Feasibility of a Manualized Occupation-Based Diabetes Management Intervention

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OBJECTIVE. We investigated the feasibility and acceptability of an occupational therapy intervention targeting diabetes management for underserved young adults.

METHOD. Eight participants completed the intervention and a battery of assessments at baseline and after the intervention. At completion, the participants and occupational therapist were interviewed about their experiences with the study. Four categories of assessment questions were used to guide the study: process, resource, management, and scientific.

RESULTS. Successes included recruitment; fulfillment of tasks by staff and partnering clinics; adequate space, financial support, and equipment; and meaningfulness of the intervention for participants. Challenges included scheduling participants for the intervention and follow-up focus groups and providing client centeredness and flexibility while reducing burden on the intervener.

CONCLUSION. This feasibility study allowed us to make necessary revisions to our study protocol before implementing a larger pilot study.

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As few as 14% of new medical discoveries enter real-world contexts (Brownson, Kreuter, Arrington, & True, 2006), and these discoveries take an average of 17 years to move from research into real-world practice (Morris, Wooding, & Grant, 2011). A special issue of the *American Journal of Occupational Therapy* (Lin, 2013) provided recommendations to accelerate intervention research and dissemination; feasibility studies were highlighted as an essential step to ensure success in intervention research (Tickle-Degnen, 2013).

Feasibility studies aim to evaluate and refine research procedures in preparation for large-scale randomized controlled trials (Arain, Campbell, Cooper, & Lancaster, 2010; Tickle-Degnen, 2013). They are distinct from pilot studies in that they evaluate whether a given intervention is possible and practical to implement rather than what effect the intervention has on outcomes (Tickle-Degnen, 2013).

In keeping with this recommendation, in this article we report on a feasibility study of an occupational therapy intervention targeting diabetes management. The Resilient, Empowered, Active Living with Diabetes (REAL) intervention was developed using an iterative process to tailor the intervention framework, content, and structure to the needs of underserved young adults with type 1 or type 2 diabetes. Conceptualized as an adaptation of Lifestyle Redesign (Jackson, Carlson, Mandel, Zemke, & Clark, 1998), the REAL intervention consists of seven modules that focus on incorporating diabetes self-management tasks into everyday routines. These modules are flexibly delivered in accordance with each individual's diabetes management goals, which are determined collaboratively by the client and therapist (for more details, see Pyatak, Carandang, & Davis, 2015).

A feasibility study was seen as a particularly important phase in this research

program because of its relative uniqueness with respect to both the targeted population and the focus of the intervention. Apart from interventions to support the transition between pediatric and adult health care systems (e.g., Spaic et al., 2013; Steinbeck et al., 2015), little research has examined interventions developed specifically to address the needs of young adults with diabetes. Additionally, few diabetes interventions have included occupational therapy as a disciplinary perspective in intervention development (Haltiwanger, 2012; Pyatak, 2011). Therefore, our aim in this study was to determine the acceptability of the REAL intervention and research protocol among a typically hard-to-reach population.

Method

Design

We modeled our feasibility assessment after Tickle-Degnen's (2013) exemplar for how to adapt the framework presented in Thabane et al. (2010) to occupational therapy research. Thabane et al. proposed a framework of four categories of questions to evaluate in feasibility studies. First, *process assessment* includes an analysis of the appropriateness of eligibility criteria, assessment procedures, and participants' intervention adherence. Second, *resource assessment* examines the time, equipment, and space needed to carry out the study procedures. Third, *management assessment* evaluates the capacity of research staff to complete tasks as assigned in the study protocol. Finally, *scientific assessment* evaluates the dose, duration, treatment effect, and participant burden associated with the intervention. We evaluated these dimensions of feasibility using a mixed-methods approach that incorporated both process data collected in the course of conducting the study (e.g., recruitment and retention rates, participant safety, intervention adherence) and poststudy interviews with participants, the intervener, and research staff.

