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Evaluating the efficacy of a text messaging-based shisha smoking cessation intervention for young adults in Hong Kong: A randomised controlled pilot trial

Tobacco consumption is one of the leading preventable causes of diseases and deaths, accounting for the loss of more than eight million lives every year worldwide.[1] Shisha smoking, a form of tobacco use, has surged popularity across the globe among the youths over the past three decades due to the introduction of the aromatic flavoured shisha leaves, waves of café and restaurant culture as well as the advances in social media.[2] In Hong Kong, a local survey indicated that shisha smoking has surpassed cigarette smoking to become the most popular form of tobacco use among university students, with the prevalence of ever-shisha use being 23.8% (vs 21.1% ever-cigarette use).[3]

Multiple incentives for shisha smoking boost its prevalence and its subsequent emergence as a major public health threat among the younger population. University students worldwide consider shisha smoking as attractive, fashionable, relaxing, pleasurable, trendy and socially acceptable.[4-6] Since shisha smoking is regarded as one type of social activity, shisha smokers also tend to cone shisha addiction as a form of social addiction instead of a consequence from nicotine dependence.[7] Indeed, social dimension plays a critical role in the wide spread of shisha smoking.[8,9] A recent study interviewing 49 shisha smokers in Hong Kong highlighted that participants believed shisha smoking could facilitate social interactions and secure their status symbols, in particular among female smokers.[10] Another qualitative study in the UK also demonstrated that young adults perceived the social benefits of shisha smoking outweighed its health risks.[11]

In addition, young people held the misconceptions that toxicants and addictive properties from shisha smoking can be filtered through the water in the waterpipe, and believed that the aromatic smoke from shisha was less harmful, and thus shisha smoking was

less addictive than cigarette smoking.[4] Similarly, local young adults perceived shisha smoking as less harmful and less addictive than all other forms of tobacco consumption, namely cigarette, E-cigarette and heated tobacco products.[12] In fact, there are around 100 to 200 times the amount of smoke, with up to 9 times more of carbon monoxide and 1.7 times more of nicotine inhaled by a shisha smoker in a typical (60-minute) shisha smoking session than smoking a single cigarette.[13] Emerging literature illustrated that the health hazards from shisha smoking are at least as harmful as cigarette smoking, contributing to significant carcinogenic risks, the development of metabolic syndromes, respiratory and cardiovascular illnesses.[6,14] Physical health asides, shisha smokers reported features of nicotine dependence with craving, withdrawal symptoms and problematic quitting.[15,16]

A systematic review summarised that up to 64% of shisha smokers were interested in abstinence from shisha smoking.[5] Nonetheless, they often failed to quit on their own.[7] Medications, like varenicline[17] and bupropion[18], had not significantly outperformed behavioural intervention on their effectiveness in shisha smoking cessation. Early interventions adopting from the tobacco smoking cessation interventions also unsuccessful in lowering the smoking rates as these interventions did not target the multifaceted features unique to shisha smoking, such as its associated social rewards, the intermittent smoking patterns and the positive attitudes towards shisha.[19,20] All these inadequacies underscore the urgent need for the development and evaluation of a shisha-smoking specific cessation intervention.

The World Health Organisation (WHO) has urged healthcare professionals, policy makers and researchers to establish cultural-specific preventing and controlling strategies to address this shisha related public health threat.[1] There are strong cultural differences for the practice of shisha smoking. For example, shisha smoking is a religiously acceptable culture that deeply ingrained in Middle Eastern countries whereas it is more of a social activity in

Hong Kong.[4,10] In fact, culture-based shisha cessation strategies showed preliminary promising results in reducing shisha smoking. For instance, an Iranian study which recruited 212 shisha-exclusive women to evaluate the effectiveness of a 4-month in-person educational programme revealed that the programme had significantly increased shisha abstinence rates, health knowledge, self-efficacy, and intention to quit when compared to the control group.[21] A recent randomised controlled trial adopting a 6-week smoker-tailored mobile messaging intervention among 319 young adults in the US demonstrated promising results in shisha abstinence and reduced the frequency of use last up to 6 months.[22]

