

Abstract:

“Stepping On” is an effective fall prevention intervention that has been tested in Australia. However, data regarding the use of this intervention in the United States are lacking. This study will examine several questions regarding dissemination including feasibility in rural versus urban settings, feasibility of uptake by different community organizations such as parish nurse, senior housing, or senior center, feasibility and effectiveness of home visit versus phone call following the 7-week class sessions, and effectiveness of the model when delivered by a professional without a health degree. Adherence and outcomes may vary according to different implementation settings, leaders, and populations served.

We propose to develop “Stepping On” for a United States setting, maintaining fidelity with the original program. Our process will begin with focus groups to evaluate existing materials and advise on revisions. In addition, we will seek input from leaders and learners who have piloted “Stepping On” previously in several Wisconsin sites. Content experts will assist with refinement of materials, and all materials and evaluation tools will again be tested with the focus group. We will pilot implementation in our first setting then revise materials. We will then implement and evaluate “Stepping On” in three community settings in Wisconsin. In all settings, we will evaluate feasibility of implementation, population served, fidelity to the original model, participant attendance, participant adherence with exercise logs and recommendations, and participant outcomes. In the first setting, a senior apartment community, “Stepping On” will be implemented by a health-degree professional leader and then by a non-health-degree professional leader. The second and third sites will test implementation by a parish nurse and by a senior center, with one location being urban, and one rural. The first group in each setting will receive a home visit following their 7 sessions, and the second a phone call instead of the home visit. Based on our findings from these evaluations, we will produce a final package of “Stepping On” for broad dissemination and use nationwide.

This proposal builds on our previous collaboration with Dr. Clemson in implementing “Stepping On” in Wisconsin. In addition, we bring to this proposal a strong history of academic-community partnerships in falls prevention, which has resulted in high quality, fruitful research. Lastly, we bring an established track record in dissemination research in injury prevention through the Injury Research Center in Milwaukee, Wisconsin.

Narrative:

Falls are a significant problem for older adults. "Stepping On" is an effective fall prevention intervention that was developed and tested in Australia. This research aims to modify "Stepping On" for a U.S. audience, evaluate the program in different community settings, and produce a final package for broad use nationwide.

BIBLIOGRAPHY & REFERENCES CITED

1. Clemson L, Cumming RG, Kendig H, Swann M, Heard R, Taylor K. The effectiveness of a community-based program for reducing the incidence of falls among the elderly: A randomized trial. *J Am Geriatr Soc* 2004; 52:1487-1494.
2. Lusardi MM, Smith EV. Development of a scale to assess concern about falling and applications to treatment programs. *J Outcome Measur* 1997; 1:34-55.
3. Clemson L, Cumming RG, Heard R. The development of an assessment to evaluate behavioral factors associated with falling. *Am J Occup Ther* 2003; 57(4), 380-388.
4. Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. *New Engl J Med* 1988; 319:1701-7.
5. Nevitt MC, Cummings SR, Hudes ES. Risk factors for injurious falls: A prospective study. *J Gerontol Med Sci* 1991;46:M164.
6. Kiel DP, O'Sullivan P, Teno JM, Mor V. Health care utilization and functional status in the aged following a fall. *Med Care* 1991;29:221
7. Tinetti ME, Williams CS. The effect of falls and fall injuries on functioning in community-dwelling older persons. *J Gerontol A Biol Sci Med Sci* 1998; 53:M112-M119.
8. Tinetti ME, Williams CS. Falls, injuries due to falls, and the risk of admission to a nursing home *N Engl J Med* 1997;337:1279.
9. Stevens JA, Corso PS, Finkelstein EA, Miller TR. The costs of fatal and non-fatal falls among older adults. *Injury Prevention* 2006; 12:290-295.
10. Wisconsin Interactive Statistics on Health, Emergency Department Visits for Injuries Module and Injury Hospitalizations Module (2005), Department of Health and Family Services, Division of Public Health, Bureau of Health Information and Policy ([Http://dhfs.wisconsin.gov/wish](http://dhfs.wisconsin.gov/wish)); prepared by C.Ofstead, WI DHFS – Bureau of Aging and Long Term Care Resources.
11. Mahoney JE, Glysch RL, Guilfoyle SM et al. Trends, risk factors, and prevention of falls in older adults in Wisconsin. *Wisc Med J* 2005; 104:22-28.
12. Nevitt MC, Cummings SR, Kidd S, Black D. Risk factors for recurrent nonsyncopal falls: a prospective study. *JAMA* 1989;261:2663-8.
13. Robbins AS, Rubenstein LZ, Josephson KR et al. Predictors of falls among elderly people. Results of two population-based studies. *Arch Intern Med* 1989; 149:1628-1633.
14. Campbell AJ, Borrie MJ, Spears GF. Risk factors for falls in a community-based prospective study of people 70 years and older. *J Gerontol Med Sci* 1989; 44: M112-117.
15. Lord SR, Clark RD, Webster IW. Physiological factors associated with falls in an elderly population. *J Am Geriatr Soc* 1991; 39:1194-1200
16. Grisso JA, Kelsey JL, Strom BL, O'Brien LA, Maislin G, LaPann K, Samelson L, Hoffman S. Risk factors for hip fracture in black women. *N Engl J Med* 1995; 332:767-773.
17. Cummings SR, Nevitt MC, Browner WS, Stone K, Fox KM, Ensrud KE, Cauley J, Black D, Vogt TM. Risk factors for hip fracture in white women. *N Engl J Med* 1995; 332:767-773.
18. Mahoney JE, Palta M, Johnson J, Jalaluddin J, Gray S, Park S, Sager M. Temporal association between hospitalization and rate of falls after discharge. *Arch Intern Med* 2000; 160:2788-2795.
19. Mahoney J, Sager M, Dunham NC, Johnson J. Risk of falls after hospital discharge. *J Am Geriatr Soc* 1994; 42:269-74.
20. Stein MS, Wark JD, Scherer SC, Walton SL, Chick P, Di Carlantonio M, Zajac JD, Flicker L. Falls relate to Vitamin D and parathyroid hormone in an Australian nursing home and hostel. *J Am Geriatr Soc* 1999; 47:1195-1201.
21. Davies AJ, Steein N, Kenny RA. Carotid sinus hypersensitivity is common in older patients presenting to an accident and emergency department with unexplained falls. *Age and Ageing* 2001; 30:289-293.
22. Brown JS, Vittinghoff E, Wyman JF, Stone KL, Nevitt MC, Ensrud KE, Grady D. Urinary Incontinence: does it increase risk for falls and fractures? *J Am Geriatr Soc* 2000; 48:721-5.
23. Leipzig RM, Cumming RG, Tinetti ME. Drugs and falls in older people: a systematic review and meta-analysis. I. Psychotropic drugs. *J Am Geriatr Soc* 1999;47:30-9.
24. Leipzig RM, Cummin RG, Tinetti ME. Drugs and falls in older people: a systematic review and meta-analysis. II. Cardiac and analgesic drugs. *J Am Geriatr Soc* 1999;47:40-50.

25. Ray WA, Griffin MR, Schaffner W, Baugh DK, Melton LJ. Psychotropic drug use and the risk of hip fracture. *N Engl J Med* 1987; 316:363-369.
26. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. *J Am Geriatr Soc.* 2001; 49:179-187.
27. Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH. Interventions for preventing falls in elderly people. *Cochane Database Syst Rev* 2003 24th June 2003.
28. Chang JT, Morton SC, Rubenstein LZ, Mojica WA, Maglione M, Suttorp MJ, Roth EZ, Shekelle PG. Interventions for the prevention of falls in older adults: systematic review and meta-analysis of randomized clinical trials. *BMJ* 2004;32: 680-3.
29. Close J, Ellis M, Hooper R, Glucksman E, Jackson S, Swift C. Prevention of falls in the elderly trial (PROFET): a randomized controlled trial. *Lancet* 1999; 353:93-97.
30. Tinetti ME, Baker DI, McAvay G, Claus EB, Garrett P, Gottschalk M, Koch ML, Trainor K, Horwitz RI. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. *N Engl J Med* 1994; 331:821-827.
31. Van Haastregt JC, Diederiks JP, van Rossum E, de Witte LP, Voorhoeve PM, Crebolder HF. Effects of a programme of multifactorial home visits on falls and mobility impairments in elderly people at risk: randomized controlled trial. *BMJ* 2000; 321:994-8.
32. Vetter NJ, Lewis PA, Ford D. Can health visitors prevent fractures in elderly people? *BMJ* 1992; 304:888-890
33. Mahoney JE, Shea TA, Przybelski R, et al. Kenosha County Falls Prevention Study: A randomized, controlled trial of an intermediate-intensity, community-based multifactorial falls intervention. *J Am Geriatr Soc*, (publication date April 2007).
34. Hogan DB, MacDonald FA, Betts J et al. A randomized controlled trial of a community-based consultation service to prevent falls. *CMAJ* 2001; 165:537-43.
35. Steinberg M, Cartwright C, Peel N, Williams G. A sustainable programme to prevent falls and near falls in community dwelling older people: results of a randomized trial. *J Epidemiol Community Health* 2000;54:227-32.
36. Holder H, Flay B, Howard J, Boyd G, Voas R, Grossman M. Phases of alcohol problem prevention research. *Alcohol Clin Exp Res.* 1999;23(1):183-194.
37. Backer TE, David SL, Soucy G. *Reviewing the Behavioral Science Knowledge Base on Technology Transfer*. 1995. Available at: <http://www.nida.nih.gov/pdf/monographs/155.pdf>. Accessed June 19, 2006.
38. Carpenter D, Nieva V, Albaghal T, Sorra J. *Development of a Planning Tool to Guide Research Dissemination*. Available at: <http://www.ahrq.gov/downloads/pub/advances/vol4/Carpenter.pdf>. Accessed June 19, 2006.
39. Oxman A D, Thomson M A, David D A, Haynes R B. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *CMAJ.* 1995;153(10):1423-1431.
40. Lavis JN, Robertson D, Woodside J M, McLeod C B, Abelson J. Knowledge transfer study group. How can research organizations more effectively transfer research knowledge to decision makers? *Milbank Quarterly.* 2003;81(2):221-248.
41. Kerner J, Riemer B, Emmons K. Introduction to the special section on dissemination: dissemination research and research dissemination: How Can We Close the Gap. *Health Psychology* 2005;24(5):443-446.
42. Sogolow E, Sleet D, and Saul J. Dissemination, implementation, and widespread use of injury prevention interventions. In: Doll LS, Bonzo SE, Mercy JA, Sleet DA, eds. *Handbook of Injury and Violence Prevention*. New York, NY: Springer Science+Business Media, Inc. 2007:493-510
43. Kraft JM, Mezoff JA, Sogolow ED, Neumann MS, Thomas PA. A technology transfer model for effective HIV/AIDS interventions: Science and practice. *AIDS Education and Prevention.* 2000; 12 (Suppl. A):7-20.
44. Nutbeam D. Improving the fit between research and practice in health promotion: overcoming structural barriers. *Canadian Journal of Public Health.* 1996;87:S18-S23.
45. Chunharas S. An interactive integrative approach to translating knowledge and building a "learning organization" in health services management. *Bulletin of the World Health Organization* 2006; 84:652-657.
46. Wasi P. The triangle that moves the mountain. Bangkok: Health System Research Institute, 2004.

47. Tugwell P, Robinson V, Grimshaw J, Santesso N. Systematic reviews and knowledge translation. *Bulletin of the World Health Organization*, 2006;84:643-651.
48. Andersson N, Martinez E, Cerrato F, et al. The use of community based data in health planning in Mexico and Central America. *Health Policy Plan* 1989; 4:197-206.
49. Lavis JN, Davies HTO, Gruen RL, et al. Working within and beyond the Cochrane Collaboration to make systematic reviews more useful to policy-makers. *Healthcare Policy* 2006; 1:21-33.
50. Centers for Disease Control and Prevention (CDC). Web-based Injury Statistics Query and Reporting System (WISQARS) [Online]. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (producer). Available: www.cdc.gov/ncipc/wisqars. 2006.
51. Guse CE, Porinsky R. Risk factors associated with hospitalization for unintentional falls: Wisconsin hospital discharge data for patients aged 65 and over. *Wisconsin Medical J* 2003; 102:37-42.
52. Minimum Data Set, Resident Assessments (Admissions, 2003), Department of Health and Family Services, Division of Disability and Elder Services, Bureau of Quality Assurance. prepared by C. Ofstead, WI DHFS – Bureau of Aging and Long Term Care Resources.
53. Division of Public Health, Wisconsin Department of Health and Family Services. Healthiest Wisconsin 2010: a partnership plan to improve the health of the public. PPH 0276. April 2002.
54. Lorig KR, Sobel DS, Stewart AL, et al. Evidence suggesting that a Chronic Disease Self-Management Program can improve health status while reducing hospitalization: a randomized trial. *Med Care* 1999; 37:5-14.
55. Delbecq AL, Van de Ven AH, Gustafson DH. Group techniques for program planning: A guide to nominal group and Delphi processes. Glenview: Scott and Foreman, 1975.
56. Passig D. Imen-delphi: A Delphi variant procedure for emergence. *Human Organisation* 1997; 56:53-63.
57. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 2006; 333:417-423.
58. Clemson L, Fitzgerald MH, Heard R. Content validity of an assessment tool to identify home fall hazards: the Westmead Home Safety Assessment. *British Journal of Occupational Therapy* 1999; 62:171-179.
59. U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, Census of Population and Housing, Small Area Income and Poverty Estimates, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits, Consolidated Federal Funds Report (<http://quickfacts.census.gov/qfd/states/55000.html>) accessed February 2007.
60. U.S. Bureau of the Census, Census 2000, Special Tabulation on Aging, prepared by Cindy Ofstead, DHFS Bureau of Aging and Disability Resources, 2/2007.
61. Stepping On, building confidence and reducing falls: A community-based program for older people. Available at: <http://www.therapybookshop.com>.
62. U.S. Census Bureau, Census 2000 (<http://factfinder.census.gov>)
63. U.S. Bureau of the Census, Census 2000, Summary File 1, prepared by Cindy Ofstead, DHFS Bureau of Aging and Disability Resources, 2/2007.
64. Jorstad EC, Hauer K, Becker C et al. Measuring the psychological outcomes of falling: a systematic review. *J Am Geriatr Soc* 2005; 53:501-510.
65. Hesse-Biber SN, Leavy P. *The Practice of Qualitative Research*. Thousand Oaks, CA: Sage Publications, Inc.; 2006.
66. Morse JM, Field PA. *Qualitative Research Methods for Health Professionals*. 2nd ed. Thousand Oaks, CA: Sage Publications, Inc.; 1995.

