Assessing the Efficacy of an Online Support Program on the Chronic Disease Management of Adolescents with Type 1 Diabetes: A Pilot Randomized Controlled Trial

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Section 1. Systematic Review: Effectiveness of Support Group Interventions for Patients with Type 1 Diabetes

Abstract

Background

Clear guidelines exist for optimizing insulin dosing, nutrition, and exercise in type 1 diabetes patients. However, recommendations regarding the management of psychosocial issues are less clear. One approach purported to effectively address these needs is diabetes support groups. This review evaluates published and unpublished literature on the effectiveness of this approach.

Methods

The MEDLINE, PsycINFO, Web of Science, CINAHL, EMBASE, and ClinicalTrials.gov databases were searched through April 2017 for studies on support group interventions in type 1 diabetes patients. One reviewer extracted all data from included trials and used the Cochrane Collaboration Tool and ROBINS-I (The Risk Of Bias In Non-randomized Studies – of Interventions) for quality assessment.

Results

Our search identified 329 published and 56 unpublished records. Only 29 records (eight of which are unpublished) were qualitatively synthesized. Diabetes skills practice groups were found to achieve small, but often statistically significant, improvements in glycemic control and psychosocial outcomes among patients with type 1 diabetes.

Conclusions

Diabetes skills practice groups have the strongest evidence in support of improving glycemic control and psychosocial outcomes in patients with type 1 diabetes. However, more research is needed within the United States to compare the effects of these groups against usual care in larger, and more diverse, populations.

Introduction

Recent epidemiological data suggest that 500,000 children under the age of 14 suffer from type 1 diabetes worldwide.[1] In the United States, there are around 3 million children and adults living with type 1 diabetes.[2] Individuals who suffer from type 1 diabetes are required to use exogenous insulin throughout their lifespan.[2] These patients must also monitor blood glucose levels, control carbohydrate intake, adjust treatment for physical activity, manage hypoglycemia, attend regular diabetes visits, and more to maintain glycemic control.[2] The American Diabetes Association has recommended that adults with type 1 diabetes achieve a hemoglobin A1c of <7.0% while youth under the age of 18 years reach a value of <7.5%.[2] Emotional distress in the diabetes population has been labeled "diabetes distress" and arises from the work required to achieve these target hemoglobin A1c values, diabetes complications, and a lack of social support.[3] Furthermore, the research literature suggests that diabetes distress has an appreciable effect on glycemic control.[3] Although clear guidelines exist for optimizing insulin treatment, nutrition, and physical activity, recommendations are less clear regarding the management of psychosocial issues in patients with diabetes.[2] One intervention method that has been cited to effectively address these needs is use of diabetes support groups.[4,5]

Searching the literature revealed only one systematic review on support groups for patients with type 1 diabetes.[5] The authors of the review assessed research studies on the efficacy and effectiveness of group psychosocial interventions published between 1970 and 2006 for improving psychological adjustment, diabetes treatment adherence, and glycemic control in children and adolescents under the age of 18 years with the disease.[5] Through their search, they found 31 eligible studies. To consolidate their findings, the authors categorized group interventions as psychoeducation/didactic, diabetes skills practice, and psychosocial.[5] There were

three psychoeducation/didactic, 12 diabetes skills practice, and 16 psychosocial interventions.[5] Most of these studies showed no appreciable change in glycemic control, as measured by hemoglobin A1c (HbA1c).[5] However, they did demonstrate improvements in treatment adherence, quality of life, perceived stress, attitude, social skills, and diabetes knowledge.[5] It is important to note that few of these studies examined their interventions in minority populations, limiting the generalizability of these findings.[5]

The purpose of this systematic review is to expand upon the prior systematic review by including support group interventions in adults with type 1 diabetes. An update on the effectiveness of group interventions in type 1 diabetes patients under the age of 18 years will also be provided. Generally, this review seeks to answer the following key question: are support group interventions effective in pediatric and adult type 1 diabetes patients?

Methods

Data Sources and Search Strategy

Both published and unpublished research studies regarding the feasibility, efficacy, or effectiveness of support group interventions in the type 1 diabetes patient population were included in this systematic review. In addition, a hand search of reference lists in all included studies was performed to identify more titles for review. Since Plante and Lobato evaluated the effects of these interventions in children and adolescents under the age of 18 years, this review only assessed the pediatric literature for studies published after 2005.[5] No time limits were set for support group interventions in adults with type 1 diabetes. While Plante and Lobato limited their search to the MEDLINE and PsycINFO databases, we expanded our search to include MEDLINE, PsycINFO, Web of Science, CINAHL, and EMBASE through April 8, 2017.[5]

Unpublished research was identified by searching the ClinicalTrials.gov database. We also used Plante and Lobato's search terms "diabetes" and "group treatment," "group therapy," "group psychotherapy," or "group intervention" as a basis for our search.[5] The search terms for this review included "type 1 diabetes" plus "support group," "group therapy," "group work," "group counseling," or "group intervention." *Appendix A* includes detailed search strategies for each database included in this review.

Study Selection

One reviewer (HG) performed title and abstract review of all identified research studies with inclusion criteria of English-language articles on original research examining the feasibility, efficacy, or effectiveness of support group or group-based interventions in patients with type 1 diabetes. We included published and unpublished studies in this review. Studies were excluded if the target population was people related to patients with type 1 diabetes or patients with comorbidities in addition to type 1 diabetes, the intervention included comprehensive care that went beyond education or support, or no evaluation data were presented. Dissertations, theses, and abstracts with no associated full-text article were also excluded. We placed no limitations on study design, comparison groups (not required), duration, setting, or outcome measures used. *Table 1* outlines the eligibility criteria in more detail. Subsequent full-text review of remaining research studies was performed using the same eligibility criteria. After full-text review, we excluded studies from 2005 or before if the target population was predominantly patients under the age of 18 years. The reference list of all remaining articles was hand searched for additional studies of relevance. Tools used for study selection are presented in *Appendix B.*

Data Extraction and Quality Assessment

We extracted data following the strategy used by Plante and Lobato in their own review.[5] Thus, data on study design (including comparison groups if applicable), type(s) of group intervention, study population, sample size, number of group sessions, and features of interventions were gathered. In addition, we collected information on study setting (country), eligibility criteria (unpublished studies only), intervention duration, outcome measures, results, and conclusions. The current status of unpublished studies is also provided. We used the Cochrane Collaboration Tool for assessing risk of bias to examine the internal validity of randomized controlled trials. This tool includes assessing for bias in random sequence generation, allocation concealment, blinding, missing data, selective reporting, and other sources of bias.[6] The Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) assessment tool was used to evaluate the internal validity of non-randomized controlled trials. This tool evaluates for bias in participant selection, intervention classification, outcome measurement, selective reporting, missing data, and bias due to deviations from intended interventions and confounding.[7] Both of these tools were slightly adapted for this review and are presented in *Appendix C*. All studies were graded to have a low, moderate, serious, or critical risk of bias according to the ROBINS-I grading scale to ease quality assessment interpretability across different study designs.

According to Cochrane guidelines, pre-post intervention studies without control groups should be excluded from systematic reviews assessing the effectiveness of an intervention, because confounding of results cannot be controlled.[6] However, we decided to include these trials in our review given that the majority of identified studies use uncontrolled pre-post designs. Instead of exclusion, we automatically rated any pre-post intervention study with no

control group to have a critical risk of bias when compared to randomized and non-randomized controlled trials.

Data Synthesis and Analysis

Given the heterogeneous nature of support group interventions in the literature, we did not perform a meta-analysis. Instead, data collected from identified research studies were synthesized in a qualitative manner. Studies were organized into the categories developed by Plante and Lobato, which include psychoeducation/didactic, diabetes skills practice, psychosocial, and emotional.[5] The category of psychosocial groups was further divided into the domains of family functioning, social skills, and stress management.[5] Within each category, study findings were summarized. We also emphasized similarities and differences across studies within the same intervention category. Any generalizable conclusions and limitations from each category of intervention were highlighted.

Results

Initially, 329 published and 56 unpublished articles were identified through the search strategy. After we removed duplicates, dissertations, and master's theses from our search findings, 301 records remained. Of these, 227 were excluded through title and abstract review using the preset eligibility criteria. The remaining articles underwent full-text review, leaving 21 eligible records for reference list hand-searching. We found eight additional articles, which brought our final total to 29 records for qualitative synthesis. Only eight of these were unpublished. *Figure 1* demonstrates the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Flow Diagram for this systematic review.

There is a total of 26 studies examining support group interventions in the type 1 diabetes population, of which 18 are published. The majority of studies were conducted outside of the United States, most notably in Northern Europe.[8–21] Even though we limited our search of the pediatric literature to a little over the past decade, we identified ten additional studies examining group interventions in patients aged 18 years or younger.[8,11,13,15,16,18,22–28] Seven studies restricted eligibility to those with poorly controlled type 1 diabetes as determined by HbA1c measurement.[9,10,19–21,28,29] Interventions lasted between 1 day and 2 years with one to 48 group sessions. The mean and median number of group sessions across all of the studies that reported this information (24 out of the 29 studies in this review) was 8.7 and 6.5 sessions, respectively. One study held an unlimited number of group sessions and was excluded from this calculation.[30] Another study held several small groups that met between six to ten separate times.[15,16] We counted ten group sessions in this study to arrive at our summary statistics above. Published studies had limited samples ranging from five to 327 participants. Only three of these published studies had sample sizes above 100 participants. *Tables 2* and *3* show more detailed information on each study.

A variety of support group interventions have been used in the type 1 diabetes population to improve glycemic control, quality of life, and psychosocial adaptation to disease. Researchers have tried psychoeducation/didactic, diabetes skills practice, psychosocial, and emotional support group strategies. Plante and Lobato describe psychoeducation/didactic group interventions as lecture-driven education on diabetes management with opportunities for group discussion.[5] Many of these groups follow standardized curricula.[5] On the other hand, diabetes skills practice groups use engaging skills-based activities to increase treatment adherence and improve diabetes management.[5] Often, participants complete homework assignments outside of

the group to reflect on their health.[5] Psychosocial group interventions focus on family functioning, social skills, or stress management.[5] Those that target family functioning usually incorporate the patient's parents or family members in groups to enhance family communication, coping abilities, and problem solving in the hopes of improving diabetes management behaviors and glycemic control.[5] Groups that develop social skills attempt to address the stigma and misunderstandings faced by patients with type 1 diabetes.[5] This may include having participants roleplay how they would describe their diabetes to others or how they would negotiate meals with family, friends, or peers.[5] It is important to note that none of the identified support group interventions in this review were categorized as a social skills group. Stress management groups address the acute and chronic stressors of having type 1 diabetes.[5] By identifying these stressors, learning how to appropriately cope with them, and knowing how to resolve them, the patient is better equipped to manage their diabetes.[5] When the group functions solely to provide patients with social support, the intervention is categorized as an emotional support group.[5] Below we walk through the results of each type of group intervention. *Table 4* presents these findings in more detail.

Psychoeducation/didactic groups

There are eight studies that employed a psychoeducational approach to the delivery of group care among patients with type 1 diabetes.[8,13–16,30–33] Of these, two were randomized controlled trials (one being unpublished and terminated due to insufficient recruitment) and one was non-randomized.[8,30,33] The remainder of studies used an uncontrolled pre-post study design. Most of these interventions had a lecture-based component or dedicated review of basic diabetes concepts. Four studies appeared to use a pre-specified curriculum to guide instruction.[8,13,15,16,31] Topics included, but were not limited to, the diabetes disease process, treatment options, blood

sugar monitoring, proper insulin injection technique, carbohydrate counting, physical activity, and acute and chronic complications of the disease. Group discussion and varying social activities were used to build group cohesion and reinforce what was covered during didactic instruction.

Psychoeducation/didactic groups demonstrated modest improvement in short and medium-term glycemic control in five of eight studies with the greatest effect shown by Warren-Boulton et al., a 2.3% mean decrease in HbA1c ($P<0.05$) among five participants from the second-half of the program to post-intervention.[32] However, all of these studies used a non-randomized or uncontrolled design to demonstrate effectiveness. For example, Mannucci E, et al. conducted a non-randomized controlled trial to examine the effect of an Interactive Educational and Support Group (IESG) on glycemic control and quality of life in patients with type 1 diabetes.[30] With the assistance of volunteer participants, diabetologists prepared topics for discussion that focused on blood glucose monitoring, insulin management, eating habits, physical activity, hypoglycemia, long-term complications, sick day management, pregnancy and contraception, and psychological adjustment to diabetes.[30] This intervention was compared to standard outpatient care and education.[30] Those within 30 kilometers from the clinic were assigned to treatment while those outside of that range were selected controls.[30] The authors included patients who refused participation (non-participants) into their analyses and found that participants of the group intervention experienced a mean decrease of 0.7% in HbA1c at one year compared to a decrease of 0.2% and 0.3% ($P<0.05$) in non-participants and selected controls, respectively.[30] Among participants, the authors found a decrease of HbA1c from 7.5±1.8% at baseline to 6.8±1.4 at one year ($P<0.001$) with maintenance of glycemic control at 2 years (6.8±1.3, $P<0.01$).[30]

In the only randomized controlled trial examining this type of group, reduction in HbA1c was not observed.[8] Christie D, et al. randomized 28 pediatric diabetes clinics to the Child and Adolescent Structured Competencies Approach to Diabetes Education (CASCADE) group program or routine care.[8] No difference in glycemic control between groups was observed at one year (0.11 mmol/l [95% CI, -0.28 to 0.50]).[8] At 2 years, CASCADE participants only reduced their HbA1c by 0.03 mmol/l (95% CI, -0.36 to 0.41) when compared to controls.[8]

Each of these studies also examined the effect of psychoeducation/didactic group interventions on self-reported psychosocial well-being. Results were mixed. In three different groups, patients experienced a small, but statistically significant, improvement in diabetes management, well-being, or diabetes-related distress.[8,14,30] While the group program of Christie D, et al. did not have an effect on glycemic control, the authors did report a small improvement in self-reported responsibility for diabetes management among CASCADE participants at 2 years when compared to those receiving routine care (Diabetes Family Responsibility Questionnaire score: 0.85 [95% CI, 0.03 to 1.61]).[8] Self-reported, diabetes-specific well-being improved among IESG participants from baseline (Mean Well-being Enquiry for Diabetes score: 75.2±11.8) to two years (82.4±10, P<0.01).[30] However, this effect disappeared when Mannucci E, et al. assessed well-being between groups.[30] In an uncontrolled pre-post study of group Diabetes Dialogue Meetings, 120 participants experienced an improvement in diabetes-related distress from baseline (Problem Areas in Diabetes [PAID] score: 30.4±16.6) to one year (27.4±17.1, P=0.03).[14] However, this result may be biased by uncontrolled confounding.

Diabetes skills practice groups

We identified ten research studies that assessed for the effectiveness of diabetes skills practice groups in the type 1 diabetes population.[9–11,17–20,24–26,28] Half were randomized controlled

trials (two of which are unpublished) while the other half were uncontrolled pre-post trials (one unpublished study with unknown status). Cognitive behavior therapy (CBT) was the most frequently used method of skills-based training delivered by these researchers.[9,10,19,26] Under the context of diabetes care, CBT involves addressing a participant's dysfunctional beliefs and attitudes toward diabetes management by developing positive coping behaviors.[19] Other studies used motivational interviewing, problem solving, and role playing to improve glycemic control and diabetes treatment management. One study used dramatic skit development as an innovative approach to encourage self-reflection of diabetes management and power relations surrounding food choice.[24,25]

Only one of seven published studies did not assess the effect of diabetes skills practice on glycemic control.[24,25] Of those that did, four demonstrated a statistically significant improvement in HbA1c, the largest difference being seen between groups in the Amsberg S, et al. randomized controlled trial (-0.94% at 24 weeks [95% CI, -1.36 to -0.51]).[9] In this study, the authors randomized participants to a CBT-based group program or routine diabetes care.[9] Both treatment arms briefly received a closed glucose monitoring system to manage blood sugars.[9] However, the group intervention also used this data to perform biofeedback.[9] In addition, the research team met with treatment group participants through a subsequent structured maintenance program that included two additional group sessions, two individual sessions, and repeated phone contact.[9] Amsberg S, et al. found that group participants maintained better HbA1c values than controls at 32 weeks (-0.72% [95% CI, -1.13 to -0.31]), 40 weeks (-0.56% [95% CI, -0.95 to -0.16]), and 48 weeks (-0.49% [95% CI, -0.87 to -0.11]).[9] Despite this success, participants did self-report an increased incidence of hypoglycemia at 24 and 48 weeks when compared those who received usual care alone, raising concern for overtreatment.[9]

In a second randomized controlled trial, van der Ven NCW, et al. compared group-based CBT to blood glucose awareness training (BGAT), which teaches patients to prevent and correct for blood sugar fluctuations, and found that CBT improved glycemic control more than BGAT at 3 months (-0.45% [95% CI, -0.86 to -0.04]).[10] However, the authors note that this difference is attributable to a statistically insignificant decrease in HbA1c among group participants and a slight increase in HbA1c in BGAT participants post-intervention.[10] Since the third randomized controlled trial conducted by Murphy HR, et al. was categorized as both a diabetes skills practice and psychosocial – family functioning group, the results are detailed under the latter category instead.[11]

The final study to demonstrate an appreciable effect on glycemic control was an uncontrolled pre-post trial assessing for the effectiveness of group-based CBT in patients with poorly controlled type 1 diabetes.[19] At 3 months, participants had a mean decrease in HbA1c from 9.3±1.2% to 8.7±1.3%.[19] This control was maintained at 6 months (8.5±0.91%, P=0.04).[19]

Unlike glycemic control, all published studies monitored the effect of diabetes skills practice on psychosocial outcomes. Results were generally favorable in group interventions. Amsberg S, et al. reported that participants self-monitored blood sugar levels more than controls at 12 (Summary of Diabetes Self-Care Activities-Blood sugar testing subscale score: 1.87 [95% CI, 0.77 to 2.96]), 24 (2.20 [95% CI, 1.19 to 3.21]), and 48 weeks (1.39 [95% CI, 0.35 to 2.44]).[9] While this trial found improvements in both glycemic control and psychosocial outcomes, van der Ven NCW, et al. did not.[10] Group-based CBT and BGAT similarly improved short-term, diabetes-specific emotional distress in patients with poorly controlled type 1 diabetes.[10] Had they compared their group intervention to usual care, statistically significant improvements might have been observed.

