A community-based randomized trial for prevention and control of brucellosis among rural population: application of the PRECEDE planning model

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Abstract

Background: Brucellosis is one of the most frequently-occurring zoonotic diseases of veterinary and public health in developing countries. It affects human and animal health and has measurable effects on productive and reproductive performance of livestock. Thus the main purpose of this study is to develop a community-based intervention program for prevention and control of brucellosis. The two-arm parallel cluster randomized controlled trial investigated the effectiveness of an integrated prevention program over six months on brucellosis in a rural population in Ahar, East Azerbaijan, Iran. Health houses were selected of villages and randomly allocated into the intervention and the control groups (16 Health Houses in all, eight per arm). Participants were recruited via household health records in the health houses presented in the villages. The PRECEDE-PROCEED model was used to design, implement and evaluate of brucellosis prevention and control program. The appropriate strategy and intervention were matched with the project priority changes according to policies, resources, and organizational situations. Social support, knowledge, attitudes, self-efficacy, behavioral and environmental factors were measured at the baseline and 6-months follow-up. Generalized mixed effects-model was used to analyze data. Results: A total of 400 individuals from the study answered the questions in the present study. The mean age (SD) of the respondents in the intervention and control groups were 35.9 (11.87) and 37.28 (11.04) years, respectively. There were significant differences between intervention and control group for Precede model-base variables after six month of intervention program adjusted for adjusted for education, history of brucellosis and family history of brucellosis. Conclusion: there is a need to consolidate collaborative efforts from the health and veterinary sectors, as well as to strengthen regular vaccination and financial resources to support farmers willing to compensate or offering slaughter facilities. This diagnostic study of educational and ecological factors
influencing behaviors and environments related to brucellosis will identify where and how interventions can be most effective.

Background

Brucellosis is one of the most frequently-occurring zoonotic diseases of veterinary and public health priority in developing countries [1]. It affects human and livestock health and it has significant and measurable effects on productive and reproductive performance of livestock [2]. The disease in livestock results in abortion, reduced productivity, and weak offspring. Therefore, brucellosis has major economic consequences for farmers with concomitant potential harms and loss of income. Brucellosis in humans, transmitted through direct contact with infected animals or unpasteurized dairy consumption, may lead to serious morbidity with severe complications [3]. Brucellosis is one of seven neglected zoonotic diseases that continue to present major challenges for public health due to physical suffering and reduced ability of those who are infected [4].

Despite major progress has been made in brucellosis control and elimination in many countries, the incidence of human and animal brucellosis is increasing [5]. Iran is one of the top five countries in the world with a high incidence of human brucellosis. The frequency of brucellosis in Iran was estimated from 0.5% to 10.9% across areas [6]. The highest risk areas in Iran have been in East Azerbaijan province [7]. Brucellosis has emerged as a cause of infection with high prevalence where the infection persists in domestic animals and, consequently, transmission can also occur frequently in the human population [8]. The infection is transmitted to people who consume milk and/or cheese products, or via inhalation or animal contact [9]. Several factors account for the failure of brucellosis control plans. On the livestock side, these include inadequate attention to livestock health, poor quality of veterinary services, availability of economic resources, irregular animal vaccination; on the human side, factors include eating habits,
consumption of dairy products [10], social and cultural customs, and socioeconomic status [11, 12].

Review of the literature shows that control of neglected brucellosis requires integrated and collaborative actions from both human and animal health sectors along with political support and consultation from other sectors or related organizations, especially on a regional scale. Tackling the problem of ‘’neglect’’ in relation to brucellosis requires high-level advocacy [13,14].

Therefore, it is necessary to identify all factors affecting dissemination of brucellosis. To elucidate such factors we used a theoretical planning framework to formulate the issue: the PRECEDE/PROCEED model for planning and evaluation of programs was selected. Green and Kreuter developed this model in the 1970s. They mentioned that in order to modify a behavior, the individual alone should not be targeted; but rather, the entire surrounding environment and the factors affecting the individual’s behavior should be considered. The model consists of several parts, including procedural constructs, namely, educational, ecological and behavioral assessments. The educational and ecological assessments also consist of three factors: predisposing factors, enabling factors and reinforcing factors [15, 16].

