Old SCHOOL Hip-Hop: Improve Alzheimer's Disease Knowledge

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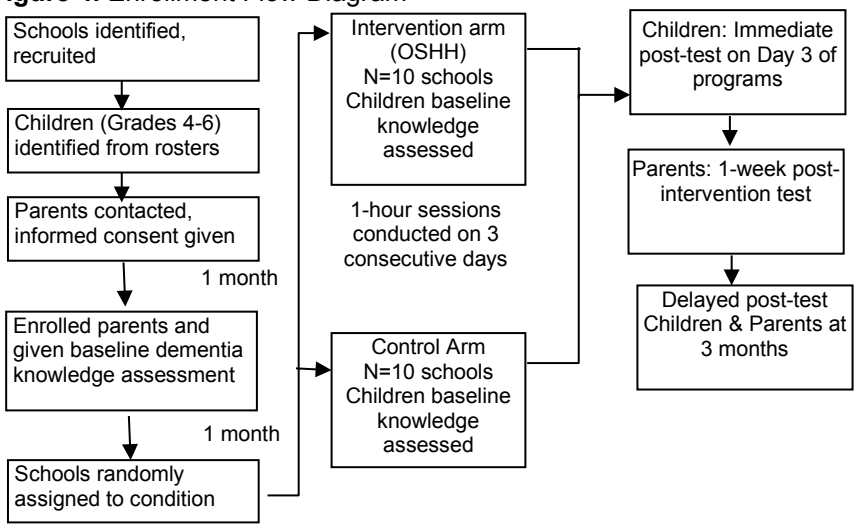
RESEARCH METHODS

6.1. Phase 1: Program Refinement. The first 6 months of the project period will focus on generating a larger item pool using focus groups and cognitive interviews. These items will be administered during the study in order to provide data for future/further development of outcome measures for AD recognition. Additionally, items to measure self-efficacy and other constructs relevant to the study goals will be added and examined in relation to the outcome; these will comprise a novel "dementia action test" (See Section 6.5.1.). Concomitantly, a 3-minute program cartoon will be developed, mapped to our song, comics, and character icons focusing on the FLOW mnemonic and primary behavioral outcomes; these products were created in advance of this application.

6.2. Phase 2: OSHH Randomized Controlled Trial

6.2.1. Study Design. We will use a cluster randomized controlled trial (RCT) design with random assignment of 10 schools to each of two arms: control and intervention (**Figure 4**). The data coordinating center has developed randomization algorithms for rolling enrollment as schools will be contacted on a rolling basis over the 5 year study period. Outcome measures are (1) Child's recall of dementia symptoms (at 3 days and 3 months follow-up), (2) parent's report of whether the child communicated the information (at 1-week follow-up) and (3) parent's recall of the symptoms and response (at 1-wk and 3-m follow-up).

Figure 4. Enrollment Flow Diagram



6.2.2. Population. 4th and 5th grade children (ages 9-11y), and their parents (age > 20 years), in selected NYC public schools with similar sociodemographic composition. **Exclusion criteria**. Schools having already received pilot OSHH and HHS programming.

6.2.3. Recruitment and Retention. School Principals identified by School District Superintendents, Department of Education Health Directors, and local relationships, will be contacted by phone. A meeting will be scheduled with research staff and the school principal to show a specially- developed 10-minute explanatory video that shows the OSHH curriculum and program objectives; and questions about the program will be answered. Once the principal has agreed for his/her school to participate, research staff will work with parent coordinators to identify 4th and 5th grade students and their parents from school rosters. Parents will be recruited in-person at school events and/or by telephone. Informed consent from parents will be obtained for the enrollment of their child and themselves in the study. Assent will be obtained from each participating child. Based on our pilot study we estimate that 35% of parents will refuse to participate. Parents and students are informed that testing will have no impact on grades or school relations.

6.2.4. Alternative recruitment strategy. In clinical trials, recruitment often becomes a problem because if the researchers have overestimated their ability to recruit at a particular site, they must have a plan to open up additional sites. That is not a relevant concern here. Once the school has agreed to serve as a site, we will include all the children in the 4th and 5th grades. If, for any reason, one or more children choose (or their parents choose) not to participate, or if the child missed school on any or all of the days on which the program was being implemented, this would not indicate a need to recruit "replacements", nor would it affect our statistical power, which is calculated using the school, not the child, as the unit of analysis.

6.3.1. Old SCHOOL Hip Hop Intervention. Hip-hop is a music genre that strongly emphasizes rhyme and dance, and is popular among diverse socioeconomic and ethnic groups.[46] Integrated rhyme and dance have been successful educational tools in non-health oriented education programs.[47-49] Hip-hop has specifically been used as a vehicle for obesity prevention in African-American preschoolers[50] as well as in our stroke education model. [1, 3, 4] Guided by an interdisciplinary team which included school principals, school-aged children with whom focus groups and semi-structured interviews were conducted, public health experts, children's education television/media experts (formerly of Sesame Street), hip hop artists, bio-behavioral researchers and clinical dementia experts, we developed our OSHH program using community engagement techniques.

In the course of project development, we were particularly mindful of the potential for introducing undue distress on these children by burdening them with the responsibility of being arbiters of family dementia knowledge. We specifically reviewed these concerns with the focus group and engaged a child psychologist, both of whom identified stroke as likely more burdensome given its immediate, urgent, and physically apparent presentations. However, due to the Entertainment Education framework of our intervention, which includes the use of the hero concept (making stroke communication to parents a potentially life-saving heroic act),we had no such adverse outcomes in the 5 year experience with our related Hip Hop Stroke (HHS) program (Section 5.1).

