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Shared Decision-Making for Periodontally Compromised Teeth: Study Protocol for an Ongoing Prospective Multicenter Before-and-After Clinical Trial

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ABSTRACT

Treatment decisions for teeth with poor periodontal prognosis are often complicated, requiring careful balancing of clinical evidence and patient values. Shared decision-making (SDM) is increasingly recognized as a beneficial approach to align clinical judgment with patient preferences. However, structured SDM implementation in dental settings remains limited. This study was designed to evaluate the effectiveness of a structured SDM protocol compared to usual care decision-making for patients with severe periodontitis and hopeless-prognosis teeth. A multicenter, before-and-after clinical trial will be conducted across 12 dental centers in South Korea. Each center will apply usual care decision-making for the first six months, followed by the SDM intervention for the subsequent six months. The SDM process involves a three-step model: team talk, option talk (aided by web-based decision aids), and decision talk. Eligible participants include patients with stage III or IV periodontitis and at least one hopeless-prognosis tooth. Each patient follows a three-visit schedule. Primary outcome is the rate of tooth preservation decisions. Secondary outcomes include measures related to SDM (SDM-Q-9, SDM-Q-Doc), patient experience (Perceived

making. Previous studies have shown that patients have a greater preference for autonomy when managing non-life-threatening conditions.¹² In this context, SDM models have emerged as an optimal approach to clinical decision-making, especially in preference-sensitive scenarios.^{13,14} Although SDM protocols are increasingly being integrated into medical practice, their implementation in dental practice remains uncommon.

This study aims to develop a tailored SDM protocol for periodontal treatment decisions that promotes collaborative engagement between dentists and patients. Specifically, we will seek to determine how SDM influences actual treatment choices in clinical practice by comparing patient treatment decisions, involvement, and decisional regret between UC and SDM approaches for patients with periodontally compromised teeth. This article outlines the SDM protocol and the multicenter before-and-after clinical trial designed to compare outcomes between the SDM and UC groups.

A STUDY PROTOCOL FOR SHARED DECISION-MAKING IN PERIODONTAL TREATMENT

Study design

This prospective before-and-after trial will be conducted in 12 centers across South Korea: 11 university dental hospitals and 1 National Health Insurance Service institute. UC decision-making and SDM will be compared in patients facing treatment decisions about a periodontally compromised tooth. This trial consists of two sequential phases—before and after—conducted within the same clinical settings. All centers will apply the UC approach during the initial 6-month phase, followed by a second 6-month phase implementing the SDM protocol. Prior to the SDM phase, all participating dental professionals (dentists and dental hygienists) will undergo training in the pre-established SDM protocol, which includes standardized communication guidelines and web-based decision aids to ensure that the intervention is implemented consistently across all participating institutions. Eligible patients with periodontally compromised teeth whose prognosis is hopeless will be recruited at each center (Fig. 1).

Eligibility criteria

Participants considered eligible for enrollment will have been diagnosed with stage III or IV periodontitis, and be deciding whether a periodontally compromised teeth with a hopeless prognosis will be extracted or retained. For patients with multiple eligible teeth, the tooth exhibiting the most-severe periodontal condition—based on clinical attachment loss, tooth mobility, furcation involvement, and presence of an endodontic-periodontal combined lesion—will be selected as the representative tooth. The exclusion criteria will include 1) teeth without viable treatment options, such as being prosthetically unrestorable or with complete periodontal destruction from a floating condition, 2) failure to provide written informed consent, or 3) systemic conditions that contraindicate dental treatment in general.

Implementation protocol

An SDM model has been developed for this study to support patients in making informed treatment decisions about periodontally compromised teeth (Fig. 2). This model was designed based on a predictive framework assessing decision-making autonomy in patients with periodontal disease, along with patient preferences identified through a comprehensive literature review. It follows a three-step process and incorporates web-based

