



EFFECTIVENESS OF STEPPED TINNITUS CARE

CBT-BASED SPECIALISED TINNITUS TREATMENT VERSUS CARE AS USUAL

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Contents

- ✓ Background
- ✓ Our Study: RCT
- ✓ Study design
- ✓ Methods
- ✓ Results
- ✓ Discussion

Background

Tinnitus Aurium: (*Tinnire = to jingle; Aurium = concerning the ear*)

The perception of a sound without the presence of an external

Source:

(Beepin, Whistling, Rustling, Drumming, Singing, Humming, Jetplanes Cruising, water-tap running, etc)

Background

Interesting facts:

- ✓ Very common (10 – 15% of adult western population)
- ✓ Three percent of this group is suffering
- ✓ Audiometric characteristics (loudness, pitch) hardly predict tinnitus suffering
- ✓ Of the hearing disabled population 70% is able to perceive tinnitus, less than half is impaired by it
- ✓ Tinnitus perception \neq tinnitus suffering



Background

Most advocated theory about pathophysiology:

Tinnitus occurs as a result of spontaneous anomalous neural activity, coinciding with changes in the auditory system at any level along the auditory axis

Also:

Phantom auditory perception or phantom auditory pain

Most common complaints:

- ✓ Severe emotional distress; anxiety, depression
- ✓ Sleeping difficulties
- ✓ Major declines in concentration
- ✓ Problems in re-directing attention
- ✓ In sum: major declines in quality of life

Background

Current effective curative treatments:

- ...???

Current standardized practice:

- ...???

Current effective treatments:

- *CBT-based treatment approaches: Evidence has been found*
- *Tinnitus retraining therapy (Extensive counselling with use of sound generating devices): Contradictory evidence has been found*

Contents

- ✓ Introduction
- ✓ The randomized controlled trial (RCT)
 - Organization
 - Methods
 - Outcomes
 - Hypothesis
- ✓ Methods
- ✓ Results
- ✓ Discussion

The RCT



Programme

Effects & Costs

Round

2007

Project title

The effectiveness & cost-effectiveness of multidisciplinary management of Tinnitus at a specialised Tinnitus Centre

Duration:

36 months (prolonged 6 months)

Start – end date:

September '07 - April'11

A Randomized Controlled Trial



The RCT

A novel multidisciplinary treatment protocol:

Combining elements from TRT in a CBT based treatment approach, organized in a 2 stepped-care framework.

A stepped-care approach is a framework for organizing health services based on individual patients' needs, with a gradual increase in the intensity of the care at each level.

