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## Observational study of administering intranasal steroid sprays by healthcare workers

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#### **BMJ** Open

Title: Observational study of administering intranasal steroid sprays by healthcare workers

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#### Abstract

Objectives: Patients with allergic rhinitis receive their information about administering intranasal corticosteroid sprays (INCS) from healthcare workers. Since the majority of patients do not administer these sprays correctly, we investigated whether healthcare workers know how to administer INCS.

Settings: we studied participants at their working place: pharmacy, outpatient clinic, or general practitioner centre for emergencies

Participants: pharmacist assistants, general practitioners, paediatricians, and ear nose throat doctors. Design: observational study

Primary outcome: number of steps of administration of INCS, based on the established INCS protocol Secondary outcome: number of the five steps that are labelled essential to obtain optimal distribution of the medication. All the participants demonstrated the administration technique with a spray device filled with water.

Results: Among the 75 participants, none performed all the steps correctly. The median of correctly performed steps in the protocol was 14 out of 29. A significantly better result was found among the pharmacist assistants. The essential steps were performed by 27 out of the 75 participants (36%). Conclusion: The majority of healthcare workers do not know how to administer INCS correctly. Patients could, therefore, receive incorrect and non-uniform instructions. The education of healthcare workers on how to administer INCS correctly may be an option for improvement

Article Summary

Strengths and limitations of this study

In this study we observed how healthcare workers, including general practitioners, ear nose throat doctors, paediatricians, and pharmacy assistants administered intranasal corticosteroid sprays (INCS).

This is the first study to observe healthcare workers administering INCS.

The administration technique was scored in a simple and robust way by the same investigator.

We used a protocol for correct administration on literature and patient information leaflets, however, not all steps are based on firm scientific evidence.

We do not know if administration of INCS depends on the instructions given by healthcare workers.

#### Introduction

Allergic rhinitis is a common chronic disease, with a prevalence ranging from 10 to 40% worldwide.<sup>1-</sup>  $^{2}$  The disease mostly affects people between 5 and 45 years old, with a peak incidence between 19 and 24 years old.<sup>3</sup> In addition to allergen avoidance, the management of allergic rhinitis consists of either antihistamines, intranasal corticosteroids or a combination of both.<sup>4-5</sup> When persistent symptoms occur, intranasal corticosteroid sprays (INCS) are the treatment of choice.<sup>6-7</sup> Studies suggest that the administration technique for INCS is associated with efficacy, adverse events and compliance.<sup>5,8</sup> For example, it was found that the optimal administration technique of INCS is spraying with a contralateral spray technique, pointing the nozzle away from the septum, because spraying towards the septum causes more nosebleeds than the recommended approach.<sup>8-10</sup> Furthermore, the head should be kept in a neutral position, and it is important to breather in calmly while spraying. This technique provides the best distribution of the medication.<sup>11-13</sup> In a recent study, we observed the method of administration among patients and found that most (94%) did not take their INCS as described in the patient information leaflets (PILs).<sup>14</sup> Moreover, the available PILs are currently incomplete and non-uniform.<sup>15</sup> Since patients do not only learn from PILs, but can also be instructed by healthcare workers, we wanted to know whether such they could demonstrate the administration of INCS correctly. As far as we know, this factor has never previously been studied. Therefore, we investigated the knowledge of healthcare workers regarding administering INCS.

#### Material and methods

#### Participants and setting

We performed an observational study in the northern part of the Netherlands. The healthcare workers observed included pharmacist assistants, general practitioners, paediatricians, and ENT physicians. Healthcare workers were excluded if they had been practising their profession for less than a year. Paediatricians and ENT physicians from eight hospitals were approached via email. We approached pharmacist assistants from six pharmacies. General practitioners were approached while working at the general practitioner centre for emergencies based at the Medical Centre Leeuwarden. Study design

When eligible healthcare workers agreed to participate, a face-to-face interview was conducted. All the participants were aware of the aim of the study. To prevent inter-observer variation, all interviews and observations were performed by the same researcher (MdB).

During the interviews, the healthcare workers answered a questionnaire containing questions about their experiences prescribing INCS and about how they provide patients with information. Then, the healthcare workers were asked to demonstrate the administration technique with a spray device filled with water. The stages assessed were preparation, administration and cleaning of the INCS [Table 1]. Assessment of the administration technique was based on the established Dutch INCS protocol. In this protocol, five steps are labelled as essential.<sup>14</sup> These steps are considered as essential because they most influence the distribution and efficacy of the medication. The essential steps include shaking the bottle, blowing or rinsing the nose, directing the nebuliser away from the nasal septum, breathing in while simultaneously squirting a spray of mist, and exhaling through the mouth.

In the statistical analysis, descriptive statistics were used to answer the question of whether healthcare workers know how to administer INCS. For the comparison of outcomes between populations, a Pearson correlation was used for continuous variables, a Spearman rho correlation for ordinal variables, and a Mann-Whitney U Test for categorical variables. The regional medical ethics committee approved the study protocol. All the participants provided written consent.

 Patient and Public Involvement

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research.

#### Results

In the period between June 11<sup>th</sup> and December 18<sup>th</sup>, 2019, 75 healthcare workers participated in our study [Table 2], none of whom performed all the steps correctly. The median of correctly performed steps in the protocol was 14 out of 29, with a range between 9 and 24 and an interquartile range of 3.5. For preparing the spray, the median was six out of seven steps. The median for administering the spray was eight out of 10 steps, and the median for cleaning the spray was one out of 10 steps. The points for attention, which are taking the spray to the pharmacy when it does not work and checking the expiry date, were not performed by most participants [Figure 1]. When analysing the differences in total score between the healthcare workers, a significantly higher result was found among pharmacist assistants compared with the other groups [Table 3].

