(a) Complete Manuscript Title: **Training Programme Intervention to Encourage Physical Activity for Health in People with Transtibial Amputation, A Feasibility Study**

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Training Programme Intervention to Encourage Physical Activity for Health in People with Transtibial Amputation, A Feasibility Study

Background: People with transtibial amputation (PTTA) would benefit from increased physical activity levels (PAL) but generic programmes developed to support increased PAL do not address the barriers which PTTA experience.

Aim: To evaluate the effect of a 12-week training programme, developed for PTTA, on their PAL.

Methods: 10 PTTA participated in a 12-week training programme, which involved one instructor-led supervised group session per week. The programme incorporated balance, flexibility, cardiovascular endurance, strength, and agility, as well as educational elements. Personalised starting level and progression intensity were based on the instructor's assessment in the first training session. The effect of the intervention on PAL (self-report questionnaire and accelerometer), fitness, walking symmetry, and adverse effects was determined by ANOVA before and after the intervention.

Results: There was a significant increase in self-reported time in moderate intensity activity and accelerometer measured step count and time in movement after the programme compared to baseline ($P=0.02$). The distance walked in the 6MWT ($P<0.001$), time to perform agility test ($P=0.01$), and lower limb strength power ($P=0.01$) and endurance ($P=0.01$) were significantly greater after the programme, and no adverse effects identified.

Conclusions: This study demonstrated an intervention designed specifically for PTTA which can increase physical activity levels.

Key Words: Physical activity: Lower Limb Amputation: Disability Activity: Amputee Activity

Background

Lower limb amputation (LLA) is a disabling condition and people with LLA have been found to be less physically active, both in the number of hours and the range of activities, compared to matched populations without a disability [1]. People with LLA report that the high energy cost of movement and its associated fatigue, along with asymmetrical loading on the remaining anatomy which can lead to pain and long-term joint degeneration, are associated with reduced physical activity levels (PAL)[2]. People with a transtibial amputation (PTTA), experience an average of two comorbidities per individual, even for individuals whose amputation is due to trauma [3]. Safe and effective interventions aimed at increasing PAL which accommodate the musculoskeletal needs of people with LLA are justified.

Programmes such as the UK's 'Couch to 5K' [4], have been developed to support adults to reach the international physical activity guidelines (150 minutes of moderate intensity activity every week)[5]. For people with LLA, barriers to participation in these programmes have been identified. These include: musculoskeletal barriers - limitations of the prosthesis and remaining musculature which increase the energy cost of moving [6–8] and impact walking, running and other movement patterns and increase the risk of falling when active [9–12]; psychosocial barriers – internal perceptions and those of the wider community, fear of pain and falling [6,13,14]; environmental barriers – accessibility and appropriate resources, cost and specialised equipment [2,15] and educational barriers – knowledge of types of physical activity

which are safe to complete and how to adapt exercises to accommodate musculoskeletal issues and residual limb skin blistering and breakdown [6,15].

Previous exercise interventions for PTTA which have been developed are limited to those focusing on developing specific components of fitness and have demonstrated improvements in those targeted components, including cardiovascular endurance [16] and strength [17]. Interventions which address multiple components of fitness have demonstrated positive results in reducing falls in ambulatory people with LLA [18], and in developing capacity for weight bearing on their prosthetic limb [19].

To the best of our knowledge there is no multiple component training programme which aims to increase PAL. A training programme which is adapted to the movement limitations experienced by PTTA and individualised to accommodate a person's initial level of overall fitness could address both short- and long-term risks associated with physical inactivity or participation in inappropriately adapted programmes. This first stage of the research was to determine if an exercise programme developed with and for PTTA, supplemented by education, was effective in increasing PAL. The findings will contribute to developing and implementing a randomised control trial to determine the efficacy of the programme.

Aim

The aim of this feasibility study was to determine if an instructor-led exercise programme, developed for PTTA, with concurrent education elements influenced PAL. The hypothesis was that the training programme would increase time in moderate and vigorous physical activity, time in movement and daily step-count.

Methods

This feasibility trial was conducted at a rehabilitation centre and was carried out as a non-randomised, single-centre study which examined the pre-post effect on the primary outcome of PAL and the secondary outcomes of physical fitness and adverse responses. The exercises and educational elements are the focus of the intervention, aiming to address musculoskeletal and educational barriers. To address environmental and psychosocial barriers, the costs were kept to a minimum (e.g., no sports limbs or specialised equipment were required) and the in-session interactions between peers created a supportive environment.

