Kenosha County Falls Prevention Study: A Randomized, Controlled Trial of an Intermediate-Intensity, Community-Based Multifactorial Falls Intervention

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OBJECTIVES: To decrease the rate of falls in high-risk community-dwelling older adults.

DESIGN: Randomized, controlled trial.

SETTING: Community-based.

PARTICIPANTS: Three hundred forty-nine adults aged 65 and older with two falls in the previous year or one fall in the previous 2 years with injury or balance problems.

INTERVENTION: Subjects received two in-home visits from a trained nurse or physical therapist who assessed falls risk factors using an algorithm. The intervention consisted of recommendations to the subject and their primary physician, referrals to physical therapy and other providers, 11 monthly telephone calls, and a balance exercise plan. Control subjects received a home safety assessment.

MEASUREMENTS: The primary outcome was rate of falls per year in the community. Secondary outcomes included all-cause hospitalizations and nursing home admissions per year.

RESULTS: There was no difference in rate of falls between the intervention and control groups (rate ratio (RR) = 0.81, $P = .27$). Nursing home days were fewer in the intervention group (10.3 vs 20.5 days, $P = .04$). Intervention subjects with a Mini-Mental State Examination (MMSE) score of 27 or less had a lower rate of falls (RR = 0.55; $P = .05$) and, if they lived with someone, had fewer hospitalizations (RR = 0.44, $P = .05$), nursing home admissions (RR = 0.15, $P = .003$), and nursing home days (7.5 vs 58.2, $P = .008$).

CONCLUSION: This multifactorial intervention did not decrease falls in at-risk community-living adults but did decrease nursing home utilization. There was evidence of efficacy in the subgroup who had an MMSE score of 27 or less and lived with a caregiver, but validation is required.
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Key words: accidental falls; RCT; aged 65 and older; noninstitutionalized populations

Falls are a significant source of morbidity and mortality for older adults. In high-risk, community-dwelling older adults, a strong reduction in falls has been demonstrated in some multifactorial intervention studies.[1–3] Components of multifactorial interventions have included physical therapy or exercise, referrals for further medical care, decreases in psychotropic medications, behavior modification to decrease risky behavior, and environmental modification.[1–5]

Multifactorial intervention studies have evaluated low- and high-intensity approaches. High-intensity multifactorial approaches, defined here as interventions having at least five contacts and directly providing progressive exercise or physical therapy, have successfully reduced falls.[2,6] Low-intensity approaches, defined as interventions with fewer than five contacts and primarily providing recommendations and referrals, have had success when targeted to a specific period (e.g., post-emergency department or post-hospital),[1,5,7] but when not targeted to a specific time period, low-intensity individualized multifactorial models have not been successful.[8–11]

There is a need to evaluate practical, intermediate-intensity, multifactorial models for their efficacy in reducing falls in the community. An intermediate-intensity multifactorial model was defined as one that provides primarily referrals and recommendations without delivering physical therapy or progressive exercise but with a greater number of contacts with the older adult than a low-intensity approach (>4). It was hypothesized that more contacts would lead to

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greater adherence and efficacy in reducing falls. The purpose of this study was to test, in a randomized, controlled trial, the efficacy of this intermediate-intensity, individual, multifactorial model to reduce falls.

METHODS

This study was conducted in Kenosha County, Wisconsin, between May 2002 and June 2004. Participants were solicited from senior centers, meal sites, senior apartment buildings, and other senior congregate sites. In addition, county caseworkers and healthcare providers could refer potentially eligible older adults. Enrollment criteria were aged 65 and older, independently living in Kenosha County, and a history of two falls in the previous year or one fall in the previous two years with injury or gait and balance problems. Persons were excluded if they were unable to give informed consent and had no related caregiver in the home, were in hospice or lived in an assisted-living facility, or were expected to move away permanently from the area. The University of Wisconsin Medical School human subjects committee approved the study. Informed consent was obtained before enrollment. Persons with inability to give informed consent were included if they gave assent and had a related caregiver in the home who gave informed consent.

Procedure

Randomization to intervention or control groups was based on a computer-generated randomization table. After obtaining informed consent and before group assignment, the study researcher performed a baseline in-home assessment for function, health services use, and risk factors for falls. After baseline assessment, a research staff member opened a sealed envelope with study group assignment. Those in the intervention group received an in-home multifactorial assessment and intervention, followed by 11 monthly telephone calls. The control group received an in-home assessment from an occupational therapist that was limited to home safety recommendations and advice to see their doctor about falls.

Intervention

The intervention model is of a community-based multifactorial intervention that links participants to existing medical care and service networks. The intervention used an algorithm based on the University of Wisconsin Falls Prevention Clinic, designed to identify predisposing factors for falls; induce risk reduction changes in medical conditions, medications, behavior, physical status, and home environment through recommendations to participants and their physicians; and make sure these changes are long-lasting through follow-up and linkages to other care networks.

