The PILI ‘Ohana Lifestyle Program

Section 1: Protocol-Based Intervention

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Developed by the PILI ‘Ohana Project; phone: (808) 692-1040 Facsimile: (808) 692-1255
e-mail: clairemt@hawaii.edu

Supported by the National Center on Minority Health and Health Disparities, National Institutes of Health (R24 MD001660).
Section 1: Protocol-Based Intervention

The PILI ‘Ohana Project’s (POP) Lifestyle intervention is to be implemented according to the POP Protocol developed by the Department of Native Hawaiian Health of the University of Hawaii and approved by the POP Intervention Steering Committee.

The Protocol specifies the following:

- The recommended goals to be set for all participants in the lifestyle intervention.
- The minimum frequency of contact to be given to all participants in the lifestyle intervention.
- The role and training of the POP lifestyle intervention staff.
- A 3-month, 8 lesson “core curriculum” for initiating weight loss adapted from the Diabetes Prevention Program’s (DPP) empirically-validated Lifestyle Program.
- A 6-month, 6 lesson “core curriculum” for weight loss maintenance that participants will receive face-to-face. The core curriculum ensures that all participants receive a standard intervention that can be easily described and translated for use in the future.
- A “tool box” (PILI PAK) of strategies and tools to help participants achieve their personal lifestyle goals.
- An emphasis on tailoring the intervention to make it more appropriate for specific populations at each community center. The purpose is to achieve individualization and flexibility within the context of a common protocol applied to all participants.
The PILI ‘Ohana Lifestyle Program

Section 2: The POP Lifestyle Intervention

Goals

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Section 2: The DPP Lifestyle Intervention Goals

All POP participants who are enrolled into the 3-month weight loss intervention are asked to achieve goals:

- To achieve a minimum weight loss of 5% of their initial body weight and
- To achieve an energy expenditure of 700 kilocalories per week through moderate physical activity (equivalent to approximately 2 ½ hours per week of brisk walking).

All POP participants in the weight loss maintenance lifestyle intervention following the 3-month weight loss program are asked to achieve two goals:

- To maintain a weight loss of 5% of their initial body weight and/or continue to lose weight, preferably between 5-10% of their initial body weight, and
- To achieve and maintain an energy expenditure of 700 kilocalories per week through moderate physical activity (equivalent to approximately 2 ½ hours per week of brisk walking).

2.1. Weight Loss and Weight Loss Maintenance Goal

**Weight loss goal:** The weight goal for the POP 3-month weight loss intervention is to achieve at least a 5% weight loss from initial body weight (as measured at start of a weight loss regime or program) and/or to lose more weight (between 5 to 10% of initial weight) by the end of three months. The recommended pace of weight loss is 1 to 2 pounds per week for 5% weight loss within approximately 12 weeks. Further information on achieving the weight loss goal is found in Section 5. Table 2.1 provides examples of 7% weight loss, if more weight loss is the goal.

**Weight loss maintenance goal:** The weight goal for the POP lifestyle intervention is to maintain at least 5% of initial body weight (as measured at start of a weight loss regime or program) and/or to lose more weight (between 7 to 10% of initial weight) throughout the weight loss maintenance phase. The recommended pace of weight loss is 1 to 2 pounds per week, if more weight loss is desired, for 7% weight loss within approximately 24 weeks. Further information on achieving the weight loss maintenance goal is found in Section 5. Table 2.1 provides examples of 7% weight loss, if continued weight loss is the goal.
2.1.1. Rationale for the Weight Goal

A 5% weight loss has been selected as the study weight goal because it is believed to be safe, effective, and feasible. Previous studies have shown that a 10% weight loss lowers glucose and improves cardiovascular risk factors, with an apparent dose-response relationship between magnitude of weight loss and improvement in these parameters. In addition, standard behavioral weight loss programs produce initial weight losses of approximately 10% of body weight.

However, the POP goal is not only to produce but also to maintain a weight loss for up to 9-months, and maintenance of weight loss has been shown to be difficult, with 10% weight loss at long-term follow-up rarely achieved in weight control programs or clinical trials. Therefore, the goal of a 5% weight loss has been selected as feasible for participants to maintain over the course of the trial.

Participants who wish to lose more than 5% of their starting weight may be encouraged to do so, although weight loss below the POP intervention goal should be encouraged only if the participant continues to have a BMI of greater than 21 (see Table 2.2) after achieving the POP goal. For example, a participant who weighs 130 pounds at Session 1 would be given a 7% weight loss goal to a goal weight of 121 pounds (Table 2.1). If the participant reaches that goal and wants to continue losing weight, the Community Peer Coach should refer to Table 2.2. If the participant’s height is 65 inches, the participant is already below a BMI of 21 (that is, below 126 pounds), so weight maintenance at 121 pounds should be encouraged rather than further weight loss.

### Table 2.1. Example DPP Lifestyle Intervention Weight Goals

<table>
<thead>
<tr>
<th>Example Starting Weight (lb.)</th>
<th>Example Starting Weight Goal (lb.)</th>
<th>Example Starting Weight (lb.)</th>
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*Note: Starting weight is the participant’s weight at start of initial weight loss efforts rounded to the nearest pound. **Calculate weigh goals for starting weights that are not included on this table.**
loss. On the other hand, if the participant’s height is 60 inches, the Community Peer Coach would be able to encourage further weight loss to 115 pounds (a BMI of 21).

Sustained weight losses of more than 3 pounds per week are not to be advised because of safety issues.

The weight goal is set at a level that should be challenging but reasonable. It is recognized that not all participants will achieve the goal at all times throughout the study. However, all participants, with the aid of their Community Peer Coach, should attempt to achieve and maintain the goal.

Table 2.2. Heights and Weights Equivalent to a Body Mass Index of 21

<table>
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<tr>
<th>Height (in.)</th>
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2.1.2. Temporary Suspensions of Efforts to Achieve Weight Goal

Efforts to achieve the weight loss and/or weight loss maintenance goal will be suspended during pregnancy and lactation. Women who become pregnant during the trial will no longer be eligible to participate further and will be instructed to follow the guidelines of their own personal physician.

During 4 to 6 month periods in which a participant is making a serious attempt to stop smoking or has ceased smoking, the participant should be encouraged to continue consuming a healthy diet, to maintain a high level of physical activity, and to try to maintain current weight. The Community Peer Coach should recognize that some weight gain may occur during smoking cessation. After 4 to 6 months surrounding smoking cessation, efforts to achieve the original weight loss and/or weight loss maintenance goal should be resumed.

Likewise, changes in body weight may occur following illness or injury. During these periods it may be necessary to temporarily suspend efforts to achieve the weight loss and/or weight loss maintenance goal. These events should be documented and brought to the attention of the Academic Co-Director.

The weight goals, however, remain in effect for all participants throughout the study. The goals are always based on weight loss and/or weight loss maintenance from Session 1. For example, if a participant weighs 180 at Session 1, and he/she lost 5% of his/her initial weight (189lbs),
Section 2:5

his/her POP weight maintenance goal is to stay at 180 ± 3lbs; this remains the weight goal even if the participant at some time gains weight to 200 pounds. If this same participant’s BMI is >21 at 180lbs, he/she may chose to continue to lose weight until a BMI of 21 is achieved.

2.2. Physical Activity Goal

The POP physical activity goal is to reach and/or maintain an energy expenditure of 700 kilocalories per week. For ease of translation to participants, the goal is described as 2 ½ hours of moderate physical activity (such as brisk walking) per week. This is to be applied to all participants, regardless of initial level of physical activity. The activity goal is to be achieved gradually over five weeks from completion of Lesson 5 of the 3-month weight loss maintenance program, if participant is not already physically active at this level (see Section 6).

2.2.1. Rationale for the Physical Activity Goal

A physical activity goal of 700 kilocalories per week has been selected because previous studies have shown that this level is sufficient to produce improvements in weight, glucose, insulin sensitivity, and overall health. Although a goal of 1000 kilocalories per week has been used in many weight loss and exercise studies, a 700-kilocalorie goal has been selected as more reasonable for participants to achieve and maintain over a 9-month clinical trial.

The physical activity goal is a minimum. Participants who wish to be more active may be encouraged to do so. Participants who are already active when they enter the study will need to determine the amount of time they are currently spending in physical activity and then add further activity to reach the 2½-hour goal. For example, a participant who already does aerobic dance for 2 hours per week may continue this and add another ½ hour of aerobic dance or another type of moderate activity to reach the 2½-hour goal. In addition, participants who are active sporadically (e.g., seasonally) should be encouraged to achieve the goal consistently throughout every month of the study.

It is recognized that not all participants will achieve the activity goal at all times throughout the study. However, all participants, with the aid of their Community Peer Coach, should attempt to achieve and maintain the goal.

2.2.2. Adjustments to the Physical Activity Goal

The physical activity goal will be adjusted during intervals of participant illness or injury. In addition, participants who are classified to have a high risk of cardiovascular complications during exercise (see Protocol) will not be allowed to participate in physical activity unless his/her physician allows it (needs medical clearance). Those who have symptoms or signs of cardiovascular disease are eligible to participate in the physical activity program, but the physical activity goals will need to be individually adjusted and only after receiving medical clearance.
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Section 3: Role and Training of the POP Intervention Staff

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e-mail: clairemt@hawaii.edu

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Section 3: Role and Training of the POP Intervention Staff

3.1. Community Peer Educators (Lifestyle Coaches)

Each POP participant will be assigned a Community Peer Educator and Manager (also called a “Lifestyle Coach”). The Lifestyle Coach will have primary responsibility for conducting the intervention with that participant (in a group setting) as well as managing him/her throughout the study. Although it is expected that the same Lifestyle Coach will continue to work with the participant throughout the POP study, a participant (or group) may be assigned a different Coach if it seems appropriate. For example, if conflicts arise between a particular participant and Coach or if a change is viewed as potentially beneficial in helping the participant achieve the DPP goals.

All Lifestyle Coaches must receive central training from the Department of Native Hawaiian Health (DNHH) Training Core (TC). The TC has identified four steps, outlined below, that should occur before a new Lifestyle Coach is assigned a participant or group of participants. All four steps should occur before the Lifestyle Coach works with participants, but it may be necessary for Step 4 to occur with actual study participants rather than with practice or pilot participants.

1. Required Reading
All new Lifestyle Coaches should be given their own copy of the POP Manual of Operations (MOP), the Participant Workbook and Handouts, the Facilitator’s Manual and the book chapters and journal articles which were distributed at the lifestyle training sessions. (See “Recommended Reading for Lifestyle Coaches” in Appendix D.1 of the MOP). A specific schedule for reading the materials should be arranged as well as an opportunity to discuss it with previously trained lifestyle staff.

