

The Effects of Family-Centered Empowerment Model on Depression, Anxiety, and Stress of the Family Caregivers of Patients with COVID-19: A Randomized Clinical Trial

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Research Article

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Abstract

Background: Taking care of patients with Covid-19 is regarded as a challenging task for family caregivers. A family-centered empowerment model (FCEM) should help them achieve greater psychological strength in the care process.

Methods: Seventy caregivers were randomized to FCEM (n= 35) or control (n= 35). The four-stage of FCEM in four online sessions through WhatsApp was provided to the intervention group from the patient's discharge until 2 weeks later. The demographic information questionnaire and Depression Anxiety Stress Scale-21 were employed both before and five days after the FCEM sessions to gather the necessary data.

Results: Caregivers included 55.8% women and 44.2% men, with a mean age of 42.5 years. The results demonstrated a substantial difference in the average score of stress ($p=0.023$), anxiety ($p=0.003$), and depression ($p=0.012$).

Conclusions: The combination of a face-to-face orientation session and online methods of FCEM is likely to lower stress, anxiety, and depression among caregivers. It can be contributed to the practicability, simplicity, and effectiveness of the intervention.

Clinical Trial Registration code: This study (IRCT20180429039463N2) was registered in Iranian Registry of Clinical Trial on 10/04/2020

Background

The novel coronavirus pandemic, COVID-19, started in Wuhan, China on December 31, 2019 [1] and World Health Organization (WHO) declared the Coronavirus epidemic as a Public Health Emergency of International Concern (PHEIC) on January 30, 2020 [2]. According to the World Health Organization, about 216,224,351 cases and 4,499,191 deaths were reported in more than 221 countries from December 2019 to August 2021. At the same time, the number of confirmed cases and deaths in Iran were 4,869,414 and 105,287 respectively [3]. Common symptoms of the COVID-19 include fever and cough [4]. However, even vaccine availability does not guarantee sufficient population vaccination as evidenced by vaccine hesitancy [5]. Lack of any definitive treatment or prevention has caused a lot of stress and anxiety in communities [6]. Besides, limited knowledge and too much media exposure about the confirmed and dead patients may cause social anxiety and fear [7]. Furthermore, strict quarantine policies and case tracking by health authorities of countries can lead to social exclusion, financial loss, discrimination, stigma, and psychological problems among people [8], so it is important to understand that to what extent the virus spread may lead to anxiety and fear among people [2].

The patient's family is one of the important caregivers during the COVID-19 pandemic [9]. A study by Anderson et al (2020) showed a patient with COVID-19 puts both patient and their family members under a lot of stress, which is doubled when the patient is admitted to the hospital [6].

The Anxiety of a family member limits their capacity to help the patient and can exacerbate the patient's anxiety too [10]. Nonetheless, caregivers of the COVID-19 patients at home are experiencing greater levels of stress and anxiety for a variety of reasons, including fear of acquiring infection or transmitting it to others, insufficient community and governmental support, lack of access to medical care, and stigma [11]. According to the principal conceptual model of caregiving, the patients and their caregivers are likely to experience significant concerns both at the initial stage and continuation of such psychological problem. Hence, caregiving should be investigated based on the basis of the family-centered empowerment model (FCEM). Accordingly, caregivers' practical stressors cause psychological stress, state-trait anxiety, and situational depression because of their challenging responsibilities. Therefore, current intervention activities should be focused on enhancing family empowerment and resilience, improving quality of life and mental wellbeing [12].

Several behavioral theories and psychological counseling interventions such as hope building, reassurance, health belief model, self-management, and guidance techniques have been proposed to reduce psychological distress and improve mental health [13, 14]. In further, nurses should exclusively cooperate with the patients and their family [15]. It is required for such nurses to afford the information, services, and supports necessary to maintain the quality of home care [15]. Based on the related reviews, psychological sides of caregivers' challenges concerning chronic illnesses were regarded essential for caregivers' families [16].

