medLong-Term Maintenance of Treatment Outcomes: “Diabetes Personal Trainer” Intervention for Youth with Type 1 Diabetes

Running Title: Maintenance of Treatment Outcomes

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Clinical Trials Registry No. NCT00340093, clinicaltrials.gov


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Objective: This manuscript describes two-year follow-up hemoglobin A1c (HbA1c) outcomes of a self-regulation intervention for youth with type 1 diabetes.

Research Design & Methods: Eighty-one youths with type 1 diabetes ages 11 to 16 were randomized to usual care versus a “diabetes personal trainer” intervention, consisting of six self-monitoring, goal setting, and problem solving sessions with trained non-professionals. HbA1c data were obtained from medical records two years post-intervention, and ANCOVA adjusting for age and baseline HbA1c was conducted.

Results: An overall intervention effect on HbA1c (8.93 control versus 8.43 intervention; F=8.24, p=0.005) and a significant intervention-by-age interaction (F=9.88, p=.002) were observed, indicating a greater effect among older than younger youths. Subgroup analyses demonstrated no treatment-group difference among pre/early adolescents, but a significant difference in HbA1c among middle adolescents (9.61 control versus 8.46 intervention; F=7.20, p=.011).

Conclusions: Findings indicate maintenance of intervention effects on HbA1c observed at one-year follow-up.
Effective behavioral programs designed to counter the deterioration in glycemic control that typically accompanies adolescence (1) could contribute substantially to improving diabetes management in this population, with the potential of impacting long-term management trajectories and health outcomes (2,3). The objective of this study was to assess two-year HbA1c outcomes of a self-regulation intervention for youth with type 1 diabetes delivered by non-professionals. Short-term and one-year outcomes have been reported previously; these showed a significant HbA1c effect and a treatment by age interaction, indicating a greater intervention effect among older than younger youths (4). The current analyses assessed whether these effects were maintained at two-year follow-up.

**RESEARCH DESIGN AND METHODS**

The study design and methods have been reported previously (4). Youth ages 11 to 16 diagnosed with type 1 diabetes for at least one year and having no other major chronic illness or psychiatric diagnosis were recruited during routine visits at two pediatric endocrinology clinics serving a multi-state area with urban, suburban, and rural populations. Of 113 eligible youth, 81 (72%) consented to participate. Data were collected by medical record review and in-home assessments with youth and parent. Random assignment was stratified by age (11 to 13 vs. 14 to 16) and HbA1c (<8.0 vs. ≥8.0), for a total of four strata. The study protocol was approved by the National Institute of Child Health and Human Development Institutional Review Board (IRB), and the Western IRB (for participating clinical sites).

The intervention consisted of six in-person semi-structured sessions, supplemented with telephone calls, conducted over approximately two months by trained non-professionals (4). The approach was guided by principles of motivational interviewing, applied behavior analysis, and problem-solving. Youth were assisted to identify areas of diabetes management difficulty and use a structured problem-solving process to improve these areas. The intervention approach was primarily youth-focused, but encouraged youth to identify and communicate ways in which parents and family members could assist as part of the problem-solving process.

HbA1c was assessed as per standard care protocol at the clinics, and data were extracted from medical records. All analyses control for baseline HbA1c. Descriptive analyses were conducted with the change in HbA1c from baseline to each follow-up period in the total sample and in each age subgroup. To determine whether the intervention effect differed across follow-up periods, a repeated measures ANOVA was conducted, and the interaction of group by follow-up tested. To assess for between-group differences at two-year follow-up, analysis of covariance (ANCOVA) was conducted, with baseline HbA1c and age included as covariates. An interaction term (group by age) was added to the model to test whether effects differed by age. If a significant interaction was found, stratified analyses were conducted, with separate models run for youths ages 11 to 13 and 14 to 16.

**RESULTS**

The baseline sample characteristics were as follows: mean duration of diabetes 7.7 years, 63% used an insulin pump, 15% minorities, 80% two or more adults in the home, and 64% households with incomes $50,000 or greater. Forty-one subjects were assigned to educational control and 40 to intervention. There were no significant differences in demographic characteristics.
between groups. No subjects changed insulin delivery from injection to pump or vice versa during the study. HbA1c data were available for 78 participants (39 intervention, 39 control) at two-year follow-up.

From baseline to two-year follow-up, the control group showed a mean increase in HbA1c of 0.30, while the intervention group showed a mean decrease in HbA1c of 0.39. The difference between groups at two-year follow-up paralleled that of the previous follow-up periods (Figure 1). In early adolescents, the control group increased 0.04 from baseline, while the intervention group decreased 0.10. In middle adolescents, the control group increased 0.56 from baseline, while those in the intervention group decreased 0.74.

Repeated-measures ANOVA indicated a significant intervention effect (F=6.92, p=.01) and intervention by age interaction (F=7.71, p<.01). There was no group by follow-up interaction, indicating that the intervention effect did not differ across follow-up periods. Results of the ANCOVA, adjusting for age and baseline HbA1c, indicated an intervention effect on HbA1c (8.93 control versus 8.43 intervention; F=8.24, p=0.05) and a significant intervention-by-age interaction, indicating a greater effect among older than younger youths (F=9.88, p=.002). Stratified analyses run with pre/early adolescents (ages 11 to 13, n=40) and middle adolescents (ages 14 to 16, n=38) indicated a significant positive intervention effect for the latter only (HbA1c 9.61 control versus 8.46 intervention; F=7.20, p=.011).

CONCLUSIONS

Findings indicated maintenance of the intervention effect on HbA1c previously demonstrated at short-term and one-year follow-up (4), suggesting the utility of this behavioral self-regulation intervention for preventing the decline in blood sugar control that typically occurs during adolescence. As was observed previously, however, the intervention only impacted HbA1c among middle adolescents, and not among pre/early adolescents. These findings suggest that a youth-focused intervention that facilitates the development of self-management and problem solving skills and uses youth solicitation of parent involvement is an effective strategy for middle adolescents, who are beginning to achieve some autonomy in aspects of their diabetes management (5). However, an intervention design that collectively engages both parents and children may be more appropriate during pre or early adolescence.

The magnitude of difference in glycemic control between treatment groups among middle adolescents was substantial and clinically meaningful; maintenance of this effect could significantly reduce long-term complications of diabetes (6-8). The effect on HbA1c was comparable in size to that obtained in behavioral interventions of substantially greater intensity, such as that reported by Grey and colleagues at 12-month follow-up after 6 weekly plus 12 monthly sessions of coping skills training (9) and by Wysocki and colleagues at 6-month follow-up in response to 12 sessions of behavioral systems family therapy delivered by professional therapists over 6 months (10). Few behavioral interventions have reported two-year follow-up outcomes. Importantly, the degree of difference at two-year follow-up in this study was virtually identical to that at one-year follow-up, providing evidence that the effect of a behavioral intervention at this important developmental time could influence adolescent’s disease management trajectory (2,3).

ACKNOWLEDGEMENTS

Disclosure: This research was supported by the Intramural Research Program of the Eunice Kennedy Shriver
National Institute of Child Health and Human Development.
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Figure 1. Change in HbA1c from baseline to each follow-up period

Note: error bars included for groups demonstrating significant differences.