In sum, the main purpose of this study is to develop a community-based intervention for prevention and control of brucellosis through educational program and advocating for strengthening prevention and control through effective collaboration with strategic partners and relevant sectors.

Methods

Trial design

The two-arm parallel cluster randomized controlled trial will investigate the effectiveness of a community-based prevention program over six months on brucellosis in a rural
population in Ahar, East Azerbaijan, Iran. Assessments were conducted at baseline [July 2016] and post assessment was done at 9 months after baseline measurements.

High prevalence rates of brucellosis in rural areas of Ahar and its crucial need for a community-based prevention program for brucellosis led to its selection as the study setting. Due to strong relationship among neighboring households in rural communities, it is unable to assign participants living in the same group. So, we performed a stratified randomized controlled trial in rural health houses as the units of randomization. Health houses are located in rural areas that provide health delivery facilities [17]. Sixteen health houses from sixteen villages with a high prevalence rate of brucellosis during previous two years were selected for recruitment of participants. Figure 1 shows the study flow chart. More details are included as an additional file 2.

Recruitment and Participants

Participants were randomly recruited from household health records in rural health houses from rural community that are at high risk for brucellosis.

Inclusion criteria

Participants 15 years of age or over, and living in the villages for at least 6 months after enrollment, were included in the study.

Exclusion criteria

People who were unwilling to provide consent for data collection and employees in the health centers or veterinary office were excluded from the study.

Randomization

A multi-stage random sampling method was used to select villages in the county. Ahar was stratified into four regions: north, south, west, and east. Two health centers were selected from each region and eight health houses that provided health delivery facilities and had a high prevalence rate of brucellosis during the last two years [14] were selected from
each center. Participants were recruited via household health files from health houses in each village. Randomization was carried out after baseline measurements. The selected health houses were randomly allocated into intervention and control groups (eight per arm). To guarantee balance in numbers of the units allocated to each arm, permuted blocks randomization (PBD) was used for random assignment of the health houses to intervention and control groups. Randomization sequence was created manually by a biostatistician using Excel software [Command in the Excel for random block sizes column: =rand()] to assign health houses to the study arms using a 1:1 allocation ratio with block size of 4. A colleague not connected to the study was 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 were conducted baseline measurements while group allocation concealment was implemented. Participants blinded to their group assignments.

Model for program planning

The PRECEDE/PROCEED model [18] was used for design development, implementation and evaluation of the brucellosis prevention and control program. PRECEDE/PROCEED includes nine phases based on assessments (PRECEDE) that should be made before planning health intervention, and evaluation (PROCEED) to enable measurement of the effectiveness of interventions at each stage of implementation, immediate and long-term effects (see Figure 2). Priority targets for intervention are established through each phase of the assessment process on the basis of importance and changeability of behavioral and ecological factors in determining brucellosis outcomes (phases 1-5). The assessment process encompasses seven behavioral and six ecological factors that have highest proportion of priority on importance and changeability (See Table 1). The evaluation
(phases 7-9) tracks the impact of the intervention on factors identified as important targets in the assessments process.

**Phases 1 - Social assessment**

Application of the PRECEDE/PROCEED model commences in phase 1 by assessing outcomes or goals of the intervention. The study began with diagnostic activities through gathering data on the community and identifying appropriate outcomes of the intervention. Brucellosis as a public health challenge in Ahar [7] plays a significant role in the national economy as well as in health-related quality of life (HRQOL). These phases involve assessment of the health of the target population.

