BMJ Open

Does the Patient-Reported Apnea Questionnaire (PRAQ) increase patient-centeredness in the daily practice of sleep centers? A mixed-methods study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025963
Article Type:	Research
Date Submitted by the Author:	10-Aug-2018
Complete List of Authors:	Abma, Inger; Radboudumc, IQ healthcare Rovers, Maroeska; Radboudumc, Health Evidence and Operating Rooms IJff, Marijke; ApneuVereniging Hol, Bernard; Albert Schweitzer Ziekenhuis, Sleep centre Nägele, Masha; Radboudumc, IQ healthcare Westert, Gert; Radboudumc, IQ healthcare Van der Wees, Philip; Radboudumc, IQ healthcare
Keywords:	SLEEP MEDICINE, patient-reported outcome measure, obstructive sleep apnea, quality of life, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Does the Patient-Reported Apnea Questionnaire (PRAQ) increase patient-centeredness in the daily practice of sleep centers? A mixed-methods study.

Inger L. Abma, MSc[1], Prof. Maroeska Rovers[2], Marijke IJff[3], Bernard Hol, MD[4], Masha E. Nägele[1], BSc, Prof. Gert P. Westert[1], Prof. Philip J. van der Wees[1]

[1] Radboud University Medical Center, Radboud Institute of Health Sciences, IQ healthcare, Nijmegen, the Netherlands

[2] Radboud University Medical Center, Radboud Institute of Health Sciences, Departments for Health Evidence and Operating Rooms, Nijmegen, The Netherlands

[3] ApneuVereniging, Doorn, The Netherlands

[4] Albert Schweitzer Ziekenhuis, Sleep Center, Dordrecht, The Netherlands

Corresponding author:
I.L. Abma
e-mail: Inger.abma@radboudumc.nl
tel: +31 24 3616359

Addres:
Radboud University Medical Center
IQ healthcare
PO box 9101, huispost 114
6500 HB, Nijmegen

ORCID iDs
I.Abma: 0000-0002-3307-6736
M. Rovers: 0000-0002-3095-170X
G. Westert: 0000-0003-3744-8207
P. van der Wees: 0000-0003-2881-5159

Word count: 4370

Keywords: Obstructive sleep apnea, quality of life, patient-reported outcome measure, patient-centeredness

Abstract

Objectives: The objective of this pilot study was to see how the Patient-Reported Apnea Questionnaire (PRAQ) impacts the daily clinical practice of sleep centers, and why it may or may not work as expected. The hypotheses were tested that this patient-reported outcome measure (PROM) empowers patients, and that it improves patient-centeredness of care by shifting the focus of care away from (only) medical problems towards the individual burden of disease and quality of life.

Design: Mixed methods. The quantitative study (surveys, patient records) was a before-and-after study.

Setting: Three sleep centres in The Netherlands (secondary care).

Participants: 27 patients and 14 healthcare professionals were interviewed. A total of 487 patients completed surveys pre-implementation, and 344 patients completed surveys post-implementation of the PRAQ. For the patient records, 125 patients were included in the pre-implementation group, and 124 other patients in the post-implementation group.

Interventions: the PRAQ was used in clinical practice for six successive months.

Primary and secondary outcome measures: Scores on individual survey items designed for the study, number of patients receiving non-medical treatment, adjustment of treatment at first follow-up, compliance with treatment.

Results: Patients were willing to complete the PRAQ and were generally positive about the usefulness of the PRAQ before and during the consultation. However, amongst healthcare professionals the willingness to make the PRAQ-report part of their consultations differed, and they reported minor impact on their consultations. The surveys and patient record study did not show an impact of the PRAQ on clinical practice.

Conclusions: Implementing the PRAQ may increase patient empowerment, but this study does not show much impact with regard to patient-centeredness of care. New Dutch guidelines for OSA care may lead to a greater emphasis on quality of life and value of care for patients, making its integration in clinical care potentially more useful.

Article summary

Strengths and limitations of this study

- The mixed methods approach of this pilot study is its major strength: the study provides insight into the reasons why the PRAQ does not work as intended
- The patient survey may not have been discriminative enough to show differences between the groups pre- and post-implantation of the PRAQ
- Patient records were only studied in one of the included sleep studies – however taking into account the interview results we do not expect different results in the other centers
- The PRAQ was in practice not used for follow-up consultations as often as intended, making evaluation of its use in this setting less robust

1. Introduction

The integration of patient-reported outcome measures (PROMs) in clinical practice has been gaining popularity in the past decade (1-3). PROM data collected in clinical practice can be aggregated and used for quality improvement purposes, or individual scores can be used in daily clinical practice to improve patient care. In this latter function PROMs can be used in different ways, e.g. as a screening tool, a monitoring or evaluation tool, a tool to inform and empower patients, and/or to increase the patient-centeredness of care by shifting the focus of care away from (only) medical problems towards the problems patients experience in their daily life (4). When using PROMs in daily clinical practice, it may be sensible to combine the use of a PROM on an individual patient level with application on an aggregate level (5). There have been a number of studies that aimed to evaluate the usefulness of PROMs in clinical practice in a variety of settings, of which the results are mixed (6-8). Though qualitative research on this topic has been synthesized in a recent review (4, 9) including a list of hypotheses on how PROMs might work, there are still many questions regarding which PROMs can be potentially useful in which settings.

This study is focused on the application of individual PROM scores in sleep centers which diagnose and treat patients with obstructive sleep apnea (OSA), a condition for which a PROM could be a useful tool to improve patient-centeredness of care. OSA is a highly prevalent but often unrecognized condition in which frequent collapse of the upper airway causes breathing stops while asleep. The subsequent arousals can result in severe sleepiness and fatigue during the day, often affecting a patient's cognitive function, psychological well-being, relationships, and ability to work (10-12). OSA has also been shown to be an independent risk factor for hypertension, heart failure and diabetes (13-15). The prevalence of OSA has been reported to be 6% to 38%, depending on the exact definition of OSA and the population studied, and is higher in men (16).

Severity of OSA and necessity for treatment has historically been based on the number of (partial) breathing stops per hour: the apnea-hypopnea index (AHI)(17, 18). However, there is no linear association between AHI and severity of symptoms or the presence of comorbidities (19-23). There is also little evidence that treating patients with mild OSA (based on AHI) or patients with low sleepiness is useful in preventing cardiovascular disease or incidents (24-27). In the past few years there has therefore been international discussion regarding new approaches to diagnose "clinically relevant" OSA (28, 29). This discussion has also made its way into recent Dutch guidelines for OSA, in which it is recommended that there should be a greater focus on the presence of potentially related comorbidities, as well as the experienced burden of disease for individual patients. The goal of treatment is the improvement of these aspects of OSA (30).

We have developed and validated a PROM for use in clinical practice which may aid this new focus of care for patients with OSA: the Patient-Reported Apnea Questionnaire (PRAQ)(31, 32), which measures OSA-related quality of life. The goal of this PROM is to improve patient-centeredness of care on an individual level by shifting the conversation away from the medical problems and towards and individual's burden of disease/quality of life, and also to measure of quality of care on an aggregate level. To develop the PRAQ, the input from patients and healthcare professionals was used to select the topics that were considered most important to discuss in clinical practice (31). The individual PRAQ scores of each patient with (suspected) OSA are captured in the 'PRAQ-report', which was designed together with patients and uses colored smileys to show the results for the 10 domains of the PRAQ.

This explorative pilot study aims to study the effect of the PRAQ and PRAQ-report on patient empowerment and patient-centeredness of care. A combination of both qualitative and quantitative methods is used that will add to the general knowledge on the circumstances under which PROMs do or do not work in clinical practice.

2. Methods

This article describes a pilot study in which the PRAQ is implemented in the clinical practice of three sleep centers. Qualitative interviews and a patient survey are used to explore patients' and healthcare providers' experiences with the PRAQ, and to identify potential barriers and facilitators to its use. Additionally, data are collected from patient records to study whether the hypotheses about the potential impact of the PRAQ mentioned in the introduction are correct. For the patient survey and the patient record study we conducted a before-and-after study. The different methods are described in more detail in the next sections.

2.1 Hypotheses

We have several hypotheses regarding how the PRAQ may influence patients and healthcare professionals, and how this could impact clinical practice. First of all, completing the PRAQ could:

- Encourage patients to consider which problems they experience that might be related to OSA and that they might want to discuss
- Aid healthcare professionals in opening a conversation about an individual patient's burden of disease (apnea-related quality of life)
- Aid healthcare professionals to evaluate treatment and identify problems that are still present

We think that this may potentially lead to:

- Higher patient compliance with treatment
- More explicit choices regarding whether clinical treatment for OSA is (potentially) beneficial to the patient
- An increase in referrals to other healthcare providers, such as psychologists
- More 'holistic' care, in which there is increased attention for the well-being of patients, including the psychological and social effects of OSA and its comorbidities

2.2 The PRAQ and its implementation

The PRAQ and its complementary PRAQ-report were designed with the input of patients with OSA and healthcare professionals (31). More information about the PRAQ-report and how the PRAQ was implemented into clinical practice can be found in Supplementary File 1.

2.3 Setting and subjects

Sleep centers of three Dutch hospitals took part in the study. The PRAQ was part of the clinical practice routine of these centers for six successive months. The PRAQ was distributed to patients attending an intake consultation for possible OSA (which takes place after a patient's diagnostic sleep study), and subsequently to

the subselection of these intake patients diagnosed with OSA who returned for a follow-up consultation after starting treatment.

2.4 Interviews

In-depth, semi-structured interviews were conducted with patients and healthcare professionals. The interview guides contained broad, open questions as well as more specific questions informed by topics previously identified in the literature(4). For patients the main goal was to assess whether completing the PRAQ was acceptable to them, and to find out the impact that the PRAQ and PRAQ report had for them on the (preparation for) the consultation. For healthcare providers, questions were mostly focused on how they used the PRAQ and why they used it this way, and the impact the use of the PRAQ has on their practice. This information can provide the basis for interpreting the results of the patient record study.

Patients were invited via email by the sleep center before their scheduled consultation, or by their healthcare professional directly after their consultation. We interviewed a total of 27 patients, with a mean age of 59 (range 31-82), nine of whom were women. Education level ranged from primary school to PhD. 18 patients were interviewed after their intake consultation, the other nine patients were interviewed after their first follow-up consultation after starting treatment for OSA. Four were interviewed together with their partner or child who had also attended the consultation. 22 patients had seen the PRAQ-report at home and/or during the consultation at the time of the interview, while five patients had completed the PRAQ but had not seen the PRAQ-report.

All healthcare professionals of the three participating sleep centers that had had the option to work with the PRAQ were invited to participate. This resulted in interviews with 14 healthcare professionals: six pulmonologists, six physician assistants (PAs) and two nurses. Two pulmonologists refused an interview because they had not seen many patients for OSA, two others because they had not used the PRAQ at all, and one PA refused for personal reasons. At least four healthcare professionals were interviewed at each of the three sleep centers.

All interviews were audiotaped and transcribed verbatim. All interviewees were provided with information about the study and signed an informed consent form or gave verbal informed consent on the audiotape. Analysis of the interviews took place via open coding, with different code books for patients and healthcare providers. IA and MN coded five interviews independently for both patients and healthcare professional interviews. A researcher (IG) experienced in qualitative research and knowledgeable about PROMs, but not involved in the study, coded one of the healthcare professional interviews independently. IG, IA, MN and PW held a collaborative coding session in which the code books were constructed. IA and MN then both analyzed all remaining interviews and reached consensus about the coding.

2.5 Surveys

The patient survey was designed for this study to study potential differences in patient empowerment and patient-centeredness of care before and after the implementation of the PRAQ. The items of the survey covered how prepared patients felt for their consultation, whether there was discussion of the health problems that patients consider relevant during the consultation, and whether patients were motivated to start their treatment.

Patients could indicate their agreement on several statements on these topics with the statement on a 7-point Likert scale.

Surveys were distributed by healthcare professionals to all of their patients attending either an intake or first follow-up consultation for (suspected) OSA. Distribution of the surveys took place in the two months before implementation of the intervention (control group), and in the last two months of the six months that the intervention was part of daily clinical practice (intervention group). For the intervention group, the survey also contained additional questions about the patient's opinion on the usefulness of the PRAQ. Participation was voluntary and anonymous. Survey data was analyzed per item with non-parametric tests.

2.6 Patient records

Patient records from one of the included sleep centers were studied to explore potential changes in treatment and compliance resulting from the use of the PRAQ. Data were collected from patients with an AHI≥5 attending an intake consultation during the final two months of the study period and during the same time period the previous year. Information was collected about treatment choice at intake, treatment adaptations at the first follow-up consultation, compliance with treatment, and patient characteristics. Compliance data is only available for patients who receive Continuous Positive Airway Pressure (CPAP), the most commonly prescribed treatment for patients with OSA. As part of standard care, hours of use are registered by the CPAP device and entered into the patient record at follow-up consultations. CPAP compliance is expressed as average hrs CPAP use/night in the month before the follow-up consultation, with an average of 4 hrs/night generally being the minimum to be considered compliant(33).

No identifying information was collected from the patient records. The data collection procedure guaranteed that the records would at all times remain anonymous to the researchers.

2.7 Patient and Public Involvement

A board member (author MI) of the Dutch patient organisation for OSA (Apneuvereniging) was involved with this study from its inception, including the research question and outcome measures and interpretation of the results. This author was also closely involved in the development of the intervention itself (the PRAQ and its complementary PRAQ-report), as were other members of the patient organization (31). They also approved of the burden and time required for the intervention. Patients were not involved in the recruitment for the study.

