

Evaluation of simplified fluid intake and output recording schemes for the self-management in patients with heart failure: a randomized controlled trial

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Abstract

Background

Fluid management plays a pivotal role for heart failure (HF) patients. Medical fluid intake and output recording scheme by health care professional is complicated, which is not easily conducive to carry out by HF patients for self-management at home. This study aimed to optimize the professional fluid records for the self-management of HF patients and evaluate the effectiveness of this simplified recording scheme of fluid intake and output.

Methods

A randomized, non-blinded, non-inferiority trial with allocation concealment was conducted. Participants meeting the diagnostic criteria for HF were randomly assigned to professional recording group (PRG) and simplified recording group (SRG) according to the random allocation sequence generated by online tool. Days from admission to clinical stability (primary outcome), clinical congestion score (CCS), Minnesota Living with Heart Failure Questionnaire (MLHFQ) and frequency of electrolyte disturbances (secondary outcomes) were collected. The outcomes judges were blinded to group assignment.

Results

A total of 140 HF patients were enrolled and randomly divided into PRG (n=70) and SRG (n=70). Ultimately, 129 HF patients (PRG, n=65, and SRG, n=64) completed these experiments. Compared to PRG patients, SRG patients also improved their HF symptoms (including shortness of breath and fluid retention), and did not show the prolonged hospitalization time after similar intravenous diuretic treatment. Additionally, the parameters of clinical stability, CCS, MLHFQ, electrolyte disturbances and body weight in SRG patients were not inferior to that of PRG patients (P >0.05).

Conclusions

This simplified fluid intake and output recording scheme was safe, efficient and non-inferior to the professional mode, which might effectively enhance their feasibility of self-management, and improve their quality of life in HF patients.

Background

Heart failure (HF) is a chronic and complicated syndrome [1, 2]. Although HF treatment has developed, the long-term mortality improves poorly [3–5]. More than 1 million of HF patients are hospitalized each year, which almost occupy the top reason for elderly subjects admitted to hospital and account for more than \$30 billion of health care expenditure in USA [6, 7]. HF decreases the quality of life, and the effective treatment and care could remarkably alleviate their signs and discomforts [8]. Although fostering self-management skills in HF patients seems to be useless to reduce their mortalities, it could improve the quality of life and decrease the readmission rates [9]. Surprisingly, the awareness rate of HF is much lower

than that of expected in these patients, even those who have recurrent HF symptoms and follow the medical instructions for many years [10, 11]. Meanwhile, most HF patients usually feel unprepared to manage their life styles at home [8].

Fluid management plays a pivotal role in the self-care of HF patients, which could avoid the recurrent dyspnea symptoms [1, 2]. However, an effective fluid management is a challenging task for HF patients owing to the dynamic fluid status. Evaluation of fluid situation in vivo include monitoring body weight, counting fluid intake and output as well as physical examination (e.g. jugular venous distention, hepatojugular reflux, lung rales and pedal edema). Physical examination usually need the assistance of health care professionals [1, 2, 12]. While either in hospital or at home, monitoring body weight and recording fluid changes of intake and output remain two basic issues, especially after HF patients return to their daily life. In fact, it is controversial to regard body weight as a major indicator for fluid evaluation. Because body weight is often affected by many factors, including clothes, diet, testing time, and ambient temperature [13]. Additionally, monitoring body weight sometimes is not easy to be performed, especially in those patients who are bedridden for years. Although many clinic guidelines for HF recommend that these patients should record their body weight every day, almost few acute HF accidences are forecasted through monitoring body weight due to the lower sensitivity of weight gain (9%) [14].

In addition, there are great differences in the diet compositions and habits between Western and Eastern subjects, causing an inconsistent understanding for water contained in foods. In Western countries, besides common solid and liquid foods, people often consume much semi-solid foods (e.g. purees and gelatin) which contain much water, and fluid in these foods is often calculated and counted [13]. In China, water in solid foods is also calculated and converted to fluid intake based on the moisture scales of foods following the professional fluid intake recoding schemes [15]. Additionally, it is awkward that the feces should always be considered. And the differences of ingredients and cooking methods, the irregularity of cognition in HF patients and their family members, and the tedious mode of professional recording scheme could all cause the poor compliance of monitoring fluid intake and output [16]. Therefore, whether the professional recording scheme could be simplified more easily for the self-management of HF patients at home, should be reconsidered.

