Research Article

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Reporting characteristics of nonsurgical periodontal therapy trials registered in ClinicalTrials.gov: an observational study

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Aim: To evaluate the completeness of the description of nonsurgical periodontal therapy interventions in clinical trials registered in ClinicalTrials.gov and correspondence of registered information for trial participants and outcome measures with published articles. **Materials & methods:** We retrieved data from ClinicalTrials.gov and corresponding publications. The completeness of intervention reporting was assessed using the Template for Intervention Description and Replication (TIDieR) checklist for oral hygiene instructions (OHI), professional mechanical plaque removal (PMPR), and subgingival instrumentation, antiseptics and antibiotics. The completeness of registration of trial protocol information was assessed according to the WHO Trial Registration DataSet for participant information (enrollment, sample size calculation, age, gender, condition) and primary/secondary outcome measures. **Results:** 79 included trials involved OHI (n = 38 trials, 48.1%), PMPR (n = 19, 24.1%), antiseptics (n = 11, 12.7%), or antibiotics (n = 11, 12.7%). There was a great variety in the terms used to describe these interventions. Most of the analyzed trials (93.7%) were completed and did not provide any data on study phase (74.7%). The description of intervention in the registry in ClinicalTrials.gov was inadequate for all analyzed interventions, with description inconsistencies in matching publications. There were also discrepancies in registered and published outcomes: for 39 trials with published results, 18 had different registered and reported primary outcomes, and 29 different registered and reported secondary outcomes. **Conclusion:** The completeness of the description of nonsurgical therapy of periodontitis in clinical trials is unsatisfactory, reducing the quality of translation of the new evidence and procedures into clinical practice. Significant discrepancy in registered and reported trial outcomes calls into question the validity of reported results and relevance for practice.

Tweetable abstract: Nonsurgical periodontal interventions are incompletely described in trials in ClinicalTrials.gov, with significant differences between the registered data and the corresponding journal articles.

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Periodontitis is one of the most common chronic inflammatory non-communicable diseases [1,2]. Mechanical subgingival instrumentation, along with oral hygiene instructions, is an essential part of a nonsurgical periodontal protocol (NSPP). NSPP is considered the 'gold standard' therapy in reducing tissue inflammation and controlling subgingival microflora in individuals suffering from periodontitis [2–5]. As an addition to mechanical subgingival instrumentation in NSPP, antiseptics, especially chlorhexidine (CHX), and antibiotics are commonly used to reduce inflammation and obtain better clinical outcomes [6–8].

Clinical practice guidelines have been developed to facilitate the treatment of periodontitis with different types of interventions for NSPP [2]. All procedures included in NSPP require a more individual approach, depending on the severity of disease, patient's risk factors and their motivation [9–11]. Considering that periodontitis is one of the most prevalent chronic diseases [12,13], it is important that clinical trials are adequately reported and that NSPP is well described so that can be correctly implemented in clinical practice. Moreover, the number of randomized

clinical trials in periodontology is generally higher in comparison to other dental medicine disciplines [14] and all interventions should be described in detail. However, medical interventions, particularly non-pharmacological interventions, are often inadequately described in published articles, thus compromising their translation into the practice [15–18]. When non-pharmacological interventions, such as dental surgical procedures, are poorly reported, it is often difficult for the evidence from clinical trials to be replicated in practice, and thus their clinical usefulness is reduced. This is in contrast to pharmacological interventions, which are much easier to describe then interventions such as health education, and physical therapy. To address these issues, a Template for Intervention Description and Replication (TIDieR) checklist [19] was developed as an extension of the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement [20] and the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) 2013 statement [21]. TIDieR checklist serves as a guide for better description of interventions and adoption of research results in clinical practice [22] and is used in studies evaluating the completeness of the intervention description in clinical trials [23–25]. However, TIDieR guidelines are still rarely used for reporting interventions in dental medicine. With publication bias remaining high in dental medicine, despite mandatory registration of protocols and summary results [26], TIDieR guidelines are very relevant for the description of interventions not only in published articles, but also in trial registries, which are often the only source of information about a clinical trial.

The aim of this study was to evaluate the completeness of the description of nonsurgical periodontal procedures in clinical trials protocols registered in ClinicalTrials.gov and correspondence of the description in the registry with that in published articles. We also evaluated the correspondence of registered trial protocol information with that in corresponding published articles.

Methods

Sample & inclusion criteria

For this observational study, we identified clinical trials from ClinicalTrials.gov on 18 March 2021, by using the advanced search term "nonsurgical periodontal therapy treatment". Trials were included if they: 1) had a ClinicalTrials.gov registration number (National Clinical Trial [NCT] number), 2) were registered on March 18, 2021 or before, 3) were reported as completed, terminated, withdrawn, active, not recruiting in the recruitment field by the same date and 4) had nonsurgical periodontal therapy treatment noted in one or more following registration fields within the Descriptive Information section of the ClinicalTrials.gov Tabular View tab: Brief Title, Official Title, Brief Summary or Intervention. Trials that reported surgical periodontal therapy as a single intervention or a part of combination intervention were excluded.

Data extraction

To assess the registration completeness of included trials, we extracted data on 21 of 24 items from the WHO Trial Registration DataSet (WHO TRDS) [27] trial ID, date of first registration, NCT number, source(s) of monetary or material support, primary and secondary trial sponsors, public title, scientific title, countries where trial was conducted, health condition(s) studied, intervention(s), inclusion criteria, study type, date of first enrolment, sample size, recruitment status, primary outcome, key secondary outcomes, date of study completion, summary results and individual participant data (IPD) sharing statement. Ethics review information and items that had administrative character were not extracted.

