Evaluation of a Web-Based Randomized Controlled Trial Educational Intervention Based on Media Literacy on Preventing Substance Abuse Among College Students, Applying the Integrated Social Marketing Approach: A Study Protocol

Hanieh Jormand

   Hamadan University of Medical Sciences School of Public Health   https://orcid.org/0000-0002-4582-1473

Saeed Bashirian

   Hamadan University of Medical Sciences School of Public Health

Majid Barati (✉ Barati@umsha.ac.ir)

   https://orcid.org/0000-0002-5152-1928

Forouzan Rezapur-Shahkolai

   Hamadan University of Medical Sciences School of Public Health

Mohammad Babamiri

   Hamadan University of Medical Sciences School of Public Health

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Abstract

Background:

Substance abuse is the actual psychosocial harm, especially in young people confronted with content marketing in nowadays media environment, a risk factor for experiencing substance abuse. Based on the literature review, education designed based on the cognitive-behavioral model and planning models, such as using a social marketing framework, is the most effective method to prevent addictive substance abuse. Also, Media literacy related to substance abuse and the prototype willingness model is considered a new integrated approach to present the intervention measures' desired results.

Methods:

The present study evaluates an intervention program based on media literacy on substance abuse prevention among students using an integrated social marketing approach. This study aims to complete the SMART model's sixth and seventh stages, implementing intervention and evaluation. Participants will be students of Hamadan University, Iran. Randomization will occur at the university and school levels, and gather data will appear at two-time (i.e., pre-test and three months follow-up). Intervention group Students will obtain both substance abuse prevention education and substance abuse media literacy (SAML) educations between pre-test and three months post-test. Students in the delayed-intervention will be given this education after study accomplishment; this group will receive their regular courses except for substance abuse prevention and media literacy titles during education intervention. The outcome variables are intentions and substance abuse behavior based on prototype willingness and substance abuse media literacy.

Discussion:

Evaluation of Substance abuse prevention and substance abuse media literacy education must be careful to ensure that they effectively enable people, especially in youth in the new media ecology and unique 'Infomedia' ecosystems, in the current digital society. The SAML education plan's evaluation has the first web-based education program in universities. No prior research has psychometrically considered SAML in students in the SMART model's sixth and seventh stages.

Trial registration: IRCT20200914048719N1

Background

According to the United Nations Office on Drugs and Crime (UNODC), in 2017, a total of 271 million people aged 15 to 64 years were drug abusers (1, 2). Due to its young people and geographical location, Iran mainly deals with this social, political, and health global problem (3). Epidemiological studies suggest an average age of 17.8 ± 3.9 years for the onset of the first use of addictive drugs, which

gradually increases with age. This age range is associated with young people's entry into universities and starting the studentship period. The first year in a university is considered the most challenging time for students. This period includes social challenges of being away from families, meeting new friends with different cultures, and mental challenges, such as successfully performing multiple assignments. In turn, it can lead to mental disorders such as depression and increase the possibility of addictive drug abuse and loneliness and estrangement (4).

On the other hand, previous studies reported, young people are the most popular social media platforms users (5, 6). Also, media have become a global culture in youth's lives. These new opportunities facilitate access to social interaction and learning (7) while, exposing them to an environmental risk factor for youth's health, including having a sedentary lifestyle (8) or lower life satisfaction (9), anxiety, sleep disturbance, (10) and stress (11). Media use levels are associated with addictive substances. The likelihood of substance abuse increases with exposure to images and the media content on substance abuse such as movies and clips (12−14). In this regard, understanding harms and functions of cyberspace and media and acquiring media literacy skills and learning skills for critical analysis of media messages are the most essential and useful requirements to prevent risky behaviors such as substance abuse, smoking, and unsafe sexual activity (15).

Education must be moral and based on defined theories and models to achieve useful and practical results. Among the ideas and models that are systematically used as a framework and roadmap for the educational process and goals to change behavior are planning models that, in addition to analyzing successes and failures, provide the necessary guidance for reviewing and diagnosing educational, Provides educational planning and intervention design methods and facilitates evaluation and reduces the confusion of educational intervention designers, one of these patterns is social marketing (16). Dann sees social marketing to promote positive behaviors and the abandonment of negative behaviors (17, 18). According to the 2002 definition of social marketing, "the customer-centric application of marketing principles and techniques to the development of programs, interventions, and evaluations to change or modify health behavior" (17−19).

