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ORIGINAL RESEARCH

Effects of home telemonitoring on transitions between frailty states and death for older adults: a randomized controlled trial

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Background: Two primary objectives when caring for older adults are to slow the decline to a worsened frailty state and to prevent disability. Telemedicine may be one method of improving care in this population. We conducted a secondary analysis of the Tele-ERA study to evaluate the effect of home telemonitoring in reducing the rate of deterioration into a frailty state and death in older adults with comorbid health problems.

Methods: This trial involved 205 adults over the age of 60 years with a high risk of hospitalization and emergency department visits. For 12 months, the intervention group received usual medical care and telemonitoring case management, and the control group received usual care alone. The primary outcome was frailty, which was based on five criteria, ie, weight loss, weakness, exhaustion, low activity, and slow gait speed. Participants were classified as frail if they met three or more criteria; prefrail if they met 1–2 criteria; and not frail if they met no criteria. Both groups were assessed for frailty at baseline, and at 6 and 12 months. Frailty transition analyses were performed using a multiple logistic regression method. Kaplan–Meier and Cox proportional hazards methods were used to evaluate each frailty criteria for mortality and to compute unadjusted hazard ratios associated with being telemonitored, respectively. A retrospective power analysis was computed.

Results: During the first 6 months, 19 (25%) telemonitoring participants declined in frailty status or died, compared with 17 (19%) in usual care (odds ratio 1.41, 95% confidence interval [CI] 0.65–3.06, $P = 0.38$). In the subsequent 6 months, there was no transition to a frailty state, but seven (7%) participants from the telemonitoring and one (1%) from usual care group died (odds ratio 5.94, 95% CI 0.52–68.48, $P = 0.15$). Gait speed (hazards ratio 3.49, 95% CI 1.42–8.58) and low activity (hazards ratio 3.10, 95% CI 1.25–7.71) were shown to predict mortality.

Conclusion: This study did not provide sufficient evidence to show that the telemonitoring group did better than usual care in reducing the decline of frailty states and death. Transitions occurred primarily in the first 6 months.

Keywords: telemedicine, high-risk elderly persons, frailty transition, functional decline

Introduction

Two primary objectives of medicine when caring for older adults are to slow the decline to a worsened frailty state and to prevent disability. Frailty is highly prevalent in older adults and confers a high risk for falls, disability, hospitalization, and mortality.[1] Additionally, frailty is a dynamic process and transitions between frailty states can occur in both directions over time, although transitions to worsened frailty states may be more common than transitions to improved states.[2] Thus, one expects potential declines over time. Telemedicine may be one method of improving care for this population. Health care providers often use home telemonitoring to reduce

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adverse health outcomes like hospital stays or emergency department visits.[3–6]

The frailty markers were added into the original Tele-ERA study[7] design under the notion that tighter control of comorbid illness might reduce progression of frailty or even improve the level of frailty. This is a reasonable hypothesis because there is general consensus within the geriatric community that comorbid burden contributes to frailty. In fact, the Rockwood model of frailty relies heavily on comorbid diagnoses in addition to disease signs and symptoms to identify frail patients.[8] In the Fried model, 68% of the frail patients had two or more comorbid illnesses,[1] and in the Tele-ERA study, the proportion was 97%.

The anticipated reduction in hospitalizations of telemonitoring participants was expected to result in further improvement of functional status as per an earlier study of hospitalized elderly patients which revealed that regular hospital care is associated with greater loss of function.[9] One study of frail adults reported a reduction in functional decline and a decrease in hospitalizations through the use of physical activity and self-management interventions.[10] A higher number of annual hospital days is also correlated with increased mortality and readmission to hospital.[11] Unfortunately, the primary results from the Tele-ERA study indicated no significant difference in number of hospital days between telemonitoring and usual care groups.[12] Thus, if we found improvement in frailty status in our analysis, then it would be likely to be because of improved chronic disease management via telemonitoring as previously mentioned.

