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Assessment of reporting quality in randomised controlled clinical trial abstracts of dental implantology published in the period 2014 – 2016

Short title: Reporting Quality in RCT Abstracts of dental implantology

Stephanie Knippschild[1], Jeremias Loddenkemper[1], Sabrina Tulka[1], Christine Loddenkemper[1], Christine Baulig[1]

Affiliation of all authors:

[1]Institute for Medical Biometry and Epidemiology

Faculty of Health, Witten/Herdecke University

Alfred Herrhausen Straße 50, D-58448 Witten (Germany)

Corresponding author:

Dr. rer. medic. Stephanie Knippschild

Institute for Medical Biometry and Epidemiology

Faculty of Health, Witten/Herdecke University

Alfred Herrhausen Straße 50, D-58448 Witten (Germany)

Phone: ++ 49 (0)2302 926 763

Fax: ++ 49 (0)2302 926 44785

stephanie.knippschild@uni-wh.de

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Objectives: Access to full texts of randomised controlled clinical trials (RCTs) is often limited, so that the brief summaries of studies play a pivotal role. In 2008 a checklist was provided to ensure transparency and completeness of abstracts. The question is to what extent the CONSORT criteria for abstracts (CONSORT-A) are considered in the preparation of RCT publications thereof.

Primary Endpoint: Assessment of means of the percentage share of compliance with the 16 CONSORT-A criteria per study.

Material and methods: This study is based on a full survey (212 RCT-abstracts in dental implantology, publication period 2014 – 2016, 45 journals, median impact factor 2.328). Apart from merely documenting "adherence" to criteria, the authors also assessed "correct implementation" of requested information where possible. Collection of data was performed independently by two dentists and final consensus. The primary endpoint was evaluated by medians and quartiles. Additionally a Poisson regression was conducted to detect influencing factors.

Results: A median of 50% [Q1-Q3: 44%-63%] was documented for the 16 criteria listed in the CONSORT-A statement. Nine of the 16 criteria were considered in less than 50% of abstracts. "Correct implementation" was attested for a median value of 43% (Q1-Q3: 31%-50%) of criteria. An additional application of Poisson regression revealed that the number of words used had a locally significant impact on the number of reported CONSORT criteria for abstracts (IRR 1.001, 95%CI 1.001 to 1.002).

Conclusion: Transparent and complete reporting in abstracts appears problematic. Limited word count seems to result in a reduction of necessary information. As current scientific knowledge is often not readily available in the form of publications, abstracts constitute the primary basis for decision-making in clinical practice and research. This

is why journals should refrain from limiting the number of words too strictly in order to facilitate comprehensive reporting in abstracts.

Strengths and limitations of this study

1. **Literature search**
   Our search was performed in one electronic database – PubMed – because it comprises more than 30 million citations for biomedical literature from MEDLINE and is declared the world's largest and most important medical bibliographic database.
2. **Dataextraction**
   Two dentists reviewed the abstracts simultaneously and independently from each other; the final set of data was drawn up by means of consent.
3. **Reporting quality by accessing the adherence and correct implementation of the CONSORT statement.**
   This approach - for accessing the reporting quality - is new in the field of dental implantology; apart from merely documenting “adherence” to criteria, the authors also assessed “correct implementation” of requested information.

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Background and Objective

Transparend and comprehensive reporting forms the basis for the evaluation and interpretation of published scientific findings. The EQUATOR network currently provides a total of 425 guidelines on reporting in health research to improve the quality of reporting in health care studies,[1].

The CONSORT statement contains recommendations for reporting controlled clinical studies (RCTs) which present the highest evidence level (Ib) and serve as a basis for recommendations and therapy decisions derived therefrom in daily clinical routines as well as evidence-based practice. The CONSORT group has developed guidelines for a variety of study designs, interventions and data and makes checklists available to authors to be used in the preparation of publications,[2]. A specific checklist to generate abstracts has been available since 2008, as this part of a publication plays a key role: researchers and physicians worldwide use information from abstracts of publications in order to assess the relevance and further exploitation of a scientific paper. An abstract, i.e. a publication in miniature format, should therefore convey all necessary information on a scientific study.

A look at the current literature reveals differences between published abstracts in terms of completeness, structure and scope, despite existing and freely available guidelines. Reporting is frequently non-transparent and incomplete, which inevitably leads to two problems:

1. **Fragmented and incomplete abstract reporting of study results prevents decision-making on therapies in daily clinical routines.**

Due to increasing time constraints in hospitals and a rapidly growing number of published study results, many interested individuals have only time to read the abstracts,[3]. On this basis they need to decide for or against the inspection or acquisition of full texts, and possibly for or against a therapy.

In regions with fewer resources in health care in particular, limited and chargeable access to full texts forces medical staff to make treatment decisions exclusively on the basis of abstracts. This involves a high risk of mistakes with possibly far-reaching consequences for patients.

More specifically, information from study reports on traditional Chinese medicine appears to be available from abstracts exclusively in most cases, since full texts are primarily published in Chinese in this discipline,[4].

2. **Fragmented and incomplete abstract reporting of study results complicates the compilation of evidence-based information in medicine.**

In projects with moderate or no funding in particular, research of the literature is followed by an abstract screening to identify relevant literature and keep costs for the procurement of literature to a minimum. Non-transparent or fragmentary reporting in abstracts entails the risk that relevant study reports will not be considered since presentation of results may be incomplete, incorrect or selective. The effect is especially critical for the drafting of recommendations, where RCT reporting is used for an evidence-based presentation of results. As a consequence of unclear and incomplete reporting the possibility cannot be

excluded that articles of importance to the formulation of therapeutic guidelines are not identified and therefore not considered.

These problems are widespread in publications from various areas of medical indication,[5-8]. No results have been presented for the field of dental implantology to date; this study therefore aimed to identify the extent to which authors in the field comply with recommendations provided in the CONSORT statement for the compilation of transparent and complete abstracts. The objective was to check RCT publications in dental implantology for information as requested in the CONSORT statement for abstracts.

Material & Methods

The authors of this study examined abstracts of published study reports in dental implantology for compliance with 16 criteria recommended by the CONSORT-A,[9]. The objective was to identify the degree – in per cent and per study – to which all criteria requested in CONSORT-A were adhered to (primary endpoint). Secondary research questions served to identify possible factors via regression analysis which might result in a better implementation of CONSORT criteria. These criteria were in addition assessed in terms of their correct and meaningful documentation. Assessment was conducted in two steps: For an assessment of the "degree of adherence I", the focus was exclusively on the documentation (retrievability) of information in abstracts as requested by CONSORT-A. For an assessment of the degree of adherence II, accuracy and completeness were evaluated. It was only possible to collect this information for 6 out of 16 criteria since an assessment of correctness would not have made sense for the remaining criteria. Assessment of the "degree of adherence II" is based on requirements defined in the CONSORT-A statement,[9] as well as on

information required in “Explanation and Elaboration”,[10]. The latter provides a clear description of reporting on individual criteria in several subsections. An assessment in terms of requirements for degree of adherence II was possible for six criteria (see supplementary table 1).

A literature search of the publication period 01/2014 to 12/2016 via the search engine PubMed of the medical database MEDLINE formed the basis for the analysis. For this purpose, the keywords “dental implantation”, “dental implant” and “tooth artificial” were combined with the logical operator OR. The type of study was restricted to randomised and controlled clinical trials (RCTs) (supplementary table 2). Electronic search yielded a data pool of 262 reports, 40 abstracts of which had to be excluded after a first screening due to a mismatch in disciplines. Ten further abstracts were excluded because the publications in question did not report clinical studies. As a result, a total of 212 abstracts of RCT publications (see Fig. 1) remained as the basis for this study. The software programme Excel,[11] was used to compile data, and the data mask was generated on the basis of the CONSORT statement for abstracts,[9]. At the start of the project, a tool to evaluate abstract quality was available from a preceding study,[6], which the planners of the study had to slightly adapt and extend for the purposes of the new area of indication. All 16 CONSORT-A criteria were included in the data compilation and analysis. General information on each publication was documented to facilitate a clear classification of reports at a later time, as well as additional data to be examined for potential impact on reporting quality (year of publication, “structured” or “unstructured” presentation of abstract, number of patients included, word count and impact factor of the respective journal). Two dentists reviewed the abstracts simultaneously and independently from each other. The final set of data was drawn up by means of consent (JL, CL). Data analysis was performed using the software programme SPSS Statistics 24 (SK, CB). The authors determined relative frequencies

and interquartile ranges for study-related implementation rates and for the implementation of individual criteria. Results at primary endpoint were depicted in the form of boxplots. Criteria-related frequencies were illustrated with barcharts,[11].

Possible factors influencing the quality of abstracts were identified by means of an additional explorative data analysis via Poisson regression (ST). Based on the Akaike information criterion (AIC), the aim was to identify the model with the highest predictive quality for the incidence of endpoints by means of a Poisson regression with backward variable selection. Incidence rate ratios (IRR) including 95% confidence interval and respective p-value determined via Wald test were used to describe the influence. Year of publication (reference: 2014), presence of a structured abstract (reference: no), number of patients analysed, impact factor and word count were examined as potential influencing factors. The analysis was conducted using the software programme R (R Core Team, 2015).

Patient and Public Involvement:

No patient involved

Results

General study characteristics and journals

The analysis included RCT abstracts from 45 journals (see supplementary table 3) with a median IF of 2,3280 (min. 0, max. 5,62). The journals “European Journal of Implantology” (36 of 212 abstracts; 17%) and “Clinical oral implants research” (36 of 212 abstracts; 17%) accounted for about one third. Table 1 shows the general study characteristics for the data pool evaluated. A major part of information was available in a structured form (174/212; 82%) with a median of 258 words (min. 94 words,[12]

and max. 659 words,[13]). The abstracts reported case numbers from published studies between 10,[14-16] and 360,[17]. The median number of study participants was 36.

Study characteristics		Frequencies
Form of abstract	structured	174 (82%)
	unstructured	38 (18%)
Year of publication	2014	101 (48%)
	2015	74 (35%)
	2016	37 (17%)
Journals	European Journal of Oral Implantology	36 (17%)
	Clinical oral implants research	36 (17%)
	The International journal of oral & maxillofacial implants	23 (11%)
	Clinical implant dentistry and related research	22 (11%)
	other	95 (45%)
Provenance	Europe	70 (33%)
	America	21 (10%)
	Africa	6 (3%)
	Asia	35 (17%)
	Not specified	80 (38%)
Word count (median)		258 [Min. 94; Max. 659]
Number of cases analysed (median)		36 [Min. 10; Max. 360]
Impact factor (median)		2,3280 [Min. 0; Max. 5,62]

Table 1: Study characteristics for 212 RCT abstracts of implantology in terms of frequency [N] and relative frequency (%).

Implementation rate per study

The studies under consideration showed a median implementation of CONSORT-A recommendations (degree of adherence I) of 50% (Q1-Q3 43,8% to 62,5%) per abstract, whereby eight out of 16 criteria were documented (min. 7, max. 14 criteria); see also supplementary figure 1. The criterion with the highest percentage of documentation was “intervention” (100%). A documentation of less than 10 % was found for “trial registration” and “funding” (see Table 2).

CONSORT criterion	Implementation N (%) Degree of adherence I	Implementation N (%) Degree of adherence II
Identification as a randomised trial ir the title	95 (45)	95 (45)*
Trial design	66 (31)	66 (31) *
Participant characteristics	154 (73)	154 (73) *
Interventions	212 (100)	200 (94)
Objective	209 (99)	209 (99) *
Definition primary endpoint	198 (93)	117 (55)
Randomisation	35 (17)	13 (6)
Blinding	41 (19)	21 (10)
Numbers ramdomised	97 (46)	97 (46) *
Recruitment	196 (93)	196 (93) *
Numbers analysed	57 (27)	57 (27)*
Results of Outcome	207 (98)	133 (63)
Harms	23 (11)	23 (11) *
Conclusion	204 (96)	47 (22)
Trial Registration	10 (5)	10 (5) *
Funding	8 (4)	8 (4) *
Total		

Table 2: Implementation N [%] of CONSORT criteria for abstracts in 212 reports of published RCTs in the field of implantology. Presentation of degree of adherence I (information given in the abstract) and degree of adherence II (correct documentation in accordance with CONSORT-A). * Variables without formal degree of adherence II.

In terms of correct implementation (degree of adherence II), a median implementation of 40,6% (6.5 criteria) was found with an interquartile range of 31,3% to 50,0%. One abstract,[18] revealed the lowest implementation with only the criterion “Objective” (6,25%), whereas Esposito et al., 2014 documented a maximum number of 13 criteria (81,25%).

For the criteria “randomisation” (documentation 17%, correct implementation 6%) and “conclusion” (documentation 96%, correct implementation 22%), the authors found a decrease of ≥ 50% in the implementation rate from degree of adherence I to degree of adherence II (see Table 2).

Implementation rates per criterion

General criteria

From 212 abstracts under consideration, 45% mentioned RCT as study design in the title of the study (95/212). 31% gave a more detailed description of the study design such as parallel group study, blinded study, placebo-controlled study (66/212).

Methods

The “aim of the study” was documented in 99% of examined abstracts (209/212). Information on “primary endpoint” was given in 93% (198/212); this information was, however, clearly defined in only 55% (117/212), including specification of the measurement variable. “Eligibility criteria für participants and the settings“ were found in 73% (154/212) of abstracts, and a complete documentation of the “intervention for each group” in all 212 abstracts (100%). 94% (200/212) reported an exact dosis/therapy for each intervention group. Random allocation of participants to the intervention group was documented in 17% (35/212) of cases; only 6% (13/212) of abstracts contained data on generation of the random sequence and on implementation. 19% (41/212) of abstracts mentioned blinding prior to the study; 10% (21/212) indicated the blinded groups of participants.

