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Multi-site evaluation of an evidence-based positive youth development program

Submission date
16/09/2013

Recruitment status
No longer recruiting

Registration date
26/09/2013

Overall study status
Completed

Last Edited
31/05/2019

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study to assess the immediate and long-term effects of a positive youth development program (the Teen Outreach Program) on high school youth. This study will answer the following questions: What is the impact of the Teen Outreach Program on sexual activity and positive youth development at the end of the program? What is the impact of the Teen Outreach Program on sexual activity, pregnancy, and positive youth development one year after the end of the program?

Who can participate?
Eligible youth include all students who are enrolled in a Health, Health Opportunities through Physical Education (HOPE), Critical Thinking, Career Research, or Leadership class in one of 28 participating high schools in Florida.

What does the study involve?
Schools will be randomly allocated to either the intervention or the control group. At treatment (intervention) schools, youth will participate in a positive youth development program, in addition to their Health, HOPE, Critical Thinking, Career Research, or Leadership class. At control (non-intervention) schools, youth will simply participate in their Health, HOPE, Critical Thinking, Career Research, or Leadership class. A survey will be given to youth at both treatment and control schools. The paper-and-pencil survey will ask questions about youth school, grades, peers, health behaviors, and behaviors related to teen pregnancy, including what the participant believes and does in regards to sexual health. The survey will be completely confidential and participant names will not be included. All survey materials have been approved by school administration and the school district office. Participants will take the survey during a class determined by their principal. This survey will take about 30 minutes to complete. Participants will be asked to complete the survey at the beginning and again at the end of the 9th grade class /school year. Participants will also be asked to participate in follow-up surveys at the end of 10th and 11th grade.

What are the possible benefits and risks of participating?
The potential benefits to participants include feeling positive that he/she is helping to decide the best health programs to use for future youth in their school. Participating in this study is

considered no more than minimal risk. Minimal risk means that risks associated with this study are no more than what these youth would face every day. Although we do not expect them to occur, possible risks for participants include being embarrassed when answering health behavior questions. However, participants do not have to answer any question that they do not want to answer.

Where is the study run from?
This study has been set up by the University of South Florida College of Public Health, in collaboration with the Florida Department of Health.

When is the study starting and how long is it expected to run for?
Recruitment for this study started in 2012. The first cohort of students joined the study in August 2012 and the second cohort of students joined the study in August 2013.

Who is funding the study?
Funding has been provided by the Office of Adolescent Health, U.S. Department of Health and Human Services.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02519530

Secondary identifying numbers
N/A

Study information

Scientific Title
Multi-site evaluation of an evidence-based positive youth development program: a school-level, longitudinal, randomized controlled trial

Study objectives
This project is a school-level longitudinal randomized controlled trial (RCT) evaluation of the Teen Outreach Program (TOP) in Florida. Research questions are as follows:

Primary research questions:
1. What is the impact of the intervention (Teen Outreach Program) relative to the standard of care condition on sexual activity one year after the end of treatment?
2. What is the impact of the intervention (Teen Outreach Program) relative to the standard of care condition on pregnancy (getting someone pregnant or having been pregnant) one year after the end of treatment?

Secondary research questions:
1. What is the impact of the intervention (Teen Outreach Program) relative to the standard of care condition on sexual activity at the end of treatment?
2. What is the impact of the intervention (Teen Outreach Program) relative to the standard of care condition on the 5'Cs (Character, Competence, Caring, Connection, and Confidence) of positive youth development at the end of treatment?
3. What is the impact of the intervention (Teen Outreach Program) relative to the standard of care condition on the 5'Cs of positive youth development one year after the end of treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Florida Department of Health Institutional Review Board, Apr 22, 2011, Protocol Number: H11180

Study design
School-level longitudinal randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Positive youth development, unintended pregnancy

Interventions
Youth in treatment (TOP) schools will receive TOP lessons delivered through Health, HOPE, Critical Thinking/Career Research, and Leadership classes. The TOP is considered supplemental education for the students in these classes, meaning that TOP facilitators supplement the information presented by the class teachers. That is, youth enrolled in these classes receive TOP in addition to (and not substituting for) Health, HOPE, Critical Thinking/Career Research, and Leadership content. TOP facilitators are Florida Department of Health (DOH) staff members who have been trained in the TOP curriculum. The TOP intervention is delivered by trained DOH staff within each county, not school staff, over a 30-week period of each school year. The completion of a health or health-type class (e.g., HOPE) and Critical Thinking/Career Research or Leadership is a graduation requirement, and these classes are taken most frequently in the ninth grade.

