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Review article

Are dental researchers asking patient-important questions? A scoping review

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ABSTRACT

Objectives: There is an increasing recognition that research outcomes should resonate with patients rather than fixating on technical aspects of interventions. We aimed to assess the nature of outcomes within a representative subset of clinical trials published in leading dental journals.
Methods: Randomized controlled trials published over a 3-year period up to December 31st, 2015 were identified in eight leading general and specialty dental journals: Journal of Dental Research, Journal of Dentistry, American Journal of Orthodontics and Dentofacial Orthopedics, Pediatric Dentistry, International Journal of Prosthodontics, Journal of Endodontics, International Journal of Oral and Maxillofacial Surgery and Journal of Clinical Periodontology. The number and nature of outcomes considered within these trials were assessed.
Results: Overall 220 RCTs involving 409 outcomes (257 primary and 152 secondary) were identified. Measures of disease activity were most commonly assessed as both primary (n = 91, 35%) and secondary outcomes (n = 59, 39%). Quality of life and functional measures were rarely considered as primary outcome domains. Overall, 182 (44%) outcomes were primarily clinician-focused, 140 (34%) were patient-centered, while 22% (n = 87) were both patient- and clinician- focused.
Conclusions: There is an undue emphasis on technical, clinician-centered outcomes within dental research common to all specialty areas. Development and adoption of core outcome sets representing the minimum set of data that should be obtained within a dental clinical trial would assist in addressing this issue.
Clinical significance: There is an acceptance that research outcomes should ultimately be of relevance and benefit to patients rather than focusing on technical aspects of interventions. This study points to an undue emphasis on technical, clinician-centered outcomes within dental research common to all specialty areas. Development and adoption of agreed dental core outcome sets would help to remedy this.

1. Introduction

The yield from biomedical research studies has been placed in sharper focus in recent years with an acceptance that a high percentage of research is of limited value with associated financial and systemic waste [1]. This relates both to conduct and reporting issues including failure to consider questions of relevance to clinicians and patients; inappropriate study design and methods; lack of visible research outputs; and biased and incomplete reporting [2]. These issues afflict both journals with high and low impact factors [3,4], and medical and dental research to a similar extent [5,6].

Research that does not address questions that are central to patients including their experiences of care, treatment-related side-effects and patient-focused outcomes may result in potential benefits and pitfalls of interventions being only partially considered [7]. There is an ensuing emphasis on the importance of involving patients and end users in the design and analysis of clinical research studies. This is evidenced by the prerequisite that

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research funding applications for clinical studies increasingly imbed patients in the planning and design of the study [8]. In order to ensure that research questions lead to a holistic and meaningful conclusion, there is also an increasing drive to incorporate patient related outcome measures. Moreover, accepted reporting guidelines have also been adapted in an effort to facilitate better reporting of these influential patient-reported outcomes [9].

A further problem related to failure to focus on agreed, important outcomes within clinical research studies is the risk that systematic reviews will be incapable of synthesis of sufficient studies for these to arrive at meaningful syntheses [10]. Moreover, the development and routine adoption of a standard set of outcomes may reduce the likelihood of preferential publication of interesting or indeed statistically significant outcomes. The latter is known as outcome reporting bias; this risks both distorted estimates of treatment effects as well as hampering our ability to combine results within systematic reviews [11].

A core outcome set (COS), which involves but is not restricted to the inclusion of core, agreed upon, important outcomes, has gained increasing traction in recent years with over 200 in existence throughout biomedical research areas [10]. An initial stage of COS development is to perform a scoping systematic review to ascertain the nature of outcomes within a specific research area [12]. Within dentistry scoping reviews have been undertaken within orthodontics and pediatric dentistry [13], with the previous exposing an undue emphasis on clinician-important outcomes including morphological features of malocclusion, such as cephalometric changes assessed in most studies [14].

The aim of this scoping review was to assess the nature of clinical trial outcomes included in a subset of leading dental journals over a period of 3 years. Specifically, we planned to ascertain whether these outcomes were of greater relevance to patients or providers. A secondary aim was to assess the distribution of outcomes within dental specialty areas.

