AUTHOR: MACDONALD, F.R.

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EFFICACY OF THE IONIC BALANCE BAND TO IMPROVE SELECTED HEALTH AND FITNESS PARAMETERS FOLLOWING A TWO WEEK EXPOSURE INTERVENTION: A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

FINDLAY ROSS MACDONALD

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TABLE OF CONTENTS

CHAPTER 3. METHODS

CHAPTER 4. RESULTS

TABLES AND ILLUSTRATIONS

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ABSTRACT

A recent trend has seen products marketed towards the health and fitness industry that proclaim beneficial effects through properties and mechanisms more commonly associated with complementary and alternative medicine. These claims are largely unsubstantiated with a lack of scientific research to support them. The Ionic Balance Band is one of several relatively new products that would appear to have a more plausible basis for an effect based upon the available literature. The Ionic Balance Band is claimed to improve the health and function of its wearer through generation of negative air ions, far infrared rays and alpha waves. This study investigated the efficacy of the Ionic Balance Band to improve selected health and fitness parameters following a two week exposure intervention under randomised, double-blind, placebo-controlled conditions.

A sample of 60 men and women, consisting primarily of sport and exercise science students, were randomly assigned to wear an Ionic Balance Band or a placebo control band for a two week period between pre- and post-test sessions. The test battery assessed physical performance parameters of; balance, lower and upper body power, muscular strength, anaerobic power and heart rate recovery as well as cognitive function and general health outcomes.

Analysis of the data revealed that no significant improvements were gained from wearing an Ionic Balance Band compared to a placebo control band for any of the parameters assessed. The results did not support the claims of improved health or function that have been anecdotally reported from wearing an Ionic Balance Band. Further research is required to evaluate and understand the broader efficacy of negative air ions, far infrared rays and alpha waves to provide beneficial effects.

Keywords: negative air ions, far infrared rays, alpha waves, health, fitness, placebo, double-blind, strength, power, cognitive ability.

CHAPTER 1. INTRODUCTION

1.1 Prelude

Over recent decades, biology and medicine have been dominated by advances in biochemistry and molecular biology. These practices employ a reductionist view of the human body, treating it as a complex structured system composed of many definitive component parts (Rubik 2002). Developments to medical, pharmacological and surgical interventions have formed the foundation of modern biomedicine. However, it has been proposed that some aspects of health and function cannot be fully explained or influenced by conventional methods (Kornstein and Clayton 2002). Several healthcare approaches have a basis or history of use outwith mainstream medicine. They are practiced either alongside or in place of conventional modalities and are commonly classified as complementary and alternative medicines (CAM) (National Centre for Complementary and Alternative Medicine 2014). These methods view the body from a holistic perspective as opposed to the reductionist outlook of conventional medicine.

Movaffaghi and Farsi (2009) describe a dynamic system in which signals are communicated freely and prevalently within and between cells, organs and constituent systems of the body. It has been proposed that this process of information transfer is beyond the understanding that contemporary biomedical knowledge allows (Rubik 2002). Reasoning for this has been put forward by Oschman (2014), who highlights that the majority of biochemical research has been conducted on cell organelles that have been extracted and isolated from their native system and possibly altered from the state they would be found naturally. Therefore some active processes or mechanisms that may only be present when investigating the body as a whole, are undetectable or lost due to the changed conditions (Oschman 2014).

A systematic review by Frass (2012) on the use and acceptance of CAM details an annual expenditure exceeding $34 billion in the United States, with a large proportion of this being paid privately as this category of treatment is not covered by many health insurance policies. This information shows that there is a large market for CAM in western societies. CAM interventions include acupuncture, homeopathy, biofield therapy, magnet therapy, electrodermal therapy and phototherapy (Fass 2012). The latter three have been collectively termed energy medicine and are thought to involve subtle interactions with energy fields that affect the body. The mechanisms central to these treatments are in general not well understood and require further research (Rubik 2002).

As mentioned above, the accumulation of knowledge gained from a wealth of research forms the basis for our understanding of the human body. Progressions made in the broader scientific disciplines of physics, chemistry and biology, have facilitated the analysis and development of athletic performance. These findings have been applied to sports nutrition (Clark 2013; Kreider et al. 2010), training methods (Baechle and Earle 2009) exercise physiology and biomechanics (McArdle, Katch and Katch 2010). Initially, advances may only be utilised or applicable to elite performance; however, aspects of these improvements filter down to use by the general population over time. At present, the large health and fitness industry is driven by a desire for improvement with individuals seeking positive change to how they look, live, think and feel. The manufacturers of clothing, footwear and equipment continue to produce many novel and innovative sports products which are designed to provide a unique benefit to the consumer.

Over the last decade a group of products that promote mechanisms commonly associated with energy medicine or the broader CAM domain have been marketed towards the fitness industry (Bringman, Kimura and Schot 2011). Predominantly, these products have comprised of wristbands but have also included necklaces, watches, pendants, insoles, shorts and surfboards

(Bringman, Kimura and Schot 2011). The majority of these products assert a form of holographic technology or magnetic therapy as the source of their effects (Brice et al. 2011). Despite a lack of scientific evidence regarding the efficacy of the products, consumer awareness and sales has continued to increase. Several independent studies have been conducted in recent years, with the consensus of the peer reviewed research contradicting the claims from the product manufacturers. These claims have included improvements to balance, flexibility, strength, sleep quality, medical conditions and pain symptoms (Pothier et al. 2013; Sari et al. 2012; Verdan et al. 2012; Teruya et al. 2012; Brice et al. 2011; Mikesky and Hayden 2003; Schall, Ishee and Titlow 2003). The empirical evidence collected ultimately led to one manufacturer acknowledging that the claims they routinely made were not substantiated by any credible scientific evidence (BBC© 2010). However, a second iteration of wristbands advocating similar effects as above, albeit incorporating a different technology, are now widely marketed towards the health and fitness industry. Importantly, these more recent products appear to provide a more plausible scientific basis. This investigation will explore the proposed mechanisms and the efficacy of a popular modern wrist brand that is marketed to provide benefits to health and fitness parameters.

1.2 Disclaimer and Acknowledgement

Ionic Balance logo is a registered Trademark of iTek Solutions Ltd trading as Ionic Balance. All Ionic Balance bands and placebo bands used in this study were provided by iTek Solutions Ltd trading as Ionic Balance. The company had no involvement in the recruitment of participants, data collection, analysis and writing of this thesis.

1.3 The Ionic Balance Band

The Ionic Balance Band is a commercially available from Ionic Balance.com. The band is composed primarily of silicone which is moulded to shape from a liquid state. During the manufacturing process, black tourmaline is added to the liquid silicone in a powdered form. The band is worn on the wrist and is advertised as safe for individuals of all ages and health status. The company state that the tourmaline contained in the band is the source of the beneficial effects to the user (Ionic Balance 2014a).

The Ionic Balance Band is a relatively new product that, at the time of writing, has not been the focus of any published peer reviewed research. The product's website provides results from an unpublished study which was conducted to investigate the efficacy of the band to improve several health and fitness parameters. The results from the study lead the author to conclude that the band significantly improved performance of the parameters tested compared to a placebo band (Tully 2012). Further details on this study are included in Chapter 2.

The following sections seek to inform the reader of the current knowledge behind the products purported mechanisms for improving health. The properties of the Ionic Balance Band, with tourmaline as the source, that are stated to benefit the wearer include emission of: 1) negative ions; 2) far infrared rays and 3) alpha waves. The wider research regarding each property will be evaluated in turn together with any linked research specifically to tourmaline.

An extensive literature search was conducted across several databases: AMED, CINHAL, MEDLINE, SPORTDiscus, ScienceDirect, PreMEDLINE and EBM. The following key search terms were used: "air ions", "negative air ions", "far infrared rays", alpha waves", "ionic balance" and "tourmaline". These key terms were also combined with: "health", "function" and "performance" to produce more results. The databases were not limited to show the results of

any particular date range or language. Additional searches were made using Google Scholar utilising the terms and methods detailed above. This allowed for any articles that were not part of the databases above to be included. Finally, Google was used to search the general web for any non-academic or unpublished data relating to the topic.

CHAPTER 2. LITERATURE REVIEW

2.1 Air ions

Ionisation is the process by which molecules or atoms either gain or lose electrons, thus altering their overall charge (Laza 2009). Air ions are molecules or atoms present in the atmosphere which have undergone this process. Separation of charge and thus ionisation, is dependent on a sufficiently high source of energy (Daniels 2002). The occurrence of air ions is a natural phenomenon and differing levels of negative and positive ions can be observed across various environments with several factors influencing their concentrations and form. The source of ionising energy, electron affinity and chemical reactivity all determine the resulting ion species and thus the net positive or negative charge observed (Daniels 2002). Sources of natural ionisation include radioactivity, water evaporation, water shearing, weather conditions, solar and cosmic radiation (Laza 2009). Table 2.1 illustrates typical air ion concentrations for several environments. The negative air ions most frequently observed are CO_3^-, O_2^- or O_2^- $(H_2O)_n$, while positive air ions are usually found as N_2^+ (Nedved 2011).

Table 2.1: Positive and negative air ion concentrations for various environments

	Ion concentration in 1cm^3 of air	
Environment	***Positive ions***	***Negative ions***
Clean mountain air	2500	2000
Rural environment	1800	1500
Typical urban environment	600	500
Light industrial plant area	400	300
Modern office environment	200	150
Closed moving vehicles	100	50

Adapted from: Nedved (2011)

Air ions can be broadly categorised into two categories, electrically generated air ions and water generated air ions (Yamada et al. 2006). The vast majority

of the research into the biological effects of air ion exposure has used specially designed ionisers to artificially produce the desired concentrations of positive and negative air ions in a controlled environment (Alexander et al. 2013). Electrical ionisers employ high voltage electricity to generate air ions. Water generated air ions are produced using ionisers that split water droplets producing electrons which combine with oxygen molecules in the air thus creating negative air ions (Yamada et al. 2006).

The biological impact of air ions has been the focus of numerous research studies spanning many decades (Nimmerichter et al. 2014; Nakane et al. 2002; Reilly and Stevenson 1993; Albrechtsen et al. 1978; Palti, De Nour and Abrahamov 1966 Blumstein, Spiegelman and Kimbel 1963; Herrington 1935). As summarised by Alexander et al. (2013), several researchers have attributed a beneficial or therapeutic effect to negative air ion exposure while a smaller number have reported a deleterious or irritant effect due to positive air ion exposure. However, many studies have reported no significant changes following exposure to air ions of either charge.

As one may expect from a research base spanning several decades, the published scientific studies vary greatly in terms of methodology, study population, technology, test environment and statistical techniques employed (Alexander et al. 2013). Alongside the customary considerations for sound research design (Gratton and Jones 2010), the following sections will provide a critique on the specific issues of exposure concentration and duration.

2.1.1 Electrical corona discharge air ions

A study conducted by Nogrady and Furnass (1983) examined the impact of electrically generated negative air ions on bronchial asthma in 19 adults over a six month period. A strong double-blind crossover design saw randomised groups exposed to negative air ion and placebo control conditions for eight weeks separated by a four week washout period. An initial two and final four week period with no ioniser present was also included. Participants were exposed to a negative air ion concentration of 150,000 cm^{-3} which was

maintained at pillow level from 10pm-8am. Measures of peak expiratory flow rate (PEFR), symptom severity and medication use were recorded by participants in a diary across the duration of the study. Statistical analysis revealed no significant differences between the negative air ion condition and placebo or no ioniser condition for any of the parameters investigated (Nogrady and Furnass 1983).

Ben-Dov et al. (1983) evaluated the effect of negative air ion exposure in children with bronchial asthma. Participants were randomly assigned to perform a bout of cycling or were exposed to histamine under both negative air ion and control conditions. Negative air ion concentrations of 400,000 cm^{-3} - 1,000,0000 cm^{-3} were produced with 11 participants challenged by the exercise protocol and 10 exposed to the histamine conditions. The results showed that the inhalation of negative air ions positively modulated the bronchial response to exercise but not for the histamine condition. A more extensive physiological testing battery was included in research carried out by Inbar et al. (1982). The authors investigated the effect of negative air ion exposure on various physiological functions during rest and exercise in a hot environment. A total of 21 men were randomly assigned to perform two sessions under either experimental or control conditions. The experimental group were exposed to neutral environmental conditions (221-256 cm^{-3} and 151-191 cm^{-3} negative and positive air ions respectively) for their first session and negative air ion conditions for their second (136,000 – 190000 cm^{-3}) session, whereas the control group performed both sessions in the neutral environment. The temperature (40 ± 1°C) and humidity (25 ± 5%) were kept constant across all testing sessions. During each session, participants were instructed to rest for 60 minutes under the test conditions before performing three 30 minute bouts on a cycle ergometer at a work load of 1.64 ± 0.6 W/Kg of body weight with seven minutes rest between each exercise bout. Measures of skin temperature, rectal temperature, blood pressure, heart rate and body weight were taken while at rest before entering the test chamber. These measurements were repeated following the initial 60 minute period spent in the chamber with subsequent measurements of heart rate, skin temperature

and rectal temperature performed during every 15 minutes of exercise. Additionally, body weight was recorded during each rest period with ratings of perceived exertion and blood pressure taken during the last minute of each exercise bout. A measure of metabolic rate was determined by collection of expired gas for a two minute period halfway through second bout of cycling. Significant differences were observed for measures of heart rate, rectal temperature and ratings of perceived exertion between the negative ion environment and neutral environment in the experimental group. It was observed that these parameters underwent a smaller increase under negative ion conditions compared to neutral conditions. These findings support the results of Sovijarvi et al. (1979) who reported that heart rate and rate of perceived exertion were significantly lowered by negative air ion exposure during bicycle exercise.

2.1.2 Water generated air ions

Ryushi et al. (1998) examined the effect of water generated negative air ion exposure on the cardiovascular and endocrine system at rest and following one hour of moderate intensity ergometer cycling. Ten healthy men that did not regularly perform exercise were exposed to a negative air ion concentration of 8,000 - 10,000 cm^{-3} for 30 minutes while at rest. Participants were then instructed to cycle for 60 minutes at 50-60% load of their maximal oxygen uptake (as determined by a preliminary ramped test) in unmodified conditions (negative air ion concentration of 200-400 cm^{-3}). The recovery period comprised a further 60 minutes in the same environment as that used during the rest condition. The same participants then repeated the above protocol but with the exercise phase taking place in the unmodified environment also. Test procedures were conducted under double-blind conditions. Measures of ventilatory profile (oxygen uptake, pulmonary ventilation and heart rate), blood pressure (systolic and diastolic) and plasma neurohormones (dopamine, adrenaline, noradrenaline and serotonin) were recorded across all phases of both conditions. The study failed to provide detail of the time period between experimental conditions; however reference is made to accounting for circadian

rhythms. Significant differences were observed during the recovery phase between negative air ion and unmodified conditions for diastolic blood pressure, plasma serotonin and plasma dopamine. Each of the results demonstrated positive effects for conditions exposed to negative air ions. No significant differences were observed for any of the other measures across the three phases of rest, exercise and recovery.

