Research Article



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A pilot study: Medication reminder technology for those living independently with heart failure

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Abstract

Background: Medication adherence is considered a major cause since it is estimated that 1 in 10 visits to the hospital results from medication mismanagement

Purpose: The purpose of this study was to examine the impact of medication reminder technology on medication adherence, readmission within 30 days, time between admissions, and length of hospital stay with those living alone with heart failure.

Methodology: The study was quasi-experimental with a convenience sample consisting of 31 control subjects and 30 intervention subjects. Intervention group utilized the MedMinderTM machine, an electronic pill box that reminds the patient when it is time to take medications through notification by light, sound, phone call and text messaging to family. The control group received usual care. With the use of cloud computing to collect data from the MedMinderTM machine, adherence with the use of the machine was measured

Result: No significance difference was found between groups; however, there was clinical significance. There was a 90% satisfaction with use of the MedMinder machine.

Conclusion: Findings indicates that the use of medication reminder technology could be beneficial in the prevention of readmission for HF. While the small subject size prohibits generalization, the findings support the need for a larger study in the use of such supportive technology.

Introduction

The numbers of elderly adults living alone in this country are increasing and will continue to do so since there are only 67,000 paid, regulated long-term care service providers serving about 9 million people in the United States. These services include 4,800 adult day care service centers, 12,400 home health agencies, 4,000 hospices, 15,600 nursing homes and 30,200 assisted living and residential communities [1]. Thus, promoting independence for as long as possible is crucial. With coordinated care and the use of technology, the goal of aging in place becomes more attainable [2]. Inadequate medication adherence is the single most important modifiable aspect of chronic disease management [3,4]. The importance of medication adherence and the low reported rates of adherence by older adults have prompted increased efforts to identify interventions to increase medication adherence in this population.

Aims

Therefore, the specific aims of this study were: 1) to determine the medication adherence when using a medication reminder technology in older adults with chronic heart failure (CHF), 2) to determine a difference between groups with the level of self-efficacy, 3) to determine a difference between groups with the quality of life, 4) to determine if a difference exists between groups and readmission rate within 30 days, and 5) to describe the intervention subjects' satisfaction with the medication reminder technology.

Literature review

Many approaches have been taken to decrease readmission rates in heart failure patients. The literature covers a wide variety of approaches, this review will focus on heart failure, older adults, medication adherence and the use of technology. This study was interested in the use of technology for medication adherence in older adults living independently with heart failure.

Heart failure

Heart failure is a chronic, serious, and expensive medical condition affecting approximately 5.8 million people in the United States [3]. Each year an additional 670,000 new cases are diagnosed and about 300,000 people die from heart failure (HF) [3]. National hospital readmission rates for Medicare beneficiaries discharged alive after HF hospitalization has approached 25% in recent years [4]. The reasons for the high rates of readmission are numerous; however, medication adherence is considered a major cause of readmission [5-7]. Indeed, it is estimated that \$290 billion in costs of emergency room visits and other

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avoidable medical expenses in the US are due to a lack of medication adherence. Despite the fact that medications can save or extend lives, the average patient fails to follow her/his pill prescription half the time [2]. HF patients are challenged with medication adherence for reasons ranging from simple forgetfulness to confusion. Yet, inadequate medication adherence is the single most important modifiable aspect of chronic disease management [3,4]. The importance of medication adherence and the low reported rates of adherence by older adults have prompted increased efforts to identify interventions to increase medication adherence in this population. Work by other investigators suggests that interventions emphasizing behavioral rather than cognitive strategies will produce better medication adherence outcomes [8]. Interventions that decrease the number of doses and employ special packaging or prompts to take medications may also be effective [2,8]. Prompts may include audible devices that cue medication administration and dispense the correct medication at the proper time. However, a meta analysis of medication adherence among older adults noted that the considerable heterogeneity in the magnitude of effects across studies and results of the moderator analyses demonstrated the need for additional empirical research to optimize interventions [8]. Older adults should be empowered to test interventions which can promote health [9]. Therefore, the goal of this proposed study was to determine the whether a medication reminder technology improves medication adherence of older adults with heart failure (CHF) who are living independently.

