# THE SCHIZOPHRENIA ORAL HEALTH PROFILE: DEVELOPMENT AND FEASIBILITY

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### Abstract

Background: The aim of this study was to present the different stages of development of the Schizophrenia Oral Health Profile (SOHP) questionnaire, aimed at assessing oral disorders and their impacts on functioning and psychosocial wellbeing for patients with schizophrenia (PWS) and to give the results of a feasibility study conducted in France

Materials and methods: The first step of this qualitative study was semi-structured interviews were conducted with 20 PWS and 6 health professionals (HP). A focus group integrating 4 PWS and 4 HP was also organised to identify the items of the SOHP. The data were analysed using a thematic analysis. Second, a feasibility study was conducted in a sample of 30 PWS who answered the SOHP questionnaire. The acceptability and understanding of the SOHP were evaluated, using a specific questionnaire.

Results: The semi-structured interviews and focus groups included 34 individuals in total. Items' selection was done with several stages and led to a SOHP scale with 53 final items related to oral disorders and their impacts on functioning and psychosocial well-being. These items were classified in 13 preselected dimensions including one additional module related to the side effects of medications (11 items). The feasibility study showed good acceptability and understanding of the items of the SOHP scale.

Conclusions: The psychometric validation of the SOHP scale, involving a large sample of PWS, is currently in progress. The SOHP is important to evaluate PWS oral health needs and to offer appropriate strategies to improve oral health of this persons.

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## Background

Questionnaires that evaluate self-perceived oral health or oral health-related quality of life (OHrQOL) have been defined as "tools to measure the extent to which oral disorders affect functioning and psychosocial well-being" [1]. OHrQoL is a complex and subjective multidimensional concept that integrates several dimensions, such as functional limitation, physical pain, psychological discomfort, physical, psychological and social disability or handicap related to the presence of oral disorders. Accurate OHrQoL tools are needed to effectively assess oral health, evaluate oral health interventions and develop appropriate strategies, encouraging or facilitating appropriate healthcare interventions [2].

Schizophrenia is a severe, disabling psychiatric disorder that affects higher brain functions [3] and occurs in 1% of the population [4]. This disorder is characterized by the presence of mental dissociations, hallucinations, dampened or inappropriate affects, and an either episodic or continuous progression [3]. Schizophrenia is a chronic disease that requires long-term medical treatments and follow-up that can result in physical, psychological, and social consequences related to both the disease and the potential side effects of its treatment [5].

Compared with the general population, persons with schizophrenia (PWS) are at greater risk of oral diseases and have higher rates of tooth loss, dental decay and gum diseases, as well as poor oral hygiene and dental neglect that lead to pain and infection processes compromising nutrition and general health [6,7]. Poor lifestyle and health behaviours (e.g., diet with high sugar, use of drugs, tobacco and alcohol consumption, and inadequate oral hygiene) along with social determinants related with low education, incomes or support explain the poor oral and general health in this population [7,8].

The relationship between oral and general health is complex, particularly in PWS. Oral diseases affect the patient's quality of life through social and psychological impacts such as the deterioration of the aesthetic of the smile, which leads to lower self-esteem and self-confidence [9-11]. Furthermore, antipsychotics generally induce hypo-salivation (xerostomia), which favours the progression of oral diseases such as dental caries. Specifically, PWS maintained on second-generation

antipsychotics have better dental health than patients treated with first-generation antipsychotics or with a combination of both [12,13]. Conversely, clozapine and olanzapine can cause hypersalivation, due to peripheral acetylcholinesterase inhibition causing discomfort in daily life [12,14]. First-generation antipsychotics may induce neurological side-effects (e.g., dystonia and dyskinesia), especially shaking, which prevent effective tooth-brushing, increase the risk of oral diseases, and even impair chewing and swallowing capacities [11,12]. Second-generation antipsychotics tend to induce metabolic side effects, obesity or diabetes, which are also chronic conditions affected by oral diseases [15-18]. Indeed, oral diseases are chronic non-communicable diseases that share with other chronic medical conditions common social, environmental and lifestyle determinants [19]. PWS also are patients that tend to neglect self-care [20] due to the negative symptoms of schizophrenia, such as a lack of concern for personal health and a lack of motivation. Negative symptoms impair a PWS's desire to maintain a good oral hygiene. In this case, they neglect their oral health or had a poor perception of dental treatment needs. Therefore, routine dental care becomes a challenging task for the patient and for their caregivers [21].

