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A Controlled Trial of a Novel Primary Prevention Program for Lyme Disease and Other Tick-Borne Illnesses

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To evaluate a theory-based educational program to prevent Lyme disease and other tick-borne illnesses (TBI), a randomized controlled trial of an educational program was delivered to ferry passengers traveling to an endemic area in southeastern Massachusetts. Rates of TBI and precautionary and tick check behaviors were measured over three summers in 30,164 passengers. There were lower rates of TBI among participants receiving TBI education compared with control participants receiving bicycle safety education (relative risk [RR] = 0.79) and a 60% reduction in risk among those receiving TBI education who visited Nantucket Island for more than 2 weeks compared to control participants (RR = 0.41, 95% confidence intervals = 0.18 to 0.95, $p < .038$). TBI-educated participants were also significantly more likely to take precautions (use repellent, protective clothing, limit time in tick areas) and check themselves for ticks. The study demonstrates that a theory-based Lyme disease prevention program can increase precautionary behavior and result in a significant reduction in TBI.

Keywords: *Lyme disease; primary and secondary prevention; health education; tick-borne illness*

Lyme disease (LD), a multisystem illness caused by *B. burgdorferi*, is the most common vector-borne illness in the United States (Centers for Disease Control and Prevention [CDC], 2002). Transmitted by the *Ixodes* tick, infection can affect the skin, nervous system, heart, and joints (Steere, 2001). More than 145,000 cases have been reported to the CDC since 1982 (2002).

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In theory, because the life cycle of the tick vector is completely understood, the causative organism is known, and effective treatment for early disease is available, Lyme disease should be completely preventable by tick avoidance or early removal of the tick and its chronic manifestations averted with early recognition and treatment. A Lyme disease vaccine is no longer available, making personal protection more compelling. Enhancing general knowledge of Lyme disease and tick avoidance has been the mainstay of public health prevention initiatives but increased knowledge about LD has not enhanced precautionary behavior (Carter, Farley, Ardito, & Hadler, 1989; Shadick, Daltroy, Phillips, Liang, & Liang, 1997).

We developed a theory-based educational intervention to increase precautionary behavior against Lyme disease and other tick-borne illnesses. We evaluated it by means of a large, simple randomized trial of a population visiting or residing in an endemic area of Lyme disease in southeastern Massachusetts.

METHOD

Study Design Overview

We conducted a randomized trial of an LD primary prevention program for passengers on ferryboats going from Hyannis, MA to Nantucket Island, MA, during three consecutive summers from 1997 to 1999. Boats were randomized to receive experimental or control educational interventions. The control participants learned how to prevent summer injuries as bicyclists and roller-bladers. Experimental participants learned how to prevent Lyme disease. Participants provided demographic information (after the educational intervention) and information about possible TBI 2 months after enrollment. Consent was implied by agreeing to complete the enrollment form. The Brigham and Women's Hospital Institutional Review Board approved the study.

Description of Theory-Based Intervention

The experimental intervention addressed behaviors known to prevent the transmission of LD. These include recognizing and avoiding tick-infested areas, wearing protective clothing and using insecticide in tick-infested areas, performing daily tick checks and safe removal of ticks, and recognizing LD symptoms to expedite prompt treatment. The intervention planning and implementation was based on Social Cognition Theory (Bandura, 1986) and a synthesis of constructs underpinning the Health Belief Model (HBM) Theory of Reasoned Action and the Theory of Planned Behavior (Ajzen, 1991; Ajzen & Fishbein, 1980) as well as incorporated research on information processing (Berman, 1979; Rudd & Glanz, 1990). These approaches have been widely used as the foundation for successful behavior change programs in health education (Carter, 1990).

To integrate these theories, voluntary behaviors with relatively low emotional, habitual, or addictive content, such as the ones listed above, are more likely to be performed when people:

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We gratefully acknowledge Drs. Bill DeJong and David Hemenway who first gave us the idea of using street entertainers as an intervention and connecting us with the troupe from *Screaming with Pleasure*. The entertainers from *Screaming with Pleasure* were Brian Smith and Bill Ross. This project was supported by National Institutes of Health grants, Charles Engelhard Fund, American Lyme Disease Foundation, GlaxoSmithKline, Arthritis Foundation, Pasteur Merieux Connaught, and the Centers for Disease Control and Prevention.

1. Believe the behavior is likely to result in desirable outcomes, and unlikely to result in undesirable outcomes.
2. Believe that important others would approve or support the behavior.
3. Have confidence in their ability to perform the behavior (self-efficacy) and control the outcome.
4. Have the skills and resources to perform the behavior and its components.