3. Results

3.1 Interviews

Patient perspective

Patients were generally willing to complete the PRAQ before their consultation, and patient response as reported by the healthcare professionals was high. About half of the interviewed patients indicated that completing the PRAQ helped them prepare for their intake consultation by giving them more insight into their complaints and functioning and how this might relate to OSA, and/or made them consider what they wanted to discuss with the healthcare professional. Many patients completed the PRAQ with a family member which instigated discussions

patients often considered useful. Patients considered the smileys of the PRAQ-report a clear and easy way of communicating the results. Box 1 contains quotes illustrating the statements in this paragraph.

The interviews also revealed some unintended effects of the PRAQ. A majority of patients assumed that the main purpose of the PRAQ was to aid their healthcare professional in setting a diagnosis, by providing information about symptoms ahead of time. A few patients believed that discussion of patient complaints during the consultation was therefore no longer necessary after completing the PRAQ, while healthcare professionals consider this discussion very important (see next section). Additionally, there were some issues around the interpretation of the smileys in the PRAQ-report. Several of the interviewed patients did not seem to view the PRAQ-report as merely a visualization of the answers they had given, but rather as a 'test result'. Some considered the number of 'unhappy' smileys as an indication of whether they were doing well or not, which made some patients reconsider the severity of their complaints (Box 2).

Box 1:

"Look, it's just very insightful. You can see instantly where the problems are and on this other [page] you can see what the improvements are. Yes, it's kinda nice." (Centre 3, patient 10)

"Yes, you know I do find it useful, because you have so many… so many things that bother you, that you forget what it is that bothers you. Or because it has become part of you, so to say. So yeah in order [not] to forget things, a questionnaire like this comes in handy." (Centre 2, patient 1)

"But there were quite a lot of questions where I was like, oh, sometimes I'm like, how does that fit with [apnea]? But most did, but there were questions where I was like, is that related to sleep apnea? So. Yes. Apparently." (Centre 3, patient 7)

"Actually I liked [seeing it beforehand], because this way I can by myself… otherwise I would have gone into it timidly like, tell me, what did you see? And now I could ask specific questions."
(Centre 3, patient 2)

Box 2:

"I think it's very good, because you can from the beginning very clearly indicate your problems. So it doesn't need to all be done during the short conversation you have with the specialist. [..] It's clear it doesn't need to be mentioned again, because it's clear to her as well what the problems are." (Centre 1, patient 4)

"Just that when you complete a questionnaire aimed at establishing something, then it's useful that you also get a sort of result. So a preliminary… not that you should instantly think like nothing is wrong, nothing needs to be done, let's get out of here. But, I did like it, yeah." (Centre 1, patient 3)

"Well, because there were only two orange [smileys], and the others were all green and then you think, well…. And then when you look at it again then I'm like, 'I can live with that'." (Centre 2, patient 7)

Willingness to use the PRAQ among professionals was moderate: one did not use it at all, a few put effort into exploring its potential benefits, and most used it in a more perfunctory manner. Some professionals stated that this was due to unwillingness to change their practice, while others mentioned a general aversion to questionnaires, and/or not being convinced that the PRAQ would offer new or useful information considering what was already discussed during a regular consultation. There were also practical issues that to some extent hindered the uptake of the PRAQ: most notably the (limited) time available for consultations, and the fact that the PRAQ was not embedded in the patient records which hindered the regular workflow. There were no notable differences in attitude towards the PRAQ between physicians, PAs and nurses.

Most of the professionals that used the PRAQ did so at the end of their usual discussion of symptoms, to check whether all topics that were problematic had been discussed and potentially address more topics. As such they could still start the conversation in their usual way, allowing patients to explain their problems in their own words, and allowing the healthcare professionals to ask their standard diagnostic questions. Professionals indicated that most "symptoms" that are part of the PRAQ were already part of the standard diagnostic questions during an intake consultation (sleepiness, problems at night), and also overlapped with their usual (diagnostic) intake questionnaire. However, several professionals mentioned that the PRAQ-report increased discussion of the topic "health concerns", which was considered valuable. Furthermore, the few professionals that indicated that they valued offering more holistic care noticed that the PRAQ was useful in drawing the conversation away from medical facts and more towards the underlying emotions related to a patient's problems. However, many other professionals did not see much added value in actively bringing up topics like emotions and social interactions. They were potentially willing to discuss these issues but considered it up to the patient to raise them. If the PRAQ was used to identify problems, it was more common for the professional to mention very briefly that these problems were likely to improve with treatment of OSA, without further discussing these problems (Box 3). Professionals reported that they did not notice any increase in OSA-related knowledge in their patients, or a difference in whether or how patients raised health complaints or quality of life issues of their own accord.

With regard to treatment choice, the professionals mentioned that the severity of symptoms generally only plays a role in patients with an AHI<15, for which shared-decision making could potentially lead to a decision not to start clinical treatment for OSA. If the AHI is≥15, professionals generally wish to treat a patient for health reasons irrespective of symptoms. Many patients also have a reason to opt for treatment: there is a motor vehicle driving ban for untreated patients with AHI≥15.

Use of the PRAQ during follow-up consultations could not be fully evaluated, because a limited number of patients had completed the PRAQ at follow-up at the time of the interviews. This was due to practical implementation issues in combination with the relatively short duration of the pilot. However, several healthcare professionals mentioned that they thought the PRAQ would be more useful during follow-up consultations than intake conversations, as it would be interesting to see which problems remained after starting treatment. Those that had the opportunity to use the PRAQ in this setting mentioned that it was nice to show patients how their problems had improved, with the improvement sometimes greater than the patients had realised. This could be used as encouragement to continue with treatment.

Box 3:

"Well I myself don't ask 'are you worried about your [health]'? I won't ask that, but that is what it shows. So then… then it's like 'hey, I would otherwise not have discussed that'." (Centre 3, healthcare provider 4)

"Yes, but then in a solution-oriented way - then you will see someone with 30 apneas an hour and you see that and you say I hope that [your problem with emotions] will get a lot better with the therapy I will start for you." (Centre 1, healthcare provider 2)

"Especially I thought people were, uhm… that lack of initiative, not going out, right? So they don't do things because of their sleep problem, that was what [the PRAQ] often showed. And I didn't always get that from taking the patient history. So people maybe find that hard to tell me, or they have trouble indicating that it really does have an impact on them. And then they try to focus more on the fact than on the underlying emotion. And that would sometimes give added value." (Centre 1, healthcare provider 1)

3.2 Survey results

A total of 487 patients completed surveys pre-implementation, and 344 patients completed surveys post-implementation of the PRAQ. Characteristics of the survey populations pre-implementation and post-implementation can be found in table 1. For follow-up patients, the severity of the symptoms or problems that the patients wanted to discuss during the consultation was significantly higher post-implementation than pre-implementation.

Table 1. Characteristics of the survey population

Intake consultations		
	Pre-implementation (n=239)	Post-implementation n=164)
Age (yrs)	53.9	55.4
Gender (% male)	68.4	69.5
Severity of symptoms[1]	6.50	6.44
Diagnosed with OSA (%)	82.8	83,2
CPAP[2] (%)	71.0	70.7
MRA[2] (%)	13.7	19.5
Other treatment[2](%)	10.7	7.4
No treatment[2] (%)	1,0	2.4
Missing[2] (%)	3.6	0.0
Follow-up consultations		
	Pre-implementation (n=248)	Post-implementation (n=180)
Age	57.33	58.54
Gender (% male)	75.3	69.7
Severity of remaining symptoms or problems with treatment[1]	4.25*	5.03*
CPAP (%)	89.1	89.4
MRA (%)	3.6	3.9
Other or missing (%)	7	5.6

*Significant difference (p=.01, Mann-Whitney U test)

1. Scale 1-10, higher is more problems
2. Percentage patients with this treatment of the total of patients diagnosed with OSA

Patients generally showed high agreement with the statements of the survey: 76.9% - 95.6% of patients indicated "agree" or "completely agree" per statement (table 2). The lowest agreement pre-implementation of the PRAQ was for the statement "I discussed with the doctor the topics I wanted to discuss" for intake patients (9.8% of patients disagreed), which did not significantly improve after implementation of the PRAQ (8.9% of patients disagreed). The other statements for intake patients also showed no significant differences in the level of agreement pre- and post-implementation. However, follow-up patients post-implementation showed less agreement with the statement "In my opinion, my treatment is worth it for me", with 3.6% fewer patients indicating "agree" or "completely agree" (p=.005).

Table 2. Survey results

	Pre-implementation PRAQ			Post- implementation PRAQ		
Scores[1]	1-3	4-5	6-7	1-3	4-5	6-7
Intake consultations						
I knew which problems I wanted to discuss with the doctor (%)	7.2	7.7	85.1	4.2	7.3	88.5
I discussed with the doctor the topics I wanted to discuss (%)	9.8	12.5	77.7	8.9	12.2	78.9
Because of my conversation with the doctor, I understand better what causes my problems (%)	6.0	6.0	88.0	3.1	5.1	91.8
The doctor and I chose the treatment together (or chose not to treat my apnea) (%)	6.0	5.2	88.8	3.6	7.3	89.1
Because of my conversation with the doctor, I understand how the treatment can benefit me (%)	5.6	5.5	88.9	2.2	5.3	92.5
I think the treatment will be worth it for me (%)	4.7	8.0	87.3	2.2	9.8	88.0
Follow-up consultations						
I knew which problems I wanted to discuss with the doctor (%)	4.5	4.6	90.9	3.4	6.9	89.7
I discussed with the doctor the topics I wanted to discuss (%)	4.0	6.6	89.4	5.7	6.4	87.9
There was enough attention for the complaints that I still have (%)	2.0	2.4	95.6	1.4	1.3	97.3
My complaints have lessened since start of my treatment (%)	8.1	15.0	76.9	11.5	14.2	74.3
In my opinion, my treatment is worth it for me* (%)	2.7	4.0	93.3	3.4	6.9	89.7
Usefulness of the PRAQ						
The PRAQ-report was useful for preparing my consultation[2]	-	-	-	9.8	14.6	75.6
The PRAQ-report was useful during my consultation[3]	-	-	-	0.0	10.9	89.1

*Significant difference between pre- and post-implementation (p=.005, Mann-Whitney U test)

1. Scale 1-7 (1 = completely disagree, 2 = disagree, 3 = disagree a little, 4 = neither agree nor disagree, 5=agree a little, 6=agree, 7= completely agree)
2. Showing results for patients who indicated they had seen the PRAQ-report before their consultation (n= 41)
3. Showing results of patients who indicated the PRAQ-report was shown during their consultation (n= 46)

Patients showed high agreement with the two statements about the usefulness of the PRAQ-report, particularly regarding its use during a consultation (table 2). However, not all patients had completed the PRAQ and seen the PRAQ-report before or during their consultation, and there number of patients that had completed these items was low (table 3).

Table 3. Percentage of patients that completed and viewed the PRAQ, and patient opinion on usefulness PRAQ

	Intake (n=197)	Follow-up (n=180)
Completed PRAQ before consultation	77.7%	51.1%
Seen PRAQ-report before consultation[1]	40.0%	44.4%
Seen PRAQ-report during consultation[1]	74.1%	60.2%

1. This percentage is a sub-percentage of the patients who indicated they completed the PRAQ

3.3 Patient record results

125 patients were included in the pre-implementation group, and 124 other patients in the post-implementation group. Patient characteristics of the two groups did not differ (table 4). No differences were found with regard to how many patients with OSA received non-medical treatment (either no treatment at all or referral to a psychologist (table 5)), or in the number of patients for whom treatment was adjusted at the first follow-up consultation after starting CPAP treatment (table 6).

In both groups, 98 patients were prescribed CPAP. Patient characteristics did not differ between the two groups of patients with CPAP (data not shown). Compliance with CPAP treatment did not differ between the two groups (table 6).

Table 4. Patient file study: patient characteristics[1]

	Pre-implementation (n=125)	Post-implementation (n=124)
Age (SD)	55,4 (12,0)	56,6 (15,7)
Gender	68% male	67,7% male
BMI (SD)	31,4 (6,5)	30,8 (6,1)
AHI (SD)	23,1(16,1)	25,0 (18,5)
AHI < 15	40,8%	33,9%
ESS (SD)	8,0 (4,8)	7,4 (5,0)
Start with CPAP at intake	78,4%	79,0%

1. If nothing is indicated, no significant difference was found.

Table 5. Treatment choice at intake[1]

	Pre-implementation (n=125)	Post-implementation (n=124)[1]	Pre-implementation, AHI <15 (n=51)	Post-implementation (n=42)
Medical treatment for OSA (incl CPAP)	98,4	99,2	96,1	97,6
No medical treatment for OSA	1,6	0,8	3,9	2,4
Referred to psychologist (%)	1,6	0	3,9	0
No treatment (%)	0	0,8	0	2,4

1. If nothing is indicated, no significant difference was found.

Table 6. Treatment adjustments and compliance in patients with CPAP at the first follow-up[1]

	Pre-implementation of PRAQ (n=98)	Post-implementation of PRAQ (n=98)
Adjustment of current treatment	45	36
Switch to different treatment	5	9
Referral to different specialization	6	2
CPAP compliance[2] (SD)	5:47 hrs (2:11)	5:53 hrs (2:10)
CPAP compliance <4hrs	25,0%	27,5%
Stopped CPAP treatment	4,1%	5,1%

1. If nothing is indicated, no significant difference was found.
2. Hours of CPAP use by patients who had stopped treatment altogether (see "stopped CPAP treatment") are not included in this number

4. Discussion

This explorative pilot study showed limited success regarding the uptake of the PRAQ in the daily clinical practice of sleep centers, and the improvement of patient empowerment and patient-centeredness of care. Most patients were willing to complete the PRAQ and were generally positive about the usefulness of the PRAQ before the consultation (e.g. because of feeling more informed) and during the consultation (due to the clear visual representation of their problems). This seems to therefore have lead to some empowerment of patients. However, amongst healthcare professionals the willingness to use the PRAQ-report in consultations differed, as the perceived need was minimal. Most of the professionals that used the PRAQ also reported that the impact on their consultations was minor. Therefore, it is not surprising that comparison of patient records pre- and post-implementation of the PRAQ did not show any differences in treatment choice and CPAP compliance.

