





Psychometric Validation Of The AASC®

Supporting Early Detection And Improving
Caregiver-HCP Communication In Agitation Associated
With Dementia Due To Alzheimer's Disease

AASC®, Agitation in Alzheimer's Screener for Caregivers; HCP, healthcare provider.

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Our Featured Speaker



Carolyn Clevenger, DNP, RN, GNP-BC, FAANP, FGSA

Professor Of Transformative Clinical Practice, Emory University School Of Nursing, Clinical Director And Gerontological Nurse Practitioner At Integrated Memory Care Clinic

Our Moderator



Jaclyn Beckinghausen, PhD

Medical Science Liaison CNS—Field Medical Affairs Otsuka Pharmaceutical Development & Commercialization, Inc.



Objectives



Review current approaches and unmet needs in recognizing agitation associated with dementia due to Alzheimer's disease



Highlight the critical role of caregiver-HCP communication in identifying agitation symptoms, and how the AASC® can support early identification of symptoms



Discuss the quantitative validation of the AASC® against IPA criteria and key findings supporting its psychometric robustness

AASC®, Agitation in Alzheimer's Screener for Caregivers; HCP, healthcare provider; IPA, International Psychogeriatric Association.



Agitation Associated With Dementia Due To Alzheimer's Disease Is Highly Prevalent And Presents A Broad Spectrum Of Symptoms

- Agitation associated with dementia due to Alzheimer's disease is a common neuropsychiatric symptom and treatable condition with a broad range of behaviors¹⁻³
- It requires separate treatment options from those used for cognitive impairment⁴

Symptoms of agitation manifest as both non-aggressive and aggressive behaviors^{5,6}:



Deferences

- 1. Cummings J, et al. Int Psychogeriatr. 2015;27(1):7-17.
- 2. Cohen-Mansfield J. Instruction manual for the Cohen-Mansfield Agitation Inventory (CMAI). Research Institute of the Hebrew Home of Greater Washington; 1991.
- 3. Gilmore-Bykovskyi A. et al. Gerontologist. 2020:60(5):896-904.

- 4. Ringman JM, Schneider L. Curr Treat Options Neurol. 2019;21(7):30.
- 5. Sano M, et al. Int Psychogeriatr. 2024;36(4):238-250.
- 6. Rabinowitz J, et al. Am J Geriatr Psychiatry. 2005;13(11):991-998.
- 7. Halpern R, et al. Int J Geriatr Psychiatry. 2019;34(3):420-431.



~1 out of 2

individuals with dementia due to Alzheimer's disease⁷

People with Alzheimer's dementia can experience behavioral and psychological conditions, with agitation being one of the most common⁷



Despite Its Prevalence, Agitation Is Often Under-Recognized By Caregivers And Underdiagnosed By HCPs

Caregivers play a critical role in recognizing and communicating agitation behaviors to HCPs¹



Caregivers

- Often the first to encounter agitation behaviors¹
- May not recognize the full breadth of agitation behaviors²⁻⁴
- May not understand that treatment of agitation differs from treatment of cognitive impairment in Alzheimer's dementia²⁻⁴
- May not readily talk about agitation behaviors with HCPs until symptoms become untenable, which can lead to underdiagnosis of agitation²⁻⁴



HCPs

- Often rely on caregivers to report agitation behaviors³
- Agitation symptoms may not be easy to detect in an office setting, especially when subtle³
- Generally, may not educate families about agitation early in Alzheimer's dementia²
- May not be made aware of agitation symptoms until burden becomes untenable for the caregiver²

HCP, healthcare provider.

- Clevenger C, et al. One minute to recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC®). Presented at: Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.
- 2. Richler LG, et al. Harv Rev Psychiatry. 2023;31(1):22-27.
- 3. Stella F, et al. Int J Geriatr Psychiatry. 2015;30(12):1230-1237.
- 4. Gilmore-Bykovskyi A, et al. Gerontologist. 2020;60(5):896-904.