People learn behavior primarily by watching others (modeling) and practicing behaviors that gradually approach the desired behavior in complexity and skill (mastery learning). People may also learn through persuasion, although this is generally less effective, and is best supplemented by modeling and mastery performance. Modeling and mastery learning complement persuasion. People's confidence (self-efficacy) in their ability is thought to be a primary mediator of performance. Efficacy is best enhanced by mastery learning, coupled with feedback that helps people correctly interpret their successes and prepares them to overcome occasional failure. Once learned, behaviors are most likely to be performed if there are environmental cues to call the correct action to mind at the right time, if resources are available, and if desirable reinforcements (outcomes) are anticipated.

In pilot studies of the target population to design the final intervention, we found unacceptably and surprisingly low levels of practicing preventive behaviors among Nantucket-bound ferry passengers and some evidence that an intervention could change reported self-efficacy for preventive behaviors (Phillips et al., 2001; Shadick et al., 1997) and thus might actually prevent Lyme disease.

The intervention was delivered by an entertainment troupe on ferries taking passengers to Nantucket during the peak of the summer vacation period. The timing took advantage of a relatively captive audience (a 2.25 hour boat ride to a vacation), attracted children who in turn brought along their caretakers, and the messages were relevant to common outdoor activities such as hiking in woods or tall grasses. The program was designed to capture audience attention for the health messages using comedy, theatre, and vaudevillian techniques.

Recruitment and Randomization of Participants

We recruited participants from passengers traveling on ferryboats from Hyannis to Nantucket Island, MA. U.S. residents 14 and older were asked to provide a name, address, length of stay on Island, resident/visitor status, prior history of TBI, knowing someone with LD, and which elements of the intervention they had seen.

Boats were assigned alternately to experimental or control conditions allowing for appropriate entertainment space for the experimental intervention. Participants enrolled on more than one trip were followed once per summer, with the first treatment assignment used for intent-to-treat analysis.

Experimental and Control Interventions

The experimental intervention was announced by the ship's bursar early in the voyage. The intervention was in a 15-minute persuasive communication act, interacting with the audience and employing humor. The message covered the severity and likelihood of acquiring LD (to increase perceived susceptibility) and the benefits of tick avoidance and search/removal behaviors, such as avoiding LD and increasing peace of mind. Tips to make these behaviors habitual and to minimize perceived hassles were offered. Social support for the recommended behaviors was encouraged by appealing to families to protect children and loved ones.

The performer demonstrated removal of *Ixodes* ticks (modeling) and encouraged passengers to find actual ticks attached to a rubber arm. This provided an opportunity for mastery behavior to raise self-efficacy for tick search and removal behaviors.

Free educational materials were given to subjects on enrollment including:

1. A wallet sized TICK ID card showing an adult and nymphal deer tick with Braille-like dots to give the user a feel of the actual tick size.
2. A laminated tick check and removal reminder card to hang in the shower.
3. Discount coupons for tweezers and insect repellent at Island pharmacies.
4. A pamphlet on LD with color photographs of a variety of Erythema Migrans rashes that are nearly pathognomic of LD is available gratis from the American Lyme Foundation.
5. A high-quality map showing tick habitats on Nantucket Island in color.
6. Lime-colored lollipops with the printed message, *Lick Lyme*.

These aids were intended to summarize action steps, provide cues to action, and remove practical barriers to the desired behavior.

Participants on control boats received free educational materials including a road safety pamphlet; a map of Nantucket bike paths; lollipops with the message, *Think Safety*; and a reflective sticker. The control health educational messages were delivered by entertainers in the first summer. In the 2nd and 3rd summers, shows were dropped for control boats because of budgetary reasons and after we determined that similar groups of participants were enrolled on both experimental and control boats regardless of recruitment method. Control participants continued to receive all educational materials.

Follow-Up

Two months after enrollment, we mailed a one-page questionnaire to participants. All study personnel were blinded to group assignment at follow-up. We asked about occurrence of various tick-borne illnesses (TBI) such as Lyme disease, Ehrlichiosis, and Babesiosis; symptoms consistent with Lyme disease based on the CDC case definition; visits to the doctor; and practice of preventive behaviors while on the Island. Adults were asked to complete a follow-up form for each child under 14 years old traveling with them. We made three attempts to obtain a follow-up questionnaire.

