



## EFFECT OF COMPUTERISED TRAINING ON COGNITION, SELF MANAGEMENT AND QUALITY OF LIFE IN ELDERLY WITH TYPE 2 DIABETES MELLITUS: A STUDY PROTOCOL FOR A SINGLE BLIND RANDOMISED CONTROLLED TRIAL

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### ABSTRACT

The prevalence rate of type 2 diabetes mellitus in elderly population is 30.42% which is an immense sprouting public health burden adversely affecting quality of life and increasing workload on the health care system. Elderly people with type 2 diabetes mellitus have decreased cognition ability when correlated to elderly without diabetes. The adverse effects of lowered cognitive ability exert a huge negative impact on the self management abilities of elderly with type 2 diabetes mellitus which adversely affects the quality of life. Hence there is a need to find effective cognitive training interventions to postpone the cognitive compromise in elderly that can be used in everyday clinical settings. The objective is to determine the effects of computerised cognitive training on cognitive abilities, self management and quality of life in elderly with type 2 diabetes mellitus. The study design is a single blind randomized control study and the patients will be recruited from K.S Hegde Charitable hospital, Mangalore. All the participants will receive standard self management care treatment techniques in type 2 diabetes mellitus. The experimental group will receive additional 20 minutes of computerized cognitive training using Fit Brains software. Fit brains is a individualised cognitive training program which trains individuals through various exercises in the areas of short- and long-term memory, language, visual-spatial processing, reasoning and problem-solving, and calculation skills. The treatment will be given three times a week for two months. Outcome measure scores of Montreal cognitive assessment scale, diabetes self management questionnaire and quality of life 36 will be taken before and after the treatment of 2 months in both experimental and control group. The statistical analysis will be done using SPSS software and p value of less than 0.05 will be considered significant. The study will be the first randomized control study that will assess the effectiveness of computerized cognitive training on cognition, diabetes self management and quality of life. Various cognitive training methods have been found effective in healthy elderly population but effects of cognitive training in self management, cognitive ability and quality of life of diabetic elderly is unknown. The clinical trial registry number is CTRI/2017/02/007881.

**KEYWORDS:** Type 2 diabetes mellitus, computerized cognitive training, elderly, cognition, self-management, quality of life



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## INTRODUCTION

Type 2 diabetes mellitus is a chronic disease wherein there is an upsurge in the glucose levels in the blood as the body fails to utilize the insulin produced efficiently. Elderly population can be classified as young old (60-69), the old (70-79) and the oldest old (80+).<sup>1</sup> Indian populations includes approximately 103.9 million elderly people, which constitutes about 8.6 percent of the total population according to the "2016 report of elderly in India".<sup>2</sup> The prevalence rate of type 2 diabetes mellitus in elderly population is reported to be 30.42% which is an immense public health burden affecting quality of life and increasing workload on the health care system.<sup>3</sup> Elderly with Type 2 diabetes mellitus are more vulnerable to develop cognitive decline and progress to dementia. Elderly people with type 2 diabetes mellitus have decreased cognition ability when correlated to elderly without diabetes. The adverse effects of lowered cognitive ability exert a huge negative impact on the self management abilities of elderly with type 2 diabetes mellitus. Previous studies have found a decline in test scores of memory, executive functions, processing speed and verbal fluency with progressing of time in type 2 diabetes mellitus.<sup>4</sup> Medha Munshi et al in the study to find association between cognitive dysfunction and poor diabetes control evaluated cognition in sixty elderly using mini mental tests and clock drawing test and it was concluded that diabetic elderly are at a greater risk of cognitive impairments which further contributes to disability and increased dependency.<sup>5</sup> Type 2 diabetes mellitus is conjoined with hyper insulinemia which slows down the uptake of insulin in the blood brain barrier due to permeation above physiologic levels. This in turn leads to decrease in insulin levels and amyloid clearance by insulin degrading enzyme. The accumulation of amyloid results in deterioration in cognitive abilities and progresses to dementia.<sup>6</sup> Ha.T Nguyen et al in his cross sectional study on linking glycemic control and executive function in rural older adults recruited ninety five participants with diabetes mellitus and evaluation of patients knowledge about self care in diabetes was done. A direct proportional relationship was found between individuals with diminished executive function and uncontrolled glucose levels. Hence an exigency was expressed to find aids for cognitive training which would augment cognition and thus in turn improvise self care behaviour and quality of life by better cognitive functioning in type 2 diabetic elderly. Thus, it is necessary to find cost effective interventions to avert or postpone cognitive compromise in diabetic patients which can be used in everyday clinical settings.<sup>7</sup> Cognitive impairments associated with type 2 diabetes mellitus in elderly emblemize as a sprouting area of public health concern as it adversely affects disease self management, increases the care giver burden, reduces independence in elderly, lowers the quality of life and increases the rate of depression in elderly. Thus it is essential to find robust methods to improve cognitive ability of diabetics.<sup>8</sup> It is already known that computerised cognitive training is effective in improving cognition in normal elderly population but there is dearth of literature on the effect of computerised cognitive training on cognition of diabetic elderly.

