#### **RESEARCH ARTICLE**



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# Effect of a fall prevention strategy for the older patients: A quasi-experimental study

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#### Abstract

**Aim:** To explore the effect of a fall prevention strategy on older patients based on the Patient Engagement Framework.

**Design:** A longitudinal quasi-experimental quantitative design.

**Methods:** Older patients who met the inclusion criteria were recruited from geriatric, oncology, neurology and cardiology departments of a teaching general hospital in China. Development of a fall prevention intervention strategy for older patients was based on the Patient Engagement Framework. Patients in the intervention group were given this fall prevention strategy (N = 58), and those in the control group were given conventional measures (N = 58). The following indicators were compared between the two groups after intervention:

(a) number of falls; (b) Knowledge-Attitude-Practice (KAP) score;

(c) Modified Fall Efficacy Scale score.

**Results:** After the implementation of an intervention strategy in older patients, the number of falls decreased from 3 to 0; the score of KAP and Modified Fall Efficacy Scale was promoted (p < .05).

#### KEYWORDS

fall prevention, hospital, older patients, Patient Engagement Framework, patient safety

# 1 | INTRODUCTION

With the increasing demographic aging of the world, the health of the older is of great concern (Bjornsdottir et al., 2021). Fall is an important issue threatening the health and safety of older patients, accounting for 40% of nursing adverse events (Tsai et al., 2017). A fall is defined as an event in which a person came to rest inadvertently on the ground, floor or other lower level (Williams et al., 2015). Fall is a major cause of injury in patients. About onethird of older patients over 65 years of age experiencing a fall every year(Cederbom & Arkkukangas 2019). The consequences of falls includ injuries, such as soft tissue injury, fracture and craniocerebral injury, as well as related fear of falls and limited mobility. Thus, falls not only seriously damaged the patients' physical and mental health and declined the quality of life, but also elongated the length of hospital stay, increased medical costs, bringing a heavy burden to the family and medical staff (Choi et al., 2020; Jun et al., 2018). Related health care expenditures in the United States reached \$55 billion in 2020 (Centers for Disease Control and Prevention Joint Commission, 2015; Wildes et al., 2015). How to effectively prevent falls in older inpatients is a great challenge for global medical institutions.

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Although there were a large number of evidence-based fall prevention interventions, patient falls still occurred and suffered from different levels of injury(Cheng et al., 2018; Pillay et al., 2021; Twibell et al., 2020). This may be due to low levels of intervention prescription by nurse and/or low uptake of interventions by older patients. A personalized fall prevention strategy was a cost-effective tool to reduce the occurrence of falls. Relevant medical organizations have proposed that encouraging patient participation was the fundamental guarantee to avoid adverse events and ensure patient safety (Patient Safety Goals, 2017).

### 1.1 | Background

Falls are the leading cause of in-hospital injury worldwide, leading to increased healthcare costs, morbidity and mortality (World Health Organization, 2018).

Older patients are at a greater risk of falling than those in the general population, mainly due to the aging process, acute illness, medicines and being unfamiliar with the hospital environment, etc (Levinoff et al., 2018). Effective fall prevention programs can ensure the safety of older patients, maximize their quality of life and have some cost-effectiveness.

Avanecean et al. (2017) and Katsulis et al. (2016) demonstrated that 92% of falls were preventable. At present, there have been many studies on the safety management of fall prevention in the world. The research content involved evidence-based nursing methods, CATCH fall management model, PISTI management model, multidisciplinary collaboration model and health education model. (Bonuel et al., 2011; Dykes et al., 2009; Jung et al., 2014). However, most of these studies were focused on nurses-led strategies and paid less attention to the core role of patients to achieve patient participation (Kiyoshi-Teo et al., 2020). For example, they kept an eye on managing the fall risk factors, such as clothing, food, housing and transportation. Despite the implementation of fall prevention measures, some older patients still fall every year.

Hill et al. (2016) and Vonnes and Wolf (2017) showed that the primary cause of falls in patients is that patients did not participate in fall prevention measures. Although nurses played an important role in patient safety management, patients' independent participation was more essential. To effectively maintain their safety, patients need to act as both supervisors and participants(Vaismoradi et al., 2014; Wright et al., 2016).

