SUMMARY STATEMENT

PROGRAM CONTACT: Christine Hunter (Privileged Communication) Release Date: 02/23/2016
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Application Number: 1 R01 DK108141-01A1

Principal Investigators (Listed Alphabetically):

GERBER, BEN STEVEN (Contact)
SHARP, LISA K

Applicant Organization: UNIVERSITY OF ILLINOIS AT CHICAGO

Review Group: HDEP
Health Disparities and Equity Promotion Study Section

Meeting Date: 02/04/2016 RFA/PA: PA14-334
Council: MAY 2016 PCC: DKH BEHV
Requested Start: 07/01/2016 Dual IC(s): NR

Project Title: mHealth for Diabetes Adherence Support

SRG Action: Impact Score:20 Percentile:8
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 2A-Only minorities, scientifically acceptable
Children: 3A-No children included, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

| Year | Direct Costs Requested | Estimated Total Cost |
|------|------------------------|----------------------|
| 1    | 483,948                | 776,325              |
| 2    | 487,577                | 782,146              |
| 3    | 492,106                | 789,411              |
| 4    | 490,389                | 786,657              |
| 5    | 502,071                | 805,397              |
| **TOTAL** | **2,456,091** | **3,939,935** |

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.
RESUME AND SUMMARY OF DISCUSSION: This application proposes a randomized, controlled trial to implement and evaluate a mHealth diabetes adherence support intervention delivered by clinical pharmacists and health coaches to improve medication adherence, healthy eating, and physical activity behaviors among African-American and Latino adults with uncontrolled type 2 diabetes. The proposed study addresses a significant public health issue among African-Americans and Latinos, many of whom are at high risk for complications given a lack of adherence to treatment recommendations. The project retains the strong features of the previous submission, including the outstanding investigative team, an appropriate cross over design and supportive preliminary data. During discussion, reviewers noted that the resubmission is also strengthened by changes that are responsive to most of the concerns identified in the previous review, including a more compelling rationale for the use of videoconferencing. The panel noted some remaining concerns; however, these were considered minor and detract only minimally from this otherwise compelling project. Overall, reviewers concurred that the proposed research is potentially very important and likely to inform strategies to reduce disparities in diabetes care and have high impact on the field of diabetes management support services.

DESCRIPTION (provided by applicant): Many African-Americans and Latinos with diabetes do not achieve recommended diabetes goals placing them at high risk for complications. Team-based models of care can help in reaching goals of therapy. Additionally, mobile health (mHealth) technologies can further improve outcomes among those more difficult to reach. This study will evaluate the impact of a team-based, mHealth intervention designed to improve medication adherence, healthy eating, and physical activity behaviors. We will compare this mHealth approach with usual care. Clinical pharmacists and health coaches (HC) will deliver our proposed team-based intervention. mHealth delivery includes mobile phone text messaging, secure videoconferencing, and HC home visits. Pharmacists will focus on medication reconciliation and adherence. Health coaches will help identify psychosocial and environmental challenges to adherence in a culturally-sensitive manner. Together, they can assist in goal-setting, problem-solving, negotiation of competing priorities, and provide social support leveraging mHealth technologies. Preliminary data from our research group supports the role of health coaches partnering with clinic-based pharmacists in improving diabetes outcomes in minorities. In the proposed mHealth intervention, patient-pharmacist videoconferencing will eliminate the need for in-person visits with a pharmacist, which is impractical for many low-income patients. In addition, our pilot work suggests that text messaging is a preferable means of communication and may facilitate more frequent contact with patients. We propose a randomized, controlled trial to evaluate the effectiveness of a mHealth diabetes adherence support intervention delivered by clinical pharmacists and health coaches. We will randomize 220 patients through UI Health to either: (1) mHealth diabetes adherence support through clinical pharmacists and health coaches; or (2) usual care. After one year, patients completing the mHealth intervention will be monitored for an additional year while the usual care group receives the mHealth approach. Outcomes include medication adherence, hemoglobin A1c, blood pressure, and LDL-cholesterol levels. The specific aims include: (1) evaluate the effectiveness of an mHealth diabetes adherence support intervention delivered by clinical pharmacists and health coaches to African-American and Latino adults with uncontrolled type 2 diabetes; (2) evaluate the maintenance of improved diabetes behaviors as well as clinical outcomes one year after completing the intervention; (3) evaluate the cost and cost-effectiveness of mHealth diabetes adherence support compared to usual care; and (4) evaluate the reach, adoption, and implementation of mHealth diabetes adherence support based on the RE-AIM framework.

PUBLIC HEALTH RELEVANCE: This research evaluates a mHealth diabetes adherence support intervention delivered by health coaches and clinical pharmacists, designed to improve adherence to medications and a healthy lifestyle. Outcomes measured include change in hemoglobin A1c, blood pressure, and cholesterol levels. This study will determine the benefit and cost of including mobile
phone text messaging, videoconferencing, health coaches, and clinical pharmacists in diabetes management support services.

