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Experience Corps: A dual trial to promote the health of older adults and children's academic success

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Abstract

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Background—As the population ages, older adults are seeking meaningful, and impactful, post-retirement roles. As a society, improving the health of people throughout longer lives is a major public health goal. This paper presents the design and rationale for an effectiveness trial of Experience Corps™, an intervention created to address both these needs. This trial evaluates (1) whether senior volunteer roles within Experience Corps™ beneficially impact children's academic achievement and classroom behavior in public elementary schools and (2) impact on the health of volunteers.

Methods—Dual evaluations of (1) an intention-to-treat trial randomizing eligible adults 60 and older to volunteer service in Experience Corps™, or to a control arm of usual volunteering opportunities, and (2) a comparison of eligible public elementary schools receiving Experience Corps™ to matched, eligible control schools in a 1:1 control:intervention school ratio.

Outcomes—For older adults, the primary outcome is decreased disability in mobility and Instrumental Activities of Daily Living (IADL). Secondary outcomes are decreased frailty, falls, and memory loss; slowed loss of strength, balance, walking speed, cortical plasticity, and executive function; objective performance of IADLs; and increased social and psychological engagement. For children, primary outcomes are improved reading achievement and classroom behavior in Kindergarten through the 3rd grade; secondary outcomes are improvements in school climate, teacher morale and retention, and teacher perceptions of older adults.

Summary—This trial incorporates principles and practices of community-based participatory research and evaluates the dual benefit of a single intervention, versus usual opportunities, for two generations: older adults and children.

Keywords

1. Introduction

1.1. The world's populations are aging [1]

We will soon live one-third of our lives post-retirement [2]. For many people the opportunity to make a lasting contribution, known as *generativity*, is a key to successful aging [3,4]. Substantial unmet societal needs exist which could be addressed through the skills, experience, and generative goals of older adults, but there are few such roles. One major societal need is ensuring the early academic success of children, which predicts success throughout life [5].

Population aging calls for new approaches to help people stay healthy throughout longer lives. Health behaviors remain central to health and function to oldest ages, including physical [6,7], social [8,9], and cognitive activities [10,11], and social engagement [12,13]. Further, physical activity and social engagement predict cognitive function [14,15]. Positive health behaviors have potential to prevent significant amounts of aging-associated frailty, disability and loss of independence [16,17]. Notably, the major behavioral interventions tried are those to increase physical activity. However, few exercise programs are successful in recruiting a broad array of older adults or retaining them long-term, particularly those

from subgroups at high risk for health disparities and adverse outcomes [18,19]. Additionally, although cognitive training programs have been successful in enhancing cognitive abilities and memory, generalizability to everyday activities is limited [20,21]. New approaches to support positive behaviors are needed that a) are attractive to diverse older adults, b) will motivate long-term participation, c) are beneficial to health and generalize to real health outcomes, and d) can have broad dissemination throughout communities.

1.2. Intervention rationale

We theorized that a program could be designed to provide older adults with generative roles that improve academic success of young children, and that this would be attractive to diverse older adults who would stay in such roles long-term if the impact was high and roles were meaningful [22–24]. Further, we theorized that if evidence-based health promotion was embedded in the program, targeting multiple behaviors to create additive or synergistic benefits, communities could be provided with long-term, "high dose" health promotion and prevention benefits, reaching older adults not reached by traditional health promotion programs [23,24].

1.3. Program origins

Building on this theoretical framework, we previously designed a program, entitled Experience Corps™ (EC) [23,24], which underwent demonstration implementation in 5 cities in 1995–7 [23], followed by the ongoing development and standardization of program components and pilot implementation in Baltimore, Maryland since 1998 [24–31]. The EC, detailed below, is now operating in multiple cities across the United States. Impact has been evaluated, to date, in several ways. First, our preliminary data indicate that the EC program is associated with improved risk factors of increased physical, cognitive, and social activities and generative fulfillment [23–30] for volunteers, and improved classroom behavior and reading performance in students [31] consistent with a priori hypotheses; this is based on the results of a pilot randomized trial of EC in Baltimore [24,25,27–30] and a case–control comparison study [26]. Separately, evaluations of the aspect of the program that specifically tutors in reading, a subset of the broader EC model, have been evaluated in 3 cities in a design in which teachers referred students who needed reading support, and they were randomly assigned to receive tutorship by EC volunteers or to a control group, and followed for 1 school year. These students showed gains in readership skills for students working with the EC volunteers, especially those who received at least 35 tutorship sessions in the year, compared to controls [32,33]. Further, case– control evaluation of EC volunteers in 17 cities across the United States indicates that EC participants report fewer self-reported depressive symptoms and functional limitations after 2 years of participation in EC, compared to controls [34]. However, definitive evaluation of bi-generational and cross-generational benefits remains to be determined, including effects on disability in older adults, aggregate effects on both reading success and school behavior in children, and evidence of the causal pathways in this multimodal intervention. The present study presents the design of the now-implemented trial of dual effectiveness of older volunteers serving in EC Baltimore both for schools and children and for older adults' health outcomes.

2. Materials and methods: study design

2.1. Overview

An intention-to-treat, randomized, controlled effectiveness trial recruiting adults 60 and older who are eligible and randomizing them to the intervention, EC participation, or to a usual volunteering opportunity, wait-list control. Those randomized to EC are assigned to serve for at least one year in a public elementary school, with grades Kindergarten through the third grade. Evaluations for older adults' outcomes are at baseline, 4, 8, 12, 16, 20, and 24 months. Schools receiving the EC program are compared to matched, nonparticipating schools. The impact of EC is evaluated at the level of the individual child as well as at the school level. The design and methods of the trial are described in detail below.

2.2. Principal hypotheses and objectives

The EC trial was designed [23,24] to test the hypotheses that older volunteers serving in this innovative model of senior volunteering, i.e., engaged in a high-intensity service program which trains volunteers in roles designed to impact children's academic success and places them in a critical mass in public elementary schools, could have significant impact on academic success of children in Kindergarten through the third grade (Fig. 1b) [23,25,31] as measured by meaningful improvements in children's reading by standardized achievement tests and school record data, as well as improvements in classroom behavior, compared to comparison schools. Secondarily, we hypothesized that a critical mass of volunteers serving with a high-intensity time commitment would positively affect school climate, teacher retention, and teacher absenteeism (Fig. 1b) [23–25,31]. Simultaneously, we hypothesized that such a program, carefully designed to deliver a clinically significant prevention "dose" of physical, social, and cognitive activities in a context supporting retention [23–25], would decrease disability in mobility (primary outcome) as well as falls, frailty, depression, and declines in memory and executive function in the volunteers, and improve social supports, generativity, self and collective efficacy, and purpose in life (secondary outcomes), compared to other volunteering opportunities (Fig. 1a). Finally, we hypothesized that the outcomes for volunteers and students would create a positive feedback loop, with children's improvements positively affecting retention and program satisfaction of volunteers, as well as personal and collective efficacy, and that the program would successfully attract older adults at risk for health disparities, providing a vehicle for ameliorating these disparities [23,24].

