

Confirmation of Values and Preferences When Considering a Musculoskeletal Diagnostic Test: A Scenario-Based Study

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Hypotheses

Primary null hypothesis:

There is no difference in the likelihood of choosing to proceed with a diagnostic test between patients exposed to randomized discussions that include versus do not include a structured diagnostic Advance Care Planning (ACP) discussion.

Secondary null hypotheses:

- There is no difference in the degree of patient confidence that a diagnostic test has more potential for benefit than harm between patients exposed to scenarios with and without a diagnostic ACP-style discussion.
- There is no difference in the perceived difficulty of the diagnostic decision between patients exposed to scenarios with and without a diagnostic ACP-style discussion.
- Patients' preferred level of involvement in diagnostic decision-making does not moderate the association between exposure to a diagnostic ACP-style discussion and decision outcomes (i.e., test acceptance, confidence, or difficulty making decision).

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ClinicalTrials.gov: Yes, not yet completed

Background and Rationale

Background

Most musculoskeletal diagnoses can be made with a high probability based on interview and examination alone.(1,2) This is in part due to the fact that there is a single common pathophysiology at most anatomical areas, many of them associated with human aging, and in part because symptoms and signs are often characteristic and can confirm the diagnosis with a high probability that is not notably increased by diagnostic tests. One example is the diagnosis of carpal tunnel syndrome, where the probability of diagnosis based on characteristic signs and symptoms is not appreciably improved by electrodiagnostic testing.(3)

Following Bayes theorem, diagnostic tests are best used to confirm a likely but still somewhat uncertain diagnosis or to disconfirm an unlikely, but possible and potentially concerning diagnosis.(2) Ordering a test in a context of complete uncertainty often has more potential for harm than benefit due to misleading results or misinterpretation of expected results. For instance, an adult over age 40 with new knee pain after a minor event and no fracture or ligamentous injury is almost certain to have symptoms from knee osteoarthritis, which most humans develop with age.(4) An MRI interpreted as "meniscal tear", when the correct diagnosis is osteoarthritis of the knee, might lead to overdiagnosis and overtreatment with iatrogenic, financial, and psychological harm. Psychological harm takes the form of false hope, uncertainty,

and anxiety about the role of these tests in health, especially when it is not clear why the test is being obtained or the potential benefits and potential harms of testing. (5) Despite this, patients often expect diagnostic tests and imagine they are a necessary step towards solving the problem.(6,7) Patients and non-specialists may think that testing is necessary for diagnosis, whereas specialists tend to make diagnoses without tests and reserve tests for planning operative interventions.

People are not accustomed to thinking about the potential harms of diagnostic testing. More information seems inherently good and it can be difficult to understand the misinformation and harm that can be associated with diagnostic tests and their interpretation. Likewise, clinicians may assume that reassurance must be tied to diagnostic testing. Yet, evidence suggests that a negative test result is rarely effective in alleviating worry and that the quality of the patient-clinician relationship is instead far more important.(8-10) Thoughtful and healthful use of diagnostic testing depends, in part, on trust between clinician and patient.(5)

Rationale

Advance Care Planning (ACP) is often considered in terms of end-of-life care among people with terminal or life-threatening illness.(5,11) During ACP, clinicians help patients ground their understanding of the illness and explore what tests and treatments matter most to them (their values). The motivation for ACP is that, in the midst of the emotion of serious illness, people might be more likely to make choices contrary to their values.(12) Having carefully considered and mapped out one's values and plans prior to serious illness can help with calm, confident navigation of difficult decisions amid serious illness. While this approach has been traditionally centered around end-of-life care, there is emerging interest in extending this approach to care throughout medicine, including plans for decisions regarding visits, tests, and treatments for non-life-threatening illness. In the field of musculoskeletal care, there is evidence that personalized treatment approaches are associated with alleviation of symptoms and enhanced patient confidence in self-management and understanding regarding their condition.(13) For instance, in patients with ongoing musculoskeletal symptoms such as low back pain and symptoms diagnosed as fibromyalgia, individualized approaches to care in which patients are active participants in their treatment decisions, can enhance patient satisfaction, quality of life, treatment adherence and self-efficacy (as measured via Patient Activation Measure).(13-16) In most cases, musculoskeletal diagnostic tests are not considered in time sensitive situations. Most of the pathophysiologies under consideration are idiopathic or senescent and the tests and treatments are optional (discretionary). There may be value in adding a step prior to ordering a test, where both the patient and clinician take time to explore what matters most to the patient and how they plan to weigh potential harms and benefits of testing.

