Impact of Two Adolescent Pregnancy Prevention Interventions on Risky Sexual Behavior: A Three-Arm Cluster Randomized Control Trial

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Objectives. To test the efficacy of *Reducing the Risk* (RTR) and *Love Notes* (LN) on reducing risky sexual behavior among youths yet to experience or cause a pregnancy.

Methods. The four dependent variables were ever had sex, condom use, birth control use, and number of sexual partners at 3- and 6-month follow-up in a 3-arm cluster randomized controlled trial of 1448 impoverished youths, aged 14 to 19 years, in 23 community-based organizations in Louisville, Kentucky, from September 2011 through March 2014.

Results. At 3 and 6 months, compared with the control condition, youths in RTR reported fewer sexual partners and greater use of birth control. At 6 months, LN participants reported greater use of birth control and condoms, fewer sexual partners, and were less likely to have ever had sex compared with the control condition.

Conclusions. We provided additional evidence for the continued efficacy of RTR and the first rigorous study of LN, which embeds sex education into a larger curriculum on healthy relationships and violence prevention. (*Am J Public Health.* 2016;106:S85–S90. doi:10.2105/AJPH.2016.303429)

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As of January 2009, Kentucky ranked eighth highest in the United States in adolescent births, with an overall adolescent birth rate of 51.3 per 1000 females aged 15 to 19 years, and a non-Hispanic Black female birth rate of 57 per 1000, which were both significantly higher than the national rate, which was 39.1 per 1000 females.[1] Major contributing factors to high adolescent pregnancy and birthrates are engagement in high-risk sexual behaviors, such as having multiple partners and lack of consistent use of condoms and other forms of birth control. In Kentucky, more than 24% of high school students reported having had 4 or more partners by graduation, and more than 50% of sexually active students had not used a condom during their last sexual intercourse.[2] One recent review found that comprehensive sex education programs are effective in reducing high-risk sexual behavior.[3] The Teen Pregnancy Prevention Evidence Review by the US Department of Health and Human Services (HHS) confirmed that 1 program, *Reducing the Risk* (RTR), showed evidence of effectiveness with increased birth control and condom use[4–7] and was tested in the present study. We chose to test the fifth edition of RTR with adaptations.[8,9]

We also tested a new approach to adolescent pregnancy prevention. *Love Notes* (LN) embeds pregnancy and disease prevention messages in a curriculum that emphasizes the importance of forming healthy relationships and avoiding intimate partner control or violence for individuals to reach their life goals. LN uses sound pedagogy and includes the use of brief lectures, video, music, discussion, workbook exercises involving self-reflection and goal setting, role plays or scenarios, games, and group activities, many of which involve the use of artistic expression. Studies have found that intimate partner violence is related to sexual risk taking, inconsistent condom use, partner nonmonogamy, and unplanned pregnancy.[10] A focus on this destructive dynamic is not emphasized in most adolescent pregnancy prevention interventions. Research on an early version of LN (*Love U2: Relationship Smarts*) with high-risk youths and delivered through the public school system found an impact on awareness of healthy versus unhealthy relationship patterns and reduction of verbal aggression.[11] A subsequent study with high-risk youths using LN in a community-based organization found that students significantly increased their knowledge about relationships, showed a significantly lower acceptance of violence in dating relationships, and significantly increased communication and conflict management skills.[12] However, the efficacy of LN as an adolescent pregnancy prevention intervention has not been tested.

Our purpose in this study was 2-fold. First, we set out to test the efficacy of an adapted version of RTR, compared with a control condition, *The Power of We* (POW), as well as with LN. Second, we tested the efficacy for the first time of a new adolescent pregnancy prevention intervention, LN, compared with the same control condition. We examined 3 high-risk sexual behavioral outcomes for the

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previous 3-month period at 3- and 6-month follow-ups, plus whether the participants engaged in sexual intercourse.

Compared with participants in the POW control condition, 3 and 6 months after the conclusion of the program, we asked if participants (1) in the RTR intervention group and (2) the LN intervention group use condoms and other forms of birth control more often and did they have fewer sexual partners? As secondary research questions, we asked whether (3) LN and RTR differed in their impact on the primary outcomes, and (4) whether LN and RTR affected the onset of engagement in sexual intercourse.

