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Validation of the Olfactory Disorders Questionnaire for English-speaking Patients with Olfactory Disorders

Authorship

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Conflict of Interest Statement

Professor Philpott is Director of Research and Medical Affairs on the board of trustees for the charity Fifth Sense.

Duncan Boak is the Founder and Chair of the charity Fifth Sense.

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Running title : Validation of ODQ for English speaking patients

Original contribution

Abstract

Objectives

1. To adapt the existing German language olfactory disorders questionnaire for use with English-speaking patients
2. To validate the adapted version for routine clinical use

Design

The translated version of the original German questionnaire was revised with a patient and a clinician to reflect British language and culture. Patients attending an olfactory dysfunction clinic were recruited to perform the adapted questionnaire on two occasions at least one month apart. Additional online participants completed the questionnaire via the charity Fifth Sense.

Main outcome measures

- Re-test reliability of the English olfactory disorders questionnaire (eODQ) in affected patients including potential for redundancy in any of the included questions
- Correlation of eODQ scores with Sniffin' Sticks scores

Results

Eighty-seven patients reporting olfactory dysfunction were recruited and had a mean age of 48 with 35% of them being male; 50 datasets were available for analysis. A total of 957 members of the charity entered responses into the online questionnaire; 699 responses could be scored with participants' mean age of 55 years and with 69% reporting as female. The eODQ score and Sniffin' Sticks TDI score at timepoint 1 were correlated to assess for

concurrent validity, (r=-0.15, p=0.17) and showed no significant correlation. Female participants had a significantly higher mean total eODQ score than men, 55.75 compared to 52.28 (p=0.001). The average score was 54.7 (SD 13.5) with a range from 26 to 87. The internal consistency of the questionnaire was good with a Cronbach's alpha of 0.90 (Confidence intervals 0.89, 0.91).

Conclusions

The results of this study support the use of the eODQ in a native English-speaking population and highlight the different distinctions between "objective" testing of olfaction with the Sniffin' Sticks test and the patient reported impact of olfactory dysfunction on daily life. These two types of assessment can be easily administered in an outpatient setting and used in the assessment and management of olfactory dysfunction.

Background

Olfactory loss is an invisible condition with a prevalence in many studies estimated to vary from 1-20% [1-4], with the higher figures probably representing older patient populations [5], and with a recent study suggesting a distribution of 1-5% with anosmia[4] and as high as 50% with hyposmia[6]. The lower figures do not include those who are unaware of their reduced olfactory capacity. Primary causes of olfactory loss include sinonasal disease (62%) and post-viral olfactory loss (11%) [7] and other causes including head trauma and neurological disease.

The sense of smell is an important and yet under-rated sense that many only appreciate once without it. It underwrites our interaction with the world in a mostly subconscious way but key overt usage is seen in the detection of danger such as a gas leak or spoiled food and

in those whose professions depend upon it such as firemen, chefs etc. It is also an important part of flavour perception, without which much of the pleasure of eating is gone. The spectrum of quality of life impact from olfactory disorders, is however, much broader with anxiety, depression and isolation common sequelae[8]. The importance of carefully evaluating olfactory disorders has gained more recognition with the publication of the Position Paper of Olfactory Dysfunction[9]. This emphasises the need to evaluate patients' olfactory performance beyond subjective reporting.

However, psychophysical smell testing may not give additional insight into the impact of an olfactory disorder to the individual. A Questionnaire of Olfactory Disorders created by Frasnelli et al. in Germany was the first questionnaire that specifically addressed olfactory dysfunction and its daily life impact, consisting of statements of different domains of daily life that could be rated[10]. Several studies have now utilised this questionnaire[11-14] but it has yet to be validated in native English speaking participants.

Aims and objectives

This study aims to validate the Olfactory Disorders Questionnaire (ODQ) for English-speaking subjects (eODQ).

Primary objective:

- To assess the test-retest reliability of the adapted eODQ

Secondary objectives:

- To correlate quality of life impairment with psychophysical testing of olfaction
- To assess the impact of patient contact (+/- intervention) on eODQ scores

Methods and Materials

Ethical Considerations and Funding

Ethical approval for the study was obtained from East of England - Cambridge East Research Ethics Committee (ref 14/EE/1010). The study was funded by a pump priming grant from the Otorhinolaryngological Research Society (now known as the British Otorhinolaryngology & Allied sciences Research Society (BOARS; www.entuk.org/about-boars). It received Clinical Research Network support from the National Institute of Health Research (CPMS ID: 16895).

