

University of Alabama at Birmingham UAB Digital Commons

All ETDs from UAB

UAB Theses & Dissertations

2017

Increasing the Accessibility of a Falls Prevention Intervention for Community-Dwelling Older Adults with Low Vision

Sarah Blaylock University of Alabama at Birmingham

Follow this and additional works at: https://digitalcommons.library.uab.edu/etd-collection

Recommended Citation

Blaylock, Sarah, "Increasing the Accessibility of a Falls Prevention Intervention for Community-Dwelling Older Adults with Low Vision" (2017). *All ETDs from UAB*. 1184. https://digitalcommons.library.uab.edu/etd-collection/1184

This content has been accepted for inclusion by an authorized administrator of the UAB Digital Commons, and is provided as a free open access item. All inquiries regarding this item or the UAB Digital Commons should be directed to the UAB Libraries Office of Scholarly Communication.

INCREASING THE ACCESSIBILITY OF A FALLS PREVENTION INTERVENTION FOR COMMUNITY-DWELLING OLDER ADULTS WITH LOW VISION

by

SARAH E. BLAYLOCK

LAURA K. VOGTLE, COMMITTEE CHAIR CYNTHIA J. BROWN TAPAN MEHTA MARY WARREN BROOKS WINGO

A DISSERTATION

Submitted to the graduate faculty of The University of Alabama at Birmingham, in partial fulfillment of the requirements for the degree of Doctor of Philosophy

BIRMINGHAM, ALABAMA

INCREASING THE ACCESSIBILITY OF A FALLS PREVENTION INTERVENTION FOR COMMUNITY-DWELLING OLDER ADULTS WITH LOW VISION

SARAH E. BLAYLOCK

REHABILITATION SCIENCE

ABSTRACT

Falls remain a costly problem as a leading cause of injuries and fatalities for individuals over the age of 65. Older adults with low vision, or non-correctable visual impairment, are estimated to be two times more likely to fall than those without vision loss. There appear to be limited falls prevention interventions available for older adults that have been tested on or designed specifically for individuals with visual impairment. The goals of this dissertation were to learn more about the availability of visually accessible falls prevention interventions and to develop an intervention that can be used with veterans receiving services within the Southeastern Blind Rehabilitation Center (SBRC) in Birmingham, Alabama. We conducted two studies to address accessible intervention development. The first study, a scoping review, indicated that falls prevention interventions available to older adults with low vision are limited. The second study served to develop an accessible falls prevention intervention using the ADAPT-ITT model for modification of evidence-based interventions and to pilot the adapted intervention. It was concluded that the intervention modifications completed in the final study were needed based on the inability of the participants to visualize the original, unmodified content, and expert feedback regarding the inaccessibility of the content. After piloting, participants showed evidence of increased knowledge of intervention content and positive verbal feedback regarding use of the intervention within the SBRC.

ii

This dissertation highlights the need for visually accessible falls prevention interventions for older adults with low vision.

Keywords: accessibility, low vision, falls prevention, visual impairment

TABLE OF CONTENTS

ABSTRACT	ii	
LIST OF TABLESvi		
INTRODUCTION		
Falls and low vision	2	
Falls prevention interventions	3	
Project description	4	
Specific aim 1	5	
Specific aim 2	6	
FALLS PREVENTION INTERVENTIONS FOR OLDER ADULTS WITH LOW VISION: A SCOPING REVIEW		
INCREASING THE VISUAL ACCESSIBILITY OF A FALLS PREVENTION INTERVENTION FOR OLDER ADULTS WITH LOW VISION	33	
DISCUSSION AND CONCLUSIONS	73	
Current status of evidence-based falls prevention interventions	73	
The development of accessible intervention materials	74	
Implications for healthcare and future studies	75	
GENERAL REFERENCES	77	
APPENDIX A: PAPER 1 INSTITUTIONAL REVIEW BOARD APPROVAL		
APPENDIX B: PAPER 2 INSTITUTIONAL REVIEW BOARD APPROVAL	87	

LIST OF TABLES

Table Page				
INTRODUCTION				
1	ADAPT-ITT model phases	,		
	FALLS PREVENTION INTERVENTIONS FOR OLDER ADULTS WITH LOW VISION: A SCOPING REVIEW			
1	Descriptions of studies included in the review)		
	INCREASING THE VISUAL ACCESSIBILITY OF A FALLS PREVENTION INTERVENTION FOR OLDER ADULTS WITH LOW VISION			
1	Outline of Intervention Educational Content			
2	Revisions implemented to SAFE intervention	,		
3	Likert scale questions for low vision occupational therapists	,		
4	Likert scale questions for older adults with low vision)		
5	Participant age and vision description70)		
6	Change in perceived learning from pre-to-post71			
7	Veteran intervention feedback	2		

INTRODUCTION

Low vision is a visual limitation that is not correctable by medical interventions, including eyeglasses, surgery, or medication.¹ Older adults are most commonly affected by low vision which usually occurs due to diseases associated with aging such as glaucoma, age-related macular degeneration, and diabetic retinopathy.^{1,2} Some usable vision remains for functional activities with low vision, in contrast to a complete loss of vision, or blindness.² Approximately 3.22 million people in the United States (US) have low vision at present; this number is expected to rise to approximately 6.95 million people by 2050.³

Low vision is commonly defined using the World Health Organization's (WHO) levels of visual impairment which utilize distance acuity, or the ability to see objects clearly in the distance, to identify impairment.⁴ The WHO levels define low vision as beginning at the level of moderate visual impairment (Snellen acuity 20/80).⁴ Though acuity is often used to identify impairment, low vision is also determined by other components of visual function including contrast sensitivity and visual field.^{2,4} Limited contrast sensitivity impairs a person's ability to distinguish between objects of similar colors within the environment. A visual field deficit decreases the area that a person can visualize either within the central or peripheral fields of sight.^{2,4}

Addressing the health care needs of older adults with low vision is necessary because they are a vulnerable population. Diagnoses causing low vision are chronic and often lead to a progression of dependence and safety concerns.¹ Multiple studies show

that low vision negatively impacts a person's independence; individuals with moderate visual impairment are four times more likely to experience deficits in the performance of daily activities.⁵⁻⁸ In addition to performance deficits, 70% of older adults with low vision present with depression.⁹ Having a visual impairment also doubles the risk of falling among older adults, which is the topic of this project.^{10,11}

Falls and low vision

For individuals over the age of 65 years, falls are a leading cause of injuries and fatalities.¹² Falls and related injuries account for approximately \$30 billion of annual medical expenditures in the United States (US).^{13,14} When an older adult falls, he or she often presents with a "post-fall syndrome," a long-term after-effect of a fall that reduces independence and increases depression and confusion.¹⁵ For an older adult with low vision, a fall can exacerbate the already heightened occurrence of dependence and depression. Visual impairment significantly increases an individual's risk for fall-related injuries, especially hip fractures, and is strongly associated with fall risk factors including decreased step accuracy, postural instability, increased fear of falling, decreased balance, and decreased physical activity.¹⁶⁻²⁵

Studies have investigated the different components of vision that are associated with falls among older adults. For individuals living in the community, decreased visual acuity, contrast sensitivity, and visual field have all separately been shown to increase fall risk, with contrast appearing to have the greatest effect. ^{24, 26-32} Older adults with impaired vision in only one eye showed significantly more falls and hip fractures than those without visual impairment, with monocular impairment showing similar fall rates to binocular impairment.^{24,31} Studies have also linked increased fall risks to common low

vision diagnoses. The risk of falling for older adults with AMD is approximately doubled compared to those without visual impairment.^{11,33} Older adults with glaucoma and cataracts are also more vulnerable to falls based on the results found within a 12-month period^{26,34}

Falls prevention interventions

With the increased fall rate, high risk of injury, and the expected growth in the population of persons with low vision, it is imperative to address falls prevention in this population. The Centers for Disease Control and Prevention (CDC) published a compendium consisting of the most successful, evidence-based falls prevention interventions for older adults.³⁵ Despite the high prevalence of older adults with low vision, many study samples in the compendium did not include participants with low vision and focused on interventions with educational content reliant on intact vision for successful delivery (i.e. handouts and slide presentations). Persons with low vision have difficulty seeing details, color, and low contrast features in environments and may experience significant difficulty reading, even with magnification.³ It is therefore unknown if older adults with low vision are able to benefit from the interventions listed by the CDC.¹⁰

Of the 41 studies reported in the CDC's compendium, only 11 acknowledged vision impairment among participants and within the protocol. Seven of these studies addressed vision during falls prevention by referring to an optometrist or ophthalmologist to update eyeglass prescriptions or receive medication/surgery if needed.³⁶⁻⁴² One study addressed switching to single lens glasses versus bifocals during mobility to prevent falls⁴³ and another studied the results of falls prevention post cataract surgery.⁴⁴ One

education-based intervention included in the compendium did include a module on the importance of vision and falls although presentation of the content was not reported in detail.⁴⁵ The final study addressed the adaptation of a falls intervention, the Otago Exercise Programme, for persons with vision impairment, but did not describe in detail how the intervention was modified to make it accessible to older adults with low vision.⁴⁶

Further research is needed to identify the most effective methods for delivering a falls intervention program to older adults with low vision. While some studies did support improvement in vision through optometry and ophthalmology appointments, there is limited information regarding interventions for individuals with permanent loss. Also, there is minimal discussion regarding the delivery format of vision-based media. This project was designed to describe the components used in the development of an accessible falls prevention interventions and to develop and pilot test an intervention specifically for older adults with low vision.

Project description

The studies in this dissertation served to modify a previously tested falls prevention intervention included in the CDC's compendium to provide an accessible format for older adults with low vision.³⁵ Ultimately, we aimed to develop an adapted intervention that can be permanently utilized within the Southeastern Blind Rehabilitation Center (SBRC), a service through the Department of Veteran Affairs that is in need of an accessible falls prevention intervention. To develop an intervention for the SBRC, we first completed a literature review to learn more about the available falls prevention interventions for older adults with low vision (paper 1). Then, we utilized a model for modifying evidence-based interventions for target populations, the ADAPT-ITT model

(see Table 1),⁴⁷⁻⁴⁹ to develop an intervention for permanent use within the SBRC. The modification study (paper 2) served to develop and test the accessible falls prevention intervention.

Specific aim 1 (first paper) - To review the evidence regarding community-based falls prevention interventions that appear inclusive of and/or accessible to individuals with low vision.

Aim 1 served to better understand the current state of falls prevention interventions and to ensure we located the most useful intervention for the veterans at the SBRC. We utilized a five-stage scoping review framework developed by Arksey and O'Malley⁵⁰ to answer the following research questions: "What evidence-based falls prevention interventions are to use with older adults with visual impairment who live in the community" and "Were these interventions effective in preventing falls?"

Of the 17 articles located through this review, only 9 showed a significant effect in relation to decreasing falls within the study samples. Five of the interventions showing significant results were studies developed specifically for older adults with visual impairment while the remaining papers discussed vision impairment within the articles' text though it was not the primary focus of the interventions. Only three of the studies in the review are located in the CDC's compendium of recommended interventions. Similar to the compendium studies, multiple interventions discussed in this review relied on education and exercise instruction, though description of the intervention delivery method was often lacking. If the delivery of education components within these interventions was reliant on intact vision to deliver the educational content to participants (i.e. slide presentations, homework assignments, and handouts), it is again unknown

whether older adults with visual limitations would benefit from the reported intervention. Specific aim 2 (second paper) - To modify and pilot a falls prevention intervention for older adults with low vision for use within the SBRC.

We used the eight phases of the ADAPT-ITT model (Table 1) to develop an accessible intervention for use within the SBRC.⁴⁷⁻⁴⁹ The ADAPT-ITT model provides a guide to developing methodology to modify and test existing evidence-based health promotion interventions for target populations. Using feedback from previous research and discussions with SBRC staff, we selected and modified the Study of Accidental Falls in the Elderly (SAFE) Health Behavior and Exercise intervention,⁵¹ a CDC recommended intervention, for use in the VA facility. The SAFE intervention consists of four, hourlong classes addressing prevention of multiple falls risk factors. During our modification, we received feedback from 15 topical experts regarding the accessibility of the modified version and integrated all feedback.

We piloted the intervention with nine veterans receiving services at SBRC using a pre-post intervention design. We hypothesized that following intervention completion, participants would have increased knowledge of the intervention content, decreased fear of falling, and a greater range of mobility. We found that participants significantly increased their test scores of intervention content post class attendance and maintained the scores at one-month follow-up. Participants also reported knowing more regarding falls prevention strategies compared to before intervention completion. There was no significant change in fear of falling or mobility outcome measure scores following intervention completion. Using the pilot test results, it is recommended to continue using the SAFE intervention within the SBRC following minor changes reported in paper 3.

Table 1: ADAPT-ITT model phases

Phase	Description
1	Assessment: Interviews or focus groups with target population regarding
	needs and staff regarding intervention feasibility.
2	Decision: Review of available evidence-based interventions and selection of
	most appropriate. Organization of needed modifications.
3	Adaptation: Modification of intervention to meet needs.
4	Production: Completion of first draft.
5	Topical experts: Review by experts in intervention content.
6	Integration: Inclusion of recommended expert changes.
7	Training: Preparing the individuals who will deliver intervention and
	complete measures during piloting.
8	Testing: Completion of intervention piloting.

FALLS PREVENTION INTERVENTIONS FOR OLDER ADULTS WITH LOW VISION: A SCOPING REVIEW

by

SARAH E. BLAYLOCK, LAURA K. VOGTLE

Blaylock, S. E., & Vogtle, L. K. (2017). Falls prevention interventions for older adults with low vision: A scoping review. *Canadian Journal of Occupational Therapy*, *84*, 139 –147. doi:10.1177/0008417417711460 [Post-print version reprinted as per copyright]

Copyright 2017 by Sarah E. Blaylock

Format adapted for dissertation

ABSTRACT

Background. Older adults with low vision are especially vulnerable to falls. There are no comprehensive reviews of fall prevention interventions for older adults with vision loss who live in the community. **Purpose.** The aim was to review the evidence regarding community-based falls prevention interventions that appear inclusive of and/or accessible to individuals with low vision. **Method.** A scoping review was completed using the framework developed by Arksey and O'Malley (2005). **Findings.** Seventeen publications were selected for this review. The analysis allowed for a thorough description of the types of falls prevention interventions (multiple component, home safety/modification, tai-chi, the Alexander Technique, improvement of vision through vision assessment and referral, vision/agility training, and yoga), how each intervention addresses vision impairment, and the relation of results to falls risk. **Implications.** Falls prevention approaches available may not be effective for older adults with permanent vision loss.

INTRODUCTION

Falls are a leading cause of accidental death worldwide (The World Health Organization [WHO], 2013). Approximately 35% of individuals over the age of 65 fall annually (Talbot, et al., 2005), with 37.3 million older adults requiring medical attention per year (Stalenhoef, Diederiks, Knottnerus, Kester, & Crebolder, 2002; WHO, 2013). Internationally, falls are a financial burden due to the resulting direct healthcare costs as well as the indirect costs associated with loss of productivity (WHO, 2007). The costs of falls are expected to rise with the rapid growth of the older adult population in the near future (WHO, 2013).

Older adults with low vision are approximately two times more likely to fall than those without vision loss (Crews, Chou, Stevens, & Saaddine, 2016; Legood, Scuffham, & Cryer, 2002; Szabo, Jannsen, Lord, & Potter, 2010). Low vision is defined as any limitation in vision that is not correctable by medical intervention, including eyeglasses (National Eye Institute [NEI], 2015). Diagnostic criteria for low vision is an acuity level of 20/80 though additional visual components also contribute to safe mobility, including contrast sensitivity and visual field, with studies linking falls to reductions in these visual components (Freeman, Muñoz, Rubin, & West, 2007; Lamoureux, Chong, Wang et al., 2008; Warren, 2011). Diagnoses causing low vision, including glaucoma and age-related macular degeneration, have also been associated with increased fall rates (Black, Wood, Lovie-Kitchin, Newman, 2008; Szabo et al., 2010; Wood et al., 2011).

