Improving Community Stroke Preparedness in the HHS (Hip-Hop Stroke) Randomized Clinical Trial

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Background and Purpose—Deficiencies in stroke preparedness cause major delays to stroke thrombolysis, particularly among economically disadvantaged minorities. We evaluated the effectiveness of a stroke preparedness intervention delivered to preadolescent urban public school children on the stroke knowledge/preparedness of their parents.

Methods—We recruited 3070 fourth through sixth graders and 1144 parents from 22 schools into a cluster randomized trial with schools randomized to the HHS (Hip-Hop Stroke) intervention or attentional control (nutrition classes). HHS is a 3-hour culturally tailored, theory-based, multimedia stroke literacy intervention targeting school children, which systematically empowers children to share stroke information with parents. Our main outcome measures were stroke knowledge/preparedness of children and parents using validated surrogates.

Results—Among children, it was estimated that 1% (95% confidence interval [CI], 0%–1%) of controls and 2% (95% CI, 1%–4%; P=0.09) of the intervention group demonstrated optimal stroke preparedness (perfect scores on the knowledge/preparedness test) at baseline, increasing to 57% (95% CI, 44%–69%) immediately after the program in the intervention group compared with 1% (95% CI, 0%–1%; P<0.001) among controls. At 3-month follow-up, 24% (95% CI, 15%–33%) of the intervention group retained optimal preparedness, compared with 2% (95% CI, 0%–3%; P<0.001) of controls. Only 3% (95% CI, 2%–4%) of parents in the intervention group could identify all 4 letters of the stroke FAST (Facial droop, Arm weakness, Speech disturbance, Time to call 911) acronym at baseline, increasing to 20% at immediate post-test (95% CI, 16%–24%) and 17% at 3-month delayed post-test (95% CI, 13%–21%; P=0.0062), with no significant changes (3% identification) among controls. Four children, all in the intervention group, called 911 for real-life stroke symptoms, in 1 case overruling a parent's wait-and-see approach.

Conclusions—HHS is an effective, intergenerational model for increasing stroke preparedness among economically disadvantaged minorities.

Clinical Trial Registration—URL: https://clinicaltrials.gov. Unique identifier: NCT01497886.

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The nationwide Get With The Guidelines stroke registry continues to demonstrate prehospital delays as the biggest rate-limiting step to improving acute stroke treatment in the United States.[1] Because of delays, only 25% of stroke patients arrive in the hospital within 3 hours.[1] Consequently, ≈7% of ischemic stroke patients in the United States are treated with intravenous thrombolysis with tPA (tissue-type plasminogen activator),[2] with lower rates of tPA use among Blacks compared with Whites.[3]

If all patients with known stroke symptom onset times called 911 immediately, 1 study showed a 24% increase in the rate of thrombolysis.[4] But efforts to improve stroke preparedness have focused on mass media campaigns that have been limited by the high costs of advertising, lack of cultural tailoring, low penetration into ethnic minority populations,[5] and outcome effects (calling 911 for stroke) that dissipate once the media campaign ends.[6]

Targeting the general public and not just individuals at risk for stroke is important because stroke patients call 911 for themselves ≈4% of the time, whereas witnesses are responsible the rest of the time.[7] This is the rationale behind targeting large groups and why stroke education in schools is gaining traction as an alternative to mass media campaigns. Children are increasingly being raised by older parents or grandparents[8]

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who may be at high risk for stroke: they may be able to serve as transmission vectors of stroke information into their households and may be the only witnesses present during a stroke.

The primary aim of this study is to evaluate the effectiveness of a stroke education intervention delivered exclusively to preadolescent children on the stroke preparedness of children and of their parents (henceforth, parents also refer to grandparents).

Hypothesis 1 (H1): There will be no differences in stroke preparedness at baseline between groups for parents and for children.

Hypothesis 2 (H2): Children in the intervention arm will demonstrate greater stroke preparedness immediately after and at 3 months after intervention when compared with those in the control arm.

Hypothesis 2a (H2a): Parents in the intervention arm will demonstrate greater stroke preparedness and stroke identification (FAST [Facial droop, Arm weakness, Speech disturbance, Time to call 911]) immediately after and at 3 months after intervention when compared with those in the control arm.

Hypothesis 3 (H3): Compared with students in the control condition, children in the intervention arm will be more likely to communicate stroke information to their parents.

Hypothesis 4 (H4): In homes in which information is shared, parents in schools assigned to the intervention arm will demonstrate greater stroke preparedness, compared with their baseline knowledge, at 1-week and at 3-month follow-up, and compared with parents in the control arm.

Mediation analysis (H4M): Analyses to establish that the effect of the intervention on adult preparedness is mediated by improvement in children's knowledge.

Methods

Data supporting findings of this study are available from the corresponding author on reasonable request.

Design

Children in fourth to sixth grades (aged 9–12 years) attending high-need New York City public schools and their parents were eligible for inclusion. Schools were randomized into either a stroke preparedness intervention (HHS [Hip-Hop Stroke]) or an attentional control (nutrition classes). Randomization occurred at the school level in a 1:1 ratio; written consent was obtained from parents for their child and themselves. Assent was obtained from each child. Details of enrollment and retention are shown in Figure 1. Further information on study procedures is available in a previous report[9] and online-only Data Supplement.

Intervention Condition

HHS is a culturally tailored intervention targeting urban minority children. Children undergo three 1-hour modules separated by at least 24 hours (Table I in the online-only Data Supplement). Theoretical models underpinning HHS are detailed in an earlier report.[10] In brief, HHS is a modular, multimedia, school-based intervention that uses hip-hop music containing stroke lyrics, 2 synergistic 3.5-minute animated narrative cartoons, a clotbuster (thrombolytic) stroke video game, and a comic book (Figure I in the online-only Data Supplement), to teach and motivate children to share stroke information with parents through homework activity that leverages an online HHS portal. No direct intervention is provided to parents. The children watch each cartoon 3× (once per module).[11] The cartoons teach recognition of the 5 SUDDENS stroke symptoms (sudden confusion or trouble speaking; unilateral numbness or weakness; trouble seeing; loss of balance, incoordination, or dizziness; and severe headache with no known cause), the availability and benefit of time-dependent thrombolysis, lifestyle prevention measures, calling 911, and encourage children to share stroke information with parents.

