

# The Feasibility and Self-Management Practices of the Real People with Diabetes Study

Justine Karduck, Ph.D., RDN, LDN, CDCES, and Karen Chapman-Novakofski, Ph.D., RDN  
 Department of Food Science and Human Nutrition, College of Agricultural, Consumer and Environmental Sciences, University of Illinois at Urbana-Champaign

## ABSTRACT

Diabetes self-management management strategies continue to develop as research and practice into successful outcomes are investigated. Health apps have gained popularity, but their integration into clinical practice has yet to be fully explored and systematically examined. Registered dietitian nutritionists (RDNs) and certified diabetes care and education specialists (CDCES) may promote and oversee food tracking with nutritional analysis and dietary recommendations through apps with their patients. This study describes the challenges of RDNs leading a research study investigating the feasibility of conducting a health app-based intervention for managing diabetes in adults using the National Institutes of Health's (NIH) design framework for feasibility studies. The study design and methods included an observational, longitudinal design using quantitative and qualitative data to serve as the basis for a future app intervention with external federal funding. Participants (n=121) were Diabetes Wellness Center patients 18 years of age or older, able to complete surveys in English, have type 2 diabetes or prediabetes, a self-reported A1c of 5.7 to 9.0%, willing to share health data with the research team, and ready to complete online or paper surveys every three months over twelve months. The six areas of feasibility examined included Acceptability, Demand, Implementation, Adaptation, Practicality, and Integration. The qualitative analysis included one-on-one interviews with healthcare administrators (n=4) and one semi-structured discussion group with CDCESs (n=5) recruited from the diabetes clinic before patient recruitment began, and inductive thematic analysis was used. Major findings included that although most participants were smartphone owners (n=87), few used health apps (n=22) to track health behaviors. Demand was medium, but Acceptability, Implementation, Adaptation, Practicality, and Integration were low. Implications for dietetics practice include that RDNs and CDCES should acknowledge that health apps may be useful for patients. Still, adequate training is needed for healthcare providers and patients before using them. This study's systematic feasibility evaluation can be a model for other clinical initiatives integrating health apps into practice. A dedicated project manager, examination of administrative protocols, adherence to clinical practice guidelines for diabetes care, and accordance between app acceptance and integration into practice need further evaluation for the success of a future app intervention.

