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Implementation of a culturally tailored diabetes intervention with community health workers in American Samoa

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Abstract

Purpose—The examination of implementation process in translation research can inform other interventions' modifications for different socio-cultural contexts. The purpose of this paper is to answer key implementation questions of a primary-care based, nurse-community health worker (CHW) team intervention to support type 2 diabetes self-management, as part of a randomized trial: 1) How was the evidence-based model adapted? 2) How were CHWs trained and supervised? 3) What was fidelity to protocols? 4) What were intervention costs? Lessons learned during implementation are also discussed.

Methods—Descriptive data are given on intervention delivery, CHW visit content, patient safety and intervention costs, along with statistical analyses to examine participant characteristics of higher attendance at visits.

Results—In the intervention sample (n=104), 74% (SD 16) of planned intervention visits occurred, guided by an algorithm-based protocol. Higher risk participants had a significantly lower dose of their weekly assigned visits (66%), than those at moderate (74%) and lower risk (90%). Twenty-eight percent of participants moved to a lower risk group over the year. Estimated intervention cost was $656 per person. Participants with less education were more likely to attend optimal percent of visits.

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Conclusions—A nurse-CHW team can deliver a culturally adapted diabetes self-management support intervention with excellent fidelity to the algorithm-based protocols. The team accommodated participants' needs by meeting them whenever and wherever they could. This study provides an example of adaptation of an evidence-based model to the Samoan cultural context and its resource-poor setting.

Keywords

community health workers; implementation; fidelity; cultural adaptation; American Samoa

Translation research aims to apply successful interventions from efficacy research to real-world settings, especially in at-risk communities, in order to reduce health disparities [1]. One key implementation question is how to modify proven interventions for different socio-cultural and economic contexts [2].

Community Health Worker (CHW) interventions have been used for decades for diabetes self-management support. CHWs extend the reach of professionals, provide care-management and bridge cultural and knowledge gaps between providers and patients [3, 4]. However few previous studies used randomized designs, and sample sizes were small, limiting clear conclusions. Reviews of CHW interventions have requested information on CHW roles, supervision, intervention content, and cost [4-6].

Our study, Diabetes Care in American Samoa (DCAS), adapted a successful nurse-CHW team intervention from Project Sugar (PS), one of the few well-designed randomized controlled trials (RCT) using a CHW model, which addressed African American diabetes patients in Baltimore, MD [7-9]. A strength of PS studies was the use of many best practice components, such as treatment algorithms, community outreach, one-on-one interventions, multiple contacts over time [10-13], as well as the application of behavior change theory with the Precede-Proceed model [14]. These strategies were employed in our DCAS intervention.

DCAS was a randomized trial that tested the effectiveness of our adapted nurse-CHW team intervention, compared with a wait-list control group receiving usual care, and found significant improvements in HbA1c, in favor of the intervention group[15]. Results of the randomized trial are presented elsewhere[15]. This report answers key implementation research questions as follows: 1) how was the PS model adapted for the American Samoa context? 2) What was the training and support of CHWs in this setting? 3) Was the intervention delivered with fidelity to planned protocols ("dose" delivered, content of visits, who utilized visits, patient safety)? 4) What were estimated intervention costs? Lessons learned about implementation in this setting are also discussed.

Methods

Research setting

The United States (US) Territory of American Samoa (AS) is a Polynesian island group in the Pacific Ocean, 2400 miles Southwest of Hawaii. The prevalence of type 2 diabetes for adults over age 18 was 21.5% in 2002 [16], compared to the US rate of 11.5% for adults over age 20 [17]. AS has a population of 55,519 [18] and 53% of families are below the poverty level [19]. Samoans have high rates of obesity, hypertension, type 2 diabetes and other cardiac risk factors, which have been increasing over the past 30 years [20]. Food choices in AS have changed from traditional plant and fish-based diets to greater reliance on imported and highly processed foods [21]. Increased fast food consumption and low levels of physical activity, associated with economic and occupational changes, have also contributed to these health risks [20, 22-24].

