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Randomized Trial of First-Line Behavioral Intervention to Reduce Need for Medication in Children with ADHD

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A study conducted in an analogue summer treatment setting showed that when concurrently receiving behavioral intervention, many children with Attention-Deficit Hyperactivity Disorder (ADHD) did not need medication or maximized responsiveness at very low doses. The present study followed participants in that summer study into the subsequent school year to investigate whether the same pattern would extend to the natural school and home settings. There were 127 unmedicated children with ADHD between the ages of 5 and 13 who were randomly assigned to receive or not receive behavioral consultation (BC) at the start of the school year. Children were evaluated by teachers and parents each week to determine if central nervous system stimulant treatment was needed. Children who received BC were approximately half as likely those who did not (NoBC) to initiate medication use each week at school or home and used lower doses when medicated at school. This produced a 40% reduction in total methylphenidate exposure over the course of the school year. BC and NoBC groups did not significantly differ on end-of-year teacher or parent ratings of behavior, which were positive. Moreover, BC and NoBC groups did not significantly differ in cost of treatment; although children in the BC condition accrued additional costs via the BC, these costs were offset by the associated delay and reduction in medication use. Results add to a growing literature suggesting that the use of low-intensity behavioral intervention as a first-line treatment reduces or eliminates the need for medication in children with ADHD.

Attention-Deficit Hyperactivity Disorder (ADHD) is a chronic (Barkley, Murphy, & Fischer, 2008) and commonly diagnosed (Danielson, Visser, Chronis-Tuscano, & DuPaul, 2018) childhood behavior disorder. The core symptoms of inattention, hyperactivity, and impulsivity lead to a variety of impairments (Fabiano et al., 2006) and result in considerable costs across sectors (Pelham, Foster, & Robb, 2007). Thus, strategies to reduce or eliminate these problems are of prominent public health significance.

There are three well-accepted, evidence-based treatments for childhood ADHD: behavioral treatment, psychostimulant medication, and their combination (Subcommittee on ADHD, 2011). The most prominent study in the field—the Multimodal Treatment of ADHD (MTA) study—compared the effectiveness of these three treatments by randomizing a large sample of young elementary-age children to receive behavioral, pharmacological, or combined interventions in school and home settings over the course of 1 year (MTA Cooperative Group, 1999a, 1999b). Primary analysis of the initial results suggested that (a) medication produced larger improvements at school and home than behavioral intervention and (b) combining the two modalities was no better than medication alone.

However, the design of the MTA precluded consideration of two key treatment issues: dosing and sequencing (Pelham, 1999). These issues are important because of their potential impact on the efficacy, tolerability, and cost of treatment. In the MTA, only one high-intensity dose of each modality of treatment was examined, leaving it unknown whether children could have been successfully treated with less intensive behavioral treatment or lower doses of medication. The behavioral treatment package included 35 sessions of behavioral parent training (BPT), an intensive 8-week summer treatment program for the child, 14 sessions of teacher consultation, and a half-time aide in the child's classroom for a school semester.

Similarly, medication doses were adjusted upward to the maximum tolerable dose in both the combined and medication-only treatment groups. In the case of behavioral treatment, dosing considerations are important because more intensive treatment is more expensive and difficult to implement. In the case of medication, dosing considerations are important because stimulants confer dose-dependent side effects such as growth suppression (Cortese et al., 2013; Swanson, Arnold, Molina, & Sibley, 2017).

The second treatment issue is sequencing. Children in the MTA's combined intervention group started medication and behavioral treatment at the same time, precluding the opportunity to investigate whether starting treatment with the behavioral component could delay, reduce, or eliminate the need for medication. Children randomized to combined treatment were taking lower doses at endpoint than children randomized to medication-only treatment, which is suggestive of this possibility (Vitiello et al., 2001). Sequencing issues are important because although medication is typically employed as the first-line treatment in primary care settings (Epstein, Kelleher, Baum, Brinkman, & Langberg, 2014; Patel et al., 2017), medication-first treatment may undermine parent participation in concurrent behavioral interventions (Pelham et al., 2016).

To begin to address these issues, Pelham and colleagues (Fabiano et al., 2007; Pelham, Burrows-MacLean, Gnagy, Fabiano, & Waschbusch, 2014) conducted a within-subject study in an analogue summer camp research setting. Children concurrently received (a) different dosages of methylphenidate (MPH) varying on a daily schedule crossed with (b) different intensities of behavior modification varying in 3-week blocks in a counterbalanced order. This design evaluated the independent and combined acute effects of the varying doses of the two treatment modalities. Results showed that low-intensity behavior modification (similar to standard behavior modification used in schools) and low-dose MPH (i.e., 0.15 mg/kg three times per day [*t.i.d.*]) both produced meaningful effects when used independently. Furthermore, when low doses of both modalities were used simultaneously, effects were comparable to those obtained when a high dose of either treatment modality was used independently. Finally, when high-intensity behavior modification and high-dose MPH (0.60 mg/kg *t.i.d.*) were used simultaneously, there was little incremental benefit beyond the use of just one of these two components and the rate of adverse events increased. Together, results showed that doses of medication and behavioral treatment that were much lower than those employed in prominent ADHD intervention studies (e.g., MTA Cooperative Group, 1999a; Wolraich et al., 2001) can be effective, particularly when combined. However, these studies did not address treatment sequencing and were conducted in an analogue summer research setting, begging extension to regular school and home settings.

A more recent study (Pelham et al., 2016) investigated treatment dosing and sequencing effects in regular school and home settings. Children were randomized to start the school year receiving either low-dose medication (0.15 mg/kg twice daily [*b.i.d.*]) or low-intensity behavioral treatment and could receive either dose escalations or multimodal treatment in the event that teachers or parents indicated need for more treatment. One third of the children who began treatment with low-intensity behavioral treatment did not require further treatment (medication or otherwise) at any point in the school year. Children who started with behavioral treatment also finished the year on lower doses of medication than children who started with pharmacological treatment. Thus, this study showed that when low-dose behavioral treatment is provided as the first line of treatment, need for medication can be reduced and in many cases eliminated. However, it did not evaluate whether initial higher-dose behavioral treatment would further reduce the need for medication.

