SUPPLEMENTARY DATA

Life-Steps[1,2] Adherence Counseling Intervention

All participants had one session of "Life-Steps", a stand-alone cognitive behavioral therapy (CBT) intervention designed to improve adherence to medical recommendations and self-care goals, in this case, set by the dietitian and nurse. The counseling begins with a discussion of their illness, including cognitions related to illness and self-care behaviors. The discussion also involves a review of general struggles with adherence, how participants have coped with their illness, and general goal setting for self-care. It then consists of eleven informational, problem-solving, and cognitive-behavioral steps that target a range of self-care behaviors. In each step, patients and the clinician define the problem, generate alternative solutions, make decisions about the alternatives, and make a plan about how to implement solutions. The steps are

1. Provide education, interactively, about adherence
2. Plan for transportation to medical appointments
3. Plan for obtaining medications or other self-care items
4. Plan for optimizing communication with medical and mental health care providers
5. Plan for coping with side-effects of medications and medical regimens
6. Formulate a daily schedule for medications and other self-care behaviors (i.e. glucose monitoring for diabetes, exercise etc).
7. Plan for storing medications
8. Develop cues for taking medications or implementing other self-care procedures (i.e. glucose monitoring)
9. Prepare for adaptively coping with slips in adherence and preventing relapse
10. Review all new plans
11. Follow-up phone call (optional)

One important aspect of the intervention is to try to help patients change their cognitions about self-care behaviors in that we elicit positive reasons for being adherent (e.g. "I want to be healthy for my children") and actively think such thoughts when engaging in adherence behaviors instead of focusing on potential cognitive barriers (e.g. "This illness limits me", "Taking these medicines remind me that I am sick"). By the end of the session the therapist and participant collaboratively establish ways to implement the goals set by the nutritionist and the nurse for diet and self-care behaviors, including glucose monitoring.

Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD)

The core modules in CBT-AD are summarized briefly below, and a more detailed description of CBT-AD can be found elsewhere.[3,4] Although the modules are presented in a specific sequence, the treatment is designed to provide the clinician with the flexibility to adapt the treatment to the patient's needs. The number of sessions spent on each module is designed to be flexible as well, in order to address areas that are particularly salient to the patient or difficult for the patient to implement.

As reviewed above, the overall intervention is organized into a one-session intervention focused on adherence,[2] followed by four modules focused on adherence and depression (CBT-AD).[3,4] After Life-Steps, nine to eleven sessions of CBT-AD focus on addressing deficits in self-care and teaching specific cognitive behavioral skills to treat symptoms of depression. Each therapist determined whether the tenth and eleventh sessions were necessary on a case-by-case basis, depending on patient needs and the therapist's assessment of patient progress. At the beginning of each treatment session, the patient completed the CES-D and several adherence questionnaires, and the patient's glucometer and pill cap were read electronically. The therapist then addressed remaining / ongoing deficits in self-care and established new goals as necessary.

SUPPLEMENTARY DATA

The first module of the intervention (approximately one session) introduces the patient to the nature of cognitive behavioral therapy and transitions into motivational interviewing for behavior change. The motivational interviewing component involves going over the pros and cons of changing to improve depression and diabetes self-care, as well as the pros and cons of not changing. It then involves providing a rating of motivation, and then the participant is asked to justify the rating. This is designed to reduce ambivalence about change, and maximize thoughts about the pros of changing and the cons of not changing.

The second module (approximately one session) focuses on behavioral activation and activity scheduling with mood monitoring. Monitoring of blood glucose levels and tracking dietary and physical activity behaviors that influence glucose levels is another key component of this module. Behavioral activation/activity scheduling involves identifying activities that the patient enjoys or used to enjoy doing, and helping them re-learn how to re-engage in these types of activities.

The third module (approximately five sessions) focuses on thought monitoring and cognitive restructuring. Elicitation of maladaptive cognitions, identification of distortions, and training in cognitive restructuring target both thoughts relevant to depression and those relevant to diabetes treatment adherence and self-care. A common cognitive strategy used with all patients was to challenge patients' tendencies to engage in self-blame or avoidance in regard to glucose monitoring (e.g., 'my glucose values are always bad so I'd rather not know' or 'I don't want another reminder of how I've failed with my diabetes') and to restructure these cognitions toward an approach to self-monitoring that was based in curiosity and hypothesis-testing rather than judgments of good versus bad numbers. For example, patients are encouraged to think about what factors (e.g., diet, exercise, adherence to medications) might explain personal variations in glucose values rather than exclusively focusing on the fact that values were too high.

