A Self-applied Positive Psychology Online Intervention Program in the Mexican population: Study Protocol of a Randomized Controlled Trial

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Abstract

Background: The Coronavirus Disease (COVID-19) pandemic has become a public health emergency of international concern that has not only threatened people's physical health but has also affected mental health and psychological well-being. It is necessary to develop and offer strategies that will reduce the affectation and promote adaptive coping with the outbreak

Objective: This study protocol aims to describe a self-administered online intervention based on the principles of Positive Psychology supported by elements of cognitive behavioral therapy and behavioral activation therapy for the reduction of symptoms of anxiety and depression, increasing positive emotions and sleep quality during and after the COVID-19 contingency through a system of telepsychology (Salud Mental COVID).

Methods: A superiority randomized controlled clinical trial with two independent groups will be used, with intra-subject measures at four evaluation periods: pre-test, post-test, follow-up at 3 and 6 months. Participants will be randomly assigned to one of two conditions: (a) self-applied intervention with assistance via chat; (b) self-applied intervention without assistance via chat.

Results: The clinical trial is ongoing. This protocol was approved by the Research Ethics Board of the Free School of Psychology University of Behavioral Sciences. Our aim is to publish the preliminary results in December 2020.

Conclusions: The central mechanism of action will be to investigate the effectiveness of an intervention based on Positive Psychology through a web platform, which can be delivered through cellphones, computers and tablets, with contents that has been rigorously contextualized to the Mexican culture in order to provide functional strategies for the target users derived from the health contingency by COVID-19. Clinical Trial: ClinicalTrials.gov NCT04468893; https://clinicaltrials.gov/ct2/show/NCT04468893

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Trial Registration: ClinicalTrials.gov NCT04468893; https://clinicaltrials.gov/ct2/show/NCT04468893

Keywords: e-health; positive psychology; COVID-19; internet; intervention; telepsychology

Introduction

The outbreak of the new Coronavirus Disease 2019 (COVID-19) has become a public health emergency of international concern that has also affected the mental health and psychological well-being. According to a study conducted to find out the impact on the mental health of people in the initial phase of the COVID-19 outbreak, more than half of the respondents evaluated the negative psychological impact of the outbreak as moderate or severe. Moreover, the participants reported depressive symptoms (16.5%), anxiety (28.8%), and moderate to severe stress levels (8.1%)[1]. Subsequently, it has been found an increase in negative emotions (anxiety, depression, and outrage) and sensitivity to social risks, as well as a decrease in positive emotions and life satisfaction after the official declaration of the epidemic of COVID-19 in China[2]. This pandemic has been confronted with public health measures to mitigate the spread of the virus, such as physical distancing and confinement around the world. However, despite these measures it can be critical to the general population to mitigate the spread of the disease, the separation of loved ones, the perception of loss of freedom and the uncertainty of the evolution of the disease, could cause adverse psychological effects both in the short and long term[3]. Due to the health contingency, it has been observed that confinement, loss of normal routine, and reduction of social and physical contact with others, frequently resulted in feelings of boredom, frustration, and isolation, which was perceived as distressing to the participants[4].

In Mexico, as of July 18th, 324,041 cumulative cases and 37,574 deaths have been confirmed[5], and it is estimated that it may continue to have devastating effects considering the structural conditions of poverty and lack of access to physical and psychological health. Research evidence about emergent social phenomena suggests that these indicators, together with coping needs of adults and elderly who can be experiencing specific collective fear, might result in social anxiety,

depression, Posttraumatic Stress Disorder (PTSD) traits, Generalized Anxiety Disorder (GAD) and Obsessive-Compulsive Disorder[6].

The challenge is twofold, since not only interventions have to be designed and developed to meet the demand for mental health services, but they also have to be adapted to the population's requirements that is currently in confinement and cannot physically attend to receive psychological support, thus it is of extreme relevance the development of remote psychological care services that provide an effective interventions[3].Therefore, it emerges the need to work with cost-effective mental health prevention interventions, not only to cover the demand for care existing after the health emergency, but also to reduce risk factors that increase the possibility of either developing mental health problems or exacerbating the symptoms of pre-existing mental disorders[7,8]. The purpose then, is to strengthen this factors with individual tools such as positive thinking, interpersonal effectiveness skills, problem-solving[7], among other mechanisms that allow the general population to positively adapt to adversity; Positive Psychology is one of the approaches that focuses on promoting such tools.

Psychological intervention based on Positive Psychology

Positive Psychology is a movement within psychology that has strived to better understand the meaning of life, strengths and how those can be developed[9]. It is defined as the scientific study of positive experiences, positive individual traits, the institutions that facilitate the development of these experiences and traits; and the programs that help to improve the quality of life of the individuals while preventing or reducing the incidence of psychopathology [10–12]. It seeks to be complementary to traditional psychology, it does not deny suffering and negative aspects in people's lives, but seeks to correct the imbalance that affects the homeostasis of each day's life[13]. The individuals can intentionally strengthen their ability to experience and maximize positive emotions, which has been shown to improve their physical, emotional, and social health[14]. People are happier and have fewer depressive symptoms after receiving Positive Psychology [15]. Seligman et al.[16] considered necessary to distinguish at least three access routes to happiness: a) positive emotions and pleasure (pleasant life); b) commitment (committed life); and c) meaning (life with meaning). Furthermore, positive and negative affect usually exist in the same continuum[17]. This is always oriented towards the prevention and treatment of emotional problems such as anxiety, depression, and stress, among others[18–22]. The objective of the professionals who carry out interventions in Positive Psychology with adults is to increase their emotional well-being [23].

