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Allison C. Sylvetsky
George Washington University

Randa Nandagopal

Tammy T. Nguyen

Marisa R. Abegg

Mahathi Nagarur

See next page for additional authors

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Authors
Allison C. Sylvetsky, Randa Nandagopal, Tammy T. Nguyen, Marisa R. Abegg, Mahathi Nagarur, Paul Kaplowitz, and Kristina I. Rother

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ORIGINAL ARTICLE

Randomized Clinical Trial

Buddy Study: Partners for better health in adolescents with type 2 diabetes

Allison C Sylvetsky, Radha Nandagopal, Tammy T Nguyen, Marisa R Abegg, Mahathi Nagarur, Paul Kaplowitz, Kristina I Rother

Allison C Sylvetsky, Radha Nandagopal, Tammy T Nguyen, Marisa R Abegg, Mahathi Nagarur, Kristina I Rother, Section on Pediatric Diabetes and Metabolism, NIDDK, National Institutes of Health, Bethesda, MD 20892, United States

Allison C Sylvetsky, Department of Exercise and Nutrition Sciences, the George Washington University, Washington, DC 20037, United States

Radha Nandagopal, Paul Kaplowitz, Division of Endocrinology, Children's National Medical Center, Washington, DC 20310, United States

Author contributions: Nandagopal R, Kaplowitz P and Rother KI designed this research; Nandagopal R, Nguyen TT and Abegg MR collected the data; Sylvetsky AC, Nagarur M and Rother KI analyzed and interpreted the data; Sylvetsky AC wrote the first draft of the article and all of the authors intellectually contributed to drafting, revising, and writing of the final manuscript; all authors approve of the submission of this manuscript.

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Informed consent statement: Informed written consent and assent (in individuals < 18 years of age) were obtained prior to enrollment.

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Correspondence to: Kristina I Rother, MD, MHSc, Section on Pediatric Diabetes and Metabolism, NIDDK, National Institutes of Health, 9000 Rockville Pike, Building 10, Room 8C432A, Bethesda, MD 20892, United States. kr58q@nih.gov
Telephone: +1-301-4354639
Fax: +1-301-4808277

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Abstract

AIM: To investigate whether assigning young, healthy and motivated lay volunteer partners ("buddies") to adolescents with type 2 diabetes improves hemoglobin A1c (HbA1c).

METHODS: Adolescents with type 2 diabetes were

randomized to partnering with a "buddy" or to conventional treatment. During the initial screening visit, which coincided with a routine outpatient diabetes clinic visit, patients with type 2 diabetes underwent a physical examination, detailed medical history, laboratory measurement of HbA1c, and completed two questionnaires (Pediatric Quality of Life Inventory and Children's Depression Inventory) to assess their overall quality of life and the presence of depressive symptoms. Patients were then randomized to the intervention (the buddy system) or conventional treatment (standard care). All patients were scheduled to return for follow-up at 3- and 6-mo after their initial visit. HbA1c was determined at all visits (*i.e.*, at screening and at the 3- and 6-mo follow-up visits) and quality of life and depressive symptoms were evaluated at the screening visit and were reassessed at the 6-mo visit.

RESULTS: Ten adolescents, recruited from a pool of approximately 200 adolescents, enrolled over a two-year time period, leading to premature termination of the study. In contrast, we easily recruited motivated lay volunteers. We found no change in HbA1c from the initial to the 6-mo visit in either group, yet our small sample size limited systematic assessment of this outcome. Participants repeatedly missed clinic appointments, failed to conduct self-glucose-monitoring and rarely brought their glucometers to clinic visits. Total quality of life scores (72.6 ± 6.06) at screening were similar to previously reported scores in adolescents with type 2 diabetes (75.7 ± 15.0) and lower than scores reported in normal-weight (81.2 ± 0.9), overweight (83.5 ± 1.8), and obese youths without diabetes (78.5 ± 1.8) or in adolescents with type 1 diabetes (80.5 ± 13.1). Among adolescents who returned for their 6-mo visit, there were no differences in total quality of life scores (70.2 ± 9.18) between screening and follow-up.

