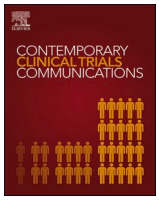
Contemporary Clinical Trials Communications 23 (2021) 100797

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



Examining the effect of waterpipe specific pictorial health warning labels among young adults in Lebanon and Tunisia: Protocol of a factorial experiment study design

Rime Jebai [a], Taghrid Asfar [b,c,d], Rima Nakkash [e], Sara Chehab [e], Habiba Ben Romdhane [f], Wasim Maziak [a,c,*]

[a] Department of Epidemiology, Robert Stempel College of Public Health, Florida International University, Miami, FL, USA
[b] Department of Public Health Sciences, University of Miami Miller School of Medicine, Miami, FL, USA
[c] Syrian Center for Tobacco Studies, Aleppo, Syria
[d] Sylvester Comprehensive Cancer Center, University of Miami Miller School of Medicine, Miami, FL, USA
[e] Health Promotion and Community Health Department, Faculty of Health Sciences, American University of Beirut, Beirut, Lebanon
[f] Cardiovascular Epidemiology and Prevention Research Laboratory, Faculty of Medicine, University of Tunis El Manar, Tunisia

ARTICLE INFO

Keywords:
Waterpipe
Health warning label
Tobacco packaging
Experimental study
Young adults

ABSTRACT

Background: Waterpipe tobacco smoking (WTS) has increased substantially in the Eastern Mediterranean Region (EMR), affecting young adults who perceive waterpipe as safer than cigarette smoking. Applying pictorial health warning labels (HWLs) on tobacco products has been effective in communicating health risks associated with tobacco smoking. However, there are few experimental studies that examined pictorial HWLs specific to WTS. Methods/design: This report describes the design and protocol of the first factorial experimental study that aims to test the effectiveness of pictorial HWLs based on their placement on waterpipe device, tobacco, and charcoal packages among young adult smokers and non-smokers residing in Lebanon and Tunisia. After completing a baseline assessment, participants will be randomly assigned to 3 experimental conditions in a 3 (HWL: pictorial HWL on tobacco package vs. pictorial HWL on 3 placements [device, tobacco, and charcoal packages] vs. text-only HWL on tobacco package) x 4 (pictorial HWLs) x 2 (waterpipe smokers vs. non-smokers) factorial design. We will use a within/between-subject design, where pictorial HWLs and time (pre vs. post-exposure) are the within-subject factors and waterpipe smoking status as the between-subjects factor. Participants will complete post-exposure measures that include attention, perceived harm, intention to quit (smokers) or initiate smoking (non-smokers). Discussion: This is the first international study examining the placements of pictorial HWLs using efficient within/between subject design. Findings will provide additional evidence to convince policymakers to consider three placements of HWLs specific to WTS as a promising regulatory target to curb WTS.

1. Introduction

Globally, waterpipe tobacco smoking (WTS) has increased dramatically, mainly affecting young people [1]. Increasing rates of WTS have been observed, particularly in countries in the Eastern Mediterranean Region (EMR), such as Lebanon and Tunisia [2]. According to the Global Youth Tobacco Survey, the prevalence of current WTS in 2011 was 36.9% in Lebanon [3]. Similarly, the prevalence of current WTS in 2017 was 7.6% among youth in Tunisia [4]. Factors that contributed to the spread of WTS in the EMR and globally include the availability of a wide selection of flavored tobacco, social acceptability, WTS venues (e.g., hookah cafés), ubiquity in social media, and lack of WTS specific policy and regulations [5,6]. More importantly, most waterpipe smokers believe that WTS is safer than cigarette smoking due to the filtering effect of the water when the smoke bubbles through it on its way to the smoker [6,7]. However, mounting evidence suggests that WTS is associated with known tobacco-related health risks, such as respiratory illness, lung cancer, and cardiovascular disease, and the spread of

Abbreviations: WTS, Waterpipe Tobacco Smoking; EMR, Eastern Mediterranean Region; HWL, Health Warning Label; FCTC, Framework Convention on Tobacco Control; NIH, National Institutes of Health; IRB, Institutional Review Board; AUB, American University of Beirut.

* Corresponding author. Department of Epidemiology, Robert Stempel College of Public Health and Social Work, Florida International University, Miami, FL, USA.
E-mail address: wmaziak@fiu.edu (W. Maziak).

https://doi.org/10.1016/j.conctc.2021.100797
Received 7 October 2020; Received in revised form 23 May 2021; Accepted 3 June 2021
Available online 8 June 2021

infectious diseases [8,9]. Therefore, refuting false beliefs about waterpipe safety and communicating health risks associated with WTS represent a priority to curb the waterpipe epidemic among young people.

Health warning labels (HWLs) are widely adopted as an effective means to communicate the health risks associated with tobacco smoking [10]. The Framework Convention on Tobacco Control (FCTC) identified HWLs on tobacco packages as a priority strategy to reduce tobacco-related morbidity and mortality globally [11]. HWLs can promote health knowledge to correct risk perceptions, stimulate intention to quit among smokers, and prevent smoking initiation among non-smokers [12]. They achieve that by increasing attention [12,13], credibility [13–15], negative [12,15–17], and cognitive reactions [13–15,18] to smoking associated risks. Based on FCTC guidelines, HWLs should cover at least 30%–50% of tobacco packaging [11], with pictorial HWLs being superior to text-only [11]. Lebanon currently requires only textual health warnings written in Arabic on tobacco products' packaging [19]. The current textual warning is: "Smoking leads to fatal and serious disease" [19]. Similarly, Tunisian law currently requires that the following health warning appears on all tobacco products' packaging: "Important Notice: Smoking damages your health" [20]. Under Tunisian tobacco control legislation, the health warning requirements are merely textual, written in the Arabic national language [20].

