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Flexible Lifestyles for Youth (FL3X) behavioural intervention for at-risk adolescents with Type 1 diabetes: a randomized pilot and feasibility trial

E. J. Mayer-Davis[1,*], **M. Seid**[2,*], **J. Crandell**[4], **L. Dolan**[6], **W. H. Lagarde**[8], **L. Letourneau**[3], **D. M. Maahs**[7], **S. Marcovina, PhD, DSc**[9], **J. Nachreiner**[3], **D. Standiford**[6], **J. Thomas**[3], and **T. Wysocki**[5]

[1]Department of Nutrition and Department of Medicine, University of North Carolina Chapel Hill, Chapel Hill, NC

[2]Division of Pulmonary Medicine and Anderson Center for Health Systems Excellence, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

[3]Department of Nutrition, University of North Carolina Chapel Hill, Chapel Hill, NC

[4]School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC

[5]Department of Research, Nemours Children's Clinic, Jacksonville, FL

[6]Division of Pediatric Endocrinology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

[7]Barbara Davis Center for Diabetes, University of Colorado School of Medicine, Aurora, CO

[8]Children's Endocrinology and Diabetes, WakeMed Children's Hospital, Raleigh, NC, USA

[9]Northwest Lipid Metabolism and Diabetes Research Laboratories University of Washington Seattle, WA

Abstract

Aim—To determine the potential effect sizes for the Flexible Lifestyle for Youth (FL3X) behavioural intervention to improve glycaemic control (HbA_{1c}) and quality of life for at-risk adolescents with Type 1 diabetes.

Methods—Participants [*n*=61; age 12–16 years, HbA_{1c} 64–119 mmol/mol (8–13%)] were randomized to FL3X (minimum three sessions) or usual care. Effect sizes (Cohen's d), comparing the mean difference between the groups, were calculated.

Results—Study retention (95%), attendance at intervention sessions (87% attended all three sessions) and acceptability were high (100% of the adolescents and 91% of parents would recommend the programme to others). Overall, 41% of participants in the intervention group and

Correspondence to: Elizabeth Mayer-Davis. mayerdav@email.unc.edu.

*These authors contributed equally to the work.

Competing interests

None declared.

24% of participants in the control group were ‘responders’ [HbA_{1c} decreased by > 6 mmol/mol (0.5%); d=0.37]. HbA_{1c} levels decreased (d= −0.18), diabetes-specific quality of life increased (d=0.29), but generic quality of life decreased (d= −0.23) in the intervention compared with the control group.

Conclusions—The FL3X programme merits further study for improving HbA_{1c} and diabetes-specific quality of life in adolescents with Type 1 diabetes.

Introduction

Poor and minority adolescents with Type 1 diabetes commonly have poor glycaemic control [1]. Diabetes self-management is key to long-term health, but can be challenging [2–4]. Efficacious interventions to improve HbA_{1c} levels, especially in at-risk young people, are urgently needed.

Motivational interviewing has proven to be efficacious in improving HbA_{1c} levels [5] and problem-solving interventions can improve self-efficacy [6], frequency of blood glucose testing [7], anxiety, stress and coping [8], and quality of life [9]. An intervention combining motivational interviewing and problem-solving could prove valuable.

Multicomponent interventions have also been shown to be efficacious. For example, diabetes-specific behavioural family systems therapy [10] improves HbA_{1c} levels and multisystemic therapy improves adherence in adolescents with chronically poor glycaemic control [11], but these interventions are intense, which raises issues of sustainability. Two multicomponent interventions suggest a way forward. Nansel *et al.* [12–13] reported improvements in HbA_{1c} as a result of a six-session behavioural self-regulation intervention implemented by a diabetes ‘personal trainer’, who used motivational interviewing techniques. Seid *et al.* [14] reported an adherence intervention that combined motivational interviewing with problem-solving skills training, and yielded important clinical benefits among low-income African-American adolescents with asthma.

The Flexible Lifestyles for Youth intervention (FL3X) combines motivational interviewing and problem-solving skills training with elements of behavioural family systems therapy and a flexible 'toolkit' of diabetes and communication technology. We sought to test the acceptability, feasibility and potential effect sizes for FL3X in at-risk adolescents with Type 1 diabetes.

Methods

Setting

The present pilot and feasibility study was performed as a three-site randomized clinical trial, comparing usual care (control) with the FL3X (intervention). The project was managed from the University of North Carolina, Chapel Hill. The three collaborating clinical sites included: 1) the Cincinnati Children’s Hospital Medical Center (Cincinnati, OH); 2) the Barbara Davis Center for Childhood Diabetes (Aurora, CO); and 3) the WakeMed Children’s Hospital (Raleigh, NC).

