Efficacy And Safety of Family Participate In The Early Mobilization of Critically Ill Patients: Study Protocol For A Randomized Controlled Trial

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Study protocol

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Abstract

Background: Long-term immobilization can cause a series of harm to ICU patients, while early rehabilitation can effectively reduce the harm of long-term immobilization and improve the medical outcome of patients. Can family members participate in the early mobilization (FMPiEM) of critically ill patients? Whether the FMPiEM of critically ill patients can reduce delirium, anxiety, depression, post-traumatic stress syndrome and other adverse emotions of ICU patients.

Objective: To explore the FMPiEM of critically ill patients on the short-term and long-term outcomes.

Methods and design: A single-center randomized controlled trial (RCT) is conducted and reported according to the CONSORT guidelines. A total of 120 samples were randomly assigned to the intervention group (FMPiEM) and the control group (without-FMPiEM).The primary outcome indicators included the incidence of ICU delirium, acquired infection, ICU mortality, and ICU-acquired weakness (ICU-AW), while the secondary outcome indicators included mechanical ventilation time, length of stay in ICU (ICU LOS), reintubation, unplanned extubation (UEX), hospitalization costs, and patient outcomes. SPSS 22.0 software was used for statistical analysis. Frequency and mean ± standard deviation were used for descriptive analysis. B test, *t* test or Mann-whitney *U* test were used for statistical inference.

Discussion: FMPiEM of critically ill patients maybe not only reduce the incidence of delirium, ICU-AW, but also reduce the mechanical ventilation time, length of stay in ICU, reintubation, UEX and hospitalization costs of critically ill patients, at the same time, without increasing the acquired infection in ICU.

Trial registration: Chinese Clinical Trial Registry, ID:ChiCTR2000028902. Registered on 06 January 2020.

Background

Clinical studies have confirmed that early mobilization (EM) is an effective intervention which has been safety and effectively applied in critically ill patients [1–6]. EM can not only enhance patients' muscle strength, reduce muscle atrophy, inhibit the release of IL-6, inhibit systemic inflammatory response[7–8], enhance patients' confidence in the treatment of diseases, but also effectively improve peripheral and central perfusion, blood circulation, and muscle metabolism[7,9–10]. Evidence-based studies have found that EM of critically ill patients can effectively prevent the Intensive care unit-acquired weakness (ICU-AW)[1,11–12], reduce the incidence of delirium[1,4,–5,13–15], shorten the mechanical ventilation time, increase the success rate of withdrawal, and reduce the length of stay in ICU (ICU LOS) [1–2,8–9,11,16–17]. Shortage of human resources is the primary obstacle to the EM and rehabilitation program implementation [8, 18]. At present, there are so many hospital lack of multidisciplinary team cooperation, duo to the shortage of respiratory therapists, physiotherapists and other professionals[18–21]. In addition, due to the restrictive visiting policies and unaccompanied care system in ICU, family members are unable to participate in EM and rehabilitation programs[22–24].

Family members are not only the most important social support for ICU patients, but also the most important emotional support[22, 24]. There are some studies found that FMPiEM not only has a positive effect on the rehabilitation effects and outcome, but also can prevent many adverse consequences caused by the psychological pressure of family members[15,22–25]. The study found that the incidence of delirium of ICU

patients without family members participate in critical care have three times than patients with family members participate in critical care, and the score of anxiety and depression was much higher than the ICU patients with family participate in critical care[15]. There are some studies found that family members participate in the care of critically ill patients can not only effectively reduce the negative emotion of ICU patients, such as delirium, anxiety, depression, and so on, that can also effectively reduce the dosage of sedatives and analgesics, and shorten the mechanical ventilation time, ICU LOS and hospitalization costs[15,22–27]. However, we had not found clinical studies which about FMPiEM of critically ill patients. Therefore, we encourage family members to actively participate in the EM of ICU patients under the guidance of medical staffs. A randomized controlled study was conducted to explore the short-term and long-term outcomes, mechanical ventilation time, ICU LOS, complications and hospitalization costs of FMPiEM on critically ill patients.

