

Title: Transdisciplinary Versus Usual Care for Type1 Diabetes in Adolescence

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2. Specific Aims: Large epidemiologic studies show that <25% of adolescents with type 1 diabetes (T1D) achieve targeted glycohemoglobin levels advocated by the American Diabetes Association ($\leq 7.5\%$) or International Society of Pediatric and Adolescent Diabetes ($\leq 7.0\%$). Optimal self-management of T1D requires daily insulin replacement by multiple injections or insulin pump, 4-6 daily blood glucose checks, regulation of carbohydrate intake and physical activity, prevention/correction of glycemic fluctuations and perhaps use of a continuous glucose monitor. This regimen places pervasive affective, behavioral, cognitive and social demands on adolescents with T1D and their families and psychosocial variables greatly impact their success in T1D self-care. Struggling with maintaining adequate glycemic control is essentially normative among adolescents, suggesting that conventional systems of care are not meeting the needs of this population. A substantial, growing literature provides an evidence base for psychosocial screening and behavioral intervention strategies targeting improved coping with the demands of T1D, but this evidence base has not penetrated fully into routine T1D care. Rigorous integration of this evidence into routine care for T1D could yield many benefits. Behavioral barriers to effective care are major concerns of all stakeholders, but conventional care is not well-equipped to address these issues. Concomitantly, the supply of board-certified pediatric endocrinologists is not keeping pace with growth of the T1D patient population, amplifying the need to validate alternative delivery systems that multiply the effective workforce of T1D health professionals. We will develop and test a novel Transdisciplinary Care (TC) approach (conjoint TC visits conducted by an Advanced Practice Nurse, Psychology Postdoctoral Fellow and Dietitian) to improve adolescents' T1D outcomes and justify a larger randomized controlled trial (RCT). In Year 1, crowdsourcing methods will engage youths with T1D, parents and health care providers (HCP) in planning a feasible, acceptable, safe and effective TC model that addresses youths' and families' psychosocial needs and capitalizes on the expertise of advanced practice nurses co-managing T1D with psychologists and dietitians. The Wallander et al. stress and coping model and the D'Zurilla and Goldfried problem solving model provide a sound conceptual framework for the TC model of care. The TC team will learn each discipline's skills in T1D management, develop a detailed TC manual to guide this work and others' future studies, see adolescents and parents together as a team, screen for potentially modifiable psychological impediments to T1D care, and promote families' coping resources by enhancing family-centered communication and problem solving, implementing empirically validated behavioral interventions and facilitating additional appropriate services for complex problems. Telehealth delivery of TC care carries several potential advantages, justifying its inclusion within a RCT comparing the effects of UC to TC delivered via various modalities on glycemic control and treatment adherence (primary outcomes) as well as quality of life and other psychosocial variables (secondary outcomes). Qualitative and economic analyses will follow the RCT, providing perspectives on mechanisms of TC effects and its sustainability. Mixed qualitative and quantitative methods will validate an innovative model of T1D care for adolescents that could then be tested in a future definitive, multi-site RCT. We will address these specific aims:

SPECIFIC AIM 1. In Year 1, with methods used effectively in our ongoing DP3 study of parents of children <6 years old with T1D, we will engage separate "crowds" of adolescents with T1D, parents, and HCPs in planning/refining a feasible, safe, acceptable and efficacious Trans-Disciplinary care model (TC) for T1D in adolescence. This crowdsourcing effort should yield a TC model that meets the needs of all key stakeholder groups, ensuring its feasibility, acceptance and efficacy.

SPECIFIC AIM 2. With study oversight by a diverse stakeholder panel and guided by a detailed intervention manual, 150 families of adolescents treated for T1D at Nemours practices in the Delaware Valley or Florida will participate in a rigorous Randomized Controlled Trial (RCT) in years 2 and 3. The RCT will compare Usual Care (UC) with Transdisciplinary Care (TC) on glycohemoglobin (HbA_{1c}), treatment adherence, health care use, T1D-related distress, quality of life, and treatment satisfaction. Delivery mode of TC will also be explored (e.g., Face-to-Face, Telehealth, Combined). The proposed trial will yield substantial information that could justify a definitive future test of this model, inform methodological planning for subsequent studies, and explore whether certain modes of delivery (e.g., Telehealth) are justified for evaluation in future trials.

SPECIFIC AIM 3. Qualitative interviews of adolescents, parents, and health care providers completed at the midpoint and end of the RCT will identify possible mediators or moderators of TC efficacy and guide refinements to the TC model. We will interview third party payers about the feasibility of dissemination of the TC model into practice and collect health care cost data. These analyses will strengthen the justification for a future, larger trial of TC, and guide refinements to the TC model to further enhance its efficacy.

3.1. RESEARCH STRATEGY: SIGNIFICANCE AND SCIENTIFIC PREMISE

Barriers to T1D care Epidemiologic studies indicate that <25% of adolescents with T1D achieve the HbA_{1c} target of < 7.5%.¹⁻³ T1D care has advanced greatly in emphasizing the merits of long-term glycemic control and through reliance on technological advances (insulin pumps, continuous glucose monitors).⁴⁻¹¹ Adolescents achieve poorer T1D outcomes than other age groups,¹²⁻²⁶ partly due to pubertal insulin resistance.²⁷ But, many studies show that T1D care interacts with psychological variables at the levels of individuals,²⁸⁻⁹¹ dyads/families⁹²⁻⁹⁷ and broader social contexts.⁹⁸⁻¹¹⁴ Treatment adherence declines during adolescence^{26-50,92} and adolescents tend to derive less benefit from technological advances in care.^{8-22,44-48,92}

Person-level characteristics of adolescents that impact T1D self-care include adjustment and behavioral problems,^{28-45,49,50,92} presence/absence of depression, anxiety disorders and eating disorders,^{47-90,93,115-118} social support from siblings and peers,^{91,98,99,101-114,119-123} and cognitive processes such as executive functioning and decisional competence.¹²⁴⁻¹³¹ Poor T1D self-care and poor glycemic control resist change, raising risks of major long term complications and psychiatric disorders. Parents of teens with T1D struggle to balance the benefits of youths' self-care autonomy with the risks of mismanaged T1D. This dilemma is a major stressor for parents that may manifest in distress and psychiatric disorders in youths and parents,^{71,132-146} caregiver "burnout" and premature parental withdrawal from involvement in care.^{93,136,147-159} Premature parental withdrawal is associated with many adverse outcomes.^{93,136,147-159} Healthy parent-adolescent teamwork, emotional affiliation and collaborative T1D problem solving are all associated with favorable outcomes.^{98-103, 148-168} Many features of families also predict T1D outcomes,^{96,160-170} which tend to be worse with single-parent family structure or low paternal involvement,¹⁶⁰⁻¹⁷⁰ low socioeconomic status,¹⁷⁰⁻¹⁷⁴ minority status,¹⁷¹⁻¹⁷⁶ higher family conflict,^{70,73,177-182} coercive parenting¹⁸³⁻¹⁸⁵ lower family cohesion¹⁸⁶ and more psychosocial dysfunction in family members.^{71,132,134-146} Little is known about how interactions with HCPs may affect T1D outcomes, but more frequent health care visits predict lower HbA_{1c}.¹⁸⁷⁻¹⁹⁰ Care encounters reflecting patient-centered communication predict greater satisfaction and agreement on the goals of care.¹⁸⁷⁻¹⁸⁹ Current models of care are ill-equipped to respond to these critical behavioral barriers to T1D care that affect so many patients and families. The tentative TC model was specifically designed to address these issues, using empirically validated tools for screening and intervention and it will be refined with deliberate stakeholder input. The proposed work rests on the observations that individual psychological characteristics of patients and parents, family/dyadic interactions around T1D care, and the broader social context of T1D management affect adherence and problem solving, which in turn affect T1D outcomes such as glycemic control, quality of life and health care use. T1D care that does not address these issues seriously cannot be broadly effective.

Psychologically informed T1D care Research on psychosocial influences on youths' T1D outcomes is penetrating T1D care guidelines,¹⁹¹ and many trials of psychosocial screening and intervention have been reported. Structured screening protocols have been validated in several large studies,¹⁹²⁻¹⁹⁴ showing that screening for psychosocial barriers to effective T1D care is feasible, acceptable and may enhance psychosocial outcomes. But, few T1D centers support routine psychosocial screening. Growing evidence also supports the efficacy of various psychological interventions,¹⁹⁵ including treatments for adolescents as individuals or in groups,^{120,196-205} using cognitive behavior therapy,^{195,200} motivational interviewing,^{198,206-209} and skills training targeting coping,²¹⁰⁻²¹² social interactions^{120,201-204} or diabetes problem solving.²¹³ Other interventions treat families as the unit of treatment, including Behavioral Family Systems Therapy,²¹⁴⁻²¹⁹ Ellis' research on Multi-systemic Therapy,²²⁰⁻²²³ Anderson and Laffel's studies^{34,224-227} of family teamwork interventions and the recent Family Management of Childhood Diabetes trial²²⁸ that all targeted promotion of healthy youth-parent teamwork in T1D care. Investigators are now adapting these interventions for e-health delivery to enhance cost effectiveness and access.²²⁹⁻²⁴³ Few pediatric T1D centers have well-integrated programs that offer these evidence-based services routinely due to lack of availability of behavior change professionals with sound T1D expertise, insurance constraints, perceived stigma around such services, dilution of efficacy of these interventions when delivered in real-world settings, and inadequate communication between community mental health providers and T1D HCPs. The proposed work emphasizes use of screening and intervention methods that can be integrated into typical T1D care, targeting the prevention of common behavioral obstacles, the remediation of mild to moderate issues before they become entrenched and facilitation of intensive services for more complex problems. The proposed work is thus highly consistent with

the encouragement of inter-professional care in the Affordable Care Act. As discussed below, telehealth delivery of T1D care^{230,234-243} and behavioral interventions¹⁹²⁻¹⁹⁵ carry many potential advantages, thus warranting consideration as a platform for delivering innovative care to adolescents with T1D and their families.

