Brief Report

An In-home Advanced Robotic System to Manage Elderly Home-care Patients' Medications: A Pilot Safety and Usability Study

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ABSTRACT

Purpose: We examined the safety profile and usability of an integrated advanced robotic device and telecare system to promote medication adherence for elderly home-care patients.

Methods: There were two phases. Phase I aimed to verify under controlled conditions in a single nursing home (n = 17 patients) that no robotic malfunctions would hinder the device's safe use. Phase II involved home-care patients from 3 sites (n = 27) who were on long-term medication. On-time dispensing and missed doses were recorded by the robotic system. Patients' and nurses' experiences were assessed with structured interviews.

Findings: The 17 nursing home patients had 457 total days using the device (Phase I; mean, 26.9 per patient). On-time sachet retrieval occurred with 97.7% of the alerts, and no medication doses were missed. At baseline, Phase II home-dwelling patients reported difficulty remembering to take their medicines (23%), and 18% missed at least 2 doses per week. Most Phase II patients (78%) lived alone. The device delivered and patients retrieved medicine sachets for 99% of the alerts. All patients and 96% of nurses reported the device was easy to use.

Implications: This trial demonstrated the safety profile and usability of an in-home advanced robotic device and telecare system and its acceptability to patients and nurses. It supports individualized patient dosing schedules, patient–provider communications, and on-time, in-home medication delivery to promote adherence. Real time dose-by-dose monitoring and communication with providers if a dose is missed provide oversight generally not seen in home care. (*Clin Ther*. 2017;39:1054–1061) © 2017 The Authors. Published by Elsevier HS Journals, Inc.

Key words: aged, home-care services, medication adherence, medication therapy management, robotic system.

INTRODUCTION

Elderly home-care (HC) patients with complex medication regimens[1] are at high risk of reduced adherence,[2] medication-related problems, and medication errors.[3] The concomitants of aging, such as impaired hearing, vision, cognitive skills, isolation, difficulty communicating with health care professionals,[4] and accessing health services[5] increase these risks. An estimated 7% of US home-dwelling persons ≥65 years of age require assistance with their medicines.[6] Of Finnish statin users, just 60% were found to be adherent with their regimen after 4 years.[7] Poor medication adherence may result in unplanned hospitalizations, adverse clinical outcomes, and increased costs.[8]

Home health care involves multiple steps in the transfer of information and medicines from the

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prescriber to a patient and subsequent actions by that patient. Each step poses a risk of service lapse and information gaps that can cause errors and can reduce medication adherence. In Finland, nurses or visiting nurses obtain medicines for HC patients from a private community pharmacy and manually dispense them to the HC patient's doset as a week's supply of medicine. Sometimes the HC patients are able to take their medicines by themselves, but usually the visiting nurse must come to the home, retrieve the medicines from the dosets, and give them to the patient. For some patients, the medicines are prepacked in unit doses.[9] This multistep process permits delays in identifying and resolving medication nonadherence.

In 2015, 12% of Finns aged $\geq$75 years used regular home-help services or home nursing.[10] These visits are intended to extend the patient's time at home and to delay transition to institutional care. Medication management is an important aspect of these visits, and often the medication schedule is the main reason for multiple daily home visits by practical nurses.

A well-engineered in-home robotic device and system could improve the coordination of patient communications with care providers. Current approaches to improving adherence, however, tend to focus on individual aspects of medication use, such as reminders, electronic monitoring and text-messaging, automated dose dispensing (ADD) systems that provide medicine sachets to patients and automatic prescription refills.[11–15] Multiple companies and diverse systems are in practice in Finland because some companies use sachets and others may use cardboard boxes, and internationally, procedures can differ.[16]

This pilot study was conducted in Finland, where the advanced robotic device and telecare system for managing medications of home-care persons on long-term pharmacotherapy was developed.[1]

Finnish Medical Device legislation follows European Medical Device Directive 93/42/EEC.[17] The approval process for a device depends on the product's classification under European guidelines. Consequently, the advanced robotic device and the telecare system are classified as Class I Medical Devices in the European Union. The directive contains essential requirements for the medical device's performance. A clinical study is used to assess the device's safety profile, clinical performance, and suitability for intended purpose. Before initiating a clinical investigation, the manufacturer ensures that there is no issue that could place the patient's safety in danger. For a Class I product, when the manufacturer has ensured regulatory compliance and successfully passed the clinical investigation, the manufacturer signs the declaration of conformity and applies the CE mark to the product.