Twenty-seven out of 75 participants (36%) performed all the essential steps. Of the essential steps, nose-blowing was performed least frequently, being carried out 46 out of 75 times (61%). Inhaling while squirting a spray of mist into the open nostril was performed most often: 69 out of 75 times (92%). Shaking the bottle was done 61 times (81%). The nozzle was directed outwards 66 times (88%). Exhaling through the mouth was done by 57 participants (76%) [Table 4].

Sixteen participants (21%) performed all the preparation steps. The least performed steps during preparation were activating the nozzle by spraying in the air (59%) and blowing or rinsing the nose (61%). Two participants (3%) performed all the administration steps. Squirting the spray while breathing in (92%) and pointing the nozzle outwards (88%) were performed by most participants. The most frequent errors in administration were, in order, keeping the other nostril closed, spraying crosswise and keeping the head upright. These steps were performed 33 times (44%), 43 times (47%) and 49 times (65%), respectively. One participant (1%) performed all the cleaning steps, including cleaning the nozzle with a tissue and extensively cleaning the nozzle with water once a week and allowing it to air dry. Approximately half the participants (38; 51%) cleaned the spray with a tissue after every use [Table 4].

#### Discussion

In this study we found that most healthcare workers involved in the care for patients with allergic rhinitis did not know and could not demonstrate how to administer INCS correctly. None of the healthcare workers performed all the steps of the checklist correctly. The median of the 75 participants was 14 out of 29 well-executed steps. The five essential steps were correctly performed by 27 out of 75 participants (36%). We found that the pharmacist assistants administered the INCS significantly better than the other healthcare workers, suggesting that pharmacist assistants are most suitable for providing information about INCS.

To the best of our knowledge, the role of healthcare workers in informing patients about the correct administration of INCS has never previously been studied. One recent study found that face-to-face instruction, consisting of both verbal information and a physical demonstration, was most effective in teaching the correct technique for asthma medication.<sup>16</sup> This finding may apply regarding the correct usage of INCS as well, meaning that it is important that healthcare workers have sufficient knowledge. Knowledge about inhaler technique for asthma and chronic obstructive pulmonary disease (COPD) has been researched using healthcare workers. These studies reveal similar results to ours; that is, inadequate knowledge regarding the use of inhalers.<sup>17-18</sup> A recent study found only 12% of

healthcare workers knew at least three essential steps of the correct metered-dose inhaler technique, and none of the participants performed all the steps correctly.<sup>19</sup>

For the checklist, we used a standardised protocol recently published in Dutch healthcare. Although this protocol is based on existing literature, a few instruction steps are only marginally substantiated by research data, and we needed to make a few assumptions about the best spray technique [Table 5]. First, an essential step while preparing for administration is blowing or rinsing the nose. This step is recommended in the literature, although no significantly better distribution of the active substance was found.<sup>20</sup> Approximately 60% of the participants performed this step. Next, it was found that an upright position of the head while spraying proved most effective.<sup>11,21</sup> Bending the head backwards can result in the active substance leaking into the pharynx, causing irritation and possibly more systemic uptake. When bending the head forward, the active substance could easily run out again. However, 45% of the ENT doctors and 10 to 20% of the paediatricians, general practitioners and pharmacist assistants bent their heads forward while breathing in the spray. Their reasoning was that the nasal cavity runs backwards, causing the spray to be sprayed towards the nasal cavity when the head is bent forward. There is a study that confirms this theory.<sup>13</sup> However, when administering the nasal spray, the nozzle should be directed away from the nasal septum to prevent nose bleeding and septum perforation. Furthermore, the lateral nasal wall has more cilia than the medial wall, so the distribution of the active substance is better.<sup>8-10</sup> We found that this essential step was performed correctly by 88% of the participants. It is also advised to use the contralateral hand while spraying, because this causes less mechanical irritation, and, thus, fewer side effects and better compliance.8 Approximately half the participants (57%) performed this step. However, not all these participants recommended this step to their patients, because it is relatively complicated to perform. Another essential step is to breathe in slowly during administration, because the airflow ensures a better contribution of the active substance. A continuous, slow flow has the best effect. Breathing hard or sniffing can lead to increased turbulence in the nose, which can cause the active substance to finish in the pharynx.<sup>12,22</sup> This was the best performed essential step: 92% of participants performed this correctly. Only one participant stated that the nasal spray should be completely cleaned with water once a week. Since these nasal sprays are used chronically and daily in many cases, good hygiene is important. However, there is no uniform instruction for cleaning the nasal spray in the package leaflets. This lack is a possible explanation why the healthcare workers did not mention this aspect. Considering that there is little substantiated research about the correct administration technique, and since the published INCS protocol is not widely known, healthcare providers apparently provide instructions according to their own insights. Further research is necessary to substantiate the most effective administration technique for nasal sprays. Currently, it is important to implement the present available instructions to achieve clarity in the instructions for the administration of nasal sprays.

#### Strengths and limitations

This study has a couple of limitations. First, we did not know what outcomes to expect, so we chose to conduct this research with a relatively small research group.<sup>23</sup> Second, we could only include 15 ENT doctors despite many attempts and visits to their offices. We cannot explain their low participation. Nevertheless, we do not think that the inclusion of five more ENT doctors would affect the outcome significantly.

The strengths of this study are as follows: since various hospitals, general practices and pharmacies were included, the results are a good reflection of the population that both prescribes and informs about INCS. All our interviews were conducted by the same researcher, so no inter-observer variation occurred. We used a simple scoring system, making the scores less sensitive to errors.

This research only studied healthcare workers' knowledge of the administration technique. Studying whether the knowledge of a healthcare worker ultimately affects the correct spray technique, and, thus, the efficacy of INCS in patients, is recommended.