Low vision is associated with increased rates of fall risk factors, including decreased step accuracy, slower gait speed, postural instability, increased fear of falling, decreased balance, and decreased physical activity (Aartolahti et al., 2013; Tinetti & Kumar, 2010). Older adults with vision deficits are also more likely to experience fall-related injuries, with Squirrell et al. (2005) determining 58% of participants with a hip fracture had some level of visual impairment.

Researchers have further explored the relationship between vision and falls in balance and gait studies through visual manipulations. Participants without visual impairment experienced increased step errors when researchers decreased acuity and contrast sensitivity (Black, Kimlin, & Wood, 2014). Helbostad, Vereijken, Hesseberg, and Sletvold (2009) showed that older adults with unaffected vision demonstrated unstable gait patterns with varying types of visual manipulations (decreased acuity, contrast sensitivity, and lighting as well as double and tunnel vision). Visual manipulations decrease step accuracy and interfere with stable gait patterns demonstrating the importance of vision in falls prevention (Black et al., 2014; Helbostad et al., 2009).

The relationship between vision and falls increases the need for appropriate utilization of falls prevention interventions for clients with low vision. While older adults with visual impairment are already at risk for decreased participation, falls can exacerbate the risk for dependence in occupational performance (O'Connor, Lamoureux, & Keeffe, 2008; Warren, 2011). Falls often result in a "post-fall syndrome" that decreases autonomy and increases confusion, depression, and immobilization (WHO, 2007, p. 9). Older adults who fall are at an increased risk of long-term care placement; just a single,

non-injurious fall increases the risk of admittance to a nursing facility (hazard ratio 4.9) (Tinetti & Williams, 1997).

To successfully prevent falls for older adults with low vision and prevent a loss of functional independence, occupational therapists require evidence-based literature to ensure effective intervention selection. Currently, there are no comprehensive reviews of the fall prevention interventions available to occupational therapists for older adults with vision loss living in the community. The purpose of this study was to address this absence in the literature by reviewing the evidence regarding community-based falls prevention interventions that appear inclusive of and/or accessible to older adults with low vision. The two-part research question was: "What evidence-based falls prevention interventions are available for occupational therapists to use with older adults with visual impairment who live in the community" and "Were these interventions effective in preventing falls?"

METHODS

A scoping review serves to outline an area of evidence that has not been comprehensively reviewed. This type of review does not serve to evaluate, but rather summarize the existing evidence (Mays, Roberts, & Popay, 2001). We utilized the fivestage scoping review framework developed by Arksey and O'Malley (2005) to guide this project. The framework stages include the following: (a) identifying the research question, (b) identifying relevant studies, (c) study selection, (d) charting the data, and (e) collating, summarizing, and reporting the results. Arksey and O'Malley (2005) provide four reasons for conducting a scoping review; we completed this review "to examine the extent, range and nature of research activity" (p.6).

Identifying the research question

We identified our research question based on the literature showing the relationship between visual impairment and falls and the trend of functional decline post falls. We designed our question to be flexible enough to locate all available interventions inclusive of and/or accessible to older adults with visual impairment.

Identifying relevant studies

To identify relevant studies, we first searched peer-reviewed literature within six databases including Embase, CINAHL, OT Search, OT Seeker, PubMed, and Scopus. Key words used in the search included: 'community', 'dwelling', 'falls', 'interventions', 'older adults', and 'vision'. We used combinations of the keywords to retrieve all relevant articles (i.e. 'community-dwelling' and 'falls interventions'). Only articles published in the last 10 years were included in the search. The article search also included the following journals: *The American Journal of Occupational Therapy (AJOT), The Australian Occupational Therapy Journal (AOTJ), The British Journal of Occupational Therapy (CJOT)*. We searched the reference lists of the returned articles for relevant publications.

Study selection

Inclusion criteria for article selection were the following: (a) addresses a falls intervention that can be performed by an occupational therapy practitioner, (b) targets older adults living in the community, (c) discusses adaptation for and/or inclusion of individuals with vision loss, (d) reports implications for older adults with visual impairment, and (e) was published after 2004.

Charting the data

After selecting all articles that meet inclusion criteria, we developed a data charting form to record the following information for each study: author, year of publication, location of the study, purpose of the study or research question, methodology, intervention, vision components, outcome measures, and relation of results to fall risk.

Collating, summarizing, and reporting the results

Charting of the data allowed analysis of the evidence both quantitatively and thematically (Arksey & O'Malley, 2005). During quantitative analysis, we assessed the geographical distribution of the relevant studies, years of publication, methodology, and the types of included interventions. During thematic analysis, a reviewer reads the relevant research and looks for commonalities that serve to better summarize the current state of the literature (Arksey & O'Malley, 2005). We performed thematic analysis by first reading the returned studies and then decided to document descriptions of the interventions, use of vision in each study, and findings in relation to falls. Through reading the literature and organizing similar categories, we gained information regarding the trends of how vision is currently addressed in falls prevention interventions for older adults and if these interventions were successful in preventing falls.

FINDINGS

The database search yielded 163 articles: 20 in CINAHL, 45 in Embase, 2 in OT Search, 7 in OT Seeker, 40 in PubMed, 42 in Scopus, and 7 through reference search. The search of occupational therapy journals yielded 102 articles: 37 IN *AJOT*, 38 in *AOTJ*, 17 in *BJOT*, and 10 in *CJOT*. A screening of the 265 abstracts resulted in the

rejection of 237 articles that did not meet the inclusion criteria, mainly due to the absence of a focus on vision loss or the exclusion of persons with visual impairment. When charting the remaining studies, 11 articles were excluded because they were review papers that did not report results of original research. Seventeen articles were selected for this review (see Table 1 for details of each article).

Study characteristics

The studies included in this review were published between 2005 and 2015. Most articles were from the United States (six) followed by Australia (three), New Zealand (three), and Taiwan (two). China, Finland, and Spain all produced one article. All of the studies used a quantitative design; all but one study were randomized controlled trials. One article utilized a quasi-experimental pre-test, post-test design. The interventions addressed included multicomponent (ten), home safety/modification (two), tai-chi (two), the Alexander technique (one), vision/agility training (one), and yoga (one). Of the articles, six (35%) directly targeted persons with visual impairment/intervention with vision focus, while the remaining 11 (65%) included vision impairment as a secondary component of the intervention.

Descriptions of interventions

Most interventions (10) assessed the effects of a multicomponent intervention for community-based falls prevention. All multicomponent interventions included an exercise component. Exercise sessions mostly occurred with a frequency of 1 session per week with durations ranging from 3 weeks (Perula et al., 2012) to 15 weeks (Fitzharris, Day, Lord, Gordon, & Fildes, 2010). Three studies tested previously developed exercise interventions including "Stepping On" (Garcia, Marciniak, McCune, Smith, & Ramsey,

2012), the "Otaga Intervention" (Elley et al., 2008), and a modified component and the "Preventive Healthcare for the Aging Program" (Fox et al., 2010). The remaining articles discussed blends of gentle aerobic, balance, and strengthening exercises without addressing a previously tested protocol. Four articles provided descriptions of home exercise components (Elley et al., 2008; Fitzharris et al., 2010; Lee, Chang, Tsauo, Hung, Huang, & Lin, 2013; Perula et al., 2012). Most multicomponent interventions contained education sessions regarding topics such as medication management, foot-ware, safety, or health education and provided referrals to needed medical professionals as necessary. Four papers described multi-component interventions based on individualized assessment using a falls risk algorithm or test results (Lord, Tiedemann, Chapman, Munro, Murray, & Sherrington, 2005; Mahoney et al., 2007; Perula et al., 2010; Salminem, Vahlberg, Salonoja, Aarnio, & Kivel, 2009).

Two studies addressed a home assessment and modification intervention; both discussed use of the Westmead Home Safety Assessment (Clemson, 1997). Campbell et al. (2005) compared the fall rates following home modification to the fall rates of two treatment groups: 1) exercise intervention (an adapted version of the Otaga intervention) plus vitamin D supplementation and 2) social visits. La Grow, Robertson, Campbell, Clarke, and Kerse (2006) assessed the use of the Westmead Home Safety assessment with additional follow-up information from participants.

Two researchers assessed the use of tai chi to increase balance and prevent falls. Chen, Fu, Chan, and Tsang (2012) described a 16-week tai chi intervention to encourage multi-directional weight shifting, head and trunk rotation, and awareness of body alignment. One study addressed a tai chi intervention with an included educational

discussion of falls risk factors (Huang, Liu, Huang, & Kernohan, 2010). One study discussed the use of the Alexander technique, an intervention stressing the importance of relaxation, as a method to improve balance among older adults with visual impairment (Gleeson, Sherrington, & Keay, 2015). Jeter, Haaz Moonaz, Bittner, and Dagnelie (2015) studied the effects of Ashtanga-based yoga therapy on postural stability of individuals who were visually impaired.

One study discussed use of vision combined with agility training for prevention of falls. Reed-Jones, Dorgo, Hitchings, and Bader (2012) utilized a Nintendo[®] Wii Fit Plus with Wii Balance Board to test the effect of vision and agility training on completing time and errors made during obstacle course performance. Vision interventions are discussed in more detail in the following section.

Inclusion of visual impairment

Six articles directly focused on falls prevention for older adults with visual impairment. Campbell et al. (2005), Chen et al. (2012), Jeter et al. (2015), and La Grow et al. (2006) assessed previously used interventions on study samples with vision impairment. Researchers in these studies discussed adapting interventions for persons with vision impairment, i.e. by providing audio recording and increasing verbal and physical cueing as needed. Campbell et al. (2005) and La Grow et al. (2006) report providing a version of the Westmead home assessment specifically modified for individuals with visual impairment though details of adaptations are not provided. Gleeson et al. (2015) discussed testing the Alexander technique on persons with vision impairment without making visual adaptations to the traditional program. Reed-Jones et al. (2012) evaluated obstacle course performance of older adults who are independently

living in the community following vision training and agility drills completed using a Nintendo[®] Wii Fit Plus with Wii Balance Board.

The remaining authors discussed vision impairment within the articles' text though it was not the primary focus of interventions within the studies. Three authors reported that a visual component was included within a multifactorial intervention (Fitzharris et al., 2010; Garcia et al., 2012; Lord et al., 2005). Lord et al. (2005) encouraged the use of single versus multiple lens spectacles when maneuvering outside. Five studies addressed vision impairment through referrals to optometrists or ophthalmologists (Elley et al., 2008; Fitzharris et al., 2010; Lord et al., 2005; Mahoney et al., 2007; Salminen et al., 2009). Huang et al. (2010) included discussion of vision loss and falls risk during tai chi classes. Participant visual acuity was measured and utilized as an outcome measure in relation to fall rate in articles by Fox et al. (2010), Lee et al. (2013), Perula et al. (2012), and Shumway-Cook et al (2007).

Relation of results to falls risk

Seven of the ten multi-component interventions did not have a significant effect on fall rate between intervention groups and controls. The multi-component interventions showing significant differences were completed by Fitzharris et al. (2010), Lee et al. (2013), and Lord et al. (2005). Some multi-component interventions did prevent falls for specific individuals within test groups. For example, Salminem et al. (2009) found rate of falls was significantly decreased for participants with a higher occurrence of depression symptoms. The two home modification studies significantly reduced falls after home assessment, showing stronger results than exercise and social groups (Campbell et al 2005; La Grow, 2006). Tai Chi with and without education reduced falls (Huang et al.,

2010) and improved knee proprioception as well as vestibular ratios (Chen et al., 2012). Ashtanga Yoga resulted in significant increases in center of pressure and somatosensory and vestibular balance measures (Jeter et al., 2015). The Alexander Technique, which is a movement strategy, (Gleeson et al., 2015) did not significantly reduce fall rate. Vision and agility training led to a significant increase in obstacle course performance (Reed-Jones et al., 2012).

DISCUSSION

The purpose of this scoping review was to examine existing literature on falls prevention interventions for older adults with low vision living in the community. In general, falls prevention for older adults is well represented in current research; however, we only found 17 articles within our inclusion criteria. Of the 17 articles found in this search, only 9 showed a significant effect in relation to falls prevention. Five of the interventions showing significant results were studies developed specifically for older adults with visual impairment. The remaining studies showing success were for older adults living in the community (not specifically older adults with visual impairment) and included three multi-component interventions including eye care referrals and tai chi. Of the limited number of articles returned in our search, roughly half of the studies showed significant effects on falls. It appears that a body of evidence on falls prevention research targeting individuals with visual impairment is limited.

Over half of the 17 studies found showed significant results, however not all interventions may be effective for older adults with visual impairment. As noted earlier, low vision is defined as any limitation in vision that is not correctable by medical intervention, including eyeglasses (NEI, 2015). Because low vision is non-correctable,

some interventions reported in this review may not serve to prevent falls for individuals in this population. Many interventions addressed vision impairment through optometry visits, vision assessments, and updating optical devices. Though it is important for all older adults to maintain continued maintenance of vision care, these interventions may not be effective as falls prevention strategies for individuals with non-correctable vision loss.

Multiple interventions discussed in this review utilized education and exercise instruction, though delivery method of content was often not thoroughly discussed. Persons with visual impairment often have difficulty seeing details, color, and low contrast features in environments and may experience significant difficulty reading even with magnification (Barstow & Crossland, 2011). If the delivery of education components within these interventions were reliant on intact vision to deliver the educational content to participants (i.e. slide presentations, homework assignments, and handouts), it is unknown whether older adults with visual limitations would benefit from the reported intervention.

Implications for practice

Low vision is prevalent among older adults and significantly impairs safety through increased fall risk (WHO, 2013). Occupational therapy practitioners should be aware of the increased fall risk for older adults with low vision, because falls can impact health and negatively affect occupational performance (WHO, 2007). Practitioners should remember that not all evidence-based interventions will be effective for all older adults. Individuals with low vision may be unable to see the written components of educational interventions or the visual demonstrations of exercise interventions. In

addition, though proper eyewear fit and prescription is very important, interventions including updated eyeglasses and vision appointments may not serve to prevent falls within this population.

Future directions

Additional research is needed that addresses falls prevention among older adults with low vision. A systematic review of the included studies would be beneficial because this study does not address the methodological strength of the returned articles. A systematic review would also provide the detail needed to perform a stronger comparison of the outcomes of the included interventions and better understand why the studies with significant effects were successful.

Study limitations

Though we developed a thorough search protocol and followed strict inclusion and exclusion criteria, when searching a large body of evidence there is a chance that relevant research was excluded. In addition, this review would have been stronger if another reviewer also completed a search of the literature to allow a comparison of findings. We also did not provide an evaluation of the strength of each included study. A systematic review might provide additional insight into why some interventions provided significant results while others did not.

Conclusion

Falls prevention research targeting individuals with vision impairment is limited and the intervention approaches available may not be effective for older adults with permanent loss. Further research is needed to show if current interventions are effective for persons with varying levels of vision impairment and to develop accessible

interventions for older adults living in the community.

Key messages

- Falls prevention is important for all older adult clients.
- Occupational therapists should consider the client's vision status when selecting interventions.
- Practitioners can use the studies listed in this review to assist in selecting falls prevention interventions for clients with low vision.

