Official Title: Coin2Dose: Behavioral Economics to Promote Insulin BOLUS Activity and Improve HbA1c in Teens

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Protocol Summary

Official Title

NIH Cash-Only Incentive to Promote Mealtime Insulin Dose Engagement (NIH COIN2DOSE): Phase 2 Randomized Controlled Trial

Brief Title

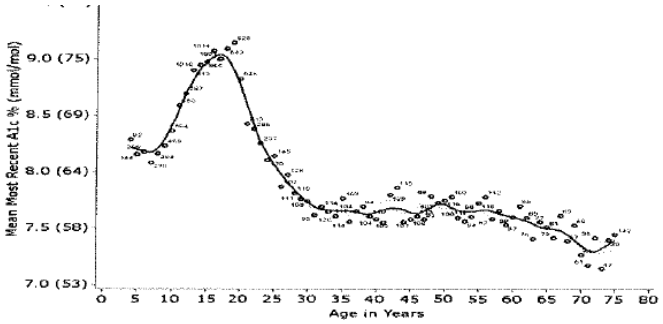
NIH COIN2DOSE

Brief Summary

This pilot randomized controlled trial will evaluate the feasibility, acceptability, and preliminary efficacy of a behavioral economic incentive intervention (COIN2DOSE) to improve mealtime insulin dosing behaviors among adolescents with type 1 diabetes. The study will compare two active treatment arms (Contingent vs Non-Contingent incentives) to Standard Care.

Detailed Description

Individuals with T1D can have a tremendous impact on their own health outcomes if they follow their T1D treatment regimen (1-3). Unfortunately, many adolescents do not adhere to their treatment and experience increased risk for both immediate medical emergencies, long-term T1D-related complications, and mortality (2-4). Diabetic ketoacidosis (DKA) occurs at a rate of 4.81/100 patient-years in individuals with established T1D and at a rate of 15.83/100 patient years in youth with an A1c >9% (5). Adolescents who have poorly controlled T1D are much more likely to develop DKA (2,6). While health care professionals can offer guidance and recommendations, traditional clinical interactions are not sufficient to promote optimal self-care and adherence for many adolescents (7) with the majority not reaching A1c targets (2). In fact, adolescents with T1D exhibit significant deterioration in glycemic control (aka rising A1c) from age 8 to 18 (8), as shown below.



Adapted from Miller et al 2015 – This figure shows mean A1C by age in years based on 16 057 participants in the Type 1 Diabetes Exchange Clinic Registry.

A few behavioral interventions have demonstrated utility in improving adherence behaviors in youth with T1D (9-14). Improved adherence behaviors are associated with better glycemic control and short and long-term health outcomes (2). On the other hand, lack of adherence can have serious consequences both acutely (DKA or severe hypoglycemic events) and long-term (retinopathy, neuropathy, nephropathy, and cardiovascular disease) (2). Missed mealtime boluses can have devastating metabolic consequences (15).

Adolescence is a particularly challenging time for individuals with T1D, with average A1c values that are 5% higher than during other periods of childhood and 14% higher than adults (1,21). Glycemic control worsens from early childhood through age 16-18 (22). It is critically important to develop interventions to prevent deterioration in glycemic control. High glycemic variability is also associated with increased risk of long-term diabetes complications, such as microalbuminuria (23). Lack of adherence to diabetes treatment plans is one of the main causes of sub-optimal glycemic control (2,6,24). A significant part of this non-adherence is omission of insulin for ingested carbohydrates at snacks and meals, both by missing boluses entirely and by inaccurate carbohydrate counting (15,26-29). Furthermore, greater than 33% of adolescents fail to give insulin for >15% of their meals and snacks (15). Adolescents, on average, miss boluses for meals two times per week (28). In one study, youth who omitted insulin at least one time per week had an A1C of 8.8-9.5%, while those who consistently

took meal-time insulin had a significantly lower A1C of 7.8-8.0% (30-31). This is of great significance as poor glycemic control increases risk of both acute and chronic diabetes related complications (32). Meal bolus alarms on insulin pumps, which alarm at a preset time, lead to transient, modest changes in dosing behavior (33). "Lost focus" has been identified as a significant reason for missed meal-time boluses in adolescents (34). Exactly how to effectively maximize engagement with mealtime insulin dosing behavior among adolescents with T1D represents a critical gap in knowledge.

