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### ► To cite this version:

Bernardo Sousa-Pinto, Ana Sá-Sousa, Rita Amaral, Wienczysława Czarlewski, Anna Bedbrook, et al.. Assessment of the Control of Allergic Rhinitis and Asthma Test (CARAT) using MASK-air. *Journal of Allergy and Clinical Immunology: In Practice*, 2022, 10 (1), pp.343-345.e2. 10.1016/j.jaip.2021.09.012 . hal-04260617

**HAL Id: hal-04260617**

**<https://hal.science/hal-04260617v1>**

Submitted on 22 Jul 2024

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## Assessment of the Control of Allergic Rhinitis and Asthma Test (CARAT) using MASK-air

**Short title:** CARAT and MASK-air

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**Conflict of interest:** JB reports personal fees from Chiesi, Cipla, Hikma, Menarini, Mundipharma, Mylan, Novartis, Sanofi-Aventis, Takeda, Teva, Uriach, other from KYomed-Innov, personal fees from Purina. JAF reports personal fees from AstraZeneca, Viatrix, grants and personal fees from Mundipharma, BSP, ASS, RA, WC, AB, JMA have no COI to declare.

**Key words:** rhinitis, asthma, EQ-5D, ARIA, MASK, WPAI-AS

### **Clinical implications**

CARAT displays moderate correlation with other scores assessing allergic rhinitis symptoms and their impact on work and activities. This reinforces its role as a tool for assessing patients with respiratory allergic disease.

Several tools can assess the control of allergic rhinitis (AR), including symptom scores, control scores (e.g., Control of Allergic Rhinitis and Asthma Test – CARAT(1); Allergic Rhinitis Control Test - ARCT(2)), patients' self-administered visual analogue scales (VASs), and patients' reported outcomes for quality-of-life and work.

Mobile apps can incorporate these tools, allowing a multidimensional assessment of AR patients. As an example, MASK-air<sup>®</sup> (Mobile Airways Sentinel Network) is a validated app for rhinitis and asthma, certified as a Good Practice of DG Santé(3). MASK-air<sup>®</sup> VASs were shown to be reliable and valid instruments(4), and to be associated with air pollutant levels and pollen exposure(5). MASK-air<sup>®</sup> uses VASs to daily register users' AR symptoms and their impact on work. In addition, users can answer optional questionnaires, such as CARAT, EQ-5D-5L and the Work Productivity and Activity Impairment: Allergic Specific (WPAI:AS)(6).

CARAT is a Patient-Reported Outcome assessing the level of control of asthma and AR in the past four weeks(1). It encompasses ten questions, with the first four (CARAT Q1-4) concerning the upper airways, and the last six (CARAT Q5-10) the lower airways. Results are presented on a scale of 0 to 30, with higher values indicating better control. A quasi-experimental study suggested that CARAT and MASK-air<sup>®</sup> provide complementary information on AR symptom control(7), although no formal comparisons were performed. Therefore, in this study, we aimed to compare the results from the CARAT questionnaire with those obtained from the MASK-air<sup>®</sup> VASs, EQ-5D-5L VAS and WPAI:AS.

We conducted a cross-sectional study using MASK-air<sup>®</sup> data (from 25 countries) from June 15, 2018 to December 6, 2020. We retrieved data from all days for which the CARAT questionnaire had been filled in by adult (16-80 years old) users. CARAT responses were then correlated with those of the other MASK-air<sup>®</sup> scores/questionnaires.

MASK-air<sup>®</sup> is freely available on Apple App and Google Play stores. The terms of reference were translated into all languages and customized according to the General Data Protection Regulation, allowing the use of the results for research purposes. An Independent Review Board approval was not needed as this was an observational study and all data were gathered in an anonymized way.