Efficacy of interventions based on Positive Psychology

The contents treated in the interventions based on Positive Psychology, such as strengths, positive emotions and emotional regulation, produce positive effects on happiness levels, therefore reducing worry, increasing the construction of personal resources and improving general well-being[17,23,24]. Positive Psychology interventions drive happiness through the activation of positive emotions[25], increase aspects of positive body image and have a significant impact on health and well-being[26]. In interventions based on gratitude of aspects related to well-being and mental health, a positive affect was found, it was observed and increase of subjective happiness, life satisfaction and negative affect and depression symptoms were reduced[27]. Sin and Lyubomirsky[28] carried out a meta-analysis of 51 interventions involving 4,266 participants, and the results revealed that Positive Psychology interventions did significantly improve well-being (mean r = .29) and decrease depressive symptoms (mean r = .31).The efficacy and effectiveness of positive interventions aimed at cultivating pleasure, commitment, and meaning have also been demonstrated[29]. However, it is interesting to note that Cognitive Behavioral Therapy and Positive Psychology are compatible and sometimes one can nurture the other. Both analyze thoughts and behaviors taking into consideration the emotions, always pursuing the psychological well-being of people[30]. Thus, it has been proven that the application of Behavioral Activation Therapy can be an effective approach to reduce anxiety and depression, since it can help to re-involve people in their lives[31].

Efficacy of Positive Psychology online interventions to enhance mental health in adults.

Online interventions through digital platforms are recommended by the Official Psychological Colleges, they offer the possibility of a two-way communication and therapeutic approach[32]. Online therapy is an advantage at times, when it is difficult or complicated to attend a therapy center, due to the COVID19 contingency, that can help to avoid the spread caused by the virus disease[33]. The use of the internet can be useful to carry out self-applied psychological interventions[34] and enhance accessibility to therapy for all those who need it[35]. It is also noteworthy, that in different reviews, self-applied treatments via the internet and computerized treatments are found to be effective[36–38]. Studies affirm that the substantial effectiveness of the intervention in Positive Psychology occurs when it is applied online[39]. In addition, online therapy in Positive Psychology with exercises designed to promote positive emotions, behavior, or positive thoughts, strengths, and virtues can be effective in reducing symptoms related to depression or any other emotional problem[40]. Furthermore, there are studies that have evaluated online treatment programs for sleep disorders in adults[41], reporting a significant improvement in participants who

received the intervention based on positive psychology[42,43]. Online Positive Psychology therapy can produce significant improvements in both well-being and depressive symptoms[44,45], significant improvements are obtained in life satisfaction and in the general well-being. Using an online Positive Psychology program could decrease psychopathology and increase well-being in university populations[46].

Technology plays a fundamental role in the transmission of positive attitudes, however, there isn't enough knowledge about the factors that influence acceptance and compliance on online interventions[47]. It is early to conclude of the psychological consequences of the COVID-19 pandemic in the population, therefore, health professionals are conducting research to collect all the influencing factors, and as has been reviewed in previous lines, it is estimated that the intervention in Positive Psychology can bring benefits and improve the wellbeing of the population.

Study Objectives

The aim of this study is to conduct a randomized controlled trial to evaluate the efficacy of an online self-applied Positive Psychology intervention program for the reduction of anxious and depressive symptoms, increase of positive emotions and sleep quality during and after the contingency by COVID-19 by means of a telepsychology system (Mental Health Platform COVID-19).