CRITIQUE 1

Significance: 1
Investigator(s): 1
Innovation: 4
Approach: 4
Environment: 1

Overall Impact: These are very skilled researchers addressing a highly significant problems in both African American and Latino populations. The investigators have been responsive to a previous review. The study design, power and statistical analyses are sophisticated and appropriate, and the process and program evaluation are salient features. Concerns about secondary outcome measures and potential contamination reduce enthusiasm for the proposal, as does the modest amount of innovation. Nevertheless, the combined pharmacist/health coach/mHealth intervention holds promise of success.

1. Significance:
   Strengths
   - Diabetes is a problem among African-Americans and Latinos, many of whom are at high risk for complications given a lack of adherence to treatment recommendations.
   - Clinical pharmacists are underutilized in terms of their potential to promote behavior change for risk reduction in community populations.
   - More proven in this regard are health coaches who can be very effective but need an expert’s guidance, as is offered through this mHealth intervention.
   Weaknesses
   - None noted

2. Investigator(s):
   Strengths
   - This study is being led by Drs. Ben Gerber and Lisa Sharp. Dr. Gerber has an MD as well as an MPH in public health informatics. Dr. Sharp has a PhD in clinical psychology with additional postdoctoral training in health psychology. Dr. Sharp also has a bachelor’s degree in nursing and worked for a decade in this area therefore, adding to her qualifications. The two have collaborated on a closely related R01 funded by NIDDK that is concluding this spring. These two and their collaborators comprise a highly qualified team well positioned to carry out this study effectively.
   - The PIs and team have relevant research experience working with all technology components of the intervention, as well as conducting research that involves the inclusion of pharmacists and health coaches.
   Weaknesses
   - None noted.

3. Innovation:
   Strengths
   - The partnership between clinical pharmacists and health coaches with the addition of mHealth is innovative and unique.
   Weaknesses
   - The assertion that health coaches using video conferencing is novel can be challenged. For example, Ramirez and her colleagues were using closed circuit TV and promotoras 30 years
ago in the Eagle Pass and Rio Grande areas of Texas. Of course, the technology was more basic but the theme was the same.

- REAIM and long term follow up are empirical strengths but are not innovations. Generally, this section is overstated.

4. Approach:
Strengths
- The randomized design and especially block randomization to ensure race, gender and site balance is commendable.
- The recruitment and retention plans are detailed, clearly based on past success.
- The sample size estimation and statistical analyses sections are clear and appropriate for the study aims and will include intention-to-treat models.
- Process and program evaluation ideas (e.g. the cost-effectiveness analysis) are also very good.
- Finally, the outcome evaluation emphasizes medication adherence, hemoglobin A-1 C, blood pressure and LDL-cholesterol, very appropriate for this study’s aims.

Weaknesses
- The conceptual framework comprises a wide range of theories (e.g. SCT and HBM) which individually would be all inclusive and very non-specific. Motivational Interviewing will be used, with no attempt to weave it into the other models. The interventions seem to be retrofitted onto this overly general framework, yielding a mixture that is really just a kitchen sink approach. Hypotheses are derived from the literature and the authors’ own research but not from these theories.
- Detail is needed on the exclusion criterion of ‘comprehension’ and ‘impaired decision making’.
- Will the pharmacist be sure not to ‘contaminate’ control subjects with intervention-based information?
- 24 hour diet recalls and the IPAQ can be challenged in terms of their reliability and validity, especially with participants who may be at lower levels of literacy and education. Internal consistencies as low as .47 would not generally be adjudged “acceptable” (p. 90).

5. Environment:
Strengths
- The campus and health system environments are excellent.

Weaknesses
- None noted

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections
- No concerns were identified.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
- Acceptable
  - No concerns were identified.

Inclusion of Women, Minorities and Children:
- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- No concerns identified.
Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Not Applicable (No Biohazards)

Resubmission:
- The resubmission is largely responsive though concerns remain about the approach and innovation.

Budget and Period of Support:
Recommend as Requested
- No concerns were identified.

CRITIQUE 2

Significance: 1
Investigator(s): 2
Innovation: 3
Approach: 4
Environment: 1

Overall Impact: This resubmission addresses the effectiveness of a mHealth diabetes care adherence support program, delivered by pharmacists and health coaches in African American and Latinos with uncontrolled diabetes. The project focuses on a compelling problem in this high risk and underserved population. The concerns raised in the previous review have been addressed. The project is well described, the investigative team is strong and previous and ongoing studies on the topic further support its merit. Inclusion of the health economist is a particular strength. Concerns include lack of information about how contamination will be prevented, and lack of detail about how motivational interviewing will be integrated. Information regarding the training and expertise (biosketches) of two of consultants was not apparent.

