East Carolina University
EMPOWER Diabetes Treatment Project

PROJECT OVERVIEW

East Carolina University’s (ECU) Health Disparities Center is the largest institutional presence in rural, eastern North Carolina working to reduce health disparities among minority populations in the region. The Health Disparities Center, working with an extensive health system and community partnership, sought to implement the first regional, culturally-appropriate community-based intervention to reduce diabetes disparities among 200 African-American women with uncontrolled diabetes within a four-county region in eastern North Carolina. This intervention used a tailored small behavioral change approach—the EMPOWER diabetes self-management education (DSME) approach—to improve patient’s eating, physical activity, and care management through individualized goal-setting and culturally appropriate community health worker support.

This initiative sought to overcome psychosocial and environmental barriers to patient diabetes management behavior by focusing on emotional, cultural, and social factors related to healthy eating, physical activity, and medication adherence in rural communities without state-of-art diabetes care. African-American women in these settings are more likely to experience behavioral and psychosocial challenges to controlling type 2 diabetes than the broader African-American community. Using a prospective randomized control trial study design, the EMPOWER project compared the effectiveness of using community health workers (CHWs) to provide a tailored small behavioral changes approach along with ongoing diabetes self-management support (DSMS), with a mail-only DSME information approach.

CONTEXT AND PARTNERS

The small behavior change approach builds upon evidence-based behavioral models (e.g., theory of planned behavior) by incorporating these unique elements: 1) personal goals that are relative to baseline behaviors rather than recommended guidelines 2) behavioral goals set by program participants rather than program staff and 3) behavioral changes that are small and manageable and not overwhelming to participants. All facets of the intervention were culturally adapted and implemented with sensitivity to the context of rural North Carolina and program participants. Program materials were developed and pilot tested in conjunction with community partners and members of the target population, and were tailored for subjects with reduced literacy. Community health workers were selected from the target communities. With its emphasis on engaging participants in small, manageable lifestyle changes, this initiative offered culturally relevant food plan options with small, healthy food choices rather than forbidding any particular food. Small successes produced by incremental behavior change served to reduce feelings of deprivation, while increasing feelings of confidence and success.

Patients that participated in this study included 200 African-American women living in rural eastern North Carolina with uncontrolled type 2 diabetes mellitus (HbA1c ≥ 7.0). A majority of these participants experienced advanced symptoms of the disease with an average disease duration of 11 years and with 60% of patients taking insulin therapy for blood sugar control (compared to 26% nationally). Exclusion criteria included those with advanced disease (e.g., end stage renal disease, advanced heart failure, blindness, and metastatic cancer), alcoholism, or major psychosis barring active participation.
The ECU Health Disparities Center partnered with the following organizations to implement the initiative:

- Peers for Progress – provided consultation and training on peer health interventions
- State of North Carolina Department of Public Health, Diabetes Control Program, and Office of Minority Health – provided assistance in training
- Cornerstone Ministries – facilitated recruitment of community health workers
- Success Dynamics, Inc. – provided assistance in training
- University Health Systems of Eastern Carolina – assisted in recruitment of participants
- Regional health departments and federally-funded community health centers – assisted in recruitment of subjects, provided space for intervention and assessment, and facilitated elements of project sustainability
- Lucille Gorham Intergenerational Center – provided space for intervention and assessment; facilitated recruitment of participants
- Tillery Community Health Center – assisted in recruiting participants

**ASSESSMENT AND PLANNING**

The EMPOWER project is based on the evidence-based small-changes behavioral approach to diabetes self-management that was previously shown to be effective in long-term weight loss by the same researchers. The small-changes behavioral approach offers some distinct advantages: 1) behavioral goals are relative to baseline values (e.g., gradually increasing average daily step counts above baseline average daily steps), 2) selected by participants, and 3) small changes to self-selected behaviors encourages engagement and prevents participants from becoming over-burdened.

