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Effect of Upper Limb Exercises on Intermittent Claudication in Patients with Diabetes: A Randomized Controlled Trial

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ABSTRACT

Background: Intermittent Claudication (IC) is a pain in the lower leg that develops during exercise. This pain is produced by a restriction of blood flow to the leg muscles as a symptom of peripheral arterial disease (PAD) which develops more in patients with type 2 diabetes mellitus (T2DM). Lower limb exercises are more common among physiotherapists than upper limb exercises (ULE), which, according to certain studies, might be a very helpful technique for patients with IC.

Objectives: This study aimed to investigate the effect of ULE on IC in patients with T2DM.

Methods: Forty T2DM patients with IC, from both sexes, ranging in age from 45 to 55 Years, were recruited from Damanhur Teaching Hospital. They were randomized into two equal groups (n=20). Twenty patients were assigned to the ULE group (group A), which received arm cranking exercise three times per week for three consecutive months plus routine physiotherapy program. Twenty patients were assigned as control group (group B), which received routine physiotherapy program alone three times per week for three consecutive months. The trial evaluated maximum walking distance (MWD), pain-free walking distance (PFWD), claudication score, ankle/brachial index (ABI) and glycated haemoglobin (HbA1c), before-treatment and after three consecutive months of treatment.

Results: The statistical analysis showed that there was a significant increase in MWD and PFWD, while significant decrease in claudication score in favor of group A compared to group B ($p < 0.05$). However, there was no significant difference in ABI and HBA1c between group A and group B ($p > 0.05$).

Conclusions: Upper limb exercises were an effective therapeutic protocol for reducing IC and associated pain, and improving walking distance in diabetic patients with IC.

Keywords: Intermittent claudication, T2DM, Arm cranking exercise.

INTRODUCTION

Diabetes mellitus (DM) is a complicated chronic metabolic disease that necessitates ongoing medical care and multifactorial risk reduction methods. Persistent of hyperglycemia due to either insulin resistance, insufficient insulin production, or both is a hallmark of DM. Over time, type 2 diabetes causes peripheral neuropathy, peripheral retinopathy, peripheral nephropathy, and early microcomplications. Late macrocomplications, which result from artery atherosclerosis, include PAD, coronary artery disease (CAD) and cerebrovascular accidents, all of which have the potential to be fatal. One of the most significant side effects of diabetes is PAD [(1)].

PAD is a serious cardiovascular condition that is typified by ischemia that can affect walking and restrictions in arterial blood flow in the lower limbs and less common in the upper limbs. PAD is frequently brought on by atherosclerosis. PAD can cause IC, unusual leg symptoms, critical limb ischemia, and functional deficits in the lower extremities. However, individuals with PAD are at a considerable risk of cardiovascular morbidity and mortality regardless of the existence of symptoms [(2)].

The medical word for lower leg (or both legs) discomfort that occurs during exertion, such as walking, and often goes away after a short period of rest is "IC". Blood supply to the leg muscles is restricted, which causes this discomfort. This limitation in blood flow is caused by the partial obstruction of arteries (Vessels that supply oxygen-rich blood across the body) by a build-up of fatty deposits (atherosclerosis). As a result, the muscles in the legs receive less oxygen [(3)]. Compared to claudicated individuals without diabetes, patients with IC and DM had worse hemodynamic state, a worse QoL, and greater risk cardiovascular factors, CVD, and disability[(4)].

Pharmacotherapy, physical exercise therapy, and surgical or percutaneous vascular procedures are among the treatment options for IC. There is substantial evidence to support the idea that exercise treatment should play a key role in the management of IC by reducing the risk of cardiovascular events and considerably improving PFWD and MWD. The general agreement is to start treating patients with IC with supervised exercise therapy since it is thought to be more beneficial than unsupervised exercise treatment,

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especially supervised exercise therapy, which often include walking on a treadmill [(5)].

