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Characterization of youth goal setting in the self-management of type 1 diabetes and associations with HbA1c: The Flexible Lifestyle Empowering Change trial

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Abstract

Introduction: Youth with type 1 diabetes (T1D) commonly do not meet HbA1c targets. Youth-directed goal setting as a strategy to improve HbA1c has not been well characterized and associations between specific goal focus areas and glycemic control remain unexplored.

Objective: To inform future trials, this analysis characterized intended focus areas of youth self-directed goals and examined associations with change in HbA1c over a 18 months.

Methods: We inductively coded counseling session data from youth in the Flexible Lifestyle Empowering Change Intervention (n = 122, 13–16 years, T1D duration >1 year, HbA1c 8–13%) to categorize intended goal focus areas and examine associations between frequency of goal focus areas selected by youth and change in HbA1c between first and last study visit.

Results: We identified 13 focus areas that categorized youth goal intentions. Each session where youth goal setting concurrently incorporated blood glucose monitoring (BGM), continuous glucose monitoring (CGM), and insulin dosing was associated with a 0.4% (95% CI: –0.77, –0.01; P = .03) lower HbA1c at the end of intervention participation. No association was observed between HbA1c and frequency of sessions where goal intentions focused on BG only (without

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AUTHOR CONTRIBUTIONS

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addressing insulin or CGM) (β :0.07; 95% CI: -0.07, 0.21; $P = .33$) nor insulin dosing only (without addressing BGM or CGM) (β : 0.00; 95% CI: -0.11, 0.10; $P = .95$).

Conclusions: Findings exemplify how guiding youth goal development and combining multiple behaviors proximally related to glycemic control into goal setting may benefit HbA1c among youth with T1D. More research characterizing optimal goal setting practices in youth with T1D is needed.

Keywords

blood glucose; glycated hemoglobin A; goals; self-management; type 1 diabetes mellitus

1 | INTRODUCTION

Day-to-day management of type 1 diabetes (T1D) involves a complex regimen to prevent both short term acute and future chronic complications associated with the disease.¹ Self-care thus demands minimizing glycemic excursions to prevent acute hypoglycemia and hyperglycemia throughout the day, as well as consistently making healthy lifestyle choices regarding factors such as diet, physical activity, sleep, and stress that influence glycemic control and longerterm health outcomes.²

Although it is challenging at any age to maximize glycemic time in range while simultaneously managing quality of life and fluctuating dietary and activity demands, adolescence presents a particular struggle for T1D self-management due to a convergence of physiological and behavioral factors, which increase the risk of both short and long-term health consequences.²⁻⁴ Hormonal changes, behavioral inconsistency, and negotiation of self-care autonomy have been cited as reasons glycemic control often drops to its lowest during adolescence: despite significant advances in diabetes self-management technology, the majority of individuals in this developmental period do not meet clinical targets for glycemic control, and many exceed an HbA1c of 9%.⁵⁻⁹

As such, there is a need to devise effective behavioral strategies that target this developmental period, not only because of the self-management nadir that this period represents, but also because adolescence is a malleable period when lifelong behaviors develop.¹⁰ Thus, investments in improving self-management during this period may carry into adulthood and significantly contribute to preventing or delaying T1D associated morbidity and mortality.¹¹

Goal setting is widely recognized as an evidence-based, “core” Diabetes Self-Management Education (DSME) strategy that enhances initiation and maintenance of new diabetes self-management behaviors and promotes positive health outcomes.¹²⁻¹⁷ The National Standards for Diabetes Self-Management and Support guidelines, among other evidence-based guidelines, asserts the importance of the development of “action-oriented behavioral goals” through communication strategies such as “collaborative goal setting, action planning, motivational interviewing (MI), shared decision-making, cognitive behavior change strategies, problem solving, self-efficacy enhancement, teachback, and relapse prevention strategies”.¹² It is often recommended that these collaborative communication strategies

should result in mutually agreed upon goals that are specific, measurable, achievable, relevant, and time specific (SMART).^{17,18} Despite the widespread implementation of goal setting (and the communication strategies such as MI that facilitate it) by diabetes providers, much of the research underpinning these strategies in diabetes counseling has been conducted in the context of adults with type 2 diabetes (T2D).^{19–22} Further, most studies have observed associations between goal setting strategies and improvement in psychosocial outcomes (e.g., quality of life) and self-reported behaviors (e.g., exercise), with relatively few studies demonstrating associations with improvement in HbA1c.^{20–24}

