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Original Article

Effectiveness of a Randomized Intervention Trial Utilizing the PRECEDE Planning Model for Brucellosis Prevention and Control in Rural Iranian Communities

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Abstract

Background: This study developed a community-based intervention program for brucellosis prevention and control.

Methods: A two-armed parallel cluster randomized controlled trial investigated the effectiveness of the program over six months in a rural population in Ahar, East Azerbaijan, Iran. Sixteen village health houses were randomly allocated to the intervention and control groups (eight per arm), and 400 participants were recruited *via* household health records in the health houses. The Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation (PRECEDE) model was employed to design, implement, and evaluate the brucellosis prevention and control program. Knowledge, attitudes, self-efficacy, social support, environmental, enabling, and behavioral factors were measured at the baseline and the six-month follow-up. A generalized mixed-effects model was used to analyze the data.

Results: The intervention led to significant improvements in individual factors such as attitudes and self-efficacy. In the intervention group, attitudes increased from 51.1 to 57.1, while in the control group, there was minimal change from 41.1 to 41.3. Similarly, self-efficacy improved in the intervention group (from 27.6 to 33.2) but decreased in the control group (from 24.3 to 19.8). These changes were statistically significant. Furthermore, behavioral factors also showed significant positive changes in the intervention group compared to the control group ($p<0.001$).

Conclusion: The intervention program, guided by the PRECEDE model, proved effective in enhancing brucellosis prevention and control in a rural population. The six-month randomized controlled trial demonstrated significant improvements in individual factors, including attitudes and self-efficacy, among the intervention group compared to the control group.

Keywords: Attitudes, Arm, Control groups, Follow-up studies, Health, Humans, Iran, Knowledge, Practice, Rural population, Self efficacy, Social support

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Introduction

Brucellosis, one of the more frequently occurring zoonotic diseases, is a public health priority in developing countries (1) due to its significant, measurable effects on the productive and reproductive performance of livestock (2). It results in miscarriage, reduced productivity, and weak offspring and has major economic consequences for farmers, including loss of income. Brucellosis is transmitted to humans through the consumption of unpasteurized dairy products and may cause serious morbidity with severe complications (3). Brucellosis remains a major public health challenge due to the physical suffering and financial losses of infected persons (4).

Although great progress has been made in brucellosis control and elimination in many countries, the incidence of human and animal brucellosis remains high in some developing countries (5). Iran's incidence of human brucellosis is among the top five globally, with a prevalence ranging from approximately 0.5 to 10.9% (6). The highest risk areas in Iran are in the East Azerbaijan province (7). Brucellosis causes a persistent infection in domesticated animals, which is frequently transmitted to the human population (8). The infection is transmitted to people who consume infected milk or cheese products as well as through inhalation or animal contact (9).

Several factors account for the failure of brucellosis control plans. For livestock, these include inadequate attention to livestock health, poor veterinary services, insufficient financial resources to curtail brucellosis, and infrequent animal vaccination. For humans, the factors include dietary habits (*e.g.,* consuming unpasteurized dairy products, such as homemade cheese from unboiled milk) (10), social and cultural customs, and socioeconomic status (11,12).

A literature review (13) revealed that addressing neglected brucellosis requires integrated, collaborative action in the public and veterinary health sectors along with political support and consultation with other sectors and related organizations, especially at the regional level. Tackling the problem of neglect in relation to brucellosis requires high-level advocacy (13,14).

