Title: A randomized controlled trial evaluating the efficacy of a peer-led theory-based intervention in promoting healthy oral behaviours among adolescents in Hong Kong

NCT number: NCT03694496

Document date: Feb 26, 2021

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STUDY PROTOCOL

a) Title:
    A randomized controlled trial evaluating the efficacy of a peer-led theory-based intervention in promoting healthy oral behaviours among adolescents in Hong Kong

b) Introduction:
    Poor oral health leads to poor general health and well-being
    Oral diseases draw much attention from researchers, health professions, and policy makers recently. Poor oral health has a profound effect on general health [1]. Oral disease has become one of the most common non-communicable diseases, as they affect people throughout their lifetime, causing pain, distress, and even death. Moreover, the oral disease has negative social impacts (e.g., stigma and social isolation [2]) and adverse consequences on quality of life [3], while their treatment places a considerable economic burden on individuals, communities, and countries.

    Investments in adolescent's oral health bring substantial and sustainable effects
    Oral health programs targeting adolescents can produce substantial and sustainable effects. Adolescence, as a transitional stage from children to adult, is a critical period to establish personality, develop knowledge/skills, and form healthy behaviour [4]. Thus, intervening in this critical period can produce substantial effects. In addition, investments in adolescent's health bring triple effects; as these investments protect the health of adolescents themselves at now, prevent health problems in their adulthood, and lay the foundations for their offspring's health in the future. Therefore, implementing interventions addressing determinants of healthy oral behaviours among adolescents has significant public health implications.

    Hong Kong adolescents are vulnerable to oral disease
    Hong Kong (HK) adolescents are especially vulnerable to oral diseases due to unmet service needs and unsatisfactory oral behaviours. Adolescents are at a risk for late diagnosis and treatment of oral diseases due to the discontinuances of free dental check-up service provided by HK government. Only primary school students (aged 6–11) in HK are eligible for free annual dental check-up. After being promoted to secondary school, students need to take care of their own dental health. A recent survey reported that two-thirds of HK adolescents did not visit dentists after promoting to secondary school [5]. Moreover, adolescent's service needs for oral diseases prevention is unmet due to a shortage of oral health care workers. HK has only 2224 registered dentists to serve a total of 7,374,900 residents (including 335,889 adolescents in secondary schools) [6]. The dentist to population ratio is about 1:3300, which is far from sufficient. The Faculty of Dentistry of the University of Hong Kong is the sole local university to provide 6-year undergraduate training in dentistry, and specialty training requires at least a further 6 years. In such circumstance of lacking professional dentists, oral health prevention and promotion to the public becomes essential in addressing the dental health needs.

    Healthy oral behaviour among HK adolescents is unsatisfactory. For example, dental flossing has not become part of adolescents' daily practice; that only 6.8% of 12-year students used dental floss daily [5]. Tooth brushing, as an effective and easily sustained healthy oral behaviour, is also unsatisfactory; that there were 30% of adolescents reported tooth brushing less than twice a day [5]. These poor oral behaviours cannot prevent oral diseases effectively.

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As a result of the above vulnerabilities, HK adolescents are at a high risk of oral diseases and associated consequences. It was quite disappointing that less than 40% of HK adolescents (13-18 years old) were caries free and less than 10% had 'healthy' periodontal status. The prevalence of severe periodontitis increased progressively from 42% in 12 years through 56% in 15 years to 68% in 18 years old [7]. Oral diseases also substantially affected children's and their families' oral related quality of life, such as missing school due do pain or treatment, avoiding smiling and being teased by peers, and parent's feeling of upset, frustrated and guilty [8]. Overall, these susceptibilities to oral diseases among HK adolescents highlight their needs for oral health promotion programs.

