"Be yourself", educational intervention with chatbot to promote self-determined motivation and prevent adolescent pregnancy: pilot trial protocol

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ABSTRACT

Introduction: Adolescent pregnancy and early initiation of sexual activity is a serious global public health problem, every year, around sixteen million adolescents between 15 and 19 years of age give birth, representing 11% of all births globally. **Objective:** To design a protocol of a pilot Randomized Controlled Trial to evaluate the preliminary efficacy of the "Be Yourself" intervention to increase self-determined motivation to prevent pregnancy in adolescents in secondary education. **Methods:** The protocol was developed based on the Protocol Items: ecommendations for Interventional Trials 2013 (SPIRIT2013) Statement, in the City of Monterrey, Nuevo León, Mexico in 2023. **Results:** The protocol outlined the design of the intervention, structured the content of the sessions using a logic model of intervention, and developed manuals for program facilitators and guides for participants. In addition, a website and a chatbot with Artificial Intelligence were developed, and the strategy for the application of the evaluation instruments was established.

Keywords: Self-determination; Teenage Pregnancy; Sexual behaviour; Prevention; Randomized controlled trial.

INTRODUCTION

Adolescent pregnancy continues to be a serious public health problem globally, affecting millions of young people every year. The World Health Organization (WHO) and the United Nations Population Fund (UNFPA) report that approximately sixteen million adolescents aged 15 to 19 give birth annually, accounting for 11% of all births. In addition, one in twenty adolescents contracts sexually transmitted infections (STIs) and 3.4 million children under 15 years of age live with Human Immunodeficiency Virus (HIV)^{1,2,3}. In Mexico, the rate of teenage pregnancies is the highest in the world, with more than 90% of new STIs in young women and a notable difference in the fertility rate between rural (2.8) and urban (2.01) areas, where 31.2% of young people under 18 years of age in rural areas are already mothers. compared to 18.3% in urban areas^{4,5,6}.

The literature reports that some reasons for risky sexual behaviors at this stage are ignorance of the use of contraceptive methods and how STIs are transmitted; lack of communication about sexual issues with parents, friends, and partners; lack of confidence in the proper use of condoms; and lack of sexual autonomy7,8. Different authors indicate that these reasons lead adolescents to some high-risk sexual behaviors, such as the early initiation of sexual relations and sexual relations without using a condom, so that at this stage the risk of unwanted pregnancies and STIs increases ^{1,9}.

Secondary sexual education remains essential to improving adolescent sexual health, as most adolescents attend school, and parents support its inclusion in the curriculum. However, many

adolescent pregnancy prevention programs, created decades ago, address only a limited range of risky behaviors. To increase effectiveness, technology has been integrated into these programs, although evaluations have not always demonstrated the specific impact of these technological components. In addition, it has been noted that programmes that rely solely on in-person education may not be in line with young people's current communication preferences^{10,11}.

Recent studies have evaluated technological adaptations in sexual and reproductive health programs, finding that access to websites, apps, and text messages may be promising, although more evaluation is required. Systematic reviews and meta-analyses have comprehensively analyzed interventions to reduce risky sexual behaviors in adolescents, highlighting the importance of psychological approaches based on theories such as Social Cognitive Theory, Planned Behavior Theory, Reasoned Action Theory, and Self-Determination Theory. While most reviews have focused on HIV and STI prevention, some have also addressed pregnancy prevention, often integrating both aspects into their approaches^{11,12}.

Global evidence indicates that psychological interventions can be effective in reducing risky sexual behaviors and preventing unwanted pregnancies. Adolescent sexual and reproductive health is therefore a national priority. In this context, Rodríguez's Self-Determination Model for Sexual Behavior for the Prevention of Pregnancy in Adolescence (MACSPEA)¹³ has proven to be useful in explaining and predicting pregnancy prevention behaviors, considering personal factors such as age, the beginning of sexual life and knowledge about prevention, as well as contextual factors such as sexual communication with parents, friends and partner. In addition, the model includes psychological factors such as intrinsic goals, satisfaction and frustration of basic psychological needs, and self-determined motivation^{14,15,16.}

For all the above, an educational intervention was developed based on the MACSPEA model, the six steps of Bartholomew's intervention mapping17 and the stages of the Transtheoretical Model of Change (MTTC) proposed by Prochaska and DiClemente18, in addition to a website that uses artificial intelligence (AI) through a chatbot as a delivery method. This intervention is aimed at adolescents aged 12 to 15 years, with the aim of evaluating the preliminary efficacy of the intervention called "Be yourself" to increase self-determined motivation and prevent pregnancies in secondary school adolescents.

