CAN-EYE: what is the evidence?

Company White Paper

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SUMMARY

Since commencing early-stage user evaluation sessions in 2019 and 2020, Inocer now has over 1,500 users, and has completed number of studies to provide objective evidence for our low vision rehabilitation app CAN-EYE. This report summarizes two key activities conducted to test and verify the positive impact on real-life validity of CAN-EYE used at-home by low vision children while assessing pilot measurable improvements in sight impact. Outcomes demonstrated large potential for CAN-EYE to improve ability of visual functions and patient wellbeing:

- 70% of patients using CAN-EYE at-home reported improved ability on object follow-up, increase in object follow-up duration and fixation on moving objects compared to other visual stimulation aids they use.
- Visual attention improved significantly by on average 3.57 units as per PreViAs questionnaire for all age groups in this study.
- Visual communication improved significantly by on average 1.51 units as per PreViAs questionnaire for all age groups in this study.
- Visio-motor coordination improved significantly by on average 3.19 units as per PreViAs questionnaire for all age groups in this study.
- Visual processing improved significantly by on average 5.40 units as per PreViAs questionnaire for all age groups in this study.
- 74% of users reported being able to do activities which they could not do before.

1. AT-HOME EVALUATION

Introduction

Between 2019 and 2020, incremental iterations of the CAN-EYE prototype were demonstrated to over 250 visually impaired children from all around the world for home usage via application stores. After arriving at a final prototype version in 2020, Inocer offered in-depth at home evaluation sessions to low vision children. Results of these evaluation sessions, running between June 2020 and December 2020, are described in this report.

Methods

Screening and at-home trial sessions

After engaging with number of charities and through exposure on social media, Inocer invited randomly 122 families with 36 months old or below low vision children for at-home evaluation of CAN-EYE. 92 participants accepted to attend at-home session in 2020 for two months. These participants had been screened to use visual stimulation cards as an other low vision stimulation aid and have similar cognitive development as to children at the same age to minimise risk of a negative impact on wellbeing.

The at-home session served to explain the CAN-EYE functionality in depth, including applied tasks resembling common recreational tasks, such as object follow-up and fixation on objects. Based on considerations of ability to see, comfort, environment to operate CAN-EYE and personal needs.

Participants

Of the 92 participants, 22% were aged <6 months (n=20), 39% were aged 6-12 months (n=36) and 39% were aged 12-36 months (n=36). The most common sight conditions were cerebral visual impairment (CVI), congenital cataracts and congenital glaucoma. Families of the most participants did not know their children's visual acuity, as they are at pre-verbal period at the time of at-home sessions. From descriptions and limited data, the vast majority of participants is assumed to fall within the WHO definition of low vision as they are referred to have visual rehabilitation by consultant ophthalmologist.

Task

Participants were instructed about the study and to use CAN-EYE to observe the tasks' ability in object follow-up for longer duration and fixation on moving objects.

CAN-EYE provided three modules of exercises for low vison children with traceability and reporting functions for ophthalmologists on mobile platforms. Module A – designed for developing children's light and shape recognition. Module B – designed for developing perception of light, colours and movements. Module C – designed to improve eye-hand coordination. Exercises which they were recommended to do by the app, based on their ages for two months period. This explicitly excluded while falling asleep, get bored and any other non-cooperative activities. Participants were advised to take regular breaks when the child is not following the screen anymore and to complete 40 minutes daily session. They were also advised discontinue use and contact the Inocer team if there were adverse effects.

During two months at-home evaluation period, participants agreed to be contacted a number of times for catch-up and support. Typically, this involved one call at the start of the evaluation period, followed

by two to three calls throughout the period. Participants were provided Inocer contact details and encouraged to call or text if they encountered any technical problems, side effects or other issues.

Reporting

At the end of the two months period, participants agreed to participate in a comprehensive reporting based on a structured interview. The same questionnaire was administered to all participants' parents, in which they were asked to give feedback on CAN-EYE, provide scores from 1-10 for their ability to do tasks and provide input regarding future development.

The reporting took the approach to compare CAN-EYE to the participant's other visual stimulating aid, not their baseline ability to see. The rationale for this approach was the expectation that any future visual stimulating aid would have to perform at least as well as current solutions in to be competitive.

If at the end of the at-home period participants wished to keep CAN-EYE, they were able to do so for a nominal fee to ensure the true interest in the solution. Since then, CAN-EYE has been made free of charge to all participants to study.

