter	Estimate	Standard Error	*P* -value	95% confidence interval	
				Lower limit	Upper limit
Intercept	-0.99	2.00	.62	-4.94	2.94
ΔM3 (M3 – baseline)	-12.49	0.84	<.001	-14.14	-10.84
ΔM9 (M9 – baseline)	-18.48	1.08	<.001	-20.63	-16.33
Baseline	-0.45	0.05	<.001	-0.55	-0.35
ΔM9 - ΔM3	-5.99	1.16	<.001	-8.28	-3.70

The calculated effect size Cohen's d was 1.15 and 1.38 after 3- and 9-months therapy, corresponding to a strong effect whereby improvement correlated with initial severity being much more pronounced in patients severely affected by tinnitus.
The improvement of mean TQ sum score was accompanied by significant reductions of the incidence of uncompensated tinnitus (TQ sum score ≥ 47). Among completers the number of patients with uncompensated tinnitus was reduced from initial 22 to 7 after 3 months (Chi^2: 9.3, P <.01) and only 1 after 9 months of treatment (Chi^2: 22.1, P <.001). No very severe cases were remaining but patients had improved to lower severity categories. In agreement, the number of patients characterized by "mild" tinnitus severity (TQ ≤ 30) increased from 25 at baseline to 63 and 73 after 3 and 9 months, respectively (Chi^2: 32.8 and 53.1; P <.001).
68 % and 80 % of completers were considered as treatment responders as their TQ sum score improved by more than the Minimal Clinical Important Difference (MCID) of 6.65 following 3- and 9-months therapy, respectively.

Aside from TQ sum score the secondary parameters stress, depression and self-efficacy were assessed.
Beneficial effects of app-based CBT were observed for PSQ20 over the whole treatment period. Significant reductions became evident already after 3 months (-4.62 points) and the score improved even further by -9.14 after 9 months of treatment (ANCOVA, P <.001). Similar significant changes (-5.66 and -9.55) were present in the completer data after 3 and 9 months as well (t-test, P <.001). The effect sizes were 0.45 after 3 and 0.60 after 9 months CBT, thus the initially small effect became intermediate in the second treatment phase.

The PHQ9 as a measure of depression severity decreased significantly by 1.40 and 2.47 points (ANCOVA, P <.001) after 3 and 9 months, respectively, as evaluated by using multiple imputation. The sensitivity analysis using the completer data set yielded comparable significant results starting with 7.77 ± 0.86 at baseline and lower value of 6.29 ± 0.75 and 5.42 ± 0.66 following treatment (t-test, P <.001). Corresponding effect sizes were 0.52 and 0.68 after 3- and 9-months representing intermediate effects. Changes of TQ and PHQ9 were correlated after 3- (r = 0.43) and 9- (r = 0.51) months of therapy.

Self-efficacy was assessed using SWOP K9. Imputed data revealed no significant improvement after 3 months (0.04, ANCOVA P = .1647), but after 9 months of treatment (0.17, ANCOVA P <.001). Completers were characterized by mean baseline values of 2.77 ± 0.51. While no significant improvement was evident after 3 months (2.78 ± 0.54, t-test P=.75), significantly higher values of 2.95 ± 0.47 were obtained after 9 months (t-test, P <.001). The 9-months effect size was 0.5 corresponding to an intermediate effect.

No adverse events were reported during this clinical study.

Discussion

The present publication reports the outcome of the total 9-months treatment period of an app-base

CBT for chronic tinnitus. It is a follow-up to the previously published data of the initial 3-months treatment period (12).

Principal results

The 9-months data confirm the highly beneficial improvement of the tinnitus burden by CBT using the Kalmeda app. Within 3 months of treatment, the TQ sum score improved significantly. There are currently two studies on the MCID of the TQ available: Adamchic and colleagues reported a MCID of 5 points (18); Hall and colleagues reported a MCID of 12 points (19). After 3 months of treatments, the average improvement of the online CBT therapy surpassed both thresholds and during the long-term treatment, tinnitus symptoms continued to improve even further leading to an additional decrease by 5.99 points of the TQ score. Importantly, as perceived improvement of tinnitus is independent of the duration of treatment but depends on baseline value, it is smaller in patients with lower initial burden. The MCID for mild tinnitus (TQ ≤ 30) corresponds to 3.17, thus is much lower than the mean value of both MCID criteria (18, 19). After the first 3 months treatment period, patients were characterized by mean TQ scores of 23.99, thus it is likely that further amelioration of their tinnitus symptoms experienced during the complete 9-months treatment is considered clinically relevant.

