Dietary Intervention for Glucose Tolerance In Teens (DIG IT): Protocol of a randomized controlled trial using health coaching to prevent youth-onset type 2 diabetes


Abstract

Background—Youth-onset type 2 diabetes (T2D) is a disease that is newly emerging and behavioral strategies for its prevention are limited. Interventions that target the lifestyle behaviors of adolescents, to improve poor dietary quality and reduce excessive sedentariness, promise to reduce the risk of developing T2D. Health coaching is effective for promoting healthy behaviors in patients who have chronic disease, but few experimental studies are in adolescents. This randomized controlled trial, in adolescents with prediabetes, will determine the effectiveness of a health coaching intervention to facilitate adoption of healthy diet and activity behaviors that delay or prevent development of T2D.

Methods/design—The Dietary Intervention for Glucose Tolerance In Teens (DIG IT) trial will involve an evaluation of a health coaching intervention in adolescents with prediabetes. Eligible participants will be randomized to receive 6 months of health coaching or a single dietary consultation that is standard-of-care. The primary outcome will be 2-hour oral glucose tolerance test concentration. Secondary outcomes will include measures of glycemia and insulin action as well as dietary, physical activity and sedentary behaviors measured using an electronic food record, and by inclinometer. Data will be collected before and after the intervention (at 6 months) and at 12 months (to assess sustainability).

Competing interests
None of the authors of the manuscript have any competing interests.
Discussion—This trial will determine whether a health coaching intervention, a personalized and low-cost approach to modify dietary and activity behaviors, is effective and sustainable for prevention of youth-onset T2D, relative to standard-of-care. Health coaching has the potential to be widely implemented in clinical or community settings.

1. Background

Youth-onset type 2 diabetes (T2D) is an emerging condition linked with pediatric obesity. The prevalence has increased approximately 30% in the United States (U.S.) between 2001 and 2009 [1]. Prediabetes is the precursor of T2D and recent studies have estimated its prevalence in adolescents to be 16.1% [2]. Once an adolescent has developed T2D, the prognosis is worrisome because of poor glycemic control, even with the use of conventional medications, leading to early progression of chronic complications and lower life expectancy [3–5]. The problem of youth-onset T2D is especially challenging since obesity is difficult to treat in children [6].

The Diabetes Prevention Program (DPP) was a landmark behavior modification intervention which was conducted in adults with prediabetes [7]. The DPP and other major clinical trials demonstrated the superiority of lifestyle intervention, which promoted weight loss, over medication, for preventing T2D [7–9]. Following the success of the DPP, efforts were underway to translate the program from academic to clinical and community settings [10]. The Bright Bodies study, conducted in youth with prediabetes, demonstrated that behavioral modification was effective in reducing glycemia [11]. However, the study was conducted in an academic setting, required on-site participation, and presumably, was labor intensive. Given the high prevalence of prediabetes in youth [2], who are therefore at risk for developing T2D, there is a critical need for a low-cost, home-based prevention program that can be individualized and easily integrated into families.

Health coaching is a personalized approach that is being widely used to improve health behaviors in patients with chronic conditions including prediabetes [12,13]. In adolescents, health coaching is a promising strategy that promotes healthy behaviors using validated techniques like motivational interviewing [14,15]. Although data from randomized clinical trials in adolescents are limited [16–18], a health coaching behavior modification program may be an effective, low-cost, personalized and flexible program that can be implemented through clinical or community settings.

A growing body of literature, from longitudinal studies, suggests that diet [19–29], physical activity [30,31], and sedentary behavior [32] may modify the risk of development of T2D, independent of effects on adiposity. Adolescence is associated with low consumption of fruits, vegetables and whole grains, excessive consumption of refined grains, saturated fats and added sugars, and high amounts of time spent in sedentary behavior [33–35]. In adolescents, we [36] and others [37–39] have shown that high dietary intakes of fat as well as sugary foods and beverages are negatively associated with elevated glycemia and insulin resistance. Also, high sedentariness negatively influenced insulin secretion and sensitivity in youth [40]. It is reasonable therefore that a diabetes prevention program that targets specific
diet and activity behaviors which are associated with T2D may be effective for management of glycemia.

