

Prevention Focused Home-Based Physical Therapy Utilizing Community Partnership Referrals  
**Study Protocol**

ClinicalTrials.gov Identifier: NCT04814459

6/23/21

**Objective:** The purpose of this study was to describe outcomes of HOP-UP-PT program participants and then to compare these outcomes to non-participants.

**Design:** Prospective randomized Controlled Trial

**Methods:**

Recruitment: Six Michigan senior centers referred adults  $\geq 65$  years who were at-risk for functional decline or falls. 144 participants ( $n=72$  per group) were randomized to either the HOP-UP-PT group or the Normal level of activity group. Physical therapists (PTs) delivered physical, environmental, and health interventions to the HOP-UP-PT group over nine encounters (six in-person, three telerehabilitation) spanning seven months. The Normal level of activity group participants were told to continue their usual physical activity routines during the same time frame. Baseline and re-assessments were conducted at 0-, 3-, and 7-months.

Randomization: Within each Senior Community Center, the first participant was randomized to either the HOP-UP-PT group or Normal level of activity and subsequent participants from that Senior Community Center were distributed in an alternating order of referral receipt and blinded to the Senior Community Center staff during the group assignment process (i.e., participant #1 assigned to HOP-UP-PT group, participant #2 Normal level of activity group, participant #3 HOP-UP-PT group). Exceptions to this process were made when participants lived in the same home (e.g., spouses, siblings, housemates, parent-child) to reduce participant observation bias. In these situations, both participants were assigned to the same group using the next open spot (i.e., if the next spot was a Normal level of activity group, both were assigned to this group and the next referral was back-filled to the HOP-UP-PT group.) Once participants were assigned to either the HOP-UP-PT group or Normal level of activity group, it was no longer feasible to blind data collectors, participants, or Senior Community Center staff to groupings.

Inclusion and Exclusion Criteria: Study participants were included if they were (1) greater than or equal to 65 years of age, (2) Senior Community Center staff identified them as 'at-risk' for decline in community dwelling status due to physical, social, economic, or community-related barriers, and (3) willing to participate in the HOP-UP-PT program. Participants were excluded if they (1) received physical therapy services within the prior two months in any setting, (2) had been hospitalized within the prior two months, or (3) were currently receiving palliative or hospice care. Additionally, participants were excluded if the initial evaluation by the licensed PT suggested that the person's cognitive status (as determined by the Mini Cog or Trail Making Test Part B) or medical status (as determined by the American College of Sports Medicine exercise preparticipation health screening) would not permit safe PT examination or interventions without further physician assessment.

**A detailed figure of the protocol is available below.**

**HOP-UP-PT Participants Protocol**

**Visit #0- Participant will receive the following via US mail:**

1. Informed Consent
2. Patient Health Questionnaire (PHQ-9)
3. Health Behavior Questionnaire (HBQ)
4. Stay Independent Brochure Questionnaire
5. Modified Falls Efficacy Scale Questionnaire

**Visit #1- In Participants Home (1-2 weeks after Visit #0)**

1. Licensed Physical Therapist (PT)secures consent and Visit #0 documents.
2. Mini Cog administered to assure not decisionally impaired (If Mini-Cog inconclusive, Trail Making Test B to be administered)
3. ACSM Participation Index
4. Assessment of blood pressure (BP) in supine (laying on back), sitting (seated), standing and heart rate, weight, height, body mass index calculated
5. Participants will be provided with an automated BP cuff which will be used by both the PT during the in-home visits and can be used by the participant if they so choose. Participants will be provided with the manufacturer's instructions including safety, maintenance and operations. Additionally, the physical therapist will provide both verbal instruction and require repeat demonstration for safe use by the participant prior to leaving in the automated BP device in the home. If the participant is deemed unsafe for independent use the device it will not be left in the home until such time the participant is considered safe.
6. Functional Co-morbidity Index administered
7. Fall Risk Assessment using STEADI Algorithm completed (Timed Up and Go (TUG) test)
8. HOME FAST assessment completed
9. Short Physical Performance Battery (SPPB) performed (Four Test Balance Scale Test, Three Meter Walk Test, Five time Sit to Stand Test)
10. Grip Strength assessed (hand grip dynamometry)
11. Results of HBQ reviewed with patient and discussed using motivation interviewing (MI) Techniques
12. If nutritional concerns, social work needs, equipment or home modifications are recommended and participant agrees, the referring Senior Center Director or Staff will be notified to assist in providing resources.

**Visit #2- In Participants Home (5-8 days after Visit #1)**

1. Document a) home or environmental modification completed b) change(s) in health status including falls c) progress regarding identified positive lifestyle modification since prior visit d) vital signs: seated BP, heart rate, and weight.
2. Wearable activity monitoring technology (i.e., Fitbit, Garmin, Apple Watch) will be provided to monitor and provide feedback to participant on ambulation volume. PT will provide education on purpose, use, functionality, and wearability.