Social marketing is a strategy for correcting social behaviors. The two education strategies and coercion can be used to promote healthy actions and correct high-risk behaviors, including substance abuse.

The social marketing model was selected as a conceptual framework and appropriate research planning by reviewing the patterns and theories of changing individual and collective behavior. Social marketing has been used in various studies to influence various topics and health problems, including promoting smoking cessation and alcohol in women and students (17, 20)and tobacco prevention, addiction, and substance abuse (20).

On the one hand, PWM[1] is a model reflected in substance abuse, tobacco, and such health risk decision-making, especially in youth and adolescents. The PMW proposes behavioral intention, an intermediate variable named behavioral willingness. Behavioral willingness is measured by this essential question

"how they react to risky behaviors in a certain social condition." Besides intention and behavioral willingness, this model contains other variables. When individuals have a positive attitude towards high-risk decision making and are more attracted to essential factors, they will be more willing to carry out dangerous behavior. According to the PWM, individuals have prototypes that play a role in high-risk behaviors (21) (Fig. 1).

Media literacy will be added to the prototype willingness model (PWM) as a background factor. It will be examined as the extended prototype willingness model, so the media is a background factor in forming the positive and negative prototype of young people and Adolescents. Prevalence of substance use in universities and its negative consequences (22) (e.g., academic motivation, academic failure, physical and mental illness, suicide, etc.) on the other hand, comprehensive study in this field and identifying the factors influencing the tendency to use drugs in students; This study's main objective is to evaluate both the pre-test and brief time (three months fallow up) effectiveness of Substance Abuse Media literacy Education and substance abuse education prevention in students. The study will also assess process evaluation, as reported. However, no information is available about aspects of media literacy about substance abuse in Iran. Therefore, this study aimed to evaluate an intervention program based on media literacy on preventing substance abuse among students using an integrated approach to social marketing. So, a randomized, controlled clinical trial with a parallel group design of students, who will be participated in present study.

[1] Prototype willingness model

Methods/design

Aim, design, and setting

The study design evaluates web-based randomized controlled trial substance abuse prevention and substance abuse media literacy (SAML) education programs. It is expected that approximately three universities include: Hamadan University of Medical Sciences, Islamic Azad University Hamadan Branch, and Bu-Ali Sina University, will take part in the study. Data will be collected from students at two-time points (i.e., pre-test and three months follow-up). Interventional research will be based on the SMART[2] pattern.

SMART is the operational model of social marketing in the field of health, which is used to improve the behavior of society in the field of health, which includes the stages of preliminary planning, formative research (customer analysis, market analysis, channel analysis), production of interventions, materials and pre-tests, intervention and Execution is evaluation (Figure 2).

Outcomes will obtain in the experimental study.

It should be noted that in this model, previous formative research including qualitative and descriptive studies to complete steps one to five of the SMART model, to determine the type of intervention and products including getting detailed information about audience peculiarities, behavioral market and communication channel by audience analysis, market analysis, and channel analysis. In a qualitative study, the need's audience and desires were identified, behavioral market determinants such as partners and components of the marketing mix, and channels were specified. An effective communication strategy was developed, which were the results of this study.

Here are three questions: 1) what is the highest prevalence of addictive substances in students? 2)Which University is the most addictive in the region? 3) Which behavioral and non-behavioral factors are involved in the health problem? For the response to these questions in the descriptive study, which is a quantitative part of formative research, students' demographic information and drug abuse behavior were assessed based on the prototype willingness model and media literacy related to substance abuse. Analysis of the qualitative and quantitative parts of formative research identified the main components of the intervention. Then, this study (protocol study) will be performed to complete the SMART model's sixth and seventh stages, including the implementation of intervention and evaluation.

It is anticipated that up to 116 students may take part in the study. This study would have taken place during the 2020 -2021 school year. Additionally, program completion and feedback on process evaluation (satisfaction, availability, and quality of material education) will be gathered from intervention students. The research team used the SPIRIT checklist for Interventional Trials to prepare this study (23).

