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OSFCOS: A core outcome set for clinical trials on oral submucous fibrosis management

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ABSTRACT

Background: Oral Submucous Fibrosis (OSF) significantly impacts oral function, quality of life and poses challenges for effective treatment evaluation due to heterogeneity in outcome reporting across clinical trials. To date, no core outcome set (COS) exists for OSF trials, leading to significant heterogeneity in outcome reporting and difficulty in comparing interventions. This study aimed to develop a COS for OSF (OSFCOS) to standardize outcome reporting in clinical trials evaluating OSF management.

Methods: The study followed COMET and COS-STAD guidelines and involved four stages: a systematic review of randomized controlled trials to identify reported outcomes; qualitative research using interviews and focus groups with OSF patients to capture patient-prioritized outcomes; a two-round Delphi survey with key stakeholders (patients, clinicians, researchers); and a consensus meeting to finalize core outcomes. Outcomes were rated using a 9-point GRADE scale, and consensus was predefined using standard thresholds.

Results: A total of 20 outcomes were identified from systematic review and 31 from qualitative analysis. After triangulation & refinement, 16 unique outcomes were prioritized in Delphi Round 1 (n = 45). Delphi Round 2 (n = 25) rated 23 outcomes; 10 reached "consensus in." A consensus meeting with 17 stakeholders reviewed 13 outcomes and finalized 7 core outcomes for OSFCOS.

Conclusion: This is the first COS developed specifically for OSF that offers a robust, stakeholder-driven framework for standardized outcome reporting, comparability and enhancing data synthesis in OSF trials for better evidence generation and patient care.

1. Introduction

Oral submucous fibrosis (OSF) is chronic persistent condition mainly associated with betel nut chewing. OSF prevalence shows significant regional variation, ranging from 0.09% to 17.6%, with the greatest incidence reported in South and Southeast Asia.[1,2] OSF accompanies myriad symptoms which include restricted mouth opening, burning sensation, fibrous bands, loss of flexibility of the mucosa, blanching of the mucosa, limited tongue movements, and a shrunken uvula.[3,4] Patients have also been found to experience different levels of hearing loss, troubles with speech, and a reduced sense of taste.[5] OSF significantly impacts the quality of life, particularly due to functional limitations. Psychosocial aspects such as anxiety and low self-esteem also contribute to social withdrawal. Literature suggests that the combination of these burdens becomes more pronounced with disease progression, leading to a lower quality of life.[6,7] The designation of OSF as an oral potentially malignant disorder (OPMD) by the WHO Collaborating Center for Oral Cancer is supported by their most recent report[8] after

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confirming it in their prior report[9] and recent data show a 4.2–6% malignant transformation rate in OSF.[10]

Earlier systematic reviews have pointed out a lack of comprehensive quality research on the treatment of OSF.[11,12] This shows there is still considerable misunderstanding regarding the optimal method and way to provide and implement OSF therapy which leads to wasteful healthcare expenditures and subpar results. The broad range of outcomes used in clinical trials adds to this problem.[13] Even in high-quality trials, the large number of outcome measures leads to insufficient inter-trial comparison, obscuring numerous interventions due to ambiguity surrounding these treatments' actual effectiveness.[11] This variability might also make it difficult to compile all the study evidence into systematic reviews or meta-analyses. Therefore, attempts to translate new evidence into practice are undermined and patients do not receive ideal care.

The COMET (Core Outcome Measures in Effectiveness Trials) initiative brings together researchers with the purpose of developing and advocating for core outcome sets (COS). These sets are standardized and a collection of outcomes which are agreed upon and should be consistentlyreported in every clinical trial conducted within a specific clinical field. The COS is the bare minimum which needs to be assessed and reported in every trial and is also suitable for other kinds of audit and study. A complete and perpetually updated COS protocols and papers are stored in a publicly accessible COMET database.[14]

To date, no COS exists for OSF trials, leading to significant heterogeneity in outcome reporting and difficulty in comparing interventions. The creation of a consensus-selected outcome set for OSF will encourage clinical researchers and trialists to select outcomes that are important to patients and clinicians which in turn will support data synthesis and sharing. Achieving the creation of a COS will enable better outcome-reporting for OSF trials while assisting in cross-comparison of competing research projects. This would assist in knowledge integration and will inform decisions on clinical measures and therapeutic recommendations that in the end can reduce redundant research and enhance the quality of patient care.

