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# Effects on Patients Home Care by Telephone Follow-up after Hospital Discharge: Study Protocol of a Randomized Controlled Trial

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#### **Abstract**

**Objective:** To investigate patients' post-discharge difficulties through periodic telephone follow-ups from the hospital nurse to the care manager.

**Methods:** The effects of the intervention will be examined using a randomized controlled trial and prospective randomized, open blinded-endpoint evaluation. This research targets patients who are older than 65 years of age, require a care manager and leave the hospital for their homes or residential care facilities. The participants, 50 pairs of patients and care managers, will provide consent for this study. In the intervention group, telephone follow ups from the hospital nurse to the care manager will be carried out three times: one week, one month, and two months after discharge; the control group will follow standard protocols. A self-administered questionnaire survey about difficulties after discharge will be conducted twice (one week and two months after discharge), and the results will be compared between groups. In addition, 10 care managers from the intervention group will be interviewed, and the contents will be analyzed as a process evaluation.

**Discussion:** The novelty of this study is that it strengthens the cooperation between the staff using telephone follow-ups and the evaluates the patients' unease and frustration. If effective, the telephone follow-up could be systematized and incorporated into standard care. Furthermore, the appropriate period, timing, and frequency of telephone follow-ups may become clear with the study. In terms of future research, the development of a new follow up program based on the results of this study and the examination of its effects will contribute to the development of the follow-up system.

**Trial registration:** This study was registered with the UMIN Clinical Trials Registry on May 7, 2018 (ID: UMIN000032251).

**Keywords:** Telephone follow-up; Discharge planning; Home care; Nurse care manager; Randomized controlled trial; Study protocol

## **Background**

In recent years, as the population has increasingly aged, the demand for medical care has intensified. Therefore, in order for healthcare resources to be used effectively, functional differentiation of the medical system has been encouraged, and home care has been promoted. In such a situation, hospitalization discharge planning is important. The typical process of discharge planning includes screening, assessment, planning, enforcement, and follow-up. One study that introduced a screening tool and conference emphasizes that ward nurses' screening and assessment ability could be improved [1]. However, while the effects on patients after discharge were examined, they were not evaluated statistically. Specifically, intervention contents were not considered along with continuous follow-ups [2].

In Japan, provision of documents and organizing conferences before or during discharge are important for continual care. However, few studies have investigated the effects of cooperation methods used to support home care after discharge. Furthermore, current research has examined the effects of these methods on the patient and the family through case studies, and an empirical investigation with larger samples of patients has not been conducted yet [3].

In other countries, telephone follow-ups after hospital discharge have been investigated. For example, using a sample of stroke patients in Sweden, a study evaluated the medication, treatment, and lifestyle counselling provided over the telephone and showed improvements in patients' blood pressure and the values of low-density lipoprotein cholesterol in the blood [4]. The effects on physical function and movement were reported through telephone feedback to patients who had high rehospitalisation risk in Australia [5]. In addition, educational instruction over the telephone to patients who needed medication treatment (e.g., the use of anticoagulants such as Warfarin) brought about increased knowledge and an understanding of the effects for the patients in the United States [6]. Many additional studies have carried out direct telephone follow-up with patients [7,8].

An investigation in Japan on care managers who were responsible for providing social resources to patients after hospital discharge reported on the impact of "confidence about job performance," "support in the workplace," and "job-related burdens" on the case managers [9]. These concerns were reported to occur simultaneously with case managers' annoyance and challenges, which may greatly

influence the quality of the home care received by patients after discharge. Against such a background with the daily responsibilities and challenges and lack of support, the hospital staff must take a role of supporting the community staff to assist patients in seamlessly shifting to home care and ensuring that the necessary care can be continuously offered.

