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Specific Aims page:

Currently over 1.8 million older adults receive rental assistance and live in federally subsidized low-income housing communities [1]. Repeatedly it has been noted that these individuals experience high rates of chronic disease including hypertension, diabetes, psychiatric illness, and cognitive impairment and the majority have difficulties performing basic activities of daily living and instrumental activities of daily living [2-5]. Chronic diseases and exacerbation of these diseases have a major impact on function and progression of functional changes [6-7]. Low-income senior housing residents are also more likely to have low adherence to health promoting activities such as immunizations, medications, heart healthy diets and recommended physical activity [8-14]. Adhering to these behaviors helps to prevent disease exacerbation and the progression of decline in function. Further these individuals experience more frequent re-hospitalizations and avoidable emergency room visits compared to the general population of older adults [15,16]. It has been recommended that on-site health care services should be incorporated into senior housing as a way to improve access to care and thereby help address disabilities, maintain or improve function, provide preventive care to avoid progression of cardiovascular disease and other chronic illnesses, improve overall health status of residents, prevent avoidable utilization of health care services, and improve ability to age in place [17,18]. A recent review [19] of 23 studies providing health care services for older adults with disabilities living in senior housing communities noted that interventions included group-based activities (e.g., computer classes), health education, blood pressure monitoring, care-coordination programs, access to immunizations, opportunities for social interaction, fall prevention via gait and balance assessments, and connecting residents with needed services [1,3,15,19]. Examples of programs included the Right Care, Right Place, Right Team Initiative [3], the Staying at Home program [20], the Richmond Health and Wellness Program [4], and an Academic Nursing Clinic [2]. Results from these programs, based on descriptive non-randomized controlled trials, generally demonstrated increased access to care coordination and health promotion activities and decreased use of emergency room services, hospitalizations and nursing home admissions. The services provided were limited in that there was little hands-on-care and they did not address motivational issues or cultural congruence for residents.

<u>Challenges to Providing On-Site Health Care Services in Senior Housing</u>

While there are noted benefits to increasing access to care for residents in senior housing living with disabilities there are numerous challenges to initiation and maintenance of such services. First, coordinated care that includes different members of the health care team is costly [21] and the resources needed are limited in these settings (e.g., limited internet access, appropriate space to provide clinical care). In addition, there can be differences in philosophies of care between the owners of the housing communities, the residents and the health care team members. There is also a need to establish trust between the residents and clinic team members. Regulations for billing to provide primary care services in senior housing can change over time and must be carefully monitored [20].

The programs published to date have been subsidized through grants from academic institutions, foundations and from local clinical practices. When costs are addressed, estimated cost savings are based on decreased use of emergency room services, reduced hospitalizations, and decreased nursing home admissions. These cost savings are important for the health care system in general but do not support the ongoing work of the clinics to cover the clinicians' time or additional resources needed to sustain these clinics.

This study is in response to the Agency for Healthcare Research and Quality Special Interest in Health Services Research to Improve Healthcare for Persons Living with Disabilities. In partnership with Enterprise Properties, we have established a clinic model, the University of Maryland Interdisciplinary Wellness Clinic (UM-IWC). The UM-IWC provides prevention and primary care services to older adults living in senior housing communities as a way to augment the primary care that they cannot access due to their functional impairment, transportation issues, or inability to navigate the current health care system. Specifically, the primary aims of this study are to implement the UM-IWC across eight senior housing communities and to recruit 280 residents from these communities to test the impact of implementation on: (1) maintaining or improving function; (2) increasing adherence to appropriate use of medications for prevention and management of cardiovascular disease (anticoagulants, antihypertensives, and anti-lipids) and adherence to healthy behaviors (physical activity, and heart healthy diets). The secondary aims are to: (1) demonstrate financial sustainability of implementation of these clinics over time; and (2) decrease adverse events for residents (falls, avoidable emergency room visits and hospitalizations). Demonstrating the effectiveness of this UM-IWC approach will allow for future dissemination of this approach locally and nationally and will provide guidance regarding policy initiatives.