CONCLUSION: Our approach, effective in adults with type 2 diabetes, was unsuccessful among adolescents and emphasizes the need for innovative strategies for diabetes treatment in adolescent patients.

Key words: Diabetes mellitus type 2; Quality of life; Adolescent; Hemoglobin A1c; Social support

Core tip: Our manuscript details results and challenges during a simple psychosocial intervention trial where young, healthy and motivated lay volunteer partners ("buddies") were assigned to adolescents with type 2 diabetes. We experienced difficulty in the recruitment and retention of adolescent patients, which ultimately led to premature study termination. Despite our negative findings, our manuscript calls attention to the fact that psychosocial approaches shown to be effective in adults with type 2 diabetes may not translate in adolescent patients and conveys a unique and important message to other investigators who may wish to attempt similar interventions among adolescents with type 2 diabetes.

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INTRODUCTION

Type 2 diabetes in adolescence is generally associated with obesity, a positive family history of type 2 diabetes, and a low-income minority background[1,2]. Beta cell failure in adolescents progresses more rapidly than in adults and responds less to medical treatment as was shown in the recently completed TODAY trial (Treatment Options for Type 2 Diabetes in Adolescents and Youth)[3]. Because the progression of diabetes.... and ending with: Critical in this patient population. This trial is the only existing large-scale intervention study in youth with type 2 diabetes, which is in part due to difficult recruitment of these individuals[4]. Obesity related co-morbidities together with potentially long-lasting diabetes, dramatically increase the risk of macrovascular disease later in life. Microvascular complications including peripheral neuropathy and retinopathy have also been shown to occur, even at such a young age[5,6].

Guidelines from the American Academy of Pediatrics recommend that clinicians combine weight management counseling focused on improving diet, increasing physical activity, and reducing television and computer screen time along with metformin administration at the time of diabetes diagnosis[1]. It is well known, however, that adolescent patients[7,8] and those from low-income minority groups[8] often have difficulties in adhering to these recommended life-style changes and medical treatments. Even among adults who historically exhibit better compliance compared to adolescents, non-adherence is one of the most important barriers to successful treatment[9]. Psychosocial interventions in adults with type 2 diabetes have shown promise in increasing adherence to treatment[10-15] and/or improving hemoglobin A1c (HbA1c)[16-22]. For example, two interventions[16,17], in which adults with type 2 diabetes were paired with age- and gender- matched lay peer mentors (who also had diabetes), were effective in improving blood glucose control. Other interventions involving diabetes self-management education conducted in a group setting[18-21] have also led to better glycemia, while diabetes support delivered *via* online[23], telephone[10,14,22], or text messaging[15] programs has improved treatment adherence. Educational and psychosocial interventions have also been effective in improving both HbA1c and psychological health in adolescents with type 1 diabetes[24], yet to our knowledge, similar studies have not been conducted in adolescents with type 2 diabetes. The objectives of this study were to test whether a low-cost

intervention in which a young, healthy and motivated lay volunteer partner is assigned to an adolescent with type 2 diabetes, can improve HbA1c, adherence to treatment, and quality of life.

MATERIALS AND METHODS

Participants

Adolescents (aged 12-20 years) with type 2 diabetes received information about the "Buddy Study" from their pediatric endocrinologists during routine outpatient diabetes clinic visits at Children's National Medical Center (CNMC) in Washington, DC and at the National Institutes of Health Clinical Center (NIH CC) in Bethesda, MD. Whenever possible, interested patients and their caregivers also met with a trained research assistant to learn more about the study immediately after their clinic appointment. Recruitment occurred between January 2010 and November 2011. The diagnosis of type 2 diabetes was based on their primary physician's assessment[25]. For study inclusion, patients had to have a documented HbA1c $\geqslant$ 7% ($\geqslant$ 53 mmol/mol). Individuals were excluded if they had a significant comorbidity or psychological disorder that would interfere with their ability to participate (*e.g.*, a history of violent behavior, which could pose a risk to the lay volunteers), or if they were pregnant or planning to become pregnant within six months of the initial visit. Informed written consent and assent (in individuals < 18 years of age) were obtained prior to enrollment. The study protocol, consents and all study procedures were approved by the Institutional Review Boards at the CNMC and the NIH CC and were in accordance with the Declaration of Helsinki.

