PHQ-9 scores are patient-reported and

Results may not be generalizable to

MHS clinics, from states other than

insurance or the uninsured

Sustained esketamine treatment

was associated with improvement

Findings from descriptive analysis

not hinder esketamine effectiveness,

suggest that while TMS experience does

TMS-naive patients may improve faster

in depressive symptoms

This study was sponsored by Janssen Scientific Affairs, LLC, a Johnson & Johnson

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company. TM is and JG was, at the time of the study, an employee and stockholder of

Mindful Health Solutions, as well as an honorarium speaker for Janssen Scientific Affairs,

employees of Analysis Group, Inc., a consulting company that has provided paid consulting

services to Janssen Scientific Affairs, LLC. which funded the development and conduction

LLC. KJ is an employee and stockholder of Johnson & Johnson. MZ, AS, DP, BM, and FJ are

patients receiving esketamine in non-

California and Washington, with public

Limitations

Conclusions

Acknowledgements

# Clinical Effectiveness and Persistence on Esketamine Nasal Spray in Patients With Treatment-Resistant Depression Overall and TMS-Naive Subgroup

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# Introduction

- Esketamine nasal spray and transcranial magnetic stimulation (TMS) are efficacious in treatment-resistant depression (TRD)<sup>1-3</sup>; however, there are no guidelines on the sequence in which these therapies should be
- The Patient Health Questionnaire (PHQ)-9 is a patient-report questionnaire used for diagnosis and treatment monitoring of depression<sup>4,5</sup>
- This analysis explored if PHQ-9-based clinical effectiveness and persistence on esketamine differ by previous TMS experience among patients treated at a large US group psychiatric practice

## Methods

#### Data source

- Retrospective de-identified data including patient demographics, esketamine and TMS treatment information, and PHQ-9 scores, were obtained from Mindful Health Solutions (MHS) clinics from 05/02/2018 to 01/15/2024
- Institutional review board exemption status under Exemption 45 CFR 46.104(d)(4)<sup>6</sup> was granted prior to commencement of the study

#### Study design

- Retrospective observational design was used
- The intake period spanned from 03/05/2019 to the end of data; the index date was the date of the first esketamine treatment session
- Adults who initiated esketamine for TRD in MHS clinics and had ≥1 baseline PHQ-9 score were included in the overall cohort; the TMS-naive subgroup included patients without history of TMS treatment before or on the index date
- Baseline PHQ-9 score was the score closest to or on the index date; during the follow-up period, which spanned the index date to end of clinical activity or data, PHQ-9 scores within 2 weeks after treatment sessions were obtained

### **Outcomes**

- PHQ-9 is a patient-reported measure of depression severity; it has a recall period of 2 weeks; scores range from 0 to 27, and higher scores indicate higher severity<sup>5</sup>
- Esketamine persistence was defined absence of gaps of >60 days between consecutive esketamine treatment sessions or the end of follow-up; the discontinuation date was the date of the last treatment session before the >60-day gap

## Statistical analysis

- Generalized estimating equation models adjusted for repeated measurements were used to estimate mean differences in follow-up PHQ-9 scores from baseline; non-parametric bootstrap procedures were used to generate 95% confidence intervals (CIs) and P values for mean change in PHQ-9 scores
- Esketamine persistence was described using Kaplan-Meier survival analysis; patients who did not discontinue treatment were censored at the end of follow-up

# Results

#### Demographics and baseline characteristics

• The overall cohort included 911 patients, of which 512 (56.2%) were in the TMS-naive subgroup; baseline characteristics are reported in **Table 1** 