Patients with IC can improve their walking abilities with exercise training, which is a low-cost, safe, and effective intervention. Enhancements in muscle strength, cardiorespiratory fitness, and quality of life (QoL) are possible further advantages. Clinical guidelines support supervised exercise training as a key treatment for IC, with walking as the preferred modality. Nonetheless, there is growing evidence that walking training may be enhanced by a variety of other forms of exercise, such as cycling and progressive resistance training. Furthermore, there is growing support for workout regimens that are done at home [(6)].

People with lower limb claudication may benefit greatly from upper arm training, or arm cranking. It has been proposed that increasing cardiovascular endurance might help with gait improvement. It has been proven that workouts of upper limbs boost the antioxidant potential and lead to the expansion of painless and maximal distance of claudication. Undoubtedly, it is also reasonable to assume that this type of exercise helps to enhance the circulatory system overall, develop the muscles in the upper limbs, and may normalize blood pressure [(7)].

The aim of the current study was to investigate the effects of ULE on IC in diabetic patients. This could be introduced through increased walking distance and reduced IC pain. Therefore, decreased patient symptoms and complain, increased functional capacity, and improved QoL in such diabetic patients with IC.

PATIENTS AND METHODS

Patient: Forty patients with T2DM suffered from IC were recruited by referral from the Internal Department of Damanhour Teaching Hospital, Beheira Governorate, Egypt. This study's participants were divided into two equal groups (n = 20). The data of this study was collected from February 2023 to February 2024.

Inclusion criteria: Both sexes, with ages ranging from 45 to 55, body mass indices between 25 and 34.9, T2DM diagnoses at least 5 years before, HbA1c levels between 7 and 7.5%, and IC.

Exclusion criteria: Pregnant women, malignancy, uncontrolled hypertension, osteoporosis, past medical history of medical conditions that might influence the provision of physiotherapy interventions e.g., (Severe asthma, chronic airflow limitation, bronchiectasis, ankylosing spondylitis or lumbar disc prolapse), and smokers.

Design: In this clinical experiment, patients were split into two groups at random using envelope method, with the same number of patients in each group. After patients consented to take part in the experiment, cards with the groups "Arm cranking exercise" and "Routine physiotherapy" inscribed on them were sealed in envelopes. The next step was to ask a physical therapist who was blind to the research protocol to select an envelope.

The chosen card was used to allocate patients to the relevant group. Following the first week of the randomized procedure, the treatment's start dates were established. The physiotherapist who served as the assessor was not informed of the intervention assignment and was not involved in the randomization procedure. Patients were told to keep their therapy assignment a secret from the physiotherapist throughout the evaluation. Patients were encouraged to report any unfavorable results during the course of therapy.

Sample size calculation: Sample size was calculated using MWD as described in the pilot research, with 90% power at $\alpha = 0.05$ level, for two groups, two measurements, and effect size = 0.56 using F test, MANOVA repeated measures, within and between interaction. The minimum required sample size was 36 individuals, plus 4 people (11% dropout), for a total sample size of 40 subjects, 20 in each group. The sample size was determined with the G*Power program (version 3.0.10).

Assessment of eligibility: Forty-five patients were evaluated for eligibility in this research. Two patients declined to take part in the trial, while three patients did not fit the inclusion requirements. Two groups of 20 patients each were randomly selected from the remaining 40 patients. Every patient assigned was monitored and subjected to statistical analysis (Figure 1).