Thus, it is required to apply an empowerment program to increase consciousness, information, and self-efficacy in patients and this will cause behavioral self-discipline and accepting defensive behaviors to improve health as well as recover the value of life [16]. As a significant procedure, empowerment may facilitate perceived self-efficacy. Consequently, individuals are more likely to investigate the actual source of the problem, share their knowledge and capabilities with healthcare providers, and resolve the issues accordingly. Such an exchange of informations and skills may lead to the perceived self-efficacy, which prepares the ground for desirable behaviors [17].

FCEM is one of the most helpful learning ways to enabling the family to improve knowledge and flexibility to improve the mental health of family and patient. A family-centered care study is regarded as the greatest method to identify physical and psychological concerns of the families as well as their immediate needs. As a result, healthcare providers and particularly caregivers will attempt to provide family caregivers with the necessary care plans. Hence, these management and planning related interactions may help develop patient-oriented care measures into a more family- and patient-centered plans. Previous research findings have demonstrated the significance of family members' contribution in healthcare plans, particularly in terms of decision making activities and patients' trust and willingness toward receiving care [18]. FCEM has been developed to reflect on the patients' and their family members' impact on the following capabilities: self-problem characteristics (e.g., perspective, perceived knowledge, & perceived threat), psychological traits (self-confidence, self-reliance, & self-control), and motivational skills [17]. Family empowerment enhances patients' quality of life, responsibility, fulfillment, collaboration with healthcare providers, compliance with treatment, and attitudes toward the diseases. It can also lead

to the anticipation of complications and the decline of treatment expenses. Tallman et al (2012) reported that family-centered care could reduce depression, nervousness, and stress in family caregivers of older individuals with dementia [19].

By highlighting the management of healthcare plans, this model can help decrease the healthcare inconveniences as well as facilitate caregivers' role and effectiveness. Achievement of an empowerment program improves self-control and adoption of preventive behaviors [16]. Few studies in Iran were done on the effectiveness of FCEM on psychological distress (depression, anxiety, and stress) [16, 18]. Accordingly, there is a lack of research on the effect of FCEM on depression, anxiety, and stress in family caregivers of patients with COVID-19. However, a study by Xiang and colleagues in China showed that online platforms to provide psychological counseling services for patients, their family members, and other people affected by the epidemic had little effect on patients with COVID-19 and their family members [20]. This is a real gap in the relevant literature. Therefore to bridge this gap designing and implementing the FCEM with a combination of a face-to-face orientation session and online methods may reduce psychological distress in family caregivers of patients with COVID-19. The present study seeks to examine the influence of online FCEM on depression, anxiety, and stress among family caregivers of patients with COVID-19 in Iran.

Methods

Setting and study design

This research is a randomized clinical trial with two groups and a pre-test and post-test design conducted based on the CONSORT checklist, (Figure1). For this purpose, Consolidated Standards of Reporting Trials checklist was employed to report the findings of the study, (S1, CONSORT checklist).

This study aimed to investigate the effects of FCEM on depression, anxiety, and stress among the family caregivers of patients with COVID-19. The four-stage of FCEM in four online sessions through WhatsApp was provided to the intervention group from the patient's discharge until 2 weeks later. Consequently, the demographic information questionnaire and Depression Anxiety Stress Scale-21 were employed to collect the data, before and five days after the FCEM sessions.

Populations, inclusion, and exclusion criteria

The statistical population includes 70 family caregivers from Torbat-e Heydariyeh with inclusion criteria participated in the study from April to July 2020. Inclusion criteria for patients include patients with confirmed COVID-19 who were treated and discharged, aged 18-60 years old, and with no underlying diseases other than COVID-19. Exclusion criteria of patients include dying of patient, presence of other diseases, and readmission. The following inclusion criteria were used for family caregivers: family member caring for a patient with COVID-19, family caregiver's access to communication devices such as mobile phones, personal computers, and tablets equipped with WhatsApp, reading and writing skills, and not being a member of the healthcare team. Exclusion criteria for family caregivers include ages less than

18 and more than 60 years, absence in more than one educational session, and unwillingness to continue the study.