In AS, a number of cultural factors must be considered in understanding the impact of economic modernization on health conditions, health literacy and behaviors, and are of special concern for developing interventions. Traditionally, Samoan culture is both hierarchical and collectivist, where the extended family is responsible for support of its members, while major healthcare decision may be designated to the m*atai* (chief) or other elders.[25]. There is a reliance on family for care, and there may be a delay in seeking healthcare, especially for preventive care [26]. Once in the healthcare system, doctors are regarded with great respect and patients often prefer doctors to be directive and not engage patients in the decision-making process [25, 27].

Intervention Adaptation

As noted, a key feature of the PS intervention was use of clinical algorithms to triage frequency and intensity of care and to prompt intervention protocols based on diabetes control and associated health risks[8]. As recommended in the translation research literature [28], the project utilized a consultant from PS to help with our adaptations. Numerous differences between the Baltimore and AS contexts required adaptation of the intervention model. AS is resource poor, and is designated as a “medically underserved” and “health professional shortage” area[29]. There is one diabetes educator at the hospital, which is some distance from TC. The nearest specialty care is Hawaii or New Zealand, both over 2000 miles away. Medical supplies are limited—for example very few patients have home glucometers and individual health insurance is rare for covering glucose monitoring supplies. Higher blood glucose (BG) levels in the AS population[30, 31] required higher algorithm cut-points to guide visit frequency and manage staff workloads. The resulting algorithm (see Table 1) was driven by HbA1C, blood pressure (BP), smoking status, alcohol use, and PHQ-9 depression scores, based on data collected at the baseline assessment.

Our project team included a nurse case manager (NCM) and four CHWs. All participants received an initial visit with the NCM and a CHW to review their personal risk profile, which guided their further visit schedule (Table 1). Safety was monitored at each visit for urgent BG and BP levels, requiring immediate referral, and for any serious adverse events (SAEs) (deaths, hospitalizations, active suicidality) that may have occurred since the last contact. SAEs were reported immediately to the TC medical director and the study principal investigator (PI).

Intervention content was guided by risk level and self-directed goals from a menu of eight topics, including basic diabetes information and seven diabetes-related behaviors (healthy eating, being active, taking medication, monitoring, reducing risk, healthy coping, and problem solving) [32]. All study protocols were approved by Institutional Review Boards in American Samoa and at Brown University.

Intervention Materials

To facilitate CHWs' teaching, the project team developed flip charts, modeled on the National Diabetes Education Program flipcharts for diabetes prevention [33] and adapted for the eight topics listed above. The CHW flipchart pages included background information, talking points, and a small view of the corresponding participant's page, while the participants' flipcharts included parallel pages with bigger images and minimal text (Figure 1). Although project staff and many Samoans are bilingual, flipcharts included both languages, as many speakers shift from one language to the other. The Precede-Proceed model also guided content, as each topic included three sections for: predisposing factors (exploring beliefs and motivation), enabling factors (building behavior change skills) and reinforcing factors (enlisting support from family, medical team and community). Cultural features identified during the formative research were incorporated, such as motivational quotes from focus groups, healthy local foods and exercise, examples of barriers to medication taking [27], sources of stress and effective coping strategies [34]. Group visits also utilized flipchart content, as well as other teaching aids in Samoan language [35, 36].

Staff Training and Supervision

Local project staff was hired early to assist with formative research focus groups and intervention development tasks. A field director reported directly to the academic investigators, served as a liaison with local staff and collaborators, supervised daily study operations, maintained research integrity, and handled local administrative requirements. Most project-related training was conducted in a series of 4-day visits by study investigators and consultants. Project staff and all TC staff received education on research practices, including why we do research, why we randomize, what is contamination across study groups and how to avoid it to protect study goals. Project staff and TC clinicians also received a review of American Diabetes Association standards of care [37], the chronic care model [38], with emphasis on the self-management support [39] and patient-centered communication skills [40]. Project staff received additional extensive training on diabetes management, assessment techniques, and study protocols. CHW training used several hands-on techniques, such as role-playing, daily quizzes and prizes for correct answers or knowing where to find correct information. Once the study was underway, an apprenticeship model was used when a new CHW was hired. This involved a checklist of content areas to be covered in brief teaching sessions with role plays, and by observation of other CHWs' visits. CHWs were certified on diabetes knowledge, BG, BP, height and weight measurement procedures. All visit progress notes were reviewed and signed off by the NCM, put in the patient's medical chart to facilitate communication with TC providers.

