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The Women Independently Living Alone with a Medical Alert Device (WILMA) Trial

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Abstract

Background—Women are more likely to live alone compared with men, and therefore have more difficulty activating emergency medical systems for stroke. The goal of this study was to examine the benefit of wearing medical alert devices to activate emergency medical systems for elderly women living alone.

Methods—This was a randomized, controlled pilot trial. Women over 60 with at least 1 stroke risk factor were recruited from Southeast Michigan. Subjects received either a medical alert device or control. The primary outcome was change in Health-Related Quality of Life (HRQOL) from baseline to 90 days of wearing the device or control.

Results—A planned sample size of 320 could not be reached and the trial was stopped at 265 women randomized prior to data examination. On average, the treatment group was older, reported lower prevalence of high cholesterol, and was less likely to complete follow-up. There was a non-significant smaller loss of healthy days in the past month in the intervention group (0.46) compared with the control group (2.23), (p=0.213). Similarly, the secondary outcomes of changes in anxiety, depression and changes in perceived isolation did not differ by treatment and control groups.

Conclusions—This study did not establish improvement in HRQOL among women who wore the device compared with those that did not, nor the feasibility of a trial to study the efficacy of medical alert devices in elderly women. Newer devices that use cellular technology may be more accepted than the land-line based system used in this study.

Keywords

Stroke; women; medical alert; emergency medical services; pre-hospital; delay

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COMPLIANCE WITH ETHICAL STANDARDS

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All subjects provided written informed consent.

All authors declare they have no conflicts of interest.

INTRODUCTION

Stroke is a leading cause of adult disability and death throughout the world [1]. Since age adjusted stroke incidence is higher in men than women [2] the disease is classically considered a male illness. However, about half of stroke deaths occur in women, and since women live longer than men they have a higher lifetime stroke risk [2]. Among those that survive stroke, functional and neurologic outcome is worse in women compared with men [3]. Effective acute stroke treatment exists, but it is time limited and rapid presentation to the emergency department is crucial for consideration of acute stroke therapy. Since stroke often renders speech and movement ineffective, it is frequently an observer who activates emergency medical services rather than the patient herself [4]. A potential impediment for elderly women getting to the hospital quickly is that they are more likely to live alone than men, and therefore a call for help for stroke is less likely to happen compared with someone who does not live alone [5]. Indeed, people who live alone get to the hospital slower, are less likely to get the clot dissolving drug, rt-PA, and have worse stroke outcome than those who do not live alone [5].

A potential way to help women who live alone get to the hospital quickly when they have a stroke is to have a medical alert device on their body that can be pushed to initiate a call for emergency medical services. We conducted a single center pilot randomized controlled trial to determine the feasibility of women wearing such a device. The possibility of reducing death, disability and expense in women with stroke by using these simple devices suggests an exciting opportunity to improve public health and reduce the stroke burden in women.

METHODS

This report contains the primary results of the pre-specified analysis of the Women Independently Living with a Medical Alert Device (WILMA) trial conducted at the University of Michigan in Ann Arbor, USA. Subjects were randomized to receive the device or not, and the main outcome measure was Health-Related Quality of Life (HRQOL) measured at 90 days. This study was approved by the University of Michigan IRB and all subjects provided informed consent. This trial was not registered with clinicaltrials.gov since it was a single center study and registration was not required at the time of study conduct.

Study Subjects

Inclusion criteria were: Women; age ≥80 or age 60–79; ≥1 stroke risk factor (hypertension, hyperlipidemia, coronary artery disease, diabetes, atrial fibrillation, current smoker, prior stroke or TIA); not currently using a medical alert device/service; has a working home phone that is compatible with monitoring service; plans to stay in current residence in Michigan for the duration of the study. Exclusion criteria were: cognitive impairment that would impede informed consent; living with someone else; residing in a facility that provided emergent care; living more than an hour by car from Ann Arbor; having an at home caregiver that provides > 3 hours per day of help.

