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Recruitment of Older Veterans with Diabetes Risk for Alzheimer's Disease for a Randomized Clinical Trial of Computerized Cognitive Training

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Abstract.
Background: Type 2 diabetes mellitus (T2DM) is prevalent in the general United States population, and in the veteran population. T2DM has consistently been linked to increased risk for cognitive impairment, dementia, and Alzheimer's disease. Computerized cognitive training (CCT) is practical and inexpensive cognitive interventions that is an alternative to medication.
Objective: To report the recruitment methods and challenges to date in an ongoing two-site randomized controlled trial (RCT) of CCT on cognitive function and T2DM management in an older non-demented veteran population.
Methods: Veterans are recruited primarily by targeted mailings or by direct contact at clinics and presentations.
Results: From 1,459 original contacts, 437 expressed initial interest, 111 provided informed consent, and 97 completed baseline assessments. Participants from the two VA Medical Centers differed in demographics and baseline characteristics. Comparing recruitment methods, the proportion of individuals contacted who were ultimately consented was significantly less from mailings (5%) than other sources (20%), primarily face–to-face clinic visits (χ^2 (1) = 38.331, $p < 0.001$).
Conclusions: Mailings are cost-effective, but direct contact improved recruitment. Not using or lacking access to computers and ineligibility were major reasons for non-participation. Within-site comparisons of demographically diverse sites can address confounding of demographic and other site differences.

Keywords: Cognition, computer games, research subject recruitment, type 2 diabetes mellitus, veterans

Trial Registration: Clinical Trials registration number: NCT01736124.

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INTRODUCTION

In the United States, type 2 diabetes mellitus (T2DM) affects 12.2% of the general population, and 25.2% of those aged 65 years or older [1]. In the veteran population, T2DM affects approximately 14.3% overall and 33.0% among those age 65 years or older [2]. T2DM has consistently been associated with increased risk for cognitive decline [3], and with mild cognitive impairment (MCI) [4], dementia [5, 6], and Alzheimer's disease (AD) [7], which impair disease management. For patients at risk for AD due to T2DM, cognitive impairment may lead to poor diabetes self-management including uncontrolled glycemic control. Poor glycemic control may in turn exacerbate cognitive impairment. To break this cycle, an intervention to improve cognitive status or prevent cognitive decline among patients with T2DM may be beneficial for both cognition and DM self-management effort [8, 9].

In view of the limited efficacy of current pharmacologic interventions for AD [10], there is strong interest in identifying non-pharmacologic interventions to prevent, delay, or treat cognitive impairment and subsequent AD [11]. Computerized cognitive training (CCT), providing standardized cognitive stimulation through clinical brain exercises and games, is a practical and inexpensive cognitive intervention [12]. "Computerized Cognitive Training to Improve Cognition in Diabetic Elderly Veterans" (ClinicalTrials.gov: NCT01736124) is an ongoing two-site randomized controlled trial (RCT) testing effects of an adaptive CCT on non-demented elderly veterans who have T2DM with evidence of less than optimal disease management.

To summarize the RCT, the design includes three overlapping processes—recruitment of eligible participants, assessment, and intervention—with six scheduled events, called "visits" (see Fig. 1 and Table 1). Some eligibility criteria are assessed in a brief telephone interview before enrollment, others only afterwards at the baseline assessment (Visit 1). Eligibility screening and baseline assessment were completed prior to randomization. Following determination of eligibility and baseline assessment, participants are randomized to the CCT intervention, Cognifit [13], or an active control task. After randomization of eligible veterans, the CCT intervention or active control is initiated at Visit 2, with a "booster" intervention initiated at Visit 4. Visits 3, 5, and 6 are outcome assessments. Each arm involves 20-min sessions of computer games requiring use of specific cognitive functions three times a week for eight weeks. The difference is that the CCT intervention adapts the difficulty of the game to the participant's recent performance level, but the active control condition does not. The RCT hypothesizes that the adaptation of the intervention will make it more effective than the control condition. All RCT procedures are completed by research coordinators at both sites, who were trained and certified by the same trainers. Any research coordinator who trained a participant or answered questions about computer use did not perform assessments of that participant.