The Flexible Lifestyle Empowering Change (FLEX) intervention (2014–2018) was therefore a novel randomized controlled trial because it tested a behavioral intervention that combined multiple evidence-based goal setting strategies to promote T1D self-management and HbA1c improvement among adolescents (HbA1c: 8–13%, Age: 13–16 years, T1D duration >1 year) in a potentially more age-appropriate way than previous interventions that used either MI or problem-solving skills training (PPST) approaches alone.^{19,25} By combining both strategies in a single intervention, FLEX aimed to facilitate adolescents' own agency and emerging autonomy, encouraging them to first explore their own motivations and then to integrate practical problem-solving skills related to T1D management. Previous work has described in detail the theory and evidence base underlying the FLEX trial design.²⁵

Despite exceeding recruitment targets, achieving outstanding intervention retention and fidelity, and improving psychosocial outcomes consistent with other goal setting interventions (e.g., motivation, problem solving, diabetes self-management profile, quality of life) as well as select secondary clinical targets (e.g., total cholesterol, diastolic blood pressure), FLEX did not achieve its primary target of improving HbA1c after 18 months.²⁶

In order to refine the design of future interventions for this population, and ultimately inform new clinical strategies to improve youth glycemic control, analyses are underway to identify the characteristics of FLEX participants who experienced an improvement in HbA1c over the course of the intervention period. In line with this aim, the purpose of the present analysis was to characterize the focus areas in the self-management goals selected by youth throughout the FLEX intervention and explore associations between different types of intended goal focus areas over the course of the intervention and change in HbA1c between beginning and end of intervention participation.

2 | RESEARCH DESIGN AND METHODS

2.1 | Study sample

This analysis relied on HbA1c and goal setting data from the measurement visits and coaching sessions of the participant youth-parent dyads in the intervention arm ($n = 127$) of FLEX ($n = 258$). Extended detail about intervention design, recruitment, delivery, measurements collected, and outcomes are described elsewhere.²⁵

In the sample used to conduct the present analysis, one participant who experienced a change in HbA1c of 9.3% (>4 SE from the mean) between first and last measurement visit was excluded. An additional four participants were excluded due to only having a baseline

HbA1c measurement (and thus no coaching session data) which precluded the examination of associations between goal setting behavior and HbA1c that was of interest to this analysis. To ensure temporality, only data from participant goal setting sessions that preceded the participant's last available HbA1c were included in the analysis. This meant that for 95% of the study sample, goal setting information was matched with a final HbA1c measurement at 18 months (n = 116 with final HbA1c measurement at 18 months, n = 2 at 12 months, n = 2 at 6 months, and n = 2 at 3 months).

2.2 | Coaching session format

All FLEX participants in the active intervention arm were initially assigned a standard intervention of four 40 to 60 minute introductory coaching sessions spaced about 1 month apart. Given the suboptimal HbA1c in the population of study, FLEX tested more frequent counseling than recommended by current guidelines. Further rationale for and detail about the trial design is discussed in previous work summarizing the protocol.²⁵ Subsequent-coaching sessions followed the same format of the first four sessions and were scheduled three to four times over each 6 month period. Because FLEX was a SMART trial designed to be cost-effective and provide the least restrictive intervention for easier integration into existing medical care teams, a priori rules (based on change in HbA1c between standardized measurement sessions) governed the length of these subsequent sessions. At each measurement session, those who met HbA1c targets were subsequently assigned "check-in" coaching sessions of length 15 to 20 minutes over phone or video-enhanced call. Those who did not meet HbA1c targets were assigned "regular" in-person coaching sessions of length of 40 to 60 minutes, with brief interim contact as needed via phone, video-enhanced call, text, or e-mail.

Broadly, the format of all coaching sessions included (1) reviewing what concerned youth about their T1D (framed as, "what bothers you about your diabetes?") to prompt youth to identify personally relevant self-management goals (2) communicating with youth using MI and teaching PSST techniques (3) contracting behavioral homework. Each coaching session ended by integrating the parent into the discussion to negotiate how they could best support the youth-identified goals, as well as to identify any joint parent-youth goals using MI and PSST techniques, which were then followed by development of joint contractual behavioral homework. Coaches were available as needed between introductory sessions through phone, video-enhanced call, text, or e-mail. The outcome of the behavioral homework was then reviewed at the subsequent session to reinforce success and motivation to continue the goal behaviors, troubleshoot obstacles to goal behavior achievement, or identify new goal behaviors using PSST and MI techniques.

