

# A qualitative investigation of the views of primary care dentists on participating in prospective studies in the North-West of England

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## IN BRIEF

- GPs identified cultural, medico-legal and commercial concerns which would make participating in or hosting research in their practice unattractive.
- There was a lack of understanding among practitioners about the management and conduct of clinical research.
- The barriers to undertaking research in practice need to be overcome through appropriate study design, funding, training and support.

**Background** There is a poor understanding of how to recruit and involve primary care dentists in clinical trials. **Aim** To use a qualitative paradigm to explore the views of primary care dentists towards participating in clinical trials and develop an understanding of the factors that facilitate and prevent their involvement. **Design, setting, subjects and methods** An iterative approach was undertaken using a focus group (n = 6) followed by phased semi-structured interviews (n = 18). Data were analysed using thematic analysis and constant comparative analysis. **Findings** The semi-structured interviews generated nine codes which were organised into three themes: technical issues for trials in primary dental care, practical issues for research in primary dental care and primary care dentists as research consumers. Overall, primary care dentists had a poor understanding of research methodology and clinical research. Barriers to participation included loss of clinical freedom and control, practice disruption, patient welfare, staff workload, financial loss and time. **Conclusions** Barriers to primary dental care research need to be overcome through appropriate protocols, funding, training and support. Joint working of primary dental care teams and academic researchers is essential, along with a constructive and open dialogue, if clinical trials are to be successfully undertaken in a practice environment.

## INTRODUCTION

Although an evidence-based model appears to be the most rigorous method of improving quality in the health service,<sup>1-3</sup> it has been suggested that much of primary dental care is still informed by clinical experience rather than a sound theoretical basis.<sup>4</sup> This means that reliance is often placed upon expert opinion<sup>3,5</sup> rather than a sound evidence base. Across the clinical sciences, the randomised controlled trial is recognised as the highest quality of evidence available, yet there remains a 'dearth of good research evidence in most areas of oral healthcare'.<sup>5</sup> In addition, concerns have been raised about trials undertaken

in secondary care settings not being representative of the outcomes experienced in primary care.<sup>6</sup>

In order to provide a robust evidence base, it is therefore apparent that randomised controlled trials need to be undertaken in practice in order to inform appropriate guidelines, but few have been reported.<sup>7</sup> In many countries practice-based research networks have been or are in the process of being established.<sup>8,9</sup> In the United Kingdom, the Faculty of General Dental Practitioners (UK) have a research network and the International Association of Dental Research has recently established a practice-based research network across Europe ([www.per-pbrn.eu](http://www.per-pbrn.eu)). However, primary care research rarely includes a learning component and published trials often fail to evaluate the process of how research in primary care has been undertaken. Indeed, a review of trials found that the published data rarely disclosed problems encountered with the progress of primary care trials.<sup>10</sup> Where experiences have been published, these are primarily the views of researchers<sup>11</sup> rather than those of the primary care clinicians and their

patients. Yet failure to evaluate and share experiences of trials in primary dental care will hinder the development of this research field.

Qualitative methods are being increasingly used in healthcare research<sup>12</sup> and aim to elicit the unique meaning that people attach to their experiences<sup>13</sup> rather than using questions set *a priori*.<sup>14</sup> As a result, they are useful when the available literature is limited,<sup>15</sup> as new themes are allowed to emerge from the data producing a richer account of behaviour.<sup>13</sup> Semi-structured interviews and focus groups are among the most common means of capturing the views of participants and allow the researcher to guide the discussion towards pertinent areas.<sup>13,14</sup> There are a number of different approaches to the subsequent analysis of the interviews and thematic analysis is particularly useful as it gives primacy to the data rather than the method of interpretation.<sup>15</sup>

The aim of this study was to utilise the qualitative paradigm to understand what motivates and prevents primary care dentists (PCDs) from participating in prospective studies in the North-West of England.

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## METHODS

### Design

This qualitative study used an iterative approach where an initial focus group was followed by individual semi-structured qualitative interviews with PCDs. This enabled the researchers to refine the questions to ask the PCDs and ensure all the relevant areas were explored in the subsequent interviews. During this latter phase, constant comparison analysis was used, which is a cyclical process to sampling, data collection and analysis. This ensures the emerging codes are grounded in the data.<sup>14,16</sup>

### Participants

Ethical approval was received from the North Staffordshire Local Research Ethics Committee (06/Q2604/80) and The University of Manchester (06145). GMPC ReGroup and CHAMP PCT Groups also provided R&D approval (RMG/06/067). Following this, a purposive sample of academic researchers, operational researchers and PCDs who had been previously involved in clinical studies in primary dental care across the North-West were invited to participate in the focus group. PCDs with a range of research experience were also invited to participate in the semi-structured interviews. Sampling was based upon characteristics such as sex, age, time since qualifying, dental school where the dentists trained, practice size, location and type, and interest and experience of primary care research. Each PCD was interviewed once. Table 1 highlights the employment characteristics of the PCDs who undertook the interviews, alongside those of the focus group.

