NIHR | Nottingham Biomedical Research Centre

FOUNDATION

Designing and assessing the feasibility of a randomised controlled trial of bilateral cochlear implantation in adults

University of Nottingham
UK | CHINA | MALAYSIA

UNIVERSITY OF LIVERPOOL

CTRC
Clinical Trials Research Centre

Nottingham University Hospitals NHS
NHS Trust

NCIUA National Cochlear Implant Users Association

UNIVERSITY OF Southampton

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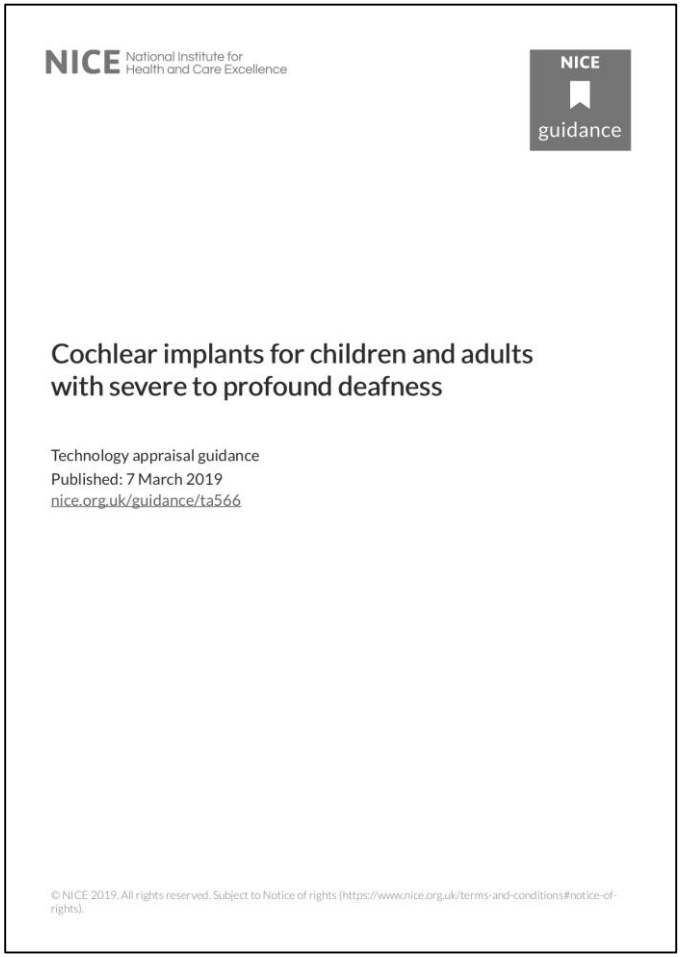
Context for FOUNDATION

NICE Technology Appraisal Guidance 166/566

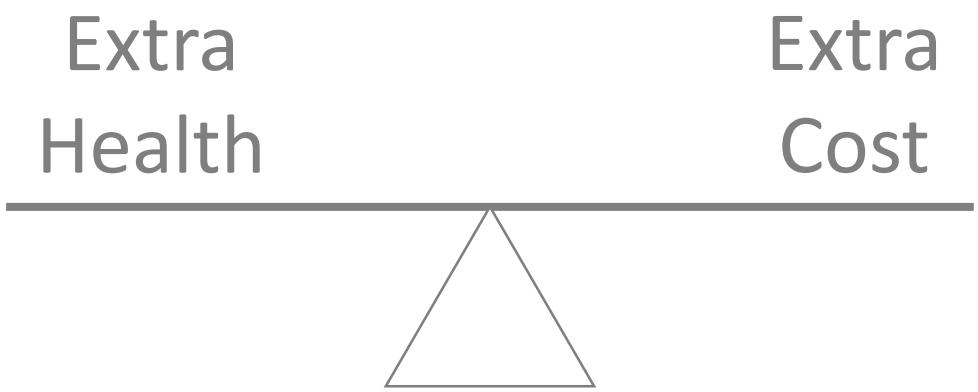


- Published in 2009; Updated 2019
- Examined the evidence for unilateral and bilateral cochlear implantation in children and adults with severe to profound deafness
- Recommends bilateral implantation for:
  - Children
  - Adults with significant visual impairment
- *Does not recommend bilateral implantation for other adults*

Why not bilateral for adults?