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Background/Evidence Gap/Significance 1 page

Low-income older adults qualify to live in federally subsidized housing via the Housing and Urban Development (HUD) Section 202 program. Established in 1959, Section 202 is the only HUD program that provides housing exclusively for older adults [1]. Currently over 1.8 million older adults receive rental assistance in these federally subsidized low-income housing communities [2]. Older adults living in these communities are known to be at risk for functional decline and to be dependent on assistive devices for ambulation [3-5,6]. Functional limitations pertain to limitations in a person's ability to do discrete actions or activities such as basic activities of daily living (e.g., bathing, dressing, and ambulating) [7]. Contributing to the high rate of functional decline among these individuals is their poor physical and mental health, chronic pain, multiple comorbidities such as hypertension, diabetes, stroke, and poor health behaviors [poor adherence to appropriate medications for prevention of cardiovascular disease (CVD), inactivity, and high fat and high sodium diets]. Further these individuals are at risk for poor health outcomes and associated functional decline due to lack of financial resources, limited access to opportunities for physical activity, healthy food options, health care services, and safe indoor and outdoor physical environments, and the impact of other social determinants of health (e.g., education) [8-11]. With regard to health behaviors, a high percentage of older adults in senior housing continue to smoke, only a very small percentage engage in any moderate level physical activity spending the majority of the day sedentary, they have a high rate of vaccine hesitancy and lack of knowledge of recommended immunizations, and poor medication and dietary adherence for management of hypertension and diabetes [4,12-15]. These behaviors all increase the risk of CVD (e.g., stroke, claudication, congestive heart failure) and progression of other chronic illnesses and result in subsequent physical and cognitive functional decline [16-19].

As noted, the majority of older adults in senior housing spend most of their day sedentary [5,20,21]. Sedentary behavior is defined as any waking behavior that is less than 1.5 metabolic equivalent of tasks (METs) while in a sitting or lying position [22]. Decreasing time spent in sedentary activity can help maintain or improve function, decrease the risk of diabetes and CVD progression, and optimize quality of life [20,23-27]. Further 31% of older adults in senior housing reported not taking their cardiovascular medications (anticoagulants and antiplatelet agents, antihypertensives, and lipid lowering medications) even when these were obtained without financial burden [15]. Lastly, despite being offered healthy resources for meals (e.g., fruit and vegetables), preferences for snack foods are selected over healthy options [15]. Due to these behaviors and other factors, the majority of senior housing residents do not meet the current guidelines for blood pressure control or heart healthy diets as recommended [28,29]. Recommended treatment guidelines for blood pressure include treating individuals when the systolic blood pressure is $\geq$ 140 mmHg or diastolic blood pressure is $\geq$ 90 mmHg and treating adults with a systolic blood pressure of 130 to 139 mmHg or diastolic blood pressure of 80 to 89 mmHg who have high cardiovascular risk (i.e., those with a history of CVD, a 10-year predicted atherosclerotic CVD risk $\geq$10%, diabetes mellitus, chronic kidney disease, or age $\geq$65 years [28,30]). Recommended heart healthy diets include a sodium intake of less than 2,300 milligrams per day and saturated fat intake of less than 10 percent of calories per day [29]. Due to a variety of factors including transportation challenges for primary care visits, health beliefs and behaviors, older adults living in low income senior housing are at increased risk for avoidable emergency room utilization (defined as a mental health disorder, substance abuse, or not needed tests, procedures or medications) [31,32], and hospital admissions [33-35].

<u>On Site Health Care Services for Senior Housing Residents</u>

The best approach to prevent progressive functional decline and persistent engagement in high-risk health behaviors that exacerbate functional decline among older adults living in senior housing is to provide on-site health care services. This improves access to care, and makes the care relevant and culturally appropriate for those living in these communities [8,11].

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Study Design/Method (include recruitment; measures; data analysis) 2 pages