Methods

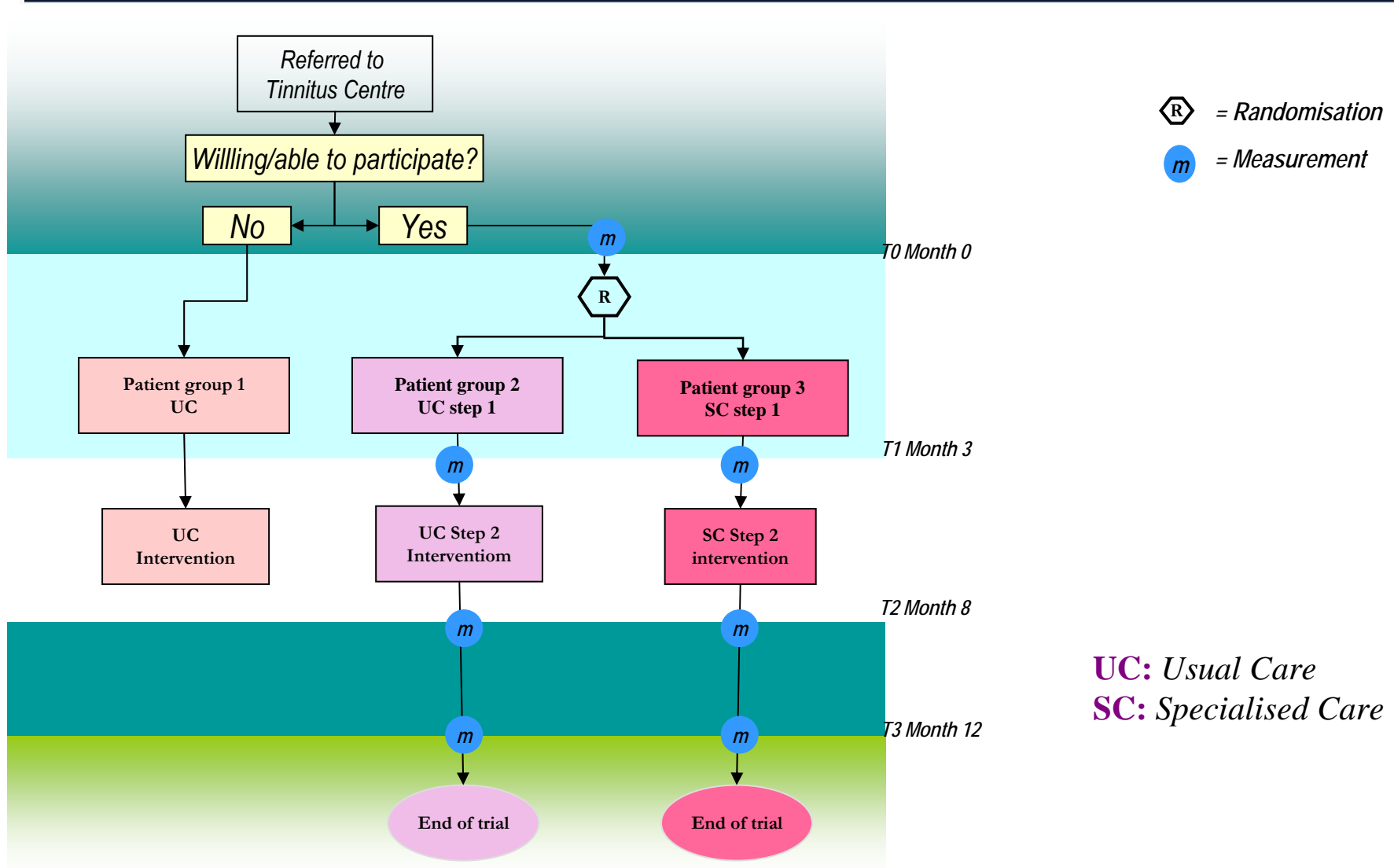
- ✓ 2 treatment conditions:
 - Specialized care **SC**
Combining elements from TRT in a cognitive behavioural framework
 - Usual care **UC**
Modelled after the average standard tinnitus care as is provided in audiological centres across the Netherlands
- ✓ Stepped Care approach: 2 steps in both conditions
 - Step 1: Audiological rehabilitation and diagnostics
 - Step 2: More intensive care (for those who need it)

Methods

- ✓ Single centre
- ✓ 2 separate teams to deliver **UC** and **SC**, on separate days of the week
- ✓ Stepped Care approach: 2 steps in both conditions
 - Step 1: Audiological rehabilitation and diagnostics
 - Step 2: More intensive care (for those who need it)
- ✓ Stratification by Tinnitus severity and hearing loss (2 strata, 4 blocks); Patients were blinded for allocation

Hypotheses

- ✓ **SC** is more effective than **UC** in increasing generic health related quality of life, in reducing distress caused by tinnitus, in reducing tinnitus related impairment
- ✓ **SC** results in relatively more patients reporting clinically relevant improvements than **UC**, in health related quality of life and tinnitus severity
- ✓ **SC** is more effective than **UC** in reducing general negative affect, in reducing the level of catastrophizing thoughts about the tinnitus, in reducing tinnitus-related fear,
- ✓ The effect of **SC**, on health related quality of life and general negative affect, is moderated by tinnitus severity, in that especially severely affected patients would benefit even more from **SC** treatment
- ✓ The effect of **SC** on health related quality of life, tinnitus severity, and tinnitus related impairment, as compared to **UC** is mediated by decreases in tinnitus related fear



