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Lessons Learned from Eight Teams: The Value of Pilot and Feasibility Studies in Self-Management Science

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Abstract

Designing and conducting effective intervention research is an important domain of nursing science. Nurse scientists have long recognized people with chronic conditions need effective self-management strategies across the lifespan, so they have led the way in establishing theoretical and

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Conflict of Interest

The authors declare no conflict of interest.

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practical grounds for the science of self-management. Guidance from pilot and feasibility research for self-management interventions is scarce. Documented exemplars of successes and failures in pilot and feasibility study designs are scant in the literature.

The purpose of this paper is to illustrate methodological approaches using pilot and feasibility examples. To maximize collective lessons learned in self-management science study design, features of our pilot and feasibility research strategies that yielded both desirable and undesirable outcomes are described, analyzed, and paired with alternative solutions.

A National Institute of Nursing Research P30 grant center, awarded grants to 8 pilot investigators to pilot self-management interventions. A wide variety of chronic conditions were addressed, including heart failure, chronic kidney disease, multiple sclerosis, diabetes, and HIV. The investigators provided their experiences of study implementation. Common themes across the studies were identified.

There were four lessons learned from these studies: 1) maximize resources and develop enough evidence for subsequent studies; 2) embed patient-centered feasibility within implementation testing with new patient populations; 3) develop a flexible participant recruitment plan to allow for adjustments when unexpected barriers arise; and 4) define study-specific data collection procedures to demonstrate feasibility.

Researchers conducting preliminary small-scale self-management intervention research must balance resources to develop and implement interventions to meet pilot and feasibility objectives.

Keywords

Self-Management; Chronic Conditions; Pilot; Feasibility; Nursing

Background

Designing and conducting effective intervention research is an important domain of nursing science (Cashion et al., 2019). Nurse scientists have long recognized that adolescents and adults with chronic conditions need effective self-management strategies across the lifespan, so they have led the way in establishing theoretical and practical grounds for the science of self-management (Schulman-Green et al., 2012). Today, effective self-management strategies are increasingly important (S. M. Moore et al., 2016) as an essential prerequisite for patient-centered care.

Well-designed self-management intervention research emerges from the knowledge and insights derived from small-scale feasibility and pilot studies. Broadly speaking, feasibility studies are conducted to estimate work that will be needed for future larger projects. Feasibility studies offer valuable insights and validation for data-driven study timelines and milestones, participant recruitment rates and characteristics, and data collection procedures (Arain et al., 2010). Pilot studies, a subset of feasibility studies, are specifically designed as small-scale versions of proposed larger projects. Such trials include testing interventions' core concepts and evaluating important parameters of study design (e.g., recruitment strategies, intervention delivery; Thabane et al., 2010). Pilot studies also include assessments

of the study's primary outcome and may be classified as "internal pilots" when data from the pilot phase will be integrated into the subsequent larger project's final analysis (Eldridge et al., 2016).

The success of pilot and feasibility trials can contribute to refining the subsequent implementation of larger trials to avoid wasting researchers' and participants' efforts, to addressing participant burden, and to justifying expanded research endeavors (Leon et al., 2011). Failures in feasibility, however, also present outputs of high value. Smaller scale tests that deem interventions to be ineffective or infeasible save substantial resources (Morgan et al., 2018). Yet despite the high value of both failures and successes in feasibility, thoughtful and pragmatic guidance from pilot and feasibility research for self-management interventions is scarce based on keyword searches of 'feasibility', 'pilot', and other terms. Researchers may share anecdotal experiences, but documented exemplars of successes and failures in pilot and feasibility study designs are scant in the literature.

Barriers to the publication of pilot and feasibility studies can be attributed to publication bias, which includes trends for the endorsement of statistically significant and positive results (Sutton, 2009). Successful large-scale trials with positive findings are more likely to be published than trials with negative findings (Hopewell et al., 2009). Beyond that, the publication of smaller scale pilot and feasibility intervention studies is limited in comparison with reports of large-scale multi-site trials, translating to less visibility and accessibility for investigators (Morgan et al., 2018)). Along with publication bias, publishing constraints (e.g., word limits) also relegate insights gained from pilot and feasibility studies to preliminary data sections of large-scale grant applications, where they remain buried within internal documentation, or they may simply remain unpublished given the focus on publishing reports of statistical significance rather than explorations of the feasibility of study processes (Sims, 2019).

