



**COMIT'ID study to agree the tinnitus-related domains comprising a Core Outcome Set for sound-based clinical trials of chronic subjective tinnitus in adults**



**Consensus meeting report, Friday 8<sup>th</sup> September**

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**EXECUTIVE SUMMARY**

***The Core Outcome Set for testing whether sound-based treatments are beneficial for tinnitus considers the domains ability to ignore, concentration, quality of sleep, sense of control, and tinnitus intrusiveness.***

Everyone taking part in the COMIT'ID study agreed that one tinnitus-related outcome domain was important to assess no matter which type of tinnitus treatment is being tested. This outcome domain is tinnitus intrusiveness. Tinnitus intrusiveness describes the state of noticing the sound of tinnitus is there and it is invading your life or your personal space. For testing sound-based therapies for tinnitus ability to ignore, concentration, quality of sleep, and sense of control should also be assessed. The final consensus group for sound-based clinical trials voted in favour of these five outcome domains with over 70% agreement.

The group strongly recommended that the definition of tinnitus intrusiveness is revisited to consider what aspects might be considered in its measurement. Opinions from this meeting suggested that intrusiveness encompasses tinnitus awareness, quality of sleep, and that it impacts on everyday life such as individual activities, social life, and work. Some others also felt that tinnitus intrusiveness also encompasses impacts of tinnitus on listening, and on holding a conversation.

The definition of sense of control also warrants further examination since there was some difference in its interpretation according to whether the trial might be evaluating sound-based or psychology-based interventions. For interventions using sound-based products, it was felt that the device could give direct sense of personal control over the tinnitus itself (a feeling that the device can be used to 'switch tinnitus off'). The working definition used by this group was therefore: Feeling you have a choice and self confidence in how to manage the impact of tinnitus and feelings caused by tinnitus. For interventions using psychology-based approaches, sense of control appeared to be more about feeling in control

over the impact of tinnitus, perhaps as a consequence of more positive coping strategies.

Future efforts will pair these selected outcome domains with suitable outcome instruments.

## **PURPOSE**

Different clinical trials measure and report patient benefit using different methods. As a consequence, the findings of different studies can't be compared and the data can't be pooled together. This hampers progress in finding the best treatments.

A Core Outcome Set refers to a small number of outcome domains and the corresponding instruments for measuring them that are recommended to be assessed and reported in all clinical trials. If we could agree a Core Outcome Set for tinnitus then that would go a long way to addressing current limitations.

The Core Outcome Set would *always* be measured in *every* clinical trial (at least before and after the intervention), but investigators would be free to add other outcomes as they wish.

The purpose of this study is to define the tinnitus-related domains comprising a Core Outcome Set for sound-based interventions of chronic subjective tinnitus in adults.

### **Stage 1. The online Delphi survey**

An online Delphi survey was completed first. Delphi surveys are a tried and tested method for developing consensus in decision making among a panel of experts. Across three survey rounds, we asked tinnitus experts to think about each one of 68 different possible outcomes related to tinnitus: "Is it critically important for deciding if a treatment has worked?"

The following figure illustrates the number of outcomes considered at each round and the number of participants in each stakeholder group. Participants were representing 31 countries across the world (UK, USA, France, Canada, Germany, Netherlands, Denmark, Australia, Italy, Portugal, Belgium, Sweden, Switzerland, Ireland, New Zealand, Poland, Singapore, Spain, Argentina, Brazil, China, Greece, India, Israel, Japan, Malta, Mexico, Norway, South Africa, Malaysia, and Iran).