MATERIAL AND METHODS

Studio Design

A randomized controlled pilot trial protocol has been developed following the guidelines of the Declaration SPIRIT¹⁹ 2013 and CONSORT²⁰ criteria, which provides a checklist to ensure quality and completeness in the development of protocols. This protocol corresponds to a randomized controlled pilot trial (RCT) with a pretest-posttest design, which will include a control group (CG) and an experimental group (EG) (Table 1).

Participants	Assigned Group	Measurement	Application	Measurement 1	Measurement 2
Teens	GE-1	Before	Intervention "Be yourself"	\rightarrow At the end	3 months
12 to 15 years	GC- 2	Before	Habitual	At the end	3 months

Table 1. Outline of the design of the Pilot RCT

Population Characteristics and Eligibility Criteria

The target population of the "Be Yourself" program are adolescents between 11 and 15 years old in secondary schools in Santa Catarina, Nuevo León. Eligibility criteria include being enrolled in a public school with access to a computer lab and internet, residing with your parents, and having become sexually active or not. The sample will be of 150 randomly selected participants. Participation will be assessed using a filter questionnaire, and adolescents will be required to register on the program's website throughout the intervention, with the option to withdraw at any time.

Sample size

To determine the sample size, the nQuery Advisor statistical package will be used. The aim is to have 150 participants, of which 75 will belong to the CG and 75 to the EG, applying a simple random probability sampling. The sample will be calculated with an error level of .05, a power of 90%, a moderate effect size of .3, considering a loss of 20%.

Design of the Intervention "Be yourself"

The "Be Yourself" educational intervention was designed to prevent sexual risk in high school adolescents through self-determined motivation. Based on MACSPEA, the model of stages of change and competency-based learning uses a website (<u>https://www.s-t-mismo.com/</u>) and a chatbot for monitoring and activities (Table 2). The intervention consists of three sessions that address the prevention of adolescent pregnancy and the strengthening of skills. It includes hands-on activities,

role-plays, and interactive sessions on contraceptive methods, effective communication, and informed decision-making. To do this, specialized human resources and specific materials are required for its execution. Manuals were designed for the intervention and training of the facilitator, and activity guides for adolescents^{21,14-18}.

		Thematic content	Time	Components of the intervention
		Pre-test assessment app	40 min	Access to the "Be Yourself" page
ų	1.	What is self-determined motivation?: Discovering our dreams	60 min	Personal factors
First Session	1.	My Body: Anatomy, Physiology, and Sexual Health.	60 min	 Age of onset of sexual life Pregnancy Prevention
	2.	Navigating relationships: preventing unplanned pregnancy in adolescents.	60 min	Knowledge
	3.	Exploring Goals and Values to Prevent Unintended Pregnancies	60 min	Contextual factors
Second Session	4.	Be yourself: stop, think and act; Introduction to Troubleshooting	60 min	1. Sexual communication with parents
	5.	Role-play: open dialogue about sexuality	60 min	 Sexual communication with friends Sexual communication with a partner
uo	6.	Navigating the Sea of Healthy Choices: Exploring Our Motivation	60 min	Psychological factors
Third Session	7.	My Space, My Decisions Exploring Our Needs	60 min	 Intrinsic and extrinsic motivation Satisfaction and frustration:
Thir	8.	Negotiating Healthy Choices: Preventing Pregnancy and STIs	60 min	autonomy, relationships and skills
Keep	9.	Building Self-Determined Motivation in Teens: Strengthening Session on Website and Chatbot	Continued individual	 Self-determined motivation, Behavioral Intent and Sexual Prevention Behavior
		Post-test assessment app	40 min	Access to the "Be Yourself" page
		Total, hours	10 hours 20	minutes more

Description of the control treatment

For the GC, two theoretical sessions are planned. In the first, an orientation on sexual health for adolescents will be offered through a one-hour PowerPoint presentation. Topics of anatomy, physiology, biological changes in adolescence and contraceptive methods will be addressed, highlighting their appropriate use and the prevention of teenage pregnancy. In the second session, also one hour, sexual health self-care skills will be developed, discussing the importance of self-care, self-respect, and informed decision-making. There will be a Q&A session to address concerns and reflect on how self-care contributes to a healthy and safe sex life.

