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William Lonneman

Western Washington University, william.lonneman@wwu.edu

Bethanne Brown

University of Cincinnati, brownbt@ucmail.uc.edu

Chalee Engelhard

University of Cincinnati, engelhcr@ucmail.uc.edu

Kimihiro Noguchi

Western Washington University, noguchk@wwu.edu

Grace McFarlane

Western Washington University, grace.mcfarlane@aol.com

See next page for additional authors

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Abstract

Purpose: The purpose of this retrospective, mixed methods study is to examine the relationship between participation in an interdisciplinary diabetes self-management education (DSME) program at an urban primary health care center and patients’ perceived knowledge and skills, as well as clinical markers, on four cohorts of patients over a two-year period. **Methods:** Participants, mainly African-American females, responded to survey questions including self-care behaviors, perceived knowledge, and self-efficacy. The researchers also reviewed the participants’ clinical records for glycosylated hemoglobin (HbA_{1c}) and body mass index (BMI) data and compared these to similar patients in the health center who had not participated in the DSME program. Additional analysis involved a cross comparison of earlier cohorts (2014-15) to later cohorts (2016-17). **Results:** Quantitative analysis showed strong statistical evidence that those in the DSME program had more control over their BMI as compared to the control group. The results also suggested that those in the program after 2016 had more control over their HbA_{1c} than those in the program before 2016, although this evidence was more limited. Qualitative themes that emerged highlighted the participants’ valuing most what they learned about nutrition, exercise, and disease management. **Conclusions:** Population specific DSME programs can help produce both quality of life and clinical improvements that persist over time in underserved populations. This study was limited by a small sample size.

Author Bio(s)

William Lonneman, DNP, RN is Assistant Professor and Interim Director of the RN-to-BSN program at Western Washington University. He was previously part of the nursing faculty at Mount St. Joseph University in Cincinnati, Ohio.

Bethanne Brown PharmD, BCACP, is a Professor of Pharmacy Practice and Residency Program Director at the University of Cincinnati College of Pharmacy. Her clinical practice includes providing chronic disease state management services for underserved populations.

Chalee Engelhard, PT, EdD, MBA, is the University of Cincinnati Doctor of Physical Therapy Program Director in the College of Allied Health Sciences (CAHS). She also serves as CAHS’ IPE Leader and the Cincinnati VAMC’s Physical Therapy Geriatric Residency Academic Director.

Kimihiko Noguchi, PhD, is an Associate Professor in the Department of Mathematics at Western Washington University in Bellingham, WA. Grace McFarlane, B.S., is a graduate of the Department of Mathematics at Western Washington University. Diane Warner, RD, LD, is a Registered Dietician with the Cincinnati Health Department. She works at the Price Hill Health Center WIC office. Akino Kishigawa, CDT, EFDA, RDH, is a dental hygienist at the Cincinnati Health Department. She works at the Deaconess Health Check at Western Hills, a school-based dental center, providing care to the underserved community.

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Authors

William Lonneman, Bethanne Brown, Chalee Engelhard, Kimihiro Noguchi, Grace McFarlane, Diane Warner, and Akino Kishigawa



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William Lonneman¹
Bethanne Brown²
Chalee Engelhard²
Kimihiro Noguchi¹
Grace McFarland¹
Diane Warner³
Akino Kishigawa³

1. Western Washington University
2. University of Cincinnati
3. Cincinnati Health Department

United States

ABSTRACT

Purpose: The purpose of this retrospective, mixed methods study is to examine the relationship between participation in an interdisciplinary diabetes self-management education (DSME) program at an urban primary health care center and patients' perceived knowledge and skills, as well as clinical markers, on four cohorts of patients over a two-year period. **Methods:** Participants, mainly African-American females, responded to survey questions including self-care behaviors, perceived knowledge, and self-efficacy. The researchers also reviewed the participants' clinical records for glycosylated hemoglobin (HbA_{1c}) and body mass index (BMI) data and compared these to similar patients in the health center who had not participated in the DSME program. Additional analysis involved a cross comparison of earlier cohorts (2014-15) to later cohorts (2016-17). **Results:** Quantitative analysis showed strong statistical evidence that those in the DSME program had more control over their BMI as compared to the control group. The results also suggested that those in the program after 2016 had more control over their HbA_{1c} than those in the program before 2016, although this evidence was more limited. Qualitative themes that emerged highlighted the participants' valuing most what they learned about nutrition, exercise, and disease management. **Conclusions:** Population specific DSME programs can help produce both quality of life and clinical improvements that persist over time in underserved populations. This study was limited by a small sample size.

