# Validation of the MASK-rhinitis visual analogue scale on smartphone screens to assess allergic rhinitis control

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SUMMARY

**Background:** Visual Analogue Scale (VAS) is a validated tool to assess control in allergic rhinitis patients.

**Objective:** The aim of this study was to validate the use of VAS in the MASK-rhinitis (MACVIA-ARIA Sentinel NetworK for allergic rhinitis) app (Allergy Diary) on smartphones screens to evaluate allergic rhinitis symptoms and disease control.

**Methods:** Each user filled 4 different VAS measuring overall, nasal, ocular, and asthma symptoms at least once. Following COSMIN guidelines, we evaluated internal consistency, (Cronbach's alpha coefficient and test-retest), reliability (intraclass correlation coefficients), sensitivity, and acceptability of the MASK-Rhinitis VAS. **Results:** Between 1 August 2015 and 31 July 2016, the app was used 14 612 times in 15 countries. A total of 1225 users used it more than once, during the evaluated period. The tool resulted to be statistically satisfactory, showing excellent internal consistency (Cronbach's test $> 0.84$, test-retest $> 0.7$), reliability ($>0.9$), and acceptability. In addition, the tool had a good sensitivity when users (n = 521) answered the VAS twice in less than 3 hours.

**Conclusions and Clinical Relevance:** The MASK-rhinitis VAS is a reliable and valid tool to assess allergic control on smartphone screens, at the population level.

KEYWORDS : allergic rhinitis, allergy, control, MASK, visual analogue scale

# 1 | INTRODUCTION

The control and severity of AR have been defined,[1-3] and several attempts have been made by physicians to find the best way to reduce the impairment due to AR. Current guidelines mainly focus on the control of symptoms to better assess the efficacy of the prescribed treatment[4] and to improve patient's quality of life (QOL) while reducing allergic symptoms.

Measures of AR control include symptom scores, patients self-administered visual analogue scales (VAS), patients reported outcomes, such as QOL, objective measures of nasal obstruction, and a recent modification of the ARIA severity classification.[5,6] A few tools have been validated for AR to evaluate disease control or the impact of symptoms on QOL. Most tools use patient-reported assessments of the intensity of the main symptoms. Administration of currently available paper-and-pencil tools is either through patient self-administration or through interviews with patients or caregivers. Emerging methods use computer-assisted questionnaire administration or computer-tailored assessments. A practical, reliable, and easy tool is the administration of a VAS that allows users to simply evaluate the degree of impairment, and physicians to assess the overall intensity of allergic symptoms,[7-9] and that has been used even on computer screens. VAS in AR incorporates symptoms and QOL.[10]

MACVIA-France (Fighting chronic diseases for active and healthy ageing in France, http://macvia.cr-languedocroussillon.fr) is one of the reference sites of the European Innovation Partnership on Active and Healthy Ageing.[11] It initiated the project AIRWAYS ICPs (integrated care pathways for airway diseases) [12,13] and the allergy sentinel network MASK (MACVIA-ARIA Sentinel NetworK).[1,14] MASK-rhinitis[15] is a simple ICT (Information and Communication Technology) tool to implement care pathways for AR from patients to healthcare providers using a common language and a clinical decision support system,[7] through a smartphones and tablets application. The corresponding app, called "ARIA Allergy Diary" (AD), may be downloaded for free both using an Android or an iOs system and is currently available in 15 European countries, Canada, Mexico, Brazil, and Australia, and will soon be available in the USA. Users may self-evaluate their AR control by a VAS that appears on their phone screen. Preliminary data showed that the app enables baseline and simple phenotypic characteristics collection.[16]

The aim of this paper was to assess the validity of the MASK-rhinitis visual analogue scale (VAS), as it appears in the AD app, in users who reported to suffer from AR.

# 2 | METHODS

## 2.1 | COLLECTED DATA

In this study, we included all users that logged into the AD app, since 1 August 2015, until 31 July 2016 (12-month period). The app

collects information on AR symptoms experienced by users, who assess their daily symptom control using the touchscreen functionality on their smart phone. To do so, users need to click on 4 consecutive VAS (ie, general allergy symptoms, nasal symptoms, ocular symptoms, and asthma symptoms). The system has been deployed in 20 countries and in 15 languages (translated and back-translated, culturally adapted, and legally compliant).