At present, consensus on which outcomes to measure in relation to the therapies assessed for OSF is lackingand thus, developing a COS for effectiveness trials on OSF treatment is the need of the hour. Accordingly, this study aimed to develop the "OSFCOS," a standardized, consensus-based core outcome set for effectiveness trials assessing management of OSF, with the following objectives: (i) to identify outcomes reported in published OSF interventional trials through a systematic review; (ii) to explore additional patient-important outcomes using qualitative interviews and focus group discussions; (iii) to prioritize outcomes through a two-round Delphi survey involving key stakeholder groups; and (iv) to finalize the core outcome set through a structured consensus meeting.

2. Materials and methods

The study is registered on the COMET database (Registration no. 2804), was developed in accordance with the COS-STAD guidelines,[15] and conducted according to a prospectively published study protocol.[16]

2.1. Ethics statement

The Institutional Ethics Committee of Government Dental College & Hospital, Nagpur, India provided ethical approval for the study (reference IECGDCHN/14/24,approval date: March 28, 2024). The present study followed the principles of the Helsinki Declaration and its subsequent updates. Participants participated in semi-structured interviews and focus groups provided informed consent and privacy rights of subjects have been observed. Participation in the Delphi surveys and presence at the consensus meeting were interpreted as agreement to participate, even when no formal consent was provided. The early pages of the survey included detailed information on the study, and survey completion was interpreted as consent.

2.2. Development of OSFCOS

The project was led by a research team (SG, AG, SS,MY) comprising a group of senior academics. The OSFCOS project comprised four stages: (1) systematic review (2) qualitative research; (3) Delphi surveys; and (4) an online consensus meeting (Fig. 1).

2.3. Stage 1:Systematic review

As a part of this study, a systematic review of RCTs on the treatment of OSF was conducted in order to compile a preliminary list of possibly pertinent outcomes, with the updated literature search performed on April 14, 2024 and included studies published from January 2000 to December 2023. A description of methodsincluding PRISMA 2020 flow diagram, search strategies for PubMed, Scopus, and Cochrane Library, inclusion/exclusion criteria, duplicate screening by two reviewersof the systematic review have been detailed in a previous publication.[13] Outcomes from the systematic review were compiled and formatted for prioritization in the Delphi process.

2.4. Stage 2: Qualitative research

OSF patients were identified and their most valued outcomes in the management of OSF were captured using semi-structured interviews and focus group discussions. Patients aged 18 years and above with a clinical diagnosis of OSF, receiving treatment, and willing to participate were purposively selected from the Department of Oral Medicine and Radiology at the Government Dental College & Hospital in Nagpur. Participants were chosen to reflect varying OSF severity, gender, and treatment stage. This research was guided by prior similar studies, which suggested a sample size of around 25-30 participants.[17,18] It was expected, however, that this number might change if new opinions or themes emerged, as is often the case in qualitative research, which relies on samples estimated pragmatically in order to reach data saturation. A semi-structured interview guide and focus group discussion guide were developed based on a review of existing literature, clinical experience, and expert input. The guides were reviewed for content validity by qualitative researchers and pilot-tested with five OSF patients and two clinicians to assess comprehensibility, after which minor refinements were made. All interviews and focus group discussions were administered in the local language by trained qualitative researcher, with field notes taken throughout. Interviews and discussions were conducted in confidential non-clinical settings where patients used pseudonyms. Demographics were collected along with informed consent. Sessions were flexibly guided using topic guides, co-led with an experienced qualitative researcher. Data were collected through three focus groups(6–8 participants each) and twelve in-depth interviews until thematic saturation. Focus group and interview field notes were recorded and verbatim typed into a transcript. Data analysis followed the Framework Analysis approach, which involves familiarization with the data, developing a thematic framework, indexing, charting, and interpreting the data in a systematic and transparent manner.[19] Two independent researchers coded transcripts, and inter-rater reliability was assessed.

Qualitative data outcomeswere triangulated with those identified in the systematic review. Individual outcomes were reviewed and discussed by research team members. Duplicate outcomes were reformed, with any necessary revisionsmade as needed to form a comprehensive list of outcomes.