Consistent with the European Medical Device guidelines, the objectives of this device and telecare system's usability trial were to assess its safety profile and clinical performance and to evaluate its usability for its intended purpose.

METHODS

This brief report concerns a safety profile and usability trial of an advanced robotic device and telecare system (Evondos E300 and Evondos Telecare System, Salo, Finland) that integrate distributing medicines, supporting individualized dosing schedules, providing patient reminders, and communicating with providers (eg, the practical nurse will receive an automatic alert if scheduled doses are not taken; Figure 1). This system is designed to promote medication adherence for persons on long-term medication regimens.

A device failure is a "failure to deliver the sachet." For example, if the robotic device could not detect the seam between the sachets or if the sachets become stuck in the delivery mechanism, then the device will first send an alarm to the technical surveillance, and an attempt is made to fix the sachet delivery remotely. As a worst case, if this remote action is not successful, a person would go to the patient's home and deliver

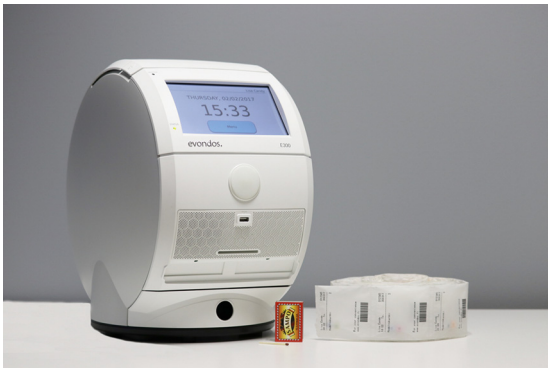

Figure 1. Evondos E300 Medicine Dispensing Robot with Multidose Sachets (Salo, Finland). The matchbox is included to indicate relative size. It measures 2.2 inches in height and 1.4 inches in width.