2.1.3 Health and fitness products with ionising properties

Sports apparel manufacturer Canterbury (Canterbury of New Zealand, Auckland, New Zealand) produced a range of garments that were marketed as being "ionically treated" (Gray et al. 2007). Financially supported by Canterbury, Gray et al. (2007) investigated the effects of the ionised undergarments on several physiological measures. In a crossover design, 12 recreational male rugby players wore ionised and non-ionised undergarments for the duration of a test battery which comprised vertical jumps, a Wingate anaerobic test (WAT), an arm-ergometer bout and a ramped cycle ergometer test to exhaustion. Mean power during the WAT was significantly higher (2.7 ± 3.3%) for ionised (730 ± 114W) over non-ionised undergarments (711 ± 126W). Additionally, minimum resting heart rate was significantly higher for the ionised garments (56 ± 8 vs. 53 ± 7 bpm). Interestingly, this latter finding contrasts other research indicating that negative ion treatment reduces heart rate (Yates et al. 1986; Inbar et al. 1982). No significant differences were observed for any of the remaining WAT measures (peak power, rate of fatigue and time to peak power), pain perception during arm ergometer use, maximum power or heart rate during the incremental cycle test or blood pressure and heart rate post-test.

A second crossover study investigating the effects of ionised garments recruited 10 well trained male athletes to complete a battery of sprint and endurance cycles whilst wearing either ionised compression tights, non-ionised compression tights or standard running tights (Burden and Glaister 2012). In contrast to the results obtained by Gray et al. (2007), no significant effect of garment type was

observed for measures of mean power during the WAT. Furthermore, no significant effect of garment type was observed for measures of 10km cycle time, mean VO_2max, mean heart rate and blood lactate.

Both the Gray et al. (2007) and Burden and Glaister (2012) studies employed robust crossover designs with randomised groups under blinded conditions; however, the small sample sizes included limit the precision of the outcomes reported. The time period between testing sessions was a minimum of 72 and 24 hours for Gray et al. (2007) and Burden and Glaister (2012), respectively. This was seen as adequate for recovery from the test battery but consideration of potential carryover effects due to exposure to ionised garments was not stated. Burden and Glaister (2012) clearly stated that the ionised garment utilised was a pair of compression tights. Contrastingly, Grey et al. (2007) failed to qualify which ionised undergarment(s) were worn. Use of both upper and lower body ionised undergarments may have influenced the differences in observed results. It was also noted that neither study quantified an estimate of negative air ion concentration produced by the garments as is expected in research of this topic. A final limitation of these studies is that the exposure time was restricted with garments worn for approximately one hour during both studies.

2.2 Far infrared rays

Infrared radiation is an invisible portion of the electromagnetic spectrum. It has a relatively long wavelength between the red end of the visible light range and microwave radiation (Toyokawa et al. 2003). Based on wavelength, infrared radiation can be categorised further into near, middle and far infrared radiation (Lin et al. 2007). Far infrared rays are classed by a wavelength of 5.6 to 1000 μm with a range of frequencies between 300GHz and 30THz (Kusky and Cullen 2010).

Inoué and Kabaya (1989) propose that the benefits from exposure to far infrared rays are a temperature increase in body tissue resulting in an elevated motility of body fluids. This viewpoint is supported by Yoo et al. (2002) who further suggest that far infrared rays can have beneficial effects on human skin cells and blood circulation. The few published studies investigating biological effects of far infrared rays include both animal and human trials with several mechanisms proposed for the observed effects.

Reports of the beneficial effects of far infrared rays have been published by researchers carrying out experiments using rat models. Toyokawa et al. (2003) investigated the effect of far infrared rays on wound healing in rats. It was reported that wound healing was significantly more rapid with irradiation of far infrared rays than without. Improved collagen regeneration and fibroblast activity were reported following histological investigation and proposed as the mechanism for the improved wound healing observed (Toyokawa et al. 2003). Additionally, it was noted that skin blood flow and temperature did not change significantly during irradiation as reported by others. Subsequent work completed by Yu et al. (2006) concluded that far infrared rays had a biological effect on skin microcirculation in rats. The paper suggested that the mechanism was not due to a temperature increase, as commonly referred to by others, but related to nitric oxide concentration which plays an important role in blood perfusion of the skin (Yu et al. 2006).

Human trials were conducted by Lin et al. (2007) to investigate the effect of far infrared therapy on haemodialysis patients. It was observed that far infrared therapy improved impaired access flow which is the main cause of hospitalisation and morbidity in haemodialysis patients. These results were obtained for both a single session of far infrared therapy and repeated sessions conducted over a year (Lin et al. 2007). The acute exposures resulted in a lower incidence and relative incidence of arteriovenous fistula malfunction, enabling more effective vascular access for the patients. In a recent systematic review conducted by Bashar et al. (2014), a further three studies were combined with the results provided by Lin et al. (2007) to provide stronger evidence that far infrared therapy could be used to enhance vascular access for the haemodialysis patients. Of these three additional studies, two were published by the same first author of the 2007 study. Lin et al. (2013a) and Lin et al. (2013b) completed further investigations in FIR therapy on haemodialysis patients. In both publications, the participants who received the FIR therapy were administered the treatment for 40 minutes, on three occasions per week over the course of a year. The results reported by Lin et al. (2013a) led them to conclude that FIR therapy may improve access flow in HD patients, especially in those exhibiting a specific genotype. However, Bashar et al. (2014) also concluded that the research designs of future studies should be enhanced with blinding and that the research should be conducted by investigators without commercial ties to far infrared therapy technologies.

2.3 Alpha waves

Electroencephalography (EEG) is the process by which electrical activity of the brain is monitored (Schomer and Silva 2012). The frequencies that EEG detects have been banded into several categories. The frequency band between 8 and 14Hz is referred to as alpha frequency brain activity. Palva and Palva (2007) explain that alpha wave detection has been shown to increase during performance of internal tasks such as mental calculation and working memory. In particular, a substantial body of evidence has amassed indicating that alpha-band oscillatory activity can act as an attentional suppression mechanism when objects or features need to be specifically ignored or selected against (Foxe and Snyder 2011). Whilst this feature of Alpha waves appear to have important functional relevance for various features of cognitive performance, there appears to be no peer reviewed research available that investigates the effects of alpha waves being generated from an external source.

2.4 Tourmaline

Tourmaline is the term used for a group of ring structured silicate minerals which are composed, in part, of boron, sodium, iron, aluminium and lithium (Hu, Xiong and Yang 2011). Variations in density and composition result in the crystals of this group adopting several colourations and forms. Each species or variety can simply be referred to as tourmaline (Schuman 2009). Tourmaline has been shown to maintain permanent paired electrodes without the need for an external electrical supply (Wang et al. 2006). This property allows for a small electrical charge to be generated across tourmaline when there is a change in either the temperature (pyroelectricity) or pressure (piezoelectricity) applied to its surface (Schuman 2009). A detailed analysis of the crystal structure of tourmaline and the resulting characteristics are explained by Lameiras, Nunes and Leal (2008).

Research studies have been conducted that report tourmaline produces negative air ions (Hu, Xiong and Yang 2011; Yeh et al. 2011). A study published by Wang et al. (2006) reports that fibres of polyethylene terephthalate containing tourmaline powder emitted between 4400 and 5100 cm^{-3} of negative air ions under frictional conditions. As discussed in section 2.1 above, selected research studies have produced results supporting the premise that negative air ion exposure could be beneficial to health. However, there is a lack of research in which tourmaline, in any form, is investigated as having a beneficial effect on participants. At present, any claim that tourmaline will improve outcome measures as shown in previous negative ion research is extremely speculative.

The studies on far infrared rays introduced above utilised ceramic plates and either heat or direct electrical supply to produce the far infrared rays. Research utilising tourmaline as a source of far infrared rays has been far more uncommon. Some preliminary work has been conducted to assess the use of tourmaline in cosmetics and jewellery. Yoo et al. (2002) described how increasing the percentage of tourmaline powder resulted in a proportional increase of far infrared wave energy detected. The study details that creams containing 1% tourmaline induced a 0.6° to 1.5° rise in skin temperature

compared to a control cream containing only oils and water. Based on the data the authors suggested that tourmaline can be used for skin temperature elevation and to improve skin blood flow and circulation (Yoo et al. 2002).

Finally, as stated above, there is no research available on the generation of alpha waves to improve health or function from any source let alone tourmaline.

2.5 Research from the Ionic Balance product website

The results from an unpublished study conducted by Tully (2012) are available on the product's website (Ionic Balanceb). The study employed a crossover design under randomised, double-blind, placebo-controlled conditions. A sample of 16 healthy men and women were assessed for measures of flexibility, balance, strength and endurance before being assigned a wristband from one of two conditions; an Ionic Balance Band or a placebo control band. Participants were instructed to wear their wristband at all times for one week before returning for secondary testing. Following this, the participants were assigned a band from the other condition which was to be worn for one week as above. A final test session was then administered at the end of the second one week period. The results show a significant improvement to all measures when the Ionic Balance Band was worn with no significant improvements attributed to the placebo. Tables 2.2 and 2.3 below display the summary statistics available from the website for the study.

Table 2.2: Summary statistics (Mean and SD) for percentage change from baseline for outcome measures with the placebo band from Tully (2012)

Outcome (units)	***Mean***	***SD***	***Min***	***Max***	***p-value (1)***	***p-value (2)***
Stetch and Reach (inches)	.30	.23	-.42	.59	.658	.0003**
Balance (seconds)	2.29	3.52	-3.32	11.55	.02	.008*
L Hand Strength	-1.00	1.75	-6.00	2.00	.037	<.001**
R Hand Strength	2.25	12.56	-4.00	49.00	.485	.249
Max Sit Ups	-.13	.34	-1.00	.00	.164	<.001**
Max Push Ups	-.06	.57	-1.00	1.00	.669	<.001**
Max Bicep Curls	.00	.00	.00	.00	1.00	.053
Reps to Failure	-.13	.72	-1.00	1.00	.497	.002*
Ave Speed (mile/hr)	.03	.35	-.30	1.20	.768	<.001**
Peak Speed (miles/hr)	.11	.45	-.40	-1.50	.344	<.001**
Ave Watts	-3.64	14.33	-57.30	1.30	.326	<.001**
Peak Watts	.27	1.49	-2.00	3.00	.479	<.001**
Ave WPKG	-.01	.03	-.10	.10	.432	<.001**
Peak WPKG	-.01	.06	-.10	.10	.432	<.001**
Calories	-.04	2.04	-6.70	2.20	.942	<.001**
Distance (miles)	.00	.68	-1.00	1.00	.718	<.001**

p-value (1) for evaluating changes from baseline within active group
p-value (2) for comparison of changes from baseline between placebo band vs. activeband
**p<.05, ** p<.001*

Table 2.3: Summary statistics (Mean and SD) for percentage change from baseline for outcome measures with the active band from Tully (2012)

Outcome (units)	***Mean***	***SD***	***Min***	***Max***	***p-value (1)***	***p-value (2)***
Stetch and Reach (inches)	12.44	7.35	4.05	28.62	<.001**	.0001**
Balance (seconds)	91.79	177.0	-31.07	686.6	<.001**	.036*
L Hand Strength	8.55	3.60	3.09	14.29	<.001**	<.001**
R Hand Strength	8.98	5.12	1.65	20.41	<.001**	.63
Max Sit Ups	11.44	6.04	3.23	30.00	<.001**	.0001**
Max Push Ups	14.01	5.06	7.50	29.41	<.001**	.0001**
Max Bicep Curls	5.94	5.51	.00	16.67	<.001**	.001**
Reps to Failure	17.63	17.20	-4.35	52.63	<.001**	.0001**
Ave Speed (mile/hr)	8.13	3.01	5.75	18.07	<.001**	.0001**
Peak Speed (miles/hr)	9.47	6.91	2.58	28.16	<.001**	<.001**
Ave Watts	15.04	9.05	8.64	44.53	<.001**	<.003*
Peak Watts	13.94	11.47	4.41	45.48	<.001**	.0001**
Ave WPKG	27.21	17.08	5.26	57.14	<.001**	.0001**
Peak WPKG	21.64	14.76	5.26	60.87	<.001**	.0001**
Calories	19.82	8.84	6.36	37.54	<.001**	.0001**
Distance (miles)	11.06	3.31	5.61	17.02	<.001**	.046*

p-value (1) for evaluating changes from baseline within active group
p-value (2) for comparison of changes from baseline between placebo band vs. activeband
**p<.05, ** p<.001*

The magnitude and consistency of the effect reported in this study is quite staggering considering the wider research. If valid, for this effect to be apparent over such a short period of time is nothing short of ground-breaking. Compared to other methods of enhancing performance these improvements seem highly unlikely. Larger sports apparel manufacturers would have surely produced their own products to capitalise on this strong performance enhancing effect. Although the study seems to have been conducted with a sound design and methodology, the impact of its results are greatly diminished by the fact that it has not been subjected to peer review.

2.6 Summary

Based on information from the Ionic Balance product website, the negative air ions produced by the Ionic Balance Band are seen as the primary property for generating a beneficial effect on the wearer. From the published research on the effects of negative air ions on health it is generally postulated that the mechanisms for improved health include removal of pollutants and particles from the air thus improving air quality, or the hypotheses that negative air ions can have a more direct effect on the body's tissues.

It is a difficult task to summarise the rationale for the beneficial effects of negative ions, far infrared rays and alpha waves on heath and function. This is due to the conflicting findings and/or the lack of previous research. The authors of previous research on negative air ions have provided several suggestions for the mechanisms in place. These include regulation of histamine and serotonin levels (Ben-dov et al. 1983 and Inbar et al. 1982). The research on far infrared rays seems to suggest the mechanism is to facilitate improved blow flow allowing for increased supply of oxygenated blood and improved recovery processes. As previously mentioned, there is no previous research on alpha waves that would allow for a basis to be suggested for their ability to improve health and function. Therefore, it could be speculated that the rationale is that the user will somehow absorb or be affected by the specific frequency in a beneficial manner.

The focus of this research will reside on a performance outcome basis and will not attempt to elucidate mechanisms behind any effects that are measured. This approach is not ideal but due to the fact that so little is known to guide the selection of outcomes, the researcher has relied upon the anecdotal evidence available alongside well established tests of physical performance. If positive outcomes are ultimately shown, then future research will further investigate which mechanisms are responsible.