To evaluate the completeness of description for interventions in NSPP, we adapted the 12-item TIDieR checklist [19] for each type of selected interventions. Main interventions were: oral hygiene instructions (OHI), professional mechanical plaque removal (PMPR) and 3) subgingival instrumentation, while additional interventions were: antiseptics and antibiotics. Other interventions that were performed in addition to NSPP were not analyzed since their use is not recommended according to clinical practice guidelines [2]. The records from ClinicalTrials.gov were downloaded and relevant data for a random 10% of the trials were extracted independently by an experienced periodontist with expertise in evidence-based medicine and systematic review methodology (MR) and a general dentist – PhD student (PS). For data that could not be assessed using the binary approach, we formed a list of subitems that should be presented within a particular item to be considered as completely described (Supplementary Table 1). A special emphasis was put on items 6, 9 and 11, which were considered to be prone to subjective assessment. After discussion of possibly unclear records with the other two reviewers (AŠ, AT), who were the final year students of dental medicine working under the supervision of MR, a consensus extraction protocol was established. Three reviewers then independently extracted and reviewed all required data for completeness (PS, AŠ, AT), after which

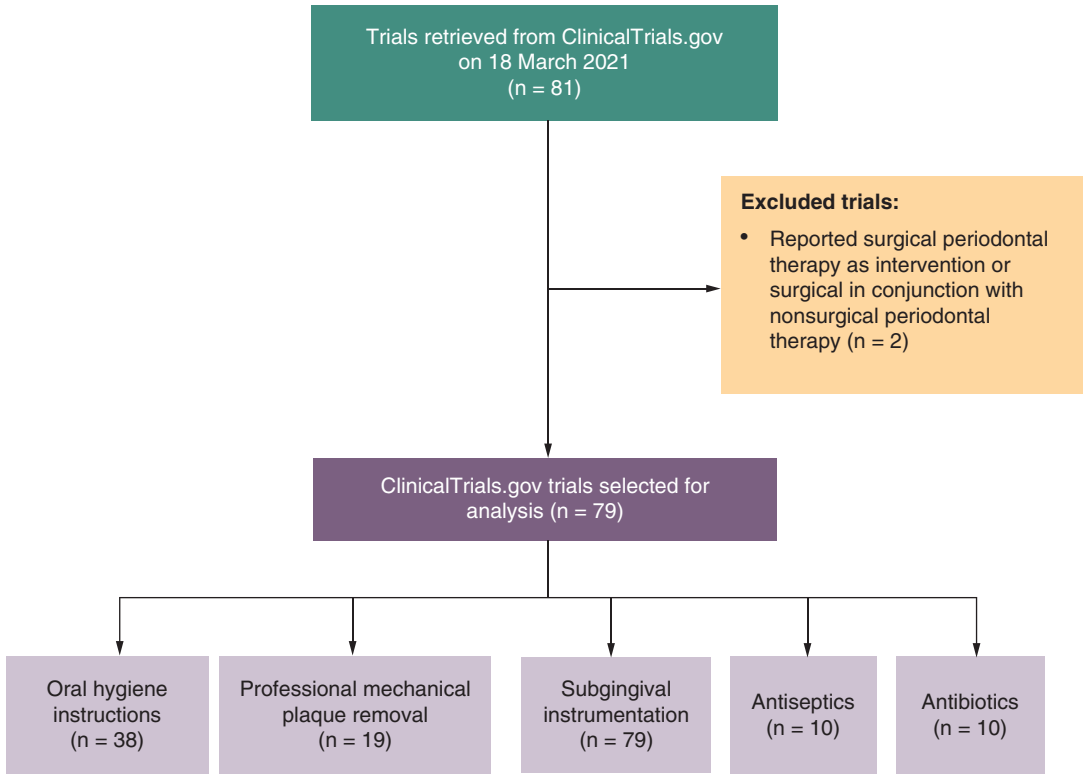

Figure 1. Flow-chart of the search and selection of eligible clinical trials for analysis.

the fourth investigator (MR), an experienced periodontist, checked all data and resolved any disagreements. The data were collected from the Descriptive Information section in ClinicalTrials.gov, except for items 10 and 12. They were reported after the end of the study and extracted from the Study Results tab in ClinicalTrials.gov in February 2022, after the extraction of other data. Since the terminology of the analyzed intervention varied between trials, as observed during the pilot extraction, two independent investigators (PS, MR) assessed and harmonized the terms noted in the registered trial protocol for different intervention types. We considered "subgingival instrumentation" and "professional mechanical plaque removal" as standard terms according to their use in the latest clinical practice guidelines [2].

The search for the corresponding publications was performed on 22 February 2022. We used the following search terms in PubMed/MEDLINE and Scopus: NCT number, names obtained within the Administrative Information section of the ClinicalTrials.gov Tabular View tab and 3) Brief and Official Title within the Descriptive Information section of the ClinicalTrials.gov Tabular View tab [28]. We compared the data from trials protocols in ClinicalTrials.gov and corresponding publications: participants' characteristics, reported interventions and their completeness using TIDieR checklist and primary and secondary outcomes. Items from the TIDieR checklist with more elements were considered as provided if at least one was reported. As 2 out of 12 TIDieR items require description of results, these were not compared because none of published studies reported their results in ClinicalTrials.gov.

Data analysis

The data was presented as frequencies and medians with 95% confidence intervals (CIs). Descriptive analysis was performed using MedCalc version 17.9.4 (MedCalc Software, Ostend, Belgium).

Results

Characteristics of trials registered in ClinicalTrials.gov

Among 81 trials on NSPP identified in ClinicalTrials.gov, 2 trials (2.5%) were excluded (Figure 1): one reported surgical periodontal therapy as an intervention (NCT02630745) and the other surgical in conjunction with non-

Table 1. Characteristics of 79 trials on nonsurgical periodontal therapy interventions registered in ClinicalTrials.gov.