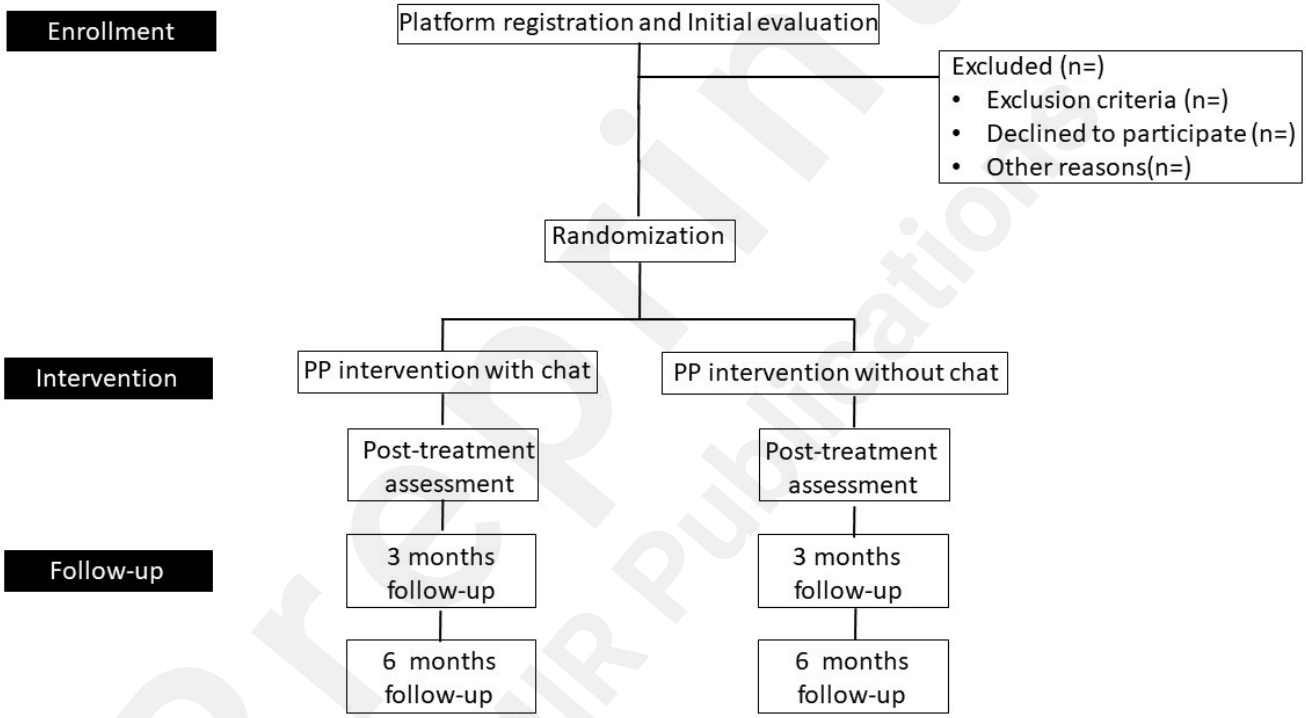
Methods

Study Design

A randomized controlled study will be carried out, following the guidelines set forth in the CONSORT statement (http://www.consort-statement.org) and CONSORT Ehealth (https://www.jmir.org/2011/4/e126/).

A superiority randomized controlled clinical trial with two independent groups will be used, with intra-subject measures at four evaluation periods: pretest, posttest, follow-up at 3 and 6 months[48]. Participants will be randomly assigned to one of two conditions: (a) Self-applied program based on positive psychology <Mental health COVID-19> with assistance via chat; (b) Self-applied program based on positive psychology <Mental health COVID-19> without assistance via chat. See Figure 1 for a detailed description of the study design.

Figure 1. Flowchart of the study design for the Mental Health Platform COVID-19.



Study setting

Sampling

A non-probabilistic, intentional, subject-type sampling in the Mexican population that meets the following criteria will be carried out:

Eligibility Criteria

Inclusion criteria: a) 18 years old or more; b) voluntarily participation c) have access to a technological device (computer, tablet, mobile, etc.) with an internet connection; d) have a valid email address; e) have basic digital skills in the use of an operational system and f) internet browsing to answer the initial assessment instruments.

Exclusion criteria: a) psychotic disorder; b) be receiving psychological and / or pharmacological treatment during the study.

Removal criteria: a) not accepting the conditions of the informed consent; b) absence on the web-platform for more than 20 days.

Sample size

The sample size was considered regarding the effect size found in controlled clinical studies where the efficacy of psychological interventions based on positive online psychology was evaluated. For the present study, the Cohen´s d index will be used, assuming that the variances of the two groups will be homogeneous if not, the Hedges g index would be used.

Furthermore, the study will include two experimental conditions, a priori analysis was carried out through the student´s t-test for the comparison of means between the two independent groups. A conservative approach was adopted and an effect size of the average magnitude of 0.25 (Cohen´s d, equivalent to g=0.5), a significance level (α) of 0.05 (p<0.05, that corresponds to a 95% of confidence) and a conventional statistical power of 80% (1- β = 0.8). For the analysis, the software GPower*V3.1.6[49] was used, and a required sample size of 128 participants was obtained (64 per group).

However, 30% will be added to control the variable related to the dropping-out of the participants during the treatment, a rate reported in the literature on treatments via the Internet[50,51]. Thus, the total required sample size will be 166 participants (83 per group).

Participant Recruitment

The participant recruitment will be done through advertisement in digital media (e.g. notes in news magazines), as well as through dissemination on social networks. The intervention program will be aimed for adults who can connect via the internet from any part of Mexico. Potential participants may contact through registration in the platform Mental Health COVID-19.

Randomization

Once the evaluation is completed, the users will be randomly assigned to one of the study conditions. The randomization will be performed by an independent researcher through the software randomization.com at a ratio 1:1, using the method of randomly permuted blocks. The coordinator

will inform the participant of the condition in which they will participate in the study (with or without assistance via chat).