In this study, a simplified recording scheme of fluid intake and output for HF patients was developed, which was safe, efficient and non-inferior to the professional mode in clinical stability, electrolyte imbalances and cardiac functions. This modified fluid recording mode, as an effective supplement to body weight for fluid self-management, might improve the quality of life and reduce the recurrent hospitalization times for HF patients.

Methods

Design

Using a blinded end-point adjudication, a single-center randomized controlled trial (RCT) was conducted to evaluate the effectiveness between the simplified and professional intake and output recording schemes.

Participants

This study was carried out from October 1, 2018 to April 30, 2019 in the department of Cardiology of a tertiary first-class comprehensive hospital in southeastern China. The inclusion criteria were (i) age ≥ 18 years, (ii) diagnosis of HF according to 2017 ACC/AHA/HFSA Heart Failure Focused Update Guidelines with combination of clinical symptoms, physical examination, chest X-ray and echocardiography [12], (iii) New York Heart Association (NYHA) class III-IV or Killip class II-IV, and (iv) daily fluid intake and output records following doctors' advices. The exclusion criteria consisted of hemodialysis, peritoneal dialysis, bedside ultrafiltration, continuous kidney substitution treatment (CRRT), cancer and another uncooperative disease (e.g. dementia and cognitive impairment).

Sample size

Sample size was calculated basing on 2-sample equivalence model. The minimum sample size was calculated as 100 participants according to the significant level of α = 0.05, the statistical power of 80%, the mean difference less than 1.3 days to clinical stability (primary outcome) between two groups, and the standard deviation of 2 days in each group from pretest [17]. Given an estimation drop-out rate (28%), including in-hospital mortality rates and the ward conversion rates, a total of 140 HF patients were enrolled.

Randomization and allocation concealment

After signing an informed consent and undergoing a basic assessment, HF patients were randomly assigned by using a random number table through an online random tool (https://tools.medsci.cn/rand/getNumWithCode) (random number seed: 70472134). Researcher No.1 was responsible for the randomization process, but not participating in the enrollment. Enrollment was performed by investigator No.2. In order to avoid mutual contamination among HF patients in the same ward, the potential patients in the same wards were also excluded. One hundred and forty patients were randomized and assigned to the professional recording group (PRG) or the simplified recording group (SRG). Eleven patients were excluded lately because of losing observation, in-hospital death, or transferring to other departments.

Interventions

PRG patients proceeded the standard recording scheme of fluid intake and output according to the nursing textbook [15]. The intake fluid included oral fluid, "embedded water" in foods, "generated water" from food metabolism, intravenous infusion and blood transfusion. The output fluid included urine, feces, insensible losses (through skin and lung), drainage liquid, vomit, hemoptysis and sputum, bleeding, and wound drainage. SRG patients carried on a simplified record which optimized the fluid embedded in or generated from foods and those in feces as shown in Table 1.

Table 1
Comparison of fluid intake and output records between SRG and PRG [14, 16]

Items	SRG	PRG			
Intake					
Oral and tube-feeding fluid	measured as "ml" by a graduated cylinder	measured as "ml" by a graduated cylinder			
Non-liquid foods	excluding	measured as "ml" if becoming liquid at room temperature; converted to water content by referring to the food moisture scale [†]			
Intravenous fluid including all fluid, whole blood or blood components	measured as "ml"	measured as "ml"			
Output					
Urine and tube drainage	measured as "ml" in a graduated cylinder	measured as "ml" in a graduated cylinder			
Feces	excluding	liquid feces measured as "ml"; recording the number of defecations			
Vomitus, hemoptysis and sputum, the drainage of wound, fistula and tube	measured as "ml" or recording the type and numbers of dressings	measured as "ml" or recording the type and numbers of dressings			
Abbreviations: SRG, simplified recording group; PRG, professional recording group.					
[†] Fluid in food should be calculated by conversion according to Chinese Textbooks [16]					

Liquid foods were measured by using a container with "ml" capacity scale. Non-liquid foods were weighed by using a uniform electronic scale and recorded as "g". Especially, PRG patients should calculate the content of water according to food moisture conversion table [15]. Urine was measured as "ml" by a graduated cylinder, and watery stools were weighed. For those patients with poor education or memory, the procedures were completed with the help of their family members or nurses.

