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A Cluster-Randomized Trial of Getting To Outcomes' Impact on Sexual Health Outcomes in Community-Based Settings

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Abstract The USA has high teen pregnancy rates compared to other developed nations. Many community-based organizations need assistance conducting evidence-based teen pregnancy prevention programs (EBPs) appropriately. This study evaluated the impact of an implementation support intervention called Getting To Outcomes (GTO) designed to help such organizations. This cluster randomized controlled trial compared 16 Boys and Girls Clubs (BGCs) implementing a teen pregnancy prevention EBP called Making Proud Choices for two years, with 16 BGCs implementing MPC augmented with GTO training, tools, and technical assistance. Participating middle school youth were compared on proximal outcomes (knowledge, attitudes, and intentions about sex and condoms from baseline to post) and sexual behaviors (frequency of sex and condom use, from baseline to 6-month follow-up). In year 1, there were no significant effects of GTO for any proximal outcome. After GTO-stimulated quality improvement in year

2, the GTO group improved significantly more on condom attitudes and use intentions. Frequency of sex and condom use did not differ between the two groups in either year; however, base rates of these behaviors in the sample were very low. Findings suggest that in typical community-based settings, detailed manuals and training common to structured EBPs may be sufficient to yield some improvement in key proximal outcomes, but that more systematic implementation support is needed to achieve greater improvement in these outcomes. Using GTO with many communities, as currently supported by various federal agencies, could yield public health impact via improvements in condom attitudes and use intentions.

Keywords Implementation support · Condom · Evidence-based program

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Community-based organizations that deliver evidence-based programs (EBPs) to prevent teen pregnancy and sexually transmitted infections (STIs) often have difficulty implementing them with sufficient quality to reach the same outcomes as the trials that established their evidence base (Kramer et al., 2005; Tibbits and Siahpush, 2016). This “gap” between research and practice (Wandersman and Florin, 2003) results from limited resources, the complexity of the 35 EBPs shown to reduce rates of teen pregnancy and STI (Goesling, Colman, Trenholm, Terzian, and Moore, 2014), and a lack of capacity—the knowledge, attitudes, and skills—needed to successfully implement “off the shelf” EBPs.

The lack of strong implementation of these EBPs has public health consequences. Although declining, the USA still has one of the highest rates of teen pregnancy among developed nations. In 2014, there were 24 births per 1000 adolescent females ages 15–19, most of which (89%) were outside of

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marriage (Hamilton, Martin, Osterman, Curtin, and Matthews, 2015) and considerable disparities exist among the nation's racial and ethnic groups (e.g., Hispanic and African American youth have higher pregnancy rates). Sexually active teens, and their children, are at high risk for poor outcomes such as sexually transmitted infections (STIs), school drop-out, and poverty, which can perpetuate cycles of social, educational, and economic disadvantage (Abma, Martinez, Mosher, and Dawson, 2004; Perper, Peterson, and Manlove, 2010; Terry-Human, Manlove, and Moore, 2005). These outcomes cost society between \$9.4 and \$28 billion a year from increased public assistance, public health, foster care, and criminal justice costs and lost revenue from lower wages and uncollected tax revenue (Hoffman, 2006).

The Centers for Disease Control and Prevention (CDC) selected teen pregnancy as one of its 10 winnable battles (i.e., critical public health issue with known interventions) to be tackled through EBPs and implementation improvement strategies—particularly the use of outside coaching and supports—to help ensure they are successfully adopted and implemented. Yet, there is little theory driven research using rigorous, experimental designs that test whether these support strategies improve participant outcomes in the domain of teen pregnancy and STI prevention. Enhancing Quality Interventions Promoting Healthy Sexuality (EQUIPS) is a 2-year, cluster-randomized controlled study of an implementation support strategy called Getting To Outcomes (GTO). In EQUIPS, community-based organizations carrying out Making Proud Choices (MPC, an EBP for teen pregnancy and STI prevention) on their own for 2 years were compared to similar groups running the same program with GTO. EBPs typically yield the strongest results from studies run by the programs' developers. However EBPs attempted by community-based practitioners often yield far fewer outcomes. Thus, the goal of this study and paper was to see if Getting To Outcomes could help community-based providers achieve outcomes similar to what was found in the original trials. A previous article described GTO's impact on MPC fidelity (Chinman, Acosta, Ebener, Malone, and Slaughter, 2016). This paper presents results regarding GTO's impact on the proximal (attitudes, knowledge) and sexual health outcomes of the middle school youth who participated in MPC.

Past Efforts to Evaluate Implementation Support in Prevention

There have not been rigorous research studies conducted testing implementation support strategies for teen pregnancy prevention programs of which we are aware. However, there have been several governmental efforts to help community-based organizations implement EBPs to prevent teen pregnancies and STIs. The CDC and the Office of Adolescent Health

within HHS has provided technical assistance (TA: outside coaching for all program activities) and funding to community-based grantees to carry out EBPs. However, these efforts were not evaluated using rigorous research designs (Philliber and Nolte, 2008; Zief, Shapiro, and Strong, 2014).

Research has evaluated implementation support strategies in other prevention areas. For example, in the domain of substance abuse prevention, implementation support interventions delivered through Communities That Care (J.D. Hawkins et al., 2009) and Promoting School-community-university Partnerships to Enhance Resilience (Spath et al., 2007) have shown improvements in EBP fidelity and outcomes in multi-site trials (J.D. Hawkins et al., 2009; Spoth et al., 2007), indicating the utility of implementation support. Rohrbach et al. (Rohrbach, Gunning, Sun, and Sussman, 2010) compared standard training of a substance abuse prevention EBP plus implementation support (i.e., outside coaching) to standard EBP training alone. The implementation support group had better fidelity and was superior in one of 10 youth outcomes.

