



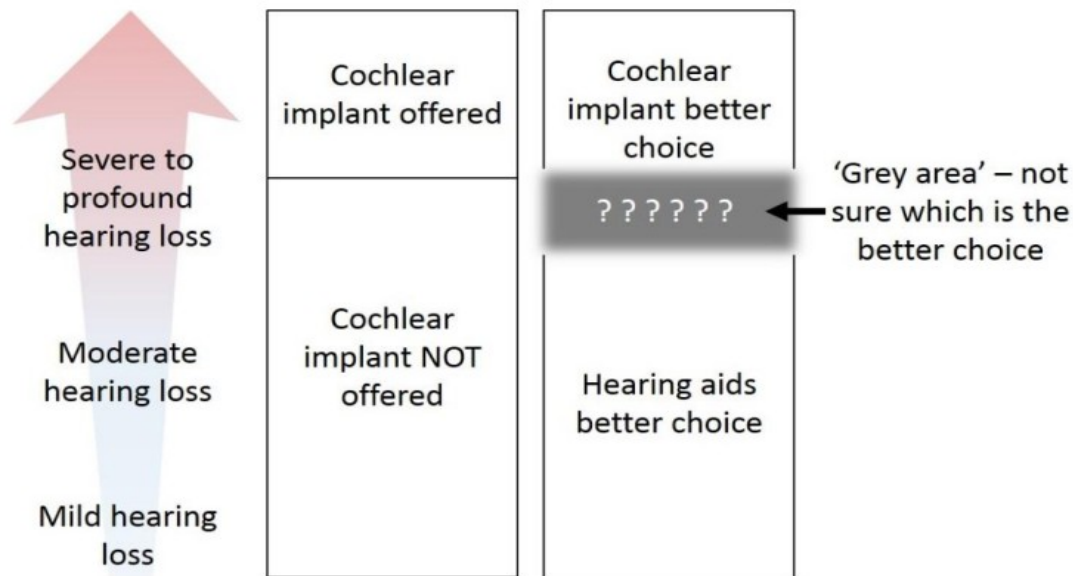
The COACH Trial

Ray Glover - Honorary Secretary, National Cochlear Implant Users Association, Member of COACH Patient & Public Involvement Panel (PPI)

- What is the COACH trial?
 - **CompA**ring **Cochlear** implants with **H**earing aids
- Why COACH is needed
 - Improvements to technology
 - Better fitting to hearing loss
 - Improved connectivity
 - Better understanding of how we hear
 - Neural plasticity – give the brain data and it will learn how to make best use of it. (Providing you do your homework!)
- Role of Public Patient Involvement (PPI) Panel
 - Help from experienced users
 - Lay oversight from Joe public on how money is being spent

What is the COACH Trial?

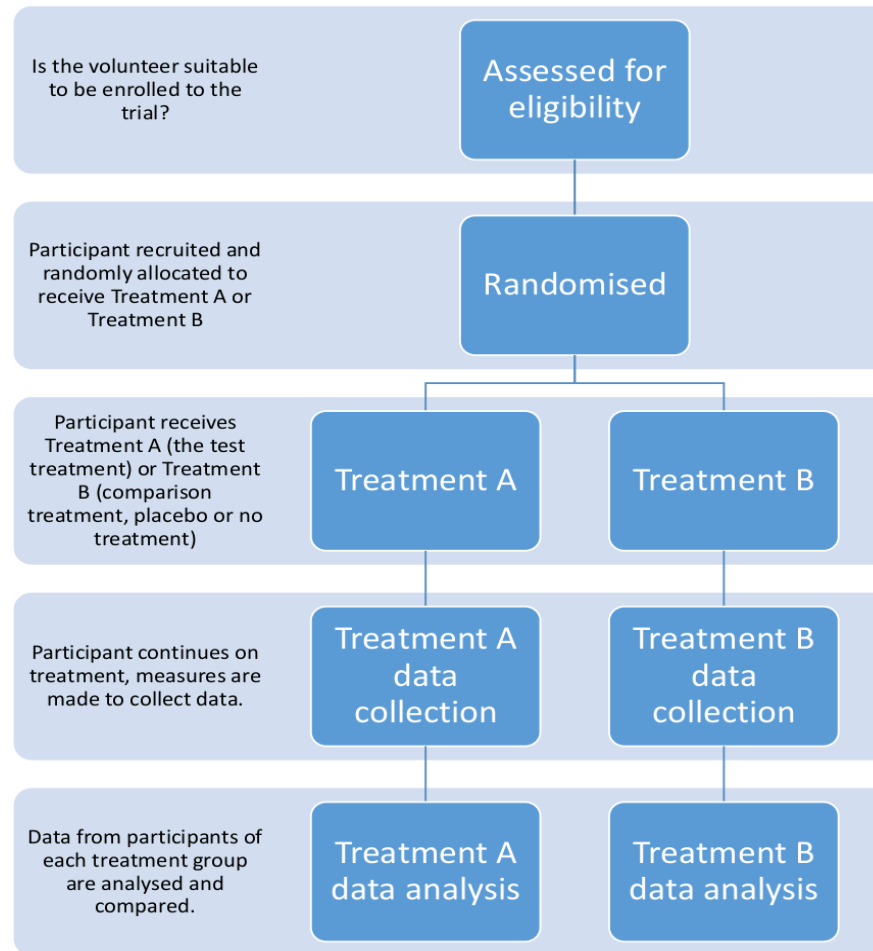
- **CompA**ring **Cochlear** implants with **Hearing** aids
 - Looking for people who are severely deaf but don't meet the criteria for a ci to investigate the 'Grey area'



