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Impact of providing free preventive dental products without health workers' counselling on infants' tooth-brushing and bottle-feeding termination practices: a randomised controlled trial

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Objectives: To investigate the impact of an integrated oral health promotion intervention, within the Syrian national immunisation programme, which provided free preventive dental health products, without health workers' counselling, on one-year-old infants' tooth-brushing and bottle-feeding termination practices. ***Research design:*** a randomised controlled parallel-group trial. ***Setting:*** A maternal and child health centre in Sweida city, Syria. ***Participants:*** 92 mothers of one-year-old infants, attending an infant vaccination clinic, were allocated into three groups: Test, Control One and Control Two. ***Interventions:*** The Test group received an oral health promotion package including an infant oral health pamphlet, a baby toothbrush, fluoride toothpaste (1,000 mg/L) and a trainer cup, without health workers' counselling. Control One received only the pamphlet, whilst Control Two received no intervention. ***Main outcome measures:*** after one month, the presence of old plaque on infants' primary teeth was checked, to assess tooth-brushing behaviour. Also, a mothers' self-completed questionnaire was administered to assess bottle-feeding use. ***Results:*** The response rate was 100% and the attrition rate was zero. There were differences in tooth-brushing and bottle-feeding termination practices between the three groups ($P>0.001$). Infants in the Test group were less likely to have old plaque and more likely to stop bottle-feeding than their counterparts in the two control groups. There were no differences in the abovementioned outcomes between the two control groups. ***Conclusions:*** Providing free preventive dental health products, without health worker's counselling, in an integrated oral health promotion intervention, was an effective measure to promote infants' tooth-brushing and bottle-feeding termination practices. These findings should be supported by long-term follow up studies.

Key words: *health promotion, national health programs, health care costs, infant, health behaviour, prevention, dental caries, Syria.*

Introduction

Establishing tooth-brushing practice at an early stage in life, together with the use of fluoride toothpaste and appropriate bottle-feeding practice, have been one of the most effective measures to prevent early childhood caries (ECC) (Department of Health and BASCD, 2009; PHE, 2014). Oral health promotion programmes, aimed at reducing ECC, for under five-year-olds, have invariably involved establishing good tooth-brushing practice with the use of an appropriate fluoride toothpaste. The conceptual framework of these programmes was based either on the health belief model/theory of reasoned action (Ajzen and Fishbein, 1980; Rosenstock *et al.*, 1988) or the precede-proceed theory (Green and Kreuter, 1991). Programmes that were based on the health belief model/theory of reasoned action (e.g. Kowash *et al.*, 2000; Mohebbi *et al.*, 2009) aimed to establish desirable child's tooth-brushing practice by changing parents' knowledge, beliefs and attitudes about child oral health and tooth-brushing, through dental health education. Whereas, programmes that were based on the precede-proceed theory (e.g. Ellwood *et al.*, 2004; Whittle *et al.*, 2008) included, besides the aforementioned dental health education, an additional element to achieve desirable child's tooth-brushing practice, which is providing enabling resources (e.g. free or subsidised baby toothbrush and fluoride toothpaste) to support parents in adopting good child's tooth-brushing practice.

Methods of delivering child's dental health education have included: printed materials (e.g. Davies *et al.*, 2005), videos (Weinstein *et al.*, 2006), on-site talks (e.g. Vachirarojpisan *et al.*, 2005), phone counselling (Plutzer and Spencer, 2008), and/or motivational interviewing (e.g. Wagner *et al.*, 2014). Enabling resources have included free-of-charge (e.g. Ellwood *et al.*, 2004) or subsidised (Wennhall *et al.*, 2008) baby toothbrushes, fluoride toothpastes and trainer cups (Davies *et al.*, 2005). The people delivering the education have included dentists (e.g. Kowash *et al.*, 2000) or health workers (e.g. Mohebbi *et al.*, 2009), such as health visitors (Whittle *et al.*, 2008). Some studies reported the impact of posting the materials to the mothers (e.g. Ellwood *et al.*, 2004). The settings for such programmes have also varied and included: child's health care settings (e.g. Vachirarojpisan *et al.*, 2005), outreach community settings (Wennhall *et al.*, 2008), infants' homes (e.g. Wagner *et al.*, 2014), and dental practices (Blinkhorn *et al.*, 2003). Another variation has been the timing of the programme delivery, which has ranged from, pregnancy (Plutzer and Spencer, 2008),