1. Significance:
   Strengths
   - Diabetes is a significant burden among African-American and Latino populations; interventions to improve self-management adherence are desperately needed.
   - Numerous barriers to successful self-management can be overcome potentially with mobile health technologies that promote easier access, communication, and patient education, including text messaging and video conferencing (mHealth).
   - Integrating services-clinical pharmacists and health coaches to support self-management.
   Weaknesses
   - None noted

2. Investigator(s):
   Strengths
   - A strong and well qualified team has been assembled to carry out the project.
   - A health economist has been added to the team as recommended in the prior review.
   Weaknesses
Dr. Fisher (consultant) will provide expertise in sustainable peer support models of diabetes management and Dr. Fairbanks (consultant) will provide training in motivational interviewing related to adherence. However, biosketches were not available nor are they listed in key personnel.

3. Innovation:
   Strengths
   - Pharmacists and health coaches, videoconferencing and text messaging technology.
   - Cost effectiveness analyses.
   - Scientific expertise, the issue of sustainability and the RE-AIM framework.
   Weaknesses
   - The field of mobile health technology and its use in under-served and high risk populations has a history of at least 25 years or more.

4. Approach:
   Strengths
   - Addresses issues raised in prior review regarding potential overlap with a current study that ends in April, 2016 (i.e. pharmacists and health coaches with no mobile health technology).
   - RCT design; further detail about behavioral outcome measures.
   - Availability of a low cost two-way text messaging application developed from experience in other studies (i.e. the Moving Forward weight loss intervention).
   - Strong pilot work with the target populations.
   - Conceptual framework guiding the study that integrates health belief, social cognitive theory, social support and problem solving.
   Weaknesses
   - Although motivational interviewing will be used, it is not clear how it is integrated with the other theories.
   - Unclear how contamination will be avoided.

5. Environment:
   Strengths
   - Excellent resources and facilities to support the study.
   Weaknesses
   - None noted

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections
- No concerns identified.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
- Acceptable
  - No concerns were identified.

Inclusion of Women, Minorities and Children:
- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- No concerns identified.
Vertebrate Animals:
Not Applicable

Biohazards:
Not Applicable

Resubmission:
- The concerns raised in the previous review have been addressed.

Budget and Period of Support:
Recommend as Requested
- No concerns were identified.

CRITIQUE 3

Significance: 2
Investigator(s): 1
Innovation: 2
Approach: 2
Environment: 1

Overall Impact: This application addresses diabetes in black and Latino adults; it uses mHealth with a clinical pharmacist and health coach. If proven effective it will provide a model for integrating pharmacists in chronic disease management and extend the use of telehealth in health disparities populations.

1. Significance:
Strengths
- It is a significant study given the morbidity and mortality associated with diabetes in racial and ethnic minority populations.

Weaknesses
- None noted

2. Investigator(s):
Strengths
- Dr. Gerber is an internist with expertise in conducting studies with diabetes population and in using mHealth and telehealth technology to impact health behaviors. He has developed mobile health applications that will be used on this study. He is supported by a team of health economists, pharmacists, behavioral health and social psychology researchers.

Weaknesses
- None noted.

3. Innovation:
Strengths
- Their prior study demonstrated that patients were reluctant to stay after a visit and discuss their care with a pharmacist because of time and they did not want to come back for a visit.
- However, videoconferencing with the pharmacist working remotely and a health coach in the home is an alternative and innovative solution which they are testing in this application.

Weaknesses
• None noted.

4. Approach:
Strengths
• A theoretical framework.
• There is a stronger rationale in the resubmission for testing video-conference rather than in-person visits.
• Demonstrated that it is acceptable to have health coaches in the home.
• Recruit from a wide range of practices.
• Build in one year of follow to assess maintenance.
• They have considered contingency plan for technical difficulties.

Weaknesses:
• Sustainability and implementation in other settings; is sustainability of the project beyond funding? The entire set up costs about $2000. The applications states a sustainability action plan will be developed. It would have been more informative if developed as part of the application not as a future endeavor.
• This works in a health care facility with a pharmacists on site, however, how would this work in community practices where pharmacists are lacking?

5. Environment:
Strengths
• University of Illinois Chicago team is well suited for this study with a wider range of support resources to enhance the implementation of this study

Weaknesses
• None noted

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections
• No concerns were identified.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
Acceptable
  o No concerns were identified.

Inclusion of Women, Minorities and Children:
• Sex/Gender: Distribution justified scientifically
• Race/Ethnicity: Distribution justified scientifically
• Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
• No concerns identified.

Vertebrate Animals:
Not Applicable

Biohazards:
Not Applicable

Resubmission:
• The resubmission was responsive to the previous review.
Budget and Period of Support:
Recommend as Requested
  - No concerns were identified.

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 R01 DK108141-01A1; PI Name: GERBER, BEN Steven

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.
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02/04/2016 - 02/05/2016

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.