Determining what significance PWS has for oral health is an issue that warrants investigation. OHrQL is a subjective measure that considers patients' perceptions. Indeed, it is not surprising to observe in PWS wider variations between a patient's perception and an objective evaluation of the patient's dental status [22]. This variation raises many questions about, for example, the way PWS experience dental pain, oral discomfort or oral dysfunctions. Clinicians usually observe unusual sensitivity to pain in their patients. Cognitive impairment and excess negative symptoms may strongly influence the PWS's expression of pain [23].

Among the existing OHrQOl scales, the Global Oral Health Assessment Index (GOHAI) exhibited excellent psychometric characteristics among PWS [24]. However, the following specific concerns for those patients are not captured by the GOHAI: side

effects of psychostimulants or antipsychotics, which include trismus, facial muscle pain, myasthenia or dyskinesia (tremors), or drooling with clozapine [8]. To our knowledge, there is no specific questionnaire for evaluating OHrQOL in PWS in a context of disturbances of consciousness. The content of QoL questionnaires should be derived from patient interviews [25], but some of the actual instruments are only derived from expert opinions or from the literature [26]. There is a need for developing a new scale to assess OHrQOL in PWS that would better capture the concept of OHrQOL in this specific population.

Our study, therefore, aimed to present the different stages of development of the "Schizophrenia Oral Health Profile" (SOHP) questionnaire, aimed at assessing oral disorders and their impacts on functioning and psychosocial wellbeing of PWS, and to give the results of a feasibility study conducted in France.

## Methods

### Design
A qualitative study that explored the OHrQOL values of importance to PWS to obtain a conceptual questionnaire for the development of a measurement instrument was conducted between June, 2016, and November, 2018, in France [27]. Semi-structured individual interviews and a focus group were used to gather information on OHrQOL components of importance for PWS. Verbatim transcriptions were recorded and data were analysed to identify the hypothetical structure of the SOHP questionnaire. The second step was a feasibility study conducted in a sample of PWS who answered the SOHP questionnaire. The acceptability and understanding of the SOHP were evaluated using a specific questionnaire (Figure 1).

### Participants
A sample of 20 PWS (inpatients and outpatients) recorded in the administrative database of the Chartreuse Hospital (Dijon, France) were recruited using telephone invitations for outpatients or face-to-face invitations for in-patients. Inclusion criteria were as follows:

patients aged > 18 years with a diagnosis of schizophrenia (according to the International Classification of Diseases 10th Revision: ICD-10) [28]; were under antipsychotics therapy with or without associated somatic diseases like metabolic disorders, overweight or obesity in accordance with Body Mass Index (BMI) [29]; informed consent was obtained to participate in the study; and French was the native language of the patient. Exclusion criteria included the following: diagnosis other than schizophrenia; and individuals were unstable from a psychiatric perspective with decompensated organic diseases or mental retardation.

A sample of health professionals of the Chartreuse Hospital (Dijon, France) comprising one dentist, one doctor, one psychiatrist, one psychologist, and two nurses were recruited by face-to-face invitations. This set of 26 individuals participated in individual semi-structured interviews [27]. To enrich the information gathered during the individual interviews, 2 focus groups were conducted with 8 other individuals from the same hospital; 1 focus group with 4 PWS and 1 focus group with 4 health professionals [30].

In total, 34 individuals participated in the study. The sample size was sufficient to obtain a "point of saturation" of the data [27].

In accordance with Lancaster et al., 30 persons with schizophrenia were included in the feasibility study [31].

All persons with schizophrenia were offered financial compensation for the time spent on the research (€20 for the first step of the study and €10 for the feasibility study).

### Ethics
This study was approved by the Committee for the Protection of Persons of the Eastern French region (registration number: 2015-A01741-48). After providing participants with a complete description of the study, informed consent was obtained from each participant or from their legal guardians for individuals under guardianship. In this case patient's legal guardian signed the informed consent.

The study was registered with www.ClinicalTrials.gov under the number NCT02730832.
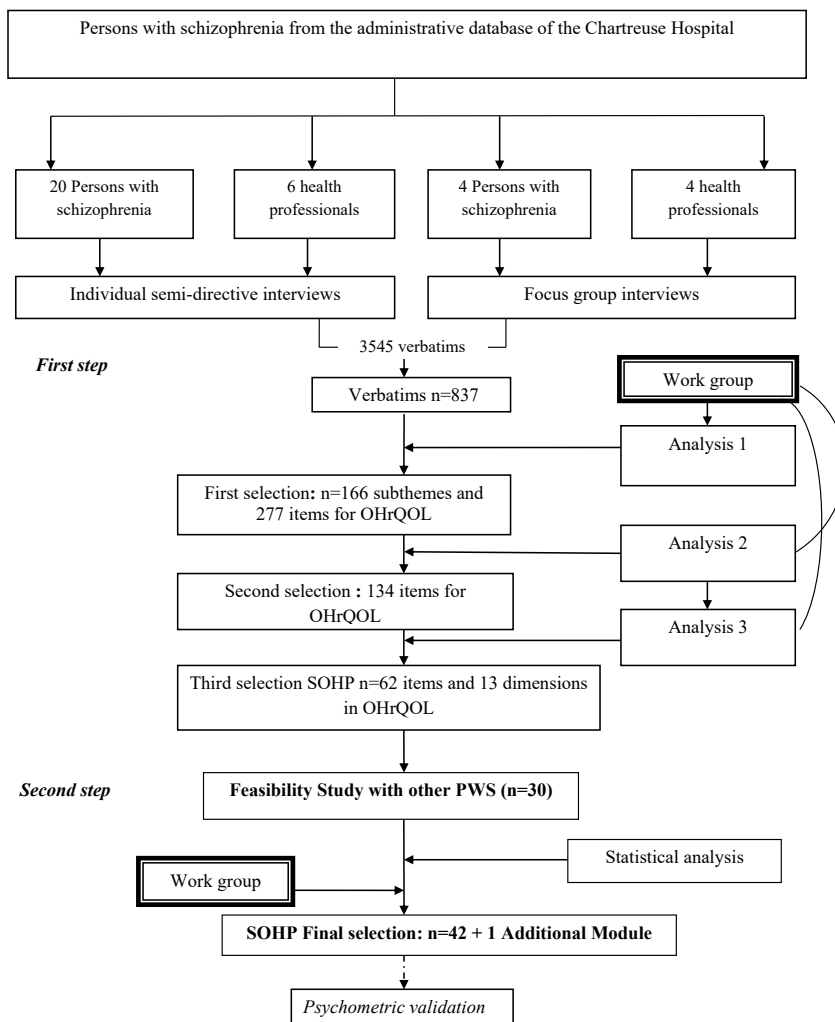
Figure 1. Flow chart of item generation.

dimensions related to the health professional's perception of the patients' OHrQOL. The persons with schizophrenia and health professional guides are available in a previously published study [33].

The semi-structured interviews took place in two stages. The first stage addressed the main themes of the interview guide. Spontaneous reactions were particularly explored to capture participants' experiences and to better understand the meaning that they attributed to OHrQOL. The second stage consisted of completing open-ended questions and follow-up questions. The interviewer reworded, reordered, or clarified the questions when necessary to better investigate the new topics introduced by the respondents. It was hypothesised that spontaneous replies would help in understanding the most important priorities, meaningful experiences or representation of oral diseases, as well as in exploring personal and sensitive themes or in identifying potential modifiable risk factors for improving health care [34]. Interviews were audiotaped, and they generally lasted no more than 30-45 minutes in accordance with schizophrenia symptoms and PWS concentration difficulties [35]. Interviews conducted with the health professionals followed almost the same principles as those carried out with the PWS. The same psychologist investigator interviewed all of the subjects.

## Generation of items (figure 1)

### First step: Qualitative study

*Individual interviews with PWS and health professionals*

Semi-structured interviews were used to collect qualitative data [30]. The aim was to identify all issues relating to OHrQOL in PWS and to obtain a "point of saturation" regarding the themes addressed by the PWS and the health professionals who manage those patients' care [30]. Participants replied based on their own experiences (for the PWS) or based on direct observations and reported experiences in managing oral health (for the health professionals). The interviews were carried out

face-to face by a psychologist with extensive experience in managing individuals suffering from mental health issues.

The psychologist had assistance from an interview guide exploring several specific areas of OHrQOL for PWS. These guides were written based on the literature, including recent studies conducted by the authors [20,24,32], after a consensus meeting organised with experts from the working group (one dental researcher, one researcher in psycho-sociology, one methodologist, one nursing researcher, and one PWS). The interview guide was drawn up according to main themes or dimensions concerning the perception of OHrQOL in relation to schizophrenia. The guide used with health professionals included main themes or

*Focus group of PWS and health professionals*
Focus groups were also carried out. Focus groups are semi-structured discussions with groups of 4 to 12 people that aim to explore a specific set of issues. The group interaction encouraged respondents to provide insights that might not have emerged during individual interviews and enriched the information gathered during the individual interviews. The participants of focus groups were encouraged by the moderators to talk and interact with each other to explore and clarify individual and shared perspectives [30]. The PWS and health professionals focus groups were managed by a focus group expert. The decision to combine focus groups and individual interviews was made in view of our experiences from a previous study [36].

This approach is a resourceful method that facilitates the collection of exhaustive data. More data are obtained, and specific themes or new ideas readily emerge, in accordance with the principle of data saturation.

The audio records for all of the individual interviews and focus groups were converted into verbatim transcripts by an administrative assistant.

*Analysis of the interview content*
The transcripts were examined, and a reading grid was applied to individual quotes. This approach aimed to identify emergent or repetitive themes and patterns throughout the transcript, to interpret data accurately from the participants' perspectives, and to select potential items, e.g., assertions likely to be included in the self-report questionnaire, after each interview [34]. Codes were then grouped into concepts, followed by grouping into major themes. We also evaluated the impact of the themes mentioned (e.g., the number of verbatim references to subthemes or dimensions).

*Initial selection: analysis 1.* All transcripts were analysed by the psychologist who had recorded the semi-structured interviews. During this first selection, duplicate verbatim items were eliminated.

*Second selection: analysis 2.* The second step of selection was carried out during a consensus meeting with the working group. Within this process, differences in opinion were discussed until a consensus was reached. The selected verbatim items were reviewed and reworded (if necessary) to keep the more specific items in relation to the experience of PWS regarding OHrQOL. Rewording also helped to avoid double negatives and negative words. The researcher of the working group made a conscious effort to set aside pre-existing conceptions or expectations during the process of reading and coding all of the transcripts. In cases of disagreement, the patient's opinion was taken.

*Third selection: analysis 3.* For the third step, the researchers of the working group met again.

Each transcript was revisited by the working group until all of the themes and subthemes were agreed upon, and only items related to the concept of OHrQOL in PWS were validated.

## Second step: Feasibility Study

*Acceptability questionnaire.* A feasibility study was conducted with other PWS recruited at the Chartreuse hospital. The same inclusion and exclusion criteria as those used for drawing up the SOHP were used. Sociodemographic data of the patients were collected. The objective was to find out whether the SOHP questions were clearly understandable. Acceptability criteria, such as the time it took for completion, the amount of missing data, and the number of questionnaires not returned or refusals to participate were assessed. The acceptability of the SOHP was explored using 7 questions with 3 possible answers each (Table 1).

*SOHP questionnaire.* There were 5 possible answers for each item, matched with scores from 1 to 5, where "1" equated to "strongly disagree" and "5" to "strongly agree." Scores for the positively worded questions were reversed to calculate the overall score so that, in effect, better oral health leads to a high score. Smileys were used to help PWS to answer the questions (Figure 2).

*Item-level analysis.* An item analysis was used to eliminate ambiguous or misleading items. Redundant items (i.e., high inter-item correlations, $r > 0.8$) were suppressed. Items with ceiling or floor effects (i.e., $0.70 \leq SD \leq 1.44$) were also suppressed. The floor effect indicated that questions were not appropriate or too difficult, and the ceiling effect indicated that questions were tautological [26].

For the final selection, the working group met again to validate the reworded items, carry out a more refined selection by choosing only items related to the concept of OHrQOL in PWS and, lastly, obtain the hypothetical structure of the SHOP questionnaire.

SAS® software was used for the statistical analyses.