2.3. Randomized trial of older volunteers

This randomized, controlled effectiveness trial is based on the principles of community-based participatory research.

2.3.1. Eligibility criteria—All persons 60 years or older agree to accept randomization to intervention or control, and further agree that, if randomized to EC, they would serve 15 or more hours per week for a full school year and would be able to travel to an assigned school. For final eligibility participants must be functionally literate at or above the 6th grade level (by WRAT-4), cognitively intact enough to be able to assist teachers and children in a safe and effective manner (based on Mini-Mental State Exam cutoff score of 24); have passed

the criminal background and alcohol breathalyzer tests required by the school system; and be behaviorally acceptable to the Principal of their assigned school.

2.3.2. Recruitment—The goal is to recruit diverse volunteers 60 and older [27], recruiting on the basis of a trial to evaluate impact of EC vs. usual volunteering roles. Outreach is conducted through a variety of vehicles, including (a) at health fairs, senior centers and housing, life care communities, churches, and community organizations; (b) mailings to members of clubs, AARP, and other retiree organizations, senior housing facilities, and senior centers; and (c) targeted radio stations, including public service announcements and advertising. Older adults responding by phone or in-person are then recruited using a five-step screening and intake protocol (Fig. 2):

Step 1	Initial screening interview obtains core eligibility information (age, time commitment, demographics, and motives for volunteering).
Step 2	Informational meetings provide full information about the trial, including goals, commitment, randomization procedures and evaluations, through standardized presentation and answering questions.
Step 3	Eligibility assessment, evaluation, and randomization: Interested, initially eligible older adults are scheduled to undergo formal eligibility assessment (WRAT-4 and MMSE) and evaluation (Table 1). If eligible, they complete informed consent and baseline evaluation and then are randomized to the EC intervention or control arm. Those randomized to the EC group proceed to Steps 4 and 5. Those randomized to the control arm are referred to the Baltimore City Commission on Aging and Retirement Education for volunteering opportunities.
Step 4	Criminal background check and alcohol breathalyzer tests are conducted by the Baltimore City Public School System, with compliance monitored through the EC data system.
Step 5	Training: Those assigned to the EC intervention arm participate in a 1-week, 30-hour training program (see Section 2.3.4.2.1).

2.3.3. Randomization algorithm for older adults—A double randomization algorithm was used to determine intervention status of consented and study-eligible adults 60 years and older based on pseudorandom numbers generated by RANUNI in SAS (SAS 6.12, SAS Institute Inc., Cary, NC). The randomization was stratified by a) sex and b) by participation in the Brain Health Study (BHS), a nested sub-study designed to evaluate intervention-related changes in biomarkers of brain health that may serve as proximal, mechanistic outcomes to more distal behavioral changes. There were four separate randomization schedules (strata): (A) men not in the BHS, (B) women not in the BHS, (C) men in the BHS, and (D) women in the BHS. Four sets of letters were generated from the randomization lists (see Fig. 3a). These letters contained the randomized treatment assignment and were placed in sequentially numbered envelopes by a staff member who was not associated with the evaluations. The study protocol directed that the envelopes were to be handed out in a strict numerical order to participants as they were determined to be eligible. During the eligibility

visit (Fig. 2), consent was obtained and eligibility determined. The baseline evaluation was then performed, after which the next envelope in the appropriate stratum was selected and handed to the participant. The envelope was opened by the participant in the presence of the study coordinator. The resulting assignments were electronically registered into the trial database.

2.3.4. Intervention arm: Experience Corps™ assignment

2.3.4.1. Overview of EC program design and roles for volunteers [23,24]: A critical mass of volunteers (generally 15–20 per school) is trained (Section 2.3.4.2.1) and placed in a given public elementary school, in teams of 7–10, to maximally impact on academic achievement by entire grades, from Kindergarten through the 3rd grade, with the number of volunteers per school chosen to meet the critical mass criteria [23–25]. Volunteers are assigned to a school based on personal preference, including convenience of geographic access, and on matching of skills of the volunteer with school needs. Those randomized to the EC intervention arm serve at least 15 h per week (generally over 3–4 days per week) for the full academic year (September through June), performing standardized roles. They are invited to continue participation for a second year.

Volunteers' roles were created by EC Baltimore [23,24,31], in a collaboration between gerontologists, cognitive psychologists, and early childhood educators, based on school Principals' identification of roles addressing the most important unmet needs for the children's academic success and on epidemiologic evidence as to potential health promoting content for the older adults. They are designed to be high-impact for individual children and entire classrooms and grades, through the placement of a critical mass [25] of trained older adult volunteers in each school and to, simultaneously, improve health outcomes for the volunteers. The roles for older volunteers, deployed in Kindergarten through the 3rd grade, include: literacy support, math support, library support, behavior management and violence prevention activities, school attendance support, computing support, and enhancing parental involvement [24,31]. All volunteers assigned to EC receive training in the first four roles, and then supplemental training if they elect to add additional roles over time. School-based teams meet formally at least biweekly for discussion and problem solving, as well as refresher training.

2.3.4.2. Core features of the intervention are performance of standardized, trained, meaningful roles designed for impact: Volunteering for a minimum of 15 h/week through the full school year, with option to continue to volunteer for a second year; training and infrastructure support provided by the program; volunteers trained and assigned in teams of 7–10; a critical mass of volunteers assigned to each school [25], defined as the number of volunteers adequate to improve major children's outcomes across whole grades and the school, i.e. aggregate success; an incentive stipend for the reimbursement of costs of volunteer participation; in-service learning and leadership opportunities; and diversity of volunteers. The program was designed to be a turn-key program, that is, conducting the recruitment, screening, training, and deployment to schools, and the ongoing management of volunteers without demand on school resources [23,24,27].

2.3.4.2.1. Experience Corhps™ training process: The Experience Corps™ training process includes:

1. Standardized training manual, materials, and videotapes; training is conducted by the staff of the Greater Homewood Community Corporation (GHCC), the community-based partner in trial and program implementation.

2. Volunteer training: Five-day, one-week long standardized training program (30 h total). The training includes lecture, discussion, exercises, role plays, and handouts designed to provide necessary skills in a) orientation to the school environment; b) working with today's children, and their needs; c) overview of roles for volunteers in the school; d) basic skills necessary to perform EC roles and e) what they can and cannot do as EC volunteers in schools (i.e., they do not run a class, either with or in the absence of a teacher, and their roles are substantially to meet major unmet needs for children's success). A secondary purpose of training is to promote a sense of community among volunteers, assign them into teams who will work in a school together, and to train them in teamwork. Training culminates in a formal graduation ceremony attended by local and national dignitaries.

3. Returning volunteer refresher training: Sessions are conducted annually at the beginning of the school year, to discuss volunteer experiences from the previous year, to review volunteer responsibilities and roles, and to introduce any changes in schools, skills, procedures, or expectations.