Outcome measurements

The primary outcome was the days from admission to clinical stability, which was defined by a decrease of 2 points of clinical congestion score (CCS) and the cessation of all intravenous pharmacotherapy (e.g. diuretics, inotropes or vasodilators) [17–19]. CCS is an instrument composed of 7 questions, which are designed to assess the congestion degrees in HF patients [20]. The score ranges from 1 to 22 points, and the higher scores imply the worse congestion degrees. Clinical stability was independently judged by investigator No.3 and cardiologist Dr.1 every day. If the judgment was not inconsistent, it should be determined by cardiologist Dr. 2. The group allocation was blinded to all judgers.

The secondary outcomes included the electrolyte disturbances, N-terminal pro brain natriuretic peptide (NT-proBNP) levels, body weight, CCS reached clinical stability, length of stay (LOS), and the scores of MLHFQ. The most common electrolyte disturbances are high or low levels of serum sodium and potassium [21, 22]. In this study, they were defined as: hyponatremia (serum sodium level < 135.00 mmol/l), hypernatremia (serum sodium level > 145.00 mmol/l), hypokalemia (serum potassium level < 3.50 mmol/l), and hyperkalemia (serum potassium level > 5.00 mmol/l) [23]. In addition, body weight was recorded after 24 hours since ceasing intravenous pharmacotherapy. All above were in the charge of researcher No. 3.

Statistical analysis

Data were expressed as mean \pm SD for normally distributed variables or as median [IQR] for skewed variables. The differences between groups were assessed by using independent Student's t test (for normally distributed variables) or Mann-Whitney test (for skewed variables). Percentages were used to summarize the categorical variables. Pearson x^2 test was used to analyze the differences between groups for categorical variables. As a non-inferiority trial, all analyses were performed by per-protocol sets. The significant level was set at P < 0.05. All analyses were performed by using statistical program IBM SPSS software (Version 25.0).

Results

Within a period of eight months, 140 participants were enrolled to the trial with 9 participants droppingout. The flow chart of the recruitment and allocating was shown in Fig. 1.

Clinical characteristics

The clinical characteristics for PRG (n = 65) and SRG (n = 64) were presented in Table 2. There was no significant difference in body weight, hemoglobin, red blood cell (RBC), hematocrit, red cell distribution width (RDW), albumin, osmotic pressure, NT-proBNP, classification of cardiac function, left ventricular ejection fraction (LVEF), complications, use of intravenous diuretics, and the completeness of intake and output records (P \boxtimes 0.05). Meanwhile, hospitalization days and CCS accessed at admission in both groups were also similar respectively (P \boxtimes 0.05).

Table 2
Clinical Characteristics of SRG and PRG Members

Variables	ALL (n = 129)	SRG (n = 65)	PRG (n = 64)	Significance	Р
Age, mean ± SD, years	69.96 ± 5.84	69.05 ± 5.92	70.89 ± 5.65	0.185 [†]	0.073
Male, n (%)	82(63.6)	40(61.5)	42(65.6)	0.233 [‡]	0.630
body weight, median [IQR], kg	65.00[10.00]	66.00[10.00]	65.00[9.75]	-1.914 [§]	0.056
Hemoglobin, mean ± SD, g/l	123.52 ± 25.21	119.74 ± 27.77	127.36 ± 21.88	2.792 [†]	0.086
RBC, mean ± SD, ×10 ¹² /I	4.18 ± 0.80	4.07 ± 0.83	4.30 ± 0.76	0.893 [†]	0.106
Hematocrit, mean ± SD	0.37 ± 0.10	0.36 ± 0.07	0.38 ± 0.06	-1.471 [†]	0.144
RDW, median [IQR], %	13.10[3.35]	13.40[2.40]	13.10[3.75]	-0.391 [§]	0.696
Albumin, median [IQR], g/l	37.00[5.00]	37.00[5.00]	37.00[5.50]	-1.658 [§]	0.097
ALT, median [IQR], units/I	22.00[18.00]	20.00[18.50]	22.50[19.00]	-0.752 [§]	0.452
AST, median [IQR], units/I	23.00[16.50]	21.00[12.00]	25.00[16.75]	-1.520 [§]	0.128
Triglyceride, median [IQR], mmol/I	1.23[0.68]	1.16[0.64]	1.28[0.80]	-0.016 [§]	0.987

§Determined by Mann-Whitney U test.

