

# Update of the UK post market pilot programme with single pulse transcranial magnetic stimulation (sTMS) for acute treatment of migraine

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## Background

- Some patients suffer disabling, frequent migraine without effective treatment as current pharmacological options are either contra-indicated, poorly tolerated or overused.
- The non-invasive, portable, sTMS device is designed for patient use and received a CE mark in 2011 for the acute treatment of migraine.
- In a previously published, randomised, sham-controlled study, SpringTMS was shown to be effective for the acute treatment of migraine with aura<sup>1</sup>.
- The safety of sTMS in clinical practice, including as an acute migraine treatment, is supported by biological, empirical, and clinical trial evidence.<sup>2</sup>
- A post market pilot programme with the SpringTMS device was initiated for patients with migraine.
- The National Institute for Clinical Excellence<sup>3</sup> (NICE) approved TMS for acute and preventive treatment of migraine in the UK.

## Objectives

- Evaluate responses in an open outpatient setting
- Assess impact on pain, associated migraine symptoms and acute medication use over an extended period (minimum three months)
- Understand patient support and educational needs
- Assist patients in establishing optimal treatment schemes for their migraine patterns
- Review options for sTMS within the UK headache care pathway

## Methods

Clinicians selected patients and prescribed the device. Patients received the device to use for a minimum period of three months. A specialist nurse had first contact with the patient to discuss treatment and use. Telephone reviews were conducted at 4 to 6-weekly intervals to support and monitor the patients' treatment and progress. Survey data was collected at the 6 and 12-week time points over the treatment period.

## Patient Characteristics

Migraine Features	# of Patients	# of Attacks Treated
Migraine with aura	61	3072
Migraine without aura	61	2253
Of these:		
Episodic	44	1704
Chronic	78	3621

## Results

- 122 (35%) patients have been using the device for a minimum of three months and completed surveys. A total of 351 patients have been prescribed sTMS.
- 88 patients (72%) reported a reduction or alleviation of pain.
- Associated symptoms (nausea 64%; photophobia 84%; phonophobia 89%) improved or did not develop.
- A reduction in the number of headache days was reported by 76 (62%).
- 71 (58%) reported a reduction in the duration of migraine symptoms per attack.
- 101 (83%) were also using an acute medication at the time of prescription. Of these, 69 (68%) reported a reduction in the number of days of medications use.
- The treatment was well tolerated with no serious adverse events reported.
- For those patients who reported clinical response, these were reproducible throughout the 3 month period and beyond.