2. Videotapes
Each POP community center has a set of DVDs (videotapes) from the lifestyle training meetings and DVD lessons. As with the reading materials, a specific schedule for viewing the tapes/DVDs should be arranged as well as an opportunity to discuss them with previously trained lifestyle staff. Ideally, the DNHH behavioral scientist or other key lifestyle intervention experts will meet with the Coach trainee to discuss key elements of the intervention. Each trainee should have their own copy of the Participant Workbook and Handouts and Facilitator’s Manual while viewing the tapes/DVDs, for reference and note-taking. It is not recommended that the trainees be handed all the tapes/DVDs at once and asked to “take a look at them”. The viewing/studying for each lesson should take no shorter than 2 hours.

3. Observation of DNHH Trained Personnel
Each new Coach should observe actual core curriculum lessons being conducted, or watch a tape/DVD of such sessions. This “modeling” of the intervention can be accomplished in one of the three following ways:

1. Sitting in on two or more core curriculum lessons with a DNHH trained Coach;
Section 3:3

2. Watching tapes/DVDs of two or more core curriculum lessons being conducted by a DNHH trained Coach; or if neither is possible,

3. Requesting tapes/DVDs of core curriculum lessons from the DNHH TC.

4. Videotaped Practice Sessions and Lifestyle Resource Core Review

It is recommended that, if time permits, a new Coach submit at least one or two videotapes of a core curriculum lesson conducted with practice participants (more can be submitted if desired). If this is not possible, all new Lifestyle Coaches should submit videotapes of lessons with actual participants.

3.2. Local Experts

Many community and clinical centers have identified local faculty and staff members with expertise in areas of relevance to the lifestyle intervention, including behavioral psychology, motivational interviewing, nutrition, and physical activity. These individuals should be consulted by the Lifestyle Coaches on an “as needed” basis or at regularly scheduled case conferences. If deemed helpful or appropriate, an individual participant can be scheduled to meet with these local experts for help in dealing with a specific problem area. More chronic or more severe problems should be discussed with the DNHH TC (see Section 3.4.).

3.3. Outside Referrals

If a participant presents ongoing problems outside of the expertise of the Coach/Case Manager, such as significant clinical depression, anxiety, or a clinical eating disorder, the Coach/Case Manager should consult with the DNHH researchers and discuss the participant’s case with the ISC. If the problem/issue is within the realm of expertise of the DNHH faculty (e.g., behavioral Psychologist), a decision between the community center and the ISC may be made to provide more intensive counseling by the POP professional. Or, if deemed appropriate, a referral to a non-POP professional in the community may be made.

3.4. Local Supervision and Support of Lifestyle Staff

The ISC strongly recommends that each POP community center set up a regularly scheduled consultation team meeting, at least biweekly, throughout the trial, during which the adherence of all lifestyle participants is reviewed in detail. The purpose is to anticipate and manage the challenges related to the long-term maintenance of weight loss and physical activity, including coping with lapse and relapse. At these meetings, supervision should be provided by the community PI and senior Lifestyle Coach. Other things that could be discussed/reviewed/practiced at these meetings are selected videotapes/DVDs of Lifestyle Coaches, role-playing of difficult intervention scenarios, and general support for one another in the long-term follow-up of participants.

It is important to recognize that although the DNHH TC intends to remain very involved and available to the community Coaches, this should not be seen as a substitute for ongoing local supervision.
3.5 Recommended Location for Conducting Lifestyle Sessions

Each Lifestyle Coach needs adequate space and privacy to conduct lifestyle sessions, phone participants, and store and display lifestyle materials. It is recommended that Coaches have a dedicated office/room. If that is not possible, Coaches need at minimum a location in which a door can be closed during lifestyle sessions or phone calls to ensure privacy and where posters and lifestyle materials can be stored and displayed.
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Section 4: Frequency of Contact with Lifestyle Participants and Required Staff

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Section 4: Frequency of Contact with Lifestyle Participants and Required Staff

The POP protocol specifies a minimum frequency of contact with each participant. Participants may be seen more often than specified if this seems desirable to achieve the study goals. The minimum frequency of contact is defined below by phase of study (weight loss and weight loss maintenance):

3-Month Weight Loss Program: Face-to-Face Group Format Lifestyle Program:

- Participants must be seen in person for 3 months by the Lifestyle Coach. This means 8 face-to-face lessons. The first lesson should start no later than 2 weeks following baseline data collection. The first 4 of the core curriculum lessons will be delivered over 4 weeks, one lesson weekly. The remaining 4 lessons will be delivered one lesson every other week, making the total length of the intervention 3 months. Each lesson should be no shorter than 40 minutes but no longer than 80 minutes.

- Participants need to make up any missed lessons. Preferable, this should be done before the start of the next lesson. For example, if the participant missed lesson 5, he or she needs to receive lesson 5, face-to-face with the Lifestyle Coach, prior to receiving lesson 6 at the regularly scheduled time. If participant’s schedule does not permit this, he or she needs to have the make-up session ASAP.

6-Month Weight Loss Maintenance Program: Face-to-Face Group Format Lifestyle Program:

- Participants must be seen in person for 6 months by the Lifestyle Coach. This means 6 face-to-face lessons. The 6 lessons will be delivered one lesson per month, making the total length of the intervention 6 months. Each lesson should be no shorter than 40 minutes but no longer than 80 minutes.

- Participants must call in or be followed-up by phone or e-mail once a week for check-ins and data collection of weights starting immediately following lesson 1. Each call should be no longer than 10 min. in duration. Thus, 18 phone calls or e-mail check-ins are needed per participant over the course of 6 months.

- Participants will also be asked to participate in 6 monthly community activities organized by the Lifestyle Coach following Lesson 8 of 3-Month Weight Loss Program, prior to Lesson 1 of maintenance phase. This activity should be no shorter than 40 minutes but no longer than 80 minutes.

See the section on Strategies to Promote Adherence to the Lifestyle Intervention for incentives for attendance and specific strategies to use in response to poor attendance.
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Section 5: Overview of Strategies to Achieve the Weight Loss Goal

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Section 5: Overview of Strategies to Achieve the Weight Loss Goal

5.1. Achieving the Weight Loss Maintenance Goal

Participants in the lifestyle intervention should try to maintain their 5% weight loss from their induction into the study throughout the study’s length. This recommendation is based on several factors. First, a 5% weight loss equals a weight loss of 5 to 15 pounds (the latter occurring in individuals weighing 300 pounds). In fact, weight gain as modest as 10-15 lbs in adulthood increases the relative risk of developing Type 2 DM by nearly 2-fold.

5.2. Self-Monitoring Weight

To help participants maintain their weight loss goals, all participants will be weighed at every face-to-face lifestyle intervention session, beginning with Lesson 1. Participants should be weighed in private at the beginning of the session. Weight can be taken with either a balance beam or a digital scale. The type of scale is not important, but an effort should be made to use the same scale throughout the study. Participants should be weighed in light-weight, indoor clothes, without shoes.

The Community Lifestyle Coach will record the weight on/in the POP Lifestyle Intervention Data Form/Database and on the weight chart in the participant’s notebook. Participants should be encouraged to complete the weight chart themselves, if possible. The Community Lifestyle Coach and participant should discuss the participant’s weight in relation to their weight loss maintenance goal (i.e. no more than 3 lbs weight regain), and the Community Peer Coach should continually encourage the participant to maintain their weight loss.

In addition to being weighed at every face-to-face session, all lifestyle participants will be encouraged to weigh themselves at home at least weekly and record their weight on their PILI weight charts. Participants should be instructed to weigh themselves on the same day(s) of the week and at the same time of day (for example, on Monday mornings).

At the beginning of the intervention, Community Lifestyle Coaches may want to assign more frequent self-monitoring of weight, for example, daily, and continue to encourage it if the participant finds it helpful. Some participants may respond to frequent fluctuations in their weight by becoming discouraged. However, the Community Lifestyle Coach can use a participant’s record of frequent ups and downs in weight to teach the participant to focus on trends rather than on single values and to respond promptly to slips with positive behavior changes until the results are seen consistently on the scales. In this way, frequent self-monitoring of weight can become a source of information and encouragement to many participants.
5.3. Setting a Fat Intake Goal

To help participants maintain their weight loss, all lifestyle participants will be encouraged to decrease their daily total fat intake and set a fat intake goal. The initial focus is on total fat rather than calories for several reasons. A focus on total fat is designed to accomplish a reduction in caloric intake while at the same time emphasizing overall “healthy eating” instead of a restrictive “diet”. Focusing on total fat also simplifies the message and streamlines self-monitoring requirements. Calorie balance is formally introduced only after Lesson 7 into the program. This delay is designed to allow time for the participant and Community Lifestyle Coach to determine whether their current self-monitoring of calorie/fat intake and physical activity is sufficient to achieve weight loss maintenance.

At any time during the study, participants who are interested in monitoring both calories and fat should be given both a fat and calorie goal and encouraged to monitor both aspects of the diet.

The fat goals have been calculated based on 25% of total calories from fat, using a calorie level estimated to produce a weight loss of 1 to 2 pounds per week (described in detail below). The various fat gram levels were then collapsed into one of four goals: 33, 42, 50, or 55 grams of fat.

A level of 25% of calories from fat was selected because it is believed to be effective, safe, and feasible. In the Women’s Health Trial, a low-fat dietary-intervention trial, more than 80% of the intervention group had met their fat gram goal, calculated as 20% of baseline calories, within 3 months of randomization and maintained that goal through the end of the trial at 3 years. Although women in this study were not encouraged to decrease energy intake or lose weight, the reduction in fat intake was associated with a 25% reduction in total calories and a weight loss of 3.1 kg after 1 year. Weight loss was more strongly associated with change in percent energy from fat than with change in total energy intake.

It should be recognized that all participants are given a fat intake goal will not immediately achieve this goal. For example, a participant who eats 40% of their calories from fat may initially find it difficult to achieve the 25% goal and may first reduce to 35% fat and then to 30% fat. However, the participant should be assigned the 25% fat goal, and all progress toward reaching this goal should be praised.

Lowering fat to a specific level is used in this study as a means to maintaining weight loss, rather than as a goal in and of itself. Thus, if a participant is consuming more than 25% of calories as fat, but is achieving the weight goal, and does not have hyperlipidemia (high cholesterol), there is no need to focus on greater reductions in dietary fat.
Table 5.1. PILI ‘Ohana Lifestyle Intervention Fat and Calorie Goals*

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<td>210</td>
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<td>215</td>
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</tbody>
</table>

*Note: To determine participants’ fat and calorie goals, round their starting weight to the nearest starting weight on this table. Starting weight here is the participant’s weight at entry into the PILI Weight Loss Maintenance Study (not their initial weight at start of weight loss program).

5.4. Setting a Calorie Goal

Some participants will achieve weight loss maintenance by self-monitoring fat intake. Others, who may continue to eat large amounts of protein and carbohydrates or inaccurately estimate fat intake, will need to add calorie monitoring to achieve their weight loss maintenance goal. At that lesson entitled Making Eating Healthy, Easy and Fun calorie counting will be introduced for participants who have not maintained their weight loss as expected.