In the general population, recruitment is often a challenge for randomized controlled trials [14], especially in studies among older adults [15]. A focus on older military veteran populations, especially those including a high rate of minority veterans, poses additional challenges [16]. For studies of CCT, the requirement of access to and familiarity with a computer and Wi-Fi in this population is a further obstacle to recruitment, although the disparities in older people are diminishing over time [17]. The potential study participants tend to have multiple health concerns [18], further intensified by the requirement in this study that, in addition to the diagnosis of T2DM, they have deficits in disease self-management. Thus, compared with the general population of older adults, recruitment for an RCT of CCT as an intervention for cognitive function and disease self-management in older veterans with T2DM poses multiple challenges. This paper reports the recruitment methods and their yields. Recruitment challenges are described and should be informative to future CCT studies of older veterans, and in particular, those with T2DM. In response to recruitment challenges, several amendments were made during and after the recruitment reported here. Baseline characteristics of the sample to date are presented, comparing the two sites.

METHODS

Participants

Veterans are recruited from the James J. Peters (Bronx, NY) and the Ann Arbor (Ann Arbor, MI) Veterans Affairs Medical Centers (VAMCs). The initial 19 months of recruitment (April 2015 to December 2016) are described here. This study is approved by the VA Central Institutional Review Board (CIRB) and the Research and Development committees of both VAMCs. The goal of the RCT is a total of 150 participants entering CCT intervention or active

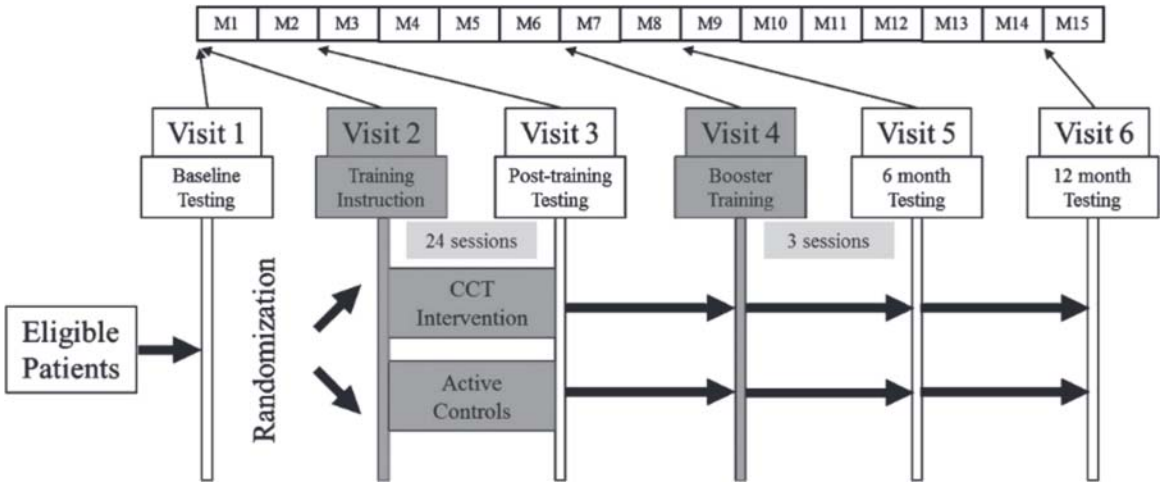

Fig. 1. Timeline of visits from the initial assessments (Month 1; M1) to the final assessments 14 months later.

Table 1
Measures at baseline and follow-up visits

	Baseline		Outcome Assessments		
	Preliminary Screening	**Visit 1** (Baseline)	**Visit 3** (Post Training Follow-Up)	**Visit 5** (6-Month Follow-Up)	**Visit 6** (12-Month Follow-Up)
Screening					
DSMQ (Participant)*	x		x	x	x
Vision Screen	x	x			
Computer/Internet Screen	x	x			
CDR (Participant and Informant)		x			x
MMSE*		x			x
Primary Outcomes					
Cognitive Function					
Memory					
Word List Memory Task (immediate recall, delayed recall, recognition)		x	x	x	x
Logical Memory (immediate recall, delayed recall)		x	x	x	X
Attention/Executive Function					
Target Cancellation (TMX, Diamonds)		x	x	x	x
Trail Making Test (A, B)		x	x	x	x
Digit Symbol Substitution		x	x	x	x
Digit Span (forward, backward)		x	x	x	x
Disease Management Behaviors					
DSMQ (Participant)*	x		x	x	x
DSMQ (Informant)		x	x	x	x
Medication Adherence		x		x	x
Diabetes Outcomes					
HbA1c Measurement		x	x	x	x
Blood Pressure		x	x	x	x

