PRIRATE 2020 guidelines for reporting randomized trials in Endodontics: a consensus-based development

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Keywords: Consensus, Endodontics, guidelines, randomized controlled trial.

Running title: PRIRATE 2020

The authors deny any conflicts of interest related to this study.

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Abstract

In evidence-based healthcare, randomized clinical trials provide the most accurate and reliable information on the effectiveness of an intervention. This project aimed to develop reporting guidelines, exclusively for randomized clinical trials in the dental specialty of Endodontology, using a well-documented, validated consensus-based methodology. The guidelines have been named: Preferred Reporting Items for RAndomized Trials in Endodontics (PRIRATE) 2020. A total of eight individuals (PD, VN, HD, LB, TK, JJ, EP, SP), including the project leaders (PD, VN) formed a steering committee. The committee developed a checklist based on the items in the Consolidated Standards for Reporting Trials (CONSORT) guidelines and Clinical and Laboratory Images in Publications (CLIP) principles. A PRIRATE Delphi Group (PDG) and PRIRATE Face-to-Face Meeting group (PFMG) were also formed. Thirty PDG members participated in the online Delphi process and achieved consensus on the checklist items and flowchart that make up the PRIRATE guidelines. The guidelines were discussed at a meeting of the PFMG at the 19th European Society of Endodontology (ESE) Biennial congress, held on 13th September 2019 in Vienna, Austria. A total of 21 individuals from across the globe and four steering committee members (PD, VN, HD, LB) attended the meeting. As a consequence of the discussions, the guidelines were modified and then piloted by several authors whilst writing a manuscript. The PRIRATE 2020 guidelines contain a checklist consisting of 11 sections and 58 individual items as well as a flowchart, considered essential for authors to include when writing manuscripts for randomized clinical trials in Endodontics.

Keywords

Consensus, Endodontics, guideline, randomized controlled trial

Introduction

Evidence-based dentistry is an approach to oral healthcare that requires judicious integration of a patient's history, oral and medical condition, the dentist's clinical expertise, the patient's treatment needs and preferences with systematic assessment of clinically relevant scientific evidence (ADA 2019). In terms of primary research studies, randomized clinical trials provide the highest level of evidence, because of their unbiased study design with minimum or no risk of systematic errors (Burns *et al.* 2011). For determining whether a cause-effect relation exists between an intervention and an outcome, this is the most rigorous and robust research study design (McCarthy 2011). However, assessment of the methodological quality of published randomized clinical studies in general medical subjects has highlighted several deficiencies, which need to be addressed (Hajibandeh *et al.* 2015, You *et al.* 2017, Zeng *et al.* 2017). Within Endodontics, the overall quality of reporting randomized clinical trials has been reported to be suboptimal (Lucena *et al.* 2016).

Individual randomized clinical trials and subsequent systematic reviews of several trials should ideally underpin clinical decision-making with the aim of improving the overall management and outcome of patients seeking endodontic treatment. Within oral health research, guidelines to assist authors in writing papers has improved the overall completeness and transparency of the resultant manuscripts (Sarkis-Onofre *et al.* 2015). Considering the importance of randomized clinical trials in healthcare research, several evidence-based tools have been developed to improve their design and reporting quality. The most accepted and validated tool to improve the reporting quality of randomized clinical trial is the Consolidated Standards for Reporting Trials (CONSORT) statement. CONSORT consists of a 25-item checklist, which assists authors when preparing the reports of trials, facilitating their complete and transparent reporting, as well as aiding in their critical appraisal and interpretation (Schulz *et al*. 2010, Moher *et al.* 2010a). Since the introduction of the CONSORT statement, many journals, including several Endodontic journals, have endorsed its recommendations for reporting clinical trials.

Due to the nature of endodontic treatments, in addition to reporting the individual components of a randomized clinical trial, in many trials it is also important to provide information on the associated images (radiographic, histological, photographic, composite figures) in an appropriate and comprehensive manner. The Clinical and Laboratory Images in Publications (CLIP) principles were developed to improve the accuracy, validity, completeness, interpretation and implications of images appearing in scientific articles (Lang *et al.* 2012).