The study was approved by the institutional review boards at all participating institutions and was registered with clinicaltrials.gov (NCT01286350).

Participants

Adolescents aged 12–16 years with a diagnosis of Type 1 diabetes for ≥1 year, literacy in English, HbA_{1c} 64–119 mmol/mol (8–13%) and at least one primary caregiver were included. Adolescents were excluded if pregnant or if they had concurrent conditions that precluded participation, such as cancer or bipolar disorder.

Participants were recruited between May 2011 and August 2011. The final follow-up visit was completed in December 2011. Potential participants were identified via medical records and recruited via their clinicians and by mail and telephone calls. Participants received $40 for each measurement visit and were provided with a basic telephone (i.e. not a smartphone) with unlimited talk and text messaging for the duration of the study.

Study groups and randomization

Participants were randomized, within each clinical site, electronically via a predetermined allocation embedded within the study website to the FL3X intervention or usual care (control) groups.

The FL3X programme is framed through motivational interviewing [14–15], and uses the Bright IDEAS problem-solving skills training [14] and behavioural family systems therapy [10]. Additionally, FL3X makes use of a ‘toolbox’ of existing off-the-shelf applications, devices and diabetes-related educational materials. The FL3X intervention included three in-person and two optional sessions over a 3-month period. Sessions lasted 40–60 min and were supplemented with short additional contacts as needed. Participants were given the option of using their telephone to create reminders about diabetes management (e.g. insulin dosing and testing reminders) and/or motivational boosters (‘messages from you to yourself’).

Participants in the control group continued with their usual diabetes care.

Intervention training

The FL3X coaches were four experienced paediatric diabetes clinicians/educators. They participated in a 2-day motivational interviewing training and a 2-day recruitment and intervention workshop. Continuing training and supervision calls for coaches were held weekly.

Outcome measures

Baseline and 4-month end-of-study measures were collected in person. The primary outcome was change in HbA_{1c} level, assessed as the percentage of participants with a reduction in HbA_{1c} of > 6 mmol/mol (0.5%) between baseline and the end of study ('responders'), and as change in HbA_{1c} as a continuous variable. Dual reporting of HbA_{1c} values was achieved using a HbA_{1c} conversion table [17].

Secondary outcomes were disease-specific health-related quality of life, measured using the Pediatric Diabetes Quality of Life (PDQ) assessment [18] and generic health-related quality of life, measured using The PedsQL™ 4.0 Generic Core Scales [16].

Fidelity

Intervention sessions were audio-recorded and reviewed by an external MINT-certified coder, who scored selected sessions using the Motivational Interviewing Treatment Integrity 3.0 system [24]. In addition, trained graduate research assistants used a behavioural checklist to reflect the extent to which the intervention providers followed the content guidelines for each session.

Analysis

The goals of the analysis were to describe feasibility, acceptability, fidelity and potential effect sizes by comparing the intervention and control groups. Potential effect sizes were assessed using Cohen's d, the average change in the intervention minus the average change in the control group, divided by the (pooled) standard deviation of change. Effect sizes were interpreted as small (d = 0.2), medium (d = 0.5) or large (d = 0.8) [19]. Although, by design, the study was not adequately powered to reject the null hypothesis, we also performed inferential statistics (*t*-tests for continuous outcomes and chi-squared tests for dichotomous outcomes).

Results

The basic demographic and clinical characteristics did not differ by randomization assignment. The mean (SD) age and diabetes duration of the participants were 13.9 (1.4) years and 7.4 (3.5) years, respectively. Baseline glycaemic control was poor [mean (SD) HbA_{1c} 83 (16) mmol/mol or 9.7 (1.5)%]. In all, 17% of the participants had low socio-economic status (the highest attained parental education level was high school or lower), and 22% of participants received government-sponsored health insurance.

Figure 1 shows the flow of participants. The potential eligible study population consisted of 384 adolescents. After making contact with 130, we stopped because our recruitment goals had been attained. Of those contacted, three adolescents were deemed ineligible or withdrew, 58 declined to participate and eight did not present for the baseline appointment, resulting in a total of 61 participants available for randomization (47% of those contacted).

Retention was excellent, with 95% attendance at the end-of-study measurements and 97, 90 and 90% attendance for Sessions 1, 2, and 3, respectively (87% of participants attended all three sessions). Intervention acceptability was high: 100% of the adolescents and 91% of their parents indicated they would recommend the programme to others.