Settings

The study was conducted in a tertiary care setting at the James Paget University Hospital and the Ipswich Hospital in East Anglia in the UK. It was also conducted online through membership of the patient support charity, Fifth Sense (www.fifthsense.org.uk), which was established in 2012 in the UK (Registered charity number 1175553.) The study was open between February 2014 and June 2015; however the final data capture point for online participants was 1st August 2017.

Study design

The original questionnaire (appendix 1) was anglicised by Philpott (clinician) and Boak (affected by olfactory disorder) to make it more culturally suited to native English speakers in the UK (see appendix 2). The questionnaire includes 24 questions (QoL score) assessing the respondent's quality of life by asking them to rank their response with one of the following options: Agree, Agree partly, Disagree partly, Disagree, I think this question has no value, I don't understand the question. The latter two response choices were added for validation purposes. Additional questions were added to rate symptoms (quantitative rating

score) and quality of life impact (QoL rating) using visual analogue scores giving a total maximum score out of 180.

Phase 1

As part of a larger study that included validation of the Sniffin' Sticks for British subjects[15], patients attending the Smell & Taste Clinic at the James Paget University Hospital and also at the Ipswich Hospital ENT Department who presented for routine clinical assessment with olfactory disorders were asked to participate in the study. Patient information leaflets were posted along with their appointment letter for the clinic. Previous clinic visitors were also invited by making the consent form available through the patient support charity Fifth Sense's website (www.fifthsense.org.uk/research). Participants in this setting also underwent psychophysical olfactory testing with the Sniffin' Sticks test. The "Sniffin' Sticks" test uses pen-like odour dispensing devices to test odour threshold, odour discrimination and odour identification to produce a composite "TDI" score[16].

Phase 2

The core questionnaire was also incorporated into a survey of members of Fifth Sense. The survey was designed to evaluate the severity of depression, anxiety, impairment of eating experiences, isolation, and relationship difficulties[8]. New members joining Fifth Sense were invited to complete an online anonymous survey regarding their quality of life with their disorder that included the adapted eODQ.

Since the questionnaire was introduced to members, an additional free text question was subsequently added, asking respondents to name the cause of their olfactory loss; however

this information was not available for all online participants. No identifiable data was requested and as the survey was not conducted through an NHS or academic outlet, no ethical approval was sought for this specific component.

Participants

Inclusion criteria:

- Subjects aged 18 years or over
- Outpatient setting: Any patient reporting an olfactory disorder regardless of cause
- Online setting: Any member of Fifth Sense self-reporting an olfactory disorder

Exclusion criteria:

- Subjects that did not understand the English language

Variables

For all hospital participants, data was recorded of their TDI scores for the extended Sniffin' Sticks test along with their demographics and diagnosis and whether they had received any treatment between visits. Second clinic visits in phase 1 coincided with follow up clinic appointments.

Data sources/management

To record the results of the Sniffin' Sticks test, the free "olaf" software download available from the Dresden Smell & Taste Clinic was used [10]. Electronic health records were used to confirm details of the diagnosis.

Sample Size

No formal sample size calculation was made for the purposes of the study, however an indicative target of 100 patients with olfactory disorders from the clinics was set out at the

beginning of the study. With the online participants joining continuously during the study duration, a recent snapshot of data collected was taken to reflect active members of the charity.

Statistical Methods

Results were logged to a secure database and analysed with Stata/SE 14 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, Texas: StataCorp LP). The questionnaires were scored and before and after treatment comparisons made using t-tests. The internal consistency of eODQ was assessed using Cronbach's alpha.

Results

Participants and descriptive data

Phase 1. Hospital participants

Eighty-seven patients reporting olfactory dysfunction were recruited from the two participating clinics and had a mean age of 47.5 (SD = 12.7) years with 35% of them being male. The aetiology of the 87 participants is characterised in table 1 and due to the nature of the wide geographic area from which participants came, the time interval between appointments varied between 3 and 12 months.

