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Primary care research: difficulties recruiting preschool children to clinical trials

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Summary. *Objectives.* The aims of the present study were to report difficulties experienced recruiting preschool children to a clinical trial and to report the acceptability of a dental intervention to their parents.
Design. The study was a randomized controlled trial (RCT).
Setting. The study took place in community dental clinics, health centres and patient homes.
Sample and Methods. Health visitors were used to recruit 508 children aged between 18 and 30 months from high caries areas of South Wales. Children with caries-free first primary molars were entered into a placebo-controlled individual RCT of fissure sealants. All children received a standard package of dental health education. Children in the test group had their first primary molars sealed with glass ionomer. All children were reviewed once. Families were asked to rate the acceptability of procedures.
Results. Health visitors referred 1228 children for screening, but only 547 were seen (44·5%) and 508 subjects were recruited to the trial. Of these, 449 (88·4%) were seen at follow-up. Some 667 children missed 1610 visits at baseline, and 373 of those recruited missed an appointment. At follow-up, 1056 appointments were staffed to review 449 children. Three-quarters of parents reported the examination to be very easy.
Conclusions. Preschool children are difficult to access for community trials. Dental examinations and sealant placement were acceptable to the majority of families who were seen.

Introduction

Evidence-based dental practice requires that proposed dental interventions should be underpinned by well-conducted clinical research, and the randomized controlled trial (RCT) is considered to be the gold standard. The concept of pooling information from different clinical trials in a systematic review to derive best practice is now well established [1,2]. However, this process has identified some weaknesses in our current evidence base. A number of recent systematic reviews, after applying inclusion criteria, have been left with fewer than five papers of appropriate quality to review [3–5]. Others have identified more papers, but have commented that the results from the systematic review were not generalizable [6]. For example, if all the RCTs are conducted in an academic hospital setting, with practitioners working without financial or time constraints, the outcomes of the studies are not easily applied to a primary dental care setting where practitioners may be operating under very different pressures. In addition, some conditions may not be referred to academic institutions, and therefore, relevant research could not be undertaken in this setting. The majority of patients, certainly the majority in the UK, are treated in a primary dental care environment, and it has been suggested that clinical trials should be undertaken in this environment [6,7].

The advantages of undertaking RCTs in an academic institution are obvious: the patients are, in

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general, more compliant and easier to follow up; and it is also easier to train and calibrate operators and examiners. In addition, many of the financial and time factors which beset practitioners are removed. Therefore, the data are likely to be more reliable. However, there are disadvantages in that the setting is quite different to those under which most patients are treated. This may influence in turn the type of patients seen, the time taken, the expertise of the operator, the payment system and so on [6].

Clearly, it is important that clinical interventions are undertaken on appropriate patients. Therefore, caries preventive strategies must be targeted at individuals at risk of dental caries. In Wales, dental epidemiological data are routinely collected based on small geographical locations known as dental planning areas (DPAs), enabling populations of children at risk of dental disease to be identified. Such areas are typically socially deprived and often have families who are irregular attenders. In 1995–1996, 32% of Welsh 5-year-olds had decay in three or more primary molars, almost all of it untreated [8]. Any attempt to decrease the level of caries in 5-year-olds requires that preschool children should be targeted.

The difficulty of organizing clinical trials in a primary dental care setting was well illustrated by Mackie [9], who reported problems for primary care practitioners in both community and general dental practice during the recruitment phase of an RCT investigating the durability of restorative materials in primary teeth in North-west England. The dentists found it difficult and time consuming to complete the paperwork, and were unhappy following the protocol. Another clinical trial of fluoridated milk in 3–5-year-old children in the UK reported high drop-out rates of between 33% and 41% [10]. The latter study was undertaken in socially deprived areas, and the authors concluded that this, in part, accounted for the drop-out rate. Although not mentioned by the authors, population mobility may also have been a factor.

The results of a RCT of a glass ionomer cement as a fissure-sealing material on primary molars in preschool children have been reported elsewhere [11]. The present paper has two objectives:

1 to review the problems encountered recruiting preschool children to an RCT in a primary care setting; and

2 to review the acceptability of a dental intervention to the parents of preschool children.

Subjects and methods

Ethical approval for the project was obtained from the BroTaf local ethics research committee. Using local dental caries data, DPAs with high levels of disease (mean dmft > 2·5 at 5 years of age) or over 60% of children at 5 years of age with decay experience were identified throughout BroTaf, South Wales. Health visitor (HV) teams in four selected areas were trained to explain the purpose of the project to the parents of children aged between 18 and 30 months. All families who wished to take part were given an information sheet with details of the study and a contact number for further information. The HV then passed their details to the research team, who arranged a screening appointment.

