<u>A Randomized Iterative Approach to Optimizing an Online Substance Use Intervention for</u> <u>Collegiate Athletes</u>

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Abstract:

Background Rates of drug use among collegiate athletes are high, yet there are few evidencebased interventions for this population. myPlaybook, an online intervention for collegiate athletes, targets multiple predictors of drug use (i.e., norms, positive and negative expectancies about use, and harm prevention intentions).

Purpose We aimed to optimize modules from myPlaybook.

Method We evaluated modules through three sequential randomized factorial trials, using the Multiphase Optimization Strategy framework. We recruited and randomized 54 (Trial 1), 47 (Trial 2), and 42 (Trial 3) schools and invited all first-year and transfer collegiate athletes to participate. Athletes completed a baseline survey, their randomly assigned modules, and immediate posttest and 30-day follow-up surveys. Across trials, 3,244 (48.8% female), 2,837 (51.9% female), and 2,193 (51.4% female) athletes participated. In Trial 1, we evaluated and revised less effective modules (defined as d < 0.3-0.4 for targeted outcomes). In Trial 2, we re-evaluated and revised less effective modules. In Trial 3, we re-evaluated the revised modules.

Results Trial 1: All effects were d < 0.15, so we revised modules to target proximal outcomes (i.e., the hypothesized mediating variables in our conceptual model), rather than specific drug use behaviors. Trial 2: Most effects were d < 0.3, so we revised all modules. Trial 3: The norms module improved descriptive and injunctive norms (all d > 0.35). The expectancies module improved alcohol positive expectancies (d = 0.3). The other modules were not effective.

Conclusions After three trials, two myPlaybook modules substantially improved proximal outcomes, increasing the likelihood that the combined intervention will have a meaningful clinical impact on collegiate athletes' drug use.

Keywords: drug prevention | collegiate athletes | multiphase optimization strategy | social norms | intervention science

Article:

Despite recent declines, rates of drug use among collegiate athletes remain high. For example, in 2017, 42% of collegiate athletes reported binge drinking compared to 33% of the general college population [1]. Interventions targeting alcohol use among college students [2,3] show some efficacy in Randomized Control Trials (RCTs), but the effects of these interventions are often small to moderate and they do not address the unique motivations for drug use among athletes. Further, the few evidence-based interventions designed for collegiate athletes [4,5] only address alcohol use, yet rates of other drug use are also problematic and collegiate athletes can face unique consequences due to this use (e.g., losing eligibility and scholarships if they test positive for banned drugs). In response, we developed myPlaybook, an online alcohol and drug use intervention for collegiate athletes that addresses drug use outcomes faced by all college students (e.g., health risks, academic consequences), while also being tailored for collegiate athletes (e.g., presenting data about rates of drug use among collegiate athletes; addressing how drug use can harm athletic performance [6]). In a previous project, we evaluated the original version of myPlaybook and found that this full intervention package significantly changed social norms and intentions to use harm prevention strategies [7]. Importantly, however, we realized that just because the full intervention package had statistically significant results did not guarantee that myPlaybook was as effective as it could be (i.e., that the public health impact had been maximized) or that all of the modules were effective. Thus, the objective of the current study was to iteratively evaluate and strengthen the effect of the individual modules as a way to strengthen (i.e., optimize) the full myPlaybook intervention package.

To meet this objective, we used the Multiphase Optimization Strategy (MOST) [8–11], which draws on engineering principles to efficiently develop an optimized multicomponent intervention (see Supplemental Figure A). MOST has three phases. During the Preparation phase, researchers develop a conceptual model, identify which components (i.e., parts of the intervention) they will evaluate, pilot test these components, and identify an optimization criterion. During the Optimization phase, researchers conduct one or more experiments to test the components and decide which components should be included in the optimized intervention. Finally, during the Evaluation phase, researchers test the full intervention using an RCT.

Prior to this study, we had completed the Preparation phase. In that phase, we created a working conceptual model (Supplemental Figure B) by using Social Norms Theory [12], the Health Belief Model, [13], and the Theory of Reasoned Action [14,15] to identify modifiable factors linked to drug use, namely norms about peer drug use, expectancies about the effects of drug use, and behavioral intentions. Empirical work supports these factors as predictors of drug use among college students [16,17] and collegiate athletes [18–20]. Using this model, we developed the original myPlaybook intervention package, which consisted of six 10-15-minute online modules. The first module described NCAA drug testing procedures and banned drugs. The other modules each targeted a specific drug: (1) alcohol, (2) marijuana, (3) tobacco, (4) performance enhancing drugs/dietary supplements, and (5) prescription/over-the-counter drugs. All five drug-focused modules addressed social norms and expectancies. The alcohol module also addressed using protective behavioral strategies to reduce harm (see [7] for more details). We also identified our optimization criterion as the largest effect size for each module that could be achieved after two rounds of testing and revision (see [11] for more details).

In this manuscript, we report the results from the Optimization phase, which consisted of three experimental (optimization) trials. In Trial 1, we evaluated the original modules, then revised the less effective modules. In Trial 2, we evaluated these revised modules. We had planned to move directly from Trial 2 to the Evaluation phase to test the optimized myPlaybook intervention

package in an RCT, but as described later, we substantially changed our conceptual model and the modules after Trial 1, so instead, we revised the modules again after Trial 2 and added Trial 3 to evaluate these revised modules. After Trial 1, we also streamlined myPlaybook to focus primarily on alcohol and marijuana use, so we only report those outcomes here.

