Cover Page

Official Title:

Effectiveness of visual pedagogy-assisted tooth-brushing training among preschoolers with special needs for oral health promotion

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Background

Children with special needs are those who have physical, mental, sensory, behavioral, emotional, and chronic medical conditions that requires health care beyond that considered routine and which involves specialized knowledge, increased awareness, attention, and accommodation (Saravanakumar, et al.,2013).

Previous studies showed that people with special needs, such as intellectual disability, had poor oral health (Yuki Oda, et al., 2015), exhibiting a higher risk of developing caries than normal individuals. Although sealant, fluoride, and oral hygiene maintenance are effective ways to prevent dental caries, 30% of mental impaired patients have never received dental treatment (Oliveira et al., 2013). Individuals with disability have a significantly reduced ability to understand new or complex information (Ayub M, et al., 2015), and it is hard for them to cooperate with dental treatment (Maeda S, et al., 2005). Blomqvist et al. also demonstrated that children with learning problems had significantly more dental behavior management problems compared with a control group (Blomqvist M., et al., 2004), which would make routine dental care less achievable, resulting in poor oral health and the progression of existing oral diseases (Chang et al., 2014). Most of the dental diseases are originated by plaque, and increasing numbers of studies about oral health promotions are focused on plaque control, such as utilization of antibacterial agents, and special cleaning devices. Among them, the mechanical means for plaque control are much safer and more practical (Garbin C., et al. 2009). In addition, Liu Z et al. showed that toothbrushing more than twice a day is one of the caries-protective factors experience in disabled children (Liu Z., et al. 2014). Toothbrush is a universally accepted method for oral hygiene promotion among children with special needs. However, majority of children show noncompliance toward brushing and they try to hide themselves from daily brushing task, because they considered it as tedious procedure and dislike the brushing (Ganesh M., 2012). As for children with special needs, the situation is much worse.

Researchers have used visual pedagogy to show a structured method and technique of tooth brushing by series of pictures. The pictures were placed in the bathroom or wherever tooth brushing was performed, and the visual pedagogy was proved to be a useful tool in helping children with special needs to improve their oral hygiene (Pilebro c., et al. 2005). Goyal S. et al. even showed that for mentally challenged individuals, manual toothbrushes reinforced with audio-visual instructions for brushing might be comparable to the use of powered toothbrushes (Goyal, S. et al. 2011).

However, to date there has been limited researches focused on the effectiveness of tooth-brushing assisted with visual pedagogy to promote oral health among special care communities. Community-based studies are necessary to provide reliable evidence to support or refute the interventions. In the proposed study, standard tooth-brushing training, along with a package of structured social stories illustrating the tooth-brushing procedure, healthy diets, and dental visit will be provided to preschool children with special needs. We hypothesized that oral-health related behaviours will be modified among children who receive visual-pedagogy (social story) -assisted tooth-brushing training, and thereby, their oral health status will be improved after intervention.

Method

Trial design

This study will be designed as a block-randomised controlled parallel blind clinical trial. Duration of the study will be 24 months.

Recruitment

Participants will be recruited from the Special Child Care Centers and Special Schools of The Spastics Association of Hong Kong (SAHK). Children aged from 2-6 years old with special care conditions such as Prader-Willi syndrome, intellectual disability (ID), autistic spectrum disorders (ASD), cerebral palsy (CP), Down's syndrome (DS), attention deficit hyperactivity disorder (ADHD), delayed development, or learning disorders will be invited to participant in this study. Consent form and information sheet will be delivered to children meet the above requirement. Only children with informed consent signed by parents will be recruited.

Exclusion criteria

Children manifested with at least one of the following conditions will be excluded from this clinical trial:

- Severe visually impaired
- Severe hearing impaired
- Severe physical disabled (cannot hold a toothbrush)
- Requiring emergent dental treatment
- Use of antibiotic within 3 months
- Dental prophylaxes in the last 6 months

Sample size calculation

The primary outcome is the development of new dental caries in the children over the 24-month study period. Based on the previous oral health promotion conducted among healthy preschool children in Hong Kong (Jiang M., 2013), the mean dmfs in control group and intervention groups are 0.3 (SD = 1.3), 0.2 (SD = 0.7), 0.4 (SD = 1.2). We assumed that the mean dmfs in control group and test group are 0.7 (SD = 1.0) and 0.3 (SD = 0.5). The program G* power 3.1.9.2 is used for sample size calculation: two-tail test, a =0.05, at a power of 95%. This give

a sample size target of 105 children per group. Considering 30% overestimation to allow for dropout in 2 years, totally 300 children will be invited, with 150 children per group.

Baseline information

Baseline information will consist of the following components:

- Clinical oral examination
- Tooth-brushing performance observation
- Questionnaire-based survey

Clinical oral examinations will be performed according to the following criteria: i) Caries status were assessed by the International Caries Detection and Assessment System(ICDAS); ii) Oral hygiene status by Simplified oral hygiene index of Greene and Vermilion (OHI-S); iii) gingival health status by Modified Gingival Index of Lobene (MGI). Dental examination will be performed at Special Child Care Centers by a pediatric dentist with a disposable mouth-mirror attached to an LED light. Tell- Show-Do (TSD) technique will be used to improve children's cooperation level. Tooth-brushing performance will be assessed by two observers. There will be 13 steps listed in the assessment form, steps which are performed by child or parent will be recorded respectively, as well as the total time for each tooth-brushing session. After dental examination and tooth-brushing assessment, a standard hands-on tooth-brushing training will be provided immediately to each child and his/her parent. Oral health instruction will also be illustrated to the participants, reinforced by social stories or conventional leaflets. Questionnaires regarding children's oral health related behaviours, family demographic information and parents' oral health literacy assessment will be completed by parents, while questionnaires assessing children's developmental profile will be filled by staff in Special Child Care Centers.

Allocation

Concealed block randomization at school levels will be used to allocate subjects into 2 group. The randomised sequence will be generated by an investigator who do not participate in the outreach service. The allocation sequence will be sealed in an envelope, and opened at the Special Child Care Centres by an assistant, who will also be responsible for delivering the materials to children and their parents. Hence, children (participant) and investigators (outcome assessor) will not know the randomised sequence. After a standard tooth-brushing training and oral health instruction, Group 1 will be set up as a positive control, receiving standard oral-health education leaflets issued by the local government, while Group 2 will act as test group, receiving social stories developed and validated by the investigators.

Follow-up appointments

Commercially available toothbrushes and fluoridated toothpaste will be delivered to each child and renewed at every three months. Meanwhile, the old toothbrush and remaining toothpaste will be returned, and toothpaste usage and toothbrush wear will be monitored. Follow-up assessments will be performed at 6-month, 12-month, 24-month. Education materials about "healthy diets" will be emphasized at 6-month follow-up, and dental-visit related education materials will be emphasized at 12-month follow-up. Tooth-brushing training was reinforced at each follow-up appointment. Education material about tooth brushing, healthy diets and dental visit will be illustrated to children and their parents, and parents will be encouraged to read those materials to their children in their daily lives. Oral examination and tooth-brushing assessment in follow-up appointment will be performed using the same methods and criteria as baseline; all parents or primary caregivers will complete a set of questionnaires on their attitudes towards the interventions and their children's oral-health related behaviours.

Significance

The present study will provide scientific evidence of effective oral health care for children with special needs. Meanwhile, the interventions adopted in the control group and test group have potential benefits to encourage the children with special needs to take care of themselves by learning tooth brushing independently at an early age status, supporting their relatively independent life in the future.

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