It is important that the introduction of calorie self-monitoring not be conveyed as “punishment” for “failing” at weight loss maintenance but rather as another learning tool or method for understanding a participant’s energy intake patterns. The proposed calorie goals were calculated by first estimating the daily calories needed to maintain starting weight (starting weight multiplied by 12). Next, between 500 and 1000 calories were subtracted to estimate the calories needed to lose 1 to 2 pounds per week to return to their initial 5% weight loss.

More calories were subtracted for heavier participants with the rationale that they have more weight to lose to return to the 5% weight loss goal (500 calories were subtracted for starting weights less than 150 pounds, 750 calories for starting weights between 150 and 200 pounds, and 1000 calories for starting weights over 200 pounds.) Finally, the ranges of calories estimated for weight loss were collapsed into one of four standard calorie levels: 1200, 1500, 1800 or 2000.

Some participants may report a low fat/calorie intake without maintaining their weight. In this case, the Community Lifestyle Coach should review the quality of the participants’ self-monitoring and if lacking, (for example, if portion sizes are being inaccurately reported, if additions such as cream to coffee are routinely forgotten, etc.), the Community Lifestyle Coach
should help the participants improve their self-monitoring skills. If a participant is still gaining weight after attempts to improve self-monitoring, it may be necessary to lower the calorie goal further to help him or her maintain their weight loss goal.

Guidelines for adjusting the calorie goal are given in the tool box (PILI PAK) for weight loss. Although the minimum goal has been set at 1200 calories, the goal may be reduced to 1000 calories if a participant is gaining weight and efforts to improve self-monitoring have been made. Because of the possibility of nutritional inadequacy at an intake of 1000 calories, a daily vitamin and mineral supplement at 100% of the Recommended Dietary Allowances should be recommended for these participants, and the overall nutritional adequacy of the participant’s eating pattern should be carefully monitored. Before assigning a calorie goal below 1000 calories, the Community Lifestyle Coach should contact the Academic Co-Director.

Lowering dietary calories to a specific level is used in this study as a means to achieving the weight loss maintenance goal, rather than as a goal in and of itself. Thus, if a participant is consuming more than their calorie goal, but is maintaining their weight (and does not have hyperlipidemia), there is no need to focus on greater reductions in calories.

Participants assigned a calorie goal will be asked to either self-monitor calories or follow a study-provided meal plan (e.g., plate method) at the prescribed calorie level. Before being distributed, the sample meal plan should be tailored to suit each participant’s food preferences. The meal plan should be presented as a flexible model from which the participant can develop an individualized eating style appropriate for weight loss maintenance, rather than as a rigid prescription set in stone.

5.5. Self-monitoring Fat and/or Calorie Intake During the Core Curriculum

All participants will be instructed on how to self-monitor fat intake in grams and daily calorie intake. All participants are encouraged to record their intake because of the extensive evidence that self-monitoring is highly correlated with success in reaching dietary change goals.

Numerous studies have shown a dose-response relationship between frequency of self-monitoring and level of success in losing weight and/or improving cardiovascular risk factors. Many experts consider self-monitoring the single most effective approach to changing dietary intake. Participants in clinical trials and behavioral weight loss studies are typically asked to record their intake daily for the first several months of the intervention.

Participants could be given the following self-monitoring tools:

- Tools for weighing and measuring foods (a food scale, metal or plastic measuring cups and spoons, a glass measuring cup, ruler).
- A “PILI Daily Food Log,” for recording daily food intake with fat and/or calorie values.
- A “PILI Weekly Meal Planner,” for planning healthy meals for a week at a time.
- “Calorie King Fat and Carbohydrate Counter,” a nutrient counter alphabetized by food name, with the fat gram and calorie content of household portions.
Section 5:6

Self-monitoring skills will be taught gradually throughout the curriculum, with self-monitoring of dietary intake and physical activity being introduced sequentially. Participants will be encouraged to be complete and accurate in self-monitoring and at the same time to feel free to use abbreviations and short-cuts that work for them (e.g., write “Breakfast, 200 calories” when they eat their standard 200-calorie breakfast, provided the Community Lifestyle Coach is well aware of the foods in the breakfast from past records). In other words, the participant is NOT taught to self-monitor with the thoroughness and detail that would be required if the records were to be entered into a computer for nutrient analyses.

It is recognized that not all participants will self-monitor daily at all times throughout the study. However, all participants should endeavor to achieve and maintain daily self-monitoring and should receive a strong and clear message that self-monitoring is the key behavior change strategy in the lifestyle intervention.

All self-monitoring records should be reviewed by the Community Lifestyle Coach. During the lesson, the review should be kept brief. The comments should highlight examples of positive changes the participant has made and help the participant solve any problems encountered, particularly those related to the topics discussed at the previous session. During the weekly phone calls, the Community Lifestyle Coach can also review self-monitoring with the participants. Because the self-monitoring records are intended to help the participant make behavior changes rather than serve as a source of dietary data, the review should not be as detailed or extensive as would be the case when documenting food records to be entered for nutrient analysis.

5.5.1. Guidelines for Individualizing the Frequency or Method of Self-Monitoring During the Core Curriculum

In some cases, a participant may have difficulty self-monitoring daily or using the standard method and tools for self-monitoring during the core curriculum. For example, some participants may have very limited reading or math skills. In these cases a simplified form of self-monitoring may be used (see the tool box for weight loss maintenance). Likewise, over time some participants may become less adherent to self-monitoring. If weight loss maintenance is progressing as expected without self-monitoring, self-monitoring should be encouraged but not required. If weight gain is occurring, the barriers to self-monitoring should be addressed and an alternate method or frequency of self-monitoring should be assigned, again with high expectations expressed. See the tool box for weight loss maintenance for a description of alternate self-monitoring tools and guidelines for using them.

5.6. Self-Monitoring Fat and/or Calorie Intake After the Core Curriculum

If weight loss is maintained, self-monitoring for at least one week every month should be strongly encouraged. For participants who have maintained their weight goal, the minimum required frequency will be one week of self-monitoring every month. For participants who are not at goal, the Community Lifestyle Coach should problem solve with the participant. The frequency of self-monitoring should be increased as necessary until the weight goal is maintained, and/or alternate self-monitoring tools should be recommended to address any
barriers to self-monitoring (see tool box for weight loss maintenance). Participants who continue frequent self-monitoring may be the ones who will be most successful at long-term behavior change.

5.7. Supervised Community Activity Sessions

5.7.1 General Guidelines

Every community center will provide a supervised monthly activity, alternating between physical activity focused and nutrition focused, sessions once a month. The purpose is to help participants achieve their fat intake and/or calorie and physical activity goal. Supervised nutrition sessions also provide group support for healthy eating and allow for the collection of data, beyond self-report, on diet.

Community Peer Coaches should strongly recommend that all participants attend the sessions. The goal is for all participants to have the opportunity to give the sessions a “good try,” receive hands-on healthy eating instruction and encouragement from the session leaders (e.g., Community Lifestyle Coach), and meet other participants with whom they can develop support networks for being active. Throughout the study, participants who are having difficulty meeting their fat intake and/or calorie goals should in particular be encouraged to attend.

The supervised activity sessions should last about 45 minutes to 1 hour. Possible locations include the farmers markets, community kitchens, grocery stores, and restaurants. The types of activity may vary and should be tailored to the skills and interests of the participants. It is recommended that at least one session involve a cooking and meal planning demonstration. Other possible types of activities include reading food labels, grocery shopping, and gardening.

The supervised activity sessions should be scheduled at times and locations to accommodate as many lifestyle participants as possible. Communities may need to experiment with various types of activities, times and locations in order to attract more participants. To determine the types of activities to offer and the most convenient times and locations, Coaches may want to periodically survey participants.

Keep in mind the following safety issues:

- If possible, during the activity sessions, considerations should be made for participants of different knowledge and income levels. For example, the leader may need to be sensitive to participants’ ability to pay at grocery stores and farmers markets.
- If the activity session is being held at a remote location with limited access to emergency medical services or a telephone the leader should have a cell phone for emergencies.

In general, it is anticipated that most of the nutrition sessions will be led by a member of the PILI staff, such as an exercise physiologist, student, Community Lifestyle Coach, or other trained peer leader. All activity session leaders should be trained in CPR. If your center has difficulty offering the required sessions or has found that these sessions are poorly attended, you can use a nutrition class in the community (e.g., a healthy eating class in a health facility in your community) provided all three of the following guidelines are followed (with this
Section 5:8

cautions: use outside classes to supplement your nutrition intervention; each center should still have an expert in nutrition on the PILI staff to guide and support participants and Coaches:

1. Before participants attend the class, meet with the leader to evaluate the facility and the nature of the class and explain the purpose of the PILI Lifestyle Intervention and the healthy eating goals. For as long as participants attend, contact the leader periodically to check on how the participants are doing. If the class leader changes, meet with the new leader to orient him or her to the PILI Lifestyle Intervention and the healthy eating goals.

2. Advertise the class to all lifestyle participants and provide any registration fees or other costs so that all who want to can attend.

3. Get written documentation from the leader that the participants attended.

If any one of the above three guidelines are not followed, the class cannot be considered a supervised session.

It is expected that attendance at each nutrition session will differ. That is, some participants may come to all sessions while others may come only on occasion. All patterns of attendance are acceptable. Support persons are encouraged to attend as well.

Centers that are having difficulty attracting participants to supervised sessions are strongly encouraged to contact the PILI Intervention Steering Committee for problem solving and support.

5.7.2 Models of Supervised Activity Sessions

The following models illustrate a few of the many possible ways to fulfill the requirement for supervised nutrition sessions. Other possibilities exist, and some centers use a combination of the following models. If the supervised nutrition sessions at your center are categorically different than the models below, please call the Academic Co-Director.

**Grocery Store Outing**
The group takes a trip to a neighborhood grocery store. The PILI staff or a Lifestyle Coach leads the outing. While at the store the group practices how to read nutrition labels, compare prices and nutritional value, learn where healthier/less fatty options are located, and practice purchasing according to their weekly meal plan.

**Cooking Demonstration**
Led by the Community Lifestyle Coach or a community-based nutrition expert, the group watches a healthy cooking demonstration. Once the demonstration is complete, participants are encouraged stay and eat using the “plate method.” Additionally, participants are provided with the recipe from the demonstration, as well as other healthy recipes.

**Weekly Meal Planning**
The group practices planning their families’ meals for a week, incorporating their fat intake and/or calorie goals. These plans should include all meals and snacks for an entire week and utilize recipes from the cooking demonstrations.
The PILI ‘Ohana Lifestyle Program

Section 6: Overview of Strategies to Achieve the Physical Activity Goal

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e-mail: clairemt@hawaii.edu

Supported by the National Center on Minority Health and Health Disparities, National Institutes
of Health (R24 MD001660).
Section 6: Overview of Strategies to Achieve the Physical Activity Goal

6.1. Achieving the Physical Activity Goal

Participants are encouraged to achieve the physical activity goal of 700 kilocalories per week (or 2 ½ hours of moderate activity) and then to maintain the goal for the remainder of the study. First, participants are simply encouraged to do something active on 3 to 4 days per week. Subsequently, they are encouraged to increase their activity level to 60, 90, 120, and finally 150 minutes per week.