**Phase 2 and 3 - Epidemiological, behavioral and environmental assessment**

We used extensive literature review and informal discussions with selected key informants, health care staff, and veterinary and agriculture organizations in the targeted area. These activities resulted in determination of problems or issues that affect brucellosis incidence, what steps can be taken to reduce the impact of the diseases, and what needs to change to achieve prevention of brucellosis. The priority targets of behavioral and environmental risk factors for intervention on the basis of importance and changeability were determined in the target population. The process resulted in seven behavioral and six ecological factors that have highest proportion of priority on importance and changeability (See Table 1).

**Phase 4 - Educational and ecological assessment**

This phase helps to identify factors for intervention which if modified, would be most likely to result in behavior change. These factors are classified as predisposing, enabling, and reinforcing factors that were identified through a literature review and key informant interviews with: health workers, health care providers, experts for surveillance and control of brucellosis in health centers, veterinary specialist and experts of agriculture.
organizations who work on brucellosis in mentioned region. The results of this process were documented elsewhere [18]. Briefly, a standardized, structured questionnaire was used to gather information from the target population about potential routes of transmission to humans, and practices regarding dealing with aborted animal fetuses and processing and consumption of milk and dairy products. This questionnaire included five parts: predisposing, reinforcing, enabling, environmental and behavioral factors. The questionnaire was used to gather information from the target population about potential routes of transmission to humans, and practices regarding dealing with aborted animal fetuses and processing and consumption of milk and dairy products. The first part consisted of predisposing factors providing a reason or motivation to perform behavior including the knowledge, attitudes and self-efficacy about prevention; transmission and control of brucellosis. The knowledge section included 11 items that measure rural population awareness and understanding about causes, modes of transmission and protective behaviors of brucellosis. The attitudes were measured through 15 item 5-point Likert scales (strongly agree, agree, don't know, disagree, and strongly disagree). Each of the five responses has a numerical value used to measure the belief. The self-efficacy section contains seven items with 5-point Likert-type responses (very uncertain, uncertain, don't know, certain, and very certain). This section assessed the confidence of participants in their ability to conduct protective behavior against brucellosis. The second part was information on reinforcing factors that encourage and support certain behavior due to social support, rewards and praise. Reinforcing factors are supporting groups such as family members’ or friends’ encouragement to take preventive measures against brucellosis. The prime source of reinforcement identified (as mentioned above through qualitative methods) in the form of social support were providing positive feedback or giving advice from family, friends and health workers. These reinforcing
factors were assessed with six items assessing encouragement of behavior to be repeated and sustained by family members or friends.

The third part assessed enabling factors allowing people to act due to financial support, resources, assistance and services. This part measured access to materials, financial and educational resources including access to personal protective equipment such as gloves and masks, financial support for renovation of barns and buildings, and veterinary services for supporting regular animal vaccination against brucellosis.

The fourth part, regarding environmental factors, assessed characteristics of the environment that facilitate behavior or resources required to attain protective behavior against brucellosis. This part assessed environmental safety measures in brucellosis transmission vectors by various direct and indirect measures targeted to reduce risk of brucellosis infection and create protective measures for the environment.

Finally, the fifth part looked at behavioral factors that were evaluated by nine items such as working in pastoral livestock, regular vaccination of animals against brucellosis, consumption of pasteurized dairy products on a regular basis and wearing protective clothes during working in barns.

*Phase 5 and 6-adminstrative, policy assessment and intervention*

In this phase, the predisposing, enabling, and reinforcing factors that influence behavior were analyzed through results from the pre-test assessment phase 3. Then, the appropriate strategies and interventions were matched with project priority changes according with policies, resources, and organizational situations.

The first priority for intervention was identified as enabling factors. This phase requires coordinated efforts and intersectional collaboration between local public health organizations, agricultural, and veterinary organizations. The activities included continuous and constant training of health workers for brucellosis prevention, provide
adequate facilities for restoration and renovation of barns, provide farmers with access to disinfectants and training for proper use of disinfectants, and compensation for farmers whose animals have died and were slaughtered due to brucellosis.

The second priority for intervention was aimed at predisposing factors: promoting knowledge, attitudes and self-efficacy of participants through designing and implementing educational interventions tailored with demographic variables.