The final intervention is a modular 1 hour/day for 3 days school-based multi-media dementia educational program designed to increase dementia literacy among 4th and 5th grade children, and to motivate them to deliver the message to their families and adult caregivers with the aid of homework activities OSHH uses dance, culturally and age-appropriate music, role-play skits, and short animated films as motivating tools to enhance a simple didactic program delivered over three days (See **Table 1**). Students are educated using interactive play, cartoons, and an original song featuring an AD-themed rap. For the development of a mnemonic novel to this program, we reviewed validated concepts of AD relevant to public health awareness including the Alzheimer Disease Knowledge Scale, [42] the Alzheimer's Association's "Know the 10 Signs," [51] as well as extensive clinical experience of the investigators. Through our experience with the HHS program, we found that six to seven key disease knowledge elements could be reasonably included in a combination of mnemonic and simple related messaging and retained for a

Figure 5. OSHH comic book excerpt distributed at the program, reviewing the "FLOW" mnemonic and examples of normal versus pathologic cognitive aging

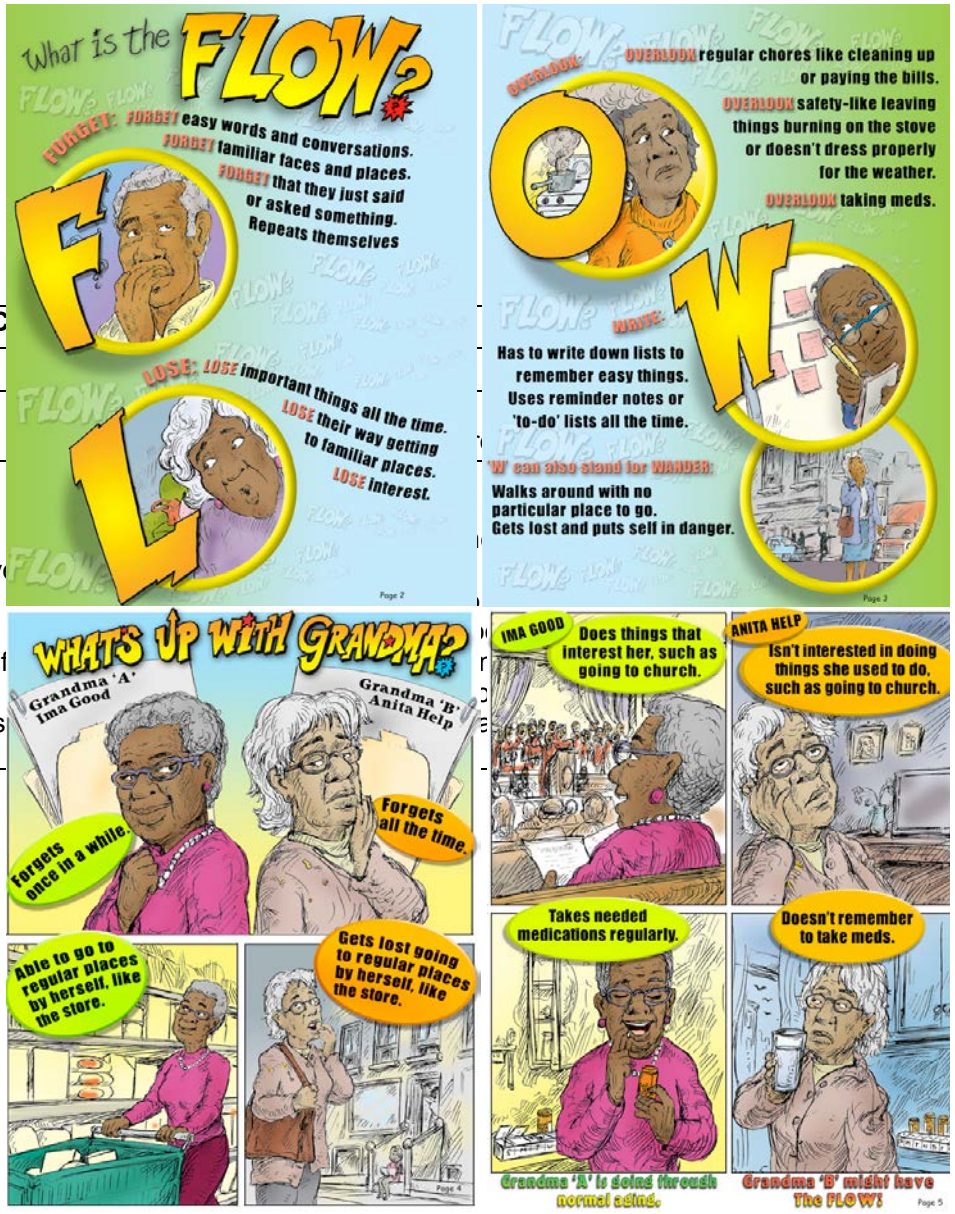


Table 1. Old SCHOOL Hip Hop Daily C

Topic	Day 1: 60 minutes
	• Pre-test and • Introduction to dementia
Content	1. Demo of electronic keypads 2. Unprompted pre-test 2. Content: a. Normal v. pathological cognitiv b. Concepts of long term storage networks c. "Go with the FLOW" animated f Section 6.5.1.b) e. Children are encouraged to dis learning's w/parents

prolonged period of time.[1, 3] As such, our group devised the "F.L.O.W." mnemonic (**F**orget, **L**ose, **O**verlook, **W**rite/**W**ander), which captures many of the cardinal symptoms of AD, including **F**orgetting conversations, words, people/names, or dates, **L**osing objects, one's way (direction), or interest, **O**verlooking bills, hygiene, household cleanliness, or safety, and increasing reliance upon **W**ritten lists or **W**andering away from the family. In addition, we include key AD educational elements of localization (that AD occurs in the brain, areas specific to memory, and the hippocampus). We also review additional AD symptoms of executive dysfunction through role play.

