How to cite this article: Moorthy S, Sagar S, Trikha V, Sagar R, Sawhne C, Kalaivani K et al. Study protocol to report the effectiveness of virtual reality therapy in combination with physical therapy protocol for improving balance in traumatic lower limb amputees: A parallel, open-label, randomized controlled trial. J Physiother Res. 2019;9(4):524-531. doi: 10.17267/2238-2704rpf.v9i4.2477

Journals BAHIANA
SCHOOL OF MEDICINE AND PUBLIC HEALTH

Study protocol to report the effectiveness of virtual reality therapy in combination with physical therapy protocol for improving balance in traumatic lower limb amputees: A parallel, open-label, randomized controlled trial

Protocolo de estudo para relatar a eficácia da terapia de realidade virtual em combinação com o protocolo de fisioterapia para melhorar o equilíbrio em amputados traumáticos de membros inferiores

Saravana Moorthy[1], Sushma Sagar[2], Vivek Trikha[3], Rajesh Sagar[4], Chhavvi Sawhne[5], Kalaivani Kalaivani[6], Avinash Dargave[7]

[1]Author for correspondence. All India Institute of Medical Sciences. New Delhi, India. ORCID: 0000-0003-2251-4013. aiimsmoorthy@gmail.com
[2]All India Institute of Medical Sciences. New Delhi, India. ORCID: 0000-0002-4700-9868. sushma.sagar@gmail.com
[3]All India Institute of Medical Sciences. New Delhi, India. ORCID: 0000-0001-9488-5847. vivek.trika@gmail.com
[4]All India Institute of Medical Sciences. New Delhi, India. ORCID: 0000-0003-4563-7841. rajesh.sagar@gmail.com
[5]All India Institute of Medical Sciences. New Delhi, India. ORCID: 0000-0002-3815-0085. chhavvi.sawhne@gmail.com
[6]All India Institute of Medical Sciences. New Delhi, India. ORCID: 0000-0002-9430-6929. kalaivani@gmail.com
[7]All India Institute of Medical Sciences. New Delhi, India. ORCID: 0000-0001-7652-3615. avinash.dargave@gmail.com

RESUMO | INTRODUÇÃO: A intervenção em realidade virtual (RV) foi viável em amputados de membros inferiores (AMI). Até onde sabemos, não existe um estudo controlado randomizado disponível sobre a reabilitação do AMI usando RV. As evidências sugerem que são necessárias mais pesquisas para reabilitação de amputados usando VR. **OBJETIVO:** Comparar a eficácia da terapia de RV como um complemento terapêutico adicional com o protocolo de fisioterapia nos limites de estabilidade e estabilidade postural, dor e qualidade de vida entre os AMI. **MÉTODOS:** Um total de 100 AMI foi recrutado por amostragem aleatória simples (gerador de número aleatório) do JPN Apex Trauma Center, AIIMS, para participar de um ensaio clínico randomizado. O AMI recrutado foi dividido aleatoriamente em dois grupos: terapia de realidade virtual juntamente com o grupo protocolo de fisioterapia (VRT-PTP) e o grupo protocolo de fisioterapia (PTP). A duração do tratamento será de 30 minutos em uma sessão / dia, durante 4 dias / semana, durante 3 semanas. Assim, cada AMI receberá 12 sessões no total. O Sistema de Equilíbrio Biodex para medir o equilíbrio dinâmico, NPRS para dor e qualidade de vida pelo WHOQOL-BREF da OMS (WHOQOL-BREF) são as medidas de resultado que serão registradas na linha de base, no final do período pós-intervenção de três semanas. O acompanhamento será realizado na 6ª e 9ª semana após a inscrição. **RESULTADOS:** A normalidade dos dados coletados será confirmada pelo teste de Kolmogorov-Smirnov. A significância estatística intra e inter grupos será determinada por testes apropriados. O tamanho do efeito e a análise de potência serão realizados. **CONCLUSÃO:** Este estudo apresentará dados para a eficácia do VRT na melhora do equilíbrio e da marcha, além do PTP.

PALAVRAS-CHAVE: Amputados. Estudos de acompanhamento. Extremidade mais baixa. Centros de trauma. Realidade virtual.