Dosing and sequencing may also have large impact on the financial cost of treatment. The MTA analyzed cost of treatment and found that high-intensity behavioral treatment was much more expensive than medication (Foster et al., 2007; Jensen et al., 2005). In contrast, the trial of low-dose treatment just described (Pelham et al., 2016) found that treatment strategies beginning with low-intensity behavioral treatment were *less* costly than those beginning with medication (Page et al., 2016). The discrepancy between these findings highlight the importance of examining cost of treatment as an outcome in studies that evaluate dosing and sequencing factors.

Finally, the current National Institutes of Health emphasis on personalized medicine (Agyeman & Ofori-Asenso, 2015) highlights the need for investigation of individual differences in response to these interventions. In the literature on treatment of ADHD, it has been common to evaluate the impact of two major variables—the child's comorbid externalizing disorders (Oppositional Defiant Disorder [ODD] and Conduct Disorder [CD]) and the parents' socioeconomic status (MTA Cooperative Group, 1999b). Due to the prevalence of medication treatment for ADHD, it has also been common to evaluate the impact of history of stimulant treatment on response to intervention. Finally, given that current treatment guidelines recommend different treatment protocols for different age groups (e.g., Subcommittee on ADHD, 2011), it is important to evaluate how age affects response to intervention.

Current Study

The current study seeks to replicate and extend the work just described by investigating whether low or high doses of first-line behavioral consultation (BC) can delay, reduce, or eliminate the need for medication. Children who participated in the analogue Summer Research Program dosing study (Fabiano et al., 2007; Pelham et al., 2014) just described, which tested acute effects of medication and

behavioral treatment over a few days per condition, were invited to participate in a follow-up study over the full duration of the subsequent school year. Thus, the follow-up investigated whether the same patterns observed in the summer study would extend to the natural school and home settings over 1 year of treatment. At the start of the school year, participants were randomized to the following conditions: no behavioral consultation (NoBC), low-intensity behavioral consultation (LBC), or high-intensity behavioral consultation (HBC). Functioning at school and home was monitored weekly, and stimulant medication was initiated only when weekly teacher or parent ratings indicated additional intervention was necessary. The current study is thus a randomized trial evaluating the effects of providing BC as a first-line school-year treatment on (a) the need for and use of medication, (b) symptomatology at end point, and (c) cost of treatment.

METHOD

Sample

Participants were children 5–13 years of age who were diagnosed with ADHD per *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; American Psychiatric Association, 1994) criteria. To make the diagnosis, a Ph.D.-level clinician conducted a semi-structured interview with parents and reviewed symptom rating and impairment scales (Disruptive Behavior Disorders Rating Scale: Pelham, Gnagy, Greenslade, & Milich, 1992; Impairment Rating Scale: Fabiano et al., 2006) completed by parents and teachers. This study was a school-year follow-up to a within-subject crossover study of the acute effects of varying doses of behavioral, medication, and combined treatments conducted in a 9-week Summer Research Program. During the prior spring, parents completed an 8-week course of large-group BPT (Cunningham, Bremner, & Boyle, 1995). Then, in the summer, children were exposed to 3-week (15-day) blocks of no, low-, and high-intensity behavioral treatment, crossed with MPH (placebo, 0.15 mg/kg, 0.30 mg/kg, and 0.60 mg/kg *t.i.d.*) varying randomly on a daily basis across the blocks (see Fabiano et al., 2007; Pelham et al., 2014, for details). At the end of the summer, all families ($N = 152$) were invited to participate in a school year follow-up.

Participant flow is shown in Figure S1. One hundred sixteen of the 152 families (76%) who participated in the summer study participated in the follow-up protocol. Children in the participating families had lower estimated full-scale IQ (Ms = 103.5 vs. 110.3, $p < .05$) and were less likely to have been previously medicated (78% vs. 97%, $p < .05$) but did not significantly differ from those in nonparticipating families on parent or teacher ratings of ADHD, ODD, CD, or impairment.

Of the participating children, 84% were male, 79% were Caucasian, and 13% were African American. Mean child age was 9.3 years ($SD = 2.0$), and 46% of families had at least one caregiver with a 4-year college degree or higher. An additional 11 families were randomized to treatment conditions but initiated medication prior to the start of the school year or provision of any treatment (Figure S1). These families were excluded from analyses.

Procedures

At the start of the school year, families were randomly assigned to one of three follow-up strategies with equal probability: (a) HBC ($n = 43$), (b) LBC ($n = 42$), and (c) NoBC ($n = 42$). Table 1 provides an overview of the treatment provided in each condition.

School-Based Interventions

In both the HBC and LBC groups, a clinician worked with the child's teacher to establish a classroom behavioral program. All programs included a daily report card (DRC; Pyle & Fabiano, 2017) with individualized home-based rewards and targets based on the child's needs. During the first weeks of the school year, a clinician met with the child's teacher three times to design and implement the DRC in both HBC and LBC groups. If the teacher subsequently indicated that the child required additional treatment, clinicians conducted further consultation visits, up to a maximum of three visits in the LBC group and nine visits in the HBC group. For those in the LBC group, additional visits were used to tailor the DRC. For those in the HBC group, additional visits could also include the implementation of more intensive classroom interventions, such as school-based rewards, response-cost systems, point systems, escalating–deescalating time out procedures, and additional individualized behavioral interventions. Requests for additional consultations and interventions always had to be initiated by the teacher. Finally, the NoBC group began the school year without a study intervention. Teachers could use any classroom management procedures they typically implemented, but they received no assistance or consultation from study staff.

Parent Interventions

Because all parents had completed group BPT in the spring prior to the summer study (Pelham et al., 2014), parent interventions took a maintenance approach (cf. teacher interventions, which were newly established in the follow-up). Parents in the HBC and LBC conditions received an initial meeting with a clinician to establish a home-based DRC for the school year (Table 1). In addition, parents could receive up to three (LBC) or eight (HBC) more individual sessions, during which

TABLE 1
Intervention Components Per Study Design

		Yes Behavioral Consultation	
Setting	*No Behavioral Consultation*	*Low-Intensity*	*High-Intensity*
School	• No study intervention; teacher was free to use any classroom management procedures in place	• Three initial teacher visits to set up DRC with home-based rewards • "Bank" of 3 additional consultation visits throughout year	• Three initial teacher visits to set up DRC with home-based rewards • "Bank" of 9 additional consultation visits throughout year • Access to consultation on school-based rewards, response-cost systems, point systems, escalating-deescalating time out, and further individualized treatment components
Home	• No study intervention; parents were permitted to implement self-guided behavior management procedures	• One initial home visit to establish a home-based DRC • "Bank" of 3 additional consultation visits throughout year • Option to attend monthly group parent training booster sessions	• One initial home visit to establish a home-based DRC • "Bank" of 8 additional consultation visits throughout year • Option to attend monthly group parent training booster sessions

Note: The listed components represent the "menu" of available services, rather than those actually received. Contrary to initial design, the low-intensity and high-intensity conditions received equivalent services—these groups were collapsed for all analyses (see Methods section). Note that all parents had received eight sessions of large-group behavioral parent training during the summer study, prior to randomization to these conditions (see Methods section). DRC = Daily Report Card.

they could discuss difficult parenting situations and home interventions as they arose. As was the case with teachers, the optional sessions were always initiated by parents. Parents in the BC groups were also offered monthly group BPT booster sessions throughout the school year. All parents were free to implement any behavioral procedures that they typically used (e.g., time out, home-based rewards) and could consult with the teacher on their own.