In response to recognizing a patient with possible AD, we teach students to "Go With The FLOW" – a call to action that includes bringing AD symptoms to the attention of unaffected adults in the family unit, encouraging medical evaluation, and using methods to improve the household safety of a person with AD. With each AD symptom, we provide comparisons with normal aging, intending to improve the sensitivity of AD symptom recognition (and lowering the false negative fraction of symptom recognition), while also focusing on deceasing the false positive symptom identification (and thus increasing specificity); we emphasize that in normal cognitive aging, symptoms occur "once in a while," whereas AD symptoms are more consistently present, occurring "all the time." The FLOW mnemonic reinforces key symptoms. Two contrasting adult characters: "Ima Good" (normal cognitive aging) and "Anita Help" (concerning for AD) are introduced to emphasize these points (**Figure 5**). After reviewing each profile, students are asked to decide if the characters are experiencing normal aging or if one "might have the FLOW" (AD). The intervention also involves behavioral engagement, with role-play of AD symptoms and communication of the AD-related information to an adult. AD concepts are introduced in a comic book (**Figure 5;** See Supplemental File: **Comic**) which is distributed during the program and made available on our website along with the program's song "Go With The FLOW." Grouped by grade, the students will be educated within school auditoriums. The educational team will be comprised of two facilitators developed and monitored as described in Section 6.4.b. Each child will be given a hand-held audience response system and an ID card with a unique 4-digit identifier – a data collection method we have used successfully in our prior studies.[52] Children will be instructed to enter the ID number during each test (See Section 6.4.b.).

3-month booster session: After 3 months, an unprompted posttest will be administered to *assess retained knowledge from the program*. This post-test will be followed by a brief OSHH booster session. **Table 1** reviews the curriculum for that date as well.

6.3.2. Attentional control condition: My Pyramid in Egypt. The program selected for the control arm, "My Pyramid in Egypt," will address nutrition, physical activity and obesity education. This program was selected because nutrition, physical activity and wellness programs are now being incorporated into New York City public school curriculums as part of a legislative directive. The New York State "Healthy Schools Act" of 2007 requires school districts to establish "School Wellness Policies" that include a nutrition education curriculum and physical activity. Trained facilitators will conduct "My Pyramid in Egypt" using Egyptian history as an entry point for the USDA's MyPyramid nutrition program. Students will learn about MyPyramid and MyPlate across the 3-day one-hour-a-day program. The educators will be shown an edited music video for Michael Jackson's Egyptian-themed video "Remember the Time." Similar to the intervention, control children will be provided with a take-home activity sheet on Day 1 to complete. Parallel pre and post-tests will be conducted with the control children, using the same test sequence as the intervention. Three months later, students will be assembled by program facilitators for an unprompted, post-test and booster "My Pyramid in Egypt" session to mirror intervention procedures.

6.4.a. Data tracking. An innovative aspect to the conduct of the trial is our use of an audience response system that allows us to track individual children's' test scores throughout the trial period.[52] The system uses a hand-held electronic wireless keypad which engages and excites children all of whom have grown up in the digital age. Each child is assigned a unique ID, entered via the keypad; and the children use the keypad to enter information, including their answers to probe questions (to assess learning and retention). The questions themselves are presented to the group by projecting them onto a large screen. This system allows us to easily keep track of real-time test results that are stored for subsequent analysis, for a large volume of participants, without the expense and transcription errors of manual data entry.

6.4.b. Program Fidelity. Program content will be standardized through a digitized, standardized curriculum (digital slide-show) and educator performance will be measured against a program standard (See Supplemental File: **Evaluator Assessment Form).** Our training program was designed for Lay Health Educators to facilitate scalability. Our Lay Health Educators having already delivered our pilot studies will be prioritized to deliver this program; their performance during the pilot program was filmed and establishes the program standard. Each additional/new Lay Health Educator will watch that performance, learn the new curriculum, and co-teach the program with one of our senior educators prior to independent facilitation. Any new educator must meet set standards for independent work prior to initiation. Research staff will thereafter perform biannual fidelity activities on program delivery to ensure compliance with OSHH protocols and procedures. Qualitative assessments of

performance will be done through videotaped performances that will be reviewed by research staff in conjunction with the educators. Educators will complete a self-assessment (See Supplemental File: **Self-Assessment Form**) in advance of being provided feedback on specific and remediable aspects of performance to meet consistent standards. Educators not meeting expected standards will be provided remediation and tracked at their subsequent performance. Two successive performances below expectations will require the educator to be formally retrained and will not be able to teach independently until meeting expectations. Quantitative assessments of educator and program performance will measured in real-time using outcomes tracked by the audience response system and linked with the qualitative observations. We will also track the use of our online program portal by participants and benchmark this access so that we can monitor it for outliers.

6.5. Procedures

6.5.1.a. Item pool generation. Focus groups and cognitive interviews will refine item generation of the planned "dementia action test" relating key FLOW items with hypothetical scenarios and expressed behavioral intent. Included will be measures demonstrating self-efficacy and attitudes, including relevant elements of the Dementia Attitudes Scale[53]

6.5.1.b. "Go With the FLOW" Cartoon development. A 3-minute program cartoon similar in style to our Hip Hop Stroke cartoons[1] will be developed and mapped to our existent song of the same title (See Supplemental File: **Lyrics**), related comics, and character icons (see **Figure 5**) focusing on the FLOW mnemonic and primary behavioral outcomes.

6.5.1.c. School selection/recruitment. The Office of School Wellness of the New York City Department of Education and local school district Superintendents will collaborate with Investigators to identify NYC schools with similar demographics, excluding schools having already participated in our programs. School Principals will be invited to participate in the research study during face-to-face presentations of the intervention and control programs. During this meeting, a specially developed 10-minute explanatory promotional video will explain the OSHH intervention and show the curriculum and program objectives, and questions will be answered.

