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Designing, Implementation and Evaluation of a Complex Intervention for COVID-19 Control based on the Intervention Mapping Approach: Study Protocol

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Abstract

Considering the high prevalence of COVID-19 disease and the ineffectiveness of effective interventions for controlling this disease, it is necessary to design and implement comprehensive interventions with a holistic approach. Therefore, the aim of the present study was to design, implement and evaluate a complex intervention for COVID-19 control based on the intervention mapping approach.

This is a sequential mixed-methods study (a mixture of qualitative and quantitative methods) that aims to evaluate a complex intervention for COVID-19 control using the intervention mapping approach. The study was designed in four phases and six sub-studies. The first phase was designed based on the first step of intervention mapping, in the form of three sub-studies. In the first sub-study, preventive behaviors, behavioral determinansts as well as barriers and facilitators of COVID-19 prevention are determined at the individual, interpersonal, organizational, social, and political levels. In the second sub-study, a questionnaire is designed and validated to assess COVID-19 preventive behaviors and behavioral determinants. In the third sub-study, a cross-sectional study will be conducted to investigate COVID-19-preventive behaviors and behavioral determinants. In the second phase, the intervention is designed at the individual, interpersonal and organizational levels in the form of the fourth sub-study based on the second to sixth steps of intervention mapping. The third phase will be performed in the form of the fifth sub-study, which will be investigate the effect of complex intervention for COVID-19 control, Its related preventive behaviors as well as healthcare utilization based on intervention mapping approach in the population covered by Torbat Heydariyeh University of Medical Sciences in a randomized controlled trial. In the fourth phase, in the form of a national study, the subject will be set on the policy agenda and the project will be approved by the National COVID-19 Center using the fifth step of intervention mapping as well as the opportunity window. Finally, the project will be implemented nationwide. This protocol reports an example of developing a training course using intervention mapping (IM). This course could be applied for COVID-19 as well as similar communicable diseases.

Keywords: COVID-19, Complex intervention, Intervention mapping

Introduction

Coronavirus, or COVID-19, is an emerging respiratory disease first reported in Wuhan, China in December 2019 [1, 2]. Following the outbreak of the disease, the World Health Organization (WHO) declared the virus a threat to public health and acknowledged that the disease was spreading at an alarming rate and causing fear and anxiety worldwide [3, 4]. The virus can be transmitted at close range to about 1.5 meters. Transmission routes include contact with contaminated surfaces and objects, as well as contact with contaminated airborne droplets spread into the air through coughing or sneezing [5, 6]. The incubation period varies from 2 days to 14 days after exposure to the infected person [7, 8]. Common symptoms of this disease include fever, cough and shortness of breath [9, 10]. An infected person may also not show any of these symptoms. The infection will be mild and does not require special treatment in most cases (80%) [11]. In order to prevent the spread of this virus, the National Health Commission issued instructions such as: identifying infected people, isolating and quarantining suspected and infected people, disinfecting public environments, and using personal protective equipment to prevent and control the virus [12, 13]. Since many vaccines have been developed against the COVID-19 virus [14], they are not yet available to everyone; therefore, prevention is the best measure that can be taken to prevent the infection. Preventive measures include using masks, covering the mouth with a suitable cloth or elbow when coughing and sneezing, washing hands regularly with soap or hand sanitizer (containing at least 60% alcohol); avoid contact with infected people, keep a proper distance as much as possible, avoid touching the eyes, nose and mouth with unwashed hands [15, 16]. One of the non-pharmacological interventions to control and prevent the spread of viruses is health education to all members of society regarding the observance of health protocols based on scientific guidelines [17, 18]. In other words, the information obtained through the process of educational intervention lead to healthy behaviors [19]. There have been few studies on COVID-19 preventive measures, but each has faced limitations; for example, the limitations of a study that examined COVID-19 preventive measures based on the health belief model, included prevention only at the individual level; however, addressing interpersonal and social levels is also of great importance [20]. Similarly, another study examined health behavior based on the theory of planned behavior and the study was limited to a certain number of people [21]. Therefore, an approach should be used that does not have the mentioned limitations and is a comprehensive and complete method to promote health behaviors.

