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SCIENTIFIC SECTION

Practical aspects to undertaking research in the primary care setting: experience from two studies

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Aims: To discuss the practical aspects of conducting research in a primary care setting, from the perspectives of the practitioner and the research team.

Methods: Various issues are discussed, including the relevance of research questions being generated in this setting, the advantages to both parties and the processes involved in conducting a study in specialist practice. This paper describes two recent studies (a randomized clinical trial and a qualitative study) conducted within specialist practice, to illustrate some of the potential difficulties.

Conclusions: The success of conducting a study in primary care is determined by a variety of factors, including an interested specialist practitioner, motivated staff in a well-organized practice and the close support of an academic-based research team.

Key words: Practical aspects, primary care setting, qualitative study, randomized clinical trial, research

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Introduction

There is currently pressure to provide evidence of high quality care in clinical practice. Since the majority of orthodontic provision in England and Wales is carried out in the primary care sector,[1] research and audit within this setting should provide data, which reflects a standard of care for the majority of orthodontic patients. The increasingly important role of research and development in primary care has lead to resources being allocated to this area to fund research activity. In 1997, the NHS National Research and Development Programme on Primary Dental Care commissioned 48 projects in primary care giving an indication of the importance of this approach to research. In addition, the Faculty of General Dental Practitioners (UK) have developed a research committee whose research strategy focuses on various issues, which include identifying research opportunities, funding and support for GDPs who need research training. Other dental practice-based research networks have been established in Scotland,[2] Manchester[3] and Birmingham.[4] The Product Research and Evaluation in Practice (PREP) Panel consists of 25 GDPs

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throughout the UK with 11 years experience in conducting clinical trials in general dental practice.[5]

Despite the growing commitment to changes in infrastructure and greater allocation of funding within primary care, most research currently undertaken in orthodontics is based in secondary care settings.[6] Research has traditionally been confined to academic institutions as an integral part of undergraduate and postgraduate training. How relevant the findings from a research project carried out in a secondary care setting may be to primary care practice will, in part, depend on the research question. For example, an economic evaluation of a new appliance system in a hospital setting is unlikely to be applicable within specialist practice. It has also been recognized that there are significant differences in the concerns and expectations of patients treated within primary and secondary care.[7] Clearly, it may be erroneous to extrapolate findings from studies in secondary care to the majority of orthodontic patients who are treated in primary care.

Within the orthodontic literature, there are only a few published clinical trials which have been conducted in the primary care setting. These have focused on issues, such as electric versus manual tooth brushing[8,9] and the impact of orthodontic guidelines on the appropriateness of referral to secondary care.[10,11] Other studies have been based in multiple specialist practices and have evaluated typical treatment times, treatment standards and predictors in order to improve clinical standards and efficiency.[12]

Qualitative research can be used to investigate practitioners', patients' and parents' attitudes, beliefs and preferences towards different interventions.[13] Bennett and Tulloch,[14] and Bennett *et al.*,[15] respectively, investigated patients' and parents' satisfaction through focus groups and interviews, in the secondary care setting. The findings from the former study highlighted dissatisfaction with some aspects of the orthodontic treatment process, whilst the latter study used the qualitative data to construct a questionnaire to measure satisfaction with orthodontic care. This could be considered an important aspect of patient management and could influence the future delivery of care. This paper discusses our experiences of conducting a randomized clinical trial (RCT) and a qualitative study in primary care, from the perspectives of both the specialist practice and research team. The RCT compared the clinical and cost effectiveness of Hawley retainers and vacuum-formed retainers over a 6-month period. The qualitative study aimed to develop, through focus groups, a patient-based measure to provide information on the delivery of orthodontic treatment.

We aim specifically to discuss:

- the advantages of undertaking research in specialist orthodontic practice;
- the practical issues, which should be considered during various stages of the research process;
- the challenges encountered and how these were overcome.

This article does not aim to provide a 'step-by-step' guide to developing research projects in the primary care sector.

Methods

What are the advantages of research projects to the specialist practice?

The advantages, to specialist orthodontic practitioners, of participating in research may not be immediately apparent. Research is primarily undertaken to find an answer to a question.[16] In daily clinical practice there are many opportunities for questions to be generated, which relate to patient care or improving clinical efficiency.