4. Principal training: 1-hour orientation session; similar to teacher training, it also includes information on selecting classrooms, how the program should be introduced to teachers, identifying an optimum critical mass of volunteers for a school [23–25,31], methods for problem-solving with the program, etc.

5. Teacher training; 1-hour standardized group training program presented prior to the placement of volunteers in the school, at the school itself. Training includes presentations on a)background and core elements of EC program design; b) volunteer eligibility criteria; c) contents of volunteer training including areas in which volunteers are trained and which are appropriate for service: literacy support, math support, library support, behavior management, etc.; d) description of volunteer duties; and e) roles that are appropriate (and those not appropriate) for volunteers.

2.3.4.2.2. Experience Corps™ volunteer placement process: The volunteers enter a school in teams who are trained together, in two approximately equal waves, a few months apart. This permits the schools to become acclimated to a small group of volunteers before the program is expanded to a critical mass of older adults in each school.

Volunteers are assigned individually to their roles in the school by the Principal, as determined to be needed and appropriate. The Principal provides additional or refresher training, as indicated. The Principal has final authority to decide if a volunteer is inappropriate or unsafe and should be asked to leave.

2.3.5. Control arm—Older adults randomized to the control arm are referred to the Baltimore City Commission on Aging and Retirement Education (CARE), where usual volunteer opportunities in Baltimore City, other than EC, are offered; these are selected to be of short duration and/or low time demand, such as volunteering at health fairs, city festivals, and senior center events. Those in the control arm are wait-listed for participation in EC after two years, should they remain interested.

2.3.6. Participant incentives—Volunteers assigned to the EC intervention arm receive a stipend of approximately $250 per month (taxable), for reimbursement of out-of-pocket expenses of this high-intensity volunteering, such as carfare and lunches at school. For participating in evaluations, both control and EC intervention arm participants receive a $10 gift card for participating in phone evaluations and a $25 incentive gift card for in-person interviews.

2.3.7. Outcomes

2.3.7.1. Primary outcome: Decreased disability in mobility. Mobility disability was defined as any self-reported difficulty of walking a distance of 1 mile and/or difficulty walking several blocks. To increase the sensitivity of detecting change in mobility over time, we will include as secondary measures of mobility disability the validated disability and function scales measured by the Late Life Function & Disability Questionnaire [35,36].

2.3.7.2. Secondary outcomes: Decreased falls and frailty [37]; decreased rate of decline in memory; increased, preserved, or slowed decline in strength, balance, walking speed, cortical plasticity, executive function, and self-reported money management.

2.3.8. Data collection for older adults—Standardized data are collected by trained interviewers at baseline, and at follow-up months 4, 8, 12, 16, 20, and 24. In-person interviews lasting 2 h are conducted at approximately baseline, 4-, 12-, and 24 months to evaluate health outcomes and participation in volunteer roles. Telephone interviews are conducted at 8-, 16-, and 20 months to assess vital status and collect brief data on health status and volunteer hours and activities, to monitor intervention fidelity and assist retention. See Table 1 for outcome measures assessed, and timing.

2.3.9. Sample size—The sample sizes for older volunteers were predetermined in this trial. This randomized, controlled trial has recruited 702 adults 60 years and older, with 352 randomized to the EC arm and 350 randomized to the control group. Volunteers are randomized, trained, and assigned from September through January of each year. A critical mass of volunteers (at least 15– 20) is assigned to each school. The sample size of 702 older adults will provide adequate power to detect meaningful EC treatment effects for the primary outcomes (Section 2.3.7.1). This sample size provides 18.5 volunteers per school, providing a critical mass within each school, based on an average of 20 volunteers per school and an estimated 9% dropout before a second year involvement in the trial.

2.4. Evaluation of impact of Experience Corps™ on public elementary schools

> *Greater Homewood Community Corporation* (GHCC) is leading the implementation of the EC program (Section 2.3) incrementally in 22 schools over 4 years, in collaboration with the Baltimore City school system.
>
> **2.4.1. Design of school evaluation—**Although randomization of schools to either receive EC or to control status is the gold standard to which we aspire, political realities made it impossible to randomize. For example, the city government wanted to select certain schools for participation based on the level of educational need or political considerations. To maximize inference validity, we therefore identified control schools via the propensity score matching approach, as detailed in Section 2.4.3.1.
>
> **2.4.2. School eligibility criteria—**To be eligible to apply, public elementary schools must be in Baltimore City and meet the following criteria if participating in EC:
>
> > **a.** have community organization partners who will collaborate in implementation;
> >
> > **b.** agree to accept a minimum of 15 EC volunteers and assign them to work with students in Kindergarten through the third grade;
> >
> > **c.** agree to provide a school-based contact person (with decision-making powers) with whom EC staff can communicate and problem solve;
> >
> > **d.** agree to provide orientation to the school and teachers for volunteers;
> >
> > **e.** commit to a 1-hour training for any teachers working with volunteers and for the Principal;
> >
> > **f.** provide a room or gathering space for volunteers and desk space for a site coordinator;
> >
> > **g.** agree to provide behavioral and attendance data, aggregated at the school level, annually (see outcome measures in Section 2.4.5).
>
> **2.4.3. School recruitment—**GHCC sends Requests for Proposals (RFP) to all public elementary schools in Baltimore City, in collaboration with the city school system. Schools that respond to the RFP are reviewed by a committee to determine their eligibility. Schools are also recruited directly through an annual school resource fair and are subject to the same eligibility requirements.
>
> **2.4.3.1. School selection:** Intervention schools that meet the above criteria are selected by a committee of investigators and GHCC in consultation with the city school system. For the selection of control schools, we used the propensity score matching method [38]. The idea is to approximate randomization to intervention vs. control arms by post-stratifying schools in a way that factors potentially related to the selection are "balanced" between intervention and control schools. In consultation with the Baltimore City School System, GHCC, and a panel of experts on school academic performance, we identified a list of school variables that might either have played a role in the decision to assign schools to the EC intervention arm or serve as indicators of child's academic performance at the school level, including 3rd

grade standardized reading test scores, 3rd grade enrollment, percent of students receiving free or reduced price lunch, Title 1 status, and Adequate Yearly Progress (AYP) status as determined by the school system. To find matching controls we will employ the strategy described by Rosenbaum and Rubin [39]: that is (i) fit a logistic regression of school assignment (intervention vs. non-intervention) on the above selected factors that are potentially confounding; (ii) stratify the study sample by the fitted values (i.e., propensity scores) from the regression; (iii) compare covariate distributions by school assignment within strata, and thus evaluate the extent to which balance has been achieved; (iv) iterate between (i) and (iii) as necessary to achieve reasonable balance; (v) per stratum in which intervention and non-intervention schools are both non-negligibly represented, conduct the primary analyses as described in Section 2.9.2; and (vi) average the stratum-specific intervention effect estimates (see Fig. 3b). In step (vi), we will inversely weight by the variances of the respective intervention effects, and in step (ii), select strata so as to optimize this weighting strategy, as proposed by Huppler-Hullsiek and Louis [40]. Finally, given the unlikelihood of having measured every factor that relates to selection, we will conduct sensitivity analyses of the extent of confounding due to unobserved factors that would result in a spurious finding, or masking an undiscovered true finding [41,42].