Design: To achieve our aims we will use an interrupted time series approach for multiple reasons: (1) testing of the UM-IWC requires a community-wide approach as the clinic will be available to all residents and practically and ethically it would difficult to randomize individuals or communities to receive the clinic services while others received no treatment or a sham control (e.g., education only); (2) the interrupted time series approach will allow us to use the individual's multiple preintervention assessments as their own control and to monitor for changes in health care issues (e.g., changes in billing opportunities, and guidelines). As the focus of the grant is on effectiveness not dissemination and implementation we included a set number of eight communities. The eight communities are divided into cohort 1 (4 communities) and cohort 2 (4 communities). We will work with the first cohort to recruit participants and collect baseline data monthly for six months pre implementation of the UM-IWC. Recruitment during the first month will be done during weekly meet and greet sessions with residents with the goal of recruiting 35 residents per community to achieve a full baseline sample of 280 residents. Once the 35 residents are recruited, any new residents that move into the community will not be invited to participate. They will, however, have access to the clinic and all clinic activities. We have successfully used this approach previously when enrolling residents in research in these communities 13,62,63. At the end of the pretreatment six months, treatment will be initiated. Treatment involves the implementation of the UM-IWC (described below). During the 12-month intervention period, monthly data will continue to be collected from the recruited residents. Our evaluators will reach out to the participants and arrange the monthly meetings at a time that is convenient for the participant. Sample size calculation was based on repeated measures and the interrupted time series design. To be conservative and optimize our capability to test each of the hypotheses for function, adherence to medication use, and healthy behaviors we assumed a small effect size (Cohen's d=.2). Based on prior research including a sample of older men and women, there was a minimal clinically important difference in scores on the Late Life Function Instrument (LLFDI) with an overall function score for older adults and an anticipated 49% of older adults having an anticipated decline in function over one year due to normal aging in men and 39% in women 65. Considering the design effect from the correlation r =.7 between the repeated measures over a total of 18 months, and clustering of the housing sites p=.02 the sample size would need to be 220 to achieve sufficient power of p>.8 with type I error p=.05.

　　Communities will be invited to participate in the project if they are an Enterprise Property community that provides low-income housing to older adults and are in Maryland. Residents will be eligible to participate if they: (1) are living in a participating community; (2) are 50 years of age or older; and (3) have a change in function defined as any difficulty in a basic activity of daily living (bathing, dressing, transferring, ambulating, or toileting) or instrumental activities of daily living (cooking, managing medications, shopping, traveling, using the telephone, managing finances) due to cognitive, psychological or behavioral issues, sensory issues, or physical impairments. Residents will be excluded if they are unable to pass the evaluation to sign consent.

　　The interdisciplinary clinical team (an advanced practice nurse, a pharmacist, a social worker, a registered nurse and a physical therapist) will work with the community managers from each of the eight communities and the Senior Program Manager for Health & Well-Being at Enterprise Properties to implement the UM-IWC: Step I Development of the Stakeholder Team: We will meet with the stakeholder group, to describe the clinics and what will be provided by the clinical research team, what facilitation help we will need from the community managers and what additional services the community might find beneficial. We will continue to meet with Ms. Scotti Hutton and the community managers from Enterprise Properties monthly online .Step II Marketing the Clinic: To introduce the clinics to the residents and the opportunity to participate in the study a resident meeting will be held weekly in the first month during a lunch and learn session that includes the community managers and the interdisciplinary team members. The interdisciplinary team members will explain to the residents what services will be provided in the clinics and identify those interested in participating in the project.

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Step III Initiation of Clinic Services: Once we have recruited 35 residents in the community and collect all 6 pre-assessments during months 1 through 6, we will initiate the UM-IWC. Services that will be offered (Table 3) by the interdisciplinary team will focus on preventing the progression of functional decline and include: (1) immunizations; (2) foot care; (3) pain management; (4) hearing evaluations and cerumen removal; (5) medication review; (6) fall risk assessments; (7) cognitive assessments; (8) annual wellness visits during birthday months; (9) assessment and management of acute problems (e.g., skin infections, dehydration); and (10) help addressing social challenges. Clinics will be held from 1 pm to 4 pm once a month in each of the senior housing communities. Step IV Ongoing Motivation of Residents to Utilize the Clinic and Engage in Appropriate Health Behaviors: Motivational techniques that were successful in prior research will guide this work . Specifically, we will provide the community managers with a flyer and sign-up sheet and ask them to place the flyer and sign-up sheet on the notice board within their community for all residents living in the community to sign up for services desired. In addition, the community managers will be asked to place a flyer each month for the clinics in the residents' personal mailboxes or at their apartment doors, and post the flyers in elevators and other common areas in the communities. All residents living in the communities will receive a separate invitation to receive an annual Medicare wellness visit during their birthday month and receive a small birthday gift.

   The primary aims as noted in specific aims guide the following hypotheses: (Hypothesis 1) Residents will maintain or improve function after implementation of UM-IWC. (Hypothesis 2) Residents will increase adherence to medications for prevention and management of CVD (anticoagulants and antiplatelets, antihypertensives, and anti-lipids) and adherence to heart healthy behaviors (decreased time spent in sedentary activity and decreased sodium and dietary fat intake) after implementation of UM-IWC. (Secondary hypothesis 3) We will be able to sustain all eight clinics based on estimated reimbursement for services provided which will cover the cost of staff time, billing services and other clinic resources. (Secondary hypotheses 4) Residents will demonstrate a decrease in falls, and avoidable emergency room visits and hospital admissions after implementation of the UM-IWC.