Existing evidence on interventions to promote oral health
A recent Cochrane review (2016) identified several community-based oral health promotion interventions under a range of health promotion strategies (e.g., educational activities, supervised tooth brushing programmes, motivational interviewing) targeting children [9]. The majority of the previous oral health interventions were health education in nature. These educational programs were able to produce short-term improvements in oral health knowledge, but they had limited effects on behavioural and clinical outcomes [10].

In addition to oral health education, motivational interviewing (a patient-centered approach focusing on building intrinsic motivation for change) was a newly developed strategy and was found to be more effective than health education strategy in eliciting positive changes in adolescents' oral health behaviours [11]. Each participant joined a one-by-one, face-to-face motivational interviewing session with an expert at first; then they received five follow up telephone calls from the expert to maintain the change and avoid relapse. Although effective, this motivational interviewing strategy was an expensive one as it took much time to complete the first interviewing one-by-one and required follow up calls to sustain the effect. The cost-effectiveness of the motivational interviewing strategy was not fair enough.

Local organizations in HK also make great efforts in promoting oral health among children and adolescents. The Oral Health Education Unit, Department of Health, the Government of HKSAR [12] is the main body which aims at promoting oral health to the public through educational and promotional activities. The majority of the current services target at primary school children (e.g., School Dental Care Service), not secondary school adolescents. Notably, this unit started a "Teens Teeth Programme" that aimed at promoting oral health among secondary school students in 2005. This program enrolled S1 students and focuses on reducing gum bleeding and supporting flossing habit. However, a wider range of oral diseases and behaviours (e.g., dental visit for check-up) need to be covered, and S1 students might have limited capacity in conducting health promotion programs as leaders. Overall, despite the great efforts that health professionals and governmental officers have made to improve oral health among adolescents, the prevailing oral health needs among HK adolescents are still unmet. Specific oral health promotion programs targeting adolescents are still needed.

Theory-based intervention to modify adolescent's cognitions
Healthy oral behaviours can prevent oral diseases to a large extent, and cognitions play an increasingly important role in affecting oral behaviours among adolescents [13]. Previous studies have found a variety of cognitive variables that were associated with oral behaviours, such as self-efficacy, perceived benefits, and cues to action (e.g., a recommendation from dentists) [14].

Cognitive factors orientated by behavioural theories would be most effective in changing oral behaviours. Various theories have been applied to explain oral behaviour, including Theory of Reasoned Action, Health Belief Model, Health Action Process Approach, and Theory of Planned Behaviour (TPB) [14]. The health belief model (HBM) and the social cognitive theory (SCT) has been used to develop effective interventions to change health-related behaviours [15].

HBM is a psychological health behaviour change model which is developed to explain and predict health-related behaviours [16]. It prescribes that perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action. A recent addition to the HBM is the concept of self-efficacy, which indicates one's ability to successfully perform an action. Perceived susceptibility is defined as one's opinion of chances of getting a condition. Perceived severity refers to one's opinion of how serious a condition and its sequences are. Perceived benefits refers to one's belief in the efficacy of the advised action to reduce risk or seriousness of impact. Perceived barriers indicates one's opinion of the tangible and psychological costs of the advised action. Cues to action are strategies to activate the readiness and stimulate overt behaviour. Self-efficacy denotes the confidence in one's ability to take action. Instruments based on the HBM has been validated and used to explain and predict oral health habits, oral hygiene, and periodontal parameters [17].

SCT is a learning theory based on the concept that people learn by observation. The theory deals with cognitive, emotional aspects and behavioural aspects for understanding behavioural change. Meanwhile, it provide ways for new behavioural research in health education [18]. The core concepts of this theory is reciprocal determinism which contains the following three determinants:
  (1) Personal: Whether the individual has high or low self-efficacy toward the behaviour.
  (2) Behavioural: The response an individual receives after they perform a behaviour.
  (3) Environmental: Aspects of the environment or setting that influence the individual's ability to successfully complete a behaviour [19].