*Used for screening and outcome. DSMQ, Diabetes Self-Management Questionnaire; CDR, Clinical Dementia Rating Scale; MMSE, Mini-Mental Status Examination; HbA1c, hemoglobin A1c.

control at both sites. Preliminary screening of the Computerized Patient Record System (CPRS), the VHA's electronic health record system, indicated that there were well over 3000 registered Veterans at each site receiving care (seen in the last year) and potentially eligible on the basis of a T2DM diagnosis and/or a high hemoglobin A1c (HbA1c;≥8.00%), age (≥65), and no evidence of exclusion criteria. The sites' CPRS rates differed in race and ethnicity. Bronx had 60% White and 39% Black, with 18% Hispanic; Ann Arbor was more homogeneous, having 90% White and 9% Black, with 2% Hispanic.

Table 2
Eligibility criteria—and changes made to these criteria

Criteria assessed during phone screen (Preliminary screening)	
Original	**Amendment**
1. 65 years old or above	60 years old or above
2. A diagnosis of Type 2 Diabetes (using ICD codes)	No change
3. Does not have dementia or prescribed AD medications	No change
4. Does not have major medical, psychiatric, or neurological conditions that affect cognitive performance	No change
5. Home access to computer and Internet (Computer/Internet screen)	No change
6. Has an informant	No change
7. DSMQ (participant) 18 or below (of 20)	No change
8. Does not have severe impairment of vision or hearing.	(Added) Vision Screen
Criteria assessed during baseline screening (Visit 1)	
Original	**Amendment**
1. CDR rating ≤ 0.5	No change
2. MMSE score above the 10^{th} percentile norm based on age, sex, and education	MMSE score ≥ 25
	(Added) Vision Screen

DSMQ, Diabetes Self-Management Questionnaire; CDR, Clinical Dementia Rating Scale; MMSE, Mini-Mental State Examination.

Eligibility criteria

The initial inclusion criteria and amendments during this phase of recruitment are shown in Table 2. A diagnosis of T2DM is defined by having the corresponding any of the diagnostic codes in the CPRS (see Supplementary Table 1), depending on the timing of the diagnosis, in CPRS. Veterans are excluded if they have been diagnosed with stroke, dementia or another neurodegenerative disorder (other than MCI), or a severe psychiatric disorder (e.g., schizophrenia); or have been prescribed a dementia-related medication (based on positive self-report or CPRS, see Supplementary Table 2 providing these and additional screening procedures). As discussed below, veterans are enrolled only if they report some impairment in diabetes management.

Recruitment

Based on their experience conducting research with respective VA populations, investigators from the two VAMCs decided separately which recruitment methods to use. At both sites, participants are recruited via mailings. At the Bronx site only, another method was face-to-face encounters—with veterans attending VAMC clinics, including T2DM, pharmacy, and primary care; referrals from primary care and endocrinology physicians; and open-house presentations— supplemented by local advertisements, including flyers and radio. At clinics, the clinic staff screen veterans for the age requirement and diagnosis of T2DM. At open-house presentations, veterans are encouraged to try one of the games offered by the CCT.

For mailings, the VAMC medical informatics staff use data from the CPRS to identify patients who meet the age requirement, and had a high HbA1c ($\geq$8.00%) and a diagnosis of T2DM—at the Bronx, but not necessarily Ann Arbor, both in the past year—but none of the exclusionary diagnoses (see Table 2). A letter describing the study and inviting participation, accompanied by an opt-out postcard, is sent to the home address. At the Bronx, this letter is sent with prior approval from the primary care physician; at Ann Arbor, the primary care physician is notified if the patient consents and enrolls in the study. Two weeks after sending the recruitment letter, the research staff phones those who do not send the "no contact" card to solicit recruitment.

Screening assessments

The screening process includes a preliminary telephone screening and a face-to-face interview (Visit 1) with the prospective participant. After Visit 1, an interview with a knowledgeable informant (typically a family member or caregiver) is also conducted, with verbal consent, to supplement self-reported information on both disease self-management and cognitive-related functional impairment (see Clinical Dementia Rating scale below).

Preliminary telephone screening

For veterans who show initial interest, a brief telephone screening (approximately 15 minutes) assesses some of the eligibility criteria (see Table 2). This can also be done in-person if convenient.

