

People with lived experience in core outcome set development.

Involving people with lived experience (PWLE) in developing a core-outcome set for implant dentistry research (ID-COSM).

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Acknowledgements

We would like to express our huge gratitude to the 31 PWLE who contributed to this project so generously with their time, thoughts and experience. Those that were happy to be acknowledged by name were: María Isabel Marquina Alonso, Milagros Pindado Jiménez, Maria Pilar Rodriguez Potel, Valeria Colas, Inmaculada Valverde, Maria Isabel Jiménez, Arminda Tielas Marcos, Domingo De la Llave, Mr. Kim Kah Hwi, Madam Tan Pue Leng, Sandar Ronald and Richard Adams. We are also extremely grateful to the assistants who took notes at the focus groups meetings and supported the writing of the meeting summaries; Dr Natalie Leow, Dr Andrea Alonso and Dr Shimin Wei. We would

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also like to thank the dental professionals and academics who participated in the consensus meeting for promoting a collaborative culture.

Author contributions

Ian Needleman conceived the manuscript and designed and led the involvement of people with lived experience in this project. The overall ID-COSM project was designed and led by Maurizio Tonetti and Mariano Sanz. All authors contributed to revising and amendments to the manuscript drafts.

Funding

No funding was received to the authors of this paper in relation to the design and conduct of the PWLE involvement elements other than payment of institutional salaries.

Running title: PPI in core outcome set development.

Funding statement: The preparation of the publication has not received external funding.

Conflict of interest disclosure: None declared.

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Abstract

Aims: The aims of this project were to establish the outcomes for dental implant research that are important to people with lived experience (PWLE) and to achieve consensus with those developed by dental professionals (DP) for a core outcome set (COS). This paper reports the process, outcomes, and experiences of involving PWLE in developing a COS for dental implant research: the ID-COSM project.

Materials and methods: Overall methods were guided by the COMET (Core Outcome Set Measures in Effectiveness Trials) initiative. Initial outcome identification was achieved from focus groups with PWLE employing calibrated methods across two low-middle income countries (China and Malaysia) and two high income countries (Spain and the UK). Following consolidation of the results, the outcomes were incorporated into a three stage Delphi process with PWLE participation. Finally, consensus between PWLE and dental professionals was achieved using a mixed live and recorded platform. The experiences of PWLE involvement in the process was also evaluated.

Results: 31 PWLE participated in four focus groups. 34 outcomes were suggested across the focus groups. Evaluation of the focus groups revealed a high level of satisfaction with the engagement process and some new learning. 17 PWLE contributed to the first two Delphi rounds and 7 to the third round. The final consensus included 17 PWLE (47%) and 19 DP (53%). Out of the total of 11 final consensus outcomes considered essential by both PWLE and health professionals, 7 (64%) outcomes mapped across to ones that PWLE initially identified, broadening their definition. One outcome (PWLE effort required for treatment and maintenance) was entirely novel.

Conclusions: We conclude that engaging PWLE in COS development can be achieved across widely different communities. Furthermore, the process both broadened and enriched overall outcome consensus yielding important and novel perspectives for health-related research.

Keywords: Patient Participation, Delphi Technique, Outcome Assessment Health Care, Dental Implants, Research Design.

Clinical relevance

Scientific rationale for the study: A standardised outcome set is needed to strengthen the evidence for implant dentistry including outcomes that are a priority for people with lived experience (PWLE).

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Principle findings: Involvement of PWLE from widely different backgrounds and locations can be achieved within focus groups and consensus stages. PWLE both broaden concepts and identify novel outcomes that are important to those receiving the intended therapy.

Practical implications: PWLE are key partners in developing oral health research. Adopting the core outcome set will lead to research with greater relevance to the target group.

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Background

Core outcome sets (COS) are agreed, standardised sets of outcomes for research of a particular condition or intervention and represent the minimum collection of measures that should be recorded and reported (COMET Initiative 2002). Standardising outcomes can greatly help compare the findings of different studies, therefore increasing the opportunity to strengthen the evidence to inform the public, practice, policymakers and other stakeholders (Carr et al. 2011, Tunis et al. 2016, Williamson et al. 2017). Meaningful involvement of patients and the public in core outcome data set development is a key recommendation (COMET Initiative 2002, Young and Bagley 2016). However, qualitative evidence suggests that developers find this difficult (Gargon et al. 2017).

In this paper, we use the term 'people with lived experience' (PWLE) to include patients and others, such as a carer for a person who has received dental implants and who might be essential for successful care. PWLE bring their expertise and perspective, which are important to capture in measuring treatment outcomes. Including outcome measures relevant to PWLE may improve health literacy and adherence to care, which are important contributors to achieving long-term health (Needleman 2014, Needleman et al. 2023). The voice of PWLE, therefore, plays an important role in identifying key outcomes for research, and this perspective might differ from or complement academic researchers and other stakeholders (Raval et al. 2021). The guidance is therefore developed with rather than just for people with lived experience of the condition or intervention.