6.5.2. Selection/recruitment of children. Children in 4th and 5th grades in participating schools will be identified from school rosters along with their parents, who will be contacted via telephone or in-person at school events by research team for the purposes of informed consent (occurs three months prior to the start of data collection).

6.5.3. Selection/recruitment of parent. To maintain statistical independence, only one adult from each family will be interviewed. Rather than arbitrarily targeting whichever parent happens to answer the phone or is met in-person, we will ask the parent to identify the adult ("parent") in the household ("household" may include relatives) who is most likely to have been the target of the child's dementia-information communications.

6.5.4. Baseline knowledge assessment in parents. Parents who have given consent will be contacted in-person at school events or by telephone one month later, and a baseline dementia knowledge questionnaire will be administered following a brief health literacy survey (see Section 6.6-6.7 for details). We will assess parental knowledge of key signs and symptoms of dementia and the correct course of action through questions identical to those used for the pre-testing of their children**.**

6.5.5. Randomization to arm. The data coordinating center has developed randomization algorithms to incorporate rolling enrollment which will be applied as schools will be contacted on a rolling basis over the 5 year study period. The investigators will not be told which arm any given school is assigned until after the baseline assessments have been completed. It is not possible to blind to condition, once intervention has been assigned.

6.5.6. Baseline knowledge assessment in children. Around one month after the baseline knowledge assessment in parents, all participating children in both arms of the trial will attend a session to be held in the school auditorium, during which children's' knowledge concerning dementia symptoms and response will be assessed (see Sections 6.6-6.7 for details).

6.5.7. Implementation of the intervention/control. The intervention and control conditions will be implemented immediately following the children's' pretest knowledge assessment. Certified lay health facilitators will conduct the intervention or usual care program in 1-hour sessions, over three consecutive days, in schools assigned to the either the intervention or control arm. An immediate post-test will be administered at the end of the third day to children in both the intervention and control arms.

6.5.8. 1-week follow-up data collection (parents). One week after the completion of the 3-day intervention and control programs, follow-up surveys will be conducted in-person at school or, when that is not possible, by telephone (with a telephone protocol of up to five telephone contact attempts if necessary). These surveys assess: (1) Has the child told parent about participating in OSHH at school and discussed dementia with them? and (2) Does the parent recall *what* the child communicated regarding the symptoms and recommended action? To assess these, the research surveyor will use a structured interview format (See Sections 6.6-6.7).

6.5.9.a. 3-month follow-up data collection (children). Three months following the 3-day intervention and control programs, students will be assembled once more in school auditoriums by program facilitators for a delayed post-test after which the educational booster sessions will be provided to students. Children in both conditions will participate in 30-minute review sessions; children in the intervention arm will see the OSHH material; those in the control arm will review the "usual care" material.

6.5.9.b. 3-month follow-up data collection (parents). Three months following the completion of the intervention and control programs, a second survey will be conducted (in-person or, when that is not possible, by telephone) on parents to assess long-term retention of the materials.

6.6. Outcome Measures

6.6.1. Dementia Symptom and Response Knowledge Assessment (student). We will use similar instruments to those in our OSHH pilot study[27] to replicate our findings by assessing children's pre- and post-test knowledge of AD symptoms and recommended action. Multiple choice questions will be given to assess knowledge of (1) *dementia localization (Where in the body does Alzheimer disease occur?(brain) In which part of the brain does Alzheimer disease happen? (Remembering part) What part of the brain helps you remember? (Hippocampus) (*2) Recognition of 6 key *signs/symptoms (Forgetting words and familiar faces and names; Losing things all the time; Overlooking chores like paying the bills and cleaning; Writing things down all the time; Having trouble counting out the right amount of money when paying; Having trouble using household appliances like a remote control or microwave) plus two distractors (Chest pains, Facial droop),* (3) *Response to symptoms presented in a hypothetical scenarios in which the dementia diagnosis is not given* (considered normal aging v. concerning for dementia (and needs to be seen by physician), (4) assessment of the FLOW mnemonic, (5) self-efficacy for dementia recognition, and (6) ability to formulate the correct action plan in response to recognizing dementia

6.6.2. Assessment of child's communication to parent about dementia signs/symptoms. This measure assesses whether the child has talked with one of the adults in the household – in both the OSHH and control arms – concerning symptoms of dementia and correct response.

6.7. Baseline measures

6.7.1. Demographic Form. Includes age, sex, and race of children and parents; also educational status, income, sex, and age of parents and caregivers; and number of adults in household. Measures of school-level economic need are available in the public domain via the NYC Department of Education.

6.7.2. Literacy Questionnaire We will assess health literacy of parents prior to baseline assessment of dementia symptoms knowledge. We will use a rapid bilingual (English and Spanish) screening tool that identifies patients at risk for low health literacy, called the "Newest Vital Sign", and has been validated by clinical studies.[54]

6.8. Power Calculations and Analyses

Power calculations were performed for the primary aim of evaluating the effect of the intervention on the parent-level recognition of AD symptoms post-test and at three months post intervention. The outcome was treated as both continuous and binary for the most conservative test of meaningful change.

