

Medication reminder device for the elderly with mild cognitive impairment

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Introduction

The population of individuals with dementia will increase considerably in the next few decades. In 2009, Alzheimer's Disease International estimated that 65.7 million people in the world will have dementia by 2030 and that this number will increase to 115.4 million by 2050<sup>1)</sup>.

Cognitive impairment is one of the risk factors for medication non-adherence in the elderly<sup>2)</sup>. Even mild cognitive impairment often results in poor adherence<sup>3-5)</sup>. An appropriate strategy for improving adherence is required for successful disease management and reduction in health care costs. However, few studies have described about strategies developed to enhance medication adherence in the elderly with cognitive impairment.

A medication reminder device is a tool that uses an alarm cue to prompt users to take medication. Some case studies have revealed that such devices may be effective in enhancing medication adherence in the elderly with mild dementia<sup>6-8)</sup>. However, the degree of efficacy of these devices and the appropriate support for this population in using such devices have not yet been determined. In addition, the security of medication

management using these devices is a concern in this population. In this study, the efficacy of such devices in medication management for the elderly with mild cognitive impairment was investigated. Empirical evidence was collected to address this concern and provide recommendations for appropriate use of medication reminder devices in this population.

## Methods

### Participants

Families of the elderly and healthcare professionals familiar with our research were offered trial use of the medication reminder devices in return for participation. One of the examiners (an occupational therapist or rehabilitation engineer) conducted a preliminary interview by phone with either the family member or the healthcare professional referring the elderly subject. The examiners visited potential participants' homes to confirm that they met the study criteria and to obtain informed consent.

Inclusion criteria were as follows: score of 0.5 or 1 on the Clinical Dementia Rating (CDR)<sup>9</sup> scale, age  $\geq 65$  years, living at home, and history of missed medication doses, overdoses, or need for verbal reminders to take medication once or more during 1 week. Exclusion criteria were as follows: visual or hearing impairment, motor dysfunction, behavioral and psychological symptoms of dementia (BPSD) sufficient to interfere with the operation of the reminder device, no fixed dosing time or place, medication in a form other than tablets or capsules, and no caregivers to fill the device with tablets or capsules.

This study was conducted from September 2008 to December 2011. The experimental protocol was approved by the Ethics Committee of the Research Institute of the National Rehabilitation Center for Persons with Disability and the Medical Ethics Committee of Shinshu University.

### Intervention

The automatic pill dispenser (Pivotell Ltd., Walden, Essex, UK; Fig. 1) was the medication reminder device used in this study. Its audible and visual stimuli remind users when to take their medication. When the alarm rings, the correct dose of medication is released into the lid opening. Users must then invert the device to obtain medication and stop the alarm.

The examiners evaluated the following points in the subjects before they used the device: users' ability to discriminate the alarm sound, initiate a search for the device on the basis of the alarm cue, obtain medication, return the device to the correct position,

and prepare a glass of water for taking medication. In case of subjects not finding any difficulty with using the device, the device and its usage were customized. Customized conditions included medication loaded into the device, loading schedule, location in the home, time of the alarm, and other individual considerations. Brief instructions regarding the operation of the device were written for each user and attached to the device. The device was occasionally used for part of the medication regimen prescribed to each user. The examiners then trained the users and their caregivers how to use the device. Evaluation, customization, and training were completed typically in one visit. An additional visit was made if necessary. The caregivers then monitored device use during the first week of its usage. They were asked to provide minimal assistance to users while using the devices, only when required.

The examiners supervised two follow-up procedures. One involved the abovementioned caregivers' monitoring. The other involved long-term monitoring to manage events causing changes in use during the follow-up period, such as altered prescriptions or changes in users' daily lifestyle or state of health.

#### Assessment

Caregivers reported the results of monitoring during the first week to the examiners by phone.

Values of the self-administration medication rate (SAMR) prior to implementation of the device were compared with those measured 1 and 3 months after onset of device use. SAMR was defined as the ratio of the number of doses taken independently to the number of all prescribed doses during 1 week. Caregivers confirmed the number of doses taken independently by monitoring the unused medication and counting the number of times help was required to use the device. The benefits from using the device other than SAMR was examined through open questioning of users and their caregivers. If users stopped using the device within the 3-month duration of the study, they were asked to provide the reasons for cessation.