Keywords: diabetes, education, self-management, long-term effects, vulnerable population

INTRODUCTION

Diabetes as a chronic illness affects populations of color at higher rates than non-Hispanic whites.¹ These individuals also experience social determinants of health that can limit their ability to gain control of their disease.² The American Diabetes Association Standards of Care recommends self-management education to promote a patient's ability to gain the skills and knowledge needed to manage this complex illness.³ As part of the standards, the education provided must be tailored and culturally appropriate to meet the patient's needs.⁴ While data exists on the benefits of this type of programming in various populations, including populations of color, most studies are of short duration and do not measure impacts long term.⁵⁻⁶

Ohio currently has over 1.3 million individuals with this diagnosis.⁷ To meet the needs of communities that have the highest rates of diabetes,⁸ the City of Cincinnati operates seven primary care clinics. One is located in the medically underserved, racially diverse neighborhood of Lower Price Hill.⁹ This area has a 28% poverty rate and a median income lower than the City of Cincinnati average.¹⁰ Health statistics for the neighborhood indicate the leading cause of death as cardiovascular disease (129 deaths/100,000) with diabetes ranked as fifth (58/100,000).¹¹ At the time of the described study, there were 1,663 patients with the diagnosis of diabetes in the seven primary care clinics operated by the City. At the Price Hill Health Center, 382 patients had this diagnosis and 107 (28%) were considered uncontrolled, with HbA_{1c} >9%.¹²

To respond to this situation, an interprofessional group of health care providers who have extensive experience in this community developed a culturally appropriate, American Association of Diabetes Educators (AADE) certified diabetes self-management education (DSME) program titled Living Well with Diabetes (LWWD). This team consisted of a dietician, nurse, and dental hygienist from the clinic and faculty and students from three local colleges representing nursing, pharmacy, and physical therapy. The pharmacist faculty member also worked at the health center; thus, there were four team members already well known and trusted by patients. This team began with planning in 2012 and offered the DSME series for the first time in January of 2013. Each two-hour group session followed the 2012 AADE 10 standards for diabetes education programming (see Figure 1 for detailed class information). Sessions ran from February to May and provided weekly instruction for four weeks then every other week for the remaining two months. Each class contained active learning and demonstrations; the classes also served as a support group, allowing participants to share successes and struggles and receive advice and encouragement from their peers and the staff. A small grant from the University of Cincinnati Center for Clinical and Translational Science and Training covered the start-up costs of the program and two years of incentives, which included items such as measuring cups and spoons and pedometers. Due to low participant turnout and poor progress towards patient attainment of goals with the patient cohorts from 2013 and 2014, the LWWD team realized the need for participants to have additional support during the weeks of the program and between DSME sessions. Therefore, the team instituted a pilot program using a few select students during the 2015 LWWD DSME program. The success of this pilot led to the full integration of health professions students as health coaches beginning with the LWWD program in 2016.

The specific objectives of this retrospective, mixed methods study were to 1) examine the relationship between participation in the DSME program and patients' perceived knowledge and skills, as well as clinical markers, on four cohorts of patients over a two-year period; and 2) determine if outcomes are different between those who participated in later versions of the program (2016 and 2017) versus those in the program during its early iterations (2014 and 2015).

METHODS

The specific objectives of this retrospective, mixed methods study were to: 1) examine the relationship between participation in the DSME program and patients' perceived knowledge and skills, as well as clinical markers, on four cohorts of patients over a two-year period; and 2) determine if outcomes are different between those who participated in later versions of the program (2016 and 2017) versus those in the program during its early iterations (2014 and 2015).

After receiving Institutional Review Board approval from the Cincinnati Health Department, 27 eligible patients were identified, spread over five cohorts (2014-2018). Six of those declined to participate. Two of the researchers, both of whom had completed human subjects' protection training, then conducted the telephone survey with the other 21 patients. All 21 also agreed to allow review of their medical records. The survey consisted of ten questions. The first eight assessed the patient's current confidence in knowledge and skills to manage their diabetes. These questions covered the essential elements of an AADE-certified DSME program and were the same questions asked of each patient at the beginning and end of the LWWD program:

"How confident are you with:

- Taking care of my diabetes
- Choosing the right foods to eat
- Taking my medications for diabetes as my doctor told me

- Changing my medications/diet/lifestyle based on my blood sugar numbers
- Exercising 30 minutes a day 5 of 7 days a week
- Buying foods in the grocery store that help my diabetes
- Caring for myself when I don't feel well either from low blood sugar or illness
- Making the changes needed in my life to improve control of my diabetes"

Participants responded to these questions using a six-point Likert scale (1= not confident, 6= confident)

