Describing the protocol for a mixed methods randomized controlled trial: ADdressing Health literacy, bEliefs, adheRence and self-Efficacy (ADHERE) program to improve diabetes outcomes

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Background

- Improving medication adherence is one of the most effective approaches to improving the health outcomes of patients with diabetes.

- Enhancing diabetes medication adherence has occurred by improving diabetes-related knowledge, but behavior change often does not follow knowledge change.

- Two crucial factors that influence medication adherence for patients with type 2 diabetes are self-efficacy in medication use and beliefs in medicines/illness. Health literacy indirectly influences medication adherence via these psychosocial factors.

- A comprehensive intervention addressing patient psychosocial dispositions as well as considering health literacy may be a more effective strategy for improving diabetes medication adherence.

Objective

- To examine whether a patient-centered intervention augmenting usual care with a health literacy-psychosocial support (ADHERE) intervention will improve medication adherence for patients with diabetes, compared to usual care.

Methods

•Study Design
- Prospective longitudinal randomized controlled trial, conducted in two phases using an intervention mixed methods design (Figure 1)
- Participants will be randomized (Figure 2) to either usual care at the diabetes clinic (control group) or usual care augmented with a 6-session intervention (Table 1).

•Participants
- English-speaking, 18–80 years old, diagnosed with diabetes, prescribed at least one diabetes medication, low diabetes medication adherence, and have poor diabetes control.

Methods

Figure 1: An intervention mixed methods design to improve medication adherence among adults with diabetes using a health literacy / psychosocial support (ADHERE) intervention
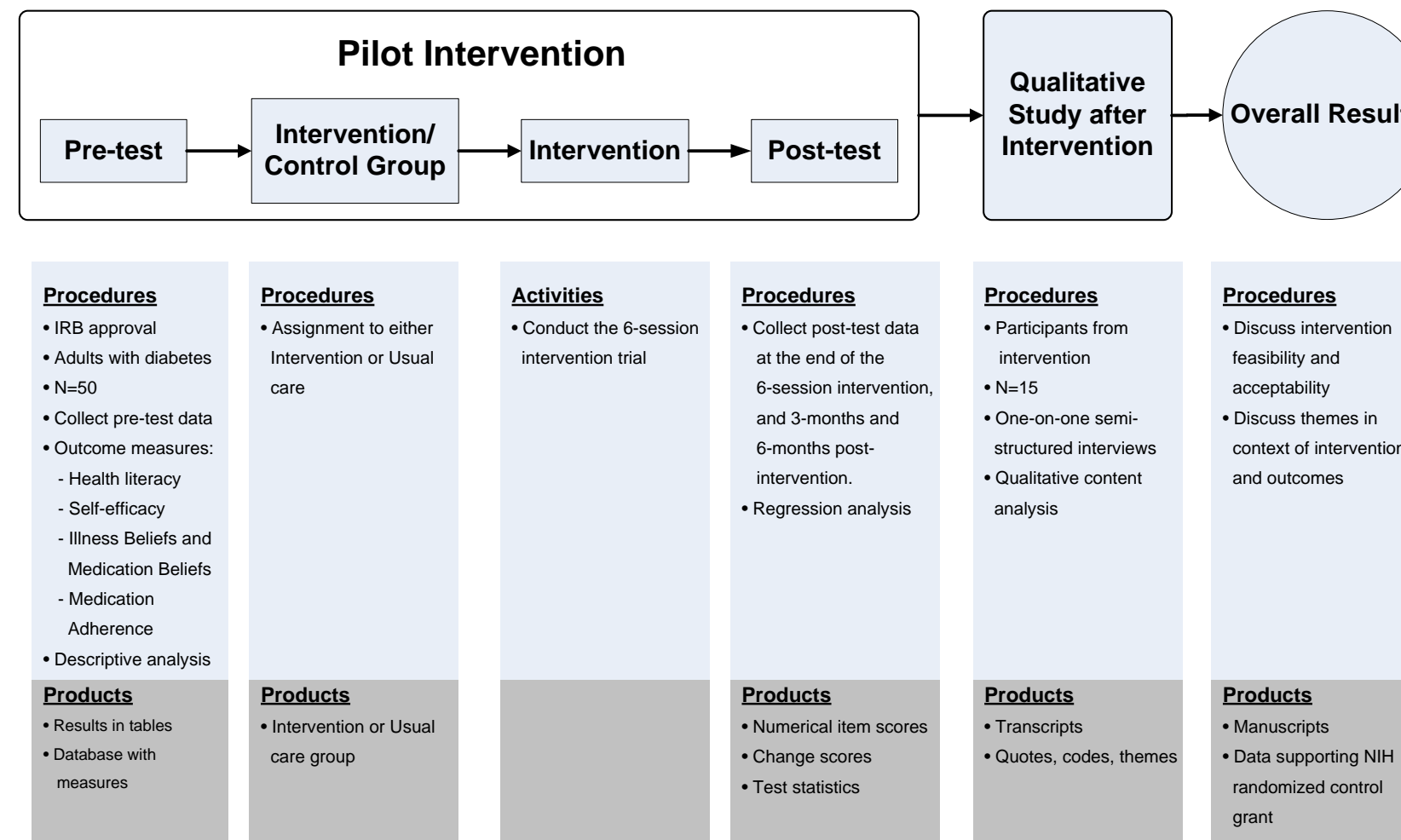

