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# Training second-grade dyslexic students using a computerized program in Asyut, Egypt

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## Abstract

**Background:** Dyslexia is characterized by difficulties in spelling and reading. The aim of this study is to identify domains of cognitive strength and weakness of students with dyslexia and to study the effect of an especially designed computerized training program on their reading abilities. This study was conducted on 2nd-grade primary school students in Asyut city, Egypt ( $n = 560$ ). Identification of students with dyslexia was done using Arabic Reading Achievement test and a newly constructed computerized Arabic Cognitive Abilities diagnostic battery for Reading (CADB-R). Training was applied using a newly constructed Computerized Cognitive abilities training battery for reading (CATB-R).

**Results:** The prevalence of dyslexia was 13.9% ( $N = 52/373$ ), and it was higher among girls (15.8%) than boys (11.7%). After application of the training program, there was a significant increase in post-training mean scores of CADB-R score in their total and all sub-items.

**Conclusions:** All struggling readers should be included in well-tailored research-based rehabilitation programs.

*Clinical trial registration* Training Second-grade Dyslexic Students Using a Computerized Program in Assiut, Egypt (Dyslexia), NCT04642859, 12 November 2020. URL: <https://register.clinicaltrials.gov/prs/app/action/Status?uid=U000495F&ts=10&sid=S000AD3G&cx=20acrp>

**Keywords:** Dyslexia, Training, Egypt

## Background

Dyslexia is a specific learning disability that is neurological in origin. It is characterized by difficulties with accurate or fluent word recognition, by poor spelling and decoding abilities, difficulty reading words in isolation, and difficulty with oral reading (slow, inaccurate, or labored). These difficulties typically result from a deficit in the phonological component of language that is often unexpected with other cognitive abilities and the provision of effective classroom instruction [1].

The phonological deficit hypothesis is the dominant explanatory theory of developmental dyslexia [2, 3]. Despite this, impaired phonological processing alone cannot explain all clinical symptoms of dyslexia. Many students with dyslexia have multiple deficits other than phonological deficits [4–8]. Of these accused deficits are visual perceptual processing deficits [9], auditory processing deficits [10], multisensory spatial attention deficits [11], as well as cerebellar dysfunction [12].

The current mandatory practical criterion for the diagnosis of dyslexia, below-average achievement, implies waiting to failure. This approach for diagnosis (must fail approach) would delay intervention for rehabilitation. Furthermore, the cut-off scores would result in over or under inclusion of cases and appear to be the least reliable and valid approach to diagnosis. Both methods lack

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a deeper understanding of the underlying reading difficulty, their neurobiological basis, and hence represent barriers against scientifically based interventions. However, improved understanding of the neurobiological basis of dyslexia will facilitate evidence-based effective intervention.

The aim of this work is to identify the domains of cognitive strength and weakness of students struggling with reading and to study the effect of an especially designed computerized training program on their reading abilities.

## Methods

### Study group

This intervention study was conducted on 2nd-grade primary school students chosen from 6 geographically distributed governmental schools in Asyut city, Egypt. One classroom was randomly selected from each school ( $n=560$ ). Students with dyslexia were chosen out of this sample. They fulfilled the following criteria:

- (1) Poor scholastic achievement: Obtaining less than mean–standard deviation (SD) score on a standardized Arabic reading achievement test specifically designed for this study;
- (2) Normal neurological, basic audiological, and ophthalmological examination.

### Control group

The control group was selected from 2nd-grade primary school students of the same public schools who fulfilled the following criteria:

- (1) Good scholastic achievement (Obtaining score more than mean+SD on a standardized Arabic achievement test);
- (2) Normal neurological, basic audiological, and ophthalmological examination.

## Methods

**Ethical consideration:** Informed written consent was signed by the parent or legal guardian of the student. This study protocol was approved by the ethical committee of Asyut university faculty of medicine with ethical approval number: 2015-03-R20 and 2015-3-R21. Also this study protocol was registered in Clinical trial.gov with Identifier: NCT04642859.