This study aims to explore how patients respond to brief hypothetical scenarios regarding potential musculoskeletal diagnostic tests, and whether a simulated ACP-style discussion embedded within the scenario affects patient preferences and confidence in understanding potential harms and benefits.

Proposed methods

Study design: Randomized, scenario-based study

Recruitment methods: Participants will be recruited from an outpatient musculoskeletal specialty clinic. After obtaining verbal consent, all participants will be asked to complete a short survey on a tablet or other electronic device via the REDCap platform (Vanderbilt University, United States).

Intervention: Patients will be invited to enroll prior to their musculoskeletal specialty care visit. Participants will be randomized (using an online random number generator) to receive one of two clinical vignettes, each involving a commonly considered diagnostic test for a non-traumatic musculoskeletal condition:

- *Group 1* – Patients will engage in a structured ACP-style discussion facilitated by a trained researcher using branching scripted prompts and recorded via verbal-to-text transcription technology (Appendix 1)
- *Group 2* – Patients will receive the same clinical vignette, including mention of consideration for an optional diagnostic test. Instead of a structured ACP-style discussion, they will be presented with a brief, standardized informational statement regarding diagnostic tests. This statement will describe what the test involves, what it may reveal and any general risks or limitations (Appendix 1)

The ACP-style discussion (intervention) will simulate the process of decision-making about diagnostic testing but will not involve actual test ordering, nor necessarily reflect diagnostic tests currently being considered for the participant. This will be clearly communicated to all participants.

Inclusion Criteria:

- Adults (18+ years)
- English literacy
- Seeking musculoskeletal specialty care
- Diagnosis of non-traumatic musculoskeletal condition (including but not limited to: carpal tunnel syndrome, lateral epicondylitis, osteoarthritis, trigger digit, Dupuytren's, De Quervain, or rotator cuff tendinopathy)

Exclusion criteria:

- Cognitive or physical impairment or severe psychiatric illness that would interfere with participation in the scenario-based discussion or completion of the survey instruments

Measured variables

Response variables (Appendix 2):

- Enthusiasm for proposed hypothetical diagnostic test (11-point Likert scale from, 0=I would definitely decline this test, 5=I am not sure if I would accept this test, 10=I would definitely proceed with this test)
- Decisional conflict regarding the diagnostic test, assessed using the 'SURE' scale (0-4 score; higher scores indicate greater certainty and lower decisional conflict) (Appendix 2)

Explanatory variables:

Exposure to diagnostic ACP discussion (yes/no)

Preferred level of involvement in diagnostic decision-making (Appendix 3)

Musculoskeletal diagnosis

Scenario test modality (XR, MRI, ultrasound, CT)

New/return status

Age (continuous)

Gender

Education level

Self-reported race

Self-reported ethnicity

Insurance status

Work status

Annual household income

Social health measure

3 items quantifying unhelpful thoughts regarding symptoms

3 item quantifying feelings of distress regarding symptoms

ANCHOR (agency measure)

Statistical analysis

Independent t-tests (or Mann-Whitney U tests, depending on data distribution) will be used to compare mean enthusiasm for the proposed diagnostic test (primary outcome, measured on an 11-point Likert scale from 0 = definitely decline to 10 = definitely proceed) between study arms. Similarly, group differences in decisional conflict (secondary outcome, measured using the SURE scale) will also be analyzed using independent t-tests or Mann-Whitney U tests.