Screening visits were arranged by postal appointment and confirmed by telephone where the number was available. The visits themselves initially took place at local community clinics, general medical practitioner surgeries and health centres. However, to improve the recruitment rate, patients' homes were used after the first 8 months of the trial. Following consent, children were examined by BASCD-calibrated examiners to ensure that only children with caries-free molars were recruited. If children were already registered with a dentist, this was noted and the practitioner informed of their inclusion in the trial. Children who already had disease were referred for treatment. Those accepted for the trial were randomly allocated to test and control groups.

All children received a standard package of dental health education at recruitment and follow-up. Children in the test group also had their first primary molars sealed with glass ionomer using a standardized protocol. This was initially undertaken at a separate second visit. However, because of the high did not attend (DNA) rate in the first 8 months of the trial, the protocol was altered to allow placement of the sealant at the screening visit if the family preferred. Clinical evaluations were planned to take place after one and 3 years, but because of recruitment and retention difficulties, this protocol was altered. Therefore, evaluations varied between 12 and 30 months.

The acceptability to the parent and the child of the examination, dental health education and, where applicable, the application of sealant was measured through an appropriate 100-mm visual analogue scale (VAS). An additional question of ease of sealant placement was included for the active group. In each case, 0 mm implied that the procedure or advice had

Table 1. Recruitment and retention of children referred by health visitors to the present study by location.

Area	Number referred by health visitors	Number seen (%)	Number excluded caries (%)	Number recruited (percentage examined)	Number (percentage of those recruited) retained at follow-up
Merthyr	182	96 (52·7)	7 (7·25)	85 (88·54)	79 (92·94)
Pontypridd	205	103 (50·2)	1 (0·97)	102 (99·0)	94 (92·16)
Cardiff	473	166 (35·1)	7 (4·21)	149 (89·76)	126 (84·56)
Cynon Valley	368	182 (49·5)	3 (1·65)	172 (95·40)	150 (87·20)
Total	1228	547 (44·5)	18 (3·29)	508 (92·87)	449 (88·38)

been useful, quick or easy, while 100 mm implied that the procedure or advice was not useful, quick or easy. Records were also kept of the number of children referred by HVs, the number of children recruited and of the number of failed appointments. These are proxy measures for the practicalities of running such a scheme.

Results

In total, 119 HVs were trained to recruit children to the study (46 in Cardiff, 14 in Merthyr, 15 in Cynon Valley and 44 in Pontypridd). Table 1 shows the breakdown of the referrals by area. In total, the HVs referred 1228 children for inclusion in the trial, 547 of whom were seen; this equates to 44·5% of those referred attending for examination. Of these children, only 18 were excluded because of dental caries. The attendance rate was similar in all areas with the exception of Cardiff, where only 35·1% attended.

Table 1 also lists the number of children recruited to the study by area and the number remaining at follow-up. Of the 547 children examined, 508 were recruited to the trial, 241 (47·40%) in the test group and 267 (52·60%) in the control group.

Of these, 449 (88·38%) were seen for follow-up. The overall drop-out rate was 11·62%, although there was a variation between areas (range = 15·44–6·83%). At follow-up, the numbers of subjects in the test and control group were 221 (drop-out rate = 8·3%) and 228 (drop-out rate = 10·59%), respectively.

Table 2 details the number of appointments missed by patients for baseline and follow-up appointments. The DNA figure includes failures to attend at clinics and for home visits. At baseline, 667 children failed to attend for appointments; in total, they missed 1610 visits. Of the 508 children recruited, 373 missed at least one appointment. A total of 1745 appointments were made and staffed. At follow-up, 840 appointments were missed by families. Of the 449 children who were seen at follow-up, 233 missed at least one appointment. Some children missed up to 15 appointments before they were finally seen. A total of 1056 appointments were given to review 449 patients.

The acceptability of both the dental examinations and dental health advice in the control group are presented in Table 3. The lower the figure, the easier the parents rated the procedure. The forms asked parents to rate the ease and speed of the examination, and the usefulness of the advice given. Acceptability data was collected for all but five of the children recruited. The mean scores for ease and speed of examination were 11·27 and 6·44 mm, respectively. The median values for the same variables were both 5 mm. However, the range of recorded values was wide, with some parents recording 0 mm and others 89 mm. A similar range of scores was recorded for the value of the dental health advice (range = 0–88 mm). The mean rating for advice was 6·73 mm. The percentiles for all three variables show that at least 75% of parents found the speed and ease of the procedure acceptable and the advice given valuable, with all of these being measured as 12 mm or less.