Research characteristics	Trials, n (%)
Status:	
Active, not recruiting	3 (3.8)
Completed	74 (93.7)
Terminated[†]	1 (1.3)
Withdrawn[‡]	1 (1.3)
Phases:	
Early phase 1	2 (2.5)
Phase 1	1 (1.3)
Phase 2	3 (3.8)
Phase 2/3	3 (3.8)
Phase 3	4 (5.1)
Phase 4	7 (8.9)
"Not applicable"	59 (74.7)
Allocations:	
Randomized	57 (72.2)
Non-randomized	14 (17.7)
Stated "Not applicable"	8 (10.1)
Interventional model:	
Single group	11 (13.9)
Crossover	1 (1.3)
Parallel	66 (83.5)
Not provided	1 (1.3)
Masking:	
"None"	20 (25.3)
"Blind"[§]	52 (74.7)
Primary purpose:	
Diagnostic	5 (6.3)
Supportive care	1 (1.3)
Prevention	3 (3.8)
Treatment	65 (82.3)
Health Services Research	1 (1.3)
"Other"	3 (3.8)
Not provided	1 (1.3)

[†]Trial registration No. NCT02568163.
[‡]Trial registration No. NCT02520375.
[§]Among blinded trials 25 (42.4%) were single-blind, 21 (35.6%) double-blind, 7 (11.9%) quadruple-blind and 6 (10.2%) triple-blind.

surgical periodontal therapy (NCT03639636). 79 included trials involved subgingival instrumentation combined with OHI (n = 38 trials, 48.1%), PMPR (n = 19, 24.1%), antiseptics (n = 11, 12.7%) as well as antibiotics (n = 11, 12.7%) (Supplementary Table 2). Most trials had subgingival instrumentation along with one or more other interventions; only 9 trials (11.4%) involved subgingival instrumentation alone. A variety of terms were used to describe NSPP and subgingival instrumentation in the registry (Supplementary Table 3).

Most of the analyzed trials (93.7%) were completed and did not provide any data on study phase (74.7%) (Table 1). A trial that had "terminated" status at the time of data extraction noted that "*the number of subjects was underestimated, which implied a reduction in the number of subjects required*" (NCT02568163). Another trial was withdrawn, but with no explanation provided (NCT02520375). Only two trials posted trial results in ClinicalTrials.gov results database (NCT02861937, NCT04027686) and one trial submitted results but were not yet posted (NCT02460926). The majority of trials included healthy volunteers (55.7%) of both genders (91.9%), between age 25 and 60 years (Table 2).

Table 2. Characteristics of participants in 79 trials on nonsurgical periodontal therapy interventions registered in ClinicalTrials.gov.

Participants' characteristics	Trials, n (%)
Sex:	
Male	1 (1.3)
Female	6 (7.6)
Both	72 (91.9)
Minimum age, years:	
Provided (median 25, 95% CI 20–30, range 10–40)	75 (94.9)
Not provided	4 (5.1)
Maximum age, years:	
Provided (median 60, 95% CI 60–65, range 18–80)	61 (77.2)
Not provided	18 (22.8)
Enrollment:	
Provided (median 42, 95% CI 40–54, range 0–514)	79 (100)
Conditions:	
Only periodontitis	42 (53.2)
Periodontitis + diabetes	17 (21.5)
Periodontitis + obesity	3 (3.8)
Periodontitis + cardiovascular disease	3 (3.8)
Periodontitis + smoking	2 (2.5)
Periodontitis + dentin sensitivity	2 (2.5)
Periodontitis + birth weight	2 (2.5)
Periodontitis + other[†]	8 (10.2)
Healthy volunteers:	
"Yes"[‡]	44 (55.7)
"No"	35 (44.3)
IPD sharing statement:	
"Yes"	3 (3.8)
"No"	25 (31.6)
"Undecided"	6 (7.6)
Not provided	45 (57)

[†]Along with periodontitis, 8 trials had a single condition other than previously stated: kidney disease, menopause, pregnancy, osteoporosis, rheumatoid arthritis, thalassemia major, obstructive sleep apnea, and erectile dysfunction.
[‡]Regarding inclusion criteria of 44 trials, 15 trials (34.1%) noted periodontitis, 7 (15.9%) none disease, 5 (11.4%) periodontitis and systemic healthy volunteers, 5 (11.4%) periodontitis and systemic condition/disease, 5 (11.4%) periodontal health, 4 (9.1%) systemic healthy volunteers or well controlled condition/disease, and 3 trials (6.8%) periodontal health and well controlled condition/disease or systemic health.
IPD: Individual participant data.

Regarding other characteristics of the trials (Supplementary Table 4), only 3 trials (3.8%) opted to share individual patient data from the trial. The most common trial sponsors were universities (89.9%). The start year of included trials ranged from 2002 to 2019, and the location was reported for around a half of the trials (58.2%), with most trials conducted in Brazil (26.1%) and in Turkey (17.4%).

Quality of description of main interventions in ClinicalTrials.gov

In 38 trials with oral hygiene instructions (OHI), adjuvant therapy was noted as the rationale for 4 trials (10.5%) (Table 3). Brushing technique was described in 28.9% trials, in which modified Bass technique was the most frequent (81.8%). In all trials that reported provider's expertise, periodontist was noted as the one responsible for giving oral hygiene instructions. The mode of delivery of OHI was poorly stated in the majority of trials. Only one trial (2.6%) reported that participants received both verbal instructions and practical demonstration (NCT03311243) and a single trial (2.6%) emphasized that oral hygiene instructions were given to each subject individually (NCT02379975) (Table 3). Moreover, only two trials (5.3%) provided TIDieR item 9, specifying that

Table 3. Quality of reporting of 12 items from the TIDieR checklist for oral hygiene instructions (OHI) in 38 trials registered in ClinicalTrials.gov[†].