A health professional (physical therapist (AS) or registered nurse (SC)) who received 3 days of additional training in a standardized fashion from a geriatrician (JM) and physical therapist (TS) on its multidisciplinary components used the algorithm in the home. The algorithm evaluated medications, distant vision, balance and gait, some neurological deficits, cognition, mood, home functioning, and home safety. Tools used for the evaluations and examples of corresponding interventions are shown in Table 1.

The therapist or nurse visited intervention participants in their homes twice within the first 3 weeks after enrollment to perform the assessment and give recommendations and referrals. Recommendations were mailed to subjects' primary physicians, and the participants were asked to see their primary physician within 1 month to review the recommendations. Recommendations were made to the physicians to evaluate and reduce psychotropic medications and provide other medical care to elucidate and treat medical causes of falls. A geriatrician (including JM, RP) reviewed all recommendations to physicians. The algorithm generated referrals and recommendations to physical therapy and other healthcare providers based on specific criteria. Required triggers for physical therapy referral included moderate impairment on Berg Balance Scale items,[12] abnormal gait on the Performance Oriented Mobility Assessment,[13] inability to stand for 30 seconds with eyes open on hard surface or foam,[14] and history of pain with walking or doing exercise. Optional triggers included loss of balance with sternal nudge,[13] positive Romberg test, absent vibratory sensation at the ankle or metatarsal phalangeal joint, inability to stand for 30 seconds with eyes closed on hard surface or foam,[14] total score less than 80 on the Activities Specific Balance Confidence Scale,[15] and any potentially risky mobility-related activity of daily living (ADL)[16] or instrumental activity of daily living (IADL),[17] per assessor's judgment. The co-investigator physical therapist (TS), who agreed 100% of the time when the algorithm did not recommend physical therapy, reviewed all assessments. If the algorithm did not recommend physical therapy or if the participant refused physical therapy, then the study therapist provided a set of balance and leg strengthening exercises. The assessment generated referrals for further medical evaluation and treatment (e.g., occupational therapy, ophthalmology, podiatry). The participant was directly referred to ophthalmology or podiatry; referrals for physical or occupational therapy required the primary physician's signature. The therapist or nurse assisted with setting up referrals and facilitated acquisition of home equipment (e.g., walker or other ambulation aid, bathroom equipment, rails). Costs were covered by private pay or through the study.

All subjects in the intervention group were given recommendations for long-term exercise. A recommended long-term exercise program was walking at least 4 to 5 days per week and performance of standing balance exercises 2 to 3 days per week, preferably in a group setting. Standing balance exercise was defined as any exercise that included weight shifts and head turn. It included activities such as dancing, bowling, and tai chi. If the subject received outside physical therapy, the assessor asked the therapist to prescribe a home exercise program at the end of therapy, to encourage participation in a group exercise program, or both. An exercise plan, a monthly exercise calendar, and 11 monthly telephone calls from the assessor facilitated adherence to exercise. The purpose of the calls was to answer questions, facilitate necessary referrals, and encourage adherence to physical therapy, exercise, and other recommendations.

Baseline Data

Baseline data included demographic information (age, sex, living arrangement), ADL function,[18] IADL function,[17]