Instruments of measurement:

Data collection instruments include a demographic information questionnaire with six items (age, sex, marital status, living place, patient-caregiver relationship, and education) and the DASS-21 that assessed depression, anxiety, and stress among family caregivers of patients with COVID-19. This questionnaire was first presented by Lovibond PF and Lovibond SH in 1995[21]. The 21-item questionnaire is on a Likert scale, and each of the three DASS-21 scales contains seven items. Stress assesses fear, shortness of breath, tremors, dry mouth, palpitation, difficulty in starting work, and difficulty in relaxing. Anxiety evaluates autonomic arousal, situational anxiety, skeletal muscle effects, and subjective experience of apprehension distress. Depression measures self-depreciation, life devaluation, hopelessness, dysphoria, the feeling of indifference/sedentary, and anhedonia [22]. Two research team members (Mehdipour and Najafi) reviewed and approved the validity and reliability of the DASS-21 [23, 24]. Besides, the quality content validity method was used to determine the validity of the DASS-21. The DASS-21 was provided to 10 faculty members of Torbat-e Heydariyeh University of Medical Sciences for evaluation, and the ultimate instrument was used once required suggestions and modifications were implemented. To confirm the reliability (internal consistency) of the study, we tested the DASS-21 tool on 10 subjects and the obtained Cronbach's alpha coefficient was 0.81. The total score of each DASS-21 subscale is obtained through the item scores related to that subscale. Each item is scored from zero (did not apply to me at all) to three (applied to me very much). Since this questionnaire is a short form of the original version (42 items), the final score of each subscale must be doubled. The DASS-21 and demographic information questionnaire were prepared online and the link was sent electronically to the family caregivers of patients with COVID-19 by WhatsApp Messenger.

Sample size and randomization:

The necessary sample size was estimated as a result of a pilot study on 20 family caregivers (10 individuals in each group) with a 95 percent confidence interval and 80 percent test power. Thirty-four family caregivers were included in each group by using the following formula:

$$n = \frac{(Z_1 - \frac{\alpha}{2} + Z_1 - \beta_2) (S_{12} + S_{22})}{(x_1 - x_2)^2}$$

Concerning 10 percent dropout, 38 family caregivers were considered in each group. Three family caregivers from the intervention group (two family caregivers due to unwillingness to continue the study and one family caregiver due to absence in educational sessions) and three from the control group (due to unwillingness to resume the study) were excluded from the study and finally, 35 families in each group were examined.

The primary caregivers were randomly assigned to control and intervention groups. Eligible patients were divided into two groups of intervention or control based on a random sequence of letters A and B, generated by SPSS software, written on small cards, and retained in a sealed envelope. Then, one card would be picked out of the envelope at the beginning of each week to decide if we should conduct the intervention during that week or it is time for the control. Accordingly, all eligible inpatients would be allocated to either the control or intervention group. Furthermore, this approach would rule out the possibility of information dissemination among those patients who are accidentally in the ward

Pre-intervention

In the intervention group, an introductory session was held with family caregivers at the time of patients' discharges from the health clinic of the hospital. First, online FCEM sessions were arranged based on participants' agreements. Then, the priorities, educational needs, and skills required to care for the patient with COVID-19 were assessed through a checklist. The important educational problems and needs of caregivers, including the disease identification, personal hygiene, methods of prevention and transmission of infection, drug use, nutrition and excretion, daily life activities, mental and psychological issues were extracted. After reviewing the needs and skills required, the researcher designed the educational content according to the literature and ideas of the research team and infectious disease specialists.

Intervention

The educational content of the online sessions was designed through a checklist based on the needs of the research units. Then, the FCEM was presented as online group discussions in five groups of seven individuals in four 40-60 minute sessions through WhatsApp and other applications used for this purpose. The FCEM was provided to the intervention group from the patient's discharge until 2 weeks later during the lockdown. The intervention, was performed in four steps consist of perceived threat, problem-solving, educational participation and evaluation, (Supplementary material 1).

Post-intervention

The intervention and control groups were evaluated five days after the FCEM sessions. The researcher made a telephone call to the caregivers as a reminder and discuss any potential issues., the link to the DASS-21 was resent to the caregivers electronically.