Subjects were recruited through direct mail, flyers and direct communication at the University of Michigan Geriatrics and General Medicine Clinics; from the Claude B Pepper

Older Americans Independence Center Research Participants Program; from the Turner Senior Resource Center; local senior centers; from local independent senior living centers; churches and other civic centers.

Randomization and Intervention

Eligible subjects were randomized to either the medical assistance device or control in a block design with block sizes of 4 and 6. Subjects randomized to receive the medical assistance device were contacted by the local provider, Huron Valley Ambulance (HVA). HVA is a not-for-profit organization that provides emergency response to the local community. HVA personnel installed the speakerphone (Visonic Amber® Select) and gave instructions for its use along with the call button device (Visonic MCT-212) per their standard protocol. A representative from HVA contacted them to set up an appointment to install a speakerphone to the subject's landline phone in their home (attached like an answering machine). The device works with a range up to 120 meters. Each person also received a small call button of two designs, a wrist band or a necklace per their preference. If a person pushed the call button, it would communicate a signal to HVA, who would respond over the speakerphone device to see if the activation was on purpose. Either no patient response or a positive response indicating assistance is needed generated immediate emergency response. During the study those randomized to the device received the device and monitoring service for free. At the end of 90 days subjects had the option of keeping the monitoring service at their expense, or having the devices collected by HVA and cease monitoring. This study was not blinded. Subjects were obviously aware of having the device or not, and the coordinator obtaining outcome data was aware of the study purpose. Subjects in both arms of the study were read a list of stroke symptoms after the knowledge of stroke symptoms was queried.

Data Collected

At baseline subjects in both groups were interviewed in person or over the phone and provided: demographics (age, race-ethnicity, marital status, socioeconomic status); contact information (telephone number, address); social isolation/connectedness scale; quality of life; anxiety; depression; and stroke knowledge questions. At follow-up the same information was obtained again except for demographics, contact information and stroke knowledge. In addition, the follow-up interview included: medical utilization (hospitalizations, ED visits, device activation); use of medical alert devices/service; and whether they would choose to keep this or a similar device if cost was not an issue.

The primary outcome, quality of life, was measured by the HRQOL instrument developed by the Centers for Disease Control and Prevention, USA. This instrument, which is comprised of four questions, captures an individual's perceived physical and mental health and has been used in elderly women to assess changes in quality of life over time [6]. The instrument asks participants to self-report the number of days in the past month when physical and mental health were not good. The primary outcome was assessed as the total number of healthy days (physical plus mental). Secondary outcomes included anxiety and depression as measured by the Hospital Anxiety and Depression Scale (HADS). The HADS is a short 14-item scale that takes two to five minutes to administer. The HADS has been

shown to be a valid method for assessing anxiety and depression in primary care and general population settings and has been used in elderly female populations [7]. Items are scored from 0–3 on a 4-point Likert-type scale, generating a range of 0 to 42 points. Higher scores represent greater symptom severity. Social connectedness, another secondary outcome was assessed using social isolation via the Perceived Isolation Index in an elderly population ages 57–85 [8]. This scale contains questions related to social support and loneliness and has been shown to have reliability in an elderly population. We modified this scale by removing questions about spouse or partner, as our population by definition was living alone. Each item on the scale was scored 1 to 3 and then standardized. The overall index was summarized as an average of all seven items with higher scores indicating greater perceived isolation. Stroke knowledge was assessed by asking participants to name stroke warning signs. We classified stroke symptoms into 5 categories: weakness, numbness, or tingling on one side of the body; difficulty speaking or understanding speech; headache; dizziness, lightheadedness, or falls; and vision problems. Participations who were able to recognize 2 or more categories of stroke symptoms were considered to have adequate stroke knowledge [9].

Statistical Analysis

Sample size was determined using standard calculations for repeated measures ANOVA. The following assumptions were made: 5% level of significance, 80% power, detectable difference of 4 healthy days (pre-post difference in quality of life between two treatment groups), a constant standard deviation of 12 for both groups, and a 0.50 correlation between pre- and post- time points. Under these assumptions, 143 subjects were needed in each group. Assuming some loss to follow-up over the course of the study the planned recruitment was 160 subjects in each group.