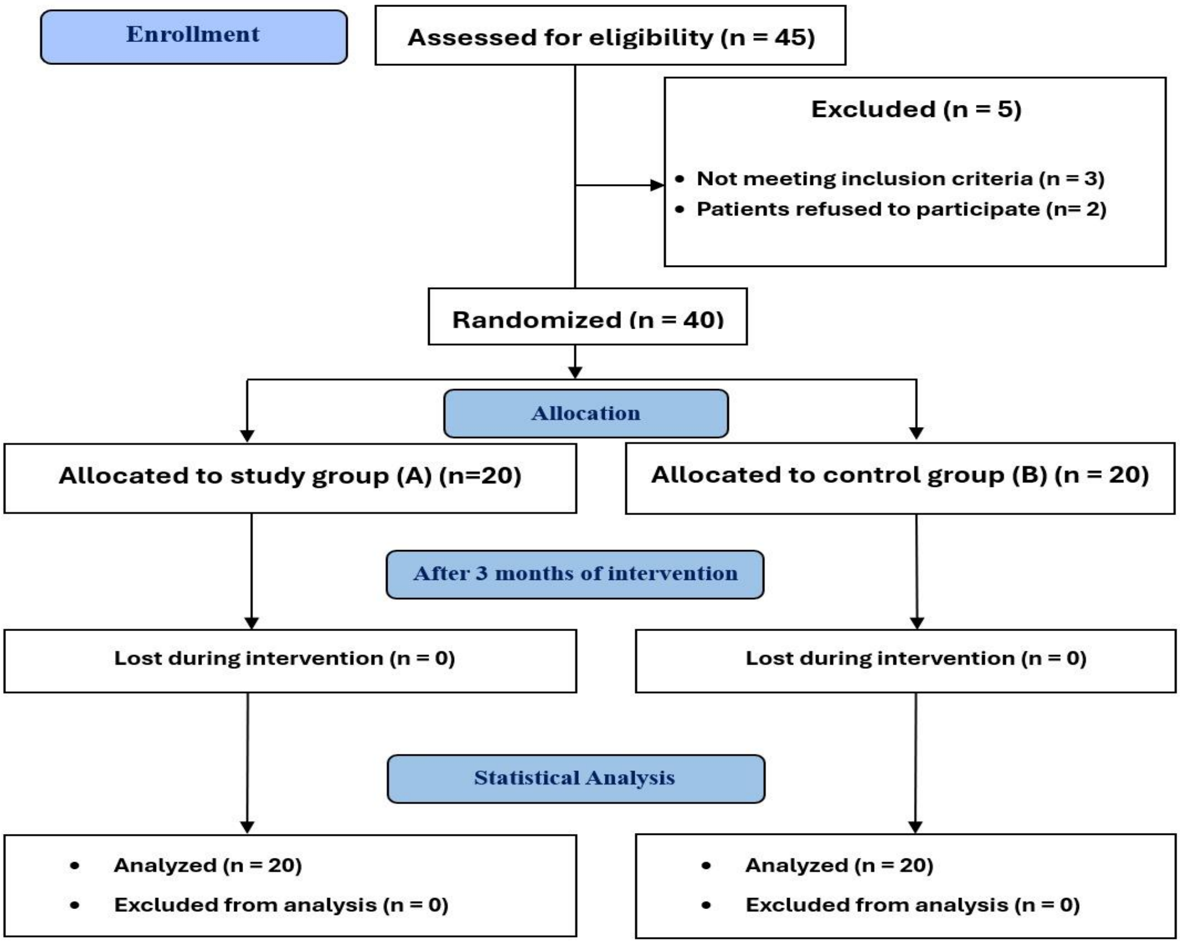

Figure (1): Flow chart of the study.

Outcome measures:

Maximum walking distance: The distance walked on the treadmill before patients were unable to continue due to excruciating claudication discomfort was known as MWD [(8)]. The patients began the MWD test on the treadmill wearing comfortable clothing and shoes, moving at a steady 3.2 km/h pace and increasing the inclination by 2% every two minutes after starting at 0%. The testing period was extended to 30 minutes (1600 meters) and the incline was increased to 10%. The treadmill distance was recorded at the point at which the patients' excruciating claudication discomfort prevented them from continuing.