The fourth module (approximately two sessions) focuses on problem-solving as a skill to aid in the decision-making process. Problem-solving can be used to address any remaining issues related to depression and self-care behaviors that have not been resolved at this point. There are two components to problem-solving as a skill: 1) selection of a solution / action plan for a particular problem, and 2) breaking down that problem into manageable steps.

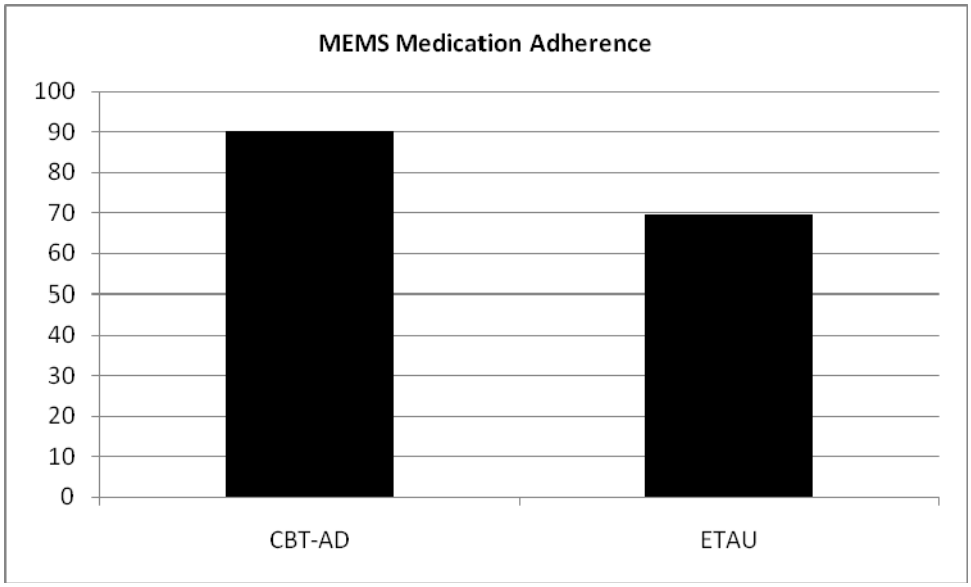
The fifth module (approximately two sessions) involves instruction in relaxation training, including diaphragmatic breathing and progressive muscle relaxation.

SUPPLEMENTARY DATA

Supplementary Table 1. Raw mean scores for all time points

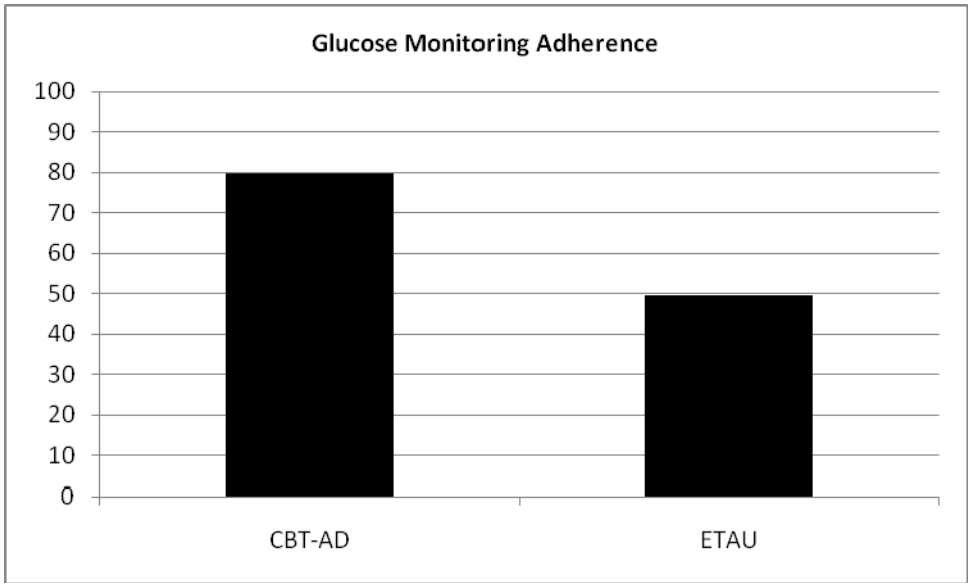
	Baseline		Month 4		Month 8		Month 12	
	CBT-AD	**ETAU**	**CBT-AD**	**ETAU**	**CBT-AD**	**ETAU**	**CBT-AD**	**ETAU**
MEMS	78.57 (23.69)	85.56 (25.86)	92.03 (9.13)	74.17 (28.59)	80.41 (24.61)	74.62 (29.21)	89.43 (10.96)	62.48 (32.32)
Glucose Monitoring	54.26 (35.62)	67.07 (32.20)	79.03 (26.04)	52.05 (31.63)	66.18 (33.84)	42.62 (38.32)	65.96 (32.13)	51.82 (36.47)
MADRS†	25.60 (8.98)	23.31 (7.20)	14.82 (11.47)	20.03 (10.01)	16.42 (10.43)	17.00 (11.13)	14.03 (10.83)	15.67 (10.10)
CGI‡	4.42 (1.28)	3.98 (1.09)	2.53 (1.54)	3.08 (1.42)	2.64 (1.58)	2.75 (1.62)	2.24 (1.46)	2.77 (1.45)
HbA1C§	8.81 (73 mmol/mol) (1.77)	8.73 (72 mmol/mol) (1.40)	7.75 (61 mmol/mol) (1.25)	8.57 (70 mmol/mol) (1.58)	7.87 (63 mmol/mol) (1.28)	8.41 (68 mmol/mol) (1.49)	7.97 (64 mmol/mol) (1.29)	8.21 (66 mmol/mol) (1.21)

Supplementary Figure 1. Graphical Depiction of Adjusted Acute (4-month) Adherence Outcome Scores.



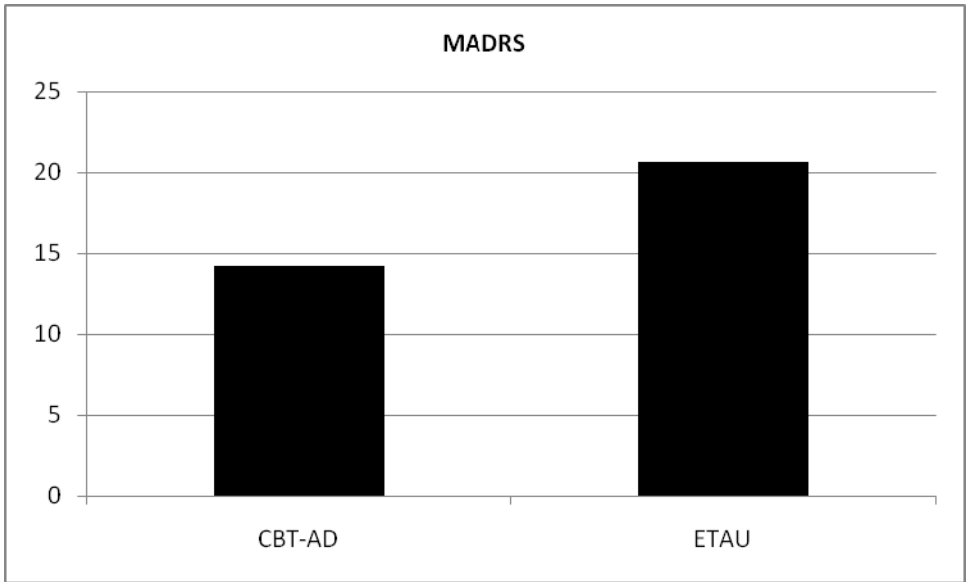
Significant effect for treatment condtion (p=.000) showing superiority of CBT-AD