## BACKGROUND

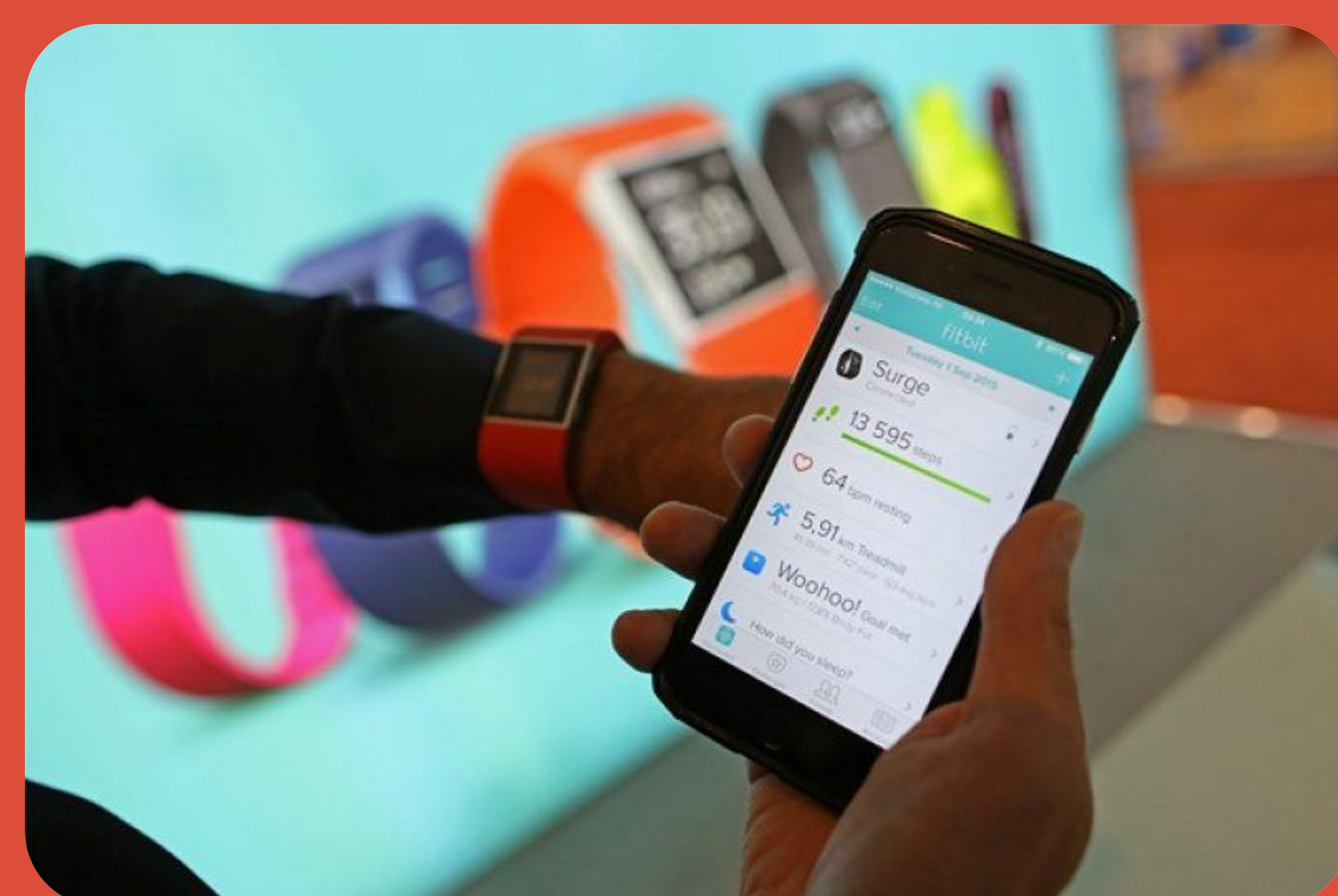
Some systematic reviews and meta-analyses have found that diabetes-specific health apps improve glycemic control, yet their use in clinical settings is still being determined.<sup>1-3</sup>

Concerns have been raised, including a lack of:

- Evidence of clinical effectiveness rather than statistical significance
- Integration into the health care delivery system and standard clinical care
- Accuracy and quality of health apps and potential threats to safety and privacy<sup>4-6</sup>

Little research has focused on how practicing RDNs use these apps in authentic patient care settings with people with diabetes (PWD).

This study describes the triumphs and challenges of RDNs leading a research project investigating the feasibility of conducting a health-based app intervention for managing type 2 diabetes using the framework from the National Institutes of Health (NIH).<sup>7</sup> The self-care practices of the PWD within the study are also analyzed.



## METHODS

An observational, longitudinal design was selected for this formative feasibility study called "Real People with Diabetes (RPWD)" to serve as the basis for a future intervention with external federal funding. Both quantitative and qualitative data were collected from participants, including:

- A1c
- Blood pressure
- Lipids,
- Weights
- Surveys about apps & self-care behaviors
- Clinician & Administrator Interviews

This study was Institutional Review Boards (IRB) approved.

The research team was comprised of:

- two UIUC RDN faculty and three dietetics students
- four RDNs CDCES and one RN, CDCES, from the Riverside Diabetes Wellness Center (RDWC) in Bourbonnais, IL.

Inclusion criteria included:

- type 2 diabetes or prediabetes diagnosis
- self-reported A1c of 5.7-9.0%
- willingness to share health data and complete surveys every three months over 12 months.