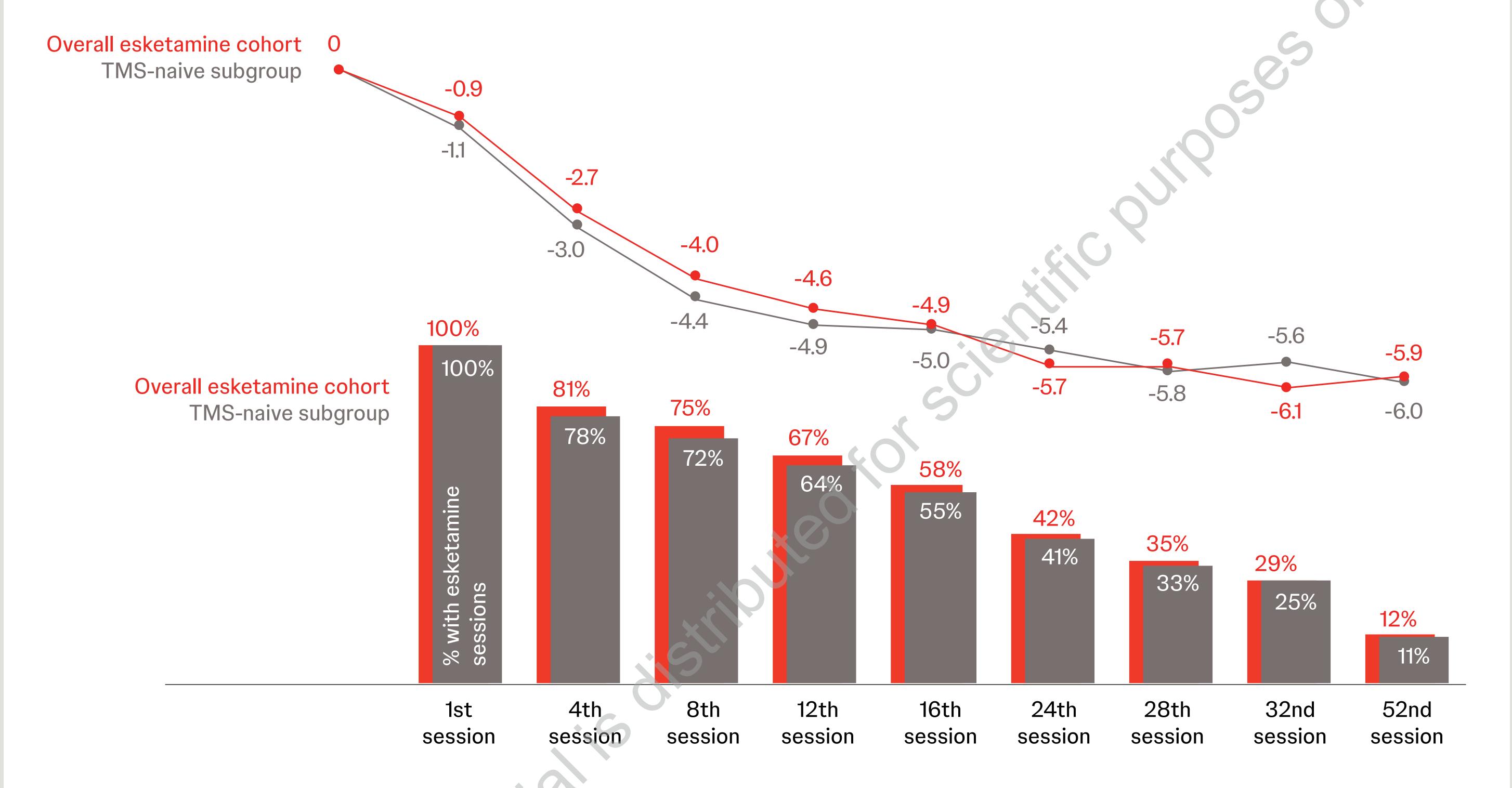
#### Mean change from baseline PHQ-9 score

- Mean duration of follow-up was 12.8 months in the overall cohort and 12.5 months in TMS-naive subgroup
- Mean number of esketamine sessions completed were 24.9 in the overall cohort and 23.8 in the TMS-naive subgroup
- Mean change in PHQ-9 scores from baseline in the overall cohort and the TMS-naive subgroup, respectively, was as follows (Figure 1): After 8 sessions, the score decreased by 4.0 points (95% CI: -4.4 to -3.5; P < 0.001) and 4.4 points (95% CI: -5.1 to -3.8; P < 0.001)
  - After 12 sessions, the score decreased by 4.6 points (95% CI: -5.0 to -4.0; P < 0.001) and 4.9 points (95% CI: -5.7 to -4.3; P < 0.001)
  - After 28 sessions, the score decreased by 5.7 points (95% CI: -6.6 to -5.0; P < 0.001) and 5.8 points (95% CI: -6.9 to -4.9; P < 0.001)
- After 52 sessions, the score decreased by 5.9 points (95% CI: -7.5 to -4.3; P < 0.001) and 6.0 points (95% CI: -8.1 to -3.6; P < 0.001)

#### Esketamine persistence

- Median persistent time on esketamine was 7.2 months in the overall cohort and 7.5 months in the TMS-naive subgroup (Figure 2)
- At 12 months, 37.0% in the overall cohort and 36.3% in the TMS-naive subgroup persisted on esketamine