Results

Improvement in object follow-up ability & duration and fixation on moving objects

A total of 70% of testers' parents scored 7 or higher about ability to do tasks with CAN-EYE. With this result we incorporated that CAN-EYE improved their children's ability in object follow-up for longer duration and fixation on moving objects for any of their chosen exercises compared to visual stimulation cards as an other visual stimulating aid, they use.

The most performed activities were Module A (77%), Module A+B (42%), Module B+C (39%) and Module A+B+C (17%) based on their conditions and ages.

For these most common uses, the rates of participants reporting a better ability to follow-up objects for longer duration and fixation on moving objects for any of their chosen exercises compared to other visual stimulating aid were as follows (**Figure 1&2**).

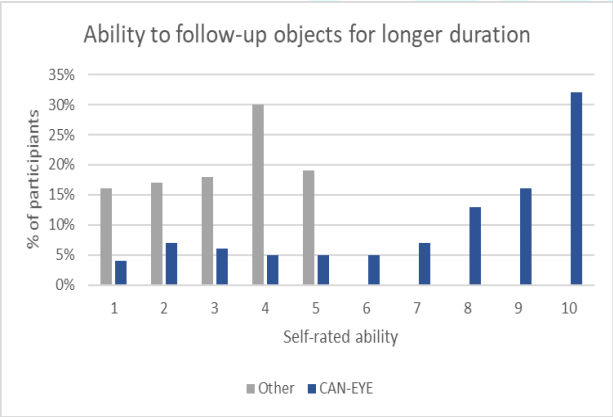

Figure 1. Self-rated ability in object follow-up for longer duration with other visual stimulating aid (grey) and CAN-EYE (blue) when doing Module A or B or C or their combinations together. 1-can't follow, 10-can follow clearly

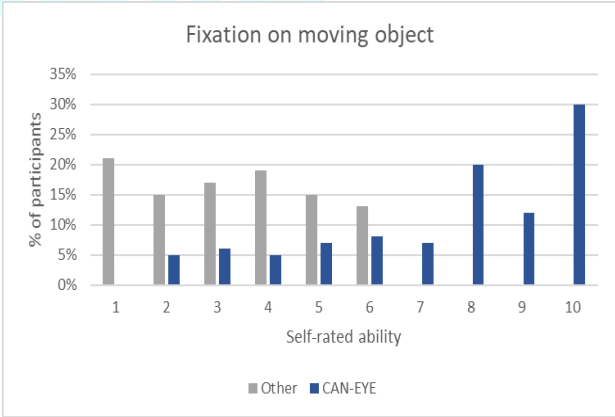

Figure 2. Self-rated ability in fixation on moving objects with other visual stimulating aid (grey) and CAN-EYE (blue) when doing Module A or B or C or their combinations together. 1-can't follow, 10-can follow clearly

Retention

At the end of the at-home evaluation session, 73% of at-home testers chose to keep CAN-EYE further. All those who chose to keep CAN-EYE reported an improvement in ability of object follow-up for longer duration and fixation on moving objects to a self-rated 7.4 out of 10 or higher for activities they do.

27% of at-home testers returned the app, 88% of which did not keep it because it was too tiring for them to do daily exercises, for example if a child does not cooperate during exercises for many reasons or had a bad day at work. The remaining participants indicated insufficient improvement in ability of object follow-up for longer duration and fixation on moving objects to justify use and other reasons.

Discussion and Conclusion

This at-home evaluation session showed that CAN-EYE can support activities of daily living as the children can learn better by seeing. Ratings for object follow-up for longer duration and fixation on moving objects during performed tasks increased substantially. Certain features showed room for improvement, for example need of assessment module for improvement and implementation of dichoptic therapy module. In general, CAN-EYE performed better than participants' current visual stimulating aid, demonstrating both the need for and potential of the remote rehabilitation solutions. While not all participants elected to keep CAN-EYE after the testing session, Inocer anticipates that those testers who returned it for reasons mentioned above may take up a proposed 2nd generation app which will address identified issues.