The comparison of active treatment to a waiting list control group is a common study design, yet, assessment of the long-term outcome is difficult once the control group receives the same treatment. In the present trial, efficacy of CBT was compared to the waiting-list control group which remained largely unchanged during the initial 3-months period but no control group was present during the full 9-months treatment period (12). In order to compensate for the lack of an internal control, treatment efficacy in the present study is compared to the outcome of untreated control groups in randomized clinical trials with comparable duration. Few studies report TQ sum scores in patients not receiving an adequate treatment over several months.

In a randomized trial testing the efficacy of tinnitus retraining therapy, no improvement was observed for patients from a waiting list control group after 12 months (20). No improvement but a tendency of worsened symptoms was observed for patients of the waiting list control over a period of 6 months (21). In patients receiving no treatment the Tinnitus Severity Index was largely unchanged after 6 and 12 months corresponding to an effect size of 0.0 and 0.1 (22).

In patients of the waiting list during a 24 weeks trial, improvement of the TQ sum score corresponded to an estimated effect size below 0.4 (23).

Summarizing the evidence from literature suggests only minor changes of tinnitus severity in untreated controls and a maximum effect size up to 0.4 corresponding to at most a small effect according to the definition by Cohen (24). In comparison, the effect size of the app-based CBT group was 1.15 after 3 months and increased even further to 1.38 after 9 months of therapy. Thus, long-term app-based CBT in this trial resulted in a pronounced improvement which not only exceeded the expected outcome in absence of any treatment by far but also that of the respective treatments applied in studies of comparable length.

Dropouts can be a problem for the outcome of clinical trials, in the present trial, 12.8 % of all patients stopped participation during the initial 3 months period until the primary endpoint was

reached. In the following study period from 3 to 9 months, dropout rates increased resulting in a total loss of follow-up of 52.9 %. A comparable rate of 51 % was reported in a previous study applying CBT in tinnitus (10). In general, dropout rates in studies using app-based treatments (~43 %) often exceed rates common for studies applying in-person treatment (25). However, despite the risk of therapy attrition, there are also advantages of treatment apps is, e.g. they are readily available without extended waiting period, they can be used 24/7, and they are available even in remote areas.
Improvement of tinnitus related distress within the first 3 months of CBT did not differ between drop outs and completers suggesting that the decision to stop treatment was not based on treatment success or failure. Likely responders reaching acceptable levels of tinnitus or patients disappointed from treatment equally ended participation prematurely as no further information on reasons for dropouts were given. The same may apply during the second study phase whereby, however, the pronounced increase in dropout suggests that the long study duration might have contributed to premature terminations as well. This is supported by the higher dropout rate of patients from the waiting list control group (54.8 %) whose involvement into the trial lasted for a full year when compared with the intervention group (43.6 %) who finished treatment 3 months earlier.
Tinnitus patient are often characterized by elevated depression and stress perception, which was measured with the PHQ-9 as well as PSQ20 in our study (26, 27). Following the 3-months treatment, PHQ-9 and PSQ20 measures had significantly improved. Both parameters decreased even further during the prolonged treatment. As suggested by Wallhauser-Franke and colleagues (28), the measures of tinnitus loudness and tinnitus distress need to be distinguished. The here reported app-based CBT does not improve perception of tinnitus loudness but significantly reduced tinnitus distress. Improvement of PHQ-9 and PSQ20 questionnaires after CBT therefore are in parallel to the observed reduction of the TQ sum score observed after 3 and 9 months of treatment.
In contrast to the two previous secondary endpoints, self-efficacy assed by SWOP-K9 was almost unchanged following 3 months of CBT but a significant improvement was evident after 9 months. This highlights the importance of a prolonged treatment beyond the initial 3 months period leading to an improvement of tinnitus burden on all tested scales.

Limitations

This study has limitations. The waiting list design allows an accurate quantification of treatment effects of CBT in comparison with the untreated control, but lacks an internal control for the whole 9 months treatment period. Thus, superiority of treatment had to be verified by comparison to studies in this indication with comparable duration.
The tinnitus distress of the included study participants was assessed with an average TQ sum score of 39.6. in group 1 and 38.3 in group 2. Patients of this amount of tinnitus distress are considered as grade II patients (out of 4 grades). The study shows that chronic tinnitus patients of this grade of severity can significantly benefit from the app-based treatment. At the current state of research, the results cannot be generalized to patients with very severe amount of tinnitus distress (grade IV).