TIDieR item	Intervention description component	Trials, n (%)
1. Brief name	Provided[‡]	30 (78.9)
	Not provided	8 (21.1)
2. Why	Noted precisely ("adjuvant therapy")	4 (10.5)
	Noted, but insufficiently described[§]	2 (5.3)
	Not provided	32 (84.2)
3. What (materials)	Provided	15 (39.5)
	Not provided	23 (60.5)
4. What (procedures)	Diet and instructions:	
	Provided	2 (5.3)
	Not provided	36 (94.7)
	Type of brushing technique:	
	Different level of details[¶]	11 (28.9)
	Not provided	27 (71.1)
5. Who provided	Providers' expertise:	
	Periodontist noted	7 (18.4)
	Unclear data provided[#]	8 (21.1)
	Not provided	23 (60.5)
	Intervention providers, n:	
	Provided	14 (36.8)
	Not provided	24 (63.2)
6. How	Verbal or practical:	
	Provided	2 (5.3)
	Not provided	36 (94.7)
	Group or individual:	
	Provided	1 (2.6)
	Not provided	37 (97.4)
7. Where	Recruitment or investigation center noted[††]	21 (55.3)
	Not provided	17 (44.7)
8. When and how much	Moment of giving instructions:	
	Provided	15 (39.5)
	Not provided	23 (60.5)
	Duration:	
	Not provided	38 (100.0)
9. Tailoring	Provided	2 (5.3)
	Not provided	36 (94.7)
11. How well planned	Provided[‡‡]	8 (21.1)
	Not provided	30 (78.9)

[†]Only one trial reported results in the CT.gov results database (NCT02861937) and did not note any modifications of intervention (Item 10) or provide the extent to which the intervention was delivered as planned (Item 12).
[‡]A total of 29 trials (76.3%) used term "oral hygiene instructions" and 1 (2.6%) used term "oral hygiene education" (NCT02618486).
[§]OHI was mostly briefly stated as an addition to another performed intervention or more details were associated with the outcomes of the intervention in 2 trials (NCT02208739, NCT03311243).
[¶]Total of 10 (26.3%) trials provided only the name of the technique, 1 (2.6%) provided only description of the technique (NCT01427764), and none trial provided both name and description of the technique.
[#]Five (13.2%) trials did not explain the expertise of intervention provider (used general terms, such as "examiner, investigator or clinician"), 2 (5.3%) only described who provided measurement and did not mention the intervention provider (NCT03343366, NCT00327561) and one (2.6%) did not clearly state if provider will be performing measurements or intervention (NCT02652026).
[††]Out of 21 trials, 4 (19%) trials noted the investigation center where intervention was administered, 12 (31.6%) noted investigation center or country under the Recruitment Information section and not within the Descriptive Information section, and the remaining 5 (13.2%) provided only data on recruitment center without clearly defining the center where the intervention was administered.
[‡‡]Four trials (10.5%) provided only hygiene control (examination, questionnaire, statistical analysis), 1 (2.6%) provided only reinstructions (NCT01951547), and 3 (7.9%) provided both hygiene control and reinstructions (NCT02208739, NCT02861937, NCT03039244).
TIDieR: Template for Intervention Description and Replication.

instructions will be given according to the specific needs or depending on the extension of the patient's periodontal condition. Oral hygiene reinstructions as a part of planned protocol were stated in only four trials (10.5%).

A total of 19 analyzed clinical trials had professional mechanical plaque removal (PMPR) as a registered intervention (Table 4). TIDieR Item 1, name of the intervention, was the most commonly reported item (89.5%). No trials used the term "professional mechanical plaque removal". For professional mechanical plaque removal, the combination of hand and powered instruments was most common (31.6%) and the mode of delivery of the intervention was the same as the mode used for subgingival instrumentation in 77.8% trials. In more than half of the trials, scaling was noted as a performed procedure (57.9%). (Table 4). Provider's expertise was adequately stated in 21.1% trials, which is almost two-times more in comparison to provider's expertise reported for subgingival instrumentation. Similar to the intervention reporting in trials on subgingival instrumentation, only a single trial reported personalization of the intervention in the context of the need for anesthesia.

For 56 trials out of 79 (70.9%), we identified incongruent number of interventions when we compared the number reported under the Intervention field with other fields within the Descriptive Information section. TIDieR Item 1, name of the intervention, was the only TIDieR item reported in all 79 trials with the administration of subgingival instrumentation noted as the intervention (Table 5). Among 34 trials that noted the information for the type of used instruments, 4 trials (11.8%) reported hand instruments, other 4 (11.8%) sonic or ultrasonic instruments, and the remaining 26 trials (76.5%) used the combination of hand and powered tools. However, the majority of trials did not provide any information related to the type of anesthesia (77.2%), expertise of intervention provider (72.2%), or the number of appointments and duration of each session (74.7% and 81.0%, respectively). Among 18 trials that noted the use of local anesthesia in its registration protocol, only one trial (1.3%) precisely stated "*infiltration or nerve block*", while all other trials provided only the term "local" (anesthesia). Regarding 28 trials that adequately reported the how subgingival instrumentation was performed, the majority of trials involved full mouth procedure (57.1%), 4 trials (14.3%) involved quadrant, 4 trials (14.3%) split mouth, 3 trials (10.7%) the combination of full mouth and a quadrant, and 1 trial (3.6%) specified that instrumentation was performed only on molars. Only a single trial (1.3%) reported individualization of the intervention, depending on the extension of the patient's periodontal condition (Table 5). Only 5 trials (6.3%) described in their protocol whether the intervention was delivered as planned, which included the smoothness and cleanliness of root surface.

Quality of description of adjuvant interventions in ClinicalTrials.gov

Among all 10 trials using antiseptics, chlorhexidine (CHX) was the only reported antiseptic. Clearly described study rationale was missing for the majority of trials (9 trials) (Supplementary Table 5). Most of the trials noted the time of CHX application (8 trials), but specific instructions regarding the administration were reported only in a single trial (NCT02379975). TIDieR item 6 was precisely defined in 3 trials, in which rinsing or subgingival irrigation was noted as the route of administration. Duration of chlorhexidine administration was recommended in periods of 7 days (4 trials), 14 days (4 trials) or 60 days (2 trials) (Supplementary Table 5). Out of 7 trials that provided applied dose, all trials reported using 0.12% concentration and 90.0% of trials reported 15-ml dosage. Only one trial stated that the administration of a mouthwash use was individually based (NCT02379975).