Results

In terms of result presentation, 93% (196/212) of abstracts provided information on the current status of the study (study completed, interim analysis after xy years). The number of randomised participants was given in 46% (97/212) of abstracts, and of analysed participants in 27% (57/212). 98% (207/212) of abstracts under consideration reported results at the primary endpoint; but only 63% (133/212) of abstracts contained a precise effect size. 11% (23/212) of examined RCT abstracts documented major (significant) harms. 96% (204/212) provided a general summary of results; only 22% (47/212), however, described the strengths and deficits of the respective study.

Registration was documented in 5% (10/212) of abstracts, and information on funding in 4% (8/212).

The additional explorative analysis by means of Poisson regression included 199 out of 212 abstracts, since 13 abstracts did not provide information on all potential influencing factors. For both degrees of adherence – I and II – the number of words used was shown to have a locally significant impact on the number of reported CONSORT abstract criteria (degree of adherence I: IRR 1.001, 95% CI 1.001 to 1.002; degree of adherence II: IRR 1.002, 95%CI 1.001 to 1.003). The percentage of explained variance according to Nagelkerke R^2 was 14% and 21% respectively. The other possible influencing variables – year of publication, presence of a structured abstract, number of patients included and impact factor – were not selected in the in the backward variable selection via AIC and had no significant influence on the number of reported CONSORT-A criteria.

Discussion

This study examined the degree to which recommendations of the CONSORT statement for abstracts were implemented in trial publications on dental implantology. 212 abstracts from the period 2014 to 2016 showed a median documentation of the required criteria (degree of adherence I) of 50%. With the focus on a “correct” compliance with the requirements of the statement (in this context: degree of adherence II), adherence declined to 40,6% (see Fig. 2 and Table 2).

A comparison of all criteria revealed that the two criteria “funding” and “trial registration” in particular were documented rarely (5% and 4% respectively). In general, journal editors request these details separately, and they are mentioned in the publication but

not in the abstract. In addition, the content of abstracts is often massively reduced by word count limitations requested by the publishers. A poisson regression analysis conducted for the purposes of this study showed that word count limits were responsible for lesser reporting quality or missing details in abstracts (IRR 1.001, 95% CI 1.001 to 1.002). The influence of the number of words used in the abstract had already been documented in a previous study by Baulig et al. (N=136) (Poisson regression based IRR 1.002, 95% CI 1.001 to 1.003). This previous study explored the abstract quality in ophthalmology RCTs for the indication of age-related macular degeneration. The analysis revealed a median implementation of seven criteria (95% CI 7 to 8),[6]. Results are similar to those found in the present study in the field of dental implantology.

Notwithstanding any word count limitations, minor additional information (such as registration ID, identification as RCT in the title, specification of patient numbers at randomisation or analysis) can be included in the text (e.g. numbers in brackets) without need for considerably more words. Such inclusions provide important information on indexing or for the benefit of readers and improve the transparency required for abstracts. A publication by Berwanger et al.,[19] offers an excellent template for transparent and comprehensive reporting in abstracts even if the word count has been restricted.

Assessment of the documentation of CONSORT-A criteria in this paper is based on abstracts exclusively. Original texts (full texts) or information provided outside the abstract text were not explored and not taken into consideration. Since the two criteria “funding” and “trial registration” need not necessarily be placed in the abstract and a subjective presentation of the implementation ratio might be the consequence, to the detriment of the authors’ duty of documentation, an additional evaluation of data on the basis of only 14 criteria seemed advisable, to the exclusion of “funding” and “trial

registration". This further evaluation yielded a somewhat higher "implementation ratio" for degree of adherence I of 57,1% with an interquartile range of 50,5% to 71,4% (see supplementary Fig. 2). For degree of adherence II, the authors found a still reduced implementation ratio of 42,9% (Q1-Q3; 35,7% - 57,1%). A median of eight criteria (interquartile range 7-10 criteria) was documented, and six criteria were correctly implemented (interquartile range 5-8 criteria). It was, however, obvious from both data pools (14 vs. 16 criteria) that a far smaller number of CONSORT-A criteria was identified as fulfilled if correct implementation was explored in addition to mere documentation (see supplentary Fig. 3).

An analysis of data for 14 CONSORT-A criteria by means of Poisson regression also revealed a locally significant influence of the abstract word count on the quality of abstracts (degree of adherence I: IRR 1.001, 95% CI 1.001 to 1.002, p< 0,001; degree of adherence II: IRR 1.002, 95% CI 1.001 to 1.003, p< 0,001). The percentage of explained variance according to Nagelkerke R^2 was 13% and 20% respectively. Other possible influencing variables, i.e. year of publication, presence of a structured abstract, number of patients included and impact factor, were again not selected in the backward selection via AIC and had no significant influence on the number of CONSORT-A criteria reported in the abstracts under consideration.

Findings from a doctoral project were presented in the context of the study; the project in question did not receive any financial support or assistance. Literature search was therefore exclusively conducted by means of the internet based literature database PubMed with a total of over 30 million quotations for biomedical literature from MEDLINE, Life-Science journals and online books which was directly available free of charge to all researchers involved. When interpreting the findings of this study, readers

should therefore be aware that inclusion of further databases might lead to a bias of results.

In order to minimise bias on the part of evaluators, two researchers/physicians performed the analysis in parallel and independently from each other. Abstract evaluation was based on .txt files which were generated directly in PubMed after completed search operation. This strategy ensured that all abstracts were available in the same visual form, and ruled out any influence due to the graphic presentation of abstracts. However, evaluators were not blinded with respect to journals, authors and publication periods, so that a possible assessor bias can be assumed.

The calculation of Cohen's Kappa shows a high conformity between both assessors for eight out of 16 criteria (see supplementary table 4). With a focus on the percentage of correlation, the lowest degree of conformity between assessors was identified for the criterion "harms" (62%; κ=0,041). Information on this aspect may possibly be more or less deduced from the abstract (if one reads between the lines), and is not always explicitly presented as health disadvantages for patients. An evaluation of abstract quality performed in a previous study in the field of ophthalmology (Baulig et al., 2018) served as a basis for the present study in terms of assessment tool, evaluation procedure and evaluation, so that no study protocol was deemed necessary for the present study.

Several publications from other areas of indication with similar research questions confirmed our results for the general implementation of criteria. Gallo et al. analysed 126 abstracts from the period 2011 to 2018 for the rate of implication. The authors found that in general seven criteria (SD ±2) were considered per publication. "Trial registration", "method of randomisation" and "source of trial funding" were documented

with a frequency of less than 5%,[20]. Chow et al. report on the adherence to CONSORT criteria in 395 abstracts in the field of anaesthesiology. Their study documented that 75% of these abstracts from RCTs published in 2016 met less than half of the 16 criteria. In line with the present study, their examination revealed that not a single one of the publications included took all 16 CONSORT criteria for abstracts into consideration. An implication rate of < 50% was found for the following criteria: “designation in the title”, “study design”, “baseline data”, “objective”, “randomisation”, “blinding” “number of randomised participants”, “outcome”, “registration” and “funding”,[21]. Speich et al. explored the abstract quality in published study reports from the field of surgery (2014 – 2016),[22]. They found a general implementation of eight criteria (95%- KI 7.83 - 8.39), whereby “randomisation”, “blinding” and “funding” were considered in less than 20%.

The above-mentioned reports are consistent with the present study, in terms of the low number of criteria met as well as of those criteria for which the lowest degree of adherence was found. The authors criticise in particular the documentation of “randomisation”, “blinding”, and “number of randomised/analysed participants”. The section “Explorations & Elaborations” describes in detail in which way the 16 required CONSORT-A criteria contribute to the completeness and sufficient transparency of an abstract, whereby the relevance of individual criteria and their processing is not under discussion in this context. The literature gives no clues as to a possibly bigger or smaller impact of criteria on reporting quality. However, further studies should consider a weighting of required criteria, with the possible consequence that future studies can present the degree of implementation in a more objective manner.

Apart from poor documentation of the criteria “blinding”, “randomisation” and “harms,” our study revealed additional massive deficits in the documentation of “definition of

primary endpoint", "results/outcomes" and "conclusion" (see Table 2 and Fig. 3). In the evaluation of "accuracy", the degree of adherence declined by at least 30%, since the pertinent information was documented in the abstract but not in the manner required by CONSORT-A. Deficits in the implementation of CONSORT-A recommendations therefore tend to occur more frequently with methodological criteria, as was confirmed by Ghimire et al. This research team reports a documentation of randomisation ("Allocation Concealment") in only 12% of abstracts, and of blinding in only 21%,[23]. Obviously there are criteria which authors adhere to in general, and a few others (statistical criteria) that are reported infrequently. It can be assumed that a large number of individuals is involved in the compilation of an abstract (publication), so that different text sections are inevitably drawn up with different prerequisites and quality requirements (transparency and completeness). This may explain deficits in specific areas. Deficits in the statistical aspects in particular might be reduced by involving medical statisticians / biometricians in the compilation of publications and also in the review process.

Currently, 585 journals refer authors to the CONSORT statement,[24]; nevertheless, there is an urgent need to improve abstracts. Findings from this study suggest that not all authors pay attention to the CONSORT statement as recommended by journals. The statement for abstracts and the corresponding checklist as well as the interactive exploration platform provided in this context (CONSORT, 2019b; Hopewell et al., 2008b) appear to be inadequate to ensure transparent and comprehensive reporting even though they contain exact and detailed instructions for implementation as well as specific examples. A particularly worrying fact is that the low rate of implementation was also found for criteria which are easy to meet, such as the identification of a publication as RCT in the title, documentation of registration ID, or number of

participants included in the analysis. It seems reasonable to assume that recommendations for the publication standard were not implemented because the authors would have to study additional literature for this purpose, and might not have the time or patience to do so. A large part of journals supports the idea to explicitly request authors to use the CONSORT checklist; CONSORT is endorsed by over 50% of the core medical journals listed in the *Abridged Index Medicus* on PubMed as per April 2020,[25]. A general request to adhere to the CONSORT-A checklist in the drafting of publications and a demand for obligatory implementation on the part of all journals may further improve reporting quality in abstracts and thus promote comprehensive and transparent presentation. Moreover, reviewers should check data for completeness and accuracy. Bearing in mind that publications are reviewed under increasing time pressure and primarily outside the job and on an honorary basis, the entire review system might have to be reconsidered. One option would be to check abstracts/publications for completeness of reporting as a preliminary step, followed by the actual review procedure.

Conclusion

Even though the CONSORT group gave recommendations for the compilation of abstracts as early as in 2008, the quality of such “mini publications” remained suboptimal. Co-authors well versed in statistics should address and/or check methodological criteria in particular in the drafting of abstracts and in the review process. Word count limitation seems to be another reason for the reduction of important information. Abstracts play a key role for readers, and journals should not restrict the admissible number of words too rigidly.

Authors' contributions: Stephanie Knippschild wrote the initial draft of this manuscript and performed major parts of the statistical analysis. Jeremias Loddenkemper screened all abstracts of the literature search through PubMed and documented suitable publications for further processing. Moreover, he extracted the necessary information for evaluating the abstract quality and performed data entry and data validation. Sabrina Tulka performed the regression analysis and revised the initial draft of this manuscript. Christine Loddenkemper conducted the validation of the pool of studies by screening all abstracts and evaluating the studies included. Christine Baulig designed the meta-investigation and its analysis concept; she implemented the literature search including the identification of those RCTs to be included in the meta-analysis and thoroughly revised the initial draft of this manuscript.

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Competing interests

This study is part of the doctoral thesis written by Mr. Jeremias Loddenkemper in pursuit of a doctoral degree in dental medicine ("Dr. med. dent.") at Witten/Herdecke University.

Furthermore, the results contained in this article have already been presented by means of an poster presentation at 33. Kongress of the DGI, Hamburg (November 28.-30. 2019)

Non-financial competing interests

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Fig. 1: Description of the selection procedure and documentation of the number of published RCTs from dental implantology, the aim being a data pool to identify – per criterion and study – the degree of adherence to the CONSORT recommendations for abstracts. 50 study reports had to be excluded from further investigation and analysis because the field of indication (N=1) or the study design (N=39) were not compatible, or the respective datasets refered to investigations of animals (N=7), were reviews (N=1) or not identifiable as RCTs (N=2).

Fig. 2: Illustration of degree of adherence per study (%) via box plot (N=212). Degree of adherence I (quantitative implementation), degree of adherence II (qualitative implementation).

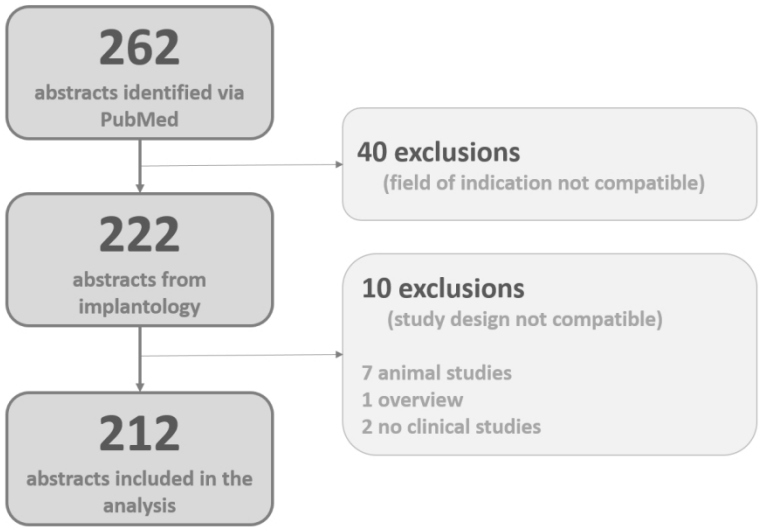
Fig. 3: Graphic display of proportional implementation of criteria to facilitate the location of pertinent information in the abstract (degree of adherence I vs. degree of adherence II).

