Effectiveness of computer-based language therapy software (Malayalam version) for post stroke patients with aphasia- Final report- April 2016

The project entitled "Effectiveness of computer-based language therapy software (Malayalam version) for post stroke patients with aphasia" was funded by Centre for Disability Studies Poojappura , Trivandrum and the first instalment of the project was received on 20th April 2013 and the project was completed by March 2016.

The proposed study was submitted to the Technical Advisory Committee (TAC) of the institute and further followed by submission to the Institutional Ethical Committee (IEC).The approval from the Institutional Ethical committee (IEC) was received on 29th July 2013.

A speech therapist has been appointed on 19th September 2013 for the study. The study involved the development of aphasia software in malayalam language and assess the effectiveness of this software in patients with post stroke aphasia.

AIMS AND OBJECTIVES:

To develop a computer based language therapy software for aphasia in Malayalam (language used in Kerala, India).

To assess the effectiveness of this language therapy software in improving the language and functional communication skills when given along with conventional speech and language therapy in early post stroke aphasia (within three months of stroke onset).

MATERIALS AND METHODS:

Our first priority was to develop computer based language therapy software for aphasia in Malayalam. The core concept of this local language software version was similar to the western language therapy software programmes available electronically and used

extensively for speech rehabilitation therapy almost in every major hospital in the United States of America and Canada. This task was assigned to a software firm with experience in developing health care augmentation assistance programmes. The software titled "MOZHI" was developed utilising an "agile strategy" which enabled periodic assessment and timely modifications if necessary during the development stage of the software. The steps in this software were organised in a hierarchy according to the presumed task difficulty and language complexity. The database of "MOZHI" consisted of the details that have to be displayed on screen, eg: multiple choice questions, their answers along with pictures. The hexarchial language hierarchy modules utilised in this software included a) Auditory verbal comprehension (body parts, common objects, food items, fruits, vegetables, animals, birds, colours, numbers, alphabets, verbs, occupation, Yes/No questions with sequential commands); b) Expression of language assessment (response to general questions); c) Naming (confrontational naming, categorical naming); d) Writing (copying, dictation); e) Reading (matching tasks, reading commands, sentence completion, story reading, functional reading) and f) Calculation (addition, subtraction, multiplication, division and complex/difficult questions).

The second phase of this project was to validate the software thus developed in a sample population. The stimuli (both pictures and questions) for the computerized language therapy software "MOZHI" thus developed were primarily tested by a different section of the company that developed the software. The first stage of validation was done by 5 experts in the speech therapy, subsequently tried on a pilot study basis in 10 normal subjects and in 10 post stroke aphasic patients**.**

Upon completion of the second phase which validated the software developed, we enrolled the study population as per the inclusion and exclusion criteria laid down for the third phase. For inclusion into the third phase, subjects needed to be right handed, aged 15 years or

above, should present for evaluation within three months of the first ever episode of ischemic stroke in the middle cerebral artery (defined on CT scan or MRI scan) with either Anomic/Broca's/Wernicke's or Transcortical motor aphasia with a Western Aphasia Battery (WAB) score of less than 93.8 on initial assessment. Those with brainstem stroke, bilateral strokes, hemorrhagic stroke, cognitive impairment (MMSE score below 24), unstable cardiopulmonary status/other diseases likely to hamper the four weeks follow up and those who could not speak/read/write Malayalam premorbidly were excluded from the study.

A prospective open randomised controlled trial was carried out with blinded endpoint evaluation of speech and language therapy (SLT). 24 consecutive patients with post ischemic stroke aphasia satisfying the inclusion and exclusion criteria were recruited from Comprehensive Stroke Center of SCTIMST, Trivandrum, India between Septmember 2013 and January 2016. They were randomised by block randomisation into two groups to receive: A) either conventional speech therapy alone (conventional arm/Group A) or B) computer based language therapy along with conventional speech therapy (intensive arm/Group B). A formal consent was obtained from the participants/or their caregivers, prior to the speech and language therapy session after explaining to them the purpose and nature of the study. All the recruited subjects received a total of 12 therapy sessions of one hour each over a period of 4 weeks on a thrice weekly basis. Speech and language evaluation was carried out thrice by SLP. The first evaluation was done at baseline prior to the intervention, second evaluation done after 4 weeks of intervention and the third evaluation done at 12 weeks of recruitment. A new speech therapist who was recruited for this study administered the therapy. Participants were summoned to receive the therapy sessions as designated upon randomisation. At end of 4 weeks and 12 weeks follow up, subjects were assessed by speech therapist of the comprehensive stroke center , who was blinded to the allotted treatment protocol. Clinical speech and language evaluation was carried out using Western Aphasia

Battery (WAB**)** and aphasia type grouping done based on the overall assessment score. The patients were reassessed after 4 weeks and 12 weeks to measure the outcome based on cutoff scores for improvement.