After the download, and before using the app, users need to approve both the terms of use and the privacy policy, which also have been translated and legally adapted for each country in which the app is available. By accepting the use of the app, subjects agree to the fact that their data could be used also for research and scientific purposes. Data collected by the AD app after the registration process are as follows:

• The user's sex and age;

• The severity of the symptoms, as indicated through 4 VAS (see below) each time users log in the app; users may evaluate their symptoms as many times as they want during the day. Of note, there is no reminder, nor a precise time imposed to score symptoms;

• The possible medications taken to control their symptoms (whether prescribed by a physician or over the counter);

• The diagnosis, which is a self-diagnosis: when patients register, they answer "I have allergic rhinitis" and/or "I have asthma."

During the evaluated period, the VAS included four items, each of which targets a specific domain. Specific domains include an organ or related disease. To complete the VAS, users are invited to touch anywhere along a line that appears on the screen to indicate how bothersome their symptoms are the left edge means their symptoms are "not at all bothersome" while the right edge is equal to "extremely bothersome," as indicated on the screen. Once users touch the line, a slider appears and they may move it, if necessary, to provide a more accurate response (Figure 1).

Users are asked to answer to one general and three symptom-specific questions that yielded to 4 VAS as follows:

• VAS 1 (Overall symptoms): Overall, how much are your allergic symptoms bothering you today?

• VAS 2 (Rhinitis): How much are your nose symptoms bothering you today?

• VAS 3 (Conjunctivitis): How much are your eye symptoms bothering you today?

• VAS 4 (Asthma): How much are your asthma symptoms bothering you today? (as current ARIA guidelines[4,9] advise to evaluate the possible asthma co-morbidity in patients suffering from allergic rhinitis, this question was included for all patients from 1 June 2016; previously, users were asked to answer this question only if they answered, during the registration process, that they were asthmatic).

**FIGURE 1** *VAS for overall allergic symptoms as it appears on smartphones screens*
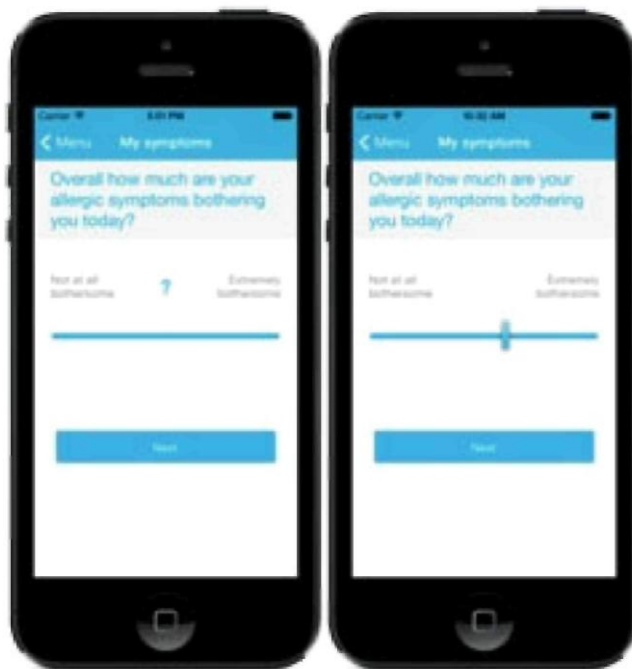


## 2.2 | Statistical methods

The associations between the different VAS were assessed using a Spearman test and a chi-square test for all users and for users logging into the app more than once as follows:

• Associations between the overall symptoms (VAS 1) and

> o Rhinitis, VAS 2,
>
> o Conjunctivitis, VAS 3,
>
> o Asthma, VAS 4,
>
> o Rhino-conjunctivitis, as the average of the collected values for VAS 2 and VAS 3, o All

organ symptoms, as the average of the collected values for VAS 2, VAS 3, and VAS 4.

• The association between the overall symptoms (VAS 1), and the cumulative VAS score given by the average of all VAS scores.

