Storytelling and Navigation to Improve Gout Follow-up: A Multicenter, Randomized Controlled Trial

Lesley E. Jackson, MD, MSPH[1], Kenneth G. Saag, MD, MSc[1], Rahima Begum, MS, MSc[1], Gary Cutter, PhD[2], Hyon Choi, MD, DrPH[3], Brett Faine, PharmD, MS[4], Nora G. Singer, MD[5], Natalie McCormick, PhD[3], Hamid Shokoohi, MD, MPH[6], Blair Alden Parry, BA, CCRC[6], Olivia K. Nelson, BS[6], James Booth, MD[7], Zachary Armor, MS[1], John D. Osborne, PhD[8], Maria I. Danila, MD, MSc, MSPH[1,9]

1 Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham; 2 Department of Biostatistics, School of Public Health, University of Alabama at Birmingham; 3 Division of Rheumatology, Allergy, and Immunology, Department of Medicine, Massachusetts General Hospital; 4 Department of Emergency Medicine and Pharmacy, University of Iowa; 5 Division of Rheumatology, The MetroHealth System at Case Western Reserve University; 6 Department of Emergency Medicine, Massachusetts General Hospital, Harvard Medical School; 7 Department of Emergency Medicine, University of Alabama School of Medicine; 8 Department of Biomedical Informatics and Data Science, University of Alabama at Birmingham; 9 Birmingham VA Medical Center.

CONCLUSIONS

While our intervention did not lead to significant improvement in outpatient encounters addressing gout, the percent of participants with an ED visit was reduced.
Findings suggest that while patient activation strategies may play a role, achieving improvements in routine gout follow-up care likely require multifaceted approaches that also address access to care.

BACKGROUND

- Patients with gout are frequently treated in emergency departments (ED) for flares but may not receive consistent outpatient care.
- Approaches to mitigate this pattern of care are understudied.

OBJECTIVES

- Test whether a direct-to-patient multimodal behavioral intervention could improve outpatient encounter addressing gout after an ED visit.

METHODS

- We conducted a multicenter, parallel group, randomized clinical trial at 4 geographically diverse sites in the U.S.
- Participants were randomized 2:1 to intervention or usual care (control).
- Intervention consisted of:
  - Storytelling video with gout patient testimonials
  - Patient navigation with phone contact after ED visit by lay navigators to encourage outpatient gout follow-up
- Primary Outcome: proportion with outpatient visit for gout within 3 months post-ED visit
- Secondary Outcomes: gout medication use, opioid use, acute care utilization within 3 months post-ED visit
- Outcomes were assessed by phone survey at 6-weeks and 3-months post-enrollment
- Intent-to-treat (ITT) and per-protocol (PP) analyses

RESULTS

- From June 2021 - June 2024, 200 individuals were enrolled: 135 were randomized to intervention and 65 to control groups (Table 1).
- ITT analyses: no significant differences between intervention vs. control groups in rates of outpatient gout follow-up (47% vs. 54%, p=0.4) (Table 2).
- Majority of gout follow-up occurred with primary care (60%) and internal medicine subspecialties (29%).

RESULTS

Table 1. Baseline demographic characteristics of randomized participants (N=200).