STATISTICS:

All the pre and post intervention measures were compared using non parametric statistics due to the small sample size. Inter group comparison of the mean values were carried out with unpaired t tests. All the statistical analysis was carried out with SPSS software version 19[IBM Corporation].

RESULTS:

Out of the 24 recruited patients, 20 completed the study (dropout rate: 16%). Two patients expired (one just after starting therapy and one after initial WAB assessment due to Stroke related secondary complications) and two of them withdrew consent after the entering into the study (after three and eight sessions respectively) on account of personal reasons. The baseline demographic data of the study population (age, gender, time post stroke, vascular risk factors, stroke severity and educational status) are depicted in Table.1. CT Head showed presence of new infarcts in almost all the subjects in the distribution of middle cerebral artery (MCA complete; inferior or superior division). MRI was available only in 13 participants and the most common pattern of involvement in the total population; conventional and intensive group was multiple diffusion restricted lesions in the MCA vascular territory (57%, 75% and 55% respectively). Etiological evaluation as per the TOAST criteria revealed undetermined etiology to be the commonest subgroup overall (55%) with 78% in the conventional arm assigned to this category. In the intensive treatment arm 36% were attributed as to be of undetermined etiology followed closely by the cardio-embolic group (27%) and large vessel atherosclerosis group (18%). Baseline language assessment of the study group revealed

Broca's aphasia to be the commonest type (50%) followed by Wernicke's aphasia (25%), Anomic (15%) and Transcortical sensory aphasia (10%). The differential distribution of baseline aphasia subtypes in the conventional and intensive treatment groups were comparable with Broca's aphasia being the commonest (55.5% and 45.5% respectively). The mean baseline aphasia quotient (AQ_1) as assessed by the Western Aphasia Battery (WAB) [Table.2] was suggestive of more severe aphasia in the conventional treatment group (p value: 0.31). Follow up language assessment was carried out after 12 sessions of SLT over a period of four weeks as per protocol in both the treatment groups. The commonest overall aphasia subtype on follow up assessment was Anomic (45%) followed by Broca's (25%), Conduction (15%) and Wernicke's (10%) aphasia. Similarly anomic aphasia constituted the most common aphasia subtype in both the conventional and intensive treatment subgroups (44% and 45%). A total of 11 participants had a change in the aphasia category on follow up assessment from the baseline, with all of them demonstrating a switch to a less severe aphasia subtype. The mean four weeks follow up aphasia quotient (AQ_2) as assessed by the Western Aphasia Battery (WAB) [Table. 2] showed a significant improvement from the baseline AQ in the total group (p value: 0.01) and conventional arm (p value: 0.02) with a less robust improvement noted in the intensive arm (p value: 0.18). A relatively better improvement of AQ score was observed in the conventional as against the intensive treatment arm (p: 0.9). The rate of rise of AQ from the baseline to the follow up was calculated in the form of a variable termed ΔAQ ($AQ_2 - AQ_1/AQ_1$), which in turn demonstrated a significantly greater value for the conventional treatment group. [1.55 (SD: 1.5; 95% CI: 0.34-2.75) versus 0.52 (SD: 0.42; 95% CI: 0.24-0.8) respectively: p value: 0.053]. Subjects were followed up till 12 weeks of recruitment with a repeat language assessment using the WAB by the SLP inorder to assess whether the therapeutic effect was persistent despite cessation of intensive therapy. The 12 weeks language assessment [Table.2] also showed a similar trend as that of the 4

weeks follow up with significant improvement from the baseline AQ in the total group (p value: 0.001) and conventional arm (p value: 0.004) with a less robust improvement noted in the intensive arm (p value: 0.10).

We were able to show that the computer based therapy is as effective as conventional therapy and this software can be used for patients at home with the help of a caregiver.

Currently we are in the process of writing up the manuscript for publication.

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