Here, we present lessons learned from eight pilot and feasibility investigations from an NIH-funded P30 Center of Excellence in Self-Management Science. The collective focus of the studies was on self-management strategies for people with chronic conditions. These pilot and feasibility investigations were designed and led primarily by new investigators. The projects were designed to assess the applicability of established self-management interventions in new patient populations (e.g., translation of a mindfulness intervention from adults to adolescents) or to develop and test the feasibility of innovative new self-management interventions. Using these studies as examples of self-management study design, we illustrate both successful and unsuccessful methodological approaches, and we describe and analyze features of pilot and feasibility research strategies that yielded both desirable and undesirable outcomes, paired with alternative solutions. We also review common barriers encountered related to study design, intervention development and implementation, recruitment, and data collection.

Methods

The Center for Transdisciplinary Collaborative Research in Self-Management Science (TCRSS), funded through the National Institute of Nursing Research's NIH P30 grant

mechanism, awarded grants to 8 pilot investigators over 5 years (2015–2019) to pilot self-management interventions. These self-management intervention studies operationalized transdisciplinary teams, and each principal investigator (PI) received mentoring from senior leadership, including leaders external to the university system, to guide intervention development and implementation. All of these pilot and feasibility intervention studies received IRB approval from the university.

For this account, the investigators who conducted either a pilot or a feasibility study within our P30 center of excellence provided their experiences of study implementation. Table 1 provides an overview of the studies. A wide variety of chronic conditions were addressed (e.g., heart failure, chronic kidney disease, multiple sclerosis, diabetes, and HIV). Adults were the studies' primary target population, with only one study recruiting adolescents (Young et al., 2019a, 2019b). Three of the self-management interventions included a mindfulness-based approach (Henneghan et al., 2019; Timmerman et al., 2017; Young et al., 2019a; Young et al., 2019b), and two modified and tailored an existing cognitive training intervention (Cuevas et al., 2018; Clinical.Trials.gov, 2019b; Morrison, 2018). Intervention gamification strategies were used by two investigators (Radhakrishnan et al., 2016; Zuniga et al., 2019). The themes that were prioritized as most useful and important for future researchers conducting pilot and feasibility studies comprised lessons learned, spanning (a) study design, (b) intervention development and implementation, (c) recruitment, and (d) data collection.

Results

There were four overall lessons learned from the pilot studies. We identified barriers and alternatives for a each lesson (see Table 2).

Lesson 1: Pilot or feasibility work should be designed to maximize resources and develop enough evidence for subsequent studies

Selecting a pilot and/or feasibility study design demands balancing available resources with the need for feasibility and/or efficacy data. Although pilot and feasibility study designs are often described together, the objectives of each approach differ. Feasibility studies aim to answer whether or not a study should be done and to assess aspects of research such as participants' willingness to be randomized, providers' willingness to recruit participants, and design of outcomes (Eldridge et al., 2016). Pilot studies focus on the implementation of the study to ensure the feasibility of key components such as recruitment, randomization, and follow-up (Eldridge et al., 2016). Frequently, investigators must choose between a two-group comparison experimental design (pilot study) or a pre-/post-quasi-experimental design (feasibility study). Each design carries advantages and disadvantages, with inherent pros and cons for the selected approach. For our participating studies, six of eight investigators conducted feasibility studies because of both the maturity of the science and resource constraints. A thoughtfully designed feasibility study of a self-management intervention is helpful for the intervention *design* of a future clinical trial, but a feasibility trial alone is often not enough to estimate the *sample size* for the next phase of research. The TCRSS investigators often found a need for subsequent pilot studies following initial feasibility

studies, because larger pilot studies could be designed to estimate effect sizes for the proposed intervention in order to estimate the sample size for a full-scale randomized controlled clinical trial (RCT). In our Center, 67% of the investigators who completed feasibility studies obtained subsequent competitive funding based on their feasibility studies' findings.