Online Intervention Mental Health COVID-19

The Online Intervention Mental Health COVID-19 aims to provide to the target population a self-applied intervention based primarily on Positive Psychology, aimed at the recognition and development of strengths and virtues from the well-being approach. In addition, it is supported by elements of the Cognitive Behavioral Therapy such as the components of emotion[52] and the Antecedent-Response-Consequence (ARC) model of emotions[53]. Elements of Behavioral Activation Therapy are also included, such as the importance of physical exercise and the relationship between physical anxiety and its effects on anxiety and depression[54]. The intervention is composed of 15 modules that are adapted to the symptoms that the population may suffer from the global contingency caused by the COVID-19 pandemic. In addition to the Positive Psychology modules, a module with psychoeducation on grief and loss was added. The detailed description of each of the modules, as well as the theory and objectives on which each module is based, can be found in Table 1.

Table 1. Modules objectives of the Online Intervention Mental Health COVID-19

Intervention modules	Theory	Main objective
1. Understanding our emotions during the COVID-19 contingency.	CBT	Learn about the importance of the emotions, including anxiety and why it is experienced[52,53,55].
2. Reflection on preventive measures regarding COVID-19.	PP	Recognize the importance of staying home for the common good[52,56,57].
3. Time for gratitude.	PP	To focus the attention on gratitude in order to reduce the negative effect caused by the contingency[58–60].

4. To the rhythm of life.	PP	Importance of leading a healthy lifestyle[61].
5. Resilience, facing adversity.	PP	Provide tools and recognize personal abilities to recover after a stressful event[62].
6. Helping my mind.	PP	Provide information on the importance of focusing on the present moment with the aim of improving or maintaining emotional balance[63].
7. Taking control.	CBT	Define achievable goals to regain a sense of self-control and increase satisfaction during the contingency as much as possible. Decrease avoidance of relevant activities[64].
8. Smile and laugh.	PP	Importance of Laughing and the Positive Effects on Mental and Physical Health[65].
9. Share concerns.	CBT & PP	Importance of communication with the family, friends, and/or partner. Importance of expressing concerns with loved ones.
10. Separated but together.	PP	Importance of technologies as means of communication to be able to be connected through telephone, chats, and video calls.
11. Time to start.	PP	Proposal for activities that are usually not carried out due to lack of time[66].
12. Exercising my mind and body.	CBT	Performing physical exercise that allows the motor skills of the body and mental exercises that allow the person to stay busy in aspects related to him or herself. Importance of sleep hygiene[54].
13. Spirituality.	PP	Provide tools that help to develop a level of spirituality and this serves as a tool for positive coping towards the contingency of COVID-19[67].
14. How to deal with grief over the loss of a loved one during the COVID-19 contingency?	BAT	Provide information about how to cope with the loss caused by COVID-19 or other losses during this time period[68].

15. My inner strength.	PP	Provide support to the participant to focus on their own strengths and know their areas of opportunity[69,70].

Module delivery procedure

The contents will be delivered through 15 videos, each module has a video duration of 10 to 20 minutes each, plus homework. At the end of each video, the participant is asked to answer a 5-question Quiz with false or true or multiple-choice answer options, with the contents observed at the end of each video. It is necessary to complete 60% (3 correct questions) to be able to advance to the next module.

The Engineering team worked on the usability and accessibility of the platform and prior to allowing access to the platform by the general population. It is confirmed that it is possible to access the system through cell phones, computers, and tablets.

The modules will be delivered to the participants with a frequency of at least 1-day distance between modules, this in order that they have time to integrate the contents and carry out the activities assigned to them. Figure 2 shows how the modules are presented to the participants.

Figure 2. Example of a module within the Mental Health COVID-19 platform

In addition, the COVID-19 Mental Health platform will have an option so that the participant can observe their progress and see any module they have already finished. The modules completed

will be marked in green. The modules available for completion are marked on gray, the upcoming or next day modules will be marked on red (Figure 3).