SUPPLEMENTARY DATA



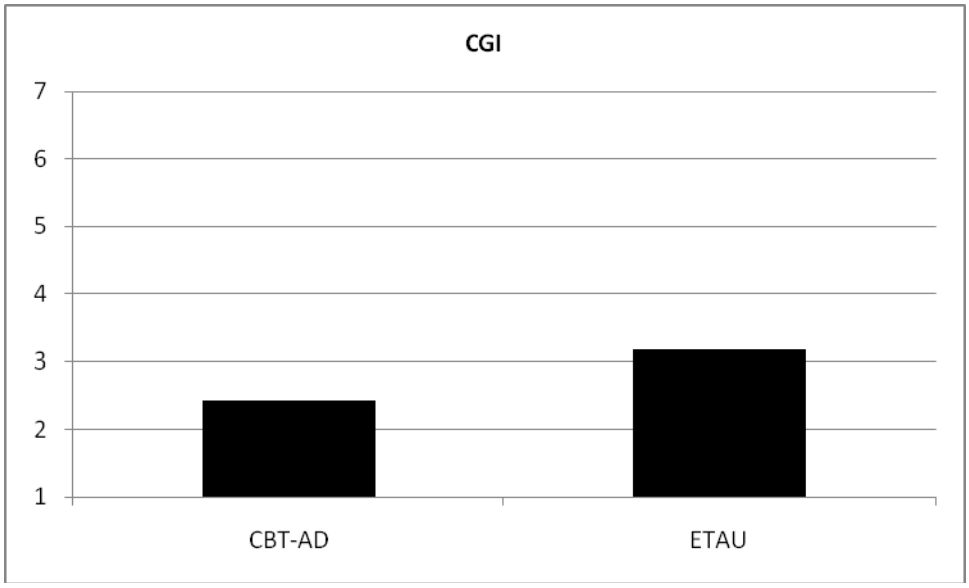
Significant effect for treatment condition (p<.0001) showing superiority of CBT-AD

Supplementary Figure 2. Graphical Depiction of Adjusted Acute (4-month) Depression Outcome Scores.



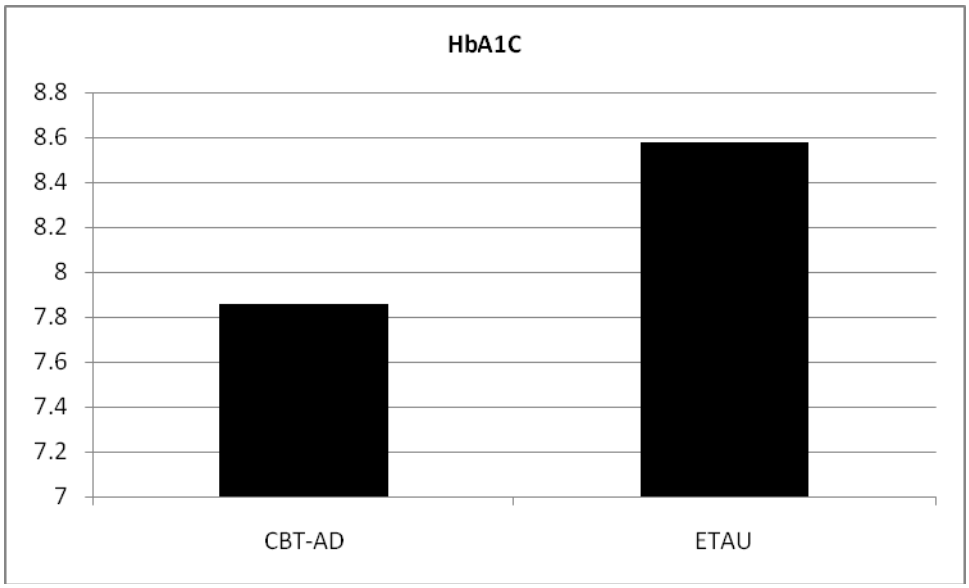
Significant effect for treatment condition (p=.002) showing superiority of CBT-AD

SUPPLEMENTARY DATA



Significant effect for treatment condition (p=.01)

