<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Self directed home based electrical muscle stimulation training improves exercise tolerance and strength in healthy elderly</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Authors(s)</strong></td>
<td>Caulfield, Brian; Prendergast, Ann; Rainsford, Gary; Minogue, Conor</td>
</tr>
<tr>
<td><strong>Publication date</strong></td>
<td>2013-07-07</td>
</tr>
<tr>
<td><strong>Publication information</strong></td>
<td>Engineering in Medicine and Biology Society (EMBC), 2013 35th Annual International Conference of the IEEE</td>
</tr>
<tr>
<td><strong>Conference details</strong></td>
<td>35th Annual International Conference of the IEEE, Osaka, Japan, 3-7 July 2013</td>
</tr>
<tr>
<td><strong>Publisher</strong></td>
<td>Institute of Electrical and Electronics Engineers</td>
</tr>
<tr>
<td><strong>Item record/more information</strong></td>
<td><a href="http://hdl.handle.net/10197/6476">http://hdl.handle.net/10197/6476</a></td>
</tr>
<tr>
<td><strong>Publisher's statement</strong></td>
<td>© 2013 IEEE. Personal use of this material is permitted. Permission from IEEE must be obtained for all other uses, in any current or future media, including reprinting/republishing this material for advertising or promotional purposes, creating new collective works, for resale or redistribution to servers or lists, or reuse of any copyrighted component of this work in other works</td>
</tr>
<tr>
<td><strong>Publisher's version (DOI)</strong></td>
<td>10.1109/EMBC.2013.6611178</td>
</tr>
</tbody>
</table>
Self directed home based electrical muscle stimulation training improves exercise tolerance and strength in healthy elderly.

Brian Caulfield, Member, IEEE, Ann Prendergast, Gary Rainsford, & Conor Minogue, Member, IEEE

Abstract—Advancing age is associated with a gradual decline in muscle strength, exercise tolerance and subsequent capacity for activities of daily living. It is important that we develop effective strategies to halt this process of gradual decline in order to enhance functional ability and capacity for independent living. To achieve this, we must overcome the challenge of sustaining ongoing engagement in physical exercise programmes in the sedentary elderly population, particularly those who experience barriers to exercise participation. Recent developments in electrical muscle stimulation technology could provide a potential solution. In this pilot case-control study we investigated the effects of a self-directed home based programme of electrical muscle stimulation training on muscle strength and exercise tolerance in a group of 16 healthy elderly volunteers (10f, 6m). Study participants completed 30 separate 1-hour electrical muscle stimulation sessions at home over a 6-week period. We observed significant improvements in quadriceps muscle strength and 6-minute walk distance, suggesting that this form of electrical muscle stimulation training has promise as an exercise modality in the elderly population.

I. INTRODUCTION

The process of ageing is associated with a gradual decline in a number of physiological systems, including the neural, muscular, and cardiovascular systems. This is associated with a gradual decline in muscle mass, strength, functional ability, aerobic capacity. The net consequence of a parallel decline in each of these capacities is a gradually reduced ability to perform activities of daily living and function independently at home and increased mortality (1). It is also associated with increased risk of falling. Falls are a major problem in older adults worldwide with an estimated 28-35% of elderly adults over 65 years of age falling each year and 21-42% of the over 75 (2). Demographic trends associated with a gradual increase in the proportion of older adults in the population mean that we urgently need to develop novel strategies to combat this problem.

Ongoing participation in targeted exercise activity is the obvious solution. Due to the requirement for specificity of exercise, it is imperative that exercise programs designed to address the gradual decline in muscle strength and aerobic capacity include both strengthening and aerobic components. This means that such programs are often very time consuming, leading to problems with ongoing adherence to the program. As a result, much of the recent focus in the literature relating to exercise training for the elderly population has been on development and evaluation of strategies for simultaneously enhancing strength and cardiovascular exercise capacity (3). The essential challenge lies in developing programs that do not involve excessive time investment on behalf of the older adult or requirement for specialized or expensive equipment, yet still promote improvements in strength and power without compromising concurrent gains in cardiovascular exercise capacity.