### Procedure

A set of opening questions for the semi-structured interviews were developed from a review of the literature and were further refined by the focus group. These were open-ended questions to facilitate discussion and evolved as the interviews progressed.<sup>17,18</sup>

Before the interviews, informed consent was gained and it was stressed that views of the participants would be anonymised. The focus group lasted 90 minutes and was held in the University of Manchester, while the individual interviews were held

**Table 1** Employment characteristics of participants in the focus group and interviews

Number of participants	Academics: NHS / Hospital / Research			Primary care dentists						Total
	Consultant	Specialist Registrar	Research Assistant	General Dental Service			Salaried Dental Service			
				Associate, NHS practice	Principal, NHS practice	Principal, private practice	Director	Senior Dental Officer	Community Dental Officer	
Focus group	2	1	1	1	1	0	0	0	0	6
Interviews	0	0	0	4	4	4	2	3	1	18
Total	2	1	1	5	5	4	2	3	1	24

**Table 2** Coding frame

Theme	Code	Description
Technical issues for research in primary dental care	1. Understanding of the research process	PCDs' knowledge of research, including study design and issues about quality
	2. Views on study design	Views of PCDs on clinical trials and other appropriate study designs for practice-based research
Practical issues for studies in primary dental care	3. Roles in research process	PCDs' perceptions of the role of the different members of the research team
	4. Factors that facilitate research in primary dental care	Factors that enable PCDs to engage in studies in primary care
	5. Barriers to research in primary dental care	Factors that stop PCDs engaging in studies in primary care
	6. Characteristics of interested and disinterested PCDs	Characteristics of PCDs who are interested/not interested in undertaking research
PCDs as research consumers	7. Views of PCDs towards research evidence	How do PCDs view research?
	8. PCDs' use of research	How do PCDs use research evidence in their practice?
	9. Characteristics of early and late adopters	Characteristics of clinicians who make changes slowly/quickly

Data is presented only in relation to prospective studies and clinical trials

at each PCD's practice and lasted up to 45 minutes. All were undertaken by the principal investigator (LH) and/or the research assistant (LM). Interviewing, sampling and data collection were undertaken in four small phases to facilitate constant comparative analysis.<sup>16</sup>

### Analysis

The interview was recorded on an Olympus DM20 Digital Recorder, and the audio-files transcribed verbatim by an audio typist into MS Word documents for thematic analysis to develop a coding frame. They were reviewed by one of the researchers [LH] for accuracy.

The verbatim transcripts were also returned to the participants for validation.<sup>19</sup>

Once approved, two of the researchers [LH, LM] immersed themselves in the data by initially reading and re-reading the transcripts in conjunction with the field notes taken at the time of the interviews. The highlighted phrases were then compared<sup>20</sup> and once agreement had been reached the coding frame was formed.

Overarching themes were developed from the coded transcripts by organising them into clusters based on the similarity of their meaning.<sup>15</sup> These were then checked against the coded extracts and the raw data to ensure that they formed a coherent pattern and were representative of what the participants were trying to convey. Specific examples were selected to create clear definitions for the

coding frame and representative quotes of each code are given in the results. In accordance with qualitative methodology, the views of the researchers interpreting the text are given below to ensure transparency.<sup>14</sup>

It was determined in advance that the interviews would continue until saturation had been reached.<sup>13</sup> Saturation was assessed by one of the authors [LH] when no new information was generated from the analyses.<sup>17</sup>

## Reflexivity

All of the research team had previously been involved in primary care research. Professor Martin Tickle has planned and undertaken a number of clinical trials in primary care and held positive views about their use. Louise Hopper and Louise Morris had both participated in clinical studies as clinicians and researchers so although they also held positive views, they appreciated some of the practical difficulties of undertaking research in the practice environment.

## FINDINGS

Three hospital staff, a research assistant and two PCDs participated in the focus group, while 18 PCDs took part in the semi-structured interviews. The latter were aged between 28 and 55 years and six of the PCDs were women. Of those, 13 had previous research experience.

The semi-structured interviews generated nine codes which were organised into three themes (Table 2): technical issues for research in primary dental care; practical issues for studies in primary dental care; and PCDs as research consumers. The latter theme and its codes have been reported separately<sup>21</sup> so this paper is limited to the first six codes associated with undertaking prospective studies and clinical trials in practice.

### Theme 1: technical issues for research in primary dental care

#### Code 1: understanding of the research process

PCDs thought that they lacked experience and poorly understood the research process. This was because undergraduate training did not provide sufficient research training and once qualified there was no

framework to enable them to become involved in research:

*'...you get an idea and you almost fall at the first hurdle because you are not sure how to set the whole thing up.'* [I3.4].

#### Code 2: views on study design

Most PCDs were willing to participate in non-randomised studies, but the majority struggled with the ethical dilemma associated with clinical equipoise, ie the idea that patients could be allocated to either a case or control group. Concerns were raised about the impact this could have on patient care, although cluster randomisation was viewed more favourably than patient randomisation.

*'Being allocated into a treatment group I would find difficult because what you are saying to me is that I am going to have to change the way I practice.'* [I2.4]

PCDs also thought that this would impact on the number of patients who were willing to participate in this type of research, given that some treatments or the absence of an intervention might be viewed as unacceptable. Many of the PCDs interviewed suggested that this required patients to be open-minded, given that they could be allocated to either of the arms in a trial.

*'...everybody wants what they think is the best!'* [I2.2]

Concerns were also raised about conducting prospective designs in primary dental care. PCDs were particularly concerned about the length of the duration of any follow-up, the time commitment involved, how to assess clinical outcomes, and the impact of staff turnover on the success of the study. However, a number of PCDs thought that a larger time burden could be offset by reducing the number of participants at recruitment.

### Theme 2: practical issues for studies in primary dental care

#### Code 3: roles in research process

The use of experienced researchers in designing, funding and managing studies in primary dental care was considered of paramount importance by all of the PCDs:

*'I think we should work in conjunction with them because they have got a lot of the skills that we haven't got.'* [I1.4]

However, PCDs thought they should be involved in assessing the suitability of protocols for primary care. This was considered important by the majority of the PCDs as it allowed them to feed back issues relating to the impact of the research on the practice and how patients might perceive planned interventions.

*'...you would want to pilot it on a few people, get feedback, amend your protocol or the way you are recording your information and then roll it out.'* [I2.1]

#### Code 4: factors that facilitate research in primary dental care

Non-judgmental relationships between the PCDs and the researchers were seen as being paramount. In particular, a culture that promoted a constructive and open dialogue between all involved parties was considered important to give PCDs the confidence in reporting adverse outcomes and any breaches of the research protocol. In addition, a number of other factors were considered to be influential: the importance given to the research, the welfare of patients, the impact on dentist-patient relationship, the reputation of the practice.

*'I would want to continue but you could imagine that there would be clinicians among us that would not be happy to do that.'* [I3.6]

#### Code 5: barriers to research in primary dental care

Many PCDs reported that they were concerned about the potential disruption and loss of control through their involvement in studies. In particular, research-reluctant dentists were more likely to want clinical freedom over the care of patients and prevented them from participating. However, dedicated research assistants were viewed favourably among many of the PCDs as a means of providing training for staff and reducing the trial burden, although a number still thought that they were too busy.

Appropriate remuneration and/or contract reductions were considered by some of the PCDs as a possible means to enable time to be set aside for research. The level of funding required was dependent on the staffing, materials and equipment that the researchers were able to provide and the financial loss the practice was able to absorb.

*'You would lose money in practice so you would need either the equivalent money from the NHS ... or just a financial grant.'* [I3.1]

However, some of the participants believed that time pressures could not be overcome by compensation and that research was acceptable only if it did not get *'in the way of treating patients'* [I2.3]. For the busy practitioner, involvement in clinical research was seen as yet another burden, especially if patients' treatments were delayed because of the need to follow the protocol.

### *Code 6: characteristics of interested and disinterested PCDs*

The principal reason why many of the PCDs became interested in becoming involved in clinical trials was to improve clinical skills. Some PCDs also expressed an altruistic desire to help develop primary dental care and give something back to their profession. Research-interested dentists were also more likely to work in a practice which was *'pro-research'* [I3.1], where there was a culture of discussing *'ways to improve'* [I3.2] clinical practice. For a number of PCDs, recognition for their involvement in research was important.

