The effects of using virtual reality devices on the eye

Submission date 07/02/2021	Recruitment status No longer recruiting	Prospectively registered		
		[X] Protocol		
Registration date 20/02/2021	Overall study status Completed	Statistical analysis plan		
		Results		
Last Edited	Condition category	Individual participant data		
01/03/2021	Eye Diseases	Record updated in last year		

Plain English summary of protocol

Background and study aims

The aim of this study is to investigate the effects of virtual reality (VR) devices on vision, including visual acuity (clarity of vision) and ocular (eye) alignment.

Who can participate?

Healthy volunteers aged 20-39 with good visual acuity (better than 20/20)

What does the study involve?

The participants use a VR device and a smartphone each for 2 hours. Half of the randomly selected participants use VR first, and the remaining participants use smartphones first. Then, the researchers measure several eye parameters and compare them.

What are the possible benefits and risks of participating?

Participants had the benefit of an eye examination by ophthalmologists. Risks include dry eye symptoms and mild neurologic symptoms such as headache.

Where is the study run from?

Chonnam National University Hospital (South Korea)

When is the study starting and how long is it expected to run for? December 2017 to February 2018

Who is funding the study?

- 1. National Grant and Hospital grant (Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Science, ICT & Future Planning (South Korea)
- 2. Chonnam National University Hospital Biomedical Research Institute (South Korea)

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

HMD01

Study information

Scientific Title

Effects of prolonged use of virtual reality devices on visual parameters

Study objectives

Although a few studies have reported that viewing stereoscopic images on 3D devices may induce visual asthenopia such as visual discomfort and fatigue, the effects of using newer types of VR devices for hours have not been investigated.

The researchers conducted this study to investigate the effects of using VR devices for 2 hours on visual parameters, including refraction, accommodation, convergence, stereopsis, and ocular alignment, as well as on choroidal thickness and subjective symptoms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/08/2017, Chonnam National University Hospital Institutional Review Board (42 Jebong-ro, Dong-gu, Gwang-ju 61469, South Korea; +82 (0)62-220-5257, 5231; cnuhirb@gmail. com), ref: CNUH-2017-217

Study design

Observational study

Primary study design

Observational

Secondary study design

Case crossover study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Effects of virtual reality devices on visual parameters

Interventions

For the VR experiment, the participants freely play a VR game (Lands End, Ustwo Games, UK) for 2 hours that is graded as "comfortable" on a platform provided by Oculus. Visual parameters including refraction, accommodation, convergence, stereopsis, and ocular alignment and measured choroidal thickness are investigated before and after the use of VR devices or smartphones. Subjective symptoms are assessed using questionnaires. The researchers analyze differences in visual parameters before and after the use of VR devices or smartphones and correlations between baseline visual parameters and those after the use of the devices.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Samsung Gear VR device

Primary outcome measure

Visual parameters measured before and after the use of VR devices or smartphones for 2 hours:

- 1. Refraction and accommodation measured using a binocular open-field refractor (Auto Ref /Keratometer WAM-5500, Grand Seiko Co. Ltd, Hiroshima, Japan)
- 2. Monocular near-point accommodation (NPA) obtained using Donder's push-up method. A 20

/30 single letter on a fixation stick positioned approximately 50 cm from the subject served as the target, and it was moved gradually closer to the subject at a rate of approximately 5.0 cm/s until the subject noticed the blurring of the target.

- 3. The near-point of convergence (NPC): the fixation target, the starting point of the examination, and moving velocity of the fixation target were the same as those previously described for the NPA measurement. The first point at which the corneal reflex of the participants began to extend outward was considered the endpoint.
- 4. Stereopsis measured using a near stereopsis vision test (Stereo Fly SO-001 test; Stereo Optical Co., Chicago, IL, USA). Stereopsis of 2500–1200 s of arc, 800–40 s of arc, and 400–100 s of arc measured using fly photos, graded circle test, and animal test for children, respectively.
- 5. The presence and magnitude of ocular deviations at far (5 m) and near (33 cm) distances verified using the cover test and alternating cover test with a prism. A standard set of loose plastic prisms was used for all measurements.

Secondary outcome measures

Measured before and after the use of VR devices or smartphones for 2 hours:

- 1. Choroidal thickness measured using the Heidelberg Eye Explorer software (Heidelberg Engineering, Heidelberg, Germany) (Version 1.9.10.0) provided by the instrument manufacturer. The researchers manually selected a new line at the choroid–scleral border (CSB). They retained the automatically defined Bruch's membrane (BM) line, and the software calculated the vertical distance between the two segmentation lines. The choroidal thickness was defined as the vertical distance between the BM and CSB.
- 2. Subjective symptoms measured using a questionnaire based on a computer vision syndrome questionnaire, including dry eye symptoms (burning, feeling of a foreign body, excessive blinking, tearing, dryness, tingling, and increased sensitivity to light), visual disturbance (blurred vision, double vision, and difficulty focusing for near vision), and neurological symptoms (headache, dizziness, and nausea). The symptom sensation questionnaire included six identical analog scales (0 = none to 6 = too severe to tolerate), and the subject recorded the magnitude of each symptoms compared relative to that at the baseline

Overall study start date 01/12/2017

Completion date 28/02/2018

Eligibility

Key inclusion criteria

- 1. Volunteers aged 20-39 years
- 2. 20/20 or better best-corrected visual acuity

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

60

Total final enrolment

58

Key exclusion criteria

Volunteers who have an ophthalmologic disorder, including amblyopia, presbyopia, or corneal or retinal disease and history of ocular surgery

Date of first enrolment

10/12/2017

Date of final enrolment

30/12/2017

Locations

Countries of recruitment

Korea, South

Study participating centre Chonnam National University and Hospital

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

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ROR

https://ror.org/00f200z37

Funder(s)

Funder type

Government

Funder Name

National Grant and Hospital Grant (Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Science, ICT & Future Planning) (NRF-2017R1D1A3B03032579)

Funder Name

Chonnam National University Hospital Biomedical Research Institute (CRI 17031-1)

Results and Publications

Publication and dissemination plan

Planned publication in SCI journal

Intention to publish date

01/03/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Hwan Heo, MD, PhD (hwanheo@jnu.ac.kr).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			01/03/2021	No	No