Extra benefits of bilateral vs unilateral implantation:

- Reduces listening difficulties
- Improves ‘spatial hearing’
- Reduces fatigue and listening effort
- Benefit to overall health and well-being



Uncertainty over whether benefit to overall health large enough to justify costs of 2nd implant

Why was bilateral not cost-effective?

All figures taken from NICE guidance

Cost-effective only if <£30,000/QALY

Unilateral:	£14,200/QALY
Bilateral:	£49,600/QALY

What if there was a discount on 2nd CI?

Assuming 25% discount	£43,028/QALY
Assuming 50% discount	£36,497/QALY

What if the health gain was larger than assumed?

Assuming +33% larger gain	£37,725/QALY

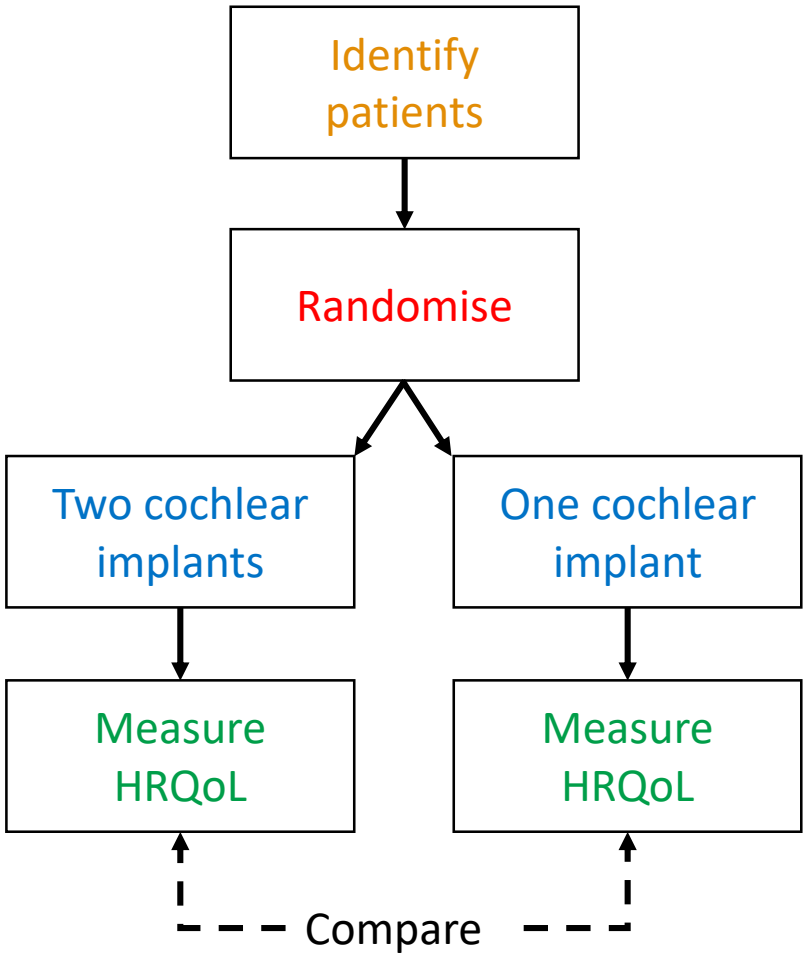
How could it be made cost effective?

Discount second device by:	75%
Health gain larger by:	+66%

NICE Research Recommendation

Recommendations for future research

The Committee recommended that a randomised controlled trial should be carried out to examine the benefit of bilateral cochlear implantation compared with unilateral cochlear implantation in adults with severe to profound deafness.

