

คุณสมบัติเชิงวินิจฉัยของการตรวจโรคพาร์กินสันด้วยชุดตรวจ SASIT ในประเทศไทย

กชกร สิริวิทยาปกรณ์¹ ศิริลักษณ์ เลิศพงษ์พิรุฬห์² กนกรัตน์ สุวรรณละออง³ อัสวชัย ช่วยพรหม⁴

¹กลุ่มงานอายุรกรรม โรงพยาบาลปัตตานี

²กลุ่มงานโสต ศอ นาสิก โรงพยาบาลปัตตานี

³กลุ่มงานอายุรกรรม โรงพยาบาลสงขลา

⁴ศูนย์วิทยาศาสตร์การแพทย์ที่ 12 สงขลา กรมวิทยาศาสตร์การแพทย์ กระทรวงสาธารณสุข

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บทคัดย่อ

การรับกลิ่นบกพร่อง (olfactory dysfunction) พบได้ ร้อยละ 75-90 ในระยะแรกของโรคพาร์กินสัน (Parkinson's disease, PD) แม้ว่าพบได้บ่อยแต่ผู้ป่วยหลายรายไม่ตระหนักถึงความผิดปกติในการรับกลิ่นของตนเองจนกว่าจะได้รับการทดสอบการรับกลิ่นด้วยวิธีมาตรฐาน ชุดทดสอบระบุชนิดของกลิ่นด้วยตนเอง (self-administered smell identification test kit; SASIT kit) ได้พัฒนาขึ้นเพื่อนำไปใช้สำหรับการวินิจฉัยความผิดปกติในการรับกลิ่นในคนไทย การศึกษานี้จึงมีวัตถุประสงค์เพื่อศึกษาคุณสมบัติเชิงวินิจฉัย (diagnostic performances) ของชุดทดสอบ SASIT kit ในการแยกผู้ป่วยพาร์กินสันออกจากคนปกติ โดยเป็นการศึกษาความแม่นยำของการวินิจฉัยเชิงสังเกตแบบตัดขวาง (observational cross-sectional diagnostic accuracy study) ที่แผนกผู้ป่วยนอก โรงพยาบาลปัตตานี และโรงพยาบาลสงขลา ในกลุ่มอาสาสมัครคนไทยปกติที่ผ่านการทดสอบการแยกกลิ่นด้วย n-butanol และกลุ่มผู้ป่วยพาร์กินสัน Hoehn&Yahr Stage (H&Y stage) 1-3 อายุมากกว่า 50 ปี ในเดือนมกราคม ถึง ตุลาคม 2567 กลุ่มผู้ป่วยพาร์กินสัน และกลุ่มอาสาสมัครคนปกติผ่านการคัดกรองด้วย PHQ-2/PHQ-9, MMSE-Thai 2002 และการส่องตรวจโพรงจมูกส่วนหน้า (anterior rhinoscopy) หลังจากนั้นทำการทดสอบการระบุชนิดของสารให้กลิ่นด้วยตนเอง (SASIT) และบันทึกผลคะแนน (SASIT score) วัดผลเปรียบเทียบข้อมูลทั่วไป SASIT score (n, %, mean±SD หรือ median [IQR]) ด้วย t-test ประเมินความแม่นยำของการจำแนกด้วยพื้นที่ใต้ receiver operating characteristic (ROC) หาค่าคะแนน SASIT score ที่เหมาะสมในการวินิจฉัยแยกผู้ป่วยโรค PD จากอาสาสมัครคนปกติ นำเสนอด้วยความไว (sensitivity) ความจำเพาะ (specificity) ค่าพยากรณ์บวก (PPV) ค่าพยากรณ์ลบ (NPV) และค่าความแม่นยำ (accuracy) ผลการศึกษาพบว่ากลุ่มผู้ป่วยพาร์กินสัน 60 ราย อายุเฉลี่ย 67.6±7.9 ปี และอาสาสมัครคนปกติ 60 ราย อายุเฉลี่ย 69.5±10.9 ปี มีคะแนน SASIT score เฉลี่ย 9.2±3.6 คะแนน และ 13.7±1.9 คะแนน ตามลำดับ ($p<0.001$) SASIT kit มีอำนาจจำแนก (AuROC) 0.88 (ความเชื่อมั่นร้อยละ 95: 0.82, 0.94) จุดตัดค่าคะแนนที่ ≤ 13 ช่วยในการวินิจฉัยแยกผู้ป่วยโรคพาร์กินสันจากคนปกติได้ โดยมีค่าความแม่นยำ ร้อยละ 79.2 มีความไว ร้อยละ 90 และความจำเพาะ ร้อยละ 68.3 ดังนั้น ชุดทดสอบ SASIT kit จึงสามารถใช้เป็นส่วนหนึ่งในการวินิจฉัยและคัดกรองผู้ป่วยโรคพาร์กินสันร่วมกับการประเมินทางคลินิกได้ การศึกษาเพิ่มเติมในกลุ่มประชากรที่หลากหลายและมีขนาดใหญ่ขึ้นจะช่วยยืนยันและขยายผลลัพธ์จากการศึกษาครั้งนี้

