



# Effectiveness of a School Based Smokeless Tobacco Intervention: A Cluster Randomized Trial

Shafquat Rozi<sup>1</sup> · Nida Zahid<sup>2</sup> · Talat Roome<sup>3</sup> · Maryam Pyar Ali Lakhdar<sup>1</sup> · Sobiya Sawani<sup>1</sup> · Anam Razzak<sup>3</sup> · Zahid Ahmad Butt<sup>4</sup>

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## Abstract

To assess the effectiveness of intervention in improving knowledge, attitude and perception regarding smokeless tobacco (SLT) use and its harmful effects and intention to quit SLT among school going adolescents. A school-based cluster randomized control trial was carried out in 18 secondary schools targeting male and female students from grades 6 to 10 in Karachi. Primary outcome was knowledge about hazards of smokeless tobacco (SLT) and secondary outcomes were attitude and Perception about hazards of SLT, and intention to quit SLT. We enrolled 738 participants in intervention group and 589 in the control group. Mean score of knowledge significantly improved in intervention as compared to control group (P value < 0.01). Intention to quit was found to be proportionately higher (33%) in the intervention group as compared to control group. Generalized estimating equations were used to assess the association of factors with knowledge regarding harmful effects of SLT use. Significant predictors of increase in knowledge score were found in children: who had seen any anti SLT messages on social media in the past 30 days, who were getting information regarding harmful effects of SLT use in school or textbooks and who had friends using SLT. A school-based intervention was effective in increasing knowledge regarding the harmful effects of SLT use and intention to quit SLT use among school adolescents. Introduction of such educational programmes on a regular basis in schools or as part of school curriculum can have an impact on reducing prevalence of SLT use. **Trial Registration** NCT03418506. <https://register.clinicaltrials.gov/NCT03418506>.

**Keywords** Smokeless tobacco · Cluster randomized trial · Adolescents · School based intervention

## Introduction

Oral cancer has now become a severe and increasing problem worldwide and is the eighth most prevalent cancer [18]. The yearly estimated incidence is around 275,000 for oral and 130,300 for pharyngeal cancers excluding nasopharynx.

Two-thirds of these cases occur in developing countries [11]. High incidence rates of oral cancer are reported from Southeast Asian region, Eastern and Western Europe, Latin America, Caribbean and in Pacific regions [35]. In South and South East Asia, 40% of the people with cancers have been diagnosed with oral cancer [1]. Oral cancer is the second

✉ Shafquat Rozi  
shafquat.rozi@aku.edu

Nida Zahid  
nida.zahid@aku.edu

Talat Roome  
talatroome@yahoo.com

Maryam Pyar Ali Lakhdar  
maryam.ali@aku.edu

Sobiya Sawani  
sobiya.sawani@aku.edu

Anam Razzak  
anamrazzak@gmail.com

Zahid Ahmad Butt  
zabutt3@yahoo.com

<sup>1</sup> Department of Community Health Sciences, Aga Khan University, Stadium Road, Karachi 74800, Pakistan

<sup>2</sup> Department of Surgery, Aga Khan University, Stadium Road, Karachi 74800, Pakistan

<sup>3</sup> Department of Pathology, Dow University of Health Sciences, University Road, Karachi 75270, Pakistan

<sup>4</sup> School of Population and Public Health, University of British Columbia, Vancouver V6T 1Z4, Canada

most prevalent cancer in Pakistani women and third in men. The age standardized rates for oral cancers are 13.8 and 14.1 in males and females respectively [5, 24].

Currently, the major forms of tobacco that are used in the South Asian countries including Pakistan are pan(betel-*quid*) with tobacco, Gutka (special tobacco formulation), packaged chewing tobacco products and bidis [15]. SLT is a type of tobacco that is not smoked or burned. It can be used as chewing tobacco or moist snuff, or inhaled through the nose as dry snuff. Smokeless tobacco contains nicotine and many harmful, cancer-causing chemicals.

Areca nut is a seed of fruit of oriental palm. It is commonly wrapped in a leaf of the piper betel plant hence more commonly named betel nut. Betel *quid* consists of a mixture of areca nut, slaked lime and catechu. Other substances coconut, cardamom, cloves and tobacco are often added. It is wrapped in a betel leaf. Gutka is a new and sweetened smokeless tobacco, legally sold packaged in bright foil and has major health implications. Pan with tobacco consists of four main ingredients namely, tobacco, areca nuts and slaked lime wrapped in betel leaf. Dry snuff is powder tobacco that is inhaled through the nasal passages or taken orally [30].

Association of betel *quid* chewing and oral cancer was first identified in 1933 based on a study of 100 oral cancer patients in India [28]. Moreover, studies from South Asia have shown a link between betel nut, areca-nut, chewable tobacco and tobacco use in the development of cancers [2, 4, 19]. A study conducted in India reported an association between oral cancer and oral tobacco use in numerous forms including ‘*paan*’ (betel leaf) with tobacco and without tobacco [14]. Other studies from South East Asia have also reported an association between red slaked lime in betel *quid* and oral cancer (OR 10.67; 95% CI 2.27–50.08) [21]. Two meta-analyses also suggested an association of SLT use and hazard of oral and oropharyngeal cancers [12, 13].

