Control placebo study to test the efficacy of the GlassesOff scientific engine and mobile application

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Introduction

Presbyopia results from a gradual decrease in accommodative power during normal ageing, leading to reduced near visual acuity and contrast sensitivity and slower visual processing speed.
Presbyopia negatively affects the quality of vision for near tasks such as reading

We showed that visual performance on a variety of tasks benefits from practice, in both young and older adults, resulting in long-term improvements. These long-term effects of repeated practice on a demanding task are termed perceptual learning (1-6)

After training generalize to untrained stimulus parameters, such as reading speed, brain processing, reaction time and more.

Aim Of The Study

A masked, placebo-controlled, 60-day trial in individuals aged 40+ with self-reported reduced near visual acuity (NVA) examined the clinical effects on NVA and visual cortex image processing speed (IPS) of training a minimum 35 sessions with the GlassesOff application on a mobile device (iOS or Android).

Methods

Participants (n = 40) were randomly divided at a ratio of 1:3 to placebo comparator cohort (GlassesOff app, muted training algorithm, n = 10) or active cohort (GlassesOff app, active training algorithm, n = 30). near visual acuity (NVA) and visual cortex image processing speed (IPS) measurements were performed at baseline and after completion of the study.

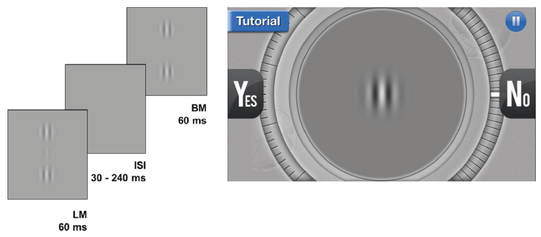
Baseline Characteristics of the Active vs Placebo Groups			
	Active (n=30)	Placebo (n=10)	
Age	49.7 ±4.3	49.3±3.4	p=0.77
Baseline NVA (logMAR)	0.39±0.15	0.38±0.16	p=0.95
NVA @ 120 ms (logMAR)	0.49±0.18	0.47±0.17	P=0.65
NVA @ 60 ms (logMAR)	0.55±0.19	0.49±0.20	P=0.92
NVA @ 30 ms (logMAR)	0.64±0.19	0.57±0.22	P=0.87

GlassesOff Training Algorithm

Participants were trained using the same Glassesoff application on their personal mobile devices. The participants in both active and placebo group installed the exact same GlassesOff application and were held under the assumption that they are using the fully-functional application. The placebo group participants were marked as "muted training algorithm" on the GlassesOff server without their knowledge, while the active group participants were marked as "active training algorithm". The participants were asked to train with the application 2-3 times per week for a minimum of 35 sessions within a 60-day period, and complete each training session. The placebo group's training session were the same amount of time and containing the same visual challenges as those in the active group. However, the placebo group training sessions did not use the active algorithm that was designed to improve the participant's NVS and IPS via gradual increase in the difficulty levels of the visual stimulations tasks.

GlassesOff Active Training Algorithm

Participants were trained on contrast detection and discrimination of Gabor targets under spatial masking, temporal masking, and spatial crowding conditions, while spatial and temporal constraints were posed on the visual processing. The training covered a wide range of spatial frequencies and orientations that were modified in accordance with the improved performance. Participants were instructed to train in a dark room from a distance of 40 cm with both eyes open.



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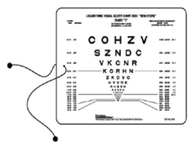
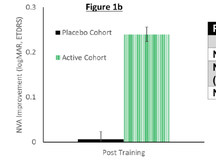
Experiment

Near visual acuity (NVA)



Results

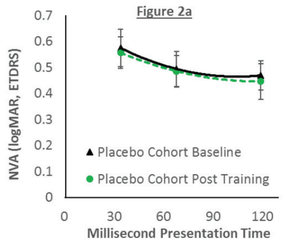


Post-Study Characteristics of the Active vs Placebo Groups			
	Active (n=30)	Placebo (n=10)	
NVA baseline (logMAR)	0.39±0.15	0.38±0.20	p=0.95
NVA improvement vs baseline (logMAR)	0.234 ±0.091	0.006 ±0.055	p=0.005
Number of training sessions	44.7 ±5.5	40.3±0.22	p=0.15

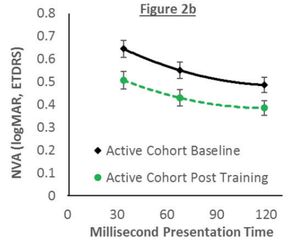
The placebo cohort's NVA improvement was close to zero, (0.006 ±0.055 logMAR, or 1.1%), while the active cohort's NVA improved by 0.234 ±0.091 logMAR (71% improvement, meaning that on average they see letters with a font size which is 29% of the baseline font size, or approximately 1/3 of the size of the baseline font).
Post training 27 out of 30 (90%) participants from the active cohort reached the study primary objective of improvement of their initial NVA by at least 0.18 logMAR positive delta (2x better NVA). In contrast, no participant from the placebo cohort reached the secondary objective.

Image processing speed

Placebo training



Active training



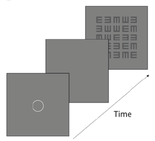


Figure 1 Stimuli and paradigm. (a) "Tumbling-E" patterns with 1-letter (large) spacing (upper) and 0.4-letter (small) spacing (bottom), in 4 representative stimulus sizes, with proportional spacing per letter size. (b) The time-line of a single trial. A fixation circle (enlarged for presentation) appeared in the center of the screen before each trial, which disappeared when the participants initiated the trial by pressing anywhere on the touch screen, after which a blank screen appeared for 300 milliseconds, followed by the stimulus presentation.

Post-Study Characteristics of the Active vs Placebo Groups		
	Active (n=30)	Placebo (n=10)
Baseline NVA @ 120 ms	0.49±0.18	0.47±0.17
Post training NVA @ 120 ms	0.38±0.16	0.45±0.21
Baseline NVA @ 60 ms	0.55±0.19	0.49±0.20
Post training NVA @ 60 ms	0.43±0.19	0.49±0.18
Baseline NVA @ 30 ms	0.64±0.19	0.57±0.22
Post training NVA @ 30 ms	0.51±0.20	0.56±0.18
Baseline presentation time required for NVA of 0.5±0.02 logMAR	120	60
Post training presentation time required for NVA of 0.5±0.02 logMAR	30	60
Image processing speed multiple post training	4x	0x

The placebo cohort showed no significant difference in IPS (P>0.38, paired t-test) between baseline and post training. However, the active cohort showed significant improvement in all 3 presentation times (p<0.00005, paired t-test). Post training, the active cohort participants were able to see on average logMAR 0.5±0.02 letters after only a 30 millisecond presentation, while their baseline for logMAR 0.5±0.02 was 120 millisecond presentation, or four times (4x) faster IPS.

Calclusions

GlassesOff application with an active training algorithm can be used to increase NVA to levels allowing reading of small fonts (newspaper font size) without the aid of reading glasses; and to significantly increase the visual cortex image processing speed (IPS) to see real-life visual events at significantly higher speeds.
The placebo group show no improvement in both near visual acuity (NVA) and image processing speed (IPS)