ABSTRACT | INTRODUCTION: Virtual reality (VR) intervention was found to be feasible in lower limb amputees (LLA). To best of our knowledge, only there is no randomized controlled trial available regarding the rehabilitation of LLA using VR. Evidence suggest that more researches for amputee rehabilitation using VR is warranted. **OBJECTIVE:** To compare the effectiveness of VR therapy as an additional therapeutic adjunct with physical therapy protocol on limits of stability and postural stability, pain and quality of life among LLA. **METHODS:** A total of 100 LLA will be recruited by the simple random sampling (random number generator) from JPN Apex Trauma Centre, AIIMS to participate in randomized controlled trial. Recruited LLA will be randomly divided into two groups, virtual reality therapy along with physical therapy protocol (VRT-PTP) group and physical therapy protocol (PTP) group. Duration of the treatment will be 30 minutes in one session/day for 4 days/week for 3 weeks. Thus, each LLA will receive 12 sessions in total. The Biodex Balance System for measuring dynamic balance, NPRS for pain and quality of life by WHO Quality of Life-BREF (WHOQOL-BREF) are the outcome measures will be recorded at baseline, end of 3-week post-intervention period. The follow-up will be taken at 6th and 9th week after enrollment. **RESULTS:** Normality of the collected data will be confirmed by Kolmogorov-Smirnov test. Statistical significance within and between the groups will be determined. Effect size and power analysis will be performed. **CONCLUSION:** This study will present data for the efficacy of the VRT in improving balance and gait in addition to PTP.

KEYWORDS: Amputees. Follow-up studies. Lower extremity. Trauma centers. Virtual reality.

Submitted 08/03/2019, Accepted 11/11/2019, Published 28/11/2019
J. Physiother. Res., Salvador, 2019 November;9(4):524-531
Doi: 10.17267/2238-2704rpf.v9i4.2477 | ISSN: 2238-2704
Designated editors: Ana Lucia Barbosa Goes, Clynton Lourenço Correa

CC BY

Background

Amputation is the surgical removal of the partial or complete limb. It can either be any level of lower limb or any level of upper limb and can be as a result of the road traffic accident, railway track accident, gunshot injury, earthquakes of significant intensity and terrorism, or carried with medical reasons to improve health status.

According to the National Health Interview Survey of USA[1], in 1996, in each year, two million people were living with an amputee and 185,000 persons undergo upper or lower limb amputations[2]. According to WHO, India has the highest number of road traffic accidents in the world with 16.8 fatal injuries per 100,000 population, and 38.9 non-fatal injuries per 100,000 populations as per the data from 2018. Thus, it can be presumed that traumatic road accidents would be a significant cause of lower limb amputation[3].

The data from JPN Apex Trauma Centre, AIIMS, New Delhi shows that there were 310 lower limb amputations done from the year 2007 to 2014. During this period, the maximum amputations (n=68) were done in 2013-2014. Above-knee amputation is the most common among all the levels of lower limb amputations. In the year 2017, the total number of amputation cases increased to 141. Among them, there were 92 cases of lower limb amputations.

People who undergo lower limb amputation suffer from decreased stability and an altered center of gravity leading to compromise in balance and gait, thus increasing the risk of falling. It also leads to a compromise in their social activity and causes depression[4]. With amputation, the sensory receptors in the lost limb and joints reduce feedback to the brain for decision making during balance and gait. Also, the original control pattern of the brain, i.e., the brain map w.r.t. balance and gait become incorrect after the loss of a lower limb[5]. Phantom limb pain sensation are experienced by 90% of the patients with lower limb amputees. It is the sensation that the missing limb is still present. Majority of these patients experiences pain in this phantom limb which is termed as phantom limb pain[6].

In 2011, Benjamin J Darter & Jason M Wilken presented a case report which described the use of Virtual Reality (VR)–based gait training program. A 24-year-old man with transfemoral amputation was treated with the intervention of the 3-week VR based gait training program which consisted of 12 sessions of treadmill walking with real-time visual feedback on full-body gait kinematics. Improvement in trunk motion was observed at the post-training assessment test, and improvements in pelvis and hip motion were observed in the 3-week follow-up test after the end of therapy. In summary, this case report indicates that the use of the VR environment–based real-time feedback holds excellent assurance in the rehabilitation of individuals with amputation patients[7].