On the other hand, there is a consensus among experts in waterpipe research that cigarette-specific policies do not apply directly to the waterpipe [21–23]. Unlike cigarette smoking, WTS involves tobacco, waterpipe device, and charcoal [24,25]. For example, waterpipe smokers in the popular hookah café setting are usually exposed only to the waterpipe device and are not exposed to the tobacco packages where HWLs are usually placed [10,25]. Furthermore, much of the harm associated with WTS is produced by inhaling emissions from the burning charcoal, yet no health warnings are currently envisioned on waterpipe charcoal packages [25]. The device itself can be a vector for infectious disease transmission due to sharing, multiple use, and lapses in cleaning and sanitation [26]. Given the uniqueness of WTS, there is an urgent need to strengthen public health policy through a waterpipe-specific framework. Our team has recently advanced such framework that takes into consideration waterpipe's multiple components (tobacco, device, charcoal), as well as its unique social use patterns and promotion on social media (Fig. 1) [24]. For example, this framework proposes disclosure of constituents and toxicants derived from WTS on café menus, in addition to the health risks associated with WTS to help effectively communicate the adverse outcomes to the consumer [24]. Therefore, it is essential to consider the variety of risks associated with different components of the waterpipe for HWLs as well as their placement for maximum effectiveness [26].

Few studies have examined whether the placement of pictorial HWLs on waterpipe parts has a different impact on changing smoking behaviors. An online survey conducted among college students in the United States (US) found that placing pictorial HWL on waterpipe apparatus such as the water bowl was useful in raising concerns about the health consequences of WTS and increased intention to quit [27]. A similar study conducted among waterpipe smokers in Jordan found that placing HWL on the waterpipe handle or head was more effective since those parts are more obvious to the smokers [28]. A cross-sectional study conducted in Egypt found that HWLs on tobacco packages motivated waterpipe smokers to change their smoking behaviors (think about quitting, reduce their consumption, forgo a smoke, or increase quit attempt), helped former smokers to quit WTS and non-smokers to remain smoke-free [29]. Another qualitative study conducted in Egypt showed that placing HWLs on the device (glass body, mouthpiece, or waterpipe hose) might prevent WTS initiation or promote cessation [30]. Recently, a randomized experiment using eye-tracking equipment to assess visual attention to 3 placements of a health warning on the waterpipe (stem, water bowl, hose) among US young adults demonstrated that HWLs on all placements stimulated visual attention and increased harm perceptions [31]. Finally, a pilot lab experiment study conducted by our team among waterpipe smokers in the US showed that placing pictorial HWL on the waterpipe device compared to no HWL (control) reduced smokers' positive experiences and exposure to exhaled carbon monoxide [32].

Two main regulatory questions emerge from the implementation of effective HWLs for WTS; 1) are pictorial HWLs on the tobacco more effective than the current text only, and 2) are pictorial HWLs on waterpipe's 3 components (tobacco, device, charcoal) more effective than on the tobacco only. Our team was funded recently by the Fogarty International Center of the US National Institutes of Health (NIH) to develop waterpipe specific HWLs and provide adequate testing to them. Because our study aims and design can be of help for a variety of HWLs studies that take into consideration the specifics of the tobacco use method and risks (e.g., e-cigarettes), especially in the context of tobacco use methods popular in developing countries, we want to make our multi-country study protocol available to other researchers and parties interested in implementing HWLs policies for tobacco products. Below we provide the design and protocol of the first experimental study that aims to test and compare the effect of pictorial HWLs on three placements (device, tobacco, and charcoal packages) to HWLs only on the tobacco package and to text-only HWL in Tunisia and Lebanon. We will look at the effects of HWLs on communication outcomes (e.g., attention, reaction), harm perception, and quit intention among young waterpipe smokers as well as non-smokers. Findings from this study will help policymakers and tobacco control researchers and advocates implement effective HWLs to help decrease waterpipe smoking among young people and reduce tobacco related morbidity and mortality.

2. Methods

2.1. Study design

This experimental study uses a factorial design to investigate multiple factors and their interactions without the need for a large sample [33]. Outcomes for the evaluation of pictorial HWLs in this study are guided by the message impact framework and standard measures used in health communication research [34]. This framework is based on communication and psychological theories, which posit that features of the HWLs can induce behavioral change through a chain of psychological events, depending on how they will be noticed [34]. As shown in Fig. 2, attention to HWLs will influence an individual's reaction, which in turn affects harm perception, intention to change, and ultimately behavior change.

We will recruit 360 waterpipe smokers and non-smokers (180 in each group) for a **3** (pictorial HWL on tobacco package, pictorial HWL on three placements, and text-only on tobacco package (control) **x 4** (different pictorial HWLs) **x 2** (waterpipe smokers and non-smokers) factorial experiment study (Fig. 3). Each participant will be randomly assigned to view 1 out of 4 pictorial HWLs displayed on the tobacco package, the same pictorial HWL on all waterpipe parts, and the text-only HWL on the tobacco package. The order of the display will be randomized and counterbalanced to mitigate the carryover and order effects. We will assess the performance of 4 selected pictorial HWLs in a within/between-subject design, where pictorial HWLs and time (pre vs. post-exposure to pictorial HWL) are the within-subject factors and waterpipe smoking status (smokers, non-smokers) as the between-subjects factor. We hypothesize that: (1) pictorial HWL on all three placements will be more effective than on one placement for study's outcomes; (2) pictorial HWL will have more effect on waterpipe non-smokers compared to waterpipe smokers, and (3) pictorial HWL will be more effective than control (text-only) on tobacco package.

2.2. Study participants and recruitment

This study will target young adults (aged 18–34 years), waterpipe smokers and non-smokers residing in Lebanon and Tunisia (for the past five years at least). Participants will be classified as waterpipe smokers if they reported smoking a waterpipe in the past 6 months. Non-smokers are those who did not smoke waterpipe in the past 6 months. A total sample of 360 participants (180 smokers and 180 non-smokers) will be recruited from each country.

The study has received Institutional Review Board (IRB) approval from Florida International University, the American University of Beirut (AUB), and the University of Tunis El Manar.

2.2.1. Recruitment strategy in Tunisia

Two recruitment methods will be followed. Through the medical student association, a brief description of the study goals and procedures, along with contact details of the research team, will be circulated using flyers that have been approved by IRB. Additionally, flyers will be distributed at the main campus of the University of Tunis El Manar and entrances of four faculties. Interested participants who will contact the research team by phone or email will be asked to provide their contact information for screening for initial eligibility. We will consider more recruitment strategies such as social media, university students' listservs if the targeted sample is not reached.

Initial screening will be conducted over the phone to confirm the eligibility of interested individuals based on the set criteria and verify their smoking status (smoker, non-smoker).