The main objective of this study was to evaluate the effectiveness of home telemonitoring in reducing the decline of worsening frailty states in older adults aged 60 years and over with comorbid health problems. To answer this question, we performed a secondary analysis of our Tele-ERA study, which evaluated telemonitoring, hospitalization, and emergency department visits.[12]

Materials and methods

Trial design

The methods of this secondary analysis of the Tele-ERA study are briefly discussed below, but the full details of our protocol and the initial cohort have been described elsewhere.[12] All participants provided their written informed consent. The study was approved by the institutional review board at the Mayo Clinic and Purdue University.[12]

Study population

Participants were adults aged 60 years or older and were enrolled in the employee community health primary care panel at the Mayo Clinic in Minnesota. Patients with an Elder Risk Assessment (ERA) score of 16 or higher were eligible for the study. An ERA score is an administratively derived score to stratify all patients for risk of hospitalization and emergency department visits.[13]

Exclusion criteria included: living in a nursing home; a clinical diagnosis of dementia; a score of ≤29 on the Kokmen Short Test of Mental Status; inability to give informed consent; and/or inability to use the telemonitoring equipment.[7]

Intervention

Usual care included various types of face-to-face visits, phone services, and home health care available to all primary care patients. Home health care includes provision of episodic and intermittent home health nursing and/or physical and occupational therapist visits. The telemonitoring intervention included usual medical care and telemonitoring case management. Telemonitoring involved placing the Intel® health guide, along with other peripheral equipment, in a patient's home and connecting it to the health system via a broadband network. The participant's blood pressure, pulse, oxygen saturation, blood glucose level, and weight were measured as per an individualized protocol, based on their medical condition.[7]

Primary outcomes

The primary outcome was the transition of frailty status at 6 months compared with baseline and at 12 months compared with 6 months. The frailty data collected were defined based upon the Fried phenotype for frailty. The characteristics of frailty included weight loss, weakness, exhaustion, low activity, and slow gait speed. Participants were placed in categories of nonfrail, prefrail, or frail. A person was categorized as frail if three or more of the criteria were met, prefrail if 1 or 2 were met, and nonfrail (robust) if none were met.[1] The primary outcome was a transition to a worsening state (ie, from prefrail to frail, nonfrail to prefrail, nonfrail to frail, and any state to death).

The five criteria for frailty were either measured or self-reported (Table 1). The participant's measured weight was taken from medical records at various time points to compute weight loss. Participants were considered weak if their measured grip strength (lb/in^2) was in the lowest quintile for their gender. Exhaustion was obtained from a question on the Patient Health Questionnaire 9, which is a validated instrument that measures depression.[14] A low physical activity level was measured using the physical part of the SF-12 score.[15]

Table 1 Adjustments to the Fried frailty criteria from the Cardiovascular Health Study

Characteristics	Original criteria	Modifications
Weight loss	Greater than 10 lbs unintentional weight loss in prior year at baseline from questionnaire or Greater than 5% of weight loss based on weight at previous year at follow-up (by direct measurement of weight)	Greater than 10 lbs unintentional weight loss in prior 6 months at baseline or Greater than 5% of weight loss during first 6 months of trial Intentional versus unintentional cause was not determined Data came from patient's medical record
Weakness	Grip strength: lowest 20% (stratified by gender and body mass index)	Grip strength at baseline and 6 months: lowest 20% (stratified by gender)
Exhaustion	Self-report based on questions from CES-D scale at baseline[33]	Self-report based on question 4 from Patient Health Questionnaire 9[14] at baseline and 6 months Question: "Over the last 2 weeks, how often have you been bothered by feeling tired or having little energy?" Answer: "More than half the days" or "Nearly every day"
Low activity	Weighted score of kilocalories expended per week at baseline: lowest 20% (stratified by gender)	Short Form-12 physical score at baseline and 6 months: lowest 20% (stratified by gender)[15]
Slow gait speed	Slowest 20% at baseline based on time to walk 15 feet (stratified by gender and standing height)	Gait speed at baseline and 6 months based on walking time/6 m): lowest 20% (stratified by gender and standing height) Gender specific cutoff at 50th percentile of height

Note: Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci.* 2001;56(3):M146–M157. Adapted with permission from Oxford University Press.[1]
Abbreviation: CES-D, Center for Epidemiologic Studies Depression.

We measured gait speed, and the slow gait speed criterion was met if the person was among the slowest 20%.[16]

Data collection

Data were collected from participants during face-to-face visits at baseline, 6, and 12 months.

Sample size

There were 205 participants randomized in the trial, of which 102 were in the telemonitoring group and 103 were in the usual care group. The power calculations for the Tele-ERA study were designed to detect a mean difference of 0.40*standard deviation in hospitalization and emergency department visits for a sample size of 100 per group. Another power analysis was calculated retrospectively to determine how many participants would have been required to reject the null hypothesis that the rates of transitioning to worse or death states for telemonitoring and usual care are equal with a probability of 0.80.

Randomization

Participants were placed in blocks of four to balance the treatment assignment for the randomization process and were allocated to groups after completion of informed consent by an envelope method.