Furthermore, it is necessary to identify all the factors affecting the transmission of brucellosis. To elucidate these factors, the PRECEDE-PROCEED model was used (in which PRECEDE is an acronym for Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation) as a framework for planning and program evaluation. According to Green and Kreuter, who developed the model in the 1970s (15), modifying a behavior requires not merely targeting the individual but also considering the entire surrounding environment and the factors affecting the individual's behavior. The model comprises educational, ecological, and behavioral assessments. The educational and ecological assessments address predisposing factors, enabling factors, and reinforcing factors (15). The selection of the PRECEDE-PROCEED model stems from its comprehensive and systematic approach to health program planning and evaluation. This model provides a structured framework that allows for a thorough assessment of both predisposing, enabling, and reinforcing factors that influence health behaviors, as well as the environmental and policy factors that contribute to overall health outcomes (15-17). The PRECEDE-PROCEED model not only emphasizes the importance of understanding the determinants of health-related behaviors but also guides the development and implementation of targeted interventions. Its phased structure, from assessing educational and ecological factors to designing, implementing, and evaluating interventions, ensures a holistic and evidence-based approach. This model's flexibility allows it to be applied across a wide range of health issues and populations, making it a valuable tool for developing tailored and effective health promotion programs (16-18).

A Generalized Mixed-Effects Model (GLMM) is a statistical framework that extends the capabilities of traditional linear mixed-effects models by accommodating non-normally distributed response variables and incorporating both fixed and random effects. This modeling approach is particularly useful in situations where the data exhibit complex structures, such as hierarchies or repeated measurements. GLMMs provide a flexible tool for analyzing diverse types of data, including binary, count, or categorical outcomes, making them applicable in various fields such as biology, psychology, and epidemiology. By accounting for both fixed effects, representing population-level trends, and random effects, capturing individual variability, GLMMs offer a more nuanced understanding of the underlying relationships within the data. The incorporation of random effects allows for the modeling of subject-specific variations, making GLMMs well-suited for addressing the complexities present in real-world datasets (19).

The aim of this study is to assess the effectiveness of a randomized intervention trial applying the PRECEDE Planning Model for the prevention and control of brucellosis in rural Iranian communities. The study hypothesizes that implementing a comprehensive community-based intervention program, guided by the PRECEDE model, will lead to significant improvements in factors influencing brucellosis prevention and control, including knowledge, attitudes, self-efficacy, social support, environmental conditions, enabling factors, and behavioral practices. It is anticipated that the intervention group, exposed to the tailored program, will exhibit substantial positive changes in these factors compared to the control group, thereby demonstrating the efficacy of the PRECEDE model as a planning and evaluation framework for infectious disease prevention in rural settings. The findings of this study could provide valuable insights into the development of effective public health strategies for brucellosis and potentially inform similar interventions in other regions facing similar challenges.

Materials and Methods

Trial design

The study employed a two-armed parallel cluster randomized controlled trial to assess the effectiveness of a community-based brucellosis prevention program over six months in a rural population in Ahar, East Azerbaijan, Iran. The trial involved an intervention group and a control group, with baseline assessments conducted in July 2016 and post-intervention assessments six months later. The high incidence of brucellosis in the rural areas of Ahar (31–41 cases per 100,000) (7) and the crucial need for a community-based brucellosis prevention program (20) led to its selection as the study setting. Due to the strong relationships among neighboring households in rural communities, a stratified randomized controlled trial using rural health houses as units of randomization was devised.

Recruitment and sampling design

Sixteen health houses, one per village, with a high prevalence of brucellosis over the prior two years, were selected for participant recruitment. A multistage random sampling method was employed, dividing Ahar into four regions and selecting two health centers in each region. From each center, eight health houses were chosen based on their high brucellosis prevalence. A total of 400 participants were recruited randomly using household health records, with inclusion criteria comprising individuals aged 15 or older residing in the villages for at least six months (7,21).

Randomization was carried out after the baseline measurements were taken. The 16 selected health houses were randomly allocated to eight intervention and eight control groups (arms) using permuted block randomization to guarantee balance in the number of units allocated to each arm. The randomization sequence was created manually by a biostatistician using Microsoft Excel software [Excel command for random block sizes column:=rand()] to assign the health houses to the study arms using a 1:1 allocation ratio with a block size of 4. A colleague not connected to the study performed equal group random allocation. The participants were recruited by an independent researcher using computer-generated random number schedules from recorded lists of household health files at the health houses. Trained research assistants gathered the baseline measurements, and group allocation concealment was implemented. The participants were also blinded to their group assignments (Figure 1).