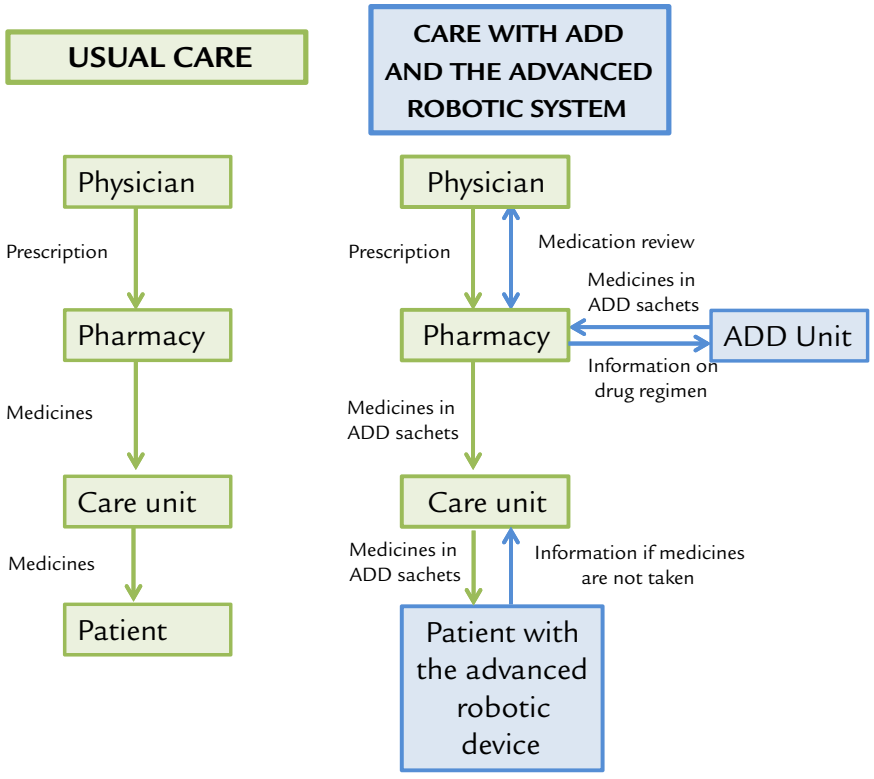

Figure 2. (Left) Usual home-care pharmacotherapy for elderly patients and (right) an integrated system, including medication review, automatic dose dispensing, an advanced robotic device, and telecare system. ADD unit = automated dose dispensing; the manufacturing unit that fills and labels the sachets.

the sachet within the time window of 1 hour before or up to 2 hours after the scheduled dose.

Intervention

The usual HC model begins with the physician's orders to the pharmacy, then the medicines are sent to the care unit and from the care unit to the patient (Figure 2). Beyond baseline, the intervention in this study added an in-home advanced robotic system (Figure 1) into the usual HC model for managing all enrolled patient's on-time medication use (Figure 2). HC patients vary in their visual and auditory acuity. Consequently, a spoken reminder message, a sound signal, a light signal in the dose button, and written instructions on the device's display are activated at individually predetermined dosing times. These remind the patient to access their medicines by pressing a dose button on the device's front panel. Reminders are also generated for medicines not in the robotic unit (eg, insulin and inhalers). When the patient presses the device's dispenser button, the device delivers a sachet containing the medicine(s). If a patient misses a sachet, the telecare system passes that information to the HC unit for action. According to the patient's needs and medicines, a nurse can contact the patient or come to the home and give the dose(s). The device sequesters unused dose(s) in a locked canister if the sachet is not retrieved within a predetermined time.

The telecare system records data on sachets dispensed or sequestered and tracks alarms. If a problem is encountered in obtaining a sachet, the device sends that information to the telecare system where there is a chain of emergency contacts. The telecare system ensures responsibility for addressing the alarm and is coordinated through successive levels of oversight. The alarm remains activated until the event causing it has been resolved.

The device is secure, monitored to detect tampering, and always connected to a central telecare system through a wireless connection. For enhanced safety, monitoring and design redundancies ensure against down time. Sachet dimensions and the information displayed varies by manufacturer. The device is

designed to bypass the lack of international data field and display standardization, and it is capable of reading the sachet's display and recording the patient's information and medication dispensing times.

Study Design and Methods

This two-phase prospective usability study was performed in Espoo, a part of Finland's capitol area, in 2013 to 2014. All patients received baseline medication reviews before initiating ADD, so the sachets sent to the pharmacy and then to the robotic unit started with a clinically validated baseline. Before the intervention, all Phase I and II patients were interviewed using a structured questionnaire to determine their experiences with the ease and regularity of taking their prescribed medicines as scheduled.

Under the controlled conditions of a single nursing home, Phase I (n = 17) was conducted to verify that there were no robotic malfunctions that would hinder the device's unsupervised, safe use in patient's homes. Throughout Phase I corrections and improvements were made to the robotic device and associated software. Examples of such improvements include, for example, reliability enhancements for the logic of handling the sachets and rules for exceptions, and enhancements in communication between the robot and the telecare system. These improvements decreased the number of failures to deliver the medicine sachets and enhanced the robotic unit's autonomous operation.

Phase II studied the device in the less-controlled setting of the patient's home (n = 27). It assessed (1) the device's performance in giving participants their medicine sachets according to their individual treatment plan and (2) patients' and nurses' perceptions on whether the device helped patients take their medicines regularly, on the device's usability, and their willingness to recommend the device.

The investigator on duty engaged in active and passive monitoring. Passive monitoring was continuous, and alerts arose from the telecare system's function that sends an alarm (1) if the medicine sachet could not be delivered or (2) if the patient did not retrieve the medicine sachet from their robotic device within a predetermined time period (the "active window"). Investigators used the telecare system to remotely but actively monitor the scheduled medication dosing intervals, detecting whether HC patients were obtaining their medicine sachets on their individualized, prescribed schedule. Investigators were also regularly in direct communication with the HC patients by telephone call or Short Message Service. In addition, investigators were in contact with the care organization who visited the HC patients, typically daily by call or short message service.