Acceptability data for the test group are given in Table 4. In addition to the three variables reported in the control groups, the families were asked to record how easy they found the sealant application. Data were not available for 73 children (30·29%). The mean scores for ease and speed of examination and usefulness of advice were 16·79, 7·14 and 7·41 mm, respectively; in each case, slightly higher than the control group. Interestingly, the mean ratings for ease of examination are higher than those for the sealant application (16·79 *vs* 10·65 mm). The range of scores is very similar to that of the control group, being between 0 and 88 mm. The percentiles for all four variables show that at least 75% of the 70% of parents who completed this form found the speed and ease of the procedures acceptable and the advice given valuable. The control group found the examination to be easier than the test group. This difference was highly statistically significant ($P < 0·001$).

Table 2. Failure to attend appointments at baseline and follow-up: (DNA) did not attend; and (N/S) patient not suitable (excluded because of caries).

	Number of children × number who DNA				
Time point	Cynon	Merthyr	Cardiff	Pontypridd	Total
Baseline					
DNA					
Not recruited	89 × 3	36 × 3	185 × 3	68 × 3	375 × 3
	37 × 2	30 × 2 (5 N/S)	77 × 2	10 × 2 (5 N/S)	152 × 2
Recruited	3 × 3				3 × 3
	8 × 2	8 × 2	8 × 2	3 × 2	27 × 2
	41 × 1	10 × 1	28 × 1	26 × 1	105 × 1
Combined DNA	407	194	753	256	1610
Combined subjects	178	84	298	107	667
Follow-up					
DNA					
Removed	2 × 5		1 × 14	1 × 3	1 × 3
	1 × 6		1 × 15		2 × 5
	1 × 12		1 × 16		1 × 6
	1 × 15				1 × 12
	2 × 16				1 × 14
Recruited	31 × 1	15 × 1	24 × 1	2 × 15	86 × 1
	16 × 2	4 × 2	8 × 2	3 × 16	43 × 2
	7 × 3	5 × 3	8 × 3	16 × 1	28 × 3
	8 × 4	3 × 4	4 × 4	15 × 2	25 × 4
	4 × 5	1 × 6	7 × 5	8 × 3	22 × 5
	1 × 6		3 × 6	10 × 4	6 × 6
	4 × 7		2 × 7	11 × 5	7 × 7
	5 × 8		1 × 8	1 × 6	6 × 8
	1 × 11		2 × 10	1 × 7	2 × 10
	2 × 11		3 × 11		
	2 × 12		2 × 12		
	2 × 13		2 × 13		
	1 × 15		1 × 15		
Combined DNA	296	56	307	181	840
Combined subjects	84	28	69	63	244

Table 3. Acceptability of examination and advice to parents in the control group.

Variable	Ease	Speed	Advice
Returned	262	262	262
Missing	5	5	5
Number	267	267	267
Mean (mm)	11·27	6·44	6·73
Median (mm)	5·00	4·00	3·00
SD (mm)	16·58	10·84	12·49
Minimum (mm)	0	0	0
Maximum (mm)	89	86	88
Percentiles			
25	1·00	1·00	1·00
50	5·00	4·00	3·00
75	12·00	7·25	8·00

Table 4. Acceptability of examination and advice, and sealant application to parents in the test group.

Variable	Ease	Speed	Advice	Sealant
Returned	182	182	181	181
Missing	59	59	60	60
Number	241	241	241	241
Mean (mm)	16·79	7·14	7·41	10·65
Median (mm)	7·00	4·00	4·00	5·00
SD (mm)	22·69	9·65	10·17	15·20
Minimum (mm)	0	0	0	0
Maximum (mm)	88	82	83	85
Percentiles				
25	3·00	2·00	2·00	1·25
50	7·00	4·00	4·00	5·00
75	18·25	9·25	9·00	12·00

At baseline, 261 children (51·38%) had been registered with a dentist. All unregistered children's families were asked if they wished to be referred to the community service. Of the 247 unregistered children, 121 were referred to the community dental service at the request of their families. At follow-up, 364 children (81·07%) were reported to be registered with dentists and a further 24 were referred to the community dental service.