Models of T1D care Pediatric endocrinologists often direct T1D care supported by diabetes educators, nurses, dietitians, social workers or psychologists. Access to pediatric endocrinologists is concentrated in the Eastern U.S., (1 per 144 youth with T1D) but elsewhere this ratio is one per 300-350 patients²⁴⁴ and most also manage other endocrine problems. The supply of new pediatric endocrinologists is not matching the growth of these populations, and so new models are needed.²⁴⁴ Pediatric endocrinologists recognize psychological barriers to T1D care, but neither their training, workflow nor payment practices facilitate addressing those barriers. An alternative care model is needed to address behavioral barriers to T1D care by engaging parents and youth as key members of the care team, screening and prevention for psychosocial problems, promoting healthy problem solving and communication about T1D care, applying empirically validated intervention tools for families with mild/moderate barriers and obtaining more intensive services for families who need them.

Engaging several disciplines in T1D care occurs on a spectrum of delivery models.²⁴⁵⁻²⁴⁹ **Multidisciplinary care**, typifying much U.S. T1D care, engages several disciplines, but each stays within its boundaries. **Interdisciplinary care** deliberately analyzes, synthesizes and harmonizes links between disciplines into a coordinated whole. **Transdisciplinary care** integrates the disciplines in a humanistic context transcending traditional boundaries. Put simply, inter-professional interaction is additive in Multidisciplinary Care, interactive in Interdisciplinary Care and holistic in Transdisciplinary Care. Research has supported TC models in scientific research initiatives involving multiple disciplines²⁴⁸⁻²⁵² and delivery of care for many clinical problems.²⁵³⁻²⁶⁸

Table 1. Comparison of Multidisciplinary, Interdisciplinary and Transdisciplinary models of care.

	MULTIDISCIPLINARY	INTERDISCIPLINARY	TRANSDISCIPLINARY
Professional activities	Additive	Interactive	Holistic
Knowledge of others' disciplines	Minimal	Incidental	Intentional and thorough
Interactions among disciplines	Distinct professional boundaries	Coordination of input from separate disciplines	Integration yields a whole exceeding sum of its parts
Boundaries between disciplines	Distinct and preserved	Blurred	Negligible
Expanded roles for all team members	Absent	Limited and passive	Integral to the model
Subordination of discipline in favor of achieving an integrated perspective	Absent	Limited and passive	Integral to the model

Trans-Disciplinary Care (TC) is conjoint delivery of T1D care by a team of HCPs from different disciplines who share the knowledge base and tools of their respective professions. In this study, TC teams (Advanced Practice Nurse/APN, Registered Dietitian/RD and Psychology Post-Doctoral Fellow/Psy. Fellow) will see families jointly at visits and collaborate in care delivery by integrating their respective knowledge and skills. Pediatric endocrinologists will monitor enrolled patients. A TC model will be refined iteratively based on stakeholder input and tested in a careful randomized controlled trial (RCT). We hypothesize that TC will achieve better T1D outcomes than Usual Care. **This application is based on the premise that current care is failing most adolescents and that careful user-centered design²⁶⁹ and testing of an innovative Transdisciplinary model of care can better address psychosocial barriers to T1D management, improving outcomes via better assessment of patients' needs and resources, better cross-discipline and parent-adolescent-HCP communication, and better collaboration with families to resolve problems that cross disciplines.** This work can validate an innovative TC model, justifying its testing in a larger RCT. A pilot evaluation of a telehealth intervention for teens with T1D delivered by a nurse-social worker team yielded excellent visit attendance among adolescents and self-care improvements in the intervention group.²⁷⁰ That care model did not employ evidence-based psychological principles and practices. We have based the TC model in a conceptual framework combining the Wallander et al²⁷¹ Chronic Disability Stress and Coping Model, treating the elements of TC as coping resources within that scheme; and the D'Zurilla and Goldfried Problem Solving model,²⁷² a framework that underlies our trials of Behavioral Family Systems Therapy for Diabetes²¹⁴⁻²¹⁹ and other intervention trials.^{213,220,224,225,228,273-277} TC will encourage

constructive, patient-centered communication via Motivational Interviewing skills^{198,206-209} and it will promote active group problem solving. TC team members will use a toolbox of methods from prior studies to resolve common clinical problems^{198-202,205,213-220,224,228-243,273,274,278} Multisystemic Therapy in T1D promotes engaging home, school, peer and health care systems in planning and delivery of that intervention,²²⁰⁻²²³ but that work has not emphasized changing health care delivery to better address psychosocial barriers to care. We expect that knowledge and skills of TC team members in one another's disciplines will be enhanced and that this will improve recognition, analysis and resolution of each adolescent's barriers to T1D self-care.

Growth of Telehealth Delivery of T1D Care and Psychological Interventions The promulgation of telehealth delivery of T1D medical care and behavioral health interventions is likely to continue.^{230-243,278} Telehealth delivery of TC could facilitate families' access to needed specialized care, capitalize on the emergence of systems for remote monitoring and communication of clinical data, and enable dissemination of TC across geographic and institutional boundaries. Thus, an element of this application is comparison of TC delivered via conventional face to face encounters versus telehealth delivery, which will be achieved by relying on Nemours' established relationship with American Well, using its AW9 telehealth platform.

3.2. RESEARCH STRATEGY: INNOVATION

Fewer than 25% of adolescents with T1D achieve the HbA_{1c} target of $\leq 7.5\%$. If indeed "**every system yields exactly the results that it was designed to achieve**",²⁷⁹ the system of T1D care for adolescents requires re-thinking. Youth and their families face challenging affective, behavioral and cognitive impediments to valued T1D outcomes and typical T1D care is ill-equipped to address these issues. Few pediatric T1D centers address these challenges well since there are too few behavior change professionals with T1D expertise, reimbursement issues, stigmatization around such services, reduced efficacy of validated interventions in real-world settings, and barriers to communication between mental health providers and T1D HCPs. The proposed work would carefully plan and test a novel TC model that identifies and targets psychological barriers to optimal care and engages stakeholders in designing and testing the TC model. As in our ongoing grant (DP3-DK-108198) we will use crowdsourcing^{280,281} to elicit stakeholder input to design and test a TC model for adolescents with T1D that is acceptable, safe, and effective. We propose a novel intervention that could be more effective than usual multidisciplinary care. TC may reduce demands on pediatric endocrinologists, freeing them to care for endocrine problems that clearly require subspecialty expertise. Extensive stakeholder input, focused qualitative work before, during and after the RCT and the planned economic analyses also enhance the potential impact. Comparison of face to face with telehealth delivery of the TC model amplifies the novelty of this work. The proposed work could provide justification for similar trials with other medical conditions.

3.3 RESEARCH STRATEGY: PRELIMINARY STUDIES

The biographical sketches affirm the team's extensive research and clinical expertise in pediatric T1D, funded research (NIH, PCORI, JDRF) and leadership in testing behavioral interventions to enhance T1D care. We describe below aspects of the team's work that are most pertinent to this application.

T1D Behavioral Intervention RCTs: Dr. Wysocki was PI for RCTs of Behavioral Family Systems Therapy for Diabetes (R01-DK43802), use of BFST-D to enhance adolescents' use of CGM (R01-DK080831), a web-based shared decision making intervention for insulin pump and CGM candidates (PCORI #805), the Family Management of Childhood Diabetes trial (# N01-HD-4-3361) and he was the only non-MD PI in the Diabetes Research in Children Network and the JDRF CGM Study Group that completed many CGM clinical trials.

Crowdsourced Design of a Web Resource for Parents: Our use of crowdsourcing (DP3-DK-108198) to design and test a social media portal for parents of very young (<6 y.o.) children with T1D will be re-purposed in the proposed work. In the ongoing study, we have enlisted 170 Parent Crowd members and 32 U.S. pediatric endocrinologists and other professionals as HCP Crowd members. A 6-member Family Advisory Council guides the research team. With expert input from Dr. Karen Aroian, Chatlos Endowed Professor of Nursing at the U. of Central Florida, the Parent Crowd answered open-ended questions and polls about their perspectives as parents of very young children with T1D. To date, 19 open-ended questions have been sent to the Parent Crowd, and a mean of 128 parents (74% of members) sent free-text replies averaging ~120 words. Also, 7 polls about narrower issues yielded similar response rates. Only 18 Parent Crowd members have not

replied to a question or poll. Systematic coding has yielded a detailed taxonomy that will drive the content and functions of the planned website. The distribution of parallel open-ended questions to the HCP Crowd has just begun. We are systematically mapping the resulting content into website functions that will be iteratively refined with crowd input until a final website has been designed and built. Results to date support an adapted Social-Ecological Model framework for organizing the voluminous content that has been compiled. A randomized controlled trial of website use on parental coping and child outcomes will follow, including qualitative interviews of trial participants at the midpoint and end of the trial. This experience will facilitate the design and evaluation of a TC model of care that is planned with careful consideration of diverse views and is acceptable to all stakeholder groups. Application of these methods to crowdsourced design of the TC model should be even more successful given the much larger clinical population of adolescents with T1D.

Qualitative Interviews of Stakeholders: We have completed qualitative interviews of 6 adolescents with T1D, 6 parents, 5 HCPs and 3 administrators with expertise in health care reimbursement about the feasibility of TC. These interviews yielded very positive reactions to the TC model, and respondents offered constructive suggestions that could improve its feasibility and acceptability. Parents and adolescents were especially enthusiastic about the possibility of telehealth delivery of TC. Stakeholder input has been incorporated into our initial TC design and these interviews will guide continued qualitative work during the initial phase of this grant. Until notice of funding, responding to some complex points will be deferred to the initial planning phase of this grant. Dedication of major time and effort to address those points is not justified until funding is certain.