Dykes et al. (2010) have suggested that fall prevention can be divided into three steps, namely (a) fall risk assessment, (b) development of a personalized fall prevention strategy and (c) effective implementation of the strategy. Among them, selecting appropriate fall risk assessment tools was the primary step (Katsulis et al., 2016).

The "i Engaging form" was developed by Tzeng & Yin, 2014 (Tzeng et al., 2015; Tzeng & Yin, 2014). It was designed to engage patients in their own fall prevention care during hospitalization. The main functions of this form included: (1) it provided an autonomous assessment of the risk of falls in older patients; (2) it identified measures selected by patients who can do it themselves to prevent falls for each identified risk factor; The form included 13 dimensions and 59 items. It has been sinicized and tested, the item content validity index ranged from 0.867 to 1.000, and the overall content validity index was 0.956. The overall Cronbach's alpha reliability coefficient was 0.973, the test-retest reliability coefficient was 0.851, and the half-reliability was 0.913, confirming that the form was reliable. Therefore, the form potentially provided patients with an incentive to recognize potential safety hazards about fall prevention, enabled patients to discover potential safety hazards in advance, promoted their understanding of their fall risks, enhanced their self-protection awareness and helped nurses and patients to jointly develop and implement personalized fall prevention protocols.

The Patient Engagement Framework (National eHealth Collaborative, 2012) was first proposed by the National Electronic Health Association of the United States in November 2012, aimed to guide medical and health organizations to develop and implement relevant measures for patient participation through electronic information, thus creating a more effective nursing-safe model and improving the quality of care. It included five parts: informing, participation, empowerment, cooperation and electronic information support. Previous studies have applied it to patients with chronic diseases and cancer survivors in the process of disease self-management, demonstrating improved patients' satisfaction and treatment outcomes(Geng & Myneni, 2015; National eHealth Collaborative, 2012).

We developed a set of fall prevention strategies based on the Patient Engagement Framework, combined with the i Engaging form, designed to reduce falls in older patient groups. The aim of this study was to investigate the effectiveness of patient engagement in fall prevention strategy in preventing falls, enhancing their level of KAP and fall efficacy in older patients.

We hypothesized that (a) older patients would independently assess fall risk using the i Engaging form and select fall prevention measures that could be completed; and (b) the nurses and patients could jointly participate in the development and implementation process of fall prevention intervention programs. This measure effectively reduced the number of falls occurring in older patients and improved patients' KAP levels and fall self-efficacy.

## 2 | METHODS

## 2.1 | Study design and setting

This study used a longitudinal quasi-experimental quantitative design, following the criteria of the TREND statement checklist.

The study was conducted at the target hospital, a comprehensive teaching hospital in the academic health system of Hubei Province, China. It included 53 specialties, 168 wards and more than 6,000 open beds. Retrospective analysis of fall incidence during the past 3 years based on national benchmarks, and the older patients in the departments with a high incidence of falls including the geriatric, oncology, cardiology and neurology departments were recruited as the study participants.

# 2.2 | Participants and sampling

Basis for the determination of sample size in this study: formula for the comparison of the means of two independent samples,  $N = [4(\mu_{\alpha} + \mu_{\beta})^2 \times \pi (1 - \pi)]/[(\pi_1 - \pi_2)^2]$ , where N is the total sample size,  $\mu_{\alpha}$  and  $\mu_{\beta}$  are the  $\mu$  values corresponding to the test level  $\alpha$  and the probability  $\beta$  of type II error,  $\pi_1$  and  $\pi_2$  are the overall rates of the control group and the experimental group,  $\pi$  is the merging rate of the two groups. Then, the sample size was confirmed as 116 cases considering the relevant inclusion and exclusion criteria and 25% lost to follow-up rate.

Inclusive criteria were as follows: (a) aged 65 years and older; (b) fall risk was determined with the Morse Fall Scale high risk was indicated with a score of greater than 45; (c) stable condition, no medical diagnosis of serious heart, brain, lung and mental disease; (d) no presence of cognitive impairment, clear consciousness and smooth communication; (e) voluntary participation in this study. Exclusion criteria: (a) severe intellectual, visual or hearing impairment; (b) absolute bed rest.