2.7 Study design justification

A pre-test/post-test control group design was selected for this study (Field and Hole 2003). A crossover repeated-measures design where all participants complete both conditions was considered but was rejected on the basis of two points. Each participant would be required to repeat the test battery a total of five times including familiarisation which would be likely to increase the rate of participant attrition. Wang and Bakhai (2006) support this notion by identifying longer study involvement as one of the main drawbacks to a crossover design. Additionally, the case for a crossover design was weakened due to potential carry-over effects (Senn 2002). The lack of peer reviewed research on the Ionic Balance Band's potential effects or their duration meant that there was no information available to construct an appropriate 'wash-out' period for changes that the product may have induced (Field and Hole 2003). Similarly, anecdotal evidence was relied upon for the length of exposure time for the study. It was indicated by the company that this was the time period that the majority of customers reported a beneficial effect by.

Clinical trials should consider bias when designing the methods to be implemented. Bias can be defined as, "any tendency which prevents unprejudiced consideration of a question" (Pannucci and Wilkins 2010). Bias can have an influence at any stage of the research process, this can be categorised into pre-trial bias, during trial bias and after trial bias (Pannucci and Wilkins 2010). Selection bias can occur during the identification of the population to be investigated and the allocation to conditions. This can be reduced by using

rigorous criteria when selecting participants and including a process for random allocation to conditions. The present study had clear inclusion and exclusion criteria and randomisation to reduce this. The pre-test provided baseline data for each participant as well as an opportunity to assess the success of the randomisation process. A familiarisation session was included to reduce the likelihood that improvements between the baseline and post-test were due to practice or learning effects (Field and Hole 2003). In order to reduce subject biases, a placebo control group was selected for this study (Mitchell and Jolley 2012). Performance bias can occur when participants or investigators have knowledge of the intervention allocation (Higgins et al. 2011). This was controlled for in the present study by implementing double-blind conditions. Thus any observed improvement in the active group's performance over the placebo control group could be attributed to the Ionic Balance Band; this assumption is only limited by the statistical uncertainty of the result (Temple and Ellenberg 2000).

2.8 Test battery justification

The testing battery was designed to assess a range of parameters that have been anecdotally proposed to be improved by wearing the Ionic Balance Band (Ionic Balance® 2014a). As multiple tests were being administered, the testing order was chosen with consideration to the: skill, coordination, fatiguing effect and main energy system requirements of each test (Miller 2012). The tests were completed in an order that would minimise the effect of the preceding test on the following. Each parameter falls under one of the following categories: 1) lifestyle measures; 2) cognitive function; 3) muscular power; 4) muscular strength; 5) anaerobic power; and 6) heart rate recovery. The following will provide justification for the chosen assessment techniques based upon current literature.

2.8.1 Lifestyle questionnaire

A questionnaire covering selected lifestyle parameters was completed by all participants during the pre- and post-test. This questionnaire was designed solely for this study. The parameters investigated included sleep quality, energy levels, injury status, exercised induced pain, recovery and medical conditions. These topics were chosen as potential indicators of an effect based upon previous research on the properties of interest (Cambell 2011), other CAM focused research (Bringman, Kimura and Schot 2011) and anecdotal product reviews. Where applicable the questions employed a 5-point Likert scale. This acted to increase the precision of the measure over a YES/NO alternative while avoiding confusion or meaningless data that could be collected from a larger scale (Bowling 2004).

It was beyond the scope of this study, and many others, to attempt to clarify all of the influences that contribute to a placebo response. However, several questions were posed to elucidate the effect of expectation, motivation and prior knowledge of the product on the results observed. Finniss and Benedetti (2005) state that expectation has an important role in modulating an individual's neurobiology and subsequent placebo response. This viewpoint is echoed by Geers et al. (2007) who concluded that anxieties, expectancies and conditioning are all important factors in studies with a placebo control group.

2.8.2 Assessment of cognitive function

Cognitive assessments were made using the ANAM (Automated Neuropsychological Assessment Metrics) Test System software produced by Vista LifeSciences (Vista LifeSciences, Parker, Colorado). The version utilised was ANAM^4 with the Core Battery of tests being administered. The assessment was undertaken on a computer workstation with participants following the on screen instructions. The parameters assessed included reaction time, learning, attention, processing speed, working memory, delayed memory and inhibition. The ANAM software was designed to be used by clinicians and researchers to

assess neuropsychological function over various time frames including daily to weekly intervals (Reeves et al. 1997). The software uses a pseudo-randomisation procedure which produces vast numbers of alternative test stimuli making it ideal for repeated measures or performance monitoring (Cernich et al. 2007). Work has been published which confirms ANAM's validity against conventional cognitive assessments (Jones et al. 2008; Bleiberg et al. 2000; Kabat et al. 2001) and its reliability (Kaminski, Groff and Glutting 2009 ; Segalowitz et al. 2007) as displayed in Table 2.4. The ANAM cognitive assessment programme was chosen over alternatives such as ImPACT (ImPACT Applications, Inc. Pittsburgh, PA) and CNS (CNS Vital Signs, Morrisville, NC) due to the flexibility of the testing battery. The ability to include/exclude specific tests enabled ANAM to fit the needs and time constraints that were present. ANAM also provided a strong research foundation due to its previous use in drug or medical intervention trials (Hamidovic, Kang and de Wit 2008; Wilken et al. 2007).

Table 2.4: Test-retest reliability (one week interval) estimates for selected ANAM tests

	Mean RT		**Processing Efficiency**	
Test	***Pearson r***	***ICC***	***Pearson r***	***ICC***
Code Substitution – Learning	.74	.74	.67	.68
Code Substitution – Recall	.83	.54	.81	.58
Running Memory	.59	.59	.72	.72
Math Processing	.44	.43	.71	.61
Matching to Sample	.80	.65	.70	.65
Simple Reaction Time	.29	.24	.48	.44

Adapted from: Segalowitz (2007)

2.8.3 Assessment of balance

The participant's centre of pressure was recorded while they were positioned on the force plate as instructed. Measurement of centre of pressure has featured frequently in previous studies where balance is of interest (Caron, Faure and Brenière 1997; Carpenter et al. 2001; Verhagen et al. 2005). Measuring postural stability by analysing the time-varying coordinates of the centre of pressure has been conducted by previous studies (Karlsson and Frykberg 2000). It has been defined by Winter (1995) as the point location of the vertical ground reaction force vector. The centre of pressure is independent of the centre of mass. It is a weighted average of all the pressures that are acting across the surface area that is in contact with the ground (Winter 1995). Analysis of centre of pressure data allows for the participant's postural sway to be calculated (Lajoie and Gallagher 2004). Postural sway represents the excursions of the centre of pressure in both mediolateral and anteroposterior directions (Winter 1995). Balance assessments were made using Kistler force plates (Kistler Instruments Ltd. HOOK, Hampshire, UK) which offer abundant and accurate quantitative data (Guskiewicz and Perrin 1996) and have been used in previous related studies (Karlsson and Frykberg 2000 and Maurer et al. 2001).

2.8.4 Assessment of lower and upper body muscular power

Powerful movements are characterised by muscle tissue exerting a large force at a high contraction speed (Baechle and Earle 2008). Vertical jump assessment has been widely implemented to provide an index of the muscular power of the legs in athletes (Bosco and Komi 1980), sedentary individuals (Bach et al. 1994) and certain patient groups (Markovic et al. 2004). Several methods have been appiled to quantify performance of this movement including contact mats, jump and reach apparatus and tape measure belt systems (Buckthorpe, Morris and Folland 2012). However, the use of a laboratory based force plate to record the vertical ground reaction force during take off is considered the criterion measure (Vanrenterghem, De Clercq and Van Cleven 2001 and Hatze 1998). Again, Kistler force plates were utilised for data collection. Similarily, a single effort

push up perfromed on the force plate was used as a measure of upper body power (Wilson, Murphy and Walshe 1996).

2.8.5 Assessment of muscular strength

Thistle et al (1967) defined isokinetics as a dynamic muscular contraction when the velocity is kept constant (Baltzopoulos and Brodie 1989). Isokinetic dynamometry is the measurement of the forces that are produced during this contraction. It requires the use of a specialised electromechanical device known as a dynamometer. The resistance of the dynamometer actively matches the muscular forces applied through a set range of motion at a chosen angular velocity. The assessment protocol for the current study was developed based on previous published work concerning angular velocities (Dvir 2004 and Kues, Rothstein and Lamb 1992), contraction cycles (Sekir et al. 2010; Sahin et al. 2008) and appropriate warm up (Reiman et al 2010). The angular velocities used in the current study have been selected to assess muscular strength across two parameters. These angular velocities have been reported to offer a reliable representation of muscular strength which may be reduced by slower or faster angular velocities, especially in inexperienced participants (Dvir 2004). For healthy populations that are not comprised high level athletes, isokinetic dynamometry is considered the gold standard of maximum muscular strength testing (Reiman et al 2010).

2.8.6 Assessment of anaerobic power

To assess the participant's anaerobic power, the Wingate anaerobic test (WAT) was performed (Bar-Or 1987). The WAT was performed on a leg cycle ergometer as described by the majority of previous studies although adaptations have been made to perform an upper body protocol in some cases (Jacobs et al. 2004 and Balmer et al. 2004). The WAT requires the participant to pedal maximally for a set time against a pre-calculated resistance. Traditionally, the WAT is performed over 30 seconds with the flywheel resistance set at 7.5% of the participant's body mass (Stewart et al. 2011). Measures of peak power, minimal power,

average power and fatigue index are most often calculated with fatigue index providing a quantitative measure of the slope of the power-time curve. (Jacobs et al. 2004).

2.8.7 Assessment of heart rate recovery

Heart rate has been the focus of much research and findings consistently show associations between higher resting heart rate and greater mortality (Lauer 2011). Heart rate recovery is a marker of favourable parasympathetic response to exercise and is associated with greater levels of physical activity (Carnethon et al. 2005). Additionally, heart rate recovery has been shown to be predictive of mortality in participants who are apparently healthy (Cole et al. 2000), diagnosed with hypertension (Polónia et al. 2006), suffering from a metabolic syndrome (Sung, Choi and Park 2006) or are heart failure survivors (Arena et al. 2010). Heart rate recovery is most commonly monitored following an incremental exercise test which aims to assess aerobic fitness (Tulumen et al. 2011). There was no such aerobic fitness assessment included in this study; therefore the heart rate and subsequent recovery was monitored during and following the WAT. This procedure has been used by Goulopoulou et al. (2006) when evaluating heart rate variability following a Wingate test. Heart rate will be recorded using a Polar wrist unit and chest strap. In line with previous research monitoring heart rate recovery (Tulumen et al. 2011; Trevizani, Benchimol-Barbosa and Nadal 2012; Shetler et al. 2001), heart rate data was recorded for five minutes following cessation of the test.

CHAPTER 3. METHODS

3.1 Research design protocol

Participants were required to attend three sessions, each lasting approximately one hour. The first of these sessions was for familiarisation purposes and was followed by a pre-test (PRE) and finally post-test (POST) session. A one week rest period interspersed the familiarisation session and pre-test, whereas the 2 week intervention interspersed the pre- and post-test sessions. The same testing protocols were used for each session. Following the pre-test, participants were randomly allocated to either the experimental (ION) or placebo control (PLA) group under double-blind conditions. The allocation was determined using the manual method of a coin flip, condition A for heads or condition B for tails. The final intake of participants were allocated to alternating conditions to achieve equal groups. The distribution of bands to participants was controlled by a supervisor who was not involved with recruitment, data collection or analysis. All of the bands were in the possession of the supervisor throughout the study and stored in a key locked storage unit. Participants allocated to the experimental group were issued an Ionic Balance Band while the placebo control group were issued a placebo band that appeared identical to the active band. Participants were instructed to wear their allocated band at all times during the intervention period. Ethical approval was sought and granted by the School of Health Sciences Research Review Group of Robert Gordon University (SRRG - SHS/MRes/12/40).

3.2 Participants

The sample for this study was drawn from consenting adults who classified themselves as physically active based upon the guidelines issued by the Department of Health (2011). The majority of the participants recruited were matriculated students at Robert Gordon University. Additional participants were sought from visitors, members and staff of the university's sport complex, RGU:Sport. In total, (35) men and (25) women volunteered to participate in this study. Participant details by gender for age, height and weight are displayed in Table 3.1 below. Permission to contact students for recruitment purposes was sought and granted from the relevant course leaders. The primary recruitment methods were email and spoken invitation to participate. Permission to recruit from visitors to RGU:Sport using posters and information sheets was granted from the Director of Sport.

Table 3.1: Participant details (mean ± SD) by gender

	Men	**Women**
Age (years)	24 ± 3	23 ± 3
Height (cm)	180 ± 3.5	164 ± 3.5
Mass (kg)	80 ± 6.7	64 ± 3.8

3.2.1 Inclusion Criteria

Individuals who satisfied the low risk stratification, as outlined by the American College of Sports Medicine (Thompson, Gordon and Pescatello 2010), were accepted to the study. This was done verbally during first meeting or via telephone. Additionally, participants were to be free from joint, muscle or other injury classification that would impair them from participating safely in physical activity. This was determined by completion of a Physical Activity Readiness Questionnaire (PAR-Q) and an informed consent form as presented in Appendix A and Appendix B respectively. The information sheet presented to the participants is included as Appendix C.

3.2.2 Exclusion Criteria

Individuals who were planning on making significant changes to either their diet or physical activity level were not accepted to the study. Additionally, individuals who currently wore an Ionic Balance Band or had done so in the previous three months were excluded from taking part. These conditions were satisfied during a verbal screening either face to face or via telephone upon the participant showing an interest in participating in the study.

3.3 Test protocol

The researcher arrived at the test location 30 minutes prior to the arrival of the participants to complete the necessary equipment calibration and set up. Participants reported to the Human Performance Laboratory at an allocated timeslot. At this point the participants were assigned a code reference number under which all of their personal information and test data was stored. Additionally, participants were issued the informed consent form before the test procedure began at the familiarisation session. The informed consent clarified the process for withdrawal from the study. The participant was allowed time to thoroughly read and complete the informed consent form. At this point the researcher collected the completed consent forms, reviewed the test procedure with the participants and any questions were answered. At the beginning of each testing session baseline biometric measurements including height and weight were then made. The participants completed the test battery in the following order; lifestyle questionnaire, cognitive assessment, balance assessment, lower body power assessment, upper body power assessment, muscular strength assessment, anaerobic power assessment and heart rate recovery assessment. Approximately two minutes rest was granted between each component of the test battery. The rest periods granted within each assessment procedure are detailed below. The total length of the protocol was approximately 1 hour 15 minutes.

3.3.1 Lifestyle questionnaire (PRE and POST sessions only)

The lifestyle questionnaire was completed on a computer workstation located within the workspace. All participants were assessed at computer workstations with similar hardware specifications. The researcher was on hand to clarify any issues relating to interpretation or understanding of the questions or technical difficulties with either the software or hardware. The pre- and post-test lifestyle questionnaires are included as Appendix C and Appendix D respectively. The questionnaire took approximately three minutes to complete.