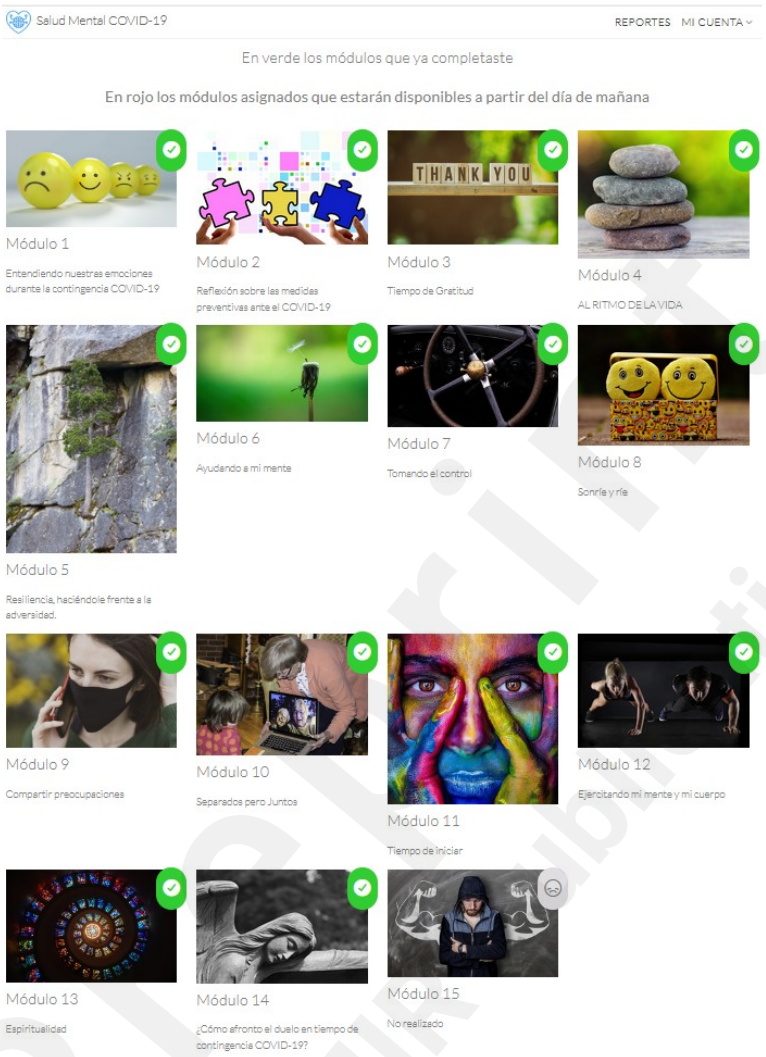


Figure 3. Menu of modules made by the participants.

Participants in the condition Intervention + Chat will have this tool at all times when they are logged in the platform. The chat service will be provided through the Tawk application where participants can receive help by trained and supervised psychologist if they have questions about a module and its activities, a technical problem, or if they need brief counseling about breath and relaxation training and problem solving strategies. More information will be provided in another article due to the length of this manuscript.

Technical details of the platform

The main objectives of this platform were the separation of the parts that make up a system, to achieve a better code administration, implement the best security techniques and achieve efficient development, therefore the Web system was developed in Visual Basic .NET language under the paradigm of object-oriented programming, the platform is made up of classes and data structures that are assembled in a three-layer architecture. The visualization layer managed through the HyperText Markup Language (HTML) markup language supports the dynamism offered by jQuery and different support libraries, communicating with the layer called “Business Rules” through asynchronous calls, taking advantage of the easy integration offered by the Active Server Pages (ASP) ASP.NET language, and its benefits as a simple syntax language that in turn, manages all interaction with the data layer, the latter managed by a Microsoft SQL server with a relational database.

All development was managed with the GIT version manager and the Continuous Integration and Continuous Delivery (CICD) methodology was used in such a way that the quality of the code was ensured at the time of its deployment in the production environment and finally its availability on the internet.

Synchronous assistance and monitoring of psychological counselors.

In the case of the intervention condition with synchronous assistance via chat, each user will be assigned to a trained psychologist with experience in clinical practice, who will receive prior training on the program of the Mental Health intervention COVID-19. The function of the psychological advisors is to motivate, guide and listen to the questions and comments of each participant, providing support about the modules of the applied intervention or brief counseling.

Measures

All instruments used over the course of the study are self-report questionnaires that are completed online and have psychometric properties regarding to the population evaluated. Table 2 gives an overview of all questionnaires with the time points of the assessments.

Primary outcomes measures:

1. Scale of Post-traumatic Stress Traits in the Mexican Youth Exposed to Social Violence, Pineda et al.[71]; validated by Chávez-Valdez et al.[72]. It measures PTSD symptomatology based on the latest version of the Diagnostic and Statistical Manual for Mental Disorders

(DSM-5) criteria. This is a brief scale consisting of 24 items that assesses traits that support a diagnosis of PTSD. It is answered through a self-report process. It has an internal consistency, with a Cronbach alpha coefficient of 0.97.

2. *Widespread fear Scale*[73]. *Adapted by Chávez-Valdez & Ríos Velasco*[74]. It is composed of seven items with options of 0 = nothing, 3 = a lot, and measures fear to adversities in the context and the feelings it disseminates, as well as others economic and social fears, in this case, adapted for the COVID-19 pandemic. It has shown an acceptable internal consistency of 0.90.
3. *CIU Urban Strategies Coping Strategies Scale*[75]. *Adapted by Chávez-Valdez & Ríos Velasco*[74]. It is composed of four factors: Affective components, physiological activation, cognitive confrontation, and Behavioral promotion. In the reliability analysis using Cronbach's alpha coefficient, performed by Vuanello[75] in Argentina, a Spanish Speaking country, it was found a Cronbach alpha of .92. A validation of this scale made by the authors in this manuscript with Mexican Population has been performed and is submitted for its publication
4. *State-Trait Anxiety Inventory (STAI) (Version in Spanish of Spielberger & Díaz-Guerrero*[76]***).*** This instrument measures the symptoms related to anxiety in general (Anxiety-Trait) or how they experience anxiety at a certain time (Anxiety-State). It is composed of 40 items, 20 for State, and 20 for Trait.
5. *The Scale for Suicide Ideation*[77]. This scale aims to assess the frequency of attitudes, behaviors, and plans to commit suicide. It is divided into 19 items with a response option of 0 to 2, giving a total of 0 to 38 where a score equal to or greater than 10 indicates an existing risk of suicide. This scale has been validated by González-Macip et al. in Mexican population, obtaining a Cronbach a Cronbach alpha of.84. For the purpose of the analysis the last item was removed since it evaluates suicide attempts and not ideation, however with only 19 items it was obtained again the same result of .84[78].
6. *The generalized anxiety disorder 7-item (GAD-7) scale*[79]. It is a brief scale consisting of 7 items designed to measure the severity of symptoms of Generalized Anxiety Disorder. The answers are based on the symptoms perceived during the last week. This scale is answered in a Likert format with scores from 0 to 3 where the total points can be 21. A score between 0 to 4 points indicates that anxiety is not perceived and from 15 to 21 is an indicator of perceived severe anxiety. The version by García-Campayo et al.[80] , was used for this study.