Control:

The patients in the control group would only experience face-to-face training (recommendation for medication and quarantine) during discharge and they used the pamphlets available in the ward, which was the same for the intervention group. All educational contents of the FCEM sessions were provided to the control group after the research.

Statistical analysis

The obtained information was statistically analyzed with SPSS version 16. Descriptive statistics (frequency distribution, mean, standard deviation) were used to describe and categorize the data. On the other hand, inferential statistics including Chi-square, independent t- and Mann-Whitney tests were used to assess the hypothesis. Paired t-test was employed to make within-group comparison. Finally, Kolmogorov-Smirnov test was implemented to examine normal distribution of quantitative variables. The 95-percent confidence level and the significance level of 0.05 were considered in all the tests.

Results

The majority of caregivers in the intervention (N=20, 57.1%) and control (N=19, 54.3%) groups were female. The majority of caregivers in the intervention (N=26, 74.3%) and control (N=24, 68.6%) groups were married. Also, children of the carers acted as caregivers in 62.9% and 65.7% of caregivers in the intervention and control groups respectively. The results of Chi-square, Mann-Whitney, Fisher's, and independent t-tests showed that the two groups were homogenous concerning age, sex, education, marital status, living place, and caregiver-patient relationship ($p > 0.05$) (Table 1).

Table 1
Demographic variables of the caregivers of patients with COVID-19

Variable		Group		P value
		Intervention	Control	
Age (mean ± SD)		43.2 ± 13.2	41.8 ± 2.0	P= 0.641****
Sex (percent/number)	Male	15 (42.9)	16 (45.7)	P= 0.810*
	Female	20 (57.1)	19 (54.3)	
Education (percent/number)	Middle/high school	7 (20.0)	9 (25.7)	P= 0.878**
	Diploma	19 (54.2)	16 (45.7)	
	Academic	9 (25.7)	10 (28.6)	
Patient-caregiver relationship	Wife/husband	11(31.4)	9 (25.7)	P= 0.810*
	Children	32 (62.9)	23 (65.7)	
	Others	2 (5.7)	3 (8.6)	
Marital status (percent/number)	Single	8 (22.9)	9 (25.7)	P= 0.790*
	Married	26 (74.3)	24 (68.6)	
	Others	1 (2.9)	2 (5.7)	
Caregiver's living place	City	32 (91.4)	31 (88.6)	P=1.000***
	Village	3 (8.6)	4 (11.4)	
* Chi-square ** Mann-Whitney *** Fisher **** Independent-t test				

In the pretest stage, the mean depression scores of caregivers in the intervention and control groups were not statistically significant (P=0.308). In the posttest stage, the mean score of depression in the intervention group (8.6 ± 3.8) was significantly lower than that of the control group (12.1 ± 7.0) (P = 0.012). Besides, the posttest depression score was significantly higher in the intervention group (3.6 ± 1.5) compared to the pretest (1.6 ± 1.1) (P <0.001). Based on the results of the within-group analysis, the mean score of depression was significantly lower in the intervention group at the posttest stage (P <0.001) (Table 2).

Table 2

Mean and standard deviation of depression, anxiety, and stress scores of caregivers of patients with COVID - 19 in two groups of intervention and control

Variable	Group				Between-group test result	
	Intervention		Control			
	Mean \pm SD	No.	Mean \pm SD	No.		
Depression	Pretest	12.2 \pm 4.8	35	13.8 \pm 7.6	35	P=0.308*
	Posttest	8.6 \pm 3.8	35	12.1 \pm 7.0	35	P=0.012*
	Pre- and posttest difference	-3.6 \pm 1.5	35	-1.6 \pm 1.1	35	P<0.001*
Within-group comparison		P < 0.001**		P < 0.001**		
Anxiety	Pretest	11.6 \pm 3.2	35	12.5 \pm 6.8	35	P=0.476*
	Posttest	7.6 \pm 2.7	35	11.2 \pm 6.3	35	P=0.003*
	Pre- and posttest difference	-3.9 \pm 1.5	35	-1.2 \pm 0.9	35	P<0.001*
Within-group comparison		P < 0.001**		P < 0.001**		
Stress	Pretest	16.0 \pm 6.2	35	15.1 \pm 7.4	35	P=0.581*
	Posttest	10.5 \pm 4.4	35	13.8 \pm 7.0	35	P=0.023*
	Pre- and posttest difference	-5.5 \pm 2.2	35	-1.3 \pm 0.9	35	P<0.001*
Within-group comparison		P < 0.001**		P < 0.001**		
* Independent-t test ** Paired t-test						