3.3.2 Assessment of cognitive function

The cognitive assessment test battery was completed at the same computer workstation as the lifestyle questionnaire. The programme was loaded for the participants and an identifier code was entered for each individual and test session. Participants were directed to follow the on-screen instructions to navigate the assessment procedure. The researcher was on hand to assist in any issues that arose during the assessment. The cognitive assessment took approximately 20 minutes to complete.

3.3.3 Assessment of balance

Balance assessments were using a unilateral standing task with eyes open and with eyes closed (Verhagen et al. 2005). Participants were allowed a practice attempt on each leg for both the eyes open and closed conditions to determine which leg they prefered to use for the actual measurements. This preference was noted and remained constant across all sessions as did the choice of footwear (trainers or barefoot). Both positions were held for 20 seconds, data was recorded for three attempts of each with 30 seconds rest between attempts. The balance assessment took approximately five minutes to complete.

3.3.4 Assessment of lower body muscular power

The participants were taken through a warm-up consisting of five minutes on a stationary Monark Cycle Ergometer loaded with resistance of 1kg at approximately 50 $Rev.min^{-1}$. This was followed by specific lower body dynamic movements including high knees, heel flicks and forward lunges (Reiman et al 2010). Participants were required to perform three countermovement vertical jumps at maximal effort while positioned on a force platform (Richter et al. 2012). Participants were instructed to position their hands on their hips and maintain this posture throughout the movement (Richter et al. 2012). Two practice attempts were permitted to familiarise the participant with the movement. Recorded attempts were separated by 30 second intervals to ensure maximum performance (Iossifidou, Baltzopoulos and Giakas 2005). This component of the test battery lasted approximately seven minutes.

3.3.5 Assessment of upper body muscular power

Participants were taken through a warm-up consisting of dynamic upper body movements including various arm circles in all three planes of motion. Participants were required to perform three single effort push-ups, extending as powerfully as they could from a flexed set position with their hands maintaining contact with the force plates throughout. Two practice attempts were given and each recorded effort was separated by a 60 second interval. This component of the test battery lasted approximately seven minutes.

3.3.6 Assessment of muscular strength

The isokinetic dynamometer (HUMAC®/NORM™ TESTING & REHABILITATION SYSTEM, Model 770, Computer Sports Medicine, Inc. [CSMI]) was set following the manufacturer's instructions for testing of the right knee in the upright sitting position (CSMI 2006). The dynamometer arm's centre of rotation was aligned with the lateral joint centre of the knee. The participant was secured using the support straps and harness. The left leg was positioned using the contra lateral limb stabiliser. Concentric extension and flexion of the knee were assessed in a

single movement sequence at angular velocities of 60°s^{-1} and 120°s^{-1}. Participants performed 10 sub-maximal repetitions at each angular velocity to familiarise themselves with the motion. Following a 45 second rest period, three maximal exertions were completed in a continuous movement sequence. One minute of rest was allocated between the two angular velocity protocols. Participants were instructed to produce maximal effort and consistent verbal feedback was provided to each participant by the same researcher to ensure standardisation. From the data recorded, values for peak torque were noted for each phase of the movement. The assessment of maximum muscular strength took approximately 10 minutes.

3.3.7 Assessment of anaerobic power and heart rate recovery

The WAT was completed using an Ergomedic 894E cycle ergometer (Monark Exercise AB, Vansbro, Sweden). Before commencing the test procedure, participants were fitted with a heart rate transmitter chest strap and wrist unit to wear throughout (Polar Electro, Warwick, England). The resistance used during the 30 second WAT was 7.5% of the participant's body mass (kg). The seat and handlebars of the cycle ergometer were adjusted for individual differences in stature and limb length to achieve the correct test position as directed by the literature (Balmer et al. 2004). The warm up protocol consisted of three minutes pedalling at 60RPM at 1kg resistance and two minutes at 25% of the calculated test resistance at 60RPM (Baker and Davies 2002). Participants were familiarised with the experience of reaching maximum cadence and applying the load basket at the end of the warm up (Doré et al. 2003). Following a 60 second period for any required adjustments, participants were instructed to achieve maximum cadence before applying the test resistance using the basket release switch on the handlebars. The participants were verbally encouraged to pedal as fast as possible for the duration of the 30 second test. The recovery protocol required the participants to continue pedalling at 60RPM for two minutes with no resistance added. Participants were then instructed to dismount the ergometer and continue their recovery for a further three minutes

while seated on a chair. This component of the test battery lasted approximately 12 minutes.

3.4 Data processing and reduction

The responses from the completed lifestyle questionnaires were compiled and entered into an Excel worksheet. The answer structures were in the form of Likert scales, a Yes / No choice or several nominal scales. The cognitive test battery's evaluation tool provided mean reaction times for each participant for all of the tests completed, these were transferred into an Excel format. Balance assessments were performed on the force platform and the root mean square of the centre of pressure trace calculated. Best performance defined as the smallest root mean square value was selected for further analysis. Vertical jumps were also performed on the force platform and jump height measured using the following formula (jump height = $\frac{1}{2}g(t/2)^2$, where g is the acceleration caused by gravity and t is the time in the air). From the three vertical jumps performed, the best performance was taken forward for analysis. Similarly for the push-up, the movement was performed on two separate force platforms and the trial that produced the largest peak combined force was selected. For muscular strength, each isokinetic movement sequence provided three peak torque values for knee extension and flexion. The highest value for each joint action at the two angular velocities assessed was taken for analysis. From the Wingate test, peak power was determined by the largest power value produced during the trial after the trace was smoothed. The power drop that had occurred was calculated by subtracting the final power value from the peak power value and dividing by the time between the two time points. The accompanying software to the Polar unit allowed for the heart rate to be tracked in phases of active and seated recovery. The parameters assessed (lifestyle questionnaire outstanding), the variables obtained and their units are displayed in Table 3.2 below.

Table 3.2: Parameters assessed and subsequent outcome variables with units of measurement

Parameters Assessed	Variables (Abbreviations)	Measurements Units (Abbreviations)
Balance	Unilateral standing-eyes open (USEO)	Millimetres (mm)
	Unilateral standing-eyes closed (USEC)	
Lower body power	Vertical jump height (VJH)	Centimetres (cm)
Upper body power	Push up force (PUF)	Newton (N)
Muscular strength	Knee extension $60°^{-1}$ (EXT60)	Newton metres (Nm)
	Knee flexion at $60°^{-1}$ (FLX60)	
	Knee extension $120°^{-1}$ (EXT120)	
	Knee flexion $120°^{-1}$ (FLX120)	
Anaerobic power	Peak power (PP)	Watts (W)
	Power drop (PD)	Watts per second (Ws^{-1})
Heart rate recovery	Active heart rate recovery (AHRR)	Beats per second (bs^{-1})
	Seated heart rate recovery (SHRR)	
Cognitive function	Simple reaction time (SRT)	Milliseconds (ms)
	Repeated simple reaction time (RSRT)	
	Procedural reaction time (PRT)	
	Mathematical processing (MP)	
	Matching to sample (MTS)	
	Go / no go (GNG)	
	Code Substitution (CS)	

3.5 Statistical analysis

Statistical analyses were performed with the software package SPSS 21 (IBM Corporation, Armonk, NY). Data from the assessment of balance, lower and upper body maximum muscular power, maximum muscular strength, anaerobic power and heart rate recovery were checked for the presence of outliers using primarily visual methods. The assumption of normality were verified using Shapiro-Wilks test. Where normality was not present standard transformations were applied to achieve such a distribution. Descriptive statistics are presented for these parameters as mean ± standard deviation (SD) or median and interquartile range where indicated. Two-factorial mixed ANOVA's with group (between factor: ION vs. PLA) and time (within factor: PRE vs. POST) as model factors were used to test for main and interaction effects. Identification of interaction effects were seen as the primary assessment measure of whether the active intervention was successful. To quantify the magnitude of any treatment effects, effect sizes using pooled pre-test SD were used $d_{ppc2} = C_P\left[\frac{(M_{post,T}-M_{pre,T})-(M_{post,C}-M_{pre,C})}{SD_{pre}}\right]$ where the pooled standard deviation is defined as $SD_{pre} = \sqrt{\frac{(n_T-1)SD^2_{pre,T}+(n_C-1)SD^2_{pre,C}}{n_T+n_C-2}}$ and $C_P = 1-\frac{3}{4(n_T+n_C-2)-2}$ (Morris 2008). The following guide was used to characterise the magnitude of the effect sizes: small (0.2), moderate (0.5) and large (0.8). The outcome variables from the cognitive function assessment included in the final grouping of Table 3.1 were reduced via principal component analysis (PCA). The resulting variables were then assessed using the above ANOVA method. The data from the lifestyle questionnaires was used to produce appropriate descriptive statistics and visual representations. Additionally, independent samples Mann-Whitney U tests, factorial ANOVAS and Chi-squared tests were ran to investigate effects and relationships where appropriate. For all statistical analyses, the level of significance was set at $p < .05$. Based on the data collected, a correlation of approximately 0.5 reflected the correlation among repeated measures for the variables analysed. The initial power calculation was set to determine the power to detect moderate effects (f = .25). With alpha set at .05 and a total sample size of 60, the post hoc analysis estimated that the power to calculate moderate effect sizes was .97. A further calculation was completed to estimate the power

to detect small effect sizes (f=0.1) and in this case the power was estimated to be 0.65.

CHAPTER 4. RESULTS

4.1 Physical performance assessments

The data obtained from the assessment of balance, lower body power, upper body power, muscular strength, anaerobic power and heart rate recovery are presented in table 4.1. The outcome variables for balance include: unilateral standing-eyes open (USEO), unilateral standing-eyes closed (USEC); for lower- and upper-body body power include: vertical jump height (VJH) and push up force (PUF), respectively; for muscular strength include: knee extension at $60°^{-1}$ (EXT60), knee flexion at $60°^{-1}$ (FLX60), knee extension at $120°^{-1}$ (EXT120) and knee flexion at $120°^{-1}$ (FLX120); for anaerobic power include: Wingate peak power (PP) and Wingate power drop (PD); and for heart rate recovery include: active heart rate recovery (AHRR) and seated heart rate recovery (SHRR).

Table 4.1: Testing Battery Results for Physical Performance Assessments: Absolute values are displayed as Mean ± SD or Median (IQR) (where variables are indicated with *).

Variable (Units)	PRE (Week 0)		POST (Week 2)		*F*(1,58) Statistic Value		P value		Effect size (d_{ppc2})
					Interaction effect		Interaction effect		
	ION	*PLA*	*ION*	*PLA*	Main effect for time	Main effect for group	Main effect for time	Main effect for group	
*Unilateral standing-eyes open (mm)	224 (140-271)	245 (200-301)	275 (223-315)	234 (180-297)	.060		.808		.04
					29.196	1.066	.0001	.306	
*Unilateral standing-eyes closed (mm)	387 (321-401)	323 (278-364)	342 (302-389)	318 (298-358)	1.72		.195		-.09
					.055	2.744	.816	.103	
Vertical jump height (cm)	30 ± 6	25 ± 4	29 ± 6	25 ± 4	3.140		.082		-.20
					.271	10.018	.605	.002	
Push up force (N)	743 ± 339	772 ± 373	736 ± 273	770 ± 395	.030		.863		.09
					.088	.125	.088	.725	
Knee extension at 60°$^{-1}$ (Nm)	177 ± 53	172 ± 50	172 ± 52	178 ± 56	8.017		.006		-.21
					.13	.003	.908	.953	

Knee flexion at 60°$^{-1}$ (Nm)	95 ± 28	97 ± 33	95 ± 26	98 ± 32	.272		.604		.03
					.145	.07	.705	.793	
Knee extension at 120°$^{-1}$ (Nm)	150 ± 51	143 ± 40	152 ± 53	145 ± 44	.132		.718		0
					.643	.204	.426	.653	
Knee flexion at 120°$^{-1}$ (Nm)	83 ± 26	82 ± 27	83 ± 27	84 ± 26	.648		.424		-.07
					.608	.001	.266	.973	
Wingate peak power (W)	748 ± 201	702 ± 206	752 ± 201	698 ± 202	.611		.438		.04
					.001	.918	.970	.342	
Wingate power drop (Ws^{-1})	12.3 ± 4.6	12.1 ± 4.5	12.2 ± 4.2	11.6 ± 4.1	.826		.367		.09
					1.140	.152	.290	.698	
Active heart rate recovery (bs^{-1})	1.78 ± .51	2.08 ± .63	1.82 ± .52	2.05 ± .58	.269		.606		.12
					.012	3.997	.913	.05	
Seated heart rate recovery (bs^{-1})	.87 ± .25	.88 ± .27	.94 ± .28	.84 ± .20	3.505		.066		.42
					.123	.650	.727	.423	

4.1.1 Unilateral standing – eyes open

A reflect and square root transformation was applied to the data to achieve normality. The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on USEO, $F(1,58) = .060$, $p = .808$. A significant main effect for time was observed, $F(1,58) = 29.196$, $p = .0001$. The scores for the pooled population were observed to improve over time. The main effect for group was not statistically significant, $F(1,58) = 1.066$, $p = .306$. The effect size quantifying the standardized difference between groups ($d_{ppc2} = .04$) illustrates that no effect was obtained from the intervention over placebo condition.

4.1.2 Unilateral standing – eyes closed

A square root transformation was applied to the data to achieve normality. The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on USEC, $F(1,58) = 1.72$, $p = .195$. Additionally, the main effects for time, $F(1,58) = .055$, $p = .816$ and group $F(1,58) = 2.744$, $p = .103$ were not statistically significant. The effect size quantifying the standardized difference between groups ($d_{ppc2} = -.09$) illustrates that no effect was obtained from the intervention over placebo condition.

4.1.3 Vertical jump height

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on VJH, $F(1,58) = 3.140$, $p = .082$. The main effect for time, $F(1,58) = .271$, $p = .605$ was not statistically significant. A significant main effect for group was observed, $F(1,58) = 10.018$, $p = .002$ with the ION group demonstrating greater jump heights across both PRE and POST tests. The effect size quantifying the standardized difference between groups ($d_{ppc2} = -.20$) illustrated a small effect favouring the placebo condition.

4.1.4 Push up force

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on PUF, $F(1,58) = .030$, $p = .863$. Additionally, the main effects for time, $F(1,58) = .088$, $p = .768$ and group $F(1,58) = .125$, $p = .725$ were not statistically significant. The effect size quantifying the standardized difference between groups ($d_{ppc2} = .09$) illustrates that no effect was apparent for the intervention over placebo condition.