The interviews showed that the professionals mostly felt that they already sufficiently address the "symptom-like" topics of the PRAQ (sleepiness, problems at night) in their usual care, in the context of setting a diagnosis. The topics of the PRAQ that are not necessary for setting a diagnosis, but could potentially be used to motivate patients for their treatment, were not seen as essential to discuss by many professionals. The limited perceived benefit of the PRAQ is likely also mitigated by the fact that many steps of the care process have to be covered during the intake consultation, including discussing the sleep study results and choosing a treatment. This leaves little extra time to discuss a patient's quality of life and detailed treatment goals. Furthermore, burden of disease plays a limited role in setting a diagnosis when AHI≥15, due to views on strict medical necessity of treatment, but also due to the driving ban for untreated patients. Therefore, adding the PRAQ to the current practice for OSA does not appear to be a sufficient trigger to increase attention to quality of life issues.

Patients generally held a more positive view towards the usefulness of the PRAQ. From the interviews it became clear that completing the PRAQ has the potential to give patients more insight into their OSA-related health complaints and encourages communication between family members. Furthermore, the patient survey results indicated that patients thought the PRAQ-report was useful for their preparation for the consultation and (when it was used by the healthcare professional) during the consultation.

Agreement to the patient survey statement "I feel like my treatment is worth it for me" was significantly lower on the post-implementation survey, while (also post-implementation) the reported severity of health complaints for which they attended the consultation was significantly higher. Potentially, patients are more

aware of which remaining symptoms they still experience because of completing the PRAQ, and therefore have higher scores on the reported severity and a more negative view of their treatment. However, the differences in agreement scores was small, and both pre-and post-implementation of the PRAQ patients were very positive about their treatment.

There appears to be room for improvement of communication around the PRAQ, as there was confusion for some patients around the necessity of still discussing symptoms during the consultation. It may be beneficial to communicate the purpose of the PRAQ more clearly in the invitation email, and/or to instruct professionals to, at the beginning of their consultation, mention the PRAQ to patients and how its results will be addressed. More in-depth discussion with the field about what is most suitable or desirable in this context is needed.

In the past few years, several similar initiatives involving PROMs have been introduced in The Netherlands, such as the Assessment of Burden of COPD (ABC) tool(34), the Nijmegen Clinical Screening Instrument for COPD(35), the QLIC-ON PROfile for children(36), and MyIBDcoach for patients with inflammatory bowel disease(37). Studies into these applications show promising results regarding their benefits (37, 38) despite some resistance from professionals who do not believe in the added benefit or believe the tool would be more useful for different professionals within the care pathway (39, 40). However, the healthcare professionals' skepticism about the potential benefits of the PRAQ seems to be more extensive. Potentially, professionals will see greater benefit of the PRAQ in the context of the recently released new guidelines for OSA (30) with their greater emphasis on (improving) burden of disease, which were not yet available at the time of this study. However, the question remains whether a more "holistic" approach to caring for OSA patients fits within the current setting of relatively short intake consultations which take place after the patients' diagnostic sleep study. It may be necessary to move towards a reorganization of care: for example to plan the intake consultations before the sleep study to allow for more focus on the individual patients' symptoms and problems, and to specifically evaluate the necessity of doing a diagnostic sleep study. Additionally, integrating the PRAQ in the electronic health record will help professionals fit the PRAQ-report better into their workflow.

Strengths and limitations of the study

The major strength of this study is that we used mixed methods, which provides insight into the reasons why the PRAQ does not work as intended. Many other studies on PROMs study only *whether* a PROM works, rather than why or how.

There are also limitations to the study. First, the survey used for this study was maybe not discriminative enough to show differences between the groups pre- and post-implantation of the PRAQ. Potentially, patients who have not completed the PRAQ do not know that, for example, their preparation for the consultation could maybe have been better than it currently was. Second, patient records were only studied in one of the included sleep centers. However, considering the information we collected in the interviews, we do not expect that we would have found different results in either of the other two sleep centers. Third, though technically there was enough time in this pilot for professionals to also use the PRAQ during the first follow-up consultation, practical implementation issues as well as a lack of initiative from healthcare professionals to actively check whether a follow-up PRAQ was available meant that it was not used often at this time point. Therefore we did not gain much insight into the potential use of the PRAQ for follow-up consultations. Lastly,

relatively few patients completed the survey items about the usefulness of the PRAQ, leaving room for potential bias (i.e. patients who have a more positive opinion may be more likely to complete these items).

Conclusions

Using the PRAQ in the daily clinical practice of OSA is viewed as useful by patients, but the enthusiasm of healthcare professionals differed per individual and was generally not very great. Implementation of the PRAQ does not seem a sufficient trigger to focus more attention to quality of life during consultations, and in current practice does not show impact on treatment choice or CPAP compliance. However, new Dutch guidelines for OSA care that have recently been published may lead to a greater emphasis on quality of life for patients, making the integration of the PRAQ in clinical care potentially more useful.

Additional information:

Funding: The first author was funded by the Radboudumc grant number R0002257. The funding organization had no role in the design, implementation, interpretation, or reporting of this study.

Conflicts of interest: All authors declare that they have no competing interests.

Author contributions: All authors were involved in the conception and design. IA and MN conducted and analysed the interviews. IA collected and analysed the quantitative data. IA and PW interpreted the quantitative data. IA drafted the manuscript. All authors critically revised the manuscript for important intellectual content.

Data sharing statement: Data is available from the corresponding author upon reasonable request.

Ethics approval: Ethical approval is not required for this type of study under Dutch law, and an exemption was obtained by the local Medical Ethics Committee "CMO Regio Arnhem-Nijmegen".

References

1. Valderas JM, Alonso J, Guyatt GH. Measuring patient-reported outcomes: moving from clinical trials into clinical practice. The Medical journal of Australia. 2008;189(2):93-4.
2. Fleischmann M, Vaughan B. The challenges and opportunities of using patient reported outcome measures (PROMs) in clinical practice. Int J Osteopath Med. 2018:1-6.
3. Howell D, Molloy S, Wilkinson K, Green E, Orchard K, Wang K, et al. Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors. Ann Oncol. 2015;26(9):1846-58.
4. Greenhalgh J, Dalkin S, Gooding K, Gibbons E, Wright J, Meads D, et al. Functionality and feedback: a realist synthesis of the collation, interpretation and utilisation of patient-reported outcome measures data to improve patient care. Health Services and Delivery Research. Southampton (UK)2017.
5. Van Der Wees PJ, Nijhuis-Van Der Sanden MW, Ayanian JZ, Black N, Westert GP, Schneider EC. Integrating the use of patient-reported outcomes for both clinical practice and performance measurement: views of experts from 3 countries. The Milbank quarterly. 2014;92(4):754-75.
6. Valderas JM, Kotzeva A, Espallargues M, Guyatt G, Ferrans CE, Halyard MY, et al. The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2008;17(2):179-93.
7. Boyce MB, Browne JP. Does providing feedback on patient-reported outcomes to healthcare professionals result in better outcomes for patients? A systematic review. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2013;22(9):2265-78.
8. Holmes MM, Lewith G, Newell D, Field J, Bishop FL. The impact of patient-reported outcome measures in clinical practice for pain: a systematic review. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2017;26(2):245-57.
9. Greenhalgh J, Dalkin S, Gibbons E, Wright J, Valderas JM, Meads D, et al. How do aggregated patient-reported outcome measures data stimulate health care improvement? A realist synthesis. J Health Serv Res Policy. 2018;23(1):57-65.
10. Bjornsdottir E, Benediktsdottir B, Pack AI, Arnardottir ES, Kuna ST, Gislason T, et al. The Prevalence of Depression among Untreated Obstructive Sleep Apnea Patients Using a Standardized Psychiatric Interview. Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine. 2016;12(1):105-12.
11. O'Donoghue N, McKay E. Exploring the impact of sleep apnoea on daily life and occupational engagement. Br J Occup Ther. 2012;75(11):609-516.
12. Reishtein JL, Pack AI, Maislin G, Dinges DF, Bloxham TJ, George CF, et al. Sleepiness and relationships in obstructive sleep apnea. Issues Ment Health Nurs. 2006;27(3):319-30.
13. Bradley TD, Floras JS. Obstructive sleep apnoea and its cardiovascular consequences. Lancet. 2009;373(9657):82-93.
14. Chan AS, Phillips CL, Cistulli PA. Obstructive sleep apnoea--an update. Intern Med J. 2010;40(2):102-6.
15. Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med. 2002;165(9):1217-39.
16. Senaratna CV, Perret JL, Lodge CJ, Lowe AJ, Campbell BE, Matheson MC, et al. Prevalence of obstructive sleep apnea in the general population: A systematic review. Sleep Med Rev. 2017;34:70-81.
17. Medicine AAoS. International Classification of Sleep Disorders. Diagnostic and Coding Manual. . In: Medicine AAoS, editor. 3rd edition ed2014.
18. Committee DCS. International Classification of Sleep Disorders: Diagnostic and Coding Manual. In: Association ASD, editor. Rochester1990.

19. Macey PM, Woo MA, Kumar R, Cross RL, Harper RM. Relationship between obstructive sleep apnea severity and sleep, depression and anxiety symptoms in newly-diagnosed patients. PLoS One. 2010;5(4):e10211.
20. Tam S, Woodson BT, Rotenberg B. Outcome measurements in obstructive sleep apnea: beyond the apnea-hypopnea index. Laryngoscope. 2014;124(1):337-43.
21. Kingshott RN, Engleman HM, Deary IJ, Douglas NJ. Does arousal frequency predict daytime function? The European respiratory journal. 1998;12(6):1264-70.
22. Turnbull CD, Stradling JR. To screen or not to screen for obstructive sleep apnea, that is the question. Sleep Med Rev. 2017;36:125-7.
23. Van Dongen HP, Baynard MD, Maislin G, Dinges DF. Systematic interindividual differences in neurobehavioral impairment from sleep loss: evidence of trait-like differential vulnerability. Sleep. 2004;27(3):423-33.
24. Abuzaid AS, Al Ashry HS, Elbadawi A, Ld H, Saad M, Elgendy IY, et al. Meta-Analysis of Cardiovascular Outcomes With Continuous Positive Airway Pressure Therapy in Patients With Obstructive Sleep Apnea. Am J Cardiol. 2017;120(4):693-9.
25. Yu J, Zhou Z, McEvoy RD, Anderson CS, Rodgers A, Perkovic V, et al. Association of Positive Airway Pressure With Cardiovascular Events and Death in Adults With Sleep Apnea: A Systematic Review and Meta-analysis. JAMA. 2017;318(2):156-66.
26. Marin JM, Agusti A, Villar I, Forner M, Nieto D, Carrizo SJ, et al. Association between treated and untreated obstructive sleep apnea and risk of hypertension. JAMA. 2012;307(20):2169-76.
27. Barbe F, Duran-Cantolla J, Sanchez-de-la-Torre M, Martinez-Alonso M, Carmona C, Barcelo A, et al. Effect of continuous positive airway pressure on the incidence of hypertension and cardiovascular events in nonsleepy patients with obstructive sleep apnea: a randomized controlled trial. JAMA. 2012;307(20):2161-8.
28. McNicholas WT. Diagnostic criteria for obstructive sleep apnea: time for reappraisal. J Thorac Dis. 2018;10(1):531-3.
29. McNicholas WT, Bassetti CL, Ferini-Strambi L, Pepin JL, Pevernagie D, Verbraecken J, et al. Challenges in obstructive sleep apnoea. Lancet Respir Med. 2018;6(3):170-2.
30. NVALT. Richtlijn diagnostiek en behandeling van obstructief slaapapneu (OSA) bij volwassenen. Richtlijnendatabase.nl: Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose; 2017.
31. Abma IL, Rovers M, IJff M, Hol B, Westert GP, Van der Wees PJ. The development of a patient-reported outcome measure for patients with obstructive sleep apnea: the Patient-Reported Apnea Questionnaire (PRAQ). Journal of Patient-Reported Outcomes. 2017;1(14).
32. Abma IL, Rovers M, M IJ, Hol B, Westert GP, van der Wees PJ. Instrument completion and validation of the patient-reported apnea questionnaire (PRAQ). Health Qual Life Outcomes. 2018;16(1):158.
33. Grunstein RR. Sleep-related breathing disorders. 5. Nasal continuous positive airway pressure treatment for obstructive sleep apnoea. Thorax. 1995;50(10):1106-13.
34. Slok AH, in 't Veen JC, Chavannes NH, van der Molen T, Rutten-van Molken MP, Kerstjens HA, et al. Development of the Assessment of Burden of COPD tool: an integrated tool to measure the burden of COPD. NPJ Prim Care Respir Med. 2014;24:14021.
35. Peters JB, Daudey L, Heijdra YF, Molema J, Dekhuijzen PN, Vercoulen JH. Development of a battery of instruments for detailed measurement of health status in patients with COPD in routine care: the Nijmegen Clinical Screening Instrument. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2009;18(7):901-12.
36. Engelen V, Haverman L, Koopman H, Schouten-van Meeteren N, Meijer-van den Bergh E, Vrijmoet-Wiersma J, et al. Development and implementation of a patient reported outcome intervention (QLIC-ON PROfile) in clinical paediatric oncology practice. Patient Educ Couns. 2010;81(2):235-44.
37. de Jong MJ, van der Meulen-de Jong AE, Romberg-Camps MJ, Becx MC, Maljaars JP, Cilissen M, et al. Telemedicine for management of inflammatory bowel disease (myIBDcoach): a pragmatic, multicentre, randomised controlled trial. Lancet. 2017;390(10098):959-68.
38. Slok AH, Kotz D, van Breukelen G, Chavannes NH, Rutten-van Molken MP, Kerstjens HA, et al. Effectiveness of the Assessment of Burden of COPD (ABC) tool on health-related quality of life in

patients with COPD: a cluster randomised controlled trial in primary and hospital care. BMJ Open. 2016;6(7):e011519.
39. Schepers SA, Sint Nicolaas SM, Haverman L, Wensing M, Schouten van Meeteren AYN, Veening MA, et al. Real-world implementation of electronic patient-reported outcomes in outpatient pediatric cancer care. Psychooncology. 2017;26(7):951-9.
40. Slok AH, Twellaar M, Jutbo L, Kotz D, Chavannes NH, Holverda S, et al. 'To use or not to use': a qualitative study to evaluate experiences of healthcare providers and patients with the assessment of burden of COPD (ABC) tool. NPJ Prim Care Respir Med. 2016;26:16074.