REFERENCES

- Aartolahti, E., Hakkinen, A., Lonnroos, E., Kautiainen, H., Sulkava, R., & Hartikainen,
 S. (2013). Relationship between functional vision and balance and mobility
 performance in community-dwelling older adults. *Aging Clinical and Experimental Research*, 25(5), 545–552. doi: 10.1007/s40520-013-0120-z
- Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology*, 8(1), 19-32. doi:10.1080/1364557032000119616
- Barstow, E.A., & Crossland, M.D. (2011). Intervention and rehabilitation for reading and writing. In M. Warren & E.A. Barstow (Eds.), *Occupational therapy interventions for older adults with low vision* (pp. 1-26).
- Black, A., Wood, J., Lovie-Kitchin, J., & Newman, B. (2008). Visual impairment and postural sway among older adults with glaucoma. *Optometry and Vision Science*, 85(6), 489-497. doi: 10.1097/OPX.0b013e31817882db
- Black, A.A., Kimlin, J.A., & Wood, J.M. (2014). Stepping accuracy and visuomotor control among older adults: Effect of target contrast and refractive blur.
 Ophthalmic & Physiological Optics, 34(4), 470-478. doi: 10.1111/opo.12141
- Campbell, A., Robertson, M., La Grow, S., Kerse, N., Sanderson, G., Jacobs, R., . . .
 Hale, L. (2005). Randomised controlled trial of prevention of falls in people aged
 > or =75 with severe visual impairment: The VIP trial. *The British Medical Journal*, 331(7520), 817. doi: 10.1136/bmj.38601.447731.55

- Chen, E., Fu, A., Chan, K., & Tsang, W. (2012). The effects of Tai Chi on the balance control of elderly persons with visual impairment: A randomised clinical trial. *Age and Ageing*, 41(2), 245-254. doi: 10.1093/ageing/afr146
- Clemson, L. (1997). Home fall hazards. A guide to identifying fall hazards in the homes of elderly people and an accompaniment to the assessment tool, the Westmead Home Safety Assessment. West Brunswick, Australia: Coordinates Publications.
- Crews, J., Chou, C., Stevens, J., & Saaddine, J. (2016). Falls among persons aged ≥65 years with and without severe vision impairment — United States, 2014. *Morbidity and Mortality Weekly Report, 65*(17), 433-437. doi: http://dx.doi. org/10.15585/mmwr.mm6517a2
- Elley, C., Robertson, M., Garrett, S., Kerse, N., McKinlay, E., Lawton, B., . . . Campbell, A. (2008). Effectiveness of a falls-and-fracture nurse coordinator to reduce falls:
 A randomized, controlled trial of at-risk older adults. *Journal of the American Geriatrics Society*, 56(8), 1383-1389. doi: 10.1111/j.1532-5415.2008.01802.x
- Fitzharris, M., Day, L., Lord, S., Gordon, I., & Fildes, B. (2010). The Whitehorse
 NoFalls trial: Effects on fall rates and injurious fall rates. *Age and Ageing*, *39*(6),
 728-733. doi: 10.1093/ageing/afq109
- Fox, P., Vazquez, L., Tonner, C., Stevens, J., Fineman, N., & Ross, L. (2010). A randomized trial of a multifaceted intervention to reduce falls among communitydwelling adults. *Health Education Behavior*, *37*(6), 831-848. doi: 10.1177/ 1090198110366003

- Freeman, E., Muñoz, B., Rubin, G., & West, S. (2007). Visual field loss increases the risk of falls in older adults: The Salisbury eye evaluation. *Investigative Ophthalmology & Visual Science*, 48(10), 4445-4450. doi: 10.1167/iovs.07-0326
- Garcia, A., Marciniak, D., McCune, L., Smith, E., & Ramsey, R. (2012). Promoting fall self-efficacy and fall risk awareness in older adults. *Physical and Occupational Therapy in Geriatrics*, 30(2), 165-175. doi: 10.3109/02703181.2012.681431
- Gleeson, M., Sherrington, C., & Keay, L. (2015). Can the Alexander Technique improve balance and mobility in older adults with visual impairments? A randomized controlled trial. *Clinical Rehabilitation*, 29(3), 244-260. doi: 10.1177/02692 15514542636
- Helbostad, J., Vereijken, B., Hesseberg, K., & Sletvold, O. (2009). Altered vision destabilizes gait in older persons. *Gait & Posture*, 30(2), 233-238. doi: 10.1016/j.gaitpost. 2009.05.004
- Huang, H., Liu, C., Huang, Y., & Kernohan, W. (2010). Community-based interventions to reduce falls among older adults in Taiwan Long time follow-up randomised controlled study. *Journal of Clinical Nursing*, *19*(7), 959-968. doi: 10.1111/j.1365-2702.2009.02834.
- Jeter, P., Haaz Moonaz, S., Bittner, A., & Dagnelie, G. (2015). Ashtanga-based yoga therapy increases the sensory contribution to postural stability in visuallyimpaired persons at risk for falls as measured by the Wii Balance Board: A pilot randomized controlled trial. *PLoS ONE, 10*(6): e0129646. doi:10.1371/journal. Pone.0129646

- La Grow, S., Robertson, M., Campbell, A., Clarke, G., & Kerse, N. (2006). Reducing hazard related falls in people 75 years and older with significant visual impairment: How did a successful program work? *Injury Prevention*, *12*(5), 296-301. Doi: 10.1136/ip.2006.01 2252
- Lamoureux, E., Chong, E., Wang., J., Saw, S., Aung, T., Mitchell, P., & Wong, T.
 (2008). Visual impairment, causes of vision loss, and falls: The Singapore Malay eye study. *Investigative Opthalmology and Visual Science*, 49(2), 528-533. Doi: 10.1167/ iovs.07-1036
- Lee, H., Chang, K., Tsauo, J., Hung, J., Huang, Y., & Lin, S. (2013). Effects of a multifactorial fall prevention program on fall incidence and physical function in community-dwelling older adults with risk of falls. *Archives of Physical Medicine & Rehabilitation*, 94(4), 606-615. Doi: 10.1016/j.apmr.2012.11.037
- Legood, R., Scuffham, P., & Cryer, C. (2002). Are we blind to injuries in the visually impaired? A review of the literature. *Injury Prevention*, 8(2), 155-160. Doi: 10.1136/ip.8.2.155
- Lord, S., Tiedemann, A., Chapman, K., Munro, B., Murray, S., & Sherrington, C. (2005).
 The effect of an individualized fall prevention program on fall risks and falls in older people: A randomized, controlled trial. *Journal of the American Geriatrics Society*, *53*, 1296-1304. Doi: 10.1111/j.1532-5415.2005.53425.x
- Mahoney, J., Shea, T., Przybelski, R., Jaros, L., Gangnon, R., Cech, S., & Schwalbe, A.(2007). Kenosha county falls prevention study: A randomized, controlled trial of an intermediate-intensity, community-based multifactorial falls intervention.

Journal of the American Geriatrics Society, 55(4), 489-498. Doi: 10.1111/j.1532-5415.2007.01144.x

- Mays, N., Roberts, E. & Popay, J. (2001) Synthesising research evidence. In N. Fulop, P.
 Allen, A. Clarke, & N. Black (eds.), *Studying the Organisation and Delivery of Health Services: Research Methods* (188-220). London: Routledge.
- National Eye Institute. (2015). *Prevalence of adult vision impairment and age-related eye diseases in America*. Retrieved from https://www.nei.nih.gov/eyedata/adultvision usa.
- O'Connor, P., Lamoureux, E., & Keeffe, J. (2008). Predicting the need for low vision rehabilitation services. *British Journal of Ophthalmology*, *92*(2), 252-255. Doi: 10.1136/bjo.2007.125955
- Pérula, L., Varas-Fabra, F., Rodríguez, V., Ruiz-Moral, R., Fernández, J., González, J. . . EPICA Study Collaborative Group. (2012). Effectiveness of a multifactorial intervention program to reduce falls incidence among community-living older adults: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*, 93(10), 1677-1684. Doi: 10.1016/j.apmr.2012.03.035
- Reed-Jones, R., Dorgo, S., Hitchings, M., & Bader, J. (2012). Vision and agility training in community-dwelling older adults: incorporating visual training into programs for fall prevention. *Gait and Posture*, *35*(4), 585-589. Doi: 10.1016/j.gaitpost. 2011.11.029
- Salminem, M., Vahlberg, T., Salonoja, M., Aarnio, P., & Kivel, S. (2009). Effect of a Risk-Based Multifactorial Fall Prevention Program on the Incidence of Falls.

Journal of the American Geriatrics Society, *57*(4), 612-619. Doi: 10.1111/j.1532-5415.2009.02176.x

- Shumway-Cook, A., Silver, I., LeMier, M., York, S., Cummings, P., & Koepsell, T. (2007). Effectiveness of a community-based multifactorial intervention on falls and fall risk factors in community-living older adults: a randomized, controlled trial. *Journal of Gerontology*, 62(12), 1420-1427. Doi: http://dx.doi.org/10.1093/ gerona/62.12.1420
- Squirrell, D., Kenny, J., Mawer, N., Gupta, M., West, J., Currie, Z., . . . Austin, C.
 (2005). Screening for visual impairment in elderly patients with hip fracture:
 Validating a simple bedside test. *Eye*, *19*(1), 55-59. Doi: 10.1038/sj.eye.6701421
- Stalenhoef, P., Diederiks, J., Knottnerus, J., Kester, A., & Crebolder, H. (2002). A risk model for the prediction of recurrent falls in community- dwelling elderly: A prospective cohort study. *Journal of Clinical Epidemiology*, *55*(11), 1088-1094.
 Doi: 10.1016/S0895-4356(02)00502-4
- Szabo, S., Jannsen, P., Lord, S., & Potter, M. (2010). Neovascular AMD: An overlooked risk factor for injurious falls. *Osteoporosis International*, 21, 855-862. Doi: 10.1007/s00198-009-1025-8
- Talbot, L.A., Musiol, R.J., Witham, E.K., & Metter, E.J. (2005). Falls in young, middleaged and older community dwelling adults: Perceived cause, environmental factors and injury. *BMC Public Health*, 5(86). Doi: 10.1186/1471-2458-5-86
- Tinetti, M., & Kumar, C. (2010). The patient who falls. *JAMA*, *303*(3), 258-266. Doi: 10.1001/jama.2009.2024

Tinetti, M.E., & Williams, C.S. (1997). Falls, injuries due to falls, and the risk of

admission to a nursing home. *New England Journal of Medicine*. 337, 1279-1284. Doi:10.1056/NEJM1997103 03371806

- Warren, M. (2011). An overview of low vision rehabilitation and the role of occupational therapy. In M. Warren & B. Barstow (Eds.), *Occupational therapy interventions* for older adults with low vision (pp. 1-26).
- Wood, J., Lacherez, P., Black, A., Cole, M., Boon, M. & Kerr, G. (2011). Risk of falls, injurious falls, and other injuries resulting from vision impairment among older adults with age-related macular degeneration. *Investigative Ophthalmology and Visual Science*, 52, 5088–5092. Doi:10.1167/iovs.10-6644
- The World Health Organization (2007). WHO Global Report on Falls Prevention in Older Age. Retrieved September, 2015, from http://www.who.int/ageing /publications/Falls_prevention7March.pdf
- The World Health Organization. (2013). Visual Impairment and Blindness. Retrieved March, 2014, from http://www.who.int/mediacentre/factsheets/fs282/en/
| Authors | Year | Title | Intervention | Vision Related Inclusion Criteria | Outcomes |
|-------------------|------|---|---|---|---|
| Campbell et al. | 2005 | Randomised controlled trial of prevention of falls in people aged $>$ or =75 with severe visual impairment: the VIP trial. | Home modification using a
modified Westmead evaluation,
adapted Otago intervention, and
vitamin D, and social visits. | Participants had acuity less than 6/24. The modified home assessment was developed for persons with visual impairment. Audio recordings of exercise instructions were provided. | Use of the home assessment
significantly reduced falls (IRR
0.59) while exercise (IRR 1.15) did
not. |
| Chen et al. | 2012 | The effects of Tai Chi on the
balance control of elderly
persons with visual
impairment: A randomized
clinical trial. | Tai Chi | Participants were recruited based
on acuity measures. | Tai Chi resulted in improved knee
proprioception ($p = 0.032$) as well
as vestibular ratios ($p = 0.006$). |
| Elley et al. | 2008 | Effectiveness of a falls-and-
fracture nurse coordinator to
reduce falls: A randomized,
controlled trial of at-risk older
adults. | Multi-component (Nurse
fall-risk assessment, needed
referrals, and completion of
the <i>Otago</i> Exercise
Intervention). | A nurse completed vision exam
and referred to eye care as needed. | There were no significant
differences between the intervention
group and participants receiving
standard care and social visits (IRR
0.96). |
| Fitzharris et al. | 2010 | The Whitehorse NoFalls trial:
Effects on fall rates and
injurious fall rates. | Multi-component
(combinations of exercise,
vision assessment, and home
modification). | Referral to the participant's usual
eye-care provider if their vision
tested below a predetermined
criteria. | Exercise group experienced fewer
falls (IRR 0.79). Vision assessment
plus exercise led to the fewest falls
that resulted in injury (IRR 0.48). |
| Fox et al. | 2010 | A randomized trial of a multifaceted intervention to reduce falls among community-dwelling adults. | Multi-component (NMF!
add-on to the Preventive
Healthcare for the Aging
Program). | Acknowledged visual impairment
as a falls risk factor and included
vision assessment as part of
comprehensive screen. | No significant differences between intervention and control groups for falls ($p < .12$). |
| Garcia et al. | 2012 | Promoting Fall Self-Efficacy
and Fall Risk Awareness in
Older Adults. | Multi-component program (<i>Stepping-On</i>). | Included a vision education module. | Modified Falls Efficacy Scale, Timed
Up and Go, and Romberg Balance
scores showed no significant change
post intervention (<i>p</i> values not
reported). Participants reported
increased ability to identify fall risks. |

. .

•

Table 1: Descriptions of studies included in the review

· · ·

Authors	Year	Title	Intervention	Vision Related Inclusion Criteria	Outcomes
Gleeson et al.	2015	Can the Alexander Technique improve balance and mobility in older adults with visual impairments? A randomized controlled trial.	The Alexander Technique	Participants recruited from organization providing service for persons with visual impairment.	No significant differences in the falls (IRR 0.64) and injury rate between intervention and usual care groups (IRR 0.61).
Huang et al.	2010	Community-based interventions to reduce falls among older adults in Taiwan – Long time follow-up randomized controlled study.	Tai Chi with and without education (nutrition, medication, proper footwear, inside and outside safety)	Discussed low vision safety during education talks throughout tai chi.	Tai Chi alone (OR 0.13) and with education (OR 0.27) reduced falls risk. Receiving both tai chi and exercise showed a significant decrease in falls over a shorter amount of time ($p = 0.0001$).
Jeter et al.	2015	Ashtanga-based yoga therapy increases the sensory contribution to postural stability in visually- impaired persons at risk for falls as measured by the Wii Balance Board: A pilot randomized controlled trial.	Ashtanga-based Yoga Therapy program	Participants with acuity worse than 20/200, visual field less than 20°, and/or stable eye condition. Researchers utilized detailed hands-on instructions to assist individuals with visual impairment.	Significant increases in center of pressure $(p = 0.01)$ and somatosensory and $(p = 0.04)$ vestibular balance measures $(p = 0.04)$ using a WII balance board compared to controls.
La Grow et al	. 2006	Reducing hazard related falls in people 75 years and older with significant visual impairment: How did a successful program work?	Home modification (modified Westmead) compared to <i>The Otaga</i> <i>Intervention</i> and Vitamin D use, or social groups	Participants recruited with distance visual acuity of 6/24 meters or worse. The home safety program was developed for persons with visual impairment.	Compared to social visits, the home program decreased more falls caused by environmental hazards (IRR 0.40) and falls without reported hazards (IRR 0.43).
Lee et al.	2013	Effects of a multifactorial fall prevention program on fall incidence and physical function in community-dwelling older adults with risk of falls.	Multi-component (exercise, health education, home modification, medication review, eye care referral)	Researchers measured contrast sensitivity. Participants were referred to eye care professionals as needed.	The intervention group showed significant improvement in fall risk ($p = 0.004$), Timed Up and Go ($p = 0.001$), reaction time ($p = 0.02$), and postural sway scores ($p = 0.006$).
Lord et al.	2005	The effect of an individualized fall prevention program on fall risks and falls in older people: A randomized control trial.	Individualized multi- component (individualized to address vision, exercise, and sensation).	Included referrals to an eye care specialist and delivery of new glasses as needed. Described extensive education including use of single lens spectacles.	The intervention significantly decreased falls risk scores ($p < 0.05$). No significant differences of falls occurrences between groups (intervention n = 183, control n = 175).