Participant recruitment

Eligibility criteria were inclusive to represent medical practice in this setting. Eligible participants needed to be: 1) ≥ 20 years old; 2) reside in TC service area; 3) self-identify as Samoan; 4) have type 2 diabetes, as diagnosed by a physician; 5) mentally competent and willing to give informed consent and to complete oral and medical assessments; 6) unlikely to leave American Samoa for > 4 months during the study; 7) no co-morbid conditions which would require specialty care or potentially to lead to death in the next year (e.g. endstage renal disease, cancer); 8) not pregnant or planning to become pregnant. Participants were randomized by village within the health center catchment area and were approached by health center staff to explain the study and obtain informed consent. Enrollment was done on a rolling basis. More detail on recruitment and randomization procedures is provided elsewhere[15].

Implementation data analysis

Fidelity was operationalized as maintaining the algorithms for expected visit frequency based on risk level, thus delivering the intended intervention "dose". Treatment dose was calculated by dividing the total visits completed by the target number of visits expected, according to individual risk levels. However, since some participants changed their risk levels during the trial, each person's target visit number was calculated individually. Dropouts were included up to the date they left the study.

ANOVA was used to compare the mean difference in dose received across the three risk levels. Higher versus lower intervention users were examined by splitting the sample at the mean and comparing socio-demographic characteristics. This was followed by a linear regression on treatment dose, where risk level at baseline was entered in the first block, followed by a second block with participant age, gender marital status, employment status, years of education, and presence of others in household with diabetes.

Intervention content was estimated for each participant, using the proportion of visits at which each topic was discussed and when goal setting was discussed. Since reminders of doctor appointment and labs needed were not relevant at every visit, these were summarized as counts. Visit content was compared across the three risk groups, using ANOVA, followed by Tukeys post hoc test, or non-parametric comparison of medians if data was not normally distributed.

In addition to counts of SAEs and urgent care referrals, patient safety was explored more closely by cross-tabulating socio-demographic variables with those who received urgent referrals versus no urgent referrals, with X^2 analysis.

Although formal cost effectiveness analysis was not planned for this study, intervention delivery costs were estimated. The field director tracked intervention expenses over a four-month period, including office supplies, telephone fees, fuel, vehicle maintenance and replacement tires, medical supplies, group session refreshments, and staff wages. The proportion of supplies used for research data collection was excluded. If the project was to be replicated locally, an administrator/manager would need to supervise staff and purchase supplies, thus an additional $10,000 salary was added for a half time person. The average monthly operating cost was divided by the number of participants enrolled during this time period to find the per person monthly cost. The full-year cost was calculated by multiplying this per-person cost by 12 months and by 104 participants, and adding the attributable proportion (104 intervention group/268 total enrollment) of the total start-up costs—which included the purchase of the CHW flipcharts, vehicles, and cellular phones for the project staff. Then this figure was divided by 104 to estimate of the yearly intervention cost per participant.

Results

Intervention sample

Intervention participants (N=104) included 57% females, mean age 55.8 (SD 12.5), with 10% allocated to lower risk, 49% to moderate risk, and 41% to higher risk (see Table 2). Among the 43 at baseline high risk, 30 were assigned based on HbA1C values, one was based on high BP values alone, one had a combination of high HbA1C, BP and daily smoking, and 12 individuals were assigned based on cigarette smoking and/or alcohol use, but had lower risk in other categories. Depression PHQ-9 scores were low in this population, with none having scores in high risk range and 10% in the moderate range.

Intervention dose

During the intervention year, the nurse-CHW team completed all 104 initial visits, 1350 individual follow-up visits, and 61 group sessions (average of 5 participants at each), totaling 1728 contacts. These included 75% with the participant alone and 25% with family members. The mean percent of accomplished visits (intervention dose) was 74% (SD 16) (range 32%-117%). While only high risk participants had access to group visits, they averaged 21% of their contacts as group visits, with the remainder individual visits, and 50% attended at least one group visit. Lower and moderate risk participants received a significantly higher dose than high risk participants ($F(2)= 15.23$ $p<0.01$)(Table 3). Those who received more than the mean dose were significantly older, had fewer years of education, were more likely unemployed, and more likely to report living with others with diabetes (all $p<0.05$). Multivariable linear regression analysis showed that only lower education level remained significant, after controlling for risk level and other demographic variables (adjusted $R^2 =0.27$, $p=0.004$).

The staff retained 91% of participants through the one-year intervention. Twenty-eight percent improved their risk level, while 70% remained at the same risk level, including 4% who fluctuated but ended at same level at which they started, and only 2% worsened their risk level.

Content of Intervention Visits

Out of 1728 completed intervention contacts, the most frequent topics were Healthy Eating (47%) Taking Medications (42%), and Monitoring (40%). Table 3 describes content by risk level. ANOVAs comparing risk groups showed differences in Monitoring (more discussion in higher risk group, $F(2)=6.02$, $p < 0.01$), Reducing Risk (more in lower versus moderate group, $F(2)=3.59$, $p=0.05$), and Being Active (more in lower vs. both other groups, $F(2)=4.37$, $p <.05$). Goal setting was discussed in a mean of 90% (SD 22) of all visits, with significantly less in the higher versus the moderate risk group $F(2)=3.37$, $p=0.04$).

Patient safety

The intervention group had 14 SAEs, including two deaths, and 12 hospitalizations. None were deemed related to the intervention, per our data safety monitor. Project staff identified 28 participants (27%) who had at least one urgent care referral due to high BG readings; among those, 27% refused the referrals, insisting that they preferred the CHWs' care, or that they would see the doctor at some later date. Participants with at least one urgent care referral were significantly younger ($p < .05$), compared to those with none.

Estimated Intervention Costs

The estimated monthly operating cost per person was $45. With the addition of $11,823 in start-up purchases, the yearly intervention cost for 104 participants was estimated to be $68,242 and the per-participant yearly cost was $656.

Discussion and Lessons Learned

In this first diabetes care intervention study in AS, the nurse-CHW team successfully delivered the diabetes self-management support intervention for one year with 74% of planned visits, and retained 91% of participants. Fidelity to the treatment algorithms was excellent, as CHWs worked to accommodate participants' needs, including rescheduling missed visits and meeting participants wherever or whenever they could meet. Patient safety was well managed. The cost was modest, at an estimated $656 per participant. The following describes lessons learned.

Fidelity to algorithms

Fidelity refers to implementation of the program as intended, yet when efficacious interventions are translated to real-world settings, adaptations are necessary, leading to a tension in translation research with how much deviation is acceptable from the evidence-based model [28, 41]. The DCAS study retained the nurse-CHW delivery approach and the algorithm framework, although it was necessary to simplify and adapt the algorithm for this population and setting. Fidelity was measured through adherence to the algorithm framework. While overall algorithm adherence was excellent, it was likely easier for lower risk participants to adhere to only four visits for the year, in contrast with weekly visits expected of higher risk participants. Nonetheless high risk participants received a remarkable 29 visits, on average, which was remarkable. The flexibility of scheduling individual visits was clearly important to achieving the high dose, as group visits were utilized less often. Only 28% improved their risk level over the year, including six individuals in moderate and 23 in the high risk group. This was less than expected and may indicate the difficulties of diabetes self-management that many participants experienced. Shifts to lower or higher risk schedules were handled well when based on HbA1c changes, and very few participants' risk levels were driven by other risk factors. However, it was more difficult for CHWs to keep track of multiple algorithm factors. A simpler algorithm would be preferable for outreach work by CHWs.

Higher users of CHW services

Those receiving more than the mean intervention dose (74% of expected visits) had less education, after controlling for other factors. The higher users may represent those who needed the services more, were more available for visits, or more comfortable with CHW contact. CHW services may be especially valuable among those with less education and lower health literacy, as these individuals likely need more help with diabetes self-management support than is possible with standard primary care services.

Patients often refused doctor referrals for urgent care

Urgent care referrals occurred for 27% of participants, who were more likely to be younger than those with none. Younger participants may be juggling many obligations in addition to their diabetes care. Among all the urgent care referrals, 27% refused to go for care. Participants often indicated they knew why their BG was high due to specific foods consumed, they ran out of their medications, had an upcoming doctor visit and/or wanted to avoid another co-pay. They generally trusted the CHWs to monitor the situation with extra visits. CHWs kept in close contact with the doctor for guidance. However, CHWs did persuade highest concern participants to come in for IV insulin or other treatments.

Content of visits

The three highest frequency topics were Healthy Eating, Taking Medications, and Monitoring. While few individuals had their own BG monitoring supplies, BG and BP were measured at each visit, permitting a discussion of the meaning of these values. Lower risk participants were perhaps more ready to discuss Being Active. CHWs reported using goal setting in most sessions; thus CHWs likely tailored visit content to participant needs. It should be noted that many non-health topics (e.g. social and family responsibilities) also needed to be addressed in these sessions, often before diabetes topics can be discussed, as others have reported as well[42].

The supervisor role in a resource poor area

Our field director spent much of the time working with local administrators on procurement of supplies and personnel-related duties (hiring, contract renewals, and ensuring timely paychecks), which in a resource-poor setting can be more complicated and inconsistent than elsewhere. However, this freed project staff to do their jobs. Other literature points to boundary concerns where lay providers may overstep their training [43]. We did not observe this, but we did experience boundary pressures between research and non-research staff, such as asking CHWs to see control participants or asking for research supplies. This pressure was heightened by the resource-poor environment and by cultural expectations of sharing. The field director was not Samoan and was able to intervene on these and explain required research grant management practices, with advice of the PI and local investigators.

CHW roles and turnover

Staff turnover of CHWs is common [43]. Two of our CHW staff stayed throughout the trial, out of eight hired and trained. However, CHWs were incredibly dedicated, working long hours to accommodate patients' needs, including working without pay when paychecks were late or contract renewals were delayed. Those who left the project did so for family obligations or to seek further nursing training. The apprenticeship model was necessary and it worked well. Our CHWs almost always made home visits in pairs. They preferred sharing duties, being reassured for their personal safety and having someone who could vouch for their accountability on the job. Working collectively is also a cultural preference.

Intervention costs

The estimated cost of intervention at $656 per intervention participant is modest and may be useful for further intervention planning in this setting. Brownson et al [44] reported on cost figures from four mainland projects which used CHWs in community health centers; costs per participant ranged from $832-$2340 in the first year, with somewhat lower costs in subsequent years. Our cost estimates are lower than these, although US mainland and AS costs may not be fully comparable, given lower salaries and higher costs for importing supplies. Training costs were not included, as trainers had to be imported, with high travel costs. If these services were to be scaled up or replicated, training resources would have to be identified to keep these costs manageable, such as training local trainers or using interactive online training resources. However, quality internet services are also inconsistent in these settings.

Conclusion

The algorithm-guided protocols provided a clear path for the nurse-CHW team to understand their job role and it offered a clear means to measure research fidelity. However further algorithm simplicity may be warranted for future work with CHW teams. Participant adherence to visit expectations was excellent, although the higher expectations for high risk participants to continue weekly visits throughout the year proved to be difficult if they did not improve risk to "graduate" to monthly visits. Still, they maintained contact on average twice a month, which is testimony to the persistence and flexibility of the CHWs, and to participants' apparent desire to receive this care. Twenty-eight percent of participants did move to a lower risk group over the year, indicating some were able to achieve improved self-management. This corresponds with our findings of significant improvement in diabetes control outcomes, in comparison with the wait list control group across all risk levels[15]. Further examinations of psychosocial and behavioral measures, and post treatment qualitative studies will help us to understand more about translation of interventions for this setting.