The Motivational Interviewing Treatment Integrity 3.0 system scores (1–5, with 5 being best) averaged 4.4 (range, 3.7–4.7) for all four intervention coaches, showing high adherence to motivational interviewing strategies. Fidelity to the intervention script for Session 1 by all four coaches was 95%; however, over all three sessions, two coaches

emerged as having 'high' fidelity (averaging 89.5% fidelity to script across all three sessions), while the other two coaches averaged a fidelity score of 51.5%.

Table 1 shows the effect sizes and inferential statistics for the outcome variables, comparing the intervention group (*n*= 29) with the control group (*n*=29). We found a modest effect size for the primary outcome: 41% of intervention participants and 24% of control participants were responders (d=0.37; *P* = nonsignificant). HbA_{1c} levels decreased by 2 mmol/mol (0.2%) for the intervention group and remained the same for the control group (d = −0.18; *P* = nonsignificant). In the subgroup of participants in the intervention group whose coaches administered the FL3X intervention with high fidelity, medium effects were found: 57% were responders (d= 0.73; *P* = 0.03 vs control group) and HbA_{1c} decreased by 6 mmol/mol (0.5%; d= −0.58; *P* = 0.09 vs control group).

For diabetes-related quality of life as measured by the PDQ, the effect size was modest (d=0.29; *P* = nonsignificant). For generic health-related quality of life, scores were slightly lower in the intervention group (d = −0.23; *P* = nonsignificant). Although scores increased numerically in the control group, this was not considered clinically relevant and was not statistically significant.

Discussion

The present pilot test of the FL3X intervention shows that the approach used is worthy of further study, including longer follow-up and a larger sample size. Nevertheless, the study has some limitations. By design, the pilot was not powered to detect a statistically significant intervention effect. Two of the four coaches were observed to have maintained moderate, as opposed to high, fidelity to the intervention. Unfortunately, our fidelity ratings were not completed in a timely enough manner to be used to deliver specific behavioural feedback in supervision sessions, which limited our ability to provide specific feedback to the coaches. This highlights the importance of fidelity for intervention delivery, and accordingly, we have developed a much more specific manual of procedures for use in future. Finally, the effect size of HbA_{1c} was small. Other studies [6–9, 12–13] suggest it takes a longer time period and a higher dose to achieve larger effects. This will need to be addressed in a fully powered, longer clinical trial.

Conclusions

The FL3X intervention shows promise as a potentially efficacious intervention for improved diabetes self-management in adolescents with Type 1 diabetes, including those at high risk of poor metabolic status related to socio-demographic status.

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What's new?

- Flexible Lifestyles for Youth (FL3X), is a new behavioural intervention that combines motivational interviewing, problem-solving skills, family communication and teamwork.
- The FL3X programme could improve metabolic status and quality of life for adolescents with Type 1 diabetes.

