Randomized Controlled Trial of a Nudge Intervention for Common Musculoskeletal Conditions

Testing a Brief Reassurance Message Before a Musculoskeletal Clinic Visit

Unique Protocol ID: STUDY00004831.3

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Title: Randomized Controlled Trial of a Nudge Intervention for Common Musculoskeletal Conditions

Hypothesis:
Primary null hypothesis:
There are no factors associated with patient pre-visit enthusiasm for a return visit, test, injection, or surgery, including exposure to a nudge towards information and reassurance alone compared to usual care.

Secondary null hypothesis:
There are no factors associated with planned return visits, diagnostic tests and treatments scheduled after a musculoskeletal specialist consultation, including whether the patient was exposed to a pre-visit nudge versus usual care.

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Introduction
Background
Variability in human thoughts and emotions regarding sensations from common musculoskeletal conditions contributes substantially to variations in reported symptom intensity (levels of discomfort and incapability). Attitudes towards optional (discretionary) visits, tests, and treatments may also be shaped by these thoughts and feelings about sensations.

Rationale
Nudge theory is grounded in the understanding that human thoughts and behaviors are largely automatic and influenced by non-rational cognitive processes. A nudge intervention uses principles from cognitive science to subtly alter choice architecture without restricting options. Given the important role of less healthy thoughts and feelings on healthcare utilization, a nudge intervention that provides reassuring, evidence-based information may encourage people to accommodate expected bodily changes and associated sensations. Such an approach has the potential to enhance personal health agency while reducing utilization of low-value visits, tests, and treatments.

Proposed methods
Study design: Single-site, two-arm Randomized Controlled Trial

Recruitment methods (if applicable):
Prior to a visit, new and return patients seeking care in one of several urban MSK specialty clinics will be invited to participate.

Randomization:
Participants will be randomized equally (1:1) to receive the nudge intervention or usual care. Randomization will occur via an online random number generator (*random.org*).

Intervention:
Participants randomized to the intervention will read LLM-generated information prior to their visit, reassuring them that most musculoskeletal pathophysiology is age-related or of uncertain (idiopathic) origin, that many people can adapt and accommodate the symptoms without seeking care, and that those who do seek care are generally able to manage their health on their own based on the advice and reassurance provided. This information will be embedded into RedCap as the first page for participants. After reading this, participants will rate their enthusiasm on the next page.

Clinicians providing care will be blinded to participants' group assignment.

Consent
Verbal informed consent will be obtained from all participants by a trained researcher

Measurements
Before a routine MSK specialty care visit, both participants in the intervention group and the non-intervention group will complete a questionnaire on a tablet.

Both intervention and non-intervention groups will rate their preference for a return visit, a diagnostic test, an injection, and a surgery from 0, no interested at all, to 10, definitely want it. Participants in the intervention group will receive the following nudge statement prior to seeing the ratings: 'I think this one visit can meet all my needs' pre-selected and the option "I'm nearly certain I will pursue additional visits, tests, or treatments" an optional choice that must be selected. People that continue with the default will be rated as 0 interest in additional visits, tests, injections, or surgery and the survey will close. The full text of the LLM-generated nudge intervention is provided in Appendix 1.

Inclusion Criteria:
Adult (18+)
English or Spanish language

New or return patient
Any non-trauma condition

Exclusion criteria:
Cognitive or other impairment precluding completion of a survey on a tablet
Acute traumatic pathophysiology – fracture, dislocation, sprain/strain

Measured variables
Response variables:
Preference to pursue with (Rated from 0, I have no interest, to10, I definitely want it)
     Return visit

Diagnostic test
Physical therapy
Injection
Surgery

Actual scheduled follow-up care (y/n) (entered by the researcher after the visit):
Return visit
Diagnostic test
Physical therapy
Injection
Surgery

Explanatory variables:
Demographics
Age (continuous)
Gender (Man, Woman, Non-binary)

Educational level (Elementary school, High school, Some college, Graduated college, Post-college graduate degree (e.g., PhD), Other)
Employment status (employed, unemployed, disabled, other (retired, student))
Annual household income (Less than $15,000, From $15,000 to $29,999, From $30,000 to $49,999, From $50,000 to $99,999, More than $100,000, Prefer not to answer)
Insurance status (Medicare, Medicaid, Private, Military, Self-pay (no health insurance), MAP, Other)

Psychosocial measures
Unhelpful thoughts regarding sensations (3 Questions)
Feelings of distress regarding sensation (3 Questions)
Social health (3 Questions)
Personal Health Agency (3 Questions)

Clinical (entered by researcher)
Region of condition: LE, UE, Spine
Specialty of original visit: Arthroplasty, hand/upper extremity, shoulder/sports, spine, foot/ankle
Diagnosis (categorized based on enrollments)

Statistical analysis

Demographic, clinical, and psychosocial characteristics will be summarized using descriptive statistics. Continuous variables will be reported as means and standard deviations (or medians and interquartile ranges if distributions are non-normal), and categorical variables will be summarized as frequencies and percentages.

- *Primary outcome* - Between-group differences (nudge intervention vs usual care) in enthusiasm scores for each outcome will be assessed using independent samples t-tests. Assumptions of normality and homogeneity of variance will be evaluated. If these assumptions are violated, non-parametric alternatives (Mann–Whitney U tests) will be used. Variables demonstrating $p < 0.10$ in bivariate analyses will be entered into multivariable analysis (linear regression model)
- *Secondary outcomes* - Between-group differences in the proportion of participants with scheduled follow-up care will be assessed using chi-square tests or Fisher's exact tests as appropriate. Variables demonstrating $p < 0.10$ in bivariate analyses will be entered into multivariable analysis (logistic regression model)

All tests will be two-sided, and statistical significance will be set at $p < 0.05$. Analyses will be performed using StataMP version 18.0.

Sample size
An a priori sample size calculation was conducted using G*Power version 3.1 for a two-tailed independent samples t-test, comparing mean pre-visit enthusiasm scores between the study arms (primary outcome). Assuming a medium effect size (Cohen's d = 0.5), a significance level (α) of 0.05, and 80% power ($1-\beta$), the required sample size was calculated to be 128 participants (64 per group). To ensure adequate power for the planned multivariable linear regression analyses of the primary outcome, a separate power calculation was performed for linear multiple regression (fixed model, R^2 deviation from zero). Assuming a medium effect size ($f^2 = 0.15$), a significance level (α) of 0.05, 80% power, and up to 6 predictor variables, the required sample size is 97 participants. To account for an anticipated attrition or non-complete response rate of approximately 10%, the final target sample size was set at **144 participants (72 per group).**

Appendix 1

Intervention paragraph:
It is common to have some bone or joint pain as we get older. Your body can start to change even in your 20s or 30s. Sometimes the brain treats pain like a sign of injury, even when the body is not hurt.

For people who have pain without a clear injury, the news is usually good. In most cases, the body is going through expected changes and is not damaged.

You can decide how much medical care you want. Many people feel better with simple things like small changes to daily habits. Visits, tests, and treatments are often a choice, not a need.