

An effectiveness study of a wearable device (Clouclip) intervention in unhealthy visual behaviors among school-age children

A pilot study

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Abstract

Introduction: The study aimed to determine the effectiveness of an intervention for unhealthy visual behaviors of school-age children using a wearable device (Clouclip).

Method: The design was a self-controlled prospective study. Clouclip, with the vibration alert disabled, was first applied to measure baseline near-work behaviors in the first week. The vibration alert was then enabled to signal unhealthy visual behaviors (near-work distance < 30 cm and >5 seconds, or near-work distance <60 cm for >45 minutes) for 3 weeks. Near-work behaviors were measured again at the first week and the first month after intervention, respectively. The changes in behaviors between the baseline and the first week and the first month after intervention were analyzed.

Results: Sixty-seven subjects were eligible for this experiment (the mean age 10.45 ± 0.50 years, 34 boys). Children who logged sufficient wearing time (12.30 ± 0.18 hours on weekdays and 12.16 ± 0.23 hours on weekends) were included for analysis. The average daily near-work distance was significantly increased after the vibration intervention. The time ratio of near-work activity <30 cm to the total <60 cm and the frequency of continuous near-work (distance <60 cm and continuous time >30 minutes) were significantly decreased after the intervention. Although some of the effects were reversed with time following the intervention, some were observed to be maintained until the end of the observation period, and the improvement of the behaviors was more prominent in children who had a shorter near-work distance (<30 cm) at baseline.

Conclusions: In conclusion, Clouclip can significantly modify near-work behaviors in school-age children and it can last a certain period of time. If these behaviors are causes of myopia development and progression, Clouclip might provide a strategy for managing myopia.

Abbreviations: AIER = aier (Chinese name) school of Ophthalmology, cm = centimeter, IBM = International Business Machine, min = minute, mm = millimeter, S = second, SPSS = Statistic Package for Social Science.

Keywords: myopia, near-work, wearable device

1. Introduction

The prevalence of myopia has increased significantly over the past decade all over the world, and is now very high in the developed countries of East Asia (China, Singapore and South Korea).^[1,2] The prevalence of myopia among middle school students in

China has reached 78.4 percent.^[3] It is estimated that nearly one-half of the world's population (4,758 million) may be myopic by 2050, with 9.8% (938 million) being highly myopic.^[4] Myopia not only carries a great cost of refraction correction and declines quality of life but also increases the risk of retinal detachment, glaucoma or other blinding eye diseases.^[5-9] Current trends in

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The authors report no conflicts of interest.

The data used to support the findings of this study are available from the corresponding author (Zhikuan Yang) upon request.

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myopia include higher prevalence, younger age of onset and a prevalence of high myopia.^[1,10–13]

Myopia is generally thought to be caused by both genetic and environmental factors.^[14] Excessive near-work and less outdoor exposure are the most likely environmental factors, known as myopia-related behaviors.^[14,15] Previous cross-sectional and two cohort studies have shown that excessive near-work leads to an increase in the incidence of myopia in school-age children.^[16–20] Ip et al demonstrated that the risk of myopia would respectively rise by 2.5 times and 1.5 times if the near-work distance is less than 30 cm and the continuous near-work time is more than 30 minutes.^[21] A recent study indicated that there is a significant increase in the axial length of students spending more than 3 hours per day of near-work compared to those spending less than 3 hours a day (23.57 mm vs 23.29 mm, $P < .001$).^[22]

Previous interventions for environmental risk factors mainly focused on outdoor exposure, and there were few interventions aiming at near-work. Wu et al adopted the intervention method of compulsory outdoor activities for children during breaks between classes.^[14] The results showed that new onset of myopia was significantly lower in the intervention group than in the control group after one year of intervention (8.4% versus 17.7%; $P < .001$). In a study by He et al, the intervention was to add one 40-minute class daily for outdoor activities on weekdays, and the prevalence of myopia in the intervention group was 9.1% lower than that in the control group after 3 years of intervention.^[23] There are few clinical trials of the effectiveness of increasing reading distance or limiting the duration of continuous reading, possibly due to the difficulty of continuously monitoring near-work behaviors that are generally estimated from questionnaire responses. Clouclip is a recently developed intelligent wearable device, which can objectively and dynamically monitor the wearer's near-work distance and duration. Our previous studies have shown that Clouclip is accurate and reliable in measuring this parameter (Wen et al IOVS 2016; 57: ARVO E-Abstract 2491). Clouclip was designed to provide a vibration alert when it detects risky near-work-related behaviors, such as particularly short viewing distances or prolonged continuous near-work.

The aim of this experiment was to investigate the effectiveness of this wearable device in correcting these potentially unhealthy visual behaviors in school-age children.

2. Methods

2.1. Subjects

Informed consent was obtained from all participants and their parents or guardians after the nature of the study and possible consequences had been explained. The study was approved by the ethics committee of AIER School of Ophthalmology, Central South University (Ethical approval number: IRB2016004) and followed the tenets of the Declaration of Helsinki. This study was registered at Clinical Trials.gov (Identifier: chiCTR-OOC-16010143).

