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Participant Recruitment to FiCTION, a Primary Dental Care Trial – Survey of Facilitators and Barriers

Abstract

Objective: To identify reasons behind a lower than expected participant recruitment rate within the FiCTION trial, a multi-centre paediatric primary dental care randomised controlled trial (RCT).

Subjects (materials) and methods: An online survey, based on a previously published tool, consisting of both quantitative and qualitative responses, completed by staff in dental practices recruiting to FiCTION. Ratings from quantitative responses were aggregated to give overall scores for factors related to participant recruitment. Qualitative responses were independently grouped into themes.

Results: 39 anonymous responses were received. Main facilitators related to the support received from the central research team and importance of the research question. The main barriers related to low child eligibility rates and the integration of trial processes within routine workloads.

Conclusions: These findings have directed strategies for enhancing participant recruitment at existing practices and informed recruitment of further practices. The results help provide a profile of the features required of practices to successfully screen and recruit participants. Future trials in this setting should consider the level of interest in the research question within practices, and ensure trial processes are as streamlined as possible. Research teams should actively support practices with participant recruitment and maintain enthusiasm amongst the entire practice team.

Introduction

The “Filling Children’s Teeth - Indicated Or Not” (FiCTION) trial is a Primary Care-based multi-site, three-arm, parallel group, patient-randomised RCT (Trial Registration - ISRCTN77044005).¹ It aims to determine which approach to the management of carious primary teeth is the most successful in the context of primary dental care in the UK. All trials estimate a target recruitment period - FiCTION started with 12 months - however, the rate of participant recruitment was lower than anticipated. The STEPS study which investigated strategies for trial enrolment and participation, found only 31% of randomised controlled trials (RCTs) recruited to time and target.² A review by Treweek and colleagues recognised that achieving recruitment is an issue in medical research, and that knowledge on how to increase recruitment at sites participating in a trial is currently lacking.³ This challenge was further reinforced by a recent survey of Clinical Trials Units Directors where “research into methods to boost recruitment in trials” was found to be their highest research priority.⁴ The FiCTION trial involves the recruitment of children (aged 3 - 7 years), which the RECRUIT study found to be even more challenging.⁵ Additionally, these children are being recruited by more than 50 general dental practices across 5 regional centres over the UK. These general dental practices were already busy and few of them had participated in research before.^{6,7}

Why attempt such a challenge? For the primary care dentist faced with the prospect of managing a child with caries, there is little direct evidence to guide their decisions. Existing evidence has shown that a number of approaches to the treatment of carious primary teeth can be successful.⁸ However, very few trials have compared the relative merits of these differing approaches in the context of primary dental care - the setting

where children in the UK routinely receive their dental care. Despite improvements in child oral health, dental caries continues to affect 28-33% of 5-year olds in the UK,^{9,10} and this is a disease that can progress to cause excruciating pain and infection.¹¹ The lack of clear answers to guide a dentist's decisions is reflected in the low care index with only 10% of decay in 5-year olds is currently restored (ft/dmft) in the UK.^{9,10}

FiCTION needs to recruit sufficient numbers of children to answer this important clinical question. With few large dental RCTs undertaken in primary dental care, little guidance was available on how barriers to participant recruitment could be overcome. It was important to ensure that, as a research team, we were doing everything possible to support FiCTION practices with participant recruitment. To understand the barriers to recruitment in medical studies, Kaur *et al.* developed a survey tool investigating recruitment in multi-centre medical RCTs.¹² Using this tool, our aim was to identify reasons for FiCTION's lower than predicted participant recruitment rate and develop practical strategies to support practices in maximising future participant recruitment.

Methods

The Kaur *et al.* survey tool was modified to reflect the context of the FiCTION trial; the major contextual themes being the dental practice setting, the primary care environment and recruitment of child participants.¹² This modification process was undertaken by a team comprising; two Clinical Chief Investigators, the Senior Trial Manager and the Clinical Researcher and incorporated their experience and observations of participant recruitment in FiCTION. Amongst this group, multiple rounds of discussion were held until a consensus was reached on the final structure of the survey.