Supplementary file 1: the PRAQ-report and its implementation in clinical practice

In the PRAQ-report, the results of each of the ten PRAQ-domains are shown in the form of a colored smiley, ranging from green (patient indicated very few problems) to dark red (patient indicated a lot of problems). Domain scores over time and individual item scores are shown on subsequent pages of the PRAQ-report. The included domains were: symptoms at night, sleepiness, tiredness, daily activities, unsafe situations, memory and concentration, quality of sleep, emotions, social activities, and health concerns. The PRAQ also contains a set of "intake questions" that were designed together with the participating centers and aimed to replace the diagnostic intake questionnaires that the centers usually distribute to all their new patients. This involved more factual, broader questions to help professionals in setting a correct diagnosis.

The PRAQ was distributed via a secure online platform (VitalHealth QuestManager) which sent out email invitations to a patient to complete the PRAQ at ten and (if the PRAQ was not yet completed) three days before the patient's consultation. After completion of the PRAQ, patients and healthcare professionals both had the ability to access the PRAQ-report directly from the online platform.

Individual implementation plans for collecting email addresses of patients, creating patient accounts, and entering consultation dates were developed for each study center to optimally fit their usual work flow.

Healthcare professionals received information about the content of the PRAQ and PRAQ-report, and instructions and a short training in how to use QuestManager. They were then encouraged to integrate the PRAQ into their own workflow in whichever way each individual professional found most convenient. After approximately two months of using the PRAQ, the researchers organized a meeting in each sleep centre in which the healthcare professionals were invited to discuss how they were using the PRAQ-report in their practice, in order to exchange ideas and potentially adjust their way of using the PRAQ.

Reporting checklist for quality improvement study.

Based on the SQUIRE guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SQUIRE reporting guidelines, and cite them as:

Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process

		Reporting Item	Page Number
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	3
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2
Problem description	#3	Nature and significance of the local problem	3
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3
Rationale	#5	Informal or formal frameworks, models, concepts, and / or	3

		theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	
Specific aims	#6	Purpose of the project and of this report	3, 4
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	4
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	4
	#08b	Specifics of the team involved in the work	5, 6
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	5, 6
	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	5
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	5, 6
	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	5
	#10c	Methods employed for assessing completeness and accuracy of data	N/A, this was a pilot study
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	5, 6
	#11b	Methods for understanding variation within the data, including the effects of time as a variable	N/A, this was a pilot study
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	15
	#13a	Initial steps of the intervention(s) and their evolution over	N/A, data

		time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	not available
	#13b	Details of the process measures and outcome	6-13
	#13c	Contextual elements that interacted with the intervention(s)	6-9
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	6-13
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	7
	#13f	Details about missing data	12
Summary	#14a	Key findings, including relevance to the rationale and specific aims	13
	#14b	Particular strengths of the project	14
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	13
	#15b	Comparison of results with findings from other publications	14
	#15c	Impact of the project on people and systems	13, 14
	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	13, 14
	#15e	Costs and strategic trade-offs, including opportunity costs	N/A, no costs studied
Limitations	#16a	Limits to the generalizability of the work	N/A
	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	14
	#16c	Efforts made to minimize and adjust for limitations	N/A, this was a pilot study
Conclusion	#17a	Usefulness of the work	15

	#17b	Sustainability	N/A, results were negative
	#17c	Potential for spread to other contexts	N/A results were negative
	#17d	Implications for practice and for further study in the field	15
	#17e	Suggested next steps	N/A, results were negative
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	15

BMJ Open

Does the Patient-Reported Apnea Questionnaire (PRAQ) increase patient-centeredness in the daily practice of sleep centers? A mixed-methods study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025963.R1
Article Type:	Research
Date Submitted by the Author:	13-Mar-2019
Complete List of Authors:	Abma, Inger; Radboudumc, IQ healthcare Rovers, Maroeska; Radboudumc, Health Evidence and Operating Rooms IJff, Marijke; ApneuVereniging Hol, Bernard; Albert Schweitzer Ziekenhuis, Sleep centre Nägele, Masha; Radboudumc, IQ healthcare Westert, Gert; Radboudumc, IQ healthcare Van der Wees, Philip; Radboudumc, IQ healthcare
Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Communication, Qualitative research
Keywords:	SLEEP MEDICINE, patient-reported outcome measure, obstructive sleep apnea, quality of life, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Does the Patient-Reported Apnea Questionnaire (PRAQ) increase patient-centeredness in the daily practice of sleep centers? A mixed-methods study.

Inger L. Abma, MSc[1], Prof. Maroeska Rovers[2], Marijke IJff[3], Bernard Hol, MD[4], Masha E. Nägele[1], BSc, Prof. Gert P. Westert[1], Prof. Philip J. van der Wees[1]

[1] Radboud University Medical Center, Radboud Institute of Health Sciences, IQ healthcare, Nijmegen, the Netherlands

[2] Radboud University Medical Center, Radboud Institute of Health Sciences, Departments for Health Evidence and Operating Rooms, Nijmegen, The Netherlands

[3] ApneuVereniging, Doorn, The Netherlands

[4] Albert Schweitzer Ziekenhuis, Sleep Center, Dordrecht, The Netherlands

Corresponding author:
I.L. Abma
e-mail: Inger.abma@radboudumc.nl
tel: +31 24 3616359

Addres:
Radboud University Medical Center
IQ healthcare
PO box 9101, huispost 114
6500 HB, Nijmegen

ORCID iDs
I. Abma: 0000-0002-3307-6736
M. Rovers: 0000-0002-3095-170X
G. Westert: 0000-0003-3744-8207
P. van der Wees: 0000-0003-2881-5159

Word count: 5218

Keywords: Obstructive sleep apnea, quality of life, patient-reported outcome measure, patient-centeredness

Abstract

Objectives: The objective of this exploratory study was to see how the Patient-Reported Apnea Questionnaire (PRAQ) may impact the daily clinical practice of sleep centers, and why it may or may not work as expected. The hypotheses were tested that this patient-reported outcome measure (PROM) makes patients more aware of which of their health complaints may be related to obstructive sleep apnea (OSA), and that it improves patient-centeredness of care by shifting the focus of care away from (only) medical problems towards the individual burden of disease and quality of life.

Design: Mixed methods. The quantitative study (surveys, patient records) was a before-and-after study.

Setting: Three sleep centres in The Netherlands (secondary care).

Participants: 27 patients and 14 healthcare professionals were interviewed. 487 patients completed surveys pre-implementation, and 377 patients completed surveys post-implementation of the PRAQ. For the health records, 125 patients were included in the pre-implementation group, and 124 other patients in the post-implementation group.

Interventions: The PRAQ was used in clinical practice for six successive months.

Outcome measures: Scores on individual survey items, number of patients receiving non-medical treatment, adjustment of treatment at first follow-up, compliance with treatment.

Results: Patients were generally positive about the usefulness of the PRAQ before and during the consultation., as they felt more informed. Healthcare providers did not consider the PRAQ very useful, and they reported minor impact on their consultations. The surveys and health record study did not show an impact of the PRAQ on clinical practice.

Conclusions: Implementing the PRAQ may be beneficial to patients, but this study does not show much impact with regard to patient-centeredness of care. New Dutch guidelines for OSA care may lead to a greater emphasis on quality of life and value of care for patients, making its integration in clinical care potentially more useful.

Article summary

Strengths and limitations of this study

- The mixed methods approach of this exploratory study is its major strength: the study provides insight into the reasons why the PRAQ does not work as intended
- The patient survey may not have been discriminative enough to show differences between the groups pre- and post-implantation of the PRAQ
- Electronic health records were only studied in one of the included sleep centers – however taking into account the interview results we do not expect different results in the other centers
- The PRAQ was in practice not used for follow-up consultations as often as intended, making evaluation of its use in this setting less robust

1. Introduction

The integration of patient-reported outcome measures (PROMs) in clinical practice has been gaining popularity in the past decade (1-3). PROM data collected in clinical practice can be aggregated and used for quality improvement purposes, or individual scores can be used in daily clinical practice to improve patient care. In this latter function PROMs can be used in different ways, e.g. as a screening tool, a monitoring or evaluation tool, a tool to inform and empower patients, and/or to increase the patient-centeredness of care by shifting the focus of care away from (only) medical problems towards the problems patients experience in their daily life (4). When using PROMs in daily clinical practice, it may be sensible to combine the use of a PROM on an individual patient level with application on an aggregate level (5). There have been a number of studies that aimed to evaluate the usefulness of PROMs in clinical practice in a variety of settings, of which the results are mixed (6-8). Though qualitative research on this topic has been synthesized in a recent review (4, 9) including a list of hypotheses on how PROMs might work, there are still many questions regarding which PROMs can be potentially useful in which settings.

This study is focused on the application of individual PROM scores in sleep centers which diagnose and treat patients with obstructive sleep apnea (OSA), a condition for which a PROM could be a useful tool to improve patient-centeredness of care. OSA is a highly prevalent but often unrecognized condition in which frequent collapse of the upper airway causes breathing stops while asleep. The subsequent arousals can result in severe sleepiness and fatigue during the day, often affecting a patient's cognitive function, psychological well-being, relationships, and ability to work (10-12). OSA has also been shown to be an independent risk factor for hypertension, heart failure and diabetes (13-15). The prevalence of OSA has been reported to be 6% to 38%, depending on the exact definition of OSA and the population studied, and is higher in men (16).

Severity of OSA and necessity for treatment has historically been based on the number of (partial) breathing stops per hour: the apnea-hypopnea index (AHI)(17, 18). However, there is no linear association between AHI and severity of symptoms or the presence of comorbidities (19-23). There is also little evidence that treating patients with mild OSA (based on AHI) or patients with low sleepiness is useful in preventing cardiovascular disease or incidents (24-27). In the past few years there has therefore been international discussion regarding new approaches to diagnose "clinically relevant" OSA (28, 29). This discussion has also made its way into recent Dutch guidelines for OSA, in which it is recommended that there should be a greater focus on the presence of potentially related comorbidities, as well as the experienced burden of disease for individual patients. The goal of treatment is the improvement of these aspects of OSA (30).

We have developed and validated a PROM for use in clinical practice which may aid this new focus of care for patients with OSA: the Patient-Reported Apnea Questionnaire (PRAQ) (31, 32), which measures OSA-related quality of life. The goal of this PROM is to improve patient-centeredness of care on an individual level by shifting the conversation away from the medical problems and towards and individual's burden of disease/quality of life, and also to measure quality of care on an aggregate level. To develop the PRAQ, the input from patients and healthcare professionals was used to select the topics that were considered most important to discuss in clinical practice (31). The individual PRAQ scores of each patient with (suspected) OSA are captured in the 'PRAQ-report', which was designed together with patients and uses colored smileys to show the results for the 10 domains of the PRAQ. The advantage of the PRAQ compared to other commonly used PROMs in the

care for patients with OSA (such as the Epworth Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ), etc) is that it provides a comprehensive overview of the possibly impacted aspects of quality of life that patients with OSA may experience. It is therefore potentially suitable for shifting the focus of care away from (only) medical problems towards the problems patients experience in their daily life.

This explorative study aims to study the impact of the PRAQ and PRAQ-report on the clinical practice of OSA, and explore *why* the PRAQ did or did not have an impact. A combination of both qualitative and quantitative methods is used that will add to the general knowledge on the circumstances under which PROMs do or do not work in clinical practice.

2. Methods

This article describes an exploratory mixed methods study in which the PRAQ is implemented in the clinical practice of three sleep centers. Qualitative interviews and a patient survey were used to explore patients' and healthcare providers' experiences with the PRAQ, and to identify potential barriers and facilitators to its use. Additionally, data were collected from electronic health records to study whether the hypotheses about the potential impact of the PRAQ mentioned in the introduction are correct. For the patient survey and the patient record study we conducted a before-and-after study. The different methods are described in more detail in the next sections.

2.1 Hypotheses

We have several hypotheses regarding how the PRAQ may influence patients and healthcare professionals, and how this could impact clinical practice. First of all, completing the PRAQ could:

- Encourage patients to consider which problems they experience that might be related to OSA and that they might want to discuss
- Aid healthcare professionals in opening a conversation about an individual patient's burden of disease (apnea-related quality of life)
- Aid healthcare professionals to evaluate treatment and identify problems that are still present

We think that this may potentially lead to:

- Higher patient compliance with treatment
- More explicit choices regarding whether clinical treatment for OSA is (potentially) beneficial to the patient
- An increase in referrals to other healthcare providers, such as psychologists
- More 'holistic' care, in which there is increased attention for the well-being of patients, including the psychological and social effects of OSA and its comorbidities

2.2 The PRAQ and its implementation

The PRAQ and its complementary PRAQ-report were designed with the input of patients with OSA and healthcare professionals (31). The questions of the PRAQ can be found in supplementary file 1. The PRAQ takes

approximately 15 minutes to complete (31). More information about the PRAQ-report and how the PRAQ was implemented in clinical practice can be found in supplementary file 2.