Older adults

The population is aging in nearly all the countries of the world, including the United States, in which the percentage of people aged 65 or older is expected to increase from 13% in 2010 to 20% in 2050 [10]. The numbers of U.S. older adults living alone in 2014 was 26%, with the majority these being women [11]. Aging in place is a goal given the high cost of assisted living and nursing home care. The use of technology among older persons has been examined and found that independence is highly valued and hence any system or technology that can prolong that independence tends to be highly regard [12].

Medication adherence

One major issue for elderly with chronic diseases is medications. This is a particularly important issue for those with chronic HF Non-adherence to medications has been found to be associated with exacerbation of HF, and it plays a major role in preventable rehospitalizations of heart failure patients [4,6]. Some studies indicate that \$290 billion per year is spent on health care due to medication non-adherence [13]. Yet medication adherence in HF is a complex and poorly understood phenomenon. Estimates of medication adherence range from a low of 7% to up to 90% depending upon the measurement used. Optimal clinical outcomes have been found to occur with an adherence rate of 88% or above [7]. Therefore, a number of studies have attempted to increase medication adherence. However, non-adherence remains a major problem.

Technology

Technology has the potential to improve medication adherence but there is little information about use of technology for this purpose. Only one study of technology use with HF patients has been published; these subjects utilized daily phone reminders and daily videotaped phone reminders, and the videotaped phone reminders significantly improved adherence, to a rate of 84% [7]. A number of other studies have looked at the effects on adherence of using technology with hypertensive subjects, [14-17], however, only Christensen et al. [15] reported any significant effects with use of technology (electronic blister card device) in older adults.

The use of cloud computing as an approach to manage medication adherence has not been evaluated with HF patients. Cloud computing is a method for delivering information technology services in which resources are retrieved from the internet through web-based tools and applications, rather than a direct connection to a server. Essential characteristics are on-demand self-service, broad network access, resource pooling, rapid elasticity, and measured service [18]. It is sold on demand, typically by the minute or the hour; it is elastic -- a user can have as much or as little of a service as they want at any given time; and the service is fully managed by the provider. Technology such as the MedMinder[™], an electronic medication reminder system, utilizes cloud computing whereby multiple end-users can access specific patient data with a code and follow patient medication compliance with on demand. Such a resource needs further evaluation for effectiveness in managing complex patients [2,19,20].

Technology such as the MedMinder^m, an electronic medication reminder system, could be one approach to help decrease readmission rates with heart failure patients. Systems such as this one need to be evaluated for efficacy and patient satisfaction with the technology itself since successful adoption of technology is crucial [21]. One small study (n=16) examined why and how subjects use health technology at home [22]. A larger study (n=1200) found that older adults were less likely than younger adults to use technology in general, computers, and the World Wide Web [21]. However, a number of years have passed since these studies and with the exponential explosion of technology; those results may not be as relevant at this time. Nevertheless, this issue requires further exploration and therefore subject satisfaction with the technology will be included as a variable in this study [20].

Research design and methods

A quasi-experimental design with pre and post tests will be used in this pilot study to evaluate an innovative intervention for medication adherence.

Setting: The HF inpatient unit at a 435 bed, not-for-profit general and acute care facility in NC was used as the recruitment site for this project. The HF unit had a patient census of approximately 180 patients a month with the diagnosis of HF. Once recruited into the study, the setting was the subjects' home for the intervention group.

Sample: The convenience sample consisted of 61subjects who ranged in age from 60 to 90 years. There were 30 interventions and 31 control subjects. Sample characteristics are provided in Table I.