Similar to the trials involving CHX, all 10 trials with antibiotic intervention(s) provided generic or brand name of used antimicrobial agent (Supplementary Table 6). Doxycycline was the most commonly used antibiotic (4 trials) and other, less reported, were combination therapy of amoxicillin and metronidazole (2 trials), azithromycin (2 trials), clarithromycin (1 trial) and metronidazole as a single therapy (1 trial). Antibiotics were delivered mostly as capsules or tablets (6 trials), then as microspheres (2 trials), and in the form of gel (2 trials). TIDieR item 8 was well reported for most of the trials: the duration of administration was clearly noted in 9 trials, and dose and dosing frequency in 7 trials (Supplementary Table 6). No trials provided the information regarding personalization or described strategies for the assessment of participants' adherence.

Comparison of registry data & corresponding publications

For 79 registered trials included in the study, we were able to identify 44 corresponding publications. Three publications did not describe interventions analyzed in the study and 2 did not have full text available and were excluded from the analysis. Out of 39 analyzed published articles (Table 6), about a half had different age range (51.3%) or the number of participants (48.7%) than what was reported in the registry. Sample size calculation was not reported in the registry for 32 trials (89%) but was reported in the published articles. Two trials did not report this item in both the registry and the published article. Primary outcomes differed in the published article

Table 4. The quality of reporting of 12 items from the TIDieR checklist for professional mechanical plaque removal (PMPR) in 19 trials registered in ClinicalTrials.gov[†].

TIDieR item	Intervention description component	Trials, n (%)
1. Brief name	Precisely provided[‡]	17 (89.5)
	Unclear data[§]	2 (10.5)
2. Why	Noted, but insufficiently described[¶]	3 (15.8)
	Not provided	16 (84.2)
3. What (materials)	Hand or powered (sonic/ultrasonic) instruments:	
	Provided	9 (47.4)
	Not provided	10 (52.6)
	Manufacturer of instruments:	
	Provided	2 (10.5)
	Not provided	17 (89.5)
4. What (procedures)	Type of anaesthesia:	
	Provided only term "local"[#]	1 (5.3)
	Not applicable[††]	18 (94.7)
	Anaesthetic agent:	
	Not applicable[††]	18 (94.7)
	Not provided	1 (5.3)
	Scaling:	
	Noted precisely	11 (57.9)
	Noted, but insufficiently described[‡‡]	1 (5.3)
	Not provided	7 (36.8)
	Planing:	
	Noted precisely	5 (26.3)
	Noted, but insufficiently described[‡‡]	1 (5.3)
	Not provided	13 (68.4)
5. Who provided	Providers' expertise:	
	Periodontist noted	4 (21.1)
	Unclear data provided[§§]	4 (21.1)
	Not provided	11 (57.9)
	Intervention providers, n:	
	Provided	8 (42.1)
	Not provided	11 (57.9)
6. How	Provided	9 (47.4)
	Not provided	10 (52.6)
7. Where	Recruitment or investigation centre noted[¶¶]	10 (52.6)
	Not provided	9 (47.4)

[†]Only one trial reported results in the CT.gov results database (NCT02861937) and did not note any modifications of intervention (Item 10) or provide the extent to which the intervention was delivered as planned (Item 12).
[‡]One of the terms presented in Suppl. Table 3 were provided in registered data, but none trial used the term "professional mechanical plaque removal".
[§]In two trials investigators reported only the removal of supragingival calculus, but did not directly name the intervention (NCT01427764, NCT04082949).
[¶]Professional mechanical plaque removal was mostly briefly stated as an addition to another performed intervention or more details were associated with the outcomes of the intervention.
[#]The type of local anaesthesia was not provided (infiltration or nerve block) NCT02460926.
[††]Trials did not mention the need for anaesthesia.
[‡‡]Two trials used only abbreviation SRP without any explanation provided (NCT04082949, NCT02660814).
[§§]Two trials (10.5%) did not explain the expertise of provider (used general terms, such as "examiner, investigator or clinician") (NCT02861937, NCT03629288), 1 (5.3%) only described who provided measurement and did not precisely identify the intervention provider (NCT00327561), and 1 (5.3%) did not clearly state if provider will be performing measurements or administer the intervention (NCT02652026).
[¶¶]Out of 10 trials, 7 (70.0%) noted the investigation centre or country under the Recruitment Information section and not within the Descriptive Information section, and 3 (30.0%) provided only data on recruitment centre without clearly defining the centre where the intervention was administered.
[##]One trial (5.3%) coded with NCT03629288 provided duration of intervention (week/hour) and 3 trials (15.8%) provided only time period between interventions (NCT00327561, NCT03039244, NCT02460926).
TIDieR: Template for Intervention Description and Replication.

Table 4. The quality of reporting of 12 items from the TIDieR checklist for professional mechanical plaque removal (PMPR) in 19 trials registered in ClinicalTrials.gov[†] (cont.).

TIDieR item	Intervention description component	Trials, n (%)
8. When and how much	Appointments, n:	
	Noted precisely	6 (31.6)
	Not provided	13 (68.4)
	Duration of each session:	
	Different details provided[##]	4 (21.1)
	Not provided	15 (78.9)
9. Tailoring	Provided	1 (5.3)
	Not provided	18 (94.7)
11. How well (planed)	Assessment described	4 (21.1)
	Not provided	15 (78.9)

[†]Only one trial reported results in the CT.gov results database (NCT02861937) and did not note any modifications of intervention (Item 10) or provide the extent to which the intervention was delivered as planned (Item 12).
[‡]One of the terms presented in Suppl. Table 3 were provided in registered data, but none trial used the term "professional mechanical plaque removal".
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TIDieR: Template for Intervention Description and Replication.

from the registered outcome for 18 (46%) trials. Out of those, two trials reported one more primary outcome in the article than in the registry, two trials had different published primary outcomes, two had fewer published primary outcomes, and in 12 trials the primary outcome measures were not clearly defined in corresponding articles. Secondary outcome measures were also different from the registry information in most of the published articles (71.8%). Ten trials had more secondary outcomes in the published article then in the registry; one trial had the same number of secondary outcomes in the registry and in the article, but they were different; one trial had fewer reported secondary outcomes in the published article; and 16 trials had unclear description of secondary outcome measures in published articles.