HBM and SCT have been widely applied in various behaviours including oral health related behaviours [18, 20, 21]. Consistent findings have been reported that the core contents of these theories were all associated with healthy oral health related behaviours (e.g., tooth brushing). However, most of the previous applications were in cross-sectional studies, and the clear paths among cognitions, behavioural intention, and behaviours were less explored and confusing. Considering the wide application of HBM and SCT in the adolescent population [20, 21], further testing on its applicability with a longitudinal design among adolescents is promising.

Peer-led programs to modify adolescent's cognitions
Peer-led health promotion programs have been widely implemented among the adolescent population. Its effectiveness in promoting adolescents' health has been proved with strong evidence [22]. For example, peer-led programs improved adolescent's health through reducing smoking, providing nutrition education and preventing risky sexual behaviours [22].

Peer-led health promotion programs have advantages over teacher-led programs or researcher-led programs. Compared to teachers/researchers, peers are more successful than teachers in passing on information because of their "insider" point of view [23]. Peers are also considered as a credible source of information. Moreover, peer leaders act as positive role models, which is an important component of the learning process (supported by Social Learning Theory). The successful experience of peer leaders helps their classmates to build up confidence, which is necessary to initiate behaviour change.

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As one important component in providing peer support, the peer-led program is perfectly applicable to the adolescent population. Erikson's Psychosocial Development Theory states that, at the stage of adolescence, adolescents try to achieve a sense of identity regarding who they are and where their lives are headed. Peer leader functions as a real-world model and helps to build up a sense of identity or belonging. Such recognition makes the peer-led program more likely to achieve a profound effect on adolescents. Moreover, HK adolescents are under enormous stress [24] due to heavy load inside and outside of schools. Peer support is beneficial to help adolescents to cope with such stresses. Thus peer-led program with peer support has great potential to improve adolescents' health, including oral health.

Knowledge gap identified

In summary, HBM and SCT are the most promising cognitive theory used to modify healthy oral behaviours, and peer-led health promotion programs are of highest effectiveness and feasibility. However, there is no previous study incorporating these two effective intervention components into one single study among adolescents. The efficacy of such kind of novel intervention has never been investigated in the domain of oral health.

The current study aims to fill this gap by testing the efficacy of a peer-led theory-based intervention in promoting healthy oral behaviours among adolescents in Hong Kong. With the longitudinal data, we are able to test a wide range of different (direct and indirect) effects and pathways, which is exactly the current case of involving personal cognitions, behavioural intentions, oral behaviours, and clinical oral health outcomes.

c) Aims and Hypotheses to be Tested:

Objectives

1) The primary aim is to evaluate the relative efficacy of a peer-led theory-based intervention in promoting healthy oral behaviours versus the control (normal practice) on increasing the prevalence of healthy oral behaviours (tooth brushing, dental flossing, and dental visit for check-up) among adolescents in Hong Kong;

2) The secondary aim is to evaluate the relative efficacy of the intervention and control groups in affecting clinical oral health outcomes, including dental caries and periodontal health;

3) The third aims are to evaluate the relative efficacy of the intervention and control groups in affecting secondary outcomes of thoery-based constructs including

i) increasing perceived susceptibility towards oral diseases,

ii) increasing perceived severity towards oral diseases,

iii) increasing perceived benefits towards healthy oral behaviors,

iv) reducing perceived barriers of performing oral health behaviors,

v) provide cues to action related to oral health behaviors,

vi) build self-efficacy of performing oral health behaviors,

vii) provide social support and professional support of oral health knowledge,

viii) increasing outcome expecatations towards healthful oral behaviours.

Hypotheses

1) The hypothesis involving clinical oral health outcomes is that a lower prevalence of dental caries and better periodontal health status will be found in the intervention group than in the control group.

2) The hypothesis includes that a higher prevalence of healthy oral behaviours (of any type) will be found in the intervention group than in the control group.