Control measures

Randomization of participants

Participants will be thoroughly selected to represent the EG. Software will perform a simple, blinded randomization, assigning participants to control or experimental groups. Managers will be informed about the "Be Yourself" sessions, the dates and locations of which will be published on the website and communicated verbally. The sessions will be group, with individual activities on the website and through a chatbot.

Recruitment

Recruitment for the intervention will take place in February 2025, after the authorization of the educational authorities. Adolescents from the educational institution will be openly invited and their suitability will be evaluated according to inclusion criteria. Those selected will be recorded and assigned to control and experimental groups using an ID to ensure data integrity.

With informed consent, participants will access the website and the chatbot for information and registration. After accepting, they will answer filter questions and receive a detailed explanation of the process. Those who do not qualify will receive a transparent explanation.

On the website, participants will record their personal data for effective communication and reminders. They will be informed about the royalties of the program at the end of the project, motivating them to participate in all activities. The information will be stored securely for one year.

Measurements and data collection

Data collection for the study will include the use of a specifically designed Personal Data Card, which will collect information about the sexuality, marital status, and education of the participants. A variety of scales will be used to measure aspects related to adolescent sexual health and behavior. The Sexual and Reproductive Health Knowledge Scale, Cronbach's alpha between .77 and .81²¹, will assess knowledge in these areas, while the Sexual Issues Communication Instrument, Cronbach's alpha from .89 to .95, will analyze sexual communication between parents, friends, and partners²². The Aspirations Index, alpha greater than .78 and .94, will measure life goals, and the Basic Psychological Needs Satisfaction and Frustration Scale will have alphas of .90 and .86²³.

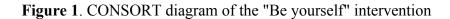
The Behavior Regulation Questionnaire, adapted to the Mexican context, will assess behavior regulation to prevent pregnancy, with alphas between .66 and .93²⁴. Likewise, the Sexual Activity Intention Scale and the Sexual Activity Scale will assess sexual intentions and behaviors, respectively, with alphas from .83 to .88 and .74 to .86²⁵. The Sexual and Reproductive Health

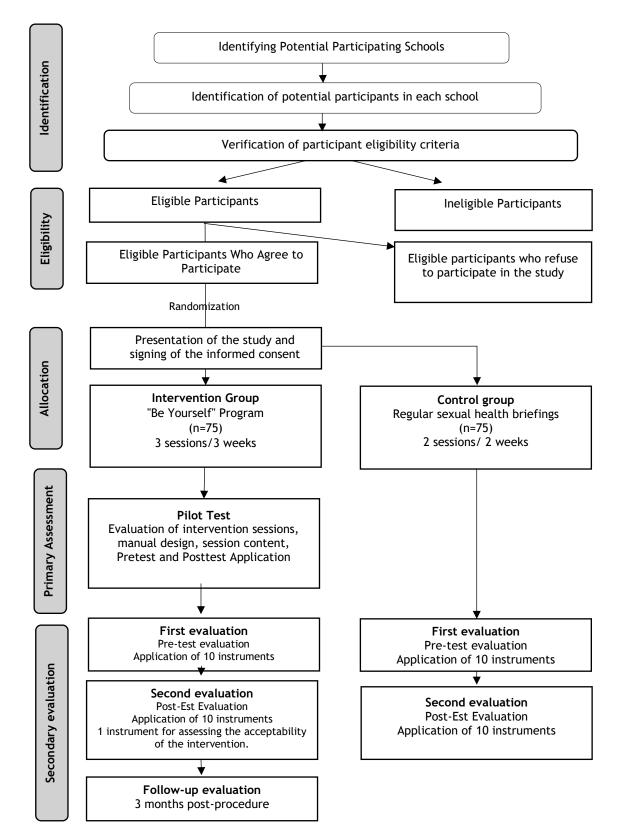
Practices Scale, which examines pregnancy prevention behavior, with alphas of .92, .77, .81 and .87 in its different adaptations²⁶.

The "Scale for the Assessment of Change on Sexual Behavior in Adolescents"27 will be adapted and validated, ensuring its reliability. To assess the acceptability and feasibility of the "Be Yourself" intervention, aspects such as participant satisfaction, meeting expectations, and facilitator quality will be analyzed, along with participant recruitment, screening, randomization, and retention procedures.

Participant Retention Plan and Follow-Up

The retention plan for the "Be yourself" intervention includes the delivery of T-shirts and caps with the logo of the program at the end, weekly sessions to avoid information saturation and a three-month follow-up. Data collection will be done through the website using digital tools to assess the effectiveness and acceptability of the program. The fidelity of the intervention will be ensured by training the principal investigator in self-determination theory and developing supporting manuals and guides. Figure 1 presents diagram CONSORT²⁰, which details the eligibility criteria, intervention, and evaluation of sessions before, after, and during follow-up at three months.