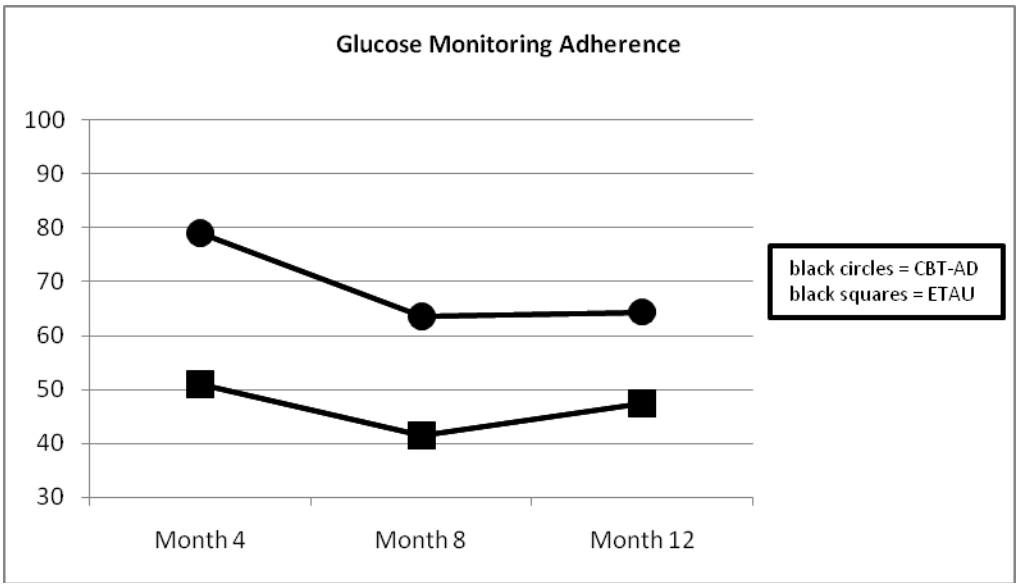
Supplementary Figure 3. Graphical Depiction of Adjusted Acute (4-month) HbA1c Outcomes.



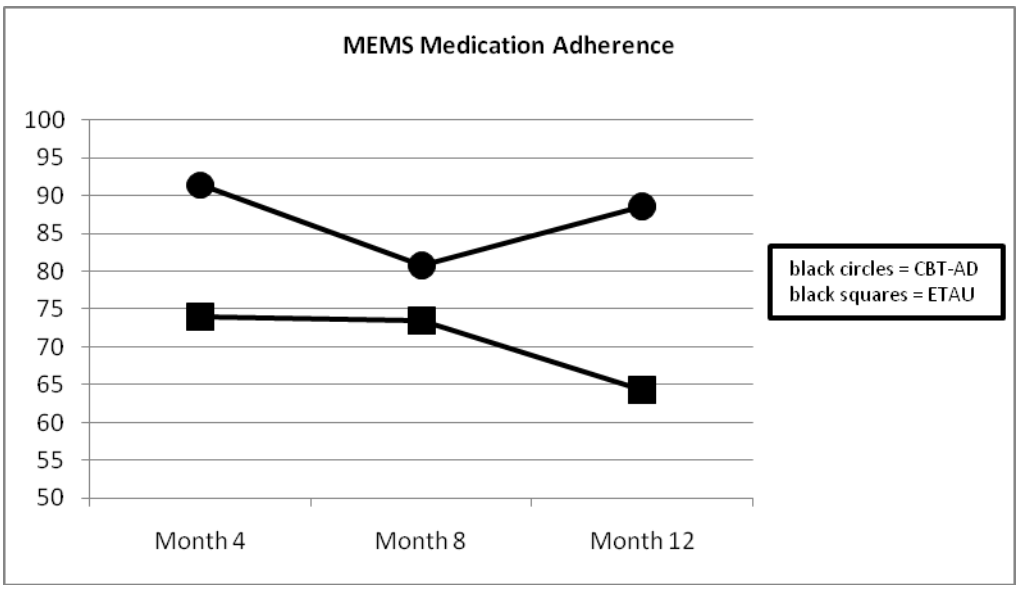
Significant effect for treatment condition (p=.001) showing superiority of CBT-AD

SUPPLEMENTARY DATA

Supplementary Figure 4. Graphical Depiction of Adjusted Follow-Up Adherence Outcome Scores.