Participants

A postal invitation was sent to 119 patients with transtibial amputation who had successfully completed prosthetic training, identified by the rehabilitation centre registration system. The response rate was low and ten people (8%) agreed to participate (participant details are included in Table 1) and were found to meet the inclusion criteria. The inclusion criteria required that they had unilateral transtibial amputation, were adults (aged ≥18 years), using their prosthetic limb and had spent a minimum of six-months at a Medicare Functional Classification Level of K2 (limited community ambulator) or higher, with or without walking aids, and were able to communicate in English. Participants were excluded if they were a professional or semi-professional sports person (i.e. are paid for participation), were currently pregnant, had been advised to refrain from physical activity by a health professional, had physical issues or had recently suffered trauma which may be aggravated by the programme and its associated testing (e.g., a recent injury, any activity related disorders, healing bone fracture), were unable to walk on their prosthesis, or if they were presently involved in or have been involved in more than two research trials in the last twelve months. The intervention protocols were reviewed and approved by the relevant research authority (ref 18/LO/0602 project ID: 232221) as well as the University Ethics Committee. Only PTTA

willing to participate and complete a consent form were included, no sample size calculation was made. All participants attended testing and training in their own appropriate clothing and their chosen prosthetic limb.

*****Insert Table 1 about here ******

Intervention

The intervention was developed in two stages. The first stage included one group of PTTA collaborating with one instructor to design the content and nature of the sessions. This allowed decisions to be made on: the number of sessions and their location (home/clinic); which exercises should be included, what they should be called and how they should be described; how the exercises should be administered in the session (resulting in the decision that the strength session should rotate the exercises at a personal station rather than the person rotating around a circuit); the levels of personalisation of exercises based on their intensity and progression; developing the home exercise sheets; identifying the educational elements required and developing the materials to support residual-limb care, understanding the principles of training and overload, method of monitoring heart-rate and information on the health-related benefits of exercise.

Thereafter, a 12-week training programme which involved one instructor-led supervised session in-clinic per week (at the recruiting rehabilitation centre) was delivered. Participants wore their prosthetic legs to each training session, all of which were led by a physiotherapist experienced in working with PTTA. Two participants from the first stage later participated in the 12-week training programme. Educational elements covering exercise theory and limb care were included throughout each session (detailed in supplement 1). All sessions included a warm-up which consisted of Tai Chi for balance and flexibility and a cool-down which consisted of agility games. The middle of the session followed either a cardiovascular focused session (walking) or a strength focused session

(bodyweight/resistance bands). The starting level and progression intensity for all elements were personalised based on the instructor's assessment during baseline tests, and during ongoing sessions using the Modified Rating of Perceived Exertion scale[20]. These could be increased or decreased following a discussion between instructor and participant, depending on their ability to perform exercises (support needed in balance, baseline heart rate in walking, ability to perform three set of 12 reps in strength etc.). Home sessions were included from Week 3 increasing from a single home session in Week 3 to 4 sessions by Week 12. The home workout programme involved repeating the class session and prescribed time in walking. A supporting handout which illustrated the exercises they should complete was made available to each participant in print or digital format (depending on participant's preference). The full programme is outlined in Supplement 1.

Outcome Measures

The trial had four primary outcomes related to PAL: time in moderate physical activity, and time in vigorous physical activity (both as defined in the International Physical Activity Questionnaire-Short Form, IPAQ-SF), step count and time in movement. The IPAQ-SF defines moderate activity as those which *"make you breathe somewhat harder than normal"*, and vigorous activities *as* those which "*make you breathe much harder than normal."*

A range of secondary outcomes, related to (i) adverse responses including falls, pain, (ii) walking asymmetry and (iii) fitness including cardiovascular endurance, strength and balance were also monitored in order to comprehensively evaluate the feasibility of the programme.

Primary outcome measures

PAL were monitored using the IPAQ-SF [21,22]ivPAL™ activity monitor [23]. The IPAQ-SF was completed in the week prior to the first session (Week 1 (Wk 1)) and repeated after

the final session (Week 12 (Wk 12)) as well as a three-month review (Week 24 (Wk 24)). The IPAQ asks participants to record the time spent being physically active in the last 7 days, considering bouts of longer than 10 minutes. Vigorous activities refer to "activities that take hard physical effort and make you breathe much harder than normal". Moderate activities refer to "activities like carrying light loads, bicycling at a regular pace or doubles tennis…do not include walking". The ActivPAL™ was placed on the thigh, following manufacturer instructions. It was affixed, by the instructor, to the ventral aspect of the thigh on the intact limb, using water-proof tape to ensure that it did not need to be detached during Wk 1 and Wk 12,and was removed before the intervention session. The device records the daily step count and free-living daily time in movement using an accelerometer to sense limb position. Although some intensity can be recorded, this is calculated by step frequency and not heart rate, thus we did not extract this measure given its insensitivity for people with amputation. ActivPAL™ has a default threshold of a minimum of 10 seconds of activity to register as a bout of activity [24]. Average data per day was calculated using a 3-day period in the middle of 7 days of wear.