Outcomes

- ✓ Primary outcome measures
 - Health related quality of life; *Health Utilities Index (HUI)*
 - Tinnitus severity; *Tinnitus Questionnaire (TQ)*
 - Tinnitus related impairment ; *Tinnitus Handicap Inventory (THI)*

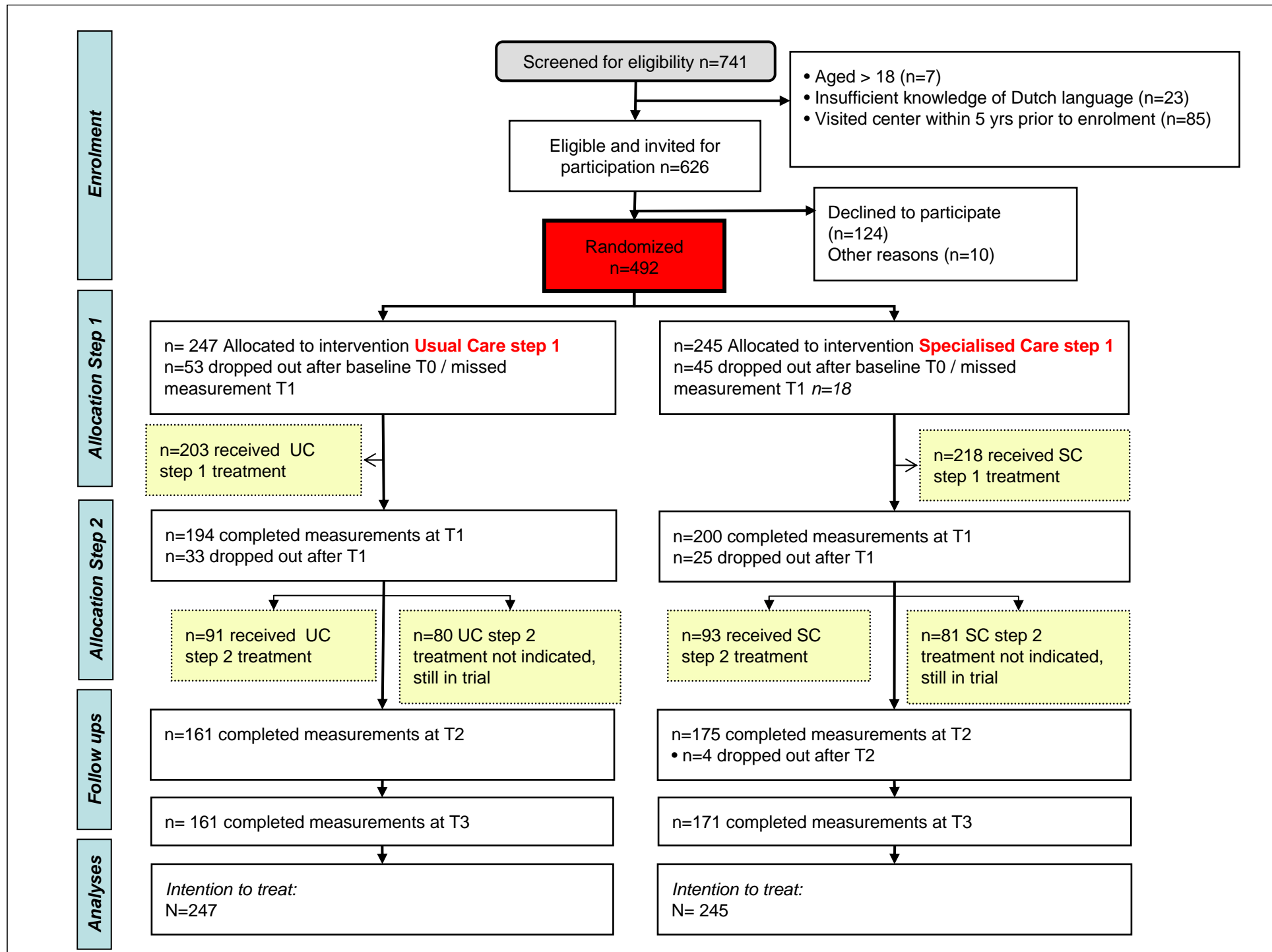
- ✓ Secondary outcome measures
 - General negative affect; *Hospital Anxiety and Depression Scale (HADS)*
 - Catastrophizing about tinnitus; *Tinnitus Catastrophizing Scale (TCS)*
 - Tinnitus related fear; *Fear of Tinnitus Questionnaire (FTQ)*

