

Breaking up prolonged sitting with a 6 min walk improves executive function in women and men esports players: a randomised trial

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To cite:

DiFrancisco-Donoghue J, Jenny SE, Douris PC, *et al*. Breaking up prolonged sitting with a 6 min walk improves executive function in women and men esports players: a randomised trial. *BMJ Open Sport & Exercise Medicine* 2021;**7**:e001118. doi:10.1136/bmjsem-2021-001118

▶ Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/bmjsem-2021-001118>).

Accepted 5 July 2021

ABSTRACT

Objective The effect of prolonged sitting on executive function and performance in competitive esports players are unknown. This study aimed to evaluate executive function following a 6 min bout of walking or rest during prolonged gaming in competitive esports players.

Methods 12 men and 9 women completed three separate 2-hour gaming session days assigned in randomised order consisting of a 6 min walk break, 6 min rest break and continuous before and after each session. Postintervention participant exit survey data were also collected.

Results The walk condition produced a significantly faster mean solution time (7613.6±3060.5 min, p=0.02) and planning time (5369.0±2802.09, p=0.04) compared with the resting condition (9477±3547.4; 6924±3247.7) and continuous play (8200.0±3031.6; 5862.7±2860.7). The rest condition resulted in the slowest mean solution time (9477.0±3547.4) and planning time (6924.0±3247.7), with the continuous play resulting in a faster mean solution time (8200.1±3031.6) and planning time (5862.7±2860.7) than the rest condition. There was no impact on game performance in any of the conditions. However, over 70% of participants felt that the walk break improved esports performance.

Conclusions Reducing sit time and breaking up prolonged sitting have acute and chronic health benefits. This study provides evidence that a 6 min walking break in the middle of 2 hours of gameplay allows gamers to have these health benefits while improving processing speed and executive function.

Trial registration number NCT04674436.

INTRODUCTION

Video gameplay is harmonious with prolonged bouts of sitting. Although players are seated for prolonged periods and do not experience the physical demands that are seen in conventional sports, competing in video games (ie, esports) can be quite physically and mentally demanding in other ways. Players can perform up to 500 actions per minute (ie, keyboard or mouse inputs) while simultaneously focusing at a level of attention

Key messages

What is already known

- ▶ Esports players are required to sit for prolonged bouts in order to practice and compete.
- ▶ Prolonged sitting may impair executive function and can have dangerous health implications in esports players as young as 12 years old.
- ▶ Many preventive measures are not well accepted or practised by esports players, coaches or stakeholders across all levels of competition.

What are the new findings

- ▶ A light-intensity 6 min walking break following an acute 1-hour session of competitive gaming improves executive function and processing speed in competitive players.
- ▶ A resting 6 min break following 1-hour acute session of competitive gaming decreased executive function speed in players.
- ▶ Over 70% of highly competitive gamers who participated preferred the walking break and reported it 'positively helped' them compared with a resting break.

that results in significant cognitive stress and high variance of physiological parameters.¹⁻⁴ In conjunction with the cognitive stress, players may suffer from the corresponding harmful health effects of prolonged sitting. These include acute health risks such as deep vein thrombosis (DVT), which can be life-threatening if the thrombosis travels to the lungs and creates a pulmonary embolism (PE).⁵⁻⁷ Aside from the acute health risks, the chronic health effects of repeated prolonged sitting are correlated with cardiometabolic risk factors and early mortality.^{8,9}

In addition, prolonged sitting acutely disrupts cerebral blood flow and may reduce oxygen supply to the brain.¹⁰ This disruption in neuronal metabolism can lead to mental fatigue, impaired cognition and reduced



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executive function.^{11–13} The relationship between prolonged gaming, executive function and physical breaks has not been thoroughly investigated. Recently, Sousa *et al* found a decrease in executive function in high-level gamers following 2.5 consecutive hours of competitive gameplay regardless of physical activity levels.¹¹

This current study set out to expand on these findings and to evaluate executive function changes following a short active break (6min walking) as compared with a short passive break (6min resting) in competitive first-person shooter (FPS) esports players during 2 hours of gameplay. The primary outcome was to evaluate executive function changes. Secondary outcomes included gaming performance as well as players' perceptions.

METHODS

Design and setting

This study was a randomised repeated measures experimental design and it was registered on clinicaltrials.gov. Due to the global COVID-19 pandemic, the study was conducted virtually with each participant. This allowed participants to use their own computers. Participants communicated with researchers via Zoom, Google Hangouts, texting and Discord. All of these platforms allow for video and chat communication except for texting through a non-social media platform.

Sample

Twenty-one participants (12 men and 9 women), 20.76 years (SD=2.61), from seven different countries, participated in this study. Men averaged a body mass index (BMI) of 20 (1.4) and women averaged a BMI of 21.9 (3.4). One subject identified as a transgender woman and had been taking hormone replacement therapy for over 1 year and was included in the analysis as such (figure 1).

Subjects were recruited online via groups and servers on Facebook, Twitter, Twitch and Discord. Twitch is the largest streaming platform for gamers, and Discord allows easy communication through voice, video, chat, text and is very popular among gamers. All subjects

signed electronic consent, and study data were collected and managed using REDcap (Research Electronic Data Capture, Vanderbilt University, Nashville, TN) tools hosted at NYIT. REDcap is a secure, web-based application designed to support data capture for research.¹⁴ Participant inclusion criteria were: (1) women or men 18–30 years of age and (2) play FPS games with over 500 hours of game time. Exclusion criteria were: (1) no competitive FPS ranking, (2) colour blindness and (3) hand injury within the last year or chronic wrist pain (table 1).

Statistical analysis

IBM SPSS V.27 was used to carry out all statistical analyses. A priori sample size calculations revealed that 20 subjects were required to detect observed differences at a power of 80%. Statistical significance for this study was set at the $p < 0.05$. To compare neuropsychological and esports performance outcomes across our three conditions, we used the General Linear Model in SPSS to compare outcomes among the conditions. Additionally, we examined any potential gender interactions.

Data collection

Data were collected on 4 separate days with at least 24 hours between each day. Following consent, participants performed a practice test of the online outcome measures to familiarise themselves on the first day. This was followed by 3 intermittent days of participant FPS gameplay that each lasted 120–135 min (2 hours±15 min) each. The 3 days consisted of (1) continuously gameplay for 120–135 min with no break, (2) a 6 min walking break with 60–75 min of gameplay before and after, (3) a 6 min supine resting break with 60–75 min of gameplay before and after (figure 2). The intervention order was randomised across participants using a Latin square design.¹⁵ The 15 min window for gameplay was to allow for participants to finish any active game. This was done by texting the subjects 10 min before the 60 min marker and 10 min before the 120 min marker. Subjects were told to finish the current game and text the investigator as soon as the game was finished. This did not impact on our study as all games were able to be completed within the time frame set. Furthermore, subjects were asked to try and maintain a similar diet on all testing days and to eat within the same time frame prior to playing for each testing day. Diets consisted predominantly of small snacks and sandwiches prior to gaming.