Several guidelines have been developed for individual clinical specialties by a modification of the original CONSORT statement, e.g. infertility treatments (Harbin Consensus Conference Workshop Group 2014), and acupuncture (MacPherson *et al.* 2010). The CONSORT statement covers the majority of the important parameters that are required for reporting randomized clinical trials in Endodontics but several items such as a list of keywords, the strength of the trial, the conclusion, the implications of

the work on future research and clinical practice as well as the quality of images are absent. As the addition of these items would conceivably improve the quality of manuscripts reporting clinical trials in Endodontics, there is a need to develop new reporting guidelines specifically designed for the discipline.

The Preferred Reporting Items for RAndomized Trials in Endodontics (PRIRATE 2020) guidelines, have been developed by modifying and integrating the CONSORT guidelines (Moher *et al*. 2010a) and CLIP principles (Lang *et al*. 2012) specifically for Endodontics. The guidelines have been developed to help authors improve the overall reporting quality of randomized clinical trials, and thus enhance clinical decision-making. The aim of this project was thus to develop the PRIRATE guidelines for reporting randomized clinical trials in the specialty of Endodontics through a consensus-based process.

Methodology

The study design was approved by the Institutional Review Board on Research and Ethics of the International Medical University (IMU), Kuala Lumpur, Malaysia (No: IMU 450/2019). The protocol for the development of the PRIRATE guidelines is based on the Guidance for Developers of Health Research Reporting Guidelines (Moher *et al.* 2010b) and is explained in a previous publication (Nagendrababu *et al*. 2019).

The phases involved in developing the PRIRATE 2020 guidelines were:

Initial steps

The project leaders (VN, PD) identified the need for guidelines for reporting randomized clinical trials in Endodontics. Following this, a steering committee (SC) consisting of eight members, including the project leaders, was formed (PD, VN, HD, LB, TK, JJ, EP, SP). The steering committee developed a preliminary draft checklist of the PRIRATE guidelines by adapting and integrating the CONSORT statements (Schulz *et al*. 2010, Moher *et al*. 2010a) and CLIP principles (Lang *et al*. 2012) to fit the specialty of Endodontology. The draft checklist was subjected to an online Delphi process to build consensus on the items of the checklist and an accompanying flow-chart.

Online Delphi process

A PRIRATE Delphi Group (PDG) was created by the steering committee, comprising of 30 members including 22 academics or researchers, four clinical endodontists, two general dental practitioners (GDPs) and two members of the public. The academic and clinical members fulfilled at least one of the following eligibility criteria: published at least one randomized clinical trial in Endodontics; published any reporting guidelines for *in vitro*/*in vivo* research; a minimum 15 years of academic or clinical experience as an endodontist or GDP. The steering committee identified individuals based on the eligibility criteria and invited 30 individuals from around the globe to participate in the online Delphi process. The bespoke invitation letter explained the need for reporting guidelines for randomized clinical trials in

Endodontics, and went on to describe the Delphi process and the role of the PDG members.

Once confirmation of their participation was received, a Delphi document was shared with the PDG. This document explained the need for PRIRATE guidelines, and contained the draft PRIRATE checklist and flowchart along with a description of the online Delphi survey that explained the criteria and scoring method for including or excluding items from the checklist. The members of the PDG evaluated each item of the draft PRIRATE checklist on its suitability and clarity and scored the individual items on whether they were clear ('yes' or 'no') and whether the item should be included using a 9-point rating Likert scale (1 = 'definitely not include' to 9 = 'definitely include'). Furthermore, members were given the opportunity to provide their views and comments on the wording and their understanding of each item (Maher *et al*. 2015). All the items included in the checklist had to receive a score between 7 and 9 by ≥70% of members and between 1 to 3 by ≤30% of members. Similarly, items were excluded from the PRIRATE checklist if ≥ 70% PDG members scored an item between 1 and 3, and ≤ 30% members scored it between 7 and 9. Items that needed modification after the first round based on the feedback were re-scored by the PDG members in the second round of the Delphi process. A summary of anonymized results of the Delphi process and scores were shared with PDG members at the end of each Delphi round. The Delphi process continued until a consensus was reached on all the items and a final set of items was agreed by all PDG members (Agha *et al*. 2017). The revised PRIRATE checklist and flowchart created by the online Delphi process was thereafter discussed during the PRIRATE Face-to-Face Meeting.