Demographic and health characteristics were summarized at baseline by treatment and control groups. Continuous variables were summarized by means and standard deviations and compared using t-tests. Categorical variables were summarized by frequencies and percents and compared using chi-squared tests. Change scores were created for the difference in number of healthy days (physical plus mental) from pre- to post-intervention and for the secondary outcomes of anxiety and depression, using the HADS score, and perceived isolation index. Change scores were then compared by treatment group using simple linear regression. Among those randomized to the intervention, frequencies and percents were used to summarize appropriate use of the device. All analyses were performed using SAS version 9.3 (Cary, NC).

RESULTS

WILMA enrolled its first subject on November 30, 2011 and last on August 5, 2014. While the goal was to enroll 320 subjects the study was stopped after 265 were enrolled prior to examining the data, due to slower than anticipated enrollment. Figure 1 is the CONSORT diagram for the study. Lack of participation was most commonly due to the fact that subjects either did not have a land-line telephone or already had a medical alert device.

There were 265 women randomized to either the treatment (n=133) or the control group (n=132). On average, the treatment group was older, reported lower prevalence of high cholesterol, and was less likely to complete follow-up (Table 1). Overall, women in the study experienced a mean loss of 1.38 (SD=10.8) healthy days. Women in the treatment group experienced a smaller loss of health days (0.46; 95% CI: −1.58, 2.50) than women in the control group (2.23; 95% CI: 0.31, 4.15), but this difference was not significant (Table 2). Similarly, for the secondary outcomes of changes in HADS score and changes in perceived social isolation, the treatment and control groups did not significantly differ.

Among those women that were randomized to the treatment group, only 1 purposefully used the device during the study period, and 9 went to the ER or used EMS without the device. There were no strokes. Half of the women reported wearing the device almost all of the time and 12% reported never wearing the device. Sixty-nine percent of the women removed the device for any reason. If cost was not an issue, 53% would want to keep the device. However, only 17% planned to keep the current device service if they had to pay for it.

DISCUSSION

The WILMA pilot trial did not find a significant improvement in HRQOL in subjects randomized to receive a medical alert device compared to control. Study recruitment was slower than anticipated and consequently missed the planned sample size suggesting that a large randomized trial of medical device use would likely not be feasible in its current form at a single center. A pivotal study would need to demonstrate that wearing a device reduces delay times to hospital arrival for stroke patients who live alone.

Due to the available technology when WILMA began, participants were required to have a land-line telephone. This excluded a large number of potential subjects who only had a cell phone. Newer technologies, especially those that incorporate cellular signal are likely to not only enroll subjects more easily but also provide coverage outside of the home. This is an excellent opportunity for biomedical engineering innovation in neuroscience. The device, however, must be worn rather than carried like a cell phone since at the time of stroke many subjects are unable to move, rendering a cell phone that is not physically on the patient useless. An ideal device would be one that is unobtrusive, easy to wear, inexpensive, able to transmit in most locations including outside the home, and one that could provide two-way communication in case of inadvertent activation.

The problem of stroke in women is receiving much needed attention after a long history of considering stroke a men’s disease [10]. Recent studies that suggest worse stroke outcome in women compared with men, differential gender response to IV rt-PA, and different stroke symptoms in men and women all point to the need for more research into stroke prevention and treatment for women [3,11,12]. WILMA spoke to the evidence that women are less likely to present to the hospital promptly for acute stroke therapy [13,14] which has not been found consistently [15]. Since women are more likely to live alone than men, a solution is needed to help women who have an acute medical emergency to call for help when the medical emergency prevents movement and/or verbal communication. This is notably important for diseases with time limited therapies. While stroke is the clearest example of

such a condition and very common, other conditions including myocardial infarction suggest the public health need for interventions to help women who live alone.

