Long-term Outcomes of EBP in patients who fail to meet ICHD-3 diagnostic criteria

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Indispensable Help Came From:

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- Meredith Barad MD
- Stanford Headache Faculty
- Stanford Neuroradiology: Bryan Lanzman, Hashmi Syed
- Stanford Neurosurgery: Gerry Grant, Casey Halpern
- Ron Pearl MD
- Elliot Krane MD
- Andrew Callen MD
- Wouter Schievink MD

Patients treated and measured from August 2016 to November 2018

1. PROMIS Global health
2. HIT-6
3. Neck Disability Index
4. Rhodes Index and Nausea Vomiting and Retching (INVR)
5. Tinnitus Handicap Inventory
6. PROMIS Applied Cognitive Questionnaire
7. Dizziness Handicap Inventory
8. PROMIS Fatigue

12:29

Major Symptoms 1: Which of the following symptoms do you experience at least once a week? Please check all that apply.

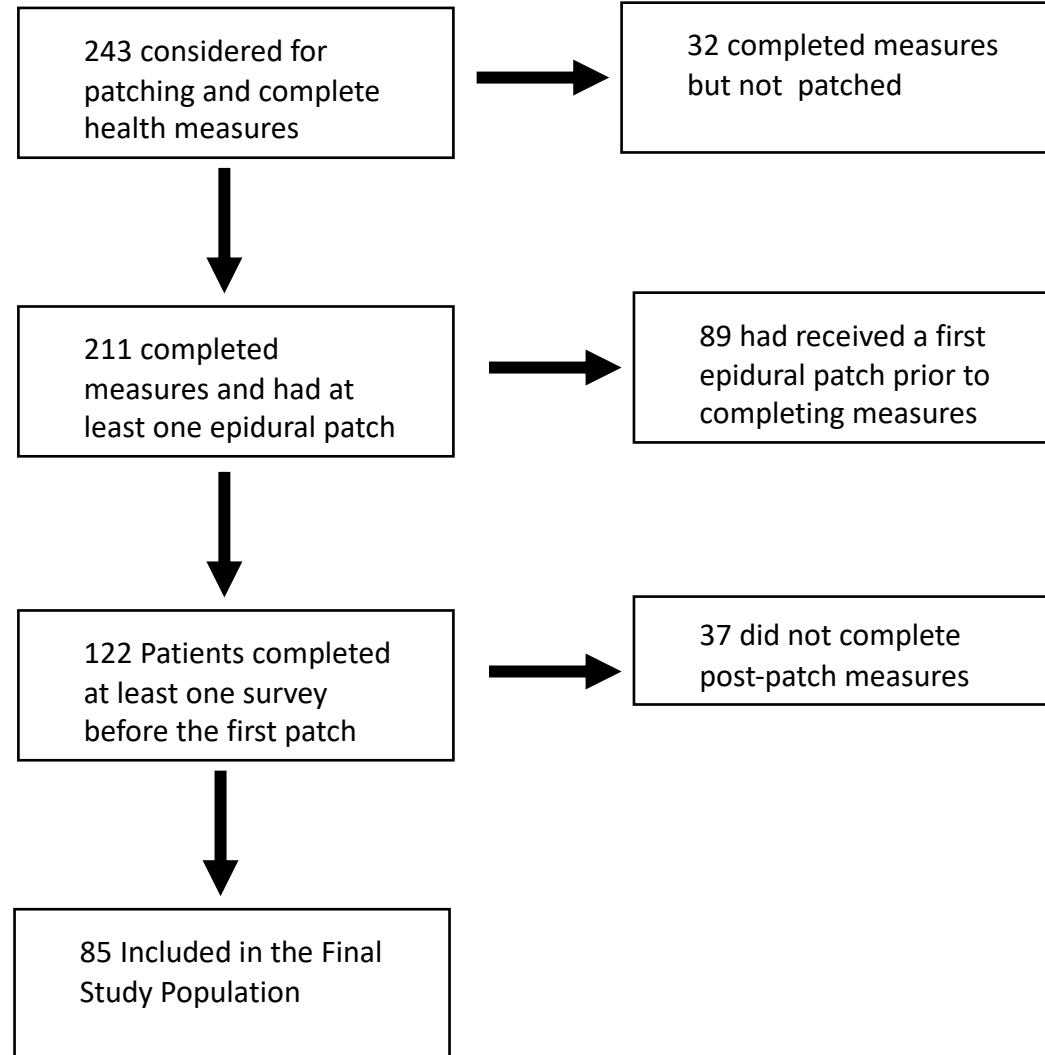|	
Head pain or pressure	Difficulty thinking, concentrating, or remembering.
Neck pain or stiffness	Fatigue
Nausea or vomiting	Tachycardia (heart beating abnormally fast for you)
Ringing in your ears (Tinnitus)	None of the above

<<   >>

Powered by Qualtrics

Patients treated and measured from August 2016 to November 2018

Characteristic		Patients With Suspected CSF Leak (N = 85) Mean± SD /n (%)
Age, years		42.5 ± 13.68
Sex		
	Male	19 (22.35)
	Female	66 (77.65)
Symptom Duration (years)		8.65 ± 8.13
General Symptoms		
	Head Pain or Pressure	84 (98.82)
	Neck Pain or Stiffness	70 (82.35)
	Tinnitus	54 (63.53)
	Cognitive Impairment	77 (90.59)
	Fatigue	81 (95.29)

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Characteristic		Patients With Suspected CSF Leak (N = 85) Mean± SD /n (%)
Orthostatic Features		
	Orthostatic Head Pain	**71 (83.53)**
	Upright Time Before Head Pain Starts	
	Quartile 1	0 secs to 5.01 minutes
	Quartile 2	5.01 to 30.03 minutes
	Quartile 3	30.03 to 108.75 minutes
	Quartile 4	108.75 to 841.02 minutes
	Head Pain Severity After Upright 1 Hour (0-10)	5.30 ± 2.36
	Head Pain Severity After Flat 1 Hour (0-10)	2.70 ± 2.46
	Head Pain Severity After Night Recumbent (0-10)	2.24 ± 2.47

Mean global physical health is at 4th percentile.

Symptom Measure		Patients With Suspected CSF Leak (N = 85) Mean± SD /n (%)
PROMIS Global Health		
	Physical	32.67 ± 6.77 (85)
	Mental	36.83 ± 8.42 (85)
Headache Impact Test-6		66.87 ± 6.77 (83)
Neck Disability Index		45.13 ± 20.57 (85)
Dizziness Handicap Inventory		42.48 ± 27.17 (85)
PROMIS Neuro		39.61 ± 7.61 (83)
PROMIS Fatigue		66.82 ± 7.51 (85)
RINVR		1.05 ± 1.09 (85)
Tinnitus Handicap Inventory		19.67 ± 22.08 (85)

Mean Headache severity is in severe range.

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Fatigue severity is in 95th percentile.

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Variable	Total N with results	Positive/ Abnormal n (%)	Negative/Normal n (%)
ICHD-3 Criteria Determined	85	16 (18.82)	69 (81.18)
MRI Brain Scan	76	5 (6.58)	71 (93.42)
MRI Spine	69	5 (7.25)	64 (92.75)
CT Myelogram	70	7 (10.00)	63 (90.00)
Opening pressure <60 mm CSF	69	4 (5.80)	65 (94.20)

ICHD-3 Status- (percent)

16

69
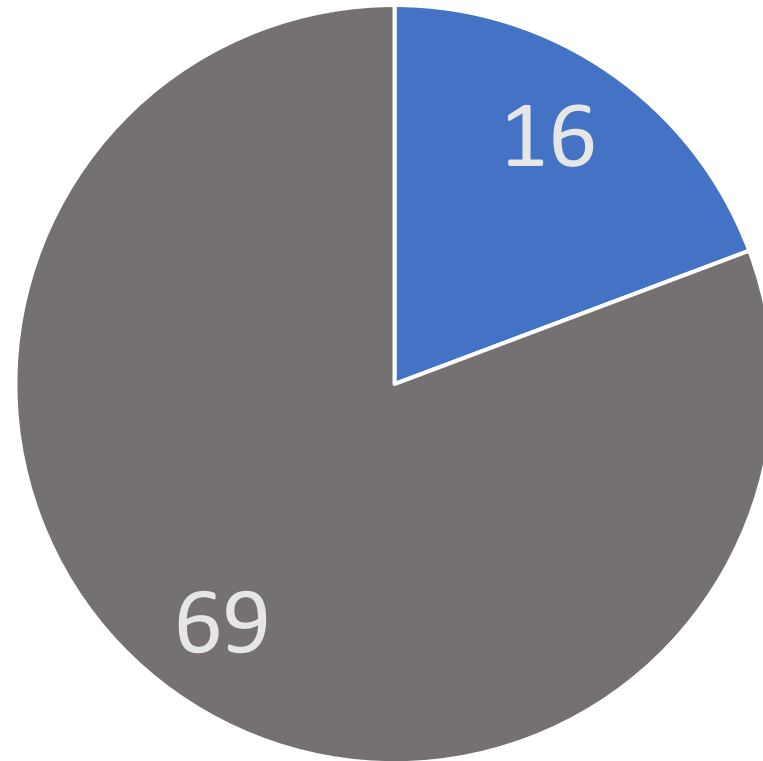
■ Conform to ICHD-3 Criteria
■ Not Conforming to ICHD-3 Criteria