3. The Otago Exercise Program (OEP) education including written handout and the exercise log will be provided. Participant will perform exercises under the direction of the PT. Modification to exercises will be documented.
4. Participant directed primary and secondary prevention education and intervention utilizing MI technique will be employed during this visit.

**VISIT #3 and #4- In Participants Home (4-5 weeks after visit #2)**

1. Document a) home or environmental modification completed b) changes in health status including falls c) participants progress regarding identified positive lifestyle modification since prior visit d) vital signs: seated BP, heart rate, and weight.
2. Confirm or assist participant to download wearable activity monitor data to computerized data base.
3. The OEP will be performed under the direction of PT. Modification to exercises will be documented. Exercise log will be reviewed.
4. Participant directed primary and secondary prevention education and intervention utilizing MI technique.

**Visit #5: (4-5weeks after Visit #4)- In Participant Home**

1. Document a) home or environmental modification completed b) change(s) in health status including falls c) progress regarding identified positive lifestyle modification since prior visit d) vital signs: supine, sitting and standing BP and heart rate. Weight will also be measured and recorded.
2. Stopping Elderly Accidents, Deaths & Injuries (STEADI) Algorithm for Fall Risk Assessment and Intervention, TUG and Modified Falls Efficacy Scale, Stay Independent Brochure Questionnaire, PHQ-9 and HBQ re-administered. Components of the SPPB will also be readministered.
3. Confirm or assist participant in downloading wearable activity monitor to computerized data base.
4. The OEP will be performed under the direction of PT. Modification to exercises will be documented. Exercise log will be reviewed.

**Phone Visit #6, 7, 8: (3 ,4, 5 months after Visit #1) -PI will contact patient by phone (telehealth visit):**

1. Document a) home or environmental modification completed b) changes in health status including falls, c) progress regarding identified positive lifestyle modification since prior visit
2. Verbal support and encourage compliance with OEP and BP monitor
3. Participant directed primary and secondary prevention education and intervention utilizing MI technique.

**Visit #9 (7 months post Visit #1)- In Participant Home**

1. Document a) home or environmental modification completed b) change(s) in health status including falls c) progress regarding identified positive lifestyle modification

since prior visit d) vital signs: supine, sitting and standing BP and heart rate. Weight will also be measured.

2. Stopping Elderly Accidents, Deaths & Injuries (STEADI) Algorithm for Fall Risk Assessment and Intervention, TUG and Modified Falls Efficacy Scale, Stay Independent Brochure Questionnaire, PHQ-9, and Health Behaviors Survey Instrument re-administered. Components of the SPPB will be readministered.
3. Confirm or assist participant to download wearable activity monitor to computerized data base.
4. The OEP will be performed under the direction of PT. Modification to exercises will be documented. Exercise log will be reviewed.
5. Discharge recommendations including reintegration into to the referring community senior center activities and a home exercise program will be provided.

#### **Normal Activity Group Participant Protocol**

##### **Visit #0- Participant will receive the following via US mail:**

1. Informed Consent
2. Patient Health Questionnaire (PHQ-9)
3. Health Behavior Questionnaire (HBQ)
4. Stay Independent Brochure Questionnaire
5. Modified Falls Efficacy Scale Questionnaire