Phase 2. Online participants

A total of 957 members of Fifth Sense entered responses into the online questionnaire. The respondents had an average age of 54.7 years (SD 13.0) ranging from 18 to 95 years old; 481 (68.8%) were female. Table 1 also shows the self-reported diagnoses of the respondents.

Outcome data

A total of 86 hospital participants completed the eODQ scores on the first visit compared to 66 on the second; a total of 50 people had observations at both time points. Of the total 957 online responses, a total of 699 could be scored. The attrition was due to partially completed questionnaires or use of the 2 alternative responses ("*I think this question has no value", "I don't understand the question"*). In terms of aetiology, 425 participants self-reported their presumed/confirmed diagnosis.

Main Results

Hospital participants (phase 1)

Table 2 characterises the results for the 50 outpatient participants. This shows significant variation between visits. It was decided that breaking the data down into subgroups based on treatment or condition would not be appropriate due to the small sample size. When restricted to only individuals with no recorded treatment the same pattern remained. Table 3 presents agreement measures between the timepoint and also restricted to only those on no treatment, these show poor agreement in the total quantitative score, total QoL rating score, and overall total, but reasonable agreement in the eODQ scores. The results do not depend greatly on the inclusion or exclusion of people on treatment.

The eODQ score and Sniffin' Sticks TDI score at timepoint 1 were correlated to assess for concurrent validity, (r=-0.15, p=0.17, table 4). These show no significant correlation between the two measures indicating that they are measuring something different. However, table 5 shows the correlation between the ***change*** in ODQ and the ***change*** in TDI components: there is a significant association between change in ODQ and discrimination, between TDI and its component scores and between threshold and discrimination. There

was no association between change in ODQ and change in total TDI score, change in threshold or change in identification. The association between change in ODQ and change in discrimination is shown graphically in Figure 1.

Online participants (phase 2)

Female participants had a significantly higher mean total ODQ score than men, 55.75 compared to 52.28 (p=0.001) (Figure 2). The average score for all participants was 54.7 (13.5) with a range from 26 to 87. The internal consistency of the questionnaire was good with a Cronbach's alpha of 0.90 (Confidence Intervals 0.89, 0.91). The distribution of ODQ scores with age is shown in Figure 3 which showed no evidence of a correlation (r = - 0.06, p=0.12). In terms of question validity, 3 questions were identified with the highest responses for "I think this question has no value" or "I don't understand this question" as demonstrated in Figure 4.

- Q2: *"My biggest problem is not that odours are less intense (or absent), but that things smell different from the way they used to"* - 105 participants did not value this question (11%)
- Q5: "*Food tastes different from what it used to"* – 100 participants did not value this question (10%)
- Q14: "*Sometimes I have thoughts and ideas I would not want other people to know of"* – 115 participants did not value this question (12%) and 43 did not understand this question (4%)
- Levels of apparent lack of understanding of questions were less than 2% with the exception of question 14.

The most well received question was Q4: *"It reduces my appreciation of food and drink"* where only 12 participants felt the question had no value and none of the participants failed to understand the question.

Discussion

Key Results

Phase 1:

Hospital participants completing the eODQ at the second visit in the clinic, reported a lower mean total eODQ score (p=0.0015). This suggests an improved score in those being seen back in the clinic, whether there had been any treatment instituted between visits or not. This reduction in score persists when those participants that did not undergo treatment between visits are analysed separately, p=0.0289. This suggests either spontaneous recovery has occurred or that the impact of visiting an olfactory dysfunction clinic can in itself change reported quality of life in those with olfactory dysfunction symptoms. This is also implied by the results that show poor correlation between Sniffin' Sticks TDI score and the total eODQ score. This lack of correlation between the two tests indicates that they measure two different things and as such are affected by different variables, i.e., the Sniffin' Sticks test is a psychophysical test and the eODQ is a patient reported health-related quality of life (HRQoL) questionnaire. It is notable that when looking at the change in score, discrimination, which is largely determined by higher cognitive influences[17], correlated significantly with a change in the eODQ score.

