A multicentre study on the effects of self-administration of medication during hospitalization on medication safety, adherence, and patient satisfaction in Dutch hospitals.

Published: 06-11-2018
Last updated: 11-04-2024

The main objective of this study is:* To determine the effect of inpatient self-administration of medication on the number of medication administration errors during hospitalization*The secondary objectives of this study are:* To determine the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48816

Source
ToetsingOnline

Brief title
Self-administration of medication (SAM) during hospitalization

Condition

- Other condition

Synonym
Different types of diseases as different wards will be included

Health condition

Aandoeningen die voorkomen op de verschillende geincludeerde afdelingen zoals de afdelingen chirurgie, kindergeneeskunde, interne en revalidatie.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: zonmw

Intervention

Keyword: Hospitalization, Medicatiion Safety, Medication, Self-administration

Outcome measures

Primary outcome

The primary outcome measure of the study is the proportion of medication administrations with one or more medication administration errors (MAEs). For all outcome measures the effect of SAM will be compared to standard care.

Secondary outcome

Secondary outcome measures will be: severity of MAEs, medication adherence after hospitalization, patient satisfaction during hospitalization, and staff satisfaction.

Study description

Background summary

In 2016 66.2% of the total Dutch population had one or more medicines provided that were eligible for reimbursement by health insurance (1). Overall, the use of prescription medication is increasing in the Netherlands (2). Moreover, the retail of self-medication, e.g. pain medication, seems to be growing as well (3). During hospitalization patients receive their medication from the hospital pharmacy, including self-medication and vitamins. In general, this implies that 31% of home medication is substituted to hospital formulary medication at admission (4). Only 57% of this substituted medication is re-initiated at discharge, increasing the risk of medication errors, for example due to duplication of medication (4). As part of standard care nurses are responsible

for medication administration in hospitalized patients. Within healthcare patient-centered care is increasingly advocated. A concept of patient-centered care is patient empowerment. In this concept care is not given according to the old paternalistic model, e.g. medication administration by nurses, but there is room for the patient*s autonomy and preferences. This may be achieved by inpatient self-administration of medication (SAM) during hospital admission. The concept of inpatient self-administration involves the use of the medication boxes from home, dispensing newly started medication packaged in boxes as would be dispensed in ambulatory care (instead of unit dose dispensing) and patient education and coaching in using the medication the right way.

Medication administration errors (MAEs) occur daily in health care and can lead to serious harm (5). A systematic review of 65 studies from 13 countries reported a median error rate of 52 errors per 100 admissions (6). Improvement of medication safety is a major concern to policymakers and health care workers. SAM could be a way to reduce MAEs, due to the recognizability of medication, no need for medication substitution to the hospitals preferences, and coaching patients to take their medication properly. Furthermore, SAM may lead to better adherence after hospital admission. Short after hospital discharge, over 60% of patients have insufficient knowledge about their current medication use due to medication changes during hospitalization, such as: discontinuation of medication and dose changes (7). In addition, 55% of elderly patients do not use their medication correct two to four weeks after hospital discharge. Three months later non-adherence occurred in 70% of these patients (8, 9). The misuse of medication, in turn, increases the risk of hospital readmission and death (8, 9). Lastly, SAM gives patients empowerment which could positively influence patients satisfaction during hospitalization.

A recent systematic review looked into the efficacy of implementing SAM during hospitalization on outcomes related to patients, staff and institutions (10). Furthermore, medicine knowledge, adherence and patient satisfaction were studied after SAM was implemented, as well as the success of implementation of SAM and satisfaction of the staff (10). Staff and institution outcomes were defined as the success of implementation of SAM and satisfaction of the staff. The review included 43 studies, none of which was conducted in the Netherlands. The review showed a positive effect on knowledge of the medication name and regimen by patients, but not on knowledge of side effects (10). Whether SAM increases medication safety, was not studied. The effect of SAM on patient adherence was inconclusive. But in general the study methodology was inadequate for accurate measurement of adherence, e.g. counting pills or questionnaires (11). Therefore more research is needed. The review showed that participation in SAM schemes leads to increased satisfaction of patient and staff (10). Patients advised that SAM should be the golden standard when hospitalized. The success rate of SAM varied from 26 to 86% (10). This argues for implementing SAM in Dutch healthcare.

Given the paucity of evidence as is illustrated by the review, we aim to study

the effects of SAM on medication safety, adherence, patient satisfaction, and staff satisfaction.

Study objective

The main objective of this study is:
* To determine the effect of inpatient self-administration of medication on the number of medication administration errors during hospitalization
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The secondary objectives of this study are:
* To determine the effect of inpatient self-administration of medication on the severity of medication administration errors during hospitalization.
* To determine the effect of inpatient self-administration on medication adherence after hospitalization
* To determine the effect of inpatient self-administration of medication on patient satisfaction during hospitalization
* To determine the effect of inpatient self-administration of medication on staff satisfaction during hospitalization

Study design

This study is a multicentre prospective quasi-experimental study with a pre-post design.

Intervention

During SAM medication is stocked at the patient*s bedside. The stock comprises the medication the patient should receive based on the information documented in the patient*s file. Patients are provided with information about the medication that is documented in their files. This information could either be shown on an electronic device or on paper, depending on what is standardly used in the hospital. When medication is scheduled to be administered, patients collect those form their own stock, administer, and document the administration by themselves. Nurses check at every administration round whether patients succeeded in the administration.
Each day, patients are qualified for SAM. For this, a checklist is used and filed in the patient*s dossier. In the case, patients do not meet the criteria of SAM, they will be excluded from SAM. In those situations, nurses will take over the administration process and patients will receive standard care as described previously.

Study burden and risks

The burden associated for patients participating with this study is limited (only 13 minutes time investment for filling in questionnaires). Furthermoren, during the post periode patient have to participate in SAM schemes. The burden

of SAM is classified as low because results of a recent questionnaire shows that admitted patients have the urge to act in SAM schemes.The risk of SAM during hospitalization is estimated as the risk patients are at home when using medication. This risk may different from the risk a patient have during usual care, when nurses are responsible for medication administration. If this risk is equal, higher or lower is the subject of this study. We expect a better medication safety for participating patients

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients (* 18 years old) admitted to the ward who use medication or will be using medication at home after hospital discharge and are able to administer (part of) this medication themselves.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Not providing informed consent
* The use of a medication box without original medication boxes
* The use of medication pre-packaged by automated dispensing system
* The need of homecare support to administer medication
* The need of an informal caretaker to help with medication administration
* Admitted from a nursing home and medication is under supervision of the staff
* Not understanding the Dutch language, written or spoken
* Due to mental state the subject is not capable of managing SAM
* Due to physical state the subject is not capable of managing SAM;The last two bullets will be re-evaluated every day as mental and physical state could change during hospitalization.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2018
Enrollment:	1875
Type:	Actual

Ethics review

Approved WMO

Date:	06-11-2018
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-12-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-01-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65717.091.18