Cognitive deficits are the major factor affecting self management and quality of life of diabetic elderly veterans hence interventions are needed to improvise the cognitive deficits of diabetics to make the diabetic elderly independent and upgrade their quality of life. The present study intends to find if computerised cognitive training would improve cognition and bridge the lacunae's in self management and quality of life for the elderly diabetic patients. Computerised cognitive training by Fit Brains includes an individualised training program which trains individuals through various exercises in the areas of short- and long-term memory, language, visual-spatial processing, reasoning and problem-solving, and calculation skills. The level of difficulty is increased as each level is cleared by the individual.

## METHODS AND ANALYSIS

### *Objectives of the study*

#### *Primary objective*

- To determine the effects of computerised cognitive training on cognitive abilities in elderly with type 2 diabetes mellitus
- To compare the difference in cognitive abilities before and after intervention.

#### *Secondary objective*

- To determine the difference in disease self management in elderly with type 2 diabetes mellitus between the experimental and control group.
- To identify the effects of intervention on quality of life in elderly with type 2 diabetes mellitus

### *Participants*

The participants will be recruited from Department of medicine of K.S Hegde Charitable hospital and old age homes in and around Mangalore.

### *Inclusion criteria*

- Elderly with age group 65-75 years
- Both genders
- Random blood sugar level between 146-194 mg/dl<sup>9</sup>
- Mini mental status examination score 17-23
- Ability to follow instructions to use phones and computers.

### *Exclusion criteria*

- Elderly people with uncorrected visual impairments preventing use of computerised cognitive training
- Elderly with existing diagnosis of dementia or dementia medications as well as
- Elderly with significant neurological or medical conditions which prevent use of computerised cognitive training.

### *Recruitment*

We aim to recruit 160 type 2 diabetic patients in a period of 2 years from the department of medicine of K.S Hedge charitable hospital. The patient will be referred to the department of physiotherapy by the physician. The patients will be screened by the investigator if they meet the eligibility criteria. If the patient fulfils the eligibility criteria he will be asked for a

voluntary consent and participant information form will be provided to him with complete details of the study.

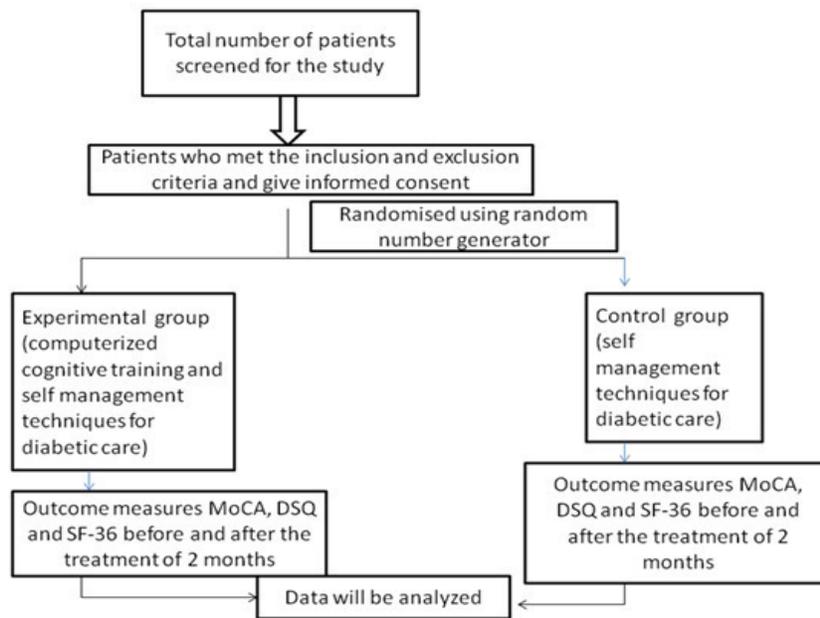
### Study design

The study design is a single blind randomised control design which will inspect the effect of computerized cognitive training on cognition, self-management and quality of life in elderly with type 2 diabetes.