Since 1979, research has been an integral part of postgraduate training in orthodontics, usually in the form of a MSc dissertation. Specialist orthodontists can easily use and develop these research skills to investigate clinical issues to enhance their own clinical practice. By constructing collaborative links with a dental institution, the quality of research can be enhanced. This may also provide an impetus for practice staff to learn and develop latent research skills. Other benefits include accessing new advances in treatment and up to date information about the treatments under evaluation.[17] Recent rulings by the GDC have made it clear that they expect practitioners to use evidence-based practice.

In the experience reported here, one participating specialist orthodontic practice included a section in their practice newsletter describing their involvement in the clinical trial. This was seen as a demonstration of their commitment to research and evidence-based practice, and was viewed as a practice builder for patients and referring GDPs.

What are the advantages to the research team?

To highlight the advantages of a specialist practice research setting, it is worth examining the RCT reported by Clerehugh *et al.*[9] The merits of this primary care research included: limiting the number of operators; tighter control on the flow of patients through the study resulting in an excellent completion rate (94%). To date, a similar completion rate of 91.4% has been

demonstrated in our RCT. Most significant of all was the recruitment of a large sample size, which is often a constraint in the hospital environment. Conducting the RCT in a practice setting enabled the research team to recruit a large sample size of 389 subjects within 21 months, which would have proved impossible in the hospital setting.

In our experience of conducting a qualitative study within the secondary care setting, the organization of focus group meetings was found to be inconvenient to patients, despite organizing meetings on mid-week evenings and at easily accessible locations. This significantly influenced the subject recruitment rate, so the protocol was adjusted to allow the research to be conducted in a specialist practice. This meant that focus group meetings could be conducted at the same time as the subjects' routine appointments, avoiding additional visits. This significantly improved the recruitment rate. Furthermore, a wider range of patient experiences of treatment in different settings could be experienced. Another advantage to the research team included the use of a computerized database, which allowed easy access to a large number of patients' records. Until the NHS has a defined information technology strategy, the use of a database will vary between hospitals and in some it will be impossible to access detailed patient information.

Practical issues to be considered when conducting research in specialist practice

Appropriateness of research. It is vital that the research question is of interest, addresses an important issue within the practice[18] or deals with a pressing issue for the specialty. Examples of areas relevant to GDPs are:

- patient attendance;
- development and audit of care protocols;
- reducing staff turnover rates;
- the impact of information technology in patient education.[19]

Specific examples of areas of interest to specialist orthodontists may include:

- clinical comparison of bonding materials;
- appliance systems;
- appliance designs;
- oral hygiene techniques;
- patient satisfaction surveys.

Where the dental practitioner has developed a research question, it is recommended by the Research Governance Framework for Health and Social Care 2001 that the project is supported by experienced researchers and/or academic departments at all stages in the development and implementation. If, however, the research question is generated by an academic department, then an early and important consideration is the engagement of an appropriate specialist practice to participate in the study. Nevertheless, unless the current crisis in academic recruitment and retention is addressed this will result in a diminution of research in all environments.[20]

Recruiting a specialist practice. An ideal specialist practice to engage in a study would have a large patient base, be well organized and have highly motivated staff, with a low turnover. The specialist practitioners involved need to have clinical equipoise with regard to the research question. This may be construed as a loss of clinical autonomy, but failure to accept this position may lead to bias when conducting the study and non-valid research outcomes. Jones *et al.*[21] encountered significant problems as a result of participating practitioners not following the research protocol. We were fortunate in that links were already established between the specialist practitioners and the local hospital. The most likely link is through patient referrals. Some specialist practitioners may supervise clinical sessions or work as part-time associate specialists, within the local hospital department. Attending local dental and orthodontic committee meetings, as well as national meetings may also provide a point of contact between practitioners and academics.

Some of the main issues raised by GDPs contemplating involvement in research within primary care have been identified by Pringle[22] and Blinkhorn *et al.*[23] Practitioners may feel they are already over committed to CPD and have difficulty in visualizing how research can be accommodated within existing working practice. Minimizing patient and staff disruption together with rigorous collection of research data may be seen as major issues. Some approaches we used to minimize patient and staff disruption during the RCT included:

- limiting the data collection to only that which was essential to the research question, enabling efficient collection and analysis of data;
- collecting data from the practice computer database when other members of practice staff did not need to use it; for example, at lunch time or at the end of a clinical session;
- carrying out any additional administration relating to the research project to minimize any additional work load on practice staff;

- where study models were required for data analysis, the research team took responsibility for their collection and storage.