Face-to-Face meeting

The PRIRATE Face-to-Face Meeting group (PFMG) included 21 individuals. The eligibility criteria for PFMG members were the same as those of the PDG with several individuals being members of both groups. The details of the venue, date and time of the Face-to-Face meeting were shared with the PFMG members. The Face-to-Face meeting was conducted on 13th September 2019 at the 19th European Society of Endodontology (ESE) biennial congress held in Vienna, Austria. The results of the online Delphi study, the checklist along with the flowchart, and the agenda were shared prior to the meeting. In the meeting, the project leaders (PD, VN) presented the results of the Delphi process, the rationale for including the checklist items and flow chart in the PRIRATE guidelines, prior to leading a discussion that debated the items and flowchart.

Post-meeting activities

A final list of the PRIRATE items and the final design of the flowchart were prepared and finalised by the steering group based on the discussions at the Face-to-Face meeting. Subsequently, the steering group reviewed the guidelines and made minor changes to improve understanding and readability.

Results

Online Delphi process
In total, 30 individuals agreed to participate in the online Delphi process and a 100% response rate was attained in rounds 1 and 2. Round 1 consisted of a PRIRATE checklist with 57 items and a PRIRATE flowchart. Of the 57 items, 55 were awarded a score between 7 and 9 by ≥70% of members and were therefore included in the PRIRATE checklist; however, consensus on two items was not achieved and these were subjected to further discussion. Thus, round 2 consisted of a PRIRATE checklist with these two items and the PRIRATE flowchart. Both items were awarded a score between 7 and 9 by ≥70% of members and they were included in the PRIRATE checklist. After analyzing individual comments received from the PDG, the flowchart was revised following round 1 and round 2.

Face-to-Face meeting
In total, four steering committee members (PD, VN, HD, LB) and 21 members attended the Face-to-Face meeting, which was chaired by two steering committee members (PD, HD). The PRIRATE checklist and flowchart were discussed to determine the views of members on whether the items should be included or excluded and whether the specific text for each item was clear and understandable, or needed modification. Several issues were raised during the meeting, which were discussed and after agreement was reached integrated into the appropriate items in the checklist. The flowchart was modified as a result of several constructive comments.

Post-meeting activities
The steering committee revised the PRIRATE checklist and flowchart based the comments from the PFMG at the Face-to-Face meeting. The final checklist and flowchart were then piloted to ensure they could be used during the development of manuscripts reporting actual randomized clinical trials. The final PRIRATE 2020 checklist comprises 11 sections (Title, Keywords, Abstract, Introduction, Methods, Results, Discussion, Conclusion, Funding details, Conflict of interest, Quality of images) with 58 individual items. Table 1 contains the PRIRATE 2020 checklist to be used when reporting randomized clinical trials in Endodontics. Figure 1 is the PRIRATE 2020 flowchart that summaries the various steps involved in reporting a randomized clinical trial and consists of 11 domains (Aim/objectives of the trial, Ethics, Number of subjects that were (i) Assessed for eligibility, (ii) Randomized, (iii) Allocated to intervention(s)/control, (iv) Received intervention(s)/control, (v) Lost to Follow-up, (vi) Analysed intervention(s)/control, Conclusion(s), Funding details and Conflict of interest).

Discussion

Many reports of randomized clinical trials lack clarity, transparency and completeness (Moher *et al*. 2008, 2010a, b) and are rejected by journals, resulting in

a waste of the time and resources that were spent on designing, conducting and reporting the research. Equally, if a poor-quality manuscript is published, readers are left with an incomplete or confused picture of what and how the research was carried out (Moher *et al.* 2010b), which can also cause confusion if others attempt to repeat the study. Furthermore, the publication of inaccurate or misleading findings has important consequences and risks for the clinical decisions that may be subsequently carried out (Sarkis-Onofre *et al*. 2015). Sarkis-Onofre *et al.* (2017) conducted a survey among the editors of dental journals on how they used reporting guidelines. They emphasized that the use of reporting guidelines had resulted in an important positive impact in the development of oral health research and had improved the quality and transparency of papers published in dentistry.

The current study aimed to develop reporting guidelines, exclusively for randomized clinical trials in Endodontics. The PRIRATE 2020 guidelines are a set of items that are considered to be essential for authors to include when writing a randomized clinical trial for publication and consists of a checklist of 11 sections with 58 individual items and a flowchart. Each section of the PRIRATE 2020 checklist addresses individual components within a randomized trial, with several items within each. If implemented, the PRIRATE 2020 guidelines will aid researchers when designing, conducting and reporting randomized clinical trials as they provide a standardized and logical template.

