Miopía y el uso de dispositivos electrónicos

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Durante los últimos años, ha habido un aumento mundial en la incidencia de miopía. La evidencia científica actual ha demostrado que el uso de pantallas está asociado al incremento de casos de miopía, así como severidad de la misma.

El análisis de estos trabajos concluye en:

A) "Association between digital smart device use and myopia: a systematic review and meta-analysis" es un metaanálisis realizado en 2021 por Foreman et al, que evaluó múltiples estudios que asociaron el tiempo de uso de pantallas con la incidencia de miopía. Como conclusión, se determinó que la exposición a pantallas se asocian a un riesgo aumentado de desarrollar miopía.

B) "Smartphone Use Associated with Refractive Error in Teenagers" es un estudio de cohorte realizado en 2021 por Enthoven et al, que evaluó a 525 adolescentes, midiendo el uso de smartphones y la incidencia de miopía. Encontraron que el uso de smartphones en períodos mayores a 20 minutos continuos se asocia a errores refractivos miópicos más elevados.

C) El factor de protección para la miopía más importante es la exposición a la luz del exterior. Esto fue comprobado por el ensayo clínico de Pei-Chang et al: "Myopia Prevention and Outdoor Light Intensity in a School-Based Cluster Randomized Trial". En dicho estudio, participaron 693 estudiantes de escuelas primarias. Un grupo fue asignado a actividades al aire libre durante al menos 11 horas semanales. Se observó que aquellos niños expuestos a la luz del exterior demostraron una disminución en la progresión de la miopía.

Considerando que la evidencia científica avala esta asociación, resulta imperativo establecer medidas para prevenir la incidencia así como el grado de severidad de la miopía que se observa en jóvenes de todo el mundo.

En base a la bibliografía actual, la Asociación Americana de Pediatría, así como la Asociación Americana de Oftalmología, recomiendan:

- Menores de 2 años: No utilizar pantallas, excepto para videollamadas
- 2 a 5 años: Uso máximo de 1 hora por día en días de semana, 3 horas por día los fines de semana
- Mayores de 5 años: Establecer límites de exposición
- Apagar todas las pantallas durante las comidas y salidas
- Evitar el uso de pantallas para calmar al niño
- Apagar pantallas y retirar los dispositivos del cuarto 30 a 60 minutos antes de dormir
- Realizar actividades diurnas al aire libre al menos 2 horas por día

Association between digital smart device use and myopia: a systematic review and meta-analysis

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Summary

Background Excessive use of digital smart devices, including smartphones and tablet computers, could be a risk factor for myopia. We aimed to review the literature on the association between digital smart device use and myopia.

Methods In this systematic review and meta-analysis we searched MEDLINE and Embase, and manually searched reference lists for primary research articles investigating smart device (ie, smartphones and tablets) exposure and myopia in children and young adults (aged 3 months to 33 years) from database inception to June 2 (MEDLINE) and June 3 (Embase), 2020. We included studies that investigated myopia-related outcomes of prevalent or incident myopia, myopia progression rate, axial length, or spherical equivalent. Studies were excluded if they were reviews or case reports, did not investigate myopia-related outcomes, or did not investigate risk factors for myopia. Bias was assessed with the Joanna Briggs Institute Critical Appraisal Checklists for analytical cross-sectional and cohort studies. We categorised studies as follows: category one studies investigated smart device use independently; category two studies investigated smart device use in combination with computer use; and category three studies investigated smart device use with other near-vision tasks that were not screen-based. We extracted unadjusted and adjusted odds ratios (ORs), β coefficients, prevalence ratios, Spearman's correlation coefficients, and p values for associations between screen time and incident or prevalent myopia. We did a meta-analysis of the association between screen time and prevalent or incident myopia for category one articles alone and for category one and two articles combined. Random-effects models were used when study heterogeneity was high ($I^2>50\%$) and fixed-effects models were used when heterogeneity was low ($I^2\leq50\%$).

Findings 3325 articles were identified, of which 33 were included in the systematic review and 11 were included in the meta-analysis. Four (40%) of ten category one articles, eight (80%) of ten category two articles, and all 13 category three articles used objective measures to identify myopia (refraction), whereas the remaining studies used questionnaires to identify myopia. Screen exposure was measured by use of questionnaires in all studies, with one also measuring device-recorded network data consumption. Associations between screen exposure and prevalent or incident myopia, an increased myopic spherical equivalent, and longer axial length were reported in five (50%) category one and six (60%) category two articles. Smart device screen time alone (OR 1·26 [95% CI 1·00–1·60]; I^2=77%) or in combination with computer use (1·77 [1·28–2·45]; I^2=87%) was significantly associated with myopia. The most common sources of risk of bias were that all 33 studies did not include reliable measures of screen time, seven (21%) did not objectively measure myopia, and nine (27%) did not identify or adjust for confounders in the analysis. The high heterogeneity between studies included in the meta-analysis resulted from variability in sample size (range 155–19 934 participants), the mean age of participants (3–16 years), the standard error of the estimated odds of prevalent or incident myopia (0·02–2·21), and the use of continuous (six [55%] of 11) versus categorical (five [46%]) screen time variables

Interpretation Smart device exposure might be associated with an increased risk of myopia. Research with objective measures of screen time and myopia-related outcomes that investigates smart device exposure as an independent risk factor is required.

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See Comment page e756

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Introduction

The prevalence of myopia is increasing worldwide, with half of the global population expected to have myopia by 2050.[1] This trend has been accompanied by a reduction in the age of onset,[2] an acceleration in the rate of progression, and an increase in the severity of myopia at stabilisation,[3,4] all of which portend a surge in the global burden of high myopia and its complications, such as irreversible blindness, in the coming decades.[1,4,5]

The myopia epidemic is likely to be driven by exposure to environmental risk factors present in ever more urbanised and developed societies, with two major risk factors of particular concern: insufficient time spent outdoors and more time engaged in so-called near-vision

Research in context

Evidence before this study

We searched MEDLINE on May 19, 2020 using natural language search terms, including "smartphone", "tablet computer", "screen time", "digital screens", "mobile phone", "cell phone", "myopia", and "refractive error", as well as corresponding indexing medical subject heading terms, including "Cell Phone", "Screen Time", "Smartphone", "Social Media", "Video Games", "Computers", "Handheld", "User-Computer Interface", "Data Display", "Myopia", and "Refractive Errors". We searched for primary research and reviews reporting associations between exposure to digital smart device screens (smartphones and tablet computers) and myopia, published in any language between database inception and May 19, 2020. We identified cross-sectional and longitudinal studies, with some investigating smart device use as an independent risk factor and others investigating smart device use together with other near-vision tasks, including computer use and reading. The findings were inconsistent, with some studies reporting strong associations between screen time and myopia (odds ratio 8·33 [95% CI 3·54–19·58] for 2–4 h per week *vs* 0–2 h per week) and others finding no associations or even protective effects of screen time. One identified meta-analysis concluded that screen time was not a risk factor for myopia. However, smartphones and tablets were not studied independently of other digital screens, a small number of studies (n=13) were included in the systematic review (five studies were included in the meta-analysis, of which only one interrogated smart devices independently of other risk factors), and the reasoning behind their statistical methods was not clear. Therefore, we did a systematic review and meta-analysis to address these gaps in the literature, to critically appraise the available studies, and to investigate whether there is a potential association between smart device exposure and myopia.

Added value of this study

We did a comprehensive systematic review and meta-analysis of the literature on the association between smart device screen exposure and myopia. Through our appraisal of 33 available articles, we identified limitations in study design, including that most studies did not investigate smartphone and tablet use independently of other near-vision tasks; many studies did not use objective clinical measures to identify myopia; and all studies used self-reported measures of screen time. Half of studies that investigated smart device use independently reported significant associations with myopia or axial elongation, whereas 60% of articles that investigated smart device use combined with computer use reported significant associations. By constructing different meta-analysis models, we analysed the associations between myopia and use of smartphones or tablets, or both, alone and in combination with computer screen time in order to distinguish associations for smart devices from other forms of near-vision tasks. We found that smartphone and tablet screen time alone and in combination with computer screen time were significantly associated with myopia, although no associations were observed when only prospective studies were pooled. High heterogeneity and an absence of objective and standardised measurement of myopia and screen time among studies, as revealed by our review, limited strong inference based on the meta-analysis models, and provides the impetus for future studies to measure smart device screen time independently and to measure myopia objectively.

Implications of all the available evidence

Further research is required, including high quality prospective studies or randomised controlled trials that objectively measure both screen time and refraction, to conclusively establish whether there is an association between smart device exposure and myopia. Nonetheless, this systematic review and meta-analysis provides some evidence to suggest that exposure to digital smart devices could be a modifiable risk factor for myopia. The increasing uptake and lengthy exposure to smart devices among children worldwide could lead to an increase in the global burden of myopia and its complications, such as irreversible vision loss. Public health interventions that promote responsible use of digital screens could support myopia control efforts.

work activities during childhood.[6–8] The ubiquitous adoption of digital smart devices (ie, smartphones and tablet computers) in the past decade constitutes a new form of near-vision work, and children use these devices for long uninterrupted periods (approximately 8 h per day), and at viewing distances closer than for conventional books.[9–11] There is emerging evidence describing the varied adverse consequences of excessive smart device use,[12–16] and, although the increased prevalence of myopia precedes the advent of smart devices,[1] it has been suggested that these devices could be exacerbating the myopia epidemic.[17] However, this association has not been extensively investigated. Population-based studies have started to reveal a link between screen time and myopia, with a higher prevalence of myopia,[18,19] increased myopic spherical equivalent,[20] and longer axial length[21] being associated with more screen time, whereas other studies have found no link,[22,23] necessitating further investigation.

A recent systematic review published in 2020,[24] attempted to clarify the association between digital screen time and prevalent or incident myopia, and found no association based on a meta-analysis of five studies. Only one included study investigated handheld devices independently of other types of digital screens, whereas the remaining studies either included a combination of handheld devices and computers, or computers alone without smart devices.

To address these important knowledge gaps, we did a systematic review and meta-analysis to investigate the association between myopia and digital screen use, with a focus on smart devices. We attempted to separate the use of smart devices from computers and other near-vision work that does not involve digital screens.

Methods

Search strategy and selection criteria

In this systematic review and meta-analysis, we searched MEDLINE and Embase, and manually searched reference lists on June 2 and June 3, 2020, for peer-reviewed original primary research articles, including observational or interventional studies, describing the association between smart device exposure and myopia. The systematic review was done in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[25] For the search of MEDLINE we used the search terms (Cell Phone OR Screen Time OR Smartphone OR Social Media OR Video Games OR Computers, Handheld OR User-Computer Interface OR Data Display OR Risk Factors OR Health Risk Behaviors OR Risk) AND (Myopia OR Refractive Errors). Search terms were chosen to be sufficiently inclusive so that publications that included smart devices as one of a multitude of risk factors for myopia were identified (see the appendix [p 1] for a full list of the search terms used). We searched for articles published from database inception to the dates of the search, with no language restrictions.

Two reviewers (JF and ATS) screened all titles and abstracts. Articles that investigated risk factors for myopia, even if smart devices were not mentioned, were not excluded at this stage because smart device use might have been reported in the main text. Articles were excluded if they were reviews or case reports, did not investigate myopia-related outcomes (ie, the prevalence or incidence of myopia, myopia progression rate, age of myopia onset, spherical equivalent, and axial length), or did not investigate risk factors for myopia.

Both reviewers (JF and ATS) read the full texts of all remaining articles. Articles were excluded if risk factor analysis did not include mobile phones or tablets, either separately or combined with other forms of near-vision tasks, or if myopia-related outcomes were not measured. Conflicts over inclusion were adjudicated by a third reviewer, MD. All excluded articles are listed in the appendix (pp 2–14). All remaining articles were appraised by use of the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Analytical Cross-Sectional Studies and the JBI Critical Appraisal Checklist for Cohort Studies to assess their methodological quality and risk of bias.[26] Studies affected by bias were not excluded from the systematic review, as their inclusion and a discussion of their limitations was necessary for a full appraisal of the literature. Studies with unclear statistical analysis or reporting of results were excluded. The remaining studies were included, and their reference lists were searched for additional literature.

All articles included in the meta-analysis were derived from those included in the systematic review. Studies were included in the meta-analysis if they reported adjusted odds ratios (ORs) for the association between exposure to smart devices and prevalent or incident myopia, or other adjusted measures of association that could be converted to ORs, such as β coefficients, associated with digital smart device screen time, alone or in combination with computer screen time.

Included articles were divided into three categories: category one studies included those in which smart devices (smartphones or tablets, or both) were investigated as an independent risk factor; category two studies included those in which smart devices were investigated but not independently of computer screen exposure; and category three studies were those in which smart device use was investigated, but not independently of other forms of near-vision activities, such as watching television, reading non-digital books, and writing.

Data analysis

Data were extracted from studies by JF, ATS, and AP. Variables that were extracted were study design, sampling methodology, sample size, participants' age and country (and city, when available) of residence, response rates, myopia definition and measurement (including objective *vs* subjective methods), screen exposure measures (including type of screen exposure, inclusion of other near-vision task exposures, screen time, and duration of measurement of exposure), myopia-related outcomes (including prevalence, incidence, progression rate, axial length, and spherical equivalent), statistical associations between smart device exposure and myopia-related outcomes (including ORs, prevalence ratios, β coefficients, 95% CIs, and p values), and variables for which associations between smart device screen exposure and myopia-related outcomes were adjusted in multivariable analysis.

See Online for appendix

The characteristics of all included studies were tabulated and described in the systematic review. The meta-analysis was done by pooling adjusted ORs for associations between screen time and incident or prevalent myopia. Univariate ORs were not included. Models were developed to explore associations for category one studies alone and for category one and two studies combined. No models were generated with category three studies.

Random-effects models were used when study heterogeneity was high (I^2>50%) and fixed-effects models were used when heterogeneity was low (I^2≤50%). ORs were weighted according to the inverse of study variance, with random-effects models accounting for both intra-study and inter-study variance, thus increasing the distribution of weights more uniformly than fixed-effects models. Transformations done to facilitate inclusion of

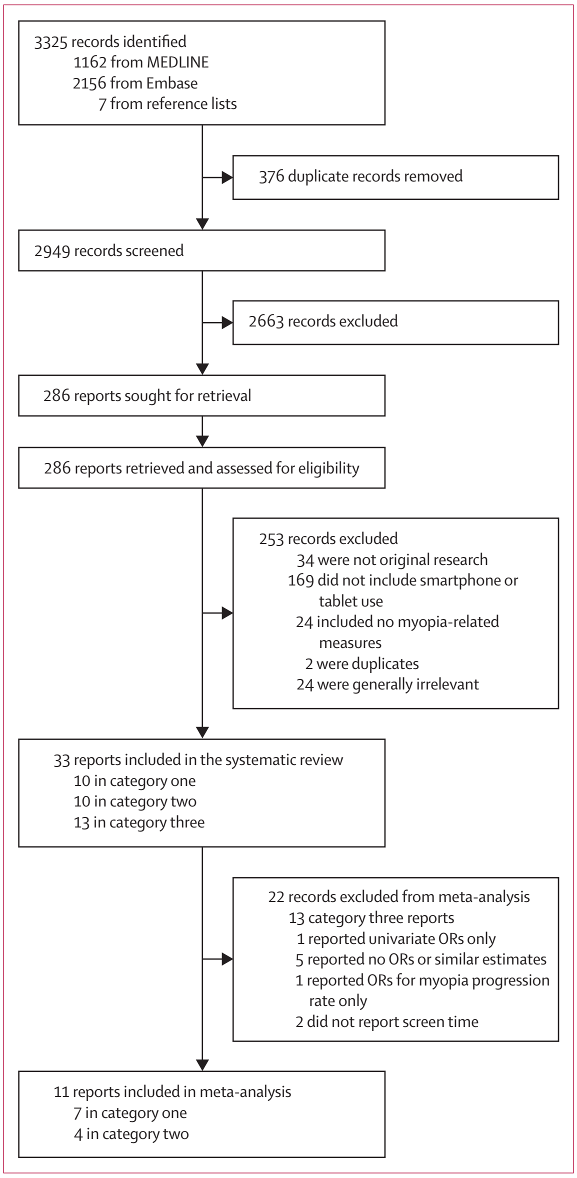


Figure 1: **Study selection**
OR=odds ratio.

results in the meta-analysis included: conversion of β coefficients to ORs;[27] standardisation of an OR associated with screen time from min per day to h per day,[28] according to the formula $OR_{h\ per\ day}=\exp(\ln[OR_{min\ per\ day}]\times 60)$, which was done with the aim of increasing homogeneity but should be considered cautiously, as it assumes an additive effect of screen time; and derivation of a reciprocal OR[18] to establish the lowest category of screen time as the reference group for compatibility with other studies. When ORs were reported for multiple groups of a categorical variable,[18,19,27,29,30] all ORs were included, as described by Yu and colleagues.[31] For studies that reported ORs for multiple exposure variables among non-mutually exclusive samples, such as weekend and weekday use[19] or duration of tablet and smartphone use,[23,32] we selected ORs for variables to which the larger sample was exposed[23,32] and for which more days of data were collected (ie, weekdays *vs* weekends).[19]

Statistical analyses were done using R, version 4.0.3.