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3) The hypothesis based on the third outcomes states that the intervention group as compared to the control group will have a higher score in positive theory-based constructs towards healthy oral behaviours

d) Plan of Investigation:
(i) <u>Subjects</u>

S2 students as the target population

Healthy oral behaviours should be formed at an early age. Therefore, adolescents in secondary schools are the target population. HK implemented new senior secondary curriculum (3+3) since September 2009; that three years from S1 to S3, and then three years from S4 to S6. S1 students are in a transitional period from primary school to secondary school, which requires adaptions. S3 students need to study most subjects in order to choose their discipline. S4-S6 students are at their benchmarks, and they need to make great efforts to prepare for exams. Therefore, S2 students are believed to be the most appropriate subpopulation to be enrolled in health promotion studies.

Inclusion criteria

Inclusion criteria for participants are 1) S2 students at the baseline recruitment (September, 2018 as the start), 2) agree to voluntarily participate, and 3) do not intend to leave Hong Kong within the next 12 months since the baseline survey. Adolescents who have cognitive impairment will be excluded.

Participants recruitment

We plan to recruit participants from secondary schools (all children are required to attend secondary school since the year 2009 by law). HK schools will be the primary sampling unit, then all S2 students in the selected schools will be recruited into this study. We will seek approval from Principle of each selected school first; then we will ask for written consents from students and their parents/caregivers. Schools that are currently receiving other oral health promotion programs will be excluded.

Sample size calculation

Sampling method for cluster randomization design will be used. There is around 110 S2 students in each secondary school, according to the data published by Education Bureau that the student's size is an average of 664 in each secondary school (a total of 335,889 secondary school students divided by 506 schools) [6].

Tooth brushing is the most important primary outcome indicator in the current study. Previous studies among adolescents in Hong Kong reported that the prevalence of tooth brushing (twice a day) was around 80% [5, 25, 26]. Given that our intervention aims to increase 20% of this baseline level, a total of nine schools (six to the intervention and three to the control, school ratio = 1:1) are needed, with the power and significance level set at 0.80 and 0.05 respectively (PASS 25) [27]. Average cluster size is assumed to be 65 (due to the participation rate is around 60%) and intra-cluster correlation coefficient is set to be 0.05 [28]. As a result, sample size of each group should be 291 [28]. Account for 85% drop-out rate, at least 688 S2 students totally should be recruited into this study (6*65=390 in the intervention group and 6*65=390 in the control group).

These twelve schools will be randomly selected from all schools, selecting four schools from each of the three regions (Hong Kong Region, Kowloon Region, and New Territories Region) of HK. As the peer-led intervention activities are open to all students (but limited to S2) in the selected schools, a total of 3984 students will be exposed to these activities (an average of 664 students from S1-S6 in each school and 6 schools in the intervention group [6]).

(ii) Methods

Pilot study

The questionnaire was developed by following the guideline of SCT and HBM [29-33]. A panel, consisting of a registered specialist in dentistry, a behavioural scientist, and an epidemiologist, held several meetings, and eliminated some overlapping items while combined others with similar meanings. 5 secondary school teachers, 5 dentists and 10 S2 students were invited to examine the face validity of the questionnaire. After this panel's refinement, the questionnaire was validated among our target population, 30 S2 students.

In the pilot study, the average item response rate was 93.3%, and the item mean ranged from 1.7 to 3.9, suggesting satisfactory acceptance and variance. The questionnaire took 15-20 minutes to complete. All students had a sufficient understanding of the items and found the questions not difficult to answer.

Exploratory Factor Analysis identified three factors (perceived benefits, perceived barriers and perceived severity) of HBM and two factors (self-efficacy and behavioural capability) of SCT. These factors accounted for 86.63% of the total variance. Cronbach's alpha coefficients were 0.74, 0.84, 0.86 for items of HBM and 0.96, 0.74 for items of SCT. Item-total and item-subscale correlation coefficients were also satisfactory (ranging from 0.62 to 0.94, all $p<0.05$).

