



Myopia Prevention and Outdoor Light Intensity in a School-Based Cluster Randomized Trial

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Purpose: To investigate the effectiveness of a school-based program promoting outdoor activities in Taiwan for myopia prevention and to identify protective light intensities.

Design: Multi-area, cluster-randomized intervention controlled trial.

Participants: A total 693 grade 1 schoolchildren in 16 schools participated. Two hundred sixty-seven schoolchildren were in the intervention group and 426 were in the control group.

Methods: Initially, 24 schools were randomized into the intervention and control groups, but 5 and 3 schools in the intervention and control groups, respectively, withdrew before enrollment. A school-based Recess Outside Classroom Trial was implemented in the intervention group, in which schoolchildren were encouraged to go outdoors for up to 11 hours weekly. Data collection included eye examinations, cycloplegic refraction, noncontact axial length measurements, light meter recorders, diary logs, and questionnaires.

Main Outcome Measures: Change in spherical equivalent and axial length after 1 year and the intensity and duration of outdoor light exposures.

Results: The intervention group showed significantly less myopic shift and axial elongation compared with the control group (0.35 diopter [D] vs. 0.47 D; 0.28 vs. 0.33 mm; $P = 0.002$ and $P = 0.003$) and a 54% lower risk of rapid myopia progression (odds ratio, 0.46; 95% confidence interval [CI], 0.28–0.77; $P = 0.003$). The myopic protective effects were significant in both nonmyopic and myopic children compared with controls. Regarding spending outdoor time of at least 11 hours weekly with exposure to 1000 lux or more of light, the intervention group had significantly more participants compared with the control group (49.79% vs. 22.73%; $P < 0.001$). Schoolchildren with longer outdoor time in school (≥ 200 minutes) showed significantly less myopic shift (measured by light meters; ≥ 1000 lux: 0.14 D; 95% CI, 0.02–0.27; $P = 0.02$; ≥ 3000 lux: 0.16 D; 95% CI, 0.002–0.32; $P = 0.048$).

Conclusions: The school-based outdoor promotion program effectively reduced the myopia change in both nonmyopic and myopic children. Outdoor activities with strong sunlight exposure may not be necessary for myopia prevention. Relatively lower outdoor light intensity activity with longer time outdoors, such as in hallways or under trees, also can be considered. *Ophthalmology* 2017;■:1–12 © 2017 by the American Academy of Ophthalmology



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The increasing prevalence of myopia has become an important public health issue in recent decades.¹ In East Asia, myopia is found to progress rapidly, by approximately -1 diopter (D) per year in schoolchildren; up to 24% of young adults are highly myopic.² The prevalence of myopia is 20% to 30% for 6- to 7-year-old children and is as high as 84% for high school students in Taiwan.² In contrast, a much lower prevalence of 1.6% to 1.9% for myopia was reported in cities of mainland China for children of this age.^{3,4} One of the reasons that a lower prevalence was reported in China may be associated with more rigorous cycloplegia and exclusion of children with

incomplete cycloplegia.³ However, future studies are required to determine the optimal regimen to use for cycloplegia in East Asian children of this age. In general, as soon as myopia sets in for young children, it will progress until the end of adolescence.^{5–7} Early myopia onset generally results in fast and longer duration for myopia progression and, consequently, a higher risk of becoming highly myopic later in life. High myopia (more than -5 D)⁸ can result in cataracts, glaucoma, retinal detachments, choroid neovascularization, macular degeneration, and blindness.^{9–11} Currently, myopia maculopathy is the leading cause of blindness in Taiwan, Japan,

and China.^{12–14} Therefore, a strategy to postpone the age of myopia onset is important and necessary for decreasing the high myopia prevalence in future generations.

Recently, evidence has shown that children who spend more time outdoors have a lower incidence of myopia.^{4,15–17} From the self-report questionnaires, it seems that approximately 10 to 14 hours weekly could abolish the additional myopia associated with higher amount of near work or parental myopia.^{15,18} However, although encouraging children to participate in outdoor activities during recess is important, exposure to direct sunlight also can result in the development of other health concerns, such as skin cancer. There is a need both for an objective assessment of time spent outdoors and for determining the amount of sunlight necessary for reducing the incidence of myopia. Our previous study indicated that the 1-year intervention of the Recess Outside Classroom program, which recommends that children should go outdoors during recess (approximately 80 minutes daily) could reduce myopia incidence by half after 1 year (8.4% vs. 17.7%).¹⁷ Recently, a cluster randomized trial with the addition of 40 minutes of outdoor activity per day at school resulted in a reduced incidence rate of myopia after 3 years (30.4% vs. 39.5%).⁴ However, no randomized study yet has used objective and quantitative measures to record participants' outdoor time and sunlight intensity and the association with myopia.