Sample size & Eligibility criteria

According to previous studies, if the intervention's minimum effectiveness is 20% (24), taking in to account the clustering coefficient of 1.5, alpha 5%, and 90% the desired power, we need 54 people per group. Also, considering the 20% probability of Attrition in the intervention process, the present study sample size was 116, including 58 in the experimental group and 58 in the control group.

$$n = \frac{\bar{p}(1-\bar{p})(Z_\beta + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Inclusion criteria for participants will be Access to the Internet and Social Networks such as

What's app, telegram, and Instagram; Being a student in one of the universities in the city of

Hamadan and they be interested in participating in the study. Before participation, Students will complete a written informed consent letter to participate in this study. Principal Investigator will access consent forms of student participant data that it will be namelessly. In consent letter also, explained that students can exit the study if they aren't willing to continue.

Internal Review Board approval

Present article extracted from the Ph.D. thesis in Health Education and Health Promotion, this study was approved by the Research Ethics Committee of Hamadan University of Medical Sciences with a number 9811018459 and had the special ID of the Ethics Committee of IR.UMSHA.REC.1398.827.

Participant characteristics

Recruitment will occur at two planes: university schools and students. It is essential mansions, Hamadan City is located in the west of Iran. It has four state universities, including Bu-Ali Sina University, Hamadan University of Medical Sciences, Hamadan University of Applied Sciences & Technology, and the Hamadan University of Technology. Moreover, it has some non-governmental universities such as Islamic Azad University Hamadan Branch and Hamadan Payam Noor University (25) . Substance Abuse Media Literacy scale and scale of substance abuse behavior based on the prototype willingness model will be evaluated in this study.

Processes

Schools of University

First university permission for conducting this study will be obtained. University administrators will access questionnaires for an estimate if demanded. Efforts will be made to balance the inclusion of both state and non-state universities and to range in their sociodemographic characteristics. Based on the previous formative research (26) and random sampling of Hamadan universities, around three universities are expected to participate. Therefore, the number of students in each school or university will be obtained by proportional assignment of students to the school (i.e., the school with the largest number of students, the largest number of students assigned) after coordinating with university officials, the research units will be rationed. Then, the samples will be randomly collected.

Students

It is anticipated that up to 161 students may be employed to participate in this study. Research team members will introduce the aims of the survey to students and distribute consent forms. Students will be eligible to participate if they are members of Hamadan universities, are enrolled, and have an appropriate willingness to receive Substance Abuse Media Literacy and Substance abuse prevention education. Students will complete consent and permission forms, respectively, before the study initiates.

Protocol

After the Research Ethics Committee Hamadan University of Medical Sciences' approval, the Principal Investigator will share a copy of the revised protocol with all the research team members to ensure

awareness of the reconsiderations. The research team will document any unexpected deviations from the protocol. Concerning the Data and Safety Monitoring Plan, the Research Ethics Committee of Hamadan University of Medical Sciences will be informed of any updates and modifications.

Randomization

Randomization will occur using stratified random sampling procedure by research team; individuals are assigned to two intervention and control groups. Randomization will occur after students complete informed consent and appropriate school and university approvals for carrying out the study.

The intervention description

Substance Abuse Media Literacy and preventive substance abuse educations are web-based, comprehensive education programs for university students that provide appropriate and medically accurate information about Substance abuse using a Media literacy education approach. The pairing of preventive substance abuse information and substance abuse media literacy education allows the program to teach students critically thinking about media messages related to substance abuse and substance abuse behavior. It mostly teaches them what Lifestyles, Values, and Points of View Represented in, or omitted From, Media Messages About Substance Abuse, such as identification and the possible implications of actual consumption of drugs, such as simulating an actor, having instant excitement, believing in the non-addictive nature of advertised substance, and having ideal moods and herbal and not harmful.

Educations consists of five web-based education sessions about substance abuse prevention and substance abuse media literacy. Each session includes 40-45 minutes of training with the question and answer methods. Group discussion (Chat rooms) will be held with multimedia Tools and reminder messages, such as the first educational session to familiarize students with Drugs and substance abuse consequences. The second session aimed to educate students with substance abuse media literacy skills, critical thinking, and the media consumption regime. The third session aimed at familiarizing students with interpersonal skills and self-awareness and the fourth session will introduce students to the saying no skills and problem-solving. The fifth session will correct students' beliefs and attitudes towards substance abuse with the mentioned web-based teaching methods and materials—each containing group discussion in the chatting room. Educations were developed by an interdisciplinary group consisting of specialists in psychology, media research, web site development, multimedia design, health education, and promotion. The intervention group students will receive lessons between completing the pre-test and the follow-up (Fig. 3). The website will contain an educator dashboard for educators. They will be one of the research teams to enroll the students in the program and group discussions, including student chatroom, to correct their belief about drugs. Educators will also have the right to use web-based education programs to help students prepare to simplify accessibility to education. All educators will be requested to review all of the materials.