Role of the funding source

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Results

The database search yielded 3318 articles, with a further seven articles included from reference lists (figure 1). A total of 286 full-text articles were assessed for eligibility. Of these, 35 were appraised with the JBI checklists, with two being excluded due to concerns regarding the statistical analysis and reporting[33,34] (appendix p 3), resulting in 33 articles[18–23,27–30,32,35–56] being included in the systematic review. The characteristics of all included studies are shown in table 1 and in the appendix (pp 28–29). Ten (30%) studies[18,20,23,27,28,32,35–38] met the criteria for inclusion in category one, ten (30%) studies[19,21,22,29,30,39–43] for inclusion in category two (table 1), and 13 (39%) studies[44–56] for inclusion in category three (appendix pp 28–29). Seven (70%) category one studies[18,20,23,27,28,32,35] and four (40%) category two studies[19,22,29,30] were included in the meta-analysis.

Risk of bias assessment with the JBI Critical Appraisal Checklists revealed the following sources of bias: the absence of valid or reliable measurement of exposure in all 33 studies; the absence of objective standard criteria for measurement of the condition in seven (21%) studies;[22,28,32,36–38,42] no assessment of confounders in nine (27%) studies;[21,39,41,42,45,48,52,55,56] insufficient strategies for dealing with confounders in nine (27%) studies;[21,28,39,40,42,45,48,52,55] incomplete follow-up in three (9%) studies;[19,51,54] the absence of strategies to address incomplete follow-up in four (12%) studies;[19,35,51,54] and unclear reporting of whether participants were free from myopia at baseline in two (6%) studies.[32,51] Specific comments about the sources of bias for each study are provided in the appendix (pp 15–27).

Most category one studies (seven [70%] of ten) and category two studies (six [60%] of ten) investigated Asian populations.[20,21,23,27,29,30,32,35–37,40,41,43] Even though some European studies[18,19,22,28,38,39,42] were included, no eligible studies from other world regions were identified. Similarly, category three studies were mostly done in east Asia (nine [69%] of 13)[45–51,53,55] or Europe (three [23%]),[44,52,54] with one done in the Middle East.[56] Eight (80%) category one studies,[18,20,27,28,32,36–38] seven (70%) category two studies,[21,22,29,30,39,41,42] and 11 (85%) category three studies[44–50,52,53,55,56] were cross-sectional, and the remaining two category one studies,[23,35] three category two studies,[19,40,43] and two category three studies[51,54] were prospective.

Population-based surveys, such as the North India Myopia (NIM) study, selected participants by cluster sampling of classes, or schools or districts, or both.[18,20,27,29,37,47] Stratification by school and age was common,[20,23,32,36,47,48,53] whereas stratification by other variables such as urban or rural location, socioeconomic status,[18] or type of school[32] was rare. Although some studies adjusted for confounders in statistical analyses,[18,19,23,32,35,37,38] variability in selected covariates could have caused bias. Some studies used pseudo-random

	Participants; age; country	Response rate	Myopia definition (measure)	Screen exposure (period of exposure)*	Myopia prevalence or incidence by smart device exposure, or screen time by myopia status	Association between exposure and myopia
Category one studies: use of smartphones or tablet computers, or both, analysed independently of other near vision activities						
Cross-sectional studies						
Guan et al (2019)[27]	19 934 primary school children; mean age 10·6 years (SD 1·15); China	100%	Spherical equivalent ≤–0·5 dioptres in at least one eye (visual acuity and auto-refraction)	Smartphone screen time (period not reported)	0 min per day 17·5%; 1–30 min per day 19·4%; 31–60 min per day 18·0%; and >60 min per day 20·0%	Multivariable analysis of smartphone use and myopia: 0 min per day β coefficient 1 (ref); 1–30 min per day 0·03 (95% CI –0·07 to 0·12, p=0·59); 31–60 min per day –0·02 (–0·22 to 0·19, p=0·89); >60 min per day 0·16 (–0·07 to 0·39, p=0·17)
Harrington et al (2019)[18]	1626 school children; age 6–7 years and 12–13 years; Ireland	98·5%	Spherical equivalent ≤–0·5 dioptres in either eye (auto-refraction)	Smartphone screen time (period not reported)	<1 h per day 8·3%; 1–3 h per day 11·7%; and >3 h per day 20·3%	Multivariable analysis of smartphone screen time and myopia: <1 h per day OR 0·3 (95% CI 0·2–0·5, p<0·001); 1–3 h per day 0·5 (0·3–0·8, p=0·001); and >3 h per day 1 (ref)
Huang et al (2019)[36]	968 first year university students; mean age 19·6 years (SD 0·9); China	96·1%	Spectacles or contact lenses for distant vision (questionnaire)	Smartphone screen time (period not reported)	0 h per day 89·7%; ≤1 h per day 87·1%; 1·01–2 h per day 89·7%; 2·01–3 h per day 86·3%; and >3 h per day 84·6%	Univariate analysis of smartphone screen time and myopia: 0 h per day OR 1 (ref); ≤1 h per day 0·78 (95% CI 0·36–1·69, p=0·52); 1·01–2 h per day 1·01 (0·47–2·18, p=0·99); 2·01–3 h per day 0·72 (0·36–1·46, p=0·36); >3 h per day 0·63 (0·33–1·20, p=0·16)
Liu et al (2019)[20]	566 primary and secondary school children; mean age 9·5 years (SD 2·1); China	88·7%	Spherical equivalent ≤–0·5 dioptres in right eye (auto-refraction)	Smartphone and tablet screen time (period not reported)	Smartphones: myopia 0·47 (SD 0·49) h per day *vs* no myopia 0·39 (0·47) h per day (p=0·038; adjusted p=0·93); tablets: myopia 0·34 (0·46) h per day *vs* no myopia 0·26 (0·47) h per day (p=0·040; adjusted p=0·11)	Smartphone screen time and myopia multivariable OR 0·90 (95% CI 0·57 to 1·43, p=0·66); tablet screen time and myopia multivariable OR 1·40 (0·86 to 2·28, p=0·18); smartphone screen time and axial length β coefficient 0·10 (95% CI 0·07 to 0·39, p=0·006); tablet screen time and axial length β coefficient –0·03 (0·23 to 0·10, p=0·45); smartphone screen time and spherical equivalent β coefficient –0·07 (–0·55 to –0·01, p=0·042); and tablet screen time and spherical equivalent β coefficient –0·05 (–0·47 to 0·08, p=0·17)
McCrann et al (2020)[28]	402 students; mean age 16·8 years (SD 4·4); Ireland	96·1%	Concave spectacle lenses (questionnaire)	Smartphone screen time (period not reported)	Myopia 288 (SD 174) min per day *vs* no myopia 258 (163) min per day (p=0·090)	Smartphone screen time and myopia multivariable OR 1·03 (95% CI 1·00–1·05)
Schuster et al (2017)[38]	12 884 children and adolescents; age 3–17 years; Germany	66·6%	Self-reported (questionnaire)	Mobile phone screen time (period not reported)	Not reported	Multivariable analysis of mobile phone screen time and myopia in participants aged 11–17 years: <0·5 h per day 1–2 h per day 0·99 (95% CI 0·78–1·25); 3–4 h per day 0·83 (0·52–1·31); and >4 h per day 1·34 (0·99–1·82); p=0·14
Toh et al (2019)[32]	1884 adolescents; age 10–18 years; Singapore	74·1%	Difficulties in seeing far (questionnaire)	Mobile touch-screen device time (number of min per day in past year)	Not reported	Smartphone screen time and myopia multivariable OR 0·97 (95% CI 0·94–0·99, p<0·05); tablet screen time and myopia multivariable OR 0·99 (0·94–1·05)
Yang et al (2020)[37]	26 433 preschool children; age 2–7 years; China	Not reported	Self-reported yes, no, or uncertain (questionnaire)	Initial age of exposure to smartphone or tablet (age of first exposure)	No exposure 1·0%; age 0–1 years 4·5%; age 1–2 years 2·1%; age 2–3 years 1·7%; and age >3 years 1·7%	Multivariable analysis of initial age of exposure: no exposure PR 1 (ref); age 0–1 years 4·41 (95% CI 2·19–8·90, p<0·001); age 1–2 years 2·46 (1·20–5·06, p<0·05); age 2–3 years 2·02 (0·97–4·17); age >3 years 1·78 (0·87–3·65)
Prospective studies						
Chua et al (2015)[35]	925 children; age 3 years; Singapore	74·8%	Spherical equivalent ≤–0·5 dioptres in right eye (auto-refraction)	Handheld device screen time (in h per day; period not reported)	Not reported	Screen time and myopia multivariable OR 1·04 (95% CI 0·67–1·61, p=0·86); screen time and spherical equivalent multivariable β coefficient –0·10 (95% CI –0·20–0·0, p=0·05); and screen time and axial length multivariable β coefficient 0·07 (0·01–0·13, p=0·03)
Toh et al (2020)[23]	1691 adolescents; age 10–19 years; Singapore	89·8%	Difficulties in seeing far (questionnaire)	Any use of smartphones, smartphone screen time, any use of a tablet, or tablet screen time (period not reported)	Not reported	Smartphone use and myopia multivariable OR 0·87 (95% CI 0·42–1·81); smartphone screen time and myopia multivariable OR 0·97 (0·91–1·03); tablet use and myopia multivariable OR 0·74 (0·48–1·15); tablet screen time and myopia multivariable OR 0·98 (0·87–1·10)

(Table 1 continues on next page)

	Participants; age; country	Response rate	Myopia definition (measure)	Screen exposure (period of exposure)*	Myopia prevalence or incidence by smart device exposure, or screen time by myopia status	Association between exposure and myopia
(Continued from previous page)						
Category two studies: use of smartphones or tablet computers, or both, combined with computer screen-time activities						
Cross-sectional studies						
Alvarez-Peregrina et al (2019)[39]	5441 school children; mean age 6·2 years (SD 0·8); Spain	88·4%	Spherical equivalent ≤–0·50 dioptres (auto-refraction)	Smartphone, tablet, and video game screen time expressed as a percentage of time (period not reported)	<25% of time aproximately 24%; 25–50% of time approximately 23%; and >50% of time approximately 53%	More screen time associated with higher prevalence of myopia (p<0·05)
Hagen et al (2018)[22]	439 school children; mean age 16·7 (SD 0·9); Norway	48·9%	Spherical equivalent ≤–0·5 dioptres in right eye (auto-refraction)	Smartphone, tablet, and computer screen time (period not reported)	Not reported	Screen time and myopia multivariable OR 1·01 (95% CI 0·78–1·31, p=0·92)
Hsu et al (2016)[41]	16 486 children; age 8 years; Taiwan	85·1%	Spherical equivalent ≤–0·5 dioptres in more myopic eye (auto-refraction)	Phone, computer, or tablet use (any use in past year)	Yes 36·0%; no 39·1%; and unknown 36·4%	Screen exposure in past year and spherical equivalent multivariable β coefficient 0·82 (0·72–0·92, p<0·001); and screen time and spherical equivalent multivariable β coefficient 0·02 (–0·01–0·13, p=0·11)
McCrann et al (2018)[42]	361 school children from urban and rural schools; age 8–13 years; Ireland	Not reported	Self-reported (questionnaire)	Phone, computer, tablet, and video game screen time (use over 1 week of study participation)	Median 135 min per day (95% CI 78–196) in people with myopia *vs* median 90 min per day (60–158) in those without myopia (ANOVA p=0·04)	Not reported
Saxena et al (2015)[29]	9884 children; mean age 11·6 years (SD 2·2); India	97·7%	Spherical equivalent ≤–0·5 dioptres in either or both eyes (visual acuity and auto-refraction)	Mobile, computer, and video game screen time (period not reported)	0 h per week 1·1%; 1–4 h per week 50·9%; and >4 h per week 48·0%	Multivariable analysis of screen time and myopia: 0 h per week OR 1 (ref); 1–4 h per week 4·50 (95% CI 2·33–8·98); and >4 h per week 8·10 (4·05–16·21)
Singh et al (2019)[30]	1234 school children; mean age 10·5 years (SD 3·0); India	Not reported	Spherical equivalent ≤–0·50 dioptres in either or both eyes (auto-refraction)	Mobile and video game screen time (period not reported)	0–2 h per day: myopia 43% *vs* no myopia 97%; >2–4 h per day: myopia 51% *vs* no myopia 2·4%; and >4 h per day: myopia 7% *vs* no myopia 0%	Multivariable analysis of screen time and myopia: 0–2 h per day OR 1 (ref); >2–4 h per day 8·33 (95% CI 3·54–19·58, p=0·0001)
Terasaki et al (2017)[21]	122 school children; age 8–9 years; Japan	87·4%	Axial length of right eye (optical biometry)	Smartphone and computer screen time (period not reported)	Not applicable	Spearman's correlation analysis between screen time and axial length *r*=0·24, p=0·008
Prospective studies						
Hansen et al (2020)[19]	1443 children; median age 16·6 years (IQR 0·3); Copenhagen, Denmark	Not reported	Spherical equivalent ≤–0·5 dioptres in right eye (subjective and objective refraction)	Smartphone, tablet, or computer screen time (use over past 2 weeks)	Weekdays: <0·5 h per day 0·6%; 0·5–2 h per day 5%; 2–4 h per day 26%; 4–6 h per day 32%; and >6 h per day 37%. Weekends: <0·5 h per day 0%; 0·5–2 h per day 4%; 2–4 h per day 20%; 4–6 h per day 32%; and >6 h per day 44%	Multivariable analysis of screen time and myopia on weekdays: <2 h per day OR 1 (ref); 2–4 h per day 1·89 (95% CI 1·09–3·28, p=0·023); 4–6 h per day 1·68 (0·98–2·89, p=0·06); >6 h per day 1·89 (1·10–3·24, p=0·021). Multivariable analysis of screen time and myopia at weekends: <2 h per day OR 1 (ref); 2–4 h per day 1·73 (95% CI 0·93–3·20, p=0·08); 4–6 h per day 1·62 (0·90–2·94, p=0·11); >6 h per day 1·97 (1·10–3·55 p=0·024)
Hsu et al (2017)[40]	3256 children; age 7·49 years (SD 0·31); Taiwan	77·3%	Spherical equivalent ≤–0·5 dioptres in more myopic eye (auto-refraction)	Phone, computer, or tablet use (use in past year)	Yes 79·91%; no 8·23%; and unknown 11·86%	Multivariable analysis of any screen use in the past year and progression rate: moderate (change in spherical equivalent of >–1·0 to –0·5 dioptres) OR 0·99 (95% CI 0·73–1·33); and fast (change in spherical equivalent of ≤–1·0 dioptres) 1·18 (0·85–1·65)
Tsai et al (2016)[43]	11 590 school children; age 8 years; Taiwan	70·3%	Incident myopia, Spherical equivalent ≤–0·50 dioptres in either eye (auto-refraction)	Phone, computer, and tablet use (use in past year)	87·2% of incident myopia in people who used devices *vs* 87·4% in those who did not (p=0·77)	Not reported

OR=odds ratio. PR=prevalence ratio. *Period of exposure refers to the overall amount of time participants had been exposed to the variable, not the duration of exposure in a defined timeframe, such as daily or weekly screen time.

Table 1: **Characteristics of studies on the association between smart device use and myopia included in the systematic review**

quota sampling[32] or convenience sampling from selected clinics[35,52] or schools,[21,30,36,39] which could have introduced selection bias.

Some studies recruited children aged younger than 7 years who might not yet have had enough time to develop myopia, given the disease's protracted natural history.[21,35] These studies did not account for the period during which myopia might have progressed in the future. By contrast, other studies investigated adults whose refraction had probably stabilised, and who were thus less susceptible to the environmental risk factors of myopia than children and adolescents.[28,36]

All 33 studies used questionnaires to measure smart device use, whereas one (3%) also used device-recorded network data consumption;[28] however, because different applications consume different quantities of network data, the reliability of this measure as an indicator of exposure is questionable (table 1). Studies tended not to account for the non-linear progression of myopia by age, with only one study[37] reporting the age of adoption of smart devices, and finding that adoption at younger ages (ie, ≤2 years) was significantly associated with myopia risk. Nine (27%) studies defined the study period during which exposure was measured (ie, the past week,[42,47,48] 2 weeks,[19] 1 month,[51] and 1 year[32,40,41,43]), but did not account for possible variations in screen time over long time periods.

All ten category one studies reported prevalent or incident myopia, although, only four (40%) studies[18,20,27,35] measured refraction. Among these four studies was the Growing Up in Singapore Towards healthy Outcomes (GUSTO) study,[35] which investigated early onset myopia (in participants aged ≤3 years) and found no increased risk with more screen time. However, each additional h per day of screen time was associated with a 0·7 mm (95% CI 0·01 to 0·13) increase in axial length and marginally increased myopic spherical equivalent (–0·10 dioptres [95% CI –0·20 to 0·0]), suggesting that children with longer screen time were at greater risk of incident myopia but were still too young for the condition to have developed. Similarly, there were no associations between prevalent myopia and screen time among children aged 6–14 years in Tianjin, China.[20] Each additional h per day of smartphone screen time was associated with longer axial length (0·10 mm [95% CI 0·07 to 0·39]) and an increased myopic spherical equivalent (–0·07 dioptres [95% CI –0·55 to –0·01]). These early trends in axial length and myopic spherical equivalent could indicate significant associations with incident myopia at follow-up.