[†]Determined by Student´s t test.

[‡]Determined by Pearson Chi-square test.

Variables	ALL (n = 129)	SRG (n = 65)	PRG (n = 64)	Significance	Р
TC, mean ± SD, mmol/l	3.72 ± 1.08	3.59 ± 1.02	3.86 ± 1.14	1.271 [†]	0.174
HDL, median [IQR], mmol/I	0.91[0.36]	0.92[0.43]	0.90[0.28]	-0.294 [§]	0.768
LDL, mean ± SD, mmol/l	2.45 ± 1.035	2.35 ± 1.01	2.56 ± 1.06	-1.127 [†]	0.262
FBG, median [IQR], mmol/l	5.70[2.05]	5.81[2.87]	5.67[1.71]	-0.290 [§]	0.772
UN, median [IQR], mmol/l	7.40[3.95]	7.30[4.25]	7.85[3.80]	-0.777 [§]	0.437
Creatinine, median [IQR], umol/I	94.00[45.50]	97.00[41.50]	93.50[48.75]	-0.040 [§]	0.968
UA, mean ± SD, umol/l	389.40 ± 132.36	383.52 ± 127.31	395.36 ± 138.05	-0.506 [†]	0.613
Osmotic pressure, median [IQR], mOSM/I	282.00[10.50]	282.00[8.50]	282[13.75]	-0.391 [§]	0.696
NT-proBNP, median [IQR], pg/ml	2764.00[3451.25]	2652.00[3485.00]	2843.00[3241.00]	-0.255 [§]	0.799
Cardiac functions, n (%)				8.179 [‡]	0.085
NYHA 🛚	39(30.2)	21(32.3)	18(28.1)		
NYHA 🛚	16(12.4)	3(4.6)	13(20.3)		

§Determined by Mann-Whitney U test.

[†]Determined by Student´s t test.

[‡]Determined by Pearson Chi-square test.

Variables	ALL (n = 129)	SRG (n = 65)	PRG (n = 64)	Significance	Р
Killip 🛚	33(25.6)	20(30.8)	13(20.3)		
Killip 🛚	26(20.2)	14(21.5)	12(18.8)		
Killip 🛚	15(11.6)	7(10.8)	8(12.5)		
LVEF, mean ± SD, %	45.26 ± 5.84	44.91 ± 5.38	45.63 ± 6.29	-0.697 [‡]	0.487
Combined with AMI, n (%)	74(57.4)	41(63.1)	33(51.6)	1.748 [‡]	0.186
Combined with Hypertension, n (%)	62(48.1)	30(46.2)	32(50.0)	0.191 [‡]	0.662
Combined with DM, n (%)	49(38.0)	25(38.5)	24(37.5)	0.013 [‡]	0.910
Combined with AF, n (%)	30(23.3)	18(27.7)	12(18.8)	1.445 [‡]	0.229
Combined with CKD, n (%)	13(10.1)	5(7.7)	8(12.5)	0.823 [‡]	0.364
IV of loop diuretics, n (%)	87(67.4)	43(66.2)	44(68.8)	0.099 [‡]	0.753
Completing intake and output record independently, n (%)	117(90.7)	57(87.7)	60(93.8)	1.403 [‡]	0.236

[†]Determined by Student´s t test.

[‡]Determined by Pearson Chi-square test.

[§]Determined by Mann-Whitney U test.

Variables	ALL (n = 129)	SRG (n = 65)	PRG (n = 64)	Significance	Р
CCS at admission, mean ± SD	9.84 ± 1.89	9.74 ± 1.88	9.95 ± 1.91	-0.642 [†]	0.522

[†]Determined by Student's t test.

[‡]Determined by Pearson Chi-square test.

§Determined by Mann-Whitney U test.