Illustrations are an effective and a rapid way to communicate information to readers. Indeed, some readers may only look at the figures without reading the main text of a manuscript. Relevant illustrations allow authors to support their findings, report their discovery, and have the potential to generate new research hypotheses (Kotz & Cals 2013, Polepalli Ramesh *et al*. 2015). Hence, due to the importance of images in many randomized clinical trials, particularly in Endodontics, several items relating to the quality of images were included in the PRIRATE 2020 checklist. The images in these guidelines refers to radiographs, CBCT/CT/MRI scans, histology slides, clinical photographs etc. The section covering the quality of images in the checklist includes 9 items, which allows authors to provide essential information to explain fully the nature of the images and the information they convey. For clarity, it should be noted that some randomized clinical trials do not require images, e.g. clinical trials on the effectiveness of local anaesthetics or effectiveness of drugs assessing postoperative pain.

A pictorial representation in a form of a flowchart helps readers obtain at a glance an overview of a randomized clinical trial; they also help authors when writing up a manuscript for publication. Egger *et al.* (2001) reported that CONSORT flowcharts were associated with improved reporting quality of randomized clinical trials. Hence, a flowchart has also been included in the PRIRATE guidelines.

Parallel group randomized clinical trials are the most commonly used design (90 %) in Endodontics (Yi *et al.* 2020). The PRIRATE 2020 guidelines have focused to a large extent on parallel study designs. One of the possible limitations of the

PRIRATE guidelines is that they are not so relevant for other randomised trial designs (e.g. cluster randomized or crossover trials). In the future, as the need arises, the PRIRATE steering committee will extend the main PRIRATE guidelines to include guidelines tailored according to the nature of specific randomised study designs.

Future plans

1. *Explanation and elaboration document*: The steering committee will prepare an explanation and elaboration document to outline the rationale and importance for each item in the checklist and for the flowchart. Additionally, each item and the flowchart will be supported and explained using suitable examples from the literature or hypothetical situations.

2. *Translation*: The PRIRATE 2020 guidelines will be translated into various languages, to benefit authors across the globe.

3. *Dedicated website*: The PRIRATE 2020 checklist and flow chart published in the *International Endodontic Journal* will be linked to a new dedicated website: Preferred Reporting Items for study Designs in Endodontology (PRIDE) (www.pride-endodonticguidelines.org). The PRIRATE 2020 checklist and flow chart will be available and freely downloadable on the website. Academics, researchers, journal editors, clinicians and students will be able to provide their feedback on the PRIRATE guidelines via the PRIDE website, which will assist the steering committee when they are revised over time.

4. *Endorsement:* The project leaders will contact the Editor-in-chief/Associate Editors of relevant Endodontology and other dental journals to seek their support in adopting the PRIRATE 2020 guidelines, by adding the website link for the guidelines in the ''Instructions to authors'' or "Author information" or "Author guidelines" section.

Conclusion

The PRIRATE 2020 guidelines have been developed using a well-documented and validated consensus process that has resulted in a checklist of 58 items under 11 sections and a flowchart, which can be used when reporting randomized clinical trial in Endodontics. The expectation is that the PRIRATE 2020 guidelines will help authors to produce high-quality reports of the randomized clinical trials they carry-out in the field of Endodontics, ultimately for the benefit of patients.

Acknowledgements

We would like to thank those who participated in the online Delphi process and face-to-face meeting: Ana Arias, Spain; Antonis Chaniotis, Greece; Athina-Maria Mavridou, Belgium; Bunsun Chong, UK; Christos Boutsioukis, Netherlands; Dag Ørstavik,

Norway; Daniel A Decurcio, Brazil; Daniel vaz de Souza, UK; Gustavo De-Deus, Brazil; Elisabetta Cotti, Italy; Fabian Davamani Amalraj, Malaysia; Fadi Jarad, UK; Gabriel Krastl, Germany; Alexis Gaudin, France; Gianluca Plotino, Italy; Jennifer Gibbs, USA; Igor Tsesis, Israel; Ikhlas El-Karim, UK; Jan Berghmans, Belgium; Jayaraman Nagaiah, India; Jayshree Hegde, India; João Miguel Marques dos Santos, Portugal; John Whitworth, UK; José Siqueira, Brazil; Kerstin Galler, Germany; Matthias Zender, Switzerland; Marc Semper, Germany; Massimo Del Fabbro, Italy; Merete Markvart, Denmark; Morgana Vianna, UK; Nastaran Meschi, Belgium; Paul McCabe, Ireland; Punam Naido, Malaysia; Ronald Ordonola–Zapata, USA; Chankrit Sathorn, Australia; Sebastian Bürklein, Germany; Stéphane Simon, France; Steve Bonsor, UK; Suma Ballal, India; Tao Ho, China; Tina Rödig, Germany; Valerie Chevalier, France; Victoria Yu, Singapore; Vivek Aggarwal, India; Yusuke Takahashi, Japan; Zhang Chengfei, China.