In the pretest stage, there were no significant differences between the mean scores of anxiety among the caregivers in the intervention and control groups ($P = 0.476$); nevertheless, the mean score of anxiety in the intervention group (7.6 ± 2.7) was significantly lower than the control group (11.2 ± 6.3) ($P=0.003$) in the posttest stage. Also, the posttest anxiety score in the intervention group (3.9 ± 1.5) was considerably higher than the control group compared with the pretest (1.2 ± 0.9) ($P < 0.001$). In within-group comparison, the mean posttest anxiety score was significantly lower in the intervention group ($P < 0.001$) (Table 2).

Although the mean stress scores of caregivers in the intervention and control groups were not significantly different ($P = 0.581$) in the pretest stage, the mean anxiety score in the intervention group (10.5 ± 4.4) was considerably lower compared to the control group (13.8 ± 7.0) ($P = 0.023$) in the posttest stage. In addition, the posttest stress score in the intervention group (5.5 ± 2.2) was significantly higher

compared to the pretest (1.3 ± 0.9) ($P < 0.001$). Eventually, the mean posttest stress score in the intervention group was considerably lower ($P < 0.001$) according to the within-group comparison (Table 2).

Discussion

The present study aimed to investigate the contribution of FCEM in depression, anxiety, and stress of family caregivers of patients with COVID-19. According to the findings related to the implementation of FCEM, depression, anxiety, and stress scores of family caregivers of patients with COVID-19 decreased by 41-point, 51-point, and 52-point respectively. We did not find a similar study on the effect of FCEM on depression, anxiety, and stress among the participants. Therefore, we decided to use findings of other studies in this regard. Zhou et al (2020) in China demonstrated that psychological interventions via the internet and telephone were effective in reducing the psychological burden of the public [25]. Holmes et al (2020) also found that digital interventions could reduce the level of stress and anxiety in patients with COVID-19 [26]. Our findings are in line with the results of both studies. It seems that making phone calls to the patient's family can be effective in strengthening and increasing their knowledge capacity. Families will have opportunities to discuss the potential issues with researchers during this telephone conversation [27]. A study by Sotoudeh et al (2015) revealed respectively 19-point, 49-point, and 33-point reductions in the rates of depression, anxiety, and stress of patients with COVID-19 through four psychological counseling sessions [28]. Aminizadeh et al reported that digital education would be a successful and efficient method if the content is properly compiled and evaluated correctly [29].

We embedded the FCEM approach in online group sessions via WhatsApp Messenger. Although online educational sessions were conducted by a nurse in the present study, our findings correspond to that study. Since one of the tasks of nurses in pandemics, is to support and help families to cope with crises and they are getting primary contact person with patients and their families, therefore their support would be vital to families to combat the inevitable consequences of the COVID pandemic such as psychological distress [30]. Ning et al (2020) showed also that intervention via the internet could reduce the symptoms of depression and anxiety in patients with COVID-19 [31]. Online interventions are complementary to face-to-face counseling and treatment. In addition, people are encouraged to use such interventions more because of their flexibility and easy use, independence of time and space, better protection of privacy, and lower costs. Online intervention can also reduce the risk of infection in psychological service providers [32]. Daveson et al (2014) indicated that the psycho-behavioral educational program could reduce the stress, anxiety, and depression of family caregivers of patients admitted to the intensive care unit [33]. Bagheri et al. (2019) showed that the FCEM reduced the care burden of caregivers of older people with Parkinson's disease [16]. Therefore, the results of these studies are similar to the present study and improve scores of depression, anxiety, and stress.