Table 1. Acceptability of the SOHP questionnaire.

|  | Yes | No | Which one? |
|---|---|---|---|
| 1. Some questions are difficult to understand |  |  |  |
| 2. Some questions are awkward or disturbing |  |  |  |
| 3. I found certain questions surprising |  |  |  |
| 4. Some questions could be added |  |  |  |
| 5. It seemed to take me a long time to answer this questionnaire |  |  |  |
| 6. I had problems answering this questionnaire |  |  |  |
| 7. Smileys helped me to answer this questionnaire |  |  |  |



Schizophrenia Oral Health Profile (SOHP) questionnaire

In order to develop strategies to improve your oral and dental health, we would like to ask you for your general opinion about your oral health.

To this end, we would like to invite you to complete this questionnaire to tell us about your feelings now, and over the past 2 weeks.

Please be as honest as possible, there is no right or wrong answer.

Please tick one box on each line, indicating the answer that best corresponds to how you feel, as shown in the following example: "I eat enough"
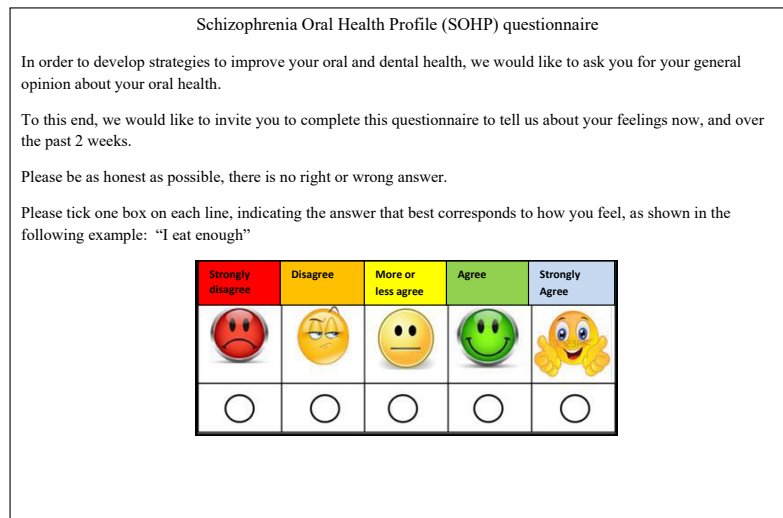
Figure 2. Likert scale modalities and smileys used for Schizophrenia Oral Health Profile.

## Results

The characteristics of the PWS who participated in the first and second step of the study are presented Table 2. All PWS were under antipsychotics therapy since more than two years, four were overweight (BMI [25-30]), one was obese (BMI>30), one patient had non-insulin-dependent diabetes and eleven were smokers.

### First step: Verbatim remarks and analysis of the content of the interviews (Figure 1)
*Initial selection*

The semi-directive interviews and focus groups were conducted at a site of the Chartreuse Hospital that is conducive to discussion; 3545 verbatim remarks were generated. An initial analysis of the thematic content provided 166 sub-themes or dimensions. The transcript yielded no new codes, indicating data saturation.  With regard to these 166 subthemes, we retained 837 items and selected 277 items according to the following criteria: "information related to OHrQOL concept for PWS," i.e., 277 topics from patients or health professionals in the form of a phrase, an item, or an assertion alluding to a sub-dimension of a given concept, with each verbatim remark belonging to only one subtheme. The distribution of the 277 items according to their origin is presented Table 3. From this analysis emerged the following two new concepts: the coping strategies for managing oral health and the satisfaction with oral health care within the 560 others items retained. These results are not presented in this study.

### Second selection

Of these 277 items, 134 were chosen and classified according to the following 13 preselected dimensions: emotional well-being, social well-being, physical activities, sleep, pain, oral limitations, autonomy, social support, self-consciousness, time managing, time perspective, global oral health and side effects of the treatments.

### Third selection

Among these 134 items, 73 were not retained

(not informative in regard to OHrQOL). One item was added (n°15, Table 4) from the content analysis, as it was deemed to be of importance by the dental researcher of the working group. At the end of this selection process, the first draft prototype of the SOHP questionnaire included 62 items classified in 13 dimensions.

