

Testing of a Tool to Elicit Patient Preferences for CTS

Study Protocol and Statistical Analysis Plan

NCT03532373

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Title: Does a preference elicitation tool improve decisional conflict for the diagnosis of carpal tunnel syndrome? A randomized controlled trial

Study purpose:

To test a novel preference elicitation tool at the point of care for patients with suspected carpal tunnel syndrome to aid in the decision to obtain a diagnostic nerve test.

Primary null hypothesis:

- There will be no difference in decisional conflict score between the intervention and control groups

Subjects

Inclusion criteria:

All new patients (>18 years) visiting the Orthopaedic Hand Service

English fluency and literacy

Able to take informed consent

Patient is suspected for carpal tunnel syndrome by a provider in clinic

Exclusion criteria:

Prior diagnostic testing for carpal tunnel (nerve test, ultrasound)

Prior carpal tunnel release

Diagnosis of C5/6 radiculopathy (double crush)

Peripheral neuropathy (ex: diabetic) (general bilateral numbness/tingling in extremities)

Worker Compensation/EMG Required

Cubital (symptoms in all fingers)

Statistical Analysis

Response variables:

- Primary: Decisional Conflict scale

Explanatory variables:

- Primary: Group assignment (intervention vs control group)

Age

Sex

Site

Treating physician

Clinical diagnosis of carpal tunnel Y/N

Number of months since onset of symptoms

Laterality of symptoms (left/right/both)

CTS-6 Score

Preference for diagnosis method

Received diagnostic method

Socioeconomic elements:

- Race/ethnicity (White, Black, Hispanic, other)
- Primary health insurance (Medicare, Medicaid, private, uninsured, workers' compensation)
- Years of education
- Work status (Working, retired, disabled, unemployed)
- Marital status
- Annual salary

Methodology:

We will measure decisional conflict in 150 new patients being evaluated for CTS with the tool compared to 150 patients being evaluated for CTS with standard care. Inclusion criteria will include new, adult patients (>18 years) with a clinical diagnosis of carpal tunnel syndrome who will undergo further diagnosis and treatment (or both). This will include women and minorities that are able to give written consent. Exclusion criteria will include patients who have already been seen by the recruiting surgeon for CTS, who have undergone prior carpal tunnel release, or who have a diagnosis of C5/6 radiculopathy (double crush). Those patients randomized to receiving the tool will use it to identify their preferences for certain attributes of care. Patients will then be presented with their preference data and the surgeon will have a discussion with the patient regarding CTS. Surgeons will have their standard discussion with the patients randomized to the standard care group (no tool).

Statistical Analysis: We will use descriptive statistics techniques to describe the sociodemographic profile and characteristics of the total sample and individual study centers. We will test the hypothesis that patients randomized to use the tool will have lower decisional conflict compared to standard care using a linear mixed-effects regression model, with a fixed and random effect for site to account for the clustering of patients within sites and within site randomization (blocking).

Power Analysis: Although this aim is primarily about feasibility and generating pilot data for a larger grant, we based our power analysis on number of sites $J = 6$, Cohen's effect size for the Decisional Conflict Scale total score $\delta = 0.5$ (i.e. 8 points), $\alpha = 0.05$, effect size variability = .20, proportion of variance explained by the blocking variable (site) - .20, and power = 0.80 yields a site-level sample size of 50. Prior studies using choice experiments have included similar sample sizes.

References

1. Hageman MG, Bossen JK, Neuhaus V, Mudgal CS, Ring D, Science of Variation Group. Assessment of Decisional Conflict about the Treatment of carpal tunnel syndrome, Comparing Patients and Physicians. *Arch Bone Jt Surg*. 2016;4(2):150-155.
2. Shapiro LM, Eppler SL, Baker LC, Harris AS, Gardner MJ, Kamal RN. The Usability and Feasibility of Conjoint Analysis to Elicit Preferences for Distal Radius Fractures in Patients 55 Years and Older. *J Hand Surg Am*. 2019;44(10):846-852. doi:10.1016/j.jhsa.2019.07.010
3. Shapiro LM, Eppler SL, Kamal RN. The Feasibility and Usability of a Ranking Tool to Elicit Patient Preferences for the Treatment of Trigger Finger. *J Hand Surg Am*. 2019;44(6):480-486.e1. doi:10.1016/j.jhsa.2019.01.005
4. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25-30. doi:10.1177/0272989X9501500105
5. Cohen-Mansfield J, Droge JA, Billig N. Factors influencing hospital patients' preferences in the utilization of life-sustaining treatments. *Gerontologist*. 1992;32(1):89-95. doi:10.1093/geront/32.1.89
6. Flynn KE, Weinfurt KP, Seils DM, et al. Decisional Conflict Among Patients Who Accept or Decline Participation in Phase I Oncology Studies. *J Empir Res Hum Res Ethics*. 2008;3(3):69-77. doi:10.1525/jer.2008.3.3.69
7. Adams J, Bateman B, Becker F, et al. Effectiveness and acceptability of parental financial incentives and quasi-mandatory schemes for increasing uptake of vaccinations in preschool children: systematic review, qualitative study and discrete choice experiment. *Health Technol Assess*. 2015;19(94):1-176. doi:10.3310/hta19940
8. Underhill ML, Hong F, Berry DL. When study site contributes to outcomes in a multi-center randomized trial: a secondary analysis of decisional conflict in men with localized prostate cancer. *Health Qual Life Outcomes*. 2014;12:159. doi:10.1186/s12955-014-0159-3
9. Fehlings MG, Nakashima H, Nagoshi N, Chow DSL, Grossman RG, Kopjar B. Rationale, design and critical end points for the Riluzole in Acute Spinal Cord Injury Study (RISCIS): a randomized, double-blinded, placebo-controlled parallel multi-center trial. *Spinal Cord*. 2016;54(1):8-15. doi:10.1038/sc.2015.95
10. Hyman DJ, Pavlik VN, Greisinger AJ, et al. Effect of a physician uncertainty reduction intervention on blood pressure in uncontrolled hypertensives--a cluster randomized trial. *J Gen Intern Med*. 2012;27(4):413-419. doi:10.1007/s11606-011-1888-1