### Round 1

66 outcomes

197 Members of the public with tinnitus,  
79 Healthcare professionals, and  
36 Clinical researchers  
24 Commercial representatives and funders

### Round 2

66 + Device usage  
Frequency of  
occurrence

160 Members of the public with tinnitus,  
60 Healthcare professionals, and  
35 Clinical researchers  
19 Commercial representatives and funders

### Round 3

68 outcomes

142 Members of the public with tinnitus,  
57 Healthcare professionals, and  
34 Clinical researchers  
19 Commercial representatives and funders

In round 1, we also invited participants to suggest any additional outcomes which they felt were missing from our original list of 66. From these suggestions, we identified 2 new outcomes that were not already covered by one of the outcomes already on the list. These were 'Frequency of occurrence: How often you experience tinnitus symptoms (e.g. how many times and for how long)' and 'Device usage: How much you used the sound device and how this compares with how you were instructed to use it'. They were both added for consideration by all participants in round 2.

### **Delphi survey findings**

The scores were evaluated for all those participants completing round 3. The study team had pre-defined agreement as when 70% or more participants in each stakeholder group said the outcome was important AND critical for determining if the sound-based treatment was working (score 7-9) AND 15% or fewer said the outcome was neither important nor critical (score 1-3). The following figure shows the results from this analysis about those outcomes reaching consensus.

**Agreement =**

70% or more people said the outcome was important AND critical for determining if the sound-based treatment was working (score 7-9)  
AND  
15% or fewer people said the outcome was neither important nor critical (score 1-3)

**Round 3**

Members of the public with tinnitus, Healthcare professionals, Clinical researchers and Commercial representatives/funders <b>all reached agreement to include</b>	21/68 outcomes
Not all four groups reached agreement to include (only one, two or three did)	31/68 outcomes
None of the groups reached agreement to include	16/68 outcomes

All stakeholder groups agreed that these 21 outcome domains are important and critical:

Ability to ignore, Ability to relax, Acceptance of tinnitus, Annoyance, Anxiety, Concentration, Conversations, Coping, Depressive symptoms, Difficulties getting to sleep, Frequency of occurrence, Helplessness (lack of control), Impact on individual activities, Impact on social life, Impact on work, Listening, Quality of sleep, Tinnitus awareness, Tinnitus intrusiveness, Tinnitus unpleasantness, Treatment satisfaction.

**Stage 2. The face-to-face consensus workshop**

19 participants attended this meeting (10 members of the public with tinnitus, 5 healthcare professionals, 3 researchers and 1 commercial representatives and funders).

In all voting, agreement was defined as at least 70% or more participants voting for either 'agree' or for 'disagree/unsure'. Where 70% was not met for either agree or disagree, following a second vote the domain was removed.

The scope of this meeting was constrained by the result of the Delphi survey in which 21 outcomes were considered to be important and critical by all stakeholder groups. If all 21 outcomes were voted into the Core Outcome Set then this could potentially mean that all clinical trials would have to include at least 21 measurement instruments. The Study Team were concerned that this was just not feasible for clinical trial sites, nor ethical in terms of burden placed

on those patients who would have to complete them all. The consensus meeting therefore started with a discussion and vote on the scope of the agenda (Q1, Table 1). It was agreed that the discussion be constrained to the 21 outcomes, and that the goal should be to reduce these down to a Core Outcome Set of no more than 6. Remember that this Core Outcome Set would *always* be measured in every clinical trial (at least before and after the intervention), but investigators would be free to add other outcomes as they wish.

### **First round: Top and bottom selections proposed by each subgroup**

Participants were divided into two subgroups (n=10, n=9). Individuals in each subgroup had been asked to choose their top three outcomes from the list of 21, prior to the meeting. The combined total of these votes was then used to lay out cards (each containing one outcome name and description) on a table, ordered from the greatest number of votes at the top downwards.

**Green table** The combined votes for the subgroup facilitated by Kathryn gave the following order:

Tinnitus intrusiveness (n=5), ability to ignore (n=3), acceptance of tinnitus (n=3), conversations (n=3), coping (n=3), quality of sleep (n=3), tinnitus awareness (n=3), depressive symptoms (n=2), impact on individual activities (n=2), ability to relax (n=1), annoyance (n=1), concentration (n=1), treatment satisfaction (n=1).

