The impact of empowerment model-based education on quality of life of transgender people under hormone therapy: A randomized clinical trial

Maryam Asadi¹, Fariba Tabari¹, Shima Haghani², Mohammad Eghbal Heidari³

¹School of Nursing and Midwifery, Tehran University of Medical Sciences, ²Nursing Care Research Center, Iran University of Medical Sciences, ³Student’s Scientific Research Center, Nursing and Midwifery University, Tehran University Medical Science, Tehran, Iran

Abstract

Introduction: Gender identity disorder is a complex psychological problem and people with this disorder are at risk of many problems, including reduced quality of life. Empowerment intervention is one of the methods that can be used to improve the quality of life of people. The present study aimed to investigate the effect of empowerment model-based training on the quality of life of transgender people undergoing hormone therapy. Methods: The present study is a randomized clinical trial that was conducted in 2012 on 81 transgender people at Tehran Welfare Center. The study samples were randomly assigned into two groups of intervention and control. The intervention group received training based on the empowerment model (threat perception, problem-solving, educational participation, and evaluation) and the control group received routine treatment. Results: According to the findings, after the intervention, a statistically significant difference was found between the two groups in terms of the mean level of overt anxiety (P = 0.045) and aspects of emotional health (P = 0.030), the general perception of health (P = 0.007), mental health (P = 0.008), and overall quality of life (P = 0.005). Also, although there was a statistically significant difference in the aspect emotional well-being in the intervention group before and after the intervention (P = 0.034), this difference was not significant between the two groups (P = 0.274). Conclusion: The results showed that the empowerment-based training program had a significant relationship with the improvement in aspects of emotional health, the overall perception of health, mental health, emotional well-being and overall quality of life.

Keywords: Empowerment model, hormone therapy, quality of life, sexual identity disorder, sexual misery

Introduction

Sexual identity is a psychological state that expresses one's sense of masculinity or femininity.² Gender identity refers to one's own feeling and awareness of being a man or woman, girl or boy, so he/she learns to think and act in a special way.³ The natural process of gender identity formation is successful in most cases, but it takes a different path in some people,² so that they begin to doubt belonging to one of the sexes or they feel they belong to gender completely opposite to their biological gender. This condition is called sexual identity disorder.² These individuals experience a strong and stable opposite-sex identity that makes them feel uncomfortable and inadequate with their assigned identity. People with this disorder feel extremely distressed and usually have problems adjusting to social, occupational, and other personal contexts.²,³ Transgender is another term that we see in the literature.

Address for correspondence: Dr. Fariba Tabari, Assistant Professor, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran.
E-mail: ftbari@ums.ac.ir

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sexual misery is generally higher in men than in women.\textsuperscript{[4,5]} According to recent studies, the prevalence of transgender in the world is 4.6 cases per 100,000 people, and this number is 6.8 for transgender men and 2.6 for transgender women. Also, the analysis of reports over the past decades indicates a significant increase in this prevalence for the last 50 years.\textsuperscript{[6]} There are no exact statistics on the number of transgender people in Iran, but studies show that the prevalence of male and female transgender is 1 per 135,000 and 1 per 145,000, respectively. According to WHO’s statistics, there are about 700 sex change requests in Iran, but according to the statistics of Forensic Medicine Center, this number is about 350.\textsuperscript{[7]} Most people with this disorder want to change their gender identity with hormone replacement therapy and sex-change surgery.\textsuperscript{[8]} They also do not become a perfect male or female after the surgery. They will be infertile after the surgery and need to take hormone medicines throughout their lives, which naturally have some side effects.\textsuperscript{[9]} Nowadays, with the increase in life expectancy, scholars and researchers began to address the issue of how one lives and in other words, the “quality of life.” Quality of life is also a complex and multidimensional concept,\textsuperscript{[10]} which refers to one’s sense of social, emotional, and physical well-being. In other words, the quality of life is equivalent to the fulfillment of one’s planning.\textsuperscript{[11]} Quality of life is a subjective issue, not observable by others, and is based on people’s understanding of different aspects of life. Thus, the quality of life of each individual is influenced by his/her contextual characteristics and social, cultural, and environmental status.\textsuperscript{[12]} Patient education is one of the most important nursing roles in any health care setting.\textsuperscript{[13]} Empowerment intervention is one of the methods that help to improve the quality of life. Patient empowerment is the process of informing patients with the use of necessary tools and promoting independence to play an active role in their health-related decisions.\textsuperscript{[14]} Empowerment model-based training is a series of measures and training programs that are designed for patients with chronic illnesses to help them acquire necessary self-care capabilities.\textsuperscript{[15,16]} In individual empowerment, people have greater control over their decisions, lifestyles, and activities that affect their well-being. It also, as a useful tool, enhances their knowledge and skills. Considering the effects of education on quality of life, this study aimed to improve the quality of life of transgender people by investigating the effect of educational intervention based on the empowerment model.