Uncontrolled pre-post trials conducted by Due-Christensen M, et al. and Waller H, et al. using an empowerment-based support group and diabetes management skills group, respectively, did show improvements in general self-care, self-efficacy and quality of life; diabetes-specific quality of life, diabetes-related distress, diabetes treatment satisfaction, and diabetes management responsibility.[17,18] Although glycemic control improved among participants in the study conducted by Snoek FJ, et al., no change was seen in general well-being, diabetes-related distress, or fear of hypoglycemia at 6 months.[19] The authors state that this demonstrated the effectiveness of the group intervention on improving diabetes health without adversely affecting a participant's psychosocial well-being.[19]

Psychosocial groups

Seven studies used a psychosocial group intervention in patients with type 1 diabetes.[11,21–23,27,29,34,35] Although four of these were randomized controlled trials, two remain unpublished (one has been completed while the other is still recruiting patients).[11,21–23,29] One unpublished non-randomized controlled trial (still recruiting patients) and two uncontrolled pre-post trials (one of which was unpublished and has since been withdrawn) were found.[27,34,35] Out of all of these studies, three were categorized as family functioning groups (one unpublished non-randomized controlled trial) and four were defined as stress management groups (two unpublished randomized controlled trials and one withdrawn uncontrolled pre-post trial). None of the psychosocial group interventions fit under the category of social skills. However, the aforementioned wait-list, randomized controlled trial by Murphy HR, et al. functioned as both a diabetes skills practice group and psychosocial – family functioning group.[11]

Family functioning

None of the studies that addressed family functioning in the type 1 diabetes population examined its effects on adult patients with type 1 diabetes aged 18 years and above. Consequently, all of these groups had parental involvement. Murphy HR, et al. held two skills-based sessions on carbohydrate counting and insulin dose adjustment, and two family-based sessions where parents and children worked together to negotiate diabetes management responsibility, and to enhance family communication and problem solving abilities.[11] Whereas these authors conducted joint parent-child sessions, the randomized controlled trial by Grey M, et al. comparing group-based coping skills training to supplementary diabetes group education had parents and children meet in separate groups to develop skills in communication, social problem solving, conflict resolution, stress management, and self-talk before joining together toward the end of each session to discuss and apply these skills to family dynamics.[22,23]

Family-based psychosocial group interventions do not appear to have any noticeable effect on glycemic control. Neither of the randomized controlled trials conducted by Grey M, et al. or Murphy HR, et al. showed a statistically significant difference in HbA1c between groups.[11,22,23] Murphy HR, et al. did find that group attendees experienced greater decreases in HbA1c than non-attendees at 12 (-0.23% [attendees] vs 0.11% [non-attendees], P=0.03) and 24 months (-0.29% [attendees] vs 0.11% [non-attendees], P=0.04).[11] However, these results are at serious risk of confounding bias given that the statistical analysis used to arrive at them was not based on the randomization to control for baseline characteristics across groups.[11]

When examining the effect of this type of group intervention on psychosocial outcomes, similar conclusions were drawn. No difference was seen in general and diabetes-specific quality of life, depressive symptoms, coping skills, family functioning, self-efficacy, diabetes

management responsibility, or diabetes-related distress between groups in the randomized controlled trials by Grey M, et al. or Murphy HR, et al.[11,22,23]

Stress management

The one published study on psychosocial stress management groups used conjunctive group psychotherapy in adult Greek patients with type 1 diabetes.[34] This type of therapy aims to improve glycemic control and psychosocial outcomes by having patients accept their disease, and modify their attitudes and beliefs toward diabetes self-management.[34] A significant part of this therapy also involves diabetes re-education.[34] Unpublished studies are attempting to use Mindfulness Based Stress Reduction, Acceptance and Commitment Therapy, and CBT to improve health outcomes in this patient population.[21,29,35] One of these unpublished studies has already been withdrawn while the rest do not have results available at this time.

Tsamparli and Siousioura assert that conjunctive group psychotherapy significantly improved glycemic control in their small sample of 32 patients with type 1 diabetes.[34] They found that participants reduced their HbA1c from 7.3% at baseline to 6.4% post-intervention.[34] However, the uncontrolled pre-post study design leaves this result at critical risk of bias due to confounding. Although the authors did not measure any specific psychosocial outcome among their participants, they did perform focused interviews to examine psychological adjustment to type 1 diabetes.[34] In general, participants commented that the group helped them accept their diabetes, communicate better, build self-efficacy, create supportive networks, and foster a positive outlook on life.[34]

Emotional support groups

Only two studies were found to run support groups based on social support alone.[12,36] One was a non-randomized controlled trial while the other was an uncontrolled pre-post study. No unpublished studies were found. While the principal investigator and a diabetes nurse specialist facilitated groups in one study, the other used a clinical psychologist to guide discussion. Both research teams attempted to create safe group environments to encourage group cohesion and open conversation.

Neither study demonstrated that emotional support groups affect glycemic control in patients with type 1 diabetes. Post-intervention, Markowitz and Laffel found that the HbA1c of participants decreased from 7.9±1.4% at baseline to 7.6±1.1% (P=0.10).[36] Hanestad and Albrektsen also reported no statistically significant difference in HbA1c between support group participants and those receiving usual care after completion of the intervention.[12]

Both studies also assessed psychosocial outcomes among their participants. While Markowitz and Laffel saw decreases in diabetes-related distress (PAID score: 55.5±15.6 to 38.5±19.2, P=0.02) and increases in self-care (Self-Care Inventory-Revised score: 63.6±12.3 to 72.0±13.7, P=0.09) post-intervention, Hanestad and Albrektsen reported no difference in quality of life between groups.[12,36] Again, the results from the uncontrolled pre-post trial by Markowitz JT and Laffel LMB suffer from confounding bias, which decreases the validity of these findings.

Discussion

An exhaustive search of the literature demonstrates that an active, but varied, approach to support group interventions in the type 1 diabetes population exists. Most researchers have used diabetes skills practice groups to help patients achieve better glycemic control and quality of life.

Although more than half of published studies (ten out of 18) demonstrated improved glycemic control in their study populations, most of this research used an uncontrolled pre-post study design. HbA1c values did not change in four of five randomized controlled trials. The one trial that did show a statistically significant improvement in glycemic control had a small sample size of 74 participants, limiting its generalizability.[9] It was difficult to assess the overall effect of these group interventions on self-reported psychosocial outcomes given the variety of patient reported outcome measures used by research teams. However, a similar degree of effectiveness was found. Eight out of 18 published trials (two being randomized controlled trials) demonstrated small, but statistically significant improvements in quality of life, diabetes-specific well-being, diabetes-specific self-care, diabetes-specific self-efficacy, diabetes-related distress, diabetes treatment satisfaction, diabetes management responsibility, and blood sugar testing adherence.

Although these research studies often expressed favorable outcomes in patients with type 1 diabetes, the quality of evidence was questionable. The majority of identified studies used an uncontrolled pre-post design to evaluate health outcomes. Any findings from these studies are affected by confounding due to age, sex, race/ethnicity, diabetes duration, baseline glycemic control, income, health care utilization, and more. Only one study was found to be at low risk of bias.[8] However, the cluster randomized controlled trial conducted by Christie, et al. found that a psychoeducation/didactic group intervention fails to improve glycemic control among families of patients with type 1 diabetes.[8] The authors only found that children held more responsibility for their diabetes management post-intervention when compared to those who received routine care alone.[8]

Applicability of these research findings is also lacking. The majority of studies contained less than 100 participants with the largest study examining the effects of support group interventions in 327 patients with type 1 diabetes.[8] This not only limits the statistical power of these studies, it also restricts their generalizability to the greater type 1 diabetes population. Most participants were white females from Northern European countries including England, Sweden, Norway, Denmark, and the Netherlands. Only one study assessed a support group intervention in Black females.[32] Furthermore, this study only enrolled five participants and followed an uncontrolled pre-post design.[32]

Given our findings, patients with type 1 diabetes are unlikely to experience substantial improvements in glycemic control or quality of life by participating in group interventions. Even though few studies examined the associated harms of group participation, the risks appear to be minimal including breaches of confidentiality and added psychological distress arising from reliving uncomfortable experiences or misunderstandings with fellow participants. A less common, but significant, side effect of group participation may include increased hypoglycemia. In one study, participants were found to have an increased risk of experiencing more hypoglycemic episodes when compared to those receiving standard diabetes care.[9] However, no diabetes-related hospitalizations were reported.[9] Thus, group interventions like these could supplement standard care for patients who seek this type of support. Any improvement in glycemic control could help reduce the risk of long-term diabetes complications such as blindness, kidney disease, foot ulcerations, and lower extremity amputations. In turn, reduced hospitalizations, medical management, and lost productivity would lessen the burden of diabetes on the health care system and economy.

More research is needed on group interventions to confirm improvements in glycemic control demonstrated by identified uncontrolled pre-post intervention studies. Future research should focus on conducting larger randomized controlled trials comparing support group interventions to usual care. By doing so, confounding of results will be minimized. Since the United States has about 3 million patients with type 1 diabetes, and yearly costs from all forms of diabetes are in the billions, more of this kind of research needs to be conducted on American populations.[2,37] Given the demographic make-up of this country, a greater emphasis needs to be placed on achieving a diverse sample population. This will require that barriers to participation are minimized. Potential barriers may include transportation, work or school obligations, and financial restrictions.[13] Regardless of the study design or population, all future research needs to report findings transparently, so that key stakeholders can assess and implement new information appropriately. However, issues with reporting have improved substantially from the oldest identified research studies to the newest.

There are a few limitations to this systematic review. Although we searched several databases, including the grey literature, our restricted search strategy may have inadvertently excluded relevant articles. Depending on the findings of unidentified research, our results may be skewed toward or away from the null hypothesis, that support group interventions do not affect glycemic control or psychosocial outcomes in patients with type 1 diabetes. In addition, we only had one reviewer identify, select, and appraise the research in this field. Thus, replicability of our research findings remains to be demonstrated.

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Figure(s) – *PRISMA Flow Diagram*

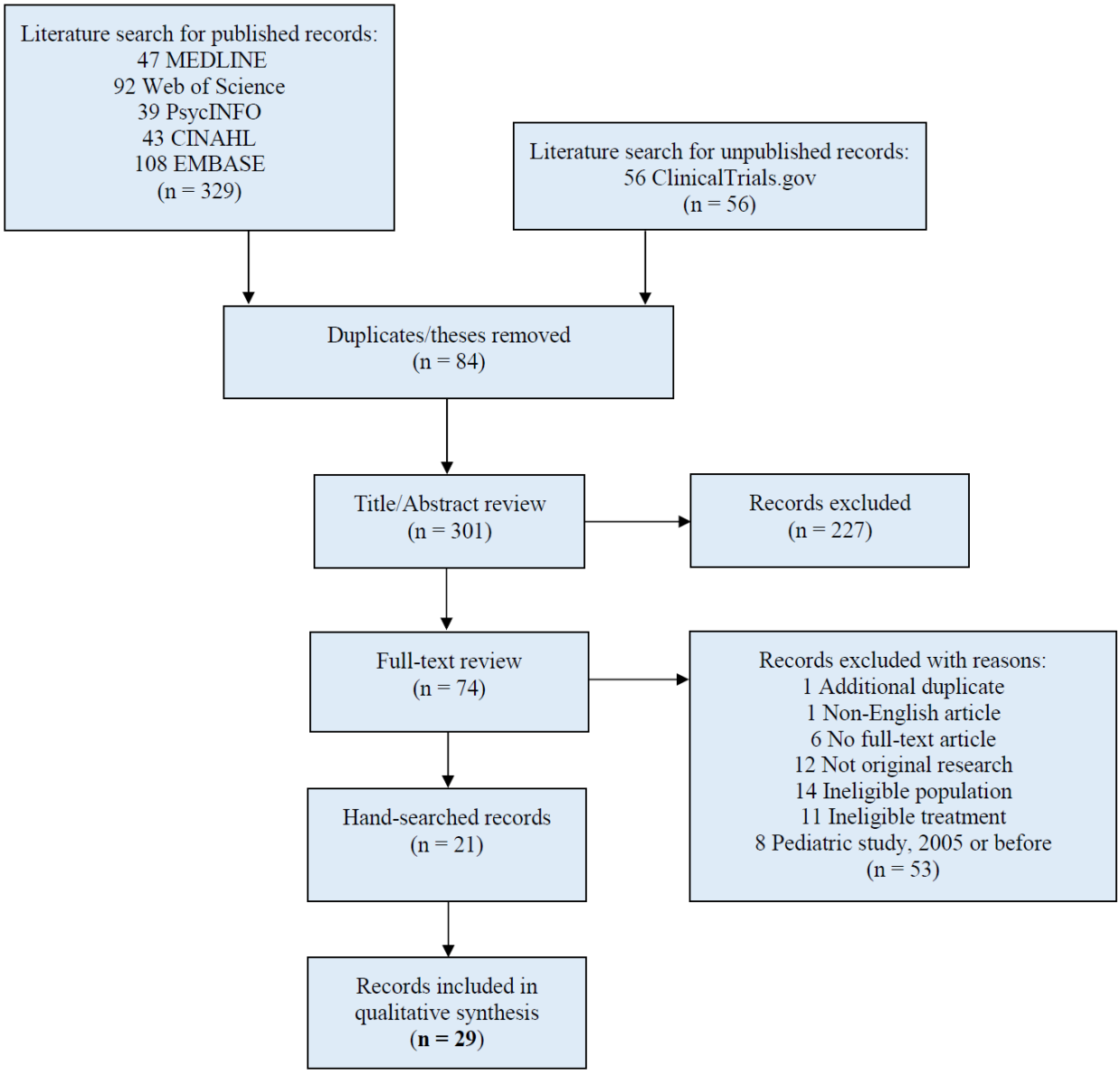


Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Flow Diagram of article selection for systematic review.

Tables – *eligibility criteria, published and unpublished study characteristics, results and quality assessment for published and unpublished studies*

Table 1. Eligibility criteria for research studies included in the systematic review.

	Include	**Exclude**
Populations	Patients with type 1 diabetes (including studies of children and adolescents under the age of 18 years if published 2006 or after)	• Studies of children and adolescents under the age of 18 years if published 2005 or before • Parents of children and adolescents with type 1 diabetes • Other people related to patients with type 1 diabetes (family, friends, health care providers, teachers, etc.) • Patients with one or more comorbidities in addition to type 1 diabetes
Intervention	Support group or group-based interventions (group therapy, group counseling, group education, etc.)	Group interventions that include comprehensive health care services that go beyond education or support (diabetes group visits, shared medical appointments, camps, etc.)
Comparisons	--	--
Outcomes	--	Studies that do not report any evaluation data (descriptive or summary reports, literature reviews, study protocols, etc.)
Timing	--	--
Setting	--	--
Study designs	--	--

Table 2. Characteristics of published support group intervention studies in the type 1 diabetes population*