Patients Undergo an Average of 3.6 Epidural Patches

N=3.6
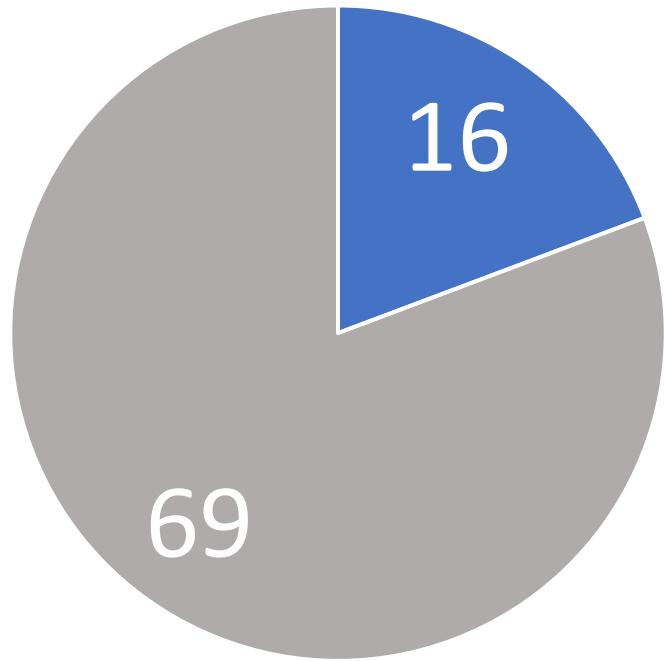
- Matching ICHD-3 Criteria
- Not Matching ICHD-3 Criteria

CSF Leak Patient Qualtrics Survey Scores					
Durable Outcomes- Change from pre-patch to last assessment (mean 521 days from first patch, 377 days from last patch)					
Survey Scores	**N**	**PRE-PATCH**	**POST-PATCH**	**P-value**	**% Change (Median)**
		N (%) Mean ± SD	**N (%) Mean ± SD**		
PROMIS Physical Health	85	32.7 ± 6.8	36.9 ± 8.6	<0.001	15.4 ▲
PROMIS Mental Health	85	36.8 ± 8.4	39.4 ± 9.1	0.003	6.9 ▲
Headache Impact Test-6 (HIT-6)	83	66.9 ± 6.8	62.9 ± 8.9	<0.001	4.4 ▼
Neck Disability Index	85	45.1 ± 20.6	38.9 ± 20.5	0.002	20.8 ▼
PROMIS Fatigue	85	66.8 ± 7.5	63.5 ± 8.8	<0.001	4.8 ▼
Rhodes Index of Nausea, Vomiting and Retching (RINVR)	85	1.1 ± 1.1	0.9 ± 1.1	0.06	33 ▼
PROMIS Neuro	82	39.6 ± 7.6	41.3 ± 9.1	0.10	3.4 ▲
Tinnitus Handicap Inventory	85	19.7 ± 22.1	21.4 ± 21.9	0.58	0
Dizziness Handicap Inventory	85	42.5 ± 27.2	38.8 ± 26.2	0.14	13.6 ▼

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Is this Clinically Meaningful?

The minimal clinically important difference of the PROMIS and qDASH instruments in a non-shoulder hand and upper extremity patient population

Nikolas H. Kazmers, MD MSE[1,*], Yuqing Qiu, MS[2], Minkyoung Yoo, PhD[3], Andrew R. Stephens, BS[1], Andrew R. Tyser, MD[1], Yue Zhang, PhD[2]

[1]University of Utah, Department of Orthopaedics, 590 Wakara Way, Salt Lake City, UT 84108

[2]University of Utah, Division of Public Health, 375 Chipeta Way, Salt Lake City, UT 84108

[3]University of Utah, Department of Economics, 260 Central Campus Dr #4100, Salt Lake City, UT, United States

Abstract

Purpose—The minimal clinically important difference (MCID) is used in research and clinical settings as a benchmark to gauge response to treatment. The purpose of this study was to provide anchor-based MCID estimates for PROMIS and legacy instruments in a non-shoulder hand and upper extremity population.

Methods—Adult patients (≥ 18 years) seeking care at a tertiary academic outpatient hand surgery clinic completed patient-reported outcome measures on tablet computers between January 2015 and August 2017. Data were collected at baseline and at six ± two weeks of follow-up. The PROMIS Upper Extremity (UE), Physical Function (PF), and Pain Interference (PI) Computer Adaptive Test (CAT) instruments were administered, along with the qDASH. A mean-change anchor-based method was used to estimate MCIDs by comparing scores between anchor groups reporting 'no change' versus 'slightly improved' in terms of function and pain.

Results—Scores for each instrument significantly improved over the study period. With significant differences in scores between groups reporting 'no change' and 'slightly improved' function, anchor-based MCID estimates were calculated as follows: 2.1 for the PROMIS UE CAT, 1.7 for the PROMIS PF CAT, and 6.8 for the qDASH. There was no significant difference in PROMIS PI CAT scores between anchor groups when queried for level of pain improvement, precluding estimation of the MCID.

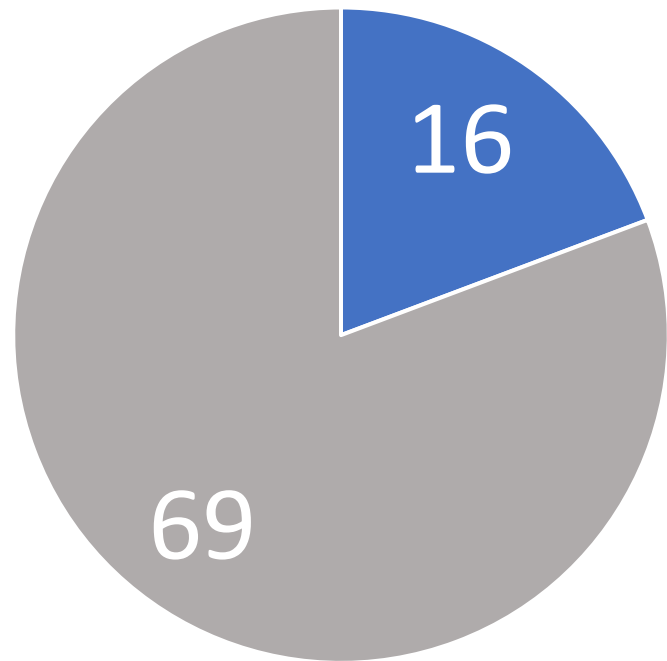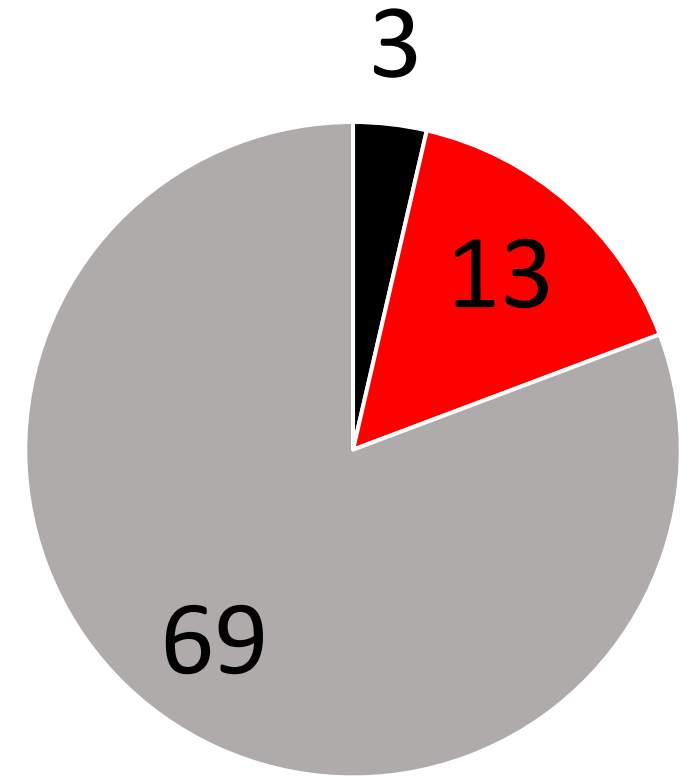# Response Rate following Epidural Patching?

