

# Reasons for Not Enrolling in a Randomized Clinical Trial and Patient Preferences for Knee Osteoarthritis Treatment

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**Disclosures:** None.

**INTRODUCTION:** Randomized clinical trials are vital to improving conservative treatment modalities in patients with knee osteoarthritis (OA). Low enrollment into trials leads to concerns about generalizability of study findings. A variety of factors may impact enrollment, including sociodemographic characteristics, treatment preferences, and treatment history. This study aimed to: 1) identify factors associated with trial enrollment and 2) identify factors that impact treatment decisions in those who decline RCT participation.

**METHODS:** Data analyzed came from the COPING (Choosing Optimal Physical Therapy or Injection Non-Operative Guidance) study, an RCT in which patients with knee OA are randomized into physical therapy (PT), intra-articular triamcinolone injection (INJ), or INJ followed by PT. Patients between the ages of 45 and 85 presenting with knee pain were identified in pre-screening via the electronic medical record. Upon identification, providers and research staff assessed patients for eligibility and interest in trial participation. Data included demographic information, treatment history, and final treatment decision. Descriptive statistics including two sample T-tests and Pearson's Chi-squared tests were performed.

**RESULTS:** Between December 2022 and April 2023, 574 patients were prescreened for participation in the COPING trial with 174 (30.3%) deemed eligible. Of all eligible patients, 37 (21.3%) were excluded for no-show/cancelled appointments and 3 (1.7%) were lost to follow up. Among eligible patients, 10 enrolled (7.5%) and 124 declined (92.5%). Eligible patients were 52.2% female, on average 62 years old, mostly white (89.6%), and had an average BMI of 30.6. There were no statistically significant demographic or treatment differences between the enrolled and declined groups. Of those who declined enrollment, 61.3% received an injection that day (57 received an injection alone and 19 an injection and PT referral). Among patients who declined enrollment, prior injection history was associated with treatment decision, wherein 79.6% of those with an injection history received another injection and 24.0% with no prior history received an injection ( $p<.001$ ).

**DISCUSSION:** Based on available data, enrollment into the COPING trial was not associated with demographic or treatment characteristics. Of patients who declined COPING enrollment, a history of injection was associated with future injection. More research is needed to detangle how past treatment history may influence a patient's treatment preference, treatment decision, and potentially deter them from RCT enrollment. For example, if they have strong treatment preferences, they may have a low tolerance to being randomized. Further, as other research has shown, patients may believe injection to be a more effective treatment that can be administered in fewer clinic visits with longer lasting pain-relief, compared to PT.<sup>1</sup>

**SIGNIFICANCE/CLINICAL RELEVANCE:** Improvement of orthopedic care relies on patient recruitment into RCTs with the intent of identifying the most effective treatment modalities. This study suggests OA patients who have had an injection in the past are highly likely to undergo repeat injection rather than enrolling in an RCT that includes PT.

**REFERENCES:** 1. Posnett, J. et al (2015). Patient preference and willingness to pay for knee osteoarthritis treatments. *Patient preference and adherence*, 9, 733–744. <https://doi.org/10.2147/PPA.S84251>

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**IMAGES AND TABLES:**

**Table 1.** Demographic and clinical characteristics by enrollment status into COPING, N=134

		Enrolled (N=10)	Declined (N=124)	Total (N=134)	P-Value
Characteristic					
Sex	Male	5 (50.0%)	59 (47.6%)	64 (47.8%)	0.120
	Female	5 (50.0%)	65 (52.4%)	70 (52.2%)	
Age, M(sd)		57.60 (8.7)	62.41 (9.39)	62.05 (9.40)	0.074
Race	White	7 (70.0%)	113 (91.1%)	120 (89.6%)	0.145
	<sup>1</sup> Non-White	2 (20.0%)	9 (7.3%)	11 (8.2%)	
	Unknown	1 (10.0%)	2 (1.6%)	3 (2.2%)	
BMI, M(sd)		33.38 (5.23)	30.40 (6.24)	30.62 (6.20)	0.516
Prior Injection <sup>2</sup>	Yes	5 (50.0%)	49 (39.5%)	54 (40.3)	0.516
	No	5 (50.0%)	75 (60.4%)	80 (59.7%)	

<sup>1</sup>Non-white race = Native Hawaiian/Other Pacific Islander (2), Black/African American (6), Asian (1), All Other races (2)

<sup>2</sup> Prior Injection = alone (30), with PT (16), and with surgery (3); No prior Injection = PT alone (11), Surgery and PT (9), Surgery alone (11), and none listed/treatment naïve (44)

**Figure 1.** Knee Treatment Decision among patients who declined enrollment in COPING, by injection history status (N=124)