6.8.1. Design Features: The design is a cluster randomized trial with random assignment of 10 schools to each of two arms. Subjects will be nested within schools and classrooms. We posit a relatively lower intra-cluster correlation coefficient (ICC) for schools than for classrooms. Estimates have been adjusted for unreliability of the outcome (estimated at R=0.70) and clustering. The variance inflation factor (V_{if}) =1.87, assuming that n_e (the average number of subjects within a class) =20; the intracluster correlation coefficient for class (ICC_{class}) =0.03 and for school (ICC_{school})=0.015; N_s (5^{th} and 6^{th} grade classes) =2. The pooled σ (standard deviation) is estimated at 1.06, based on our prior work. *Assuming a two-tailed test with α=0.05, power (1-β=80%), n=400 parents per group will be adequate to detect posited effect sizes shown below.*

6.8.2.Power and Analyses for 3 Level Cluster Sampling and Evaluation of Pre- and Post-Intervention, Treating AD Symptom Recognition as Continuous: Power calculations were from the perspective of least detectable group differences in rates of change (slopes), adjusted for the design effects of correlations induced by repeated measures of subjects nested within classrooms and schools. Different scenarios regarding correlations among the repeated outcomes were considered. The mixed model for rate of change in outcome: $y_{ijk} = \beta_0 + \beta_k T_{ij} + FU_{lm}$, (equation 1) where ijk refers to subjects, time points and group; FU_{lm} is the random effect associated with school and class; T=0 is the pre-test and immediate post-test and T=1 is the 3 month post-test. The sample size formula for the rate of change[55] is: $m' = \frac{2(z_\alpha + z_\beta)^2 \sigma^2 (1-\rho)}{n s_x^2 d^2}$, with $m=m^* V_{if}/R$;[56]

$s_x^2 = \sum (t_j - \bar{t}) = 0.667$ $V_{if} = (1+(n_e-1)\rho_e)(1+(n_s-1)\rho_s n_e \rho_e / (1+(n_e-1)\rho_e))$, where n_e is the number of subjects within class, n_s *is the number of classes within schools,* rho e is the ICC for classes, rho s is the ICC for school.[57] For different values of ρ_{rm} (the average correlation of the repeated outcome measures, we provide detectable rates of change and accompanying Cohen's d effect sizes. For ρ_{rm}=0.4, the detectable rate of change (β_1=0.29) over 3 months from the model in equation (1) translates to a Cohen's d (endpoint difference between the intervention and control group/pooled standard deviation) of 0.27 or for ρ_{rm}=0.6, β_1=0.27 and Cohen's d=0.25. Given the above scenarios, we will be able to detect relatively small effect sizes in terms of endpoint differences between the intervention and control groups. The Ancova model using a pretest score as covariate will improve power. The formula is $y_{ijk} = y_{i0k} + \beta_0 + \beta_{jk} + FU_{lm}$ where y_{i0k} is pretest score for subject i in group k and j is the time point (j=1 for immediate post-test and j=2 for the 3 month post-test). Assuming the intervention group improves by δ (Cohen's d=δ/σ) over the control group at the 3 month post-test, we can use different weights for the immediate post-test in calculating power (a_1=0 indicates no increased test performance for the intervention as contrasted with the control group at immediate post-test, a_1=1/2 indicates 50% increased performance of the intervention over the control group, and a_1=1 indicates 100% increased performance of the intervention as contrasted with the control group). The sample size formula for the Ancova model[58] is: $m' = \frac{2(z_\alpha + z_\beta)^2 \sigma^2 (1-r_b^2)}{\Delta^2}$ with $m=m^* V_{if}/R$, $r_b^2 = \sum (a_i r_{i1}) / \sqrt{\sum\sum a_i a_j r_{ij}}$, $\Delta = \sum (a_i d_i) / \sum\sum (a_i a_j r_{ij})$. As shown in **Table 2**, smaller effect sizes are detectable under the scenario that there is some improvement immediately as well as at 3 months.

Table 2. Power Analyses for Ancova.			
Correlation	a_1=0	a_1=1/2	a_1=1
ρ=0.4	δ=0.315 (d=0.300)	δ=0.210 (d=0.200)	δ=0.158 (d=0.149)
ρ=0.5	δ=0.298 (d=0.281)	δ=0.199 (d=0.188)	δ=0.149 (d=0.141)
ρ=0.6	δ=0.275 (d=0.259)	δ=0.184 (d=0.174)	δ=0.138 (d=0.130)
ρ=0.7	δ=0.246 (d=0.232)	δ=0.164 (d=0.154)	δ=0.123 (d=0.116)
The difference between intervention and control at 3 month post-test: (δ is the point difference in AD symptom recognition and d is Cohen's d)			

6.8.3. Power for 3 Level Cluster Sampling and Evaluation of Pre- and Post-Intervention, Treating AD Symptom Recognition as binary: A generalized linear model with a canonical (logit) link will be modeled using GLIMMIX. Subgroup analyses will be conducted by inclusion of interaction terms for moderator variables. Using the canonical link (Logit), the generalized linear mixed model (GLIMMIX):
$\eta = \log(p_{ijk}/(1-p_{ijk})) = \beta_k + \beta_{jk} T_{ijk} + FU_{lm}$, where i is for subjects, j time points (j=0 for pretest, j=1 for the immediate post-test and j=2 is for 3 month post) and k is for the group (1=control and 2= intervention), FU_{lm} is the random effect associated with school and class, t_j=0 is the pre-test and immediate post-test and t_j=1 is the 3 month post-test, with variance inflation factor (V_{if}). The sample size formula for intervention-control comparison of repeated binary measurements[59] is: $m' = \frac{2(z_\alpha + z_\beta)^2 (v_1/r_1 + v_2/r_2)}{d_b^2}$, where d_b is an adjusted effect size that represents the difference in log odds of passing the test for the intervention group as contrasted with the control group; $m=m^* V_{if}/R$, $v_k = (s_k^2 + c_k^2)/s_k^4$, $s_k^2 = \sum (p_{kj} q_{kj} (t_j - \tau_k)^2$, $c_k^2 = \sum\sum_{i \neq j'} \rho_{jj'} \sqrt{p_{kj} q_{kj} p_{kj'} q_{kj'}} (t_j - \tau_k)(t_{j'} - \tau_k)$, $\tau_k = \sum p_{kj} q_{kj} t_j / \sum p_{kj} q_{kj}$, $d_b = \eta_{22} - \eta_{21} - (\eta_{12} - \eta_{11}) = \log(\frac{p_{22} p_{11} (1-p_{21})(1-p_{12})}{p_{21} p_{12} (1-p_{11})(1-p_{22})})$, $r_1=r_2=1/2$ for equal subjects per group, and variance inflation factor (V_{if}) as specified above. The proportion passing (operationalized as getting 80% of items correct), assuming that the two groups are equivalent at the pre-test, and that there is no change in the