7. *Beck Depression Scale second version (BDI-II)*[81]. This self-applied scale measures the presence and severity of depression symptoms in adolescents and adults. It contains 21 items with a response option on a Likert scale from 0 to 3, with the exception of items 16 and 18 that have seven response options each. The score ranges from 0 to 63, where a total of 0 to 13 indicates minimal depression, 14 to 19 mild depression, 20 to 28 is moderate depression, and a score of 26 to 63 indicates severe depression. The study of the psychometric properties of the Spanish version of the BDI for the Mexican population was carried out by Jurado et al.[82], and González et al.[83] for version II (alpha Cronbach between .87 and .92).

8. *The Pittsburgh Sleep Quality Index*[84]. This instrument evaluates sleep patterns that differentiate people with poor sleep quality from people with good sleep quality. In this scale seven areas are evaluated: sleep duration, sleep disturbance, sleep latency, daytime dysfunction due to drowsiness, sleep efficiency, overall quality of sleep, and use of sleep medication[84]. The evaluation in the Mexican population showed solid reliability criteria (α = 0.78)[85].

Acceptance / Satisfaction / usability measures

1. *Opinion about the treatment*[35] . This questionnaire is composed of four questions that report the level of satisfaction with the treatment if they would recommend the treatment to a friend or family member, if the patient considers the treatment useful and if he/she thinks that the treatment was difficult to manage or if it was aversive. The items are answered in a scale from 1 (nothing) to 10 (very much).
2. System Usability Scale[86]. It is an instrument designed to validate the usability of a system, it is composed of 10 items, which are answered on a 5-point Likert-type scale with respect to the degree of conformity of the product (1= completely disagree to 5 = completely agree). To obtain the global score of this scale, all the values obtained must be added together and multiplied by 2.5, and this will result in a number between 0 and 100, which will be the global value of this scale.

Table 2. SPIRIT figure to display the study's schedule of enrolment, interventions, and assessments.

	STUDY PERIOD					
	Enrolment	**Allocation**		**Post-allocation**		
Timepoint	*t0*	*0*	*t1: PRE*	*t2: Post*	*t3: Follow-up 1*	*t4: Follow-up 2*
Enrolment:						
Eligibility criteria	X					
Informed consent	X					
Allocation		X				
Interventions:						
PP intervention with chat						
PP intervention without chat						
Assessments:						
Primary Outcome Measure:						
Scale of Post-traumatic Stress Traits	X			X	X	X
Widespread fear Scale	X			X	X	X
Urban Strategies Coping Strategies Scale (CIU)	X			X	X	X
State-Trait Anxiety Inventory (STAI)	X			X	X	X
The Scale for Suicide Ideation	X			X	X	X
The generalized anxiety disorder 7-item (GAD-7) scale	X			X	X	X
Beck Depression Scale (BDI-II)	X			X	X	X
The Pittsburgh Sleep Quality Index	X			X	X	X
	X					
Further Outcome Measures:						
Opinion treatment questionnaire System				X		
Usability Scale				X		

Data Collection and Management

Participant retention and withdrawal

Due to the structure of how the platform is built, it is possible to know when the participants did not log in to the platform in more than 3 days. For this purpose, it will be considered sending a generic email to all the participants reminding about the benefits of continuing with the intervention[87].

All the participants may withdraw from the treatment at any time for any reason they consider relevant to interrupt the intervention. The participants will not need to notify any member of the project about the withdrawal of the intervention, although the main contact ways such as email or therapists in the chat will record any notification received about the withdrawal of any participant and this will be analyzed at the end of the study.

Statistical Analysis

Descriptive analyzes will be carried out to characterize the study sample based on demographic variables such as: age, sex, occupation, and residence. The abandonment data by experimental condition, region of the country and sociodemographic characteristics will be considered. For the analysis of clinical indicators, the intensity of symptoms, duration, comorbidity with other psychological problems will be reviewed, as well as measures focused on the enhancement of positive emotions, strengths, and virtues.

In order to determine the differences in sociodemographic and diagnostic variables that could affect the efficacy of the study between the two treatment groups (assisted by psychological counselors via chat or without assistance), statistical analysis will be performed before the intervention.

The Kruskal-Wallis test, with a level of significance ($P \leq .05$), will be calculated for categorical variables through $\chi 2$ test analysis. The results will be presented in three sections: (a) contrast analysis to measure the efficacy of the interventions. In this regard, specific measures of anxiety and depression symptoms and adaptive adjustment will be analyzed, before and after the COVID-19 Mental Health treatment program. (b) Analysis for moderating variables (coping strategies) and (c) measures acceptance/satisfaction and usability of the system.