Inclusion criteria: To be included, subjects had New York Heart Association (NYHA) Stage I, II, III, IV heart failure [23]. The subjects' NYHA classification was determined by a provider. In addition, subjects had to give informed consent; speak and read English; and be discharged home either living alone or with minimal oversight which did not included medication management. No home management was provided by a hospital or specialized clinic.

Recruitment and protocol: Patients admitted to the in-patient HF unit were approached 24 hours after admission by a nurse research assistant (RA) and asked if they wanted to participate in the study. A script was used by the RA. RAs were trained to recruit subjects, set up the equipment in the home and monitor subjects throughout the study to ensure consistency and to administer the questionnaires. As

well as in setting up the equipment in the home. All subjects signed a consent form that was IRB approved. The consent form included a HIPAA form granting access to their medical records.

Once the individual agreed to participate, the nurse research assistant provided the written questionnaires, a clipboard and pen, and offered to answer any questions. Questionnaires were answered in a private room. In addition to the administration of baseline questionnaires, a medical record review was conducted of the chart. Information about medical diagnoses and CHF treatment was obtained using a standardized demographic tool. The questionnaires were completed within 30 minutes, checked for missing data, and placed in an envelope.

The patients were told about the MedMinder and individuals selfselected whether they would utilize the machine (intervention) or be a control. The control group self-selected to not participate in the intervention group. Those in the control group received usual care. Over the duration of the study, we were not able to get enough intervention subjects for data analysis. Due to the difficulty in recruitment for intervention subjects, the study was conducted over a 2-year period. Over 117 patients were approached to be in the intervention group and refused for a variety of reasons. The control group did not want nurses coming into the home to set up the MedMinder[™] due to a community culture of valuing privacy. Some stated they were too sick, they did not want anyone coming into the home, or they felt that they could manage their medicines on their own, or family members stated that they were taking care of the patient. These comments are typical of the belief system with many rural communities.

Therefore, the research team started utilizing financial incentive of \$25 gift card after IRB approval. The incentive resulted in 17 more subjects recruited for the intervention group. The subjects that were given incentive to enroll in the intervention group were analyzed to identify differences which may have existed between paid and unpaid subjects. The analysis included age, gender, race, marital status, heart failure classification, functional status, and 30-day readmission. No significant differences were found. Therefore, we analyzed the paid and unpaid subjects as one group receiving the intervention.

Table 1 has the demographics of the intervention and control groups. There were a total of 28 males (45.9%) and 33 females (54.1%) in the sample for the study.

Design: Pretest/posttest design was used to examine difference between baseline and at 30 days between two groups. At time of hospitalization consented subjects completed a demographic sheet, Medication Adherence Self Efficacy Scale (MASES) [24], and the Minnesota Living with Heart failure (MLHF) [25] instrument for baseline data. At the end of 30 days both groups completed the MASES and MLHF QOL instrument. The control group was phoned and asked the questions on the instruments. In addition to these instruments, the intervention group completed a technology satisfaction survey when the nurse came to remove the medication reminder system. The RA gave subjects information on the cost of the MedMinder[™] as well as other medication reminder system on the market so that subjects could decide if they want to purchase/subscribe to the service on their own.

Intervention: The intervention group received 2 home visits (one at the beginning and end of the study). The first visit for the intervention group included a review of the list of home medications, the medication reminder technology set up with subject training, and insurance that the cloud technology was in operation. The intervention

Table 1. Demographics.