### Second step:
*Feasibility Study and Item-level Analysis*

The average time needed to complete the SOHP questionnaire was 12.5 minutes ± 4.8 (min = 6; max = 24). There was a 100% return rate (n = 30), and there was no instance of refusal to participate. Eight patients (26.6%) had no difficulty in understanding all of the questions of the SOHP questionnaire, and for 93.3% of the participants the "Smileys" helped them in answering the questionnaire. Four participants (13%) said that it took them a long time to answer the questionnaire. No participants suggested new questions to be added to the SOHP questionnaire. Fourteen participants found that at least one question was hard to understand. The SOHP was awkward or disturbing for 10% of the PWS, and

16.6% found one question to be surprising, although they did not specify which one(s). Overall, the items were clearly understood and accepted. The missing data were low (between 1.6 and 3.2% according to the items).

Ceiling effects were observed with eight items, and a floor effect with two items. We observed 10 items with strong intercorrelations. Finally, we deleted 20 items of the initial selection of the SOHP. The final SOHP questionnaire included 42 items classified in the following 13 preselected dimensions: emotional well-being (3 items), social well-being (7 items), physical activities (2 items), sleep (1 item), pain (4 items), oral limitations (8 items), autonomy (2 items), social support (2 items), self-consciousness (9 items), time managing (2 items), time perspective (1 item), global oral health (1 item) and one additional module related to side effects of the treatments (11 items) (see Table 4).

The English version of the draft prototype of the SOHP questionnaire was obtained using a process of translation and back translation [37]. This English version of the SOHP scale is declared to the "Institut National de la Propriété Industrielle" under number DSO2017001193.

Table 2. Characteristics of the 20 PWS included in the first step of the study and the 30 PWS included in the feasibility study.

| Variables | First step  N (%) | Mean (SD) | Feasibility N  (%) | Mean (SD) |
|---|---|---|---|---|
| Gender | | | | |
| Male | 12 (60) | | 17 (56.7) | |
| Female | 8 (40) | | 13 (43,3) | |
| Age (years) | | 45.8 (9.5) | | 44.6 (11.9) |
| ≤34 | 2 (10) | | 6 (20) | |
| 35-44 | 7 (35) | | 0 (33.3) | |
| 45-54 | 6 (30) | | 9 (30) | |
| ≥54 | 5 (25) | | 5 (16.6) | |
| In-patients | 2 (10) | | 10 (33.3) | |
| Out-patients | 18 (90) | | 20 (66.7) | |

SD: Standard deviation

Table 3. Distributions of the items brought up by patients and health professionals

| | Interviews of Patients | Interviews of Health Professionals | Subthemes common to patients & health professionals | Focus group With patients | Focus group with Health professionals |
|---|---|---|---|---|---|
| Items *n* (%) | 180 (65%) | 28 (10%) | 30 (11%) | 25 (9%) | 14 (5%) |

Table 4. List of the SOHP items obtained by back translation, theoretical dimensions, frequency/item and missing data.