Control Condition

The United States Department of Agriculture My Pyramid nutrition program constituted the attentional control program. This was adapted into three 1-hour class modules to mirror the intervention and delivered by a trained facilitator.

Outcomes

Primary outcomes were child and parental stroke knowledge/preparedness. Parental outcomes were assessed with in-person surveys at baseline and by telephone during follow-up. Child outcomes were assessed in-person within classrooms. A secondary/exploratory outcome was the assessment of the occurrence and response to familial stroke-like symptoms after participating in study arms: whether 911 was called, and the child's role in facilitating stroke recognition or emergency medical services activation. An independent stroke neurologist adjudicated the self-reported stroke event in a telephone interview.

Measures

(1) A 7-item instrument was used to assess stroke knowledge/preparedness. This primary outcome measure was administered to children and parents. It included knowledge of the 5 SUDDENS symptoms, a question from the Stroke Action Test evaluating intent to call 911,[12] and a distractor item—sudden chest pain—to facilitate comparison with the nationwide Behavioral Risk Factor Surveillance Survey.[13] (2) A second outcome measure administered only to parents assessed as knowledge of the FAST.[14] This measure has been used to promote stroke identification and urgent action by mass media campaigns globally, identifies 88.8% of stroke/transient ischemic attack patients,[15] and has been associated with reduced prehospital delays to stroke care.[16]

Additional information about child-parental sharing was provided by a question asked of parents at post-test. Did your child share any information from the program with you?

We added a self-efficacy scale with subconstructs for stroke recognition, appropriate action in response to stroke symptoms, ability to describe a stroke event to a 911 operator, and ability to teach a friend or family member how to recognize a stroke.

Covariates

A 7-item composite of barriers to calling 911 (eg, cost of ambulance and hospitalization) derived from focus groups on representative adults and literature review was included in the parent questionnaire as a covariate. In addition, sociodemographic variables (Table 1), parental health literacy,[17] and parental stroke experience (presence of stroke in a family member, close relative, or close friend with whom the parent has had contact) were assessed.

Data Analysis

For the stroke preparedness instrument, internal consistency reliability estimates, including Cronbach α and McDonalds omega total, were calculated. In addition, the explained common variance, an estimate of dimensionality derived from a factor analysis model, was computed. Psychometric analyses were conducted using the psych package in R.[18] α, McDonald omega total, and explained common variance were computed using tetrachoric correlations for binary data. Observed means and SEs were computed using SPSS complex samples.[19]

Analysis of longitudinal data was performed on an intention to treat basis and adjusted for clustering of subjects within schools using Statistical Analysis System Procedures Mixed[20] for continuous outcomes and Statistical Analysis System Procedures Glimmix for binary outcomes. The statistical tests were based on trajectories (slopes) estimated from observed data points over 3 waves of data

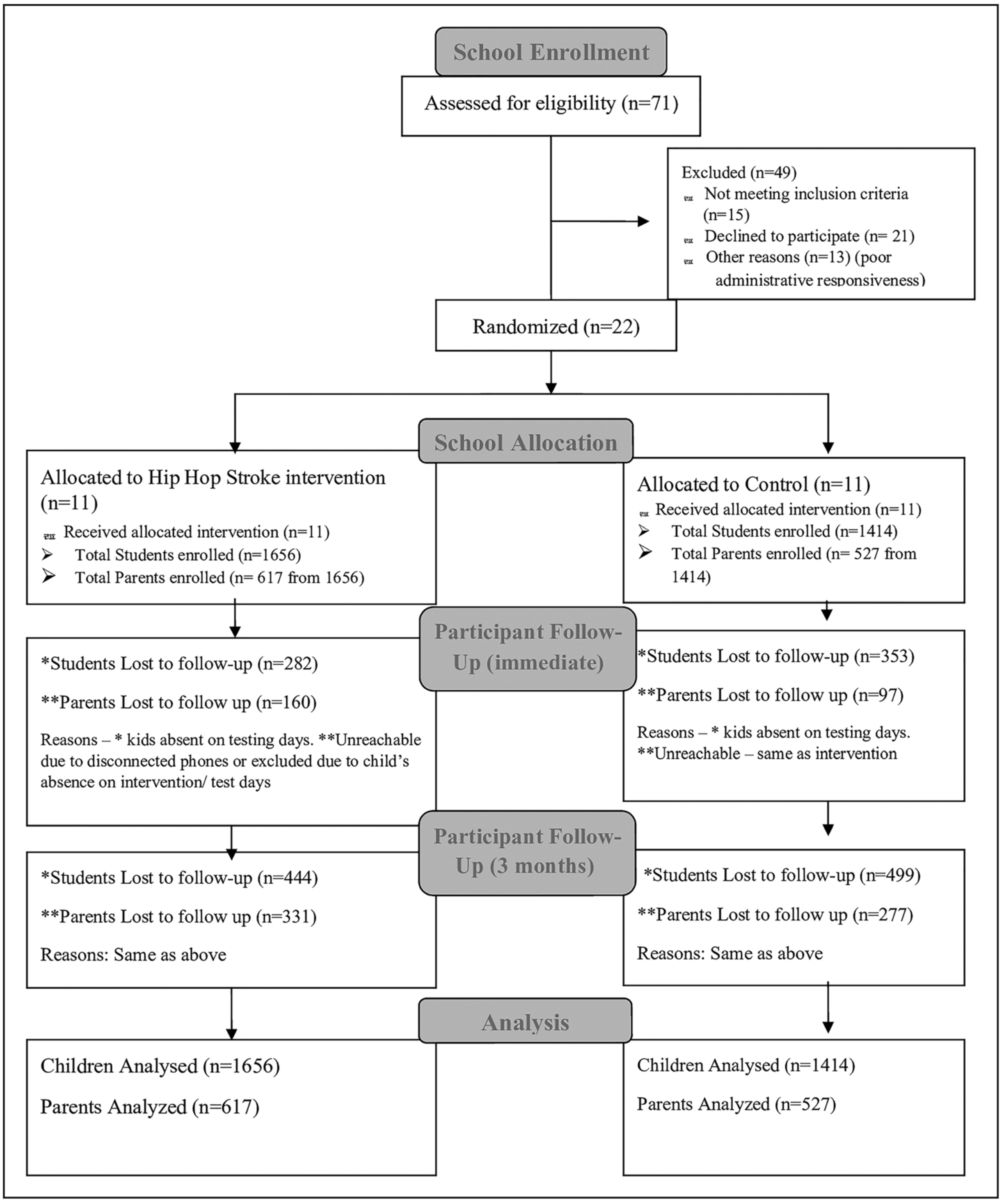

Figure 1. CONSORT (Consolidated Standard of Reporting in Trials) flow diagram of subjects in the Hip-Hop Stroke Trial.

