The National Institutes of Health established the Patient-Reported Outcomes Measurement Information System (PROMIS) in 2004 to improve the assessment of patient-reported outcomes and development of instrument with the goals of reliability, precision, and construct validity.[99] PROMIS has created QOL questions that have undergone rigorous modern validity testing for cross-sectional, content, and clinical validity.[40-42] No CI-specific PROM has been developed using this rigorous validation methodology.

# Cochlear implantation outcomes evaluated with general patient-reported outcome measures

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## Abstract

**Objective:** To determine the change in general health-related quality of life (HRQOL) after cochlear implantation and its association with speech recognition.
**Study Design:** Meta-analysis
**Methods:** Search was performed independently following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement by two authors using PubMed, Medline, Scopus, and CINAHL. Studies on adult cochlear implant (CI) patients measuring HRQOL before and after cochlear implantation were included. Standardized mean difference (SMD) for each measure and pooled effects were determined. A subset analysis of Health Utilities Index -3 (HUI-3) measures was conducted. A meta-analysis of correlations was also performed between all non-disease-specific patient-reported outcome measures (PROMs) and speech recognition after cochlear implantation.
**Results:** Twenty-two articles met criteria for meta-analysis of HRQOL improvement, but 15 (65%) were excluded due to incomplete statistical reporting. From the seven articles with 274 CI patients that met inclusion criteria, pooled analyses showed a medium positive effect of cochlear implantation on HRQOL (SMD = 0.79). Subset analysis of the HUI-3 measure showed a large effect (SMD = 0.84). Nine articles with 550 CI patients met inclusion criteria for meta-analysis of correlations between non-disease specific PROMs and speech recognition after cochlear implantation. Pooled analysis showed a low correlation between non-disease-specific PROMs and word recognition in quiet (r = 0.35), sentence recognition in quiet (r = 0.40), and sentence recognition in noise (r = 0.32).
**Conclusion:** Although regularly used, HRQOL measures are not intended to measure nor do they accurately reflect the complex difficulties facing CI patients. Accordingly, only a medium positive effect of cochlear implantation on HRQOL was observed and a low correlation between non-disease-specific PROMs and speech recognition.

## Introduction

- Quality of life (QOL) patient reported outcomes measures (PROMs) are commonly used to determine the impact of an intervention on an individual's life. These PROMs can be subdivided in to two major categories—general and disease-specific. The former are generalizable instruments that are meant to be applied to large diverse populations to evaluate overall QOL or an individual construct. Conversely, disease-specific metrics are typically validated for a particular population that share a common deficit or illness.
- Studies have shown conflicting data on the correlation of speech recognition and patient self-reported QOL improvement in this population.[1-4]
- We focused this meta-analysis on HRQOL PROMs that are routinely used in the literature, but not designed explicitly for individuals with hearing loss. As a comparison to our prior work, we sought to determine if HRQOL PROMs showed similar impact on CI recipients' lives as hearing and CI-specific instruments and determine their utility in the CI population. A second meta-analysis evaluated the correlation of these HRQOL PROMs and speech recognition ability.

## Methods

- When selecting articles for meta-analysis of QOL improvement, studies meeting the following inclusion criteria were ultimately selected: assessment of HRQOL in an adult CI cohort before and after surgery (or in a post-treatment cohort versus a control cohort); sample size, mean, and standard deviation available for PROM data; and follow-up of at least 3 months.

- When selecting articles for meta-analysis of correlations, studies meeting the following inclusion criteria were used: correlation values of speech recognition scores versus any general PROM in an adult cohort after cochlear implantation; complete data available (sample size and Pearson or Spearman correlation values); and postoperative follow-up of at least 3 months.

