

Recruitment and Enrollment Protocol – FOR REVIEW

RECRUITMENT GUIDELINES & STRATEGIES

A. Guidelines

1. Inclusion/Exclusion criteria for CHW Intervention

Patients of participating primary care clinic sites must meet the specific criteria in order to be eligible to participate in the study (See Figure 1):

Figure 1. Inclusion / Exclusion Criteria for Study Participation

Inclusion Criteria (must satisfy all, confirmed through practice EHR and screening form)

- ☒ South Asian ethnicity; and
- ☒ Diagnosis of diabetes (verified in EHR, or self-reported through community recruitment); and
- ☒ Diagnosis of hypertension (verified in EHR, or self-reported through community recruitment); and
- ☒ Uncontrolled blood pressure reading (>130/80mmHg) in the last 6 months or at screening

Exclusion Criteria (cannot satisfy either of the below)

- ☐ Age is <21 or >75 years old.
- ☐ Pregnant at the time of screening.
- ☐ Type 1 diabetes or diabetes secondary to other conditions (e.g. steroid-induced, pancreatic insufficiency, or chemotherapy-induced)
- ☐ Inability to perform unsupervised physical activity

CHWs are provided with EHR-based Registry Lists of eligible participants, and can confirm eligibility by completing the *Screening Form* with the participant. CHWs may also screen patients referred by the provider or identified via clinic-based or community-based recruitment. Please note that participants not identified through the registry list must have their eligibility verified via the *Screening Form* and a blood pressure measurement (>130/80mmHg). If there are any questions about an individual's ability to participate meaningfully in the program beyond the specific eligibility criteria (e.g. the individual will be away from Atlanta for longer than 1 month during the intervention period), the CHW should present the information to the Project Coordinator for further consideration.

B. Strategies

1. Identification via EHR-based Registry Lists

In order to identify and recruit eligible participants at each of the PCP sites, the study team will generate a list of all patients meeting eligibility criteria from the practice EHR system. Patients drawn from registry lists will be mailed an invitation letter (*Recruitment Letter*) and flyer to participate in the CHW Intervention, on behalf of the practice physician. The mass mailing should be prepared using the IRB-approved recruitment letter with the current date and

patient contact information inserted. The letter should be sent in English and the appropriate translation. The study team may choose to send female patients a letter from a female CHW, or with the female CHW's contact information highlighted, and visa versa for male patients. After the invitation letters are sent, CHWs will follow up with personal phone calls. Follow-up phone calls (at varying days and times) will be made to recruit individuals into the study (*See Recruitment Phone Follow-up Protocol*). CHWs will complete the *Screening Form* with all interested individuals, either via phone or in-person (Figure 2).

Figure 2. SCRIPT for phone calls to individuals identified via EHR-based Registry Lists and who were sent a Recruitment Letter:

CHW: "Hello! I am a community health worker and I am calling on behalf of Dr. [PCP Name] regarding a letter that you should have received in the mail about a health education program that can help patients manage their high blood pressure and diabetes. I am calling to see if you have any questions or might be interested in participating in this program."

[*See Figure 3 for Suggested Talking Points*]

1. If patient has questions, CHW should answer them and if the patient seems interested, then complete the *Screening Form*:

CHW: "Thank you for taking the time to learn about our health education program. If you don't mind, I would like to ask you a few questions to make sure that this type of program would be a good fit for you."

➔ Complete *Screening Form*.

Note: CHWs should note any reasons why an individual may not be able to participate meaningfully in the program beyond the specific eligibility criteria (e.g. the individual will be away from Atlanta for longer than 1 month during the intervention period). This should be discussed with the Project Coordinator.

Once *Screening Form* is completed and eligibility is verified:

CHW: "There is some paperwork we will need to fill out before the first education session begins. Would you have time to meet me in-person at Dr. [PCP Name]'s office in the next 2 weeks to complete this paperwork and officially enroll into the program?"

➔ Schedule a date and time that works best for the participant to meet in-person to be consented and complete the *Intake Form*. This should be completed anytime within 30 days of attending Session 1, or on the same day prior to attending Session 1.

2. If patient is interested but cannot stay on the phone line to complete *Screening Form*:

CHW: "If it is okay with you, I can call you tomorrow to go over a few questions. When would be the best time to call you back?"

3. If patient is NOT interested:

CHW: "Thank you for your time. If you change your mind about participating in this program, you can always call me at the following number." [give business card]

Figure 3: Suggested Talking Points

Develop talking points for conversations with potential participants.

For example, you should ...

1. Identify the purpose of your call
2. Explain what you do
3. Tell them what benefits they get
4. Invite them to participate

Some suggested talking points:

1. Identify the purpose of your call

- Hello, my name is _____. I am calling from Emory and I work with Dr. [Name] on a program for **high blood pressure and diabetes**.
- Dr. [Name] thought this would be a good program for you **because you have diabetes and recently had a high blood pressure reading**.
- Did you receive the letter from the doctor about this program? *(If no, verify address)*

2. Explain what you do

- I am a **Community Health Worker** at Emory
- I am working in **partnership with your doctor** (or state the name of the clinic)
- I **provide health education for South Asian patients** (in-language, tailored for our culture) and follow-up as part of a 6-month **diabetes and high blood pressure management** program – **one of the only programs** like this for South Asians!
- Education classes are **once a month for 1.5 hours** at your doctor's office or in a convenient community location

3. Tell them what benefits they get

- Learn how to control your high blood pressure:
 - Eat healthier
 - Exercise
 - Lose weight
 - Manage stress
- **Referrals to social services**
- **Connect with others** with high blood pressure
- **Family members are welcome** to attend each session
- Refreshments and incentives at every session

4. Invite them to participate

- Would you be interested in participating in this program and **checking out our first class** about how to better manage your diabetes and blood pressure? Space is limited.
- *If interested:* Do you have a minute for me to ask you some questions to see if this program is right for you? *Complete Screening Questionnaire*.
- *Confirm availability and schedule Session 1.*

2. CHW Tabling at Practice Sites

Tabling can be an valuable strategy to promote the initiative (including the role of CHWs, the partnership between the University and the clinic, and the benefits of prevention/ management), as well as recruit potential participants for the intervention. CHWs can set up an information table at the participating PCP sites and be available to explain the project. While tabling, it is important to provide as much information about the project as possible. Copies of the outreach flyer should be available at the table for potential participants to take home.