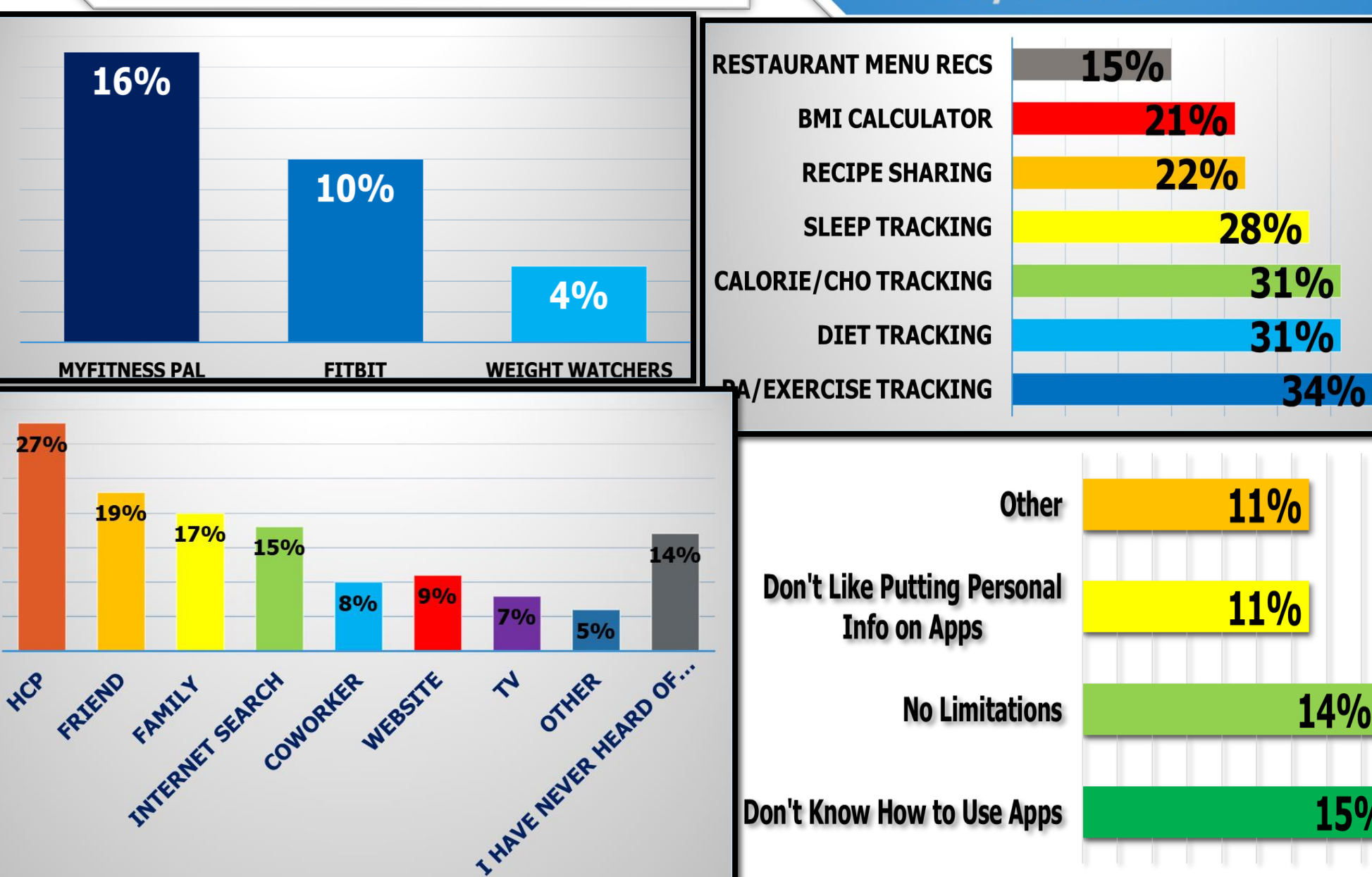
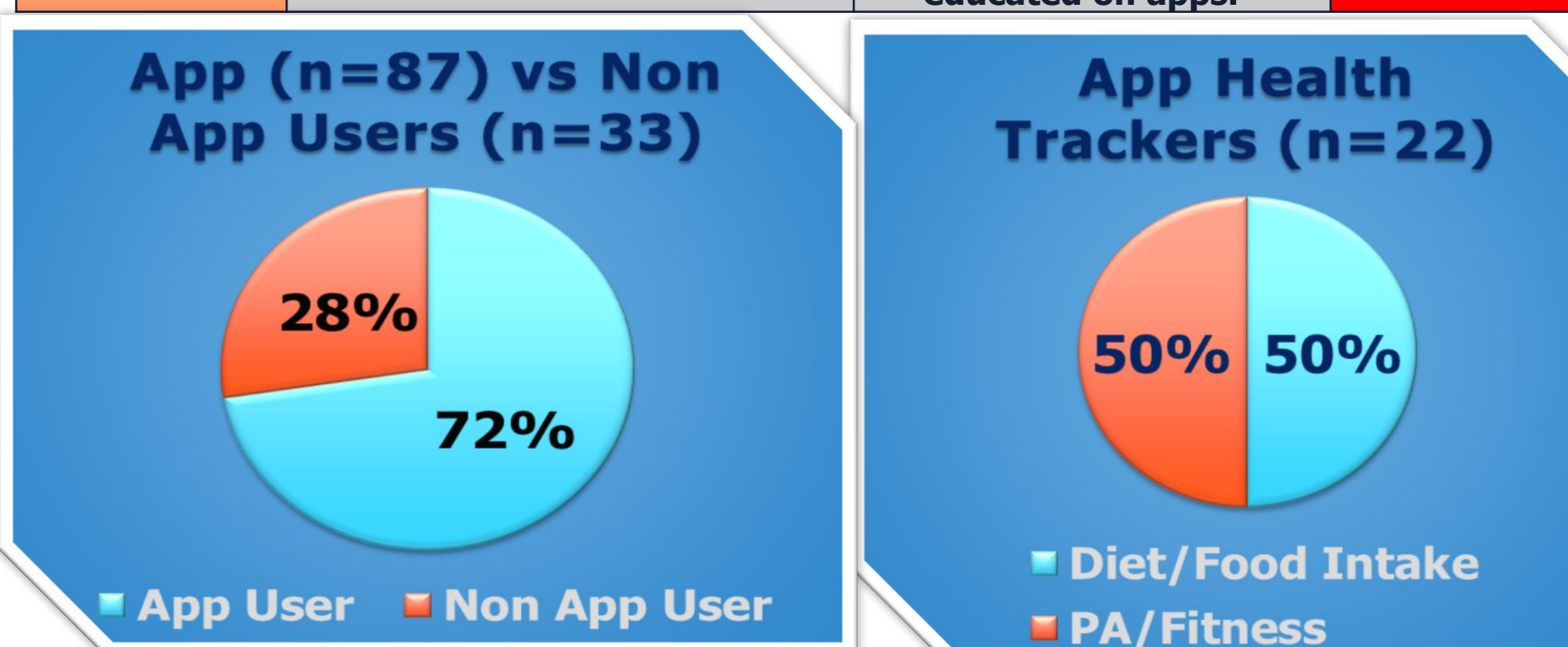
Six NIH feasibility areas were examined; expansion and limited efficacy testing were excluded. (Table 1).