2.2.2. Recruitment strategy in Lebanon

Participants will be recruited through email that will be sent to AUB students and research assistants among the AUB faculty and staff. The list of emails will be a random set of those who fall within our targeted age group of 18–34 years. The emails will include the study flyers that have been approved by IRB, a brief description of the study, along with contact details of the research team. In addition, potential participants will be asked to forward the email to people who might be interested in this study or to provide their contact information to the AUB research team.

In order to recruit participants from outside AUB, a recruitment company will be hired through AUB. This company will act as a link between the potential participants and the AUB team. They will contact people from their list of participants who have previously consented to be part of any study. They will also use the flyers that have been approved by IRB to clarify the topic of the experimental study to the participants. The recruitment company will only confirm the eligibility and interest of the potential participants. They will not have any further interaction with the participants.

2.3. Study procedures

Due to COVID-19, the study will be held exclusively online in Lebanon and Tunisia using Sphinx that will be hosted on each university-home institution server. The study will take up to 1 h. Therefore, the emails sent by the research team will also include a link to the Sphinx. Interested participants will be asked to click on the Sphinx link and prompted to answer a few questions to confirm their eligibility. Participants recruited by the company in Lebanon will also receive an email with a link to the Sphinx and will be reconfirming their eligibility once they click on the link.

If eligible, participants will be directed to the consent page. Upon consent, participants will have access to the survey. At the end of the study, participants will be asked to select their preferred compensation mode: either a $10 credit transfer to their mobile phone lines or any other prepaid phone number they wish to recharge or a $10 gift card from a bookstore.

Given the rapidly evolving COVID-19 pandemic worldwide, we have developed a tentative plan of the study procedures subject to change if the need arises.

The current situation of COVID-19 in Lebanon and Tunisia does not permit in-person research. Therefore, the study will be held exclusively online in both countries to ensure the protection of both the research team and participants.

All forms (pre-exposure and post-exposure) will be done on Sphinx. First, participants will be asked to complete the pre-exposure assessment. Then, each participant will see one image of the: 1) 1 pictorial HWL on the tobacco, 2) the same pictorial HWL on 3 placements, and 3) text-only warning on the tobacco package (control), one at a time in random and counterbalanced order to mitigate carryover and order effect. After each label view, participants will be given 10–15 min to complete a set of post-exposure measures.

2.4. Sample size calculation

To have 80% power detecting a significant between-subject, within-subject, and interaction effects of a small effect size Cohen's $f = 0.25$ for comparisons of the main outcomes (e.g., intention to quit) [34] at the two-tailed 0.05 alpha level, we will need 41 participants per HWL and smoking group. This is assuming a correlation among repeated measures within-subject of 0.5 and nonsphericity correction of 1 and adjusted for two main comparisons (pictorial HWL on the tobacco vs. pictorial HWL on all, and pictorial HWL on the tobacco vs. text-only on the tobacco) and Bonferroni correction for multiple comparisons. Thus, we need a total sample size of 41 x 4 (HWLs) x 2 (smokers/non-smokers) = 328 participants, which will provide 80% power for the planned analyses. However, we will recruit 360 participants to account for 10% of missing responses (e.g., <10% for Salameh et al., 2014 study looking at smoking among 3384 students from 17 universities in Lebanon [35]). The sample size also provides at least 80% power to detect the secondary within-subject effect of HWLs among 4 HWLs with a small effect size Cohen's $f = 0.25$ and with Bonferroni correction for pairwise comparisons at two-tailed 0.05 alpha level assuming a correlation within-subject of 0.5.

2.5. Measures

2.5.1. Baseline assessment

2.5.1.1. Sociodemographic questions. Gender, age, nationality, marital status, educational level, employment status, and household income will be collected at baseline.

2.5.1.2. Waterpipe smoking [36]. Questions include waterpipe smoking status, age of initiation for smokers, the reason for waterpipe smoking initiation, location, number of waterpipes smoked per month, session duration, time of the day when waterpipe is smoked, last smoking session, number of family and friends who smoke waterpipe, addiction, and harm perception compared to cigarettes, quit attempts, intention to quit, and perceived likelihood and severity. The Syrian Center for Tobacco Studies-13 (SCTS-13) will be used to assess dependence among waterpipe smokers [37]. The SCTS-13 is composed of 13 items, with a score of 0–2 points/item. The total scale ranges from 0 to 26. The higher the total score, the stronger is the nicotine dependence.

2.5.1.3. Cigarette smoking history [38]. Questions include cigarette smoking status, frequency of smoking, number of cigarettes smoked per day, past quit attempts, intention to quit, and self-efficacy among smokers. Nicotine dependence is evaluated using the Fagerstrom test [39]. The test consists of six items that assess the quantity of cigarette consumption, the compulsion to use, and dependence. The items are summed to yield a score of 0–10. A score of 6 or higher indicates a strong dependence on nicotine. Additionally, intention to start cigarette

smoking is assessed for non-smokers by the question, "do you intend to smoke cigarettes in the next year?" Finally, perceived harm of cigarette smoking is evaluated for both cigarette smokers and non-smokers using the questions (1) "if you regularly smoke cigarettes, what is the chance that you would one day get cigarette-related health problems? (2) how much would be getting cigarette smoking-related health problems affect your life?"

2.5.1.4. Other tobacco use. Current use (use in the past 30 days) of midwakh, cigar, electronic cigarette use will be assessed using the question do you currently smoke midwakh/cigar/e-cigarette?

2.5.2. Post-exposure assessments

Pictorial HWLs are evaluated on communication outcomes that include ***attention*** to the warning measured by the question, "how much does this message grab your attention?" [40], warning reaction that will assess participants' cognitive, emotional, and physiological reactions and includes: ***believability*** measured by the question "how believable is this message?" [41], ***cognitive elaboration*** measured by the questions "how much does the message cause you to think about the health problems caused by smoking waterpipe? How much does the message cause you to think about the information they convey? How much does the message cause you to think about quitting waterpipe? How much does the message cause you to think about quitting other tobacco methods?" [42–44], ***negative affect*** measured by the questions "how much the messages make the person: feel anxious, sad, scared, guilty, and disgusted?" [40,45], ***reactance*** measured by "the message is trying to manipulate me, the message annoys me, the message is overblown" [46,47], ***social interaction*** about the message measured by the question "How likely are you to talk about this message with others in the next week?" [48,49], and ***avoidance*** measured by the questions "how likely is it that you would try to avoid thinking about this message if all waterpipe has the message on them? how likely is it that you would try to avoid looking at this message?" [18,50].