MASK-air<sup>®</sup> comprises six mandatory symptom daily monitoring questions whose responses are provided by means of VASs (4). In addition, if users report to be working, they are asked “how much allergic symptoms affected work activities on that day” (VAS Work). Users are then asked to provide their daily medication using a regularly updated scroll list customised for each country and including all over-the-counter and prescribed AR (and asthma) medications. MASK-air<sup>®</sup> users can also answer non-mandatory questionnaires, including (i) CARAT, (ii) EQ-5D-5L, whose VAS assesses the general health status on that day(8), and (iii) WPAI:AS, a 9-item questionnaire assessing the impact of

allergies on work and academic productivity over the last week. Regarding the latter, we assessed the “degree allergy affected regular activities” (“WPAI:AS activities”) and the “percent overall work impairment due to allergy” (“WPAI:AS work”). All questions in MASK-air® are available in the main official languages of the countries where MASK-air® is implemented.

Crude and adjusted (for age and sex) Spearman correlation coefficients were computed to measure the correlation between CARAT and daily monitoring VASs, EQ-5D-VAS, “WPAI:AS Work”, and “WPAI:AS activities”. Separate analyses were performed using CARAT Q1-4 (“nasal”) and CARAT Q5-10 (“asthma”).

Of the 17,780 MASK-air® eligible users, 1,086 filled the CARAT questionnaire at least once, providing a total of 2,042 responses (Table 1; Table E1 in the online repository). There were 1,507 (73.8%) responses by women, and participants displayed a mean±SD age of 39.0±12.4 years. An average CARAT score of 16.4±6.9 was observed, with 1,698 (83.2%) responses indicating suboptimal disease control (i.e., CARAT score<24).

Correlations between CARAT and the remaining scores were mostly moderate, ranging from -0.36 (correlation with VAS Work) to -0.60 (correlation with “WPAI:AS activities”) (Table 2). CARAT Q1-4 and Q5-10 had lower correlations than CARAT as a whole. Of note, CARAT Q1-4 (“nasal”) had its strongest correlation with VAS Nose (-0.53), while CARAT Q5-10 (“asthma”) had its strongest correlation with VAS Asthma (-0.60). Similar results were observed when adjusting Spearman correlation coefficients for age and sex (Table E2).

In this study, we observed that CARAT was moderately correlated with other measures of AR control, suggesting its complementarity and non-redundancy with other tools. This may stem from the differences in time periods covered by each assessed tool. In particular, CARAT assesses asthma and AR control in the previous four weeks (although the most recent weeks appear to play a more prominent role(9)), while daily monitoring VASs assess a single day. Therefore, while CARAT can provide an overview of AR control over the last month, MASK-air® VASs can capture short-term fluctuations on AR symptoms and their impact.

Overall, “complete CARAT” (Q1-10) displayed a better performance than its subscores, pointing to the importance of evaluating upper and lower airway symptoms when assessing AR control.

Of note, CARAT specifically measures disease control, while the assessed comparators concern the severity of symptoms or the impact of allergic diseases on work and activities. While this is not a limitation *per se* of this study, it should be considered when interpreting its results.

This study has some limitations, including the possibility that MASK-air® users – particularly those providing CARAT data – are not representative of AR patients (as suggested by the low percentage of

males and smokers), resulting in selection bias. Nevertheless, we performed adjusted analyses for age and sex. Strengths of this study include the assessment of a large volume of real-world multinational data, the absence of missing data within each daily questionnaire response, and the fact that most assessed tools (including CARAT and MASK-air<sup>®</sup> VASs(1,4)) have been validated.

In conclusion, real-world mHealth data showed that CARAT is moderately correlated with scores assessing AR symptoms and impact, reinforcing its role as a complementary tool for assessing patients with respiratory allergic disease. In particular, CARAT gives a 4-week overview whereas MASK-air<sup>®</sup> assesses a single day, respectively analogous to HbA1c and blood glucose in diabetes patients monitoring.