**Methods**

**Type of study**

The present study is a randomized clinical trial with two groups of intervention and control. The ability to read, write, and collaborate was considered until the end of the project. Samples in this study were selected by the available sampling method. The researcher obtained necessary permissions from the Ethics Committee of Tehran University of Medical Sciences and Tehran Welfare Center. Informed consent was obtained from all participants.

**Participants**

The study population consisted of all transgender people who attended the Welfare Organization of Tehran for treatment follow-up. A sample size of 42 persons was considered for each group, but it was increased to 45 taking into account the possibility of sample drop. Inclusion criteria were having a definitive diagnosis of sexual identity disorder based on the DSM-5 diagnostic criteria for sexual ambiguity (diagnosed by a psychologist and a psychiatrist recorded in the client’s file); being at least 18 years old and no older than 30 years old, having at least 6 months of hormone therapy and having at least minimum level of education or ability to read, write, and collaborate until the end of the project. Out of 123 reviewed cases, a total of 90 clients who met the inclusion criteria were selected. Samples entered into the study after giving informed consent. Samples in the intervention group were provided with the necessary information about the number of training sessions and their specification. They also were assured about the confidentiality of their information and the possibility of withdrawal from the study at any time without any consequences. Two samples withdrew from the study in the intervention group and 1 from the control group. So in total, 43 patients in the intervention group and 44 patients in the control group completed the study.

**Randomization**

Randomization was performed using random permutation blocks of two with blocks of four. The letter A was used for the intervention group and the letter B for the control group. Then, all the permuted combinations of the letters A, A and B, and B (which were six different combinations) were written (AABB for digit 1, ABBA for digit 2...) and one digit was randomly selected from digits 1 to 6. For example, if digit 2 is selected, it means that the first person is assigned to the intervention group, the next two persons are assigned to the control group, and the fourth person is assigned to the intervention group. This method was continued until the sampling was completed.

**Intervention**

The training sessions were held in the classrooms of the medical center. Educational content included patient education booklet and drug treatment pamphlets, which were based on the patient’s condition and needs.

To implement the empowerment model step by step and practically, four coherent and consistent steps were designed including threat perception, problem-solving, educational participation, and evaluation.

The first step was to increase the perceived threat of the empowering factor, which was the patient’s sexual misery. This step consisted of two 1-h training sessions. Problem-solving, or the second step, included a group discussion, where the participants encountered a problem and learned about the problem-solving process, which included providing solutions...
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Table

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randomly assigned to two intervention and control groups. The attended Tehran Welfare Center. In total, 90 transsexuals were participants in this study were 18–35 years old transsexuals who attended Tehran Welfare Center. In total, 90 transsexuals were randomly assigned to two intervention and control groups. The mean age of the intervention group was 27.86 ± 5.03 years and in the control group, it was 28.81 ± 4.39 years. Independent t-test showed no statistically significant difference between the two groups in terms of demographic variables (P < 0.05). The complete demographic characteristics of participants are listed in Table 1. Comparison of the quality of life of transgender people undergoing hormone therapy between the control and intervention groups showed that the mean quality of life in the intervention group was 58.74 with the standard deviation of 7.16, these values in the control group were 58.37 and 7.28, respectively. There was no significant difference between the two groups before the intervention (P = 0.813), [Table 2].