(iii) Study design

Baseline survey and dental examination

The baseline survey will collect information on participants' background characteristics (e.g., socio-demographics), theory-based variables (perceived benefits, perceived barriers, perceived severity, self-efficacy and behavioural capability), and oral health behaviors. Validated scales have been identified and will be used in the survey [34, 35].

To comprehensively assess each participant's oral health status at baseline, their caries experience and periodontal condition will be recorded following the recommendations of the World Health Organization (WHO) for oral health surveys [36]. Oral hygiene status will be recorded through plaque index (PI) (Quigley Hein, 1972) on a scale of 0 to 5. Dental caries experience will be recorded by counting the numbers of permanent teeth that are decayed (DT), missing due to caries (MT), and filled (FT) to generate a DMFT score. Periodontal condition will be recorded using the Community Periodontal Index (CPI). Two trained and calibrated examiners (kappa = 0.81 - 0.87 for intra- and inter-examiner reliabilities for the assessment of DMFT and CPI) will perform the clinical examinations using a plane disposable plane intra-oral mirror with a built-in LED light source and a WHO CPI periodontal probe. Ten percent of the participants will be randomly selected and re-examined in each school to continuously monitor intra- and inter-examiner reliabilities of assessing PI DMFT and CPI.

Randomization

Twelve selected schools will be randomly allocated into the intervention group and control group (intervention/control = 1:1) by having sealed opaque envelops drawn by the research staff. Six intervention schools will receive the peer-led theory-based intervention programs during a 6-month period. Six control schools will continue their present practice and receive oral health pamphlets only, such as oral health education class (if any).

Introduction of the peer-led theory-based intervention

a. Peer leader: selection and training

We plan to select 2-8 peer leaders in S2 students within each school in the intervention group. A total of 25-48 peer leaders will be selected and trained in this study. Students who meet these criteria will be considered as a priority: 1) demonstrate strong leadership, 2) have a willingness to participate in the training, 3) have prior experience to be a peer leader

An experienced behavioural scientist will train the peer leaders through lectures, workshops, and individual counselling. A variety of topics will be covered by the training, including

1) knowledge and skills related to oral health,
2) adolescent's development and characteristics (e.g., Erikson's Psychosocial Development Theory),
3) introduction of SCT and HBM,
4) knowledge and skills related to peer leading,
5) how to conduct peer-led programs, and
6) how to improve illness representations towards existing oral diseases (guided by Common-Sense Model of illness representations [37, 38]).

A total of 6 hours training (3 hours per day x 2 days) will be conducted during weekends. Peer leaders will practice in groups, and only those who pass the evaluation are allowed to conduct peer-led interventions. We will record the performance and give specific feedback to each peer leader.

b. Contents of the intervention activities

A total of five peer-led activities will be conducted in the intervention schools by the well-trained peer leaders within a 6-month intervention period.

1) In the 1st month of intervention, peer leaders will deliver a poster and a leaflet providing information on healthy oral behaviors based on SCT and HBM. Such materials will be provided at the entrance of the school gate, the canteen, and each class. Peer leaders will encourage students to ask questions when they receive such materials. Participants are free to take an on-site quiz to check assess their knowledge level,
2) In the 2nd month of intervention, peer leaders will give a specific health talk aiming to raise the awareness of healthy oral behaviors. Schools teachers will encourage all students to participate in this talk. We will video-record this health talk and make it available online to reach more students. This talk will be guided by SCT and HBM, and it will include short testimonials of the good experiences of the peer leaders when performing healthy oral behaviors,
3) In the 3rd month of intervention, peer leaders will organize a workshop aiming to help the participants practicing skills in performing healthy oral behaviors. Regarding different oral behaviors (tooth brushing, dental flossing, and dental visits), targeted skills will be practiced, and

4) In the 4th month of intervention, peer leaders are encouraged to self-design and conduct one more oral health-related activity that they are interested. Necessary support will be provided by the team. We will record details of this peer leader-initiated activity.