The third priority for intervention was aimed at reinforcing factors: the main source of reinforcement as identified by local confidants, family members and friends. The activities were included encouraging more people to properly dispose of animal waste, help to bury aborted animal fetuses and support for regular animal vaccination against brucellosis, respectively.

We selected an advocacy strategy for intervention and changing policies, brucellosis occurrence, and prevention program in Ahar. The advocacy goal was built on decreasing the prevalence of brucellosis and increasing health related quality of life up to 10% in cooperation with the Health Centers, veterinary, and agricultural organizations, by the end of 2016.

Stakeholders are all those who gain or lose from reaching the goal set for our advocacy efforts. We identified stakeholders through informal interviews and consultation with related organizations. The stakeholders were categorized into four groups, including beneficiaries (farmers, household women, primary health care network of Ahar, veterinary organizations), partners (primary health care network of Ahar, farmers, veterinary and agricultural organizations), decision makers (primary health care network of Ahar, farmers, veterinary and agricultural organizations) and adversaries. The approaches and persuasion techniques of advocacy are clarified in Table 2.

Project activities integrate veterinary and public health campaigns to increase public
awareness of brucellosis and to provide information about ways in which people can reduce the risk of the disease. Close cooperation and coordination between all partners is crucial to success.

**Measurement tools**

All participants also were asked demographic questions: gender, age, marital status, educational qualifications, job, history of brucellosis and family history of the disease. A standardized, structured questionnaire including five parts (predisposing, reinforcing, enabling, environmental and behavioral factors related to brucellosis) is used [18].

**Sample size**

The sample size will be calculated based on standard deviation increase in knowledge (6.8) [21] as one of the most important variables. As such a study with a power of 90% at 5% significance level, 185 participants in each group will need. Given that there might be an attrition risk, 200 participants per group would be sought. According to the total sample size of the study, from each health houses, samples proportion to the population of the health houses was considered.

**Statistical analysis**

The characteristics of participants were summarized as numbers and percent or means with standard deviations if appropriate. If the continuous variables were not being normally distributed, appropriate transformations were performed to close them to normal distribution.

Generalized mixed effects-model was used to analyze data. This model in cluster randomization incorporate random effects to reflect the correlation among observations made of members of the same health house. According to distribution of our outcomes, appropriate distribution and link functions were selected. For all parameters, 95% confidence intervals will be defined. Two-sided \( p \) values of less than 0.05 will be regarded
as statistically significant. All analyses will be performed with the Statistical Package for Social Sciences version 23 (SPSS Inc., Chicago, IL).

Results

**Demographic characteristics of the participants**

Demographic characteristics of the two groups are presented in Table 2. A total of 400 individuals from the study answered the questions in the present study. The mean age (SD) of the respondents in the intervention and control groups were 35.9 (11.87) and 37.28 (11.04) years, respectively. 89% of the participants in the intervention and 86.5% in the control groups were married. Furthermore, 12.5% and 4.5% of the respondents in the intervention and control groups had 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 family history of brucellosis.

**Comparison of differences in The Precede Model variables at baseline and after six months of follow-up**

The results of the study indicated there were no significant differences between the two groups regarding demographic characteristics and precede model-based variables except for history of brucellosis, family history of brucellosis and education. As presented in Table 3, the results showed that there were significant differences between intervention and control group for Precede model-base variables after six month of intervention program adjusted for adjusted for education, history of brucellosis and family history of brucellosis.

Discussion

The current study described the planning process and results of an integrated intervention program for prevention and control of brucellosis in a rural population in East Azerbaijan.
Prevention and control of brucellosis requires planning and diagnosis of all transmission routes of the disease in both humans and animals. The World Health Organization recommends focusing on education for all potentially exposed people. In fact, there is a need to consolidate collaborative efforts from the health and veterinary sectors as well as to strengthen regular vaccination and financial resources to compensate farmers willing to slaughter and/or offer slaughter facilities. This diagnostic study of educational and ecological factors influencing behaviors and environments related to the prevention and control of brucellosis identifies where and how interventions can be most effective. With the implementation of interventions directed at these priorities, including advocacy for policies, we expect to find that brucellosis incidence in human and animal populations will have been reduced.