Variables	Control (N=31)	Intervention (N=30)
Age (years)		
60-70	17 (27.9%)	11 (18.0%)
71-80	8 (13.1%)	12 (19.7%)
81-90	6 (9.8%)	7 (11.5%)
Race		
White	26 (83.9%)	25(83.3%)
Black	5 (16.1%)	5 (16.7%)
Gender		
Male	18 (58.1%)	10 (33.3%)
Female	13 (41.9%)	20 (66.7%)
Marital Status		
Separated	1 (3.2%)	1 (3.3%)
Divorced	6 (19.4%)	4 (13.3%)
Widow	7 (22.6%)	12 (40.0%)
Never Married	2 (6.5%)	3 (10.0%)
Married	15 (48.4%)	10 (33.3%)
Heart Failure Stage		
Stage I	2 (6.7%)	2 (6.7%)
Stage II	12 (40.0%)	17 (56.7%)
Stage III	13(43.3%)	7 (23.3%)
Stage IV	3 (10.0%)	4 (13.3%)
Functional Status		
No deficit	16 (53.3%)	6 (2.0%)
Cane	5 (16.7%)	7 (23.3%)
Walker	7 (23.2%)	16 (53.3%)
Wheel Chair	2 (6.7%)	0 (0)
Motorized Chair	1 (3.3%)	1 (3.3%)
Readmission within 30 days		
Yes	7 (22.6%)	2 (6.7%)
No	24 (77.4%)	28 (93.3%)

used is called the MedMinder[™] also known as Maya, an electronic pill box that reminds the patient when it is time to take medications. It looks like a plastic pill box, with 4 dosing sections per day in a oneweek package. Installation is as simple as plugging the power cord into an electrical outlet. *There is no need for a computer, wireless router or any other form of internet access.* The technology uses an internal wireless modem to communicate with MedMinder's central server. This particular method of service is called cloud computing.

The MedMinder[™] which prompts the patient if medications are forgotten first by having the right medication compartment start flashing, if the cup is not removed, after a period of time, other alerts such as beeps, phone calls, emails or text messages can be initiated to the patient, family and provider. There is no need for programming consequently, those who may be resistant to technology will feel at ease and comfortable with the unit. The unit's compartments can be remotely accessed to program. The caregiver can access the MedMinder[™] server at any time to view patient's compliant or non-compliant behavior.

Instruments administered at baseline and at 30 days

The instruments administered at baseline and at 30 days are listed below:

Demographic sheet: Because demographics and subject satisfaction may have a direct effect on the results, the following was collected: age, race, gender, marital status, stage of heart failure, co-morbidities, functional deficit, list of medications, and contact for MedMinder[™] system. This information was obtained from the medical record and verified with the subject. The medical record provided data on subject readmission rate, time between admissions, and length of stay over a 30-day period. The RA was trained on medical record data retrieval. Table 2 provides the list of study variables with instruments used for measurement.

Table 2. Measurement of study variables.

Variables	Definition	Source
Medication Adherence	Daily reports of adherence generated by MedMinder TM Medication Adherence Self-efficacy Scale	Reports from MedMinder™ MASES [24]
Readmission	Readmission within 30 days	Medical Record Review (MRR)
Time between admissions	Days	MRR
Length of stay	Days	MRR
Quality of Life	Minnesota living with heart Failure	MLHF [25]
Subject Satisfaction	Subject satisfaction withinterventionaltechnology	Patient Technology Satisfaction Tool [26]

The MASES and MLHF tools were used to identify a difference between the groups at baseline. There were no differences between the groups given that both control and intervention group self-selected to use the MedMinder[™] or receive regular care. Therefore, both the control and intervention groups were similar.

Medication Adherence Self-efficacy Scale (MASES): The MASES [24] was used to measure self-efficacy. This is a 26-item scale that is used to assess patient's confidence in their ability to take medications in a variety of situation. Some examples of situations include "when busy at home" "while at work," "when they cause some side effects." Items are scored from 1 (not at all sure) to 4 (extremely sure) and a total score on the measure is computed by averaging across responses to all items. This scale has demonstrated validity and reliability. Higher scores indicate a greater level of efficacy. Cronbach's alpha for the measure was 0.95. Minnesota Living with Heart Failure Questionnaire (MLHF) [25]: The MLHF tool measures patients' perception of the effects of heart failure on their lives, i.e., quality of life. Patients respond to 21 items using a Likert scale (0-5) with 0 indicating that heart failure has had no adverse effect on their lives and a score of 5 indicating a "very much" effect on their lives. This tool measures physical, socioeconomic and psychological impairments that patients relate to their heart failure. This questionnaire is specific to the heart failure population, has demonstrated reliability and validity and measures the patients' perceptions of the effect of heart failure on their quality of life. The questionnaire has been used in trials of varying designs to evaluate the quality of life over time [25]. Cronbach's alpha for the measure was 0.92.