3.4. RESEARCH STRATEGY: APPROACH

Part 1: Crowdsourced Design of the TC Model. In our ongoing DP3 grant, we use crowdsourcing to solicit input of parents of children with T1D < 6 years old to plan a social media portal designed for similar parents. For the proposed work, we will recruit separate “Crowds” of Parents (n=100-120), Adolescents (n=100-120) and HCPs (n=~30) via direct contact with Nemours families and HCPs, e-mails to T1D HCPs at other U.S. centers and posting ads on Diabetes Online Community sites. These methods yielded 170 Parent Crowd members in <1 month and, since T1D is much more common among adolescents, enrolling parents and adolescents for this grant should proceed quickly. Our experience is that demographically diverse Crowds of 100-120 members will suffice and, if necessary, more members can be added. Initially, the crowds’ activities will be segregated, but the Parent and Adolescent Crowds may elect to combine the crowds. We will regularly apprise the Parent, Adolescent and HCP Crowds of the nature of responses sent by the other Crowds.

Dr. Karen Aroian will expertly direct these qualitative research procedures: 1.) Online distribution of open-ended qualitative questions to adolescents, parents and HCPs to define an acceptable, feasible, and effective TC model for testing in the RCT (Aim 1); 2.) Qualitative interviews to obtain TC team members’ perspectives of the structure, process and efficacy of the TC training, once just after training is completed and again 1 year later (Aim 2); 3.) Qualitative interviews of TC participants and HCPs at the midpoint and end of the RCT about their TC care experiences (Aim 3); and 4.) Qualitative interviews of representatives of third party payers after the RCT (Aim 3). Dr. Aroian will develop questions, train coders and interviewers, ensure adequate reliability across coders and work with the research team to incorporate qualitative findings in the design and evaluation of TC. Many CHDS staff are experienced in qualitative interviewing and coding. The qualitative research component will systematically reveal the key elements of a TC model of care and to identify stakeholders’ perspectives of potential benefits and challenges in implementing TC. Purposive sampling will ensure diversity in family demographics. At least 28% of youths/parents will be of African American or Hispanic race/ethnicity. Participants will receive a summary of TC and planned model elements. They will be asked to relate helpful/unhelpful aspects of their recent T1D care, identify barriers to optimal care and evaluate several realistic vignettes of typical TC visits. Preliminary interview findings suggest that communication during T1D clinic visits will be an important and productive intervention target. Plans for subsequent questions will be adapted as the responses to the earlier questions are analyzed. In our ongoing work, we have assigned transcripts of responses to 11 trained coders working in four teams, given them one week to reach consensus about their assigned transcripts, followed by a meeting to further integrate the teams’ findings and suggestions. The Parent, Adolescent and HCP Crowds will review behavioral homework assignments, problem solving guides, parenting handouts and other materials from Dr. Wysocki’s T1D intervention trials,²¹⁴⁻²¹⁹ and from other published, manualized trials.^{206-228,275} The Crowds will evaluate TC elements including the nature of

psychological interventions integrated into T1D care, the circumstances/schedule under which the adolescent and parent would see the physician; the proportion of each visit in which families would see several TC team members together; and the extent to which team members might see the adolescent privately. Crowds will comment on the merits, feasibility, and acceptability of each such element, and they will be asked to suggest improvements. After one round of Crowd input, the research team will draft a detailed outline of a proposed TC model and will share it with the Crowds. This iterative refinement will be repeated until all three Crowds find the final TC model to be feasible and acceptable. Then, the researchers will engage Nemours administrators responsible for billing, coding, and EMR documentation to review the final TC model *vis a vis* its integration into work flow and other practical considerations. A detailed TC manual will promote transparency and reproducibility both within this work and for others' future work. Certain features are expected to characterize the final TC model: extensive sharing of discipline-specific knowledge/skills among team members, less frequent MD contacts with TC patients, involvement of TC team members concurrently during TC visits, screening for psychosocial impediments to T1D care, promotion of family-centered communication, shared medical decision making and negotiated goal setting, and reliance on motivational interviewing, cognitive behavior therapy, problem solving training and other brief interventions.

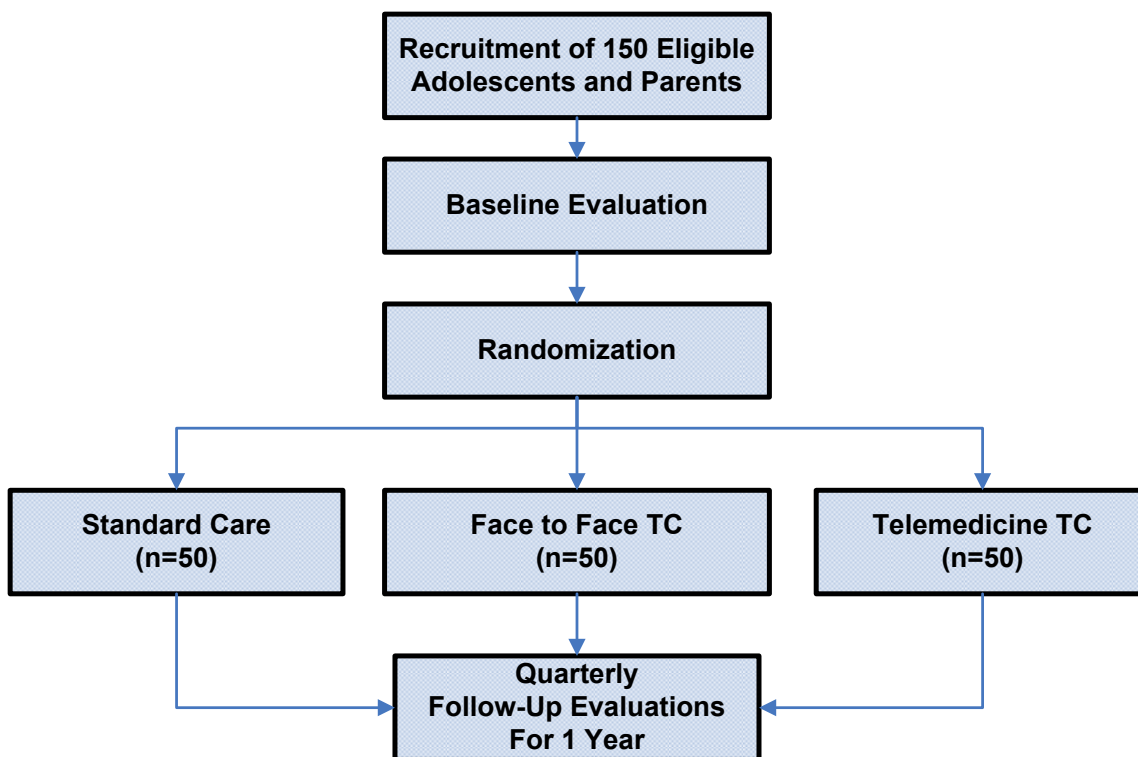
Table 2. Comparison of implementation of Multidisciplinary and Transdisciplinary Care.

	Multidisciplinary Care	Transdisciplinary Care
Visit Structure	Disciplines may see a patient sequentially during a visit, often with little prior or later interaction about their varied perspectives.	Co-management by HCPs from several disciplines who see the adolescent and parent as a team, not individually. Visits with one HCP are uncommon.
Visit Frequency	Approximately quarterly; Difficult to arrange more frequent appointments.	Approximately quarterly; More often if necessary with individual team members
Visit Length	Visit duration may be longer for the adolescent and parent if several providers must be seen on the same or different days.	Total visit duration may be shorter for the family, but care providers may be involved with a given family for a longer period during a given visit.
Contact with Physician	Visits are MD-centered; MD is seen at each visit.	Visits are family- and team-centered, with MD as consultant. MD is seen annually.
Role of Advanced Practice Nurse	APN or PA may be the primary provider of T1D care to adolescents. .	APN or PA provides T1D care to adolescents conjointly with dietitian and psychologist. APN acquires skills in psychology and nutrition.
Role of Dietitian	As needed based on physician judgment.	Routine part of TC visits with APN/PA and psychologist. RD acquires skills in medicine and psychology
Role of Psychologist	On referral, usually seen on another day.	Routine part of TC visits with APN/PA and dietitian. Psychologist acquires skills in medicine and nutrition.
Interaction Among Disciplines	Non-systematic, without planned interaction among disciplines about their perspectives.	Integral to the model; APN/PA, Dietitian and Psychologist seen as a group at each visit.
Boundaries Between Disciplines	Distinct professional roles; Disciplines teach each other by observation and clinical interaction.	Intentional blurring of boundaries. HCPs train each other actively in their knowledge bases and skills.
Contact with Diabetes Educator	Diabetes Educator sees adolescents and parents at most/all visits.	Diabetes Educator sees adolescents and parents at most/all visits.
Contact with Social Worker	As needed based on MD judgment.	As needed, based on TC team judgment.
Psychosocial Screening	Typically not done routinely.	Systematic screening for psychosocial impediments to effective care.
Treatment Planning	Each HCP negotiates a discipline-specific treatment plan with each family.	Teams develop treatment plans that reflect joint input from the family and each discipline.
Visit Time Dedicated to Behavioral Issues	Little, unless very poor self care is evident.	A major part of every visit, emphasizing prevention, problem solving and family communication.
Reliance on Evidence Based Psychological Practice	Mostly for adolescents who are referred for serious problems in managing T1D. Uncommon during routine follow-up visits.	Proactive, preventive services are emphasized; Extensive use of handouts and guides from trials of evidence-based treatments.
Visit Documentation	Each team member separately documents his/her own interactions and observations.	TC treatment plan prepared by one team member, edited by all team members, entered into the EMR and sent to the family and attending MD.

Qualitative interviews about TC training for HCPs will evaluate curriculum structure, clarify perceived value of curriculum elements, and specify content requiring more emphasis. These will occur at the end of training and 1 year later after TC HCPs have TC experience. Trained raters will employ a descriptive level of analysis, using a well-accepted method of content analysis with Atlas-ti software to extract the primary themes emerging from these interviews. Dr. Aroian will help us incorporate these themes into the TC model and manual. Table 2 differentiates Multidisciplinary and Transdisciplinary Care based on our preliminary conceptualization.