Method

Prior to starting the study, the IRB at UNC Greensboro approved all methods and surveys. During the fall semesters of 2011 (Trial 1), 2012 (Trial 2), and 2013 (Trial 3), a National Collegiate Athletic Association (NCAA) representative emailed all member institutions with general study information and encouraged them to attend an informational webinar about the study; these webinars were led by research staff and did not involve anyone from the NCAA. To minimize contamination across conditions, we used a cluster randomized design, with schools as clusters. Because drug use varies across NCAA athletic division [1], we stratified by division and used a computer-generated sequence to randomize recruited schools to condition.

During the subsequent spring semester, we obtained email addresses of eligible athletes at each school. Eligible athletes had to be (1) enrolled full time at a participating school, (2) participating in at least one NCAA sport, and (3) either a first-year or transfer student. Focusing on incoming students allowed us to conduct optimization trials in three subsequent years without recruiting new schools each year. Research staff emailed eligible athletes to invite them to participate in the study. Athletes who consented then completed the baseline survey, followed by their assigned myPlaybook modules, and an immediate posttest survey. Trials 1 and 2 also included a 30-day follow-up survey. Athletes accessed surveys and modules online through a learning management system. Per NCAA rules, we could not provide incentives to individual athletes. Instead, we provided incentives to schools, to encourage coaches and athletic staff to support the study (e.g., sending out their own email messages to encourage participation). Specifically, in all three trials, we provided schools with a survey participation rate $\geq 80\%$ a custom report with aggregated data about their athletes (we counted athletes who accessed the survey, but did not consent, toward the school's participation rate). In Trial 3, our research team also provided up to \$3000 to schools based on athlete retention rates. Table 1 provides the baseline descriptive information about participating athletes in each Trial.

	Trial 1, $\%(n = 3,244)$	Trial 2, $\%(n = 2,837)$	Trial 3, $\%(n = 2,193)$
Sex			
Female	48.8	51.9	51.4
Male	51.2	48.1	48.6
Competition status			
In season	56.3	57.2	47.3
Off season	43.7	42.8	52.7
Year of eligibility			
First year	86.2	87.4	86.8
Second year or higher	13.8	12.6	13.2
Race			
White	73.3	80.2	75.6
Black	12.0	11.1	13.1
Other	15.7	8.7	11.3
Lifetime alcohol use			
Ever used alcohol	68.2	68.8	71.6

 Table 1 Descriptive information for each optimization trial

Never used alcohol	31.8	31.2	28.4
Lifetime marijuana use			
Ever used marijuana	13.4	14.3	21.4
Never used marijuana	86.6	85.7	78.6

Note. The sample size indicates the number of students who completed the baseline survey along with at least one of the follow-up surveys.

Trail 1. METHODS

We decided that all athletes would complete the informational module, regardless of their assigned intervention condition, given that the content was foundational; therefore, we did not evaluate this module. To evaluate the other five modules, we used a 25-1 fractional factorial design with 16 conditions [21,22]; using a fractional factorial design allowed us to assign at least one school from each NCAA division to each condition. Table 2 shows which modules athletes in each condition received. Note that we did not compare the 16 conditions directly to each other or to a single "control" condition; instead, we used all 16 conditions (i.e., the full sample) to evaluate each module. For example, we evaluated the alcohol module by comparing the alcohol-related outcomes between athletes who received the alcohol module (conditions 9–16) and athletes who did not receive the alcohol module (conditions 1-8).

As part of MOST, we developed an a priori process to identify and strengthen less effective modules. We operationalized effectiveness as a main effect of $d \ge 0.3$ on its targeted drug use outcomes; we selected this cutoff as it represents a clinically meaningful reduction in drug use. If a module met this cutoff, and did not weaken the effect of other modules (i.e., no significant iatrogenic 2-way interactions), we would classify it as effective and not revise it. If a module did not meet this criterion, we then evaluated its effect on proximal outcomes (i.e., the hypothesized mediating variables in our conceptual model) at immediate posttest and 30-day follow-up. If a module had an effect of $d \ge 0.4$ on these outcomes, we would use this information to decide how to proceed (see [11] for more details). After identifying less effective modules, we collected feedback from (1) focus groups of 8–12 athletes at four schools who had completed one or more myPlaybook modules (led by the school's myPlaybook liaison), (2) an expert advisory panel (EAP) with a health education specialist from the NCAA and three prevention scientists with program development and content expertise, and (3) instructional design experts at LeanForward, who led the technical development of each module. We used their feedback to inform our revisions, although the research team made all final decisions about what to revise.

