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Featured Article

Computerized cognitive training for older diabetic adults at risk of dementia: Study protocol for a randomized controlled trial

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Abstract

Background: Older adults with type 2 diabetes are at high risk of cognitive decline and dementia and form an important target group for dementia risk reduction studies. Despite evidence that computerized cognitive training (CCT) may benefit cognitive performance in cognitively healthy older adults and those with mild cognitive impairment, whether CCT may benefit cognitive performance or improve disease self-management in older diabetic adults has not been studied to date. In addition, whether adaptive difficulty levels and tailoring of interventions to individuals' cognitive profile are superior to generic training remains to be established.

Method: Ninety community-dwelling older (age $\geq$ 65) diabetic adults are recruited and randomized into a tailored and adaptive computerized cognitive training condition or to a generic, nontailored, or adaptive CCT condition. Both groups complete an 8-week training program using the commercially available CogniFit program. The intervention is augmented by a range of behavior-change techniques, and participants in each condition are further randomized into a global or cognition-specific phone-based self-efficacy (SE) condition, or a no-SE condition. The primary outcome is global cognitive performance immediately after the intervention. Secondary outcomes include diabetes self-management, meta-memory, mood, and SE.

Discussion: This pilot study is the first trial evaluating the potential benefits of home-based tailored and adaptive CCT in relation to cognitive and disease self-management in older diabetic adults. Methodological strengths of this trial include the double-blind design, the clear identification of the proposed active ingredients of the intervention, and the use of evidence-based behavior-change techniques. Results from this study will indicate whether CCT has the potential to lower the risk of diabetes-related cognitive decline. The outcomes of the trial will also advance our understanding of essential intervention parameters required to improve or maintain cognitive function and enhance disease self-management in this at-risk group.

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Keywords: Diabetes mellitus; Dementia; Mild cognitive impairment; Computerized cognitive training; Brain training; Self-management

Trial registration: www.ClinicalTrials.Gov, NCT02709629, retrospectively registered on: 25/2/16.

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1. Background

1.1. Diabetes is a risk factor for cognitive impairment and dementia

Dementia is firmly established as one of the most pressing public health concerns faced by societies worldwide, because of its very high and growing prevalence rates and the staggering direct and indirect costs associated with its management. Indeed, the World Health Organization ranked dementia third in terms of disease burden [1], and accordingly, it is listed as a National Health Priority in several countries, and coordinated global efforts to fight dementia are reflected in legislation (e.g., National Alzheimer's Project Act, 2011) and campaigns such as the National Plan to Address Alzheimer' Disease [2].

Several factors, including the lack of effective treatments to halt, alleviate, or reverse dementia symptoms, recent failures of phase 2–3 trials of disease-modifying treatments [3], the identification of modifiable risk and protective factors, and a prolonged preclinical phase, have contributed to the shifting of focus and resources to the possibility of preclinical prevention of dementia. Indeed, pharmacological and nonpharmacological intervention efforts increasingly target individuals at risk of dementia, reflecting hopes that interventions delivered before full-blown dementia develop are more likely to lead to improved outcomes.

Among the potentially modifiable risk factors for dementia, chronic metabolic conditions such as type-2 diabetes have been repeatedly shown to be associated with increased risk of cognitive decline [4,5], conversion of mild cognitive impairment to dementia [6], and development of dementia-related disorders in general [7–9]. Although it has been suggested that midlife onset of diabetes is more strongly associated with dementia relative to onset of diabetes in older age [10], others found no modulating effect of diabetes duration on dementia risk [11], and yet others reported that relative to nondiabetic older adults, cognitive compromise in older diabetic adults is independent of age [12]. Among the overall number of worldwide cases of diabetes, which is currently estimated as 171 million and expected to increase to 366 million by the year 2030, type 2 is expected to represent most cases [13] and currently has a 12% to 25% prevalence rate among individuals aged 65 years and older [13,14]. Therefore, the elderly population is slated to be most afflicted as the incidence of diabetes continues to climb, contributing to the risk of cognitive decline and dementia-related disorders in the elderly.

1.2. Cognitive impairment affects diabetes management

Importantly, even subtle decline in cognition and memory among people with diabetes has been shown to have negative implications on disease self-management [15]—the daily regimen that individuals with diabetes are expected to adhere to effectively manage their diabetes. Self-management in diabetes encompasses behaviors such as taking medication (orally and/or intravenously), monitoring blood glucose levels, exercising, adhering to appropriate dietary guidelines, foot care, and maintaining regular health care visits. In addition to the negative implications that compromised cognition has on diabetes self-management, untreated diabetes and poor self-management practice can themselves lead to progressively worse cognition [16]. Our group has previously reported that high hemoglobin A1c (HbA1c), which is a leading predictor of type 2 diabetes complications, modulates the association between prolonged untreated diabetes and cognitive functioning [17]. Furthermore, poor glucoregulatory control among untreated diabetic patients causes greater cognitive decrement [18], whereas improved glycemic control obtained by a reform of subsequent medication adherence can attenuate cognitive decline in individuals with diabetes [15,19,20]. Interestingly, in the ACCORD trial [21], a large randomized control trial (RCT) aimed at evaluating the effects of intensive pharmacological glycemic control in adults with type 2 diabetes, a small but significant benefit on the cognitive outcome (as reflected in performance on the Digit-Symbol Substitution Test) was found at the 20-month posttreatment evaluation in the intensive glycemic control relative to the standard treatment condition disappeared by an 80-month follow-up [22]. However, this finding could be explained by a range of factors, including that glycemic control in participants assigned to the intensive and standard treatment conditions at baseline was no longer different at the follow-up evaluation, reliance on a single test of processing speed to measure cognitive outcome, and participant dropout. Importantly, the intensive glycemic control condition was terminated prematurely due to increased mortality among participants in that arm, and the presence of more adverse events, including hypoglycemia and weight gain [21], highlighting the importance of careful lifestyle and risk factor management in the achievement of optimal disease control in type 2 diabetes.

1.3. Rationale for computerized cognitive training to improve cognition in diabetics

As effective diabetes self-management is central to minimizing the risk of complications, including cognitive and functional decline, and because of the possible contribution of preexisting, possibly subclinical cognitive impairment to ineffective self-management in diabetes, interventions to enhance cognitive functions have the potential to disrupt this downward spiral. A conceptual framework for cognitive training in diabetes is shown in Fig. 1. Although the evidence regarding the utility of cognitive training for persons with dementia is relatively negative [23], recent high-quality systematic reviews with meta-analysis encourage computerized cognitive training (CCT) in relation to cognitive outcomes in people at risk of dementia due to mild cognitive impairment (MCI) [24–26], as well as among cognitively healthy older adults [27–29]. However, whether CCT can enhance cognitive functioning, and importantly, contribute to

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