Diabetes Self-Management Questionnaire (DSMQ) [19, 20]. This five-item self-report or

informant scale—measuring difficulty managing medications, exercising, following an eating plan, monitoring blood glucose levels, and foot care—is a validated reflection of diabetes self-care behaviors [21].

As a screening measure, a participant score of 18 or less is required for inclusion, implying some key T2DM area of care may yet be improved. As an outcome measure, the score is the average of self-report and informant totals for applicable areas, each prorated to the maximum total of 20.

Computer/Internet Screen [22]. Seven questions assess regular use of a computer and access to a computer with Internet service (see Supplementary Table 3). Veterans with at least weekly use of a computer with internet access are eligible.

Preliminary Vision History Screen [23]. Four questions assess visual problems and medical response. Veterans who do not have uncorrected vision problems, or have vision problems that do not impair their daily activities, are eligible.

Medical History Screen. Veterans are asked about any exclusionary medical, psychiatric, or neurological conditions that can affect cognition (Table 2).

Visit 1 informed consent and screening

Veterans not excluded by the preliminary screening are scheduled for a face-to-face meeting with a research coordinator at Visit 1. Here Veterans provide signed informed consent and HIPAA authorization. After consent is obtained, research staff review the CPRS, to confirm T2DM and review exclusion criteria. At Ann Arbor, where the preliminary screening for mailing accepted T2DM diagnosis and high HbA1c even if once and long before the previous year, veterans were asked whether they had T2DM. Informant contact information is also obtained. For participants who are still eligible, Visit 1 continues with additional screening measures below.

Clinical Dementia Rating (CDR) Scale [24]. Severity of cognitive-related functional impairment is assessed from the participant and an informant. "No dementia" (0) or "questionable dementia" (0.5) is required for inclusion, with no compelling evidence from any source for a higher score (1 through 5), indicating dementia level.

Mini-Mental State Exam (MMSE) [25]. This 30-point questionnaire assesses global cognition, including orientation, concentration, memory, and language. A score 25 or above, prorated based on testable items, is required for inclusion.

Vision Performance Screen. In the second portion of the Vision Screen, participants are asked to play the CogniFit [13] game, "Reaction Field," in which participants must hit properly colored targets when they appear, using the mouse. The research coordinator judges the participant's ability to distinguish between different colors and to read instructions from the monitor.

Computer/Internet Use Screen. The research coordinator judges the performance during the Vision Screen to determine that the veteran can efficiently use the mouse and keyboard, and navigate the website.

Final eligibility decision

After collecting all screening measures, including the informant interview, a final eligibility decision is made.

Primary outcome measures

Three primary outcomes reflect the objectives of this RCT: cognitive function, diabetes self-management behavior, and diabetes outcomes. These measures are evaluated at baseline (Visit 1, participant DSMQ at preliminary screening) and as outcomes (Visit 3 immediately post-training, Visit 5 six months post-training, and Visit 6 twelve months post-training). Secondary outcome measures collected in the RCT – for which baseline characteristics are not presented here – are not described.

Cognitive function

The tests included in the neuropsychological battery are listed below and have been described in detail previously [26]. The tests comprising the two cognitive functions were identified a priori. (Other cognitive functions, such as language, and overall cognition were not primary outcomes of the RCT.)

Memory. Word List Memory: immediate recall, delayed recall, recognition; Logical Memory (Story A): immediate recall, delayed recall.

Attention/Executive function. Target Cancellation Tests: TMX, Diamonds; Trail Making Test: A, B; Digit Symbol Substitution Test; Digit Span: forward, backward.

Disease management behaviors

Diabetes Self-Management Questionnaire (DSMQ) see Screening assessments. The participant and the informant scores are averaged for analyses.

Medication Adherence. Prescription and refill history of anti-glycemic and hypertension medications are obtained from CPRS. The Continuous, Multiple interval measure of Gaps in therapy (CMG) [27–29] was used to assess baseline medication adherence during the year prior to the commencement of the training sessions. (For the outcome analyses, medication adherence will be assessed between Visits 1 and 5, and also between Visits 1 and 6.).

Diabetes outcomes

Hemoglobin A1c (HbA1c). A fingerstick of blood is taken from the participant by a research coordinator at baseline and every outcome assessment to determine HbA1c level, using the Siemens DCA Vantage Analyzer [30]. High HbA1c indicates poor glycemic control.

Blood pressures. Systolic and diastolic pressures are measured twice, 5 min apart after resting at least 15 min. The research coordinator uses the Omron HEM-780, with an approximately 6-inch wide cuff. The averages of the two measures are used for analyses.