Table 1. Major Components of Assessment and Corresponding Interventions

Risk Factor and Assessment	Trigger for Further Action	Examples of Actions
Medications 1. Benzodiazepines 2. Other sleeping medications 3. Antidepressants 4. Neuroleptics	Use of medication, over the counter or prescribed	Recommendations to discuss medication with physician, reduce usage of as-needed medication; advice for nonpharmacological options for sleep; recommendation to physician to decrease medication dose as able
Vision 1. Distant vision (Diabetic Retinopathy Log Scale)[33] each eye separately and both eyes together	$<$20/40 either eye or vision differs between eyes	Recommendations regarding lighting, caution in dark or outdoors; remove clutter, throw rugs and cords; referral to ophthalmologist or optometrist; Caution with maneuvers and turns, turn head to
2. Visual fields	Visual field loss	compensate, discuss with physician; Information provided to physician
Balance and gait 1. Clinical Test of Sensory Integration and Balance[14] 2. Sternal nudge[13] 3. Selected Berg Balance Scale items[12] 4. Gait items from Performance Oriented Mobility Assessment[13] 5. Time to walk and step over obstacles holding and not holding glass of water[34]	Abnormalities on balance or gait testing	Depending on specific abnormality: Referral to physical therapy, occupational therapy, or both; recommendations for safe performance of mobility tasks in home, to use assistive device, to increase attention to environment, and to avoid multitasking; environmental interventions; information provided to physician
Neurologic evaluation (selected) 1. Vibratory sensation 2. Romberg test	Absent at medial malleolus or metatarsal-phalangeal joint Positive test	Information provided to physician; recommendation to physician to consider further testing if etiology not already known Recommendation to patient to use assistive device, increase caution in dark or on uneven surfaces, remove clutter
Cognition Mini-Mental State Examination[19]	Score $<$ 24	Information provided to physician, with recommendation for further testing (thyroid-stimulating hormone, vitamin B_{12}) if not already evaluated Discussion with patient and caregiver regarding fall risk and need for supervision
Mood Short Geriatric Depression Scale[20]	Score $>$ 5	Information provided to physician, along with recommendations for starting with lowest dose of antidepressant and avoiding first-generation tricyclic antidepressants Referral to counseling service
Functional status Independence and fall risk with selected activities (toileting, bathing, dressing, meal preparation, shopping, housekeeping, laundry, yard work, getting mail, car transfer, answering phone/door)*	Any potentially risky activity, according to self-report or assessor judgment	Patient and caregiver education regarding safe performance of task; recommendations for assistive device use with task, glasses or footwear to improve task safety, physical or occupational therapy referral, task modification for specific tasks, increased supervision, chore help, or other assistance
Home hazard evaluation†	Any hazards according to checklist or assessor judgment	Removal of throw rugs and other hazards, recommendations for bathroom safety (grab bars, raised toilet seat, tub seat), other home safety recommendations, referral to supplier, occupational therapy referral

* Selected Katz activity of daily living items[16] and Lawton instrumental activities of daily living items.[17]
† Home hazard evaluation checklist developed by the University of Wisconsin Falls Prevention Clinic.

Mini-Mental State Examination (MMSE) score,[19] short Geriatric Depression Scale (GDS) score,[20] prior history of falls, use of assistive device, history of impaired vision, comorbid medical conditions,[21] number of prescribed medications and psychotropic medications, current exercise, and self-perceived health.[22] Psychotropic medication categories included antidepressants, antipsychotics, sedative hypnotics, and antihistamines. Current exercise was eval-

uated as the number of times the subject had walked for exercise in the past 2 weeks.

Measures of Adherence (Intervention Group)

Adherence to recommendations was monitored using monthly telephone calls from the study assessor. Adherence was categorized as visits to the primary physician, visits to other referral providers if recommended, visits to physical therapy if recommended, changes in medications if recommended, use of a current assistive device or acquisition of a new assistive device, and exercise. A recommendation was adhered to if it was at least partially completed at any time in the 12-month period. Days of balance exercise and days and minutes of walking were monitored using a monthly calendar or a telephone call if a calendar was not returned. The physical therapist to whom the participant was referred corroborated information regarding number of physical therapy visits.

Follow-Up Measures

Participants were followed for falls using monthly calendars.[23,24] At the baseline interview, before group assignment, the study researcher gave each participant 12 monthly falls diaries and calendars. Caregivers were asked to help with calendar reporting.[23–25] The study researcher, blinded to treatment assignment, called subjects who did not return calendars. When a fall was reported, the researcher interviewed the subject or caregiver to verify the fall. An accidental fall was defined as "an event which results in a person coming to rest inadvertently on the ground or other lower level, and other than as a consequence of the following: sustaining a violent blow; loss of consciousness; sudden onset of paralysis, as in stroke; an epileptic seizure."[26] Determination of "sustaining a violent blow" was based on consensus of the research assistant and geriatrician.[23, 25] Falls occurring in the hospital, nursing home, or community-based residential facility were excluded from analysis.

Participants were followed for hospitalization and nursing home utilization for 12 months using a monthly calendar. Positive reports of hospitalization or nursing home use were followed by telephone call to inquire about dates and circumstances. All hospitalization and nursing home reports were verified using medical records. ADLs and short GDS scores were assessed at 1 year using a mailed questionnaire.[1] If a questionnaire was not returned, information was obtained by telephone.

Study Outcomes

The primary outcome was the difference between the intervention and control groups in rate of accidental falls in the community in 1 year. The denominator for the rate of falls only included days in the community.[25] Days in a hospital, community-based residential facility, or nursing home were excluded from fall rate analyses. Secondary outcomes included all-cause hospitalization and nursing home utilization (number of admissions and number of days) per 52 weeks, change in ADL function (Barthel score) from baseline to 1 year, and change in short GDS score from baseline to 1 year.

Statistical Analysis

Differences in the primary outcome of falls rate and secondary outcomes of hospitalization rate and nursing home admission rate were tested with the use of negative binomial (overdispersed Poisson) regression models. The models were used to estimate rate ratios (RRs) and 95% confidence intervals (CIs). Rates were expressed on an annual basis and defined as the rate per 365.25 days in the community.