There have been various approaches aimed at developing, implementing, and evaluating health-promotion interventions. But one of the most well-known of these approaches is intervention mapping [22]. Intervention mapping (IM) was developed for health promotion planning in the 1990s [23]. It is an evidence-based approach and a systematic process for using existing empirical evidence to develop health education programs [24]. In this approach, attempt should be made to ensure the math between the needs of the society and the field of intervention during planning. Health problems are also investigated in intervention mapping at different levels (individual, interpersonal, organizational and social levels) [25]. Therefore, intervention mapping has several unique strengths that distinguish it from other approaches, including; a) intervention in different level of ecological model, b) evidenc- based approach c) a systematic process for using evidences.

IM consist of six steps including; Step 1) Conducting a needs assessment or problem analysis, Step 2) creating the matrices of change objectives based on the determinants of behavioral and environmental conditions, Step 3) selecting theory-based intervention methods and practical strategies, Step 4) Translating methods and strategies into an organized program, Step 5) planning for adoption, implementation, and

sustainability of the program, Step 6) generationg an evaluation plan [24,25].

Considering the importance of the subject and the lack of a comprehensive study in this field, the present study was designed with the aim of designing, implementing and evaluating a complex intervention for COVID-19 control based on the intervention mapping approach.

Methods

This is a complex intervention designed based on the intervention mapping approach at different ecological levels (individual, interpersonal, organizational, social, and political levels). Each level is also implemented at five levels of prevention (primordial, primary, secondary tertiary, and quaternary) in four phases and six sub-studies.

Phase 1:

Study Design

This is a sequential mixed-methods research (a combination of qualitative and quantitative methods) that aims to plan a complex intervention for COVID-19 control using the intervention mapping approach. The study is designed in four phases and six sub-studies. The first phase was designed aimed at fulfilling the first step, i.e. intervention mapping, in the form of three sub-studies. In the first sub-study, preventive behaviors as well as barriers and facilitators of COVID-19 prevention are determined at the individual, interpersonal, organizational, social, and political levels. In the second sub-study, a questionnaire is designed and validated to assess COVID-19-preventive behaviors and behavioral determinants. In the third sub-study, a cross-sectional study will be conducted to investigate COVID-19-preventive behaviors and behavioral determinants. In the second phase, the intervention is designed at the individual, interpersonal and organizational levels in the form of the fourth sub-study based on the second to sixth steps of intervention mapping. The third phase is performed in the form of the fifth sub-study. The fifth study investigates the effect of complex intervention for COVID-19 control and related preventive behaviors based on the intervention mapping approach in the population covered by Torbat Heydariyeh University of Medical Sciences in a randomized controlled trial. In the fourth phase, in the form of a national study, the subject matter is set on the policy agenda and the project is approved by the National COVID-19 Center using the fifth step of intervention mapping as well as the opportunity window. Finally, the project will be implemented nationwide.

Designing a comprehensive health education system:

It should be noted that the exact details of this system are determined by the participatory planning group. However, general explanations are provided to clarify the issue in this section.

Considering that there is currently no comprehensive system for public health education and accurate management of public health education status, on one hand, and holding face-to-face training sessions increases the risk of COVID-19 transmission on the other hand, the aim of the present study was to design and use a comprehensive system. To take into account all aspects of this system, all employees of public and governmental institutions and organizations are accurately registered with the responsibility of the relevant administrators. Moreover, considering the number of employees of each organization, a number of people will be selected as training officials. With regard to the syndicates, all people are registered in the system from among all employees of different syndicates and occupations, with the responsibility of the administrator of different syndicate unions and the administrator of industrial units. To ensure easier access, the mobile version of the system is also developed that enables accurate monitoring of educational activities and comparison of different institutions and organizations, as well as different syndicates in this field. Considering that the training official for each person is known, it is possible to accurately determine the performance of intermediaries or education officials in each section. It is also even possible

to consider the incidence of the disease among the population covered by each individual, as a criterion for evaluating the outcome of their performance.