Resources:

The proposed study will occur in the performance sites of: 1) the Geriatrics Section of the University of Wisconsin School of Medicine and Public Health, Madison, WI; 2) the Injury Research Center, Medical College of Wisconsin, Milwaukee, WI; and 3) Kenosha County Division of Aging Services, Kenosha, WI.

Resources are described in detail below:

University of Wisconsin School of Medicine and Public Health

The University of Wisconsin is a premier research institution steeped in academic excellence. Founded in 1849, the UW is a public, land-grant institution that provides on a single campus a complete spectrum of liberal arts studies and professional programs. UW-Madison has an annual budget of \$1.3 billion, an enrollment of 43,500 students, and 2,100 faculty making it fifth largest among US universities.

The Geriatric Section, within the Department of Medicine of the University of Wisconsin School of Medicine and Public Health, has a distinguished history of research in the biology, health services, and clinical aspects of aging. The UW Section of Geriatrics is identified as one of the largest in the country, with a total of 20 faculty members. Of these, 15 members are fellowship-trained geriatricians while the other 5 are PhD investigators with acknowledged expertise in aging research. The Section sponsors core programs (The Geriatric Research, Education and Clinical Center (GRECC) of the William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin; The Wisconsin Alzheimer's Institute (WAI); The DHHS-funded National Center of Excellence in Women's Health Research), and in addition, works collaboratively with the established programs at the University of Wisconsin-Madison (Wisconsin Comprehensive Memory Program (WCMP); Osteoporosis Clinical and Research Program; NIH-funded Aging and Cancer Program; the Institute on Aging). Within the Department of Medicine resources include computer, grants management, and biostatistical support services. Additional resources are available through ties with the Department of Population Health.

Dr. Mahoney has a primary office in The Geriatrics Section office suite, located in close proximity to Department of Medicine administrative offices and a short distance from campus. Dr. Mahoney's space consists of her office and 2 large rooms for her research staff. Each of these rooms contains 3 workstations with desktop PCs, file cabinets and bookshelves. These rooms will be available for study personnel for this study (grant coordinator, study hourly, physical therapist consultant). The office suite additionally houses a conference room and the offices for the Head of the Geriatrics Section and two secretarial support staff. The suite has a common printer, photocopier, and fax machine. Postage is provided through the Dept of Medicine. The telephone system provides 3-way calling including overseas dialing, and Wisc Line may be used if more than 3 lines are needed. Secretarial support for Dr. Mahoney and her research staff is available through the Section of Geriatrics.

Desktop PCs for Dr. Mahoney and her research staff are Pentium 4 Processor 2.00 GHz, 400 FSB 512K Cache Intel Gigabyte NIC with 256 MB memory. Computer

and software support is provided by the Department of Medicine Information Systems support staff. All computers are equipped with Microsoft Word, Excel, Access, and Power Point, and are linked to Department of Medicine computing network. The Dept of Medicine Wide Area Network (WAN) handles about 1000 nodes and involves 14 different geographic locations. The departmental Novell SuperServer provides resources sharing for users. Resources-sharing includes data files, software, and peripherals. This WAN is capable of linking to other campus resources, such as the Clinical Health Sciences Library-Medline and is capable of connecting to the Internet for world wide access. All data will be entered into desktop PCs at Dr. Mahoney's research offices, into Access database, and stored on the Department of Medicine server in a secure location (password protected to Dr. Mahoney's research team).

Quantitative data analysis will be provided by Ronald Gangnon, PhD, through the Department of Biostatistics and Medical Informatics, which is located in close proximity to Dr. Mahoney's office. The Department of Biostatistics and Medical Informatics provides a vital environment for statistical collaboration. The Department recently was ranked sixth among peer departments by NIH for its total NIH funded research support. Currently, there are 33 PhD-level statisticians and computer scientists with appointments (full or partial) in the Department, ten with joint appointments in the Statistics Department and five with joint appointments in the Computer Sciences Department. In addition to faculty the Department currently employs over 80 individuals, including MS-level biostatisticians, programmers, and data managers. The Department has developed an extensive UNIX and Window NT workstation and server network providing state-of-the-art computing for statistical computation and software development. The core of this environment is an integrated, fault tolerant network of 130 state-of-the-art Sun, Linux, and Microsoft NT computers. The facility currently consists of 105 networked servers configured to supply the computing needs of 400 users within the Department and other sites within the Medical School. Access to the facility is provided by 140 UNIX workstations and 300 Windows desktop computers. The central facility and its desktop clients are administered by the Biomedical Computing Group, a highly skilled group of 20 computing professionals within the Department. A full complement of up-to-date computational tools is available, including Splus, R, SAS and Matlab for statistical exploration. Both Dept of Medicine and Department of Biostatistics and Medical Informatics are connected via the 21st Century Network of the University of Wisconsin – Madison.

Medical College of Wisconsin:

Founded in 1893 as the Wisconsin College of Physicians, the Medical College of Wisconsin is a private academic institution dedicated to leadership and excellence in education, research, patient care, and service. Located in suburban Milwaukee, MCW is the heart of the Milwaukee Regional Medical Center, a modern and continually expanding campus, which houses its major teaching partners: Froedtert Memorial Lutheran Hospital (FMLH), Children's Hospital of Wisconsin (CHW), the Milwaukee County Mental Health Complex (MCMHC), Curative Rehabilitation Center (CRC), and the Blood Research Institute of the Blood Center of Wisconsin (BRI). FMLH has the distinction of housing the top-ranked Trauma Center in the country. The Medical College of Wisconsin and its affiliates benefit from joint strategic planning and coordinated operations, and share a close working relationship with the Zablocki Veterans Affairs Medical Center (ZVAMC), Marquette University (MU), Milwaukee

School of Engineering (MSOE), and the University of Wisconsin-Milwaukee (UWM), all located within a few miles of the campus. Through the college's affiliations with area hospitals and health care facilities, more than 6,000 teaching beds are available in a metropolitan area of more than 1.2 million people, involving almost 2,000 MCW faculty and trainees.

The Injury Research Center at the Medical College of Wisconsin is a comprehensive federally funded Injury Control Research Center, established in 2001, to address the burden of injury across the lifespan in the Great Lakes region (Wisconsin, Minnesota, Illinois, Indiana, Michigan and Ohio). The IRC-MCW is an interdepartmental collaboration of Emergency Medicine, Family and Community Medicine, Neurosurgery, Surgery, Pediatrics, Physical Medicine and Rehabilitation, Orthopedics, Ophthalmology, Plastic and Reconstructive Surgery, and Population Health. The IRC-MCW also partners with the State of Wisconsin's Department of Health and Family Services on numerous injury surveillance and prevention programs and policies. The location of the IRC at MCW is significant. The medical school's trans-disciplinary faculty directs and supports the trauma programs at Children's Hospital of Wisconsin and at Froedtert Hospital. This leadership has led to outstanding clinical, educational and research accomplishments in the acute care and rehabilitation of injured patients. The IRC-MCW balances scientific research, reflecting areas of expertise of faculty and staff with core programs to support educational, public policy, prevention and community service goals of the Center. The IRC-MCW's mission is carried out by four major core programs: a Management and Administrative Core, a Research Development and Support Core, an Education and Training core, and a Policy Core.

The IRC-MCW has 1567 square feet available for research to be conducted, including two conference rooms for meeting space. The office is equipped with two Hewlett Packard Laser Jet Printers, one Color Model 3700dn and one Black & White Model 4100N and a Canon Image Runner Model 330S Fax/Copier. The IRC has twelve computer workstations with Windows XP Operating Systems and Microsoft Office 2003. The IRC-MCW has licenses for data analyses packages. Also available to faculty and staff is a Compaq Notebook Computer and NEC Model LT-156 Color LCD Projector. Conference rooms have access to a 3M Model 9550 Overhead Projector and a Kodak Model 4600 Slide Projector and Carousel. The IRC utilizes the MCW Emergency Medicine server, secured in a locked, environmentally controlled server cabinet. This is a Windows 2003 Server with Exchange Server 2003 with Dual Xeon 2.8GHz Processors with 4GB ECC RAM, redundant RAID-5 700GB Hard Disk Subsystem, redundant power supplies and NICs, a 600GB single tape backup system with Fdsull nightly backups, and 1500VA battery backup UPS w/ automated software. The IRC is connected to the MCW network as well, which has a Cisco firewall 525 w/ VPN Concentrator, and redundant DS3 internet connections.

Kenosha County Division of Aging Services:

The Kenosha County Division of Aging Services has administered services and grants for older adults since 1979. It operates an Aging and Disability Resource Center, a unique center that provides information, assistance, long-term care consultation and screening, and many services including prevention. It conducts multiple programs in collaboration with community partners such as senior centers, area churches, senior apartment buildings and the Kenosha Community Health Center. It has strong links with

Racine County, which is adjacent, and with Waukesha County, which is approximately 70 miles away. Thus, Kenosha County Division of Aging Services is well situated geographically and politically to spearhead implementation of "Stepping On" at the 3 designated community sites in southeastern Wisconsin: 1) Schuetze Recreation Center, under the jurisdiction of the City of Waukesha Parks, Recreation and Forestry Department, Waukesha, Wisconsin; 2) Lincoln Lutheran Senior Housing in Racine, Wisconsin, and 3) a rural site in Kenosha County, Wisconsin, where the program will be provided by an Aurora Hospital Parish Nurse.

The Kenosha County Division of Aging Services is housed in the County's Human Service Building and Aging and Disability Resource Center. The office suite houses the Director of the Division, L. Jaros, and has work stations for other study staff (S. Cech, A. Schwalbe) with telephone and filing cabinets. There are three printers, two copiers, and two fax machines in the suite. Additional file cabinets can be arranged as needed. Each of the staff has access to a desktop PC and all desktop PCs are connected by local network, with password protection for all files as needed. Computer support is provided by the Information Assistance Department.

2. SPECIFIC AIMS

An important opportunity and challenge to reduce the health and economic burden of fall-related injuries in the United States is the translation of interventions found to be beneficial in research studies into effective community-based prevention programs and practices. "Stepping On" is an effective fall prevention intervention that was developed, evaluated, and shown to be effective in Australia (1). Data regarding the use and effectiveness of this intervention in the United States, however, are lacking. Key issues that need to be addressed in order to disseminate effective interventions into widespread community practice include: the translation of program materials for use in the United States; research on the feasibility, acceptability, reach and uptake of the program for both community organizations and individual participants; an assessment of a community organization's fidelity to the key elements of the original program; and a comparison of participant outcomes to determine whether the US program is able to achieve results that are similar to the original study.

We propose to translate "Stepping On" for implementation in a United States setting, maintaining fidelity with the original program. In phase one, content experts, including Lindy Clemson, PhD, OT, the creator of "Stepping On" in Australia, will identify key elements of the program and assist with refinement of materials. We will convene focus groups of potential class leaders and participants to evaluate existing materials and advise on revisions. In addition, we will seek input from class leaders and participants who have piloted "Stepping On" previously in several Wisconsin sites. Materials for the program package will be developed utilizing this input, and then all materials and evaluation tools will be tested again with focus groups. In phase two, we will pilot implementation in one setting, a senior apartment community, and revise the program package based on findings from the pilot. In phase three, we will implement and evaluate "Stepping On" in three community settings in Wisconsin. In all settings, we will evaluate feasibility of implementation, population served, fidelity to the original model, participant attendance, participant adherence with personal goals and exercise logs, and participant outcomes. In one setting, a senior apartment community, "Stepping On" will be implemented by a health-degree professional leader and then by a non-health-degree professional leader. The other sites will test implementation by a parish nurse at a church, and by a health-degree professional at a community center, with one location being urban, and one rural. The first group in each setting will receive a home visit following their 7 sessions, and the second a phone call instead of the home visit. We hypothesize that "Stepping On" will be feasible to implement in all 3 settings, and that all programs will achieve participant outcomes on the Mobility Efficacy Scale (2) and Falls Behavioral Scale (3) similar to those achieved by "Stepping On" in the original study. We hypothesize that implementation by a non-health professional will demonstrate fidelity as assessed by content experts. Lastly we hypothesize that adherence with recommendations will not diminish when a phone call is substituted for a home visit.