Nevertheless, only limited researches have been conducted focusing on reducing shisha use. The Cochrane Review Groups only located 9 interventional studies for their systematic review and meta-analysis to conclude the benefits from behavioural intervention to promote shisha abstinence (risk ratio = 3.19, 95% CI: 2.17-4.69) with a remark of its unsatisfactory level of evidence.[23] The Groups further suggested that more interventional studies with the use of e-health behavioural interventions for shisha smoking cessation might enhance the robustness on its efficacies.[23] And up-to-date, to our best knowledge, there is no Chinese- or Hong Kong-culture based shisha smoking intervention programme available. Thus, the development of a culture specific shisha cessation interventional programme for shisha smokers in Hong Kong is deemed necessary.

In light of such contexts, we developed a culture specific smartphone text messaging-based shisha smoking cessation intervention for young adults in Hong Kong using the well-structured intervention mapping method. Intervention mapping is an iterative process that is commonly used to develop, implement and evaluate theory-based health or behavioural interventions. It has been widely adopted to design and implement behavioural interventions in shisha smoking and cigarette smoking cessation studies.[21] Based on the shisha smoker's individual characteristics, the developed text messaging-based intervention contains

personalised messages with both text and visual elements emphasising the negative impacts of shisha smoking.[22] Supported by previous overseas and local studies using mHealth intervention,[24,25] together with the high penetration rates of smartphone use in Hong Kong and the openness to mobile health interventions[22], smartphone instant messaging applications, such as WhatsApp, Telegram and Signal, will be the powerful and effective delivery modes for this text messaging-based shisha smoking cessation intervention among Hong Kong young adults.

With the growing popularity of shisha smoking among young adults worldwide, including Hong Kong, cessation interventions for shisha smoking are in utmost demand. The current randomised controlled pilot trial is pioneered to fill in the existing research gap for shisha smoking cessation by evaluating the efficacy of the very first systematically developed, culture specific smartphone text messaging-based shisha smoking cessation intervention for young adults in Hong Kong. This study will also meet the call from to WHO to tackle shisha smoking as a public health threat, to achieve the Government's health policy to build a vibrant, healthy and tobacco-free Hong Kong,[26] to reduce the preventable shisha-associated diseases and mortalities on public health, and to provide an efficacious yet influential clinical tools for shisha smoking cessation.

Primary Objective

- To compare the self-reported shisha abstinences between intervention and control group to evaluate the efficacy of the culture specific text-messaging based shisha smoking cessation intervention.

Secondary objectives

- To compare outcomes in participants in intervention or control group during the study period on their:

i) Level of dependency

ii) Knowledge on risk

iii) Readiness to quit

iv) Attitudes on shisha smoking

Study Method

1. Study Design: a 3-month, prospective, 2-arm, randomised controlled pilot trial. Outcome assessments and data will be collected from all participants at baseline, 6th-, and 12th-week follow-up via telephone call or face-to-face interview in a research room at the University of Hong Kong.
2. Study duration: 2 years
3. Sample size: 100 young adult shisha smokers in Hong Kong will be recruited for this study. With references to a similar 3-month pilot randomised controlled trial in the UK that had 67 young adult shisha smokers completed the study,[27] and assuming 30% drop-out rate, 100 young adult shisha smokers shall be appropriate to evaluate the efficacy of this novel smartphone text-messaging based intervention in this pilot trial.
4. Eligibility:

Inclusion criteria:

- young adults aged 18 to 35 years who are interested in quitting shisha
- smoked shisha within the 30 days at the time of enrolment (current smoker)
- smoked for more than twelve times in 12 months (i.e., on a monthly basis)[22]
- able to read and communicate in Chinese or English

Exclusion criteria:

- scored 10 (‘’have already quitted’’) on Contemplation Ladder assessment at baseline

- unable to provide consent
- unable to read and communicate in Chinese or English

5. Randomisation:

- participants will be randomised into either the intervention or the control group on a 1:1 ratio according to the sequences from the computer-generated random number
- allocation concealment will be performed using sealed opaque envelopes with a card inside outlining the group allocation.
- if a group of shisha smokers are recruited at the same time, the whole group will be allocated to the same treatment group to minimise the spill-over effect between the two treatment arms.