The pattern of tobacco use varies according to social status and age. Tobacco use primarily begins in early adolescence, typically by age 16; first use mostly occurs before the time of high school graduation [3, 32]. The use of chew tobacco and snuff has been increasing among adolescents [7].

A study from Karachi, Pakistan reported prevalence of tobacco use among school going children of 16.1% [30]. Another study from Pakistan has documented the association of betel *quid*, areca and tobacco use with head and neck cancers [19, 22]. However, there is scarcity of data on the association of SLT use with oral cancers and interventions or programmes to reduce, prevent or stop SLT.

School based interventions are effective strategies for reducing and preventing tobacco use among adolescents. Intervention studies from China [9], United Arab Emirates [27] and India [16] have reported improvement in enhancing knowledge and changing attitudes and behaviours about

tobacco use and its harmful effects among school going adolescents. Other school based programs focusing on smoking prevention have shown an increase in adolescent’s knowledge and attitudes regarding smoking [20, 29] and were successful in reducing intention to smoke [17, 20, 33] and behaviours [10, 33]. A pilot school based study from Papua New Guinea reported an increase in knowledge about betel *quid* consumption and its harmful effects among students [8].

For countries with limited resources such as Pakistan, it is imperative to prevent oral cancer by improving knowledge about its important risk factors such as betel *quid*, areca-nut and chewable tobacco. Since prevalence of tobacco use among school going children in Pakistan is 16.1% [30], therefore, schools can play an important role in supporting interventions to stop tobacco use especially among adolescents. To the best of our knowledge, no intervention study has been done in Pakistan to assess the effectiveness of a school based intervention on knowledge, attitudes and perception of school aged children regarding SLT use and its harmful effects particularly oral cancers. Therefore, we aimed to implement a cluster randomized trial in secondary schools to assess the effectiveness of intervention in improving knowledge, attitude and perception regarding smokeless tobacco (SLT) use and its harmful effects and intention to quit SLT among adolescents.

## Methods

### Study Setting

Karachi is a cosmopolitan city with diverse groups of cultures, traditions, and ethnicities. Urdu, which is the national language of Pakistan, is also the dominant language of Karachi. Other major ethno-linguistic groups include Pushtu, Punjabi, Siraiki, Sindhi, Balochi and Bengali speaking people. We identified high prevalence of tobacco use of 16.1% among school going adolescents at three sites of district East (Gadap, Bin-Qasim town, and Malir) [30, 31]; therefore, we conducted this intervention study at these sites. There is an ethnic mix of people residing in these three towns with majority belonging to the middle and lower middle socio-economic status.

### Study Design

A school-based cluster randomized control trial was carried out in 18 secondary schools in Karachi. The data collection period was for 6 months from September 30, 2017 to November 30, 2017. The target population was school going boys and girls from grades 6 to 10 in both intervention and control group.

## Sample Size

The sample size for cluster randomized trial was calculated using the computer program WHO ACluster. We required a minimum number of clusters of 22 schools (11 schools in each arm) with an average cluster size of 50 with 95% confidence interval, 80% power, and an intra-class correlation (ICC) between students was assumed to be of 0.2. The difference to be detected in knowledge/attitude/perception was assumed to be 2 with a standard deviation of 9.5 [34]. After adjusting for 10% non-response rate, we expected to recruit 605 students with 50 students from each school.

## Sampling Technique and Randomization Procedure

A two-stage cluster sampling with stratification on school type (government or private) was employed for the selection of schools and recruitment of students. With the assistance of district head of education department, we have received a list of all secondary schools (Class 6 to 10) in Malir, Gadap and Bin Qasim town. Schools having grades 6–10 were then stratified on public and private schools type. After stratification, schools were selected randomly proportionate to the number of type of schools. Each school was considered as a cluster and schools were the primary unit of randomization. Randomization was performed by the principal investigator through a computer generated sequence using SPSS and applied to the list of schools by another co-investigator who was not involved in the analysis of the data. The selected schools were randomly assigned by simple randomization to an intervention or control group. There was no difference between schools in terms of schools location, geographically close to each other, with a distance of about 4 km from one to another. There were no differences between schools in term of students' size, and their background characteristics. To avoid contamination between clusters randomization was carried out at the school level. Recruitment of participating schools was based on their willingness to participate in the study. Students of grade 6–10 were randomly selected through simple random selection from each cluster (schools) by program providers and were invited to participate in the study. A total of 738 students were recruited from 10 schools in the intervention arm and 589 students from 8 schools in the control group.

## Eligibility Criteria

Inclusion criteria for schools and participants.

- Secondary schools registered with Board of Secondary Education Karachi
- Schools having at least 15 students in each grade from grades 6 to 10.