There was a small fraction of participants in at-home trial sessions, who felt that CAN-EYE could not sufficiently improve their ability of object follow-up for longer duration and fixation on moving objects. In the future, it will be important to explore the scope and limitations to sight enhancement using the methods incorporated in CAN-EYE. In this study, participants were not screened out based on their ability to see, as the study aimed at exploring the potential of the app. In the future, it may become apparent that certain patient groups may benefit more from sight enhancement than others. At present, Inocer is not aware of thresholds in acuity or contrast sensitivity. At the same time, there is potential to stimulate visual function with extended app use, even if there is no immediate effect. These are questions which will need to be addressed in the future in order to scope out which patients are most likely to benefit from an app and to develop solutions for those patients who currently do not benefit.

2. PILOT IMPACT ASSESSMENT

Introduction

Following the two months at-home evaluation sessions conducted in 2020, those participants who wished to keep the CAN-EYE were enabled to do so. After a prolonged and continuous usage time, it was however unclear what CAN-EYE usage pattern children had adopted and to what extent they benefitted from CAN-EYE in the long-term. To answer these questions, Inocer followed up with new users by gathering data between January-August 2021 after three months applying CAN-EYE continuously. While administering validated questionnaires in order to explore their sensitivity to changes in participants' lives, assessment focused on "Preverbal Visual Assessment (PreViAs) questionnaire", which classifies visual behaviours into four cognitive domains: visual attention, visual communication, visio–motor coordination, and visual processing. 30 questions in PreViAs were classified into one or more of the four domains. Inocer used PreViAs to also serve as a pilot study for a future health economic assessment, partially balancing the CAN-EYE study group (n=57) to explore volunteer responsiveness and effect sizes.

Visual cognitive functions of preverbal infants are evaluated by means of a behavioural assessment. In this pilot work, visually impaired infants under 24 months of age (main indication CVI) participated in an assessment of their visual behaviour before and after applying CAN-EYE app. This represented an opportunistic sample and was conducted as part of an ongoing user study run by Inocer. As part of this studies article about CAN-EYE have since been published in 'Middlesex Association for the Blind - Outlook' Magazine.

Methods

Participants

Assessment of the visual skills of preverbal children is highly dependent on the time available for the evaluation and the experience of the examiner. As well, behavior in a hospital environment may not be representative of a child's abilities. Information supplied by parents or other caregivers thereby provides a broader understanding of a child's daily activities and invaluable knowledge regarding a child's behaviour.

57 long-term CAN-EYE users participated in this follow-up study. This study cohort was age-, gender- and condition balanced identified from Inocer's volunteer network. Participants comprised 57 infants (29 girls, 28 boys) with CVI, congenital eye abnormalities resulting from various conditions and preterm birth. 37% of the whole sample was aged 12-15 months (n=21), 35% was aged 15-18 months (n=20) and 28% was aged 9-12 months children (n=16) with their parents answering on their behalf.

Questionnaire

Data was gathered using validated Preverbal Visual Assessment (PreVias) questionnaire, for visual assessment, and to capture the impact of CAN-EYE which were provided on a mobile platform, on visual outcomes of infants in the study group.

Identifying visual difficulties and communicating them to parents can position the child at the starting point of an active management approach. It is the basis of many questionnaires used by paediatricians to monitor the development of children. Early assessment of infants in the risk group for CVI and early approaches for habilitation are positively effective on outcome.

Since questionnaire had not been administered when first providing CAN-EYE, this study took a retrospective approach, asking participants to answer 30 questions for the time before they had applied CAN-EYE and after. Based on the literature examining the impact of this retrospective design, the bias introduced is expected to be small. In the future, a prospective design will be adopted as it is the preferred method for impact assessment.

Results

All participants reported having used CAN-EYE continuously during study. Non-usage for any technical reasons were not reported as the technical issues were resolved with follow-up support. Usage frequency showed that 81% of respondents used CAN-EYE daily, often multiple times per day in order to complete 40-minutes sessions daily. The remainder reported using CAN-EYE less frequently means some days of the week and less than proposed exercise duration.

The duration per session for which infants used CAN-EYE varied: 60% of participants used CAN-EYE on average for 40 minutes or more, while another 21% used it for 10 to 40 minutes several times and the remaining participants reporting usage duration for less than 10 minutes several times.

The study group classified visual behaviours into four cognitive domains: visual attention, visual communication, visio–motor coordination, and visual processing. 30 questions were classified into one or more of the four domains, as shown in PreviAs. The results were scored with 1 point per item achieved. The maximum possible scores were 30 for the overall score, 11 for the visual attention domain, 5 for the visual communication domain, 13 for the visio–motor coordination domain and 20 for the visual processing domain. For all infants, the questionnaire was completed by the person accompanying him or her to the medical visit, e.g., mother, father, grandmother, and others.