Blinding

The trial participants and the clinical trial staff were not blinded, because of the use of telemonitoring equipment.[12]

Statistical analysis

Descriptive statistics were calculated for participants who completed the assessment at baseline and at 6 and 12 months. Thus, this was a per protocol analysis. Fisher's Exact test and/or two sample *t*-tests were used to compare participant demographics, frailty characteristics, and the rate of transition. Multiple logistic regression analyses were conducted to estimate the odds ratio (OR) of transitioning to a worse or death state between telemonitoring and the usual care groups, and to assess if being telemonitored decreased the odds of worsened transitions. We controlled for demographics (ie, age, race, and gender) and baseline characteristics. (ie, frailty status, Kokmen score, whether they lived alone, and number of chronic diseases). Although models developed for a randomized controlled trial do not typically require adjustments, we elected to do these adjustments because we were dealing

with a smaller subset of the initial cohort, which may not have been balanced at baseline and at six months.

A secondary analysis involved an evaluation of the measures of frailty criteria and evaluating them for mortality using a Kaplan–Meier method,[17] a comparison with the log-rank test, and a computation of unadjusted hazard ratios (HR, or relative risks) associated with being telemonitored by the Cox proportional hazards method.[18] Using mortality as an endpoint for the entire group, we analyzed baseline frailty status, as well as each of the five measures of frailty to predict mortality.

Statistical analyses were conducted at a $P < 0.05$ significance level and a two-sided alternate hypothesis using Stata software version 9.2 (Stata Corporation, College Station, TX, USA). The power analysis was computed using nQuery Advisor, version 7 (Statistical Solutions, Saugus, MA, USA).

Results

The baseline characteristics for this cohort have been previously reported.[12] There were no significant differences between the groups at the beginning of the study. In total, 77 of 102 participants in the telemonitoring group and 90 of 103 participants in the usual care group completed the 12-month follow-up. Telemonitoring and usual care groups were similar based on the number of participants with complete frailty data at each time point (Table 2). The telemonitoring cohort had a similar number of participants in prefrail or frail states as those in the usual care group at baseline and at 6 months. However, the telemonitoring group consistently had fewer nonfrail participants than those in the usual care group throughout the trial. Only participants with frailty or mortality data at both end points of the transition period were analyzed, amounting to 76 and 68 participants in the telemonitoring group for the first and latter 6-month period, respectively, and 90 and 80 participants in the usual care group. The baseline demographic characteristics for the Frailty transitions for each 6-months period are shown in Table 3.

There was no statistically significant difference between the two groups in rate of transition between different frailty states and death during the 12-month follow-up period. During the first 6 months, the number of participants who transitioned to a worse or death state in telemonitoring and usual care groups was 19 (25%) and 17 (19%), respectively. No transitions between frailty states occurred during the latter 6 months, except for the five participants who transitioned to death on telemonitoring and one on usual care alone. The odds of participants in the telemonitoring group having functional decline actually showed a nonsignificant increase in functional decline during the first 6 months (OR 1.41, 95% confidence interval [CI] 0.65–3.06, $P = 0.38$) and the latter 6 months (OR 5.94, 95% CI 0.52–68.48, $P = 0.15$).

Participants who were frail at the beginning of the trial were at a significantly higher risk of transitioning to the death state during the trial. The HR associated with being frail at baseline was significant (HR 4.21, 95% CI 1.72–11.03, $P = 0.002$). The two primary individual components of frailty that predicted mortality were gait speed and low activity,

