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Trial of the Effect of "16 and Pregnant" on Teen Girls' Attitudes About Pregnancy

This study is ongoing, but not recruiting participants.

Sponsor:
University of Michigan

Collaborator:
Society of Family Planning

Information provided by (Responsible Party):
Audrey Lance, University of Michigan Health System

ClinicalTrials.gov Identifier:
NCT01795885

First received: February 8, 2013
Last updated: February 20, 2013

Last verified: February 2013
[History of Changes](#)

Full Text View	Tabular View	No Study Results Posted	Disclaimer	How to Read a Study Record
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Tracking Information	
First Received Date <small>ICMJE</small>	February 8, 2013
Last Updated Date	February 20, 2013
Start Date <small>ICMJE</small>	November 2012
Estimated Primary Completion Date	March 2013 (final data collection date for primary outcome measure)
Current Primary Outcome Measures <small>ICMJE</small> (submitted: February 20, 2013)	Attitudes about teen pregnancy and teen parenting [Time Frame: Baseline and at 6 weeks] [Designated as safety issue: No] The primary outcome will be the change in attitudes on teen pregnancy and teen parenting over the intervention period. This will be measured as the change in the composite score of the subjects' responses to the 44 questions from the Thoughts on Teen Parenting survey. This survey uses 5-point Likert scales for all responses. There is a minimum score of 44 and maximum score of 220, with lower scores indicating less favorable attitudes towards teen pregnancy. The change in the attitudinal score in the intervention group after the intervention will be compared to the change in the attitudinal score in the control group.
Original Primary Outcome Measures <small>ICMJE</small>	<i>Same as current</i>
Change History	Complete list of historical versions of study NCT01795885 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures <small>ICMJE</small>	<i>Not Provided</i>
Original Secondary Outcome Measures <small>ICMJE</small>	<i>Not Provided</i>
Current Other Outcome Measures <small>ICMJE</small>	<i>Not Provided</i>
Original Other Outcome Measures <small>ICMJE</small>	<i>Not Provided</i>
Descriptive Information	
Brief Title <small>ICMJE</small>	Trial of the Effect of "16 and Pregnant" on Teen Girls' Attitudes About Pregnancy
Official Title <small>ICMJE</small>	Can "16 & Pregnant" Change Teens' Attitudes About Teen Pregnancy? A Randomized Controlled Trial
Brief Summary	

	<p>The purpose of this study is to determine whether watching the MTV (Music Television) television show "16 and Pregnant" could affect teen girls' attitudes about teen pregnancy, teen parenting, and pregnancy prevention. The investigators will recruit teen girls, ages 15-18, who will be randomized to the intervention group (who will be asked watch 4 episodes of the show over a 4 week period) or the control group (who will not be intentionally exposed to watching the show, and will not be told which show the intervention group is watching). The investigators will evaluate, through survey, their attitudes about teen pregnancy and teen parenting before and after the intervention period, and compare the two groups at the conclusion of the study.</p> <p>The investigators' hypothesis is that the teens that are exposed to watching the show will have less favorable attitudes towards teen pregnancy and teen parenting than those teens who are not exposed to watching the show.</p>
Detailed Description	<p>The objective of this study is to evaluate whether a television show, 16 and Pregnant, can be used as entertainment-education - specifically if it changes teens' attitudes about teen pregnancy and teen parenting. The primary outcome measure will be the change in attitudes about teen pregnancy and teen parenting after the intervention period.</p> <p>Specific Aim: To determine the effect that watching the TV (television) show 16 and Pregnant has on teen girls' attitudes about teen pregnancy and teen parenting. Attitudes will be measured using the Thoughts on Teen Parenting Survey, which is a 44-item survey with 5-point Likert scale responses. Scores for the entire survey as well as sub-scale scores will be calculated both pre- and post-intervention.</p> <p>Hypothesis: Teens who are exposed to themes of unintended teen pregnancy will have less favorable attitudes towards teen pregnancy and teen parenting when compared with similar teens not exposed to those themes.</p> <p>In order to determine if the TV show 16 and Pregnant has any effect on teen girls' attitudes around teen pregnancy and parenting, the investigators plan to conduct a randomized controlled trial of an intervention consisting of watching the television program once a week for 4 weeks. Participants will be randomized to either the intervention arm, which will watch an approximately 45-minute commercial-free episode of the show 16 and Pregnant once a week for 4 weeks, or the control arm, which will not be intentionally exposed to the show. Each group will complete the same pre- and post-test survey to allow for comparisons between the groups.</p> <p>All participants will be female teens between the ages of 15 and 18. Teens will be excluded if their parents do not permit them to participate, or if they do not assent to participate. They will also be excluded if they report having watched more than one episode (or more than 60 minutes) of 16 and Pregnant previously. The investigators plan to recruit approximately 215 teens to get a sample of 150 participants.</p> <p>The survey instrument will be based on two previously developed surveys. The Thoughts on Teen Parenting Survey (TTPS) will be used to measure attitudes towards teen pregnancy and teen parenting. This is a previously validated 44-item survey designed to be used with adolescents ages 14-19 to evaluate teens' perceptions on teen pregnancy and teen parenting. A few additional questions, though not previously validated, will be used to evaluate teens' attitudes towards contraception, pregnancy options other than parenting (adoption or abortion), and sexual activity. These will be used to describe the population of teens in the study. The knowledge portion of the survey will be based on questions from the The National Survey of Reproductive and Contraceptive Knowledge (NSRCK), developed by The Guttmacher Institute and The National Campaign to Prevent Teen & Unplanned Pregnancy. This survey was originally designed to measure contraceptive knowledge among 18-29 year olds. The reading level of many of the questions will be changed to accommodate a younger audience, but the content of the questions will remain the same. Again, this section of the survey will mainly be used to describe the group of teens in the study in terms of their level of contraceptive and reproductive health knowledge.</p> <p>All surveys will be internet-based and will be administered by Knowledge Networks, a company that specializes in online survey research. Demographic information will be obtained via self-disclosure on the survey, as well as from the demographic information that is collected by Knowledge Networks when the participant agrees to join the KnowledgePanel®. Information about other sources of reproductive health knowledge will be assessed as well, including prior exposure to the show 16 and Pregnant.</p> <p>Participants in the intervention group will complete a brief survey after watching each episode, as a measure to ensure that they actually watched the episode.</p>
Study Type <small>ICMJE</small>	Interventional
Study Phase	<i>Not Provided</i>
Study Design <small>ICMJE</small>	Endpoint Classification: Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label
Condition <small>ICMJE</small>	<ul style="list-style-type: none"> • Pregnancy in Adolescence • Teenage Pregnancy and Teen Parenting