Our previous experience with implementing "Stepping On" in Wisconsin will form the foundation for this current proposal. We will obtain feedback from current "Stepping On" leaders and learners in Wisconsin as we develop the implementation package. We have collaborated with Dr. Clemson in piloting "Stepping On" in Wisconsin, and have brought to the collaboration our experience with both falls prevention models and chronic disease self-management models. This proposal also builds on our history of academic-community partnerships in falls prevention, which has resulted in high quality, fruitful research. Lastly, we bring an established track record in dissemination research in injury prevention through the Injury Research Center in Milwaukee, Wisconsin.

The specific aims of this research are to:

1. Translate "Stepping On" into a U.S. Community program utilizing advice of content experts and of focus groups to inform development of the program package and program evaluation;
2. Test implementation of "Stepping On" in a community setting and revise the program package based on the pilot implementation;
3. Evaluate uptake, reach, feasibility, fidelity, adherence and outcomes related to implementation of "Stepping On" in the following situations:
 - Implementation by an OT, PT, RN versus a non-health degree professional who works with seniors
 - Implementation by a retirement community versus a community center versus a parish nurse
 - Implementation at a rural versus an urban site
 - Implementation utilizing a phone call after the last class rather than a home visit;
4. Produce a final package of "Stepping On" for broad dissemination and use nationwide.

3. BACKGROUND AND SIGNIFICANCE

Approximately one-third of community-living older adults fall each year (4). Ten percent of falls result in serious enough injury to require hospitalization (4,5). Fallers are at increased risk for functional decline and greater use of medical services (6,7), and are at greater risk of nursing home placement (6,8). The cumulative total of fall-related fatal and non-fatal injuries in the United States is staggering. In 2000, there were over 12,900 fall-related deaths, 1.67 million emergency department visits, and 388,000 subsequent hospitalizations for fall-related injuries among adults aged 65 and over, with an associated direct medical cost of \$19.2 billion dollars (9).

Falls are a significant health problem in Wisconsin. In 2005, among adults age 65 and over, falls led to 27,073 emergency room visits and 26,412 hospital admissions (10). Two-thirds of those admitted to the hospital for falls-related injury were discharged to a nursing home or rehabilitation facility (11). From 2000 to 2004, the age-adjusted death rate due to falls increased 16% for men and 26% for women (10). Wisconsin's death rate from falls is almost twice the national average (11).

Risk Factors for Falls. Risk factors for falls and hip fractures include gait and balance impairments, cognitive impairment, use of psychotropic medications, visual deficits, orthostatic hypotension, depression, and medical conditions including stroke, arthritis, and Parkinson's (4,12-19). The greater the number of risk factors, the greater the risk for falls (4,12). Risk is increased during and immediately after acute illness (4,18,19). More recent studies have linked falls to low Vitamin D status, carotid sinus syndrome, and urge incontinence (20-22). Specific medications associated with falls include serotonin-reuptake inhibitors, tricyclic antidepressants, neuroleptic agents, benzodiazepines, anticonvulsants, and class IA antiarrhythmic agents (23-25). Successful falls prevention requires a multifactorial approach, with reduction of risk factors and increased exercise.(26-30).

Group Multifactorial Interventions. Applying individualized multifactorial models in the community setting has had limited success (31-34). Thus, there has been increased interest in group multifactorial models. Steinberg et al demonstrated a significant decrease in falls with a group multifactorial program consisting of information plus a monthly exercise class, compared to an information session alone, with a hazard ratio of 0.43 for time to first fall (35). Clemson et al has shown a significant benefit from the multifactorial group model "Stepping On" to reduce falls (1). Clemson evaluated a program of 7 weekly classes plus 1 booster class to reduce falls led by an occupational therapist and content experts. Classes focused on increasing self-efficacy, encouraging behavioral change and providing balance and strength exercise. Behavioral changes focused on improving home and community environmental and behavioral safety, encouraging vision screen, coping with low vision and medication review. The intervention was targeted to high risk individuals (age 70+ with a fall in the past year or a concern about falling). There was a 31% reduction in falls; (RR =0.69 (0.5 to 0.96). In examining the subgroup with a prior history of falls, the relative risk for falls was 0.66 (0.46 to 0.95) and for ≥ 2 falls was 0.65 (0.46 – 0.94). Better outcomes for intervention subjects were shown, including maintaining confidence in mobility tasks as measured by the Mobility Efficacy Scale (MES) $p=0.042$. They also used more protective behaviors as shown by the Falls Behavior Scale for Older People (FaB) $p=0.024$. Thus, the "Stepping On" program provides an efficacious small-group multifactorial intervention to reduce falls.

Adherence compared favorably with other successful falls studies (1). At the end of 14 months, 59% of program participants were still doing the program exercises routinely, and 41% were still doing their exercise using the ankle cuff weights. A greater proportion of the subjects who did not have a vision check up prior to randomization initiated a vision assessment during the follow-up period ($p=0.002$). Program participants ($n=11$, 8%) were less likely to start taking a new psychotropic drug than the control subjects ($n=20$, 16%) ($\chi^2 = 6.4$, $p=0.04$).

Need to Disseminate Evidence-Based Fall Prevention Interventions. Dissemination research attempts to understand how research findings can be translated into effective community practice (36). Traditional methods to disseminate research findings are largely done through publication in journals and presentations at professional conferences. Scholars of dissemination and diffusion research argue that simply providing this information to be picked up by whoever happens to have access to a particular journal or attend a conference is not an effective method for transferring information about evidence-based programs to community organizations and government agencies (37-42). Sogolow and colleagues argue that often the publication of

intervention research does not address key implementation issues that make the translation of this research into practice possible (42). These details include staff requirements, space and training needs, and financial resources, along with information about the delivery of the intervention, elements of the intervention that are essential to its effectiveness, and what adjustments are possible for particular audiences and circumstances (42,43).

The randomized community trials that demonstrate effectiveness of interventions are generally conducted in ideal circumstances with considerable resources. Such studies can demonstrate the *theoretical* effectiveness of the intervention, under the best circumstances, but not the *use* effectiveness of the intervention in less ideal circumstances and, typically, with fewer resources. In practice, local health departments and other community-based organizations receive only modest funding for public health prevention programs, yet they are expected to implement programs that have a broad impact on the populations they serve. For falls prevention, a number of individual and multifactorial fall injury prevention interventions have been shown to prevent falls or fall-related injuries in older adults in controlled studies, including “Stepping On”. The next step is the translation of this evidence-based program into an intervention that can be used more broadly. To achieve this, it is important to understand how knowledge translation occurs both within an individual and within a community organization.

Gap Between Researchers and Community Organizations. One possible reason for the dearth of knowledge about effective dissemination of research findings is the gap between researchers and community organizations. Nutbeam argues that neither group has previously had much incentive to work with the other to learn about these processes. Researchers are rewarded professionally with grant funding and publications based on prevention research that closely resembles traditional experimental designs and focuses on problem identification and solution generation. Researchers, therefore, have little incentive to study or include in their research designs steps to understand how their findings could be broadly disseminated beyond peer-reviewed journals and conferences (40,44). By changing these incentives, researchers would be more inclined to ensure that their research findings are translated into practice. One potential way to change this system is for funding agencies to encourage researchers to have plans for how their findings can be disseminated beyond a research study environment (40). Community organizations and government agencies also need incentives, motivation, and funding to take these research studies and adapt them into community programs. Requiring community programs to have a stronger focus on outcomes would be one incentive for them to seek out studies that have previously been demonstrated to be effective (44).

Integrated Interactive Model of Knowledge Translation. Chunharas has proposed an integrated interactive model of knowledge translation that posits that knowledge translation is context specific, and occurs through a non-linear process (45). It is based on the concept of a “learning organization”, defined as “one in which the environment is structured in such a way as to facilitate learning as well as the sharing of knowledge among members or employees.” Further, “knowledge translation must be seen as a part of knowledge management within an organization so that a learning organization can be created.” The model states that knowledge translation occurs as part of the four-stage problem-solving cycle for an organization, which begins with identification of a problem, then a search for a solution, then implementation, and finally monitoring. As the problem-solving cycle occurs within an organization, three types of knowledge interact to affect decisions made at each and every point in the cycle: management information systems, personal knowledge of decision-makers, and research findings. The stages of problem-solving and the sources of knowledge come to play in four dimensions of translation and decision-making, which can help guide those interested in knowledge translation. These dimensions are:

1. The stage of the problem-solving cycle
2. Contextual factors (e.g. financial, demographic)
3. The nature of knowledge or evidence that is available (e.g. availability of research findings)
4. The process for translation and communication of knowledge, which is non-linear.

This model is “integrated in the sense that it needs to take place during the problem-solving cycle rather than following researchers’ own cycle of work. It is interactive because it requires close interaction among groups of stakeholders during the problem-solving cycle as well as during the research-production process. It is both integrative and interactive because it attempts to include other sources of knowledge and to consider such knowledge rather than placing less value on it or trying to exclude it.”(45).

As predicted by the model, dissemination processes that involve only researchers and policy-makers may not reach viable solutions. The model predicts that involving stakeholders is essential for sustained success of

the translation process. A model involving researchers, decision-makers, and affected stakeholders has been dubbed “the triangle that moves the mountain”(46).

Understanding barriers and facilitators to knowledge translation. Tugwell has proposed that the first step in knowledge translation is an assessment of the barriers and facilitators. Barriers should be identified across multiple domains including the individual, the public, the provider, the organization, the health system, and the non-health-care sector (47). Focus groups can provide important community input into the process of identifying and prioritizing barriers for modification (48). Assessment of barriers and facilitators should lead to an end-result of understanding why, when, and under what conditions an intervention works (49).

Significance of Problem Being Addressed The impact of unintentional injury on mortality, morbidity, and disability among adults aged 65 and over is well recognized. In 2002 over 100,000 older Americans died of an unintentional injury. Injuries due to falls accounted for over 17,000 deaths in 2003, making it the third leading cause of unintentional injury fatality after motor vehicle traffic-related injuries and unintentional poisonings (50). Falls were an even more important cause of nonfatal injuries. Based on emergency department data from 2004, the CDC estimates that there were over 8 million fall injuries requiring treatment in emergency departments, far more than any other injury-related cause of emergency department visits. Fall-related injuries were the number one cause of injury visits to emergency departments for all age groups from less than one year of age to 65 years of age and older, with the exception of the 15-24 year old age group in which it was the third most common cause of emergency department injury visits. The sharp increase in the risk of fall injuries with increasing age results in a substantial risk for elderly Americans. The rate of fatal fall injuries in Americans 85 years of age and older is 136 per 100,000 person years; the corresponding rate for nonfatal injuries requiring emergency department visits is 11,422 per 100,000 person years, indicating that over 11% of senior citizens 85 years of age and older each year experience a fall injury requiring an emergency department visit. (50).

Wisconsin experiences an even higher rate of fall injury mortality than these national statistics and Wisconsin’s fall injury mortality rate has increased over the past 10 years (11, 51). Our state has the fourth highest rate of death from falls in the United States (50). Falls account for more than 25% of Wisconsin’s injury-related emergency room visits, totaling more than 125,000 in 2005. Charges for fall-related ER visits totaled \$108 million in 2005 (10). Falls also account for almost half of all Wisconsin’s injury-related admissions for in-patient hospital stays.(10) Older Wisconsinites account for 71 percent of fall-related hospitalizations, although they make up 13 percent of the population. Falls also increase older persons’ risk of nursing home placement. Of all those admitted to Wisconsin nursing homes in 2003, 40% had a fall in the previous 30 days (52). The Wisconsin state health plan, Healthiest Wisconsin 2010, has identified the prevention of falls-related injury and death across the life span as one of its priorities (53).

Significance of this proposed research. This proposal will advance scientific knowledge through testing and evaluation of the “Stepping On” program as modified for a U.S. community. If the aims of the application are achieved, an effective “Stepping On” program will be developed based on elucidation of key elements, input from focus groups, refinement from testing at one site, and implementation and evaluation at two other sites to answer key research questions regarding site location, background of class leaders, and usefulness of a home visit. Our research will produce a program package for dissemination and will provide guidance on implementation across a number of community settings. This information will enhance effective translation of Stepping On across the United States, to maximize the likelihood of reducing falls in as many settings as possible.

4. PRELIMINARY STUDIES

Our research team individually and collectively has a strong background in fall prevention research and program dissemination. This background ranges from research at the academic level to application at the state and community level. Our areas of expertise are:

- Community prevention programming (L Jaros, S Cech)
- State policy-making in falls prevention (L Hale, T Ellingson, B Kopp)
- Clinical expertise in falls (J Mahoney, MD, L Clemson, OT, S Cech, RN)
- Community-based falls and injury prevention research (J Mahoney, L Clemson, P Layde, A Christiansen)
- Dissemination research (P Layde, A Christiansen, L Clemson, J Mahoney).

The preliminary work below demonstrate the research team's commitment to a leadership role in developing and disseminating evidence-based interventions in falls prevention. The research team's preliminary studies include:

- Multifactorial falls prevention research study in Kenosha County, Wisconsin (Mahoney, Jaros, Cech).
- Multifactorial falls prevention research study in Dane County, Wisconsin (Mahoney, Hale).
- Implementation and program evaluation of the Chronic Disease Self-Management Program (CDSMP) (54) in Kenosha County (Mahoney, Jaros, Cech)
- Implementation and program evaluation of "Stepping On" in Wisconsin (Mahoney, Clemson, Jaros, Cech)
- Dissemination research in falls prevention through the Injury Research Center of the Medical College of Wisconsin (Layde, Hale, Christiansen)
- Implementation of the Wisconsin Falls Initiative, a collaboration of state and local Wisconsin stakeholders in falls prevention (Mahoney, Hale, Ellingson, Kopp)
- Evaluation of dissemination of "Stepping On" among culturally diverse populations in Australia (L Clemson)

We describe the most relevant of these below.