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after baby's birth (Wagner *et al.*, 2014), to the time of first tooth eruption or shortly after that (e.g. Weinstein *et al.*, 2006; Whittle *et al.*, 2008). The number of contacts between the educator and the mother has also varied from one (Wagner *et al.*, 2014) to multiple visits (e.g. Blinkhorn *et al.*, 2003; Ellwood *et al.*, 2004).

The published literature shows infant oral health promotion programmes had different effectiveness and financial implications. For example, the effectiveness of health education alone in achieving desirable oral health outcomes has been questioned (Kay and Locker, 1996). In addition, there is a growing consensus that integrated infant oral health promotion programmes within general health care programmes are more effective in accessing their target population (infants) than those run by dental care programmes and more likely to have an impact on reducing oral health inequalities (PHE, 2014). Such integrated programmes share the costs of manpower and training with other health and social programmes in order to maximise the value of investment in terms of oral health improvement for spend. Yet, the cost of securing and training suitable health workers to deliver the counselling and interviewing aspects might still constitute a financial burden working against introducing and sustaining programmes on a large scale in lower middle and low income countries. Thus, developing integrated infant oral health programmes without the aforementioned cost implications of human resource could be of paramount importance. However, no evidence is available regarding the effectiveness of such programmes in establishing desirable infant oral health behaviours.

Syria, like many lower middle and low income countries, has a high prevalence of ECC, from 74% in 1991 (Beiruti and van Palenstein Helderman, 2004), 82% in 2007 (Shaheen, 2007) to 86% in 2013; with a recent dmft value of 7.7 (SD=4.9) (Abedallah, 2013). This presents a great need for developing an integrated low cost infant oral health promotion programme. Thus, the current study aimed to test the effectiveness of an integrated oral health promotion intervention within the Syrian national immunisation programme, which delivered a printed dental health education material (an infant oral health pamphlet), a baby toothbrush, fluoride toothpaste (1,000 mg/L) and a trainer cup, without health workers' counselling, in establishing one-year-old infants' tooth-brushing and bottle-feeding termination practices.

Materials and Methods

Ethical approval was obtained from the Damascus University Faculty of Dentistry Research Ethics Committee and the Syrian Ministry of Health. Written consent was obtained from mothers. At the end of the trial, both of the control groups received oral health promotion packages. The trial's registration number is NCT02200536 and the protocol is available at https://clinicaltrials.gov/ct2/show/NCT02200536.

The randomised controlled parallel-group trial allocated equal numbers of mother-infant pairs to the trial's three groups (arms) from recruited mothers with one-year-old babies attending a baby vaccination clinic, in a maternity and child health centre in Sweida city, Syria. The trail included infants who were healthy, single (not twins), full-term (≥37 weeks), with a birth weight ≥2.5kg and a family size of three children or fewer (including the infant), and had their first tooth erupted with no reported tooth-brushing practice.

The Test group received an oral health promotion package including an infant oral health pamphlet, a baby toothbrush, fluoride toothpaste (1,000 mg/L; 1,000 ppm) and a trainer cup. The Control One group received only an infant oral health pamphlet, while the Control Two group received no intervention. The infant oral health pamphlet was designed based on the evidence-based guidelines for prevention of caries in children aged zero to three years (Department of Health and BASCD, 2009). It covered different topics including bottle-feeding termination at one year, the use of a trainer cup and brushing baby's teeth twice a day with a smear of fluoride toothpaste (1,000 mg/L) since the first tooth is erupted (with illustrative photographs).