Maintaining an upright posture (balance) is a complex motor skill based on the integration of the visual, sensory, and vestibular systems. The VR technology can be used to provide the user an interactive experience by giving full-body control of animated virtual characters in different scenarios and thus can be used to improve balance and gait[8].

The primary aim of our study is to compare the effectiveness of Virtual Reality Therapy as an additional therapeutic adjunct with physical therapy protocol on limits of stability and postural stability among lower limb amputees. The secondary aims are to compare the effectiveness of Virtual Reality Therapy as an additional therapeutic adjunct with the physical therapy protocol on pain, quality of life and phantom limb pain among lower limb amputees.

Methods/Design

Ethical statement

The study protocol was approved by the institutional research and ethics committee from the AIIMS Ethical Committee, New Delhi (Ref. no. IECPG/110/30.12.2015, RT-39/27.01.2016). The study will be done strictly in accordance with the guidelines of Helsinki declaration, revised 2013. The study will also follow the ethical guidelines issued by the Council for International

Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) under titled, "International Ethical Guidelines for Health-related Research Involving Humans", 2016. After obtaining ethical approval from the institutional ethics committee, the study protocol will be uploaded in open access clinical trial registry platform, Clinical Trials Registry - India (http://ctri.nic.in/), approved by WHO's International Clinical Trials Registry Platform (ICTRP) and International Committee of Medical Journal Editors (ICMJE), with unique Universal Trial Number (UTN), U1111-1238-0243. A Written informed consent will be taken from the participants prior to their enrollment in the study. Permission was obtained from WHO to use WHO Quality of Life-BREF (WHOQOL-BREF) on 1st November 2015. The intervention will be conducted in the physiotherapy unit of the JPN Apex Trauma Centre by an experienced physiotherapist.

Recruitment

This protocol study design will be a Parallel open-label randomized control trial. A total of 100 LLA will be recruited by the simple random sampling (random number generator) from JPN Apex Trauma Centre, AIIMS to participate in randomized controlled study. The participants will be randomized to either receive the Virtual Reality Therapy in addition to the physical therapy protocol (VRT-PTP) or to receive the physical therapy protocol (PTP).

Participants

Patients who have undergone traumatic amputation of lower-limb in JPN Apex Trauma Centre, AIIMS and are coming to amputation clinic for follow-up will be our potential participants for this study. Patients fulfilling the inclusion criteria will be proposed to take part in this RCT. The patients will be informed about the study in vernacular language and participation will be on a volunteer basis. Randomization will be done once the recruitment is complete.

Eligibility criteria

Inclusion criteria

- Community-dwelling adults between 18-60 years of age
- Both male and female patients
- Unilateral traumatic Lower-limb amputees (transtibial or transfemoral)
- Patients who can follow verbal commands
- Medically stable patients
- Patients who can wear the prosthesis for 45-60 min

Exclusion criteria

- Patients with known neurological disorders
- Patients with circulatory disorders
- Patients with a spinal deformity
- Patients who have uncontrolled diabetes
- Patients under Psychiatric Medication
- Patients within 6 months post amputation to minimize the incidence of phantom limb pain[9]
- Patients with BMI ≥ 30