2.5. Stage 3: Delphi surveys

To ensure diverse and balanced input, key stakeholders including OSF patients, clinicians, and researchers/experts were invited to participate in a structured Delphi survey. The Delphi approach does not require statistical power and has been shown to produce adequate findings with 10-15 participants.[20,21] Therefore, this research sought to

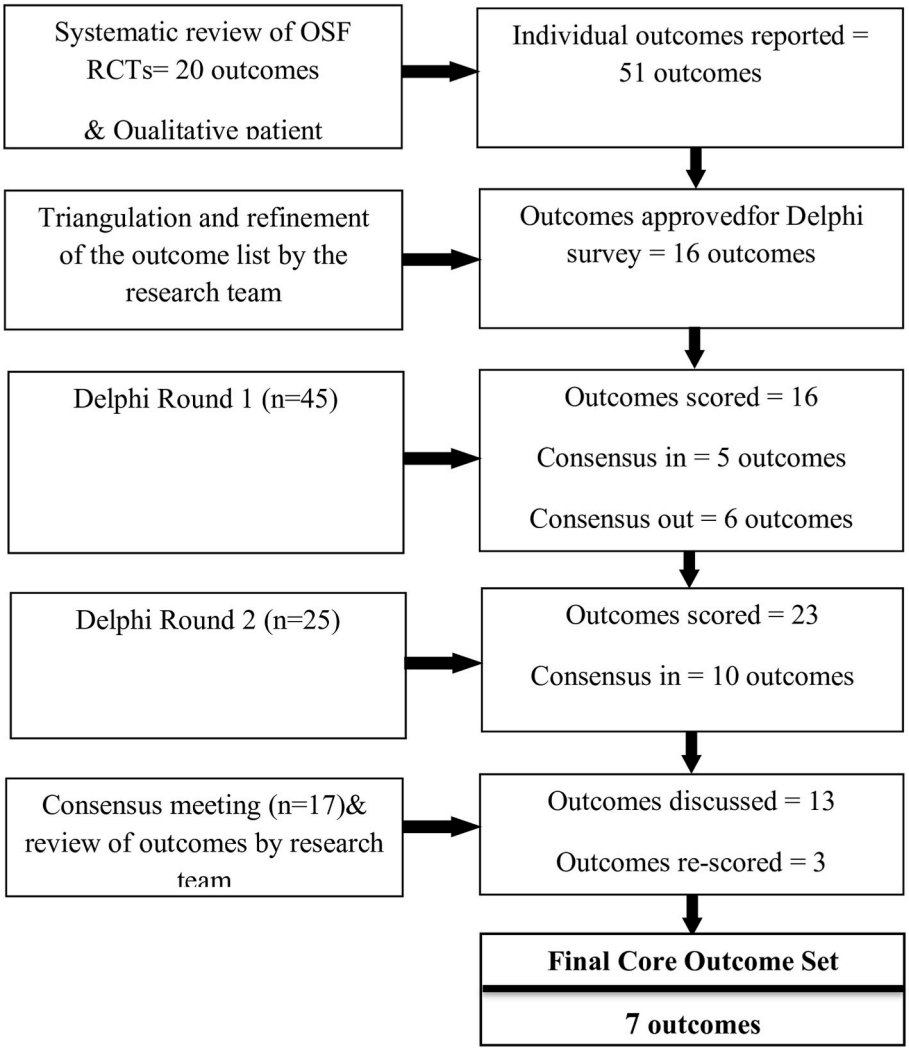

Fig. 1. Overview of the COS development process.

enroll at least 15 individuals from each stakeholder group.

Patients were randomly selected from study center, excluding those who had participated in earlier qualitative phases. Clinicians were identified through professional bodies such as the Indian Academy of Oral Medicine and Radiology and the Indian Dental Association and were invited via email, contingent on their willingness to complete all two Delphi rounds and to preserve confidentiality. Researchers/experts were purposively sampled based on their publications, clinical experience, and interdisciplinary involvement in OSF and patient-centered research. To ensure standardization, participants received detailed instructions for completing the survey. Each Delphi round was developed and piloted by research team membersprior to distribution.