Secondary outcome measures

To determine if participation in the exercise programme had a detrimental effect on the participants, adverse responses were recorded. Participants were given education and support in reviewing the skin on their residual limb before and after activity and to report any adverse responses. The self-reported number of trips (caught the feet but did not start to fall), stumbles (almost fallen but able to right themselves) and falls (made contact with the floor) were recorded by the instructor at the start of the in-clinic supervised weekly session. Pain intensity and quality were recorded using the McGill Scale [25] at Wk 1 and Wk 12.

Walking symmetry was determined by assessing the acceleration of an accelerometer placed on the sacrum during straight line walk [26] which was performed twice over an eight-meter distance.

Tests to determine if participation in the exercise programme resulted in fitness gains included: walking cardiovascular endurance (6MWT); strength (power: time for 5 sit to stand, endurance: number of sit-to-stand in 30s, Systemic: isometric handgrip); balance (30s single leg balance) and agility (modified T-Test); Details on the testing protocol and their results are included in Supplement 2.

Data analysis

Data were acquired from the same 10 participants. Following Shapiro-Wilk test for normal distribution the difference in data between Wk 1 and Wk 12, and Wk 24 were assessed using Friedman test (as all were found to be non-normally distributed), and between Wk 1 and Wk 12, where relevant, were assessed using a paired t-test or Wilcox sign-rank test (for non-normally distributed data). All data were assessed using SPSS (IBM, version 26).

Results

10 PTTA participants met the participation criteria and were able to attend training (Table 1). Adherence to the programme was good with an average of 77% attendance maintained at supervised sessions.

Primary Outcomes

The group median (inter-quartile range) and each participant's self-reported time in moderate physical activity, time in vigorous physical activity are presented in Figure 1 (a-b). There was a significant increase in time in moderate physical activity across the three testing times ($\chi 2(2) = 9.00$, $p = 0.01$). Post hoc pairwise analysis was conducted with significance adjusted by the Bonferroni correction. A significant increase in time in moderate activity was identified between baseline (Wk 1) and three-months post completion of the programme (Wk

24). Between Wk 1 and Wk 12 the increase in time in moderate intensity activity tended towards significance and a large effect size was found between Wk 1 and both Wk 12 and Wk 24. No significant difference was found for time in vigorous physical activity, but a moderate effect size was found between Wk 1 and Wk 12, and between Wk 1 and Wk 24.

**** Insert Figure 1 about here ****

Analysis of the ActivPAL™ data indicated that step count and time in movement (regardless of intensity) were significantly different before and after the intervention (Figure 2 (a-b)). One participant's time in movement data (I6) was not included as an ActivPAL™ recording error was noted (ActivPAL™ reported standing for the majority of day and night for full time of wear).

**** Insert Figure 2 about here ****

Secondary Outcomes

Adverse response: Supplement 2B shows the results of the secondary outcomes. At the start of Wk 1, one participant reported one fall in the preceding week, one participant reported two trips and eight participants reported no trips, stumbles, or falls. At Wk 12, the participant who previously reported two trips reported one stumble in the preceding week, no other incidence of trips, stumbles or falls were reported by any participant over the training period, despite increased PAL which may expose a person to more activities, with a higher risk of falling. No participants reported residual limb issues in relation to performing physical activity. The pain intensity ($p=0.03$) and pain quality ($p=0.04$) scores significantly reduced after the programme with a large effect size.-

Walking symmetry: There was no difference in walking symmetry.

Fitness: The distance walked in the 6MWT ($p<0.00$), and lower limb strength power ($p=0.01$) and endurance ($p=0.01$) were significantly greater after the programme, while time

to complete the agility test ($p=0.01$) was significantly reduced. There was no effect on, balance, or systemic strength ($p>0.05$).

Discussion

A repeat-measures within-subject design was conducted to explore the feasibility of an instructor-led 12-week training intervention for PTTA. As hypothesised, participants who completed the training programme reported increased PAL after the intervention. The increased PAL was sustained three months after the intervention was completed. There was evidence that the participants' experienced less pain, no evidence that the increased PAL resulted in more falls and walking asymmetry was not affected. There was some evidence that physical fitness was enhanced, evidenced by increased walking distance completed in 6 minutes, agility and strength were improved, but there was no effect on balance.