2.4.4. Intervention and description of the two treatment arms

2.4.4.1. Intervention schools: After schools are selected, Principals and teachers receive training as to how to effectively utilize EC volunteers (see above). Schools receive placement of a critical mass of volunteers, who are assigned to roles by the Principal.

2.4.4.2. Control schools: Control schools have no direct interaction with the trial. All data are collected through the school system.

2.4.5. Outcome measures and methods—Outcomes are at the level of both the individual child and the school, with all measures except teacher questionnaire data obtained from the Baltimore City Public School system for intervention and control schools, as well as city-wide. No outcome data are collected from children directly.

2.4.5.1. Primary outcomes: Increases in reading achievement, as measured by standardized tests [43,44], and decreases in disruptive classroom behavior measured as frequency of disciplinary actions for behavior problems (see Fig. 1b).

2.4.5.2. Secondary outcomes: Retention in grade, attendance, improvements in school climate [45], teacher morale and retention, and teacher perceptions of older adults (the latter two are collected in questionnaires administered by the trial in all EC schools).

2.4.6. Sample size—A cumulative total of 22 eligible schools have been assigned to the intervention arm; the rest of the schools in the Baltimore City School System will be considered potential control schools in the analysis of EC treatment effects. This sample size for the intervention arm is the maximal number we can reasonably recruit within the trial budget and the time frame allotted.

2.5. Community-based participatory research approach

This trial is a collaboration between university-based researchers and community representatives of the *Greater Homewood Community Corporation* (GHCC). GHCC is a community organization serving 40 neighborhoods in Baltimore City whose mission is to strengthen the public schools in those neighborhoods. GHCC and the Johns Hopkins Center on Aging and Health (COAH), initially jointly implemented the EC in a pilot program in 6 schools over 8 years. Representatives of the two organizations continue to work together to implement this intervention trial as designed [23–25,31], ensure fidelity of the intervention, engage community members, employ local knowledge in the understanding of health problems and the design of the interventions, and invest community members in the processes, dissemination and use of research findings. A GHCC Community Program Advisory Board, including city-wide representation from community leaders, university representation, GHCC senior staff; school system representatives, and a GHCC Policy Board, oversees the partnership between GHCC and COAH, and is also partners in the trial. Finally, this trial and program were also implemented in partnership with the Mayor of Baltimore, the Baltimore City Commission on Aging and Retirement Education, and the Baltimore City Public School System.

2.6. Retention of volunteers

Recruiters contact each trial subject through telephone calls every four months to monitor participation in volunteer activities, as well as incidence of falls since the previous contact, and enhance retention. Reasons for dropping out are ascertained by interview at phone calls every four months (Section 2.6) (e.g., medical problems, lack of time, loss of interest, mortality).

2.7. Adverse event monitoring

Adverse events for older adults are monitored in the schools, including acute infectious illnesses, falls, hospitalizations, and, for both older adults and children, any episodes of violence between older adults and children. A Data Safety and Monitoring Board (DSMB) monitors study progress and advises the Steering Committee. The board is completely independent; its members are selected by the National Institute on Aging. The DSMB met in the first year of the study to define its role, procedures, and practices, and meets semi-annually thereafter to review reports.

2.8. Fidelity

Fidelity monitoring complements the administrative support the EC program staff provides to the school. The components of fidelity monitoring and the methods for accomplishing this are:

2.8.1. Training fidelity—Ongoing monitoring and refining of the standardized volunteer training manuals, content of training, attendance at training and refresher sessions, video-audio taping of selected training sessions and independent scoring for content/process and selective feedback.

2.8.2. Intervention fidelity—For EC arm participants, monitoring of ongoing activities (e.g., record weekly hours of attendance in school and roles, as well as classroom and school observations by trained staff), and of retention for at least one full school year (unless loss to illness, drop out, or mortality). For the control arm, monitoring of referral to CARE and participation in volunteer activity (if any) through a volunteer questionnaire administered at regular intervals.

2.8.3. Program implementation—Fidelity monitoring of program implementation is conducted to assess any school-system level changes that may impact the EC intervention, such as hiring a new principal, staff lay-offs, introducing new curricula, or change in Title 1 status. In addition, fidelity monitoring assesses any changes to community-partner involvement (via principal interviews), maintenance of a critical mass of volunteers, teacher and principal satisfaction and support for the program, concurrent non-EC intervention programs in the school, overall school learning environment (as assessed by school climate surveys), and ongoing volunteer opportunities at EC and control schools, as well as onsite program management by GHCC site coordinators (e.g., conducting weekly team meetings, keeping records of volunteer attendance, supervising volunteer activities).

2.8.4. Fidelity effects on RCT outcomes—Analyses of the successes or failures of meeting explicit fidelity criteria on the major outcomes of the EC-RCT will be conducted. This will be done through the application of statistical models to estimate the effects of different levels of program implementation on RCT outcomes. Specifically, we will use complier average causal effect (CACE) [46] models, which allow estimation of the effects of levels of program implementation. It is important to note that these analyses accounting for fidelity will not replace the standard "intent to treat" estimates that will be the primary outcome analyses. As discussed by Flay and Collins [47], providing both "intent-to-treat" estimates of the effects of being offered the program as well as CACE estimates of the effects of fully implementing the program helps provide a more complete view of the effects of the program and how results might generalize.

2.9. Data analysis

A description of the analytic models and approaches to methodological challenges, including missing data, are below.

2.9.1. Results: planned analytic approach. Overview—The overall goal of this trial is to evaluate the effectiveness of the EC program as a community-based model for the health promotion for older adults, compared to usual volunteering experiences, and effectiveness in improving academic and behavioral outcomes of children in public elementary schools (Fig. 1a, b). To accomplish this, we will follow five general principles for the analysis of this trial. First, for primary analyses we will rely on intention-to-treat analysis (ITT) to present the comparative results of the trial. Second, all participants, including those who are found to be ineligible after randomization or those who discontinue the program or the follow-up assessment, will be counted in their assigned study group once their assignment has been revealed. Third, all events following randomization will be counted. Fourth, analyses that utilize the post-randomization data on treatment compliance

[48–51] will be discussed as secondary analyses. Finally, it is to be expected that numerous comparisons of effectiveness for the secondary outcomes must be performed. Rather than adjust p-values for multiple comparison, p-values will be interpreted as descriptive statistics of the evidence, and not as absolute indicators for a positive or negative result.

2.9.2. Models—In the following, we describe methodologies to address the primary challenges that the EC trial, as well as other community-based trials, poses for statistical reasoning, and outline the statistical models we will use to evaluate the effectiveness of the trial. This section describes the analytic models which will be used for cross-sectional and longitudinal analysis. We begin with child outcomes, followed by analytic models for adult outcomes.