Lay volunteers, or "buddies", between 18 and 25 years of age were recruited from a pool of research assistants at the National Institutes of Health (NIH). Volunteers were screened and selected by the study physicians and were matched by gender with an adolescent patient. This was deemed necessary to facilitate the home visits. Further matching was not conducted (*e.g.*, by race, ethnicity, body mass index or education) for practical reasons due to the known demographic characteristics of the NIH research assistants. The lay volunteers did not have type 2 diabetes. All volunteers underwent standardized training and criminal background check in collaboration with the NIH Volunteer Services office and received specific training about the management of home visits from a NIH social worker.

Study design

The "Buddy Study" was a randomized, parallel-group study of six months duration conducted at CNMC in Washington, DC and the NIH CC in Bethesda, MD. The NIH CC depends on physician-referred or self-referred research participants while CNMC is a tertiary medical center in which approximately 120 youths with type 2 diabetes (new and established disease) are seen annually. During the initial screening visit, which coincided with a routine outpatient diabetes clinic visit, patients with type 2 diabetes underwent a physical examination, detailed medical history, laboratory measurement of HbA1c, and completed two questionnaires (Pediatric Quality of Life Inventory (PedsQL)[26] and Children's Depression Inventory (CDI)[27] to assess their overall quality of life and the presence of depressive symptoms. Patients were then randomized to the intervention (the buddy system) or conventional treatment (standard care). All patients were scheduled to return for follow-up at 3- and 6-mo after their initial visit. Participants received modest financial compensation for their time and inconvenience ($100).

The intervention arm (buddy group) was designed to receive weekly telephone calls from their assigned buddies and one home visit per month (lasting 30-60 min) to encourage "bonding" in a comfortable environment. Meetings between patients and buddies took place at locations of the patient's choice (preferably at their home), and contacts were made *via* phone, cell phone, and e-mail. Alternative buddy-patient meeting places included schools, coffee-shops, or libraries chosen by both parties at a mutually convenient time if home visits were declined by the participant or his/her family. Buddies were encouraged to not only ask the patient about diabetes management and provide telephone reminders for diabetes follow-up appointments, but also to discuss the patient's home and social life in order to promote a nurturing and motivating relationship. Buddies were strictly prohibited from providing medical advice and were told to contact the Principal Investigator should a need for medical advice arise. Details of the study procedures are shown in Figure 1.

Measures

The primary outcome was the effect of the intervention on hemoglobin A1c (HbA1c), which was measured using the Siemens-Bayer DCA 2000+. At all visits, HbA1c, height and weight were measured, and body mass index (BMI) was calculated. Change in HbA1c for the intervention arm (buddy group) *vs* the conventional treatment group was compared using the Student's *t*-test. Socio-demographic and clinically relevant information including self-reported race/ethnicity, family history of diabetes and patient medication use was also collected. All clinical information and laboratory data were compiled in the *eSphere* Clinical Trials Data Management System (Espirit Health, Chicago, IL).

Adolescents' quality of life and depressive symptoms were evaluated at the screening visit and were reassessed at the 6-mo visit using the PedsQL[26], a validated 23-item questionnaire to assess physical, emotional, social and school functioning and the CDI[27], a validated 27-item self-report measure designed to determine the extent and severity of depressive symptoms in children (cut-off for depression score $\geqslant$ 13), respectively.