Rationale

There is an urgent need for a sustainable method that improves patient engagement with delivering mealtime insulin boluses. Improved engagement with mealtime boluses will lead to better glycemic control and will ultimately help reduce the risk of acute and chronic diabetes related complications.

Recent evidence suggests that Behavioral Economics Incentives (BEI) can successfully increase adherence to blood glucose monitoring among adolescents and young adults with type 1 diabetes with moderate to large treatment effect sizes (36-42). Specifically, one study of 10 adolescents evaluated a BEI program that delivered $0.10 per fingerstick blood glucose test, with bonus incentives for ≥4 tests per day and a maximum achievable incentive of $251.40 over 12 weeks (38). The authors found that SMBG increased from 1.8 ± 1.0 to 4.9 ± 1.0 tests per day ($P < 0.001$) with 90% completing four or more checks per day; that mean A1c fell from 9.3 ± 0.9% to 8.4 ± 1.5% ($P = 0.05$); and that adolescents and parents reported high satisfaction with procedures (38). In another study, 90 adolescents and young adults demonstrated that a $60 monthly incentive opportunity significantly increased adherence to glucose monitoring goals in the 90-day incentive period (50.0% vs 18.9%; adjusted difference, 27.2%; 95% CI, 9.5% to 45.0%; $P = .003$), though the effect was not sustained during the post-interventional 90-day observation period (15.3% vs 8.7%; adjusted difference, 3.9%; 95% CI, -2.0% to 9.9%; $P = .20$), and A1c did not improve (42). The evidence, to date, suggests that it is feasible to increase adherence behaviors among adolescents and young adults with type 1 diabetes. However, it is unclear whether targeting blood glucose monitoring behaviors is always associated with an improvement in A1c and whether BEI can produce a sustained improvement in monitoring. Additionally, these methods have not been applied to mealtime insulin use, so whether BEI improve adherence to mealtime insulin dosing among adolescents remains unknown.

There is a strong rationale for targeting adherence to mealtime insulin dosing to promote more optimal A1c. Specifically, prior observational research suggests a 1.5% decrease in A1c levels for every one-bolus increase in daily mealtime doses, supporting our premise (30,31).

There is a strong rationale for exploring a treatment arm that does not use Contingent BEI. Contingent BEI implies that the participant earns the incentive *Contingent* on the performance of the target behavior (36,41,43). In contrast, Non-Contingent BEI implies the incentive is paid out irrespective of the performance of the target behavior (43). There are some studies, particularly in adult smoking cessation, that show a better outcome for Contingent BEI (e.g., received vouchers specifically for not smoking) versus Non-Contingent BEI (e.g., received vouchers irrespective of smoking behaviors) (44-45). However, in youth with T1D there is one study that tested the incremental benefit of Contingent BEI versus Non-Contingent BEI on daily SMBG frequency and found virtually no benefit (36). It is harder to deliver Contingent BEI than Non-Contingent BEI for the completion of T1D self-care behaviors and this would negatively impact future scalability to the real world (e.g., Contingent BEI requires individual monitoring of the target behavior, while Non-Contingent BEI does not). Thus, in an exploratory aim, our RCT Pilot trial proposes to compare two active treatments: a Contingent COIN2DOSE version and a Non-Contingent COIN2DOSE version to explore if contingency is necessary to promote daily BOLUS scores and improved A1c in adolescents with T1D.