Table 1: Contents of the 6-session ADHERE intervention

Details of the intervention	
Session 1	Face-to-face: Discuss participants' self-management goals, self-efficacy and details of the intervention based on baseline evaluation of their psychosocial factors
Session 2-Session 5	Phone call follow-up: Reinforcement of participants' psychosocial factors to improve their medication adherence and self-management skills
Session 6	Face-to-face: Reexamination of participants' goals of diabetes management and psychosocial factors

Figure 2: The randomization process in the study
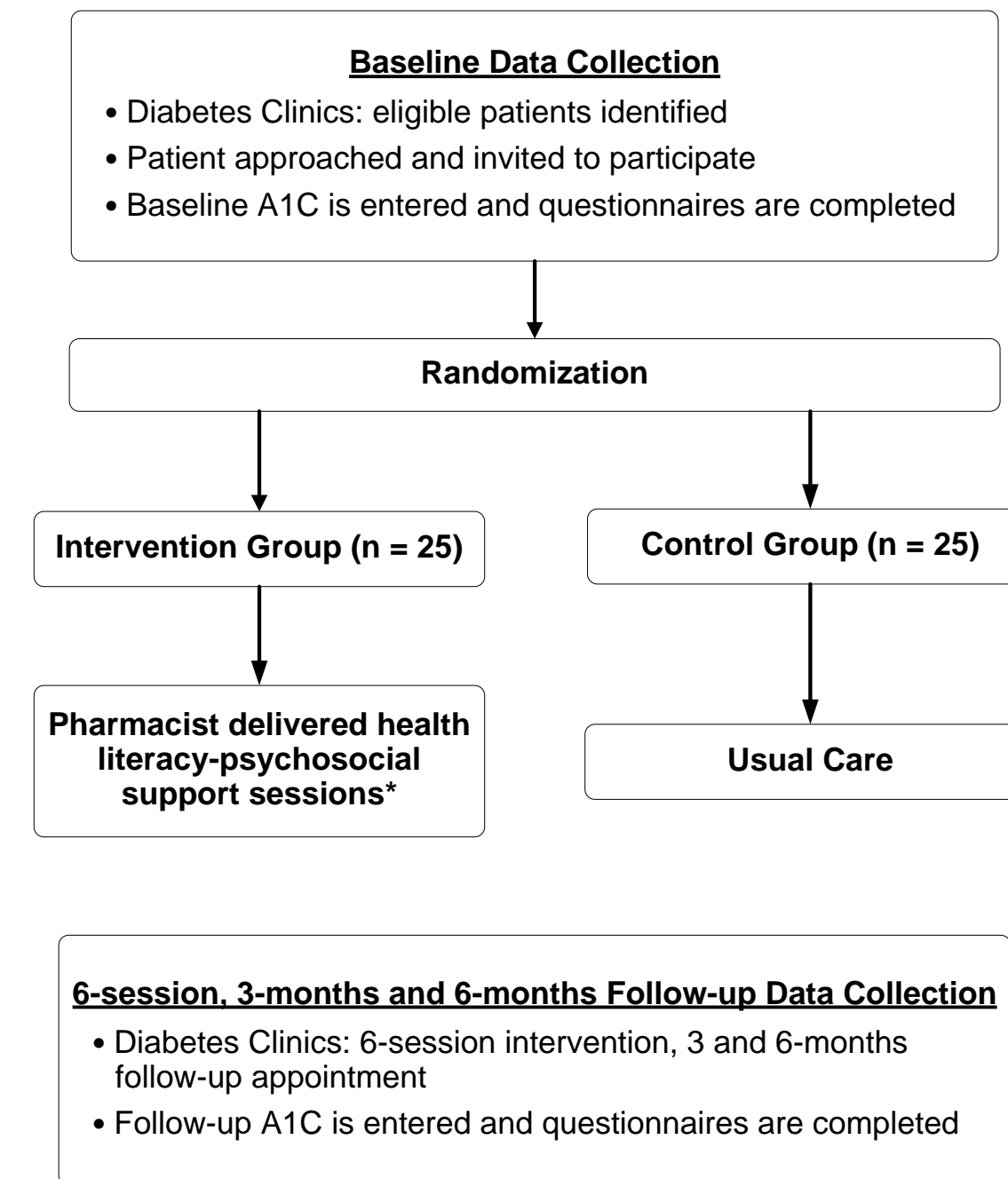
Discussion

- The first longitudinal randomized controlled trial which aims to improve participants medication adherence by addressing various psychosocial and health literacy factors simultaneously.
- The ADHERE intervention aims to improve the psychosocial support offered to patients by building self-efficacy and addressing negative beliefs about medicines and diabetes.

- The ADHERE trial should offer valuable insight on the effectiveness, acceptability, and sustainability of tailored health literacy-psychosocial support strategies to improve the medication adherence of patients with diabetes.