Discussion

Dental caries data in children is usually first collected at 5 years of age. At this age, access to children can easily be managed through their schools. Before this age, it is very difficult to access groups of preschool children. However, in South Wales, many children already have evidence of dental disease by their fifth birthday [8]. To be effective, any preventive programme needs to recruit the children before disease is present. Health visitors are the only group of health professionals who have regular access to preschool children, and since they have a remit for preventive health care, seemed the obvious group to assist in recruitment.

The HV teams knew that dental caries was an issue in their area and were keen to assist, as shown by the 1228 referred families. Unfortunately, the acceptance rate from patients was not high. Despite repeated efforts to contact them, over half (55·5%) of all families failed to attend for an examination.

This disparity may be for a number of reasons. The HVs believed that it was in their patients' interests to take part in the trial, and therefore, referred as many children as possible. While referral only occurred if the parent's permission was obtained, it is possible that families said 'yes' to their HVs because it was easier to do so than to explain to them why they did not want to take part. Alternatively, they may have agreed to be referred because they did not want to disappoint their HVs. It is possible that parents agreed initially and then changed their minds because of concerns about the research. However, this option seems less likely since only five telephone calls were received (a free phone line was available) during the project from parents wanting more information before they agreed to take part. Interestingly, all five attended for appointments.

The high numbers of referrals received from HVs suggest that they are a suitable group of health professionals to contact preschool children and pass on information. The large number of failures for dental screening visits suggests that this is not an ideal way for dental staff to make initial appointments. This may be because some effort was required to attend the dental examination, whereas the initial contact was made at a pre-existing appointment. Even when examinations were organized at prearranged home visits, a high failure rate existed. Alternatively, this may reflect the difficulty of conducting community trials in areas with social deprivation [10].

The problem of drop out had been anticipated and the original power calculations allowed for a 20% drop out. The difficulty in accessing preschool children had been considered, and the study utilized dental clinics and health centres close to patients' homes to facilitate access. However, it was clear within the first year that recruitment was too slow for the original timetable to be met. The reasons for failure were not explored with families, but a number of explanations are possible. The disparity between HV referrals and patient attendance has already been discussed.

There were several recurrent problems which made follow-up difficult:

- population mobility was an issue for some families;
- many families changed addresses several times during the study and several had missed appointments before the change of address was located via HVs;
- some of the children started nursery school during the study and they could only be examined during the half of the day when they were not at school;
- other families had several young children who needed collecting from different schools, making it difficult for parents to be available for appointments; and
- many of the families did not have access to cars and lived in areas not well served by public transport. If they were not on the telephone, this was not always identified until a cold call was arranged.

Over half (55·5%) of children who were referred were never seen and there were 1442 missed appointments for this group alone. In many cases, families who missed appointments when contacted reported that they still wished to be seen and then missed the rescheduled appointment too. This may suggest that families wanted to please the research team and say the right thing. A significant, although lower, failure rate was also found amongst families who were recruited to the study. Among the 508 children recruited were 135 who missed 168 appointments before finally being seen and accepted.

The difficulty recruiting patients had a major impact upon the protocol and a number of different initiatives were introduced to improve the recruitment rate. The original protocol required two visits for the test group. This was reduced to a single visit, with sealants being placed at the consent visit. Twenty-six venues were used for the trial, with the dental team travelling to the families rather than

families coming to central clinics. Local community dental clinics, health centres and general medical practitioners throughout the study area allowed access to either dental surgeries or examination rooms. This allowed the families to be seen at a venue close to their homes. However, the failure rate remained very high, with approximately 50% of each booked clinic failing appointments even when reminder phone calls were made. From August 2000, home visits were offered for both baseline and follow-up assessments if families had failed a clinical attendance. Approximately 65% of all appointments were made to patient's homes.

The same difficulties existed when trying to retain patients in the trial. Once recruited to the study, the fall-out rate was quite low, with 11·62% being lost overall, i.e. less than the anticipated 20% drop out. The drop-out rate was slightly higher in the control than the test group (10·59% and 8·3%, respectively). However, great efforts were made to ensure that, once recruited, children were retained. Some children missed up to 15 appointments before being seen. This considerably extended their follow-up period. Many of these appointments were not pre-booked: instead, dental teams visited the children's homes whenever they were in the area for another visit. It required 1056 visits to see 449 children for follow-up.

Extra sessions were offered during the school holidays to make it easier for families with children of school age. Out-of-hours appointments were offered, but were not popular. Most families wanted to be seen between 10:00 and 16:00 h. The recruitment period was extended to allow new children to be seen until December 2001, allowing new patients to be seen until the start of the last year of the trial. While the drop-out rate was very low, it was achieved by intensive efforts and was clearly not a cost-effective way of delivering preventive care to these families.