RESULTS

Forty adolescents with type 2 diabetes were screened

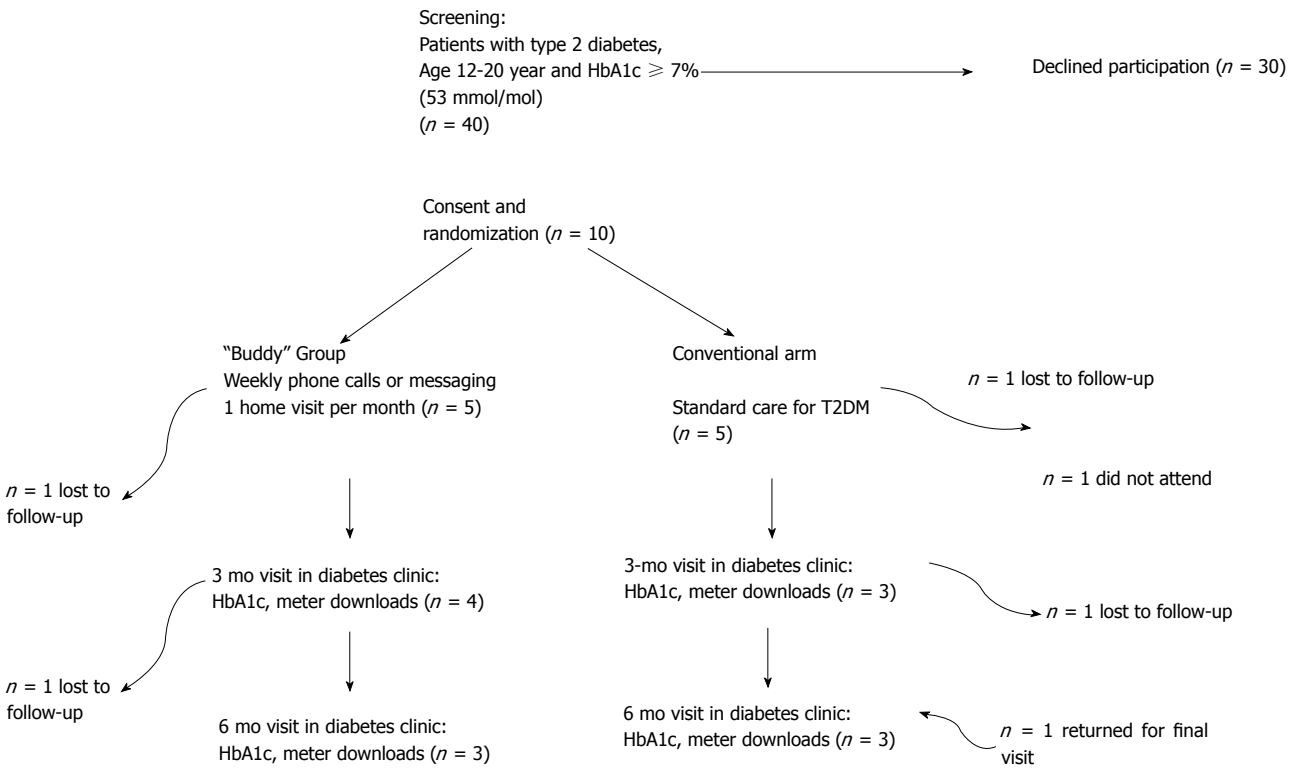

Figure 1 Forty adolescents with type 2 diabetes were screened and eligible for participation in the "Buddy Study". Ten adolescents were enrolled in the study, of whom five were randomized to the intervention arm and paired with a buddy. The remaining five adolescents were randomized to the standard care group and were not paired with a buddy. Five adolescents (three randomized to the buddy group and two to the conventional arm) returned to the clinic for both 3- and 6-mo follow-up visits and six adolescents completed the six month study. HbA1C: Hemoglobin A1C.

and eligible. As shown in Figure 1, ten adolescents were enrolled in the "Buddy Study", of whom five were randomized to the intervention arm and paired with a buddy. Five adolescents (three randomized to the buddy group and two to the conventional arm) returned to the clinic for both 3- and 6-mo follow-up visits. Baseline characteristics and a brief case description for each adolescent are shown in Table 1. The majority of our study participants were non-Hispanic Black, obese (mean BMI 37.0 ± 13.7 kg/m^2) and all but one had a positive family history for type 2 diabetes. The average age was 15.8 ± 2.0 years, diabetes duration 22.1 ± 20.4 mo, and the starting HbA1c was 10.6% ± 3.0% (92.4 mmol/mol) with all participants receiving metformin and four of ten receiving insulin. Diabetes and obesity related comorbidities were documented in 50%, but not all patients had undergone screening for retinopathy.