As recommended by DSME consensus guidelines, individualized T1D education consistent with American Diabetes Association (ADA) and International Society of Pediatric and Adolescent Diabetes (ISPAD) clinical practice guidelines was incorporated as needed throughout the goal setting and troubleshooting process of all sessions, including specific training in how to develop SMART goals.¹⁸ Consistent with the principles of the goal setting strategies underpinning FLEX and widely promoted empowerment-based diabetes self-management programs, coaches did not set a minimum or maximum restriction on number

of goals or number of focus areas to be incorporated into youth goals at each session, nor did they direct youth selection of goal target area(s).¹⁴ Although the content areas of goals were youth-directed and thus flexible, a structured module developed from MI and PSST strategies was used by coaches to support youth goal setting in a standard way at each intervention session. Specifically, this involved using MI communication techniques (e.g., eliciting change talk, summarizing) to guide participants through a standard sequence of worksheets in the youth intervention booklet, which included reflecting on previous action plans, executing decisional balancing, using willingness and readiness rulers, developing SMART goals, and anticipating obstacles and planning for strategies to overcome identified obstacles using Bright Ideas.^{27,28} Semi-structured intervention scripts for each session promoted consistency across participants and sessions as regards the type of MI and PSST techniques used and the time spent on each portion of the goal setting module.

FLEX coaches were existing members of T1D medical care teams (i.e., dietician, nurse, and certified diabetes educator) who were trained by experienced psychologists with expertise in both MI and behavioral interventions. As described in more detail in previous work summarizing study procedures, coaches attended in-person training on the intervention for an initial 6 month period, were required to pass fidelity checks at multiple points before and during the intervention, and received consistent support and feedback throughout the study by the same psychologists who trained them.²⁵

In response to prompts included in the standardized encounter form that coaches completed at each intervention session, coaches provided free-response summaries of the session goal setting discussion and the action plans committed to by youth (and their parents, if relevant).

2.3 | Goal setting measures

We synthesized goal setting information from the encounter form responses using an iterative, inductive coding approach that involved “participant guided” generation of goal categories that emerged from the coaching session descriptions in the encounter forms.²⁹ This method contrasts with a deductive approach of categorizing goal focus areas based on preconceived notions of the areas that participants might select as part of a diabetes self-management intervention. Although clinical experience led us to expect youth would set goals about diabetes self-management behaviors such as dosing insulin, checking blood glucose and analyzing trends, and incorporating continuous glucose monitoring (CGM) technology into self-management behaviors, we selected an inductive approach to identify youth-selected goal focus areas. This decision was made due to limited existing literature describing the specific content area of self-management goals among youth with T1D and because of the participant-centered theoretical design of the intervention where youth were asked to determine the goals they would attempt instead of being given categories from which they could select goal targets.²⁹ Further, this inductive approach aligned with the exploratory nature of our study, which included an interest in describing the self-management goal setting behavior of youth with T1D when they are given the latitude that is promoted by diabetes self-management coaching strategies and clinical guidelines.¹⁸ Comparing how goals generated in this youth-directed context corresponded to the self-

management areas promoted by clinical guidelines was also an area of qualitative interest.
14,16,18,30

A preliminary codebook was developed based on repeated reading (“immersion”) of the encounter forms followed by multiple inductive coding passes by a lead analyst with 11 years of qualitative research experience (A. C. S).²⁹ Two additional analysts trained by A. C. S. independently executed initial coding of the encounter forms after reaching >90% concordance with A. C. S. (determined based on achieving >90% concordance in applying the preliminary codebook to 10 encounter forms at a time).

After this initial coding, meetings between all three analysts were held to discuss discrepancies in coding, develop additional codes, eliminate code redundancy, and ensure consistent application of the coding scheme across the data set, which led to the development of a final codebook. Once >90% concordance was reached between A. C. S. and the two analysts using the final codebook, the two analysts freshly applied the codes to the encounter forms, which finalized the goal focus area categories. Codes were not mutually exclusive, meaning that if an intended goal incorporated multiple areas, both codes were applied to the goal setting intentions described in the encounter form (see example in Figure 1).

Once we specified the goal focus areas and coded the encounter forms with the target area(s) selected at each coaching session, for every participant, we summed the number of times each intended goal area was selected over the course of the intervention.

In addition, given that standard T1D self-management counseling recommendations place a particular focus on the fundamental areas of dosing insulin, monitoring blood glucose, and increasingly, using diabetes-related technology such as CGM, we summed the number of times participants combined or did not combine these focus areas in their goal setting intentions at each session (e.g., number of times goal setting intentions incorporated BGM with CGM technology, but did not incorporate insulin dosing).^{16,18}

2.4 | Outcome measure

Youth HbA1c, measured via venous blood draw and analyzed in a central laboratory using standard clinical methods, was obtained at baseline, 3, 6, 12, and 18 months of the intervention. This variable was selected as the outcome measure since a key aim of this exploratory analysis, as previously discussed, was to learn from those who experienced an improvement in HbA1c, the outcome measure that was the intended target of the original trial.