IPA Criteria Offer A Foundation For Recognition Of Agitation In Cognitive Disorders¹

To standardize diagnosis of agitation in cognitive disorders, the IPA developed a consensus definition that includes 4 criteria:

- 1. The patient meets the criteria for **cognitive impairment or dementia syndrome**
- 2. The patient exhibits ≥1 agitation behavior(s) associated with emotional duress that is persistent or frequently recurrent for ≥2 weeks or the behavior represents a dramatic change from the patient's usual behavior*
- 3. The behaviors are **severe** and associated with **excess distress** or produce **disability** beyond that due to cognitive impairment
- 4. The behaviors cannot be attributed to another psychiatric disorder, medical condition (including delirium), suboptimal care conditions, or the physiological effects of a substance

Excessive motor activity behaviors:

- Pacing
- Rocking
- Gesturing
- Pointing fingers
- Restlessness
- Performing repetitious mannerisms

Agitation behaviors include:



Verbal aggression behaviors:

- Yellina
- Speaking in an excessively loud voice
- Using profanity
- Screaming
- Shouting



Physical aggression behaviors:

- Grabbing
- Shoving
- Pushing
- Resistina
- Hitting others
- or people
- Slamming doors
- Kicking objects Tearing things

Throwing objects

Hitting self

Scratching

Biting

Destroving property

*In special circumstances, the ability to document the behaviors over 2 weeks may not be possible and other terms of persistence and severity may be needed to capture the syndrome beyond a single episode. IPA, International Psychogeriatric Association

Reference:

Sano M, et al. Int Psychogeriatr. 2024;36(4):238-250.



Unmet Needs In The Recognition Of Agitation In Patients With Alzheimer's Dementia

Agitation symptoms, particularly non-aggressive ones, are among the earliest and most common occurrences in Alzheimer's dementia, yet they are often under-recognized^{1,2}

Recognition of agitation symptoms³⁻⁵

Timely recognition, correct diagnosis, and appropriate management may improve outcomes for most patients and their caregivers

Available rating scales that measure agitation^{3,5}



Cohen-Mansfield Agitation Inventory (CMAI)



Neuropsychiatric Inventory (NPI) and NPI-C

Current scales may not aid patient care³⁻⁶:

- Not designed to quickly and exclusively screen for agitation
- Often scored differently by caregivers and HCPs
- Not widely or easily used in clinical practice

Unmet needs identified⁶:

- There is no agitation screener tool exclusively designed for caregivers of individuals with Alzheimer's dementia
- There is no clinical tool that is easy and quick to use in clinical practice

HCP, healthcare provider; NPI-C, Neuropsychiatric Inventory–Clinician Rating Scale.

- Lanctôt KJ, et al. Alzheimers Dement (NY). 2017;3(3):440-449.
- Grossberg G, et al. Dementia (London). Published online May 14, 2025.
- Stella F, et al. Int J Geriatr Psychiatry. 2015;30(12):1230-1237.
- Gilmore-Bykovskyi A, et al. Gerontologist. 2020;60(5):896-904.
- Richler LG, et al. Harv Rev Psychiatry. 2023;31(1):22-27.
- 6. Clevenger C, et al. One minute to recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC®). Presented at: Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.

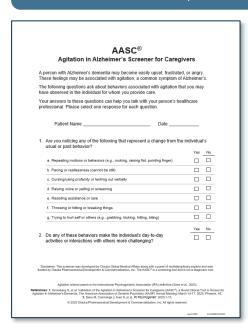


The Agitation In Alzheimer's Screener For Caregivers (AASC®)

The AASC® was based on and assessed against the IPA criteria for agitation in cognitive disorders to support its clinical utility^{1,2}

Goals of the AASC®

- To educate caregivers about agitation symptoms¹
- To facilitate caregiver-HCP conversations about agitation¹
- To help HCPs in screening for agitation associated with dementia due to Alzheimer's disease¹



The AASC® is the first clinical tool based on IPA criteria¹

Items screen for both the **presence and impact** of agitation symptoms¹

Can be completed in <1 minute¹

Simple to score

A positive screen for agitation in Alzheimer's dementia requires¹:

'Yes' to any symptoms in Ouestion 1

AND

✓ 'Yes' to Question 2

Use the digital version or download and print the AASC® at www.theaasc.com



The AASC® is available in 4 other languages:

Traditional Chinese, Simplified Chinese, Spanish, and Japanese

HCP, healthcare provider; IPA, International Psychogeriatric Association.