16

69

N=3.6
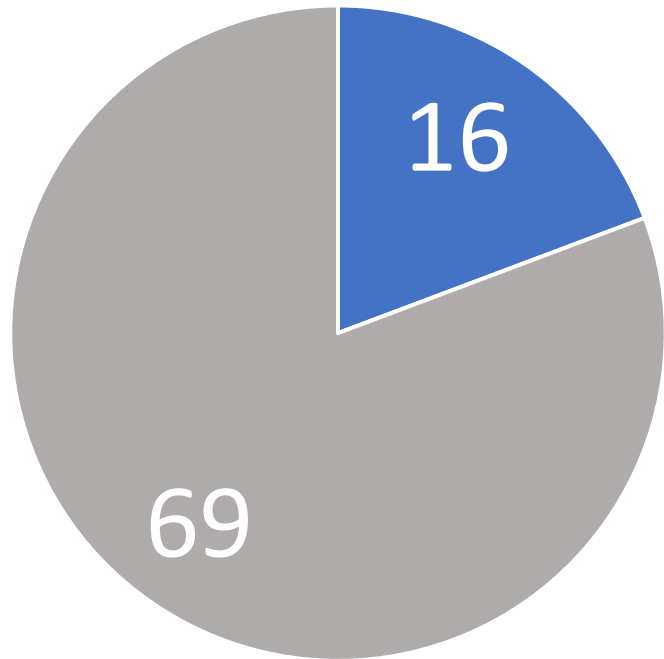
■ Matching ICHD-3 Criteria
■ Not Matching ICHD-3 Criteria
■

81% (95% CI: 54%-96%) Clinically Meaningful Response Rate

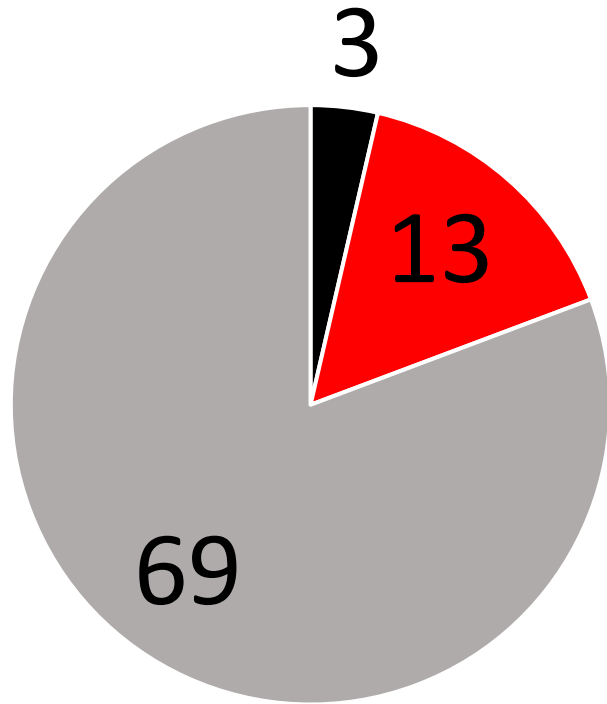# What about the 81% of patients not conforming to ICHD-3 criteria?

- Imaging negative
- Normal opening pressure

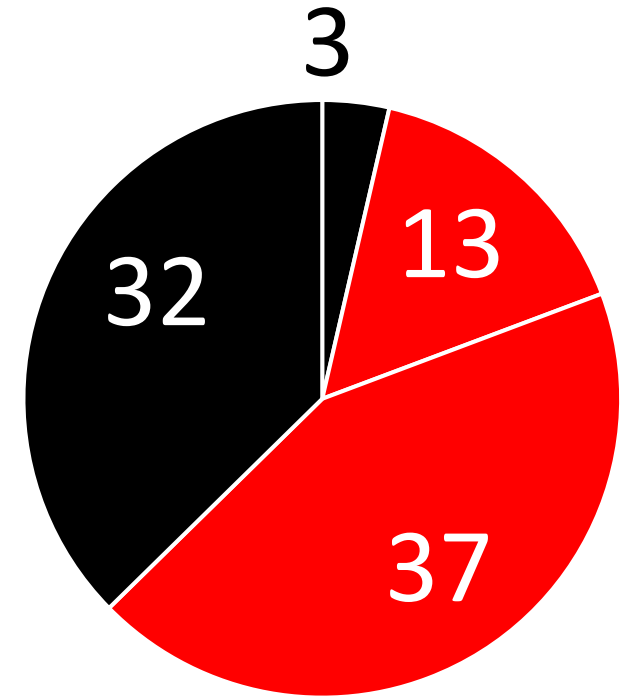# Patients Undergo an Average of 3.6 Epidural Patches
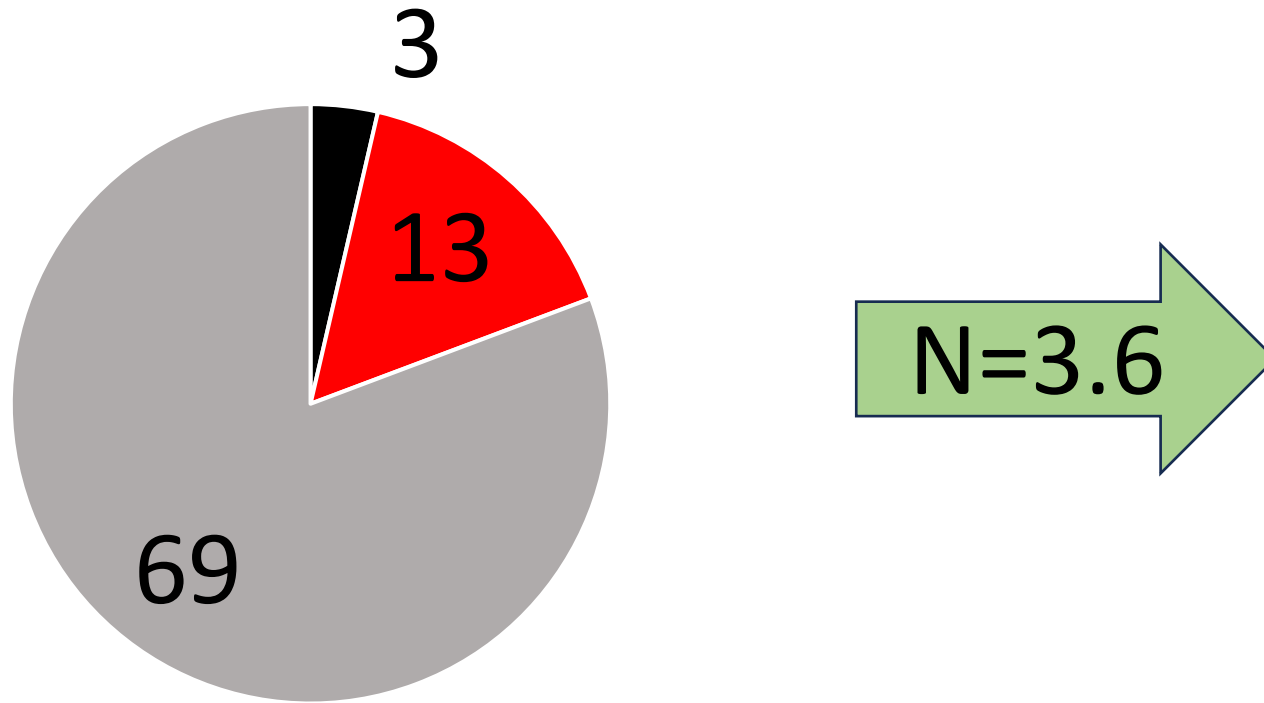
- ■ No Clinically Meaningful Response
- ■ Clinically Meaningful Response
- ■ Not Conforming to ICHD-3 Criteria

