Treatment should be individualized to the patient; the choice of treatment should factor in drug class, previous ADHD medications were discontinued. Permanent enablers of behavior since the patient's last visit. C-SSRS = Columbia-Suicide Severity Rating Scale; MPH XR-ODT = methylphenidate extended-release orally disintegrating tablet.

Participants were male and female children aged 6 to 12 years. Informed consent/assent was obtained. Previous ADHD medications were discontinued. Permanent enablers of behavior since the patient's last visit. C-SSRS = Columbia-Suicide Severity Rating Scale; MPH XR-ODT = methylphenidate extended-release orally disintegrating tablet.

Figure 1

**METHODS**

Study Design and Participants

- A parallel, randomized, double-blind, placebo-controlled, laboratory classroom study.
- Participants were male and female children aged 6 to 12 years. Informed consent/assent was obtained.
- Double-blind treatment period:
  - Previous ADHD medications were discontinued. Permanent enablers of behavior since the patient's last visit. C-SSRS = Columbia-Suicide Severity Rating Scale; MPH XR-ODT = methylphenidate extended-release orally disintegrating tablet.

**RESULTS**

**Participant Disposition and Baseline Characteristics**

<table>
<thead>
<tr>
<th>Group</th>
<th>Enrolled (n = 87)</th>
<th>Completed Dose Optimization (n = 85)</th>
<th>Optimized Post-Dose Stabilization (n = 83)</th>
<th>Participants (full analysis set [FAS]: n = 82; per protocol set [PPS]: n = 80) disposition is detailed in Table 1.</th>
<th>Safety population</th>
<th>Analysis set</th>
<th>n</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPH XR-ODT</td>
<td>44</td>
<td>42</td>
<td>42</td>
<td>Only 2 AEs were reported: vomiting (n = 1) and upper respiratory infection (n = 1).</td>
<td>60.7 ± 8.36</td>
<td>82</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>41</td>
<td>38</td>
<td>38</td>
<td>Only 2 AEs were reported: vomiting (n = 1) and upper respiratory infection (n = 1).</td>
<td>61.1 ± 8.92</td>
<td>80</td>
<td>NS</td>
<td></td>
</tr>
</tbody>
</table>

**Primary efficacy endpoint (SKAMP-Combined score)**

<table>
<thead>
<tr>
<th>Group</th>
<th>Placebo (n = 41)</th>
<th>MPH XR-ODT (n = 44)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SKAMP-Combined score</td>
<td>14.3 (12.2, 16.4)</td>
<td>25.3 (23.0, 27.6)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

**Secondary efficacy endpoints**

- Combined SKAMP-Attention and SKAMP-Deportment scores—Placebo: 75.7 (67.0, 84.4); p <0.0001
- Relative decrease (LS means ± SE) in SKAMP-Attention and SKAMP-Deportment scores: Placebo vs MPH XR-ODT: -11.04 (-13.9, -8.2) (p <0.0001) on the classroom study day

**Adverse Event Management**

- The mean (SD) ADHD-RS-IV scores for the safety population decreased from baseline to the end of the open label period by 20.4 (8.2) and 22.4 (9.7) for the MPH XR-ODT (n = 44) and placebo (n = 41) groups, respectively. The decrease was greater for MPH XR-ODT vs placebo at all assessment visits throughout the study (p <0.0001). Table 3.

**Safety Monitoring**

- No suicidal ideation or behavior, or serious TEAEs occurred during the study period. Only 2 AEs were reported: vomiting (n = 1) and upper respiratory infection (n = 1).

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NextWave; and Ironshore. She has served on a Speakers Bureau for Shire, Novartis, Mallinckrodt, and Shire.

**REFERENCES**