Measures: Measurs will be collected monthly by a research assistant. All measures are provided in Table 1 in the appendix. [if you are short on space you can put the measures in a table/apprendix.

Data Analysis:

       Describe your data anlaysis plan for each of your hypotheses….example for hypothesis 1 here: Hypothesis 1: **Residents will maintain or improve function after implementation of UM-IWC.** We will use an interrupted time series (ITS) analysis to evaluate the effects of implementation of UM-IWC on changes in scores of the LLFDI in terms of slope (change over time) during pre-implementation months, jump (intercept changes) and slope during post implementation months. We will test the hypothesis with two approaches. We will first aggregate the outcome data by month to catch dynamic changes of the outcome over time and plot the outcome by month to examine potential patterns. When a linear pattern is observed, we will use the segmented regression model as shown in the following equation.

$Y_t = \beta_0 + \beta_1 \times time + \beta_2 \times intervention + \beta_3 \times time\ since\ intervention + \varepsilon_t$ -Eq. 1.

   Where Y_t is the outcome at a given month (t), the time variable represents the month since start of the study period, the intervention variable indicates the implementation of UM-IWC (0/1), and the time since the intervention variable is time elapsed from implementation of the intervention, taking a value of 0 prior to the intervention. In this model, estimation of β_1, β_2, and β_3 will test the effects of the UM-IWC. β_1 represents the slope during the pre-intervention period, β_2 is the level change (i.e., jump) following the intervention, and β_3 the change in slope following the intervention [100,101]. Estimation of β_2 ≥ 0 and/or $\beta_3 - \beta_1 \geq 0$ demonstrate that function was improved or maintained.

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Appendix

Table 1 Measures (baseline is first assessment pre implementation of the UM-IWC; 6 months is the end of pre implementation; and 12 months is 12 months post implementation of the UM-IWC)

Measure	Description	Time Point	Psychometrics and Strengths and Limitations
The intake form	Resident's demographic information, comorbidities, medications, health promotion behavior, pain (numeric rating scale) [85], health status, advance directives, cognition based on the Clock Test [86] and the Papadum/Pizza Test[87].	Baseline, 6 and 12 months post implementation.	This is mainly descriptive data and used to serve as control variables if indicated [4,5]. The Clock test has evidence of interrater reliability of 80% [86] and the Papadum/Pizza test had a 76% agreement [87] and is useful for low levels of education.
Late Life Function Inventory [7].	The Late-Life Function Instrument (Late-Life FDI) assesses for change in two distinct outcomes: function and disability.	Monthly	There was evidence for test-retest reliability (correlation of .91-.98); evidence of construct validity and differences between known groups[7].
Height; Weight and waist circumference [88] during the intake assessment	Height and weight will be based on use of the AvaWeigh MSB600 600 lb Digital Physicians Scale with Height Rod. For participants that are unable to stand we will obtain the height and weight based on recall. Waist Circumference will be calculated using the standardized instructional videos at myhealthywaist [88].	At baseline and 12 months post implementation for descriptive purposes	The AvaWeight MSB600 uses digital operation with a 1" LCD, backlit display 14 3/4" x 10 13/16" platform with removable anti-slip plastic base, a retractable aluminum height rod which measures 23" - 83" high.
Blood Pressure	We will use the Center for Disease Control and Prevention recommendations for measurement [89]. The residents will be instructed to sit in a chair for 5 minutes prior to testing, place feet flat on the floor and have their arm supported at chest height. The cuff will be placed snugly and the residents instructed not to talk during the reading.	Monthly	Prior research has supported the accuracy of blood pressure testing using aneroid sphygmomanometers. Virtually 100% of the values from the aneroid device were within the 4–mm Hg range recommended by the Association for the Advancement of Medical Instrumentation [90]. Monitoring of the devices for any defects will be done every 6 months.
Completion of Advance Directives	Participants will be asked if they have completed advance directives.	At baseline, 6 months and 12 months post implementation	Based on Maryland regulations we will focus on completion of the required MOLST form [91].
The Yale Physical Activity Survey (YPAS) [92]	Participants will be asked about time spent in culturally relevant activities over the past week.	Monthly	Evidence of two-week repeatability (r=0.63, p<.001) and validity supported when compared with physiological variables[92].
MotionWatch8 Accelerometry[93]	Participants will wear the Motion Watch 8 for 5 days with data used during days 2, 3, and 4. The Motion Watch 8 measures physical movement of the wrist which approximates body movement.	Baseline, 6 months and 12 months post implementation	Test retest reliability, construct validity, and cutpoints have been established for older adults.[94,95]. We will focus on time spent in sedentary behavior. Three full days provides reliable data in older adults [92,93].
Medication Behavior Related to Prevention of CVD	A triangulation approach will be used including: (1) asking participants about difficulty taking their CVD medications; (2) pill counts; (3) checking with the pharmacy for ordering discrepancies.	Monthly	Prior research has supported the accuracy of pill count assessment [96]. The accuracy of this assessment will be further confirmed based on resident input and pharmacy input as needed for clarification.