•	•	•		•
•	•	•	•	•

Table 1: Continued

Authors	Year	Title	Intervention	Vision Related Inclusion Criteria	Outcomes
Mahoney et al.	2007	Kenosha County falls prevention study: A randomized, controlled trial of an intermediate-intensity, community-based multifactorial falls intervention.	Algorithm to determine multi-component intervention (assessed distant vision, medications, home function/safety, balance and gait, and some neurological deficits.)	Included impaired distance vision as a risk factor in falls prevention algorithm.	No significant difference of fall rates between intervention and control groups ($p = 0.27$). Rate of falls significantly decreased for participants with Mini-Mental State Examination scores below 27 ($p = 0.05$).
Pérula et al.	2012	Effectiveness of a multifactorial intervention program to reduce falls incidence among community-living older adults: A randomized controlled trial.	Multi-component (individualized advice, exercise, and home visits).	Utilized vision as an outcome measure for statistical regression.	No significant difference for total falls $(p = 0.56)$. Participants in the intervention group had significantly fewer falls within the home than those in the control group $(p = 0.04)$.
Reed-Jones et al.	2012	Vision and agility training in community-dwelling older adults: Incorporating visual training into programs for fall prevention.	Vision and agility training, or exercise	Included visual training using the Nintendo® Wii Fit Plus with Wii Balance Board.	Vision training provided greatest increase (22%) in obstacle course performance.
Salminem et al.	2009	Effect of a risk-based multifactorial fall prevention program on the incidence of falls.	Multi-component (geriatric assessment of multiple fall risk components, exercise, home modification, falls prevention lectures, social groups)	Referred participants to an ophthalmologist if distance visual acuity was less than 0.5 using a Snellen Chart, there was a difference in vision between eye greater than 0.3, or if there were reports regarding vision concerns.	The intervention did not significantly reduce falls (IRR 0.92) however falls were significantly decreased for participants with higher occurrence of depression symptoms (IRR 0.50). The intervention significantly reduced falls with participants that had three or more previous falls (IRR 0.59) or had greater self-perceived risk of falling (IRR 0.77).
Shumway- Cook et al.	2007	Effectiveness of a community- based multifactorial intervention on falls and fall risk factors in community- living older adults: a randomized, controlled trial.	Multi-component (exercise, falls prevention education, risk assessment)	Discussed vision as a falls risk factor and included vision assessment.	No significant difference for falls rate. There were significant improvements for the Timed Up and Go (mean difference -0.7), Berg Balance (mean difference +1.5 points), and Chair Stand scores (mean difference +1.2).

*IRR = incidence rate ratio; OR = odds ratio

INCREASING THE VISUAL ACCESSIBILITY OF A FALLS PREVENTION INTERVENTION FOR OLDER ADULTS WITH LOW VISION

SARAH E. BLAYLOCK, CYNTHIA J. BROWN, MARY WARREN, DONALD LEIN

Submitted to *The Gerontologist* Format adapted for dissertation

ABSTRACT

Introduction. Falls prevention interventions designed specifically for older adults with low vision are limited. The purpose of this study was to produce and pilot test a visually accessible version of an evidence-based intervention for community-dwelling older adults with low vision receiving services through the Southeastern Blind Rehabilitation Center (SBRC). Methods. We used the ADAPT-ITT model to develop an accessible version of the Study of Accidental Falls in the Elderly (SAFE) Health Behavior and Exercise intervention. We piloted the intervention with nine veterans receiving services at SBRC using a quasi-experimental, pre-post intervention design. **Results.** We found that participants significantly increased their test scores of intervention content post class attendance and maintained the scores at one-month follow-up. Participants also reported knowing more regarding falls prevention strategies compared to before intervention completion. **Discussion.** Using the pilot test results, it is recommended to continue using the SAFE intervention within the SBRC following minor changes based on study findings.

INTRODUCTION

Falls are the leading cause of nonfatal and fatal injuries for adults over age 65, with an estimated 2.5 million older adults treated in emergency rooms annually and 734,000 requiring hospitalization.¹ Falls and related injuries account for approximately \$30 billion in annual medical expenditures in the United States (US).^{3,4} By 2020, annual fall-related costs are expected to reach \$67.7 billion driven by the rapid growth of the older adult population in the US.⁴

Older adults with low vision - visual limitation that cannot be corrected through medical intervention - are at an increased risk for falls.⁵⁻¹³ Crews et al⁶ found that significantly more older adults with severe visual impairment experienced falls (46.7%) when compared to those without impairment (27.7%). Visual impairment significantly increases an individual's risk for fall-related injuries, especially hip fractures, and is strongly associated with fall risk factors including decreased step accuracy, postural instability, greater fear of falling, decreased balance, depression, and decreased physical activity.¹⁴⁻²⁰ The number of older adults in the US with low vision is expected to rise to over 5 million by 2030.²¹

Falls prevention interventions designed specifically for older adults with low vision are limited.⁶ The Centers for Disease Control and Prevention (CDC) published a compendium consisting of the most successful, evidence-based falls prevention interventions for older adults.²² For most studies, the educational content of the interventions (i.e. handouts and slide presentations) made no allowances for persons with

low vision who experience limitations in their ability to read common text, even with magnification and to discern details, color, and low contrast features in environments. Thus, these interventions are most likely inaccessible to participants with low vision.^{6,23}

Accessible versions of evidence-based falls prevention interventions are needed to ensure that older adults with vision impairment receive equivalent benefit from falls prevention interventions as normally sighted adults. We sought to address the need for accessible interventions for individuals with low vision by adapting a CDC recommended program titled: The Study for Accidental Falls in the Elderly (SAFE) Health Behavior and Exercise intervention.²⁴ The purpose of this study was to produce and pilot test a visually accessible version of an evidence-based intervention for community-dwelling older adults with low vision.

METHODS

The University of Alabama at Birmingham (UAB) and Birmingham Department of Veteran Affairs Medical Center institutional review boards approved this study.

Intervention modification process

We used the ADAPT-ITT model to modify a falls prevention intervention for individuals with low vision. The ADAPT-ITT model, which was originally developed for adapting health promotion interventions for individuals with HIV, provides a guide to developing methodology to modify and test existing evidence-based health promotion interventions for target populations.²⁴⁻²⁶ The model consists of eight steps: 1) assessing the health risk and needs of the population of interest, 2) selecting an intervention based on the needs of relevant individuals, 3) receiving feedback regarding the original

intervention by members of the target population, 4) developing an adapted draft maintaining fidelity to the original intervention, 5) soliciting topical experts to review the adapted draft, 6) integrating expert feedback into the design of the modified intervention 7) training qualified persons to deliver the intervention and gather data, and 8) completing pilot testing to test the intervention.²⁴ All steps were completed during this study. The only modification was the combination of steps 3 and 5 to allow selected experts to provide feedback of the original and adapted interventions during a single session.

Assessing the health risk and needs of the target population

We utilized results from a qualitative study to better understand the current status of falls prevention services available to older adults with low vision and to provide information regarding the key modifications required to create visually accessible falls prevention intervention materials.²⁷ Ten community-dwelling older adults with low vision diagnoses that interfered with reading completed face-to-face, semi-structured interviews. Interview questions elicited information on how to improve the visibility (e.g. how easily printed text can be seen and navigated) and readability (how quickly and easily a person can understand the content) of intervention materials.

When questioned on falls history, all of the study participants reported having fallen at least one time and affirmed a lack of falls prevention services. Although all participants had fallen, only one individual reported having received falls prevention education while receiving rehabilitation services for other reasons. No participants had received falls prevention services prior to a first fall or as a direct result of falling.

When questioned about text visibility and reading, the participants identified four characteristics that enhanced text visibility and/or readability: enlarged font size, a sanserif e.g. block style font, high contrast between the text and the page, and structured organization of content through use of bullet points and simplified information. The participants' suggested modifications aligned with guidelines on accessible print published by the American Foundation for the Blind and American Printing House for the Blind.²⁸ Recommendations included: enlarging titles to 20-point font and content to 16-point font, using only san-serif font, having 1.5 spacing between lines, bolding all titles, using bullet points and tables to organize text, and removing the use of paragraphs. **Selecting an intervention based on the needs of older adults with low vision**

The authors selected the SAFE intervention developed by Hornbrook et al in 1994²⁹ to modify for older adults with low vision because it provided an evidence-based, cost-effective group intervention that could be conducted within healthcare and community settings. The intervention is delivered through four, educational group sessions that heavily rely on educational media that requires intact vision. The classes address physical, behavioral, and environmental factors that a person can modify to reduce falls risk (see Table 1). The age of the intervention also provided an opportunity to update the content to adhere to current nutrition and exercise guidelines and ensure that program components met current recommendations for facilitating health literacy.

Developing an adapted draft

Recommendations from the low vision participants in the qualitative study were used to improve the visibility and readability of the educational handouts. The SAFE intervention was developed prior to research conducted on functional health literacy that

showed the importance of simplifying words and text to enhance readability and comprehension of health materials.³⁰ Adults with low vision struggle to read printed health education materials that are not visually accessible and as a result have lower functional health literacy levels than normally sighed adults.³¹ To improve readability, intervention handouts were modified to adhere to recommendations from the *TOOLKIT for Making Written Material Clear and Effective* developed by the US Department of Health and Human Services, specifically the guidelines in part 9 of the toolkit that addressed facilitating health literacy in older adults.³⁰ The modifications to improve text readability focused on simplifying the wording of the content and included: reducing the length of sentences, using high frequency words, avoiding medical jargon, abbreviations and acronyms, rewording sentences to use active voice, and reformatting paragraphs into bulleted statements.

Expert topical review on readability and visibility of the handouts

Content experts were recruited to evaluate the readability, visibility, and accuracy of the materials. A university faculty member with expertise in low vision and health literacy reviewed the first version of the modified handouts for text visibility and readability and the handouts were revised to incorporate the faculty member's suggestions. Three content experts then reviewed the accuracy of the information provided in their content area to ensure that it aligned with current medical guidelines. A geriatric physician who specializes in mobility and falls prevention reviewed the medication safety content. A registered dietitian who provides health education on nutrition in a university-based osteoporosis clinic and directs a dietetic internship reviewed the calcium handouts. A physical therapist who specializes in exercise

development and health promotion for older adults reviewed the falls prevention exercises. The handouts were revised a second time to incorporate the feedback from the content experts, and a second health literacy expert reviewed the newly revised handouts for readability. Table 2 describes the revisions made to the handouts based on the expert reviews.

Six occupational therapists with expertise in low vision rehabilitation were recruited to review the original and adapted handouts to determine if the modified versions were more visually accessible. The experts also were asked their opinion regarding the availability of falls prevention programs for older adults with low vision. Inclusion criteria for the occupational therapy experts included formal education and/or credentialing in low vision rehabilitation and a minimum of two years providing low vision rehabilitation to adults with age-related eye disease at least 16 hours per week. The therapists reviewed the handouts, completed a 9 item online survey with Likert scaling (Table 3) that asked them to assess the value of the modifications made to handouts. After the survey was completed, Author (SB) conducted a follow up telephone call with each expert to solicit a rationale for their survey answers and additional feedback on how to strengthen the printed handouts.

Likert responses to the survey were analyzed as a dichotomous variable with 'agree' being strongly agree or agree and 'disagree' being neutral, disagree, or strongly disagree. Using these criteria, all but one expert agreed that there are limited falls prevention interventions for older adults with low vision. The single dissenting expert offered this justification during the follow-up interview: "This question is hard to answer but ultimately it comes down to creativity. Using an eclectic approach typically allows

targeting of the problem. I do agree that as far as set, multi-component interventions, they are not great for people with low vision." All five participants agreed with remaining Likert questions verifying that the modified handouts were visually accessible.

As a final step to ensure the content validity of modified intervention, five older adults with low vision were recruited to compare the modified handouts with the original handouts for ease in reading and comprehension and provide additional recommendations to improve the modified handouts. To participate, individuals had to be 65 years old or older, community dwelling, and have a documented diagnosis of a condition causing low vision that interferes with reading. A face-to-face interview was conducted in the participant's home. The participants read three excerpts from the original handout and were interviewed about their ability to see the words and read the sentences on the page. The process was repeated using corresponding excerpts from the modified handout. Participants were then tested on their comprehension of the original and modified materials by reading the handout on how to manage daily calcium intake and then locating how much calcium was in one serving of whole milk from a table. Lastly, participants used a Likert scale to rate the modified handouts (Table 4) and provided suggestions to improve the handouts. Field notes were recorded during the visit to verify accuracy.

When asked to read the original, un-adapted handouts, four participants responded that they were unable to read the information. One participant stated, "I could probably read this but it is going to take too long and honestly, I don't want to take the time." One participant who used a magnifier to read a 258-word excerpt from the original handout took approximately 10 minutes to read the passage aloud. Although the participant

accurately read the excerpt she was unable to locate the amount of calcium in whole milk on the table. In contrast, all participants were able to read the adapted handouts and find the correct amount of calcium. One participant stated "Yes, this is much better. I can make out the letters and where everything is. I still need my magnifier but I can do much better." All participants reported that the block style font and the organization of the handouts was helpful and did not suggest additional modifications. The five participants responded, "strongly agree" to the survey questions.

Training qualified persons to deliver the intervention and gather data

The intervention was piloted at the Southeastern Blind Rehabilitation Center (SBRC) within the Department of Veteran Affairs. The center provides a residential low vision rehabilitation program to enable veterans with low vision or blindness to regain independence in activities of daily living. This site was chosen based on the need for accessible falls prevention education within the facility and the availability of older adults with low vision to complete a four-week intervention while residing in a common facility.

Author SB delivered the intervention during piloting. SB developed a checklist developed using the intervention manual to support intervention fidelity during piloting. To mitigate investigator bias during data collection, three masters level occupational therapy students were trained to gather data on the outcome measures. Though the students were aware of the study's purpose, they were never told the correct responses to outcome measure questions and had no personal benefit from the success of the intervention. Each student practiced completing the measures on SB prior to

administering them to study participants and was observed for accuracy during their first session with a participant.

Pilot testing

We used convenience sampling to recruit participants. Inclusion criteria included: veterans receiving services at SBRC; 60 years of age or older; remaining functional vision allowing for reading (with or without use of magnifying devices); sufficient hearing (hearing threshold < 25 dB HI); and less than 2 weeks since admission to SBRC to allow for intervention completion.