Key research questions

- Can family members participate in the early mobilization (FMPiEM) of critically ill patients?
- Whether the FMPiEM of critically ill patients can reduce delirium, ICU acquired weakness, anxiety, depression, post-traumatic stress syndrome and other adverse emotions of ICU patients.
- Whether the FMPiEM of critically ill patients can increase ICU acquired infections?
- To explore the short-term and long-term outcomes, mechanical ventilation time, ICU LOS, complications and hospitalization costs of FMPiEM on critically ill patients.

Methods

2.1 Study design

This was a prospective, single-center, randomized, single blind, controlled trial with 1:1 allocation. The present study protocol (version 1.1, dated December 20, 2019) was registered in the Chinese clinical trial register (registration No. ChiCTR2000028902) on 06 January 2020, and we design this protocol in accordance with the Standard Protocol Items: Recommendation for Interventional Trials 2013[28]. In this study, 120 adult patients (age ≥ 18 years old) who were treated in the ICU department of the first hospital of Lanzhou university from March 1,2020 to May 1, 2021 were selected. And the patients who met the inclusion criteria, eligible participants, and signed informed consent were divided into the intervention group and the control group according to the computer random sequence. The flowchart of the study is shown in Fig. 1.

2.2 Ethics approval and consent to participants

The study protocol (version 1, 20 December 2019) was approved by the ethics committee of the first hospital of Lanzhou university (No. LDYYLL2019-255) on 25 December 2019. The study was conducted in accordance with the declaration of Helsinki, and all participants were coded and their privacy was not involved. Informed consent will be obtained from all participants prior to inclusion. All patients must agree to participate voluntarily and will be free to withdraw from the study at any time. During the trial, all patient data will be kept in a secure data management system of first hospital of Lanzhou University which accessible only by research personnel. The study protocol is publicly available via the institution's website: http://www.chictr.org.cn/showprojen.aspx?proj=47200

2.3 Participates

2.3.1 Inclusion criteria:

Participants are eligible if age ≥ 18 years, mechanical ventilation time greater than 48 hours, Glasgow coma scale score was greater than 11 score and paticipants and their families volunteered to participate in the study.

2.3.2 Exclusion criteria:

Patients will be excluded if they have the following symptoms: hemodynamic instability, increased intracranial pressure (≥ 20 mmHg), active bleeding, unstable fracture, limb deformity or limb movement dysfunction, Pregnant, aortic aneurysm rupture or leakage, patients and their families who refuse or give up treatment, patients or their families have participated in similar rehabilitation activities.

2.3.3 Elimination criteria and withdrawal case

Patients will be eliminated if they did not follow the protocol. Patients will be considered as expulsion cases if they have the following conditions during the early mobilization: the deterioration of diseases, patient withdrawal, occurrence of serious adverse events (serious arrhythmia, angina pectoris, myocardial infarction and so on).

2.3.4 Sample

The researchers recruited participants from the first hospital of Lanzhou university by putting up posters and word-of-mouth publicity. The recruitment is now on-going. And the eligible participants will sign the informed consent who meeting the criteria and voluntary. The sample size was calculated by the following formula based on the maximum incidence of delirium in other studies which reported the maximum incidence of delirium in control group was 60%, and in the intervention group was 20%[13–15,29–30]. Thus we set the control group incidence p_1=0.6,incidence of intervention group p_2=0.2, $\bar{p} = (p_1 + p_2)/2 = 0.4$, $\alpha = 0.05$, and the $\beta = 0.01$, $Z_{1-\alpha/2}=1.96$, $Z_\beta = 2.326$. Taking into account the accidents such as loss to follow-up and drop out, and considering the 20% loss rate on the basis of the calculation results, and then the sample size of each group is 60 people, and the total sample size is 120 people.

Formula: **N=**
$$\frac{[Z_{1-\alpha/2}\sqrt{2\bar{p}(1-\bar{p})} + Z_\beta\sqrt{p_1(1-p_1)+p_2(1-p_2)}]^2}{(p_1-p_2)^2}$$

2.4 Randomization and blinding

Patients blindness and data collector blindness were used in this study. SPSS 22.0 software was used by a statistician to design the random sequence and decide which kind of random number is the control group and which kind is the intervention group. The statistician did not participate in the data collection or analysis. Participants, primary nurse, physiotherapists, data collectors and outcome assessors in this trial will remain blinded to allocated intervention until the study completion. Unblinding is permissible in the following circumstance that the participants develop another severe disease that need to be treated urgently and serious adverse event. Elimination and withdrawal occurs when a participant's allocation or intervention is revealed.