(pre, immediate post, and 3-month delayed post-tests). Significance tests were 2-tailed, and the α level was set at 0.05 for each primary outcome. The end points entered into the models when treated as continuous variables did not require prior transformation, based on graphical inspection of the distribution of the outcome and of the residuals from the models. Adjusted means (SE) of the end points during follow-up were estimated as follows. Power terms were added if a nonlinear model provided a better fit. The stroke preparedness measure evidenced a nonlinear trajectory; thus, a quadratic (group×test2) term was included to model the nonlinearity. A significant quadratic term indicates differences between treatment groups, with one of the groups exhibiting a U-shaped distribution of the outcome over time. Group heterogeneity in cluster and residual variances also required modeling. Sensitivity analyses were conducted using the same methodology described above including participants that completed at least 2 tests (n=2789 for the students and n=887 for the parents).

The best covariance structure was selected based on examination of the Akaike Information Criterion[21] and Schwarz Bayesian Information Criterion.[22] An unstructured covariance structure was observed to be superior and was thus used in all analyses.

Power calculations were performed for the group and method with the most stringent requirements. Power calculations were performed for end point analyses, treating the outcome as binary (100% correct versus <100%) on the knowledge/preparedness and FAST literacy tests (details are given in the online-only Data Supplement). Power was >0.90 for the child preparedness test and the parent FAST test, but the study was underpowered for the parent preparedness test (treated as binary), given the observed effect sizes (shown below).

The potential mediating effect of child knowledge on parent knowledge was also evaluated through the assessment of *P* values for the mediating path coefficients. Details of the analyses are in the online-only Data Supplement. Finally, the effect of the child sharing information about the program with parents was evaluated using a mixed model evaluating the continuous version of the parental stroke knowledge/preparedness and FAST composite outcomes. An interaction term was used to examine whether shared information resulted in larger effects.

Ethics review approval was obtained from the New York City Department of Education Institutional Review Board and Columbia University Institutional Review Board.

Table 1. Baseline Parent Demographics (n=1144)

	Total (n=1144)	Control (n=527)	Intervention (n=617)
	n (%)	n (%)	n (%)
Age			
25 or younger	22 (1.9)	8 (1.5)	14 (2.2)
26–35	399 (34.9)	200 (38.0)	199 (32.3)
36–45	469 (41.0)	191 (36.2)	278 (45.1)
46–55	190 (16.6)	98 (18.6)	92 (14.9)
55 and older	48 (4.2)	23 (4.3)	25 (4.1)
No response, data missing	16 (1.4)	7 (1.3)	9 (1.5)
Sex			
Male	176 (15.4)	91 (17.3)	85 (13.8)
Female	963 (84.2)	435 (82.5)	528 (85.6)
No response, data missing	5 (0.4)	1 (0.2)	4 (0.6)
Ethnicity			
Black or African American	837 (73.2)	414 (78.6)	423 (68.6)
White	63 (5.5)	18 (3.4)	45 (7.3)
Non-Black Hispanic	55 (4.8)	24 (4.6)	31 (5.0)
Asian Pacific Islander	53 (4.6)	4 (0.8)	49 (7.9)
Other	23 (2.0)	14 (2.7)	9 (1.5)
No response, data missing	113 (9.9)	53 (10.0)	60 (9.7)
Hispanic			
Yes	154 (13.5)	72 (13.7)	82 (13.3)
No	706 (61.7)	268 (50.9)	438 (71.0)
No response, data missing	284 (24.9)	187 (35.4)	97 (15.7)
Highest level of education			
Less than high school	114 (9.0)	49 (8.7)	65 (9.2)
Completed high school	300 (26.2)	136 (25.8)	164 (26.6)
Some college/Associate's degree	336 (29.3)	170 (32.2)	166 (26.9)
Completed Bachelor's degree	227 (19.8)	95 (18.0)	132 (21.4)
Graduate/advanced degree (or some work toward it)	110 (9.6)	47 (8.9)	63 (10.2)
No response, data missing	57 (5.0)	30 (5.7)	27 (4.4)

Results

Reliability of Measures

Data on the psychometric properties of measures used can be found in the online-only Data Supplement.

Attrition

Overall, 3070 fourth to sixth graders in 22 schools and 1144 of their parents were enrolled. The primary analyses were intent-to-treat, and therefore, all children and parents enrolled were analyzed (Figure 1). In sensitivity analyses, 2789 children (90.87%) and 887 parents (77.5%) who completed at least 2 tests were included in the analyses. A parent was considered as followed if they completed the pre-test and at least 1 post-test. There were 257 parents with no follow-up tests and 887 parents with at least 1 follow-up test. There were no significant differences between those parents who were followed or not.

Children (H1, H2)

There was no significant difference in baseline tests between the intervention and control groups (H1) regardless of whether stroke preparedness was analyzed as a binary variable (perfect score on the knowledge/preparedness test) or as a continuous measure. Model-based means from the analyses of the binary outcomes (H2) for children were similar to the observed means (Table 2). The model-based means were 1% (95% confidence interval [CI], 0%–1%) in the control and 2% (95% CI, 1%–4%; P=0.09) in the intervention group demonstrated optimal stroke preparedness (perfect scores) at baseline, increasing to 57% (95% CI, 44%–69%) immediately after the program in the intervention as contrasted with 1% (95% CI, 0%–1%; P<0.001) in the control. At 3-month follow-up, 24% (95% CI, 15%–33%) of the intervention retained optimal preparedness, compared with 2% (95% CI, 0%–3%; P<0.001) in the control. Treated as a continuous measure, examined over 3 time points, the intervention group evidenced significantly greater gains in preparedness relative to controls (P<0.0001). Self-efficacy across all subconstructs increased significantly (P<0.0001) relative to the control group.