In almost 20 000 Chinese children from rural areas, the prevalence of myopia was 18–20% in those who used smartphones for 1 min per day to more than 60 min per day, which was not significantly higher than the prevalence of myopia among those who reported no use of smartphones (18%); although, smartphone use for more than 60 min per day was associated with reduced uncorrected visual acuity.[27] However, the age-specific prevalence of myopia in this study was lower than in the general Chinese population,[57] and screen-time categories did not reflect the real-world use of smartphones, which could be as high as 8 h per day,[58] and the rural environ—ment might have been a protective factor against myopia.[59] By contrast, in a study of Irish children, when a category of longer smartphone screen time duration was used (ie, >3 h per day) and children from urban areas were included, myopia was considerably more prevalent with increased screen time.[18]

The remaining six (60%) of ten category one studies[23,28,32,36–38] relied on self-reported or parental-reported myopia, or visual inspection of spectacles by a study investigator to identify myopia.[28] Although smartphone screen time was neither associated with myopia among German[38] nor Chinese students,[36] each additional min per day was associated with a 2·6% increased risk of myopia among Irish students.[28]

Eight (80%) of ten category two studies[19,22,29,30,39,40,41,43] measured refraction, with the remaining two studies using either self-reported myopia[42] or optical biometry to measure axial length.[21] Six (60%) of ten studies[19,21,29,30,39,42] reported that digital screen use was associated with myopia or increased axial length, whereas three (30%) studies[22,40,43] reported no association. Two (20%) studies involving individuals aged 5–15 years in north India revealed some of the most significant associations between screen time and myopia; on the one hand, more than 2 h per day of screen time was associated with 8·33-times higher odds of myopia compared with less than 2 h per day among children at private schools,[30] and, on the other hand, more than 4 h per week of screen time was associated with 8·10-times higher odds of myopia compared with no screen time among children from ten randomly selected schools.[29] The prevalence of myopia was as high as 37–44% among Danish teenagers who used digital screens for more than 6 h per day compared with only 0–0·6% among those who used digital screens for less than 0·5 h per day.[19]

Any digital screen exposure in the past year was associated with a lower odds of myopia compared with no exposure in the past year among Taiwanese children.[41] Regression analysis showed no difference in the myopic spherical equivalent between these two groups,[41] and screen exposure was not significantly associated with myopia progression at follow-up.[40]

All 13 category three studies measured refraction, and most (seven [54%]) found no association between the duration of near-vision work and either myopia[44,49–51,53] or spherical equivalent.[46,49,50,56] Each additional h per week of near-vision work (ie, use of a smartphone, computer, or television, or reading books or studying) was associated with a 1% increase in the odds of myopia[47] and a 26% increase in the odds of severe myopia[48] in two nationwide Taiwanese studies, respectively. The prevalence of myopia in Italian children who played video games for 30 min per day or more and used digital devices for 3 h per day or more was 6·8%, compared with a prevalence of 0% among those who played video games for less than 30 min per day and used digital devices for less than 3 h per day, although no statistical associations were provided.[52]

	Screen exposure measure (number of participants)	Adjusted factors	Published outcome	OR (95% CI) in meta-analysis
Cross-sectional studies				
Guan et al (2019)[27]	Smartphone screen time: 0 min per day (n=13 161); 1–30 min per day (n=5360); 31–60 min per day (n=829); and >60 min per day (n=584)	Age, sex, family wealth, parental migrant status, parental education, child's residence, and correlation between eyes	0 min per day β coefficient 1 (ref); 1–30 min per day 0·03 (95% CI –0·07–0·12); 31–60 min per day –0·02 (–0·22–0·19); and >60 min per day 0·16 (–0·07–0·39)	0 min per day 1 (ref); 1–30 min per day 1·03 (0·94–1·12); 31–60 min per day 0·99 (0·81–1·20); and >60 min per day 1·17 (0·93–1·48)*
Harrington et al (2019)[18]	Smartphone screen time <1 h per day (n=313); 1–3 h per day (n=707); and >3 h per day (n=582)	Age and ethnicity	<1 h per day OR 0·30 (95% CI 0·20–0·50); 1–3 h per day 0·50 (0·30–0·80); and >3 h per day 1 (ref)	<1 h per day 1 (ref); 1–3 h per day 1·67 (1·00–2·67); and >3 h per day 3·33 (2·00–5·00)†
Toh et al (2019)[32]	Tablet screen time in h per day (n=1884)	Gender, grade at school, mental health score, amount of physical activity and total duration of technology use	OR 0·99 (95% CI 0·94–1·05)	0·99 (0·94–1·05)
Liu et al (2019)[20]	Tablet screen time in h per day (n=566)	Not stated (multivariable)	OR 1·40 (95% CI 0·86–2·28)	1·40 (0·86–2·28)
McCrann et al (2020)[28]	Smartphone screen time in min per day (n=396)	Age, myopia status of parents, sex, and belief that technology can negatively affect eyes	$OR_{min\ per\ day}$ 1·03 (95% CI 1·00–1·05)	$OR_{h\ per\ day}$ 4·66 (1·08–20·13)
Hagen et al (2018)[22]	Screen time in h per day (n=898)	Sex	OR 1·01 (95% CI 0·78–1·31)	1·01 (0·78–1·31)
Saxena et al (2015)[29]	Mobile, computer, and video game screen time: <1 h per week (n=186); 1–4 h per week (n=1383); and >4 h per week (n=881)	Age, sex, school, family myopia, maternal education, socioeconomic status, near work time, TV time and outdoor time	<1 h per week OR 1 (ref); 1–4 h per week 4·50 (2·33–8·98); and >4 h per week 8·10 (4·05–16·21)	<1 h per week 1 (ref); 1–4 h per week 4·50 (2·29–8·83); >4 h per week 8·10 (4·05–16·20)
Singh et al (2019)[30]	Mobile and video game screen time: 0–2 h per day (n=1061); and >2–4 h per day (n=155)	sex, age, family history, spherical equivalent, outdoor time, study hours, video game time	0–2 h per day OR 1 (ref); and >2–4 h per day 8·33 (3·54–19·58)	0–2 h per day 1 (ref); >2–4 h per day 8·33 (3·54–19·59)
Prospective studies				
Chua et al (2015)[35]	Smart device screen time in h per day (n=541)	Age, sex, ethnicity, and maternal education	OR 1·04 (0·67–1·61)	1·04 (0·67–1·61)
Toh et al (2020)[23]	Tablet screen time in h per day (n=1413)	Gender, school level, musculoskeletal symptoms in the past month or visual health measures, mental health, physical activity, and total technology use	OR 0·98 (0·87–1·1)	0·98 (0·87–1·1)
Hansen et al (2020)[19]	Smartphone, tablet, or computer screen time on a weekday: <2 h per day (n=127); 2–4 h per day (n=360); 4–6 h per day (n=470); and >6 h per day (n=478)	Age, sex, weight, height, and physical activity	<2 h per day OR 1 (ref); 2–4 h per day 1·89 (1·09–3·28); 4–6 h per day 1·68 (0·98–2·89); and >6 h per day 1·89 (1·10–3·24)	<2 h per day 1 (ref); 2–4 h per day 1·89 (1·09–3·28); 4–6 h per day 1·68 (0·98–2·88); and >6 h per day 1·89 (1·10–3·24)

OR=odds ratio. *For all values, ORs were derived through transformation of reported β coefficients. †For all values, ORs were reversed to convert lowest screen time to referent for inter-study consistency.

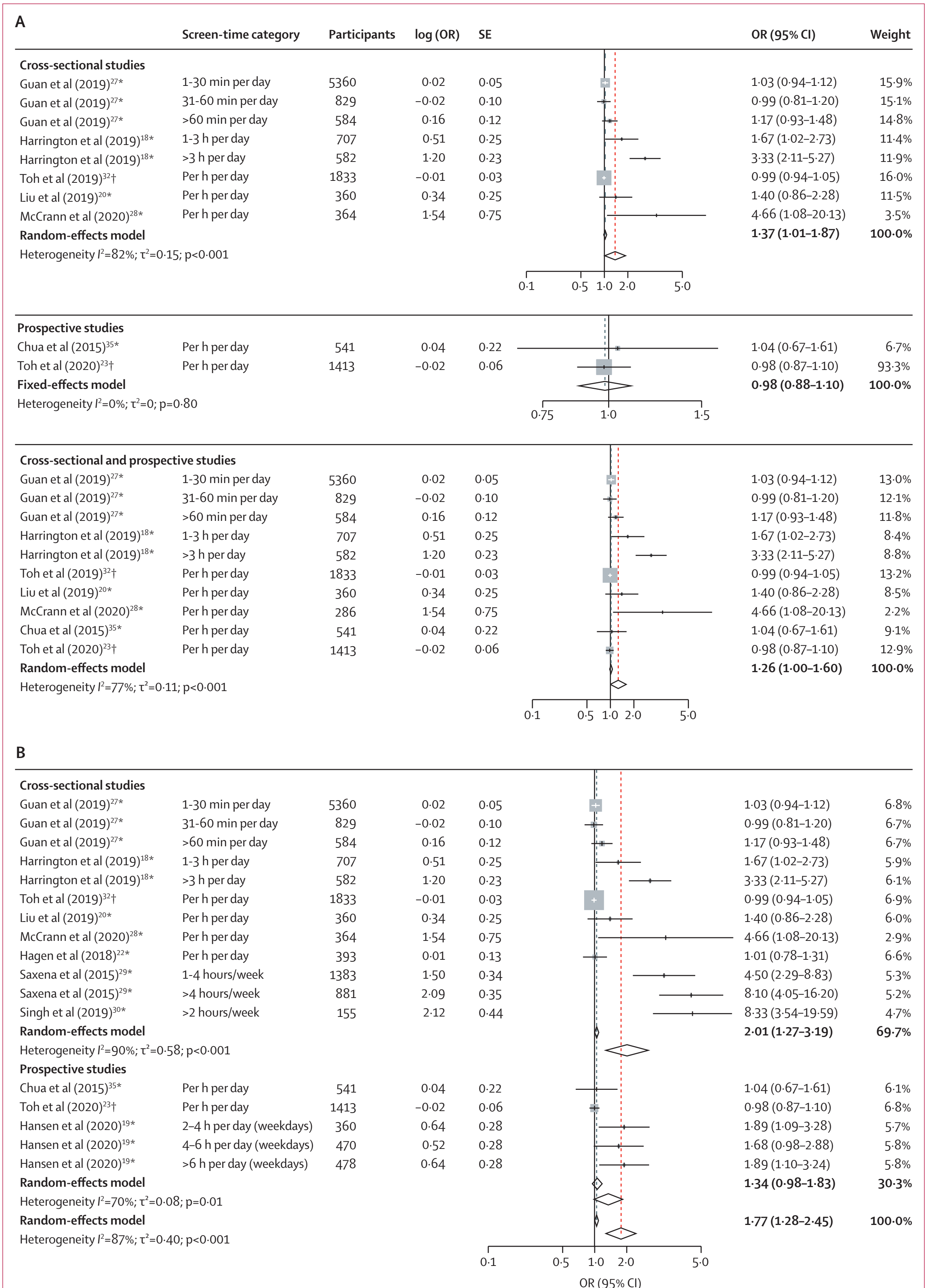
Table 2: **Results from articles reporting associations between digital smart device use and incident or prevalent myopia included in meta-analysis models**

The ORs included in the meta-analysis models are presented in table 2. The meta-analysis of seven (70%) of ten category one studies (n=12 495) reporting associations between smart device screen time and myopia[18,20,23,27,28,32,35] produced a pooled OR of 1·26 (95% CI 1·00–1·60), suggesting that more smart device screen time is associated with myopia (figure 2). This association was conserved for cross-sectional category one studies (five studies [n=10 651]; 1·37 [1·01–1·87]), but not for the prospective category one studies (two studies [n=1954]; 0·98 [0·88–1·10]).

After pooling data from all 11 relevant category 1 and 2 studies[18–20,22,23,27,28,29,30,32,35] (n=13 968), a significant association between screen time on smartphones or tablets, or both, either alone or in combination with computer screen time, and myopia was observed (OR 1·77 [95% CI 1·28–2·45]). Although this significant association was maintained after pooling ORs from only cross-sectional category one and two studies (eight studies [n=13 968]; 2·01 [1·27–3·19]), no significant association was found among only prospective category one and two studies (three studies [n=3262]; 1·34 [0·98–1·83]).

Figure 2: **Forest plots showing the association between smart device screen time and myopia**

(A) Associations between smart device screen time (category one articles only) and prevalent myopia. For cross-sectional and prospective studies combined, all studies were re-weighted to sum to 100%, and their weights displayed for the random-effects model. (B) Associations between smart device or computer screen time, or both (category one and two articles) and prevalent or incident myopia. Studies were not re-weighted to sum to 100% because both cross-sectional and prospective models used random-effects models, and the sum of their combined weights equalled 100%. ORs for categorical variables represent the relative odds for prevalent or incident myopia associated with each screen time category compared with the reference category (OR=1), as shown in table 2. OR=odds ratio. *Objective measurement of myopia. †Subjective measurement of myopia.


A
Screen-time category | Participants | log (OR) | SE | OR (95% CI) | Weight
Cross-sectional studies
Guan et al (2019)[27]* | 1-30 min per day | 5360 | 0·02 | 0·05 | 1·03 (0·94–1·12) | 15·9%
Guan et al (2019)[27]* | 31-60 min per day | 829 | −0·02 | 0·10 | 0·99 (0·81–1·20) | 15·1%
Guan et al (2019)[27]* | >60 min per day | 584 | 0·16 | 0·12 | 1·17 (0·93–1·48) | 14·8%
Harrington et al (2019)[18]* | 1-3 h per day | 707 | 0·51 | 0·25 | 1·67 (1·02–2·73) | 11·4%
Harrington et al (2019)[18]* | >3 h per day | 582 | 1·20 | 0·23 | 3·33 (2·11–5·27) | 11·9%
Toh et al (2019)[32]† | Per h per day | 1833 | −0·01 | 0·03 | 0·99 (0·94–1·05) | 16·0%
Liu et al (2019)[20]* | Per h per day | 360 | 0·34 | 0·25 | 1·40 (0·86–2·28) | 11·5%
McCrann et al (2020)[28]* | Per h per day | 364 | 1·54 | 0·75 | 4·66 (1·08–20·13) | 3·5%
Random-effects model | 1·37 (1·01–1·87) | 100·0%
Heterogeneity I^2=82%; τ^2=0·15; p<0·001
0·1 0·5 1·0 2·0 5·0
Prospective studies
Chua et al (2015)[35]* | Per h per day | 541 | 0·04 | 0·22 | 1·04 (0·67–1·61) | 6·7%
Toh et al (2020)[23]† | Per h per day | 1413 | −0·02 | 0·06 | 0·98 (0·87–1·10) | 93·3%
Fixed-effects model | 0·98 (0·88–1·10) | 100·0%
Heterogeneity I^2=0%; τ^2=0; p=0·80
0·75 1·0 1·5
Cross-sectional and prospective studies
Guan et al (2019)[27]* | 1-30 min per day | 5360 | 0·02 | 0·05 | 1·03 (0·94–1·12) | 13·0%
Guan et al (2019)[27]* | 31-60 min per day | 829 | −0·02 | 0·10 | 0·99 (0·81–1·20) | 12·1%
Guan et al (2019)[27]* | >60 min per day | 584 | 0·16 | 0·12 | 1·17 (0·93–1·48) | 11·8%
Harrington et al (2019)[18]* | 1-3 h per day | 707 | 0·51 | 0·25 | 1·67 (1·02–2·73) | 8·4%
Harrington et al (2019)[18]* | >3 h per day | 582 | 1·20 | 0·23 | 3·33 (2·11–5·27) | 8·8%
Toh et al (2019)[32]† | Per h per day | 1833 | −0·01 | 0·03 | 0·99 (0·94–1·05) | 13·2%
Liu et al (2019)[20]* | Per h per day | 360 | 0·34 | 0·25 | 1·40 (0·86–2·28) | 8·5%
McCrann et al (2020)[28]* | Per h per day | 286 | 1·54 | 0·75 | 4·66 (1·08–20·13) | 2·2%
Chua et al (2015)[35]* | Per h per day | 541 | 0·04 | 0·22 | 1·04 (0·67–1·61) | 9·1%
Toh et al (2020)[23]† | Per h per day | 1413 | −0·02 | 0·06 | 0·98 (0·87–1·10) | 12·9%
Random-effects model | 1·26 (1·00–1·60) | 100·0%
Heterogeneity I^2=77%; τ^2=0·11; p<0·001
0·1 0·5 1·0 2·0 5·0
B
Cross-sectional studies
Guan et al (2019)[27]* | 1-30 min per day | 5360 | 0·02 | 0·05 | 1·03 (0·94–1·12) | 6·8%
Guan et al (2019)[27]* | 31-60 min per day | 829 | −0·02 | 0·10 | 0·99 (0·81–1·20) | 6·7%
Guan et al (2019)[27]* | >60 min per day | 584 | 0·16 | 0·12 | 1·17 (0·93–1·48) | 6·7%
Harrington et al (2019)[18]* | 1-3 h per day | 707 | 0·51 | 0·25 | 1·67 (1·02–2·73) | 5·9%
Harrington et al (2019)[18]* | >3 h per day | 582 | 1·20 | 0·23 | 3·33 (2·11–5·27) | 6·1%
Toh et al (2019)[32]† | Per h per day | 1833 | −0·01 | 0·03 | 0·99 (0·94–1·05) | 6·9%
Liu et al (2019)[20]* | Per h per day | 360 | 0·34 | 0·25 | 1·40 (0·86–2·28) | 6·0%
McCrann et al (2020)[28]* | Per h per day | 364 | 1·54 | 0·75 | 4·66 (1·08–20·13) | 2·9%
Hagen et al (2018)[22]* | Per h per day | 393 | 0·01 | 0·13 | 1·01 (0·78–1·31) | 6·6%
Saxena et al (2015)[29]* | 1-4 hours/week | 1383 | 1·50 | 0·34 | 4·50 (2·29–8·83) | 5·3%
Saxena et al (2015)[29]* | >4 hours/week | 881 | 2·09 | 0·35 | 8·10 (4·05–16·20) | 5·2%
Singh et al (2019)[30]* | >2 hours/week | 155 | 2·12 | 0·44 | 8·33 (3·54–19·59) | 4·7%
Random-effects model | 2·01 (1·27–3·19) | 69·7%
Heterogeneity I^2=90%; τ^2=0·58; p<0·001
Prospective studies
Chua et al (2015)[35]* | Per h per day | 541 | 0·04 | 0·22 | 1·04 (0·67–1·61) | 6·1%
Toh et al (2020)[23]† | Per h per day | 1413 | −0·02 | 0·06 | 0·98 (0·87–1·10) | 6·8%
Hansen et al (2020)[19]* | 2–4 h per day (weekdays) | 360 | 0·64 | 0·28 | 1·89 (1·09–3·28) | 5·7%
Hansen et al (2020)[19]* | 4–6 h per day (weekdays) | 470 | 0·52 | 0·28 | 1·68 (0·98–2·88) | 5·8%
Hansen et al (2020)[19]* | >6 h per day (weekdays) | 478 | 0·64 | 0·28 | 1·89 (1·10–3·24) | 5·8%
Random-effects model | 1·34 (0·98–1·83) | 30·3%
Heterogeneity I^2=70%; τ^2=0·08; p=0·01
Random-effects model | 1·77 (1·28–2·45) | 100·0%
Heterogeneity I^2=87%; τ^2=0·40; p<0·001
0·1 0·5 1·0 2·0 5·0
OR (95% CI)

Discussion

This systematic review and meta-analysis provides some evidence to suggest that smart device exposure could be associated with myopia. However, the paucity of studies that used objective and standard measures of screen time and myopia, or that investigated smartphones and tablets independently, necessitates further research.