6.2. Self-monitoring of Physical Activity

All participants will be encouraged to self-monitor physical activity daily throughout the study. Participants will be given weekly calendars on which to plan and record daily physical activity as part of the PILI Pak (tool kit).

Self-monitoring skills will be taught gradually throughout the curriculum, with self-monitoring of physical activity and dietary intake being introduced sequentially.

Achievement of the physical activity goal is based solely on participant self-monitoring records (unlike with weight loss maintenance, there is no objective measure to verify self-report of physical activity level). Thus, it is important that all participants continue to record their activity weekly throughout the study and that accurate information be obtained. If physical activity is not increasing as expected, alternate methods of self-monitoring should be used. See the PILI PAK (tool box), physical activity section, for a description of alternate self-monitoring tools and guidelines for using them.

All self-monitoring records will be reviewed by the Community Peer Coach during the lessons and, if necessary, during weekly check-ins. The group and Community Peer Coach will highlight positive changes the participants have made and help them address any barriers to physical activity encountered.
Section 6:3

6.3. Definition and Examples of Moderate Physical Activities

The intent of the PILI lifestyle intervention is to encourage all types of physical activity. However, depending on the intensity of the activity, more or less than 2 ½ hours of time doing the activity may be required to use 700 kilocalories. We believe that most participants will use walking as their primary type of physical activity. These individuals should be instructed to walk briskly for 2 ½ hours during the week. Other activities that are similar in intensity to brisk walking are shown in Table 6.1; as with brisk walking, participants who do these activities for 2 ½ hours per week will typically expend 700 kilocalories.

Table 6.1. Moderate Physical Activities Usually Equivalent to Brisk Walking

The following physical activities are usually equivalent in intensity to a brisk walk.

- Aerobic dance (high impact, low impact, step aerobics)
- Skiing (cross-country, Nordic Track)
- Dancing (square dancing, line dancing)  
  Note: Be careful not to include breaks.
- Soccer
- Bicycle riding (outdoors or on an indoor, stationary bike)
- Stair Master
- Tennis
- Hiking
- Water Aerobics
- Swimming (laps, snorkeling, scuba diving)
- Strength Training (free weights, Nautilus, etc.)
- Walking (outdoor, indoor at mall or fitness center, treadmill)
- Volleyball
- Skating (ice skating, roller skating, rollerblading)
- Rope jumping
- Jogging (outdoor, indoor, treadmill)
- Karate
- Rowing (canoeing)

Many physical activities may or may not be equivalent to brisk walking, depending on how they are performed by an individual participant. For example, the following activities may be more intense than brisk walking, depending on how they are performed: basketball, squash, handball, and racquetball. On the other hand, the following may be less intense than brisk walking, depending on how they are performed: golf (walking only and carrying or pulling clubs), softball, and baseball. Participants who regularly perform physical activities other than those listed in Table 6.1 should be made aware of this variation and consult the “PILI Calories Burned List” in the PILI Pak (tool kit) for average calories expenditures for other activities.

In addition, the Community Peer Coach should discuss the physical activities that participants do or plan to do and evaluate them in terms of its application toward the study goal. Participants should not be given a list, such as that in Table 6.1., and told that these are “acceptable” activities whereas others are not. Rather, participants should discuss their activities with the Community Peer Coach and/or the exercise physiologist available at the local center to identify a way in which the participants can expend at least 700 kilocalories per week in physical activity.

The following general guidelines are provided to help Community Peer Coaches judge whether an activity is equivalent to brisk walking:
The activity should last at least 10 minutes, not including breaks (although some activities such as tennis or jumping rope may involve short “breaks” in the activity).

For job-related activities, in addition to the above two criteria, the physical activity should comprise at least 50% of the job.

For example:

<table>
<thead>
<tr>
<th>Equivalent to brisk walking</th>
<th>Not equivalent to brisk walking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using a gas-powered push mower to mow several acres of lawn with a great deal of exertion.</td>
<td>Using a gas-powered push mower to mow a tiny lawn in five minutes, without much exertion. Using a riding mower to mow several acres of lawn without much exertion.</td>
</tr>
<tr>
<td>Delivering the mail if 75% of the day is spent walking.</td>
<td>Delivering the mail if 75% of the day is spent driving a truck.</td>
</tr>
<tr>
<td>Going to a dance and dancing most of the evening.</td>
<td>Going to a dance and dancing only a few times during the evening. Spending most of the time socializing and watching others dance.</td>
</tr>
</tbody>
</table>

Some sports and leisure activities are clearly not equivalent in intensity or duration to brisk walking, such as archery, bowling, fishing, light gardening, and pool. These are to be encouraged as part of an active lifestyle but are not to be applied toward the activity goal. Likewise, other activities, such as light yard work and light housework are to be encouraged as part of an active lifestyle but not self-monitored or applied toward the goal because they usually do not represent a level of activity equivalent to brisk walking. The criteria of “equivalent to brisk walking” is used with the rationale that such activities will be most likely to help participants lose weight, lower glucose, and improve cardiovascular risk factors.

Some participants may choose to do more vigorous activities, such as running. In these cases it may be unnecessary to do 2 ½ hours of activity to achieve the 700 kilocalorie goal. These cases are expected to occur infrequently and should be discussed with local experts in exercise physiology and with the Academic Co-Director before making any reductions in the 2 ½ hour goal.

If questions arise about whether a particular activity as performed by a participant may be applied toward the study goal, the Community Peer Coach should contact the Academic Co-Director of POP.

### 6.4. Supervised Community Activity Sessions

#### 6.4.1 General Guidelines

Every community may provide a monthly supervised activity, alternating between physical activity-focused and nutrition-focused sessions at least once a month. The purpose is to help participants achieve the physical activity goal. Supervised activity sessions also provide group
support for exercise and allow for the collection of data, beyond self-report, on participation in
exercise.

Community Peer Coaches should strongly recommend that all participants attend the sessions. The goal is for all participants to have the opportunity to give the sessions a “good try,” receive hands-on physical activity instruction and encouragement from the session leaders, and meet other participants with whom they can develop support networks for being active. Throughout the study, participants who are having difficulty meeting their exercise goal should in particular be encouraged to attend.

The monthly community activity focusing on physical activity does not need to be an actual exercise class. It could be activities designed to identify and learn about community resources for physical activity, such as parks, gyms, and exercise classes. The supervised activity sessions should last about 45 minutes to 1 hour. If an exercise class is being done as a community activity, ensure that all participants have medical clearance and that the exercise includes a warm-up period, followed by about 30-40 minutes of exercise and a cool-down period. Possible locations include the malls, parks, gymnasiums, or exercise facilities such as a YMCA or private health club. The types of physical activity may vary and should be tailored to the skills and interests of the participants.

It is recommended that at least one session involve brisk walking. Other possible types of activities include aerobic dance, resistance training, and step aerobics. The activities offered must be equivalent to brisk walking (see Section 6.3. Definition and Examples of Moderate Physical Activities). Activities not on Table 6.1. should be approved by the PILI ISC before being offered as a supervised activity session.

The supervised activity sessions should be scheduled at times and locations to accommodate as many lifestyle participants as possible. Communities may need to experiment with various types of activities, times and locations in order to attract more participants. To determine the types of activities to offer and the most convenient times and locations, Coaches may want to periodically survey participants during lessons.

Keep in mind the following safety issues:

- If possible, during the activity sessions, considerations should be made for participants of different fitness levels. For example, the leader may need to split his or her time between the slow and fast walkers or consider walking on a track so that a variety of paces can be accommodated. Some centers may have adequate staff to provide more than one leader.
- If the activity session is being held at a remote location with limited access to emergency medical services or a telephone (such as on a hiking trail), the leader should have a cell phone for emergencies and, if possible, a First Aid kit with bandages, ace wrap and cold pack for minor injuries.
Leaders should emphasize hydration during the activity sessions (especially in warmer weather) and should have water available for participants who do not bring water.

In general, it is anticipated that most of the supervised physical activity sessions will be **led by a member of community center who is a certified trainer or exercise physiologist**. All activity session leaders should be trained in CPR. If your center has difficulty offering the required sessions or has found that these sessions are poorly attended, **you can use an exercise class in the community** (e.g., an aerobics class in a health facility at your university) **provided all three of the following guidelines are followed** (with this caution: use outside exercise classes to supplement your physical activity intervention; each center should still have an expert in exercise on the PILI staff to guide and support participants and Coaches):

1. **Before participants attend the class, meet with the leader** to evaluate the facility and the nature of the class and explain the purpose of the PILI Lifestyle Intervention and the activity goal. For as long as participants attend, contact the leader periodically to check on how the participants are doing. If the class leader changes, meet with the new leader to orient him or her to the PILI Lifestyle Intervention and the activity goal.

2. **Advertise the class to all lifestyle participants who are at an appropriate fitness level and provide any registration fees** or other costs so that all who want to can attend.

3. **Get written documentation from the leader that the participants attended.**

If any one of the above three guidelines are not followed, the class cannot be considered a **supervised activity session**, although it could count toward the participants’ self-reported activity minutes.

It is expected that attendance at each activity session will differ. That is, some participants may come to all activity sessions while others may come only on occasion. All patterns of attendance are acceptable. Support persons are welcome to attend as well.

Centers that are having difficulty attracting participants to supervised activity sessions are strongly encouraged to contact the Academic Co-Director for problem solving and support.

The PILI Pak (tool kit) that each participant will receive will have several DVDs with various exercise videos that cover a range of exercises. The participants should be encouraged to use these DVD outside of the PILI lessons and activities. The Community Peer Coach may choose to use these exercise DVDs as part of the monthly community activity.

**6.4.2 Models of Supervised Activity Sessions**

The following models illustrate a few of the many possible ways to fulfill the requirement for supervised activity sessions. Other possibilities exist, and some centers use a combination of the following models. If the supervised activity sessions at your center are categorically different than the models below, please call the Academic Co-Director.
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*Neighborhood Group Walks*
Two or more group walks are offered per week in separate neighborhoods around the city, convenient to different participants. The PILI exercise consultant or a Community Peer Coach leads the walks. When possible, the walks are tied into training for a community walking event such as the local ADA walk.

*Cardiac Rehabilitation Unit*
Participants use the cardiac rehabilitation unit affiliated with a medical or health center. The unit includes a treadmill, exercise bike, recumbent bike, stair master, and free weights. The Coach introduces the participants to the unit, and then participants set up a regular schedule with the staff.