## Exclusion Criteria

- School authorities who did not grant permission to conduct the research study in their school
- School students who were not willing to participate in the study

## Ethical Approval

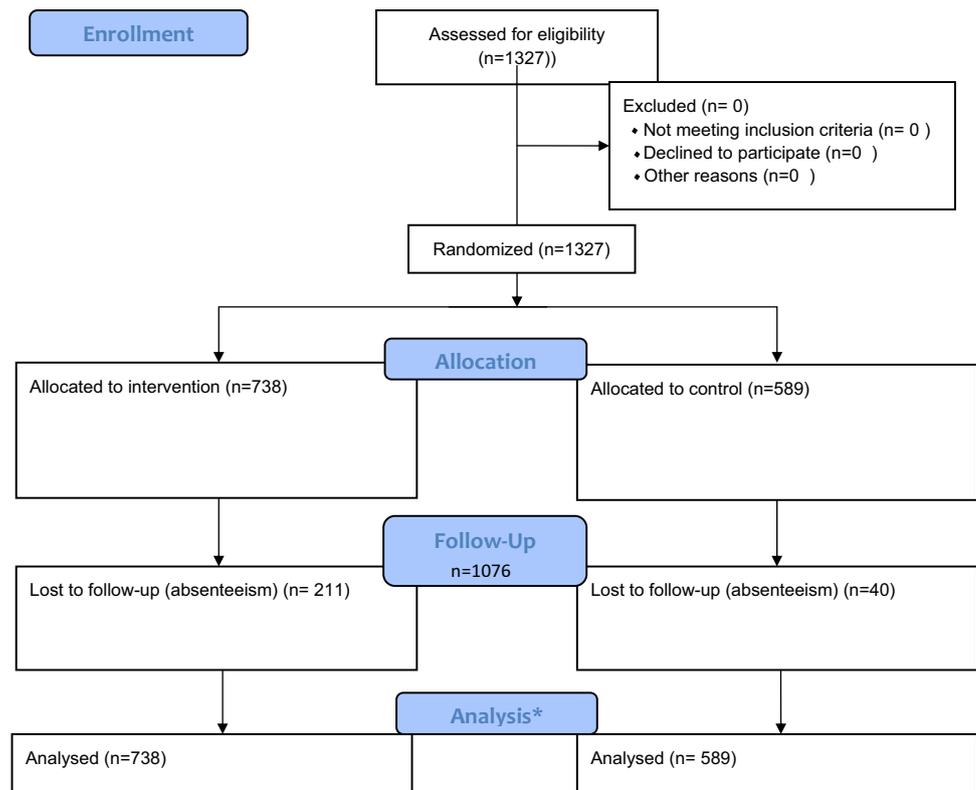
Ethical approval for the study was obtained for the institutional review board. Additional approval was obtained from school authority after explaining the purpose of the study and reassurance was given to the schools that the name of schools and students will not be disclosed at any forum. Written informed consent was taken from all participating schools and it was communicated to the students that participation is completely voluntary. Schools have informed parents by sending a note that their children will participate in the educational sessions related to hazards of tobacco and the teaching materials have been reviewed and approved by schools management and it was clearly indicated that the parents can withdraw their children from the study at any point in time. In this study none of the students requested to withdraw. However, if any student or their parents would have requested to withdraw at any point in time from the study, we would have allowed them to withdraw from the study. This trial is registered in the ClinicalTrials.gov registry (NCT03418506). The intervention was educational based and the content that we used was adapted and modified from literature according to our cultural context for which we received ethical approval from Ethical Review Committee. We have followed CONSORT guidelines (Fig. 1).

## Study Procedure

At baseline interview visit, all participants were assessed for socio-demographic characteristics and knowledge, attitude and perception regarding smokeless tobacco by administering a tool that was adapted and modified from WHO in both intervention and control group.

## Intervention Group

After baseline assessment the intervention program was executed by trained program providers. On the first day the intervention group received 30 min of educational session through presentation, posters, and pictorial booklets. The students were taught about the hazardous effects of SLT. Four weeks after the first intervention session, the students were reinforced for the hazardous effects of SLT through a game show named “need for speed”. A post assessment

**Fig. 1** CONSORT 2010 flow diagram

was performed 8 weeks after the baseline assessment for assessing student's knowledge, attitude and perception about smokeless tobacco use after intervention.

### Control Group

After baseline assessment the control group received self-reading educational leaflets (majority of which were pictorial). The pamphlets focused on hazards of SLT. Post assessment regarding knowledge, attitude and perception about smokeless tobacco was conducted 8 weeks after baseline assessment was done in the intervention arm.

### Intervention Programme

A health education programme was conducted for 8 weeks in one academic year for all the selected schools. Before commencing the intervention, the selected schools chose a date for an allocated class to complete the pre-test questionnaire. The intervention sessions included a 30 min PowerPoint presentation, two posters, one pictorial booklet and video game on the hazards of use of various tobacco products, chewing tobacco/Gutka, formation of chewing tobacco, snuff and snus, short term effects of SLT (stained teeth, bad breath, cavities, canker sores, mouth

ulcer, plaque, drooling, gum bleeding and swelling etc.), long term effects of SLT (cancers of mouth, tongue, throat, oesophagus or stomach and lips, bone loss, stomach ulcers, tooth abrasion, heart diseases, psychological problem and altered reproductive system). Emphasis was also given on danger signs of oral cancer and different strategies of quitting SLT was also explained to the students. All the content was translated in Urdu language as the schools had both English and Urdu medium. To maintain uniformity, we preferred delivering the intervention in Urdu. Apart from PowerPoint, this content was also displayed in the form of posters and pictorial booklet. Moreover, a 30 min game show was conducted at follow-up visit. The game show "need for speed" was designed by the study team. The purpose of this game show was to reinforce about the hazardous effects of SLT. All the material for intervention was adapted from Global Youth Tobacco Survey (GYTS) [36] which is a validated tools. The programme was conducted by a professional team of physicians trained in this field. After completion of intervention programme, the same group of students completed the post-test questionnaire. Educational materials about hazards of betel quid, areca-nut and smokeless tobacco were distributed to both intervention and control groups. To avoid bias at programme provider level all those who were conducting sessions were not involved in the post assessment process.