Disincentives Students will receive a gift card of $30 for participating in the study. Participating in all data gathering phases (two times) will be drawing for a $50 gift card at follow-up. Students will have access until the end of the semester to Substance Abuse Media Literacy and Substance abuse prevention educations.

Delayed-intervention group

Students in the delayed intervention group will obtain lessons during the study, but educators will be requested to abstain from any substance abuse or SAML topics. Simultaneously, Educators in the delayed-intervention group will not train them until after study completion (i.e., collecting student data at three months follow-up).

Implementation procedure

As mentioned, participants in this study are familiar with E-learning class and online education for other courses, especially in the coronavirus crisis. Educators will obtain access to the web-based educator's control panel, giving them access to programs. The Principal Investigator and all research team will visit the website. Privacy shields will be given to block their computer or tablet screens from view to ensure confidentiality. Secret ID numbers will be used in place of names in the chat room, and during receiving education programs, admin and educator sessions were offered to students before education. Students will be instructed that they may withdraw from the study at any time for any reason. Follow-up questionnaires will be completed with paper copies of the pre-test questionnaire. After pre-test data collection is completed, educators in the intervention group will educate substance abuse prevention and substance abuse media literacy educations over three weeks. It is predicted that the program could be done in five 45-min. At up fallow period, students in the intervention group will also make available program feedback. Educators will return all answers to the follow-up questionnaire to administer and Principal Investigator after approximately three months. After the follow-up data are collected, educators in the delayed-intervention group can train substance abuse media literacy and substance abuse prevention education with students and provide feedback on their experiences.

Measures

Student measures

Students will complete questionnaires at two-time points: pre-test and three months follow-up (Fig. 1). The student questionnaire, containing around 100 items, will cover substance abuse behavior based on the prototype willingness model variables outcomes (e.g., attitudes, normative beliefs, behavioral intentions, willingness), and self-reports of substance abuse media literacy scale (SAMLS) and process evaluation. In addition to Demographic questions will comprise the student's age, education level, and socioeconomic status, sex, gender, parental education level, Marital Status, Name of University, schools

and courses, History of smoking and alcohol consumption, Addiction status in parents, Close Friends substance abuse status, Internet access, amount of social media exposure and use of social media, motivation to use social media.

Outcome measures

-Scales of substance abuse behavior based on the prototype willingness model includes constructs of attitude, subjective norms, behavioral willingness, as well as prototype and intents of behavior (27).

- **Substance Abuse Media literacy Scale (SAMLS)** with 13 questions.

-Process evaluation checklist

Process evaluation includes Student satisfaction, availability of material education, quality of material education will be asked items to indicate on 5-point Likert scales.

Plans to promote participant retention and complete follow-up

It is essential to be mention, after complete inform consent letter by students, Participants will be given randomly assigned ID numbers to be used in the education program. A list of names and ID numbers will be reserved privately on a secure server accessible to the principal Investigator and the administration staff (who are skilled in the ethical study). If any participant who discontinue or deviate from education plan, administration staff will effort to encourage him/her to participated to study during two contact.

Blinding description

Students participating in the study will be placed in intervention or control groups (delayed intervention group) after obtaining informed consent. Trials are planned so that people are aware of all the aims of the study. Based on the research group's planning, all members of the intervention or delayed-intervention group will have access to all educations. The intervention group members will be educated initially, and the members of the delayed-intervention group will receive training three months after receiving the post-test results. It is necessary to mention; students are unaware of assignments to studying groups.

Fidelity of implementation Process

These educations will be start and end based on research team planning. The real lessons of the online session will be accessible to all students without any deficiency.