| N° Items | Title of items | Theoretical dimensions | Missing data: frequency/item (n, %) |
|---|---|---|---|
| **Currently and/or over the past 2 weeks, regarding my oral health, I can say that:** | | | |
| 1 | I have anxiety attacks | Emotional well-being | 0 |
| 2 | I take things easy, without feeling stressed | Emotional well-being | 0 |
| 3 | My living conditions are pleasant (food, accommodation, transport) | Social well-being | 1 (1.6%) |
| 4 | I engage in physical activity | Physical Activities | 0 |
| 5 | I feel physically well | Physical Activities | 1 (1.6%) |
| 6 | I sleep well | Sleep | 0 |
| 7 | I have a good appetite | Emotional well-being | 0 |
| 8 | My teeth hurt | Pain | 2 (3.2%) |
| 9 | My jaw hurts | Pain | 0 |
| 10 | I have muscular pain in my face | Pain | 1 (1.6%) |
| 11 | My jaw and my teeth don't feel right | Dysfunction | 0 |
| 12 | I'm lost in thought, I'm rehashing my memories | Self-consciousness | 0 |
| 13 | I am self-confident, I have good self-esteem | Self-consciousness | 1 (1.6%) |
| 14 | Because of how my mouth looks, I'm afraid of how others see me | Social well-being | 0 |
| 15 | I need care for my oral well-being (for my oral and dental health) | Self-consciousness | 1 (1.6%) |
| 16 | My mouth is sensitive to hot and cold | Dysfunction | 0 |
| 17 | It hurts when I brush my teeth | Pain | 1 (1.6%) |
| 18 | I find it hard to swallow comfortably | Dysfunction | 0 |
| 19 | I have bad breath | Self-consciousness | 0 |
| 20 | I grind my teeth | Dysfunction | 1 (1.6%) |
| 21 | My gums bleed | Dysfunction | 0 |
| 22 | My mouth feels dry or sticky | Dysfunction | 0 |
| 23 | I can articulate sounds correctly | Dysfunction | 1 (1.6%) |
| 24 | I have difficulty chewing | Dysfunction | 0 |
| 25 | I'm worried about my oral health | Self-consciousness | 0 |
| 26 | I am embarrassed to speak because of the state of my mouth | Social well-being | 0 |
| 27 | I'm embarrassed to smile because of the state of my mouth | Social well-being | 1 (1.6%) |
| **I pay attention to:** | | | |
| 28 | My breath | Self-consciousness | 0 |
| 29 | I am motivated to brush my teeth | Self-consciousness | 1 |
| 30 | I hate brushing my teeth | Self-consciousness | 0 |
| 31 | I am open to meeting other people | Social well-being | 0 |
| 32 | I take care of myself (I do my hair, wear make-up, shave…) | Self-consciousness | 1 (1.6%) |
| 33 | I talk to my friend(s) about my oral health problems | Social well-being | 0 |
| 34 | I talk to my family about my oral health problems | Social well-being | 0 |
| 35 | I feel that my friend(s) are supportive towards me | Social support | 0 |
| 36 | I feel that my family is supportive towards me | Social support | 0 |
| **Currently and/or over the past 2 weeks, regarding my oral health, I can say that:** | | | |
| 37 | I need help to manage my feelings | Autonomy | 2 (3.2%) |
| 38 | I take the time to get the care I need | Time managing | 0 |
| 39 | I have projects (for holidays, for work, for my family life…) | Time perspective | 0 |
| 40 | I manage to organise all my activities and appointments | Time managing | 0 |
| 41 | I need help to manage my health | Autonomy | 0 |
| 42 | I'm satisfied with my oral health | Global Oral Health | 0 |

| N° Items | Title of items | Theoretical dimensions | Missing data: frequency/item (n, %) |
|---|---|---|---|
| **Additional module: Side effects of treatments, I can say that:** | | | |
| 1 | *At the end of meals, I'm still hungry* | *Treatment* | *1 (1.6%)* |
| 2 | *The joint of my jaw is stiff, my jaw is clenched* | *Treatment* | *0* |
| 3 | *I have yellow teeth* | *Treatment* | *0* |
| 4 | *I sleep more* | *Treatment* | *1 (1.6%)* |
| 5 | *I salivate more* | *Treatment* | *0* |
| 6 | *My mouth is dry or pasty* | *Treatment* | *0* |
| 7 | *I gain weight* | *Treatment* | *2 (3.2%)* |
| 8 | *The taste of food has changed* | *Treatment* | *0* |
| 9 | *I can't move my hand normally/without shaking* | *Treatment* | *1 (1.6%)* |
| 10 | *I have trouble articulating when I speak* | *Treatment* | *0* |
| 11 | *I have a burning sensations in my throat* | *Treatment* | *0* |

## Discussion

This study described the various steps in the development of an OHrQOL tool intended to help caregivers assess how oral disorders affect functioning and psychosocial wellbeing in PWS. We attempted to listen to what is usually ignored or forgotten. Our approach in establishing the SOHP questionnaire was based on comments made by patients and health professionals during semi-structured interviews.

Our results confirmed the benefit of conducting individual and group interviews with both patients and health professionals in regard to the richness of the information obtained. We observed that health professionals had a broad view of the difficulties encountered by patients. Health professionals help patients in everyday life to look after their oral health and to manage the fear and anxiety induced by dental care. Within this approach, high prevalence but low impact items may be more highly scored than items with low prevalence and higher impacts [38]. The psychometric validation process takes into account the prevalence and impact of the items, as suggested by Guyatt et al. [39] to capture the values of individual patients. During the psychometric validation process with a large sample, some items of the initial version of the SOHP questionnaire will likely need to be removed.