1. Multifactorial falls prevention research study in Kenosha County (Mahoney, Jaros, Cech). Dr. Mahoney and colleagues developed an individualized multifactorial intervention based on the University of Wisconsin Falls Prevention clinic. The intervention utilized an algorithm to evaluate medications, vision, balance and gait, cognition, home functioning, and home safety. A therapist or nurse trained to provide the multidisciplinary evaluation visited the participant in the home twice in 2 weeks to do the evaluation and make recommendations. Recommendations were mailed to the person's primary physician, and referrals to physical therapy and other health care providers were made based on the algorithm. The therapist or nurse called the intervention participants monthly for 11 months to encourage compliance and problem-solve.

We tested the intervention in a randomized, controlled trial in Kenosha County, WI, in collaboration with the Kenosha County Division on Aging (33). The intervention was implemented by a nurse (S Cech) and physical therapist (A Schwalbe). Study enrollment criteria were: age 65 and over, community-living, and high risk for falls, based on criteria from the American Geriatric Society Guideline for the Prevention of Falls in Older Persons (26). Participants were followed for falls, hospitalization and nursing home utilization for 12 months, and hospitalization and nursing home reports were verified by medical records. We enrolled 349 older adults. Mean age was 80 ± 7.48 years and 78.5% were female. Overall, there was a 19% reduction in falls but this was not significant (RR = 0.81, 95% CI 0.57 to 1.17). However, nursing home days were significantly reduced (RR = 0.50, 95% CI 0.25 to 0.97).

The subgroup with Mini-Mental State Examination (MMSE) score of 27 or less benefited in particular from the intervention, with a 45% reduction in falls, and a two-thirds reduction in nursing home admissions and nursing home days. This was primarily related to having a caregiver in the home, as shown in the table on the next page.

Table 1. Effect of intervention on falls rate per year and other outcomes among those with MMSE of 27 or less

Subgroups	Intervention /Control Falls rates per year	Falls rate per year		Nursing home admits per year		Nursing home days per year	
		Rate ratio int/control	p-value	Rate ratio int/control	p-value	Rate ratio int/control	p-value
MMSE 27 or less (n=131)	2.34 / 4.26	0.55	.05	0.35	.02	0.33	.02
MMSE 27 or less:							
Lives alone (n=61)	1.48 / 1.42	1.04	.89	1.78	.67	0.63	.43
Lives with someone (n= 70)	3.10 / 6.92	0.45	.07	0.15	.003	0.13	.008

This study has led to two further lines of work. First, through funding from the Centers for Disease Control and Prevention, we are testing this intervention, combined with health care provider education, in a randomized, controlled trial in Dane County, Wisconsin. Five hundred older adults have been enrolled and data analysis is in progress. Second, through funding from the Wisconsin Partnership Program in 2006 to L Jaros of the Kenosha County Division of Aging Services, we have begun dissemination of this model across Wisconsin. The program is targeted to older adults with a history of falls who have some cognitive impairment and have a caregiver in the home. S. Cech, A. Schwalbe, and Dr. Mahoney have led three 3-day trainings for 18 providers (OT, PT, RN, and NP) from diverse organizations (senior retirement community, rehabilitation and other clinics, and Medicaid-waiver organizations). Approximately 50 high-risk older adults have been assessed since summer 2006. Outcome measures include change in FaB for program participants from baseline to 6 months, and adherence to falls prevention recommendations at 6 months. This work demonstrates our ability and commitment to perform rigorous research to test new interventions and evaluate program dissemination in falls prevention.

2. Implementation of "Stepping On" in Wisconsin (Mahoney, Clemson, Jaros, Cech). In 2006, L. Jaros of the Kenosha County Division of Aging Services in collaboration with Dr. Mahoney, received funding from the UW Wisconsin Partnership program to disseminate "Stepping On" in five counties in Wisconsin. We worked with Dr. Clemson to develop a training program for leaders to accompany the "Stepping On" curriculum. In addition, with concurrence of Dr. Clemson, we modified the original "Stepping On" program to add a lay co-leader, delete the home visit, and provide a booster session at the second, fourth and sixth months after completion of each class. Lay co-leaders were added based on our experience with the Chronic Disease Self Management Program (CDSMP) (54). CDSMP is similar to Stepping On in that it utilizes a small group model to effect behavior change using principles of self-efficacy. The CDSMP model considers lay leaders to be a core element.

In May 2006, nine professional leaders and three lay co-leaders were trained over 2 days to conduct "Stepping On" classes. The training covered program content along with essential background information on the underlying concepts. The training focused on understanding the program process, running the program and administering the evaluation tool. Marketing and recruitment were also addressed. Phone consultation with Dr. Clemson to address questions and to clarify understanding aided the training process.

The current leaders for "Stepping On" are part of the Aging Service Network, the Aging and Disability Resource Centers, Meals on Wheels, Congregate Nutrition Programs and other programs that are in the best position to identify older persons who would benefit from "Stepping On". Stanford University's experience with CDSMP, our experience with the Kenosha County Falls Prevention Study, and other counties' experience with prevention programs, all indicate that these sorts of direct connections to the target population are more successful at identifying at-risk older persons than is reliance on medical referrals, media or other methods of marketing.

As of February, 2007, 153 people at risk of falls have participated in "Stepping On" classes. Comments from participants include:

- "This class helped me to learn the right kind of exercises for balance- I hadn't realized that there were specific balance exercises"
- "I learned how to use a cane correctly" (from several participants)
- "When I'm working in my yard now--I know how to look where I'm putting my feet"
- "I feel more confident going up and down my basement steps"
- "I learned the correct way to walk heel first".

Outcome measures include change in FaB for class participants from baseline to 6 months, and adherence to falls prevention recommendations at 6 months.

The table below shows characteristics of “Stepping On” implementation within the 5 counties.

Table 2. Characteristics of “Stepping On” implementation by county

County	Leader(s)* Professional Background	Leader Title	Sponsor/ Supervisor	Class Location	# of Participants	Lay Co-Leader(s) background (if used)**
Kenosha/ Racine	1. RN	1. Prevention Coordinator	Sandy Cech, RN Kenosha Co. ADRC	1. Privately owned PT Clinic	12	1. Trained in CDSMP, retired RN, history of falls 2. Trained in CDSMP, Educator, history of falls 3. history of falls
	2. RN	2. Intake Specialist, Aging and Disability Resource Center (ADRC)		2. Privately owned Fitness Center	4	
				3. Library	9	
Rock	1. Health Educator 2. Director	1. Health Educator 2. Director	Rock County Council on Aging; Dane County Area Agency on Aging	1. Senior Center 2. Senior Housing	13 29	
Kewaunee	1. Social Worker 2. Rehab Counselor	1. Director 2. MS	Aging Services Unit, Kewaunee	1. Aging Services Unit	7	
Marathon	Community Health Educator	BS	Aging and Disability Resource Center of Central WI	1. Senior Apartment 2. ADRC 3. ADRC	14 16 15	Older adult, history of falls
Buffalo/ Eau Claire	1. Registered Dietician 2. Aging Unit Director	1. BS 2. High School Degree	Buffalo County Aging Unit	1. Church	15	

* If two are listed under Leader(s) professional background, there were two leaders (co-leaders) for each class

** If no lay co-leader is listed, then class was provided without a lay co-leader.

The data above demonstrate the tremendous variability across counties. In particular, there is substantial variability in background of the class leader, with some leaders having health professional degrees and others not. There has been no data evaluating performance by non-health degree professionals, and data is sorely needed to inform choice of class leader.

3. Dissemination research in Falls Prevention through the Injury Research Center at the Medical College of Wisconsin. Three community-based fall prevention initiatives are being implemented and evaluated through the Injury Research Center, funded by The Medical College of Wisconsin’s Healthier Wisconsin Partnership Program.

Wisconsin Injury Prevention Coalitions, Peter Layde, MD, MSc, Principal Investigator, Ann Christiansen, MPH Co-Investigator, Clare Guse, MS, Co-Investigator (\$450,000, 2005-2008). This project aims to reduce the burden of intentional and unintentional injuries in Wisconsin by supporting the development of community-based injury prevention coalitions across Wisconsin. These public-private community-based coalitions bring together professionals and interested citizens with a vested interest in reducing injuries. Together, they identify, prioritize, and intervene to change areas of injury that have the most impact on their communities. The program is unique to Wisconsin and has the potential to be a model for other state and local partnerships by linking community and academic partners to provide resources, guidance, and leadership to coalitions in their injury prevention planning and evaluation. This project brings together both Wisconsin medical schools and the state health department to form a partnership whose mission is to work collaboratively with the county health departments and other community-based organizations by providing extensive support and technical assistance to the translation of evidence-based injury prevention interventions. Three of the communities are focusing on implementing falls prevention programs in their communities. One example is from Manitowoc County where their coalition is in the process of developing a program to enhance the current fall risk screening process among several local health care agencies to identify older persons at risk for a fall. The

program expects to work with four local service agencies, two Lifeline service providers and two homecare providers, to utilize a tested fall risk-screening tool to assess all clients at the time of admission to their respective programs. If the risk screen indicates an increased risk of falls, the client would be referred to local health care providers for further assessment.

Partners in the project include five county health departments (Kenosha, Manitowoc, Rush, Sawyer, and Vernon), the Wisconsin Department of Health and Family Services Injury Prevention Program, and the Wisconsin Public Health and Health Policy Institute. The academic partners are the Medical College of Wisconsin Injury Research Center and Family and Community Medicine.

Barron County Fall Prevention Program (\$19,471, 2005-2006), Peter Layde, MD, MSc, Principal Investigator, Ann Christiansen, MPH Co-Investigator, Clare Guse, MS, Co-Investigator. The primary goal of the Barron County Fall Prevention Project is to prevent falls and fall-related injuries among older adults in Barron County, Wisconsin by establishing a system for screening elderly Barron County residents, either in the community or in residents' homes, to assess risk factors for falls and to link older adults at risk for falls and fall-related injuries to existing health services. Those at high risk participate in fall prevention interventions tailored to their particular risk factors. Interventions include: 1) home hazard assessment, recommendations, and in some cases actual home repairs, 2) medication consultation/review, and 3) balance and strength training. The project is currently assessing the impact of these interventions on the prevention of fall-related injuries.

Northwest Wisconsin Falls Prevention Collaborative (\$45,588.17, 2006-2007) Peter Layde, MD, MSc, Principal Investigator, Ann Christiansen, MPH Co-Investigator, Clare Guse, MS, Co-Investigator. The major purpose of this project is to reduce the number of falls by older adults in 3 rural northwestern Wisconsin counties. The Northwest Wisconsin Falls Prevention Collaborative (NWFFC), formed with Barron, Douglas and Washburn medical, social service, and volunteer organizations will work in partnership with the Medical College of Wisconsin to develop organizational system changes to prevent falls in older adults. This process will result in the development of a region wide fall prevention and intervention strategy to be implemented in subsequent years.

Additionally, investigators from the Injury Research Center conducted an assessment of Wisconsin's 2000 hospital inpatient data to identify the particular risk factors for falls among the elderly in this state. One reason for this study was to understand why Wisconsin's fall death rate increased over 90% from 1990 to 1998 (32.06 to 60.97 per 100,000). Results of this study demonstrated that alcohol-related problems, and motor and mechanical problems significantly increase the risk of a falls diagnosis (51).

4. Implementation of the Wisconsin Falls Initiative, a collaboration of state and local Wisconsin stakeholders in falls prevention (Mahoney, Hale, Ellingson, Kopp).

The State of Wisconsin has a substantial history of falls prevention work in partnership with Dr. Mahoney, the Medical College of Wisconsin, and other stakeholders. The timeline below describes the development and accomplishments of the Wisconsin Falls Initiative and other state activities in falls prevention.

1999 (Fall/Winter). Age Advantage, Wisconsin's largest Aging Services Area, contacted the State Injury Prevention Section (Linda Hale), Bureau of EMS and Injury Prevention, Division of Public Health, WI Department of Health and Family Services (DHFS) to discuss falls in the aging population in Wisconsin. Data sources were identified for analysis to determine the magnitude of the problem. This work led to the identification of falls as a priority for the Injury Prevention Section.

2000. The Injury Prevention identified and sought partners to discuss the problem of falls in Wisconsin's aging population. Partners within the DHFS included Department of Disabilities and Elder Services (DDES), Bureau of Long Term Care and Aging Resources; external partners included the UW School of Medicine (Dr. Jane Mahoney), Dane County Safe Communities, local Aging and Disability Resource Centers (ADRCs) including Kenosha County ADRC, County Aging Units, and local health departments. Discussions occurred regarding research about the problem, ongoing activities to address this issue both in Wisconsin and nationally, resources available, and gaps, including identification of further stakeholders. Initial work included development of a "Community-Medical Model" for falls prevention in Wisconsin, and establishment of regular meetings with identified partners. A half day falls prevention educational session was developed to accompany the DDES Annual Long Term Care Conference in Madison, WI.