Getting To Outcomes—An Implementation Support Strategy

The implementation support strategy tested in this study is called Getting To Outcomes (GTO). GTO builds capacity for implementing EBPs by strengthening practitioners' knowledge, attitudes, and skills required for key practices associated with running any EBP successfully (Livet and Wandersman, 2005). The GTO approach includes: the GTO manual of text and tools originally published by RAND (http://www.rand.org/pubs/technical_reports/TR101.html) and then applied to teen pregnancy (Lewis et al., 2012), face-to-face training, and ongoing, onsite TA. Rooted in social cognitive theories of behavioral change (Fishbein and Ajzen, 1975) and implementation science theories such as the Consolidated Framework For Implementation Research (Damschroder et al., 2009), the logic model for GTO states that the assistance increases capacity for all key programming activities (e.g., goal setting, planning, evaluation, not just program delivery), which improves how well practitioners perform these activities. Better performance of these activities improves program delivery (operationalized as fidelity), which in turn leads to better outcomes (see Chinman et al., 2016 for details).

With practitioners of drug prevention programs, GTO has been found to improve the capacity of individual practitioners and the performance of prevention programs in both quasi-experimental (Chinman et al., 2008) and randomized controlled trials (Acosta et al., 2013; Chinman, Tremain, Imm, and Wandersman, 2009). However, those studies involved programs of widely varying type and quality, and thus it was not possible to assess youth outcomes. In an earlier report

from the EQUIPS study (Chinman et al., 2016), Boys and Girls Club (BGC) sites with GTO implementation support were rated, via structured interview, to have performed various programming activities better than BGC sites without GTO, in both years. BGC sites with GTO had much stronger MPC fidelity than non-GTO BGC sites in year 2 (rated via blinded outside observer), after the quality improvement activities of GTO took place.

Methods

Design Overview

EQUIPS is a two-year, cluster randomized controlled trial comparing 16 BGC sites that received training to implement Making Proud Choices (J. B. Jemmott, Jemmott, and Fong, 1998) (MPC-only) with 16 BGC sites that received the same MPC training, plus GTO tools, training and TA (MPC + GTO). A strength of EQUIPS is that it isolates the impacts of GTO's implementation support by having both the experimental and control groups receive typical training in the same EBP and complete the same measures of program performance, fidelity, and outcomes. We collaboratively decided upon MPC with the BGCs because they serve 11–13 year olds (MPC's target population), reported needing teen pregnancy prevention programming, and that MPC's Afro-centric curriculum fit well with their mostly African-American membership. GTO was delivered over a two-year period. All sites delivered MPC once a year for 2 years to a different group of youth. The study assesses three sets of variables: performance in carrying out various program implementation tasks, fidelity of MPC implementation, and the proximal and sexual health outcomes of participating youth. In this paper, we report on the proximal and sexual health youth outcomes. EQUIPS was approved by RAND's Institutional Review Board. Harms of GTO and MPC were monitored by data collectors and TA staff. None were reported.

Study Sites

We recruited 32 BGC sites as a convenience sample for this study. Sixteen were from metro Atlanta, Georgia, and another 16 were in multiple locations in three small metro areas in Alabama (Montgomery, Huntsville, Auburn-Opelika, which all have populations from about 150,000 to 200,000). Using a random number generator, the project statistician randomized at the BGC site level within each state so each state had both eight MPC-only and MPC + GTO sites (16 sites in each study group). BGCs provide youth programming ranging from unstructured time in large common rooms and gyms to character education, health and wellness, and tutoring. Although there is some variability across sites, each site has

its own facility and a small number of staff and part-time volunteers ($n = 7-10$). The Alabama sites as a whole, and in both study groups, had similar staff demographic makeup (no significant differences). Two-thirds of the staff were female; most were aged 50–65 (50%) or 26–49 (44%); most (88%) had some college education or greater; and most were African-American (81%) or White (19%). As a whole, the Georgia staff were mostly female (68%); aged 50–65 (50%) or 26–49 (50%); had some college or greater education (100%); and were African-American (81%) or White (19%). There were no significant differences between the MPC and MPC + GTO groups in Georgia on gender, education, or race. However, sites' staff in the MPC + GTO group were somewhat older (89% were 50–65 vs. 17%). As described in a previous report from this study (Chinman et al., 2016), we measured at baseline all participating staff at each site on their individual capacity for quality prevention, attitudes toward EBPs, and organizational support for EBPs to further assess comparability of sites between the MPC and MPC + GTO groups. We found no significant differences between the groups on these measures.

The sites also had similar youth demographics. Atlanta sites (enrollment of about 1450 middle school youth) were about 81% Black, 10% Latino, 2% White, 7% mixed race or other. Alabama sites (about 2550 youth) were about 90% Black, 5% White, and 5% Latino.