The difference between subjective and objective olfactory dysfunction has been previously noted and explored. It can be shown that people with hyposmia on objective testing can report normal smell function and people with normal olfactory function on objective testing can have persistent poor QoL socres on questioning[18]. Similarly, people with hyposmia display poorer results on QoL questionnaires compared to people with complete anosmia[19]. This possibly reflects the lack of compensation in daily activates and lack of acceptance in those people with some persistent or fluctuating olfactory function. It should be noted though, that in other studies, a correlation between QoL testing and objective testing has been found. In 2009, Croy et al found a weak correlation between measured olfactory function and rated olfactory function[20]. Gudziol et al found a significant increase in the TDI scores of patients treated for hyposmia who stated their olfaction had improved, compared to those patients in the group who had stated that their olfaction was the same as before treatment[21]. The authors did note that there were some participants in the improved reported olfaction group that actually had a worse TDI score and some in the group that reported no change in olfactory function that had higher TDI scores. This also displays the variation in reported olfactory function and the difference in perceived function or QoL affected by olfactory dysfunction and the measured or objective olfactory function.

Phase 2:

When looking at the online questionnaire results, it can be seen that more women chose to complete the questionnaire than men, which may reflect the self-selecting nature of this group, either women report more olfactory dysfunction, have a higher symptom burden associated with olfactory dysfunction or the incidence in women is higher, which is known to be the case in post-viral olfactory loss. It has been shown before that women achieve higher scores than men in the threshold task of the Sniffin'Sticks test[17] and that women

report a higher consequence of olfactory dysfunction than men[20]. Women have been shown to have lower HRQoL scores than men even after adjusting for age, race, marital status, education and income[22].

There were three questions for which the response "I think this question has no value" was given more frquently by the respondents completing the online questionnaire (figure 4). These questions were "My biggest problem is not that odours are less intense (or absent), but that things smell different from the way they used to", "Food tastes different from what it used to" and "Sometimes I have thoughts and ideas I would not want other people to know of". It may be surprising that a question asking about food elicits this response, however the first two of these questions are specific to parosmia sufferers so those without this distortion will perhaps not appreciate the relevance of them but it is nonetheless important to retain for those with qualitative disturbances. The last question was conceived in the original version as a "lie" question to be able to ascertain the quality of the answers given. Similar issues were noted in the study reported to validate the ODQ in a Korean population. So called sincerity questions were altered to suit a Korean language and culture[11]. Whilst our study does not support removing or altering these questions, it is noted that some respondents find these to be unusual or irrelevant in the subject of olfactory dysfunction, but they are very pertinent to those with qualitative disturbances[23]

Limitations

The second eODQ completed by participants in the clinic, was completed at follow up appointments. The nature of the clinic means that these participants travel to the clinic

from different areas of the country, this has led to variation in the time between both questionnaires being completed. This also led to fewer respondents completing the questionnaire for the second time as they were lost to follow up.

We have not performed separate analysis of results based on diagnosis, treatment or main symptom; the difference in eODQ scores given by those suffering from parosmia or hyposmia is reported elsewhere[9]. For future reference it will be useful to provide a scaling for the test score, categorising the score as mild, moderate or severe. This will require further validation work which is beyond the scope of the data collected here but we will endeavour to undertake this accordingly in a new study.

Generalisability

The use of the eODQ has been shown to successfully assess the impact olfactory dysfunction has on a sufferers quality of life in other populations. We found similar patterns in response and gender bias as other studies[9] and with the measures of consistency we have validated an easily administered questionnaire in an English-speaking population.

Conclusion

The results of this study support the use of the eODQ in a native English-speaking population and highlight the different distinctions between “objective” testing of olfaction with the Sniffin’ Sticks test and the patient reported impact of olfactory dysfunction on daily life. These two types of assessment can be easily administered in an outpatient setting and used in the assessment and management of olfactory dysfunction. Further research may allow for refinement of the questionnaire and stratification of severity into mild, moderate and severe.