Using the IPAQ-SF, prior to intervention 40% of the participants were classed as inactive, performing less than 30 minutes of moderate (or equivalent vigorous) physical activity a week. This was comparable to the percentage of inactive people with lower limb amputation identified in previous studies [27]. By the end of the intervention, all participants increased their time in activity such that they exceeded both the 30-minute threshold defining community ambulation and also met the government recommendations, performing equivalent to more than 150 minutes of moderate activity. This level of activity was maintained three months after completion of the programme, implying that participants replaced the supervised training sessions with another activity of their choosing.

Participants in the current study reported low levels of moderate intensity activity participation (IQR 0-90 minutes per week) before starting the intervention which was significantly higher at the end of the study (IQR 480 -1013 minutes per week (Figure 1a)). For vigorous activity participation the participants in the current study reported a mean of 0 (IQR 0-60) minutes per week before starting the intervention which increased by the end of

the study though this was not a significant effect with an average of 15 (IQR 0-210) minutes per week (Figure 1b). Although there are indications that greater health benefits may be derived from vigorous activity in a shorter amount of time than moderate activity, injury risk is high when sedentary individuals move straight into vigorous activity [28]. More vigorous activities carry risks, such as increased joint forces and loading rates, which may exacerbate some comorbidities and further research is needed to explore the possible management of these risks.

Objectively measured activity levels, using the ActivPAL™ to quantify step count and time spent in movement, indicated significantly increased PAL for both measures with a small effect size (Figure 2 a,b). Before the intervention one participant was not sufficiently active for the ActivPAL™ to record any bouts of activity and four could be considered sedentary (under 5000 steps) [29]. Eight participants met the relatively low threshold of 1450 steps threshold to be considered community ambulators [30]. At Wk12 no participants were considered 'sedentary', with one participant rated as 'active', exceeding 10,000 steps [31]. Both increasing daily step count and daily time in movement are associated with health benefits of increased activity, although there is little consensus on the optimal daily step count for either maintained or improved physical health. The research available in the general population identifies a 10% reduction in cardiovascular risk for every 2000 steps performed each day, which plateaus before 10,000 steps are reached [32].

The intervention was developed to increase PAL while accommodating the physical limitations to mobility due to the prosthesis and the exercises used were informed by the general fitness constructs. Secondary measures to determine any adverse response (on falls, pain, skin condition), walking asymmetry, and fitness (walking endurance, strength, balance, and agility) were analysed. Six measurements indicated significant improvements: walking endurance through the 6MWT ($p=0.05$), agility through the T-test ($p=0.01$), and strength

power and endurance through time to complete 5 sit to stands and number of sit to stands completed in 30 seconds (both p=0.01) and demonstrated increased muscular strength of the lower limb. There was no effect on falls, walking symmetry, or balance, however 80% of participants attempted to run when performing the agility test whereas none attempted this before the intervention. No participants reported residual limb issues, suggesting that the exercises included and supported by the educational elements were sufficient to minimise the exposure of tissues to injurious stresses.

These findings should be considered as indicative trends, due to the uncontrolled study design and possible influences of the non-blinded data collection and analysis methods. This study was limited by the small number of participants and that it was conducted at one location only. The reasons for the small number (8%) of people who came forward to participate is not known, though the self-selection bias is likely to effect the results. To increase recruitment, personal contact and referral from a trusted source may support future efforts [33]. If this issue with recruitment can be addressed, further work to assess the efficacy of the intervention through a randomised control trial can be conducted. Detailed data on activities and the heart rates zones reached were not reported as participants were not asked to report their adherence to the home exercise programme, time in walking, or time in activity outside of sessions other than through the IPAQ-SF.

Additionally, no quality of life, psychosocial, or lifestyle data (smoking, drinking habits, type of work etc.,) were collected and these factors may impact outcomes and ability to adhere to such a programme. This study was conducted in a heterogeneous group with a range of ages, time since amputation, cause of amputation, experience with prosthesis and types of prosthesis, which indicates the impact of the training across this broad spectrum. While this is beneficial for application of the training programme across the wider PTTA population, further work is required to assess the effect of the training on homogeneous

subcategories of this population and adaptations necessary to include additional levels of amputation.