## Outcome Measures

### Primary Outcome Measure

Knowledge about hazards of SLT.

### Secondary Outcome Measures

1. Attitude about hazards of SLT
2. Perception about hazards of SLT
3. Intention to quit SLT

All outcomes were assessed through a self-administered questionnaire.

## Questionnaire

Pre-testing was done on 10% of sample. Data was collected from students using self-administered, pre-coded questionnaire which consisted of three sections adapted from Global Youth and Adult Tobacco Survey (GYTS) [36]. The first section consisted of 17 items with questions on socio-demographic information of students. The second section comprised of 30 items including questions on ever use, type, and duration of SLT, and school environment. The third section was on knowledge, attitudes and perception about SLT. The knowledge part comprised of 40 items, the correct answer was coded as 1 else 0. It included information on SLT use, common sites of placing chewing tobacco, dry snuff, formation of chewing tobacco, snus, and addiction, health hazards of using SLT, short and long term complications of using SLT, signs of oral cancers, common cancers, role of social media and peer pressure in SLT use, different strategies for quitting SLT and appropriate brushing techniques. The component that comprised of questions on attitude had seven items with a maximum score of 15. It included questions on; usage of SLT, family and peer pressure, advertisements/social media and the desire to quit SLT use. The section on perception comprised of eight items including; perception of child on usage of SLT, young people and image of SLT, pocket money usage on SLT, ban on SLT, advertisements of SLT on media and health warning on media about usage and quitting of SLT. Filling the questionnaire took approximately 15–20 min. Reassurance was given to the students that the information they provided will remain confidential and thus, we encouraged them to provide truthful responses. The questionnaire was originally developed in English, translated in Urdu and distributed according to the students' level of understanding of languages. Pre and post-intervention assessment questionnaires were

administered before and after the intervention program by study research assistants in the class rooms.

## Training

A 2 days training programme was organized for the programme providers by a professional team of physicians trained in this field. The objectives of this training were to maximize the impact of the programme and to make sure that each intervention should be delivered in a similar way regardless of schools or providers. Training programme comprised of an outline of the programme, summary of teaching methods, and an assessment of available resources. The researchers and experts shared their knowledge and experience with the programme providers.

## Data Entry

Data were entered and checked for accuracy and consistency with the help of EPI-Info software; version 3. Two data entry operators double entered the data to ensure its validity; files were compared and rechecked. Analysis was done in statistical package STATA version 12. Absolute confidentiality of the data was maintained throughout the study.

## Statistical Analysis

Descriptive statistics were computed for categorical variables by computing frequencies and significance was assessed by Chi square. The distribution of quantitative variables was examined by means and standard deviations. Comparison of knowledge, attitude and perception between intervention and control group was examined using independent *t* test. We performed multivariable analysis using generalizing estimating equation (GEE) to assess associations between the knowledge score and all study variables while accounting for the clustering structure in the data. Confounding was assessed by change in estimate of coefficient by 15%.

## Results

### Descriptive Socio-demographic Characteristics of Study Population for Intervention and Control Group

We enrolled 738 participants in intervention group and 589 in the control group. The overall attrition rate of participants was 19% (16% intervention group vs. 3% control group) due to absenteeism at the time of post intervention. The mean age of adolescents participating in school based intervention study for both groups was almost similar; intervention group was 14.19 (SD=0.06) years while it was 14.24 (0.06)

**Table 1** Socio-demographic characteristics of study participants (n = 1327) by intervention and control groups at selected schools of Karachi, Pakistan