It may be necessary to do interventions including education and family therapy to mediate the pressures on caregivers as well as improve the status of mental and physical health among the patients and the caregivers [34]. Tallman et al (2012) acknowledged that family instructional plans could reduce stress,

anxiety, and depression in caregivers of older people with dementia [19]. Their findings indicate that educational family-centered intervention can increase the awareness, perceptions, and skills of caregivers and facilitate care for caregivers because of their knowledge of different dimensions and problems of the disease and the training of practical care skills. Khalilzadeh et al. demonstrated that family-centered care reduced the level of anxiety in parents of children with urinary tract infections more than other therapeutic methods [35].

Therefore, training of the patient and family increases the patient's level of information and reduces anxiety [36]. Jankovic et al (2011) suggest that increasing patient care responsiveness can help moderate anxiety and stress among caregivers of patients with lung transplants [37]. It is noteworthy that caregivers often perceive they lack enough knowledge to provide appropriate care and therefore experience a lot of stress and anxiety [38]. Chien et al. (2006) reported that a family-centered program could significantly reduce the anxiety of the patient family. In our study, the family-centered program was continuous and in addition to face-to-face education, families were telephoned at least once a day [39]. The results of the aforementioned studies somehow support our results. We made post-discharge telephone calls and follow-up which had an important role in the reduction in depression, anxiety, and stress of patients' family caregivers.

In the present study, the rate of depression, anxiety, and stress reduced in the control group at the end of the study, which was also lower compared to the intervention group. The reason may be that macro-policies related to adherence to health protocols, including public education through the national media were adopted because of the COVID-19 epidemic to reduce the prevalence of the disease in the world, especially in Iran. Therefore, the public awareness of the disease, caring methods, and adaptation increased, which was unchangeable from the researchers' viewpoints. However, our findings and other studies highlight on the significance of raising knowledge, awareness, and problem-solving management in dealing with patients' problems, the FCEM enables the family to better cope with stressors so that they can tolerate the psychological, physical, and economic effects of care through participatory planning. One of the limitations of this study was the different learning levels of families and the transfer of education to patients. The intervention lasted only two weeks because of the nature of COVID-19 disease (incubation period, illness, and recovery), so more interventions may be needed for more stable changes. However, it was not possible to do sampling in other cities of Iran, and there may be a bias in the completion of the electronic questionnaires.

Conclusion

The results of the present study showed that the combination of a face-to-face orientation session and online methods of FCEM could reduce the depression, anxiety, and stress scores of family caregivers of patients with COVID-19. Such interventions seem to help the family caregivers of patients, especially patients with COVID-19 and increase the quality of care because they are efficient, inexpensive, safe, and effective. Nonetheless, it is essential to conduct further studies to examine the mechanism of the influence of FCEM on depression, anxiety, and stress. Therefore, online FCEM is suggested to be used for

other diseases in further research particularly during the limitations of the current pandemic and difficulties in performing education and care of patients. However, the duration of the FCEM intervention should be increased to obtain more accurate results.

Abbreviations

- **FCEM:** family-centered empowerment model
- **WHO:** World Health Organization
- **PHEIC:** Public Health Emergency of International Concern
- **DASS-21:** Depression, Anxiety and Stress Scale

Declarations

Acknowledgment :

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Ethics approval and consent to participate:

The research was approved by the Research Ethics Committees of Torbat Heydariyeh University of Medical Sciences with the code of ethics No. IR.THUMS.REC.1398.060 , which was presented to the authorities of the research setting, the manager, and the head nurse of the hospital for COVID-19. The research purpose was explained face-to-face and online informed consent was in the first part of the online questionnaire and the family caregivers completed the questionnaire only after registration of the informed consent. The research units were explained about the information confidentiality and the voluntary nature of the participation in the study. All methods were performed in accordance with the relevant guidelines and regulations which are aligned in accordance with the Declaration.

Consent for publication:

Not applicable.

Conflict of interest:

The authors declare that there is no conflict of interest in the publication of this article.

Author's Contributions:

All authors have read and approved the manuscript. Study design: MNN, TSH, SM; data collection and analysis: MNN, TSH; manuscript preparation: MNN, TSH, SM, NB and Critical Review: NB

Availability of data and materials:

All data generated or analysed during this study are included in this published article (and its supplementary information files).