Conclusions

This study revealed a pronounced effect of an app-based CBT on tinnitus distress and in the course of treatment the number of patients affected by uncompensated tinnitus decreased significantly. In addition, the majority were characterized by mild tinnitus severity during final assessment.

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Conflict of Interest

Kristina Röschmann-Doose, Thomas Wittig, and Jörn Thomsen are employees of G. Pohl-Boskamp GmbH & Co. KG (distribution partner for Kalmeda), and Winfried Schlee, Uso Walter and Lothar Bleckmann received personal fees from G. Pohl-Boskamp GmbH & Co. KG. All other authors declare no conflict of interest.

Multimedia Appendix 1

Supplemental figures and tables.

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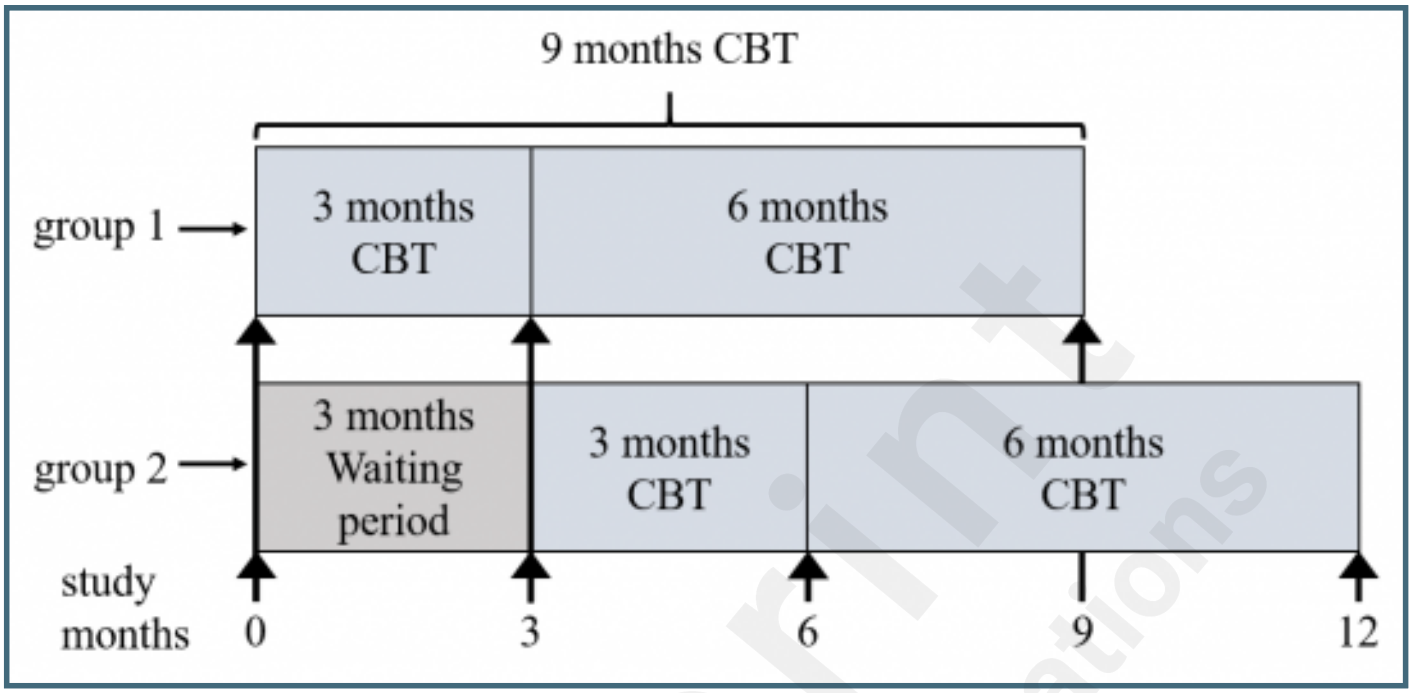
Abbreviations