Sample

We recruited 55 NCAA colleges and universities (16 Division I, 21 Division II, and 18 Division III schools). One Division III school dropped out after randomization, but prior to data collection. We invited all 5,802 eligible athletes at the remaining 54 schools to participate. After excluding athletes who did not consent, those who were under 18 years old, and those who had identifiable response patterns (e.g., answering all 100+ non-demographic items with the same number), our baseline sample was 3,859 athletes (66.5% of the eligible population). Of these athletes, 3,191 (82.7%) completed the immediate posttest survey and 2,193 (56.8%) completed the 30-day follow-up survey (53 of these athletes had not completed the immediate posttest survey, but we retained them in the analyses evaluating change from baseline to 30-day follow-up). Therefore, the final

	Received module? ^a				Schools	Eligible Students	Excluded students ^b		Time 1 ^c		Time 2 ^d		Time 3 ^e				
Cond.	INFO	ALC	MAR	TOB	PER	OTC	N	N	С	D	Р	N	%	N	%	N	%
1	\checkmark					\checkmark	4	474	0	2	1	270	57.0	225	83.3	137	50.7
2	\checkmark				\checkmark		3	343	3	4	2	266	77.6	225	84.6	154	57.9
3	\checkmark			\checkmark			3	332	0	0	1	252	75.9	229	90.9	139	55.2
4	\checkmark			\checkmark	\checkmark	\checkmark	3	167	0	1	1	161	96.4	147	91.3	111	68.9
5	\checkmark		\checkmark				4	355	0	1	3	288	81.1	260	90.3	190	66.0
6	\checkmark		\checkmark		\checkmark	\checkmark	3	334	0	4	5	278	83.2	239	86.0	146	52.5
7	\checkmark		\checkmark	\checkmark		\checkmark	3	348	1	0	2	273	78.4	240	87.9	168	61.5
8	\checkmark		\checkmark	\checkmark	\checkmark		3	230	1	4	0	134	58.3	109	81.3	74	55.2
9	\checkmark	\checkmark					3	322	0	1	2	232	72.0	206	88.8	133	57.3
10	\checkmark	\checkmark		\checkmark	\checkmark	\checkmark	3	444	1	8	0	136	30.6	54	39.7	26	19.1
11	\checkmark	\checkmark				\checkmark	4	483	3	2	1	276	57.1	230	83.3	167	60.5
12	\checkmark	\checkmark		\checkmark	\checkmark		4	409	1	4	1	263	64.3	220	83.7	161	61.2
13	\checkmark	\checkmark	\checkmark			\checkmark	4	402	7	3	1	185	46.0	130	70.3	103	55.7
14	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		3	336	0	4	0	186	55.4	107	57.5	74	39.8
15	\checkmark	\checkmark	\checkmark				3	320	0	1	4	307	95.9	291	94.8	213	69.4
16	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	4	503	0	5	3	352	352	70.0	279	79.3	197
Total								5802				3859	66.5	3191	82.7	2193	56.8

Table 2. Trial 1 description of conditions and participation rates by condition

^aIndicates whether student in a given condition received a particular module, with $\sqrt{}$ = received the module (INFO = Informational module about drug testing and banned drugs; ALC = Alcohol, MAR = Marijuana, TOB = Tobacco, PER = Performance enhancing/supplements, OTC = Over the counter/prescription drugs.

^bReasons students were excluded: C = No Consent or reported that they were under age 18, D = Consented but didn't provide any data, P = Patterns in their data (e.g., answering all 100+ non-demographic items with the same number).

^cpercent of eligible students.

^dpercent of time 1 students who completed time 2 (immediate posttest).

^epercent of time 1 students who completed time 3 (30-day follow-up).

analytic sample was 3,244 athletes who completed the baseline and at least one follow-up survey. Table 2 provides recruitment and retention information by condition.

Measures

Drug Use

On the baseline and 30-day follow-up surveys, athletes reported average number of drinks per sitting, how often in the past two weeks they had 4+ (female) or 5+ (male) drinks in a sitting, and how many days in the past month they got drunk. They also reported past 30 day use of alcohol and marijuana (I have never used this; I have used this but not in the past 30 days; once; twice; 3- 5 days; 6-9 days; 10+ days).

Proximal outcome measures

On each survey, athletes answered questions about: (1) Descriptive norms (perceptions about the frequency of others' drug use), (2) Injunctive norms (perceptions about whether others approved of drug use), (3) Positive expectancies (the extent to which athletes expected drug use to lead to positive outcomes, such as having more fun), and (4) Negative expectancies (the extent to which athletes expected drug use to lead to negative outcomes, such as addiction). We also measured intentions to use protective behavioral strategies (e.g., alternating alcoholic and non-alcoholic drinks) to evaluate the alcohol module. See supplemental tables G-N for more information about each measure.

Additional Measures

We also measured demographic characteristics (e.g., sex, race) and sports-specific information (e.g., year of NCAA eligibility; whether their sport was in season).

Statistical Analysis

We evaluated each module using intent-to-treat principles and estimated multilevel linear regression models with random intercepts in SAS, version 9.4, to account for the nesting of athletes within schools. We estimated separate models for each outcome. Each model included the corresponding baseline variable to control for pre-intervention differences and adjusted for sex, race, year in school, and season, to control for any pre-existing differences across conditions that occurred, despite random assignment. Models for alcohol-related outcomes adjusted for lifetime alcohol use (yes/no) and models for marijuana-related outcomes adjusted for lifetime marijuana use (yes/no). Regardless of the outcome, we included variables for all five experimentally manipulated modules and the two-way interactions between each pair of modules; we used effect-coding (i.e., -1 = did not receive module, +1 = received the module) rather than dummy coding (0,1) to ensure that the estimated effects are relatively uncorrelated, even when the sample sizes across conditions were unequal [21]. In these models, the main effects for the alcohol and marijuana modules indicate whether each module changed its targeted outcomes.

Trial 1 RESULTS

We found that neither the alcohol nor the marijuana module reduced drug use at the 30-day followup (all d < .1). Table 3 provides the main effects of these two modules on the proximal outcomes (for full results, see Supplemental Tables A and B). Importantly, the effect sizes for all significant main effects were below d = .4 (range: d = .07 to d = .15), indicating that we needed to revise each module. Because no main effects met our specified criterion, requiring us to revise all modules, we did not interpret the few significant two-way interactions.