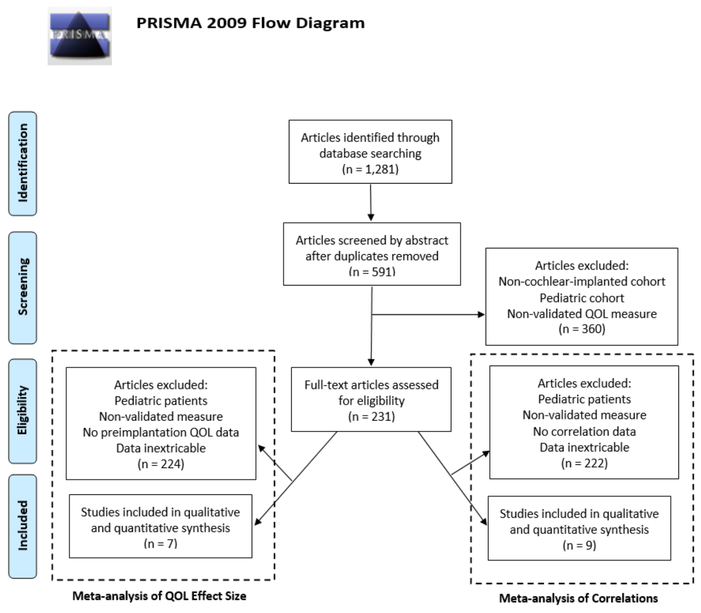
- The following thresholds were used for subjective assessment of effect size: 0.2 - small effect, 0.5 – medium effect, and 0.8 – large effect.[5]

- The following thresholds were used for subjective assessment of correlation values (r): 0 - 0.3, negligible; 0.3 – 0.5, low; 0.5 – 0.7, medium; 0.7 – 0.9, high; 0.9 – 1.0, very high.[6,7]

## References

1. Damen GW, Beynon AJ, Krabbe PF, Mulder JJ, Mylanus EA. Cochlear implantation and quality of life in postlingually deaf adults: long-term follow-up. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery. 2007;136(4):597-604.
2. Kumar RS, Mawman D, Sankaran D, et al. Cochlear implantation in early deafened, late implanted adults: Do they benefit? Cochlear implants international. 2016;17 Suppl 1:22-25.
3. Luxford WM, Ad Hoc Subcommittee of the Committee on H, Equilibrium of the American Academy of O-H, Neck S. Minimum speech test battery for postlingually deafened adult cochlear implant patients. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery. 2001;124(2):125-126.
4. Francis HW, Chee N, Yeagle J, Cheng A, Niparko JK. Impact of cochlear implants on the functional health status of older adults. The Laryngoscope. 2002;112(8 Pt 1):1482-1488.
5. Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ.* 1997;315(7109):629-634.\
6. Hedges LV, Olkin I. Statistical methods for meta-analysis. Orlando: Academic Press; 1985.
7. Lee Rodgers J, Nicewander WA. Thirteen ways to look at the correlation coefficient. The American Statistician. 1988;42(1):59-66.
8. Kumar RS, Mawman D, Sankaran D, et al. Cochlear implantation in early deafened, late implanted adults: Do they benefit? Cochlear implants international. 2016;17 Suppl 1:22-25.
9. Dawes P, Emsley R, Cruickshanks KJ, et al. Hearing loss and cognition: the role of hearing AIDS, social isolation and depression. PLoS One. 2015;10(3):e0119616.
10. Tambs K. Moderate effects of hearing loss on mental health and subjective well-being: results from the Nord-Trondelag Hearing Loss Study. Psychosom Med. 2004;66(5):776-782.
11. McRackan TR, Bauschard MJ, Hatch JL, et al. Meta-analysis of quality of life in cochlear implant patients and its association with speech recognition abilities Laryngoscope. 2017;submitted.
12. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. J Clin Epidemiol. 2010;63(11):1179-1194.

## Search Method




## Results

| Category | r | 95% CI | $I^2$ | p |
|---|---|---|---|---|
| **Subtotal: HRQOL** | | | | |
| Word recognition in quiet | 0.330 | 0.191 – 0.456 | 64.39% | 0.0027 |
| Sentence recognition in quiet | 0.335 | 0.180 – 0.475 | 57.53% | 0.0949 |
| Sentence recognition in noise | 0.323 | 0.193 – 0.442 | 0.00% | 0.4163 |
| **Subtotal: Psychological** | | | | |
| Word recognition in quiet | 0.413 | 0.282 – 0.530 | 0.00% | 0.7943 |
| Sentence recognition in quiet | 0.445 | 0.316 – 0.557 | 0.00% | 0.9919 |
| Sentence recognition in noise | NA | NA | NA | NA |
| **Total** | | | | |
| Word recognition in quiet | 0.353 | 0.252 – 0.445 | 51.46% | 0.0110 |
| Sentence recognition in quiet | 0.397 | 0.299 – 0.487 | 0.00% | 0.5126 |
| Sentence recognition in noise | 0.323 | 0.193 – 0.442 | 0.00% | 0.4163 |

Table 1: Pooled correlation values (r and 95% confidence interval [CI]) and heterogeneity statistics ($I^2$ and p) for meta-analysis of correlations. NA: Not Applicable.