There is a strong rationale for using a yoked control design to explore for any benefit of the Contingent COIN2DOSE versus Non-Contingent COIN2DOSE. In a yoked control design, a participant in one group is matched to a participant in a second group such that the participant's behavior in the first group determines the outcome for the participant in the second group (45). In our proposed use of a yoked control design, adolescents randomized to Contingent COIN2DOSE *will receive BEI based on their own* daily insulin BOLUS scores. In contrast, adolescents randomized to Non-Contingent COIN2DOSE *will not receive BEI based on their own* BOLUS scores, instead they will receive BEI based on the BOLUS scores of their matched counterpart in the Contingent COIN2DOSE group. This design will enable us to promote equivalence in the level of BEI earned

across the two groups (45), which may further help isolate any incremental effect of Contingent BEI (personalized) versus Non-Contingent BEI (non-personalized). Alternative Non-Contingent designs (e.g., variable-ratio schedule) could also offer non-personalized BEI but may not achieve equivalence in the level of BEI earned across the two groups (46-47).

To conclude, the objective of the present study is to obtain initial feasibility, acceptability, and efficacy data to test if COIN2DOSE can promote daily insulin BOLUS scores, A1c, and TIR in adolescents with suboptimal insulin use.

Study Design

Study Type: Interventional (Clinical Trial)
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Behavioral
Estimated Enrollment: 150 adolescents + 150 parents (up to 300 participants)

Arms

Arm 1: COIN2DOSE - Cash incentives either based on participant's own mealtime insulin dosing behavior (Contingent) or based on yoked partner's dosing behavior (Non-Contingent).
Arm 2: Standard Care - Weekly text reminders and small incentives for data sharing only.

Interventions

Behavioral: COIN2DOSE - Incentives tied to insulin bolus behavior and data sharing.
Behavioral: Standard Care - Weekly reminders and minimal incentive for data sharing.

Primary Outcome Measures

1. Change in Hemoglobin A1c from baseline to 90 days [Time Frame: 3 months]
2. Change in mealtime insulin bolus score from baseline to 90 days [Time Frame: 3 months]

Secondary Outcome Measures

Change in A1c and bolus score at 180 days
Change in Time in Range (70–180 mg/dL)

Eligibility Criteria

Inclusion: Adolescents aged 11–17.99 years, T1D ≥6 months, insulin pump or Bluetooth-enabled pen, mean daily bolus score <2.5 or HbA1c >8.0%, English-speaking, parent willing to participate.
Exclusion: Diabetes other than T1D, conditions affecting A1c accuracy, no internet access, comorbid chronic conditions.

Study Timeline

Duration per participant: 26 weeks (12-week intervention + 14-week observation)
Estimated Study Start: 2/2023
Estimated Primary Completion: 11/2024
Estimated Study Completion: 9/2025

Statistical Plan

Primary Outcomes:

Mean Daily Insulin BOLUS scores: objective measure of insulin use. We will use 14-days of insulin pump downloads to calculate a mean daily insulin BOLUS score for adolescents.

HbA1c: proxy measure of glycemic control. We will use fingerstick blood samples and a valid mail-in dried blood spot kit to measure adolescent's HbA1c at a central laboratory.

Secondary Outcomes:

Time in Range (TIR): measure of glycemic control. We will use the CGM data we collect from adolescents to calculate TIR. We will define TIR based on Bergenstal et al. or glucose values falling between 70-180mg/dl.

Other Variables:
Parent:
Demographics and T1D History: study specific measure to capture family/adolescent demographics, use of personal CGM, history of T1D-related acute complications (e.g., hypoglycemia/diabetes ketoacidosis).
Problem Areas in Diabetes-Parent Revised (PAID-PR)[50]: 18-item survey of diabetes distress (DD) validated for parents. PAID-PR yields a total score and two subscale scores reflecting immediate and long-term distress.
Diabetes-Specific Family Conflict Scale (DSFC)[49]: 19-item survey of perceived family conflict validated for use in parents and youth. DSFC yields a total score and two subscale scores reflecting direct and indirect conflict.
Treatment Satisfaction Measure: 14-item survey to assess satisfaction with Coin2Dose treatment. Yields a total score.

Adolescent:
Problem Areas in Diabetes-Pediatric Version (PAID-Peds)[48]: 20-item survey of DD validated for youth 8-17-years old. PAID-Peds yields a total score.
Diabetes-Specific Family Conflict Scale (DSFC)[49]: 19-item survey of perceived family conflict validated for use in parents and youth. DSFC yields a total score and two subscale scores reflecting direct and indirect conflict.
Treatment Satisfaction Measure-Child: 8-item survey to assess satisfaction with Coin2Dose treatment. Yields a total score.