List of abbreviations

ODQ – Olfactory disorders questionnaire

eODQ – English ODQ

TDI – threshold, discrimination and identification

QoL – quality of life

Table 1: Aetiology of all participants

Diagnosis	Frequency	Percentage	Frequency	Percentage
CRS and subtypes	25	29%	58	14%
Post-viral olfactory loss (PVOL)	18	21%	119	28%
Idiopathic	13	15%	78	18%
Post-traumatic olfactory loss (PTOL)	9	10%	82	19%
Congenital	9	10%	25	6%
Olfactory Cleft Disease	6	7%	-	-
Iatrogenic	3	3%	16	4%
Nasal septal deviation	2	2%	6	1%
Neoplasia	-	-	10	2%
Parkinson's Disease	-	-	15	4%
Neurological	-	-	5	1%
Diabetes	-	-	1	0.2%
Granulomatosis with polyangiitis (GPA)			2	0.4%
Presbyosmia			3	1%
Toxic Rhinitis			5	1%
other	2	2%		

Table 2: Summary of differences between study visits in individuals with data at both timepoints.

All subjects (n=50)	**Visit 1**	**Visit 2**	
Outcome	Mean (SD)	Mean (SD)	P-value
Total QoL question score	54.18 (14.32)	49.30 (16.18)	**0.0033**
Total quantitative score	17.10 (6.08)	14.34 (6.25)	**0.0052**
Total QoL rating score	25.12 (10.01)	21.42 (13.66)	**0.0414**
Total	96.40 (23.34)	85.06 (31.40)	**0.0015**
Subjects with no treatment recorded (n=26)			
Total QoL question score	50.92 (13.01)	46.92 (16.18)	**0.0345**
Total quantitative score	17.46 (5.37)	13.54 (6.69)	**0.0059**
Total QoL rating score	23.77 (10.21)	19.85 (14.16)	0.1501
Total	92.15 (22.76)	80.31 (33.39)	**0.0289**

Table 3: Measures of concordance/agreement between timepoints based on individuals who have data at both timepoints.

Outcomes	Lin Concordance (confidence intervals)	ICC (confidence intervals)
All subjects		
Total QoL question score	0.70 (0.56,0.83)	0.68 (0.54,0.77)
Total quantitative score	0.38 (0.16,0.60)	0.38 (0.21,0.54)
Total QoL rating score	0.44 (0.29,0.64)	0.41 (0.24,0.56)
Total	0.58 (0.41,0.74)	0.56 (0.40,0.69)
Subjects with no treatment		
Total QoL question score	0.78 (0.63,0.92)	0.77 (0.63,0.86)
Total quantitative score	0.33 (0.04,0.62)	0.39 (0.15,0.59)
Total QoL rating score	0.38 (0.08,0.69)	0.40 (0.16,0.60)
Total	0.54 (0.30,0.78)	0.56 (0.34,0.71)

Table 4: Correlation between TDI score and ODQ in hospital participants.

Outcome	Spearman correlation	p-value
Total QoL question score	-0.12	0.28
Total quantitative score	-0.09	0.43
Total QoL rating score	-0.18	0.10
Total	-0.15	0.17

Table 5: Spearman Correlation between ODQ and TDI in hospital participants. Cells are correlation (r value) and significance (p-value)

Variable	ODQ	TDI	T	D
TDI	-0.23 (0.12)			
T	-0.03 (0.85)	0.71 (<**0.0001**)		
D	-0.33 (**0.02**)	0.70 (<**0.0001**)	0.44 (**0.0017**)	
I	-0.17 (0.26)	0.55 (**0.0001**)	0.10 (0.49)	0.15 (0.30)

Figures

Figure 1: Correlation between the change in the eODQ scores and change in discrimination scores (hospital participants)