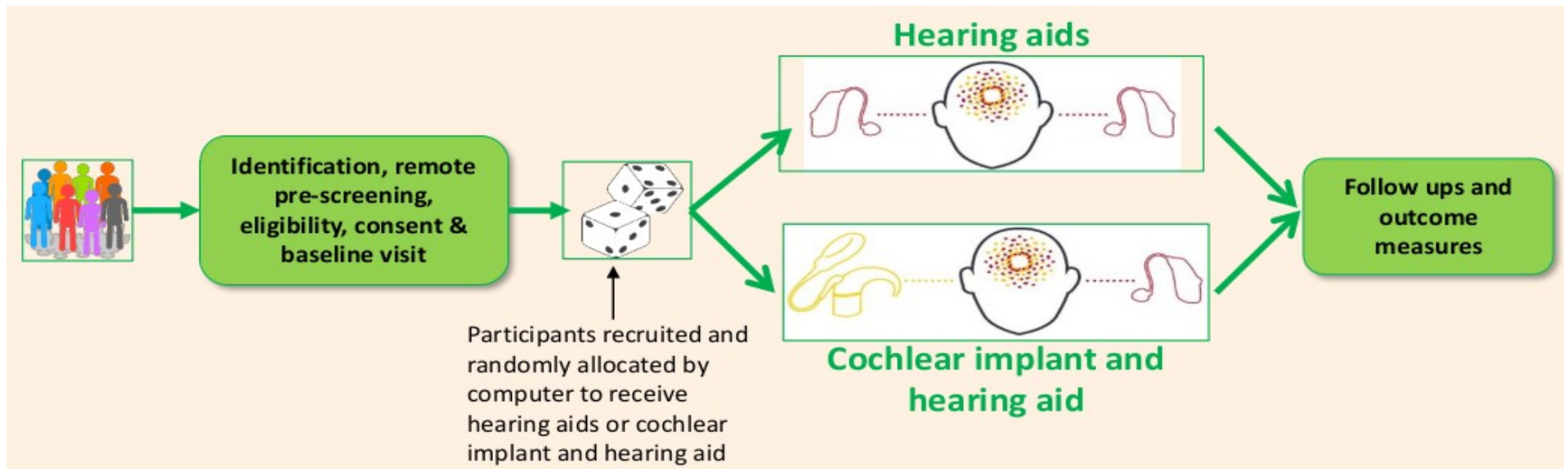
- NHS funding for a cochlear implant regulated by NICE TA566, (2019)
 - hearing loss > 80dB for two or more frequencies 500, 1k, 2k, 3k, 4k Hz
 - not getting adequate benefit from hearing aids i.e. <50% correct phoneme recognition on Boothroyde (AB) word test after minimum 3 month trial.
- Previously, TA166 (2009) required >90dB at 2k and 4kHz and <50% score BKB sentences
 - *(For each 10dB of hearing loss the mechanical parts of hearing would have to vibrate 3.3 times more to compensate)*
- By 10 years later there was expert consensus that ci's could help more deaf people
- **BUT** hearing aids have got better, some hearing functions get worse with ci's
 - directionality, music, separating separate speakers
- Hence grey area where nobody knows if a ci is or ha's are the best choice.
- **If** the NICE TA566 criteria need to change research is needed to elucidate the grey area



Procedure of a Random Trial



COACH Trial procedure



- Participants are introduced via several routes:
 - An audiologist recognises patient as possible candidate
 - Audiologists need to be aware of COACH
 - Participant Identification Centres (PIC) in audiology clinics & GP surgeries
 - Self-referral after dissatisfaction with hearing aids and searching the web. <https://www.coachtrial.ac.uk/home.aspx>
 - Likely to seek knowledge to confirm their belief that a ci is the best option
 - Self-referral after meeting a ci recipient who hears better than they do.
 - May have unrealistic expectations
 - Unaware of the drawbacks of listening with a ci