Funding

This work was supported by the International Medical University, Kuala Lumpur, Malaysia under Grant no: IMU 450/2019

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Legends

Table 1: PRIRATE 2020 checklist of items to be included when reporting randomized trials in Endodontics.

Figure 1: PRIRATE 2020 flowchart

Table 1: PRIRATE 2020 checklist of items to be included when reporting randomized trials in Endodontics.

Section/ Topic	Item number	Checklist Items	Reported on page number
Title	1a	The phrase "Randomized clinical trial" or "Randomized controlled trial" must be included in the title	
	1b	Details of the specific area(s) of interest using words and phrases that identify the clinical problem and the intervention(s), must be provided	
Keywords	2a	Keywords indicating the specific area(s) of interest using MeSH terms must be included	
Abstract	3a	The Introduction of the Abstract must explain briefly the rationale for the trial	
	3b	The aim/objective(s) of the trial must be provided at the end of the Introduction section within the Abstract	
	3c	The Methodology section within the Abstract must provide essential information on the nature of the trial (e.g. superiority, non-inferiority, equivalence), its design (e.g. parallel, split-mouth, crossover), the inclusion/ exclusion criteria, randomization process, blinding process and statistical analysis	
	3d	The Results section within the Abstract must describe the number of participants that were randomized and analyzed, the size and direction (group favoured) of the difference(s) between the intervention(s) and control groups with statistical analysis (p values and 95% CI). Adverse events or side-effects (if any) must also be reported or if none occurred, that must be mentioned explicitly	
	3e	The Conclusion section within the Abstract must summarise the findings and emphasise the clinical implication(s) of the results	
	3f	The prospective registration (number and name of the registry) and source(s) of funding must be provided	
Introduction	4a	The scientific background and rationale for the trial must be provided, including the gap(s) or inconsistencies in knowledge	
	4b	The specific aim/objective (s) of the trial must be provided and the main clinical research question formulated clearly, preferably using the PICO framework (Problem/Population, Intervention, Control and Outcome)	

Methods *Trial Design*	5a	Details of the nature of the trial (superiority, non-inferiority, equivalence of experimental intervention(s)), its design (parallel, split mouth, crossover, single/double blinded) and test:control allocation ratio must be provided. If applicable, important information about the study design must also be provided, e.g. pragmatic or preference trial, phase (drug trials), patient or public involvement in planning etc	
	5b	Changes to the methodology after the trial commenced (such as eligibility criteria) must be provided along with detailed explanations	
a priori protocol	5c	Details of the ethical approval of the protocol and the process for obtaining informed consent must be provided	
	5d	Details of the trial protocol including registration number and name of registry/clinical database and where it can be accessed (open access webpage, if applicable) must be provided	
Participants (patients, operators, evaluators)	5e	A list of inclusion and exclusion criteria at the individual/tooth/root level must be provided	
	5f	Details of the setting/environment of the trial must be provided. Details on how many operators were involved in performing the intervention and control and their relevant experience/qualifications are essential. The setting where the data were collected must be described. If several operators are included and/or if it is a multi-centre set-up, details of how standardization/calibration between individuals or centres was achieved must be provided	
	5g	The treatments in the intervention (experimental) group(s) must be described with sufficient detail to allow replication, including how and when they were actually administered	
	5h	The intervention(s) or absence of intervention(s) in the control group must be described with sufficient details to allow replication, including how and when the intervention(s) was actually administered	
Outcomes measures	5i	The primary and secondary (if any) outcome measures must be described, including how and when they were assessed and by whom	
	5j	Details of any changes made to the study outcomes after the commencement of the trial must be described	
	5k	If primary or secondary outcomes are to be regarded as surrogate outcomes, the rationale and empirical support for the connection between surrogate(s) and the outcome(s) of clinical relevance must be provided	
Sample size	5l	How the sample size was determined must be described with reference to the published literature, or a pilot study. The sample size	