**Orange table** The combined votes for the subgroup facilitated by Deborah gave the following order:

Difficulties getting to sleep (n=5), Anxiety (n=4), Coping (n=3), Treatment satisfaction (n=3), Acceptance of tinnitus (n=2), Concentration (n=2), Frequency of occurrence (n=2), Helplessness (lack of control) (n=2), Tinnitus awareness (n=2), Listening (n=1), Tinnitus intrusiveness (n=1).

The goal for each subgroup was to initially discuss and jointly agree which domains are sufficiently critical and important to make it into the Core Outcome Set (maximum = 6) and which are **not** sufficiently critical to include in every clinical trial. To facilitate discussion, the cards could be moved around the table and reordered according to the majority views of the subgroup. Two pieces of string marked the cut-offs for the top and bottom selections proposed by each subgroup.

Results from both groups were first pooled to cluster outcomes into three categories:

Outcomes that were included in the top 'set' by both subgroups were: Awareness, Coping, and Difficulties getting to sleep.

Outcomes included in the top set by one subgroup but not the other were: Ability to ignore, Acceptance, Annoyance, Anxiety, Concentration, Conversations, Depressive symptoms, Helplessness, Intrusiveness, Quality of sleep, Treatment satisfaction, and Listening.

Outcomes that both subgroups judged were **not** to be critical and important for every clinical trial of a sound-based intervention were: Ability to relax, Frequency of occurrence, Impact on individual activities, Impact on social life, Impact on work, and Tinnitus unpleasantness.

This selection led to full group discussion and then voting on Q2 (Table 1). 95% of the group agreed to set aside Ability to relax, Frequency of occurrence, Impact on individual activities, Impact on social life, Impact on work, and Tinnitus unpleasantness from the Core Domain Set. Reasons given can be found in Table 2.

Two separate issues arose from the subgroup discussions. First, there was further discussion about 'Awareness' and agreement by the full group to set it aside because it was considered to be encompassed within the outcome Intrusiveness (see Q2A, Table 1). Second, Sarah presented data from the Delphi survey for 'Sense of control' which describes whether or not you feel you have a choice in how to manage the impact of tinnitus and feelings caused by tinnitus. This had not made it into the top 21, but had reached consensus for three of the stakeholder groups (Scoring 7-9: Members of the public = 86%, Healthcare professionals = 88%, Clinical researchers = 65%, and Commercial representatives and funders = 95%). There was further discussion about 'Sense of control' and agreement by the full group to include it in further discussion. This gave 15 outcomes for further discussion and voting.

### **Second round: Top and bottom selections proposed by each subgroup**

The next goal for each subgroup was to discuss and jointly agree on no more than 6 outcomes for further consideration. To facilitate discussion, the cards could be moved around the table. This time only one piece of string marked the cut-off for the top and bottom selections proposed by each subgroup. The results from both groups were pooled to cluster the outcomes into three categories.

Outcomes that were included in the top 'set' by both subgroups were: Ability to ignore, Concentration, Coping, Intrusiveness, and Sense of control.

Outcomes included in the top set by one subgroup but not the other were: Quality of sleep, Treatment satisfaction

Outcomes that both subgroups judged were **not** to be critical in every clinical trial were: Acceptance of tinnitus, Annoyance, Anxiety, Conversations, Depressive symptoms, Difficulties getting to sleep, and Listening.

This selection led to full group discussion and then voting on Q3 (Table 1). The decision was to set aside these outcomes from the Core Domain Set. Reasons given can be found in Table 2. This left 8 outcomes for individual voting.

### **Voting on the remaining individual domains**

Table 1 Q4-15 shows the voting scores for Ability to ignore, Concentration, Coping, Helplessness, Quality of sleep, Sense of control, Tinnitus intrusiveness, Treatment satisfaction.

For some of the outcomes, there was no initial consensus. These were therefore discussed and revisited again, before a final vote (without the option to select 'unsure'). Details are presented in Table 1.