This experiment is a self-controlled prospective study. Seventy-three volunteers in grade five of primary school in NingXiang, Hunan province, China were recruited. The subjects invited to participate in our study, who were assigned to wear Clouclip all day (except for bathing and sleeping) during the experiment, were free of strabismus and amblyopia and had no history of ocular trauma, or surgery. In addition to definite medical/ophthalmic

disorders (such as heart disease, mental disorder, glaucoma, cataract, etc.), the exclusion criteria were the existence of any other ocular diseases as well as any ocular surgery, mental retardation or speech disorder.

2.2. Intelligent intervention

We used an eye behavior intervention device, called Clouclip (Model F1, Patent NO.2017109797802), by HangZhou Glasson Technology Co., Ltd. The device incorporates an infrared sensor for real-time measurement of the near-work distance (measurement range: 15–60 cm). In addition, it contains an angular acceleration sensor (X, Y, Z axes) for the differentiation between wearing or not wearing. If the angular acceleration sensor is unchanged for more than 40 seconds, it automatically switches to dormant and stops collecting “real data.” Clouclip monitors the wearer's near-work distance and automatically stores the data in its memory chip every 2 minutes. Therefore, researchers can immediately access the collected data for analysis through mobile APP (the cloud service of Clouclip eye care on WeChat) or through the cloud platform after the completion of the experiment. We set a near-work distance < 30 cm (excessive near-work distance) or continuous near-work > 45 minutes (excessive near-work time) as unhealthy visual behaviors. These unhealthy visual behaviors triggered a reminder by Clouclip. Our previous study has shown that Clouclip is accurate and reliable in monitoring these parameters; there was significant correlation between the measured and actual values in near-work distance ($r = 0.998$, $P < .001$), the 95% limit of agreement in near-work distance was 0.18 to 3.10 cm, and the relative errors for near-work distance was 2.4% to 6.5%.^[24]

2.3. Research procedures

2.3.1. Installing the device. The medical silicone clip was put on the right leg of the spectacle frames. For those subjects who did not habitually wear spectacles, lensless frames were provided to carry the device. The device was then put on the clip, and the window for data collection was set parallel to the surface of the spectacle frame.

2.3.2. Quality control. All Clouclip devices were calibrated for distance measurement and the vibration alert function was tested before distribution. To ensure normal function, Clouclips must be charged every night (the battery life of Clouclip under fully charged conditions is approximately 48 hours). The data collected by Clouclip were uploaded and saved to the cloud platform data center system by the same researcher who is skilled in experimental.

2.3.3. Experimental process. All subjects were asked to wear Clouclip (without the vibration alert function) for three days to allow adaptation to this device; this period was called the adaptive phase and data was not recorded. The procedure after the adaptive phase was divided into four periods as follows (Fig. 1).

Week 1: One week before starting the intervention. All subjects wore the devices to collect baseline data on visual behaviors. The vibration alert function was turned off during this period.

Weeks 2–4: Intervention for 3 weeks. The Clouclip vibration alert function was turned on from the first day of the intervention period. The device continuously monitored wearer behavior, and the vibration alert was triggered as described above. At the end of this period, the subjects were asked to score their feelings about the vibration alert on a scale from 0 (no problems) to 10

(major problems). A subject's score of 10 points indicated that Clouclip interfered with and interrupted their normal studies and lives, and the feelings were very negative. A score of 0 indicates that there was basically no interference from the device. In other words, the lower the score, the less the interference.

Week 5: One week after intervention. The vibration alert function was turned off again on the first day of the fifth week, to investigate whether the behavior had been changed after three weeks intervention. At the end of this week, all Clouclips were returned to the researchers.

4) Week 8: One month after intervention. All subjects were enrolled to wear Clouclip for one more week in order to collect data on the subjects' visual behavior and to investigate how the behavior had changed one month after the end of intervention. The vibration alert function was turned off during this week. Clouclips were returned to the researchers at the end of the study and all subjects were asked about their willingness to continue wearing the Clouclip.

2.4. Data processing and definition of parameters

2.4.1. Data processing. Near-work distance data were downloaded from the cloud platform. A raw data document containing all behavioral parameters was generated for each subject. The data were displayed in chronological order with 2-minute intervals, and the data comprised the near-work distance measured (in cm) at each collection time point. The raw data sets contained two types of measurements: "real data" and "dormant data." Real data referred to the actual near-work distance of the subjects under normal working mode. "Dormant

data" meant that if the triaxial acceleration sensor in the Clouclip detected no change within 40 seconds, the Clouclip would stop recording real data and enter dormant mode, with the output of a fixed value of "distance=0". We decided not to analyze the "dormant data" due to its susceptibility to inaccurately reflect the wearer's actual visual behaviors.