Making Proud Choices

Making Proud Choices (MPC) is a universal teen pregnancy/STI prevention EBP intended for African-American, Hispanic and White adolescents, ages 11–13. MPC has eight 1-h sessions called “modules” designed to influence adolescents' knowledge, beliefs, and intentions to increase condom use and reduce the frequency of sex (J. B. Jemmott et al., 1998). A randomized controlled trial found that post-intervention, MPC participants improved, compared to control, on eight of 14 measures that MPC creators report are proximal outcomes mediating sex behaviors—i.e., knowledge, attitudes and intentions around sex and condom use. MPC participants also had a higher frequency of condom use at all follow-ups compared to control and less frequent sex and unprotected sex at 6 and 12 months post-intervention among those who had had sex at baseline (J. B. Jemmott et al., 1998). MPC is one of the most commonly implemented EBPs for teen pregnancy/STI in the USA (Chinman et al., 2016). Mathematica conducted a systematic review of programs for the Office of Adolescent Health and found 35 that reduced rates of teen pregnancy and STI in randomized trials. MPC was one of those 35 programs and has been included in multiple meta analyses (Johnson, Carey, Marsh, Levin, and Scott-Sheldon, 2003; Johnson, Scott-Sheldon, Huedo-Medina, and Carey,

2011; Mullen, Ramirez, Strouse, Hedges, and Sogolow, 2002; Scher, Maynard, and Stagner, 2006).

Making Proud Choices Implementation Supported by GTO

At each of the 16 MPC + GTO sites, GTO was implemented for 2 years, staggered across the sites over a 3-year period (2012–14). During that time, two half-time, Atlanta- and Alabama-based, TA providers trained in MPC and GTO delivered the manual; provided face-to-face training on both MPC and GTO; and provided onsite TA (totaling about 65 h per site). Prior to the BGCs running MPC, TA providers delivered three training sessions to teach each site to conduct various GTO planning activities and also held bi-weekly, one-on-one meetings with BGC staff to further facilitate MPC planning with GTO. Then, BGC staff implemented the first year of MPC and facilitated the collection of fidelity and youth outcome data (described below). BGC sites then received training on the evaluation and quality improvement steps of GTO, along with feedback reports summarizing their data, which were used in a TA-facilitated quality improvement process that yielded plans for the second year of MPC implementation. All BGC sites received US\$3000 a year to defray some costs of their participation. Additional details about using GTO with MPC are available elsewhere (Chinman et al., 2013; Chinman et al., 2016).

Measures and Data Collection

Procedures In each of the 2 years, the BGC staff in both groups recruited participants for MPC from their membership. This involved BGC staff sending information flyers to parents, approaching parents when they were present at the site, and/or holding special MPC information sessions at the site. Parents provided written consent and youth provided assent. A youth survey was administered by study staff (blind to study condition) at each BGC site's first (baseline) and last (post) MPC modules and at pre-arranged meetings for a 6-month Follow-up. Youth completed the survey on a laptop using audio, computer-assisted self-interviewing technology, which presents questions on-screen and orally through headphones. This method has shown to reduce social desirability bias compared to paper methods (Metzger et al., 2000).

Proximal Outcomes At baseline and post, we assessed the same 14 measures that J. B. Jemmott et al. (1998) reported were important mediators of sexual behavior. Items assessing attitudes and intentions toward condom use and abstinence used a 5-point response scale (strongly agree to strongly disagree). Items assessing knowledge were true/false. Baseline and Post descriptive statistics for the proximal outcomes in year 2 (the year of greatest anticipated intervention effects)

are presented in Table 1. The table has each proximal outcome's definition, number of items, and McDonald's (1999) coefficient omega with confidence interval. Omega is a measure of internal consistency on the same metric as coefficient alpha. It has advantages over alpha in that it makes more realistic assumptions, has fewer problems with inflation due to number of items, and has confidence intervals to more accurately evaluate reliability (Dunn, Baguley, and Brunson, 2014). Omega was calculated across both years for maximal precision. The median coefficient omega = .77. Omegas ranged from .61 to .88 except for Intentions to Use Condoms: omega = .35, 95% CI: .28, .41. We also evaluated differences in coefficient omega by gender. One subscale, Hedonistic Beliefs regarding condom use, showed lower internal consistency for girls, omega = .50, 95% CI: .38, .60, than for boys, omega = .72, 95% CI: .63, .78. The impact of this discrepancy on the results is considered below (Ancillary Analyses).

Sexual Activity and Condom Use We used three of the five sexual behavior outcomes from J. B. Jemmott et al. (1998). At Baseline and Follow-up, youth were asked to report: whether they ever had sexual intercourse, frequency of intercourse (days out of last 90), and days of unprotected sex when they had sex. Percent always using condoms and unprotected sex were calculated consistent with Jemmott et al. (1998). However, low rates of reported sex and unprotected sex precluded the use of the days of intercourse and unprotected sex measures.

Demographics and Social Desirability At Baseline, youth were asked about their grade, gender, race/ethnicity, and living situation. The survey also included a 12-item, true/false social desirability scale (e.g., "I am always respectful to older people") (Carfio, 1994).