Type(s) of Group Intervention	Reference(s)	Country	Study Population	Sample Size (I/C)	Number of Sessions	Duration	Features of intervention(s)	Outcome measures
Randomized controlled trials								
Psychoeducation/didactic	Christie D, et al. (2014)	England	Age: 8-16 years Gender (I/C): 57.2% F/53.6% F €Families included	Cluster RCT: 28 clinic sites (14/14) Participants: 327 (159/168)	4	4 months	I: clinic-based structured education program for families of children with type 1 diabetes including psychological techniques for behavior change. C: routine NHS care.	P: HbA1c at 12 and 24 months S: hypoglycemic episodes, hospital admissions; self-reported diabetes regimen, knowledge, skills, management responsibility (DFRQ), frequency of missed insulin dosing, intervention compliance, clinic utilization, emotional and behavioral adjustment ('Impact Supplement' of SDQ), happiness with bodyweight, skipping insulin to lose weight, general and diabetes-specific QoL (PedsQL) at 12 and 24 months^.
Diabetes skills practice	Amsberg S, et al. (2009)	Sweden	Age: 18-65 years Gender (I/C): 44.4% F/57.9% F ¥Poor glycemic control	74 (36/38)	9	48 weeks	I: CBT-based program including biofeedback using CGMS data with 7 group sessions, 1 individual session, and a subsequent structured maintenance program with 2 group sessions, 2 individual sessions, and additional phone contact. C: routine diabetes care with brief CGMS use.	P: HbA1c at 8, 16, 24, 32, 40, and 48 weeks. S: self-reported psychosocial questionnaires including SDSCA, DSCI, PAID, HFS, WBQ-12, PSS, and HAD at 12 (SDSCA only), 24, and 48 weeks.
	van der Ven NCW, et al. (2005)	Netherlands	Age: 20-60 years Gender+: 59.1% F ¥Poor glycemic control	88 (45/43)	6	6 weeks (with 3-month run-in period)	I: CBGT C: Dutch adaptation of BGAT.	P: HbA1c, self-reported diabetes-specific self-efficacy (CIDS), and diabetes-related distress (PAID) at 3 months S: self-reported psychosocial questionnaires including CES-D and DSCI at 3 months; general program appreciation post-intervention.
Psychosocial – family functioning	Grey M, et al. (2009); Ambrosino JM, et al. (2008)	United States	Age: 8-12 years Gender (I/C): 57% F/69% F €Parents included	82 (53/29)	6	6 weeks	I: CST with separate parent group; parents brought in toward end of each session. C: supplementary group diabetes education.	P: HbA1c, self-reported QoL (DQOL), depressive symptoms (CDI), coping (Issues in Coping with T1D-Child Scale), self-efficacy (SED), and family functioning (DFBS) at 1, 3, 6, and 12 months^.
Diabetes skills practice AND Psychosocial – family functioning	Murphy HR, et al. (2007)	England	Age: 8-16 years Gender (I/C): 45% F/44% F €Families included	Wait-list RCT: 78 (33/34) Cross-over: 11 (7 to I, 4 to C)	4	1 year	I: family-centered structured education program held during scheduled clinic visits; 2 sessions were skills-based; 2 were family-based. C: delayed start by 1 year.	P: HbA1c every 3 months; self-reported QoL (Peds QL), diabetes-related distress (PAID), and diabetes management responsibility (DFRQ) post-intervention^.
Non-randomized controlled trials								
Psychoeducation/didactic	Mannucci E, Pala L, Rotella CM (2005)	Italy	Age: 15-45 years Gender (I/selected controls): 56.2% F/56.8% F	181 (96/37 selected controls/48 non-participants)	Unlimited (met every other week)	Unlimited	I: IESG program that allowed new participants to enter if existing participants withdrew. C: standard outpatient care and education.	P: HbA1c and self-reported QoL (WED) at 1 and 2 years; daily number of insulin injections, and total daily insulin dosing.
Emotional support	Hanestad BR, Albrektsen G (1993)	Norway	Age: 17-74 years Gender (I/C): 45.8% F/41.7% F ₭Self-reported reduced QoL	60 (24/36)	12	6 months	I: support group led by the principal investigator and a diabetes nurse specialist. C: usual care.	P: self-reported QoL post-intervention. S: HbA1c post-intervention.
Uncontrolled pre-post trials								
Psychoeducation/didactic	Cai RA, et al. (2017)	England	Age: 8-16 years Gender: 36.4% F €Families included	22	1	1 day (~5.5 hours)	Several interactive and educational group activities throughout the day; parents met in separate groups, but worked with children most of the time.	P: feasibility (program uptake, final attendance, drop-out rate, and participation barriers) and self-reported program acceptability. S: HbA1c, number of hypoglycemic episodes, and self-reported fear of hypoglycemia (HFS-II) at 1-3 months post-intervention^.
	Due-Christensen M, Hommel E, Ridderstrale M (2016)	Denmark	Age: 21-76 years Gender: 75% F	120	4	17 months	DDMs started with introductory diabetes lectures, followed by experience-based talks from guests with type 1 diabetes, and ended with small group discussions.	P: self-reported diabetes-related distress (PAID) at 1 year. S: HbA1c and self-reported diabetes competence (PCD) at 1 year.
	Loding RN, Wold JE, Skavhaug A (2008); Loding RN, et al. (2007)	Norway	Age: 13-18 years Gender: 52.6% F €Parents included	19	6-10	1 year	Group therapy focused on diabetes re-education that included warm-up activities (i.e., painting, movement exercises) and group discussion; parents met in separate groups.	P: HbA1c during participation, and at 1 and 2 years; self-reported QoL (DQOL) at 4 months, and 1 and 2 years; and self-reported patient satisfaction at 2 years+, ^.
	Shalom R (1991)	United States	Age: 17-31 years Gender+: unknown	20	10	10 weeks	Didactic diabetes lectures with group discussion.	P: HbA1c, self-reported diabetes knowledge and behavior, and an essay on "How did the group experience affect you?" post-intervention.
	Warren-Boulton E, et al. (1981)	United States	Age: 17-23 years Gender: 100% F	5	18	18 months	Educational group review of diabetes-related medical records to improve diabetes management.	P: HbA1c, mean blood glucose levels, cholesterol, and self-reported diabetes treatment adherence and self-management behaviors post-intervention.
Diabetes skills practice	Due-Christensen M, et al. (2012)	Denmark	Age: ≥21 years Gender: 79.6% F	54	8	3-4 months	Support group based on empowerment, motivational interviewing, and problem-solving interventions.	P: self-reported diabetes-related distress (PAID) at 4,6, and 12 months. S: HbA1c and self-reported psychosocial questionnaires including SCL-90-R and WHO-5 at 4, 6, and 12 months.
	Basso RVJ, Pelech WJ (2008)	Canada	Age: 4-12 years Gender+: unknown	35	3	1 week	Dramatic skit development with group discussion.	P: Self-reported goal attainment (diabetes and general health knowledge) and thematic analysis.
	Waller H, et al. (2008)	England	Age: 11-16 years Gender: 47.9% F	48	5	5 days	Skills-based education on carbohydrate counting and insulin dose adjustment.	P: HbA1c, BMI, and number of hypoglycemic episodes (diary report) at 3 and 6 months; and self-reported psychosocial questionnaires including PedsQL, DTSQ, DFRQ, SED, and DFCS at 2 weeks, and 3 and 6 months^.
	Snoek FJ, et al. (2001)	Netherlands	Age: 18-50 years Gender: 62.5% F ¥Poor glycemic control	24	4	4 weeks	CBGT	P: HbA1c and self-reported psychosocial questionnaires including PAID, WBQ-12, DSCI, BDQ, and HFS at 3 and 6 months.
Psychosocial – stress management	Tsamparli A, Siousioura D (2009)	Greece	Age: 19-38 years Gender: 59.4% F	32	48	2 years	Conjunctive Group Psychotherapy with supplemental education provided by endocrinologists or dieticians as needed.	P: HbA1c, thematic analysis (focus interviews) post-intervention.
Emotional support	Markowitz JT, Laffel LMB (2012)	United States	Age: 18-30 years Gender: 93% F	15	5	5 months	Unstructured support group facilitated by a clinical psychologist.	P: HbA1c, clinic visit frequency, and self-reported diabetes-related distress (PAID) and QoL (SCI-R) post-intervention.

*Abbreviations: I/C (intervention/control); F (female); P (primary outcome measure/s); S (secondary outcome measure/s); NHS (National Health Service); T1D (type 1 diabetes); HbA1c (glycosylated hemoglobin); CGMS (continuous glucose monitoring system); BMI (body mass index); QoL (quality of life); CBT (cognitive behavior therapy); CBGT (cognitive behavioral group training); BGAT (blood glucose awareness training); CST (coping skills training); IESG (Interactive Educational and Support Group); DDMs (Diabetes Dialogue Meetings); DFRQ (Diabetes Family Responsibility Questionnaire); SDQ (Strengths and Difficulties Questionnaire); PedsQL (Pediatric Quality of Life Inventory); SDSCA (Summary of Diabetes Self-Care Activities); DSCI (Diabetes Self-Care Inventory); PAID (Problem Areas In Diabetes); HFS (Hypoglycemia Fear Survey); WBQ-12 (Well-Being Questionnaire-12); PSS (Perceived Stress Scale); HAD (Hospital Anxiety and Depression); CIDS (Confidence In Diabetes Self-care); CES-D (Centre for Epidemiological Studies scale for Depression); DQOL (Diabetes Quality of Life Scale for Youth); CDI (Children's Depression Inventory); SED (Self-Efficacy for Diabetes); DFBS (Diabetes Family Behavior Scale); WED (Well-being Enquiry for Diabetes); PCD (Perceived Competence in Diabetes); SCL-90-R (Symptom Checklist-90-Revised); WHO-5 (World Health Organization 5 well-being index); DTSQ (Diabetes Treatment Satisfaction Questionnaire); DFCS (Diabetes Family Conflict Scale); BDQ (Barriers in Diabetes Questionnaire); SCI-R (Self-Care Inventory-Revised).

€Families/parents were included as participants in some portion of the intervention provided. See cited reference(s) for more information.

¥Study limited inclusion to those with poor glycemic control (based on glycosylated hemoglobin). See cited reference(s) for cut-off thresholds.

₭Study limited inclusion to those with self-reported reduced quality of life. See cited reference(s) for cut-off thresholds.

+Insufficient information provided by authors. Presented data unclear/unavailable.

^Parent outcome measures not presented. See cited reference(s).

Table 3. Characteristics of unpublished support group intervention studies in the type 1 diabetes population*

Type(s) of Group Intervention	Principal Investigator (ClinicalTrials.gov Identifier)	Country	Eligibility Criteria	Sample Size	Number of Sessions	Duration	Features of intervention(s)	Outcome measures	Current Status€
Randomized controlled trials									
Psychoeducation/didactic	Mannucci E (NCT02443532)	Italy	Inclusion: diagnosis of type 1 diabetes, 15-65 years of age, all sexes Exclusion: serious diabetes complications (i.e. lower limb amputation, renal failure requiring dialysis, blindness), illiteracy	72	6	6 weeks	I: group education focused on improving diabetes management. C: usual care.	P: HbA1c at 12 months. S: incidence of hypoglycemia (requiring hospitalization and/or help from third parties) and self-reported quality of life (WED), treatment satisfaction (DTS), and fear of hypoglycemia (FH-15) at 12 months.	Terminated (insufficient recruitment)
Diabetes skills practice	Graue M (NCT01317459)	Norway	Inclusion: diagnosis of type 1 diabetes with HbA1c ≥8%, 18-55 years of age, all sexes Exclusion: pregnancy, decreased cognitive function and/or serious mental health disturbances, language barriers to Norwegian language	216	7	No information provided	I: GSD C: usual care.	P: HbA1c at 9 and 18 months. S: self-reported psychosocial questionnaires including WHO-5, TSRQ, PAID, Rosenberg's self-esteem scale, PCD, HCCQ, and DDS at 9 and 18 months.	Active, no recruiting
	No information provided (NCT02839031)	France	Inclusion: diagnosis of insulin-treated type 1 diabetes for at least 1 year, 6-18 years of age, all sexes, followed in the pediatric diabetology department of the Arnaud de Villeneuve Hospital, with informed consent from parents and child Exclusion: developmental delay, severe mental disorders, language delay, non-French speaking, does not live with at least one parent, residence is not compatible with frequent visits to University Hospital of Montpellier, clinical status not compatible with study questionnaire assessment	80	No information provided	No information provided	I: CBT for children with type 1 diabetes and their parents. C: phone contact without CBT.	P: HbA1c at 12 months.	Recruiting
Psychosocial – stress management	Ellis D (NCT02760303)	United States	Inclusion: diagnosed with type 1 diabetes for at least 6 months, HbA1c ≥9%, 16-20 years of age, all sexes Exclusion: mental health conditions that might compromise data integrity, comorbidities affecting diabetes management, inability to speak or read English	108	9	9 weeks	I: MBSR; CBT C: diabetes education in a support group format.	P: HbA1c at 3 and 6 months. S: frequency of glucose meter testing and self-reported regimen adherence (daily diary, DMS), general (PSS, Hassels and Uplifts Scale) and diabetes-specific psychological stress (DSQ), and QoL (DQOL) at 3 and 6 months.	Completed (no results posted)
	Anderbro T (NCT02914496)	Sweden	Inclusion: diagnosis of type 1 diabetes for at least 2 years, with HbA1c >60 mmol/mol, 18-70 years of age, all sexes Exclusion: non-Swedish speaking, untreated or severe ongoing psychiatric disease, cortisone treatment, untreated thyroid disease, insulin pump therapy started in last 3 months	70	7	14 weeks	I: ACT C: usual care.	P: HbA1c at 12 months. S: self-reported self-care (Manchester Short Assessment of Quality of life) and other psychosocial questionnaires including Depression Anxiety stress scales, HFS, PAID, Acceptance and action diabetes questionnaire, and Summary of Self-Care Activities at 1-5 years.	Enrolling by invitation
Non-randomized controlled trial(s)									
Psychosocial – family functioning	Kichler J (NCT01626586)	United States	Inclusion: diagnosis of type 1 diabetes for at least 6 months, 10-17 years of age, all sexes, at least one parent/caregiver participates Exclusion: co-existing diagnosis of mental retardation, pervasive developmental disorder, substance abuse, eating disorders, psychosis, or other acute psychiatric or medical needs (i.e., suicidality); not fluent in the English language	80	6	7 weeks	I: group therapy; parents meet in separate groups but come together toward the end of each session; "booster" follow-up sessions. C: individual therapy with parents coming in toward the end of each session; "booster" follow-up sessions.	P: self-reported diabetes responsibility, adherence, and parent-child interactions post-treatment, and at 2 and 4-month follow-up^. S: HbA1c and health care utilization (number of emergency room visits, inpatient hospitalizations) post-treatment and at 6-month follow-up.	Recruiting
Uncontrolled pre-post trials									
Diabetes skills practice	MacKenzie H (NCT02212158)	Canada	Inclusion: documented history of elevated HbA1c values for at least 3 months, 13-17 years of age, all sexes Exclusion: patients with type 2 diabetes, who are medically unstable (comorbidities), and refuse to participate	20	8	8 weeks	Motivational interviewing group using cognitive behavioral techniques; parents participate in three out of eight sessions.	P: HbA1c at 3, 6, 9, and 12 months. S: self-reported self-efficacy (SED), family support (Diabetes Family Behavior Scale), symptoms of depression (BDI-Y), QoL (DQOL), readiness to change (Diabetes Management Questionnaire), hypoglycemia (Low Blood Sugar Survey), and hope (Children's Hope Scale) at 8, 16, and 60 weeks^.	Unknown
Psychosocial – stress management	Merwin R (NCT02256293)	United States	Inclusion: diagnosed with type 1 diabetes, 18-65 years of age, all sexes, currently monitored by physician for diabetes Exclusion: psychosis or mania, substance abuse, intellectual deficits that preclude informed consent, non-English speaking	No information provided	8	8weeks	ACT	P: acceptability (post-intervention questionnaire) at 8 weeks. S: self-reported diabetes self-management (pre-post intervention questionnaire) at 8 weeks.	Withdrawn

*Abbreviations: I/C (intervention/control);); P (primary outcome measure/s); S (secondary outcome measure/s); HbA1c (glycosylated hemoglobin); GSD (Guided Self-determination); CBT (Cognitive Behavioral Therapy); MBSR (Mindfulness Based Stress Reduction); ACT (Acceptance and Commitment Therapy);); WED (Well-being Enquiry for Diabetes); DTS (Diabetes Treatment Satisfaction); FH-15 (Fear of Hypoglycemia 15-item scale); WHO-5 ((World Health Organization 5 well-being index); TSRQ (Treatment Self-Regulation Questionnaire); PAID (Problem Areas in Diabetes); PCD (Perceived Competence in Diabetes); HCCQ (Health Care Climate Questionnaire); DDS (Diabetes Distress Scale); DMS (Diabetes Management Scale); PSS (Perceived Stress Scale); DSQ (Diabetes Stress Questionnaire); DQOL (Diabetes Quality of Life); HFS (Hypoglycemia Fear Survey); SED (Self-efficacy for Diabetes scale); BDI-Y (Beck Depression Inventory for Youth).

€ClinicalTrials.gov Current Status: Completed; Active, not recruiting; Recruiting; Enrolling by invitation; Withdrawn; Terminated; Unknown

^Parent outcome measures not presented. See cited reference(s).

Table 4. Results and quality assessment of published support group intervention studies in the type 1 diabetes population*