Four groups of participants completed the modified SAFE intervention. The number of participants in each group ranged from two to three. The participants attended intervention classes two times per week; each class lasted approximately 60 minutes. The classes were taught in the SBRC dining room. The well-lit room is used daily by the participants. The room was cleared of distractions with the doors closed to eliminate additional noise during the intervention sessions. The participants sat around a single table to allow for discussion and were encouraged to bring any devices typically used for reading. There was also available space on one side of the room for demonstration and practice of recommended exercises. All participants received a binder of the modified handouts to refer to during and between classes and use as a resource after the intervention. Each handout was separated by a large divider to promote easy access to the binder contents.

The four classes were primarily led by author SB with frequent opportunities for participants to discuss the topics and ask questions. Each class began with a 15-minute general description of the contents of the day's session (Table 1). For classes 2-4, the first

15 minutes also included a homework review. The following 30-40 minutes included a discussion of the daily topic. For example, during class 1, participants spent this time learning about the dangers of falls, analysis of risky behaviors, and aerobic exercise using the corresponding handouts. For classes 2-4, there was also an exercise component where the participants learned approximately 3 new exercises to increase strength, balance, or flexibility. The final 15-minutes allowed for a brief review of the daily topics and an opportunity for questions from the participants.

Author SB facilitated discussion among the participants on the weekly session topic and used a checklist to ensure each class covered the required information from the intervention manual. SB checked that each person could locate the appropriate handout in the binder to use for the class session and between sessions. When reviewing exercises, SB first verbally described each exercise while the participant followed the information in the binder then assisted each participant to ensure he or she was properly completing the exercise. SB required each participant to independently replicate the exercises and verbalize the recommended intensity and duration of each exercise prior to continuing the session. During the final 15 minutes of the class, SB asked participants to summarize the content reviewed during the session in order to verify the participants' understanding.

Descriptive measures

Descriptive measures were completed at baseline to describe the sample. Measures of acuity, contrast sensitivity, and visual field were used to ascertain and describe the participant's ability to use vision to read. We selected additional measures to provide a description of factors commonly associated with increased fall risk including depression, global health, social participation, and physical performance and recorded

whether the participant had experienced a fall within the last year. Although there was no expectation of improvement on these measures pre and post intervention due to the short time frame of the study (post or one-month following the intervention), as important falls risk factors we felt they were needed to thoroughly describe the sample.

A low vision optometrist from the center assessed the visual function of each participant including distance acuity, contrast sensitivity, and visual field. These three visual functions are commonly impaired in persons with low vision and all may affect reading performance.^{6,23} Participants were assessed using their habitual correction. The optometrist used a Snellen chart³⁴ to measure distance visual acuity for all but two participants who were tested with the Feinbloom³⁵ acuity chart. The Peli-Robson chart³⁶ was used to assess contrast sensitivity. The Peli-Robson is widely used in research to measure letter by letter contrast acuity. Visual field was measured using a Zeiss Humphrey Field Analyzer³⁷ or a Goldmann perimeter.³⁸

Three Patient Reported Outcome Measurement System (PROMIS) measures were used to describe the participants' health and participation: The Satisfaction with Participation in Social Roles Short Form, the Emotional Distress-Depression Short Form, and the Global Health Short Form.³⁹ The global health assessment is divided into two factors for scoring, a physical health component and a mental health component. The PROMIS assessments were selected because each had undergone psychometric testing to provide reliable and valid measures of a person's health. Raw scores are converted to standardized *t*-scores on the PROMIS measures; each assessment has a mean of 50 ± 10 . A score >50 indicates more of the concept being measured (depression, participation, etc.) compared to the norms of the population.³⁹

We utilized the Short Physical Performance Battery (SPPB)³³ to describe the lower extremity performance of the participating veterans. Research shows the SPPB is reliable and valid for use with older adults with intraclass correlation coefficients ranging from 0.88 - 0.92 (measures completed 1-week apart).⁴² The SPPB score is determined through three timed evaluations including standing balance, gait speed, and sit-to-stand tests. Scores range from 0-12;⁴⁰ an SPPB score of ≤ 6 is associated with an increased risk of recurrent falling.⁴¹

Outcome measures

We selected four outcome measures to assess the effect of the intervention. We created a short knowledge assessment comprised of multiple choice and verbal answers to test the participants' understanding of the intervention content. We developed a set of questions using Likert ratings to assess whether participants believed that they had benefited from the intervention and felt that they knew more about how to low their risk for a fall after attending class attendance compared to before. Lastly, because two goals of the original SAFE intervention were to use education to increase mobility and decrease fear of falling, we also included measures to assess mobility and fear of falling one day and one month after the intervention concluded.

Knowledge assessment. Participants completed a knowledge test to assess their understanding of the content provided in each class; the measure was administered one day before the intervention, one day after the intervention, and one month after the intervention. The knowledge test consisted of 12 items for a maximum score of 100%. The first component of the measure was a 10-item multiple-choice quiz to assess comprehension and retention of intervention content. The quiz consisted of one question

on each topic described in the intervention manual. Topics included: factors that lead to falls, what to do if you fall, daily calcium and vitamin D intake, walking, strength and balance exercises, appropriate footwear, home modification, risky behaviors, and questions to ask healthcare providers. Each question had four possible, multiple-choice answers.

For the second component of the measure, participants were asked to "teach back" two educational components provided in the intervention. The teach-back method is commonly used to increase comprehension of health education content and has been shown to be an effective method to assess learning.^{43,44} The Teach-back questions addressed calculation of calcium in a food item (whole milk) and strategies used for safe medication management. The wording of the questions and answers were reviewed by an occupational therapist with expertise in low vision and health literacy but the test was not piloted on the target population. Participant answers were recorded verbatim on the measurement packets. Questions were scored wrong if the participant reported an incorrect value for calcium or if the participants reported a medication management strategy deemed unsafe by the authors.

Perceived learning and feedback. Retrospective pre-post data was collected following the intervention to determine how much the participants believed they learned from the classes. The pre-post design^{45,46} was selected because it has been shown to solicit a more accurate self-report assessment from participants as to their change in knowledge or understanding of a newly learned topic. Participants with limited or no knowledge of a subject may overestimate their understanding of the subject based on a false perception of knowledge. Allowing the participants to reflect on their pre-

intervention knowledge compared to current knowledge following the intervention, provides a more accurate assessment of self-reported gains in understanding.^{45,46} Participants were first asked to rank their knowledge of falls prevention strategies after attending the class on a scale of 1 to 10 (10 being complete knowledge). Then, each participant used the same scale to rank falls prevention knowledge before the intervention.

Immediately after ranking their knowledge of falls prevention strategies, participants were asked to provide verbal feedback on the intervention content. The participant was asked to provide a general opinion of the intervention, if the materials were accessible, and the changes needed to strengthen the class content/presentation. The responses were recorded verbatim on the measurement packet.

Fear of falling and life space assessment. Participants completed two measures to assess fear of falling and mobility before and after intervention. The Falls Efficacy Scale-International (FES-I),⁴⁷ was administered at pre, post, and follow-up time points to assess fear of falling. The FES-I is a 16-item questionnaire- wherein a participant uses a four-point Likert scale to rate his or her possibility of falling when performing various activities. The values from each question are summed to calculate a score ranging from 16 to 64 with a higher score indicating a greater fear of falling. In a community-dwelling older adult population, the FES-I showed excellent internal consistency (Cronbach's alpha values of 0.96 and 0.92) and test-retest reliability (ICC of 0.96 and 0.83).⁴⁸

The second measure, the UAB Life-Space Assessment (LSA), was administered one day prior to and one-month following intervention delivery. The LSA is a validated measure of an individual's pattern of mobility determined by the distances a person

typically travels to during the month prior to the assessment date.^{49,50} Questions in the assessment address places traveled, with locations ranging from within the individual's home to outside of an individual's town. A composite score consists of where and how often one travels and the amount of assistance required from equipment or another person.⁵⁰ Composite scores range from 0 to 120 with higher scores representing greater mobility with less assistance. The LSA was selected because it provided a standardized method to assess and compare the actual places traveled within a one-month period. The assessment has a test-retest reliability with an ICC of 0.96.⁵⁰

Data analysis

Descriptive statistics were used to describe the sample. To test the comprehension and retention of the intervention content as well as it's effect on fear of falling and mobility, we compared the pre-post and pre-follow-up scores of the knowledge tests, Falls Efficacy Scale-1, and LSA. Due to small sample size, we utilized a Wilcoxon Signed Ranks test to assess the pre-post and pre-follow-up scores. For perceived learning data, we used the change in pre-to-post scores to assess the ordinal data.

RESULTS

Description of participants

Nine participants completed pre and post measures for the piloting of the falls prevention class (eight males and one female). Five of the participants completed followup measures. Three additional individuals signed informed consent forms but did not participate due to illness (2) and schedule conflict (1). Two participants were African American and seven were Caucasian. Participant ages ranged from 64 years to above 90 years. All had graduated from high school; six completed college; all lived within the

community in apartments and single family homes. All participants reported having fallen at least one time within the last year.

Age, vision measures, and vision diagnoses for all participants are summarized in Table 5. Participants had a range of diagnoses causing low vision including glaucoma, diabetic retinopathy, age-related macular degeneration, and hemianopia. Using the World Health Organization levels of visual impairment, ⁵¹ 56% of participants had Snellen visual acuity scores below the diagnostic range for low vision (20/80): one with normal acuity (20/20) and four with near-normal vision (20/30-20/60). The participants with normal or near normal acuity presented with significant contrast sensitivity and visual field deficits that interfered with reading ability. Forty-four percent of participants had Snellen acuities falling within low vision diagnostic categories: one with moderate low vision (20/80-20/160), one with severe low vision (20/200-20/400), and two with profound low vision (20/500-20/1000). All participants had scores below 1.5 (range 0.45-1.35) on the Peli Robson test chart indicating impaired contrast sensitivity.⁵² Two individuals were unable to complete contrast sensitivity assessment due to difficulty reading the font size on the chart. Two participants had near normal visual fields (field >100°) while four had partial loss with fields ranging between 20° and 100°. Three individuals had severely restricted visual fields (field less than 20°).

Additional descriptive measures provided detail on the physical and emotional characteristics of participants. On the PROMIS measures, participants rated their global mental health approximately three points above the standardized t-score (53.1±7.8) indicating that their perceived mental abilities were close to the population mean. Participants reported experiencing fewer feelings of depression compared to the

population average (47.6 \pm 7.4) and were slightly less satisfied with participation in daily activities (46.7 \pm 12.6). The participants rated their global physical health approximately eight points lower than the established population mean indicating self-perceived deficits in physical health (43.0 \pm 7.1). The mean Short Physical Performance Battery score for participants was slightly higher than the value defining individuals at increased risk of recurrent falling (6.3 \pm 3.2).

Effectiveness of the intervention

Knowledge. Using the knowledge test, participants answered 12 questions regarding class content. Eight participants increased their score on the test following intervention and one participant had the same score pre and post. The participants' median score on the multiple-choice and teach-back test of intervention content before the intervention was 60% (maximum score of 100%). Following the intervention, the median score increased to 80% (Z=-2.4, p < 0.02). The median test score (90%) remained significantly higher than scores before the intervention (Z=-2.0, p=.04) for the five participants who completed the test 30 days post intervention,

The most commonly missed questions pre-intervention asked about daily calcium values (78%) and daily vitamin D values (67%). Post intervention, 22% of participants missed the calcium question and 33% missed the vitamin D question. For the pre-intervention teach-back questions, 33% of participants answered both questions correctly and 67% missed one question (calculation of calcium). Following intervention, 67% participants answered both questions correctly and 33% missed the calcium calculation.

Perceived learning. Using retrospective pre-post measures, participants estimated how much they believed they now knew about falls prevention after receiving

the intervention compared to before using a 10-point scale (10 being complete knowledge). All of the participants (100%) reported an increase in learning from pre to post intervention. The increases in perceived learning ranged from one to eight points. Thirty-three percent of participants reported a score of 10 after attending the class indicating a perception of complete understanding of the falls prevention content. Perceived learning scores detailed in Table 6.

FES-1 and LSA. The assessments for fear of falling (pre and post) and mobility (pre and follow-up) showed no significant change after intervention. The one-day post intervention median FES-1 score (33) was 13 points lower than pre-intervention FES-1 score (46) which suggests a decrease in fear of falling, but the values were not significantly different (Z=-1.6. p=.11). The median one-month follow-up FES-1 score (28) was 18 points lower than the pre intervention median, but the value was still not significantly different than the average pre class score (Z=-1.8, p=0.08). The median Life Space Assessment score increased 8 points from 52 pre intervention to 60 at the one-month follow-up, suggesting an increase in life space, but the value was not statistically significant (Z=-.4 p=.72).

Verbal feedback. All participants provided positive feedback regarding the intervention and no participants described negative components or suggested changes. Multiple participants stated the course should be a permanent installment within the SBRC and accessible to veterans of all ages receiving services. Participant quotes are provided in Table 7.

DISCUSSION

This study pilot tested a visually accessible version of an evidence-based falls risk prevention intervention for community-dwelling older adults with low vision. Participants receiving the visually accessible handouts significantly increased their knowledge of the intervention content from their baseline level before intervention and were able to retain that knowledge for one-month post intervention. In addition, participants perceived that that they had a better understanding of the content material after the intervention than before the intervention began and they expressed satisfaction with the intervention. Participants did not significantly decrease their fear of falling or increase their mobility post intervention, most likely due to the small sample size and short time frame of the intervention.

We will make changes prior to using the intervention again within the SBRC. The median score post intervention was 80% and only 33% of the participants had a perceived learning score of 10 post intervention. This finding suggests a need to improve intervention delivery. Participants committed similar errors on questions, especially those with numerical responses (i.e. calcium and vitamin D values). We will dedicate additional class time to reviewing nutrition content including one homework assignment to check participant completion of calcium and vitamin D calculation.

The study participants were representative of a typical population receiving services through the VA Blind Rehabilitation Centers.^{54,55} The SBRC low vision services were comparable to those provided at other Blind Rehabilitation Centers.⁵⁴ The study participants were male, mostly Caucasian and over the age of 60 years. Similarly, the mean age of veterans receiving services from Blind Rehabilitation Centers nationwide is

80±10.5 with approximately 97.2% of veterans being male and 90.4% Caucasian, matching the participants of our sample.⁵⁴⁻⁵⁵ In addition, the participants in our study had a higher mean level of educational attainment (14.7 years) compared to the typical years of education reported by the VA (12.6 years).

The study participants shared similar qualities to non-veteran older adults with low vision. All of the participants reported having experienced one or more falls which is consistent with research showing that older visually impaired adults are vulnerable to falls.⁵⁻¹³ The participants predominantly had low vision from age-related eye disease including age-related macular degeneration, glaucoma, and diabetic retinopathy. The participants self-reported physical performance was below the population mean and their SPPB scores were only slightly above the value defining an increased risk of recurrent falling. This finding is consistent with research showing that older adults with low vision tend to be weaker, less physically active, and demonstrate decreased balance.¹⁴⁻²⁰

The study participants also presented with characteristics that may be unique to veterans receiving low vision services through the Blind Rehabilitation Centers. Whereas the study participants were male, research shows that the majority of older Americans with low vision are female.^{23,56-57} Most participants were also Caucasian, whereas minorities including African Americans, Hispanic Americans and Native Americans experience higher rates of vision impairment than Caucasian Americans.⁵⁶⁻⁵⁷ In addition, the study participants reported satisfaction with daily participation scores similar to the population norm and expressed fewer feelings of depression compared to the general population of older adults with low vision where depression rates as high as 70% have been reported.⁵³ This finding might be attributed to the level of support and intensity of

low vision rehabilitation services provided by the VA. Veterans receiving services at the SBRC receive individualized learning opportunities, community support, and low vision adaptive equipment/assistive technology. Non-veteran older adults do not receive comparable low vision rehabilitation services or community support and must pay for adaptive equipment and that may contribute to increased depression rates among the greater population of older adults with low vision.⁵⁴ Thus, the intervention should be piloted with a more representative sample of older adults with low vision prior to use outside of the VA system.