Pain free walking distance: The distance that patients could walk before experiencing claudication discomfort was known as PFWD [(8)]. The patients began the PFWD test on the treadmill wearing comfortable clothing and shoes, moving at a steady 3.2 km/h pace and increasing the inclination by 2% every two minutes after starting at 0%. The testing period was extended to 30 minutes (1600 meters) and the incline was increased to 10%. They assessed the distance walked prior to the onset of claudication discomfort. To categorize the level of functional impairment in IC patients, both MWD and PFWD were employed. It has been demonstrated that both distances are accurate measurements with high repeatability[(9)]. All patients had their MWD and PFWD assessed and documented both before and after the study's length.

Claudication score: The claudication pain scale is a continuous scale with 1 denoting no pain and 5 denoting extreme pain. Patients are frequently instructed to walk until their pain levels are close to their maximum [(10)]. The patients selected from charts 1 for no pain, 2 for the start of discomfort, 3 for mild pain, 4 for moderate pain, and 5 for severe (maximal) pain once they had completed 200 meters on the treadmill. All patients had their claudication scores taken both before and after the study's length.

ABI: In clinical practice, the ABI is frequently employed as a non-invasive technique to identify the existence and severity of PAD. ABI ultrasonography measures blood flow to the legs and feet quickly, painlessly, and non-invasively. In order to investigate for any issues and gather data on general blood circulation, a medical professional compared the arterial blood pressure in the ankle to the blood pressure in the arms. Blood flow to the extremities may have been hampered by blocked or constricted arteries, as indicated by a low ABI number [(11)]. The timeliness and consistency of peripheral ischaemia screening can be improved by using ABI testing, which is sufficiently valid and reliable for use during routine exams [(12)]. The ABI was determined for each subject both before and after the study's length by dividing the SBP at the ankle by the SBP at the arm.

HbA1c: Glycated hemoglobin is referred to as HbA1c. It is the mean of the last two to three months' blood glucose (sugar) readings. 48 mmol/mol (6.5%) or less is the optimal HbA1c level [(13)]. HbA1c was detected at laboratory field by blood sampling measurement for all patients before and after the duration of the study.

Intervention:

Arm cranking exercise: The study group received ULE by arm crank ergometer for sixty mints, 3 times per week for three consecutive months combined with routine physiotherapy program. The arm crank ergometer can be used to measure physical fitness and it is reliable and valid [(14)]. Before starting the program, patients completed an adaptation session to become familiar with the ergometer and to determine the appropriate training load. First, the seat height was adjusted to align the patient's shoulders horizontally with the machine's rotational axis. The patient assumed an upright position then was asked to move his/her arms in a clockwise or counterclockwise direction for two minutes of warm-up against no resistance then he started baseline arm-ergometry test by maintaining a steady pace of sixty rotations per minute with a workload of ten watts. Until the patient was unable to continue, the intensity was manually raised by ten watts every three minutes. The power at which the patient ceased exercising was noted as the maximum power attained [(15)].

Every patient started exercising at a pace of fifty cycles per minute, one work level (ten watts) lower than the maximal level attained during their baseline arm-ergometry test. For up to sixty minutes, participants fought sporadically against this load by exercising for two minutes at a time and then resting for two more minutes. Exercise intensity was raised to the work level in watts attained at the baseline arm-ergometry test following three weeks of training. Throughout the training period, the amount of time spent exercising was gradually raised by one minute every two to three weeks, and the amount of time spent resting was reduced to one minute. This resulted in a maximum volume of five minutes of activity and one minute of rest for sixty minutes [(16)].

Routine physiotherapy program: As part of their usual physical treatment, both groups were given monitored treadmill walking sessions. The concepts of this treatment are based on the 2007 TASC II (Inter-Society Consensus for the Management of Peripheral Disease) recommendations and the 2017 ESC (European Society of Cardiology) guidelines, which were developed in partnership with the ESVS [(17,18)].