#### Conclusion

The majority of healthcare workers do not know how to administer an INCS correctly. This lack of knowledge may prevent them from being able to provide adequate instructions to their patients. Clear arrangements should be made regarding who provides these instructions and what these instructions include. Healthcare workers should continually update their knowledge regarding the correct spray technique. The established INCS protocols can be used to address this issue.

#### Acknowledgement

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#### Author contributions

Marielle de Boer was involved in developing the study protocol, interviewed the participants, analysed the data and wrote the first draft. Corine Rollema was involved in developing the study protocol, analysing the data, and in the process of writing. Eric van Roon was involved in developing the study protocol and the process of writing. Tjalling de Vries had the original idea, was involved in developing the study protocol, analysing the data, and the process of writing. All authors read the final version and agree.

#### Conflict of interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi\_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

#### Data statement section

Technical appendix, statistical code, and dataset available from the authors

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18.	Extensively wash the nozzle once a week.
19.	Take off the dust cap and nozzle.
20.	Rinse the dust cap and nozzle with warm water.
21.	Shake off water.
22.	Air dry the dust cap and nozzle.
23.	Replace the nozzle.
24.	Firmly shake the bottle.
25.	Squirt a few sprays into the air until you see a
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26.	Replace the dust cap.
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$\frac{100}{411} \frac{30(73)}{100}$	No	56 (75)
	$\frac{110}{11 \text{ yoluog or } \mathbf{r} \left(\frac{0}{1}\right)}$	50(75)

Table 2 Deutisin and about statistics

Table 3. Difference in total score checklist								
Healthcare worker	N	Mean rank	P-value between groups*					
Pharmacist assistant	20	54.58 <sup>a</sup>	0.001					
General practitioner	20	30.98						
Paediatrician	20	34.85						
ENT physician	11	29.47						

Tested using Kruskal-Wallis test (post hoc Mann-Whitney U) P < 0.05. a Significant difference compared with general practitioners, paediatricians and ENT physicians.

to beet terien only

Table	e 4. Number of well-executed steps protocol						
Pre	paration	n (%)					
29.	Discuss purpose and action of the medication.	75 (100)					
30.	Take off the dust cap.	75 (100)					
31.	Firmly shake the bottle.*	61 (81)					
32.	Place forefinger and middle finger on both	58 (77)					
	sides of the nozzle and place thumb	× /					
	underneath the bottle.						
33.	Point the nozzle upwards and away from	44 (59)					
	yourself.						
34.	Squirt a few sprays into the air until you see a cloud of mist.	44 (59)					
35.	Blow the nose or rinse the nose with saline if the nose is clogged.*	46 (61)					
Adn	ninistration	n (%)					
36.	Place forefinger and middle finger on both sides of the nozzle and place thumb	60 (80)					
	underneath the bottle.	10.44-1					
37.	A. Keep the head upright and place the nozzle in the nose.	49 (65)					
	B. Use the right hand for spraying in the left nostril, and the left hand for spraying in the right nostril.	43 (57)					
38.	Point the end of the nozzle slightly outwards,	66 (88)					
30	Close the other nostril with your opposite	33 (44)					
57.	hand	JJ (++)					
40.	Squirt a spray of mist in the nose while	69 (92)					
	breathing in.*						
41.	Breathe out through the mouth.*	57 (76)					
42.	Repeat steps 8 through 13 for the other nostril.	75 (100)					
43.	If two sprays per nostril are prescribed, repeat steps 11 through 16 for both postrils	75 (100)	F.				
44	Replace the dust can	75 (100)					
Cles	ning	n (%)					
45	Wipe the nozzle with a tissue or handkerchief	38 (51)					
10.	after every use.	50 (51)					
46.	Extensively wash the nozzle once a week	1(1)					
47	Take off the dust cap and nozzle	1(1)					
48.	Rinse the dust cap and nozzle with warm	4(6)					
.0.	water.	. (0)					
49.	Shake off water.	1(1)					
50.	Air dry the dust cap and nozzle.	1(1)					
51.	Replace the nozzle.	1(1)					
52.	Firmly shake the bottle.	1(1)					
53.	Squirt a few sprays into the air until you see	1(1)					
	a cloud of mist.	(-)					
54.	Replace the dust cap.	1(1)					
Poir	its for attention	n (%)					
55.	If the nozzle does not spray properly, perform						
	the cleaning steps. If this does not work, take						
	the spray to the pharmacy. Never puncture the						
	opening.	13 (17)					
56.	Check the expiry date on the package and the						
	expiry date after opening.	11 (15)					
$*\overline{Es}$	sential steps						

ble 4. Number of well-executed steps protoc
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3	Table 5. Scientifically and non	n-scientifically based steps in the	
4	corticosteroid nasal spray pro	tocol	
5	Scientifically based steps	Non-scientifically based steps	
6	- Blow the nose or rinse	- Firmly shake the bottle.	
7	the nose is closed $2^{0}$	- Squift a few sprays into the	
8	- Keen the head	mist	
9	upright. <sup>11,21</sup>	- Close the other nostril with	
10	- Use the right hand for	your opposite hand.	
11	spraying in the left	- Breathe out through the	
12	nostril, and the left hand	mouth.	
13	for spraying in the right	- Wipe the nozzle with a	
14	nostril. <sup>13</sup>	tissue or handkerchief after	
15	- Point the end of the	every use.	
16	away from the centre	- Extensively wash the	
17	ridge of the nose	nozzie once a week.	
18	- Squirt a spray of mist in		
19	the nose while breathing		
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Figure 1. Median score checklist per stage, per group of healthcare workers



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### Reporting checklist for cross sectional study.