Candidature

- Hearing loss > 70 dB at any two frequencies
- $<60\%$ correct on AB phoneme test
- Sensori-neural (BAHA may be more appropriate for conductive loss)
- Non-progressive, non-fluctuating hearing loss
- Willing to take part in tests for up to a year
 - Tests and questionnaires at 1m, 3m, 6m, 9m post ci activation or ha optimisation
- Has reasonable access to a COACH member centre



COACH Procedure

- Cochlear Uk Ltd sponsor the research
- CI Centres recruited and audiologists trained so that candidate recruitment and follow-up procedures are uniform
- Once identified as qualifying the participant is randomly assigned either to receive one Nucleus 7 Nucleus 8 or Kanso 2 ci and a hearing aid in the other ear
- **Or** binaural hearing aids, **alternatively**, they may use their existing ha's, if appropriate.
- CI implant insertion operation **or** hearing aid optimisation
- Online or postal questionnaire at 1 month after switch-on for ci or optimisation of hearing aids.
- Face-2-face follow up with audiologist at 3, 6, 9 months
- Multiple questionnaires to ensure the research is comparable internationally

- **Problems arise:**

- Clinics resource limited, assessment costly, program delayed if candidates drop-out.

- **Candidates:**

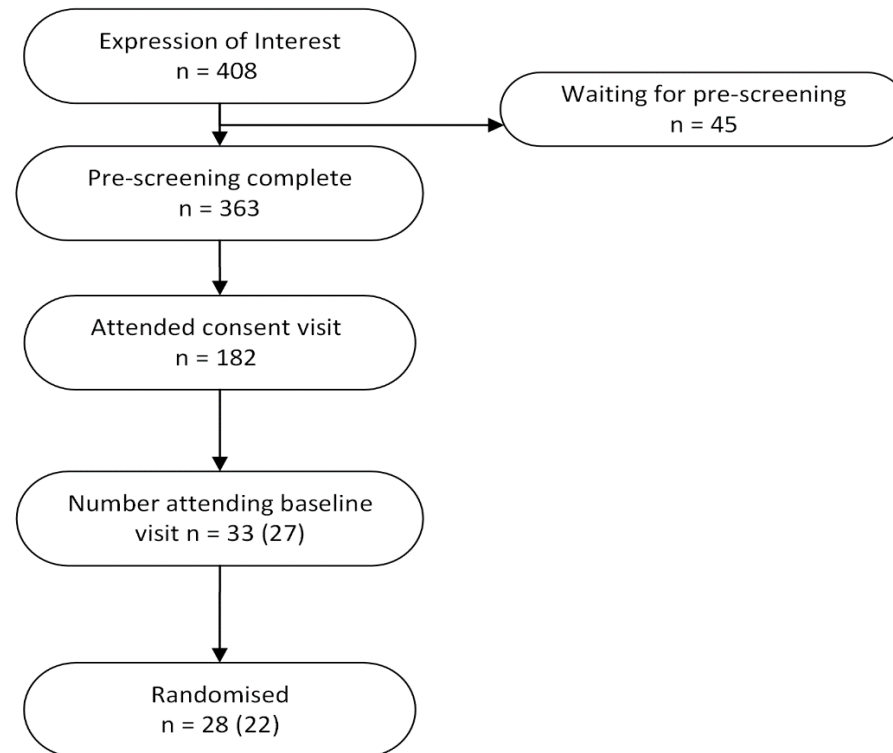
- May have pre-conceived ideas that ci is better and be disappointed if selected for ha's
- Would attend clinic follow-up if ci but not ha
- Becomes aware of the risks of a ci and drops out before op.
- Joins trial but burden of follow-up tests proves too great



Role of PPI Panel

- 12 members either ci or ha users
 - 3 members of NCIUA
- Meet with the COACH research team via video conferencing
- Design and review of patient information media and hand-outs
 - Help with video explaining COACH
 - Stress importance of giving information in an understandable format
- Give insight into how patients may interpret the procedures necessary for research
 - Someone might argue that they would only join if they were promised a ci at the end of the trial.
 - Discussion as to how audiologists can give disappointing news regarding eligibility and expectation.
 - Handle patient reaction to multiple, overlapping questionnaires
- Signpost prospective candidates to the COACH website

COACH Progress



Conclusions

- The PPI panel has made significant revisions to the COACH patient information documents and made one aware of a range of points of view during our discussions.
- National Institute of Health Research (NIHR) insists that patient orientated research projects have a PPI panel to review and advise the research. NCIUA often receives requests for volunteers. Do consider becoming one for a rewarding experience by sharing your own.