For the chi-square analysis, we categorized patients into 3 different classes: class 0, for asymptomatic patients (VAS < 20); class 1, for those presenting with mild symptoms (<20 VAS < 50); and class 2, for those as with moderate-to-severe symptoms (VAS > 50). As for the asthma question (VAS 4), we also evaluated the association with the overall symptoms VAS before 1 June (when only asthmatic users answered to the fourth question) and after 1 June 2016 (when all users were asked to complete VAS 4 as well).

The analysis of the psychometric characteristics of the AD app, in compliance with the COSMIN guidelines,[17] aimed to verify for this tool:

• The *internal consistency.* It was assessed through the Cronbach's alpha coefficient and the test-retest procedure, evaluating the results given by users logging into the app and filling the VAS for two consecutive days, when no change in medications intake is recorded;

• The *reliability.* It was assessed by analysing correlations between VAS measures taken twice in the same day, through intraclass correlation coefficients (ICCs). As the magnitude of correlation coefficients is affected by the range of scores included in the sample, increasing as the range of scores increases, ICCs were calculated separately for VAS scores above and below 50 mm;

• The *sensitivity.* It was evaluated by the Cronbach' alpha coefficient, the difference of measures and the standard deviation in the VAS, for those users logging into the app more than once per day, but self-assessing their symptoms with a interval of less than 3 hours (thus, eliminating bias related to possible changes in allergen exposure and/or drug intake).

• The *external validity* having already been described in a previous paper.[16]

We also verified the population *acceptability,* defined as the persistence of self-assessment over at least two consecutive days in more than 40% of users using the app and the persistence of self-assessment at least 4 days a week in more than 30% of users downloading the app.

All analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA). All *P-values* < .05 were considered as statistically significant.

# 3 | RESULTS

## 3.1 | VAS ACCEPTABILITY—DESCRIPTION OF THE USERS

Between 1 August 2015 and 31 July 2016, the AD app was used 14 612 times, by 2497 individuals. A total of 1272 subjects used the app only once, while 1225 (49.1%) subjects used it at least twice (12 076 accesses): 845 individuals used it for 2 to 7 days, 154 for one to 2 weeks, 128 for 2 to 4 weeks, and 98 for more than 30 days. The VAS was completed on two consecutive days for 6328 times.

Of the 1225 users connecting to the AD more than once, 809 logged into the app for at least two consecutive days (66.0% and 32.4% of the whole cohort). In the same group, 461 subjects (37.6%) entered their VAS for at least 4 days during the same week. Also, 196 of these 461 users (42.5%) assessed their symptoms for at least two consecutive weeks and 90 (19.5%) for at least 4 consecutive weeks. Considering only these subjects, the mean value of consecutive weeks during which they used the app for at least 4 days per week was 2.41 weeks (min 1, max 23, SD 2.66).

The associations between the different VAS for all users and for users logging into the AD app more than once are shown in Table 1 and Table 2. In both groups, when considering one organ only, the highest correlation coefficient was observed between rhinitis (VAS 2) and conjunctivitis (VAS 3) (Table 1). The correlation was very elevated when considering together rhinitis and conjunctivitis. The association with asthma was less strong compared to the other

symptoms. These results were confirmed when analysing the VAS once categorized into the three previously described classes (Table 2).

Figure 2 shows the correlation between the overall symptoms (VAS 1) and the average values obtained by all the other three VAS, both for all users using the app and for those using it more than once.

**TABLE 1** *Association between overall symptoms (VAS 1) and rhinitis (VAS 2), conjunctivitis (VAS 3), asthma (VAS 4), rhino-conjunctivitis (average value of VAS 2 and VAS 3), and all organ symptoms (average value of VAS 2, VAS 3, and VAS 4), in all subjects who ever used the app, and in those who used it more than once, through Spearman test*

| VAS 1 | | | | |
|---|---|---|---|---|
| | All users (total data = 14612) | | Users logging in more than once (total data = 12076) | |
| | Spearman's coefficient of correlation | *P-value* | Spearman's coefficient of correlation | *P-value* |
| VAS 2 | .879 | <.001 | .878 | <.001 |
| VAS 3 | .656 | <.001 | .692 | <.001 |
| VAS 4 | .583 | <.001 | .595 | <.001 |
| VAS 2 and 3 | .889 | <.001 | .894 | <.001 |
| VAS 2, 3 and 4 | .893 | <.001 | .897 | <.001 |
| VAS 4: before 1 June 2016 | .668 | <.001 | .642 | <.001 |
| VAS 4: after 1 June 2016 | .478 | <.001 | .522 | <.001 |