control group at immediate post-test. The table below assumes fixed adjusted differences of16.7%. (The 3 month post-test difference adjusted by the immediate post-test (P_{22}-P_{21}-(P_{12}-P_{11})=16.7%.) This restriction permits comparison of the power across different models. The models show either 5% improvement in rates of passing at 3 month post-test in the control group and or 5% or no improvement at the immediate post-test in the intervention group. **Table 3** shows that for different pre-test passing rates (from 30% to 50%), the posited adjusted difference of 16.7% can be detected with > 80% power when the correlation between repeated measure ρ=0.4 (which is conservative considering that the 3 repeated measures are within 3 months, and that increasing ρ will increase power). It also shows that as the average passing rate at 3 months approaches 50%, power will be the lowest in comparison with lower or higher passing rates. If we only used two waves of data (pretest and 3 month), the minimal detectable difference in passing rates between the intervention and control groups at 3 month post-test would be18%. Dropping the immediate post-test will result in a slight loss in power.

Table 3. Power Analyses for AD recognition

Model	Pre-Test	Immediate Post-test		3 month Post-test		Adjusted difference	Power	
	P_0	P_{11}	P_{12}	P_{21}	P_{22}	P_{22}-P_{21}-(P_{12}-P_{11})	ρ=0.4	ρ=0.5
No improvement in control Immediate post test	30%	30%	30%	30%	46.7%	16.7%	85.37%	89.51%
	40%	40%	40%	40%	56.7%	16.7%	83.05%	86.54%
	50%	50%	50%	50%	66.7%	16.7%	83.45%	85.87%
Improvement in intervention Immediate post test	30%	30%	35%	30%	51.7%	16.7%	83.33%	87.27%
	40%	40%	45%	40%	61.7%	16.7%	82.71%	85.69%
	50%	50%	55%	50%	71.7%	16.7%	84.81%	86.67%
Improvement in intervention and control post test	30%	30%	35%	35%	56.7%	16.7%	80.00%	84.02%
	40%	40%	45%	45%	66.7%	16.7%	82.93%	85.62%
	50%	50%	55%	55%	76.7%	16.7%	87.82%	89.27%

Passing rate: P_{jk} (y=1): j is the time point (j=0 for pre-test, j=1 for immediate post-test and j=2 for 3 month post-test. K=1 for control, k=2 for intervention)

6.8.4. Secondary Aims

Analyses of Correlates and Predictors of AD Recognition: Treating the outcome as continuous, relationships with variables such as economic need, educational attainment and other demographic variables will be examined using a mixed model similar to that described above for continuous outcomes.

Measurement Analyses: The proposed Data Coordinating Center (DCC) has considerable experience in the conduct of measurement analyses. A detailed explication is beyond the scope of this proposal. Briefly, qualitative methods will be used to develop an item pool for future analyses and development of an ancillary outcome measure. Although extensive qualitative work informed the development of the proposed legacy outcome measure used to power this study; it is recognized that additional measurement work would be a valuable contribution of this project. Given the large sample sizes, it would be possible to begin the development of additional measures of AD recognition. Development of the measure using factor analytic and item response theory models is beyond the scope of this project; however, generation of the item pool will be an invaluable first step in this process. The qualitative methods will include (1) convening experts and focus groups to generate additional items for the item pool; (2) ratings of the importance of the items and relationship to the construct; (3) cognitive interviews to determine the meaning of the items; (4) translation of the items.

6.8.5. Missing Data: Analyses will follow the intent-to-treat principle. Based on previous experience with similar programs, we anticipate minimal missing data. Using the above-described FIML approach to estimate treatment effects, assuming that missing data are either missing completely at random or at random; this method, with a covariate to adjust for attrition bias, yields intent-to-treat parameter estimates that are consistent with that expected if there were no missing data. Scales will be prorated for missing data, using individual imputation algorithms. If substantial missing outcome data are observed, we will use a specific imputation approach, e.g., Markov Chain Monte Carlo procedures[60] based on the amount and pattern of missing data. In the event of substantial missing data, SAS Proc MI will be used in sensitivity analyses. We will perform joint simultaneous imputation; at least 50 multiple imputations will be generated and PROC MIAnalyze will be used to combine the results and estimate the log-odds, adjusted standard errors and significance. If substantial imbalance is observed, we will use propensity score analyses to equate the groups.

6.8.7. Data Management: The Research Division of the Hebrew Home at Riverdale will serve as the DCC, and will perform data monitoring and quality assurance checks of the data, including periodic review of data distributions. Statistical staff will convert data files to SPSS or SAS in order to facilitate performance of analyses. (See subcontract budget justification for further details).

6.9 Timeline. We plan for a 6-month startup period, entering the first school in Month 7 of Y1, and thereafter in new schools, approximately every 1-2months during the 6-7month accessible school year (eliminating vacation and summative test periods; parental assessments can occur year-long). Data collection for all but follow-up reports of events will cease in Month 3 of Year 5, allowing a 9-month period for data analysis, preparation of results, and completion of recruitment measures. Throughout the timeline, schools receiving the intervention arm and having completed all study components will receive the active control condition, as requested by our partnering schools given NYC mandates to general health education initiatives. **Table 4** shows the timeline.