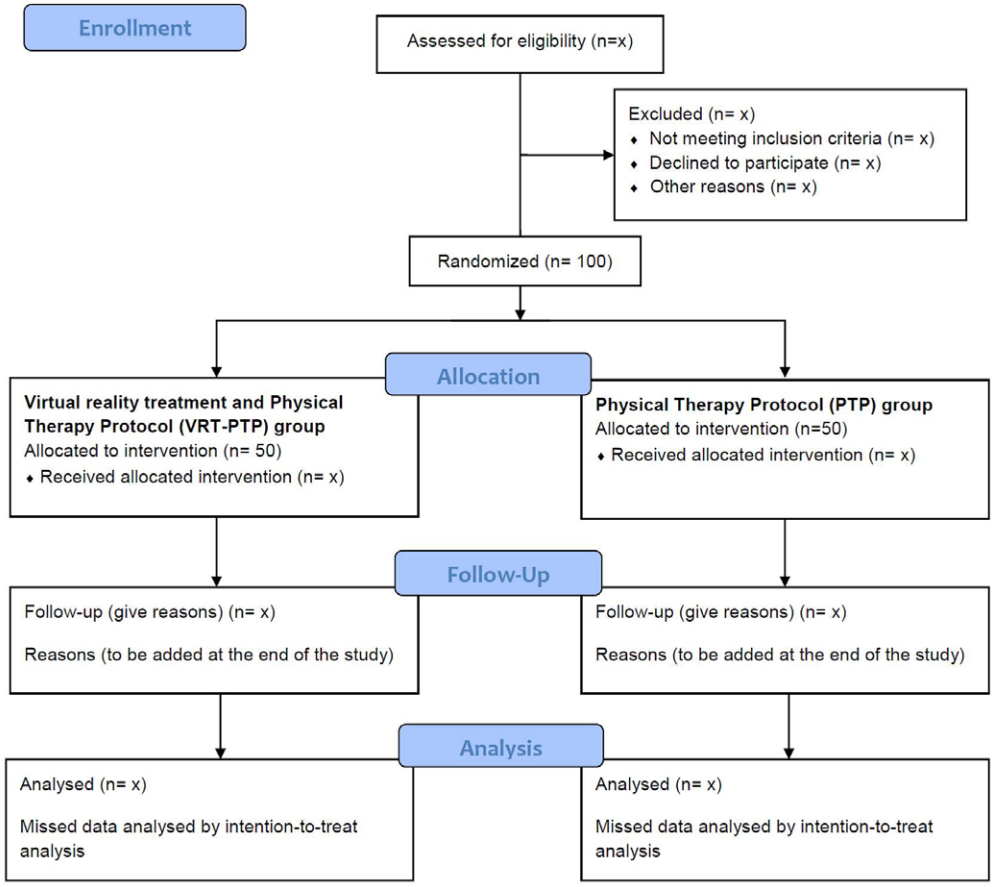
Sample size calculation

The previous study reported that the baseline mean±SD of limits of stability (LOS) for the right limb was 133.89±47.0 in ankle injured young competitive male athletes (n=63). Anticipating 30 units less in the protocol group and 60 units less (73.0±47.0) in the VRT group from the baseline LOS (reported in Vernadakis N et al., 2014) with 5% level of significance and 90% power, the estimated sample size is 44 per group[8]. We will enroll 50 patients considering a 10% loss to follow-up.

Procedure

The patients who have undergone lower limb amputation in JPN Apex Trauma Centre, AIIMS and are coming to its amputation follow-up will be recruited for this study. They will be assessed by the surgeon and detailed musculoskeletal evaluation by trained physiotherapist in the amputation clinic and will be invited to contact the project investigator. The potential participants will be clinically examined to confirm their eligibility. Patient with all the amputation levels will be considered and without distinction as to post-operatory time. Block randomization method will be used. Computer generated blocks of 5 will be used to ensure an equal distribution of participants in each group. The information about the intervention which the enrolled participant will receive will be in the concealed envelope. The envelope will be handed over to the participant by the receptionist of the physiotherapy unit where the intervention will be given. The participant will then show the intervention contained in the envelope to the physiotherapist. Accordingly, the physiotherapist will give the intervention. The physiotherapist will keep the record of every session. The participants will be asked to keep a record of home exercises in a log book. The detailed study protocol is displayed in Figure 1.

Figure 1. Flow diagram



Outcome assessment

Outcomes will be assessed at baseline (time of joining) and at the end of three weeks, six weeks and nine weeks of enrollment. There will be twelve times of 30 minutes sessions in three weeks duration. The intervention will be of three weeks and follow-ups will be until nine weeks.

Primary outcome measures

The primary outcome is stability, both in terms of limits of stability, i.e., to move and control their center of gravity within their base of support, and, the overall stability (Postural stability test) which is the ability to maintain the center of balance. These outcomes will be assessed by the Biodex Stability System (BSS) scoring. Its assessment is reliable as many studies have been done to test its reliability[10].