Multivariable linear regression analysis will be used to assess associations between outcomes and explanatory variables (including age, gender, education level, musculoskeletal diagnosis, and test modality). Statistical significance will be set at $p < 0.05$.

To assess whether patients' preferred level of involvement in diagnostic decision-making moderates the association between exposure to a structured diagnostic Advance Care Planning (ACP)-style discussion and decision outcomes (test acceptance and decisional conflict), interaction terms between ACP exposure and preferred decision-making role will be included in the regression models. Significant interaction effects will be interpreted as evidence of moderation. Subgroup or stratified analyses may also be performed to further explore differential effects across levels of preferred decision-making involvement.

Sample size calculation

For the primary outcome (enthusiasm for diagnostic test, 0-10), assuming a moderate effect (Cohen's $d=0.40$; 1-point mean difference with $SD\sim 2.5$), a two-sample t-test (two-sided $\alpha=0.05$, 80% power) requires 98 participants per arm (196 total). Allowing for 10 percent attrition and incomplete data, we plan to recruit **220 participants** in total.

For the secondary outcome (SURE score), this sample size provides $\geq 80\%$ power to detect 0.5-point differences. Analyses of moderation (between preferred involvement in decision-making and exposure to ACP-style discussion or decision outcomes) will be considered exploratory given expected power constraints for small interaction effects.

References

1. Karel YH, Verkerk K, Endenburg S, Metselaar S, Verhagen AP. Effect of routine diagnostic imaging for patients with musculoskeletal disorders: A Meta-analysis. *Eur J Intern Med.* 2015; 26(8):585-95. doi: 10.1016/j.ejim.2015.06.018
2. Herrle SR, Corbett EC, Fagan MK, Moore CG, Elnicki DM. Bayes' Theorem and the Physical Examination: Probability Assessment and Diagnostic Decision Making. *Acad Med.* 2011;86(5):618-627. doi: 10.1097/ACM.0b013e318212eb00
3. Graham B. The value added by electrodiagnostic testing in the diagnosis of carpal tunnel syndrome. *J Bone Joint Surg Am.* 2008 Dec;90(12):2587-93.
4. Bedson J, Jordan K, Croft P. How do GPs use x-rays to manage chronic knee pain in the elderly? A case study. *Ann Rheum Dis.* 2003;62: 450-454. doi: 10.1136/ard.62.5.450
5. Epstein RM, Franks P, Shields CG, Meldrum SC, Miller KN, Campbell TL, et al. Patient-Centered Communication and Diagnostic Testing. *Ann Fam Med.* 2005;3(5): 415-421. doi: 10.1370/afm.348
6. van der Weijden T, van Velsen M, Dinant GJ, van Hasselt CM, Grol RP. Unexplained complaints in general practice: Prevalence, patients' expectations, and professionals' test-ordering behavior. *Med Decis Making.* 2003; 23(3): 226-231. doi: 10.1177/0272989X03023003004
7. Kravitz RL, Bell RA, Azari R, Kelly-Reif S, Krupat E, Thom DH. Direct observation of requests for clinical services in office practice: what do patients want and do they get it? *Arch Intern Med.* 2003; 163: 1673-1681. doi: 10.1001/archinte.163.14.1673.
8. McDonald IG, Daly J, Jelinek VM, Panetta F, Gutman JM. Opening Pandora's box: the unpredictability of reassurance by a normal test result. *BMJ.* 1996;313(7053):329-332. doi: 10.1136/bmj.313.7053.329