The description of the intervention also often differed in the published article compared with the registry (Table 7). OHI were described in 16 published articles even though they were not in the corresponding ClinicalTrials.gov protocol. When comparing completeness of TIDieR checklist regarding OHI, 8 out of 15 publications reported more items than in the registered protocol. Similarly, PMPR was described in four articles but was missing from their registered protocol information. The description quality of subgingival instrumentation was much better in most of the published articles (82.1%), but changes of one or two items from TIDieR checklist were found in half of the publications (48.7%). The use of antiseptics, found in 4 journal articles, was not reported in the registry.

Discussion

Our study showed that the registration of trials testing nonsurgical periodontal interventions is not often complete, that appropriate description of the intervention is not provided, and that published articles differ in what was reported from the information registered in a clinical trial registry. Important discrepancies in trial characteristics between the registry and published articles included enrolment information, sample size calculation and age of participants, as well as primary and secondary outcomes.

The limitation of our study is its main focus on data from a clinical trial registry, as almost half of the registered trials did not have corresponding publications, and only two trials had results registered in ClinicalTrials.gov. While the published results have most significant impact on practices, the information in trial registries is important as at least a third of clinical trials results remain unpublished, mostly because of negative findings [29,30]. Therefore, trial registries should serve as a great resource, and sometimes the only source, for obtaining the information about

Table 5. The quality of reporting of 12 items from the TIDieR checklist for subgingival instrumentation in 79 trials in ClinicalTrials.gov[†].

TIDieR item	Intervention description component	Trials, n (%)
1. Brief name	Provided[‡]	79 (100.0)
2. Why	Noted precisely ('gold standard')[§]	5 (6.3)
	Noted, but insufficiently described[¶]	61 (77.2)
	Not provided	13 (16.5)
3. What (materials)	Hand or powered (sonic/ultrasonic) instruments:	
	Provided	34 (43.0)
	Not provided	45 (57.0)
	Manufacturer of instruments:	
	Provided for one or all instruments[#]	8 (10.1)
	Not provided	71 (89.9)
4. What (procedures)	Type of anaesthesia:	
	Local anaesthesia noted[††]	18 (22.8)
	Not provided	61 (77.2)
	Anaesthetic agent:	
	Provided only type or dose and type[‡‡]	5 (6.3)
	Not provided	74 (93.7)
	Scaling:	
	Noted precisely	62 (78.5)
	Noted, but insufficiently described[§§]	2 (2.5)
	Not provided	15 (19)
	Planing:	
	Noted precisely	57 (72.2)
	Noted, but insufficiently described[§§]	2 (2.5)
	Not provided	20 (25.3)
5. Who provided	Providers' expertise:	
	Oral hygienist or periodontist noted[¶¶]	10 (12.7)
	Unclear data provided[##]	12 (15.2)
	Not provided	57 (72.2)
	Intervention providers, n:	
	Noted precisely	20 (25.3)
	Not provided	59 (74.7)
6. How	Provided	28 (35.4)
	Not provided	51 (64.6)
7. Where	Recruitment or investigation center noted[†††]	50 (62.0)
	Not provided	29 (38.0)

[†]Only one trial reported results in the CT.gov results database (NCT02861937) and did not note any modifications of intervention (Item 10) or provide the extent to which the intervention was delivered as planned (Item 12).
[‡]Only one trial (1.3%) reported term "subgingival instrumentation" and other 78 (98.7%) used other terms which are presented in Suppl. Table 3.
[§]Trials coded with NCT01128374, NCT02208739, NCT02618486, NCT04082949, NCT02215460.
[¶]Subgingival instrumentation was mostly briefly stated as an addition to another performed intervention or more details were associated with the outcomes of the intervention.
[#]Trial coded as NCT03039244 provided manufacturer data only for one instrument.
[††]Only one trial precisely stated "*infiltration or nerve block*" as the type of local anesthesia (NCT03354312).
[‡‡]One trial (1.3%) provided type and dose of anesthetic (NCT03354312), and 4 trials (5.1%) provided only type of anesthetic.
[§§]Two trials used only abbreviation SRP without any explanation provided (NCT04082949, NCT02660814).
[¶¶]A total of 9 trials (11.4%) stated that intervention was performed by periodontist and oral hygienist was noted as the intervention provider in one trial (1.3%) (NCT03354312).
[##]Three trials (3.8%) did not explain the expertise of provider (used general terms, such as "examiner, investigator or clinician"), 8 (10.1%) only described who provided measurement and did not precisely identify the intervention provider, and 1 (1.3%) did not clearly state if provider will be performing measurements or administer the intervention (NCT02652026).
[†††]Five trials (6.3%) noted the investigation center where intervention was administered, 38 (48.1%) noted investigation center or country under the Recruitment Information section and not within the Descriptive Information section, and the remaining 7 (8.9%) provided only data on recruitment center without clearly defining the center where the intervention was administered.
[‡‡‡]A total of 6 trials (7.6%) provided duration of intervention (week/hour) and 9 (11.4%) provided only time period between interventions.
[§§§]Trial No. NCT01433744 ("The treatment was performed in one or two sessions depending on the extension of the patient's periodontal condition.").
[¶¶¶]Trials No. NCT03729167, NCT01128374, NCT03343366, NCT03412331, NCT03039244.
TIDieR: Template for Intervention Description and Replication.

Table 5. The quality of reporting of 12 items from the TIDieR checklist for subgingival instrumentation in 79 trials in ClinicalTrials.gov[†] (cont.).