Characteristics	Intervention Group N=135	Control Group N=65	p
Current Age in Years, mean (SD)	57.6 (13.6)	58.9 (12.4)	0.5
Sex, N (%)			0.7
Male	101 (74.8)	50 (76.9)	
Female	34 (25.2)	15 (23.1)	
Race /Ethnicity, N (%)			0.1
Black or African American	92 (68.2)	45 (69.2)	
White	35 (25.9)	16 (24.6)	
Asian, Hispanic or Latino, Unknown/other	8 (5.9)	4 (6.2)	
Marital Status, N (%)			0.5
Married	41 (31.1)	23 (35.4)	
Not Married	91 (68.9)	42 (64.6)	
Health Status, Excellent or Very Good, N (%)	26 (19.6)	15 (23.4)	0.5
Health Literacy, Inadequate, N (%)	39 (29.3)	21 (32.3)	0.7
PROMIS Depression 4a Measure T-score, mean (SD)	46.4 (13.7)	48.3 (10.8)	0.3
Education Level, N (%)			0.9
High School graduate or less	65 (49.2)	30 (46.2)	
Vocational training or some college	44 (33.3)	23 (35.4)	
4-year degree or more completed	23 (17.4)	12 (18.5)	
Employment Status, N (%)			0.1
Full-time work	61 (46.6)	19 (29.2)	
Part-time work or not seeking work	37 (28.2)	22 (33.9)	
Unemployed	25 (19.1)	16 (24.6)	
Yearly income, N (%)			0.4
Less than $30,000	42 (33.9)	20 (31.8)	
$30,000 to less than $60,000	13 (10.5)	13 (20.6)	
$60,000 to less than $100,000	14 (11.3)	8 (12.7)	
Greater than $100,000	11 (8.9)	4 (6.4)	
Prefer not to answer	44 (35.5)	18 (28.6)	
Smoking status, N (%)			0.4
Currently smoking every day	17 (12.9)	9 (14.3)	
Currently smoking some days	18 (13.6)	4 (6.4)	
Not smoking at all	97 (73.5)	50 (79.4)	
Alcohol use, N (%)			0.4
2 or more times per week	24 (18.3)	10 (15.4)	
2-4 times per month	53 (40.5)	22 (33.9)	
Never	54 (41.2)	33 (50.8)	

RESULTS

- **No statistically significant differences in self-reported new allopurinol use post-ED visit (17% vs 11%, p=0.2).**
- **Intervention group was less likely to have subsequent ED visits (intervention vs. control 32% vs 49%, p=0.02).**
- **No differences in opioid prescription use or incident hospitalizations.**
- **PP analyses trends were similar.**

Table 2. Results for primary and secondary outcomes by randomization group, intent-to-treat and per protocol analyses; number (%) represented unless otherwise stated. P<0.05 represented in bold

	Intent-to-treat			Per Protocol		
	Intervention (N=135)	Control (N=65)	*p*	Intervention (N=117)	Control (N=64)	*p*
Primary Outcome						
Presence of gout follow-up, N (%)	64 (47.4)	35 (53.8)	0.4	58 (49.6)	34 (53.1)	0.7
Secondary Outcomes						
Allopurinol use, [α] N (%)	23 (17.0)	7 (10.8)	0.2	23 (19.7)	7 (10.9)	0.1
Opioid use, [β] N (%)	66 (48.9)	34 (52.3)	0.7	59 (50.4)	33 (51.6)	0.9
Subsequent ED visits, [γ] mean (SD)	0.3 (0.6)	0.6 (1.2)	0.09	0.3 (0.6)	0.6 (1.2)	0.09
Subsequent ED visits, [γδ] (yes/no), N (%)	43 (31.9)	32 (49.2)	**0.02**	38 (32.5)	32 (50.0)	**0.02**
Subsequent hospitalizations, [γ] mean (SD)	0.1 (0.4)	0.1 (0.4)	0.8	0.1 (0.4)	0.1 (0.4)	0.8
Subsequent hospitalizations, [γδ] (yes/no), N (%)	14 (10.4)	7 (10.8)	0.9	12 (10.3)	7 (10.9)	0.9

[α]self-reported new prescription medication use following the index ED visit for a gout flare.
[β]composite outcome of self-reported current medication use or electronic health record (EHR) evidence of prescription use of opioids (i.e., hydrocodone-acetaminophen, oxycodone, oxycodone-acetaminophen, tramadol, hydromorphone) in the 3 months post-ED visit for a gout flare.
[γ]EHR evidence of acute care utilization occurring in the 3 months post-ED visit for a gout flare.
[δ]composite binary outcome representing presence/absence of 1 or more subsequent visits based on self-report or EHR documentation in respective health systems.