The data had to meet the following requirements for analysis: We defined a valid day as a day in which real data could be collected for not less than 80% of the required wearing time (from 7:00 AM. to 8:00 PM, the normal daily timetable of Chinese school-age children) during the course of the experiment. Therefore, a cut-off value of 10 hours was used to define a valid collection. Moreover, a valid subject sample was defined as one who had valid collections for at least 3 days during weekdays (from Monday to Friday) and at least one day during the weekend. Sixty-seven valid samples were considered after the final screening. Data were processed and analyzed on the Anaconda platform by Python. We first loaded, cleaned and preprocessed the initial near-work distance data and then used the Pandas data-analysis package for a series of actions such as grouping and aggregating. We ultimately obtained the outcome measures of all valid samples.

2.4.2. Definitions of parameters to describe near-work behavior. Since the maximum distance range of the Clouclip is 60 cm, we set a distance of <60 cm as near-work distance. Outcome measures of this study were the average daily near-work distance, the time ratio of excessive near-work and the frequency of continuous near-work. These are defined as follows:

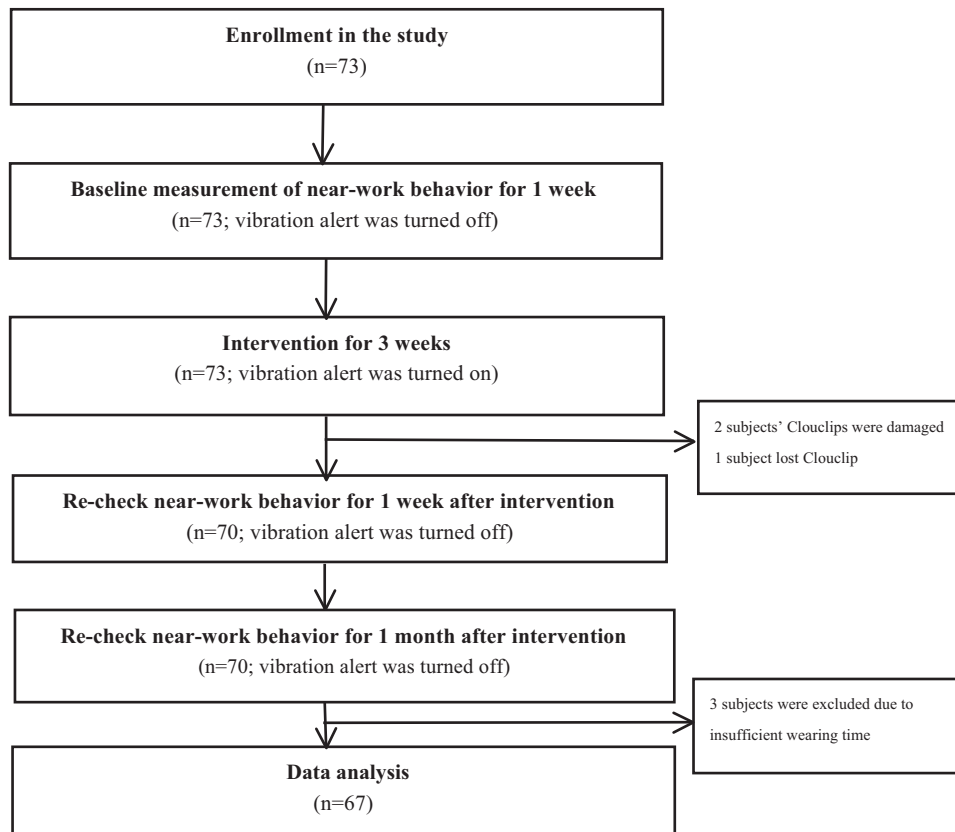


Figure 1. Flowchart of the study.

- 1) Average daily near-work distance (cm): the mean of the viewing distance for each day.
- 2) Time ratio of excessive near-work: Previous studies have shown that a near-work distance of <30 cm was associated with an increased prevalence of myopia.^[21,25] Therefore, we defined a distance of <30 cm as excessive near-work distance. The time ratio of excessive near-work activity to the total near-work activity (<60 cm) was calculated.
- 3) Frequency of continuous near-work: Previous research suggests that a continuous near-work time of >30 minutes is associated with a more myopia refraction.^[21,26,27] The frequency of continuous near-work (distance <60 cm and continuous time >30 minutes) was counted.

2.5. Statistical analysis

Since the data on the outcome measures and the ratings from the questionnaires were not normally distributed, medians and the 25th and 75th percentiles were used for statistical description. The outcome measures for different data collection periods were compared using the rank-sum test. Post-hoc Bonferroni pairwise comparison was conducted if significant differences were found. The rating scores at the end of the intervention period were tested by a nonparametric rank-sum test, with post-hoc Bonferroni pairwise comparison. All statistical analyses were performed using SPSS version 25.0 software (IBM SPSS Statistics), with two-tailed $P < .05$ considered to be significant.

3. Results

3.1. General characteristics of participants

Seventy-three volunteers participated in the study. During the study, one subject lost a Clouclip, and two subjects had their

Clouclips damaged. Three additional subjects were excluded due to the insufficient wearing duration. Thus, data from 67 subjects were used for analysis. These valid subjects had a mean age of 10.45 ± 0.50 years and 49.0% ($n=34$) were boys. The average daily duration to wear the devices was 12.30 ± 0.18 hours on weekdays and 12.16 ± 0.23 hours on weekends.