#### Results

The examiners visited 19 potential participants' homes. One subject was excluded because of lack of an adequate caregiver to operate the device. Thus, in total, 18 subjects (age,  $81.2 \pm 6.2$  years; 15 females) participated in this study. Seventeen subjects (94.4%) lived alone, and 1 subject lived with an elderly spouse (Table 1). Alzheimer's disease was the most common underlying cause of cognitive impairment ( $n = 11$ , 61.1%) (Table 1). No formal diagnosis related to cognitive impairment had been made in 3 subjects (Table

1). The CDR score of 10 subjects (55.6%) was 0.5 and that of remaining subjects was 1 (Table 1). The Mini Mental State Examination scores of 13 subjects (72.2%) ranged from 21 to 26 (mild cognitive impairment)<sup>10</sup>. Scores for the remaining subjects were >11 (moderate impairment)<sup>10</sup> (Table 1). Caregivers for filling medication of 10 subjects (55.6%) were their family members living separately (Table 1). At the beginning of the study period, the most widely administered regimen programmed into the device involved taking medication once each morning (n = 11, 61.1%) (Table 1). Medications for the following ailments were administered using the device: hypertension, dementia, and gastrointestinal illnesses (Table 2). Seven people used the device for part of their prescribed medication regimen at the beginning of the study period (Table 1). For medications not administered using the device, some users received caregivers' assistance but others received no assistance.

Fifteen subjects (83.3%) could use the device during the first examiners' visit. One subject (5.6%) required additional visits before initiating the use of the device. The remaining 2 subjects (11.1%) needed practice with their family members before initiating device use. Because most participants were initially unwilling to use the device, the examiners requested their cooperation in order to decrease family members' anxiety about the medication and to allow us to examine the utility of the device.

Once and more during the first week, 15 caregivers (83.3%) reported that they helped the users to manipulate the device or find unused medication in the device after the scheduled dosing time. Among them, 5 (27.8%) reported these events on two or more consecutive occasions during this period.

Changes in SAMR 1 month after onset of device use are shown in Fig. 2. Ten users (55.5%) showed 100% improvement in SAMR values from before onset of use to 1 month after onset. SAMR values for 5 users (27.8%) showed an improvement of <100% (28.6%, 57.1%, 78.6%, 85.7%, and 85.7%). No improvement was observed in the SAMR value for 1 user (5.6%). The remaining 2 users (11.1%) ceased to use the device within the first month.

Changes in SAMR at 3 months are shown in Fig. 3. Nine users (49.9%) maintained SAMR values of 100%, and 1 user (5.6%) showed 100% improvement in SAMR values. SAMR values for 3 users (16.7%) showed continual improvement from the onset of use but were still <100%. These values were 14.3%, 64.3%, and 76.2%. No improvement was observed in the SAMR value for 1 user (5.6%).

Four users (22.2%) ceased to use the device during the 3 months of the study (at 10 days, 22 days, 2 months, and 2.5 months). Their respective reasons for cessation were as follows: embarrassment about the warning beep due to improper operation of the device,

wrist fracture due to a fall, occasionally forgetting to take medication despite use of the device, and onset of low back pain necessitating changes in prescription. Only in the third case was discontinuation prompted by the caregiver.

Caregivers reported the following benefits from using the device: maintenance of normal blood pressure in users, reduction of caregivers' burdens, and decreased care costs. Users reported gaining self-confidence because of improved SAMR and success at learning the skills necessary to use the device.

## Discussion

According to previous reviews<sup>11,12</sup>, factors hindering good use of memory aids generally included old age and lack of experience using similar types of aids premorbidly. However, the results of this study suggested that people with these two conditions and CDR scores of 0.5 or 1 can become good users of medication reminder devices. This discrepancy might be due to the fact that the aid was externally programmed and prepared, and therefore required minimal cognitive resources for utilization. In addition, professional support and monitoring by caregivers at the onset of use may also have contributed to the success of the elderly subjects using the device in this study. In many cases, elderly people with mild cognitive impairment are unwilling to use new technology; they may also have difficulty with some types of learning<sup>13-15</sup>.