Recent developments in neuromuscular electrical stimulation (NMES) technology suggest that it might provide a potential solution in this regard. Until quite recently NMES was used primarily in the exercise/rehabilitation field to elicit sustained tetanic isometric contractions in skeletal muscles. A range of research reports has demonstrated that this technique is effective in terms of improving muscle strength (4,5). However, it is not effective in producing a significant increase in oxygen consumption and training programs that utilize this strategy are not likely to result in increases in cardiovascular exercise capacity, except in very deconditioned patient groups (6). Newly developed NMES protocols that elicit an ongoing series of sub-tetanic contractions in the large leg muscle groups do, however, result in significant increases in oxygen consumption (7) and therefore have the capability of resulting in improvements in cardiovascular exercise capacity when applied repeatedly over time (8,9). This means that NMES could potentially be used to facilitate participation in home-based training programs designed to counteract age related decline in muscle and cardiovascular function. A big attraction of NMES in this regard is its ability to be applied at the same time as other activities (such as watching TV or reading a book), thus increasing the likelihood that users will adhere to programs.

To address both aspects of training needs a hybrid NMES protocol that combines strategies for both strengthening (isometric tetanic contractions) and cardiovascular (isometric sub-tetanic contractions) exercise, separated into distinct phases in an exercise session, is needed. In this paper we report on a prospective case controlled study which was carried out to investigate the effects of a custom designed hybrid strengthening/cardiovascular exercise NMES mediated program on muscle strength and cardiovascular exercise capacity in a group of healthy elderly volunteers.
II. METHODS.

A. Study Participants

Sixteen participants (10f, 6m; BMI 26.8±4.2Kg.m⁻²; age 65.56 ± 4.84years), volunteered to take part in a home-based training program involving thirty sessions of neuromuscular electrical stimulation (NMES) training, each lasting one hour, over a six week period (five days on, two days off per week). All participants were medically cleared by their GP, and all met the inclusion criteria (aged between 60 and 80, able to follow instructions, and cleared for exercise participation by their GP). Participants were excluded if they had any contraindications to exercise participation or neuromuscular electrical stimulation. Each participant received a clear explanation of what the study involved and written consent was obtained. Height and weight were recorded prior to initial baseline testing and the average mass and body mass index (BMI) were 75.78 ±13.10 kg and 26.96 ±4.64 kg respectively.

B. Study Design

This was a prospective case control study in which we followed each study participant for a period of 8 weeks with 3 measurement points in each case. Measures of exercise capacity and muscle strength were taken at baseline, following a 2 week period in which study participants adhered to their habitual activity patterns (control phase), and following 6 weeks of habitual activity supplemented with 30 1-hour sessions of NMES training (training phase). All participants were required to attend a familiarisation/education session in the University prior to baseline testing. Each participant was fully competent at assembling the NMES unit and donning the neoprene garments containing adhesive electrodes prior tocommencing their 6-week home-based program. Participants were instructed to wear shorts, t-shirt and sports footwear for the testing sessions and not to participate in any sporting activity on the day of testing.

C. Cardiovascular Exercise Capacity Evaluation

Cardiovascular exercise capacity was assessed using a six-minute walk test along a 20m stretch of indoor track. Participants were instructed to walk as far as possible in six minutes, back and forth along the track, turning briskly around the cones at each end. Participants were allowed to slow down, stop and rest as necessary but were to continue walking as soon as they were able. Participants were instructed not to talk during the test unless a question was asked of them or if they experienced chest pain or dizziness. Standardized verbal encouragements were given by the tester after every minute. Heart rate and oxygen saturation levels were recorded using a portable pulse oximeter (2500 Nonin Medical Inc., Plymouth, MN, USA). Participants rated their perceived exertion on the Borg RPE Scale. Participants were seated for two minutes after completing the walking test.

D. Strength Evaluation

Unilateral (right leg) knee extensor and flexor isometric muscle strength was measured using a Cybex Dynamometer (HUMAC2009). Participants were seated on the Cybex chair with the back supported and the hip in approximately 90° - 100° flexion. Stabilization of the participant was achieved using a diagonally directed belt across the upper body, a thigh strap, and a contralateral limb stabilization bar. The right leg was secured to the dynamometer lever arm with the cushioned pad approximately 1 inch above the malleolus. The axis of rotation of the dynamometer was aligned with the anatomical axis of rotation of the participant’s knee. Correction of gravity effect was calculated by the computer while the participant relaxed their leg completely at 40° knee flexion. Each participant was required to carry out a familiarization test prior to their real trial. The isometric test included 5 reps of 5 seconds duration, with a 5 second rest period provided between each direction (flexion/extension) and rep. Hands crossed the chest during the test. Participants did not grasp the hand-grips. The trunk was kept in contact with the back-rest. Standard verbal encouragement was provided to each participant throughout each repetition. Peak torque was identified for each separate rep in each direction and the average of 5 was used to represent isometric knee extension/flexion strength for each study participant as appropriate.