The study's primary outcome measure was the presence of old plaque on infants' primary teeth as a proxy measure of their tooth-brushing practice. The secondary measure was the stopping of bottle-feeding. These outcomes were measured at baseline and after one month by oral examination of the infants and a piloted mothers' self-completed structured questionnaire, respectively.

Previous trials had ECC as their primary outcome, therefore, it was not feasible to assess *a priori* the effect size for power calculation for the current study. A 10% difference in the presence of old plaque between the three groups was considered of clinical significance as a 10% difference is conventionally considered the smallest of epidemiological relevance. It was estimated that a sample of 270 infants, distributed in three groups (90 infants each), would detect such a difference by Chi-square test, at α of 5% and 80% power. As the current trial was the first of its type, a decision to terminate it was planned if larger differences than the expected were reported. A preliminary data analysis was planned when the sample size reached one third of the estimated size.

Infants were randomly allocated to Test, Control One or Control Two groups. The trail used a balanced blocked random method for allocation, stratified (blocked) by maternal educational level (the high level indicated post-secondary education, whereas the low level indicated secondary education or lower). A random table was used to generate the random allocation sequence. Sequentially numbered opaque sealed envelopes were prepared by one researcher (EJ) with enrolment and assignment to groups carried out by another researcher (MA).

Mothers were approached by a researcher (MA) in the waiting room before baby's vaccination. Inclusion/exclusion criteria having been checked, an informative letter explaining the study's nature and purpose was distributed to the mothers of selected infants. The random allocation was carried out and mothers were asked to complete a piloted structured questionnaire on socio-demographic background (maternal age, infant's gender, birth order, parents' working status, occupation as a proxy for social class, and educational level), infants' tooth-brushing practice (tooth cleaning frequency and tool and use of fluoride toothpaste) and bottle-feeding use (yes/no).

Infants' oral examinations, in knee-to-knee position (as recommended by the World Health Organization), was performed by the trained and calibrated researcher (MA) to detect the presence of old (dark blue coloured) plaque after applying a plaque disclosing solution (Plaqsearch) with an ear bud on infants' primary teeth. The presence of old plaque was reported as Yes or No. Headlamp and sterilised mouth mirrors were used under optimal conditions of cross-infection control. Both the infants' oral examination and mothers' questionnaire were performed and completed at baseline and at follow up. The follow up assessment after one month took place at the infant's scheduled 13-month vaccination visit. To assess the reliability of questionnaire-collected data, 10% of mothers were asked to complete the questionnaire again after the baby's vaccination.

Chi-square tests were performed to investigate the significance of differences in tooth-brushing and bottle-feeding termination practices amongst the study groups.

Results

The response rate was 100% with no mother dropping out of the study or changing the group that her baby was randomly allocated. Of the 92 infants randomly allocated, 32 were in the Test group and 30 each in the Control One and Control Two groups (Figure 1). The recruitment started in March and ended in May 2013, when a preliminary data analysis, as the sample size reached one third of the estimated sample size, showed statistically significant differences between the study groups. The current pilot intervention did not continue after the trial termination, as the intervention was funded by a higher education body to establish evidence for a larger scale programme run by relevant governmental departments. The reliability of questionnaire responses and the correlation between the presence of old plaque and reported tooth-brushing practice were both excellent (both rho=1).

The 92 infants included 33 (36%) males and 59 (64%) females. Overall, 53% were bottle- or both breast- and bottle-fed. Table 1 summarises the frequency of socio-demographic variables between the groups at baseline.

The differences in old plaque presence were statistically significant between the three groups (P>0.001) when comparing baseline and follow up (Table 2). At follow up, infants in the Test group were less likely to have old plaque on their primary teeth than those in the two control groups with no such differences found between the two control groups (P=0.640). A similar pattern was found in bottle-feeding termination with differences between the three groups (P>0.001) and infants in the Test group more likely to have their bottle-feeding terminated than their counterparts in Control One (P=0.010) or Control Two (P<0.001) groups but no differences between the two control groups (P=0.140) (Table 3).