Supplementary Fig. 1: Graphic display of proportional implementation of criteria to facilitate the location of pertinent information in the abstract (degree of adherence I).

Supplementary Fig. 2: Illustration of degree of adherence per study (%) via box plot (N=212). Degree of adherence I (quantitative implementation), degree of adherence II (qualitative implementation). Evaluation of reduced datapool with 14 criteria (excluded: “registration” and “funding”).

Supplementary Fig. 3: Illustration of degree of adherence per study (%) via box plot (N=212) as comparison of datapools with 14 vs. 16 criteria. Degree of adherence I

(quantitative implementation), degree of adherence II (qualitative implementation). Evaluation of reduced datapool was based on 14 criteria (excluded: “registration” and “funding”).



Description of the selection procedure and documentation of the number of published RCTs from dental implantology, the aim being a data pool to identify – per criterion and study – the degree of adherence to the CONSORT recommendations for abstracts. 50 study reports had to be excluded from further investigation and analysis because the field of indication (N=1) or the study design (N=39) were not compatible, or the respective datasets refered to investigations of animals (N=7), were reviews (N=1) or not identifiable as RCTs (N=2).

283x182mm (150 x 150 DPI)

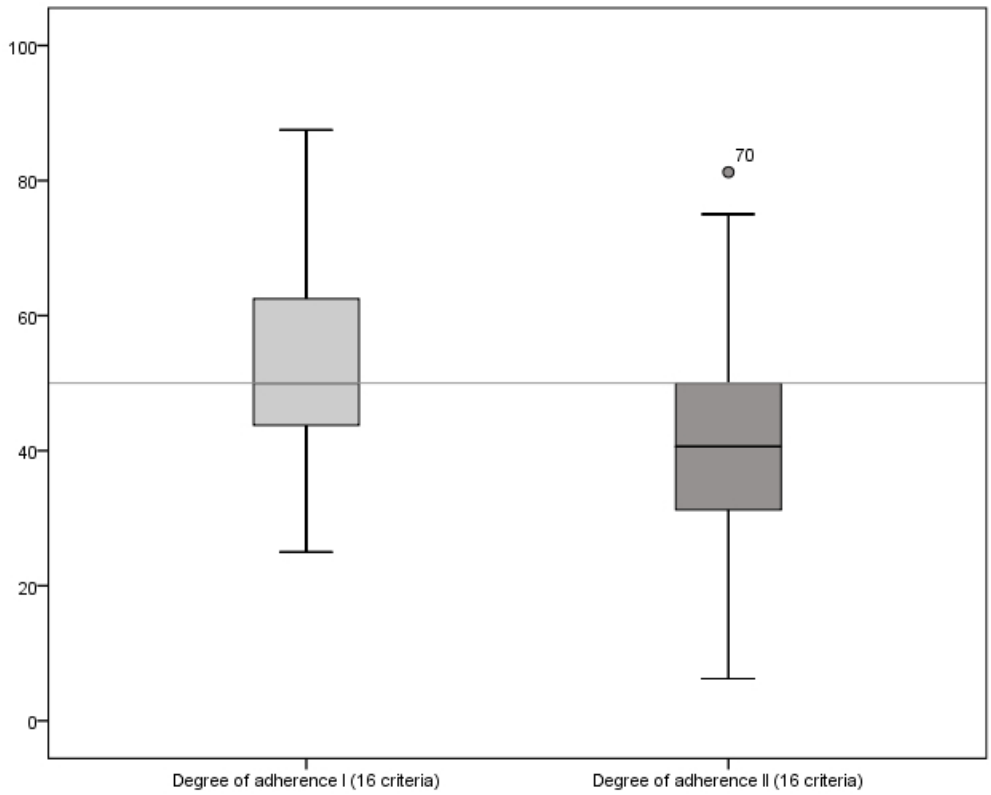
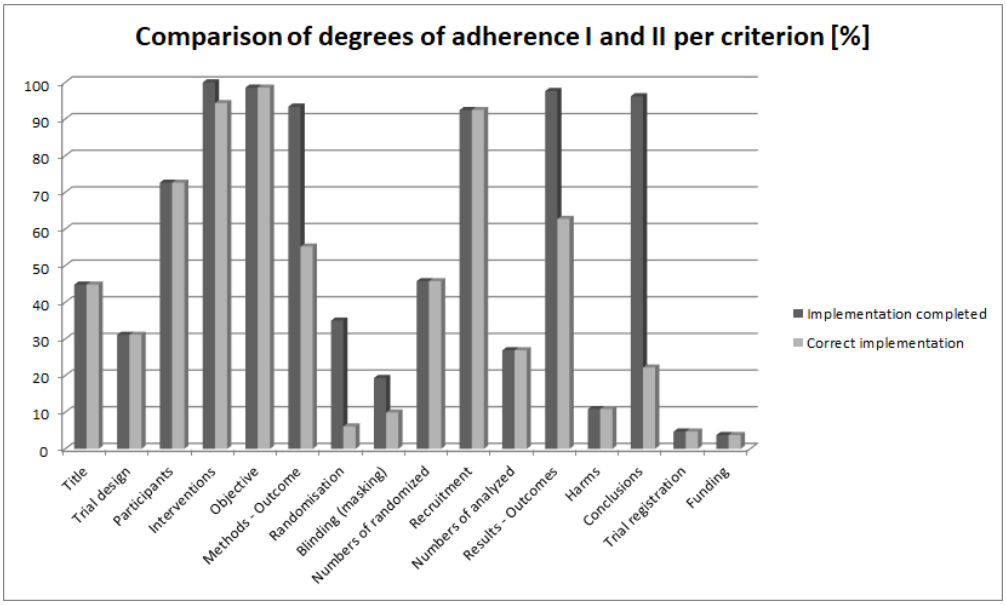


Illustration of degree of adherence per study (%) via box plot (N=212). Degree of adherence I (quantitative implementation), degree of adherence II (qualitative implementation).

220x176mm (72 x 72 DPI)



Graphic display of proportional implementation of criteria to facilitate the location of pertinent information in the abstract (degree of adherence I vs. degree of adherence II).

69x41mm (300 x 300 DPI)

CONSORT criterion	Degree of adherence I	Degree of adherence II
Identification as a randomised trial in the title	Does the title contain "randomised controlled trial" or RCT?	*
Trial design	Description of design in addition to: RCT (randomised, controlled) and Multicentre…	*
Participant characteristics	To document patient characteristics in the abstract, it is not enough to say that patients are suitable for the therapy.	*
Interventions	Intervention indicated	Intervention for each group including dosis indicated
Objective	Specific objective or hypothesis	*
Definition primary endpoint	Documentation of (multiple) endpoints	Clearly defined primary endpoint including measurement variables
Randomisation	Documentation of randomisation ratio in the section Material and Methods	Description of method used to generate the random allocation sequence and implementation in the section Material and Methods
Blinding	Documentation of "blinded" procedure using "masked", "blinded", "doubleblind" or similar descriptions	Exact indication of which patient group was blinded
Numbers randomised	Number of patients randomised to each group must be given, or at least total number with randomisation ratio!	*
Recruitment	Dates defining the trial period (trial completed/interim report/trial from ... to …) .	*
Numbers analysed	Number of participants analysed in EACH group	*
Results of outcome	Results reported in section "Results"	Results were reported with reference to the primary endpoint. Effect size and precision are reported for each group.
Harms	General description	*
Conclusion	The abstract contains a conclusion or summary.	The conclusion refers to the research question/results and lists benefits and limitations of the study
Trial registration	Registration number	*
Funding	Source of funding	*

Supplementary table 1: Evaluation basis for CONSORT-A criteria referring to degree of adherence I (information given in the abstract) and degree of adherence II (correct documentation in accordance

with CONSORT-A). * Variables without formal degree of adherence II. Values from degree of adherence I are transferred.

Search	MesH Therms	No. of studies
#8	**Search ((""randomized controlled trial""[Publication Type]) AND (""2014""[Date - Publication] : ""2016""[Date - Publication])) AND human) AND (((dental implantation) OR dental implant) OR tooth artificial)**	**262**
#7	((dental implantation) OR dental implant) OR tooth artificial	46684
#6	Search dental implantation	21511
#4	Search human	16842581
#2	Search (""2014""[Date - Publication] : ""2016""[Date - Publication])	3387284
#1	Search ""randomized controlled trial""[Publication Type]	429525

Supplementary table 2: Result from literature research in the electronic database PubMed on March 7, 2017

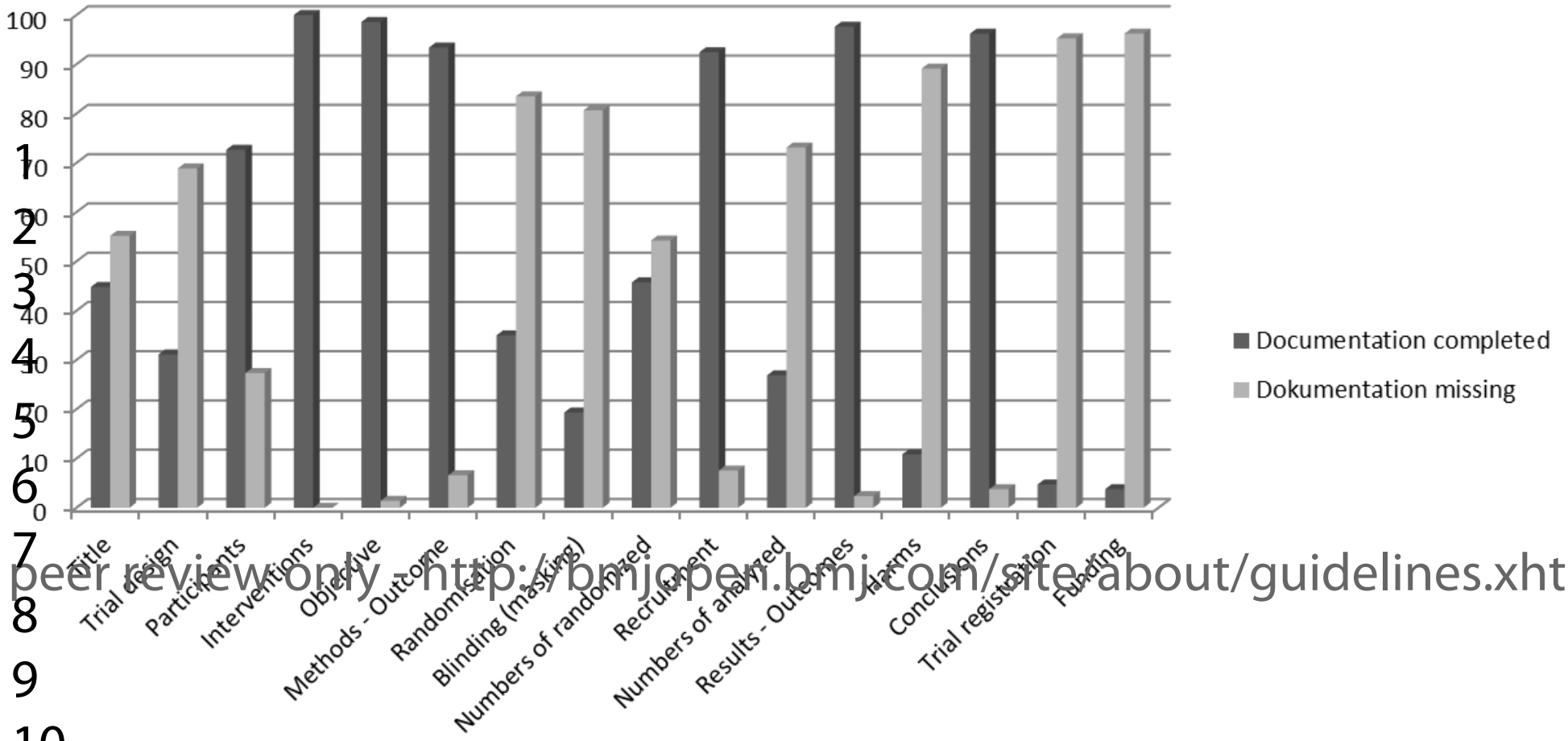
Journal *[journal title abbreviation]*	**Number** *[N]*	**Proportion** *(%)*	**5-year IF** *[as per 2018]*	**Word count limits** *[words]*
Acta Bioeng Biomech	1	0,5	1,112	150-250
Acta Odontol Scand	3	1,4	1,565	250
Am J Dent	1	0,5	0,720	No limit
Am J Orthod Dentofacial Orthop	2	0,9	1,911	250
Angle Orthod	1	0,5	1,880	250
Ann Anat	2	0,9	2,241	No limit
Biomed Res Int	3	1,4	2,197	300
Br J Oral Maxillofac Surg	2	0,9	1,164	250
Clin Implant Dent Relat Res	22	10,4	3,212	150-200
Clin Oral Implants Res	36	17,0	3,825	250
Compend Contin Educ Dent	1	0,5	0	n.a.
Curr Med Res Opin	1	0,5	2,345	250
Eur J Oral Implantol	36	17,0	2,513	250
Eur J Orthod	1	0,5	1,841	330
Hua Xi Kou Qiang Yi Xue Za Zhi	2	0,9	0	No limit
Int J Oral Maxillofac Surg	7	3,3	1,961	300
Int J Oral Maxillofac Implants	23	10,8	1,734	350
Int J Periodontics Restorative Dent	7	3,3	1,228	75-100
Int J Prosthodont	7	3,3	1,533	350
Implant Dent	5	2,4	1,214	225
J Biomater Appl	1	0,5	2,442	No limit
J Bone Miner Res	1	0,5	5,711	300
J Clin Periodontol	9	4,2	4,164	200
J Craniofac Surg	1	0,5	0,785	200
J Dent	1	0,5	3,280	250
J Dent Res	4	1,9	5,125	300
J Oral Implantol	3	1,4	5,125	250
J Oral Maxillofac Surg	1	0,5	1,781	300
J Oral Rehabil	3	1,4	2,341	250
J Periodontol	4	1,9	2,768	250
J Periodontal Res	1	0,5	2,613	250
J Plast Reconstr Aesthet Surg	1	0,5	2,228	250
J Prosthodont	2	0,9	2,636	350
Med Oral Patol Oral Cir Bucal	3	1,4	1,284	150-300
Oral Maxillofac Surg	1	0,5	1,781	300
Oxid Med Cell Longev	1	0,5	4,868	200
Prog Orthod	1	0,5	1,381	350
Quintessence Int	1	0,5	1,392	250
Saudi Med J	2	0,9	1,055	230
Sci Rep	1	0,5	4,011	200
Stomatologiia	1	0,5	0	250
Swed Dent J	1	0,5	0,818	300