In relation to dental implant research, no core outcome set has yet been published. More than ten years ago, the Academy of Osseointegration State of the Science on Implant Dentistry Conference concluded that there was a need for such an initiative and emphasised the importance of ensuring relevance to PWLE (Carr et al. 2011). Similarly, the VIII European Workshop on Periodontology, while proposing the adoption of three broad domains for implant dentistry research, highlighted the need for stakeholder involvement, including patients (Tonetti & Palmer 2012). Whilst there is no set method for involving PWLE and members of the public in developing COS (Young and Bagley 2016), guidance and supporting resources are available from organisations such as COMET (Barrington et al. 2022). COS have been developed for other oral health applications in periodontal research and have included involvement of PWLE (Needleman et al. 2023). However, a limitation of these projects has been that selection of candidate outcomes has only included ones previously published.

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Therefore, PWLE were not asked to identify what really matters to them, only what they think of existing outcomes.

This report summarises our attempts to establish the key outcomes important to PWLE for dental implant research as an integral part of the Implant Dentistry Core Outcome Sets and Measures (ID-COSM) project. We also discuss learnings from our experiences that will help future researchers when developing COS.

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Methods

The methods were guided by the recommendations of the COMET Initiative (COMET 2002) and registered *a priori* on the database: <https://www.comet-initiative.org/Studies/Details/1765>.

Participants

We recruited participants from four locations, two representing low-middle-income economies (Malaysia and the People's Republic of China) and two from high-income economies (Spain and the UK). Recruitment for such studies is not intended to be representative of all people receiving dental implants as it might be for a randomised controlled trial. Instead, the PWLE represent their own experiences of care which are unique. We aimed to capture a wide variety of experiences through the diverse social, economic and cultural values and norms across the centres and such an approach is standard for core-outcome set development. Eligibility criteria were:

1. Had received at least one dental implant placed six months or more ago.
2. At least 18 years of age.
3. Able to read documents and take part in discussions.
4. Able to commit to the focus group and three phases of the online Delphi survey.
5. Access to a computer and internet.

One lead clinician recruited participants by personal contact at each centre from a mix of public and privately funded clinics. Potential participants were advised of the nature of the project and their required commitment. Brief project details were sent to potential participants. We aimed for 6-10 participants from each centre to allow for withdrawals. Participants were offered tokens of appreciation for participation in the order of €20 value.

PWLE Focus Group Process

We aimed to elicit unprejudiced potential outcome measures. In other words, participants were not advised on what was already collected in implant research to minimise the risk of constraining the discussions by knowledge of what was already in the literature. However, the following COMET Initiative resources were sent to recruited participants before the focus group:

1. Link to the core outcomes sets explanatory video available with subtitles in Spanish, Chinese and English as well as other languages (www.youtube.com/watch?v=g1MZi2mzK1U)

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2. The Core Outcome Set / COMET plain language summary document (English only) (www.comet-initiative.org/assets/downloads/COMET%20Plain%20Language%20Summary%20v4.pdf)
3. The Delphi Process plain language summary document (English only). (www.comet-initiative.org/assets/downloads/Delphi%20plain%20language%20summary%20for%20COMET%20website.pdf)

To standardise approaches across each centre as far as possible, we developed and agreed on a topic guide for the four focus groups (additional material 1). The topic guide was initiated by a dental professional with training and experience in designing and conducting focus groups and involving PWLE and the public in research (IN) and then discussed and agreed with the other centres. The guide was translated as needed by the moderator of each group. The topic guide contained three key topics with additional suggestions for prompts. The topics were:

1. Decision-making regarding choosing implant treatment.
2. Dental implant treatment.
3. Living with dental implants.

Additional topics were:

1. The most important thing for dental implant researchers to measure.
2. Other aspects of dental implants that have not been discussed.

A moderator led each focus group, and the session was recorded with written consent from participants. Three focus groups were conducted online and one in person. A separate observer also attended the session to make notes of the participants' comments.

The moderator introduced the session by reviewing the aims and background of the project. In addition, it was stressed that responses would only be captured anonymously, that everyone could speak freely and would be listened to with courtesy by other participants. The purpose of the project was explained, namely, to identify outcomes for future research into dental implants that were important to PWLE. The moderator was instructed to refocus the discussion on outcomes if it moved into areas not relevant to the aims of the focus group and to actively include all participants to ensure that all voices were heard.

Following the focus group, the meeting recording was reviewed together with the meeting notes to produce a final report of participants' responses and suggested outcomes. To standardise this, a

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template was provided to each centre to guide the writing of the report. Where suggestions were broader topics rather than outcome measures, we attempted to revise them towards research outcomes if, in our opinion, revision was relatively minor and did not change the spirit of the comment. In addition, the report from each focus group was sent to the respective participants to seek feedback on accuracy and completeness and amended as needed.

