Partners in Care Diabetes Lifestyle Program

Manual of Procedures (MOP)

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Introduction

The Partners in Care (PIC) intervention is designed to improve the self-management skills and behaviors of individuals with diabetes to prevent or delay diabetes-related complications. The educational materials adhere to the American Diabetes Association’s 2010 Clinical Guidelines. The content is guided by focus groups conducted with Native Hawaiians and Pacific Island People in four community sites. Social cognitive theory provides the theoretical framework for the educational lessons.

The educational intervention is designed to be delivered by trained community peer educators to small groups of individuals (10-15) with physician-diagnosed type 2 diabetes. The primary outcome is improvement in hemoglobin A1c, and quality of life as measured by the Problem Areas in Diabetes (PAID) instrument. Secondary outcomes are lipids, blood pressure, body mass index, and diabetes-related knowledge and behaviors.

The following will be discussed in the Partners in Care Manual of Procedures:

- Recruitment
- Informed Consent
- Assessments
  - Baseline
  - 3 Month
  - 6 Month
- Delivery of Partners in Care Educational Material
- Retention and Attendance
Recruitment

Community sites will recruit and enroll 25 individuals to participate in the Partners in Care study. Prospective participants may or may not be enrolled in the PILI Ohana program.

Enrollment Criteria

Inclusion Criteria:

a) Self-reported Native Hawaiian, Filipino, or other Pacific Islander ethnic background,
b) Adults age ≥18 years,
c) English-speaking,
d) Physician-diagnosed type 2 diabetes, and
e) Baseline hemoglobin A1c ≥8%

Hemoglobin A1c eligibility

1) There are two methods to determine A1c eligibility (i.e., ≥8%):

a) The individual may provide an A1c value from their healthcare provider if it was assessed within the past 3 months. Even if the individual is eligible to participate based on the A1c value from the provider, A1c should still be assessed at baseline and recorded on the Clinical Data form in the questionnaire,

OR

b) An individual’s A1c may be assessed after informed consent has been obtained and before the baseline assessment. If the individual is eligible to participate, the eligibility A1c value the study assessor obtained may be recorded as their baseline A-1c on the Clinical Data form.

2) Potential participants should be informed that they will be expected to attend the 12 weekly, 1-hour meetings. However, no individual will be disenrolled for non-attendance. Attendance will be adjusted for in the final analysis. Therefore, it will be necessary to recruit only 25 individuals who state that they are committed to attending the 12 weekly meetings.
Informed Consent and Assessments

Informed Consent

1) A folder containing an eligibility form, contact information form, informed consent, baseline, 3 and 6 month questionnaires, and meeting attendance should be prepared for each enrolled participant.

2) If an individual is eligible to participate in the intervention, informed consent will be obtained. The participant should sign two copies of the informed consent. Keep one of the signed copies in the participant’s folder. The other copy is for the participant to keep.

Assessments

There will be three assessments during the study: baseline, 3 months, and 6 months. At baseline assessment, participants will be provided with details of the first Partners in Care class (i.e., date, location) and expectations of their attendance at the 12 weekly meetings. After the baseline assessment is complete, participants will receive the intervention right away during the following 12 weeks. They will undergo the same assessment after the classes (3 months), and three months later (6 months after baseline).

Baseline Assessment

1) After informed consent is obtained, administer the baseline questionnaire and assess baseline A1c (if not already obtained for eligibility), lipid panel, blood pressure, and height and weight. Participants do not need to fast for the lipid panel. However, please record the time of the assessment and if the participant is fasting at the top of the Clinical Data form.

2) Record A1c, lipids, blood pressure, and height and weight on Clinical Data form in the baseline questionnaire. Record the same values on “Your Health Screening Information” form and give to the participant to keep and share with their health care provider.

Three Month Assessment

Participants shall complete the 3 month assessment within 2 weeks after the final class. The questionnaire and clinical measures are the same as the baseline assessment.

Six Month Assessment

Three months after the 3-month assessment, participants will do their 6-month assessment. The questionnaire and clinical measures are the same as the baseline and 3-month assessments.
Partners in Care Informed Consent and Assessments

Eligibility Criteria for Partners in Care:

- a) Self-reported Native Hawaiian, Filipino, or other Pacific Islander,
- b) Adults age ≥18 years,
- c) English-speaking,
- d) Physician-diagnosed type 2 diabetes, and
- e) Baseline hemoglobin A1c ≥8%

Informed Consent and Baseline Assessment

Participants receive PIC Program intervention during the next 12 weeks

3-Month Assessment

6 month assessment
PIC Program Intervention

Delivery of Partners in Care Educational Materials

1. The Partners in Care classes will be conducted during 12 consecutive weeks. Each meeting will be delivered to groups of participants and will last about one hour.

2. The educational materials are written in a conversational tone and in plain language. The materials are designed to be read as a script because the information is medical information that adheres to the American Diabetes Association 2010 Clinical Guidelines. Because this is clinical information, educational materials should be delivered as scripted to ensure conveyance of accurate and complete information. Facilitators can, however, provide additional information from reliable sources if participants are interested in other topics.

3. All participants should sign-in when they arrive at each meeting. Active participation should be encouraged from all individuals in the group(s). In each lesson, there will be 1-2 activities to build skills and increase knowledge related to the topic of the lesson. In addition, there are questions posed during lessons and facilitators should generate discussion from participants when they see this symbol.

4. Participants will be asked to set a goal at the end of each meeting and complete a 3-item participant satisfaction questionnaire. Participants do not need to provide their names on the questionnaire.

5. Participant attendance will be tracked using the sign-in sheet and the participant attendance form in each participant’s folder.

The format of each lesson is:

1) Participant sign-in
2) Welcome
3) Review of previous lessons (after lesson 1)
4) Story
5) Meeting content
6) Set a goal
7) Participant satisfaction questionnaire
8) Additional information in pocket
9) Incentives for each meeting are optional
The titles of the twelve meetings are:

1) Glucose Balance Makes A Difference
2) Medicine and Glucose Balance
3) Food and Glucose Balance
4) Plan Meals for Glucose Balance
5) Move More, Sit Less!
6) Diabetes and a Healthy Heart!
7) Cholesterol and Diabetes
8) Healthy Feet Keep You Going!
9) Stress, Depression, and Diabetes
10) Preventing Complications
11) You and Your Diabetes Team
12) Living Well With Diabetes

Retention and Attendance

1. Participants will be encouraged to attend all 12 educational meetings. Participants will not be disenrolled if they miss, or choose not attend, any or all of the educational meetings. Therefore, the facilitators should simply document attendance of participants by using the sign-in sheet and transfer individual attendance to the participant’s folder. Attendance will be adjusted for in the final analyses.

2. There will be no “make-up” lessons delivered unless there is another group class that will be delivered at another time that an individual may attend. The content of the missed lesson may be provided to the participant when they attend the following meeting for self-review.