For three straight months, three times-weekly, 30- to 60-minute training sessions were held. The treadmill's incline ranged from 0 to 10, and the walking speed remained constant at 3.2 km/h. Additionally, it is stressed that walking should never cause the greatest amount of discomfort in ischemic muscles. The improvement in walking time was a sign that the training level should be raised (The treadmill's inclination should be gradually increased to a maximum of ten). At first, training sessions lasted around thirty minutes. Training sessions were prolonged by five minutes every two weeks [(7)].

Ethical approval:

The study's full scope was explained, all patients provided informed permissions, and the study was authorized by The Research Ethical Committee, Faculty of Physical Therapy, Cairo University [No:P.T.REC/012/005716]. The Helsinki Declaration was followed throughout the course of the investigation.

Statistical analysis

SPSS for Windows, version 20.0, was used for statistical analysis. The assumption of normalcy, homogeneity of variance, and the existence of extreme scores were checked in the data. Since all of the measured variables were found to be regularly distributed by the Shapiro-Wilk test for normality, Mean.± SD, X^2-test and MANOVA were utilized to examine the data. The alpha threshold is 0.05. To find out how the intervention affected the variables being assessed, a MANOVA was used. In addition to the substantial effects of treatment (p=0.001) and time (p=0.001), there was a significant interaction effect of (treatment * time) (p=0.001).

RESULTS

Age, weight, height, and BMI mean values did not significantly differ between the two groups (p = 0.179, 0.763, 0.198, and 0.315, respectively). The groups' sex distributions did not differ significantly (p = 1) (Table 1).

Table (1): General characteristics of subjects of two groups

	Group A	**Group B**	**t-value**	**p-value**
Age (years)	49.2 ± 3.3	50.4 ± 3.3	-1.4	0.179
Weight (kg)	83.5 ± 6.7	82.8 ± 7.4	0.3	0.763
Height (cm)	165.2 ± 6	167.3 ± 4.5	-1.3	0.198
BMI (kg/m²)	30.3 ± 2.7	29.7 ± 2.2	1	0.315
Sex Females Males	12 (60%) 8 (40%)	12 (60%) 8 (40%)	$\chi^2 = 0$	1

MWD: After the research, the mean MWD value in group A increased by 19% (p = 0.001), while the mean MWD value in group B increased by 4% (p = 0.001), both of which were statistically significantly increased. The mean MWD values before and after the study did not change statistically significantly (p = 0.525), although group A benefited from a statistically significant difference (p = 0.001) after the research (Table 2).

PFWD: Both group A and group B showed statistically significant increases in their mean PFWD values after the trial, with group A's mean value rising by 43% (p = 0.001) and 6% (p = 0.001), respectively. Pre-study PFWD mean values did not differ statistically significantly between groups (p = 0.477), while post-study PFWD mean values did differ statistically significantly between groups (p = 0.001), favoring group A (Table 2).

Claudication score: For group A, the mean claudication score decreased by 45% (p = 0.001) after the research, while for group B, the mean claudication score decreased by 30% (p = 0.001) after the study. The mean claudication score values before and after the trial did not change statistically significantly (p = 0.477 and p = 0.042, respectively), although group A benefited from a statistically significant difference after the study (Table 2).

ABI: After the research, the mean ABI value in group A increased by 16% (p = 0.001), while the mean ABI value in group B increased by 9% (p = 0.001), both of which were statistically significantly increased. The mean ABI values before and after the trial did not alter statistically significantly (p = 0.493 and p = 0.094 respectively) and were not statistically significant (Table 2).

HBA1c: After the study, the mean HBA1c value in group A decreased by 4% (p = 0.001), while the mean HBA1c value in group B decreased by 2.5% (p = 0.001), both of which were statistically significant. When comparing the mean HBA1c readings before and after the trial, there was no statistically significant change between the groups (p = 0.594 and p = 0.339 respectively) (Table 2).