		Reporting Item	Page Number
Title and abstract			
Title	<u>#1a</u>	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	<u>#1b</u>	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	<u>#2</u>	Explain the scientific background and rationale for the investigation being reported	3
Objectives	<u>#3</u>	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	<u>#4</u>	Present key elements of study design early in the paper	3
Setting	<u>#5</u>	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Eligibility criteria	<u>#6a</u>	Give the eligibility criteria, and the sources and methods of selection of participants.	3
	<u>#7</u>	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3
Data sources / measurement	<u>#8</u>	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for exposed and unexposed groups if applicable.	3
Bias	<u>#9</u>	Describe any efforts to address potential sources of bias	3
Study size	<u>#10</u>	Explain how the study size was arrived at	3

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Quantitative variables	<u>#11</u>	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	3
Statistical methods	<u>#12a</u>	Describe all statistical methods, including those used to control for confounding	3
Statistical methods	<u>#12b</u>	Describe any methods used to examine subgroups and interactions	3
Statistical methods	<u>#12c</u>	Explain how missing data were addressed	3
Statistical methods	<u>#12d</u>	If applicable, describe analytical methods taking account of sampling strategy	3
Statistical methods	<u>#12e</u>	Describe any sensitivity analyses	3
Results			
Participants	<u>#13a</u>	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for exposed and unexposed groups if applicable.	4
Participants	<u>#13b</u>	Give reasons for non-participation at each stage	4
Participants	<u>#13c</u>	Consider use of a flow diagram	
Descriptive data	<u>#14a</u>	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	4
Descriptive data	<u>#14b</u>	Indicate number of participants with missing data for each variable of interest	4
Outcome data	<u>#15</u>	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	4
Main results	<u>#16a</u>	Give unadjusted estimates and, if applicable, confounder- adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	4

Page	1	9	of	18
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Main results	<u>#16b</u>	Report category boundaries when continuous variables were categorized	4
Main results	<u>#16c</u>	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	4
Other analyses	<u>#17</u>	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	4
Discussion			
Key results	<u>#18</u>	Summarise key results with reference to study objectives	4
Limitations	<u>#19</u>	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	5
Interpretation	<u>#20</u>	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	5
Generalisability	<u>#21</u>	Discuss the generalisability (external validity) of the study results	5
Other Information			
Funding	<u>#22</u>	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	7

None The STROBE checklist is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist can be completed online using <u>https://www.goodreports.org/</u>, a tool made by the <u>EQUATOR Network</u> in collaboration with <u>Penelope.ai</u>

BMJ Open

# **BMJ Open**

## Observational study of administering intranasal steroid sprays by healthcare workers

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Manuscript ID	bmjopen-2020-037660.R1				
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<b>Primary Subject Heading</b> :	Ear, nose and throat/otolaryngology				
Secondary Subject Heading:	Pharmacology and therapeutics				
Keywords:	Allergy < THORACIC MEDICINE, THERAPEUTICS, OTOLARYNGOLOGY				





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Page 2 of 18

#### BMJ Open

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3	1	Title: Observational study of administering intranasal steroid sprays by healthcare workers
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30	27	Kaywords: Intranasal corticostaroid sprays, allergic rhinitis, administration techniques, quality of
38	27	A subjustice in the state and second sprays, and give ministration techniques, quanty of
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1	Abstract
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2	Objectives: Detients with allergic rhinitis receive their information shout administering intronecal
3	Objectives. Patients with anergic minuts receive their miorination about administering intranasar
4	corticosteroid sprays (INCS) from healthcare workers. Since the majority of patients do not
5	administer these sprays correctly, we investigated whether healthcare workers know how to
6	administer INCS.
7	Settings: we studied participants at their working place: pharmacy outpatient clinic, or general
, o	prostitioner centre for emergencies
0	practitioner centre for entergencies
9	Participants: pharmacist assistants, general practitioners, paediatricians, and ear nose throat doctors.
10	Design: observational study
11	Primary outcome: number of steps of administration of INCS, based on the established INCS protocol
12	Secondary outcome: number of the five steps that are labelled essential to obtain optimal distribution
13	of the medication All the participants demonstrated the administration technique with a spray device
13	of the medication. An the participants demonstrated the administration teeninque with a spray device
14	filled with water.
15	Results: Among the 75 participants, none performed all the steps correctly. The median of correctly
16	performed steps in the protocol was 14 out of 29. A significantly better result was found among the
17	pharmacist assistants. The essential steps were performed by 27 out of the 75 participants (36%).
18	Conclusion: The majority of healthcare workers do not know how to administer INCS correctly
10	Detients could therefore receive incorrect and non uniform instructions. The education of healthcore
19	Patients could, meretore, receive incorrect and non-uniform instructions. The education of nearmcare
20	workers on how to administer INCS correctly may be an option for improvement
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24	Strengths and limitations of this study
24	Strengths and minitations of this study
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27	This is the first study to observe healthcare workers administering INCS.
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29	We conducted this study in a small research group consisting of 75 healthcare workers
20	We conducted this study in a small research group, consisting of 75 neutricate workers.
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31	The administration technique was scored in a simple and robust way by the same investigator.
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33	We used a protocol for correct administration based on literature and patient information leaflets,
34	however, not all steps are based on firm scientific evidence.
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#### 1 Introduction