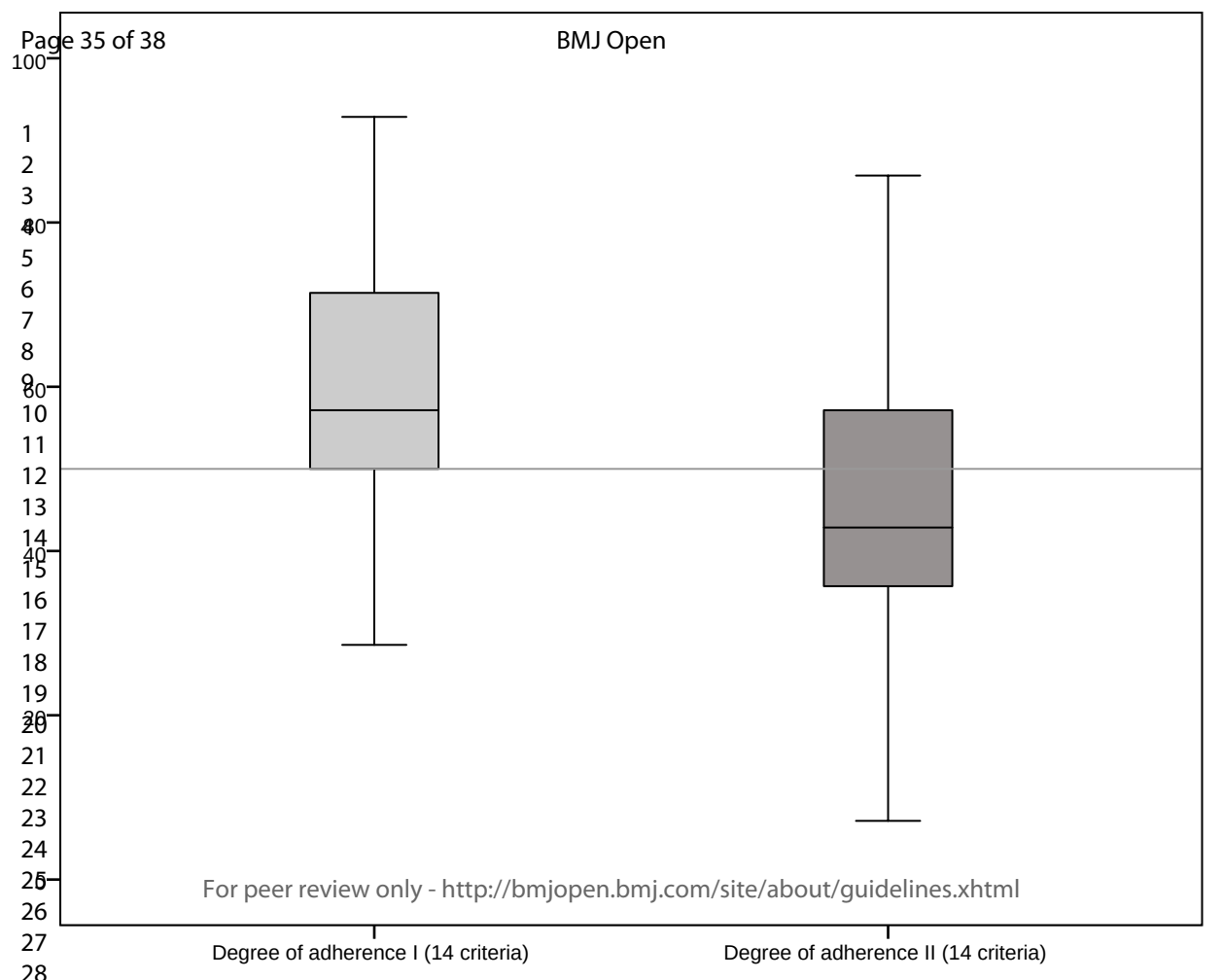
Trials	3	1,4	1,975	350
Vestn Ross Akad Med Nauk	1	0,5	0	300-500
Vojnosanit Pregl	1	0,5	0,272	450
Total	**212**	**100,0**		

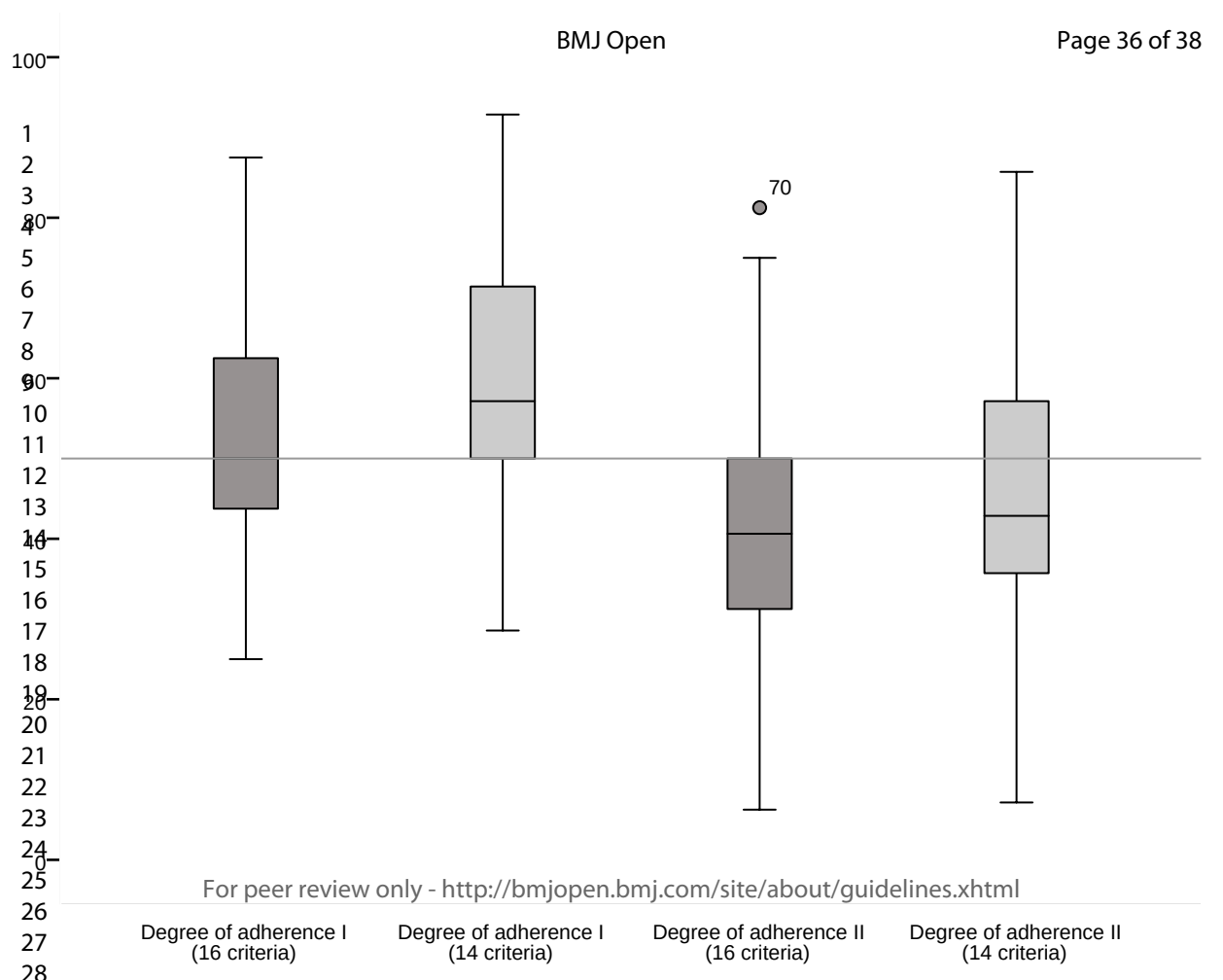
Supplementary table 3: List of journals [N] (%) from which information was extracted for final analysis, 5-year Impact Factor [2018] and word count limits for each journal as per 2019

Criterion	Percentage match	Kappa	*Kappa 0.61 – 1.0 (essential match and almost perfect match)
Title	83%	0,677	*
Trial design	89%	0,738	*
Participants	90%	0,744	*
Interventions	100%	n.a.	
Objective	100%	0,798	*
Outcome	91%	0,312	
Randomisation	82%	0,318	
Blinding (masking)	92%	0,726	*
Numbers randomised	76%	0,515	
Recruitment	85%	0,310	
Numbers analysed	84%	0,606	
Outcome	100%	1,000	*
Harms	62%	0,041	
Conclusions	100%	1,000	*
Trial registration	97%	0,449	
Funding	99%	0,762	*

Supplementary table 4: Calculation of Kappa for inter-rater reliability; percentage match between evaluators; Kappa, n.a.= in this case calculation of Kappa was not performed (SPSS) since one evaluator had rated the criterion “intervention” as 1 for all publications; (*) for criteria which showed an essential match or an almost perfect match between evaluators.







PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	II
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n.a.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4-5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary table 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4 Figure 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3-4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	n.a. -> Accessment of Abstracts
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	4-5

PRISMA 2009 Checklist

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n.a.

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n.a. -> Accessment of Abstracts
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	5
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Table 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	5-6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	n.a. -> Accessment of Abstracts
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	n.a. -> Accessment of Abstracts
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n.a. -> Accessment of Abstracts
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n.a. -> Accessment of Abstracts
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	8-9
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	12-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	11-12
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15

PRISMA 2009 Checklist

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	III 11

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

BMJ Open

Assessment of reporting quality in randomized controlled clinical trial abstracts of dental implantology published from 2014 – 2016

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Secondary Subject Heading:	Dentistry and oral medicine, Evidence based practice
Keywords:	ORAL & MAXILLOFACIAL SURGERY, ORAL MEDICINE, STATISTICS & RESEARCH METHODS

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Assessment of reporting quality in randomized controlled clinical trial abstracts of dental implantology published from 2014 – 2016

Short title: Reporting quality in RCT abstracts of dental implantology

Stephanie Knippschild[1], Jeremias Loddenkemper[1], Sabrina Tulka[1], Christine Loddenkemper[1], Christine Baulig[1]

Affiliation of all authors:

[1]Institute for Medical Biometry and Epidemiology

Faculty of Health, Witten/Herdecke University

Alfred Herrhausen Straße 50, D-58448 Witten (Germany)

Corresponding author:

Dr. rer. medic. Stephanie Knippschild

Institute for Medical Biometry and Epidemiology

Faculty of Health, Witten/Herdecke University

Alfred Herrhausen Straße 50, D-58448 Witten (Germany)

Phone: ++ 49 (0)2302 926 763

Fax: ++ 49 (0)2302 926 44785

stephanie.knippschild@uni-wh.de

Word count: 4846

Keywords: quality, abstracts, CONSORT, CONSORT-A

Objectives: Access to full texts of randomized controlled clinical trials (RCTs) is often limited, so brief summaries of studies play a pivotal role. In 2008, a checklist was provided to ensure the transparency and completeness of abstracts. The aim of this investigation was to estimate adherence to the reporting guidelines of the CONSORT criteria for abstracts (CONSORT-A) in RCT publications.

Primary endpoint: Assessment according to the percentage of compliance with the 16 CONSORT-A criteria per study.

Materials and methods: This study is based on a full survey (212 RCT abstracts in dental implantology, PubMed search, publication period 2014–2016, 45 journals, median impact factor: 2.328). In addition to merely documenting "adherence" to criteria, the authors also assessed the "complete implementation" of the requested information where possible. The collection of data was performed independently by two dentists, and a final consensus was reached. The primary endpoint was evaluated by medians and quartiles. Additionally, a Poisson regression was conducted to detect influencing factors.