We requested permission to contact physicians when the participant reported a doctor visit for: LD; Babesiosis; Ehrlichiosis; large, red expanding rash; facial droop; severe headache; neck pain or neck stiffness and swollen joint(s); and flu-like illness or fever. Physicians were asked for their impression of TBI, details of the clinical manifestations, and results of diagnostic studies. For each survey, we made three attempts to contact respondents.

Statistical Methods

We analyzed rates of self-reported TBI (LD, Babesiosis, and Ehrlichiosis, pooled) as the primary outcome. The planned sample size was 30,000 subjects with follow-up information (15,000 per group), enrolling 40,000 (25% loss to follow-up expected). We estimated the incidence of LD would be 1%; the protective efficacy of the experimental program was 33%. With $\alpha = .05$, 30,000 participants provided 80% power to detect a relative risk of 0.67 for TBI in the experimental versus control group.

We used logistic regression models to examine the effect of the intervention on self-reported TBI at 2 months, analyzing by individual in an intention-to-treat analysis. We examined age, sex, education, length of time on Nantucket prior to enrollment and post

enrollment, time spent in tick areas, permanent residence, history of LD or knowing someone with LD, as possible covariates. We examined the interaction of the intervention with time spent on Nantucket, knowing someone with LD, age, gender, and education, as we hypothesized that the intervention might differ in efficacy by subgroup. For instance, those who knew someone with LD might be expected to respond more favorably to an educational program designed to reduce their risk.

We also compared groups on level of self-reported tick avoidance/prevention and tick check/removal behaviors at 2 months, and assessed the extent to which those behaviors were associated with TBI rates. We separated out the impact of the intervention for visitors versus Nantucket residents because the background level of exposure to both on-island education and risky environments is likely to be both quantitatively and qualitatively different for the two groups. This provided an opportunity to evaluate the relative impact of a public health education campaign on visitors to an endemic area and residents. We divided visitors according to length of stay, at 2 weeks or less versus more than 2 weeks. Eighty-eight percent of visitors stayed 2 weeks or less. All analyses were performed using SAS software (SAS Institute, 1990). The chi-square and Mantel-Haensel chi-square tests and Student's *t* test were used to compare qualitative and continuous variables, respectively, and *p* values of .05 or lower on two-tailed testing were considered statistically significant.

RESULTS

Participants

Between May 1997 and September 1999, we enrolled 30,164 participants out of 81,296 (37%) ferry passengers from 292 study boats traveling to Nantucket Island on 88 days. Of the total enrolled, 13,562 (45%) subjects were on experimental boats and 16,602 (55%) subjects were on control boats.

Subjects are described in Table 1. There were no meaningful differences between experimental and control groups, although some differences achieved statistical significance probably because of the large sample size.

At 2 months, 21,852 participants returned a form, 17,076 were more than 14 years of age. This is a follow-up rate of 72%. When we compared the characteristics of respondents versus nonrespondents among the 15,995 subjects who traveled without children less than 14 years of age, nonrespondents were more likely male, under 30 years of age, less educated, a Nantucket resident, and staying less than 1 week (Data not shown).

Ascertainment of Tick-Borne Illness (TBI) Cases

At 2 months follow-up, 533 participants reported a variety of symptoms of tick-borne illness (rash, arthralgias, headache, etc). Of these, 145 participants reported a tick-borne illness, either LD ($n = 144$) with or without Babesiosis ($n = 16$) or Ehrlichiosis ($n = 11$). We obtained physician data on 176/533 (33%), including 64 of the 145 participants reporting tick-transmitted disease. Physicians confirmed tick-borne illness (with some co-infection) in 47/64 (73%) participants (28 control; 19 experimental). There were 43 cases of LD, 4 of Babesiosis, and 4 of Ehrlichiosis.

Table 1. Characteristics of Enrollees

	Baseline (<i>N</i> = 30,164)	
	Experimental (<i>N</i> = 13,562)	Control (<i>N</i> = 16,602)
Age		
14-29	27.24%	30.58%
30-49	47.13%	45.38%
50-70+	25.63%	24.04%
Male gender	42.63%	40.24%
Educational attainment		
High school or less	16.61%	14.9%
Trade school/some college	17.8%	18.76%
College graduate	65.6%	66.35%
Number of children on boat less than 14 years		
0	60.6%	65.09%
1-2	31.09%	27.24%
3+	8.31%	7.66%
Prior visit to Nantucket (before enrollment)		
Yes	19.27%	19.92%
No	80.73%	80.07%
Nantucket zip code	3.52%	3.91%
Planned length of stay		
Less than 1 week	52.5%	51.07%
1-4 weeks	40.8%	41.56%
More than 4 weeks	6.7%	7.37%
Know someone with Lyme disease	49.21%	47.28%
Prior Lyme disease	5.45%	5.42%

NOTE: Differences between groups of >1.6% are significant at $p < .05$ and differences of >2.1% are significant at $p < .01$.