Youth in all non-intervention (control, or non-TOP) schools are enrolled in similar Health, HOPE, Critical Thinking/Career Research, and Leadership classes. We refer to this counterfactual condition as the standard of care (SOC) condition (i.e., what youth would receive in the absence of the TOP). Public school teachers deliver content in the classroom to youth in the SOC condition. There are four SOC conditions, depending on the school.

Duration: Both intervention and the control arms are approximately nine months.
Follow-up will be at one- and two-years post-intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Sexual activity, to be assessed one year after the end of treatment through self-report survey: Have you ever had sexual intercourse?
2. Pregnancy, to be assessed one year after the end of treatment through self-report survey: "To the best of your knowledge, have you ever been pregnant or gotten someone pregnant, even if no child was born?

All outcomes for cohort 1 (includes youth from both treatment and control schools, class beginning in August 2012) and cohort 2 (includes youth from both treatment and control schools, class beginning in August 2013) will be assessed at baseline (T1), nine months later at immediate post-program (T2), and one year post-program (T3). The first cohort of youth will also be assessed at two years post-program (T4).

Secondary outcome measures
1. Sexual activity, to be assessed at the end of treatment through self-report survey: Have you ever had sexual intercourse?

2. 5'Cs of positive youth development, to be assessed at the end of treatment through self-report survey: The outcome is a composite of 5 domains: Character (20 items), Competence (16 items), Caring (9 items), Connection (16 items), and Confidence (11 items).
3. 5'Cs of positive youth development, to be assessed one year after the end of treatment through self-report survey: The outcome is a composite of 5 domains: Character (20 items), Competence (16 items), Caring (9 items), Connection (16 items), and Confidence (11 items).

All outcomes for cohort 1 (includes youth from both treatment and control schools, class beginning in August 2012) and cohort 2 (includes youth from both treatment and control schools, class beginning in August 2013) will be assessed at baseline (T1), nine months later at immediate post-program (T2), and one year post-program (T3). The first cohort of youth will also be assessed at two years post-program (T4).

Overall study start date
27/08/2012

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Both male and female between 13-18 years old
2. Eligible youth include all students who are enrolled in a Health, Health Opportunities through Physical Education (HOPE), Critical Thinking, Career Research, or Leadership class in one of 28 participating high schools in Florida, except in high schools where random sub-sampling occurred at the class level.

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
10,000

Total final enrolment
7976

Key exclusion criteria

Youth are deemed ineligible if:
1. They are not enrolled in a class randomly selected for the evaluation
2. They joined a participating class after the time at which the robo-call was made and permission forms were distributed
3. They had any illness or disability that prevented them from participating in the survey.

Date of first enrolment
27/08/2012

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United States of America

Study participating centre
Department of Community and Family Health
Tampa
United States of America
33612

Sponsor information

Organisation
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Sponsor type
Government

Website
http://www.hhs.gov/

ROR
https://ror.org/033jnv181

Funder(s)

Funder type
Government

Funder Name
U.S. Department of Health and Human Services (USA) (OPHS/OAH-TPP 1 TP1AH000017-01-00)

Alternative Name(s)
United States Department of Health and Human Services, Department of Health and Human Services, The U.S. Department of Health & Human Services, U.S. Health & Human Services, U.S. Dept. of Health & Human Services, US Department of Health and Human Services, Department of Health, Education, and Welfare, HHS, USDHHS, DHHS, HEW

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2016	31/05/2019	Yes	No