2.5 | Statistical analysis

Linear regression modeling was used to explore associations between the number of times each intended goal area was selected and change in HbA1c between participants’ first and last measurement visit. Analyses were conducted using SAS, version 9.4.

In part 1 of our analysis, we examined associations between number of times each intended goal focus area or combination of multiple goal focus areas was selected (without

accounting for the number of times other goal focus areas were selected) and change in HbA1c between the beginning and end of intervention participation. These models regressed HbA1c at the last measurement visit on number of times a goal focus area was selected over the course of intervention participation, baseline HbA1c, and total number of coaching sessions attended (in order to account for how the number of times a goal focus area was selected would differ based on varying numbers of intervention sessions, and thus the number of opportunities to select a goal focus area).

Part 2 of our analysis investigated whether the associations observed in part 1 between types of goal focus areas selected over the intervention period and HbA1c at the last measurement visit were still meaningful when participant selection of other focus areas was accounted for. We thus explored the effect on HbA1c of increasing the number of times a certain goal focus area was selected throughout the intervention period while accounting for the number of times other types of focus areas were selected, the number of times no focus area was selected, and HbA1c at baseline. This fully adjusted model was developed based on the associations observed in part 1 that had effect estimate magnitudes that were clinically relevant. The total number of goal focus areas a participant selected over the study period was captured by the variables included in this model.

3 | RESULTS

3.1 | Baseline characteristics

Our final sample ($n = 122$) was 45.9% female and 77.9% non-Hispanic white, with mean age of 14.8 ± 1.1 years. At baseline, mean diabetes duration was 6.5 ± 3.8 years, HbA1c was $9.7 \pm 1.2\%$, and daily number of blood glucose checks was 2.2 (0.92). 68.6% reported using a pump for insulin administration the previous day, and 21.4% reported any CGM use within the month before the baseline visit. Baseline characteristics are displayed in Table 1.

Participants in our sample attended an average of 12.4 ± 4.4 intervention sessions, during which they had the opportunity to set zero or more goals. Table 2 displays the goal focus areas that emerged from our coding process in descending order of frequency, as well as an example of each goal focus area.

3.2 | Part 1

Tables 3A and 3B displays results from our first exploration of the relationship between the focus areas of youth goal intentions and change in HbA1c throughout the intervention, as well as the mean number of times participants incorporated these areas in their goal intentions over the course of their intervention participation. In descending order of frequency, the 10 focus areas that most frequently characterized participant goal intentions were parent support (i.e., a goal devised by youth that incorporates help from a parent), insulin dosing, BGM (e.g., checking blood glucose or reviewing trends), other diabetes-specific (e.g., exercise), parent joint (i.e., a goal collaboratively devised by youth and parent), carbohydrate counting, incorporating continuous glucose monitoring (CGM) technology (e.g., learning more about CGM, calibrating CGM, or using CGM as part of BGM), other not diabetes-specific (e.g., planning to study for a school exam), and family

communication. In Table 3A, the beta coefficient in each row was generated from a model that included the number of sessions the nonmutually exclusive goal area was selected (indicated in the left-most column) and mean HbA1c at the end of the intervention, adjusted for baseline HbA1c and total number of intervention sessions (goal setting opportunities). In Table 3B, the beta coefficient in each row was generated from a model that included the number of sessions where different combinations of BGM, CGM, and insulin dosing focus areas were selected, adjusted for baseline HbA1c and total number of intervention sessions.

In our sample, each increase in number of sessions where BGM was selected together with CGM, but without insulin dosing, was associated with a 0.32% (95% CI: -0.61, -0.03; $P = .03$) lower HbA1c at the end of the intervention, adjusting for baseline HbA1c and total number of intervention sessions. Further, each increase in number of sessions where all three areas were incorporated into goal setting intentions (BGM, CGM, and insulin dosing) was associated with a - 0.50% (95% CI: -0.87, -0.13; $P = .01$) lower HbA1c at the end of the intervention. The number of times other diabetes-specific areas (e.g., diet, exercise) were incorporated into goal setting intentions was also associated with a slightly lower HbA1c at the end of the intervention (β : -0.11%; 95%CI: -0.22, 0.01; $P = .06$). In contrast, each increase in the number of sessions where CGM was incorporated into goal setting intentions, but where insulin dosing or BGM were not also incorporated, was associated with a 0.15% (95% CI: -0.02, 0.32; $P = .09$) higher HbA1c at the end of the intervention. Each increase in number of sessions where goal setting involved eliciting nonparental diabetes-specific self-management support (e.g., from siblings or friends) was associated with a 0.27% (95% CI: 0.03, 0.51; $P = .03$) higher HbA1c at the end of the intervention.