We have proposed herein an intervention to be conducted in adolescents with prediabetes that aims to improve glycemia through modification of specific diet and activity behaviors, which reflect guidelines from the American Diabetes Association, American Academy of Pediatrics, American Heart Association and U.S. Department of Health and Human Services and Department of Agriculture [41–44]. The objective of this trial is to compare the effectiveness of a 6-month, home-based, individualized health coaching program, which focuses on modification of diet, physical activity, and sedentary behavior, versus a single dietary consultation, in preventing T2D in adolescents who are overweight or obese and have prediabetes. Health coaches will facilitate behavior change regarding consumption of specific foods and time spent in physical activity/inactivity using techniques such as motivational interviewing and goal setting that have been shown to increase self-efficacy [14,15] (see conceptual framework Fig. 1). We hypothesize that compared to receiving a single dietary consult, which is the usual care [45], patients who receive a one-on-one health coaching program will exhibit reduced glycemia as measured by 2 h oral glucose tolerance test (OGTT) at the end of the 6-month intervention, and that this impact will be sustained for an additional 6 months. We expect that increased consumption of specific nutrients and foods (dietary fiber, proteins, whole grains and fruits and vegetables), and decreased consumption of foods and beverages that are high in saturated fat and in added sugars, will modulate improvements which are observed in insulin sensitivity and beta-cell function. The research will also explore the contribution of biological, social, and behavioral factors as predictors or covariates of gluco-regulation including anthropometric measures of total and regional adiposity, measures of sleep behavior, depression, and food insecurity, as well as readiness and self-efficacy for behavior change. Perceptions of the health and behavior of the adolescent participants, by their parents/guardians, will also be obtained. This manuscript describes the study design and methodology for recruitment, data collection and data analysis that will test the stated hypothesis.

2. Methods/design

2.1. Recruitment

The main activities of the study are presented in a flow diagram (Fig. 2). Boys and girls who are between the ages of 10–21 years and are overweight or obese (body mass index > 85th percentile for age and sex) will be recruited into the study. In Indiana, the most recent estimates suggest 15.9% of adolescents are overweight and 12.8% are obese, which together make up one-third of the adolescent population [46]. Various outreach strategies will be used to inform participants/families and health care providers as well as the general community about the study. Participants who are recruited through primary care clinics will be considered to be recruited by clinic referral. Physicians at pediatric primary care practices in the Central Indiana region have been made aware of the study through in-service presentations by the study investigators at Indiana University School of Medicine and at Purdue University. In addition, we will recruit subjects from Riley Youth Diabetes Prevention Clinic (YDPC), Adolescent Medicine Diabetes Clinic, and HealthNet Pediatric
and Adolescent Care Center with recruitment assistance by the Indiana Pediatric Research Network (PRES-NET, https://www.indianactsi.org/programs/researchnetworks/presnet). Participants who are recruited from community-outreach efforts will be considered to be recruited via self-referral. Community outreach strategies include sending mass emails and flyers to targeted audiences, either through Purdue Extension, or to employees of Purdue University. In addition, information about the study can be found at ClinicalTrials.gov, registration number NCT02535169.

2.2. Informed consent procedure

Potential participants and their parents/guardians will meet the study team at a public venue to obtain informed consent/assent. During this time, participants and families will be provided with a detailed description of the study including responsibilities, as well as risks, and benefits of participation. Procedures for obtaining consent have been reviewed and approved by the Indiana University and Purdue University Institutional Review Boards (IRB Study #: 1403986016). After reviewing the materials, and signing the consent forms, adolescents will undertake further screening for eligibility to participate in the study. During the screening process, participants will undergo a detailed assessment of diet and activity behavior to be followed by a clinical assessment of glycemic status and insulin action. Diet and activity behavior will be assessed with electronic technology using validated methods that are enabled for use in free living individuals.