### Randomization

Following baseline measures, participants will be randomly allocated to the experimental and control group. A random number generator sequence will be used and concealed envelopes will be made by another physiotherapist. The patient will be randomly allocated using the concealed envelope in experimental and control groups.

### Consort flow diagram of methodology



### Experimental group treatment

The experimental group will be given 20 minutes of computerized cognitive training using Fit brains for 2 months three times in a week. Fit brains is a individualised cognitive training program which trains individuals through various exercises in the areas of short- and long-term memory, language, visual-spatial processing, reasoning and problem-solving, and calculation skills. Each game lasts exactly 60 seconds during which individuals aim to answer as many questions correctly. The difficulty of the game increases after each correct answer. Each game has three level of difficulty: 1) novice; 2) intermediate; and 3) advanced. The level of difficulty is increased as each level is cleared by the individual.<sup>11</sup> Tutorials will be provided before starting the cognitive training program. The participant has the right to withdraw from the study at any time if they are not willing to participate or if health status is degrading. The data till the withdrawal date will be collected and the number of drop outs will be reported at the end of the study.

### Control group

The control group will be provided with self management techniques which include instructions on regular monitoring of blood sugar level, dietary control, aerobic exercises<sup>10</sup> which includes 10 minutes of warm up session comprised of stretching of major muscle groups, followed by circuit training which includes brisk walking for 10 minutes, static cycling for 10 minutes and 10 repetitions of resistance training for major

muscle groups at 40-50% of 1RM. Cool down session for 5 minutes including deep breathing exercises and stretching exercises. Individualized prescription of aerobic exercise on the basis of maximum heart rate from baseline of 35-50% and progressing to 50-70% of MHR will be done. Patient will also be advised on timely intake of medications. Feet and hand care advice will be rendered to address the sensory problems. Feet care advice comprises of periodic skin examination of feet for reddish blemishes, bruises, swelling, and blisters, keeping nails trimmed, applying lotions and safeguarding from thermal and cold substances, wearing appropriate socks and footwear.<sup>12</sup> Hand care techniques in diabetes include periodic hand washing, trimming nails, skin evaluation, protecting from thermal and cold and applying lotions. Eye care advice includes periodic routine evaluation of eyes by ophthalmologist using dilated eye examination. Ophthalmologic consultation is suggested if patients vision gets blurred occasionally, experiences difficulty on reading words, diplopia, experiences deterioration in vision and finds color discolorations in eye. Patient will also be advised for annual renal test screening. The self management techniques will be provided for 30 minutes.

### Adherence to the treatment

The adherence to the computerized cognitive training program Fit Brains can be evaluated using the stored data in the software which marks the progress of each individual and keeps record of date and time. The physiotherapist administering the study will record the

training duration and level of Fit Brains game reached by the patient on a daily basis. The physiotherapist will also monitor exercises and keep track on whether medications are being taken regularly and routine checkups are done.

### **Blinding**

The participants will be blinded and unaware of the group in which they are included in the study. The investigator will use concealed envelopes to randomize them in control and experimental group. The investigator will be aware of the group to which the participant belongs and the outcome measure scales will be taken by the investigator at the baseline and following a period of two months.

### **Outcome measures**

- The number of participants who were screened and number of participants who cleared the inclusion criteria will be documented. The rate of drop outs as well number of participants who completed the treatment for 2 months will be documented. The documentation of number of participants who refused to give an informed consent will be reported.

### **The primary and secondary outcome measures scales used in the study are as follows**

- Montreal cognitive assessment scale -The Montreal Cognitive Assessment (MoCA) is a reliable and valid screening tool to assess mild cognitive dysfunction. The various cognitive areas examined by MoCA are attention and concentration, executive functions, memory, language, visuo-constructional skills, conceptual thinking, calculations, and orientation.<sup>13,14</sup>
- Diabetes self management questionnaire-It comprises of 16 items to evaluate abilities for self care. It consists for four subscales which evaluates various areas associated with self care comprising of glucose management, dietary control, physical activity and health care use.<sup>15</sup>
- Short form 36 scale- it is a 36 item questionnaire to evaluate the quality of life in elderly subjects. It is a reliable and valid scale to measure the quality of life.<sup>16</sup>
- Random blood sugar levels will also be collected using a glucometer pre and post treatment sessions.

