VERIFIABLE CPD PAPER

IN BRIEF

- Evidence-based dentistry needs to have information relevant to the dental primary care setting to help general dental practitioners improve their patients' oral health outcomes.
- No summary of clinical research exclusively conducted in the dental primary care setting has previously been available.
- This review identifies forty three clinical trials conducted in dental primary care from the Cochrane Controlled Trials Register.
- A description of the studies is followed with a discussion of the merits and shortcomings of the research designs used.
- The review found no evaluations of strategies to improve general dental practitioners' participation in primary care-based clinical research.

Clinical trials in dental primary care: what research methods have been used to produce reliable evidence?

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Objective
To identify controlled clinical trials done exclusively in dental primary care and to classify the research according to design. Details of any procedures used to recruit general dental practitioners and any special organisational arrangements were also collected.

Design
A scoping literature review.

Setting
Dental primary care defined as general dental practice, community and school dental settings.

Participants
Published randomised controlled trials using randomised or quasi randomised approaches and controlled clinical trials were considered for inclusion in the review. Reports were excluded if they did not describe either a randomised controlled trial or a controlled trial. Studies were excluded if the setting was not primary dental care or the intervention was for non-dental conditions. Conference abstracts without a full report and trials published in a language other than English were also excluded.

Main outcomes
Experimental and quasi-experimental designs, clinical areas and different kinds of strategies used to recruit dentists, any organisational arrangements made to support research in dental primary care.

Results
The search of the Cochrane Oral Health Group Controlled Trials Register found 174 articles. Forty-three randomised controlled trials met the inclusion criteria. Trials to evaluate the effects of interventions for types of anaesthesia, periodontal diseases, smoking cessation techniques, dental materials, organisational aspects of dental care, patient anxiety, post extraction healing rates, antibiotics were identified. All were done in general dental practice. Trials in school and community settings were also included.

Conclusions
Practice-based research needs to be encouraged to provide dental primary care with relevant evidence upon which effective treatment can be based. This review shows there are few trials done in dental primary care to inform clinical practice, most of which have been reported since 1997. The range of trial designs shows that this method of evaluation can be used to evaluate dental primary care interventions and this is promising for those with an interest in improving dental patient outcomes. More research on how to recruit dentists into clinical trial research must be done.

INTRODUCTION

Dentistry has been described as an 'essentially primary care discipline' taking place mostly in community settings.[1] The results from trials conducted in secondary care that might not produce the same outcomes in patients treated in primary care and concerns have been expressed about the lack of evidence to inform treatments provided in general dental practice.[2,3] Wilson and co-workers[2] recommended that the evaluation of clinical outcomes for general dental practitioners (GDPs), should be conducted by GDPs so that 'real world' information about treatment effectiveness could be produced. But the difficulties in running practice-based research are considerable and there are cost implications.[4]

Good research designs are essential to ensure that valid and reliable data are collected about all healthcare interventions.[2] The best method with which to evaluate the effectiveness of treatments is the randomised controlled trial (RCT). Conducting trials in primary care is far from easy however, as complex organisational and practical issues can be obstacles to clinicians' participation.[5]

A lack of involement by clinicians can mean that trials in primary care will almost certainly fail to recruit enough patients to allow the detection of effective treatments. This has two important implications; firstly, trials will be underpowered and be less likely to detect true effects from interventions and secondly, trial findings will not be relevant to the general population. Ways to increase clinician participation have received some attention recently but little is known of the effectiveness of different types of clinician recruitment strategies, for example research networks.[6,7]

The purpose of this paper is to describe the findings of a scoping review of research conducted exclusively in the dental primary care setting. Scoping reviews are used to map the literature before embarking on a systematic review.[8]

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Table 1 Anaesthesia

Author	Type of study	Intervention	Outcomes	Patients n
Duckworth 1998	RCT	1. Oral power jet 2. Sham device	Pain of injection Pain of gingival probing	14
Jones 1996	CCT	1. TENS 2. LA	Pain during cavity prep	187
Pollock 1992	RCT	1. Methohexitone 2. Propofol	Heart rate	100
Wahl 2001	CCT	1. Prilocaine plain 2. Lidocaine with epinephrine	Injection pain	310

NS (Not stated).