Effect of the Intervention on Precautionary Behaviors and Rates of TBI

Although a main effects model showed lower rates of self-reported TBI among experimental participants than control participants (relative risk [RR] = 0.79; see Table 2), the difference was not statistically significant. We believe that this is partly because of the low rates of LD and other tick-borne infections observed during the particular years of the study. However, interaction analyses showed a significant impact of the intervention among long-term visitors (greater than 2 weeks) versus short-term visitors. Among short-term control group visitors (the reference group), the base TBI rate was 2.7/1000. The relative risk for experimental short-term visitors was 1.04. However, compared with the short-term RR, the intervention reduced rates of TBI among experimental participants versus control participants among longer-term visitors (RR for interaction = 0.41, 95% confidence interval = 0.18 to 0.95, $p < .038$) as well as among Nantucket residents, although the latter effect was not statistically significant (RR for interaction = 0.75, 95% confidence interval = 0.30 to 1.89, $p < .54$).

Interaction effects are shown in Figure 1. Controlling for covariates, the rates of TBI are higher among longer-term visitors than short-term visitors, and highest among Nantucket residents. Among visitors who stayed longer than 2 weeks, the estimated risk of TBI in the

Table 2. Predictors of Tick-Borne Illness: Results of Multiple Logistic Regression

Main Effects Model			
Predictor	Relative Risk	95% Confidence Limits	<i>p</i> value
Knowing someone with Lyme disease	1.52	1.06 to 2.19	<.024
Stay on Nantucket prior to study ^a	1.43	1.11 to 1.86	.0058
High tick season	1.49	1.06 to 2.10	.020
Nantucket resident	4.73	2.56 to 8.73	<.0001
Visitor, more than 2 weeks	2.72	1.77 to 4.18	<.0001
Educational intervention	0.79	0.56 to 1.10	<.17
Interaction Effects Model			
Predictor	Relative Risk	95% Confidence Limits	<i>p</i> value
Know someone with Lyme disease	1.51	1.05 to 2.18	<.026
Stay on Nantucket prior to study ^a	1.44	1.11 to 1.86	.0055
High tick season	1.50	1.06 to 2.10	.020
Nantucket resident	5.35	2.58 to 11.06	<.0001
Visitor, more than 2 weeks	3.71	2.23 to 6.18	<.0001
Educational intervention	1.04	0.67 to 1.63	<.86
Education by Nantucket residence	0.75	0.30 to 1.89	<.54
Education by length of stay among visitors	0.41	0.18 to 0.95	<.038

a. On Nantucket more than a week, a week or less, or not at all, prior to study enrollment.

experimental group is only 43% of the risk among controls. The risk among Nantucket resident experimental participants is 78% of that among control participants.

Those who spent the most time in tick areas reported the most frequent practice of precautionary and tick check behaviors. Seventy-one percent of participants who spent 1 or more days in tick areas reported taking precautions at least some of the time versus 37% of participants who said they spent no time in tick areas. Similarly, 50% of participants who spent 1 or more days in tick areas reported checking themselves for ticks at least some of the time versus 15% of participants who said they spent no time in tick areas.

We examined the impact of the intervention on self-reported behaviors among Nantucket residents (see Table 3). Experimental and control participants reported similar number of days spent and hours per day in tick areas. However, experimental participants were more likely than control participants to take precautions against TBI, and to check themselves for ticks daily.

Participant Exposure and Rates of TBI

Several indicators of participant exposure to tick bite were associated with a dose-response increase in TBI. This included time on Nantucket before enrolling (Case rate 0.45% none, 0.85% 1-6 days, 1.78% >7 days, $p < .0001$) and planned length of stay (Case rate 0.33% 1-6 days, 0.52% 1-2 wks, 0.7% 3-4 wks, 3.29% >5 wks, $p < .0001$). Participants (including Nantucket residents) who enrolled during May and June, the highest-risk tick season (Piesman, Mather, Dammin, et al., 1987), were also more likely to report TBI in the subsequent two months than those who enrolled in July and August (Case rate 0.92% vs. 0.51%, $p < .0004$).