Furthermore, perceived effectiveness of the warning will assess perceptions of the effectiveness of warning messages and includes: ***perceived message effectiveness*** measured by "this message makes me concerned about the health effects of waterpipe, this message makes waterpipe seem unpleasant to me, this message discourages me from wanting to smoke waterpipe", and ***perceived effectiveness of the HWL on others*** measured by the questions "how effective the message would be in making people more concerned about the health risks of waterpipe smoking, motivating waterpipe smokers to quit, and preventing young people from starting to smoke waterpipe?" [51].

Communication outcomes will also include ***perceived harm*** measured by the questions "if you regularly smoke waterpipe, what is the chance that you would one day get waterpipe-related health problems? how much would be getting waterpipe smoking-related health problems affect your life?" [52], ***affective risk*** measured by the question "when you think about waterpipe smoking-related health problems for a moment, to what extent do you feel scared?", ***experiential risk*** measured by the question "how concerned are you about developing waterpipe smoking-related health problems in your lifetime?" [53], and ***intention to quit*** measured by the questions "do you intend to quit waterpipe smoking? Do you intend to reduce waterpipe smoking? how motivated are you to quit waterpipe smoking in the next month?" [54].

All these items are assessed on a 5-point Likert scale (1 = not at all progressing to 5 = very much).

2.6. Data analysis

Descriptive statistics will be used to present the sample sociodemographic characteristics stratified by waterpipe smoking status. T-test and correlation analyses will be used to determine if there is an association between sociodemographic characteristics and outcome measures. Characteristics that are statistically or theoretically related to the outcomes will be included in subsequent models for hypotheses testing. General linear mixed model (GLMM) techniques will be used to analyze outcome data. In general, the models will include fixed effects for one or two between-subjects' factors (smoking status, label placement) and a single repeated measure plus interaction terms. A random intercept will be fit with subjects nested within the between-subjects' factors. An unstructured covariance matrix will be used to represent the correlated data structure. Models may include fixed effects for covariates of interest. To test whether gender differences affect the relationship between exposure to HWLs and the outcome measures, we will stratify by gender and rerun the analysis. Planned contrasts will be used to test for significant differences, with two-tailed alpha level 0.05 considered significant (using SAS v.9.3).

3. Discussion

To our knowledge, the current experiment is the first to examine and compare the effect of pictorial compared to textual waterpipe-specific HWLs based on their placement (tobacco vs. all/device, tobacco, and charcoal packages) on several communication outcomes using efficient within and between-subject factorial experiment design in two countries in the EMR. The use of factorial design will enable the investigation of multiple factors and their interactions without the need for large samples [33]. Consequently, the study will have enough power to detect differences between the different placement of pictorial HWLs as well as between these pictorial HWLs and text-only label. Furthermore, the inclusion of both smokers and non-smokers will help to understand the impact of pictorial HWLs on quitting as well as initiation outcomes and will increase the generalizability of results. On the other hand, this study will examine the effectiveness of HWLs developed specifically for WTS following a scientific and systematic approach. First, our team has developed 28 pictorial HWLs corresponding to five priority themes related to waterpipe health effects, including health risks, addiction, harm to others, waterpipe-specific harm, and waterpipe harm compared with cigarettes [23]. These HWLs were developed based on waterpipe literature review that identified the harmful effect of WTS [23], followed by a Delphi study conducted among international experts in tobacco control to reach a consensus on the top 13 HWLs [23]. We further refined and adapted these HWLs to young adults (waterpipe smokers and non-smokers) in Lebanon and Tunisia by conducting focus group studies. Based on participants' feedback on 13 HWLs, the top four HWLs in terms of overall effectiveness were selected from each country and will be tested in this experimental study.

To date, limited research has examined the effectiveness of pictorial HWLs specific to WTS in the EMR. For example, the cross-sectional survey conducted in Egypt [29] assessed the effectiveness of existing generic pictorial HWLs that are not specific to WTS on waterpipe tobacco packs among smokers and non-smokers. Similarly, cross-sectional study designs were used in Lebanon [55] and Jordan [28]. The study conducted in Lebanon compared pictorial to textual HWL on waterpipe tobacco packs only among smokers recruited from selected café/restaurants [55]. Furthermore, the Lebanese study did not assess important outcomes such as motivation to quit waterpipe. The study in Jordan used an online survey to assess the best placement of pictorial HWLs among current and former waterpipe smokers [28], limiting the ability to test the effectiveness of HWLs on the initiation of WTS among never smokers. Additionally, the HWLs assessed were presented in the same order to participants and did not adjust for the carryover effect. On the other hand, two qualitative studies from Egypt [56] and 6 countries across the EMR [57] both showed that the placement of pictorial HWLs on waterpipe device could increase awareness of health risks associated with WTS, stimulate intention to quit among smokers, and prevent smoking initiation among never smokers [56,57]. However, these qualitative studies using face-to-face interviews could have introduced social desirability bias and involved samples not representative of the

target population. They also did not apply a study design that allows to test hypotheses about the effectiveness of HWLs and make causal inferences of that effect. Therefore, our experimental study will help advance the implementation of HWLs related to waterpipe and will fill an important gap in the literature on examining and adapting pictorial HWLs specific to WTS and demonstrating the importance of their placement on different parts of the waterpipe.

The study has limitations. This experimental study will be conducted in an online setting where participants will be exposed to HWLs on different placements and will complete a post-exposure assessment following each condition. While the scenario proposed in this experiment (exposure to HWLs on device, tobacco, and charcoal packages at the same time) does not exactly mimic reality, it provides the best approximation of cumulative exposure to HWLs that can take place if the HWLs were to be placed on the 3 waterpipe components. Moreover, these scenarios differ from the natural waterpipe smoking environment where smokers usually perform this habit with their friends and family. However, the HWLs display will be similar to the real-life setup (HWLs placed on the actual device, tobacco, and charcoal packs), which help the participant better assess the HWLs. Another limitation may be derived from people who will participate via online recruitment sources. This group may be different from those in the general population. However, we will employ more than one recruitment method to include a more representative sample from each country. Considering the current COVID-19 pandemic, the study procedures were adapted according to each country.