2.5 Intervention

Patients in the control group received ICU routine care which included the following routines[31–33]: according the patient's condition to give symptomatic support treatment; changing posture and percussing back every 2 hours; the ICU physiotherapists completed the patients' functional exercise according to the early mobilization protocol, 30 min/ time, and 2 times/day. On the basis of the control group, the family members were encouraged to

participate in the patients' function exercise. The primary nurse instructs the family members to carry out functional exercise for the patient from 16:00 to 16:30 pm every day, and the specific content is to repeat the physiotherapists' activity content of the day.

2.5.1 Early mobilization protocol

The early mobilization protocol of ICU patients is a progressive, goal-oriented functional exercise which divided into 6 levels[32–34]: level 1 is passive functional exercise in bed; level 2 is active joint motion in bed; level 3 is dynamic sitting that included sitting on the edge of the bed unsupported; level 4 is transferring from bed to chair and from chair to bed; level 5 is standing balance; level 6 is mobility training and stepping. Early mobilization is based on the patient's condition start from the passive physical function exercise on the bed, and then gradually transition to higher level of activity. If the patients' conditions meet the terminate indication of activity during the process of rehabilitation exercise, and then the activity will be ended.

2.5.2 Suspension indicators

Rehabilitation exercises of patients will be suspended if they met the following symptoms[32–35]: resting heart rate less than 40 beats/min or more than 130 beats/min, arrhythmia, myocardial infarction and using new antiarrhythmic drugs; blood oxygen saturation less than 88%; diastolic pressure more than 180 mmHg or/and mean arterial pressure(MAP) less than 65 mmHg or MAP more than 110 mmHg and even add vasoactive drugs; respiratory rate(RR) less than 5 times/min or RR more than 40 times/min; the patient is agitated and refuses to initiate activity.

2.5.3 Termination indicators

Rehabilitation exercises of patients will be terminated if they met the following symptoms[32–33, 36]: arrhythmias and heart rate more than 130 times/min or increase more than 20% on the basis of heart rate before activity; RR more than 35 times/min or increased more than 20% on the basis of RR before activity; diastolic pressure less than 90 mmHg or more than 180 mmHg; blood oxygen saturation less than 88% and the duration more than 1 minute; the patient is intolerant or rejetive.

2.6 Outcome measurements

The schedule of enrolment, interventions, and outcomes are shown in Table 1 which was accorded to the standard protocol items recommendations for interventional trials (CONSORT). The observational indicators of the study included demographic indicators, primary outcome indicators, secondary outcome indicators and long-term outcome indicators. At baseline, demographic information including age, sex, occupation, primary diagnosis, APACHE□score and previous history. Primary outcome indicators included the incidence of delirium, the incidence of ICU-AW, ICU-acquired infection, and ICU mortality. Secondary outcome indicator included the duration of delirium,mechanical ventilation time, ICU LOS, reintubation rate, incidence of UEX, hospitalization costs, and discharge. Long-term indicators included quality of life and survival rates one year after discharge.

Table 1
Schedule of the study process

Item			Recruit	Intervention	Transfer	Discharge	Follow-up
Recruit	Informed consent		×				
	Inclusion/exclusion		×				
	Baseline	Year	×				
		Gender	×				
		APACH□score	×				
		ICU-CAM score	×	×	×	×	
		MRC-Score	×	×	×	×	
		Type of ICU	×				
		Primary diagnosis	×				
Point to start early mobilization				×			
Primary outcome	Delirium			×			
	ICU-acquired infection			×			
	ICU-AW			×			
	ICU mortality			×			
Secondary outcome	Duration of delirium			×			
	Time of MV			×			
	ICU LOS			×			
	Reintubation			×			
	UEX			×	×		
	Hospitalization	ICU Hospitalization			×		
		Total cost				×	
	Outcome	Transfer word			×		
		Transfer hospital			×		
		Discharge			×		

Note: FMPiEM = Family Members Participate in the Early Mobilization, wFMPiEM = without Family Members Participate in the Early Mobilization, ICU LOS = Length of Stay in ICU, MV = Mechanical Ventilation, ICU-AW = ICU-acquired weakness, UEX = Unplanned Extubation, CAM-ICU = The Confusion Assessment Method of Intensive Care Unit, MRC-Score = the Medical Research Council Score