Study data consisted of the documentation electronically saved by the system (alerts, number of times a patient responded to the alert by pressing the button, whether the sachet was removed from the device), observations made by the investigators about its technical functioning, and feedback from the study participants and their primary nurses before and after the study. The structured interview was developed by the research group before the research plan was approved. Questions in the structured interview were selected to determine reliability, usability, suitability for intended use, and possible adverse effects of the advanced robotic system. Consequently, both closed and open-ended questions were used. A clinically trained investigator used a structured questionnaire to interview patients and their nurses about their experiences with the device.

Nurses/practical nurses recruited participants to be representative of each location's typical HC patients. Participants had to be able to give their informed consent for the study. If their voluntary participation was uncertain, they were excluded. When the robotic device did not deliver the sachet, the investigator on duty gave the medicines to the patient within 1 to 2 hours of the alarm being sent by the telecare system.

Phase I comprised 17 patients in a single nursing home. Before Phase I, the nursing home had used an ADD service from a local community pharmacy, with the nurse giving the medicine sachet to the resident at the correct times (Figure 2). In Phase I, the advanced robotic device was placed in each resident's room, and, when reminded, the resident removed the sachet and took his or her medicines themselves.

Phase II participants were home-dwelling patients of three HC units. They were (1) on long-term daily tablet or capsule medicines, (2) native Finnish speakers, (3) at least 18 years of age, and (4) assessed by a nurse to be committed to treatment and to taking their medicines. Mild cognitive impairments did not preclude participation; 3 subjects had early-stage dementia, and 2 other subjects were diagnosed with schizophrenia.

Data Analysis

In both phases of this trial, data were recorded on (1) the number of times a patient was reminded to press the dispenser button to receive a medicine

Table. Dispensing and removal of medicine sachets as documented by the robotic device, by study phase.

Variable	Phase I (n = 17)	Phase II (n = 27)
Number of daily dosing times		
Mean (SD)	3.5 (1.5)	2.9 (0.8)
Range	2–8	1–5
Study patients' days of use of the robotic device per patient		
Mean (SD)	26.9 (24.9)	26.9 (4.6)
Range, n	5–104	17–40
Aggregate days the robotic device was used, n	457	727
Alerts to press the dispenser button to receive a medicine sachet, n	1,371	2,090
Patient pressed the dispenser button and a sachet was delivered, n (%)	1,344 (98.0)	2,075 (99.3)
Patient did not remove the sachet, n	5	12
Failure to deliver the sachet,* n (%)	27 (1.97%)	15 (0.72%)
On-time medicine sachet removal %†	97.7	98.7

*In these cases, the investigator on duty responded to the alarm given by the telecare system and gave the patient their medicines within 1 to 2 hours.
†Determined as [(pressed dispenser button and a sachet was delivered) – (sachet not removed)]/(total number of alerts to press the dispenser button to receive a medicine sachet).

sachet, (2) the number of times a patient then pressed the dispenser button and retrieved the sachet, (3) the number of times the medicine sachet was not taken (a patient, not a device-related issue), (4) the number of times a medicine sachet was not delivered, (5) the aggregate number and mean days of device use, and (6) mean number of times medicines were to be taken per day (Table).

Responses to the patient and nurse questionnaires were coded and entered into Excel (Microsoft, Redman, Washington). Descriptive statistics (i.e., frequencies, percentages, and means) were computed from both data sources.

Ethics Approval and Device Approval According to the European Union Regulation

The research protocol has the approval of Helsinki University Hospital Coordinating Ethics Committee (March 25, 2013), permission for study was granted by the City of Espoo Social and Health Services (May 20, 2013), and the National Supervisory Authority for Welfare and Health Valvira (May 30, 2013) notified the researchers that it had no objections (June 2, 2013). The advanced robotic automated system and telecare system have CE-marking according to the European Union Medical Device Directive 93/42/EEC.[17]

RESULTS

Patients in Phase I were predominantly men (65%), but most Phase II patients were women (59%). Ages were similar for each phase (73.0 versus 75.3 years). Phase I patients took medicines an average of 3.5 times per day and Phase II patients 2.9 times per day. Most Phase II patients (78%) lived alone at home, and 52% of them required from 2 to 3 HC visits per week to at least once daily, with 22% of them requiring at least one daily visit.