The current study was carried out along seven stages:

### **First stage: identification of students with reading disability (Dyslexia)**

- a. Construction of Arabic Reading Achievement Test: it was carried out by 2 professors of educational psychology (see Additional file 1). Then its validity and reliability were assessed in a pilot study on 185 2nd-grade students, and were correlated with their school scores.
- b. All students in 2nd grade from the chosen six public primary schools in Asyut city ( $n=560$  students) were included in this study except those who were absent during their school visits ( $n=84$ ) or those who refused to participate in this study ( $n=103$ ). The rest of the sample ( $n=373$ ) completed this study under the supervision of 4 neuropsychiatrists, two expert psychometrists, and 12 social workers.

All students ( $n=373$  students) were subjected to the following:

- (1) Evaluation of achievement level: by the new scale of Arabic Reading Achievement Test (ARAT), specially designed for this study. Students were classified according to their achievement level into three groups:
  - a) Group I: Poor achievers (scores < mean – SD), considered students with reading disability or dyslexia (our target in this study) ( $n=52$  students)
  - b) Group II: Average achievers (with scores = mean  $\pm$  SD) ( $n=295$  students)
  - c) Group III included those with good achievement (score > mean + SD) and were considered as a control group ( $n=26$  students).  
Thereafter, the students with reading disability were subjected to the following:
    - (2) Audiological assessments: audiometry and tympanometry to exclude peripheral hearing loss.
    - (3) Ophthalmological examination: visual acuity by counting fingers at 6 m to exclude gross visual deficits.

### **Second stage: construction of a computerized Arabic cognitive abilities diagnostic battery for reading (CADB-R)**

This stage was carried out by seven expert staff members in the fields of neurology and education. The constructed battery was designed in a game-like manner to test a wide range of cognitive skills that are supposed to be important in the early stages of learning to read. It includes the following skills:

- (1) Text Reading comprehension: It includes give word meaning, true or false, give the opposite, plural, singular, match the word with an appropriate picture, and match the sentence with the appropriate picture.
- (2) Visual discrimination: it includes letter identification and word identification.
- (3) Auditory discrimination: Al-tanween, Al-mad, and Al-shad.
- (4) Phonological awareness: It includes: match pictures of rhyming words, give words of the same rhyme, blending of syllables, heard words rhyme or not, match pictures starting with the same letter.
- (5) Visuospatial skills: it includes identification of letter relations to others, proper dotting of letters, and word formation from letters.
- (6) Audio-Visual correspondence: identification of nonverbal sounds, match the heard word with the proper picture, word segmentation, substitute the 1st letter and pronounce the word, identification of words starting with the heard letter sound, and complete with appropriate syllable.
- (7) Auditory memory: it includes the memory of sentences and memory of words.

### **Third stage: standardization of the constructed diagnostic battery**

- (1) Reliability: by assessment of internal consistency reliability, which in turn depends on the measurement of values of Cronbach's Alpha correlation coefficient [13], and corrected item-total correlation coefficient [14].
- (2) Validity of the constructed battery depends on measuring the following:
  - a) Judgment validity: the test was judged by well-experienced referees (7 experts; 4 of neuropsychiatry medical field; and 3 of educational field) to show the relevance and appropriateness of individual test items to the study purpose
  - b) Contrasted group validity: *t*-test was used for comparison of scores of the reading cognitive abilities of students with dyslexia (group I) and the control group (group III), using the newly constructed Cognitive Abilities Diagnostic Battery for Reading (CADB-R)
  - c) Diagnostic validity: sensitivity, specificity, positive predictive value, and negative predictive value were used to determine diagnostic validity.

### **Fourth stage: detailed study of the cognitive profile**

Study the cognitive profiles of students with dyslexia ( $n = 52$ ) using the newly constructed CADB-R to identify their cognitive skill deficit or deficits that might contribute to their disability (dyslexia).

### **Fifth stage: construction of a computerized cognitive abilities training battery for reading (CATB-R)**

This constructed training battery will be used for the development and enhancement of cognitive skills that contribute to learning to read. The constructed training battery is composed of the same visual and auditory cognitive skills of the diagnostic battery. Still, it is a more extended game like (multiple levels of increasing difficulty) and has unlimited time. The child is not allowed to pass to the next level until he masters the current one.

