



Bringing Research In Diabetes to Global Environments and Systems

Application number:

Letter of intent, part 3

Project Title

Integrating and Evaluating Community Workers in a Diabetes Care Delivery System

Total amount requested for the project (in US DOLLARS) if already available

1. Non-technical summary (max. 100 words)

With the increasing diabetes incidence and resource constraints worldwide, it is increasingly important to develop and evaluate low-cost interventions in high risk communities. The proposed study will determine if integrating community workers (CW) in rural, underserved communities to provide self-management support will improve patient outcomes. This intervention will be compared with standard diabetes self-management education, which is not supported by CW. Training, a web-site and supervision from diabetes educators will be available to the CW as an ongoing resource. We will evaluate patient outcomes, CW satisfaction and retention rates, and the long term impact and sustainability of the project.



2. Information on the project (maximum 3 pages)

Background: A body of evidence demonstrates that interventions that foster diabetes self-management improve health status and lower health care costs ^(Barlow). Diabetes self-management education (DSME) is critical in laying the foundation for promoting the knowledge and skills for patients to perform self-care tasks. However, DSME alone is not sufficient to maintain improved behaviors over a lifetime and sustained improvements require time, contact, and follow up.

Programs are now putting a greater emphasis on providing ongoing support to sustain DSME gains ^(Nat'l Standards; Siminerio) and attempting to incorporate self-management support (SMS) into their structure ^(Tang; Galzier; Anderson 2005; Wagner; Glasgow & Funnell). Despite these efforts, the numbers of DSME programs and educators to provide this service are shrinking while the rates of diabetes are increasing ^(Hiss; Pearson; Coonrod). Thus, opportunities for comprehensive services that increase access and include SMS are critical.

In a meta-analysis of diabetes quality improvement efforts, those that addressed team changes showed more robust improvements in glycemia than any other strategy. ^(Shojania) To facilitate a team approach in primary care, the University of Pittsburgh Diabetes Institute (UPDI) integrated certified diabetes educators (CDE) into primary care practices (PCP) to deliver DSME and organize follow-up support groups. We repeatedly demonstrated the benefits on improving access and outcomes ^(Siminerio; Siminerio; Piatt; Emerson), but to our knowledge, building on this model to include long term SMS has not been done.

There is a growing body of literature that provides evidence for interventions using community workers (CW). ^(Tang; Funnell2005; Lorig2001; Heisler 2006; Galzier; Kright 2005) CWs are used effectively to increase awareness, link people to the health system, and provide social support and cultural mediation ^(Tang; Funnell2005; Lorig2001; Heisler 2006; Galzier; Kright 2005). In the face of growing numbers of people with diabetes and significant resource constraints facing health systems worldwide, it is increasingly important to develop and evaluate low-cost interventions that build on available resources. CWs provide a unique opportunity to serve as a resource for ongoing community-based SMS.

Community Need: Nearly half of the world's population lives in rural areas and are considered to be the "forgotten minority" ^(North Carolina State University, 2007). Implementing and evaluating interventions is particularly critical in rural communities as this population experiences increased rates of chronic disease including diabetes, as well as smoking, obesity, and lack of exercise ^(Committee on the Future of Rural Healthcare, 2005; Koproski; Ho; Bloomfield; Shiel). Additionally, the supply of health professionals is also less in rural settings. ^(US Congress; CDC) Since 30% of the population in Pennsylvania is classified as rural, Pennsylvania provides a forum to test strategies that have applicability in underserved rural communities worldwide.

Aims/Hypotheses/Research Questions

Specific Aim 1: Determine the effectiveness of CW supported vs. non-CW supported DSME programs within four rural PCP sites using the 5As for Self-Management Support Model as a process to facilitate team communication between CWs, primary care providers and patients.

Specific Aim 1 Research Question: Will the addition of CWs support long-term benefits in behavior change, improved quality of life and clinical outcomes following the provision of DSME with CW support in the PCP setting compared to DSME without CW support in the PCP setting?

Specific Aim 2: To assess the sustainability of the program through the use of community focus groups that includes diabetes educators, primary care providers, CWs, and patients. Perceptions of the use of CWs to support DSME and perceptions of how to best retain and reward CWs will be assessed.



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Specific Aim 2 Research Question: How will integration of CWs into a PCP delivery system be perceived by primary care providers, CDEs, CWs, and patients and what is necessary to reward and retain CWs?

Specific Aim 3: To assess the sustainability of the program in terms of cost-effectiveness of the CW supported DSME intervention compared to non-CW supported DSME on complication incidence using simulation modeling.

Specific Aim 3 Research Question: Are primary care based DSME programs that implement CWs cost-effective and sustainable in comparison to primary care based DSME programs that do not implement CWs?

The investigators already received funding for the focus group and cost effectiveness parts of the project and therefore are not requesting funding from BRIDGES for specific aims 2 and 3.