คำสำคัญ: การวินิจฉัย; ความผิดปกติในการรับกลิ่น; โรคพาร์กินสัน; ชุดทดสอบระบุชนิดของกลิ่นด้วยตนเอง

ผู้สนับสนุนผลงาน:

กชกร สิริวิทยาปกรณ์

กลุ่มงานอายุรกรรม โรงพยาบาลปัตตานี

2 ถนนหนองจิก ตำบลสะบารัง อำเภอเมืองปัตตานี จังหวัดปัตตานี 94000

อีเมล: patkotchakorn@gmail.com

Diagnostic performance of the SASIT kit for Parkinson's disease patients in Thailand

Kotchakorn Sirivitayaphakorn¹, Sirilak Lertpongpiroon², Kanokrat Suwanlaong³, Aussavashai Shuayprom⁴

¹Department of Medicine, Pattani Hospital

²Department of Otolaryngology, Pattani Hospital

³Department of Medicine, Songkhla Hospital

⁴Regional Medical Sciences Center 12 Songkhla, Department of Medical Sciences, Ministry of Public Health

Abstract

Olfactory dysfunction is found in 75-90% of patients in the early stages of Parkinson's disease (PD). Despite its widespread occurrence in PD, many patients remain unaware of their olfactory dysfunction until they undergo standardized smell testing. The self-administered smell identification test kit (SASIT kit) was developed for use in diagnosing olfactory dysfunction in Thai individuals. This study aims to evaluate the diagnostic performance of the SASIT kit in differentiating PD patients from healthy individuals. This observational, cross-sectional diagnostic accuracy study was conducted at the outpatient departments of Pattani Hospital and Songkhla Hospital. Age-matched healthy volunteers who could perceive the normal n-butanol threshold, and Parkinson's disease patients with Hoehn & Yahr Stage (H&Y stage) 1-3, aged 50 years and older, were included. The study was conducted between January and October 2024. Participants were screened using PHQ-2/PHQ-9, MMSE-Thai 2002, and anterior rhinoscopy. Subsequently, they performed the self-administered smell identification test (SASIT), and the SASIT scores were recorded. Baseline clinical characteristics and SASIT scores (n, %, mean $\pm$ SD, or median [IQR]) were compared using a t-test. Diagnostic accuracy was assessed using the area under the receiver operating characteristic (ROC) curve. The optimal SASIT score cutoff for distinguishing PD patients from healthy volunteers was determined and presented with sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. The study included 60 PD patients (mean age 67.6 ± 7.9 years) and 60 healthy volunteers (mean age 69.5 ± 10.9 years) with mean SASIT scores of 9.2 ± 3.6 and 13.7 ± 1.9 , respectively ($p < 0.001$). The SASIT kit showed an AuROC of 0.88 (95% CI: 0.82, 0.94). A cut-off score of ≤ 13 yielded 79.2% accuracy in differentiating PD patients from healthy individuals, with 90.0% sensitivity and 68.3% specificity. Therefore, the SASIT kit can be used as part of a multimodal diagnostic approach alongside clinical evaluation for diagnosing PD. Further studies with broader population samples are recommended to validate and expand upon the results gained by this study.