Differences in secondary outcomes of hospital days and nursing home days were tested with use of *t* tests, not assuming equal variances in the two groups. Hospital days and nursing home days were assessed as a fraction of the total study follow-up days and expressed on an annual basis (per 365.25 study days).

Exploratory (post hoc) subgroup analyses were performed based on sex (male or female), eligibility category ($\geq$2 falls in prior year; 1 fall in prior year with injury; 1 fall in prior year with gait or balance problems; no qualifying fall in prior year but at least 1 fall in prior 1–2 years with injury or gait or balance problems). Exploratory analyses were also examined based on MMSE score, selecting the median score in the sample (27) as the cut off. Subgroup analyses were performed for MMSE score ($\geq$28 vs $<$28); and for MMSE score and living status ($\geq$28, lives alone; $\geq$28, lives with someone; $<$28, lives alone; $<$28, lives with someone).

All analyses were conducted based on intention-to-treat principle. All tests were two-tailed. A nominal *P*-value of .05 was regarded as statistically significant.

Sample Size

Assuming a falls rate of 1.14 falls per 365.25 community days and a negative binomial variance parameter of 0.58, it was determined that 144 subjects would be required in each group to provide 80% power to detect a reduction in the falls rate of 44% in the intervention group using a two-tailed 5% level test.[1,2]

RESULTS

Follow-Up and Baseline Characteristics

From April 2002 to July 2003, 616 people were referred to the study, 418 (68%) were eligible, and 349 (83%) enrolled (Figure 1).

Five subjects (3 in the control group, 2 in the intervention group) had no postrandomization follow-up. Of the remaining 344 subjects, 274 (80%) had at least 365 days of follow-up. The median follow-up was 408 days; mean follow-up was 363 days. Three subjects had fewer than 10 days of follow-up. There was no difference between intervention and control groups in number of days of follow-up.

Baseline characteristics for intervention and control groups are presented in Table 2. Three-fourths of the sample were female; 55% lived alone. The sample had moderate disability in IADLs. The average MMSE score was 27 of 30. Eighty-seven percent had fallen at least once in the prior year, and 54% had fallen multiple times. One-third used an assistive device for ambulation.

Primary Outcome: Falls

There was no significant difference in rate of falls between the intervention and control groups (1.88 vs 2.31 falls per