Contents

- ✓ Background
- ✓ Our Study: RCT
- ✓ Study design
- ✓ Methods
- ✓ Results
 - CONSORT
 - Treatment fidelity
 - Intention to treat: mixed (multilevel) regressions
 - Clinically relevant changes
 - Moderation-mediation
- ✓ Discussion

Results

Flow of participants: CONSORT



Results

Treatment fidelity:

- ✓ 2 treatment experts identified specific treatment elements
- ✓ 1 trial specific instrument
- ✓ 5 specific treatment element categories:
 - *essential and unique*
 - *essential but not unique*
 - *unique but not essential*
 - *allowed,*
 - *prohibited*
- ✓ 2 independent raters rated random sample of $n = 40$ per treatment condition (and cross checked with several databases).

Results

Treatment fidelity:

Treatment differentiation:

- In **97%** of the cases correct classification of treatment condition
- ✓ Protocol adherence:
 - on average **87%** of essential treatment elements (both unique and not unique) actually occurred during the delivery of both treatments
- ✓ Contamination:
 - On average only **6%** of the prohibited treatment elements took place during treatment delivery
- ✓ Most importantly: no difference between treatment conditions in adherence and contamination
- ✓ This means that the: following analyses are legitimate!

Results

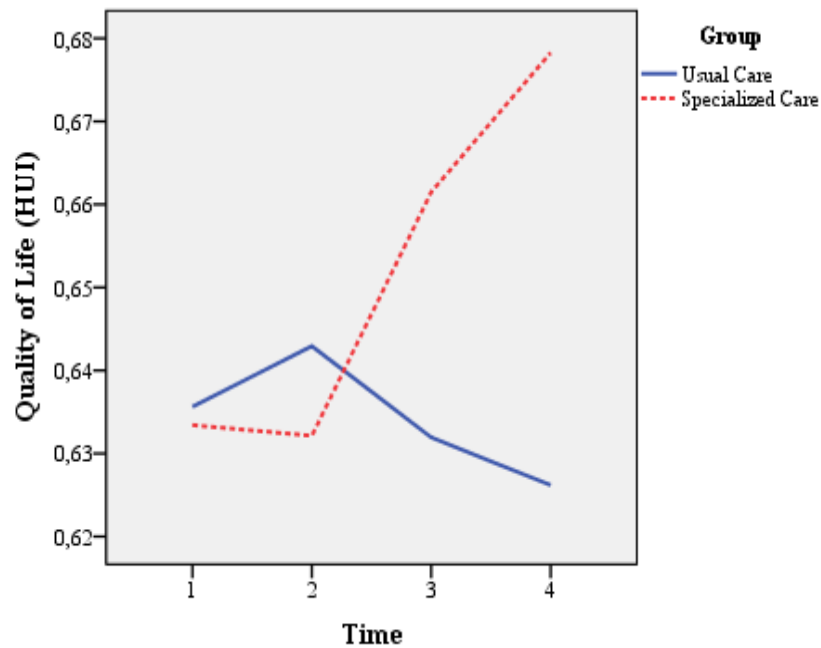
Intention –to-treat analyses (no need for imputation):

Series of mixed (multilevel) regressions: fixed part is modelled (unstructured correlation matrix), random part is unspecified; most general model.