9. Van Ravesteijn H, van Dijk I, Darmon D, van de Laar F, Lucassen P, Olde Hartman T, et al. The reassuring value of diagnostic tests: a systematic review. *Patient Educ Couns.* 2012;86(1):3-8. doi:10.1016/j.pec.2011.02.003
10. Van Bokhoven MA, Koch H, van der Weijden T, Grol RP, Kester AD, Rinkens PE, et al. Influence of watchful waiting on satisfaction and anxiety among patients seeking care for unexplained complaints. *Ann Fam Med.* 2009; 7(2): 112-120. Doi:10.1370/afm.958
11. Krones T, Anderson S, Borensztein C, Fromme E, Götze K, Lasmarias C, et al. Editorial: Advance Care Planning as Key to Person Centered Care: Evidence and Experiences, Programmes and Perspectives. *Z Evid Fortbild Qual Gesundhwes.* 2023;180:1-6. doi: 10.1016/j.zefq.2023.07.001.
12. Schenker Y, White DB, Arnold RM. What Should Be the Goal of Advance Care Planning. *JAMA Intern Med.* 2014;174(7):1093-1094. Doi: 10.1001/jamainternmed.2014.1887
13. Stellman S, Ellis B, Dawson H, Kocsis A, Mundra J, Hill C, et al. Piloting a new model of personalised care for people with fibromyalgia in primary care with secondary care multidisciplinary support. *Musculoskeletal Care.* 2023;21(2):582-591. doi: 10.1002/msc.1708.
14. Rogers CJ, Hackney ME, Zubkoff L, Echt KV. The use of Patient-Led Goal Setting in the Intervention of Chronic Low Back Pain in Adults: A Narrative Review. 2022. *J Pain Manag.* 2022;12(5); 653-664. doi: 10.2217/pmt-2021-0118
15. Rossetti G, Latini TM, Palese A, Jack SM, Ristori D, Gonzatto S, et al. Determinants of patient satisfaction in outpatient musculoskeletal physiotherapy: a systematic, qualitative meta-summary, and meta-synthesis. *Disabil Rehabil.* 2020;42(4); 460-472. doi: 10.1080/09638288.2018.1501102
16. Slade SC, Molloy E, Keating JL. 'Listen to me, tell me': a qualitative study of partnership in care for people with non-specific chronic low back pain. *Clin Rehabil.* 2009;23(3). doi: [10.1177/0269215508100468](https://doi.org/10.1177/0269215508100468)

Appendix 1 – Scenario Structure (Example Layout)

Please consider the following hypothetical situation:

Your clinician is considering an imaging test [XR/MRI/CT/USS scan] for you.

Group 1: We're going to simulate a discussion between you and the clinician treating you about whether or not the test is right for you. You can think about your own symptoms if that helps. Would that be okay?

- "What are you hoping the test might do for us?"
- "What is the best thing that happen when you do a test?"
- "What is the worst thing that can happen when you do a test?"
- "What is the likelihood that the results of this test will improve your health?"
- "In what ways could the test harm your health?"
- "What matters to you most as we decide whether or not to move forward with this test?"
- "What else do you need to feel ready to decide about whether or not to get this test?"

Group 2: Please read the following information regarding diagnostic tests.

- Imaging tests are not usually necessary to make a diagnosis.
- Imaging tests are primarily used to confirm a likely diagnosis and to help plan surgery.
- People tend to think of imaging tests are completely harmless, but there are risks of misdiagnosis, overdiagnosis, mistreatment, and overtreatment.
- Imaging tests should therefore be considered carefully as they do have a potential for harm.

Appendix 2 – Diagnostic Testing Preference Questions

Decision to proceed with diagnostic test:

How enthusiastic are you about proceeding with the proposed (hypothetical) imaging test?

Slider scale with 0 = I would definitely decline this test, 5= I am not sure if I would accept or decline this test, 10 = I would definitely proceed with this test

Short-form decision conflict scale (SURE):

S	Are you sure that this is the best choice for you?	Yes/No
U	Do you feel you clearly understand the potential benefits and harms of the test?	Yes/No
R	Are you clear about which risks and benefits matter most to you?	Yes/No
E	Do you feel you have enough support and advice to make a choice?	Yes/No

Appendix 3 – Question to assess patient preferred level of involvement in diagnostic decision-making

In general, how involved do you like to be in the decision about whether or not to have a test?

- I prefer my doctor to make the decision alone
- I prefer the doctor to make the final decision, but consider my opinion
- I prefer to make the decision together
- I prefer to make the final decision, after considering the doctor's opinion
- I prefer to make the decision alone