CBT:	Cognitive Behavioral Therapy
MCID:	Minimal Clinically Important Difference
PHQ9:	Patients Health Questionnaire
PSQ20 :	Perceived-Stress-Questionnaire
SWOP-K9:	Self-Efficacy-Optimism-Pessimism
TQ:	Tinnitus Questionnaire

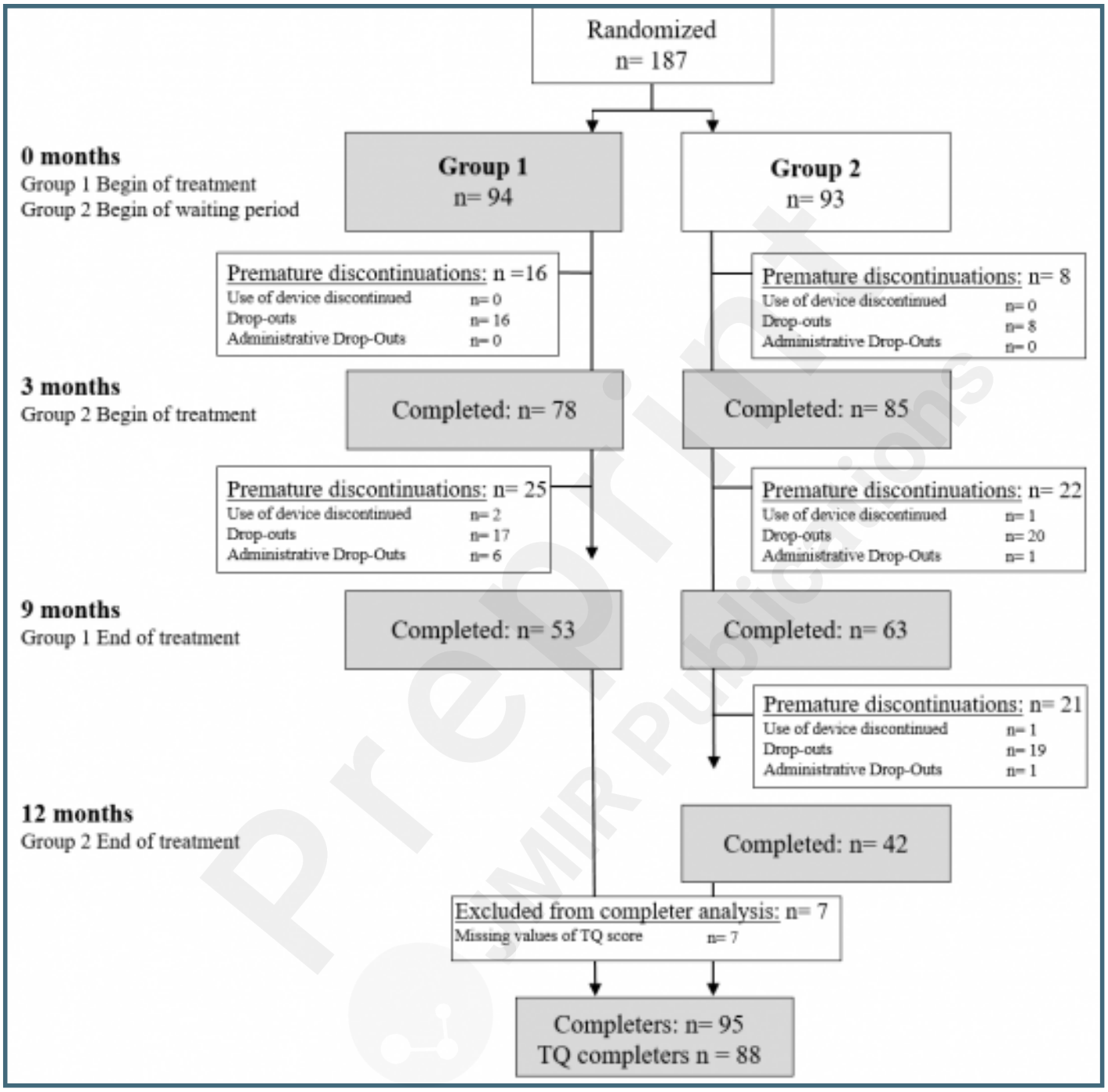
Supplementary Files

Figures

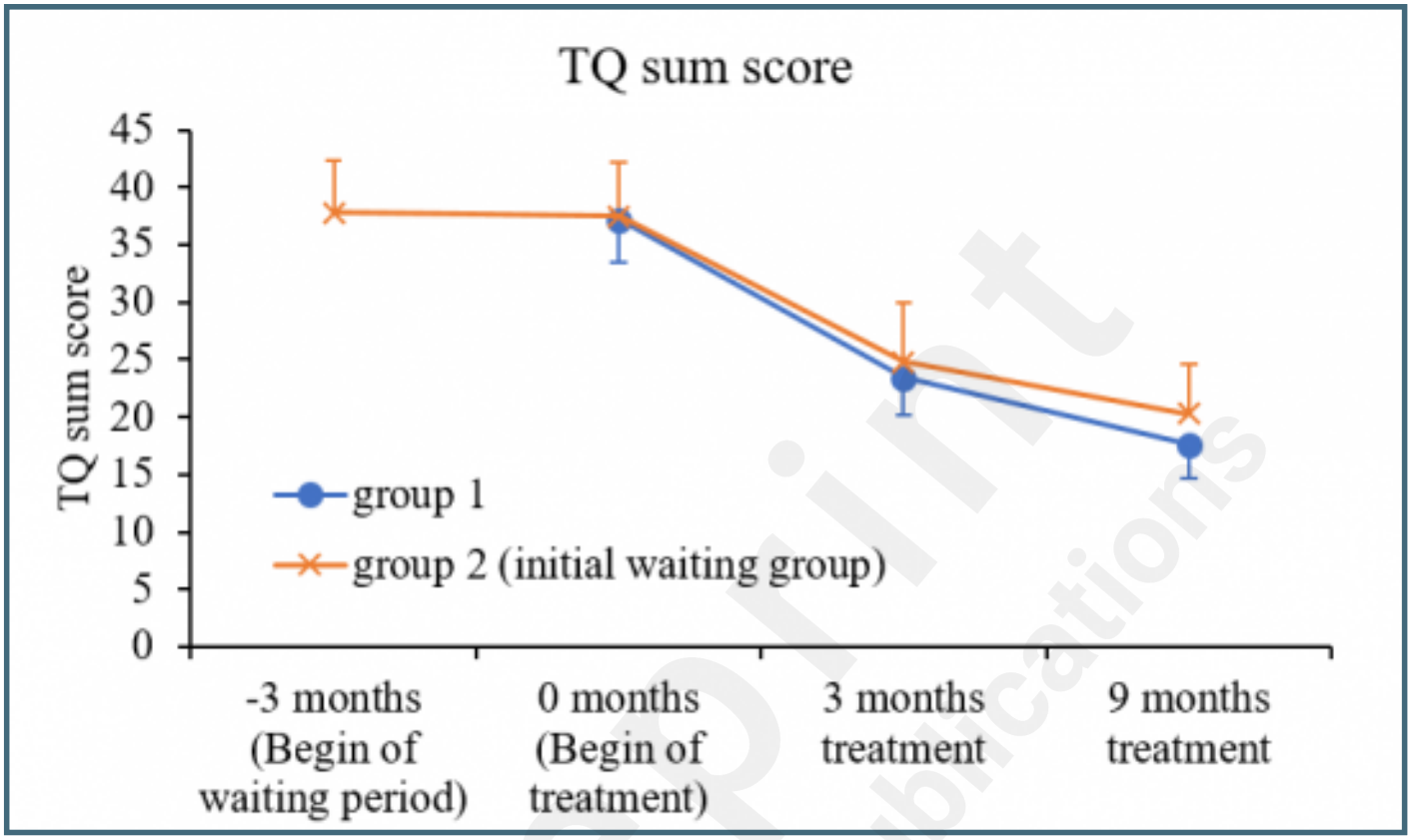
Scheme of the study design. Time points of assessments in group 1 and 2 (initial waiting group) are indicated by arrows, CBT: Cognitive Behavioral Therapy.



Disposition of patients in the trial. The term “Completers” encompasses all patients with complete entries without any missing data of the Tinnitus Questionnaire; n = number.



TQ sum score of completers in group 1 (blue) and 2 (orange) during the waiting (group 2 only) and the app-based treatment period; Mean ± 95% confidence interval. For improved clarity of the treatment effect, the improvement during the app-based treatment period is shown in parallel for both groups.



Multimedia Appendixes

Supplemental Information.
URL: http://asset.jmir.pub/assets/e86503ff1bfa33da4de2379d68a57d76.docx