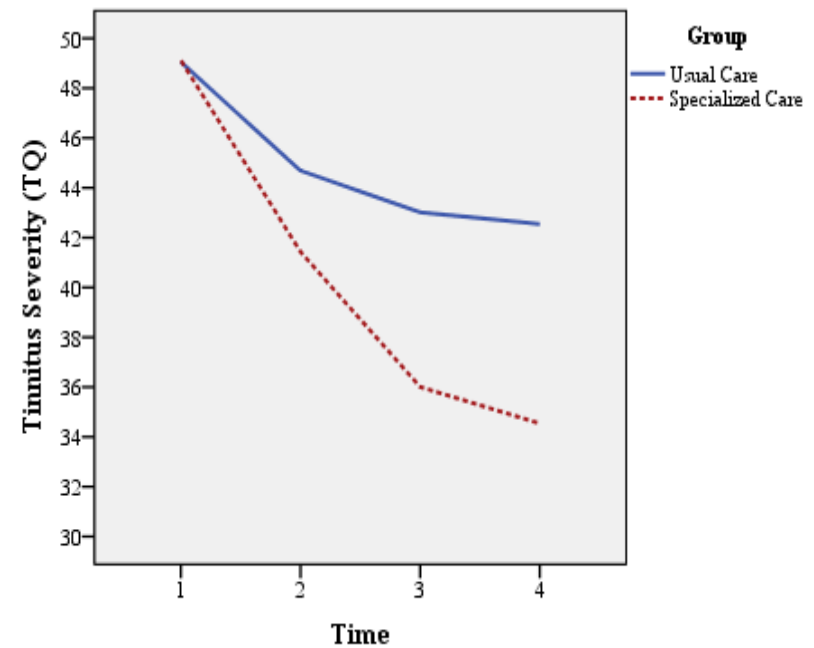
$$Y_{ti} = \beta_0 + \beta_1 \text{group} + \beta_2 \text{cov} + \beta_3 \text{followup1} + \beta_4 \text{followup2} + \beta_5 \text{followup3} + \beta_6 \text{group} \times \text{followup1} + \beta_7 \text{group} \times \text{followup2} \\ + \beta_8 \text{group} \times \text{followup3} + \beta_9 \text{cov} \times \text{followup1} + \beta_{10} \text{cov} \times \text{followup2} + \beta_{11} \text{cov} \times \text{followup3} + e_{ti}$$

Results

General Health (HUI)

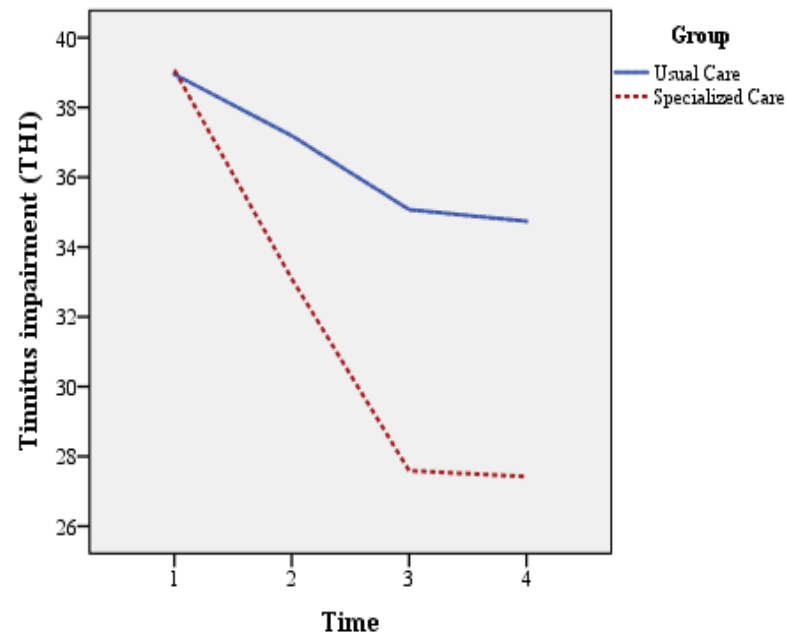


Tinnitus Severity (TQ)