The survey tool was web-based with quantitative and qualitative sections.¹³ For the quantitative section, respondents were presented with a six point Likert scale, -3 for a strong barrier, to +3 for a strong facilitator (no 0 score), and were asked to rate 44 factors related to participant recruitment. These factors were grouped into six categories; Trial Features (9 factors), Practice Administration (4 factors), Child/Parent Traits (12 factors), Practice Team (10 factors), Family Information and Consent (4 factors) and FiCTION Research Team (5 factors). Factors that respondents had not experienced or considered not applicable to the recruitment process were rated as N/A.

The qualitative section contained five free-text boxes with open questions.

Respondents were encouraged to express their experiences and to make suggestions to improve participant recruitment.

For the analysis of the quantitative section, a summary score for each of the 44 factors was calculated by totalling the number and strength of responses. A score of "7" could be achieved if 3 respondents rated a factor "+3" and one respondent rated it "-2".

These summary scores for each factor were placed in ranked order, and factors scoring a summary score of $> +3$ were considered facilitators, factors scoring < -3 were considered barriers and those scoring between -3 and $+3$ were considered neutral factors.

For the analysis of the qualitative section, two investigators independently grouped the open responses into themes. The derived lists of themes and allocation of responses were compared and any areas of disagreement resolved through discussion and mutual agreement (NI and AK).

Results

There were 39 individual responses, which are broken down by the geographical FiCTION centre and practice team role in Table 1; for context the number of practices recruiting to the trial in each area is also given.

Ranking of factors related to recruitment

The overall scores that respondents gave to the 44 factors, categorised as Facilitators, Neutral and Barriers are shown in Tables 2-4. In order to determine the relative influence of the 6 categories, a sum of all factor scores within each category was generated. The ranking of the sum scores were; FiCTION Research Team (267), Practice Team (171), Trial Features (136), Family Information and Consent (-26) Practice Administration (-45) and Child/Parent Traits (-101).

Themes from free-text responses

The respondents were asked to give responses to 5 open questions. From the responses to these questions, the main themes are given illustrated by example quotes.

Facilitators to recruitment

Respondents were asked to identify the facilitators considered as being most important to participant recruitment; when analysed 3 themes developed:

- Positive support from central FiCTION Research Team. “Even though my recruitment numbers are small to date I have received excellent support and encouragement from the FiCTION trial team. There has not been undue pressure

imposed as there is an understanding of our practice profile” - Site Lead (Scotland).

- Involvement of full practice team. “Strong practice team motivation and sheer number of invites coupled with parent willingness to participate” - Practice Manager (Wales).
- Excitement of being involved in generation of new knowledge. “Staff motivation, keen to make a difference to the future of dentistry” - Site Lead (London).

When asked to suggest how facilitative factors could be implemented across the trial, 3 themes arose:

- Regular communication between central FiCTION Research Team and practices. “They have been implemented through regular email contact and especially with one to one phone discussion” - Site Lead (Scotland).
- Training and delegation of tasks amongst full practice team. “Giving responsibility of the trial to the correct staff” - Site Lead (London).
- Ensure appropriate resources are available. “Appeal to our better nature or increase the funding” - Site Lead (Wales).

Barriers to recruitment

When ask about the barriers considered as being most important, 6 themes emerged:

- Low numbers of eligible children encountered. “Number of eligible patients -

time taken for initial app(ointment), child gets bored" - Dental Nurse (Scotland).

- Families response to being invited to participate in research. "To (sic) much info that was sent to parents tended to frighten them off. Parents were more likely to attend during school holidays. The question about injections was the question most likely to 'frighten' them off" - Site Lead (North East).
- Families ability to comprehend information about participating in research. Example - "Parents low level understanding" - Dentist (London).
- Families established preferences about dental treatment. "Parents/patients have a preferred treatment option. SSCs and no LA. Parents prefer dentist to make decision on best treatment option" - Site Lead (Scotland).
- The additional burden research places on the family. "Some eligible patients declined to take part because of the amount of paperwork involved" - Dental Nurse (North East).
- Ensuring that practices are appropriately and promptly reimbursed for work done. "Payment complex and not occurring" - Practice Manager (North East).