In this study, the questionnaire scores of infants before and after applying CAN-EYE and those were compared with each other.

Results (**Figure 3,4,5,6&7**) demonstrated a significant improvement in mean global score and four domains of PreViAs questionnaire with CAN-EYE compared with not using the app.

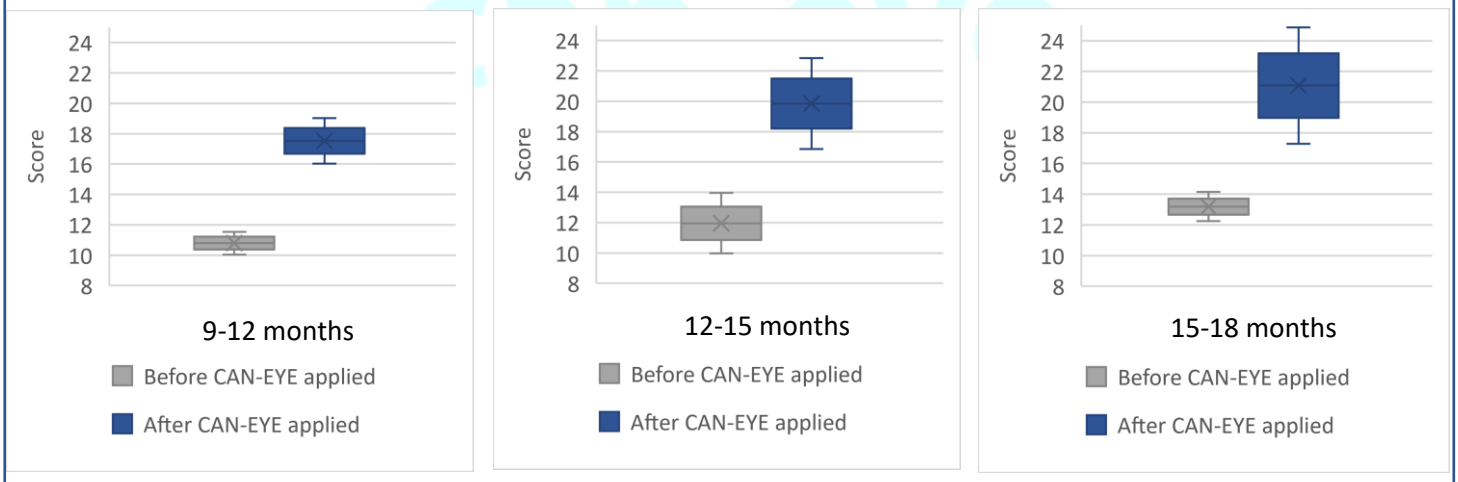

Figure 3. Statistically significant (p=0.02) improvement for testers on mean global scores on a scale from 0 to 30 for 9-12 months (10.84 points to 17.63, n=16), for 12-15 months (11.96 points to 19.85, n=21) and for 15-18 months (13.24 points to 21.28, n=20)