6. Blinding: single blind – only the outcome assessors will be blinded to the treatment arms (Blinding will not be applied to the researcher who is responsible to deliver the interventions for the two treatment arms. Full blinding will not be employed to participants as they might communicate with each other, leading to the potential observational bias on the study results.)
7. Setting: self-administered questionnaire via telephone call or face-to-face interview
8. Treatment groups:

Intervention group

- Participants will receive smartphone text messaging-based intervention and support that contained personalised messages with both text and visual elements over 6 weeks under a manualised programme.
- The manualised programme consists of 6 sessions: 1) Programme overview, 2) Psychoeducation on the health risks, 3) Social support, 4) Stress management, 5) Craving and withdrawal symptoms management, and 6) Summary and relapse prevention.

- Except for the first face-to-face encountering with the participants for informed consents and baseline assessments, researcher will follow the intervention manual and deliver the relevant customised information and personalised messages (in Chinese or English) to the participants via their preferred smartphone text- messaging applications, such as WhatsApp, WeChat, Signal, etc. commencing on every preceding Thursday (2 days before weekend).

Control group

- participants in the control group will only receive a leaflet about the health risks of shisha smoking (the exact identical contents received by the participants in the intervention group at Session 2) in either Chinese or English.

9. Ethics: This study will employ a text messaging-based intervention and the assessments will be self-administered questionnaire.

- Both intervention and assessments will not cause any particular side effects/disadvantages/risks
- The risks incurred to subjects who are participating in this study shall be minimal.
- The study will carefully observe and operate in compliance with the Declaration of Helsinki of the World Medical Association
- The trial will be conducted in accordance with the Good Clinical Practice and the CONSORT eHealth checklist.
- The trial will be registered at the US ClinicalTrials.gov

10. Data management: All subject's personal and research data will be managed in accordance with the following the principles from the *HKSAR Personal Data (Privacy) Ordinance (Cap. 486)* and the principles from the *Policy on the Management of Research Data and Records, the University of Hong Kong*.

All the research data collected during the study will be strictly confidential and for the stated research study and purpose only. Consented participants have the rights of access to

personal data and publicly available study results, if and when needed. The data can only be accessed by the authorized members in the research team. The research data collected during the study period will be retained for 10 years. Afterwards, the collected research data will be erased and destroyed.

11. Assessments for outcomes:

    Demographic characteristics and reasons of first shisha smoking will be assessed at baseline assessments. The following assessments will be asked on all 3 data collection timepoints:

    i. Shisha smoking patterns and Timeline Followback Method[28]

    ii. Health knowledge of shisha smoking

    iii. Attitudes towards shisha smoking

    iv. The Contemplation ladder (CL)

    v. The diagnostic criteria from the Structured Clinical Interview for DSM-5 Disorders (SCID-5) on Other Substance Use Disorder[29]

12. Statistical method and data analysis:

    a. Intention to treat analysis, missing data will be handled by the last observation carried forward approach from the 6th week follow-up onwards

    b. Unless otherwise specified, $p \leq 0.05$ will be considered statistically significant

    c. Baseline demographic characteristics, treatment adherence rate, shisha smoking, and other tobacco product smoking behaviours are presented with descriptive statistics in overall and by treatment arm

    d. Between group differences will be compared by nonparametric tests, such as Pearson's chi-squared and likelihood ratio tests at baseline

    e. Generalised linear mixed models will be performed to explore the comparisons within and between treatment conditions for all outcome measures

f. Cox regression model will be conducted to determine the between group abstinence duration by hazard ratio.

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