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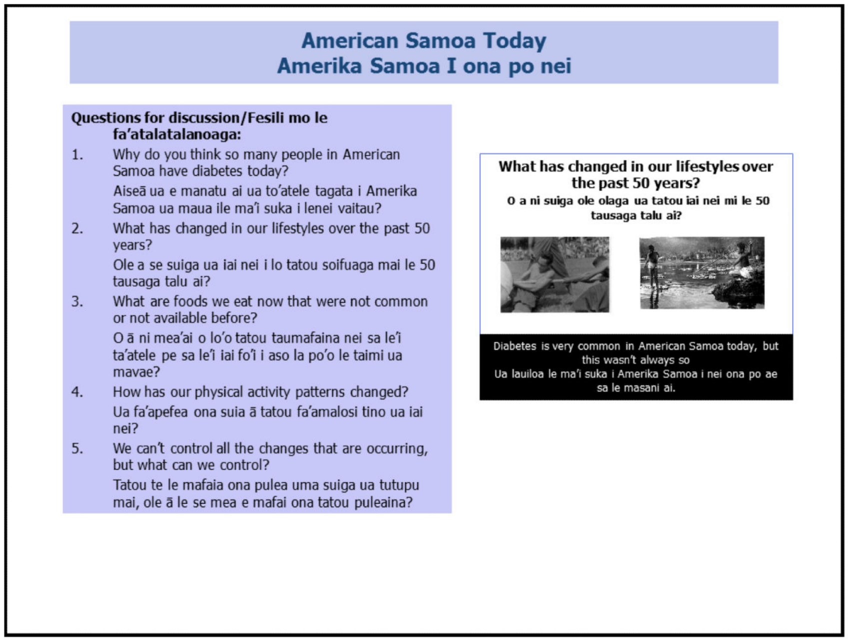

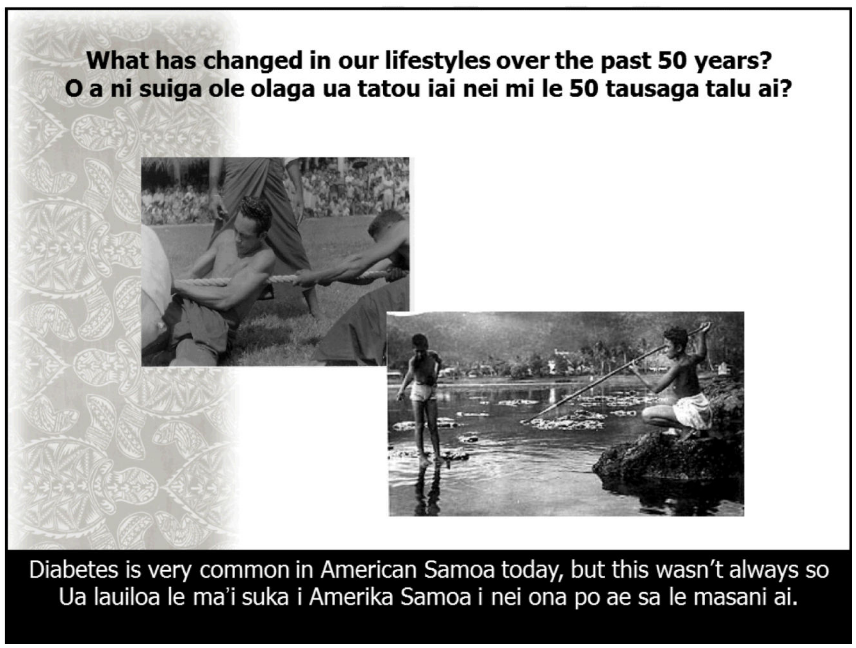

Figure 1.

Sample pages CHW and Patient Flipcharts

Note: photos are from the American Samoa Preservation Office archives and are available to the public.

