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Efficacy of an app-based intervention on the simulated driving performance of teen drivers

Submission date
16/03/2016

Recruitment status
No longer recruiting

Registration date
29/03/2016

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Motor vehicle collisions (MCVs) are the leading cause of death among teens worldwide. Over 80% of fatal MVCs in North America involve some form of driver distraction. Current strategies that focus on reducing the number of MVCs involving teens only look at removing phones as external sources of distraction, but do not address the ability of teens to detect (visual scanning) and respond (adjustment to stimuli) to critical information on the road. Given teen's wide adoption and embracement of technology, this study is investigating the efficacy of the DriveFocus Ipad app as an intervention (program) on the visual scanning of critical roadway information and adjustment to stimuli of teen novice drivers, assessed via a Drive Safety CDS-200 high fidelity driving simulator.

Who can participate?
Healthy teen volunteers between the ages of 16 and 19, with a valid G1 or G2 driving license, who are able to read and understand English, and that can come to the study location.

What does the study involve?
The study involves 9 sessions (1 hour long, once a week for 9 weeks). All participants take part in a baseline assessment (first session) which includes: a series of pencil and paper tests that looks at different visual, cognitive and motor skills, a 7 minute acclimation drive on the simulator, and a 15 minute test drive. On the following three sessions, participants practice 1 hour with the app, which requires them to go through a series of interactive videos and identify critical items on the road. A first post-test is conducted on week 5, which consist s of the acclimation and testing drives only, followed by three more intervention sessions. On week 9, all the tests of week 1 are completed again.

What are the possible benefits and risks of participating?
This research study presents no substantial risk to the volunteer. While driving the simulator, he /she may be prone to experiencing some discomfort. Please note that simulated driving performance does NOT have reporting or legal implications on a person's ability to maintain their license and/or progress through the graduated licensing process. The possible benefits may be: to have the opportunity to practice driving skills in a safe way, via the driving simulator. Also, participants may gain awareness on critical errors they make when driving. If beneficial, the

intervention may also help recognize critical information on the road. The possible benefits to society may be: to provide evidence for the efficacy of an intervention that can helps teen drivers improve their skills, and potentially be safer road users.

Where is the study run from?
i-Mobile Research Lab, Western University, London, ON, Canada

When is the study starting and how long is it expected to run for?
September 2015 to December 2016

Who is funding the study?
Hotpathz, Inc.

Who is the main contact?
Dr Liliana Alvarez
lalvare2@uwo.ca

Study website
https://www.facebook.com/i-Mobile-Research-Lab-1681503042138814/?fref=ts

Contact information

Type(s)
Public

Contact name
Dr Liliana Alvarez

Contact details
1201 Western Road
Office 2581
London
Canada
N6G1H1
5196612111 EXT. 88957
lalvare2@uwo.ca

Type(s)
Scientific

Contact name
Dr Sherrilene Classen

Contact details
1201 Western Road
London
Canada
N6G1H1

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Driving App Research for the Empowerment of teen drivers

Acronym
i-DARE

Study objectives
The number of visual scanning and adjustment to stimuli errors, as well as the braking actuation and velocity patterns of teen drivers in response to five scripted hazardous events on a simulated drive will differ among baseline, post-test 1 and 2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Western University Non Medical Research Ethics Board, 16/11/2015, ref: 107267

Study design
Interventional single-centre repeated measures efficacy trial

Primary study design
Interventional

Secondary study design
Repeated measures design

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Driving distraction among healthy teen novice drivers

Interventions
Given teen's wide adoption and embracement of technology, this study is investigating the efficacy of the DriveFocus Ipad app as an intervention on the visual scanning of critical roadway information and adjustment to stimuli of teen novice drivers, assessed via a Drive Safety CDS-200 high fidelity driving simulator. Designed by an occupational therapist and certified driver rehabilitation specialist, the fidelity and usability-tested DriveFocus app provides a structured approach to learning to detect and respond to critical roadway information. All teens will participate in a 6 week intervention (1 hour sessions once a week). Participants will receive their schedule for intervention sessions, and will attend the sessions in groups of 6. During the session, each participant will receive an iPad with the installed app. The app includes "drives" in 3 tours (different cities). Each tour includes up to 6 drives (interactive videos of drives thorugh different cities) . During the tours participants must notice critical objects on the road and touch them on the screen as they identify them. These critical objects include brake lights, pedestrians, other cars entering from side streets, and traffic controls.The drives are ordered in complexity from easiest to most difficult. According to their performance, teens can "unlock" the next complexity level when they obtain a high score for the previous level. The duration of the drives ranges from three to five minutes. Thus, it takes approximately 24 minutes to complete a tour if scores are always high enough for the teen to unlock subsequent levels. Teens will navigate 1 tour in each 1 hour session (for a total of 6 sessions) allotting for adequate time to improve their scores and navigate through the different levels of difficulty of each tour.

Intervention Type
Behavioural

Primary outcome measure
1. Number of visual scanning and adjustment to stimuli errors made during the drive
2. Braking actuation
3. Velocity (m/sec)
4. Forward acceleration (m/sec2)

All measured via real-time kinematic simulator data, and in response to each scripted event at baseline, posttest 1 and 2.

Secondary outcome measures
The number of visual scanning errors, as observed by a human evaluator during the drive

Overall study start date
01/09/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
A teen will be included if he or she:
1. Has a parent or guardian to accompany them
2. Is >16 years old and < 19 years old
3. Has not had seizure in the previous year

4. Is able to read and understand English as per parental and self-report (all assessment batteries and tests have been standardized for an English-speaking population
5. Has a valid G1 or G2 driving license; (6) is able to travel to the study location

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
42

Key exclusion criteria
A teen will be excluded if he or she:
1. Has been diagnosed by the family or treating physician with a severe psychiatric (e.g., psychoses) or physical condition (e.g., missing limbs) that would preclude full participation
2. Uses medications that would negatively impact mental or physical functioning due to side-effects (established per parent/ self-report)
3. Is pregnant per parent/self-report (no previous driving simulator studies have assessed the potential risks to pregnant teens); (4) does not have a visual acuity of at least 20/50 with both eyes open and examined together (Ministry of Transportation of Ontario (MTO) requirement), as per visual acuity assessment that will be conducted in the first assessment session

Date of first enrolment
26/03/2016

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
Canada

Study participating centre
University of Western Ontario
1201 Western Road
London
Canada
N6G1H1

Sponsor information

Organisation
University of Western Ontario

Sponsor details
Western University, Research, Support Services Building
London
Canada
N6G1G9

Sponsor type
University/education

Website
http://www.uwo.ca/research/services/ethics/index.html

ROR
https://ror.org/02grkyz14

Funder(s)

Funder type
Industry

Funder Name
Hotpathz, Inc.

Results and Publications

Publication and dissemination plan
We are planning to publish two manuscripts pertaining to this data set. Targeted journals include: the American Journal of Occupational Therapy and Accident Analysis and Prevention. We expect to submit these publications by the end of 2016 (December). We will also disseminate our findings at national and international conferences including: Canadian Association of Occupational Therapists, American Occupational Therapy Association, and the Association of Driving Rehabilitation Specialists annual conferences.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethics dispositions for this protocol. The data set will be stored at the University of Western Ontario.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		20/12/2017	16/01/2018	No	No
Other publications		24/05/2019	26/04/2023	Yes	No