METHODS

We recruited youths aged 14 to 19 years who were at high risk for adolescent pregnancy and who were involved in out-of-school activities at 23 youth-serving organizations to participate in a camp. The camp occurred across 2 consecutive Saturdays and was given the acronym of CHAMPS! (Creating Healthy Adolescents through Meaningful Prevention Services!). The 23 participating community-based organizations where CHAMPS! camps occurred included faith-based agencies, community centers, child welfare–serving social service agencies, and resource centers located in low-performing schools in the parts of Louisville with the highest poverty rates and minority youths.

Participants were recruited and participated in the trial from September 2011 through March 2014. During completion of the baseline survey, youths were organized into clusters by the research manager. Youths were randomly assigned to clusters, except for 5 youths for whom the research manager made adjustments to ensure gender balance, and to ensure that all members of the same household were in the same cluster, to avoid cross-condition effects. The clusters were then randomly assigned to each of 3 conditions (RTR vs LN vs POW control) in a cluster randomized controlled trial. There were 39 CHAMPS! camps or cohorts. In 8 of these, there were too few participants to assign to all 3 conditions, so the clusters were randomly assigned to the 2 interventions. There were a total of 39 RTR, 39 LN, and 31 POW sessions. Randomization was performed by the research manager, who used statistical software. The randomization was double-blind, because the evaluators were blinded to each condition.

Sample

To be eligible to participate in the study, participants needed the following:

1. parental informed consent for enrollment in the program and research sessions (if aged 14–17 years);
2. personal assent (if aged 14–17 years) or consent (if aged 18 or 19 years) for participation in the workshop and research sessions;
3. to be aged between 14 and 19 years;
4. affiliation with youth serving organizations, or part of a current foster youth or former foster youth alumni group;
5. to be unmarried;
6. able to participate verbally in English;
7. no cognitive impairment that precluded the subject from giving assent or informed consent; and
8. never been pregnant, had a child, or caused a pregnancy.

A total of 1448 youths attended all of day 1 of CHAMPS camps (515 RTR, 511 LN, and 422 POW), whereas 1378 youths attended the entire intervention or control training (both full days of camp) for an overall dosage rate of 95% (n = 481 or 93% for RTR, n = 484 or 94% for LN, and n = 413 or 98% for POW).

Description of Interventions

We adapted 2 interventions and tested them for efficacy in reducing high-risk sexual behavior. Adaptations were needed for many reasons. First, because these curricula were delivered in out-of-school-time settings rather than in school, there was no guarantee that youths would attend every session to receive the full dosage. Focus groups with youths indicated that using the "camp" format across 2 consecutive Saturdays would ensure full dosage. We learned during pilot sessions that most youths did not know anatomy, so videos explaining the reproductive systems were added. Finally, other videos were added to capture the attention of youths and reinforce key concepts, such as the importance of abstinence, types of contraception, and sexually transmitted infections.

RTR consists of sixteen 45-minute modules (12 hours) that cover risk behaviors, abstinence, HIV and sexually transmitted infection prevention, and skills development. Six additional short videos, because of the previously noted 2 adaptations noted, brought the hours of content to 13 hours. In a third adaptation, several exercises were modified or replaced to clarify exercises (see Langley et al[9] for a full description of adaptations).

LN aims to educate youths about healthy relationships and reduce adolescent dating violence and unprotected sex. LN is a 13-module curriculum,[13] partially derived from the Prevention and Relationship Enhancement Program,[14] which is listed as an evidence-based practice for healthy relationships by the Substance Abuse and Mental Health Services Administration (http://www.samhsa.gov). LN covers issues of decision-making, communication, and conflict resolution. It aims to reduce adolescent dating violence, which includes control tactics and coercive sexual encounters, and unprotected sex (and thus pregnancy, the spread of sexually transmitted infections, and being subject to the controlling behavior of others). The curriculum builds on social exchange theory and meets the needs of youths who are in need of loving personal relationships. The 13 modules include setting life goals, personality and family-of-origin issues in relationships, smart love, sliding versus deciding, safety issues, healthy communication strategies, problem solving, commitment and relationship decision-making, and sexuality in close relationships.

There were 4 adaptations to the 2008 version of LN. First, instead of training youths in thirteen 1-hour sessions or four 3-hour sessions, youths were offered LN during 2 consecutive Saturdays. Second, the curriculum developer enhanced the module on sexuality before the intervention began to ensure medical accuracy and comprehensiveness. Third, 4 educational videos on anatomy and

reproduction, abstinence, HIV, and birth control were added (bringing the intervention time to 13 hours). Fourth, PowerPoint slides (Microsoft, Redmond, WA) and abbreviated versions of the training materials were created to focus facilitators on key information from the full training manual.