Consenting participants were invited to rate each outcome on a 9-point Likert scale, per the GRADE framework (1–3: not important; 4–6: important but not critical; 7–9: critical).[22] In round 1, participants rated each outcome on 9-point Likert scale andasked to suggest any additional outcomes that they feel is crucial via free-text fields. Outcomes with ≥70% rating 7–9 and ≤15% rating 1–3 in Round 1 were deemed to have reached consensus for inclusion. Only Round 1 participants were invited to Round 2. In the round 2, participantsreceivedanonymized group feedbackon their previous scoresalong with group-level averagesfor each outcomeand an opportunity to re-rate these. Consistent with COMET guidance, even "consensus in/out" outcomes were re-presented in Round 2 for validation. All outcomes, including suggestions from Round 1, were rated in Round 2. Each round remained open for four weeks with biweekly reminders via email.

In each Delphi round, the percentage of participants in each stakeholder group rating outcomes as 1–3 (not important), 4–6 (important), and 7–9 (critical) was calculated. Consensus was assessed using predefined criteria: an outcome was considered "consensus in" if ≥ 70% of participants rated as 7–9 and less than 15% as 1-3, and "consensus out" if ≥ 70% of respondents gave a score of 1-3, and less than 15% had scored an outcome as 7-9. According to earlier studies, any other combinations will be regarded as "no consensus".[18,23]

2.6. Stage 4: Consensus meeting

A consensus meeting was convened with key stakeholders who had completed both the Delphi rounds, with an aim to ensure balanced representation across groups. The meeting was hosted on Zoom on 24th May2025. The meeting was led by an experienced chairperson (SS) who remained neutral and did not participate in the voting process. Outcomes categorized as either 'consensus in' or 'no consensus' during the round 2 of the Delphi survey were presented, along with stakeholder-specific response data. Each outcome was discussed openly, with participants encouraged to evaluate its relevance to the treatment of OSF. Following the discussion, attendees voted on the inclusion of each outcome in the COS using a simple 'yes' or 'no' format. Outcomes, that was received a 'yes' vote from ≥70% participants were incorporated into the final COS. The recommended measurement instruments for

each core outcome were first compiled and proposed during the Delphi rounds based on stakeholder suggestions and existing literature. Final selection and confirmation of these instruments were completed during the consensus meeting, where stakeholders discussed feasibility, validity, and clinical applicability before reaching agreement.

The data were compiled using Microsoft Excel and presented as simple percentages through tables.

3. Results

Participant characteristics for each phase of the study are summarized in Table 1.

3.1. Systematic review

The methods including database search strategies, screening methods, eligibility criteria, PRISMA flowchart, or list of included studies and results summarizing study characteristics, outcomes extracted, and study context of the systematic review had been published previously. In summary, 20 individual outcomes were identified across the reported trials.[13]

3.2. Qualitative research

Three focus group discussions and 12 qualitative interviews were conducted with a total of 30 participants (mean age: 33.50 ± 2.41 years) undergoing OSF treatment. Participants commonly expressed concerns related to various aspects of oral health–related quality of life (OHR-QoL), with a strong desire to see improvement through treatment. Thematic analysis of the qualitative data yielded four overarching themes: functional impairment; psychological wellness; physical wellness; and social wellness. These themes were translated into 31 potential outcomes through discussions with the research team (Table S1).

Following review and refinement of the outcomes extracted from these 2 stages, the research team finalized a list of 16 distinct outcomes to be included in the round 1 of the Delphi process (Table S2).

3.3. Delphi surveys

Delphi Round 1 was completed by 45 stakeholders representing three broad categories: OSF patient representatives (n = 10; 22%), researchers/experts (n = 15; 33%) and clinicians (n = 20; 45%). At the end of this round, five outcomes met the criteria for "consensus in," and six outcomes were categorized as "consensus out." The remaining five outcomes were classified as having "no consensus," as summarized in Table 2. Additionally, seven free-text responses suggesting new outcomes were received and reviewed by the research team, resulting in their inclusion for further consideration.

In Delphi Round 2, 25 participants evaluated a total of 23 outcomes (Table S3). Of these participants, 12 (48%) were clinicians, 8 (32%) were researchers/experts, and 5 (20%) were OSF patients. Following Round 2, ten outcomes reached "consensus in," ten outcomes were rated as "consensus out," and three outcomes remained in the "no consensus" category (Table 3).

Table 2
The results of the Delphi round 1.