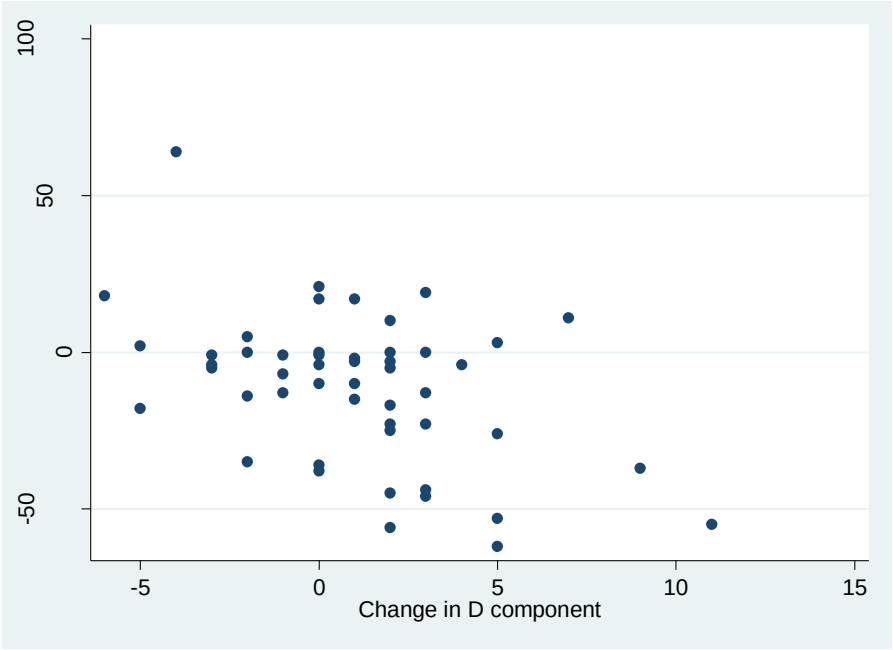


Figure 2: Distribution of ODQ scores by gender (online participants)

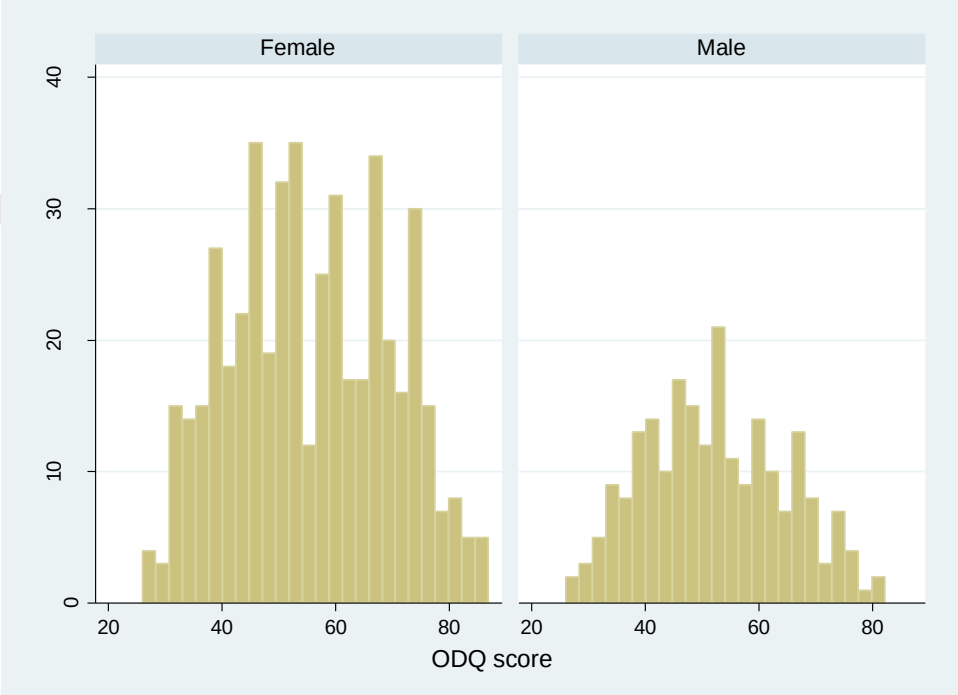


Figure 3: Scatter graph of age against ODQ score (online participants)