2001. A Statewide Falls Prevention Initiative was formalized through hosting quarterly statewide conference calls with partners such as physical therapists, occupational therapists, health educators, nurses, physicians, nutritionists, local Health Departments, and Aging Network members (from Aging Units and ADRCs). Educational sessions related to falls and nutrition were provided to all Nutrition Site Coordinators. A

day long falls prevention session was held as part of the DDES Annual Long Term Care Conference for Wisconsin. A multifactorial falls assessment tool was developed by Dr. Jane Mahoney, in collaboration with the University of Wisconsin Falls Prevention Clinic. Prevention funding through DHFS DDES, Bureau of Long Term Care and Aging Resources (BLTCAR) was secured by UW School of Medicine (Dr. Jane Mahoney) in partnership with Kenosha County ADRC to research a multifactorial intervention to decrease falls.

2002. DHFS, Injury Prevention Section in partnership with UW School of Medicine wrote and received a three year grant from the Centers for Disease Control and Prevention, entitled “A Research Study to Assess Multifaceted Fall Prevention Intervention Strategies Among Older Adults”. Ongoing quarterly Falls Prevention Initiative conference calls continued, and new partners were identified and added to the calls.

2003. Quarterly conference calls continued.

2004. At the direction of the Wisconsin DHFS’ Secretary (Helene Nelson), an internal falls workgroup (Office of Strategic Finance within the Secretary’s Office, DDES, DPH represented) was formed. A workplan was developed.

2005. The Medical College of Wisconsin Injury Research Center received a Medical College of Wisconsin Healthier Wisconsin Partnership Program grant to fund 5 local coalitions, one in each of the five DHFS Health regions, in collaboration with the DHFS’ Injury Prevention Program. Four of the five coalitions identified falls as one of their priorities within their communities and coalition’s activities. The State of Wisconsin Injury Prevention Section and its Bureau on Aging and Disability Resources hosted a 1-1/2 day long Falls Prevention Summit featuring Lynn Beattie, National Council on Aging. Partners from community agencies, assisted living, acute care centers, long term care attended. The CDC falls research/cooperative agreement received approval to continue the work of the grant through Sept. of 2006. Also in 2005, Dr. Mahoney and the Kenosha County Division of Aging Services received a Wisconsin Partnership Program grant to disseminate “Stepping On” in 5 counties in Wisconsin.

2006. DHFS (DDES and DPH) wrote and received an Administration on Aging grant, “Empowering Older People to Take More Control of Their Health through Evidence-Based Prevention Programs”. This grant includes introduction of “Stepping On” in the northeastern part of Wisconsin.

Dr. Lindy Clemson visited Wisconsin from Australia, meeting with Dr. Mahoney, Sandy Cech and LaVerne Jaros from the Kenosha County Division of Aging Services, and Linda Hale and Tracy Ellingson from the State of Wisconsin Dept of Health and Family Services.

The State of Wisconsin DHFS put out a Request for Proposals in prevention programming for older adults, and required that a minimum of 60% of the funding allocation go to falls prevention programming. In fact, almost 80% of the 1.25 million dollar allocation was in support of comprehensive program offerings in falls prevention. Proposals were only funded if more than one county was included.

2007. LaVerne Jaros and Sandy Cech with the Kenosha County Aging and Disability Resource Center received funding from the State of Wisconsin DHFS DDES BLTCAR to begin adaptation of “Stepping On” materials for American audience and develop a Train the Trainers manual. Quarterly conference calls of the Wisconsin Falls Initiative continue.

In summary, our research team has substantial experience in falls prevention research and dissemination. We also have substantial experience working collaboratively as a multidisciplinary team. Importantly, our research team has previously collaborated to begin disseminating “Stepping On” in Wisconsin communities. The initial phase of implementation in 5 counties has led us to develop a set of key questions about where the program could be implemented, who could lead the program, and what, if anything, could substitute for the home visit.

In January 2007, S Cech, LJaros, and LClemson began the process of modifying program materials through limited funding from the State of Wisconsin DHFS BLTCAR. More work, beyond the scope of funding from Wisconsin DHFS, is needed to translate the program to fit U.S. needs. For example, changes are needed to the program manual, display, and video to make the package more user-friendly and “Americanized”. Our preliminary work forms the foundation upon which this proposal builds. Based on our previous experience with falls prevention and specifically with dissemination of “Stepping On”, we have confidence that we can accomplish the research plan and create an outstanding program package for dissemination nationwide.

5. RESEARCH DESIGN AND METHODS

5a. Conceptual Framework

The conceptual framework for this implementation study is the “integrated, interactive model of knowledge translation” of Chunharas (45). This model can be applied at the level of the individual, research team, and research proposal. At an individual level, “Stepping On” reflects the principles of this model. Adult learners use a problem-solving cycle to make decisions in a non-linear way integrating different sources of knowledge (personal knowledge, background information available to them). At the level of the research team, our previous activity in falls prevention, presented in the Preliminary Studies section, follows this model. This work in falls prevention involves stakeholders, policy-makers and researchers, and helps inform decisions within the problem-solving cycle of organizations by providing accessible, contextually-based research information that is process-sensitive.

In the context of this research study, Chunharas’ model proposes that learning organizations (i.e. program sites) use a problem-solving cycle to make decisions to implement knowledge (i.e. “Stepping On”) through a non-linear process integrating different sources of knowledge (information systems, personal knowledge, research evidence). This research study will facilitate dissemination of “Stepping On” by providing knowledge for organizations in the following dimensions of Chunharas’ model: 1) contextual factors (e.g. likelihood of success at different sites or with different target groups); 2) nature of knowledge or evidence that is available (e.g. developing a program package that can be disseminated in this country, helping define key elements, helping define feasible, high-fidelity, acceptable variations of model); and 3) process by which knowledge is translated or communicated (e.g. helping define technical assistance needs for training and coaching).

5b. Research Design Overview:

The purpose of this proposal is to:

1. Translate “Stepping On” into a U.S. community program
2. Test implementation of “Stepping On” in a community setting
3. Conduct dissemination evaluation research focusing on uptake, reach, feasibility, fidelity, adherence, and outcomes, and
4. Prepare a final package for dissemination.

This proposal is in alignment with NCIPC goals to increase capacity of injury prevention and control programs to address prevention of injury. The outcomes of this proposal are aligned with the NCIPC Research Agenda priority areas to disseminate effective interventions to reduce older adults falls and fall-related injuries. This research will help define strategies for widespread dissemination and implementation, and help determine best formats and channels for delivering interventions to ensure that older adults adopt them.

In Phase 1, we will develop a draft program package of “Stepping On” for dissemination to a U.S. audience. We will first use content experts to advise on key elements of the program and on the draft of the program package. Then, we will use focus groups of participants and focus groups of leaders/site coordinators to explore barriers and facilitators to guide dissemination and implementation in the U.S. context.

In Phase 2, we will pilot the program in one Wisconsin site (Lincoln Lutheran Senior Housing, an independent-living retirement community). We will gather qualitative and quantitative measures regarding the program and modify the program package based on findings.

In Phase 3, we will implement the program a total of 7 more times in a total of 3 sites. The program implementation design allows us to answer specific questions about spread and use of the program:

1. Do measures of implementation vary across 3 dissemination sites: independent-living retirement community, senior center, parish nurse program?
2. Do measures of implementation vary depending on professional background of the class leader?
3. Do measures of implementation vary depending on whether the site is urban or rural?
4. Do measures of implementation differ if a phone call by the class leader is substituted for the home visit following 7 weeks of classes?

Each program implementation will occur either in a different site, or have a different class leader, or use a different format. With each program implementation, we will evaluate reach, uptake (adoption), feasibility, implementation fidelity and acceptability, and participants’ adherence and outcomes. Data collection will utilize quantitative, semi-quantitative, and qualitative methods.

In Phase 4, we will produce a final package that can be broadly disseminated and used nationwide.

5c. Procedures

Specific Aim #1: Translate “Stepping On” into a U.S. Community program utilizing advice of content experts and of focus groups to inform development of the program package and program evaluation (Phase 1)

Content experts. Content experts will determine key elements using the Delphi consensus technique (55,56). The Delphi consensus technique combines anonymous gathering of responses, feedback to respondents and the opportunity to alter responses based on their feedback. Evaluator bias is reduced as each individual is responsible for reviewing their own ideas and not obliged to concur with other members. This is an iterative process that continues until the differences between responses are sufficiently narrow to suggest consensus. It is a cost effective method of collecting and analyzing data in stages and, most importantly, a way of including experts beyond those in the local area. A recent example demonstrates successful use of the Delphi technique via internet to obtain consensus among international experts (57).

The first step will be identifying and recruiting key experts in falls prevention and adult learning/group process. National and international content experts in evidence-based falls prevention, adult learning, and behavioral change theory will be contacted and invited to participate. Experts who form part of this grant will also participate. These include: L Clemson (OT, PhD, adult learning expert), S Cech (RN, chronic disease self-management expert), J Mahoney (MD), J Janczewski (DPT).

Each expert will be sent information regarding the project and asked to comment on issues related to the four key content areas (balance and strength exercise; home and community safety; medication management; vision correction and adaptation). In addition, we will ask experts to comment on key elements in adult learning and group process. They will address issues related to background and prior experience of class leaders, and training, technical assistance and coaching that is required to produce and sustain successful class leaders. They will also address elements required for success with the invited class expert. They will formulate key elements for successful execution of the exercise program, both in class and at home. Lastly they will formulate key elements for the home visit/phone call and booster class.

Responses will be collated, summarized and returned to the individual by e-mail for further analysis, clarification and expansion. Data analysis will be in stages, with each round of data being summarized and grouped into common themes assisted by NVivo software. The list will be discussed, analyzed and refined in stages until consensus is achieved on key elements in knowledge and process. An outcome of this phase will be a list of key elements. Dr. Mahoney and Dr. Clemson will co-lead the Delphi process. Dr. Clemson has previous experience with this technique (58)

In our preliminary work with implementation of “Stepping On” in Wisconsin, we added a lay co-leader, based on our experience with CDSMP (54). Addition of a lay co-leader has face validity, and following our model, Clemson recently added lay co-leaders in her “Stepping On” program that she is evaluating for dissemination in different cultural communities in Australia. The expert group will be asked to comment on this modification.

Focus groups. This study will employ a total of 6 focus groups (See Table 3, next page). Four of these groups will convene prior to the development of program materials and evaluation tools and two will convene after the development of these pieces. Wisconsin's previous experience implementing “Stepping On” allows investigators the unique opportunity to conduct separate focus groups with former participants and leaders to understand their experiences with the program, including the barriers to participating and leading the program and their insights into what program elements might need to be modified to translate the program for US audiences. Additional focus groups will be held with potential participants and program leaders from the community organizations that are participating in the proposed study, but who have not previously participated in “Stepping On”. These focus groups will center on understanding their perceived barriers to the program, the incentives for participating in the program, and what materials they anticipate will be helpful in implementing the program. Two additional focus groups will be held with these individuals upon completion of the program materials and evaluation tools. The purpose of these focus groups is to get their feedback on these materials prior to their use in the study and make any necessary modifications.

A member of the research team will facilitate all six focus groups, transcribe them, and perform thematic and content analyses to identify common themes and topics related to participating in the “Stepping On”

program, including perceived feasibility of the program and use of program materials. The results of these focus groups will be used to inform the development process of the program and related materials.

Table 3. Plan for Focus Groups

Focus Group participants	Number of times meeting, when	Purpose
Former participants in “Stepping On” in Wisconsin	1 – before development of program package and evaluation tools	Ascertain barriers, what worked and didn’t work; what is it important to evaluate?
Former leaders/lay leaders/organization stakeholders	1 – before development of program package and evaluation tools	Ascertain barriers to hosting and leading class, what worked and didn’t work; what is it important to evaluate?
Potential new participants in “Stepping On”	2 – before and after development of program package and evaluation tools	<u>1st meeting</u> : Ascertain barriers and incentives to participating in class <u>2nd meeting</u> : Evaluate program package and monitoring tools
Potential new class leaders/lay leaders/organization stakeholders (Lincoln Lutheran, Senior Center, Parish Nurse)	2 – before and after development of program package and evaluation tools	<u>1st meeting</u> : Ascertain barriers and incentives to hosting and leading class <u>2nd meeting</u> : Evaluate program package and monitoring tools

Specific Aim #2: Test implementation of “Stepping On” in a community setting and revise the program package based on the pilot implementation (Phase 2)

Setting. We will test implementation of “Stepping On” at the Lincoln Lutheran of Racine, Inc. Independent Living Apartments. Lincoln Lutheran of Racine, Inc. is a long-established, faith-based non-profit organization that has, among many other senior services, five independent living apartment buildings in the city of Racine. Racine is an economically and ethnically-diverse community located in far southeast Wisconsin along Lake Michigan. With a population of 81,855 people, the racial makeup of the city is 68.91% White, 20.32% African American, 0.40% Native American, 0.61% Asian, 0.05% Pacific Islander, 7.14% from other races, and 2.57% from two or more races. Hispanic or Latino of any race is 13.95% of the population. The median household income is \$37,164 (59). Among the group age 65 and over, over 6% have income below the poverty level (60).

Procedure. S. Cech will work with the administrators of the Independent Living Apartments to help identify a class leader and lay co-leader. The class leader and co-leader will attend a 3-day training held by S. Cech. The training will be based on that which we have used previously in Wisconsin to disseminate “Stepping On”, but will be modified based on information we receive from content experts and focus groups in Phase 1. Training will cover program content along with essential background information on underlying concepts. Training will focus on understanding the program process, running the classes, recruiting invited experts, and performing home visits. Marketing and recruitment will also be addressed.