Recruitment

Within the process assessment, we monitored our ability to recruit and retain participants throughout the study duration. Eligibility

criteria for participants were as follows: (1) age 18–30 yr, (2) diagnosis of type 1 or type 2 diabetes for a minimum of 1 yr, (3) hemoglobin A1c (HbA1c; measure of average blood glucose) of $\geq 8\%$ (indicating poor diabetes control), and (4) not pregnant or planning to become pregnant. Participants were recruited using two strategies: (1) A graduate student worker recruited participants in person at a young adult diabetes clinic held weekly at a large urban county hospital, and (2) potentially eligible participants were identified from a medical chart review at the young adult clinic and invited to participate by telephone. The study was approved by the University of Southern California institutional review board (IRB), and all participants provided informed consent at the time of study enrollment.

Measures

Participants completed a demographic questionnaire, and their medical charts were reviewed to ascertain their medical history, current diabetes treatment regimen, and relevant comorbid conditions. An assessment battery was administered at enrollment and again immediately after completion of the intervention. This included HbA1c testing, using an Afinion point-of-care machine (Alere, Waltham, MA) which provides immediate results using a finger-prick blood test, as well as the following behavioral and psychosocial self-report measures:

- Diabetes self-care activities (Summary of Diabetes Self-Care Activities; Toobert, Hampson, & Glasgow, 2000)
- Diabetes-related quality of life (Audit of Diabetes-Dependent Quality of Life; Bradley et al., 1999)
- Diabetes distress (Problem Areas in Diabetes Scale; Welch, Jacobson, & Polonsky, 1997)
- Depressive symptoms (Patient Health Questionnaire–9; Kroenke, Spitzer, & Williams, 2001)
- Global life satisfaction (Satisfaction With Life Scale; Diener, Emmons, Larsen, & Griffin, 1985)
- Habit strength for checking blood glucose and taking diabetes medication (Self-Report Habit Index; Verplanken & Orbell, 2003)

- Diabetes problem-solving (Diabetes Problem-Solving Interview; Glasgow, Toobert, Barrera, & Strycker, 2004)
- Activity participation (Participation Objective, Participation Subjective; Wilkie et al., 2011)
- Diabetes self-efficacy (Diabetes Empowerment Scale–Short Form; Anderson, Fitzgerald, Gruppen, Funnell, & Oh, 2003)
- Diabetes knowledge (Diabetes Knowledge Questionnaire; Garcia, Villagomez, Brown, Kouzekanani, & Hanis, 2001).

As part of the process assessment, we monitored the completeness of assessments throughout data collection to evaluate the practicality and burden of data collection procedures and usability of outcome measures. In addition, participants were interviewed to provide feedback about their experiences at the conclusion of the study.

Intervention

The REAL intervention framework and process of intervention development are described elsewhere (Pyatak et al., 2015). Three staff members were involved in the implementation of the study: The principal investigator (PI; Elizabeth A. Pyatak) oversaw the study and performed administrative tasks, a bachelor's-level student recruited participants and conducted testing, and a licensed occupational therapist pursuing a clinical doctoral degree provided the intervention.

In brief, the occupational therapist and participant established diabetes-related goals in accordance with each participant's values and needs. The occupational therapist then provided customized, activity-based sessions based on four core intervention principles and seven modules of manualized intervention content. Before intervention delivery, the occupational therapist completed advanced training including 8 hr of diabetes-related continuing education and 12 hr of motivational interviewing training.

As part of the scientific assessment, the occupational therapist recorded detailed treatment notes and general notes regarding feasibility and acceptability of the intervention after each session using REDCap, a secure online data management system (Harris et al., 2009). To maintain

intervention fidelity and problem-solve emergent challenges, the occupational therapist had weekly meetings with the PI and had access to a social worker and endocrinologist for consultation as needed. The occupational therapist was interviewed at the end of the study to collect suggestions for improving the intervention and overall study procedures.

