SWAT 217: Enhancing recruitment to the CHOICE trial in irregular dental-attending children via a dental nurse-led school outreach activity

Objective of this SWAT
To assess the effects on recruitment of adding a family oral health toolkit to the motivational letter to promote engagement of harder to reach families (i.e., those who are none or irregular dental attenders) in the CHOICE trial for children attending nursery and primary school.

Study area: Recruitment
Sample type: Participants
Estimated funding level needed: Very Low

Background
Achieving recruitment targets and widening access for all eligible participants is a common challenge in dental clinical trials.[1] Therefore, we plan to put in place additional measures (motivational letter with or without a family oral health toolkit) from the outset of recruitment to the CHOICE trial (ISRCTN87811904) and to evaluate these measures over the first six months of the trial, alongside its internal pilot.

At the moment, widespread and effective long-term screening of children's oral health in school is not undertaken in England and Northern Ireland.[2,3] In England, biennial surveys of the dental health of children aged 5 years are conducted according to a national protocol and co-ordinated by Public Health England. From 1985-2007, these surveys took place under a nationally co-ordinated programme in which children were examined under a passive consent process: an information letter was sent to parents advising of the survey and allowing them to withdraw their child if they wished, but explicit parental consent was not sought. Participation rates were 75% and above. From 2007/08, the Department of Health's guidance changed to a requirement for positive parental consent for dental surveys.[4] The process of recruitment to screening of children's oral health remained by letter to parents through schools, with one reminder advised but, to undertake the dental examination, a signed return is required from parents. In 2017, the proportions of parents of 5-year-olds who consented and whose children received dental examinations for the National Dental Epidemiology Programme were 52% in Essex, 51% in Liverpool and 56% in Leeds. Only 6% of parents declined to participate, and absenteeism on the day of examination was low at 3%, but the most common reason for non-participation was non-response (32%).[5] When this change to parental consent was introduced, studies were done to compare strategies for maximising consent rates for the dental surveys but these found no differences and concluded that further research was needed.[6]

A range of possible strategies have been identified including greater promotion of the surveys to school head teachers, teachers, parents and pupils; reminder contacts; and having a member of the survey team coordinate and closely monitor the recruitment process.[1] Taking the above into account, recruitment of the target population to clinical trials is particularly challenging especially when reaching diverse communities. A systematic review of studies of recruitment and retention to randomised trials involving children identified several barriers.[1] These included younger parents, those from a low socio-economic status and ethnic minority background as well as those who had completed less education. However, inconsistencies across the studies mean that these characteristics do not necessarily predict recruitment and retention into randomised trials, but the review authors did recommend exploring the process of participation for families in these groups. Against this background, we recognise the challenges of recruitment to the CHOICE trial, with many children who develop dental caries having sporadic attendance at dental practice and often only attending when acute problems arise when limited treatment options are available.

Interventions and comparators
Intervention 1: Parents or primary caregivers of potential participants are sent a motivational letter and a voucher for a family oral health toolkit (containing Kitten's First tooth storybook, toothbrush, toothpaste) to be redeemed at the first dental visit for each child; delivered to home via school with the motivational letter for parents and primary caregivers encouraging a visit for a dental check-up.
Intervention 2: Parents or primary caregivers of potential participants are sent a motivational letter to encourage attendance for a dental check-up, without the voucher for a family oral health toolkit.

Index Type: Method of Randomisation

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: (1) response rate of attendance for a dental check-up in potential participants who are none or irregular attenders, and (2) proportion of potential participants who consent to join and are recruited into the CHOICE trial.
Secondary: participant-reported experience of recruitment to the trial.

Analysis plans
The primary analysis will compare attendance for a dental check-up and consent/recruitment into the CHOICE Trial between the SWAT intervention groups. Interviews with participants will be analysed using Reflexive Thematic Analysis.[7]

Possible problems in implementing this SWAT
Some dental practices may not have the capacity to take on new child dental patients.

References
1. Robinson L, Adair P, Coffey M, et al. Identifying the participant characteristics that predict recruitment and retention of participants to randomised controlled trials involving children: a systematic review. Trials 2016;17:294.
2. Arora A, Nagraj SK, Khattri S, et al. School dental screening programmes for oral health. Cochrane Database of Systematic Reviews 2022;(7):CD012595.
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4. Davies G, Jones C, Monaghan N, et al. The caries experience of 5 year-old children in Scotland, Wales and England in 2007-2008 and the impact of consent arrangements. Reports of co-ordinated surveys using BASCD criteria. Community Dental Health 2011;28:5-11.
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6. Glenny A, Worthington HV, Milsom KM, et al. Strategies for maximizing consent rates for child dental health surveys: a randomised controlled trial. BMC Medical Research Methodology 2013;13:108.
7. Braun V, Clarke V. Reflecting on reflexive thematic analysis. Qualitative Research in Sport, Exercise and Health. 2019;11(4):589-97.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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