Our findings support the supposition that some CDC recommended falls interventions are not accessible to individuals with visual impairment.⁶ There was agreement between the occupational therapy experts in low vision and older adults with low vision that the content of the original SAFE intervention was not accessible to older adults with visual impairment. The participants with visual impairment who reviewed the original handouts strongly agreed that they had difficulty reading content and preferred the modified version because it was more visually accessible. Comments revealed they did not want to attempt to read the original intervention handouts. No participants could locate the correct number of calcium on the original handout but were successful with the modified content.

The use of non-accessible intervention materials is important because this problem extends into all areas of health education for older adults with low vision. The use of non-accessible materials to deliver health information and resulting feelings of limited health-related knowledge are common complaints among older adults with visual impairment.³¹ The number of older adults with visual impairment has been estimated to

increase to approximately 6.95 million by 2050.⁵⁸ Like all older adults, these individuals will be at increased risk for falls and will need to be able to adeptly manage multiple chronic conditions to reduce their risk of disability and continue to live independently. Inaccessible health education materials may needlessly create a preventable and easily remediable barrier to assisting these older adults to safely age-in-place.

Our results also indicate that some recommended evidence-based interventions may include not only visually in-accessible but also outdated content. The original SAFE intervention recommended in the CDC's most recent compendium was published in 1994²⁹ and included information on calcium, medication, and exercise instruction that did not align the current guidelines. When considering an intervention, it is important to note the year it was developed and review the educational content to ensure that it adheres to present guidelines.

Limitations

The findings of this study support implementation of the modified SAFE intervention within the SBRC. However, the study findings may not generalize to older adults with low vision who are ineligible for SBRC services. This pilot study also did not include a control group which prevented us from determining whether knowledge gains were due to solely to the intervention or resulted from a practice effect or regression to the mean. In addition, although the SBRC staff assured us that information from the SAFE intervention content was not regularly provided within the facility, veterans receive multiple co-interventions within the SBRC which might have included falls prevention. Also, although the outcome measures were validated for use with older adults, the psychometric properties of the selected tools may not have not been

established on a population that included persons with low vision. Having measures with mean values for older adults with low vision would provide a better comparison of scores.

Future directions

We plan to deliver the intervention within the SBRC using a larger sample. Before implementation, we will revise the presentation to include additional discussion of calcium and vitamin D intake to address the most commonly missed knowledge test questions. We will follow participants for a longer period of time and monitor the number of falls post intervention and additional falls related outcomes. We will include a control group to ensure the outcomes are due to participation, and not statistical regression or co-intervention. As well, we plan to deliver the intervention in a setting outside of the VA to determine the intervention's effectiveness with older adults in a more typical community setting.

REFERENCES

- Centers for Disease Control and Prevention. Falls among older adults: An overview. http://www.cdc.gov/homeandrecreationalsafety/falls/adultfalls.html. Accessed February 20, 2015.
- 2. Tinetti ME, Williams, CS. Falls, injuries due to falls, and the risk of admission to a nursing home. *NEJM*. 1997; 337: 1279-1284. Doi: 10.1056/NEJM199710303371806
- Stevens JA, Corso PS, Finkelstein EA, Miller TR. The costs of fatal and non-fatal falls among older adults. *Injury Prevention*. 2006; 12(5): 290-295. doi: 10.1136/ip.2005.011015
- Centers for Disease Control and Prevention. Costs of falls among older adults. http://www.cdc.gov/HomeandRecreationalSafety/Falls/fallcost.html. Published September 22, 2014. Accessed February 25, 2015.
- Adams T. Connecting falls to elder vision. OVS. 2014; 91(6): 591-592. doi: 10.1097/OPX.0000000000000292
- 6. Crews J, Chou C, Stevens J, Saaddine J. Falls among persons aged ≥ 65 years with and without severe vision impairment United States, 2014. *MMWR*. 2016; 65(17): 433-437. doi: http://dx.doi.org/10.15585/mmwr.mm6517a2
- Freeman EE, Muñoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: The Salisbury eye evaluation. *IOVS*. 2007; 48(10): 4445-4450. doi: 10.1167/iovs.07-0326
- 8. Lamoureux E, Gadgil S, Pesudovs K, et al. The relationship between visual function, duration and main causes of vision loss and falls in older people with low vision.

Graefes Arch Clin Exp Ophthalmol. 2010; 248(4): 527-533. doi: 10.1007/s00417-009-1260-x

- Lord SR, Smith ST, Menant JC. Vision and falls in older people: Risk factors and intervention strategies. Clin Geriatr Med. 2010; 26: 569–581. doi: 10.1016/j.cger.2010.06.002
- Reed-Jones RJ, Solis GR, Lawson KA, Loya AM, Cude-Islas D, Berger CS. Vision and falls: A multidisciplinary review of the contributions of visual impairment to falls among older adults. *Maturitas*. 2013; 75: 22–28. doi: 10.1016/j.maturitas.2013.01.019
- Szabo SM, Jannsen PA, Lord SR, Potter MJ. Neovascular AMD: An overlooked risk factor for injurious falls. *Osteoporos Int.* 2010; 21: 855-862. doi: 10.1007/s00198-009-1025-8
- Wood JM, Lacherez P, Black AA, Cole MH, Boon MY, Kerr GK. Risk of falls, injurious falls, and other injuries resulting from visual impairment among older adults with age-related macular degeneration. *IOVS*. 2011; 52(8): 5088-5092. doi: 10.1097/OPX.0b013e31822f4d6a
- National Eye Institute. Low vision frequently asked questions. https://www.nei.nih. gov/lowvision/content/faq. Accessed March 1, 2015.
- Willis JR, Vitale SE, Agrawal Y, Ramulu PY. Visual impairment, uncorrected refractive error, and objectively measured balance in the United States. *JAMA Ophthalmol.* 2013; 131(8): 1049-1056. doi: 10.1001/jamaophthalmol.2013.316
- Black AA, Wood JM, Lovie-Kitchin JE, Newman BM. Visual impairment and postural sway among older adults with glaucoma. *OVS*. 2008; 85(6): 489-497. doi: 10.1097/OPX.0b013e31817882db

- 16. Black A, Kim J, Wood J. Stepping accuracy and visuomotor control among older adults: Effect of target contrast and refractive blur. *OPO*. 2014;
 34(4): 470-478. doi: 10.1111/opo.12141
- Ramulu PR, Van Landingham SW, Massof, RW, Chan, ES, Ferrucci L, Friedman DS. Fear of falling and visual field loss from glaucoma. *Ophthalmology*. 2012; 119(7): 1352-1358. doi: 10.1016/j.ophtha.2012.01.037
- Van Landingham SW, Massof RW, Chan E, Friedman DS, Ramulu PY. Fear of falling in age-related macular degeneration. *BMC Ophthalmol.* 2014; 14(10). doi: 10.1186/1471-2415-14-10
- 19. Cox A, Blaikie A, MacEwen CJ, et al. Optometric and ophthalmic contact in elderly hip fracture patients with visual impairment. *Ophthal and Physl Opt.* 2005; 25(4): 357-362. doi: 10.1111/j.1475-1313.2005.00307.x
- Felson DT, Anderson, JJ, Hannan MT, Milton RC, Wilson PW, Kiel DP. Impaired vision and hip fracture: The Framingham Study. *J Am Geriatr Soc.* 1989; 37(6): 495-500. http://www.ncbi.nlm.nih.gov/pubmed/2715555
- 21. National Eye Institute. Prevalence of adult vision impairment and age-related eye diseases in America. https://www.nei.nih.gov/eyedata/adultvision_usa. Accessed February 23rd, 2015.
- 22. Stevens JA, Burns E. A CDC Compendium of effective fall interventions: What works for community-dwelling older adults. 3rd ed. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. 2015.
- Warren M, Barstow E, eds. Occupational Therapy Interventions for Adults with Low Vision. Bethesda, MD: American Occupational Therapy Association; 2011.

- 24. Wingood GM, DiClemente RJ. The ADAPT-ITT model: A novel method of adapting evidence-based HIV interventions. *J Acquir Immune Defic Syndr*. 2008 Mar 1; 47 Suppl 1: S40-46. doi: 10.1097/QAI.0b013e3181605df1
- 25. Latham TP, Sales JM, Boyce LS, Renfro TL, Wingood GM, DiClemente RJ, Rose E. Application of ADAPT-ITT: Adapting an evidence-based HIV prevention intervention for incarcerated African American adolescent females. *Health Promot Pract.* 2010 May; 11(3 Suppl): 53S-60S. doi: 10.1177/1524839910361433
- 26. Card J, Solomon J, Cunningham S. How to Adapt Effective Programs for Use in New Contexts. *Health Promotion Practice*. 2011; 12(1): 25-35. doi:10.1177/15248399093 48592
- 27. Blaylock S, Warren M, Vogtle LK. Accessible falls prevention interventions for older adults with low vision. *Top Geriatr Rehabil*. In press.
- Tips for making print more readable. American Foundation For the Blind website. http://www.afb.org/info/reading-and-writing/making-print-more-readable/35. 2016. Accessed May, 2016.
- 29. Hornbrook MC, Stevens VJ, Wingfield DJ, Hollis JF, Greenlick MR, Ory MG. Preventing falls among community-dwelling older persons: Results from a randomized trial. *The Gerontologist*. 1994; 34(1): 16–23. https://www.ncbi.nlm.nih.gov/pubmed/8150304
- 30. US Department of Health and Human Services. TOOLKIT for Making Written Material Clear and Effective. https://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/index.html?redirect=/writtenmaterialsto olkit/. Published 2012. Accessed June 2016.

- Warren M, DeCarlo DK, Dreer LE. Health literacy in older adults with and without low vision. *Am J Occup Ther.* 2016; 70(3). doi: 10.5014/ajot.2016.017400
- 32. U.S. Department of Health and Human Services. 2008 physical activity guidelines for Americans. https://health.gov/PAGuidelines/pdf/paguide.pdf. Accessed September 2016.
- 33. Giangregorio LM, McGill S, Wark JD, Laprade J, Heinonen A, Ashe MC, MacIntyre AM, Cheung AM, Shipp K, Keller H, Jain R, Papaioannou. Too fit to fracture: Outcomes of a Delphi consensus process on physical activity and exercise recommendations for adults with osteoporosis with or without vertebral fractures. *Osteoporosis Int.* 2015; 26: 891-910. doi: 10.1007/s00198-014-2881-4
- 34. Boslaugh S. Snellen's chart. In: Zhang Y., Encyclopedia of Global Health. Thousand Oaks, CA: Sage Publications, Inc; 2008: 1577.
- 35. Hardgrave N, Hatley J, Lewerenz D. Comparing LEA Numbers low vision book and Feinbloom visual acuity charts. *Optometry Vision Sci.* 2012; 89(11): 1611-1618. doi: 10.1097/OPX.0b013e31826ab10a
- 36. Elliott D, Sanderson K, Conkey K. The reliability of the Pelli-Robson contrast sensitivity chart. *OPO*. 1990; 10(1): doi: 10.1111/j.1475-1313.1990.tb01100.x
- 37. Landers J, Sharma A, Goldberg I, Graham S. A comparison of visual field sensitivities between the Medmont automated perimeter and the Humphrey field analyzer. *Clin Exp Ophthalmol.* 2010; 38(3): 273-276. doi: 10.1111/j.1442-9071.2010.02246.x
- 38. Dersu I, Wiggins M, Luther A, Harper R, Chacko J. Understanding visual fields, partI: Goldmann perimetry. *JOMT*. 2006; 2(2). doi: http://www.jomtonline.com/jomt/

articles/volumes/2/2/visualfields.pdf

- 39. National Institutes of Health. PROMIS: Dynamic tools to measure health outcomes from the patient perspective. http://www.nihpromis.org/patients/measures. Accessed March 1, 2015.
- 40. Puthoff ML. Outcome measures in cardiopulmonary physical therapy: Short physical performance battery. *Cardiopulmonary PT J.* 2008; 19(1): 17-22. http://www.ncbi. nlm.nih.gov/pmc/articles/PMC2845214/
- 41. Pavasini, R., et al. Short Physical Performance Battery and all-cause mortality: Systematic review and meta-analysis. *BMC Medicine*. 2016;14(215). doi: 10.1186/s12916-016-0763-7
- 42. Volpato S, Cavalieri M, Sioulis F, Guerra G, Maraldi C, Zuliani G, Fellin R, Guralnik J. Predictive value of the Short Physical Performance Battery following hospitalization in older patients. *J Gerontol.* 2011; 66a(1): 89-96. doi: https://doi.org/10.1093/gerona/ glq167
- 43. Schillinger D, Piette J, Grumbach K, et al. Closing the loop: physician communication with diabetic patients who have low health literacy. Arch Intern Med 2003:163(1):83-90.
- 44. White M, Garbez R, Carroll M, Brinker E, Howie-Esquivel J. Is "teach-back" associated with knowledge retention and hospital readmission in hospitalized heart failure patients? *J Cardiovasc Nurs*. 2013; 28(2): 137-146. doi: 10.1097/JCN. 0b013e31824987bd
- 45. Rockwell S, Kohn H. Post-Then-Pre Evaluation: Measuring behavior change more accurately. *J Extension*. 1989; 27(2). http://www.joe.org/joe/1989summer/a5.html

- 46. Pratt C, McGuigan W, Katzev A. Measuring program outcomes: Using retrospective pretest methodology. *Am J Eval.* 2000; 21(3): 341-349. doi: 10.1177/109821400002 100305
- 47. Greenberg S. Assessment of fear of falling in older adults: The falls efficacy scaleinternational (FES-I). *Best Practices in Nursing Care to Older Adults*. 2011; 29. http://consultgerirn.org/uploads/File/trythis/try_this_29.pdf
- Dewan N, MacDermid J. Fall Efficacy Scale International (FES-I). Journal of Physiotherapy. 2014; 60(1): 60. https://doi.org/10.1016/j.jphys.2013.12.014
- 49. Brown C, Roth D, Allman R, Sawyer P, Ritchie C, Roseman J. Trajectories of Life-Space Mobility after Hospitalization. *Ann Intern Med.* 2009; 150(6): 372–378. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2802817/
- Baker P, Bodner E, Brown C, Kennedy R, Allman R. Life-Space Assessment composite score rationale. *Clin Rehabil.* 2015; 30(1): 95-97. doi: 10.1177/0269215515614295
- Colenbrander A, Fletcher DC. Basic concepts and terms for low vision rehabilitation.
 Am J Occup Ther. 1995: 49, 865–869. doi: 10.5014/ajot.49.9.865
- 52. University of Calgary. Testing for contrast sensitivity. http://www.ucalgary.ca/ pip369/mod4/spatial/ testingsensitivity. Accessed April 15, 2017.
- 53. Crews J E, Jones GC, Kim JH. Double Jeopardy: The effects of comorbid conditions among older people with vision loss. *J Visual Impair Blin.* 2006; 100, 824-848. http://www.afb.org/jvib/jvib001307.asp
- 54. Stelmack JA, Tang C, Reda DJ, Rinne S, Rickilyn MM, Massof RW, et al. Outcomes of the veterans affairs low vision intervention trial (LOVIT). *Arch Ophthalmol.* 2008;