Part 2: Randomized Controlled Trial (RCT) of Trans-Disciplinary Versus Usual Care In Years 2-3, we will conduct a rigorous RCT of the TC model versus Usual Multidisciplinary Care (UC) in a projected sample of 150 youth (11-<17years old) with T1D. The Senior Research Coordinator in Jacksonville will randomize participants to Usual Care (UC: n=50), or to TC delivered In Person (TC-IP; n=50) or via Telehealth (TC-TH; n=50).

FIGURE 1. STUDY DIAGRAM OF ORIGINAL RANDOMIZED CONTROLLED TRIAL



Participants: The RCT would test the TC model with appropriate clinical candidates who could benefit from a relatively low intensity intervention but who may not need more intensive psychological services. We will enroll 150 Nemours T1D patients at Nemours Children’s Hospital (NCH) in Orlando, FL, or the Alfred I. du Pont Hospital for Children (AIDHC) in Wilmington, DE (~75/site), including ~21 African American and ~21 Hispanic youth (~28% minorities). The Facilities and Resources section confirms the feasibility of the sampling plan. Each parent/youth will sign IRB-approved Parental Permission and Assent Forms prior to participation. State laws require that participants in telehealth sessions must all be physically present in a state in which the participating HCPs are licensed and the team will ensure this. Youth eligibility criteria are: Age, ≥ 11 and < 17 yrs old; T1D for > 1 yr; Most recent HbA_{1c} or mean HbA_{1c} over the prior year 7.5-10.0%, inclusive; Able to complete questionnaires in English; No other medical obstacles to participation per the treating MD; No concurrent enrollment in other T1D studies, and no T1D clinic visits in the preceding 12 months in which two or more care providers saw the patient together. Parent eligibility criteria are: Biological parent/legal caregiver of an enrolled patient; At least weekly involvement in T1D care; Able to complete questionnaires in English; Plans to continue T1D care at Nemours for > 1 yr; No reporting of the family for child protection complaints within the prior 3 years. Two parents of the same child may enroll, but they would jointly complete one set of questionnaires. HCPs (MDs, Advanced Practice Nurses, Dietitians, Social Workers and Psychologists) who have provided care to study participants also contribute data and will provide informed consent.

Experimental Design: Two TC teams (APN, RD and Psy. Fellow) will be constituted and trained, one each at NCH and AIDHC. A backup for each team member will also be identified and trained. Families will be randomized by Dr. Wysocki's staff to TC-IP (n=50), TC-TH (n=50) or UC (n=50), using a prepared randomization list, stratified by insulin modality (pump or injections) and HbA_{1c} (\leq or $>$ 8.7%). We rejected randomization by sites due to logistical obstacles and since site differences might obscure detection of treatment effects. Randomization at the level of families reduces those concerns but introduces contamination issues as TC elements could intrude into UC visits. Efforts to counter this potential confound are described below. Each youth/parent will receive the assigned care (TC or UC) for approximately 4 successive follow-up visits across approximately 12 months. This period is adequate to detect clinically meaningful changes in HbA_{1c} and adherence. The design also permits exploratory analyses of modality of care (Face-to-Face vs. Telehealth), gender, race and ethnicity as moderators of treatment outcomes.

Treatment Conditions: The original RCT design is shown above. Treatment conditions include Usual Care and Transdisciplinary Care delivered in person or through telehealth. Elements of TC care are employed with some adolescents with T1D at AIDHC (i.e., APN and Psychologist see some patients together); this is much less true at NCH. AIDHC patients who have had such a visit within 12 months are ineligible for this study.

Usual Care (UC) will include the multidisciplinary health care, education and supports that are routinely available to Nemours families of youth with T1D. This includes ~quarterly clinic visits with a pediatric endocrinologist or advanced practice nurse, with referrals to a certified diabetes educator, dietitian, social worker or psychologist as deemed clinically necessary by that HCP. T1D visit data will be extracted from Nemours EMR for each adolescent. Parental reports of care received elsewhere will be recorded. An EMR "Smart Form" used in several of Dr. Wysocki's studies enables electronic capture of granular T1D visit data. Over 90% of Nemours T1D patients are on intensified regimens, i.e., insulin pump (~60%) or multiple daily insulin injections (~40%) using a "basal-bolus" approach and dietary carbohydrate counting. Treatment targets are HbA_{1c} $<$ 7.5% ($<$ 7.0% if deemed safe by attending MD) and minimization of symptomatic or severe hypoglycemia. A small, but growing, number of patients use continuous glucose monitors as part of their care.

Transdisciplinary Care will include all elements of UC T1D care, but quarterly T1D visits will consist of co-management by an APN, RD and a Psychology Fellow who will provide care to the adolescent and parent(s) as a team during each visit. TC will consist of the model resulting from the qualitative interviews and crowdsourcing data from the Parent, Adolescent and HCP Crowds. A central TC feature will be active incorporation of evidence-based psychosocial care for T1D into visits based on empirically supported conceptual frameworks. The TC model derives from the Wallander et al ²⁷¹ Chronic Disability Stress and Coping model in conceptualizing TC visits as coping resources to help adolescents and parents identify address impediments to family management of T1D. The TC model also derives from the D'Zurilla and Goldfried Problem Solving model ²⁷² since visits will emphasize applying a systematic problem solving and family communication framework to each family's self-identified T1D challenges. TC visits will include interaction with all three team members jointly, with subsequent interaction between the parent/youth or both with a subset of this team as decided by family and team consensus during the visit. The TC team will partner with a pediatric endocrinologist who will have the discretion to see any TC patient as deemed necessary and to see these patients for routine care as often or as infrequently as the physician deems necessary. The three Crowds will set the "default" frequency of scheduled visits with the endocrinologist during Year 1 (possibly once each at study entry and end of study).

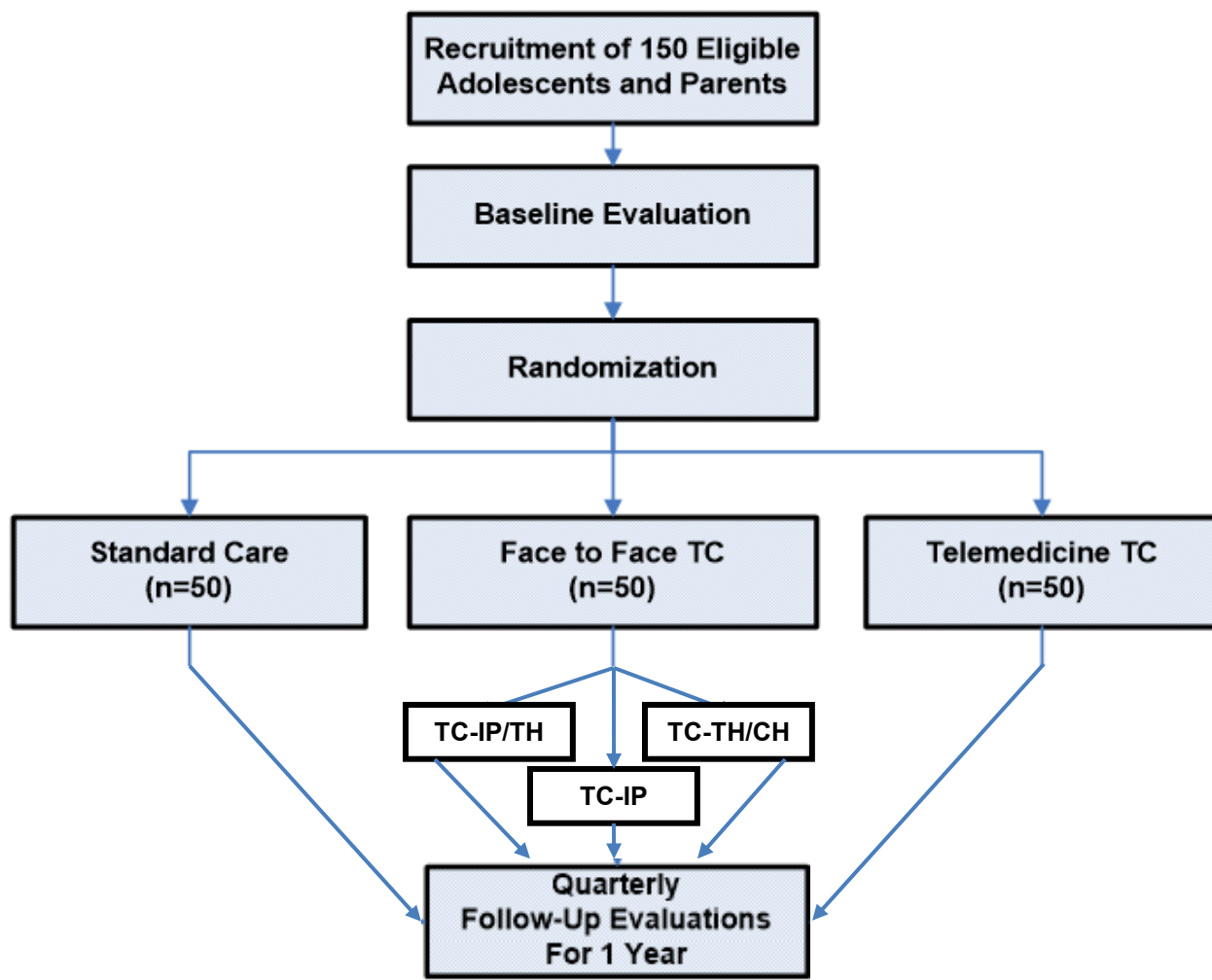
TC visits will recognize and normalize the challenges of T1D care, and use constructive, family-centered communication, active problem solving regarding behavioral barriers to optimal T1D care, and negotiated problem solving plans to achieve families' T1D goals. TC team members will be trained in Motivational Interviewing to enhance their patient-centered communication skills. The TC Psy. Fellow will assure that problem solving plans or behavioral interventions are appropriate to the adolescent's developmental status, that family-team negotiations yield measurable, achievable, and sustainable short-term goals and that these plans are documented carefully in the EMR. The final TC model is likely to have certain features, including extensive sharing of discipline-specific knowledge and skills among team members, reduced frequency of MD contacts with TC patients, conjoint involvement of all TC team members during TC visits, psychosocial

screening of all TC patients and families at study entry, active reliance on motivational interviewing, patient-centered communication, shared medical decision making and negotiated goal setting during visits, and use of a “toolbox” of low-intensity behavioral interventions targeting common behavioral barriers to care. Family handouts and guides developed in behavioral intervention trials will be used with TC families.^{206-228,275} Results of study questionnaires may lead to referrals for further assessment or intervention external to the study.