The fact that most studies did not categorise smart devices as an independent risk factor is understandable, given the recent introduction of these devices over the past 13 years and the convention for much of the previous literature to have grouped diverse behaviours into so-called near-vision work.[60] However, because of the longer viewing durations and closer viewing distances associated with smart devices than with books and other non-digital reading materials,[61] we recommend that future studies aim to investigate smart devices independently to better understand their effects on ocular health.

Most studies that investigated smart devices independently did not use objective clinical measures of myopia. Given the questionable sensitivity (76%) and specificity (74%) of self-reporting for myopia,[62] these findings should be considered cautiously. Those studies that did measure refraction objectively had inconsistent findings. For instance, although screen time was not associated with spherical equivalent, it predicted reduced visual acuity in one Chinese study,[27] whereas in another study,[20] increased screen time was associated with greater axial length and more myopic spherical equivalent, but not prevalent myopia. Further research might elucidate whether these subtle biometric associations portend clinically significant myopic shifts, such as those observed in Irish children, in whom more than 3 h per day of smartphone use was associated with three-times higher odds of myopia.[18]

Category two studies tended to report stronger associations between digital screen exposure and myopia than category one studies, including in two Indian studies that reported a 4–8 times higher risk of myopia.[29,30] This finding could suggest that computer screens are more myopigenic than smart devices; although, because these devices were not investigated separately, strong inferences cannot be made. Policy makers and parents should consider the amount of time spent using computers and smart devices in myopia control strategies. Due to the digitisation of education, controlling computer screen time could be more challenging than for smart devices, which tend to be used for leisure.

The meta-analysis results suggested that screen time on smartphones or tablets, or both, either alone or in combination with computer screen time was associated with myopia when cross-sectional and prospective studies were combined or when cross-sectional studies were analysed alone; however, the heterogeneity implicit in these analytical models warrants cautious interpretation of the results. The small number of prospective studies severely limits interpretation of the absence of an association in their pooled estimates. Nonetheless, one previous meta-analysis found that each additional h per week of near-vision work increased the odds of myopia by 2%.[60] Given that smart devices are used for longer durations and at closer distances than other forms of near-vision work,[9,10] it is possible that they could be similarly myopigenic.

This review differed from the systematic review by Lanca and Saw (2020) in several ways.[24] For reasons that are unclear, key studies included in our review that reported significant associations between screen time and myopia[18,19,30,37,42] were excluded from their review. Also noteworthy is that the authors weighted the non-significant OR of just one study[35] to account for 98·7% of the variance in the pooled OR, whereas we used a random-effects meta-analysis to accommodate high heterogeneity and permit all studies to influence the model. Finally, some of the non-significant ORs in their model were derived from transformations of significant ORs in source articles, which probably contributed to the observed absence of an association in their meta-analysis.

It can be argued that the associations reported in observational studies do not reveal causal links, and that the causal direction can be reversed, such that people with myopia are predisposed to spend more time on smart devices because their existing impairment renders distance viewing more demanding. However, there are several plausible mechanistic explanations that substantiate a unidirectional causal association between screen time and myopia. These explanations include those that apply to near-vision tasks generally, including the axial elongating effects of excessive accommodative convergence and peripheral defocus,[28] as well as the fact that the small screens and the font size of smart devices promote even closer viewing distances, placing greater demand on accommodation and vergence than conventional print materials.[10] Additionally, because screen use usually occurs indoors, the corresponding reduction in exposure to protective aspects of outdoor environments, such as higher luminosity and more uniform dioptric space could further disrupt emmetropisation.[63] This disruption could be caused, in part, by the inhibition of sunlight-induced retinal dopaminergic neurotransmission, a process that is instrumental in regulating normal refractive development.[64] Mendelian randomisation has provided strong unidirectional evidence that education, which involves a substantial amount of near-vision work, might be a cause of myopia, thus lending theoretical support to a potential influence of smart device use.[65] However, exploring these mechanistic explanations was beyond the scope of this study.

The key strengths of this study included the investigation of smart devices, both alone and in combination with other types of digital screens, to better discriminate the associations between the use of each type of device and myopia. Another strength is the comprehensive systematic component of the literature review, which identified significant methodological issues that, if addressed in future research, could facilitate a better understanding of the association between digital device use and myopia. There were also several limitations of the study. As most studies were done in Asian populations, it is not clear whether the results are generalisable to all populations. Additionally, because fewer than one-third of studies distinguished smart device screen time from other near-vision tasks, and because inter-study heterogeneity necessitated the construction of several meta-analysis models, strong conclusions about the link between smart device exposure and myopia cannot be drawn. In addition, all studies included in our study were limited by the use of parental-reporting or self-reporting to measure the amount of digital screen exposure, apart from in the study by McCrann and colleagues,[28] which attempted to provide objective measures through device-recorded network data consumption. Given that people tend to underestimate their own digital screen time (by as much as 40%),[66] future studies would benefit from using objective measures of screen time to eliminate recall bias. One solution could be to exploit the digital devices' own technology by installing an application on children's devices that tracks real-time use, permitting precise investigation of the dose-dependent influence of device use on the incidence and progression of myopia in longitudinal studies. Objective measurements of face-to-screen proximity, ambient light, and posture and viewing angle, as well as the types of applications used, could further elucidate the mechanisms by which digital device use might influence myopia. A randomised-controlled trial that reduces digital screen time as an intervention would permit robust causal inference. In future prospective studies, it would be important to follow participants until refractive stabilisation to account for later onset or progressive myopia, which was likely to have been missed in studies included in our review.

In conclusion, this systematic review and meta-analysis shows that there is insufficient and conflicting literature on the association between smartphone and tablet exposure and myopia, which is unsurprising given their relatively recent introduction. The results of the meta-analysis suggested that smart device screen time, alone and in combination with computer screen time, could be associated with an increased risk of myopia. As children continue to adopt digital devices at ever younger ages and their screen time increases, there is a pressing need for researchers to investigate the effects of these devices on eye health in diverse populations, and to use objective measures and clear and standardised categories of device exposure to better understand the role it might play in the escalating myopia epidemic. A better understanding of the association between digital screen exposure and myopia will be important for informing parenting, education, clinical practice guidelines, and public health policy.

Contributors

JF, ATS, and MD conceived the study. JF and ATS wrote the initial protocol, did the literature search, and screened articles. JF wrote the initial manuscript. JF, ATS, and AP organised the data and constructed tables. ATS, DF, and JF did the statistical analysis. All authors provided crucial feedback on the study protocol and contributed important intellectual content to the manuscript, including revisions. All authors had access to all the data in the study and had final responsibility for the decision to submit for publication. JF, ATS, DF, and DSWT have verified the data, with DSWT being independent of Plano.

Declaration of interests

JF, ATS, and DF are employees of Plano. AP was an employee of Plano at the time of writing. JC is a shareholder in Plano. MD is the co-founder, a shareholder, and the current managing director of Plano. Plano is a health technology start-up that was created as part of the Singapore Eye Research Institute-Singapore National Eye Centre Ophthalmic Technologies Incubator Programme to develop evidence-based technological and educational solutions to address the global burden of myopia. In accordance with policies of the Singapore National Eye Centre, TYW has received grants, contracts, consulting fees, honoraria, and travel support from, and has participated on advisory boards for Allergan, Bayer, Boehringer Ingelheim, Eden Ophthalmic, Genentech, Iveric Bio, Merck, Novartis, Oxurion (ThromboGenics), Roche, Samsung, Shanghai Henlius, and Zhaoke Pharmaceutical. TYW is the co-founder of Plano and EyRiS. The commercial relationships have not influenced the methods used in this study. All evidence has been presented and appraised in a balanced manner, and all data have been collected and analysed rigorously and without bias. DSWT, MGH, and RRAB declare no competing interests.

Data sharing

The extracted data for all the included studies in the meta-analysis and the analysis codes are available online at: https://github.com/dwightfonseka/metaanalysis.

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Smartphone Use Associated with Refractive Error in Teenagers

The Myopia App Study

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Purpose: To investigate the association between smartphone use and refractive error in teenagers using the Myopia app.

Design: Cross-sectional population-based study.

Participants: A total of 525 teenagers 12 to 16 years of age from 6 secondary schools and from the birth cohort study Generation R participated.

Methods: A smartphone application (Myopia app; Innovattic) was designed to measure smartphone use and face-to-screen distance objectively and to pose questions about outdoor exposure. Participants underwent cycloplegic refractive error and ocular biometry measurements. Mean daily smartphone use was calculated in hours per day and continuous use as the number of episodes of 20 minutes on screen without breaks. Linear mixed models were conducted with smartphone use, continuous use, and face-to-screen distance as determinants and spherical equivalent of refraction (SER) and axial length-to-corneal radius (AL:CR) ratio as outcome measures stratified by median outdoor exposure.

Main Outcome Measures: Spherical equivalent of refraction in diopters and AL:CR ratio.

Results: The teenagers on average were 13.7 ± 0.85 years of age, and myopia prevalence was 18.9%. During school days, total smartphone use on average was 3.71 ± 1.70 hours/day and was associated only borderline significantly with AL:CR ratio ($\beta = 0.008$; 95% confidence interval [CI], −0.001 to 0.017) and not with SER. Continuous use on average was 6.42 ± 4.36 episodes of 20-minute use without breaks per day and was associated significantly with SER and AL:CR ratio ($\beta = -0.07$ [95% CI, −0.13 to −0.01] and $\beta = 0.004$ [95% CI, 0.001−0.008], respectively). When stratifying for outdoor exposure, continuous use remained significant only for teenagers with low exposure ($\beta = -0.10$ [95% CI, −0.20 to −0.01] and $\beta = 0.007$ [95% CI, 0.001−0.013] for SER and AL:CR ratio, respectively). Smartphone use during weekends was not associated significantly with SER and AL:CR ratio, nor was face-to-screen distance.

Conclusions: Dutch teenagers spent almost 4 hours per day on their smartphones. Episodes of 20 minutes of continuous use were associated with more myopic refractive errors, particularly in those with low outdoor exposure. This study suggested that frequent breaks should become a recommendation for smartphone use in teenagers. Future large longitudinal studies will allow more detailed information on safe screen use in youth. *Ophthalmology 2021;128:1681-1688 © 2021 by the American Academy of Ophthalmology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).*

Supplemental material available at www.aaojournal.org.

Myopia is a refractive error caused by disproportionate eye growth during childhood and adolescence.[1] The prevalence of myopia is rising all over the world.[2,3] Currently, almost 50% of the young adults in Europe and 80% to 90% of the young adults in urban areas of East Asia are myopic.[2,4,5] Early onset of myopia results in higher degrees of myopia in adulthood.[6,7] This can lead to visual impairment and even blindness resulting from retinal complications later in life.[8,9] The rise in myopia prevalence in the last decade is caused by many lifestyle and behavioral changes.[10] For instance, spending less time outdoors is an established risk factor; the role of prolonged near work is still debated, but many reports conclude an association.[11−13] These environmental factors also may explain why children growing up in urban areas more often are myopic than those growing up in rural areas.[14−16]

In recent years, researchers have speculated that smartphone use is an additional risk factor for myopia. Time spent on smartphones adds considerably to the total hours spent on near work among teenagers.[17] However, the so-called myopia boom started in 1950,[18] when smartphones did not yet exist. Smartphones are relatively new, and children

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growing up with smartphones are yet to become adults. Long-term effects, including the influence on the myopia prevalence, are yet to be determined. Smartphone use is prone to underreporting and therefore is difficult to determine by questionnaire.[19] For the current study, we developed a smartphone application (the Myopia app; Innovattic) that registers smartphone use and face-to-screen distance electronically to allow for objective measurements. We assessed the associations among smartphone use, outdoor exposure, and refractive error as measured by the Myopia app and self-reported outdoor exposure. We hypothesized that increased smartphone use is associated with a more myopic refractive error and that this association may be modified by outdoor exposure.

Methods

Study Populations: Myopia App Study and Generation R

Teenagers 12 to 16 years of age from 2 cohorts were eligible to enrol in the study: participants in the Myopia App Study (MAS) and the Generation R study. The MAS participants were recruited from 6 secondary schools in semiurban areas in The Netherlands. Schools were asked to disseminate information on MAS among their pupils, and 300 teenagers from the first, second, and third grades (ages, 12−16 years) consented to participate (Fig S1, available at www.aaojournal.org). Generation R is a large, prospective, population-based birth cohort in which 9778 pregnant mothers were enrolled between 2002 and 2006. Details of the methodology of this study have been described elsewhere.[20,21] Of the initial cohort, 4929 children (50%) visited the research center at 13 years of age. The app measurements were introduced during the final part of the study phase in April 2019, and 225 teenagers signed informed consent (Fig S1).

The app and ophthalmic measurements were performed between November 2018 and December 2019 in both cohorts. Two participants did not undergo eye measurements; 361 participants installed the app. Valid smartphone and eye measurements were available for 272 participants, because 25% of participants did not allow the app to run in the background of the operating system or technical issues hampered registration (Fig S1). Written informed consent from both parents and the teenagers was obtained before eye examination and app measurements. The study protocol was approved by the Medical Ethical Committee of the Erasmus Medical Center, Rotterdam (identifiers, MEC-2018-005, NL63977.078.17 [MAS] and MEC-217.595/2002/20 [Generation R study]). The study project was conducted according to the tenets of the Declaration of Helsinki.

Mobile Application

The Myopia app was developed by the company Innovattic (www.innovattic.com) and was made available for the smartphone operation systems iOS and Android. This smartphone logging app registered smartphone use and face-to-screen distance (see next section). The teenagers received questions about outdoor exposure twice weekly through pop-up notifications in the app. To encourage the teenagers to answer all questions, gamification techniques were implemented in the app, that is, different levels were used to perform the measurements. Participants were rewarded with extra points after a questionnaire was completed, and an avatar received new gadgets (i.e., hat or sunglasses) with an increasing number of points. After 5 weeks, the teenagers were rewarded with an online shopping voucher with a value corresponding to the amount of questions answered (up to €7.50).

Smartphone Use

Smartphone use was measured over 5 weeks. The time of locking and unlocking the smartphone was registered using Unix time stamps, and participants were advised not to close the app. In that way, the app continued running in the background, which was needed because the closed operating systems of iOS and Android hampered continuous registration. We took particular care to identify measurement errors that occurred when participants (unintentionally) closed the app. Depending on whether the last measurement was registered as screen off or screen on before the app stopped running in the background, this resulted in days with very low smartphone use or extremely long continuous smartphone use. Days with fewer than 5 minutes of smartphone use in total or days with more than 5 hours of continuous use without locking the screen were excluded (on average, 7.9 days per participant [33.9%]), resulting in an average of 19.7 measurement days (standard deviation [SD], 14.5 measurement days; median, 17.0 measurement days; interquartile range [IQR] 7.0 to 30.0, 23 measurement days) per participant. To check for bias because of measurement error, we also excluded days with less than 1 minute of smartphone use in total or days with more than 4 hours of continuous use (on average, 8.7 days per participant [35.7%]), resulting in an average of 19.0 measurement days (SD, 14.0 measurement days; median, 17.0 measurement days; IQR 7.0 to 28.0, 21.0 measurement days) per participant, and days with less than 10 minutes of smartphone use in total. Excluding days with more than 6 hours of continuous use (on average, 7.4 days per participant [32.1%]) resulted in an average of 20.3 measurement days (SD, 14.7 measurement days; median, 18.0 measurement days; IQR 8.0 to 30.0, 22.0 measurement days) per participant. The main analyses were performed using the first data processing manner (excluding days with < 5 minutes in total and > 5 hours of continuous use). Sensitivity analyses were performed using the second (more strict) and third (less strict) data processing manner (excluding days with < 1 minute in total and > 4 hours of continuous use and excluding days with < 10 minutes in total and > 6 hours of continuous use) to ensure that the association between smartphone use and refractive error was not driven by our choice of excluding measurement days.