Statistical Plan by Aims/Hypotheses:

Aim 1: Examine the feasibility and acceptability of our semi-automated BEI intervention (Coin2Dose) to target daily BOLUS scores in adolescents with T1D.

H1: Coin2Dose will be feasible, acceptable, and easy to use.

Analysis Plan. We will assume the Coin2Dose is feasible adolescents share weekly insulin pump data with the research team for $\geq$75% of weeks across the Phase 2: RCT Pilot trial and we have $\leq$20% attrition after randomization. We will calculate mean and SD for the responses that youth and parents provide on our Treatment Satisfaction survey (post-treatment). We will assume acceptability if scores reflect $\geq$85% acceptability.

Aim 2: Examine the preliminary efficacy of our semi-automated BEI intervention (Coin2Dose) versus a standard care control on youth daily BOLUS scores, HbA1c, and TIR.

H2a: Adolescents receiving Coin2Dose will demonstrate improvements in BOLUS scores, HbA1c, and TIR when compared to SC adolescents corresponding to at least medium effect sizes.

H2b: At 3-month follow-up, adolescents who received Coin2Dose will demonstrate greater improvements in BOLUS scores, HbA1c, and TIR than SC adolescents.

Analysis Plan. We will score primary and secondary outcome measures as continuous variables and calculate within-group standardized effect sizes (in SD units) for youth based on data collected at baseline, post-treatment, and 3-month follow-up. We will do this for youth randomized to our standard care control group (n=50) and for a Coin2Dose group that combines both the Contingent and Non-Contingent versions (n=100) because our only goal for Aim 2 is to test for the overall effect of BEI. We will also use Generalized Estimating Equations (GEE) to test for any between-group differences on our primary and secondary outcomes at post-treatment and 3-month follow-up. In between-group models, we will control for baseline values of our dependent measures. We will also we will consider covariates (e.g., age) in our between-group models.

Exploratory Aim: Examine the incremental impact of using Contingent versus Non-Contingent incentives on youth's BOLUS scores, HbA1c, and TIR.

Analysis Plan. To test our Exploratory Hypothesis that there will be a beneficial incremental effect of using Contingent versus Non-Contingent BEI in Coin2Dose, we will calculate within-group standardized effect sizes (in SD units) for our primary outcomes for youth randomized to the Contingent C2D and Non-Contingent C2D groups. Plus, we will use another series of GEE to explore any between-group differences in our primary outcomes for youth randomized to the Contingent C2D and Non-Contingent C2D groups.

Power/Sample Size Justification

The purpose of our Phase 2 RCT Pilot trial will be to generate data to support a full randomized clinical trial. However, based on comparing youth HbA1c differences as a primary outcome, n=150 adolescents randomized to a control group (n=50) or our Coin2Dose group (n=100), and study assessment points at equally spaced (12-week) time intervals for baseline, post-treatment, and follow-up, we would have a power of 0.80 when using a two-sided Wald Test from a generalized estimating equation (GEE) analysis to test whether the time-average difference in HbA1c between Coin2Dose participants differs from that of control participants by more than 0.50 at a significance level of 0.05. In calculating power for the GEE, we assumed a residual standard deviation of the errors was 0.90 and we expressed measurements as proportions of the total study time: 0.00, 0.50, and 1.00 with the assumed proportions missing at each measurement time equal to 0.20. We conducted our power analysis using PASS 2019, v19.0.5.

If we assume an attrition rate of 20% and we propose to recruit n=150, we may assume to only have data from at least n=120 adolescent/parent dyads to analyze. While at this smaller sample size we will no longer have the power to test for a between-group difference in youth HbA1c for our Coin2Dose and standard care control adolescents, we would still retain a sample size that is sufficient to estimate effect sizes for all of our study outcomes, which is a goal of this FOA.

Locations

Children's Mercy Hospital (Kansas City, MO)
Nemours Children's Health (Jacksonville, FL)

Contacts

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