Control Description

The control condition, the POW, helps youths learn more about assets in their neighborhoods and ways to bring about positive change. Youths walked their neighborhood to gather information about assets and watched films like *Waiting for Superman* to learn how to bring about community change. They created videos or artwork to demonstrate what they learned about community building and change. The content of POW did not include any mention of individual planning, self-esteem, sexual health, healthy relationships, or intimate partner violence, and thus had zero overlap with content in either RTR or LN. The developer of POW, Network Center for Community Change, delivered POW to participants over 13 hours.

Measures

Four questions were asked of participants. (1) In the past 3 months, have you had sexual intercourse without a condom? (2) In the past 3 months, have you had sexual intercourse without you or your partner using any of these methods of birth control (condoms, birth control pills, Depo-Provera [Pfizer, New York, NY] or any injectable birth control, Nuva Ring [Merck & Co, Whitehouse Station, NJ] or any birth control ring, Implanon [Merck & Co, Whitehouse Station, NJ] or any implant, intrauterine device, withdrawal method)? (3) How many different partners have you had sex with in the last X months (last 12 months for baseline, last 3 months for the assessments at 3 and 6 months following the intervention)? On that question, many participants provided text answers such as "none," "about 5," or they left the space blank. A consistent algorithm was used to translate those entries into numbers. For missing data for number of partners, zero values were imputed for those reporting that they had no sexual experience, and 1 was imputed for those who reported that they had been involved in sexual activity during the previous 3 months. (4) Participants also were asked, "Have you ever had sexual intercourse? By 'sexual intercourse,' we mean a male putting his penis into a female's vagina."

These 4 questions were included in all surveys administered at baseline and 3 and 6 months after the program ended. Data collectors were members of the university evaluation team who had training in protection of human participants. They read the surveys aloud to aid in comprehension and to maintain a good pace, so that participants would not second guess and provide a socially desirable response. Participants filled in the bubble corresponding to their answer for each question, and were instructed to cover their answers while completing the survey. Data collectors gathered the surveys at the end of the hour, placed the surveys into manila envelopes that were sealed and transported back to campus and placed in a locked file cabinet. Each survey included an identifying number to ensure that responses from the same youth could be tracked across the pre–post, and all follow-up periods. Once information from the surveys were entered into SPSS version 21 (IBM, Armonk, NY), the sheet with identifying information about youths was separated from the surveys. Surveys were stored in 1 set of

TABLE 1—Key Baseline Demographic Characteristic Measures and Outcome Measures for Youths Completing CHAMPS!: Louisville, KY, 2011–2014

Baseline Measure	RTR	LN	POW	RTR vs POW *P*	LN vs POW *P*	RTR vs LN *P*
Demographic characteristics						
Age						
Mean, y	15.77	15.69	15.71	.47	.81	.52
Sample size	431	412	365			
Gender						
% female	63.60	64.32	62.27	.69	.55	.51
Sample size	445	426	379			
Race/ethnicity						
% non-Hispanic White	7.62	7.96	6.04	.38	.29	.61
% non-Hispanic Black	88.79	86.18	91.86	.05	.01	.16
% Hispanic	3.00	4.80	2.72	.83	.12	.18
% Asian	0.45	0.23	0.26	.64	.94	.29
Sample size	446	427	381			
Primary questions						
Sex without condom past 3 mo						
% at baseline	14.17	15.11	15.37	.76	.89	.67
Sample size	487	483	397			
Sex without birth control past 3 mo						
% at baseline	11.16	13.11	13.27	.52	.76	.31
Sample size	484	473	392			
No. of partners past 12 mo						
Mean	1.06	1.07	0.87	.24	.21	.95
Sample size	473	471	393			
Supplementary question						
Ever had sex						
Yes, %	41.30	42.80	39.60	.99	.79	.62
Sample size	487	480	398			

Note. CHAMPS! = Creating Healthy Adolescents through Meaningful Prevention Services!; LN = *Love Notes*; POW = *Power of We*; RTR = *Reducing the Risk*. *P* values determined by t-test.

locked file cabinets, whereas sheets that contained youth-identifying information were stored in a separate set of locked file cabinets. No identifying information was contained in the database, thus all responses were kept confidential. Demographic characteristic questions included those that assessed age, gender, race, and ethnicity.