Analyses

Overview All the analyses described below were run separately with the youth sample from Years 1 and 2. This was done because the earlier report showed that MPC + GTO sites dramatically improved their MPC fidelity from years 1 to 2, while the MPC-only sites' moderate level of fidelity remained unchanged (Chinman et al., 2016). Given the goal of this cluster randomized trial was to assess the degree to which site level improvements in capacity ultimately led to improvements in youth outcomes, it was important the youth outcome analyses reflect the improvement in fidelity achieved in Year 2. We hypothesized a) the proximal and sexual behavior outcomes would improve significantly more for the youth in the MPC + GTO sites than those in the MPC-Only sites in Year 1 and b) that the amount of improvement would be greater in year 2 given that the quality improvement component of GTO

Table 1 Measures, year 2 means, and reliability of proximal outcomes (mediators) at baseline and post

Domain (number of items)	Definition	MPC-Only				MPC + GTO				Total Sample	
		Baseline M(SD)	N	Post M(SD)	N	Baseline M(SD)	N	Post M(SD)	N	Baseline Omega (CI)	Post Omega (CI)
Abstinence attitudes/intentions	How much a youth feels....										
Prevention beliefs (3)	abstinence prevents pregnancy	3.16 (1.18)	195	3.26 (1.06)	148	3.12 (1.15)	214	3.32 (1.14)	174	.85 (.83–.87)	
Goal attainment beliefs (4)	abstinence helps one to achieve goals	3.21 (1.10)	195	3.51 (1.07)	148	3.12 (1.10)	221	3.45 (1.08)	173	.78 (.76–.81)	
Attitudes toward sex/abstinence (1)	about having sex in the next 3 months	4.18 (1.02)	195	4.17 (1.11)	150	4.17 (1.08)	218	4.26 (1.05)	178	NA	
Intentions to have sex/abstain (1)	they will have sex in the next 3 months	4.30 (0.89)	196	4.32 (0.90)	146	4.31 (0.88)	222	4.25 (0.90)	174	.80 (.76–.83)	
Condom attitudes/ intentions	How much a youth feels....										
Prevention beliefs (3)	condoms prevent STIs, AIDS, pregnancy	3.64 (1.13)	187	3.89 (1.18)	146	3.48 (1.14)	216	3.96 (1.21)	178	.84 (.81–.87)	
Hedonistic beliefs (6)	condoms interfere with sexual pleasure	3.37 (0.73)	174	3.70 (0.75)	144	3.31 (0.75)	194	3.65 (0.78)	172	.61 (.53–.67)	
Availability control (5)	they could get condoms when needed	2.77 (0.96)	177	3.44 (0.88)	141	2.87 (0.94)	200	3.55 (0.82)	170	.71 (.66–.75)	
Impulse control (3)	they could control themselves enough to use a condom	3.67 (1.07)	178	3.79 (1.15)	141	3.63 (1.12)	205	3.91 (1.05)	172	.76 (.72–.79)	
Negotiation beliefs (4)	they could convince a partner to use a condom	3.41 (1.02)	175	3.79 (0.94)	142	3.55 (0.91)	200	3.94 (0.82)	172	.76 (.72–.79)	
Technical skills beliefs (3)	they could use a condom properly	3.46 (1.08)	170	3.65 (1.05)	137	3.32 (1.09)	196	3.80 (1.00)	171	.79 (.75–.82)	
Self-efficacy to use (1)	they could use a condom	4.03 (1.13)	173	4.00 (1.20)	139	3.80 (1.23)	194	4.17 (1.03)	170	NA	
Intentions to use condoms (3)	they will use a condom in the next three months if they have sex	3.36 (0.87)	194	3.24 (0.80)	147	3.23 (1.00)	218	3.39 (0.78)	174	.35 (.28–.41)	
Knowledge of HIV/condoms	True/false questions about facts on...										
HIV/STD (16)	HIV and STD (Average % correct)	0.26 (0.25)	197	0.52 (0.33)	151	0.31 (0.28)	222	0.56 (0.29)	180	.88 (.87–.89)	
Condoms (4)	Condoms (Average % correct)	0.16 (0.25)	197	0.43 (0.36)	151	0.16 (0.26)	222	0.48 (0.34)	180	.68 (.64–.72)	

Note: Omega was calculated on the total sample at baseline for maximal precision

occurred between years 1 and 2 (and thus would only be reflected in year 2 results). All analyses of intervention effects were performed using SAS version 9.4. PROC MIXED or PROC GLIMMIX was used to fit mixed effects models. Estimates of coefficient omega and their confidence intervals were calculated with the function `ci.reliability` in the R package MBESS, v4.0.0.

Baseline Analyses The tests for baseline equivalence modeled the effects of treatment group, year, and their interaction in separate linear mixed models for baseline demographics, living situation indicators, parental attributes, and the baseline measurement of the 14 proximal outcomes and three sexual behavior outcomes used by J. B. Jemmott et al. (1998). To account for clustering, we included random effects of site nested within state.

Proximal Outcomes The primary analysis strategy was multivariate four-level linear regression modeling testing effects of experimental condition on three multivariate sets (in separate models) of the measures described in Table 1—Abstinence attitudes/intentions (“Abstinence measures”), Knowledge of HIV/condoms (“Knowledge measures”), and Condom attitudes/intentions (“Condom measures”). The 14 outcomes were analyzed this way, treating measures within each set as exchangeable, to increase power and reduce the likelihood of spurious discoveries. The multivariate indicators of each set were nested in youth, youth in site, and site in the blocking variable of state. Intercepts were modeled as random effects at each level; all other effects were modeled as fixed. Condition was modeled as a site-level predictor. A secondary analysis estimated three models including data from both conditions in both years to test 2-way interactions (Condition X Year) that could reflect improvements observed in fidelity between years 1 and 2.