Recruitment occurred from May 1 to December 31, 2020. The sampling plan stratified participants into two groups. Four departments randomly selected one ward as the intervention group and another ward as the control group. According to the inclusion and exclusion criteria, 58 participants were selected in the control group from May to August 2020 to implement conventional fall prevention measures; another 58 participants were selected in the intervention group from September to December 2020 to implement patients' participation in the fall prevention strategy.

#### 2.3 | Intervention

#### 2.3.1 | Control group

We summarized routine fall prevention measures through a literature review and implemented them in the control group. We included the responsible nurse who used the Morse Fall Assessment Scale to assess the patient's fall risk at admission. Then, the nurse distributed the guidance manual to the patient and educated the patient on fall prevention knowledge from the aspects of clothing, food, lying, walking and environment, respectively. The whole procedure was repeated every day during hospitalization.

#### 2.3.2 | Intervention group

A fall prevention research team consisting of one deputy director from the nursing department, four charge nurses, sixteen responsible nurses and three researchers was established, and each member of the team received specialized training. (a) The deputy director of the nursing department was the group leader, responsible for comprehensive guidance and coordination management; (b) the head nurse of each department was the deputy group leader, who was responsible for including the study participants, and supervision and quality control of the interventions; (c) each department selected and assigned four responsible nurses with more than 3 years of work experience, who were responsible for implementing interventions and data collection; (d) Three researchers were responsible for consulting materials, data analysis and quality control.

The intervention group took the Patient Engagement Framework as the theoretical framework. Through literature review, thematic group discussion and pre-survey, we developed and implemented an intervention strategy for older patients' participation in fall prevention, including five parts: informing, participation, empowerment, cooperation and electronic information support.

#### Step1: Informing

Within 4 hr after admission, the responsible nurse played the fallrelated videos for the patient through tablet computers, including the definition, incidence and adverse consequences of falls, so that the patients were aware of the severity of falls and the importance of preventing falls. Moreover, they explained the significance and specific methods of independent participation in fall prevention to promote patient's understanding and cooperation.

#### Step2: Participation

The responsible nurse instructed the patient to fill in the "i Engaging form" online to assess the fall risk and selected the fall prevention measures that the patient was able to complete. The system automatically generated the assessment results.

#### Step3: Empowerment

Nurses and patients jointly analysed the results of the fall risk assessment. The nurse explained the fall cases with similar risk factors to the patient if the patient missed or chose more options so that the patient could correctly understand the personal risk and the correct behaviour. After the nurse and patient reached a consensus, the assessment results were adjusted appropriately, and the personalized fall prevention plan sheet was automatically generated, which was printed out and retained by the nurse and patient for one copy each. The fall prevention plan included the following contents: basic information on patient admission, fall risk factors and corresponding fall prevention measures. The responsible nurse distributed the "Fall Prevention Guidance Manual" to the patient and played the fall prevention video during hospitalization so that the patient was familiar with the fall risk factors and the corresponding fall prevention behaviours. If there were still unclear parts, the nurse cooperated with the patient to read the manual and watch the video again to further promote the understanding and memory of the patient. In addition, the patient could choose colour cards with common fall prevention points written on and hung beside the bed as a reminder. During hospitalization,

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if the patient found any factors that might increase the risk of falling, such as failure of call bell, failure of bed rail or bed wheel, liquid or obstacles on the ground, and damage of ground lamp, the patient could inform the nurse at any time.

## Step4: Cooperation

To deepen the patient's understanding of fall scenarios and correct behaviours to prevent falls, those patients with a history of falls were invited to share the experience. After each intervention, the nurse communicated with the patient to evaluate their mastery of fall prevention measures through situational demonstrations and role-plays in different scenarios, such as getting up, walking, going to the toilet and using assistive devices. If necessary, the nurse demonstrated the correct behaviour on the spot until the patient mastered the key points. In addition, the nurse should encourage the patient to express doubts and difficulties encountered during the intervention, listen to their psychological feelings patiently, discuss solutions with both sides and adjust the intervention plan appropriately. According to the patient's condition and tolerance, the nurse could flexibly arrange the daily intervention time and specific content, which should be limited to 30 min. Then, the patient signed and marked in the corresponding column according to the mastery of the measures. The responsible nurse evaluated the patient's feedback, daily behaviour intervention and situational demonstration. The head nurse asked about the patient's knowledge level at any time and supervised the effective implementation of the patient's daily behaviour with the nurse. Finally, the results were fed back to the researchers, who should also regularly go to the bedside to follow the implementation of the patient's plan and make appropriate adjustments.