The TC team who will see each family together will not include Social Workers or Diabetes Educators. This decision was based on concerns revealed in our preliminary studies that too many professionals would be overwhelming to families, cumbersome logistically and too expensive for this mechanism. Services of these professionals can be considered a “given” in any well-resourced T1D clinic and will be available to all study participants. The decision to exclude them from the TC teams will be re-visited with the Adolescent and Parent Crowds in Year 1 of the proposed work.

Transdisciplinary Care: In Person (TC-IP) versus Telehealth (TC-TH) Delivery TC-IP involves face-to-face sessions with the TC team meeting together with the family at the diabetes clinic. TC-TH will be the same as TC-IP except T1D visits will occur with families at their homes or other remote location via a HIPAA-compliant telehealth platform such as American Well AW9 (<https://www.americanwell.com/aw9-launched-at-himss/>). This platform has been used by Nemours CareConnect in Florida since 2015 and in Delaware since May, 2016. Patients/parents can access CareConnect from any PC, Apple or Android device. Technical support from Nemours Telehealth is budgeted.

FIGURE 2. STUDY DIAGRAM OF REVISED RANDOMIZED CONTROLLED TRIAL



Changes to Experimental Design and Treatment Conditions related to COVID-19 Precautions In March of 2020, Nemours began transitioning all T1D clinical care visits to telehealth as a precaution against spread of the novel coronavirus, COVID-19. About one third of the families randomly assigned to TC-IP had completed the study. Those randomized to TC-IP and part way through the study and those recently randomized to TC-IP were not able to complete face-to-face visits. After considering the options of: 1) halting delivery of all TC care across all arms of the study until in person care was possible again; and, 2) providing TC-IP families with TC delivered through telehealth, our study DSMB recommended the latter. Because we could not predict when in person visits would again be allowed and suspending TC care would result in a smaller “dose” of the experimental treatment, the option to alter delivery mode was chosen to gather as much information as possible about the potential efficacy of TC and to explore additional questions about mode of delivery (e.g., feasibility, family preference).

Families who had already received some TC-IP visits were transitioned to receiving TC through telehealth and were reclassified as “TC-IP/TH.” Those randomized to TC-IP who had received no TC-IP visits but were due for clinical care also received TC through telehealth and moving forward will be allowed to choose (to the extent allowed by precautions) whether they want to receive TC visits in person or remain with telehealth. They are being tracked as “TC-TH/CH.” See Figure 2 above. Because these new arms of the study will be small and combine IP and TH delivery of TC, all TC arms of the study will be combined for primary comparisons against UC and comparisons will be made between the TC groups (size permitting) to explore whether delivery mode is important for outcomes. It is important to note that UC appointments are, for now, also being delivered through telehealth. This previously available option for UC was not widely used.

TC Team Training: An optimal test of TC requires that team members have requisite knowledge, skills and practical experience at trial initiation. Careful training also promotes integrity of the TC arms of the study. Key elements of TC are sharing of knowledge and skills among disciplines and lowering of inter-professional boundaries. TC team training will comprise: 1.) Knowledge of TC and its distinction from other models; 2.) Teaching one another about the evidence base and clinical practices for each of the team’s professions; and 3.) Experiential learning in applying TC with simulated patients and then actual clinical cases. Reaching agreement on what comprises TC is also a prerequisite to achieving it in the RCT. TC team members will discuss directed readings,^{282,283} categorize hypothetical programs as Multi-, Inter- or Trans-Disciplinary models, and interview colleagues about T1D care at their institutions and evaluate them from a TC perspective. Qualitative interviews of team members during the RCT will guide refinements to TC training and implementation, yielding an empirically validated TC curriculum for future RCTs.

Team members will collaborate on a curriculum for teaching the others about their disciplines, with content guided by diabetes organizations.^{282,283} The researchers will develop test items for a TC Knowledge Test covering the knowledge base of each discipline, such as sample items from CDE Certification Exam practice tests on managing T1D in adolescents. As was done for another of Dr. Wysocki’s NIH grants, training will include two full-day experiential seminars at a one-month interval offered by a Certified Motivational Interviewing Trainer, to equip the TC team members with key MI skills. Practical experience will be gained in the following month and the team will audio-record simulated or real clinical interactions for review at the 2nd session. Team members will practice these skills in their clinical work and give each other feedback to refine these skills. Once each team member achieves a score of $\geq 90\%$ on the TC Knowledge Test, the curriculum will turn to experiential, team-building activities to equip the team members to co-manage patients with T1D, first with “simulated” and later with real clinical cases, including both face to face and telehealth delivery experience. Several of Dr. Wysocki’s staff are experienced simulated patients/parents. These sessions will involve the TC team conducting a simulated clinic visit with a “patient” and a “parent”. Once the TC team has gained comfort with simulated patients, they will extend this to the care of a few T1D patients who are ineligible for the RCT. TC teams will collaboratively evaluate clinical problems and negotiate problem solving plans with families. Evaluation of TC training will consist of scores on the TC Knowledge Test for each HCP and two qualitative interviews, once at the end of training and again after 1 year of TC experience. These data will guide refinement of the TC curriculum and manual for training HCPs in TC delivery in a future multi-site trial.

Prevention of TC-UC Contamination: Treatment integrity and internal validity of the RCT will be optimized by minimizing intrusion of TC elements into UC visits. We seek to prevent receipt of elements of the TC model of care during UC visits, including seeing multiple HCPs simultaneously, use of motivational interviewing or problem solving communication training methods during visits, receipt of behavioral and psychological interventions that are explicitly integrated with the patient's T1D care and education, and the intentional blurring of professional roles that are critical to the TC model. More TC teams would be ideal, but not affordable. Adolescents will be ineligible for the study if they have had one or more T1D clinic visits in the prior year that mimic TC (More than one health care provider seeing the adolescent concurrently) UC patients will continue to see their established HCPs. Thorough training of study clinicians about the need to segregate the TC and UC arms will further reduce contamination. A post-visit checklist completed by parents and a post-study questionnaire completed by HCPs providing care in the past year to study participants will assess the extent to which contamination occurs. Feedback to, or retraining of, project staff will be done if necessary. We will verify via EMR documentation any UC visits that include instances of multiple clinicians seeing the patient/family together. UC patients/families needing psychological services will be referred to psychologists who are not TC team members. We will document any psychological or psychiatric interventions received by UC patients outside of the study. It would be unethical for the researchers to constrain UC patients from receiving needed mental health interventions outside of the study.

Measurement Schedule and Protocol:

Measures will be obtained at clinic visits at Baseline and ~quarterly for 1 year. Primary outcomes are change in HbA_{1c} and the Diabetes Self Management Profile Self-Report Form total score over 1 year. Other planned measures will be reviewed and refined by the Adolescent and Parent Crowds during RCT planning. To promote retention, encourage timely completion of questionnaires and minimize missing data, each adolescent will receive \$40 credited to a gift card when all measures scheduled for a given study visit are completed. Also, adolescents will receive a \$10 bonus if they complete all of the questionnaires within 7 days of the research team's e-mail containing a link to the REDCap platform for questionnaire administration at Baseline, 6 and 12 months. Online completion of questionnaires will be available for those with internet access using REDCap. Those who do not complete questionnaires online before visits can do so at visits via PC, tablet or hard copy or online during TC visits. Table 3 shows the measurement schedule, including estimated participation burden per measure. Respondents are indicated by A (Adolescent), P (Parent) or HCP (Health Care Provider). Participation burden has been minimized in several ways. Questionnaire completion is limited to study visits at 0, 6 and 12 months rather than every quarterly visit. Questionnaire completion time at the Baseline visit is 75-80 minutes for parents and adolescents and 65-70 minutes at 6 and 12 months. Online completion of questionnaires via REDCap can minimize inconvenience by enabling participants to complete questionnaires at convenient times or over several distinct periods.

Table 3. Measurement schedule.

Measures	Burden (Min/Visit)	~Quarterly Clinic Visits				
		0	3	6	9	12
Demographic Information (P)	10	•				
HbA _{1c} ; Device downloads; Glycemic variability; Hypoglycemia Diary (A,P)	20	•	•	•	•	•
Appointment keeping; Health Care Use, Costs, Time expended (P; EMR)	5	•	•	•	•	•
Type 1 Diabetes and Life Measures (A,P)	15	•		•		•
Diabetes Self Management Profile-Self Report (A,P)	15	•		•		•
Problem Areas in Diabetes Scale (A,P)	15	•		•		•
Collaborative Parent Involvement Scale (A)	5	•		•		•
Family-Centered Care Self-Assessment Tool (A,P)	10	•		•		•
Diabetes-Specific Risk-Taking Inventory (A)	10	•		•		•
Readiness Assessment for Emerging Adults with Diabetes Diagnosed in Youth (A)	5	•		•		•
Diabetes Care Inventory (HCP)	5					•

Demographic information: This form records child and parent age, gender, race, ethnicity, family composition, education, occupational category, socioeconomic status²⁸⁴ and certain details of the child's medical history. Adolescents will be asked if wish to provide their cell phone numbers to permit text message reminders from the research team about questionnaire completion. It will be made clear that this is entirely optional.

Glycohemoglobin (HbA_{1c}): will be measured at the NCH or AIDHC labs, or at insurer-mandated labs certified by the National Glycohemoglobin Standardization Program, to index recent glycemic control.^{285,286} TC-TH patients can do this at many Nemours satellite clinics so results will be available at visits.

