

Integrated Management of Type 2 Diabetes Mellitus and Depression Treatment to Improve Medication Adherence: A Randomized Controlled Trial

BACKGROUND:

- There is a bidirectional association between diabetes and depression. Depression is a risk factor for diabetes, and diabetes increases the risk for depression. Depression contributes to poor medication adherence, dietary regimens, and glycemic control which ultimately decrease the quality of life.

OBJECTIVE

- To examine the effectiveness of integrated care management of type 2 diabetes and depression in comparison with the usual care patients receive in primary care practices on adherence with medications.

METHODS

- **Design:** Multiple site, randomized controlled parallel study; Duration: 3 months
- **Inclusion criteria:** 30 years old or older, diagnosis of type 2 diabetes with a current prescription for an oral hypoglycemic agent, and a current prescription for an antidepressant
- **Exclusion criteria:** if they were unable to give informed consent, cognitive impairment at baseline using the Mini-Mental State examination was less than 21, a resident of a care facility that provides medications on a schedule, and unwilling or inability to use the Medication Event Monitoring System (MEMs)
- **Outcome measures:** Adherence and clinical outcomes were measured. Clinical outcomes were measured as an A1c less than 7%, mean A1c change from baseline, PHQ-9 score less than 5, and mean PHQ-9 score change from baseline. Adherence was reported as greater than or equal to 80% adherence to the oral hypoglycemic and to the antidepressant.
- 182 patients randomized:
 - 88 patients received usual care
 - 94 patients received integrated care intervention that consisted of 3, 30 minute in person sessions and 2, 15 minute telephone-monitoring contacts. Patients received education on depression and type 2 diabetes, emphasizing the importance of controlling depression to manage diabetes, explanations for the rationale for antidepressants and hypoglycemic agents, assessment of side effects, assistance in their management and referrals, monitoring and response to life threatening symptoms, and assessment for progress.
- No power was reported in this study
- Data handling method was intent-to-treat

RESULTS

- All patients completed the study in the usual care group and 2 patients were lost to follow up in the integrated care intervention group
- Outcome measures:
 - Adherence outcomes: At 6 and 12 weeks there was a significant improvement in adherence to oral hypoglycemic and antidepressant agents between groups; $p < 0.001$
 - Clinical outcomes:
 - There was a significant difference in patients who achieved an A1c less than 7% between groups. The between group difference = 8.48 (95% CI 3.24 to 22.2; $p < 0.001$)

- There was a significant difference in patients who achieved a PHQ-9 score less than 5 between groups. The between group difference= 6.15 (2.93 to 12.92; $p < 0.001$)
- **Author's conclusion:** Brief intervention integrating treatment of type 2 diabetes and depression is successful in improving rates of adherence to oral hypoglycemic and antidepressant agents as well as greater glucose control and fewer depressive symptoms.

STRENGTHS

- Controlled randomized parallel study design was used to make groups equivalent
- Outcomes measured were appropriate for the objective of the study
- No conflicts of interest existed within the study
- Adherence was properly measured

LIMITATIONS

- Short study duration
- Hawthorne effect which is when patients, particularly in the usual care group for this study, may change their behavior simply because they are part of a study
- Inclusion criteria did not include a diagnosis for depression and should have contained more precise characteristics
- Integrated care managers were not health care professionals
- Study design did not account for other factors that could affect outcome measures such as diet and exercise
- The mean A1c and PHQ-9 scores were not very high before integrated care intervention was initiated
- The study did not report how many hypoglycemic and antidepressant agents the patients were actually taking
- Patients enrolled were all from the same area

CONCLUSION

Although the study showed integrated care intervention improves adherence, glucose control, and improves depression symptoms there were several limitations to consider. Patients' initial mean A1c was around 7.0 and 7.2 so therefore achieving an A1c less than 7% was not a difficult task. The same could be said for the PHQ-9 scores. Patients who have A1c's of 7.0-7.2% are more likely to be adherent to their medication than patients with an A1c of 10%, therefore adherence may have already been high in this study population. Integrated care intervention did show significant improvements but further research should be conducted to see the true effects.

- Future research:
 - Additional studies should be done that includes patients with a higher mean A1c and PHQ-9 score to determine the true benefit of integrated care intervention. This study should blind the patients to treatment vs. usual groups in order to eliminate the Hawthorne effect.

Reference: Bogner HR, Morales KH, de Vries HF, Cappola AR. (2012) Integrated Management of Type 2 Diabetes Mellitus and Depression Treatment to Improve Medication Adherence: A Randomized Controlled Trial. *Ann Fam Med* 2012; 10:15-22.

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