High drop-out rates have previously been reported to be a problem in clinical trials in the UK [9,10]. In one socially deprived area of the UK, a drop-out rate of 33–41% over 4 years was reported in a community clinical trial of milk fluoridation for 3–5-year-olds [10]. This is considerably higher than the drop-out rate reported in the present study, where the major difficulty was recruitment. This may be a reflection of the difficulty in identifying preschool children who can participate, since they are not a group who usually attend the dentist unless they are in pain. Alternatively, it may be because the children whom the present authors recruited were from families who were most interested in dental care and health issues. In contrast, those who declined to take part may constitute a group of families with less interest in health issues. It is possible that, if such a selection bias existed, then those who participated in the trial might also have been those at lower risk of dental disease. It is not possible to determine whether this occurred or whether this might have influenced the results.

Overall, parents in the control group found the examination and advice to be acceptable, with low mean scores for all variables. The percentile scores indicate that at least 75% of parents found the check up to be very easy, having scored under 12 mm for the examination. However, as the maximum scores indicate (86–89 mm), a few parents found that even this short examination was difficult. For example, 3·8% (10 parents) marked greater than 50 mm on the 100-mm VAS when recording how easy the examination was. There was a high correlation between ease of examination, speed of examination and helpfulness of advice. Parents who found the examination difficult did not find the advice helpful. This may reflect their own underlying dental anxieties. Alternatively, since the questionnaire was completed after the examination, it is possible that their negative experience may have affected their feelings about the advice given.

In the test group, parents generally found the examination, sealant placement and advice to be acceptable. Interestingly, the mean scores for sealant application (10·65 mm) are lower than for the ease of examination (16·79 mm). There was a highly significant difference regarding the ease of examination between the two groups. It may be that the placement of the sealants influenced the parents in the test group in their completion of this question. All the comparable mean scores are higher in this group than the control group, suggesting that the addition of sealants did make the visit slightly more difficult. However, the differences were small, the largest being the ease of dental check ups, where control and test group means were 11·27 mm and 16·79 mm, respectively. A minority of parents recorded high scores for all variables (82–88 mm). The ranges were similar to the control group, suggesting that the addition of the sealants did not make the procedures more difficult for these parents.

However, 59 (24·48%) parents did not complete the form. This is much higher than the control group, only five of whom (1·87%) did not complete

the paperwork. It is possible that the sealant visit forms were not handed out on all occasions for the parents to complete. At the start of the study, the fissure sealant visit took place at a separate second visit. After the first 8 months, the sealants were placed at the baseline visit, which was therefore longer, making it more likely that the paperwork was not completed. The more likely explanation is that these parents found the visit difficult and chose not to return the questionnaire. However, the drop-out rate from the test group was lower than the control group, so the procedure did not result in these families being lost. Indeed, only 20 children in the test group did not attend for follow-up.

At baseline, 51% of children were registered with a dental surgeon, but this figure had risen to 81% at follow-up. At both baseline and follow-up, unregistered families were asked if they wished a dental referral to be organized. At baseline, 121 families were referred on, the equivalent figure at follow-up was 24. Exact figures for attendance rates with the community dental service could not be identified since the families were referred to their nearest community clinic and not to a central list, but telephone calls to individual clinics were made by staff on the trial. This identified a high DNA rate for referred children: at least half never attended.

Conclusions

Recruitment of preschool children to this community trial was very problematic despite the assistance of enthusiastic HVs. It is likely that the resulting samples were biased in that they may not have represented the whole community from which they were drawn. Once recruited, the drop-out rate was very low, but a high number of visits were missed by the participants. These factors undermine:

1 the ability to introduce effective dental health promotion strategies in some deprived and mobile families;
2 the likelihood of reducing health inequalities in such a community; and
3 the validity of any research carried out within such communities.