Model for program planning

The PRECEDE-PROCEED model (15) informed the design, implementation, and evaluation of the brucellosis prevention and control program. The model includes nine phases based on assessments (PRECEDE) that are made before planning a health intervention as well as an evaluation (PROCEED) that enables measuring both the effectiveness of the intervention at each stage of implementation and the immediate and long-term effects (Figure 2).

The priority targets for the intervention were established at each phase of the assessment based on the importance and changeability of specific

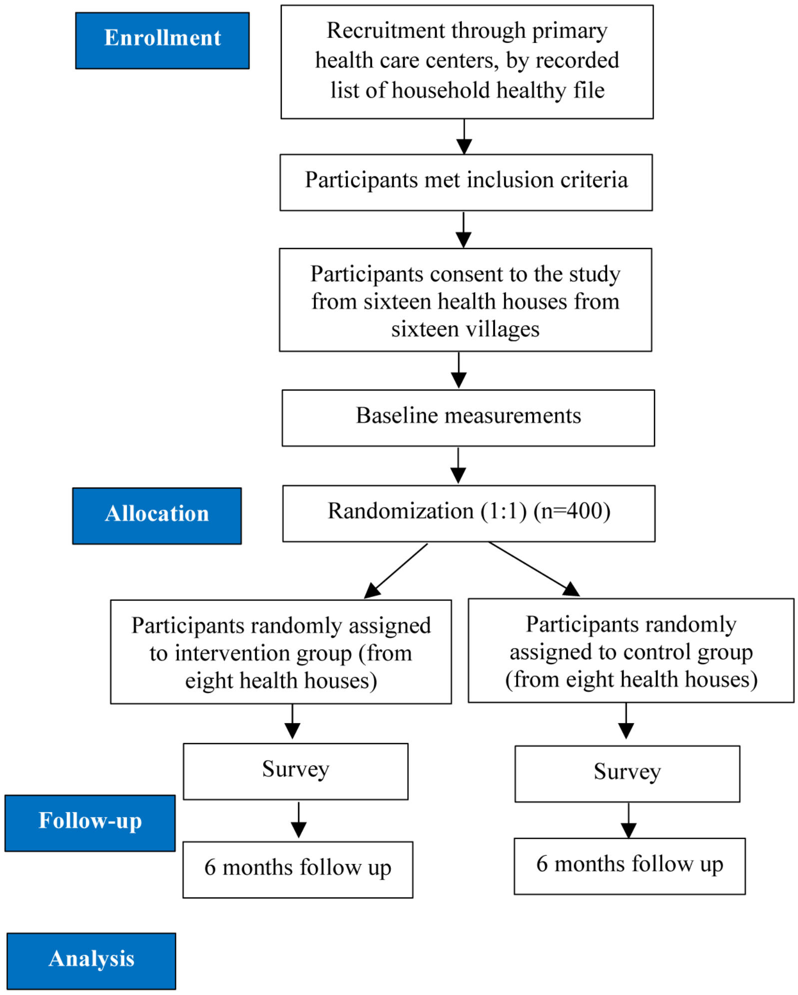

Figure 1. The study flowchart.