- 2 Allergic rhinitis is a common chronic disease, with a prevalence ranging from 10 to 40% worldwide.<sup>1</sup>
- 3 The disease mostly affects people between 5 and 45 years old, with a peak incidence between 19 and
- 4 24 years old.<sup>2</sup> In addition to allergen avoidance, the management of allergic rhinitis consists of either
- <sup>8</sup> 5 antihistamines, intranasal corticosteroids or a combination of both.<sup>3-4</sup> When persistent symptoms
- 6 occur, intranasal corticosteroid sprays (INCS) are the treatment of choice.<sup>5-6</sup>
- 11 7 Studies suggest that the administration technique for INCS is associated with efficacy, adverse events
- 12 8 and compliance.<sup>4,7</sup> For example, it was found that the optimal administration technique of INCS is 13 9 arraying with a controlatoral spray technique, pointing the pozzle away from the control because
- 13 9 spraying with a contralateral spray technique, pointing the nozzle away from the septum, because
- 10 spraying towards the septum causes more nosebleeds than the recommended approach.<sup>7-9</sup>
- 16 11 Furthermore, the head should be kept in a neutral position, and it is important to breathe in calmly
- 17 12 while spraying. This technique provides the best distribution of the medication. $^{10-12}$
- <sup>18</sup> 13 In a recent study, we observed the method of administration among patients and found that most <sup>19</sup> 14 (04%) did not take their INCS as described in the notion is formation leaflate (DL a) <sup>13</sup> Management
- 19 14 (94%) did not take their INCS as described in the patient information leaflets (PILs).<sup>13</sup> Moreover, the
- 15 available PILs are currently incomplete and non-uniform.<sup>14</sup> Since patients do not only learn from
- PILs, but can also be instructed by healthcare workers, we wanted to know whether such they could
- demonstrate the administration of INCS correctly. As far as we know, this factor has never previously
   been studied. Therefore, we investigated the knowledge of healthcare workers regarding.
- 24 18 been studied. Therefore, we investigated the knowledge of healthcare workers regarding
   25 19 administering INCS.
- 26 27

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#### 28 21 Material and methods

- 29 22 Participants and setting
- We performed an observational study in the northern part of the Netherlands. The healthcare workers
- 32 24 observed included pharmacist assistants, general practitioners, paediatricians, and ENT physicians.
- Healthcare workers were excluded if they had been practising their profession for less than a year.
   Readistrigions and ENT physicians from eight hospitals were approached via smail. We approached
  - 26 Paediatricians and ENT physicians from eight hospitals were approached via email. We approached
- <sup>35</sup><sub>36</sub> 27 pharmacist assistants from six pharmacies. General practitioners were approached while working at
- the general practitioner centre for emergencies based at the Medical Centre Leeuwarden.
- 38 29 Study design
- 39 30 When eligible healthcare workers agreed to participate, a face-to-face interview was conducted. All
- 40 31 the participants were aware of the aim of the study. To prevent inter-observer variation, all interviews
- and observations were performed by the same researcher (MdB).
- $\frac{1}{43}$  33 During the interviews, the healthcare workers answered a questionnaire containing questions about
- their experiences prescribing INCS and about how they provide patients with information. Then, the
- 45 35 healthcare workers were asked to demonstrate the administration technique with a spray device filled
- 46 36 with water. The stages assessed were preparation, administration and cleaning of the INCS [Table 1].
- Assessment of the administration technique was based on the established Dutch INCS protocol.
- 38 During administration, this protocol was used as a scoring sheet, consisting of 29 steps. One point was
- 39 given each time the participant performed a step correctly. In the INCS protocol, five steps are
   40 labelled as essential <sup>14</sup> These steps are considered as essential because they most influence the
- 40 labelled as essential.<sup>14</sup> These steps are considered as essential because they most influence the
   41 distribution and efficacy of the medication. The essential steps include shaking the bottle, blowing or
- $\frac{1}{53}$   $\frac{1}{54}$   $\frac{1}{54}$   $\frac{1}{54}$  rinsing the nose, directing the nebuliser away from the nasal septum, breathing in while
- 54 42 Finsing the nose, directing the neounser away from the nasal septum, oreath
  55 43 simultaneously squirting a spray of mist, and exhaling through the mouth.
- 56

- 57 45 Statistical analysis
- $\frac{58}{59}$  46 In the statistical analysis, descriptive statistics were used to answer the question of whether healthcare
- 47 workers know how to administer INCS. For the comparison of outcomes between populations, a

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1 Kruskal Wallis test was used. Post hoc analysis was performed using a Mann Whitney U test. The

- regional medical ethics committee approved the study protocol. All the participants provided writtenconsent.
- 5 Patient and Public Involvement
- 6 Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination
- 7 plans of our research.

#### 9 Results

In the period between June 11<sup>th</sup> and December 18<sup>th</sup>, 2019, ten ENT-departments, seven paediatrician departments and eight pharmacies were asked to participate in this study. General practioners were approached at the GP's emergency centre and asked to participate on the spot. 75 healthcare workers participated in our study [Table 2], none of whom performed all the steps correctly. The median of correctly performed steps in the protocol was 14 out of 29, with a range between 9 and 24 and an interquartile range of 3.5. For preparing the spray, the median was six out of seven steps. The median for administering the spray was eight out of 10 steps, and the median for cleaning the spray was one out of 10 steps. The points for attention, which are taking the spray to the pharmacy when it does not work and checking the expiry date, were not performed by most participants [Figure 1]. When analysing the differences in total score between the healthcare workers, a significantly higher result was found among pharmacist assistants compared with the other groups [Table 3]. 

- Twenty-seven out of 75 participants (36%) performed all the essential steps. Of the essential steps,
  nose-blowing was performed least frequently, being carried out 46 out of 75 times (61%). Inhaling
  while squirting a spray of mist into the open nostril was performed most often: 69 out of 75 times
  Shaking the bottle was done 61 times (81%). The nozzle was directed outwards 66 times
- 32 24 (92%). Shaking the bottle was done of times (81%). The hozzle was directed butw
   33 25 (88%). Exhaling through the mouth was done by 57 participants (76%) [Table 4].