Characteristics	Intervention (n = 738)	Control (n = 589)	P-value
Age			
Mean (SD)	14.19 (0.06)	14.24 (0.06)	0.62
Gender			0.03
Male	461 (62.47)	335 (56.88)	
Female	277 (37.53)	254 (43.12)	
Religion			0.40
Muslim	722 (97.83)	572 (97.11)	
Christian/Hindu/other	16 (2.17)	17 (2.89)	
Area of residence			<0.01
Bin Qasim	294 (39.84)	291 (49.41)	
Gadap	145 (19.65)	0 (0.00)	
Malir	299 (40.51)	298 (50.59)	
Type of school system			0.88
Government	370 (50.14)	293 (49.75)	
Private	368 (49.86)	296 (50.25)	
Father's education status			0.14
Illiterate	111 (15.04)	67 (11.38)	
Grade 10 and lower	288 (39.02)	244 (41.43)	
Above grade 10	339 (45.93)	278 (47.20)	
Father's occupation			<0.01
Retired/not working	20 (2.71)	29 (4.92)	
Labour	264 (35.77)	248 (42.11)	
Office/medical related/clerk	284 (38.48)	210 (35.65)	
Business man/landlord	86 (11.65)	36 (6.11)	
Others	84 (11.38)	66 (11.21)	
Did fathers suffer from any disease			0.03
No	619 (83.88)	518 (87.95)	
Yes	119 (16.12)	71 (12.05)	
Mother's education status			<0.01
Illiterate	226 (30.62)	129 (21.90)	
Grade 10 and lower	285 (38.62)	265 (44.99)	
Above grade 10	227 (30.76)	195 (33.11)	
Mother's employment status			0.58
Unemployed	679 (92.01)	537 (91.17)	
Employed	59 (7.99)	52 (8.83)	
Did Mothers suffer from any disease			0.07
No	670 (90.79)	517 (87.78)	
Yes	68 (9.21)	72 (12.22)	
Number of siblings			0.22
Mean (SD)	4.01 (0.07)	3.86 (0.08)	
Did sibling suffer from any disease			0.53
No	700 (94.85)	563 (95.59)	
Yes	38 (5.15)	26 (4.41)	
Mother tongue			<0.01
Urdu	248 (33.60)	258 (43.80)	

**Table 1** (continued)

Characteristics	Intervention (n = 738)	Control (n = 589)	P-value
Sindhi	258 (34.96)	87 (14.77)	
Others	232 (31.44)	244 (41.43)	
Family's monthly income			0.10
Less than 10,000	135 (18.29)	83 (14.09)	
10,000 to 30,000	329 (44.58)	269 (45.67)	
More than 30,000	274 (37.13)	237 (40.24)	

years in control group (Table 1). In our study, most of the participating adolescents were males (62.47% in the intervention group vs. 56.88% in the control group). An almost similar proportion was observed for government and private school participants (50.14% in the intervention vs. 49.75% in the control group were from government setting). More than half of the fathers of participating adolescents had their education above grade 10 (45.93% in the intervention vs. 47.20% in the control group) whereas for mothers, majority of them had their education grade 10 and lower (38.62% in the intervention vs. 44.99% in the control group). In this study, more than four-fifth of the adolescent's fathers (97.28% in the intervention vs. 95.08% in the control group) and very few (7.99% in the intervention vs. 8.83% in the control group) mothers were employed. Most of them (44.58% in the intervention vs. 45.67% in the control group) had family income of 10,000 to 30,000 Pakistani Rupees (Table 1).

### Information Regarding SLT Use Among Study Population for Intervention and Control Group

More than three-fourths of the adolescents participating in the study were SLT users (73.85% in the intervention vs. 80.48% in the control group) (Table 2).

Among all adolescents using SLT, the majority of them were using betel nut with tobacco/gul/gudaka (69.65% in the intervention vs. 77.25% in the control group). In the past 30 days proportion of participants who used SLT for 1–9 days were approximately 28% in the intervention group versus 36% in the control group. Around 20% of participants from the intervention versus 17% from the control group were using SLT for 10 days and above. There were 21% of adolescents from both intervention and control group using SLT at home, 16.94% from intervention and 24.79% from control using SLT at school. Almost 35% from intervention and control group were using SLT at different places like work place, friend's house and social events. In this study, 46.48% of adolescents from intervention and 54.84% from control have reported that SLT is available near their school premises. About 50.9% students from control and 27.9% from intervention group have seen

**Table 2** Information regarding SLT use of study participants (n = 1327) by intervention and control groups at selected schools of Karachi, Pakistan

Characteristics	Intervention (n = 738)	Control (n = 589)	P-value
Ever smokeless tobacco user			0.004
Yes	545 (73.85)	474 (80.48)	
No	193 (26.15)	115 (19.52)	
Type of SLT product used			0.008
Non-user	193 (26.15)	115 (19.52)	
Tobacco leaf/Gutka/Mishri/Snuff such as nas/naswar	31 (4.20)	19 (3.23)	
Betel nut with tobacco/gul/gudaku	514 (69.65)	455 (77.25)	
Age at which first STL used			<0.01
Less than 12	95 (12.87)	76 (12.90)	
12 or more	64 (8.67)	75 (12.73)	
Don't know	385 (52.17)	323 (54.84)	
N/A	194 (26.29)	115 (19.52)	
Time at which you stopped SLT			0.03
Not stopped	353 (47.83)	310 (52.63)	
1 year and less	147 (19.92)	130 (22.07)	
More than 1 year	45 (6.10)	34 (5.77)	
N/A	193 (26.15)	115 (19.52)	
In past 30 days, # of days you used SLT			<0.01
0 days	385 (52.17)	279 (47.37)	
1–9 days	206 (27.91)	211 (35.82)	
10 and above	147 (19.92)	99 (16.81)	
During past 30 days, # of times you used SLT per day			0.08
Did not use SLT during past 30 days	385 (52.17)	279 (47.37)	
≤ 1 time per day	231 (31.30)	218 (37.01)	
> 1 times per day	122 (16.53)	92 (15.62)	
Place of SLT use			<0.01
At home	159 (21.54)	127 (21.56)	
At school	125 (16.94)	146 (24.79)	
Others	261 (35.37)	201 (34.13)	
Non-users	193 (26.15)	115 (19.52)	
Purchase and use of SLT in the past 30 days			<0.01
Did not use SLT during past 30 days	378 (51.71)	278 (47.20)	
Store or shop/street vendor	242 (33.11)	173 (29.37)	
Got from my friends	84 (11.49)	115 (19.52)	
Got from family and others	27 (3.69)	23 (3.90)	
Is it easy or difficult to buy SLT from a shop			0.01
Do not usually buy SLT from a shop	368 (49.86)	268 (45.50)	
Easily	273 (36.99)	262 (44.48)	
Difficult	97 (13.14)	59 (10.02)	