Sensitivity analysis for children's data including respondents with at least 2 waves of data was conducted using a mixed model approach that was the same as that of the intent-to-treat analysis (the covariance structure was unstructured, with heterogeneous group variances, and school treated as a random effect). A total of 281 cases were excluded (102 in the intervention group and 179 in the control group). The estimates were similar to those from the intent-to-treat analyses for both continuous and binary outcomes. For example, for the continuous outcome, the estimates of the fixed effects for the intent-to-treat and at least 2 wave analyses, respectively, are as follows: intercept: 3.46 versus 3.45, intervention group: 2.71 versus 2.72, test: 0.17 versus 0.19, intervention group by test: 0.93 versus 0.91, intervention group by quadratic test: −1.59 versus −1.57, and all with a P value <0.0001 (Table II in the online-only Data Supplement).

Parents Knowledge/Preparedness (H1, H2a)

There were no significant differences in stroke preparedness between control and intervention groups at baseline (H1). Model-based means from the analyses of the binary outcome (H2a) showed that 17% (95% CI, 13%–20%) of parents in the control and 19% (95% CI, 16–23%) in the intervention group demonstrated optimal stroke preparedness, and this increased to 29% (95% CI, 24%–34%) immediately after the program in the intervention group as contrasted with 21% (95% CI, 17%–25%) in controls. However, end point differences were less (21% in controls and 24% in the intervention; P=0.0892). The observed and model-based means were similar. Treated as a continuous knowledge measure, and examined over the 3 time points, the intervention group evidenced significantly greater gains in preparedness relative to the controls (P=0.0012). The model-based mean differences were 2 points on a 7-point scale. Thus, the effect was an average of 3.5 of 7 (50% correct) versus 5.6 of 7 (80%), a significant and clinically important difference.

Parents FAST Literacy (H2a)

Model-based means for the binary FAST outcome (H2a) showed that only 3% (95% CI, 2%–4%) of parents in the intervention could identify all letters of the FAST acronym at baseline but this increased to 20% at immediate post-test (95% CI, 16%–24%) and 17% at the 3-month delayed post-test (H2: 95% CI, 13%–21%; P=0.0062), whereas no significant changes were observed in controls (Table 3; Figure 2). The observed and model-based means were similar.

Self-efficacy increased significantly across all subconstructs (P<0.0001; not shown) relative to controls.

Sensitivity analysis for parental knowledge/preparedness data using respondents with at least 2 waves of data was conducted using a mixed model approach that was the same as that of the intent-to-treat analysis (the covariance structure was unstructured, with heterogeneous group variances, and school treated as a random effect). A total of 257 cases were excluded (160 in the intervention group and 97 in the control group). The estimates were similar to those from the intent-to-treat analyses for both continuous and binary outcomes. For example, for the continuous outcome, the estimates of the fixed effects for the intent-to-treat and at least 2 wave analyses, respectively, are as follows: intercept: 5.53 versus 5.55, intervention group: 0.33 versus 0.33, test: 0.15 versus 0.14, intervention group by quadratic test: −0.22 versus −0.21, all with P values <0.002 (Table III in the online-only Data Supplement).

Covariates

Although 61% of parents reported stroke experience at both pre-test and post-test, we found no association between this and stroke preparedness. In addition, health literacy and barriers to calling 911 were not associated significantly with stroke preparedness.

Sharing and Mediation

There was an intervention effect for information sharing (H3). The results (adjusted for clustering) were that among the control group, 42% reported sharing information as contrasted with 81% of the intervention group (P<0.0001). Over time, parental stroke preparedness scores in the intervention group whose children shared stroke information (H4) with them showed greater increase than intervention parents whose children did not share stroke information (stroke preparedness items, P=0.0183; FAST composite, P=0.0019; data not shown). The model-based means for the parental preparedness test for the intervention group whose children shared information increased from 5.60 to 5.96, as contrasted with those who shared information in the control group (5.52–5.68). The comparable data for the ere 0.20 to 1.11 (intervention) and 0.07 to 0.10 (control).

We found no significant mediation effect (H4M) of child stroke preparedness scores and prevention knowledge on parental stroke preparedness scores and prevention knowledge (Figure II in the online-only Data Supplement).

Stroke Events (Secondary Aim)

We performed a total of 315 stroke event interviews on parents (200 intervention and 115 control) over a 3-year follow-up period. We found 27 (8.6%) self-reported stroke events affecting a family member, with 18 in the intervention (9%) and 9 in the control group (8%). Emergency medical services activation occurred in 14 of 18 cases (77%) in the intervention

Table 2. Child-Based Stroke Knowledge/Preparedness Over the Course of the Study (n=3070)

	Continuous (Knowledge/Preparedness Score)			Binary (1=Answered All Questions Correctly)		
	Estimate	SE	P Value	Estimate	SE	P Value
Intercept	3.4581	0.1265	<0.0001	−4.7356	0.3659	<0.0001
Intervention	2.7135	0.1736	<0.0001	4.9983	0.4470	<0.0001
Test	0.1721	0.0304	<0.0001	0.5074	0.1407	0.0003
Intervention by test	0.9298	0.0400	<0.0001	0.7870	0.1671	<0.0001
Quadratic test	−0.0973	0.0513	0.0579	0.0890	0.2659	0.7380
Intervention by quadratic test	−1.5871	0.0659	<0.0001	−2.7903	0.2863	<0.0001

		Control		Intervention		Control	Intervention
		N	Mean (SE)	N	Mean (SE)	Mean (SE)	Mean (SE)
Pre-test	Observed	1414	3.16 (0.17)	1656	3.38 (0.09)	0.01 (0.01)	0.02 (0.01)
	Model based	1414	3.19 (0.12)	1656	3.39 (0.12)	0.01 (0.00)	0.02 (0.01)
Immediate post-test	Observed	1061	3.37 (0.14)	1374	6.18 (0.07)	0.01 (0.01)	0.56 (0.03)
	Model based	1061	3.46 (0.13)	1374	6.17 (0.12)	0.01 (0.00)	0.57 (0.06)
3-month follow-up	Observed	915	3.47 (0.14)	1212	5.59 (0.13)	0.03 (0.01)	0.24 (0.04)
	Model based	915	3.53 (0.13)	1212	5.59 (0.12)	0.02 (0.01)	0.24 (0.05)

Nonlinear models predicting stroke preparedness, adjusted for clustering within school and heterogeneity in group and residual variances.