**Table 1. Questions discussed and votes cast during the consensus meeting**

	Agree	Disagree	Unsure
Q1) Today's discussion will focus on the 21 outcome domains that all 3 groups (Members of the public with tinnitus, Healthcare professionals, and Clinical researchers) agreed to include in the COS. The remaining 47 domains will not be discussed. Do you agree?	89	5	5
Q2) These outcome domains are not critical to be measured in every clinical trial for sound-based tinnitus treatment. Do you agree? 'Ability to relax' 'Frequency of occurrence' 'Impact on individual activities' 'Impact on social life' 'Impact on work' 'Tinnitus unpleasantness'	95	5	0
Additional Q2A) 'Awareness' and 'intrusiveness' are different things, but 'intrusiveness' encompasses 'awareness' because for tinnitus to be intrusive you also need to be aware of it. Do you agree?	100	0	0
Additional Q2B) 'Ability to ignore' is different from 'awareness' or 'intrusiveness', and should be left for discussion. Do you agree?	89	11	0
Action: agreed 'Awareness' is covered by intrusiveness and therefore set aside without further discussion			
Q3) These outcome domains are not critical to be measured in every clinical trial for sound-based tinnitus treatment. Do you agree? 'acceptance of tinnitus' 'annoyance' 'anxiety' 'conversations' 'depressive symptoms' 'difficulties getting to sleep' 'listening'	89	5	5
Comments relevant to 'anxiety' and 'depressive symptoms' are that these can be captured in some of the other core outcome candidates especially 'coping', 'sense of control', 'treatment satisfaction' and 'intrusiveness'.  Rationale against 'acceptance' (mainly amongst patients) was that it can be perceived as a 'passive' outcome that does not represent an improvement/reduction in the tinnitus symptoms.			
Q4) Do you agree that 'Ability to ignore' is critical	89	0	11

to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: Consensus 'in' reached - include</b>			
<p>For some, 'ability to ignore' seems linked to 'annoyance' since if you can successfully ignore tinnitus then it's not so annoying. If anything, 'ability to ignore' was felt to be more relevant than simply 'annoyance'. One patient felt 'annoyance' trivialised the impact of the tinnitus.</p> <p>Ability to ignore considered one of the primary objectives for using a sound therapy.</p>			
Q5) Do you agree that 'helplessness' should be set aside and not discussed further?	100	0	0
Q6) Do you agree that 'Sense of control' should be discussed in place of 'helplessness'?	95	5	0
Q7) Do you agree that 'Sense of control' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: Consensus 'in' reached - include</b>	95	0	5
<p>One subgroup placed 'Helplessness' in their top 6 but there was a substantive concern even within that subgroup that 'Helplessness' is concerned with deep suffering which is relevant only to some patients. In contrast, 'sense of control' describes a similar state but one that is less extreme. Participants therefore asked the facilitator to share the voting scores for this outcome which had not reached the top 21.</p>			
Q8) Do you agree that 'Concentration' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: Consensus 'in' reached - include</b>	74	16	11
<p>There was a feeling that some sort of measure of hearing performance that also captures ability for successful 'listening' and 'conversation' is important to be included in the core set. The group agreed that the measure of 'concentration' should include a question about conversations.</p> <p>Dissenting voices (voting disagree or unsure) felt that 'concentration' difficulties were rather narrowly focussed such that they were already encompassed by 'ability to ignore'. Another felt that this outcome did not affect them personally.</p>			
Q9) Do you agree that 'coping' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: No consensus, discuss and revisit</b>	68	16	16
Q10) Do you agree that 'treatment satisfaction' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: No consensus, discuss and revisit</b>	37	63	0
Q11) Do you agree that 'tinnitus intrusiveness' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: Consensus 'in' reached - include</b>	100	0	0
Comments to consider further include the notion that 'intrusiveness' will			