2.9.2.1. Cross-sectional multilevel models for child outcomes: Because the proposed EC trial collects child-level data on academic performance, such as the Maryland School Assessment (MSA) Test, analyses must allow for predictors at both the child- and school-levels and statistical inference must acknowledge possible correlations among the study outcomes of children in the same school, even after accounting for their individual and school characteristics. All of our analyses on students must account for the clustering of students in schools. To achieve these goals, we will use multilevel models (also termed random or mixed effects models), following ITT rules, which cast performance as varying at the individual level within schools and formulate an explicit mechanism by which between- and within-school variation arises [52,53]. To motivate the models, let Y_{ij} be the reading score of MSA of the jth child in the ith school and z_{ij} be an individual-level characteristic of the child (i,j). Multilevel models describe the individual-level MSA score through the two-level formulation:

$$\text{Individual level:} Y_{ij} = b_{0i} + \beta_2 z_{ij} + \varepsilon_{ij}; \text{ School level:} b_{0i} = \beta_0 + \beta_1 x_i + \beta_3 u_i + e_i \quad (1)$$

where x_i represents school i's intervention status (1-EC, 0-control), u_i represents other variables of school i including those used by the city to name schools and the variables used for matching. In [I], b_{0i} represents mean MSA score for school i (i.e., random effect); β_2 has a school-specific interpretation— say, comparing MSA scores across grades of entry into the EC program for two children in the same school. The multilevel models conveniently specify the full distribution of hierarchically sampled data, and hence facilitate maximum likelihood (ML) estimation. In turn, they allow inferences that are more robust to incomplete observation at the individual level than models not estimated by ML [54]. Moreover, multilevel models can be used to assess the extent of between-school variation that is not explained by measured individual- and school-level characteristics. Importantly, the methodology correctly accounts for within-school correlations and hence provides tests and confidence intervals that validly adjudicate the precision with which the respective models' parameters have been estimated [55].

To summarize, we will use multilevel models for testing our hypotheses related to school outcomes. Eq. (1) easily generalizes to include more than one school-level covariate, more than one individual-level covariate, interactions between school and individual level variables. Models like [I] have also been adapted for analyzing discrete responses within the

Generalized Linear Mixed Effects Model framework [56–60]. We will use proc MIXREG (SAS 6.12) for continuous outcomes and proc MIXNO for categorical outcomes [61] in the multilevel analyses.

2.9.2.2. Longitudinal multilevel models for child outcomes: In the case of longitudinal data analysis, we need to include in model [I] an extra equation to account for within-person correlation of repeated measurements over time. Taking Y_{ijt} to represent the MSA reading score of participant j in school i at visit k, the new longitudinal model is:

$$\text{Time level:} Y_{ijk} = b_{0ij} + \beta_1^* t_k + \beta_2^* t_k \cdot x_i + \beta_w w_{ijt} + \varepsilon_{ijt};$$
$$\text{Individual level:} b_{0ij} = b_{0i} + \beta_z v_{ij} + \delta_{ij} \quad (2)$$
$$\text{School level:} b_{0i} = \beta_0 + \beta_x x_i + \beta_v u_i + e_i$$

Here, w_{ijt} are time-varying covariates that are not influenced by intervention status, v_{ij} (which equals 1 if subject i is in the intervention arm and 0 otherwise); x_i, and u_i are defined similarly as in [I]. Within the right side of each equation, random effects (denoted by "b") and errors (denoted by ε_{ijt}, δ_{ij}, and e_i) are assumed to be mean-0 normally distributed and mutually independent. β_2^* characterizes the difference in the rates of change in the outcome between the intervention and control groups. Eq. (2) assumes the average rates of decline β_1^* and $\beta_1^* + \beta_2^*$, respectively for those in EC and control schools, to be constant across individuals and schools. If the serial correlation structure so warrants, we will also allow slopes that vary across individuals and/or schools.

2.9.2.3. Multilevel models for adult volunteer outcomes: The outcomes of adult volunteers will be analyzed using the same methodology as we have outlined above for the school outcomes, with one exception. Model [I] is based on the assumption that the unexplained school effects e_i are governed by independent 'mechanisms' that are roughly similar across schools (i.e., exchangeable), which implies that all group effects at the school level come from the same population. To assess the effects of the EC program on health outcomes of older adults, however, one needs to take into account the fact that school-level effects only apply to adult volunteers in the intervention schools, whereas adults in the control arm are independent units. Because of this difference, the residual variance and the variance of the random intercept at the individual level may, in fact, vary between the intervention and control arms. Models that fail to accommodate heteroscedasticity, i.e., non-constant residual variance, will yield biased effect size estimates and standard errors. To address this challenge, we will build multilevel models that (i) explicitly allow the individual level random error δ_{ij} to depend linearly on intervention assignment, i.e. $\delta_{ij} = \delta_{0ij} + \delta_{1ij} v_{ij}$, such that the linear variance function for δ_{ij} can then be expressed as $\sigma_0^2 + 2\sigma_{01} v_{ij}$, where σ_0^2 and σ_{01} are variance of δ_{0ij} and covariance of $(\delta_{0ij}, \delta_{1ij})$, respectively, and we constrain the variance of the v_{ij} coefficient to be zero, and (ii) fix school-level random intercept at zero for the controls by setting var(e_i) = τ^2 = 0. Thus, the combined individual-level and school-level variance for EC volunteers is $\sigma_0^2 + 2\sigma_{01} + \tau^2$ and σ_0^2 for controls. Expansion of the dependence of variance on other individual level and/or school level covariates besides intervention status is straightforward. We will use MIXREG and MIXOR

[61] for the proposed analyses. Deviance tests comparing homoscedastic and heteroscedastic models will be used to evaluate the degree of heteroscedasticity.

2.9.3. Other methodological challenges

2.9.3.1. Missing data: While our pilot study had a low dropout rate of volunteers (2–4%; 24), there were missing data due to illness and risk of differential loss to the follow-up of controls compared to cases — as in any trial, particularly community trials. We therefore must address these missing data in order to achieve maximum validity of ITT analyses.

To treat missing outcomes, we will begin with the analyses that assume data are MAR (Missing At Random) [62]. Maximum likelihood estimation provides valid estimates under the MAR assumption [54]; we will apply such estimation as appropriate, using the E–M algorithm [63] as necessary (e.g., for incidence and transition analyses). GEE estimation does not preclude biases under MAR; therefore, we will apply a recently proposed weighting method that corrects this shortcoming [64]. Because outcomes may not be MAR for some analyses, we will also fit models that assume that missing outcomes and observed outcomes differ systematically after accounting for observed covariates and past responses (non-ignorably missing; [65–67]). Because inferences from these models are sensitive to statistical assumptions [68], we will use them for sensitivity analyses, ultimately compiling a range of findings over a range of assumptions about how data came to be missing.