The four meeting reports were then analysed under the separate addressed questions to determine the final list of topics and outcomes from PWLE. Topics common to groups were identified as well as those unique from a particular meeting.

Evaluation of process (additional materials)

Following the focus group meeting, a standardised survey was sent to all participants to obtain feedback on how the focus group was run and the participants' experience of taking part. Some centres distributed this as an e-document by email and others as an online survey.

Participation of PWLE in the Delphi survey.

The finalised list of outcomes was then included in the first of three rounds of Delphi survey. This process is described in more detail in Carillo de Albornoz et al. (2023). In brief, participants were sent detailed instructions by email on how to complete the surveys using the web-based system DelphiManager (www.comet-initiative.org/delphimanager/). The survey included both the outcomes derived from the dental professionals based on new systematic reviews of dental implant research outcomes conducted by dental professionals prior to the Delphi survey and those from the PWLE focus groups. Attempting to remove barriers to PWLE in participating in the Delphi survey we took the following actions;

1. We emphasised that responses were anonymous.
2. Although the Delphi survey was only available in English, PDF help text was also available in Spanish and Chinese.
3. Individual support to help with survey completion was provided to PWLE by facilitators at each centre in response to by PWLE requests.
4. Participants were instructed to only complete their relevant section i.e. health professionals not to respond to the PWLE outcomes and vice versa. The numbers of responses received support that this was achieved.

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The third round was conducted as an online Zoom meeting. Participants were requested to complete an online poll to identify a preferred date and time despite differences in time zones. Prior to Delphi 3, a set of filters were applied to the results from the first two rounds to reduce the number of outcomes. These were;

1. For each outcome: at least 70% scores from individual participants were graded 7-9 in importance and less than 15% scores 1-3 where 9 was the highest score achievable.
2. Must be an outcome that could be assessed in research.
3. Delete duplicate outcomes.

The meeting was structured to review the first two rounds of Delphi followed by discussion of each outcome and online anonymous voting on each using the Vox Voting platform. Participants were asked to vote in one of three categories for each outcome:

- A. Essential to include.
- B. Can be dropped.
- C. Do not know.

Participation of PWLE in the Final Consensus

Following completion of the Delphi survey, a full-day consensus meeting was held in Copenhagen with a focus on the technical elements of the COS. PWLE were not involved in this session although care was taken not to eliminate any of their suggested outcomes remaining after Delphi 3.

Therefore, a final online meeting was planned to include PWLE following this session. The final consensus involved an online Microsoft Teams meeting with 15 dental professionals and three PWLE. During the meeting participants were asked to vote anonymously on adoption of the core-outcome set. Since the meeting time was not convenient for a number of PWLE, a recording was shared immediately afterwards to provide the opportunity to submit votes to local organisers (since the meeting poll was no longer active) which were collated anonymously. Support was again made available to individual PWLE regarding the content, interpretation and voting by centre facilitators according to need.

Results

Insert Figure 1 here.

PWLE participation

The flow chart for PWLE participation is shown in Figure 1. Overall, 31 PWLE participated in the focus groups, 10 male (32%) and 21 female (68%) (Table 1). For three centres, all PWLE approached agreed

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to participate. For one centre, 12 PWLE were approached with 4 declining to participate group: 3 due to inconvenient time and 1 unfamiliar with computer setup. Participants had lived with implants from 6 months -30 years and had between 1 and 10 implants each. The numbers of PWLE and professionals invited to round 1 Delphi voting were: PWLE: 26, dental professionals: 142 and industry: 11. Of these, 17 PWLE completed both rounds 1 and 2 of the Delphi survey. We did not seek reasons for non-completion.

The numbers of PWLE and professionals invited to round 1 voting were: PWLE: 26, dental professionals: 142 and industry: 11. For the third Delphi round held as a Zoom meeting with anonymous voting, 7 (23%) PWLE (from London, Kuala Lumpur and Shanghai) and 15 dental professionals participated. Including both the live final consensus Teams meeting and those who viewed and voted on the recording, the number of participants was 17 PWLE (53%) and 15 dental professionals 15 (47%). The 17 PWLE comprised: UK n=4, China n=3, Malaysia n=2 and Spain n=8.

Insert Table 1 here.

PWLE evaluation of focus groups.

The evaluation of the focus groups revealed considerable satisfaction with the groups and process (Table 2). Most participants were satisfied with the preparatory materials and felt able to contribute to the focus group discussions (*'Yes, the Delphi plain language paperwork was clear and easy to understand'*). Similarly, participants felt they were listened to and the sessions were balanced and without bias for a particular opinion. Participants generally found it useful to listen to others and to think differently or confirm ideas about the care they had received. Some participants expressed a preference for more time in the sessions and for simpler questions. A number of people felt the sessions had been valuable in learning from the experiences of others, for instance in helping them to consider the importance of their oral hygiene and supportive implant care.

Insert Table 2 here.