Table 3. Parent-Based Stroke Knowledge/Preparedness Over the Course of the Study (n=1144)

	Stroke Knowledge/Preparedness						FAST Stroke Identification Composite					
	Continuous			Binary (1=Answered All Questions Correctly)			Continuous			Binary (1=Answered All Questions Correctly)		
	Estimate	SE	*P* Value	Estimate	SE	*P* Value	Estimate	SE	*P* Value	Estimate	SE	*P* Value
Intercept	5.5321	0.0642	<0.0001	−1.3130	0.1448	<0.0001	0.0699	0.0236	0.0077	−4.2877	0.4216	<0.0001
Intervention	0.3254	0.0854	0.0001	0.4277	0.1962	0.0293	0.7636	0.0763	<0.0001	2.8931	0.4376	<0.0001
Test	0.1465	0.0340	<0.0001	0.1602	0.0759	0.0349	0.0437	0.0189	0.0209	0.5126	0.2718	0.0595
Intervention by test	−0.0296	0.0462	0.7792	−0.0312	0.1037	0.7632	0.2802	0.0467	<0.0001	0.4522	0.3023	0.1348
Quadratic test	−0.0135	0.0494	0.7844	−0.1425	0.1130	0.2074	0.0322	0.0227	0.1554	0.1521	0.4449	0.7326
Intervention by quadratic test	−0.2200	0.0680	0.0012	−0.2613	0.1537	0.0892	−0.4027	0.0705	<0.0001	−1.2975	0.4739	0.0062

		Control		Intervention		Control	Intervention	Control	Intervention	Control	Intervention
		N	Mean (SE)	N	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
Pre-test	Observed	527	5.37 (0.06)	617	5.50 (0.09)	0.17 (0.02)	0.20 (0.02)	0.06 (0.02)	0.14 (0.04)	0.01 (0.01)	0.03 (0.01)
	Model based	527	5.37 (0.06)	617	5.49 (0.06)	0.17 (0.02)	0.19 (0.02)	0.06 (0.02)	0.14 (0.03)	0.01 (0.00)	0.03 (0.01)
Immediate post-Test	Observed	430	5.55 (0.05)	457	5.88 (0.06)	0.21 (0.02)	0.30 (0.03)	0.07 (0.02)	0.84 (0.08)	0.01 (0.01)	0.20 (0.02)
	Model based	430	5.53 (0.06)	457	5.86 (0.06)	0.21 (0.02)	0.29 (0.02)	0.07 (0.02)	0.83 (0.07)	0.01 (0.01)	0.20 (0.02)
3-month follow-up	Observed	250	5.70 (0.06)	286	5.78 (0.05)	0.23 (0.03)	0.26 (0.03)	0.15 (0.04)	0.80 (0.07)	0.03 (0.01)	0.17 (0.02)
	Model based	250	5.67 (0.07)	286	5.76 (0.06)	0.21 (0.03)	0.24 (0.03)	0.15 (0.04)	0.79 (0.08)	0.03 (0.01)	0.17 (0.02)

Nonlinear models predicting stroke preparedness, adjusted for clustering within school and heterogeneity in group and residual variances. FAST indicates Facial droop, Arm weakness, Speech disturbance, Time to call 911.

group and 6 of 9 (66%) cases in the control group. Because of the low number of events, we were unable to draw meaningful conclusions from these data. However, 4 children, all in the intervention group, called 911 for stroke events, in 1 case overruling a parent's wait-and-see approach.

Discussion

This randomized controlled trial of a school-based stroke education program showed significant and relatively large gains in stroke preparedness for both parents and children that were sustained over at least 3 months. Using our definition of optimal stroke knowledge/preparedness (perfect scores), it was estimated that 24% of school children aged 9 to 12 years exposed to the HHS intervention as contrasted with 2% of those who were not exposed became and remained stroke prepared at 3 months. HHS children demonstrated high self-efficacy for stroke recognition, calling 911, describing stroke event to a 911 operator, and teaching their parents about stroke. Although we did not find a mediation effect between children's stroke preparedness scores and their parent's stroke preparedness scores, parents of children who shared stroke information with them showed greater increase in stroke preparedness over time than parents whose children did not share stroke information, supporting our transmission vector hypothesis. Overall, parents showed an increase in stroke knowledge/preparedness at immediate post-intervention, followed by a decline toward pretest values after 3 months, which nonetheless remained greater for the intervention than control parents. Although greater missing data at 3 months were observed for the parents (53.15%) in contrast to children (30.72%), nonlinear models for average change over time were significant in the direction of significantly greater estimated stroke knowledge/preparedness in both intervention groups relative to the control group. Moreover, significant gains in FAST literacy were observed among parents in the intervention group, and this persisted at 3 months. Translated into real-world gains in stroke preparedness, for every 100 parents whose children are exposed to the HHS intervention, 14 additional parents will pass the FAST literacy test with a perfect score.

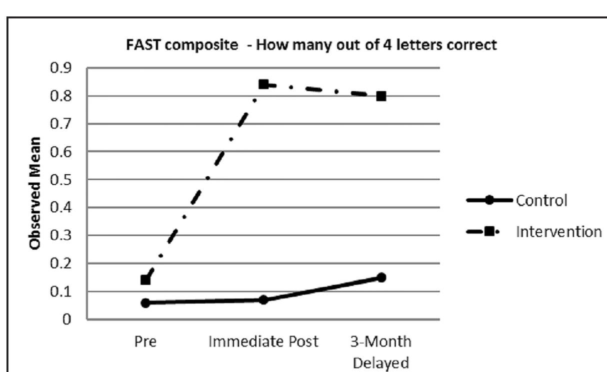

Figure 2. Stroke preparedness of parents measured by the FAST (facial droop, arm weakness, speech disturbance, time to call 911) acronym.

Beside these cognitive effects, 4 intervention children called 911 for real-life stroke occurrences among family members. These cases, combined with an additional 2 cases reported in our pilot studies,[23] although few in number (n=6), show that our intervention not only improves stroke preparedness of children, it can also translate into behavior change. We note that in our collective experience at a major New York City stroke center, it is highly unusual for preadolescent children to be a family leader in making decisions to call 911 for a recognized stroke.

One systematic literature review of school-based stroke interventions included 12 studies, which provided data on 3312 children and 612 parents.[24] The authors found a single randomized clinical trial (the second randomized clinical trial reported was an interim analysis of the same study), which enrolled older children in Sixth, seventh, and eighth grades.[25] Unfortunately, this study did not analyze parental data because of low parental participation (17% or 77/462 parents completed testing). The systematic review also found a lack of data supporting the ability of stroke-educated children to recognize and respond appropriately to stroke in the real world, and in their ability to transfer stroke knowledge to the parents.[24] A subsequent school-based randomized clinical trial involved an intervention delivered to eighth graders (adolescents) by a neurologist in the form of a stroke lecture.[26] Encouragingly, the authors provided evidence supporting the ability of these children to transfer stroke information to parents, although psychometric data on their stroke knowledge instrument were not presented. The current trial, which to the best of our knowledge is the largest of its kind to date, targets preadolescent children through Lay Health Facilitators equipped with culturally tailored multimedia that can be accessed for free online. It may therefore represent a more scalable approach.

Limitations

We had significant parental attrition over time with similar dropout rates in both arms, but maintained statistical power for the FAST outcome because of our large sample size. Sensitivity analyses examining only those respondents with at least 2 waves of data yielded estimates very close to those found in the primary intent-to-treat analyses of all respondents. These challenges reflect the practical problems of parental recruitment and retention in school-based studies, especially those targeting schools within economically disadvantaged communities. We did track and model gains in parental stroke preparedness relative to child engagement in family stroke preparedness conversations; however, the exact dose of each child's engagement cannot be determined. On stroke events, we were severely underpowered to detect meaningful differences, although this was a secondary outcome. Notwithstanding, our observations suggest that stroke-educated children aged 9 to 12 years can recognize stroke and appropriately call 911 in the real world.

Conclusions

Children may be underused conduits for reaching economically disadvantaged ethnic minorities with critical stroke information. HHS may represent an effective intergenerational alternative to mass media campaigns and may be used to support annual public stroke education requirements for stroke center certification in the United States.

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Disclosures

None.

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Stroke

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Improving Community Stroke Preparedness in the HHS (Hip-Hop Stroke) Randomized Clinical Trial

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SUPPLEMENTAL MATERIAL

Key Study Dates

The study was conducted between September 2010 and August 2015. Staggered entry recruitment of 22 schools (and child-parent dyads nested within schools) along with delivery of intervention/control programs occurred during this period. Schools were eligible if they had a high percentage of Black students (>15%), a high percentage of students who receive free lunches (>50%), and a low percentage of English Language Learners (<20%). The intervention/control program was delivered to the first school in October 2011 over three days (one hour per day) and this was preceded by a pre-test and followed by a post-test. The 3-month post-test for the first school occurred in January 2012. The final school received intervention/control programming in March 2015. This was preceded and followed by a pre-test and post-test respectively, with 3-month post-testing in June 2015.

Randomization procedures

Randomization occurred at the school level, rather than by child or classroom, to ensure minimal cross-contamination between intervention and control groups. The project statistician developed an assignment scheme using a random number generator; the PI and co-investigators were blinded to study group assignments. However for logistical reasons it was not possible for Research Coordinators to be blinded to study group assignment, which they were instructed not to disclose. An innovative aspect to the conduct of our trial was our use of an audience response system (ARS) that allowed us to track childrens' test scores throughout the trial period. The system uses a hand-held electronic wireless keypad; each child is assigned a unique password, entered via the keypad; and the children used the keypad to enter information, including their answers to probe questions (to assess learning and retention). The questions themselves were presented to the group by projecting them onto a large screen. This system allowed us to keep track of real-time test results that were stored for subsequent analysis, for a large volume of participants, without the expense and transcription errors of manual data entry. This system also ensured consistency of program content (digitized curriculum presented as a slide-show and linked with each child's keypad), format, and delivery. Data was transmitted from the ARS into an excel document along with codes and uploaded into a central repository for access by statisticians for outcome analysis. An independent group of statisticians performed the analyses. The statistician performing the main analyses was not aware of the content of the intervention.

Supplemental Figure I: Hip Hop Stroke Media

Legend: A.

This 3.5-minute, musical narrative, "role play" cartoon teaches children the relationship between stroke risk factors and stroke occurrence, and the child's power to positively influence parents' behavior. **B.** This downloadable comic book features an extended storyline from the narrative cartoons and contains an activity sheet to be completed with parents. **C.** This video game involves navigating a clot- busting spaceship intra-arterially, shooting clots that occlude the passage of blood to the brain, and highlights the importance of "time is brain". **D.** This 3.5-minute, musical narrative, "role play" cartoon teaches FAST and *non-FAST* stroke symptoms, calling 911, and the benefit of early thrombolysis.

Supplemental Table I: Hip Hop Stroke Curriculum

Modules (1 hour each)	**Topics Covered** (media A-D images can be viewed in Supplemental Figure I)
1	Pre-test. Introduction to Stroke and Subtypes. Signs and symptoms. Urgency of calling 911. Clotbuster treatment for Stroke. Viewing of Cartoons A and D. Homework Activities including sharing comic book B activities and playing Video Game C.
2	Risk Factors and Stroke Risk behaviors. Primary and Primordial Prevention measures. Review of signs and symptoms and EMS activation. Viewing of Cartoons A and D. Homework Activities including sharing comic book B activities and playing Video Game C.
3	Review of Modules 1 and 2. Viewing of Cartoons A and D. Post-test. Homework Activities including sharing comic book B activities and playing Video Game C.