If a potential participant seems interested in the project, the CHW should confirm if the patient is listed on the EHR list, and assess participant eligibility by completing the *Screening Form*.

Those who were not identified via the EHR list will need to have their eligibility verified via the *Screening Form* and a blood pressure measurement (>130/80mmHg). The potential participant may or may not have time to complete the full *Screening Form* at that time. In these cases, the CHW may collect contact information on a *Request for Information Sign-in Sheet*, and let the individual know that they will be receiving a follow-up phone call within two days. The following script can be used as a guide for this process (See Figure 4):

Figure 4. SCRIPT for screening form completion for patients encountering a CHW during Tabling Event / Not identified via EHR Registry:

CHW: [Describe program, *See Figure 3 for Suggested Talking Points*] “Thank you for taking the time to learn about our health education program. If you don’t mind, I would like to ask you a few questions to make sure that this program would be a good fit for you.”

1. If patient cannot stay to complete *Screening Form* and Blood Pressure Measurement

CHW: “If it is okay with you, I can call you in the next two days to go over a few questions. When would be the best time to call you?” [Record patient contact information on *Request for Information Sign-in Sheet* for follow-up call]

2. If patient can stay: Complete *Screening Form* and Blood Pressure Measurement.

☒ If patient is not eligible:

CHW: “Unfortunately, you are not eligible to participate in this program for the following reason(s’): [DESCRIBE WHY PARTICIPANT IS NOT ELIGIBLE.] “Although we won’t be able to enroll you into this program, I can give you some health information you may find useful.” [DISTRIBUTE INFORMATION].

☒ If patient is eligible:

CHW: “There is some paperwork we will need to fill out before the first education session begins. Would you have time to meet me in-person at Dr. [PCP Name]’s office in the next 2 weeks to complete this paperwork and officially enroll into the program?”

➔ Schedule a date and time that works best for the participant to meet in-person to be consented and complete the *Intake Form*. This should be completed anytime within 30 days of attending Session 1, or on the same day prior to attending Session 1.

3. If patient is NOT interested:

CHW: “Thank you for your time. If you change your mind about participating in this program, you can always call me at the following number.” [give business card]

A good source of referrals and recruitment will be for participants to recommend the program to friends and neighbors within the community who are also patients of a participating PCP site. In order for these word-of-mouth recommendations to occur, it is important for CHWs to engage all patients about the project. Even if that particular person isn't eligible, they may know someone else who is.

3. Sign-in Sheet with PCP Front Office Staff

Front office staff at each of the practice sites will also keep a copy of the *Request for Information Sign-in Sheet*, on which patients may sign up to receive follow-up calls from the CHW to learn more information about the program. Office staff will forward the names and contact information of those interested patients to the project team for recruitment and screening. The CHW will call interested individuals to explain the program and complete the Screening Form and blood pressure measurement (Figures 5).

Figure 5. SCRIPT for screening form completion for patients who sign up for with front desk staff / Not identified via EHR Registry:

CHW: "Hello! I am a community health worker and I am calling on behalf of Dr. [PCP Name] regarding your request to learn more about a health education program that can help patients manage their high blood pressure and diabetes." [See Figure 5 for Program

Description/Suggested Talking Points]

CHW: "Thank you for taking the time to learn about our health education program. If you don't mind, I would like to ask you a few questions to make sure that this program would be a good fit for you."

1. If patient does not have time to complete Screening Form and Blood Pressure Measurement:

CHW: "If it is okay with you, I can call you in the next two days to go over a few questions. When would be the best time to call you?"

2. If patient is available: Complete Screening Form and Blood Pressure Measurement

X If patient is not eligible:

CHW: "Unfortunately, you are not eligible to participate in this program for the following reason(s)": [DESCRIBE WHY PARTICIPANT IS NOT ELIGIBLE.] "Although we won't be able to enroll you into this program, I can give you some health information you may find useful." [DISTRIBUTE INFORMATION].

√ If patient is eligible:

CHW: "There is some paperwork we will need to fill out before the first education session begins. Would you have time to meet me in-person at Dr. [PCP Name]'s office in the next 2 weeks to complete this paperwork and officially enroll into the program?"

➔ Schedule a date and time that works best for the participant to meet in-person to be consented and complete the Intake Form. This should be completed anytime within 30 days of attending Session 1, or on the same day prior to attending Session 1.

3. If patient is NOT interested:

CHW: "Thank you for your time. If you change your mind about participating in this program, you can always call me at the following number." [give business card]

C. Screening to Intake

Once a potential participant has been screened, and eligibility is verified, the CHW should schedule a date/time to complete the consent process and intake form to be enrolled into the program. It is advised that the intake meeting be scheduled within one week, if possible, to maintain continued interest about participation in the program.

It is possible that once a participant has been screened and/or consented, they may become unreachable via phone for various reasons. In order to increase retention between screening and baseline (intake), a phone follow-up protocol has been developed to maximize participant engagement without this contact becoming too intrusive. Each attempt at contact as well as the call outcome should be recorded in detail in the Encounter Log or in REDCap.

Recruitment Process Flowchart (Clinic-/Community-based Event)