Outcomes recommended by PWLE

Numbers of outcomes

The focus groups identified a total of 89 topics for outcomes and this number ranged per centre from 16 to 37. There was substantial overlap and duplication between the responses from centres. After analysis, 34 potential topics were identified (Table 3) which went forward to Delphi 1 and 2. Following completion of the second Delphi survey and application of the three filters (see below), 22

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outcomes remained which were the basis of the Delphi 3 online meeting. These were reduced to 13 outcomes of which 8 mapped across to ones initially suggested by PWLE. We recognised that some outcomes did not have validated instruments for their measurement. However, rather than moving these from mandatory categories to those requiring further research development, the consensus was to maintain them as mandatory due to their perceived importance. With minor reordering and amalgamation of duplications, 11 domains were agreed at the final consensus meeting of which 7 (64%) mapped to ones initially (at least in part) from the PWLE focus groups and 4 (36%) exclusively from dental professionals.

Types of outcomes

The outcomes suggested by PWLE could be grouped into two main types. Firstly, those that overlapped with dental professional items and broadened the domains. These included outcomes within the domains of surgical morbidity, complication free-survival, overall satisfaction and comfort, function, quality of life and access to care. The second type of outcome suggested by PWLE were novel outcomes that had not previously been considered in research, in particular, efforts required for treatment and maintenance. These included the time taken for personal plaque control around the implants and prosthesis (or comparative interventions) and its difficulty or complexity as experienced by PWLE as well as the time required by the PWLE separately for treatment and for supportive care. Measuring duration of time would be straightforward but would be based on overall time for the PWLE. Difficulty/complexity of personal plaque control could be assessed by a single question in a scale or by a series of questions to identify the components of the difficulty.. Extensive detail on the overall outcomes is presented in the related paper, Tonetti et al. 2023.

Insert Table 3 here.

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Discussion

Key findings

We have demonstrated that it is possible to involve PWLE in core-outcome set development from widely differing geographical, cultural and economic settings. The 4 focus groups achieved their planned recruitment of 6-10 participants each with a total of 31 PWLE participating. The process was facilitated by the increased familiarity of the public in using online meeting platforms such as Zoom and Teams as a result of the lockdowns and travel restrictions imposed during the COVID-19 pandemic. Whilst the exact instruments for measuring these outcomes have not yet been specified, 7 out of the final agreed 11 core-outcomes i.e. 53%, map across to ones suggested by PWLE during focus groups at least in part. Therefore, we believe that this signifies a high potential level of relevance to PWLE from research that employs this outcome set. The experience of participating in the focus groups was overwhelmingly positive with high levels of engagement. The findings that some PWLE reported benefits of improved understanding of their treatment and long-term care has also been reported by others (Biggane et al. 2019).

Influence of PWLE on final COS

The influence of the PWLE was both important and measurable. In terms of content, outcome domains were enriched and broadened by PWLE input. For example, domain 5, included not only a global measure of satisfaction but also of comfort which was viewed as important by PWLE. Function (domain 7) was strengthened to include four elements: mastication, aesthetics, speech, and denture retention. One entirely novel domain was also recommended as important by PWLE i.e., the efforts required for treatment and maintenance. Once identified, it can easily be understood why this is important to PWLE and therefore important to evaluate to facilitate informed choices of therapy. Furthermore, incorporation of the outcome has the potential to drive innovation to improve such daily burdens. Therefore, the influence of the PWLE has been to encourage consensus on outcomes with greater patient and public relevance. The influence is therefore measurable both in terms of the number of outcomes/domains and their breadth.

Strengths and limitations

This is the first core-outcome set project in oral health to seek and integrate PWLE input unconstrained by the existing research literature, and this is a strength of the project. This is an

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important and distinctive approach for the ID-COSM project since there has been very little involvement of PWLE in developing research methods in oral health. More widely, a recent systematic review found that less than a third of studies developing core-outcome sets included PWLE to develop outcomes *a priori* to Delphi phases of voting (Barrington et al. 2021). Therefore, basing core outcomes only on existing literature could greatly limit relevance to PWLE since the outcome set would have been defined by dental professionals and researchers. A recent review has highlighted that these limitations remain within the field of periodontology (Needleman et al. 2023). The involvement of PWLE can be considered part of the 'citizen-science' initiative. Citizen Science involves non-traditional academic researchers to 'provide experimental data and facilities for researchers, raise new questions and co-create a new scientific culture' (Sanz Serano et al. 2014). A key difference with PWLE is that their contribution to research is specifically based on their lived experience of a health condition or therapy.

We followed COMET recommended methodology for deriving the core-outcome set. The methods provided helpful structure and valuable resources including explanatory video with multiple language subtitles and plain language summaries of the process. Despite the pandemic limiting opportunities for project developers to meet, we were able to provide a level of calibration between focus group moderators by agreeing and devising topic guides to lead discussion. Furthermore, the analysis of the responses from each focus group was supported by a template. Evidence that these steps were successful includes the feedback from participants and the comparability of the outputs from the separate focus groups. A further strength is the inclusion of PWLE from both low-middle- and high-income economies. All participants (both PWLE and professionals) could see all possible outcomes during the Delphi surveys although each group were requested not to respond to the others' section. Assessing the number of responses indicates that this was achieved. Clearly, there is scope for each group to be influenced by viewing the others' outcomes during the survey. This is a standard approach with Delphi survey and considered a strength as it allows individuals to reflect both on their own responses but also those of the other participants.

