

# Update of the UK post market pilot programme with single pulse transcranial magnetic stimulation (sTMS) for acute treatment of migraine: SpringTMS® use in 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 in migraine in the UK.

## Objectives

- Evaluate responses to sTMS in an outpatient setting
- Assess impact on pain and associated migraine symptoms over an extended period (minimum three months)
- 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 clinical liaison 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. Patients treated per eNeura MAB guidelines using an average of 6-8 sTMS pulses per day.

## Patient Characteristics

Migraine Features	# of Patients	# of Attacks Treated
<b>Migraine with aura</b>	<b>55</b>	<b>2522</b>
Episodic	21	
Chronic	34	
<b>Migraine without aura</b>	<b>52</b>	<b>2012</b>
Episodic	21	
Chronic	31	
<b>Episodic</b>	<b>42</b>	<b>1360</b>
<b>Chronic</b>	<b>65</b>	<b>3174</b>

## Results

- A total of 266 patients were prescribed sTMS. 107 (40%) patients used the device for a minimum of three months and completed three surveys.
- 75% of patients (80) reported alleviation or reduction of pain.
- 68% (60) of patients using an acute medication at the time of prescription reported a reduction in the number of days of medications use.
- 65% of patients (57) reported associated symptoms were improved or did not develop.
- 62% (66) of patients reported a reduction in the number of headache days.
- 57% (62) of patients reported a reduction in the duration of migraine symptoms per attack.
- The treatment was well tolerated with no serious adverse events reported.
- For patients reporting a clinical response, patients continued to respond beyond the 3 month treatment period.