126(5): 608-617. doi:10.1001/archopht.126.5.608

- 55. Stelmack JA, Tang C, Wei Y, Wilcox DT, Morand T, OD; Brahm K, Sayers S, Massof RW. Outcomes of the veterans affairs Low Vision Intervention Trial II (LOVIT II): A randomized clinical trial. *JAMA Ophthalmol.* 2017; 135(2): 96-104. doi: 10.1001/jamaophthalmol.2016.4742
- National Eye Institute. Low vision. https://nei.nih.gov/eyedata/lowvision. Accessed June 6, 2017.
- 57. Congdon N, O'Colmain B, Klaver CC, Klein R, Muñoz B, Friedman DS, Kempen J, Taylor HR, Mitchell P. Causes and prevalence of visual impairment among adults in the United States. *Arch Ophthalmol.* 2004; 122(4): 477-85. Doi: 10.1001/archopht.122.4.477
- Varma R, Vajaranant T, Burkemper B, Wu S, Torres M, Hsu C...McKean-Cowdin R. Visual impairment and blindness in adults in the United States: Demographic and geographic variations from 2015 to 2050. *JAMA Ophthalmol.* 2016; 134(7), 802-809. doi: 10.1001/jamaophthalmol.2016.1284.
| Intervention
Session | Session Components | Printed Handouts
Requiring Modification |
|-------------------------|---|---|
| Class 1 | Introduction to program Discussion of importance of falls and falls safety Behavior risk action plan with discussions of physical changes and increasing aerobic exercise Homework: Develop risk action plan | Falls handout with statistics Exercise handout Walking guide Behavior risk action plan |
| Class 2 | Review of safety hazards Examples of home safety equipment Discussion of home exercise and risk plans Flexibility, strength, and balance exercise Calcium analysis review Homework: Calcium analysis and home assessment | Exercise handout Calcium education form Calcium analysis form |
| Class 3 | Calcium education Homework review Review of exercises Medication safety | Medication safety handout Side effects of common
medications handout Exercise handout |
| Class 4 | How to fall Review of exercises Correct footwear Gait and posture | • Exercise and posture handout |

Table 1: Outline of intervention educational content

Reviewer	Included Changes
Health literacy and low vision expert	Simplified additional wording
	 Improved use of active voice
	 Included tables to present listed information
Physician	• Removed some of the medication brands that are no longer
	utilized
	Added current medications
	 Listed additional medication side effects
Registered dietitian	• Updated recommended daily dosage of calcium for women and the amount of calcium located in many foods
Physical therapist	• Updated exercises to match the current guidelines provided by 2008 Physical Activity Guidelines for Americans and Giangregorio et al ^{32,33}
	 Added commonly used strengthening and balance exercises; sit-to-stand_tandem standing_and tandem walking
	 Added information regarding exercise progression through increased repetitions and duration, and the inclusion of upper extremity and lower extremity weights
Low vision occupational therapists	• Recommended consistency in spacing (1.5 between each text
	line)
	 Simplified additional medical terms
	 Included total pages with page number (i.e. 1 of 10)
	Removed underlining
Older adults with low vision	No recommended changes

Table 2: Revisions implemented to SAFE intervention

Table 3: Likert scale questions for low vision occupational therapists

5: The font style of the adapted materials will increase the visibility of the text for older adults with low vision.

6: The contrast changes made to the text will increase the visibility of the text for older adults with low vision.

7: The changes to the formatting of the text will increase the visibility for older adults with low vision.

8: The changes made to simplify wording and sentence structure will increase the readability of the materials for older adults with low vision.

9: Are there additional changes that we should make to increase the visibility and readability of the materials for older adults with low vision?

Likert scale responses: 1=Strongly Agree, 2=Agree, 3=Neutral, 4=Disagree, 5=Strongly Disagree

^{1:} There are limited falls prevention interventions for older adults with low vision.

^{2:} The original, non-adapted SAFE intervention materials are not accessible to older adults with low vision.

^{3:} Overall, the changes made to the intervention materials increase the visibility and readability of the SAFE intervention content.

^{4:} The changes to font size of the adapted materials will increase the visibility of the text for older adults with low vision.

Table 4: Likert scale questions for older adults with low vision

2: The changes made to the adapted handout are helpful in allowing you to more easily understand the information.

3: I feel that I could use handouts adapted in this manner to learn about falls prevention.

Likert scale responses 1=Strongly Agree, 2=Agree, 3=Neutral, 4=Disagree, 5=Strongly Disagree.

^{1:} You are able to read the adapted handout.

Participant	Age, years	Diagnosis	Acuity, Snellan	Contrast	Visual Field
1	67	Diabetic retinopathy, Glaucoma	20/150	1.20	Severe restriction
2	64	Left hemianopia	20/20	1.05	Partial restriction
3	76	CVA	20/30	1.35	Severe restriction
4	65	Diabetic retinopathy, Left hemianopia	20/700	0.45	Partial restriction
5	76	Age-related macular degeneration	20/280	0.60	Limited restriction
6	69	Diabetic retinopathy	20/40	1.05	Partial restriction
7	88	Glaucoma, Trauma	20/40	1.05	Partial restriction
8	>90	Age-related macular degeneration	20/1000		Limited restriction
9	82	Glaucoma	20/50		Severe restriction

Table 5: Participant age and vision description

For visual field: Severe = $< 20^{\circ}$, partial = 20° - 100° , limited= $>100^{\circ}$.

Participant	Post Intervention	Pre-Post Increase
	Rank	(% Change)
1	10	5(100)
2	9	2(28.6)
3	10	8(400)
4	8	4(100)
5	7	5(250)
6	8	1(14.3)
7	9	2(28.6)
8	9	2(28.6)
9	10	5(100)

Table 6: Change in perceived learning from pre-to-post

 Table 7: Veteran intervention feedback

Participant	Feedback
1	Helpful-Very helpful! The younger people here need to take it also.
2	Yes. Very accessible, readable, and compatible for people like me. Vision loss. Very helpful and every veteran should get the class.
3	Outstanding structure, very clear. If I did not understand something, she explained it clearly.
4	I really like the class because it is set in such a way for people who have poor vision.
5	I thought it was helpful.
6	Very helpful! Large, big and bold print is best for reading and that is what it had.
7	Useful with accessible materials.
8	I really can't think of anything you can do better. I greatly appreciate your help. I feel safer. I'm taking this binder with me.
9	I think it was very helpful. I knew about exercising but I didn't know it was good for balance.

DISCUSSION AND CONCLUSIONS

The final chapter of this dissertation will focus on the results of the included studies and how they impact accessible falls prevention services for community-dwelling older adults with low vision. This discussion serves to describe the lack of accessible interventions currently available and advocate for not only the use of the modified SAFE Health Behavior and Exercise intervention within the SBRC but also for the use of accessible health education interventions for all older adults. The use of non-accessible intervention materials is important because this problem most likely extends to interventions outside of falls prevention. With the future growth of the older adult population, inaccessible health education will not adequately prepare the large population of older adults to safely age in place.

Current status of evidence-based falls prevention interventions

Using the scoping review, we examined the evidence-based falls prevention interventions for older adults with low vision living in the community. Of the limited number of articles (17 total) returned in our search, roughly half of the studies showed significant effects on falls. Though nine studies showed significant results for falls prevention, the interventions may not be effective methods for falls prevention for older adults with low vision.

Low vision is permanent, so thus, many of the interventions recommended by the articles in the scoping review may not benefit individuals with non-correctable impairment. Receiving regular vision care is a necessity among older adults, however, the

73

optometry referrals, surgery, and prescriptions recommended by the studies we reviewed may not be effective as falls prevention strategies. Although several study interventions utilized education and exercise instruction, the studies did not provide detailed descriptions of the delivery method. If the delivery of education components within these interventions were presented in a non-accessible format (i.e. small font, low contrast), it is unknown whether older adults with visual limitations would benefit from the reported interventions.

The lack of evidence-based interventions specifically for older adults with low vision as seen in the scoping review is also evident in the CDC's compendium of falls prevention interventions. Within the compendium, only 11 studies addressed vision impairment among participants and within the study protocols. Similar to the scoping review, seven articles in the compendium relied on optometry or ophthalmological services to address falls including referrals to eye-care professionals,³⁶⁻⁴² new prescriptions,⁴³ or cataract surgery.⁴⁴ One education-based intervention within the compendium included a module on the importance of vision and falls and another addressed the modification of a falls intervention for persons with vision impairment but neither intervention described the modifications made to make it accessible to older adults with low vision.⁴⁵⁻⁴⁶

The development of accessible intervention materials

We used the ADAPT-ITT model⁴⁷⁻⁴⁹ to develop a visually accessible intervention, the SAFE Health Behavior and Exercise intervention,⁵¹ for permanent use within the SBRC. Pilot testing our visually accessible handouts with nine veterans receiving services from the SBRC supported continued use of the modified intervention. Following

74

intervention completion, participants significantly increased their knowledge of the intervention content and perceived that they had a better understanding of the content material. All veterans also expressed satisfaction with the intervention content and accessibility.

The findings from this study show that not all evidence-based interventions for older adults are accessible to individuals with visual impairment. Experts in low vision including occupational therapists and older adults with vision impairment reported that the original SAFE intervention is not accessible to persons with visual impairment. The original intervention was not only inaccessible visually but also included outdated medication and exercise content not matching current recommendations and established guidelines. Overall, there is a need for updated and accessible handouts for older adults with low vision.

Implications for healthcare and future studies

We will continue use of the SAFE Health Behavior and Exercise intervention⁵¹ within the SBRC. To further assess the intervention's effectiveness, we will modify the methodology used in this study to measure the number of falls post intervention using a larger sample and to follow participants for a longer period of time. We will also include a control group in order to rule out co-interventions or other contributors to falls prevention outside of the intervention. The intervention should be studied outside of the SBRC setting to determine the intervention's effectiveness with older adults in a community setting.

Based on the findings of this dissertation, falls prevention should be addressed earlier and more often for all older adults, including persons with low vision. Healthcare

75

professionals should also understand that even though an intervention is evidence-based, an older adult with visual impairment may receive little benefit if the content is presented in an inaccessible format. Practitioners providing falls prevention services to older adults should ensure educational materials are visually accessible to benefit as many individuals as possible.

Research is needed to assess the effects of established evidence-based falls prevention services on older adults with low vision. Once interventions are tested using samples with visual impairment, we can better determine what interventions would be best for use with this population. Research is also needed to further support the development of accessible interventions and to establish guidelines to design accessible interventions. Having accessible interventions will ensure that older adults can access the health information needed to remain safe and independent for as long as possible.

GENERAL REFERENCES

- 1. Information for Healthy Vision: What you should know. National Eye Institute website. https://www.nei.nih.gov/lowvision/content/know. Accessed April, 2017.
- Warren, M. (2011). An overview of low vision rehabilitation and the role of occupational therapy. In M. Warren & B. Barstow (Eds.), *Occupational therapy interventions for older adults with low vision* (pp. 1-26).
- Varma R, Vajaranant T, Burkemper B, Wu S, Torres M, Hsu C...McKean-Cowdin R. Visual impairment and blindness in adults in the United States: Demographic and geographic variations from 2015 to 2050. *JAMA Ophthalmol.* 2016; 134(7), 802-809.
- Colenbrander A, Fletcher D. Basic concepts and terms for low vision rehabilitation. *Am J Occup Ther.* 1995; 49, 865–869. doi: 10.5014/ajot.49.9.865.
- Blaylock S, Barstow E, Vogtle L, Bennett D. Understanding the occupational performance experiences of individuals with low vision. *Brit J Occup Ther*. 2015; 78(7), 412-^{*}421. doi: 10.1177/0308022615577641
- Brown J, Goldstein J, Chan T, et al. Characterizing functional complaints in patients seeking outpatient low vision services in the United States. *Opthalmology*. 2014; 121(8), 1655–1662. doi: 10.1016/j.ophtha.2014.02.030
- Girdler S, Packer T, Boldy D. The impact of age related vision loss: A focus group study. *OTJR-Occup Partici H.* 2008; 28, 110–120. doi: 10.3928/15394492-20080601-05

- McGrath C, Rudman D. Factors that influence the occupational engagement of older adults with low vision: A scoping review. *Brit J Occup Ther*. 2013; 76(5): 234–241. doi: 10.4276/030802213X13679275042762
- Crews J E, Jones GC, Kim JH. Double Jeopardy: The effects of comorbid conditions among older people with vision loss. *J Visual Impair Blin*. 2006; 100, 824-848. http://www.afb.org/jvib/jvib001307.asp
- 10. Crews J, Chou C, Stevens J, Saaddine J. Falls among persons aged ≥ 65 years with and without severe vision impairment United States, 2014. MMWR. 2016; 65(17), 433-437. doi: http://dx.doi.org/10.15585/mmwr.mm6517a2
- Szabo S, Jannsen P, Lord S, Potter M. Neovascular AMD: An overlooked risk factor for injurious falls. *Osteoporosis Int.* 2010; 21, 855-862. doi: 10.1007/s00198-009-1025-8
- 12. Falls Fact Sheet. The World Health Organization website. http://www.who.int/ mediacentre/factsheets/fs344/en. Accessed April 15, 2015.
- Stevens JA, Corso PS, Finkelstein EA, Miller TR. The costs of fatal and non-fatal falls among older adults. *Inj Prev.* 2006; 12(5): 290-295. doi: 10.1136/ip.2005. 011015
- Costs of Falls Among Older Adults. Centers for Disease Control and Prevention website. http://www.cdc.gov/HomeandRecreationalSafety/Falls/fallcost.html. Accessed February 25, 2015.
- 15. WHO Global Report on Falls Prevention in Older Age. The World Health Organization website. http://www.who.int/ageing/ publications/Falls_ prevention7March.pdf. Accessed September, 2015.