Sexual Activity and Condom Use Like J. B. Jemmott et al. (1998), we assessed outcomes at Follow-up controlling for levels at baseline. For intercourse and unprotected intercourse outcomes, we fit a generalized logistic regression model using all youth who responded to the baseline survey (those lost at follow-up still contributed to the model). These models included a covariate for whether the youth reported sexual intercourse at baseline. For the models related to the proportion reporting unprotected sexual intercourse, we also stratified the models by sexual experience at baseline. Models were fit with site nested within state random effects, unless the estimate for the site within state variance was zero, in which case the model was fit without random effects. Type III F tests and their associated p values were calculated for the main predictor, treatment group. The intra-class correlation (ICC) was calculated when site level random effects were able to be included in the model.

Results

Study Sample Characteristics

None of the analyses testing for baseline equivalence were significant after applying the Benjamini-Hochberg correction to maintain the False Discovery Rate (FDR) of .05. Across both years and groups, at baseline, youth were mostly African-American (88%), in middle school (74%), and had parents who were never married (38%). Approximately half were female (49%) (Table 2).

Response rates did not differ between groups. Across all sites, 477 youth completed the baseline survey in year 1, 384 completed the post-intervention survey (“Post”; 81%), and 316 completed the 6-month Follow-up (“follow-up”; 66%). In year 2, 419 youth completed the baseline survey, 331 completed the post (79%), and 264 completed the 6-month Follow-up (63%). Flow diagrams by study condition are available online. The average site sample size was 16 for year 1 (range: 5 to 29) and 14 in year 2 (4 to 24). In order to assess whether attrition was likely to have biased our between-year and between-condition comparisons, we conducted a two-point, proportional-hazard, discrete-time survival analysis testing differences in the hazard of a youth dropping out. These analyses showed that neither year nor condition was significantly related to attrition. In a 2 (year) X 2 (condition) model, the two predictors and their interaction taken together did not predict attrition, Likelihood Ratio χ^2 (3, $N = 2191$) = 4.87, $p = .182$. The 95% confidence interval of the hazard ratio included 1.00 in separate models testing only year, HR = 0.88, 95% CI (0.60, 1.29) and only condition, HR = 1.03, 95% CI (0.70, 1.52).

Proximal Outcomes

Results of the multivariate mixed models are summarized in Table 3 as individual effects and a set of planned comparisons highlighting the condition differences. We re-centered the post measures of each indicator based on the participant’s baseline measure to show within-person change from baseline and improve interpretability.

Year 1 Models There was no significant effect of MPC + GTO over MPC-only, $ps > .05$, for any of the three multivariate models (upper portion of Table 3). Separate within group analyses on each study condition showed that the knowledge and condom measures were similarly increasing over time within both conditions.

Year 2 Models As shown in the lower portion of Table 3, the condition main effect was significant and positive (favoring MPC + GTO) for the Condom measures, $b = 0.227$, 95% CI (0.019, 0.435), Hedges’s g (adjusted for design effects) = 0.09, but not for the Abstinence measures, $b = 0.036$, 95% CI

Table 2 Demographics by study conditions at baseline and post

Demographics	Definition	MPC-only		MPC + GTO	
		Baseline % (n)	Post % (n)	Baseline % (n)	Post % (n)
Gender	% female	52 (213)	55 (174)	51 (227)	51 (186)
Ethnicity	% African-American	87 (364)	88 (285)	92 (421)	92 (344)
Grade	% 4th–5th	22 (94)	22 (73)	19 (91)	19 (74)
	%6-8th	75 (320)	76 (251)	74 (345)	75 (285)
	%9th–12th	3 (12)	2 (8)	7 (33)	6 (23)
Living status	% married, living together	24 (103)	23 (77)	20 (96)	21 (80)

(−0.116, 0.188), or the Knowledge measures, $b = 0.032$, 95% CI (−0.059, 0.124). Figure 1 shows the Years 1 and 2 Condom measures findings. Results for the individual scales among the Condom measures appear in Table 4. For three of the eight scales—Impulse Control, Self-Efficacy to Use Condoms, and Intentions to Use Condoms, the point estimates of condition differences favored MPC + GTO (95% confidence intervals excluding zero). Within condition, seven of the eight Condom measures improved over time among MPC + GTO youth; four—Hedonistic Beliefs, Availability Control, Negotiation Beliefs, and Technical Skills Beliefs—showed improvement among MPC-only youth.

Year x Group Models Interaction effects for the Condom measures, $b = 0.250$, 95% CI [−0.016, 0.516], were suggestive (see Fig. 1 for Condom measures), but none of the three interaction terms, including the Knowledge measures, $b = 0.089$, 95% CI [−0.024, 0.202], and Abstinence measures, $b = 0.032$, 95% CI [−0.166, 0.229], was statistically significant.

Sexual Activity and Condom Use

In both years, the MPC + GTO and MPC-only youth showed no statistically significant differences across any of the three sex behavior outcomes at Follow-up (see Table 5). However, a

Table 3 Multivariate fixed effects for proximal outcomes

Proximal Outcomes	Condition at post (CI)				Change from baseline (CI)			
	Item-level N	Between conditions ^a	Site ICC	Hedges' g	Within MPC + GTO ^b	Cohen's d	Within MPC-only ^c	Cohen's d
Year 1								
Abstinence attitudes/intentions ^d	1488	0.014 (−0.129, 0.156)	.004	0.01	0.076 (−0.023, 0.175)	0.06	0.062 (−0.040, .165)	0.04
Knowledge of HIV/condoms ^e	768	−0.059 (−0.134, 0.016)	.030	−0.12	0.225 (0.172, 0.277)	0.39	0.284 (0.230, 0.338)	0.69
Condom attitudes/intentions ^d	2732	−0.026 (−0.213, 0.162)	.019	−0.01	0.328 (0.197, 0.458)	0.15	0.353 (0.219, 0.487)	0.14
Year 2								
Abstinence attitudes/intentions ^d	1280	0.036 (−0.116, 0.188)	.002	0.03	0.124 (0.019, 0.228)	0.09	0.088 (−0.023, 0.198)	0.07
Knowledge of HIV/condoms ^e	662	0.032 (−0.059, 0.124)	.042	0.05	0.292 (0.229, 0.356)	0.66	0.260 (0.194, 0.326)	0.38
Condom attitudes/intentions ^d	2328	0.227 (0.019, 0.435)	.012	0.09	0.441 (0.297, 0.585)	0.21	0.214 (0.063, 0.365)	0.08