4.1.5 Knee extension at 60°$^{-1}$

The two-factorial mixed ANOVA revealed a statistically significant interaction between group and time for EXT60, $F(1,58) = 8.017$, $p = .006$. Investigation into the interaction effect showed that the mean for the ION group decreased by approximately the same as the mean for the PLA group increased. The main effects for time, $F(1,58) = .013$, $p = .908$ and group $F(1,58) = .003$, $p = .953$ were not statistically significant. The effect size quantifying the standardized difference between groups ($d_{ppc2} = -.21$) illustrates a small effect favouring the placebo condition.

4.1.6 Knee flexion at 60°$^{-1}$

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on FLX60, $F(1,58) = .272$, $p = .604$. Additionally, the main effects for time, $F(1,58) = .145$, $p = .705$ and group $F(1,58) = .070$, $p = .793$ were not statistically significant. An effect size of $d_{ppc2} = .03$ illustrates that no effect was obtained from the intervention over placebo condition.

4.1.7 Knee extension at 120°$^{-1}$

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on EXT120, $F(1,58) = .132$, $p = .718$. Additionally, the main effects for time, $F(1,58) = .643$, $p = .426$ and group $F(1,58) = .204$, $p =$

.653 were not statistically significant. An effect size of d_{ppc2} = 0 illustrates that no effect was obtained from the intervention over placebo condition.

4.1.8 Knee flexion at 120°-1

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on FLX120, $F(1,58) = .648$, $p = .424$. Additionally, the main effects for time, $F(1,58) = .266$, $p = .608$ and group $F(1,58) = .001$, $p = .973$ were not statistically significant. An effect size of d_{ppc2} = -.07 illustrates that no effect was obtained from the intervention over placebo condition.

4.1.9 Wingate peak power

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on PP, $F(1,58) = .611$, $p = .438$. Additionally, the main effects for time, $F(1,58) = .001$, $p = .970$ and group $F(1,58) = .918$, $p = .342$ were not statistically significant. The effect size quantifying the standardized difference between groups (d_{ppc2} = .04) illustrates that no effect was obtained from the intervention over placebo condition.

4.1.10 Wingate power drop

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on PD, $F(1,58) = .826$, $p = .367$. Additionally, the main effects for time, $F(1,58) = 1.140$, $p = .290$ and group $F(1,58) = .152$, $p = .698$ were not statistically significant. An effect size of d_{ppc2} = .09 illustrates that no effect was obtained from the intervention over placebo condition.

4.1.11 Active heart rate recovery

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on AHRR, $F(1,58) = .269$, $p = .606$. Additionally, the main effects for time, $F(1,58) = .012$, $p = .913$ and group $F(1,58) = 3.997$, $p =$

.05 were not statistically significant. An effect size of d_{ppc2} = .12 illustrates that no effect was obtained from the intervention over placebo.

4.1.12 Seated heart rate recovery

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on SHRR, $F(1,57) = 3.505$, $p = .066$. Additionally, the main effects for time, $F(1,58) = .123$, $p = .727$ and group $F(1,58) = .650$, $p = .423$ were not statistically significant. An effect size of d_{ppc2} = .42 illustrates that a small to moderate effect was obtained for the intervention compared with the placebo condition.

4.2 Cognitive Assessment

The cognitive test battery yielded data on seven separate test procedures including simple reaction time (SRT), repeat simple reaction time (RSRT), procedural reaction time (PRT), mathematical processing (MP), matching to sample (MTS), go / no go (GNG) and code substitution (CS). The results for the cognitive tests are displayed in Table 4.2 as reaction time in milliseconds (ms).

Table 4.2: Absolute values for reaction times (mean ± SD) for the cognitive tests

Cognitive Test	Pre (Week 0)		Post (Week 2)	
	ION	***PLA***	***ION***	***PLA***
Simple Reaction Time (ms)	284 ±19	280 ± 21	283 ± 17	279 ± 22
Repeat Simple Reaction Time (ms)	290 ± 23	288 ± 16	290 ± 24	294 ± 38
Procedural Reaction Time (ms)	584 ± 55	556 ± 36	594 ± 76	550 ± 34
Mathematical Processing (ms)	2394 ± 550	2294 ± 542	2180 ± 455	2189 ± 539
Matching to Sample (ms)	1355 ± 267	1356 ± 392	1360 ± 300	1379 ± 394
Go / No go (ms)	353 ± 27	345 ± 22	355 ± 25	345 ± 22
Code Substitution (ms)	1007 ± 18	966 ± 13	998 ± 15	950 ± 11

A principal component analysis (PCA) was employed to determine if the information obtained from these tests could be conveyed by a smaller number of variables. The PCA ran on the PRE data yielded a two factor solution accounting for 70.5% of the variance in the original data set. The original scores were thus transformed to the smaller two dimensional subspace for analysis. The component loadings illustrated that the first variable was an amalgamation of each cognitive test (PCA1), and the second variable contrasted simple reaction time and ability to match (PCA2). The PRE and POST group scores for the lower dimensional variables are displayed in Table 4.3.

Table 4.3: Principal Component Results from Cognitive Data: Absolute values for group scores (mean ± SD) for PCA variables

Variable (Units)	PRE (Week 0)		POST (Week 2)		*F*(1,58) Statistic Value		P value		Effect size (d_{ppc2})
					Interaction effect		Interaction effect		
	ION	*PLA*	*ION*	*PLA*	Main effect for time	Main effect for group	Main effect for time	Main effect for group	
Principal Component Analysis 1 (ms)	3934 ± 529	3821 ± 497	3807 ± 471	3758 ± 455	.784		.380		-.13
					6.887	.449	.011	.506	
Principal Component Analysis 2 (ms)	1688 ± 265	1642 ± 309	1587 ± 273	1566 ± 279	.243		.624		-.09
					12.709	.236	.001	.629	

4.2.1 PCA1

As with the variables in the previous section, a two-factorial mixed ANOVA was employed to investigate any effects present. There was no statistically significant interaction between group and time on *PCA1*, $F(1,58) = .784$, $p = .380$. However, a main effect for time, $F(1,58) = 6.887$, $p = .011$ was observed, indicating that improvements for the pooled data were obtained across the intervention. The main effect for group, $F(1,58) = .449$, $p = .506$ was not statistically significant. The effect size quantifying the standardized difference between groups ($d_{ppc2} = -.13$) illustrates that no effect was apparent for the intervention over placebo condition.

4.2.2 PCA2

The two-factorial mixed ANOVA revealed no statistically significant interaction between group and time on *PCA2* , $F(1,58) = .243$, $p = .624$. However, a main effect for time, $F(1,58) = 12.709$, $p = .001$ was observed, again indicating that improvements for the pooled data were obtained across the intervention. The main effect for group, $F(1,58) = .236$, $p = .629$ was not statistically significant. The effect size quantifying the standardized difference between groups ($d_{ppc2} = -.09$) illustrates that no effect was apparent from for the intervention over placebo.

4.3 Lifestyle questionnaire

4.3.1 Quality of sleep

Participants were asked the following question on both PRE and POST test dates: "How would you rate your quality of sleep over the past two weeks?". Responses were measured using the four point Likert Scale (1="Very Good"; 2= "Fairly Good"; 3= "Fairly Bad"; and 4= "Very Bad"). Group means were calculated for ION and PLA for the PRE and POST tests using these values. These are presented in Table 4.4 with standard deviations and statistical results. Additionally, on the POST test date participants were asked the following question: "Since wearing the wristband, has your sleep quality improved?" A yes or no answer was obtained for the question. The results for the ION and PLA groups are presented in Figure 4.1 as percentages.

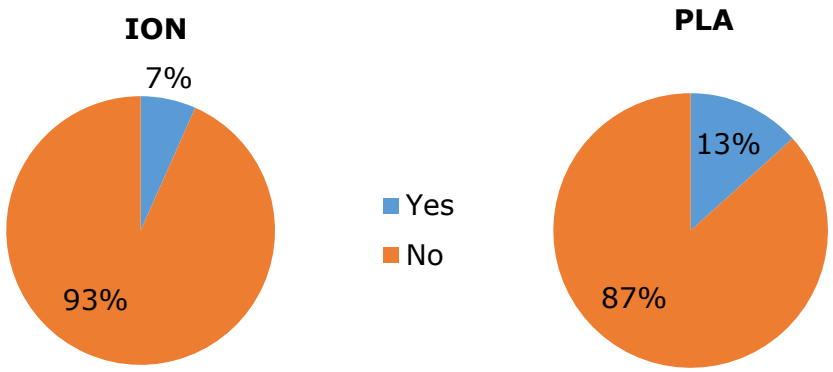
Independent samples Mann-Whitney U Tests demonstrated no significant differences between groups in sleep quality pre- and post-intervention (p = .581 and p = .813, respectively). In addition, the factorial ANOVA showed no interaction effects ($F(1,58)$ = .097, p = .757). Finally, no significant differences were noted in improved sleep quality between the groups ($\chi^2(1)$ =1.388, p=.239).

Table 4.4: Calculated values from responses to; "How would you rate your quality of sleep over the past two weeks?"

	ION	***PLA***	**Independent samples Mann-Whitney U Tests Sig. (*p*)**	**Factorial ANOVA interaction effect**	
				***F*(1,58)**	**Sig. (*p*)**
PRE group*	2.60 ± .89	2.47 ± .78	.581	.097	.757
POST group*	2.53 ± .63	2.53 ± .51	.813		
POST-PRE mean difference	-.06 ± .89	.06 ± .68			
Percentage change*	-2.56 ± 43.11	2.70 ± 38.17			

*A lower mean or percentage shows better quality of sleep

Figure 4.1: Response percentages for; "Since wearing the wristband has your sleep quality improved?"



4.3.2 Morning energy levels

Participants were asked the following question on both PRE and POST test dates: "Over the past two weeks, how often have you felt lethargic first thing in the morning?". Responses were measured using the five point Likert Scale (1="Everyday"; 2= "Frequently"; 3= "Occasionally"; 4= "Rarely" and 5= "Never"). Group means were calculated for ION and PLA for the PRE and POST tests using these values. These are presented in Table 4.5 with standard deviations and statistical results. Additionally, on the POST test date participants were asked the following question: "Since wearing the wristband, have you noticed an improvement in feelings of lethargy first thing in the morning?". A yes or no answer was obtained for the question. The results for the ION and PLA groups are presented in Figure 4.2 as percentages.

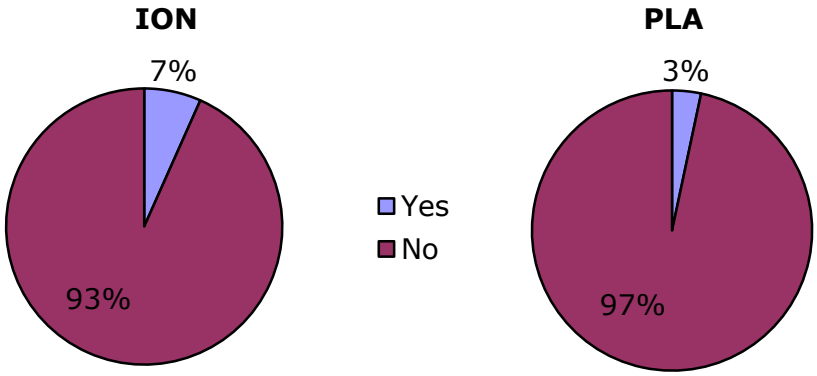
Independent samples Mann-Whitney U Tests demonstrated no significant differences between groups in morning energy levels pre- and post-intervention (p = .442 and p = .679, respectively). In addition, the factorial ANOVA showed no interaction effects ($F(1,58)$ = .226, p = .636). Finally, no significant differences were noted in improved morning energy levels between the groups ($\chi^2(1)$ =.947, p=.330).

Table 4.5: Calculated values for responses to; "Over the past two weeks, how often have you felt lethargic first thing in the morning?"

	ION	***PLA***	**Independent samples Mann-Whitney U Tests Sig. (*p*)**	**Factorial ANOVA interaction effect**	
				***F*(1,58)**	**Sig. (*p*)**
PRE group*	2.57 ± .97	2.40 ± 1.04	.442	.226	.636
POST group*	2.43 ± .77	2.37 ± .85	.679		
POST-PRE mean difference	-.13 ± .76	-.03 ± .84			
Percentage change*	-5.19 ± 33.43	-1.39 ± 45.48			

*A higher mean or percentage shows less feelings of lethargy

Figure 4.2: Response percentages for; "Since wearing the wristband, have you noticed an improvement in feelings of lethargy first thing in the morning?"



4.3.3 Afternoon/evening energy levels

Participants were asked the following question on both PRE and POST test dates: "Over the past two weeks, how often has your energy or motivation dipped in the afternoon/evening?". Responses were measured using the five point Likert Scale (1="Everyday"; 2= "Frequently"; 3= "Occasionally"; 4= "Rarely" and 5= "Never"). Group means were calculated for ION and PLA for the PRE and POST tests using these values. These are presented in Table 4.6 with standard deviations and statistical results. Additionally, on the POST test date participants were asked the following question: "Since wearing the wristband, have you noticed an improvement in your energy levels during the afternoon/evening?". A yes or no answer was obtained for the question. The results for the ION and PLA groups are presented in Figure 4.3 as percentages.

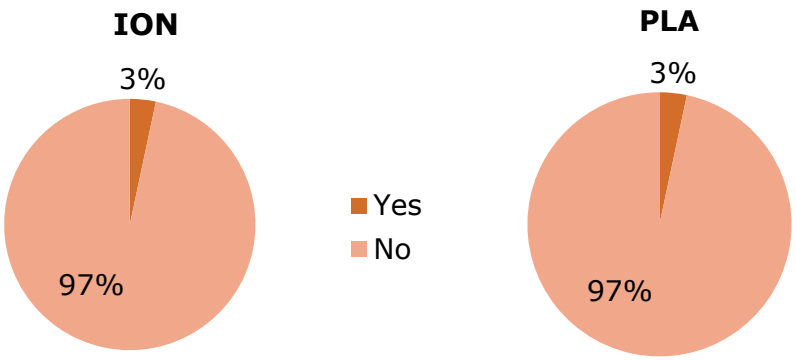
Independent samples Mann-Whitney U Tests demonstrated no significant differences between groups in afternoon/evening energy levels pre- and post-intervention (p = .392 and p = .668, respectively). In addition, the factorial ANOVA showed no interaction effects (F(1,58) = .193, p = .891). Finally, no significant differences were noted in improved afternoon/evening energy levels between the groups ($\chi^2(1) = 0$, $p=1$).

Table 4.6: Calculated values from responses to; "Over the past two weeks, how often has your energy or motivation dipped in the afternoon/evening?"

	ION	***PLA***	**Independent samples Mann-Whitney U Tests Sig. (*p*)**	**Factorial ANOVA interaction effect**	
				***F*(1,58)**	**Sig. (*p*)**
PRE group*	2.73 ± .64	2.60 ± 1.00	.392	.193	.891
POST group*	2.70 ± .79	2.6 ± .81	.668		
POST-PRE mean difference	-.03 ± .95	0 ± .89			
Percentage change*	-1.22 ± 36.81	0 ± 52.15			

*A higher mean or percentage shows less dips in energy

Figure 4.3: Response percentages for; "Since wearing the wristband, have you noticed an improvement in your energy levels during the afternoon/evening?"



4.3.4 Muscle Soreness

Participants were asked the following question on both PRE and POST test dates: "Following physical activity, do you suffer from muscle soreness?". Responses were measured using the five point Likert Scale (1="Never"; 2= "Rarely"; 3= "Occasionally"; 4= "Frequently" and 5= "Always"). Group means were calculated for ION and PLA for the PRE and POST tests using these values. These are presented in Table 4.7 with standard deviations and statistical results. Additionally, on the POST test date participants were asked the following question: "Since wearing the wristband, have you noticed an improvement in recovery following exercise?". A yes or no answer was obtained for the question. All participants across both groups responded "No", therefore a graphical representation has not been provided.

Independent samples Mann-Whitney U Tests demonstrated no significant differences between groups in muscle soreness pre- and post-intervention (p = .228 and p = .987, respectively). In addition, the factorial ANOVA showed no interaction effects (F(1,58) = .985, p = .325). Finally, no significant differences were noted in muscle soreness between the groups ($\chi^2(1) = 0$, $p=1$).

Table 4.7: Calculated values from responses to; "Following physical activity, do you suffer from muscle soreness?"

	ION	*PLA*	Independent samples Mann-Whitney U Tests Sig. (*p*)	Factorial ANOVA interaction effect	
				F(1,58)	Sig. (*p*)
PRE group*	2.67 ± .61	2.87 ± .78	.228	.985	.325
POST group*	2.73 ± .58	2.73 ± .74	.987		
POST-PRE mean difference	.07 ± .73	-.13 ± .81			
Percentage change*	2.5 ± 57.33	-4.65 ± 44.82			

*A lower mean or percentage shows less muscle soreness

4.3.5 Additional pre-test questions

Participants were also asked the following questions on the PRE test date: "Do you have any prior knowledge of the Ionic Balance Band and its efficacy?"; "What is your main motivation for participating in this study?" and "What are your expectations on the effect that wearing the Ionic Balance Band will have on test results?". Figures 4.4, 4.5 and 4.6 display the response options and percentages recorded for each of the preceding questions.

Figure 4.4: Response percentages for; "Do you have any prior knowledge of the Ionic Balance Band and its efficacy?"

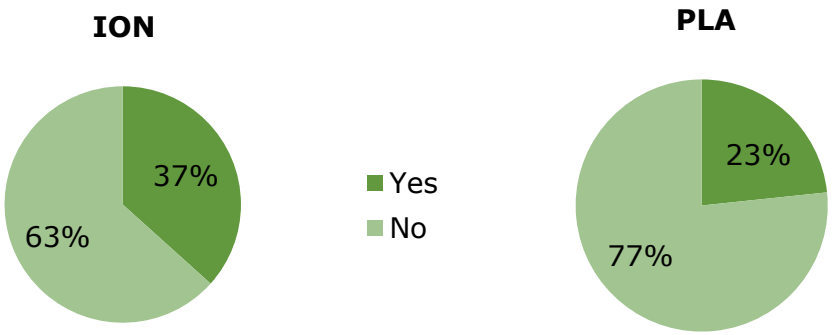


Figure 4.5: Response percentages for; "What is your main motivation for participating in this study?"

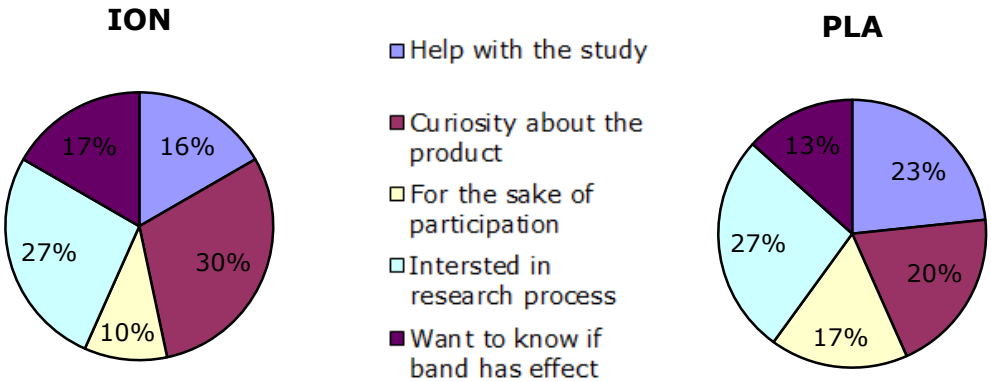
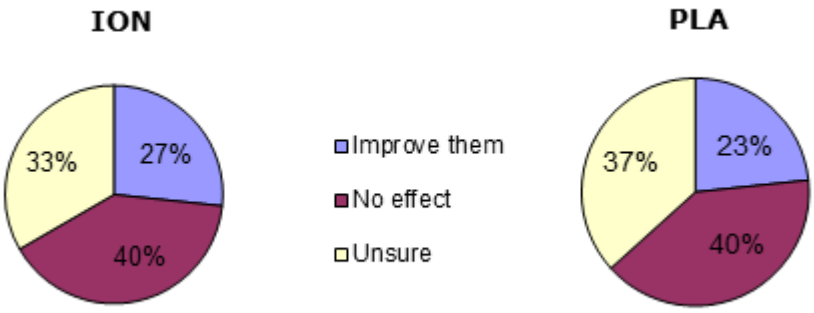


Figure 4.6: Response percentages for; "What are your expectations on the effect that wearing the Ionic Balance Band will have on test results?"



The results displayed by Figure 4.4 show that approximately the same number of participants in each group had some knowledge of the product before taking part in the study. Additionally, the main motivation for taking part in the study showed similarity between the groups as displayed by Figure 4.5 and mainly concentrated on providing assistance with the study, interest in the research process and curiosity regarding the effects of the product. Finally, similar response percentages were observed for both groups on the expected effect that the Ionic Balance Band would have on test results (Figure 4.6) with approximately one quarter of the participants expecting an improvement and in both groups 40% of participants expecting there to be no effect.

4.3.6 Additional post-test questions

Participants were also asked the following questions on the POST test date: "If you suffer from snoring or sleep apnoea, has there been an improvement since wearing the wristband?"; "Has there been a decrease in any joint pain or discomfort since wearing the wristband?"; "Since wearing the wristband, have you noticed improved recovery or healing related to injuries or bruising?"; "Has there been an improvement to any medical condition since wearing the wristband?" and "Do you think you have been wearing an Ionic Balance Band or

a placebo band over the last two weeks?". Figures 4.7, 4.8, 4.9, 4.10 and 4.11 display the response options and percentages recorded for each of the preceding questions. A Chi-squared test was completed using the data presented in Figure 4.12.

Figure 4.7: Response percentages for; "If you suffer from snoring or sleep apnoea, has there been an improvement since wearing the wristband?"

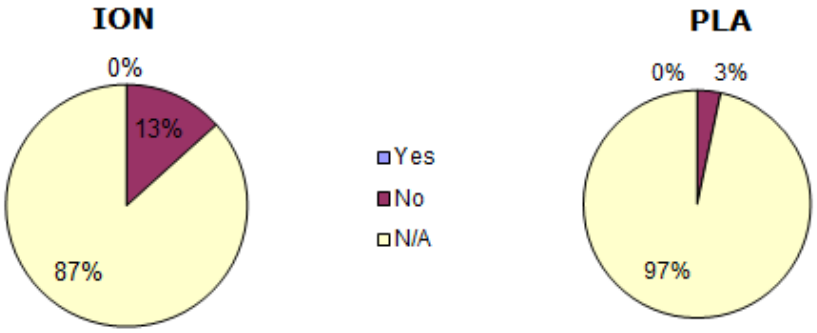


Figure 4.8: Response percentages for; "Has there been a decrease in any joint pain or discomfort since wearing the wristband?"

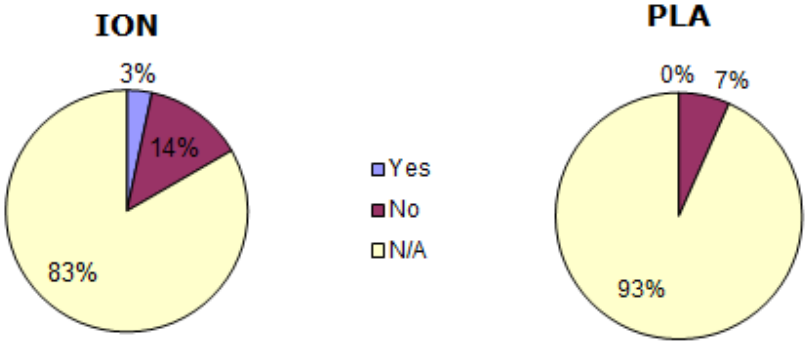


Figure 4.9: Response percentages for; "Has there been an improvement to any medical condition since wearing the wristband?"

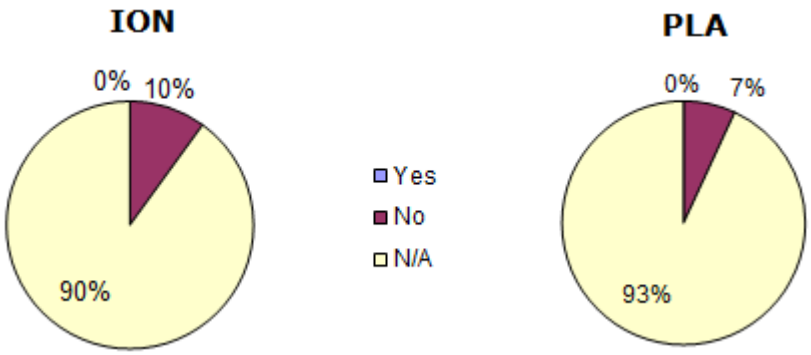


Figure 4.10: Response percentages for; "Since wearing the wristband, have you noticed improved recovery or healing related to injuries or bruising?"

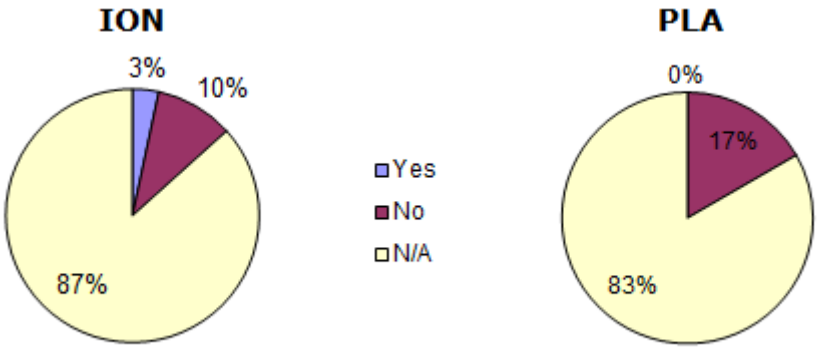
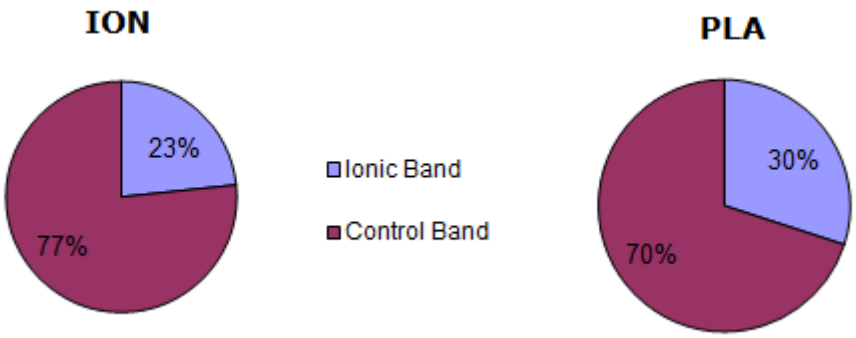


Figure 4.11: Response percentages for; "Do you think you have been wearing an Ionic Balance Band or a placebo band over the last two weeks?"



The results displayed in Figures 4.7, 4.8, 4.9 and 4.10 show that no meaningful difference was observed between the groups for improvements to symptoms of snoring or sleep apnoea, joint pain, medical conditions or recovery from injuries. Finally, Figure 4.11 shows that a similar percentage of participants in each group postulated that they had been wearing an Ionic Balance Band over the course of the intervention. No significant differences were noted in identification of band allocation between the groups, the Chi-square statistic was .341. The *p*-value was .559.

CHAPTER 5. DISCUSSION

5.1 Introduction

The aim of this study was to assess the efficacy of the Ionic Balance Band to improve selected health and fitness parameters, compared to a placebo control, following a two week exposure intervention under randomised double-blind conditions. Statistical analysis of the data gathered revealed no significant improvements from wearing the Ionic Balance Band over the placebo control band for any of the parameters investigated. A foundation for the Ionic Balance Bands' potential to improve the health and function of its wearer could be made with a selective view of the literature. However, a wider perspective reveals that the published research on its main property exhibits a lack of depth, rigour and consensus with even less evidence for the health benefits of its secondary properties. As the study conducted by Tully (2012) is the only other direct research on the Ionic Balance Band, the results of the present study will be compared to this primarily followed by related findings from the wider research.

5.2 Outcome measures

5.2.1 Balance

In the present study, the Ionic Balance Band was not effective at improving measures of balance over a placebo control. These findings are in disagreement with those of Tully (2012) who reported a significant balance improvement from wearing the Ionic Balance Band compared to a placebo control. The task performed was similar to the present study in that it was unilateral standing with eyes closed but the data gathering technique employed was different. The broader research reveals another study which has investigated the effects of an ionic energy product on balance. In line with the present findings, Bringman, Kimura and Schot (2011) found that postural control as assessed by centre of pressure deviations was not improved by wearing an "ionic bracelet" compared to an inert bracelet. Although as stated

in the Introduction, the study by Bringmam, Kimura and Schot (2011) does not provide a product name or ion output concentration for comparison. In the present study, an improvement in USEO was observed in both groups over the intervention period. These improvements were deemed to exhibit the presence of a practice or learning effect rather than a placebo effect, as will be discussed below.

5.2.2 Lower body muscular power

Vertical jump height was not improved by the Ionic Balance Band when compared to placebo control in the present study. The ION group produced consistently higher jump heights than the PLA group although as stated above, no additional improvement was observed as a result of wearing the band. Direct equivalent research on lower body power of this nature is not available for the Ionic Balance Band. However, findings reported by Bringmam, Kimura and Schot (2011) are in agreement with the present study whereby no improvement in power was observed from wearing an ionic bracelet while performing vertical jumps.