The findings indicated that knowledge in the intervention group increased significantly compared to the control group 6 months after the intervention. It seems that the educational program has been effective on knowledge among the rural population in the intervention group. This is in line with a study performed in Khomeinshahr, Iran, using the precede model in order to the rural people to prevent brucellosis [21]. The findings of the present study are also consistent with the study by Liu et al [23] as well as the ones performed by Jin et al [23] on reduction of brucellosis. Studies indicated that having low knowledge on zoonotic diseases may lead to its prevalence and causes problems in controlling them [24]. For example, in the study conducted by Jedgal et al [25] among people with pulmonary tuberculosis, a significant association was observed between knowledge and health promoting behaviors.

We found that the intervention significantly increased the attitudes related to brucellosis preventive behaviors in the intervention group compared to the control group. These results are in line with those obtained by Ourogi et al. [21] and Liu et al [22]. Attitudes
should be considered as a main potential determinant for actual actions in promoting health behaviors. Probably, providing some suitable measures should be taken to create positive attitudes towards health promoting behaviors [28].

The results of the current study indicated that the mean score of self-efficacy among rural population in the intervention group increased significantly following the intervention, which was consistent with the findings of a study conducted by Babaei et al [26]. They confirmed that conducting an educational program could improve perceived self-efficacy in the rural people regarding the brucellosis preventive behaviors. Beliefs in high personal self-efficacy to health behaviors strongly decreased the perceived barriers of performing it. In line with our findings, Babaei et al [27] reported that lower perceived barriers and higher perceived self-efficacy were associated with brucellosis behavior among stockbreeders. These findings suggest that considering self-efficacy during planning educational interventions could have important role in changing behavior.

Considering the environmental factors scores, a statistically significant difference is found between the two groups before and after the intervention, which is consistent with the results of the study conducted by Orogi et al [21]. Environmental factors are those social and physical factors to the individual and often beyond his or her personal control that can be modified to support the behavior or influence the health outcome [29].

Regarding enabling factors, a statistically significant difference was observed between the two groups’ scores before and after the intervention. Enabling factors are antecedents to behavioral or environmental change that allow a motivation or environmental policy to be realized [30].

It can be said that PRECEDE-PROCEED model may be considered as an applicable framework for educational interventions to increase brucellosis preventive behaviors.

Conclusion
The findings indicated that after the intervention, a significant increase was observed in the variables of PRECEDE-PROCEED model and the brucellosis preventive behaviors in the intervention group compared to the control counterparts. Thus, the study results suggest that PRECEDE-PROCEED model could be applied in order to attract the cooperation of the individuals living in rural areas for involving in brucellosis preventive activities and train such individuals to do environmental actions as well as personal beliefs to prevent brucellosis.

List Of Abbreviations

SPSS: statistical package for social science software package

Declarations

Ethics approval and consent to participate

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

Consent to publish

Not applicable.

Availability of data and materials

The data collection tools and datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interest

The authors declare that they have no competing interest.

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Authors’ contribution

LJ is the supervisor of the study, design the study and wrote the draft. TB conduct requirements for study design. PS contributed to the study analysis. All authors read and approved the paper.