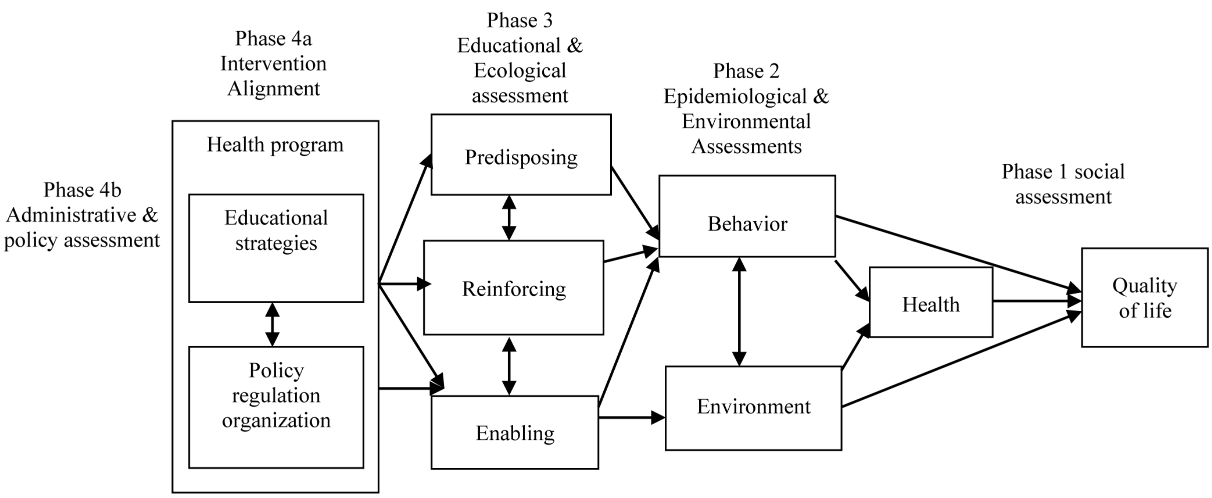

Figure 2. The PRECEDE model.

behavioral and ecological factors in determining brucellosis outcomes (phases 1–6). Specifically, the assessment focused on the seven highest-priority behavioral factors and six highest-priority ecological factors.

Phase 1-6: assessments and intervention design

The model's assessment phases focused on social, epidemiological, behavioral, environmental, educational, and ecological factors influencing brucellosis outcomes. Predisposing, enabling, and reinforcing factors were identified, and intervention strategies were matched with high-priority project changes. Strategies addressed enabling factors through coordinated efforts, while predisposing factors were targeted with tailored educational interventions. Reinforcing factors were addressed through activities promoting positive behavior and support.

Measurement tools

The following demographic data were collected from all the participants: gender, age, marital status, educational qualifications, job, history of brucellosis, and family history of the disease. As described above, a standardized, structured questionnaire was used that was comprised of five parts (addressing predisposing, reinforcing, enabling, environmental, and behavioral factors related to brucellosis) (20). The questionnaires were filled out in writing; the participants were also interviewed.

Sample size

The sample size was calculated on the basis of a mean and Standard Deviation (SD) increase in knowledge (6.8) (23), as this was one of the more important variables. A study with a power of 90% at the 5% significance level would need 185 participants in each group. Considering the risk of attrition, 200 participants were sought per group. The number of participants selected from each health house was based on the proportion of the population it served.

Statistical analysis

The characteristics of the participants were summarized as numbers, percentages, or means with SDs as appropriate. If the continuous variables were not normally distributed, appropriate transformations were performed to achieve normal distribution. The data were analyzed with a generalized mixed-effects model that used cluster randomization to incorporate random effects so as to reflect correlations among the observations of members of the same health house. The appropriate distribution and link functions were selected according to the distribution of our outcomes. For all the parameters, 95% confidence intervals were defined, and two-sided p-values of less than .05 were considered statistically significant. All the analyses were performed with the Statistical Package for the Social Sciences (SPSS) 23 (IBM Corp., Armonk, NY, USA).

Results

Demographic characteristics of the participants

Table 1 presents the demographic characteristics of the two groups. Of the 400 total respondents, the mean ages (SD) in the intervention and control groups were 35.9 (11.87) and 37.28 (11.04) years, respectively. Eighty-nine percent of the participants in the intervention group and 86.5% in the control group were married while 12.5% and 4.5% of the respondents in the intervention and control groups, respectively, had a history of brucellosis. The results also revealed that 19.5% of the participants in the intervention group and 10.5% in the control group had a family history of brucellosis. There were no significant differences between the two groups in terms of demographic characteristics and the PRECEDE model–based variables with the exceptions of history of brucellosis, family history of brucellosis, and education.