Table 4. School Enrollment Timeline

Year	Visit	Month											
		1	2	3	4	5	6	7	8	9	10	11	12
1	Start	Item pool generation Start-up period; recruitment; cartoon creation (As described in 6.5.1.a-c.)						S1			S2		
	1-wk							S1			S2		
	3-m										S1		
2	Start		S3	S4			S5	S6			S7	S8	
	1-wk		S3	S4			S5	S6			S7	S8	
	3-m	S2				S3	S4			S5	S6		
3	Start		S9	S10			S11	S12			S13	S14	
	1-wk		S9	S10			S11	S12			S13	S14	
	3-m	S7	S8			S11	S12			S11	S12		
4	Start		S15	S16			S17	S18			S19	S20	
	1-wk		S15	S16			S17	S18			S19	S20	
	3-m	S13	S14			S15	S16			S17	S18		
5	Start				Data analysis, manuscript preparation; final data collection if necessary								
	1-wk												
	3-m	S19	S20										

REFERENCES:

1. Williams O, Noble JM. 'Hip-hop' stroke: a stroke educational program for elementary school children living in a high-risk community. Stroke; a journal of cerebral circulation 2008;39:2809-2816.
2. Williams O, Leighton-Herrmann E, DeSorbo A, et al. Hip Hop Stroke: Study Protocol for a Randomized Controlled Trial to Address Stroke Literacy. Journal of clinical trials 2015;5.
3. Williams O, Desorbo A, Noble J, Shaffer M, Gerin W. Long-term learning of stroke knowledge among children in a high-risk community. Neurology 2012;79:802-806.
4. Williams O, DeSorbo A, Noble J, Gerin W. Child-Mediated Stroke Communication: findings from Hip Hop Stroke. Stroke; a journal of cerebral circulation 2012;43:163-169.
5. Fillenbaum GG, Heyman A, Huber MS, et al. The prevalence and 3-year incidence of dementia in older Black and White community residents. J Clin Epidemiol 1998;51:587-595.
6. Gurland BJ, Wilder DE, Lantigua R, et al. Rates of dementia in three ethnoracial groups. Int J Geriatr Psychiatry 1999;14:481-493.
7. Hendrie HC, Osuntokun BO, Hall KS, et al. Prevalence of Alzheimer's disease and dementia in two communities: Nigerian Africans and African Americans. Am J Psychiatry 1995;152:1485-1492.
8. Heyman A, Fillenbaum G, Prosnitz B, Raiford K, Burchett B, Clark C. Estimated prevalence of dementia among elderly black and white community residents. Arch Neurol 1991;48:594-598.
9. Husaini BA, Sherkat DE, Moonis M, Levine R, Holzer C, Cain VA. Racial differences in the diagnosis of dementia and in its effects on the use and costs of health care services. Psychiatr Serv 2003;54:92-96.
10. Perkins P, Annegers JF, Doody RS, Cooke N, Aday L, Vernon SW. Incidence and prevalence of dementia in a multiethnic cohort of municipal retirees. Neurology 1997;49:44-50.
11. Schoenberg BS, Anderson DW, Haerer AF. Severe dementia. Prevalence and clinical features in a biracial US population. Arch Neurol 1985;42:740-743.
12. Tang MX, Cross P, Andrews H, et al. Incidence of AD in African-Americans, Caribbean Hispanics, and Caucasians in northern Manhattan. Neurology 2001;56:49-56.
13. Unverzagt FW, Gao S, Baiyewu O, et al. Prevalence of cognitive impairment: data from the Indianapolis Study of Health and Aging. Neurology 2001;57:1655-1662.
14. Weintraub D, Raskin A, Ruskin PE, et al. Racial differences in the prevalence of dementia among patients admitted to nursing homes. Psychiatr Serv 2000;51:1259-1264.
15. Tang MX, Stern Y, Marder K, et al. The APOE-epsilon4 allele and the risk of Alzheimer disease among African Americans, whites, and Hispanics. Jama 1998;279:751-755.
16. Connell CM, Scott Roberts J, McLaughlin SJ. Public opinion about Alzheimer disease among blacks, hispanics, and whites: results from a national survey. Alzheimer Dis Assoc Disord 2007;21:232-240.
17. Werner P. Knowledge about symptoms of Alzheimer's disease: correlates and relationship to help-seeking behavior. Int J Geriatr Psychiatry 2003;18:1029-1036.
18. Blay SL, Piza Peluso Ede T. The Public's ability to recognize Alzheimer disease and their beliefs about its causes. Alzheimer Dis Assoc Disord 2008;22:79-85.
19. Arai Y, Arai A, Zarit SH. What do we know about dementia?: a survey on knowledge about dementia in the general public of Japan. Int J Geriatr Psychiatry 2008;23:433-438.
20. Rimmer E, Wojciechowska M, Stave C, Sganga A, O'Connell B. Implications of the Facing Dementia Survey for the general population, patients and caregivers across Europe. Int J Clin Pract Suppl 2005:17-24.
21. Werner P. Lay perceptions about mental health: where is age and where is Alzheimer's disease? Int Psychogeriatr 2005;17:371-382.
22. Mukadam N, Cooper C, Livingston G. A systematic review of ethnicity and pathways to care in dementia. Int J Geriatr Psychiatry 2011;26:12-20.
23. Hinton L, Franz CE, Yeo G, Levkoff SE. Conceptions of dementia in a multiethnic sample of family caregivers. J Am Geriatr Soc 2005;53:1405-1410.
24. Alzheimer’s Foundation of America. ICAN 2: Investigating Caregivers’ Attitudes and Needs.2007.
25. Clark PC, Kutner NG, Goldstein FC, et al. Impediments to timely diagnosis of Alzheimer's disease in African Americans. J Am Geriatr Soc 2005;53:2012-2017.
26. Fox C, Buchanan-Barrow E, Barrett M. Children's understanding of mental illness: an exploratory study. Child Care Health Dev 2008;34:10-18.
27. Noble JM, Hedmann MG, Williams O. Improving dementia health literacy using the FLOW mnemonic: pilot findings from the Old SCHOOL hip-hop program. Health education & behavior : the official publication of the Society for Public Health Education 2015;42:73-83.
28. Wimo, Winblad, Jönsson. An estimate of the total worldwide societal costs of dementia in 2005.