Technology satisfaction tool: Satisfaction with the use of the MedMinder[™] was measured at the end of the study with a 10-item, investigator-developed tool with a Likert scale from 1-5 for each item. This tool has been piloted with 10 subjects and revised to be used in this study [26]. The ten questions address use of technology (set up and explanation), confidence with use of technology, meeting medication care needs, and would they recommend use of the technology to others. This tool was given to intervention group at the end of the study.

Data analysis

Sample size calculation fort-test with G*Power software [27] was completed a priori with an alpha level of 0.05, medium effect size (F2= 0.15), and a statistical power level of 0.5 requiring a total sample size of 60 [28]. Power analysis is estimated to be 0.92 with a 70% adherence for the intervention group and 30% for the control group.

All data were de-identified, and SPSS version 23 was used for data analysis. The number and percentage were used to summarize the sample characteristics. Data was entered into an Excel spreadsheet for conversion to and analyses in SPSS (Version 23) [29]. Descriptive statistics were computed to provide a summary of the sample and the variables measured by the surveys and medical record review. To determine the efficacy of MedMinder^{ss} in improving medication adherence (Aim 1, 2, and 4) we used a chi square to identify significant differences between control and intervention groups on medication adherence, MASES, readmission within 30 days, time between admissions, and length of hospital stay. To determine a difference between the groups with the quality of life (Aim 3) a chi square was utilized and then with Aim 5 analyzing subject satisfaction with technology, we used means and percentages on the technology subject satisfaction survey questions.

Results

The medication adherence when using the medication reminder technology in older adults with chronic heart failure (CHF) was measured using percentage of compliance with use of the machine. Table 3 shows that the majority of intervention subjects utilized the machine 90 percent or more during the 30 days. The mean percentage of adherence 95%. However, the majority 22 (73.4%) people had greater than 99% compliance with the use of the device.

The Medication Adherence Self-efficacy scale (MASES) was used to identify whether the groups were different at baseline. A chi square was performed and there was no significant difference between groups on the total self-efficacy score at baseline or at 30 days. The MLHF scale was used to identify whether groups were different at base. A T-test was performed and no significance between groups was found at base line or at 30 days.

To determine if a difference exists between groups on the hospital readmission rate within 30 days a Chi Square was utilized. There was no significant difference between groups. This may be due to the small sample size. However, there is a clinical significance of only 2 intervention subjects being readmitted within 30 days. Table 4 shows the results of the Chi Square.

The ease of use of the MedMinder was measured using a 10 question Liker tool called the Patient Technology Satisfaction Tool. The maximum score which could occur is 50. The intervention group was satisfied with the use of the med minder as evidence by 93.3% (n=28) scoring the questions as a 4 or higher. Satisfaction with the use of the MedMinder[™] was measured at the end of the study with the intervention subjects. Chronbach's apha was .806 for the ten item satisfaction questionnaire about the MedMinder. Results for 9 out of the 10 questions averaged between 4.41 and 4.9 out of 5. The item related to "plan to continue use" averaged .83. Table 5 displays the score and frequency that score was chosen.

The Nurse Research Assistants scored a 4 question dichotomous item survey at the end of each set up of the machine in the intervention subject home. Once during set up, the nurse research assistant could not get the machine connected to the cloud. The problem was associated

Table 3. Percentage of compliance with MedMinderTM.