TIDieR item	Intervention description component	Trials, n (%)
8. When and how much	Appointments:	
	Noted precisely	20 (25.3)
	Not provided	59 (74.7)
	Duration of each session:	
	Different details provided[‡‡‡]	15 (19.0)
	Not provided	64 (81.0)
9. Tailoring	Clearly noted[§§§]	1 (1.3)
	Not provided	78 (98.7)
11. How well (planed)	Assessment described[¶¶¶]	5 (6.3)
	Not provided	74 (93.7)

[†]Only one trial reported results in the CT.gov results database (NCT02861937) and did not note any modifications of intervention (Item 10) or provide the extent to which the intervention was delivered as planned (Item 12).
[‡]Only one trial (1.3%) reported term "subgingival instrumentation" and other 78 (98.7%) used other terms which are presented in Suppl. Table 3.
[§]Trials coded with NCT01128374, NCT02208739, NCT02618486, NCT04082949, NCT02215460.
[¶]Subgingival instrumentation was mostly briefly stated as an addition to another performed intervention or more details were associated with the outcomes of the intervention.
[#]Trial coded as NCT03039244 provided manufacturer data only for one instrument.
[††]Only one trial precisely stated "*infiltration or nerve block*" as the type of local anesthesia (NCT03354312).
[‡‡]One trial (1.3%) provided type and dose of anesthetic (NCT03354312), and 4 trials (5.1%) provided only type of anesthetic.
[§§]Two trials used only abbreviation SRP without any explanation provided (NCT04082949, NCT02660814).
[¶¶]A total of 9 trials (11.4%) stated that intervention was performed by periodontist and oral hygienist was noted as the intervention provider in one trial (1.3%) (NCT03354312).
[##]Three trials (3.8%) did not explain the expertise of provider (used general terms, such as "examiner, investigator or clinician"), 8 (10.1%) only described who provided measurement and did not precisely identify the intervention provider, and 1 (1.3%) did not clearly state if provider will be performing measurements or administer the intervention (NCT02652026).
[†††]Five trials (6.3%) noted the investigation center where intervention was administered, 38 (48.1%) noted investigation center or country under the Recruitment Information section and not within the Descriptive Information section, and the remaining 7 (8.9%) provided only data on recruitment center without clearly defining the center where the intervention was administered.
[‡‡‡]A total of 6 trials (7.6%) provided duration of intervention (week/hour) and 9 (11.4%) provided only time period between interventions.
[§§§]Trial No. NCT01433744 ("The treatment was performed in one or two sessions depending on the extension of the patient's periodontal condition.").
[¶¶¶]Trials No. NCT03729167, NCT01128374, NCT03343366, NCT03412331, NCT03039244.
TIDieR: Template for Intervention Description and Replication.

Table 6. Changes in reporting items of clinical trials in published articles (n = 39) with their protocols registered in ClinicalTrials.gov.

Study characteristics	Articles with different information from registered data, n/total
Participants:	
Enrolment	19/39
Sample size calculation	32/39[†]
Age	20/39
Sex	0/39
Condition	1/39
Outcome measures:	
Primary outcome measures	18/39[‡]
Secondary outcome measures	28/39[§]

[†]32 clinical trials did not report sample size calculation in the registry but did in published article; two trials did not report this item in both the registry and the published article.
[‡]Out of 18 trials, two had one more primary outcome in the article than in the registered protocol, two had different primary outcomes and two had fewer primary outcomes in the published article; and 12 trials did not clearly describe primary outcome measures in the published article.
[§]Out of 28 trial, 10 reported more secondary outcomes in the published article than in the registry, one trial had the same number of secondary outcomes in the published articles but were not all the same, one trial reported fewer secondary outcomes in the published article, and 16 trials had secondary outcome measures not clearly defined in the published article.

a clinical trial and its results that are not easily available to the public. Another limitation of our study is that not all interventions from clinical trials protocol were analyzed, as not all types of adjunctive therapy is recommended according to the clinical guidelines [2].

At the time of the analysis in this study, about a half of registered clinical trials had journal publications without their results registered in ClinicalTrials.gov. This could be partially explained with the fact that results submission in ClinicalTrials.gov it mandatory only for trials covered by the Food and Drug Administration Amendments

Table 7. Differences in the description of interventions in published articles (n = 39) and in protocol registered in ClinicalTrials.gov.

Interventions‡	Reported TIDieR items†		
	ClinicalTrials.gov	Published articles	Same items provided
OHI§	4/10	6/10	No¶
PMPR#	4/10	7/10	No††
Subgingival instrumentation	5/10	8/10	No‡‡
Antiseptics§§	6/10	8/10	No¶¶
Antibiotics	5/10	7/10	No##

†Since none of the 39 clinical trials had published results in ClinicalTrials.gov, items 10 and 12 could not be determined. Therefore, those items were not compared with ones in published articles.
‡Out of 39 published articles, 32 of them were analysed for OHI, 12 for PMPR, 39 for subgingival instrumentation, 13 for antiseptics and 5 for antibiotics.
§OHI were not reported in ClinicalTrials.gov protocol of 16 publications and one published article did not mention OHI even though there were in their ClinicalTrials.gov protocol.
¶Out of 15 published articles five articles had the same number of items, five articles had more items provided, two articles had fewer items reported, two articles had more items reported but one changed item, one article had fewer items provided but one changed item and one article had the same number of items with two changed items.
#Four articles did not report PMPR in their ClinicalTrials.gov protocol.
††Out of 8 published articles one article reported PMPR in their ClinicalTrial.gov protocol but not in published article, three articles had more items provided, one article had fewer items provided and one article had fewer items provided but changed one item.
‡‡Out of 39 published articles two articles had the same number of provided items, 17 articles had more items provided, 6 provided more items and changed two items, 9 provided more items and changed one item, one provided fewer items, two provided fewer items and changed two of them and two articles provided fewer items and changed one of them.
§§One article reported variation of the original protocol in ClinicalTrial.gov and did not use antiseptics in their study and four articles did not report use of antiseptics in their ClinicalTrials.gov protocol.
¶¶Out of 8 published articles one article had the same number of items, one provided more items, two provided more items but changed two of them, three articles provided more items but changed three of them and one provided fewer items and changed one of them.
##Out of 5 published articles two articles provided more items, one provided more items but changed one, one article provided fewer items and one provided fewer items and changed two.
OHI: Oral hygiene instruction; PMPR: Professional mechanical plaque removal.

Act (FDAAA), which includes trials using drugs, but not specific intervention and devices [31]. However, posting of results in ClinicalTrials.gov are recommended in order to be publicly available and easily interpreted [32].