Comparison of the quality of life of transgender people in control and intervention groups after the intervention showed that the mean quality of life in the intervention group was 62.01 with the standard deviation of 6.10 and these figures in the control group were 58.03 and 6.73, respectively. The result of the independent t-test showed a significant difference between the two groups after the intervention so that the quality of life in the intervention group (Table 3, P = 0.005) was significantly better than the control group.

Also, comparison of the quality of life of transsexual people undergoing hormone therapy in the two groups before and after the intervention showed that total score of quality of life in the intervention group was 3.26 with the standard deviation of 6.47 and in the control group it was −0.34 with the standard deviation of 6.46. The changes were positive in the intervention group while the control group had a decreasing trend of less than one unit. The changes in the total score of quality of life in the intervention group showed an increase compared to the control group, and the result of the independent t-test showed a statistically significant difference between the two groups in terms of changes in the total score of quality of life [Table 3].

Data collection

Demographic characteristic inventory and SF-36 quality of life questionnaire were used for data collection. The demographic characteristic inventory was a self-reporting questionnaire that contained two sections of demographic information (6 questions) and medical history (4 questions). The quality of life questionnaire (SF-36) with 36 questions consisted of two categories and eight subcategories, each containing 1 to 10 items. Due to the complexity of scoring this questionnaire, complete scoring was done in several stages. Each of the eight subcategories had a score of 0 to 100. The mean score of quality of life subcategories was 50, with higher and lower scores indicating higher and lower status, respectively.

Statistical analysis

After data collection and entry into SPSS software version 16, the frequency distribution table was used for qualitative variables and to test the homogeneity of these variables in the two groups, the Chi-square test was used. In some cases, if the condition was not right for the Chi-square test, Fisher’s exact test was used instead. For quantitative variables, numerical indexes such as mean and standard deviation were used and to compare these variables in the two groups, independent t-test was used. Descriptive statistics such as frequency distribution table and mean and standard deviation were also used to answer the study question. Independent t-test was used to compare the means in two groups before and after the intervention and a paired t-test was used to compare the anxiety level in each group.

Findings

Participants in this study were 18–35 years old transsexuals who attended Tehran Welfare Center. In total, 90 transsexuals were randomly assigned to two intervention and control groups. The mean age of the intervention group was 27.86 ± 5.03 years and in the control group, it was 28.81 ± 4.39 years. Independent t-test showed no statistically significant difference between the two groups in terms of demographic variables (P < 0.05). The complete demographic characteristics of participants are listed in Table 1. Comparison of the quality of life of transgender people undergoing hormone therapy between the control and intervention groups showed that the mean quality of life in the intervention group was 58.74 with the standard deviation of 7.16, these values in the control group were 58.37 and 7.28, respectively. There was no significant difference between the two groups before the intervention (P = 0.813), [Table 2].

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Discussion

This is the first randomized clinical trial to evaluate the effectiveness of the educational intervention on the quality of life of transgender people under hormone therapy. The results of this study in relation to “determining and comparing the quality of life of transsexual people undergoing hormone therapy in the control and intervention groups before and after the intervention” showed that the mean score of quality of life in the two study groups (58.74 intervention group and 58.37 control group) was at a moderate level and there was no statistically significant difference between the two groups (P = 0.813).

The results also showed that the maximum mean of quality of life before the intervention (86.86 in the intervention group and 83.06 in the control group) was related to the aspect of physical performance. The minimum mean of quality of life (17.82 in the intervention group and 19.75 in the control group) was related to the aspect of mental problems or the role of emotional dysfunction, indicating no statistically significant difference
between the two groups ($P = 0.713$) before the intervention. In the study of Weirks et al. (2011), the lowest score of quality of life was related to the aspect of vitality and the highest score was related to the aspect of physical performance.[37] In the study