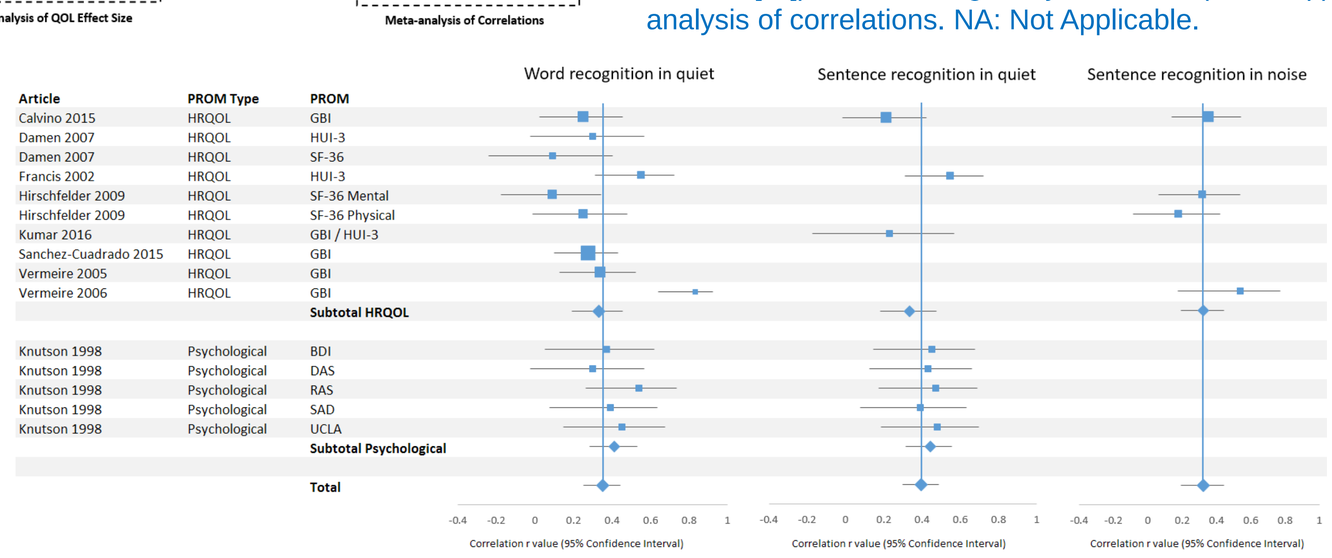



Figure 1: Forest plots pertaining to meta-analysis of correlations for articles reporting health-related QOL (HRQOL) (top) and psychological QOL (bottom) measures versus speech recognition in various conditions. Pooled correlations are represented by diamonds. PROM: patient-reported outcome measure; CI: cochlear implant