Alzheimer's & Dementia: The Journal of the Alzheimer's Association 2007;3:81-91.
29. ADI. Common Questions [online]. Accessed December 11, 2006.
30. Honig LS, Tang MX, Albert S, et al. Stroke and the risk of Alzheimer disease. Arch Neurol 2003;60:1707-1712.
31. Hutchinson RG, Watson RL, Davis CE, et al. Racial differences in risk factors for atherosclerosis. The ARIC Study. Atherosclerosis Risk in Communities. Angiology 1997;48:279-290.
32. Luchsinger JA, Mayeux R. Cardiovascular risk factors and Alzheimer's disease. Curr Atheroscler Rep 2004;6:261-266.
33. Noble JM, Manly J, Schupf N, Mayeux R, Luchsinger J. Possible disparate contribution of diabetes to cognitive impairment in elderly minorities.[abstract]. Neuroepidemiology 2007;28:125.
34. Morley JE, Morris JC, Berg-Weger M, et al. Brain health: the importance of recognizing cognitive impairment: an IAGG consensus conference. Journal of the American Medical Directors Association 2015;16:731-739.
35. Gauthier SG. Alzheimer's disease: the benefits of early treatment. European journal of neurology 2005;12 Suppl 3:11-16.
36. Weimer DL, Sager MA. Early identification and treatment of Alzheimer's disease: social and fiscal outcomes. Alzheimer's & dementia : the journal of the Alzheimer's Association 2009;5:215-226.
37. Ngandu T, Lehtisalo J, Solomon A, et al. A 2 year multidomain intervention of diet, exercise, cognitive training, and vascular risk monitoring versus control to prevent cognitive decline in at-risk elderly people (FINGER): a randomised controlled trial. Lancet 2015;385:2255-2263.
38. Norton S, Matthews FE, Barnes DE, Yaffe K, Brayne C. Potential for primary prevention of Alzheimer's disease: an analysis of population-based data. The Lancet Neurology 2014;13:788-794.
39. U.S. Census Bureau. Resident Population by Age and Sex: 1980 to 20072008 May 1.
40. Simmons T, Dye JL. Grandparents Living with Grandchildren: 2000. Census 2000 Brief: U.S. Department of Commerce, U.S. Census Bureau, Customer Service Center. Tel: 301-763-4636; e-mail: webmaster@census.gov; Web site: http://www.census.gov., 2003.
41. Seshadri S, Beiser A, Kelly-Hayes M, et al. The lifetime risk of stroke: estimates from the Framingham Study. Stroke 2006;37:345-350.
42. Carpenter BD, Balsis S, Otilingam PG, Hanson PK, Gatz M. The Alzheimer's Disease Knowledge Scale: development and psychometric properties. The Gerontologist 2009;49:236-247.
43. Fishbein M. A reasoned action approach to health promotion. Medical decision making : an international journal of the Society for Medical Decision Making 2008;28:834-844.
44. Coleman MT, Pasternak RH. Effective strategies for behavior change. Primary care 2012;39:281-305.
45. Singhal A, Rogers EM. A theoretical agenda for entertainment—education. Communication theory 2002;12:117-135.
46. NielsenMedia. Soundata Music Consumer Panel Question 23: How many rap purchases have you made in the last six months? [provided by The Nielsen Company]2001 October.
47. Garvin K. Rhyme and Reason: Teaching With a Hip-Hop Beat; Duo Helps Kids Learn With the Music they Love [online]. Available at: http://abcnews.go.com/US/story?id=2249916&page=1. Accessed June 1.
48. Capps R. Multiplication Hip-Hop lays down the 411 on Math. Washington Post 2003 Monday, July 7, 2003;Sect. C01.
49. Staum MJ. A music/nonmusic intervention with homeless children. Journal of Music Therapy 1993;30:236-262.
50. Fitzgibbon ML, Stolley MR, Schiffer L, Van Horn L, KauferChristoffel K, Dyer A. Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. The Journal of pediatrics 2005;146:618-625.
51. Alzheimer's Association. Know the 10 Signs [online]. Available at: http://www.alz.org/national/documents/checklist_10signs.pdf. Accessed December 1, 2011.
52. DeSorbo AL, Noble JM, Shaffer M, Gerin W, Williams OA. The use of an audience response system in an elementary school-based health education program. Health education & behavior : the official publication of the Society for Public Health Education 2013;40:531-535.
53. #39, Connor ML, McFadden SH. Development and Psychometric Validation of the Dementia Attitudes Scale. International Journal of Alzheimer's Disease 2010;2010.
54. Shealy KM, Threatt TB. Utilization of the Newest Vital Sign (NVS) in Practice in the United States. Health communication 2015:1-9.
55. Diggle P, Heagerty P, Liang KY, Zeger S. Analysis of Longitudinal Data: OUP Oxford, 2013.

56. Fleiss JL. Design and Analysis of Clinical Experiments: Wiley, 2011.
57. Teerenstra S, Moerbeek M, van Achterberg T, Pelzer BJ, Borm GF. Sample size calculations for 3-level cluster randomized trials. Clinical Trials 2008;5:486-495.
58. Overall JE, Doyle SR. Estimating sample sizes for repeated measurement designs. Controlled clinical trials 1994;15:100-123.
59. Jung SH, Ahn CW. Sample size for a two‐group comparison of repeated binary measurements using GEE. Statistics in medicine 2005;24:2583-2596.
60. Rubin DB. Multiple imputation after 18+ years. Journal of the American statistical Association 1996;91:473-489.