



VISIT 2 (Randomization)

Date: / / .

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
2.1.	<p>Document blood pressure and weight. (SC)</p> <ul style="list-style-type: none"> Record in CPRS Cover Sheet (before RD opens VDF in CPRS). Scale used (must be same scale used at visit 1). 	
2.2.	<p>If participant is diagnosed with HTN (SC)</p> <ul style="list-style-type: none"> If SBP>160 and/or DBP>95 the participant must be put on hold until his physician gives <i>medical clearance</i> to continue. (If participant put on hold, have them complete the top section of a medical clearance form. Obtain Actical and <i>Actical Wearing Log</i>, record that it was returned on the <i>Actical Log</i>, and upload data. Give participant phone card and complete <i>Payment Record/Receipt</i>. Contact the participant's physician to have them give medical clearance - file the medical clearance in the study file. Reschedule Visit 2 once medical clearance has been received. If medical clearance is not received, complete a Participant Dropout/Termination Form and fax it to Ann Arbor, (<i>complete CPRS Template for termination of study participation?</i>) 	
2.3.	<p>Medical Clearance (SC)</p> <ul style="list-style-type: none"> Confirm completed Medical Clearance Form is on file. Let participant know that his physician gave medical clearance. 	
2.4. (2.15, 2.17, 2.19)	<p>Query for Adverse Events (SC)</p> <ul style="list-style-type: none"> Ask participant if they have had any of the following new symptoms or worsening of existing symptoms since Visit 1: Shortness of breath, Chest pain, Headache, Faintness, Dizziness, Any other problems. (If yes, discuss with RD. Complete an <i>Adverse Event Form</i> and fax to Ann Arbor. Follow all instructions on <i>Adverse Event Form /Fax Cover Sheet</i>. If participant is put on hold, have them sign a new <i>Medical Clearance Form</i>. Contact participant's physician to ask them for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i>, then put it in the study file. Complete 2.5 and 2.9. Reschedule the rest of Visit 2 (randomization) once medical clearance received. If medical clearance is not received, complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, complete (<i>CPRS template for termination of study participation?</i>) 	
2.5. (2.7, 2.8)	<p>Obtain Actical and <i>Actical Wearing Log</i> from participant (SC)</p> <ul style="list-style-type: none"> Upload Actical data to computer to make sure that it recorded properly (at least a full 7 days of data). Save file to hard drive or disc. Record that Actical was returned on the <i>Actical Log</i>. (If Actical did not record at least 7 full days of data, re-dispense an Actical and record on the <i>Actical Log</i>. Give participant <i>an Actical Wearing Log</i>, phone card, and complete a <i>Payment Record</i>. Reschedule Visit 2 at least 7 full days from today, up to 14 days from today. Give the participant an appointment card and document it in your planner.) 	
2.10	<p>Randomization (SC)</p> <ul style="list-style-type: none"> Assign the randomization ID on <i>Crosswalk 1</i>. Select next randomization envelope in sequence (numeric and by season). Record the envelope # on <i>Crosswalk 1</i>. Obtain the binder with this randomization envelope, take out the randomization envelope and Participant Study File, give participant binder. Open the sealed envelope to determine participant's group assignment. Maintain randomization assignment paper in the Participant's Study File. 	

Veterans Walk for Health Subject Checklist



ENROLLMENT ID: 5 ___ ___ ___ 1.