## Step 5: Electronic information support

The relevant scales and questionnaires were imported into the hospital's electronic information system. And the results could be automatically generated. Nurses and patients adjusted the fall prevention program sheet according to the assessment results. Besides, to help the patients comprehensively understand their diseases and fall risk, nurses played fall-related videos for patients on tablet computers and patients could check their health records using tablet computers at any time.

# 2.4 | Instruments

# 2.4.1 | KAP scale

The scale was composed of three dimensions: knowledge (11 items), attitude (9 items) and practice (13 items). Each item was scored from one (unclear) to four (very clear). The higher the score, the higher the level of KAP. The scale exhibited good internal consistency reliability with Cronbach's alpha = 0.952 and content validity = 0.945 (Li, 2016).

# 2.4.2 | Modified fall efficacy scale

MFES mainly evaluated the patients' confidence in avoiding falling when they were engaged in relevant activities, including nine indoor items and five outdoor items. The scores ranged from 0 to 10 points. 0 indicated no confidence, five indicated general and 10 represented high confidence. The lower the total score, the lower the fall efficacy or confidence and the higher the fear of falling. The Cronbach's alpha was equal to 0.921, the test-retest reliability coefficient was equal to 0.906, and the total content validity index was equal to 0.834(Edwards & Lockett, 2008).

#### Additional Instructions

All research tools included in this study were used with the permission of the original author or translator email. Regarding KAP scale and MFES, the study used the instruments without any modifications or translation. And through translation, back translation, crosscultural debugging, expert consultation and pre-investigation, the study used the Chinese version of the "i Engaging form."

# 2.5 | Data collection

The intervention was started on the day of admission and ended on the day of discharge. Before the intervention, patients filled in a general data questionnaire online for baseline assessment. Before and after the intervention, the KAP scale was used to measure the level of knowledge and belief in fall prevention in older patients; MFES was used to assess the level of fall self-efficacy in patients, and the data were directly entered into a web-based database through an iPad. Falls were defined as previously described, the responsible nurse counted the fall data.

#### 2.6 | Data analysis

Data analysis was performed by using SPSS Version 26.00 (IBM, Chicago, IL, USA) (IBM Corp, 2012). Participant characteristics were described using frequencies or percentages for categorical variables and means, standard deviations, medians and interquartile ranges (IQR) for continuous variables. In addition, the t-test, chi-square test and rank-sum test were performed depending on whether the normal distribution was met. All tests were two-tailed and p-values less than 5% were considered statistically significant.

## 2.7 | Ethical considerations

This study was reviewed and deemed exempt by the Institutional Review Board of target Hospital, which was affiliated with the university where the research team worked. Informed consent was obtained from all eligible participants. The authors deny any conflict of interest. LEV\_NursingOpen

#### 3.1 **General information**

As shown in Table 1, there were no statistically significant differences between the intervention group and control group in basic demographic information including gender, age, educational levels, living conditions, the main source of income, payment category, main caregivers during hospitalization and fall history.

#### 3.2 Number of falls

A total of three falls occurred in the control group, while no falls occurred in the intervention group.

#### 3.3 **KAP** score

As shown in Table 2, statistically significant difference in KAP scores before and after the intervention. The mean score of "knowledge, attitude and practice" in the intervention group was  $(24.22 \pm 2.29)$ , (18.76  $\pm$  1.95) and (28.79  $\pm$  2.42), which was significantly (p < .01) higher than  $(19.64 \pm 2.40)$ ,  $(15.69 \pm 2.31)$  and  $(25.41 \pm 2.27)$  in the control group, respectively.