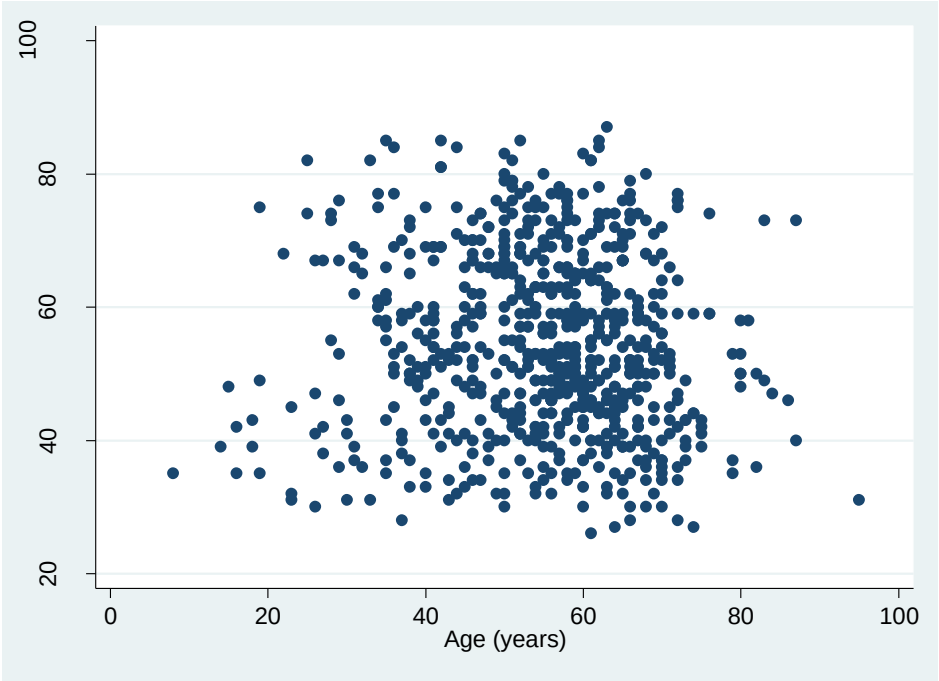
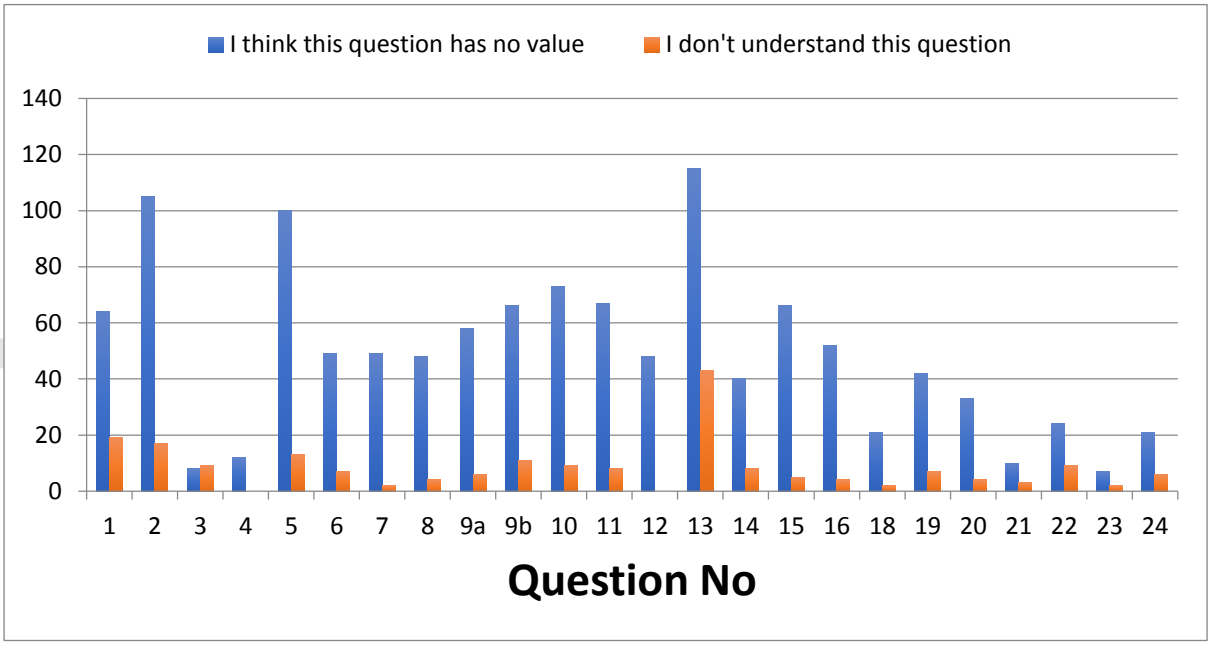


Figure 4: Frequency of responses where participants did not value or understand specific questions



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Appendix 1: Original German version of ODQ in English

Questionnaire for Olfactory Disorders

Schmecken & Riechen

Dresden, January 22nd, 2003

Dear patient,

as part of our diagnostic procedures, we would like to ask you to answer the questions below. To each question, please check one of the following 4 answers: "I agree", "I agree partly", "I disagree partly", and "I disagree".
This questionnaire aims to record your first spontaneous reaction to the questions. This is not a test you may fail or pass. Please make sure not to miss one of the questions!
Thank you for your cooperation!