The 6 min break was based on findings by Christmas *et al*, who found a 3 min walking break at 30 min improved attention and executive function.¹⁶ Breaking up an esports game every 30 min is not reasonable. Therefore, we chose to break at 60 min of play using the cumulative break time of 6 min. All participants were required to play using the same FPS game title, same gaming setup and not change any equipment they used in previous sessions. All data were collected within the same time of day across sessions.

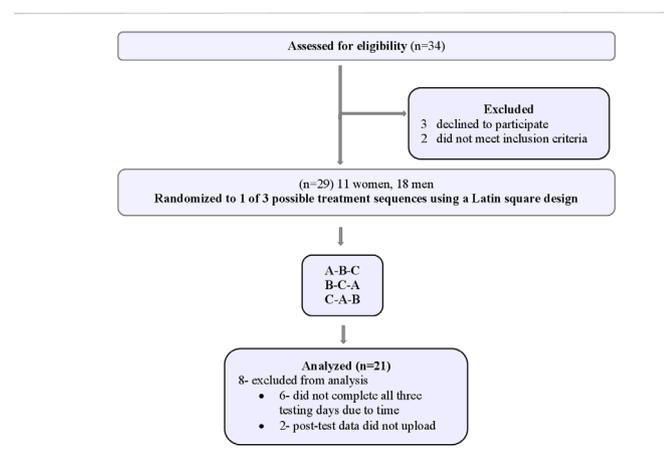


Figure 1 Study flow diagram.

Table 1 Demographic data

Men	n=12	Women	n=9
Age (SD)	20 (1.4)	Age (SD)	22 (3.4)
Weight (kg) (SD)	85.7 (27.8)	Weight (kg)	66.2 (11.8)
Height (in) (SD)	70 (1.4)	Height (in)	66.1 (2.7)
BMI (SD)	20 (1.4)	BMI	21.9 (3.4)
Current residence (%)		Current residence (%)	
United States	66	United States	56
Netherlands	8	Canada	11
France	8	Sweden	11
England	18	Finland	33
Education level (%)		Education level (%)	
High school	33	High school	44
Associates degree	8	Associates degree	0
Current bachelor's student	33	Current bachelor's student	34
Bachelor's degree	26	Bachelor's degree	11
Master's degree	0	Master's degree	11
Ethnicity (%)		Ethnicity (%)	
Caucasian	50	Caucasian	67
Asian	42	Asian	22
Prefer not to answer	8	Prefer not to answer	11
Right-handed	85	Right-handed	100
Primary game (%)		Primary game (%)	
Overwatch	33	Overwatch	45
Valorant	33	Valorant	11
Team fortress	9	Fortnite	11
Counter strike	9	Counter strike	11
Rainbow six	9	Halo	22
Apex legends	9		
Hours played weekly (%)		Hours played weekly (%)	
More than 6	100	More than 6	67
5–6 hours weekly	0	5–6 hours weekly	22
3–4 hours weekly	0	3–4 hours weekly	11
Tournament rankings % (varies by game)		Tournament rankings (may varies by game) (%)	
Top 500 globally	15	Top 500 globally	0
Master	15	Master	33
Platinum	7	Platinum	22
Diamond	24	Diamond	0
Gold	7	Gold	22
Silver 3	7	Silver 3	0
Other	24	Other	22

BMI, body mass index.

Day 1

Interested participants were asked to complete an online consent form, demographic form and the International Physical Activity Questionnaire (IPAQ) Long Version¹⁷ in REDcap. Instructions for baseline completion of executive function measures were administered and completed within 2 days of testing for familiarisation. The online executive function tests were administered through

Millisecond Software (Seattle, Washington) remote psychological testing.

Days 2, 3 and 4

Before testing, each participant was connected to a researcher virtually. On completing each gaming session, participants were asked not to leave the gaming station and immediately take the online tests again. After

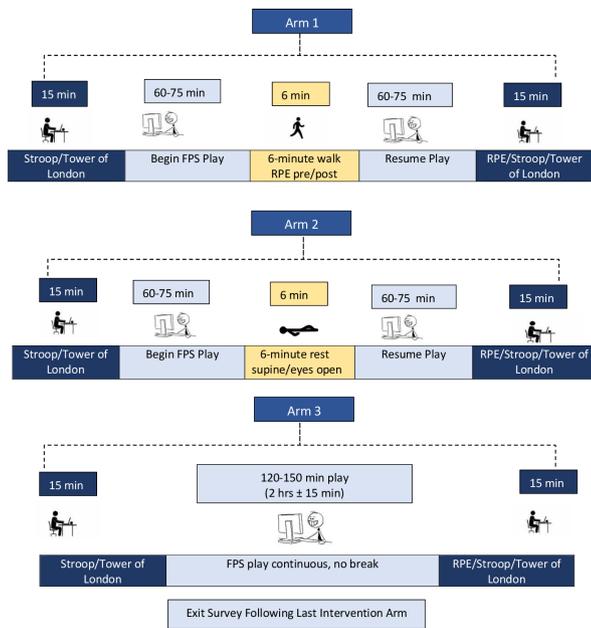


Figure 2 Virtual study protocol. FPS, first-person shooter; RPE, Rating of Perceived Exertion.

completing all three arms, subjects completed a final exit survey through REDcap that focused on perceptions of the effectiveness of each of the three-arm conditions on their gaming performance.

The three arms

The walking intervention

Participants were asked to find a place near their gaming setup that they were able to walk for 6 min on a flat surface back-and-forth while holding their smartphone in their hand to hear the investigators' cues. Before gaming, the investigator instructed the participant to open the testing links and to begin the tests. Once the completed tests were confirmed, the participant logged onto their game and told the investigator when they began. At 55 min, the investigator instructed the participant to finish their current game and alert them when they do. The average time before a break was 1 hour and 7 min (67.4 ± 7.9 min). Each investigator used the same verbiage: 'You will now get up and walk for 6 uninterrupted minutes. You are to walk briskly but comfortable. I will let you know when you are halfway done. After, I will ask you how hard your effort was while walking using the scale between 6–20 that I show you'. The 6–20 Borg Rating of Perceived Exertion (RPE) Scale was shown to the participant via the video conference screen. The Borg scale is a validated scale to measure how hard a person feels they are working during physical activity and has been validated to correlate heart rate and perceived effort during active video game play.¹⁸ The participants then returned directly to gaming. At the 55 min marker, they were instructed to alert the investigator when they completed the current game. The average time of the second gaming segment was 1 hour 7 min (66.5 ± 8.3 min). On completion of gaming, RPE was recorded and the number of wins, losses and kill–death

ratio (KDR) for each game. Following this, participants were instructed to complete the online executive function tests immediately. KDR is an individual FPS player statistic, equal to the number of opponent 'kills' divided by the number of player 'deaths' recorded across an entire game. A KDR of greater than one indicates more kills were recorded than deaths. For example, a player with 23 kills and 16 deaths would have a KDR of 1.44 for that game.