Analytic Methods

The analytic sample consisted of all trial participants who met program eligibility requirements and were present in both the baseline and at least 1 of the follow-up assessments.

To analyze data generated in the cluster randomized controlled trial design, we used the basic approach of hierarchical linear modeling (HLM[15]). HLM is a form of ordinary least-squares (OLS) regression that analyzes variance in the outcome variable when the predictor variables are at varying hierarchical levels, such as different clusters or cohorts. HLM offers the option of Bernoulli analysis for binary outcomes (0, [1]), which was used for the condom use, birth control use, and ever had sex outcomes. Standard HLM was used for the number of partner's variable. In addition to controlling for the cohort and probability of being assigned to a cluster, each HLM analysis controlled for small variations in race/ethnicity across conditions. This was expressed as a level 1 covariate in the form of the ratio of non-Hispanic Black to other racial/ethnic groups in the baseline sample. Gender and age also were used as level 1 covariates, along with the baseline assessment of the outcome measure. The level 1 residuals were analyzed using SPSS analysis of variance to produce confidence intervals, effect sizes and power estimates, and are reported as Table C available as a supplement to the online version of this article at http://www.ajph.org. The tests between the interventions and between each intervention and the control condition had a priori predictions, so *t*-test or least-significant difference statistics were used for the comparisons because that approach provided the best balance of the risk of type I and type II errors. All significant effects remained with Benjamini–Hochberg corrections. An outcome of *P* less than or equal to .05 was considered statistically significant.

RESULTS

At the 3-month follow-up, 1090 participants completed the questionnaire, for an overall response rate of 75% (386 RTR, 367 LN, 337 POW) and at the 6-month follow-up, 991 participants from all clusters completed the questionnaire, for an overall response rate of 68% (338 RTR, 345 LN, 308 POW). No demographic characteristic difference between conditions emerged from attrition, but participant retention was slightly higher for POW (80% at 3 months, 73% at 6 months) compared with RTR (75% and 66%, respectively) and LN (72% and 67.5%, respectively). This suggests that POW was effective in creating group cohesion and high morale. If such variables in the control condition tended to reduce sexual behavior, they would work against finding effects for RTR and LN.

Demographic characteristic analyses of the sample are presented in Table 1. Because race/ethnicity was significantly different across intervention groups, the proportion of non-Hispanic Black participants to those from other racial/ethnic groups was used as a covariate in all analyses, along with gender and age, but this did not substantially affect outcomes.

TABLE 2—Postintervention Hierarchical Linear Modeling Estimated Effects of Treatments at 3 Months: CHAMPS!, Louisville, KY, 2011–2014

Measure	RTR	LN	POW	RTR vs POW *P*[a]	LN vs POW *P*[a]	RTR vs LN *P*[a]
Demographic characteristics						
Mean age at baseline, y	15.78	15.65	15.64	.12	.47	.20
% female	64.40	66.60	63.50	.81	.39	.52
% non-Hispanic Black	91.20	87.10	92.90	.52	.01	.09
Sample size	362	342	312			
Sex without condom past 3 mo						
% at baseline	12.15	13.74	13.14			
% at 3-mo follow-up	9.85	11.25	10.60	.73	.91	.68
Sample size	362	342	312			
Sex without birth control past 3 mo						
% at baseline	9.14	13.17	10.65			
% at 3-mo follow-up	7.60	8.70	11.60	.05	.12	.58
Sample size	361	334	310			
No. of partners						
In past 12 mo at baseline, mean	0.74	0.83	0.74			
In past 3 mo at 3-mo follow-up, mean	0.26	0.42	0.41	.03	.96	.14
Sample size	332	317	294			
Ever had sex						
% at baseline	38.12	36.95	38.84			
% at 3-mo follow-up	30.90	34.45	35.95	.09	.43	.06
Sample size	362	341	314			

Note. CHAMPS! = Creating Healthy Adolescents through Meaningful Prevention Services!; LN = *Love Notes*; POW = *Power of We*; RTR = *Reducing the Risk*. Hierarchical linear modeling (HLM) analysis used baseline outcome measure, age, gender, race/ethnicity, cohort, and probability of assignment to cluster as level 1 variables, and treatment as a level 2 variable. For reports of number of partners that had missing values, scores of zero were imputed for participants who reported than that they had no sexual experience and scores of 1 were reported for participants who reported that they had sex within the past 3 months. Outcome means are based on HLM fitted values, averaged across the 2 contrasts when there were small differences.