Type(s) of Group Intervention	Reference(s)	Results€	Conclusions	Quality Assessment¥
Randomized controlled trials				
Psychoeducation/didactic	Christie D, et al. (2014)	Mean difference in HbA1c between groups: 12 months (0.11 mmol/l [95% CI, -0.28 to 0.50]); 24 months (0.03 mmol/l [95% CI, -0.36 to 0.41]) Mean difference in DFRQ score between groups^: 24 months (0.85 [95% CI, 0.03 to 1.61]) Mean difference in happiness with body weight score between groups: 24 months (-0.56 [95% CI, -1.03 to -0.06])	Although cost per site was low, glycemic control among CASCADE participants did not improve when compared to non-participants. Thus, the program was not cost-effective. Post-intervention, participants were also less satisfied with their body weight when compared to non-participants. However, responsibility for diabetes management improved more among participants than non-participants.	Low
Diabetes skills practice	Amsberg S, et al. (2009)	Mean difference in HbA1c between groups: 8 weeks (-0.67% [95% CI, -0.97 to -0.36]); 16 weeks (-0.89% [95% CI, -1.30 to -0.48]); 24 weeks (-0.94% [95% CI, -1.36 to -0.51]); 32 weeks (-0.72% [95% CI, -1.13 to -0.31]); 40 weeks (-0.56% [95% CI, -0.95 to -0.16]); 48 weeks (-0.49% [95% CI, -0.87 to -0.11]) Mean difference in SDSCA score between groups: Blood sugar testing at 12 weeks (1.87 [95% CI, 0.77 to 2.96]); 24 weeks (2.20 [95% CI, 1.19 to 3.21]); 48 weeks (1.39 [95% CI, 0.35 to 2.44]) Hypoglycemic at 24 weeks (2.33 [95% CI, 0.46 to 4.21]); 48 weeks (2.34 [95% CI, 0.01 to 4.66])	A CBT-based intervention including both group and individual sessions, and a structured maintenance program, appeared to improve glycemic control and diabetes self-management more than routine diabetes care alone in adults with poorly controlled type 1 diabetes. A side effect of the intervention was increased hypoglycemia among participants.	Moderate
	van der Ven NCW, et al. (2005)	Mean difference in HbA1c between groups: 3 months (-0.45% [95% CI, -0.86 to -0.04]) Mean difference in CIDS score between groups: 3 months (0.10 [95% CI, -3.12 to 3.31]) Mean difference in PAID score between groups: 3 months (-0.74 [95% CI, -6.29 to 4.82]) Mean difference in CES-D score between groups: 3 months (-0.54 [95% CI, -3.95 to 2.88])	This CBGT did not improve short-term glycemic control when compared to BGAT. The difference between groups was due to a slight decrease in HbA1c after CBGT with a small increase after BGAT. However, data suggest that both CBGT and BGAT similarly improved short-term diabetes-specific emotional distress in patients with poorly controlled type 1 diabetes.	Serious
Psychosocial – family functioning	Grey M, et al. (2009); Ambrosino JM, et al. (2008)	Rate of change per year in HbA1c between groups: 0.52 (CST) vs 0.29 (GE), P=0.265 Rate of change per year in DQOL score between groups: Impact (-1.84 vs -1.96, P=0.957); Worry (-1.10 vs 0.33, P=0.08); Satisfaction (1.72 vs 1.00, P=0.758) Rate of change per year in CDI score between groups: -0.47 vs -0.612, P=0.574 Rate of change per year in Coping score between groups: How hard to (-1.46 vs -1.58, P=0.911); Coping upsets me (-1.01 vs -1.62, P=0.448) Rate of change per year in SED score between groups: Diabetes (5.98 vs 5.93, P=0.984) Rate of change per year in DFBS score between groups: Guidance and control (-2.17 vs -2.39, P=0.867); Warmth and caring (0.24 vs -0.16, P=0.821)^	Improvements in psychosocial adaptation of children with type 1 diabetes and their parents were similar between CST and GE over time.	Serious
Diabetes skills practice AND Psychosocial – family functioning	Murphy HR, et al. (2007)	Mean change in HbA1c between groups:12 months (-0.08% [immediate] vs -0.07% [delayed], P=0.9); 12 months (-0.23% [attendees] vs 0.11% [non-attendees], P=0.03); 24 months (-0.29% [attendees] vs 0.11% [non-attendees], P=0.04)^	Glycemic control among attendees of the family-centered structured education program appeared to improve more than in non-attendees.	Serious
Non-randomized controlled trials				
Psychoeducation/didactic	Mannucci E, Pala L, Rotella CM (2005)	Mean change in HbA1c between groups: 1 year (-0.7% [IESG] vs -0.2% [non-participants] vs -0.3% [selected controls], P<0.05) Mean change in WED score between groups: 1 year (NS)+ Mean HbA1c of IESG participants: 7.5±1.8% [baseline] to 6.8±1.4 [1 year], P<0.001; 7.5±1.8% [baseline] to 6.8±1.3 [2 years], P<0.01 Mean WED score of IESG participants: 75.2±11.8 [baseline] to 76.9±12.9 [1 year], NS; 75.2±11.8 [baseline] to 82.4±10 [2 years], P<0.01	IESG improved medium-term metabolic control better than standard outpatient care alone in patients with type 1 diabetes.	Serious
Emotional support	Hanestad BR, Albrektsen G (1993)	Mean difference in general QoL score between groups: NS+ Mean difference in HbA1c between groups: NS+	This support group did not appear to affect self-reported QoL or glycemic control when compared to usual care in patients with type 1 diabetes.	Serious
Uncontrolled pre-post trials				
Psychoeducation/didactic	Cai RA, et al. (2017)	Feasibility: 33% of eligible families enrolled (39.3% declined due to unwillingness to miss school); 64.7% of enrolled families attended sessions (35.3% drop-out) Acceptability: mean score for recommendation of services on the day [9.0, R 6.5-10], at follow-up [9.1, R 8-10], usefulness [8.6, R 5-10], enjoyment [8.9, R 3-10], comfort speaking about diabetes before participation [6.0, R 1-10], and after participation [7.4, R 3-10])^ Pre-post mean HbA1c: 8.2±1.1% to 8.1±1.2% Pre-post median number of hypoglycemic episodes: 9.0 [IQR, 2.3-9.0] to 4.0 [IQR, 2.0-9.0]	This was an acceptable and age-appropriate self-management group program for families of children and adolescents with type 1 diabetes. It was also found to reduce the number of hypoglycemic episodes experienced by participants. However, issues with feasibility need to be addressed.	Critical
	Due-Christensen M, Hommel E, Ridderstrale M (2016)	Mean PAID score: 1 year (30.4±16.6 to 27.4±17.1, P=0.03) Mean PCD score: 1 year (NS)+ Mean HbA1c: 1 year (7.8±3.1% to 7.5±3.1%, P<0.0001)	DDMs improved glycemic control and diabetes-related distress in patients with type 1 diabetes.	Critical
	Loding RN, Wold JE, Skavhaug A (2008); Loding RN, et al. (2007)	Mean DQOL score: 1 year (-2.3 to 5.6, NS) Mean HbA1c: 2 years (9.2% to 8.7%, NS) Mean HbA1c among boys [n=9]: 2 years (8.9% to 9.2%, NS) Mean HbA1c among girls [n=10]: 2 years (9.4% to 8.4%, P=0.039)^	Group therapy improved glycemic control in adolescent girls with type 1 diabetes without negatively affecting health-related QoL.	Critical
	Shalom R (1991)	Pre-post mean HbA1c: 8.16% to 6.10%, P<0.001	This peer-based support group improved metabolic control in college students with type 1 diabetes.	Critical
	Warren-Boulton E, et al. (1981)	Mean blood glucose levels: 1 year (255 to 149 mg/dl, P<0.01) Mean decrease in HbA1c: during second half of program to completion (2.3%, P<0.05)+ Pre-post mean cholesterol: 193 to 163 mg/dl, P<0.05+ Pre-post mean daily insulin dosage: 56 to 49 units/day+	An intensive group education approach improved glycemic control and cholesterol levels in 5 inner-city, black, young, adult women with type 1 diabetes.	Critical
Diabetes skills practice	Due-Christensen M, et al. (2012)	Mean PAID score: 12 months (37.36±16.16 to 27.92±17.88, P≤0.001) Mean SCL-90-R score: 12 months (0.69±0.45 to 0.53±0.36, P≤0.001); Depression (1.12±0.84 to 0.90±0.69, P=0.020) Mean WHO-5 score: 12 months (53.41±18.11 to 55.33±18.89, P=0.324) Mean HbA1c: 12 months (8.2±1.3% to 8.2±1.2%, P=0.777)	A support group reduced medium-term diabetes-related and psychological distress in highly-distressed type 1 diabetes patients with both good and poor glycemic control.	Critical
	Basso RVJ, Pelech WJ (2008)	Pre-post mean diabetes knowledge score: 3 to 3.5 Pre-post mean general health knowledge score: 3 to 3	Dramatic skit development for children with type 1 diabetes is feasible and empowering.	Critical
	Waller H, et al. (2008)	Mean HbA1c: 8.58±1.80% [baseline] to 8.67±1.98% [3 months]; 8.58±1.80% [baseline] to 8.70±1.98% [6 months], P=0.57 Mean DTSQ score: 6 months (2.83±0.69 to 3.47±0.63, P=0.002) Mean PedsQL score: 6 months (81.79±11.05 to 88.53±10.40, P=0.001) Mean diabetes-specific PedsQL score: 6 months (72.13±13.61 to 81.63±12.78, P=0.001) Mean DFRQ score: 6 months (2.40±0.70 to 2.01±0.72, P=0.001) Mean SED score: 6 months (2.02±0.64 to 1.62±0.64, P=0.001)^	The KICk-OFF program did not improve glycemic control in children and adolescents with type 1 diabetes. However, participants did show clinically significant improvements in quality of life.	Critical
	Snoek FJ, et al. (2001)	Mean HbA1c: 9.3±1.2% [baseline] to 8.7±1.3% [3 months]; 9.3±1.2% [baseline] to 8.5±0.91% [6 months], P=0.04 Mean PAID score: 6 months (39.9±16.0 to 31.2±17.4, P=0.06) Mean BDQ score: 6 months (61.7±13.7 to 56.6±12.3, P=0.019) Mean WBQ-12 score: 6 months (22.3±4.99 to 22.6±6.5, NS) Mean HFS score: Worry, 6 months (30.5±12.5 to 28.8±14.4, NS)	CBGT improved short-term glycemic control in adults with poorly controlled type 1 diabetes without adversely affecting their psychological well-being.	Critical
Psychosocial – stress management	Tsamparli A, Siousioura D (2009)	Pre-post mean HbA1c: 7.3% to 6.4%	Participation in Conjunctive Group Therapy improved metabolic control and psychological adjustment to diabetes in Greek patients with type 1 diabetes.	Critical
Emotional support	Markowitz JT, Laffel LMB (2012)	Pre-post mean HbA1c: 7.9±1.4% to 7.6±1.1%, P=0.10 Pre-post PAID score: 55.5±15.6 to 38.5±19.2, P=0.02 Pre-post SCI-R score: 63.6±12.3 to 72.0±13.7, P=0.09 Pre-post mean clinic visit frequency: 8.6±7.2 to 7.9±5.6	This support group improved social support, but not glycemic control, in young adults with type 1 diabetes.	Critical

Unless otherwise specified, values (n) with standard deviations (SD) are presented as follows: n±SD

*Abbreviations: CI (confidence interval); R (range); IQR (interquartile range); NS (statistically non-significant); HbA1c (glycosylated hemoglobin); QoL (quality of life); CASCADE (Child and Adolescent Structured Competencies Approach to Diabetes Education); CBT (cognitive behavior therapy); CBGT (cognitive behavioral group training); BGAT (blood glucose awareness training); CST (coping skills training); GE (group education); IESG (Interactive Educational and Support Group); DDMs (Diabetes Dialogue Meetings); KICk-OFF (Kids in Control of Food); DFRQ (Diabetes Family Responsibility Questionnaire); SDSCA (Summary of Diabetes Self-Care Activities); CIDS (Confidence In Diabetes Self-care); PAID (Problem Areas in Diabetes); CES-D (Centre for Epidemiological Studies scale for Depression); DQOL (Diabetes Quality of Life Scale for Youth); CDI (Children's Depression Inventory); SED (Self-Efficacy for Diabetes); DFBS (Diabetes Family Behavior Scale); WED (Well-being Enquiry for Diabetes); PCD (Perceived Competence in Diabetes); SCL-90-R (Symptom Checklist-90-Revised); WHO-5 (World Health Organization 5 well-being index); DTQS (Diabetes Treatment Satisfaction Questionnaire); PedsQL (Pediatric Quality of Life Inventory); BDQ ((Barriers in Diabetes Questionnaire); WBQ-12 (Well-Being Questionnaire-12); HFS (Hypoglycemia Fear Survey); SCI-R (Self-Care Inventory-Revised).

€Select primary and secondary outcome measure results presented. Given the volume of outcome measures assessed by each study, only a portion are shown here. See cited reference(s) for further information on any excluded results.

¥Quality Assessment Grading per the ROBINS-I[7]: Low / Moderate / Serious / Critical risk of bias

+Insufficient information provided by authors. Presented data unclear/unavailable.

^Parent outcome measure results not presented. See cited reference(s).

Appendix A – *Database search strategies*

The detailed MEDLINE search strategy is presented below:

Search /Add to builder /Query /Items found

#4 Add Search ((((("diabetes mellitus, type 1"[MeSH Terms] OR "type 1 diabetes mellitus"[All Fields] OR "type 1 diabetes"[All Fields])) AND ("support group" or "group therapy" or "group work" or "group counseling" or "group intervention")))) 47

#3 Add Search (("diabetes mellitus, type 1"[MeSH Terms] OR "type 1 diabetes mellitus"[All Fields] OR "type 1 diabetes"[All Fields])) AND ("support group" or "group therapy" or "group work" or "group counseling")) 35

#2 Add Search "diabetes mellitus, type 1"[MeSH Terms] OR "type 1 diabetes mellitus"[All Fields] OR "type 1 diabetes"[All Fields] 76085

#1 Add Search type 1 diabetes 76085

The search terms for the remaining databases are presented below:

Web of Science –

((type 1 diabetes) AND (“support group” or “group therapy” or “group work” or “group counseling” or “group intervention”))

PsycINFO –

Type 1 diabetes AND "support group" or "group therapy" or "group work" or "group counseling" or “group intervention”

CINAHL –

Type 1 diabetes AND "support group" or "group therapy" or "group work" or "group counseling" or “group intervention”

EMBASE –

'type 1 diabetes' AND ('support group' OR 'group therapy' OR 'group work' OR 'group counseling' OR ‘group intervention’)

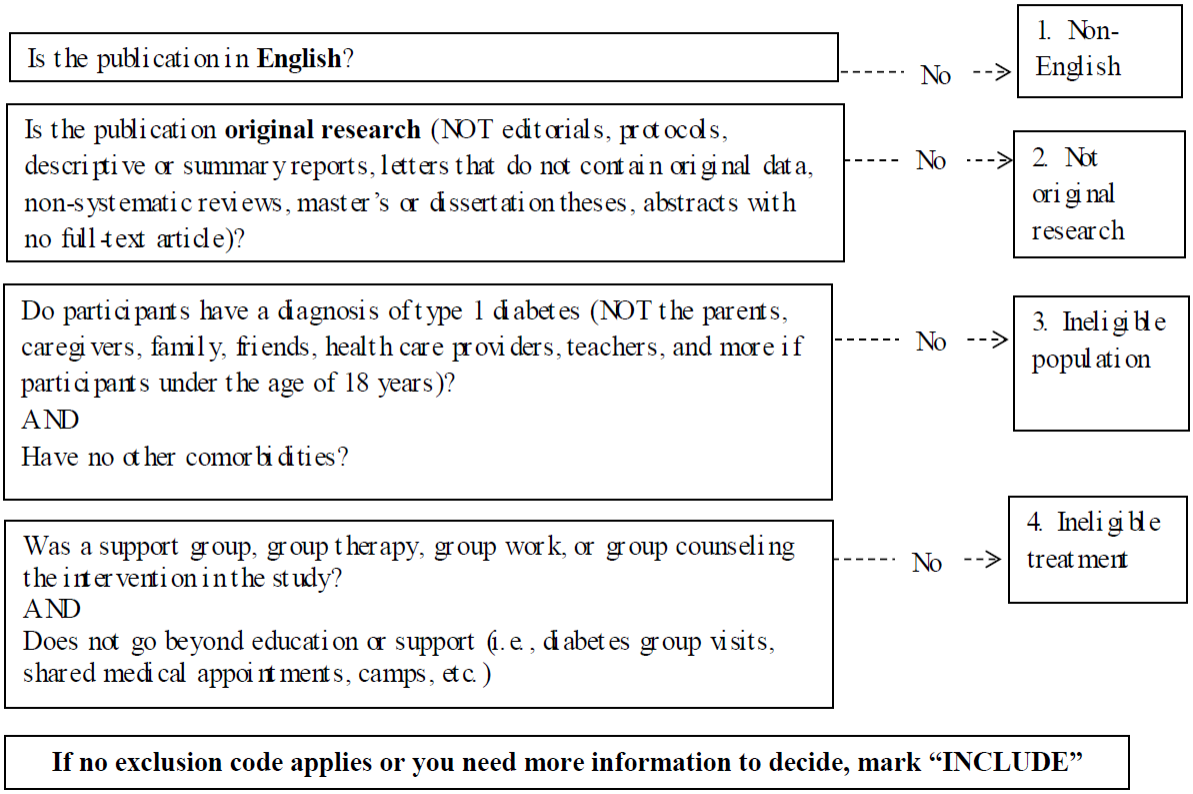
ClinicalTrials.gov –

Type 1 diabetes AND (“support group” OR “group therapy” OR “group work” OR “group counseling” OR “group intervention”)

Appendix B – *Tools for study selection*

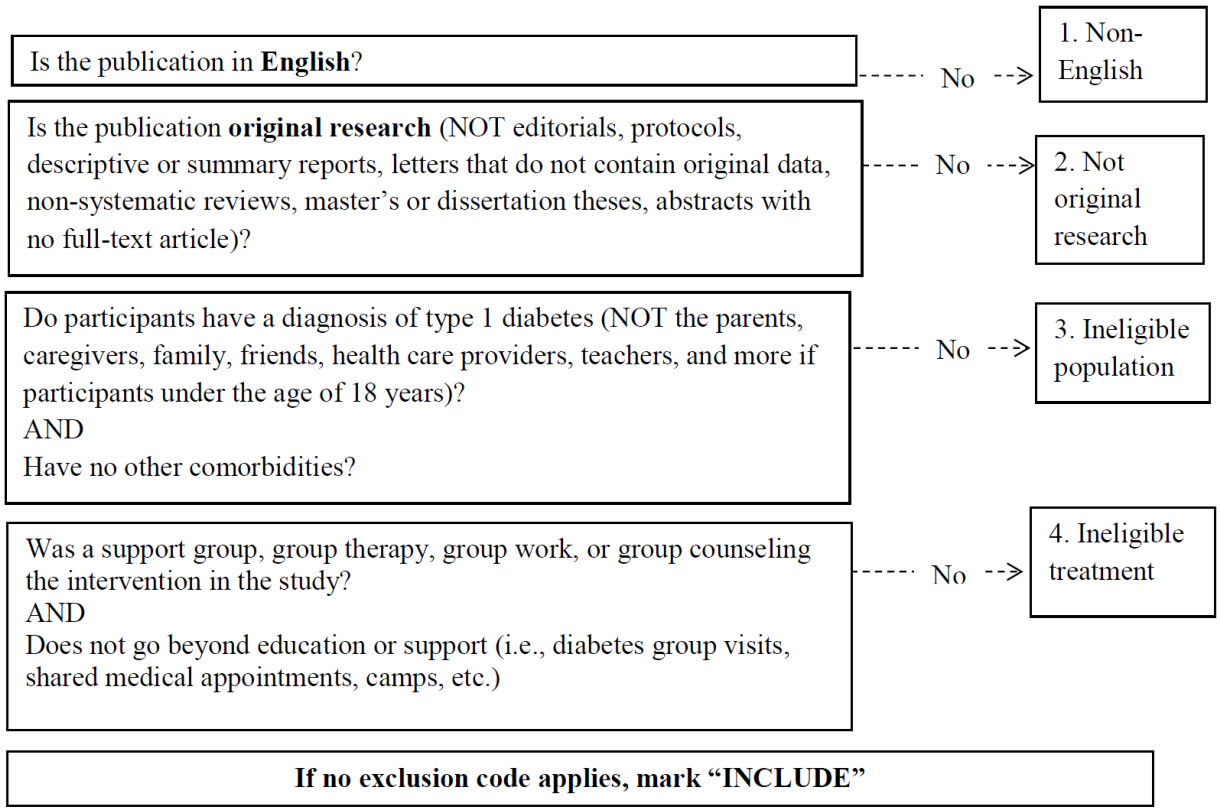
The abstract review selection tool is presented below:

Type 1 Diabetes Support Group Interventions ABSTRACT Review Guide



The full-text review selection tool is presented below:

Type 1 Diabetes Support Group Interventions FULL TEXT Review Guide



Appendix C – *Tools for quality assessment*

The Cochrane Collaboration tool for randomized controlled trials is presented below:

Table 8.5.a: The Cochrane Collaboration's tool for assessing risk of bias

Authors		
	Review author 1's judgement	**Support for judgement 1**
Selection bias		
Random sequence generation		
Allocation concealment		
Performance bias		
Blinding of participants and personnel		
Detection bias		
Blinding of outcome assessment		
Attrition bias		
Incomplete outcome data		
Reporting bias		
Selective reporting		
Other bias		
Other sources of bias		
Overall risk of bias		
***Score**		

*Quality Assessment Grading per the ROBINS-I: Low / Moderate / Serious / Critical risk of bias / No Information

The ROBINS-I tool for non-randomized clinical trials is presented below:

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Authors:		
Signalling questions	**Description**	**Response options**
Bias due to confounding		
1.1 Is there potential for confounding of the effect of intervention in this study? **If N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered		Y / PY / PN / N
If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:		
1.2. Was the analysis based on splitting participants' follow up time according to intervention received? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, go to question 1.3.		NA / Y / PY / PN / N / NI
1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)		NA / Y / PY / PN / N / NI
Questions relating to baseline confounding only		
1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?		NA / Y / PY / PN / N / NI
1.5. **If Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?		NA / Y / PY / PN / N / NI
Questions relating to baseline and time-varying confounding		
1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding?		NA / Y / PY / PN / N / NI
1.8. **If Y/PY to 1.7**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to confounding?		Favours experimental / Favours comparator / Unpredictable

Bias in selection of participants into the study		
2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention?		Y / PY / PN / N / NI
If N/PN to 2.1: go to 2.4		
2.2. **If Y/PY to 2.1**: Were the post-intervention variables that influenced selection likely to be associated with intervention?		NA / Y / PY / PN / N / NI
2.3 **If Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?		NA / Y / PY / PN / N / NI
2.4. Do start of follow-up and start of intervention coincide for most participants?		Y / PY / PN / N / NI
2.5. **If Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases?		NA / Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to selection of participants into the study?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in classification of interventions		
3.1 Were intervention groups clearly defined?		Y / PY / PN / N / NI
3.2 Was the information used to define intervention groups recorded at the start of the intervention?		Y / PY / PN / N / NI
3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?		Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to classification of interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias due to deviations from intended interventions		
If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2		
4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?		Y / PY / PN / N / NI
4.2. **If Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?		NA / Y / PY / PN / N / NI
If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6		
4.3. Were important co-interventions balanced across intervention groups?		Y / PY / PN / N / NI
4.4. Was the intervention implemented successfully for most participants?		Y / PY / PN / N / NI
4.5. Did study participants adhere to the assigned intervention regimen?		Y / PY / PN / N / NI
4.6. **If N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk of bias judgement		
Optional: What is the predicted direction of bias due to deviations from the intended interventions?		

Bias due to missing data		
5.1 Were outcome data available for all, or nearly all, participants?		Y / PY / PN / N / NI
5.2 Were participants excluded due to missing data on intervention status?		Y / PY / PN / N / NI
5.3 Were participants excluded due to missing data on other variables needed for the analysis?		Y / PY / PN / N / NI
5.4 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across interventions?		NA / Y / PY / PN / N / NI
5.5 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Is there evidence that results were robust to the presence of missing data?		NA / Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to missing data?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in measurement of outcomes		
6.1 Could the outcome measure have been influenced by knowledge of the intervention received?		Y / PY / PN / N / NI
6.2 Were outcome assessors aware of the intervention received by study participants?		Y / PY / PN / N / NI
6.3 Were the methods of outcome assessment comparable across intervention groups?		Y / PY / PN / N / NI
6.4 Were any systematic errors in measurement of the outcome related to intervention received?		Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to measurement of outcomes?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in selection of the reported result		
Is the reported effect estimate likely to be selected, on the basis of the results, from...		
7.1. ... multiple outcome *measurements* within the outcome domain?		Y / PY / PN / N / NI
7.2 ... multiple *analyses* of the intervention-outcome relationship?		Y / PY / PN / N / NI
7.3 ... different *subgroups*?		Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall bias		
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the overall predicted direction of bias for this outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

The ROBINS-I grading scale is presented below[38]:

Table 2. Reaching an overall RoB judgement for a specific outcome.

RESPONSE OPTION	CRITERIA
Low risk of bias (the study is comparable to a well-performed randomized trial);	The study is judged to be at **low risk of bias for all domains**.
Moderate risk of bias (the study appears to provide sound evidence for a non-randomized study but cannot be considered comparable to a well-performed randomized trial);	The study is judged to be at **low or moderate risk of bias for all domains**.
Serious risk of bias (the study has some important problems);	The study is judged to be at **serious risk of bias** in at least one domain, but not at critical risk of bias in any domain.
Critical risk of bias (the study is too problematic to provide any useful evidence and should not be included in any synthesis);	The study is judged to be at **critical risk of bias in at least one domain.**
No information on which to base a judgement about risk of bias.	There is no clear indication that the study is at serious or critical risk of bias *and* there is a lack of information in one or more key domains of bias (*a judgement is required for this*).

Declaring a study to be at a particular level of risk of bias for an individual domain will mean that the study as a whole has a risk of bias at least this severe (for the outcome being assessed). Therefore, a judgement of "Serious risk of bias" within any domain should have similar implications for the study as a whole, irrespective of which domain is being assessed.

Because it will be rare that an NRSI is judged as at low risk of bias due to confounding, we anticipate that most NRSI will be judged as at least at moderate overall risk of bias.

The mapping of domain-level judgements to overall judgements described in Table 2 is a programmable algorithm. However, in practice some "Serious" risks of bias (or "Moderate" risks of bias) might be considered to be additive, so that "Serious" risks of bias in multiple domains can lead to an overall judgement of "Critical" risk of bias (and, similarly, "Moderate" risks of bias in multiple domains can lead to an overall judgement of "Serious" risk of bias).

Section 2. Assessing the Efficacy of an Online Support Program on the Chronic Disease Management of Adolescents with Type 1 Diabetes: A Pilot Randomized Controlled Trial

Abstract

Background

Guidelines surrounding the medical treatment of type 1 diabetes are clear. They are less clear for managing the psychosocial effects of the disease. Research has shown that educational group interventions can be effective at improving glycemic control and psychosocial outcomes in this patient population. Photovoice could serve as a novel diabetes group intervention for improving psychosocial outcomes in adolescents with type 1 diabetes.

Methods

We conducted a pilot randomized controlled trial on 17 patients with type 1 diabetes aged 13-17 years to compare the effects of an online support group using photography to one not using photography on diabetes-specific psychosocial outcomes. These outcomes were assessed using the Diabetes Distress Scale, Diabetes Empowerment Scale-Short Form, and Diabetes Management Questionnaire. Feasibility and acceptability were also examined.

Results

An online support group program using photography is feasible and accepted by adolescents with type 1 diabetes. No improvements in diabetes-related distress, diabetes empowerment, or diabetes treatment adherence were seen when compared to an online support group using no photography. However, exploratory data suggest that this group intervention reduces regimen-related distress among participants 4 weeks post-intervention.

Conclusions

To our knowledge, this is the first study to examine the effects of an online Photovoice-based group intervention on diabetes-specific outcomes. More research is needed to demonstrate its efficacy on glycemic control and other diabetes-specific outcome measures.

Introduction

Type 1 diabetes affects about 3 million people in the United States alone and requires intensive treatment that includes constant blood sugar monitoring, carbohydrate counting, and insulin injections.[1] Recent estimates reveal that all forms of diabetes are costing the nation $245 billion per year.[2] With the rising incidence and prevalence of disease, more efforts have been placed on optimizing medical treatment.[1–3] However, clinicians and researchers alike acknowledge that appropriate diabetes care also involves addressing the effects of chronic disease on psychosocial well-being.[1,4] Unfortunately, guidelines surrounding this issue are less clear.[1] Some experts in the field assert that diabetes support groups could be one approach to addressing mental health in patients with type 1 diabetes.[5,6]

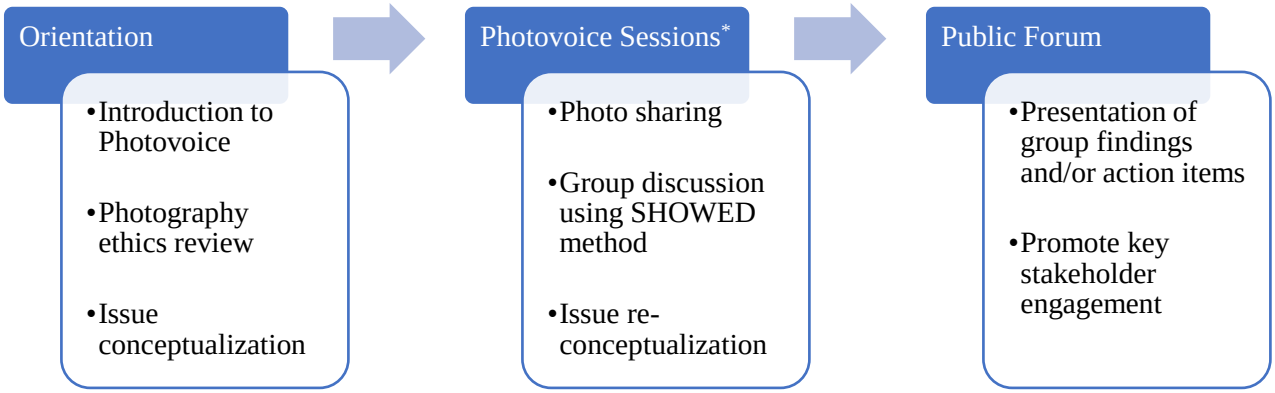
A small field of research has focused on the effects of support group interventions in the type 1 diabetes population. Investigators, Wendy A. Plante and Debra J. Lobato, have categorized the most frequently used group interventions as psychoeducation/didactic, diabetes skills practice, and psychosocial.[6] Psychoeducation/didactic groups often use standardized curricula to provide diabetes education through lectures and group discussion.[6] Diabetes skills practice groups employ a more interactive approach to diabetes support and knowledge acquisition.[6] Instead of didactic instruction, these group interventions have participants practice tangible skills to increase treatment adherence and improve diabetes management behaviors.[6] Some examples include cognitive behavior therapy, motivational interviewing, problem solving, and dramatic skit development.[7–12] Psychosocial groups tend to address issues with diabetes and family functioning, social skills, or stress management.[6] Those aimed at exploring family dynamics often treat children or adolescents with type 1 diabetes. In these groups, parent(s) and affected child work together to improve family communication, coping abilities, and problem

solving.[6] Social skills groups attempt to examine and correct misunderstandings that occur when patients discuss their diabetes with others.[6] Much attention is placed on improving a patient's communication style in certain situations to diminish diabetes-related distress and improve quality of life.[6] Groups that aim to improve stress management frequently assist patients in developing coping mechanisms for common stressors associated with having type 1 diabetes.[6] Examples include Conjunctive Group Psychotherapy, Mindfulness Based Stress Reduction, and Acceptance and Commitment Therapy.[13–16] Only a few studies have strictly provided social support to group participants.[17,18] These types of groups tend to be more unstructured and focus on group cohesion to promote open conversations, storytelling, and teamwork.[6]

In general, diabetes skills practice groups appear to have the strongest evidence for improving glycemic control and psychosocial outcomes in patients with type 1 diabetes.[7–12,19,20] In one randomized controlled trial comparing the effect of a cognitive behavior group therapy (CBGT) program to usual care, Amsberg S, et al. demonstrated that group participants experienced improvements in glycemic control at 8 (glycosylated hemoglobin [HbA1c]: -0.67%; 95% confidence interval [CI], -0.97 to -0.36), 16 (-0.89%; 95% CI, -1.30 to -0.48), 24 (-0.94%; 95% CI, -1.36 to -0.51), 32 (-0.72%; 95% CI, -1.13 to -0.31), 40 (-0.56%; 95% CI, -0.95 to -0.16), and 48 weeks (-0.49%; 95% CI, -0.87 to -0.11) when compared to controls.[7] In addition, the authors showed that group participants adhered to regular blood sugar testing more than those who received routine care alone.[7]

Another potential form of diabetes skills practice, Photovoice, could have beneficial effects on the glycemic control and psychosocial outcomes of patients with type 1 diabetes. Photovoice is a health behavior research method that allows group participants to discuss existing issues within their own communities through photography.[21] The process usually begins

with the identification of existing community issues.[21] After participants agree on the conceptualization of the problem, they spend time outside of the group capturing themes surrounding this issue through photography.[21] When they come back together, photos are shared to elicit discussion.[21] Often, these conversations are facilitated by the SHOWED method, which asks "What do we SEE here?" "What is HAPPENING?" "How does the story relate to OUR lives and how do we feel about it?" "WHY has the problem arisen (on an individual, family, and societal level)?" "Explore how we can become EMPOWERED with our new social understanding," and "What can we DO about these problems in our lives?"[22] This process is repeated as often as needed.[21] Frequently, the end goal of this research strategy is to develop action items for presentation to key stakeholders within the community.[21] *Figure 1* demonstrates the basic structure of a Photovoice program.



**Repeat as needed*

Figure 1. A general example of the Photovoice process.

Photovoice has been shown to produce positive experiences for various patient populations.[23–25] However, there is limited research within the type 1 diabetes population.[26] We conducted a pilot randomized controlled trial in adolescents with type 1 diabetes to assess the effect of an online photography support group, similar in design to a Photovoice project, on diabetes-related distress, diabetes-specific empowerment, and diabetes treatment adherence. Feasibility outcomes were evaluated by recruitment numbers, patient attendance, drop-out, loss to follow-up, and program satisfaction.

Methods

Trial design –

We conducted a parallel randomized controlled trial using a 1:1 allocation ratio to compare the efficacy of an online support program using photography with one not using photography on the chronic disease management of adolescents with type 1 diabetes. There was also a two-week pre-trial pilot of the group interventions to address any structural or functional issues with program design. Each of these interventions were hosted through a free videoconference application called ooVoo. Approval for this study was obtained from the University of North Carolina (UNC) at Chapel Hill Institutional Review Board.

Participants –

A convenience sample was drawn from the UNC Hospitals' Pediatric Endocrinology Department. Academic faculty host a Pediatric Diabetes Clinic at two separate clinic sites – the UNC Hospitals Children's Specialty Clinic and the NC State Park Scholars Children's Specialty Clinic, A Service of UNC Hospitals on the Rex Health Care campus. Recruitment occurred at

both locations. The principal investigator met with patients during an in-person clinic visit or by telephone based on physician recommendation.

We aimed to consent twenty adolescents for the study. Four additional adolescents were recruited for a wait-list to mitigate drop-out and loss to follow-up before the start of the trial. Patients were included in the study if their parent(s) consented to enrollment; they assented, were male or female, aged 13-17 years, had type 1 diabetes for greater than 12 months, were English-speaking, had age-appropriate reading and computer (or electronic device) literacy, had no objection from their diabetes provider, had access to an electronic device with the ability to install and reliably use ooVoo, had access to a camera device to take photographs, and had the desire and time to participate in all program activities. Those new to ooVoo received a short orientation on account creation and use.

Patients were excluded if they had any history of a serious or unstable physical or psychological disorder that would impede their ability to participate in the study, or endanger their safety or that of another participant. This was based on the judgement of the participant's diabetes provider.

After enrollment, each patient was given a unique subject ID number. To facilitate data collection, we also obtained contact information from the participant and their parents. This included both phone numbers and e-mails. All patients who completed the baseline measures and participated in at least one online group session received $20 for the study. Those who completed the study intervention and 6-week surveys received $30 for the study. If participants completed all study tasks, including the 10-week surveys, they received $40 for the study. Participants of the pre-trial pilot program were compensated similarly.

Interventions –

The principal investigator acted as the online group facilitator for the two-week long pre-trial pilot program. Each week, participants met online using ooVoo to discuss their daily life with type 1 diabetes through photographs. At the first session, program details, photo ethics, and participant questions were addressed. The participants and facilitator shared their photos one-by-one during the second session with discussion centered on one photo using the SHOWED method.[22] Each session lasted one hour each. Between these sessions, the facilitator offered individual time with participants through ooVoo for any questions or concerns. Pre-trial pilot participants were not allowed to participate in the full-trial interventions of this study.

The principal investigator also facilitated the full-trial program interventions. Both the treatment and control programs consisted of one-hour online group sessions through ooVoo each week for a total of six sessions run contemporaneously. Discussion was based on the core educational topics outlined by the American Association of Diabetes Educators and American Diabetes Association Task Force in the National Standards for Diabetes Self-Management Education and Support.[27] These topics were grouped into six program sessions as follows: the diabetes disease process and treatment options; acute diabetes complications; chronic diabetes complications; medication management, blood glucose monitoring and self-management strategies; nutrition and physical activity; and strategies to address psychosocial and behavioral change.

While the control group met online to discuss their experience with type 1 diabetes, the treatment group was instructed to take photographs before each session to guide dialogue. Conversations were loosely structured using the Photovoice SHOWED method.[22] All information that was disclosed in either group was held confidential unless information

suggested that the participant was an imminent danger to another person or their self. It is important to note that the sixth session of the treatment group was replaced by a photo exhibit of participant photos and associated quotes. The exhibit was held in the UNC Children's Hospital Lobby and open to the public. This special session was incorporated into the treatment program to remain consistent with the typical structure of a Photovoice project. Consequently, the fifth treatment group session covered both nutrition and physical activity; and strategies to address psychosocial and behavioral change, which were covered in the fifth and sixth control group sessions, respectively. *Appendix A* outlines each study intervention in greater detail.