Sixteen participants (21%) performed all the preparation steps. The least performed steps during preparation were activating the nozzle by spraying in the air (59%) and blowing or rinsing the nose (61%). Two participants (3%) performed all the administration steps. Squirting the spray while breathing in (92%) and pointing the nozzle outwards (88%) were performed by most participants. The most frequent errors in administration were, in order, keeping the other nostril closed, spraying crosswise and keeping the head upright. These steps were performed 33 times (44%), 43 times (47%) and 49 times (65%), respectively. One participant (1%) performed all the cleaning steps, including cleaning the nozzle with a tissue and extensively cleaning the nozzle with water once a week and allowing it to air dry. Approximately half the participants (38; 51%) cleaned the spray with a tissue after every use [Table 4]. 

#### 37 Discussion

In this study we found that most healthcare workers involved in the care for patients with allergic rhinitis did not know and could not demonstrate how to administer INCS correctly. None of the healthcare workers performed all the steps of the checklist correctly. The median of the 75 participants was 14 out of 29 well-executed steps. The five essential steps were correctly performed by 27 out of 75 participants (36%). We found that the pharmacist assistants administered the INCS significantly better than the other healthcare workers, suggesting that pharmacist assistants are most suitable for providing information about INCS. To the best of our knowledge, the role of healthcare workers in informing patients about the correct administration of INCS has never previously been studied. One recent study found that face-to-face instruction, consisting of both verbal information and a physical demonstration, was most effective in 

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teaching the correct technique for asthma medication.<sup>15</sup> This finding may apply regarding the correct usage of INCS as well, meaning that it is important that healthcare workers have sufficient knowledge. Knowledge about inhaler technique for asthma and chronic obstructive pulmonary disease (COPD) has been researched using healthcare workers. These studies reveal similar results to ours; that is, inadequate knowledge regarding the use of inhalers.<sup>16-17</sup> A recent study found only 12% of healthcare workers knew at least three essential steps of the correct metered-dose inhaler technique, and none of the participants performed all the steps correctly.<sup>18</sup> For the checklist, we used a standardised protocol recently published in Dutch healthcare. Although this protocol is based on existing literature, a few instruction steps are only marginally substantiated by research data, and we needed to make a few assumptions about the best spray technique [Table 5]. First, an essential step while preparing for administration is blowing or rinsing the nose. This step is recommended in the literature, although no significantly better distribution of the active substance was found.<sup>19</sup> Approximately 60% of the participants performed this step. Next, it was found that an upright position of the head while spraying proved most effective.<sup>10,20</sup> Bending the head backwards can result in the active substance leaking into the pharynx, causing irritation and possibly more systemic uptake. When bending the head forward, the active substance could easily run out again. However, 45% of the ENT doctors and 10 to 20% of the paediatricians, general practitioners and pharmacist assistants bent their heads forward while breathing in the spray. Their reasoning was that the nasal cavity runs backwards, causing the spray to be sprayed towards the nasal cavity when the head is bent forward. There is a study that confirms this theory.<sup>12</sup> However, when administering the nasal spray, the nozzle should be directed away from the nasal septum to prevent nose bleeding and septum perforation. Furthermore, the lateral nasal wall has more cilia than the medial wall, so the distribution of the active substance is better.<sup>7,9</sup> We found that this essential step was performed correctly by 88% of the participants. It is also advised to use the contralateral hand while spraying, because this causes less mechanical irritation, and, thus, fewer side effects and better compliance.<sup>7</sup> Approximately half the participants (57%) performed this step. However, not all these participants recommended this step to their patients, because it is relatively complicated to perform. Another essential step is to breathe in slowly during administration, because the airflow ensures a better contribution of the active substance. A continuous, slow flow has the best effect. Breathing hard or sniffing can lead to increased turbulence in the nose, which can cause the active substance to finish in the pharynx.<sup>11,21</sup> This was the best performed essential step: 92% of participants performed this correctly. Only one participant stated that the nasal spray should be completely cleaned with water once a week. Since these nasal sprays are used chronically and daily in many cases, good hygiene is important. However, there is no uniform instruction for cleaning the nasal spray in the package leaflets. This lack is a possible explanation why the healthcare workers did not mention this aspect. Considering that there is little substantiated research about the correct administration technique, and since the published INCS protocol is not widely known, healthcare providers apparently provide instructions according to their own insights. Further research is necessary to substantiate the most effective administration technique for nasal sprays. Currently, it is important to implement the present available instructions to achieve clarity in the instructions for the administration of nasal sprays. Strengths and limitations This study has a couple of limitations. First, we did not know what outcomes to expect, so we chose to conduct this research with a relatively small research group in a particular region.<sup>22</sup> Further research must determine to what extent our results apply to other regions and countries. Second, we could only include 15 ENT doctors despite many attempts and visits to their offices.. Reasons given were that they were too busy or not interested in participating. Nevertheless, we do not think that the

<sup>60</sup> 48 inclusion of five more ENT doctors would affect the outcome significantly. Thirdly, it is possible that

- healthcare workers only agreed to participate in this study when they felt an affinity with the topic. Greater interest might influence the knowledge of a correct administration technique. Healthcare workers with less affinity would possibly score lower. Given the disappointing results of the studied population, this only highlights the fact that the healthcare workers' knowledge about the correct
  - administration technique must improve. Lastly, we studied the knowledge of healthcare workers, not
- the actual instruction patients receive from them.
- The strengths of this study are as follows: since various hospitals, general practices and pharmacies
- were included, the results are a good reflection of the population that both prescribes and informs
- about INCS. All our interviews were conducted by the same researcher, so no inter-observer variation
- occurred. We used a simple scoring system, making the scores less sensitive to errors.
- This research only studied healthcare workers' knowledge of the administration technique. Studying
- whether the knowledge of a healthcare worker ultimately affects the correct spray technique, and,
- thus, the efficacy of INCS in patients, is recommended.