impact on aspects of sleep.			
Q12) Do you agree that 'quality of sleep' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: No consensus, discuss and revisit</b>	68	21	11
Q13) Second vote: Do you agree that 'coping' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: No consensus, set aside</b>	53	47	Unsure no longer an option
Reasons to exclude coping were that it was felt to be covered by aspects of sense of control. Confusion about how 'coping techniques' are relevant to a sound-based treatment – it was felt that the 'technique' would be the action of using the sound and in this context that wouldn't make sense. Agreed that sound-based treatments don't really employ techniques.			
Q14) Second vote: Do you agree that 'quality of sleep' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: Consensus 'in' reached - include</b>	79	21	Unsure no longer an option
There was a strong feeling within the group that sound-based therapies (as an intervention category) are directly relevant addressing sleep complaints associated with tinnitus, and that sound therapies currently play a major role in improving sleep. Sleep complaints acknowledged as the most/ one of the most reported, problematic complaints associated with tinnitus. Sleep issues argued as highly important given the potential to have an impact on overall wellbeing/ can influence a variety of other domains.  Dissenting voices (voting to disagree) felt that 'quality of sleep' was perhaps secondary to 'intrusiveness' and 'ability to ignore'. It was also acknowledged that sleep complaints were not relevant to all individuals with tinnitus and therefore it was questioned whether this domain should be core.			
Q15) Second vote: Do you agree that 'treatment satisfaction' is critical to be measured in every clinical trial for a sound-based tinnitus treatment? <b>Decision: No consensus, set aside</b>	32	68	Unsure no longer an option
The view in favour of 'treatment satisfaction' felt that this outcome was sufficiently broad to cover a range of therapeutic devices. It's also important for patients to be satisfied with the device they are prescribed in order for them to be motivated to use it (potentially an indicator for adherence/compliance)  Dissenting voices (voting to disagree) felt that 'treatment satisfaction' may be coloured by factors not related to the treatment, such as a grumpy clinician etc. Moreover, 'treatment satisfaction' was felt not so suitable for early evaluation of a novel therapy (i.e. a clinical trial) because it measures satisfaction with the overall therapeutic process, not the sound devices in isolation.			

**Table 2. Major comments raised during the workshop**

Outcome domain reaching consensus in the Delphi	Comments in favour	Comments against
Ability to ignore	<ul style="list-style-type: none"> <li>• Linked to, but more relevant than, 'annoyance'</li> <li>• Considered one of the primary objectives for using a sound therapy</li> </ul>	N/A
Ability to relax	<ul style="list-style-type: none"> <li>• N/A</li> </ul>	<ul style="list-style-type: none"> <li>• Some felt this was covered by sleep domains</li> </ul>
Acceptance of tinnitus	<ul style="list-style-type: none"> <li>• N/A</li> </ul>	<ul style="list-style-type: none"> <li>• Some patients perceived this as a 'passive' outcome that does not reflect an improvement/ reduction in the tinnitus symptoms</li> <li>• One patient mentioned she was never going to 'accept' her tinnitus, but that doesn't mean she can't cope with it</li> <li>• Sense of control was felt to cover elements of acceptance.</li> </ul>
Annoyance	<ul style="list-style-type: none"> <li>• N/A</li> </ul>	<ul style="list-style-type: none"> <li>• For some, 'linked to 'ability to ignore' since if you can successfully ignore tinnitus then it's not so annoying</li> <li>• One patient felt 'annoyance' trivialised the impact of tinnitus</li> </ul>
Anxiety	<ul style="list-style-type: none"> <li>• Some felt that it is important for the COS to cover the emotional impact of tinnitus</li> </ul>	<ul style="list-style-type: none"> <li>• As with 'depressive symptoms', could be covered by other domains e.g. 'coping', 'sense of control', 'treatment satisfaction' and 'intrusiveness'</li> <li>• Some felt this domain was too niche/ clinically focussed and therefore not relevant to all</li> <li>• Some felt this symptom could not be changed with sound therapy</li> </ul>
Concentration	<ul style="list-style-type: none"> <li>• Important to many different aspects of life</li> <li>• The group recommended that the measure of concentration' should include a question about conversations</li> </ul>	<ul style="list-style-type: none"> <li>• Narrowly focussed</li> <li>• Already encompassed by 'ability to ignore'</li> <li>• Some patients stated this does not affect them personally</li> </ul>
Conversations	<ul style="list-style-type: none"> <li>• Important to measure tinnitus</li> </ul>	<ul style="list-style-type: none"> <li>• Not a prominent issue for all</li> </ul>