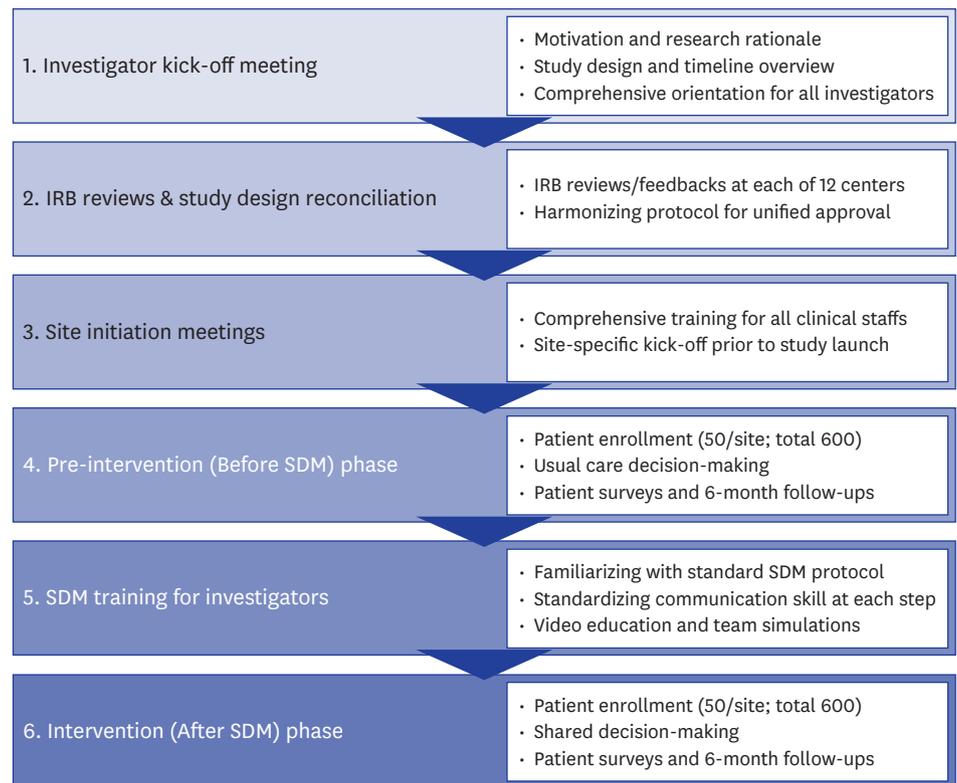


Fig. 1. Study flow of a multicenter before-and-after clinical trial in 12 institutions. This diagram illustrates the sequential application of two intervention phases: a 6-month usual care phase followed by a 6-month SDM phase, with participants enrolled independently in each phase. SDM = shared decision making.

decision-support tools, including flash cards and video clips tailored to clinical conditions and patient preferences, as follows:

- 1) Step 1 – team talk: The first step emphasizes the patient’s right to participate in treatment decisions. The dentist explains the patient’s periodontal condition and prognosis based on clinical findings, with an emphasis on decision-making being a collaborative process involving both clinician and patient, rather than a decision made unilaterally by the clinician. The explanation should highlight the patient’s autonomy in choosing a treatment option and the clinician’s role in providing expert information as part of a decision-making team. Once the patient is actively engaged, the dentist introduces available treatment options.
- 2) Step 2 – option talk: A trained dental professional (dentist or dental hygienist) applies this step with the aid of a web-based decision-support tool developed for this study. The tool assesses the patient’s decision-making autonomy and elicits the patient’s treatment preferences. Through a structured conversation, the dental professional presents comparative information on multiple treatment options using flash cards and short video clips that highlight the benefits, risks, and expected outcomes of each option. This process encourages patients to reflect on their own preferences, with the insights gathered serving as reference information for the final decision-making discussion with the dentist.

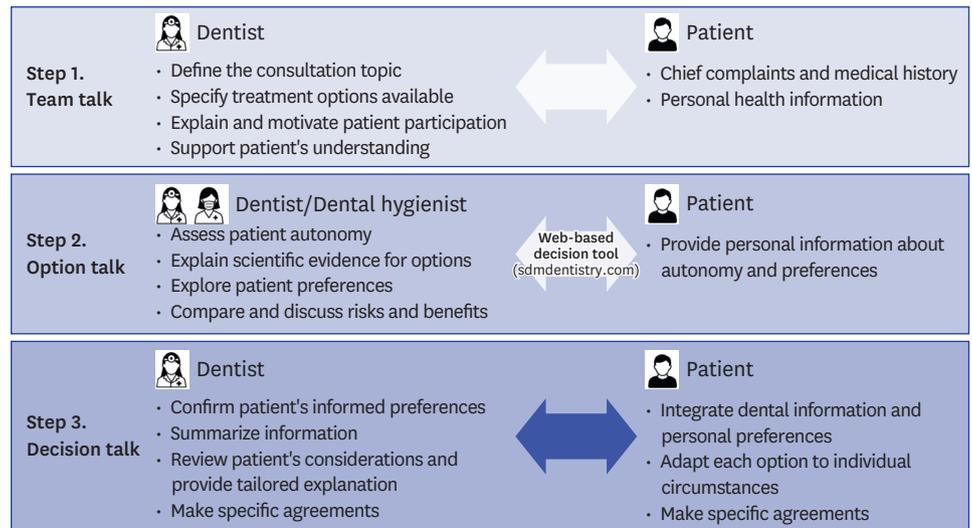


Fig. 2. The three-step SDM model in periodontal treatment planning. This figure presents a structured three-step SDM model applied in the periodontal treatment planning process. Engaged participants and their roles are described in each step. Especially, in the second step of 'Option talk,' the specific website-based decision tool is used for assessing patient autonomy, providing scientific evidence, and exploring patients' preferences (www.sdmdentistry.com). SDM = shared decision making.