There may be extra costs to the practice for participating in a study. In our experience, these costs included:

- the alginate for extra impressions;
- phone calls to subjects to remind them to attend their appointments;
- the use of surgery space.

In order to offset the costs for the participating practice, an agreement was made whereby a member of the research team, not only collected the research data, but also reviewed all the subjects' retainers during the same appointment. This reduced the clinical staff costs of the practice.

Ethical approval. Ethical approval is necessary to protect research subjects. It is essential for studies involving people, human tissue, current or past clinical records, whether they are conducted in private, hospital or government practice, in the UK or abroad. Despite this, Harrison[24] found that only 16% of published clinical trials between 1989 and 1998 stated that ethical approval had been obtained. Failure to obtain ethical approval and informed consent where appropriate will result in rejection from many scientific and professional journals.[25]

It was the responsibility of the research team to apply for ethical approval to the local research ethics committee (LREC). It should be noted that LRECs are set up for Trust patients and not the practice patients. It is therefore necessary for the researchers to identify which Trust is appropriate for the practices concerned. It is the centre covering the geographic location of the practice and not the place of residence for patients, which may be some distance from the practice. Guidance and updates on applications to LREC can be obtained from http://www.corec.org.uk.

Funding issues. Funding is usually required to cover research expenses, such as administrative and equipment costs. Funding is available from a variety of sources, such as the Department of Health's Research and Development programme (http://www.doh.gov.uk.), orthodontic manufacturers, and the British Orthodontic Society (BOS, http://www.bos.org.uk). The latter has a number of funding streams, which include the BOS clinical effectiveness fund and the BOS Foundation Award.

Data protection. Any research where patient information or records are collected must comply with the Data Protection Act 1998. It is the entire research team's responsibility to ensure that the study complies with these regulations. Each university pays an annual subscription to be registered with the Information Commissioner for the Government, which covers researchers who are affiliated with the university. Researchers dealing with data off-site need to be registered and are advised to seek advice from the Data Protection Officer of the university department at the outset of the study. Independent researchers in practice, however, should contact the Information Commissioner's Office for advice and, if required, registration, which can be done online (www.informationcommissioner.gov.uk). The annual registration fee for independent researchers is currently £35.

Establishing and managing research in specialist practice

Pilot study. Testing the study methodology is an important aspect of the research process and is usually carried out as a pilot study. We found that the practice was keen to begin the clinical trial before it had been piloted. It was therefore necessary to explain to the practice staff that the purpose of the pilot study was to allow both the research team and practice to identify any potential problems so that the protocol can be modified prior to recruitment of patients. Any changes to the protocol, made as a result of the pilot study, must be reported to the appropriate ethics committee.

In both studies, our protocols were influenced by the fact that we could not change the existing practices and their organization. Although these restrictions may lead to a less rigid research design, they are pragmatic and relevant, since this is how most patients are treated.

Staffing issues. If members of the research team are to carry out clinical sessions within the practice they will be required to have additional medico-legal cover. They will also be required to apply to the local primary care Trust to be included on the supplemental list for non-principal workers. This may raise contractual issues, since salaried researchers are employed by another organization and should not, therefore, be paid by the practice. Potentially, this can be solved by researchers taking unpaid leave.

Practice staff training. Members of practice staff are not usually involved in collecting research data. Their

role is to ensure the flow of subjects through a study. The research team should be responsible for providing appropriate staff training, whereby all members of staff who are willing to participate in the study fully understand their role. The staff should be instructed to give all patients the same information and not express any biases towards one or other intervention. Piloting the protocol is helpful to ensure that everyone understands, and is comfortable with the procedures. In our experience, an information folder containing criteria guidelines; sample information sheets; and a flow chart of the protocol served as a useful reminder to practice staff when the research team were not present.

