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# A randomized controlled trial evaluating the efficacy of tailored migraine self-management tools

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**Background** Botulinum toxins can play a role in reducing pain and headache disorders and recent evidence suggests that there is migration of BontA to the CNS from peripheral injection sites.

**Methods** 48 patients [35f, 13 m] were entered. All received intradermal BontA, 100 units, given on the side of predominant side of TMD/migraine involvement. All patients were followed monthly. Migraine frequency and severity, along with TMD symptom severity, were assessed monthly.

**Results** BoNTA showed statistically significant reductions of migraine frequency and severity both at 1 month and at 3 months. Headache/migraine frequency was 17.2 headaches per month, as compared with 3.6 headaches per month after BontA treatment. ( $p < .001$ , 2-tailed t test). Reductions in migraine severity continued at  $p < .002$  compared to baseline data after 3 months. TMD pain reduced 73% VAS) after BoNTA treatment for an average of 12.6 weeks (6.4–21.7). Reductions in migraine severity continued at  $p < .002$  compared to placebo over 12.5 weeks. No side effects were noted with BontA, other than minor discomfort at injection sites. Safety and tolerability of intradermal BontA were excellent.

**Conclusions** Intradermal dosing may involve mechanisms of action that do not utilize cholinergic motor nerve elements and may involve alterations in pain transmission pathways.

Intradermal BontA reduced significantly the frequency and severity of migraines and TMD symptoms, including pain. Safety and tolerability of intradermal BoNTA was excellent. Intradermal BontA dosing may involve mechanisms of action that do not utilize motor nerve elements and may involve alterations in pain transmission. Double-blind studies are needed for intradermal BontA for face pain and migraine disorders.

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### A randomized controlled trial evaluating the efficacy of tailored migraine self-management tools

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**Background** Migraine is a chronic disease with attacks that vary in frequency. A hallmark of chronic disease management is patient self-management. In order for patients to optimize migraine management and prevention they need knowledge and tools. Tailoring self-management materials for migraine management and prevention would enhance personal relevance and in theory be more efficacious than generic materials.

**Objective** This randomized controlled trial evaluated the impact of tailoring migraine self-management (miSelf-T) vs. generic miSelf (miSelf-G) and compared these groups to those keeping daily diaries (DD) or usual care (UC). The following outcomes (12 weeks post-baseline) were considered:

- headache days per month;
- number of days modifiable migraine triggers (sleep, stress, skipping meals) were elevated;
- headache-related disability; and
- whether cognitive factors moderated efficacy.

**Methods** 119 individuals with migraine (91% female; Age M = 41.66, days with headache per month M = 9.83) were randomized to one of 4 conditions (miSelf-T, miSelf-G, DD, UC). The

miSelf program consisted of 8 newsletters and provided education and tools for “managing triggers, managing medication, and managing life”. Materials were tailored on demographics, risk of triggers, self-efficacy/locus of control (LOC), and disability. Individuals kept a daily web-based diary.

**Results** The miSelf-T group showed the greatest improvement, especially among those with high efficacy/LOC at baseline. MiSelf T or G showed significant improvement at 12 weeks relative to those in the DD or UC group for disability ( $p < .05$ ) and headache days relative to UC ( $p < .05$ ). Relative to UC, all other conditions showed significant improvement in managing triggers ( $p < .01$ ). Cognitive factors also showed improvement, especially among those in miSelf-T.

**Conclusions** Providing self-management materials improved migraine management, especially among those with high efficacy/LOC at baseline. Tailoring these materials enhanced the efficacy of the materials and suggests that more elaborate tailoring be researched to evaluate its added benefit.

**Conflict of interest** Nicholson R.A. Funded by NIH grant NS048288. Provided consultative services for Endo Pharmaceutical, Merck & Co during the past 12 months.

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### Evidence for CGRP re-uptake in rat dura mater encephali

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**Background and purpose** Calcitonin gene-related peptide (CGRP), a potent vasodilator, is distributed in trigeminovascular sensory nerve fibres and CGRP is released upon its activation.

Release of CGRP is thought to be one of the underlying mechanisms of migraine pathogenesis. Uptake and re-release of peptide signalling molecules is generally not believed to occur, but we have previously found functional evidence for uptake in a guinea pig basilar artery preparation. We investigated CGRP release as well as uptake in the intact dura mater.

**Experimental approach** The hemi-sected skull model was used to study CGRP release and uptake from rat dura mater. The released CGRP was measured using an enzyme-linked immunoassay. We used four successive capsaicin challenges to deplete CGRP followed by CGRP incubation to allow uptake. Immunohistochemistry was performed to visualize the depletion and uptake of CGRP from sensory nerves.

**Key results** Capsaicin-induced CGRP release was attenuated by the TRPV1 antagonist capsazepine and by calcium ion free environment. Subsequent to depletion of CGRP skull halves were incubated with exogenous CGRP which caused an increase in capsaicin-induced CGRP release as compared to the challenge just prior to incubation. The CGRP uptake was not influenced by a  $Ca^{2+}$ -free environment. Sumatriptan, olcegepant and CGRP<sub>8-37</sub> did not affect the uptake of CGRP. However, a monoclonal CGRP-binding antibody decreased