To treat missing covariates other than noncompliance, we will use multiple imputation methods [69]. In some cases there will be enough information on the missing data mechanism to impute specific values, e.g., "zero" strengths for those unable to complete strength testing. In many other cases, there will not be sufficient information on the missing data mechanism. Therefore, we will conduct sensitivity analyses imputing over a range of assumptions about missing [70] and amounts of observed data used to impute the missing cases.

2.9.3.2. Non-compliance: There has been growing interest in developing more complex models that incorporate measures of individual compliance with the intended intervention regimens, so that estimates of effect size are not diluted by lack of compliance, as they would be in a standard ITT analyses [47,48,71]. We will model compliance data as a valuable complement to the prime formality of analysis by ITT.

3. Discussion

This novel trial involves two inter-related studies, a randomized, controlled trial and a study of matched intervention and control schools, based in a community-based participatory research framework. It is designed to provide evidence as to whether the EC program is effective in improving academic performance and school behavior of children in public elementary schools, and whether older adults' participation in the program results in lower rates of disability in mobility, and thus maintenance of independence, compared to those randomized to the control group. If the trial results in the hypothesized findings, the implications are substantial in terms of demonstrating the potential benefits of an aging society and in terms of new approaches to optimizing healthy aging at the population level.

We will soon live in a world where there are as many older adults as children; having roles attractive to older adults that also bring new social capital to societal needs could provide a positive framing of society's aging. Finding effective approaches to accomplish these multiple goals as a win–win is of critical importance to our future societal well-being. The EC program, if demonstrated effective, would offer goals, criteria, and methods for the creation of new types of meaningful and productive roles for older adults and demonstrate the value of this novel social model for the health promotion for older adults [24].

This trial design addresses numerous challenges relevant, particularly, to the conduct of community-based participatory research. This includes realistic recognition of political and community realities that, here, necessitate selection of schools through a flexible method of matching. Further, given the realities of contextual differences from school to school, the EC program defines the intervention in terms of the core features of the intervention that can be fully standardized: EC eligibility; roles and training of volunteers, Principals, and teachers; the volunteer placement process; and quality control through fidelity assessment and feedback. We recognize that in this community-based research, the day-to-day experiences of the volunteers are not within the control of any sponsoring agency or trial, but under the direction of the school Principal. Focusing the trial's defined intervention on those elements that can be standardized makes the trial results realistic and generalizable.

For children, improved readiness to learn is a powerful predictor of motivation to learn, concentration, student achievement, reduced utilization of special school services, self-respect, concern for others, propensity towards lifelong learning, and adult health status, as well as future educational and occupational achievement. Participation in the EC program is expected to enhance student's readiness for learning, even among students who initially display little interest in performing well in school. The EC program is also hypothesized to lead to improved reading ability. In itself, this is critical for future success in school; in addition, early literacy has lifelong implications ranging from cognitive and language development and literacy to long-term success in preventing school drop-out and improving occupational opportunities and mental health outcomes. Furthermore, educational level achieved is a significant predictor of a wide range of health outcomes, including health status in late life. Overall, success in the early elementary school years is critical to subsequent life outcomes. If EC can significantly improve the likelihood of early school success, particularly across whole grades of children (rather than just one or a few children), then it has the potential to positively affect lifelong outcomes for individuals and for whole communities and to be highly cost-effective for society [72,73].

At the same time, if the trial indicates a beneficial impact on the rates of development of disability in older adults, and/or decreased rates of falls, frailty, and memory decline, EC will represent the first successful community-based intervention designed to decrease morbidity and preserve independence for older individuals, both at the individual level and at the level of communities. Mobility difficulty and cognitive impairment each independently predicts onset of disability and dependency in Instrumental Activities of Daily Living (IADL) — essential to independent living in one's home [17]. Prevention or amelioration of mobility disability and cognitive decline, independently or in combination, through the EC intervention could thus be a potent community-based approach to preserving

independence in aging. EC was designed to reach large numbers of older adults when scaled up, and to be attractive to diverse older adults, including minorities and low socioeconomic status groups at highest risk of health disparities [24,25]. With pilot retention rates for EC older volunteers in Baltimore of 80% from one year to the next [24], this approach of using civic engagement as a vehicle or social context for health promotion has substantial potential for effectively improving health of at-risk older adults and maintaining health for those still healthy. The combined effects of impact on the health of the individual and the potential to involve and retain large numbers of older adults suggest that this could be an important component of a societal strategy for effecting a compression of morbidity for an aging population [74].

We hypothesize that the central design elements of the intervention are key to the potential for positive outcomes (Fig. 1). The meaningful roles designed for high impact are important for attracting older adults to the program and retaining them to meet generative goals. Their retention and commitment of substantial time each week over a prolonged period of time are keys to both the impact on children and the potential health promotion "dose" and benefits for older adults. The potential for extended exposure of older volunteers to roles designed to reduce four independent risk factors for disability (Fig. 1a) has the potential to effect a meaningful delay in time to onset of disability associated with aging. Additionally, the attractiveness of this program to minority older adults at the highest risk of disability and dependency means that, if their health behaviors are effectively improved, this program could be a valued vehicle for bringing effective health promotion into minority communities, reaching large numbers of older adults, retaining them, and potentially diminishing health disparities. The deployment of a critical mass of older adults into schools is theorized to be essential to having an aggregate effect across whole grades or even the whole school climate, so that "all boats get raised" [23–25,31]; this critical mass is, we theorize, also crucial to older adults' initial recruitment – because they observe that this program is positioned for a broad impact for children and that they will not be alone in trying to accomplish this – as well as to older adults' social networks resulting from the program. We hypothesize that the resulting social networks, teamwork, and critical mass result in collective efficacy, further amplifying both retention and health impact.

4. Conclusion

Overall, this dual trial and case-comparison study will provide insights into the potential of older adults, in our aging population, to bring their skills, knowledge, time, and desires for generativity to bear on important societal needs. Findings from this trial have the potential to shape our societal approaches to roles for older adults and our understanding of the potential benefits of an aging society, while informing societal approaches to health promotion for older adults. As such, the findings could impact on broad policy approaches to maximize these benefits, offering an initial example of how and where to invest resources to create societal win–win situations and reap their rewards.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Abbreviations

|	
BHS	Brain Health Study
CARE	Baltimore City Commission on Aging and Retirement Education
COAH	Johns Hopkins Center on Aging and Health
EC	Experience Corps™
GHCC	Greater Homewood Community Corporation
IADL	Instrumental Activities of Daily Living
MMSE	Mini-Mental State Exam
MSA	Maryland School Assessment