## 3.2 | VAS VALIDATION—INTERNAL CONSISTENCY

The Cronbach's alpha coefficient for each VAS and for the average values of all collected VAS in subjects using the app for two consecutive days (n = 6328) was as follows:

• VAS 1, overall allergic symptoms: alpha coefficient 0.85;

• VAS 2, nose symptoms: alpha coefficient 0.84;

• VAS 3, ocular symptoms: alpha coefficient 0.85;

• VAS 4, asthma symptoms: alpha coefficient 0.89;

• Average of all collected VAS by each patient: alpha coefficient 0.88.

When evaluating for test-retest the group of users logging into the app for two consecutive days (n = 809), we highlighted the following ICCs:

• VAS 1, overall allergic symptoms: ICC 0.737 (CI 95%, 0.725-0.748, P < .0001);

• VAS 2, nose symptoms: ICC 0.727 (CI 95%, 0.715-0.738, $P < .0001$);

• VAS 3, ocular symptoms: ICC 0.748 (CI 95%, 0.737-0.759, $P < .0001$);

• VAS 4, asthma symptoms: ICC 0.797 (CI 95%, 0.785-0.808, $P < .0001$);

• Average of all collected VAS by each patient: ICC 0.799 (CI 95%, 0.789-0.808, $P < .0001$).

**TABLE 2** *Relation between overall symptoms (VAS 1) and rhinitis (VAS 2), conjunctivitis (VAS 3), asthma (VAS 4), and all organ symptoms (average value of VAS 2, VAS 3, and VAS 4), in all subjects who ever used the app, and in those who used it more than once, through chi-squared test*

| | | VAS1 Data from all users (N = = 14612) | | | | VAS 1 Data from users logging in more than once (N = 12076) | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Class 0 | Class 1 | Class 2 | *P-value* | Class 0 | Class 1 | Class 2 | *P-value* |
| VAS 2 | Class 0 | 86.49% | 15.42% | 4.74% | <.0001 | 86.67% | 16.80% | 4.62% | <.0001 |
| | Class 1 | 11.19% | 67.05% | 16.36% | | 11.42% | 64.93% | 17.00 | |
| | Class 2 | 2.33% | 17.53% | 78.90% | | 1.91% | 18.28% | 74.20% | |
| VAS 3 | Class 0 | 91.01% | 54.58% | 23.86% | <.0001 | 91.25% | 49.58% | 22.97% | <.0001 |
| | Class 1 | 6.93% | 34.97% | 25.15% | | 7.09% | 39.29% | 23.79% | |
| | Class 2 | 2.06% | 10.46% | 50.99% | | 1.66% | 11.13% | 53.24% | |
| VAS 4 | Class 0 | 94.51% | 74.95% | 60.92% | <.0001 | 94.32% | 71.69% | 58.13% | <.0001 |
| | Class 1 | 4.20% | 18.62% | 13.84% | | 4.47% | 21.36% | 13.98% | |
| | Class 2 | 1.29% | 6.43% | 25.24% | | 1.21% | 6.94% | 27.89% | |
| Average of VAS 1, 2 and 3 | Class 0 | 95.02% | 63.47% | 43.28% | <.0001 | 93.96% | 37.12% | 20.77% | <.0001 |
| | Class 1 | 4.11% | 31.23% | 25.84% | | 5.30% | 57.72% | 25.02% | |
| | Class 2 | 0.86% | 5.30% | 30.88% | | 0.75% | 5.16% | 54.21% | |