2.3. Dietary assessment

Dietary information will be collected for four days, including at least one weekend day, using the Technology Assisted Dietary Assessment (TADA) mobile food record [47]. The TADA application enables individuals to create a mobile food record by capturing food and beverage images “before” and “after” eating occasions using the camera on an iPod® [47]. The TADA application has been validated in the adolescent population [47,48]. Graduate assistants, who are trained in techniques of dietary assessment at the Dietary Assessment Center at Purdue, will be involved in the data collection for dietary assessment. Their responsibilities will be to 1) review all images with study participants to verify quantities and to obtain missing information; and to 2) to create a food record by evaluating each before and after image, and determining the food types and portion sizes of each food item, using a fiducial marker as a reference. If the fiducial marker is absent, other reference markers such as standard plates or utensils will be used. The quantities consumed of foods and beverages which are identified from the images will be evaluated using the Nutrition Data System for Research (NDSR, developed by the Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Reported daily intake is calculated as a mean of the four days. Levels of intake of nutrients will be compared to those recommended for adolescent girls and boys, in the Dietary Guidelines for Americans reports [49,50]. Completeness of dietary records will be evaluated by determining energy requirements and calculating the percentage of calories reported versus estimated energy requirements. Energy requirements were estimated using equations for overweight children and adolescents who are in a weight maintenance situation [51]. Underreporting of energy intake will be indicated if energy intake is less than 1 standard deviation below predicted energy requirements [50,52].
2.4. Assessment of physical activity and inactivity

Time spent in seated, standing, and ambulatory physical activity will be assessed over 7 days using an activPAL™ monitor (PAL Technologies, Glasgow, United Kingdom), a device which utilizes accelerometer and inclinometer functions [53]. activPAL™ is considered the reference method for estimating sedentary time in free-living individuals [54]. The inclinometer function is used to detect posture and thus can distinguish between sitting and standing. The device is highly objective and more accurate than traditional methods such as self-report and survey, and has been validated in the adolescent population [53,55]. The instrument also has the capability to measure various tempos of physical activity by generating stepping cadence. Data from the activPAL™ will be categorized into six variables including four activity intensity levels (light physical activity [LPA], moderate physical activity [MPA], vigorous physical activity [VPA] and moderate-to-vigorous physical activity [MVPA], plus total steps taken and total stepping time. Children will be classified as sedentary if they obtain less than 30 min of MPA; low active if they obtain 30 to 60 min of MPA; and active if they obtain greater than 60 min of MPA [51].

2.5. Clinic screening visit

Immediately following the week of collection of dietary and activity information, the study volunteer and their parent/guardian will attend a clinical research center (Clinical Research Centers at Indiana University Hospital or Riley Hospital for Children) for assessment of clinical and anthropometrical measures, which are used to determine their eligibility for the study. The participant will attend the screening visit in the morning after an 8-hour overnight fast. The clinical and anthropometric measures will include blood pressure, and indices of general and abdominal obesity (height, weight, body mass index [BMI], waist circumference [WC], hip circumference, and sagittal abdominal diameter [SAD]) [56]. BMI percentiles and Z-scores will be calculated from age-and sex-specific reference values as defined by the Centers for Disease Control and Prevention (CDC) growth charts [57]. Blood pressure will be measured after 5 min of rest, on the right arm in the supine position, using a sphygmomanometer with an appropriately sized cuff [58]. An intravenous line will be placed and blood is drawn for biochemistries, including concentrations of blood glucose, hemoglobin A1c, liver enzymes (alanine amino transferase and aspartate amino transferase), as well as a comprehensive lipid profile, and a metabolic panel. Concentrations of plasma lipids (total cholesterol, triglycerides [TG], high-density lipoprotein [HDL]), will be measured in the Indiana University Core Laboratory, using Alere Cholestech LDX System (Alere, Orlando, FL). Low-density lipoprotein (LDL) cholesterol will be calculated using the Friedewald equation [59].