### Table 1: Demographic characteristics

| Group | Variable                     | Intervention No. 43 | Control No. 44 | Results          |
|-------|------------------------------|---------------------|----------------|-----------------|
|       | Age (year)                   |                     |                |                 |
|       | <25 years                    | 16 (37.2)           | 9 (20.5)       | $r=0.946$, $df=85$, $P=0.347$ |
|       | 25-29 years                  | 9 (20.9)            | 14 (31.8)      |                 |
|       | 30 years and more            | 18 (41.9)           | 21 (47.8)      |                 |
|       | Marital status               |                     |                |                 |
|       | Single                       | 41 (95.3)           | 41 (93.2)      | $P=0.999$       |
|       | Married                      | 2 (4.7)             | 3 (6.8)        |                 |
|       | Occupation                   |                     |                |                 |
|       | Unemployed                   | 25 (58.1)           | 24 (54.5)      | $P=0.409$       |
|       | Laborer                      | 0 (0.0)             | 1 (2.3)        |                 |
|       | Office worker                | 3 (7.0)             | 7 (15.9)       |                 |
|       | Self-employed                | 15 (34.9)           | 12 (27.3)      |                 |
|       | Education                    |                     |                |                 |
|       | Under diploma                | 0 (0.0)             | 0 (0.0)        | $r^2=0.553$, $df=1$, $P=0.457$ |
|       | Diploma                      | 19 (44.2)           | 16 (36.4)      |                 |
|       | University degree            | 24 (55.8)           | 28 (63.6)      |                 |
|       | Time passed from diagnosis (year) |                     |                |                 |
|       | Less than 4                  | 7 (16.3)            | 3 (6.8)        | $r=0.958$, $df=85$, $P=0.341$ |
|       | 4-9                          | 15 (34.9)           | 14 (31.4)      |                 |
|       | 10-14                        | 12 (27.9)           | 14 (29.4)      |                 |
|       | 15 or more                   | 9 (20.9)            | 9 (19.5)       |                 |
|       | Time passed from taking hormone therapy drugs (year) |                     |                |                 |
|       | <4                           | 24 (55.8)           | 23 (52.3)      | $r=0.032$, $df=85$, $P=0.975$ |
|       | 4-9                          | 11 (25.6)           | 13 (29.5)      |                 |
|       | 10-14                        | 4 (9.3)             | 3 (6.8)        |                 |
|       | 15 or more                   | 4 (9.3)             | 5 (11.4)       |                 |
|       | History of surgery           |                     |                |                 |
|       | Yes                          | 30 (69.8)           | 31 (70.5)      | $r^2=0.005$, $df=1$, $P=0.994$ |
|       | No                           | 13 (31.2)           | 13 (29.5)      |                 |

### Table 2: numerical indexes of quality of life and its aspects in the two groups before the intervention

| Group | Quality of life and its aspects | Intervention | Control | Independent t-test |
|-------|--------------------------------|--------------|---------|--------------------|
|       |                                | Mean         | SD      | Mean               | SD      | $t$-value |
|       | Physical performance           | 86.86        | 10.96   | 83.06              | 17.12   | 0.223     | df=45 |
|       | Physical problems              | 41.86        | 24.22   | 48.86              | 27.99   | 0.216     | df=45 |
|       | Emotional health               | 17.82        | 24.50   | 19.75              | 24.22   | 0.713     | df=45 |
|       | Vitality and happiness         | 60.11        | 11.92   | 58.97              | 11.13   | 0.664     | df=45 |
|       | Emotional well-being           | 58.04        | 13.47   | 57.81              | 13.01   | 0.936     | df=45 |
|       | Social performance             | 66.27        | 9.65    | 63.63              | 16.13   | 0.358     | df=45 |
|       | Pain                           | 74.76        | 11.15   | 74.09              | 15.75   | 0.813     | df=45 |
|       | General health                 | 64.18        | 18.32   | 60.79              | 18.70   | 0.396     | df=45 |
|       | Subscale of physical health    | 66.91        | 8.91    | 66.70              | 8.47    | 0.909     | df=45 |
|       | Subscale of mental health      | 50.56        | 8.10    | 50.04              | 8.04    | 0.764     | df=45 |
|       | Quality of life                | 58.74        | 7.16    | 58.37              | 7.28    | 0.813     | df=45 |