### **Sixth stage: application of the training battery (CATB-R)**

Only 16 students with dyslexia accepted to continue the next stage of the study (rehabilitation and reassessment). Rehabilitation was carried out in the neuroepidemiology centre at Asyut University, along two months. Each student attended with one or both his/her parents received five sessions per week. Each session lasted for 90–120 min with intervening one or two breaks in between. Two sessions were held per day (from 9 to 11 and from 12 to 14), and each student's parents were allowed to choose their suitable sessions for attendance.

### **Seventh stage: reassessment**

Reassessment of students with dyslexia at the end of the training program was done, using the CADB-R for evaluation of their cognitive skill abilities after rehabilitation. Their reading achievement level was also reassessed after training using Arabic Reading Achievement test (ARAT) (Additional file 1).

## **Results**

### **Arabic reading achievement test (ARAT)**

Reliability and validity of the newly constructed Arabic Reading Achievement Test (ARAT) were assessed in a pilot study on 185 2nd-grade primary school students. Cronbach's alpha coefficient value of ARAT was 0.785. It showed minimal decrease following the deletion of any component of the achievement test, and this means high internal consistency of ARAT. Pearson's correlation revealed a significant correlation between the newly constructed ARAT and end-year Arabic achievement school

test ( $r=0.601$ ) (Criterion-related validity). Using the newly constructed ARAT, it was found that the prevalence of dyslexia among 2nd-grade public school students of Asyut city was 13.9% ( $N=52/373$ ), and it was higher among girls (15.8%) than boys (11.7%) (Table 1).

Table 1 shows Reading achievement level of 2nd-grade public school students. The prevalence of dyslexia among 2nd-grade public school students of Asyut city was 13.9% ( $N=52/373$ ), and it was higher among girls (15.8%) than boys (11.7%).

**Standardization of cognitive abilities diagnostic battery for reading (CADB-R)**

The newly constructed CADB-R for students with dyslexia has high internal consistency with Cronbach’s alpha coefficient value of 0.741. Comparison between mean scores of cognitive skill abilities of poor and good achievers among 2nd-grade public school students of Asyut city shows that students with poor Arabic academic achievement have significantly lower mean score on the total and

**Table 1** Reading achievement level of 2nd-grade public school students

Arabic achievement level	Arabic (N = 373)					
	Male		Female		Total	
	N	%	N	%	N	%
Group I: Poor achievers	20	11.7	32	15.8	52	13.9
Group II: Average achievers	137	80.1	158	78.2	295	79.1
Group III: Good achievers	14	8.2	12	5.9	26	6.97
Total	171	45.8	202	54.2	373	100

**Table 2** Contrasted group validity

Studied reading cognitive skill	Poor achiever (N = 52) Mean ± SD	Good achiever (N = 26) Mean ± SD	T	P-value	95% CI
Reading achievement test	18.46 ± 5.65	40.0 ± 0.0	19.37	0.0001	– 23.75: – 19.32
Reading comprehension	55.56 ± 8.39	62.96 ± 6.22	9.89	0.0001	– 22.11: – 14.47
Visual discrimination	21.17 ± 3.60	23.77 ± 0.65	3.64	0.0001	– 4.02: – 1.18
Auditory discrimination	9.38 ± 4.28	17.92 ± 3.32	8.90	0.0001	– 10.45: – 6.63
Phonological awareness	14.63 ± 5.03	24.19 ± 4.24	8.65	0.0001	– 11.09: – 6.95
Visuospatial skills	12.21 ± 4.05	18.08 ± 2.21	6.88	0.0001	– 7.56: – 4.17
Audio-visual correspondence	21.27 ± 4.18	28.77 ± 2.07	8.61	0.0001	9.23: – 5.77
Auditory memory	5.87 ± 2.21	8.12 ± 1.40	4.73	0.002	– 3.20: – 1.30
Reading ability score	129.10 ± 23.97	184.19 ± 13.74	10.84	0.0001	– 65.22: – 44.97