Revision Process

Based on our results and feedback from athletes and our EAP, we substantially revised the myPlaybook modules and our optimization criterion, described in more detail below.

Changes in how modules were structured

We restructured the modules so that the content in each module targeted a specific proximal outcome from our conceptual model: norms, expectancies, or intentions to use protective behavioral strategies (see Supplemental Figure C). In Trial 1, the content in each module focused on a specific drug use behavior and targeted all of these proximal outcomes, but it was inefficient for athletes to learn about these outcomes separately for each drug. Further, the original structure may have limited our ability to detect effects on proximal outcomes by creating spillover effects. For example, athletes learned about norms in each module, which might explain the null effects of each module on norms.

Changes in conceptual model

We also updated the model to reflect that the content of the harm prevention module attempts to shift intentions to use harm prevention strategies, rather than self-efficacy to use these strategies.

Changes in targeted drugs

The revised modules primarily focused on alcohol and marijuana use. We selected these drugs because alcohol is the most prevalent drug used by collegiate athletes and marijuana is not only increasing in prevalence, it also has consequences for NCAA athletes' eligibility to compete (i.e., it is a banned drug that is included in drug testing panels). Other drugs are either less prevalent (e.g., steroids) or do not affect NCAA athletes' eligibility (e.g., smokeless tobacco use; supplements). To increase the likelihood of transfer to other drugs, however, we also included generic language about drug use throughout the modules.

Table 3. Results from T	Trial 1
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		No Module <u>a</u>	Module ^a	Difference	<i>p</i> -value	d	N
		Mean (95% CI)	Mean (95% CI)	Mean (95% CI)			
Descriptive nor	ms						
Alcohol:	Immediate posttest	4.22 (4.10, 4.33)	3.87 (3.75, 4.00)	0.35 (0.18, 0.51)	<.001	0.15	3088
	30-day follow-up	4.31 (4.09, 4.53)	3.91 (3.68, 4.14)	0.40 (0.08, 0.72)	0.02	0.11	2137
Marijuana:	Immediate posttest	1.78 (1.72, 1.84)	1.72 (1.66, 1.77)	0.06 (-0.02, .14)	0.17	0.05	2969
	30-day follow-up	1.72 (1.64, 1.81)	1.71 (1.64, 1.78)	0.01 (-0.10, 0.13)	0.81	0.01	2051
Injunctive norn	18						
Alcohol:	Immediate posttest	1.70 (1.66, 1.74)	1.64 (1.60, 1.68)	0.06 (0.01, 0.12)	0.03	0.08	3160
	30-day follow-up	1.72 (1.68, 1.76)	1.66 (1.61, 1.71)	0.05 (-0.01, 0.12)	0.11	0.07	2172
Marijuana:	Immediate posttest	1.52 (1.48, 1.55)	1.51 (1.48, 1.55)	0.00 (-0.05, 0.05)	0.87	0.01	3137
	30-day follow-up	1.51 (1.45, 1.56)	1.50 (1.45, 1.55)	0.01 (-0.06, 0.09)	0.76	0.01	2151
Positive expecta	incies						
Alcohol:	Immediate posttest	2.11 (2.07, 2.14)	2.05 (2.02, 2.09)	0.05 (0.00, 0.10)	0.04	0.07	3146
	30-day follow-up	2.22 (2.17, 2.27)	2.12 (2.07, 2.18)	0.09 (0.02, 0.17)	0.02	0.11	2159
Marijuana:	Immediate posttest	1.80 (1.76, 1.84)	1.79 (1.75, 1.83)	0.01 (-0.05, 0.07)	0.77	0.01	3118
	30-day follow-up	1.82 (1.77, 1.87)	1.82 (1.78, 1.86)	0.00 (-0.07, 0.06)	0.95	0.00	2139
Negative expect	ancies						
Alcohol:	Immediate posttest	2.65 (2.60, 2.69)	2.62 (2.57, 2.67)	0.02 (-0.04, 0.09)	0.50	0.02	3148
	30-day follow-up	2.77 (2.71, 2.83)	2.78 (2.72, 2.85)	-0.02 (-0.11, 0.08)	0.71	0.02	2158
Marijuana:	Immediate posttest	2.57 (2.52, 2.62)	2.66 (2.62, 2.71)	-0.09 (-0.16, -0.02)	0.01	0.09	3118
	30-day follow-up	2.63 (2.57, 2.70)	2.74 (2.69, 2.80)	-0.11 (-0.20, -0.03)	0.01	0.11	2138
Intentions to us	e protective behavioral stra	ategies					
Alcohol:	Immediate posttest	3.26 (3.20, 3.32)	3.22 (3.15, 3.29)	0.04 (-0.05, 0.13)	0.42	0.04	1674
	30-day follow-up	3.25 (3.17, 3.32)	3.23 (3.14, 3.32)	0.02 (-0.10, 0.13)	0.76	0.02	1123

Note: Each model included the corresponding baseline variable, and indicators for female sex, White race, Black race, first year student, and in-season. Models for alcohol-related outcomes adjusted for lifetime alcohol use and models for marijuana-related outcomes adjusted for lifetime marijuana use. Results for these parameters are not shown here.