Outcomes –

Diabetes-specific, psychosocial outcome measures

Participants were instructed to complete three patient-reported outcome (PRO) questionnaires on their own at baseline, post-intervention, and one month after program completion. Each measure was used to assess one of three primary outcomes – diabetes distress, diabetes empowerment, and diabetes treatment adherence. An attempt was made to reduce respondent burden by selecting diabetes-specific questionnaires with fewer items.

The Diabetes Distress Scale (DDS) is a 17-item measure of diabetes-related emotional distress with good reliability (Cronbach's $\alpha > 0.87$), validity, and generalizability.[28] Responses are rated on a 6-point Likert scale from 1 "Not a problem" to 6 "A very serious problem."[28] This instrument is composed of four subscales including emotional burden, physician-related distress, regimen-related distress, and diabetes-related interpersonal distress.[28] It is scored by summing all items together and dividing by the total number of items. Subscale scores are obtained in the

same manner. Higher scores overall, and within subscales, indicate greater diabetes-related distress.

The Diabetes Empowerment Scale Short-Form (DES-SF) is an 8-item questionnaire created by the Michigan Diabetes Research Center for the assessment of psychosocial self-efficacy in patients with diabetes and has good reliability ($\alpha = 0.84$).[29] Responses are rated on a 5-point Likert scale from 1 "Strongly disagree" to 5 "Strongly agree."[29] The instrument is scored by summing all items together and dividing by the total number of items. Higher scores indicate greater diabetes empowerment.

Since the DDS and DES-SF were validated in adult diabetes populations, results from these instruments should be interpreted with caution. In contrast, the Diabetes Management Questionnaire (DMQ) is a 20-item measure of diabetes treatment adherence that was tested in patients with type 1 diabetes aged 8 to 18 years and their parents.[30] The instrument was found to have fair reliability ($\alpha > 0.79$), good test-retest reliability (intraclass correlation coefficient = 0.65), and good content, predictive, and convergent validity.[30] Responses are rated on a 5-point Likert scale from 1 "Almost never" to 5 "Almost always."[30] Each item is scored using a range from 0 to 4, summing all items together, dividing by the total number of items, and multiplying by 25 for ease of interpretability.[30] Six of the items were reverse-scored.[30] Higher scores indicate greater diabetes treatment adherence.

The three study questionnaires were consolidated into one online diabetes survey through Qualtrics. Participants were provided with an anonymous link by email and were instructed to label completed surveys with their corresponding subject ID number.

Program feasibility and satisfaction

Feasibility was measured by tracking recruitment numbers, patient attendance, drop-out, and loss to follow-up. Program satisfaction was assessed in pre-trial pilot participants post-intervention to inform structural and/or functional changes to the full-trial program interventions. During the full-trial period, the program facilitator tracked attendance at each session and marked a participant in attendance if they were present for at least half of the session. To ensure equivalent contact time across treatment arms, session length was also recorded. At the end of each program, satisfaction was assessed through Qualtrics by asking participants whether they were satisfied with their experience in the program and at each online group session. As previously noted, there were small discrepancies in program content between the treatment and control groups. We accounted for this by asking treatment group participants, "Were you satisfied with…The session on nutrition, physical activity, emotional issues and behavior change?" and "…The experience of the public exhibit?" and control group participants, "Were you satisfied with…The session on nutrition and physical activity?" and "…The session on emotional issues and behavior change," for the fifth and sixth sessions, respectively. Responses were rated on a 4-point Likert scale ranging from "Not satisfied" to "Very satisfied." We also included the response, "Not Applicable" for those who did not attend one or more of the online group sessions.

Demographics

We collected participant's weight, height, and body-mass index (BMI) at enrollment with assistance from the clinic nurses. In addition, participant date of birth, gender, race/ethnicity, year of type 1 diabetes diagnosis, years of education completed, previous diabetes education history, North Carolina county of residence, insurance status, family size, and approximate

household income were gathered from parents through Qualtrics. Self-reported insulin treatment regimens were also collected at baseline, post-intervention, and one month after program completion. This data was categorized into continuous subcutaneous insulin infusion (CSII), multiple daily injection (MDI), and twice daily injection. We sought this information to account for potential confounding attributable to the difference in treatment difficulty across these different regimens.

Qualitative data

Treatment group participants shared their photos with the program facilitator by email or text before each session. To contextualize these photos and group discussions, quotes were collected across both treatment arms. This was facilitated by video and audio-recording of each session for subsequent transcription. Participants were informed when recording was started and stopped, and were allowed to decline recording at any time. The facilitator transcribed all recordings and removed any personally identifiable information before extracting quotes. These quotes are for educational purposes only and were not included in our data analysis. Quotes from treatment group participants were paired with photos for the exhibit. Quotes from both arms will be used for presentations to key stakeholders including physicians, health professional faculty, and students as well as for inclusion in the UNC Pediatric Endocrinology Department website, so that a greater audience can learn about daily life with type 1 diabetes.

Sample size –

A priori pilot sample size calculations were based on resource limitations. ooVoo only allows for twelve participants per online session. Most other videoconferencing applications are constrained to ten individuals per session. Thus, we limited our sample size to eleven participants

per group including the program facilitator, which gave us a total potential sample size of twenty participants.

Randomization –

Randomization was performed after all enrolled participants completed the baseline surveys. To achieve allocation concealment, a randomization schedule was created by a member of the research team unassociated with the delivery of program interventions. The randomization schedule was created using STATA 14 (StataCorp, LP, College Station, Tx). Participants were randomly assigned to the treatment and control groups in a 1:1 allocation ratio using permuted block randomization with a block size pattern of four, two, four. We stratified our randomization by gender to minimize confounding and increase the precision of our estimates.

Blinding –

During the enrollment process, participants were only given a general description of the program interventions. No information was provided on the unique structure of each program. Thus, participants were blinded to our comparison of an online support group using photography with one not using photography. Given that all of our outcome measures are self-reported, blinding of outcome assessors was also achieved. However, we were unable to blind the principal investigator given that he participated as program facilitator for both treatment arms.

Statistical methods –

We performed descriptive statistics on all collected demographic and baseline variables. The mean and standard deviation are provided for continuous baseline characteristics. Frequency and percentage values are reported for categorical variables. We dichotomized yearly household

income as <$50,000 and ≥$50,000. In addition, we dichotomized family size (excluding participant) as <3 and ≥3 family members.

Given the small sample size of this study, we conducted an exploratory intention-to-treat analysis. Paired t-tests were performed to assess within group differences among treatment group and control group participants from baseline to 6 and 10 weeks. In addition, we performed a post-hoc analysis on all program participants using a paired t-test to assess whether simply enrolling in this study improved the primary outcomes at 6 and 10 weeks. Simple linear regression was used to model the effect of our treatment intervention on the pre-specified primary outcomes and program satisfaction. Since sessions 5 and 6 differed between intervention groups, we also performed a sensitivity analysis on program satisfaction by removing these questions and assessing for the mean difference in satisfaction between groups. All participants who submitted requested surveys were included in these analyses. Missing item responses within submitted surveys were imputed with the corresponding survey mean score of the participant. A 95% confidence interval excluding the null value was established to indicate statistical significance. The null hypothesis was defined as no mean difference in examined outcome measures across treatment arms. Given the number of analyses conducted, we used the Benjamini-Hochberg procedure to minimize the chance for type 1 error. The statistical program STATA 14 (StataCorp, LP, College Station, Tx) was used to perform all analyses.

Results

Participants were recruited from an academic tertiary care clinic in North Carolina that serves approximately 450 patients with type 1 diabetes. Recruitment for the two-week long pre-trial pilot program occurred between January 25, 2017 and January 30, 2017. Three out of four (75%) eligible patients agreed to participate in the intervention. The one patient who declined

participation felt uncomfortable with group conversation. Although all enrolled participants submitted photos for group discussion, one did not attend either session.

Pre-trial pilot participants were very satisfied with the group intervention. There was high satisfaction with the explanation of program goals and reminders, how photos were shared during group, educational information and support received, group conversation, and survey distribution. However, two participants expressed only moderate satisfaction with group session length, one expressed moderate satisfaction with the explanation of program tasks, and two participants expressed slight to moderate satisfaction with the videoconference application, ooVoo, used for group discussion.

This and other feedback prompted us to make slight modifications to the program. Even though the facilitator shared participant photos through ooVoo's "share screen" function, participants using the ooVoo phone application could not see this on their screen. Thus, we distributed anonymous and temporary links to photos through ooVoo's group chat function. During group discussion, the SHOWED method caused some confusion among participants, so the facilitator used this technique to scaffold conversation, but asked more pointed questions to guide participants through the exercise. At the end of the program, we attempted to collect quotes from participants to accompany their photos. Only one responded to our request. To mitigate this low response rate and capture more organic responses, we decided to record all group sessions instead of recording at the end of the program. Finally, we eliminated individual ooVoo chat meetings between group sessions as no participant expressed interest in this service. Instead the facilitator provided each participant with his phone number and email for questions or concerns with the program.

Recruitment for the full-trial pilot was started once a sufficient number of pre-trial pilot participants were enrolled (January 30, 2017 to March 6, 2017). We stopped recruiting after 24 patients enrolled in the study with four being placed on a wait-list. Out of 45 patients that were reached, 15 (33.3%) declined to participate, three (6.7%) were deemed ineligible to participate (one would turn 18 before trial commencement, one was found to have a diagnosis of maturity onset diabetes of the young, and one did not have a camera device for participation), and another three (6.7%) were lost to follow-up after initial contact for recruitment. After recruitment was complete, we distributed baseline surveys through Qualtrics. During this process, we had three patients drop out of the study and four other patients who were unable to be reached. With wait-list patients included, we randomized 17 patients one week before full-trial commencement. We had eight patients randomized to treatment and nine patients randomized to control.

Both programs ran between March 30, 2017 and May 6, 2017. Treatment group sessions were held on Tuesday evenings while the control group met on Thursday evenings. During the trial, we had one control participant discontinue the intervention and lost three control participants to follow-up. Although the treatment group had no drop-out, one participant was only able to contribute photos to the group. He did not have the opportunity to attend any sessions given his many school and work obligations. At 10-weeks, one treatment and two control participants were lost to follow-up. *Figure 2* outlines the flow of participants throughout the study period.

Figure 2. Participant flow throughout study period.

Our baseline data contains few missing values. We are missing one response for items 5 and 10 on the DDS, and items 2, 16, 19, and 20 on the DMQ. The parent of one participant did not provide their yearly household income. Another participant did not provide their baseline insulin regimen. Several people did not provide their insulin regimen at 6 (nine out of 17) or 10 (fourteen out of 17) weeks. There are no missing values in the data collected from respondents of the 6-week diabetes surveys. However, one response is missing for questions 1, 2, and 5 on program satisfaction, two responses are missing from question 3, and five responses are missing from question 6. In addition, only three of five remaining control group participants responded to these questions. Of those who took the 10-week surveys, two responses are missing for item 7 on the DES-SF. One response is missing for items 12, 13, and 14 on the 10-week DMQ.

Most baseline characteristics appear to be evenly distributed across intervention groups (*Table 1*). Our sample predominantly consisted of young, White female patients of normal body mass index who have had diabetes for more than nine years, use insulin pumps, are insured, and have family household incomes greater than $50,000. They are representative of Orange, Wake, Moore, Johnston, Harnett, Scotland, Alamance, and Chatham counties in North Carolina. In the previous year, few participants had exposure to a diabetes education program (i.e., diabetes camp, diabetes support group, appointment with a nutritionist or diabetes educator). In general, participants expressed slight diabetes-related distress, moderate diabetes empowerment, and moderate adherence to diabetes management behaviors. It is important to note that more participants in the control group had families with ≥ 3 family members, performed multiple daily insulin injections, and expressed greater diabetes treatment adherence.

Table 1. Baseline characteristics across treatment arms.

	Intervention (n=8)	**Control (n=9)**
Mean (SD)		
Age	15.1 (1.4)	15.3 (1.7)
Body mass index	22.3 (3.9)	24.2 (5.4)
Years of education (including pre-school)	11.4 (1.8)	11.4 (1.5)
Years with diabetes	10.3 (4.0)	9.1 (4.0)
DDS+	1.9 (0.8)	2.1 (0.7)
Emotional	2.1 (1.1)	2.6 (1.1)
Physician-related	1.1 (0.3)	1.3 (0.4)
Regimen-related	2.3 (1.0)	2.4 (0.9)
Interpersonal	1.8 (0.8)	1.7 (0.7)
DES-SF+	4.0 (0.8)	3.9 (0.5)
DMQ+	62.8 (19.3)	68.2 (9.3)
N (%)		
Gender (female)	5 (62.5%)	5 (55.6%)
Race/ethnicity (White)	6 (75.0%)	7 (77.8%)
Family size (≥3 members, excluding participant)	5 (62.5%)	8 (88.9%)
Approximate yearly household income (≥$50,000)	6 (85.7%)	6 (66.7%)
Insurance status (insured)	8 (100.0%)	9 (100.0%)
Previous exposure to diabetes education programs in the past year	2 (25.0%)	2 (22.2%)
Current self-reported insulin regimen		
CSII	6 (85.7%)	5 (55.6%)
MDI	1 (14.3%)	4 (44.4%)
Twice daily injection	0 (0.0%)	0 (0.0%)

*SD (standard deviation); n (frequency); DDS (diabetes distress scale); DES-SF (diabetes empowerment scale-short form); DMQ (diabetes management questionnaire; CSII (continuous subcutaneous insulin infusion); MDI (multiple daily injections).
+Missing values were imputed with corresponding survey mean scores of participants.

There was a noticeable difference in attendance between groups throughout the study (*Table 2*). While the treatment group had a median attendance of 5.5 participants per session, the control group had a median of 3.0 participants per session. During session 3, only one control group participant attended. Since the 6th session of the treatment program involved physically attending the public photo exhibit, only one participant was able to attend. However, the treatment group consistently had as many, but often more, participants attend group sessions than

the control group. The program facilitator did attempt to provide an equivalent amount of contact time to each group of participants (*Table 3*).

Table 2. Participant attendance across treatment arms.

	Attendance (n)	
	Intervention (n=8)	*Control (n=9)*
Session 1	6	5
Session 2	6	3
Session 3	6	1
Session 4	4	4
Session 5	5	3
Session 6	1	3
Median total	5.5	3.0

*n (frequency)

Table 3. Contact time across treatment arms.

	Contact time (minutes)	
	Intervention (n=8)	*Control (n=9)*
Session 1	64.4	61.9
Session 2	69.7	63.3
Session 3	64.9	64.1
Session 4	65.1	66.2
Session 5	63.0	65.6
Session 6	65.0	64.0
Mean total, n (SD)	65.3 (2.3)	64.2 (1.6)

*n (frequency); SD (standard deviation)

Although more treatment group participants attended online group sessions, conversation flowed more easily in the control group. While controls simply discussed their experience with type 1 diabetes in group, treatment group participants had to follow a more structured format of dialogue. This was complicated by the online setting. For example, participants using phones had to wait to receive temporary and anonymous links to photos. The SHOWED method often confused the treatment group and led the program facilitator to ask more direct questions. Instead of walking through the SHOWED questions, the facilitator asked each participant to describe

their photo(s) and explain why they took it/them. Afterwards, participants selected one photo to examine more closely. This photo often served as a starting point to more detailed conversation on the diabetes topic of the session. The more rigid format made group cohesion harder to achieve than in the control group. However, weak internet connections, microphone interference, and video outages interrupted conversation in both groups.

At 6 weeks, no statistically significant improvements in diabetes-related distress, diabetes empowerment, or diabetes treatment adherence were seen in either group. Among treatment group participants, the largest improvement was seen in interpersonal distress (-0.208; 95% CI, -0.539 to 0.123). In control group participants, it was seen in diabetes treatment adherence (1.206; 95% CI, -4.185 to 6.597).

Table 4. Mean difference on diabetes-related distress, diabetes empowerment, and diabetes treatment adherence within groups from baseline to 6 weeks[+].

Measure	**Intervention (n=8)**	**95% CI**	**Control (n=5)**	**95% CI**
DDS	-0.025	-0.352 to 0.303	0.047	-0.386 to 0.480
Emotional	0.150	-0.346 to 0.646	0.080	-0.773 to 0.933
Physician-related	-0.031	-0.105 to 0.043	-0.050	-0.605 to 0.505
Regimen-related	-0.084	-0.689 to 0.520	0.040	-0.526 to 0.606
Interpersonal	-0.208	-0.539 to 0.123	0.133	-0.725 to 0.992
DES-SF	0.078	-0.305 to 0.461	-0.100	-0.771 to 0.571
DMQ	-2.656	-11.653 to 6.341	1.206	-4.185 to 6.597

*DDS (diabetes distress scale); DES-SF (diabetes empowerment scale-short form); DMQ (diabetes management questionnaire); n (frequency); CI (confidence interval).
+Missing values were imputed with corresponding survey mean scores of participants.

At 10 weeks, treatment group participants expressed a statistically significant reduction in regimen-related distress (-0.696; 95% CI, -1.253 to -0.140). However, significance did not remain after correction for multiple testing. The control group also saw the largest improvement in regimen-related distress at 10 weeks. However, it was not found to be statistically significant

(-0.600; 95% CI, -1.461 to 0.261). *Tables 4* and *5* present data on within group mean differences for the remainder of our primary outcomes at 6 and 10 weeks.

Table 5. Mean difference on diabetes-related distress, diabetes empowerment, and diabetes treatment adherence within groups from baseline to 10 weeks[+].