Note: Tabled values for Between Condition are regression coefficients for the outcome on condition and 95% confidence interval (CI). Italics indicate a statistically significant difference. Tabled values for Within MPC + GTO/MPC-only are estimates of changes in means for the outcomes and 95% CI (significant where the CI does not include zero). Positive values indicate beneficial effect of MPC + GTO (Between Condition) or increase from Baseline within each study group (Within MPC + GTO or MPC-only). Significance is noted at $p < .05$, after False Discovery Rate (FDR) correction applied within each table column. Hedges' g and Cohen's d have been adjusted for design effects

^a Year 1 $N = 477$, cluster $k = 32$; Year 2 $N = 419$, cluster $k = 32$

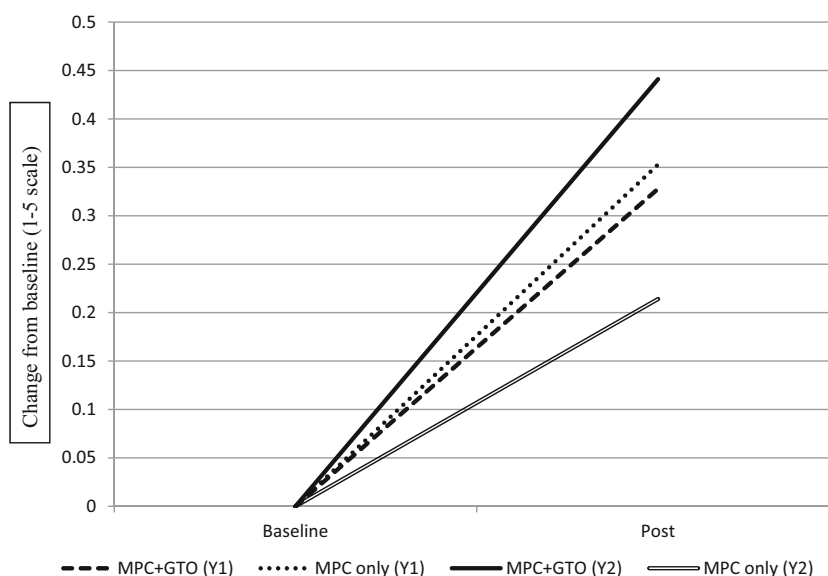
^b Year 1 $N = 248$, cluster $k = 16$; Year 2 $N = 222$, cluster $k = 16$

^c Year 1 $N = 229$, cluster $k = 16$. Year 2 $N = 197$, cluster $k = 16$

^d Effects are on original measure scale (1–5)

^e Effects are on scale of proportion correct (0–1)

Fig. 1 Improvements in aggregated condom measures by condition and year



total of only 46 (8%) of 580 youth responding to follow-up surveys across groups and years reported recent sexual intercourse, resulting in power too low to detect differences.

Ancillary Analyses

We considered potential differences in our results as functions of race and gender. Gender showed no significant moderation of the GTO effect on any of the three proximal multivariate outcomes in either year ($ps > .13$). The small sample of participants who were not identified as African-American means such comparisons would have had very low power, but

sensitivity analyses excluding those participants showed no meaningful differences in our hypothesis tests. Finally, we also conducted sensitivity analyses excluding the Hedonistic Beliefs scale from the Condom measures analyses due to concerns about differential measurement properties by gender. Again, there was no meaningful difference in the hypothesis tests.

Discussion

The EQUIPS study was designed to assess the impact of GTO implementation supports on fidelity and outcomes of an EBP

Table 4 Univariate findings for individual Condom measures in Year 2

Condom attitudes/intentions	Condition at post (CI)			Change from baseline (CI)			
	Between conditions ^a	Site ICC	Hedges' <i>g</i>	Within MPC + GTO ^b	Cohen's <i>d</i>	Within MPC-only ^c	Cohen's <i>d</i>
Prevention beliefs	0.352 (−0.078, 0.783)	.144	0.22	0.595 (0.291, 0.899)	0.35	0.242 (−0.062, 0.547)	0.16
Hedonistic beliefs	0.024 (−0.221, 0.268)	.109	0.02	0.351 (0.178, .523)	0.36	0.327 (0.154, 0.500)	0.30
Availability control	0.140 (−0.223, 0.502)	.164	0.10	0.695 (0.439, 0.952)	0.53	0.556 (0.299, 0.813)	0.38
Impulse control	<i>0.295 (0.021, 0.569)</i>	.087	0.24	0.399 (0.206, 0.592)	0.33	0.104 (−0.090, 0.298)	0.08
Negotiation beliefs	0.091 (−0.258, 0.440)	.161	0.06	0.423 (0.176, 0.669)	0.39	0.332 (0.085, 0.579)	0.19
Technical skills beliefs	0.240 (−0.127, 0.606)	.135	0.17	0.531 (0.272, 0.790)	0.38	0.292 (0.032, 0.551)	0.19
Self-efficacy to use	<i>0.484 (0.044, 0.924)</i>	.151	0.29	0.473 (0.163, 0.784)	0.32	−0.010 (−0.322, 0.301)	−0.01
Intentions to use	<i>0.292 (0.035, 0.548)</i>	.083	0.26	0.173 (−0.008, 0.355)	0.15	−0.118 (−0.300, 0.064)	−0.11