Limitations

In terms of generalisability, the most significant limitation is that we only recruited PWLE with dental implants. This might have distorted the spectrum of participants including some who were able to afford such an expensive treatment (where not provided within socialised medicine schemes) or to

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afford the time not only for the implant and prosthodontic treatment but which might also include extensive care to achieve good oral health prior to placing dental implants. Future studies should evaluate systematic differences between PWLE with dental implants and those without.

Involving PWLE to co-design the project from the outset would be an improvement that could be made. Areas that would be especially valuable for such input would include improving diversity and inclusion of recruitment, guidance and support to help PWLE participate e.g., with logging in to online meetings and completion of online Delphi surveys and format of the focus groups and design of the topic guides. It is important to recognise that experience and confidence with on line meetings varies amongst PWLE more than academic professionals. We did not consider adequately beforehand the support that participants might require for instance to navigate the Delphi surveys or to move between different online platforms (Zoom/Teams). We would recommend more time spent planning support for participants and to keep to one type of platform throughout.

A further limitation is that we did not collect data on participants' diversity such as socioeconomic status and ethnicity. This could be particularly important with dental implant treatment as discussed above in order to understand inclusivity of recruitment and potential implications for generalisability. We did not evaluate participants' experiences of Delphi phases although we assessed this for the focus groups. The information from the Delphi survey participation could have helped to interpret the final selection. For instance, a previous study found that some PWLE without experience of Delphi surveys found the process unclear and the scoring challenging which might impact on the validity of the findings (Biggane et al. 2019).

Three centres opted to run the focus groups online and one in-person, based on local conditions (mostly related to the COVID-19 pandemic) and preference. Arguably, greater comparability might have been served by keeping to one format for all meetings. There is evidence that online vs. in-person focus groups differ in the type of interactions and information that participants feel confident to offer (Bruggen 2009). This was expressed by more than one participant in the current study: *'More difficult to speak about personal aspects when you can't see everyone.'* However, much of the research investigating these differences was conducted before the worldwide COVID-19 pandemic and consequently pre-dates the enhanced familiarity with these online platforms. Although it is not possible to fully evaluate the impact of the different meeting formats on the

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process, the comparability and breadth of outcomes across the centres suggest that the approach was satisfactory for the purposes of this project. Further research would be helpful since online platforms offer potential for greater accessibility to PWLE at much lower research cost.

Implications

Dental implant research has made huge contributions to transforming the way that lost teeth are replaced, restoring lost function and improving oral health-related quality of life. This ID-COSM project provides an opportunity for the research community to transform the relevance of research in relation to collecting outcomes which PWLE state are the most important to them. By implication this will also change the design of studies to ensure that these outcomes are collected and will likely influence the research questions addressed. Since the majority of the findings of such research are intended to be offered to PWLE, it seems critical that future studies collect information that PWLE both want and need to know.

However, employing this core outcome set alone is only part of the journey towards improving the relevance of research to PWLE and the public more widely. Other elements will include involving PWLE and the public as co-researchers in the team, ensuring the diversity of recruited participants matches the target population(s) and using a wide array of platforms to share results from research studies, both to the public and to health professionals (Raval et al. 2021, Needleman et al. 2023). Furthermore, implementation of COS is challenging with low uptake in published studies and systematic reviews (Williamson et al. 2022).

Conflict of interest disclosure

Ian Needleman is an Editor with Cochrane Oral Health. Maurizio S. Tonetti received grant support and/or personal fees from Geistlich Pharma AG, Straumann AG, Nobel Biocare, Procter and Gamble and Sunstar SA, which are unrelated to the present work. Mariano Sanz received grant support and/or personal fees from Straumann, Nobel Biocare, Sweden and Martina, Dentsply Implants, TiCare Implants, Klockner Implants, Dentaaid, Sunstar, Geistlich Pharma, Osteology Foundation, Oral Reconstruction Foundation, ITI Foundation, which are unrelated to the present work.

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List of figures.

Figure 1. Flow chart showing numbers of participants and outcomes at the different stages of the process.

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Table 1. Demographics of ID-COSM PWLE focus groups

Characteristic		
Number of participants		
	Male	Female
London	2	5
Kuala Lumpur	4	4
Shanghai	3	6
Madrid	1	6
Total	10 (32%)	21 (68%)
How long have you lived with dental implants (years)		
	Range	
London	0.5-30	
Kuala Lumpur	1-20	
Shanghai	0.5-18	
Madrid	1-14	
How many implants do you have (per participant)?		
	Range	
London	1-8	
Kuala Lumpur	1-2	
Shanghai	1-12	
Madrid	1-10	

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Table 2. Evaluation of focus groups.