Based on the baseline data collected in the first week and with 30 cm as the cut-off for the average near-work distance, subjects were further divided into two categories: 13 subjects with excessively close working distance (7 boys, 53%; mean age 10.46 ± 0.52 years) and 54 subjects with normal working distance (27 boys, 50%; mean age 10.44 ± 0.50 years). There were no significant differences in age or sex between the 2 categories. There were no significant differences between the subjects with excessively close working distance and subjects with normal working distance in spherical equivalent (t test, $P = .242$).

3.2. Effectiveness of intervention

3.2.1. Average near-work distance (Fig. 2). On weekdays, the baseline near-work distance before intervention was 33.96 (30.83, 35.19) cm. After 3 weeks of intervention with the vibration alert, the average near-work distance was found to significantly increase to 38.62 (36.01, 40.13) cm one week after intervention ($P < .001$). But the value dropped to 35.25 (32.88, 37.54) cm one month after the intervention ($P < .001$). However, the value was still statistically significantly greater than the baseline value ($P = .001$). In contrast, no significant difference was found in the average near-work distance for the weekends of the 3 periods.

For those 13 subjects with excessively close working distance, the baseline near-work distance on weekdays before intervention was 27.20 (25.79, 29.18) cm. The distance significantly increased to 35.89 (33.41, 37.44) ($P < .001$) one week after intervention, and was maintained at a similar level one month after

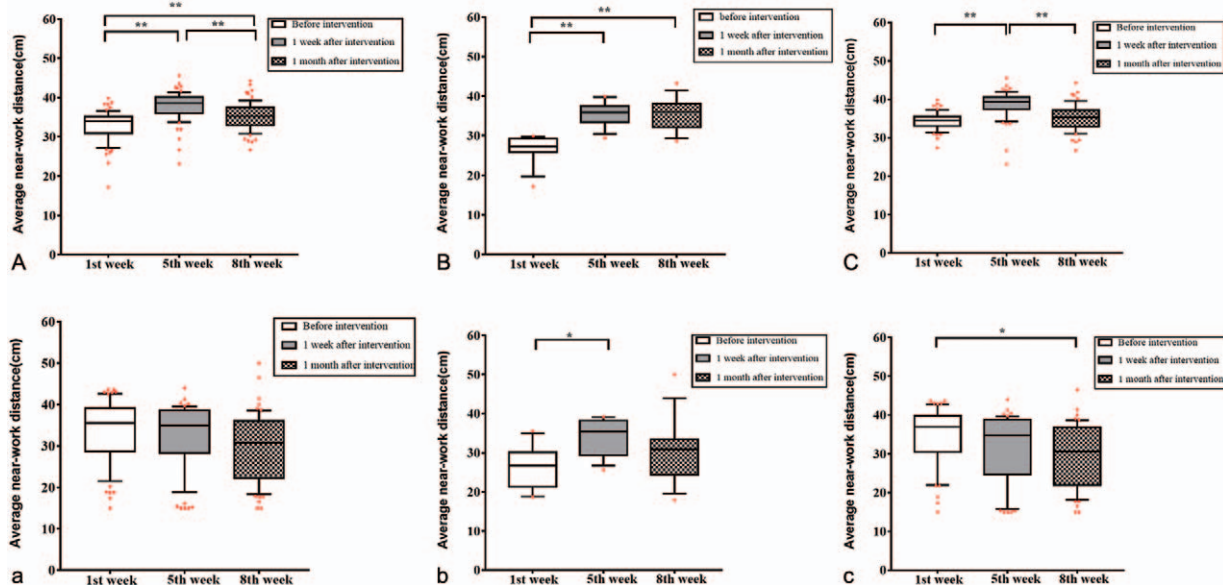


Figure 2. The average near-work distance to describe all subjects ($n=67$) before intervention, 1 week after intervention and one month after intervention on weekdays (A) and weekends (a), respectively. The average near-work distance to describe subjects with excessive near-work distance ($n=13$) before intervention, 1 week after intervention and one month after intervention on weekdays (B) and weekends (b), respectively. The average near-work distance to describe subjects with normal near-work distance ($n=54$) before intervention, 1 week after intervention and one month after intervention on weekdays (C) and weekends (c), respectively. * Pairwise comparison, $P < .05$; ** Pairwise comparison, $P < .001$.

intervention 35.95 (32.06, 38.10) cm ($P=.001$). On weekends, the average near-work distance increased from 26.74 (21.20, 30.16) cm at baseline to 35.41(29.42, 38.18) cm ($P=.032$) one week after intervention, but fell back to 30.86(17.93, 35.45) cm 1 month after intervention.

For those 54 subjects with normal working distance, the baseline near-work distance in weekdays before intervention was 34.50 (33.07, 35.52) cm. The distance significantly increased to 39.31 (37.45, 40.58) cm ($P<.001$) one week after intervention, but dropped to 35.24 (32.88, 37.13) cm ($P<.001$) after 1 month. On weekends, the baseline near-work distance in weekends before intervention was 36.95 (30.44, 39.79) cm, and it decreased to 34.72 (24.74, 38.78) cm one week after intervention ($P=.277$), and to 30.66 (21.98, 36.78) cm ($P=.489$) 1 month after the intervention. However, there was a significant difference between the baseline level and the level one month after intervention ($P=.006$).