hawkers sell SLT and other harmful tobacco products outside their school. Additionally, 41.7% from control group reported sale of tobacco products inside school premises. About 68.2% adolescents from control versus 65.3% from intervention group have informed that their family members have ever used SLT. In our study, approximately 50% of adolescents from control versus 39.43% from intervention stated that their school staff used SLT (Table 3).

### Comparison of Knowledge, Attitude and Perception Scores 8 Weeks After Intervention at Selected Schools of Karachi, Pakistan

All students in intervention and control group were compared 8 weeks after intervention to see the difference in knowledge, attitude and perception scores (Table 4). It was observed that the post scores of intervention group as

**Table 3** Information regarding SLT use of study participants (n=1327) due to environmental and social factors by intervention and control groups at selected schools of Karachi, Pakistan

Characteristics	Intervention (n = 738)	Control (n = 589)	P-value
Is SLT available near school			<0.01
Yes	343 (46.48)	323 (54.84)	
No	3959 (53.52)	266 (45.16)	
Did you see any hawkers selling SLT outside school			<0.01
No	532 (72.09)	291 (49.41)	
Yes	206 (27.91)	298 (50.59)	
Did you see SLT being sold in school premises			<0.01
No	597 (80.89)	343 (58.23)	
Yes	141 (19.11)	246 (41.77)	
In past 30 days, did anyone refuse to sell you SLT because of your age			0.04
Did not try buying SLT during past 30 days	385 (52.17)	279 (47.37)	
Yes, refused to sell due to my age	103 (13.96)	71 (12.05)	
No, my age did not keep me from buying SLT	250 (33.88)	239 (40.58)	
How often do you see your father/stepfather using SLT in home			0.07
Never	447 (60.57)	392 (66.55)	
Sometimes	175 (23.71)	121 (20.54)	
About every day	116 (15.72)	76 (12.90)	
How often do you see your mother/stepmother using SLT in home			0.257
Never	579 (78.46)	459 (77.93)	
Sometimes	114 (15.45)	104 (17.66)	
About every day	45 (6.10)	26 (4.41)	
How often do you see your family member living in your home using SLT			<0.01
Never	439 (59.49)	399 (67.74)	
Sometimes	211 (28.59)	144 (24.45)	
About every day	88 (11.92)	46 (7.81)	
How often do you see your friends using SLT			0.22
Never	155 (21.00)	109 (18.51)	
Sometimes	314 (42.55)	239 (40.58)	
About every day	269 (36.45)	241 (40.92)	
Did you see any school teacher/staff/principal using SLT in school premises			<0.01
No	447 (60.57)	304 (51.61)	
Yes	291 (39.43)	285 (48.39)	
Have you ever received help/advice to stop using SLT			<0.01
No	425 (57.59)	263 (44.65)	
Yes, from a (friend/family member/teacher or professional)	313 (42.41)	326 (55.35)	
In past 30 days, have you seen any anti SLT messages on local media like television/radio/newspaper/SMS/posters/billboard			0.01
Yes	610 (82.66)	456 (77.42)	
No	128 (17.34)	133 (22.58)	
In past 30 days, have you seen any anti SLT messages on Internet/Facebook/Twitter/YouTube/Instagram			<0.01
Yes	504 (68.29)	335 (56.88)	
No	234 (31.71)	254 (43.12)	
In past 30 days, have you seen any messages promoting SLT usage on local media like television/radio/newspaper/SMS/posters/billboard			<0.01
Yes	271 (36.72)	312 (52.97)	
No	467 (63.28)	277 (47.03)	
In past 30 days, have you seen any messages promoting SLT usage on international media like television			0.23
Yes	307 (41.60)	226 (38.37)	

**Table 3** (continued)

Characteristics	Intervention (n = 738)	Control (n = 589)	P-value
No	431 (58.40)	363 (61.63)	
In past 30 days, have you seen any messages promoting SLT usage on Internet/Facebook/Twitter/YouTube/Instagram			0.74
Yes	145 (19.65)	120 (20.37)	
No	593 (80.35)	469 (79.63)	

**Table 4** Comparison of knowledge, attitude and perception score 8 weeks after intervention at selected schools of Karachi, Pakistan

Characteristics (8 weeks after intervention)	Intervention (Mean $\pm$ SD)	Control (Mean $\pm$ SD)	P-value*
Knowledge	30.56 $\pm$ 4.90	22.46 $\pm$ 7.49	< 0.01
Attitude	11.65 $\pm$ 3.16	11.11 $\pm$ 3.37	< 0.01
Perception	6.14 $\pm$ 1.53	5.84 $\pm$ 1.64	< 0.01

\*P value using t test using 2 independent sample

compared to control for knowledge, attitude and perception were significantly higher.