Survey question	Y	N	Comments (<i>verbatim</i>)
1 Did the materials provided before the focus group prepare you enough?			
London	7	0	
Shanghai	7	2	
KL	8	0	
Madrid	8	0	
			<i>'Yes, the Delphi plain language paperwork was clear and easy to understand.'</i>
			<i>'They informed me very well and I understood from the beginning the objective of the meeting'</i>
2 Did you feel able to contribute to the discussion as much as you wished?			
London	6	1	
Shanghai	6	3	
KL	8	0	
Madrid	8	0	
3 Is there anything that would have helped you to contribute more?			.
London	0	7	
Shanghai	2	7	
KL	1	7	
Madrid	2	6	
			<i>'A little more time to get to know the other participants - perhaps necessary because of the online medium. More difficult to speak about personal aspects when you can't see everyone.'</i>
			<i>'The questions should be more simple and answer yes or no.'</i>
4 Do you feel that the facilitator listened to your points?			

People with lived experience in core outcome set development.

London	7	0	
Shanghai	8	1	
KL	8	0	
Madrid	8	0	
			<i>'I wish to help more and see the technology advancement that will benefit the general public.'</i>
5	Do you feel that the focus group was run in a balanced way without bias for any particular opinion or thought?		
London	7	0	
Shanghai	7	2	
KL	8	0	
Madrid	8	0	
			<i>'The discussion is great, maybe more time could be helpful.'</i>
6	Did you find it useful to listen to other participants?		
London	7	0	
Shanghai	6	3	
KL	6	2	
Madrid	5	3	
			<i>'Useful to hear their experiences, especially when you think it is something that you alone have dealt with.'</i>
			<i>'I was able to learn more about implants from listening to other participants.'</i>
			<i>'Not really, since everyone had a very good experience with having dental implant.'</i>
			<i>'More confident towards implants.'</i>
			<i>'Everyone had different reasons to have implants, was very informative.'</i>

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			<i>'It didn't bring me anything new to listen to others'</i>
7	Did taking part in the focus group help you to think differently about your care or confirm ideas you already had?		
	London	5	2
	Shanghai	8	1
	KL	7	1
	Madrid	5	3
			<i>'Made me want to be even more careful about oral hygiene.'</i>
			<i>'There were possibly more options than I'd been aware of - eg 'all in a day' or a 'glued-in' - so to speak - tooth instead of a bridge.'</i>
			<i>'This mutual communication has expanded my knowledge of dental implant care, and it shows great care for patients.'</i>
			<i>'About the follow-ups.'</i>
			<i>'Now I value more the fact that I have to take care of my implants.'</i>
			<i>'Ideas I already had were confirmed.'</i>
			<i>'I take better care of my implants.'</i>
			<i>'I feel even more fortunate to be able to have implants, and that everything is going well, after hearing the experiences of others.'</i>
8	Was there anything that you learnt from taking part in the focus group?		
	London	6	1
	Shanghai	6	3
	KL	7	1
	Madrid	8	0
			<i>'A fruitful exchange of opinion probably needs more than 90 minutes.'</i>

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<i>'I would highlight the issue of the importance of hygiene that other patients commented on.'</i>		
9 Do you have any final comments about the focus group?		
London	4	3
Shanghai	6	3
KL	0	8
Madrid	0	8
<i>'The chairing of the meeting was excellent, ... led the meeting including everyone in each section of the discussions. The meeting flowed and I for one after being nervous to start with felt relaxed and happy to talk openly.'</i>		
<i>'The kindness of the facilitator stood out.'</i>		
<i>'I (afterwards) found it interesting that no one talked about intimacy as one of the reasons for having implants. I suspect that this was because of the format of the focus group.'</i>		

People with lived experience in core outcome set development.

Table 3. Outcomes and topics recommended by PWLE. Note, where these overlap with dental professionals' outcomes they are amalgamated into one. Those outcomes mapping across to ones suggested at initial PWLE focus groups (even in part) are in bold.