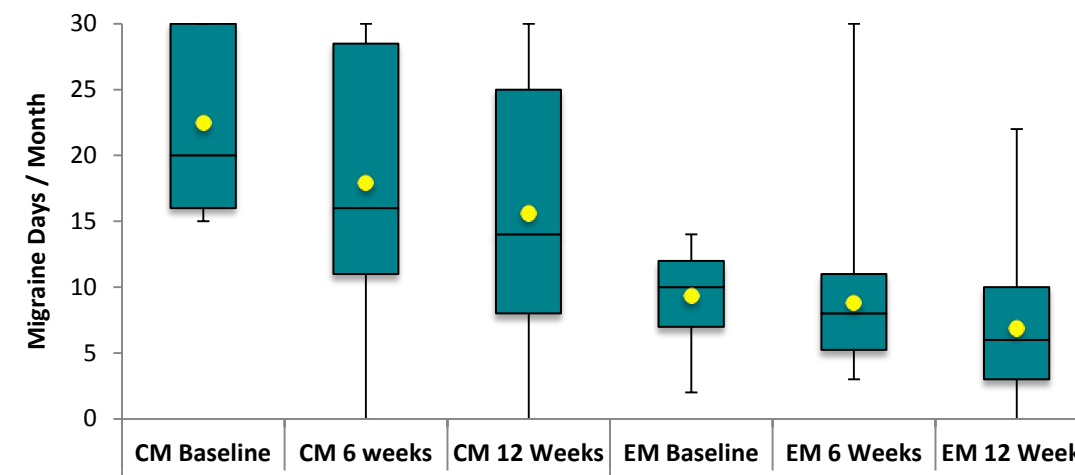


Figure 1: Change in headache days

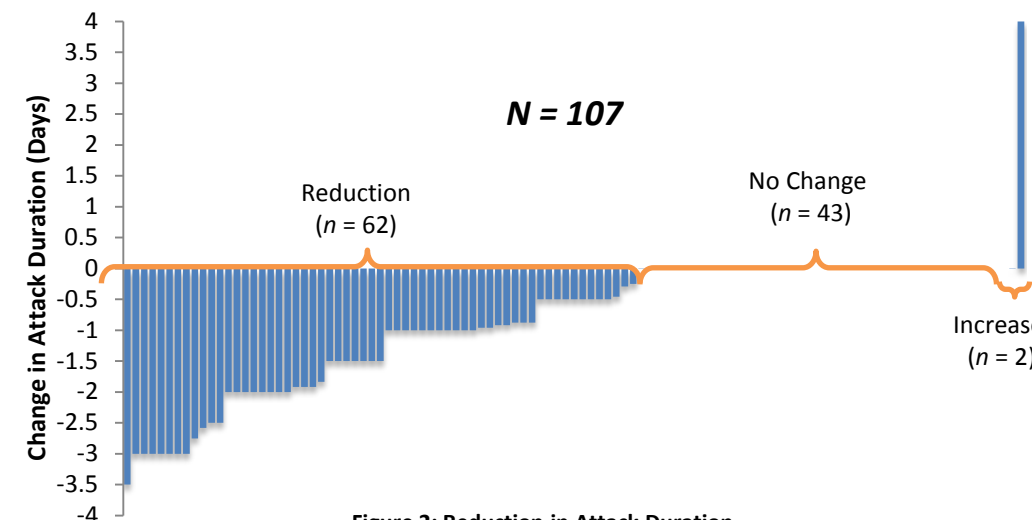


Figure 2: Reduction in Attack Duration

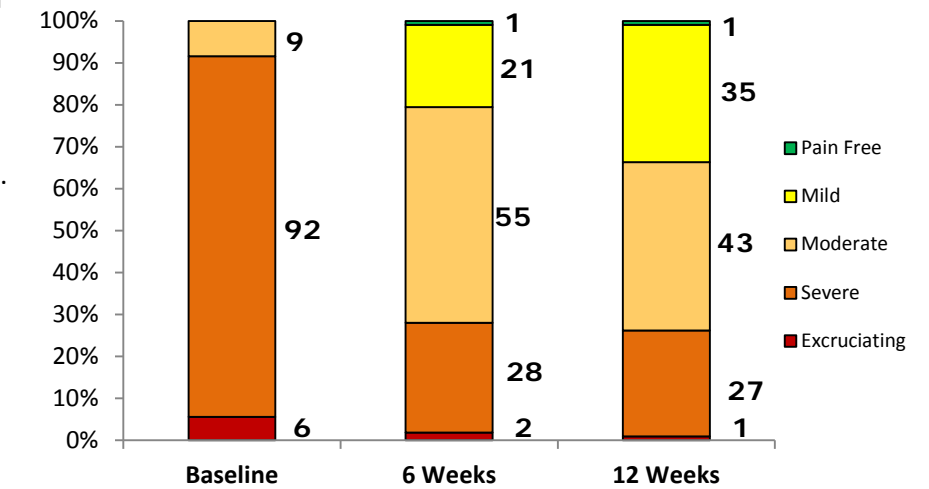


Figure 3: Effectiveness on Acute Treatment of Pain

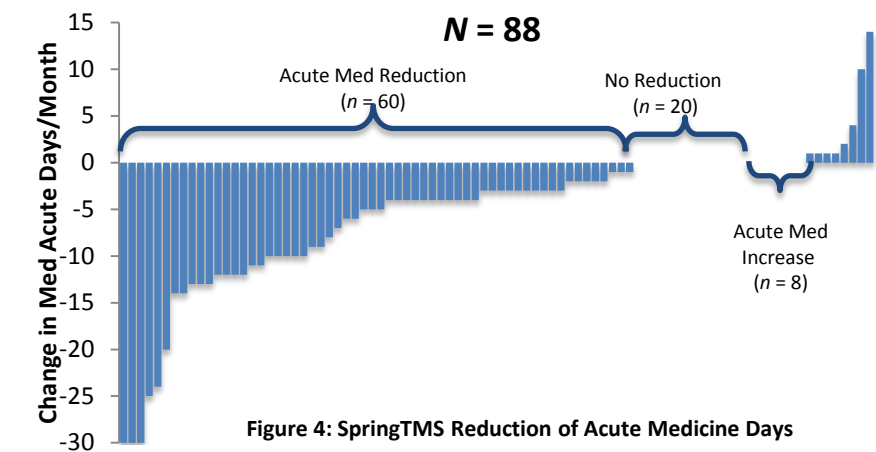


Figure 4: SpringTMS Reduction of Acute Medicine Days

## Conclusion

- sTMS is an effective NICE (UK) approved non-drug treatment option for patients with migraine.
- sTMS provides effective, sustainable pain relief for migraine patients.
- The results indicate that sTMS (SpringTMS) is safe for use in outpatient practice.
- The data indicates SpringTMS can reduce the amount of acute medication used for the treatment of migraine.

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<sup>1</sup> 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.

<sup>2</sup> Dodick D.W, Schembri C.T., Helmuth M et al. Transcranial magnetic stimulation for migraine: a safety review. Headache 2010; 50:1153-1163.

<sup>3</sup> NICE www.nice.org.uk/IPG477