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## Tables

**Table 1: Characteristics of the observations of assessed participants**

	All observations (N=2042)
<b>Different users – n</b>	1086 <sup>a</sup>
<b>Age [years old] – mean (SD)</b>	39.0 (12.4)
<b>Females – n (%)</b>	1507 (73.8)
<b>Asthma – n (%)</b>	1173 (61.2) <sup>b</sup>
<b>Smokers – n (%)</b>	
<b>Current smokers</b>	122 (6.0)
<b>Former smokers</b>	96 (4.7)
<b>Days under medication – n (%)</b>	1252 (61.3)
<b>CARAT – mean (SD)</b>	16.4 (6.9)
<b>N controlled – n (%)</b>	344 (16.8)
<b>CARAT Q1-4 – mean (SD)</b>	5.0 (3.6)
<b>N controlled – n (%)</b>	374 (18.3)
<b>CARAT Q5-10 – mean (SD)</b>	11.5 (4.5)
<b>N controlled – n (%)</b>	469 (23.0)
<b>VAS Global allergy symptoms – median (P25-P75)</b>	28 (8-54)
<b>VAS Nose – median (P25-P75)</b>	27 (9-54)
<b>VAS Eyes – median (P25-P75)</b>	10 (2-35)
<b>VAS Asthma – median (P25-P75)</b>	7 (0-34)
<b>VAS Work – median (P25-P75)</b>	12 (3-35)
<b>VAS Sleep – median (P25-P75)</b>	31 (8-58)
<b>EQ-5D VAS – median (P25-P75)</b>	79 (64-90)
<b>WPAI:AS activities – median (P25-P75)</b>	17 (5-46)
<b>WPAI:AS work – median (P25-P75)</b>	18 (3-49)

CARAT=Control of Allergic Rhinitis and Asthma Test; CARAT Q1-4=Questions 1-4 of CARAT (“CARAT upper airways”); CARAT Q5-10=Questions 5-10 of CARAT (“CARAT lower airways”); P25-P75=Percentile 25 – Percentile 75; SD=standard-deviation; VAS=Visual analogue scale; WPAI:AS activities=Degree allergy affected regular activities in Work Productivity and Activity Impairment: Allergic Specific; WPAI:AS work= Percent overall work impairment due to allergy in Work Productivity and Activity Impairment: Allergic Specific; <sup>a</sup> Of those 1086 users, 157 (14.5%) had provided data on MASK-air<sup>®</sup> for a single day, 449 (41.3%) for 2-14 days, 132 (12.2%) for 15-30 days, and 324 (29.8%) for >30 days (irrespective of whether CARAT information had been provided or not). The average difference between the last and the first observations were of 169 days. <sup>b</sup> No information/unknown status on 124 observations.

**Table 2: Spearman correlation coefficients between the Control of Allergic Rhinitis and Asthma Test - CARAT [95% confidence interval] (N observations) and other comparators**