The supine rest intervention

The same procedures used for the walking intervention were followed for the rest intervention, except instead of walking, the participants laid supine for 6 min with their eyes open next to their gaming area. The reason participants kept their eyes open was to avoid any rest of the eyes that was not given while doing the 6 min walk break. The first gaming segment before rest averaged 1 hour 3 min (63.2 ± 3.9), while the subsequent postrest gaming session averaged 1 hour 2 min (62.3 ± 4.7).

The continuous gaming session

Participants were asked to complete the executive functioning measures before playing. Following 115 min, they were to complete their current game. The average gaming time during continuous gaming was 2 hours 5 min (125.3 ± 6.0 min).

Outcome measurements

Colour word Stroop with keyboard (Stroop)

The colour word Stroop is a measure of reaction time, speeded inhibitory control and set switching.¹⁹ The Stroop test was administered online via the Inquisit Lab software, developed by Millisecond Software (Seattle, Washington).

The Tower of London

The Tower of London test is a neuropsychological instrument that measures the executive functioning area of planning and non-verbal problem-solving abilities.²⁰

Exit survey

On completing all three intervention arms, participants were surveyed on how they believed each impacted their gaming performance. As prescribed by Creswell and Poth,²¹ open-response data were first open coded to find primary themes. Then, data were reanalysed via axial coding and finally selective coding to finalise the major themes through cross-referencing the interrelationships of the major coded primary themes.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

For neuropsychological outcomes, there were significant differences among conditions for the Tower of London

means solution time and planning time. For both of these outcomes, the walking condition produced the fastest solution time (7613.6 ± 3060.5 min, $p=0.02$) and planning time (5369.0 ± 2802.1 , $p=0.04$). The continuous play condition produced the second-fastest solution time (8200.1 ± 3031.6 min) and planning time (5862.7 ± 2860.7 min) and the resting condition produced the slowest solution time (9477.0 ± 3547.4 min) and planning time (6924.0 ± 3247.7 min). There were no significant differences among conditions for neuropsychological outcome variables, including Tower of London total accuracy,

Stroop reaction time and Stroop proportion correct. Ratings of perceived exertion were not significantly different between conditions ($p=0.08$). The percentage of esports games won was not significantly different across conditions ($p=0.6$), nor was KDR ($p=0.8$). There were no significant interactions by participant gender for any of the analysed dependent variables (table 2).

Exit survey findings

As seen in table 3, over 70% of participants perceived that the 6min walk break 'positively helped' gaming

Table 2 Outcome measurements following a walking break, resting break and continuous play

Outcome variable	Women (n=9)	Men (n=12)	Group (n=21)	P value	P value
				By group	Gender interaction
Total accuracy		Number correct (SD)			
Walk	34.2 (1.1)	33.4 (2.3)	33.8 (1.9)		
Rest	34.2 (2.4)	33.4 (2.4)	33.8 (2.4)	0.7	0.9
Continuous	34.3 (1.7)	33.9 (2.7)	34.1 (2.3)		
Mean solution time		Time/ms (SD)			
Walk	7325.5 (1925.2)	7829.7 (3770.3)	7613.6 (3060.5)		
Rest	10098.2 (3625.9)	9011.1 (3573)	9477 (3547.4)	0.02*	0.5
Continuous	8331.9 (4139.4)	8101.1 (2055.2)	8200.1 (3031.6)		
Planning time		Time/ms (SD)			
Walk	5061.7 (1566.9)	5599.5 (3516.1)	5369 (2802.9)		
Rest	7612.2 (3454.3)	6407.9 (3133.9)	6924 (3247.7)	0.04*	0.4
Continuous	6069.6 (3883.9)	5707.5 (1961.3)	5862.7 (2860.7)		
RPE following gameplay		6–20 Borg			
Walk	12.3 (4)	13.1 (2.9)	12.8 (3.3)		
Rest	11.6 (4.3)	11.3 (2.6)	11.4 (3.3)	0.08	0.8
Continuous	12.9 (2.1)	13.4 (2.9)	13.2 (2.5)		
Reaction time incongruent trials		Time/ms (SD)			
Walk	642.1 (99.9)	683.3 (99.4)	665.6 (99.3)		
Rest	944.4 (601.4)	761.4 (192.7)	840 (416.8)	0.07	0.4
Continuous	748 (127.3)	684.9 (191.7)	712 (166.5)		
Proportion correct		% (SD)			
Walk	92 (6.0)	93 (6.0)	92 (6.0)		
Rest	90 (6.0)	92 (5.0)	92 (5.0)	0.6	0.7
Continuous	91 (6.0)	90 (8.0)	91 (7.0)		
Kill/death ratio		KDR (SD)			
Walk	2.0 (1.2)	2.8 (2.3)	2.5 (2.0)		
Rest	1.9 (1.2)	2.6 (2.2)	2.3 (1.9)	0.8	0.5
Continuous	2.1 (1.2)	2.2 (1.6)	2.2 (1.4)		
Percentage of games won		% (SD)			
Walk	40.2 (27.7)	65.4 (20.1)	53.8 (26.4)		
Rest	38.3 (37.1)	51.1 (35.5)	45.2 (35.3)	0.6	0.4
Continuous	53.5 (10.1)	53 (18.7)	53.2 (14.7)		

*Significance.

RPE, rate of perceived exertion.

Table 3 Participants' perception data on each condition

How do you believe the 6min walk break impacted your gaming performance?					
Positively helped (%)	Negatively impacted (%)	No impact (%)		Representative positively helped comment:	Representative negatively impacted comment:
73.9	8.7	17.4		'It was good to take a break, but I think its active nature helped me stay prepared physically while offering me a more mental break.'	'It was a light movement and didn't fatigue me, but did break focus on the game.'
How do you believe the 6min rest break impacted your gaming performance?					
39.1	26.1	34.8		'I treated it like meditation! I focused and reflected on the previous games to try and prepare myself better for the following ones.'	'While the 6 -minute rest itself felt great, when I got back to my computer, I felt slow and lethargic, and it took me a while to get back into the game and warmup again.'
Which of the following do you think is most effective to help gaming performance?					
Walking break (%)	Rest break (%)	Continuous play (%)	No difference (%)	Representative walking break preference comments:	Representative rest break preference comment:
52.2	21.7	21.7	4.3	'I can't tell exactly why, but physically moving my body helped me feel more refreshed when I started the game again vs when I rested on my bed.'	'The lying down rest allowed me to more quickly relax after being fairly tense during play, which made the 'mental reset' feel more impactful on [future] play.'
				'(The) walking break definitely has the best impact on gaming performance. It helps you clear your mind while doing something physical. Even if you are walking slowly, it helps you calm down and forget the high pressure from the gaming environment. Your brain isn't going overboard anymore.'	Representative continuous play preference comment: 'No break allows [you] to stay in the zone and keeps you warmed up. Pro esports players have been caught taking Adderall so that they can stay in-game longer. Dedicating the most amount of time possible is the only way to get better at a game. It [is] exactly like a real sport.'

performance. Most commonly noted was the walk provided a good mental break, while half commented on its effectiveness of being physically active.