Weekly Monitoring Procedures

Parents and teachers completed weekly ratings of children's behavior using a modified version of the Impairment Rating Scale (Fabiano et al., 2006). Each Friday, parents and teachers were contacted by phone or fax and asked to rate the child's impairment and need for additional treatment, *given the interventions that were currently in place*. Need for additional treatment was rated on a scale of *definitely not, probably not, maybe, probably yes*, and *definitely yes*.

Determining the Need for Medication

Each week, study staff reviewed the parent and teacher ratings. If a rater indicated that the child probably or definitely needed additional treatment, clinician contacted the rater immediately to discuss the rater's suggestion for additional treatment.

In the HBC and LBC groups, an additional consultation visit for teacher or parent was scheduled immediately if the rater indicated that a change to the behavioral system was needed. After this visit, if a child received two additional consecutive weekly ratings indicating continued impairment, a school-based medication assessment was initiated. In the NoBC condition, three consecutive weekly ratings indicating need for additional treatment were required to initiate a medication assessment. This requirement ensured that the same number of consecutive weekly ratings indicating continued impairment (i.e., three) was needed to initiate medication in all conditions. Additional medication was always initiated for the school setting first; home-based medication was considered if subsequent parent ratings indicted continued impairment.

Medication Initiation and Monitoring

Once a child in any condition met criteria to initiate medication, the study team implemented a school-based, double-blind, within-subject evaluation of the same doses of immediate-release MPH used in the summer study (i.e., placebo, 0.15, 0.30, and 0.60 mg/kg MPH) with all doses given *b.i.d*. Assessments were conducted over a 3- to 5-week period on school days only. Doses were randomized by day (Pelham et al., 2002). If parents indicated a need for home-based medication, the same procedure was used. At home, medication doses of immediate-release MPH were administered at 3:30 p.m. on school days and morning, noon, and 3:30 p.m. on weekends. During the medication assessment, daily behavior and side-effect ratings, as well as records of meeting or failing to meet individualized behavior goals, were collected from parents and teachers (Pelham et al., 2002). Following the medication assessment, the clinical team (clinicians, M.D. and Ph.

D. supervisors, and the research coordinator) evaluated the results and recommended the dose that produced maximum benefit in the area of impairment with minimal side effects. If children started medication following a medication assessment, study staff continued to monitor the weekly ratings. Medication dosage was allowed to increase following 2 consecutive weeks of ratings indicating continued impairment. Study physicians conducted monthly medication maintenance visits and medical monitoring for children who began medication.

Preventing Attrition

Given that a major goal of this study was to follow up children for an entire school year, every effort was made to prevent participant dropout. Toward that end, participants were retained in the study even if they deviated from the treatment protocol by initiating or changing medication treatment outside of the protocol. A total of 26 families deviated from the medication protocol. Twenty-one families started medication before the preceding criteria were met, two families were unsatisfied with the results of the medication assessment and elected to take formulations or doses of stimulant medication that differed from those recommended within the protocol, one family wanted an immediate dose escalation, one family could not follow protocol because of teacher noncompliance in conducting a medication assessment, and one child was hospitalized because of severe aggression and medicated by the hospital psychiatrist. These families were retained in the study, and detailed information about their medication use was collected from these parents and included in analyses of medication use.

Measures

Previous Use of Medication

At intake, parents reported whether the child had been taking ADHD medication at school and/or at home during the *prior* school year (note that all participants received medication during the summer study). This report was used to create two binary indicators (no vs. yes) of previous use of medication at school and at home.

Child Age

The child's age in years was computed at the beginning of the school year.

Parent Education

Parent education was defined as the highest level of education attained by either parent. Values ranged from 1 to 7, coded as follows: less than seventh grade (1), seventh to ninth grade (2), high school without graduation (3), high school graduate (4), partial college or specialized training (5), 4-year college or university (6), or graduate/professional training (7).

Teacher- and Parent-Rated ODD/CD Symptoms

Comorbid ODD and CD symptoms were assessed using the Disruptive Behavior Disorders Rating Scale (Pelham et al., 1992) and used as predictors of need for medication during the school year. Symptoms of ODD and CD were rated by parents and teachers prior to the summer study using a 0 (*not at all*) to 3 (*very much*) Likert scale. The mean score was then calculated across the ODD and CD items to yield a teacher-rated and a parent-rated ODD/CD symptom score with acceptable reliability and validity (Pelham et al., 1992).

Medication Use

A variable was created indicating the length of time, measured in weeks, between the beginning of the school year and the initiation of medication treatment for each child. This variable was created separately for the school and home settings. Medication dosage was recorded for each week based on records of that prescribed by study physicians (for those on-protocol) or parent report (for those off-protocol). All dosages were standardized to the metric of immediate-release MPH. For each child, total MPH intake was calculated by summing weekly MPH intake across the full school year.

End-of-Year Symptom Ratings

Parents and teachers completed IOWA Conners Rating Scales (Pelham, Milich, Murphy, & Murphy, 1989; Waschbusch & Willoughby, 2008) at the end of the school year. The IOWA consists of 10 items rated on Likert scales that range from 0 (*not at all*) to 3 (*very much*), including five items that are summed to compute an inattentive/overactive scale and five items that are summed to compute an oppositional-defiant scale. These scores have acceptable reliability and validity (Pelham et al., 1989).

Cost of Treatment

To analyze the cost of treatment, resources expended were determined from records of medication initiation and dose titration, as well as records of the number of school visits, home visits, and BPT sessions received. The duration of these visits was operationalized using published data on nearly identical treatment procedures (Page et al., 2016) as follows: school visit (29 min), individual BPT session (45 min), physician visit (17 min), and group BPT booster session (97 min). Because BPT booster sessions entailed one clinician providing treatment to a group of families, the clinician time spent on these sessions was divided by the

median number of families in attendance at these sessions per study records (i.e., eight families per session).

Analytic Plan

Collapsing the LBC and HBC groups

Contrary to our initial study design, parents and teachers assigned to the HBC condition did not use the high dose of behavioral treatment to which they had access—the LBC and HBC conditions received equivalent number of therapeutic contacts (all subsequent values based on $N = 116$). Those families assigned to LBC used a mean of 3.4 school visits ($SD = 1.6$, range = 0–6), compared to 4.0 for those families assigned to HBC ($SD = 1.6$, range = 1–9). Those in the LBC condition used a mean of 0.9 individual parenting sessions ($SD = 0.9$, range = 0–3), compared to 1.3 for those in the HBC condition ($SD = 2.4$, range = 0–9). Finally, those in LBC attended an average of 2.9 booster group parent-training sessions ($SD = 3.1$, range = 0–9), compared to 2.6 for those in the HBC condition ($SD = 2.6$, range = 0–8). In other words, there was functionally no difference between the low-dose and high-dose BC conditions. Thus, for all of the subsequent analyses, these two groups were combined, and we compared BC to NoBC.

We compared the BC and NoBC groups at baseline to verify the demographic and behavioral equivalency of these new unequally sized groups (Table S1). The two groups differed substantially on both history of medication in school (58% vs. 81%, respectively) and history of medication at home (33% vs. 44%), two variables that were expected to be highly prognostic of outcomes in the current design. Thus, these variables were included as covariates in all analyses comparing the NoBC and BC groups.

Handling of Missing Data

Data were nearly complete for medication use outcomes (≥ 97% of values present), cost of treatment outcomes (≥ 98%), and covariates (≥ 98%). There were more missing data for end-of-year teacher (73% present) and parent ratings (84% present). We used multiple imputation by chained equations (White, Royston, & Wood, 2011) to address missing data. See supplement for details.

Survival Analyses

The number of weeks until initiation of medication (i.e., survival unmedicated) was modeled using Cox proportional hazards regression (Cox, 1972). The proportional hazards assumption, which states that the effect of each predictor on that hazard rate is constant over time, was tested using the method of Lin, Wei, and Ying (1993); see supplement for details. Survival unmedicated was modeled in the school and home settings separately, and covariates were entered in sets to examine their explanatory power incrementally. Model 1 included baseline characteristics potentially related to survival of medication: age, parental education, and teacher or parent rated ODD/CD symptoms (depending on setting). Model 2 added a binary indicator of previous use of medication in the setting being modeled (home or school), with the expectation that this might be related to the likelihood of returning to medication. Finally, Model 3 added an indicator of intervention group (NoBC vs. BC) to examine whether receipt of BC prolonged survival off medication.

End-of-year Outcomes

Next, we compared the means of the NoBC and yes behavioral consultation (YesBC) groups on a series of end-of-school-year outcomes. For each outcome, we regressed the outcome variable on a dummy variable indicating membership in the treatment group (i.e., YesBC vs. NoBC). The statistical significance of the coefficient on this dummy variable then indicated the significance of the effect of BC on that outcome. Teacher and parent ratings were modeled using ordinary least squares regression, as were medication dosages. Medication status was binary and thus was modeled using logistic regression.

Cost of Treatment

Finally, we analyzed cost of treatment using the procedures described in Page et al. (2016). The following resources were considered: medication used, physician time, clinician time, paraprofessional time, teacher time, and parent time. Although parents were not paid as a part of treatment, their participation in treatment (e.g., attending BPT) implies a loss of leisure time that we considered an "implicit" cost, valued based on their hourly wage. Time (i.e., personnel) resources were converted into costs using national wage estimates from the Bureau of Labor Statistics (U.S. Department of Labor, 2011, 2013). Medication resources were converted into costs using medication reimbursement rates from the New York State Medicaid database (NYS Department of Health, 2013). See supplement for wages and medication prices.

The total cost of treatment was computed by summing the various cost components. Because the study was conducted using immediate-release medication formulations that are no longer routinely employed (Scheffler, Hinshaw, Modrek, & Levine, 2007), costs were recomputed using the prices of equivalent extended-release formulations (e.g., *b.i.d.* Ritalin IR was converted to Metadate ER; *t.i.d.* Ritalin IR was converted to Ritalin XR). Thus, the immediate-release results address the cost of the treatment as delivered in the study, and the extended-release results address what the cost of that same treatment would be if delivered today. Moreover, to examine cost from both societal and payer perspectives (Drummond, O'Brien, Stoddard, & Torrance, 2005), total treatment costs were computed both including and excluding implicit time cost

to parents (e.g., for attending BPT sessions). We used the same procedure just described for end-of-year outcomes (i.e., regression analysis) to evaluate whether the mean cost of treatment per child differed in the NoBC and YesBC groups.

RESULTS

School Setting Outcomes

Survival Unmedicated

Supremum tests for all covariates were not statistically significant ($p > .05$), suggesting the proportional hazards assumption was reasonable. Likelihood ratio tests indicated that the *newly* added predictors did not significantly improve prediction of survival unmedicated in Model 1 (i.e., including baseline covariates only), $\chi^2(3) = 5.95$, *ns*, but did significantly improve prediction in Model 2 (i.e., including previous medication), $\chi^2(1) = 5.80$, $p < .05$, and Model 3 (i.e., including treatment condition), $\chi^2(2) = 6.44$, $p < .05$.

Table 2 indicates the relationship of predictors to the hazard function across the three models. Estimates were generally consistent across the three models, so we discuss the values from the most inclusive final model. Effects are presented as hazard ratios, or the ratio of two rates of occurrence of an event (here, initiation of medication), adjusting for the other predictors in the model. The hazard ratio of the treatment group dummy variable was 0.53, indicating those in the BC condition were about half (53%) as likely as those in the NoBC condition to initiate medication each week (Figure 1, Panel A). Children who were previously medicated at school were 2.65 times more likely to start medication each week (Figure 1, Panel C). Increased age was associated with *reduced* probability of medication initiation: For each additional year in age, the child was 13% less likely to initiate medication each week. Parental education, previous medication use at home, and teacher-rated ODD/CD symptoms were not significantly predictive of survival unmedicated at school. The model-estimated median survival times were 5 weeks for the NoBC group and 18 weeks for the BC group, indicating the time points at which 50% of each group is expected to have initiated medication.