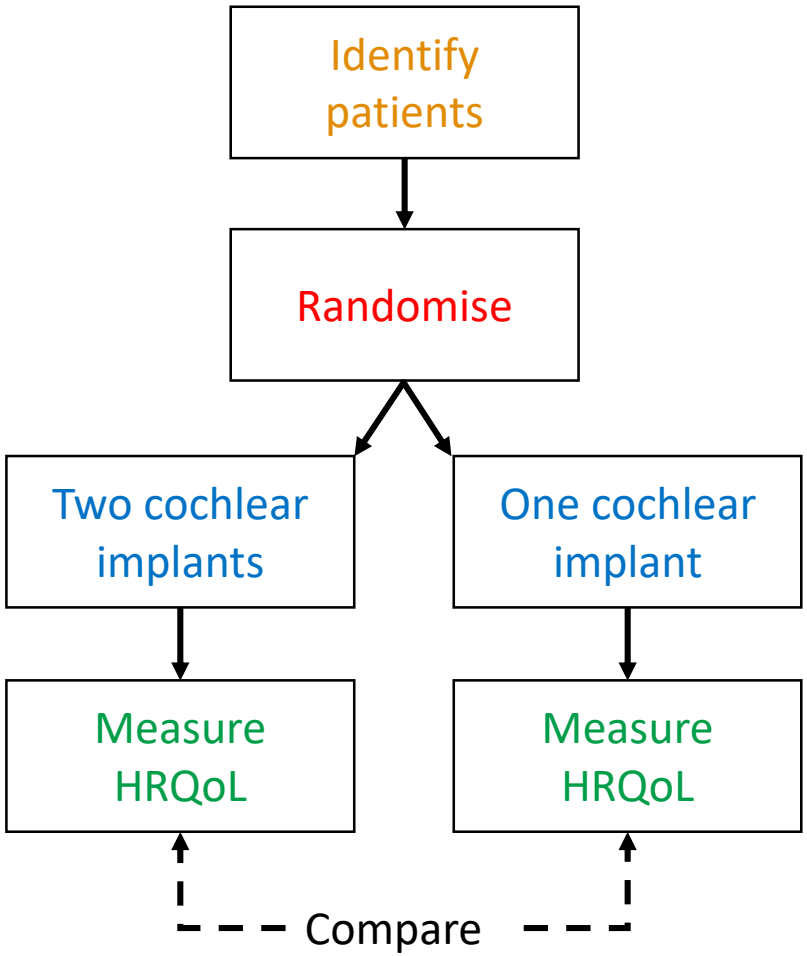


Aims of FOUNDATION

FOUNDATION study

Can we conduct this trial?

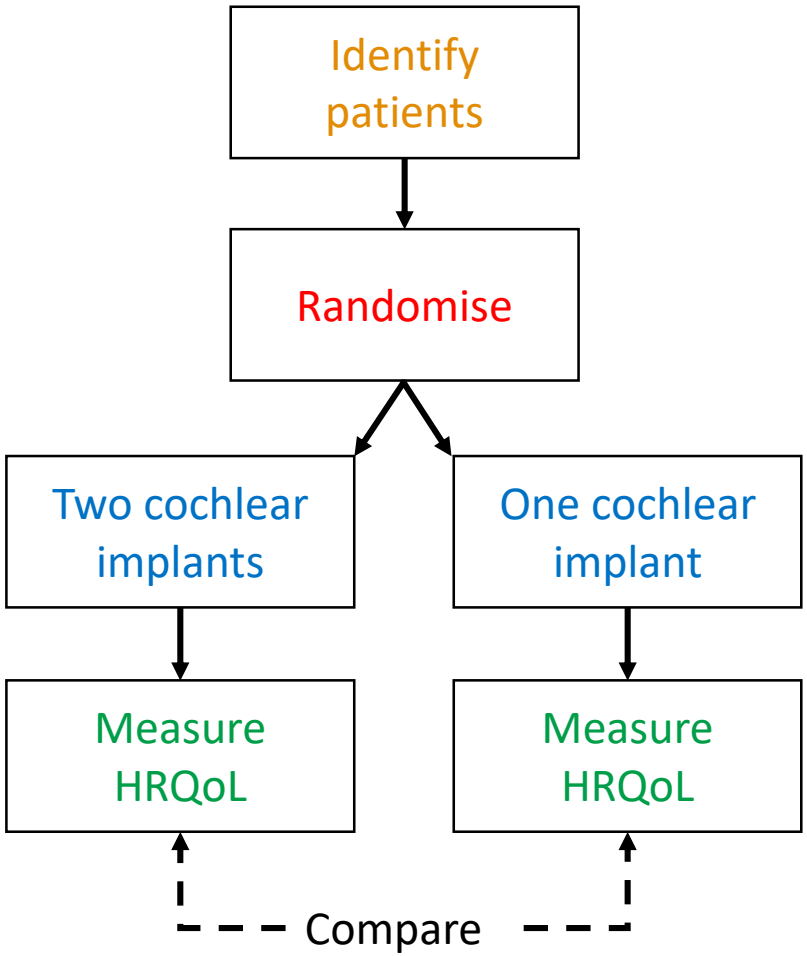
- Will patients be willing to take part?
- When should patients be approached about the trial?
- Will they accept to being randomised?
- Will they stay in the study if they get randomised to receive one implant?
- Will they be willing to complete the study questionnaires?