When asked to suggest as to how barriers could be addressed, 3 themes emerged:

- Additional efforts by practice to screen children. "We have taken on a number of patients between the ages of 3 - 8 in the last few months. Patient who did not respond to a recall reminder we followed up ideally with a phone call asking patient if they would like to make appointment. If we were unable to contact by

phone we sent a follow up letter” - Dental Nurse (North East).

- Helping families understand the nature of the research. “Had to explain to parents what they received. Some were confused what it meant” - Site Lead (North East).
- Utilising additional diagnostic tests to find eligible children. “Radiographs where appropriate when examining child patients” - Practice Manager (North East).

Suggestions to improve organisation of research in general dental practice

When asked to suggest how to improve participant recruitment in the context of general dental practice, 5 themes emerged:

- Practices actively supported by FiCTION Research Team. “Trial team very supportive. Parents very keen to be part of the trial” - Practice Manager (North East).
- Efforts by families and practice team is recognised, and involvement is a rewarding experience. “Children love it! Love the colouring in and merchandise” - Site Lead (North East).
- Trial processes and paperwork simplified and streamlined. “Simplify initial visit, too much paperwork, takes too long” - Dental Nurse (Scotland).
- Focus recruitment efforts on groups likely to be willing to participate. “Regular attenders 'trusted' what we told them about the trial” - Site Lead (North East).

- Eligibility criteria inclusive as possible. “Increase the age range.” - Dental Nurse (Yorkshire).

Strategies for maximising recruitment

These results identified a range of facilitators and barriers to recruitment, some of which related to inflexible elements of the trial. Of the elements that could be modified at this stage of the trial, the following themes have been targeted to maximise the remaining recruitment period:

- *Efforts by families and practice team is recognised* - Alongside promotional merchandise already distributed for participating children, practices that were successful in monthly recruitment were offered FiCTION branded mugs along with a tea break set. This limited gesture of thanks, recognising additional efforts practices make towards recruitment, was aimed at developing a positive atmosphere of fun and community amongst the practice teams.
- *Low numbers of eligible children encountered* - Recruitment of additional practices to increase the pool of children available for screening.
- *Involvement of full practice team* - The survey results formed the basis of open discussions with practices prior to committing to FiCTION, ensuring that newly recruited practices had as many of the positive features identified.
- *Training and delegation of tasks amongst full practice team* - Delivery of training was modified to maximise the practice team included, by delivering as much of it as possible within the individual practice.

- *Positive support from central FiCTION Research Team* - Close support from the FiCTION Research Team was offered to these new practices, particularly during the initial stages of setting up the key administrative processes.

Discussion

For successful participant recruitment to a RCT within a typical general practice environment, our experience is that the whole practice team must be motivated towards it. The importance of this is reflected in the survey results which suggest that practice teams who believe that their additional hard work is worthwhile and contributes to important research of substantive relevance to their working lives, will commit the necessary effort. Respondents rated the FiCTION research question as a facilitator and whilst this will help promote recruitment, it can only achieve so much. The FiCTION Research Team has limited direct influence on the established practice team dynamics, however, the results of the survey identifies the key avenues – communication/support from research team, dental team training, and gestures of thanks to recognise efforts to recruit to the trial.

Communication between the practice team and the FiCTION Research Team is important even before a practice becomes fully involved. Whilst the local FiCTION Clinical Leads did utilise existing local knowledge and had discussions with practices prior to their involvement, there was no tool or exercise to formally evaluate a practice's ability to successfully recruit. This meant that any pre-existing issues at practices did not become apparent until recruitment was due to begin. This survey has helped to guide recruitment of additional practices, informing open discussions with interested practices prior to them becoming fully involved in an attempt to pre-empt

problems.