The class leader will advertise “Stepping On”, identify a class site, identify and contact outside experts to visit the class, and conduct the program. S. Cech will be available throughout the program to assist the class leader with problem-solving related to program implementation. The interaction of the research study with the pilot program implementation is shown in the table on the following page.

Table 4. Implementation and evaluation of 1st “Stepping On” Program

1) S Cech will train class leader and lay co-leader in 3-day training program; class leader and co-leader will show return-demonstration of key components
2) Research staff will perform baseline interview of Lincoln Lutheran project coordinator/class leader (1/2 to 1 hour)
3) Class leader will determine and carry out marketing strategies, identify outside experts to come to specified classes, and recruit 8 older adults for the class
4) Research staff will obtain consent for questionnaires and administer baseline questionnaires to participants
5) Class leader and lay co-leader will hold 7 classes. Class leader and lay co-leader will maintain attendance logs, collect home exercise logs from participants, and keep field notes. Class leader and co-leader will provide S. Cech with feedback on areas where program can be improved.
6) S. Cech and PT consultant will attend classes to evaluate fidelity and identify areas for program package modification or tailoring.
7) Research staff will administer follow-up questionnaire for participant outcomes (FaB and Mobility-Efficacy Scales) after the 7 th class.
8) Research staff will conduct follow-up qualitative interview (1/2 to 1 hour) with participants after the 7 th class to assess barriers, successes and challenges.
9) Class leader will conduct home visits and take field notes.
10) S. Cech and PT consultant will attend home visit to evaluate fidelity and identify areas for program package modification or tailoring
11) Research staff will conduct follow-up interview with class leader and site manager after the home visits to assess barriers, successes and challenges.
12) Class leader will conduct 1 booster classes, 2 months after the last day of class.

The research team will develop tools for evaluation during Phase 1, utilizing input from content experts, focus groups, and collaborators at the Centers for Disease Control and Prevention. Specific components of evaluation, and instruments to be used, are shown in Tables 6 and 7. Based on findings from the pilot evaluation, we will modify program package materials to improve delivery and facilitate implementation.

Specific Aim #3: To evaluate uptake, reach, feasibility, fidelity, adherence and outcomes related to implementation of “Stepping On” in the following situations: (Phase 3)

- 1) Implementation by an OT, PT, RN versus a non-health degree professional who works with seniors;
- 2) Implementation by a retirement community versus a community center versus a parish nurse;
- 3) implementation at a rural versus an urban site
- 4) implementation utilizing a phone call after the last class rather than a home visit

Research questions and Rationale. The research questions we have proposed address both the spread and use of “Stepping On” in this country. These research questions are discussed below.

1) How do measures of implementation vary depending on professional background of the class leader?

This question likely has significance for both the fidelity of the program and the participant outcomes that can be achieved relative to the original “Stepping On”. The class leader in the original “Stepping On” had a health degree background (occupational therapist). In addition, the “Stepping On” manual states “This manual is for occupational therapists, physiotherapists, and other health professionals and health promotion workers in the area of falls-prevention with older people.” (61). Fidelity to key elements may be compromised and participant outcomes may diminish if a leader without a health-degree background is used.

On the other hand, feasibility of implementation and acceptability of the program to community organizations is likely improved when a non-health degree professional is permitted as class leader. Our preliminary experience with implementation of “Stepping On” in Wisconsin suggests this is a key question for organizations. A number of community organizations we approached stated they could provide non-health degree professionals to lead classes but could not easily engage health degree professionals for this purpose. In our first training of 9 leaders, only 2 have health degree backgrounds (both are RNs). It is unknown how use of non-health degree professionals affects measures of fidelity and participant outcomes.

2) How do measures of implementation vary across different dissemination sites? We selected independent-living senior housing, community center, and parish nurse sites because each of these venues has the potential to: (a) reach large numbers of older adults at risk for falls; (b) serve a different population, and (c) feasibly implement “Stepping On”.

3) How do measures of implementation vary depending on whether a site is urban or rural? This question has significance for feasibility and acceptability of the program. Twenty-one percent of the United States population is rural, based on the 2000 Census (62). In Wisconsin, 36% of the population aged 65 and over is rural (63). Rural sites may face substantial transportation challenges with implementation. Rural programs may cost more due to transportation needs; therefore, additional assurance of the program’s impact in rural areas will facilitate dissemination. Acceptability to older adults and quality of participant outcomes at a rural class site will be our primary areas of interest.

4) Do measures of implementation differ if a phone call from the class leader is utilized instead of the home visit? This question has implications for feasibility and acceptability to organizations. The original study utilized a home visit by the occupational therapist shortly after the last class. Feasibility and acceptability to the organization may improve when a phone call is substituted for the home visit, but fidelity and participant outcomes may suffer.

Plan to Address Research Questions. Seven “Stepping On” programs will be held in addition to the pilot program discussed in Specific Aim #2. Each program will be open to adults age 65 and over with a history of a fall in the past 12 months. Class enrollment criteria are chosen based on findings by Dr. Clemson and on the American Geriatric Society guidelines for the prevention of falls (1,26). Class size will be 8 participants. The procedure for implementation for each program will be the same as in the pilot phase (see Table 4).

Three programs will be held at Lincoln Lutheran of Racine Senior Housing, two at an urban Senior Center, and two at a rural parish nurse site. At Lincoln Lutheran, one program will be led by a health degree professional, and two by a non-health degree professional. At the senior center and parish nurse sites, the first program at each site will utilize a home visit and the second, a phone call. Table 5 shows program sites, background of the class leader, program format and research question being addressed.

Table 5. Plan for Program Implementation to Address Research Questions

Program site	Urban versus rural	Class leader background	Format (home visit vs phone call)	Research Question (Programs)
1. Lincoln Lutheran Senior Housing		Health degree	Home visit	Comparison of sites (1, 4, 6) Comparison of leader (1, 2, 3)
2. Lincoln Lutheran Senior Housing		Non-health degree	“	Comparison of leader (1, 2, 3)
3. Lincoln Lutheran Senior Housing		Non-health degree	“	Comparison of leader (1, 2, 3)
4. Community Center (Schuetze Recreation Center, Waukesha)	Urban	Health degree	Home visit	Comparison of sites (1, 4, 6) Comparison of urban versus rural (4,6) Comparison of format (4, 5)
5. Community Center (Schuetze Recreation center, Waukesha)	Urban	“	Phone Call	Comparison of urban versus rural (5, 7) Comparison of format (4, 5)
6. Parish Nurse (Burlington)	Rural	Health degree	Home visit	Comparison of sites (1, 4, 6) Comparison of urban versus rural (4, 6) Comparison of format (6, 7)
7. Parish Nurse (Burlington)	Rural	“	Phone Call	Comparison of urban versus rural (5, 7) Comparison of format (6, 7)

Class Settings. The sites, and cities/towns where sites are located, are described below.

Lincoln Lutheran Senior Housing, Racine, WI. The site and city of Racine are described in Specific Aim #2. A letter of support is provided in Section 16 of the proposal.

Schuetze Recreation Center, Waukesha, WI. The City of Waukesha Parks, Recreation & Forestry Department has provided recreational programs and services for older adults of the Waukesha community at the Schuetze Recreation Center for over 40 years. The Center offers a comprehensive program for older adults focusing on people’s physical, social and cognitive needs; the most popular activities include water and

land exercise classes, bridge/card groups, day trips and other enrichment/educational classes. Many of the services are held in collaboration with the Waukesha County Department of Senior Services and other Waukesha non-profit agencies, to provide a comprehensive program of service delivery. Seventy-five percent of the center's participants are older adults. The city of Waukesha, which is located near Milwaukee, WI, has a total population of 64,825. The racial make-up of the city is 91% white, 1% African-American, 0.3% Native American, 2% Asian, 3% from other races, and 2% from two or more races. Hispanic or Latino of any race make up 9% of the population. The median income for a household in the city is \$50,084 (59). Six percent of the population age 65 and over have income below the poverty level (60). A letter of support from the Schuetze Recreation Center is provided in Section 16.

Parish Nurse Site, Burlington, WI. Parish nursing is a specialty nursing practice that merges health ministry with community-based nursing. Specific parish nurse roles include personal health counselor, health educator, facilitator of support groups, and health care advocate working within a faith community. The parish nurse will lead the "Stepping On" class in St. Charles Church in Burlington, WI. St. Charles Church has 2616 members (850 families). Fourteen percent of parishioners are over age 65, and the Church serves a significant Hispanic population (personal communication, Sue Schaus, Parish Nurse Program). The city of Burlington, WI, located in the western part of Kenosha County, has a total population of 9,936. The racial make-up is 96% white, and Hispanic or Latino of any race make up 5% of the population. The median income for a household in the city is \$43,365 (59). Four percent of the population age 65 and over live below the poverty level (60). The primary sources of livelihood are farming or employment at a Nestle chocolate factory. A letter of support from Sue Schaus, Manager, Parish Nurse Program, Aurora Health Care, who will oversee the program, is provided in Section 16.

Research Evaluation. The research evaluation will employ quantitative, semi-quantitative, and qualitative research methods. During this phase of the research, we will continually evaluate findings from programs, using that information to inform successive program implementations. For example, process data may identify needs for more training or coaching (technological assistance). In this case, later programs will intensify elements of training and technological assistance. The table below shows how we will address each of the components of evaluation (participant outcomes, fidelity, reach, uptake, feasibility and acceptability).

Table 6. Components of implementation evaluation

What	Method	Frequency	Measures	Research Questions
Participant Outcomes	Survey	Baseline, 7 weeks, 12 months	Mobility Efficacy Scale (2), FaB (3), Adapted from Clemson et al. See Appendix 7	<ol style="list-style-type: none"> 1. How do participant outcomes compare with original study ? 2. Do participant outcomes at 7 weeks correlate with outcomes at 12 months ? 3. Will participant outcomes be similar across all classes ? 4. Will class and booster session attendance and completion of home exercise logs correlate with outcomes at 12 months ?
Fidelity	Observer checklist	During classes	Based on essential elements of program determined by Dr. Clemson and expert group	<ol style="list-style-type: none"> 1. Will fidelity with essential elements be maintained across all classes? 2. Will fidelity be similar comparing home visit and phone call?
Reach (Individual)	Pre-participation demographic assessment of people who sign-up	Before each class cohort	Age, gender, education, living situation, transportation, fall history, mobility, how found out about program, previous fall prevention classes	<ol style="list-style-type: none"> 1. Will reach differ across sites?
What	Methods	Frequency	Measures	Research Questions

Uptake (Individual and organization)	Class logs Home exercise logs Questionnaire to evaluate follow-through on goals (1) (Adapted from Clemson) - 12 months		Who attended the classes and booster? Who completed home exercise logs? Who did home exercise and how often? Who followed-through on goals by 12 months?	1. Will uptake differ across sites, correlating with transportation availability and living proximity to class site? 2. Will completion of home exercise logs correlate with class attendance, and with outcomes? 3. Will adherence with recommendations correlate with class attendance and outcomes?
	Post-class Participant Interview	After each class cohort	How many classes did they attend? Why did they not attend a particular class? Why did they or did they not perform home exercise? What worked and why? What did not work and why? What were barriers to participation?	What factors affect participant uptake?
	Class Leader Interview and Field notes	After each class cohort	How likely would you be to implement program in the future? What adjustments need to be made for your organization to implement this program? What worked and why? What did not work and why?	1. What factors affect class leader uptake? 2. Will factors differ across sites? 3. Will factors differ based on professional background of class leader?
Feasibility (organization)	Class Leader Interview and Field notes	After each class cohort	Does your organization have the time, money, staff to implement program as it currently is? What modifications would need to be made? What aspects of the program are feasible to implement?	1. What factors affect organizational feasibility? 2. Will factors differ across organizations?
Acceptability (Individual and organization)	Post-class Participant Interview	After each class cohort	Did you like/dislike the program? What did you like/dislike about it? What worked and why? What did not work and why?	1. What factors affect acceptability of the program? 2. Will acceptability improve across programs (over time, comparing earlier versus later programs) as factors are addressed?
	Class Leader Interview and Field notes	After each class cohort	Did you like/dislike the program? What did you like/dislike about it? What worked and why? What did not work and why?	1. What factors affect class leader acceptability of the program? 2. Will factors differ based on professional background of class leader?

Acceptability (Individual and organization, cont)	Invited Class Experts Interview	After each class cohort	Did you like/dislike the program? What did you like/dislike about it? What worked and why? What did not work and why?	1. What factors affect class expert acceptability of the program? 2. Will acceptability improve over time, comparing earlier versus later programs, as factors are addressed?
Adaptability Adaptation of the class leader and setting	Analytically compare differences between different groups (Lincoln Lutheran Senior Housing, Senior Center Site, Parish Nurse Site), and between different class leader backgrounds (health degree professional versus non-health degree professional)		Will assess with all measures from above, but fidelity and participant outcomes in particular	1. Will fidelity and participant outcomes remain high with adaptation at all sites? 2. What tailoring is done at each site? 2. Will fidelity and participant outcomes decrease with adaptation to using non-health degree professional class leader versus health-degree professional class leader? 3. Will fidelity and participant outcomes decrease with adaptation to utilize phone call instead of in-home visit at the end of the 7 weeks of classes?