TABLE 2
Cox Regression Analysis of Survival Unmedicated

		Model 1		*Model 2*		*Model 3*	
Dependent Variable	*Predictor*	*Hazard Ratio*	*95% C.L.*	*Hazard Ratio*	*95% C.L.*	*Hazard Ratio*	*95% C.L.*
Survival unmedicated in school setting	Child age in years	0.92	[0.82, 1.03]	0.88	[0.78, 0.99]	0.87	[0.76, 0.98]
	Parental education	0.93	[0.76, 1.15]	1.00	[0.81, 1.24]	0.99	[0.80, 1.23]
	Teacher-rated ODD/CD symptoms	1.39	[0.98, 1.98]	1.20	[0.83, 1.74]	1.06	[0.73, 1.54]
	Previously medicated at school	-	-	1.95	[1.12, 3.41]	2.65	[1.37, 5.13]
	Previously medicated at home	-	-	-	-	0.93	[0.56, 1.54]
	Received behavioral consultation	-	-	-	-	0.53	[0.33, 0.86]
Survival unmedicated in home setting	Child age in years	0.97	[0.86, 1.09]	0.92	[0.81, 1.04]	0.90	[0.79, 1.03]
	Parental education	0.88	[0.70, 1.1]	0.87	[0.69, 1.09]	0.83	[0.65, 1.06]
	Parent-rated ODD/CD symptoms	1.58	[0.86, 2.91]	1.33	[0.70, 2.53]	1.37	[0.71, 2.66]
	Previously medicated at home	-	-	1.98	[1.14, 3.41]	2.22	[1.20, 4.13]
	Previously medicated at school	-	-	-	-	1.21	[0.59, 2.48]
	Received behavioral consultation	-	-	-	-	0.43	[0.26, 0.73]

Note: ODD = Oppositional Defiant Disorder, CD = Conduct Disorder. Hazard ratios for which the confidence interval does not include the value of 1 are statistically significant at $\alpha = .05$.

End-of-year Outcomes

Table 3 reports end-of-year outcomes in the school setting. Eighty-one percent of the NoBC group was medicated at endpoint compared to 63% of the BC group (*ns*). Among those children medicated at school, those in the BC group were taking lower doses than those in the NoBC group (0.32 mg/kg vs. 0.41 mg/kg, $p < .10$). The NoBC and BC groups did not differ

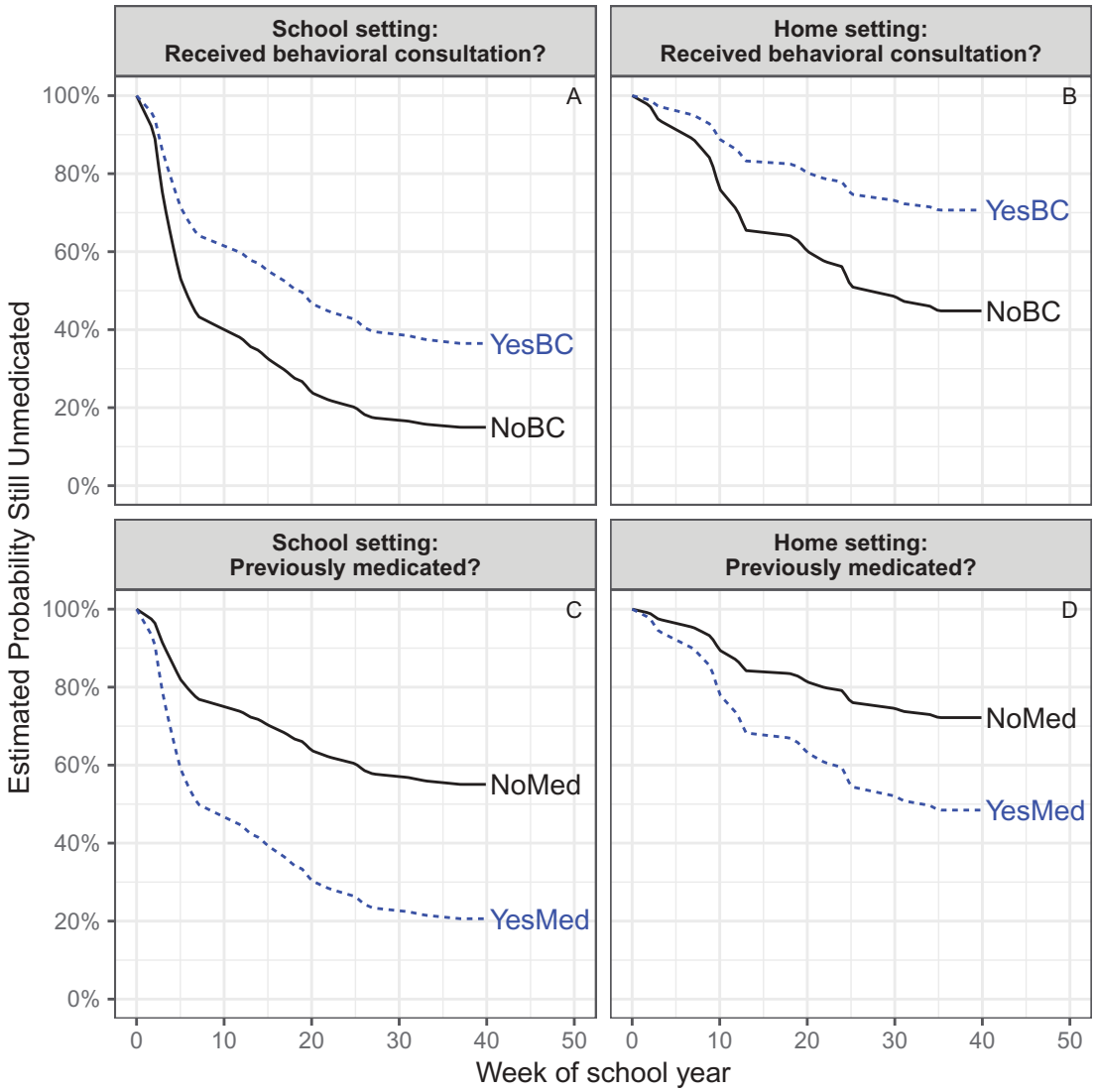

FIGURE 1 Survival unmedicated at school and home. *Note*: Curves indicate the estimated survival probability over time for participants in the labeled group (based on Model 3 in Table 2; all covariates fixed at sample mean). NoBC = no behavioral consultation; YesBC = yes behavioral consultation; NoMed = not previously medicated; YesMed = yes previously medicated.

significantly on teacher ratings of inattention/overactivity or oppositionality/defiance (*ns*).