Supplemental Table II: Sensitivity Analyses: Child based stroke preparedness over the course of the study for children that completed at least two tests (n=2789)

	Continuous			Binary (1=Answered all questions correctly)		
	Estimate	Std. Err.	p-value	Estimate	Std. Err.	p-value
Intercept	3.4532	0.1280	<0.0001	-4.7497	0.3771	<0.0001
Intervention	2.7198	0.1757	<0.0001	5.0131	0.4607	<0.0001
Test	0.1876	0.0308	<0.0001	0.5140	0.1466	0.0005
Intervention by test	0.9145	0.0405	<0.0001	0.8034	0.1745	<0.0001
Quadratic test	-0.1108	0.0515	0.0313	0.0807	0.2752	0.7693
Intervention by quadratic test	-1.5728	0.0662	<0.0001	-2.8055	0.2964	<0.0001

Model Based Means	Control			Intervention			Control		Intervention	
	N	Mean	Std. Err.	N	Mean	Std. Err.	Mean	Std. Err.	Mean	Std. Err.

Pre-Test	1235	3.15	(0.13)	1554	3.39	(0.12)	0.01	(0.00)	0.02	(0.01)
Immediate Post-Test	1061	3.45	(0.13)	1374	6.17	(0.12)	0.01	(0.00)	0.57	(0.07)
3-Month follow-up	915	3.53	(0.13)	1212	5.59	(0.12)	0.02	(0.01)	0.24	(0.05)

Results of non-linear models predicting stroke preparedness, adjusted for clustering within school and also heterogeneity in group and residual variances. An unstructured covariance structure was used in all analyses**.**

Supplemental Table III: Sensitivity Analyses: Parent-based stroke preparedness over the course of the study for parents that completed at least two tests (n=887)

	Continuous						Binary (1=Answered all questions correctly)			
	Estimate		Std. Err.			p-value	Estimate	Std. Err.		p-value
Intercept	5.5494		0.0604			<0.0001	-1.3032	0.1504		<0.0001
Intervention	0.3252		0.0788			<0.0001	0.4117	0.2047		0.0444
Test	0.1397		0.0347			<0.0001	0.1525	0.0773		0.0485
Intervention by test	-0.0163		0.0473			0.7307	-0.0252	0.1062		0.8127
Quadratic test	-0.0092		0.0495			0.8529	-0.1360	0.1136		0.2310
Intervention by quadratic test	-0.2132		0.0684			0.0018	-0.2662	0.1551		0.0862
Model Based Means	Control			Intervention			Control		Intervention	
	N	Mean	Std. Err.	N	Mean	Std. Err.	Mean	Std. Err.	Mean	Std. Err.
Pre-Test	430	5.40	(0.06)	457	5.53	(0.06)	0.17	(0.02)	0.19	(0.02)
Immediate Post-Test	430	5.55	(0.06)	457	5.87	(0.05)	0.21	(0.03)	0.29	(0.03)
3-Month follow-up	250	5.68	(0.07)	286	5.78	(0.06)	0.22	(0.03)	0.24	(0.03)

Parents that completed at least two tests sample: Results of non-linear models predicting stroke preparedness, adjusted for clustering within school and also heterogeneity in group and residual variances. An unstructured covariance structure was used in all analyses.

Power Analysis:

Power calculations were performed originally with given assumptions regarding the baseline rates. The study was adequately powered based on these assumptions.

Power was again estimated after study completion using the actual data from the study. The results were similar to the original except that because of different observed baseline proportions of correct responses to the knowledge preparedness questions for parents, the study was underpowered for detection of the smaller effects observed for parents in knowledge preparedness. However, power was 0.90 or greater for the child knowledge preparedness measure and for the parental stroke identification (FAST) outcome. The following are the results from re-estimation of power after data collection.

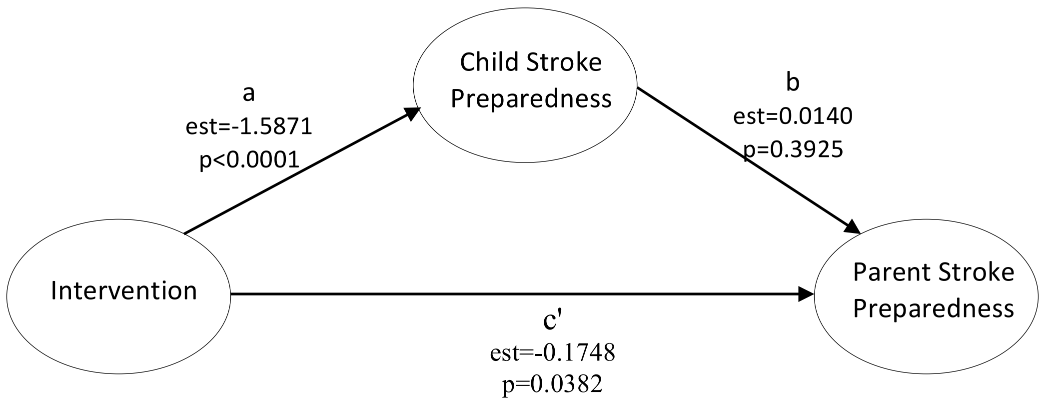
Power calculations were for endpoint differences in the proportion of children achieving 100% knowledge/preparedness. This binary outcome was used because it is that requiring the *largest sample size.* Assuming equivalence at baseline between the control and intervention groups, the difference at study end was assumed to be about 20% (the intervention group increased in children's knowledge/ preparedness by 24% and the control group by 4%); almost exactly that observed (24% and 2% increase). The assumptions were: $\alpha=0.05$ (two sided test), power=90%, intracluster correlation coefficient for clustering within schools=0.1, cluster size = 140 and reliability of outcome data of 0.90. The minimum sample size was 1023 per group for a total of 2046 students, less than the original proposed number and to that in the final sample (n=3070).

Similar scenarios were posited for parents; however, due to difficulty recruiting parents, the study was underpowered for examination of the binary outcome, knowledge/preparedness, given the smaller sample (n=1144) and effect sizes observed. However, as expected, the continuous treatment of the variable resulted in a significant effect for the preparedness variable. For the FAST measure administered to parents, and treated as binary, the net group difference observed at study end was 12% (the intervention group improved 14% and the control group 2%, adjusted by baseline). Given the above effect size, $\alpha=0.05$ (two sided test), assuming a lower intracluster correlation coefficient (0.06), and observing a cluster size of 50 parents per school, reliability (R=0.9), the minimum sample size was 515 per group (total 1030) for power=90%. Given the sample size of 1144, the study was powered for detection of the effect sizes observed for the FAST.