Intervention <small>ICMJE</small>	Behavioral: 16 and Pregnant Participants in this arm will be asked to watch an approximately 45-minute commercial-free episode of the MTV television show "16 and Pregnant" once a week for 4 weeks. They will receive an email that contains a link to watch an episode of the show on the internet. The site where the videos are hosted is password protected and they are given the password in the same email. They can watch the video at any time, and can come back to it later if they need to stop watching it. The participants are asked to all watch the same episode each week. Four episodes were selected for the intervention from the first three seasons of the show.		
Study Arm (s)	Experimental: 16 and Pregnant Participants in this arm will be asked to watch an approximately 45-minute commercial-free episode of the show "16 and Pregnant" once a week for 4 weeks. Intervention: Behavioral: 16 and Pregnant		
Publications *	<i>Not Provided</i>		
* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.			
Recruitment Information			
Recruitment Status <small>ICMJE</small>	Active, not recruiting		
Enrollment <small>ICMJE</small>	153		
Estimated Completion Date	April 2013		
Estimated Primary Completion Date	March 2013 (final data collection date for primary outcome measure)		
Eligibility Criteria <small>ICMJE</small>	Inclusion Criteria: <ul style="list-style-type: none"> • English speaking • Female • 15-18 years old • Parental consent if under 18 Exclusion Criteria: <ul style="list-style-type: none"> • Have watched more than one episode of "16 and Pregnant" in the past • Lack of parental consent 		
Gender	Female		
Ages	15 Years to 18 Years		
Accepts Healthy Volunteers	Yes		
Contacts <small>ICMJE</small>	<i>Contact information is only displayed when the study is recruiting subjects</i>		
Location Countries <small>ICMJE</small>	<i>Not Provided</i>		
Administrative Information			
NCT Number <small>ICMJE</small>	NCT01795885		
Other Study ID Numbers <small>ICMJE</small>	SFPRF12-22		
Has Data Monitoring Committee	No		
Responsible Party	Audrey Lance, University of Michigan Health System		
Study Sponsor <small>ICMJE</small>	University of Michigan		
Collaborators <small>ICMJE</small>	Society of Family Planning		
Investigators <small>ICMJE</small>	Principal Investigator:	Audrey A Lance, MD	University of Michigan

	Study Chair:	Lisa H Harris, MD	University of Michigan	
Information Provided By	University of Michigan			
Verification Date	February 2013			
ICMJE Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP				