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Preliminary Results from a mixed methods randomized controlled trial: ADdressing Health literacy, bEliefs, adheRence and self-Efficacy (ADHERE) program to improve diabetes outcomes

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Introduction

- Improving medication adherence is one effective approach to improving health outcomes for patients with diabetes.[1]

- Enhanced adherence sometimes occurs by improving diabetes knowledge, but adherence behavior changes often does not follow increased knowledge.

- Health literacy indirectly influences adherence via self-efficacy in medication use and health beliefs in medicines and illness.[2]

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

Methods

Study Design
➢ Prospective longitudinal randomized controlled trial: participants randomized to usual care (control group) or usual care augmented with ADHERE intervention – pharmacist-provided tailored health literacy-psychosocial support based on barriers identified in patient survey and participant chosen domains for improvement (Fig. 1).

Participants
➢ English-speaking, 18–80 years old, clinical notes indicating low diabetes medication adherence and poor diabetes control (Hemoglobin A1c ≥ 8%).
➢ Enrollment goal is 50 participants -- 25 in each group

Data Collection
➢ Questionnaire administered at baseline and post-intervention to measure changes in participants' medication adherence and psychosocial factors (Table 1).

Data Analysis
➢ Descriptive statistics calculated for all participants (Table 2)
➢ Analysis focused on most frequently reported beliefs that negatively affect medication adherence (Fig. 2)
➢ Calculated differences in scores pre/post-intervention
➢ Applied Mann Whitney U test to difference scores to examine whether there was a significant difference between the control and intervention groups (Table 3).

Table 1: Questionnaire outcome measures

Outcome	Measure	Range	Higher scores indicate
Primary			
Medication Adherence	ARMS-D	11-44	better medication adherence
Secondary			
Necessity Beliefs about medicines	BMQ	5-25	stronger beliefs - necessity of glycemia medicines, current
Concern beliefs about medicines	BMQ	5-25	stronger concerns about glycemia medicines, current
Illness perception	BIPQ	0-80	more threatening view of diabetes

ARMS-D: Adherence to Refills and Medication Adherence, BMQ: Beliefs about Medicines Questionnaire, BIPQ: Brief Illness Perception Questionnaire

Results

Table 2: Baseline Demographic & Clinical Characteristics

	Control (n=11)	Intervention (n=9)	Total (n=20)
Age, yrs *mean (SD)*	58.1 (9.2)	55.9 (14.2)	57.1 (11.4)
Gender *% (n)*			
Male	100 (11)	100 (9)	100 (20)
Race *% (n)*			
White	91 (10)	89 (8)	90 (18)
Other	9 (1)	11 (1)	5 (1)
Diabetes diagnosis, yrs *mean (SD)*	17.8 (9.3)	12.1 (5.5)	15.3 (8.2)
Hemoglobin A1C *mean (SD)*	9.3 (1.1)	9.3 (1.8)	9.3 (1.4)
Diabetes Type *% (n)*			
Type 1	9 (1)	22 (2)	15 (3)
Type 2	91 (10)	78 (7)	85 (17)
Diabetes meds *mean (SD)*	2.6 (1.2)	2.8 (1.0)	2.7 (1.1)
Insulin use *% (n)*			
Yes	64 (7)	89 (8)	75 (15)
No	36 (4)	11 (1)	25 (5)

Figure 1. ADHERE Intervention Details

Session 1	**Face-to-face:** Discuss participants' self-management goals based on baseline survey of their psychosocial factors
Session 2-5	**Follow-up phone calls:** 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