FOUNDATION study

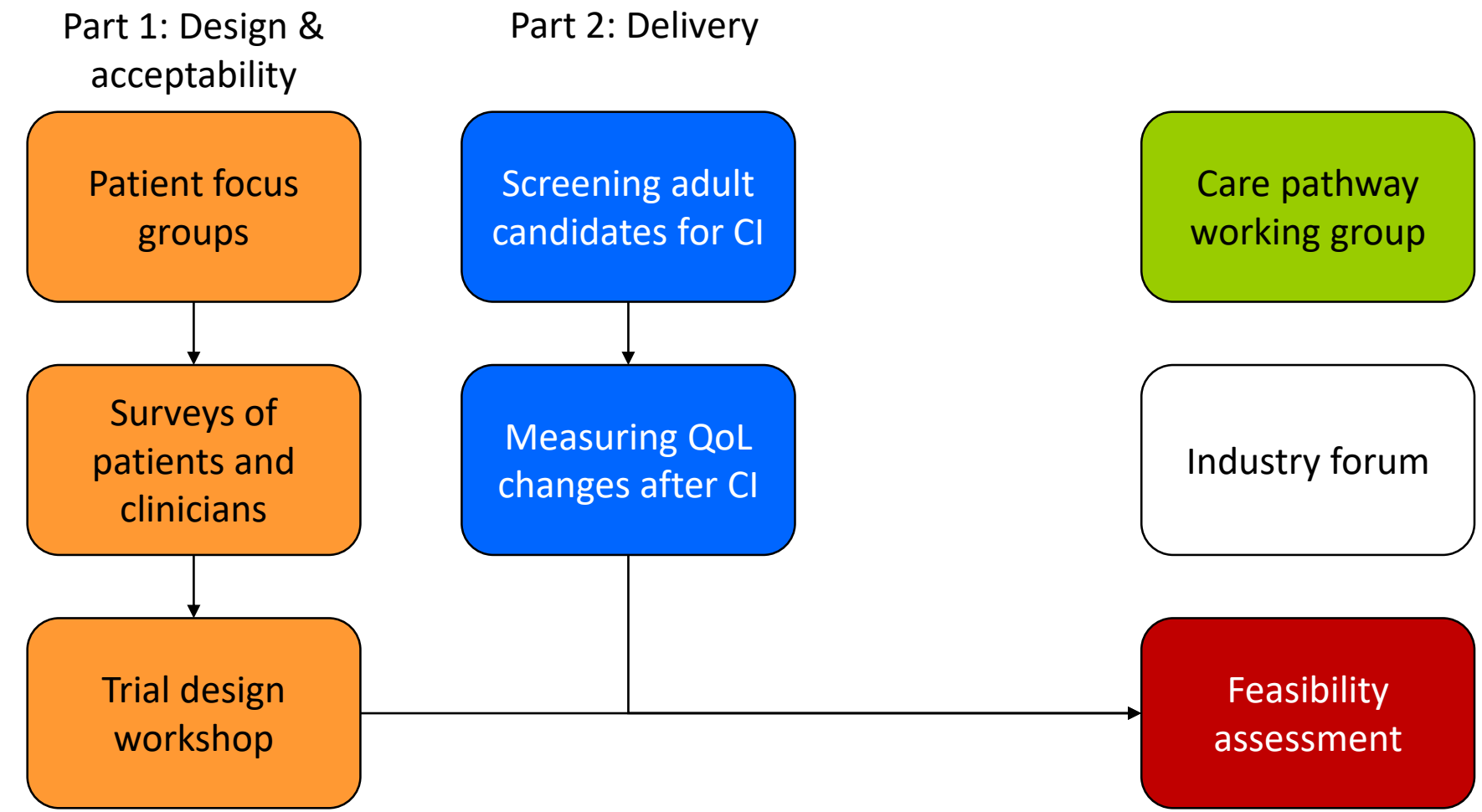
Can we conduct this trial?