Item		Recruit	Intervention	Transfer	Discharge	Follow-up
	Death		×			×
Tertiary outcome	One year Quality of life					×
	One year Survival rate					×

Note: FMPiEM = Family Members Participate in the Early Mobilization, wFMPiEM = without Family Members Participate in the Early Mobilization, ICU LOS = Length of Stay in ICU, MV = Mechanical Ventilation, ICU-AW = ICU-acquired weakness, UEX = Unplanned Extubation, CAM-ICU = The Confusion Assessment Method of Intensive Care Unit, MRC-Score = the Medical Research Council Score

2.7 Data

2.7.1 Collection data

Demographic data, mechanical ventilation time, ICU LOS, hospitalization costs, reintubation rate, and incidence of UEX were all obtained from the HIS system. We used the acute physiology and chronic health evaluation to calculate the patients' APACHE II score, used the Confusion Assessment Method for the ICU[37–38] (CAM-ICU) to assess delirium, and used the MRC-Score less than 48[39–40] to diagnosis ICU-AW. ICU acquired infection[41–42] is defined as the infection caused by specific ICU operations and specific bacterial after more than 48 h of treatment in ICU which including ventilator-associated pneumonia(VAP), catheter-related blood stream infection (CRBSI), and catheter-associated urinary tract infection(CAUTI), etc. The quality of life was assessed by the Short Form 36-item Health Survey (SF-36)[43–44] one year after discharge. Physiotherapists and nurse be responsible for the implementation of study protocol. One year after discharge, the follow-up department of hospital completed the investigation about the quality of life and survival rate.

2.7.2 Statistical analysis

The *EpiData 3.1* software was used to double logging data, and the *SPSS 22.0* software was used for statistical analysis. Frequency and percentage were used to describe the counting data, and X^2 test was used for inter-group comparison. Mean ± standard deviation, median and quartile were used for quantitative data, and *t* test and Mann-whitney U test were used for inter-group comparison. Statistical tests were conducted on both sides, and $P \leq 0.05$ was considered as statistically significant. The prospective results are shown in Table 2.

Table 2
Study outcome

Item			FPiEM	wFPiEM	Type of EE	EE(CI)	*P*
Primary outcome	Delirium		x/x (xx.x)	x/x (xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
	ICU-acquired infection		x/x (xx.x)	x/x (xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
	ICU-AW		x/x (xx.x)	x/x (xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
	ICU mortality		x/x (xx.x)	x/x (xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
Secondary outcome	Duration of delirium		xx.x(xx.x)	xx.x(xx.x)	HR	x.xx(x.xx-x.xx)**	xx.x
	Time of MV		xx.x(xx.x)	xx.x(xx.x)	MD	x.xx(x.xx-x.xx)**	xx.x
	ICU LOS		xx.x(xx.x)	xx.x(xx.x)	MD	x.xx(x.xx-x.xx)**	xx.x
	Reintubation		x/x (xx.x)	x/x(xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
	UEX		x/x (xx.x)	x/x(xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
	Hospitali-zation	ICU Hospitalization	xx.x(xx.x)	xx.x(xx.x)	MD	x.xx(x.xx-x.xx)**	xx.x
		Total cost	xx.x(xx.x)	xx.x(xx.x)	MD	x.xx(x.xx-x.xx)**	xx.x
	Outcome	Transfer word	x/x(xx.x)	x/x(xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
		Transfer hospital	x/x(xx.x)	x/x(xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
		Discharge	x/x(xx.x)	x/x(xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
		Death	x/x(xx.x)	x/x(xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x
Tertiary outcome	One year Quality of life		xx.x(xx.x)	xx.x(xx.x)	MD	x.xx(x.xx-x.xx)*	xx.x
	One year Survival rate		x/x(xx.x)	x/x(xx.x)	RR	x.xx(x.xx-x.xx)*	xx.x

Note: FMPiEM = Family Members Participate in the Early Mobilization, wFMPiEM = without Family Members Participate in the Early Mobilization, ICU LOS = Length of Stay in ICU, EM = Early mobilization, ICU-AW = ICU-acquired weakness, UEX = Unplanned Extubation, EE = Effect estimate

Research Progress

Recruitment will begin in January 2020 and is currently under way. We will complete data collection in March 2021 and statistical analysis in August 2021.