Statistical analyses

Two cognitive functions were assessed using six neuropsychological tests from which twelve scores were derived. Trails A and B were reversed, so that a low time score refers to good cognition, and test scores from the two sites were pooled. Word List Recognition was missing for one subject; the mean was substituted. The memory and attention/executive functioning measures were the sums of z-scores for the respective sets of tests. No transformation was performed because the skewedness (memory: –0.763, attention/executive: –0.356) and kurtosis (memory: 0.536, attention/executive: 0.065) did not indicate substantial non-normality. The baseline coefficients of the z-scores will be used to calculate the respective follow up cognitive function scores.

For each categorical baseline characteristic, Pearson's chi-square or Fisher's exact test provided a familiar comparison of sites, rather than a test of hypothesized differences. For continuous measures, analysis of covariance controlling for age and education was used for memory, attention/executive function, and MMSE since age and education are associated with these outcomes. Sex was not included as a covariate due to the small number of women. A *t*-test was used for other continuous measures. Since the samples from the two sites were very similar in size, analysis of covariance and *t*-test are robust against distributions that are not normal or have unequal standard deviation.

Pearson's chi square or Fisher's exact test was used to compare recruitment via mailings at the two sites, and the two recruitment methods at the Bronx.

RESULTS

Figure 2 presents the recruitment process with initial contact of 1,459 veterans; of 437 indicating interest in the study, 109 were eligible and thus enrolled. Three columns in the upper portion indicate different recruitment methods or sites: 1) mailings at Ann Arbor, the predominant method at this site; 2) mailings at the Bronx; and (3) other methods at the Bronx, primarily face-to-face encounters at specialty clinics.

Comparing recruitment by mailings at the two sites, the first two stages are different ways of showing lack of interest. Combining them, the rates of those who initially expressed interest among those recruited visa mailing were very similar at the two sites—both 27%. Among the initially interested, a "deferred" response is distinguished from "prescreened out" because the former may participate in the future; but, of the deferrals, there have been sparse results so far. There were more deferred responses at the Bronx than Ann Arbor (χ^2 (1) = 72.860, $p < 0.0005$), but more were screened at Ann Arbor (χ^2 (1) = 34.224, p=<0.0005). These site differences were balanced—the overall consent rate among the initially interested did not differ significantly between mailings at the two sites (χ^2 (1) = 2.27, $p = 0.13$). Overall, the percentage of consented among those recruited via mailing did not differ between the two sites by the mailing method (Ann Arbor, 7%; Bronx, 5%).

Comparing recruitment methods at the Bronx, nonresponse was significantly higher from mailings (46%) than for other sources (10%) (χ^2 (1) = 71.76, $p < 0.0005$), which were primarily face–to-face clinic visits. The methods did not differ substantially on lack of interest or time for participation among those who responded. Among the initially interested, there were more deferred responses among those recruited by mailing (45%) than those recruited from other sources (17%; χ^2 (1) = 18.425, $p < 0.0005$), but the