- Can sites screen and recruit enough patients to support a trial?
- How many patients are needed for a trial?
- How can we assess whether 2 CIs are more cost-effective than 1 CI?

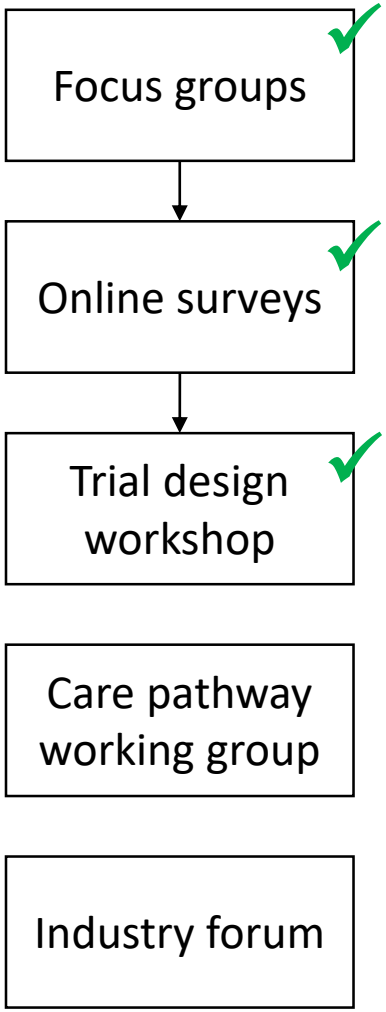


Design and Progress

FOUNDATION study



Part 1 - Objectives



Identify design and acceptability issues

Assess importance of design and acceptability issues

Obtain consensus on solutions to design issues

Gather information about CI care pathway
Completion due in July 2019

Discuss potential for industry support for a trial
Completion due in July 2019

Part 1 - Progress

Patient & Clinician Focus Groups

14 CI users & candidates for CI
6 HCPs (ENT/Audiology/Rehab)

Online surveys: 136 respondents

97 Patients

39 HCPs

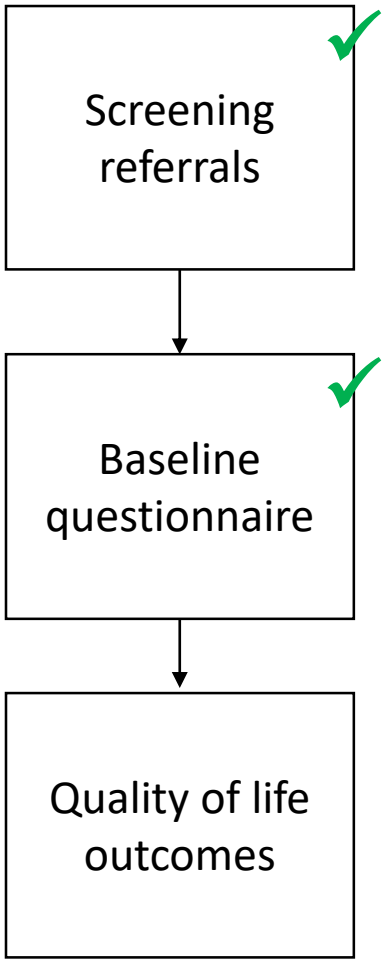
Trial design workshop:

8 HCPs (ENT/Audiology/Rehab)

1 CI user collaborator

6 Researchers / Trial staff

Part 2 - Objectives



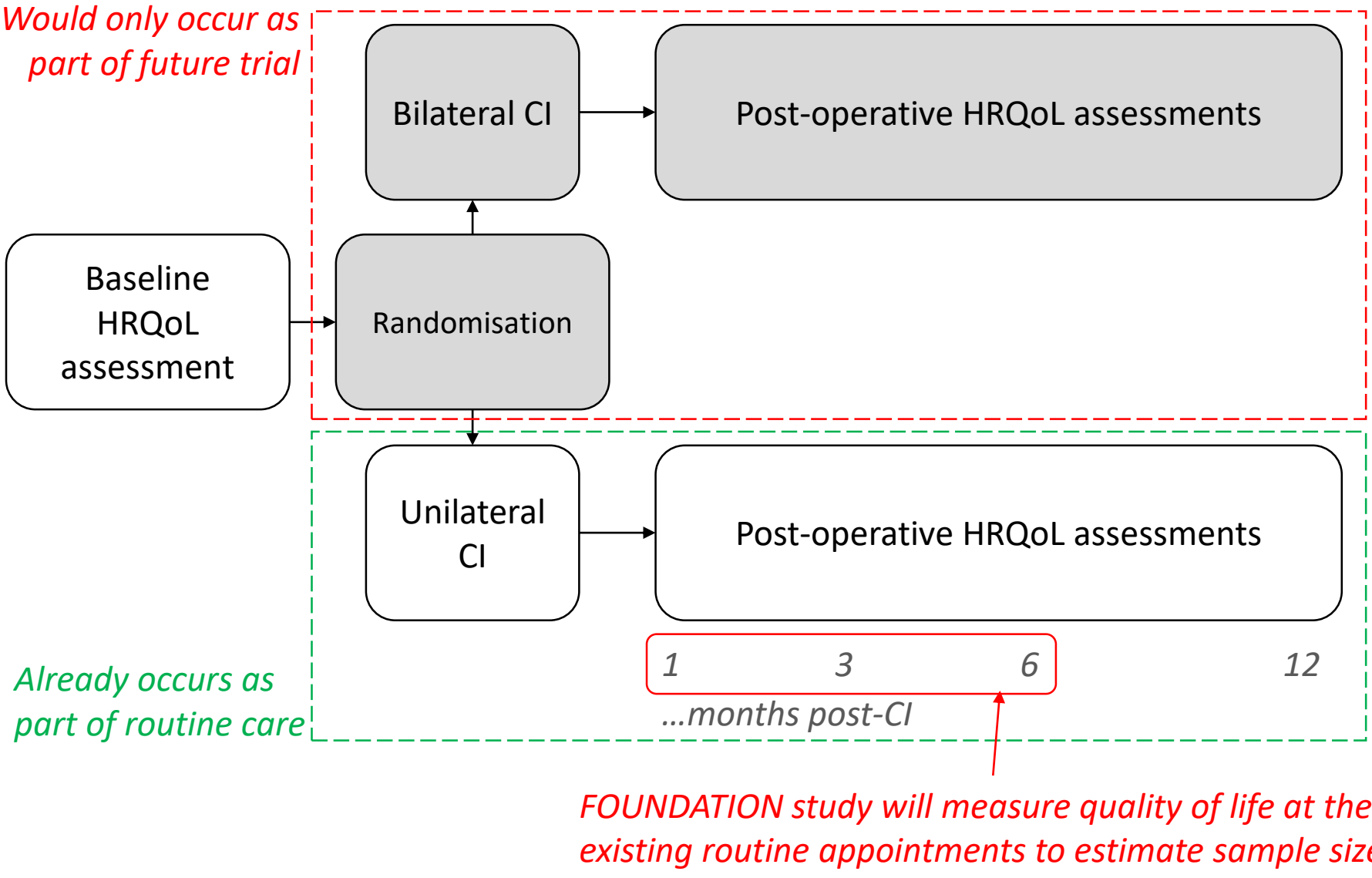
- Determine what proportion of adult referrals would have been eligible to participate in the trial
- Assess capacity to screen patients for eligibility

- Assess acceptability of trial

- Assess capacity to recruit and follow-up patients
- Assess questionnaire completion rates
- Estimate sample size for future trial