**Table 3** Diagnostic validity of CADB-R

Studied cognitive skill	TP	TN	FP	FN	Sensitivity	Specificity	PPV	NPV
Reading comprehension	44	264	57	8	84.6%	82%	43.5%	97%
Auditory-Visual discrimination	41	271	50	11	79%	84%	45%	96%
Auditory discrimination	42	278	43	10	80.8%	87%	49%	97%
Phonological awareness	39	261	60	13	75%	81%	41%	95%
Visuospatial skills	39	266	55	13	75%	83%	41%	95%
Visual discrimination	28	295	26	24	0.0	97	0.0	0.0
Auditory memory	30	260	61	22	58%	81%	33%	92.2%
Total cognitive skills for reading	45	271	50	7	86.5%	84%	45.9%	97%

\*TP = True Positive (dyslexics scoring < cut-off); TN = True Negative (control scoring > cut-off); FP = False Positive (control scoring < cut-off); FN = False Negative (dyslexics scoring > cut-off); Sensitivity = TP/(TP + FN); Specificity = TN/(TN + FP); Positive Predictive Value (PPV) = TP/(TP + FP); Negative Predictive Value (NPV) = TN/(TN + FN)

all sub-items of the CADB-R than their good achieving peers (contrasted group validity) (Table 2).

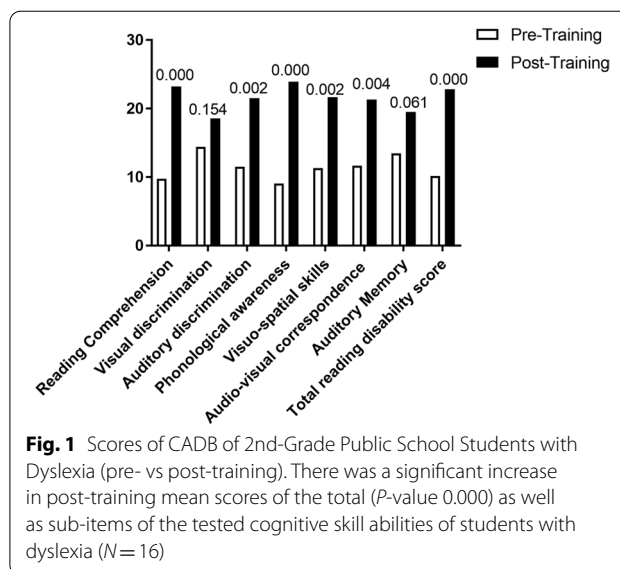
The CADB-R for students with dyslexia had sensitivity 86.5%, specificity 84.4%, positive predictive value 47.4%, and negative predictive value 97.5% (Table 3).

Multiple correlations between Arabic achievement test as a dependent variable and the studied cognitive skills of the battery as independent variables revealed that 61% of variations in Arabic achievement scores are attributed to these studied cognitive skills collectively, and the remaining 39% are attributed to other factors (Table 4). Multiple correlations between Arabic achievement test as a dependent variable and sub-items of the cognitive skill battery, as independent variables, revealed that audio-visual discrimination had the highest contribution (47%) upon which Arabic achievement level depends (Table 4).

Table 2 shows contrasted group validity. Comparison between mean scores of cognitive skill abilities of poor and good achievers among 2nd-grade public school students of Asyut city shows that students with poor Arabic academic achievement have significantly lower mean score on the total and all sub-items of the CADB-R than their good achieving peers.