2.3 Setting and subjects

Sleep centers of three Dutch hospitals took part in the study. The PRAQ was part of the clinical practice routine of these centers for six successive months. The PRAQ was distributed to patients attending an intake consultation for possible OSA (which takes place after a patient's diagnostic sleep study), and subsequently to the subselection of these intake patients diagnosed with OSA who returned for a follow-up consultation after starting treatment.

2.4 Interviews

In-depth, semi-structured interviews were conducted with patients and healthcare professionals in the last two months of the study. The interview guides contained broad, open questions as well as more specific questions informed by topics previously identified in the literature (4). For patients the main goal was to assess whether completing the PRAQ was acceptable to them, and to find out the impact that the PRAQ and PRAQ report had for them on the (preparation for) the consultation. For healthcare providers, questions were mostly focused on how they used the PRAQ and why they used it this way, and the impact the use of the PRAQ has on their practice. This information can provide the basis for interpreting the results of the electronic health record study.

Patients were invited via email by the sleep center before their scheduled consultation, or by their healthcare professional directly after their consultation (for more information see supplementary file 3). Only patients who had completed the PRAQ were invited. We interviewed 27 patients. Data saturation was reached. Characteristics of the interviewed patients and of the interviews can be found in table 1.

All healthcare professionals of the three participating sleep centers that had had the option to work with the PRAQ were invited to participate. This resulted in interviews with 14 healthcare professionals: six pulmonologists, six physician assistants (PAs) and two nurses. Two pulmonologists refused an interview because they had not seen many patients for OSA, two others because they had not used the PRAQ at all, and one PA refused for personal reasons. At least four healthcare professionals were interviewed at each of the three sleep centers.

More information on the (analysis of) the interviews can be found in supplementary file 3.

Table 1. Characteristics of the interviewed patients and the interviews

Patient characteristics (n=27)	
Age (mean, range)	59 (31-82)
Gender (male)	18
Highest education level (range)	Primary school - PhD
Interview characteristics (n=27)	
Interview after intake consultation (n)	18
Interview after follow-up consultation (n)	9
Interview together with partner or other relative that attended the consultation	4
Patients who had not seen the PRAQ-report at the time of the interview[1]	5

1. Viewing the PRAQ-report before the consultation was optional, and not all healthcare providers showed the report to the patient during the consultation

2.5 Surveys

The patient survey was designed for this study to study potential differences in patient empowerment and patient-centeredness of care before and after the implementation of the PRAQ. The items of the survey covered how prepared patients felt for their consultation, whether there was discussion of the health problems that patients consider relevant during the consultation, and whether patients were motivated to start their treatment. Patients could indicate their agreement on several statements on these topics with the statement on a 7-point Likert scale. The survey was checked by the members of the research team, which included a patient, but was not pilot tested. A translated version of the survey can be found in supplementary file 4.

Surveys were distributed by healthcare professionals to all of their patients attending either an intake or first follow-up consultation for (suspected) OSA. Distribution of the surveys took place in the two months before implementation of the intervention (control group), and in the last two months of the six months that the intervention was part of daily clinical practice (intervention group). For the intervention group, the survey also contained additional questions about the patient's opinion on the usefulness of the PRAQ. Participation was voluntary and anonymous.

2.6 Electronic health records

Electronic health records from one of the included sleep centers were studied to explore potential changes in treatment and compliance with treatment resulting from the use of the PRAQ. Data were collected from patients with an AHI≥5 attending an intake consultation during the final two months of the study period and during the same time period the previous year. Information was collected about treatment choice at intake, treatment adaptations and compliance with treatment at the first follow-up consultation, and patient characteristics. Compliance data is only available for patients who receive Continuous Positive Airway Pressure (CPAP), the most commonly prescribed treatment for patients with OSA. As part of standard care, hours of use are registered by the CPAP device and entered into the health record at follow-up consultations. CPAP compliance is

expressed as average hrs CPAP use/night in the month before the follow-up consultation, with an average of 4 hrs/night generally being the minimum to be considered compliant (33).

No identifying information was collected from the health records. The data collection procedure guaranteed that the records would at all times remain anonymous to the researchers.

2.7 Statistical analyses

Mann-Whitney U tests were conducted for each of the survey items that patients were asked to complete both pre- and post-implementation of the PRAQ. For the electronic health record study, treatment choice at intake was studied by aggregating the choice into two variables: medical treatment of OSA (e.g. CPAP, MRA, referral for surgery) and no or non-medical treatment (e.g. lifestyle advice), as these are the variables which we potentially expected the PRAQ to influence. A Chi-Square test was used to test for statistical significance. For the follow-up variables of the patient record study, Chi-Square tests (for dichotomous variables) and an independent samples T-test (for CPAP compliance in minutes) were conducted.

No correction for multiple testing was performed because this is an exploratory study. A p-value of <0.05 was therefore taken as a significant difference, which can be interpreted as an indication that this is a potentially interesting variable for a possible future study.

2.8 Patient and Public Involvement

A board member (author MI) of the Dutch patient organisation for OSA (Apneuvereniging) was involved with this study from its inception, including the research question and outcome measures and interpretation of the results. This author was also closely involved in the development of the intervention itself (the PRAQ and its complementary PRAQ-report), as were other members of the patient organization (31). They also approved of the burden and time required for the intervention. Patients were not involved in the recruitment for the study.

3. Results

3.1 Interviews

Patient perspective

Patients were generally willing to complete the PRAQ before their consultation, and patient response as reported by the healthcare professionals was high. About half of the interviewed patients indicated that completing the PRAQ helped them prepare for their intake consultation by giving them more insight into their complaints and functioning and how this might relate to OSA, and/or made them consider what they wanted to discuss with the healthcare professional. Many patients completed the PRAQ with a family member which instigated discussions patients often considered useful. A great majority of interviewed patients indicated that they did not mind taking the time to complete the PRAQ, and many also considered the smileys of the PRAQ-report a clear and easy way of communicating the results. Box 1 contains quotes illustrating the statements in this paragraph.

The interviews also revealed some unintended effects of the PRAQ. A majority of patients assumed that the main purpose of the PRAQ was to aid their healthcare professional in setting a diagnosis, by providing information about symptoms ahead of time. A few patients believed that discussion of patient complaints during the consultation was therefore no longer necessary after completing the PRAQ (box 2), while healthcare

professionals consider this discussion very important (see next section). What may have played a role here is that several interviewed patients seemed eager to hear their sleep study results, rather than (first) spend much time talking about their symptoms or problems.

Additionally, there were some issues around the interpretation of the smileys in the PRAQ-report. Several of the interviewed patients did not seem to view the PRAQ-report as merely a visualization of the answers they had given, but rather as a 'test result'. Some considered the number of 'unhappy' smileys as an indication of whether they were doing well or not, which made some patients reconsider the severity of their complaints (box 2).

Box 1:

"Look, it's just very insightful. You can see instantly where the problems are and on this other [page] you can see what the improvements are. Yes, it's kinda nice." (Centre 3, patient 10)

"Yes, you know I do find it useful, because you have so many… so many things that bother you, that you forget what it is that bothers you. Or because it has become part of you, so to say. So yeah in order [not] to forget things, a questionnaire like this comes in handy." (Centre 2, patient 1)

"But there were quite a lot of questions where I was like, oh, sometimes I'm like, how does that fit with [apnea]? But most did, but there were questions where I was like, is that related to sleep apnea? So. Yes. Apparently." (Centre 3, patient 7)

"Actually I liked [seeing it beforehand], because this way I can by myself… otherwise I would have gone into it timidly like, tell me, what did you see? And now I could ask specific questions."
(Centre 3, patient 2)

Box 2:

"I think it's very good, because you can from the beginning very clearly indicate your problems. So it doesn't need to all be done during the short conversation you have with the specialist. [..] It's clear it doesn't need to be mentioned again, because it's clear to her as well what the problems are." (Centre 1, patient 4)

"Just that when you complete a questionnaire aimed at establishing something, then it's useful that you also get a sort of result. So a preliminary… not that you should instantly think like nothing is wrong, nothing needs to be done, let's get out of here. But, I did like it, yeah." (Centre 1, patient 3)

"Well, because there were only two orange [smileys], and the others were all green and then you think, well…. And then when you look at it again then I'm like, 'I can live with that'." (Centre 2, patient 7)

Healthcare professional perspective

Most healthcare professionals used the PRAQ during consultations (table 2), but usually briefly. Several professionals mentioned that, especially during intake consultations, they used it for the sake of the study. Only a few tried to provide more holistic care with the PRAQ. Some professionals stated that their minimal use of the PRAQ was due to unwillingness to change their practice, while others mentioned a general aversion to questionnaires, and/or not being convinced that the PRAQ would offer new or useful information considering what was already discussed during a regular consultation. There were also practical issues that to some extent hindered the uptake of the PRAQ: most notably the (limited) time available for consultations, and the fact that

the PRAQ was not embedded in the electronic health records which hindered the regular workflow. There were no notable differences in attitude towards the PRAQ between physicians, PAs and nurses.

Table 2. Use of PRAQ-report by interviewed healthcare professionals

Use of the PRAQ-report during intake consultations				
Discussed it with patients	Only looked it up	Did not look at it		N/A[1]
8	1	3		2
Use of the PRAQ-report during follow-up consultations				
Discussed it with patients	Only looked it up	Did not look at it	Want to use it[2]	N/A[1]
3	1	3	6	1

1. Not all healthcare professionals held both intake and follow-up consultations
2. Did not see (many) patients with follow-up PRAQ but are interested in using it in this setting

Most of the professionals that used the PRAQ did so at the end of their usual discussion of symptoms, to check whether all topics that were problematic had been discussed and potentially address more topics. As such they could still start the conversation in their usual way, allowing patients to explain their problems in their own words, and allowing the healthcare professionals to ask their standard diagnostic questions. Professionals indicated that most "symptoms" that are part of the PRAQ were already part of the standard diagnostic questions during an intake consultation (sleepiness, problems at night), and also overlapped with their usual (diagnostic) intake questionnaire. However, several professionals mentioned that the PRAQ-report increased discussion of the topic "health concerns", which was considered valuable. Furthermore, the few professionals that indicated that they valued offering more holistic care noticed that the PRAQ was useful in drawing the conversation away from medical facts and more towards the underlying emotions related to a patient's problems. However, many other professionals did not see much added value in actively bringing up topics like emotions and social interactions. They were potentially willing to discuss these issues but considered it up to the patient to raise them. If the PRAQ was used to identify problems, it was more common for the professional to mention very briefly that these problems were likely to improve with treatment of OSA, without further discussing these problems. Professionals reported that they did not notice any increase in OSA-related knowledge in their patients, or a difference in whether or how patients raised health complaints or quality of life issues of their own accord. Box 3 contains quotes illustrating the statements in this paragraph.

With regard to treatment choice, the professionals mentioned that the severity of symptoms generally only plays a role in patients with an AHI<15, for which shared-decision making could potentially lead to a decision not to start clinical treatment for OSA. If the AHI is ≥15, professionals generally wish to treat a patient for health reasons irrespective of symptoms. Many patients also have a reason to opt for treatment: there is a motor vehicle driving ban for untreated patients with AHI≥15.

Use of the PRAQ during follow-up consultations could not be fully evaluated, because a limited number of patients had completed the PRAQ at follow-up at the time of the interviews. This was due to practical implementation issues in combination with the relatively short duration of the study. However, several healthcare professionals mentioned that they thought the PRAQ would be more useful during follow-up consultations than intake conversations, as it would be interesting to see which problems remained after starting

treatment (table 2). Those that had the opportunity to use the PRAQ in this setting mentioned that it was nice to show patients how their problems had improved, with the improvement sometimes being greater than the patients had realised. This could be used as encouragement to continue with treatment.

Box 3:

> "Well I myself don't ask 'are you worried about your [health]'? I won't ask that, but that is what it shows. So then… then it's like 'hey, I would otherwise not have discussed that'." (Centre 3, healthcare provider 4)
>
> "Yes, but then in a solution-oriented way - then you will see someone with 30 apneas an hour and you see that and you say I hope that [your problem with emotions] will get a lot better with the therapy I will start for you." (Centre 1, healthcare provider 2)
>
> "Especially I thought people were, uhm… that lack of initiative, not going out, right? So they don't do things because of their sleep problem, that was what [the PRAQ] often showed. And I didn't always get that from taking the patient history. So people maybe find that hard to tell me, or they have trouble indicating that it really does have an impact on them. And then they try to focus more on the fact than on the underlying emotion. And that would sometimes give added value." (Centre 1, healthcare provider 1)

3.2 Survey results

A total of 487 patients completed surveys pre-implementation, and 377 patients completed surveys post-implementation of the PRAQ. Characteristics of the survey populations pre-implementation and post-implementation can be found in table 3.