##### **Visit #1- In Participants Home (1-2 weeks after Visit #0)**

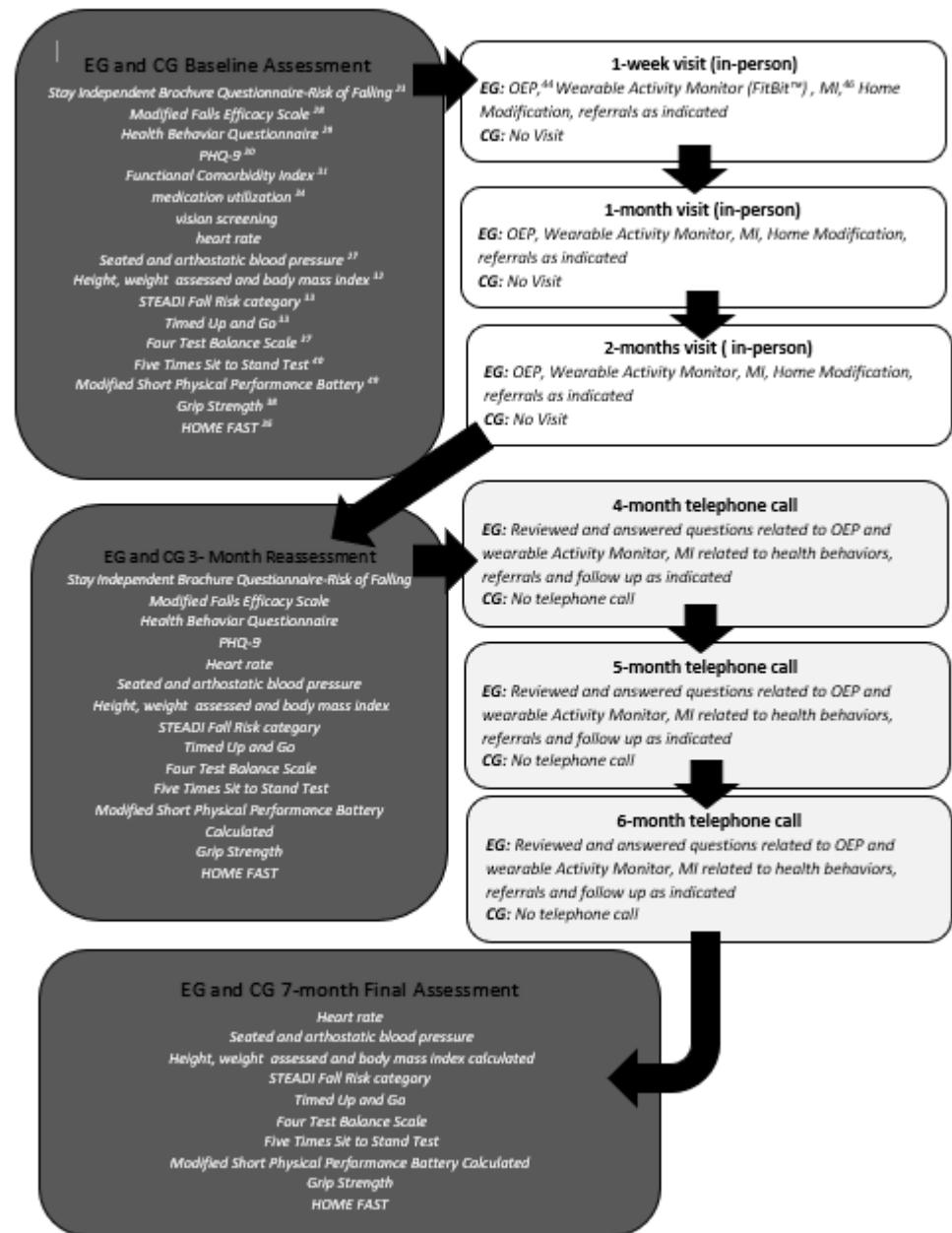
1. Licensed Physical Therapist (PT) secures consent and Visit #0 documents.
2. Mini Cog administered to assure not decisionally impaired (if Mini Cog is inconclusive, Trail Making Test Part B is administered)
3. ACSM Participation Index
4. Assessment of blood pressure (BP) in supine (laying on back), sitting (seated), standing and heart rate, weight, height, body mass index calculated
5. Functional Co-morbidity Index administered
6. Fall Risk Assessment using STEADI Algorithm completed (Timed Up and Go (TUG) test)
7. HOME FAST assessment completed
8. Short Physical Performance Battery (SPPB) performed (Four Test Balance Scale Test, Three Meter Walk Test, Five Time Sit to Stand Test)
9. Grip Strength assessed (hand grip dynamometry)

##### **Visit #2 and #3: (3 and 7 months after Visit #1)- In Participant Home**

1. Document health status including falls, HOME FAST, vital signs: supine, sitting and standing BP and heart rate. Weight will also be measured and recorded.
2. Stopping Elderly Accidents, Deaths & Injuries (STEADI) Algorithm for Fall Risk Assessment and Intervention, TUG and Modified Falls Efficacy Scale, Stay Independent Brochure Questionnaire, PHQ-9, HBQ, and SPPB re-administered.
3. Control group participants offered opportunity to participate in HOP-UP-PT program after concluding their role as CG participants.

## Figure

Figure 1. Key assessments and interventions performed during each encounter



### Statistical Analysis Plan

Descriptive statistics will be generated to analyze demographic and outcome variables. The baseline encounters for the HOP-UP-PT group at visit 1 (E1) and the Normal level of activity group at Visit 1 (C1) were compared to 3-month encounters (visit 5) (E2 and C2) and 7-month encounters (visit 9) (E3 and C3) via a two-sample Wilcoxon test (for continuous or ordinal variables) and a Chi-squared test (for binary variables). As adjusted means will be utilized for interval changes, 95% confidence intervals will be included. Statistical analysis will be performed by Henry Ford Health Systems Public Health Science Department using SAS v.9.4 (SAS Institute, Cary, NC) software for Windows with significance determined at  $P < .05$ .