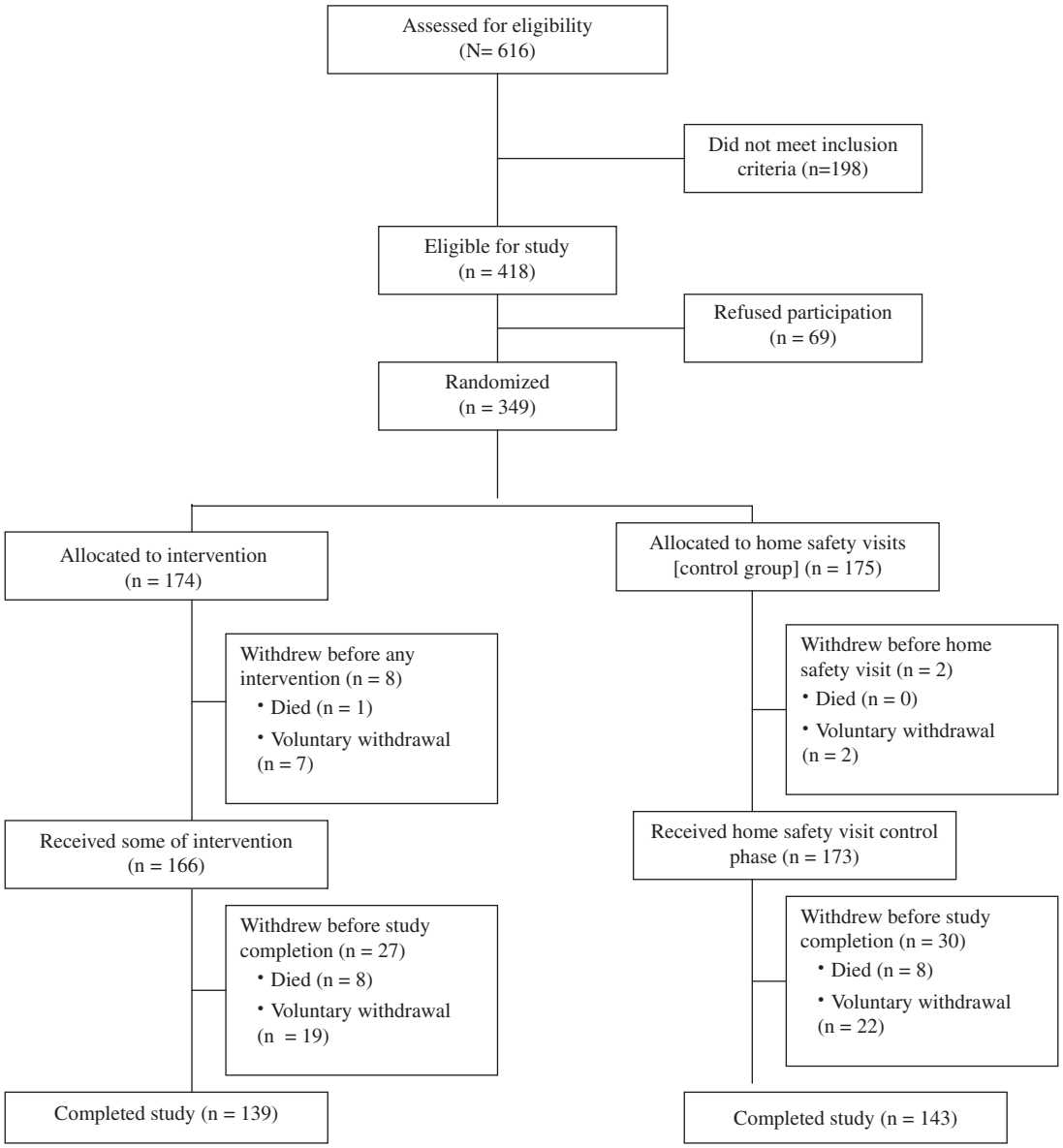

Figure 1. Flow of subjects through the trial.

patient per year, RR = 0.81, 95% CI = 0.57–1.17; $P = .27$) (Table 3).

Exploratory analyses showed that subjects with a MMSE score less than 28 assigned to the intervention group had a lower rate of falls than subjects assigned to the control group (2.35 vs 4.26, RR = 0.55, 95% CI = 0.30–1.00; $P = .05$). For the subgroup of those with a MMSE score less than 28, the reduction in falls related to the intervention was primarily for subjects living with someone. Subjects in the intervention group with an MMSE score of less than 28 who lived with someone had a lower rate of falls than subjects in the control group (3.10 vs 6.92, RR = 0.45, 95% CI = 0.19–1.06; $P = .07$). The rate of falls was similar in the intervention and control groups for subjects with a MMSE score less than 28 who lived alone (1.48 vs 1.42, RR = 1.04, 95% CI = 0.56–1.96; $P = .89$).

There were no significant differences in the rate of falls between the intervention group and the control group in other subgroups.

Secondary Outcome

Hospitalizations and Hospital Days

There were no significant differences between the intervention and control groups with respect to hospitalizations (0.66 vs 0.63 hospitalizations per year, RR = 1.05, 95% CI = 0.71–1.55; $P = .82$) (Table 3) or hospital days (3.9 vs 4.2 days per year; $P = .80$).

Subjects in the intervention group with a MMSE score less than 28 who lived with someone had a lower rate of hospitalizations than subjects in the control group (0.79 vs 1.79 hospitalizations per year, RR = 0.44, 95% CI = 0.20–0.99; $P = .05$).

Subjects in the intervention group who had had one fall in the prior year with gait or balance problems had a higher rate of hospital admissions (0.62 vs 0.16, RR = 4.02, 95% CI = 1.04–15.5; $P = .04$) and hospital days (2.3 vs 0.4; $P = .01$) than subjects in the control group.

There were no significant differences in rate of hospital admissions or number of hospital days between the

Table 2. Baseline Characteristics of Intervention and Control Participants

Baseline Characteristic	Intervention (n = 174)	Control (n = 175)
Age, mean ± SD	79.6 ± 7.2	80.3 ± 7.7
Female, n (%)	137 (78.7)	137 (78.3)
Living arrangement, n (%)		
Alone	96 (55.2)	95 (54.3)
With spouse	51 (29.3)	52 (29.7)
With other	27 (15.5)	28 (16.0)
Number of independent instrumental activities of daily living, mean±SD (maximum 6)	4.8 ± 2.3	4.9 ± 2.2
Barthel activity of daily living score, mean ± SD (maximum 100)	85.3 ± 16.4	88.5 ± 16.8
Mini-Mental State Examination score, mean ± SD (maximum 30)	26.9 ± 4.2	27.3 ± 4.6
Short Geriatric Depression Scale score, mean ± SD (maximum 15)	2.7 ± 2.6	3.2 ± 3.1
Number of falls in previous year, mean ± SD	2.4 ± 2.6	2.4 ± 2.4
Number of prescription medications, mean ± SD	5.6 ± 3.3	5.7 ± 3.4
Number of psychotropic medications (antidepressants, antipsychotics, anxiolytics, sedative hypnotics, antihistamines), mean±SD	0.2 ± 0.7	0.2 ± 0.7
Use assistive device, n (%)	64 (36.8)	61 (34.9)
Decreased vision (unable to read newspaper), n (%)	30 (17.2)	28 (16.0)
Eligibility category (falls in previous year), n (%)		
≥2	93 (53.4)	96 (54.9)
1 with injury	34 (19.5)	30 (17.1)
1 with gait/balance problems	27 (15.5)	24 (13.7)
0	20 (11.5)	25 (14.3)

SD = standard deviation.

intervention and control groups in subgroups of men or women or in other subgroups of eligibility categories.