54% (95% CI: 41%-66%) Clinically Meaningful Response Rate
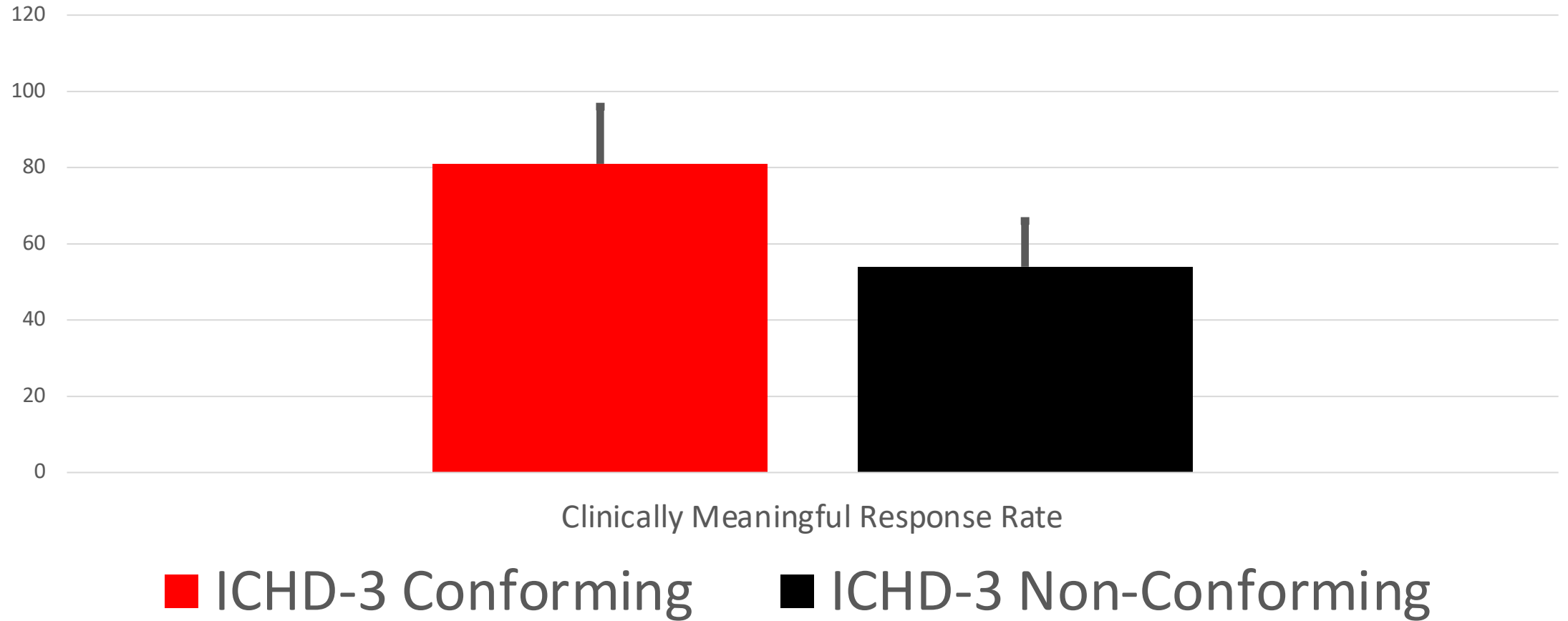
Clinically Meaningful Response in Global Physical Health

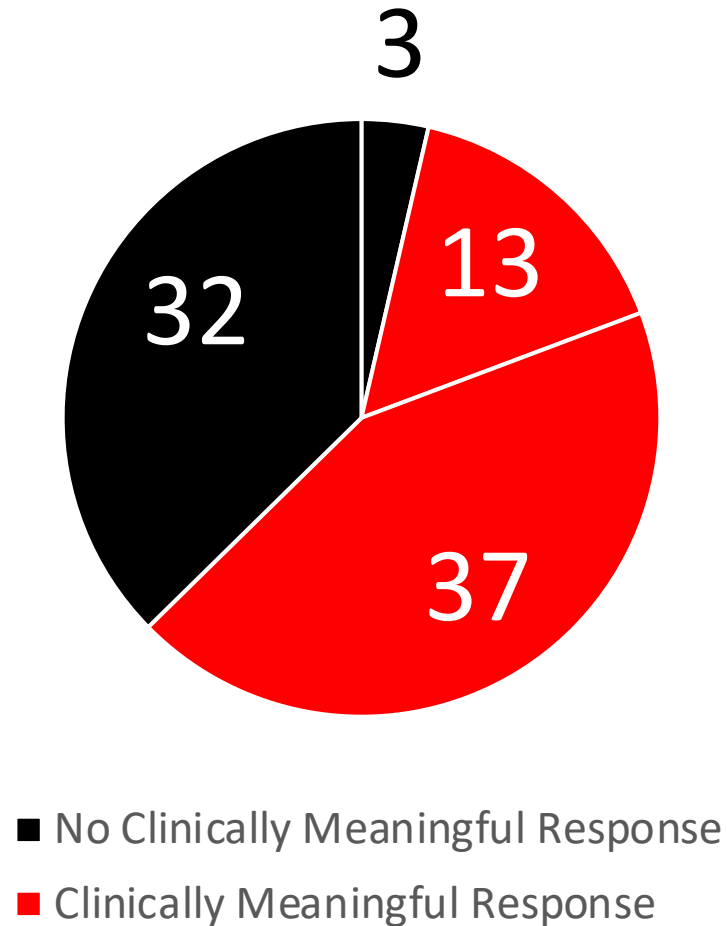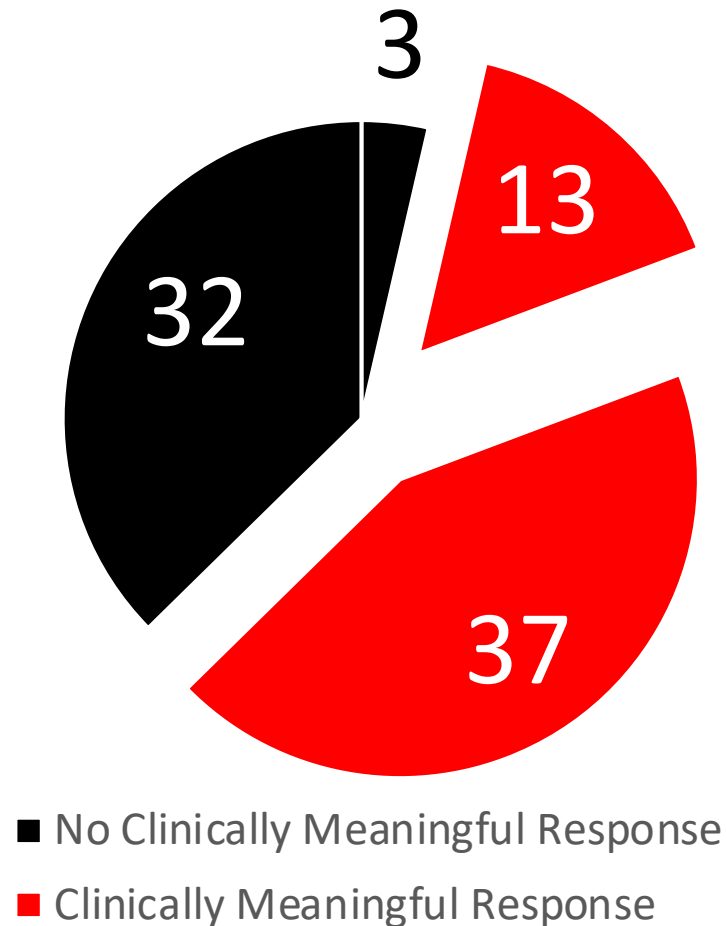Clinically