Evaluation Instruments. Tools for evaluation will be developed during Phase 1, utilizing input from the Research Team, content experts, and focus groups. Tools will be refined during Phase 2, utilizing findings from the pilot implementation. Evaluation tools will be utilized in Phase 3, where we answer research questions related to dissemination and implementation. Participant Outcome Measures will utilize measures from the original “Stepping On” Study that showed significance across groups at 14 months (FaB, change in Mobility Efficacy Scale). In addition, to compare participant adherence with that of the original study, we will utilize the “Follow-through on Goals Questionnaire” from the original study.

The table below shows specific evaluation instruments, when they will be administered, to whom, and the type of data that will be collected from the instrument (quantitative, semi-quantitative, qualitative).

Table7. Evaluation Instruments

Instrument	Frequency	Number of surveys	Type of data collected
Outcome questionnaire (adapted from Clemson et al, see Appendix 7) o FaB (3) o Mobility Efficacy Scale (2) o Follow-through on Goals Questionnaire (12 months only) (1)	Baseline, seven weeks, 12 months	--8 sites (4 @ Lutheran, 2 Senior Site, 2 Parish Nurse) --8 students per site (64 people) --3 data collection times (192 surveys)	Quantitative
Pre-participation assessment	Baseline	8 sites with 8 students (64 people)	Quantitative (demographics, function, mobility, depressive symptoms, locus of control)
Post participation interview	Seven weeks (right after classes)	8 sites with 8 students (64 people)	Semi-Quantitative and Qualitative
Post-program class leader interview and field notes	Seven weeks (right after class)	8 sites with 1-2 leaders (8-16 people)	Semi-Quantitative and Qualitative
Post-program invited class expert interview	Seven weeks (right after classes)	8 sites with 2-3 invited experts per site (16-24 people)	Semi-quantitative and Qualitative
Fidelity Observer Assessment	Throughout program	7 classes per site = 56 observations 448 observations total (56*8 sites)	Quantitative and Qualitative

Established Data Collection Measures. Participant outcome measures will utilize established questionnaires, which were selected based on demonstration of significant change or usefulness with

measuring adherence with the original “Stepping On” intervention (1). These questionnaires are described below.

Falls Behavioral Scale (FaB). The FaB was developed by Dr. Clemson to evaluate behavioral factors that affect falls risk (3). Scores range from 1 (most risky) to 4 (most protective). Internal consistency of the FaB scale was 0.84 (Cronbach alpha). Construct validity was shown in a group of 418 older volunteers with mean age of 76.8 years. Thirty-four percent reported one or more falls in the past year. Scale scores were positively associated with increasing age ($r_s = 0.46, p < .01$) and negatively associated with greater physical mobility ($r_s = -.68, p < .01$), and leaving home more often in the past week ($r_s = -.51, p < .01$). Test retest reliability at a two-week interval showed ICCs ranging from 0.78 to 0.96 for factor subscales. The intervention trial of “Stepping On” showed a significant mean difference in FaB score between groups at 14 month follow-up (3.19 in intervention group vs 3.07 in control group) (1).

Mobility Efficacy Scale (MES). The MES scale asks about confidence with a wide variety of functional tasks using a 10 point scale of “not at all” to “completely confident” for each item (3). It has a Cronbach alpha of 0.82, and a correlation of 0.77 with the adapted Falls Efficacy Scale (3). This scale has recently been classified as a fear of falling scale (64). In the original study of “Stepping On”, mean change was 0.89 in the intervention group versus -3.38 in the control (mean difference between groups = $4.28, p < .05$) (1).

Follow-through on Goals Questionnaire. This questionnaire was used in Dr. Clemson’s “Stepping On” intervention study (1). The list of actions/recommendations was generated by the occupational therapist as part of the home visit. At 14 months, participants were asked about their follow-through with the home visit recommendations. It provided useful information on follow-through with exercise, change in behaviors associated with community mobility, and modification of home hazards.

Specific Aim #4: To produce a final package of “Stepping On” for broad dissemination and use nationwide (Phase 4)

During this phase, we will utilize findings from previous phases to build a final program package. A graphic artist consultant will assist with formulation of materials for class leaders, visiting experts, and participants to enhance usability. The final program package will be reviewed and approved by the Research Team, content experts, stakeholders at program sites (coordinators, class leaders, visiting experts), and CDC collaborators.

Deliverables will include:

- “Stepping On” Manual and Supporting Materials modified for U.S. community
- Guidelines for implementation of program, including roles of organization, class leader, lay-leader, expert visitors
- Guidelines for tailoring program to suit local needs (i.e. modification of key characteristics)
- Boundaries for program change by local organizations (i.e. description of core elements)
- Training program for class leaders and co-leaders, including training manual
- Description of core elements for training
- Recommendations for establishment of a registry to maintain standardization across training programs
- Recommendations for sustainability including development of master trainer program
- Recommendations for mechanism to modify package as new evidence develops regarding effective fall prevention interventions
- Recommendations for state and county agencies to support dissemination and quality monitoring

Potential problem areas and alternative tactics to achieve aims. Program sites may choose to implement other prevention programs, or to implement “Stepping On” sooner through another source. We will utilize existing networks to find other program sites (senior housing, parish nurse, senior center). There are over 50 senior centers, and over 2 large independent living apartment and over 20 large independent living apartment communities in Southeast Wisconsin that could be approached.

Attrition from classes is a potential problem. If class size becomes too small, the group process is less effective. We will use a number of measures to minimize attrition. We will call participants prior to the first class to make sure the person still plans to attend. If there are any drop-outs prior to or at the first class, we will invite an older adult from a waiting list. If a person misses a class after the first class, the class leader will call to find out if there is a problem and encourage attendance.

We anticipate that our program classes at the Catholic Church in Burlington (led by the Parish Nurse) will enroll a number of participants who are Hispanic, as the Church serves a significant Hispanic population. With the exception of Hispanic or Latino ethnic groups, our ability to enroll minorities may be limited due to the population demographics of the areas where programs will be implemented. Program sites were selected based on the presence of existing relationships with Kenosha County Division of Aging. Capitalizing on these relationships enhances our organizational capacity and maximizes the likelihood of success. To ensure minority representation in the translation process, we will require that both class leader and participant focus groups contain African-American, Asian, and Hispanic members. In addition, during Specific Aim #4, we will ensure that the final program package is reviewed and approved by minority stakeholders (including potential coordinators, class leaders, and participants).

Statistical power will be limited to detect differences in outcomes from the original “Stepping On”. However, analytic techniques will be used to assess for homogeneity of outcomes across outcomes, allowing us to combine classes where appropriate to maximize statistical power.

5d. Data Collection and Analysis

Focus Groups. As discussed previously in Section 5c (Research Design and Methods, Procedures), six focus groups will be employed in the early phases of the project. The purpose of the first round of focus groups is to identify barriers and challenges related to both participating in and implementing “Stepping On” among people who have already participated in the program in Wisconsin. Separate focus groups will be held with prior participants and course and lay leaders for the “Stepping On” program. The purpose of the second round of focus groups is to assess the perceived or potential barriers related to participation in and implementation of “Stepping On” among the particular groups participating in this study. Both participants and course and lay leaders will be invited to participate in a focus group prior to the development of program materials and evaluation tools to gain their insights into the best design and methods needed to develop these products. These individuals will then be asked to participate in another focus group once materials and tools have been developed to obtain their feedback and to determine whether any additional modifications are needed.

All focus groups will be facilitated by the Evaluation Director and notes will be taken by the Evaluation Coordinator. Focus groups will be audiotaped and a member of the research team will make verbatim transcripts of the sessions. The Evaluation Director and Coordinator will verify the accuracy of written transcripts by reading the transcript and reviewing their session notes and the audiotapes.

The Principal Investigator, along with both the Evaluation Director and Coordinator will independently review the transcripts of both focus group sessions. The Evaluation Director will oversee a transcript-based analysis to examine the data. To validate the thematic coding, both the Evaluation Director and Coordinator will independently identify relevant themes in the transcript text of each focus group session. *NVivo*, a qualitative data analysis software program, will be used to assist with this analysis. They will also each manually highlight and margin code themes on the focus group transcripts. The Evaluation Director and Coordinator will then compare the computer-generated and manually derived themes with one another, as well as across the different focus groups using the constant comparative method from grounded theory. Major themes common to both focus groups will be identified and recorded (65,66), and divergent themes will also be noted. This information will then be provided to the research team to discuss the themes and their interpretation of the findings. A final summary report on the focus group results will be prepared for the research team.

Informant Interviews. Informant interviews will be conducted with all participants, site or organization directors, and course and lay leaders in the proposed study to assess the reach, uptake, feasibility, adaptability and acceptability. Interview guides will be created to assess these elements at both an individual participant level as well as at an organizational level.

All participants in the different “Stepping On” classes will be interviewed by the research team upon completion of the seven-week program. Program participants will be asked general questions about how many classes they participated in, whether they had any problems or barriers to participating in the classes, and why they did or did not perform the home exercises. Participants will also be asked what aspects of the overall program and specific classes they liked and disliked. They will also be asked how the program compared to any other fall prevention programs they may have participated in.

All course and lay leaders who organize and implement the “Stepping On” program will also be interviewed by the research team upon completion of the program. Similar to the course participants, the class and lay

leaders will be asked about what aspects of the overall program and the specific classes they liked and disliked. Additionally, the leaders will be asked about how likely their organization would be to implement the program in the future, and what adjustments might be necessary to make for future programs, including the need for available time, money, and staff. The class and lay leaders will be asked to discuss the elements of the program that are currently feasible to implement and what elements might need to be adjusted.

The Evaluation Coordinator will take notes during the interviews to capture individual responses to questions. The interviews will also be audiotaped to verify the accuracy of the Evaluation Coordinator's notes. The Evaluation Coordinator will analyze the open-ended questions using a similar process to the focus group analyses. She will identify common themes and compare these themes across the different interviews. The Evaluation Coordinator will also conduct a descriptive analysis of the close-ended items on the survey instrument. Close-ended items on the interview guide will be analyzed using STATA software. Both the qualitative and quantitative interview results will be shared with the research team and prepared for a summary report.

Field Notes. The class and lay leaders will be asked to write down their experiences and account of each individual class soon after each class is completed. These field notes will record their perceptions of how they thought the class went, what aspects of the class could have been modified to make the class more effective, what they liked or disliked about a particular class session, etc. The same will occur after the home visit or phone call. Copies of the field notes will be provided to the evaluation team to provide additional insights into the data analysis. Field notes will be formally analyzed similar to the other qualitative data using thematic analysis.

Fidelity Assessment. The research team will create an instrument for each class to assess the degree to which the class and lay leaders are adhering to the key elements identified by the Expert Group. A content expert (S Cech, J Mahoney, J Jancewzski, A Schwalbe) will observe all classes and record her observations using this assessment tool. This information will be entered into a database and differences in fidelity between the different "Stepping On" cohorts will be assessed.

Outcome Assessment. FaB and Mobility Efficacy Scale measures will be obtained at baseline, the end of the seven weeks of classes, and at 12 months. Follow-through on Goals Questionnaire will be obtained at 12 months. The study coordinator will give the questionnaires to class participants prior to the first class and again at the end of the 7th class. At 12 months, the study coordinator will mail questionnaires to individuals. If questionnaires are not received back within 2 weeks, then the study coordinator will call the participant and obtain the information by phone.

Changes in participant outcomes, e.g. FaB and Mobility Efficacy Scale, from baseline to 14 months will be analyzed using analysis of variance (ANOVA) models. An overall F-test will be used to assess heterogeneity of outcomes across classes. Means and 95% confidence intervals will be calculated both for each class and, if appropriate, for all subjects, and then compared with similar summaries for "Stepping On" in Australia. Additionally, we will determine correlations between outcome measures at the end of the 7th class and outcome measures at 12 months. We will also correlate attendance records and exercise logs with 12 month outcomes. The purpose of the correlation analyses is to determine whether attendance records, exercise logs, and outcomes at the end of the 7th class can serve as useful proxies for 12 month outcomes.

5e. Data Management

Quantitative data will be entered into an Access database by a student hourly, under the supervision of Dr. Mahoney and the study coordinator. 10% data re-entry will be done for quality monitoring. Data will be backed-up daily on the Department of Medicine Network, which has secure access.

5f. Organization Plan

The research will be carried out by the PI, with the assistance of the Research Team, using a shared decision making model with program sites, and collaborating with the Centers for Disease Control and Prevention.

Research Team. This is the overarching organizational structure of the research program. It is comprised of:

- Mahoney: PI, falls research investigator, content expert
- Clemson: Co-I, falls research investigator, content expert
- Layde: Co-I, Injury Prevention dissemination research investigator
- Christiansen: Injury Prevention dissemination research investigator
- Cech: content expert, program implementation expert
- Jaros: program implementation expert
- Ellingson: state policymaker, older adult prevention programming
- Kopp: state injury prevention coordinator
- Hale: state policymaker, injury prevention programming

This research team contains all the elements of the “triangle that moves the mountain” (46) (research experts, policymakers, local programming experts). The team has been very effective in falls prevention research and dissemination activities in Wisconsin in the last 5 years. The team also has a track record with dissemination and evaluation of the Chronic Disease Self Management program for older adults, a group model with similarities to “Stepping On”. This team will help set the timetable for activities, evaluate activities to meet Specific Aims, monitor “Stepping On” program implementation, evaluate research findings, and advise regarding package modification.

The research team investigators have appropriate training and background for this proposal. The PI and other researchers have ample experience individually and as a team for the work proposed. The research team brings complementary and integrated expertise to the proposal and lastly, the research team includes investigators who are well versed in dissemination research.