### Table 3: Numerical indexes of changes in the score of quality of life in the two groups before and after the intervention

| Group | Quality of life and its aspects | Intervention | Control | Independent t-test |
|-------|--------------------------------|--------------|---------|--------------------|
|       |                                | Mean         | SD      | Mean               | SD      | $t$-value |
|       | Physical performance           | 1.97         | 6.55    | 1.36               | 7.42    | 0.684     | df=85 |
|       | Physical problems              | 1.16         | 28.84   | -4.54              | 21.07   | 2.946     | df=85 |
|       | Emotional health               | 13.17        | 27.35   | -0.81              | 24.28   | 0.013     | df=85 |
|       | Vitality and happiness         | 2.55         | 10.25   | 1.47               | 7.74    | 0.580     | df=85 |
|       | Emotional wellbeing            | 3.53         | 10.59   | 1.13               | 8.81    | 0.254     | df=85 |
|       | Social performance             | -0.290       | 11.07   | -0.56              | 11.10   | 0.907     | df=85 |
|       | Pain                           | -3.31        | 12.94   | -2.38              | 12.41   | 0.734     | df=85 |
|       | General health                 | 7.32         | 13.59   | 1.59               | 12.23   | 0.042     | df=85 |
|       | Subscale of physical health    | 1.78         | 8.32    | -0.99              | 6.47    | 0.085     | df=85 |
|       | Subscale of mental health      | 4.74         | 8.80    | 0.31               | 8.60    | 0.020     | df=85 |
|       | Quality of life                | 3.26         | 6.47    | -0.34              | 6.46    | 0.011     | df=85 |
of Bayat et al. (2010), aspects of physical performance with the mean of 87 accounted for the highest score among all aspects of quality of life,[24] which is consistent with the present study.

In the study of Weirks et al. (2011), the lowest score of quality of life was related to the aspect of vitality.[17] Similarly, in another study by Weir et al. (2009), the lowest score of quality of life in female transsexuals was related to the aspect of vitality.[19] These results are not consistent with the finding of the present study. In regard to “determining and comparing the quality of life of transsexual people undergoing hormone therapy in both control and intervention groups after the intervention,” the results showed that although after the intervention the highest quality of life in both groups was related to the aspect of physical performance and there was an increase in the quality of life in both groups (88.83 intervention group and 84.43 control group), this increase was not statistically significant (P = 0.119). Also, there was no statistically significant difference in the mean of quality of life between the two groups after the intervention in terms of the aspects of role disorder in relation to physical problems (P = 0.782), vitality and happiness (P = 0.332), emotional well-being (P = 0.274), social function (P = 0.117), pain (P = 0.935), and overall physical health (P = 0.611). However, in regard to the aspect of overall quality of life or overall perception of health, the results showed a significant increase in the intervention group before (64.18) and after the intervention (71.51). The mean of the overall perception of health in the intervention group was higher than the control group so that the difference was statistically significant between the two groups after the intervention (P = 0.007). In regard to the aspect of role disorder regarding emotional health after the intervention, result of independent t-test showed a statistically significant difference between the two groups after the intervention and the participants in the intervention group performed better (P = 0.030). In regard to the aspect of mental health, the results also showed a significant difference between the two groups after the intervention, so that mental health in the intervention group was better than the control group (P = 0.008).

As shown by the results, there was a significant increase in the mean score of overall quality of life in the intervention group (62.01) after the intervention, whereas in the control group this figure was (58.03), and this difference between the two groups was statistically significant (P = 0.005).