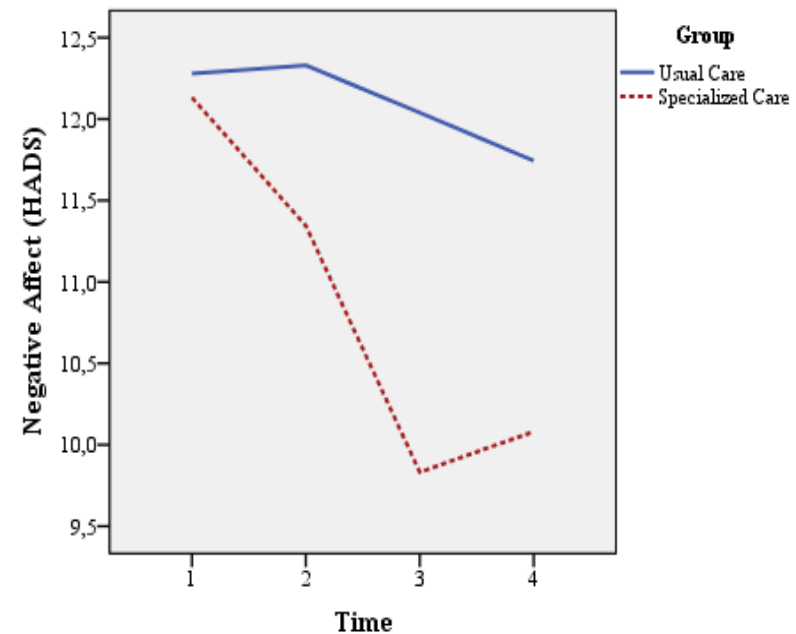


Results

Tinnitus impairment (THI)

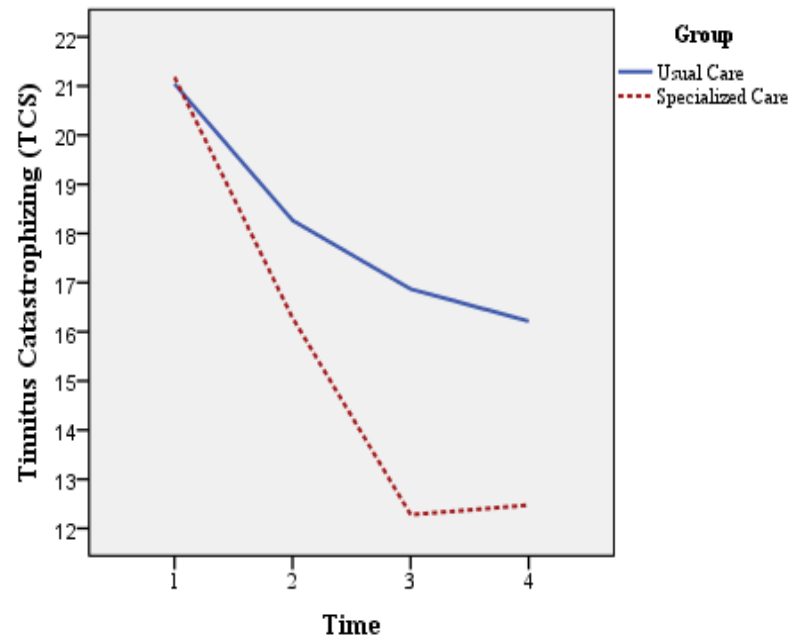


Negative Affect (HADS)