Smartphone use (hours per day) was calculated by summing the total time of smartphone use divided by the number of days the app was running. Continuous smartphone use was calculated by the sum of screen times of 20 minutes or longer divided by 20. For example, if a participant had 5, 53, 22, 19, and 68 minutes of smartphone use on one day, then continuous use was calculated by summing 53, 22, and 68 (143 minutes) divided by 20, that is, 7.15 episodes of 20 minutes of continuous smartphone use. Continuous use was determined by the sum of these episodes divided by the number of days the app was running. Smartphone use and continuous use were calculated for school days and non−school days separately. Non−school days consisted for 75.5% of weekend days and 24.5% of holidays. The density plots of smartphone use and continuous smartphone use during school days defined by the 3 different data processing manners are shown in Figure S2 (available at www.aaojournal.org).

Validation Study

We performed a validation study that included 5 Android users and 5 iOS users. They installed the Myopia app on their smartphone for 2 weeks. Smartphone use measured by the Myopia app was compared with smartphone use measured by the inbuilt screen time tracker of the smartphone. The Spearman correlation coefficient between the smartphone use measured by the Myopia app, and the smartphone use measured by the inbuilt app was calculated.

Face-to-Screen Distance

Face-to-screen distance was measured using the front camera of the smartphone. Android device users calibrated the app by holding their smartphone exactly 29.7 cm in front of their eyes (the length of the long side of an A4 piece of paper); iOS device users did not need to calibrate face-to-screen measurement because of the technical similarities among iPhones. Face-to-screen distance was measured when the app was active and open (i.e., when participants were filling out questions). The number of face-to-screen measurements on average was 592 measurements (SD, 1246 measurements; median, 272.0 measurements; IQR 152.0 to 555.3, 403.3 measurements) per person. Mean face-to-screen distance was calculated. Sensitivity analyses were performed excluding participants with fewer than 100 measurements to ensure that measurement reflected most commonly used smartphone distance.

Outdoor Exposure

Outdoor exposure was asked repeatedly in the app for 5 weeks. On Monday afternoon and Friday evening, the participants received the question: "How much time did you spend outdoors last Saturday/Sunday/Monday or Tuesday/Wednesday/Thursday/Friday? For example, cycling, sports, walking, playing outdoors, or being outdoors with friends or family." Mean outdoor exposure per day (in hours per day) was calculated for school days and non−school days separately.

Other Covariates

Sex, age at examination, season of app measurement, ethnic background, and operating system (iOS or Android) were considered as covariates. Ethnic background was defined according to the definitions by Health Statistics Netherlands, that is, based on the country of birth of the (grand) parents. It was assessed through a questionnaire in the app for the MAS participants and by questionnaires filled out by the parents for the Generation R participants and was stratified into European and non-European backgrounds. Operating system was assessed through the app.

Eye Measurements

The eye examination consisted of presenting monocular visual acuity with logarithm of the minimum angle of resolution−based Early Treatment Diabetic Retinopathy Study charts at 3 m by means of the fast Early Treatment Diabetic Retinopathy Study method. Ocular biometry was measured by Zeiss IOLMaster 500 or 700 (Carl Zeiss Meditec). Five axial length measurements per eye were averaged to calculate mean axial length; 3 measurements of corneal radius (K1 and K2) were averaged to calculate the mean corneal radius, and axial length-to-corneal radius (AL:CR) ratio was calculated. Cycloplegic refractive error of the nondominant eye was measured with handheld Retinomax 3 (Righton) in the MAS participants, of both eyes in the Generation R participants, both 30 minutes after 2 doses of cyclopentolate 1%. Spherical equivalent of refraction (SER) was calculated by the sum of the full spherical value plus half of the negative cylindrical value. Mean SER for Generation R participants was assessed by averaging SER of the right and left eyes. Myopia was defined as SER of −0.50 diopter (D) or less.

Data Analyses

Differences between participants who were included in the analyses and who were excluded because of missing data, as well as differences between the school-based cohort and Generation R cohort, were analyzed with independent *t* tests for continuous variables and chi-square tests for dichotomous variables. Spearman correlation coefficients were calculated for smartphone use, continuous use, face-to-screen distance, and outdoor exposure during school days and weekend days. To take into account the similarities between teenagers from the same study site, linear mixed models with restricted likelihood estimation from the nlmer package in R software (R Foundation for Statistical Computing) were used to perform the analyses (Table S1, available at www.aaojournal.org).[22] The associations between smartphone use, continuous use (20 minutes), outdoor exposure, and face-to-screen distance as exposures and SER and AL:CR ratio as outcomes variables were investigated, with random intercept for study sites (schools), and adjusted for age, sex, season of app measurement, and operating system (iOS or Android). The following sensitivity analyses were performed. First, outliers in smartphone use and continuous use were excluded, that is, > 4/6 hours continuous use, and days with < 1/10 minutes smartphone use (see above). Second, we additionally adjusted for outdoor exposure to ensure an independent association among smartphone use, continuous use, SER, and AL:CR ratio. Third, participants with fewer than 100 measurements for face-to-screen distance were excluded (see previous). Fourth, because of the large number of missing data for ethnicity and because the MAS participants were 97% European, we did not adjust for ethnicity in the main analyses but instead performed sensitivity analyses with European participants only. Finally, interaction analysis was performed with smartphone use, outdoor exposure, and an interaction term as exposures and SER and AL:CR ratio as outcomes variables, with random intercept for study sites (schools), and adjusted for age, sex, and operating system. Stratified analyses were performed for teenagers with high and low outdoor exposure based on the median. Analyses were performed in IBM SPSS version 25 and R statistical software version 3.6.1.

Results

The teenagers on average were 13.7 ± 0.85 years of age; 54% were girls. Myopia prevalence was 18.9%, SER was +0.40 ± 1.90 D, AL:CR ratio was 2.99 ± 0.11, and axial length was 23.4 ± 0.88 mm. The teenagers spent on average 3.71 ± 1.70 hours/day on their smartphone on school days and 3.82 ± 2.09 hours/day on non−school days, with an average face-to-screen distance of 29.1 ± 6.25 cm. Participants had 6.42 ± 4.36 episodes of 20 minutes of continuous use per day during school days and 7.10 ± 5.28 episodes during non−school days. Outdoor exposure was 2.37 ± 0.94 hours/day on school days and 2.77 ± 1.13 hours/day on non−school days. Participants with myopia demonstrated a more negative SER and larger AL:CR ratio and axial length compared with participants without myopia. Differences between participants with (n = 45) and without (n = 193) myopia regarding sex, ethnicity, smartphone use, continuous use, face-to-screen distance, outdoor exposure, season of app measurement, operating system, and study site did not reach statistical significance (Table 1).

Variables that differed between the MAS cohort and Generation R were age ($P = 0.02$), ethnic background ($P < 0.001$), and outdoor exposure during school days ($P = 0.01$). Participants who were included in the analyses were younger (13.7 years vs. 13.9 years; $P = 0.01$) and more often from a European ethnic background (86.5% vs. 67.9%; $P \leq 0.001$) than those who were not included because of missing data on smartphone use and eye

Table 1. General Characteristics

	Total (n = 272)	Missing (%)	Myopia (n = 45)	No Myopia (n = 193)	*P* Value
Age (yrs)	13.7 ± 0.85	0.0	13.5 ± 0.96	13.7 ± 0.87	0.36
Sex (female)	53.7	0.0	60.0	52.3	0.41
Ethnicity (European)	86.5	15.4	81.8	87.7	0.39
Spherical equivalent (diopters)	0.40 ± 1.90	12.5	−2.36 ± 2.10	1.04 ± 1.11	< 0.001
Myopia	18.9	12.5	NA	NA	NA
Axial length corneal radius ratio	2.99 ± 0.11	2.6	3.14 ± 0.13	2.96 ± 0.08	< 0.001
Axial length (mm)	23.4 ± 0.88	0.4	24.2 ± 0.91	23.2 ± 0.73	< 0.001
Smartphone use (hr/day)					
During school days	3.71 ± 1.70	7.7	3.75 ± 1.55	3.67 ± 1.73	0.78
During non–school days	3.82 ± 2.09	5.9	3.54 ± 2.11	3.77 ± 2.09	0.52
Continuous use (episodes of ≥ 20 min)					
During school days	6.42 ± 4.36	7.7	6.62 ± 4.32	6.13 ± 4.17	0.50
During non–school days	7.10 ± 5.28	5.9	6.51 ± 5.95	6.91 ± 5.11	0.66
Face-to-screen distance (cm)	29.1 ± 6.3	14.7	29.1 ± 7.47	29.4 ± 5.72	0.76
Outdoor exposure (hr/day)					
During school days	2.37 ± 0.94	11.8	2.10 ± 0.90	2.41 ± 0.96	0.06
During non–school days	2.77 ± 1.13	1.5	2.48 ± 1.21	2.83 ± 1.07	0.05
Season of app measurement		0.0			0.65
Spring	71.3		66.6	72.0	
Summer	20.2		20.0	19.2	
Autumn	8.5		13.3	8.8	
Operating system (Android)	60.7	0.0	68.9	59.1	0.24
Study site		0.0			0.16
Generation R	25.7		22.2	15.5	
School 1	36.4		28.9	44.6	
School 2	13.6		20.0	14.0	
School 3	8.8		11.1	8.3	
School 4	4.0		0.0	5.7	
School 5	4.0		8.8	3.6	
School 6	7.4		8.8	8.3	

Data are presented as mean ± standard deviation or percentage.

measurements. Differences between children included in the analysis and those excluded regarding sex, SER, myopia, axial length, and AL:CR ratio were not observed. The Spearman correlation coefficient between the Myopia app and the inbuilt app in our validation study was 0.97 (Fig S3, available at www.aaojournal.org).

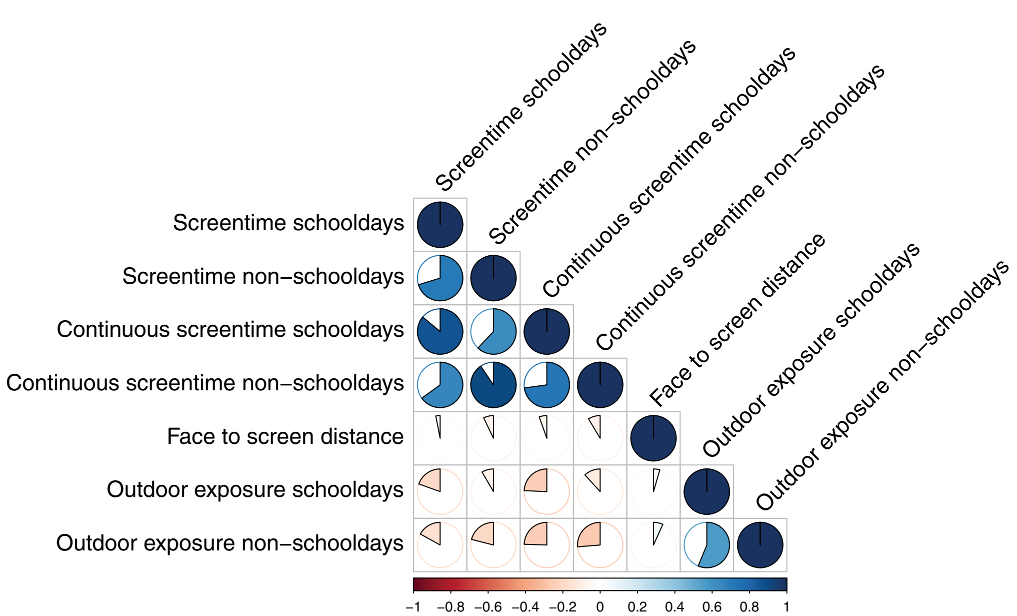

Figure 1. Diagram showing correlations between smartphone use, continuous use, face-to-screen distance, and outdoor exposure during school days and holidays. Dark blue represents a positive correlation of 1, whereas dark red represents a negative correlation of −1.

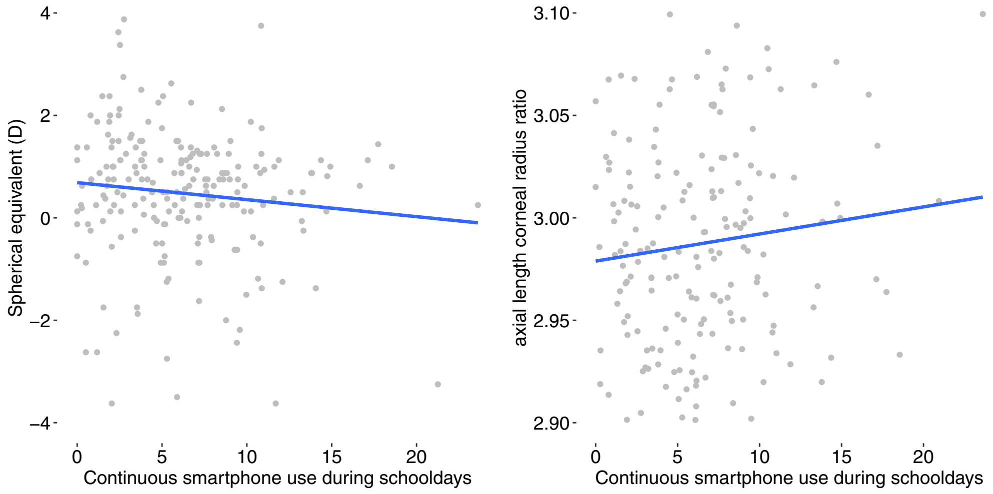

Figure 2. Scatterplots showing the association between continuous smartphone use (episodes of ≥ 20 minutes) and (**A**) spherical equivalent and (**B**) axial length-to-corneal radius ratio. Blue lines represent the unadjusted regression lines. D = diopter.

Correlations between smartphone use, face-to-screen distance, and outdoor exposure are depicted in Figure 1. Smartphone use, face-to-screen distance, and outdoor exposure were distributed normally; continuous use was slightly right skewed (Fig S2). Smartphone use was correlated strongly with continuous use ($r = 0.86$ and $P < 0.001$ during school days; $r = 0.90$ and $P < 0.001$ during weekend days), and outdoor exposure was correlated inversely with smartphone use and continuous use (smartphone use: $r = -0.19$ and $P = 0.006$ during school days; $r = -0.21$ and $P = 0.003$ during weekend days; continuous use: $r = -0.24$ and $P < 0.001$ during school days; $r = -0.26$ and $P < 0.001$ during weekend days). Face-to-screen distance was not correlated with smartphone use, continuous use, or outdoor exposure.

Continuous use during school days was associated with SER (per each extra episode of 20 minutes continuous use: $\beta = -0.07$ [95% CI, −0.13 to −0.01]) and AL:CR ratio ($\beta = 0.004$ [95% CI, 0.001−0.008]; Fig 2). Smartphone use during school days showed a similar trend and was borderline associated significantly with AL:CR ratio ($\beta = 0.008$ [95% CI, −0.001 to 0.017]) but not with SER ($\beta = -0.09$ [95% CI, −0.25 to 0.07]). Outdoor exposure was associated with SER ($\beta = 0.33$ [95% CI, 0.07−0.60] and $\beta = 0.32$ [95% CI, 0.10−0.55] both during school days) and with AL:CR ratio during non−school days ($\beta = -0.016$ [95% CI, −0.029 to −0.003]). Face-to-screen distance, continuous use during non−school days, and smartphone use during non−school days were not associated with SER or AL:CR ratio (Table 2). Sensitivity analyses with different definitions of smartphone use or adjustment for outdoor exposure yielded similar results; excluding non-Europeans and those with missing data on ethnicity resulted in similar, albeit not significant, β coefficients. Face-to-screen distance excluding participants with fewer than 100 measurements was not associated significantly with SER or AL:CR ratio (Table S1 available at www.aaojournal.org).

Stratified analyses showed that the association between continuous use and SER and AL:CR ratio was observed for teenagers with low outdoor exposure ($\beta = -0.10$ [95% CI, −0.20 to −0.01] for SER and $\beta = 0.007$ [95% CI, 0.001−0.013] for AL:CR ratio) but not for teenagers with high outdoor exposure (Table 3).