*Class 0 = asymptomatic (VAS < 20), class 1 = mild symptoms (<20 VAS < 50), and class 2 = severe symptoms (VAS > 50). Bold values highlight the correlation between values considered from the same class of patients.*

**FIGURE 2** *Correlation between the results of the overall symptoms VAS (VAS 1) and all organ symptoms (average value of VAS 2, VAS 3, and VAS 4) (A) in all subjects who ever used the app; and (B) in those subjects who used the app more than once*
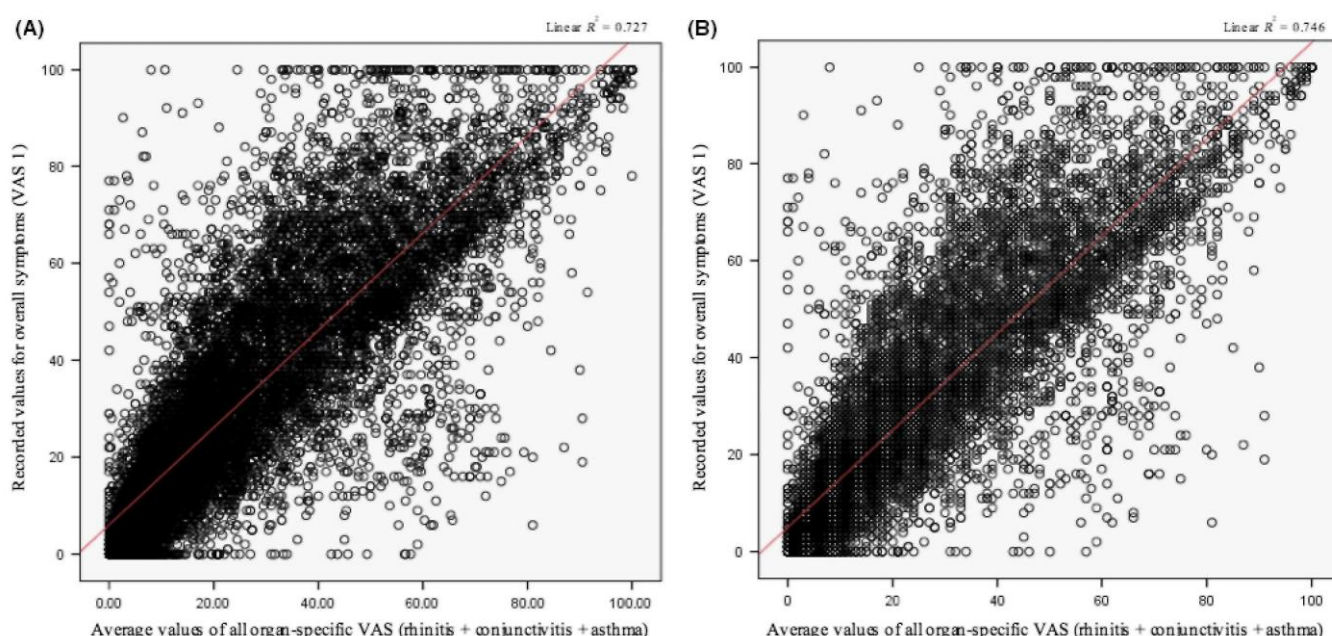


## 3.3 | VAS VALIDATION—RELIABILITY AND SENSITIVITY

A total of 521 individuals recorded the VAS more than once over three consecutive hours. Reliability was evaluated considering no external interaction effect, in this population, and then in the subgroups of users reporting a VAS of more and less than 50%, as shown in Table 3. ICCs were higher than 0.87 and thus excellent in the entire population and in users reporting VAS values < 50, and between good and excellent in users reporting VAS values > 50.

Sensitivity was evaluated as good for each VAS, through classical statistical analysis, t-student test, and alpha coefficient, as shown in Table 4.