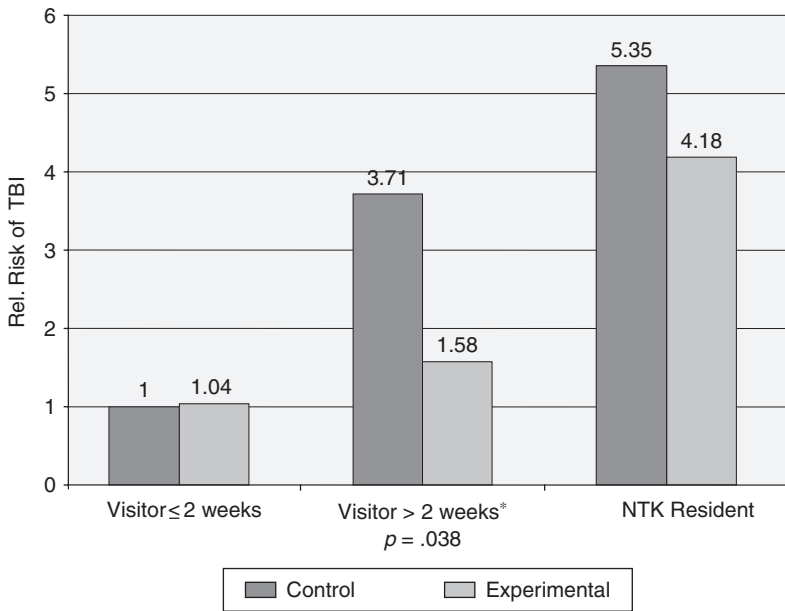


Figure 1. Effect of educational intervention on risk of tick disease by length of visit and residency controlling for prior time on Nantucket, knowing someone with Lyme disease and arrival during high tick season.
NOTE: NTK = Nantucket Island.

Table 3. Impact of the Educational Intervention on Participant Behaviors While on Nantucket Island

	Experimental	Control	<i>p</i> value
Days in tick areas			
None	37%	34%	
1 to 6 days	50%	52%	<.32
7 or more days	13%	14%	
Hours per day in tick areas			
None	27%	32%	
Less than 1 to 2 hours	58%	52%	<.02
3+ hours	15%	16%	
Take precautions (use repellent, protective clothing, limit time in tick areas)			
Every day or most days	58%	39%	<.0001
Some days or never	42%	61%	
Check self for ticks			
Every day or most days	51%	37%	<.0001
Some days or never	49%	63%	

DISCUSSION

Public health efforts to contain LD in endemic areas have used a variety of approaches including environmental modification, prophylaxis, wildlife management, and behavioral intervention to reduce disease, each of which has costs and benefits (E. Hayes, Maupin, Mount, & Piesman, 1999; E. B. Hayes & Piesman, 2003; Mount, Haile, & Daniels, 1997). Host reduction and habitat modification pose significant challenges. Mice are free ranging and elimination of the deer population pits the values of conservationists against public health advocates. Application of host and habitat acaricide is also effective but only in the short term and has unknown long-term consequences (Mather, Duffy, & Campbell, 1993; Pound, Miller, George, & Lemeilleur, 2000; Schulze, McDevitt, Parkin, & Shisler, 1987; Schulze, Taylor, Jordan, Bosler, & Shisler, 1991; Schulze, Taylor, Vasvary, Simmons, & Jordan, 1992). Pharmacological strategies are currently limited to treating presumed infection with a single dose of 200mg of doxycycline given within 72 hours after an *I. Scapularis* tick bite (Nadelman et al., 2001). A LYMESIM computational model used to estimate the strength of a variety of environmental interventions found that pooling deer reduction, vegetation reduction, and acaricide treatment, reduced tick density by less than 50% in 5 years (Mount et al., 1997). Development of a vaccine is still an area of great interest and potentially cost-effective (Shadick, Liang, Phillips, Fossel, & Kuntz, 2001) but the first one approved by the Food and Drug Administration with the caveat that its long-term consequences be studied had only a brief history and is no longer manufactured. Even if another were developed, it is not clear what its net public health benefit would be as it might make at-risk populations more cavalier about practicing tick avoidance behaviors and increase the likelihood of other TBI.