This study had limitations that warrant consideration. There was a greater loss to follow-up among the intervention compared with the control group which may have implied dissatisfaction with the device. This was an unblinded study. Since the purpose was to determine the feasibility of participating and wearing a device it was impossible to mask the study subjects with a sham device. The outcome assessor was also unblinded although the primary outcome measure was a structured questionnaire that was not subject to coordinator interpretation. The study failed to achieve its planned sample size and as such was under powered to detect a change in the primary outcome. WILMA was a single center study and results may not generalize to other settings.

In summary, this study did not find improvement in HRQOL in women who received the device compared to those that did not, perhaps due to a small sample size. The study suggested a lack of feasibility for a larger trial since enrollment was much slower than expected. Newer technology that utilize cellular systems, can be worn in any location and is aesthetically pleasing to women would improve feasibility and may be a solution to activating emergency medical systems for time-limited acute medical conditions like stroke.

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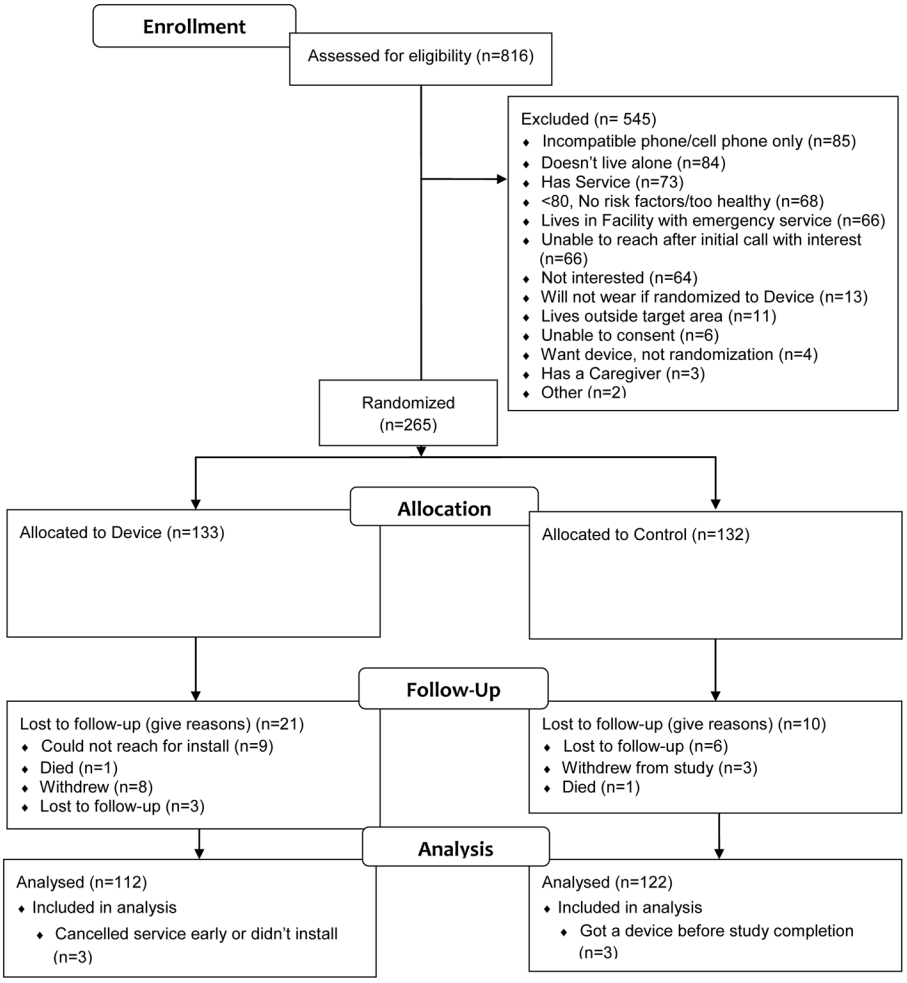

Figure 1.
CONSORT diagram of study participation.