Table 2 Perodontology

Author	Type of study	Intervention	Outcomes	Patients n
Clerehugh 1998	RCT	1. Powered TB 2. Manual TB	Plaque scores Gingivitis scores	84
Heneke 2001	RCT	Chlorhexidine chip 1. SRP 2. SRP+ 3. SRP+CHX chip	Probing pocket depth Probing attachment level	484
Glavind 1985	RCT	1. P instruction group 2. S instruction group	Plaque index/ bleeding index	55
Brown 1994	RCT Cluster)	1. Educational intervention 2. Standard care	Probing depth measures	600
Eaton 1997	RCT	1. Chlorhex MW 2. Placebo	Plaque scores	98
Killoy 1993	RCT	1. Powered toothbrushes 2. Placebo	Cost of periodontal treatment	32

NS (Not stated).

Table 3 Smoking cessation

Author	Type of study	Intervention	Outcomes	Patients n
Severson 1998	RCT (cluster)	1. Usual care 2. Min smoking intervention 3. Extended smoking intervention	Quit rates	3,603
Cohen 1989	RCT (Cluster)	1. Control 2. Gum 3. Reminder 4. All 3	Quit rates	1,027
Humphris 2000	RCT (cluster)	1. Leaflet 2. No leaflet	Intention to have a screen for oral cancer	800
Humphris 2001	RCT (cluster)	1. Leaflet 2. No leaflet	Knowledge of oral cancer	800
Gordon 2001	RCT (Cluster)	1. Self study 2. Workshops 3. Delayed instruction	Quit rates	NA
Gordon 2001	RCT (Cluster)	1. Smoking cessation intervention (various) 2. Control	Quit rates	500
Stevens 1995	Quasi RCT	1. Smoking cessation intervention (various) 2. Control	Quit rates	518
Andrews 1999	RCT (Cluster)	1. Usual care 2. Intervention (various)	Quit rates	633

NS (Not stated).

The aim of the scoping review

This review aims to identify the existence of trials conducted in the dental primary care setting and classify the research according to design. The reports were scrutinised for details of trial methods, the interventions evaluated, any recruitment procedures and organisational arrangements.

Dental primary care is defined here as general dental practice, and the provision of dental interventions and care in community and school dental settings. The strengths and weaknesses of the research designs used to evaluate dental practice are discussed. The scoping review also seeks to identify recruitment strategies and organisational arrangements designed to secure dentists' participation in practice based research.

Research questions

The review focused on the following questions:

- What experimental and quasi-experimental designs have been used to evaluate interventions in dental primary care?
- What broad clinical areas have been evaluated?
- What different kinds of recruitment strategies have been used to recruit dentists?
- What trial organisational arrangements were made to accommodate research in dental primary care?

METHOD

Search strategy

The Cochrane Library and the Database of Abstracts of Reviews of Effects (DARE) were searched for systematic reviews of interventions evaluated in general dental practice. The Cochrane Controlled Trials Register (CENTRAL) was searched for RCTs and controlled clinical trials using the following search terms: general practice dentists, dental offices, dental practitioners, dental practice, private practice, general practice and primary care.

Study selection

RCTs using randomised or quasi-randomised approaches (methods of allocating participants to an intervention which were not strictly random eg date of birth, hospital record, number or alternation) and controlled clinical trials were considered for inclusion in the review. The full published reports were scrutinised by a single reviewer (FC) and abstracts checked by a colleague (GT) to corroborate the inclusion and exclusion of all the identified studies. Disagreements were resolved by discussion.

Exclusion criteria

In the first instance, reports were excluded if they did not describe either a RCT or a controlled trial. Studies were excluded if the research setting was not clearly primary dental practice. Conference abstracts without a subsequent full report were excluded. Finally, trials published in a language other than English were also excluded. Research conducted in general dental practice and simultaneously in dental hospital or university settings were excluded.

RESULTS

No systematic reviews of interventions evaluated in general dental practice were identified. The search of the Cochrane Oral Health Group Controlled Trials Register identified 174 articles. Forty-three RCTs were identified which met the inclusion criteria (Tables 1-10).[9-52] One hundred and thirty-one trials were excluded from the review and the reasons for exclusion, together with a list of references are available from the author.

Types of trial designs

Of the 43 included reports seven were cluster trials.[10,14,24,33,35,41,45] Split-mouth designs were used in five

trials.[11,12,40,46,51] Controlled trials were used in four evaluations.[13,35,44,49] One used a quasi random design.[44] The most commonly used was the parallel group design. Twenty-six trials used a randomised trial design with parallel interventions or controls.[6,9,15,16,18-20,22,23,25-32,31,36,38,39,42,43,48,50,52]

The cluster design was used by Brown[14] and O'Brien[41] to evaluate educational interventions for periodontal disease and orthodontics. Seven cluster trials evaluated smoking cessation techniques.[10,23,31,31(x2),33,34,45] Coventry[24] used a cluster design to evaluate dental remuneration under either a capitation system or a fee-for-service system.