Considering the project made based on the intervention mapping approach, several specialized working groups will be formed (for example, the system technical support working group and the online education working group). Based on the results of the intervention planning steps, the online education working group will produce general and specific educational content in a professional manner. General educational content can be used by all members of the society, and specific educational content is specific to a specific job or profession, etc.

Information of institutions, organizations, and syndicates is collected and analyzed based on standardized questionnaires and checklists before the intervention and at regular intervals after the intervention. Moreover, interventions are revised and modified based on the relevant feedback or new interventions will be designed and implemented.

Step 1: Conducting needs assessment or problem analysis

First, we will establish a planning group that includes all stakeholders. Then, eleven specialized working groups including a specialized working group for health education and health promotion, a specialized working group for online education, a specialized working group for environmental health, a specialized working group for occupational health, analysis and forecasting working group, a specialized working group for mental health, a specialized working group for nutrition, a specialized working group for information technology (IT), a specialized working group for treatment, and a specialized working group for statistics and epidemiology will be established. However, other working groups may be established based on the opinion of the planning team. The members of the specialized working groups will consist of faculty members and staff of the executive system.

Literature Search

In each specialized working group, English keywords "COVID-19", "Prevention" and "Preventive behaviors", etc. will be used to search for COVID-19 preventive behaviors in databases such as Google Scholar, ScienceDirect, Scopus and PubMed at the individual, interpersonal, organizational, social, and political levels and in the fields of health education and promotion, environmental health, occupational health, nutrition, mental health, and treatment. However, the final search strategy will be determined after the initial search of articles. Studies are selected based on the title and abstract in the first step, and full text in the second step. Inclusion criteria will include English articles as well as studies focusing on COVID-19 prevention behaviors at the individual, interpersonal, organizational, social, and political levels. Exclusion criteria also include unavailability of the full-text studies and lacking the inclusion criteria of the present study.

Qualitative Study

In the present study, the conventional content analysis is used. Experts and stakeholders are selected using purposive and snowball sampling methods. Data are collected using interviews and group discussions. An interview guide will be used to conduct the study, and the interview guide will be designed during the study. Data analysis is also performed using conventional qualitative method based on Lundman's and Graneheim's content analysis approach. The criteria of credibility, dependability, confirmability, and transferability proposed by Guba and Lincoln are used to confirm the scientific accuracy and robustness of the results.

Nominal Group Technique

Once COVID19-preventing behaviors are identified at various levels, a consensus is reached on the most important and modifiable behaviors using the nominal group technique.

Developing a needs assessment questionnaire

This is a methodological study. Firstly, COVID-19 preventive behaviors will be determined based on a literature review as well as qualitative study. Then, behavioral determinants will be determined based on literature review. After developing the questionnaire, its face and content validity will be assessed, and its construct validity will be assessed using confirmatory factor analysis (CFA) in AMOS software. Finally, the questionnaire reliability will be assessed by determining Cronbach's alpha coefficient and interclass correlation coefficient (ICC) using SPSS software ver. 20.

A study questionnaire

This is a cross-sectional study and its population will include employees of institutions and organizations covered by Torbat Heydariyeh University of Medical Sciences. Inclusion criteria will include having at least six months of work experience, willingness to participate in the study. Exclusion criteria will include unwillingness to continue cooperation in the study and incomplete completion of the questionnaire. In the present study, all employees of institutions, organizations, syndicates, and industrial units covered by Torbat Heydariyeh University of Medical Sciences will be included in the study by census method. In order to increase the accuracy of the measurement and reduce the measurement error, the questioners will be trained before data collection stage. To this end, the questions and areas of the questionnaire as well as the method of completing the questionnaire are taught to the questioners. Data are collected in two ways: electronic questionnaire and paper questionnaire. After being encoded according to the data encoding instructions, data will be entered into SPSS ver. 20 and data analysis will be carried out. Kolmogorov-Smirnov test will be used to check the normality of the data. To describe the basic features of the data, descriptive statistics including mean and standard deviation, number and percentage and frequency distribution tables are used. Pearson correlation coefficient is used to investigate the correlation between constructs. Backward elimination is also used to determine performance predictors.