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Figures

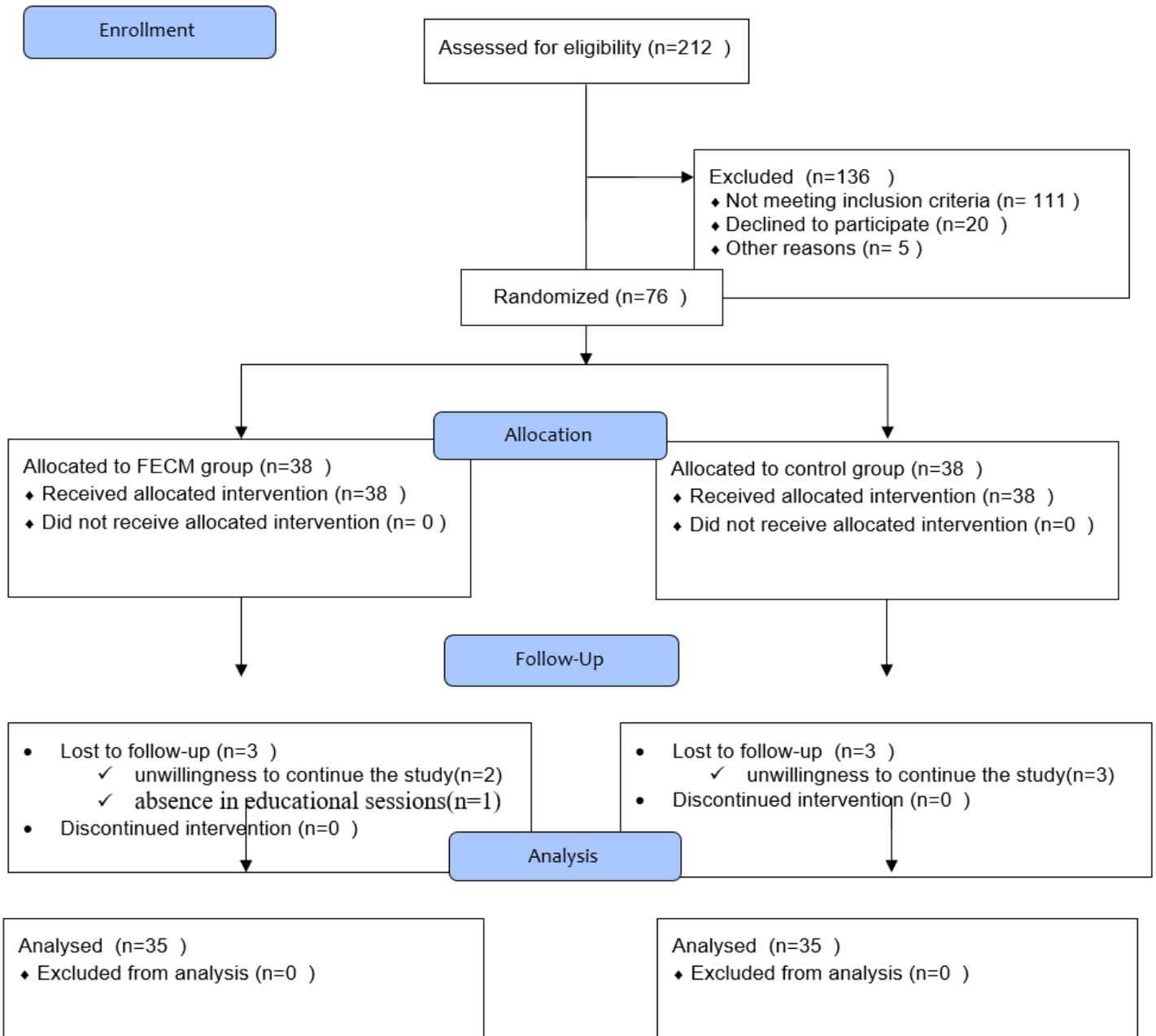


Figure 1

The CONSORT checklist of study

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