^aModule refers to alcohol module for alcohol outcomes and marijuana module for marijuana outcomes.

Changes in how effective modules were identified

We decided that in subsequent trials, we would classify a module as effective if it had a main effect of $d \ge 0.3$ on its targeted proximal outcomes and did not have any significant iatrogenic 2-way interactions. We changed our focus to proximal outcomes instead of drug use behaviors for several reasons. First, in our revised conceptual model, each module targets one proximal outcome; these modules likely have smaller effects on drug use than a module that addresses all of the proximal outcomes, thus we would have needed a larger sample size to detect the effects of the revised modules on use. Second, unlike the low base rates of past 30-day marijuana use (2.5% in Trial 1), baseline scores on proximal outcomes were higher, and changed faster, than use, making them better for decision-making purposes in our optimization trials. Third, the strong theoretical and empirical work linking these proximal outcomes to drug use suggested that strengthening the effect of modules on proximal outcomes would improve the impact of the final intervention package on drug use. We also changed our criterion for proximal outcomes to an effect size of $d \ge 0.3$ (instead of $d \ge 0.4$) because we expected that if multiple modules met this cutoff, then the combined effect of these individual modules in the final intervention package would meet our original goal (i.e., a clinically meaningful effect size of $d \ge 0.3$ for drug use).

Trial 2. METHODS

Trial 2 evaluated the three revised myPlaybook modules. We used a longitudinal, full factorial design with $2^3 = 8$ conditions (See Table 4).

Sample

We recruited 47 NCAA schools (n = 16 Division I, n = 19 Division II, and n = 12 Division III schools). Thirty-nine of these schools (72%) had participated in Trial 1. There were two primary reasons that schools did not return for Trial 2. First, we did not invite schools with very low Trial 1 participation rates to participate again. Second, in some schools, new athletic administrations (due to turnover) no longer prioritized study participation. Because we targeted first year and transfer athletes, no athletes from Trial 1 were eligible for Trial 2. We invited all 4,945 eligible athletes at these schools to participate. The final analytic sample was N = 2,837 (see Table 4 for breakdown of recruitment and retention rates across conditions).

Measures

We used the same proximal outcome measures as Trial 1, although we changed some items in response to feedback during the revision process (See Supplemental Tables G-N).

TRIAL 2 RESULTS

We used the same analytic approach as Trial 1, except that we added a 3-way interaction among modules (because we used a full factorial design, it was not aliased with other terms). Table 5 provides the main effects for the norms, expectancies, and harm prevention modules on the proximal outcomes (for full results, see Supplemental Tables C and D). All effects for descriptive norms were d > .3, but none of the effects for injunctive norms met this criterion. In addition,

	Received Module? ^a				Schools	Eligible students	Excluded students ^b			Time 1 ^c		Time 2 ^d		Time 3 ^e	
Cond.	INTRO	NORM	EXP	HARM	Ν	Ν	С	D	Р	Ν	0∕0 ^a	N	⁰∕₀ b	N	%°
1	\checkmark				6	595	2	8	2	439	73.8	396	90.2	326	74.3
2	\checkmark			\checkmark	6	521	7	10	2	392	75.2	350	89.3	322	82.1
3	\checkmark		\checkmark		6	691	6	8	2	394	57.0	310	78.7	205	52.0
4	\checkmark		\checkmark	\checkmark	6	540	3	3	0	322	59.6	243	75.5	180	55.9
5	\checkmark	\checkmark			6	527	6	2	1	417	79.1	363	87.1	281	67.4
6	\checkmark	\checkmark		\checkmark	6	624	3	6	0	326	52.2	288	88.3	215	66.0
7	\checkmark	\checkmark	\checkmark		5	602	6	10	6	504	83.7	439	87.1	365	72.4
8	\checkmark	\checkmark	\checkmark	\checkmark	6	845	3	7	2	419	49.6	352	84.0	251	59.9
Total					47	4945				3213	65.0	2741	85.3	2145	66.8

Table 4. Trial 2 description of conditions and participation rates by condition

^aIndicates whether student in a given condition received a particular module, with \checkmark = received the module (INFO = Informational module about drug testing and banned drugs; NORM = Peer norms; EXP = Expectancies about drug use; HARM = Harm prevention).

^bReasons students were excluded: C = No Consent or reported that they were under age 18, D = Consented but did not provide any data, P = Patterns in their data (e.g., answering all 100+ non-demographic items with the same number).

^cpercent of eligible students.

^dpercent of time 1 students who completed time 2 (immediate posttest).

^epercent of time 1 students who completed time 3 (30-day follow-up).