Some studies have also been carried out in line with the present study, including the study of Hasan et al. (2017) entitled: “The effect of empowerment intervention on people with schizophrenia.” Results of a randomized controlled trial showed that the mean score of quality of life in the intervention group increased from 47.65 to 63.43 after the intervention which was a significant increase (P = 0.001). Also, in the study of Chin et al. (2017) that examined the impact of empowerment on the quality of life of breast cancer survivors, a positive correlation was found between the empowerment and quality of life of patients (P < 0.001).[21] A study by Bayoumy et al. (2017) entitled: “The effectiveness of an empowerment program on patients with end-stage renal failure undergoing dialysis,” found that samples in the intervention group initially had significantly lower quality of life than the control group but after the intervention, their quality of life significantly increased (P < 0.001).[22] In another study on the effectiveness of an empowerment program for Taiwanese patient with type 2 diabetes, Chen et al. (2015) showed that after the intervention, HbA1c level was significantly reduced by 0.87% and self-care behaviors, self-efficacy, and quality of life of patients were enhanced in the two studied hospitals.[23] A study by Nassehi et al. (2014) on the effect of an empowerment program on the quality of life of patients with asthma showed that the mean score of quality of life in the intervention group increased from 20.37 to 32.85 after the intervention, which was a significant difference (P = 0.001).[25] In regard to determining and comparing the quality of life of transgender people undergoing hormone therapy in both groups before and after the intervention, no statistically significant difference in the mean quality of life was found in the control group in terms of the aspects of physical performance (P = 0.23), role disorder regarding physical problems (P = 0.160), emotional health (P = 0.824), vitality and happiness (P = 0.213), emotional well-being (P = 0.397), social performance (P = 0.736), pain (P = 0.209), general health (P = 0.393), physical health (P = 0.314), mental health (P = 0.814), and overall quality of life (P = 0.726). Also, the results showed no statistically significant difference in the intervention group before and after the intervention in terms of the aspects of physical performance (P = 0.055), physical problems (P = 0.793), vitality (P = 0.109), social performance (P = 0.864), pain, and overall physical health (P = 0.166), but in terms of the aspects of emotional health (P = 0.003), emotional well-being (P = 0.343), the general perception of health (P = 0.001), mental health (P = 0.001), and overall quality of life (P = 0.002), the difference was statistically significant before and after the intervention. A study by Moattari et al. (2012) investigated the impact of an empowerment program on the quality of life, self-efficacy, and clinical and laboratory indexes of patients under dialysis and found a significant difference between the two groups of intervention and control before and after the intervention (P < 0.001), indicating the effectiveness of empowerment program.[26] A study conducted by Rahimparvar et al. (2015) compared the quality of life of transsexual and normal women and showed that the quality of life of transsexual women was at a moderate level (69.98).[26] A clinical trial by Khazri et al. (2016) that investigate the impact of self-management empowerment model on the quality of life of elderly with hypertension showed a statistically significant increase in the quality of life before and after the intervention in the intervention group compared to the control group (P < 0.05),[27] which is consistent with the present study.

Therefore, as one of the factors that affect the quality of life of transgender people is the inadequate understanding of high-risk
individuals about the related consequences, and since any positive changes in the circumstances such as appropriate education, health care, family support, etc. would increase the quality of life of people, increasing the knowledge of people about this issue, its complications and side effects lead to a positive attitude toward the prevention of complications and side effects. Furthermore, as people become more sensitive toward the side effects and complications, their motivation for preventive measures increases. Drawing attention to the consequences of preventive behaviors increases self-control and eventually normalizes preventive behaviors that lead to improved quality of life.

Final conclusions
Based on the findings of the present study, it can be concluded that empowerment programs can increase the perception of transgender people toward risk, and encourages and motivates them to change their behavior to a more preventive and healthy behavior by increasing their knowledge and enhancing their self-awareness. By doing so and gaining the ability to control the factors that affect their health, these people can increase their quality of life. Also, as clients become more involved in the empowerment program, they have a chance to practice and learn more. This way, they will become aware of the challenges and this increases their self-esteem, which leads to improved quality of life.

All members of the community and their families, members of the health care team, including physicians, nurses, psychologists, counselors, and social workers, as well as health authorities and policymakers, can utilize the findings of this study as needed. They can also use these results and consider them in dealing with and providing services to these people. It is hoped that in the light of further research on this issue and by providing awareness and information about the realities of these people’s lives, the social taboo and stigma surrounding the life of them will be lifted and they will become accepted by their families and society just like other citizens. Therefore, it is recommended that studies with different interventions and longer follow-up should be performed to improve the quality of life of transgender people. Also, given the importance of family members in the health of individuals, it seems useful to conduct a study to determine the effect of a family-centered empowerment model on the quality of life of these individuals.

Research limitations
Unfortunately, there was no guarantee that the control group would receive only routine clinical training and it was possible to receive outside information from family members, friends, colleagues, or the media, which was out of the researcher’s control. Also, there is always the possibility of bias in a self-reporting questionnaire. However, the researcher attempted to reduce these limitations by communicating well with the research samples and conducting research at an appropriate time interval.

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Conflicts of interest
There are no conflicts of interest.

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