Glycemic status (categorized as having normal glucose tolerance [NGT], prediabetes or T2D based on American Diabetes Association criteria) [60] will be assessed using an OGTT. Blood samples will be obtained at −15, 0, 15, 30, 60, 90, 120 min relative to ingestion of a glucose drink in a dose of 1.75 g/kg body weight (maximum 75 g glucose). Concentrations of blood glucose and HbA1c will be measured using the i-STAT System (Abbott Point of Care, Princeton, NJ) and DCA Vantage Analyzer (Siemens Medical Solutions USA, Inc., Malvern, PA) instrumentation respectively, which enable point-of-care testing. For measures of insulin action, serum fractions from the OGTT will be frozen at −80 °C until analysis.
Concentrations of glucose will be determined using an automated chemistry analyzer (COBAS Integra 800, Roche Diagnostics, Indianapolis, IN); insulin, and c-peptide will be assessed using an Elecsys Systems immunoassay analyzer (Roche Diagnostics). The homeostasis model assessment of insulin resistance (HOMA-IR) will be calculated from glucose and insulin concentrations in the fasting state [61]. Whole-body insulin sensitivity index (WBISI), the insulinogenic index (IGI), and the oral disposition index (DI) will be calculated as described [62,63].

2.6. Eligibility criteria

Participants who meet eligibility criteria, by having a diagnosis of prediabetes, will be enrolled into the study intervention and randomly assigned into the single dietary consult group or the health coaching intervention. Prediabetes will be defined by having one or more of the criteria recommended by the American Diabetes Association, namely: 1) impaired fasting plasma glucose (IFG) concentration of 5.6 to 6.9 mmol/L; 2) impaired glucose tolerance (IGT) a 2 hour OGTT glucose concentration of 7.8 to 11.0 mmol/L, or 3) an elevated hemoglobin A1c concentration of 5.7 to 6.4% [60]. Exclusion criteria include pregnancy, use of medications that affect glucose metabolism (such as glucocorticoid-containing medications or atypical antipsychotics), and syndromic obesity (such as Prader Willi, hypothalamic obesity, or Laurence-Moon-Biedl). Participants who are characterized as NGT or T2D will not be eligible to enroll in the study and complete the study at this point. At the end of the screening clinic visit, all participants, regardless of glycemic status, will undergo a consultation with a clinic dietitian regarding diet and lifestyle behaviors.

2.7. Randomization

Randomization will be carried out at subject level, by using the random number generator built in the Research Electronic Data Capture software (REDCap, Vanderbilt University, Nashville, TN). Specifically, participants will be randomly assigned to the Health Coaching or the Single Dietary Consult groups. A randomization table that pre-defines how each subject will be randomized as they are added to the study will be generated by a statistician and uploaded to the REDCap database. Neither the participants and their families nor the study team will be blinded to treatment allocation.

2.8. Description of health coaching intervention and single dietary consult groups

2.8.1. Single dietary consult—For participants who are enrolled in the single dietary consult group, a dietary consultation at the end of the screening visit serves as the standard of care intervention. The clinic dietitian will provide to the participant and their parental guardian, evidence-based, individualized nutrition and physical activity information regarding expert guidelines for prevention of obesity and diabetes (U.S. Dietary Guidelines, American Heart Association, American Diabetes Association, and American Academy of Pediatrics) [41–43,49]. Evidence-based nutrition messages will include: reducing consumption of sugary sweetened beverages and foods, increasing fruit and vegetable consumption, practicing portion control, reducing the frequency of eating out, and choosing healthy snacks. Evidence-based physical activity messages will include: being physically active for 60 min daily including cardiovascular, weight bearing, and flexibility exercises,
and reducing screen time to 120 min or less per day. Other than the single dietary consult, during the intervention, participants in this group will not receive any additional consultation from the study dietitian; for further guidance they will be advised about provider services in their region.

