

Several RCTs in dentistry failed to justify the reasons for their exclusion criteria.

The Problem

Randomized clinical trials (RCT) evaluates the effect (benefits and harms) of an intervention. The heterogeneity of the participants included is reduced by applying eligibility criteria (inclusion and exclusion criteria), which also improves the internal validity of the study. However, poorly justified reasons for exclusion criteria may also lead to a reduction of generalizability of findings, which deprives specific patient populations from having evidence available to inform their healthcare decision. The aim of this pilot study was to determine the extend of the appropriateness of the justifications provided by RCTs authors for excluding specific populations from the trials.

Methods

1. Search for RCTs in dentistry (2017 - 2019).



2. Four reviewers screened records by T&A.



3. Two reviewers assessed for eligibility the full-texts.



4. Two reviewers extracted descriptive data and assessed the appropriateness of the justification of exclusion criteria.

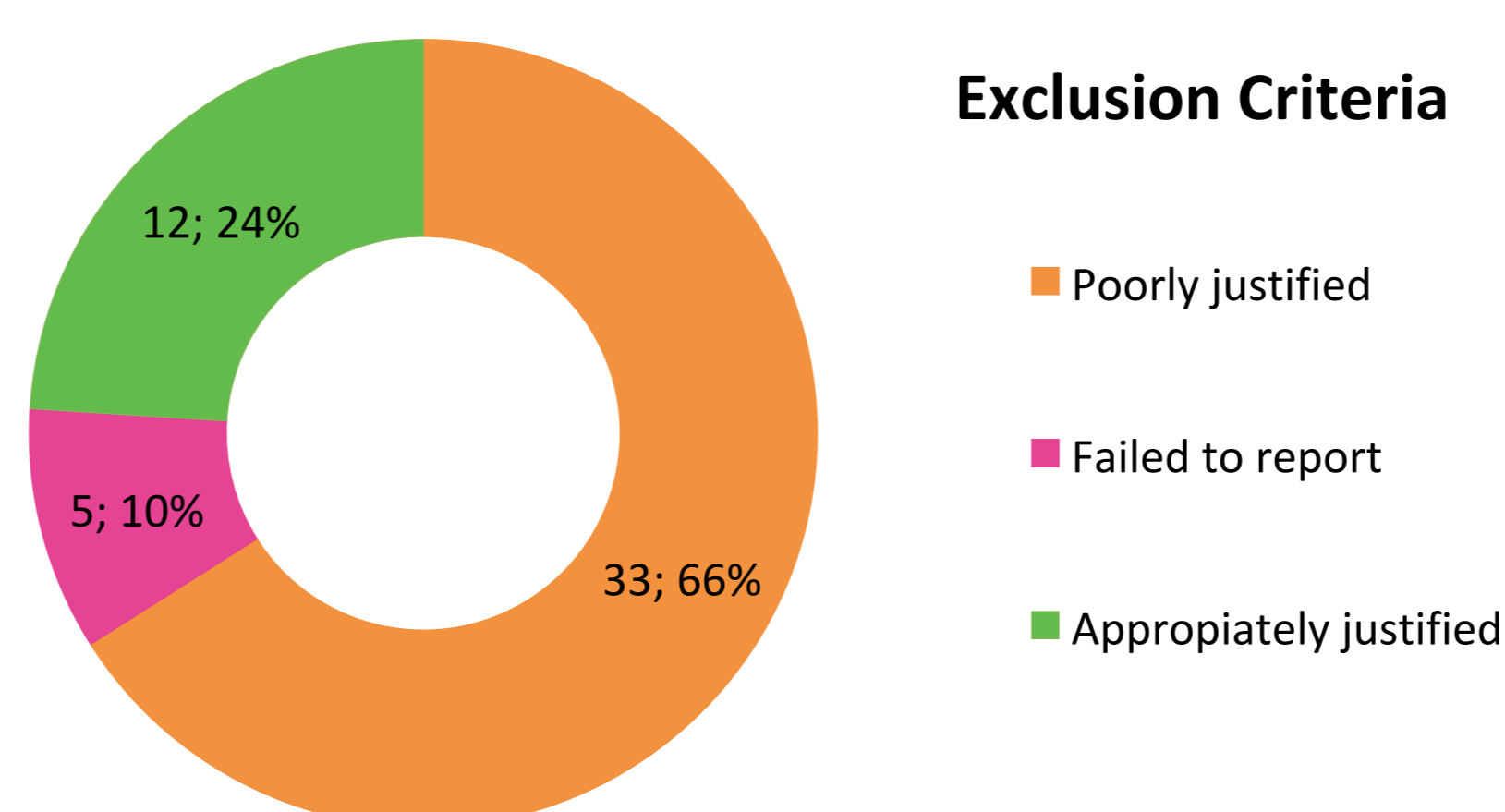


5. One reviewer calculated descriptive statistics, including proportions and means.



Key Results

- 2132 records retrieved.
- 639 records were included after T&A screening.
- 64 (10%) of studies were selected for this pilot study.
- 50 RCTs were included after full-text assessment.