Keywords: diagnosis test kit; olfaction disorders; Parkinson's disease; self administration; SASIT

Corresponding Author:

Kotchakorn Sirivitayaphakorn

Department of Medicine, Pattani Hospital

2 Nongjik Road, Sabarang Sub-district, Mueang District, Pattani 94000, Thailand

E-mail: patkotchakorn@gmail.com

Introduction

Parkinson's disease (PD) is a neurodegenerative disorder characterized by the loss of dopaminergic neurons in the substantia nigra and the intracellular protein accumulation of α -synuclein. These changes affect basal ganglia circuits, resulting in both motor symptoms—including bradykinesia, rigidity, tremor, and postural instability—and non-motor symptoms such as constipation, cognitive impairment, sleep disturbances, and olfactory dysfunction, which significantly affect the quality of life for those impacted¹⁻³.

Olfactory dysfunction is one of the most common non-motor symptoms associated with PD, often appearing months or even years before the emergence of motor symptoms. This condition affects approximately 75-90% of patients during the early stages of the disease, making it a potential biomarker for early detection⁴⁻⁶. Olfactory dysfunction significantly impacts patients' quality of life by impairing hazard awareness, reducing the enjoyment of food, and decreasing overall food intake^{7,8}. Despite its widespread occurrence in PD, many patients remain unaware of their olfactory dysfunction until they undergo standardized smell testing^{9,10}.

Smell identification tests are widely used and more practical for evaluating olfactory dysfunction. However, a limitation of these tests is their dependence on participants' prior familiarity with the odors. Cultural differences may explain variations in olfactory identification test results across countries, potentially due to differences in

odorant exposure or dietary habits¹¹⁻¹³. Commercially available smell identification tests, such as the University of Pennsylvania Smell Identification Test (UPSIT)¹⁴, often include odors that are unfamiliar to Asian populations, potentially compromising their diagnostic reliability in diverse contexts.

In Thailand, no standardized tool exists to assess olfactory dysfunction in PD patients¹⁵. The self-administered smell identification test (SASIT) kit was prepared by medical scientists at the laboratory of the Department of Medical Sciences, Ministry of Public Health, from September to November 2022. Each kit consists of 16 sealed opaque black aluminum foil pouches, each containing a piece of paper infused with essential oil at a suprathreshold concentration level—sufficient to elicit a detectable olfactory response. The pouches are sealed using a vacuum sealer. The scent items included orange, traditional Thai scented water, chocolate, garlic, pineapple, lemongrass, fish sauce, rose, corn, tamarind, camphor, baby powder, durian, mint, eucalyptus, and coconut. The kits are inexpensive and designed for ease of self-administration. The SASIT kit has been continuously produced for research purposes. Currently, the Department of Medical Sciences has not yet conducted shelf-life testing; therefore, the exact duration of stability cannot be confirmed. However, it is estimated that the product can be stored for up to three years. The test kits used in this study were manufactured within one year before testing¹⁶⁻¹⁸.

The SASIT kit was evaluated among healthy Thai volunteers aged over 50 to determine its applicability for the diagnosis and monitoring of olfactory dysfunction. It represents a promising tool to assess olfactory dysfunction in PD patients, offering advantages such as being disposable, user-friendly, cost-effective, and culturally relevant for the Thai population. This study aims to evaluate the diagnostic performance of the SASIT kit in differentiating PD patients from healthy individuals in Thailand.

Materials and Methods

Study Design

A cross-sectional diagnostic accuracy study with an observational design was conducted at the outpatient neurology departments of Pattani Hospital and Songkhla Hospital.

Participants and recruitment

Participants included age-matched healthy Thai volunteers and PD patients who were examined between January and October 2024. Sixty-eight PD patients and seventy-four healthy volunteers aged over 50 years were recruited for the study. Healthy volunteers were recruited from a population without PD. Fourteen healthy volunteers were excluded due to pre-existing conditions (hypothyroidism, neurological disease, history of radiation at the head and neck, inability to perceive normal n-butanol threshold) or an inability to complete the tests. Sixty-eight PD patients were diagnosed by a neurologist according to

the clinical criteria of the United Kingdom Parkinson's Disease Society Brain Bank (UKPDSBB).¹⁹ Eight PD patients were excluded due to Hoehn and Yahr (H&Y) stage 4-5 or an inability to complete the tests (Figure 1).