3.3 | Part 2

Table 4 displays results from part 2 of our exploration of the relationship between frequency of selecting each goal focus area and change in HbA1c throughout the intervention, when accounting for frequency of selecting all other goal focus areas, number of sessions in which no goal focus area was selected, and HbA1c at baseline. As in part 1 of our analysis, frequency of the number of sessions where BGM, CGM, and insulin dosing were concurrently incorporated into goal setting intentions was associated with improvement in HbA1c (β : -0.39%; 95% CI: -0.77, -0.01; $P = .03$). This model also reinforced the unfavorable associations observed in part 1 of our analysis, where number of sessions that CGM was incorporated without incorporating BGM or insulin dosing (β : 0.16%; 95% CI: -0.02, 0.34; $P = .08$), as well as number of sessions in which nonparental support was incorporated (β : 0.20; 95%CI: -0.04, 0.45; $P = .10$), were both associated with an increase in HbA1c at the end of the intervention.

4 | DISCUSSION

We identified 13 distinct focus areas that characterized the goal setting intentions of youth who were supported by coaches in executing self-management goals throughout the 18-month FLEX intervention.

When considering the relative magnitude of our models' beta coefficients, we found that increased frequency of goal-setting intentions that incorporated BGM, CGM technology, and

insulin dosing together was associated with the greatest improvement in youth HbA1c between the beginning and end of study participation. Each session of coaching where all three of these goal focus areas were selected was associated with a 0.5% lower HbA1c at the end of the intervention period (in part 1 when we adjusted for HbA1c at baseline, and total number of sessions), and a 0.4% lower HbA1c in the fully adjusted model (in part 2 when we adjusted for HbA1c at baseline, the number of times each of the other goal areas were selected, and the number of times no goal areas were selected). Part 1 of our analysis also suggested a favorable association between frequency of selecting BGM combined with CGM even without insulin dosing (β : -0.32; 95% CI: -0.51, -0.03; $P = .03$), but this association was reduced in magnitude and not statistically significant in our model in part 2 ($P = .19$). The magnitude of our beta coefficients and P-values in part 2 of our analysis suggest the insufficiency of focusing only on BGM, CGM, or insulin dosing without also simultaneously selecting the other goal focus areas. Indeed, we observed that intending to set CGM related goals that did not incorporate BGM or insulin dosing (e.g., calibrate CGM, read more about using CGM) was associated with an increase in HbA1c at the end of the intervention period in both part 1 and 2 of our analysis. This latter finding supports caution against the perception of CGM as a “silver bullet” for diabetes self-management and the need for it to complement ongoing glucose analysis and insulin dosing efforts for its benefits to be realized.^{7,17} This cautionary message is particularly important in light of evidence of a steep rate of increase in CGM use among individuals with T1D, particularly among youth.³¹ It is also important to emphasize the lowaverage frequency at which youth in our sample took the initiative to integrate all three focus areas (insulin dosing, BGM, CGM) into their goal setting intentions. Taken together, our results thus point to the insufficiency of focusing goal setting on just one aspect of the fundamental self-management skill areas of insulin dosing, BGM, and increasingly, using diabetes self-management technology tools, and suggest the importance of more guided counseling that helps youth integrate these multiple areas in the development of more complex behavior change goals.^{16,18}

The most common theme we observed across goal intentions of FLEX participants was the incorporation of parental assistance into youth instigated goals (parent-support goals), which characterized the goal setting intentions of youth at an average of five (over one third of) intervention sessions. Comparatively, goals that were co-developed by youth and parent (joint goals) characterized the goal intentions at about two participant sessions, on average. The relative frequency of these themes aligns with the established understanding that adolescents with T1D are moving from dependence to autonomy in their diabetes self-management during this time period.^{4,17,32} We did not observe indication of a positive or negative association between frequency of intention to elicit parent support or frequency of intended joint goals and youth glycemic control in our sample, but it is possible this lack of association is the result of a mixing of effects, and that both goal categories represent a mix of self-management promoting and challenging parent-child dynamics (e.g., “adaptive” vs “maladaptive” communication, discrepancies in decision-making autonomy) that have been shown, respectively, to be favorably and unfavorably associated with youth HbA1c.^{10,32–34}