Comparison of differences in the PRECEDE model variables at baseline and after six months

As shown in table 2, significant differences emerged in the PRECEDE model–based variables between the intervention and control groups after six months (adjusted for education, history of brucellosis, and family history of brucellosis). The generalized mixed-effects model yielded significant differences between the intervention and control groups for the knowledge, attitudes, self-efficacy, social support, environmental, enabling, and behavioral factors ($p<0.001$). The individual factors that improved significantly after intervention were attitudes (from 51.1±4.7 to 57.1±1.6 in the intervention group *vs*. 41.1±5.7 to 41.3±5.8 in the control group) and self-efficacy (27.6±5.4 to 33.2±1.5 in the intervention group *vs*. 24.3±3.6 to 19.8±3.3 in the control group) ($p<0.001$). Additionally, the behavioral factors changed significantly more in the intervention

Table 1. Descriptive characteristics of the intervention and the control group participants

		Intervention (n=200)	Control (n=200)	p-value
Age (mean, SD)		35.9(11.8)	37.2(11.0)	0.226
Gender n (%)	Male	95(47.5)	94(47.3)	0.271
	Female	105(52.5)	106(52.7)	
Education	Illiterate	20(10.0)	15(7.5)	0.023
	Elementary	103(51.5)	123(61.5)	
	Secondary	58(29.0)	55(27.5)	
	University	21(10.5)	7(3.5)	
Marital status	Married	178(89.0)	173(86.5)	0.325
	Single	18(9.0)	18(9.0)	
	Widowed/divorced	4(2.0)	9(4.5)	
Employment status	Farmer/agriculture	55(27.5)	63(31.5)	0.603
	Self-employment	32(16.0)	37(18.5)	
	Household	101(50.5)	91(45.5)	
	Student	12(6.0)	9(4.5)	
History of brucellosis of individuals	Yes	25(12.5)	-	0.004
	No	-	9(4.5)	
Family history of brucellosis	Yes	-	21(10.5)	0.012
	No	39(19.5)	-	

Table 2. Comparison of PRECEDE model-based variables before and after the intervention in the intervention and the control groups

	Intervention (n=200)			Control (n=200)			p-value*
	Baseline	6-months	p-value	Baseline	6-months	p-value	
Knowledge	12.3±1.1	13.8±0.38	<0.001	7.12±1.3	6.82±1.3	<0.001	<0.001
Attitudes	51.1±4.7	57.1±1.6	<0.001	41.1 ±5.7	41.3±5.8	0.009	<0.001
Self-efficacy	27.6±5.4	33.2±1.5	<0.001	24.3±3.6	19.8±3.3	<0.001	<0.001
Social support	26.4±4	34.7±2	<0.001	25.3±4.3	25.6±±4.9	0.122	<0.001
Environmental factors	13.2±2.7	17.2±1.8	<0.001	12.1±2.6	12.3±2.8	0.147	<0.001
Enabling factors	12.5±3	11.7±1.6	<0.001	10.9±3.3	13.9±3.3	<0.001	<0.001
Behavioral factors	30±4.8	39.7±1.8	<0.001	27.7±4.1	27.7±4.1	0.169	<0.001

* p-value: Derived from the generalized mixed effects model and adjusted for education, history of brucellosis, and family history of brucellosis.

group (from 30±4.8 at baseline to 39.7±1.8 after intervention) than in the control group (27.7±4.1 at baseline to 27.7±4.1 after intervention) (p<0.001).

Discussion

The current study describes the planning process and results of an integrated intervention program for the prevention and control of brucellosis in a rural population in Ahar, East Azerbaijan, Iran. The prevention and control of brucellosis requires planning and the identification of all the disease's transmission routes in both humans and animals. The World Health Organization recommends focusing on education for all potentially exposed people (3). It is also necessary to consolidate the collaborative efforts of the health and veterinary sectors as well as to strengthen regular vaccination practices and provide adequate financial resources to compensate farmers willing to slaughter and/or provide slaughtering facilities.