The planning phase of this initiative lasted 6 months. During this period project leaders and community members formed a steering committee and developed strategic plans for program implementation, hired a project coordinator, selected and trained six community health workers (CHWs), and prepared the infrastructure for the delivery of the intervention (i.e., secured letters of agreement, secured meeting space, and finalized materials and protocols for the initiative’s implementation and evaluation).

The primary intervention components of the EMPOWER Diabetes Project were delivered by trained CHWs. To assure cultural competence and to promote connectedness through shared cultural values between staff and participants, CHW applicants were required to be adult African-American women with strong interpersonal skills, residing in the target area for at least 5 years. Potential CHWs were recommended through local health agencies and then interviewed by ECU investigators to determine adequate levels of interpersonal skills and suitability. A total of six CHWs were hired, three to deliver the EMPOWER DSME training to participants and three that provided ongoing DSMS and navigation to community resources. Each CHW received 50 hours of training by ECU investigators based on a peer self-management support curriculum developed by the researchers that included self-study, didactic instruction, and role playing exercises. Material created for this study are not propriety. The curriculum included content related to: 1) General diabetes knowledge, 2) Assistance in diabetes management/daily living and small changes behavioral goal selection and monitoring, 3) Social and emotional support, and Linkage to clinical care and integration of peer support elements.
Participants in the EMPOWER Program were recruited from regional primary care practices and ongoing community-based programs (e.g., offered through local churches and community centers). In clinical practices (e.g., University Health Systems, federally funded community health centers), patients meeting the inclusion criteria were selected through medical record databases. Those participating in community-based programs received targeted mailings, announcements and flyers in local churches and community centers, and word of mouth at community events.

**INTERVENTION**

The EMPOWER Diabetes Project participants were randomly assigned to one of two treatment groups. Those in the EMPOWER intervention group received a tailored small behavioral changes approach to lifestyle intervention and medication adherence involving 16 sessions, along with ongoing diabetes self-management support (DSMS) delivered face-to-face or via telephone by culturally competent CHWs. Those in the comparison group received 16 mailings of DSME information mailed to them directly. Each group contained 100 participants. Table 1 below summarizes the main intervention components and specific elements of the Fund’s Together on Diabetes project:

<table>
<thead>
<tr>
<th>INTERVENTION COMPONENTS</th>
<th>SPECIFIC ELEMENTS</th>
<th>MODE OF DELIVERY</th>
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<tbody>
<tr>
<td>Diabetes Self-Management Education</td>
<td>Diabetes self-management education featuring the EMPOWER small changes behavioral approach plus navigation/support. Face-to-face or via phone-based diabetes self-management education included 16 contact sessions which featured the following topics (intervention group only):</td>
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<tr>
<td></td>
<td>1. Program orientation</td>
<td>Community health workers delivered the curriculum either through scheduled face-to-face visits or via telephone to patients.</td>
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<td></td>
<td>2. Goal setting</td>
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<td>3. Monitoring nutrition</td>
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<td>4. Physical activity</td>
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<td></td>
<td>5. Diabetes education</td>
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<td></td>
<td>6. Mindfulness and awareness</td>
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<td></td>
<td>7. Self-talk</td>
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<td></td>
<td>8. Problem solving</td>
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<td></td>
<td>9. Social support</td>
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<td></td>
<td>10. Coping and stress</td>
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<td></td>
<td>11. Planning for non-typical weeks</td>
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<td></td>
<td>12. Expectations for weight loss</td>
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<td></td>
<td>13. Managing relapse</td>
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<td></td>
<td>14. Planning and time management</td>
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<tr>
<td></td>
<td>15. Community and social support</td>
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<tr>
<td></td>
<td>16. Program review and termination</td>
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<tr>
<td></td>
<td>Patient self-management education packets that featured resources from the Academy of Nutrition and</td>
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<td></td>
<td>Undergraduate research assistants mailed out</td>
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</table>
Dietetics across 16 home mailings. These topics included (Mail – control group only):

- Glycemic index
- Glycemic control
- Sugar intake
- Diabetes and traveling
- Diabetes and medication
- Diabetes and sick days
- Diabetes self-management
- Herbs & dietary supplements
- Insulin
- Weight loss
- Physical activity
- Diabetes complications
- Eating out
- Snacking behavior
- HbA1c, blood pressure, & cholesterol

Information packets to patients.