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Dietary Fat and Salt Intake	The Block Dietary Fat Questionnaire and Sodium Screener evaluate 24 hr saturated fat and sodium intake.	Monthly	Evidence of test retest reliability and validity when compared to other dietary intake measures[97].
Annual Wellness Visit	Participants will be asked if they have completed an Annual Wellness Visit over the past year.	Baseline and 12 months	The focus is on prevention and increasing access to preventive services [98].
Adverse events (falls, avoidable emergency visits, hospitalizations)	Participants will be asked the numbers and reasons for these events over the past month.	Monthly	Based on subjective reporting, recall and Medicare and Medicaid data. Avoidable visits are defined as mental health disorders, substance abuse, or not needing tests, procedures or medications. We will obtain Medicare and Medicaid utilization data at baseline and 12 months post implementation from the Research Data Assistance Center (ResDAC) by applying for data use agreement to obtain service use data.

Timeline

Cohorts will be run in groups of four communities per cohort with each starting one month after the other for all study activities. The two cohorts will be implemented over 5 years (total 8 communities included).	
Study Months	**Activities**
STUDY ACTIVITIES:	
Month 1-4 Initial Planning	IRB has been approved for this study but any needed modifications will be completed. Safety Officer review and approval of protocol, Staff training, finalizing community recruitment and randomization; cohort 1 Coordination with communities and leadership staff; planning for and implementation of the introduction meeting for residents about the clinics.
Month 5	Recruitment of 35 participants from each of the four communities for Cohort 1; collection of baseline data.
Month 6-11	Collection of data monthly in months 2-6 (to complete the first 6 assessments pre intervention) for Cohort 1
Month 12-27	Cohort 1 communities will be exposed to the monthly clinics for 12 months in each of their communities. Residents will be evaluated monthly during this time period for outcome measures as shown in Table 4.
Month 28-30	Cohort 2 Coordination with communities and leadership staff; planning for and implementation of the introduction meeting for residents about the clinics.
Month 31	Recruitment of 35 participants from the four communities for Cohort 2 and collection of baseline data
Month 32-40	Collection of data months 2-6 (to complete the first 6 assessments pre intervention) for Cohort 2.
Month 37-53	Cohort 2 communities will be exposed to the monthly clinics for 12 months in each of their communities. Residents will be evaluated monthly during this time period as shown in Table 4.
Month 1-60	Development of REDCap data base; Data entry and management; Data analysis after all final data are obtained; sustainability data analysis regarding reimbursement for services provided against cost of maintaining these services. Manuscript development and grant development for larger dissemination work.

Sample Template

Budget

Budget	
Personnel	
Supplies	
Equipment	
Travel	
Computer Costs	
Other	
Total	

Budget Justification

Budget - Itemized Description & Justification Amount PERSONNEL (SALARY FOR PRINCIPAL INVESTIGATOR AND CO-

RESEARCH ASSISTANT/EVALUATOR SALARY: xx HOURS OVER 12 MONTHS AT $25 PER HOUR which will be a C1 (if/when with contracts for 6 months at a time and a maximum 19 hours / week). The current C1 fringe rate is 8.2% of the requested salary. $12,000 plus fringe of 8.2% of 984=$12,984

SUPPLIES:

TRAVEL: Travel to conference

OTHER Thank you gifts ; publication costs

Sample Template

References