Note: $N = 419$, cluster $k = 16$. Tabled values for Between Condition are regression coefficients for the outcome on condition and 95% confidence interval (CI). Italics indicate a statistically significant difference. Tabled values for Within MPC + GTO/MPC-only are estimates of changes in means for the outcomes and 95% CI (significant where the CI does not include zero). Positive values indicate beneficial effect of MPC + GTO (Between Condition) or increase from Baseline within each study group (Within MPC + GTO or MPC-only). Hedges' *g* and Cohen's *d* have been adjusted for design effects. Effects are on original measure scale (1–5)

^a Year 1 $N = 477$, cluster $k = 32$; Year 2 $N = 419$, cluster $k = 32$

^b Year 1 $N = 248$, cluster $k = 16$; Year 2 $N = 222$, cluster $k = 16$

^c Year 1 $N = 229$, cluster $k = 16$. Year 2 $N = 197$, cluster $k = 16$

Table 5 Self-reported sexual behavior by intervention group at 6-month follow-up

	Year 1			Year 2		
	Study group			Study group		
	MPC + GTO	MPC-only	F stat (df), <i>p</i>	MPC + GTO	MPC-only	F stat (df), <i>p</i>
Sexual behavior in past 3 months						
Proportion who had sexual intercourse (N)	.10 (158)	.11 (158)	1.07 ₍₁₂₈₅₎ , <i>p</i> = .303	.05 (147)	.07 (117)	0.08 ₍₁₂₃₄₎ , <i>p</i> = .668
Proportion reporting consistent condom use (N)	.50 (16)	.61 (18)	0.42 ₍₁₃₂₎ , <i>p</i> = .520	.50 (8)	.25 (8)	1.09 ₍₁₆₎ , <i>p</i> = .337
Proportion reporting unprotected sexual intercourse (N)	.04 (158)	.04 (158)	0.29 ₍₁₂₈₅₎ , <i>p</i> = .589	.02 (147)	.04 (117)	1.08 ₍₁₂₃₄₎ , <i>p</i> = .300
Sexually inexperienced at pre-intervention ^a	.03 (119)	.02 (133)	0.33 ₍₁₂₅₀₎ , <i>p</i> = .568	.01 (135)	.03 (100)	0.61 ₍₁₂₃₃₎ , <i>p</i> = .435
Sexually experienced at pre-intervention ^a	.14 (28)	.24 (21)	0.71 ₍₁₄₇₎ , <i>p</i> = .403	.09 (11)	.17 (12)	0.28 ₍₁₂₁₎ , <i>p</i> = .601

Note: Tabled values are proportions and within-cell denominator sample sizes. *N* varies by cell, as noted. Within-condition cluster *k* = 16. ICC (intra-class correlation) cells with “NA” indicate site within state random effects were not included in the model because the variance for the random effect was estimated to be zero. Tests of significance are Type III F tests with degrees of freedom in parentheses.

^a Analyses by pre-intervention sexual experience only include youth with non-missing responses to that item at baseline

for teen pregnancy prevention conducted in low-resourced, community-based settings. After 1 year of GTO support, there were no differences between groups on the proximal outcomes, contrary to our year 1 hypothesis. Youth in both groups had no improvement on abstinence attitudes/intentions, and showed similar improvement on the multivariate knowledge of HIV/condoms and condom attitudes/intentions. However, in year 2, youth in MPC + GTO sites improved significantly more on the multivariate condom proximal outcome and three of the individual Condom proximal outcomes, consistent with our year 2 hypothesis. Youth in the MPC + GTO group also improved more on the aggregated abstinence and knowledge proximal outcomes in year 2, but not significantly. Sexual behaviors did not improve at follow-up or differ between the two groups in either year.

One reason for these Year 2 findings may be because the quality improvement support of GTO utilizes year 1 evaluation data to enhance year 2 planning and implementation and thus could only influence year 2 results. This is likely why MPC fidelity was similarly moderate in both groups in year 1, but considerably higher in the MPC + GTO sites in year 2. In turn, the improved fidelity in GTO sites in year 2 likely had an impact on the proximal outcomes between the groups in year 2. Implementation supports in other domains—e.g., Communities that Care (J. D. Hawkins et al., 2008) and Toward No Drug Abuse (Rohrbach et al., 2010)—also improved similar proximal outcomes among youth in communities receiving implementation support.