Class	Responsible Instructor	Learning Objectives
Living Well with Diabetes	Interprofessional Team	<ul style="list-style-type: none"> ○ Gain a full understanding of the educational program using both written and verbal materials presented ○ Set individual health-related goals collaboratively with the help of interprofessional student health coach ○ Describe diabetes and the disease process in their own words when asked by providers
Living Well and Eating Right	Registered Dietitian	<ul style="list-style-type: none"> ○ Identify macronutrients and their effect on blood glucose ○ State how the timing of meals effects blood glucose ○ State most important personal reasons and goals in diabetes self-management ○ Demonstrate measuring and meal planning skills and the reasons how these will help achieve self-management goals.
Living Well with Exercise	Physical Therapist	<ul style="list-style-type: none"> ○ Understand the importance of the role of exercise in daily life ○ Demonstrate understanding of current fitness level by use of exertion/exercise scale ○ Understand the signs/symptoms to be aware of when exercising
Living Well and Planning Meals ^a	Registered Dietitian	<ul style="list-style-type: none"> ○ Identify macronutrients and their effect on blood glucose ○ State how the timing of meals effects blood glucose ○ State most important personal reasons and goals in diabetes self-management ○ Demonstrate measuring and meal planning skills and the reasons how these will help achieve self-management goals.
Living Well and Taking Meds and Tracking Progress	Pharmacist	<ul style="list-style-type: none"> ○ Understand the side effects associated with the most commonly prescribed medications for diabetes ○ Demonstrate how to use a blood glucose meter and document their readings in a log book ○ Set goals for adherence to medication regimens using adherence aides (pill boxed, phone alarms)
Living Well and Shopping Smart	Registered Dietitian from Local Grocery Store Chain	<ul style="list-style-type: none"> ○ Identify healthy food choices in a grocery store setting ○ Learn how to choose the best option when faced with numerous choices ○ Learn how to shop while watching budget ○ As a group, determine the most valuable information based on current eating habits
Living Well Makeup Class ^b	Interprofessional Team	<ul style="list-style-type: none"> ○ Handling temptations/comfort foods ○ Alternative stress reducers ○ Sparking motivation for physical activity
Living Well Without Fear	Pharmacist	<ul style="list-style-type: none"> ○ Know 100% of the time how to correct hypoglycemia ○ Identify from a list of symptoms both hypo- and hyperglycemia

- Describe step to take care for self when ill
- Living Well and Celebrating Change Interprofessional Team
 - Participants will be able to state their most important personal reason and goals in diabetes self-management
 - Participants will be able to recognize stress and learn way to cope with stress in their lives

Figure 1. Living Well with Diabetes Class Content

^a content is expanded upon between Living Well and Eating Right and Living Well and Planning Meals

^b inserted to account for class cancellation due to weather conditions

The final two questions of the survey were open-ended: 1) How has your health been, both physically and emotionally? 2) It's been two (three, four) years since you were in the program. What did you learn in the classes that is still helping you today? What parts of those classes have stayed with you? The two researchers who conducted the surveys noted the patients' responses to the Likert scale questions. They wrote out the patients' responses to the two open-ended questions and then read back the texts to the patient to guarantee that they were accurate.

After the participants completed the surveys, the researchers reviewed the medical records of the participants and extracted both demographic and clinical data. Demographic data included age, gender, and ethnicity as well as smoking status. Clinical data collected included BMI and HbA_{1c} from the time of entry into the DSME program until 730 days (two years) after. At this time, three patients were excluded because clinical data was not available for the time period studied (these patients were no longer patients of the Price Hill Health Center). The remaining 18 participants were then split into two cohorts in order to compare earlier participants to later ones; those in the program during 2014 and 2015 comprised one group (n=11) and those in the program during 2016-2017 comprised the other (n=7). The participants had an average age of 60 (range 46 to 72) and were majority female (n=15 or 83%). They were diverse, with 46% stating their ethnicity as Caucasian and the remaining 54% as African American. To establish a control group for the study, BMI and HbA_{1c} data were collected on a similar, randomly selected group of 100 patients with diabetes at the same health center. Their ages were 45-75; there were no other exclusion criteria. Based upon the sizes of the intervention group, the control group consisted of sixty females and ten males whose first visits took place in either 2014 or 2015, and twenty-five females and five males whose first visits were in either 2016 or 2017.

For the purpose of valid statistical analysis, it was later determined that individuals needed to have at least four data points (HbA_{1c} or BMI). This reduced the numbers in the groups; the final sample sizes for the eight groups are summarized in Table 1.