Device downloads: Youth will receive \$5 credited to a gift card for downloading a glucose meter, insulin pump or continuous glucose monitor prior to each study visit. These data will quantify monitoring frequency/use, mean and SD of blood glucose, mean daily glycemic excursions, other glycemic variability measures²⁸⁷⁻²⁸⁹ and, for insulin pump users, mean daily frequency of premeal bolus infusions.

Hypoglycemia Diary: This measure, used in Dr. Wysocki's recent studies, records episodes of moderately severe hypoglycemia (requiring help) or severe hypoglycemia (with seizure or loss of consciousness). This will be submitted by parents via REDCap just after each study visit.

Health care use, costs and time expended: At each visit, parents will complete a form used in the JDRF CGM trial for tracking health care use and costs to capture direct and indirect costs of the youth's care.^{290,291} We will use EHR data to measure the interval between electronically recorded check-in (or login for TC-TH) and check-out times (logout for TC-TH). Parents will also estimate time expended for each visit, including travel.

Diabetes Self Management Profile-Self Report Version (DSMP-SR): Among T1D adherence measures,²⁹²⁻³⁰² the 24 item DSMP-SR assesses self-care behaviors that typify current T1D care and it has a mean correlation of .48 with HbA_{1c}, α of .79 and parent-youth correlation of .63.²⁹⁷⁻³⁰⁰

Type 1 Diabetes and Life (T1DAL) Measures: Separate versions of this quality of life questionnaire³⁰³⁻³⁰⁴ have been developed for 8-11 year olds with T1D (36 items), 12-17 year olds with T1D (44 items), parents of 8-11 year olds with T1D (47 items) and parents of 11-17 year olds with T1D (50 items). Empirically derived condensed versions of these instruments are undergoing validation.

Problem Areas in Diabetes Scale (PAID): (Teen and Parent brief versions). Respondents rate their agreement with 14 (Teen) or 15 (Parent) statements related to their worry and burden about their diabetes.³⁰⁶⁻³⁰⁸ Items are rated on a 6-point scale from "not at all" to "serious problem", and higher scores reflect less perceived burden/worry. Wasserman et al.³⁰⁹ recently validated the condensed versions of both scales.

Diabetes-Specific Risk-Taking Inventory (DSRI): The DSRI is a 34-item adolescent report measure that assesses the frequency with which adolescents (ages 15-18) engage in diabetes-specific risk-taking behaviors.³¹⁰ Adolescents report the frequency of each behavior on a 5 point likert scale, with the options of "Daily (5), Weekly (4), Monthly (3), Every few months (2), Yearly (1), Never (0), and Not Applicable." A mean score is used, with a higher score indicating more frequent diabetes-specific risk-taking behavior. In a validation study with 224 adolescents, the DSRI demonstrated excellent internal reliability ($\alpha = .90$).

Family-Centered Care Assessment (FCCA): The FCCA³¹¹ is a consumer-driven measure of the degree to which medical care received for a specific medical condition achieves ten accepted principles of family centered care. There are parallel, validated, 24-item forms for completion by parents and adolescents.

Collaborative Parent Involvement Scale (CPI): The 12-item CPI obtains youths' level of teamwork in T1D care with a specified adult.¹⁵⁷ Those living with two parents will complete the CPI separately about each. Higher total scores indicate that the youth perceives more T1D collaboration with that caregiver. Cronbach's α was .93 and .96 for youths' ratings of primary and secondary caregivers, respectively.

The Readiness Assessment for Emerging Adults Diagnosed with Diabetes in Youth (READDY): The READDY is a 13 item self-assessment of adolescents' readiness to transfer from pediatric to adult care for T1D. The scale has been validated by researchers at Cincinnati Children's Hospital and Children's Hospital of Seattle and a publication reporting these findings is under editorial review at this time.

Diabetes Care Inventory (DCI): This 17 item scale was developed by the research team to assess the nature of diabetes care provided to each participant in the study and to gauge the extent to which elements of Transdisciplinary Care are being provided to participants. Completed by healthcare providers, the measure includes questions regarding the provider's approach to care (i.e., use of motivational interviewing), the extent of their collaboration with providers outside of their discipline, the nature of their communication with other providers, and the format of care visits (e.g., multiple providers in the room at the same time). Aspects of the measure are based upon a provider-completed measure of use of motivational interviewing techniques.³¹² The DCI will be completed by all endocrinologists, nurse practitioners, dietitians, social workers, and psychologists seeing the patient during the course of the study (identified through the patient's EHR) after the final study visit for each enrolled adolescent.

Post-RCT Qualitative Interviews: These interviews (See Appendix) will obtain parent/adolescent views of the TC process, factors affecting its efficacy, advantages/disadvantages of the model, and suggested refinements. Qualitative interviews of representatives of third party payers will seek their views of the viability of the TC model, based on the RCT results and costs relative to UC. Audio recordings of interviews will be transcribed verbatim and coded by trained coders under the supervision of Dr. Aroian.

Analytic Plans Primary endpoints are change in HbA_{1c} and DSMP-SR total score (treatment adherence) over 1 year. Secondary endpoints are: # of severe hypoglycemic events (Hypoglycemia Diary); measures of glycemic variability at each visit; and questionnaires obtained quarterly. The Full Analysis Set will include those who provide data at ≥ 1 follow-up visit. The Completer Analysis set will include those who provide data at all follow-ups. Efficacy analyses will be done on both sets.³¹³⁻³¹⁵ We will use multiple imputation for treatment of missing data.³¹³⁻³¹⁵ Obtained data will be summarized in graphs and tables. Categorical variables will be summarized by frequencies and percentages; continuous variables by mean, median, standard deviation (or SEM), minimum and maximum. Data will be summarized by primary group (UC and TC), secondary group (TC-TH, TC-IP, TC-IP/TH, TC-TH/CH) and measurement points.^{316,317} Model assumptions will be checked before analyses, and appropriate transformations or non-parametric methods will be used when indicated. For summarization of normally distributed data, group means and SEM will be presented. In case of substantial deviation from normality, boxplots will be presented. Exploratory subgroup analyses (e.g. race, ethnicity, gender, SES, secondary group) will be conducted as needed.^{318,319} Most tests will be performed against a two-sided alternative at the $\alpha = 0.05$ significance level and a 95% confidence interval and/or a p-value will be provided for inferential purposes. Data from both clinics will be pooled for analyses.^{316,317} All analyses will be done using the most recent version of SAS, SPSS, R or M-Plus.³¹⁵⁻³²² Demographic variables (age, gender, race, ethnicity, family structure, marital status, SES) and baseline values of primary and secondary end points, and questionnaire results will be summarized by group. If the normality assumption holds, t-tests of continuous baseline variables and Fisher exact test/chi-square test/CMH test for categorical variables will be used to compare the TC and UC groups at baseline; one-way ANOVA will be used for comparisons of secondary groups. The statistician will select analytic methods based on data distributions and any imbalanced baseline scores.³²³ Linear mixed effects modeling (continuous outcomes) or generalized linear mixed modeling (categorical outcomes) is planned for the hypotheses below.³¹⁵⁻³²² Treatment group (UC vs TC) and demographic characteristics will be fixed effects in these models, while site, physician, and within-subject effects will be random effects. The same analyses will be attempted for secondary groups, sample size permitting. We will use Holmbeck's methods³²⁴ to evaluate baseline demographic variables and questionnaire scores as moderators of TC-UC effects on primary outcomes and to evaluate mediation of effects on primary endpoints. Candidate mediators are variables that are obtained serially concurrent with the primary endpoints at ≥ 3 visits.

Sample Size and Statistical Power: Recruitment ended at the end of March 2020. A total of 115 families were recruited. Allowing for some attrition prior to randomization, a sample of 100 patients (65 TC and 35 UC) yields 87.4% power to detect a clinically meaningful group differences in mean HbA_{1c} of 0.5% (~0.7 SD) versus the alternative of equal means using a t test with $p = .05$. Limiting recruitment to those with HbA_{1c} = 7.5-10.0% is anticipated to reduce the SD from 1.5% for the general adolescent T1D population to 0.7%, boosting effective statistical power for the RCT. The predicted 12-month means are 8.1% (TC) and 8.6% (UC). If the SD is 1.0%, our power is reduced to 71.3%; if it is 1.5% as in the general population, our power is 50.9%. This sample size also achieves power of 78.2% to detect a clinically meaningful mean differences in the DSMP-SR

total score of 7.0 points (~0.6 SD) at 1 year. The estimated mean values are 63.0 (TC) and 56.0 (UC). This preliminary trial will yield rich data that could be used to guide the sampling plan for a future, more ambitious, multi-center trial.³²⁵⁻³²⁷ The following hypotheses will be tested:

Hypothesis 1: Compared with UC patients, those randomized to TC will have significantly more favorable primary (HbA_{1c} and DSMP-SR scores) and secondary (frequency of severe hypoglycemia and level of glycemic variability) diabetes management outcomes at their 6, 9, and 12 month follow-up visits.

Hypothesis 2: Compared with UC patients, those randomized to TC will demonstrate more favorable scores on the T1DAL, PAID, and CPI at follow-up measurements.

Hypothesis 3: Significantly higher scores will be obtained on the DCI completed by HCPs describing TC care compared to HCPs describing UC care.

Hypothesis 4: Effects of TC on HbA_{1c} and DSMP-SR scores will be moderated by demographic variables (youth age, family SES, # of adult caregivers in the home) and by baseline scores on the T1DAL, PAID, and CPI. More benefit from TC will accrue to youth who are younger, from two-parent families with higher SES, and with more favorable scores on the T1DAL, PAID and CPI.

Hypothesis 5: Effects of TC on HbA_{1c} and DSMP-SR scores will be mediated by changes in scores on the T1DAL, PAID, and CPI. More benefit from TC will accrue to youth with favorable changes in T1DAL, PAID and CPI scores during the 12 months of the study.