Nursing Home Admissions and Nursing Home Days

There was no significant difference in rate of nursing home admissions (0.29 vs 0.41 admissions per year, RR = 0.72, 95% CI = 0.38–1.35; $P = .30$) (Table 3). The intervention group had significantly fewer nursing home days than the control group (10.3 vs 20.5 days per year; $P = .04$).

Men who were assigned to the intervention group had fewer nursing home days than men assigned to the control group (7.3 vs 38.6 days per year; $P = .03$). For women, the rate of nursing home admissions and the number of nursing home days were similar in the intervention and control groups.

Subjects in the intervention group with a MMSE score less than 28 had a lower rate of nursing home admissions (0.36 vs 1.03 admissions per year, RR = 0.35, 95% CI = 0.15–0.83; $P = .02$) and nursing home days (13.8 vs 46.0 days, $P = .008$) than those in the control group. This difference was related to living with someone. Subjects in the intervention group with a MMSE score less than 28 who lived with someone had a lower rate of nursing home admissions (0.22 vs 1.44 admissions per year, RR = 0.15, 95% CI = 0.04–0.54; $P = .003$) and fewer nursing home days (7.5 vs 58.2 days; $P = .008$) than those in the control group.

Subjects in the intervention group with two or more falls in the prior year had a lower rate of nursing home admissions (0.27 vs 0.62 admissions per year, RR = 0.44, 95% CI 0.21–0.91; $P = .03$) and fewer nursing home days (9.6 vs 32.6 days, $P = .005$). For other eligibility categories, the rate of nursing home admissions and number of nursing home days were similar in the intervention and control groups.

Depression and Functional Status

The effect of the intervention on depressive symptoms and ADL function was evaluated. For evaluation of depression, 136 people in the intervention group and 140 people in the control group had baseline and 1-year GDS scores. Mean change in GDS score from baseline to 1 year was 0.3 for participants in the intervention group, versus 0.4 for participants in the control group ($P = .67$). Baseline and 1-year Barthel scores were available on 130 intervention and 135 control subjects. At 1 year, Barthel scores declined by 2.7 points in the control group, versus 1.0 points in the intervention group ($P = .29$). Of those with a MMSE score less than 28, there was significantly less decline in ADL function at 1 year (change score -0.5 for intervention vs -9.1 for control, $P = .03$).

Adherence

Table 4 shows adherence to recommendations at 4 months and 1 year. At 4 months, adherence to recommendations ranged from 32% (seeing podiatrist) to 93% (using assistive device more). In general, adherence was similar at 4 months and 1 year, with the exception of podiatry and ophthalmology visits and changing psychotropic medications.

Table 3. Effect of a Multifactorial Falls Intervention on Fall Rate, Hospitalization Rate, and Nursing Home Admissions (Per 365.25 Community Days)