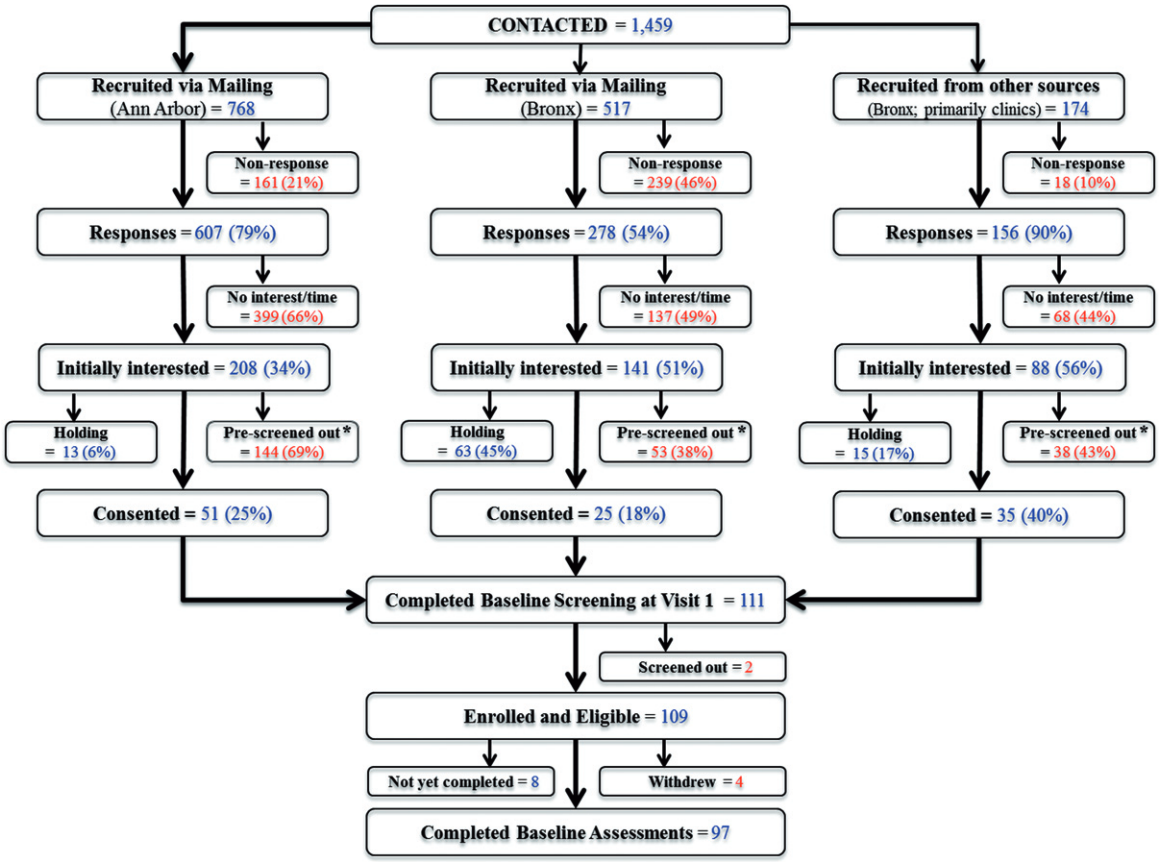

Fig. 2. Combined recruitment tree for both research study sites. *See Table 3.

percentage of veterans who were prescreened out did not differ substantially. Thus, the rate of successful consent among those initially interested was higher for those recruited by other sources compared with mailings (χ^2 (1) = 13.62, $p < 0.0005$). Overall, there was also a markedly higher proportion of individuals being consented from other sources (20%) than from mailings (5%) (χ^2 (1) = 38.331, $p < 0.0005$).

Table 3 presents reasons why veterans were preliminarily screened out—the three columns corresponding to the columns in Fig 2 Of particular interest to this study, when the initial recruitment contact was through mailings, the proportion of veterans who lacked a computer or access to the Internet differed significantly between the two sites (Ann Arbor 1%, Bronx 32%; χ^2 (1) = 23.021, $p < 0.0005$). Lacking a computer or internet access were similar for the two recruitment methods in the Bronx, for which none of the Table 3 comparisons were significant. For mailings at different sites, the large discrepancy in recruiting veterans without a T2DM diagnosis reflects the initial broader inclusion in the preliminary screening at Ann Arbor with the additional self-reported diagnosis of T2DM at Visit 1 (χ^2 (1) = 28.528, $p \leq 0.0005$). Other differences between sites – informant availability, home location, and English ability – were less strongly significant ($0.01 < p < 0.05$).

Table 4 presents comparisons of the sites on baseline demographic, screening, and clinical measures, and cognitive measures. Ann Arbor had significantly more Whites but fewer Hispanics and African Americans; this difference is, in fact, representative of the veteran population in the two VAMCs. Participants from Ann Arbor also had significantly better cognitive (MMSE), glycemic control (lower HbA1c), and systolic blood pressure (lower), but poorer reported diabetic self-care (DSMQ) performance. Participants from Ann Arbor were significantly better on both the memory and attention/executive function cognitive measures after controlling for age and education.