Power

To determine the efficacy of the intervention program, a repeated measures analysis of variance will be computed through the SPSS statistical program, which will compare the pretest measures against the posttest measures in the two experimental conditions. Results will be assessed by performing effect size analyzes for each intervention group and between treatment groups (unassisted and therapist-assisted), using the G* Power 3.1.6 software[49]. A conservative approach will be adopted and the size effect will be estimated using Cohen's d index with a significance level (α) of 0.05 (P <0.05, which corresponds to 95% reliability) and will be estimated with a power conventional 80% statistic (1- β = 0.8).

Confidentiality and ethical conditions

This study will strictly adhere to the guidelines expressed in the American Psychological Association's Code of Ethics for Psychologists[88]. The project supervisors will protect user confidentiality and interaction records during chat support. All participants must read and accept the informed consent, which details the objectives of the study, and then proceed to respond to the evaluation instruments that will provide support to evaluate the effectiveness of the intervention. These instruments are attached within the Mental Health COVID-19 platform, so it will not be necessary to go to links provided by other servers, thus taking care of the identity and data of the users. At all times, the rights to confidentiality and privacy of personal data will be respected. The personal data of the participant will be protected for consultation only by the study researchers and the user may request at any time that their data be removed from the registry and abandon the study. Participation is voluntary and the intervention is free of charge for the entire Mexican adult population, which meets the inclusion criteria for the study.

It is included in the platform a section on privacy policy and privacy rights which can be found at the following link: https://www.saludmentalcovid.com/privacy.aspx. It describes the objectives of the platform and provides information regarding the uses of the collected data, use of cookies, links to third parties, and control of personal information. This study has the approval of the Ethics Committee of the Free School of Psychology University of Behavioral Sciences.

Results

The clinical trial is ongoing. This protocol was approved by the Research Ethics Board of the Free School of Psychology University of Behavioral Sciences (reference number Folio 2008) on

May 1, 2020. Data collection started on June 15, 2020. As of July of 2020, enrollment has been completed. We aim to publish the preliminary results in December 2020.

Discussion

COVID-19 has turned out to be an international public health problem and has had a great impact on the population at a social, physical, and psychological level. The present study has focused on attending to the psychological repercussion and its objective is to test the effectiveness of the online intervention for the population psychologically affected by the pandemic, to provide a self-applied intervention based on the principles of Positive Psychology, and it is also supported by elements of Cognitive Behavioral Therapy and components of Behavioral Activation Therapy are added. Some reviews show that Internet-based treatments for depression and computerized treatments are effective interventions[36–38,44,45]

The objective of this intervention is for the participants to internalize and consolidate what they have learned in each module, to improve their sleep quality, decrease the anxious depressive symptoms characteristic of the post-traumatic stress generated by the pandemic and to use the learned contents as coping strategies and skills in their day to day basis. It is important to notice that it is possible to apply evidence-based treatments through the internet[34], these reduce the contact time between patient and therapist and also due to confinement this would not have been possible otherwise.

Thus, with the implementation of positive psychology modules, it is expected that negative affect and anxiety will decrease significantly and that positive affect will increase, this would be in accordance with the study by Mira et al.[89], in which they suggest that the techniques Positive Psychology studies can have an impact on clinical symptoms and highlight the need to include these techniques to achieve a change in measures of positive functioning. Also, in interventions based on gratitude, improvement is found in anxiety, depression, and optimism[27,90].

Particularly, the Behavioral Activation module can help users to pay attention to the activities they carry out daily and realize how this affects their emotional state in their stress level and coping capacity. Quintana et al.[91] affirm that strategies to increase physical activity can increase adherence to healthy lifestyles and improve some psychological variables such as quality of life, quality of sleep, and anxiety. In the same way, the aim of the Cognitive Behavioral Therapy module with components of emotion, will be to decrease the sleep disorders such as insomnia, nightmares and the

symptoms of Post-traumatic stress disorder present in the study sample[92] and also to reduce symptoms of anxiety and depression[93].

The discussion of the study will be in line with what Botella et al.[94] highlight to be taken into account when evaluating a psychological intervention. Attention will be paid in light of the results between the axis of efficacy, or internal validity, which will allow the available evidence from the study to be analyzed against alternative explanations, and in the axis of the effectiveness implied by the generalization or external validity of the intervention, in terms of the feasibility of applying the intervention in various social, cultural contexts of individuals, as well as associated benefits for its dissemination in the context of the health contingency derived from COVID-19.

To summarize, this platform will offer the possibility of reaching a large number of people, it will reduce costs because it will be carried out at home and will offer useful tools for the mental health care of the Mexican population. The online methodology offers the possibility of interacting creatively with vignettes, videos, audios, etc., which makes it more attractive than traditional interventions.

Limitations

It should be noted that this study has some weaknesses such as the lack of ease for some people with Internet management, especially the elderly, and the dropout rate may be higher than in traditional therapy[34]. In addition, a high drop-out rate is observed in online interventions carried out by the participants themselves, and the influencing factors in treatment adherence and sabotage that may appear during the course of therapy are unknown [34]. It is to be hoped that in the near future online self-applied treatment may become a generality in the therapeutic community.