In conclusion, this study will provide the first evidence on the effectiveness of pictorial HWLs and their placement on waterpipe parts in an experimental study design. Furthermore, because our study aims and design can inform a variety of HWLs studies that take into consideration the specifics of tobacco use methods that are popular in developing countries, our multi-country study protocol can guide other researchers and parties interested in implementing HWLs for tobacco control in the EMR. Finally, this study will help advance WTS-specific HWLs sensitive to its unique setup and components (tobacco, device, and charcoal), which will likely play a crucial role in increasing the effectiveness of HWLs at the population level.

Author agreement

All authors have seen and approved the final version of the manuscript. All authors confirm that neither the entire paper nor any of its content has been submitted, published, accepted by another journal or under consideration for publication elsewhere.

Authors' contributions

RJ drafted the manuscript. WM and TA designed the study and developed the protocol and will oversee its conduct. WM, TA, RN, HBR contributed to the study design and initial implementation. All authors contributed to the revision of the protocol and approved the final manuscript.

Funding

This work was supported by the National Institutes of Health and Fogarty International Center, (NIH FIC) under award number R01TW010654.

Declaration of competing interest

The authors declare that they have no competing interests.

Appendices.

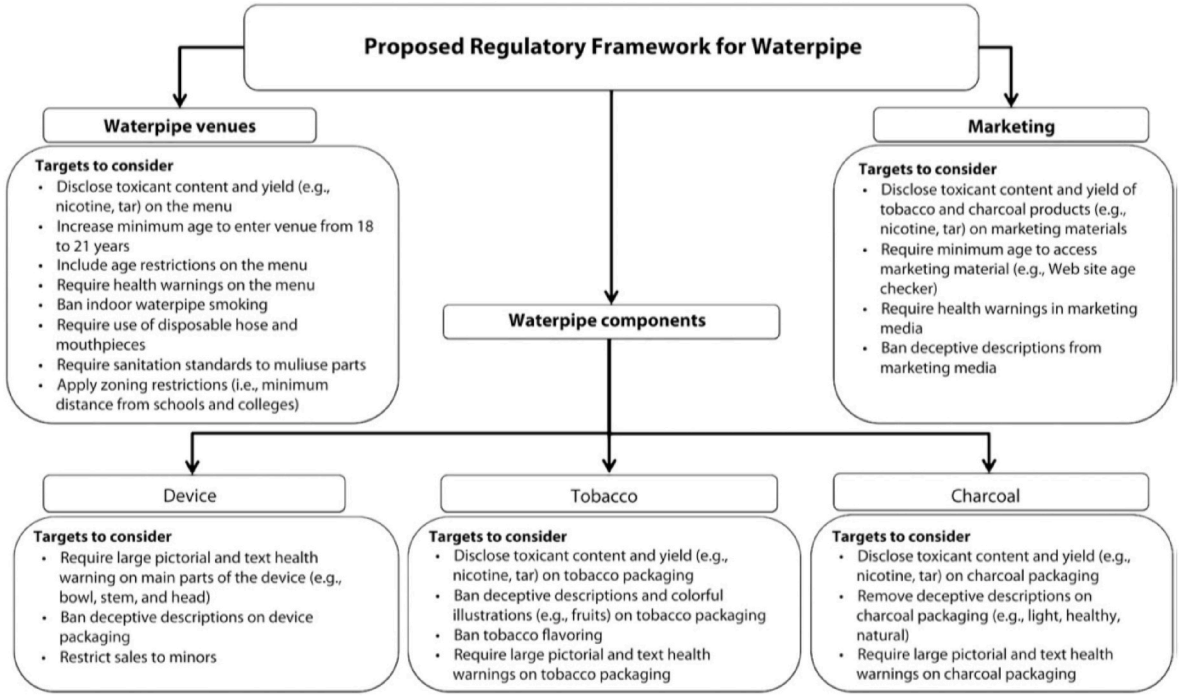


Fig. 1. Proposed schematic of the Waterpipe's main components, use context, and marketing environment to guide research and regulatory efforts into its unique features and complex nature (Salloum, 2016).

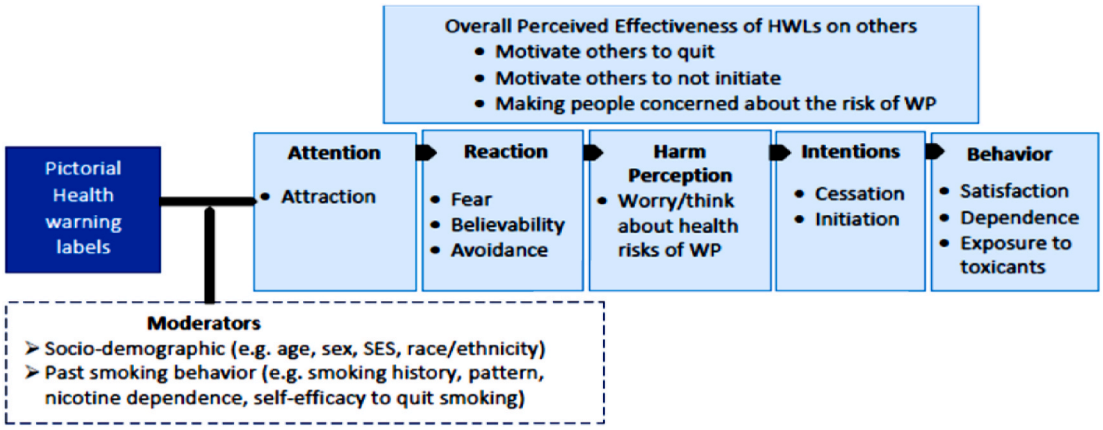


Fig. 2. Message impact framework of response to health warning labels.