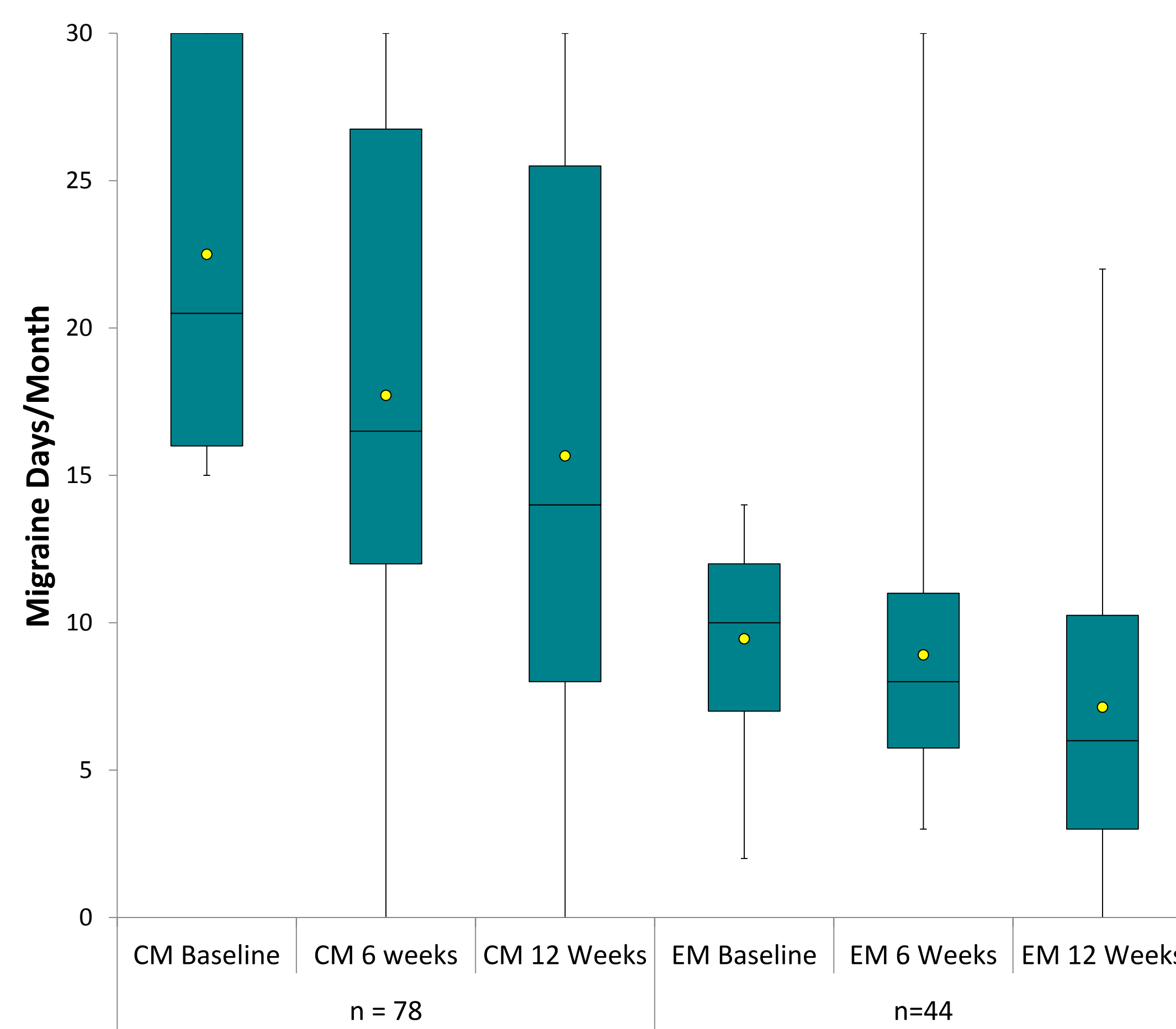


Figure 1: Change in headache days

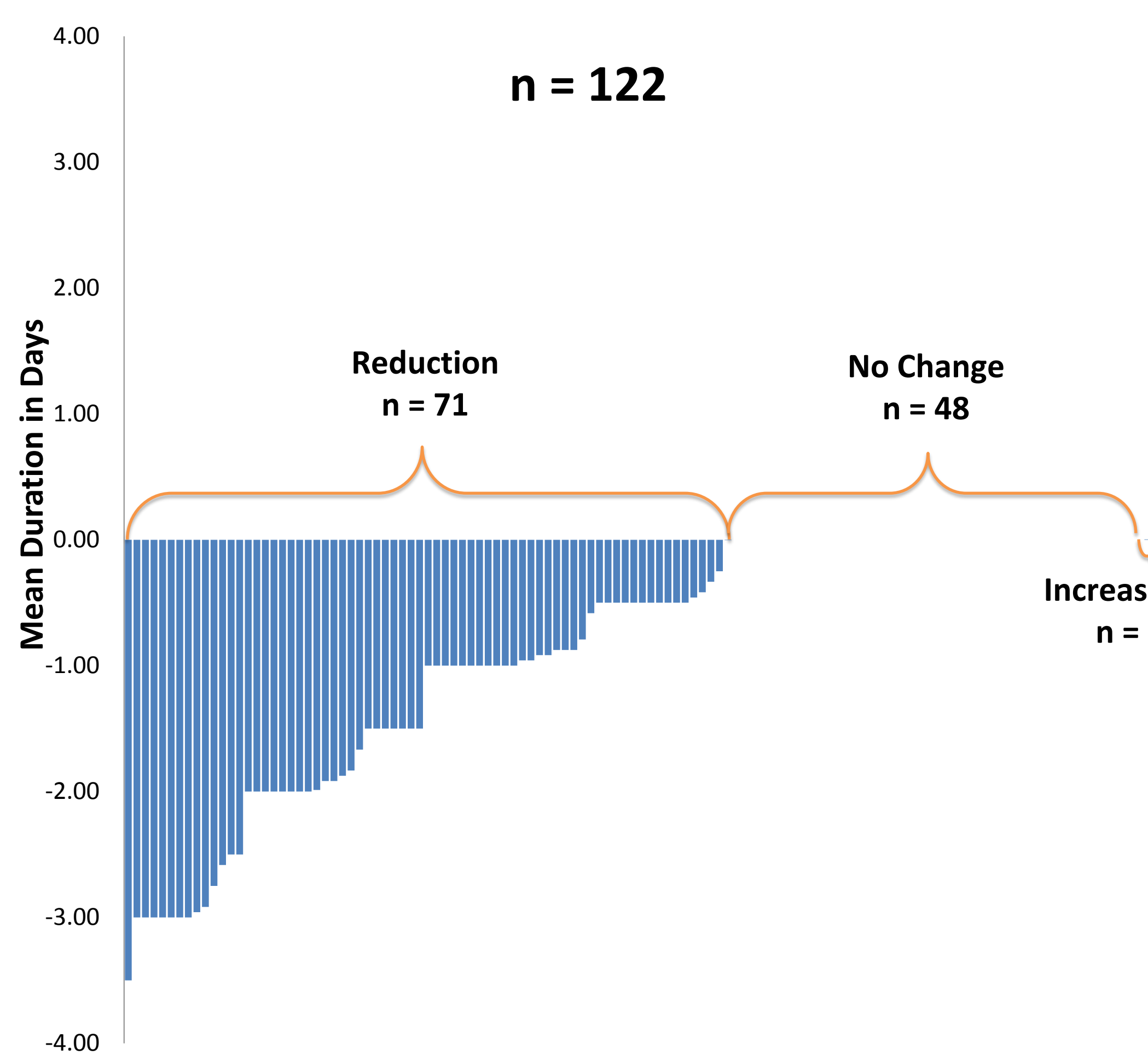


Figure 2: Reduction in Attack Duration

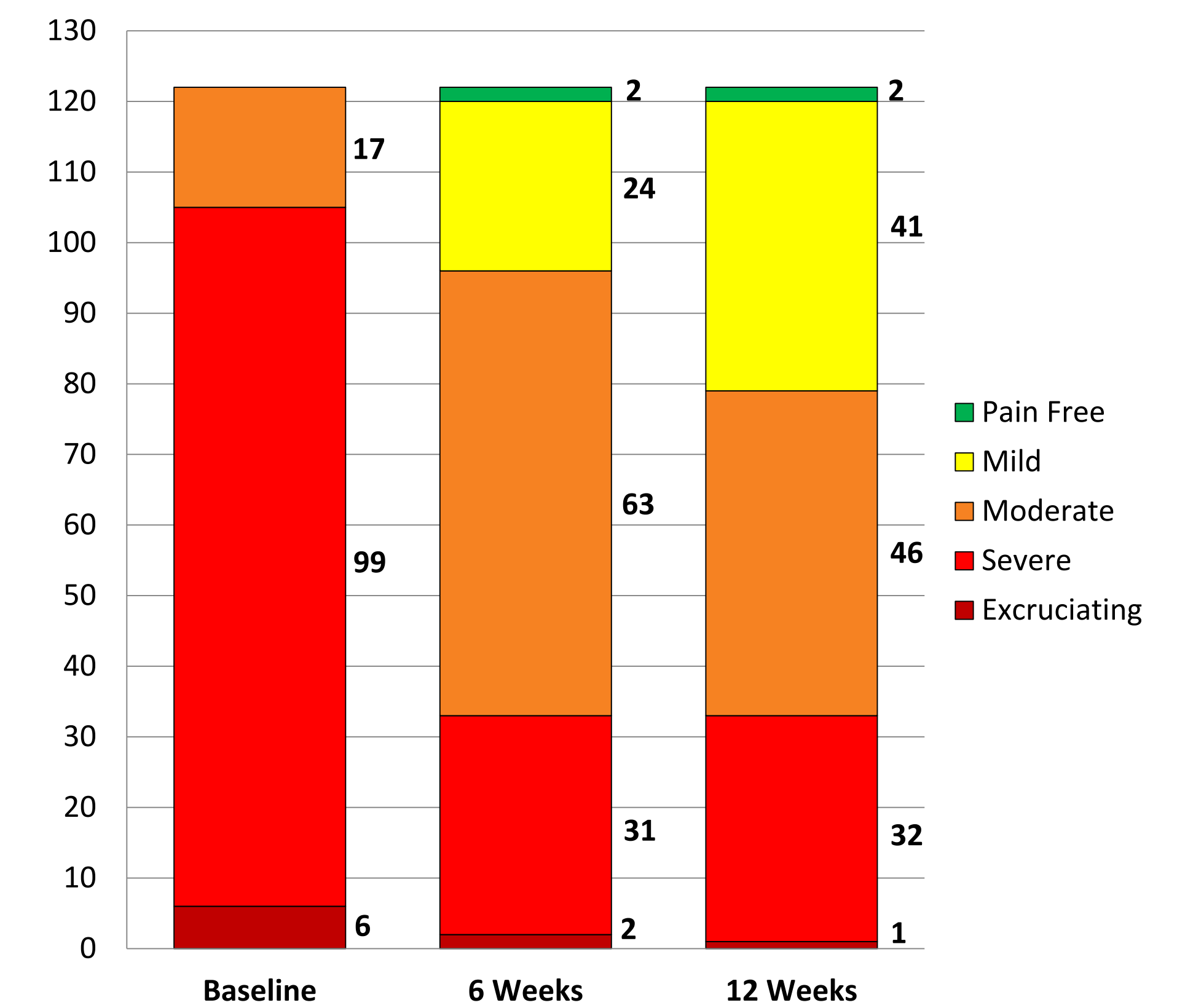


Figure 3: Effectiveness on Pain

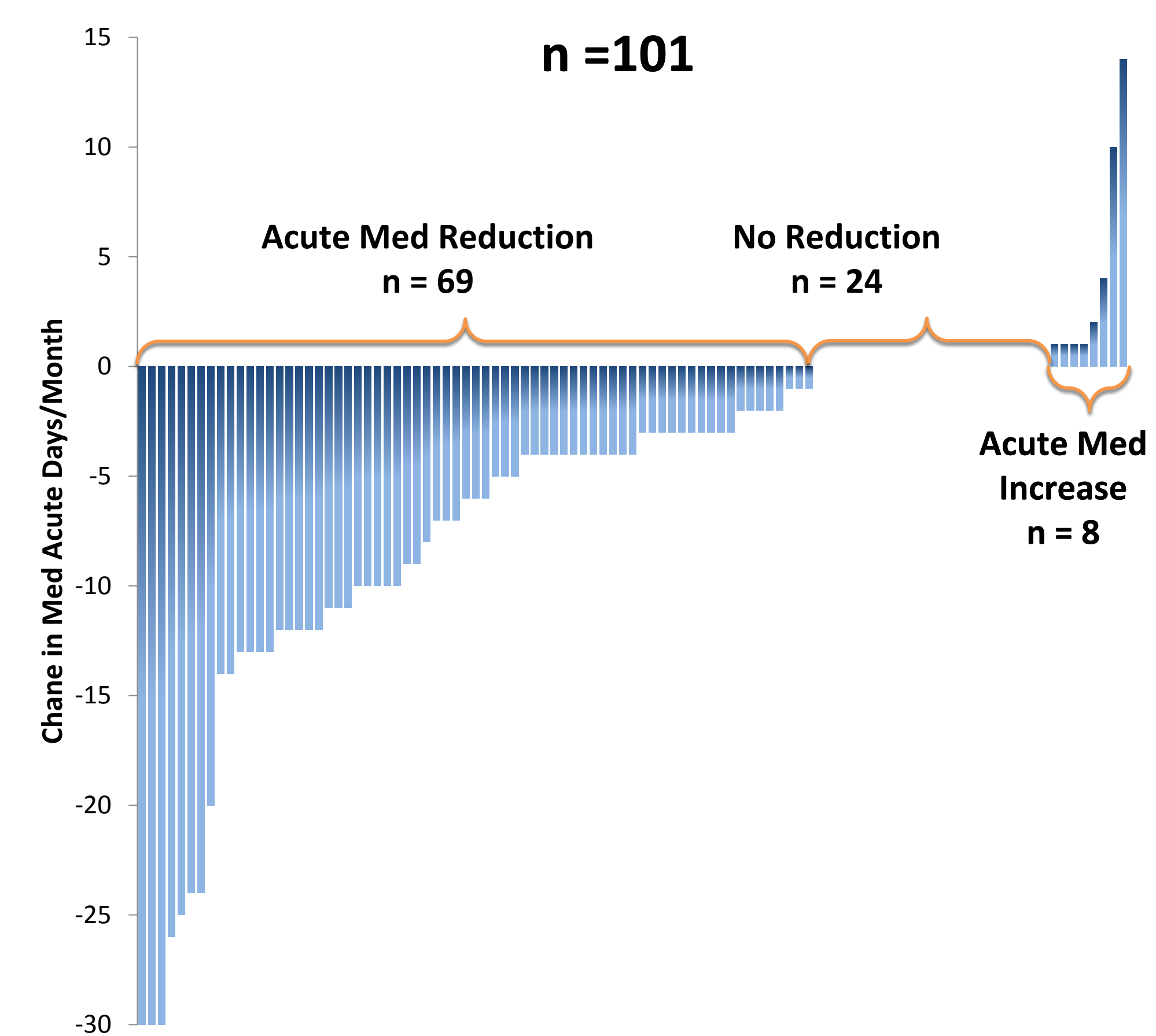


Figure 4: SpringTMS Reduction of Acute Medicine Days

## Conclusion

- SpringTMS is a new and effective NICE UK-approved, acute and adjunctive, non-drug treatment option for patients with migraine.
- These results are consistent with this CE marked device being safe to use in outpatient practice.
- The data suggests the device, in responders, continues to provide reliable, reproducible effects on migraine over time.

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1 Lipton R.B., Dodick D.W., Silberstein S.D et al. Single-pulse transcranial magnetic stimulation for acute treatment of migraine with aura: randomized, double-blind, parallel-group, sham controlled trial. The Lancet Neurology 2010;9:373-380.  
 2 Dodick D.W., Schembri C.T., Helmuth M et al. Transcranial magnetic stimulation for migraine: a safety review. Headache 2010; 50:1153-1163.  
 3 NICE www.nice.org.uk/IPG477