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Résumé. *Objectifs.* Rapporter les difficultés à recruter des enfants pré-scolaires pour un essai clinique et rapporter l'acceptabilité par les parents d'une intervention dentaire.
Protocole. Essai randomise avec témoin.
Mise en place. Cliniques dentaires communautaires, centres de santé, domiciles des patients.
Echantillon et Méthodes. Des visiteurs médicaux ont été utilisés pour recruter 508 enfants âgés de 18 à 30 mois dans des zones à forte densité carieuse du sud du Pays de Galles. Les enfants avec premières molaires temporaires indemnes de carie ont été inclus dans un RCT témoin placebo individuel de scellement de sillons. Tous les enfants ont reçu un ensemble standard d'éducation à la santé dentaire. Les premières molaires temporaires des enfants du groupe test ont été scellées à l'aide verre ionomère. Tous les enfants ont été revus une fois. Il a été demandé aux familles de ratifier l'acceptation des procédures.
Résultats. Les visiteurs de santé ont adressé 1228 enfants pour évaluation. Seulement 547 ont été vus (44,5%) et 508 recrutés pour l'essai. Parmi ceux-ci, 449 (88,4%) ont été suivis. 667 enfants ont manqué 1610 visites initiales, 373 des enfants recrutés ont manqué un rendez-vous. Lors du suivi, 1056 rendez-vous ont concerné 449 enfants. Les 3/4 des parents ont rapporté que l'examen était très facile.
Conclusions. Les enfants pré-scolaires sont difficiles à recruter pour des essais communautaires. Les examens dentaires et les scellements de sillon ont été acceptés par la majorité des familles vues.

Zusammenfassung. *Ziele.* Darstellung der Probleme der Rekrutierung von Vorschulkindern für eine klinische Studie und Bericht der Akzeptanz einer zahnmedizinischen Behandlung für Eltern.
Design. Kontrollierte Studie.
Setting. Kommunale Behandlungseinrichtungen, Praxen und häusliche Umgebung.
Stichprobe und Methoden. Gesundheitsbetreuer wurden beauftragt, 508 Kinder im Alter von 18 bis 30 Monaten in einer Gegend mit hohem Kariesaufkommen in Südwales zu rekrutieren. Kinder mit kariesfreien ersten Milchmolaren wurden in eine placebokontrollierte randomisierte klinische Studie von Fissurenversiegelungen einbezogen. Alle Kinder erfuhren eine einheitliche Zahngesundheitsunterweisung. Die Kinder der Testgruppe bekamen die ersten Milchmolaren mit Glasionomerzementen versiegelt. Alle Kinder wurden einmalig nachuntersucht.

Die Familien wurden gebeten, die Annehmbarkeit der Maβnahmen zu bewerten.
Ergebnisse. Die Gesundheitsberater schickten 1228 Kinder zum Screening, davon wurden nur 547 (44.5%) vorstellig und 508 rekrutiert. Von diesen wurden 449 (88.4%) bei der Nachkontrolle gesehen. 667 Kinder versäumten insgesamt 1610 Termine der Baseline-Untersuchung, 373 der rekrutierten Kinder verpassten einen Termin. Zur Kontrolluntersuchung wurden 1056 Terminvereinbarungen erforderlich, um letztlich 449 Kinder untersuchen zu können. Drei Viertel der Eltern stuften die Untersuchung als sehr einfach ein.
Schlussfolgerungen. Vorschulkinder sind schwierig für kommunale Untersuchungen zu gewinnen. Zahnärztliche Untersuchung und Fissurenversiegelung waren für die Mehrheit der Familien akzeptabel.

Resumen. *Objetivos*. Informar de las dificultades experimentadas para reclutar preescolares para un ensayo clínico e informar de la aceptabilidad de la intervención dental a sus padres.
Diseño. Ensayo aleatorio controlado.
Lugar. Clínicas dentales comunitarias, centros de salud, domicilios de los pacientes.
Muestra y métodos. Se utilizaron visitadores sanitarios para reclutar 508 niños entre 18 y 30 meses de áreas con alto índice de caries del Sur de Gales. Los niños con los primeros molares primarios libres de caries entraron en un placebo controlado individualmente RCT de selladores de fisuras. Todos los niños recibieron un paquete estándar sobre educación en salud dental. Los niños en el grupo del test tenían los primeros molares primarios sellados con ionómero de vidrio, todos los niños se revisaron una vez. A las familias se les pidió valorar el grado de aceptación de los procedimientos.
Resultados. Los visitadores sanitarios refirieron 1228 niños para examinar, sólo se vieron 547 (44,5%) y 508 se reclutaron para el ensayo. De estos 449 (88,4%) se vieron en el seguimiento. 667 niños omitieron 1610 visitas basales, 373 de los niños reclutados omitieron una cita. En el seguimiento de 1056 citas se reclutaron para revisar 449 niños. Tres cuartas partes de los padres informaron que el examen era muy fácil.
Conclusiones. Es difícil que los niños preescolares accedan a ensayos comunitarios. Los exámenes dentales y la colocación de sellador fueron aceptados por la mayoría de familias vistas.

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