Results: A median of 50% [Q1-Q3: 44%-63%] was documented for the 16 criteria listed in the CONSORT-A statement. Nine of the 16 criteria were considered in fewer than 50% of the abstracts. "Correct implementation" was achieved for a median of 43% (Q1-Q3: 31%-50%) of the criteria. An additional application of Poisson regression revealed that the number of words used had a locally significant impact on the number of reported CONSORT criteria for abstracts (IRR 1.001, 95% CI 1.001 to 1.002).

Conclusion: Transparent and complete reporting in abstracts appears problematic. A limited word count seems to result in a reduction in necessary information. As current scientific knowledge is often not readily available in the form of publications, abstracts constitute the primary basis for decision-making in clinical practice and research. This

is why journals should refrain from limiting the number of words too strictly in order to facilitate comprehensive reporting in abstracts.

Strengths and limitations of this study

1. **Literature search**
   We searched one electronic database – PubMed – because it comprises more than 30 million citations for biomedical literature from MEDLINE and has been declared the world's largest and most important medical bibliographic database.
2. **Data extraction**
   Two dentists reviewed the abstracts in parallel and independently of each other; the final set of data was produced in consensus.
3. **Reporting quality by assessing the adherence and correct implementation of the CONSORT statement**
   This approach - for assessing the reporting quality - is new in the field of dental implantology; in addition to merely documenting “adherence” to criteria, the authors also assessed “correct implementation” of the requested information.

Funding

This research received no specific grant from any funding agency in the public, commercial or nonprofit sectors.

Assessment of reporting quality in randomized controlled clinical trial abstracts of dental implantology published from 2014 – 2016

Background and Objective

Transparent and comprehensive reporting forms the basis for the evaluation and interpretation of published scientific findings. The EQUATOR network currently provides a total of 425 guidelines on reporting in health research to improve the quality of reporting in health care studies[1]. The CONSORT statement contains recommendations for reporting randomized controlled clinical studies (RCTs) that present the highest evidence level (Ib) and serve as a basis for recommendations and therapy decisions derived from these trials in daily clinical routines as well as evidence-based practice. The CONSORT group has developed guidelines for a variety of study designs, interventions and data and makes checklists available to authors to be used in the preparation of publications[2]. A specific checklist to generate abstracts has been available since 2008, as this part of a publication plays a key role: researchers and physicians worldwide use information from abstracts of publications to assess the relevance and further exploitation of a scientific paper. An abstract, i.e., a publication in miniature format, should, therefore, convey all necessary information from a scientific study.

A look at the current literature reveals differences among published abstracts in terms of completeness, structure and scope, despite existing and freely available guidelines. Reporting is frequently nontransparent and incomplete, which inevitably leads to two problems:

1. **Fragmented and incomplete abstract reporting of study results prevents decision-making about therapies in daily clinical routines.**

   Due to increasing time constraints in hospitals and a rapidly growing number of published study results, many interested individuals only have time to read the abstracts[3]. On this basis, they need to decide for or against the inspection or acquisition of full texts and possibly for or against a therapy.

   Even though it is strongly advised to include the full texts for decision-making, there may be circumstances in which this advice cannot always be followed. This is also regularly described in publications[4]. In regions with fewer health care resources, in particular, limited, chargeable and expensive access to full texts forces medical staff to make treatment decisions exclusively on the basis of abstracts[5]. This leads to a high risk of mistakes with possibly far-reaching consequences for patients.

2. **Fragmented and incomplete abstract reporting of study results complicates the compilation of reviews, meta-analyses and evidence-based information in medicine.**

   In 2021, Lund et al. published the following key finding: “An evidence-based research approach – the use of existing evidence in a transparent and explicit way – is needed to justify the need for and design a new study”[6]. Especially in projects with moderate or no funding, a literature search is followed by abstract screening to identify relevant literature and to reduce the costs for the procurement of literature to a minimum. Non-transparent or fragmentary reporting in abstracts entails the risk that relevant study reports will not be considered since the presentation of the results may be incomplete, incorrect or

selective. Relevant studies could not be found for the preparation of reviews and meta-analyses. This effect is especially critical for the drafting of recommendations, where RCT reporting is used for an evidence-based presentation of the results. As a consequence of unclear and incomplete reporting, it cannot be excluded that articles of importance to the formulation of therapeutic guidelines are not identified and therefore not considered.

These problems are widespread in publications on various clinical indications[7-10]. In oral implantation, we found one publication that assessed the reporting quality in abstracts of randomized controlled trials[11]. This study determined a mean overall reporting quality score of 58.6% in RCTs by focusing on six leading implantology journals between 2008 and 2012. Our investigation aimed to provide updated results to identify the extent to which authors in the field comply with recommendations provided in the CONSORT statement for the compilation of transparent and complete abstracts. The objective was to check RCT publications in dental implantology (2014-2016) for information as requested by the CONSORT statement for abstracts.

Materials and Methods

The authors of this study examined abstracts of published study reports in dental implantology for compliance with 16 criteria recommended by CONSORT-A[12]. The objective was to identify the degree – by percent and per study – to which all criteria requested in CONSORT-A were adhered to (primary endpoint). Secondary research questions served to identify possible factors via regression analysis, which may result in a better implementation of CONSORT criteria. These criteria were also assessed in terms of their correct and meaningful documentation. Assessment was conducted in two steps. For an assessment of the “degree of adherence I”, the focus was exclusively

on the documentation (retrievability) of information in abstracts as requested by CONSORT-A. For an assessment of the degree of adherence II, correctness and completeness as required by CONSORT-A[2, 12, 13] were evaluated. It was only possible to collect this information for 6 out of 16 criteria since an assessment of correctness would not have made sense for the remaining criteria. Assessment of the "degree of adherence II" is based on requirements defined in the CONSORT-A statement,[12] as well as on information required in "Explanation and Elaboration"[13]. The latter provides a clear description of reporting on individual criteria in several subsections. An assessment in terms of requirements for the degree of adherence II was possible for six criteria (see Supplementary Table 1).

A literature search of the publication period 01/2014 to 12/2016 via the PubMed search engine of the MEDLINE medical database formed the basis for the analysis. We performed a very unrestricted search to obtain as many hits as possible. For this purpose, the keywords "dental implantation", "dental implant" and "tooth artificial" were combined with the logical operator OR. The type of study was restricted to randomized controlled clinical trials (RCTs) (Supplementary Table 2). The software programme Excel[14] was used to compile data, and the data mask was generated on the basis of the CONSORT statement for abstracts[12].

At the start of the project, a tool for evaluating abstract quality was available from a preceding study[8], which had to be slightly adapted and extended for the purposes of this investigation by its planners. All 16 CONSORT-A criteria were included in data compilation and analysis. General information on each publication was documented to facilitate a clear classification of reports at a later time, as well as additional data to be examined for their potential impact on reporting quality (year of publication, "structured" or "unstructured" presentation of the abstract, the number of patients included, the word count and the impact factor of the respective journal).

Two dentists reviewed the abstracts in parallel and independently of each other. The final data set was drawn up in consensus (JL, CL). Data analysis was performed using the SPSS Statistics 24 software programme (SK, CB)[15]. The authors determined relative frequencies and interquartile ranges for study-related implementation rates and for the implementation of individual criteria. The results at the primary endpoint are depicted in box plots. Criteria-related frequencies are illustrated with bar charts[14].

Possible factors influencing the quality of the abstracts measured by the number of criteria fulfilled per publication were identified by means of an additional explorative data analysis via Poisson regression (ST). Backward variable selection was performed with the Akaike information criterion (AIC). Incidence rate ratios (IRRs), including 95% confidence intervals and respective p-values determined via the Wald test, were used to describe the impact. Year of publication (reference: 2014), presence of a structured abstract (reference: no), number of patients analysed, impact factor and word count were examined as potential influencing factors. The analysis was conducted using the software programme R (R Core Team, 2015).

Patient and public involvement:

No patients were directly involved.

Results

Research results

The electronic search yielded a data pool of 262 reports, 40 abstracts of which had to be excluded after a first screening due to a mismatch in disciplines. Ten additional abstracts were excluded because the publications in question did not report clinical

studies. As a result, a total of 212 abstracts from RCT publications (see Fig. 1) were included in this study.

General study characteristics and journals

The analysis included RCT abstracts from 45 journals (see Supplementary Table 3) with a median IF of 2.3280 (min. 0, max. 5.62). Two journals, the "European Journal of Implantology" (36 of 212 abstracts; 17%) and "Clinical oral implants research" (36 of 212 abstracts; 17%), accounted for approximately one-third of the abstracts. Table 1 shows the general study characteristics for the data pool evaluated. Most of the information was available in a structured form (174/212; 82%) with a median of 258 words (min. 94 words[16] and max. 659 words[17]). The abstracts reported case numbers ranging from 10[18-20] and 360[21] from published studies. The median number of study participants was 36.

Study characteristics		Frequencies
Form of abstract	structured	174 (82%)
	unstructured	38 (18%)
Year of publication	2014	101 (48%)
	2015	74 (35%)
	2016	37 (17%)
Journals	European Journal of Oral Implantology	36 (17%)
	Clinical oral implants research	36 (17%)
	The International Journal of Oral & Maxillofacial Implants	23 (11%)
	Clinical implant dentistry and related research	22 (11%)
	other	95 (45%)
Provenance	Europe	70 (33%)
	America	21 (10%)
	Africa	6 (3%)
	Asia	35 (17%)
	Not specified	80 (38%)
Word count (median)		258 [Min. 94; Max. 659]
Number of cases analysed (median)		36 [Min. 10; Max. 360]
Impact factor (median)		2.3280 [Min. 0; Max. 5.62]

Table 1: Study characteristics of 212 RCT abstracts of implantology in terms of the frequency [N] and relative frequency (%).

Implementation rate per study

The studies included showed a median implementation of CONSORT-A recommendations (degree of adherence I) of 50% (Q1-Q3 43.8% to 62.5%) per abstract, whereby eight out of 16 criteria were documented (min. 7, max. 14 criteria); see also Supplementary Figure 1. The criterion with the highest percentage of documentation was “intervention” (100%). A documentation of less than 10% was found for “trial registration” and “funding” (see Table 2).

CONSORT criterion	Implementation N (%) Degree of adherence I	Implementation N (%) Degree of adherence II
Identification as a randomized trial ir the title	95 (45)	95 (45)*
Trial design	66 (31)	66 (31) *
Participant characteristics	154 (73)	154 (73) *
Interventions	212 (100)	200 (94)
Objective	209 (99)	209 (99) *
Definition primary endpoint	198 (93)	117 (55)
Randomization	35 (17)	13 (6)
Blinding	41 (19)	21 (10)
Numbers randomised	97 (46)	97 (46) *
Recruitment	196 (93)	196 (93) *
Numbers analysed	57 (27)	57 (27)*
Results of Outcome	207 (98)	133 (63)
Harms	23 (11)	23 (11) *
Conclusion	204 (96)	47 (22)
Trial Registration	10 (5)	10 (5) *
Funding	8 (4)	8 (4) *
Total		

Table 2: Implementation N [%] of CONSORT criteria for abstracts in 212 reports of published RCTs in the field of implantology. Presentation of the degree of adherence I (information given in the abstract) and degree of adherence II (correct documentation in accordance with CONSORT-A). * Variables without a formal degree of adherence II.

In terms of correct implementation (degree of adherence II), a median implementation of 40.6% (6.5 criteria) was found with an interquartile range of 31.3% to 50.0%. One abstract[22] revealed the lowest implementation with only the “Objective” criterion

(6.25%), whereas Esposito et al., 2014 documented a maximum number of 13 criteria (81.25%).

For the “randomization” (documentation 17%, correct implementation 6%) and “conclusion” (documentation 96%, correct implementation 22%) criteria, the authors found a decrease of ≥ 50% in the implementation rate from the degree of adherence I to the degree of adherence II (see Table 2).

Implementation rates per criterion

General criteria

Among the 212 abstracts included, 45% mentioned RCTs as the study design in the title of the study (95/212). Thirty-one percent provided a more detailed description of the study design, such as parallel group studies, blinded studies, and placebo-controlled studies (66/212).

Methods

The “aim of the study” was documented in 99% of the abstracts examined (209/212). Information on the “primary endpoint” was given in 93% (198/212); this information was, however, clearly defined in only 55% (117/212), including specification of the measurement variable. “Eligibility criteria for participants and the settings” were found in 73% (154/212) of the abstracts, while complete documentation of the “intervention for each group” was found in all 212 abstracts (100%). Ninety-four percent (200/212) reported a detailed description of the intervention for each group. Random allocation of participants to the intervention group was documented in 17% (35/212) of cases; only 6% (13/212) of abstracts contained data on the generation of the random sequence and its implementation. Nineteen percent (41/212) of abstracts mentioned blinding prior to the study; 10% (21/212) also indicated blinded groups of participants.

Results

In terms of result presentation, 93% (196/212) of abstracts provided information on the current status of the study (study completed, interim analysis after xy years). The number of randomized participants was given in 46% (97/212) of abstracts and in 27% (57/212) of the analysed participants. A total of 98% (207/212) of abstracts included reported results at the primary endpoint, but only 63% (133/212) of abstracts contained a precise effect size. Eleven percent (23/212) of the examined RCT abstracts documented major (significant) harms. Ninety-six percent (204/212) provided a general summary of the results; only 22% (47/212) described the strengths and deficits of the respective study. The registration ID was documented in 5% (10/212) of the abstracts, and information on funding was documented in 4% (8/212).