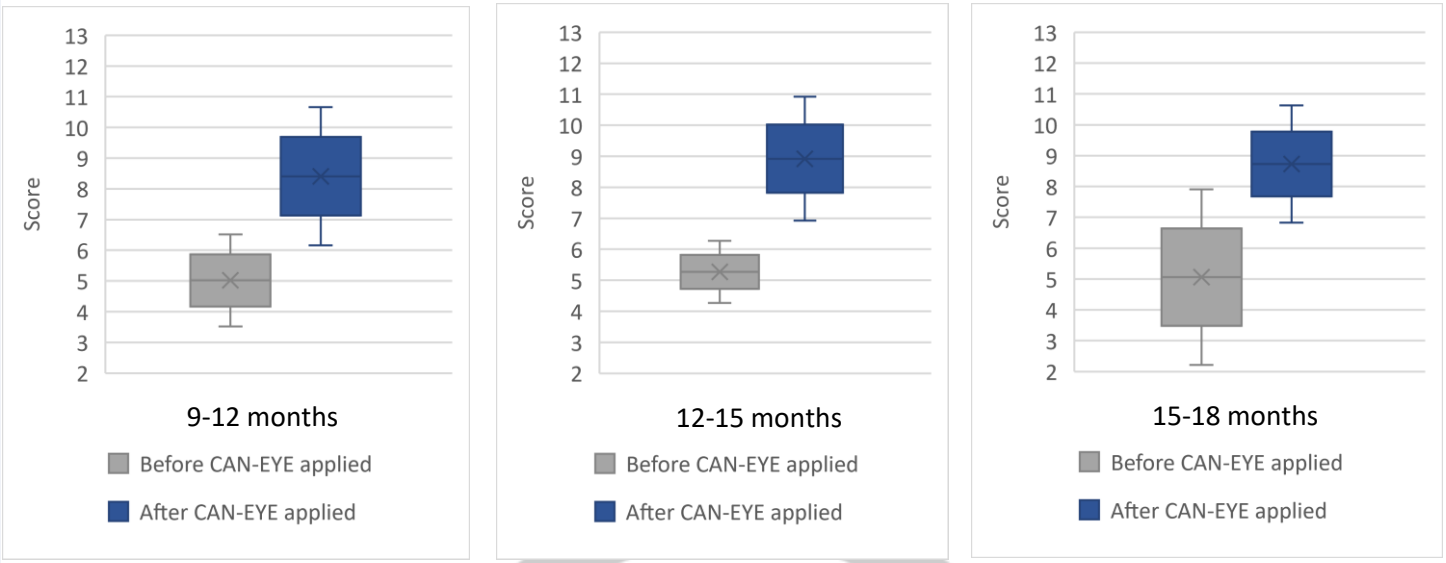

Figure 4. Statistically significant (p=0.02) improvement for testers on mean visual attention scores on a scale from 0 to 11 for 9-12 months (5.12 points to 8.56, n=16), for 12-15 months (5.27 points to 8.92, n=21) and for 15-18 months (5.21 points to 8.86, n=20).

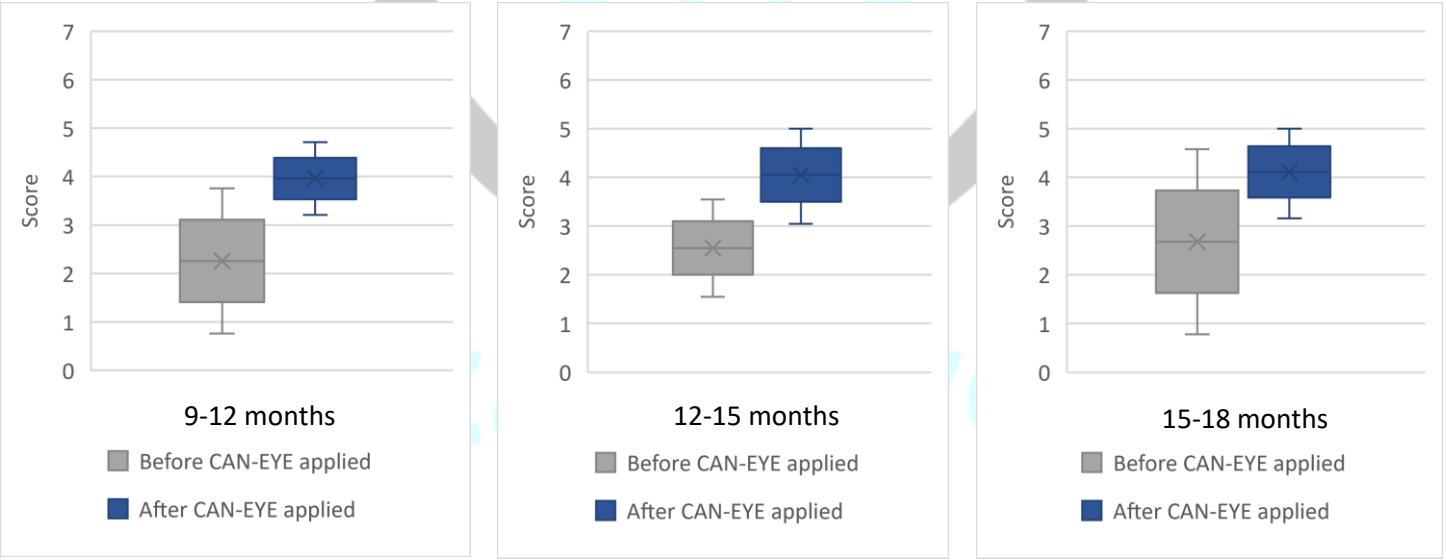

Figure 5. Statistically significant (p=0.02) improvement for testers on mean visual communication scores on a scale from 0 to 5 for 9-12 months (2.36 points to 4.01, n=16), for 12-15 months (2.55 points to 4.05, n=21) and for 15-18 months (2.78 points to 4.16, n=20).