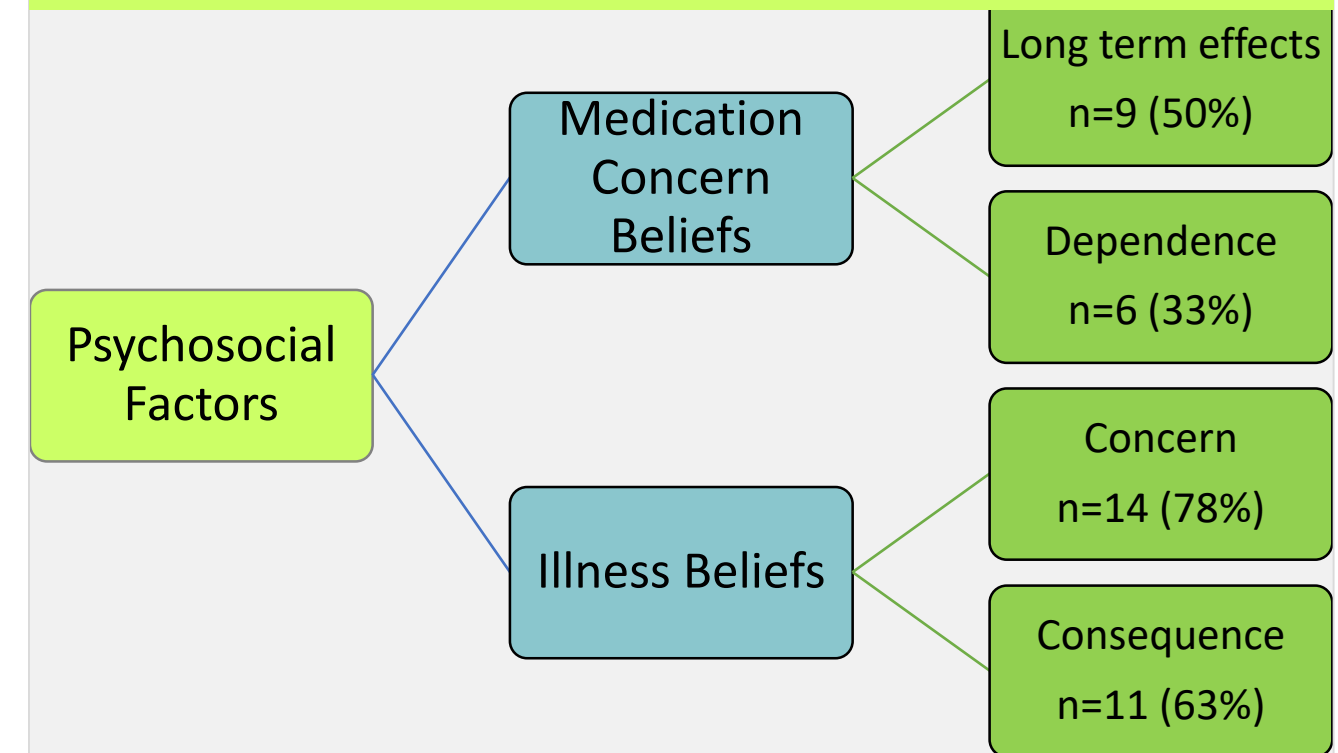### Figure 2. Most frequently reported negative medication and illness beliefs at baseline

Psychosocial Factors → Medication Concern Beliefs → Long term effects n=9 (50%); Dependence n=6 (33%)

Psychosocial Factors → Illness Beliefs → Concern n=14 (78%); Consequence n=11 (63%)

Table 3: Baseline and Post-Intervention Results for Selected Domains

	Baseline		Post Intervention Follow-up		Mann Whitney U-test
	Control (n=10)	Int. (n=8)	Control (n=10)	Int. (n=8)	n = 18
ARMS-D mean (sd)	17.4 (2.1)	16.3 (2.8)	--	--	--
HbA1C mean (sd)	9.5 (1.0)	9.3 (1.8)	9.5 (1.3)	9.0 (1.9)	U= 36 (p=0.762)
BMQ mean (sd)					
Concern beliefs	11.1 (4.8)	15.4 (4.6)	11.0 (5.8)	14.5 (2.8)	U= 28 (p=0.481)
long term effect of diabetes meds	2.6 (1.5)	3.0 (1.7)	2.6 (1.3)	3.8 (0.9)	U= 44 (p=0.481)
becoming dependent on diabetes meds	2.3 (1.3)	2.9 (1.0)	2.2 (1.3)	2.6 (0.7)	U= 23 (p=0.236)
BIPQ mean (sd)	45 (4.8)	43 (11)	40 (3.4)	43 (6.9)	U= 59 (p=0.101)
Consequence	7.7 (1.9)	6.5 (3.4)	6.3 (1.6)	6.0 (3.1)	U= 50 (p=0.408)
Concern	8.0 (1.8)	7.4 (3.3)	8.2 (1.8)	8.1 (1.7)	U= 36 (p=0.762)

Discussion

❖ ADHERE intervention aims to improve the psychosocial support offered to patients by building self-efficacy and addressing negative beliefs about medicines and diabetes.

❖ Downward trend in the mean A1c for the intervention group suggests improved diabetes control.

❖ Negative medication concern beliefs trending down for the intervention group, suggesting an improvement

❖ Illness belief about the effect of diabetes on participant's lives reported by over half of participants -- post intervention mean scores suggest an improvement in this belief

❖ Non-significant Mann Whitney U test results may have been due to our small sample size. This suggests there is no compelling evidence that the groups differ.

Future Activities

➢ Qualitative interviews with intervention participants about effectiveness, acceptability, and sustainability of ADHERE intervention.

➢ Future analyses of pharmacist patient session transcripts to identify the domain the participant choose to address.

References

1. R.K. Campbell, Recommendations for improving adherence to type 2 diabetes mellitus therapy-focus on optimizing insulin-based therapy, Am. J. Manag. Care 18 (3 Suppl) (2012) S55–S61.

2. Y.M. Huang, O.O. Shiyanbola, H.Y. Chan, A path model linking health literacy, medication self-efficacy, medication adherence, and glycemic control, Patient Educ. Counsel. 101 (11) (2018) 1906–1913.