Table 2. Linear Regression Analyses of Smartphone Use, Continuous Use during School Days and Non−School Days, and Face-to-Screen Distance on Spherical Equivalent and Axial Length-to-Corneal Radius Ratio

	Spherical Equivalent Refraction					Axial Length-to-Corneal Radius Ratio				
	No.	*Estimate*	*Standard Error*	*95% Confidence Interval*	*P Value*	*No.*	*Estimate*	*Standard Error*	*95% Confidence Interval*	*P Value*
Smartphone use (hr/day) during school days	207	−0.09	0.08	−0.25 to −0.07	0.30	227	0.008	0.005	−0.001 to −0.017	0.10
Continuous use (≥ 20 min) during school days	207	−0.07	0.03	−0.13 to −0.01	0.03	227	0.004	0.002	0.001−0.008	0.02
Smartphone use (hr/day) during non−school days	204	−0.02	0.10	−0.21 to −0.18	0.88	226	0.002	0.006	−0.010 to −0.013	0.75
Continuous use (≥ 20 min) during non−school days	204	−0.03	0.03	−0.11 to −0.04	0.34	226	0.002	0.002	−0.002 to −0.006	0.29
Outdoor exposure (hr/day) during school days	213	0.33	0.13	0.07−0.60	0.01	235	−0.011	0.008	−0.027 to −0.005	0.17
Outdoor exposure (hr/day) during non−school days	235	0.32	0.11	0.10−0.55	0.004	261	−0.016	0.006	−0.029 to −0.003	0.02
Face-to-screen distance	201	0.00	0.02	−0.04 to −0.04	0.98	226	0.000	0.001	−0.003 to −0.002	0.84

Adjusted for age, sex, season of app measurement, and operating system.

Table 3. Linear Regression Analyses of Smartphone Use and Continuous Use during School Days and Holidays on Spherical Equivalent Refraction and Axial Length-to-Corneal Radius Ratio Stratified by High versus Low Outdoor Exposure

		Spherical Equivalent Refraction					Axial Length-to-Corneal Radius Ratio				
Outdoor Exposure	**Smartphone Use during School Days**	*No.*	*Estimate*	*Standard Error*	*95% Confidence Interval*	*P Value*	*No.*	*Estimate*	*Standard Error*	*95% Confidence Interval*	*P Value*
Low	Hours/day	99	−0.12	0.13	−0.36 to −0.12	0.35	112	0.010	0.007	−0.004 to −0.024	0.17
	Continuous use (≥20 min)	99	−0.10	0.05	−0.20 to −0.01	0.03	112	0.007	0.003	0.001−0.013	0.02
High	Hours/day	99	−0.04	0.11	−0.25 to −0.17	0.72	105	0.003	0.006	−0.009 to −0.014	0.65
	Continuous use (≥20 min)	99	−0.02	0.05	−0.12 to −0.07	0.61	105	0.001	0.002	−0.003 to −0.006	0.59

Adjusted for age, sex, season of app measurement, and operating system.

However, the interaction term between continuous use and outdoor exposure was not significant ($P = 1.00$ for SER; $P = 0.40$ for AL:CR ratio).

Discussion

In this study, we used a mobile application to determine smartphone use in relationship to refractive error. We showed that those with more episodes of continuous use demonstrated a more myopic refractive error. This association disappeared in teenagers with high outdoor exposure, suggesting that outdoor exposure may moderate this effect.

Smartphone use is a relatively new behavior among youth. It became increasingly popular after the introduction of the first iPhone in 2008. Worldwide, 139 million smartphones were sold in 2008, which increased to 1496 million smartphones sold in 2016. Most smartphone owners are from the United States and Western Europe, but the Chinese market is also on the rise.[23] Research reports addressing the effect of smartphone use on myopia in teenagers are scarce. In our study, smartphone use was 3.71 hours/day during school days according to the Myopia app, which is comparable with the 4 hours/day among 19-year-old university students from the United States measured with the Moment app.[17] A Chinese study showed that 1 hour/day increase in smartphone use was associated with −0.28 D SER after adjustment for age, sex, reading behavior, outdoor exposure, and sleep in 566 children 6 to 14 years of age.[24] We observed a particular association with continuous use: SER was −0.07 D more myopic and AL:CR ratio was 0.005 larger for each extra episode of 20 minutes of continuous use. The SER was −0.10 D more myopic and the AL:CR ratio 0.008 larger for each hour of daily smartphone use, but this association was not significant ($P = 0.22$ for SER and $P = 0.07$ for AL:CR ratio). Studies focussing on reading behavior also reported that continuous reading was associated more prominently with myopia than total reading time,[12,25] despite their high correlation. Continuous near work may be a more important risk factor than time spent on near work, suggesting that regular breaks during near work (including smartphone use) will help to prevent myopia from developing in teenagers.

Although the association between screen time and myopia was debatable for a long time,[26,27] recently, the results of many studies support the presence of such an association.[28−32] Exposure to screen time before the age of 1 year was associated with myopia (prevalence ratio, 4.02) among 26,433 preschool children in China.[28] Irish school children who spent more than 3 hours/day on a screen more often were myopic (odds ratio, 3.70), and a 1-hour increase in computer use was associated with myopia (odds ratio, 1.005) in a former study among 9-year-old children.[29,30] Adolescents using a screen for more than 6 hours/day more often were myopic than those with fewer than 2 hours/day of screen use (odds ratio, 1.95) in Copenhagen.[31] A longitudinal study among 5- to 15-year-old children from India showed that more than 7 hours/day of screen time also was associated with myopia progression compared with fewer than 4 hours/day of screen time (odds ratio, 3.53).[32] Together with our current findings, this suggests that screen use may become an established risk factor for myopia.

Reading distance has been identified as a risk factor for myopia in many cross-sectional and longitudinal studies.[12,25,30,33] Reading distance often was measured using a questionnaire for parents, and these studies reported positive associations for 30 cm,[25,30] 20 cm,[12] and 33 cm.[33] The sensitivity analysis in our study showed that a 1-cm-shorter face-to-screen distance was associated with −0.03 D (95% CI, 0.02 to −0.08 D) more myopia, but this association failed to reach statistical significance. Face-to-screen distance was not correlated with smartphone use in our study. Ip et al[25] and Li et al[12] did not identify a correlation between reading distance and reading time either, adding to the discrepancies in the associations with refractive error for continuous smartphone use and face-to-screen distance.

Strengths of this study are the objective measurement of smartphone use and face-to-screen distance using the Myopia app. The Myopia app was made available for both iOS and Android devices and thus was accessible to almost any smartphone user. Our validation study showed a high correlation between smartphone use measured by the Myopia app and smartphone use measured by the inbuilt screen time tracker of the smartphone, supporting an accurate registration. Sensitivity analyses with different definitions of smartphone use yielded similar results, indicating that the association was robust. Nevertheless, some limitations should be borne in mind. First, the cross-sectional design of this study hindered causal interpretation of the data. Current smartphone use most likely reflects previous smartphone use; however, cumulative smartphone use depends on the age of smartphone acquisition. In the Netherlands, most children own a smartphone from the age of 10 years onward,[34] and we expect that most teenagers in our study already had 2 to 3 years of smartphone exposure time. Second, the relatively large number of days with unrealistic measurements and the limited sample size may have led to inconclusive results. Future studies should incorporate a longitudinal study design in a large sample. Third, some activities on the smartphone, like calling someone, were registered as smartphone use, while not involving near work. Yet because time spent on calling is usually very short in teenagers of this age, we do not expect that this had a major influence on our results.[34] Finally, only the nondominant eye was measured with cycloplegia in the MAS participants. Nondominant eyes may be more hyperopic than dominant eyes in children with anisometropia.[35,36] This may have resulted in an underrepresentation of myopia in the MAS participants but did not distort AL:CR ratio because this was measured in both eyes.

In conclusion, our study showed that Dutch teenagers use their smartphone almost 4 hours/day. A higher number of episodes of more than 20 minutes of continuous use was associated with more myopic SER and a larger AL:CR ratio. This association was not present in teenagers with high outdoor exposure, suggesting that outdoor exposure moderates the association. Because smartphone use is becoming increasingly popular, awareness of the potential negative consequences of prolonged smartphone use is warranted. The 20-20-2 rule as recommended earlier remains good advice.[37]

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Footnotes and Disclosures

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Abbreviations and Acronyms:
AL:CR = axial length-to-corneal radius; **CI** = confidence interval; **D** = diopter; **iOS** = iPhone operating system; **IQR** = interquartile range; **MAS** = Myopia App Study; **SD** = standard deviation; **SER** = spherical equivalent of refraction.

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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 ($\geq$200 minutes) showed significantly less myopic shift (measured by light meters; $\geq$1000 lux: 0.14 D; 95% CI, 0.02–0.27; $P = 0.02$; $\geq$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 2018;125:1239-1250 © 2018 by the American Academy of Ophthalmology*

Supplemental material available at www.aaojournal.org.

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,

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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

Table 1. Summary of Intervention Items between Recess Outside Classroom Trial 711 Program and Control Groups

Intervention items	Recess Outside Classroom Trial 711	Control
Recess outside classroom program	Yes	No
Outdoor-oriented school activities	Yes	No
Weekend sun-time passport assignment	Yes	No
Booklet for teacher–parent communication	Yes	No
Outdoor learning assignments in summer vacation	Yes	No
Eye health education for teachers and students, promote outdoor activity and 30/10 rule for myopia prevention.	Yes	Yes
Sport & Health 150: an initiative to promote an additional 150 minutes of exercise per week. This initiative was started during the late period of this study.	Yes	Yes
Tien-Tien 120: an initiative that promotes outdoor activities for 120 minutes daily. Although this initiative was not compulsory, 5% of the elementary schools in Taiwan were selected by the Bureau of Education for monitoring compliance with time outdoors. None of the schools in this study were among the selected schools.	Yes	Yes

30/10 = 30 minutes of near work followed by a 10-minute break.

was 81.29% (standard deviation [SD], 13.88%) and for control schools was 61.11% (SD, 11.85%; $P = 0.007$).

Outcomes

Refraction measurements were performed at the beginning of the study, when the schools initiated participation, and at the end of the study. Changes in spherical equivalence refraction (SER) and axial length were computed from values measured at baseline and at the end of the study. Myopia was defined as at least −0.5 D of SER on cycloplegic autorefraction performed using an autorefractometer (KR-8100; Topcon, Tokyo, Japan). Corneal anesthesia was used to minimize the discomfort caused by the cycloplegic drops. For cycloplegia, 1 drop of 0.5% proparacaine was followed by 1 drop of 1% tropicamide (Mydriacyl; Alcon, Puurs, Belgium) and 1% cyclopentolate hydrochloride (Cyclogyl; Alcon Laboratories, Fort Worth, TX) administered 5 minutes apart. Measurements were obtained 30 minutes after the initial drop was administered and the pupil size was more than 6 mm in diameter. Five to 8 consecutive readings were obtained for each child. Measurements of ocular biometric parameters (axial length and keratometry) were performed with a noncontact ocular biometry system (Lenstar LS 900; Haag-Streit AG, Köniz, Switzerland). This instrument works on the principle of optical low-coherence reflectometry. Children with best-corrected visual acuity not achieving 20/25 or those diagnosed with amblyopia were excluded from this study. Those undergoing orthokeratology treatment or atropine eye drop treatment also were excluded from this study.

Outdoor time was evaluated for schoolchildren. Participants wore light meters (HOBO, Contoocook, NH) on their collars for 7 consecutive days and completed a 1-week diary in which they recorded activities every half hour to determine their outdoor activity time. The light meter records light intensity (lux) every 5 minutes, which corresponds to a total of 288 readings per day. These values of light intensity then were transformed into an Excel (Microsoft, Redmond, WA) file for each individual student. As shown in Figure 1, the lower left column indicates the date, time (AM or PM, hour, minute, second), and the values of light intensity. The individual data files were imported into Statistical Analysis Software version 9.3 (SAS Institute, Cary, NC). The actual light intensities at different areas of schools are shown in Figure 2, which shows that in any areas outside of the classroom, the light intensities were measured to be at least 1000 lux. Therefore, we defined the child as being outdoors when a value of light intensity of more than 1000 lux was measured from the light meter (Fig 1C). Because the light meter records the light intensity every 5 minutes, we calculated the time spent outdoors as the number of light intensity readings of 1000 lux or more times 5 minutes. The total minutes of exposure to 3000 lux or more, 5000 lux or more, or 10 000 lux or more light intensities also were calculated in a similar manner. The first-grade schoolchildren in Taiwan attend half-day morning courses during all weekdays except Tuesday, which includes a full-day course. The weekly outdoor time was calculated by the light meters, which recorded outdoor time during weekday mornings and Tuesday afternoons (in-school outdoor time); outdoor time during the afternoon (afternoon out-of-school outdoor time) and outdoor time during the weekend (weekend outdoor time) were obtained from the diary log.

The weather conditions also may affect the time spent outdoors. Therefore, to obtain the total hours of sunshine corresponding to the week that each schoolchild wore the light meter, daily hours of sunshine for the study period of the 6 cities or counties were obtained from the Taiwan Central Weather Bureau. We then matched the same dates that the light meter was worn and summed the total hours of sunshine during the week. To minimize missing data, teachers were responsible for reminding participants to wear the light meters during school time and parents were educated about the importance of using the light meter and diary log that were sent home during off-school time on weekdays and weekends. Activities that were performed outside a building during the day, such as riding bicycles, park visits, walking around the neighborhood, and outdoor sports, were all classified as outdoor activities. Indoor activities were defined as inside a building or an enclosed space or travelling in a car or train.

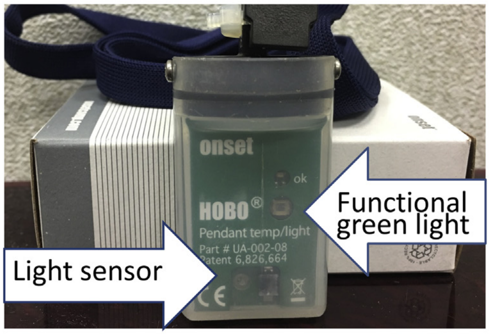
Dharani et al[22] recommended using a diary and light meter in randomized control trials of outdoor intervention. The light meter has the advantage of objectively and precisely recording the duration and intensity of light exposure. In this study, the compliance of wearing light meters was monitored by teachers during school time. However, during the time out of school, wearing light meters was not monitored closely and the compliance decreased. Therefore, we used the diary log to calculate outdoor time during the period out of school. In addition, because of the changing climate in different regions of Taiwan, our analysis also adjusted for the daily regional sunlight hours when calculating outdoor times for all schools.

The habit of near-work breaks (30/10) was evaluated by questionnaires filled out at baseline and at the end of the study. Parents accompanied by their children answered the question "Do you use the 30/10 rule: 30 minutes followed by a 10-minute break during near-work activities, such as reading, writing, painting, computer or smartphone, and so on?" Weekly diopter-hours of near work were computed by summing up 3 × number of hours of reading, 2 × number of hours of other mid-distance near work, 2 × number of hours of using computer, and 1 × number of hours of watching television.

Statistical Analysis

A power calculation was conducted to determine the sample size necessary to detect changes in the primary outcome of SER

A Setting light meter



B Wearing meter during school time

C Examples of intensity readings from recorders

Thursday 7:20~8:55 AM

Time, AM/PM h:m:s	Intensity, Lux
AM 07:20:00	344.4
AM 07:25:00	742.7
AM 07:30:00	1022.6
AM 07:35:00	204.5
AM 07:40:00	236.8
AM 07:45:00	527.4
AM 07:50:00	258.3
AM 07:55:00	215.3
AM 08:00:00	20666.8
AM 08:05:00	23422.4
AM 08:10:00	27555.7
AM 08:15:00	27555.7
AM 08:20:00	143289.8
AM 08:25:00	75.3
AM 08:30:00	376.7
AM 08:35:00	505.9
AM 08:40:00	226
AM 08:45:00	129.2
AM 08:50:00	290.6
AM 08:55:00	2325

Friday 3:10~4:45 PM

Time, AM/PM h:m:s	Intensity, Lux
PM 03:10:00	10.8
PM 03:15:00	0
PM 03:20:00	0
PM 03:25:00	0
PM 03:30:00	21.5
PM 03:35:00	441.3
PM 03:40:00	118.4
PM 03:45:00	10.8
PM 03:50:00	10.8
PM 03:55:00	10.8
PM 04:00:00	387.5
PM 04:05:00	6544.5
PM 04:10:00	215.3
PM 04:15:00	290.6
PM 04:20:00	1162.5
PM 04:25:00	10.8
PM 04:30:00	0
PM 04:35:00	0
PM 04:40:00	10.8
PM 04:45:00	0