Table 2 Characteristics of participants

	All			Telemonitoring			Usual care		
	Baseline	6 months	12 months	Baseline	6 months	12 months	Baseline	6 months	12 months
Characteristics (%)	n = 194	n = 166	n = 145	n = 97	n = 74	n = 65	n = 97	n = 92	n = 80
Age, mean ± SD	80.4 ± 8.3	81.5 ± 7.8	81.5 ± 7.8	80.4 ± 8.9	82.1 ± 8.3	81.9 ± 8.1	80.4 ± 7.6	81.0 ± 7.4	80.9 ± 7.8
Gender, female	105 (54.1)	88 (53.0)	78 (53.8)	50 (51.5)	36 (48.6)	32 (49.2)	55 (56.7)	52 (56.5)	46 (57.5)
Race, white	190 (97.9)	163 (98.2)	142 (97.9)	93 (95.9)	71 (95.9)	62 (95.4)	97 (100)	92 (100)	80 (100)
Live alone	89 (45.9)	80 (48.2)	70 (48.3)	43 (44.3)	36 (48.6)	31 (47.7)	46 (47.4)	44 (47.8)	39 (48.8)
Chronic conditions,[a] mean ± SD	3.0 ± 1.1	3.0 ± 1.2	3.2 ± 1.1	3.1 ± 1.2	3.0 ± 1.1	3.2 ± 1.2	3.0 ± 1.1	2.9 ± 1.3	3.2 ± 1.1
Mental status score,[b] mean ± SD	34.5 ± 2.3	34.3 ± 3.3	33.8 ± 4.3	34.5 ± 2.2	34.4 ± 2.8	34.0 ± 4.1	34.5 ± 2.3	34.2 ± 3.7	33.7 ± 5.3
Frailty group (%)	n = 205	n = 205	n = 205	n = 102	n = 102	n = 102	n = 103	n = 103	n = 103
Nonfrail	75 (36.6)	68 (33.2)	63 (30.7)	33 (32.3)	26 (25.5)	23 (22.5)	42 (40.8)	42 (40.8)	40 (38.8)
Prefrail	87 (42.4)	82 (40.0)	70 (34.1)	47 (46.0)	40 (39.2)	36 (35.3)	40 (38.8)	42 (40.8)	34 (33.0)
Frail	32 (15.6)	16 (7.8)	12 (5.9)	17 (16.7)	8 (7.8)	6 (5.9)	15 (14.6)	8 (7.8)	6 (5.8)
Death (from start of trial)	0 (0.0)	5 (2.4)	19 (9.3)	0 (0.0)	4 (3.9)	15 (14.7)	0 (0.0)	1 (1.0)	4 (3.9)
Missing/incomplete data	11 (5.7)	34 (16.6)	41 (20.0)	5 (4.9)	24 (23.5)	22 (21.6)	6 (5.8)	10 (9.7)	19 (18.5)

Notes: [a]Only include six chronic diseases: diabetes, heart disease (coronary artery disease/myocardial infarction/congestive heart failure), stroke, chronic obstructive pulmonary disease, cancer, and dementia; [b]Kokmen Short Test of Mental Status.
Abbreviation: SD, standard deviation.

Table 3 Number and rate of transitions[a] between frailty states and death and type of transition

From To	All		Telemonitoring		Usual care	
	Baseline to 6 months	6 to 12 months	Baseline to 6 months	6 to 12 months	Baseline to 6 months	6 to 12 months
Nonfrail (%)						
Nonfrail	43 (65)	60 (97)	16 (57)	21 (91)	27 (71)	39 (100)
Prefrail	22 (33)	0	12 (43)	0	10 (26)	0
Frail	0	0	0	0	0	0
Death	1 (2)	2 (3)	0	2 (9)	1 (3)	0
Total	66	62	28	23	38	39
Prefrail (%)						
Nonfrail	21 (29)	0	9 (26)	0	12 (32)	0
Prefrail	41 (56)	70 (96)	21 (60)	36 (95)	20 (53)	34 (97)
Frail	9 (12)	0	3 (9)	0	6 (16)	0
Death	2 (3)	3 (4)	2 (6)	2(5)	0	1 (3)
Total	73	73	35	38	38	35
Frail (%)						
Nonfrail	1 (4)	0	0	0	1 (7)	0
Prefrail	17 (63)	0	6 (46)	0	11 (79)	0
Frail	7 (26)	12 (92)	5 (38)	6 (86)	2 (14)	6 (100)
Death	2 (7)	1 (8)	2 (15)	1 (14)	0	0
Total	27	13	13	7	14	6
Transition type (%)						
Same or better	130 (78)	142 (96)	57 (75)	63 (93)	73 (81)	79 (99)
Worse or death	36 (22)	6 (4)	19 (25)	5 (7)	17 (19)	1 (1)
Total	166	148	76	68	90	80

Note: [a]Transition rates were calculated based on participants who had data on frailty or death at the beginning and ending time point for the follow-up period.

with an HR of 3.49 (95% CI 1.42–8.58, $P = 0.007$) and 3.10 (95% CI 1.25–7.71, $P = 0.015$), respectively.

The power analysis indicated that this secondary analysis was underpowered. We needed 753 participants in each group to detect a difference in the rates of transitioning to a worse or death state with 80% power based on outcome of the first 6 months.

Discussion

In this randomized controlled trial, home telemonitoring did not decrease the rate of functional decline as measured by frailty states and mortality in older adults. With telemonitoring, 25% of participants had worsening frailty status, compared with 19% on usual care ($P = 0.35$), while 20% had improved frailty status versus 27% on usual care ($P = 0.36$). These findings represent the first attempt to evaluate the impact of telemonitoring on frailty.