Home Setting Outcomes

Survival Unmedicated

Supremum tests for all covariates were not statistically significant ($p > .05$), suggesting that the proportional hazards assumption was reasonable. Likelihood ratio tests indicated that the *newly* added predictors did not significantly improve prediction of survival unmedicated in Model 1, $\chi^2(3) = 3.91$, *ns*, but did significantly improve prediction in Model 2, $\chi^2(1) = 5.78$, $p < .05$, and Model 3, $\chi^2(2) = 9.56$, $p < .01$.

Table 2 indicates the relationship of predictors to the hazard function across the three models. Again, estimates were generally consistent across the three models, so we discuss the values from the final model, with hazard ratios adjusted for the other predictors. The hazard ratio of the treatment group dummy variable was 0.43, indicating those in the BC condition were only 43% as likely to start medication each week (Figure 1, Panel B). Previous use of medication at home was also predictive of survival: Those that had been previously medicated at home were 2.22 times more likely to start medication each week (Figure 1, Panel D). Age, parental education, and parent-rated ODD/CD symptoms were not significantly predictive.

TABLE 3
End-of-School-Year Outcomes

Variable	*No Behavioral Consultation*	*Yes Behavioral Consultation*	*Effect Size*	*Stat. Sig.*
Taking Medication at School	81% [64, 91]	63% [45, 78]	OR = 0.44 RR = 0.88	
Taking Medication at Home	63% [45, 78]	26% [17, 38]	OR = 0.21 RR = 0.50	**
For Those Medicated at School, Mean School Dose IR MPH (mg/kg/dose *b.i.d.*)	0.41 [0.33, 0.48]	0.32 [0.26, 0.37]	—	†
For Those Medicated in Evening, Mean Evening Dose IR MPH (mg/kg/dose *q.d.*)	0.31 [0.23, 0.39]	0.28 [0.21, 0.35]	—	
For Those Medicated on Weekend, Mean Weekend Dose IR MPH (mg/kg/dose *b.i.d.*)	0.37 [0.26, 0.47]	0.30 [0.21, 0.40]	—	
Total Methylphenidate Intake Over Full Year (mg)	4263 [3228, 5299]	2443 [1762, 3124]	—	**
Teacher Iowa Conners Sum Score Inattention/Overactivity	5.5 [4.2, 6.8]	6.9 [6.0, 7.9]	d = −0.41	
Teacher Iowa Conners Sum Score Oppositional/Defiant	3.5 [1.9, 5.0]	3.7 [2.6, 4.7]	d = −0.04	
Parent Iowa Conners Sum Score Inattention/Overactivity	8.3 [7.3, 9.3]	7.4 [6.7, 8.1]	d = +0.34	
Parent Iowa Conners Sum Score Oppositional/Defiant	7.0 [5.6, 8.5]	5.7 [4.7, 6.7]	d = +0.32	

Note: Values in second and third columns are pooled, least-square means, adjusting for previous use of medication at school and home, with numbers in brackets indicating 95% confidence intervals about these means. *d* is Cohen's *D*, calculated here as the difference between the least squares means over the sample-wide pooled standard deviation (positive sign indicates an advantage of Yes behavioral consultation). The Stat. Sig. column indicates statistical significance of the comparison of those assigned to behavioral consultation vs. no behavioral consultation. *OR* = odds ratio; RR = relative risk; IR = instant release formulations; MPH = methylphenidate; *b.i.d.* = twice daily; *q.d.* = every day.

†$p < .10$. *$p < .05$. **$p < .01$.

End-of Year Outcomes

Table 3 reports end-of-year outcomes in the home setting. Sixty-three percent of the NoBC group was medicated at endpoint compared to 26% of the BC group ($p < .01$). Among those children medicated at home, doses in the evenings and weekend did not significantly differ between the NoBC and BC groups (*ns*). The NoBC and BC groups did not differ significantly on parent ratings of inattention/overactivity or oppositionality/defiance (*ns*).

Total Methylphenidate Intake

Over the full duration of the school year, children in the NoBC group consumed 75% more MPH than children the BC group (*M* exposure = 4,263 mg vs. 2,443 mg, $p < .01$).

Cost of Treatment Outcomes

The results of the cost analysis are presented in Figure 2. Expenses for medication and physician time were greater in the NoBC group (*p*s < .05), whereas expenses for clinician, paraprofessional, teacher, and parent time were greater in the BC group (*p*s < .05). When the prices of generic, immediate-release medication formulations were used, the total treatment cost of the NoBC group was significantly lower whether parent implicit time costs were included (*p*s < .05). However, when the prices of current extended-release formulations were used, the NoBC and BC groups did not significantly differ in cost of treatment (*ns*).

DISCUSSION

The current study was a randomized trial evaluating the effects of providing BC as a first-line school-year treatment on (a) the need for and use of medication, (b) symptomatology at end point, and (c) cost of treatment. Participating families had previously completed an eight-session large-group parenting program, so consultation in the home setting was effectively booster treatment that extended this prior exposure. BC provided to teachers and parents at the start of the school year delayed the use of medication at school and at home, reduced the dose taken by those medicated at school, and reduced the prevalence of use at home, altogether substantially reducing cumulative exposure to MPH. These reductions in medication