Caregiver's help is a prerequisite for use of the medication reminder device examined in this study. Caregivers were required to fill the device with medication and monitor both its effect on the users and any events necessitating changes in its use, including cessation of use. Furthermore, this device simply prompts users to take medication at a fixed time and in a particular place. Therefore, its use is not applicable to some types of medication, such as medication taken only when necessary and medication with contraindicated conditions after administration. Thus, this device has only limited application for scheduled doses. Moreover, the device cannot be used under conditions included in the exclusion criteria of this study. From the standpoint of medication management for people with cognitive impairment, this device should be developed as a technical aid for use with caregivers' help.

This study design has certain limitations. First, the outcome measure of the status of taking medication was estimated according to the amount of unused medication counted by the caregivers in this study. Assessment of outcome in this manner resulted in problems in some cases. For example, users forgot to take medication after extracting it from the device, and subsequently the medication was lost. To prevent this problem, concurrent visual observation would be more effective in using the status of taking

medication as an outcome measure. Second, no generalizations can be made on the basis of the high success rate with the reminder device because this result was obtained through convenience sampling of the participants. In this study, people who referred participants to the examiners either became caregivers or encouraged caregivers in the utilization of the device. Therefore, almost all caregivers were strongly supportive of the intervention in this study, which may have influenced the results positively. Third, because of the non-systematic data collection methods used in this study, no generalizations can be made about the contribution of this device to good disease management, decreasing of care costs, reducing of family members' burdens, and increasing users' self-confidence. To expand on the findings of this study, future randomized, controlled trials must include these measures and refine the measurement of the status of taking medication. In addition, the contribution of this device to disease management in users, e.g., blood pressure management in users taking hypotensive drugs, can be assessed in future studies. Questionnaires may also be administered to evaluate family members' burden and users' self-confidence.

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Table 1. Characteristics of participants

Age, years	81.2 ± 6.2
Mean ± SD [range]	[70–93]
Sex	
Female	15 (83.3%)
Household	
Elderly alone	17 (94.4%)
Diagnosis of cause of cognitive impairment	
Alzheimer's disease	11 (61.1%)
Mixed dementia	1 (5.5%)
Vascular dementia	3 (16.7%)
None	3 (16.7%)
Clinical Dementia Rating	
0.5	10 (55.6%)
1	8 (44.4%)
Mini Mental State Examination	
21–26	13 (72.2%)
14– 21	5 (27.8%)
SAMR* prior to using the device	
SAMR 0%	11 (64.1%)
SAMR of <80%	4 (22.2%)
SAMR of >80%	3 (16.7%)
Caregiver for filling the medication	
Family members living separately	10 (55.6%)
Caregiver/Visiting nurse	8 (44.4%)
Medication regimen administered by the device	
Each morning	11 (61.2%)
Each evening	1 (5.5%)
Each morning and evening	2 (11.1%)
Each morning, noon and evening	4 (22.2%)
The device can be used for	
All medicines prescribed to the user	11 (61.1%)
A part of the medicines prescribed to the user	7 (38.9%)

\*SAMR (self-administration medication rate): the ratio of the number of doses taken independently to the number of all prescribed doses during 1 week

Table 2. Types of medications administered using the device

Hypotensive drugs	11	(61.1%)
Antidementia drugs	10	(55.6%)
Gastrointestinal drugs	8	(44.4%)
Drugs for heart failure	4	(22.2%)
Antithrombotic drugs	4	(22.2%)
Antipollakiuria drugs	3	(16.7%)
Vitamin preparation	3	(16.7%)
Hematopoietic drugs	2	(11.1%)
Others	6*	(33.3%)

(multiple answers)