Lesson 2: Embed patient-centered feasibility within implementation testing with new patient populations

All pilot investigators adapted evidence-based interventions to tailor intervention delivery and content to focus on self-management in new patient populations and diverse settings (see Table 1). For example, an established mindful restaurant eating self-management intervention to prevent weight gain for perimenopausal women was adapted as an intervention to improve dietary intake, which could reduce chronic kidney disease (CKD) progression; this intervention used self-management with mindful eating for adults with CKD (Timmerman & Brown, 2012; Timmerman et al., 2017).

To tailor intervention adaptation, most of the pilot investigators assessed feasibility using focus groups, eliciting direct feedback on intervention design. For example, Zuñiga et al. (2019) used a focus group to broaden an existing diabetes self-management intervention for applicability to dual diagnoses in persons living with HIV and diabetes. Timmerman et al. (2017) used participant goal-setting via focus groups after participants reported this strategy as most helpful. Additionally, Young et al. (2019a; Young et al., 2019b) conducted semi-structured interviews with a subset of participants after their study intervention was complete.

Pilot and feasibility tests of interventions contribute high-value insights on the acceptability of participant burden and accessibility for study participants. *Minimizing participant burden* to promote translation to clinical practice is critical to self-management intervention design. In our self-management pilot and feasibility work, competing commitments (e.g., occupational and social factors) that affected transportation logistics for study participation were prevalent. Examples included dependence on others for transportation (e.g., parents' availability to drive adolescent participants) and concerns related to traffic and availability of parking.

Pilot and feasibility testing allowed for near real-time *intervention adaptations*. For example, in the Memory, Attention, and Problem-Solving Skills for People with Diabetes (MAPSS-DM) intervention and the PCOS-Kind Mind intervention (Cuevas et al., 2019; Young et al., 2019a; Young et al., 2019b), poor participant recruitment was attributed to the time burden required for attending the interventions in person. Changes to the interventions were within the scope of the pilot and feasibility work, so the research teams successfully adapted and tested an abbreviated mode of delivery and explored web-based adaptations.

Pilot and feasibility testing also allowed for *content adaptation and improvement* to further embed patient-centered priorities into self-management intervention development. For example, participants in a meditation intervention (Henneghan et al., 2019) reported that their daily meditation was repetitive and that they stopped doing the meditations, resulting in

lower adherence. The research team then integrated rationales for completing the same meditation daily rather than varying the meditations to promote information-sharing for participant adherence.

Across these pilot and feasibility studies, data-driven adaptations to intervention delivery were developed to decrease burden, increase accessibility, and embed patient-centered priorities into subsequent self-management interventions. Data driving the adaptations included frequencies and trends in participant non-participation in study interventions (i.e., time of day, day of week) and attrition rates over the course of the study.

Lesson 3: A Flexible Participant Recruitment Plan is Essential

A significant challenge for the TCRSS pilot studies was participant recruitment, which can be problematic in nursing research aimed at unique populations (Cudney et al., 2004; Wallace & Bartlett, 2013). Several of the pilot studies targeted highly specific populations that can be difficult to reach, including samples with narrow age ranges or samples with transportation barriers (ClinicalTrials.gov, 2019a; Young et al. 2019a; Young et al., 2019b; Zuñiga et al., 2019). Recruitment challenges impacted study protocol feasibility and resulted in changes to expand participant pools, diversify recruitment strategies, and leverage clinical relationships.