Responses were more varied regarding whether participants perceived the 6min laying down rest break impacted gaming performance as under 40% felt it positively helped. Participants who perceived that the rest break negatively hurt performance commonly noted that the rest made them sleepy, lethargic and slowed them.

When asked, 'Which of the following do you think is most effective to help gaming performance?' over half preferred the walking break. Common themes across participants who favoured the walking break perceived that the walk helped them provide an active break for their body and mind while at the same time physically preparing them for the next gaming session. Participants who favoured no break felt this helped keep in-game focus and consistent performance, with multiple participants noting that many professional esports players take Adderall for this very purpose. Adderall (generic name: amphetamine, dextroamphetamine mixed salts) is a prescription medication that belongs to a class of drugs known as central nervous system stimulants. It is typically prescribed to treat symptoms of attention deficit and hyperactivity disorder (ADHD) and impulse control. In people who do not suffer from ADHD, it produces

excess dopamine in the brain that can create increased energy levels and euphoria. Recreation abuse can lead to dangerous health effects²² (table 3).

DISCUSSION

This study was conducted virtually due to the lockdown regulations imposed globally from the COVID-19 pandemic during July through December 2020, comparing a 6min active break, a 6min passive break and no break on competitive FPS player performance and executive function. It is the first to demonstrate that an active break improves executive function compared with a passive (ie, rest) break while not impacting game performance. Interestingly, the continuous play (no break) performed superior to the resting break. Hence, a resting break may be a detriment to esports players.

The complexity and fast-paced demands of FPS gameplay place a significant demand on attention, cognition, working memory and executive function.^{1 2} In gaming, on a neural basis, elite esports players demonstrate enhanced cognitive control and attention.^{2 23} These cognitive demands elicit a sympathetic nervous system response presented by heart rate variability, heart rate fluctuations, respiratory rate increases, ventilation changes and blood pressure changes.^{3 11} This type of

demand may lead to mental fatigue, cognitive decline and, possibly, poor performance over time.

This project studied FPS gamers ranked at a highly competitive level. FPS games require rapid speed and reaction time, fine motor hand–eye coordination and demand high amounts of executive function and simultaneous actions.³ FPS gameplay also facilitates HR variability, HR fluctuations and increased cortisol levels.^{1 3 11} Finally, 2 hours of continuous esports gameplay have resulted in less accuracy and more impulsivity.¹¹ Given the cognitive demands required for high-level esports and the multiple hours of being seated, it is of interest to players and health professionals to incorporate practical ways to improve on performance while also improving health. To date, there are no studies that have comprehensively evaluated the physiological parameters in gamers. Therefore, the mechanisms described below of the underlying effects of prolonged sitting are based on previous studies in other populations and have been well established.

Cerebral blood flow and prolonged sitting

The middle cerebral artery (MCA) accounts for 70%–80% of the brain's perfusion. In healthy individuals who were not gamers, uninterrupted sitting for 4 hours caused a significant decrease in MCA blood flow velocity to 1.4–3.2 cm/s.¹⁰ This may not seem relevant, but this decline has been correlated to decreased focus and fatigue. Simply taking a 2 min light walking break every 30 min prevented these declines and improved cerebral autoregulation.¹⁰ Moreover, Wennberg *et al* found that 3 min of light walking, following 30 min of being seated, reduced fatigue and improved cognition in overweight adults.¹³ Although we were unable to collect biological variables in this study, we demonstrated an improvement in decision-making and impulsivity following a 6 min light walking break at the 60 min marker.

Endothelial function and prolonged sitting

Thrombotic events are concern in gamers despite age or activity level.^{5 7} The underpinning mechanism resulting in DVTs is endothelial function changes and blood flow, resulting from bouts of prolonged sitting. Following 1 hour of sitting, there is a significant reduction in superficial femoral artery flow-mediated dilation and a decrease in popliteal flow-mediated dilation that can last up to 3 hours or more.²⁴ Furthermore, endothelial changes and blood volume changes create an environment that can create blood pooling and more dangerous DVTs or PE. However, these blunted and vascular impairments caused by prolonged sitting were reversed with very light short bouts of activity.²⁵

Exercise intensity

De Las Heras *et al* exercised gamers using HIIT for 15 min at an RPE of 15.17 (0.34), which translates to working 'hard' or 'heavy'.²⁶ The average RPE for participants in the walking condition in this study was 10.5 (2.8), which

translates to 'light' intensity effort. Interestingly, the RPE for gaming was higher than the RPE for the walking break. The average perceived intensity level of gameplay was 13.5 (1.2), which is 'somewhat hard', further demonstrating the perceived demands of gaming.¹⁸ This study demonstrated improvement in cognitive abilities with as little as 6 min of light movement. Additionally, 73.9% of participants perceived that the active walking break positively helped their gaming performance. Based on the results of the IPAQ, there was no relationship between physical activity level and preference for a walking break.

Limitations

There are several limitations to this study. To collect data during the lockdowns of a pandemic, compromises had to be made. Collecting valid objective biometric data proved to be difficult and not feasible. Therefore, the walking effort was determined using the Borg RPE scale. Although this scale is validated, self-report bias may exist. The nature of the online data collection may have impacted how subjects conducted the tests without being in a testing environment. However, this is more reflective of a typical gaming environment than conducting the tests in a lab, which may have increased external validity. Results indicated no study intervention arm significantly impacted player win/loss rate or KDR. Still, other extraneous factors may also impact this (eg, quality of opponent or teammate gameplay, varying maps across games etc). Although there were no executive function changes seen between genders, the physiological changes from prolonged gaming while improving executive function could not be tested in this cohort.

CONCLUSION

This study has several implications. First, gaming performance and executive function were investigated in relation to an active 6 min break and a passive 6 min break, compared with continuous gameplay. While either intervention did not impact gaming performance, the active break showed an increase in speed with no change in accuracy, whereas the passive break had no change. Continuous play was slightly better than the resting break. Second, this is the first study to compare competitive gamers by gender in terms of executive function and gaming performance. Finally, this study showed the efficacy of conducting a virtual clinical trial. This is important in the gaming environment for a few reasons: (1) many investigators do not have easy physical access to esports players and (2) in cases of a pandemic or social distancing, there are valid and effective tools that can be used to assess outcomes virtually.