Meaningful Response in Global Physical Health
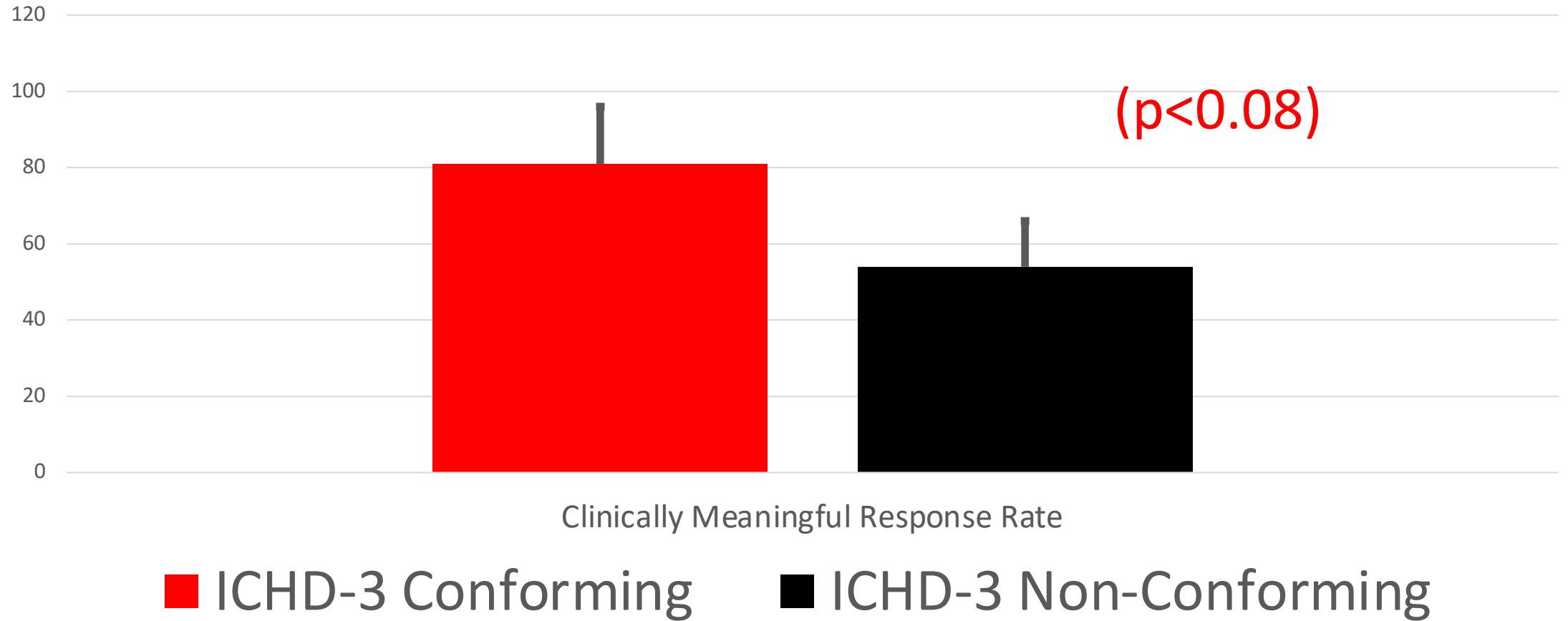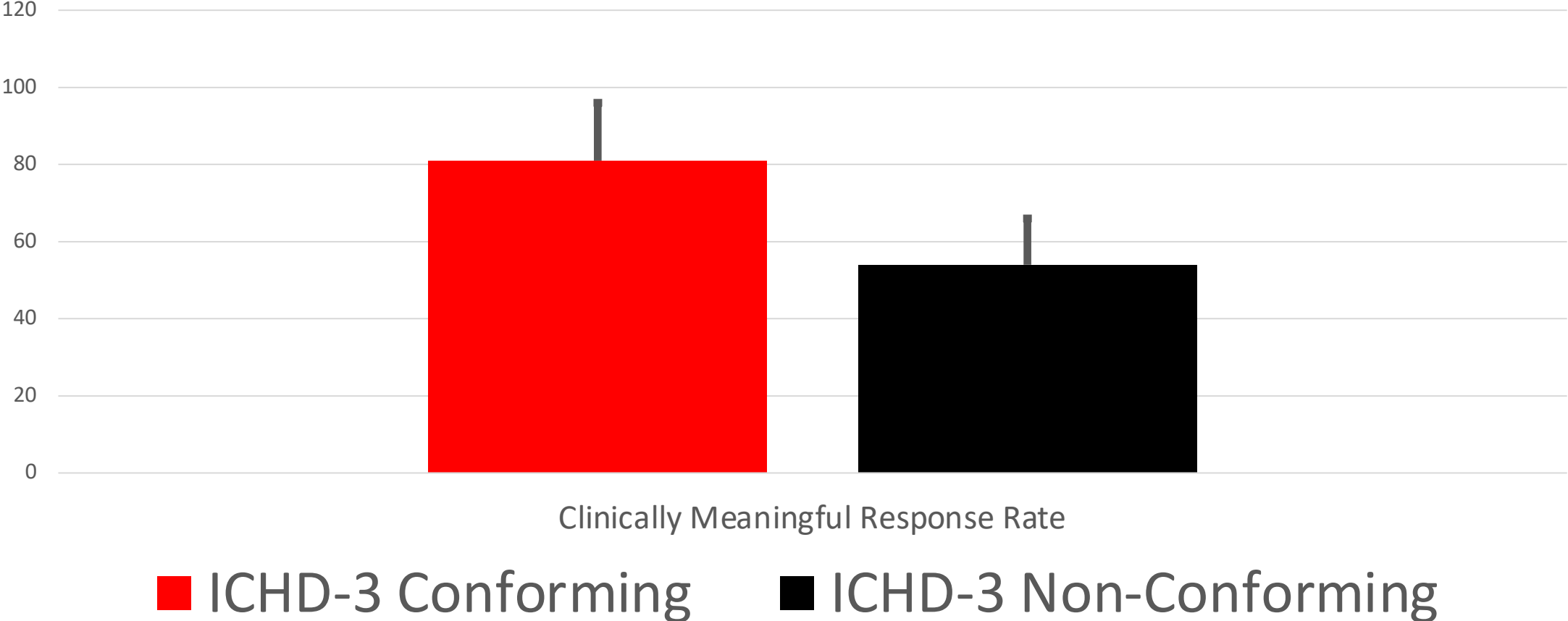
And if you want to help the highest number of people who can meaningfully benefit- don't do that.