There was a 12.38 points increase in knowledge of intervention arm and 5.55 point increase in control arm. The results showed an increase in knowledge from baseline not only in the intervention arm but also in the control arm. However, there was very slight change in post intervention scores from the baseline for attitude and perception (11.12 to 11.65) and (5.93 to 6.14) respectively.

### Multivariable Analysis

The multivariable analysis was performed for primary outcome measure knowledge score about hazardous effect of SLT. Table 5 reveals the final multivariable model that indicates a 2.84 units (95% CI 1.96, 3.74) increase in the mean score of knowledge in intervention arm as compared to control arm.

The change in the mean score of knowledge increased by 1.52 units (95% CI 0.91, 2.13) among children who had seen any anti SLT messages on Internet/Facebook/Twitter/YouTube/Instagram in the past 30 days as compared to those who had not watched. The change in the mean score of knowledge increased by 1.15 units (95% CI 0.48, 1.81) among children who were getting information regarding harmful effects of SLT/betel quid in school as compared to those who were not getting any information on smokeless tobacco. Children who were reading textbooks about health effects of tobacco were found to have an increase in the change in the mean score of knowledge by 0.77 units (95% CI 0.09, 1.44). The change in the mean score of knowledge increased by 1.41 units (95% CI 0.77, 2.05) among

children having family members that have ever used SLT. The change in the mean score of knowledge increased by 2.22 units among children with fathers who were laborer. Among children with friends who were always using SLT, the change in mean score of knowledge increased by 1.46 units as compared to children with friends who had never used SLT. The change in the mean score of knowledge increased by 3.35 units among male children (3.26 units, 95% CI - 4.43, - 2.10) who were in the intervention group. With every 1 year increase in age, the change in the mean score of knowledge among government school increased by 0.41 units (95% CI 0.06, 0.75). We also performed sensitivity analyses evaluating the effect of intervention on intention to quit among study participants (Supplementary Table 1) and also assessed the effect of intervention on those who were ever users of smokeless tobacco (Supplementary Table 2). A higher proportion of study participants reported intention to quit in the intervention group 8 weeks after intervention (14.76% versus 46.15%; percent increase 33%). A significant difference was found in mean knowledge score of study participants who had ever used SLT versus who didn't use SLT (P-value 0.008) (Supplementary Table 2).

### Discussion

In our study, knowledge scores at baseline and after intervention were significantly different in the intervention group which indicates that the intervention had a significant effect on improvement of knowledge of the participants about hazardous effects of SLT use. This is comparable to other school-based intervention studies that showed an improvement in student's knowledge about tobacco use and its effects [8, 9, 16, 27].

In our study, we found a significant association of improvement in knowledge scores with exposure to anti SLT messages on social media, female gender, reading textbooks with information on ill effects of smokeless tobacco, father's employment status and age of students. Participants who were in the intervention group had seen proportionately more anti SLT messages on social media as compared to the control group. Therefore, it is likely that their knowledge regarding SLT hazards could have been affected by this

**Table 5** Multivariate analysis of factors associated with knowledge score among intervention and control groups at selected schools of Karachi, Pakistan

Characteristics	Adjusted $\beta$ (SE ( $\beta$ ))	95% CI	P-value ( $\alpha \leq 0.05$ )
Outcome: knowledge score			
Treatment group			
Intervention	2.84 (0.45)	1.94, 3.74	<0.01
Control	–	–	–
In past 30 days, have you seen any anti SLT messages on Internet/Facebook/Twitter/YouTube/Instagram			
No	–	–	–
Yes	1.52 (0.31)	0.91, 2.13	<0.01
Gender			
Female	–	–	–
Male	–4.44 (0.46)	–5.56, –3.75	<0.01
Did anyone in school provide you with any information regarding harmful effects of SLT			
No/don't know	–	–	–
Yes	1.15 (0.34)	0.48, 1.81	<0.01
Type of school			
Government	–2.58 (2.53)	–7.82, 2.11	0.26
Private	–	–	–
In past 12 months, have you read in your school textbooks about effects of tobacco			
No	–	–	–
Yes	0.77 (0.34)	0.09, 1.44	0.02
Family members ever used SLT			
No	–	–	–
Yes	1.32 (0.33)	0.66, 1.97	<0.01
Father's occupation			
Retired/not working	–	–	–
Labour	2.22 (0.82)	0.60, 3.84	<0.01
Office/medical related/clerk	1.86 (0.83)	0.23, 3.50	0.02
Business man/landlord	0.71 (0.91)	–1.14, 2.56	0.45
Others	1.57 (0.90)	–0.19, 3.34	0.08
How often do you see your friends using SLT?			
Never/do not have friends	–	–	–
Sometimes	1.36 (0.42)	0.53, 2.18	<0.01
About every day	1.46 (0.43)	0.60, 2.31	<0.01
Interaction (intervention vs. gender)			
Intervention/male	3.35 (0.61)	2.17, 4.53	<0.01
Interaction (type of school vs. age)	0.41 (1.77)	0.06, 0.75	0.02