Lyme disease protective behaviors are voluntary, inexpensive for the individual, and especially suitable for short-term visitors to endemic areas. Each preventive behavior can interrupt the infection process. As the likelihood of tick infection is a function of exposure (Piesman, Mather, Dammin, et al., 1987), an increase in any or all of the behaviors will reduce the likelihood of infection. An additional benefit is that other tick-borne illnesses could also be prevented. From a public health standpoint, this is important, as 100% adoption of all behaviors is not necessary to confer protection. Each behavior, although perhaps a nuisance or not practiced daily, is relatively easy to perform, and has analogs in other common practices, such as the use of creams, repellents, and clothing for mosquito protection and sun protection. A skin check in the shower may be similar to behaviors suggested for mole checks or breast self-exam. These health behaviors may already be in people's repertoires and may only need to be called up for new circumstances. Tick check and removal behaviors can be effective because ticks must feed for a minimum of 24 hours before infection results (Piesman, Mather, Sinsky, & Spielman, 1987).

Although promotion of precautionary behaviors is appealing as a means to prevent LD, prior studies have not shown substantial effects from public educational campaigns in reducing Lyme disease (Ley, Olshen, & Reingold, 1995; Orloski et al., 1998; Smith, Benach, White, Stroup, & Morse, 1988). Several studies show that personal precautions are practiced routinely by less than one half of residents in endemic areas despite knowledge of risk and transmission (Herrington et al., 1997; Lyme disease knowledge, attitudes, and behaviors, 1992). In a previous study, we noted that precautionary behaviors were performed when there was a perception of LD as a serious illness as well as high self-efficacy (self-confidence) that one could perform a tick check and recognize early symptoms of LD (Shadick et al., 1997). A variety of public health educational

efforts already existed on Nantucket during our study. In fact, 89% of control subjects in our study reported learning about LD from one or more sources during their stay on the Island. Exposure to non-study sources was similar among experimentals and controls. Our study demonstrates that a carefully designed, relatively inexpensive health education message based on social learning theory (Ajzen, 1991; Ajzen & Fishbein, 1980; Bandura, 1986; Becker, 1974; Janz & Becker, 1984) can be delivered to an at-risk population and result in increased precautionary behavior that reduces the rate of LD, even against a background of widespread information.

Implications for Practice

Lyme disease protective behaviors are voluntary, inexpensive for the individual, and especially suitable for short-term visitors to endemic areas. The study demonstrates that theory-based interventions that are timely and persuasive, address identified misconceptions, and provide tools and resources that enable and reinforce desired behavior could successfully change tick-borne illness preventive behavior.

The creation of theory-based interventions requires sufficient investment in pilot studies to identify barriers and common misconceptions with the target audience to create effective and persuasive messages.

The study replicated prior work that found persuasive messages are educational cues that alert participants to the seriousness of the illness to themselves and family members as well as convey corrective and timely action that would prevent or mitigate illness. Linked to persuasiveness was the need to enhance skills and resources to increase individual confidence in performing corrective actions. Our study recommended that the incorporation of the desired behavior be linked to one's normal daily activities.

The study also demonstrates that relatively inexpensive health education messages based on social learning theory can be delivered to an at-risk population and result in increased precautionary behavior even against a background of widespread information.

This study has limitations. Although the true rate of incident cases in this study is probably somewhat inflated (because of participants' self-report), there is no reason to suspect a significant bias that would affect the comparison of control participants and experimental participants. In fact, inflation of the rates would add random error that would weaken our ability to detect significant differences. Nearly three quarters of participants reporting a TBI had the illness confirmed in their first doctor's visit (76% of controls, 70% of experimentals). The slightly higher rate of false negatives among the experimental participants would be consistent with greater vigilance and a lower threshold for reporting suspicious symptoms. The clear dose response relationship of cases with all measures of exposure lends validity to the self-report measure.

In the short term, more symptoms and follow-up may have been observed in the experimental group because of increased awareness of LD. Moreover, those with LD in the control group may be more likely to respond to the 2-month follow-up than those without LD, which will inflate the disease rate among control participants. Furthermore, nonrespondents were more likely to be shorter-stay control participants and less likely to have a TBI. These are conservative biases, which would tend to diminish the efficacy of the experimental intervention.

The study demonstrates that a theory-based intervention that is timely and persuasive and employs humor, opportunities to view and practice the target behaviors, and follow-up cues to stimulate behavior at appropriate times can successfully change TBI prevention behaviors. The intervention was potent even against a background of widespread public

information campaigns and general knowledge about tick-borne disease. The next challenge is to take the principles demonstrated here and apply them creatively to larger populations so as to increase prevalence of tick-borne disease preventive behaviors and maintain their practice.

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