Unfortunately, neither our primary nor secondary analysis supports our hypothesis regarding the efficacy of the intervention; this might be for any of a number of reasons, including inherent lack of efficacy of the intervention, an underpowered study, a short study period, and an inappropriate target population. Nevertheless, it certainly has made us a bit circumspect about the value of this level of technology as an isolated intervention in this population. Our current hypothesis is that the technology may need to be embedded in a more comprehensive care model, for instance with home visits akin to those implemented by the Veterans Health Administration.[3,19–20]

There are several possible explanations as to why there was no difference in functional decline between the two groups. First, the act of using technology to measure and track biometric data by itself does not improve or lessen the decline in frailty status. Telemonitoring is primarily designed to help with comorbid health concerns and may not directly address the components of frailty; however, it may help with frailty status if it is combined with enhanced disease management. There is a clear need for a combination of interventions and protocols that directly address functional decline, but these were not incorporated in the study.

All of the transitions in frailty (either with improvement or decline) occurred within the first 6 months of enrolment. This may indicate the time taken to return to the mean level of functioning is short. We found that there was a statistically equal chance of improving or worsening, which reflects similar findings in longer-term longitudinal studies.[2] This study differed because the frailty state was evaluated over a shorter time period of 6 months. Transitions to a worsened state of frailty had been shown to be more common than to improved states, and the likelihood of transitioning

from frail to nonfrail to be very low.[2] Our study identified only one participant who transitioned from frail to nonfrail. Further, we found no statistically significant difference in the numbers of patients who transitioned to worsened states compared with improved states of frailty. One possible explanation is that over a shorter assessment period, people can improve or worsen. A previous study of frailty transition lasted longer with extended intervals between follow-ups (every 18 months for a total of 54 months).[2] Thus, over a longer period, one might observe a gradual decline in functional status, whereas a shorter observation period highlights a potential improvement from baseline. Another reason could also be the increased percentages of missing frailty data and deaths over the study period (5.7% at baseline, 19% at 6 months, and 29.3% at 12 months).

The study had some strengths and limitations. First, it had internal validity because it was a randomized controlled trial. The randomization should provide some assurance of the comparability of the two groups at baseline. The study used the Fried phenotype for frailty to assess and track frailty, which is widely considered to be the standard measure of the frailty phenotype.[1] We found that gait speed predicts mortality, which has been validated in numerous other studies.[21–23] There were some limitations to the study due to having more dropouts and deaths than anticipated. Further, the study may have suffered from the Hawthorne effect because it was unblinded. The Hawthorne effect typically yields improved outcomes with observation; however, with increased interactions with the health care system, it might yield negative effects. We also analyzed the data for patients completing the study, so there is a potential for some survivorship bias as well, in which the groups remaining may not represent the group as a whole. We do not have a good measure of sensitivity of the frailty measures over time. The functional status of gait speed is probably the best predictor; however, its overall sensitivity over this short time frame remains unknown. We redefined frailty in this sicker, higher risk population by using 20% cutoff values for the population within the trial rather than a set cut point for frailty eg, 0.8 m/sec for gait speed[24] or 18 kg/cm^2 for grip strength in women.[1,25] The definition of frailty is still evolving. However, the advantage of our method is that it is a well known standard phenotype of frailty that is accepted. It is possible that another method of frailty might have shown something different. Weaknesses and new trends in frailty research are outlined in a summary paper from the American Geriatrics Society/National Institute on Aging Research Conference on Frailty in Older Adults[26] and in a systematic literature review on identification of frailty from 1997 to 2009.[27] One important issue is whether to include disability and functional decline as a component of frailty[28,29] or regard them as outcome.[1,30] More recent studies are exploring the addition of cognition to the Fried's components.[31]

The findings from this trial clearly indicate a need for future work on telemonitoring and frailty. A study to explore the effects over shorter transition periods, such as 3 or 4 months, might also be considered. An even more important point is the need for interventions on measures of frailty and not just monitoring, such as nutrition support, exercise program, and/or physical therapy.[32,34] Another consideration would be to conduct a crossover trial where participants are telemonitored alternately to find patterns of behavior or transitions. Given the prediction of death in participants who entered the study in a frail state, a larger study with adequate power can be conducted to determine the point of no return that would aid clinicians in determining whether curative services or initiation of palliative care should be provided, with a secondary opportunity to study quality of life for rehabilitation.

Overall, this study generated several unanticipated hypotheses for future research with regard to the optimal timing of telemonitoring intervention to show how it can be combined with other interventions to enhance outcomes.

Conclusion

Home telemonitoring by itself without a change in the overall clinical care process did not significantly impact a frailty state transition in this high-risk aging population. This study did not provide sufficient evidence to show that the telemonitoring group did better than usual care in the decline of frailty states and death over 12 months of follow-up.

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