3) Step 3 – decision talk: In the final step, the patient clarifies their treatment preferences and articulates priorities. Insights obtained during the option talk give the dentist a deeper understanding of what matters most to the patient. The final treatment decision is then made collaboratively, integrating the patient's informed preferences with the clinician's professional judgment. The aim of this stage is to develop a treatment plan that meaningfully reflects both the patient's preferences and the clinician's expertise.

This SDM model will be implemented in the intervention group (SDM group) and applied throughout the treatment decision-making process. In contrast, the control group will be managed with UC, which typically involves an explanation of the patient's condition, presentation of treatment options, and the patient's decision being based largely on the clinician's recommendations.

Schedule of study visits and procedures

Patients will be assigned to either the UC group (before intervention) or the SDM group (after intervention) and will follow a structured three-visit schedule, as shown in Fig. 3.

Visit 1 (Screening)

At the initial visit, a clinical examination will be first performed to determine patient eligibility based on the predefined inclusion and exclusion criteria. Following confirmation of their eligibility, patients will be invited to complete a structured, self-reported questionnaire administered in face-to-face mode by trained research personnel. The questionnaire is based on the AOHSS (Adult Oral Health Standard Set), and includes items on sociodemographic characteristics and oral-health-related behaviors (autonomy reference). For the SDM group, additional items will be incorporated to evaluate patient autonomy and treatment preferences. In accordance with the SDM protocol, patients in the SDM group will engage in both team talk and option talk during this visit.

	Visit 1	Visit 2	Visit 3
Usual care group: Usual care decision-making (n = 600)	<ul style="list-style-type: none"> • Screening • Explanation of test results • Usual care decision-making • Questionnaires: AOHSS 	<ul style="list-style-type: none"> • Usual care decision-making (cont'd.) • Questionnaires: SDM-Q-9, SDM-Q-Doc 	<ul style="list-style-type: none"> • 6-month follow-up • Questionnaires: PICS, DRS • Clinical periodontal exam. • Treatment compliance, cost analysis
SDM group: Shared decision-making (n = 600)	<ul style="list-style-type: none"> • Screening • Explanation of test results • Shared decision-making (Step 1 & 2) • Questionnaires: AOHSS, autonomy, patient preference 	<ul style="list-style-type: none"> • Shared decision-making (Step 3) • Questionnaires: SDM-Q-9, SDM-Q-Doc 	<ul style="list-style-type: none"> • 6-month follow-up • Questionnaires: PICS, DRS • Clinical periodontal exam. • Treatment compliance, cost analysis

*Visit 1 and 2 can be conducted together for some patients if preferred.

Fig. 3. Schedule of study visit and procedures. This figure outlines the study’s three-visit schedule for both usual care and SDM groups. Each participant was enrolled in only one phase, reflecting a fixed-sequence before-and-after study design. SDM = shared decision making, AOHSS = Adult Oral Health Standard Set, SDM-Q-9 = Shared Decision-Making Questionnaire—patient version, SDM-Q-Doc = Shared Decision-Making Questionnaire—physician version, PICS = Perceived Involvement in Care Scale, DRS = Decision Regret Scale.

Visit 2 (0 Months, Baseline consultation)

At the second visit, patients in the UC group will receive standard care based on conventional clinical decision-making practice, while those in the SDM group will receive care guided by the structured SDM protocol developed for this study. As part of the SDM protocol, patients will access evidence-based treatment information and visual decision aids via a bespoke web-based platform to facilitate informed and preference-sensitive decisions. If family members or other individuals are the primary decision-makers (surrogates) but were unavailable to participate in the decision-making steps during Visit 1, both the team talk and option talk will be repeated with them at Visit 2. After these steps, the decision talk will be conducted to finalize the treatment plan in alignment with the informed preferences of the patient (or their surrogates) and the clinician’s judgment. The extent of SDM will be assessed in both groups immediately after the consultation using the Shared Decision-Making Questionnaire—patient version (SDM-Q-9) for the patients, and the Shared Decision-Making Questionnaire—physician version (SDM-Q-Doc) for the clinicians.¹⁵

Visit 3 (6 Months, Follow-up)

At the 6-month follow-up, patients in both groups will complete a posttreatment questionnaire. Outcomes will be assessed using the Perceived Involvement in Care Scale (PICS)¹⁶ and Decisional Regret Scale (DRS),¹⁷ as will the periodontal statuses of the target tooth and its adjacent teeth, and the treatment compliance, with a cost analysis also being performed. These measures will be used to evaluate the impact of the SDM intervention on both clinical and patient-centered outcomes.