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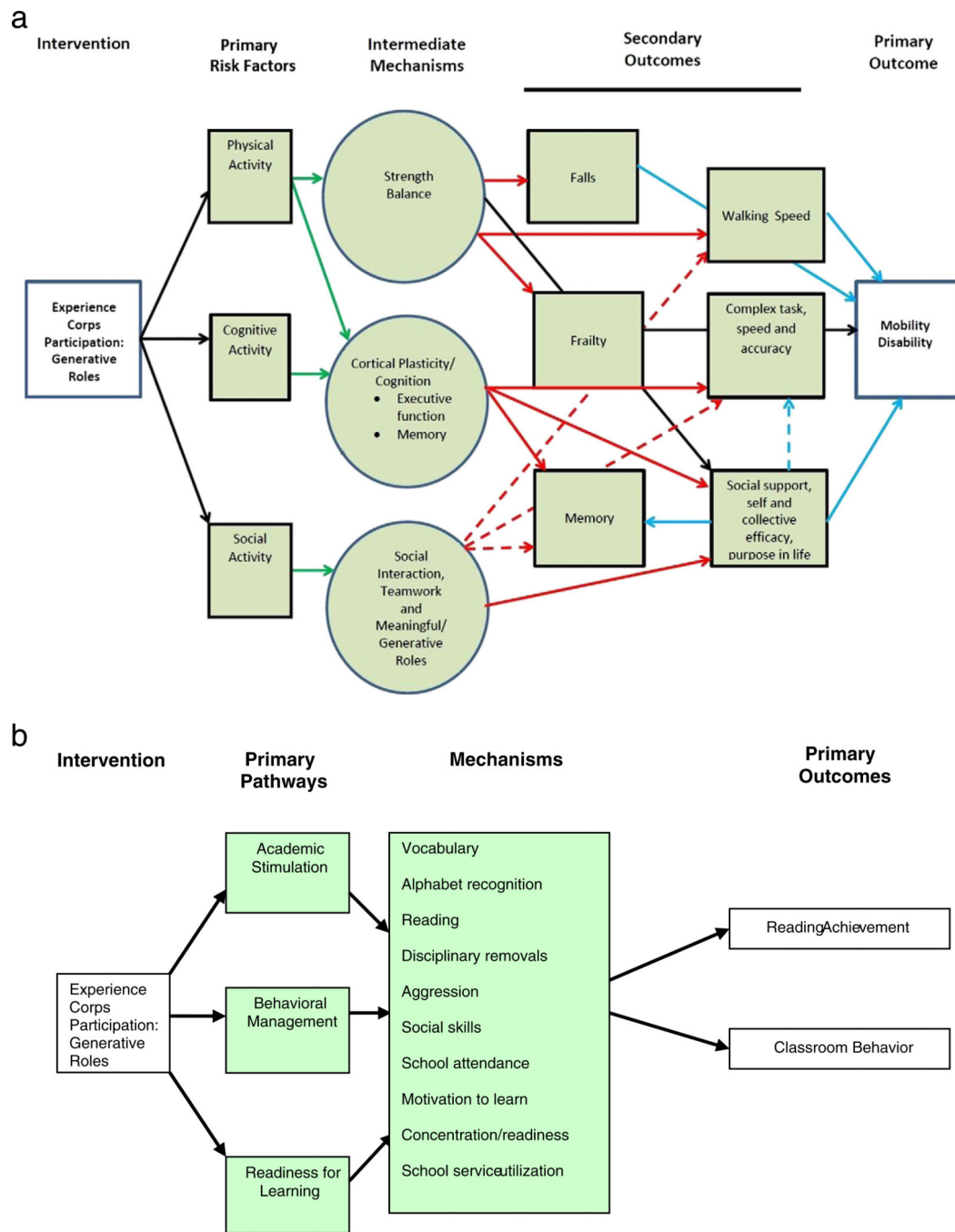
Fig. 1.
Hypothesized causal pathways of the Experience Corps™: The white boxes indicate the intervention and primary outcomes for both older adults and children and schools; the shaded boxes identify the causal pathways which the intervention is designed to effect. The steps in the causal pathway are measured in the studies. The primary outcome for each study is the distal outcome. The secondary outcomes are intermediary outcomes on the pathway to the primary outcome. The arrows represent causal directions, with solid arrows representing direct effects and dashed arrows representing indirect effects. a Hypothesized Experience