NIH Focus Area	Criteria NIH Description
Acceptability	<ol style="list-style-type: none"> <li>Medical center recruitment and retention.</li> <li>Adequate subject recruitment.</li> <li>Length of time recruiting subjects to achieve target enrollment.</li> <li>Adequate subject retention.</li> </ol>
Demand	<ol style="list-style-type: none"> <li>Achievement of a target enrollment of smartphone users.</li> <li>Achievement of a target enrollment of health app users.</li> <li>Overall positive perception of health apps by subjects.</li> <li>App users tracking health behaviors related to ADCE57 Self-Care Behaviors.</li> </ol>
Implementation & Adaptation	<ol style="list-style-type: none"> <li>Fit with the organizational culture of the medical centers.</li> <li>Adherence to study protocols.</li> <li>Faculty researcher travel time to the clinic.</li> <li>Changes to subject recruitment criteria.</li> <li>Clinical data obtainment.</li> <li>Research staff retention.</li> <li>Collaborators' meetings attendance.</li> <li>Current A1c levels on all subjects.</li> </ol>
Practicality	<ol style="list-style-type: none"> <li>Timely completion of participant questionnaires.</li> <li>Electronic completion of participant questionnaires.</li> <li>Electronic gift card compensation for participant study participation.</li> <li>Time and communication efforts of faculty researchers.</li> <li>Participant and staff training on study procedures.</li> </ol>
Integration	<ol style="list-style-type: none"> <li>Based on the NIH criteria, a future app intervention would be feasible.</li> <li>Administrators and DEs app usage.</li> <li>Apps recommended to participants.</li> <li>DEs' and participants' app education.</li> </ol>

## RESULTS

Table 2. Summary of Feasibility Results.