	<p>impact on hearing ability</p> <ul style="list-style-type: none"> <li>• One patient argued that this was a prominent issue for him.</li> <li>• The green table subgroup wanted tinnitus intrusiveness to encompass aspects of holding a conversation.</li> </ul>	<p>patients</p> <ul style="list-style-type: none"> <li>• Difficult to differentiate from outcomes related to hearing loss</li> <li>• Could be covered by intrusiveness</li> </ul>
Coping	<ul style="list-style-type: none"> <li>• Measuring coping could indicate the patient's progress e.g. high levels of coping techniques required in early stages vs. fewer coping techniques needed as the patient progresses</li> </ul>	<ul style="list-style-type: none"> <li>• Covered by aspects of sense of control</li> <li>• Confusion about how 'coping techniques' are relevant to a sound-based treatment. It was felt that the 'technique' would be the action of using the sound and, in this context, to measure this wouldn't make sense. Agreed that sound-based treatments don't really employ 'techniques'</li> <li>• Overlap with ignore and concentration</li> </ul>
Depressive symptoms	<ul style="list-style-type: none"> <li>• Some felt that it is important for the COS to cover the emotional impact of tinnitus</li> <li>• One individual argued that sound treatment can alleviate depressive symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• As with 'anxiety, could be covered by other domains e.g. 'coping', 'sense of control', 'treatment satisfaction' and 'intrusiveness'</li> <li>• Some felt this domain was too niche/ clinically focussed and therefore not relevant to all</li> <li>• Some felt this symptom could not be changed with sound therapy</li> </ul>
Difficulties getting to sleep	<ul style="list-style-type: none"> <li>• Critical complaint for some patients</li> </ul>	<ul style="list-style-type: none"> <li>• One subgroup felt that 'quality of sleep' was more important than 'getting to sleep' – a more holistic measure of sleep problems</li> <li>• One subgroup felt that difficulties was covered by quality of sleep. Argued that it is about the right amount of sleep rather than difficulties.</li> <li>• Difficulties getting to sleep can also be caused by other conditions, not related to the tinnitus</li> <li>• Not every patient has difficulties getting to sleep</li> </ul>
Frequency of occurrence	<ul style="list-style-type: none"> <li>• One professional argued that this is an indicator of tinnitus perception and source. Treatments may perform differently depending on this.</li> </ul>	<ul style="list-style-type: none"> <li>• Many others argued the type of tinnitus is not relevant to measuring the effect of a treatment</li> <li>• This domain could inform subgrouping of patients within a study but it is not seen as a meaningful outcome</li> </ul>