While early study termination prevented us from systematically assessing the primary outcome, HbA1c did not improve at 6 mo compared to screening in either group. Total quality of life scores (72.6 ± 6.06) at screening were similar to previously reported scores in adolescents with type 2 diabetes (75.7 ± 15.0)[28] and lower than scores reported in normal-weight (81.2 ± 0.9), overweight (83.5 ± 1.8), and obese youths without diabetes (78.5 ± 1.8)[29] or in adolescents with type 1 diabetes (80.5 ± 13.1)[28]. Among adolescents who returned for their 6-month visit, there were no differences in total quality of life scores (70.2 ± 9.18) between screening and follow-up. Using the CDI criteria for depression, three adolescents were depressed but none was suicidal at screening. No participant received treatment with antidepressants.

The average age of our lay volunteers (buddies) was 23.0 ± 0.71 years and four of the five volunteers were female, as adolescent patients and buddies were gender matched. The four female buddies all self-identified as non-Hispanic White, while the one male buddy self-identified as Asian.

DISCUSSION

In this study, we aimed to test whether a "buddy" intervention in adolescent patients with type 2 diabetes was effective in improving HbA1c, adherence to treatment, and quality of life. This particular approach has been shown to be promising in adults with type 2 diabetes and similar educational and psychosocial interventions have been successful in adolescents with type 1 diabetes[24], but has not been tested in adolescents[10,11].

Recruitment of adolescents with type 2 diabetes was difficult. Only ten adolescents, recruited from a pool of approximately 200 outpatients at CNMC, enrolled over a two-year time period, which led to premature termination of the study. In contrast, we easily recruited motivated lay volunteers. We found no change in HbA1c

Table 1 Socio-demographic characteristics and case descriptions of adolescents with type 2 diabetes mellitus in the Buddy Study

ID	Age (yr)	Diabetes duration (mo)	Sex	Ethnicity/race	Medications (hypoglycemic agents)	BMI (kg/m^2)	T2DM family history	Complications, comorbidities	Case description
1	14	22	Male	Non-hispanic black	Metformin, insulin	24.1	Yes	None	Control group. Poor medication and dietary compliance. Frequently consumed sugar-sweetened beverages and sneaked food late at night. Mother attributed behavior to depression and stress from a recent custody battle. Significant behavioral issues in school
2	19	42	Female	Non-hispanic white	Metformin	39.5	Yes	Pre-hypertension	Buddy group. Fairly compliant with oral medications but noncompliant with insulin administration or blood glucose monitoring. Improved dietary habits but not exercise
3	18	48	Male	Non-hispanic black	Metformin	39.5	Yes	Cataract	Control group. History of anorexia. Complicated relationship with food. Has developmental delay and is in special education classes at school. Motivated to change lifestyle. Poor compliance with medication and glucose monitoring
4	14	11	Female	Non-hispanic black	Metformin	42.9	Yes	Hypertension	Buddy group. Poor compliance with medication. Skipped breakfast and lunch. Snacked excessively after school and in the evening. Mother had limited ability to supervise because she was not often home
5	13	5	Female	Non-hispanic black	Metformin	71.5	Yes	Microalbuminuria	Control group. First seen in clinic for obesity at age 6, then lost to follow-up for 7 yr prior to entering study. Gained 109.4 kg during this period. Discontinued sodas and juices and signed up for an exercise class, however, was subsequently lost to follow-up
6	14	13	Female	Hispanic	Metformin	34.2	Yes	None	Buddy group. Unmotivated to initiate behavior change and non-compliant with medication and blood glucose monitoring. Unresponsive to communication attempts by assigned buddy. Did not report any exercise. No attempt to alter dietary habits. Lost to follow-up
7	16	3	Male	Asian/pacific islander	Metformin	32.7	Yes	None	Control group. Very motivated and successful at lifestyle modification. Reverted to poor diet and exercise following family emergency. Medications subsequently re-initiated but compliance remained poor
8	17	60	Female	Asian/pacific islander	Metformin, Insulin	24.7	Yes	None	Buddy group. Poor medication compliance. No exercise despite parental encouragement. Removed sugar-sweetened beverages from diet but struggled with portion control. Improved compliance with medication regimen following hospitalization
9	17	11	Male	Non-hispanic black	Metformin, Insulin	34.3	Yes	Microalbuminuria hypertension	Buddy group. Compliant with medication but not glucose monitoring or diet. Mother encouraged portion control with little success. Patient had developmental delay but appeared to understand importance of lifestyle modification and was motivated. However, lost to follow-up
10	16	6	Male	Non-hispanic black	Metformin, Insulin	26.8	No	None	Control group. Poor compliance with medication and blood glucose monitoring. Lost to follow-up
n = 10	15.8 ± 2.0	22.1 ± 20.4	50% F	60% Non-hispanic black	100% metformin 40% insulin	37.0 ± 13.7	90% yes	50% yes	