Table 3 shows Diagnostic Validity of CADB-R. The CADB-R for students with dyslexia had sensitivity 86.5%, specificity 84.4%, positive predictive value 47.4%, and negative predictive value 97.5%

Table 4 shows multiple correlation coefficient test. Multiple correlations between Arabic achievement test as a dependent variable and the studied cognitive skills of the battery as independent variables revealed that 61% of variations in Arabic achievement scores are attributed to these studied cognitive skills collectively, and the remaining 39% are attributed to other factors. Multiple correlations between Arabic achievement



**Fig. 1** Scores of CADB of 2nd-Grade Public School Students with Dyslexia (pre- vs post-training). There was a significant increase in post-training mean scores of the total ( $P$ -value 0.000) as well as sub-items of the tested cognitive skill abilities of students with dyslexia ( $N = 16$ )

test as a dependent variable and sub-items of the cognitive skill battery, as independent variables, revealed that audio-visual discrimination had the highest contribution (47%) upon which Arabic achievement level depends.

**Pre- and post-training mean scores of cognitive skill abilities**

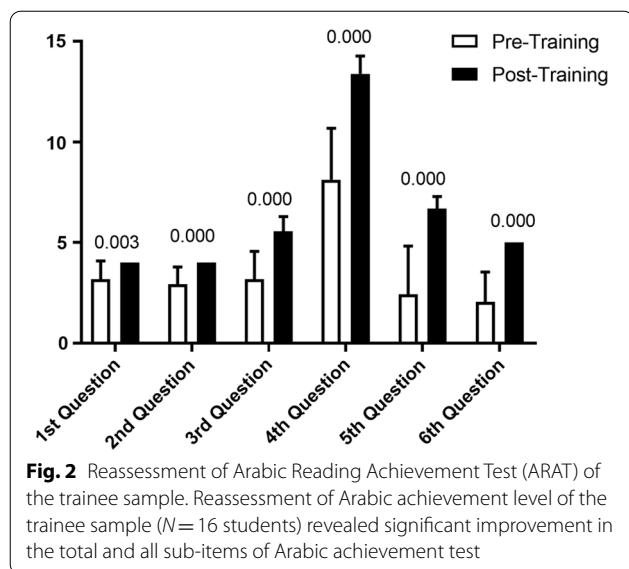
There was a significant increase in post-training mean scores of the total ( $P$ -value 0.000) as well as sub-items of the tested cognitive skill abilities of students with dyslexia ( $N = 16$ ) (Fig. 1). Reassessment of Arabic achievement level of the trainee sample ( $N = 16$  students) revealed significant improvement in the total and all sub-items of Arabic achievement test (Fig. 2).

**Table 4** Multiple correlation coefficient test

Dyslexia battery	Correlation Coefficient	Relative efficiency			Coefficient of determination		Coefficient of multiple correlation		F-Ratio (regression)	
		P.R	R <sup>2</sup>	Efficiency	Each item	Total	Each item	Total	Each item	Total
Reading comprehension	0.69	0.18	0.59	9.18	39.50%	61%	62.80%	78%	29.66	94.02
Audio-Visual correspondence	0.67	0.30	0.57	27.43	47%		69%		40.72	
Auditory Discrimination	0.65	0.21	0.59	12.82	46%		68%		104.33	
Phonological awareness	0.53	0.09	0.6	2.36	37%		61%		43.29	
Visuospatial skills	0.59	0.16	0.6	7.11	39%		63%		79.87	
Auditory memory	0.39	0.08	0.6	1.75	22%		46%		50.84	

Number of Cases (373); PROB > (0.001)





## Discussion

Dyslexia occurs across all languages (alphabetic languages, such as English, French, German, Arabic, and logographic languages, such as Chinese and Hieroglyphs). It is recorded in all socioeconomic statuses, cultures, and ethnic backgrounds [15]. However, the prevalence of dyslexia is not the same in all countries. In Finnish, there is a good correlation between orthography (the way a letter looks) and phonology (the way it sounds). It is easy for children to read, and so there is a lower prevalence of reading disability in countries speaking Finnish [16]. On the other hand, in English, the relationship between orthography and phonology is inconsistent. One letter can represent several different sounds. For example, the letter “s” is pronounced differently in each of the words “sun”, “sugar”, and “lens”, and the sound of the letter “F” is written differently in “left” and “elephant”. Thus, the prevalence of dyslexia is higher among English speakers than among speakers of many other languages [16]. In the USA, reading disabilities (dyslexia) comprise 80% of all learning disabilities, and as many as 43.5 million Americans have dyslexia [15]. Again Arabic is a language with deep orthography, for example, the letter “Alef” (أ) is pronounced differently in different words as أ، هم، اس، أ، دم، ح، أ، and hence has a high prevalence of dyslexia that was also found by Naama Friedmann, Manar Haddad-Hanna (2012) [17].