Measure	Intervention (n=7)	95% CI	Control (n=3)	95% CI
DDS	-0.381	-0.919 to 0.156	-0.137	-0.858 to 0.584
Emotional	-0.400	-1.116 to 0.316	0.067	-1.451 to 1.585
Physician-related	0	-0.400 to 0.400	0	0 to 0
Regimen-related	-0.696[^]	-1.253 to -0.140	-0.600	-1.461 to 0.261
Interpersonal	-0.333	-1.168 to 0.501	0.111	-1.154 to 1.376
DES-SF	0.084	-0.350 to 0.519	0.185	-0.592 to 0.961
DMQ	3.761	-5.502 to 13.023	5.343	-15.485 to 26.171

*DDS (diabetes distress scale); DES-SF (diabetes empowerment scale-short form); DMQ (diabetes management questionnaire); n (frequency); CI (confidence interval).
+Missing values were imputed with corresponding survey mean scores of participants.
^Found to be statistically insignificant after Benjamini-Hochberg correction.

Among all study participants, a statistically significant reduction in regimen-related distress was seen at 10 weeks (-0.668; 95% CI, -1.039 to -0.296). This effect did not remain after correction for multiple testing. *Table 6* presents the remaining data derived from our post-hoc analysis at 6 and 10 weeks.

Table 6. Mean difference on diabetes-related distress, diabetes empowerment, and diabetes treatment adherence among all participants from baseline to 6 and 10 weeks[+].

Measure	6-weeks (n=13)	95% CI	10-weeks (n=10)	95% CI
DDS	0.003	-0.216 to 0.222	-0.308	-0.671 to 0.055
Emotional	0.123	-0.241 to 0.487	-0.260	-0.783 to 0.263
Physician-related	-0.038	-0.200 to 0.123	0	-0.253 to 0.253
Regimen-related	-0.037	-0.408 to 0.335	-0.668[^]	-1.039 to -0.296
Interpersonal	-0.077	-0.397 to 0.243	-0.200	-0.775 to 0.375
DES-SF	0.010	-0.279 to 0.300	0.114	-0.182 to 0.410
DMQ	-1.171	-6.497 to 4.155	4.235	-2.285 to 10.756

*DDS (diabetes distress scale); DES-SF (diabetes empowerment scale-short form); DMQ (diabetes management questionnaire); n (frequency); CI (confidence interval).
+Missing values were imputed with corresponding survey mean scores of participants.
^Found to be statistically insignificant after Benjamini-Hochberg correction.

When comparing between groups, no statistically significant difference in diabetes-related distress, diabetes empowerment, or diabetes treatment adherence was seen at 6 or 10 weeks. The largest difference between groups was seen in diabetes treatment adherence. It appears that control group participants improved their diabetes management behaviors more than treatment group participants at 6 (-14.094; 95% CI, -35.412 to 7.224) and 10 weeks (-11.180; 95% CI, -33.615 to 11.255). *Table 7* presents data on between group mean differences for the remainder of our primary outcomes at 6 and 10 weeks.

Table 7. Mean difference in diabetes-related distress, diabetes empowerment, and diabetes treatment adherence between groups at 6 and 10 weeks[+].

Measures	**6-weeks**	**95% CI**	**10 weeks**	**95% CI**
DDS	-0.056	-1.00 to 0.882	-0.401	-1.520 to 0.719
Emotional	-0.070	-1.626 to 1.486	-0.981	-2.982 to 1.020
Physician-related	-0.038	-0.282 to 0.207	0.107	-0.284 to 0.498
Regimen-related	-0.015	-1.558 to 1.528	-0.229	-1.534 to 1.078
Interpersonal	-0.125	-0.791 to 0.541	-0.397	-1.712 to 0.923
DES-SF	-0.038	-0.849 to 0.774	-0.202	-1.257 to 0.854
DMQ	-14.094	-35.412 to 7.224	-11.180	-33.615 to 11.255

*DDS (diabetes distress scale); DES-SF (diabetes empowerment scale-short form); DMQ (diabetes management questionnaire); CI (confidence interval).
+Missing values were imputed with corresponding survey mean scores of participants.

Regarding program satisfaction, there was no statistically significant difference seen between groups (-2.72; 95% CI, -7.488 to 2.055). However, control group participants consistently expressed more satisfaction with group sessions than treatment group participants. It is important to note that there were only three control group respondents when compared to eight in the treatment group. *Table 8* presents data on session and program satisfaction within each treatment arm.

Table 8. Participant satisfaction with online support group programs at 6 weeks[+].

	Mean satisfaction, n (SD)	
Satisfaction with…	*Intervention (n=8)*	*Control (n=3)*
Session 1	3.3 (0.9)	4 (0)
Session 2	3.3 (0.7)	3.3 (0.6)
Session 3	3.6 (0.5)	3.6 (0.5)
Session 4	3.4 (0.7)	4 (0)
Session 5	3.6 (0.5)	4 (0)
Session 6	3.3 (0.7)	3.9 (0.1)
Program	3.6 (0.5)	4 (0)
Mean difference	-2.72 (95% CI, -7.488 to 2.055)	

*n (frequency); SD (standard deviation); CI (confidence interval).
+Missing values were imputed with corresponding survey mean scores of participants.

Select photographs and quotes from treatment group and control group participants are presented in *Appendix B.* Study participants often discussed hypoglycemic episodes, doctor's visits, stays at the hospital, experiences at school with friends and teachers, being singled out for having type 1 diabetes; constantly having to educate peers, friends, family, and teachers on their health condition; and more.

Discussion

We have found it feasible to perform an online support program using photography with adolescents who have type 1 diabetes. However, issues with implementation remain. It was difficult to build group cohesion through online group videoconferencing. Dialogue was limited to the whole group and could not be divided among group participants for more personal encounters. Differences in strength of internet connection led to several dropped calls throughout group sessions. In addition, poor connections made it difficult for everyone to appear on the screen at the same time. Instead, for parts of many sessions, we would only be able to hear other group participants until their video came back online. Microphone interference augmented these communication issues. With several participants in each videoconference call, microphones would often echo or distort voices, making it difficult to understand participants at times.

However, only having one microphone on at a time helped mitigate this problem. Attendance varied significantly between groups. While treatment group participants consistently attended sessions, control group participants did not. It may be that having a more concrete task (i.e., photography) for group builds a sense of responsibility and encourages participation.

With regard to diabetes-related distress, diabetes empowerment, and diabetes treatment adherence, minimal improvements were seen within both groups at 6 and 10 weeks. This effect is partially attributable to our small sample size and the questionnaires used to assess these constructs. We only observed a statistically significant reduction in regimen-related distress among treatment group and all participants at 10 weeks. However, significance did not remain after correction for multiple testing. This finding suggests that using photography or another group engagement activity could help lessen the stress associated with performing daily diabetes management behaviors by openly working through these thoughts and feelings with other patients with type 1 diabetes. Between groups, there was no difference seen in diabetes-related distress, diabetes empowerment, or diabetes treatment adherence. This might have been different had the comparison been between our online photography support group and routine diabetes care.

The results of our pilot randomized controlled trial were not as robust as those seen in other studies examining this type of group intervention. In the Amsberg S, et al. study, participants allocated to a CBGT-based intervention demonstrated greater reductions in diabetes-related distress at 24 and 48 weeks, and greater adherence to blood sugar testing at 24 and 48 weeks when compared to controls who received routine diabetes care.[7] Important differences include that this group intervention was delivered by a trained psychologist and diabetes nurse specialist to adult patients with type 1 diabetes and included a comprehensive maintenance

program.[7] In another randomized controlled trial conducted by van der Ven NCW, et al., CBGT appeared to have no effect on psychosocial outcomes.[8] Participants of CBGT did not experience greater improvements in diabetes confidence, diabetes-related distress, or depressive symptoms when compared to those who received blood glucose awareness training.[8] Again, statistically significant differences may have been seen had the comparison been made to usual care. Compared to the only other study found to use an online Photovoice-based group intervention in patients with type 1 diabetes, our program covered similar topics of discussion.[26] Feasibility of implementation was also similar.[26] Whereas we had 13 active participants across both groups throughout the study period, the authors of this study reported 12 active Instagram participants.[26] Since the Instagram study did not assess for the efficacy of their group intervention, we cannot compare the efficacy of our intervention to any previously performed intervention of this type.

Our study had several strengths. We were able to conceal the allocation of participants from the program facilitator until groups commenced. Randomization appeared to be successful as there were minimal differences in baseline characteristics across groups. This reduced our concern for both selection bias and confounding. In addition, participants were blinded to allocation, which mitigated potential social desirability bias on primary and secondary outcome measures. All of our patient-reported outcome measures had documented validity and reliability. Privacy was ensured by having participants take these instruments online without the presence of research personnel. Both interventions were purposefully structured in a similar manner to isolate the effects of photography on diabetes-related psychosocial outcomes.

There were also a few limitations to our study. Although the DMQ was validated in an adolescent population, the remainder of our questionnaires were not. While the DDS and DES-SF helped us reduce respondent burden, they were both tested in adult diabetes populations.

Given our time restrictions and summertime conflicts with participants, we only reassessed our primary outcomes at one month follow-up. This limited our ability to demonstrate long-term effects of online support with photography on diabetes-related psychosocial outcomes.

Future research will assess the effect of this group intervention on glycemic control as measured by glycosylated hemoglobin (HbA1c). In addition, a subsequent randomized controlled trial will extend the recruitment period and attempt to collaborate with other pediatric diabetes clinics to reach a more diverse patient population. More research personnel will be needed to increase the capacity of participants served. This will require a more standardized protocol to ensure that each program facilitator is providing the same group environment. However, this will allow for our sample size to increase, which will better our ability to find improvements in diabetes-specific health outcomes. Although respondent burden will still be considered in subsequent research, more reliable survey instruments will be used to measure pertinent psychosocial outcomes. While one of the aims of this study was to see if Photovoice could provide another form of diabetes skills practice to influence diabetes health in adolescents, we may modify our program to host a public exhibit online, so that more patients can attend. For example, we may use Facebook or Instagram to make a group photo library that is open to the public for a brief period of time. In addition, we may allow participants to choose the topics they want to cover instead of basing sessions off of national standards on diabetes support and education. This could individualize the intervention to more closely fit the needs of each group. More follow-up periods will also be conducted to confirm that any effects seen across groups are sustained.

Although we did not find a statistically significant health benefit of participation in an online support program using photography, we were able to demonstrate its feasibility and

acceptability. Photovoice as a group intervention for patients with type 1 diabetes could also benefit surrounding communities. Since participants worked throughout the study period to illustrate their daily life with type 1 diabetes through photography, we now have personal and informative depictions of this disease. These educational materials could help inform the practice of local pediatric endocrinologists and reduce stigmatization by educating the general public on type 1 diabetes. Even though we were unable to demonstrate increases in diabetes empowerment through group photography, achievement of improved diabetes self-confidence could lead to increased treatment adherence and subsequent improvements in glycemic control. Better control then helps reduce the risk of developing the long-term complications of diabetes.

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Appendix A – Study interventions

Pre-trial pilot program –

We aimed to recruit two to five participants for a two-week long pre-trial pilot of our program interventions. This pilot consisted of one-hour online group sessions held each week through ooVoo. There was a total of two sessions that were relatively unstructured. The principal investigator of the study facilitated these sessions and tracked attendance. Multiple email and text reminders were sent to participants and their parents throughout the program period regarding upcoming sessions and task completion. In these reminders, parents were instructed to allow their children to take their own photos.

Session 1

The program goals, requirements, confidentiality, and schedule were reviewed at the start of the session. Photo ethics and participant safety were emphasized throughout. Time for any questions or concerns were provided before group discussion commenced.

Group introductions were performed. After everyone was acquainted with each other, participants were informed of tasks that they needed to complete prior to the second session. They were instructed to take photos of people, places, objects, or scenarios that helped them illustrate how diabetes affects their nutrition and physical activity. Participants then emailed their photos to the program facilitator. Before closing the session, the facilitator reminded participants that they would need to obtain consent from any person they photographed.

Session 2

The facilitator started this session by sharing example photos he took regarding his own type 1 diabetes. Each participant was then allowed to share their own photos. After selecting one photo to discuss in more detail, the facilitator guided participants through a practice SHOWED session.[22] To build a supportive environment, participants were encouraged to openly share their thoughts and questions with the group. However, no medical advice was provided by the facilitator of this program. Questions of this nature were deferred to a participant's health care provider. At the end of the session, participants were thanked for their participation in the pilot and asked about their satisfaction with the program through Qualtrics.

Between sessions

In between these two sessions, the facilitator offered individual ooVoo chat sessions with participants to address any questions or concerns they had with the program. Each chat session was limited to 15-30 minutes per participant.

Full-trial pilot programs –

We aimed to recruit twenty participants, ten in each treatment arm, for this six-week long pilot study. Each program consisted of one-hour online group sessions held each week through ooVoo. There was a total of six sessions that were relatively unstructured. The principal investigator of the study also facilitated these sessions, and tracked attendance and session length. Each of the program sessions were recorded to collect quotes for the photo exhibit in the treatment group, and to collect quotes for educational presentations in both treatment arms. Multiple email and text reminders were sent to participants and their parents throughout the

program period regarding upcoming sessions and task completion. In these reminders, parents of treatment group participants were instructed to allow their children to take their own photos.

Treatment group –

Session 1 (Discussion topic: the diabetes disease process and treatment options)

The program goals, requirements, confidentiality, and schedule were reviewed at the start of the session. Photo ethics and participant safety were emphasized throughout. In addition, the following group agreements were adapted to guide group dynamics: confidentiality, "amnesty", use of "put-ups", "passing rights", respectful listening, allowing for feelings to happen, use of "I"-statements, personal accountability, being present, and assuming the best intentions from others.[31] Participants were encouraged to modify these agreements according to the group's mutual values. Time for any questions or concerns were provided before group discussion commenced.

Group introductions were performed. After everyone was acquainted with each other, the facilitator guided the group through a practice SHOWED session using example photos he took regarding his own type 1 diabetes.[22] To build a supportive environment, participants were encouraged to openly share their thoughts and questions with the group. However, no medical advice was provided by the facilitator of this program. Questions of this nature were deferred to a participant's health care provider. Toward the end of the session, participants were informed of tasks that they needed to complete prior to the second session. They were instructed to take photos of people, places, objects, or scenarios that helped them illustrate their experience with high and low blood sugars. Participants then emailed their photos to the program facilitator.

Before closing the session, the facilitator reminded participants that they would need to obtain consent from any person they photographed.

Session 2 (Discussion topic: acute complication prevention, detection and treatment)

The facilitator asked each participant to share their own photos. After selecting one photo to discuss in more detail, the facilitator guided participants through a SHOWED session. This method was adapted when participants expressed confusion with the SHOWED questions and their relation to the photos. Instead, conversation evolved by having each participant describe how their diabetes related to each of the photos shared with the group. From there, the facilitator would guide discussion based on what participants shared. The remaining sessions followed this format. At the end of this session, participants were reminded of their task for the next session. Again, they were instructed to take photos that related to the next session's discussion topic.

Session 3 and 4 (Discussion topics: chronic complication prevention, detection and treatment; and proper medical management, blood glucose monitoring and self-management strategies, respectively)

These sessions followed the same format as Session 2 described above.

Session 5 (Discussion topics: nutrition and physical activity; and strategies to address psychosocial issues and health and behavior change)

Most of this session followed the same format as Sessions 2 through 4. However, two discussion topics were covered in this session to account for the photo exhibit in the next session. In addition, participants were informed of the photo exhibit and what to expect. Participants were strongly encouraged to attend the exhibit but were not required to do so.

Session 6 (photo exhibit)

The facilitator confirmed the best date and time to hold the photo exhibit with the participants during the first online group session. The exhibit was scheduled in conjunction with the UNC Hospitals Volunteer Services for Saturday, May 6, 2017. It was placed in the stage area of the UNC Children's Hospital Lobby. De-identified transcriptions from all online group sessions were used to extract quotes for each participant photo. Quotes and photos were printed by the facilitator. These were tacked onto poster boards and propped up with easels for presentation to family members, friends, interested health care providers, and the general public.

Participants who attended the photo exhibit were encouraged, but not required, to stand by their photos and share their experience with exhibit attendees. They were also free to walk around and engage with others at the exhibit as they pleased. The exhibit remained open to the public for about one hour.

After the exhibit, participants were provided with a Qualtrics link to complete the study surveys and program satisfaction. They were also asked to self-report any changes to their current insulin regimen.

Between sessions

Since no one expressed interest in having individual ooVoo chat sessions during the pre-trial pilot program, we removed this aspect of the program from the full-trial interventions. Instead, participants were provided with the facilitator's phone number and email for any questions or concerns they had with the program.

One-month follow-up

Participants were contacted one month after the conclusion of their participation in this study to complete the final set of study surveys through Qualtrics. Again, they asked to self-report any changes to their current insulin regimen.

C*ontrol group* –

Session 1 (Discussion topic: the diabetes disease process and treatment options)

The program goals, requirements, confidentiality, and schedule were reviewed at the start of the session. In addition, the following group agreements were adapted to guide group dynamics: confidentiality, "amnesty", use of "put-ups", "passing rights", respectful listening, allowing for feelings to happen, use of "I"-statements, personal accountability, being present, and assuming the best intentions from others.[31] Participants were encouraged to modify these agreements according to the group's mutual values. Time for any questions or concerns were provided before group discussion commenced.

Group introductions were performed. After everyone was acquainted with each other, the facilitator guided the group through the discussion topic. To build a supportive environment, participants were encouraged to openly share their thoughts and questions with the group. However, no medical advice was provided by the facilitator of this program. Questions of this nature were deferred to a participant's health care provider. Toward the end of the session, participants were informed of tasks that they needed to complete prior to the second session. They were instructed to actively think about people, places, objects, or scenarios related to their experience with high and low blood sugars.

Sessions 2 through 6 (acute complication prevention, detection and treatment; chronic complication prevention, detection and treatment; proper medical management, blood glucose monitoring and self-management strategies; nutrition and physical activity; and strategies to address psychosocial issues and health and behavior change, respectively)

Each of these sessions started with an open discussion on any additional points of conversation left over from the previous encounter. Aside from a change in discussion topic, the format of these sessions remained the same.