Being flexible but purposive in inclusion criteria provided the most participants with the opportunity to be included in the pilots. Although Young et al. (2019a; Young et al., 2019b) initially used a traditional definition of adolescence (age <18 years), it became possible to widen the age inclusion criteria to capture transitional age youth (i.e., up to 24 years) who had similar experiences with the chronic condition and would also benefit from the intervention. Future studies by Zuñiga will include people who are prediabetic as well as those already diagnosed with diabetes, which will increase the population eligible for the study while providing greater benefit for the population. While inclusion and exclusion criteria must remain relatively stable for validity in a full-scale clinical trial, researchers in feasibility studies can be deliberative and thoughtful in developing criteria that leave room for expansion. Flexibility in feasibility studies provides valuable insights into participant eligibility, recruitment trends, and attrition rates, which are critical to data-based recruitment site selection and study duration for subsequent full-scale trials.

All of the TCRSS researchers had recruitment plans with letters of support from recruitment sites. However, some of the planned recruitment sites did not yield expected participation rates. When the research teams focused only on community or clinic settings, recruitment often risked being insufficient. Clinic settings, where the majority of participants were expected, were often inadequate (Radhakrishnan et al., 2016; Young et al., 2019a; Young et al., 2019b; Zuñiga et al., 2019). In those projects, as a result of recruitment challenges, additional locations that served similar target populations were then located. Radhakrishnan et al. (2016), for example, changed recruitment from home health agencies serving patients with heart failure to outpatient cardiac clinics.

The researchers who recruited participants in community settings tested several recruitment strategies before they could identify an efficient recruitment method. Young et al. (2019a;

Young et al., 2019b) expanded recruitment to strategies based on social media. Zuñiga et al. (2019) were able to recruit successfully only in person; indirect recruitment methods had no impact. Zuñiga's team found that in-person recruitment in both a community setting and a clinic setting reached the greatest potential, especially when coordinated with specific community events that were well attended or held on specific days at the clinic, such as days on which clinical pharmacists saw patients with diabetes. Timmerman et al. (2017) attempted several different strategies (i.e., flyers, shadowing health care providers) before finding a clinic that would allow direct access to a patient database for recruitment. Other researchers who were given permission through the P30 mechanism to recruit at specific clinics were unable to access similar databases at other clinics due to clinic policies that prevented coordination.

Allocating resources for bilingual staff is particularly helpful; in our studies, some clinic locations used for recruitment had large Spanish-speaking populations. In Young's (Young et al., 2019a; Young et al., 2019b) PCOS study, almost all of the adolescent participants spoke English, but many had parents who spoke only Spanish. Once this was identified, the inclusion/exclusion criteria were modified, a bilingual staff member was hired, and documents were translated; but the fact that these methods were not in place at the outset of the pilot study caused the team to miss potential participants.

Lesson 4: Defining study-specific data collection procedures to demonstrate feasibility

In addition to feasibility-related outcome measures (e.g., participation rates), self-management intervention studies often include self-reported data from participants and/or reviews of medical records. Defining and refining study-specific data collection procedures within pilot and feasibility studies provides insight for study-specific procedures to measure participants' actual completion times and to estimate participant attrition related to data collection.

Stand-alone survey completion estimates are valuable for study planning, but assessments of survey completion durations embedded within overall participant visits or interactions contribute more substantively to overall intervention feasibility. For example, initial estimates of survey completion times might be deemed appropriate prior to study start-up, but when surveys are completed by participants who consent, the duration may be classified as unacceptable and/or adversely affected by interruptions related to the study setting (Young et al., 2019a; Young et al., 2019b).

Data collection can contribute to excessive burden and influence participants' attrition rates. As a result of pilot and feasibility work, participants in some of the self-management intervention studies did not return for follow-up. Attrition was attributed to (a) absence of follow-up incentives; (b) duration of follow-up data collection procedures; and (c) logistics barriers associated with blood-draw-related follow-up visits at additional locations (e.g., a commercial laboratory; Zuñiga et al., 2019).

Participant burden specific to data collection procedures can impact data quality (e.g., non-response, attrition, negative evaluations of the intervention), increase study costs, and threaten the value of intervention assessment. It is important to consider participants' time as

a valuable, finite resource. Overall, data collection procedures informed by pilot and feasibility work strengthen funding applications for investigators seeking subsequent larger scale funding, and explicit highlights of those procedures in proposal applications can strengthen such applications for review.