Phase 2: study Designing based on Intervention Mapping

Step 2: creating the matrices of change objectives based on the determinants of behavioral and environmental conditions

The second step is to map the intervention of the objectives matrix (OMAX), which includes four tasks.

Task 1: expressing the expected outcomes of the program on health behavior and environmental conditions: In this task, the expected changes in preventive behaviors will be identified at individual, interpersonal and organizational levels according to the results of the needs assessment step and evidence analysis.

Task 2: assigning behavioral and environmental outcomes to performance objectives: In this task, the general and performance (specific) objectives of the study will be determined according to the behavioral and environmental outcomes.

Task 3: selecting important and changeable determinants for behavioral and environmental outcomes: In this task, the most important and changeable individual and environmental determinants will be identified.

Task 4: constructing a matrix of objectives change: Change objectives will be formed and the objectives matrix (OMAX) will be constructed in this task by combining functional objectives and determinants.

Step 3: selecting theory-based intervention methods and practical strategies

The third step of intervention mapping includes theory-based methods and practical applications, which include five tasks.

Task 1: in this task, the initial ideas that are already created by reviewing the relevant texts will be reviewed for the planning group in collaboration with the planning group, according to the conditions prevailing in the studied

university and the health system, and more applicable new ideas will be formed.

Task 2: identifying theoretical methods that can influence the changes of determinants and clarify the conditions under which the proposed method is likely to have the greatest impact. According to the results of the literature review, theoretical methods will be extracted.

Task 3: selection of theoretical methods of the intervention program. At this step, the most effective and important methods will be determined from the identified theoretical methods and will be approved by the research team.

Task 4: selecting or designing practical applications for implementing methods in the intervention program. At this step, practical applications are determined for the selected theoretical methods in the task 3 based on resources and approval of the research team.

Task 5: ensuring that the final applications address the change objectives in the matrices. In this section, the planning group uses the results of the sixth step in preparing process evaluation questions in order to examine each of the theoretical methods related to the determinants and practical applications for them and ensures that items are taken into account.

Step 4: translating methods and strategies into an organized program

The fourth step of intervention mapping is the production of program components (intervention planning), which includes seven tasks.

Task 1: re-consulting with the target participants of the program and consider their priorities while designing the program. At this step, the working group for the production of the program components, will invite representatives of the studied groups to receive their views on the program components and consider their priorities in program design.

Task 2: creating the theme, scope and sequence of the program and a list of its required components. In this step, based on the results of the previous steps, the program theme, scope and sequence as well as necessary components will be determined.

Task 3: preparing design documents to guide the production of program components and protocols. In the present study, in order to compile and produce program components and protocols, based on the opinion of the participatory planning group, we will welcome cooperation between the university student associations and the university EDC content production unit. According to the intervention mapping protocol, two groups of design documents (matrices and project information letter) are provided to the manufacturer. In addition to the matrices, the project information letter, including the product, its objective (expected impact), and key outcomes will be provided to the University student centers and the University EDC content development unit to be used in designing the program logo and educational content. The program logo and educational content will eventually be approved by the planning team.

Task 4: reviewing the available components of the program in order to make or adopt it as appropriate as possible aiming to address the change objectives, methods and applications. In the present program, the components of other existing programs are investigated and parts of existing programs that meet the inclusion criteria of the present study will be used at the discretion of the planning group.

Task 5: drafting the program components and protocols. In this task, the initial draft of the program components and protocols, including educational media and the program logo, will be prepared.

Task 6: pre-testing of program components and protocols. Before producing the final program components, program components and protocols will be pretested on a group of representatives of different departments. Moreover, the prepared messages and components will be examined in terms of efficiency and comprehensibility, and the necessary corrections will be made according to the results of this pretest.