The postural stability test will measure the ability to maintain the center of balance. The patient's score on this test assesses deviations from the center; thus a lower score is more desirable than a higher score. To test this, the Dynamic Balance test of the Biodex Balance System will be used. In this test, the platform will be unstable surface. The protocol is as follows: Test Duration: 20 seconds; Stability Level: 8 (extent of instability of the platform, range is from static (0 to 12); Stance: Two Legs. The score ranges from 0-20[10].

The Limit of Stability test challenge patients to move and control their center of gravity within their base of support. The platform is static in this test. During each test trial, patients must shift their weight to move the cursor from the center target to a blinking target and back to the centre as quickly and with as little deviation as possible. In the same manner, each of the nine targets is repeated; the targets on the screen blink in random order. The test is a good indicator of dynamic control within a normalized sway envelope. Poor control, inconsistencies or increased times suggests further assessment for lower extremity strength, proprioception, vestibular or visual deficiencies[10].

Secondary outcome measures

There are two secondary outcomes measures- pain and quality of life.

Pain

Pain assessment will be done by the Numeric Pain Rating Scale (NPRS). It measures the average pain the patient has on a scale from 0 to 10. This scale assesses the average pain of the last two weeks. The Phantom limb sensation and its assessment will also be done using NPRS scoring. The NPRS scale has shown better reliability and responsiveness than the VAS (Visual Analog Scale)[11].

Quality of life (QoL)

Quality of life assessment will be done by WHO Quality of Life-BREF (WHOQOL-BREF) scoring. It measures the individual's perceptions of their position in the context of the culture and value systems in which they live and concerning their goals, expectations, standards, and concerns. The WHOQOL-BREF domain scores show good internal consistency and test-retest reliability, content validity, and discriminant validity[12].

Intervention

Recruited patient with lower limb amputee will be provided with the prosthesis of suction pin suspension system and pneumatic prosthetic knees. The VR therapy will be provided by the use of Microsoft X-Box 360 KineticTM. The Xbox 360 KinectTM is a Microsoft AVG console which uses the VR technology to enhance the experience of the user. It provides a video gaming system for full-body control of animated virtual characters an interactive system and thus can work as a VR based technique to improve balance and gait. The reason for selecting seven different games is that in every game, the gameplay is different, which will make sure that the participant is exposed to different scenarios and will adapt to the prosthesis quickly.

The Xbox 360 KinectTM provides a video gaming system for full-body control of animated virtual characters giving the user an interactive experience. The participants will be asked to play seven games viz. River rush 20,000 leaks, Target kick, Super saver, One bowl roll, Rally Tally (Table tennis), Boxing. The intervention protocol is as follows- The patient will be informed about the games before the VR therapy starts. The participant will be familiarized with the game by a trial session of 1-2 min per game on the first day before the beginning of the actual intervention. At the starting of each game, the participant, i.e., the player will follow the instruction of the X-Box 360 for calibration of its motion sensor. The patient will be asked to play the seven games in 30 min session. There will be a 3-4 min session for each game. The total duration of VR therapy is 30 min. The physiotherapist will make sure that the therapy is completed in this period. The participant balance will be assessed by the Biodex Stability System at baseline and the end of therapy, i.e., at the end of 3 weeks after having completed 12 sessions of 30 min each. Apart from the VRT, every participant will be treated with physical therapy protocol (mentioned in the control group).

The physiotherapist will be with the participant during the VRT and physical therapy protocol session. He/she will guide the participants and motivate them during the session in case they are afraid of falling while playing the X-Box game as a part of the VRT session. Also, the physiotherapist will monitor that the participant is playing the game correctly. He/she will also keep track of time to make sure the participant plays all the seven games within the time limit.

Biodex Stability System will be used for the assessment of Balance.