*Community Exercise Class or Facility*
Participants attend aerobic dance classes or step aerobic classes at the local Wellness Center and YWCA. The Coach introduces the participants to the class leaders. If funding is available in the community center’s budget, PILI pays the registration fees for the classes.
The PILI ‘Ohana Lifestyle Program

Section 7: Principles and Guidelines for Implementing the PILI Lifestyle Intervention

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Developed by the PILI ‘Ohana Project; phone: (808) 692-1040 Facsimile: (808) 692-1255
e-mail: clairemt@hawaii.edu

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Section 7: Principles and Guidelines for Implementing the PILI Lifestyle Intervention

7.1. Key Principles

The 3 key principles underlying the PILI lifestyle intervention are:

1. **It is based on clearly defined study goals.**

   All participants set their goals for weight loss maintenance and health living. From the beginning of the intervention, the Community Peer Coaches should help the participants develop these goals. Once developed, the Community Peer Coaches should state these goals without equivocation and set high expectations for participants in terms of achieving them for the length of the trial. The rationale is that reaching and maintaining the goals is what will reduce the risk of diabetes and cardiovascular disease association with overweight and obesity.

2. **The intervention is based on participant self-management.**

   Although the overall study goal of weight loss maintenance is a given, each participant makes personal choices about how to achieve that goal. This allows flexibility and reinforces the ability of the participants to shape and evaluate their own progress by self-monitoring, developing personal goals and action plans, and problem solving. The role of the Community Peer Coach is to guide and support the participants in the process of self-management.

   To achieve a balance between the study goal and participant self-management, Community Peer Coaches will need to draw on all of their professional skills and experience. Central to the success of the intervention is the relationship between Community Peer Coach and participant. Ideally, this relationship might be compared to that between a talented coach and a prized member of an athletic team. As “community peer coaches,” we recommend that Community Peer Coaches practice the following.

   - **Express support and acceptance** for participants regardless of their progress toward study goals.
   
   - **Look for success and build on it**, no matter how small or gradual.
   
   - At the same time, **maintain the highest of standards and expectations**. Don’t lessen the study goals to match what seems “realistic” or “do-able” for a participant, any more than a health care provider would ask a patient to aim for less than optimal glucose monitoring and regulation. Instead, the Community Peer Coach should express ongoing confidence that the participant will be able to reach and maintain the study goals and then provide the utmost support in helping the participant address any barriers to that end. As we all know,
expectations are often self-fulfilling. If expected to do poorly, participants are more likely to do poorly; if expected to do well, many participants will rise to the occasion.

- Along the same lines, **do not assume that a barrier to the study goals exists until it is evident** (for example, that a participant who has a lower level of education will be unable to calculate fat grams when self-monitoring). Such assumptions are often based on hidden biases that may prove false (for example, many interventionists have reported that it is the less educated participants who do the most thorough self-monitoring).

- **When barriers do become evident, involve the participant as much as possible in addressing them, through goal setting and problem solving.** Use and convey an experimental approach--the evidence of a barrier is not a sign of failure on the part of the coach or the participant but rather is a valuable piece of information to be used to design and test a better experiment, together.

- **Be the “coach”**. Be confident and firm when assigning the strategies for change presented in the intervention (such as self-monitoring of fat gram intake and physical activity). Stress that previous research has shown these strategies to be highly successful for many, many people. However, be flexible about using other strategies as needed. Information and behavioral strategies have been included in the intervention because of their likelihood of enhancing achievement and maintenance of the study goals, not as ends in themselves.

3. The intervention is to be tailored to participant lifestyle, learning style, and culture.

The PILI lifestyle intervention program should be tailored to participants’ lifestyle, learning style, and culture. Many, many factors (such as ethnic heritage, socioeconomic status, marital status, and roles at work and at home) will have an impact on the eating and activity behaviors of participants. Such factors will also be at work in the lives of the Community Peer Coaches themselves and will influence the way they interact with participants.

Community Peer Coaches should therefore remain open and sensitive to whatever factors may be important to each individual participant and at the same time, avoid stereotyping or making assumptions. The goal is to implement the PILI lifestyle intervention with awareness, consideration, and careful communication so that differences can be used to enhance the intervention rather than get in its way.

Some points to keep in mind regardless of a participant’s lifestyle or cultural heritage:
- Be careful to avoid interpreting a behavior within your own cultural context without asking.
• Low-literacy English is not a sign of intelligence or a predictor of success in the DPP.

7.2. Core Curriculum

There are 14 lessons of the PILI lifestyle intervention program, called the “core curriculum,” and include 4 review lessons. In the core curriculum, all participants are taught the same basic information about weight loss and physical activity and are given the opportunity to practice related behavioral skills both during the intervention lessons and at home. Also it is during the core curriculum that the Community Peer Coaches and participants get to know each other and learn how best to work together to achieve the study goals.

7.2.1. Type and Frequency of Contact

Participants must be seen a **minimum of 14 times during the curriculum**, and the entire curriculum must be presented within 9 months. Although the exact schedule of visits will vary depending on holidays, illnesses, travel, and so on, we strongly recommend that participants are seen weekly for the first month, bi-monthly for the next 2 months and then monthly for the last 6 months. More frequent contact schedules have been shown to produce greater weight losses, so the maximum frequency of contact should be maintained as long as possible, given participant willingness and staff and budget constraints. However, to produce maintenance the study must last at for a minimum of 9 months. The tool box for attendance specifies procedures to be tried if participants are not attending lessons and when calls to the Academic Co-Director are to be made. Phone calls to participants between visits may be helpful and can be used to reinforce and encourage behavior change.

Participants will be seen on a group basis. Lessons should be scheduled at times most convenient to the participant, for example, in the evening for participants who work during the day and prefer evening meetings.

Participants are encouraged to bring a family member or other support person to all the lessons. Decisions about whether to include another family member or support person should be based on the participant’s wishes.

7.2.2. Role of the PILI Staff

The all of the lessons must be presented by a trained Community Peer Coach. The intended role of the Community Peer Coach, or other staff member who presents the lessons, is one of educator, facilitator, and “coach.” The participant is responsible for implementing and evaluating strategies to reach the study goals, with the support and guidance of the Community Peer Coach or other staff. Self-monitoring, goal setting, and home activities are included in each lesson to reinforce the participant’s sense of personal responsibility for the success of the intervention.
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7.2.3. Location of Lessons

Most lessons should be held in a private room or similar setting. A scale (balance beam or digital electric) must be available so that the participants can be weighed at each lesson. On some occasions, the Community Peer Coach may wish to conduct a lesson while at another location selected for an educational goal, such as at a park. However, the location should enhance rather than distract from the basic content of the lesson. Because the lessons are dense with fundamental information and skills, it may be best to reserve most alternate locations for the monthly community exercise/nutrition activity, for example, holding a group supermarket tour at a grocery store.

7.2.4. Maintaining the Basic Content and Sequence of Lessons

The basic content and sequence of the lessons must be consistent across clinical centers and from group to group within each center. Otherwise, at the end of the trial we will not be able to describe the intervention program as implemented or draw conclusions about its efficacy. Specific instructions for conducting each lesson are given in Appendix A.

The Community Peer Coach should proceed through the 14 lessons in the order prescribed, varying only the timing of the flexible lessons. This will ensure that all participants receive the same intervention program, that lessons on physical activity, nutrition, and behavioral topics are interspersed, and that topics that build on those presented earlier come in the correct sequence.

If a participant is having trouble in an area and the lesson on that topic does not occur until later in the core curriculum, the Community Peer Coach should briefly address the issue and problem solve with the participant as appropriate. At the same time, the Community Peer Coach should keep the focus on the topic for the current lesson and delay the formal presentation of the other material until it appears in the standard curriculum. For example, during the activity “Be a Fat Detective”, a participant might say, “I eat out for lunch all the time. How can I find low-fat foods when I eat out?” The Community Peer Coach might suggest that the participant:

a. Use the Fat Counter to self-monitor when she eats out just as she would at other times, and if a food isn’t in the Counter, find one that is the most similar,

b. Ask the waiter for any nutrient information, if available, and

c. For the next lesson, bring in any nutrient information she collects plus menus from the restaurants he eats at during the week and together the participant and Community Peer Coach will estimate the fat grams for various choices on the menus.

This response keeps the focus of the lesson on self-monitoring, rather than shifting it to a lengthy discussion of various strategies for healthy eating when eating out, which is formally presented in the activity “Four Keys to Healthy Eating Out” in a later lesson. Indeed, many participants will be faced with challenges related to eating out before that lesson, but the topic formally appears this late in the curriculum because the lesson builds on previous lessons that address self-monitoring, cues, and problem solving. Similarly, if
a participant says he will be unable to lower his fat intake or increase his physical activity because of family pressures, lack of motivation, and so on, the problems raised by the participant should be discussed and strategies suggested to deal with the problem. However, the formal presentation of social support, problem solving, lapses, and so on, would be held until the appropriate lesson.

7.2.5. Guidelines for Tailoring the Presentation of the Lessons

While maintaining a standard curriculum in terms of the basic content and sequence of the lessons, the Community Peer Coach should tailor the presentation of the lessons to different learning styles, stage of change, and progress toward the study goals. For instance, the Community Peer Coach should explain concepts in the lessons by using examples that are relevant to participants’ ethnicity, financial means, and preferences. The Community Peer Coach should feel free to replace any of the examples given in Appendix A and on participant work sheets with other, more relevant, examples. Similarly, the Community Peer Coach should feel free to use supplementary educational aides if it is clear that this approach will enhance learning for participants and not draw attention or time away from the basic concepts presented.

Some examples of appropriate ways to tailor a lesson: Displaying test tubes filled with shortening to varying levels to illustrate the fat content of different foods, providing individual samples of low-fat food products to taste.

Some examples of inappropriate ways to tailor a lesson: Having a hypnotist come to the lesson on motivation; dropping the lesson on slips because the participant has not had any lapses; presenting a cooking demonstration on low-fat vegetarian cooking at the lesson entitled, “Healthy Eating.” (This last example is considered inappropriate because it would take time away from the many basic concepts to be presented at this lesson and would not be relevant to all participants. However, this topic may be appropriate for a community activity if a number of participants express a need for or interest in this topic.)

7.2.6. Guidelines for Using the Participant Work Sheets

Each PILI lifestyle participant will be given a three-ring binder and at each lesson will receive a copy of the materials for that lesson. Participants are not to be given the entire set of materials at one time. Participants should take the binder home with them at the end of each lesson and bring it to the next lesson.

The Community Peer Coach should use the facilitator guide during the lesson to present the main points while the participants follow along in their workbooks. The Community Peer Coach and participants should feel free to write or draw on the work sheets, indicating points of emphasis, adding examples, and so on. The participant should fill in any blanks or complete any practice activities in his or her own words whenever possible.

Some lessons may have worksheets, these are to be inserted into the participant’s study notebook during or at the end of the lesson.
7.2.7. Use of Supplemental Materials and Tools of Presentation during the Lessons

A great deal of information is presented to participants, and there is concern that participants not be overloaded with additional information and related materials. For this reason, **no supplemental materials should be given to participants without prior approval from the Academic Co-Director**. Similarly, any tools of presentation that an individual clinical center or Community Peer Coach would like to use should be sent to the Academic Co-Director for review beforehand. This process is designed to help the Community Peer Coaches maintain the needed focus of each lesson, and it will also allow the Academic Co-Director to bring supplemental materials and tools of presentation to the attention of the other centers so that all can benefit. It is important that Community Peer Coaches realize that more information is not always better. In fact, the key concepts of the intervention may be lost if participants are given too much information or too many handouts.