E. NMES Intervention

The NMES program was delivered using a battery powered handheld muscle stimulator (INKO RS, BioMedical Research Ltd, Galway, Ireland). This stimulator was programmed to elicit a combined strengthening and aerobic training program in 2 separate phases lasting a total of 60 minutes. The stimulator current waveform was designed to produce contractions in the quadriceps and hamstring muscle groups. These contractions were achieved by means of delivering a burst of 4 mixed frequency pulses at different ‘beat’ frequencies, depending on the functional objectives of each phase of the training session. In the first phase of the program, lasting 15 minutes, the beat frequency was set at 25Hz in order to elicit a series of tetanic strengthening contractions in the thigh muscles. The duty cycle in this phase was 5 seconds contraction (on) followed by 10 seconds relaxation (off), providing a total of 60 contraction cycles with a total cumulative duration of 5 minutes over the 15 minutes phase duration. For the 2nd phase of the program, of 45 minutes duration, the beat frequency was set at 4Hz, resulting in a pattern of rhythmical sub-tetanic isometric contractions of the thigh muscles that was associated with an aerobic exercise effect. In this phase the contractions were continuous with no relaxation period. The maximum peak output pulse current used in the present study was 140mA. Impulses were delivered through an array of 4 adhesive electrodes on each leg (area per leg = 800 cm²), with a different combination of electrodes from the array being involved in delivery of each of the 4 pulses in a burst. The current pathways, electrode combinations per pulse and pulse train characteristics are outlined in Figure 1. The electrode arrays were applied to the body via a neoprene ‘wrap’ garment that was secured to the thigh with velcro straps. The highest amplitude reached in each session was recorded in a training diary.
F. Statistical Analysis

We obtained quadriceps strength measures (Nm) and 6-minute walk distances (M) from each participant at baseline, following the control phase, and following the training program. Repeated measures ANOVA F-tests were carried out to test for differences across the 3 measurement points for each variable of interest. Subsequent to this post hoc paired 2-sided t-tests were performed to test for differences between baseline and week 3, week 3 and week 9 and baseline and week 9 respectively. The level of significance was set at P<0.05.

III. RESULTS

All 16 participants completed the home training programme as prescribed without any adverse events. There were a further 2 participants who had initially agreed to take part in the study but, having attended a screening and information session, were admitted to hospital for unrelated reasons and therefore were not included in the study. Group mean results for muscle strength (quadriceps/hamstrings isometric torque) and cardiovascular exercise capacity (6-minute walk distance) at baseline, post control phase, and following the training phase are detailed in Table 1, whereas the results from follow-up post hoc testing are detailed in Table 2.

We observed no significant differences between values for strength or cardiovascular exercise capacity obtained at baseline or following the control phase (P>0.05), indicating stability during this period. When group mean values for quadriceps strength and cardiovascular exercise capacity following the control phase and following training were compared we observed significant increases in both quadriceps isometric torque and 6-minute walk distance (P=0.02 and P=0.01 respectively). However, we observed no significant differences in hamstring peak isometric torque during the same period (P=0.20). A similar pattern of differences was observed when initial baseline values and post training values were compared (differences in isometric torque and 6-minute walk distance yet no difference in isometric hamstring torque).

Table 1. Group mean (SD) values for Strength and Cardiovascular Exercise Capacity at baseline, following control phase, and following the training phase.

<table>
<thead>
<tr>
<th></th>
<th>Baseline 1 (Week 0)</th>
<th>Baseline 2 (Week 3)</th>
<th>Follow-Up (Week 9)</th>
<th>Within Group Effects</th>
<th>Level of Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isometric Quadriceps Torque (Nm)</td>
<td>114.2(32.6)</td>
<td>117.2(29.2)</td>
<td>132.0(36.2)</td>
<td>P&lt;0.05</td>
<td></td>
</tr>
<tr>
<td>Isometric Hamstrings Torque (Nm)</td>
<td>59.4(16.8)</td>
<td>61.2(20.5)</td>
<td>64.9(21.6)</td>
<td>P=0.05</td>
<td></td>
</tr>
<tr>
<td>6-minute Walk Distance (M)</td>
<td>570.0(56.9)</td>
<td>571.8(57.2)</td>
<td>591.4(58.7)</td>
<td>P&gt;0.05</td>
<td></td>
</tr>
</tbody>
</table>

All values are group mean (SD). Level of significance calculated using repeated-measures ANOVA F-test (sphericity assumed).