Ethical considerations

This study complies with the ethical regulations of the Regulations of the General Health Law, ensuring respect for the dignity and rights of the participants. The protocol has been approved by the Ethics and Research Committee of the Faculty of Nursing of the Autonomous University of Nuevo León, with registration number FAEN-D-2021. Informed consent will be obtained from the parents and assent from the adolescents. Participation will be explained in detail to parents and teens, including risks and benefits. The research will be suspended if there is a risk to the health of the participants or if they wish to withdraw²⁸.

Data analysis plan

The research will use statistical software SPSS version 26.0 for data processing. The analysis will begin with the Kolmogorov-Smirnov test to evaluate the distribution of the data and determine the suitability of applying parametric or nonparametric tests. The statistical analysis will include a descriptive level, using percentages, means, and standard deviation, to assess feasibility and acceptability. For hypotheses, inferential tests such as paired sample t-test, ANOVA, and Mann-Whitney U will be used to examine knowledge about pregnancy prevention, sexual communication, motivation, satisfaction of psychological needs, sexual intention, pregnancy prevention behavior, and stages of change in sexual behavior²⁹.

Table 3 describes the objectives and hypotheses proposed in this study, both descriptive and inferential statistics will be used

Objective	Analysis	Statistical
1 Examining feasibility	Descriptive	Measures of frequency, central tendency, and dispersion: percentages, means, ranges, Standard Deviation, confidence intervals, recruitment and retention rates.
2 Analyze acceptability	Descriptive	Percentages, means, ranges, Standard Deviation, confidence intervals, recruitment and retention rates
Hypothesis	Analysis	Statistical
 3 Hypothesized results: H 1. Knowledge about Pregnancy Prevention H 2. Sexual Communication Parent, Friends & Partner. H 3. Intrinsic and extrinsic motivation H 4. Satisfactory and Frustration of NPBs (autonomy, relationship and competencies) H 5. Self-Determined Motivation H 6. Intention in Sexual Activity H 7. Pregnancy Prevention Sexual Behavior H 8. Stages of Change for Sexual Behavior 	Inferential	t-test of paired or ANOVA samples Test de Friedman Test de Wilcoxon U de Mann-Whitney

Table 3. Statistical analysis by objective and/or hypothesis

EXPECTED RESULTS

The protocol of the "Be Yourself" intervention includes the structural design of the sessions, the development of two facilitator manuals and a participant workbook, and the creation of a web page with a chatbot based on OpenAI's GPT. The intervention is expected to increase adolescents' self-determination to abstain from sexual activity, improve their positive attitude toward sexuality, and expand their knowledge about pregnancy prevention. In addition, a greater adoption of preventive behaviors is anticipated compared to those who do not participate, which would suggest a positive impact on sexual decision-making.

FINANCING

This project did not receive any funding **DECLARATION OF CONFLICTS OF INTEREST** The author declares that they have no conflict of interest

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Logical Model of the "Be Yourself" Intervention