D Line plots from intensity readings

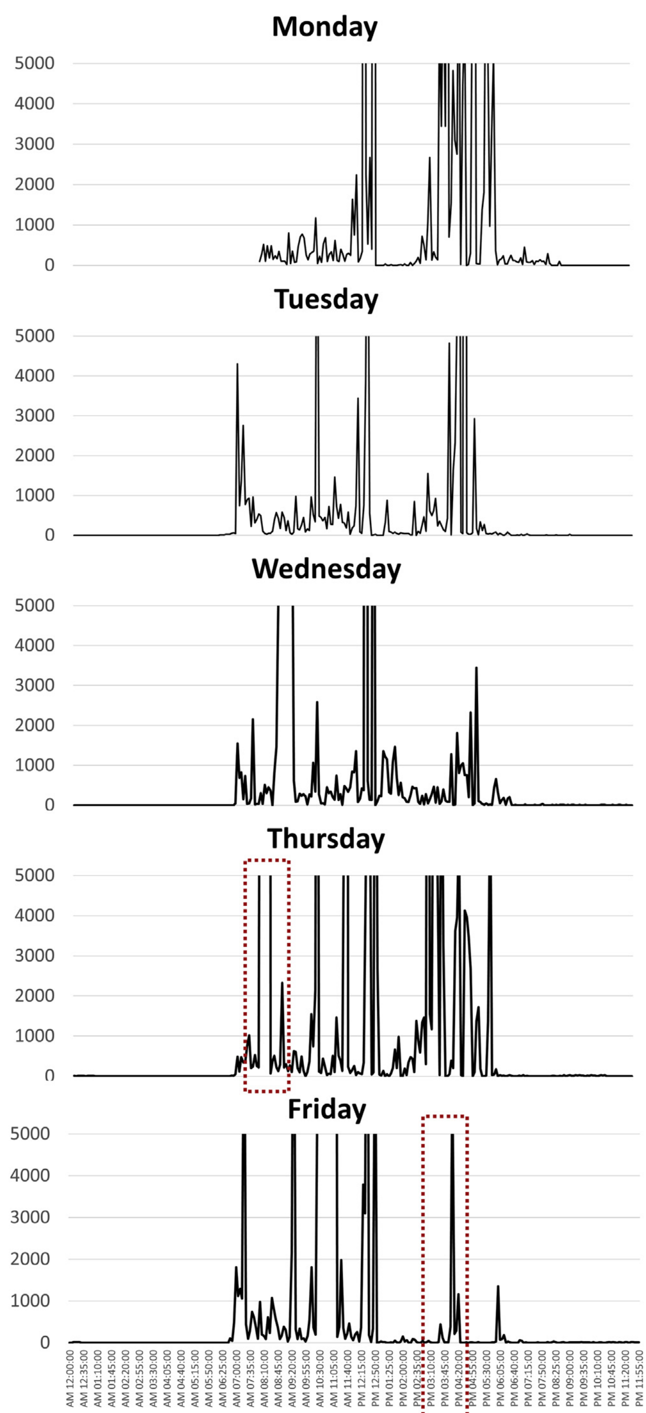


Figure 1. Images showing light meter wearing and recording. **A**, Setting light meter. **B**, Wearing meter during school time. **C**, Examples of intensity readings from recorders. The light meter records light intensity (lux) every 5 minutes, which corresponds a total of 288 readings per day. These values of light intensity then were transformed into an Excel (Microsoft, Redmond, WA) data sheet for each individual student. **D**, Line plots from readings on weekdays.

changes. According to our previous result of a difference in myopia shift of 0.13 D/year between intervention and control groups (−0.25 D/year vs. −0.38 D/year; $P = 0.029$),[17] a myopia shift of 0.13 D/year was regarded as clinically important and achievable in children. Using an α of 0.05 and power of 80%, a sample size of 443 students per group was needed to detect a 0.13-D/year difference (SD, 0.69 D/year) between groups. Therefore, the ROCT711 study consisted of a cluster-randomized controlled trial

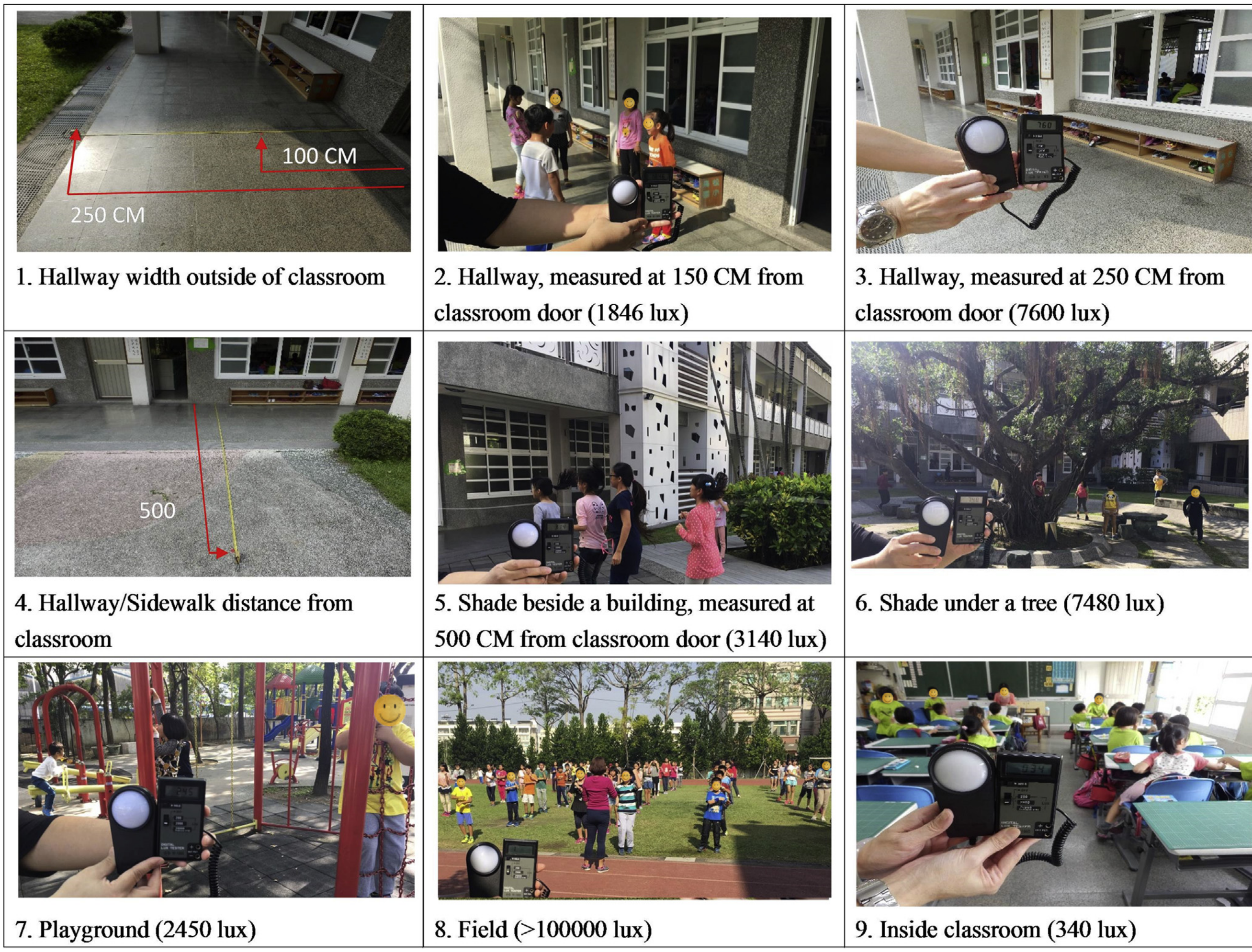


Figure 2. Photographs showing light intensity in different areas of the school. Light intensities were measured using the Digital Lux Tester (YF-1065; Tecpel, Taipei, Taiwan) at Kaohsiung Niaosong Elementary School. CM = centimeter.

with first-grade students from 24 primary schools. Of these 24 schools, 16 were followed up for 1 year and 8 schools were followed up for half of a year because of a delayed administration process.

Descriptive statistics, 2-sample *t* tests, and chi-square tests were used to compare baseline characteristics between the intervention and control groups. Analyses of primary and secondary outcomes were conducted using the generalized estimating equation to account for possible deviations from the normal distribution and cluster effects. The covariates in the analysis models included the corresponding baseline measures, age, gender, area, parental myopia, and the total sun hours during light meter wearing week. SAS software version 9.3 (SAS Institute, Inc., Cary, NC) was adapted for the analysis. All *P* values were considered statistically significant when they were less than 0.05.

Results

A total of 930 students in 16 schools (365 in the intervention group and 565 in the control group) consented and attended baseline assessments. Overall, the average age was 6.34 years (SD, 0.48 years) and 47.85% were girls. At baseline, 10.53% of participants were myopic after excluding myopic children with current treatment. Table 2 displays the baseline demographic information of both groups. The intervention and control groups were fairly comparable, and there was no statistically significant difference between the 2 groups when considering various baseline factors (all $P \geq 0.05$; Table 2). After excluding 120 students with ongoing myopia treatments, a total of 693 students in 16 schools completed the full 1-year program (267 in the intervention group and 426 in the control group; Appendix, available at www.aaojournal.org). Figure 3 illustrates the flowchart of participant recruitment.

Primary Outcome: Myopia Change

After the students completed the 1-year trial, the myopic shift was significantly less for the intervention group than for the control group (0.35 D vs. 0.47 D; difference, 0.12 D; 95% confidence interval [CI], 0.05−0.19; $P = 0.002$; Table 3). There was significantly less axial length elongation in the intervention group than in the control group (0.28 mm vs. 0.33 mm; difference, 0.05 mm; 95% CI, 0.02−0.08; $P = 0.003$). The incidence of new myopia onset in the intervention group was

Table 2. Baseline Characteristics of Recess Outside Classroom Trial 711 and Control Groups

Characteristic	Recess Outside Classroom Trial 711 Group	Control Group
Total (n = 930)	365	565
Gender		
Male	201 (55.07)	284 (50.27)
Female	164 (44.93)	281 (49.73)
Age (yrs)		
6	237 (64.93)	373 (66.02)
7	128 (35.07)	192 (33.98)
Myopia (n = 927)		
Yes	51 (14.01)	89 (15.81)
No	313 (85.99)	474 (84.19)
No. of myopic parents (n = 796)		
0	56 (17.89)	102 (21.12)
1	126 (40.26)	200 (41.41)
2	131 (41.85)	181 (37.47)
Near work breaks 30/10 (n = 813)*		
Yes	95 (29.78)	120 (24.29)
No	224 (70.22)	374 (75.71)
Diopter hours per week (n = 681; 288 vs. 393), mean ± SD†	46.75±25.82	46.47±23.25
Primary end point baseline		
SER (D; n = 927; 364 vs. 563), mean ± SD	0.36±1.14	0.30±0.99
AXL (mm; n = 922; 361 vs. 561), mean ± SD	22.78±0.77	22.81±0.76

AXL = axial length; SD = standard deviation; SER = spherical equivalence refraction.
Data are no. (%) unless otherwise indicated. Chi-square tests and 2-sample *t* tests were used for comparing differences between groups, and none of these comparisons reached statistical significance.
*Children are encouraged to take breaks from near work (30 minutes of near work followed by a 10-minute break).
†Weekly diopter hours are computed by summing up 3 × number of hours of reading, 2 × number of hours of other mid-distance near work, 2 × number of hours of using a computer, and 1 × number of hours of watching TV.

less than that in the control group (14.47% vs. 17.40%), and there was 35% less risk of myopia (odds ratio, 0.65; 95% CI, 0.42−1.01; $P = 0.054$). The fast myopia shift rate (more than −0.5 D/year) for the intervention group was significantly less than that for the control group (21.7% vs. 31.0%), and there was a 54% lower risk of fast myopia progression (odds ratio, 0.46; 95% CI, 0.28−0.77; $P = 0.003$). We also computed the event rates based on the intention-to-treat approach with the last observation carried forward strategy. Based on the intention-to-treat approach, the event rates for new incidences of myopia were 10.86% (34/313) and 14.14% (67/474) for the intervention and control groups, respectively, and the percentages of myopia shift of −0.5 D or more were 15.89% (58/365) and 23.36% (132/565), respectively (data not shown in Tables). The statistical significance remained the same for the intention-to-treat approach.

The changes from baseline for nonmyopic and myopic children were analyzed further separately. For the nonmyopic children at baseline, the myopic shift was significantly less in the intervention group than in the control group (0.32 D vs. 0.43 D; difference, 0.11 D; 95% CI, 0.02−0.20; $P = 0.02$). There was significantly less axial length elongation in the intervention group than in the control group (0.26 mm vs. 0.30 mm; difference, 0.03 mm; 95% CI, 0.01−0.06; $P = 0.02$). For the myopic children at baseline, the myopic progression was significantly less in the interventional group than the control group (0.57 D vs. 0.79 D; difference, 0.23 D; 95% CI, 0.06−0.39; $P = 0.007$). There was significantly less axial length elongation in the intervention group than in the control group (0.45 mm vs. 0.60 mm; difference, 0.15 mm; 95% CI, 0.02−0.28; $P = 0.02$).

Secondary Outcome: Outdoor Time

Table 4 shows the weekly outdoor time spent by both groups at different light intensities (1000, 3000, 5000, and 10 000 lux). The intervention and control groups were not significantly different at baseline. At the end of the study, the intervention group had spent more time outdoors than the control group during weekdays in school, out of school during weekdays, and weekends, although these were not statistically different. However, when analyzing the time spent outdoors per week, which combines the amount of time with exposure to 1000 lux or more during school and the amount of time recorded on self-reported diaries outside of school, schoolchildren in the intervention group spent significantly more time outdoors (mean, 669.36 minutes; SD, 22.98 minutes) than the control group (598.81±16.20 minutes), with a difference of 70.55 minutes (95% CI, 16.51−124.59 minutes; $P = 0.01$). Similarly, when evaluating the time spent outdoors per week, combining the amount of time recorded on self-reported diaries and the time during school with exposures of 3000 lux or more, 5000 lux or more, or 10 000 lux or more, significant differences between the 2 groups also were found ($P = 0.04$, $P = 0.047$, and $P = 0.04$, respectively). When assessing whether a goal of ROCT711 of spending at least 11 hours of outdoor time weekly had been reached, we found that a significantly higher percentage of participants in the intervention group (119/239 participants [49.79%]) had spent more than 11 hours of outdoor time per week compared with the control group (85/374 participants [22.73%]; $P < 0.001$).

Noncompliance occurred in the intervention group, and the control group also may have included schoolchildren who spent time outdoors. We further pooled all participants (including intervention and control groups) and conducted a post hoc analysis for the different durations of weekly outdoor time during school. Table 5 shows the relationship between time spent outdoors (at different levels of light intensity) during school and SER changes. We separated the participants into 3 groups according to their weekly in-school outdoor time (<125 minutes, 125−199 minutes, and ≥200 minutes). The group with the least time outdoors in school was the reference group. When assessing SER changes compared with the reference group, participants who had 200 minutes or more of weekly outdoor time during school hours in the 1000 lux or more, or 3000 lux or more environment had significantly less myopic shift (≥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; $P = 0.048$]).

Participants who had 200 minutes or more of weekly outdoor time during school and were not myopic at baseline had significantly less myopic shift when exposed to moderate light intensity in the 1000 lux or more, 3000 lux or more, or 5000 lux or more environments (0.18 D [95% CI, 0.04−0.32; $P = 0.01$], 0.22 D [95% CI, 0.06−0.37; $P = 0.006$], and 0.24 D [95% CI, 0.14−0.33; $P < 0.001$], respectively). However, when assessing participants who had 125 to 199 minutes of outdoor time during school, only those without myopia at baseline who were exposed to a 10 000 lux or more environment had significantly less myopic shift (0.16 D [95% CI, 0.08−0.24; $P < 0.001$]). This suggests that schoolchildren who have less outdoor time may need exposure to high bright light intensity (≥10 000 lux) to achieve protective effects against myopia, whereas in those who have longer durations of

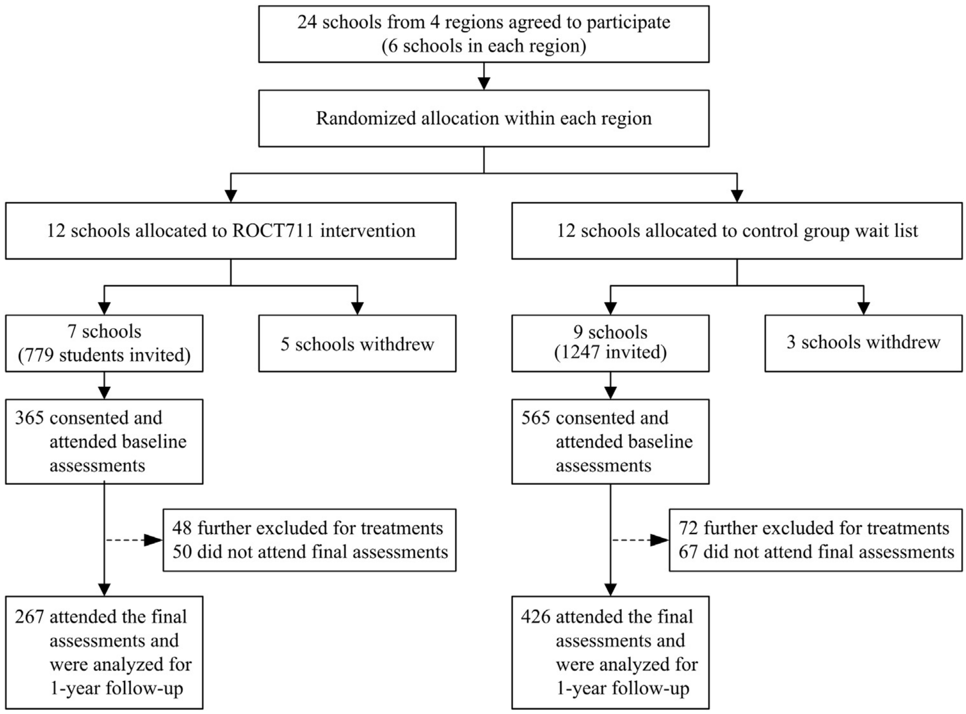


Figure 3. Flowchart showing process of recruiting participants. ROCT711 = Recess Outside Classroom Trial 711.

outdoor time, moderate levels of light intensity (≥1000 lux or ≥3000 lux) may be sufficient to protect against myopia.

