A Randomized Controlled Trial Comparing Motivational Interviewing in Education to Structured Diabetes Education in Teens with Type 1 Diabetes

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Short Title: Compare education and motivational interviewing.

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**Objective** - Compare motivational interviewing-based education (MI) and structured diabetes education (SDE) at improving hemoglobin A1c (HbA1c) and psychosocial measures in adolescents with type 1 diabetes.

**Research Design and Methods** - A 9-month randomized controlled trial comparing MI (n=21) to SDE (n=23). Interventions were at baseline (T0) and 3 months (T1) with HbA1c and psychosocial measures obtained at 6 months (T2), and 9 months (T3).

**Results** - Over the 6 months of follow-up, the SDE group had lower adjusted mean HbA1c value (least squares mean=10.31, SE=0.32) than the MI group (least squares mean=11.35, SE=0.34), \( p = .03, d = -0.66 \). There were no differences on any of the psychosocial measures.

**Conclusions** - SDE is effective at improving metabolic control in adolescents with type 1 diabetes. Diabetes educators were proficient in learning MI.
Adolescents with poorly-controlled type 1 diabetes represent a challenge. They report adequate knowledge of diabetes, yet have poor compliance with self-care activities [1]. They are difficult to engage, and often demonstrate poor self-awareness regarding the need for change [2].

RESEARCH DESIGN and METHODS
A 9-month randomized controlled trial at Children’s Medical Center Dallas compared the effectiveness of motivational interviewing-based education (MI) and structured diabetes education (SDE) in improving metabolic control and psychosocial outcomes in adolescents aged 12-18 years with type 1 diabetes for > 1 year and hemoglobin A1c (HbA1c) ≥ 9% on 2 consecutive visits. Written informed consent was obtained from the parents and assent from the subjects. The Institutional Review Board at UT Southwestern Medical Center approved this study, which began in August 2006 and ended in May 2008.

Participants were randomized to either the MI or SDE group based on a gender-stratified schedule. Diabetes educators performed the interventions. Patients’ physicians were blinded to the intervention.

Two intervention sessions were scheduled, the first (T0) at enrollment. Two phone follow-ups were scheduled one and two months later. The second session (T1) occurred 3-4 months after enrollment. A third education session was planned (T2) if HbA1c continued to be ≥ 9%.

Three diabetes educators were assigned to the MI arm and trained on motivational interviewing at a two-day workshop. Skills refreshers were done with a MI psychologist. MI manuals were created based on concepts described by Miller and Rollnick [3], journal articles [4], and guidance from the MI trainer and psychologist.

The remaining six educators were assigned to the SDE arm and did not receive additional training. Educators used a comprehensive checklist compiled using core content recommended by the American Diabetes Association (ADA) on medication, monitoring, acute complications and lifestyle [5].

All SDE and MI visits were taped. To ensure fidelity to MI strategies, all audiotapes were coded using the Motivational Interviewing Treatment Integrity 3.0 (MITI 3.0) Coding System [6]. The coder attended a 2-day workshop on MITI 3.0 and was blinded to the treatment groups.

Outcome Measures: Hemoglobin A1c (HbA1c, measured via DCA Vantage Analyzer) and psychosocial measures were collected at baseline, 3, 6, and 9 months (T3). The primary outcome variable was HbA1c over the 6 months of follow-up.

Psychosocial measures included the Center for Epidemiologic Studies Depression Scale (CES-D)[7], the Epidemiology of Diabetes Interventions and Complications Quality of Life Questionnaire (EDIC-QOL)[8], and the Summary of Diabetes Self-Care Activities [9].

Statistical Analysis: The mixed model procedures of PROC MIXED in SAS version 9.2 (SAS Institute, Inc., Cary, NC) were used for the primary analysis. The level of significance was set at α = .05.

Baseline values of HbA1c and each baseline psychological measure were included as covariates in the respective analyses. The main effect of Treatment Group and the Treatment Group × Time Period interaction effect were examined. Cohen’s d was interpreted as the effect size estimator for the between-subjects Treatment Group effect.
RESULTS

Twenty-six participants were randomized to the MI group and 28 to the SDE group. Six-month data (T2) were available on 21 and 23 patients in the MI and SDE groups, respectively (Table 1). Four patients each in the MI and SDE groups had a third education session at T2.

Treatment groups did not differ in baseline characteristics (Table 1.)

Metabolic Control: After adjusting for baseline HbA1c, the pattern of omnibus least squares (LS) mean HbA1c values differed between groups ($F = 4.84, df = 1, 42.1, p = .03$) over the 6 months of follow-up; the SDE group had lower HbA1c (LS mean=10.31, SE=0.32) than the MI group (LS mean=11.35, 0.34), $d = -0.66$ (medium effect size). No overall Time Period effect emerged ($F=0.33, df = 2, 34.8, p = .72$) and no treatment group × time interaction effect was found ($F = 0.20, df = 2, 34.8, p = .81$) (Table 1.)

Psychosocial Measures: After controlling for baseline, there were no differences between the groups on any psychosocial outcome, none of which improved in either group (Table 1.)

MITI 3.0: There were 21 subjects in MI and 22 in SDE groups with interpretable tapes and MITI scores. When 2 tapes were available for a subject, the average score was used. The groups differed on all indicators of fidelity to MI in the expected direction ($p < 0.001$, repeated measures ANOVA) (Table 1.)