# Aim and hypotheses

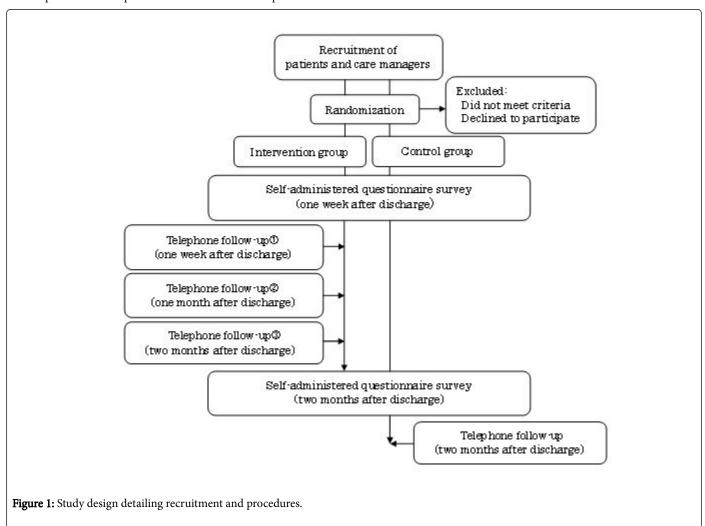
The purpose of this study is to investigate the effects of periodic telephone follow-ups from hospital nurses to care managers about patients' challenges after hospital discharge. The following hypothesis was developed: a patient whose care manager receives telephone follow-ups from a hospital nurse will face fewer problems after

discharge than a patient whose care manager receives the usual follow-

# Methods/Design

## Study design

As shown in (Figure 1), the designs of this intervention will a randomized controlled trial and prospective randomized, open blinded-endpoint evaluation. This study was approved by the Ethical Review Board at the Sonoda Women's University (No.17-04-005) and was registered with the UMIN Clinical Trials Registry (ID: UMIN000032251).



# Participants' eligibility criteria

This research targets patients who are older than 65 years of age, who are being discharged from a medical facility with 150 beds, and who have finished acute care but need the support to return to being at home. Eligible patients will require a charge care manager and will be leaving the hospital to go home or to residential care facilities. The pairs of patients and care managers that will participate in this study will have provided informed consent.

# Recruitment

During hospitalization, an explanation of the study and request for cooperation will be provided both orally and in written form by nurse managers to patients who meet the criteria. Similarly, the study explanation and request for cooperation will be provided to the care managers during the discharge conference. An agreement of study cooperation will be established, and a signature will be obtained for written consent from participants.

#### Randomization

A computer will generate a random number list before the start of this study. Once an agreement is signed, a study ID will be assigned. An ID pair that corresponds to a random extracted number will be assigned to the intervention group; in cases where one care manager works with multiple patients, all such patients will be assigned to the same group.

## Sample size calculation

To understand the probability of the outbreak of annoyance after discharge between the two groups, a difference of 30% is necessary (intervention group: 10%, control group: 40%). Thus, 64 people in total (32 people from each group) are required to be able to detect a statistically significant difference at a power of 80%, significance level 0.05 (both sides). Furthermore, to account for the possibility of dropouts, 100 people in total (50 groups) will be recruited.

## **Study intervention**

Theoretical basis of the intervention: Positive psychological effects of telephone follow-up have been shown for patients with chronic kidney failure in China [10] and patients with chronic heart failure in Hong Kong [11]. Furthermore, in a study of family caregivers needing medical treatment, troubles arose within two months after discharge. In addition, the technical acquisition needed by the patients and their families requires two months after discharge [12]. For patients with a chronic disease [13] or vascular brain disease [14], several telephone follow-ups during the first two weeks after discharge did not produce a statistically significant difference. As to the timing of the telephone follow-ups, in many studies patients are initially contacted one week after discharge and the interval of time for subsequent contact with the patients gradually increases [15-17]. In reference to these previous studies, the timeline of the telephone follow-ups of the present study will be set to less than one week, one month, and two months after discharge.