2.8.2. **Health coaching intervention**—In addition to receiving a single dietary consultation, participants who are randomized to the health coaching intervention will receive assistance from a health coach for 6 months to modify diet and activity behavior. Health coaches will have undergraduate training from nutrition and kinesiology programs and will be highly knowledgeable about clinical practice guidelines regarding diet and physical activity strategies for obesity and diabetes management. The protocol for the health coaching intervention builds on the DPP framework [64], but will be adapted to be delivered via one-on-one counseling with a health coach and tailored to fit each participant’s needs. Thus the health coaching program is designed to be a patient-centered approach, focused on assisting participants to adopt healthy nutrition and physical activity behaviors, through motivational-interviewing and other engagement techniques. Health coaches will also tailor the delivery of information and the setting of goals to the participant’s readiness for change of specific diet and activity behaviors.

The program consists of weekly phone calls and monthly in person or “face” contacts over the course of six months. Participants will meet weekly by phone with the health coach at scheduled appointment times. The health coach will offer availability during the evening to best accommodate appointment times that are convenient for participants. Communication may be delivered by email if preferred.

2.9. **Follow-up clinic visits at 6 and 12 months**

At 6 months following randomization to the groups, participants will undergo a follow-up assessment. As before, during the week prior to a clinic visit, dietary and activity behaviors will be assessed under free-living conditions, using the TADA and activPAL™ tools. Participants will then return to the clinic for assessment of all other outcomes including status of glycemia. To determine the durability of the study intervention, all enrolled participants will undergo a similar assessment of diet, activity and glycemic measures at 12 months following the random assignment to groups. After this assessment, participants will have completed the study. At this time, focus groups will be conducted with participants and their parents/guardians to obtain feedback about their experience, and the discussions will also include quantitative and qualitative measures of patient satisfaction [65].

2.10. **Outcomes**

Outcomes will to be obtained at baseline and at 6 and 12 months following random assignment into the health coaching or dietary consult groups. A listing of all study outcomes and the timing of collection is provided in Table 1.

2.11. **Data analysis and sample size estimates**

Data will be analyzed using linear mixed-effect models and controlled for a subject level effect. Adjusted means will be reported for the different treatments at the different time...
points (baseline, 6 month post intervention, and 12 month follow up). Confounding factors such as sex, Race/ethnicity and age, as well as dietary intakes of nutrients and physical activity known to influence glycaemia and insulin action dynamics, will be controlled for in the linear mixed models. Since other outcomes including sleep [66] and mood disturbances [67] may affect study outcomes, we may include these in the model. Continuous data will be tested for normality and if the data is skewed, log transformation may be used to normalize data or non-parametric statistics will be used. Differences between groups will be analyzed using Chi-squared for categorical data and independent t-tests for continuous data. Data will be expressed as mean ± standard error, and P values less than or equal to 0.05 will be considered to indicate significant differences.

A sample size of 35 per group will be needed to determine an effect size of 0.67 standard deviations as statistically significant at a two sided alpha level of 0.05 and power of 0.8. This sample size will detect a difference of 0.17 mg/dL 0.94 mM in concentration of glucose at 2 h following the OGTT as statistically significant assuming a standard deviation of approximately 25 mg/dL (1.4 mM) [11]. To account for an attrition of 30%, this sample size will be increased to 46 per group.

3. Discussion

The DIG IT intervention aims to determine if health coaching can be used to prevent type 2 diabetes by improving self-efficacy of adolescents (and their families) regarding incorporation of healthy diet and activity behaviors. The prevalence of prediabetes in adolescents is high [2], fueled by the rising rates of obesity in this population [68]. In the context of the emerging epidemic of youth-onset T2D, an emphasis on strategies for prevention is warranted, especially since effective strategies for treatment are lacking. Lifestyle behaviors of adolescents are characteristically low in amount of physical activity, and excessively sedentary, high in dietary intake of refined grains, saturated fats and added sugars, and low in intake of fruits and vegetables. Independent of obesity, these lifestyle factors may promote the risk of developing T2D [36–40]. An intensive behavior modification program, demonstrated the efficacy of lifestyle intervention to improve nutrition and physical activity for reducing the risk of type 2 diabetes in adolescents, but it was conducted in the academic setting [11]. Such studies demonstrate efficacy but may be limited in ability to reach broad populations. Therefore there is a critical need for randomized controlled trials to translate diabetes prevention programs to the community or clinical setting.