Methods

Both PD patients and healthy volunteers were screened using PHQ-2/PHQ-9, MMSE-Thai 2002, and anterior rhinoscopy. Participants were required to abstain from eating or drinking, except for plain water, 30 minutes before starting the test. Participants received an explanation of how to use the SASIT kit for testing and were prepared to take the test themselves in the examination room (Temperature 28-35°C). All participants were asked to start by opening the packet containing the odors, beginning with odor number 1, and holding each approximately 2 cm away from their noses. No more than 20 seconds were allowed for each odor to be sniffed before proceeding to answer. The second scent was initiated 20-30 seconds after the first scent, and the process continued in the same manner until all 16 scents had been sniffed. SASIT scores were recorded.

Statistical analysis

Baseline clinical characteristics and SASIT scores (n, %, mean $\pm$ SD, or median (IQR)) were compared using a t-test. Diagnostic accuracy was assessed using the area under the receiver operating characteristic (ROC) curve. The optimal SASIT score cutoff for distinguishing PD patients from healthy

volunteers was determined, exhibiting sensitivity, specificity, PPV, NPV, and accuracy. All

statistical analyses were performed using Stata statistical software version 16.1 (StataCorp).

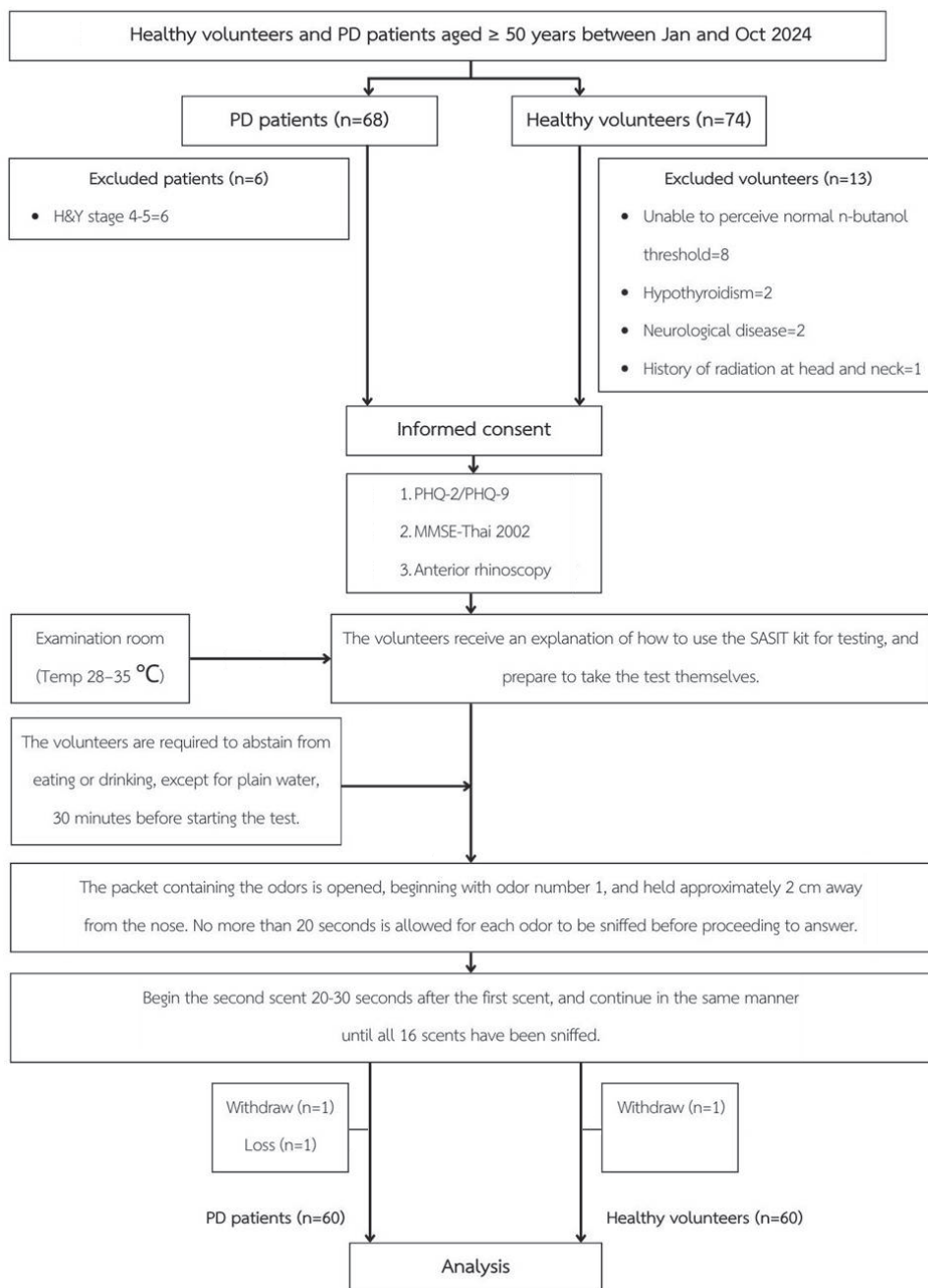


Figure 1 Study flowchart

PD=Parkinson disease, H&Y=Hoehn and Yahr, PHQ=Patient Health Questionnaire, MMSE=Mini-Mental State Examination

Results

The study included 60 PD patients (mean age 67.6 ± 7.9 years) and 60 healthy volunteers (mean age 69.5 ± 10.9 years). Neither group showed any significant differences in gender, age, education, underlying disease,