Conclusion

The research assessed the feasibility of an instructor-led education and population-specific, multiple component, personalised exercise intervention to increase PAL for PTTA. Participants indicated increased time in PAL, evidencing more time spent in activity and increased daily step count, along with timed walking distance, agility, and lower limb strength. There were no negative effects on secondary outcome measure (adverse responses, walking symmetry, or fitness). Additionally, the intervention used was performed with minimal resources and costs. However, a randomised control trial is recommended at various locations to support the validity of these findings and their long-term effects.

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Figure Legends

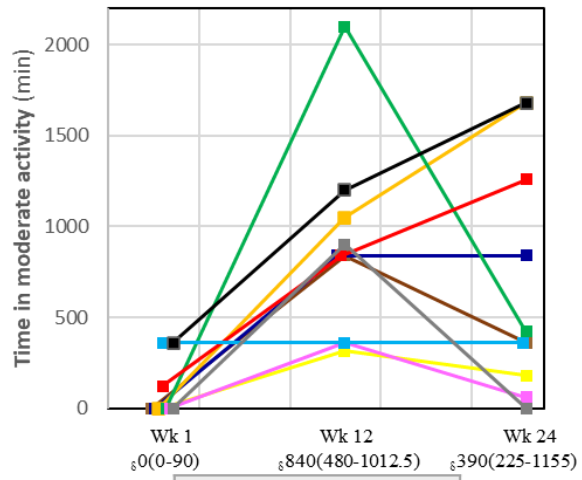
*Figure 1. IPAQ self-reported time in moderate physical activity (A), and time in vigorous physical activity (B). Median (Interquartile range) pre-intervention (Wk1), post-intervention (Wk12), and three month follow up (Wk24) for each participant (I-10). * Indicates a significance difference ($p<0.05$). # Indicates a large effect size ($g>0.08$). [a] Adjusted by the Bonferroni correction.*

*Figure 2 ActivPAL™ data for Step count (A) and Time in movement (B). Displayed with † mean(SD) pre-intervention (Wk 1) and post-intervention (Wk 12) for each participant. * Indicates a significance difference ($p<0.05$). # Indicates a large effect size ($g>0.08$).*

Table 1 Participant details

	Sex	**Age**	**Time since amputation (years)**	**Prosthetic foot**	**Private or Public health care prescription**	**Suspension type (PTB= Patellar Tendon Bearing Supracondylar)**	**Number of reported comorbidities**
I1	MALE	70	3	SACH-	Public	PTB with socks	1 (arthritis)
I2	MALE	20	4	SACH	Public	PTB with socks	0
I3	MALE	70	10	SACH	Public	PTB with socks	1 (hypertension)
I4	FEMALE	60	8	SACH	Public	PTB with socks	2 (diabetes and arthritis)
I5	MALE	71	65	SACH	Public	Silicon Suction Socket - Pin locking liner	2 (hypertension and heart disease)
I6	MALE	51	30	SACH	Public	PTB with socks	1 (hypertension)
I7	MALE	76	4	SACH	Public	PTB with silicon liner	2 (diabetes and heart disease)
I8	MALE	56	4	Elan	Private	PTB with silicon liner	0
I9	MALE	72	9	SACH	Public	PTB with silicon liner	1 (arthritis)
I10	MALE	56	1	SACH	Public	PTB with socks	1 (arthritis)

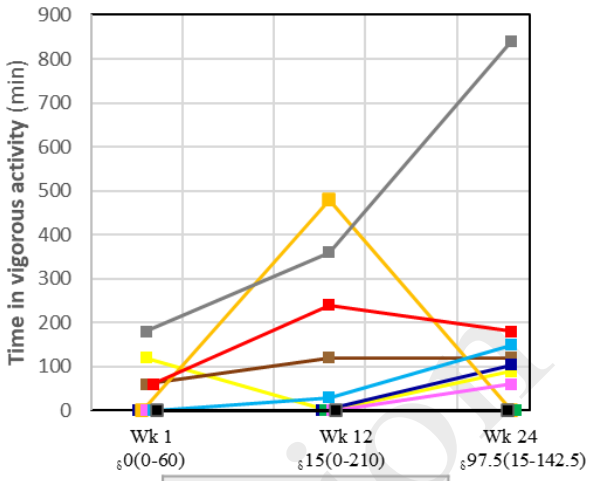
A



$\chi^2(2) = 9.00,\ p = 0.01$*

	Effect size	Post-hoc pairwise analysis[a]
Wk1-12	g = 1.97#	p = 0.06
Wk1-24	g = 1.23#	p = 0.02*
Wk12-24	g = 0.32	p = 1.00

B



$\chi^2(2) = 5.21,\ p = 0.07$

	Effect size
Wk1-12	g = 0.58
Wk1-24	g = 0.59
Wk12-24	g = 0.14