Changes in Near Work

After the intervention, there were no significant differences in near-work breaks and diopter-hours between the intervention and control groups (33.85% vs. 24.57% and 46.36 vs. 45.85; $P = 0.08$ and $P = 0.80$, respectively; data not shown). We further evaluated improvement in the near-work breaks and found that 18.14% of children in the intervention group had changed to follow the 30/10 rule from baseline to the end of the study ($P = 0.046$, McNemar's test), whereas only 12.73% in the control group did so ($P = 0.37$, McNemar's test). When assessing the changes of near-work

Table 3. Comparing Primary End Points of Recess Outside Classroom Trial 711 and Control Groups

End Points	Total	Recess Outside Classroom Trial 711 Group No.	Recess Outside Classroom Trial 711 Group Adjusted Mean (Standard Deviation)*	Control Group No.	Control Group Adjusted Mean (Standard Deviation)*	Estimated Difference*	95% Confidence Interval	P Value
Total								
Changes from baseline SER (D)	693	267	−0.35 (0.58)	426	−0.47 (0.74)	0.12	0.05–0.19	0.002
Changes from baseline AXL (mm)	688	265	0.28 (0.22)	423	0.33 (0.35)	−0.05	−0.08 to −0.02	0.003
Nonmyopic children at baseline								
Changes from baseline SER (D)	620	235	−0.32 (0.58)	385	−0.43 (0.75)	0.11	0.02–0.20	0.02
Changes from baseline AXL (mm)	615	233	0.26 (0.18)	382	0.30 (0.32)	−0.03	−0.06 to −0.01	0.02
Myopic children at baseline								
Changes from baseline SER (D)	73	32	−0.57 (0.40)	41	−0.79 (0.38)	0.23	0.06–0.39	0.007
Changes from baseline AXL (mm)	73	32	0.45 (0.28)	41	0.60 (0.19)	−0.15	−0.28 to −0.02	0.02
			Event/No. (%)		Event/No. (%)	Odds Ratio		
New incidences of myopia	620		34/235 (14.47)		67/385 (17.40)	0.65	0.42–1.01	0.05
Percent of myopia shift of −0.5 D or more	693		58/267 (21.72)		132/426 (30.99)	0.46	0.28–0.77	0.003

AXL = axial length; D = diopter; SER = spherical equivalence refraction.
*Estimates were computed by the generalized estimating equation to account for possible deviations from the normal distribution and cluster effects. The covariates in the analysis models included the corresponding baseline measures, age, gender, area, parental myopia, and the total sun hours during light meter wearing week.

Table 4. Comparison of Outdoor Time between Recess Outside Classroom Trial 711 and Control Groups

		Recess Outside Classroom Trial 711 Group (n = 267)			**Control Group (n = 426)**					
	Measurement Method	*No.*	*Adjusted Mean (Minutes)**	*Standard Error*	*No.*	*Adjusted Mean (Minutes)**	*Standard Error*	**Estimated Difference***	**95% Confidence Interval**	***P* Value**
Baseline										
Weekdays during school	Light meter ≥1000 lux	252	171.33	22.76	413	162.09	18.86	9.24	−34.74 to 53.21	0.68
	≥3000 lux		83.17	9.01		86.31	11.28	−3.14	−29.77 to 23.49	0.82
	≥5000 lux		62.47	7.36		65.56	8.90	−3.09	−24.44 to 18.26	0.78
	≥10 000 lux		35.91	6.50		36.29	7.06	−0.37	−17.55 to 16.80	0.97
Weekdays out of school	Self-report diary	223	143.08	7.48	376	146.34	4.56	−3.26	−12.27 to 5.74	0.48
Weekends	Self-report diary	223	271.22	5.38	376	268.47	5.82	2.76	−1.41 to 6.92	0.20
End of study										
Weekdays during school	Light meter ≥1000 lux	256	216.51	14.44	409	202.35	8.34	14.16	−16.79 to 45.11	0.37
	≥3000 lux		118.59	8.18		113.27	6.92	5.32	−18.76 to 29.40	0.67
	≥5000 lux		88.09	7.33		85.79	6.98	2.30	−20.80 to 25.40	0.85
	≥10 000 lux		51.62	5.59		49.76	5.40	1.86	−15.81 to 19.54	0.84
Weekdays out of school	Self-report diary	239	156.76	6.94	374	148.28	11.85	8.49	−14.50 to 31.47	0.47
Weekends	Self-report diary	239	291.33	16.55	374	250.60	10.57	40.74	−9.00 to 90.47	0.11
1 week total	Light meter ≥1000 lux & self-report diary	239	669.36	22.98	374	598.81	16.20	70.55	16.51−124.59	0.01
	≥3000 lux & self-report diary		575.23	25.52		503.70	14.13	71.53	3.54−139.52	0.04
	≥5000 lux & self-report diary		543.56	24.94		475.47	13.92	68.09	0.99−135.20	0.047
	≥10 000 lux & self-report diary		505.17	23.16		439.91	12.98	65.26	3.07−127.44	0.04
	% of 11+ hrs by light meter ≥1000 lux & self-report diary, no. (%)	239	119	49.79%	374	85	22.73%			< 0.001

*Estimates were computed by the generalized estimating equation to account for possible deviations from the normal distribution and cluster effects. The covariates in the analysis models included the corresponding baseline measures, age, gender, area, parental myopia, and the total sun hours during light meter wearing week.

Table 5. Analysis of Myopia Shift with Outdoor Times Measured by Different Cutoff Points of Light Intensity in All Participants

	Time Outdoors during School (Minutes)						
		125–199			200+		
Measured by	*<125*	*Estimate**	*95% Confidence Interval*	*P Value*	*Estimate**	*95% Confidence Interval*	*P Value*
Students with 1-year of follow-up							
≥1000 lux	Ref.	0.10	−0.14 to 0.34	0.41	0.14	0.02–0.27	0.02
≥3000 lux	Ref.	0.07	−0.05 to 0.20	0.26	0.16	0.002–0.32	0.04
≥5000 lux	Ref.	0.09	−0.05 to 0.23	0.19	0.07	−0.23 to 0.37	0.65
≥10 000 lux	Ref.	0.07	−0.12 to 0.26	0.47	—	—	—
Students with 1-year of follow-up and no myopia at baseline							
≥1000 lux	Ref.	0.12	−0.12 to 0.36	0.32	0.18	0.04–0.32	0.01
≥3000 lux	Ref.	0.10	−0.04 to 0.23	0.15	0.22	0.06–0.37	0.006
≥5000 lux	Ref.	0.12	−0.03 to 0.26	0.13	0.24	0.14–0.33	<0.001
≥10 000 lux	Ref.	0.16	0.08–0.24	<0.001	—	—	—

Ref. = reference group; SER = spherical equivalence refraction; — = not enough observations.
*Estimates are spherical equivalence refraction (in diopters), estimated differences from the reference, and were computed by the generalized linear model with a generalized estimating equation to account for possible deviations from the normal distribution and cluster effects. The covariates in the analysis models included the corresponding baseline measures, age, gender, area, parental myopia, and the total sun hours during light meter wearing week.

diopter-hours, the control group increased 6.04 hours per week (SD, 27.42 hours), which was significantly higher than the 0.59 hours (SD, 28.60 hours) of the intervention group ($P = 0.02$).

Above all, the ROCT711 intervention group had statistically significant differences in having higher classroom clearance rate, less myopic shift and axial elongation, less incident myopia, and less children with rapid myopic shift. Children in the intervention group spent more time outdoors and a higher percentage of children achieved the ROCT711 goal of spending at least 11 hours per week outdoors. They were also more compliant with the 30/10 rule.

Discussion

This study was a multi-area cluster-randomized intervention trial of the ROCT711 program, which promotes more outdoor time for schoolchildren to prevent myopic changes. It used objective measurements to assist in the validation of the relationship of time spent outdoors and myopia. The results show that completing the 1-year ROCT711 program effectively can inhibit a myopic shift and axial elongation and can decrease the risks of myopia onset and fast myopia shift. It was effective in retarding both myopia shift in nonmyopic children and myopia progression in myopic children. Spending enough time outdoors during school hours in moderate to high sunlight intensity can slow the myopic shift. Myopia protection can be achieved by briefer periods of higher light intensity or longer periods of more moderate light intensity.

The prevalence of myopia is approximately 20% to 30% in 6- to 7-year-old children in Taiwan,[2] whereas the prevalence of myopia in our study population was approximately 10% (Table 1). This discrepancy was the result of the exclusion of children receiving myopia control treatment, representing 13% (48/365) of the intervention arm and 13% (72/565) of the control arm. If we include these initially enrolled children without applying exclusion criteria, then the myopia prevalence rises to 22% ((32 + 48)/365) in the intervention arm and 20% ((72 + 41)/565) in the control arm. Therefore, the prevalence of myopia was similar to that of previous reports of approximately 20% to 30% in 6- to 7-year-old children.

In contrast to the usual expectation of a 1-mm increase in axial length corresponding to the −2.564-D change in adults,[23] we found that the corresponding change in SER and axial length was much lower in the children in this study, which was approximately −1 D of change for every 1-mm increase in axial length. Because the participants in this study were approximately 6 to 7 years of age and most were hyperopic at baseline, this can be explained readily by the parallel loss of lens power and axial elongation during the process of emmetropization as part of normal ocular development in children. It has been reported that lens thickness, and hence lens power, continues to decrease from 6 to 10 years of age and then shows little change afterward.[24,25] Lens thickness and lens power do not always run in parallel. After 11 to 13 years of age, the lens starts to thicken, but it continues to lose power.

Previous studies suggested that the effects of time outdoors are seen primarily in nonmyopic children, but not in myopic children.[17,26,27] Our results show that the myopic progression of myopic children was significantly less in the interventional group as compared with the control group (0.57 D vs. 0.79 D; difference, 0.23 D), which is the first report to reveal that outdoor activities could inhibit progression in myopic children significantly, with approximately a 30% (0.23 D/0.79 D) reduction in 1 year. Although the effectiveness did not reach the clinical significance (approximately 50% or more reduction of myopia progression) that usually can be accomplished by atropine or orthokeratology,[28,29] outdoor activities may be an adjuvant treatment to control myopia progression. The sample size of myopic children was relatively small, and therefore a further large-scale study is warranted.

From our previous outdoor intervention studies, we defined the myopia incidence reduction rate by calculating the difference in the incidence rates between the intervention and control group (17.65% − 8.41% = 9.24%) and dividing by the incidence rate of the control group (17.65%). The myopia incidence reduction rate is approximately 52% (9.24/17.65).[17] In this ROCT711 study, the myopia incidence reduction rate was approximately 17% (2.93/17.40), which was much lower than in our previous ROC study. One discrepancy is that the participants from our previous study were 7 to 11 years of age and most children were required to have 80 minutes of outdoor time per day, whereas the current participants were 6 to 7 years of age and were encouraged to spent approximately 40 minutes outdoors per day during school time. In Taiwan, the first- and second-grade school children attend school for only a half day in the morning for all weekdays except Tuesday, which has a full-day course. Usually, the total recess time is 40 minutes during the morning half-day course and 80 minutes for a full-day course. We speculate that noncompulsory with less compliance and spending less time outdoors may have contributed to the lower myopia incidence reduction rate.

The children in the current study of ROCT711 are very similar in age and ethnicity to those who were involved in the 3-year Guangzhou Outdoor Activity Longitudinal Study, although the current study covered only 1 year. In the Guangzhou Outdoor Activity Longitudinal Study, the 3-year cumulative incidence rate of myopia was 30.4% in the intervention group and 39.5% in the control. The difference of 9.1% in the incidence rate of myopia represents a 23% relative reduction in incident myopia after 3 years. In ROCT711, there was a 17% relative reduction in incident myopia after 1 year. It could be anticipated that a longer intervention period for ROCT711 would result in greater cumulative reduction.

For the in-school outdoor time, there was no significant difference between the 2 groups. During our study period, 2 national initiatives were ongoing that promoted greater time spent outdoors for students, and these programs were encouraged in response to our published results from the initial Recess Outside Classroom study.[17] We speculate that the Sport & Health 150 project and the Tien-Tien 120 program initiated by the Ministry of Education of Taiwan may have contributed to the nonsignificant difference between the groups when considering in-school outdoor time. The time spent outdoors was not significantly different between the groups when in-school or outside-school time were analyzed separately. However, for the total 1-week outdoor time including in school and outside school, the intervention group had significantly greater time outdoors than the control group. During our 2 audits of the classroom evacuation rate during recess, there were significant differences between the 2 groups. In addition to better adherence to the 30/10 rule, these results suggest that the ROCT711 policy has been well implemented in the intervention schools.

One of the special characteristics of the ROCT711 program is that it encourages schoolchildren to go outside the classroom during recess, which increases the intermittent outdoor time during school. Chicken and primate experiments have shown that high levels of ambient light can inhibit the developmental form of deprivation myopia.[30,31] The most likely biological explanation for this association is that the retina responds to high levels of light by releasing dopamine, which inhibits axial length growth.[32,33] It also should be noted that the animal studies and the human studies do not really correspond. In the animal studies, the increased protection was observed only at much higher light intensity than the ROC programs. In this study, we found that the intervention group had less myopic shift and axial elongation. The ROCT711 program encourages schoolchildren to participate in outdoor activities during recess. During a normal school day, there are 4 classes and 3 recesses (10 minutes, 20 minutes, and 10 minutes) during the morning for first-grade schoolchildren. Recently, an animal study showed that intermittent episodes of bright light suppressed myopia in chickens more than continuous bright light did[34]; the strategy of having recess outside the classroom provides intermittent episodes of bright light for the children.

This study also showed that the participants with 200 minutes of outdoor time during school in 1000-lux or more or 3000-lux or more environments showed significantly less myopic shift. However, in those who had 125 to 199 minutes of outdoor time during school, only the participants without myopia at baseline and those exposed to a 10 000-lux or more environment showed significantly less myopic shift. This suggests that in those with shorter outdoor time, high bright light exposure ($\geq$10 000 lux) had protective effects against myopia, but longer durations under moderate light intensity conditions ($\geq$1000 lux or >3000 lux) also may have protective effects against myopia. This is in contrast to the animal studies[35,36] where high bright light exposure ($\geq$10 000 lux) was required for the prevention of myopia. In relation to the animal studies, it is worth noting that the myopia-inducing stimulus is constant. In contrast, although we do not know precisely what it is, in humans it is likely to be intermittent. This may help to explain the different response to light intensities. Our findings in this study are in agreement with a previous study by Read et al,[37] who found that the duration of light exposure to 1000 lux or more may be the contributing factor that sets emmetropic and myopic children apart, and therefore gives support to the concept that exposure to light intensity of less than 10 000 lux may be sufficient to protect against myopia. In this study, recess outside the classroom with light intensities of 1000 or 3000 lux (such as in the hallway or under the shade of a tree) with enough time was sufficient for myopia protection. This finding has an important implication in reducing the possible side effects of very bright sunlight exposure, such as cataracts, maculopathy, or skin cancer.

To our knowledge, no previous trials have shown the association between light intensity and time outdoors in terms of myopia prevention. The limitations of this study are the relatively short intervention period and that some schools withdrew and did not complete the 1-year program. A longer interventional trial is warranted. Initially, the school principals of all 24 schools agreed to participate. However, when the informed consent forms were presented to principals and parents, a number of them withdrew from the study. We obtained our ethical approval from a medical center, so the informed consent forms conformed to their requirements and the seal of the Human Clinical Trial Committee was printed on the forms. We admit that we did not expect refusals for this reason. Because classes had already started at that time, we did not have enough time to recruit other schools for completing 1-year study. Although this fact may raise concerns about the effectiveness of the randomization, our comparisons of drop-out rates between intervention and control groups were not significantly different (5 of 12 schools vs. 3 of 12 schools; $P = 0.3865$; 267 of 779 participants vs. 426 of 1247 participants; $P = 0.9585$). In Taiwan, there is no academic classification in the primary school system, and there is practically minimal academic stress on the first-grade schoolchildren. All of the schools follow the same curriculum and have the same amount of recess time and physical education classes; however, this does not mean that students have similar times outdoors. Although the drop-out rates of the 2 groups were similar, the effect on randomization should not be overlooked.

The study's enrollment criteria included an informed consent signature and attending the baseline assessment including cycloplegia. Before cycloplegic examination, the parents and children were given an introduction to the procedure. On the day of cycloplegia assessment, the ophthalmologist and nurse stayed in the school and every participant received a new pair of sunglasses to prevent photophobia. Therefore, the compliance of the enrolled participants was as high as 100%. Fifty of 365 participants in the intervention group and 67 of 565 participants in the control group did not attend the final assessment, so the compliance was approximately 86% and 88%, respectively. With regard to wearing the light meter, compliance was quite high (665/693 [96%]) at the end of study during weekday in-school time. Because teachers could not monitor the children's use, there was relatively poor compliance during the out-of-school time and on weekends. Therefore, we used the self-report diary to represent the children's outdoor time (Table 4).

In conclusion, the school-based ROCT711 program may stabilize the myopic shift effectively, may decrease the axial length elongation, and may decrease the risk of myopia onset and fast myopia shift. Both nonmyopic and myopic children benefitted from this outdoor activity program for myopia control. Although parents may be concerned about children's direct exposure to strong light intensities, we found that longer duration of exposure to moderate light intensities such as 1000 lux or more or 3000 lux or more outdoors also may have a myopia prevention effect. A program involving recess outside the classroom that provides these light intensity-level environments, such as in hallways or under a tree, also may reduce the concerns of possible side effects from exposure to strong sunlight. To prevent myopia shift and progression, children are encouraged to spend enough outdoor time both in school and out of school every week in the elementary school system.

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Abbreviations and Acronyms:
CI = confidence interval; **D** = diopter; **ROCT711** = Recess Outside Classroom Trial 711; **SD** = standard deviation; **SER** = spherical equivalence refraction; **30/10** = 30 minutes of near work followed by a 10-minute break.

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