3.2.2. Time ratio of excessive near-work (Fig. 3). On weekdays, the time ratio of excessive near-work of all subjects before intervention was 0.37 (0.32, 0.49). It decreased to 0.22 (0.16, 0.28) one week after intervention ($P<.001$), but bounced back to 0.39 (0.27, 0.45) 1 month after intervention ($P<.001$). Thus, there was no significant difference between 1 month after intervention and the baseline level ($P=.172$). On weekends, no difference in the time ratio of excessive near-work was found among the three periods.

For subjects with excessively close working distance, the baseline time ratio of excessive near-work was 0.61(0.56, 0.68). It dropped to 0.28(0.24, 0.39) 1 week after intervention ($P<.001$) but returned to 0.42(0.37,0.49) one month after intervention ($P=.005$), which was not significantly different between one week after intervention and one month after intervention ($P>.99$). On weekends, the baseline time ratio of

excessive near-work was 0.64(0.54, 0.71). It decreased to 0.33 (0.24, 0.47) 1 week after intervention ($P=.001$), and returned to 0.49 (0.42, 0.57) one month after ($P=.233$). Again, no significant difference was found between before intervention and one month after intervention ($P=.233$).

For those subjects with normal working distance, the baseline time ratio of excessive near-work was 0.36(0.30, 0.41) and dropped to 0.19(0.16, 0.25) one week after intervention ($P<.001$), but returned to 0.38(0.26, 0.45) one month after intervention ($P<.001$), with no significant difference between before intervention and 1 month after intervention. On weekends, no difference in the time ratio of excessive near-work was found between the three periods.

3.2.3. Frequency of continuous near-work (Fig. 4). On weekdays, the frequency of continuous near-work of all subjects was 3.00 (2.00, 4.00), and this dropped to 1.00 (1.00, 2.00) ($P<.001$) 1 week after intervention. The frequency returned to 3.00 (2.00, 4.00) one month after intervention, which was greater than one week after intervention ($P<.001$) but still significantly lower than the baseline level ($P=.041$). On weekends, no difference in the frequency of continuous near-work was found between the three periods.

For subjects with excessively close working distance, the frequency of continuous near-work in weekdays before the intervention was 5.00(4.00, 5.50) and dropped to 2.00 (1.50,3.50) ($P=.002$) 1 week after intervention, and remained at a similar level of 3.00 (2.50,4.00) ($P>.99$) one month after intervention. Thus, there was a significant difference in the frequency of continuous near-work between the level of 1 month after intervention and that at baseline level ($P=.018$). On weekends, the frequency of continuous near-work in weekends before the intervention was 5.00 (4.00, 6.00), and this dropped