Comparison of outcomes

Compared to PRG patients, SRG patients also improved HF symptoms (e.g. shortness of breath and peripheral fluid retention) in the similar treatment duration after using intravenous diuretics. Shortness of breath and peripheral fluid retention are two important items in CCS [20]. Collectively, CCS between two groups also showed no statistical differences (SRG, 3.89 ± 0.99 vs. PRG, 4.19 ± 1.10 ; P = 0.110). In addition, there were no significant differences of clinical stability in the days from admission to improvement between two groups. Furthermore, SRG patients also did not show the prolonged hospitalization time. Therefore, both groups exhibited the similar improvement in HF symptoms and clinical signs. Besides, there was no statistical significance in the incidence of hypokalemia, hypornatremia, and hypernatremia as reported in Table 3 (P\(\text{P}\(\text{0}.05 \)).

Table 3
Comparison of the days to clinical stability between two groups

Outcomes	SRG	PRG	Significance	Р
Hypokalemia or hyperkalemia, n (%)	17(26.2)	14(21.9)	0.323 [§]	0.570
Hyponatremia or hypernatremia, n (%)	17(26.2)	15(23.4)	0.128 [§]	0.721
NT-proBNP, median [IQR], pg/ml	1781.00[3188.75]	1764.00[2730]	-0.672 [†]	0.502
Body weight, median [IQR], kg	65.00[13.50]	65.00[10.75]	-0.758 [†]	0.449
Days to clinical stability, median [IQR], days	7.00 [4.00]	7.00 [3.75]	-0.556 [†]	0.578
CCS reached clinical stability, mean ± SD	3.89 ± 0.99	4.19 ± 1.10	-1.608 [‡]	0.110
LOS, mean ± SD, days	14.32 ± 2.37	15.05 ± 2.99	-1.525 [‡]	0.130

Abbreviations: CCS, clinical congestion score; IQR, interquartile range; LOS, length of stay; NT-proBNP, N-terminal pro brain natriuretic peptide; PRG, professional recording group; SD, standard deviation; SRG, simplified recording group.

Discussion

HF is a terminal outcome of many cardiovascular diseases [2]. Effective fluid management is a principal way for HF treatment and care [24]. Body weight, urine volume and net fluid balance are considered to reflect the dynamic changes of fluid in vivo [1, 2, 12]. However, it is a hard challenge to obtain an accurate net fluid output and a series of body weight changes both in hospital and at home every day [14, 25]. In this study, we simplified the fluid intake and output recording scheme that was much easier than the professional mode for the self-management of HF patients, and it was also efficient to monitor clinical stability and electrolyte balances. Therefore, this simplified fluid recording scheme might effectively help HF patients improve the quality of life, reduce the recurrent hospitalization times, and especially enhance the feasibility of self-management.

Given the decreased activities of endurance and the difficulties of changing positions from recumbent to standing, monitoring weight daily is often rejected by HF patients. In addition, the accuracy of body weight measurement was also interfered by many factors [26]. Furthermore, as one of the common markers to

[†]Determined by Mann-Whitney test.

[‡]Determined by Student's t test.

[§]Determined by Pearson Chi-square test.

assess congestion, daily weight loss has no direct relationships with fluid loss and symptom improvement [27, 28]. Thus, only monitoring body weight hardly reflect the daily fluid balance.

Measuring fluid intake and output has long been supposed to be precise and normative. However, it is hard to carry out owing to the low self-management abilities and the complexities of counting fluid intake and output for HF patients [16]. These patients often forget to record fluid intake, reduce the cooperation to collect urine and stool, and ignore to count the fluid contained in foods (such as fruits and vegetables) [29]. In many cases, HF patients are educated to regularly measure fluid intake and output following the textbook disciplines. However, these patients often encounter the changes of lifestyle and physiological state, including bedridden with weakness, urea incontinence and so on. Therefore, this study simplified the professional recording scheme, defining fluid intake and output as net fluid volume. In contrast to the professional mode, it is easier to be manipulated and followed by HF patients. And it did not change the clinical stability and increase the disorders of electrolyte in HF patients. The body weight and NT-proBNP also presented no significant difference (P > 0.05). Some studies also showed that non-dogmatic recording schemes does not cause other adverse results [30].