The ability of patients to discuss their condition is still very much an issue of debate

in the psychiatric community. Therefore, the instruments currently used are considered expert-centred measures, since the items are generated either from expert opinions or the literature [40]. Our results show the importance of taking into account the point of view of PWS. Items generated without a qualitative study might not have been well adapted for an OHrQOL tool. Our findings confirmed that the individuals who were best able to define the major themes were the patients [40]. In our study, 74% of the items were generated by PWS (Table 3).

There is now substantial literature concerning the concept of oral health that is based on various theoretical approaches and conceptual frameworks [1,2,41]. In accordance with previous studies and OHrQOL tools, dimensions relating to pain (items 8,9,10,17) dysfunctions (items 11,16,18,20-24) and psychosocial impacts of oral diseases (items 3,14,26,27,31,33,34) emerged in the SOHP questionnaire.

The SOHP also highlighted a dimension labeled "emotional well-being" (items 1,2,7). Schizophrenia involves difficulties in thinking (e.g., disorganized thinking, delusions) and in perceptions (e.g., hallucinations). In particular, negative symptoms such as anhedonia (diminished experience of pleasure) and avolition (diminished motivation) [42] are often difficult to treat with medication. These symptoms are associated with poor overall functioning, integrating lower "physical activities" (items 4 and 5) or "sleep disturbance"

(items 1) that emerged from the analysis of the verbatims.

Items related to "self-consciousness" (items 12,13,15,19,25,28-30,32) demonstrate the affinities among the schizophrenic symptoms by showing their rootedness in certain disturbances of self-experience, some of which could be correlated with poor OHrQOL. These items may allow for the discrimination between essential affinities that occur in positive/negative symptoms and the status of OHrQOL.

The autonomy dimension is evaluated with item 41. Autonomy is related to the possibility of independence, i.e., not being subject to the will of somebody else. When PWS are symptomatic, they are constrained by the illness and have difficulty rationalizing and making decisions that are good for themselves and others, such as making an appointment at the dentist or brushing their teeth every day. PWS thus expressed that they need support in daily life ("Social support", items 35 and 36).

One item (item 42) concerns the patients' global perception of OHrQOl, mixing perceptions related to psyche, somatics, oral health and general health. In building the hypothetical structure of the SOHP questionnaire, we hypothesized that better OHrQOl is associated with lower grade symptoms and better management of mental illness.

The items regarding the concept of time (time managing, items 38 and 40 and Time perspective, items 39) are related to the fear and apprehension of the progression of the

disease, future plans, and possible changes to life plans. The analysis of this dimension is useful for evaluating patients' OHrQOL, as a poor time perspective is related to depressive states and oral symptoms [43].

The side effect of treatments emerged with 11 items. Different medications produce different side effects (dry mouth, weight gain, drowsiness, restlessness, stiffness, tremors, muscle spasms and tardive dyskinesia) [5,8]. Although people differ in the extent and severity of side effects, they frequently experience side effects of antipsychotic medications.

## Limitations

Difficulty arises from the potential unreliability of information elicited from patients, even though the PWS included were stable from a psychiatric perspective. Psychiatric diagnoses may be especially vulnerable to instability over time [44]. For this reason, a psychologist with experience in managing individuals suffering from mental health disorders carried out the interviews to discern certain delirious remarks made by the patients.

## Conclusions

This is the first study that developed a specific tool to assess OHrQOL in PWS with PWS and health professionals in close collaboration. The feasibility study showed that the scale was well accepted and understood. This questionnaire will allow practitioners to evaluate all dimensions of OHrQOL in PWS to better understanding how perception in oral disorders affect behaviours of PWS in regard to health in the aim to offer appropriate strategies to improve their oral health. A multicentre study involving a larger sample of PWS is underway to carry out the psychometric validation of the SOHP scale. The SOHP is an important tool to support clinical research in oral health and quality of life for PWS in the future.

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## Conflict of interest

The authors report no conflicts of interest.

## Authors' contributions

FD was the signatory investigator on the study. FD and NR contributed to the concept and design of the study. All of the authors contributed to the interpretation of the data, revised the manuscript, and approved the final content of the manuscript.

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