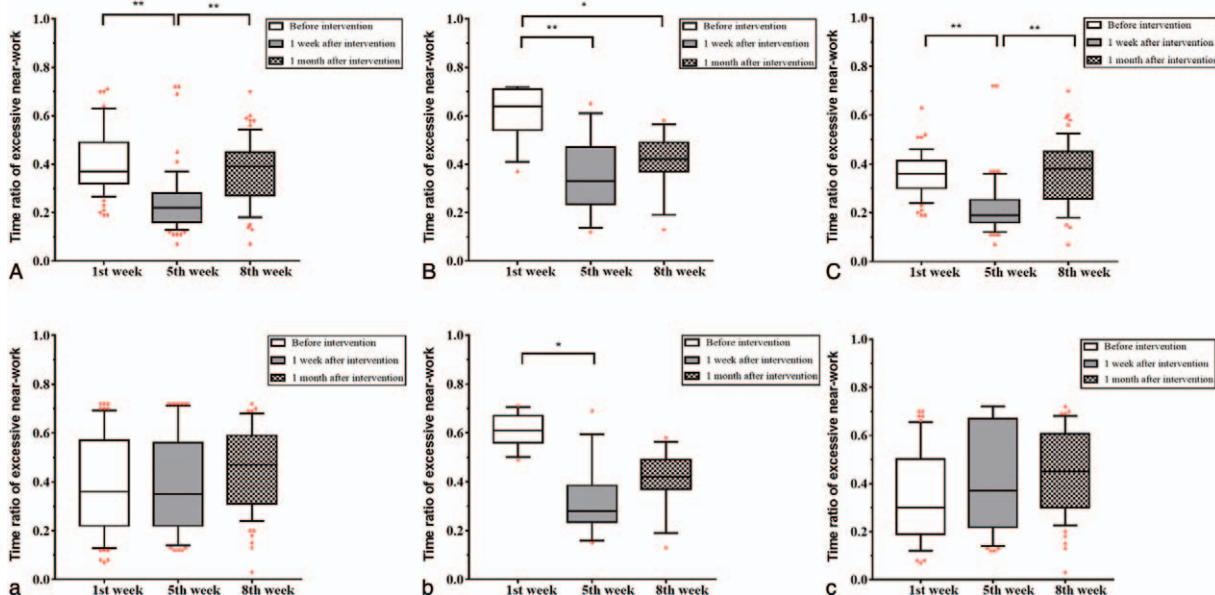


Figure 3. The time ratio of excessive near-work to describe all subjects ($n=67$) before intervention, 1 week after intervention and one month after intervention on weekdays (A) and weekends (a), respectively. The time ratio of excessive near-work to describe subjects with excessive near-work distance ($n=13$) before intervention, 1 week after intervention and one month after intervention on weekdays (B) and weekends (b), respectively. The time ratio of excessive near-work to describe subjects with normal near-work distance ($n=54$) before intervention, 1 week after intervention and one month after intervention on weekdays (C) and weekends (c), respectively.* Pairwise comparison, $P<.05$; ** Pairwise comparison, $P<.001$.

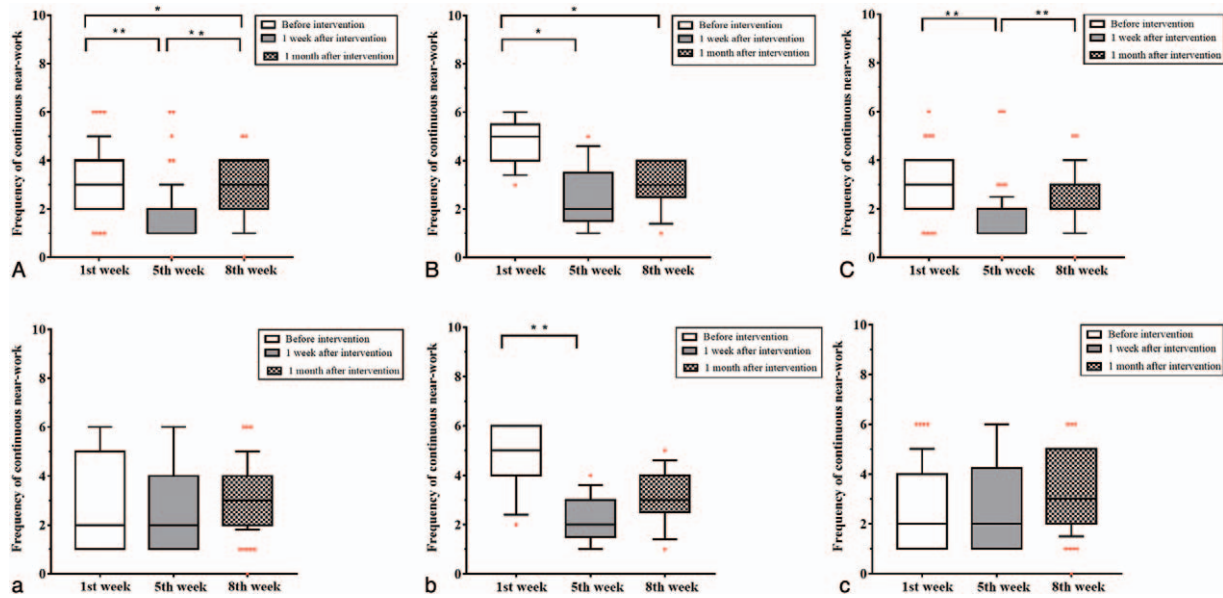


Figure 4. The frequency of continuous near-work to describe all subjects ($n=67$) before intervention, 1 week after intervention and 1 month after intervention on weekdays (A) and weekends (a), respectively. The frequency of continuous near-work to describe subjects with excessive near-work distance ($n=13$) before intervention, 1 week after intervention and one month after intervention on weekdays (B) and weekends (b), respectively. The frequency of continuous near-work to describe subjects with normal near-work distance ($n=54$) before intervention, 1 week after intervention and one month after intervention on weekdays (C) and weekends (c), respectively. * Pairwise comparison, $P < .05$; ** Pairwise comparison, $P < .001$.

significantly to 2.00 (1.50, 3.00) 1 week after intervention ($P < .001$), and increased slightly to 3.00 (2.50, 4.00) ($P = .287$) one month after intervention. There was no significant difference between the baseline level and that one month after intervention ($P = .072$).

For subjects with normal close working distance, the frequency of continuous near-work in weekdays before the intervention was 3.00 (2.00, 4.00). It dropped significantly to 1.00 (1.00, 2.00) 1 week after intervention ($P < .001$), but increased to 3.00 (2.00, 3.00) one month after intervention ($P < .001$). There was no significant difference between the baseline level and that 1 month after intervention ($P = .489$). On weekends, the frequency of continuous near-work before the intervention was 2.00 (1.00, 4.00), there was no significant difference between the baseline level and that one week after intervention 2.00 (1.00, 4.25) ($P = .148$). No difference was found between the baseline level and that observed one month after intervention 3.00 (2.00, 5.00).