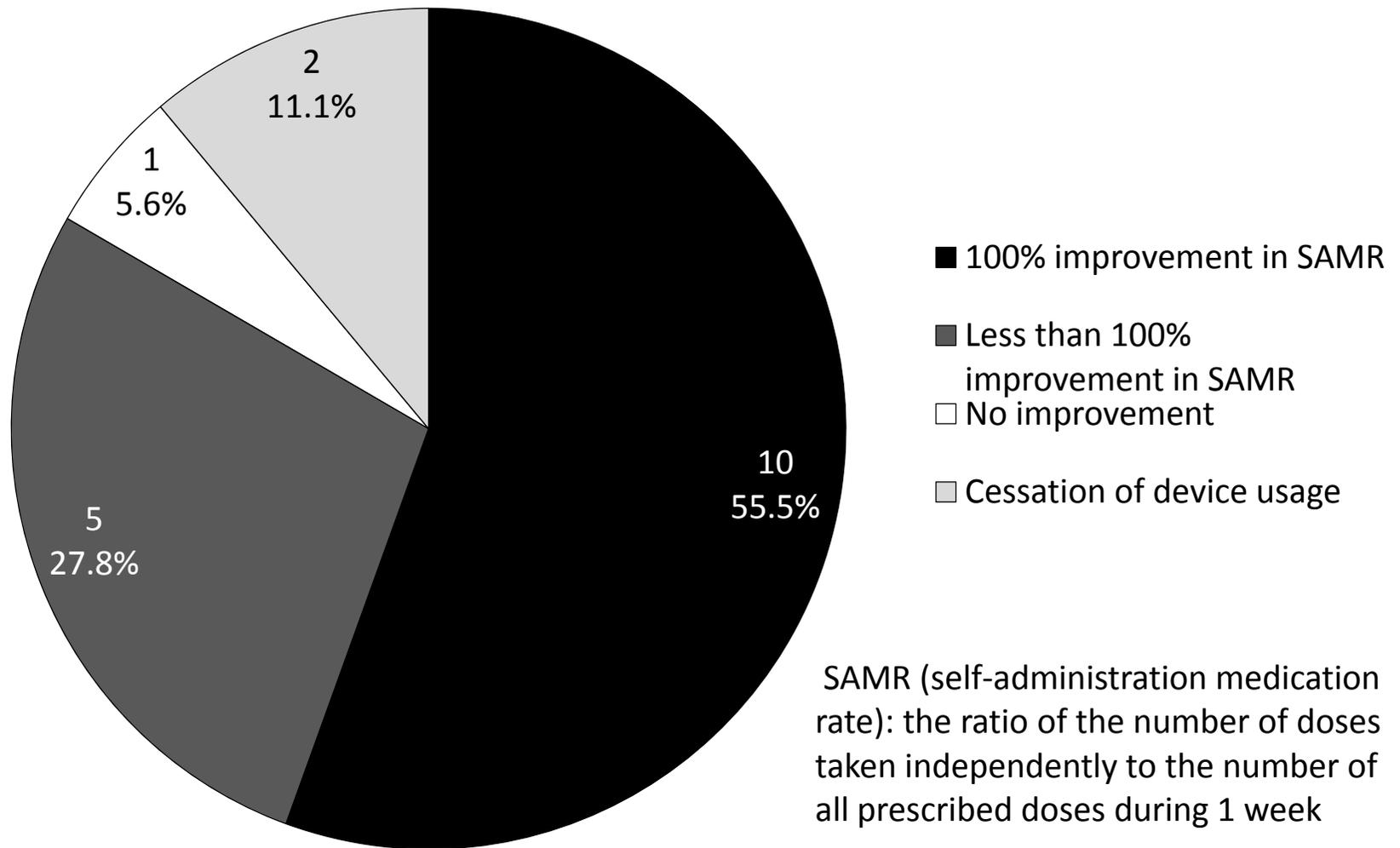
\*Includes six different types of medications.