**TABLE 3** *Intraclass correlation coefficients (ICC) in all subjects who used the app twice in the same day (whole population) and in those evaluating their symptoms as moderate-to-severe (VAS > 50) and not (VAS < 50). The analysis was conducted for each VAS completed by users (n = 521)*

|  |  | Included subjects | ICC | Min-Max (95% Cl) | *P-value* |
|---|---|---|---|---|---|
| Whole population | VAS 1 | 498 | 0.924 | 0.909-0.936 | <.001 |
|  | VAS 2 | 521 | 0.928 | 0.914-0.939 | <.001 |
|  | VAS 3 | 521 | 0.949 | 0.940-0.957 | <.001 |
|  | VAS 4 | 316 | 0.959 | 0.949-0.967 | <.001 |
| VAS > 50 | VAS 1 | 169 | 0.645 | 0.520-0.738 | <.001 |

|          | VAS 2 | 165 | 0.619 | 0.482-0.720 | <.001 |
|          | VAS 3 | 119 | 0.661 | 0.513-0.764 | <.001 |
|          | VAS 4 | 52  | 0.841 | 0.724-0.909 | <.001 |
| VAS < 50 | VAS 1 | 329 | 0.889 | 0.862-0.911 | <.001 |
|          | VAS 2 | 356 | 0.865 | 0.834-0.891 | <.001 |
|          | VAS 3 | 402 | 0.913 | 0.895-0.929 | <.001 |
|          | VAS 4 | 264 | 0.891 | 0.861-0.914 | <.001 |

*ICC, intraclass correlation coefficient; Cl, confidence interval; Min, minimum; Max, maximum.*

# 4 I DISCUSSION

Current AR guidelines emphasize that allergic rhinitis control is a key therapeutic goal and recommend evaluating symptoms control to guide step therapy.[18] So far, no tool is considered as a gold standard for AR. Nevertheless, current trend in assessing different aspects of diseases is the use of a simple Visual Analogue Scale, a simple tool for both patients to complete and for physicians to evaluate. Another advantage of the VAS is that it may be used in most age groups and in a wide variety of languages and that it may assess the severity of the disease as well.[8,19] The VAS, as a tool to assess AR severity, according to ARIA (Allergic Rhinitis and its Impact on Asthma) guidelines, has already been validated and is considered as an easy-to-use tool.[19,20] A VAS score of 50/100 mm (or 60/100, based on different studies) is suggestive of moderate-to-severe AR.[18,21] Such considerations lead to conduct a survey at the 2013 congress of the European Academy of Allergy and Clinical Immunology (EAACI), where physicians were asked to evaluate and approve the usefulness of a VAS to monitor AR control.[22]

As the use of information and communications technology (ICT), such as apps running on consumer smartphones, is increasingly popular and has the potential to profoundly affect health care, MASK-rhini-tis developed an app, as one of the implementation tools of the B3 Action Plan of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA).[11,12,15] The app is currently included as a tool of the ARIA guidelines to monitor users' symptoms.[18] The ARIA Allergy Diary app uses a quick VAS system for the assessment of AR control, although 4 simple questions. A pilot study has been completed in AR to assess the relevance of the AD app and showed the importance of the tool to stratify users and assess their symptoms severity and control and highlighted the external validity of the app.[16]

The tool proved its acceptability following defined criteria, with 49% of users logging into the app more than once and more than 30% using it for at least 4 times a week. When an app is free to download, its usefulness is important for the users, and a great number of people may download it without even knowing the purpose of it. The fact that almost a half of all people who downloaded the app used it more than once makes its acceptability verified.

Internal consistency was validated both by alpha coefficient and test-retest. Cronbach's alpha showed an excellent internal consistency (>0.84) for each VAS and for all the average VAS, when evaluating users answering to the 4 questions over two consecutive days. Test-retest showed an

acceptable ICC for each VAS and for all the average VAS, in the same group of users, as well (ICC > 0.7, $P < .0001$).

Reliability was confirmed by the assessment of ICCs in users answering to the 4 VAS twice in the same day. Intraclass coefficients were excellent when considering the whole population (>0.9, $P < .001$) and users with no to mild symptoms, that is with a VAS <50 (>0.8, $P < .001$). On the other hand, users with elevated values of VAS showed lower values of ICC (>0.6, $P < .001$) and reliability is to considered as adequate. Nevertheless, in this group of moderate-to-severe patients (VAS > 50), reliability was excellent in those users with moderate-to-severe symptoms of asthma (0.841, 95% CI, 0.724-0.909, $P < .001$).