I	Problem	Self-determined motivati	on fo	r adolescent pregnanc	cy pre	evention.		
	Meta That adolescents achieve the stage of action and maintenance of self-determined motivation to prevent adolescent pregnancy.							
Ju	ıstificatio n					n for the Prevention of Pregnar e Competency-Based Learnin		
	As	ssumptions		Entrance Resources		Outputs Activities	Outputs	Results
a.	may not recog pregnancy if t	the precontemplation stage gnize themselves at risk for they lack awareness of the usequences and risks.		Human: Researcher, research assistant Financial:		Session 1: Getting to know yourself, steps to achieve your "Be Yourself" goals Knowledge and awareness	 "Be Yourself" faithfully implemented. Videos viewed on 	Primary 1.Increase in Self-Determined Motivation Indices to Prevent Adolescent Pregnancy (H5).
b.	If teens don't hat pregnancy pre	ave enough knowledge about evention, condom use, and they're likely to stay in the		Operating budget for the production of the material. Space: Computer		1. What is Self-Determined Motivation?: Discovering Our Dreams 2. My Body: Anatomy,	 web platform Participants discuss condom use and 	 2.Increased Level of Knowledge about Pregnancy Prevention (H1). 3.Improved Communication on Sexual Issues (H2.
c.	A lack of toward abstine	self-determined motivation ence and condom use can escents' transition to the		room of the educational institution Materials: didactic		Physiology and Sexual Health. Problem solving, negotiation.	negotiation 4. There is a discussion about abstinence and	 4. Change in Life Goals (H3): Significant increase in orientation toward intrinsic life goals (such as personal and academic development).
d.	A lack of se parents, friend difficult for te stage, where	exual communication with ds, and partners can make it evens to move into the action to they are expected to anges in sexual behavior and		and recreational materials for the intervention. Access to the web platform		3. Navigating Relationships: Preventing Unwanted Teen Pregnancy. Session 2: Building Personal Commitments: Conduct,	prevention of pregnancy 5. Negotiation and rejection skills are practiced	 5. Satisfaction of Basic Psychological Needs: autonomy, relationships and competence. (H4). Secondarys Intention to Risk and Protect (H6):
e.	behavior. Lack of sexu negotiate cond be factors infl	ual autonomy, inability to lom use, and abstinence may luencing adolescents' ability positive changes in sexual		Interactive digital educational material. Technical support to solve possible problems.		Behavior, and Sexual Communication 1. Exploring Goals and Values to Prevent Unintended Pregnancies 2. Be yourself: stop, think	 through role plays. Acquired problem skills. Self-confidence in decision- 	Significant decrease in intention to risk (such as willingness to have unprotected sex) and significant increase in intention to protect (such as use of contraception and protection against STIs).
f.	Adolescents ar sexual behav intervention ar	re more likely to change their vior and behavior if the nd prevention messages are affectionate and supportive.				 and act; Introduction to Troubleshooting Role-Play: Open Dialogue on Sexuality 	making - Practice sexual communication	 2.Frequency of Nonsexual Sexual and Affection Behaviors (H7): Significant decrease in the frequency of risky sexual behaviors and increase in the
g.	Maintaining a	an effective self-determined sed on learning is essential				Session 3: Empowerment and Concrete Actions:		frequency of nonsexual affection

Pregnancy and STIs	 for the consolidation of change in the sexual conduct and behavior of adolescents. h. Believing in themselves and their abilities, feeling valued, and having opportunities to practice skills with the support of parents, friends, and partners are key factors in preventing relapses of risky sexual behaviors and behaviors. 	improving negotiation and rejection skills 1. Navigating the Sea of Healthy Choices: Exploring Our Motivation. 2. My space, my decisions exploring our needs. 3. Negotiating Healthy Choices: Preventing	 behaviors (such as holding hands and kissing on the mouth). 3. Highly preventive behavior with favorable attitudes and behaviors toward pregnancy prevention (H8) 1. Intention and Willingness to Change Sexual Behavior in the Next Three Months (H9)
i regnancy and 5115	behaviors and behaviors.	Pregnancy and STIs	

Products

Session 1: Getting to know yourself, steps to achieve your "Be Yourself" goals (Knowledge and awareness)

- 1. The adolescent becomes aware of pregnancy prevention and what is involved in increased knowledge of the risks associated with sexual activity, as well as an understanding of the importance of family planning and the prevention of unintended pregnancy.
- 2. Detailed knowledge about the correct use of condoms and awareness of their importance in protecting against STIs are key results in promoting sexual health.
- 3. Improved negotiation skills are reflected in an increased ability to communicate and reach agreements, accompanied by the development of empathic skills and a broader understanding of others' perspectives.

Session 2: Building Personal Commitments: Conduct, Behavior, and Sexual Communication

- 1. Exploring Goals and Values: Teens identify personal goals and strategies to prevent pregnancy through hands-on exercises and role-playing.
- 2. Problem-solving: Communication skills and informed decision-making are developed in relationships, focusing on values and limits.
- 3. Role play: Open communication about sexuality is practiced with parents, friends and partners, evaluating progress and challenges.

Session 3: Empowerment and Concrete Actions: improving negotiation and rejection skills

- 1. Teens will create a "Negotiation and Rejection Skills Guide." This guide would include specific strategies learned during the session, practical tips for coping with challenging situations in preventing unintended pregnancy.
- 2. Adolescents participate in the "Motivational Campaign on Sexual Health", promoting the importance of personal empowerment, informed decision-making and self-motivation on issues related to sexual health. This campaign could include inspirational messages, testimonials, and helpful resources to foster self-determination among peers.
- 3. "Interactive Simulation with Chatbot", which simulates situations of negotiation and rejection in the context of sexual relations and prevention of unplanned pregnancy, allows adolescents to practice and reinforce the skills learned, providing instant feedback on their choices and decisions.