Clinical evaluations and outcomes

Trials to evaluate the effects of interventions for types of anaesthesia (Table 1), periodontal diseases (Table 2), smoking cessation techniques (Table 3), dental materials (Table 4), organisational aspects of dental care (Table 5), patient anxiety (Table 6), powder free gloves (Table7), antibiotics (Table 8), post extraction healing rates (Table 9), were all conducted in general dental practice. Trials conducted in community dental and school settings are presented in Table 10.

Recruitment strategies and organisational arrangements

Seven trials reported inviting dentists to participate in research.[10,14,24,30,31,36] In the trial by Goodey[30] dentists who had referred patients to oral surgery were identified and invited to participate in the research. The reports by Goodey[30] or Brown[14] did not explain how patients were invited (letter or telephone call). In addition to letters and follow-up telephone calls, Andrews[10] reported conducting presentations of the proposed research in each dental practice as well as at national and international hygienists meetings. Coventry[24] reported the use of several recruitments strategies in a nationwide trial of two types of remuneration for paediatric dentistry including letters, practice visits and evening meetings. Joshi[36] held meetings to present details of the trial arrangements to dentists and trial protocols were agreed with the clinicians before the trial commenced.

Fifteen trials provided information about additional organisational arrangements that were made to support the conduct of the research. These included reimbursement for work done[14,24] seminars and academic detailing[16,41] supply of materials[15] intense training sessions[10,28,47,31,31] and the provision of dedicated research staff.[14,18,22,42,48,52]

DISCUSSION

Trial design

The first RCT done in general dental practice was published in 1981. Since 1997, there has been an increase in research activity in general dental practice (Fig. 1).

Parallel group designs (patient level randomisation)

The most commonly used RCT in primary dental care is the parallel group design where two or more groups of patients are studied simultaneously, which allows direct comparisons of outcomes to be made. Using RCTs to evaluate interventions gives the advantage of removing known and unknown biases associated with non-randomised studies.

Split-mouth trial designs (tooth/quadrant level randomisation)

In dentistry, trials using a split-mouth design are commonplace and in the dental primary care setting the most frequently used experimental design in the evaluation of dental materials.[11,12,40,46,51] These within-patient comparisons are extremely useful to evaluate the highly idiosyncratic conditions in which dental materials exist. Within-patient studies allow a more precise comparison of treatments and need smaller

Table 4 Dental materials

Author	Type of study	Interventions	Outcomes	Patients n
Smales 1991	RCT (SM)	1. Valiant -PhD 2. LojicN amalgam alloy	Clinical acceptability criteria	73 (1114)
Attin 2001	RCT (SM)	1. TPH hybrid RBC 2. Compoglass compomer	Clinical acceptability criteria	52 (190)
Attin 2000	RCT (SM)	1. Composite resisn 2. TPHS spectrum	Clinical acceptability criteria	47 (132)
Wilson 2002	RCT (SM)	1. Z2SO adhesive 2. Disperse alloy composite	Clinical acceptability criteria	49 (106)
Wilson 2001	RCT	1. Putty + automix light viscosity material 2. Putty + automix regular viscosity material 3. Putty + tubed light viscosity material 4. Putty + tubed regular viscosity material	Amount of wasted impression material	100

NS (Not stated).

Table 5 Organisational Aspects of Dental Care

Author	Type of study	Intervention	Outcomes	Patients n
Burden 1997	RCT	1. IOTN Learning package 2. No learning package	Appropriate orthodontic referrals	363
Reekie 1998	CCT	1. Postal prompts 2. Manual prompts 3. Telephone prompts 4. Control group	FTA rates	2000
O'Brien 2000	RCT (cluster)	1. Guidelines 2. No guidelines	Appropriate orthodontic referrals	123
Goodey 2000	RCT	1. Computer programme 2. Paper-based algorithm 3. Control	Appropriate referrals for 3rd molar extractions	107
Coventry 1989	RCT (Cluster)	1. Capitation system for children's dentistry 2. Fee for service system	Dentist, patients and administrators satisfaction. Levels of prescribing	1919

NS (Not stated).