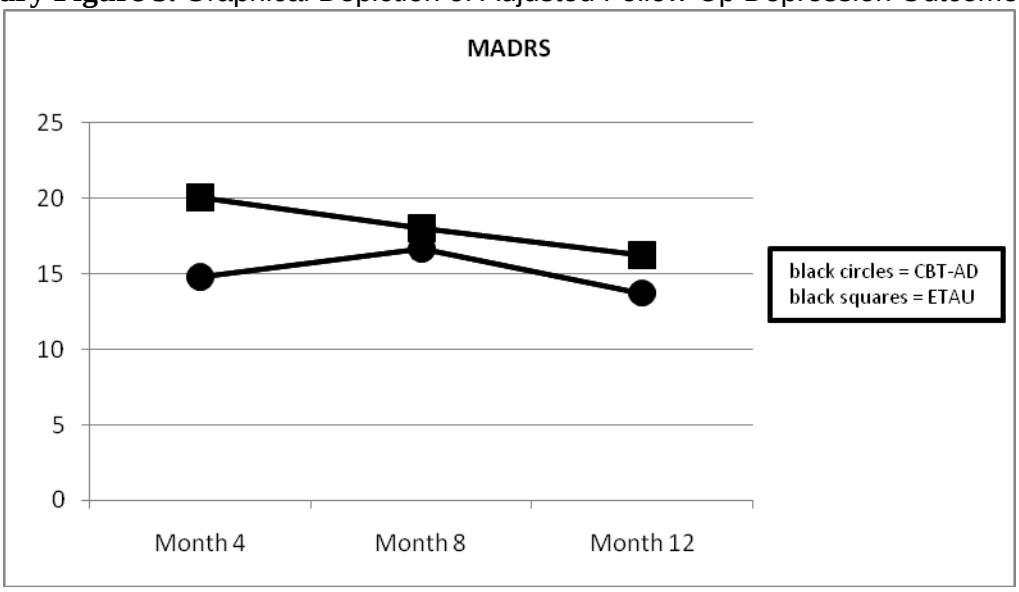
Main effect for treatment condition (p=.001) showing superiority of CBT-AD.
Main effect for time (p=.001) showing that month 8 (p=.001) and month 12 were lower than month 4.
Interaction of time x condition not signifcant.



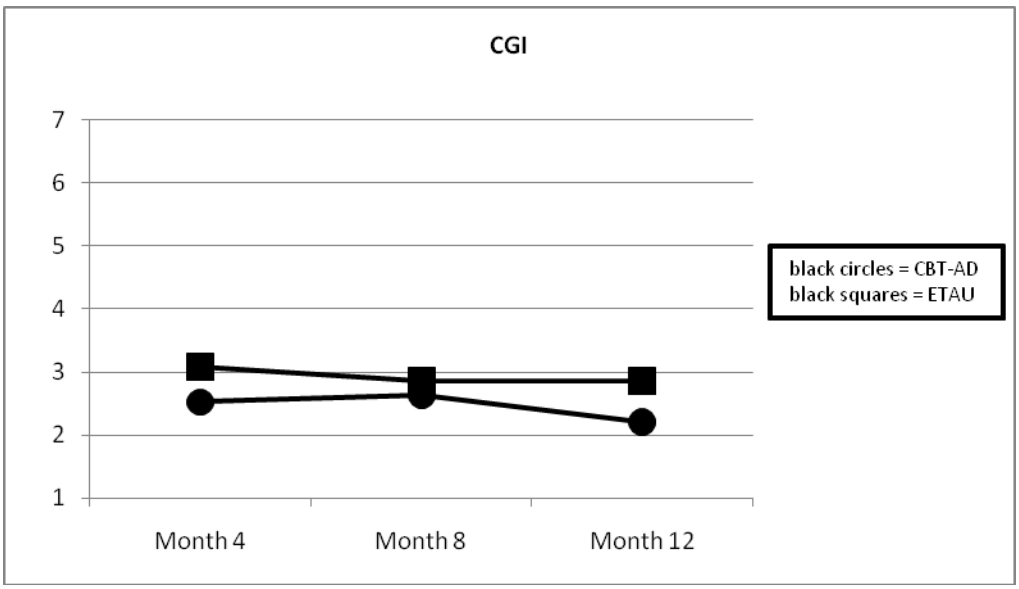
Main effect for treatment condition showing superiority of CBT-AD (p<=.001)
Main effect for time not significant showing that CBT-AD maintained their gains.
Interaction of time x condition not significant.