		No Module ^a	ule ^a Module ^a Difference		<i>p</i> -value	d	N
		Mean (95% CI)	Mean (95% CI)	Mean (95% CI)			
Descriptive nor	ms						
Alcohol:	Immediate posttest	4.07 (3.92, 4.21)	2.37 (2.23, 2.52)	1.69 (1.49, 1.90)	<.0001	0.65	2661
	30-day follow-up	4.10 (3.94, 4.26)	2.96 (2.80, 3.12)	1.14 (0.91, 1.37)	<.0001	0.44	2082
Marijuana:	Immediate posttest	2.20 (2.09, 2.32)	1.50 (1.39, 1.62)	0.70 (0.54, 0.86)	<.0001	0.35	2628
	30-day follow-up	2.16 (2.04, 2.29)	1.56 (1.43, 1.68)	0.61 (0.43, 0.78)	<.0001	0.31	2055
Injunctive norm	ns						
Alcohol:	Immediate posttest	1.60 (1.57, 1.63)	1.43 (1.40, 1.46)	0.17 (0.13, 0.22)	<.0001	0.28	2650
	30-day follow-up	1.52 (1.47, 1.58)	1.47 (1.42, 1.52)	0.06 (-0.02, 0.13)	0.12	0.07	2080
Marijuana:	Immediate posttest	1.70 (1.66, 1.74)	1.50 (1.46, 1.54)	0.21 (0.15, 0.26)	<.0001	0.29	2636
	30-day follow-up	1.71 (1.65, 1.77)	1.60 (1.54, 1.66)	0.11 (0.03, 0.19)	0.01	0.12	2078
Positive expecta	ancies						
Alcohol:	Immediate posttest	2.77 (2.72, 2.82)	2.48 (2.42, 2.53)	0.29 (0.022, 0.37)	<.0001	0.31	2635
	30-day follow-up	2.79 (2.74, 2.85)	2.67 (2.61, 2.73)	0.13 (0.04, 0.21)	0.004	0.14	2066
Marijuana:	Immediate posttest	2.13 (2.10. 2.17)	1.93 (1.89, 1.97)	0.20 (0.14, 0.25)	<.0001	0.28	2590
	30-day follow-up	2.10 (2.06, 2.15)	2.05 (2.00, 2.10)	0.05 (-0.01, 0.12)	0.12	0.07	2030
Negative expect	tancies						
Alcohol:	Immediate posttest	2.77 (2.72, 2.81)	2.80 (2.76, 2.85)	-0.04 (-0.10, 0.03)	0.26	0.04	2634
	30-day follow-up	2.77 (2.72, 2.82)	2.80 (2.74, 2.85)	-0.03 (-0.10, 0.05)	0.48	0.03	2064
Marijuana:	Immediate posttest	2.56 (2.51, 2.61)	2.52 (2.46, 2.57)	0.04 (-0.03, 0.12)	0.25	0.05	2590
	30-day follow-up	2.60 (2.54, 2.66)	2.57 (2.50, 2.63)	0.04 (-0.05, 0.13)	0.42	0.04	2028
Intentions to us	e protective behavioral	strategies					
Alcohol:	Immediate posttest	3.74 (3.69, 3.79)	3.82 (3.77, 3.88)	-0.08 (-0.16, -0.01)	0.03	0.08	2635
	30-day follow-up	3.75 (3.68, 3.82)	3.79 (3.72, 3.87)	-0.04 (-0.15, 0.06)	0.41	0.04	2065

Table 5. Results from Trial 2

Note: Each model included the corresponding baseline variable, and indicators for female sex, White race, Black race, first year student, and inseason. Models for alcohol-related outcomes adjusted for lifetime alcohol use and models for marijuana-related outcomes adjusted for lifetime marijuana use. Results for these parameters are not shown here.

^aModule refers to norms module for norms outcomes, expectancies module for expectancies outcomes, and harm prevention module for intentions to use protective behavioral strategies.

although the effects for alcohol positive expectancies at immediate posttest were d > .3, all other effects for expectancies were d < .3, as were the effects for the harm prevention module.

Trial 3. METHODS

Trial 3 evaluated the revised myPlaybook modules and the new life skills module. Because we only recruited 42 schools, we used a fractional factorial design with $2^{4-1} = 8$ conditions (see Table 6) to allow us to assign at least one school from each NCAA division to each condition. We also did not collect any 30-day follow-up data because we planned to select which modules to include in the final myPlaybook intervention using only the effects at the immediate posttest. Excluding the 30-day follow-up allowed us to delay the start of Trial 3 by a month, giving us more time to create the new life skills module between Trials 2 and 3 while still completing Trial 3 before the end of the academic year.

Sample

We recruited 42 NCAA colleges and universities (n = 15 Division I, n = 17 Division II, and n = 10 Division III schools). Twenty-eight schools had participated in Trials 1 and 2, five schools had participated in Trial 2, and one school had participated in Trial 1 but not 2. We then invited all 4,411 eligible athletes to participate; as before, we targeted incoming athletes, so no athletes from Trial 1 or 2 were eligible for Trial 3. A total of N = 2,193 (85.9%) athletes completed the baseline and immediate posttest survey and constituted our analytic sample. See Table 6 for breakdown of recruitment and retention rates across conditions.

Measures

We used the same proximal outcome measures as the previous studies, with minor exceptions. We also included several items about using drugs to cope with stress to evaluate the life skills module. (See Supplemental Tables G-N for details).

Trial 3 RESULTS

We used the same analytic approach as Trials 1 and 2. Table 7 provides the main effects for each modules on the proximal outcomes (for full results, see Supplemental Tables E and F). The norms module reduced alcohol and marijuana descriptive and injunctive norms (all $d \ge .39$). The expectancies module reduced alcohol positive expectancies (d = .3) and increased marijuana negative expectancies (d = .16). The effect size for the harm prevention module and the life skills module were both d < .05. There was a small significant negative interaction between the norms and expectancies modules on intentions to use protective behavioral strategies (see Supplemental Table E). We did not focus on this interaction in our decision-making process, however, because this interaction may have been due to chance (it was the only significant interaction out of the 30 we tested) and because it was confounded with the interaction between the harm prevention and life skills modules due to our fractional factorial design.