Sr. no.	Outcome name	% Not important (1-3)	% Important but not critical (4-6)	% Critical (7-9)	Consensus Status
1.	Burning sensation of oral mucosa	6	10	84	Consensus in
2.	Restricted mouth opening	8	11	81	Consensus in
3.	Blanching of oral mucosa	12	12	76	Consensus in
4.	Vesicles of oral mucosa	24	26	50	No consensus
5.	Oral ulcerations	26	24	50	No consensus
6.	Restricted tongue movements	10	16	74	Consensus in
7.	Alteration/loss of taste sensation	15	20	65	No consensus
8.	Reduced cheek flexibility	16	22	62	No consensus
9.	Dryness of oral mucosa	20	25	55	No consensus
10.	Shrunken/ deviated uvula	74	14	12	Consensus out
11.	Difficulties in chewing/ biting food	74	14	12	Consensus out
12.	Difficulties in speaking	72	14	14	Consensus out
13.	Difficulties in performing oral hygiene	74	14	12	Consensus out
14.	Difficulties in swallowing	86	8	6	Consensus out
15.	Deafness	82	5	13	Consensus out
16.	Oral health related quality of life	10	19	71	Consensus in

3.4. Consensus meeting

After Round 2, further discussion was needed to finalize which outcomes to include in the final OSFCOS. A consensus meeting was convened, attended by 17 participants who had completed both Delphi rounds and were thus eligible to vote. The group included representatives from all stakeholder categories: patients (n = 4), researchers/experts (n = 5), and clinicians (n = 8). Thirteen outcomes were discussed during the meeting. Three of these outcomes were re-scored on the day and subsequently re-categorized as "consensus out." Discussions centered on outcome measurability, definition consensus, and clinical relevance. The final OSFCOS outcome list was confirmed at the meeting's end. A total of 7 core outcomes were agreed upon and are presented in Table 4 (Part 1). The final set of measurement instruments was finalized at the consensus meeting and is presented in Table 4 (Part 2).

Table 1
Participant characteristics by study phase.

Study Phase	n	Stakeholder Groups	Mean age (years)	Gender (M/F)	Professional Experience (years)
Qualitative phase (interviews + FGDs)	30	OSF patients	33.50 ± 2.41	18/12	–
Delphi Round 1	45	Patients (10); Experts (15); Clinicians (20)	38.2 ± 6.5	28/17	Experts: 9.8 ± 3.5; Clinicians: 11.4 ± 4.1
Delphi Round 2	25	Patients (5); Experts (8); Clinicians (12)	40.1 ± 5.9	15/10	Experts: 10.4 ± 3.2; Clinicians: 12.1 ± 4.0
Consensus meeting	17	Patients (4); Experts (5); Clinicians (8)	41.3 ± 4.8	10/7	Experts: 11.2 ± 2.9; Clinicians: 13.3 ± 3.7

Table 3
The results of the Delphi round 2.

Sr. no.	Outcome name	% Not important (1-3)	% Important but not critical (4-6)	% Critical (7-9)	Consensus Status
1.	Burning sensation of oral mucosa	4	8	88	Consensus in
2.	Restricted mouth opening	8	6	86	Consensus in
3.	Blanching of oral mucosa	6	11	83	Consensus in
4.	Vesicles of oral mucosa	12	18	74	Consensus in
5.	Oral ulcerations	8	20	72	Consensus in
6.	Restricted tongue movements	10	16	74	Consensus in
7.	Alteration/loss of taste sensation	12	17	71	Consensus in
8.	Reduced cheek flexibility	14	14	72	Consensus in
9.	Dryness of oral mucosa	13	16	71	Consensus in
10.	Shrunken/ deviated uvula	76	10	14	Consensus out
11.	Difficulties in chewing/biting food	78	13	9	Consensus out
12.	Difficulties in speaking	74	15	11	Consensus out
13.	Difficulties in performing oral hygiene	74	14	12	Consensus out
14.	Difficulties in swallowing	88	9	3	Consensus out
15.	Deafness	86	6	8	Consensus out
16.	Oral health related quality of life	9	16	75	Consensus in
17.	Depressed cheeks	72	14	14	Consensus out
18.	Tightening of lips/reduced flexibility of lips	13	22	65	No consensus
19.	Reduced oral commissure	73	13	14	Consensus out
20.	Prominent angles of mandible	74	14	12	Consensus out
21.	Coexistence with other premalignant disorder	12	20	68	No consensus
22.	Malignant transformation risk	71	15	14	Consensus out
23.	Nasal twang	14	21	65	No consensus