Table (2): Comparison between pre- and post-study mean values of MWD, PFWD, claudication score, ABI and HbA1c of both groups

Measured variables	Group A	Group B	f-value	P value
MWD (m)				
Pre-study	269.4 ± 7.8	270.9 ± 7.4	0.4	0.525
Post-study	320± 8.1	280.8± 8.2	229	0.001*
% of change	19%	4%		
(P-value)	0.001*	0.001*		
PFWD (m)				
Pre-study	138.7 ± 6	139.9 ± 4.9	0.52	0.477
Post-study	199 ± 12.4	148 ± 7.4	261.8	0.001*
% of change	43%	6%		
(P-value)	0.001*	0.001*		
Claudication score				
Pre-study	3.1 ± 0.79	3.15 ± 0.75	0.04	0.838
Post-study	1.7 ± 0.73	2.2 ± 0.77	4.4	0.042* * *
% of change	45%	30%		
(P-value)	0.001*	0.001*		
ABI				
Pre-study	0.67 ± 0.08	0.68± 0.07	0.48	0.493
Post-study	0.78 ± 0.09	0.74 ± 0.07	2.95	0.094
% of change	16%	9%		
(P-value)	0.001*	0.001*		
HbA1c				
Pre-study	7.2± 0.17	7.2 ± 0.18	0.29	0.594
Post-study	6.92 ± 0.3	7.02 ± 0.38	0.94	0.339
% of change	4%	2.5%		
(P-value)	0.001*	0.002*		

MWD: maximum walking distance, ABI: ankle brachial indices, HBA1c: glycated hemoglobin, *: significant.

DISCUSSION

This study aimed to investigate the effect of ULE on IC in diabetic patients. In this study, the results showed that there was significant increase in MWD, PFWD, and ABI post-treatment compared with that pretreatment in both groups (p >0.001). The percent of change in MWD, PFWD and ABI in study group was 19% and 43%, 13% respectively, while in control group was 4%, 6% and 9% respectively. There was significant decrease in study group in claudication score and HBA1c by 45% and 4% respectively, while in control group was 30%, 2.5% respectively. Between groups analysis, there was significant difference in MWD, PFWD, and claudication score in favor of group (A). Therefore, it was beneficial to add arm cranking exercises to routine physiotherapy program prescribed for such diabetic patients with IC.

Exercise training in both upper extremity (UE) and lower extremity (LE) formats was well tolerated, but since ULE training prevents the ischemia discomfort that occurs when LE effort occurs, it might be utilized in the initial phases of an exercise rehabilitation program until patients feel more capable and secure enough to perform LE exercises. For individuals with more severe condition, it could also be the preferable form of exercise. Painful UL arthritis and other musculoskeletal disorders that impair arm or grip strength are contraindications to this type of exercise training [(19)].

Many patients may be deterred from engaging in LE exercise rehabilitation due to the frequency and intensity of ischemia discomfort brought on by basic walking routines, dynamic and static leg exercises, and customized treadmill exercises. Furthermore, the high comorbidity rates make it difficult to do LE exercises and discourage some patients from participating in such programs. Alternative training techniques, such as UE exercises, might help overcome these obstacles and lessen or even eliminate claudication discomfort when training. Current knowledge of peripheral endothelial function supports the possibility that such exercise regimens might have further effects [(20)].

Numerous investigations have been carried out to look at how ULE affects IC. A research comparing the effectiveness of arm-ergometry and treadmill exercise training to increase walking distance in claustrophobic patients was conducted by **Treat-Jacobson *et al.*** [(16)]. In comparison with a control group, 41 claudication patients received twelve-weeks of supervised exercise instruction utilizing arm-ergometry, treadmill walking, or a combination of the two. Before, during, and after a twelve-weeks follow-up, measurements of PFWD and MWD were made. At twelve-weeks, MWD significantly increased in the arm-ergometry, treadmill, and combination groups as compared to the control group. At twenty four weeks, MWD gains were sustained by the arm-ergometry and treadmill groups, but not by the combination group. The arm-ergometry group saw a substantial rise in PFWD after twelve-weeks, which was maintained at the twenty four weeks follow-up. In contrast, the treadmill and combination groups did not exhibit any discernible improvement in PFWD. Compared to LE claudication in the treadmill group, the arm-ergometry group in this study had a higher chance of a systemic training impact since their exercise training length and intensity were only constrained by exercise-induced exhaustion.