There have been several calls for improving gamers' health, with exercise being the primary focus.^{26–29} However, there may be a fair misconception that if one exercises regularly, one is not prone to negative health ramifications of prolonged sitting. Being less sedentary with frequent breaks may have a greater health impact than increasing exercise.⁸ This study provides evidence

that a 6min walking break improved executive function following a single bout of prolonged gaming and that an active break was preferred compared with a resting break. These findings suggest further investigation into multiple bouts of prolonged gaming to further understand the long-term implications an active break may have in competitive gamers.

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Contributors JD-D, SEJ, PD, AS, SA, KY, TH, HG, KA contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This study was approved by the NYIT Institutional Review Board.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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NEW YORK INSTITUTE OF TECHNOLOGY
 Institutional Review Board for the Protection of Human Participants
 Northern Blvd, Old Westbury, NY 11568
 516-686-7738 ♦ <http://iris.nyit.edu/sponsoredprograms/>

Application Checklist for Expedited or Full Review

The following checklist must be completed by the Principal Investigator with the submission of any expedited or full review protocol to the Institutional Review Board for the Protection of Human Participants.

Principal Investigator: Joanne Donoghue

Department: OMM

Protocol Title: Can a 6-minute walking or resting break improve executive function and gaming performance in competitive men and women gamers: A virtual protocol

	Attached	N/A
Application Form (with <u>all</u> required signatures)	<input checked="" type="checkbox"/>	
Attachment A	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Attachment B	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Attachment C	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Attachment D	<input checked="" type="checkbox"/>	
Abstract (limit 400 words)	<input checked="" type="checkbox"/>	
Protocol Description	<input type="checkbox"/>	
Purpose	<input checked="" type="checkbox"/>	
Source(s) of Subjects and the Selection Criteria	<input checked="" type="checkbox"/>	
Procedures	<input checked="" type="checkbox"/>	
Assessment of Risks & Benefits	<input checked="" type="checkbox"/>	
Protection of Data/Privacy	<input checked="" type="checkbox"/>	
Debriefing Process	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Consent Procedures	<input checked="" type="checkbox"/>	
Investigator Background and other Relevant Information	<input checked="" type="checkbox"/>	
Draft Consent Form	<input checked="" type="checkbox"/>	
Draft Assent Form	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Fliers/Advertisements/Announcements	<input type="checkbox"/>	<input type="checkbox"/>
Surveys/Questionnaires	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Interview Questions	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Vitas of all Investigators	<input checked="" type="checkbox"/>	
Copy of Certificate of Completion of Online Training Module for all key personnel	<input checked="" type="checkbox"/>	
Authorization from Performance Sites	<input checked="" type="checkbox"/>	<input type="checkbox"/>

The application checklist, application form and protocol description, and additional materials should be submitted to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at the Office of Sponsored Programs and Research, North House, Second Floor.

NYIT Institutional Review Board for the Protection of Human Participants**APPLICATION FOR EXPEDITED OR FULL REVIEW**

- This form must be completed for all protocols that do not qualify for exemption. (To request an exemption, review the exempt categories carefully and submit the Request for Exemption form.)
- The Principal Investigator (PI) assumes responsibility for the conduct of the study. Students and non-NYIT personnel may not serve as principal investigators. The PI should complete sections I through IV of this form and attachments A, B, C or D as applicable.
- Submit the application checklist, application form and attachments and other materials as needed to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at North House, Second Floor.

Protocol title: Can a 6-minute walking or resting break improve executive function and gaming performance in competitive men and women gamers: A virtual protocol

I. PERSONNEL

Principal Investigator: (Last) Donoghue (First) Joanne

Check one: Faculty Staff Other _____

Department: OMM

Address (where you want notification sent): AHCC Riland Building

Telephone (Home): 516--686-3759 Campus: Old Westbury

E-mail: jdonoghu@nyit.edu

*If the project has additional investigators, including students, complete **ATTACHMENT A**.*

II. PROTOCOL**1. Assessment of Risk**

Minimal risk (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Moderate risk (minor increase over minimal risk)

Considerable risk (greater than minor increase over minimal risk)

Comments Regarding Risks: _____

2. Type of Review

*Indicate the type of review you are requesting. If you select expedited, check the number of the review category that best fits your research. **Final decisions about the appropriate level of review rest with the IRB.***

I am requesting an EXPEDITED REVIEW under category: 1 2 3 4 5 6 7 8 9

Submit the original and three (3) copies of your application to the IRB.

I am requesting a FULL REVIEW because my research does not fit precisely into any of the expedited review categories.

Submit the original and fifteen (15) copies of your application to the IRB.

PLEASE NOTE: Applications that qualify for Expedited Review are reviewed on a rolling basis. Check the IRB web site for a listing of IRB meeting dates and application receipt deadlines for full review protocols.

3. Participant Information: Will data be collected from any of the following populations?

- | | |
|--|---|
| <input type="checkbox"/> Minors (Under 18 yrs of age; Specify age range) _____ | <input type="checkbox"/> Staff/Employees _____ |
| <input type="checkbox"/> Prisoners _____ | <input type="checkbox"/> Students _____ |
| <input type="checkbox"/> Fetuses _____ | <input type="checkbox"/> Non-English speakers _____ |
| <input type="checkbox"/> Pregnant women _____ | <input type="checkbox"/> Poor/Uninsured _____ |
| <input type="checkbox"/> Cognitively impaired (including comatose) _____ | |

4. Research Support: Do you plan to or have you applied for funding for this project? Please review the sponsor's guidelines carefully and allow sufficient time for IRB review.

- Yes Please provide the funding source: _____
 Program/Grant Number (if Known): _____

Please provide one (1) copy of the complete grant proposal or contract.

No

Please check the following as appropriate:

- The above-referenced sponsor intends to fund 100% of the costs associated with participant participation in the research protocol.
- The above-referenced sponsor intends to fund 100% of the costs associated with participant care that is beyond regularly required care. Regular care will be billed to the participant or the participant's insurance.
- The above-referenced sponsor intends to fund only a portion of the total costs associated with participant care. Explain fully in the protocol description.

5. Financial Conflict of Interest: Does the principal investigator, any co-investigator or study coordinator involved in the study (or in aggregate with his/her spouse, dependents or members of his/her household):

- A. Have an equity interest in the entity that sponsors this research or the technology being evaluated that exceeds 5% ownership interest or a current value of \$10,000?
 Yes
 No
- B. Receive salary, royalty, licensing fees, or other payments from the entity that sponsors this research or the technology being evaluated that is expected to exceed \$10,000 per year?
 Yes
 No
- C. Have a license agreement with the University or an external entity that would entitle sharing the current or future commercial proceeds of the technology being evaluated?
 Yes
 No

If yes to any of the above, please submit detailed information on a separate sheet.

- 6. Study site(s):** NYIT-Central Islip NYIT-Old Westbury
 NYIT-Manhattan NYITCOM

Other (Please specify): This study will be conducted virtually from the investigators private locations and the participant's private location.