BMI: Body mass index; T2DM: Type 2 diabetes mellitus.

from the initial to the 6-mo visit in either group, yet our small sample size limited systematic assessment of this outcome. The early termination of the "Buddy Study" was particularly disappointing, as the scientific community supported the "Buddy Study" as an important and worthwhile trial. One team member (RN) was awarded the 2010 Endocrine Fellows Foundation Marilyn Fishman Grant for Diabetes Research for designing the protocol.

Furthermore, the study was promoted by the Scientific Director of the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK) as part of the "Healthy Moments" radio series[30]. Our experience may serve to caution other investigators in attempting to implement similar strategies for diabetes management among adolescents. It is possible that others have conducted but not reported such experience, because bias against submission and publication of negative study findings is problematic in the medical literature[31]. Our seemingly "unexciting" findings convey a unique message for other investigators[32].

Challenges in the recruitment of adolescents into clinical research protocols have been well described[4,33,34]. Similar to most adolescents, these youths with type 2 diabetes strive to fit in with peer norms and wish to conform to their perception of what is "normal", posing a barrier to participation in research studies[35]. Even in the TODAY trial, the largest and most resource-intensive randomized, controlled intervention trial to be conducted in adolescents with type 2 diabetes[36], recruitment was difficult and the projected recruitment period had to be extended by two years[37]. This emphasizes the need for improved recruitment strategies specifically targeting adolescents.

As reflected in our cohort, data from both TODAY and the "Search for Diabetes in Youth" (SEARCH) trials[37,38] have demonstrated that type 2 diabetes disproportionately affects youth from racial/ethnic minority groups. In addition to facing difficulties with recruitment of individuals from minority groups[39,40] and younger age groups[41] into chronic disease prevention and treatment programs, epidemiologic data suggest that poor blood glucose control is most prevalent among these subgroups[38]. In accordance with the emerging field of molecular pathological epidemiology (MPE)[42], complex diseases including type 2 diabetes may comprise various subtypes involving heterogeneous subpopulations. Because the etiology underlying type 2 diabetes is multifactorial, different disease subtypes may be associated with different biological, social, and environmental determinants and diverse natural histories. Thus, diabetes may progress at different rates and respond differently to interventions and treatments in certain individuals[43], as we observed in our study of adolescents with type 2 diabetes.

We observed low self-reported quality of life and frequent depressive symptoms, both of which are associated with exacerbated metabolic disturbance and poor glycemia control[44]. Given the high rates of treatment failure on metformin among adolescents[36], the implementation of a buddy system to encourage and sustain lifestyle changes and improve psychosocial health was a seemingly hopeful undertaking. However, even the best-designed programs cannot be effective if adolescents do not participate[45] nor can they be successful if adolescents who do participate are not compliant with medications and study requirements. This is exemplified by the high frequency of missed clinic appointments, continued failure to conduct self-glucose monitoring, and widespread non-compliance with medication and lifestyle recommendations. Of note, the "Buddy Study" was designed to place the burden and inconvenience of study participation on the research team rather than on the study participants (*e.g.*, meetings between patients and buddies took place at locations of the patient's choice, and contacts were made *via* phone, cell phone, and e-mail).