5) In the 5th or 6th month of intervention, peer leaders will deliver a special talk regarding illness representations for students with existing oral diseases only. The talk will focus on improving illness representation in both cognitive and emotional aspects, and coping strategies will be practiced.

The exact timeslots to conduct the above activities will be decided during discussion with the peer leaders themselves to ensure feasibility and the minimum interruption on their study. However, activities are highly encouraged to be conducted at a monthly frequency.

As a friendly reminder, all S2 students in the intervention group will get a text message from their teachers about the activity details (e.g., place, main theme) from the school one day before each activity will be conducted. Participants will get a stamp from the peer leader after completing each activity. We will use this stamp record to reflect the actual number of intervention activities that the participants are successfully involved.

c. Intervention materials development
All the materials needed in the activities will be designed by an expert panel, including a behavioral scientist, a health psychologist, an epidemiologist, and a registed specialist in Pediatric Dentistry. The development of such materials will be mainly guided by SCT and HBM [18, 31]. Our team is experienced in materials development, and our previous work has been well acknowledged and disseminated in multiple settings, such as clinics, kindergartens, and primary schools.

d. Conditions in the control group
Participants in the control group will continue their present practice, and no additional interventions will be given except for pamphlete delivery. We will keep a record of their present practice in detail. Because control groups and intervention groups are in different schools, so the chance for them to get access to the peer-led activities conducted in the intervention group is very low. Contamination would be quite minimum.

The first follow-up at months 6
The first follow-up at months 6 will include two parts. The first part is to collect participants' self-reported data through survey. An experienced fieldworker who are blind to group allocation will facilitate the survey process. The data collected at month 6 indicates an immediate impact of the intervention, as all the intervention activities will be conducted within this 6-month intervention period. The proposed time interval (6 months) is reasonable and feasible, as 6 months is the most frequently adopted time point to evaluate behaviour changes and the dental visit for check-up is recommended to adolescents every 6 months. We will compare changes before and after this intervention within intervention groups, and we will also investigate the differences between intervention group and control group.

The second part is to collect data to evaluate the intervention implementation process, following the WHO recommendation [39]. We will check participant's exposure to intervention activities. Three indicators will be used, including the percentage of peer leaders who successfully deliver the required number of intervention activities during the intervention period, the coverage rate of

each intervention activity (number of participants in a specific activity divided by number of all S2 adolesents), and the number of intervention activities that each student is actually exposed to. We will collect participant's self-reported data and also check their stamp records for confirmation.

In addition, participant's subjective measures (e.g., rating on whether it's interesting, helpful, informative, comprehensible) towards the intervention activities will be also collected. An evaluation form will be distributed to participants who have participated in at least one of the five intervention activities to collect their opinions on each of these activities.

The second follow-up at months 12
The second follow-up at months 12 will include two parts. The first part is to collect participants' self-reported data through survey, the same procedure as the first follow-up at 6 months. The 12-month follow up data suggest a prolonged impact of the intervention, as no intervention activities will be conducted between months 6 and months 12.

The second part is to do dental re-examination, using the same methods and criteria as the baseline examination. We will compare the changes of the oral health status before and after the intervention. The consistency between self-reported healthy oral health behaviors and dental examination outcomes will also be calculated. No dental examination will be conducted at 6-month follow up, as oral health status is not likely to change much within a short time period like 6 months.

Outcome indicators and potential confounders
The primary outcome is the prevalence of performing each of the three types of healthy oral health behaviors, including tooth brushing, dental flossing, and dental visit. The increase in performing healthy oral behaviors is the key of public health significance. The secondary outcome is the prevalence and severity of oral diseases, including dental caries and poor periodontal status. The third outcome is the prevalence of theory-based constructs regarding the above healthy oral behaviors, including perceived benefits, perceived barriers, perceived severity, self-efficacy and behavioural capability.