Table 3. Characteristics of the survey population

Intake consultations		
	Pre-implementation (n=239)	Post-implementation (n=197)
Age (yrs)	53.9	55.4
Gender (% male)	68.4	69.5
Severity of symptoms[1]	6.50	6.44
Diagnosed with OSA (%)	82.8	83.2
CPAP[2] (%)	71.0	70.7
MRA[2,3] (%)	13.7	19.5
Other treatment[2] (%)	10.7	7.4
No treatment[2] (%)	1.0	2.4
Missing[2] (%)	3.6	0.0
Follow-up consultations		
	Pre-implementation (n=248)	Post-implementation (n=180)
Age	57.33	58.54
Gender (% male)	75.3	69.7
Severity of remaining symptoms or problems with treatment[1]	4.25	5.03
CPAP (%)	89.1	89.4
MRA[3] (%)	3.6	3.9
Other[4] or missing (%)	7	5.6

CPAP = continuous positive airway pressure, MRA = mandibular repositioning device 1. Scale 1-10, higher is more problems

2. Percentage of patients with this treatment of the total of patients diagnosed with OSA

3. Device worn over the teeth that pushes tongue and jaw forward to hold the airway open

4. Other possible treatments are surgery of the jaw or throat, and methods that will help a patient with positional OSA (who experiences breathing stops mainly when they lie on their backs) sleep on their side

Patients generally showed high agreement with the statements of the survey: 73.3% - 97.3% of patients indicated "agree" or "completely agree" per statement about the intake and follow-up consultations (table 4). Follow-up patients post-implementation showed significantly less agreement with the statement "In my opinion, my treatment is worth it for me" (p=.005). The main difference between pre- and post-implementation scores lies in distribution between scores 6 and 7 ('agree' and 'completely agree'), with 68.2% of pre-implementation patients giving a score of 7, and 54.3% of post-implementation patients giving a score of 7. The other statements showed no obvious or statistically significant differences in the level of agreement pre- and post-implementation.

Table 4. Survey results[1]

	Pre-implementation PRAQ					Post- implementation PRAQ				
Scores	1-3 % (n)	4-5 % (n)	6-7 % (n)	N /A[2] n	Median	1-3 % (n)	4-5 % (n)	6-7 % (n)	N /A[2] (n)	Median
Intake consultations										
I knew which problems I wanted to discuss with the doctor	17 (7.2)	18 (7.7)	200 (85.1)	4	6	8 (4.2)	14 (7.3)	170 (88.5)	5	6
I discussed with the doctor the topics I wanted knew I wanted to discuss beforehand	22 (9.8)	28 (12.5)	174 (77.7)	15	6	16 (8.9)	22 (12.2)	142 (78.9)	17	6
Because of my conversation with the doctor, I understand better what causes my problems	14 (6.0)	14 (6.0)	206 (88.0)	5	6	6 (3.1)	10 (5.1)	178 (91.8)	3	6
The doctor and I chose the treatment together or together chose not to treat my apnea	14 (6.0)	12 (5.2)	206 (88.8)	7	6	7 (3.6)	14 (7.3)	172 (89.1)	4	6
Because of my conversation with the doctor, I understand how the treatment can benefit me	12 (5.6)	12 (5.6)	192 (88.9)	23	6	4 (2.2)	10 (5.4)	172 (92.5)	11	6
I think the treatment will be worth it for me	10 (4.7)	17 (8.0)	196 (87.3)	26	6	4 (2.2)	18 (9.8)	161 (88.0)	14	6
Follow-up consultations										
I knew which problems I wanted to discuss with the doctor	11 (5.1)	10 (4.7)	194 (90.2)	33	7	5 (3.4)	10 (6.9)	130 (89.7)	35	7
I discussed with the doctor the topics I wanted to discuss	10 (4.7)	14 (6.5)	190 (88.8)	34	6	8 (5.7)	9 (6.4)	123 (87.9)	40	6
There was enough attention for the complaints that I still have	7 (3.2)	6 (2.7)	206 (94.1)	29	7	2 (1.4)	2 (1.4)	144 (97.3)	32	7
My complaints have lessened since start of my treatment	21 (8.9)	36 (15.3)	179 (75.8)	12	7	19 (11.5)	25 (15.1)	121 (73.3)	15	6
In my opinion, my treatment is worth it for me*	7 (2.9)	10 (4.2)	222 (92.9)	9	7	6 (3.4)	12 (6.9)	157 (89.7)	5	7
Usefulness of the PRAQ										
The PRAQ-report was useful for preparing my consultation[3]	-	-	-	-	-	6 (6.5)	22 (23.9)	64 (69.6)	2	6
The PRAQ-report was useful during my consultation[4]	-	-	-	-	-	3 (2.3)	18 (13.6)	111 (84.1)	29	6

* Significant difference between pre- and post-implementation (p=.005, Mann-Whitney U test)

1. Scale 1-7 (1 = completely disagree, 2 = disagree, 3 = disagree a little, 4 = neither agree nor disagree, 5=agree a little, 6=agree, 7= completely agree)
2. "not applicable" (see supplementary file 4) or missing
3. Showing results for patients who indicated they had seen the PRAQ-report before their (intake or follow-up) consultation (n=94)
4. Showing results of patients who indicated the PRAQ-report was shown during their (intake or follow-up) consultation (n=161)

Patients showed high agreement with the two statements about the usefulness of the PRAQ-report, particularly regarding its use during a consultation (table 4). However, not all patients had completed the PRAQ and seen the PRAQ-report before or during their consultation. Patients who did not look up the PRAQ-report before their consultation may also have been the ones less interested in using the PRAQ-report, so the reported results may be somewhat biased towards are more positive evaluation (table 5).

Table 5. Percentage of patients that completed and viewed the PRAQ, and patient opinion on usefulness PRAQ

	Intake (n=197)	Follow-up (n=180)
Completed PRAQ before consultation	77.7%	51.1%
Seen PRAQ-report before consultation[1]	40.0%	44.4%
Seen PRAQ-report during consultation[1]	74.1%	60.2%

1. This percentage is a sub-percentage of the patients who indicated they completed the PRAQ

3.3 Electronic health record results

125 patients were included in the pre-implementation group, and 124 other patients in the post-implementation group. Patient characteristics are described in table 6. No differences were found with regard to how many patients with OSA received non-medical treatment (either no treatment at all or referral to a psychologist (table 7)), or in the number of patients for whom treatment was adjusted at the first follow-up consultation after starting CPAP treatment (table 8).

In both groups, 98 patients were prescribed CPAP. Patient characteristics did not differ between the two groups of patients with CPAP (data not shown). Compliance with CPAP treatment did not differ between the two groups (table 8).

Table 6. Patient file study: patient characteristics

	Pre-implementation (n=125)	Post-implementation (n=124)
Age (SD)	55,4 (12,0)	56,6 (15,7)
Gender	68% male	67,7% male
BMI (SD)	31,4 (6,5)	30,8 (6,1)
AHI (SD)	23,1(16,1)	25,0 (18,5)
AHI < 15	40,8%	33,9%
ESS (SD)	8,0 (4,8)	7,4 (5,0)
Start with CPAP at intake	78,4%	79,0%

Table 7. Treatment choice at intake[1]

	Pre-implementation (n=125)	Post-implementation (n=124)[1]	Pre-implementation, AHI <15 (n=51)	Post-implementation, AHI <15 (n=42)
Medical treatment for OSA (incl CPAP) (n,%)	123 (98.4)	123 (99.2)	49 (96.1)	41 (97.6)
No medical treatment for OSA (n,%)	2 (1.6)	1 (0.8)	2 (3.9)	1 (2.4)
Referred to psychologist (n, %)	2 (1.6)	0 (0)	2 (3.9)	0 (0)
No treatment (n, %)	0 (0)	1 (0.8)	0 (0)	1 (2.4)

1. If nothing is indicated, no significant difference was found.

Table 8. Treatment adjustments and compliance in patients with CPAP at the first follow-up[1]

	Pre-implementation of PRAQ (n=98)	Post-implementation of PRAQ (n=98)	Missings
Adjustment of current treatment	45	36	N/A[2]
Switch to different treatment	5	9	N/A[2]
Referral to different specialization	6	2	N/A[2]
CPAP compliance[3] (SD)	5:47 hrs (2:11)	5:53 hrs (2:10)	Pre-impl.: 11 Post-impl: 7
CPAP compliance <4hrs	25.0%	27.5%	Pre-impl.: 11 Post-impl: 7
Stopped CPAP treatment	4.1%	5.1%	N/A[2]

1. If nothing is indicated, no significant difference was found.
2. If nothing was noted down in the patient health record, it was assumed this did not take place. Therefore missings are not applicable.
3. Hours of CPAP use by patients who had stopped treatment altogether (see "stopped CPAP treatment") are not included in this number.

4. Discussion

This exploratory study showed limited success regarding the uptake of the PRAQ in the daily clinical practice of sleep centers, and the improvement of patient-centeredness of care. From the interviews it became clear that most patients were willing to complete the PRAQ and were generally positive about the usefulness of the PRAQ before the consultation (e.g. because of feeling more informed) and during the consultation (due to the clear visual representation of their problems). This may therefore have lead to some improvement of preparation for the consultation by patients, and better communication, though this is not reflected in the results of the patient survey. Amongst healthcare professionals the willingness to use the PRAQ-report in consultations differed, as the perceived need was minimal. Most of the professionals that used the PRAQ also reported that the impact on their consultations was minor. Therefore, it is not surprising that comparison of health records pre- and post-implementation of the PRAQ did not show any differences in treatment choice and CPAP compliance.

The interviews showed that the professionals mostly felt that they already sufficiently address the "symptom-like" topics of the PRAQ (sleepiness, problems at night) in their usual care, in the context of setting a diagnosis. The topics of the PRAQ that are not necessary for setting a diagnosis, but could potentially be used to motivate patients for their treatment, were not seen as essential to discuss by many professionals. The limited perceived benefit of the PRAQ is likely also mitigated by the fact that many steps of the care process have to be

covered during the intake consultation, including discussing the sleep study results and choosing a treatment. This leaves little extra time to discuss a patient's quality of life and detailed treatment goals. Furthermore, burden of disease plays a limited role in setting a diagnosis when AHI≥15, due to views on strict medical necessity of treatment, but also due to the driving ban for untreated patients. Therefore, adding the PRAQ to the current practice for OSA does not appear to be a sufficient trigger to increase attention to quality of life issues.

Patients generally held a more positive view towards the usefulness of the PRAQ. From the interviews it became clear that completing the PRAQ has the potential to give patients more insight into their OSA-related health complaints and encourages communication between family members. Furthermore, the patient survey results indicated that patients thought the PRAQ-report was useful for their preparation for the consultation and (when it was used by the healthcare professional) during the consultation.

Agreement to the patient survey statement "I feel like my treatment is worth it for me" was significantly lower on the post-implementation survey than on the pre-implementation survey. The main difference was in the number of patients indicating "agree" versus "completely agree", meaning both pre-and post-implementation of the PRAQ patients were very positive about their treatment. This being an exploratory study, statistically significant results should be interpreted with caution, and we deem the relevance of this finding to be limited.

There appears to be room for improvement of communication around the PRAQ, as there was confusion for some patients around the necessity of still discussing symptoms during the consultation. Whereas some patients seemed to be more interested in hearing their sleep study results than talk about their symptoms, for the healthcare professionals hearing about the patient's symptoms in their own words is an essential part of the diagnosis. It may be beneficial to communicate the purpose of the PRAQ more clearly in the invitation email, and/or to instruct professionals to, at the beginning of their consultation, mention the PRAQ to patients and how its results will be addressed. More in-depth discussion with the field about what is most suitable or desirable in this context is needed.

In the past few years, several similar initiatives involving PROMs have been introduced in The Netherlands, such as the Assessment of Burden of COPD (ABC) tool (34), the Nijmegen Clinical Screening Instrument for COPD(35), the QLIC-ON PROfile for children (36), and MyIBDcoach for patients with inflammatory bowel disease(37). Studies into these applications show promising results regarding their benefits (37, 38) despite some resistance from professionals who do not believe in the added benefit or believe the tool would be more useful for different professionals within the care pathway (39, 40). However, the healthcare professionals' skepticism about the potential benefits of the PRAQ seems to be more extensive. Potentially, professionals will see greater benefit of the PRAQ in the context of the recently released new guidelines for OSA (30) with their greater emphasis on (improving) burden of disease, which were not yet available at the time of this study. However, the question remains whether a more "holistic" approach to caring for OSA patients fits within the current setting of relatively short intake consultations which take place after the patients' diagnostic sleep study. It may be necessary to move towards a reorganization of care: for example to plan the intake consultations before the sleep study to allow for more focus on the individual patients' symptoms and problems, and to specifically evaluate the necessity of doing a diagnostic sleep study. Additionally, integrating the PRAQ in the electronic health record will help professionals fit the PRAQ-report better into their workflow.

Another option that can be explored is to adapt the PRAQ itself or the context in which it is used, in order to fit better to healthcare professionals' preferences. For example, an option would be to remove the domains of the PRAQ focused on symptoms that are (nearly) always discussed already, and instead put the focus on the additional domains. It is also possible to distribute the PRAQ to a more select group of patients, for example by moving the first measurement moment to the follow-up consultation, therefore targeting only patients with a diagnosis and treatment. It could then be used to identify those patients still experiencing problems. Downside to both of these adaptations is that they limit the option to monitor changes over time on all domains that are relevant for patients with OSA, while monitoring over time is what most interviewed healthcare professionals are interested in. Not having a baseline measurement would also limit the options to usefully study the PRAQ data on aggregate level. It may be most feasible to let sleep centers decide how they want to use the PRAQ in the context of what is desirable to them, which may also evolve over time. It is hoped that they will also take into account the patient perspective when deciding how to use the PRAQ.

Strengths and limitations of the study

The major strength of this study is that we used mixed methods, which provides insight into the reasons why the PRAQ does not work as intended. Many other studies on PROMs study only *whether* a PROM works, rather than why or how.