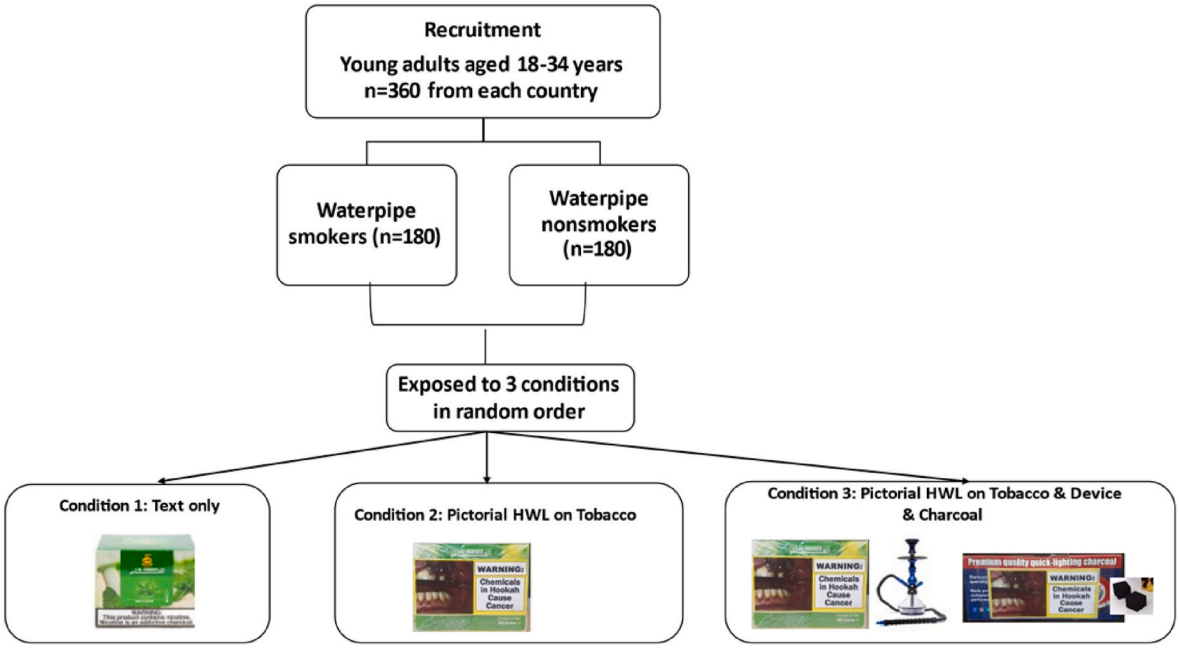


Fig. 3. General design of the experimental study.

References

[1] W. Maziak, Z. Ben Taleb, R. Bahelah, et al., The global epidemiology of waterpipe smoking, Tobac. Contr. 24 (2015), https://doi.org/10.1136/tobaccocontrol-2014-051903 i3-i12.

[2] W. Maziak, K.D. Ward, R.A. Afifi Soweid, T. Eissenberg, Tobacco smoking using a waterpipe: a re-emerging strain in a global epidemic, Tobac. Contr. 13 (4) (2004) 327–333, https://doi.org/10.1136/tc.2004.008169.

[3] M. Jawad, R. Charide, R. Waziry, A. Darzi, R.A. Ballout, E.A. Akl, The prevalence and trends of waterpipe tobacco smoking: a systematic review, PloS One 13 (2) (2018), e0192191, https://doi.org/10.1371/journal.pone.0192191.

[4] Le Tabagisme En Tunisie, Tunisia. http://www.yezzi.tn/le-tabagisme-en-tunisie, 2017. (Accessed 8 July 2020).

[5] W. Maziak, R. Nakkash, R. Bahelah, A. Husseini, N. Fanous, T. Eissenberg, Tobacco in the Arab world: old and new epidemics amidst policy paralysis, Health Pol. Plann. 29 (6) (2013) 784–794, https://doi.org/10.1093/heapol/czt055.

[6] E.A. Akl, K.D. Ward, D. Bteddini, et al., The allure of the waterpipe: a narrative review of factors affecting the epidemic rise in waterpipe smoking among young persons globally, Tobac. Contr. 24 (2015) i13–i21, https://doi.org/10.1136/tobaccocontrol-2014-051906.

[7] R. Nakkash, J. Khalil, R.A. Afifi, The rise in narghile (shisha, hookah) waterpipe tobacco smoking: a qualitative study of perceptions of smokers and non smokers, BMC Publ. Health 11 (1) (2011) 315, https://doi.org/10.1186/1471-2458-11-315.

[8] K.D. Ward, The waterpipe: an emerging global epidemic in need of action, Tobac. Contr. 24 (2015) i1–i2, https://doi.org/10.1136/tobaccocontrol-2014-052203.

[9] R. Waziry, M. Jawad, R.A. Ballout, M. Al Akel, E.A. Akl, The effects of waterpipe tobacco smoking on health outcomes: an updated systematic review and meta-analysis, Int. J. Epidemiol. 46 (1) (2017) 32–43, https://doi.org/10.1093/ije/dyw021.

[10] D. Hammond, Health warning messages on tobacco products: a review, Tobac. Contr. 20 (5) (2011) 327–337, https://doi.org/10.1136/tc.2010.037630.

[11] World Health Organization, Guidelines for implementation of article 11 of the WHO framework convention on tobacco control (packaging and labelling of tobacco products), World Health Organization, 2008. http://www.who.int/fctc/guidelines/adopted/article_12/en/. (Accessed 25 May 2020).

[12] D. Hammond, J.L. Reid, P. Driezen, et al., Are the same health warnings effective across different countries? An experimental study in seven countries, Nicotine Tob. Res. 21 (7) (2019) 887–896, https://doi.org/10.1093/ntr/nty248.

[13] A. Ngo, K. Cheng, C. Shang, J. Huang, F.J. Chaloupka, Global evidence on the association between cigarette graphic warning labels and cigarette smoking prevalence and consumption, Int. J. Environ. Res. Publ. Health 15 (3) (2018) 421, https://doi.org/10.3390/ijerph15030421.

[14] J.F. Thrasher, M.J. Carpenter, J.O. Andrews, et al., Cigarette warning label policy alternatives and smoking-related health disparities, Am. J. Prev. Med. 43 (6) (2012) 590–600, https://doi.org/10.1016/j.amepre.2012.08.025.

[15] S. Mutti-Packer, J.L. Reid, J.F. Thrasher, et al., The role of negative affect and message credibility in perceived effectiveness of smokeless tobacco health warning labels in Navi Mumbai, India and Dhaka, Bangladesh: a moderated-mediation analysis, Addict. Behav. 73 (2017) 22–29, https://doi.org/10.1016/j.addbeh.2017.04.002.