Statistical methods

The data will be analyzed with Spss-23 using chi-squared, independent T-test analyses, and other tests. If necessary, missing data will be examined at each time point and handled with an appropriate imputation method. All data of the full protocol and intervention study are potentially shareable after unidentified Individuals. All researchers who request to vice Chancellor for Research and Technology of Hamadan University of Medical Sciences data access is obtainable.

Oversight and monitoring

As mentioned, this study will be performed to complete the SMART model's sixth and seventh stages, including the implementation of intervention and evaluation. Confidentiality will be assured to all participants. Participants will be given randomly assigned ID numbers to be used in the education program. A list of names and ID numbers will be reserved privately on a secure server accessible to the principal Investigator and the administration staff (who are skilled in the ethical study). After the ended education in fallow- up time, collection of data will occur. Students complete questioners with a number answer. Identifying information couldn't be shared by the student, so, Secret ID numbers will be used in place of names in the chat room and receiving education programs. This study is a minimal risk. Any adverse events that occur will be informed to the Principal Investigator and reported to the Research Ethics Committee Hamadan University of Medical Sciences to make the final decision to terminate the trial or continue it.

Serious adverse events will be evaluated within 24 h, and any other challenges will be considered within 72 h; reporting to the Research Ethics Committee Hamadan University of Medical Sciences will occur within two weeks. Procedure of auditing is checked by Principal Investigator 3 times, when includes drafting proposal, conducting study and end of study.

Ethics and dissemination

Vulnerable University Students will be recruited for this study by the Research Ethics Committee of Hamadan University of Medical Sciences. The study team will receive student assent. Researcher contact information will be printed on the forms in case students have questions about the study. Also, this study was approved by the Research Ethics Committee of Hamadan University of Medical Sciences with a number 9811018459 and had the particular ID of the Ethics Committee of IR.UMSHA.REC.1398.827.

Sharing plan

All data is potentially shareable after unidentified individuals. All researchers request data access to the Vice-Chancellor for Research and Technology of Hamadan University of Medical Sciences. It is necessary to be mention that results from this study will be prepared for publication in scholarly journals and updated in https://www.irct.ir/.

Confidentiality

As it mentions, confidentiality will be assured to all participants in all process of implementation procedure and monitoring since of end of education programs. Participants will be given randomly assigned ID numbers to be used in the education program. A list of names and ID numbers will be reserved privately on a secure server accessible to the Principal Investigator and the administration staff (who are skilled in the ethical study).

[2] Social Marketing Assessment and Response Tool (SMART)

Discussion

Substance abuse media literacy & substance abuse prevention education programs must be carefully evaluated to ensure that they effectively enable people in youth health and media literacy skills mainly about substance abuse behavior in the new media ecology and unique 'Infomedia' ecosystems digital society. The substance abuse media literacy education programs being evaluated in this study can be the first web-based education program in universities that no prior research has psychometrically considered the substance abuse media literacy in students, who are among the high-risk groups in the field of drug use. The study design, obviously including students' data collection, allows for evaluating the program's immediate effects on student outcomes and any behavioral effects during the three months after the students receive the program. Also, gather student feedback will help determine the chance of program implementation by universities.

Trial status

The protocol is Version 1, dated 6 October 2020. The trial is registered on the Iranian Registry of Clinical Trials, IRCT20200914048719N1, with the available title "Effect of an Educational Intervention Based on Media Literacy on Substance Abuse Prevention among College Students" and the scientific title "The Effect of Educational Intervention Based on Media Literacy on Substance Abuse Prevention among College Students Applying the Integrated Social Marketing Approach: a clinical trial study." The recruitment date began on 5 November 2020; recruitment is scheduled to be finished by the end of May 2021. The problem of the study is substance abuse prevention in youth. The trial sponsor is Hamedan University of Medical Sciences with a number 9811018459.

Abbreviations

SAML: Substance abuse media literacy;

Declarations

Acknowledgments

Authors' contributions

MB and HJ designed the trial. SB conducted the data analysis. MB will supervise the implementation of the study and is the principal Investigator. HJ will lead to study recruitment and data collection efforts and obtain consent, permission, and education programs. MB & HJ contributed to writing the first several drafts of this paper. FRS and MB led the intervention program and resources; all authors edited and approved the final manuscript.

Funding

Availability of data and materials

All data may be obtainable from the corresponding author.