Most of the trials in our study were without a recorded trial phase in the registry, so it was not clear whether they were under mandate of the ICMJE and FDAAA (Food and Drug Administration Amendments Act) reporting requirements. The reasons for this finding are not clear, but the increase of registered trials without the information on the trial phase is a trend observed for interventional trials from 2000 to 2020 [33].

The finding of discrepancies between important aspects of clinical trials involving NSPP, including primary outcomes, in the trial registry and related journal articles points to low transparency and questionable validity of the trials, creating problems in adequate introduction of tested interventions in clinical practice. While the registration mandate by journals, followed by legislative mandates, has greatly increased the transparency of trial protocol information [33,34], the problem of trial registration quality persists, not only in dental medicine, as demonstrated in our study, but in other clinical disciplines [35,36].

Periodontitis is a disease of a great significance for public health, and NSPP as therapeutic measure can prevent more severe physical disability, such as tooth loss, reduce pain and patient's discomfort, and in that way accomplish better social and economic outcomes [5,37]. Since clinical guidelines are based on high quality of published or registered evidence and its applicability in clinical practice [2], it is important that NSPP interventions are adequately reported. Recently, some published articles with periodontal therapy have mentioned TIDieR recommendations as a part of their study protocol [38–40]. However, it is still not clear how well these recommendations are implemented for NSPP interventions. To the best of our knowledge, our study is the first in assessing the completeness of describing NSPP intervention in registered clinical trials and relevant publications.

Adequate description of interventions is particularly important for NSPP. While oral hygiene devices such as tooth brushes and interdental brushes are generally recommended and used in general practice for obtaining plaque control [41,42] in the treatment of periodontitis, these devices can differ in number and shape of their fibres, and their use greatly depends on patient's dental status, motoric skills and preferences [43]. Also, among powered tooth brushes, not only there are variations in fibres shape and number, but also in mechanism of their performance, such as rotary and sonic systems and their use depends not only on patient's periodontal condition, but it is also on their socioeconomic status and availability of the devices [44]. Furthermore, interdental brushes that are necessary for obtaining periodontal health differ in material and sizes [45] and are used not only for teeth cleaning but also for prosthetic works such as crowns, bridges and implants. All the above suggest that individualization of the

intervention is needed and therefore should be clearly described in the trial protocol and subsequent publication. Also, it is more likely that patients will adequately use these instruments if they are demonstrated how to use them properly, which indicates the importance of describing whether oral hygiene instructions were given verbally or practically [46,47]. The demonstration of the correct application of interventions is important for all nonsurgical periodontal therapy. Not only that the therapy depends on the severity of periodontal disease, but also it is associated with systemic conditions, compliance and motivation of patients [2,9–11]. Considering all these factors, it may not be possible to have unique treatment of periodontitis. Therefore, when these interventions are developed and tested, it is necessary that each part is comprehensively described. The results of our study demonstrate that such descriptions are insufficient both in the registered information about trial protocols and in published articles. Thus, new interventions may not be adequately understood and applied by clinical practitioners, reducing the benefit for individual patients.

The finding that subgingival instrumentation was described more comprehensively in the majority of corresponding publications may reflect the quality control in journals versus trial registries. Journals use checklists from reporting guidelines to ensure the completes of reporting [19–21], whereas the responsibility for the registry input is with the responsible entity providing the registry data. ClinicalTrials.gov provides quality checks, as well as structured reporting and sufficient word limits in each intervention-related field. It could be also that, due to their complexity, interventions in dental medicine require many details to be appropriately interpreted and replicated, and maybe dental journal editors and peer reviewers were more stringent with the required quality of description of the applied intervention, despite manuscript length restrictions. However, reporting in both sources – trial registries and scientific journals, was far from being adequate, identifying many fields for improvement.

Conclusion

Our study showed that the description of interventions in trials testing nonsurgical periodontal interventions was incomplete. Also, there were differences between published and registered data related to trial participants and primary and secondary outcomes, as well as in the description of reported interventions. The completeness of intervention reporting is important equally in registries and published articles [48], since information about an intervention can sometimes be available only in registries due to publication bias. Clinical researchers, funding agencies, journal editors and registries should work together to ensure that interventions in clinical trials are adequately described to allow adequate translation into a clinical practice for the benefit of the patients.

Summary points

- Interventions that are a part of nonsurgical periodontal protocol (NSPP) are incompletely described in ClinicalTrials.gov registry.
- The information on trial characteristics for NSPP trials is incomplete and there are important differences in registered and reported data, including primary and secondary outcomes.
- Inadequate quality of NSPP description is also demonstrated for corresponding journal publications.
- There are discrepancies between published and registered data, with better described interventions in corresponding publication and performed interventions which were missing in registered data.
- Among all the interventions that are a part of NSPP, subgingival instrumentation was the most completely reported.
- Even though oral hygiene instructions and professional mechanical plaque removal are important parts of NSPP, they were not reported in more than half of the analyzed clinical trials.
- Since it is not possible to have a unique protocol for the treatment of periodontitis because of the large number of factors that affect the outcome of the therapy, it is crucial that every intervention is comprehensively described both in trial registries and published articles.
- Description of intervention in both registered and published data should be controlled by investigators, ClinicalTrials.gov quality checkers, journal editors, and peer reviewers, to provide more complete, coherent and transparent data.
- When describing periodontal interventions and other dental procedures, implementation of the TIDieR checklist (Template for Intervention Description and Replication) is a critical step that could significantly improve the quality of trial data and translation to clinical practice.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: https://bpl-prod.literatumonline.com/doi/10.57264/cer-2023-0058

Author contributions

P Stazić contributed to conception, design, data acquisition, analysis and interpretation, drafted and critically revised the manuscript. D Jurić contributed to conception, design, data acquisition, analysis and interpretation and critically revised the manuscript. A Turić contributed to conception, design, data analysis and critically revised the manuscript. A Šošić contributed to conception, design, data analysis and critically revised the manuscript. A Marušić contributed to conception, design, data interpretation, and critically revised the manuscript. M Roguljić contributed to conception, design, data interpretation and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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Data sharing statement

The datasets used and/or analyzed during the current study are available on reasonable request from the corresponding author.

Open access

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