Methods

Overall Research Design: The proposed study is a cluster randomized controlled trial designed to test the effectiveness of incorporating CWs into existing diabetes care teams in two rural, underserved PCPs to provide self-management support (SMS) (intervention group). This intervention will be compared with standard DSME visits in the primary care setting, which are not supported by CWs (usual care/control group). We will evaluate the effect of a CW intervention on patient behavioral, psychosocial and clinical outcomes, and patient participation in meeting the ADA Standards of Care. To evaluate the role of the CW in an ongoing system of care, we will also measure CW, patient, and provider satisfaction with the program and the retention rate of the CWs. The proposed intervention will be delivered by CDEs and CWs to subjects with diabetes in the PCP setting. The study population will be recruited from four rural, underserved primary care offices in southwestern Pennsylvania. Practices will be randomly assigned, by toss of a coin, to the intervention or control group following and informed consent process. Study participants will be recruited from the consented primary care offices. Follow-up assessments will be conducted immediately following the last of six DSME classes, immediately following six months of support groups, and at 12 months post-DSME.

During periods 5 and 6, four individual focus groups will be conducted for providers, CDEs, CWs, and patients to assess and determine perceptions of using CWs to support DSME programs and how to best retain and reward CWs. Additionally, we will determine if the CWs were able to increase CDE efficiency and provide aid to CDEs in patient communication.

Cost effectiveness models comparing the costs of the intervention using CWs will be compared to the control group. Costs will be measured from the health care system perspective, thus considering direct costs only. The outcome will be cost per Quality Adjusted Life Year (QALY). The probability of complication outcomes will be based on the Centers for Disease Control and Prevention cost-effectiveness model for type 2 diabetes.

Study Design: This study design is a cluster randomized controlled trial where the unit of randomization is the site where DSME will be delivered. The University of Pittsburgh Medical Center has 35 ADA recognized sites, 13 of which are PCPs. In order to achieve the required power for the study, we anticipate recruiting four PCPs, which will be matched on geographic, demographic and socioeconomic status. The sites will be randomly assigned to CW supported DSME or non-CW supported DSME

Target Population: It is estimated that among the identified PCP groups, approximately 4000 people with diabetes are seen annually and are eligible to take part in DSME programs delivered in the PCP setting. These numbers are based on available billing data.



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Inclusion/Exclusion Criteria: Inclusion criteria include adults age 18 or greater, and ICD-9 code (250**, or glucose value > 200 mg/dL, or A1c test, or diabetes medication), and at least one visit to the primary care practice within the previous 12 months. Exclusion criteria include individuals under age 18, gestational diabetes, or non-ambulatory.

Sample size: Sample size calculations incorporate the multilevel cluster design of the study. Calculations are based on the mean change of 0.6% in A1c between groups. In each of the four sites, 60 subjects will be recruited for a total of 240 subjects. We will have 80% power to detect this difference ($\beta=0.02$, 2 sided $\alpha=0.05$). This sample size accounts for a 10% drop-out rate, which is comparable to other community-based studies we have done. We also accounted for the clustering of patients within site using an intracluster correlation coefficient of 0.0005.

Data Collection Tools: Non laboratory data will be collected using the Diabetes Self Management Program Initial Assessment form, the Chronicle electronic data system, the SF-12 and D-39 Quality of Life questionnaires, and the Empowerment Scale. A blood draw will be done for A1C and lipids. Anthropometric measures (height and weight) will be captured. Blood pressure will be measured according to the Hypertension Detection and Follow-Up protocol (HDFP) [97] and a urine sample will be collected to assess microalbumin. Blood glucose meter downloads will also be captured. The initial assessment form and Chronicle system include demographic information, medical history, medication use, self-care behaviors and barriers to behavior change.

Data Analysis: In univariate analyses, paired t-tests for continuous data and McNemar's test for categorical data will be used to determine within group differences between baseline and follow-up visits. In order to examine differences between the study groups, a combined between and within group analysis of variance will be performed for each outcome of interest. Mixed modeling will be used to analyze the change in outcome values from baseline to follow-up between study groups. The effect of study group will be adjusted for the clustering of patients within primary care practices in all models. Baseline values of the dependent variable will be adjusted for if significant differences occur between baseline and follow-up values. While the geographic location of the practices should yield similar populations, differences may exist. If this occurs, these differences will be accounted for in the multivariate analyses.

Outcome Measures: Primary outcomes will include change in self care behaviors and change in the proportion of patients who achieve the goal for A1c (<7%). Secondary outcomes will include change in quality of life (SF-12, D-39) and change in the proportion of patients who achieve goals for blood pressure (<130/80mmHg), LDLc (<100mg/dl), and microalbumin (<30ug/mg). We will also examine satisfaction and empowerment scores.

Key Indicators and Milestones: 1. Protocol development including review and satisfaction of institutional review board requirements. 2. Randomization of primary care offices. 3. Implementation of the intervention in each study group. 4. Collection of primary and secondary outcome data. 5. Conduction of trial analyses. 6. Reports/publications on trial. 7. Conduction of focus groups. 8. Collection of cost of care data on the completed trial. 9. Conduction of cost-effectiveness analysis. 10. Reports/publications on cost-effectiveness.

Sustainability Plan: Results of this study will be used to "set the stage" for community-based, geographically appropriate diabetes self management support sessions using CWs. Information gathered from specific aims 2 and 3 will allow us to assess the perception of CWs for self management support and whether CWr utilization is cost effective. As many of the elements of the proposed intervention are already present in communities, it may be feasible for CWs to become part of the ongoing system of diabetes care.