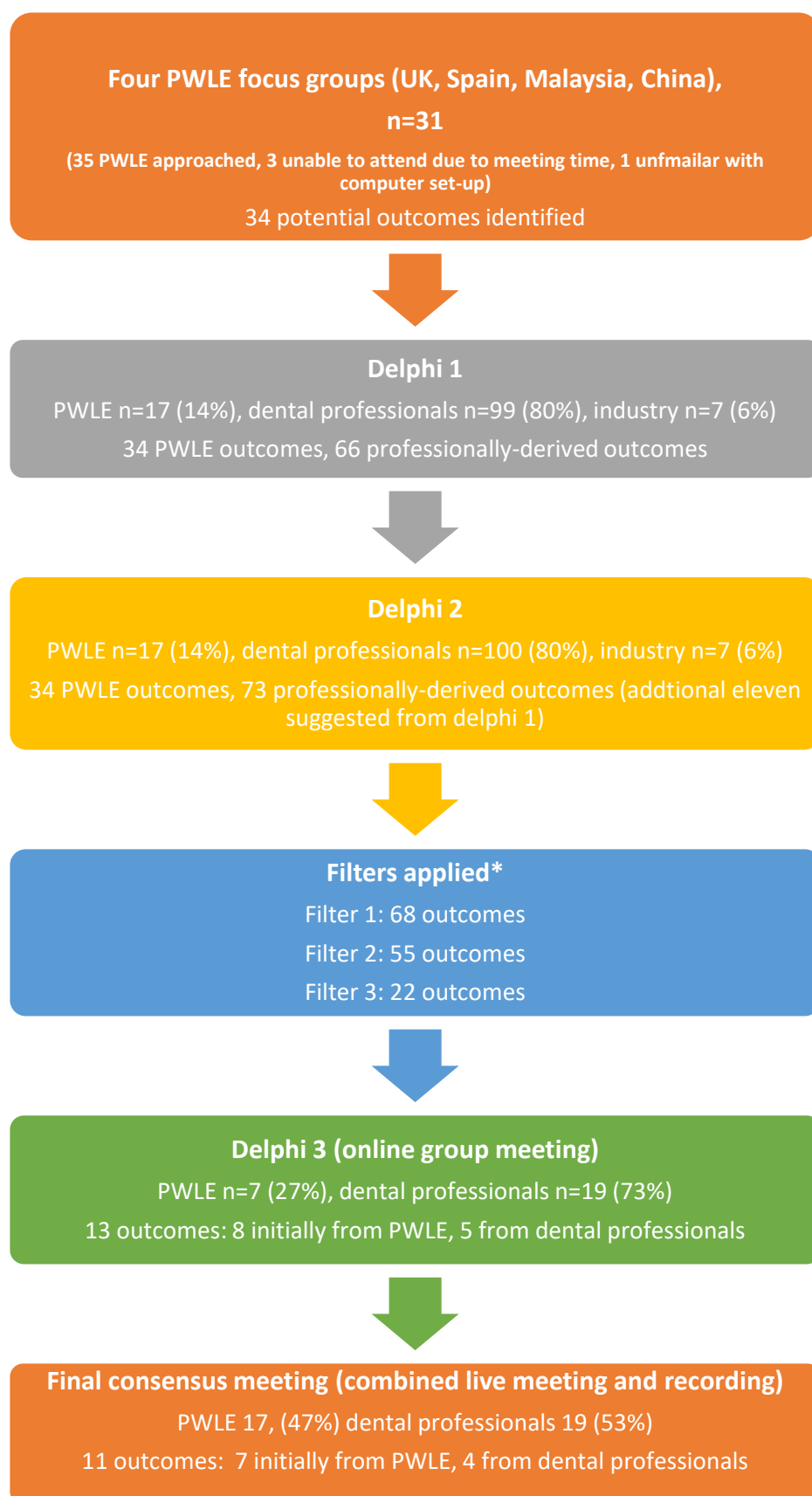
PWLE focus groups only	After applying filters to Delphi 1 & 2 (Dental professional and PWLE measures combined)	Agreed 'essential' list of outcomes following Delphi 3	Final consensus list ID-COSM 'ONION' Tonetti et al. 2023
1. Long-term success	1. Mastication/chewing power	1. Mastication/chewing power	Mandatory in all trials 1. Surgical morbidity and complications (until delivery of final restoration) 2. Peri-implant tissue health 3. Intervention-related adverse events (including implant/prosthesis loss – after delivery of final restoration) 4. Complication free survival 5. Overall patient satisfaction and comfort Mandatory in specific type of trials 6. Effort required for treatment and maintenance 7. Function (mastication, aesthetics, speech, denture retention) 8. Quality of life 9. Access to care – cost effectiveness 10. Bone augmentation 11. Soft tissue augmentation
2. Chewing power	2. Aesthetics/overall appearance	2. Aesthetics/overall appearance	
3. Comfort	3. Speech	3. Speech	
4. Adaptation (time to accommodate to dental implants)	4. Denture retention	4. Denture retention	
5. Decision making (for choosing implants)	5. Surgical complications	5. Surgical complications	
6. Information methods (about dental implants)	6. Implant health status	6. Implant health status	
7. Adequacy of information (for choosing implants)	7. Marginal bone level	7. Marginal bone level	
8. Complications	8. Adverse device events	8. Adverse device events	
9. Hygiene time (for oral hygiene)	9. Implant & restoration survival/success	9. Implant & restoration survival/success	
10. Duration of planning and treatment (time)	10. Implant loss/failure/fracture	10. Implant loss/failure/fracture	
11. Treatment time	11. Retreatment	11. Quality of life	
12. Implant hygiene education methods	12. Quality of life	12. Overall satisfaction	
13. Food impaction	13. Comfort	13. Effort for maintenance: (oral hygiene education)	
14. Patient reported outcomes of treatment success	14. Overall satisfaction		
15. Patient reported outcomes to predict success	15. Adaptation		
16. Post-operative care education	16. Pain		
17. Oral hygiene education	17. Effort for maintenance: (oral hygiene education)		
	18. Time effort for treatment		
	19. Professional experience of team (treatment)		