Task 7: management of the Final Product Components and Protocols. In order to comply with the necessary standards and study objectives, researchers will be responsible for managing production of the final product and protocols.

Step 5: planning for adoption, implementation, and sustainability of the program

The fifth mapping step is to adopt and implement a program that includes seven tasks.

Task 1: identifying potential adopters and implementers of the health promotion program. Attempts are made in the present study to include representatives of all stakeholders in the planning group.

Task 2: re-evaluation of the planning group to ensure the introduction of potential adopters and implementers of the program. In order to prevent negligence of potential adopters and implementers, this issue will also be reviewed by the planning group and new people will be appointed if necessary.

Task 3: expressing the program outcomes and specifying the performance objectives for the adoption, implementation and sustainability of the program. In this step, the performance objectives for the adoption, implementation and sustainability of the program will be determined.

Task 4: determining the determinants of adoption, implementation and sustainability of the program. Determinants of adoption, implementation and sustainability of the program will be determined by the planning group and by reviewing the scientific literature.

Task 5: constructing a matrix of change objectives to adopt, implement and sustain the program. In this step, based on the performance objectives and determinants identified in the previous steps, three matrices of change objectives, including matrices of adoption, implementation and sustainability of the program will be constructed.

Task 6: selection of practical methods and applications in the adoption, implementation and sustainability of the program. Practical methods and applications will be prepared and compiled based on literature review and also group discussion in the planning group.

Task 7: planning interventions for adoption, implementation and sustainability of the program. Based on the previous tasks and steps, the aim of the present task is to plan implementation of interventions related to the adoption, implementation and sustainability of the program by the planning group.

Step 6: generating an evaluation plan

The sixth step of the mapping intervention is evaluation plan, which consists of six tasks. It should be noted that this step will be designed based on the results of the other steps.

Task 1: reviewing the logical pattern of the program in order to guide the formation of evaluation questions.

Task 2: preparing impact assessment questions based on the objectives of the program for behavioral and environmental changes

Task 3: preparing evaluation questions based on matrices related to the change objectives among the determinants of behavioral and environmental outcomes

Task 4: preparing process evaluation questions in order to evaluate the appropriateness of methods, practical applications, program components and implementation

Task 5: developing indices and scales to answer evaluation questions

Task 6: defining the evaluation plan. To evaluate the program, a randomized controlled trial was designed, the details of which are given below.

Phase 3: Randomized controlled trial

This is a randomized controlled trial. The study population in the fourth sub-study will include employees of institutions and organizations covered by Torbat Heydariyeh University of Medical Sciences, syndicates, factories and industrial units, etc. In this study, Torbat-e Heydarieh city is considered as the intervention group and Zaveh and Mehvalat cities are considered as the control group. Inclusion

criteria include being covered by Torbat Heydariyeh University of Medical Sciences and having informed consent to participate in the study. Exclusion criteria also included unwillingness to continue attending the study and incomplete completion of the questionnaire. All employees of the syndicates will be selected by census method and will be included in the study based on the priority, factories and industrial units, etc. In order to increase the measurement accuracy and reduce the measurement error before data collection, the questioners will be trained. To this end, special sessions will be held for the questioners to explain about the study objectives, the questions and areas of the questionnaire as well as the method of completing the questionnaire. Data are collected by self-fulfillment method in two steps including before the intervention and one month after the intervention. The data collection instrument is a questionnaire that will be designed and psychoanalyzed in the second sub-study. Data related to the number of patients will be extracted from the relevant system.

Sub-study educational intervention: considering the fact that the design, implementation, and evaluation of the educational intervention is based on the intervention mapping approach, so, the intervention details are considered as the results of the application of this approach, therefore, detailed information about the educational intervention will be published after the implementation phase. After being coded, the data were entered into SPSS ver. 20 according to the data coding instructions and were statistically analyzed. Kolmogorov-Smirnov test was used to evaluate the normality of the data. Data analysis was carried out using chi-square, Fisher, independent t-test, and paired t-test. Cohen's Kappa index was used to evaluate the effect of the intervention.

