

TEENCOPE: An Internet Coping Skills Training Program for Teens With Type 1 Diabetes

This study is currently recruiting participants.

Verified by National Institute of Nursing Research (NINR), July 2009
 First Received: May 21, 2008 Last Updated: July 13, 2009 [History of Changes](#)

Sponsored by:	National Institute of Nursing Research (NINR)
Information provided by:	National Institute of Nursing Research (NINR)
ClinicalTrials.gov Identifier:	NCT00684658

► Purpose

The purpose of the study is to compare the effects of a 5-week internet-based coping skills training program (TeenCope) with a 5-week internet education program (Managing **Diabetes**) in youth (age 11-14) with **type 1 diabetes** on intensive insulin therapy.

Condition	Intervention	Phase
Type 1 Diabetes	Behavioral: TeenCope Behavioral: Managing Diabetes	Phase III

Study Type: Interventional

Study Design: Randomized, Double Blind (Caregiver, Investigator, Outcomes Assessor), Parallel Assignment

Official Title: An Internet Coping Skills Training Program for Teens With **Type 1 Diabetes**

Further study details as provided by National Institute of Nursing Research (NINR):

Primary Outcome Measures:

- Hemoglobin A1c (HbA1c) [Time Frame: 18 months]
[Designated as safety issue: No]
- Pediatric Quality of Life Inventory (PedsQL) [Time Frame: 18 months]
[Designated as safety issue: No]
- **Diabetes** Family Conflict Scale [Time Frame: 18 months]
[Designated as safety issue: No]

Secondary Outcome Measures:

- Perceived Stress Scale (PSS) [Time Frame: 18 months]
[Designated as safety issue: No]
- Self-Efficacy for **Diabetes** Scale [Time Frame: 18 months]
[Designated as safety issue: No]
- Children's Depression Inventory [Time Frame: 18 months]
[Designated as safety issue: No]
- Self-Perception Profile for Adolescents [Time Frame: 18 months]
[Designated as safety issue: No]
- Responses to Stress Questionnaire (RSQ) [Time Frame: 18 months]
[Designated as safety issue: No]
- **Diabetes** Family Behavior Scale [Time Frame: 18 months]
[Designated as safety issue: No]
- Self Management of **Type 1 Diabetes** [Time Frame: 18 months]
[Designated as safety issue: No]

Estimated Enrollment: 300

Study Start Date: May 2008

Estimated Study Completion Date: May 2012

Estimated Primary Completion Date: May 2012 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
1: Experimental Internet-based Coping Skills Training	Behavioral: TeenCope Teencope consists of a series of 5 sessions designed to increase children's sense of competence and mastery by retraining inappropriate or non-constructive coping styles and forming more positive styles and patterns of behavior. Each week a new 30-45 minute session is uploaded to a password-protected website on

	the Yale server for youth to complete. Youth are grouped with 8-12 peers who complete the same weekly sessions in an asynchronous manner. Youth interact with each other on an online discussion board moderated by a clinical psychologist
2: Active Comparator Internet-based Diabetes Education	Behavioral: Managing Diabetes Managing Diabetes consists of 5 sessions on educational content related to diabetes self management targeted to adolescents. As with the TeenCope program, each week a new 30-45 minute session is uploaded to a password-protected website on the Yale server for youth to complete. Youth complete educational sessions independently over 5 weeks. There is no online discussion board or peer interaction.

Detailed Description:

It is well established that for many youth with type 1 diabetes (T1D), the developmental stage of puberty is characterized by a significant deterioration in metabolic control. Previous research conducted by the Yale School of Nursing demonstrates that providing cognitive-behavioral coping skills training program (CST) as a supplement to intensive medical treatment regimen enhances physiological and psychosocial outcomes - most notably in youth as they approach adolescence. Successful CST programs studied at Yale consist of weekly, in-person group sessions over a 5-week period conducted by a clinical psychologist or social worker.

Rapid advances in technology have made the internet a compelling tool to reach out to youth and significantly broaden the application of CST programs.

Investigators at Yale (scientists, NPs, clinical psychologists) have teamed with web specialists (computer programmers, web designers, graphic artists, and illustrators) and youth with T1D and their parents to adapt the successful CST program for use on the internet. In this trial, internet-based CST (TeenCope) will be evaluated by comparing it to an internet-based education program for managing diabetes (Managing Diabetes).

Three hundred (300) youth from 4 different sites within the U.S will take part in the study. Youth will be randomly assigned to complete either the TeenCope or Managing Diabetes program right away, and will be given the opportunity to complete the alternate program after 12 months. Data on psychosocial and disease management parameters will be collected at baseline, 3, 6, 12 and 18 months through youth filling out online questionnaires (lasting approximately 30 minutes). Clinical outcome data (height, weight, HbA1c, episodes of hypoglycemia, DKA, and hospitalization) will be collected from the medical chart throughout the study, and parents will complete a demographic data form.

This study has great potential for working with youth with type 1 diabetes. If proven effective, the investigators are interested in continued dissemination and translation of this intervention beyond their geographical location.

Eligibility

Ages Eligible for Study: 11 Years to 14 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Age 11-14
- English speaking
- Youth assents and parent consents to participation
- School grade is appropriate to age within 1 year
- Type 1 diabetes for a minimum of 6 months
- Access to high speed internet service for 5 week intervention (will be arranged by study if not presently in the home)

Exclusion Criteria:

- Other significant chronic health problems requiring intensive self-management
- Previous exposure to Yale School of Nursing's Coping Skills Training or Managing Diabetes materials

▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00684658

Contacts

Contact: Lauren Liberti, MS 20... lauren.liberti@yale.edu

Locations

United States, Arizona

University of Arizona **Recruiting**
Tucson, Arizona, United States, 85721

United States, Connecticut

Yale University School of Nursing **Recruiting**
New Haven, Connecticut, United States, 06519

United States, Florida

University of Miami **Recruiting**
Miami, Florida, United States, 33136

United States, Pennsylvania

Children's Hospital of Philadelphia **Recruiting**
Philadelphia, Pennsylvania, United States, 19104

Sponsors and Collaborators

National Institute of Nursing Research (NINR)

Investigators

Principal Investigator: Margaret Grey, DrPh, FAAN, CPNP Yale School of Nursing

Principal Investigator: Robin Whittemore, PhD, APRN Yale School of Nursing

▶ More Information

Publications:

Whittemore, R., Lindemann, E., Ambrosino, J., Jaser, S., & Grey, M. (2007). Development and pilot of an internet-based CST program for teens with T1D. *Diabetes*, 56 (Suppl 1), A709-710.

[Grey M, Boland EA, Davidson M, Li J, Tamborlane WV. Coping skills training for youth with diabetes mellitus has long-lasting effects on metabolic control and quality of life. *J Pediatr*. 2000 Jul;137\(1\):107-13.](#)

[Grey M, Boland EA, Davidson M, Yu C, Sullivan-Bolyai S, Tamborlane WV. Short-term effects of coping skills training as adjunct to intensive therapy in adolescents. *Diabetes Care*. 1998 Jun;21\(6\):902-8.](#)

Responsible Party: Yale University School of Nursing (Lauren Liberti, MS, TeenCope Trial Coordinator)

Study ID Numbers: R01NR004009, R01 NR004009

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Health Authority: United States: Federal Government