Outcomes

Primary outcome

The primary outcome is the tooth preservation decision rate, defined as the proportion of patients who choose a tooth-retentive treatment.

Secondary outcomes

SDM-related outcomes

- The SDM-Q-9 and SDM-Q-Doc will be used to assess the extent of SDM from the perspectives of the patient and the clinician, respectively. Each of these tools consists of nine items rated on a 6-point Likert scale (1 = strongly disagree, 6 = strongly agree).

Patient-experience-related outcomes

- The PICS will be used to evaluate the information needs, communication experiences, and overall satisfaction of patients. This tool includes 13 items rated on a 5-point Likert scale (1 = strongly agree, 5 = strongly disagree).
- The DRS will be used to assess the level of regret related to the treatment decision at 6 months after making the decision regarding the periodontally compromised tooth. This tool includes 18 items rated on a 5-point Likert scale (1 = strongly agree, 5 = strongly disagree), with total scores converted to a scale from 0 to 100.
- Treatment adherence will be assessed through attendance at scheduled clinical visits and patient self-reports of compliance with the treatment plan.

Clinical outcomes

- The clinical periodontal parameters will include the clinical attachment level, probing pocket depth, bleeding on probing, gingival recession, and tooth mobility.
- The treatment costs will be assessed as the total financial burden associated with care, including direct medical expenses such as consultation fees, procedural expenses, and material costs.

Sample size

The required sample size for two independent proportions was determined using a power analysis implemented with the TWOSAMPLEFREQ statement in the POWER procedure of SAS software (version 9.4; SAS Institute, Cary, NC, USA). Although the study consists of two sequential phases (UC and SDM), each participant is enrolled in only one phase, and therefore the sample size was estimated based on an independent-groups comparison. The analysis assumed independence between tooth extraction decisions made during the first study period (UC group) and the second study period (SDM group), with expected extraction rates of 69% and 61.4%, respectively (risk ratio = 0.89). Using a two-sided alpha of 0.05, power of 80%, and a 1:1 allocation ratio, the required sample size was calculated to be 1,010 participants. To account for an anticipated 10% dropout rate, the target sample size was increased to 1,200 (i.e., approximately 100 per institution).

Data collection

Primary and secondary variables specified in the study protocol will be collected at each site using an electronic case report form (eCRF) via the REDCap (Research Electronic Data Capture) system. All data—including demographic information, clinical measurements, and patient-reported outcomes collected from questionnaires—must be accurately entered into the eCRF. Each eCRF is to be completed and electronically signed by research personnel authorized by the principal investigator, who bears overall responsibility for data accuracy. Before finalizing each eCRF, the research team must ensure that all fields are complete in order to minimize subsequent data queries and maintain data integrity.

Statistical methods

The primary outcome of the tooth preservation decision rate—defined as the proportion of patients opting for retentive (i.e., nonextractive) treatment—will be analyzed using McNemar's test within a fixed-sequence before-and-after design. The secondary outcomes include measures of SDM, patient-reported outcomes, periodontal clinical indicators, treatment costs, and treatment adherence. Continuous secondary outcomes will be evaluated using linear mixed models to assess within-subject changes in each group over time, from baseline to the 6-month follow-up. The UC and SDM groups will be compared

using independent *t*-tests or analysis of variance, according on how the data are distributed. All statistical analyses will be conducted using SAS software (version 9.4), with a two-sided *P* value of < 0.05 indicating statistical significance.