smoking history, MMSE-Thai 2002 scores, or PHQ-2 & PHQ-9 scores. PD patients had a mean H&Y stage of 1.8 ± 0.7 , with a median disease duration of 18 months. Median UPDRS-I and UPDRS-II scores were 2 and 7.5, respectively, indicating mild disease severity (Table 1).

Table 1 Baseline characteristics

	PD n=60		Healthy volunteers n=60		p-value
	n	%	n	%	
Gender					
Male	23	38.3	15	25	0.169
Female	37	61.7	45	75	
Age (years), mean ($\pm$ SD)	67.6 $\pm$ 7.9		69.5 $\pm$ 10.9		0.276
Education					
Uneducated	6	10	3	5	0.056
Elementary school	26	43.3	16	26.7	
High school	14	23.3	14	23.3	
Bachelor's degree or higher	14	23.3	27	45	
Underlying disease					
No underlying disease	18	30	13	21.6	0.404
With an underlying disease					
Diabetes mellitus	11	18.3	6	10	0.295
Hypertension	21	35	21	35	1.000
Dyslipidemia	18	30	15	25	0.683
Ischemic heart disease	2	3.3	2	3.3	1.000
Prior ischemic stroke	4	6.7	0	0	0.119
Smoking history					
Yes	12	20	9	15	0.632
No	48	80	51	85	
MMSE-Thai 2002, median [IQR]	28 [27,29]		28 [26,30]		0.715
PHQ-2&PHQ-9					
No depression	55	91.7	56	93.3	0.757
Minimal depression	3	5	1	1.7	
Mild depression	2	3.3	3	5.0	

Table 1 Continued

	PD n=60		Healthy volunteers n=60		p-value
	n	%	n	%	
Disease duration (months), median [IQR]	18 [6-48]				
Hoehn & Yahr Stage, mean (±SD)	1.8 (0.7)				
Stage 1	12	20			
Stage 1.5	21	35			
Stage 2	12	20			
Stage 2.5	7	11.7			
Stage 3	8	13.3			
UPDRS-I, median [IQR]	2 [1,3]				
UPDRS-II, median [IQR]	7.5 [5,10]				

Abbreviations: PD=Parkinson disease, H&Y=Hoehn and Yahr, PHQ=Patient Health Questionnaire, MMSE=Mini-Mental State Examination, UPDRS=Unified Parkinson's Disease Rating Scale