However, we did observe an unfavorable association between frequency of intention to elicit diabetes-specific, instrumental support (vs. emotional support) from friends or siblings and worsening glycemic control.^{32,35} Existing literature on the effect of peer support on T1D

self-management is mixed, and mechanisms by which the various types of peer support positively or negatively affect glycemic control have been hypothesized but not clearly elucidated or quantified.³⁵ The unfavorable association observed in our sample aligns with hypotheses that increased expressed intention to rely on peers may be indicative of a nascent level of youth self-reliance for self-management or indicative of certain challenging family contexts, both of which might contribute to self-management difficulties and poorer glycemic control.^{32–34} Moreover, the direction of this observed association highlights the more general need for further exploration of the relevance to the adolescent age group of certain empowerment-based diabetes self-management counseling principles developed from research with adults, especially those that recommend counselors invite participants to include family and social support “as desired” in diabetes self-management, and “affirm that patients are experts on their own support needs”.¹⁴

Despite the inclusion of physical activity and healthy eating in the “core” self-care behaviors promoted by the American Association of Diabetes Educators (AADE) and other clinical guidelines, these areas did not appear frequently enough in the self-directed goal setting intentions of our sample of youth to emerge as independent focus areas, and were thus collapsed into the “other diabetes-specific” goal focus area.^{16,18} Their inclusion in this category is possibly why we observed that this category was associated with a slight reduction with HbA1c (β : -0.1% ; 95% CI: $-0.22, 0.01$; $P = .06$) in part 1 of our analysis. Goals that were not specific to diabetes in our characterization of goal setting behavior were also fairly common (e.g., improve school grades, spend more time with friends, purchase clothing) as it was a focus area of goal intentions at an average of two intervention sessions per participant. These observations together illustrate how youth in this age group, when unguided, may not utilize goal setting opportunities to address areas proximally related to their diabetes self-management—a key lesson learned from FLEX that should inform the design of the goal setting component of future trials in this population.

Limitations include that the FLEX study was not designed a priori to support the present exploratory investigation, which limits the strength of the inferences we can draw from our results. HbA1c was chosen as our study outcome to be consistent with the primary outcome of the FLEX trial, but we acknowledge the limitation of using this measure given the high degree of glucose variability in adolescents. Our modest sample size required constraining the number of variables included in our models and resulted in low precision in our results, which limits our ability to ascertain the magnitude of the observed favorable and unfavorable associations between frequency of goal focus areas selected by youth and glycemic control. Although our sample size limited the number of goal target areas we could examine in combination, future research should evaluate the role of parental involvement in analyses of youth goal setting and health outcomes, given evidence of the importance of parental involvement in the broader T1D literature, and the need to understand more specifically in what scenarios, and to what extent, parental support can improve or hinder youth T1D self-management.¹⁸ Further, the moderate social homogeneity (e.g., parental income and education), racial homogeneity, and size of our sample limited adjustment for informative modifiers (e.g., maturity, socioeconomic status, motivation, self-efficacy), which could lend greater insight into the relationship between focus areas of youth-directed goal setting and glycemic control.

The structure of the data collection instruments used to collect information about goal setting in FLEX also posed analytical limitations. First, information about whether youth attempted to implement their goal intentions, and whether these actions were successful or unsuccessful, was not systematically documented throughout the intervention. Incorporation of this information would more clearly elucidate the relationship of interest to the present study, and help rule out other factors that may confound the mechanism between frequency of intended self-management goals expressed throughout the intervention by youth and observed changes in glycemic control. Second, the number of focus areas coded in the encounter forms provide insight into the type of self-management behavior selected as goal targets and the extent to which they were incorporated into youth goal setting, which increases current understanding of the extent to which goals generated by youth align with the areas recommended by consensus guidelines, and provides some insight into goal complexity by quantifying the extent to which youth goal intentions span multiple areas; however, the way data were recorded on the encounter forms precluded ability to consistently distinguish between one goal focusing on multiple areas, or multiple independent goals focused on different areas. The encounter forms were also not set up to assess other characteristics of goal setting behavior that clinical guidelines and existing research promote as supportive of glycemic outcomes, such as goals that are an appropriate level of challenge (vs. too ambitious) or to what degree they meet all the principles of SMART goals.^{17,18} We did, however, have the capacity to explore the level of focused goal setting by calculating the number of times a goal area was maintained as a focus by the participant over subsequent sessions. We found that each session increase where the same goal area was selected across sessions was associated with an approximate 0.2% lower HbA1c at the end of the intervention, after adjustment for HbA1c at baseline and total number of intervention sessions attended (95% CI: -0.32, 0.00; P = .046). These results are perhaps suggestive of the benefit of encouraging persistence in youth goal setting as compared to switching the focus of the goal setting because, for example, a previous action plan was unsuccessful. Designing data collection instruments that capture the aforementioned characteristics of youth goal setting in a standard and systematic way is important to enhance comparability of findings across the evidence base and better pinpoint the characteristics of goal setting behavior that most benefit the health of youth with T1D.