Thus, a quantitative method to estimate objectively the required outdoor time and sunlight strength is needed. Based on the principal protective factor which is outdoor activities, and principal risk factor, which is prolonged duration of near work (e.g., reading, painting, writing, screen time),^{19–21} we developed the school-based Recess Outside Classroom Trial 711 (ROCT711) program to increase outdoor time for schoolchildren, including recess outside the classroom, incentive-based outdoor homework, and other assignments. In this study, we performed a multi-area, cluster-randomized ROCT711 program trial in Taiwan to investigate its effect on myopia and axial length change in 6- to 7-year-old schoolchildren. A light meter was used to measure objectively the outdoor time and light intensity to validate the relationship between time spent outdoors and myopia.

Methods

Study Design and Participants

We conducted a multi-area cluster-randomized controlled trial for myopia prevention from September 2013 through February 2015. This study adhered to the tenets of the Declaration of Helsinki. Ethics approval for this study was obtained from the institutional review board of the Chang Gung Memorial Hospital and the trial is registered with the Clinical Trials registry (identifier, NCT02082743). Study participants and parents provided written informed consent. Schoolchildren in both groups underwent assessments of cycloplegic refraction and noncontact axial length measurements, wore a light meter recorder for 1 week, and completed weekly activity diary logs and questionnaires with the help of their parents at baseline and at the end of the study. Measurements were performed by ophthalmologists and trained research assistants who were blinded to intervention conditions.

Four geographical areas (north, central, south, and west) in Taiwan were identified first. Within each area, 1 or 2 cities or counties were selected based on local weather and sunshine time so that the selected schools would cover a variety of weather conditions. For example, Keelung has the most rainy days, and Kaohsiung and Taitung have more sunny days. In total, 6 cities or counties were chosen. Within each city or county, we obtained their districts' education statistics from the Department of Household Registration, Ministry of the Interior. The proportions of adults with education of college or more were ranked within each city or county, and the districts that are the median of these proportions were selected. Finally, 4 schools in each of the 6 districts were selected randomly as an intervention group or a control group. The random allocation sequence was generated by a computer-based random number-producing algorithm and completed by a researcher not involved in the project to ensure an equal chance of a school being allocated to each group.

Procedures

The ROCT711 intervention program was devised based on the Recess Outside Classroom pilot study,¹⁷ which required first-grade schoolchildren to go outdoors during recess and while out of school for a minimum amount of time. The ROCT711 program encourages schoolchildren to participate in outdoor activities during recess. During a normal school day in Taiwan, there are 4 classes and 3 recesses (10, 20, and 10 minutes in duration) in the morning for first-grade schoolchildren. If a child goes outside the classroom during every recess, then he or she would have 200 minutes of in-school outdoor time during the 5 school days every week. Teachers were invited to assign homework that included outdoor activities during weekends, holidays, and summer vacation. Parents were encouraged to bring children for outdoor activities during out-of-school time.

During our study period, there were 2 initiatives for myopia prevention: Sport & Health 150 promoted an additional 150 minutes of exercise time per week and Tien-Tien 120 promoted outdoor activities for 120 minutes every day. Although the latter initiative was not compulsory, schools were encouraged to promote these activities. Thus, the control schools were already receiving some intervention to minimize myopia. [Table 1](#) is a summary of intervention items in both groups.

In the intervention group, participants were encouraged to have 11 hours or more of outdoor time every 7 days (ROCT711). Teachers, children, and parents received eye health education from ophthalmologists regarding a new concept of myopia prevention using evidence-based medicine as well as possible complications induced by myopia. Children were encouraged to take specific breaks from near work that included reading, writing, painting, screen time, and others (30 minutes of near work followed by a 10-minute break [30/10]). We designed a series of ROCT711 program components to enhance the compliance of outdoor activities. To encourage family weekend outdoor activities, there were routine learning assignments, honor rewards for students, and local upcoming outdoor family event information for outdoor activities and near-work breaks. A detailed outline of the program components is given in the [Appendix](#) (available at www.aaojournal.org). The same eye health education was provided for teachers, children, and parents in the control group, but no ROCT711 intervention was performed during the study period.

To investigate the compliance of students spending recess time outside of the classroom, we performed 2 school audits during the study period without prior notice. The classroom clearance rate during recess in each school was calculated by dividing the number of children outside the classroom by the total children in the class. The average classroom clearance rate for the intervention schools

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