[16] J.A. Sutton, S. Yang, J.N. Cappella, Perceived effectiveness of objective features of pictorial warning messages, Tobac. Contr. 28 (e1) (2019) e24–e30, https://doi.org/10.1136/tobaccocontrol-2018-054488.
[17] H.H. Yong, R. Borland, J.F. Thrasher, et al., Mediational pathways of the impact of cigarette warning labels on quit attempts, Health Psychol. 33 (11) (2014) 1410–1420, https://doi.org/10.1037/hea0000056.
[18] A.T. Evans, E. Peters, A.A. Strasser, L.F. Emery, K.M. Sheerin, D. Romer, Graphic warning labels elicit affective and thoughtful responses from smokers: results of a randomized clinical trial, in: K. Matsuo (Ed.), PLoS One, vol. 10, 2015, e0142879, https://doi.org/10.1371/journal.pone.0142879, 12.
[19] Lebanon Details _ Tobacco Control Laws (n.d.). Retrieved May 20, 2021, from https://www.tobaccocontrollaws.org/legislation/country/lebanon/pl-health-warnings#:~:text=Health.
[20] Tunisia Details | Tobacco Control Laws (n.d.). Retrieved May 20, 2021, from https://www.tobaccocontrollaws.org/legislation/country/tunisia/laws.
[21] A.A. Lopez, T. Eissenberg, M. Jaafar, R. Afifi, Now is the time to advocate for interventions designed specifically to prevent and control waterpipe tobacco smoking, Addict. Behav. 66 (2017) 41–47, https://doi.org/10.1016/j.addbeh.2016.11.008.
[22] E.L. Sutfin, E.K. Soule, K. McKelvey, D. Jenson, Implications and challenges for implementation of the FDA's final deeming rule for waterpipe tobacco, Tobac. Contr. 27 (3) (2017) 347–351, https://doi.org/10.1136/tobaccocontrol-2017-053634.
[23] T. Asfar, M. Schmidt, M. Ebrahimi Kalan, et al., Delphi study among international expert panel to develop waterpipe-specific health warning labels, Tobac. Contr. 29 (2) (2020) 159–167, https://doi.org/10.1136/tobaccocontrol-2018-054718.
[24] R.G. Salloum, T. Asfar, W. Maziak, Toward a regulatory framework for the waterpipe, Am. J. Publ. Health 106 (10) (2016) 1773–1777, https://doi.org/10.2105/AJPH.2016.303322.
[25] R. Nakkash, J. Khalil, Health warning labelling practices on narghile (shisha, hookah) waterpipe tobacco products and related accessories, Tobac. Contr. 19 (3) (2010) 235–239, https://doi.org/10.1136/tc.2009.031773.
[26] W. Maziak, O. Osibogun, T. Asfar, Waterpipe smoking: the pressing need for risk communication, Expet Rev. Respir. Med. 13 (11) (2019) 1109–1119.
[27] F. Islam, R.G. Salloum, R. Nakkash, W. Maziak, J.F. Thrasher, Effectiveness of health warnings for waterpipe tobacco smoking among college students, Int. J. Publ. Health 61 (6) (2016) 709–715, https://doi.org/10.1007/s00038-016-0805-0.
[28] M.W. Darawad, R. Salloum, M. Alhussami, M. Maharmeh, Evaluating health warning messages specific to waterpipe smoking among university students in Jordan, J Am Assoc Nurse Pract 31 (2) (2019) 133–138, https://doi.org/10.1097/JXX.0000000000000107.
[29] A. Mostafa, H. Mohammed, R. Hussein, et al., Do pictorial health warnings on waterpipe tobacco packs matter? Recall effectiveness among Egyptian waterpipe smokers & non-smokers, PloS One 13 (12) (2018), https://doi.org/10.1371/journal.pone.0208590 e0208590.
[30] A. Mostafa, H. Mohammed, W. Hussein, et al., Would placing pictorial health warnings on waterpipe devices reduce waterpipe tobacco smoking? A qualitative exploration of Egyptian waterpipe smokers' and non-smokers' responses, Tobac. Contr. 28 (4) (2019) 475–478, https://doi.org/10.1136/tobaccocontrol-2018-054494.
[31] E.G. Klein, M.A. Alalwan, M.L. Pennell, et al., Waterpipe warning placement and risk perceptions: an eye tracking study, Am. J. Health Behav. 45 (1) (2021) 186–194, https://doi.org/10.5993/AJHB.45.1.15.
[32] W. Maziak, Z. Ben Taleb, M. Ebrahimi Kalan, et al., Pictorial health warning labels on the waterpipe device are effective in reducing smoking satisfaction, puffing behaviour and exposure to CO: first evidence from a crossover clinical laboratory study, Tobac. Contr. 28 (e1) (2019) E37–E42, https://doi.org/10.1136/tobaccocontrol-2018-054682.
[33] L.M. Collins, J.J. Dziak, R. Li, Design of experiments with multiple independent variables: a resource management perspective on complete and reduced factorial designs, Psychol. Methods 14 (3) (2009) 202–224, https://doi.org/10.1037/a0015826.
[34] S.M. Noar, M.G. Hall, D.B. Francis, K.M. Ribis, J.K. Pepper, N.T. Brewer, Pictorial cigarette pack warnings: a meta-analysis of experimental studies, Tobac. Contr. 25 (3) (2016) 341–354, https://doi.org/10.1136/tobaccocontrol-2014-051978.
[35] P. Salameh, J. Salamé, M. Waked, B. Barbour, N. Zeidan, I. Baldi, Waterpipe dependence in university students and effect of normative beliefs: a cross-sectional study, BMJ open 4 (2) (2014), e004378, https://doi.org/10.1136/bmjopen-2013-004378.
[36] W. Maziak, Z. BenTaleb, M. Jawad, et al., Consensus statement on assessment of waterpipe smoking in epidemiological studies, Tobac. Contr. 26 (3) (2017) 338–343, https://doi.org/10.1136/tobaccocontrol-2016-052958.
[37] M.M. Alam, K.D. Ward, R. Bahelah, et al., The Syrian Center for Tobacco Studies-13 (SCTS-13): psychometric evaluation of a waterpipe-specific nicotine dependence instrument, Drug Alcohol Depend. 215 (2020) 108192. https://doi:10.1016/j.drugalcdep.2020.108192.