5.2.3 Upper body muscular power

The results indicate that the Ionic Balance Band was not effective at improving upper body power compared to a placebo control as assessed by the force generated during a push up. Some equivalence could be drawn between this test parameter and variables investigated by Tully (2012). In contrast to the present study, significant improvement were observed for measures of left hand grip strength, one rep max bicep curl and maximum push ups in 30 seconds (Tully 2012). Although these parameter are more indicative of muscular strength and muscular endurance respectively, no comparable effect of the Ionic Balance Band was observed in the present study.

5.2.4 Muscular strength

Lower body muscular strength was assessed by isokinetic dynamometry in the present study. A significant interaction effect was observed for group and time on peak torque during knee extension at $60°^{-1}$. However, investigation of the interaction effect showed that it had been caused by a non-significant change in scores in opposite directions for the Ionic Balance Band and placebo group. The rest of the isokinetic measures (FLX60, EXT120 and FLX120) showed no such effect or any additional effect due to differences in the groups. No direct equivalent research is available for leg strength while wearing an Ionic Balance Band. Looking at the wider negative ion research, Bringmam, Kimura and Schot (2011) did include a leg strength measure of sorts when they tasked their participants to complete a maximum effort isometric dead lift by pulling on a handlebar chained to a platform. Although this test does not match the one employed for measuring muscular strength in the present study, the outcome was the same in that the ionic bracelet was not effective at improving muscular strength over a placebo.

5.2.5 Anaerobic power

As derived from the WAT data, peak power and the rate of power drop were not found to be improved by wearing an Ionic Balance Band over a placebo band. The test battery conducted by Tully (2012) did not include a WAT. However, two components of the test battery did task a similar aspect of fitness as the WAT. Tully (2012) observed significant improvements to both the maximum number of push ups and sit ups completed in 30 seconds (while wearing the Ionic Balance Band) which although not leg orientated, would still involve an aspect of anaerobic fitness. The work conducted by Burden and Glaister (2012) and Gray (2007) presents conflicting results for the efficacy of an ionised sports undergarment to improve WAT performance. Gray (2007) reported an increase to average power due to the presence of an ionised garment while Burden and Glaister'S (2012) results supported the current findings as no such change was witnessed. Additionally, the work conducted

by Nimmerichter et al. (2014) also found no improvement in WAT performance under very high negative air ion concentrations.

5.2.6 Heart rate recovery

The current study showed a small to moderate effect for the Ionic Balance Band over the placebo band for measures of heart rate recovery. Again this parameter has been included as a variable of interest in several previous studies. Although Ryushi et al. (1998) reported improved recovery for certain parameters following exercise in negative air ion conditions, heart rate was not one of them. However, work presented by Inbar et al. (1982) and Sovijarvi (1979) both concluded that exposure to negative air ions had a positive effect on heart rate recovery following exercise.

5.2.7 Cognitive assessment

The results of the cognitive assessment did not show an improvement for the Ionic Balance Band over the placebo control. A main effect for time was observed for both of the variables (PCA1 and PCA2) yielded from the PCA. These variables showed a reduction in score, thus faster reaction times, across the intervention period regardless of group. These improvements were deemed to exhibit the presence of a practice or learning effect rather than a placebo effect, as will be discussed below. No direct comparison of results can be made due to a lack of additional research into the Ionic Balance Band's efficacy to improve cognitive ability. However, several papers have reported results on the effect of negative air ions on cognitive performance. Nakane et al. (2007) observed an improvement in performance of a computer based task under exposure to negative air ions. Additionally, Hawkins and Baker (1978) reported an improvement to visual simple reaction times and mirror drawing following negative ion exposure. These studies all report findings in contrast to the present study.

5.2.8 Lifestyle questionnaire

Analysis of the lifestyle questionnaire data demonstrated no meaningful or statistically significant differences between the Ionic Balance Band group and the placebo control group. In contrast with the present study, Tully (2012) found that participants reported significantly higher energy levels when wearing the Ionic Balance Band compared to a placebo band. Additionally, quality of sleep (Deleanu and Stamatiu 1985) and energy levels (Lips et el. 1987) have been reported to be improved by exposure to negative ait ions. However, similar results were not reported by all who investigated these parameters with several studies finding no effect of negative air ion exposure (Albrechtsen et al. 1978; Terman, Terman and Ross 1998). Furthermore, a comprehensive meta-analysis conducted by Perez, Alexander and Bailey (2013) on the research concerning negative air ion exposure and mood outcomes, echoed the present findings. There was no consistent influence of positive or negative air ions on mood, relaxation, sleep, or anxiety (Perez, Alexander and Bailey 2013). The questions concerning prior knowledge, expectation and motivation did not show any relationships or trends between either the Ionic Balance Band or placebo band. Additionally, no significant difference was observed between the groups for the ability to correctly identify which band they had been wearing.

5.3 Concentration of negative air ions

As detailed in section two, several of the previous studies investigating the impact of air ions on human health (specifically the beneficial effect of negative air ions) exposed participants to "industrial quantities" of air ions (Ben-Dov et al. (1983; Nogrady and Furnass 1983; Inbar et al. 1982; Ryushi et al. 1998). Even at the lower end of this spectrum, the utilisation of electrical or water based air ion generators has yielded concentrations far in excess of anything that has been observed in a natural environment. The results from these trials did not produce a consensus on the effects of negative air ion exposure. However, concerning the research that did show a beneficial effect, the disparity between the negative air ion concentrations employed in those studies (typically 10,000 to 200,000 cm^{-3}) and the reported output of the Ionic Balance Band used in the current study (up to 4421 cm^{-3}) could theoretically account for the difference in their respective outcomes. It would not be unfair to hypothesise that electrical or water based generators which allow for a constant, modifiable and considerably higher concentration of negative air ions to be produced may elicit a stronger effect than a wristband containing gram quantities of a powdered mineral. The restricted surface area, inherent of the wristband's design should be considered alongside this. The lack of knowledge on any potential dose-response relationship impairs the understanding of how the source and concentration of negative air ions may influence the individuals exposed.

5.4 Magnitude of effect

As detailed in the literature review, of the studies that reported a beneficial effect to exposure of negative air ions or far infrared rays, the majority found a change in a physiological parameter such as heart rate (Inbar et al. 1982), skin temperature (Ryushi 1998) or fluid mobility (Yoo et al. 2002) under specific conditions. The present study involved many large motor actions such as vertical jump, push ups and maximal strength and anaerobic power testing. The difference between the assessment methods for evaluating if an effect had taken place could be a potential reason for the differences in observed results.

It may be that exposure to negative air ions or far infrared rays can cause significant changes to focussed physiological parameters but whether this will translate into a measurable improvement in sports performance is questionable, especially in light of the present findings.

5.5 Blinding and randomisation evaluation

A lack of participant blinding to group assignment can lead to responses that may weaken or invalidate results. Similarly, blinding of investigators including individuals involved with research design, enrolment, data collection and data analysts is also a crucial step in reducing bias for many trials (Schulz and Grimes 2002). Procedures implemented to achieve varying degrees of blinding in clinical trials are often reported briefly or not included at all in publications. It has been found that the interpretation of 'single', double' and 'triple' blinding varies between textbooks, practitioners and researchers causing confusion and inconsistencies (Schulz and Grimes 2002). It is common for articles to cite one of the above blinding conditions without detailing the process to attain them. Additionally, tests of blinding are shown to be lacking or unreported in many cases.

To the above point, Hrobjartsson et al. (2007) reported that of a sample of 1599 trials with blinded conditions, only 31 publications (2%) provided information on the success of blinding. Of these trials, 14 concluded that the blinding had been successful, seven concluded blinding was unsuccessful with the remaining 10 reporting unclear results. From the sample of 1599, Hrobjartsson et al. (2007) also contacted 200 authors who had not reported results or mentioned tests of blinding in their initial publications. They received 130 responses with only 15 stating that formal tests of blinding had taken place without them being reported, the remaining 105 did not complete any tests of blinding. It was concluded that although blinding procedures could reduce bias in trials, they may be unsuccessful and that the methodological uncertainty surrounding how best to assess this required action (Hrobjartsson et al. 2007).

The uncertainty mentioned above was a key point discussed in a review article by Kolahi, Bang and Park (2009) who detailed some of the common methods for assessing the success of blinding. Regarding the design of the question, it was reported that trial participants may be asked which condition they believed they had received, for example 'active' or 'placebo'. Participants may also be given the option to express uncertainty alongside the options for choice of condition, for example 'active', 'placebo' or 'do not know'. An alternative method highlighted was to utilise a 5-point scale so that participants could rate their level of certainty regarding condition allocation (Kolahi, Bang and Park 2009). A final method to ascertain information on the success of blinding is detailed that involves a pre-trial evaluation using a group of individuals who are not part of the main trial. These individuals would be asked to distinguish between the conditions by whichever approach was deemed appropriate based on the nature of the intervention. This final method highlights the issue of timing in relation to administering tests of blinding. With regards to what has been reported by previous studies, Kolahi, Bang and Park (2009) recommend the following points relating to the timing of tests - an assessment of blinding should be implemented: before a trial by on a separate group, during the early stages of the trial and at the end of the trial.

The present study posed the question, "*Do you think you have been wearing an Ionic Balance Band or a control band over the last two weeks?*" to the participants as part of their POST testing session. As can be seen in figure 4.12, those who had been in the ION group answered: Ionic Band – 23%, Control Band - 77%, while those in the PLA group answered: Ionic Band – 30%, Control Band – 70%. Statistical analysis of the information presented in figure 4.12 revealed that no significant differences were found between the groups for responses to this question (Chi-square statistic was .341, *p*-value was .559). These results may not reflect what was expected based on previous research. Kolahi, Bang and Park (2009) suggest that a question of this nature, in a trial where the overall findings suggest no effect for the treatment, should produce equal responses within and between each group to indicate successful blinding. Only one of these expectations has been met in

the current study. The inclusion of an 'Unsure' option may have produced results closer to those anticipated as successful blinding would be suggested by many participants choosing that option. Similarly, the high percentage of participants selecting 'Control Band' may be a reflection of their perceptions of the performance of their band. Indicated by the expanded questionnaire results, the vast majority of participants (across both groups) reported no improvements. Participants may have opted for 'Control Band' as they held the belief that the lack of effect experienced was down to their assignment to the control.

As mentioned previously, multiple tests of participant blinding under the conditions discussed could have been included to strengthen the procedures. The active and control bands used in the present study appeared identical and the blinding procedures explained in the methods section were seen as sufficient. However, the researcher and supervisor could have been subjected to tests of blinding also to evaluate the procedures used and to assess possible bias. Although extensive procedures could have been implemented to provide enhanced tests of blinding for the current study, the results for the question, *"Do you think you have been wearing an Ionic Balance Band or a control band over the last two weeks?"* (as described above and summarised in figure 4.11) can be viewed as a legitimate test of blinding. This view is supported when consideration is made to the common practices found in published research as described above. From these results, it could be interpreted that blinding was successful due to the non-significant difference between the groups and that the within group results may have been influenced by the participant's expectations of the band.

Reflection upon the methods used to implement randomisation in the present study allow for certain weaknesses to be highlighted. The use of a coin toss was believed to provide an appropriate randomisation of participants. However, it has been highlighted that manual methods such as this have several drawbacks. Kang, Ragan and Park (2008) reported that a coin toss can result in imbalanced samples sizes. The present study encountered the above issue and the procedure used to produce equal groups introduced an

element of bias. Additionally, a coin toss does not provide an audit trail which could be used to evaluate the methods implemented (Kim and Shin 2014).

Evaluation of the methodology highlighted a factor that should have been considered during recruitment and randomisation. Table 2.1 details the differing levels of positive and negative air ions in several locations. The participant's exposure to differing levels of air ions should have been quantified to make a judgement on eligibility. Prolonged exposure towards the extremes of this table could have affected the results of the test battery.

5.6 Placebo effect

Analysis of the pooled group data did not show a consistent improvement in performance over the course of the intervention. As mentioned in the above paragraphs, aside from unilateral standing with eyes open (USEO) and the measures of cognitive performance (PCA1 and PCA2) no other parameters significantly improved from the PRE to POST test sessions. If more of the outcome measures had yielded an improvement when analysing pooled data, it could have suggested the presence of a placebo effect. It could be postulated that placebo effects would be more evident in subjective, participant response parameters rather than objective exercise outcome measures. However, the results from the lifestyle questionnaire support the notion of no placebo effect as no meaningful changes were observed for any of the measures. In terms of detecting a placebo effect, the study design could have been improved to include a third group. This group could have been allocated to a 'no band' condition throughout the duration of the study.

5.7 Influences on sales and commercial success

As explained in the introduction, complementary and alternative medicine (CAM) is used either alongside or in place of conventional approaches. The extent to which CAM is integrated into the public health system or sought independently by patients differs between regions of the world. Debas, Laxminarayan and Straus (2006) reported a considerably higher availability and use of CAM in developing countries, the far-east and Japan compared with westernised regions. Several socioeconomic and cultural factors influence these observed differences. The lower availability and potentially higher cost of conventional medicine together with a stronger religious and spiritual vindication in the general population, are key influences to a higher incidence of CAM in the stated regions (Chiu 2014 and Coulter and Willis 2004).

Harris et al. (2012) conducted a meta-analysis on the prevalence of CAM use in the general population with a particular focus on western societies. Perhaps surprisingly based on the information above, it was found that one in four adults in the United Kingdom used some form of CAM while one in eight had consulted a CAM practitioner during the year of 2005. The not insignificant percentage of people found to be using a form of CAM, may go some way to explaining the trends seen in the health and fitness industry of late. It would appear that there is a considerable market for novel products with CAM orientated effects in western societies. The holographic wristband trend mentioned in the first chapter sees many of the manufacturers behind the products adopting phrases and language commonly used to advertise or promote CAM modalities (Verdan et al. 2012). They combine this with images, diagrams and text which suggested a scientific basis for the products claimed effects despite no evidence existing. The success that these products enjoy demonstrate that an "openness" to CAM exists in many consumers who may not have used similar modalities previously. Additionally, it would appear that the substantiation of claims by manufacturers is not a prerequisite for the individuals making a purchase.