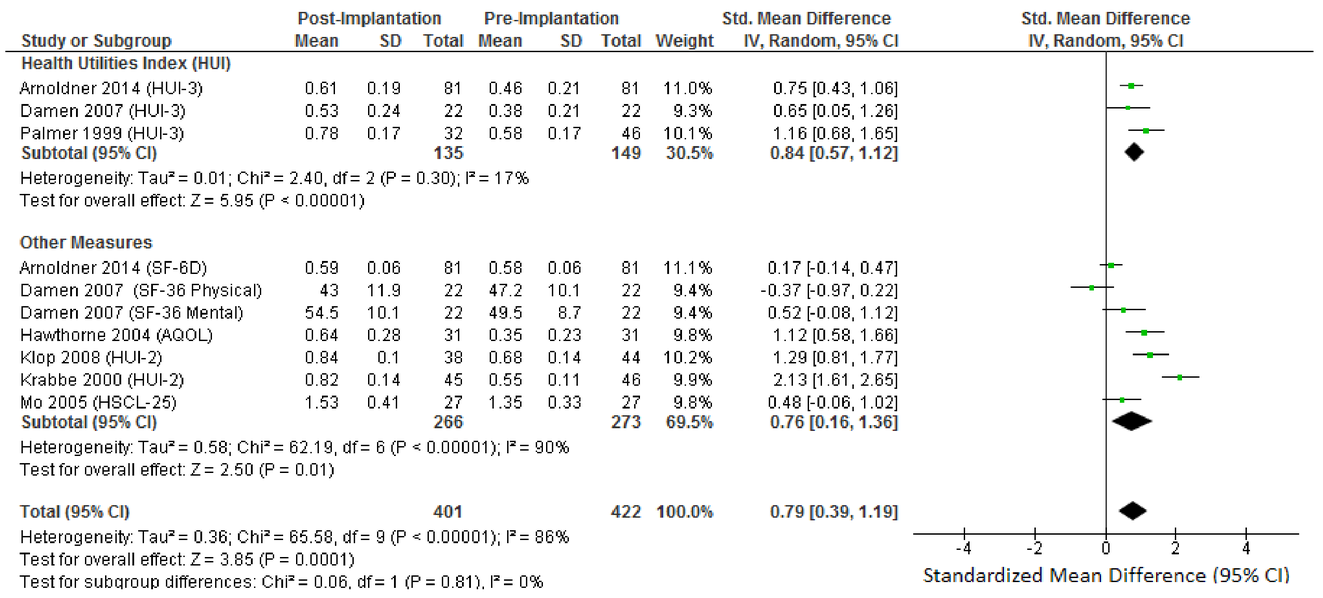



Figure 2: Forest plot of HRQOL PROMs including subset analysis of Health Utilities Index 3 (HUI-3) and other HRQOL measures. 36-Item Short Form (SF-36); 6-item descriptive system (SF-6D); Assessment of Quality of Life (AQOL); Hopkins Symptom Checklist-25 (HSCL-25); IV: Inverse Variance.
HUI-3: large effect (SMD = 0.84 [0.57 – 1.12]); Other HRQOL PROMs: medium effect (SMD = 0.76 [0.16 – 1.36])
HRQOL: medium effect (SMD = 0.79 [0.39 – 1.19])

## Discussion

- In the current study, we found that cochlear implantation was associated with medium improvement in HRQOL, which is far less improvement than we reported for hearing and CI-specific QOL PROMs (SMD = 1.82 and 1.69, respectively).[8]

- The range of SMDs from all HRQOL PROMs in our study ranged from -0.37 to 2.13 with a corresponding $I^2$ value of 86%, indicating a high amount of heterogeneity. This reveals that either HRQOL PROMs are not a homogenous of instruments, and/or there was a large amount of heterogeneity in the populations evaluated among the studies.

- The above emphasizes the importance of using QOL PROMs developed and validated in the CI population. With improved communication abilities, we anticipate that patients are likely to improve with respect to social wellness and participation, as opposed to loneliness, isolation, and depression.[9,10]

- The narrow range of correlation values (r = 0.32 – 0.45) demonstrates that PROMs have a low correlation with all categories of speech recognition testing. These correlation values are similar to and slightly higher than the correlations between hearing/CI-specific QOL measures and speech recognition scores (0.20 – 0.28 and 0.21 – 0.26, respectively).[11]

## Conclusion

- The National Institutes of Health established the Patient-Reported Outcomes Measurement Information System (PROMIS) in 2004 to improve the assessment of patient-reported outcomes and development of instrument with the goals of reliability, precision, and construct validity.[12]

- Our meta-analysis of HRQOL improvement showed a medium positive effect of cochlear implantation on HRQOL. In contrast, our meta-analysis of correlations showed negligible pooled correlations between speech recognition scores and HRQOL PROMs. Disease-specific measures that focus on domains of significance to QOL in CI patients have greater utility in the CI population.

- **New CI-specific QOL PROMs are needed that are developed and validated according to established guidelines and that capture changes in patient QOL after cochlear implantation.**

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