\*Multivariable analysis:  $\beta = 12.37$ , Overall  $\chi^2$  T.S = 487.32

exposure. This indicates that media can play an important role in increasing awareness about harmful effects of SLT use [26]. We found that females did better on knowledge scores regarding hazardous effects of SLT as compared to males. A plausible explanation of this could be that females are more concerned about ill effect of any product that could affect their health and physical appearance as compared to males. Physical appearance and oral health have been reported to be of great value among female adolescents [25]. However, this observed gender differential requires further investigation. Moreover, our study results also showed that students who were reading textbooks with information on ill effects of smokeless tobacco had better knowledge about

SLT hazardous effects. This has important implications as it indicates that incorporating information about harmful effects of SLT and tobacco use in school curriculum can have an impact on reducing or stopping SLT use. It was also seen that students with fathers in blue collar jobs (laborers) had better knowledge regarding smokeless tobacco hazardous effects. It is plausible that their fathers may be suffering from illnesses due to its hazardous effects which might have increased student's awareness regarding its ill effects or this could be a proxy for poor socio-economic status or lower educational attainment. Previous studies have reported increased rates of tobacco use among illiterate and primary educated parents [27].

We also observed that students whose friends were using smokeless tobacco products had better knowledge about its hazardous effects. It is likely that these students must have either witnessed the hazardous effects among their friends or had discussed it among themselves and; therefore, were more aware about it. Our study results also indicate that the students who were older had better knowledge about its hazardous effects. This is consistent with findings from another study from India which showed an increase in knowledge scores with increasing age of students after an anti-tobacco awareness program [16].

In this study, we also assessed the attitude and perception of students about smokeless tobacco use. However, the change in attitude and perception of students after the intervention was very slight. It is possible that the intervention was more effective towards increasing knowledge and less so for attitude and perception. Other studies on school based education program on tobacco use in Papua New Guinea [8] and China [9] have also reported improvement in knowledge scores but not in attitudes. This could be attributed to peer pressure or cultural norms that could affect attitudes toward tobacco use [8] and are more difficult to change than awareness and knowledge [6]. We observed a 33% increase in the proportion of study participants in intervention group who indicated their intention to quit SLT use after intervention program. Additionally, we also noted an increase in the knowledge scores of a sub-sample of study participants who had ever used SLT. We were unable to assess the changes in SLT use among students as our intervention program was for 8 weeks and we cannot expect behavioral change in such a short period of time. However, in future we intend to conduct long term studies for a period of at least 4 years to assess the effectiveness of intervention in reducing the smokeless tobacco use. A study conducted in USA to assess the effectiveness of an institutional intervention aimed at decreasing prevalence of tobacco use over a 4-year period reported a significant decrease in smokeless tobacco use [23]. Moreover, study participants were recruited from three towns of Karachi that is Malir, Gadap and Bin Qasim as we have mentioned earlier, that residents of these town belongs to mix ethnic and socioeconomic background; thus, study findings can be generalizable to all towns with middle and lower socioeconomic background.

Our study has some limitations. Although, our study showed a significant increase in knowledge regarding harmful effects of SLT, by design, we are unable to judge if students would quit using SLT or would not start SLT after the intervention. Due to the cluster randomized design of our study, where randomization was done at the school level instead of individuals, there may still be differences between groups at baseline in knowledge, attitude and perception. Therefore, residual confounding may still

occur after adjustment for differences in these variables at baseline as previously reported in other studies [34]. We were also unable to judge the effectiveness of each individual component within the health education sessions. Future analyses would look at the individual effect of each component within the multicomponent educational intervention. Additionally, our study focused on school based intervention; however, there may be lack of a supportive environment outside the school which may have affected the effectiveness of our intervention. Nevertheless, this study is the first cluster randomized trial to evaluate the effectiveness of a school based educational intervention in Pakistan on the knowledge, attitude, and perceptions of students about SLT use, using multicomponent health education sessions. Trial was conducted on public and private secondary schools from three towns in Karachi with a diverse, multi-ethnic population.

Our study results indicate that a school based intervention program is effective in increasing knowledge regarding the harmful effects of smokeless tobacco, areca nut and betel quid among school going adolescents. Thus, it is essential to introduce such educational programs on a regular basis in schools. Furthermore, such educational programs could also be integrated in the curriculum of all schools to impart knowledge regarding the hazards of smokeless tobacco. We also recommend involvement of parents and school staff that can support this school based intervention program and initiation of family and community based anti-tobacco programs so that messages regarding harmful effects of tobacco use are consistent across home, school and the broader community.

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**Author Contributions** SR: conceived and designed the study, education material, data analysis, manuscript drafting and finalized. NZ: responsible for manuscript writing, and reviewing the paper and educational material. ML: assisted in data analysis, preparing educational material and supervised field activities. SS: data management and basic descriptive analysis. TR: contributed to manuscript drafting. AR: coordinated budget and logistics of the study. ZB: reviewed the final manuscript. All authors saw and approved the final version of manuscript.

## Compliance with Ethical Standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical Approval** Ethical approval for the study was obtained for the institutional review board at Dow University of Health Sciences.

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