## DISCUSSION

This study demonstrates that although PCDs are interested in undertaking clinical research in practice, there are a number of barriers present and a constructive and open relationship between the different parties involved in the design, planning and implementation of the studies is critical. In 1997 the Department of Health set an agenda for research to be undertaken in primary care.<sup>22</sup> However, in dentistry this has been hampered by a poor skills base,<sup>23</sup> inadequate training and a poor research infrastructure for practice-based research.<sup>24</sup>

In this study, PCDs recognised the need for joint working with researchers as well as training and support. However, in similarity to earlier studies,<sup>4,25</sup> great variation was seen between the dentists. More specifically, failure to understand the purpose of the research protocol in clinical research and the importance of clinical equipoise illustrate how dental teams require training and support, given the need to understand

the research process that they are engaged in, while complying with Good Clinical Practice and other relevant research governance issues.

The importance of clear protocols was also stated to be critical by the vast majority of the PCDs. This has been shown to be important in medicine, where poor recruitment and failure of trials due to methodological problems<sup>25,26</sup> has been overcome by careful planning and piloting<sup>27</sup> and simple inclusion criteria.<sup>28</sup> Protocols need to be piloted to assess their feasibility, either by formalised systems of joint working<sup>29</sup> or on an *ad hoc* basis.

Practice-based research networks (PBRNs) have been one way of successfully developing research skills within primary care alongside academic researchers.<sup>4,29,30</sup> In Europe, training has been made a requirement for all clinicians in clinical trials.<sup>31</sup> However, like medicine,<sup>32</sup> it is again thought that the potential for practice-based research is still not being fully realised.<sup>32,33</sup> In 2007, the Faculty of General Dental Practice (UK) developed a set of research competencies, which outlined the knowledge, understanding and practical experience required to be able to carry out research in primary dental care.<sup>34</sup> However, in a survey of their Divisional Research Contacts across the United Kingdom, it was found that while all rated their levels of knowledge and skills as being good, their ability to undertake large scale research and apply for grant income was not as highly scored.<sup>35</sup>

Although clinical trials have been undertaken in primary care dentistry there has been no evaluation of recruitment strategies of dentists<sup>7</sup> or participants. This study shows that as in other areas of clinical practice,<sup>36,37</sup> dentists' ethos and that of the practice influences their involvement in research. Involvement has been associated with increased respect from patients,<sup>38</sup> but there is a need for appropriate recognition by the research team.<sup>30</sup> In medicine the importance of intellectual engagement and ownership of the research, as well as being open to develop clinical experience and skills, has also led to increased recruitment.<sup>39</sup> However, issues of comparable treatments, randomisation and loss of clinical freedom must be addressed if clinical trials are to be more acceptable to PCDs.

Many of the PCDs in this study were concerned about a loss of earnings, given that they worked largely in a publicly-funded system, with incomes mainly dictated by a cost and volume system of remuneration. Although some PBRNs have found that dentists were willing to absorb the financial losses,<sup>38</sup> others have emphasised the need for appropriate remuneration for dentists<sup>11,30</sup> and participants. Financial recompense needs to be factored into research bids<sup>32,40</sup> and this can make primary dental care research appear more expensive than comparative medical research. However, following publication of the national research strategy 'Best Research for Best Health'<sup>41</sup> and the subsequent establishment of the National Institute of Health Research set out in the Science and Innovation Investment Framework (2004-2014),<sup>42</sup> unprecedented levels of funding are available for health services research in the UK. Therefore, funding to support high quality research in dental practice is available and if obtained, may resolve some of the barriers identified in this paper. Dental academics, PCDs and commissioners need to work collaboratively to ensure that dentistry obtains its fair share of this research funding so that the evidence base for clinical dentistry can be improved and inform the development of care pathways as recommended in the Steele Review.<sup>43</sup> However, as highlighted above, PCDs were not only concerned with financial recompense. In similarity to Kay *et al.*,<sup>23</sup> concerns were also expressed about a loss of clinical freedom and control, practice disruption, patient welfare and staff workload. While partly ameliorated by the potential use of dedicated research assistants, some PCDs remained of the belief that they were simply too busy to engage in research, and time pressures could not be overcome by compensation.

## CONCLUSION

Barriers to primary dental care research are significant and include financial concerns, loss of clinical freedom and control, practice disruption, patient welfare and staff workload. These need to be overcome through the design of appropriate protocols, funding, training and support. Joint working of primary dental care teams and academic researchers is essential, along with a constructive and open

dialogue, if prospective clinical research is to be successfully undertaken in a practice environment.

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