Table 1: Sample size of different groups

Sample Size	2016-2017 (HbA _{1c})	2014-2015 (HbA _{1c})	2016-2017 (BMI)	2014-2015 (BMI)
DSME participants	3	3	6	10
Control group	7	36	16	59

STATISTICAL METHODOLOGY

The HbA_{1c} and BMI data were log-transformed prior to the analysis, as the original values were all positive. Then, using the log-transformed data as response variables, simple linear regressions on time were fitted assuming that the slope and intercept are random for each participant. To assess whether or not there was any difference at all between the 2014-2015 participants and 2016-2017 participants, equality of their overall regression structures (overall intercept, slope, and variance) and equality of individual residual variance were examined.

The above statistical quantities were evaluated for the following three types of comparisons: 1) 2016-2017 participants vs. 2014-2015 participants; 2) 2016-2017 General Population vs. 2014-2015 General Population; and 3) DSME Program participants vs. General Population. Even though the second comparison is uninteresting, it is important to strengthen any statistically significant findings made in the first.

Due to small sample sizes, to improve the reliability of the statistical results we computed the adjusted p-values for the three overall regression structures mentioned above using non-parametric bootstrap with 10,000 resamples by selecting each participant in each group at random. The adjusted p-values were computed in two steps. In the first step, three t-statistics each corresponding

to each regression feature was computed by applying the bootstrap-t method.¹³ Then, their adjusted p-values were calculated using the MaxT method.¹⁴ Statistical significance was declared at the adjusted p-value < 0.05.

For assessing the equality of residual variances, the non-parametric bootstrap-t method with 10,000 resamples was applied to the F-statistic for the variance ratios. As this setting was treated separately from checking the overall structures, no p-value adjustments were made. Statistical significance was declared at the p-value < 0.05.

In addition to assessing the statistical significance, various effect sizes were also calculated to supplement any important findings. For the overall regression structures (overall intercept, slope, and variance), raw differences (for the overall intercept and slope) and ratio (for the overall variance) were reported. For the residual variances, their ratios were reported. The effect sizes provide more intuitive understanding of the results than (adjusted) p-values.

RESULTS

The telephone survey results included both the eight “confidence” questions as well as the two open-ended questions. The Likert-scale “confidence” questions showed that the participants had highest confidence in “Taking my medications for diabetes as my doctor told me” (mean score of 5.8 out of 6). This was followed by the two questions reflecting self-efficacy in diabetes self-management: “Taking care of my diabetes” (mean score of 5.3) and “Making the changes needed in my life to improve control of my diabetes” (mean score of 5.1). There was no significant difference between the overall scores of the two participant groups (2014 and 2015 vs. 2016 and 2017) to these questions.

Qualitative analysis of these open-ended questions occurred using thematic analysis as outlined by Braun and Clarke.¹⁵ Constant comparison of the open codes yielded emergent themes across the participants’ responses. With respect to the qualitative data linked to the first open-ended question, the themes yielded that the participants felt that their health ranged from good to fair. This is illustrated by two participants’ responses. Participant 9 responded, “Good. I feel I do the best I can to control my diabetes”. Participant 19 said, “I feel I’m doing an ok job taking care of myself. But I do know I can do better”.

Themes

Regarding the second open-ended question, lessons learned in the class that are still having an impact today, the primary theme that emerged from the qualitative data was that the participants learned the most about nutrition. Participant 23 stated, “Looking at the food and checking out the ingredients. You showed me the food that I can substitute for the food that I really liked. Information that has been very useful.” Exercise surfaced as a secondary theme. This is illustrated in a quote from Participant 11, “The importance of good diet (and) keeping regular exercises”. A third theme, disease management, revealed the importance of persistence and accurate self-assessment in patients with diabetes. The participants acknowledged that people with diabetes can have moments where they are not going to fully adhere to the practices being taught by the educators. They shared that it is important to acknowledge that this will happen and then to fall back in line with the instructions of the health care providers. Participant 17 shared this response, “Not to be frustrated. Get back on the horse and start over again. Be honest with yourself”.

Statistical analysis of the clinical data shows that the residual variance for HbA_{1c} values among the 2016-2017 participants was only 27.2% of that of 2014-2015 participants ($p = 0.012$; effect size = 0.272; see Tables 2 and 3).

Table 2: List of (adjusted) p-values. Note: 1. 2016-2017 participants vs. 2014-2015 participants; 2. 2016-2017 General Population vs. 2014-2015 General Population; 3. DSME Program vs. General Population. Adjusted p-value for overall mean is calculated as the minimum of the adjusted p-values for the overall intercept and overall slope. Similarly, adjusted p-value for the overall structure is calculated as the minimum of the adjusted p-values for the overall intercept, overall slope, and overall variance. Statistically significant results (< 0.05) are indicated in bold.