#### Modified fall efficacy scale score 3.4

As shown in Table 3, statistically significant difference in MFES scores before and after the intervention. The score of the modified fall efficacy scale in the intervention group ( $64.34 \pm 6.27$ )

		Intervention	Control		
Variable	Categories	Group( <sup>-</sup> X ± SD)/N(%)	Group( <sup>-</sup> X±SD)/N(%)	Statistics	p-Value
Gender				$\chi^2 = 1.945$	.163
	Male	36(62)	43(74)		
	Female	22(38)	15(26)		
Age(years)		73.67±8.23	$71.34 \pm 7.61$	<i>t</i> = 1.759	.081
Education degree				Z = .247	.805
	Primary school and below	17(29)	19(32)		
	Middle school or secondary school	25(43)	23(40)		
	College degree and above	16(28)	16(28)		
Living conditions				$\chi^2 = 2.030$	.566
	Live alone	4(7)	6(10)		
	Live with spouse	37(64)	36(62)		
	Live with family	17(29)	16(28)		
The main source of income				$\chi^{2} = .738$	.691
	Provided by relatives	13(22)	17(29)		
	Pension	41(71)	37(64)		
	other	4(7)	4(7)		
Payment category				$\chi^2 = 2.692$	.442
	Own expense	1(2)	3(5)		
	Medical insurance	49(84)	49(84)		
	Cooperative medical service	8(14)	5(9)		
	other	0(0)	1(2)		
Main caregivers during hospitalization				$\chi^{2} = .287$	.962
	Spouse	29(50)	31(53)		
	Relatives	25(43)	24(42)		
	Nursing Workers	3(5)	2(3)		
	No	1(2)	1(2)		
Fall history				$\chi^{2} = .210$	.647
	Yes	13(22)	11(19)		
	No	45(78)	47(81)		

#### **TABLE 1** Demographic and clinical characteristics (N = 116)

TABLE 2 Comparison of the scores of KAP of the two groups before and after the intervention

		Knowledge sco	$Attitude \ score(^{-}X \pm SD) \qquad Attitude \ score(^{-}X \pm SD)$		Practice score( $X \pm SD$ )		
Groups	Numbers	Before	After	Before	After	Before	After
Control group <sup>a</sup>	58	$19.57 \pm 2.37$	$19.64 \pm 2.40$	$15.62 \pm 2.25$	$15.69 \pm 2.31$	$25.33 \pm 2.55$	$25.41 \pm 2.27$
Intervention group <sup>b</sup>	58	19.33±2.56	24.22±2.29	$15.97 \pm 2.70$	$18.76 \pm 1.95$	25.34±2.98	$28.79 \pm 2.42$
t		.527	10.510	.747	7.731	.033	7.756
р		.599	.000	.456	.000	.973	.000

<sup>a</sup>May-August 2020.

<sup>b</sup>August-December 2020.

TABLE 3 Comparison of the scores of MFES of the two groups before and after the intervention

		Fall efficacy score( $X \pm SD$ )		
Groups	Numbers	Before	After	
Control group <sup>a</sup>	58	$60.71 \pm 7.50$	61.07±7.55	
Intervention group <sup>b</sup>	58	59.14±8.22	64.34±6.27	
$t/\chi^2$		1.073	2.542	
р		.285	.012	

<sup>a</sup>May-August 2020.

<sup>b</sup>August-December 2020.

was significantly increased compared with that in the control group ( $61.07 \pm 7.55$ ) (p < .05).

# 4 | DISCUSSION

In this study, a patient-centered intervention based on the Patient Engagement Framework resulted in a reduction in the number of falls, and the level of knowledge and belief and fall efficacy of patient fall prevention were improved. This intervention strategy developed personalized measures based on fall risk factors in different patients, while conventional fall prevention measures were targeted at multiple fall risk factors. These targeted approaches were an effective strategy to optimize implementation.

# 4.1 | The influence of an intervention strategy on the incidence of falls among older patients

Gettens et al. (2018) study revealed that in a hospital setting, a more individualized and patient-centered approach to fall prevention may improve the effectiveness of fall interventions. Studies such as Dykes et al. (2017) have shown that patient engagement is the key to effective fall prevention.

This study confirmed that the intervention strategy involving older patients' participation in fall prevention significantly reduced the number of falls. The intervention eliminated the blindness and passivity of conventional measures, and realized the transition from the traditional fall prevention mode to the new mode of patient participation in fall prevention. The patients in the intervention group participated in the process of self-assessment, targeted planning, implementation and dynamic evaluation of fall prevention, creating an atmosphere of "everyone participates in patient safety management." Based on the informatization platform, the intervention process could be optimized, and the evaluation results and personalized fall prevention plan sheet were automatically generated. The nursing staff implemented the corresponding measures according to individual conditions, through the step-by-step process of "understanding-familiarity-mastery," which ensured the standardization, systematicness and efficiency of the fall prevention intervention process.