Direct comparisons to MPC’s efficacy trial are not possible because J. B. Jemmott et al. (1998) involved youth with higher rates of sexual activity and implemented MPC and the baseline and post testing all in 1 day. In EQUIPS, MPC was implemented once a week for 8 weeks. However, the pattern of proximal outcome results of the MPC + GTO group in year 2—i.e., improvement on knowledge of HIV/condom and condom attitudes/intention measures; no change in abstinence attitudes/intention measures—are generally comparable to the Jemmott et al. (1998) trial. Thus, one reason abstinence attitudes/intentions did not change in our study could be that the MPC program from the start has not been able to improve these outcomes. To further place these results in context, we looked at effect sizes from meta-analyses of sexual education randomized trials that included outcome measures that most closely matched EQUIPS. The effect sizes ranged from 0.2 to 0.5, (Johnson et al., 2003; Johnson et al., 2011; Mullen et al., 2002; Scher et al., 2006), which were generally comparable to those in EQUIPS (*d* for within MPC + GTO group change = 0.08 to 0.66 for knowledge and condom measures in year 2, median 0.30). However, one should be cautious interpreting this comparison because the EQUIPS study did not have a no-intervention control group and no meta-analysis available included trials testing implementation support like was done in EQUIPS.

There are several implications of these findings. First, these results suggest that in typical community-based settings, detailed manuals and training common to structured EBPs may be sufficient to yield some improvement in key proximal outcomes (evidenced in year 1), but that full use of an implementation support like GTO is needed to achieve greater improvement in these outcomes (evidenced in year 2). Key to the improved outcomes in the second year was the data-driven quality improvement component, which specifically identified areas of weakness and stimulated plans for improving those areas (the GTO-based quality improvement process could be completed more rapidly if an organization ran their EBP more often than once a year). Second, these findings are generalizable to low-resourced, community-based settings such as Boys and Girls Clubs, using a teen pregnancy prevention EBP. MPC's scope and structure is similar to substance abuse prevention EBPs, the domain for which GTO was first developed. Also, we believe GTO could be used with success in organizations with greater resources and staff. Third, it should be noted that these results were achieved with about 65 h of GTO training and TA time, per site, over the 2 year intervention period (Chinman et al., 2016), suggesting GTO could be feasible on a large scale. This amount is similar to other implementation support models like Communities That Care—34 h 1 year, 41 h in the next in one study (Feinberg, Ridenour, and Greenberg, 2008)—but more than is typically provided by program developers upon purchase of the curriculum. Given that condom knowledge, attitudes, and intentions are key factors that influence actual condom use (Jemmott et al., 1992), GTO (and other implementation support interventions like it) could have significant public health impact on teen pregnancy if the improvements in condom knowledge, attitudes and use intentions found here were applied on a large scale. For example, the US Office of Adolescent Health is funding 75 communities to use GTO to implement EBPs for teen pregnancy prevention for 5 years and is providing the same level of TA support described here. While TA does increase cost, implementation support models in the substance abuse prevention domain have shown the cost could be recouped by the savings expected by better outcomes (Kuklinski, Fagan, Hawkins, Briney, and Catalano, 2015). Still, more research is needed on the cost implications of GTO.

These results advance the field of implementation science. As argued by Glasgow et al. (2012), more implementation research is needed in low resourced settings. These findings suggest that Boys and Girls Clubs, an example of community-based, low resourced settings, can achieve better outcomes in the area of teen pregnancy and STI prevention with targeted implementation support from GTO, over and above the guidance typically provided by EBP materials and training. Also, implementation supports like GTO often include multiple components in order to build capacity across the wide range of activities that must be completed to successfully put an

EBP into place. This study begins to identify specific components—specifically, support for conducting data-driven quality improvement—that lead to better fidelity and outcomes. More research is needed that evaluates the contributions of specific implementation support components.

There are some limitations that should be noted. First, base rates of sex behavior across the sample were very low, which made it difficult to detect group differences on the sexual behavior outcomes similar to the proximal outcomes. Second, it is possible that GTO effects were masked because the MPC-only group received some GTO-like support. For example, we found that MPC-only sites inadvertently received some TA (Chinman et al., 2016), and being in the MPC-only study group itself may have organized sites similarly to what GTO provides (e.g., responding to research staff about dates and locations of program delivery). This contamination could have reduced observed group differences relative to an ideal implementation. Third, GTO sustainability was not evaluated. Future research is needed to investigate the durability of capacity, implementation, and outcome improvements produced by GTO beyond the 2-year study period. Fourth, while MPC has been labeled an EBP in peer-reviewed meta-analyses and by federal funders, the program's outcomes have not been replicated by independent researchers. Thus, because EQUIPS did not include a non-intervention control group, it is possible that the improvements shown here were not due to MPC or GTO, but naturally occurred as youth aged over the 6-month follow-up period. Fifth, we were not able to specifically track turnover of the Boys and Girls staff, which could have impacted the findings. While some turnover did occur, it did not appear to occur more frequently in one group versus another. In our current GTO study, we are now tracking Boys and Girls staff who work on the project. Finally, while EQUIPS was a large trial, the cluster-level sample size of 32 was still small. Future studies are needed in which the impact of implementation support is assessed on a scale that approximates the size of large federally or state funded initiatives such as those by Office of Adolescent Health. Despite these limitations, the strength of EQUIPS is its rigorous design in which we sought to isolate, and then similarly measure, the impacts of GTO over and above the training community-based sites typically receive after acquiring an EBP—an EBP that is one of the most popular teen pregnancy and STI prevention programs in the USA (Chinman et al., 2016).

In conclusion, community-based organizations need support to appropriately implement EBPs, including those on teen pregnancy and STI. While more research is needed on GTO's long term impacts and cost effectiveness, the EQUIPS study suggests that GTO can provide such support. While GTO could help communities address the teen pregnancy winnable battle, it could also be a valuable tool for increasing the public health impact of a variety of EBPs.

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Compliance with Ethical Standards

Conflict of Interests The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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