**BACKGROUND**

- Hallucinations and delusions are common neuropsychiatric symptoms in persons with dementia and can be due to underlying disease, medication, or psychosis. DRP3 is one of several neuropsychiatric symptoms associated with dementia. It is not only associated with cognitive, functional, and behavioral decline, and higher patient and caregiver burden.
- Approximately 50% of patients diagnosed with dementia in the US have DRP and experience hallucinations and delusions. “There is an unmet need for their accurate, timely identification in a rapidly growing dementia population.”

**METHODS**

**DRP3 Screen Development**

- Subject matter experts collaboratively developed a novel, practical, single screening tool with face-valid preliminary screening questions to detect hallucinations and delusions in patients with dementia.
- The panel engaged in refinement of the questions and ultimate assignment of a method to assess the potential for clinical use of the tool.

**Content Validation Alignment Exercise**

- The subject matter experts completed the Content Validation Alignment Exercise, in which each rater independently rated the content of each of the DRP3 questions with each of the following:
  - 1. B-Axis D6 (somatic delusions) from the SAPS-H+D questionnaire.
  - 2. Q-questions from the NPI-Q domain related to hallucinations and delusions, and
  - 2. Items from the IPA Criteria for Psychosis in Alzheimer’s Disease related to hallucinations and delusions.

- The raters were instructed to use the following scale to indicate the extent to which the reference assessment would be captured by the DRP3 Screen.

<table>
<thead>
<tr>
<th>Scale</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No relevance</td>
</tr>
<tr>
<td>1</td>
<td>Some relevance</td>
</tr>
<tr>
<td>2</td>
<td>Moderate relevance</td>
</tr>
<tr>
<td>3</td>
<td>High relevance</td>
</tr>
</tbody>
</table>

- Inter-rater reliability of the Content Validation Alignment Exercise was assessed using Fleiss’ kappa statistic based methodology.

**DRP3 Screen**

- The HARMONY trial (NCT03325556) was a phase 3, double-blind, placebo-controlled randomized discontinuation trial that enrolled 382 patients with DRP. 
- Based on findings from the Content Validation Alignment Exercise with SAPS-H+D, a retrospective assessment of the ability of the DRP3 Screen to detect the patient population included in the HARMONY trial was conducted.
- The HARMONY trial was established to determine DRP reference assessments; and
- To retrospectively apply the DRP3 Screen to detect the patient population that was identified for inclusion in a phase 3 clinical trial evaluating treatment for DRP (HARMONY, NCT03325556).

**RESULTS**

**KEY TAKEAWAY: The DRP3 Screen's content validity aligned with current reference assessments.**

**Content Validation Alignment Exercise Findings**

- The content validation alignment exercise was conducted with SAPS-H+D, NPI-Q, and IPA Criteria.

**Table 1. Summary of inter-rater agreement of content alignment of reference assessments with the DRP3 Screen**

<table>
<thead>
<tr>
<th>Reference Assessment</th>
<th>kappa</th>
<th>SE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAPS-H+D Ratings</td>
<td>0.37</td>
<td>0.02</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>NPI-Q Ratings</td>
<td>0.26</td>
<td>0.06</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>IPA Criteria Ratings</td>
<td>0.45</td>
<td>0.07</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

**DRP3 Screen**

- The DRP3 Screen contains 3 yes/no questions to help assess people with dementia for the presence of hallucinations and delusions.

<table>
<thead>
<tr>
<th>Question</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The person is aware of the hallucinations or delusions, or is not aware of their existence, or both?</td>
<td>YES/NO</td>
</tr>
<tr>
<td>2. Is the person feeling flexible or doing things that are usually uncharacteristic?</td>
<td>YES/NO</td>
</tr>
<tr>
<td>3. Is the person feeling flexible or doing things that are unusual, unusual, or strange?</td>
<td>YES/NO</td>
</tr>
</tbody>
</table>

**Figure 1. Summary of SAPS-H+D ratings for alignment with DRP3 Screen; N = 6 raters.**

**Figure 2. Summary of (A) NPI-Q and (B) IPA Criteria ratings for alignment with DRP3 Screen; N = 6 raters.**

**REFERENCES**

- Chambers-Grundy Center for Transformative Neuroscience, Department of Brain Health, School of Integrated Health Sciences, University of Nevada Las Vegas, Las Vegas, NV, USA; Mohr’s Clinic, University of Calgary, Alberta, Canada; Toronto Western Neurological Sciences, General Hospital, Inc., USA; *The University of the Arts Medical School, Brussels, Belgium; *Louisiana State University of Medicine, Shreveport, LA, USA; *Vanderbilt University Inc., Nashville, TN, USA; *University of California, Irvine, CA, USA; *Wexner State Health Institute,4 Institute for Health, San Diego, CA, USA, and Integrated Medical School Alumni and Women’s Health, Boston, MA, USA.

**OBJECTIVES**

1. Develop the DRP3 Screen, an innovative screening tool for detection of psychosis in patients with dementia in a clinical setting.
2. Conduct a Content Validation Alignment Exercise designed to determine content alignment of the DRP3 Screen questions with established DRP reference assessments; and
3. Retrospectively apply the DRP3 Screen to detect the patient population that was identified for inclusion in a phase 3 clinical trial evaluating treatment for DRP (HARMONY, NCT03325556).

**DISCLOSURES.**

- Support were provided by Health & Wellness Partners, LLC, funded by Acadia Pharmaceuticals Inc. ABBREVIATIONS. CI, confidence interval; DRP, dementia-related psychosis; IPA Criteria, International Psychogeriatric Association Criteria; NPI-Q, Neuropsychiatric Inventory Questionnaire; SAPS-H+D, Comprehensive Psychopathological Rating Scale for Dementia.

**Statistical analysis.**

- Inter-rater reliability was assessed using Fleiss’ kappa statistic for each agreement among raters; and through successful retrospective application to existing trial population.

**CONCLUSIONS.**

- The novel DRP3 Screen is a brief tool designed to assess the presence of hallucinations and delusions in persons with dementia.
- Present for its clinical application has not been established, but to facilitate your research assessments, with significant agreement among raters; and through successful retrospective application to an existing trial population.