		may be modified after an internal feasibility study**.** Sample size calculations should generally refer to the primary outcome measure. If secondary outcome measures constitute the base for sample size calculation, an explanation must be provided	
	5m	Any interim analyses and stopping guidelines must be described, when applicable	
Randomization and allocation concealment	5n	The method used to generate the random allocation sequence along with any details of the type of restriction (e.g. blocking) if applicable must be described. The persons responsible for randomization and recruitment must be provided. For multi-centre trials a central randomization procedure is preferred and must be described. The unit of randomization should be specified and justified. Any stratification variables must be detailed	
	5o	Methods for allocation concealment up to the assignment of the participants into the intervention groups must be described	
Blinding	5p	Information on who was/were blinded after assignment to the interventions (e.g. participants, care-givers, evaluators) must be described in detail. Blinding through masking of interventions (e.g. similar looking drugs/instruments) should be described. Detailed reasons for lack of blinding (if applicable) must be described	
Statistical analysis	5q	The statistical methods used for analysis of the primary and secondary (if any) outcomes, additional subgroup analyses and adjusted analyses (if applicable) must be described in detail. Consideration of drop-outs should be included in the calculations	
	5r	How any cluster effects were managed during the analysis must be described	
Results	6a	The number of participants who were randomly assigned, received the intended treatment, and were analysed for the primary and secondary (if any) outcome(s) for each group must be described. A flowchart must be provided	
	6b	Reasons for losses/drop-outs and exclusions after randomization must be described for each group and included in the flow chart. If intention to treat analyses are used, details of the process must be provided	
	6c	The dates of recruitment, follow-up and study duration must be described	
	6d	Reason(s) for any early termination of the trial must be described	
	6e	The baseline demographic and clinical characteristics of each group must be provided	

	6f	The results for each group for each primary and secondary (if any) outcome(s), along with the estimated effect size and its precision, must be provided	
	6g	Both absolute and relative effect sizes for binary outcomes must be provided	
	6h	The results from any other analyses performed must be described, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
	6i	The incidence and management of any adverse effects or unintended effects in each group must be described	
Discussion	7a	An estimate of the overall internal validity must be provided as well as the generalizability (external validity, applicability, real-world relevance) of the trial findings	
	7b	The rationale for inclusion, exclusion criteria and study duration must be provided	
	7c	An explanation of the clinical relevance of the primary and secondary outcomes must be provided	
	7d	A detailed interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence must be provided	
	7e	The strength(s) of the trial must be provided	
	7f	The limitations of the study must be provided, addressing the sources of potential bias, imprecision and, if applicable, multiplicity of analyses	
	7g	Implication for future research and clinical practice must be described	
Conclusion	8a	A rationale for the conclusion(s) must be provided, and the clinical significance highlighted	
	8b	Explicit conclusion(s) from the trial must be provided	
Funding details	9a	Sources of funding and other support (such as supply of drugs, equipment) as well as the role of funders must be acknowledged and described	
Conflict of interest	10a	An explicit statement on conflicts of interest must be provided	
	11a	Details of the equipment, software and settings used to acquire the image(s) must be described in the text or legend	

Quality of images (if applicable)	11b	The reason why the image(s) was acquired and the rationale for its inclusion in the manuscript must be provided in the text. A justification for all images which involve radiation must be included	
	11c	The circumstances (conditions) under which the image(s) were viewed and evaluated by the authors must be provided in the text	
	11d	The resolution and any magnification of the image(s) or any modifications/enhancements (e.g. adjustments for brightness, colour balance, or magnification, image smoothing, staining etc) that were carried out must be described in the text or legend	
	11e	Patient(s) identifiers (names, patient numbers) must be removed to ensure they are anonymised	
	11f	An interpretation of the findings (meaning and implications) from the image (s) must be provided in the text	
	11g	The legend associated with each image must describe clearly what the subject is and what specific feature(s) it illustrates. Images of patients must describe the age, gender and ethnicity of the person, if relevant	
	11h	Markers/labels must be used to identify the key information in the image(s) and defined in the legend	
	11i	The legend of each image must include an explanation whether it is pre-treatment, intra-treatment or post-treatment and, if relevant, how images were standardised over time	

PRIRATE 2020 Flowchart