Using the specifically constructed Arabic Reading Achievement Test (ARAT), it was found that the prevalence of dyslexia among 2nd-grade public school students of Asyut city was 13.9%,  $N = 52/373$ . It lies at the upper range of the worldwide, estimates of prevalence which vary from 2 to 15% of the population. It has acceptable

reliability according to National Institutes of Health 2007, which reported that, for the tests to be reliable, its Cronbach’s value should be 0.70 or more. Moreover, deletion of any of its constituent sub-items shows a minimal decrease in its Cronbach’s alpha value, which indicates the significance of all constituent sub-items [14, 18].

Despite the proved validity and reliability of the constructed ARAT (Cronbach’s alpha 0.785 & Pearson’ correlation  $r = 0.601$  with end-year Arabic achievement school test) in the identification of students with dyslexia, it is better for all students who are struggling in the early stages of learning to read, to be subjected to detailed study and rehabilitation programs, not to wait to proven failure.

The specifically constructed Cognitive Ability Diagnostic Battery for Reading (CADB-R) had Cronbach’s alpha coefficient value 0.741 and all values of its corrected item–total correlation were 0.2 or more, which indicates acceptable reliability [13, 14]. Again, deletion of any sub-item of the diagnostic battery results in a minimal decrease of the total Cronbach’s alpha value indicating internal consistency and high reliability of the total battery and its sub-items.

Regarding the studied reading cognitive skills, the students with poor Arabic academic achievement had significantly lower scores than those with good Arabic academic achievement at the total and all sub-items of the CADB-R (Fig. 1).

The significantly low scores of poor achievers compared with good achievers on the text reading comprehension task of the battery ( $P < 0.001$ ) may indicate the importance of comprehension as a cognitive process intimately related to reading and justifies its deficit as underlying pathophysiology of dyslexia. This impairment of comprehension tasks might be attributed to poor vocabulary store of those children. This may highlight the necessity of early enrichment of vocabulary store of young children to improve their comprehension strategies. This finding is supported by the significantly impaired mean scores of giving the word meaning or opposite word sub-test obtained by children with dyslexia compared to good readers. Impaired comprehension results in low responding to teacher’s instructions, in re-reading of the text more and more with consequent slow reading and low level of achievement. Consistent with these results are the findings of Vellutino in 1991, who mentioned that failure to use good comprehension strategies could contribute to poor reading and reduced scores in spelling [19].

Over the past three decades, accumulated evidence demonstrates that dyslexia involves difficulty within the language system, specifically phonology [20]. The phonological deficit hypothesis relies on the converging

evidence from laboratories around the world which demonstrated what has been termed “neural signature of dyslexia”. This describes the inefficient functioning of the left posterior reading system (Wernicke’s area, angular gyrus, and striate cortex) [21]. In the present study, poor achievers performed significantly worse than good achievers on phonological awareness (0.001). Difficulties in phonemic awareness are typically observed in students with dyslexia and impact a student’s ability to learn letters and the sounds associated with a given letter shape and to understand the alphabetic principle (audio-visual correspondence), resulting in difficulties in decoding words and accurate spelling. These findings are consistent with the study done by Gentile (2005), who considered a weakness in rhyme detection and phonological awareness as a precursor of dyslexia [22].

Students with dyslexia had lower visuospatial skills than good achievers (0.001). The significantly poor visuospatial skills of students with Arabic reading disability in comparison to good readers could be explained by their inability to discriminate between similar Arabic letters specially dotted letters as (ح خ ح), (ن ب). Moreover, these impaired visuospatial skills are the underlying contributor for letter reversal within a word. This view is confirmed by the significantly lower scores of poor readers on their ability to form words from letters, and their lower but insignificant lower scores on proper dotting of letters.