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Tables

Table 1: The priority targets of behavioral and environmental risk factors for intervention
on the basis of importance and changeability

| Changeable       | High importance for planning |
|------------------|-----------------------------|
| Behavioral factors |                             |
| 1. Boiling raw milk for 5 minutes before consumption |
| 2. Wearing gloves during barn works |
| 3. Wash the udder properly before milking |
| 4. Vaccinate the cattle during the disease season |
| 5. Avoiding use of fresh cheese and unpasteurized dairy products |
| 6. Disinfect the abortion places of the animals |
| 7. Wearing mask during barn works |

| Environmental factors |                             |
|-----------------------|-----------------------------|
| 1. Referring to the veterinary organization for regular animal vaccination |
| 3. Diagnoses and slaughtered infected animals from veterinary organization |
| 4. Disposing animal waste in dumpsites located far from the village |
| 5. Locating livestock away from living home and close proximity of farmers |
| 6. Renovation of barn and offer building facilities by agriculture organization |

| Hardly changed       | High importance for innovative programs |
|----------------------|----------------------------------------|
| Behavioral factors   |                                         |
| 1. Digging the hole for aborted fetuses that is physically hard work |
| 2. Compensation is paid for any infected animals culled |
| 3. Disinfection of barn by veterinary organization |

Table 2. Descriptive characteristics of the participant in the intervention and the control group

|                          | Intervention (n=200) | Control (n=200) |
|--------------------------|----------------------|-----------------|
| Gender n (%)             |                      |                 |
| Male                     | 95 (52.7)            | 94 (47.2)       |
| female                   | 105 (52.8)           | 106 (47.3)      |
| Education                |                      |                 |
| Illiterate               | 20 (57.1)            | 15 (42.9)       |
| Elementary               | 103 (54.4)           | 123 (54.4)      |
| Secondary                | 58 (50.5)            | 55 (49.5)       |
| University               | 21 (75)              | 7 (25)          |
| Marital status           |                      |                 |
| Married                  | 178 (89.0)           | 173 (86.5)      |
| 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)       |
| 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   | Yes                  | 25 (12.5)       |
| Family history of brucellosis | Yes                 | 39 (19.5)      |

Table 3. Comparison of Precede model-based variables before and after the intervention in the intervention and the control group

|                          | Intervention (n=200) | Control (n=200) |
|--------------------------|----------------------|-----------------|
| Knowledge                |                      |                 |
| Baseline                 | 12.3 ± 1.1           | 7.12 ± 1.3      |
| 6-months                 | 13.8 ± 0.38          | 6.82 ± 1.3      |
| p-value                  | <0.001               | <0.001          |
| Attitudes                |                      |                 |
| Baseline                 | 51.3 ± 4.7           | 41.1 ± 5.7      |
| 6-months                 | 57.1 ± 1.6           | 41.3 ± 5.8      |
| p-value                  | <0.001               | <0.001          |
| Self-efficacy            |                      |                 |
| Baseline                 | 27.6 ± 5.4           | 24.3 ± 3.6      |
| 6-months                 | 33.2 ± 1.5           | 19.8 ± 3.3      |
| p-value                  | <0.001               | <0.001          |
| Social support           |                      |                 |
| Baseline                 | 26.4 ± 4             | 25.3 ± 4.3      |
| 6-months                 | 34.7 ± 2             | 25.6 ± 4.9      |
| p-value                  | <0.001               | 0.3             |
| Environmental factors    |                      |                 |
| Baseline                 | 13.2 ± 2.7           | 12.1 ± 2.6      |
| 6-months                 | 17.2 ± 1.8           | 12.3 ± 2.8      |
| p-value                  | <0.001               | 0.1             |
| Enabling factors         |                      |                 |
| Baseline                 | 12.5 ± 3             | 10.9 ± 3.3      |
| 6-months                 | 11.7 ± 1.6           | 18.9 ± 3.3      |
| p-value                  | <0.001               | <0.001          |
| Behavioral factors       |                      |                 |
| Baseline                 | 30 ± 4.8             | 27 ± 4.1        |
| 6-months                 | 39.7 ± 1.8           | 27.7 ± 4.1      |
| p-value                  | <0.001               | 0.1             |
p-value: Derived from Generalized mixed effects-model adjusted for education, history of brucellosis and family history of brucellosis

Figures

Figure 1

the study flowchart
Predisposing factors: knowledge, attitude and self-efficacy
Reinforcing factors: social support
Enabling factors: access to material, financial and educational resources

Figure 2
The Precede Model