Chocolate, Fish sauce, and Durian odors showed the highest identifiability among both groups (76.7%, 71.7%, and 73.3% in PD patients; 96.7%, 91.7%, and 96.7% in healthy volunteers). Mean SASIT scores were 9.2±3.6 for PD patients and 13.7±1.9 for healthy volunteers ($p<0.001$) (Table 2). The ROC curve

had an area under the curve of 0.88 (95% CI: 0.82-0.94, $p<0.001$) (Figure 2). At a cut-off score of ≤13, SASIT demonstrated 79.2% accuracy in differentiating PD patients from healthy individuals, with 90.0% sensitivity and 68.3% specificity (Table 3).

Table 2 Percentage of correct odor identification

Item	Odorant	PD (n=60)		Control (n=60)		p-value
		n	%	n	%	
1	Orange	32	53.3	52	86.7	<0.001
2	Thai traditional scented water	25	41.7	48	80	<0.001
3	Chocolate	46	76.7	58	96.7	0.002
4	Garlic	41	68.3	57	95	<0.001
5	Pineapple	19	31.7	39	65	<0.001
6	Lemongrass	38	63.3	57	95	<0.001
7	Fish sauce	43	71.7	55	91.7	0.008
8	Rose	30	50	51	85	<0.001

Table 2 Continued

Item	Odorant	PD (n=60)		Control (n=60)		p-value
		n	%	n	%	
9	Corn	42	70	56	93.3	0.002
10	Tamarind	37	61.7	57	95	<0.001
11	Camphor	35	58.3	57	95	0.000
12	Baby powder	36	60	45	75	0.118
13	Durian	44	73.3	58	96.7	0.001
14	Mint	30	50	46	76.7	0.004
15	Eucalyptus	36	60	50	83.3	0.008
16	Coconut	16	26.7	37	61.7	<0.001
SASIT score						
	Mean ($\pm$ SD)	9.2 ($\pm$ 3.6)		13.7 ($\pm$ 1.9)		<0.001
	Median [IQR]	10 [6.5-12]		14 [12.5-15]		
	Min - Max	1-15		7-16		

Abbreviations: PD=Parkinson disease, SASIT score=Self-administered smell identification test score

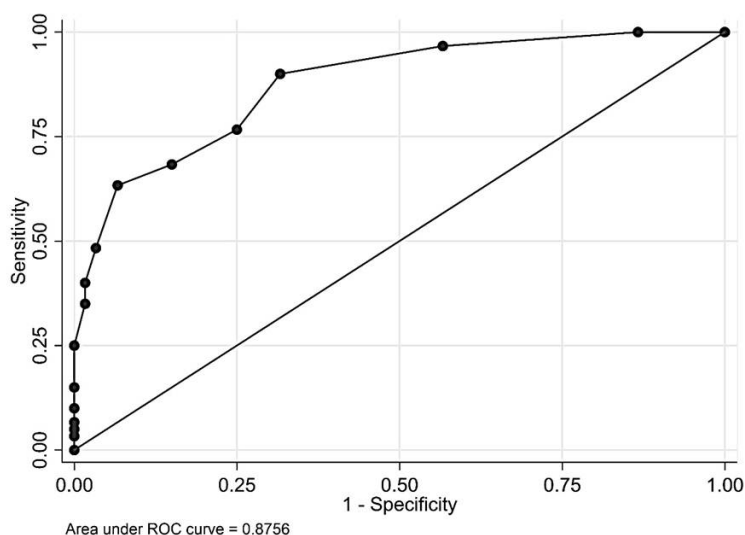


Figure 2 The ROC curve of the SASIT kit for diagnosing PD. Area under the curve 0.88 (95% CI: 0.82-0.94), $p<0.001$

Table 3 Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of the SASIT kit

SASIT score	Cut point	PD (n=60)		Normal (n=60)	
		n	%	n	%
	≤13	54	90.0	19	31.7
	>13	6	10.0	41	68.3
Diagnostic performances	Statistic	Estimate (%)		95%CI (%)	
	Sensitivity	90.0		79.5-96.2	
	Specificity	68.3		55.0-79.7	
	PPV	74.0		62.4-83.5	
	NPV	87.2		74.3-95.2	
	Accuracy	79.2		71.9-86.4	