Some studies suggest that arm cranking, or upper arm training, can be a very helpful treatment for people with lower limb claudication. Enhancing cardiovascular endurance has been proposed as a potential factor in improving gait. It has been shown that UL workouts improve antioxidant capacity and enhance the painless and maximal claudication distance. It is reasonable to assume that this type of training will also help to strengthen the UL muscles, possibly normalize blood pressure, and enhance the circulatory system overall. The load should be selected with the best conditions for cardiovascular training in mind [(7)]. Furthermore, a research comparing the effects of upper-versus LE aerobic exercise training on health related QoL in individuals with symptomatic PAD was conducted by **Saxton *et al.*** [(19)]. After six weeks of exercise training, there were only little changes, however, throughout the course of the 24- to 72-week follow-up period, the UL group showed more notable improvements. According to the study's findings, arm-cranking exercise may be able to stimulate systemic anti-inflammatory responses in IC patients more effectively than LE exercise, which might improve cardiovascular health. Arm-cranking exercises that increase upper-body strength and endurance may also have a good effect on day-to-day activities.

Bronas *et al.* [(21)] examined how walking distance and central cardiorespiratory improvement were affected by upper body-ergometry aerobic training vs treadmill training in 28 individuals with PAD-related claudication. For twelve weeks, they participated in three hours a week of supervised exercise training using either treadmill walking or arm ergometry. Both exercise modalities significantly improved walking distance and cardiorespiratory performance, according to the study, and there were moderate associations between walking distance changes and cardiorespiratory characteristics. The study found a strong correlation between improved PFWD and MWD in claudication patients and improvements in cardiorespiratory function after arm ergometry or treadmill training. These results provide credence to the systemic effects of exercise training on walking capacity gains. In both the arm-ergometer and treadmill-walking exercise groups, this study demonstrated the important contribution that enhanced overall physical conditioning and systemic cardiorespiratory function made to improve walking ability. However, a comprehensive review of upper vs lower limb exercise training in individuals with IC was conducted by **Tompra *et al.*** [20]. Although, neither UE nor LE training was determined to be better than the other, this review showed that both were successful in increasing MWD, claudication distance, and VO_2peak. Even though LE exercises are often utilized by therapists, patients typically do not respond well to them because of the physical discomfort they suffer throughout the exercise. Other workout routines, like UE training, might offer a compelling complimentary option. Additionally, **Jansen *et al.*** [3] evaluated the impact of other forms of supervised exercise treatment in comparison with conventional walking exercise in patients with IC by using systematic reviews on exercise training methods for IC. Five more studies were included for this update, bringing the total number of randomized trials using IC to ten, which comprised 527 individuals. Numerous exercise rehabilitation modalities were examined, including Nordic walking, upper-arm ergometry, cycling, LE resistance training, and combinations of these activities. Because the studies utilized various measurements, a meta-analysis was performed exclusively on the walking impairment questionnaire (WIQ) distance score. There was little to no difference across groups, according to the results. Overall, it was shown that supervised walking exercise and other types of exercise did not significantly differ in their ability to increase maximal and PFWD in people with IC.

CONCLUSION

ULE were an effective therapeutic protocol for reducing IC and associated pain, and improving walking distance. Therefore, increased exercise capacity and functional abilities, decrease risk of cardiovascular morbidity and mortality, and improved QoL in such diabetic patients with IC.

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