

Supplementary Appendix

Emotional distress predicts reduced type 2 diabetes treatment adherence in the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) Study

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Supplementary Item 1. GRADE Research Group Listing

GRADE Research Group (April 30, 2021)

Designations: Principal Investigator (PI); Co-Principal Investigator (Co-PI); Co-Investigator (Co-I); Study Coordinator (SC); Recruitment/Retention Coordinator (RC); Research Staff (RS)

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Baylor College of Medicine: Balasubramanyam, A (PI); Gaba, R (Co-I); Gonzalez Hattery, E (SC); Ideozu, A (SC); Jimenez, J (SC); Montes, G (RC); Wright, C (RS, past)

Baylor Scott & White Research Institute (Baylor Research Institute): Hollander, P (PI); Roe, E (Co-I, past); Jackson, A (SC); Smiley, A (SC); Burt, P (SC, past); Estrada, L (RS); Chionh, K (RS, past)

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Columbia University Medical Center: Goland, R (PI); Pring, J (SC); Alfano, L (SC); Kringas, P (SC, past); Hausheer, C (RC, past); Tejada, J (RC, past); Gumpel, K (RS, past); Kirpitch, A (RS, past); Schneider, H (RS, past)

Duke University Medical Center: Green, JB (PI); AbouAssi, H (Co-I); Chatterjee, R (Co-I); Feinglos, MN (Co-I, past); English Jones, J (SC, RC); Khan, SA (SC, RC); Kimpel, JB (SC, past); Zimmer, RP (SC, past); Furst, M (RC, past); Satterwhite, BM (RS); Thacker, CR (RS); Evans Kreider, K (RS, past)

Indiana University: Mariash, CN (PI); Mather, KJ (PI, past); Ismail, HM (Co-I); Lteif, A (Co-I, past); Mullen, M (SC); Hamilton, T (SC, past); Patel, N (SC, past); Riera, G (RC); Jackson, M (RC, past); Pirics, V (RC, past); Aguillar, D (RS, past); Howard, D (RS, past); Hurt, S (RS, past)

International Diabetes Center: Bergenstal, R (PI); Carlson, A (Co-I); Martens, T (Co-I); Johnson, M (SC); Hill, R (SC); Hyatt, J (SC); Jensen, C (SC); Madden, M (SC); Martin, D (SC); Willis, H (SC); Konerza, W (RS); Yang, S (RS); Kleeberger, K (RS, past); Passi, R (RS, past)

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Miami VA Healthcare System/University of Miami: Garg, R (PI), Lagari-Libhaber, V (PI); Florez, HJ (PI, past); Valencia, WM (PI, past); Marks, J (Co-PI, past); Casula, S (Co-I); Oropesa-Gonzalez, L (SC); Hue, L (SC, past); Cuadot, A (SC, past); Nieto-Martinez, R (SC, past); Riccio Veliz, AK (SC, past); Gutt, M (RC, past); Kendal, YJ (RS, past); Veciana, B. (RS, past)

Oregon Health & Science University: Ahmann, A (PI); Aby-Daniel, D (Co-I); Joarder, F (Co-I); Morimoto, V (Co-I); Sprague, C (Co-I); Yamashita, D (Co-I); Cady, N (SC); Rivera-Eschright, N (SC); Kirchhoff, P (SC, past); Morales Gomez, B (RC); Adducci, J (RC, past); Goncharova, A (RC, past)

Pacific Health Research and Education Institute/VA Pacific Islands: Hox, SH (PI); Petrovitch, H (Co-PI); Matwichyna, M (SC); Jenkins, V (SC, past); Broadwater, L (RS); Ishii, RR (RS); Bermudez, NO (RS; past)

Pennington Biomedical Research Center: Hsia, DS (PI); Cefalu, WT (PI, past); Greenway, FL (Co-I); Waguespack, C (Co-I); King, E (SC); Fry, G (SC); Dragg, A (SC); Gildersleeve, B (SC); Arceneaux, J (SC); Haynes, N (SC, past); Thomassie, A (SC, past); Pavlionis, M (SC, past); Bourgeois, B (RC, past); Hazlett, C (RS)

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University of Alabama Birmingham: Garvey, WT (PI); Cherrington, AL (Co-PI); Dyer, D (SC); Lawson, MCR (SC); Griffith, O (SC, past); Agne, A (RC); McCullars, S (RC)

University of Cincinnati/Cincinnati VA Medical Center: Cohen, RM (PI); Craig, J (SC); Rogge, MC (SC, past); Burton, K (SC, past); Kersey, K (SC, RC, past); Wilson, C (SC, past); Lipp, S (RC, past); Vonder Meulen, MB (RC, past); Adkins, C (RS); Onadeko, T (RS)

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University of Iowa: Sivitz, WI (PI); Cline, E (SC); Knosp, LK (SC); McConnell, J (SC, past); Lowe, T (RC)

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Study Units

NIH/NIDDK (Sponsor): Cefalu, WT (Director, Division of Diabetes, Endocrinology and Metabolic Diseases); Fradkin, J (Director, Division of Diabetes, Endocrinology and Metabolic Diseases, past); Burch, HB (Project Scientist); Bremer, AA (Project Scientist, past)

Chairman's Office, Massachusetts General Hospital, Harvard Medical School: Nathan, DM (Study Chair, Study Co-PI)

Executive Committee: Nathan, DM (Study Chair, Study Co-PI); Lachin, JM (U01 Contact PI, Study Co-PI); Buse, JB (Co-I); Kahn, SE (Co-I); Krause-Steinrauf, H (Co-I, Project Director); Larkin, ME (Co-I, SC); Tiktin, M (Co-I, SC); Wexler, D (PI); Burch, HB (Program Scientist); Bremer, AA (Project Scientist, past)