CONCLUSIONS

Although we hypothesized that lack of motivation more than poor knowledge impedes good metabolic control, we found that one brief intervention followed by a short education session could decrease mean HbA1c levels by 1%. Subsequent sessions did not further impact the HbA1c and the positive effect was maintained at 9 months. We should have assessed knowledge of diabetes pre- and post-education to show that improved knowledge played a role in our results. However, we did find a higher amount of “given information” in the SDE group compared to the MI group by MITI scoring. The lack of efficacy of MI in our study is consistent with a recent trial in adult patients with poorly controlled Type 1 diabetes [10]. In contrast, MI improved both metabolic control and psychosocial measures over a 12-month period in teens with diabetes [11], but this study had more interventions over a longer period than ours.

This was a small study that detected a treatment effect in the direction opposite to that hypothesized. Perhaps the educators in the MI group were not proficient in MI compared to other studies [11-13], but the MITI demonstrated good fidelity of our intervention to MI principles.

In conclusion, brief motivational interviewing-based counseling with no pre-established level of educational content does not lead to improved metabolic control, whereas ongoing education is important for teens with poorly controlled diabetes. We did show that we could train diabetes educators in MI with adequate proficiency. Before translating research to clinical practice one should consider the considerable investment necessary to be proficient in MI. Future studies should compare structured diabetes education and SDE plus motivation in a multi-center setting for a longer follow-up period.

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Table 1. Baseline characteristics, HbA1c, psychosocial measures, and MITI 3.0

| Measure                     | MI Group (n = 21) | SDE Group (n = 23) | F (p value) |
|-----------------------------|------------------|--------------------|-------------|
| Age in Years M (SD)         | 15.3 (1.4)       | 15.6 (1.7)         |             |
| Years of Diabetes M (SD)    | 6.7 (3.4)        | 7.6 (4.7)          |             |
| Gender                      |                  |                    |             |
| Male (%)                    | 9 (43)           | 13 (56)            |             |
| Female (%)                  | 12 (57)          | 10 (44)            |             |
| Race                        |                  |                    |             |
| Caucasian (%)               | 13 (62)          | 17 (74)            |             |
| Other (%)                   | 8 (38)           | 6 (26)             |             |
| Insurance                   |                  |                    |             |
| Private (%)                 | 17 (81)          | 13 (57)            |             |
| CHIP/CHSCN (%)              | 2 (9.5)          | 4 (17)             |             |
| Medicaid (%)                | 2 (9.5)          | 6 (26)             |             |
| HbA1c %                     |                  |                    |             |
| T0 Unadjusted HbA1c         | 10.9 (0.4)       | 11.1 (0.3)         |             |
| T1 Adjusted HbA1c           | 11.3 (0.3)       | 10.4 (0.3)         |             |
| T2 Adjusted HbA1c           | 11.1 (0.4)       | 10.2 (0.4)         |             |
| T3 Adjusted HbA1c           | 11.7 (0.6)       | 10.3 (0.5)         |             |
| Omnibus effect over study * | 11.4 (0.3)       | 10.3 (0.3)         | 4.84 (0.03) |
| Measure                     | Sub-scales       |                    |             |  |
| EDIC-QOL †                  |                  |                    |             |  |
| Part A (Satisfaction)       | 2.22 (0.07)      | 2.27 (0.06)        | 0.23 (0.63) |
| Part B (Lifestyle)          | 2.03 (0.06)      | 2.04 (0.05)        | 0.02 (0.88) |
| Part C (Worry)              | 1.69 (0.12)      | 1.56 (0.11)        | 0.64 (0.43) |
| CES-D ‡                     | 1.72 (0.06)      | 1.65 (0.06)        | 0.75 (0.39) |
| Self-Care §                 | 4.49 (0.16)      | 4.57 (0.15)        | 0.17 (0.68) |
| MITI 3.0                    |                  |                    |             |  |
| Spirit ‖                    | 4 (0.4)          | 2.6 (0.5)          | < 0.001     |
| Given Information ¶         | 2.3 (1.8)        | 6.7 (2.8)          | < 0.001     |
| MI Adherence §              | 6.8 (3.3)        | 2.1 (1.4)          | < 0.001     |
| Non-MI Adherence **         | 2.9 (1.4)        | 5.8 (2.6)          | < 0.001     |
| Total Reflections ††        | 9.5 (3.7)        | 1.1 (1.1)          | < 0.001     |

Note. LS Mean = Least Squares Means are adjusted for each respective baseline measure; SE = Standard Error; F = F statistic was used to test for omnibus mean difference on each measure between the two treatment groups over 6 months of follow-up.

* Primary outcome variable, least squares means for HbA1c, adjusted for baseline over 6 months of follow-up.
† Lower number indicates higher quality of life.
‡ Lower number indicates less depressive symptoms.
§ Mean days out of 7 of adherence to self-care.
‖ Overall competence of the clinician in using MI based on a global rating scale of 1 to 5 where 1 is low spirit and 5 is high spirit. Fidelity to MI would correspond to higher scores on this variable. The score for beginning proficiency and competency are 3.5 and 4, respectively.
¶ Giving information, education, providing opinion without advising. Number is based on frequency of occurrences. Fidelity to MI would correspond to lower scores on this variable.
# Asking permission before giving advice, affirming, emphasizing control and supporting the participant. Number is based on frequency of occurrences. Fidelity to MI would correspond to higher scores on this variable.
** Advising without permission, confronting, and directing the participant. Number is based on frequency of occurrences. Fidelity to MI would correspond to lower scores on this variable.
†† Reflections made by the clinician to comments made by the participant. Number is based on frequency of occurrences. Fidelity to MI would correspond to higher scores on this variable.