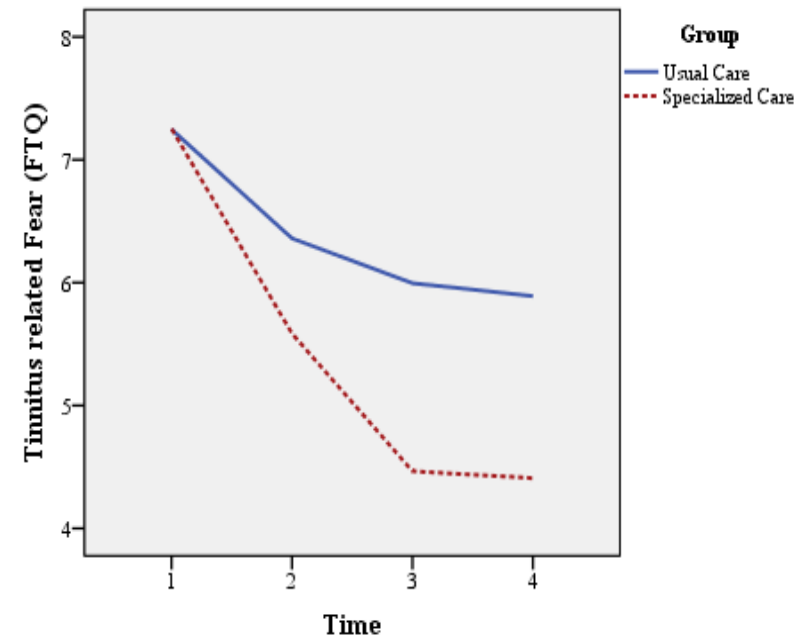


Results

Tinnitus Catastrophizing (TCS)



Tinnitus Related Fear (FTQ)



Results

Primary outcomes	B	95% C.I.	P	E.S.	95% C.I.
Health related QoL (HUI)					
3 months	-0.009	0.056 0.039	.642	-0.04	0.036 0.056
8 months	0.038	0.005 0.071	.026	0.18	0.038 0.053
12 months	0.059	0.025 0.094	.001	0.24	0.051 0.069
Tinnitus Severity (TQ)					
3 months	-3.315	-5.612 -1.019	.005	0.43	241.804 332.533
8 months	-7.070	-9.561 -4.580	.000	0.41	247.713 338.505
12 months	-8.062	-10.829 -5.295	.000	0.20	297.791 401.149
Tinnitus impairment (THI)					
3 months	-4.257	-7.065 -1.449	.003	-0.32	147.530 215.742
8 months	-7.626	-10.713 -4.539	.000	-0.52	174.805 248.775
12 months	-7.506	-10.661 -4.352	.000	-0.45	233.484 317.875

Results

Secondary outcomes	B	99% C.I.		P	E.S.	99% C.I.	
Negative affect (HADS)							
3 months	-0.857	-2.180	0.465	.094	-0.15	24.739	38.519
8 months	-2.086	-3.514	-0.658	.000	-0.35	27.188	41.558
12 months	-1.507	-2.867	-0.148	.004	-0.24	32.409	47.542
Tinnitus catastrophising (TCS)							
3 months	-2.102	-3.955	-0.249	.004	-0.31	33.633	58.325
8 months	-4.683	-6.938	-2.428	.000	-0.60	46.432	75.706
12 months	-3.830	-6.185	-1.475	.000	-0.41	72.220	107.849
Tinnitus related fear (FTQ)							
3 months	-0.785	-1.486	-0.084	.004	-0.35	3.484	6.400
8 months	-1.550	-2.353	-0.748	.000	-0.58	5.417	8.835
12 months	-1.502	-2.317	-0.688	.000	-0.48	8.006	11.958