The survey highlighted numbers of eligible children as a barrier to recruitment. With the reported 28-33% of 5 year olds in the UK having obvious dental caries experience, it is initially counter-intuitive to suggest that this is a problem.^{9,10} However, the distribution of caries in children is such that the obvious disease is carried by those with more severe disease, and, as a result, many of the “easy” recruits have been found to be ineligible due to pain/sepsis. The use of bitewing radiographs in children has been shown to improve the detection of caries before it becomes clinically obvious.¹⁴ As such, radiographic examination presents a method of increasing the number of children found to be eligible at routine examination. The FiCTION trial protocol emphasises the use of radiographs in line with the UK FGDP guidelines, however, the low level of utilisation of bitewings in children is a known issue in primary dental care.^{15,16}

Along with the numbers of eligible children, trial processes and paperwork was identified as a barrier to recruitment. Trial processes are standardised across research for good reason,¹⁷ but unnecessary complexity will sap motivation and every effort should be made to avoid overwhelming the practices. Prior to the main FiCTION trial a pilot rehearsal study was undertaken, which led to the refinement of many processes.¹⁸ For most practices, FiCTION is their first experience of being involved in a research trial requiring development of new skills. With a number of larger clinical trials now being undertaken in primary dental care, hopefully a pool of research capacity is being built for the future.

Regular communication between the research team and practices was highlighted as an

important facilitator. As well as allowing for the transfer of knowledge, good communication allows practices to bring issues to the attention of the FiCTION Research Team. For example, it is important that practices are reimbursed Service Support Costs (SSCs) in a timely and comprehensive manner. The Primary Care Trusts (PCTs), who had responsibility for such payments in England, were dissolved during the FiCTION recruitment period. Confusion amongst Clinical Commissioning Groups, intended to assume PCT responsibilities, compounded the issue of payment of SSCs. Whilst the FiCTION Research Team was not directly responsible, we pursued payments on behalf of FiCTION practices and kept practices informed.

Along with assisting practices with some of the bureaucratic challenges they have faced, the FiCTION Research Team provides practical support, such as assisting practices with setting up administrative processes to begin participant recruitment. Delivering support and training within the practice itself continues to be a useful method to ensure knowledge of FiCTION permeates the whole practice team. Participant recruitment is particularly reliant on administrative tasks. In general, these administrative tasks are assigned to dental nurses, receptionists and practice managers and therefore it is important that training is provided to the entire practice team.

We recognise that the trial sits in competition with many other demanding tasks in primary dental care. To help ensure that the trial remains prominent in the minds of practices, beyond our regular communication with practices, we have developed some limited gestures of thanks including local competition between practices, along with

challenges to win trial branded items such as mugs. Initial reports from practices suggest that these gestures are appreciated and useful, primarily in introducing an element of “fun” to the recruitment process, but also helping to keep trial recruitment prominent within the practice.⁵ Once participant recruitment to FiCTION is successfully completed we intend to evaluate the impact of the strategies developed from this survey on the overall process of recruitment.

This survey was developed to provide input to an ongoing recruitment process. There was no opportunity to undertake a piloting exercise to validate the questions and responses. It would have been interesting to investigate the recruitment issue from the perspective of families involved, but the practicalities precluded investigation of this area at present. In due course, this aspect will be investigated further as part of the qualitative component of the FiCTION trial itself. To encourage respondents to be open and honest about the recruitment process, no efforts were made to track completion to individual practices or team members, or to determine whether the response represented an individual or collective opinion. This has meant that it has been impossible to calculate an overall response rate.

A number of reviews have been undertaken on the topic of recruitment to RCTs.^{3,19,20} The evidence base drawn on by these reviews primarily originates from secondary care and are medical in nature. Whilst there is a suggestion that some intervention may be effective in improving recruitment (i.e. telephone reminders or financial incentives), the reviews consistently comment on the limited evidence base and the inability to draw any definitive conclusions. Within the context of primary dental care literature on this

topic is limited. However, our results compliment many of the findings from general dental practitioner (GDP) interviews in their views on research in the primary dental care setting.²¹ These interviews found the relevance of the research question to be important and that GDPs had concerns about the time and financial implication of participating in trials.

Conclusions

Undertaking this scale and complexity of RCT in the primary dental care setting is a novel experience and has highlighted the unique challenges this environment presents. However, if we are to meet the demand for RCTs to answer these research questions, then it is crucial that trials understand how to successfully engage with practice teams. This online survey tool was found to be useful in developing a profile of the features required of practices to successfully screen and recruit participants. This practice profile has been successfully utilised in the screening of additional practices to join this ongoing trial, and at the time of writing over 60 practices across the UK are contributing to the recruitment of over 1,000 children. Our findings suggest that future trials in this setting should be cognisant of the inherent level of interest in the research question within primary care, as this can facilitate motivation to overcome the inevitable challenges involved with research. Primary care trials should strive to streamline research processes where possible to minimise further burden in an already time pushed environment, whilst provide adequate support from the central research team.