4. Discussion

The OSFCOS initiative emerged in response to the pressing need for consistent and standardized outcome reporting in OSF research. It represents the first concerted attempt to create a COS for OSF treatment and adopted a rigorous, pre-registered methodology. The project synthesized information from a systematic review, qualitative patient data, and multi-stakeholder Delphi rounds, which led to consensus meeting with representation from clinicians, researchers, and patients. This collaborative approach ensured that the selected outcomes captured all relevant perspectives; thereby aligning the OSFCOS with international COMET and COS-STAD standards. This initiative is particularly novel and important as it attempts to address the lack of consistent outcome

Table 4
Final list of outcomes included in OSFCOS for all future studies of treatment interventions in OSF patients [Part 1: Outcome and Part 2.: Recommended Measurement Instrument(s)].

Sr. No.	Outcome
1.	Burning sensation of oral mucosa
2.	Restricted mouth opening
3.	Blanching of oral mucosa
4.	Oral ulcerations
5.	Restricted tongue movements
6.	Reduced cheek flexibility
7.	Oral health related quality of life

Sr. No.	Outcome	Recommended Measurement Instrument(s)	Recommended Assessment Timepoints
1	**Burning sensation of oral mucosa**	Visual Analogue Scale (VAS, 0–10 cm) or Numerical Rating Scale (NRS, 0–10); record highest daily score in past week	Baseline, monthly during therapy, and at 3-, 6- and 12-month follow-up
2	**Restricted mouth opening**	Interincisal distance (mm) measured with a calibrated Vernier caliper between mesioincisal edges of upper and lower central incisors	Baseline, monthly during therapy, and at 3-, 6- and 12-month follow-up
3	**Blanching of oral mucosa**	Clinical grading using Pindborg&Sirsat classification or standardized photographic documentation under consistent lighting	Baseline, at 3-, 6- and 12-month follow-up
4	**Oral ulcerations**	Clinical examination (count and record site, size, duration, and pain score); photographic documentation recommended	Baseline, monthly during therapy, and at 3- and 6-month follow-up
5	**Restricted tongue movements**	Tongue protrusion distance (mm) measured from upper incisal edge to tongue tip; optionally graded using Khanna & Andrade scale	Baseline, at 3-, 6- and 12-month follow-up
6	**Reduced cheek flexibility**	Cheek flexibility (CF) test as per Bailoor&Nagesh: (CF = (B–A)/2 mm), where A = distance between two commissures at rest, B = on maximal stretch	Baseline, at 3-, 6- and 12-month follow-up
7	**Oral health–related quality of life (OHRQoL)**	Oral health related quality of life-Oral submucous fibrosis (OHRQoL-OSF) or Oral Health Impact Profile–14 (OHIP-14)	Baseline, at 6- and 12-month follow-up

measures in clinical trials dealing with OSF. Consequently, the OSFCOS project defined 7 core outcomes which are recommended for reporting in interventional trials of OSF. The OSFCOS is foundational towards creating uniformity in research conducted in this domain and increasing comparison across studies.

The OSFCOS project followed the COMET Handbook[14] and Core Outcome Set-Standards for Development (COS-STAD) guidelines.[15] The systematic review focused exclusively on outcomes reported in RCTs because the aim was to formulate a COS designed particularly for interventional trials in OSF management. Though this approach may have led to selection bias, this limitation was addressed by including qualitative research-derived patient reported outcomes (PRO). In Round 1 of the Delphi survey, patients were asked to propose additional outcomes that they considered essential within the scope of treating OSF. Additionally, outcomes were excluded only if $\geq$ 70% from all stakeholder groups scored them 1–3 with less than 15% scoring 7–9 which permits more outcomes to be discussed at consensus meeting.

Integrating PRO in developing COS is crucial toidentifyoutcomes that matter the most to them as opposed to those captured in clinical trials.[14] The unique views of OSF patients were captured through quantitative methods in this study, which is a step forward toward highlighting the outcomes that matter for the stakeholders. Embracing patients as contributors helped build the consensus since they participated in key phases of the study such as qualitative interviews, Delphi surveys, and consensus meeting. This type of participation improves the validity, relevance and acceptability of COS and hence more robust outcome measures are developed for clinical trials.