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Conflicts of Interest

The authors declare they have no conflicts of interest. This research did not receive a specific grant from any funding agency.

Authors' Contributions

Conceptualization: ADR and ADLRG. Methodology: ADR, ADLRG, MJHJ and PAL. Web platform development: JAS, JEGH and ADR Original draft: ADR, ADLRG, MJHJ, PAL, SCML, CAS and VAG. Review and editing: ADR, ADLRG, MJHJ, PAL, SCML, CAS, VAG JAS and JEGH.

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Abbreviations

ASP = Active Server Pages

BAT = Behavioral Activation Therapy.

BDI-II = Beck Depression Scale second version

CBT = Cognitive Behavioral Therapy.

CICD = Continuous Integration and Continuous Delivery

COVID-19 = Coronavirus Disease 2019

DSM-5 = Diagnostic and Statistical Manual for Mental Disorders version 5

GAD = Generalized Anxiety Disorder

HTML = HyperText Markup Language

PP = Positive Psychology

PTSD = Posttraumatic Stress Disorder

SPSS = Statistical Package for Social Sciences

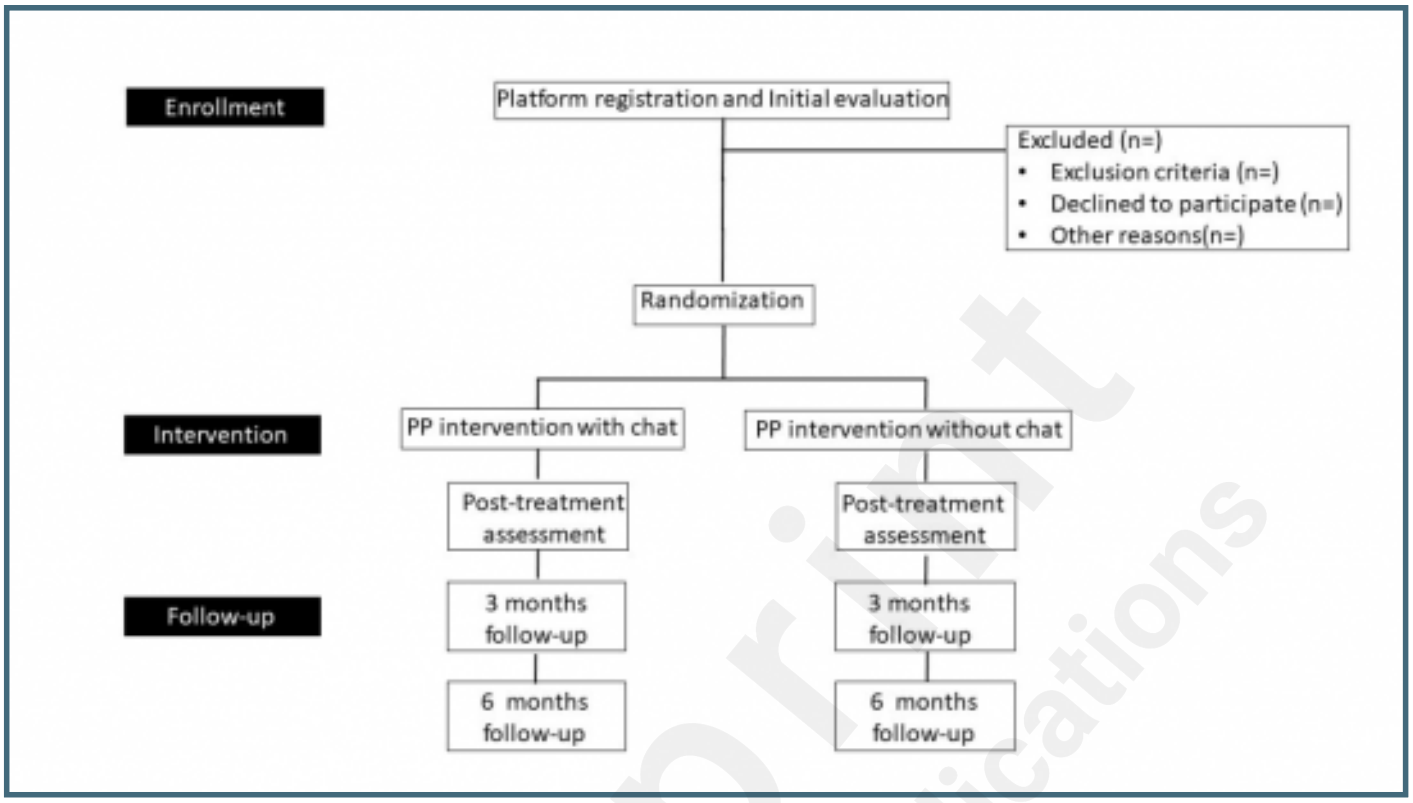
STAI = State-Trait Anxiety Inventory

Supplementary Files

Figures

Example of a module within the Mental Health COVID-19 platform.

Flowchart of the study design for the Mental Health Platform COVID-19.



Menu of modules made by the participants.