Physical therapy protocol group

Patients in the physical therapy protocol (PTP) group will be treated with regular physical therapy only. The therapy will comprise of traditional prosthetic training consisting of weight-shifting, dynamic balancing activities, stool stepping, braiding, gait exercises, and climbing/descending stairs. Forward-backward and side to side weight shifting exercises will be given to the amputee so that the patient would experience the orientation of the center of mass over the base of support. Single limb balance exercises will be given (stool-stepping) to increase weight bearing on the prosthesis, while advancing the sound limb. Forward and backward stepping with the sound and prosthetic limb, sidestepping and braiding will be taught to patients. Braiding will be given to improve prosthetic control, balance, and coordination. Participants will be trained for three weeks consisting of 12 sessions of 30 minute each.

Training of both groups with prosthetics will be initiated in parallel bars with double arm support and progressed to single arm support. When the amputee succeeds in performing the activities without support, training will continue in an open area.

In both groups, the therapy will be given for three weeks in 12 sessions of 30 min each. In the VRT group, the VRT treatment will be given for 30 min in each of the 12 sessions, in addition to the physical therapy protocol. VRT will be provided soon after the therapy that is set up in protocol, which will make them to have an hour of activities. Then the follow-up will be taken at the end of 6th week and 9th week from the start of therapy/enrollment in the study to assess the retention of balance stability after the VRT treatment.

Statistical analysis

The collected demographic and outcome measures will be assessed for their normality using Kolmogorov-Smirnov test. If the data follow normal distribution, then the descriptive statistics will be expressed in mean ± standard deviation. Paired t test will be adopted to find out the differences within experimental group and control group for pre-post intervention changes. While independent t- test will be used to compare the changes in mean values of the outcome measures between experimental group and control group at baseline and end of 3 week intervention and follow-ups at 6^{th} and 9^{th} week. If the data does not follow normal distribution, then the descriptive statistics will be reported in median with 95% confidence interval (CI) and range. Wilcoxon signed rank test will be adopted to find out the differences within

experimental group and control group for pre-post intervention changes. While Mann Whitney U test will be used to compare the changes in mean values of the outcome measures between experimental group and control group at baseline and end of 3-week intervention. Follow-up will be noted at 6th and 9th week. Missing data during unavoidable dropouts will be analyzed using intention-to-treat analysis. In case of impossibility to achieve the sample size calculated, Post hoc (retrospective) power analysis will be performed using G* Power 3.1.9.4 software to calculate power of the study with the sample size of 60 and analyzed effect size. All the data will be analysed using statistical software, statistical package for social science (SPSS), IBM SPSS version 20.0 (Armonk, NY: IBM Corp.). The p-value ≤0.05 was considered to be statistically significant.

Results

It would be appropriate to expect at least two tables, one with sociodemographic data and another with clinical data of the participants. It would be appropriate to display the numerical data of the results, as well as the length between groups and differences between men and women if applicable.

Discussion

Virtual Reality is an inexpensive and interactive system that provides its users with the illusion of entering a virtual world to encourage people with neuromotor disabilities to regulating the voluntary movement and to improve the proprioception. This study describes the phase-I RCT to assess the effect of VRT in improving balance and gait, pain reduction and quality of life in patients with lower limb amputation.

Our study aims to determine the efficacy of VRT intervention in addition to the current physiotherapy intervention available. The control group will be receiving the physical therapy protocol intervention. This protocol intervention will be used to treat all the patients including the VRT group. The balance, pain and QoL of participants will be assessed and compared between the two groups at the end of treatment (3 weeks), and follow-up assessment will be until nine weeks.

This study will assess the effect on VRT in improving balance, reducing pain in the limb which has undergone amputation, phantom limb sensation and associated pain, and improvement in the psychosocial state by evaluating Quality of life. This work would provide the foundation for the use of a novel and economical therapy in improving the balance and gait of patients with lower limb amputation. Moreover, this therapy could also be accessible to the patient at home.

A recent research carried out by Godlwana et al.[13] have demonstrated the importance of home-based exercise intervention on person with lower limb amputations. Similarly, the conventional method of rehabilitation demonstrated to have high importance by the recent systematic review[14]. But the same review has highlighted the importance of VRT and software-based programs for rehabilitation among the person with lower limb amputations[14]. Hope this study would add clinical relevant information with reference to lower limb rehabilitation by VRT after amputations.