Potential confounders include socio-demographic characteristics, pre-existing oral diseases, and utilization of dental services (except for dental check-up) during the follow-up period. Such information will be collected at the baseline and follow-up survey, and between-group differences will be tested for statistical significance. Any significant differences will be adjusted in the analysis evaluating the efficacy of the intervention as compared to the control group.

Incentives
To encourage participation, a teeth cleaning kit (value of HK$ 15) will be given to participants upon completion of each survey, and another gift (value of HK$ 25) will be given upon completion of dental examination. No incentives will be given to students to participate in the intervention activities.

(iv)   <u>Data processing and analysis</u>
The intra- and inter-examiner reliabilities of assessing PI, DMFT and CPI at the tooth level will be tested through the use of the kappa statistic. Data of DMFT and CPI at the tooth level will be used to generate the oral health status at the subject level.

Intention-to-treat analysis will be conducted. Multiple imputation methods will be used [40] to deal with missing data if it occurs. Between-group (intervention versus control) baseline differences in the frequency distributions of potential confounders will be compared by using chi-square test, t-test, Mann-Whitney test or other statistics. The absolute and relative risks and number needed to treat (and 95% confidence intervals) for the binary outcomes comparing the two groups at months 6 and 12 will be derived. Comparisons between the intervention and control groups will be made for all binary outcomes, adjusting for any potential confounders showing $p<.10$ in the between-group baseline comparisons (if any), using modified Poisson regression with robust sandwich variance estimation. SPSS will be used for data analysis; $p<.05$ (2-sided) will be taken as statistically significant. The research team is very experienced in performing data analysis.

Based on the number of intervention activities that the participants are actually exposed to, we will conduct a regression analysis to explore whether the incease of numbers of activities will increase the efficacy of the intervention. Subgroup analysis will also be conducted to compare the efficacy among participants who are exposed to different (or different combinations of) intervention activities.

We will consider the variables of oral health status at baseline, and test its mediating effect on the relationship between theory-based cognitions (and changes) and healthy oral behaviors (and changes). In statistics, a mediating effect can be tested by using an interaction term, whereby the effect of an independent variable on a dependent variable varies by the level of the mediator [41]. The mediating hypothesis is supported if the regression coefficient of the interaction term onto the dependent variable is statistically significant.

We will finally test a pre-designated theory-based Structural Equation Modelling (SEM) with the longitudinal data. SEM has the advantage of testing the theoretical models involving complex patterns of relationships among multiple predictors and dependent variables simultaneously [42]. As a general rule, SEM is indicated when more than one regression equation is necessary for statistical modeling of the phenomena under investigation. SEM is extremely helpful when it is truly interested in exploring a wide range of different effects and pathways (i.e., direct and indirect effects) across an entire set of variables for several different outcomes, which is exactly the current case of exploring various determinants of intention/oral behaviors/and dental outcomes.

<u>(v) Purpose and potential</u>

This is the first peer-lead theory-based RCT tested in adolescents in HK. The intervention activities cover 3984 S2 students in secondary schools, and the improved cognitions and healthy oral behaviors will benefit adolescent's oral health substantially from adolescence to adulthood. The longitudinal data make path analysis possible to explore the existence and strength of both direct and indirect (mediating) effects. It provides evidence to health care providers on decision making regarding cost-effectiveness.

If this intervention is found to be effective, the peer-lead theory-based intervention can be scaled up to the rest secondary schools. All developed education materials can be reused. At the same time, the well-trained peer leaders are also able to deliver intervention activities after the funding period to keep a sustainable effect. These peer leaders also have the capacity to deliver other peer-led activities (e.g., physical activity, depression prevention), which will contribute further to the building of adolescents' general health.

Last but not least, in addition to the improvement of adolescent's oral health related cognition and skills, the community (secondary schools) have been actively involved and empowered, which is beneficial for community health outcomes of Hong Kong in the long run.

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