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Economic Evaluation and Assessment Center:

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Centers for Disease Control and Prevention: Shao, H (RS); Zhang, P (RS)

Neurocognitive Coordinating Center, Columbia University Medical Center: Luchsinger, J (PI); Sanchez, D (SC); Assuras, S (RS)

QWB Reading Center, University of California San Diego Health Services Research Center: Groessl, E (PI); Sakha, F (SC); Chong, H (SC, past); Hillery, N (RS)

Collaborators

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Collaborating Investigators (Recruitment Sites): Abdouch, I (University of Nebraska Medical Center/Omaha VA); Bahtiyar, G (SUNY Downstate Medical Center); Brantley, P (Pennington Biomedical Research Center (LSU)); Broyles, FE (Swedish Medical Center); Canaris, G (University of Nebraska Medical Center/Omaha VA); Copeland, P (Massachusetts General Hospital); Craine, JJ

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Continuous Glucose Monitoring Sub-study: Higgins, J (Massachusetts General Hospital; Harvard Medical School)

Emotional Distress Sub-study: Golden, S (Johns Hopkins University); Gonzalez, J (Yeshiva University; Albert Einstein College of Medicine); Naik, A (Baylor College of Medicine); Walker, E (Albert Einstein College of Medicine)

National Diabetes Education Program (NDEP) Sub-study: Doner Lotenberg, L (Hager Sharp); Gallivan, JM (National Institutes of Health); Lim, J (Hager Sharp); Tuncer, DM (National Institutes of Health)

Recruitment Ancillary Study: Behringer-Massera, S (The Mount Sinai Hospital, Beth Israel Medical Center)

Table S1. Associations among baseline characteristics and medication adherence as a continuous variable.

	Estimates	p-value *
Age (years)	0.17	<0.0001
T2DM Duration (years)	0.18	0.0501
Sex (%)		
Female	-1.37	0.0157
Race/Ethnicity		
Non-Hispanic Black or African American vs. Hispanic	-0.99	0.2666
Non-Hispanic Other vs. Hispanic	0.72	0.5053
Non-Hispanic White vs. Hispanic	2.94	<0.0001
Education		
High school/GED or less vs. College/Graduate School	-1.54	0.0159
Some College vs. College/Graduate School	-0.94	0.1417
Income		
10-20k vs. <10k	2.24	0.1170
20-50k vs. <10k	0.77	0.5354
50k+ vs. <10k	3.66	0.0024
Living		
With another adult vs. Alone	0.45	0.5233
With children only vs. Alone	-4.08	0.0063
Employment		
Currently retired vs. Currently employed full or part-time	2.37	<0.0001
Other vs. Currently employed full or part-time	-0.97	0.1792
Smoking		
Past vs. Never	1.41	0.0148
Current vs. Never	-0.79	0.3409
BMI (kg/m ²)	-0.07	0.0674
Hypertension	2.13	0.0046
Any Diabetes Complications	0.64	0.2338
Macrovascular	1.01	0.3219
Diabetes Self-Management	0.37	<0.0001
Depression/Anxiety Medication	0.25	0.7202
HbA1c	-0.75	0.1723
DDS Average Score	-2.68	<0.0001
PHQ8 Total Score	-0.45	<0.0001
Treatment Satisfaction	1.00	0.0061
Specific Necessity	1.76	<0.0001
Specific Concerns	-2.54	<0.0001
Self Efficacy	-0.03	0.7149
Control of Diabetes	0.14	0.1911

* The bivariate linear regression estimates the medication adherence as continuous outcome at baseline as a function of the participant characteristics.

Table S2. Association of medication adherence with next-visit depression symptoms and diabetes distress

	Unadjusted		Adjusted	
	Estimates (95 % CI)	p-value*	Estimates (95 % CI)	p-value*
Depressive Symptoms				
PHQ-8 Total Score	-0.003 (-0.007, 0.001)	0.1700	-0.001 (-0.005, 0.003)	0.6666
PHQ-8 Somatic Score	-0.0003 (-0.0009, 0.0003)	0.3167	-0.00003 (-0.0006, 0.0005)	0.9192
PHQ-8 Cognitive-Affective Score	-0.0007 (-0.001, -0.0002)	0.0123	-0.001 (-0.001, 0.0001)	0.1093
Diabetes Distress				
DDS Average Score	-0.0009 (-0.002, -0.0001)	0.0191	-0.0001 (-0.0009, 0.0006)	0.7040
DDS Emotional Burden	-0.0004 (-0.001, 0.0005)	0.3664	0.0004 (-0.0005, 0.001)	0.3660
DDS Regimen Related Distress	-0.0027 (-0.004, -0.002)	<0.0001	-0.002 (-0.003, -0.0005)	0.0037
DDS Physician Related Distress	-0.0002 (-0.001, 0.0006)	0.6000	0.0003 (-0.0006, 0.001)	0.5458
DDS Interpersonal Distress	-0.0005 (-0.001, 0.0005)	0.3175	0.00004 (-0.0009, 0.001)	0.9311

PHQ-8= Patient Health Questionnaire assessing depressive symptoms; DDS=Diabetes Distress Scale

*The adjusted linear mixed effect model estimates the medication adherence at subsequent follow-up visit as a function of the emotional distress factors adjusting for age, sex, race/ethnicity, randomized treatment group, and longitudinal duration of T2DM, BMI and HbA1c.