Phase 4: National Study

Task 1: identifying potential adopters and implementers of the health promotion program in the country. Attempts are made in the present study to include representatives of all stakeholders in the planning group.

Task 2: re-evaluation of the planning group to ensure the introduction of potential adopters and implementers of the program. In order to prevent negligence of potential adopters and implementers, this issue will also be reviewed by the planning group and new people will be appointed if necessary.

Task 3: expressing the program outcomes and specifying the performance objectives for the adoption, implementation and sustainability of the program. In this step, the performance objectives for the adoption, implementation and sustainability of the program will be determined.

Task 4: determining the determinants of adoption, implementation and sustainability of the program. Determinants of adoption, implementation and sustainability of the program will be determined by the planning team and by reviewing the scientific literature.

Task 5: constructing a matrix of change objectives to adopt, implement and sustain the program. In this step, based on the performance objectives and determinants identified in the previous steps, three matrices of change objectives, including matrices of adoption, implementation and sustainability of the program will be constructed.

Task 6: selection of practical methods and applications in the adoption, implementation and sustainability of the program. Practical methods and applications will be prepared and compiled based on the literature review and also group discussion in the planning group.

Task 7: planning interventions for adoption, implementation and sustainability of the program. Based on the previous tasks and steps, the aim of the present task is to plan implementation of interventions related to the adoption, implementation and sustainability of the program by the planning group.

Discussion

Considering the complexity of human behavior as well as various measures to control infectious diseases, including COVID-19,

comprehensive and complex solutions are needed. Therefore, the aim of the present study was to design, implement and evaluate a complex intervention for Covid-19 control based on the intervention mapping approach.

The current study has several strengths, as follows:

- This is a systematic program, and also has a feedback self-correct system.
- All steps of the program are evidence-based and based on best practices.
- Participatory planning method is used and all stakeholders will be involved; therefore, the program applicability increases.
- Intervention is carried out at all ecological levels (individual, interpersonal, organizational, social, and political).
- All capacities of the city are used to control the disease (COVID-19 in all policies / all for COVID-19 control); for example, police cameras are used to check the percentage of pedestrians who wear masks or identify people and take necessary measures.
- Intervention is carried out at four prevention levels plus interventions in physical, mental and social health dimensions.
- When the comprehensive health education system is set up, it will be possible to instantly monitor the program with a few clicks.
- The main program is like a puzzle, in which each working group completes a part of the puzzle and align all the efforts of colleagues in one direction.
- Creating a strong link between the scientific department (faculty members) and the executive department (Deputy chancellor of Health and Deputy chancellor of Treatment).
- Accurate implementation of this project, considering its focus on different levels of prevention, controls not only COVID-19 but also non-communicable diseases.
- Use of the principles of social marketing (categorizing the audiences and prioritizing the target groups, applying strategies related to the product, price, location, advertising, etc.)
- According to literature review, it seems that this project is implemented in Iran and the world for the first time and is quite innovative.

This study has a few limitations. First, it took a very long time to design. Second, it might be difficult to find enough participants, keep them involved in the study, and make sure the intervention is delivered consistently throughout. Future research could look into how cost-effective this intervention is and how it affects people's health in the long run, not just COVID-19.

Conclusion:

This protocol reports an example of developing an IM-based training course. This course could be applied for COVID-19 as well as similar communicable disease. In conclusion, this study presents a novel and comprehensive intervention strategy for COVID-19 control by using intervention mapping. By leveraging a participatory approach, multi-level targeting, and evidence-based practices as well as a systematic approach. This program can be used to fight COVID-19 and other communicable diseases. This program has the potential to significantly improve public health because it involves people from the community, targets different levels (individuals, communities, etc.), uses proven methods, and follows a structured approach. Future research could investigate how well this intervention mapping approach can be applied to other situations and how effective it is in the long term.

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