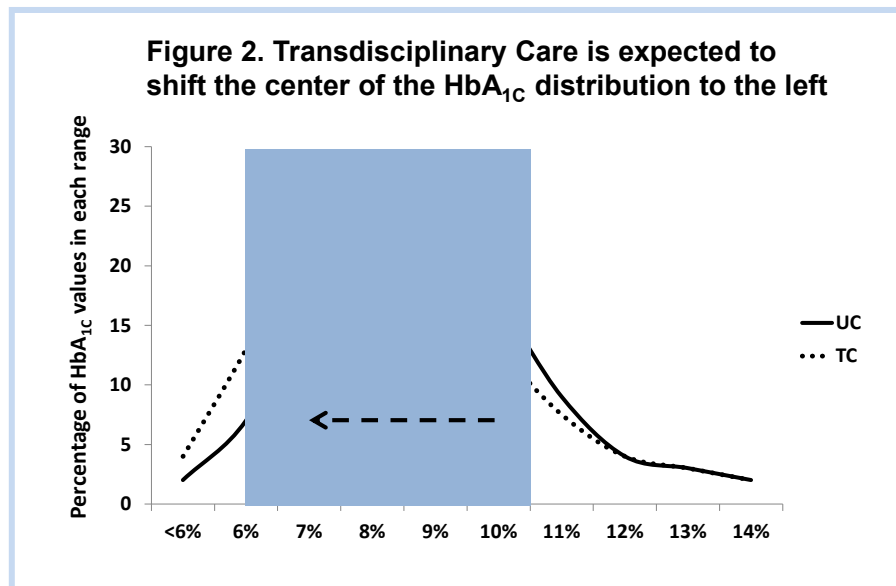
Hypothesis 6: TC-TH adolescents will keep significantly more appointments than either TC-IP or UC youths.

Limitations: Aspects of this application could have been done differently: 1.) Randomization at the level of patients/families was selected over randomizing sites in a Cluster RCT design. A Cluster RCT could reduce the potential for contamination, but it introduces problems in that differences between Nemours sites could obscure detection of treatment effects. We opted for randomization of patients/families to treatments with concomitant efforts to minimize possible contamination. Since this funding mechanism seeks to develop preliminary data to support a larger multi-site RCT in the future, empirical evaluation of our success in detecting, preventing and managing possible contamination effects would be an important feature of a future application of that type. 2.) The original structure of the RCT as a 3-arm trial (UC vs TC-IP vs TC-TH) introduces added complexity and expense and may decrease the sample size available for each study arm. Since telehealth delivery of subspecialty care for chronic conditions may be the wave of the future, it is prudent to capitalize on the availability of the DP3 mechanism to provide initial data on if and how telehealth delivery of the proposed TC intervention may be superior to conventional face to face delivery of that same care. Unfortunately, precautions due to COVID-19 spread has limited the TC-IP arm of the trial but comparisons are possible between UC and TC-TH as originally planned. 3.) The enrolled sample represents a period of marked developmental change. We have not planned specific adaptations to the TC model, but a key role of the Psychology Post-Doctoral Fellow will be assurance that negotiated interventions are developmentally appropriate for each adolescent.

Time Frame: The first few months of the 36 month study period will include hiring/assigning project staff, writing a procedure manual, obtaining IRB approval, constituting the Parent, Adolescent and HCP Crowds and starting qualitative interviews of stakeholders. Qualitative analyses of stakeholder responses to crowdsourcing questions will continue through month 6, and we will then ensure that themes derived from those analyses are reflected in planning of the TC model and in training the TC HCPs. TC training will begin at month 6 and continue for about 6 months, during which the teams will practice the TC model with simulated parent-adolescent dyads and several study-ineligible dyads. Recruitment and data collection for the RCT will begin near the end of Year 1 and will continue until the midpoint of Year 3. Statistical analysis of RCT results, cost-effectiveness analyses, post-study qualitative interviews of parents, adolescents, HCPs and other stakeholders and dissemination of study results will occur during the latter half of Year 3.

3.5. OVERALL IMPACT Conventional multidisciplinary care for T1D in adolescents is not meeting their needs and it is not yielding acceptable health or psychological outcomes. A fresh look at how care is delivered to this population, careful user-centered design of an alternative model of care and rigorous testing of a well-

articulated transdisciplinary care model will set the stage for a definitive multi-site randomized clinical trial. The proposed work could change how adolescents with T1D receive health care by rigorously validating a novel, manualized model of care that applies evidence-based assessment and intervention methods targeting known psychosocial mechanisms. Figure 2 illustrates that the TC model is designed to shift the center of the HbA_{1c} distribution to the left by helping adolescents achieve clinically significant improvement in glycemic control. The TC model could yield a substantial return on investment in improved health and quality of life, efficient use of scarce human resources, reduction of excess health care use, and lower costs, and the findings may apply to other pediatric chronic conditions.



4. INCLUSION AND ENROLLMENT REPORT (Not Applicable)

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6. PROTECTION OF HUMAN PARTICIPANTS

Nemours' Office of Human Subjects Protection is nationally accredited by the Accreditation Agency for Human Research Protection Programs (AAHRPP) and is one of the few strictly pediatric programs to have attained this distinction. NOHSP operates two Institutional Review Boards under its Federal-Wide Assurance: Nemours IRB 1, and Nemours IRB 2, which was chaired by Dr. Wysocki (FWA# 00000293). Since the two IRBs are each empowered to review and approve research occurring at any Nemours location, the present research will be submitted to the Nemours IRB 1 as the IRB of record and Dr. Wysocki will recuse himself from deliberations related to this work.

The proposed research consists of both qualitative (crowdsourcing and qualitative interviews) and quantitative (RCT) components. These two components of the application are treated separately in the section below.

Human participants' involvement, characteristics and design

Qualitative research component: About 100-120 adolescents with T1D, and 100-120 of their parents, and ~30 T1D HCPs will be recruited via flyers mailed to U.S. T1D referral centers, e-mails to T1D HCPs, internet announcements, and handouts at national conferences to constitute the membership of the respective crowds. Current Nemours T1D patients who are at least 16 years old and who otherwise meet the eligibility criteria for the RCT portion of the proposed work, (and their parents) will also be recruited for this component, since the patients would be too old to be eligible for the planned RCT. The intent is to enlist as many members as possible who are not affiliated with Nemours as a patient, parent or HCP so that prospective Nemours participants remain naïve to the RCT aims and procedures and thus remain eligible for participation in the RCT. Parents, adolescents and HCPs will enroll as members of the pertinent Crowd after authenticating an IRB-approved electronic parental permission, adolescent assent or informed consent form, as was done for our current NIH DP3 grant and PCORI-funded shared decision making study. About 5-10 representatives of third party payers from Nemours service regions in Florida and the Delaware Valley will be recruited to participate in qualitative interviews about the feasibility of the TC model from that perspective. Members of the Parent, Adolescent and HCP Crowds will provide written narrative responses to open-ended questions about their perceptions of a proposed Trans-Disciplinary Care (TC) model. HCPs will participate first and their perspectives will be reflected in a revised TC model, followed by solicitation of perspectives of that model from the Adolescent and Parent Crowds. This process will be repeated as the TC Model is iteratively refined and ultimately finalized. The TC model emerging from this iterative process will be the model to be tested in the RCT.

HCPs on the Orlando and Wilmington TC teams for this study will be interviewed at the completion of TC team training and again one year later to obtain their perspectives of the training curriculum and of the structure, process and outcomes of TC care.

Adolescents with T1D and their parents who are randomized to TC will undergo qualitative interviews as they leave the study concerning their perspectives after experiencing the TC model of care delivery, its advantages and disadvantages and possible influences on efficacy.

Finally, representatives of third party payers will be interviewed after the initial RCT results have been analyzed and their perspectives will be sought regarding how these data might be interpreted from their companies' perspectives.

Quantitative (RCT) Research Component: The RCT will enroll 150 youth who have established care for T1D at either Nemours Children's Hospital in Orlando, Florida or Alfred I. du Pont Hospital for Children in Wilmington, Delaware. At least one parent or other legal caregiver of each adolescent must also participate. About 75 participants will be enrolled at each site. Oversampling of racial/ethnic minorities is expected to yield a sample comprised of at least 21 African-American and at least 21 Hispanic adolescents (At least 28% of the sample will be racial or ethnic minorities). Each parent will sign an IRB-approved Parental Permission and Informed Consent Form and thereafter each youth will sign an IRB-approved Assent Form prior to collection of any research data. Enrollment criteria for youth are: Age, At least 11, but not yet 17, years old at enrollment; T1D for at least 1 year; Most recent HbA_{1c} or mean value over the prior year 7.5% to 10.0% inclusive; Able to complete study questionnaires independently; No other chronic medical conditions that, in the opinion of the treating physician, represent obstacles to study completion. Enrollment criteria for parents are: Biological

parent or legally appointed caregiver of an enrolled patient; Primary or shared responsibility for monitoring the medical care of the youth with T1D; Able to complete study questionnaires in English; Stated intent to continue medical care for T1D at Nemours Children's Clinic for 12 months following enrollment. Two parents of the same child may participate, in which case one set of the parent-administered questionnaires will be completed at each assessment point by both parents together. Randomization will be at the level of families; for any family with two or more eligible adolescents, all of those adolescents would be randomized to the same condition. The HCPs who will implement the clinical aspects of this protocol will also be viewed as research participants and will sign IRB-approved Informed Consent Forms prior to their involvement in the research. These persons will complete questionnaires and post-study qualitative interviews about their satisfaction with the respective care models and they will also be the subject of certain questionnaires completed by parents and adolescents. Also, HCPs who see study patients will complete certain questionnaires and a qualitative interview about their perceptions of the TC model at the end of the study. Data for cost-effectiveness analyses will be collected throughout the study from parents and from participants' electronic medical records and analyzed after the RCT is complete.