	Received Module?ª			Schools Eligible students			Exclud	luded students ^b			Time 1 ^c		Time 2 ^d	
Cond.	INTRO	NORM	EXP	HARM	SKILL	N	N	С	D	Р	Ν	0∕0 ª	N	0⁄0 ^b
1	\checkmark				\checkmark	5	508	10	1	1	246	48.4	212	86.2
2	\checkmark			\checkmark		6	562	12	1	1	369	65.7	332	90.0
3	\checkmark		\checkmark			5	534	14	7	1	207	38.8	153	73.9
4	\checkmark		\checkmark	\checkmark	\checkmark	5	686	16	5	2	396	57.7	312	78.8
5	\checkmark	\checkmark				5	540	5	2	2	393	72.8	358	91.1
6	\checkmark	\checkmark		\checkmark	\checkmark	5	550	21	3	5	327	59.5	303	92.7
7	\checkmark	\checkmark	\checkmark		\checkmark	5	464	7	2	4	249	53.7	202	81.1
8	\checkmark	\checkmark	\checkmark	\checkmark		6	567	10	10	1	366	64.6	321	87.7
Total						42	4411				2553	57.9	2193	85.9

Table 6. Trial 3 description of conditions and participation rates by condition

^aIndicates whether student in a given condition received a particular module, with \checkmark = received the module (INFO = Informational module about drug testing and banned drugs; NORM = Peer norms; EXP = Expectancies about drug use; HARM = Harm prevention; SKILL = Life skills and coping).

^bReasons students were excluded: C = No Consent or reported that they were under age 18, D = Consented but did not provide any data, P = Patterns in their data (e.g., answering all 100+ non-demographic items with the same number).

^cpercent of eligible students.

^dpercent of time 1 students who completed time 2 (immediate posttest).

Table 7. Results from Trial 3

		No Module <u>a</u>	Module ^{<u>a</u>}	Difference	<i>p</i> -value	d	N
		Mean (95% CI)	Mean (95% CI)	Mean (95% CI)			
Descriptive norms	5						
Alcohol:	Immediate posttest	4.70 (4.56, 4.84)	2.76 (2.63, 2.90)	1.94 (1.74, 2.13)	<.0001	0.89	2151
Marijuana:	Immediate posttest	2.89 (2.79, 2.99)	1.83 (1.74, 1.93)	1.06 (0.92, 1.20)	<.0001	0.69	210
Injunctive norms							
Alcohol:	Immediate posttest	2.11 (2.06, 2.16)	1.64 (1.59, 1.69)	0.47 (0.39, 0.54)	<.0001	0.59	2146
Marijuana:	Immediate posttest	1.87 (1.83, 1.92)	1.59 (1.54, 1.63)	0.29 (0.23, 0.35)	<.0001	0.39	2095
Positive expectance	eies						
Alcohol:	Immediate posttest	2.77 (2.72, 2.82)	2.53 (2.47, 2.58)	0.24 (0.17, 0.32)	<.0001	0.3	2136
Marijuana:	Immediate posttest	2.11 (2.06, 2.15)	2.05 (2.00, 2.11)	0.05 (-0.02, 0.12)	0.14	0.07	2074
Negative expectan	cies						
Alcohol:	Immediate posttest	2.79 (2.72, 2.85)	2.85 (2.78, 2.92)	-0.07 (-0.16, 0.03)	0.16	0.06	2136
Marijuana:	Immediate posttest	2.49 (2.44, 2.55)	2.63 (2.57, 2.69)	-0.14 (-0.22, -0.06)	0.002	0.16	2071
Intentions to use p	orotective behavioral	strategies					
Alcohol:	Immediate posttest	3.75 (3.70, 3.80)	3.78 (3.72, 3.84)	-0.04 (-0.12, 0.04)	0.37	0.04	2130
Coping: Drug use							
	Immediate posttest	1.58 (1.53, 1.62)	1.56 (1.51, 1.60)	0.02 (-0.05, 0.08)	0.57	0.02	2082

Note: Each model included the corresponding baseline variable, and indicators for female sex, White race, Black race, first year student, and in-season. Models for alcohol-related outcomes adjusted for lifetime alcohol use and models for marijuana-related outcomes adjusted for lifetime marijuana use. Results for these parameters are not shown here.

^aModule refers to norms module for norms outcomes, expectancies module for expectancies outcomes, harm prevention module for intentions to use protective behavioral strategies, and the skills module for the coping outcome

Assembling the final myPlaybook intervention package

The goal of Trial 3 was to identify which modules to include in the final myPlaybook intervention package, which we planned to test with first year collegiate athletes in a subsequent RCT. Our optimization criterion—the largest effect size that we could achieve for each module after three rounds of testing and revision—indicated that we should include the strongest version of each module. We found the strongest effects from the norms and expectancies modules in Trial 3, so we decided to include these modules in the final myPlaybook intervention. By contrast, the harm prevention and life skills modules did not appear to be effective (d < .3), so we had to decide whether to retain these potentially ineffective modules or leave them out to keep the intervention shorter (i.e., more efficient). We believed that the harm prevention module might primarily affect use of protective behavioral strategies behaviors, which we did not measure. Given this concern, along with no evidence of iatrogenic effects on any proximal outcomes, we decided to include the harm prevention module. To keep myPlaybook as efficient as possible, however, we decided to exclude the life skills module from the final myPlaybook intervention package

Discussion

To address high rates of alcohol and marijuana use among collegiate athletes, we previously developed myPlaybook, a brief online drug use intervention [7]. The goal of this study was to optimize myPlaybook by iteratively strengthening, or optimizing, the individual modules. To achieve this goal, we used MOST, an innovative framework for optimizing interventions. By contrast, the standard approach to intervention development—initiating an RCT after obtaining promising pilot results—often leads to interventions that are not as effective or efficient as possible. Using MOST, we identified and revised modules with weak, albeit statistically significant, effects. Because we experimentally isolated the effects of each module, we also were able to identify ways to streamline the final myPlaybook intervention (e.g., structuring modules around proximal outcomes rather than individual drugs; removing a module with no significant effects).