[a]*P* values determined by t-test. $P \leq .05$ is considered significant.

TABLE 3—Postintervention Hierarchical Linear Modeling Estimated Effects of Treatments at 6 Months: CHAMPS!, Louisville, KY, 2011–2014

Baseline Measure	RTR	LN	POW	RTR vs POW *P*[a]	LN vs POW *P*[a]	RTR vs LN *P*[a]
Demographic characteristics						
Mean age at baseline, y	15.73	15.69	15.62	.41	.86	.71
% female	64.04	64.06	63.79	.98	.97	.99
% non-Hispanic Black	91.80	88.13	92.76	.46	.04	.12
Sample size	317	320	290			
Sex without condom past 3 mo						
% at baseline	13.56	12.81	13.79			
% at 3-mo follow-up	12.30	9.70	16.60	.08	.007	.30
Sample size	317	320	290			
Sex without birth control past 3 mo						
% at baseline	11.04	11.18	12.24			
% at 6-mo follow-up	9.10	8.30	17.50	.005	.001	.72
Sample size	317	313	286			
No. of partners						
In past 12 mo at baseline, mean	0.82	0.71	0.59			
In past 3 mo at 6-mo follow-up, mean	0.41	0.32	0.71	.05	.01	.57
Sample size	273	279	255			
Ever had sex						
% at baseline	40.38	36.99	38.49			
% at 6-mo follow-up	36.78	34.00	40.60	.08	.02	.48
Sample size	317	319	291			

Note. CHAMPS! = Creating Healthy Adolescents through Meaningful Prevention Services!; LN = *Love Notes*; POW = *Power of We*; RTR = *Reducing the Risk*. Hierarchical linear modeling (HLM) analysis used baseline outcome measure, age, gender, race/ethnicity, cohort, and probability of assignment to cluster as level 1 variables, and treatment as a level 2 variable. For reports of number of partners that had missing values, scores of zero were imputed for participants who reported than that they had no sexual experience and scores of 1 were reported for participants who reported that they had sex within the past 3 months. Outcome means are based on HLM fitted values, averaged across the 2 contrasts when there were small differences.

[a]*P* values determined by t-test. $P \leq .05$ is considered significant.

Baseline equivalence analyses are reported in Table 1, with appropriate HLM control for clustering. As characteristic of an urban sample, 41.03% of study participants reported having had sexual experience. That made the participants at high risk for pregnancy and sexually transmitted diseases, and an appropriate group to test the interventions.

For research question 1, we found no significant difference between RTR and POW in failure to use condoms at both 3 months (9.95% vs 10.60%; $t(672) = 0.3$; $P = .73$) and 6 months (12.30% vs 16.60%; $t(605) = 1.73$; $P = .08$) after the conclusion of the program (Tables 2 and 3). (We report estimated means that have been adjusted for cohort, probability, baseline outcome measure, age, gender and race/ethnicity. Because separate analyses were conducted for RTR vs POW and LN vs POW, the adjusted means will vary slightly across analyses.) The RTR group was significantly less likely to fail to use some other form of birth control at 3 months (7.60%) and at 6 months (9.10%) than the POW control group (11.60%; $t(669) = 2.00$; $P = .05$, and 17.50%; $t(601) = 2.84$; $P = .005$, respectively; Table 3 and Table D [available as a supplement to the online version of this article at http://www.ajph.org]). There also was a significant difference between RTR and POW in number of recent sexual partners 3 months after the conclusion of the program (0.26 vs 0.41; $t(624) = 2.16$; $P = .03$) and again at 6 months (0.41 vs 0.71; $t(526) = 1.93$; $P = .05$). We found no significant difference between RTR and POW in reporting ever having had sex at both 3 months (30.50% vs 35.95%; $t(651) = 1.71$; $P = .09$) and 6 months (36.78 vs 40.60; $t(651) = 1.74$; $P = .08$).