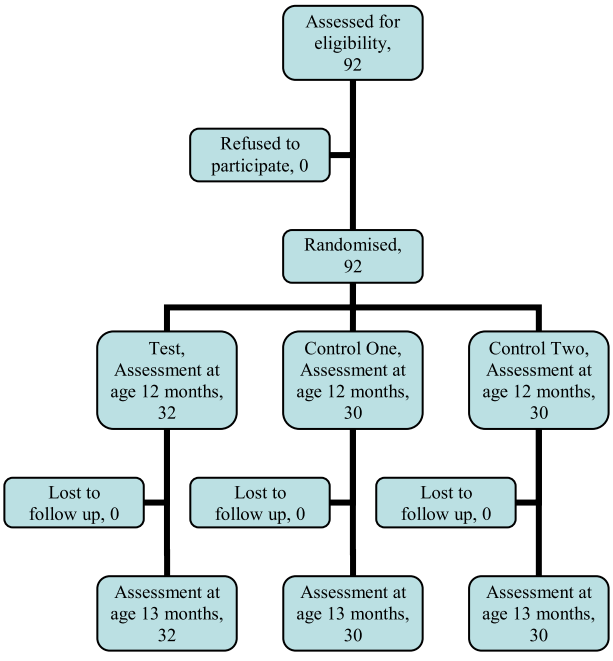

Figure 1. *Flow diagram of participation in the trial from the recruitment of infants through to the assessment at 13 months of age*

Table 1. Frequency of the socio-demographic variables of the current trial's groups, n (%)

Variable and Category	*Test group n=32*	*Control One n=30*	*Control Two n=30*
Infant's gender			
Male	13 (39%)	09 (27%)	11 (33%)
Female	19 (32%)	21 (36%)	19 (32%)
Mother's age			
≥ 30 years old	11 (25%)	16 (36%)	17 (39%)
<30 years old	21 (44%)	14 (29%)	13 (27%)
Birth order			
First	12 (33%)	9 (24%)	17 (43%)
Second or third	20 (36%)	21 (38%)	14 (26%)
Father's social class			
High	12 (27%)	17 (39%)	15 (34%)
Low	19 (43%)	12 (27%)	13 (30%)
Father's education			
Higher level	17 (38%)	15 (33%)	13 (29%)
Lower level	15 (32%)	15 (31.9%)	17 (36%)
Father's employment			
Working	31 (35%)	29 (33%)	28 (32%)
Not working	1 (25%)	1 (25%)	2 (50%)
Mother's employment			
Working	9 (41%)	7 (32%)	6 (27%)
Not working	23 (33%)	23 (33%)	24 (34%)

Table 2. Old plaque presence at baseline and after one month in the trial's three groups

	Baseline assessment			*One month assessment*			
	Test (n=32)	*Control One (n=30)*	*Control Two (n=30)*	*Test (n=32)*	*Control One (n=30)*	*Control Two (n=30)*	*P-value*
Old plaque presence, % of infants	100	100	100	9.4	90	93.3	<0.001

Table 3. Bottle-feeding practice at baseline and after one month in the trial's three groups

	Baseline assessment			*One month assessment*			
	Test (n=16)	*Control One (n=13)*	*Control Two (n=16)*	*Test (n=16)*	*Control One (n=13)*	*Control Two (n=16)*	*P-value*
Bottle-feeding practice, % of infants	100	100	100	18.8[1,2]	69.2[2]	93.8[1]	<0.001

See text for significance values for comparisons between individual groups.

Discussion

This study was the first to show the effectiveness of an integrated oral health promotion intervention, within an immunisation programme, which delivered a printed dental education material, a baby toothbrush, fluoride toothpaste (1,000 mg/L) and a trainer cup, without health workers' counselling, in establishing one-year-old infants' tooth-brushing and stopping bottle-feeding. The present study's intervention lends support, in infant oral health promotion, to the effectiveness of giving both dental health education and enabling resources (PHE, 2014).