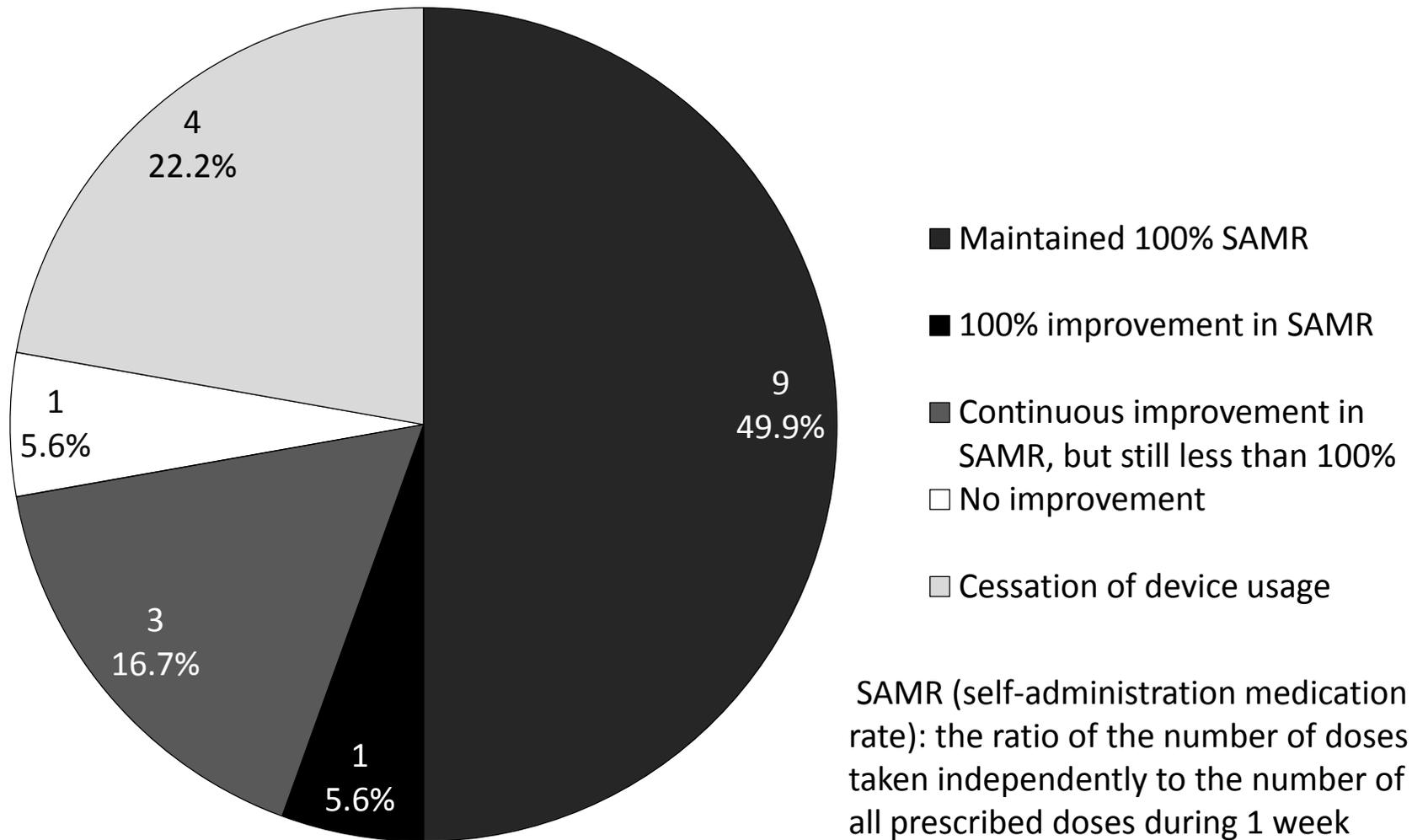
**Fig. 1** The automatic pill dispenser (Pivotel Ltd., Walden, Essex, UK)

is w.180 × h.56 × d.190 mm and 480 g (including batteries).

Left: the device in closed position. Right: the device in open position to set the alarm and insert medication. The device can be locked using a key.



**Fig. 2 Changes in SAMR after 1 month**



**Fig. 3 Changes in SAMR after 3 months**