Please provide letters of agreement and/or complete **ATTACHMENT B**.

7. If this proposal has been submitted to another Institutional Review Board, give the name of the institution and date of review. Supply copies of approval letters and recommendations of that committee.

Institution: None Date of review: / /

8. **Timetable:** What is the estimated duration of the entire study?

Begin: 06 / 15 /2020 End: 6 / 1 /2021

9. **Participant time commitment.** What is the time commitment for each participant participating in the study? Indicate the number of visits/sessions and the time involved per visit/session.

Visits/Sessions: 4 Time per visit/session: 1st session- 20 min- sessions
2,3,4- 2:30-3 hours

10. **Compensation.** If compensation to participants is intended, indicate how much and in what form (cash, taxi fare, meals, etc). The amount of compensation is subject to IRB approval.

Is any form of compensation being provided?

Yes Describe: We will be offering a drawing for one participant to win a Fitbit Versa Smart watch when they complete the study.

No

III. PROTOCOL DESCRIPTION

Please respond to the following requests on a separate sheet.

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study. Briefly discuss the background and rationale for the study. Is the study design appropriate to prove the hypothesis? Provide references for the background information. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.

ESports is electronic gaming and is also referred to as pro-gaming or competitive video gaming. Guidelines for maintenance of health of eSports players and the cognitive changes that accompany competitive gaming are understudied. Additionally, the difference between genders in terms of these factors has not been examined in any paper found, to date. Executive functioning is an important cognitive skill for an eSports player. In our most recently submitted publication, we found that executive functions were changed after a session of eSports gaming, with increased reaction time, but decreased accuracy for inhibitory tasks and problem-solving tasks.¹ Previous findings from other researchers suggest a relationship between eSports players and executive function abilities.² Similar to our findings, in comparisons of certain aspects of executive function

(reaction time and inhibitory control) in First Person Shooter (FPS) vs. Multiple Online Battle Arenas' (MOBAs), one other study found that gamers who played FPS presented faster reaction times, but a lower control over inhibition than gamers who favored MOBAs.³

The relationship between executive functions and physical exercise has been well established.^{4,5} However, the effects of prolonged sitting regardless of physical activity level has not been established. For example, prolonged uninterrupted sitting reduces cerebral blood flow.^{6,7} Reduced cerebral blood flow is associated with lower cognitive function and fatigue.⁶⁻⁸ This decrease in cerebral blood flow has been shown to be offset by frequent and short walking breaks anywhere between 30 minutes and 60 minutes. These short breaks can be as little as 2 minutes at 30 minutes, and 6 minutes following 60 minutes of prolonged sitting. The rationale is the increase in blood flow and the positive effects this has on metabolic responses.⁸ The primary purpose of this study is to evaluate executive function changes following a 6-minute walking break to a 6 minute resting break in competitive esports players following 60-75 minutes of prolonged play. Additionally, sex differences between these changes will be examined.

2. Describe the source(s) of participants, the selection criteria and the recruitment methods. Selection of participants must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. Provide a detailed description of the participant population including criteria for inclusion/exclusion, number of participants involved in the study, age, sex and health status. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential participants **must be attached**.

Design

The study is a randomized repeated measures design.

Setting

The study will take place remotely on four separate days. This allows participants to utilize their computers while maintaining social distancing measures due to the COVID-19 pandemic. Research participants will be connected with researchers via Zoom, Google Hangouts, or other modalities of internet based video chatting.

Sample

Subjects will be recruited online via groups and servers on Facebook, Twitter, Slack, Twitch, and Discord. Participants will be incentivized to partake in the study through an opportunity to be randomly selected to win a Fitbit™ Versa smart watch for participating.

Inclusion criteria: 1. Women or men 18-25 years of age 2. Play first-person shooter games with a ranking of “gold” or higher (self reported).

Exclusion Criteria: 1. Any participants that do not have a competitive ranking 2. Any participants that are colorblind (self reported) 3. Any participants that have sustained previous hand injuries within the last year, or suffer from chronic wrist pain.

3. Provide a detailed description of the procedures to be followed. If applicable, include a detailed description of all drugs to be used including dosages, dosage changes varying from manufacturers' recommendations, frequency of use, FDA status of a formerly approved drug being used for new therapies, IND# of all new drugs and all other drug information necessary. Include copies of questionnaires and/or interview protocols, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of participants' involvement. Include a time line for the study.

Thirty participants (15 men and 15 women) will be recruited via social media websites.

From this pilot data a power analysis will be calculated.

Data Collection will be done over 4 separate days.

Subjects will have one day of completing the consent form and conduct a practice test of the outcome measures to familiarize themselves. This will be followed by each participant completing three days of gaming that will entail one day of continuous play, one day a 6- minute walking break between minutes 60-75 of game play, and one day of a 6- minute resting break between minutes 60-75 of game play. The window for game play is to allow for the participants to complete any started video game during the gaming session. Dunstan et al.⁹ demonstrated that breaking up

prolonged sitting with 2 minute light walking breaks every 20 minutes for 5 hours reduced glycemic and insulin responses. Carter et al.⁷ demonstrated that light walking for 2 minutes following 30 minutes of prolonged sitting prevented a decline in cerebral blood flow. Breaking up an esports game every 20-30 minutes is not feasible nor reasonable, therefore we chose to break at 60- 75 minutes of play using the cumulative time of 6 minutes rather than the more frequent 2 minute breaks. Both studies demonstrated light walking to be just as effective as moderate walking.

Each session will be within one week of the prior testing day with a minimum of 72 hours between testing days. All participants will be required to play on the same PC device and not change any equipment they used in the previous session

Day 1

An online consent form will be executed through REDcap a secure HIPPA compliant web application. Interested participants will be asked to fill out a demographic form and will be administered the International Physical Activity Questionnaire Long Version (PAQ-L). Instructions for a baseline completion of executive functions measures will be administered and completed prior within 2 days of testing for familiarization.

The order of the arms will be randomized using an online program, Research Randomizer <https://www.randomizer.org/>.

Days 2, 3, and 4

Subjects will be asked to connect to a researcher before each study day via Google Hangouts, Zoom, Facetime or Duo. They will be asked to complete the executive functioning measures

before playing (administered through redcap via email). After completion of each testing day they will be asked to play games for 120 to 150 minutes. Upon completion of the last gaming session, all participants will complete a final short open-ended questionnaire focused on how the participants' perceived the 6- minute walk break, the resting break, and whether they feel it did or did not impact their gaming performance.