If a participant asks for more detailed information on a topic or asks for information on a topic not presented in the curriculum (for example, the cholesterol content of foods), we caution Community Peer Coaches to evaluate the request carefully before proceeding. For example, at first glance, it may seem that more highly educated participants who ask for additional information should be given as much information as possible to encourage their sustained interest and adherence. However, the opposite may be the case if a participant is “intellectualizing” rather than dealing with the behavioral issues that need to be addressed if change is to occur.

To evaluate when and whether to provide additional information, consider the following:

- Did the participant ask technical questions indicating the desire for additional information or seem interested in knowing more?
- If yes, would additional information address the questions or interests **and** increase the likelihood of the participant reaching the goals for lifestyle change?
- If yes, provide the information. If no, determine how to move the focus back to the lifestyle change issue at hand.

Community Peer Coaches and participants may find it helpful to remember that the intervention extends over one and a half years. It is best to present new skills and information slowly and have participants practice these new skills before adding others.

Finally, Community Peer Coaches are to present **only** the strategies described in the protocol and approved for use in the tool boxes or by the Academic Co-Director. Strategies that have worked for a friend who has tried to lose weight (e.g., a nutrient bar or shake or an unusual exercise machine) should not be recommended to participants without prior approval from the Academic Co-Director.
7.2.8. General Guidelines for Conducting a Lesson

Specific guidelines for conducting each lesson are given in Appendix A. General guidelines are given below.

Before the participants arrive for each lesson, the Community Peer Coach should:

- Review the participants’ charts and the script in Appendix A for the previous lesson, noting the home activities assigned, action plans made, and any other pertinent issues.
- Review the script for the upcoming lesson in Appendix A.
- Prepare all materials required for the lesson, including supplementary materials suggested in the tool boxes or Appendix A, if appropriate, and any small motivational items (such as mugs, key chains, and so on) to be distributed.

During every lesson, the Community Peer Coach should perform the following, in the sequence given here, unless otherwise indicated in Appendix A. The entire lesson should last approximately 60 minutes, with the exception of Lesson 1 which is likely to last 1 and ½ hours.

1. **Weigh the participant.**
   Participants should be weighed in private at the beginning of each lesson. Weight can be taken with either a balance beam or a digital scale. The type of scale is not important, but an effort should be made to use the same scale throughout the study. Participants should be weighed in street clothes, without shoes.

   Record the weight on the PILI Lifestyle Intervention Data Form, and have the participant record their weight in their weight chart.

2. **Review the last lesson.** Briefly summarize the main points of the previous lesson, and discuss any related thoughts and experiences the participant has had, including any home activities, goals, or action plans that were assigned.

3. **Receive and review any Keeping Track records** completed since the last lesson.
   Record summary data for both weight and physical activity on the Lifestyle Intervention Data Form, as instructed on the form. Give the participants feedback and helpful suggestions and enter the weight on the weight chart in the participants’ workbook. Participants should be encouraged to complete the graphs themselves, if possible.

   At the beginning of each lesson there is a section for reviewing the participants’ weight charts and/or activities. At any time, however, the Community Peer Coach should be alert to any lapse in basic self-monitoring skills that may have an impact on achievement of the study goals and should review the skills as necessary.
Throughout the trial, the Community Peer Coach should praise some aspect of the participants’ weight charts and action plans, no matter how small (for example, the Community Peer Coach should not overlook the very fact that the records were returned, regardless of whether goals were reached or the quality of the record keeping). In addition, Community Peer Coaches should be careful not to discourage participants by providing too many suggestions for improvement.

4. **Discuss successes and difficulties in meeting the study goals** since the last lesson.

5. **Present the new topic.** The should follow the script in Appendix A in terms of what to present and in what sequence, while tailoring exactly how the topic is presented (such as the language and examples used) to the participants’ learning styles. In no instance should the Community Peer Coach “read” the script to the participants. The script is provided only as a model to guide and help the Community Peer Coach.

   Using the facilitator guide for the lesson, present the main points while the participant follows along on the work sheets. Indicate on the work sheets anything you want to emphasize or clarify (for example, feel free to add examples, underline main points, and so on). Have the participants fill in any blanks or complete any practice activities directly on the work sheets. The work sheets are to be inserted into the participant’s notebook during or at the end of the lesson.

6. **Set goals, develop action plan(s), and assign home activities** for the coming week(s). Complete any related work sheets with the participants.

   After each lesson, telephone calls may be made to participants as needed to support the achievement of study goals. Phone calls after the early lessons will be particularly important to reinforce the basic skills taught in those lessons and to support the participants in applying those skills. All telephone calls to participants should be documented.
The PILI ‘Ohana Lifestyle Program

Section 8: Overview of Intervention Study

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e-mail: clairemt@hawaii.edu

Supported by the National Center on Minority Health and Health Disparities, National Institutes of Health (R24 MD001660).
Section 8: Overview of Intervention Study

8.1 Overview of Intervention

This figure summarizes all activities occurring, in order of occurrence, during the entire 9-month study:

**Eligibility Screening**
- a) Self-reported Native Hawaiian, Filipino, or other Pacific Islander ethnic background;
- b) Age 18 years or older;
- c) Overweight or Obese defined as BMI $\geq 25$ kg/m$^2$ (NH or Pacific Islanders) or $\geq 23$ kg/m$^2$ (Filipino ethnic background);
- d) Willing and able to follow a weight loss maintenance intervention program that could include 150 minutes of brisk walking per week (or equivalent) and a dietary regimen designed to maintain weight loss;
- e) Able to identify at least one family, friend, or co-worker who would be willing to support the participant during the course of the study.

**Obtain Informed Consent**

**Complete Baseline Assessment**
- Weight (kg) and height (cm)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test
- Demographic information

**3 Month PILI Weight Loss Intervention**
- 8 lessons over the course of 3 months

**Complete 3-Month Assessment**
- Weight (kg)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test

**6-Month Weight Loss Maintenance Intervention**
- 6 lessons over the course of 6 months

**Complete 9-Month Assessment**
- Weight (kg)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test
As the above figure illustrates, all participants will first undergo screening for eligibility (see PILI Assessment MOP for screening and eligibility information). For those who are eligible and willing to participate, informed consent will be obtained next and prior to any further data collection. After informed consent is obtained and documented, every participant will undergo a baseline assessment (see PILI Assessment MOP for more details) and within two weeks every participant will receive the PILI 3-month weight loss program to initiate weight loss (see Section 2 of this MOP for program goals). Upon completion of the 3-month weight loss program, participants will receive the face-to-face PILI weight loss maintenance program. Follow-up outcome assessments will occur at 3 months and 9 months.

8.2. Summary of Intervention Curriculum

PILI Weight Loss Program Curriculum (first 3-months of study)

<table>
<thead>
<tr>
<th>Lessons</th>
<th>Topic</th>
<th>Lesson-based Activities/Handouts</th>
</tr>
</thead>
</table>
| Lesson 1         | **Introduction to PILI Lifestyle Intervention** | o Passport to Health Booklet  
| (Month 1)        | o The Slippery Slope of Lifestyle Change  
|                  | o Ways to Stay Motivated                  | o Daily Food Diary  
|                  |                                           | o Nutrition Log  
|                  |                                           | o My Progress Chart                                                  |
| Lesson 2         | **Getting Started**                       | o Keep It Safe Brochure  
| (Month 1)        | o Three Ways to Eat Less Fat              | o Safe & Easy Exercises Brochure  
|                  | o Getting Started Being Active             | o Menu Makeover  
|                  | o Being Active: A Way of Life              | o My Menu Makeover                                                   |
| Lesson 3         | **Get Moving**                            | o Cooking Light Brochure  
| (Month 1)        | o Be a Fat Detective                      | o My Food Label  
|                  | o Move Those Muscles                       | o Nutrition Facts Label  
|                  |                                           | o Lower Fat in Meats                                                  |
| Lesson 4         | **Making it Fun**                         | o Eating Out Brochure  
| (Month 1)        | o Healthy Eating                          | o Free Foods  
|                  | o The Four Keys to Healthy Eating Out      | o Social Gatherings Brochure  
|                  | o Starting Your Activity Plan              | o F.I.T.T. Plan                                                      |
| Lesson 5         | **Keeping it Going**                      | o My Grocery List Write-in Card  
| (Month 2)        | o Tip the Calorie Balance                  | o PILI Grocery Checklist Card  
|                  | o Economics of Healthy Eating              | o Eat Smart, Eat Fresh, Brochure                                    |
| Lesson 6         | **Taking Charge**                         | o Options Wallet Card                                                |
| (Month 2)        | o Take Charge of What’s Around You         |                                                                      |
|                  | o Make Social Cues Work for You            |                                                                      |
| Lesson 7         | **Talking it Out**                        | o Lifestyle Balance Problem Solver  
| (Month 3)        | o General skills for effective communication – i.e., talking w/ doctor | o Roadblocks Brochure  
|                  | o Problem Solving Skills                   | o Talk With Doc Handout                                              |
| Lesson 8         | **Wrapping it Up**                        | o None                                                              |
| (Month 3)        | o Talk Back to Negative Thoughts           |                                                                      |
|                  | o You Can Manage Stress                    |                                                                      |
|                  | o Wrap Up – Discuss Next Phase (follow-up) |                                                                      |
## PILI Weight Maintenance Program Curriculum (remaining 6 months of study)