Shared decision-making with program sites. As part of the integrated interactive model of knowledge translation, program sites will be integrated into and inform the study process at all levels. Focus groups will provide input from sites during Year 1/2 (see Table 3). During program implementation, sites will be responsible for determining how they want to advertise, recruit participants, and host classes. Class leaders will identify and invite in outside experts. The training program will provide materials and suggestions for recruitment and implementation, and S. Cech will be available throughout the program to provide guidance and assist with problem-solving as needs arise. Sites will provide feedback to the Study Coordinator and S. Cech throughout the implementation cycle. Following each implementation cycle, researchers will meet with site leaders, organization coordinators, and participants to obtain information on barriers and incentives, determine what worked, why, and when, and obtain suggestions for improvement. In Year 4, program sites (leaders, organization coordinators, and class participants) will be asked to provide feedback on final package materials.

Collaboration with the Centers for Disease Control and Prevention. If this proposal is funded, the PI and the Research Team will collaborate with the CDC on all phases of the research project. The monthly to bi-monthly phone calls by the research team will provide the primary structure for integration with CDC collaborators. The PI and another member of the research team will meet yearly with CDC investigators in Atlanta.

5g. Management of Program Activities

Development and Implementation of “Stepping On” in a U.S. Community. These activities will be under the supervision of the PI, with assistance from the Research Team. In the first year, Dr. Mahoney and Dr. Clemson will lead the content expert process to define key elements. The Grant Coordinator, with assistance from S. Cech, will convene focus groups. S. Cech will attend focus groups and develop the program package, with assistance from Dr. Mahoney and the Research Team. S. Cech with assistance from L Jaros will coordinate implementation of programs at sites. S Cech will train class leaders. She will meet with Dr. Mahoney by phone weekly to bi-weekly as needed.

Evaluation. The evaluation component will be under the supervision of the PI, with assistance from Dr. Layde and A. Christiansen. Dr. Mahoney and A. Christiansen will develop evaluation tools using focus group and content expert input as well as the Research Team. A Christiansen and Dr. Mahoney will train research staff in data collection tools and methods and oversee collection of data. The content experts on the research team will assist with training of expert observers who will evaluate fidelity of observation. Research personnel for data collection include:

- Evaluation Coordination (N Angresano) – collection and analysis of qualitative and semi-quantitative data (focus groups, interviews, analysis of field notes)
- Student hourly - The student hourly will transcribe qualitative information as needed, and perform data entry for quantitative information.
- Physical therapist (A. Schwalbe) – Collection of data as expert observer
- S Cech, Co-Investigator – Collection of data as expert observer

Dr. Mahoney and A Christiansen will meet with research staff on a weekly basis as research tools are developed and tested, and on a weekly to biweekly basis as needed during data collection. Quantitative analysis will be performed by Ron Gangnon in collaboration with Dr. Mahoney, Dr. Layde and A. Christiansen, with assistance from the research team.

Development of the final package. The Study Coordinator will develop the final package, with assistance of S Cech and under the oversight of the PI and the research team. A graphic designer will assist with package modifications to enhance user friendliness. Program sites (participants, leaders, lay leaders, organizational sponsors) will be invited to provide feedback on the final package.

An organizational chart for the proposed research study is in Appendix 2.

CONCLUSION

This application, "Dissemination Research on Fall Prevention: "Stepping On" in a Wisconsin Community", proposes to translate "Stepping On" for a U.S. community audience, pilot the translated package in a Wisconsin community setting, revise materials based on the pilot, then test several research questions regarding dissemination and implementation. Lastly, we will produce a program package that can be disseminated nationwide. Our proposal addresses important research questions and applies appropriate scientific methods and data analytic techniques to answer those questions. Further, the proposal addresses potential problems and alternative tactics to achieve aims. The members of the research team have outstanding skills, knowledge, background, and resources to perform the proposed research. Most importantly, we have prior experience with implementation of "Stepping On" in collaboration with Dr. Clemson, and we have a strong track record in conducting falls prevention randomized trials and dissemination research. We have a history of successful collaborative research with the Centers for Disease Control and Prevention and with state and local partners. These elements augur success for this research proposal.

8. PROTECTION OF HUMAN SUBJECTS

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

Proposed involvement of human subjects includes:

- i) Focus groups = 1 focus group of older adult former participants (meeting one time) and 1 focus group of older adult potential participants (meeting twice)
- ii) "Stepping On" classes = 8 classes of 8 subjects each = 64 subjects.

Characteristics of the subject population. We expect to enroll 64 subjects, age range 65 to 100 years, with a history of a fall in the past year. The health status is likely to be moderately impaired, with some disability in instrumental activities of daily living (iADL's). Participants must be cognitively intact, able to give informed consent, and able to travel to class by foot or by private or public transportation. This study will not enroll special classes of subjects.

Collaborating sites are: 1) Parish Nurse, Burlington, WI; 2) Waukesa Community Center, Waukesha, WI; and 3) Lincoln Lutheran Senior Housing, Racine, WI

Coordinators/class leaders will be determined by each site. The project will provide training, consultation, the cost of class supplies and the lay leader/co-facilitators' stipends. The site coordinator/class leader will arrange the site, market to targeted seniors, participate in training (est. 3 ½ days), facilitate classes and provide reports to the grant coordinator.

b. Sources of Materials

The following data will be obtained from human subjects:

1. Qualitative data from focus group transcripts and summaries – collected by study investigators
2. Questionnaire prior (demographics, functional information, FaB, MES) – collected by study coordinator
3. Interview prior – collected by Evaluation Coordinator
4. Attendance logs – collected by class leader, then provided to the study investigators, who will substitute subject id number for name
5. Exercise logs – collected by class leader, then provided to the study investigators, who will substitute id number for name
6. Observations of classes – performed by study investigators
7. Questionnaire at end of classes (FaB, MES) – collected by Study Coordinator
8. Interview at end of classes – collected by Evaluation Coordinator
9. Questionnaire at 12 months (FaB, MES, Follow-through on Goals) – collected by Study Coordinator (mailed, with phone administration of questionnaire if mailed questionnaire not returned in 2 weeks)

All of the above data will be collected specifically for the proposed research project. Class leaders will have names and contact information of subjects. The class leader will destroy information regarding name and contact information following subject participation in the booster class. The Study Coordinator will have access to subject identities in order to contact subjects for the 12 month questionnaire. Each subject will be assigned a participant id number, and all data from that subject will be coded by id number. The link to the name will be destroyed after the 12 month questionnaire.

c. Potential Risks

Potential risks to subjects include the risk of falling or of musculoskeletal injury either during the classes or while performing the home exercises. Other risks include fatigue from the classes, questionnaires, or interviews. There is a risk of loss of confidentiality. The most likely risk is of fatigue from the classes, questionnaires, or interviews. The risk of falling or musculoskeletal injury related to performance of the class or home exercise is very low. In the original study there were no recorded falls during classes or home exercises (personal communication, L. Clemson). In a few instances (< 10%) exercises needed to be modified

by the physical therapist of class leader due to pain or other needs of participants (personal communication, L. Clemson). The risk of breach of confidentiality is also very low as a number of steps will be taken to prevent this.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent.

The study will be reviewed by the University of Wisconsin, Medical College of Wisconsin, and Centers for Disease Prevention and Control Institutional Review Boards as required. For the focus groups of older adults (former participants and potential participants), we will invite participants from previous classes held in Wisconsin, and from new sites where classes will be held. We will ask the class leaders to mail out a letter inviting participation. For each focus group, those interested will be invited to call the study coordinator or mail in a return postcard. The study coordinator will call those older adults who express interest and explain the focus group's purpose and what it involves. Informed consent will be obtained prior to the focus group.

For recruitment for "Stepping On" classes, the coordinator/class leader at each site will market the "Stepping On" classes by brochures and notices in organization newsletters. The notices will invite participation by adults aged 65 and over who have fallen in the last year. The notices/brochures will indicate that a component of participation in the class includes questionnaires and interviews as part of a research study to evaluate "Stepping On". Interested individuals will call the class leader, who will screen for eligibility (age, history of fall in the past year) and provide further information on what the "Stepping On" classes and research involves. Prior to the first class, the study coordinator or another study investigator will obtain informed consent. There will be no payment for participation in the class. There will be no cost for participation but the participant will be expected to obtain transportation through private pay or public means.

As part of the informed consent process, all eligible subjects will be informed of all the elements of informed consent (purpose of study, what the study involves, any costs, risks, benefits or payment for participation, any compensation for injury, what will happen if the person does not wish to join, who to contact, and freedom to stop at any time) and will give written informed consent. A copy of the written consent will be kept in a locked file by the principal investigator, and a copy will be given to the participant.

b. Protection Against Risk

To prevent falls and/or musculoskeletal injury, all exercises will be taught by a licensed physical therapist. The class leader and a physical therapist will assist with monitoring exercise performance during the first exercise session. A physical therapist will also attend sessions where outdoor mobility is practiced and where exercises are advanced. The physical therapist will instruct subjects in proper performance of the exercises at home, and ask them to demonstrate back performance during the first session. Six of the programs will be led by a health-degree professional (PT, RN, OT), who has the training to work with older adults in an exercise or physical activity session. At each class, the class leader will monitor safe performance of physical activity and exercise, and encourage omission of any activity or exercise that the leader or participant feels is potentially unsafe. Two of the classes will be held by a non-health degree professional. For these classes, to ensure safety, a study investigator health professional (PT, RN, or MD) will be present for all sessions.

There is a risk of fatigue with the classes, interviews, or questionnaires. The participants will be informed they can stop and rest at any time, or omit whatever part of the classes, interviews or questionnaires they wish. There is a risk of breach of confidentiality. Names and contact information will be maintained in locked files in the class leaders' offices until the last booster class, then destroyed. Names and contact information will be kept by the study coordinator until 12 months after the first class (i.e. until after the 12 month questionnaire) then destroyed. All data will be coded by participant id number, and publication data will not allow identification of any individual participant.

The above procedures are assessed to be effective in protecting against risk. In the event of adverse effects to subjects, class leaders will utilize systems in place for their site for dealing with injury or other adverse event.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

The proposed research may decrease the risk of falling for those participating in "Stepping On" classes, as demonstrated in the original randomized trial. The research may potentially benefit many older adults at risk for falls. If this study demonstrates effective dissemination and implementation of "Stepping On" in Wisconsin sites, then "Stepping On" may be implemented in other sites in Wisconsin and nationally in a

manner that maximizes likelihood of benefit and minimizes risk. Risks to subjects are very minimal, and the anticipated benefits to study subjects and others is large. Falls carry substantial costs to older adults. Almost one half of falls result in injury and one in 10 result in hospitalization. Thus the benefit from decreasing the risk of falling is substantial.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

The knowledge to be gained from the proposed research has substantial importance. Findings from this study should permit effective dissemination of "Stepping On" across many areas of the United States; thus it has the potential to decrease falls risk for many older adults. Risks to the subjects are minimal, as demonstrated in the original study. Currently there are few effective community-based strategies to decrease falls. "Stepping On" has been shown to be effective in an Australian community. This study could provide a program package for dissemination of an effective community-based falls prevention strategy nationwide.

9. INCLUSION OF WOMEN AND MINORITIES

Inclusion of women is anticipated at approximately 60%, based on the percentage of population aged 65 and over who are female. Inclusion of minorities is likely to be low, reflective of the low percentage of population who are minorities in Kenosha, Racine, and Waukesha Counties. Our targeted/planned enrollment figures are based on the US Census 2000 figures for the age 65 and over population in Kenosha, Racine, and Waukesha Counties, where “Stepping On” classes will be held. However, the targeted enrollment for Hispanic or Latino ethnic category may be greater than their percentage in the population because we are holding two “Stepping On” classes at a Catholic Church, which is located in a town that has a higher percentage of Hispanic adults than do other areas of Wisconsin. Enrollment by minorities will be encouraged at all “Stepping On” class sites. Specifically, we will contact and meet with minority spokespersons and/or opinion leaders who attend each site to encourage minority enrollment. In addition, we will ensure that minorities are represented in focus groups (Phase 1) and in review of the final package (Phase 3).

10. TARGETED/PLANNED ENROLLMENT

TARGETED/PLANNED ENROLLMENT TABLE

Study Title: “Dissemination Research on Fall Prevention: “Stepping On” in a Wisconsin Community”

Total Planned Enrollment: 80 total (64 in 8 “Stepping On” classes, plus 16 in 2 focus groups)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	3	3	6
Not Hispanic or Latino	45	29	74
Ethnic Category: Total of All Subjects *	48	32	80
Racial Categories			
American Indian/Alaska Native	0	1	1
Asian	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	1	3
White	45	30	75
Racial Categories: Total of All Subjects *	48	32	80

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

11. INCLUSION OF CHILDREN

Children will be excluded from the proposed research. Children are excluded because the research topic is not relevant to children. The program "Stepping On" is targeted specifically to older adults at falls risk.

15. CONSORTIUM/CONTRACTUAL ARRANGEMENTS

We are establishing a contractual arrangement with Kenosha County Division of Aging Services. Key personnel from this performance site will lead implementation of “Stepping On” at community sites, serve on the research team, and assist with development of the “Stepping On” package and evaluation of implementation fidelity. Their budget is attached, and more detail is provided in the budget justification.

We are establishing a contractual arrangement with Medical College of Wisconsin Injury Research Center. Key personnel from this performance site will serve on the research team and assist with development of the “Stepping On” package and evaluation of implementation. Their budget is attached, and more detail is provided in the budget justification.