Corps™ Baltimore program effects on physical, cognitive, and social health in older adults. b Hypothesized causal pathway of the Experience Corps™ Baltimore program effects on children.
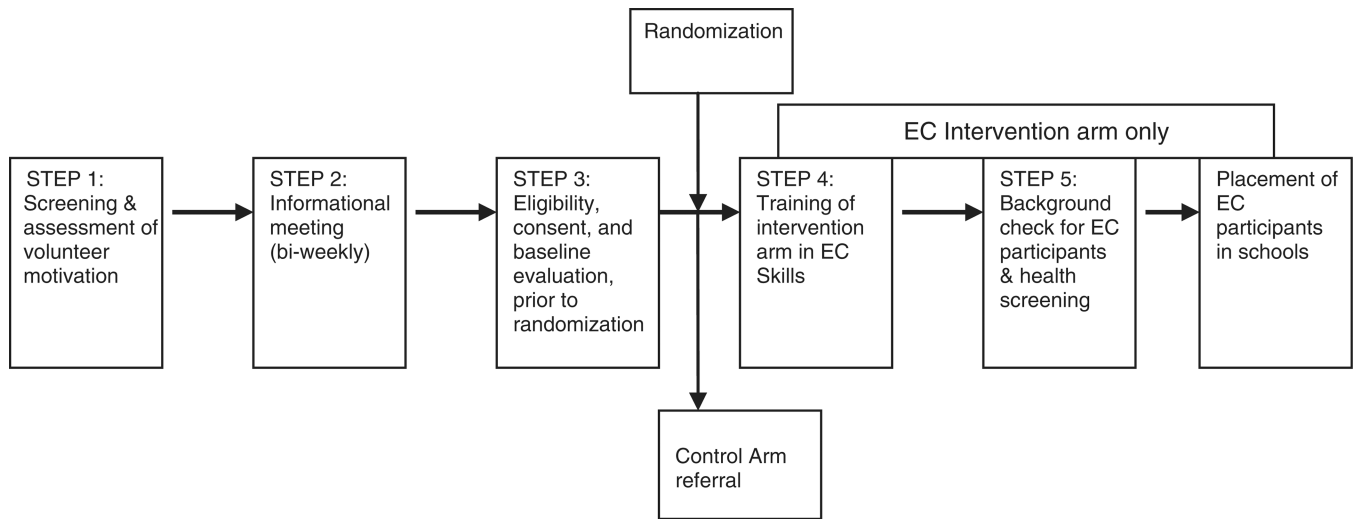
Fig. 2.
5-Step recruitment, screening and intake process for Experience Corps™ trial volunteers.
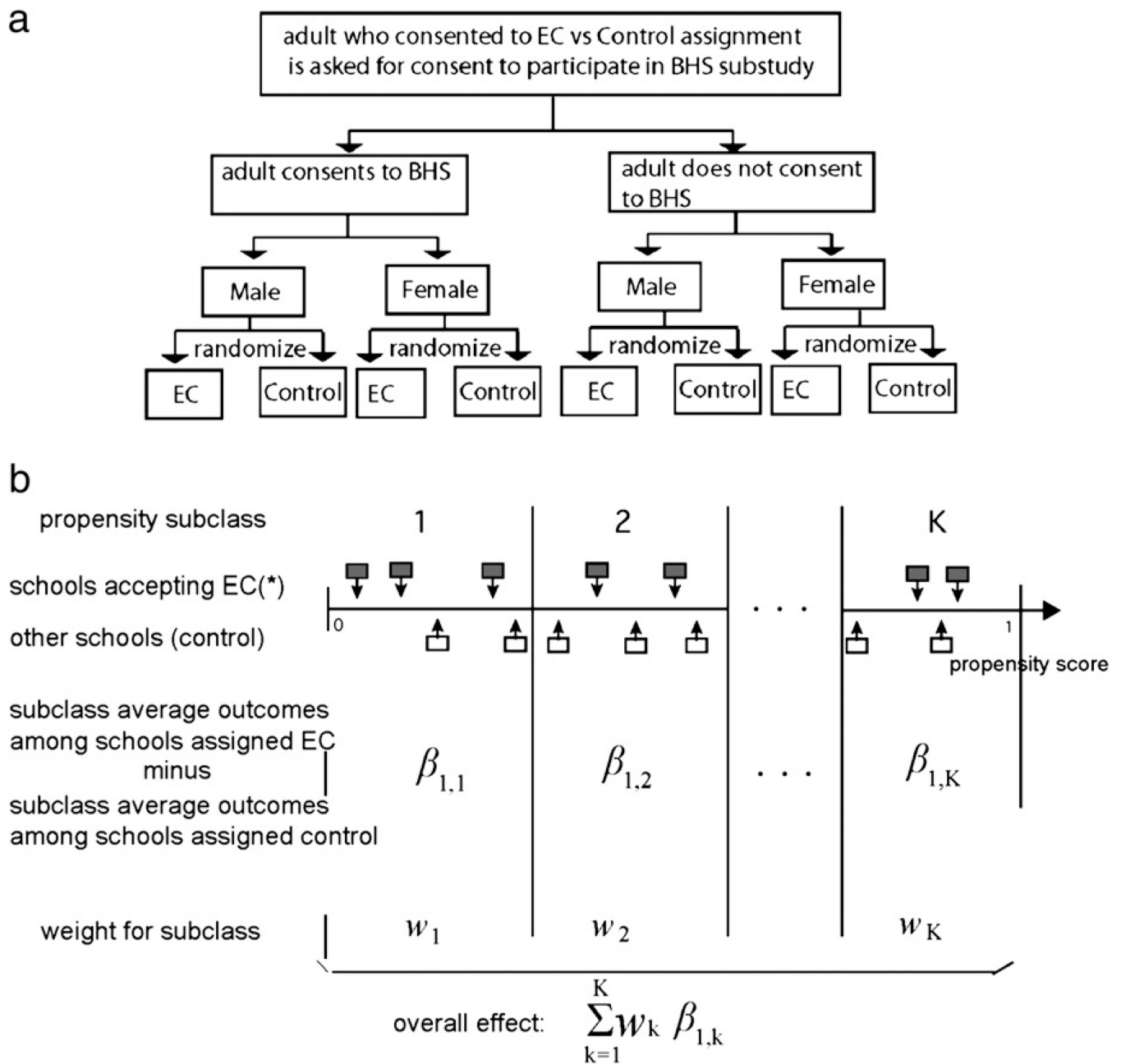
Fig. 3.
Designs for the randomization of older volunteers and school selection. a Design for assigning adults to EC vs Control. The random assignment of adults who consent to participate to the main EC vs Control study is stratified by gender and by further consent or no consent to participate also in a nested brain substudy (BHS; see Section 2.3.3). b Comparison between schools accepting Experience Corps and control schools (*,this categorization was selective, as randomization was not an option). First, subclasses are formed based on the estimated propensity score between EC and eligible control schools (steps (i)–(iv) of Section 2.4.3.1). Then, among each propensity subclass k, the effect $\beta_{1,k}$ between EC and control schools on children's outcomes is estimated using the model of

expression [I] of Section 2.9.2.1 (step (v) of Section 2.4.3.1), and the overall effect is estimated as a weighted average of the estimated effects $\beta_{1,k}$ (step (vi) of Section 2.4.3.1).

Table 1

Constructs and measures used in Experience Corps evaluations of intervention and control participants: adults 60 years.

Measures	Months from baseline						
	0	4	8[a]	12	16[a]	20[a]	24
Type of visit							
Baseline and eligibility	✓						
In-person follow-up		✓		✓			✓
Telephone follow-up			✓		✓	✓	
Consent and eligibility tests							
Consent	✓						
Medicare release form	✓						
MMSE	✓						
WRAT4	✓						
Eligibility checklist	✓						
Demographics	✓			✓			✓
Outcomes							
-Mobility disability	✓	✓	✓	✓	✓	✓	✓
-Late life function and disability	✓	✓	✓	✓	✓	✓	✓
-Falls	✓	✓	✓	✓	✓	✓	✓
Frailty CES-D questions	✓	✓	✓	✓	✓	✓	✓
-EuroQol	✓	✓	✓	✓	✓	✓	✓
Disability questionnaire	✓	✓	✓	✓	✓	✓	✓
Physical health							
Health behaviors	✓			✓			✓
Physical activity							
CHAMPS (shortened)	✓	✓		✓			✓
Paffenberger	✓	✓		✓			✓
Health status	✓	✓	✓	✓	✓		✓
Height	✓	✓		✓			✓
Weight	✓	✓		✓			✓
Blood pressure	✓	✓		✓			✓

Measures	Months from baseline						
	0	4	8[a]	12	16[a]	20[a]	24
Sleep	✓						✓
Health care utilization	✓	✓	✓	✓	✓	✓	✓
Perceived SES question	✓		✓		✓	✓	✓
Falls	✓	✓	✓	✓	✓	✓	✓
Fatigue questionnaire	✓	✓		✓			✓
Cognitive measures							
Cognitive activities questionnaire	✓	✓		✓			✓
Pattern comparison	✓			✓			✓
Stroop	✓			✓			✓
Hopkins Medication Schedule	✓			✓			✓
RAVLT	✓			✓			✓
Performance measures							
Grip strength	✓			✓			✓
Walking speed	✓	✓		✓			✓
Balance (stands)	✓	✓		✓			✓
Chair stands	✓	✓		✓			✓
Psychosocial questionnaires							
Perceived SES							
Social ties and interaction	✓	✓		✓			✓
Social support and conflict	✓	✓		✓			✓
Generativity	✓	✓		✓			✓
Perceptions of usefulness	✓	✓		✓			✓
Self-efficacy	✓	✓		✓			✓
Geriatric depression scale	✓	✓		✓			✓
Psychological well-being	✓	✓		✓			✓
Views of aging	✓	✓		✓			✓
Expectations regarding aging (ERA)	✓	✓		✓			✓
Volunteering history	✓	✓	✓	✓	✓	✓	✓
Resource questionnaire	✓	✓	✓	✓	✓		✓

[a] Indicates telephone interview.