Relevant change

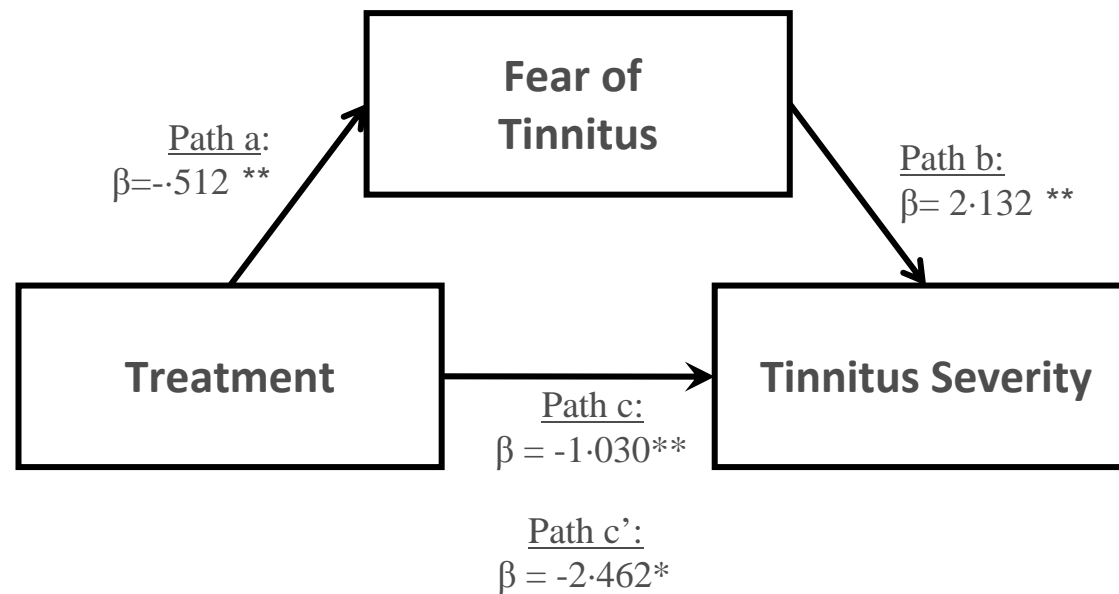
Primary outcomes	Baseline	Mean change (SD)
	Mean (SD)	Baseline to follow up 3
Health related QoL (HUI)		
UC	0,641 (0,295)	0,006 (0,237)
SC	0,628 (0,284)	-0,043 (0,214)
Tinnitus Severity (TQ)		
UC	48,87 (19,22)	6,00 (14,51)
SC	49,39 (18,50)	14,73 (13,98)
Proportion of patients reporting		Follow up 3
clinically relevant change		
Health related QoL (HUI)		
UC		62/161 (38,5%)
SC		90/170 (52,6%)
Tinnitus Severity (TQ)		
UC		58/161 (36,0%)
SC		104/171 (60,8%)

Moderation

No moderating effect of tinnitus severity on either Health related quality of life or Negative affect was found,

- ✓ The effect of **SC** compared to **UC** does not depend on tinnitus severity.
- ✓ Differences between treatment conditions in favour of SC were the same for both lesser impaired participants as for the more severely impaired.

Mediation



'The treatment effect of SC can be explained by the reductions in tinnitus related fear'

Note 1: * $P < .05$ (2-tailed); ** $P < .001$ (2-tailed)

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- ✓ Background
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- ✓ Study design
- ✓ Methods
- ✓ Results
- ✓ Conclusion

Conclusions

- ✓ Firm evidence of effectiveness of Specialized Tinnitus Care
- ✓ Sufficient protocol adherence and absence of contamination
- ✓ Proportion of patients reporting clinically relevant change is significantly larger in SC
- ✓ No moderation of tinnitus severity:
Both for mild and severe sufferers: effects of SC the same!
- ✓ Fear mediates the effects of treatment on tinnitus related impairment



Thank you!

Questions? Remarks?

Concerns? Suggestions?