More than 20% of patients in both phases (24% in Phase I, 22 % in Phase II) reported that remembering to take their medicines according to the prescription or treatment plan was difficult. At baseline, all Phase I nursing home residents took their medicines regularly, because the medicines were given by the nurses. However, at baseline 18% of Phase II home-dwelling patients reported missing doses at least 2 times a week.

Three participants began but did not complete the study. In Phase I, 1 participant died after being in the study for 5 days. In Phase II, 1 participant, who participated for 1 day, discontinued because of lack of trust, and another, who participated for 7 days, withdrew because of fear of technology. These patients are not included in the 17 participants in Phase I, or the 27 participants in Phase II.

Phase I: Verification of the Robotic Function to Assure the Device's Unsupervised, Safe Use in Patients' Homes

The 17 nursing home patients had 457 total days using the device in Phase I (mean, 26.9 per patient) (Table). They responded to the device's reminder and successfully pressed the dispenser button 98.0% of the time (1344 presses/1371 alerts), but on 5 occasions they did not remove the medicine sachet. On-time sachet retrieval occurred in 97.7% of the alerts. Technical malfunctions that prevented the sachet from being ejected from the device occurred with 1.97% of the alerts (27 of 1371). The nurses unanimously reported that the remote care system, and its functions, did not cause an actually dangerous or near dangerous situation for any patient. These failures to deliver a medicine sachet were not dangerous because in every case of a technical malfunction (i.e., the device did not deliver the sachet) the patient still received their medicines (because the telecare system immediately sent information about the malfunction and the sachet was removed manually). Thus, no medication doses were missed, just the time to take them was delayed maximally by 1 to 2 hours.

Phase II: Device's Performance in Assisting Participants to Take Their Medicines According to Their Individual Treatment Plan and the Device's Ease of Use

The device was used for 727 days by 27 patients (mean, 26.9 days per patient). The device's dispenser button was pressed successfully 99.3% of the time (2075 presses/2090 alerts), and 98.7% of the alerts resulted in on-time medicine sachet retrievals by the patients. Failure to deliver the medicines sachet declined by 63% from Phase I to Phase II (1.97% to 0.72%).

All but one of the Phase II patients reported that the device functioned reliably. That one respondent stated that the device functioned "reliably, except for the sound function."

HC nurses regarded the machine as safe, except in two cases: (1) the medication was not taken by the patient because the machine's audio instructions stopped, and (2) one psychiatric patient was afraid of the machine's sound. All patients and 96% of the nurses found the device to be easy for the patients to use. The one nurse who stated the devices use not to be easy, responded that the patient had said "I need a human being, not a machine." In Phase II, 89% of patients and 88% of nurses would recommend or probably recommend this device for further use. The patient who responded that he probably would not recommend the device wanted the device to be smaller.

DISCUSSION

This pilot study demonstrates the device and telecare system's (1) reliability, (2) device-mediated communications, and (3) among motivated HC patients, patient and nurse satisfaction with the device.

Steadily increasing need and costs for HC services make them a major unresolved issue for Finland's social service and health care system. The in-home advanced robotic device and telecare system in this pilot study directly addresses a critical aspect of this concern: the quality and costs of in-home pharmacotherapy for aged patients. Sequestering medicines in a tamper-proof robotic device and delivering them on predetermined individually optimal dosing schedules focuses on the patient's clinical need rather than on a caregiver's schedule. The system is a new approach to organizing HC services and assuring on-time home medicine use without the direct assistance of a nurse. For optimal outcomes, the patient's medications and dosing times are reviewed before enrolling the patient in the robotic service. The medication review assures that clinically optimal medicines and schedules are customized to the patient's daily routines.