The Three Arms:

The walking intervention group: The 6-minute walk will be conducted indoors at the location where the participant is playing. They will be asked to find a place that they are able to walk for 6 minutes on a flat surface back and forth or in a circle while holding the timer on their smart phone in their hand. Between 60-75 minutes of game play, they will be instructed to “get up and walk for 6 uninterrupted minutes”. Before this walk the participants will be shown the 6-20 BORG Rating of Perceived Exertion Scale (RPE) that will be held up by the investigators. This RPE is a validated scale to measure how hard a person feels they are working during physical activity and has been validated to correlate heart rate and perceived effort during active videogame play.¹⁰

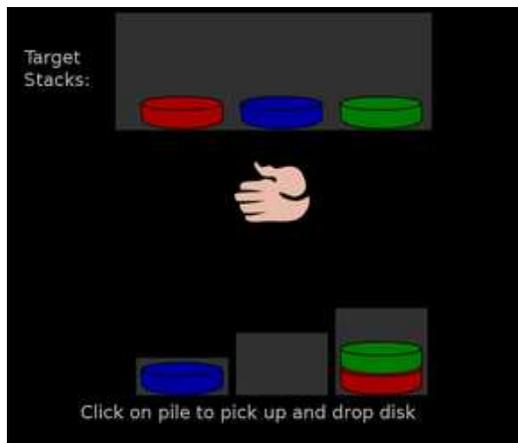
The silent rest intervention group: Between 60-75 minutes of game play, they will be instructed to lie down in a pre-determined area that can be seen by the investigators and lie supine with their eyes open for 6 minutes. The eyes will remain open to stay consistent with the 6 minute walking intervention and to avoid the closed eyes as a confounding variable. Before this rest the participants will be shown the 6-20 BORG RPE scale that will be held up by the investigators. Following the 6-minute rest, participants will return to their gaming console to resume play. Investigators will collect RPE before game play continues.

The control session: Subjects will be asked to complete the executive functioning measures before playing. After completion of the test, they will be asked to play games for 120 to 150 minutes.

Following the 120 to 150 hours of gameplay on all three testing days, the participants will be prompted to repeat the Stroop and Tower of London tests again. Number of FPS video game wins and losses will also be recorded.

Outcome Measurements:

1. The Tower of London is a neuropsychological test to assess executive functioning and planning. The computer uses image of colored objects and relates them to classic problem solving puzzles.



2. Color Word Stroop with Keyboard (Stroop): The Stroop is based on the observation that individuals can read words much faster than they can identify and name colors. The cognitive dimension tapped by the Stroop is associated with cognitive flexibility, resistance to interference from outside stimuli, creativity, and psychopathology—all of which influence the individual's

ability to cope with cognitive stress and process complex input.¹¹ It measures cognitive processing and provides valuable diagnostic information on brain dysfunction and cognition. The test assesses the ability to inhibit cognitive interference by processing a stimulus feature at the same time as processing another attribute of the same stimulus. In the the most common version of the Stroop test, subjects are required to read three different tables as fast as they could. Two of the tables represented “congruous conditions,” where patients would be required to read names of colors printed in black ink and name different color patches, In the third table, the words were printed in different colors of ink (i.e. the word blue was in yellow ink), forcing participants to name the color of the ink instead of reading the word. This mechanism forces participants to engage in a less automated task (naming ink color), while also inhibiting the interference that comes from a more automated task (reading the word) therefore known as the Stroop effect. In present day, the Stroop test can be administered online through various softwares. The specific program we are using for the purposes of the study is Inquisit Lab, developed by Millisecond (Figure 2).

In the following trials you will see words presented in different colors. Your task is to indicate the COLOR in which each word is printed in while ignoring what the words actually say.

Indicate the color of the word by pressing either of the following keys:

- - d for **red** words
- - f for **green** words
- - j for **blue** words
- - k for **black** words

Example: if you see the word **RED** printed in the color GREEN press 'f' for green words regardless of the meaning of the word.

Try to respond as quickly and accurately as you can, because you will be timed. If an incorrect response is made, a red **X** will be flashed onto the screen.

Press [space] to continue

Figure 2. Colored Stroop Test with Keyboard Responding by Inquisit Lab

The software mimics the paper version of the Stroop test, but also measures the time to reaction in milliseconds. This facilitates data collection because time to reaction is recorded, essentially distinguishing the automated task time. The test should take an estimated 3-5 minutes to complete

3. Borg Rating of Perceived Exertion

Borg's Rating of Perceived Exertion (RPE) Scale

Perceived Exertion Rating	Description of Exertion
6	No exertion. Sitting & resting
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

4. Describe any potential harms or benefits to be derived by participants, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety. Discuss how risks will be minimized and additional safeguards for vulnerable subjects.

This study has no risk involved. The tests being administered can be terminated at any time if the subject wants to stop.

5. Describe the specific methods by which confidentiality or anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.

Subject data will be coded on a master list in REDcap. When viewing, analyzing, discussing data, it will be done only in reference coded numbers, never using subject names.. Only

the principle investigator and co-investigators have access to this project in REDcap. We plan on submitting this study for publication.

6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

No deception is included in the study.

7. Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent. Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent forms. When the consent form to be used will be in a language other than English, an English translation must be provided. Use the Informed Consent Checklist (**ATTACHMENT D**) as a guide in drafting your consent form.

8. Please provide information about your background. You may attach a CV or resume for all investigators. CV's have been attached for all investigators.

IV. CERTIFICATION AND APPROVAL

By signing this document, I certify that in my opinion the protocol and safeguards described in this application meet the standards of the New York Institute of Technology (NYIT) and all Federal regulatory requirements concerning experiments that use human participants. I accept responsibility for assuring adherence to Federal and NYIT policies relative to the protection of the rights and welfare of participants in this study. I certify that my participation and the participation of any co-investigators does not violate the NYIT policy on conflicts of interest.

By signing below, I certify that I have undergone training in basic human participants protections and will ensure that all key personnel complete this training before working on this protocol.

PI Signature _____ / / _____
Department Chair _____ / / _____

*If students will be involved in the project, complete **ATTACHMENT C**.*

ATTACHMENT A:**ADDITIONAL INVESTIGATORS AND KEY PERSONNEL**

Fill out this section if additional investigators will work on this project. Attach additional pages as necessary.

1. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

Student Faculty Staff Other _____

Name: (Last) Ahmad _____ (First) _____ Sophia _____

Department: _____ OMS III _____

Telephone #: _____ E-mail: <sahmad11@nyit.edu> _____

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: _____ / _____ / _____

Department Chair: _____ Date: _____ / _____ / _____

2. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

Student Faculty Staff Other _____

Name: (Last) _ Yuen _____ (First) _____ Kyle _____

Department: _____ OMS III _____

Telephone #: _____ E-mail: _____ kyuen02@nyit.edu _____

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: _____ / _____ / _____

Department Chair: _____ Date: _____ / _____ / _____

3. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student Faculty Staff Other _____

Name: (Last) _Hassan _____ (First) ___ Tamzid _____

Department: _OMS III _____

Telephone #: _____ E-mail: ___ thassa03@nyit.edu _____

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: ____ / ____ / ____

Department Chair: _____ Date: ____ / ____ / ____

4. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student Faculty Staff Other _____

Name: (Last) _Bedell _____ (First) ___ Mariel _____

Department: _OMS III _____

Telephone #: _____ E-mail: ___ mbedell@nyit.edu _____

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: ____ / ____ / ____

Department Chair: _____ Date: ____ / ____ / ____

5. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student Faculty Staff Other _____

Name: (Last) _Sousa _____ (First) ___ Amber _____

Department: _OMM _____

Telephone #: _____ E-mail: ___ asousa@nyit.edu _____

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: ____ / ____ / ____

Department Chair: _____ Date: ____ / ____ / ____

6. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student Faculty Staff Other _____

Name: (Last) _Douris _____ (First) ___ Peter _____

Department: _Physical Therapy

Telephone #: _____ E-mail: ___ pdouris@nyit.edu _____

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: ____ / ____ / ____

Department Chair: _____ Date: ____ / ____ / ____

7. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student Faculty Staff Other _____

Name: (Last) _Jenny _____ (First) ___ Seth _____

Department: _ Department of Exercise and Rehabilitative Sciences, Slippery Rock University of Pennsylvania

Telephone #: _____ E-mail: ___seth.jenny@sru.edu___

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: ____/____/____

Department Chair: _____ Date: ____/____/____

8. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

Student Faculty Staff Other _____

Name: (Last) _ Gan _____ (First) ___Hillary_____

Department: _OMS II_____

Telephone #: _____ E-mail: ___hgan@nyit.edu___

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: ____/____/____

Department Chair: _____ Date: ____/____/____

9. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

Student Faculty Staff Other _____

Name: (Last) _ Abraham _____ (First) ___Kenney_____

Department: _OMS II_____

Telephone #: _____ E-mail: ___kabrah06@nyit.edu___

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: _____ Date: ____/____/____

Department Chair: _____ Date: ____/____/____

ATTACHMENT B:**RESOURCES**

The following consultants and service departments (e.g. Radiology, NYIT/NYCOM Academic Health Care Center [AHCC], Hospital Department, Medical Records, School Principal or Superintendent, Counseling Center Supervisor, etc), affected by elements of this protocol, have been consulted and agree to participate to the extent required by the protocol. Any protocol involving the NYIT/NYCOM Academic Health Care Center (AHCC), Old Westbury, and/or the NYIT/NYCOM Family Health Care Center (FHCC), Central Islip, must be reviewed by the Medical Director of the AHCC/FHCC. The investigator is responsible for submitting the protocol to the AHCC/FHCC Medical Director for his/her signature.

This project does does not involve the NYITCOM Academic Health Care Center (AHCC).

This project does does not involve the NYITCOM Family Health Care Center (FHCC).

Service or Consultant (Please print)

Department/Organization: _____ Name: _____

Signature: _____ Date: ____ / ____ / ____

Department/Organization: _____ Name: _____

Signature: _____ Date: ____ / ____ / ____

Department/Organization: _____ Name: _____

Signature: _____ Date: ____ / ____ / ____

Department/Organization: _____ Name: _____

Signature: _____ Date: ____ / ____ / ____

Department/Organization: _____ Name: _____

Signature: _____ Date: ____ / ____ / ____

Letters of agreement may be substituted for signatures here.

HIPAA Certification

On April 14th, 2003, privacy regulations went into effect that regulate the access and handling of medical information. The investigator, not the IRB, is responsible for understanding and ensuring that the regulations are followed. If the protocol involves any unit of the Academic Health Care Center at NYIT/NYCOM, you must discuss the protocol with the compliance officer of NYIT/NYCOM, currently Nancy Bono, DO, in the Old Westbury Academic Health Care Center. If there is any doubt whether this applies, please discuss it with the HIPAA compliance officer. If the project involves medical records at any other institution, you must discuss your proposal with the compliance officer of that institution.

I certify that I have discussed my proposal involving medical records of any kind with the appropriate compliance officer, and understand and will comply with the requirements of HIPAA regulations.

PI Signature: _____ / ____ / ____

ATTACHMENT C:**STUDENT PARTICIPATION IN RESEARCH****Principal Investigator**

I certify that I have instructed the student(s) listed below in research techniques and human protections standards; I have reviewed the entire research proposal, including any components composed by the student(s); any student role will be consistent with the description I provide in this proposal and in compliance with NYIT Human Protections Policies, to the best of my knowledge.

PI Signature: _____ Date ____ / ____ / ____

Students

I certify I am at least 18 years of age and that to the best of my understanding I will comply with the NYIT policies regarding Human Research Protections and will participate in research consistent with the descriptions in the submitted protocol

Student Name (print/type)	Signature	Date
Sophia Ahmad		____ / ____ / ____
Kyle Yuen		____ / ____ / ____
Tamzid Hassan		____ / ____ / ____
Marisol Bedell		____ / ____ / ____
Hillary Gan		____ / ____ / ____
Abraham Kenney		____ / ____ / ____

ATTACHMENT D:**INFORMED CONSENT CHECKLIST**

Please use this checklist to develop your informed consent form(s). Sample consent forms are available at <http://iris.nyit.edu/sponsoredprograms>. Submit **ONE** copy with your copies of the proposal and other forms.

Unless waived by the IRB, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the participant or the participant's legally authorized representative.

The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by Federal regulations (45CFR46.116). This form may be read to the participant or the participant's legally authorized representative. The investigator should give either the participant or the representative adequate opportunity to read it and ask questions before it is signed. Copies of the consent form should be given to the participant(s).
2. A short form written consent document, stating that the elements of informed consent required by 45CFR46.116 have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there should be a witness to the oral presentation. The IRB must approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness should sign both the short form and a copy of the summary, and the person obtaining consent should sign a copy of the summary. A copy of the summary should be given to the participant or the representative, in addition to a copy of the short form.

Please check one:

- I am requesting a waiver for documentation of informed consent.**
Complete Section 1 below
- I have enclosed a draft informed consent form and assent form (if applicable).**
Complete Section 2 below.

Section 1:

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either:

- 1). That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
- 2). That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

- A. Does the research present more than minimal risk to the participants?
- Yes
- No
- B. Will a waiver adversely affect the rights and welfare of the participants?
- Yes
- No

- C. Can this research be practicably carried out without the waiver?
 Yes
 No
- D. Will participants be provided with additional pertinent information after participation?
 Yes
 No

Section 2:

Consent documents must be written in lay language at the 6th grade reading level and include the following required elements:

Included

- A statement that the study involves research and an explanation of the purposes of the research, the expected duration of the participant's participation, and a description of the procedures to be followed and identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the participant
- A description of any benefits to the participant or to others, which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- NA For research involving more than minimal risk, an explanation as to whether any compensation will be offered, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled
- Additional elements, as appropriate:

Included N/A

- | | | |
|-------------------------------------|-------------------------------------|--|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Any additional costs to the participant that may result from participation in the research |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | If minors are involved, an assent form |

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