Communication with the specialist practice. We found that maintaining a good relationship between the researchers and the practice requires effective communication channels. This can be easily achieved via emails, telephone, or informal visits to the practice. Ideally, a member of the practice staff should be designated as the main contact for the study. The importance of good communication has been highlighted in a multi-centre trial by Tognoni *et al.*[26]

The research team must provide adequate support and be easily contactable. Throughout both studies, we regularly visited the specialist practices to answer staff queries and carry out all additional administrative duties to help minimize practice disruptions. Regular contact with the practices allowed early detection of problems and enabled the research team to adapt to the dynamic changes in the practice, for example, regular training of new members of staff. The researchers should be accountable for all the patients involved in the study, on a regular basis, to ensure that none are unnecessarily 'lost to follow-up'.

Ward *et al.*[17] advocated a regular one page 'news flash', which provided a continual update on the study's progress. This has the additional benefit of making the staff feel actively involved in the study. We found regular practice meetings provided a forum for all participating members of the research and practice teams to discuss relevant issues relating to the study. Social events were organized for members of the practice by the research team after certain targets in the recruitment of patients were reached. This proved not only to be a successful way of demonstrating the research team's appreciation towards the specialist practice, but also of keeping members of the practice motivated, particularly nurses and receptionists, who are unlikely to directly benefit from the study.

Recruiting patients. Patient recruitment can be carried out either by the research team, with the help of the practice staff or purely by the practice staff. It is often difficult for logistic reasons for the research team to regularly recruit patients. It is therefore reasonable to consider delegating this to the practice staff. This may be advantageous because the patients already know the practice staff and may be encouraged to participate in the study. However, there are also disadvantages—there were occasions when it was impractical for practice staff to explain all the details of the study and allow time for the patients to fill in the consent forms. To simplify this, the research team provided an attractive and accessible information pack for the patients, with the contact details of the research team.

Written consent. Written consent must be obtained from all subjects participating in the study. Patients aged 16 years or older are presumed to be competent to give consent for themselves. Separate patient and parent consent forms need to be signed when the patient is under the age of 16. The parental right to determine whether a child below this age will undergo treatment, however, terminates if the patient is found to have sufficient intelligence to enable him/ her to understand what is fully proposed (http://confidential.oxfordradcliffe.net/Gillick). If this is the case, the patient is considered to be Gillick Competent. In these circumstances, only the patient consent form needs to be signed. There should be three copies of each consent form, whereby one is given to the patient and parent, and the other two are retained by the specialist practice and the research team.

Information to referring GDPs. It is usually a condition of ethical approval that a patient's GDP is informed about a study involving one of the patients under their care. Not only is this an ethical requirement, but is also courteous. Orthodontics is unusual because patients usually see two dental professionals simultaneously. It is therefore advisable, as part of the letters about the study, to warn the GDP about the possibility of influencing the study. In our study letter, we requested the GDPs not to express any bias towards one intervention over another that may be detrimental to the study.

Dissemination of results

It is important for the research team to publish the results of a study in a peer-reviewed scientific journal.

Failure to disseminate results on the grounds of trying to avoid publishing data where the outcomes are unexpected and unwanted is unethical. In addition, they should inform the practice staff and participating subjects of the outcome of the study. These groups and the patients' parents are usually very interested in the outcomes of the studies. We found that some parents decided to enrol their child into the study because the results may have proved some potential benefit to treatment of their other children.

Conclusion

Clinical orthodontics often generates relevant hypotheses that can be tested in specialist practice:

- Our own experiences of conducting two independent research studies (an RCT and a qualitative study) demonstrate that conducting research in specialist practice is possible, and can have benefits, particularly in terms of ease and speed of recruitment.
- The results of the study are more likely to be applicable to specialist practice where the majority of children are treated.
- Although specialist practitioners may initially be reluctant to participate in research, our experience was that the practice staff involved in our studies were genuinely glad to have participated.
- The success of conducting a study in primary care appears to be determined by various factors, including a willing specialist practitioner, motivated staff in a well-organized practice, with the close support of an academic-based research team.
- There appears to be mutual benefit to both parties in this approach.

Authors and contributors

Lisa Hichens, Heidi Rowland and Annalise McNair were responsible for co-ordinating the studies described, collecting data, data interpretation and drafting of the article. Darren Hills, Peter Huntley, S Ransome, Mark Forty and Jeremy Peak were the Specialist Practitioners who allowed access to their patients and helped organize and co-ordinate the studies. Alison Williams and Steven Clark were the main organizers in relation to conception and design. Jonathan Sandy was responsible for drafting and critical revision of the paper and final approval of the published version. Alison Williams is the guarantor.

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