P1	Food tastes different from what used to.	I agree I agree partly I disagree partly I disagree
P2	Often I perceive a bad smell, regardless whether a potential odor source is present.	I agree I agree partly I disagree partly I disagree
P3	Other people find odors pleasant which are unpleasant to me.	I agree I agree partly I disagree partly I disagree
P5	My biggest problem is not that odors are less intense (or absent), but that things smell different from what they used to.	I agree I agree partly I disagree partly I disagree

Appendix 2: Anglicised Olfactory Disorders Questionnaire (eODQ)

Regarding your smell/taste disturbances:	I agree	I agree partly	I disagree partly	I disagree	I don't understand the question	I think the question has no value
1. Often I perceive a bad smell/taste*, regardless whether a potential odour/taste source is present * delete as appropriate						
2. My biggest problem is not that odours are less intense (or absent), but that things smell different from the way they used to						
3. I am aware of my problem all day long						
4. It reduces my						

appreciation of food and drink						
5. Food tastes different from what it used to						
6. I now eat less than I used to						
7. I now eat less healthily than I used to						
8. I am now more careful about the food I eat						
9. I have gained (G) or lost (L) weight * delete as appropriate	G/L*	G/L*				
10. I go to restaurants less often than I used to						
11. I am wondering if I will ever be able to live with this problem						
12. I am more stressed than I used to be because of this problem						

13. Sometimes I have thoughts and ideas I would not want other people to know of						
14. Most of my problems are due to the difficulties with my sense of smell						
15. I visit friends, relatives, or neighbours less often						
16. I find it harder to relax						
17. I can't imagine adjusting to my difficulties with smelling						
18. The difficulties with my sense of smell make me feel alone and isolated						
19. I avoid groups of people						
20. This problem is just one of the many problems in life one has to live with						

21. I am scared of getting exposed to certain dangers (e.g., gas, rotten food).						
22. I have problems taking part in many of the daily activities of life						
23. The difficulties with smelling make me feel angry and/or frustrated						
24. My relationship with my partner/family/friends is affected by my difficulties with smelling						

		From smell/taste loss?	For other reason?
25. Do you suffer with depression?	Yes		
	No		
26. Do you suffer with	Yes		

anxiety?	No		

27. Please indicate with a circle around the score where you would place your symptoms today:

a. Loss of sense of smell:

No loss 0 1 2 3 4 5 6 7 8 9 10 Total loss (unable to smell)

b. Loss of taste (referring **only** to sensations of salt, sweet, sour and bitter):

No loss 0 1 2 3 4 5 6 7 8 9 10 Total loss (unable to taste)

c. Nasal symptoms:

Normal 0 1 2 3 4 5 6 7 8 9 10 Stuffy, runny, etc

d. Oral symptoms:

Normal 0 1 2 3 4 5 6 7 8 9 10 Sore, dry mouth etc

28. Please use the scale below to rate how **annoying** the difficulties with smelling/tasting are to you.

Not annoying at all 0 1 2 3 4 5 6 7 8 9 10 extremely annoying

29. Please use the scale below to rate how **much** it affects your enjoyment of food.

None of the time 0 1 2 3 4 5 6 7 8 9 10 all the time

30. Please indicate on the scale below how severely the difficulties with smelling/tasting affected your **professional performance** during the last month.

Not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

31. Please indicate on the scale below how severely the difficulties with smelling/tasting affected your **recreational activities** during the last month.

Not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

32. Please indicate on the scale below how severely the difficulties with smelling/tasting affected your **private life** during the last month.

Not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

For doctor to complete:

Total QoL question score	/100
Total quantitative score (27 a+b+c):	/30
Total QoL rating score (28-32):	/50
Total OGDQ score:	/180