Patient self-monitoring using a personal journal. Participants monitored and recorded daily step count, daily nutrition (using the “stoplight” guide), blood-glucose, and weekly weight. (EMPOWER intervention and mail control groups)

Patients recorded personal, daily values.

Support for Managing Diabetes and Distress

Patient self-management support that included information on medication adherence and problem solving for patients having difficulties taking prescribed medication. (EMPOWER intervention group only)

Phone sessions were delivered by undergraduate research assistants.

Patient self-management support for accessing community resources that addressed barriers to care including social and economic factors (e.g., where to find healthy food and physical activity venues, accessing medical and pharmacy care, and how to secure monitoring supplies). Additionally, CHWs assisted participants with navigating social service delivery systems. (EMPOWER intervention group only)

Community health workers delivered patient support via telephone.

Community health worker delivered cognitive-behavioral therapy that included individualized coaching to participants on “trigger foods,” coping with depression, stress eating, stimulus cues, social support, and cognitive restructuring. (EMPOWER intervention group only)

Community health workers delivered the individual therapy either through scheduled face-to-face visits or via telephone to patients.

EMPOWER staff conducted phone-based supervisory sessions with CHWs to review participant treatment

EMPOWER Project staff provided quality assurance via telephone.
Story of Community Transformation: Community Health Worker Delivered Small Changes Diabetes Treatment

African Americans have frequently identified mistrust of medical providers in the clinical setting as a barrier to care. Delivering a lifestyle intervention, a method traditionally delivered by clinicians in a medical or university setting, to rural African Americans required an innovative approach to promote acceptance and engagement with the intervention. To address this, the EMPOWER project used culturally-competent, Community Health Workers to deliver face-to-face and telephone-based coaching sessions. Community Health Workers were chosen because they are trusted by patients, are attuned to the available resources within the community, and increase social relevance of the intervention through cultural tailoring. The CHW-delivered small change intervention was successful at improving health outcomes among patients, particularly those that were not using insulin and were at an early phase of disease progression (see Table 1 & 2). Modifying lifestyle behaviors early in trajectory of type 2 diabetes is a promising strategy for improving diabetes-related outcomes and preventing complications from developing over time.

Story of Personal Transformation

The EMPOWER small changes intervention was successful at improving diabetes self-management among program participants. Two noted areas of improvement include increased self-management behavior and increased diabetes knowledge. For example, prior to the program, one participant failed to check her blood sugar, but developed the habit of checking it every day after participating in the EMPOWER program. Another patient had physical difficulties that made it difficult to walk and engage in other forms of physical activity, however, as a result of her participation in the EMPOWER program, now engages in water exercises. Another patient had described that through the program, she learned that it was important to continue to monitor her blood glucose, even on days she felt well, something she was not doing prior to her enrollment in EMPOWER. Patients also commented on their increased knowledge of diabetes complications and problems that can result from uncontrolled diabetes.

Testimony from an EMPOWER Community Health Worker reveals her insight regarding lessons learned by patients:

“I thought if you had diabetes and you lose weight then you would be cured, or like eventually with taking the insulin and eating right you would be cured. I think some people think taking the medicine is a cure all and they can eat what they want. I think they think that by taking their medication they will be ok.”

Many of the African-American women living in rural North Carolina experiencing type 2 diabetes who participated in the EMPOWER diabetes treatment intervention felt it had an important and meaningful effect on their lives.
EVALUATION RESULTS AND FINDINGS

Data on Project Implementation

Figure 1 displays program implementation—the unfolding of services provided to the program’s clients over time. (Note: In this cumulative line chart, each month, new activities are added to all prior activities.) The data show steady implementation of services provided throughout the course of the grant period with associated key events and milestones depicting an intervention timeline.