Reliability

The device and system have been engineered to remove steps in the medicines use process in which human and system errors can occur. Accidental medicine use and missed doses are minimized, and potential adherence is improved. Automating clerical tasks also reduces the administrative burden of assuring adherence to a drug regimen, which then increases the proportion of a nurse's patient contact time that can be focused on higher quality patient interactions and observation of their condition(s).

Device-mediated Communications

Real-time dose-by-dose monitoring and communication serve not only as a medicine schedule reminder and delivery system but also as a mode for communication with the often isolated elderly HC patient (78% in this study lived alone). The system provides bidirectional communications between the HC patient and his or her provider. The device proved to be reliable with a high

percentage of doses taken at the correct times without assistance from an in-home visit by the nurse. Because the patient was reminded to take the medicine, retrieved the sachet from the device, and no remaining medicines were in the retrieved sachets, it is assumed that the medicine was taken when the sachets were retrieved.

Satisfaction

In this study the HC patients were satisfied with the device and willing to use a robotic system, and the nurses' opinions were positive.

This kind of device could further reduce the need for nurses to visit HC patients' homes if the purpose is solely to give medicines. Instead, their home visits could be planned and focused on educating patients about their conditions and medicine use, including a review of their medications. On a population level, the increase in efficiency of use of professional personnel is substantial. This could also improve quality of care as one of the current major problems in geriatric care is inappropriate medication use.[18,19]

A larger clinical trial to study the device's effects on clinical care end points is planned. Current plans and future plans focus on expanding communications between patients and their providers, performing a longer outcomes trial of health and humanistic outcomes after improved medication adherence to individualized regimens, and use by patients who have poorer motivation and baseline adherence. The communication feature can be developed to provide even more detailed and customized verbal instructions for each of the medicines in use. Communication through the device can be easily extended to cover the wanted and unwanted effects of each of the medicines taken. HC patients in this study were committed to treatment. Future studies should address (1) those who are less committed because they may benefit even more than the present study group, and (2) whether patients with cognitive decline may benefit from this kind of easy-to-use robotic system.

Study Limitations

This pilot clinical safety and usability study has limitations: (1) small sample size, (2) short duration, (3) no direct observation of medicine consumption (patients were selected by nurses based on their assessment that the potential participant was motivated to take their medicines), and (4) data were missing on the frequency of home visits by nurses at baseline in Phase II. Failure to deliver the medicines sachet declined by 63% from Phase I to Phase II (1.97.0% to 0.72%). Engineering will continue to address improvements to lower this experience. Because the device is part of a system, redundant backup features alert caregivers so that they are able to respond in time to ensure that no patient misses his or her scheduled medicine delivery.

CONCLUSIONS

This trial reported the safety profile and usability of an in-home advanced robotic device and telecare system and its acceptability to patients and nurses. It supports individualized patient dosing schedules, patient–provider communications, and on-time, in-home medication delivery to promote high adherence. Missed doses were reported and followed-up in real time, and unretrieved doses were sequestered to prevent later misuse.

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All authors had full access to all of the data, with independence of interpretation, conclusions and manuscript submission: concept and design (P. Rantanen), preforming the trial (P. Rantanen, T. Parkkari), acquisition of data (P. Rantanen, T. Parkkari), analysis and interpretation of data (P. Rantanen, T. Parkkari, S. Leikola, M. Airaksinen, A. Lyles), clinical report (P. Rantanen, T. Parkkari), literature review (M. Airaksinen, A. Lyles), manuscript draft (S. Leikola, M. Airaksinen, A. Lyles), critical revisions of the manuscript for important intellectual content (P. Rantanen, T. Parkkari, S. Leikola, M. Airaksinen, A. Lyles), data analysis (P. Rantanen, T. Parkkari, S. Leikola, M. Airaksinen, A. Lyles), and conceptualization and construction of the figure (S. Leikola, M. Airaksinen).

CONFLICTS OF INTEREST

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this study. A. Lyles received compensation for participation on this project. S. Leikola works for an automated dose dispensing (ADD) firm and received compensation from Evondos for contributing to coordinating the writing of this manuscript. The authors have indicated that they have no other conflicts of interest regarding the content of this article.

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