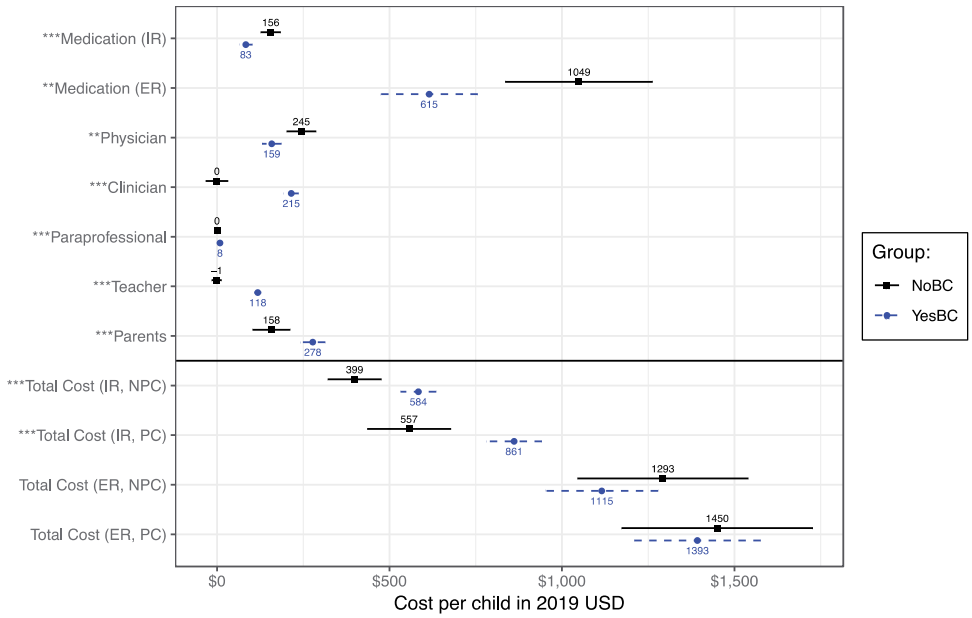

FIGURE 2 Cost of treatment per child. *Note*: Points are pooled, least-squares means, adjusting for previous use of medication at school and home, with error bars brackets indicating 95% confidence intervals about these means. See Table S2 in supplementary material for exact values. NoBC = no behavioral consultation; YesBC = yes behavioral consultation; IR = assuming instant release formulations; ER = assuming extended release formulations; NPC = no implicit parent time costs; PC = with implicit parent time costs.
*$p < .05$. **$p < .01$. ***$p < .001$.

use were achieved without exacerbating ADHD/ODD symptoms at endpoint and without increasing the overall cost of treatment. Thus, results add to a growing literature suggesting that providing first-line behavioral treatment (without medication) is an effective intervention strategy for many children with ADHD (Macphee, Altszuler, Merrill, & Pelham, 2017).

Impact of First-Line BC on Need for Medication, Dosing of Medication, and Behavioral Functioning

Children assigned to BC procedures were maintained substantially longer in the school year before needing adjunctive medication at both school and home (Figure 1). Reductions in need for medication were particularly great in the home setting, where many children did not initiate medication at any point—their parents never indicated need for additional treatment after the initial BC sessions. This finding suggests that the widely adopted practice of extended-release, 7-days-per-week dosing regimens (AACAP, 2007; Subcommittee on ADHD, 2011) that cover evening/home hours confer extra exposure to MPH that may be unnecessary for many children if BPT is provided before medication. It may also be ineffective for key home goals; for example, Merrill et al. (2017) found no benefit of extended-release medication (OROS methylphenidate) beyond and in comparison to behavioral interventions in improving children's performance on evening homework. Thus, prescribing an 8-hr (vs. 12-hr) formulation may be a more appropriate medication treatment for families presenting with school-related concerns.

Given the delay and in some cases elimination of medication use, children in the BC group were exposed on average to 1,820 fewer total mg of MPH over the school year, a reduction of more than 40%. Because greater medication exposure at present predicts greater medication exposure in the future (Swanson et al., 2017), the difference in total exposure observed in this 1-year follow-up might have continued to grow in the years after the trial ended. Exposure reductions of this magnitude continued over the course of childhood and adolescence are associated with taller adult heights (vs. stimulant-induced growth suppression) and no difference in children's functional outcomes (Swanson et al., 2017).

In addition, children in both conditions exhibited reduced ADHD and oppositional/defiant symptomatology relative to baseline (see supplement). Reductions were comparable to those found in prior studies of behavioral treatments (e.g., MTA Cooperative Group, 1999a; Pelham et al., 2016). Thus, the BC was effective on typical outcome measures used in ADHD studies, and the reductions in concurrent medication use and dose did *not* result in worse symptoms in the treated children. Taken together, results of this follow-up replicate and extend the findings of the summer analogue study (Fabiano et al., 2007; Pelham et al., 2014) and other recent work (Altszuler et al., 2019; Merrill et al., 2017; Pelham, Burrows-

MacLean, Gnagy, Fabiano, & Hoffman, 2005; Pelham et al., 2016) in showing that low-intensity behavioral treatment reduces need for and dose of medication in typical school, home, and peer settings.

Dose of Behavioral Consultation

Contrary to our planned design, we were unable to compare the effects of LBC versus HBC on need for medication, as was done in the summer portion of the study (Fabiano et al., 2007; Pelham et al., 2014). In the current, less controlled setting, parents and teachers in the low- and high-dose behavioral conditions *both* selected low doses (i.e., few sessions with clinicians). Several factors may have contributed to this pattern. First, all teachers reported using various forms of behavioral classroom management regardless of assigned condition and thus may have thought it unnecessary to ask for additional help. Similarly, all parents had previously received group BPT during the spring and thus may have felt that booster sessions were unnecessary. Second, parents and teachers may have preferred to initiate or escalate medication treatment (by reporting residual impairment) rather than implement the more difficult or time-intensive behavioral strategies. Parents may have viewed the offered high-intensity behavioral parent consultation as too burdensome or unrealistic (Eyberg, Boggs, & Jaccard, 2014; Eyberg, Nelson, & Boggs, 2008; Kolko & Lindhiem, 2014). Indeed, studies that query parents and teachers find that many express a preference for consultation/therapy interventions that are less intensive than traditional full-program approaches (Wymbs et al., 2016; Wymbs et al., 2017). Our findings document parents' and teachers' manifest choice of lower doses of BC in this context; add to the literature documenting effectiveness of low doses; and underscore the need for novel delivery methods (e.g., mobile applications, telehealth models) that can make these services more palatable for parents and teachers and widely used in regular home and school settings (Kazdin, 2019).