Discussion

The eight pilot and feasibility studies reported here as part of the TCRSS P30 Center grant had varying degrees of success, but all of the studies provided significant findings. Feasibility studies resulted in identifying participant recruitment rates and characteristics and refining data collection procedures. Pilot studies included preliminary assessments of study outcomes. All of the studies were deemed feasible, though most needed modifications and further testing prior to being scaled up to a large study. They all moved the science forward for research. The majority led to additional research funding or well-scored competitive applications to the NIH. All of the researchers had to balance available resources and time constraints in order to achieve realistic, accomplishable research goals. Using resource-saving techniques such as adapting successful interventions to distinct populations, technology that enables remote participation, and off-the-shelf approaches may increase the ability of the intervention to be successfully implemented with a small budget and a tight time frame.

Each investigator was guided by a theory or model, as was required as part of the proposal process to the P30 Center of Excellence and nursing has a long history of using theory to guide research (Coryn, Noakes, Westine, & Schröter, 2011). None of the investigators stated that the theory was a barrier to developing or conducting their intervention. Additionally, several of the investigators continue to apply the same model to guide subsequent research (Zuñiga, Jang, Walker, Ohueri, García, 2019; Cuevas et al., 2018; Timmerman et al., 2017). Selecting a theory or model to guide research at the pilot study level provides researchers the ability to not only test an intervention but test for fit of a model.

Participants' perceptions of *intervention burden* involve psychological, physical, and/or economic hardships associated with the research process (Ulrich et al., 2005). Such burdens can vary in intensity and degree, depending on intervention procedures, participants' health status, and support systems. Strategies to reduce burdens might include integrating multiple ancillary studies, revising content, and providing a central registration for recruitment (Ulrich et al., 2005).

Future research could explore how best to capture perceived benefits or burdens of interventions. The benefits of participating in a study should in some way mitigate its burden, and capturing the extent to which participants experience benefits and burdens provides important data for planning subsequent studies. Objective approaches to measuring burdens could also be used, such as the estimation of total time required, the calculation of the number of survey requests versus the number of surveys completed, and the quantification of the number and size of tasks required. Another possibility is to partner with participants so that they can help identify ways to improve a study for future participants.

Technologies such as online surveys or touch-enabled tablet computers can be employed to make data collection more user-friendly.

Researchers need to determine how to minimize intervention burden while maintaining the optimal dose needed for interventions to have an impact. In other words, care needs to be taken in our eagerness to reduce intervention burden such that we do not water down the intervention, thereby rendering it ineffective. Approaches for informing the optimal dose of behavioral interventions are described elsewhere (Voils et al., 2014).

Family and friends are also key in self-management. Self-management is not achieved alone or in a vacuum; the support of families and friends can improve self-management outcomes and behaviors (Gallant, 2003; Rosland et al., 2008). Although all of the TCRSS interventions were created for individuals, families and friends were important in facilitating intervention participation. Indeed we found that our studies were more dependent on family and friends than we anticipated. For example, many of our participants depended on friends and family for transportation, even though most of the studies provided incentive pay for travel. To address the issue of interdependency and the importance of family and friends, future studies should include them in focus groups and in home interventions whenever possible.

Conclusion

The TCRSS P30 Center has been actively nurturing junior investigators who are engaged in innovative, transdisciplinary collaborative research to improve self-management in populations with chronic conditions. Large-scale trials require small tests of change and/or pilot and feasibility trials to confirm the appropriateness of long-term, large-scale investment for funders, clinicians, and researchers. Data-based recruitment timelines developed in feasibility studies are compelling elements of successful grantsmanship. Failures in feasibility can also be incorporated into main study results when possible, with alternative solutions published as additional brief reports of research.