Results

Our findings are organized on the basis of the four categories of assessment conducted in a feasibility study: process, resources, management, and scientific (Thabane et al., 2010). A summary of findings is provided in Table 1.

Process Assessment

Our partnering hospital clinics reported that they followed approximately 90 patients who met eligibility criteria. Target recruitment was reached in 7 wk. Eight participants (age 22.1 ± 1.2 yr; 87.5% Hispanic–Latino; 75.0% with type 1 diabetes) completed baseline testing, and 7 completed follow-up testing. Testing sessions averaged 120 min, which we found to be too long to maintain the attention span of both tester and participant. Postintervention focus groups also proved challenging to implement; after several attempts to schedule focus group sessions, only 2 participants attended. Therefore, the remainder of participants completed individual interviews in their homes.

Two changes were incorporated during the recruitment process. First, a comorbidity exclusion criterion was added, because we found it necessary to exclude otherwise-eligible participants with conditions that the intervention was not sufficiently equipped to address (e.g., significant intellectual disabilities). Second, we learned that many of the patients with type 2 diabetes seen at our partnering clinic had been lost to follow-up. Thus, we submitted an IRB amendment to identify prospective participants with type 2 diabetes through medical chart review and recruit them by telephone.

In terms of retention, 1 participant was lost to follow-up after one intervention session and was unable to be reached for follow-up testing. The 7 remaining participants attended a median of 8 weekly occupational therapy

sessions each and completed follow-up testing. Treatment sessions ranged from 45 min to 120 min each, with initial evaluations averaging 89 min and subsequent sessions averaging 66 min.

Resources Assessment

Participants' study involvement lasted an average of 3 mo, including 8 days to complete baseline testing after participant enrollment and informed consent, 8 days to schedule the initial intervention session after baseline testing, 60 days of intervention, and 16 days to complete follow-up testing after being discharged from the intervention. The occupational therapist and tester used office and cellular telephones to contact participants; text messaging emerged as participants' preferred communication modality.

The study took place in two settings: (1) the PI's office space to conduct treatment planning, documentation, and store and analyze data and (2) community settings to conduct assessments and deliver the intervention. No issues in either location affected completion of the respective tasks. We experienced one issue with the Afinion HbA1c testing machine: Because of a delay in conducting follow-up testing with one participant, the test cartridges had expired, resulting in missing HbA1c data for this participant.

The study was conducted within an occupational therapy department at a research university, which provided access to technological and administrative support. Software and computer programs available for data management, qualitative and quantitative data analysis, and data storage compliant with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) were adequate. We also partnered with a local hospital clinic whose physicians fulfilled their commitments to assist with recruitment. Finally, the doctoral resident, study supplies, and PI's time and salary were supported through departmental financial support and grant funding from the university's Clinical and Translational Science Institute.

Management Assessment

The occupational therapist delivering the intervention experienced burden related to

participants' frequent requests to cancel or reschedule appointments, often at the last minute. Because the intervention had to be delivered within a short time frame, the therapist needed to remain flexible to accommodate participants' preferences, regardless of practical considerations such as driving time. The therapist further reported that the diabetes continuing education course was invaluable and felt that additional training surrounding psychosocial challenges specific to the target population would be beneficial.

All data were collected using paper forms and entered into REDCap for data management. Two separate databases were used, one for participants' contact information and therapist treatment notes and the other for deidentified medical information and survey responses. The online database had convenient and secure accessibility in both the office and the field. The therapist requested an additional narrative text box to document events not captured in previously designated response options.

Study procedures included a suicide assessment protocol that was used with one participant who revealed suicidal ideation to the occupational therapist during an intervention session and to the tester at follow-up testing. The therapist consulted with the social worker to develop a suicide risk assessment and continually monitor the client during the intervention. The tester appropriately followed the suicide assessment protocol during follow-up testing.