73% of clinically meaningful responders would never have received the treatment that helped if patching had been contingent on positive Imaging or low opening pressure

- No Clinically Meaningful Response
- Clinically Meaningful Response

What can help us identify patients most likely to have a clinically meaningful response among patients not conforming to ICHD-3 criteria?

Characteristic		Not Improved (N = 31)	Clinically Meaningful Improvement (N = 36)	Odds Ratio	P Value
		Mean ± SD; (n= respondents)	Mean ± SD; (n= respondents)		
Orthostatic Features					
	Orthostatic Head Pain	25 (80.65)	31 (86.11)	1.49	0.79
	Upright Time Before Head Pain Starts (minutes)	76.25 ± 97.59	54.77 ± 73.30	1.00	0.43
	Head Pain Severity After Upright 1 Hour (0-10)	5.73 ± 2.41	5.14 ± 2.06	0.88	0.29
	Head Pain Severity After Flat 1 Hour (0-10)	3.63 ± 2.36	2.08s ± 2.20	0.74	0.004
	Head Pain Severity After Night Recumbent (0-10)	2.97 ± 2.91	1.56 ± 2.08	0.79	0.02

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Lets look at that raw data…
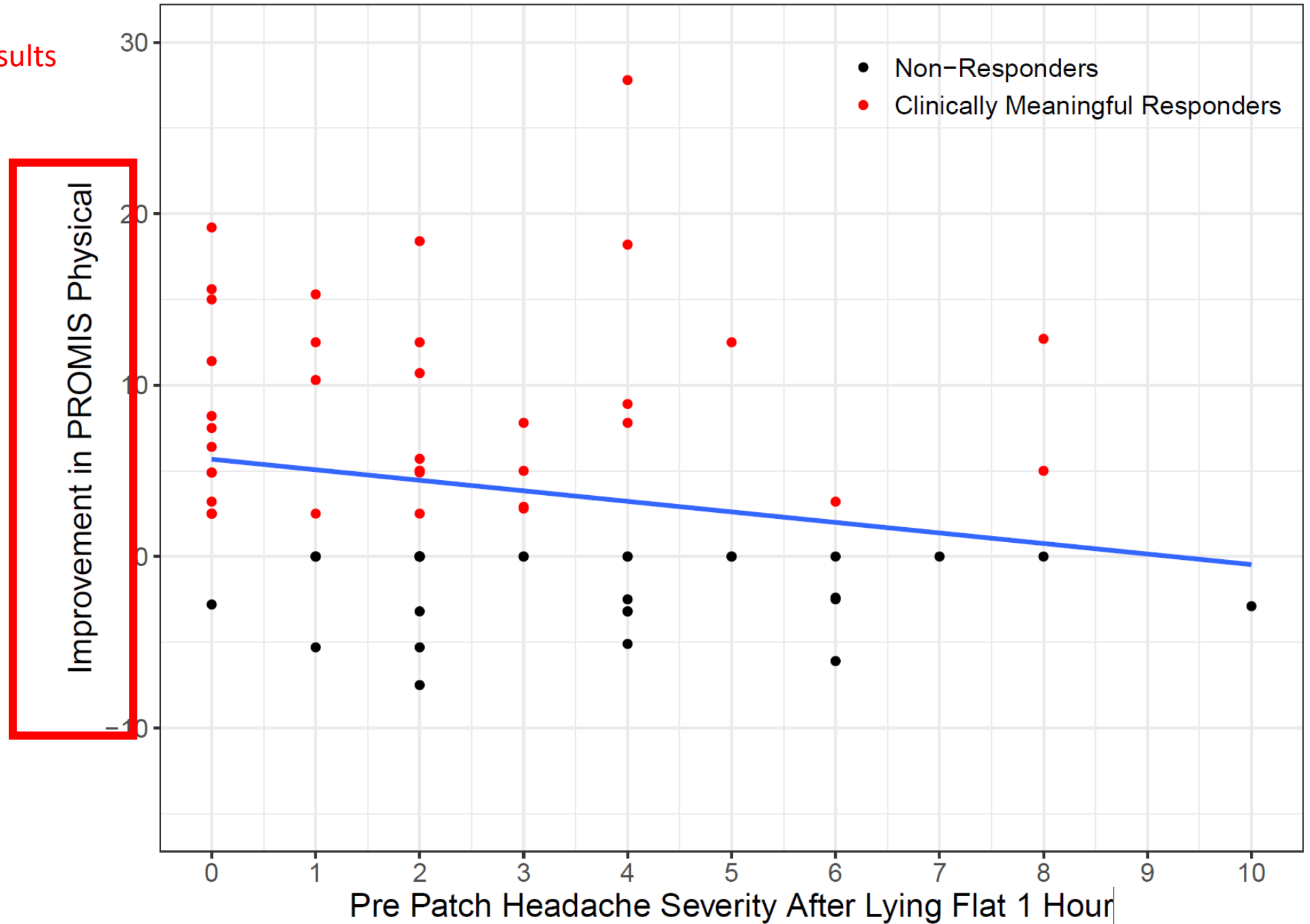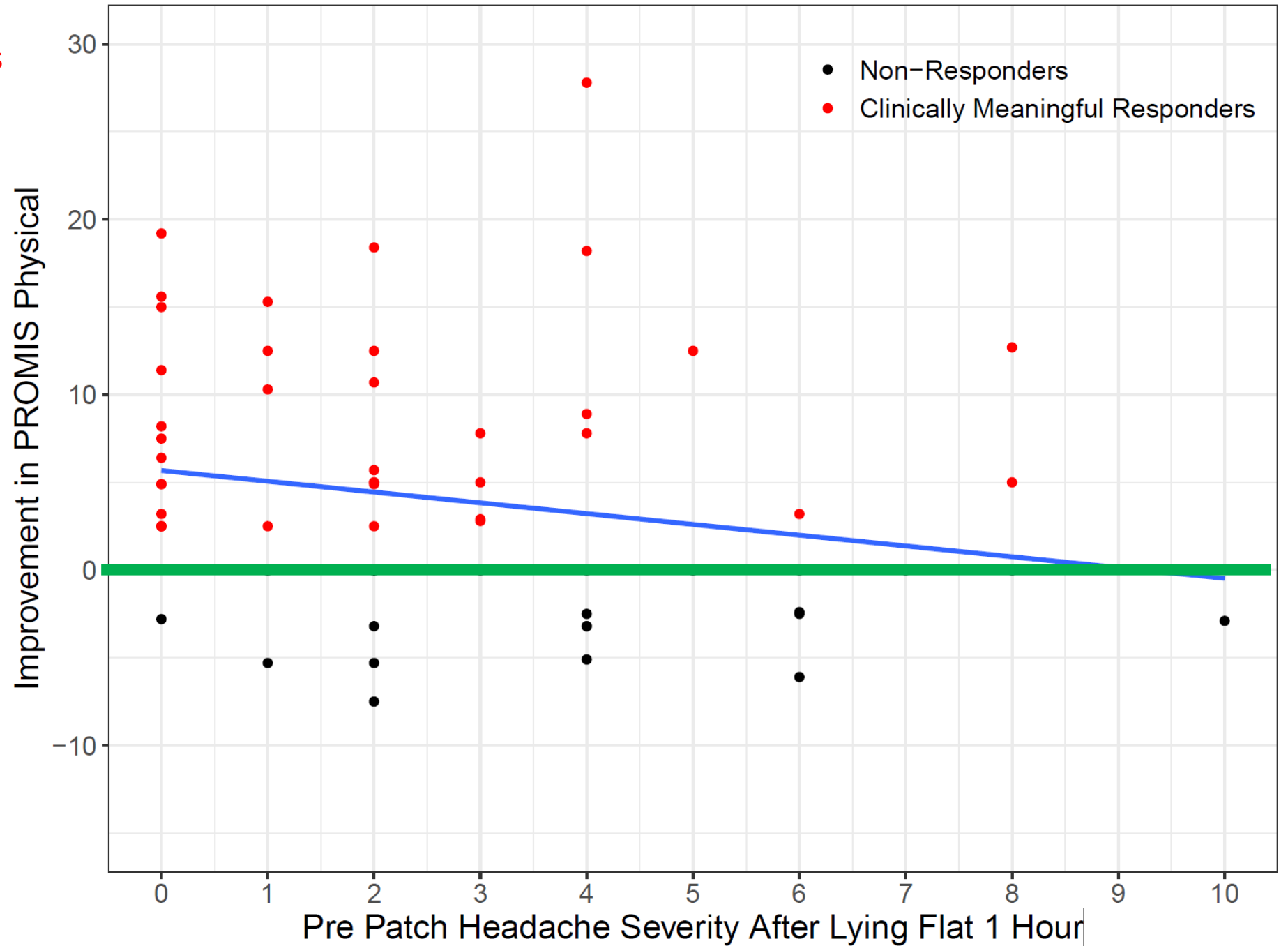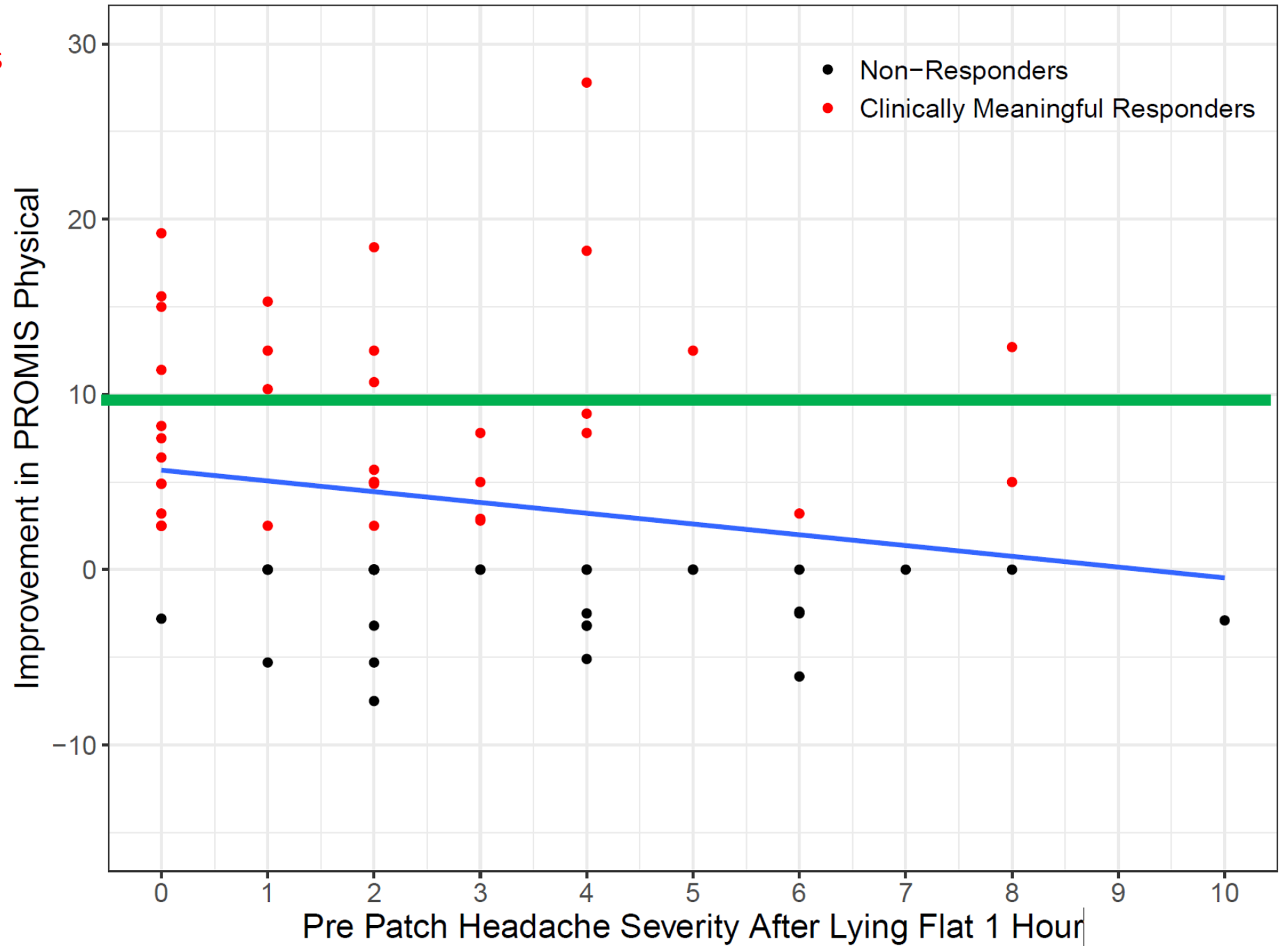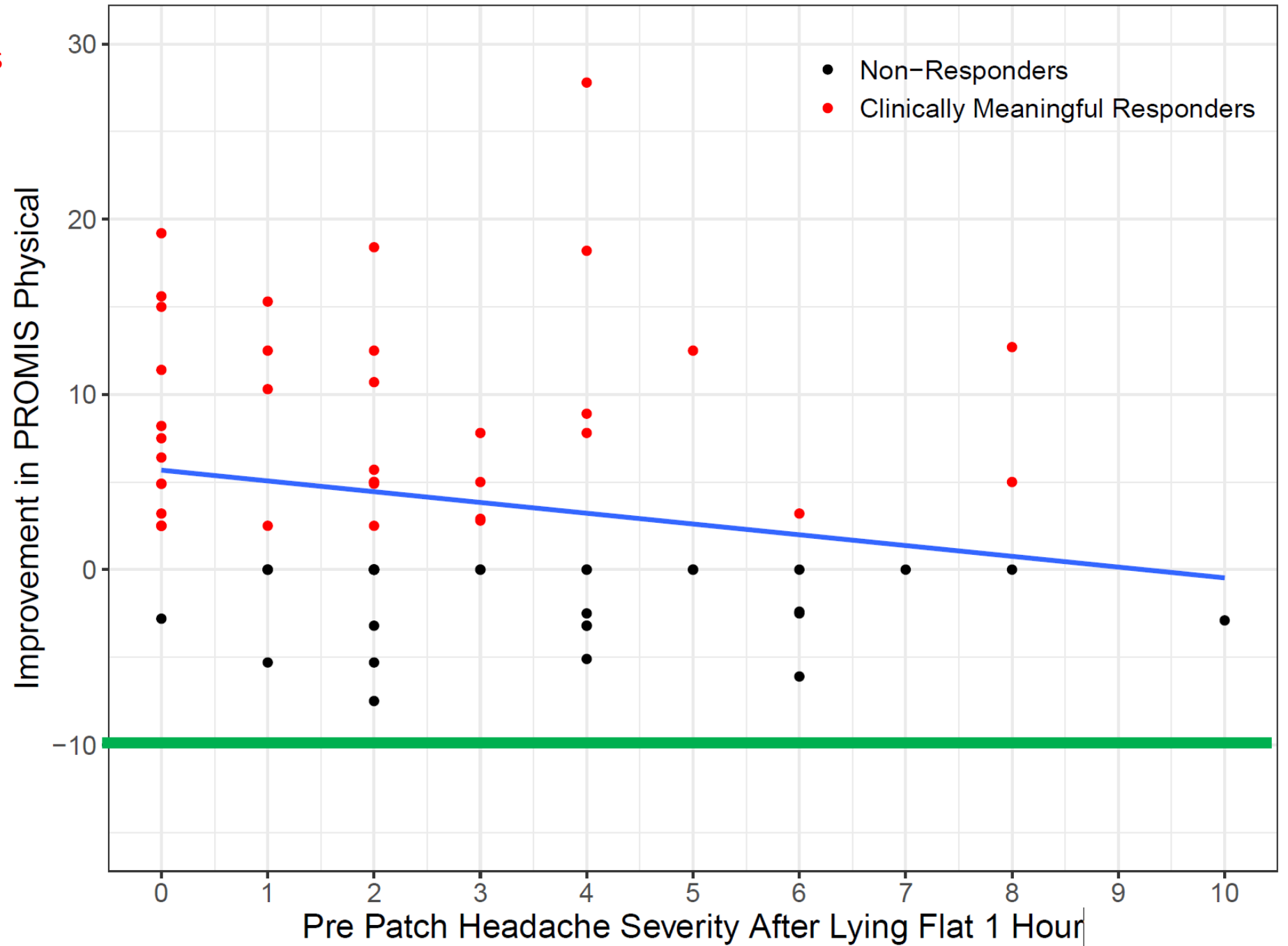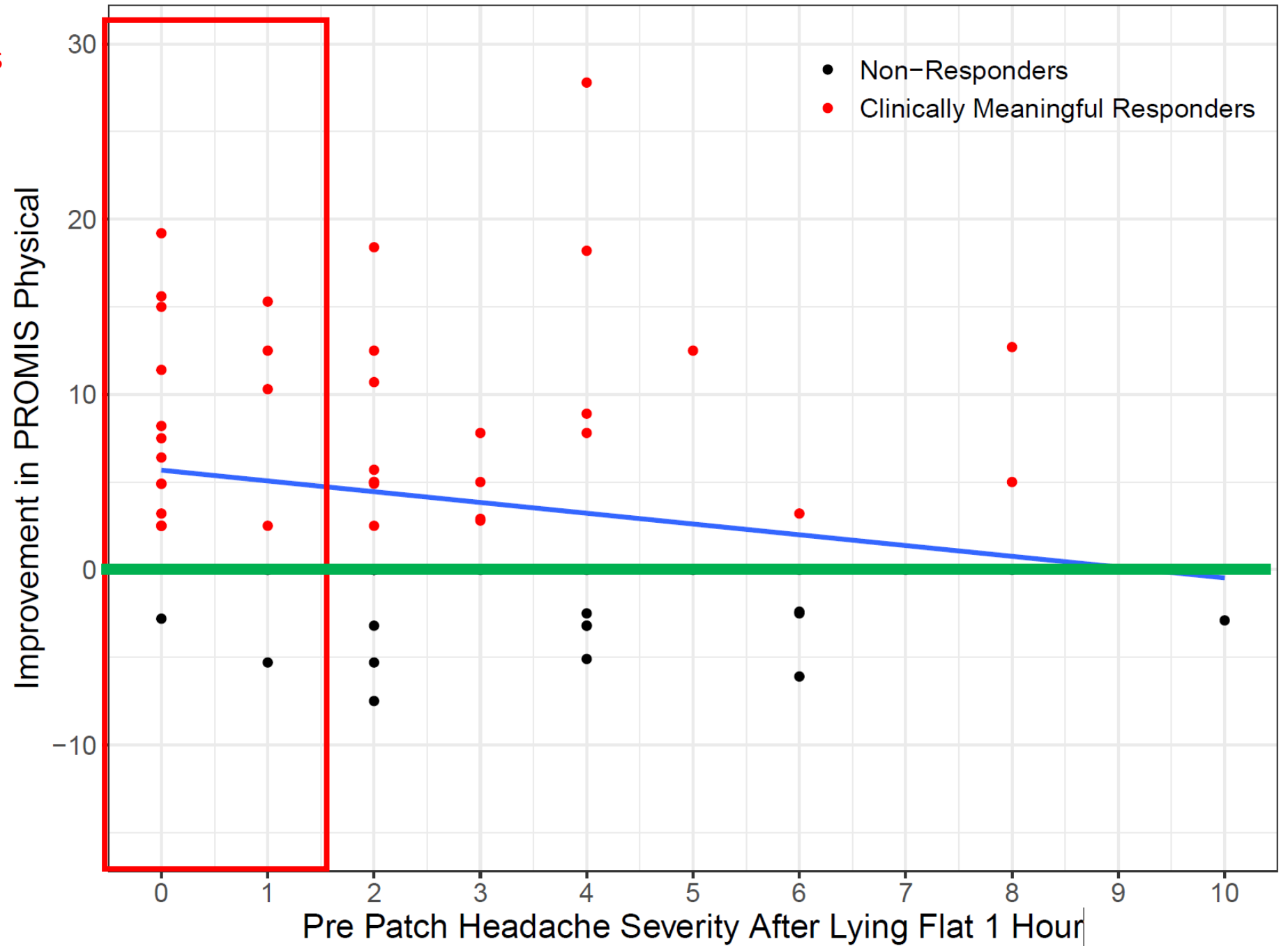
ICHD-3 negative results
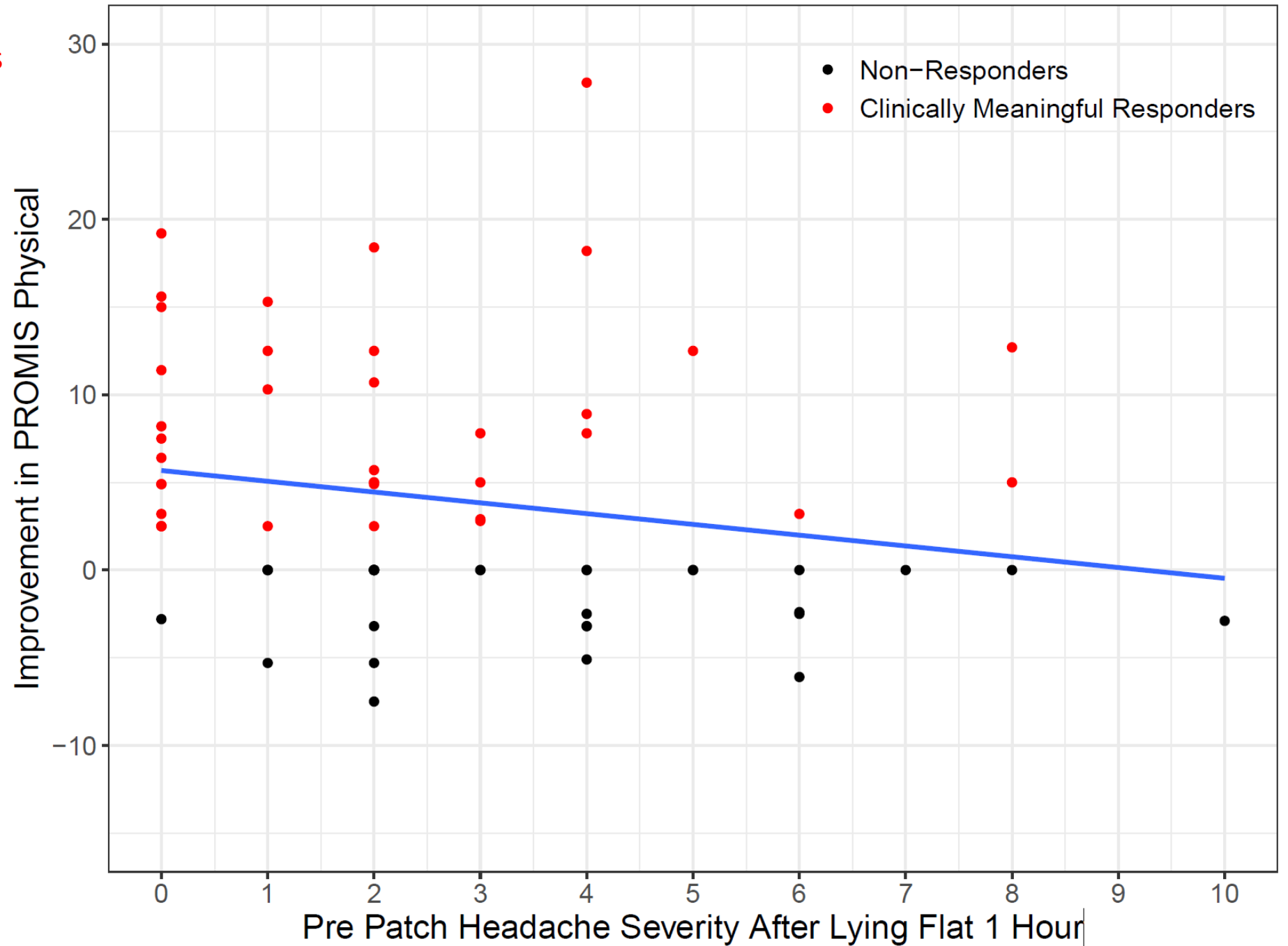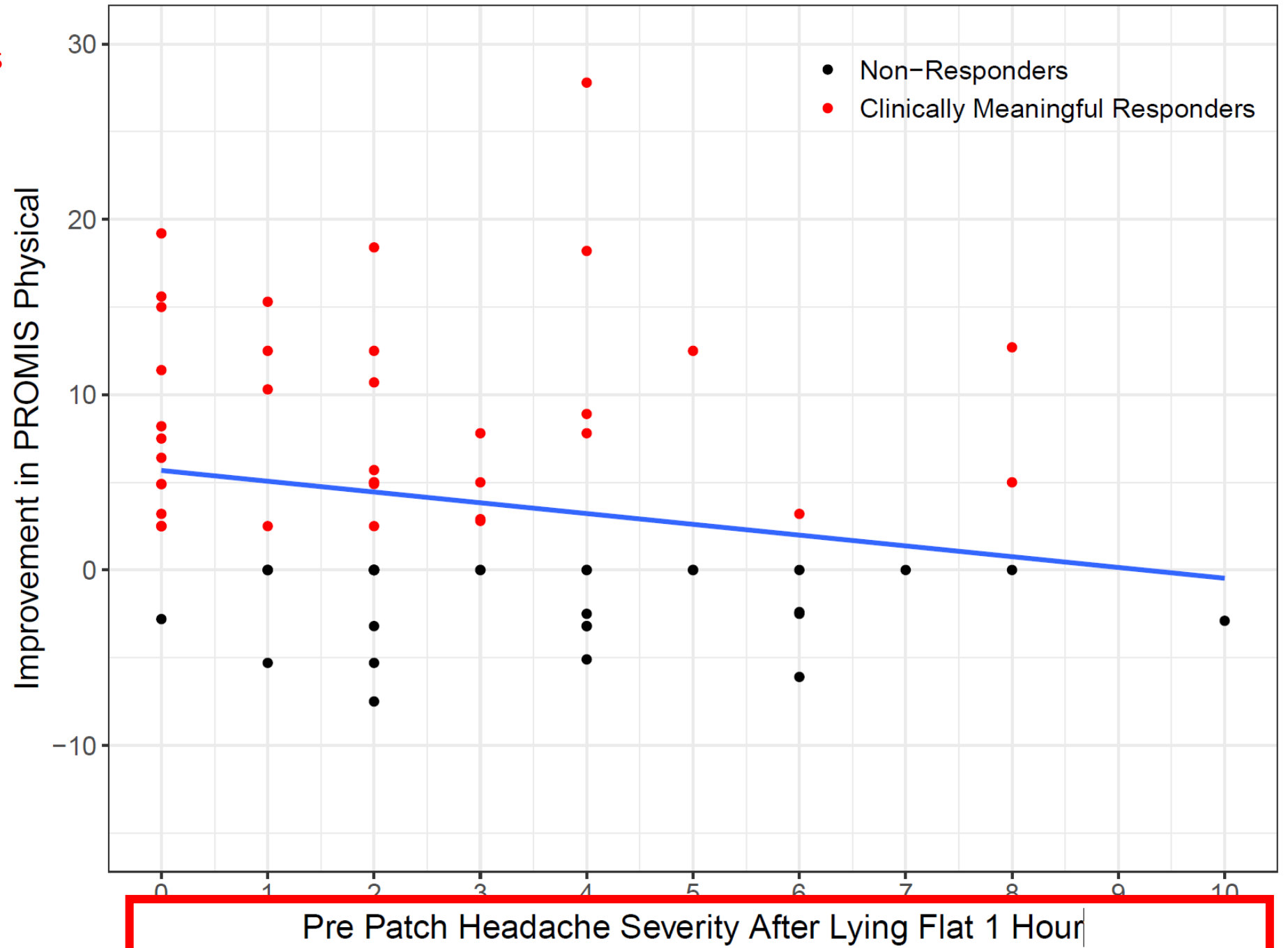
ICHD-3 negative results

ICHD-3 negative results

Conclusions:

- Its hard to explain the statistically significant relationship between relief when flat (two measures) and subsequent clinically meaningful improvement amongst **ICHD-3 negative patients** with placebo response, regression to the mean or Hawthorne effect.

Conclusions:

- Among patients with chronic, disabling, symptoms suggesting CSF leak in whom imaging does not confirm a leak, 54% of patients show clinically meaningful improvement at long term follow up after an average of 3.6 epidural patches.

- Two factors specifically associated with CSF leak- more complete resolution of head pain upon reclining for an hour ($p<0.004$) or overnight ($p<0.02$)—significantly predicted the likelihood of being a clinically meaningful responder in global physical health.

- **Most of the patients who experienced meaningful clinical improvement following epidural patching came from the ICHD-3 negative group by a ratio of 3:1**

- Nonetheless, a higher rate of response is seen among ICHD-3 positive patients.

- So think about your goals: high rate of response vs helping the most people.