Health coaches use a personalized approach that involves goal setting and motivational interviewing to assist individuals with behavior change. This approach may be successful in promoting the self-efficacy of adolescents, and their families, to adopt a healthy lifestyle. Potential advantages of using health coaches are 1) they are highly knowledgeable about evidence-based practices for lifestyle modification; 2) they can tailor recommendations to meet individual challenges and barriers; and 3) interactions between health coaches and participants can be convenient and inexpensive since they will be conducted through phone calls and email. The DIG IT protocol described will determine whether health coaching can be used to promote behavior change in adolescents in the free-living environment.
The impact of health coaching on diet and physical activity behaviors of the participants will be evaluated using objective measures that are non-invasive and well suited to the free-living environment. The TADA and activPAL instruments have been validated in adolescents to obtain highly-detailed information on diet and activity/inactivity. The measures will be used to assess participant’s adherence to the messages received from the intervention in terms of health coaching or single dietary consult. Thus we will be able to evaluate the fidelity of the treatment by directly assessing target behaviors. In addition, diabetes risk will be assessed using oral glucose tolerance testing which yields dynamic measures of insulin resistance and beta-cell function. We believe that the detail of information on diet, physical activity/inactivity as well as glucose and insulin action is a novel aspect of this project. Limitations of the protocol are that the neither the participants nor the study team will be blinded to treatment allocation, thus findings will be subjected to expectation bias. The data obtained may inform about direct influence of specific diet, activity as well as sedentary factors on markers of diabetes risk. This information will provide useful information about specific modifiable targets, besides weight loss, for preventing diabetes in adolescents who are at risk. Weight loss is particularly challenging to achieve in adolescents [6], therefore a low-cost, health coaching approach which enables adolescents to incorporate lifestyle behaviors that are anti-diabetogenic may have a positive and widespread impact on this emerging major public health issue.

Acknowledgments

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References


Fig. 1.
Conceptual framework of study.
Fig. 2.
## Table 1

### Description of outcome measures.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Detail of measures obtained</th>
<th>Instrument</th>
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<tr>
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<td>Secondary outcomes</td>
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<tr>
<td>Insulin action</td>
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<td>Elecsys Systems</td>
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<td>LPA, MPA, VPA, MVPA, total steps, total stepping time</td>
<td>activPAL™</td>
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<td>Sedentary behavior</td>
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<td>Height, weight, BMI, waist and hip circumference, SAD</td>
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<td>Quality of life</td>
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<tr>
<td>Parental perceptions of behavior</td>
<td>Perceived problems with weight-related behavior and self-efficacy</td>
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<td>Stage of change for health behavior</td>
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<tr>
<td>To be collected at 12 month follow-up</td>
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<tr>
<td>Focus groups</td>
<td>Participant/guardian satisfaction with the study</td>
<td>Quantitative and qualitative questions about satisfaction with study [65]</td>
</tr>
</tbody>
</table>

Abbreviations: HbA1c, hemoglobin A1c; OGTT, oral glucose tolerance test; WBISI, whole body insulin sensitivity index; IGT, insulinoergic index; DI, disposition index; HOMA, homeostatic model assessment; TADA, Technology Assisted Dietary Assessment; LPA, light physical activity; MPA, moderate physical activity; VPA, vigorous physical activity; MVPA, moderate to vigorous physical activity; NHANES, National Health and Nutrition Examination Survey; TC, total cholesterol; TG, triglycerides; HDL, high density lipoprotein; LDL, low density lipoprotein; SBP, systolic blood pressure; DBP, diastolic blood pressure.