Conclusion

This study will present data for the efficacy of the VRT in improving balance and gait in addition to PTP. These findings will guide the feasibility of phase-II RCT, taking the study to the next level, if VRT improves balance significantly.

Author contributions

Moorthy S and Sagar S conceived and designed the study, conducted research, provided review materials, collected and organized data and wrote the initial draft of article. Trikha V, Sagar R, Sawhne C and Dargave A provided the logistic and technical support. Kalaivani provided statistical assistance and support. All the seven authors approved the final draft.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

References

1. Sinha R, van den Heuvel WJA, Arokiasamy P. Adjustments to amputation and an artificial limb in lower limb amputees. Prosthet Orthot Int. 2014 Apr;38(2):115-21. doi: 10.1177/0309364613489332

2. Adams PF, Hendershot GE, Marano MA. Current estimates from the National Health Interview Survey, 1996. Vital Health Stat 10. 1999;(200):1-203.

3. WHO. Global status report on road safety 2018 - World Health Organization [Internet]. 2018. [cited 2019 Aug 3]. Available from: https://www.who.int/violence_injury_prevention/road_safety_status/2018/English-Summary-GSRRS2018.pdf

4. Hyland NW. A Comparative Analysis of Two Gait Training Approaches for Individuals with Transtibial Amputation [Internet]. Seten Hall University; 2009. [cited 2019 Aug 2]. Available from: https://scholarship.shu.edu/dissertations/56

5. Petrofsky JS, Khowailed IA. Postural sway and motor control in trans-tibial amputees as assessed by electroencephalography during eight balance training tasks. Med Sci Monit. 2014; 20:2695-704. doi: 10.12659/MSM.891361

6. Ambron E, Miller A, Kuchenbecker KJ, Buxbaum LJ, Coslett HB. Immersive Low-Cost Virtual Reality Treatment for Phantom Limb Pain: Evidence from Two Cases. Front Neurol. 2018;9:67. doi: 10.3389/fneur.2018.00067

7. Darter BJ, Wilken JM. Gait training with virtual reality-based real-time feedback: improving gait performance following transfemoral amputation. Phys Ther. 2011 Sep;91(9):1385–94. doi: 10.2522/ptj.20100360

8. Vernadakis N, Derri V, Tsitskari E, Antoniou P. The effect of Xbox Kinect intervention on balance ability for previously injured young competitive male athletes: a preliminary study. Phys Ther Sport. 2014 Aug;15(3):148-55. doi: 10.1016/j.ptsp.2013.08.004

9. Karanikolas M, Aretha D, Tsolakis I, Monantera G, Kiekkas P, Papadoulas S, et al. Optimized perioperative analgesia reduces chronic phantom limb pain intensity, prevalence, and frequency: a prospective, randomized, clinical trial. Anesthesiology. 2011 May;114(5):1144-54. doi: 10.1097/ALN.0b013e31820fc7d2

10. Schmitz R, Arnold B. Intertester and Intratester Reliability of a Dynamic Balance Protocol Using the Biodex Stability System. J Sport Rehabil. 1998;7:95-101.

11. Firdous S, Mehta Z, Fernandez C, Behm B, Davis M. A comparison of Numeric Pain Rating Scale (NPRS) and the Visual Analog Scale (VAS) in patients with chronic cancer-associated pain. J Clin Oncol. 2017;35(31_suppl):217. doi: 10.1200/JCO.2017.35.31_suppl.217

12. Development of the World Health Organization WHOQOL-BREF quality of life assessment. The WHOQOL Group. Psychol Med. 1998;28(3):551-8. doi: 10.1017/s0033291798006667

13. Godlwana L, Stewart A, Musenge E. The effect of a home exercise intervention on persons with lower limb amputations: a randomized controlled trial. Clin Rehabil. 2019;16:269215519880295. doi: 10.1177/0269215519880295

14. Ulger O, Yildirim Sahan T, Celik SE. A systematic literature review of physiotherapy and rehabilitation approaches to lower-limb amputation. Physiother Theory Pract. 2018 Nov;34(11):821-34. doi: 10.1080/09593985.2018.1425938