### **Data collection methods**

The data collected will be documented in the data collection sheet. The screening for diabetes will be done by the physician. Data screening tool will be used to screen the patients for inclusion and exclusion criteria.

### **Sample size**

The sample size for the study is 160 subjects. The sample size was determined by statistician using n Master software. 10 percent dropouts have been included while estimating the sample size.

### **Data management**

The patient data will be entered in the data collection sheet and screening tool forms on paper. The data will

be entered in secure electronic database. The original data sheets will be kept confidential and secure based on the rules and regulations of the research committee. All the documents will be entered and documented by the investigator.

### **Data analysis**

Data will be analysed and summarised using SPSS software. The following measures will be analysed in the study.

- The total number of patients who were screened for the study
- The record of number of patients who met the inclusion criteria and were included in the study
- The total number of patients who did not meet eligibility criteria
- The total number of patients who declined to give the informed consent and subjects who were unable to give informed consent
- The number of patients who participated in the computerized cognitive training and self management intervention for duration of 3 months
- The number of drop outs in the study
- The effect of the computerized cognitive training on cognitive status, quality of life and diabetes self management will be analysed

The experimental group will be compared with the control group for all primary and secondary outcome variables

The collected information will be summarised by using frequency and percentage for qualitative data and mean, standard deviation, median and inter-quartile range for quantitative data. To compare outcome measures before and after intervention paired t test will be used. If data is not normally distributed then Wilcoxon sign rank test will be used. To compare changes in outcome measures between groups independent t test will be used. If data is not following normal distribution Mann Whitney U test will be used. Chi Square test and Fischer exact test will be used for comparing qualitative tests. The p value less than 0.05 will be considered significant.

### **Trial status**

The ethical clearance for the study was obtained on 22 December 2016 from Nitte institutional ethical committee. The registration of the study in clinical trials registry of India was done on February 15, 2017. The subjects are yet to be recruited for the study. The clinical trial registry number is CTRI/2017/02/007881.

### **Ethics**

The ethical clearance reference number was NIPT/IEC/PHD/2016-2017/dated 17/12/2016. The participant information form and informed consent form will be provided to the patient. The patient will be informed about the associated risk, discomfort, benefits, right to withdraw and investigators information for contact.

### **Dissemination of findings**

The results of the study will be published in standard journals as short pilot study, case reports, large scale randomized control trials and made known to the

public. The future planned approach of the project will also be revealed to the public.

## DISCUSSION

Cognitive decline conjoined with type 2 diabetes has a high level of negative impact on the self management and quality of life of the elderly community dwellers. Hence it is of great clinical importance to develop robust tools that can reduce the cognitive decline associated with type 2 diabetes mellitus. The present study is the first large scale single blind randomized controlled study to evaluate the effectiveness of computerised cognitive training on the cognitive abilities, self management and quality of life of the elderly Indian population with diabetics. Previous studies by Deborra LP had combined psycho-educational intervention with traditional cognitive training program to evaluate its effects on cognition; attitude and knowledge related to diabetes in elderly with type 2 diabetes mellitus. A significant improvement was found in the cognitive ability following the training in diabetic elderly<sup>8</sup> but as the sample size of the study was limited to 34 subjects, hence generalisation of the

results to the community could not be made strongly. The present study has a greater sample size comparatively and advanced cognitive training method. An exigency was reported by Kingshuk Pal et al in a systematic review for future studies to find the effects of computerized training on health outcomes with a long term follow up. It was found that there is scarce evidence regarding the impact of computerized training effects in the elderly population with diabetics.<sup>17</sup> The present study uses a novel and robust method using Fit Brains for training cognition which is an individualised program that tracks individual performance and provides summary of training sessions, compares every day performance and also allows to access history of training thus provides effective feedback to the participant. The routine treatment for care of diabetics neglects the area of cognitive training. Hence, if cognitive training turns to be effective in the study it can be added as a routine part in diabetes management of elderly population.

## CONFLICTS OF INTEREST

Conflicts of interest declared none.

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