Ethics statement

The study protocol described here was approved by the Institutional Review Board (IRB) of all 12 participating institutions under the following approval numbers: Yonsei University Dental Hospital (2-2020-0066), Seoul National University Dental Hospital (CRI25002), Pusan National University Dental Hospital (PNUDH 2025-02-011), Chosun University Dental Hospital (CUDHIRB 2503 004), Dankook University Dental Hospital (DKUDH IRB 2025-05-001), Kyungpook National University (KNUDH-2025-02-06-00), Wonkwang University Dental Hospital (WKDIRB202503-01), National Health Insurance Service Ilsan Hospital (NHIMC IRB 2025-03-001-001), Gangneung-Wonju National University Dental Hospital (GWNUDH-IRB2025-A001), Chonnam National University Dental Hospital (CNUDH-2025-011), Kyung Hee University Dental Hospital (KH-DT25005), and Jeonbuk National University Dental Hospital (CUH 2025-02-018-003). Prior to being enrolled, each participant will receive a detailed explanation of the study and then provide written informed consent. The trial was registered in the Clinical Research Information Service of the National Research Institute of Health, South Korea, on April 10, 2025 (No. KCT0010405).

CLINICAL IMPLICATIONS

The presented study protocol describes a multicenter before-and-after clinical trial designed to evaluate the impact of structured SDM in patients with periodontally compromised teeth whose prognosis is hopeless. The primary aims are to identify how different decision-making approaches in dental practice influence the choice between tooth retention and extraction, and to determine their effects on patient-centered processes and clinical outcomes.

The primary outcome focuses on whether the SDM approach increases the proportion of patients opting for tooth preservation rather than irreversible extraction and implant replacement. Conventional dental treatments aim to save even severely compromised teeth. However, the advent of dental implants has broadened the clinical indications for tooth extraction, by offering strategic tooth replacement as a viable treatment option. Treatment decisions can profoundly influence patients' quality of life, financial burden, and the risk of complications such as peri-implantitis. However, the decision to retain or extract a compromised tooth can be driven not only by the expectations of a patient but also by the experience and treatment preferences of the clinician.⁸ This underscores the critical need for an SDM process that considers both perspectives.

Previous studies have demonstrated that when patients are well informed and actively engaged through SDM, they report greater satisfaction and are more likely to adhere to the chosen treatment plan.^{18,19} However, evidence regarding the impact of SDM on actual treatment decisions and patient-reported outcomes in dentistry remains weak. This trial is expected to provide crucial insights into how the SDM intervention 1) facilitates the understanding that patients have of available treatment options, 2) supports autonomous decision-making, and 3) potentially increases the likelihood of a tooth-preserving strategy being chosen.

The described study will also explore the effects of the SDM intervention on the experiences and involvement of the patient across several domains. The secondary outcomes are organized into three categories: 1) SDM-related outcomes (SDM-Q-9 and SDM-Q-Doc), 2) patient-experience-related outcomes (PICS, DRS, and treatment adherence), and 3) clinical outcomes (periodontal parameters and treatment costs). SDM-Q-9 and SDM-Q-Doc are validated tools that assess the process quality of SDM from the perspectives of patients and clinicians, respectively, focusing on information exchange, elicitation of patient preferences, and collaborative deliberations.¹⁵ We ensured that a structured SDM process will be applied by adapting the three-talk model by Elwyn et al.,²⁰ which guides decision-making interactions through sequential stages of team talk, option talk, and decision talk.

Patient-experience-related outcomes, as measured using the PICS and DRS, assess how actively involved patients feel while they are receiving healthcare. The PICS measures communication clarity, informational adequacy, and acknowledgment of personal preferences,¹⁶ factors that are closely linked to SDM process quality.²¹ The DRS captures posttreatment regret,¹⁷ which is often reduced when patients are well informed and actively engaged, making it an important indicator of patient-centered decision-making.^{22,23} Treatment adherence is another key secondary outcome, which reflects how well patients follow their treatment plan—not as passive compliance but as an indicator of alignment with the preferences of patients.^{24,25}

The clinical outcomes include both biological and financial measures of treatment effectiveness. The investigated periodontal parameters will provide objective clinical data for comparing outcomes between the SDM and UC groups. Additionally, treatment costs will be analyzed to assess the financial implications of each option, offering insight into how financial considerations can influence patient autonomy and treatment decisions.³ Understanding these financial implications also supports evaluating whether SDM affects the choice of treatments in the presence of different financial burdens.

This study aims to produce meaningful evidence on the practical value of a structured SDM approach in dentistry, particularly in complex periodontal treatment planning where patient preferences and clinical uncertainties intersect. By examining the effects of SDM on decision-making processes and associated clinical and patient-reported outcomes, this research may inform strategies that will provide a better balance between clinician expertise and patient autonomy. While SDM protocols have increasingly been integrated into medical practice, structured implementation and evaluations in dentistry remain uncommon. This trial seeks to address that gap by introducing and assessing a tailored SDM protocol for patients with periodontally compromised teeth. Ultimately, the findings may support evidence-based periodontal care that fully respects patient preferences and also fosters the broader adoption of SDM in dental practice.

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