Several modifications to our study may have facilitated improved enrollment and/or enhanced compliance with treatment recommendations. First, pairing adolescents with peer volunteers who themselves have type 2 diabetes[16] and had successfully improved their glycemia[46] or with lay volunteers of the same race/ethnicity and/or socio-economic status[46] may have been more effective in building trust between adolescents and their buddies[47] and generating interest in study participation. Approaching adolescents at the time of their diabetes diagnosis may also have been helpful, as early intervention has shown promise in chronic disease management[48]. Future efforts to raise adolescent understanding of the physiology of type 2 diabetes may also be worthwhile in enhancing participation[49].

Another hurdle is the limited time a practicing physician can afford to spend on clinical trial recruitment. In our study, several patients were not informed about the study by the treating physician because the medical, psychological and/or psychosocial situation was so complicated that no further topics could be discussed in the short time of the clinic visit. Though we attempted to have a research assistant present at all times, logistically this was not feasible.

In summary, our study provides insight into the difficulties of translating an intervention effective in adults with type 2 diabetes into a successful approach in adolescents with the same condition. The challenges faced during the "Buddy Study" may serve as a caution to other investigators attempting to implement similar strategies for diabetes management among adolescents. Our findings emphasize the urgent need for improved recruitment strategies specifically targeting adolescents.

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COMMENTS

Background

Type 2 diabetes in adolescence is generally associated with obesity, a positive family history of type 2 diabetes, and a low-income minority background. Obesity related co-morbidities together with long-lasting diabetes dramatically

increase the risk of micro-and macro-vascular complications at a young age.

Research frontiers

Psychosocial interventions in adults with type 2 diabetes and in youth with type 1 diabetes have shown promise in increasing adherence to treatment, improving psychological health in adolescents with type 1 diabetes, and/or lowering hemoglobin A1c (HbA1c), yet similar studies have not been conducted in adolescents with type 2 diabetes.

Innovations and breakthroughs

The study tested an intervention shown to be effective in adults with type 2 diabetes in a cohort of adolescents with the same condition. The findings provide insight into the difficulties of translating an intervention effective in adults with type 2 diabetes into a successful approach in adolescents and highlight the need for innovative strategies to improve recruitment and retention of adolescents with type 2 diabetes into diabetes treatment programs.

Applications

Given the recruitment challenges faced, the authors' study may serve as a caution to other investigators attempting to implement similar strategies for diabetes management among adolescents. Based on their experience, additional practical considerations for designing interventions in adolescents may include pairing adolescents with peer volunteers who themselves have type 2 diabetes and had successfully improved their glycemia or with lay volunteers of the same race/ethnicity and/or socio-economic status. In addition, future efforts to raise adolescent understanding of the physiology of type 2 diabetes may also be worthwhile in motivating adolescents to participate in diabetes treatment programs.

Terminology

While they expect that the terminology in our manuscript is familiar to most readers, they wish to define two critical terms mentioned repeatedly in the manuscript: psychosocial intervention and (HbA1c). Psychosocial interventions are interventions that are designed to change behavior and have a direct focus on a person's social environment including interpersonal interactions and social support. This is in contrast to a medical approach, in which participants are prescribed medication or assigned to a specific diet. (HbA1c) is a commonly used indicator of glycemic control over a 3-4 mo period. (HbA1c) measures the percentage of one's hemoglobin (a protein in red blood cells) that is glycosylated or in other words, has sugar attached to it.

Peer-review

The study is an interesting analysis about the insight into the difficulties of translating an intervention effective in adults with type 2 diabetes into a successful approach in adolescents with the same disease.

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