- Black AA, Wood JM, Lovie-Kitchin JE, Newman BM. Visual impairment and postural sway among older adults with glaucoma. *OVS*. 2008; 85(6), 489-497. doi: 10.1097/OPX.0b013e31817882db
- 17. Black A, Kim J, Wood J. Stepping accuracy and visuomotor control among older adults: Effect of target contrast and refractive blur. *OPO*. 2014; 34(4), 470-478. doi: 10.1111/opo.12141
- Lord SR, Smith ST, Menant JC. Vision and falls in older people: Risk factors and intervention strategies. *Clin Geriatr Med.* 2010; 26, 569–81. doi: 10.1016/j.cger. 2010.06.002
- Ramulu PR, Van Landingham SW, Massof, RW, Chan, ES, Ferrucci L, Friedman DS. Fear of falling and visual field loss from glaucoma. *Ophthalmology*. 2012; 119(7), 1352-1358. doi: 10.1016/j.ophtha.2012.01.037
- Van Landingham SW, Massof RW, Chan E, Friedman DS, Ramulu PY. Fear of falling in age-related macular degeneration. *BMC Ophthalmology*. 2014; 14(10). doi: 10.1186/1471-2415-14-10
- Willis JR, Vitale SE, Agrawal Y, Ramulu PY. Visual impairment, uncorrected refractive error, and objectively measured balance in the United States. *JAMA Ophthalmology*. 2013; 131(8), 1049-1056. doi: 10.1001/jamaophthalmol.2013.316
- Cox A, Blaikie A, MacEwen CJ, et al. Optometric and ophthalmic contact in elderly hip fracture patients with visual impairment. *Ophthal and Physl Opt.* 2005; 25(4), 357-362. doi: 10.1111/j.1475-1313.2005.00307.x

- 23. Dargent-Molina P, Favier F, Grandjean H, et al. Fall related factors and risk of hip fracture: The EPIDOS prospective study. *The Lancet*. 1996; 348(9024), 416. doi: http://dx.doi.org/10.1016/S0140-6736(96)01440-7
- Felson DT, Anderson, JJ, Hannan MT, Milton RC, Wilson PW, Kiel DP. Impaired vision and hip fracture: The Framingham Study. *J Am Geriatr Soc.* 1989; 37(6), 495-500. http://www.ncbi.nlm.nih.gov/pubmed/2715555
- 25. Ivers RQ, Robyn N, Cumming RG, Butler M, Campbell J. Visual impairment and hip fracture. *Am J Epidemiol*. 2000; 152(7), 633-639. http://aje.oxfordjournals.org/ content/152/7/633.full.pdf
- 26. Ivers RQ, Cumming RG, Mitchell P, et al. Visual impairment and falls in older adults: The Blue Mountains Eye Study. *J Am Geriatr Soc.* 1998; 46, 58-64. doi: 10.1111/j.1532-5415.1998.tb01014.x
- 27. Klein BE, Moss SE, Klein R, et al. Associations of visual function with physical outcomes and limitations 5 years later in an older population: The Beaver Dam Eye Study. *Ophthalmology*. 2003; 110, 644-65. doi: http://dx.doi.org/10.1016/S0161-6420(02)01935-8
- Lord SR, Menz HB. Visual contributions to postural stability in older adults. *Gerontology*. 2000; 46, 306-310. doi: 10.1159/000022182
- 29. Nevitt MC, Cummings SR, Kidd S, et al. Risk factors for recurrent nonsyncopal falls: A prospective study. *JAMA*. 1989; 261, 2663-2668. doi: 10.1001/jama.1989.034201 80087036

- 30. Coleman AL, Cummings SR, Yu F, et al. Binocular visual-field loss increases the risk of future falls in older white women. *J Am Geriatr Soc.* 2007; 55, 357-364. doi: 10.1111/j.1532-5415.2007.01094.x
- Lord SR, Dayhew J. Visual risk factors for falls in older people. J Am Geriatr Soc.
 2001; 49, 508-515. doi: 10.1093/ageing/afl085
- 32. Lord SR, Ward JA. Age-associated differences in sensori-motor function and balance in community dwelling women. *Age Ageing*. 1994; 23, 452-460. doi: 10.1093/ ageing/23.6.452
- 33. Szabo SM, Janssen PA, Khan K, et al. Older women with age-related macular degeneration have a greater risk of falls: A physiological profile assessment study. *J Am Geriatr Soc.* 2008; 56, 800-807. doi: 10.1186/1471-2415-14-10
- Lamoureux EL, Chong E, Wang JJ, et al. Visual impairment, causes of vision loss, and falls: The Singapore Malay Eye Study. *Invest Ophthalmol Vis Sci.* 2008; 49, 528-533. doi: 10.1167/iovs.07-1036
- 35. Stevens JA. *A CDC compendium of effective fall interventions: What works for community-dwelling older adults*. 3rd ed. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. 2015.
- Close J, Ellis M, Hooper R, Glucksman E, Jackson S, Swift C. Prevention of Falls in the Elderly Trial (PROFET): A randomised controlled trial. *Lancet*. 1999; 353(9147), 93–7. doi: 10.1186/1471-2318-7-15
- 37. Davison J, Bond J, Dawson P, Steen IN, Kenny RA. Patients with recurrent falls attending accident and emergency benefit from multifactorial intervention: A randomised controlled trial. *Age and Ageing*. 2005; 34(2), 162–168. doi: 10.1093

/ageing/afi053

- Day L, Fildes B, Gordon I, Fitzharris M, Flamer M, Lord S. Randomised factorial trial of falls prevention among older people living in their own homes. *Brit Med J*. 2002; 325(7356), 128–33. doi: https://doi.org/10.1136/bmj.325.7356.128
- Palvanen M, et al. Effectiveness of the Chaos Falls Clinic in preventing falls and injuries of home-dwelling older adults: A randomised controlled trial. *Injury*. 2014; 45(1), 265–71. doi: 10.1186/ISRCTN48015966
- 40. Salminen MJ, Vahlberg TJ, Salonoja MT, Aarnio PTT, Kivelä SL. Effect of a riskbased multifactorial fall prevention program on the incidence of falls. *J Amer Geriatr Soc*. 2009; 57(4), 612–619. doi: 10.1186/1477-7525-5-20
- 41. Spice CL, Morotti W, George S, Dent THS, Rose J, Harris S, Gordon CJ. The Winchester falls project: A randomised controlled trial of secondary prevention of falls in older people. *Age and Aging*. 2009; 38(1), 33–40. Doi: 10.1093/ageing/ afn192
- 42. Wagner EH, LaCroix AZ, Grothaus L, Leveille SG, Hecht J, Artz K, Odle K, Buchner DM. Preventing disability and falls in older adults: A population-based randomized trial. *Am J Public Health*. 1994; 84(11), 1800–1806. doi: https:// www.ncbi.nlm.nih.gov/pmc/articles/PMC1615188/pdf/amjph00462-0090.pdf
- 43. Haran MJ, Cameron ID, Ivers RQ, Simpson JM, Lee BB, Tanzer M, et al. Effect on falls of providing single lens distance vision glasses to multifocal glasses wearers:
 VISIBLE randomised controlled trial. *Brit Med J.* 2010; 340, c2265. doi: https://doi.org/10.1136/bmj.c2265

- 44. Harwood RH, Foss AJ, Osborn F, Gregson RM, Zaman A, Masud T. Falls and health status in elderly women following first eye cataract surgery: A randomised controlled trial. *Brit J Ophthalm.* 2005; 89(1), 53–9. doi: 10.1136/bjo.2004.049478
- 45. Clemson L, Fiatarone Singh MA, Bundy A, Cumming RG, Manollaras K,
 O'Loughlin P, et al. Integration of balance and strength training into daily life activity to reduce rate of falls in older people (the LiFE study): A randomised parallel trial. *Brit Med J.* 2012; 345:e4547. doi: https://doi.org/10.1136/bmj.e4547
- 46. Campbell AJ, Robertson MC, La Grow SJ, Kerse NM, Sanderson GF, Jacobs RJ.
 Randomised controlled trial of prevention of falls in people aged ≥75 with severe visual impairment: The VIP trial. *Brit Med J.* 2005; 331(7520), 817–25. doi: https://doi.org/10.1136/bmj.38601.447731.55
- 47. Wingood GM, DiClemente RJ. The ADAPT-ITT model: A novel method of adapting evidence-based HIV interventions. *J Acquir Immune Defic Syndr*. 2008 Mar 1; 47
 Suppl 1: S40-46. doi: 10.1097/QAI.0b013e3181605df1
- 48. Latham TP, Sales JM, Boyce LS, Renfro TL, Wingood GM, DiClemente RJ, Rose E. Application of ADAPT-ITT: Adapting an evidence-based HIV prevention intervention for incarcerated African American adolescent females. *Health Promot Pract.* 2010 May; 11(3 Suppl): 53S-60S. doi: 10.1177/1524839910361433
- 49. Card J, Solomon J, Cunningham S. How to Adapt Effective Programs for Use in New Contexts. *Health Promotion Practice*. 2011; 12(1): 25-35. doi:10.1177/1524839909348592

- Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology*, 8(1), 19-32. doi:10.1080/1364557032000119616
- 51. Hornbrook MC, Stevens VJ, Wingfield DJ, Hollis JF, Greenlick MR, Ory MG. Preventing falls among community-dwelling older persons: Results from a randomized trial. *The Gerontologist*. 1994; 34(1): 16–23. https://www.ncbi.nlm. nih.gov/pubmed /8150304

APPENDIX A

PAPER 1 INSTITUTIONAL REVIEW BOARD APPROVAL

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form Identification and Certification of Research Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 24, 20 17. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator: BLAYLOCK, SARAH HAMMOND

 Co-Investigator(s):
 VOGTLE, LAURA K

 Protocol Number:
 VIsto 18005

 Understanding Best Presentation Of Falls Prevention Education Materials For Older A

 dults With Low Vision

to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review. IRB Approval Date: $\underline{7}-1 + 5$

IRB Approval No Longer Valid On: 7

14-16

HIPAA Waiver Approved?: No Partial HIPAA Waiver Approved?: Yes

Taulon

Member - Institutional Review Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building 701 20th Street South 205.934.3789 Fax 205.934.1301 irb@uab.edu The University of Alabama at Birmingham Mailing Address: AB 470 1720 2ND AVE S BIRMINGHAM AL 35294-0104

APPENDIX B

PAPER 2 INSTITUTIONAL REVIEW BOARD APPROVAL



Institutional Review Board for Human Use

Form 4: IRB Approval Form Identification and Certification of Research Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for

Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 24, 2017. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator: BLAYLOCK, SARAH HAMMOND Co-Investigator(s): HALBROOKS, VICTORIA VOGTLE, LAURA K Protocol Number: X160427005

Protocol Title: Adaptation of the Study of Accidental Falls in the Elderly (SAFE) Health Behavior and Exercise Interventions

The IRB reviewed and approved the above named project on <u>SPC blb</u>. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review. IRB Approval Date: $5 \left[2 \right] \left[\frac{1}{2} \right]$

Date IRB Approval Issued: 5-26-16 IRB Approval No Longer Valid On: 52レリ

Expedited Reviewer Member - Institutional Review Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approv al to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building 701 20th Street South 205.934.3789 Fax 205.934.1301 irb@uab.edu The University of Alabama at Birmingham Mailing Address: AB 470 1720 2ND AVE S BIRMINGHAM AL 35294-0104

APPENDIX C

PAPER 3 INSTITUTIONAL REVIEW BOARD APPROVAL

Birmingham VA Institutional Review Board (IRB) Birmingham Veterans Affairs Medical Center Research Service VA Research Service (151) • 700 South 19th Street • Birmingham, AL 35233 • 205-933-8101 • Fax: 205-933-4471

IRB APPROVAL - Initial Review

October 6, 2016

Date: From: Investigator: Pamela E. Parker, MD Cynthia J. Brown, MD

4 Jun 10 6 2016

Protocol: Increasing the Accessibility of a Falls Prevention Intervention for Community Dwelling Older Adults ID: 01633 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 09/14/2016 meeting, contingent upon stipulations in each item marked with an asterisk (*):

- Abstract (08/10/2016)
- * Initial Review Application (08/14/2016)
- * Consent Form (08/15/2016)
- Clean, Unstamped
- Brown Addendum C Intervention Questions (08/15/2016)
- Brown Scope of Practice (08/15/2016)
- Cover Memo (08/15/2016)
- Master Participant List (08/15/2016)
- Brown Addendum A Intervention Syllabus (08/12/2016)
- Brown Addendum B Adapted Handouts (08/12/2016)
- CITI Training 2016
- * HIPAA Authorization (08/15/2016)
- * Checklist for Reviewing Privacy, Confidentiality & (08/25/2016)
- Protocol Blaylock Dissertation Proposal (08/12/2016)

Initial Review Application (08/14/2016) was returned to you with stipulations. The following revised items incorporate the stipulations and are now approved:

• Initial Review Application (10/05/2016)

Consent Form (08/15/2016) was returned to you with stipulations. The following revised items incorporate the stipulations and are now approved:

• Consent Form (10/06/2016) New, Unstamped

HIPAA Authorization (08/15/2016) was returned to you with stipulations. The following revised items incorporate the stipulations and are now approved:

• HIPAA Authorization (10/05/2016)

The Birmingham VAMC IRB is not connected with, has no authority over, and is not responsible for human researc h conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews,

continuing reviews, amendments, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.

Checklist for Reviewing Privacy, Confidentiality & (08/25/2016) was returned to you with stipulations. The following revised items incorporate the stipulations and are now approved:

• Checklist for Reviewing Privacy, Confidentiality & (09/19/2016)

Conditions of Approval are attached. These conditions are further detailed in the HHS, FDA, and VA regulations, which are available in the Research Office.

Approval is granted for a period of 12 months and will expire on 09/13/2017. No Continuing Review is scheduled.

The protocol was determined to have the following level of risk: Minimal

The protocol was determined to have the following level of benefit to participants: Prospect for direct benefit to participants

All stipulations noted within the Contingent Approval letter were submitted for review on 10-5-16 and the Chair provided final approval on 10-6-16.

The checklists for ensuring minimal IRB review requirements and for determining the risk-benefitratio were utilized.A risk assessment of minimal was assigned with a prospect for direct benefit toparticipants.This study will require annual review.

Full Application (Initial or Continuing) Available Electronically on the Birmingham VA Research SharePoint

The Birmingham VA Medical Center Institutional Review Board (IRB) is duly constituted (fulfilling FDA requirements for diversity) and has written procedures for initial and continuing review of clinical trials: prepares written minutes of convened meetings and retains records pertaining to the review and approval process; all in compliance with the requirements defined in 21 CFR Parts 50, 56, and 312 (Code of Federal Regulations) and International Conference on Harmonization (ICH) guidance relating to Good Clinical Practice (GCPs).

FULL IRB APPLICATION (INITIAL AND CONTINUING) AVAILABLE ELECTRONICALLY.

Approval by each of the following is required prior to study initiation (unless Exempt):

Birmingham VA Institutional Review Board (IRB) Research and Development Committee

Approval for study initiation is contingent upon your compliance with the requirements of the Research Service for the conduct of studies involving human subjects.

The Birmingham VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews,

continuing reviews, amendments, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.

A COMPANY AND A REPORT OF A COMPANY AND A COMPANY AND A COMPANY

Birmingham Veterans Affairs Medical Center Research Service

Research Service

700 South 19th St. • Birmingham, AL 35233 • 205-933-8101 • Fax: 205-933-4471

Conditions of IRB Approval

What Are the Conditions of IRB Approval?

1. Adhere to ethical principles: (1) Respect for persons - consent, privacy, confidentiality, (2) Beneficence - maximize possible benefits to the subject and minimize possible harms, and (3) Justice - equitable selection.

2. Obtain informed, written consent from each human subject or his legally qualified guardian or next-ofkin, unless specifically waived by the IRB. If the subject lacks decision making capacity or has been declared incompetent, surrogate consent is required. You are required to place the original, signed consent form in the medical record (and document it in the electronic record), provide a copy to the subject, provide a copy to the Research Office (if applicable), and keep a copy for your files.

3. Promptly report all local Serious Adverse Events and Unexpected Events to the IRB. Offsite Serious Adverse Events or Serious and Unexpected Events are to be reported in a spreadsheet during the time of Continuing Review. The FDA defines Serious Adverse Events as: (1) death, (2) lifethreatening, (3) hospitalization - initial or prolonged, (4) disability, (5) congenital anomaly, (6) required intervention to prevent permanent impairment/damage, or (7) serious and unexpected severity or frequency of expected events.

 Promptly report all deviations (including error and accidents) from the approved protocol and do not initiate any unapproved changes (amendments, consent form modifications, advertisements) without
 IRB review and approval, except where necessary to eliminate apparent immediate hazard to human subjects.

5. Report Emergency Use of unapproved test articles to the IRB within 5 days.

6. If applicable, provide a copy of each subject's consent form and the Investigational Drug Information Record (VA Form 10- 9012) to the Investigational Pharmacist prior to your request to receive, store, and dispense study medications. (The Investigational Pharmacist is responsible for the storage and dispensing of investigational drugs.)

7. Submit Continuing Review information to the IRB by the date specified and inform the IRB when your study is completed (federal law requires that every protocol must be reviewed a minimum of once per year). File a final report upon completion or termination of a study.

What Are the Penalties for Non-Compliance?

1. Non-compliance may result in suspension of approval or a particular project. Serious or continuing non-compliance may result in suspension of your privilege to conduct research at this VAMC.