	CARAT	CARAT Q1-4	CARAT Q5-10
<b>All participants</b>			
VAS Global	-0.54 [-0.57;-0.51] (2042)	-0.50 [-0.53;-0.47] (2042)	-0.44 [-0.47;-0.40] (2042)
VAS Nose	-0.52 [-0.55;-0.49] (2042)	-0.53 [-0.56;-0.50] (2042)	-0.39 [-0.43;-0.35] (2042)
VAS Eyes	-0.40 [-0.43;-0.37] (2042)	-0.32 [-0.36;-0.29] (2042)	-0.35 [-0.38;-0.31] (2042)
VAS Asthma	-0.45 [-0.49;-0.42] (2042)	-0.12 [-0.15;-0.07] (2042)	-0.60 [-0.63;-0.57] (2042)
VAS Work	-0.36 [-0.41;-0.30] (965)	-0.25 [-0.30;-0.20] (965)	-0.36 [-0.41;-0.30] (965)
VAS Sleep	-0.47 [-0.50;-0.44] (1808)	-0.42 [-0.46;-0.38] (1808)	-0.37 [-0.41;-0.33] (1808)
EQ-5D VAS	0.56 [0.51;0.60] (1299)	0.37 [0.33;0.42] (1299)	0.56 [0.53;0.60] (1299)
WPAI:AS activities	-0.60 [-0.64;-0.55] (1038)	-0.44 [-0.49;-0.40] (1038)	-0.53 [-0.57;-0.48] (1038)
WPAI:AS work	-0.56 [-0.61;-0.50] (641)	-0.35 [-0.42;-0.28] (641)	-0.56 [-0.62;-0.48] (641)
<b>Participants with asthma</b>			
VAS Global	-0.60 [-0.64;-0.56] (1173)	-0.54 [-0.58;-0.49] (1173)	-0.50 [-0.54;-0.45] (1173)
VAS Nose	-0.58 [-0.62;-0.54] (1173)	-0.58 [-0.61;-0.54] (1173)	-0.45 [-0.49;-0.40] (1173)
VAS Eyes	-0.37 [-0.42;-0.31] (1173)	-0.27 [-0.32;-0.21] (1173)	-0.36 [-0.42;-0.31] (1173)
VAS Asthma	-0.43 [-0.47;-0.38] (1173)	-0.16 [-0.21;-0.11] (1173)	-0.57 [-0.62;-0.53] (1173)
VAS Work	-0.30 [-0.39;-0.21] (548)	-0.17 [-0.25;-0.08] (548)	-0.34 [-0.41;-0.26] (548)
VAS Sleep	-0.53 [-0.57;-0.49] (1079)	-0.52 [-0.57;-0.47] (1079)	-0.39 [-0.43;-0.34] (1079)
EQ-5D VAS	0.60 [0.54;0.65] (744)	0.40 [0.34;0.44] (744)	0.62 [0.57;0.67] (744)
WPAI:AS activities	-0.65 [-0.71;-0.59] (503)	-0.53 [-0.59;-0.46] (503)	-0.56 [-0.62;-0.50] (503)
WPAI:AS work	-0.60 [-0.68;-0.52] (255)	-0.38 [-0.49;-0.26] (255)	-0.63 [-0.70;-0.55] (255)
<b>Participants with no asthma</b>			
VAS Global	-0.54 [-0.59;-0.47] (745)	-0.43 [-0.49;-0.37] (745)	-0.44 [-0.50;-0.38] (745)
VAS Nose	-0.52 [-0.58;-0.47] (745)	-0.47 [-0.52;-0.42] (745)	-0.39 [-0.45;-0.32] (745)
VAS Eyes	-0.47 [-0.52;-0.41] (745)	-0.36 [-0.43;-0.30] (745)	-0.39 [-0.45;-0.33] (745)
VAS Asthma	-0.26 [-0.34;-0.18] (745)	-0.04 [-0.11;0.03] (745)	-0.37 [-0.43;-0.30] (745)
VAS Work	-0.48 [-0.57;-0.39] (357)	-0.32 [-0.42;-0.23] (357)	-0.47 [-0.55;-0.37] (357)
VAS Sleep	-0.36 [-0.44;-0.28] (626)	-0.19 [-0.27;-0.12] (626)	-0.39 [-0.45;-0.32] (626)
EQ-5D VAS	0.51 [0.45;0.57] (497)	0.31 [0.22;0.40] (497)	0.48 [0.41;0.55] (497)
WPAI:AS activities	-0.58 [-0.63;-0.51] (480)	-0.39 [-0.46;-0.30] (480)	-0.55 [-0.62;-0.47] (480)
WPAI:AS work	-0.54 [-0.61;-0.45] (355)	-0.34 [-0.42;-0.25] (355)	-0.53 [-0.60;-0.46] (355)

CARAT Q1-4=Questions 1-4 of CARAT ("CARAT upper airways"); CARAT Q5-10=Questions 5-10 of CARAT ("CARAT lower airways"); VAS=Visual analogue scale; VAS Global=VAS Global allergy symptoms; WPAI:AS activities=Degree allergy affected regular activities in Work Productivity and Activity Impairment: Allergic Specific; WPAI:AS work= Percent overall work impairment due to allergy in Work Productivity and Activity Impairment: Allergic Specific.