PD=Parkinson disease, SASIT score=Self-administered smell identification test score, PPV=Positive predictive value, NPV=Negative predictive value

Discussion

Olfactory dysfunction in PD arises from pathological changes caused by early accumulation of α -synuclein in the olfactory bulb, olfactory tract, and anterior olfactory nucleus. These regions are affected during the prodromal stages of the disease, preceding dopaminergic neuronal loss in the substantia nigra^{20,21}. As a result, olfactory impairment is one of the earliest manifestations of PD. The smell identification tests can detect this early pathological process by assessing odor identification, which depends on the integrity of both peripheral olfactory neurons and higher-order cortical networks. α Synuclein-mediated synaptic dysfunction and neuronal loss disrupt olfactory signal transmission and cortical integration in regions such as the piriform and orbitofrontal cortices, leading to selective deficits in identifying specific odors²²⁻²⁴.

In this study, the SASIT kit showed that the percentage of correct odor identification using the kit was significantly lower in PD patients compared to healthy volunteers, aligning with previous evidence that olfactory dysfunction is an early and prevalent symptom of PD⁴⁻⁶. This finding reinforces the clinical relevance of using olfactory tests to support early screening.

Among the 16 scented items in the SASIT kit, chocolate, fish sauce, and durian were the most easily identified among both groups, highlighting the importance of cultural familiarity in odor recognition. These three scents, distinctly rooted in Thai culture, are not found in standardized commercially available tests such as the UPSIT^{14,25}. The comparable pattern of odor identification between PD patients and healthy individuals supports the strong influence of cultural exposure and sensory experiences in olfactory

recognition, an important consideration when developing region-specific diagnostic tools^{12,13}.

At a cut-off score of ≤ 13 , the SASIT kit demonstrated high sensitivity (90%) and moderate specificity (68.3%). The high sensitivity indicates its potential utility as a screening tool in clinical practice. SASIT scores ≤ 13 may warrant additional neurological evaluation to explore early-stage PD. False-positive results may arise from age-related olfactory decline, sinonasal disease, environmental exposures such as smoking or pollution, or other neurological disorders, including Alzheimer's disease, that also impair olfactory function. Conversely, false negatives may occur in early-stage PD patients who retain near-normal olfactory function, or in individuals familiar with the test odors, leading to artificially elevated scores²⁶⁻²⁸. Additional sources of error include self-administration issues, such as misreading instructions or cognitive impairment, both of which may mask the true test results¹⁶. Therefore, while the SASIT kit has potential utility as a screening tool for detecting olfactory impairment in PD, it should not be used in isolation. Instead, it might be used as part of a multimodal diagnostic approach, alongside clinical evaluation to improve diagnosis accuracy.

Despite the aforementioned, this study has certain limitations. The diagnosis of PD was established through clinical evaluation, without confirmation via functional imaging or histopathological analysis. While this approach reflects real-world diagnostic conditions in many clinical settings, it may limit the precision

of disease classification and the generalizability of the results. Furthermore, the PD patient group had a mean H&Y stage of 1.8, indicating early-stage disease. While the SASIT kit is appropriate for assessing early-stage olfactory dysfunction, the results may not reflect the entire spectrum of PD, including advanced stages. Future studies could aim to include a broader range of disease severities to validate the test's effectiveness. Additionally, validation studies in diverse populations within Thailand (e.g., Northern, Northeastern, and Central regions) are needed to assess the applicability of the SASIT kit for all Thai patients.

Conclusions

The SASIT kit demonstrated promising diagnostic performance in distinguishing PD from healthy individuals within the Thai population. With its high sensitivity, cultural relevance, ease of use, and cost-effectiveness, the SASIT kit has the potential to be part of a multimodal diagnostic approach alongside clinical evaluation for diagnosing PD. The findings also highlight the importance of incorporating culturally adapted olfactory assessments in diverse settings to enhance diagnostic accuracy. Further studies with broader population samples are recommended to validate and expand upon the results gained by this study.

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