Despite these limitations, our exploratory work is the first to our knowledge to characterize how youth with T1D direct their goals in a counseling context where they are given the freedom to decide on topics to focus their diabetes self-management behavior. The directions of the observed associations in our sample are suggestive evidence that youth may benefit from more guided goal development between 13 to 16 years of age, particularly in the development of behavioral goals that combine self-management behaviors which are proximally related to glycemic control such as dosing insulin, monitoring BG, and effectively using CGM technology to support ongoing glucose checking and analysis. The insights from our investigation generate useful hypotheses and lessons learned to help focus the way goal setting counseling is designed and documented in future interventions among youth with T1D.

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CONFLICT OF INTEREST

JK reports grants from the NIH/NIDDK during the course of the study as a coinvestigator. MS reports grants from NIH/NIDDK during the conduct of the study and has a financial interest in intellectual property licensed by Cincinnati Children's Hospital Medical Center to Hive Networks, a company developing information technology to support collaborative learning health systems. DMM reports funding by NIH/ NIDDK during the course of the study and has had research support from the NIH, JDRF, NSF, and the Helmsley Charitable Trust. DMM's institution has had research support from Medtronic, Dexcom, Insulet, Bigfoot Biomedical, Tandem, and Roche. DMM has consulted for Abbott, the Helmsley Charitable Trust, Sanofi, Novo Nordisk, Eli Lilly, Medtronic, and Insulet. Angelica Cristello Sarteau, Elizabeth Mayer-Davis, and Jessica Wang have nothing to disclose.

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“She is going to work on bolusing before her after school snack. She is really hungry when she gets home, due to skipping lunch at school. She is going to bolus and then go do dishes, make her bed, and clean up before she eats her snack. She and mom are going to continue to do the same plan for BG. Participant will share her BG results with her mom daily and mom will not ask or nag her about what her BG results are. Communication seems to be going a little better, and they are going to work on keeping this going”.

Codes applied:

Insulin dosing
Blood glucose monitoring
Family communication
Parent joint
Continued

Codes not applied:

Carbohydrate counting
CGM
Parent support
Non-parental support
Pump
Site change
Other not diabetes specific
Other diabetes specific
No goal

FIGURE 1.

Example coding of goal setting intentions summarized in encounter form. BG, blood glucose monitoring; CGM, continuous glucose monitoring

TABLE 1

Characteristics of FLEX Participants in study sample (n = 122)

Characteristic	Mean (SD) or N (%)
Age (years)	14.8 (1.1)
Female sex	56 (45.9)
Race and ethnicity	-
Non-Hispanic white	95 (77.9)
Black	6 (4.9)
Hispanic	14 (11.5)
Other	7 (5.7)
Parental education	-
High school or less	13 (10.7)
Some college	36 (29.5)
4 y college	47 (38.5)
Graduate degree	26 (21.3)
Private insurance	84 (68.9)
Weight status	-
Not overweight	81 (66.4)
Overweight	25 (20.5)
Obese	16 (13.1)
Diabetes duration (years)	6.5 (3.8)
HbA1c	-
Mean (%)	9.7 (1.2)
≤9.0% (%) ^a	38 (31.2)
>9.0% (%)	84 (68.9)
Pump ^b	83 (68.6)
Daily blood glucose checks	2.2 (0.92)
CGM use (% yes in past month) ^c	24 (21.4)

Abbreviations: CGM, continuous glucose monitoring; FLEX, flexible lifestyle empowering change.

^a n = 5 (4.1%) with baseline HbA1c < 8.0%.^b missing: n = 1.^c missing: n = 10.

TABLE 2

Goal areas selected by participants

Goal area	Example
Parent support	Ask parent to prepare to-go breakfast before school
Insulin dosing	Bolus before school lunch
Blood glucose monitoring (BGM)	Check blood glucose before sleeping, review blood glucose logs every week for patterns
Other diabetes-specific	Take a 20 min walk after dinner
Carbohydrate counting	Consume 10–20 g of carbohydrate before cross country practice
Continuous glucose monitoring ^a (CGM)	Read more information about CGM (if not currently using a CGM); calibrate CGM, use of CGM for blood glucose monitoring (if currently using a CGM)
Parent joint ^b	Parent and youth cook plant-based meals together two times per week
Other not diabetes-specific	Put in study time for upcoming school exam
Family communication	Text parents after checking blood glucose
Pump	Download data from pump
Nonparental support	Ask friend to remind youth to bring glucometer to gym class
Site change	Change site location in a timely fashion
No goal	Youth does not want to work on anything

^a If participant goal setting involved using a CGM to monitor blood glucose, goal setting was characterized by both BGM and CGM focus areas.