Scientific Assessment

There was a general consensus among participants that the intervention made a meaningful contribution to improving their diabetes management. There were no indications that the disclosure of suicidal ideation mentioned previously was related to the intervention, and no other adverse events were reported. Although the number of sessions was seen as adequate to address participants' self-identified diabetes management goals, both the participants and the therapist indicated that the intervention would benefit from delivery over a longer period of time and with greater flexibility regarding the timing and duration of sessions.

Table 1. Feasibility Assessment Results

Assessment Question (drawn from Thabane et al., 2010)	Successes	Challenges and Adaptations for a Future Trial
Process Assessment		
What is the expected recruitment rate when partnering with local clinics?	Expected recruitment rate was achieved within given time frame.	Incorporate recruitment strategies to identify young adults with type 2 diabetes.
Are the eligibility criteria clear enough to distinguish inclusion and exclusion for complex medical cases?	Eligibility criteria were clearly defined and appropriate for the target population.	Refine eligibility criteria to exclude participants with complex care needs beyond scope of intervention.
What are the expected adherence rates to the REAL intervention over a period of 6 mo?	7/8 participants completed target number of intervention sessions.	N/A; adherence rates were acceptable.
What are the expected retention and follow-up rates?	7/8 participants completed follow-up testing and qualitative interviews.	N/A; retention and follow-up rates were acceptable.
Do participants understand the questions in the chosen assessments? Are the number of questionnaires and duration of the testing session appropriate and without excess burden?	Participants understood and could respond appropriately to questions within the chosen assessments.	Use eight-question Patient Health Questionnaire-9 to avoid eliciting suicidality during testing sessions. Shorten assessment protocol. Use individual interviews rather than focus groups to elicit qualitative feedback.
Resource Assessment		
Do we have appropriate communication strategies in place to maintain contact with participants throughout the study?	Text messaging was best strategy to contact participants.	N/A; communication strategies were appropriate.
What are the expected time frames for recruitment, data collection, data cleaning, and data analysis?	Recruitment, data collection, data cleaning, and data analysis were completed in a reasonable time frame.	Allow additional time and staff to score Diabetes Problem-Solving Interview assessment (time consuming to score, but best assessment to measure construct).
Do we have the appropriate equipment and materials to conduct data collection and provide the intervention?	HbA1c testing equipment performed as expected.	Implement a system to monitor expiration dates and replace supplies as appropriate.
Are there any challenges in collaborating with other organizations and agencies?	University, clinics, and funding agencies fulfilled commitments.	N/A; collaborators were responsive.
Management Assessment		
Are the training requirements for the occupational therapist adequate to address participants' diabetes management needs?	Staff were adequately trained to complete responsibilities within time frame and budget.	Implement additional training specific to therapeutic techniques for target population.
Are the structure and format of the study database adequate to capture desired process and outcome data?	Computer software and physical space allowed for storage of confidential data.	Increase flexibility for therapist documentation (i.e., open-ended sections for narrative documentation). Explore use of electronic tools in place of paper forms to expedite data entry.
Are staff adequately trained in ethical procedures to ensure the protection of participants?	Staff conducted themselves in accordance with ethical principles.	N/A; research ethics training was sufficient.
Are there sufficient staff to carry out all functions of the research project?	Staffing (principal investigator, student worker, and occupational therapist) was sufficient to carry out all study functions.	N/A; staffing was sufficient.
Scientific Assessment		
Do intervention procedures minimize both participant burden and therapist burden?	Participant burden was nonexistent or minimal.	Implement communication and scheduling strategies to reduce therapist burden. Increase duration of overall intervention. Increase flexibility for timing and duration of therapy sessions.
Are the assessments and outcome measures meaningful to the target population?	Participants' feedback indicated meaningfulness of assessments.	N/A; measures were meaningful and appropriate.
Is there an appropriate safety protocol in place to address the physical and mental health concerns of participants?	No safety concerns were identified with intervention protocol; staff responded appropriately to a participant's disclosure of suicidal ideation.	Develop a full adverse-event protocol.
What can we learn about future effects on outcome measures in response to the intervention? Are there any variables (e.g., mediators, moderators) that should be included in a revised theoretical framework?	Changes in assessments were in the anticipated direction.	Feedback from the intervener and participants suggested mechanisms of change to incorporate in a revised theoretical framework.