3.3. Survey of acceptability of the Clouclip intervention

The scores given by the subjects regarding their feelings about the vibration alert and for the 3-week intervention overall were 5.00 (4.00, 6.00), 5.00 (3.00, 5.00) and 3.00 (2.00, 5.00), respectively. Statistical analysis revealed a significant decrease of scoring with time, and post-hoc pairwise comparison indicated the scoring of the fourth week was significantly lower than in the second and the third week ($P < .05$). Overall, 97.0% of subjects expressed willingness to wear Clouclip to improve their visual behaviors (two subjects were unwilling to wear Clouclip again because they were not accustomed to wearing the lensless frames).

4. Discussion

Excessive near-work is one of the most commonly known environmental factors relating to myopia and many studies have

shown that it can speed the occurrence and development of myopia.^[15,28] Despite the number of scholars worldwide that have conducted studies on environmental risk factors related to myopia, its specific mechanism and the extent of its impact is still intangible. Nonetheless, improving visual environment factors on the probability that it is related to the development of myopia is one of crucial directions of myopia prevention and control.^[29–31] A previous intervention study has shown that elevated light intensity in classrooms could reduce the risk of myopia, but the intervention program was not perfect regarding the intensity of illumination or uniformity of blackboards.^[31] Furthermore, rebuilt elevated lighting systems may be costly. Eye exercises are a compulsory measure during school days introduced by Chinese educational departments in order to protect the vision of school-age children; however, the frequency of this intervention is very low (once each in the morning and the afternoon on weekdays, approximately 5 min every time). Furthermore, most children (90%) are unable to find the accurate points around eyes or do not have appropriate pressure for eye exercises, hence, the efficacy is unknown.^[32–34] A previous experiment corrected unhealthy visual behaviors of school-age children through education and advocacy, yet the study did not elaborate on the intervention method, and no quality control was included.^[35] Therefore, the effectiveness of this intervention needs further study.

Due to limitations of technology, prior to our study there was no device available for near-work intervention. To our knowledge, this is the first application of such a device for the in this field of study in the world, and we were able to give real-time intervention in unhealthy visual behaviors of the wearers. Some research has indicated that the incidence of myopia is higher during the school-age period.^[28,36,38] This might be related to the near-work load of school-age children.^[37,38] In the present study, Clouclip was applied to intervene in the unhealthy visual behaviors of 67 school-age children, and the comparison of

all outcome measures showed statistically significant differences before and after intervention.

Regarding near-work distance, as a whole, intervention by vibration was able to increase the average near-work distance by 13.72% (4.66 cm) during weekdays. The effect seemed to be more prominent in subjects who have a shorter near-work distance at baseline, as the near-work distance was significantly improved by 31.95% (8.69 cm) and 32.42% (8.67 cm) on weekdays and weekends, respectively. In addition, the near-work distance during weekdays was found to remain at a higher level 1 month after the cessation of the intervention, although the near-work distance on weekends returned to the baseline level. In contrast, in subjects with normal near-work distances at baseline, the improvement in near-work distance only occurred during weekdays and with a relatively small magnitude (13.94% or 4.81 cm). Furthermore, the improvement did not last to the one-month follow-up visit.

Compared with the impact on near-work distance, intervention by vibration seemed to be relatively less effective in reducing the time ratio of excessive near-work. In general, the time ratio of excessive near-work decreased by 40.50% after intervention for all subjects during weekdays, but the effectiveness was not maintained one month after the intervention. For the subjects with excessively close near-work distance, intervention by vibration significantly decreased the ratio by 54.10% and 56.58% for weekdays and weekends, respectively. Although the ratio on weekdays after one month was still 31.14% lower than baseline level, the ratio had already rebounded by 50.00% compared with that observed immediately after the intervention. The effect during weekends was not seen after one month. For the subjects with normal working distance, intervention by vibration significantly decreased the ratio by 47.22%, but the effect disappeared by the one-month follow-up visit.

The frequency of continuous near-work was significantly decreased by the intervention of vibration by 66.67% and rebounded slightly to the reduction magnitude of 33.33% after one month for all subjects. The approach performed better in subjects with excessively close near-work distance. On both weekdays and weekends, the reduction in magnitude was 60.00% and 40.00%, respectively. However, the effect had vanished at the one-month follow-up visit. For subjects with normal near-work distance, this approach was only effective for the weekday activity, with a reduction in magnitude of 66.67%, which was not detected in the one-month follow-up visit.

All these results showed that the device was able to improve most of the near-work-related behaviors. Furthermore, some of the modified habits lasted for at least one month after the cessation of the intervention. In addition, 97.00% of the participants showed their willingness to improve the visual habits by this manner. Therefore, the device has proven not only to be able to significantly help school-age children develop good visual behaviors but also to be a good experience.