^b Parent support goals were developed independently by youth but involved an element of parental assistance, whereas parent joint goals were developed collaboratively by youth and their parents in the coaching session via MI and PSST techniques.

Number of sessions each goal area was selected and change in HbA1c (%) over period of intervention participation (models adjusted for total number of sessions and baseline HbA1c)

TABLE 3A

Number of sessions goal area was selected	Mean (SD)	% change in HbA1c (95% CI)	P-value
BGM	2.6 (4.5)	-0.02 (-0.08, 0.04)	.49
CGM	1.6 (2.2)	-0.02 (-0.14, 0.11)	.81
Insulin dosing	4.5 (3.3)	-0.04 (-0.13, 0.05)	.40
Other goals (sum of below)	-	-0.01 (-0.05, 0.03)	.51
Carbohydrate counting	1.6 (2.0)	-0.05 (-0.18, 0.09)	.48
Pump	1.1 (1.5)	-0.05 (-0.23, 0.12)	.54
Site change	0.4 (0.9)	-0.04 (-0.31, 0.23)	.75
Family communication	1.2 (1.9)	0.10 (-0.04, 0.23)	.16
Parent joint	1.9 (2.2)	-0.03 (-0.14, 0.09)	.64
Parent support	5.0 (3.4)	0.01 (-0.08, 0.10)	.82
Nonparental support	0.8 (1.0)	0.27 (0.03, 0.51)	.03
Other diabetes-specific	2.5 (2.4)	-0.11 (-0.22, 0.01)	.06
Other not diabetes-specific	1.5 (1.9)	-0.09 (-0.23, 0.05)	.22
Number of goal areas selected over intervention period	26.1 (14.0)	0.00 (-0.03, 0.02)	.50
Number of goal areas selected per session	1.9 (0.8)	0.0 (-0.3, 0.36)	.80
Number of times a goal area was a continued focus across consecutive sessions	1.7 (1.7)	-0.17 (-0.32, 0.00)	.046
Number of sessions no goal area was selected	0.4 (0.9)	-0.02 (-0.30, 0.26)	.89

Abbreviations: BGM, blood glucose monitoring; CGM, continuous glucose monitoring.

TABLE 3B

Number of sessions during which combinations of BGM, CGM, and insulin goal areas were selected and change in HbA1c (%) over period of intervention participation (models adjusted for total number of sessions, and baseline HbA1c)

Number of sessions goal area was selected	Mean (SD)	% change in HbA1c (95% CI)	P-value
BGM without CGM or insulin dosing	1.0 (2.0)	0.05 (−0.07, 0.18)	.40
BGM and insulin dosing without CGM	0.8 (1.59)	0.00 (−0.16, 0.17)	.96
BGM and CGM without insulin dosing	0.2 (0.86)	−0.32 (−0.61, −0.03)	.03
BGM and CGM and insulin dosing	0.2 (0.68)	−0.50 (−0.87, −0.13)	.01
CGM without insulin dosing or BGM	0.9 (1.48)	0.15 (−0.02, 0.32)	.09
CGM and insulin dosing without BGM	0.4 (0.82)	0.12 (−0.19, 0.44)	.44
Insulin dosing without BGM or CGM	3.2 (3.0)	−0.03 (−0.12, 0.07)	.59

Abbreviations: BGM, blood glucose monitoring; CGM, continuous glucose monitoring.

TABLE 4

Number of sessions goal area was selected and change in HbA1c over period of intervention participation (fully adjusted model)

Number of sessions goal area was selected	% change in HbA1c (95% CI)	P-value
BGM, CGM, and insulin dosing	−0.39 (−0.77, −0.01)	.04
BGM and CGM without insulin dosing	−0.21 (−0.52, 0.10)	.19
CGM without BGM or insulin dosing	0.16 (−0.02, 0.34)	.08
BGM without CGM or insulin dosing	0.07 (−0.07, 0.21)	.33
Insulin dosing without CGM or BGM	0.00 (−0.11, 0.10)	.95
Nonparental support	0.20 (−0.04, 0.45)	.10
Other goal	−0.03 (−0.06, 0.01)	.11
No goal	−0.05 (−0.32, 0.24)	.77
Baseline HbA1c	0.66 (0.46, 0.88)	<.0001

Abbreviations: BGM, blood glucose monitoring; CGM, continuous glucose monitoring.