Box classification of exclusion criteria

Strongly Justified Reasons for Excluding Individuals From a Randomized Controlled Trial

- Decision maker is unable to grant informed consent
- Intervention or placebo would likely be harmful
 - Unacceptable risk of known adverse reaction to intervention
 - Unacceptable risk of assignment to placebo or withholding of intervention
- Intervention would likely be ineffective
 - Individual not likely to have the condition of interest
 - Individual not at risk for outcome
 - Individual has type of disease that is likely not to respond to treatment
- Effect of intervention will be difficult to interpret
 - Individual has a co-intervention that will likely confound the treatment effect
 - Individual has an independent condition with signs and symptoms similar to the condition of interest that will make the treatment effect difficult to assess.

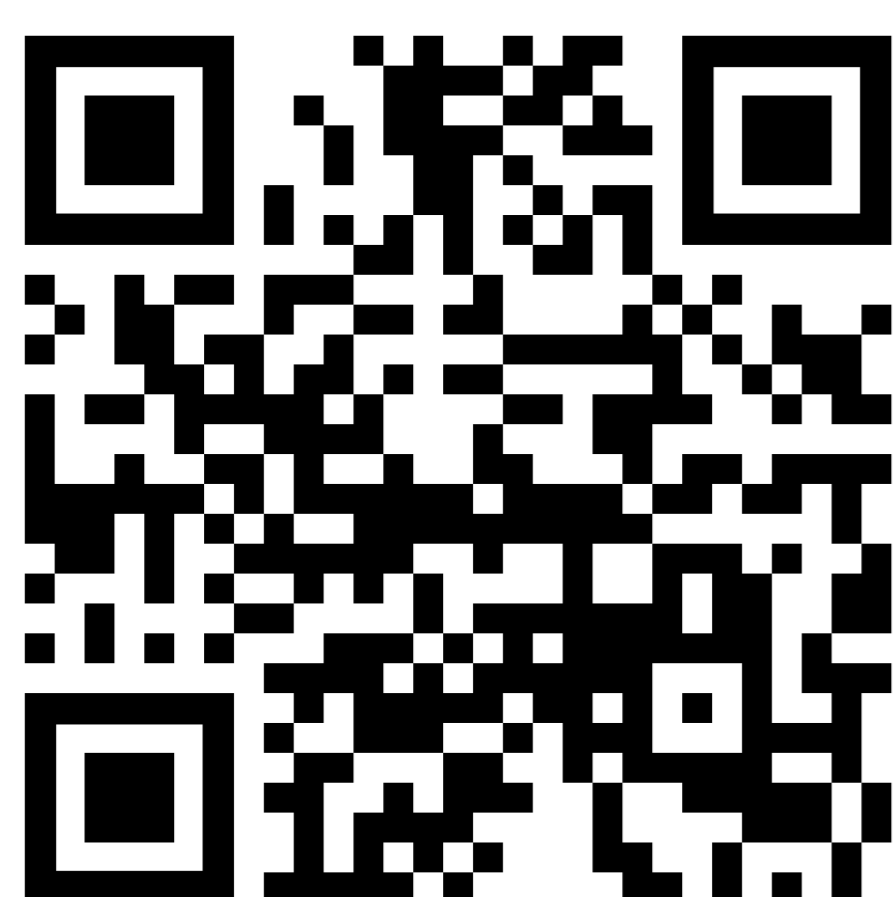
Poorly Justified Reasons for Excluding Individuals From a Trial

- Is not a strongly justifiable reason: The exclusion is based on ≥ 1 of the following factors:
 - Age
 - Sex**
 - Sex-specific conditions such as menstruation, pregnancy, or lactation
 - Racial, ethnic, or religious background
 - Spoken or written language ability
 - Educational background
 - Socioeconomic status
 - Cognitive ability or IQ**
 - Physical ability or disability
 - Chronic health condition**
 - The condition under investigation and/or the Intervention is not specific to the factors described above
 - The factors described above have no direct bearing on the condition, intervention, or results

Potentially Justified Reasons for Excluding Individuals From a Trial

- Is neither a strongly justified reason nor a poorly justified reason as described above
 - Individual may not adhere to intervention
 - Individual may not complete follow-up

Van Spall H, Toren A, Kiss A, Fowler R. 2007. Eligibility Criteria of Randomized Controlled Trials Published in High-Impact General Medical Journals, A systematic sampling review. JAMA 297 (11)



Assessment of the exclusion criteria among randomized controlled trials (RCTs) in dentistry: preliminary results of a pilot study

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