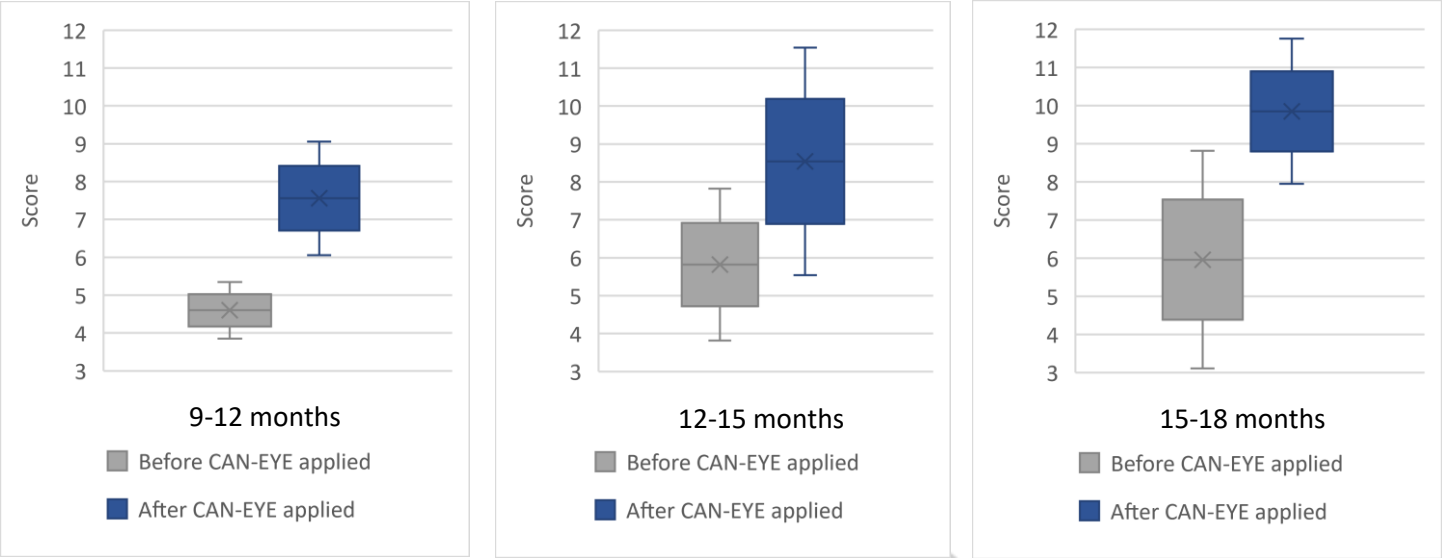

Figure 6. Statistically significant (p=0.02) improvement for testers on mean visio-motor coordination scores on a scale from 0 to 13 for 9-12 months (4.65 points to 7.66, n=16), for 12-15 months (5.82 points to 8.54, n=21) and for 15-18 months (6.11 points to 9.95, n=20).