Predictors of Survival Unmedicated

We also considered individual differences by evaluating several factors as predictors of the length of time before medication was needed. The only child characteristic that predicted time until medication use was child age (Table 2); older children went longer into the school year before requiring medication. This finding may reflect the fact that older (vs. younger) children with ADHD showed less disruptive classroom behavior and thus were less likely to be rated by their teachers as in need of more treatment. Comorbid ODD/CD was not predictive of time until medication initiation, consistent with existing literature suggesting that response to behavioral, pharmacological, and combined treatment is similar in ADHD children with and without comorbid externalizing problems (Evans, Owens, Wymbs, & Ray, 2018; Fabiano et al., 2009; MTA Cooperative Group, 1999b). Neither was parental education predictive of survival unmedicated.

Previous use of medication was a powerful predictor of survival unmedicated. Children who had been previously medicated were more than twice as likely to initiate medication each week, with history of medication use at school as most predictive of initiation at school and history of medication use at home as most predictive of initiation at home. This effect could not be explained by previously medicated children exhibiting more severe symptoms (e.g., ODD/CD comorbidity), because previous use of medication was uncorrelated with baseline teacher and parent ratings (all rs < .10). Rather, we suspect that teachers' and parents' ratings of need for additional treatment were influenced by their past experiences with the child while medicated. If teachers or parents recalled medication as having produced large positive changes in the child's behavior, they might have preferred to start medication immediately rather than wait to see whether behavioral interventions were sufficient.

Consistent with this hypothesis, families whose children had previously used medication were less likely to enroll in the school year follow-up study (72% vs. 96% of families). Parents who believed medication had helped their child in the past may have been hesitant to enroll in a study that required them to start the school year unmedicated. Similarly, once enrolled, families with previously medicated children were more likely to deviate from the protocol and start medication prior to meeting study criteria for doing so (28% vs. 7% of families). Familial experiences with (and attitudes toward) medication may constrain treatment options, such that parents who have observed their child medicated in the past may be less willing to forgo its use in the future. This would imply that once medication is prescribed, children are tracked into a pharmacological treatment approach, and alternative treatments (e.g., behavioral, academic, family) are less likely to be used (Macphee et al., 2017; Pelham et al., 2016). Because most children presenting with ADHD in primary care settings receive medication as first-line treatment (Epstein et al., 2014), treatment sequencing is a critical issue for clinical practice in primary care settings.

A similar finding was reported in one of our previous trials (Pelham et al., 2016). Families that were randomized to begin treatment with medication were less likely to participate in subsequent large-group BPT than families who started treatment with behavioral intervention. In that study, initial medication use reduced uptake of behavioral intervention that was provided only a few months later. Thus, the history-of-medication use effect that we observed in this study may not require years of medication use but occur almost immediately. A small literature has explored how parents' treatment goals drive preferences for initial medication (vs. behavioral) treatment (e.g., Fiks, Mayne, DeBartolo, Power, & Guevara, 2013;

Waschbusch et al., 2011), and similar designs could be used to understand how experience with medication drives future treatment goals and preferences.

Cost of Treatment

Surprisingly, the NoBC and BC groups did not significantly differ in total cost of treatment when using the prices of modern extended-release medications (Figure 2). Costs in the clinician, teacher, and parent domains were significantly greater in the BC group; costs in the medication and physician domains were significantly greater in the NoBC group. Thus, although there were differences on every component cost, there was no difference between protocols when the costs of these components were summed. Providing initial BC incurred additional treatment costs for therapist and teacher time, but these costs were offset by the associated delay of medication initiation and thus accumulation of pharmacological and physician costs. This finding adds to those from our earlier study (Page et al., 2016) in showing how the inclusion of low-dose behavioral intervention can reduce the cost of multimodal treatment. Of note, the behavioral treatments delivered in both that study and the present one were substantially less expensive than the high-dose behavioral treatments used in the MTA (Jensen et al., 2005).

While the extended-release results are most applicable to current practice, we also calculated total costs using the prices of the less expensive immediate-release medications that were used in this study ($0.23 to $0.34 per pill for immediate release vs. $4.48 to $7.55 per pill for extended release; see supplement). With immediate-release regimens, cost of treatment was significantly lower in the NoBC group than in the BC group. Thus, one cost-saving strategy would be to use generic immediate-release formulations, to which the new generation of medications routinely show equivalent effects (e.g., Pelham et al., 2001) and that allow more flexible, targeted treatment (e.g., medication can be provided just for school hours).

Limitations

The current study has several limitations that could be addressed with further studies. All families had completed an eight-session course of large-group BPT, and all children had been acutely exposed to multiple doses of medication and behavioral treatment in a 9-week crossover research program prior to the beginning of the school year. This history may have attenuated the observed effects of randomization to BC services, as parents in both the NoBC and BC groups had completed a prior course of large-group BPT (i.e., randomization was effectively to booster sessions). On the other hand, perhaps the behavioral services provided in the follow-up would have been insufficient to produce change had families not previously participated in BPT or children been exposed to behavior modification in the summer research study. Finally, because all children in the study had received a blinded trial of stimulant medication during the summer, the impact of previous medication use may have been attenuated.

As in typical practice, we did not initiate use of medication at home until use had been initiated at school. Group differences in the home setting may have been smaller if parents were allowed to begin medication prior to medication initiation in school. However, this same pattern (i.e., larger differences at home than at school) was observed in a similar trial that permitted children to start home medication at any point (Hart et al., 2019, in preparation).

Another limitation was discussed earlier: Families with a history of medication use were less likely to participate in the trial. Findings generalize only to families that are willing to try starting the school year with the child unmedicated. In this sample, 22% of families were unwilling to attempt this treatment strategy (Figure S1). More research is needed to better understand this subset of parents' treatment preferences and evaluate alternative ways to minimize their children's exposure to medication and enhance outcomes.

Conclusions

The current study adds to a growing literature showing that the use of relatively low-intensity behavioral interventions as the first-line treatment for childhood ADHD can delay, reduce, or eliminate the need for medication in school and home settings. This strategy may improve outcomes (Pelham et al., 2016), reduce cost of treatment (Page et al., 2016), minimize side effects, and limit cumulative exposure to MPH. Given the emerging literature about the lack of long-term efficacy and tolerability of extended use of central nervous system stimulants (Swanson et al., 2017), it appears prudent to minimize lifetime dosing. Further, the finding that a history of medication use powerfully predicted future need for medication (independent of symptom severity) underscores the need for further research on treatment sequencing, treatment preferences, and the influence of treatment experience on subsequent treatment uptake. For now, providers and payers who want to increase use of behavioral services should recommend them prior to prescribing medication.

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SUPPLEMENTARY MATERIAL

Supplemental data for this article can be accessed on the publisher's website.

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