- 1. Clevenger C, et al. One minute to recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC®). Presented at: Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.
- 2. Grossberg G, et al. Validation of the Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel clinical tool to screen for agitation in Alzheimer's dementia. Presented at: The American Association of Geriatric Psychiatry Annual Meeting; March 14-17, 2025; Phoenix, AZ.



AASC® Screening Tool Items Developed In Collaboration With A Multidisciplinary Team Of Experts And A Patient Representative^{1,2}

AASC® Magnified

1.		e you noticing any of the following that represent change from the individual's usual or past behavior?	Yes	No
	a.	Repeating motions or behaviors (eg, rocking, raising fist, pointing finger)		
	b.	Pacing or restlessness (cannot be still)		
	C.	Cursing/using profanity or lashing out verbally		
	d.	Raising voice or yelling or screaming		
	e.	Resisting assistance or care		
	f.	Throwing or hitting or breaking things		
	g.	Trying to hurt self or others (eg, grabbing, kicking, hitting, biting)		
2.		any of these behaviors make the individual's day-to-day tivities or interactions with others more challenging?	Yes	No

AASC® Multidisciplinary Team

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Clay Jackson, MD, DipTh			
	nt Professor of Family Medicine and Psychiatry, nnessee College of Medicine		
Jared Stroud,	MD, PharmD		
Geriatrician and Safety, OhioHea	d Assistant Medical Director, Quality and Patient alth		
Sue Peschin			
President and 0	CEO, Alliance for Aging Research		

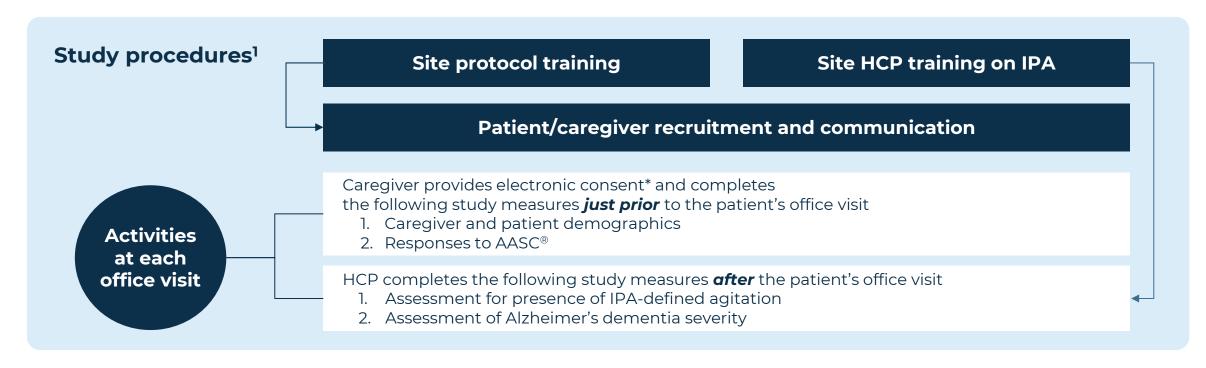
Disclaimer: This screener was developed by Otsuka Global Medical Affairs along with a panel of multidisciplinary experts and was funded by Otsuka Pharmaceutical Development & Commercialization, Inc. The AASC® is a screening tool and is not a diagnostic tool. **Acknowledgment: RTI Health Solutions provided developmental support.**AASC, Agitation in Alzheimer's Screener for Caregivers; DipTh, diploma of theology; DNP, doctor of nursing practice; MD, doctor of medicine; RD, registered dietitian; ScD, doctor of science.

- 1. Clevenger C, et al. One minute to recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC®). Presented at: Gerontological Society of America Annual Scientific Meeting; November 8-12, 2023; Tampa, FL.
- Grossberg G, et al. Validation of the Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel clinical tool to screen for agitation in Alzheimer's dementia. Presented at: The American Association of Geriatric Psychiatry
 Annual Meeting; March 14-17, 2025; Phoenix, AZ.