There are also limitations to the study. First, the survey used for this study was not tested and maybe not discriminative enough to show differences between the groups pre- and post-implantation of the PRAQ. Potentially, patients who have not completed the PRAQ do not know that, for example, their preparation for the consultation could maybe have been better than it currently was. Second, electronic health records were only studied in one of the included sleep centers. However, considering the information we collected in the interviews, we do not expect that we would have found different results in either of the other two sleep centers. Third, though technically there was enough time in this study for professionals to also use the PRAQ during the first follow-up consultation, practical implementation issues as well as a lack of initiative from healthcare professionals to actively check whether a follow-up PRAQ was available meant that it was not used often at this time point. Therefore we did not gain much insight into the potential use of the PRAQ for follow-up consultations. Lastly, only patients who looked up the PRAQ-report could give an opinion on its usefulness for preparing the consultation in the survey. However, patients who did not look up the PRAQ-report may also be generally less interested in these kinds of tools and, if they had looked it up, may have experienced it as less useful. Additionally, patients who have a more positive opinion on the PRAQ may be more likely to complete the items on its usefulness.

Conclusions

Using the PRAQ in the daily clinical practice of OSA is viewed as useful by patients, but the enthusiasm of healthcare professionals differed per individual and was generally not very great. Implementation of the PRAQ does not seem a sufficient trigger to focus more attention to quality of life during consultations, and in current practice does not show impact on treatment choice or CPAP compliance. However, new Dutch guidelines for OSA care that have recently been published may lead to a greater emphasis on quality of life for patients, making the integration of the PRAQ in clinical care potentially more useful.

Additional information:

Funding: The first author was funded by the Radboudumc grant number R0002257. The funding organization had no role in the design, implementation, interpretation, or reporting of this study.

Conflicts of interest: All authors declare that they have no competing interests.

Author contributions: IA, MR, PW, MI, GW and BH were involved in the conception and design. IA and MN conducted and analysed the interviews. IA collected and analysed the quantitative data. IA and PW interpreted the quantitative data. IA drafted the manuscript. IA, MR, PW, MI, MN, GW and BH critically revised the manuscript for important intellectual content.

Data sharing statement: Data is available from the corresponding author upon reasonable request.

Ethics approval: Ethical approval is not required for this type of study under Dutch law, and an exemption was obtained by the local Medical Ethics Committee "CMO Regio Arnhem-Nijmegen".

References

1. Valderas JM, Alonso J, Guyatt GH. Measuring patient-reported outcomes: moving from clinical trials into clinical practice. The Medical journal of Australia. 2008;189(2):93-4.
2. Fleischmann M, Vaughan B. The challenges and opportunities of using patient reported outcome measures (PROMs) in clinical practice. Int J Osteopath Med. 2018:1-6.
3. Howell D, Molloy S, Wilkinson K, Green E, Orchard K, Wang K, et al. Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors. Ann Oncol. 2015;26(9):1846-58.
4. Greenhalgh J, Dalkin S, Gooding K, Gibbons E, Wright J, Meads D, et al. Functionality and feedback: a realist synthesis of the collation, interpretation and utilisation of patient-reported outcome measures data to improve patient care. Health Services and Delivery Research. Southampton (UK)2017.
5. Van Der Wees PJ, Nijhuis-Van Der Sanden MW, Ayanian JZ, Black N, Westert GP, Schneider EC. Integrating the use of patient-reported outcomes for both clinical practice and performance measurement: views of experts from 3 countries. The Milbank quarterly. 2014;92(4):754-75.
6. Valderas JM, Kotzeva A, Espallargues M, Guyatt G, Ferrans CE, Halyard MY, et al. The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2008;17(2):179-93.
7. Boyce MB, Browne JP. Does providing feedback on patient-reported outcomes to healthcare professionals result in better outcomes for patients? A systematic review. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2013;22(9):2265-78.
8. Holmes MM, Lewith G, Newell D, Field J, Bishop FL. The impact of patient-reported outcome measures in clinical practice for pain: a systematic review. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2017;26(2):245-57.
9. Greenhalgh J, Dalkin S, Gibbons E, Wright J, Valderas JM, Meads D, et al. How do aggregated patient-reported outcome measures data stimulate health care improvement? A realist synthesis. J Health Serv Res Policy. 2018;23(1):57-65.
10. Bjornsdottir E, Benediktsdottir B, Pack AI, Arnardottir ES, Kuna ST, Gislason T, et al. The Prevalence of Depression among Untreated Obstructive Sleep Apnea Patients Using a Standardized Psychiatric Interview. Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine. 2016;12(1):105-12.
11. O'Donoghue N, McKay E. Exploring the impact of sleep apnoea on daily life and occupational engagement. Br J Occup Ther. 2012;75(11):609-516.
12. Reishtein JL, Pack AI, Maislin G, Dinges DF, Bloxham TJ, George CF, et al. Sleepiness and relationships in obstructive sleep apnea. Issues Ment Health Nurs. 2006;27(3):319-30.
13. Bradley TD, Floras JS. Obstructive sleep apnoea and its cardiovascular consequences. Lancet. 2009;373(9657):82-93.
14. Chan AS, Phillips CL, Cistulli PA. Obstructive sleep apnoea--an update. Intern Med J. 2010;40(2):102-6.
15. Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med. 2002;165(9):1217-39.
16. Senaratna CV, Perret JL, Lodge CJ, Lowe AJ, Campbell BE, Matheson MC, et al. Prevalence of obstructive sleep apnea in the general population: A systematic review. Sleep Med Rev. 2017;34:70-81.
17. Medicine AAoS. International Classification of Sleep Disorders. Diagnostic and Coding Manual. . In: Medicine AAoS, editor. 3rd edition ed2014.
18. Committee DCS. International Classification of Sleep Disorders: Diagnostic and Coding Manual. In: Association ASD, editor. Rochester1990.

19. Macey PM, Woo MA, Kumar R, Cross RL, Harper RM. Relationship between obstructive sleep apnea severity and sleep, depression and anxiety symptoms in newly-diagnosed patients. PLoS One. 2010;5(4):e10211.
20. Tam S, Woodson BT, Rotenberg B. Outcome measurements in obstructive sleep apnea: beyond the apnea-hypopnea index. Laryngoscope. 2014;124(1):337-43.
21. Kingshott RN, Engleman HM, Deary IJ, Douglas NJ. Does arousal frequency predict daytime function? The European respiratory journal. 1998;12(6):1264-70.
22. Turnbull CD, Stradling JR. To screen or not to screen for obstructive sleep apnea, that is the question. Sleep Med Rev. 2017;36:125-7.
23. Van Dongen HP, Baynard MD, Maislin G, Dinges DF. Systematic interindividual differences in neurobehavioral impairment from sleep loss: evidence of trait-like differential vulnerability. Sleep. 2004;27(3):423-33.
24. Abuzaid AS, Al Ashry HS, Elbadawi A, Ld H, Saad M, Elgendy IY, et al. Meta-Analysis of Cardiovascular Outcomes With Continuous Positive Airway Pressure Therapy in Patients With Obstructive Sleep Apnea. Am J Cardiol. 2017;120(4):693-9.
25. Yu J, Zhou Z, McEvoy RD, Anderson CS, Rodgers A, Perkovic V, et al. Association of Positive Airway Pressure With Cardiovascular Events and Death in Adults With Sleep Apnea: A Systematic Review and Meta-analysis. JAMA. 2017;318(2):156-66.
26. Marin JM, Agusti A, Villar I, Forner M, Nieto D, Carrizo SJ, et al. Association between treated and untreated obstructive sleep apnea and risk of hypertension. JAMA. 2012;307(20):2169-76.
27. Barbe F, Duran-Cantolla J, Sanchez-de-la-Torre M, Martinez-Alonso M, Carmona C, Barcelo A, et al. Effect of continuous positive airway pressure on the incidence of hypertension and cardiovascular events in nonsleepy patients with obstructive sleep apnea: a randomized controlled trial. JAMA. 2012;307(20):2161-8.
28. McNicholas WT. Diagnostic criteria for obstructive sleep apnea: time for reappraisal. J Thorac Dis. 2018;10(1):531-3.
29. McNicholas WT, Bassetti CL, Ferini-Strambi L, Pepin JL, Pevernagie D, Verbraecken J, et al. Challenges in obstructive sleep apnoea. Lancet Respir Med. 2018;6(3):170-2.
30. NVALT. Richtlijn diagnostiek en behandeling van obstructief slaapapneu (OSA) bij volwassenen. Richtlijnendatabase.nl: Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose; 2017.
31. Abma IL, Rovers M, IJff M, Hol B, Westert GP, Van der Wees PJ. The development of a patient-reported outcome measure for patients with obstructive sleep apnea: the Patient-Reported Apnea Questionnaire (PRAQ). Journal of Patient-Reported Outcomes. 2017;1(14).
32. Abma IL, Rovers M, M IJ, Hol B, Westert GP, van der Wees PJ. Instrument completion and validation of the patient-reported apnea questionnaire (PRAQ). Health Qual Life Outcomes. 2018;16(1):158.
33. Grunstein RR. Sleep-related breathing disorders. 5. Nasal continuous positive airway pressure treatment for obstructive sleep apnoea. Thorax. 1995;50(10):1106-13.
34. Slok AH, in 't Veen JC, Chavannes NH, van der Molen T, Rutten-van Molken MP, Kerstjens HA, et al. Development of the Assessment of Burden of COPD tool: an integrated tool to measure the burden of COPD. NPJ Prim Care Respir Med. 2014;24:14021.
35. Peters JB, Daudey L, Heijdra YF, Molema J, Dekhuijzen PN, Vercoulen JH. Development of a battery of instruments for detailed measurement of health status in patients with COPD in routine care: the Nijmegen Clinical Screening Instrument. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2009;18(7):901-12.
36. Engelen V, Haverman L, Koopman H, Schouten-van Meeteren N, Meijer-van den Bergh E, Vrijmoet-Wiersma J, et al. Development and implementation of a patient reported outcome intervention (QLIC-ON PROfile) in clinical paediatric oncology practice. Patient Educ Couns. 2010;81(2):235-44.
37. de Jong MJ, van der Meulen-de Jong AE, Romberg-Camps MJ, Becx MC, Maljaars JP, Cilissen M, et al. Telemedicine for management of inflammatory bowel disease (myIBDcoach): a pragmatic, multicentre, randomised controlled trial. Lancet. 2017;390(10098):959-68.
38. Slok AH, Kotz D, van Breukelen G, Chavannes NH, Rutten-van Molken MP, Kerstjens HA, et al. Effectiveness of the Assessment of Burden of COPD (ABC) tool on health-related quality of life in

patients with COPD: a cluster randomised controlled trial in primary and hospital care. BMJ Open. 2016;6(7):e011519.

39. Schepers SA, Sint Nicolaas SM, Haverman L, Wensing M, Schouten van Meeteren AYN, Veening MA, et al. Real-world implementation of electronic patient-reported outcomes in outpatient pediatric cancer care. Psychooncology. 2017;26(7):951-9.

40. Slok AH, Twellaar M, Jutbo L, Kotz D, Chavannes NH, Holverda S, et al. 'To use or not to use': a qualitative study to evaluate experiences of healthcare providers and patients with the assessment of burden of COPD (ABC) tool. NPJ Prim Care Respir Med. 2016;26:16074.

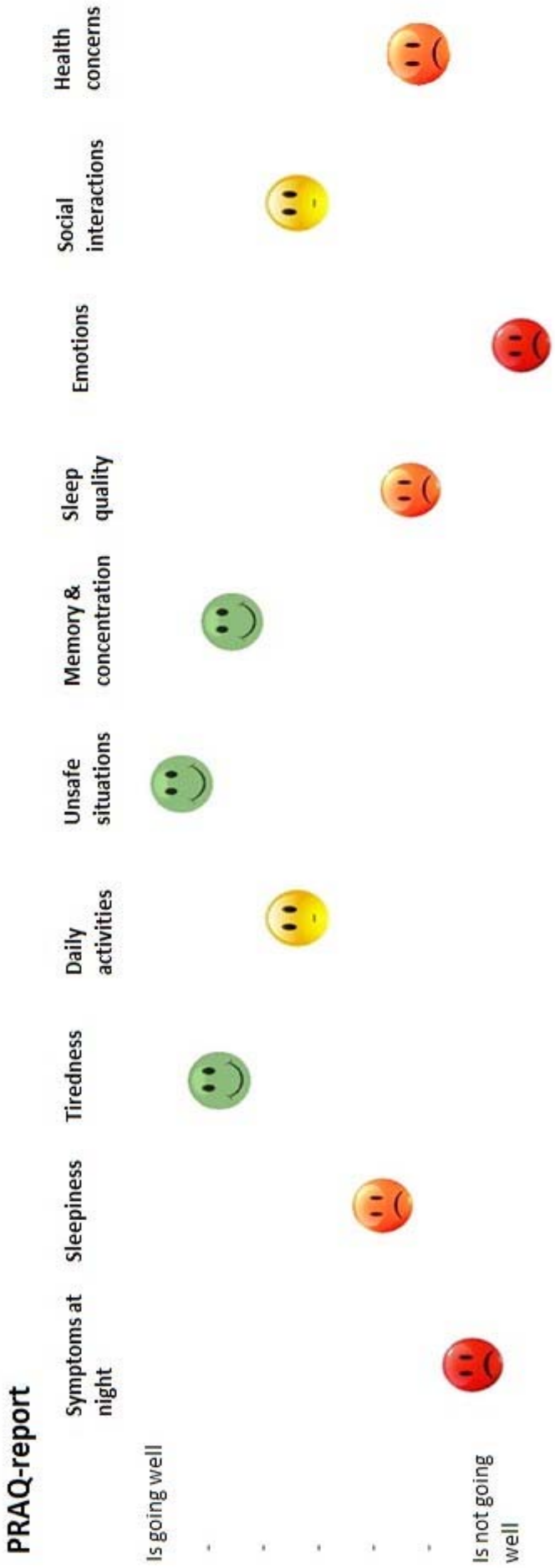
Supplementary file 1: The PRAQ-report and its implementation in clinical practice

In the PRAQ-report (shown on the next page), the results of each of the ten PRAQ-domains are shown in the form of a colored smiley, ranging from green (patient indicated very few problems) to dark red (patient indicated a lot of problems). Domain scores over time and individual item scores are shown on subsequent pages of the PRAQ-report. The included domains were: symptoms at night, sleepiness, tiredness, daily activities, unsafe situations, memory and concentration, quality of sleep, emotions, social activities, and health concerns. The PRAQ also contains a set of "intake questions" that were designed together with the participating centers and aimed to replace the diagnostic intake questionnaires that the centers usually distribute to all their new patients. This involved more factual, broader questions to help professionals in setting a correct diagnosis.