Table 6 Anxiety

Author	Type of study	Intervention	Outcomes	Patients n
Dailey 2002	RCT	1. Collected anxiety score 2. Did not collect anxiety score	Speilberger state anxiety inventory	123
Di Angelis	RCT	1. Blood pressure measurement in dental practice 2. Blood pressure measurement in medical practice	Systolic, diastolic pressure and pulse	74

NS (Not stated).

Table 7 Powder Free Gloves

Author	Type of study	Intervention	Outcomes	Gloves n
Brunton 2000	RCT	1. Glove A 2. Glove B	Ease of donning, tearing	1,600 (2x800)

NS (Not stated).

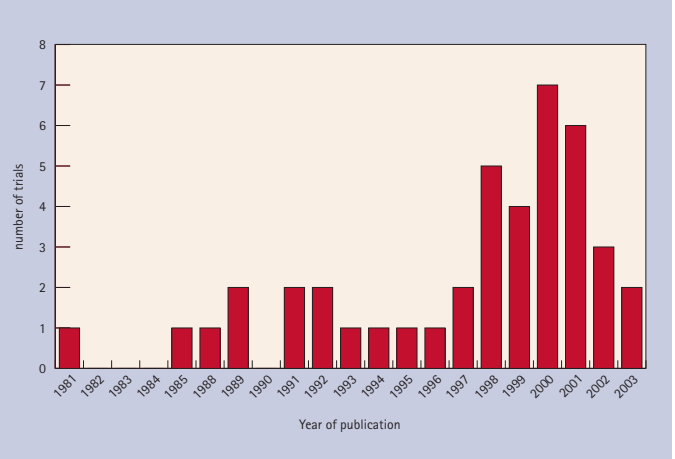

Fig. 1 Trials conducted in dental primary care

numbers of patients for the detection of benefit or harm. The simultaneous comparison of different types of treatment is also used in ophthalmology where different treatments are applied to each eye[53] and are generally useful where matching parts of the anatomy are affected by the same condition.

Within-patient comparisons are similar to cross-over trials but are distinct in the following ways: patients in cross-over trials do not receive both treatments at once, but instead receive the treatments in sequence. Whilst cross-over trials share the benefit of the smaller sample sizes, unlike split-mouth designs they have disadvantages, e.g. the need for a wash-out period to ensure that the findings during the second period are not affected by the treatment given in the first. The drop out of patients after the first period also threatens the validity of findings from cross-over trials.[53]

Cluster trial designs (group level randomisation)

The use of a cluster design in five trials to evaluate educational interventions used in general dental practice reflects the increasing use of this complex trial design in health services research. Its use is prompted by the rapid increase in research into the effect of educational, health promotion and guideline implementation interventions.[54]

The level at which randomisation (tooth, patient, practice, health authority) should correctly occur depends on whether the assumption of independence of participating individuals can be made and the likelihood that trial participants have a physical, social or geographical connection which would produce 'group effects'. These group effects can result in contamination and represent a considerable threat to the validity of results from clinical trials conducted in dental and medical practice.

Cluster trials reduce the effects of contamination which can arise when the participants randomised to the control group receive the experimental intervention as a result of their close proximity to the active treatment group. If the dental practice is the unit of randomisation, practice patients included in the trial will all receive the same treatment according to the random allocation for that practice.

Quasi randomised trials

The use of systematic methods to allocate patients to either treatment or control group are not considered truly random or without bias (eg dates of birth with even numbers allocated to treatment A and those with odd numbers allocated to treatment B). Quasi randomised trials are susceptible to bias because knowledge of which treatment the patient will receive can influence the decision to enter them into the trial in the first place.[55] For example, Stevens[47] used the quasi random method to allocate patients to a smoking cessation intervention and in so doing potentially exposed the trial data to selection bias and Di Angelis[26] allocated patients to two blood pressure measurement appointments in a dental and medical office setting according to the day of the week the patient contacted the dental surgery to request an appointment. It is possible that older patients attend certain clinics on particular days and therefore comparisons of data collected in this way may be confounded by a systematic bias.

The main reason to use randomisation to allocate treatments to patients is to avoid bias that can arise when treatment is allocated on the basis of other factors (eg disease state or prognosis). The allocation of patients to interventions should be truly unpredictable.[55]

Randomisation also confers the benefit of producing equal groups, or groups that differ only by chance and thereby creates groups with similar characteristics at baseline.[55] However, different types of bias can threaten the validity of randomised controlled trials, for example an inadequately sized sample population may produce misleading conclusions simply because it is too small to detect important effects. A number of checklists now exist to aide readers' assessment the quality of trial conduct[56] and many journals require authors to use the CONSORT statement when reporting the findings from an RCT.[57] The results from poorly conducted randomised trials can be spurious and may be less reliable than well-conducted controlled trials but, in general, the allocation of patients by some method of randomisation is always desirable. There are, of course, circumstances under which the random allocation of patients to interventions is not possible, for example the ethical considerations of evaluating the effects of smoking did not permit the use of a randomised controlled trial design.