Discussion

With the improvement of medical level, the treatment success rate of critically ill patients has been significantly improved, and the health-related quality of life of patients after discharge has become more and more important[45–46]. There is no drug therapy to treat ICU-AW and delirium which are important complications that affect the quality of life of ICU patients after discharge, but the early mobilization is an economical, safety and effective preventive measure[1,47–48]. Early mobilization can integrate the rehabilitation treatment into the whole treatment process of critical patients, and carry out rehabilitation intervention for the corresponding complications to avoid and reduce sequelae as soon as possible. However, lack of medical personnel and equipment resources are the important factors which are hindering the implementation of ICU early mobilization at home and abroad [19–21, 42]. Critical care professionals, physiotherapists and respiratory therapists are not yet able to meet the current treatment needs in China. Therefore, how to improve the rate of ICU patients' early mobilization is an urgent problem for contemporary medical.

As the most important social support and spiritual support for patients, family members play an important role in the psychosomatic demands needs of patients, which cannot be achieved by medical staffs[22–24]. There are some evidence suggests that the unrestrictive visiting policy(UVP) not only can be beneficial to the families and patients, but also the UVP is an effective intervention to reduce the incidence of delirium, anxiety score and depression score[22,24–25]. Therefore, the protocol hypothesized that it is feasible and secure to encourage family members to participate in the early mobilization of ICU patient on the basis of UVP, and provided theoretical basis for family members to participate in the early mobilization of ICU patients.

Quality control

Before the start of the study, the study protocol was approved by the ethics committee of the research unit. all participants were given a unified professional training to clearly master the research purpose, research content, research significance and other considerations. During the study, the subjects were included in strict accordance with the inclusion criteria, the data were accurately measure and the researchers conducted follow-up instructions. In addition, research members give regular feedback about the research situation and timely discuss and solve the existing problems. The data was recorded using *EpiData* 3.1 software and managed with SPSS22.0 software by two researchers.

Abbreviations

FMPiEM=Family Members Participate in the Early Mobilization, wFMPiEM=without Family Members Participate in the Early Mobilization, RCT=Randomized Controlled Trial, ICU LOS=Length of Stay in ICU, EM=Early mobilization, ICU-AW=ICU-acquired weakness, UEX=Unplanned Extubation, UVP=Unrestricted Visiting Policy, CAM-ICU =The Confusion Assessment Method of Intensive Care Unit, MRC-Score=the Medical Research Council Score, HIS system= the hospital information system.

Declarations

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Availability of data and materials: During the trial, all patient data will be kept in a secure data management system of First Hospital of Lanzhou University. Data can be requested from the Ethics Committee(contact via the First Hospital of Lanzhou University, Lanzhou, Gansu, China, email: ldyylwh@126.com) for researchers who meet the criteria for access to confidential data when the trial was completed.

Author contributions

YCW and ZGZ conceived the study and wrote the first draft of the protocol. JHT and BL will lead the project. GQW, LZ and K C will recruitment patients. QLL and HPW will coordinate training and quality control. ZGZ and NND will analyze project data and draft manuscript. All authors have read and approved the final version of this protocol.

Ethics approval and consent to participate

The study protocol was approved by the ethics committee of the first hospital of Lanzhou university (approval No. LDYYLL2019-255) on 25 December 2019. The study protocol (version 1, 20 December 2019) was registered in the Chinese clinical trial register (registration No. ChiCTR2000028902) on 06 January 2020. Informed consent will be obtained from all participants prior to inclusion. All patients must agree to participate voluntarily and will be free to withdraw from the study at any time. All patient details will be fully anonymous. During the trial, all patient data will be kept in a secure data management system of first hospital of Lanzhou University which accessible only by research personnel. The study protocol is publicly available via the institution's website: http://www.chictr.org.cn/showprojen.aspx?proj=47200

Trial Status: The trial was began at 20 May 2020. The study protocol version 1, 20 December 2019. Patient recruitment for this trial is on-going, and the recruitment will be completed at June 2021.

Consent for publication

No individual-level participant data will be presented in scientific papers.