Researchers recommended that severe HF patients should moderately restrict fluid, including no more than intaking 1,500–2,000 ml of water, and over 500 ml of additional net output every day [1, 9, 12]. Generally, healthy subjects intake fluid about average 1,500 ml/day in normal conditions. However, the body actually need about 2,500 ml of water to maintain the physical functions. The additional 1,000 ml of water is acquired from "embedded water" (150 ml) contained in foods and "generated water" (750 ml) from food metabolism which is produced from tricarboxylic acid (TCA) cycle and oxidative phosphorylation processes (mainly carbohydrate and fatty acids) (13). The fluid output include: urine about 1,400-1,500 ml/day, feces about 100–200 ml/day, and insensible loss about 800–900 ml/day (e.g. perspiration and evaporation through skin, and water vapor expired to air through lungs) [13]. Coincidentally, the content of water in food is close to that of feces plus insensible loss from skin and lungs. Therefore, when we monitor fluid intake and output in HF patients, we could almost ignore the fluid intake from foods and the fluid output from feces and insensible loss.

Limitations

Frankly, there are several limitations in the present study. First, this study was performed in a single center, and a hospital-specific bias could not be excluded. Second, this study just observed the changes of HF patients in hospital, but not at home. We hope SRG patients could also adaptively record their net fluid intake and output as a part of his/her daily lifestyle every day. Third, more importantly, we wonder whether this simplified fluid intake and output records together with monitoring body weight could really improve the quality of life and reduce the hospitalization times in these patients for a long time. And we are proceeding a follow-up procedure now.

Conclusions

This study found that the simplified fluid intake and output recording scheme was safe, efficient and non-inferior to the professional mode in clinical stability, electrolyte balance, body weight and NT- proBNP levels. We expected that the simplified fluid records combined with monitoring body weight might effectively help HF patients enhance the compliance of self-management, improve the quality of life and reduce the times of rehospitalization.

Declarations

Ethics approval and consent to participate

The study was approved by the ethics committee of the hospital (No: K2018-09-004), and registered in Chinese Clinical Trials Registry (Identification Number: ChiCTR1800018523). All participants were completely informed the content of the consent form with signatures.

Consent for publication

The copy of consent form would be available with reasonable request at any stage (including after publication).

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to the proceeding follow-up procedure, but are available from the corresponding author on reasonable request.

Competing interests

The authors confirm that there are no competing interests.

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Authors' contributions

Na Lin conceived the study and wrote the manuscript. Xiaohuan Chen was responsible for data management and study design. Xiufang Huang, Donghui Liu, and Zhiyong Wu supported several experiments and analyzed the data. Yansong Guo and Hong Li supervised the research and revised the manuscript. All authors read and approved the final manuscript.

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Abbreviations

AF

atrial fibrillation;

ALT

alanine aminotransferase;

AMI

acute myocardial infarction;

AST

aspartate aminotransferase;

CCS

clinical congestion score;

CKD

chronic kidney diseases;

CRRT

continuous kidney substitution treatment;

DM

diabetes mellitus;

FBG

fasting blood glucose;

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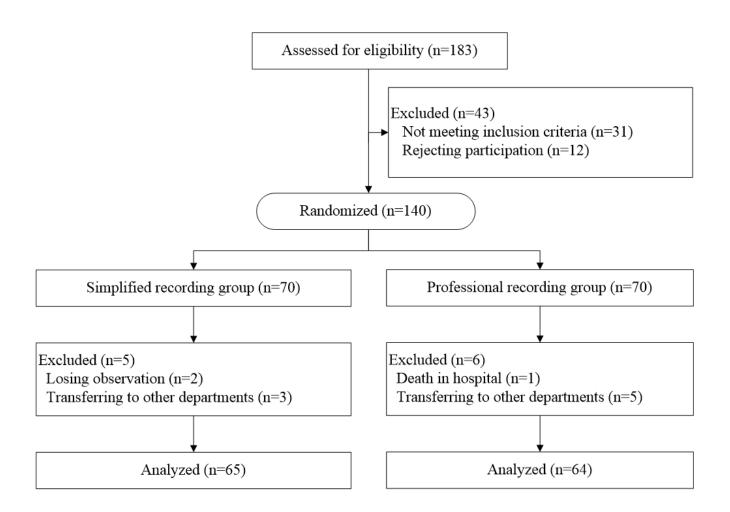
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Figures



Flow chart of patients screening and allocating.