Controlled trials

Clinical trials which have not used any method of randomisation to allocate the patients to the interventions under investigation were used in three trials conducted in dental primary care. Controlled trials were used in three of the identified dental primary care reports: evaluation of TENS and local anaesthesia with and without epinephrine[35,49] and interventions to reduce failed-to-attend rates in dental practice[44] would all have benefited from the use of random allocation and there is no obvious reason why they did not.

Recruitment strategies and organisational arrangements

A combination of different methods of invitation to participate in practice based research in the form of letters, telephone calls and practice visits have all been used to recruit dentists. Other methods include remuneration, holding meetings to present controlled trial arrangements and amending the protocol in accordance with dentists' circumstances.

Organisational arrangements are necessary to support research in dental primary care. Seminars and intense training sessions and the provision of dedicated research staff are associated with the successful completion of practice-based research. This review did not identify any evaluations comparing the success of different recruitment strategies or organisational arrangements. This is consistent with medical primary care; recruitment strategies such as reminders, audit and feedback, payments, research networks, marketing merchandise, and opinion leaders have all been used in trials in medical practice, but little direct evaluation of the benefits has been conducted.[58]

CONCLUSIONS

Most dental primary care research is done by university-based academics and uses either epidemiological or survey methods.[59] Practice-based RCTs are required to provide dental primary care with relevant research evidence upon which effective treatment can be based. This scoping review shows that although relative-

ly few controlled trials had been conducted in dental primary care prior to 1997, there has been an increase since then. These reports of different trial designs demonstrate that the most reliable methods of clinical evaluation can be successfully employed to evaluate dental primary care and this is extremely promising for those with an interest in improving dental patient outcomes.

There is little information about how best to recruit dentists into clinical trials in the general practice setting and investigations to determine the best way to do this are needed. Dentists working in primary care should be aware of the value of practice-based, well conducted randomised controlled trials as a reliable source of evidence for their clinical practice.

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Table 8 Antibiotics

Author	Type of study	Intervention	Outcomes	Patients n
Adriaenssen 1998	RCT	1. Azithromycin 500mg 2. Co amoxiclov 625mg	Cure Periapical sepsis	203

NS (Not stated).

Table 9 Healing rates

Author	Type of study	Intervention	Outcomes	Patients n
Neiburger 1999	RCT (SM)	1. Helium Neon diode laser 2. Control no-laser	Time to heal	58

NS (Not stated).

Table 10 School and Community Based Settings

Author	Type of study	Intervention	Outcomes	Pupils n
Boj (1989)	CCT	1. Tape slide presentation + oral exam 2. Standard care	Melamed's behaviour rating scale	28
Curnow (2002)	RCT	1. Supervised tooth brushing on school days 2. Standard care	dmft	561
Davies (2001)	RCT Dmft	1. 440ppmF toothpaste 2. 1450ppmF 3. Standard care	dmft	3,731 (children 12 months – 5.5 years)
Del Gaudio (1991)	RCT	1. Exposed to multi component treatment 2. Exposure to based coping skills training 3. video tape modelling condition 4. Non-exposure based coping skills training 5. information dissemination/ discussion 6. waiting list control	Speilberger state anxiety inventory	68
Joshi (2000)	RCT	1. Direct referral for day case oral surgery 2. Standard care	Appropriate referrals	872
Kohler (1981)	RCT	1. Dietary counselling 2. Professional tooth cleaning and oral hygiene instruction 3. Standard care	Microbiological analysis	249 (mothers)
ter Horst (1989)	RCT	1. Film and questionnaire 2. Film and placebo questionnaire (2nd) 3. Film and placebo questionnaire (1st)	Knowledge, attitude behaviour	425
Pine (2000)	RCT	1. Supervised tooth brushing at school + home based incentive scheme 2. Standard care	Parental attitudes to tooth brushing	461
Winick (1999)	RCT	1. Active cranial stimulation (ACS) 2. Sham ACS	Anxiety	33
Zarod (1992)	RCT	1. Parental prompts for dental screening 2. Standard care	Dental attendance	528

NS (Not stated).

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