#### Conclusion

- The majority of healthcare workers do not know how to administer an INCS correctly. This lack of
- knowledge may prevent them from being able to provide adequate instructions to their patients. Clear
- arrangements should be made regarding who provides these instructions and what these instructions
- include. Healthcare workers should continually update their knowledge regarding the correct spray
  - technique. The established INCS protocols can be used to address this issue.

review only

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2	We thank the healthcare workers studied for their time and effort in this study.							
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5	This research received no specific grant from any funding agency in the public, commercial or not-							
6	for-profit sectors.							
7								
8	Author contributions							
9	Marielle de Boer was involved in developing the study protocol interviewed the participants							
10	analysed the data and wrote the first draft. Corine Rollema was involved in developing the study							
11	protocol analysing the data and in the process of writing Fric van Roon was involved in developing							
12	the study protocol and the process of writing. Tialling de Vries had the original idea, was involved in							
12	developing the study protocol analysing the data and the process of writing. All authors read the final							
13	version and agree							
15								
15	Conflict of interests							
17	All authors have completed the ICMIE uniform disclosure form at www.icmie.org/coi. disclosure.pdf							
18	and declare: no support from any organisation for the submitted work: no financial relationships with							
10	and declare: no support from any organisation for the submitted work; no financial relationships v any organisations that might have an interest in the submitted work in the previous three years: no							
20	other relationships or activities that could appear to have influenced the submitted work							
20	other relationships of activities that could appear to have influenced the submitted work.							
21	Data statement section							
22	Technical appendix, statistical code, and dataset available from the authors							
23	reeninear appendix, statistical code, and dataset available noin the authors							
27								
25	Figure 1 legend: Median score checklist per stage per group of healthcare workers							
20	rigure riegend. Median score enceknist per stage, per group of neartheare workers							
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20	Deferences							
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1	Discuss nurnose and action of the medication
1. 2	Take off the dust cap
2.	Firmly always the hettle *
3.	Firmly shake the bottle.*
4.	Place forefinger and middle finger on both side
-	the nozzle and place thumb underneath the bottle
5.	Point the nozzle upwards and away from yourse
6.	Squirt a few sprays into the air until you see a c of mist.
7.	Blow the nose or rinse the nose with saline if the
<b>L</b> A	
Adr	ninistration
8.	the nozzle and place thumb underneath the bottle
9.	A. Keep the head upright and place the nozzle i
	B Use the right hand for anraying in the laft no
	and the left hand for spraying in the right nostril.
10.	Point the end of the nozzle slightly outwards, a
	from the centre ridge of the nose.*
11.	Close the other nostril with your opposite hand.
12	Sauirt a spray of mist in the nose while breathing
13	Rreathe out through the mouth *
14	Repeat steps 8 through 13 for the other postril
15	If two sprays per postril are prescribed repeat ste
15.	through 14 for both postrils
16	Penlace the dust can
10. Cla	Replace the dust cap.
17	Wine the neggle with a tissue or handkershief
17.	whe the hozzle with a tissue of handkerchief
10	Every use.
18.	Extensively wash the hozzle office a week.
19.	Take off the dust cap and nozzle.
20.	Kinse the dust cap and nozzle with warm water.
21.	Shake off water.
22.	Air dry the dust cap and nozzle.
23.	Replace the nozzle.
24.	Firmly shake the bottle.
25.	Squirt a few sprays into the air until you see a c
	of mist.
26.	Replace the dust cap.
Poir	nts for attention
27.	If the nozzle does not spray properly, perform
	cleaning steps. If this does not work, take the spra
	the pharmacy. Never puncture the opening.
28.	Check the expiry date on the package and the exp
	date after opening.
* F 6	scential stens

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Variable	Overall (n = 75)
Healthcare worker, n (%)	
Pharmacist assistant	20 (26)
General practitioner	20 (26)
Paediatrician	20 (26)
ENT physician	15 (20)
Gender, n (%)	
Male	27 (36)
Female	48 (64)
Age (mean), range (95% C	CI)
	45.2 ±11
Years of professional prac	ctice, n (%)
1-5 years	18 (24)
5-10 years	12 (16)
10-20 years	22 (29)
> 20 years	23 (31)
Number of INCS prescrip	tions per week. n (%)
0 times	20 (27)
< 1 time	19 (25)
1 - 4 times	17 (23)
4 - 8 times	5(7)
> 8  times	$\frac{3(7)}{14(19)}$
Number of INCS instructi	(1)
< 1 time	24 (32)
1 - 4 times	$\frac{27(32)}{27(36)}$
1 - 8 times	$\frac{27(30)}{9(12)}$
$\sim 9 \text{ times}$	$\frac{15(2)}{15(2)}$
Number of checks on INC	S inhalations par wook n
(%)	S minatations per week, in
< 1 time	62 (83)
1 - 4 times	15 (14)
4 - 8 times	2 (3)
> 8  times	$\frac{2}{0}$ (0)
Use of information materi	al. n (%)
Yes	19 (25)
No	56 (75)
110	50(75)

Table 3. Difference in total score checklist								
Healthcare worker	N	Median	Mean	Mean rank	P-value between groups*			
Pharmacist assistant	20	16	16,2	54.58ª	0.001			
General practitioner	20	13,5	13,3	30.98				
Paediatrician	20	14	13,8	34.85				
ENT	15	12	13,1	29.47				

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Tested using Kruskal-Wallis test (post hoc Mann-Whitney U) P < 0.05. a Significant difference compared with general practitioners, paediatricians and ENT physicians.