2. Materials and methods

Randomized controlled trials (RCTs) published over a 3-year period up to 31st December 2015 were identified in 2 general dental journals with highest impact factor and within 6 leading dental specialty journals based on the Thomson Reuters List 2014 by searching the electronic archives of the respective publications. Journals assessed included: Journal of Dental Research (JDR), Journal of Dentistry (JDent), American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO), Pediatric Dentistry (PD), International Journal of Prosthodontics (IJP), Journal of Endodontics (JOE), International Journal of Oral and Maxillofacial Surgery (IJOMS) and Journal of Clinical Periodontology (JCP).

Studies considered relevant for inclusion were identified by two authors (PSF, DK) by independent searching. A data collection form was developed following initial consultation on the classification of outcomes based on an earlier systematic review [7]. Outcomes were to be classified as either short-term measures of disease activity, physical consequences of disease, functional status, quality of life, side effects of therapy or health resource utilization. A judgment as to whether the outcome was primarily patient- or clinician- centered was also made. Following initial piloting and calibration on 10 studies, data from eligible clinical trials were extracted independently and entered in pre-piloted standardised forms. Disagreements were resolved by discussion or, if necessary, with adjudication by a third researcher (NP).

Descriptive statistics were obtained for included studies in relation to journal of publication, specialty area, region of publication, number of authors, and number and nature of primary and secondary outcomes. Cross-tabulations were undertaken to investigate associations between outcome type and area of publication. All statistical analyses were conducted with STATA® version 12.1 software (Stata Corporation, College Station, Texas, USA).

Table 1
Characteristics of the included RCTs (n = 220).

	Total	
	N	%
Journal		
AJODO	14	6
IJOMS	26	12
IJP	4	2
JCP	75	34
JDent	37	17
JDR	26	12
JOE	31	14
PD	7	3
Specialty Area		
Endodontics	32	15
Implantology	20	9
Oral Surgery	30	14
Orthodontics	16	7
Pedodontics	15	7
Periodontology	65	30
Prosthodontics	12	5
Restorative Dentistry	28	13
Other[a]	2	1
Continent of authorship		
Europe	103	47
America	71	32
Asia/other	46	21
Total	220	100

[a] Other corresponds to Oral Microbiology and Radiology specialty areas.

3. Results

Two hundred and twenty RCTs were identified within the eight journals (Table 1). The highest number of trials was identified in JCP (n = 75, 34%), followed by JDent (n = 37, 17%), JOE (n = 31, 14%) and IJOMS (n = 26, 12%). The majority of studies were undertaken either in Europe (n = 103, 47%) or the Americas (n = 71, 32%) with a median of 6 authors within each publication (range: 2–14). In terms of specialty area, the highest percentage of studies related to periodontology (n = 65, 30%) with similar numbers relating to endodontics (n = 32, 15%), oral and maxillofacial surgery (n = 30, 14%), restorative dentistry (n = 28, 13%) and implantology (n = 20, 9%). Periodontology and pediatric dentistry appeared to be more clinician-centered with respect to the primary focus of their outcomes (73/138; 53% and 13/21, 57%, respectively). In contrast, a

Table 2
Frequency distributions of primary focus of outcomes across specialty area (n = 409).

Specialty Area	Primary Focus of Outcomes			
	Patient N (%)	Both N (%)	Clinician N (%)	Total
Endodontics	14 (31)	17 (38)	14 (31)	45 (100)
Implantology	12 (25)	11 (24)	24 (51)	47 (100)
Oral Surgery	37 (62)	3 (6)	19 (32)	59 (100)
Orthodontics	9 (33)	9 (33)	9 (33)	27 (100)
Pedodontics	2 (10)	7 (33)	13 (57)	21 (100)
Periodontology	35 (25)	30 (22)	73 (53)	138 (100)
Prosthodontics	14 (61)	3 (13)	6 (26)	23 (100)
Restorative Dentistry	17 (37)	7 (15)	22 (48)	46 (100)
Other[a]	0 (0)	0 (0)	3 (100)	3 (100)
Total	140 (34)	87 (21)	182 (45)	409 (100)

[a] Other corresponds to Oral Microbiology and Radiology specialty areas.