Ethics approval and consent to participate

This study was approved by the Research Ethics Committee of Hamadan University of Medical Sciences with a number 9811018459 and had the Ethics Committee of IR's particular ID.UMSHA.REC.1398.827.

Dissemination policy:

This trial results, will be publish in scholarly journals to share result for participants, healthcare professionals, the public, and other relevant groups.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Sponsor contact information

Vice-Chancellor for Research and Technology of Hamadan University of Medical Sciences was funder and sponsor of this trial study with Email address: internationalaffairs@umsha.ac.ir and Postal code: 65178-38678, address: Director for international, inter-university and congress affairs, Vice-chancellor for research and technology, Hamedan University of Medical Sciences

Shahid Fahmideh Street, Hamedan, Iran

Coordinating committee

This study was approved by the Research Ethics Committee of Hamadan University of Medical Sciences with a number 9811018459 and had the particular ID of the Ethics Committee of IR.UMSHA.REC.1398.827.

Trial status:

The protocol is Version 1, dated 6 October 2020. The trial is registered on the Iranian Registry of Clinical Trials, IRCT20200914048719N1, with the available title "Effect of an Educational Intervention Based on Media Literacy on Substance Abuse Prevention among College Students" and the scientific title "The Effect of Educational Intervention Based on Media Literacy on Substance Abuse Prevention among College Students Applying the Integrated Social Marketing Approach: a clinical trial study." The trial sponsor is Hamedan University of Medical Sciences with a number 9811018459.
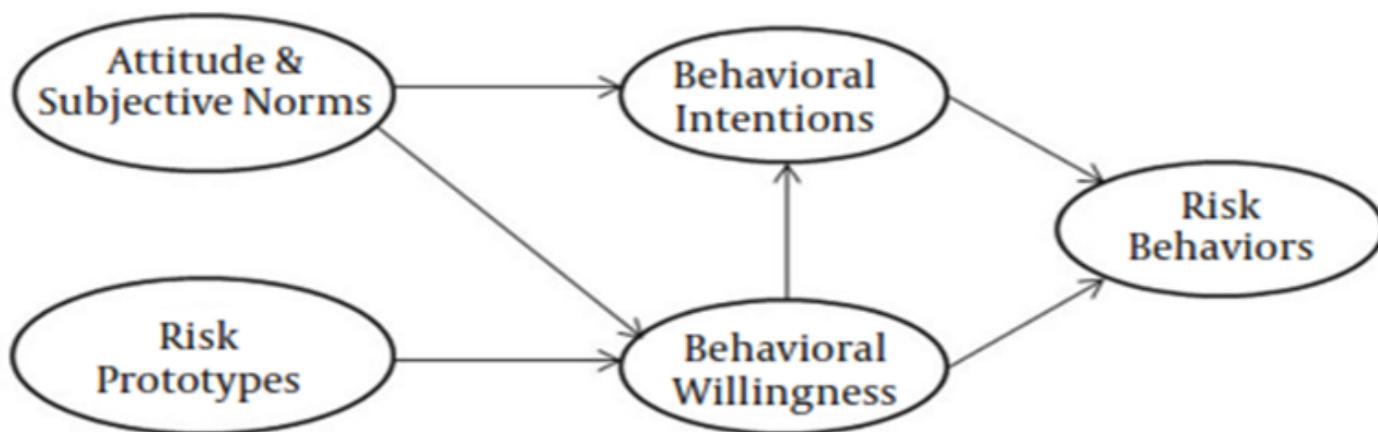
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Figures