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
2.11	If Randomized to Group 1 (SC) <ul style="list-style-type: none"> Give RD a <i>Calendar</i> for the participant to record minutes walked each day (in Participant Binder). Give RD the copy of pages 4-7 of the <i>Baseline Survey</i> labeled with patient name and last four digits of his SSN (from yellow visit 2 folder). 	
2.12	If Randomized to Group 2 (SC) <ul style="list-style-type: none"> Give RD a <i>Calendar</i> for the participant to record number of steps walked each day, and <i>Digiwalker Use</i> Handout (in Participant Binder). Give RD the copy of pages 4-7 of the <i>Baseline Survey</i> labeled with patient name and last four digits of his SSN (from yellow visit 2 folder). Dispense Digiwalker and safety strap to the dietitian for the participant. Record date and randomization ID on the <i>Digiwalker Log</i>. 	
2.13	If Randomized to Group 3 (SC) <ul style="list-style-type: none"> Arrange computer access for the participant. Give RD the copy of pages 4-7 of the <i>Baseline Survey</i> labeled with patient name and last four digits of his SSN (from yellow visit 2 folder). Dispense a Sportbrain / cord / safety strap to the dietitian for the participant. Record date and randomization ID on the <i>Sportbrain Log</i>. Record user name/password for the Sportbrain on the <i>Sportbrain Use</i> handout (in Participant Binder). 	
2.16	Give participant phone card (SC) <ul style="list-style-type: none"> Complete <i>Payment Record/Receipt</i> and have the participant sign. 	
2.16	Schedule Visit 3 (SC) <ul style="list-style-type: none"> This appointment needs to be scheduled at least 7 days from today. This visit can be up to 14 days after Visit 2. Give patient an appointment card or write in <i>Calendar</i>. Note appointment in your planner, note reminder call in planner. 	
Transition from SC to RD		
	Use <i>Visit Documentation Form</i> to document visit, either as a paper form or as a CPRS template note. (RD)	
2.20	If patient has diagnosis of diabetes, Give "Walking Safely with Diabetes" handout. (RD)	
2.21	If Randomized to Group 1 (RD) <ul style="list-style-type: none"> Instruct participant to record minutes walked each day on <i>Calendar</i> in Participant Binder. Instruct participant to bring <i>Calendar</i> to each study visit. 	
2.21	If Randomized to Group 2 (RD) <ul style="list-style-type: none"> Give participant Digiwalker and safety strap. Instruct participant to record steps walked each day on <i>Calendar</i> in Participant Binder. Instruct participant on how to position Digiwalker. Instruct the participant to wear the device each day from first thing in the morning until going to bed. Instruct participant to reset counter each morning, and do a 20 step test Do 20 step test (if not within 18-22, reposition to back and try again). 	

Veterans Walk for Health Subject Checklist



ENROLLMENT ID: 5 ___ ___ ___ 1.

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
2.21	If Randomized to Group 3 <ul style="list-style-type: none"> • Give participant the Sportbrain / cable / safety strap. • Show the participant how to position the Sportbrain. • Instruct the participant to wear the device each day from first thing in the morning until going to bed. • Instruct participant to reset counter each morning, and do a 20 step test. • Do 20 step test (if not within 18-22, reposition to back and try again). 	
2.22	Test method with 10 minute walk (RD)	
2.21	If Randomized to Group 3 demonstrate upload of Sportbrain (RD) <ul style="list-style-type: none"> • Review upload section of <i>Sportbrain Use</i> handout in Participant Binder. • Demonstrate download of Sportbrain software from website. • Demonstrate connection of cable and Sportbrain to computer and upload of data. • Instruct participant to upload Sportbrain data at least once a week. • Update participant height and weight on website. 	
2.23	Set Walking Goal (RD) <ul style="list-style-type: none"> • Walk every day. 	
2.24	Nutritional Counseling (RD) <ul style="list-style-type: none"> • Use SOC from the baseline survey (return to SC to file in the Participant Study File and give back at next visit). • Use motivational interviewing techniques. 	
2.24.	Set nutritional goals. (RD) <ul style="list-style-type: none"> • Record on <i>Visit Documentation Form</i>. 	
2.24.	Distribute nutritional/walking handouts as appropriate. (RD) <ul style="list-style-type: none"> • Record on <i>Visit Documentation Form</i>. 	
2.26	<i>Visit Documentation Form</i> to Ann Arbor (SC) <ul style="list-style-type: none"> • If CPRS template, print note, obliterate participant name and SSN, write enrollment ID on the top margin. • Send to Ann Arbor in monthly shipment. 	
2.26	<i>Actical Wearing Log</i> and <i>Actical File</i> download to Ann Arbor (SC) <ul style="list-style-type: none"> • Maintain a copy of <i>Actical Wearing Log</i> in participant's study file. • Send original to Ann Arbor in monthly shipment • Send a copy of the <i>Actical file</i> download on disc to Ann Arbor 	
2.27	Reminder call to participant before next study visit (SC) <ul style="list-style-type: none"> • Date of reminder call: ____/____/____ • Remind participant to bring calendar (if in group 1 or 2). • Remind participant to wear pedometer to visit (if in group 2 or 3). 	