Percentage of Compliance	Frequency (N=30)	percentage
.50	1	3.3
.78	1	3.3
.90	2	6.6
.92	1	3.3
.94	1	3.3
.95	1	3.3
.97	1	3.3
.99	7	23.4
1.00	15	50

Table 4. Readmission at thirty days.

		Control / Intervention		Control / Intervention		
Count		control	intervention	Total		
Readmissions in thirty	yes	7 (22%)	2 (.07%)		9	
days	no	24	28	52		
Tota	ıl	31	30	61		
			Chi-Square Tests			
		Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Ch	i-Square	3.070ª	1	.080		
Continuity C	orrection ^b	1.935	1	.164		
Likelihoo	d Ratio	3.234	1	.072		
Fisher's Ex	act Test				.147	.081
Linear-by-Linea	r Association	3.020	1	.082		
N of Valid	l Cases	61				
a. 2 cells (50.0%) have expe	ected count less than 5	. The minimum expected cou	int is 4.43.			
b. Computed only for a 2x2	table					

with the remoteness of the subject. This subject was withdrawn from the study. Table 6 displays the results of the Research Assistant evaluation of the setting up of the technology.

Discussion

The goal of this study was to examine the Medminder $\mbox{}^{\mbox{}^{\mbox{}^{\mbox{}^{\mbox{}^{}}}}$ as a tool for increasing medication adherence and decreasing 30 day hospital readmission for individuals with heart failure. A medication reminder system was installed in intervention group homes and monitored through cloud computing for medication adherence. Medication adherence ranged from 95-99% in all subjects but one. The one subject had a 77% adherence rate and had a hospital readmission within 30 days of discharge. While there was not a significant difference between groups due to the small number of readmissions relative to the total sample size of 61, the trend is going in the right direction.

Clinical implications

Medication adherence plays a key role in readmission of heart failure patients and in acute exacerbation of their disease process. There have been few interventions that effectively improved medication adherence, reduced hospital readmissions and extended the length of time to hospital readmission.

Even though the results of this study did not demonstrate statistical significance, the researchers believe the data did demonstrate clinical significance. The researchers are using the following definition of clinical significance in their review of their results: Clinical significance is a decision based on the practical value or relevance of a particular treatment, and this may or may not involve statistical significance as an initial criterion [30]. Consequently, the results of this study indicate that there is clinical significance with respect to the use of medication reminder technology. This interventional trial used an innovative cloud computing approach to impact medication adherence in older adults with heart failure patients living independently.

Limitations

Because of the quasi-experimental study design there are several limitations including sampling approach and sample size, methods and measurement. A small convenience sample from one geographic region was utilized for this study. We did not control for potentially confounding variables. Another limitation is that the variability between patient's severity of illness, disease processes, and comorbidities were not controlled for in this study. This variability may have influenced Table 5. Subject satisfaction with technology.

Score	Frequency
27.00	1
38.00	1
40.00	1
42.00	2
43.00	1
44.00	5
45.00	2
46.00	17
Total	30

Table 6. Ease of set up for research assistants.

		Times the machine was set up	Percent
Score for Ease of set up by RA	4.00	20	.67
	5.00	9	.30
	6.00	1	.03
	Total	30	100.0

to what extent those choosing the machine were more self-motivated. The use of Likert scales may have resulted in raters providing neutral responses, which could be problematic in terms of understanding the study findings. Due to these limitations, the generalizability of this study is limited and findings should be viewed with caution. While many limitations exist we believe that the findings show a trend in the right direction and warrant a larger study.

Conclusion

These reported findings indicate that there is clinical significance that the use of medication reminder technology could be beneficial in medication adherence and delay readmission for HF patients beyond 30 days. With regard to the data related to use of technology by older adults with HF, data demonstrates that those individuals that self-selected to use the technology were satisfied with the technology in general. While the small subject size of this research prohibits generalization, the findings support the need for a larger study in the use of such supportive technology.

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