The additional explorative analysis by means of Poisson regression included 199 out of 212 abstracts, since 13 abstracts did not provide information on all potential influencing factors. For both degrees of adherence – I and II – the number of words used was shown to have a locally significant impact on the number of reported CONSORT abstract criteria (degree of adherence I: IRR 1.001, 95% CI 1.001 to 1.002; degree of adherence II: IRR 1.002, 95% CI 1.001 to 1.003). The percentages of explained variance according to Nagelkerke's R^2 were 14% and 21%, respectively. The other possible influencing variables – year of publication, presence of a structured abstract, number of patients included and impact factor – were not selected in the backward variable selection via AIC and had no significant influence on the number of reported CONSORT-A criteria.

Discussion

This study examined the degree to which recommendations of the CONSORT statement for abstracts were implemented in trial publications on dental implantology. A total of 212 abstracts published 2014 to 2016 showed a median documentation of the required criteria (degree of adherence I) of only 50%. When focusing on "correct" compliance with the requirements of the statement (in this context: degree of adherence II), adherence declined to 40.6% (see Fig. 2 and Table 2).

A comparison of all criteria revealed that the two criteria, "funding" and "trial registration", were rarely documented (5% and 4%, respectively). In general, journal editors request these details separately, and they are mentioned in the publication but quite often not in the abstract.

In addition, the content of abstracts is often massively reduced by word count limitations requested by the publishers. A Poisson regression analysis conducted for the purposes of this study showed that word count limits were responsible for lesser reporting quality or missing details in abstracts (IRR 1.001, 95% CI 1.001 to 1.002). The influence of the number of words used in the abstract was documented in a previous study by Baulig et al. (N=136) (Poisson regression-based IRR 1.002, 95% CI 1.001 to 1.003). This previous study explored the abstract quality in ophthalmology RCTs on age-related macular degeneration. The analysis revealed a median implementation of seven criteria (95% CI 7 to 8)[8]. The results are similar to those found in the present study in the field of dental implantology. In 2020, Xie et al. also investigated the quality of 249 randomized controlled trial abstracts published in dental science[23]. They found major gaps in the documentation of general items (5.6% documented trial registration), methods (only one publication, i.e., 0.4%, noted the sequence generation procedure for randomization and allocation concealment; in 7.6% of the papers reviewed, blinding was described; and a clearly stated primary outcome

was documented in only 16.9%), trial results (the number of participants analysed was only described in 8.8%, and adverse events were described in only 14.9%). As in our study, this research group also found a significant association between word count requirements and reporting quality (multivariable linear regression (B=0.020; P<0.001)). Notwithstanding any word count limitations, minor additional information (such as registration ID, identification as RCT in the title, specification of patient numbers at randomization or analysis) can be included in the text (e.g., numbers in brackets) without the need for more words. Such inclusions provide important information on indexing or for the benefit of readers and improve the transparency required for abstracts. A publication by Berwanger et al.[24] offers an excellent template for transparent and comprehensive reporting in abstracts even if the word count has been restricted.

The assessment of the documentation of the CONSORT-A criteria in this paper is based exclusively on abstracts. Original texts (full texts) or information provided outside the abstract text were not examined and were not taken into consideration. Since the two criteria “funding” and “trial registration” do not necessarily have to be included in the abstract and a subjective presentation of the implementation ratio might be a consequence, to the detriment of the authors’ duty of documentation, an additional data evaluation seemed advisable, based on only 14 criteria after excluding the “funding” and “trial registration” criteria. This further evaluation yielded a somewhat higher “implementation ratio” for the degree of adherence I of 57.1% with an interquartile range of 50.5% to 71.4% (see Supplementary Fig. 2). For the degree of adherence II, the authors still found a reduced implementation ratio of 42.9% (Q1-Q3; 35.7% - 57.1%). A median of eight criteria (interquartile range 7-10 criteria) was documented, and six criteria were correctly implemented (interquartile range 5-8 criteria). It was, however, obvious from both data pools (14 vs. 16 criteria) that a far

smaller number of CONSORT-A criteria were identified as having been included when correct implementation was examined in addition to mere documentation (see Supplementary Fig. 3).

A data analysis of 14 CONSORT-A criteria by means of Poisson regression also revealed a locally significant influence of the abstract word count on the quality of abstracts (degree of adherence I: IRR 1.001, 95% CI 1.001 to 1.002, p< 0.001; degree of adherence II: IRR 1.002, 95% CI 1.001 to 1.003, p< 0.001). The percentage of explained variance according to Nagelkerke's R^2 was 13% and 20%, respectively. Other possible influencing variables, i.e., year of publication, availability of a structured abstract, number of patients included and impact factor were again not selected in the backward selection via AIC and had no significant impact on the number of CONSORT-A criteria reported in the abstracts included.

Findings from a doctoral project were presented in the context of this study; the project in question did not receive any financial support or assistance. A literature search was therefore exclusively conducted by means of the internet-based literature database PubMed with a total of over 30 million quotations for biomedical literature from MEDLINE, life science journals and online books that were directly available free of charge to all researchers involved. When interpreting the findings of this study, readers should therefore be aware that the inclusion of only one database might lead to a bias of results (deviation in the estimated degree of implementation).

However, we assume that only a few publications could have been found when searching additional databases, as PubMed includes all relevant implantology journals. The evaluation of congress abstracts, which might have been found in Embase, were explicitly not part of this investigation. In this respect, the authors assumed that the

results would not have been significantly improved if a few additional studies had been considered in this analysis. The search was limited in time to the three-year period from 01/2014 - 12/2016. Up to 2012, implantological abstracts had been examined by Kiriakou et al. A follow-up examination should therefore be carried out on more recent studies.

To minimize bias on the part of the evaluators, two researchers / physicians performed the analysis in parallel and independently of each other. Abstract evaluation was based on .txt files that were generated directly in PubMed after completing the search operation. This strategy ensured that all abstracts were available in the same visual form and ruled out any influence due to the graphical representation of the abstracts. However, evaluators were not blinded with respect to the journals, authors and publication periods, so a possible assessor bias can be assumed.

The calculation of Cohen's kappa shows a high conformity between the assessors for eight out of 16 criteria (see Supplementary Table 4). With a focus on the percentage of correlation, the lowest degree of conformity between assessors was identified for the "harms" criterion (62%; κ=0.041). Information on this aspect may possibly be more or less deduced from the abstract (if one reads between the lines) and is not always explicitly presented as health disadvantages for patients. An evaluation of abstract quality performed in a previous study in the field of ophthalmology (Baulig et al., 2018) served as a basis for the present study in terms of the assessment tool, evaluation procedure and the evaluation so that no study protocol was deemed necessary for the present study.

Several publications on other clinical indications with similar research questions confirmed our results for the general implementation of criteria. Gallo et al. analysed

126 abstracts from 2011 to 2018 for the rate of implementation. The authors found that in general, seven criteria (SD ±2) were considered per publication. “Trial registration”, “method of randomization” and “source of trial funding” were documented with a frequency of less than 5%[25]. Chow et al. reported on adherence to CONSORT criteria in 395 abstracts in the field of anaesthesiology. Their study documented that 75% of these abstracts from RCTs published in 2016 met less than half of the 16 criteria. In line with the present study, their examination revealed that not a single one of the included publications took all 16 CONSORT criteria for abstracts into consideration. An implementation rate of < 50% was found for the following criteria: “designation in the title”, “study design”, “baseline data”, “objective”, “randomization”, “blinding”, “number of randomized participants”, “outcome”, “registration” and “funding”[26]. Speich et al. explored the abstract quality in published study reports from the field of surgery (2014 – 2016)[27]. They found a general implementation of eight criteria (95% CI 7.83 - 8.39), with “randomization”, “blinding” and “funding” have been considered in less than 20%.

The abovementioned reports are consistent with the present study in terms of the low number of criteria met, as well as of those criteria for which the lowest degree of adherence was found. The authors criticize in particular the documentation of “randomization”, “blinding” and “number of randomized/analysed participants”. The “Explorations & Elaborations” section describes in detail how the 16 required CONSORT-A criteria contribute to the completeness and sufficient transparency of an abstract, with the relevance of individual criteria and their processing not being under discussion in this context. The literature provides no clues as to a possibly larger or smaller impact of criteria on reporting quality. However, future studies should consider a weighting of required criteria, with the possible consequence that future studies can present the degree of implementation in a more objective manner.

In addition to the poor documentation of the “blinding”, “randomization” and “harms” criteria, our study revealed additional massive deficits in the documentation of “definition of primary endpoint”, “results/outcomes” and “conclusion” (see Table 2 and Fig. 3). In the evaluation of “correctness”, the degree of adherence declined by at least 30%, since pertinent information was documented in the abstract but not in the manner required by CONSORT-A. Deficits in the implementation of CONSORT-A recommendations therefore tend to occur more frequently for the methodological criteria, as was previously confirmed by Ghimire et al.

This research team reports a documentation of randomization (“Allocation Concealment”) in only 12% of abstracts and of blinding in only 21%[28]. Obviously, there are criteria that authors adhere to in general, and a few others (statistical criteria) that are reported infrequently. It can be assumed that a large number of individuals are involved in the compilation of an abstract (publication), so that different text sections are inevitably drawn up in different contexts while applying different quality standards (transparency and completeness). This may explain deficits in specific areas. Deficits in statistical aspects in particular might be reduced by involving medical statisticians/biometricians in the compilation of publications and during the review process.

To date, some investigations have been conducted on reporting quality in abstracts in dental research. Flemming et al. reported an overall reporting quality score of 60.2% in abstracts of five orthodontic journals from 2006 to 2011[29]. For this evaluation, 117 RCT abstracts were assessed by using a modified CONSORT for abstract checklists containing 21 items. In particular, the items “randomization procedures”, “allocation concealment”, “blinding”, “failure to report confidence intervals” and “harms” were found to be reported insufficiently. Seehra et al. published a mean overall reporting quality in dental specialty journals of 62.5% (N= 228 RCT abstracts)[30]. The research

group found that randomization restrictions, allocation concealment, blinding, numbers analysed, confidence intervals, intention-to-treat analysis, harms, registration and funding were rarely described. The research group from Faggion et al. compared the quality of reporting in abstracts between 2005-2007 and 2009-2011 in seven leading journals of periodontology and implant dentistry[31]. They included 392 abstracts in their review and found the quality of reporting to be improvable. Only the documentation of the title significantly improved over time.

The reporting quality in abstracts of randomized controlled trials in oral implantology was assessed by Kiriakou et al. in 2012[11]. Therefore, six leading implantology journals were reviewed from 2008 to 2012. Abstracts were assessed as providing either “no description”, “inadequate description” or “adequate description”. The results showed a mean overall reporting quality score of 58.6% (95% CI: 57.6 – 59.7), with insufficient reporting of the randomization procedures and allocation concealment items. They also found failure in reporting confidence intervals, effect estimates and sources of funding.

In contrast to existing investigations assessing abstract reporting quality in dentistry, we used CONSORT-A without modifying the number of items. However, we found a similar degree of implementation as the authors mentioned above. The new findings from our investigation clearly show that there is a difference between the implementation of guidelines and fully documented/correct implementation (50% implementation vs. 40.6% fully/correct implementation).

Currently, 585 journals refer authors to the CONSORT statement[32]; nevertheless, there is an urgent need to improve abstracts. Findings from this study suggest that not all authors pay attention to the CONSORT statement as recommended by journals. The statement for abstracts and the corresponding checklist as well as the interactive

exploration platform provided in this context (CONSORT, 2019b; Hopewell et al., 2008b) appear to be inadequate to ensure transparent and comprehensive reporting even though they contain exact and detailed instructions for implementation as well as specific examples. A particularly worrying fact is that this low rate of implementation was also found for criteria that are easy to meet, such as the identification of a publication as an RCT in the title, documentation of registration ID, or reporting the number of participants included in the analysis. It seems reasonable to assume that recommendations for the publication standard were not implemented because authors would have to study additional literature for this purpose, and might not have the time or patience to do so.

Many journals support the idea of explicitly requesting authors to use the CONSORT checklist; CONSORT is endorsed by over 50% of the core medical journals listed in the *Abridged Index Medicus* on PubMed as of April 2020[33]. A general request to adhere to the CONSORT-A checklist in the drafting of publications and a demand for obligatory implementation on the part of all journals may further improve reporting quality in abstracts and thus promote comprehensive and transparent presentation. Moreover, reviewers should check their data for completeness and correctness according to CONSORT-A. Bearing in mind that publications are reviewed under increasing time pressure, and primarily outside the job and on an honourary basis, the entire review system might have to be reconsidered. One option would be to check abstracts/publications for completeness of reporting as a preliminary step, followed by the actual review procedure. By implementing this additional step, papers that are not well structured and non-transparent may be identified early in the review process and sent back for revision. Even if that means that additional human resources have to be deployed, it seems to be an opportunity to focus the journals' review process on content-related items.

Conclusion

Even though the CONSORT group gave recommendations for the compilation of abstracts as early as 2008, the quality of such “miniature publications” remains suboptimal. Co-authors well versed in statistics should address and / or check methodological criteria, in particular when drafting abstracts and during the review process. Word count limitations seem to be another reason for the omission of important information. Abstracts play a key role for readers, and journals should not restrict the admissible number of words too rigidly.