Sources of research data

Qualitative research component: Transcripts of crowdsourced responses to questions posed to the Adolescent, Parent and HCP Crowds will be downloaded directly from Yammer.com and then edited to remove any identifying information. Each response will be coded for qualitative themes as described above. Qualitative interviews of representatives of key stakeholder groups will be audio-recorded and then transcribed verbatim without any personal identifiers used. Once transcribed, the audio recordings will be erased, eliminating any link between the interview respondents and their comments.

Quantitative Research Component: The data for the study will consist of blood samples for glycohemoglobin tests (HbA_{1c}), hypoglycemia diaries, glucose meter downloads, measurement of health care utilization and costs and a variety of questionnaires and interviews that pertain to family management of diabetes. The measurement schedule for the study appears in a table in the Approach section. Copies of the measures are provided in an Appendix to this application.

Potential risks

Qualitative research component: The Crowdsourcing component of the research carries the risks associated with privacy and confidentiality in that other crowd members will be able to see and read responses uploaded by any other crowd member. Participants are free to enter a response or not to any question posed to the crowd.

It is difficult to imagine any risks of participation in answering crowdsourcing questions or qualitative interviews for adolescents with diabetes, their parents, HCPs or representatives of third party payers. The only conceivable risks are threats to privacy and confidentiality. These risks are considered negligible since the interview questions will address quite innocuous content that is unlikely to be upsetting or to threaten the participants' employment, finances, health or social status in any way. Participants in the Adolescent, Parent, or HCP Crowds can simply decline to answer any question(s) that they see as threatening in any way. In our ongoing crowdsourcing study involving parents of very young children with T1D, we have not observed any clinically significant emotional or psychiatric complications associated with study participation. In fact, a number of parents have volunteered that their study participation was comforting and therapeutic.

Quantitative Research Component: As an RCT, it is possible that adolescents randomized to either the Usual Care or Trans-Disciplinary Care treatments might fare more poorly than if they had been randomized to the other treatment. Each youth's attending pediatric endocrinologist will have access to the TC team's progress notes regarding each of these patients and will retain the discretion of seeking additional consultation or other indicated services for such patients as that physician sees fit.

Adequacy of protections against risks

Qualitative research component: Transcripts of written responses will be stripped of identifiers before being forwarded to trained coders. All crowd members will be taught to respect the confidentiality of other crowd members. Members will also be aware that answering a given question is entirely optional and so they can

choose to refrain from entering a written response. Participants also have the option of sending a given response to the facilitator only rather than to the entire crowd.

Recordings of in-person interviews will be transcribed verbatim without participants' identities. Once transcribed in this way, the recordings will be erased, thus eliminating any possibility that participants could be identified if the security of the transcribed data were somehow compromised. Audio recordings will not be saved to Nemours computer network since the files on the entire network are backed up nightly, meaning that no file on the network at the time of the backup can ever be completely deleted.

Quantitative Research Component: Medical management of each enrolled patient will continue to be under the supervision of each adolescent's attending endocrinologist and the endocrinologists will have the discretion to intensify the patient's treatment, seek consultation of other professionals or pursue any other reasonable course of action deemed necessary in the patient's best interests.

Potential benefits to participants and others

Qualitative research component: Participants in our ongoing crowdsourcing study have volunteered reports indicating that sharing personal and sensitive experiences and feelings has had therapeutic effects for them by helping them to realize that their reactions are normal and shared by others in the same situation. Nonetheless, the consent documents make no claim for the prospect of direct benefits and that is how we would intend to portray the proposed work if this grant is funded.

There are no likely direct benefits to parents, adolescents or HCPs who participate in the qualitative interviews.

Quantitative Research Component: Participants randomized to any of the RCT study conditions could realize improved glycemic control, better treatment adherence, and better quality of life, although this is probably more likely for those randomized to TC-IP and TC-TH. There are unlikely to be any direct benefits to the HCPs who complete questionnaires about team function the end of the study. However, TC team members could benefit by expanding their knowledge and skill repertoires that they could apply in their T1D clinical care to patients not enrolled in this study.

Importance of the knowledge to be gained

Qualitative interview component: The knowledge to be gained in this aspect of the proposed work is essential to finalizing the optimal design of the Trans-Disciplinary Care model so that it is perceived as acceptable, feasible, safe and effective by all pertinent groups of stakeholders. Engagement of stakeholders in all phases of the research enterprise is a cornerstone of patient-centered outcomes research.

Quantitative Research Component: The RCT will determine if Trans-Disciplinary Care is more efficacious than Usual Care in terms of glycemic control, treatment adherence and various measures of psychological adjustment to diabetes among adolescents and it will analyze the incremental cost-effectiveness of implementing this model of care. The RCT will also explore whether face to face versus telehealth delivery of TC care yields differences in any of the measured outcomes. Since adolescents with T1D often struggle with management of this condition, empirical and economic validation of an alternative model of care would be extremely valuable from a public health standpoint.

Data and safety monitoring plan

Qualitative research and crowdsourcing component: There does not appear to be a need for a Data and Safety Monitoring Plan for these aspects of the proposed research since the study poses negligible risks and is not a clinical trial. There are no expected adverse events for this study. Unanticipated problems or complaints related to the research will be handled in accord with the relevant NOHSP Policy and Procedure governing such events.

Quantitative Research Component: Please see the appendix and separate document entitled "DSMP_FINAL" for a comprehensive description of the Data and Safety Monitoring Plan.

7. REPRESENTATION OF WOMEN AND MINORITIES

We expect to enroll about 50% female adolescents with T1D, and we expect that about 80-90% of participating parents will be women. Among HCPs and representatives of third party payers, we expect at least 50% representation of females, but this will be dependent upon the specific employees who are eligible for

participation. We plan oversampling of racial/ethnic minorities so that both the Qualitative and Quantitative components of the research enroll a sample reflecting at least 25% representation of racial and ethnic minorities. The race/ethnicity distribution of HCP Crowd members may be slightly less diverse than that for the Adolescent and Parent Crowds. Separate Targeted/Planned Enrollment Tables for the Crowdsourcing/Qualitative Research and RCT aspects of the proposed work accompany this application.

8. TARGETED/PLANNED ENROLLMENT TABLE

Study Title: Trans-Disciplinary versus Usual Care for Type 1 Diabetes in Adolescence

QUALITATIVE RESEARCH COMPONENT: 120 adolescents with type 1 diabetes; 120 parents of youth with type 1 diabetes; 30 HCPs; 10 representatives of third party payers.

TARGETED/PLANNED ENROLLMENT: Number of Participants			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	15	15	30
Not Hispanic or Latino	105	105	210
Ethnic Category: Total of All Participants *	120	120	240
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	3	3	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	12	12	24
White	105	105	210
Racial Categories: Total of All Participants *	120	120	240

Targeted/Planned Enrollment Table

Study Title: Trans-Disciplinary versus Usual Care for Type 1 Diabetes in Adolescence

RANDOMIZED, CONTROLLED TRIAL: 150 adolescents with type 1 diabetes; 150 parents.

TARGETED/PLANNED ENROLLMENT: Number of Participants (Adolescents)			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	11	10	21
Not Hispanic or Latino	64	65	129
Ethnic Category: Total of All Participants *	75	75	150
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	10	11	21
White	65	64	129
Racial Categories: Total of All Subjects *	75	75	150
TARGETED/PLANNED ENROLLMENT: Number of Participants (Parents)			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	15	6	21
Not Hispanic or Latino	110	19	129
Ethnic Category: Total of All Participants *	125	25	150
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	15	5	21
White	110	19	129
Racial Categories: Total of All Subjects *	125	25	150

9. REPRESENTATION OF CHILDREN

All patients with T1D will be below the age of 17 at enrollment. The 11-<17 year old age range was chosen since this is the age range during which T1D adherence issues emerge and in which effective management of the condition becomes increasingly challenging. Major epidemiologic studies indicate that this age group achieves targeted levels of HbA1c infrequently (< 25% of patients) compared with other age groups.

10. VERTEBRATE ANIMALS (Not Applicable)

11. SELECT AGENT RESEARCH (Not Applicable)

12. MULTIPLE PI LEADERSHIP PLAN (Not applicable)

13. CONSORTIUM/CONTRACTUAL ARRANGEMENTS

Karen Aroian, Ph.D., Chatlos Professor of Nursing at the University of Central Florida College of Nursing, will provide expert consultation in qualitative research methods and community-based participatory research for this work. The details of her involvement are summarized in the research strategy and her time and effort is reflected in the budget and budget justification.

14. LETTERS OF SUPPORT

Dr. Aroian's letter of support accompanies this application.

15. RESOURCE SHARING PLAN

Upon acceptance for publication of journal articles addressing the primary specific aims and hypotheses as delineated in this application, the final data set will be stripped of all HIPAA-defined personal identifiers and then archived in a data repository that is accessible to interested members of the public. Even though the final dataset will be stripped of identifiers prior to release for sharing, there may remain the possibility of deductive disclosure of subjects with unusual demographic characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to attempt to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.

Other "deliverable" resources that can be made available to interested parties after the proposed work is complete will include the curriculum for training health care providers in the Trans-Disciplinary Care model, and the procedure manual for this study that will detail the structure, process and evaluation of the care model. These resources could be exceptionally valuable should the proposed work progress on to the design and implementation of a more ambitious and definitive multi-center trial of the TC model.

APPENDIX

- Tentative qualitative interview questions for parents, adolescents and health care providers about the structure and process of a tentative trans-disciplinary care model
- Tentative qualitative interview questions for members of the trans-disciplinary care team regarding the adequacy of the TC training curriculum
- Revised post-RCT qualitative interview questions for parents and adolescents about the advantages and disadvantages of trans-disciplinary care
- Tentative post-RCT qualitative interview questions for representatives of third party payers about the economic viability of trans-disciplinary care, given the results of the RCT
- Copy of parent-completed health care utilization record used in the JDRF continuous glucose monitoring trial.
- Copies of questionnaires to be administered during the RCT.
- NIDDK approved DSMP/DSMB description for randomized controlled trial