Figure 1: Cumulative Number of Education Sessions Provided over Time
Data on Clinical Outcomes

Table 1 below summarizes the results for key patient participant clinical outcomes for those in the mail-only and EMPOWER intervention conditions (using pre- and post-intervention assessments with participating clients; repeated measures and ANOVA were the statistical tests used):

Table 1: Clinical data for the EMPOWER Diabetes Project participants.

<table>
<thead>
<tr>
<th>CLINICAL OUTCOME</th>
<th>Mail Only (n = 100)</th>
<th>EMPOWER (n = 100)</th>
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<tbody>
<tr>
<td></td>
<td>Baseline (SD)</td>
<td>6 months (SD)</td>
</tr>
<tr>
<td>Avg. HbA1c</td>
<td>9.1 (1.9)</td>
<td>8.9 (2.1)</td>
</tr>
<tr>
<td>Avg. SBP</td>
<td>137.8 (20.2)</td>
<td>145.2 (22.1)</td>
</tr>
<tr>
<td>Avg. DBP</td>
<td>84.7 (11.8)</td>
<td>88.5 (12.0)</td>
</tr>
<tr>
<td>Avg. BMI</td>
<td>38.8 (8.4)</td>
<td>38.9 (8.4)</td>
</tr>
<tr>
<td>Avg. Weight</td>
<td>229.2 (55.8)</td>
<td>229.7 (55.8)</td>
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Table 2 below summarizes the results for key patient participant clinical outcomes for those who are and are not taking insulin (Repeated measures and ANOVA were the statistical tests used):

Table 2: Clinical data for the EMPOWER Diabetes Project participants: Insulin vs. non-insulin dependent participants.

<table>
<thead>
<tr>
<th>CLINICAL OUTCOME</th>
<th>Insulin (n = 122)</th>
<th>Non-Insulin (n = 78)</th>
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<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>6 months</td>
</tr>
<tr>
<td>Avg. HbA1c</td>
<td>9.5</td>
<td>9.4</td>
</tr>
<tr>
<td>Avg. SBP</td>
<td>136.3</td>
<td>138.2</td>
</tr>
<tr>
<td>Avg. DBP</td>
<td>84.9</td>
<td>85.6</td>
</tr>
<tr>
<td>Avg. BMI</td>
<td>36.3</td>
<td>36.6</td>
</tr>
<tr>
<td>Avg. Weight</td>
<td>213.5</td>
<td>215.3</td>
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</tbody>
</table>

Implementing a small changes intervention delivered by CHWs was effective at improving the health of African-American women. Those in the EMPOWER intervention experienced improvement in blood pressure when compared to those in a mail-only control group. Further, those patients that were not using insulin experienced additional improvement in observed clinical measures over those patients using insulin. Patients not taking insulin experienced marked improvement in HbA1c, diastolic blood pressure, body mass index, and weight (see Table 2).
**WHAT WE ARE LEARNING**

Systematic reflection on the results and meaning of this project by ECU investigation staff helped to identify key restraining and facilitating factors.

Several key restraining factors or challenges that make it more difficult to implement the program and achieve improvements in clinical outcomes with this population experiencing health disparities:

- Many of the participants recruited for this project were in the advanced stages of diabetes. This proved challenging for the delivery of the targeted intervention. The small-changes behavioral approach was designed for use with patients with recent disease onset.
- Remaining in contact with all of the women to deliver small changes intervention content over the 12-month period was challenging. Project staff addressed this by connecting to patients on the phone and CHWs met patients at convenient locations, such as home or work, to deliver these components.
- Rural African-American women participating in this study were at a low level of health literacy. As a result, the intervention was tailored to ensure messages were understood (i.e., enhanced one-on-one education, picture-dense messages).