For research question 2, we found no difference between LN and POW at the 3-month mark in failure to use condoms (11.40% vs 10.60%),[2] failure to use birth control (8.70% vs 11.60%), number of sexual partners (0.42% vs 0.41%), or ever had sex (34.45% vs 35.95%). However, by the 6-month follow up, those in the LN group were significantly less likely than the POW control group to fail to use condoms (9.70 vs 16.60%; $t(608) = 2.72$; $P = .007$), and to fail to use some other forms of birth control (8.30% vs 17.50%; $t(597) = 3.40$; $P = .001$). At 6 months, the LN group also reported significantly fewer sexual partners than the POW group (0.32 vs 0.70; $t(532) = 2.48$; $P = .01$), and was significantly less likely to report ever having had sex compared with the POW group (34.00% vs 40.60%; $t(608) = 3.36$; $P = .02$).

Although RTR produced more significant effects than LN at 3 months, and LN produced more significant effects than RTR at 6 months, none of the differences between RTR and LN were statistically significant.

DISCUSSION

Preliminary behavioral findings using a randomized control trial design support the impact of RTR on curbing 2 types of risky sexual behavior: failing to use birth control, and having sex with multiple partners at both 3 and 6 months past the intervention, even when delivered in the community during a shorter intervention time frame. Similar findings regarding birth control use were found for past quasi-experimental studies on RTR administered across 16 class periods in a school setting.[5] Because our findings are based on an experimental design, support several past findings, and extend those findings with the inclusion of number of sexual partners, the generalizability to other youths, particularly non-Hispanic Black youths living in urban settings, is encouraging. This was also the first randomized control trial to test the efficacy of LN on reducing risky sexual behavior. The positive impact on ever having had sex, birth control, condom use, and number of sexual partners at 6 months after intervention is promising. A replication of

these results is needed to increase the strength of the evidence for the intervention.

Study Limitations

Despite these important findings, we also noted a handful of limitations. Although we found important differences between 2 interventions and a control condition, the study design led to smaller sample sizes in each of the 3 conditions than if only 1 intervention had been examined. Some of the nonsignificant trends (marginally greater use of birth control at 3 months for LN and lower levels of sexual initiation at 3 and 6 months in RTR) might have been significant if we had had a larger number of participants in each condition. In addition, we felt it was important for the youths to have a meaningful experience in the control condition; therefore, we exposed them to a positive training on community assets. Our control condition was so positive that it might have had beneficial impacts on youth sexual behavior, despite having no program content on that topic. A review of positive youth development programs with no content on sex education found that many have a positive impact on sexual and reproductive health.[16]

In a longitudinal study, there is always the possibility of attrition. To ensure that this did not cause spurious differences between groups, we tested for the comparability of the conditions on the baseline demographic and outcome measures at both 3 months and 6 months, and also used those measures as covariates. We plan to look at attrition dynamics in more detail in future analyses, along with additional outcome measures. Finally, in a self-report study, there is always a risk of participants concealing their actual behavior and making false, socially desirable, or random statements, which could result in biased or imprecise data. Our administration procedures were designed to minimize such tendencies, and there is no reason to expect that would cause differences between randomized groups.

Conclusions

Despite these limitations, our study added to the growing literature on "what works" to reduce risky adolescent sexual behavior. This adaptation of RTR had an impact on more than 1 type of risky sexual behavior using a more condensed delivery method. Also, by exposing youths to a heavy dose of life planning, healthy relationship, and violence prevention material in the context of adolescent pregnancy prevention, the LN intervention was also successful in reducing risky sexual behavior. Our study of LN contributed to public health's search for comprehensive programming to increase adolescent health across multiple areas.[17] Addressing life planning and more than 1 high-risk behavior might be more cost effective both in terms of time and expenditures in enhancing positive youth development and reducing maladaptive behavior. AJPH

CONTRIBUTORS

A. P. Barbee conceptualized and designed the study, interpreted the data analyses, wrote the Introduction, Methods, and Discussion sections, edited the Results section, and approved the final version of the article. M. R. Cunningham contributed to the conceptualization and design of the study, conducted the analyses, wrote the Results section, and edited other sections of the article. M. A. van Zyl contributed to the conceptualization and design of the study, consulted on analyses of the study, and edited an earlier draft of the article. B. F. Antle contributed to the conceptualization and design of the study, and edited later drafts of the article. C. N. Langley contributed to the conceptualization and design of the study, oversaw randomization and implementation, and edited the last draft of the article.

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HUMAN PARTICIPANT PROTECTION

The study was approved by the University of Louisville institutional review board.

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