The current undertaking of large RCTs in UK primary dental care, such as FiCTION, has shown that it is feasible to answer fundamental clinical questions by undertake trials in this setting. The experiences gained from such trials ought to be utilised to help

develop sustained capacity answer further research questions in the primary care setting.

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Table 1. Responses by FiCTION Centre and practice team role

FiCTION Centre (number of recruiting practices)	Total Number of Responses	Number of Responses by Practice Team Role			
		Site Lead / Principal Dentist	Dentist	Dental Nurse	Practice Manager
Scotland (n = 9)	11	4	2	3	2
North East England (n = 11)	8	3	0	3	2
Yorkshire (n = 7)	6	3	0	2	1
Wales (n = 4)	5	1	0	0	4
London (n = 9)	9	2	2	4	1
Totals (n = 40)	39	13	4	12	10

Table 2. Overall scores for factors rated as facilitators to recruitment

Category	Factor	Overall Score
6	Ease of ability to contact the FiCTION Trial Team	77
6	Clarity and frequency of communication from the FiCTION Trial Team	65
6	Frequency of evening meetings with other practices and local FiCTION Trial Team	56
6	Motivation of the FiCTION Trial Team	55
4	Interest in the particular research question within practice	43
1	Trial publicity and merchandise	40
1	Organisation of training day	38
4	Importance of research generally in clinical practice	36
4	Research experience of practice team	32
1	Clinical equipoise	28
4	Motivation of practice team	27
4	Clinician attitude to involving patients in research	27
1	Patient inclusion criteria	24
4	Presence of designated research nurse/practitioner within practice	19
1	Payments to practice to reimburse time	15
6	Timely processing and payment of Service Support Costs	14
4	Research culture in local area	9
5	Experience and training of clinical team in seeking consent	5
3	Childs'/parents' attitude towards taking part in a clinical trial	4
4	Clinician preference for particular treatment	4

Category Key – 1 = "Trial Features", 2 = "Practice Administration", 3 = "Child/Parent Traits", 4 = "Practice Team", 5 = "Family Information and Consent", 6 = "FiCTION Research Team"

Table 3. Overall scores for factors rated as neutral to recruitment

Category	Factor	Overall Score
4	Unfamiliarity in discussing research with patients	3
1	Time required for collection of clinical data (i.e. ICDAS)	1
3	Additional trial investigations for children/parents	0
5	Difficulty in approaching patients for consent	0
3	Childs'/parents' familiarity with the clinical treatments involved	-1
3	Childs'/parents' concerns about a treatment new to them	-2
3	Language or cultural barriers amongst families	-2
1	Seasonal variation in patient attendance	-3
1	Clarity in presentation of trial information	-3

Category Key – 1 = "Trial Features", 2 = "Practice Administration", 3 = "Child/Parent Traits", 4 = "Practice Team", 5 = "Family Information and Consent", 6 = "FiCTION Research Team"

Table 4. Overall scores for factors rated as barriers to recruitment

Category	Factor	Overall Score
1	Study protocol compared to usual clinical practice	-4
2	Time between training and opening recruitment at practice	-4
2	Time between opening recruitment at practice and achieving first recruit	-5
3	Trial questionnaires for children/parents	-6
3	Childs'/parents' preference for a particular treatment	-8
2	Recruitment target	-9
5	Time and setting of consent seeking	-10
3	Additional travel/time for children/parents	-11
3	Impact of pre-existing social and emotional dynamics within families on discussion of trial participation	-11
3	Childs'/parents' attitude to treatment choice by random allocation	-14
3	Duration of trial and follow up	-20
5	Amount and complexity of trial information provided	-21
2	Time to complete administrative work related to the trial	-27
4	Clinical workload	-29
3	Number of eligible children	-30

Category Key – 1 = "Trial Features", 2 = "Practice Administration", 3 = "Child/Parent Traits", 4 = "Practice Team", 5 = "Family Information and Consent", 6 = "FiCTION Research Team"