Well-conducted pilot and feasibility studies with clear aims and objectives and methodological rigor can inform high quality larger studies and produce results with the potential to advance the science (Thabane et al., 2010). The literature provides tutorials on the conduct of meaningful pilot studies with objectives based on feasibility as well as on obtaining preliminary data on interventions' efficacy; and appropriate analytic plans and criteria for evaluating the success of pilot studies have also been published (Moore et al., 2011; Thabane et al., 2010). In this article, we have shared experiential lessons learned in implementing pilot or feasibility studies.

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Highlights

- Leverage resources through asynchronous or tele-conference to meet the needs of all participants
- Embed patient-centered feasibility within implementation testing in order to address competing priorities
- Develop a flexible recruitment plan to allow for adjustments when unexpected barriers arise
- Create study-specific data collection procedures to decrease participant burden

Table 1.

Self-management Interventions: Pilot and Feasibility Trial Characteristics

Pilot	Design, Sample, Setting, Theory	Objectives	Intervention
Adaptation of a Cognitive Training Intervention for Diabetes Self-Management PI: Cuevas, H. (2016)	<i>Design:</i> One group pretest/posttest <i>Sample:</i> 9 adults with diabetes <i>Setting:</i> Outpatient endocrinology clinic <i>Theory:</i> Social Cognitive Theory (Bandura, 1986).	Feasibility: To build on an existing cognitive rehabilitation intervention and adapt it for T2DM	An 8-week group based cognitive training intervention for people with diabetes to improve self-management and cognitive functioning. Modified from Stuifbergen 2011 (Stuifbergen, et al. 2001)
Peer Support for Post Intensive Care Syndrome PI: Danesh, V. (2019)	<i>Design:</i> RCT <i>Sample:</i> 8 adults with a history of critical illness <i>Setting:</i> Outpatient pulmonary clinic <i>Theory:</i> Individual and Family Self-Management Theory (IFSMT; Ryan & Sawin, 2009)	Feasibility & Pilot: To demonstrate the feasibility of peer mentor availability, interest in peer mentoring, and training completion.	90-day phone-based peer-led intervention to connect recent ICU survivors with those that have made successful recoveries to prevent post intensive care syndrome. Modified from Allicock 2014 (Allicock et al., 2014)
Improving Cognition in Breast Cancer Survivors using Meditation: A Pilot Study Henneghan, A. (2019)	<i>Design:</i> RCT <i>Sample:</i> 31 breast cancer survivors <i>Setting:</i> Community-dwelling <i>Model:</i> Hess's Conceptual Model of Chemotherapy-Related Changes in Cognitive Function (Hess & Insel, 2007)	Feasibility & Pilot: To measure attention and relaxation in the intervention group, to estimate effect sizes for future RCT.	8-weeks of mHealth delivery of daily 12-minute guided meditation compared to classical music to improve cognitive, psychological functioning, and markers of inflammation among breast cancer survivors post-chemotherapy.
A Cognitive Self-Management Intervention for Persons with MS: Adapting Web-based Technology PI: Morrison, J. (2017)	<i>Design:</i> RCT <i>Sample:</i> 20 adults (21 to 70 years old) with multiple sclerosis <i>Setting:</i> Community-dwelling <i>Theory:</i> Social Cognitive Theory (Bandura, 1986).	Feasibility & Pilot: To build upon an existing cognitive rehabilitation intervention adapting it to emphasize physical activity and be delivered via web-based video conferencing.	An 8-week group-based cognitive training intervention delivered via web-based video conferencing for persons with multiple sclerosis to improve MS-specific self-management and neurocognitive functioning. Modified from Stuifbergen 2011.
Interactive Digital E-Health Game for Heart Failure Self-management Radhakrishnan, K. (2015)	<i>Design:</i> One-group Pretest/posttest <i>Sample:</i> 19 older adults with heart failure <i>Setting:</i> Community-dwelling <i>Theory:</i> Gagne's Learning Principles (Gagne, 1965)	Feasibility: To demonstrate concept of using a game to engage HF older adults in self-management, and to obtain feasibility data to plan a pilot intervention on games for HF self-management behaviors.	Digital e-health game using a casino slot game to provide self-management tips tailored to a low-literacy, older adult population living with heart failure
Self-Management of Dietary Intake for Chronic Kidney Disease PI: Timmerman, G. (2015)	<i>Design:</i> Prospective, one-group Pretest/posttest <i>Sample:</i> 19 adults (45 to 78 years old) with mild to moderate CKD <i>Setting:</i> Community-dwelling <i>Model:</i> Explanatory Model of Health Promotion and QOL in Persons with Chronic Disabling Conditions (Stuifbergen, Seraphine, & Roberts, 2000)	Feasibility: To determine feasibility of standardized intervention protocol, translate from theory to practice, and translate from post-menopausal women to those with CKD.	6-week group based self-management and mindful eating intervention for adults with mild to moderate chronic kidney disease to better manage their dietary recommendations.
Integrated Self-Management Intervention for Adolescents with Polycystic Ovary Syndrome PI: Young, C. C. (2019)	<i>Design:</i> RCT <i>Sample:</i> Females, 14-24 year old with PCOS <i>Setting:</i> Clinic and community based in Central Texas <i>Theory:</i> Individual and Family Self-Management Theory (Ryan & Sawin, 2009)	Feasibility & Pilot: to integrate a new component into a successful mindfulness intervention that was tested previously.	Group based, 5-week mindfulness-based healthy lifestyle intervention to improve adolescent and young adult self-management of PCOS
Self-Management of Diabetes for Persons with HIV PI: Zuñiga, J.A. (2019)	<i>Design:</i> One group pretest/posttest <i>Sample:</i> 25 adults with HIV and diabetes <i>Setting:</i> Community HIV clinic <i>Model:</i> Chronic Care Model and Brown's Diabetes Self-Management Model (Brown et al, 2016)	Feasibility: New population for the intervention, new recruitment site, limited time and funding.	6-week, structured psycho-behavioral group education intervention using gamification strategies, followed by 6 weekly telephone counseling sessions to improve self-management in persons living with a dual diagnosis of HIV/AIDS and Type 2 Diabetes. Modified from Kim (2015)