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Twibell et al. (2020) have also proposed to encourage nurses to cooperate with patients and families to develop personalized fall prevention plans, which helps to promote patient participation in fall prevention; however, the study mentioned that patients were willing to call nurses before going to the toilet to participate in fall prevention but were reluctant to wait a long time to get help. Hill et al. (2016) & Radecki et al. (2018) research indicated that waiting time was listed as the main obstacle factor for patients to participate in fall prevention, so it is still necessary to explore relevant protocols to shorten the waiting time for patients to go to the toilet and other matters, so as to promote the effective operation of patients to participate in fall prevention.

# 4.2 | The influence of an intervention strategy on the KAP levels of older patients

It was found that the intervention strategy involving older patients' participation in fall prevention significantly improved the KAP levels of older patients (p < .01). The previous report has shown that the key to preventing patients from falling is to correct their fall prevention behaviours, based on obtaining sufficient knowledge and forming a correct attitude(Tao et al., 2014). The studies of Zhao et al. (2016) and Radecki et al. (2018) have shown that patient participation is not determined by the information delivered by medical staff, but the information truly digested and absorbed by patients. When the perceptibility of both sides was consistent, the patients had a better experience of seeking

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medical care, which might promote their enthusiasm to participate. The above result was consistent with that of this study.

Fall risk assessment was essential to prevent falls in older patients, and "healthcare reevaluation, zero patient involvement" was a widespread problem at present. Radecki et al. (2018) found that patient participation in fall risk factor assessment could help them understand why nurses value fall prevention and give nurses a deeper understanding of patients' cognitive situation. Patients in the intervention group used the "i Engaging form" to independently assess fall risk, which could find risk factors that nurses might not pay attention to, thus obtaining more accurate fall risk assessment results. According to the evaluation results, nurses and patients jointly developed a personalized fall prevention plan to avoid conveying useless information by nurses' subjective judgement, so that patients could learn and consolidate necessary knowledge within a limited time. Meanwhile, explanation manuals, videos, situational demonstration, role-play, peer support and other diversified activities were arranged in the fall prevention plan, according to the needs of patients, to help patients effectively absorb and transform the knowledge into daily behaviours.

# 4.3 | The influence of an intervention strategy on the fall efficacy of older patients

Fall efficacy refers to the degree of individual confidence to avoid falling daily activities and it is an important indicator to predict whether falls reoccur (Li & Cheng, 2016). Kiyoshi-Teo et al. (2019) showed that concerns about falls and patient activity related to fall prevention were positively correlated with the frequency of fall prevention behaviours. This study confirmed that an intervention strategy involving older patients' participation in fall prevention significantly improved the patients' level of fall efficacy (p < .05). After the patients participated in the assessment of fall risk and the development of preventive measures, they understood the severity of fall risk and preventive ability, which helped them overcome the fear of falls and enhance confidence in avoiding falling during daily activities. In addition, an intervention strategy encouraged patients to perform daily activities within their capacity and promoted muscle strength recovery, thereby effectively improving the level of fall efficacy.

# 5 | LIMITATIONS

This study has various limitations. Firstly, this study did not employ a randomized method to recruit study subjects. Secondly, a singlecenter study with relatively limited study time and sample size may not represent other non-urban centers, limiting the generalizability of the study. Thirdly, interventions can be refined based on an evidence-based approach, increasing their scientificity and practicality. Finally, in addition to the primary outcome measures, multiple secondary indicators, such as economic benefits, should be set to comprehensively evaluate the overall effect of an intervention strategy reflected in different fields.

# 6 | CONCLUSIONS

In this study, we developed and implemented a fall prevention intervention strategy for older patients based on the Patient Engagement Framework, and realized the whole process of patient participation in fall prevention assessment-plan-implementation-evaluation. An intervention strategy reduced the occurrence of falls; they effectively improved the score of KAP and MFES of fall prevention in patients. It is expected to provide a reference for nursing staff to prevent falls clinically.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

#### ETHICS STATEMENT

This study was approved by the Institutional Review Board of the Ethics Committee of the Affiliated Tongji Hospital, Tongji Medical College of Huazhong University of Science and Technology (TJ-IRB20191209). All the subjects approved participation in the study and signed the informed consent.

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