The significantly low scores of auditory memory tasks of the battery among poor achievers compared to good achievers (0.002) might indicate the importance of auditory memory deficits in the aetiology of dyslexia and justifies its importance in the newly constructed diagnostic battery. These results agree with the study of Slaghuys and Ryan, who found that dyslexic children have auditory memory deficit [23]. Poor auditory memory makes dyslexic students forget parts of words, phrases, or sentences before they have been completely understood, resulting in poor comprehension and this necessitates re-reading more and more with consequently slow reading [24]. Moreover, memory for letter patterns, letter sequences, and the letters in whole words (orthographic processing) may be selectively impaired or may coexist with phonological processing weaknesses and poor auditory memory that contribute to dyslexia [24].

In the present study, poor readers scored significantly lower scores on audio-visual correspondence tasks than their peers with good reading. The beginning reader should connect the shape of letters (graphemes) to the sounds of spoken letters, or the elemental particles of speech (phonemes), i.e., grapheme-phoneme correspondence. The phonological deficit hypothesis represents the most robust and specific correlate of reading disability

[25]. And also, grapheme-phoneme correspondence or mastery of audio-visual correspondence skills are crucial not only for the beginning readers but also for early developing infant to connect the heard words to the corresponding objects around him. Thus, understanding this underlying pathophysiology represents the basis of most successful programs of an evidence-based intervention designed to improve reading.

Evaluation of sensitivity and specificity of the newly constructed Cognitive Abilities Diagnostic Battery for reading revealed that the new battery had high sensitivity as a screening tool (86.5%), and it is a useful tool for diagnosis of dyslexia (specificity = 84%) according to Cicchetti [26]. Moreover, some of its sub-items, e.g. visual discrimination (97%), auditory discrimination (87%), and audio-visual correspondence (84%) have excellent specificity for the diagnosis of dyslexia cases.

After training of sixteen students with reading disability was done, there was a significant improvement on the total battery score of cognitive skills as well as its sub-items. This improvement in reading cognitive abilities was associated with a significant improvement in reading achievement as evaluated by ARAT. These findings document the importance of the studied cognitive skills and their relevance to the development of the reading process.

## Conclusions

Dyslexia is a disorder amenable for rehabilitation and improvement, particularly with early intervention during periods of fruitful neuroplasticity. Well-tailored research-based rehabilitation programs, according to identified points of weakness, could result in improvement of cognitive skills and, consequently, reading achievement.

Lastly, it is recommended to change the terminology to students with reading difficulties instead of reading disabilities, as it is amenable for rehabilitation and improvement. All struggling readers should be included in special education programs and offered services to meet their unique needs.

## Abbreviations

ARAT: Arabic reading achievement test; CADB-R: Cognitive abilities diagnostic battery for reading; CATB-R: Cognitive abilities training battery for reading.

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s41983-022-00480-y>.

**Additional file 1.** Arabic reading achievement test.

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**Author contributions**

WF and HE were the main contributors for the research idea, for writing the protocol and reviewing the manuscript. AR and MA designed the computerized diagnostic and training programs. MA, RB, and GS reviewed the diagnostic and training programs and also wrote the main sections of manuscript. SE supervised the application of the diagnostic and training programs and also analysed and interpreted the data. KO wrote the discussion section. All the authors read and approved the final manuscript.

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**Availability of data and materials**

The datasets generated and/or analysed during the current study are not publicly available due individual privacy but are available from the corresponding author on reasonable request.

**Declarations****Ethics approval and consent to participate**

Informed written consent was signed by the parent or legal guardian of the student. This study protocol was approved by the ethical committee of Assiut university faculty of medicine with ethical approval number: Prof. Waffa Farghaly (2015-03-R20) and Prof. Reda Badry (2015-3-R21). Also this study protocol was registered in Clinical trial.gov with Identifier: NCT04642859.

**Consent for publication**

Not applicable as the manuscript does not contain any individual person's data in any form (individual details, images or videos).

**Competing interests**

The authors declare that they have no competing interests.

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