## FIGURE 1. Mean difference in PHQ-9 score from baseline by number of esketamine sessions completed



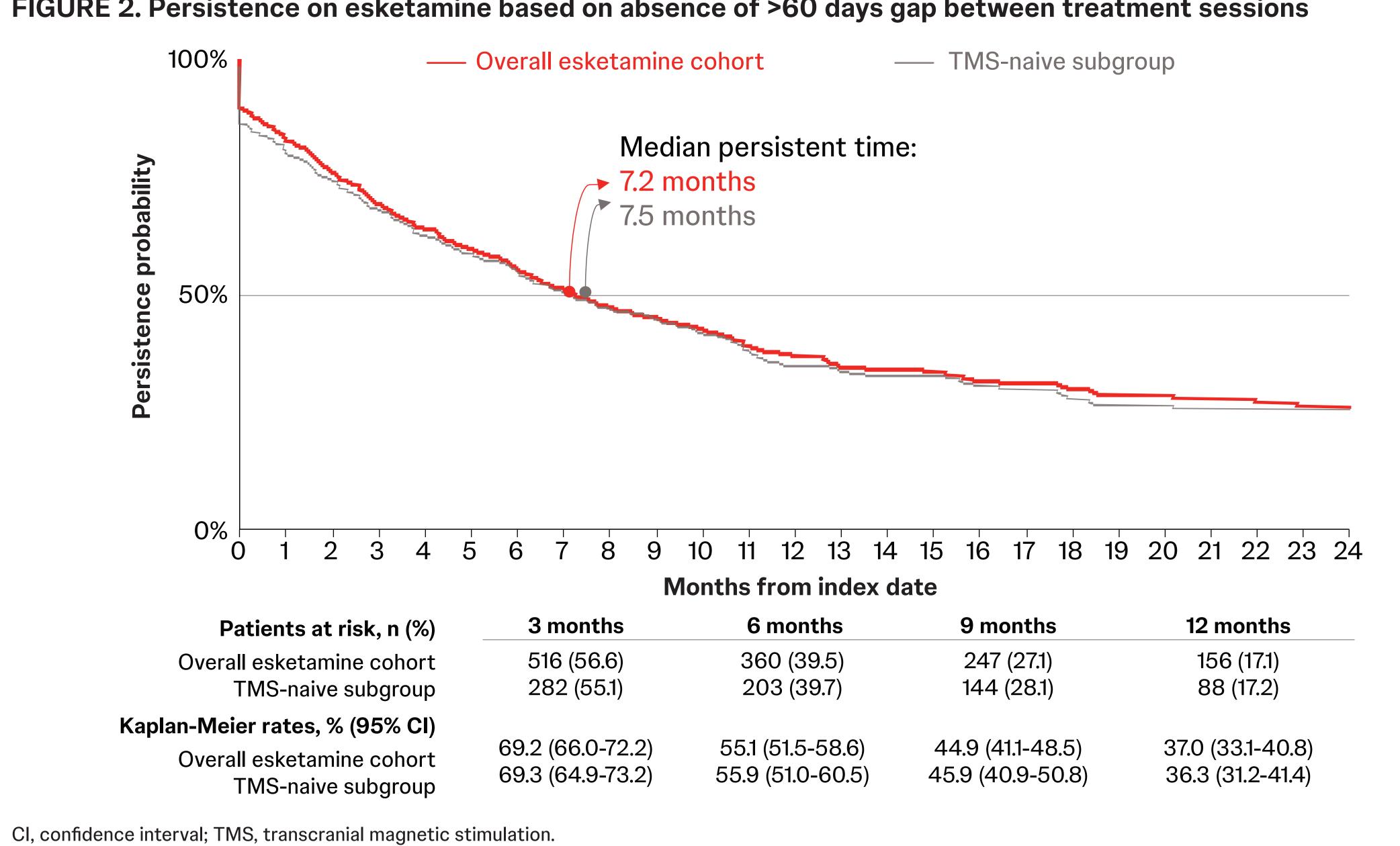
PHQ-9, Patient Health Questionnaire 9; TMS, transcranial magnetic stimulation.

# TABLE 1. Baseline demographic and clinical characteristics

Mean ± SD [median] or n (%)	Overall esketamine cohort (N = 911)	TMS-naive subgroup (n = 512)
Age at index date, years	43.7 ± 13.7 [42.0]	42.6 ± 13.7 [40.0]
Female	516 (56.6)	278 (54.3)
State		
California	894 (98.1)	501 (97.9)
Washington	17 (1.9)	11 (2.1)
Year of index date		
2021	190 (20.9)	107 (20.9)
2022	394 (43.2)	228 (44.5)
2023 and 2024	327 (35.9)	177 (34.6)
PHQ-9 scores	<u> </u>	
Baseline PHQ-9 score (out of 27)	16.3 ± 6.1 [17.0]	15.6 ± 6.3 [16.0]
Time from baseline score to index date, days	3.6 ± 12.6 [0.0]	3.0 ± 11.9 [0.0]
Patients with a PHQ-9 score ≥10	773 (84.9)	419 (81.8)
MADRS scores		
Patients with a baseline MADRS score	849 (93.2)	461 (90.0)
Baseline MADRS score (out of 60)	34.9 ± 7.9 [36.0]	35.3 ± 7.7 [36.0]

MADRS, Montgomery-Åsberg Depression Rating Scale; PHQ-9, Patient Health Questionnaire 9; SD, standard deviation; TMS, transcranial magnetic stimulation.

# FIGURE 2. Persistence on esketamine based on absence of >60 days gap between treatment sessions



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