	Fall Rate				Hospitalization Rate				Nursing Home Admissions			
Characteristic	Control Rate	Intervention Rate	RR (95% CI)	*P*-value	Control Rate	Intervention Rate	RR (95% CI)	*P*-value	Control Rate	Intervention Rate	RR (95% CI)	*P*-value
Overall (N = 349)	2.31	1.88	0.81 (0.57–1.17)	.27	0.63	0.66	1.05 (0.71–1.55)	.82	0.41	0.29	0.72 (0.38–1.35)	.30
Male (n = 75)	4.31	3.93	0.91 (0.44–1.88)	.80	1.06	0.60	0.56 (0.22–1.45)	.24	0.84	0.27	0.32 (0.08–1.25)	.10
Female (n = 274)	1.78	1.36	0.76 (0.51–1.14)	.19	0.55	0.67	1.21 (0.79–1.87)	.38	0.31	0.29	0.95 (0.47–1.92)	.82
Falls in prior year												
≥2 (n = 189)	3.49	2.68	0.77 (0.48–1.22)	.26	0.95	0.72	0.76 (0.46–1.28)	.30	0.62	0.27	0.44 (0.21–0.91)	.03*
1 with injury (n = 64)	0.98	1.03	1.05 (0.40–2.76)	.92	0.39	0.60	1.52 (0.68–3.40)	.30	0.15	0.22	1.42 (0.31–6.45)	.65
1 with gait or balance problems (n = 51)	1.17	1.22	1.04 (0.46–2.37)	.92	0.16	0.62	4.02 (1.04–15.5)	.04*	0.25	0.69	2.82 (0.35–22.5)	.33
0 (n = 45)	0.90	0.63	0.70 (0.35–1.40)	.32	0.30	0.49	1.65 (0.48–5.75)	.43	0.00	0.11	Inf (0.87–Inf)	.06†
Mini-Mental State Examination score												
≥28 (n = 218)	1.56	1.51	0.97 (0.62–1.50)	.88	0.41	0.57	1.38 (0.83–2.27)	.21	0.18	0.23	1.31 (0.53–3.22)	.56
Lives alone (n = 131)	1.85	1.44	0.78 (0.45–1.36)	.39	0.44	0.62	1.39 (0.71–2.71)	.33	0.17	0.27	1.54 (0.46–5.12)	.48
Lives with someone (n = 87)	1.19	1.59	1.33 (0.64–2.75)	.44	0.37	0.51	1.38 (0.64–2.98)	.41	0.18	0.19	1.04 (0.26–4.15)	.96
<28 (n = 131)	4.26	2.35	0.55 (0.30–1.00)	.05*	1.21	0.77	0.63 (0.34–1.15)	.14	1.03	0.36	0.35 (0.15–0.83)	.02*
Lives alone (n = 61)	1.42	1.48	1.04 (0.56–1.96)	.89	0.75	0.74	0.99 (0.41–2.37)	.98	0.67	0.52	0.78 (0.25–2.41)	.67
Lives with someone (n = 70)	6.92	3.10	0.45 (0.19–1.06)	.07†	1.79	0.79	0.44 (0.20–0.99)	.05*	1.44	0.22	0.15 (0.04–0.54)	.003*

* Statistically significant.
† Borderline statistically significant.
RR = rate ratio; CI = confidence interval.

Physician adherence was more than 90% with ordering physical therapy when it was recommended. Physical therapy was recommended for 84% of participants, but only two-thirds of those visited a therapist. The primary reason for not seeing a therapist when recommended was participant refusal. For those who received therapy, the median number of therapy visits was eight (interquartile range 7–13), median duration of therapy was 37 days (interquartile range 23–52), and all had started seeing a therapist by 4 months. The average number of days per month that balance exercise was performed was 11.3 ± 9.7. Intervention subjects reported they walked a mean of 17.4 ± 9.8 days per month, spending an average of 14 ± 1.8 minutes on each day walking.

Whether adherence was better in those with a MMSE score less than 28 who lived with someone was examined. Those with a MMSE score less than 28 who lived with someone had a higher frequency of recommendations for a new assistive device (39%). If they received physical therapy, they had a higher number of visits (median 12) over a greater number of days (median 49 days). Otherwise, this group was similar to the overall intervention group.

Table 4. Adherence to Recommendations at 4 Months and 1 Year

Recommendation	Adherence n (%)	
	4 Months	1 Year
Discuss falls with primary physician		
Recommended	158 (100)	159 (100)
Followed	113 (72)	140 (88)
Use assistive device more		
Recommended	60 (37)	63 (39)
Followed	55 (93)	55 (95)
Obtain new assistive device		
Recommended	39 (24)	41 (25)
Obtained	25 (64)	29 (76)
Used	21 (84)	25 (89)
See physical therapist		
Recommended	136 (84)	135 (82)
Seen	86 (63)	84 (62)
See occupational therapist		
Recommended	9 (6)	8 (5)
Seen	4 (50)	4 (50)
See podiatrist		
Recommended	22 (14)	24 (15)
Seen	6 (32)	9 (47)
See ophthalmologist		
Recommended	89 (55)	91 (56)
Seen	27 (36)	52 (75)
Change over-the-counter or as-needed sleep medication		
Recommended	21 (13)	21 (13)
Changed	10 (50)	12 (67)
Discuss psychotropic medications with primary physician		
Recommended	54 (33)	54 (33)
Discussed	17 (33)	37 (70)
Changed	5 (31)	18 (51)

DISCUSSION

These results demonstrate that an intermediate-intensity, community-based multifactorial intervention is not effective in decreasing falls in community-dwelling older adults, although it appears effective in certain subgroups. An exploratory analysis found that the rate of falls was 45% lower for those with a MMSE score less than 28. Living with a caregiver appeared to mediate this. In addition, why the intervention was effective in this subgroup is unknown. Reasons for effectiveness may be related to the delivery of the intervention (caregiver influencing adherence to the multifactorial program) or may have been due to the fact that the caregiver gained a heightened awareness of falls prevention and might have been behaving differently around the individual (e.g., accompanying them more frequently). Finally, the relationship between cognitive function, based on the MMSE, and the intervention should be treated cautiously, because education and age strongly influenced the MMSE. Future studies should attempt to incorporate standard neuropsychological testing, as well as the MMSE.