Table 2.

Lessons Learned: Participant Recruitment Barriers and Strategies

Lessons Learned	Barriers	Alternative Strategies
Leveraging small-scale resources	<ul style="list-style-type: none"> • Small group intervention was difficult to schedule since it was held at an outpatient clinic. 	<ul style="list-style-type: none"> • Intervention could be asynchronous, teleconference, or self-directed, to meet the needs of all participants.
Patient-centered feasibility: Implementation testing	<ul style="list-style-type: none"> • Potential participants did not want to attend 8 weekly in-person classes. • Participants did not want to travel to the intervention site every week for 8 weeks. • Participants resisted participation due to disease complexity, fatigue, scheduling conflicts with clinic appointments. • Participants had competing demands and were unable to attend group interventions. • Average number of hours completed was 2.7 of 6. 	<ul style="list-style-type: none"> • When classroom time was reduced (see Implementation), recruitment accelerated. • Changed the classroom time to 4 classes that met every other week and reduced the time from 2 hours to 1.5 hours. Future versions of the intervention will be delivered via webinar. • Decreased the number of visits, but kept the hours of contact.
Participant recruitment plan flexibility	<ul style="list-style-type: none"> • Recruitment and enrollment took longer with each participant through November-January 1. • Low home health staff buy-in to refer patients. • Recruitment was slow. 	<ul style="list-style-type: none"> • Out-patient heart failure clinics who served the same community-dwelling HF patients as the home health staff. • In-home data collection using tablet computers and electronic surveys (Qualtrics). • Added a new recruitment site, and future research will include people with pre-diabetes.
Refining data collection protocols	<ul style="list-style-type: none"> • Arthritis comorbidity may impact completion of paper surveys. • Participants did not get blood collection from commercial lab. 	<ul style="list-style-type: none"> • Tablets loaded with the intervention were given to the participants for the duration of the intervention. • Blood collection should be done by point-of-care to minimize burden to participants.

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