<table>
<thead>
<tr>
<th>Lessons</th>
<th>Topic</th>
<th>Lesson-based Activities/Handouts</th>
<th>Community-Based Activities (optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesson 1</td>
<td><em>Ohana is the Key to Success</em></td>
<td>o Family Goal</td>
<td>o None</td>
</tr>
<tr>
<td>(Month 4)</td>
<td>o What will happen in this program?</td>
<td>o Setting Exercise</td>
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<tr>
<td></td>
<td>o How is family important to living</td>
<td>o Family Time</td>
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<tr>
<td></td>
<td>healthy?</td>
<td>Calendar Worksheet</td>
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<tr>
<td></td>
<td>o What are other benefits for my family?</td>
<td></td>
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<tr>
<td></td>
<td>o Goals of the program</td>
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<tr>
<td></td>
<td>o Role of family support person</td>
<td></td>
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<tr>
<td></td>
<td>o Using our values to set healthy lifestyle</td>
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<tr>
<td></td>
<td>goals</td>
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<tr>
<td>Lesson 2</td>
<td>Eat Together as an <em>Ohana</em></td>
<td>o Family Eating</td>
<td>o None</td>
</tr>
<tr>
<td>(Month 5)</td>
<td>o Review family activities and action plans</td>
<td>History</td>
<td></td>
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<tr>
<td></td>
<td>o Importance of eating together as a</td>
<td>o Family Meal</td>
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<td></td>
<td>family</td>
<td>Planning</td>
<td></td>
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<tr>
<td></td>
<td>o Why is it important to eat healthy?</td>
<td>o Community Resources</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>o Healthy Eating Tips</td>
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<tr>
<td>Lesson 3</td>
<td>Let’s be Active Together!</td>
<td>o Family Activity</td>
<td>o None</td>
</tr>
<tr>
<td>(Month 6)</td>
<td>o Review family activities and action plans</td>
<td>Planning Worksheet</td>
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<tr>
<td></td>
<td>o Importance of being active</td>
<td>o Fit Family Challenge</td>
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<tr>
<td></td>
<td>o Why is it important to be active together</td>
<td>o Parks and Recreation Brochure</td>
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<td></td>
<td>as family/friends?</td>
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<tr>
<td></td>
<td>o Helpful tips</td>
<td></td>
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<td></td>
<td>o How can we be supportive of each other?</td>
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<td></td>
<td>o Fit Family Challenge</td>
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<tr>
<td>Lesson 4</td>
<td>Social Situations and Cultural Beliefs</td>
<td>o Meal &amp; Activity</td>
<td>o None</td>
</tr>
<tr>
<td>(Month 7)</td>
<td>o Review family activities and action plans</td>
<td>Planning Social Situations</td>
<td></td>
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<tr>
<td></td>
<td>o What is challenging about social</td>
<td>o Challenging Social Situations</td>
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<td></td>
<td>situations?</td>
<td>o Support Circle</td>
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<td></td>
<td>o How do you prepare for challenging</td>
<td>o Community Resources</td>
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<td></td>
<td>situations?</td>
<td></td>
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<td></td>
<td>o Advantages of eating healthy at social</td>
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<td></td>
<td>gatherings</td>
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<td></td>
<td>o Ways to incorporate physical activities</td>
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<td>into social gatherings</td>
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<td></td>
<td>o How do your cultural beliefs relate to</td>
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<td></td>
<td>healthy living?</td>
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<td></td>
<td>o How do social support helps you meet your</td>
<td></td>
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<td></td>
<td>weight goals</td>
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<tr>
<td>Lesson 5</td>
<td>Managing and Reducing Negative</td>
<td>o High Risk</td>
<td>o None</td>
</tr>
<tr>
<td>(Month 8)</td>
<td>Thoughts and Emotions</td>
<td>o Situations Activity</td>
<td></td>
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<tr>
<td></td>
<td>o Review family activities and action plans</td>
<td>o Manage Negative</td>
<td></td>
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<tr>
<td></td>
<td>o What are negative thoughts and</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>emotions?</td>
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<tr>
<td>What kinds of situations can lead to negative thoughts or emotions?</td>
<td>Thoughts</td>
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<tr>
<td>Common negative thoughts and what we can do about them</td>
<td>Common Negative Thoughts</td>
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<tr>
<td>Changing negative thoughts into positive thoughts</td>
<td>Change Negative to Positive</td>
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<tr>
<td>What events, feelings, or situations can lead to overeating or physical inactivity?</td>
<td>Deal with Negative Emotions</td>
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<tr>
<td>“During meal” behaviors that lead to overeating</td>
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<tr>
<td>High risk situations</td>
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</tbody>
</table>

**Lesson 6 (Month 9)**

**Let’s Review What We Learned**
- Review family activities and action plans
- Review lessons 1-5
- Weight loss maintenance tips

**My Master Action Plan**
- Activity
- Summary

**None**
The PILI ‘Ohana Lifestyle Program

Section 9: 3-Month Weight Loss Program

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  e-mail: clairemt@hawaii.edu

Supported by the National Center on Minority Health and Health Disparities, National Institutes of Health (R24 MD001660).
Section 9: 3-Month Weight Loss Program

The 3-month weight loss program is the first intervention that all participants in the POP study receive before the 6-month weight loss maintenance program. The figure below here depicts (the bolded box) were in the overall study activities this intervention is situated.

Eligibility Screening
- a) Self-reported Native Hawaiian, Filipino, or other Pacific Islander ethnic background;
- b) Age 18 years or older;
- c) Overweight or Obese defined as BMI ≥ 25 kg/m² (NH or Pacific Islanders) or ≥ 23 kg/m² (Filipino ethnic background)
- d) Willing and able to follow a weight loss maintenance intervention program that could include 150 minutes of brisk walking per week (or equivalent) and a dietary regimen designed to maintain weight loss;
- e) Able to identify at least one family, friend, or co-worker who would be willing to support the participant during the course of the study.

Obtain Informed Consent

Complete Baseline Assessment
- Weight (kg) and height (cm)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test
- Demographic information

3 Month PILI Weight Loss Intervention
8 lessons over the course of 3 months

Complete 3-Month Assessment
- Weight (kg)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test

6-Month Weight Loss Maintenance Intervention
6 lessons over the course of 6 months

Complete 9-Month Assessment
- Weight (kg)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test
9.1 Background of the 3-Month Weight Loss Program

The 3-month weight loss program is a culturally-informed and behaviorally-based intervention designed to initiate weight loss in Native Hawaiians and other Pacific Islanders. It is adapted from the Diabetes Prevention Project’s Lifestyle Intervention (DPP-LI). All the basic content area and behavioral principles and strategies were maintained. Although the DPP-LI included 16 lessons delivered over a 6 month period. The PILI weight loss program here was condensed to 8 lessons delivered over a 3 month period. Because 3 months is a short period of time to achieve significant and clinically meaningful weight loss (i.e., 5 to 10% weight loss) for many people, it is intended to initiate weight loss in people and for them to continue on in a weight loss maintenance phase in which they can either continue to lose weight (for those who did not meet their weight loss goals) or to maintain their weight loss (for those who achieved their weight loss goals).

To make the 3-month DPP-LI adapted intervention culturally-informed, a series of focus groups, informant interviews, and surveys were conducted to gather information from Native Hawaiians and other Pacific Islanders (i.e., Samoans, Chuukese, and Filipinos) around obesity-related concerns and ideas for best strategies to address obesity in their communities. Over 300 Pacific Islanders participated in this process. This information was used to ensure that the content and strategies in the intervention were culturally acceptable and feasible. As a result, two additional content areas were added to the intervention: 1) economical eating and 2) communicating effectively with a physician.

The adapted 3-month weight loss program of the POP has led to significant, albeit modest, weight loss in Native Hawaiians and other Pacific Islanders. In a pilot study with 239 Native Hawaiians and other Pacific Islanders, 12-weeks mean weight loss of 1.5 kg (95%CI -2.0,-1.0) was found with 26% of participants losing >3% of their baseline weight. Among participants who completed all 8 sessions, mean weight loss at 12 weeks was modestly better (1.8 kg) compared to the overall mean weight loss. Mean systolic and diastolic blood pressures decreased by 6.0 mmHg (95%CI -8.5,-3.5) and 2.8 mmHg (95%CI -4.4,-1.3), respectively. Significant improvements in physical functioning (6 min walk test; 95%CI 25, 58) and dietary fat intake (95%CI -0.32,-0.22) were found (Mau et al., in press). The finding that more weight loss was achieved with better adherence to the program demonstrates the importance of attending every session as prescribed here.

9.2. Summary of Intervention Curriculum

PILI 3-Month Weigh Loss Program Curriculum

<table>
<thead>
<tr>
<th>Lessons</th>
<th>Topic</th>
<th>Lesson-based Activities/Handouts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesson 1 (Week 1)</td>
<td>Introduction to PILI Lifestyle Intervention</td>
<td>o Passport to Health Booklet</td>
</tr>
<tr>
<td></td>
<td>o The Slippery Slope of Lifestyle Change</td>
<td>o Daily Food Diary</td>
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<td></td>
<td>o Ways to Stay Motivated</td>
<td>o Nutrition Log</td>
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<tr>
<td></td>
<td></td>
<td>o My Progress Chart</td>
</tr>
<tr>
<td>Lesson 2 (Week 2)</td>
<td>Getting Started</td>
<td>o Keep It Safe Brochure</td>
</tr>
<tr>
<td></td>
<td>o Three Ways to Eat Less Fat</td>
<td>o Safe &amp; Easy Exercises Brochure</td>
</tr>
<tr>
<td></td>
<td>o Getting Started Being Active</td>
<td>o Menu Makeover</td>
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<tr>
<td></td>
<td>o Being Active: A Way of Life</td>
<td>o My Menu Makeover</td>
</tr>
</tbody>
</table>
### 9.3. Intervention Curriculum

The weight loss and physical activity goal of the program and the structure of each session are described in detail in the previous sections of this MOP. Refer to the 3-month weight loss maintenance facilitator manuals for details about each of the 8 sessions and instructions of how to facilitate the sessions (the facilitator manuals for the 3-month weight loss sessions should be included as part of this section).

The 3-month weight loss program must be conducted in the sequence and timing outlined in the Table above. Each of the 8 sessions must be conducted following the detailed facilitator guides included with this MOP. Any changes to this study protocol needs to be approved by the PILI ISC prior to initiating any changes. However, because this is a controlled trial, very few changes will be allowed to maintain standardization and consistency between community sites and facilitators.

All community peer educators (i.e., facilitators) need to receive formal training by the DNHH staff and review this MOP and the facilitator’s manual prior to facilitating any session. See Section 3 of the MOP for details about training for community peer educators.

<table>
<thead>
<tr>
<th>Lesson 3 (Week 3)</th>
<th>Get Moving</th>
<th>Cooking Light Brochure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>o Be a Fat Detective</td>
<td>o My Food Label</td>
</tr>
<tr>
<td></td>
<td>o Move Those Muscles</td>
<td>o Nutrition Facts Label</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Lower Fat in Meats</td>
</tr>
<tr>
<td>Lesson 4 (Week 4)</td>
<td>Making it Fun</td>
<td>Eating Out Brochure</td>
</tr>
<tr>
<td></td>
<td>o Healthy Eating</td>
<td>o Free Foods</td>
</tr>
<tr>
<td></td>
<td>o The Four Keys to Healthy Eating Out</td>
<td>o Social Gatherings Brochure</td>
</tr>
<tr>
<td></td>
<td>o Starting Your Activity Plan</td>
<td>o F.I.T.T. Plan</td>
</tr>
<tr>
<td>Lesson 5 (Week 6)</td>
<td>Keeping it Going</td>
<td>My Grocery List Write-in Card</td>
</tr>
<tr>
<td></td>
<td>o Tip the Calorie Balance</td>
<td>PILI Grocery Checklist Card</td>
</tr>
<tr>
<td></td>
<td>o Economics of Healthy Eating</td>
<td>Eat Smart. Eat Fresh. Brochure</td>
</tr>
<tr>
<td>Lesson 6 (Week 8)</td>
<td>Taking Charge</td>
<td>Options Wallet Card</td>
</tr>
<tr>
<td></td>
<td>o Take Charge of What’s Around You</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Make Social Cues Work for You</td>
<td></td>
</tr>
<tr>
<td>Lesson 7 (Week 10)</td>
<td>Talking it Out</td>
<td>Lifestyle Balance Problem Solver</td>
</tr>
<tr>
<td></td>
<td>o General skills for effective communication – i.e., talking w/ doctor</td>
<td>Roadblocks Brochure</td>
</tr>
<tr>
<td></td>
<td>o Problem Solving Skills</td>
<td>o Talk With Doc Handout</td>
</tr>
<tr>
<td>Lesson 8 (Week 12)</td>
<td>Wrapping it Up</td>
<td>Preparing for Phase II (weight loss maintenance)</td>
</tr>
<tr>
<td></td>
<td>o Talk Back to Negative Thoughts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o You Can Manage Stress</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Wrap Up – Discuss Next Phase (follow-up)</td>
<td></td>
</tr>
</tbody>
</table>
Section 10: PILI Lifestyle Maintenance Program via Face-to-Face in Group Setting
Section 13: PILI Lifestyle Maintenance Program via Face-to-Face in Group Setting

The figure below here depicts (the bolded box) were in the overall study activities this intervention arm is situated.

