NCT number: [2021]075

A multicenter randomized controlled trial of low-dose single-wavelength red light in the decrease of myopia incidence rate in the setting of school

Shanghai Eye Disease Prevention and Treatment Center

March 27, 2021

A multicenter randomized controlled trial of low-dose single-wavelength red light in the decrease of myopia incidence rate in the setting of school.

Study aims and rationales		A multicenter randomized controlled trial exploring the effectiveness of low-dose single-wavelength red light on the prevention of myopia and the decrease of myopia incidence rate in children of grade 1-4 of primary schools (age of 6-12 years).
Primary aim		To examine the effectiveness of low-dose single-wavelength red light on the prevention of myopia and the decrease of myopia incidence rate in the setting of school.
Secondary aim		To examine the effect of low-dose single-wavelength red light on spherical equivalent (SE) and uncorrected visual acuity in school-aged children who are in pro-myopia status.
Study design		A multicenter randomized controlled trail.
Study participants and estimated enrollment		Primary school students of grade 1-4 who are in pro-myopia status will be enrolled as study participants.
Inclusion criteria		1. Students of grade 1-4 in the participating schools; 2. Students who are in pro-myopia status, as defined as cycloplegic SE between -0.5D(exclusive) and 0.5D (inclusive); 3. Students whose mother and/or father are in myopia status (SE≤-3.0D for either of eyes); 4. Students whose parents sign informed consent and agree to let their kids participate in study.
Exclusion criteria		1. Students whose parents do not sign informed consent; 2. Students who have strabismus and/or other binocular vision abnormality; 3. Students who have other eye diseases and/or systematic diseases 4. Students who meet the standards with which investigators and study physicians think it is not appropriate to enroll.
Sample size		A total of 534 students will be included in the study, half of which(267) in the intervention group and half in the control group
Arrangement for baseline and follow-up ophthalmic examinations		Baseline ophthalmic examinations will be conducted in March 2021; a total of three times of follow-ups will be administered in June, September and December 2021; end-point examinations will be conducted in march 2022.
Trial duration		The trial will last 12 months starting from the baseline in March 2021 to the end point in March 2022.
Intervention	**Intervention group**	The enrolled students will be first stratified according to grade within each of the participating schools; within each of the stratified grade, the students will be randomly assigned in a ratio of 1:1 to either the intervention group or the control group. Participants in the intervention group will receive low-dose single-wavelength red light intervention in the setting of school from the first day to the fifth day of the week; on summary and winter vocations, the participants will receive intervention at home every day.

		The intervention lasts three minutes one time, two times a day, the interval between two exposures in a day should be more than 4 hours.
	Control group	Participants in the control group will not receive the intervention.
Primary outcome		The cumulative incidence rate of myopia among intervention and control groups.
Statistical hypothesis		The intervention of low-dose single-wavelength red light can prevent myopia and decrease the incidence rate of myopia.
Key words		School-aged children, low-dose single-wavelength red light, prevention of myopia.
Supplementary information		None.