Table 1

Algorithm to determine visit frequency and priorities for treatment

Value	Lower Risk	Moderate Risk	High Risk	Urgent
HbA1C (%)	<8	8-10	>10	
Finger stick blood glucose (mg/dL)				>400
Blood Pressure (mmHg)	< 140/90	140/90-180/110	180/110-200/120	>200/120
Smoking	No	Non-daily or Daily if not ready to quit	Daily and ready to quit	
Alcohol	<2/d	2-4/day	>4-5/day	
Depression (PHQ-9 score)	<5	5-14	>15	Suicidal thoughts
Visits	Quarterly CHW visits Annual NCM visit	Monthly CHW visits Biannual NCM visits	Weekly NCM groups or CHW visits	Follow-up after referral Proceed to high risk schedule

Values for initial risk levels were drawn from baseline assessments. Finger stick blood glucose values were not part of the visit algorithm, but this was assessed at each visit to identify any urgent care needs. **Lower risk level** required all values in that level. If any of the 5 factors was in higher risk range, that person began treatment at a higher risk level. **Moderate risk** meant that no values were at High Risk and at least one value was in Moderate range. To be at **High Risk**, at least one value was in high range. **Urgent** levels were referred immediately to the clinic physician or to the hospital emergency department, if after clinic hours.

If high risk participants were unable to attend the group, CHWs arranged individual visits. All individual visits were held either at the participant's home, workplace, or the clinic, per the participant's choice.

To shift to lower risk category during intervention, the patient's risk had to remain at next lower risk for 2 months, then they could shift to the lower visit schedule. **If participant risk level increased** during intervention, their visit schedule increased to the next level immediately and stayed at the higher level until their risk stabilized again at a lower level.

Table 2

Characteristics of Intervention Sample (n=104)

Baseline Characteristics	Mean (SD) or %
Age	56 (12.5)
Married/with partner (%)	79
Education (%)	
0 to 11th grade	16
High School graduate	49
Some college	21
16 yrs or more	13
Females (%)	57
Employed (%)	43
Preferred language of interview (%)	
Samoan only	66
English & Samoan	34
HbA1C	9.6 (2.1)
HbA1C Risk levels (%)	
< 8%	25
8-10%	40
> 10%	35
On oral meds for diabetes (%)	63
On insulin (%)	18
On blood pressure meds (%)	46
Total meds (among 94% on meds)	2.6 (2.0)
Body mass index, kg/m^2	35.6 (6.5)
Systolic blood pressure, mmHg	132 (17.4)
≥140 (%)	35
Diastolic blood pressure, mmHg	84 (7.8)
≥ 90 (%)	25
Waist circumference, cm	118 (SD 18.8)
Current Daily Smoker (%)	10
Lifetime Alcohol abstainer (%)	90
PHQ-9[1] score	2.6 (2.4)

[1] Patient Health Questionnaire 9-item depression screener

Table 3

Intervention dose and content delivered, according to Risk Group[1]

	Risk Group[1]		
Intervention Dosage	**Low (N = 16)**	**Moderate (N = 57)**	**High (N = 31)**
Visits			
Mean (SD) Percent of expected visits[2]***	90% (12.9)	74% (13.1)	66% (15.8%)
Median number of visits***	5.5	11	28
Median total minutes***	245	400	955
Median Length of visits**	36.7	34.0	31.6
Educational Content			
Diabetes Intro[2]	8%(12)	6%(8)	9%(11)
Monitoring[2]**	33%(15)	39%(13)	47%(14)
Healthy coping[2]	29%(14)	29%(15)	29%(9)
Reducing risk[2]*	35%(17)	26%(14)	32%(13)
Healthy eating[2]	48%(22)	45%(17)	50%(17)
Being active[2]*	32%(9)	29%(12)	23%(9)
Taking meds[2]	36%(16)	43%(17)	45%(18)
Problem solving[2]	29%(12)	28%(12)	26%(12)
CHW-Participant Goal setting and Reminders			
Review Doctor Appointments[3] median*	2.5	4	4
Review Labs needed[3] median	1	1	1
Set/Reviewed Goals[2]*	93%(21)	93%(15)	81%(30)

* $p < 0.05$

** $p < 0.01$

*** $p > 0.001$

[1]Risk Group refers to algorithm category assigned for the greatest amount time over the intervention year, taking into account changes in risk (see Table 1)

[2]Percents of visits in which educational content was discussed.

[3]Review of doctor appointments and lab tests due occurred as needed, according to ADA guidelines per year[37], using count data.