Helplessness (lack of control)	<ul style="list-style-type: none"> <li>N/A</li> </ul>	<ul style="list-style-type: none"> <li>One subgroup placed 'helplessness' in their top 6 but there was a substantive concern even within that subgroup that 'helplessness' is concerned with deep suffering which is relevant only to some patients</li> </ul>
Sense of control	<ul style="list-style-type: none"> <li>Describes a similar state as helplessness, but one that is less extreme</li> <li>Believed to be highly relevant to sound-based treatments which many felt can give patients direct 'control' over their tinnitus. One patient explained that sound based treatment literally allows them to 'turn their tinnitus off'</li> <li>One subgroup felt that "sense of control" might cover "coping" as this was more about feelings of managing tinnitus, which also would encompass impact of activities, relationships and social life that have been removed.</li> </ul> <p><i>Note: Sense of control was interpreted very differently in the context of psychology based treatment. In that other context, participants felt that it was not possible to directly 'control' tinnitus but it was possible to have a feeling of being in control of the impact of tinnitus.</i></p>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Impact on individual activities	<ul style="list-style-type: none"> <li>N/A</li> </ul>	<ul style="list-style-type: none"> <li>Could be covered by 'coping' or 'intrusiveness'</li> </ul>
Impact on social life	<ul style="list-style-type: none"> <li>N/A</li> </ul>	<ul style="list-style-type: none"> <li>Could be covered by 'coping' or 'intrusiveness'</li> </ul>
Impact on work	<ul style="list-style-type: none"> <li>N/A</li> </ul>	<ul style="list-style-type: none"> <li>Could be covered by 'coping' or 'intrusiveness'</li> </ul>
Listening	<ul style="list-style-type: none"> <li>Important to measure tinnitus impact on hearing ability.</li> <li>The green table subgroup wanted tinnitus intrusiveness to encompass aspects of listening.</li> </ul>	<ul style="list-style-type: none"> <li>Not a prominent issue for all patients</li> <li>Difficult to differentiate from outcomes related to hearing loss</li> <li>Could be covered by intrusiveness</li> </ul>
Quality of sleep	<ul style="list-style-type: none"> <li>Strong feeling that sound-based therapies (as an intervention category) are directly relevant to</li> </ul>	<ul style="list-style-type: none"> <li>Some felt that 'quality of sleep' was perhaps secondary to 'intrusiveness' and 'ability to ignore'.</li> </ul>

	<p>addressing sleep complaints associated with tinnitus</p> <ul style="list-style-type: none"> <li>• Currently play a major role in improving sleep</li> <li>• Acknowledged as the most/ one of the most reported, problematic complaints associated with tinnitus</li> <li>• Argued as highly important given the potential to have an impact on overall wellbeing/ can influence a variety of other domains</li> </ul>	<ul style="list-style-type: none"> <li>• Acknowledged that sleep complaints were not relevant to all individuals with tinnitus and therefore it was questioned whether this domain should be core</li> <li>• Some felt sleep problems were more relevant to the acute/ initial phase of tinnitus and therefore maybe not appropriate for the COS which should be relevant to both short and long term symptoms</li> </ul>
Tinnitus awareness	<ul style="list-style-type: none"> <li>• Sensitive outcome to sound based therapy</li> <li>• Seen as the 'root domain' of tinnitus intrusiveness (and other domains (e.g. a reduction in awareness would mean reduced intrusiveness))</li> </ul>	<ul style="list-style-type: none"> <li>• Covered by 'tinnitus intrusiveness' according to several participants</li> <li>• Does not capture the emotional impact/distress that tinnitus causes</li> <li>• For some this is simply a 'baseline' that does not necessarily call for relief/ treatment</li> <li>• 'Tinnitus intrusiveness' potentially more sensitive to change</li> </ul>
Tinnitus intrusiveness	<ul style="list-style-type: none"> <li>• Broad coverage of tinnitus impact (e.g. can cover aspects of sleep, listening, conversation....)</li> <li>• Captures the 'emotional' impact of tinnitus where 'awareness' does not</li> </ul>	<ul style="list-style-type: none"> <li>• One researcher questioned whether awareness would be more important, given that it is the 'root' of tinnitus intrusiveness</li> </ul>
Tinnitus unpleasantness	<ul style="list-style-type: none"> <li>• N/A</li> </ul>	<ul style="list-style-type: none"> <li>• Not as important as 'tinnitus intrusiveness'</li> </ul>
Treatment satisfaction	<ul style="list-style-type: none"> <li>• This outcome is sufficiently broad to cover a range of therapeutic devices</li> <li>• It's important for patients to be satisfied with the device they are prescribed in order for them to be motivated to use it (potentially an indicator for adherence/compliance)</li> </ul>	<ul style="list-style-type: none"> <li>• May be coloured by factors not related to the treatment, such as a grumpy clinician etc. Moreover, 'treatment satisfaction' was felt not so suitable for early evaluation of a novel therapy (i.e. a clinical trial) because it measures satisfaction with the overall therapeutic process, not the sound devices in isolation.</li> <li>• Satisfaction could be achieved without effectiveness</li> <li>• Satisfaction is something to measure later down the line.</li> </ul>