Eligibility Screening
a) Self-reported Native Hawaiian, Filipino, or other Pacific Islander ethnic background;
b) Age 18 years or older;
c) Overweight or Obese defined as BMI $\geq 25$ kg/m² (NH or Pacific Islanders) or $\geq 23$ kg/m² (Filipino ethnic background)
d) Willing and able to follow a weight loss maintenance intervention program that could include 150 minutes of brisk walking per week (or equivalent) and a dietary regimen designed to maintain weight loss;
e) Able to identify at least one family, friend, or co-worker who would be willing to support the participant during the course of the study.

Obtain Informed Consent

Complete Baseline Assessment
- Weight (kg) and height (cm)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test

3 Month PILI Weight Loss Intervention
8 lessons over the course of 3 months

Complete 3-Month Assessment
- Weight (kg)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test

6-Month Weight Loss Maintenance Intervention
6 lessons over the course of 6 months

Complete 9-Month Assessment
- Weight (kg)
- Systolic/diastolic blood pressure
- Daily self-weighing frequency (self-report)
- Eating Habits Questionnaire
- Brief Physical Activity questionnaire
- 6-min Walk Test
Section 13:3

13.1. Overview

The PILI Lifestyle Maintenance Program (PLM) is delivered face-to-face in a group setting.

13.2 Details about the PILI Lifestyle Maintenance Program Delivered Face-to-Face

Participants will be given a scale and a PILI Pak for their own personal use and to keep (whether they complete the study or not). The PLM face-to-face participants will receive a portable DVD player to keep only after they have completed the entire 6 PLM lessons and all follow-up assessments. Thus, they will only be given a portable DVD at the end of the 9-months and only if they remained in the study.

Scales and PILI Pak: A digital scale is given to all PLM face-to-face participants after the 3-month follow-up assessment. They should be given to the participants at completion of the 3-month assessment. The scale is for the participants’ use and will be used to help them with their weight loss maintenance in conjunction with the PLM Program. The PILI Pak is also given to provide participants with tools to help them maintain their weight loss or achieve further weight loss. Over the 6-month weight loss maintenance phase, the participants can contact their community-peer educators for more PILI Pak materials as they run out. The participants’ may keep their scales and PILI Pak whether or not they stay in the study.

Monthly PILI Community Activities: PLM face-to-face participants will be invited to participate in monthly PILI community activities. Each community site will conduct a community activity relevant to that month’s lesson during the weight loss maintenance phase of the study. The first monthly community activity occurs prior to Lesson 1 of the PILI Lifestyle Maintenance Program, after of 3-month weight-loss program is completed. Thus, there are 6 monthly community activities starting the month of Lesson 1 of the PILI Lifestyle Maintenance Program. These activities should be no longer than 1½ hours. See Section 8 of the MOP for the sequence and general topic/theme for the monthly community activities.

Weekly Weight Check-Ins: All PLM face-to-face participants will be asked to monitor their weights daily (at best) and make weekly weight check-ins to their community peer educator with their weights. The day of the week for the weekly weight check-ins are up to the community peer educator, but should be on the same day for the entire 6-months of this phase of the study. Most often, Fridays are ideal. The participant need only provide his or her weight for that day’s weighing. If they are not able to provide that day’s weight the next closest weight measurement taken will do (such as the weight taken the day before). If a lesson is being given that week, weight check-ins can be done at that lesson (before or after). The weekly weights can be collected in different ways, such as by telephone, in person, or by e-mail.

13.3 Assessment of PLM face-to-face Group Participants

PLM face-to-face participants will undergo four assessments: 1) Baseline assessment, 2) 3-month follow-up assessment, and 3) 9-month follow-up assessment. See the PILI Assessment MOP for more details about the assessments and how to conduct them. Also, see the Figure above for an outline of when the assessments occur. It is very important that all participants attend every assessment occasion throughout the study.

13.4 Contact Details
As described above, PLM face-to-face participants will have regular contact with the community peer-educator during the weight loss maintenance phase (6-month phase) by participating in the regularly scheduled PLM lessons, the monthly PILI community activities (each lasting no more than 1 ½ hours in length), and in their weekly weight call-ins. The community site may offer other community activities and PLM face-to-face participants can take part in these other activities as long as they are not the PILI-related activities other than the agreed upon monthly PILI community activity. It must be made clear to the PLM face-to-face participants that these other community activities are not part of the PILI study and are not required for their involvement.

Since community-peer educators should not be conducting assessments of their own participants (other than baseline), there should be no contact between the community-peer educator and his/her own assigned PLM face-to-face participant at any follow-up assessments.

### 13.5 PILI Weight Loss Maintenance Program Curriculum

<table>
<thead>
<tr>
<th>Lessons</th>
<th>Topic</th>
<th>Lesson-based Activities/Handouts</th>
<th>Community –Based Activities (optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesson 1 (Month 4)</td>
<td>‘Ohana is the Key to Success</td>
<td>o Family Goal Setting Exercise</td>
<td>o None</td>
</tr>
<tr>
<td></td>
<td>o What will happen in this program?</td>
<td>o Family Time Calendar Worksheet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o How is family important to living healthy?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o What are other benefits for my family?</td>
<td></td>
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<tr>
<td></td>
<td>o Goals of the program</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o Role of family support person</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o Using our values to set healthy lifestyle goals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesson 2 (Month 5)</td>
<td>Eat Together as an ‘Ohana</td>
<td>o Family Eating History</td>
<td>o None</td>
</tr>
<tr>
<td></td>
<td>o Review family activities and action plans</td>
<td>o Family Meal Planning</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Importance of eating together as a family</td>
<td>o Community Resources</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Why is it important to eat healthy?</td>
<td>o Healthy Eating Tips</td>
<td></td>
</tr>
<tr>
<td>Lesson 3 (Month 6)</td>
<td>Let’s be Active Together!</td>
<td>o Family Activity Planning Worksheet</td>
<td>o None</td>
</tr>
<tr>
<td></td>
<td>o Review family activities and action plans</td>
<td>o Fit Family Challenge Brochure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Importance of being active</td>
<td>o Parks and Recreation Brochure</td>
<td></td>
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<tr>
<td></td>
<td>o Why is it important to be active together as family/friends?</td>
<td></td>
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<tr>
<td></td>
<td>o Helpful tips</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o How can we be supportive of each other?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>o Fit Family Challenge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesson 4 (Month 7)</td>
<td>Social Situations and Cultural Beliefs</td>
<td>o Meal &amp; Activity Planning Social Situations</td>
<td>o None</td>
</tr>
<tr>
<td></td>
<td>o Review family activities and action plans</td>
<td>o Challenging Social Situations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o What is challenging about social situations?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>o How do you prepare for challenging situations?</td>
<td></td>
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</tr>
</tbody>
</table>
### Section 13:5

<table>
<thead>
<tr>
<th>Lesson 5  (Month 8)</th>
<th>Managing and Reducing Negative Thoughts and Emotions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Review family activities and action plans</td>
</tr>
<tr>
<td></td>
<td>What are negative thoughts and emotions?</td>
</tr>
<tr>
<td></td>
<td>What kinds of situations can lead to negative thoughts or emotions?</td>
</tr>
<tr>
<td></td>
<td>Common negative thoughts and what we can do about them</td>
</tr>
<tr>
<td></td>
<td>Changing negative thoughts into positive thoughts</td>
</tr>
<tr>
<td></td>
<td>What events, feelings, or situations can lead to overeating or physical inactivity?</td>
</tr>
<tr>
<td></td>
<td>“During meal” behaviors that lead to overeating</td>
</tr>
<tr>
<td></td>
<td>High risk situations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesson 6  (Month 9)</th>
<th>Let's Review What We Learned</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Review family activities and action plans</td>
</tr>
<tr>
<td></td>
<td>Review Lessons 1-5</td>
</tr>
<tr>
<td></td>
<td>Where do we go from here?</td>
</tr>
<tr>
<td></td>
<td>Helpful weight loss maintenance tips</td>
</tr>
</tbody>
</table>

### Community Resources
- Role Playing
- Nice Ways to Say No

### High Risk Situations
- Negative Thoughts
- Change Negative to Positive
- Deal with Negative Emotions
The PILI ‘Ohana Lifestyle Program

Section 11: PILI Physical Activity Kit (PILI PAK)

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Developed by the PILI ‘Ohana Project; phone: (808) 692-1040 Facsimile: (808) 692-1255
e-mail: clairemt@hawaii.edu

Supported by the National Center on Minority Health and Health Disparities, National Institutes of Health (R24 MD001660).
Section 14: PILI Physical Activity Kit (PILI PAK)

14.1. Background & Rationale

Each participant will be given a toolkit called the PILI Physical Activity Kit (PAK). The PILI PAK will provide participants with tools to help them maintain their weight loss or achieve further weight loss.

14.2 Details about the PILI PAK

The PILI PAK should be organized in a closing accordion folder with the materials grouped in nutrition and physical activity. The nutrition materials are designed to help participants plan their meals, keep track of calories consumed, learn and use healthy recipes, and eat healthier when they eat out. The nutrition materials include:
- PILI PAK Recipes
- Daily food diary
- Weekly diet tracker
- Weekly meal planner (versions 1 and 2)
- Nutrition log
- HI Food Choice
- Calorie King book

The physical activity section of the PILI PAK is designed to help participants increase the amount of exercise they are getting, vary the types of exercise they get, keep track of the calories they burn, and plan their weekly exercise in conjunction with their meal planning. The physical activity materials include:
- Resistance tube for stretching and strengthening
- Resistance tube exercises (short and long lists)
- Calories Burned (short and long lists)
- Exercise DVDs
- Weekly calories burned chart
- Weekly family schedule

Please see the below PILI PAK for examples of these tools.