There are a number of key points regarding the effectiveness of this model. First, one-third of participants refused physical therapy when it was recommended. Reasons given were difficulty traveling, concern about cost, and disbelief in its efficacy. Approximately half of the participants received one-time balance exercise instruction rather than a course of physical therapy. Second, for those receiving physical therapy, the format of physical therapy was unknown but may have been suboptimal. The median duration of physical therapy was slightly more than a month, which may not be sufficient to improve balance.[3,27–29] Third, the physical therapist did not always prescribe a home exercise program at the end of therapy. Although participants reported, per monthly calendar, doing balance exercises an average of 1 of every 3 days during a month, there may have been no exercise progression. Previous literature has suggested that progressive exercise of long duration is essential.[2,3,27,28] Last, there was delay in adherence to some components of the intervention, including psychotropic medication changes and visits to an ophthalmologist.

In the community setting, economic factors may make implementation of high-intensity models impractical. Financial barriers often limit the numbers of visits that participants make. In addition, financial constraints may limit direct provision of physical therapy, exercise, or other interventions by public health professionals, forcing reliance on referrals to fee-for-service or managed care providers. To be economical to implement in the community setting, a multifactorial intervention needs to link individuals back to existing physical therapy and to their primary provider for further health care and to existing community resources for balance exercise programs and social services. As suggested by previous studies, low-intensity models that rely on recommendations and referrals may not gain patient adherence or provide enough direct intervention to be efficacious.[8–11] This study shows that telephone follow-up alone does not significantly increase the efficacy of a multifactorial model that provides assessment, recommendations, and referrals.

This model reduced falls in those with a MMSE score less than 28, although the positive finding in this subgroup is hypothesis generating rather than hypothesis confirming. Although the data suggest that those with lower MMSE scores may benefit most from this model, caregiver support appears essential, because the reduction in fall rate was present only in those who lived with a caregiver. These results are important, because no prior study has demonstrated an efficacious intervention for this group. One study demonstrated that a multifactorial intervention was not effective for patients with cognitive impairment seen in the emergency department after a fall, but they did not include telephone follow-up as part of the intervention.[29] The current study is also important, because, in the subgroup with lower MMSE scores, the intervention was associated with a reduction in nursing home admissions and nursing home days. This is a group that is at high risk for falls and for acute and long-term healthcare utilization, as shown by the high rates of outcome events in the control group in this study and by other research.[30] Given the high rate of falls and high healthcare utilization for older adults with cognitive impairment and the expected growth in the population of older adults with dementia as the population ages, beneficial interventions for this group are particularly important.

The intervention group as a whole experienced significantly fewer nursing home days than the control group. Men, those with two or more falls in the prior year, and those with MMSE less than 28 had fewer nursing home days. The intervention algorithm evaluated multifactorial causes of falls, which may be causes of other geriatric syndromes as well. Other studies have shown that geriatric evaluation can decrease nursing home use.[21,31] This finding is important, because reduction in nursing home use carries large cost-savings.

This exploratory analysis found more hospitalizations in the subgroup with 1 fall in the prior year who had gait or balance problems who received the intervention. There was no associated increase in falls in this subgroup to explain this finding. This may be due to chance, although future studies should evaluate this further.

This study has a number of limitations. First, it was only single-blinded. Second, adherence to recommendations was only tracked at 4 months and 1 year. Third, adherence to exercise relied on self-report, which may be subject to bias.[32] Fourth, it is not known to what extent the effect in the group with low MMSE scores was due to starting medications for dementia. Fifth, contamination of the control group was possible, which may also have biased toward the null. Control subjects may have sought out other services for falls prevention as a result of the occupational therapist's visit, and physicians and physical therapists in Kenosha County may have increased their awareness of falls and appropriate therapies as a secondary effect of the intervention, thus potentially improving care for control patients. Sixth, health behavior change theory was not used to frame the follow-up telephone calls for the intervention group, and adherence may have been better with use of such a theoretical framework. Finally, it was not possible to evaluate efficacy of the intervention in subjects with a MMSE score less than 24 because of small numbers.

In summary, this study shows that a multifactorial model of assessment and monthly telephone follow-up, with referrals for provision of interventions, is not successful in decreasing falls, although nursing home days are reduced. This has important public policy implications. Provision of community-based models of individualized multifactorial falls prevention that are primarily referral based, even with addition of heightened intensity of telephone follow-up, does not warrant investment of public health dollars for the purpose of decreasing falls. However, in the subgroup of older adults at risk for falls who have a MMSE score less than 28, efficacy appears likely in reducing falls, nursing home admissions, and nursing home days. Efficacy appears to be enhanced for those living with someone. Validation of this multifactorial model in those with low MMSE scores is important and merits further research.

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