Out of the systematic review, 20 individual outcomes were identified along with an additional 31 outcomes emerging from qualitative research. With little guidance available on defining, extracting grouping and counting trial outcomes,[24] the research team set out on extensive iterative refinement of these results through meticulous review processes. To minimize respondent fatigue, this method led to a refined collection of 16 distinct outcomesfor consideration in Delphi Round 1.

The Delphi method is often used as a means to collect expert opinions and facilitate decision-making in a more structured way.[25] All essential stakeholders took part in the Delphi survey to rate the distinct outcomes. These participants brought different expertise concerning OSF which enhanced the process of selecting outcomes. Currently, there is no agreement on ratio between healthcare professionals (HCPs) or other researchers and patients during Delphi processes or consensus meetings.[26] In OSFCOS project, the consensus meeting was mainly attended by researchers and clinicians along with 4 OSF patient representatives. While this imbalance may introduce potential bias, but these few patients bring immense value as their narratives were part of the major decision-making process. The attending patients actively expressed their views on important outcomes so their votes were considered during group decisions and final voting. Anonymous voting during the meeting allowed participants to vote freely, while the facilitator ensured all views were heard and discussions informed decision-making.

The OSFCOS project adopted a standardized approach to create a COS with the goal of facilitating future research on OSF. Akey strength of the OSFCOS project was incorporating qualitative approaches early on in the study to detect PRO so that COS would capture the priorities and lived experiences of OSF patients. Throughout the study, patients retained a strong voice especially during the Delphi survey and consensus meeting, which upholds reliance on patient perspectives. This contribution served to enhance the validity of the OSFCOS thus producing a COS that adequately tracks what matters most to patients. Additionally, the Delphi process enabled participants to consider the perspectives of others before re-evaluating each outcome, fostering structured dialogue and mutual understanding among stakeholders. This iterative feedback was crucial for reaching consensus across a diverse range of expert opinions.

The consensus of key stakeholders supports the uptake of the COS. While stakeholder involvement was strong, patient response rates were lower than expected, possibly due to survey length, delivery method, or clarity of questions; factors not formally assessed. Patient recruitment was limited to India, which may affect the generalizability of findings, as priorities could differ in other healthcare systems. Nonetheless, patient representation in the consensus meeting helped mitigate the risk of a clinician-centric outcome set. Further studies in diverse settings are needed to explore potential variations in outcome priorities. Although developed using a rigorous, evidence-based approach, the COS remains influenced by the perspectives of those involved and may be subject to interpretation. Importantly, OSFCOS is designed to be dynamic and adaptable, allowing for future refinement to ensure ongoing relevance and utility.

Even though valuable, there is still low uptake of COS. It is noted that 96% of clinical trials published in leading medical journals did not incorporate pertinent COS because of lack knowledge about them and their value.[27,28] In this respect, we hope to engage all stakeholders like researchers, reviewers, editors, trial managers, and even funders to enhance visibility and usage of OSFCOS. The OSFCOS team plans to advocate for its use at both national and international conferences arguing in favour for consistent outcome measurement; improved evidence synthesis; reduced research waste and enhanced patient care systems.

In conclusion, with its rigorous multi-phase approach, the OSFCOS project achieved the first core outcome set for oral submucous fibrosis clinical trials. The study identified 7core outcomes through systematic review, qualitative research, Delphi surveys, and a consensus meeting which capture the essential needs of patients, clinicians, and researchers. The objectives of OSFCOS are standardization of outcome reporting to decrease heterogeneity in research and enhance comparability across studies to make data synthesis simpler in systematic reviews and meta-analyses. It will contribute towards evidence-based research by enhancing appropriate monitoring of pivotal outcomes during clinical trials and routine practice for better OSF patient care. Future iterations of OSFCOS should involve multi-center recruitment across different sociocultural settings to improve generalizability.

Patient consent statement

Participants provided informed consent and privacy rights of subjects have been observed.

Ethics approval statement

The Institutional Ethics Committee of Government Dental College & Hospital, Nagpur, India provided ethical approval for the study (reference IECGDCHN/14/24 dated March 28, 2024).

Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

Permission to reproduce material from other sources

Not applicable.

Clinical trial registration

The study is registered on the COMET database (Registration no. 2804).

Funding statement

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jobcr.2026.101421.

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