Quantitative Validation Of The AASC®: Study Method

- The AASC® was initially developed based on the IPA definition of agitation symptoms and underwent a rigorous, iterative qualitative and quantitative validation process involving clinical experts and a patient representative^{1,2}
- Quantitative validation involved a 2-phase observational study across 12 clinical sites in the US to assess predictive validity of the AASC®
 against the IPA criteria for agitation²



*Wet signature or electronic consent will be determined based on IRB review and approval. The need for additional consent and release of information from the patient will also be determined. AASC®, Agitation in Alzheimer's Screener for Caregivers; HCP, healthcare provider; IPA, International Psychogeriatric Association; IRB, institutional review board.

1. Clevenger C, et al. Study protocol: quantitative evaluation of The Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel tool for improving recognition of agitation in Alzheimer's dementia. Presented at: The Alzheimer's Association International Conference; July 28-August 1, 2024; Philadelphia, PA.

2. Grossberg G, et al. Validation of the Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel clinical tool to screen for agitation in Alzheimer's dementia. Presented at: The American Association of Geriatric Psychiatry Annual Meeting; March 14-17, 2025; Phoenix, AZ.



Quantitative Validation Of The AASC®: Study Inclusion Criteria¹

Patient Inclusion Criteria:



Community-dwelling (ie, does not live in a residential or long-term care setting)



Has a recorded, though not necessarily confirmed, diagnosis of Alzheimer's disease or Alzheimer's dementia*



Not currently in a state of delirium



Not diagnosed with schizophrenia, bipolar disorder, or any potentially confounding condition

Caregiver Inclusion Criteria:



Provides care and assistance to the patient with Alzheimer's disease for ≥10 hours in a typical week



Aged 18 to 85 years and able to speak, read, and comprehend English

HCP Inclusion Criteria:



Current caseload includes ≥10% of patients with any form of dementia



Willing to complete IPA criteria training

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Reference:

1. Grossberg G, et al. Validation of the Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel clinical tool to screen for agitation in Alzheimer's dementia. Presented at: The American Association of Geriatric Psychiatry Annual Meeting: March 14-17, 2025: Phoenix. AZ.



^{*}Precludes rule-out and differential diagnoses, including other forms of dementia (eg, vascular dementia, Lewy body dementia related to Huntington disease, Parkinson's disease dementia, or frontotemporal dementia). Imaging or biomarker confirmation of Alzheimer's disease not required.

Quantitative Validation Of The AASC®: Key Characteristics Of Caregivers, Patients, And Healthcare Providers¹

Caregiver/Patient Key Characteristics*	Total (N=226)		
Caregiver/Patient Rey Characteristics	Caregiver	Patient	
Age, y, mean (range)	60.7 (18-90)	75.5 (52–93)	
Sex, n (%)			
Female	140 (61.9)	133 (58.9)	
Male	86 (38.1)	92 (40.7)	
Relationship to patient with Alzheimer's, n (%)			
Family member	158 (69.9)		
Non-family member [†]	68 (30.1)		
Hours of care provided per week, mean (range)	59.9 (9-168)		
Race and ethnicity, n (%)			
White	136 (60.2)	145 (64.2)	
Hispanic, Latin American, or Latinx	38 (16.8)	36 (15.9)	
African American or Black	30 (13.3)	30 (13.3)	
Asian American	10 (4.4)	9 (4.0)	
Other	6 (2.7)	2 (0.9)	
Education level, n (%)			
High school or equivalent	71 (31.4)	83 (36.7)	
Some college/associate's degree	73 (32.3)	48 (21.2)	
Bachelor's degree	27 (11.9)	41 (18.1)	
Some graduate school	13 (5.8)		
Professional/advanced degree	35 (15.5)	27 (11.9)	

HCP Characteristics	Total (N=22)				
HCP medical specialty, n (%)					
Family	8 (36.4)				
Geriatrics	7 (31.8)				
Neurology	7 (31.8)				
Internal	5 (22.7)				
General	4 (18.2)				
Psychiatry	4 (18.2)				
HCP dementia practitioner category, n (%) ‡					
Generalist	15 (68.2)				
Specialist	7 (31.8)				

Reference:

^{1.} Grossberg G, et al. Validation of the Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel clinical tool to screen for agitation in Alzheimer's dementia. Presented at: The American Association of Geriatric Psychiatry Annual Meeting; March 14-17, 2025; Phoenix, AZ. 2. Data on file. Otsuka America Pharmaceutical, Inc; 2025.