Several facilitating factors appear to have contributed to the program’s success. These include:

- The use of African-American CHWs has been integral to implementation of the EMPOWER Diabetes Project. The African-American community has a long history of distrust with healthcare providers. Using CHWs with shared cultural values is an important approach to build relationships of trust for the delivery of long-term lifestyle change interventions.

Key lessons learned include:

- Patients that were not using insulin experienced greater and more significant improvement to weight, body mass index, HbA1c, and diastolic blood pressure than participants who were using insulin.
- Addressing lifestyle behaviors early in the disease trajectory may be the best strategy for minimizing disease complications.
- Implementing a CHW-delivered, small changes intervention is most effective with patients who are in the early stages of diabetes progression. Although some clinical improvements were observed between the EMPOWER and mail-only education comparison groups (i.e., blood pressure), the greatest improvement was observed among EMPOWER participants that were not using insulin. Those patients that require insulin treatment may require a more intensive intervention (e.g., more intensive behavior change approaches, pharmacological).
**MOVING FORWARD AND PLANS FOR SUSTAINABILITY**

The EMPOWER Diabetes Project included the following tactics of sustainability:

<table>
<thead>
<tr>
<th>TACTICS OF SUSTAINABILITY</th>
<th>SPECIFIC APPROACH</th>
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<tbody>
<tr>
<td>1) Incorporate the initiative’s activities or services into another organization with a similar mission</td>
<td>The use of community health workers was an important component to this project and could be an important standardized practice in diabetes care. The EMPOWER team has been active in advocacy efforts to expand the usage of CHWs for delivering diabetes care, but have not finalized a strategy. Amidst restructuring of North Carolina’s Medicaid program, the role of CHWs in diabetes care is unknown. One CHW has been retained to support East Carolina University’s second Together on Diabetes project: COMRADE.</td>
</tr>
<tr>
<td>2) Solicit in-kind support - Seek goods and services the organization would otherwise have to purchase (e.g., donations of office supplies from a local business).</td>
<td>Testing equipment and supplies used to measure HbA1c were donated to local health departments to support community efforts for evaluating diabetes self-management education.</td>
</tr>
</tbody>
</table>

**PROJECT PUBLICATIONS AND MATERIALS**

- A research poster was presented on the development of a single-session medication adherence intervention for EMPOWER participants in the intervention group. This poster was presented at East Carolina University’s Research and Creative Achievement Week on April 10, 2013. The goal was to disseminate knowledge to other clinical researchers regarding the need for medication adherence intervention.


- Bert Hambidge and an undergraduate student presented a poster at The Jean Mills Health Symposium to the attendees. The focus of the symposium was on enhancing minority health in the millennium and our program is an example of engaging a minority group.
• Two undergraduate research assistants presented a research poster outlining the design and rationale of a single-session medication adherence intervention for EMPOWER participants in the intervention group. This poster was presented at the State of North Carolina Undergraduate Research and Creativity Symposium on Saturday, November 17, 2012. The goal was to disseminate knowledge to other clinical researchers regarding the development for medication adherence intervention.

• Doyle Cummings and another EMPOWER staff member attended a 2-day conference on diabetes disparities and presented an academic poster outlining the design and rationale of the EMPOWER diabetes program at the American Diabetes Association’s 5th Disparities Partnership Forum on October 22nd in Washington DC. The goal of this conference and presentation was to share ideas about ways to reduce health disparities in diabetes treatment programs.


• Materials created as a result of this project include a training manual and a small changes lifestyle change treatment manual used by community health workers.
PROJECT CONTACT INFORMATION

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EVALUATION CONTACT INFORMATION

This case study was prepared by the Work Group for Community Health and Development team (Charles E. Sepers, Jr., Jenna Hunter-Skidmore, & Ithar Hassaballa) at the University of Kansas http://communityhealth.ku.edu, in collaboration with the Whittier Street Health Center, and as part of the evaluation of the BMSF’s Together on Diabetes Program.

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