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- | | |
|--|--|
| 18. Anxiety | 20. Professional experience of team
(managing complications) |
| 19. Pain | 21. Information |
| 20. Patient reported outcomes of temporary phase | 22. Affordability |
| 21. Professional experience
(training/experience of professionals involved in implant treatment) | |
| 22. Treatment cost | |
| 23. Professional training methods for maintenance | |
| 24. Professional training methods for complications | |
| 25. Motivation for oral care | |
| 26. Oral hygiene effectiveness | |
| 27. Maintenance frequency | |
| 28. Extracted tooth status (on future implant success) | |
| 29. Success of implant failure re-treatment | |
| 30. Technical complications | |
| 31. Affordability | |
| 32. Overall function | |
| 33. Overall appearance | |
| 34. Setting (where implants placed) | |

People with lived experience in core outcome set development.

Figure 1. Flow chart showing numbers of participants and outcomes at the different stages of the process.



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*Filter 1: For each outcome: at least 70% scores from individual participants were graded 7-9 in importance and less than 15% scores 1-3 where 9 was the highest score achievable.

Filter 2: Must be an outcome that could be assessed in research.

Filter 3: Delete duplicate outcomes.

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Additional material 1

Topic guide for ID-COSM focus groups

Ian Needleman version 1.3

18 June 2021

Keep to maximum of 90 minutes

Introduction [5 minutes]

‘Thank you very much for taking part in today’s Focus Group and welcome. My name is.... and I’m... [describe your role in the project. Introduce anyone else in the room from the project]

Aims and objectives

‘The purpose of this focus group is to hear about your experiences of dental implant treatment and living with dental implants. We are holding focus groups in four locations, Shanghai, Kuala Lumpur, Madrid and London, to hear from as wide a range of experiences as possible. We will use the information to build a list of your most important outcomes related to dental implants that should be included in future research. These will be included in a survey which we will ask to you to complete in a few weeks. The survey will give an opportunity for the entire patient group to comment and decide which are the most important outcomes to measure. The results of the survey will form a key part of the final stage of this project, a conference taking place in Shanghai, China in January 2022 when the final list of measures will be discussed, debated and agreed by consensus.’

Explain to group the ground rules

Everyone here is important and I would value hearing your experiences and thoughts. Please show respect to other participants and their opinions and there are no right or wrong answers. Please turn off your mobile phone or to silent.

[Be prepared to politely refocus the group on outcomes. Patients may wish to talk about many personal aspects that could rapidly dominate the discussion]

1. Easy starter question, for example. [5 minutes]

- a. Could you please tell us your name and how long you had dental implants and if you can remember, how many implants you have? [Ask each person in turn].

People with lived experience in core outcome set development.

2. I would now like you to think about when you were deciding whether to have dental implants. [10 minutes]

- a. What was the most important information about dental implants that helped you to decide to go ahead with them or chose implants?
 - i. Prompts:
 1. What other options other than dental implants did you consider or were you offered?
 2. Why did you choose implants and not the alternatives?

3. I would now like you to think about the treatment itself. Is there any information that was missing that you would like to have had about dental implant treatment? [10 minutes]

- i. Prompts:
 1. What do you now know about treatment that you didn't know before?
 2. What would you think other people should know about dental implant treatment if they were thinking about having it?
 3. What were the best and worst aspects of the treatment for you?

4. I would now like you to think about living with dental implants. [10 minutes].

- a. What difference have they made to you?
 - i. Prompts
 1. Has it made any difference to your life quality?
 2. How were you feeling before having dental implants and what has changed?
- b. Can you tell us about how you look after your dental implants and what is important to you about this?
- c. What are the best parts of having dental implants?
- d. What are the worst parts of having dental implants?

5. If you could speak to a dental implant researcher, what would you tell them was for you the most important think to measure? [10 minutes]

- a. Prompts
 - i. You might think about your experiences of treatment or your experiences since treatment of living with the dental implants.

6. Is there anything else that you would like to say about measuring outcomes in dental implant studies? [5 minutes]

- a. Prompts: Is there anything that you wanted to mention that you have not had a chance to or that you would like to highlight to us?

Finish [5 minutes]

Thank you very much for your time today and for all your valuable thoughts and comments. We will now put these together with the comments from the other groups and summarise them for the Delphi survey in a few weeks. We will be back in touch soon with the survey and look forward to your important involvement with this project. Once the project is complete, we will be happy to send you a copy of the report if you would like to receive it.

People with lived experience in core outcome set development.