The mean difference and the standard deviation of the values entered by users when logging into the app twice in less than 3 hours proved a good sensitivity of the tool.

At last, the VAS showed a good association between overall symptoms and rhinitis symptoms, rhino-conjunctivitis symptoms and all organ symptoms through Spearman test. Eyes symptoms and asthma symptoms showed a weaker association with the "overall symptoms" VAS, if compared with the other variables. Also, until 1 June 2016, users were not obliged to answer to the asthma question, if they claimed not to suffer from this condition, while after that date, each user was required to answer the question (VAS 4). The Spearman test showed an even weaker association between asthma symptoms and overall symptoms after that date. All these considerations are valid for both analysis run on all the subjects who downloaded the app (n = 2497) and those who used it at least twice (n = 1272). When evaluating results with a chi-squared test, we categorized users according to their VAS: no symptoms if their VAS was < 20, mild symptoms when <20 VAS < 50 and moderate-to-severe when VAS > 50. We run the same analysis both on all the subjects who ever used the app (n = 2497) and on those who used it more than once (n = 1272). In both case, the chi-squared test resulted significant (P < .0001). We noticed that when users reported to have no overall symptoms, their answer was strongly correlated with the answers to the other three VAS. On the contrary, when overall symptoms are mild, they correlate well with nasal symptoms, but users mainly respond not to be bothered by eyes and asthma symptoms. Moreover, when overall symptoms are moderate-to-severe, they correlate very well with nasal symptoms and well with eyes symptoms, but most of users claim to have no asthma symptoms. These results may be explained by the fact that not all patients suffer from asthma, and it could therefore be a bias in our analysis. Nevertheless, we could also hypothesize that what bothers allergic patients are mostly their nasal symptoms and secondly their eyes symptoms when their allergic condition becomes severe and that asthma symptoms are either less important or patients are used to those chronic symptoms and thus, they seem less bothersome during an allergy peak.

The present study showed that the use of a VAS for AR on smartphone screens can be validated. Indeed, we highlighted the acceptability, the internal consistency, the reliability and sensitivity of the tool. External validity was demonstrated in a previous paper.[16] Even though the acceptability criterion was satisfied, the drop-off rate was quite big. The reasons for this could probably be linked to the fact that the app is free to download and anyone might use it, without being consistent. The implementation of the app with the clinical decision support system and the healthcare-provider version will be more appealing and useful and we might speculate that

the patients who would actually benefit from the app will used it more consistently. For the same reason, data on medication used should be better exploited in further analysis.

As a conclusion, VAS can be considered as a validated tool to assess allergic rhinitis control in users suffering from AR even on smartphones screen, as in the AD app, and is well accepted by physicians. The MASK-rhinitis tool uses VAS to stratify users and evaluate symptom severity and control, through the ARIA Allergy Diary app for smartphones. The implementation of the app, through a clinical decision support system (CDSS) and a healthcare providers' version, will help not only users to better handle their symptoms, but also both the pharmacists, to guide them in the prescription of OTC medications and refer uncontrolled users to physicians, and the doctors, to prescribe appropriate treatment and assess symptom control in their patients. The current study is of great importance for the transfer of innovation to the Reference Sites of the European Innovation Partnership on Active and Healthy Ageing[23,24]

**TABLE 4** *Sensitivity of the four VAS, in users evaluating their symptoms with a less than 3 h of interval*

|  | Cronbach's alpha coefficient | Mean difference | Standard Deviation | Cl 95% | t-Student test |
|---|---|---|---|---|---|
| **VAS 1** | 0.858 | 1.143 | 14.993 | -0.177; 2.463 | 1.701 |
| **VAS 2** | 0.865 | 0.495 | 14.917 | -0.789; 1.779 | 0.758 |
| **VAS 3** | 0.904 | 1.207 | 12.58 | 0.125; 2.29 | 2.19 |
| **VAS 4** | 0.922 | -0.003 | 10.464 | -1.161; 1.155 | -0.005 |

*Cl, confidence interval; Min, minimum; Max, maximum.*

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