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Fabl	e 4. Number of well-executed steps protocol		
Pre	paration	n (%)	
1.	Discuss purpose and action of the medication.	75 (100)	
2.	Take off the dust cap.	75 (100)	
3.	Firmly shake the bottle.*	61 (81)	
4.	Place forefinger and middle finger on both	58 (77)	
	sides of the nozzle and place thumb	× /	
	underneath the bottle.		
5.	Point the nozzle upwards and away from	44 (59)	
	yourself.		
6.	Squirt a few sprays into the air until you see	44 (59)	
7	Play the pass or rings the pass with saling if	46 (61)	
/.	blow the nose of time the nose with saline if the nose is clogged *	40 (01)	
A di	ministration	n (%)	
Au	Disco forefinger and middle forger on both	<u>II (70)</u>	1
δ.	sides of the nozzle and place thumb	60 (80)	
9.	A. Keep the head upright and place the nozzle in the nose.	49 (65)	
	B. Use the right hand for spraying in the left nostril, and the left hand for spraying in the right nostril.	43 (57)	
10.	Point the end of the nozzle slightly outwards, away from the centre ridge of the nose *	66 (88)	
11.	Close the other nostril with your opposite	33 (44)	
12.	Squirt a spray of mist in the nose while	69 (92)	
12	Dreatha out through the mouth *	57 (76)	
1). 11	Dependent out intrough the mouth.	75 (100)	
14.	nostril	75 (100)	
15.	If two sprays per nostril are prescribed, repeat	75 (100)	•
	steps 11 through 16 for both nostrils.		
16.	Replace the dust cap.	75 (100)	
Cle	aning	n (%)	
17.	Wipe the nozzle with a tissue or handkerchief	38 (51)	
	after every use.		
18.	Extensively wash the nozzle once a week:	1(1)	4
19.	Take off the dust cap and nozzle.	1 (1)	
20.	Rinse the dust cap and nozzle with warm water.	4 (6)	
21.	Shake off water.	1(1)	
22.	Air dry the dust cap and nozzle.	1 (1)	
23.	Replace the nozzle.	1(1)	
24.	Firmly shake the bottle.	1(1)	
25	Squirt a few sprays into the air until you see	1(1)	
	a cloud of mist.	<b>N P</b>	
26	Replace the dust cap	1(1)	
<u></u> Pni	nts for attention	n (%)	
27.	If the nozzle does not spray properly, perform the cleaning steps. If this does not work take	n (70)	
	the spray to the pharmacy Never nuncture the		
	opening.	13 (17)	
28	Check the expiry date on the nackage and the		
<u>_</u> 0.	expiry date after opening	11 (15)	
* F	ssential stens	(15)	
$\mathbf{L}$	sommer stops		

ble 4. Number of well-executed steps protoco	ol
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3	Table 5. Scientifically and non	n-scientifically based steps in the	
4	corticosteroid nasal spray pro	tocol	
5	Scientifically based steps	Non-scientifically based steps	
6	- Blow the nose of finse the nose with saline if	- Firmly snake the bottle.	
7	the nose is clogged $^{19}$	air until you see a cloud of	
8	- Keep the head	mist.	
9	upright. <sup>10,20</sup>	- Close the other nostril with	
10	- Use the right hand for	your opposite hand.	
11	spraying in the left	- Breathe out through the	
12	nostril, and the left hand	mouth.	
13	for spraying in the right	- wipe the nozzle with a tissue or handkerchief after	
14	<ul> <li>Point the end of the</li> </ul>	every use	
15	nozzle slightly outwards.	- Extensively wash the	
16	away from the centre	nozzle once a week.	
17	ridge of the nose.		
18	- Squirt a spray of mist in		
19	the nose while breathing		
20	<u>in.</u>		-
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#### Figure 1. Median score checklist per stage, per group of healthcare workers



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### Reporting checklist for cross sectional study.

		Reporting Item	Page Number
Title and abstract			
Title	<u>#1a</u>	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	<u>#1b</u>	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	<u>#2</u>	Explain the scientific background and rationale for the investigation being reported	3
Objectives	<u>#3</u>	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	<u>#4</u>	Present key elements of study design early in the paper	3
Setting	<u>#5</u>	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Eligibility criteria	<u>#6a</u>	Give the eligibility criteria, and the sources and methods of selection of participants.	3
	<u>#7</u>	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3
Data sources / measurement	<u>#8</u>	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for exposed and unexposed groups if applicable.	3
Bias	<u>#9</u>	Describe any efforts to address potential sources of bias	3
Study size	<u>#10</u>	Explain how the study size was arrived at	3

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Quantitative variables	<u>#11</u>	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	3
Statistical methods	<u>#12a</u>	Describe all statistical methods, including those used to control for confounding	3
Statistical methods	<u>#12b</u>	Describe any methods used to examine subgroups and interactions	3
Statistical methods	<u>#12c</u>	Explain how missing data were addressed	3
Statistical methods	<u>#12d</u>	If applicable, describe analytical methods taking account of sampling strategy	3
Statistical methods	<u>#12e</u>	Describe any sensitivity analyses	3
Results			
Participants	<u>#13a</u>	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for exposed and unexposed groups if applicable.	4
Participants	<u>#13b</u>	Give reasons for non-participation at each stage	4
Participants	<u>#13c</u>	Consider use of a flow diagram	
Descriptive data	<u>#14a</u>	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	4
Descriptive data	<u>#14b</u>	Indicate number of participants with missing data for each variable of interest	4
Outcome data	<u>#15</u>	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	4
Main results	<u>#16a</u>	Give unadjusted estimates and, if applicable, confounder- adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	4

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Main results	<u>#16b</u>	Report category boundaries when continuous variables were categorized	4
Main results	<u>#16c</u>	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	4
Other analyses	<u>#17</u>	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	4
Discussion			
Key results	<u>#18</u>	Summarise key results with reference to study objectives	4
Limitations	<u>#19</u>	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	5
Interpretation	<u>#20</u>	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	5
Generalisability	<u>#21</u>	Discuss the generalisability (external validity) of the study results	5
Other Information			
Funding	<u>#22</u>	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	7

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