Mediation Analysis

The potential mediating effect of child knowledge on parent knowledge was evaluated. The pre-specified alpha level for each outcome was set at 0.05. Methods for examination of mediation effects have been evaluated in terms of statistical power[1] and performance. Although evidence from Monte Carlo studies support simple joint significance tests of the mediating path coefficients;[2,3] also examined were two other formal tests of mediation effects[4,5]. The mediating paths examined were between the intervention and the child knowledge, and between the child knowledge and parent knowledge. If both paths were statistically significant, we considered the child knowledge parameter to be mediating the effect of the intervention on parent knowledge. These formulas are appropriate for multilevel analyses with random effects such as those used to provide estimates of the path coefficients[6]. For these analyses, Aroian Z, MacKinnon & Lockwood asymmetric distribution of products[7], and joint significance of the coefficient relating the intervention with the mediator (a), and the mediator with the outcomes (b) were used[7]. Confidence intervals for the product of (a) and (b) were determined using the method of MacKinnon, Lockwood, and Williams[2].

Supplemental Figure II: Mediation effect of child stroke preparedness on parent stroke preparedness. Non-linear models predicting continuous stroke preparedness, adjusted for clustering within school and heterogeneity in group and residual variances. An unstructured covariance structure was specified in all analyses. Estimates and p-values represent the intervention by quadratic test terms (n=1005).



Reliability of Measures

Internal consistency estimates for the stroke preparedness measure for children were 0.433 at pre-test, and 0.870 and 0.766 respectively on the immediate and 3-month delayed post-tests. McDonald's omega total was 0.454 at pre-test, and 0.873 and 0.774 respectively on the immediate and 3-month delayed post-tests. The explained common variance (ECV) estimates were 25.46% at pre-test, and 62.26% and 73.00% respectively at immediate and 3-month delayed post-tests. Lower internal consistency and dimensionality indices likely reflect random response and guessing by children during the pre-test.

Among parents, internal consistency estimates for stroke preparedness items were 0.749 at pre-test, 0.745 at immediate post-test, and 0.726 at 3-month delayed post-test. Similarly, for the parent sample, the McDonald's Omega Total was greater than 0.7 and ECV estimates were greater than 45% for each test.

Deviations from the original protocol

All pre-planned analyses as reflected in the hypotheses were performed; they were presented in the order of the hypotheses. However, an additional hypothesis 2a was added to test the parental knowledge and stroke identification. The sample size analyzed was 1656 children and 617 parents in the intervention and 1414 children and 527 parents in the control groups. Eleven schools were randomized to the intervention and control groups. This number conforms to the original protocol, in which it was specified that 22 schools would be recruited and randomized. It was estimated in the protocol that 3,500 children would be in the final sample; this number is somewhat larger than that in the final sample: 3070. The power calculations from the original protocol assume that about 860 parents would be recruited. More parents (1144) were recruited. The power calculations assumed a lower base rate for knowledge questions.

"Based on our pilot data, we will use a conservative estimate of the intervention effect. We will assume a 4% baseline (parental) rate for knowledge of all five cardinal stroke symptoms plus chest pain as a distracter symptom, plus calling 911 in response to a hypothetical stroke-in-action scenario, and a 24% increase over this rate in the intervention arm." The observed baseline rate for parents was higher than anticipated: 17% in the control and 20% in the intervention. Finally, we initially included as a secondary aim the "assessment of events, latency to arrival at the emergency room". Our timeframe for these outcomes were: 12 months from completion, and every 12 months afterwards for a minimum of 2 years. Unfortunately, we were only able to record a total of 27 stroke events over an annual follow up period of 3 years. Due to this low number of events we did not pursue this outcome further as we would have been unable to draw meaningful conclusions.

Questionnaires

FAST Question:

Have you ever heard of the word "F.A.S.T." in the context of someone having a stroke? That is, do you know what each of the letters in F.A.S.T. - "F" "A" "S" "T" stands for?

( ) Yes (Please write out what FAST stands for here): F ________________________
A ________________________
S ________________________
T ________________________

( ) No, I do not know what FAST stands for.

7-item Stroke Knowledge questions:

1) Is sudden blurry vision or loss of vision a sign of stroke?
( ) Yes
( ) No

2) Are sudden chest pains a sign of stroke?
( ) Yes
( ) No

3) Is one side of the face drooping all of a sudden a sign of stroke?
( ) Yes
( ) No

4) Is sudden slurred speech or confusion a sign of stroke?

( ) Yes
( ) No

5) Is a sudden horrible headache for no known reason a sign of stroke?
( ) Yes
( ) No

6) Is sudden clumsiness or imbalance a sign of stroke?
( ) Yes
( ) No

7) You are eating lunch with a friend and suddenly, pieces of his sandwich start falling out of the right side of his mouth, and you notice that the right side of his face is drooping down. What should you do?
( ) Call '911' immediately.
( ) Call the doctor's office immediately.
( ) Tell him to lie down and take a nap.
( ) Tell him to drink lots of water.

<u>Self-Efficacy questions</u>

1. I can tell that someone is having a stroke.
( ) I am very confident that I can do this.
( ) I am confident that I can do this.
( ) I am not sure if I can do this.
( ) I do not feel confident that I can do this.
( ) I definitely cannot do this at all.

2. I know what to do if I think that someone is having a stroke.
( ) I am very confident that I can do this.
( ) I am confident that I can do this.
( ) I am not sure if I can do this.
( ) I do not feel confident that I can do this.
( ) I definitely cannot do this at all.

3. When I call '911', I can describe to an operator why I think that my friend is having a stroke.

( ) I am very confident that I can do this.
( ) I am confident that I can do this.
( ) I am not sure if I can do this.
( ) I do not feel confident that I can do this.
( ) I definitely cannot do this at all.

4. I can teach my family and friends how to tell if someone is having a stroke.
( ) I am very confident that I can do this.
( ) I am confident that I can do this.
( ) I am not sure if I can do this.
( ) I do not feel confident that I can do this.
( ) I definitely cannot do this at all.

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