Table 3
Primary reasons Veterans were preliminarily screened out—presented by recruitment method and site: N (%)

	Recruited via Mailing (Ann Arbor)	Recruited via Mailing (Bronx)	Recruited from other sources (primarily clinics) (Bronx)	Total
Computer non-user	42 (29%)	14 (26%)	8 (21%)	64 (27%)
Not diabetic	42 (29%)	1 (2%)	3 (8%)	46 (20%)
No computer/no internet	1 (1%)	17 (32%)	12 (32%)	30 (13%)
Diagnosis/event that affects cognition	13 (9%)	5 (9%)	8 (21%)	26 (11%)
Physical limitations	17 (12%)	6 (11%)	0	23 (10%)
High DSMQ score	10 (7%)	2 (4%)	1 (3%)	13 (6%)
No informant	9 (6%)	0	0	9 (4%)
Location (too far)	8 (6%)	0	0	8 (3%)
Vision issues	2 (1%)	2 (4%)	1 (3%)	5 (2%)
Does not speak English	0	4 (8%)	0	4 (2%)
Hearing problems	0	1 (2%)	2 (5%)	3 (1%)
Takes medication for memory	0	1 (2%)	1 (3%)	2 (1%)
Other	0	0	2 (5%)	2 (1%)
Total	144	53	38	**235**

Table 4
Site differences for demographic, clinical, and cognitive measures

		Bronx ($N=48$) Mean (SD)	Ann Arbor ($N=49$) Mean (SD)	Total ($N=97$) Mean (SD)	p
Demographic Information	Male N (%)	45 (94%)	49 (100%)	97 (97%)	0.117[a]
	White N (%)	20 (42%)	39 (80%)	59 (61%)	**<0.0005[b]**
	Hispanic N (%)	13 (27%)	1 (2%)	14 (14%)	**<0.0005[b]**
	African American N (%)	20 (42%)	9 (18%)	29 (30%)	**0.012[b]**
	Age, years	69.96 (7.22)	70.80 (4.20)	70.38 (5.87)	0.485[c]
	Education, years ($N=95$)	14.12 (2.64)	14.56 (2.17)	14.30 (2.40)	0.494[c]
Cognitive Screening	CDR 0.5 (%)	9 (23%)	4 (8%)	13 (15%)	0.057[b]
	MMSE (0–30)	28.10 (1.28)	29.01 (1.36)	28.59 (1.40)	**0.001[d]**
Diabetes Outcomes	HbA1c ($N=96$)	7.96 (1.62)	6.82 (0.87)	7.38 (1.41)	**<0.0005[c]**
	Systolic BP, mmHg ($N=95$)	135.62 (18.56)	127.98 (16.58)	131.68 (17.88)	**0.037[c]**
	Diastolic BP, mmHg ($N=95$)	76.22 (8.37)	73.47 (12.14)	74.8 (10.52)	0.205[c]
Disease Management Behaviors	DSMQ (0–20)	14.71 (2.33)	12.55 (2.80)	13.62 (2.78)	**<0.0005[c]**
	Medication Adherence (N: Bronx = 43, Ann Arbor = 33)	14.07 (12.56)	16.50 (17.73)	15.12 (14.96)	0.522[d]
Cognitive Outcomes	Memory	−1.35 (3.76)	1.32 (3.43)	0 (3.82)	**<0.0005[d]**
	Attention/Executive Function	−1.20 (2.98)	1.17 (2.71)	0 (3.07)	**<0.0005[d]**

[a] Fisher's exact test; [b]Chi-square; [c] t-test; [d]Analysis of covariance controlling for age and education CDR, Clinical Dementia Rating Scale; MMSE, Mini-Mental State Examination; BP, blood pressure; DSMQ, Diabetes Self-Management Questionnaire (average of informant and participant reports).

DISCUSSION

The interim number of participants enrolled in the present study is similar to other studies that have reported significant findings on the effectiveness of computerized cognitive training [31, 32]. When recruiting participants, direct mailings targeting potentially interested or eligible members of a certain population has been regarded as more efficient and cost-effective [33], including in older adults [34], when compared with less targeted alternatives such as newspaper ads, brochures, and television ads. The present study demonstrated comparable enrollment rates across sites via mailings (18% at the Bronx and 25% at Ann Arbor). However, the other methods implemented at the Bronx, primarily rely-

ing on face-to-face encounters at clinics, resulted in a 40% recruitment rate—double the rate procured by mailings at the Bronx. Though in-person recruitment requires substantially more time and staff effort, such intensive targeting may be a worthwhile investment. This is consistent with the recommendation for improving recruitment and retention of frail elderly by establishing trust through personal contact [15, 35].