It is worthwhile to mention that while Clouclip can significantly modify the unhealthy visual behaviors of school-age children, there was a different protective effect of Clouclip between weekdays and weekends. Clouclip intervenes in the subjects' unhealthy visual behavior by means of vibration. A previous study showed that the near-work load is heavier on weekdays than on weekends.^[39] Moreover, the baseline visual behavior of our experiment showed that average near-work distance was 32.85 ± 3.95 cm and 33.24 ± 7.68 cm on weekdays and weekends, respectively. Therefore, we speculate that this

difference in effect was maybe due to the near-work load on weekends being lighter than weekdays, and therefore that the vibration intervention of Clouclip was relatively less on weekends compare to weekdays. The frequency of vibration intervention on weekdays and weekends was statistically analyzed, and we found that the frequency of vibration on weekdays was significantly more than on weekends (all subjects, 305.85 ± 121.67 on weekdays vs 254.44 ± 101.90 on weekends, $P < .001$; subjects with excessively close near-work distance ($n=13$), 443.15 ± 101.37 on weekdays vs 335.31 ± 94.45 on weekends, $P < .001$; subjects with normal close near-work distance ($n=54$), 272.80 ± 101.84 on weekdays vs 234.98 ± 94.46 on weekends, $P < .001$) (Fig. 5). In addition, the frequency of vibration intervention of subjects with excessively close near-work distance ($n=13$) was significantly more than that of subjects with normal near-work distance ($n=54$) on both weekdays and weekends (on weekday, $P = .005$; on weekend, $P = .016$). There is, therefore, a significant difference between the frequency of vibration intervention on weekdays and weekends, which may be one of the reasons for the different effects of intervention on weekdays and weekends.

The present study has some noteworthy advantages. First, the device wearing time for the participants met the standard throughout the experiment. Secondly, the fluctuation of average weekly temperature was 3.84 degrees centigrade during the experimental period, and there were 35 days (83.00%) without rain. Third, the school life of the participants was normal and usual (they did not need to prepare for a test, and the school did not hold a sports meeting during this period). To sum up, neither the weather nor special arrangements of the school had any influence on the subjects' visual behaviors; therefore, the data collected in our study is reliable.

The results of our study were, however, affected by some limitations that ought to be considered. First, the sample size is

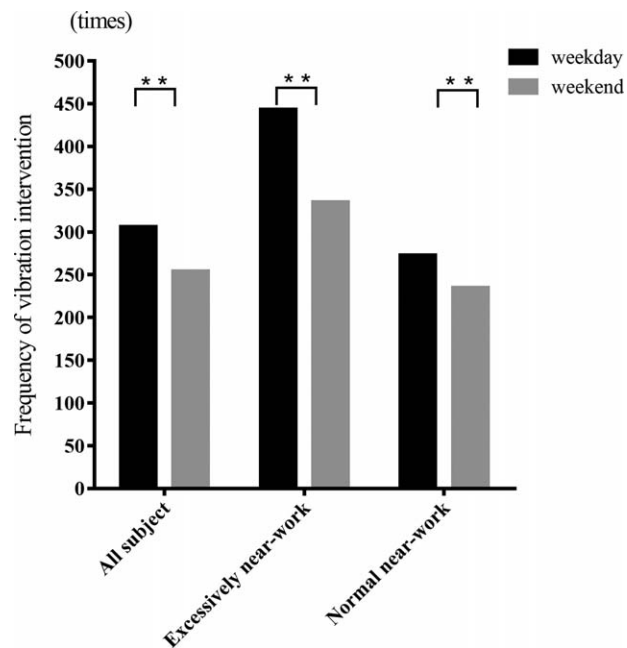


Figure 5. "All subjects" indicates all valid samples ($n=67$). "Excessively near-work" indicates subjects with excessively near-work distance ($n=13$). "Normal working distance" indicates subjects with normal working distance ($n=54$). Data are shown as mean \pm standard error, $**P < .001$ was considered to be significant.

relatively small, and we will expand the size in future studies. Furthermore, we will also be conducting a prospective study to determine whether Clouclip can truly prevent and control myopia in school-age children by correcting these potentially unhealthy visual behaviors. Secondly, the reminder function of Clouclip needs to be optimized for stopping other unhealthy visual behaviors (such as improper head positions or reading in low intensity of light); this may help the children wearing Clouclip to form better visual behaviors. Thirdly, the design of the device can be improved, for instance, by developing more modes for wearers in addition to the existing spectacle frames.

At this stage, it has not been demonstrated that the associations between myopia and the specific near-work behaviors we studied are causal, and if causal, the direction of causality. Future experiments are planned to use the Clouclip to provide answers to these important questions that will determine how useful this device may be in preventing the development of myopia. Furthermore, the visual behaviors data collected objectively by Clouclip will be combined with refractive parameters (such as refractive error, axial length, curvature of the cornea and lens thickness, etc.) and genetic background (such as parental myopia) to establish a prediction model of myopia progression with the behavioral patterns as variables. Subsequently, a clinical trial will be conducted to verify the model by modifying the influential myopia-related patterns.

5. Conclusion

Clouclip can significantly modify the unhealthy visual behaviors of “excessive near-work distance” and “excessive near-work time” in school-age children. It was found that the vibration alert by Clouclip could significantly increase the near-work distance, reduce the time ratio of excessive near-work and the frequency of continuous near-work for children. This effect was more prominent for subjects with excessively close working distance.

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