Completion due in July 2019

Part 2 - Design



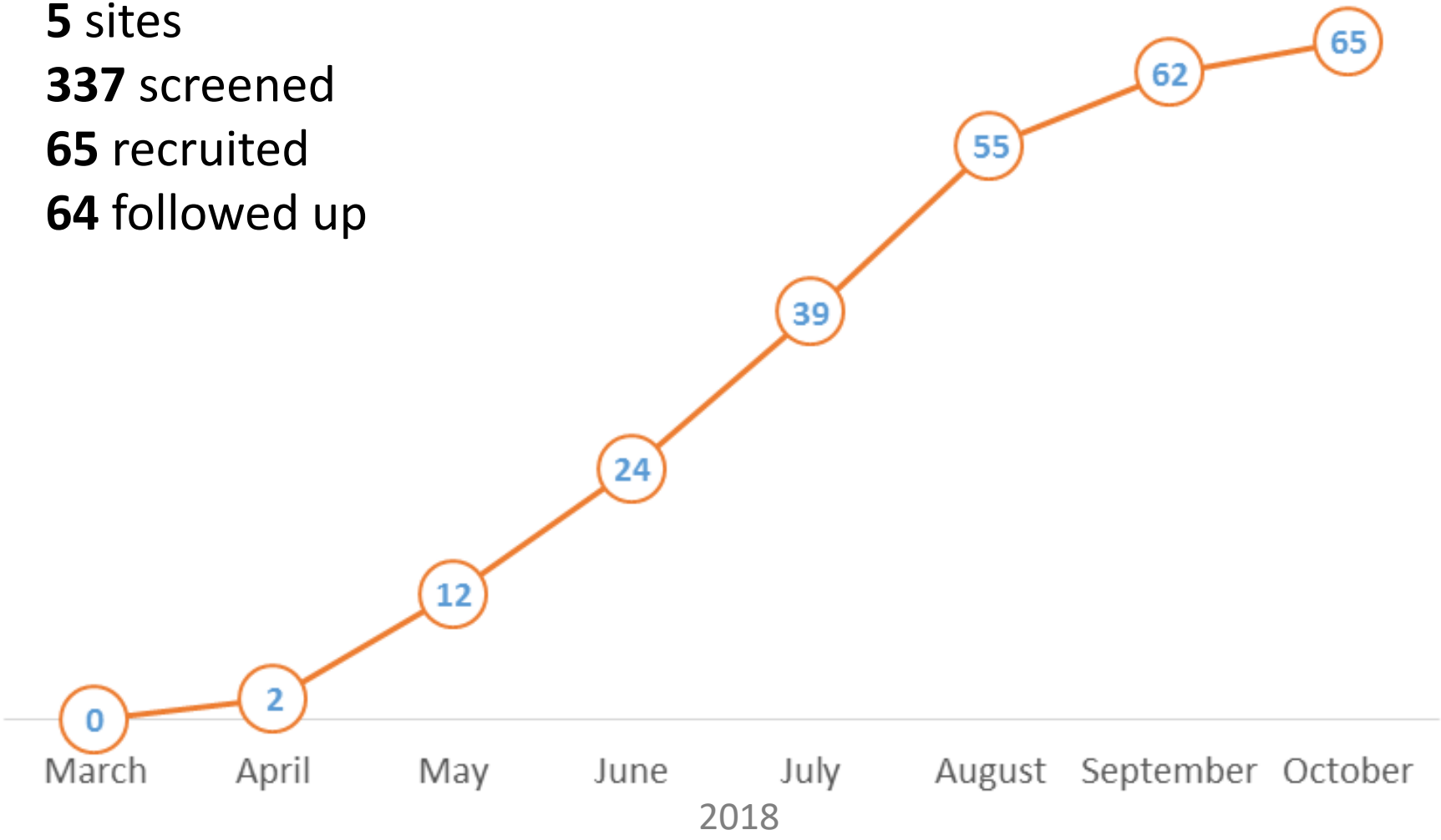
Part 2 - Progress

Participating centres

- Nottingham Auditory Implant Programme
- Midlands Hearing Implant Programme
- St. Thomas' Hearing Implant Centre
- Richard Ramsden Centre for Auditory Implants
- Southampton Auditory Implant Service

Part 2 - Progress

5 sites
337 screened
65 recruited
64 followed up



Next steps

June 2019

Complete multi-centre quality of life exercise

- Gather and analyse all QoL data
- Estimate possible sample sizes for future trial

July 2019

Joint meeting of study management & steering groups

- Assess all data on acceptability & delivery of the trial
- Make decision about whether trial is feasible to conduct

Hold industry forum

Early 2020

Seek funding for multi-centre RCT if trial is feasible

FOUNDATION

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This presentation presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0815-20039). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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