[38] M.L. Saddleson, L.T. Kozlowski, G.A. Giovino, G.G. Homish, M.C. Mahoney, M. L. Goniewicz, Assessing 30-day quantity-frequency of U.S. adolescent cigarette smoking as a predictor of adult smoking 14 years later, Drug Alcohol Depend. 162 (2016) 92–98, https://doi.org/10.1016/j.drugalcdep.2016.02.043.
[39] T.F. Heatherton, L.T. Kozlowski, R.C. Frecker, K.O. Fagerstrom, The fagerström test for nicotine dependence: a revision of the Fagerstrom tolerance questionnaire, Br. J. Addict. 86 (9) (1991) 1119–1127, https://doi.org/10.1111/j.1360-0443.1991.tb01879.x.
[40] J. Nonnemaker, M. Farrelly, K. Kamyab, et al., Experimental Study of Graphic Cigarette Warning Labels: Final Results Report, RTI International, Research Triangle Park, NC, 2010.
[41] A.J. Lazard, A. Schmidt, H. Vu, et al., Icons for health effects of cigarette smoke: a test of semiotic type, J. Behav. Med. 40 (4) (2017) 641–650, https://doi.org/10.1007/s10865-017-9833-3.
[42] N.T. Brewer, M. Jeong, J.R. Mendel, et al., Cigarette pack messages about toxic chemicals: a randomised clinical trial, Tobac. Contr. 28 (1) (2019) 74–80, https://doi.org/10.1136/tobaccocontrol-2017-054112.
[43] C. Moodie, A.M. Mackintosh, G. Hastings, A. Ford, Young adult smokers' perceptions of plain packaging: a pilot naturalistic study, Tobac. Contr. 20 (5) (2011) 367–373, https://doi.org/10.1136/tc.2011.042911.
[44] D. Hammond, G.T. Fong, P.W. McDonald, R. Cameron, K.S. Brown, Impact of the graphic Canadian warning labels on adult smoking behaviour, Tobac. Contr. 12 (4) (2003) 391–395, https://doi.org/10.1136/tc.12.4.391.
[45] D. Watson, L.A. Clark, A. Tellegen, Development and validation of brief measures of positive and negative affect: the PANAS scales, APA PsycNet Direct 54 (6) (1988) 1063–1070. https://psycnet.apa.org/buy/1988-31508-001.
[46] M.G. Hall, P. Sheeran, S.M. Noar, K.M. Ribisl, L.E. Bach, N.T. Brewer, Reactance to health warnings scale: development and validation, Ann. Behav. Med. 50 (5) (2016) 736–750, https://doi.org/10.1007/s12160-016-9799-3.
[47] M.G. Hall, P. Sheeran, S.M. Noar, K.M. Ribisl, M.H. Boynton, N.T. Brewer, A brief measure of reactance to health warnings, J. Behav. Med. 40 (3) (2017) 520–529, https://doi.org/10.1007/s10865-016-9821-z.
[48] M.G. Hall, K. Peebles, L.E. Bach, S.M. Noar, K.M. Ribisl, N.T. Brewer, Social interactions sparked by pictorial warnings on cigarette packs, Int. J. Environ. Res. Publ. Health 12 (10) (2015) 13195–13208, https://doi.org/10.3390/ijerph121013195.
[49] J.C. Morgan, B.G. Southwell, S.M. Noar, K.M. Ribisl, S.D. Golden, N.T. Brewer, Frequency and content of conversations about pictorial warnings on cigarette packs, Nicotine Tob, Res. Tobacco Research 20 (7) (2018) 882–887, https://doi.org/10.1093/ntr/ntx180.
[50] Population Assessment of Tobacco and Health Study, PATH: population assessment of tobacco and health, 2018. Available: http://www.Path study info.nih.gov/UI/HomeMobile.aspx. (Accessed 18 May 2021).
[51] S.A. Baig, S.M. Noar, N.C. Gottfredson, M.H. Boynton, K.M. Ribisl, N.T. Brewer, UNC perceived message effectiveness: validation of a brief scale, Ann. Behav. Med. 53 (8) (2018) 732–742, https://doi.org/10.1093/abm/kay080.
[52] S.M. Noar, J.A. Rohde, C. Horvitz, A.J. Lazard, J. Cornacchione Ross, E.L. Sutfin, Adolescents' receptivity to E-cigarette harms messages delivered using text messaging, Addict, Beyond Behav. 91 (2019) 201–207, https://doi.org/10.1016/j.addbeh.2018.05.025.
[53] R.A. Ferrer, W.M.P. Klein, A. Persoskie, A. Avishai-Yitshak, P. Sheeran, The tripartite model of risk perception (TRIRISK): distinguishing deliberative, affective, and experiential components of perceived risk, Ann. Behav. Med. 50 (5) (2016) 653–663, https://doi.org/10.1007/s12160-016-9790-z.
[54] W.M.P. Klein, L.E. Zajac, M.M. Monin, Worry as a moderator of the association between risk perceptions and quitting intentions in young adult and adult smokers, Ann. Behav. Med. 38 (3) (2009) 256–261, https://doi.org/10.1007/s12160-009-9143-2.
[55] S. Hallit, N. Layoun, D. Malaeb, et al., The impact of textual and pictorial warnings on tumbac (waterpipe tobacco) boxes on the motivation and intention to quit waterpipe smoking in Lebanon: a cross-sectional study, Environ. Sci. Pollut. Res. 26 (36) (2019) 36647–36657, https://doi.org/10.1007/s11356-019-06801-8.
[56] A. Mostafa, H. Mohammed, W. Hussein, et al., Plain packaging of waterpipe tobacco? A qualitative analysis exploring waterpipe smokers' and non-smokers' responses to enhanced versus existing pictorial health warnings in Egypt, BMJ Open 8 (10) (2018), e023496, https://doi.org/10.1136/bmjopen-2018-023496.
[57] R.G. Salloum, N. Abu-Rmeileh, R. Hamadeh, et al., Policy-relevant context of waterpipe tobacco smoking among university students in six countries across the Eastern Mediterranean region: a qualitative study, Asian Pac. J. Cancer Prev. APJCP 18 (9) (2017) 2533–2540, https://doi.org/10.22034/APJCP.2017.18.9.2533.