The PRECEDE model plays a substantial role in designing a planning framework for public health practices and in evaluating public health promotion efforts. The PRECEDE elements enable researchers to employ a backward approach from the research outcomes to inform the creation of the intervention (24). The structure of the PRECEDE model gives researchers a conceptual framework that enables them to design an intervention that impacts the predisposing, reinforcing, and enabling factors, and it outlines a diagnostic planning program to manage a targeted public health challenge, such as brucellosis (20). This diagnostic study of the educational and ecological factors that influence behaviors and environments related to the prevention and control of brucellosis identified where and how interventions can be most effective. It was expected that the implementation of interventions aimed at these priorities (*e.g.*, referrals to veterinary organizations for regular animal vaccination), including advocacy for policy changes, will reduce the incidence of brucellosis in human and animal populations.

The findings indicate that the knowledge levels of those in the intervention group increased significantly compared to those of the control group after six months, proving the effectiveness of the educational program in the intervention group. This aligns with a study in Khomeinshahr, Iran that used the PRECEDE model to prevent brucellosis infection in a rural population (23). The findings of the present study are also consistent with those of studies by Liu *et al* (25) and Jin *et al* (26) on the reduction of brucellosis. Other studies (25-28) indicate that a poor knowledge of zoonotic diseases may exacerbate their prevalence as well as problems in controlling them. For example, a study by Jedgal *et al* (28) of people with pulmonary tuberculosis found a significant association between knowledge and health promotion behaviors.

In this study, it was found that the present intervention significantly improved attitudes related to brucellosis prevention behaviors in the intervention group compared to the control group. These results are in line with those of Oruogi *et al* (23) and Liu *et al* (25). Therefore, attitudes should be considered as a primary potential determinant of actions promoting health behaviors. Accordingly, suitable measures should be taken to create positive attitudes toward health promotion behaviors (29).

In the current study, the mean self-efficacy score of the intervention group participants rose significantly following the intervention, which is consistent with the findings of Babaei *et al* (29), who confirmed that an educational program can improve perceived self-efficacy among rural people regarding brucellosis prevention behaviors. A belief in high personal self-efficacy regarding health behaviors greatly lowered the perceived barriers to performing those behaviors. In line with findings of the current study, Babaei *et al* (30) reported that lower perceived barriers and higher perceived self-efficacy were associated with brucellosis prevention behaviors among stockbreeders. These findings suggest that taking self-efficacy into account when planning educational interventions may play an important role in changing behaviors.

A statistically significant difference was found between the environmental factor scores of the two groups before and after the intervention, which is consistent with the results of Oruogi *et al* (23). Environmental factors—social and physical factors related to individuals but often beyond their personal control—can be modified to support certain behaviors or influence health outcomes (31).

A statistically significant difference was also observed between the enabling factors scores of the two groups before and after the intervention. Enabling factors are antecedents to behavioral or environmental change that allow a specific motivation or environmental policy to be realized (32). The study was developed on the basis of the PRECEDE model (the first six phases of the PRECEDE-PROCEED model), but the authors were not able to conduct the second part (the PROCEED model) because of time limitations. Another limitation was related to the small and significant reduction in knowledge in the control group and is probably related to random responses of participants in the control group.

Conclusion

The intervention program, guided by the PRECEDE model, proved effective in enhancing brucellosis prevention and control in a rural population. The six-month randomized controlled trial demonstrated significant improvements in individual factors, including attitudes and self-efficacy, among the intervention group compared to the control group. These positive changes underscore the relevance and success of the program in influencing knowledge, attitudes, and behaviors related to brucellosis prevention. The findings highlight the potential of the PRECEDE model as a valuable framework for designing and implementing health interventions in community settings.

Ethics approval

Informed written consent was obtained from all participants. Also, for participants under 16 years old, written informed consent was obtained from a parent or guardian. The study received ethical approval from the Ethics Committee of the Tabriz University of Medical Sciences (NO: IR. TBZMED. REC.1394.596).

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Conflict of Interest

Authors declare no conflict of interest.

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