Response to recruitment difficulties

In response to recruitment difficulties faced by research staff members, investigators have made changes to the inclusion criteria for this ongoing study. The minimum age was reduced from 65 to 60, to increase the number of eligible participants and the likelihood of computer and Internet familiarity. This change in age is justified as cognitive impairment develops early among patients with T2DM, even at middle age [36]. In addition, the original MMSE criterion for eligibility—at least the 10th percentile norm by age, sex, and education—was simplified to MMSE at least 25, to avoid excluding some without dementia by CDR who would otherwise be eligible. To increase sensitivity further by reducing the cutoff would have lowered specificity of this criterion for not being demented.

In response to explanations about the reasons for non-participation, the reimbursement for time and effort was increased from an initial total of $60 to $125; early participants were retroactively compensated. After the sample described in this paper was recruited, reimbursement was increased to $185, without retroactive compensation, to enhance recruitment further. These increases were approved by the IRB. Such increases may tend to increase the SES characteristics of the sample by increasing attractiveness for those with less immediate need.

After the sample described in this study was recruited, laptop computers with mobile Wi-Fi hotspots are being lent to veterans who need them.

Demographic challenges to CCT participation

One challenge to using CCT with older adults is the lack of familiarity with the technology. A substantial proportion of veterans (40%) were excluded from the present study primarily due to lack of computer experience or home internet access. To evaluate familiarity, the Computer/Internet Screen at Visit 1 provides a game such as used in the intervention. The instruction at Visit 2 includes demonstration by the research coordinator to familiarize the veteran with the specific procedures of this CCT. Then the veteran performs the first training session with the coordinator present. Census estimates from 2001 to 2012, showing consistent increases in internet use by those aged 65 at any location (19.8 to 51.4%), with use at home almost as high [17], suggest that unfamiliarity is gradually diminishing.

For future studies implementing CCT, pilot studies of the proposed population may suggest strategic allocation of assistance, e.g., providing courses introducing computers to non-users.

In Census estimates, internet access and use were both higher in households with higher incomes. Thus, older veterans from low socio-economic status (SES) may be even less likely to participate in, and benefit from, CCT due to lack of access to computers and internet. The median household income of veterans in Washtenaw County, Michigan (where Ann Arbor is located) is approximately $42,000 [37], while it is approximately $30,000 [37] in the Bronx, New York. About 41% of the veteran population is estimated to have a college degree in Washtenaw County, while only 20% is estimated in the Bronx. This appreciable disparity in SES may have contributed to the greater number of veterans in the Bronx, compared with Ann Arbor, who did not have access to a computer with internet.

Within-site comparisons of demographically diverse sites can address confounding of demographic and other site differences. Similar to the site populations, the site samples also differed in race and ethnicity. The Ann Arbor sample is predominantly White (18% African American, 2% Hispanic, 80% White), but the Bronx sample is quite diverse (42% African American, 27% Hispanic, 42% White, with Hispanics overlapping other categories). It is important to assess generalizability of CCT efficacy across sites and demographic characteristics.

Other challenges to CCT participation

Some site differences are not simply reconciled by demographic differences. For example, Ann Arbor had poorer reported diabetic self-care performance but better glycemic control, although poor glycemic control is often attributed to poorer self-care. When the study is completed, larger sample sizes will facilitate interpretation of site differences and within-site demographic differences.

In addition to computer use and access, other abilities pertaining to CCT participation were assessed: hearing, vision (including color vision), and upper extremity impairments (keyboard/mouse use). Table 3 suggests, however, that the prevalence of those primarily screened out due to these issues, was small.

Conclusions

A strength of this study is the inclusion of two demographically different sites. The diverse Bronx sample will permit potentially valuable race/ethnicity comparisons.

Another strength is access to the VA Computerized Patient Records System (CPRS). By recruiting only from the VA, we have relatively consistent access to a uniform medical system, which is especially useful for calculating medication adherence, confirming T2DM diagnoses and checking for exclusionary diagnoses. Inclusion of T2DM diagnosis in the Bronx CPRS screening for the mailing list reduced subsequent exclusion.

Despite these strengths of a VA sample, an accompanying limitation is the rarity of female veterans in this age range. Another limitation, is the lack of uniformity in recruitment methods between sites. While this allowed each site to use what their prior experience suggested would lead to optimal recruitment, it limited the ability to compare each method at each site.

As interest in applying CCT continues to grow, the description of our recruitment methods, their strengths and weaknesses, may help investigators address the challenges of designing clinical trials for specific disease groups and the general older population.

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SUPPLEMENTARY MATERIAL

The supplementary material is available in the electronic version of this article: http://dx.doi.org/10.3233/JAD-180952.

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