Note. HbA1c = hemoglobin A1c; N/A = not applicable; REAL = Resilient, Empowered, Active Living with Diabetes intervention.

The primary outcome, HbA1c, was feasible to measure and meaningful to most participants. However, because participants received the intervention over an average of 60 days we could not detect changes in this outcome given that HbA1c measures average blood glucose levels over a 3-mo period. With respect to other outcomes, although the purpose of a feasibility study does not include evaluation of intervention effects, we found that participants' changes in behavioral and psychosocial outcomes were in the expected direction, with effect sizes (Cohen's *d* correcting for dependence among means) ranging from 0.20 (small effect) to 0.80 (large effect).

Discussion

In this feasibility study, we examined practical issues surrounding the implementation of a novel occupation-based diabetes management program and the intervention's applicability to real-world challenges faced by young adults with diabetes. Conducting a feasibility study allowed us to evaluate multiple aspects of our study protocol, confirming the appropriateness of some aspects of the study design and providing an opportunity to resolve unanticipated challenges related to the study protocol before implementation of a larger trial.

This stage in the research process was particularly critical given that previous studies targeting this population encountered significant feasibility challenges. For example, one study of a transition program for young adults with diabetes recruited only 26 participants, falling far short of its recruitment goal of 90 participants and limiting the researchers' ability to draw conclusions about the efficacy of the program (Steinbeck et al., 2015). Similarly, poor intervention attendance was a major limitation in an innovative mind-body group intervention, embedded in a larger transition intervention, pilot tested by our research group among young adults with diabetes; fewer than 50% of prospective participants attended more than one group session, and only 33% consistently attended the group (Weigensberg et al., 2014). Given the substantial challenges associated with providing intervention to this population,

the feasibility study was essential to determine whether a large-scale evaluation of the intervention would be possible and practical to implement.

Overall, the feasibility study revealed both successes and challenges in all aspects of study procedures. In our process assessment, we were successful in recruitment and retention but required adjustments to our eligibility criteria and data collection methods. In our resource assessment, we found that we had adequate time, space, and technology to complete the study as planned. In our management assessment, we found that we had adequate staff capacity to complete the study protocol but that therapist burden was higher than anticipated because of the instability of participants' schedules and the complexity of their psychosocial challenges. In our scientific assessment, we found that our assessments demonstrated utility to the participants and sensitivity to track change over time and that the participants agreed on the benefit of this intervention for their diabetes management and its potential relevance to similar peers. In a randomized pilot study of the intervention now under way (Pyatak et al., 2017), we have addressed many of these challenges, including refining our inclusion criteria, conducting individual interviews rather than focus groups at follow-up testing, and incorporating more supports for therapists (e.g., team coverage to address emergent client concerns, on-call consultation, greater scheduling flexibility) to minimize burden.

Implications for Occupational Therapy Practice

This study has the following implications for occupational therapy practice:

- Conducting a community-based intervention for diabetes management is feasible and acceptable for young adults with diabetes.
- Feasibility studies are a critical step in refining study design and intervention procedures before large-scale implementation, particularly in emerging practice areas.

Conclusion

Feedback from participants and the research team enabled us to evaluate our

study protocol and ensure its applicability to real-world settings. In conducting this study, we demonstrated the feasibility and acceptability of an individualized, community-based intervention for an at-risk population with significant unmet health care needs. The intervention was effective in addressing participants' diabetes care challenges and, with targeted protocol adjustments, is practical to implement on a larger scale in a randomized trial to evaluate the efficacy of the intervention. Thus, this study represents a promising approach for the field of occupational therapy to fill a gap in chronic disease management. ▲

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