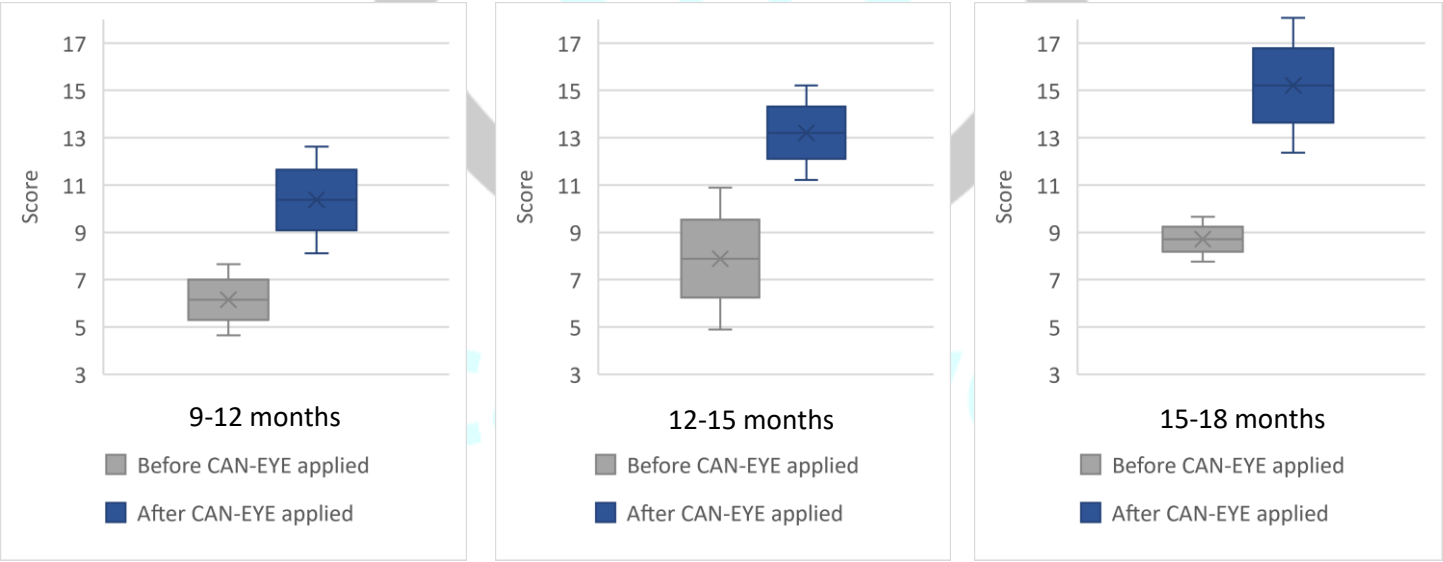

Figure 7. Statistically significant (p=0.02) improvement for testers on mean visual processing scores on a scale from 0 to 20 for 9-12 months (6.25 points to 10.52, n=16), for 12-15 months (7.89 points to 13.21, n=21) and for 15-18 months (8.76 points to 15.36, n=20).

Discussion and Conclusion

This study achieved a response rate of 81% of current testers based on duration per session who had been using the device for three-months continuously. Of them, the absolute majority (92%) reported still using the app, often daily (63%). The impact of the app included increased visual attention, visual communication, visio–motor coordination, and visual processing. Further, 74% % of users reported there were significant positive effects on activities they could not do before due to their sight.

CAN-EYE was found to have a significant effect on global score, visual attention, visual communication, visio–motor coordination, and visual processing as defined by the Preverbal Visual Assessment (PreViAs) Questionnaire. This change amounted to 7.57 units on average for global score, 3.57 units on average for visual attention, 1.51 units on average for visual communication, 3.19 units on average for visio–motor coordination, 4.40 units on average for visual processing for testers from all ages in the study.

As the PreViAs questionnaire is a paediatric instrument, it can be used for future work to accurately capture the on clinical impact for all age groups as defined. This indicates that CAN-EYE is a versatile visual rehabilitation app providing lots of improvements in visual and cognitive functions for low vision children and children in low vision risk group.

Occupational therapists advise the environmental arrangements required for visual stimulation to the families of low vision children. CAN-EYE might be applied to low vision children in addition to environmental arrangements. Healthy term infants who were not in the low vision risk group should also be evaluated monthly with the PreViAs questionnaire in order to create awareness.

From comparing pilot impact assessment group results with a reference result in PreViAs questionnaire study, this study showed that the children using CAN-EYE have closer scores to PreViAs questionnaire in visual attention, visual communication, visio–motor coordination, and visual processing after the period of intervention.

While there are currently no published data in the peer reviewed literature on the effect of digital visual simulation tools on the market, results compared with data presented in PreViAs questionnaire. Similar clinical research should be conducted in the future in order to standardise the results and estimate an accurate effect size with CAN-EYE including control groups for all age groups as defined In PreViAs questionnaire.

References

Pueyo, Victoria et al. 2014. Development of the Preverbal Visual Assessment (PreViAs) Questionnaire. Early Human Development, Volume 90, Issue 4, Pages 165-168, ISSN 0378-3782, https://doi.org/10.1016/j.earlhumdev.2014.01.012.