^{*}Percentages may not sum to 100% due to missing data or unlisted responses. †Most non-family caregivers were paid caregivers and associated with a single clinical site. ‡For the purposes of this study, specialists are defined as health care providers (HCPs) who meet criteria for "dementia proficiency" aligned with Guiding an Improved Dementia Experience (GUIDE) (1) who hold a specialist degree (eg, neurologist, psychiatrist, gerontologist) and (2) whose patient caseload over the last 5 years includes ≥25% of patients with cognitive impairment or dementia (not including cognitive impairment).

AASC®. Agitation in Alzheimer's Screener for Caregivers: HCP, healthcare provider.

Quantitative Validation Of The AASC®: Study Analyses^{1,2}

Phase 1

(n=121 caregiver-HCP dyads)

Phase 2 (n=105 caregiver-HCP dyads)

Classification accuracy of the AASC® in recognizing agitation in patients with Alzheimer's dementia

Initial assessment of predictive validity metrics of the AASC® and further refinement of the tool as needed

Final analyses of predictive validity of the AASC® against the IPA criteria

AASC®, Agitation in Alzheimer's Screener for Caregivers; HCP, healthcare provider; IPA, International Psychogeriatric Association.

- 1. Clevenger C, et al. Study protocol: quantitative evaluation of The Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel tool for improving recognition of agitation in Alzheimer's dementia. Presented at: The Alzheimer's Association International Conference; July 28-August 1, 2024; Philadelphia, PA.
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Predictive Validity Of The Optimized AASC® Against IPA Criteria^{1,2}

Assessing the predictive metrics of the AASC® against the IPA criteria in recognizing agitation associated with dementia due to Alzheimer's disease found:

73.3% AGREEMENT

77%
SENSITIVITY

70%
SPECIFICITY

- Agreement=(true positives + true negatives)/total sum
- Measures how often the caregiver-HCP dyads agree on the same answer about presence/absence of agitation in Alzheimer's dementia out of the total number of caregiver-HCP dyads; ranges from 0 to 1
- Sensitivity=proportion of true positives
- Measures how well the AASC® correctly identifies individuals with agitation
- Specificity=proportion of true negatives
- Measures how well the AASC® correctly identifies individuals without agitation

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- 1. Grossberg G, et al. Validation of the Agitation in Alzheimer's Screener for Caregivers (AASC®), a novel clinical tool to screen for agitation in Alzheimer's dementia. Presented at: The American Association of Geriatric Psychiatry Annual Meeting; March 14-17, 2025; Phoenix, AZ;
- Data on file. Otsuka America Pharmaceutical, Inc; 2025.



Summary



Recognition of agitation remains a challenge, as caregivers may not recognize the full breadth of agitation symptoms, which delays diagnosis and treatment¹⁻⁴

- However, HCPs and caregivers often do not discuss agitation symptoms until they become untenable for the caregiver⁴
- The AASC® was designed in collaboration with multidisciplinary experts in Alzheimer's dementia and a patient advocate to support caregivers and HCPs with early detection of agitation in Alzheimer's dementia⁵
- The AASC® uses 2 caregiver-friendly questions to screen for agitation in Alzheimer's dementia at home, in waiting rooms, or in clinics⁶
- The AASC® has undergone a rigorous development and qualitative and quantitative validation process to optimize its accuracy and improve its utility for caregivers and HCPs, resulting in^{5,6}:
 - 73.3% agreement
 - 77% sensitivity
 - 70% specificity



The AASC® combines practicality and accuracy for use in busy clinical practices, helping HCPs diagnose and manage agitation in Alzheimer's dementia⁶

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- 1. Stella F, et al. Int J Geriatr Psychiatry. 2015;30(12):1230-1237.
- 2. Sano M, et al. Int Psychogeriatr. 2024;36(4):238-250.
- Gilmore-Bykovskyi A, et al. Gerontologist. 2020;60(5):896-904.
- 4. Richler LG, et al. Harv Rev Psychiatry. 2023;31(1):22-27.

- 5. Clevenger C, et al. One minute to recognition: The Agitation in Alzheimer's Screener for Caregivers (AASC®).

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