Authors' contributions: Stephanie Knippschild wrote the initial draft of this manuscript and performed major parts of the statistical analysis. Jeremias Loddenkemper screened all abstracts of the literature search through PubMed and documented suitable publications for further processing. Moreover, he extracted the necessary information for evaluating the abstract quality and performed data entry and data validation. Sabrina Tulka conducted the regression analysis and revised the initial draft of this manuscript. Christine Loddenkemper validated the pool of studies by screening all abstracts and evaluating the studies included. Christine Baulig designed the review and its analysis concept; she implemented the literature search, including the identification of those RCTs to be included in the review and thoroughly revised the initial draft of this manuscript.

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Competing interests

This study is part of the doctoral thesis written by Mr. Jeremias Loddenkemper in pursuit of a doctoral degree in dental medicine ("Dr. med. dent.") at Witten/Herdecke University.

Furthermore, the results contained in this article have already been presented as part of a poster presentation at the 33rd DGI Congress, Hamburg (28-30 November 2019).

The authors declare that they have no competing financial, professional or personal interests that might have influenced the performance or presentation of the work described in this manuscript.

Non-financial competing interests

Data sharing

This manuscript contains data from an ongoing doctoral project. Therefore data cannot be made available until completion.

Ethics Statement

This study constitutes an analysis of published abstracts on RCTs and therefore does not require approval by an ethics committee.

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Fig. 1: Description of the selection procedure and documentation of the number of published RCTs from dental implantology, the aim being a data pool to identify – per criterion and study – the degree of adherence to the CONSORT recommendations for abstracts. Fifty study reports had to be excluded from further investigation and analysis because the clinical indication (N=1) or the study design (N=39) were not compatible or the respective data sets referred to investigations of animals (N=7), were reviews (N=1) or were not identifiable as RCTs (N=2).

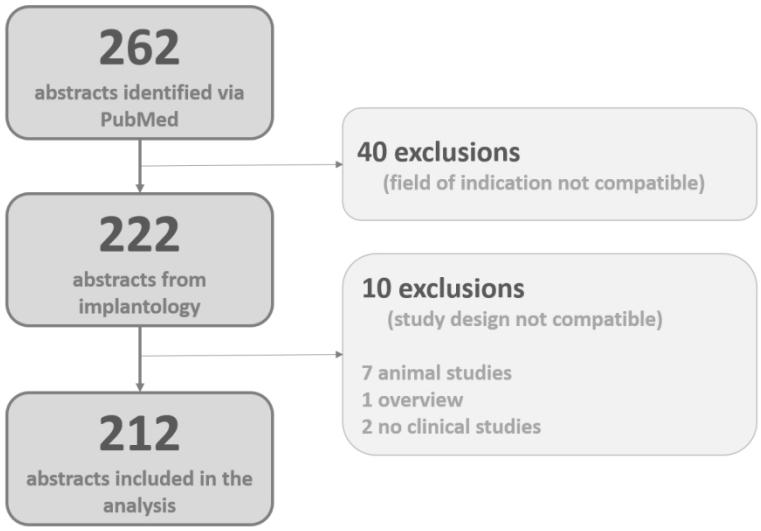
Fig. 2: Illustration of the degree of adherence per study (%) in a box plot (N=212). Degree of adherence I (quantitative implementation), degree of adherence II (qualitative implementation).

Fig. 3: Graphical representation of proportional implementation of criteria to facilitate locating the corresponding information in the abstract (degree of adherence I vs. degree of adherence II).

Supplementary Fig. 1: Graphical representation of proportional implementation of criteria to facilitate locating the corresponding information in the abstract (degree of adherence I).

Supplementary Fig. 2: Illustration of the degree of adherence per study (%) in a box plot (N=212). Degree of adherence I (quantitative implementation), degree of adherence II (qualitative implementation). Evaluation of the reduced data pool with 14 criteria (excluded: “registration” and “funding”).

Supplementary Fig. 3: Illustration of the degree of adherence per study (%) in a box plot (N=212) as a comparison of data pools with 14 vs. 16 criteria. Degree of adherence I (quantitative implementation), degree of adherence II (qualitative implementation). Evaluation of the reduced data pool was based on 14 criteria (excluded: “registration” and “funding”).



Description of the selection procedure and documentation of the number of published RCTs from dental implantology, the aim being a data pool to identify – per criterion and study – the degree of adherence to the CONSORT recommendations for abstracts. 50 study reports had to be excluded from further investigation and analysis because the field of indication (N=1) or the study design (N=39) were not compatible, or the respective datasets refered to investigations of animals (N=7), were reviews (N=1) or not identifiable as RCTs (N=2).

283x182mm (150 x 150 DPI)

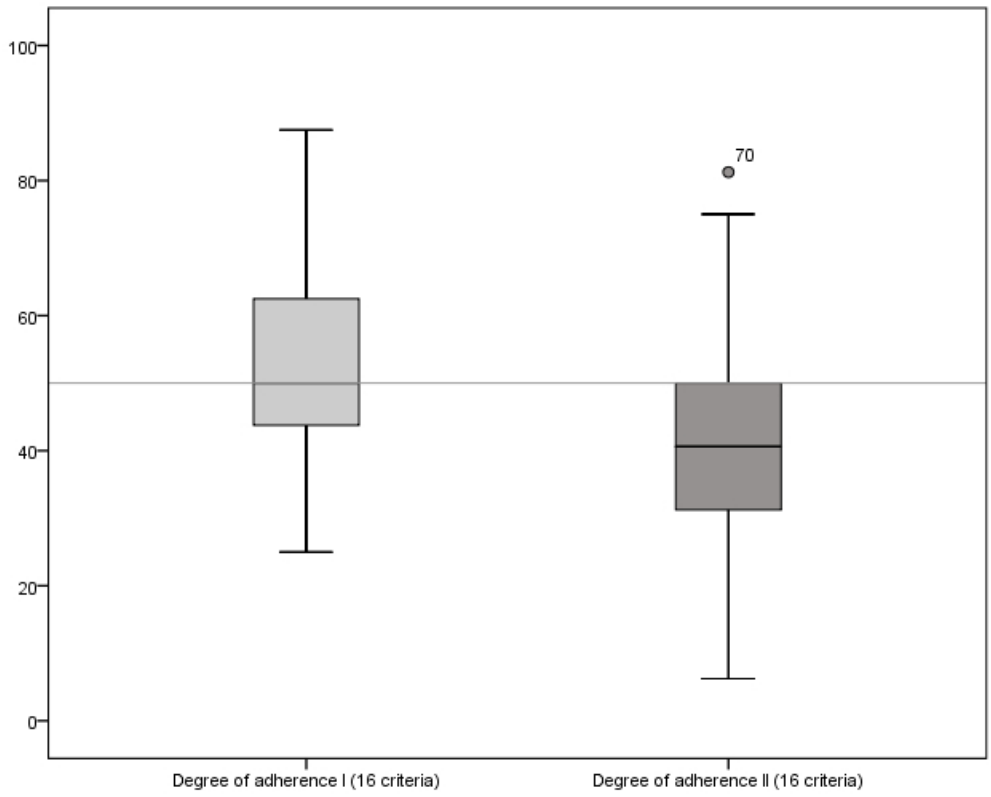
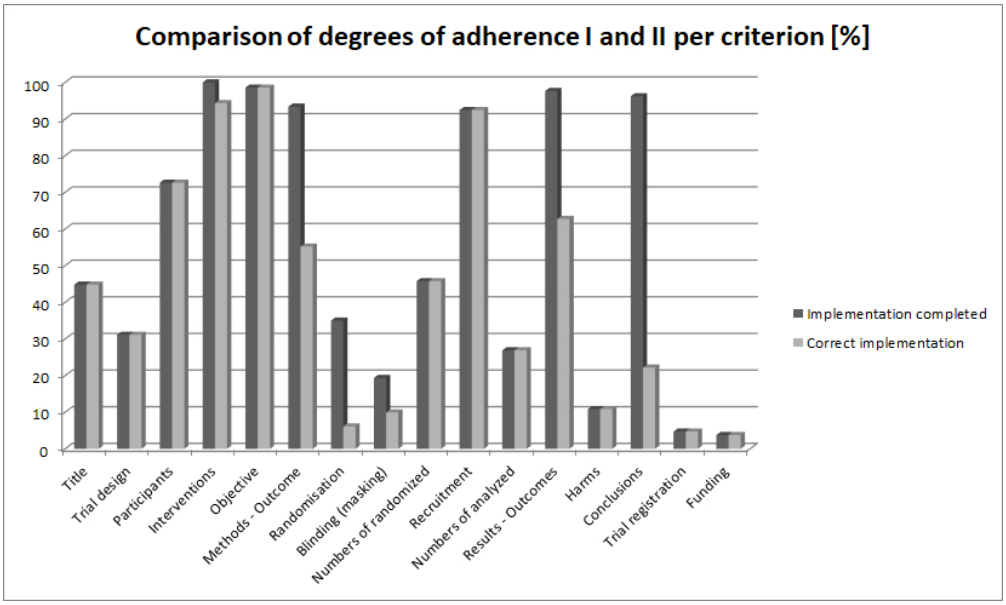


Illustration of degree of adherence per study (%) via box plot (N=212). Degree of adherence I (quantitative implementation), degree of adherence II (qualitative implementation).

220x176mm (72 x 72 DPI)



Graphic display of proportional implementation of criteria to facilitate the location of pertinent information in the abstract (degree of adherence I vs. degree of adherence II).

69x41mm (300 x 300 DPI)

CONSORT criterion	Degree of adherence I	Degree of adherence II
Identification as a randomised trial in the title	Does the title contain "randomised controlled trial" or RCT?	*
Trial design	Description of design in addition to: RCT (randomised, controlled) and Multicentre…	*
Participant characteristics	To document patient characteristics in the abstract, it is not enough to say that patients are suitable for the therapy.	*
Interventions	Intervention indicated	Intervention for each group including dosis indicated
Objective	Specific objective or hypothesis	*
Definition primary endpoint	Documentation of (multiple) endpoints	Clearly defined primary endpoint including measurement variables
Randomisation	Documentation of randomisation ratio in the section Material and Methods	Description of method used to generate the random allocation sequence and implementation in the section Material and Methods
Blinding	Documentation of "blinded" procedure using "masked", "blinded", "doubleblind" or similar descriptions	Exact indication of which patient group was blinded
Numbers randomised	Number of patients randomised to each group must be given, or at least total number with randomisation ratio!	*
Recruitment	Dates defining the trial period (trial completed/interim report/trial from ... to …) .	*
Numbers analysed	Number of participants analysed in EACH group	*
Results of outcome	Results reported in section "Results"	Results were reported with reference to the primary endpoint. Effect size and precision are reported for each group.
Harms	General description	*
Conclusion	The abstract contains a conclusion or summary.	The conclusion refers to the research question/results and lists benefits and limitations of the study
Trial registration	Registration number	*
Funding	Source of funding	*

Supplementary table 1: Evaluation basis for CONSORT-A criteria referring to degree of adherence I (information given in the abstract) and degree of adherence II (correct documentation in accordance

with CONSORT-A). * Variables without formal degree of adherence II. Values from degree of adherence I are transferred.

Search	MesH Therms	No. of studies
#8	**Search ((((""randomized controlled trial""[Publication Type]) AND (""2014""[Date - Publication] : ""2016""[Date - Publication])) AND human) AND (((dental implantation) OR dental implant) OR tooth artificial)**	**262**
#7	((dental implantation) OR dental implant) OR tooth artificial	46684
#6	Search dental implantation	21511
#4	Search human	16842581
#2	Search (""2014""[Date - Publication] : ""2016""[Date - Publication])	3387284
#1	Search ""randomized controlled trial""[Publication Type]	429525

Supplementary table 2: Result from literature research in the electronic database PubMed on March 7, 2017