Competing interests: The authors have declared that no competing interests exist

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Figures

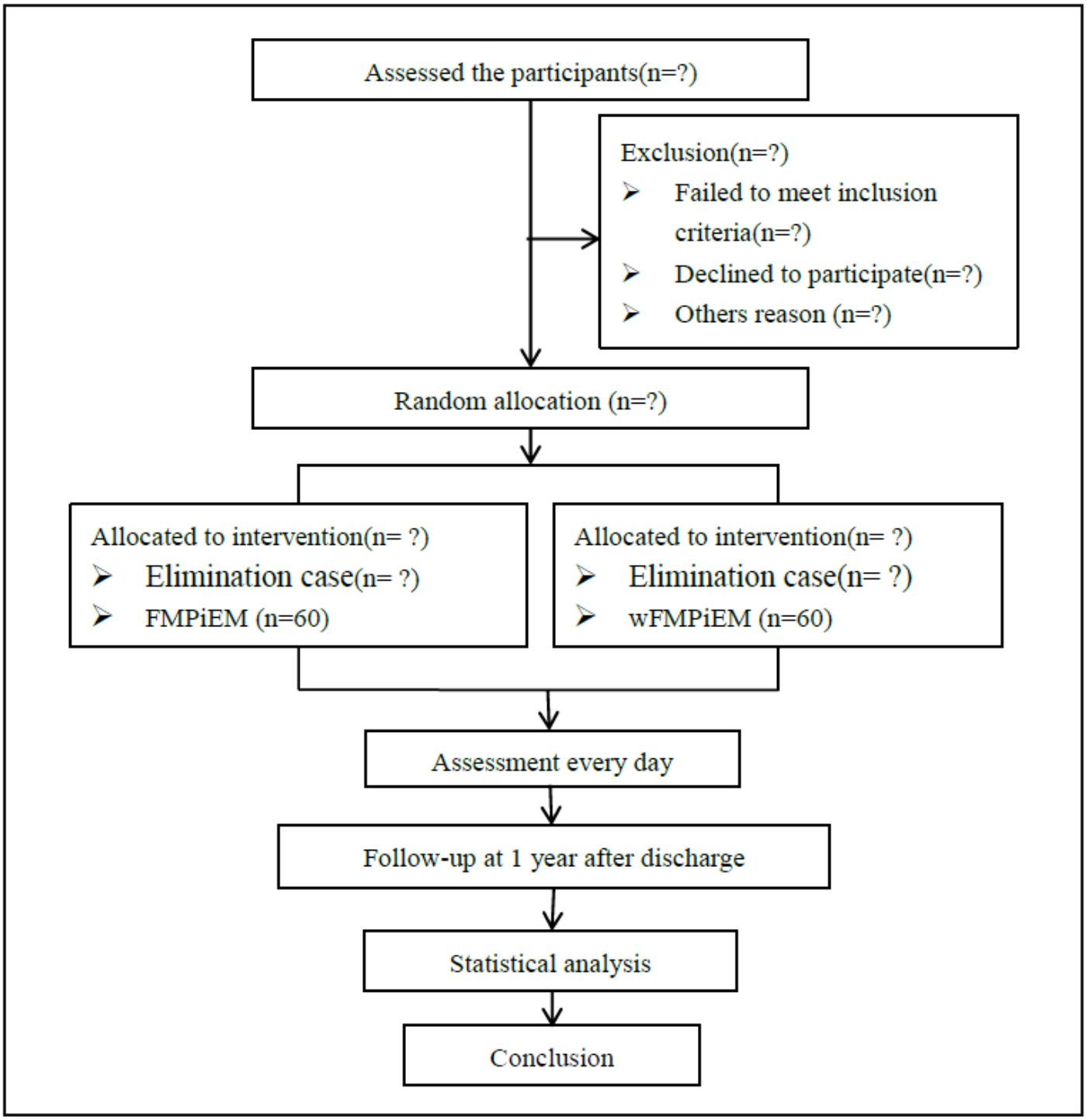

Figure 1

Flowchart of the study. This figure reports patient recruitment and follow-up over the course of the study. FMPiEM= family members participate in the early mobilization, w FMPiEM =without family members participate in the early mobilization (FMPiEM) n=sample size

Supplementary Files

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- SPIRITChecklist.pdf