Table 1

Demographics, clinical factors, baseline measures of the study population

Demographic Characteristic	Category	Total	Treatment N (%)	Control N (%)	p-value
			N=133	N=132	
Age, mean (SD)		265	76.95 (8.51)	75.05 (8.20)	0.064
Race	White	237	120 (90.2)	117 (88.6)	0.6744
	Black	24	11 (8.3)	13 (9.8)	
	Asian or Pacific Islander	3	2 (1.5)	1 (0.8)	
	Other	1	0 (0)	1 (0.8)	
Ethnicity	Non-Hispanic	264	132 (99.2)	132 (100)	0.3182
	Hispanic	1	1 (0.8)	0 (0)	
Marital Status	Single	52	31 (23.3)	21 (15.9)	0.3572
	Married	1	0 (0)	1 (0.8)	
	Significant Other	9	4 (3)	5 (3.8)	
	Divorced	74	32 (24.1)	42 (31.8)	
	Widowed	128	66 (49.6)	62 (47)	
	Separated	1	0 (0)	1 (0.8)	
Education	Graduate Education	107	49 (36.8)	58 (44.3)	0.5932
	College	124	68 (51.1)	56 (42.7)	
	Skill or Trade School	12	7 (5.3)	5 (3.8)	
	High School	18	8 (6)	10 (7.6)	
	Some High School	3	1 (0.8)	2 (1.5)	
Residence	Independent Living	10	2 (1.5)	8 (6.1)	0.1501
	Private house/apartment	249	128 (96.2)	121 (91.7)	
	Other	6	3 (2.3)	3 (2.3)	
Health	Excellent	38	10 (7.5)	28 (21.2)	0.0169
	Very Good	122	71 (53.4)	51 (38.6)	
	Good	81	40 (30.1)	41 (31.1)	
	Fair	19	9 (6.8)	10 (7.6)	
	Poor	5	3 (2.3)	2 (1.5)	

Demographic Characteristic	Category	Total	Treatment N (%)	Control N (%)	p-value
			N=133	N=132	
Hypertension	Yes	186	89 (66.9)	97 (74)	0.2043
	No	78	44 (33.1)	34 (26)	
High Cholesterol	Yes	188	87 (65.4)	101 (76.5)	0.0466
	No	77	46 (34.6)	31 (23.5)	
Diabetes	Yes	48	21 (15.9)	27 (20.5)	0.3384
	No	216	111 (84.1)	105 (79.5)	
Heart Disease	Yes	42	21 (16.3)	21 (16.2)	0.9782
	No	217	108 (83.7)	109 (83.8)	
A Fib	Yes	28	18 (13.6)	10 (7.8)	0.1299
	No	232	114 (86.4)	118 (92.2)	
Current Smoking	Yes	14	10 (7.5)	4 (3)	0.1024
	No	251	123 (92.5)	128 (97)	
History TIA	Yes	28	11 (8.5)	17 (13)	0.2471
	No	232	118 (91.5)	114 (87)	
Adequate Stroke Knowledge	Yes	196	100 (75.2)	96 (72.7)	0.6481
	No	69	33 (24.8)	36 (27.3)	
Follow-up complete?	Yes	234	112 (84.2)	122 (92.4)	0.0375
	No	31	21 (15.8)	10 (7.6)	
HRQOL Days, mean (SD)	[Higher better]	265	24.70 (8.87)	22.50 (10.03)	0.076
HADS, mean (SD)	[Lower better]	265	7.57 (4.57)	8.31 (4.78)	0.1991
Perceived Isolation Index, mean (SD)	[Lower better]	265	−0.06 (0.59)	0.06 (0.67)	0.0952

HADS—Hospital Anxiety and Depression scale

Table 2

Mean change and 95% confidence interval in outcome measure for each group and the treatment effect.

Outcome	Treatment	Control	p-value
Number of healthy days	0.46 (−1.58, 2.50)	2.23 (0.31, 4.15)	0.213
Hospital Anxiety and Depression Scale	0.24 (−0.43, 0.91)	0.34 (−0.30, 0.98)	0.84
Perceived Isolation Index	−0.03 (−0.11, 0.06)	0.05 (−0.03, 0.13)	0.211