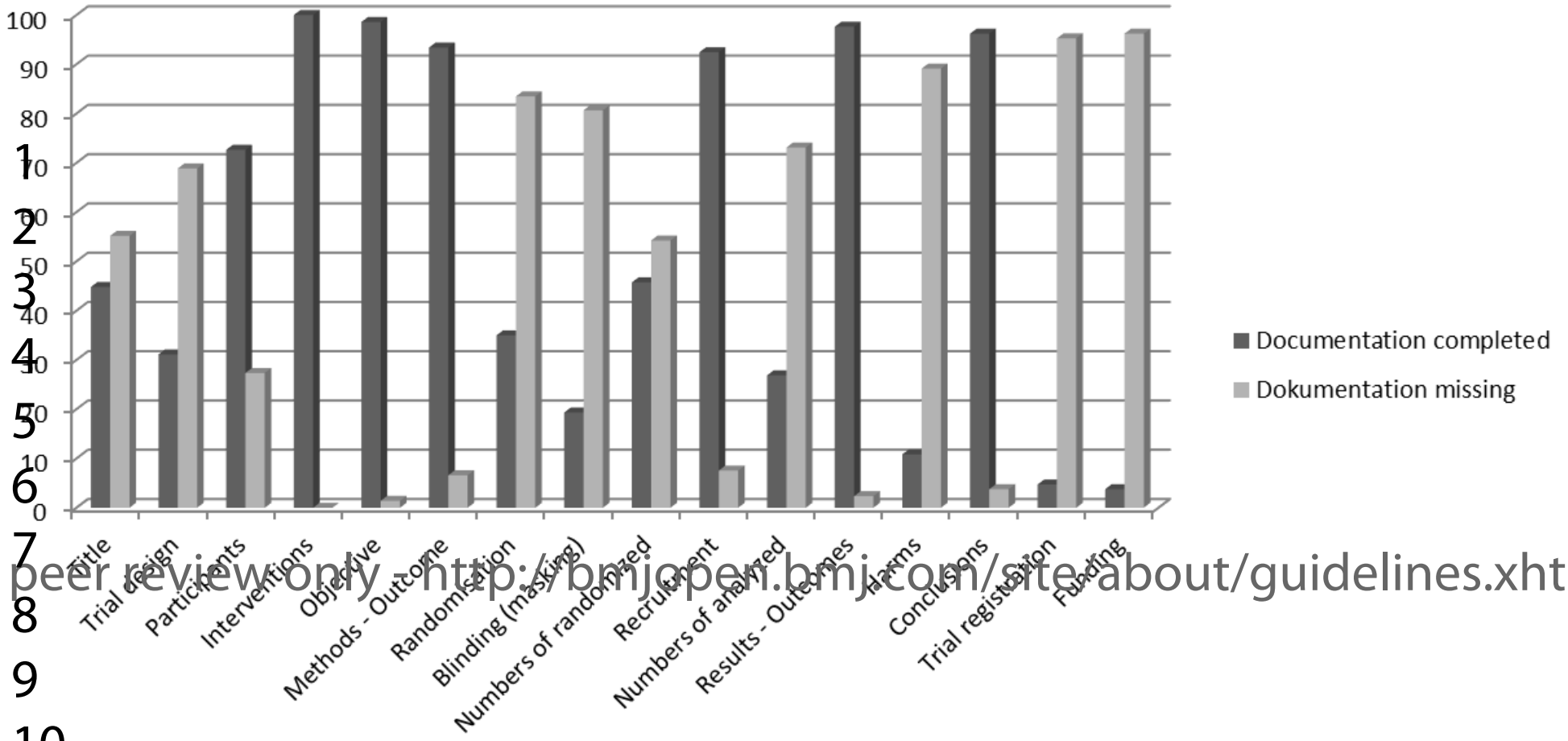
Journal *[journal title abbreviation]*	**Number** *[N]*	**Proportion** *(%)*	**5-year IF** *[as per 2018]*	**Word count limits** *[words]*
Acta Bioeng Biomech	1	0,5	1,112	150-250
Acta Odontol Scand	3	1,4	1,565	250
Am J Dent	1	0,5	0,720	No limit
Am J Orthod Dentofacial Orthop	2	0,9	1,911	250
Angle Orthod	1	0,5	1,880	250
Ann Anat	2	0,9	2,241	No limit
Biomed Res Int	3	1,4	2,197	300
Br J Oral Maxillofac Surg	2	0,9	1,164	250
Clin Implant Dent Relat Res	22	10,4	3,212	150-200
Clin Oral Implants Res	36	17,0	3,825	250
Compend Contin Educ Dent	1	0,5	0	n.a.
Curr Med Res Opin	1	0,5	2,345	250
Eur J Oral Implantol	36	17,0	2,513	250
Eur J Orthod	1	0,5	1,841	330
Hua Xi Kou Qiang Yi Xue Za Zhi	2	0,9	0	No limit
Int J Oral Maxillofac Surg	7	3,3	1,961	300
Int J Oral Maxillofac Implants	23	10,8	1,734	350
Int J Periodontics Restorative Dent	7	3,3	1,228	75-100
Int J Prosthodont	7	3,3	1,533	350
Implant Dent	5	2,4	1,214	225
J Biomater Appl	1	0,5	2,442	No limit
J Bone Miner Res	1	0,5	5,711	300
J Clin Periodontol	9	4,2	4,164	200
J Craniofac Surg	1	0,5	0,785	200
J Dent	1	0,5	3,280	250
J Dent Res	4	1,9	5,125	300
J Oral Implantol	3	1,4	5,125	250
J Oral Maxillofac Surg	1	0,5	1,781	300
J Oral Rehabil	3	1,4	2,341	250
J Periodontol	4	1,9	2,768	250
J Periodontal Res	1	0,5	2,613	250
J Plast Reconstr Aesthet Surg	1	0,5	2,228	250
J Prosthodont	2	0,9	2,636	350
Med Oral Patol Oral Cir Bucal	3	1,4	1,284	150-300
Oral Maxillofac Surg	1	0,5	1,781	300
Oxid Med Cell Longev	1	0,5	4,868	200
Prog Orthod	1	0,5	1,381	350
Quintessence Int	1	0,5	1,392	250
Saudi Med J	2	0,9	1,055	230
Sci Rep	1	0,5	4,011	200
Stomatologiia	1	0,5	0	250
Swed Dent J	1	0,5	0,818	300

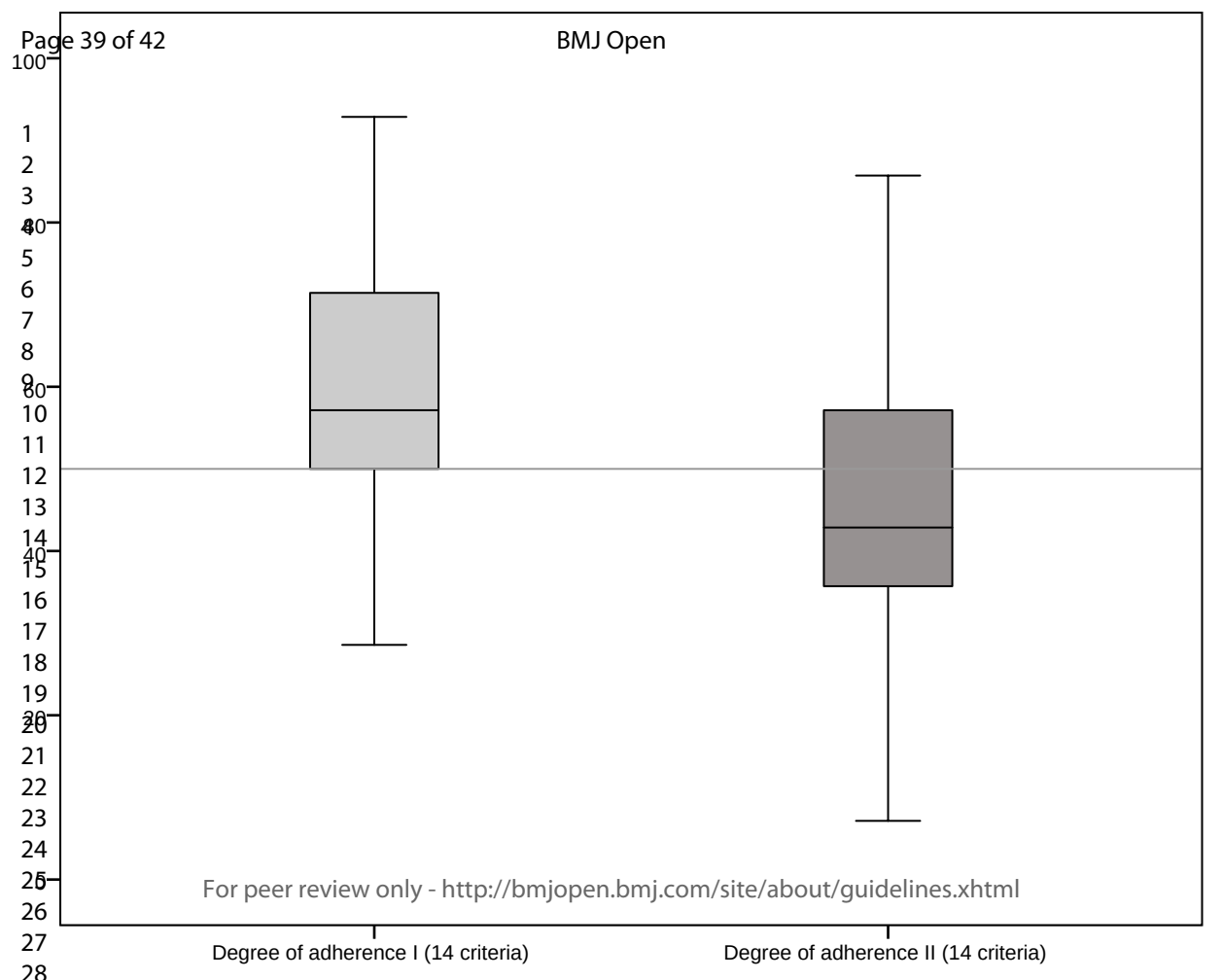
Trials	3	1,4	1,975	350
Vestn Ross Akad Med Nauk	1	0,5	0	300-500
Vojnosanit Pregl	1	0,5	0,272	450
Total	**212**	**100,0**		

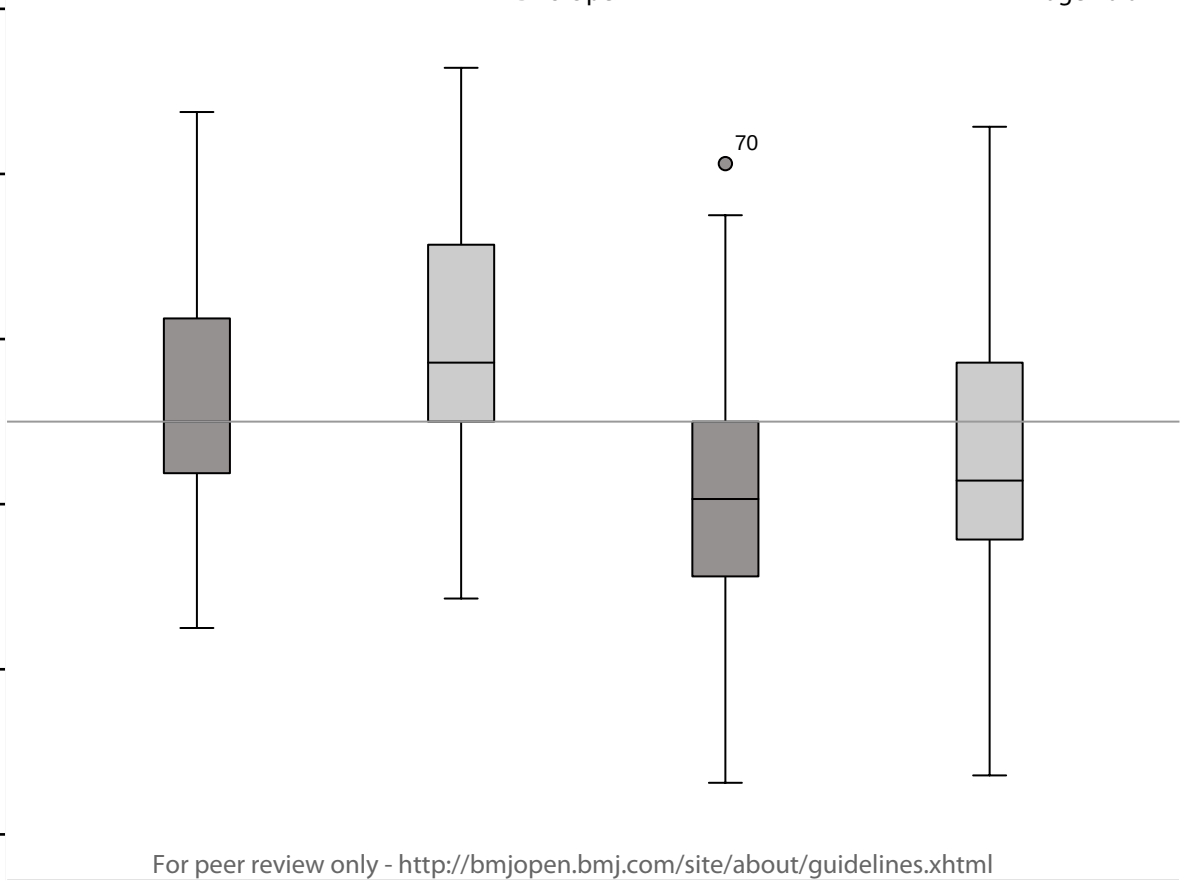
Supplementary table 3: List of journals [N] (%) from which information was extracted for final analysis, 5-year Impact Factor [2018] and word count limits for each journal as per 2019

Criterion	Percentage match	Kappa	*Kappa 0.61 – 1.0 (essential match and almost perfect match)
Title	83%	0,677	*
Trial design	89%	0,738	*
Participants	90%	0,744	*
Interventions	100%	n.a.	
Objective	100%	0,798	*
Outcome	91%	0,312	
Randomisation	82%	0,318	
Blinding (masking)	92%	0,726	*
Numbers randomised	76%	0,515	
Recruitment	85%	0,310	
Numbers analysed	84%	0,606	
Outcome	100%	1,000	*
Harms	62%	0,041	
Conclusions	100%	1,000	*
Trial registration	97%	0,449	
Funding	99%	0,762	*

Supplementary table 4: Calculation of Kappa for inter-rater reliability; percentage match between evaluators; Kappa, n.a.= in this case calculation of Kappa was not performed (SPSS) since one evaluator had rated the criterion “intervention” as 1 for all publications; (*) for criteria which showed an essential match or an almost perfect match between evaluators.







PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	II
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n.a.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4-5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary table 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4 Figure 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3-4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	n.a. -> Accessment of Abstracts
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	4-5

PRISMA 2009 Checklist

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n.a.

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n.a. -> Accessment of Abstracts
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	5
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Table 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	5-6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	n.a. -> Accessment of Abstracts
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	n.a. -> Accessment of Abstracts
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n.a. -> Accessment of Abstracts
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n.a. -> Accessment of Abstracts
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	8-9
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	12-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	11-12
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15

PRISMA 2009 Checklist

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	III 11

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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