The costs of the current study's intervention are only those costs of printing health education materials and purchasing equipment (baby toothbrushes, fluoride toothpastes and trainer cups), i.e. US$3.5 per child. In the view of the need for multiple rather than one-off delivery of toothbrushes and toothpastes (PHE, 2014), the expected cost of running a five year cohort with children having four deliveries per year would be approximately US$38 per child, in Syria. A similar low cost intervention, that is, giving free preventive dental health products without health workers' counselling, has been reported in the UK (Davies *et al.*, 2005; Ellwood *et al.*, 2004). However, the programme delivery was by post and was not integrated within an established health programme. Such an intervention relies on a reliable universal postal system so might not be applicable in the majority of lower middle and low income countries. As many of these countries have infant immunisation programmes, this study begins to build evidence on the value of integrating low cost oral health promotion interventions within their existing programmes.

The current study chose printed materials (pamphlet) to deliver its dental health education against other methods such as CDs/videos. This should be viewed within the context of lower middle and low income countries, where access to CDs or videos might not be widespread. Printed materials do though depend on the target group's literacy. All the study population were literate. Literacy among Syrian females aged 15 and above is relatively high (79%) according to the World Bank (2012) data. Yet, targeting the minority of illiterate mothers is fundamentally important and needs different dental health education approaches. The timing of the study intervention (at age one year) was chosen to overlap with first tooth eruption as well as the timing of baby's vaccinations (to facilitate their integration).

The present intervention included providing fluoride toothpaste. The latter might be the only vehicle that could provide Syrian infants with an access to fluoride. Implementing community-based water or salt fluoridation has to date not been possible in Syria, as in many other lower middle and low income countries (Sheiham and Williams, 2015). Whole population fluoride varnish and/or supplements would also be difficult in terms of securing the funding and human resources needed. Therefore, fluoride toothpaste seems to be the only feasible fluoride vehicle for infants in Syria and in many other lower middle and low income countries.

One of this study's potential limitations is related to its short-term follow up. Evaluating the sustainability of the established infant tooth-brushing behaviour was beyond the scope of the study. Nevertheless, it is expected that with multiple deliveries of toothbrushes and fluoride toothpastes, the established tooth-brushing behaviour is likely to continue as found on other studies, e.g. Vachirarojpisan *et al.* (2005) with a one year follow up. The study cannot rule out the possibility of information contamination between the two control groups, which might explain the lack of differences in desirable oral health practices between them. Infants were selected from the same centre in the waiting room. Yet, the observed similarity between the control groups agrees with the dental literature on the weak impact of dental health education delivered to mothers on establishing desirable infant tooth-brushing and/or dietary practices (Ammari *et al.*, 2007). Participant blinding was not feasible in this trial due to the nature of the intervention. Also, the examiner was not blind in the present study. However, to guard against any potential examiner bias, the study's data on the presence of old plaque were triangulated with the mother's reported infants' tooth-brushing practice. Indeed, there was an excellent agreement between the two measures. The decision to terminate the trial when larger differences were found might potentially affect the comparability of the study groups in terms of weakening the randomisation to distribute the potential confounding factors equally amongst the trials arms. Nonetheless, the differences in all socio-demographic variables amongst the study's groups were much smaller than the differences in the present study's outcome variables; confirming that the findings cannot be accounted for or confounded by socio-demographic factors. Finally, the findings of this study cannot be extrapolated to Syrian infants with different characteristics from those in the sample or whose mothers are illiterate.

The potential policy implications of the current study's findings pertain to designing a larger multi-centre project covering different geographical areas across the country to test the feasibility, effectiveness and cost-effectiveness of running such a population-based, integrated oral health promotion programme, within the national maternal and child's health programme, over a longer follow up timeframe, to reduce the growing burden of ECC in Syria.

In conclusion, an integrated oral health promotion intervention, within the Syrian national immunisation programme, which delivered a printed dental health education material, a baby toothbrush, fluoride toothpaste (1,000 mg/L) and a trainer cup, without health workers' counselling, was effective in establishing one-year-old infants' tooth-brushing and bottle-feeding termination practices. These findings should be supported by long-term follow up studies.

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