This study demonstrates the benefits of using an iterative approach in the Optimization phase of MOST. We observed dramatic improvements in proximal outcomes across trials, particularly for norms. For example, the effect for alcohol descriptive norms at immediate posttest increased almost 6-fold from Trial 1 (d = .15) to Trial 3 (d = .89) and the effect size for marijuana descriptive norms increased almost 14-fold from Trial 1 (d = 0.05) to Trial 3 (d = .69). Although some improvements between trials might reflect item changes (see Supplemental Tables G-L), we observed the largest increases for descriptive norms, which had identical items across all trials, suggesting that these changes likely reflect changes to the modules across trials.

Notably, myPlaybook is one of only a few empirically tested interventions designed to meet the needs of collegiate athletes. To our knowledge, it is also the first to address marijuana use among this population. Importantly, we expect that our findings are generalizable to all NCAA athletes. Our sample included students from all three NCAA Divisions, and although we focused on first-year and transfer students, we expect that the proximal outcomes targeted by myPlaybook are important for all NCAA athletes. There were minor differences in our sample demographics compared to the demographics of all NCAA athletes—our sample included higher percentages of females (49–52% across trials) and white athletes (73–80%) compared to the general NCAA

student-athlete population (44% and 64% respectively; [24])—but we do not expect that these small differences affect the generalizability of our results.

Limitations

Our study had several limitations. First, after Trial 1, we used proximal outcomes, rather than drug use, to evaluate the myPlaybook modules. This decision was driven by our expectation that the individual proximal outcomes combine to reduce drug use, making it difficult to detect changes in use within the constraints of our study. These proximal outcomes are well-established predictors of drug use [16–20], but it will be critical to evaluate the effect of the final optimized myPlaybook intervention package on drug use in a future RCT. Second, baseline response rates ranged from 58 to 67%. These rates are relatively high for web-based surveys of college students, but non-response bias is possible. Third, all measures were self-reported. Given that we focused on proximal outcomes (e.g., social norms), rather than drug use, we expect that social desirability did not affect our responses. Finally, we did not test whether effects varied across individual (e.g., gender; season) or institutional (e.g., NCAA division) characteristics. We wanted to develop a brief universal intervention that could be delivered to all NCAA athletes, so we balanced these factors across conditions (i.e., we stratified by NCAA division and controlled for factors such as gender and in-season status). Still, future studies should test whether the effects of myPlaybook vary across groups, measure additional factors that can shape drug use and related norms (e.g., Greek life affiliation; school or sport program culture), and explore whether more intensive, indicated interventions are needed for athletes at the highest risk of drug use.

Conclusion

Using MOST, we iteratively strengthened multiple modules in a drug use intervention designed for collegiate athletes. After three optimization trials, two modules had meaningful effects on proximal outcomes, increasing the likelihood that the full myPlaybook intervention will have a meaningful clinical impact on drug use among collegiate athletes.

Supplementary Material

Supplementary material is available at Translational Behavioral Medicine online.

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Compliance with Ethical Standards

Conflicts of Interest: Dr. Wyrick is the President of Prevention Strategies, LLC which is the company licensed by the UNC Greensboro to manage the commercialization of myPlaybook, the intervention described in this study. Dr. Milroy has received money from Prevention Strategies, the company that manages myPlaybook as a contracted worker. All three authors received funding from NIDA to conduct the research for this paper. NIDA did not play any role in the study design, collection, analysis, or interpretation of the data. The authors used money from NIDA to present findings at scientific meetings. Dr. Rulison received money from Prevention Strategies to cover her time spent writing the manuscript after grant funding had finished.

Human Rights: 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. IRB protocol name: Drug and Alcohol Prevention for College Athletes, Phase II. Initial IRB approval: 3/29/2012 at the University of North Carolina Greensboro.

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

Welfare of Animals: This article does not contain any studies with animals performed by any of the authors.

Transparency Statements

Study registration. Trial 1 was registered after the study began. The study is registered at ClinicalTrials.gov, NCT04253158, at <a href="https://www.clinicaltrials.gov/ct2/show/NCT04253158?term=Implementation+of+a+Webbased+Alcohol+and+Other+Drug+Prevention+Intervention+for+Collegiate+Student-athletes&draw=2&rank=1. Trials 2 and 3 have not been formally registered.

Analytic plan pre-registration. The analysis plan was not formally pre-registered.

Data availability: De-identified data from this study are not available in an a public archive. Deidentified data from this study will be made available (as allowable according to institutional IRB standards) by emailing the corresponding author.

Analytic code availability. Analytic code used to conduct the analyses presented in this study are not available in a public archive. They may be available by emailing the corresponding author.

Materials availability. Materials used to conduct the study are not publicly available.

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