After the sixth and final session, the facilitator provided participants with a Qualtrics link to complete the study surveys and program satisfaction. They were also asked to self-report any changes to their current insulin regimen.

Between sessions

Since no one expressed interest in having individual ooVoo chat sessions during the pre-trial pilot program, we removed this aspect of the program from the full-trial interventions. Instead, participants were provided with the facilitator's phone number and email for any questions or concerns they had with the program.

One-month follow-up

Participants were contacted one month after the conclusion of their participation in this study to complete the final set of study surveys through Qualtrics. Again, they were asked to self-report any changes to their current insulin regimen.

Appendix B – Select participant photographs and quotes

Treatment group participants –

1.

Participant 1: "…has anybody had it where a health teacher or something would make you like stand up in class and tell everybody about [diabetes]?"

Participant 2: "Um, when I was in middle school we would, we would always go over like diabetes in a science class or health class. So, I think it was my…I wanna say my 7th or 8th grade year. My teacher knew that I had diabetes and she made me walk up to the front of the

class and show everyone my [insulin] pump and just kind of use me as a model like I was like an example of something."

Facilitator: "How did that make you feel?"

Participant 2: "I mean…As someone who's had diabetes since they were a little kid…like it's okay to like talk about it and like educate people, but it was kind of embarrassing. Like, I'm 12 years old. Like I don't want to be in the front of a class used as a model."

2.

Participant: “Um, the lowest blood sugar I’ve ever had was around 15…didn’t feel it right away. Um, my mom said that I looked really really pale, and sleepy…I mean, I had a long day and we actually had gone on a field trip. And it was in the fourth grade...and like my mom…[came] with me because the school nurse couldn’t. So, when I checked it, it was 15 and we didn’t have anything on the bus, so we actually had to stop the whole school bus and go into like a gas

station and get me something. I thought it was completely embarrassing...I felt very embarrassed because, I mean, there [were] a lot of kids on that bus…"

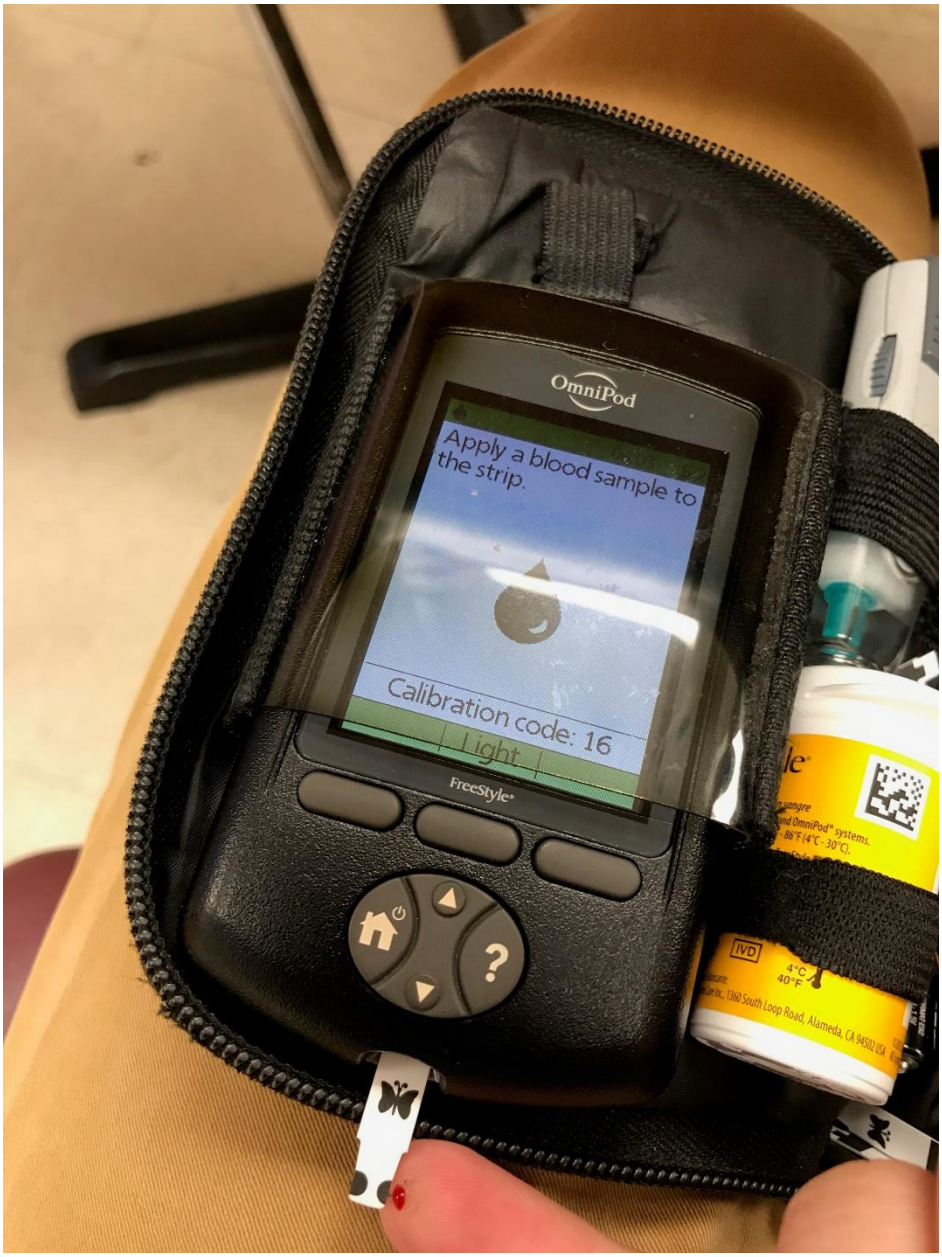
Facilitator: "…how were other people reacting?"

Participant: "Well, the bus driver was the most scared out of all of us. I think the bus driver was even more terrified than I was actually. Like she was for real freaking out. Like she was yelling…She was asking me if I needed water. Like she was like 'Do you need water? Do you need water? Do you need water?' and like every 5 minutes after, my mom would be like "no, she's fine," And she kept asking. And it's, it's…It was awful. I felt bad."

Facilitator: "And so, what happened…for the rest of the trip…Did anything change about how people treated you?"

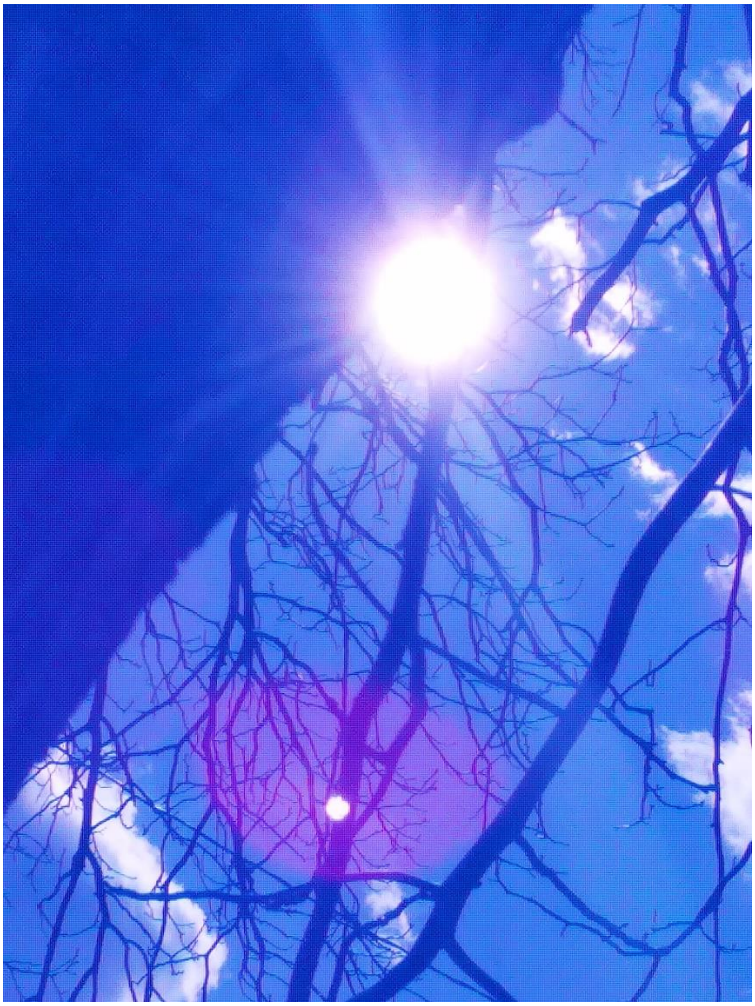
Participant: "It actually…a lot of kids were scared to come near me for some reason. They thought it meant like I had…gotten sick or something. I mean, like I was sick but…somehow they thought they could catch it."

3.



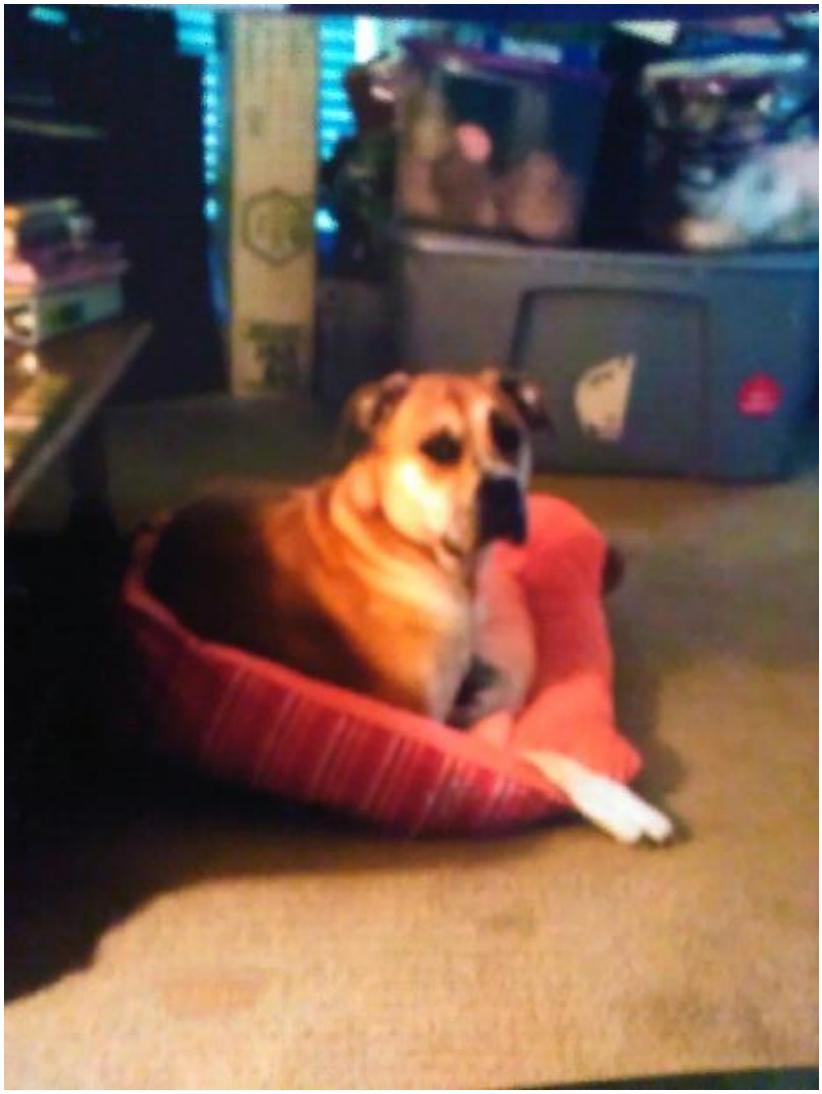
"…it's just like [classmates] wouldn't want to come near me. And like it was actually…it was like in a school health class and the teacher put on the board like diseases you could catch and one's you couldn't catch. And this kid saw that you couldn't catch [diabetes]. And they were like 'oh my god! I can talk to her?' Like yea, yea, yea it's, you're not going…it's fine. You can breathe near me. I'm not gonna like give you anything…so it was kind of embarrassing really…"

4.



"I'm in drumline at my school and I'm in charge of like all of the kids who do drumline and so when my blood sugar…it drops low all the time when I'm…on the field or when we're practicing and just…having to sit out for a long amount of time cuz I have to make sure my blood sugar gets…up to like the higher level so that I can…stay on the field longer. Making sure that it won't keep dropping continuously…I just kind of…feel like I'm letting people down because like I can't be there for…the people that I'm helping out and…I can't…do my like leadership position when I'm low. And so, it makes me kind of upset…I don't want to like be seen as a slacker, which I think is like the main thing…I'm just, I just kind of freak out when people think I'm just trying to…get an easy way out or like sit out more."

5.



“A few months ago, I lost my grandfather…His kidneys shut down on him…and after his kidneys, the rest of his organs, and we lost him. He was on life support for a little while before that and he was a diabetic as well…He was definitely supportive of what I went through…Like every time I got a chance to see him…he would always ask me how it was going and if I was like taking care of [my diabetes] really well and he was always like ‘don’t be like me’. His exact words, ‘don’t be like me. Take care of yourself.’ And after losing him, it was really really hard to get back on board with…like even really caring about the whole blood sugars. Like, after losing him, I was like…I don’t know. Kind of lost for a little bit.”

6.

"What I worry about the most actually is probably finding a job where they understand that I have [diabetes], because I know sometimes…like let's say you work in retail. They might be like 'no you can't take a break now. You can't…have stuff on the sales floor.' And like I have too, because what if my blood sugar drops and I have to stop and eat something. You know? So, I just kind of worry about that."

Control group participants –

1. "Yea, um...last year we were taking a test on the computer in science and my [blood] sugar dropped like really fast…And the person in front of me was like, 'hey…are you okay? Your face is turning colors,' and I was like, 'I'm not okay honestly. Let me finish this test.' So, I failed this test because I…went through it so quickly and I wasn't reading the questions…I couldn't. My eyes being blurry and stuff…and I got up…and I went to the teacher and she was like, 'are you okay?' and I was like, 'No. I need to go to the office and check my sugar and stuff,' and she just said, 'do you need someone to go with you?' And I said, 'Yea.' …I had to get to the office, which was like…a distance away and that…I got there and it was only like 62, but I was high in the morning and so it dropped really fast."

2.

Facilitator: "…do you feel like your life is any different because of your diabetes?"

Participant: "Um, definitely…Like [my diabetes] being there. I mean, not being able to eat certain foods, not being able to eat like…sweets, not being able to eat a lot of dessert, not being able to play when I'm low or have…If I, like, I've had this happen to me multiple times where if I'm playing a game and then I start feeling low, then I have to like, I have to quit and stop and go and eat something or…One of the scariest things for me was…I was at school and I didn't have anything to bring up my lows and…I had eaten [all my low blood sugar snacks] and I was about to…restock the place where I keep all of it, um…that like next day but…I didn't have anything and I ended up going really, really low that day at school. So, I kinda, um, I thought I set in my pump and I ate something and I said, 'alright it'll slowly come up...' Well, the thing was, one of the hardest things for me was, it was just like, I was like. I had no idea what was going on. I couldn't think. I couldn't do any work. I was, I was upset. I was emotional. It was weird… I was

really emotional and like, eventually I called my mom. She brought honey and that was a relief. But I've had this happen to me more than once now where I was…I was getting my haircut and I was sitting in a chair and I start feeling low. And the hair...I knew the haircut was almost done but it took a really long time. Um, but I knew that the haircut was almost done but in, in my head I kept having to tell myself that. It was really strange. I, I was low and it felt like it was never gonna end and so I kinda just sat there, kinda looked at the TV a bit. It's just…Like once I…the thing that I don't get is once I start thinking about it, I felt like I went lower. Like I was in the dentist…and I have to kinda just go to…like I feel like I had to go to sleep just to, to kinda get it to leave my mind. Like I was sitting in the chair and I was trying to make as little movement as possible, cuz I felt like if I do anything it'd just make it lower and that's what I feel like really…It's weird…Like thinking about it and that makes it more low. It's strange."

3. "I…same thing like as [other participant's name], like, I have times where [the insulin pump infusion set will] hit…I don't know what it hits but it will just go in and it'll sting really bad or like for a long amount of time. Um, or…One of the most frustrating things is when it doesn't…when I put it in. Maybe it doesn't hurt but, like, I don't know an hour later my blood sugar will be like 300 and it, and it keeps rising and I'll realize, 'okay the site's not working.' But I still got this whole vial of insulin in the pump, so I've gotta change it but usually the good thing is with the pump, like, I can take…the reservoir cap off and still use that reservoir…just have to use a new site, so. But still, I mean, it's frustrating."

4. "Everyone at school makes me feel different…It actually, it happens every day too. Um, I'll be at lunch and I go to the bathroom before I eat lunch to check my [blood] sugar but like after I eat everything and I put my [calculations] into my [insulin] pump, people ask me, 'What's that? What's that?' And I don't want to tell them, because I know that if I tell them they're gonna ask

me a whole bunch of questions and try and act like…everything is okay, when I'm different than everyone else and they don't understand that."

5.

Facilitator: "If you could live in an ideal world, what would other people do [about diabetes]?"

Participant: "For me, I feel like teenagers, especially, would be so judgmental about things. Like, diabetes…They're really like, they look at you funny because they know that you're different, because they don't have this, not disease, but this condition that they do. And they don't understand it. So, they just think, 'oh, if I don't understand this, then I'm just gonna pick on you for it.' And I feel like that shouldn't be happening."

6. "My best friend always has food with her, so if I want something, if I want some of it, she's like, '[participant's name] don't eat that!" I'm like, 'Why not?' She's like, 'because you have…because I'm trying to protect you.' I'm like, 'There's nothing to protect me from. I can handle it. I've got it.' And she's like, 'I'm just trying to make sure you're okay.' I'm like, 'I understand that but I'm hungry!' She's like, 'I'm just trying to be your best friend.' I'm like, 'I know…I just want you to understand that I can eat it as long as I can cover for it.' And I have to keep reminding her about it too."