The PRAQ was distributed via a secure online platform (VitalHealth QuestManager) which sent out email invitations to a patient to complete the PRAQ at ten and (if the PRAQ was not yet completed) three days before the patient's consultation. After completion of the PRAQ, patients and healthcare professionals both had the ability to access the PRAQ-report directly from the online platform.

Individual implementation plans for collecting email addresses of patients, creating patient accounts, and entering consultation dates were developed for each study center to optimally fit their usual work flow.

Healthcare professionals received information about the content of the PRAQ and PRAQ-report, and instructions and a short training in how to use QuestManager. They were then encouraged to integrate the PRAQ into their own workflow in whichever way each individual professional found most convenient. After approximately two months of using the PRAQ, the researchers organized a meeting in each sleep centre in which the healthcare professionals were invited to discuss how they were using the PRAQ-report in their practice, in order to exchange ideas and potentially adjust their way of using the PRAQ.



Supplementary file 2 – The Patient-Reported Apnea Questionnaire (PRAQ) and PRAQ-report

Symptoms at night
During the past 4 weeks, did you have a problem with: 1. Snoring loudly? 2. Waking up frequently to urinate? 3. Waking up at night with the feeling that you are choking? 4. A feeling that you are sleeping restlessly? 5. Having a dry or painful mouth when you wake up? 6. Waking up in the morning with a headache?
Sleepiness
During the past 4 weeks, did you have a problem with: 7. Fighting to stay awake during the day? 8. Suddenly falling asleep? 9. Difficulty staying awake during a conversation? 10. Difficulty staying awake while watching something? (concert, movie, television) 11. Falling asleep at inappropriate times or places?
Tiredness
During the past 4 weeks, did you have a problem with: 12. Feeling very tired? 13. Lacking energy? 14. Still feeling tired when you wake up in the morning?
Daily activities
During the past 4 weeks: 15. How difficult was it for you to do your most important daily activity? (such as your job, studying, caring for the children, housework) 16. How often did you use all your energy to accomplish only your most important daily activity? (such as your job, studying, caring for the children, housework) 17. Did you feel you have a decreased performance with regard to your most important daily activity? (such as your job, studying, caring for the children, housework) 18. How much difficulty did you have finding energy for your hobbies? 19. How difficult was it for you to get your chores done?
Unsafe situations
During the past 4 weeks: 20. Did you have problems while driving a car due to sleepiness?[1] 21. Were you concerned about your safety or that of others due to your sleepiness? (for example in traffic, or when operating machinery)
Memory and concentration
During the past 4 weeks: 22. Were you sometimes forgetful? 23. Did you sometimes have difficulty concentrating?
Quality of sleep
During the past 4 weeks, did you have a problem with: 24. Falling asleep when you go to bed at night? 25. Getting back to sleep after you woke up at night?
Emotions
During the past 4 weeks: 26. How often did you feel depressed or hopeless? 27. How often did you feel anxious? 28. How often did you lose your temper? 29. How often did you feel that you could not cope with everyday life? 30. How often did you feel irritated? 31. How often did you have a strong emotional reaction to everyday events?

Social interactions
During the past 4 weeks: 32. Did you sometimes feel upset because others were disturbed by your snoring? 33. Was it a problem for you that you sometimes had no energy or no desire to do things with your family or your friends? 34. Did you feel guilty towards your family or friends? 35. Did you feel upset because you argued frequently? 36. Did you sometimes experience problems in the relationship with your partner?[1] 37. Did you feel upset because you could (maybe) not sleep in the same room as your partner?[1] 38. Did you sometimes think up excuses because you were tired or sleepy? 39. Did you have a problem with unsatisfying and/or too little sexual activity? (by yourself or with another)[1]
Health concerns
40. Were you concerned about other conditions that may be related to sleep apnea? (such as diabetes, high blood pressure, cardiovascular disease, being overweight)

1. These items had an additional response option “not applicable” or (for item 39) “no answer”

Supplementary file 3: information about the interviews and coding

Interviewers IA and MN held the patient interviews based on the interview guides, mostly together but MN did some patient interviews alone, and IA did some patient and some professional interviews alone. IA had some training in qualitative research/interviewing, and participated in qualitative study with interviews before. MN did not have official training but received some interview training from IA. IA was the developer of the PRAQ and PRAQ-report, and the healthcare professionals were aware of this, which may have lead to bias. However, this was specifically addressed before the start of the interviews, reminding the interviewees that this was scientific research and the researchers were looking for honest opinions in order to learn more about the application of PROMs in clinical practice, and negative opinions were also welcome. The patients were not told that IA was the developer of the PRAQ.

Patient recruitment took place in two different ways:

- Patients were approached via email by the sleep center before their scheduled consultation. The email was sent directly via the online platform as an added message to the invitation to complete the PRAQ, or by a team member of the sleep center.
- All patients scheduled on a certain specific day for a specific healthcare professional that had completed the PRAQ, were invited by their healthcare professional to participate directly after their consultation.

18 patients were interviewed face to face at the sleep center after their consultation in a private room; 9 patients were interviewed over the phone for convenience reasons. The patient interviews lasted on average 15 minutes. Healthcare provider interviews lasted on average 44 minutes and were all held at the sleep center. All interviews were audiotaped, transcribed verbatim and anonymised. All interviewees were provided with information about the study and signed an informed consent form or gave verbal informed consent on the audiotape. Transcripts of the interviews were not provided to the interviewees. Analysis of the interviews took place via open coding, with different code books for patients and healthcare providers. IA and MN first coded five interviews independently for both patients and healthcare professional interviews. A researcher (IG) experienced in qualitative research and knowledgeable about PROMs, but not involved in the study, coded one of the healthcare professional interviews independently. IG, IA, MN and PW held a collaborative coding session in which the code books were constructed. MN analyzed all remaining interviews, which IA then read and checked to the code book. When there was a disagreement about the coding, IA and MN reached consensus.

Supplementary file 4: Patient survey. Version: intake consultation, post-implementation of the PRAQ.

When answering the questions, keep in mind the consultation that you just attended.

1. I knew which problems I wanted to discuss with the doctor

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable*
☐	☐	☐	☐	☐	☐	☐	☐

2. I discussed with the doctor the topics I knew I wanted to discuss beforehand

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable*
☐	☐	☐	☐	☐	☐	☐	☐

3. Because of my conversation with the doctor, I understand better what causes my health complaints or problems

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable*
☐	☐	☐	☐	☐	☐	☐	☐

4. The doctor and I chose the treatment together, or together chose not to treat my apnea

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable**
☐	☐	☐	☐	☐	☐	☐	☐

5. Because of my conversation with the doctor, I understand how the treatment can benefit me

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable**
☐	☐	☐	☐	☐	☐	☐	☐

6. I think the treatment will be worth it for me

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable**
☐	☐	☐	☐	☐	☐	☐	☐

Clarifications:
* I have no complaints or problems / I did not think of anything to discuss
** I don't have sleep apnea / no choice was made yet

Questions about the PRAQ-report

7. Your sleep center asked you to fill out a questionnaire before attending your consultation, about your health complaints and daily functioning (the PRAQ). Did you complete this questionnaire?

☐ Yes
☐ Partially (go to question 12 at the bottom of this page)
☐ No (go to question13, on the next page)

The results of the questionnaire are summarised in a report, with on the first page smileys for each topic. The questions below are about whether you looked at this report, and whether you thought this was useful. Answer each question in the way that fits you or your situation best. **Please answer the questions as well if you have not seen the report.**

8. I looked at the report before my consultations with the doctor.

☐ Yes, elaborately
☐ Yes, briefly
☐ No, not important or didn't get around to it
☐ No, I didn't know that there was a report or how to open it

9. The report was shown during the consultation with the doctor
(for example, you looked at the smileys together and discussed your health complaints)

☐ Yes, elaborately
☐ Yes, briefly
☐ No, not at all

10. I thought the report was useful as preparation of my consultation with the doctor
(if you did not look at the report beforehand, you may answer "not applicable")

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable*
☐	☐	☐	☐	☐	☐	☐	☐

11. I thought the report was useful during my consultation with the doctor
(If the report was not shown during the consultation, you may answer "not applicable")

completely disagree	disagree	disagree a litte	don't agree, don't disagree	agree a little	agree	completely agree	not applicable*
☐	☐	☐	☐	☐	☐	☐	☐

12. Is there anything else about the PRAQ-questionnaire or the report that you would like to share? We are happy to hear your opinion.

We would also like to know something about you.

13. What is your age? ☐☐☐ year

14. Gender: ☐ man ☐ woman

15. What is the highest level of education you finished with a diploma?

☐ No education (did not finish primary school)

☐ Primary school

☐ Basic vocational education (LTS, LEAO)

☐ General secundary education (MAVO, VMBO)

☐ Intermediate vocational education (MTS, MEAO, MBO)

☐ Senior secundary general education or pre-university education (HAVO, VWO, grammar school)

☐ Higher professional education (HBO, HEAO, HTS)

☐ University

☐ Other, which is: _____

16. How bothered are you by the health complaints or problems for which you attended the sleep center today?

Not bothered at all ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Very bothered

17. Did the doctor diagnose you with sleep apnea?

☐ Yes, I have sleep apnea ☐ No, I do not have sleep apnea ☐ Don't know (yet)

18. If you answered "yes" to the previous question, was a treatment chosen and if so, which one?

☐ No treatment

☐ Yes, CPAP (mask)

☐ Yes, MRA (device over teeth)

☐ Yes, lifestyle advice

☐ Other, which is: _____

SRQR

Topic / item	Response
S1 Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	We mention in the title that it is a mixed-methods study, but to keep the title brief we do not elaborate on the data collection methods in the title
S2 Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	Abstract was structured as required by BMJ Open
S3 Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Described in the introduction
S4 Purpose or research question	Described in the introduction
S5 Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale	Described in supplementary file 3
S6 Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Described in supplementary file 3
S7 Context - Setting/site and salient contextual factors; rationale	Described in supplementary file 3
S8 - Sampling strategy	Described in section 2.4 and supplementary file 3
S9 - Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Ethics approval is described on page 17, informed consent in supplementary file 3
S10 Data collection methods- Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis,	Described in the methods section 2.4, for as far as relevant. No modification of procedures took place.

iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale	
S11 Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Described in section 2.4 and supplementary file 3. The instruments did not change over time.
S12 Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Described in section 2.4
S13 - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	Described in supplementary file 3
S14 – Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	Described in supplementary file 3.
S15 - Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale	This was not performed, now mentioned in supplementary file 3.
S16 - Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Described in results section 3.1
S17 Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Quotes are provided in results section 3.1
S18 - Integration with prior work, implications, transferability, and contribution(s) to the field	Described in discussion section. We do not claim transferability as this was the evaluation of a very specific intervention, and this study was not aimed at transferability.
S19 - Limitations	Described in the discussion section
S20 - Conflicts of interest	No conflicts of interest, mentioned in the additional information below the manuscript
S21 - Funding	Funder did not have any influence on the study or article, mentioned in the additional information below the manuscript

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Response
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	This was done.
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	This was done.
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Described in the introduction section
Objectives	3	State specific objectives, including any prespecified hypotheses	Described in introduction section and methods section 2.1
Methods			
Study design	4	Present key elements of study design early in the paper	Described in first paragraph of methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Described in section 2.2, 2.3, and sections 2.5 and 2.6.
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Sources and selection of participants for the quantitative parts of the study are described in sections 2.5 and 2.6.
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	When relevant, these are described in the methods sections 2.5 and 2.6
Data sources/ measurement	8*	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	This is described in sections 2.5 and 2.6
Bias	9	Describe any efforts to address potential sources of bias	We discuss bias in the discussion but did not make specific efforts to tackle it beforehand, so not described
Study size	10	Explain how the study size was arrived at	The size of this exploratory study was arrived at through practical choices (time of

			inclusion 2 months)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Described in section 2.7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Described in section 2.7. No correction for confounding took place.
		(*b*) Describe any methods used to examine subgroups and interactions	Not relevant.
		(*c*) Explain how missing data were addressed	Missing data are reported in the results section but they were not otherwise addressed.
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(*e*) Describe any sensitivity analyses	Not applicable

Results			
Participants	13*	(a) 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	Not available, as survey distribution was done by the healthcare professionals. Non-eligible participants of the health record study were not registered.
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Described in results sections 3.2 and 3.3
		(b) Indicate number of participants with missing data for each variable of interest	Indicated in table 4 for the survey, and in table 8 for the health record study
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	Not applicable
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	We have reported the results of the intervention and control group in the results sections 3.2 and 3.3
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) 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	Not applicable
		(*b*) Report category boundaries when continuous variables were	Relevant for one variable

		categorized	(CPAP compliance) reported in table 8
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Described in 3.2 and 3.3
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussed in the limitations section
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	This was done.
Generalisability	21	Discuss the generalisability (external validity) of the study results	Since this was an explorative study with a very specific intervention, we do not claim generalisability
Other information			
Funding	22	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	This is present in the additional information below the manuscript.

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.