Intervention group: The telephone follow-up will be conducted by a director of nursing who is well-versed in discharge support. The director will ask about the patient's living conditions after discharge and the difficulties and problems experienced by the care manager regarding about the patients' home care after discharge and their involvement after taking charge of the patients. If necessary, additional consultations and correspondence will be carried out.

Control group: According to typical procedures, the hospital nurse will tell the care manager at the time of discharge to contact the hospital if consultation is necessary. A telephone follow-up from the hospital nurse to the care manager will be conducted one time (two months after discharge).

### Data collection

Main outcomes: The irritations after the patient's discharge will be based on a Likert-style scale of four points (I am not troubled, I am not very troubled, I am somewhat troubled, and I am troubled) with reference to 17 items that have already been identified [18]. These 17 items represent issues related to physical condition, treatment policy, emergency correspondence, hospital visit and consultation, content of meals, medicine, medical treatment, arrangement of medical equipment and medicaments, the welfare system and the long-term care insurance system procedure, contents of the home services,

arrangement of care article, house and house repair, daily life, household affairs, care burden on family, economy, and future medical treatment location. The self-administered questionnaire will be completed twice (one week and two months after discharge).

Process evaluation: To evaluate the process, the care managers who receive telephone follow-ups by a hospital nurse will be interviewed. After the intervention period, 10 care managers from the intervention group will participate in a semi-structured interview about the method of calling, as well as the content and timing of the telephone follow-ups after discharge. Permission will be provided beforehand, and the content of the interview will be recorded using a voice recorder.

## Blinding

Because the hospital nurse will be involved in both groups and will contact the care manager at different frequencies and intervals depending on group assignment, blinding with regard to the groups will be difficult. Because all patients will be asked to complete a selfadministered questionnaire about the irritations after discharge twice, it will be possible to ensure blinding with regard to the patients. In addition, because the researcher inputting and analyzing the selfadministered questionnaire only knows the ID allocations, blinding can be maintained during data entry.

# Statistical analysis

Patient's demographic characteristics and attributes (e.g., age, sex, diagnosis [international statistical classification of diseases], nursing care insurance, daily activities, cohabitation characteristics, and length of hospital stay), care manager demographic characteristics and attributes (e.g., age, sex, qualifications, years of experience), and the irritations within one week after discharge will be analyzed quantitatively using a chi-square test for each item to confirm the results of the intervention and control groups.

Each item that poses a difficulty from two months after discharge will be categorized and analyzed quantitatively using a chi-square test for both the intervention and the control group.

The content of the recorded interview with the care manager will be analyzed to determine effects and issues with the telephone follow-ups using qualitative inductions.

# Discussion

Cooperation between the staff that followed-up with the patients using the telephone, from the hospital nurse to the care manager helping the patient after discharge, will be strengthened, and those effects will be evaluated by the patients. These findings will represent the study's benefits to the field, as the telephone has not been evaluated as a means for cooperation between staff, and previous research has not examined the effects of this cooperation on the patients. If this investigation can clarify the effects for patients, telephone follow-ups can be further utilized with patients who are leaving the hospital to go to a distant place, and it may be possible to systematize the process of telephone follow-ups.

In addition, by analyzing the effects of the telephone follow-up for each item on the questionnaire, we considered the items that represented difficulties that were faced in the follow-ups conducted over the telephone.

Furthermore, the content of the interviews with the care managers who receive telephone follow-ups can clarify the changes that may be necessary for care managers and identify the demands on them for the follow-ups and cooperation. Through these analyses, the duration, frequency, and timing of the follow-ups can be analyzed.

In the future, a program with a new process for follow-up communication based on the results of this study should be developed. The examination of its effects may contribute to the development of a follow-up system among the staff. However, telephone follow-ups may obstruct nonverbal communication, so other methods of communication and cooperation using Information and Communication Technology such as Skype, which has recently been analyzed [19,20], should also be examined.

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