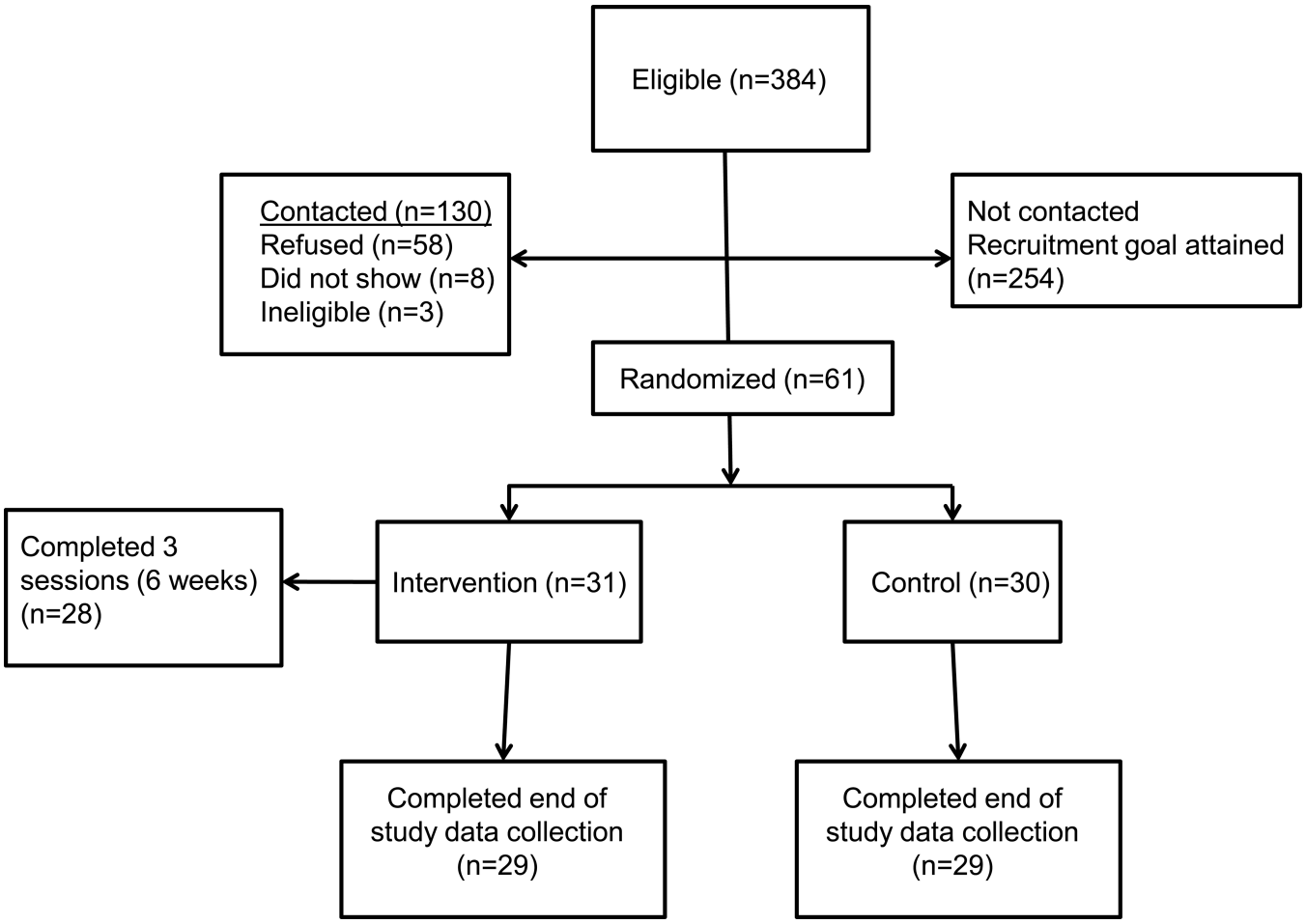

FIGURE 1.
Flexible Lifestyles for Youth (FL3X) pilot and feasibility study: CONSORT flow diagram.

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Table 1

Estimated intervention effects from the FL3X pilot and feasibility study

	FL3X intervention group, *n*=29				**Control group, *n*=29**				**Intervention effect**		
	Baseline	**End of study (post intervention)**	**Difference, mean (SD)**	***P***	**Baseline**	**End of study**	**Difference, mean (SD)**	***P***	**Intervention-Control**	**Effect size, Cohen's d**	***P***
Primary outcome[*],				0.44				0.98	−1 (0.01)	−0.18	0.50
Mean (SD) HbA_{1c}									−1 [−0.1]	−0.18	
mmol/mol	84 (18)	83 (16)	−1 (13)		80 (14)	80 (13)	0 (8)				
%	9.8 (1.6)	9.7 (1.5)	−0.1 (1.2)		9.5 (1.3)	9.5 (1.2)	0 (0.7)				
Percentage of responders[†]		41%				24%			17%	0.37	0.17
Secondary outcome											
Mean (SD) PDQ score	61.76 (14.79)[‡]	66.01 (14.31)[‡]	4.26 (9.15)[‡]	0.02	60.37 (12.35)[§]	62.13 (14.11)[§]	1.76 (8.63)[§]	0.30	2.496	0.29	0.30
Mean (SD) PedsQL score	82.58 (9.48)[*]	81.86 (10.77[*]	−0.72 (10.08)[*]	0.7	80.85 (9.09)[¶]	82.28 (9.97)[¶]	1.44 (8.65)[¶]	0.41	−2.159	−0.23	0.40

FL3X, Flexible Lifestyles for Youth; PDQ, Pediatric Diabetes Quality of Life questionnaire; PedsQL, PedsQL™ 4.0 Generic Core Scales (generic health-related quality of life questionnaire). Higher PDQ and PedsQL scores indicate better quality of life; higher diabetes family interaction scores indicate more diabetes-related family conflict

All HbA_{1C} mmol/mol values are rounded to the nearest whole number and % values are rounded to one decimal point.

[*] $n = 29$;

[†] HbA_{1C} decrease ≥ 6 mmol/mol (0.5%);

[‡] $n = 28$;

[§] $n = 27$;

[¶] $n = 26$.