Figure 1

The PWM model

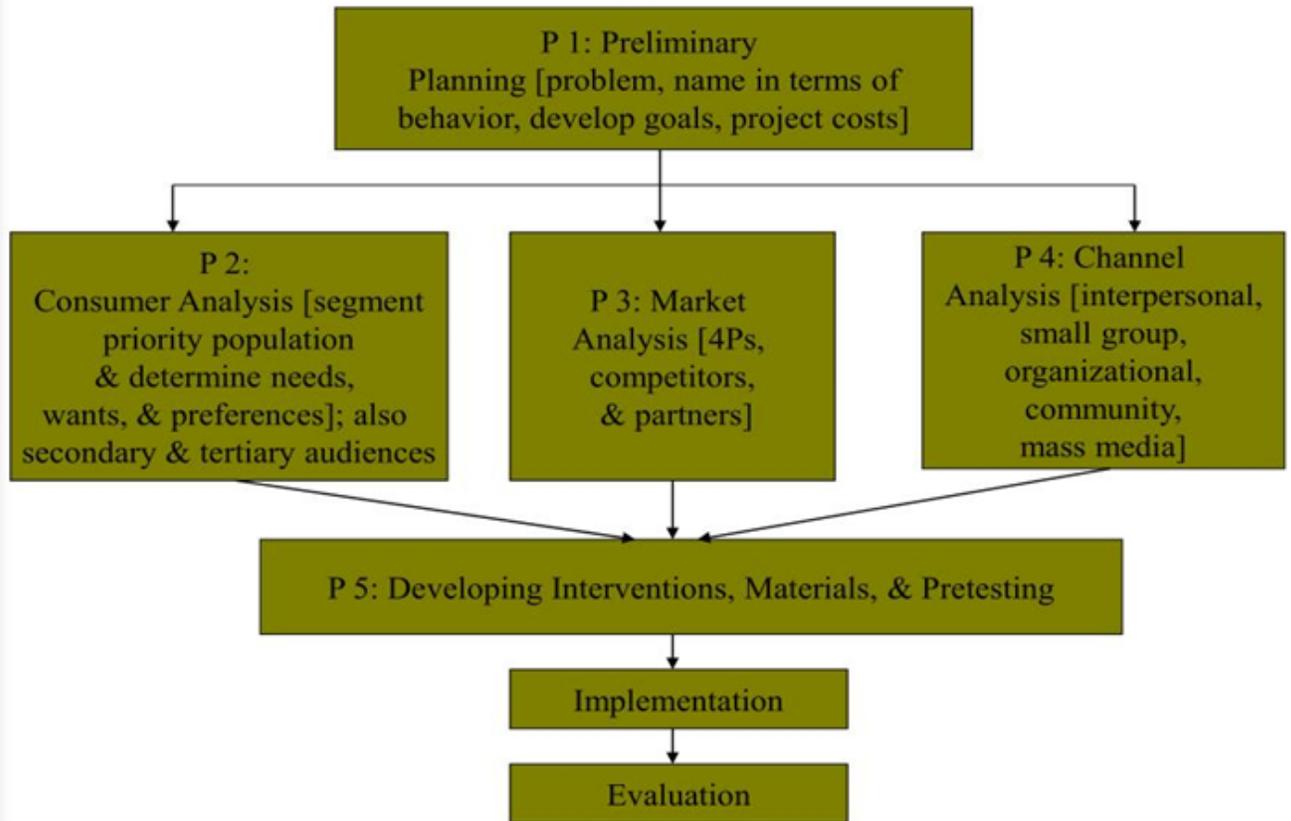# Social Marketing Assessment & Response Tool (SMART)

(Neiger, 1998)

P 1: Preliminary Planning [problem, name in terms of behavior, develop goals, project costs]

P 2: Consumer Analysis [segment priority population & determine needs, wants, & preferences]; also secondary & tertiary audiences

P 3: Market Analysis [4Ps, competitors, & partners]

P 4: Channel Analysis [interpersonal, small group, organizational, community, mass media]

P 5: Developing Interventions, Materials, & Pretesting

Implementation

Evaluation

Figure 2

(SMART)

TIMEPOINT**	Enrolment	Allocation	Post-allocation						Follow up & Close-out	
	(1-5)Month		Section₁	Section 2	Section 3	Section 4	Section5	Section6	3 month posttest	Delay intervention GET SAML+ Substance abuse prevention education
ENROLMENT:										
University/school Eligibility screen	X									
University permission to conduct research	X									
Students Informed consent	X									
Allocation		X								
INTERVENTIONS:										
[substance abuse prevention education+ SAML education]				◆————————————◆						
[Delay intervention]=other healthy course expt. SAMLE & substance abuse prevention education]				X	X	X	X	X		X
ASSESSMENTS:										
[Pre-test all outcome variables]			X							
[3 month later all outcome variables+ Process Evaluation]									X	

Figure 3

Template of SPIRIT recommended content for the schedule of enrolment, interventions, and assessments.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITchecklist.docx