Table 2. Post hoc comparisons between conditions.

<table>
<thead>
<tr>
<th></th>
<th>Baseline Vs Post Control Phase</th>
<th>Post Control Phase Vs Post Training Phase</th>
<th>Baseline Vs Post Training Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isometric Quadriceps Torque (Nm)</td>
<td>0.43</td>
<td>0.02</td>
<td>0.01</td>
</tr>
<tr>
<td>Isometric Hamstrings Torque (Nm)</td>
<td>0.48</td>
<td>0.20</td>
<td>0.08</td>
</tr>
<tr>
<td>6-minute Walk Distance (M)</td>
<td>0.97</td>
<td>0.01</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Values are P values, calculated using 2-sided paired t-tests.

IV. DISCUSSION

The principal finding in this study was that a training program that leveraged NMES technology resulted in significant improvements in measures of strength and cardiovascular exercise capacity in a group of healthy elderly volunteer participants. The observed improvements were achieved using a training approached that used a small handheld stimulator, and garment applied electrodes, that could be
easily used by elderly users without the need for supervision on the behalf of qualified personnel. As such, this technique holds significant promise as an exercise modality that could be used to counteract age related decline in strength and cardiovascular exercise capacity in this population.

Though we did observe significant training effects, the increases that were observed in this study were modest in absolute and relative terms. In the case of 6-minute walking distance, an average increase of just 20m, or 3.5%, was observed following training. This is equivalent to the level of ‘small meaningful clinical change’ that has been reported for the geriatric population. Thirteen of the 16 participants exhibited increased 6-minute walk distances following training. The participants in this study reported high levels of physical activity, with the majority reporting that they walked on most days of the week. Despite this self-reported high level of physical activity they exhibited average baseline 6-minute walk distances that were within previously published age related norms (11). Therefore, their baseline values were not in such a high range that larger increases following training could not have reasonably been expected. The average increase in quadriceps torque during the same period was 13%, whereas there was no change in hamstring torque. Again, the baseline values observed for both quadriceps and hamstrings torque were in line with age related norms (12). The improvement observed in quadriceps torque is within the range of changes observed in voluntary training programs in the same population (3). It is difficult to interpret the lack of a change in hamstring strength in our participants and compare it to other studies as the majority of similar studies only report results for quadriceps torque, most likely a reflection of the functional anti-gravity importance of the quadriceps in this population.

Study participants were able to carry out the entire training program in their own homes without specialist supervision. Each participant underwent one training session under the supervision of a Physiotherapist in the University prior to beginning his or her training phase. At follow-up, each participant was again observed setting themselves up for training to ensure that they had been doing it as instructed and no issues were encountered. This suggests that the application of the NMES protocol in the home posed no problems for our study population. However, though participants were able to perform their training in their homes while reading or watching TV, we did receive feedback from them that indicated that tolerance of the sensation of the electrical current was an issue for most, yet not all participants. This is a widely reported issue with NMES (13). Therefore, the NMES application as applied in the present study would require further modification to address issues of comfort before it could be recommended as a widely acceptable exercise modality. This may be achieved by means of modulating stimulation parameters (eg pulse duration, frequency, and pathways) or electrode configurations (array distribution, size, shape, location). Relative comfort levels can also be influenced by means of implementing accommodation/habituation protocols (13) and avoiding use in people with excessive fat mass or very dry skin. Further studies are needed to optimize application protocols.

V. CONCLUSION

This study has demonstrated a moderate therapeutic effect associated with self application of an NMES application protocol that targeted improvements in muscle strength and cardiovascular exercise capacity in an elderly population. This is a promising first step towards development of an NMES application protocol that could eventually be widely used by older adults to counteract the detrimental effects of ageing.

ACKNOWLEDGMENT

We would like to express our gratitude to the volunteer participants in this study.

REFERENCES