NIH Focus Area	Researcher Targets	Results	Overall Summary
Acceptability	<ol style="list-style-type: none"> <li>2 medical centers recruited and retained.</li> <li>260 subjects recruited.</li> <li>Recruitment would last 12 months.</li> <li>70% retention of subjects (n=182).</li> </ol>	<ol style="list-style-type: none"> <li>1 recruited and retained.</li> <li>140 subjects recruited (54% of projected)</li> <li>Recruitment lasted 20 months (8 months longer than expected)</li> <li>68% of subjects retained (n=95)</li> </ol>	Low, 0 targets met
Demand	<ol style="list-style-type: none"> <li>80% smartphone users.</li> <li>50% health app users.</li> <li>50% positive perception of apps.</li> <li>25% tracking ADCE57 Self-Care Behaviors.</li> </ol>	<ol style="list-style-type: none"> <li>63% (n=87) smartphone users.</li> <li>25% (22) health app users.</li> <li>51% (n=64) positive perception of apps.</li> <li>69% (n=83) tracking ADCE57 Self-Care Behaviors.</li> </ol>	Medium, 50% (2/4) targets met.
Implementation & Adaptation	<ol style="list-style-type: none"> <li>Good fit with organizational culture (80% positive).</li> <li>80% adherence to study protocols.</li> <li>No researcher travel time to the clinic for recruitment.</li> <li>No changes to subject recruitment.</li> <li>Monthly clinical data obtainment.</li> <li>90% medical center staff retention.</li> <li>80% attendance at collaborator meetings.</li> <li>90% of subjects would have quarterly A1c levels.</li> </ol>	<ol style="list-style-type: none"> <li>Good fit with organizational culture (&gt; 80% positive).</li> <li>&lt; 80% adherence to study protocols.</li> <li>Monthly visits to the clinic for recruitment by the researcher.</li> <li>Three changes to subject recruitment.</li> <li>Clinic data obtainment difficult.</li> <li>&lt; 9% medical center staff retention.</li> <li>50% attendance at collaborator meetings.</li> <li>80% (n=112) had one A1c level.</li> </ol>	Low, 13% (1/8) targets met.
Practicality	<ol style="list-style-type: none"> <li>80% of subjects would return surveys promptly.</li> <li>80% complete surveys electronically</li> <li>80% request electronic gift cards,</li> <li>Researcher efforts would take &lt; less than 5 hours weekly.</li> <li>&lt; 20% would need additional training on study procedures.</li> </ol>	<ol style="list-style-type: none"> <li>&lt; 80% returned surveys promptly.</li> <li>&lt; 80% completed surveys electronically.</li> <li>&lt;80% electronic gift cards.</li> <li>Researcher efforts took more than 5 hours weekly.</li> <li>&gt; 20% required additional training on study procedures.</li> </ol>	Low, 0 targets met
Integration	<ol style="list-style-type: none"> <li>3 NIH areas would be feasible.</li> <li>80% of administrators and DEs would use health apps.</li> <li>Health apps would be recommended to subjects by DEs.</li> <li>80% of DEs and subjects would be educated on apps.</li> </ol>	<ol style="list-style-type: none"> <li>Only one area is feasible.</li> <li>&lt; 80% of administrators and DEs using health apps.</li> <li>Apps were not being recommended by DEs.</li> <li>&lt;80% of DEs and subjects were educated on apps.</li> </ol>	Low, 0 targets met.



## LIMITATIONS

- Recruitment was difficult, and RDWC does not regularly conduct research.
- SES data was not collected.
- Small sample size (n=121) & few pts were using apps.
- Few subjects were able to communicate electronically.
- Incomplete clinical data, decreased ability to complete planned statistical analyses.

## CONCLUSIONS

- This systematic feasibility evaluation is a framework for other clinical initiatives integrating health apps into practice.
- The leadership of RDNs in practical research, with academic dietitians collaborating with medical center clinicians, was unique.
- Several assumptions about administrative protocols, clinical practice guidelines adherence for diabetes care and monitoring, and discordance between app acceptance and app use or integration into practice had to be re-examined.
- These results support the necessity of a dedicated project manager to help overcome the challenges.

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