Comparison	1 (HbA1c)	1 (BMI)	2 (HbA1c)	2 (BMI)	3 (HbA1c)	3 (BMI)
Adj. p-value for overall intercept	0.777	0.721	0.881	0.881	0.750	0.986
Adj. p-value for overall slope	0.848	0.626	0.855	0.855	0.341	0.285
Adj. p-value for overall variance	0.952	0.831	0.827	0.827	0.995	0.985
Adj. p-value for overall mean	0.777	0.626	0.855	0.855	0.341	0.285

Adj. p-value for overall structure	0.777	0.626	0.827	0.827	0.341	0.285
P-value for residual variance	0.012	0.002	0.855	< 0.001	0.699	< 0.001

Table 3: List of effect size measures. *Note: 1. 2016-2017 participants vs. 2014-2015 participants; 2. 2016-2017 General Population vs. 2014-2015 General Population; 3. DSME Program vs. General Population.*

Comparison	1 (HbA1c)	1 (BMI)	2 (HbA1c)	2 (BMI)	3 (HbA1c)	3 (BMI)
Effect size (diff.) for overall intercept	0.073	-0.051	-0.033	-0.042	-0.018	0.055
Effect size (diff.) for overall slope	0.000	0.000	0.000	0.000	0.000	0.000
Effect size (ratio) for overall variance	1.289	0.537	0.656	1.113	1.143	0.763
Effect size (ratio) for residual variance	0.272	0.340	0.888	0.177	1.194	0.173

Similarly, the residual variance for BMI values for those in the DSME program is only 17.3% of that in the general population, giving statistically significance difference ($p < 0.001$; effect size = 0.173). Furthermore, the p-value for the residual variance for the comparison between the 2016-2017 participants and the 2014-2015 participants is quite small ($p = 0.002$; effect size = 0.340), as is the p-value for the residual variance for the comparison between the 2016-2017 general population and the 2014-2015 general population ($p < 0.001$; effect size = 0.177). Lastly, the overall structures of any groups being compared are similar for all the comparisons as their adjusted p-values are all high with negligible effect sizes.

DISCUSSION

In the telephone survey, all participants reported a high degree of self-efficacy regarding their ability to manage their disease. The qualitative analysis found that they particularly valued new knowledge related to nutrition, exercise and disease management. These results confirm the wisdom of emphasizing the enhancement of daily lifestyle skills in DSME programs. Moreover, based on strong statistical evidence, the clinical data indicates that those who participated in the DSME program had more control over their BMI than similar patients in the same health center when tracked over a two-year period. The findings also suggest that the 2016-2017 participants may have had more control over their HbA_{1c} than the 2014-2015 participants, although this finding needs to be interpreted with caution due to the small sample sizes. It is not possible to determine if the observed differences indicate that program impacts fade over time or whether they are due to improvements in the 2016 and 2017 programs, such as the addition of students as health coaches.

The results of this study are consistent with prior studies. Williams et al looked at a similar population of African American women, albeit in a rural setting. They found that BMI values decreased significantly in participants during a 12-month follow-up, while reported self-efficacy increased.¹⁶ Peek, Cargill, and Huang performed a systematic review of health care interventions for diabetes targeted to minority populations.¹⁷ They found that nearly all of the studies that measured dietary habits, physical activity, and weight changes noted improvements, even when other health outcomes such as mean HbA_{1c} were unaffected. The same authors noted, "Only a few of the studies in our review had long-term follow-up, which is necessary to assess the sustainability of interventions and to capture the effect on health outcomes that may take longer to manifest". By contrast, Ryan et al did not find significant changes in BMI among their participants, although HbA_{1c} did decrease; those authors acknowledge that the 6-month follow-up may have been too short to notice other changes.⁵

Limitations

The major limitation of this study is the small sample size. While the number of participants over the five cohorts was small, those with sufficient data and willingness to participate reduced the data available for analysis even further. This may limit the generalizability of the results to other populations, including those in underserved communities. Further studies tracking interventions for diabetes in historically underserved patients over longer periods of time are warranted.

CONCLUSION

This study set out to examine the relationship between participation in a DSME program in an urban health center and improvement in both perceived knowledge and skills, as well as clinical markers, over a two-year period. Such longitudinal studies are rare in the literature. Analysis of the data shows that participants did indeed make progress in two important clinical measures compared to non-participants. Survey respondents also expressed confidence in their ability to manage several key aspects of their disease and appreciation for knowledge and skills gained through the program. The data also indicates that later iterations of the DSME program, which included health coaches for each patient, may have enhanced program effects.

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