SUPPLEMENTARY DATA

Supplementary Figure 5. Graphical Depiction of Adjusted Follow-Up Depression Outcome Scores.



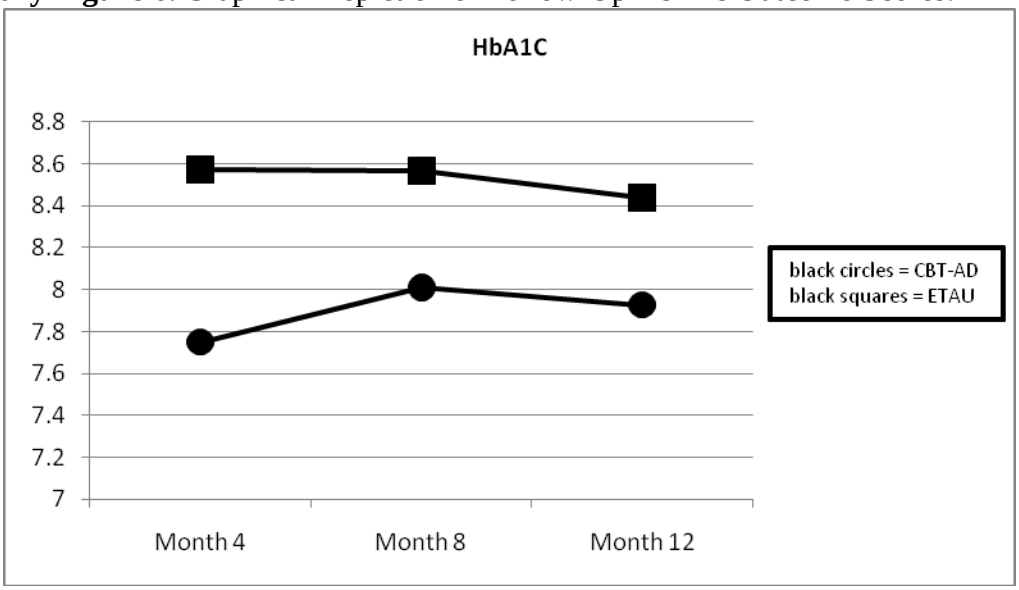
Main effect for study condition not significant.
Trend for continued improvement in both conditions (p=.06) with month 12 being lower than month 8 (p=.-03) and month 4 (p=.04).
Interaction not significant.



Main effect for study condition not significant
Main effect for time not significant (showing that CGI depression scores did not improve or decline during the follow-up period).
Interaction not significant.

SUPPLEMENTARY DATA

Supplementary Figure 6. Graphical Depiction of Follow-Up HbA1c Outcome Scores.



Main effect for treatment significant (p=.03) showing superiority of the CBT-AD condition.
Main effect for time not significant, showing that HbA1c values did not improve or worsen after the 4 month assessment.
Interaction not significant.

References

1. Safren SA, Otto MW, Worth JL. Life-steps: Applying cognitive behavioral therapy to HIV medication adherence. *Cogn Behav Pract*. 1999;6(4):332–341.
2. Safren SA, Otto MW, Worth JL, et al. Two strategies to increase adherence to HIV antiretroviral medication: life-steps and medication monitoring. *Behav Res Ther*. 2001;39(10):1151–1162.
3. Safren S, Gonzalez J, Soroudi N. *Coping with Chronic Illness: A Cognitive-Behavioral Approach for Adherence and Depression Therapist Guide*. 1st ed. New York, NY: Oxford University Press; 2007.
4. Safren S, Gonzalez J, Soroudi N. *Coping with Chronic Illness: A Cognitive-Behavioral Therapy Approach for Adherence and Depression*. 1 Workbook ed. New York, NY: Oxford University Press; 2007.