At the time of writing, the Ionic Balance Band is advertised and promoted in a somewhat contradictory form when compared to the methods employed by other wristband manufacturers who have claimed similar effects. As detailed in the literature review of this report, one of the Ionic Balance Band's claimed properties (production / generation of negative air ions) has been the subject of several peer reviewed research articles (Tully 2012 was not peer reviewed), with beneficial effects found by some researchers (Gray et al. 2007; Ryushi et al. 1998; Inbar et al. 1982). Although these results were not obtained directly from the use of an Ionic Balance Band or even tourmaline as the source, potential customers could still be directed towards this information as a marketing tool. In contrast, the holographic wristbands are based on what can only be described as pseudoscience with no related research for the manufacturers to attempt to substantiate their claims. In view of this difference, it is perhaps surprising to see such a similarity between the design of the Ionic Balance Band and the most popular holographic wristband as shown in Figure 5.1. In most circumstances, it would be beneficial for a manufacturer to differentiate their product from one that has been shown to be ineffective as with the Power Balance Band (Verdan et al. 2012 and Brice et al. 2011). However in this particular case it can only be speculated that the benefit of having a product design which emulates the most popular wristband in the sector outweighs the negative of being visually associated with a debunked product.

Figure 5.1: The Ionic Balance Band (left) and the Power Balance Band (right).

5.8 Limitations, strengths and weaknesses of the present study

Although a relatively large sample was recruited and participated in the study, the demographic they were drawn from does impose limitations on the wider applicability of the outcomes. The sample primarily consisted of healthy and physically active students who were free form injury or medical conditions. Different results may have been observed with participant's who exhibited lower levels of fitness or an increased incidence of injury or medical complaint. Additionally, the enrolment procedures could have been improved in relation to the data presented in Table 2.1. This table shows that various environments have differing levels of

The assessment methods employed in this study are seen as objective and sound. However there is an abundance of other potential assessment methods to evaluate the chosen parameters which may yield different outcomes to those presented. As previously mentioned, consideration was given to the ordering of the tests included. The guidelines followed were taken from Miller (2012) who states that fitness tests should be carried out in the following order: nonfatiguing; agility, power and strength, sprints, muscular endurance, anaerobic and aerobic (Miller 2012). This order was seen as the most practical approach to minimise the fatiguing affect from one test to another in a battery

of this nature. A relatively extensive battery of tests was employed in the present study with a view to providing a fuller assessment of the product. Isolated tests may have yielded different results as any carry- over effects would have been reduced further.

The participants were instructed to wear their assigned wristband at all times during the two week intervention period. However participants may have removed wristbands for periods between the pre and post-test dates.

5.9 Principal Implications

Based on the findings of the present study, the Ionic Balance Band is ineffective at improving physical performance measures of balance, lower and upper body power, leg strength, anaerobic power and heart rate recovery. Additionally, no improvements were observed for any health related measures as assessed by the lifestyle questionnaire. These results directly contradict those of Tully (2012) and call into question the Ionic Balance Band's efficacy to improve the health and function of the wearer. There are several other wristbands available which proclaim improvements via the same properties as the Ionic Balance Band, these claims should be treated with caution. The present results cast doubt on the likelihood of any improvement to health or function from exposure to negative air ions, far infrared rays and alpha waves with tourmaline as the source. The company relies heavily on anecdotal evidence and a strong social media presence to promote its products. This study does not provide any scientific evidence to aid in the promotion of the product tested.

5.10 Recommendations for future research

The respective research findings on the efficacy of negative air ions, far infrared rays and alpha waves to improve health or fitness is divided, speculative and non-existent. In view of this, it would seem premature to conduct any further research on the Ionic Balance Band or tourmaline when so little is known about the properties from a general perspective. Further research is required to understand any mechanism(s) that could explain the influence of negative air ions observed in certain studies. A breakthrough in this area could lead to the establishment of a dose-response relationship which would enable further focussed research to be conducted. The effect of far infrared rays has received much less research focus with a paucity of knowledge on their efficacy to improve physical performance parameters. Whether any of the beneficial effects observed from exposure to far infrared rays can translate into a measurable improvement in performance should be a priority. A range of intensities and sources should be investigated. Any claim that alpha waves produced from an external source can influence humans in a measurable way appears completely unfounded. Initial exploratory research would have to be conducted before any claims could be considered further.

A thorough peer review process is the foundation that academic journals base their publication criteria on. An example of the considerations made before a transcript is passed to the peer review process is provided by Johnson and Domingo (2013). They state that the following measures guide the process: the potential scientific and social interest of the study; the scientific curricula/experience of the senior author(s) and the fitting of the study in the aims of scope of the journal (Johnson and Domingo 2013). Subsequently, several experienced researchers who have contemporary knowledge in the field of interest will then review the article. With this in mind, it is interesting to look at how negative research findings are reported in peer reviewed publications. Fanelli (2011) found that the number of articles with negative results being published has been dropping steadily between 1990 and 2007. In contrast, the number of articles published with headline positive results has

grown by 22% in the same period (Fanelli 2011). There may be several reasons for this trend. Strong positive results are seen as prestigious publications whereas negative findings are often not put forward for peer review. Anderson (2012) described that there may be a perception of negative results damaging a researchers reputation. That negative results are viewed as indicative of poor research design and this reflects on the researcher's incapability. Contrary to these views, negative results in research should be shared as they present another opportunity for information to be shared and discussed between practitioners. Refocussing on the present study, negative findings in research hold even greater importance for topics of interest that have thus for produced conflicting results.

5.11 Summary and conclusion

The present study investigated the efficacy of the Ionic Balance Band to improve selected health and fitness parameters under randomised, double-blind, placebo-controlled conditions. The Ionic Balance Band is one of several products that has been marketed towards the health and fitness industry in recent years as part of a wider trend. The beneficial effects claimed for such products are attributed to properties and mechanisms commonly associated with complementary and alternative medicine. However, these claims are largely unsubstantiated and the vast majority of peer reviewed research has not supported the manufacturer's claims. The Ionic Balance Band is claimed to improve the health and function of its wearer through generation of negative air ions, far infrared rays and alpha waves. Review of the literature revealed conflicting findings for the beneficial effects of negative airs ions in general while little to no research evidence existed on the beneficial effect of far infrared rays and alpha waves. The testing battery consisted of assessments to physical performance, cognitive function and lifestyle/health outcomes under the conditions stated above.

The present study revealed no significant improvements from wearing an Ionic Balance Band over a placebo control Band for any of the parameters assessed. The findings of the present study contradict those of the only other available research on the Ionic Balance Band. Tully (2012) reported a substantial improvement from wearing the Ionic Balance Band compared to a placebo control for several parameters. The reasons why the author has not sought further exposure considering such profound results is not known. Looking at the wider literature, it was postulated that the beneficial effects observed in some of the published research could be attributed to exposure of higher concentrations of negative air ions than produced by the Ionic Balance Band.

The peer reviewed research on exposure to negative air ions, far infrared rays and alpha waves does not provide sufficient support to the claims that have been made anecdotally about the Ionic Balance Band. This study endeavoured

to provide a scientific perspective on these claims through the application of a strong research design and objective assessment methods. The consistency in findings across assessments of physical performance, cognitive function and health status strengthen the conclusion drawn from the study; the Ionic Balance Band was not effective in improving the selected health and fitness parameters compared to a placebo control.

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APPENDICES

Appendix A

PAR-Q

Prior to undertaking any exercise test, a physical activity readiness questionnaire (PAR-Q) should be completed. The purpose of the PAR-Q form is to identify any health hazards which would affect an individual's ability to exercise safely.

Please read the following questions carefully and tick the appropriate box (yes or no) as applies to you.

	YES	NO
Has your doctor ever said you have a heart condition and that you should not do physical activity recommended by a doctor?		
Do you feel pain in your chest when you do physical activity?		
In the past month, have you had chest pain when you were not doing physical activity?		
Do you lose balance because of dizziness or do you ever lose consciousness?		
Do you have a bone or joint problem that could be made worse by a change in your activity?		
Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?		
Do you have any musculoskeletal problems in lower limbs that limit your physical activity?		
Do you know of any other reason why you should not do physical activity?		

If you answered **NO** honestly to all PAR-Q questions you can be reasonably sure that you can participate in this exercise test.

However, delay any physical activity if you have a minor illness (e.g. cold or fever).

If you answered **YES** to one or more PAR-Q question, you should consult your doctor if you have not done so recently. Your doctor should be consulted before participating in an exercise test.

I have read, understood and completed the questionnaire honestly. Any questions I had were answered to my full satisfaction.

NAME_____

SIGNATURE _____ DATE__

Appendix B

School of Health Sciences

School Research Review Group (SRRG)

Informed Consent Form

Generic Information	
SRRG Ref No:	SHS/MRes/12/40
Title (short):	Short-term exposure to the Ionic Balance Band

	Please initial each box
1. I confirm that I have read and understand the participant information sheet dated xx/xx/xxxx for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
3. I understand that data collected during the study will be looked at by individuals from Robert Gordon University where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data.	
4. Study specific questions as appropriate.	
5. Study specific questions as appropriate.	
6. I agree to take part in the above study.	

Participant:	
Name:	
Signature:	
Date:	

Person taking consent:	
Name:	Findlay MacDonald

Appendix C

School of Health Sciences

School Research Review Group (SRRG)

Participant Information Sheet for Competent Adults (PISCA)

Generic Information	
SRRG Ref No:	SHS/MRes/12/40
Title (short):	Short-term exposure to the Ionic Balance Band
Date:	

Introduction:
My name is Findlay MacDonald; I am a Masters student studying at Robert Gordon University. I am looking for volunteer participants to take part in my research project.
The study:
The purpose of this study is to evaluate the effects of wearing the Ionic Balance Band for two weeks on measures related to health and fitness. The band is; worn on the wrist, waterproof, does not contain magnets and is safe to wear at all times. The study is being conducted as this product has achieved considerable commercial success and received many reports of improved health or function from its users. This study will aim to give a scientific perspective on the products efficacy. This study is a placebo trial which means that a placebo control group will be required. Participants in the placebo group will receive a wrist band that does not contain any tourmaline, which is the active component of the Ionic Balance Band. Participants will be randomly allocated to either the active or control group. The participants and the researcher will not know which group each individual has been allocated to until all assessment measures have been completed. The study is aimed at physically active adults who are free from injury or condition which would impair their ability to exercise safely. Individuals who are about to make major changes in either their activity level or diet are not sought for inclusion. Additionally, any individuals who currently wear the

Ionic Balance Band or any other product containing tourmaline are not sought for inclusion.

Participation in the study is completely voluntary. If you would prefer not to take part or wish to stop at any point during the process then you can do so and do not have to offer a reason.

Taking part:

- The research will take place in the Human Performance Laboratory in the Faculty of Health and Social Care which is located on the Garthdee campus of Robert Gordon University.
- Participants will have access to changing and showering facilities on site and are requested to bring appropriate clothing for exercise.
- Participants should be well hydrated and have eaten a light meal no more than three hours before they report to the laboratory and are advised to take their own fluids and nutrition to testing sessions.
- Participants will be required to take part in 3 sessions each lasting approximately one hour. The dates and times for each session will be agreed between the researcher and individual participants.
- Participants will be required to complete a questionnaire on general wellbeing which will gather information on: sleep, energy levels, injuries, expectation and motivation.
- A computer based cognitive assessment tool will be completed which will investigate: reaction time, learning, attention, processing speed, working memory, spatial working memory, delayed memory, reaction time and inhibition.
- Participants will be required to complete several exercise tests: balance assessment, vertical jump, muscular strength assessment, anaerobic power assessment and heart rate recovery
- Data will also be collected for age, height and weight
- During the first session, participants will be familiarised with the test procedure. Participants will return at an agreed date and time for initial data collection and random allocation to either an Ionic Balance Band or a control band.
- Participants will be instructed to wear the band issued to them at all times during the two week period between the data collection sessions.
- The participants will be retested for secondary data collection two weeks after initial data collection.

Expenses and payment:

Participation in the study is voluntary. No expenses or payments will be made for taking part in the study.

Advantages and disadvantages of taking part:

There will be no advantages to taking part in the study however participants will be given an insight into the research process which may be of value to their personal interests or career. The results from the participant's assessments can act as a personal fitness evaluation, if requested participants will be provided will normative data taken from the population to see how they compare.

Participation in any physical activity comes with an inherent risk. Several measures are in place to reduce the likelihood of a risk occurring and to appropriately handle the situation should it arise. The Human Performance Laboratory has been designed as a safe testing environment. The features contributing to this are: purpose built equipment which is regularly maintained, safe and effective protocols for use, optimal: – lighting – temperature – ventilation and workspace, emergency telephone and access to first aid trained individuals.

Confidentiality, data protection and anonymity:

Confidentiality: All information collected will be confidential and available only to the research team (student researcher and supervisor).

Anonymity: It will not be possible to link individual results/data/findings back to named individuals. No names or other personal identifiers will be included in any report from the research.

Data Protection: all data will be collected and stored within the requirements of the Data Protection Act (1998). Data will be stored in a password protected computer and accessible only to the research team (student researcher and supervisor).

What happens if there is a problem?

Discuss this with the researcher and supervisor (contact details given at the end of this sheet). Complaints to the SRRG convenor Dr Sue Barnard s.barnard@rgu.ac.uk or Head of School of Health Sciences l.hancock@rgu.ac.uk

What will happen to my research data?

The information will be used for a Masters research study; the data presented in the scientific paper will not be attributable to any individual

participant. Results from the study may be published or presented for commercial uses but again, information will not be attributable to any individual participant.

Assurance of research rigour:

This research has been approved by the School Research Review Group at the School of Health Sciences, Robert Gordon University, Aberdeen. The research is funded by Itek Solutions Limited trading as Ionic Balance.

What happens now?

If after reading this information sheet you are interested in taking part in this research project please contact the researcher at the postal or email address below.

Further information and contacts:

Researcher:	*Supervisor:*
Findlay MacDonald Course Title: Masters in Research School of Health Sciences Robert Gordon University Garthdee Road Aberdeen AB10 7QG Email: 0604755@rgu.ac.uk	Paul Swinton School of Health Sciences Robert Gordon University Garthdee Road Aberdeen AB10 7QG Email: p.swinton@rgu.ac.uk Tel: 01224 263361

Appendix D

Can a negative ion wristband improve your health and fitness?

This is an invitation to participate in a research project at Robert Gordon University.

The purpose of this study is to evaluate the effects of wearing the Ionic Balance Band for two weeks on measures related to health and fitness.

Study details;

- Participants will be required to complete; a questionnaire on general wellbeing, a cognitive assessment programme and several exercise tests
- Attendance of 3 sessions lasting approximately one hour each
- Participants will be allocated to either an Ionic Balance Band or a control band.
- Participants to wear the band at all times during a two week period between 2nd and 3rd sessions.

Location: Human Performance Laboratory, Faculty of Health and Social Care, Garthdee campus of Robert Gordon University.

If you are interested in participating or would like further information, please contact via the email address shown below.

Findlay MacDonald

Email: 0604755@rgu.ac.uk

Appendix E

Questionnaire delivered on pre-test date

How would you rate your sleep quality over the past two weeks?

○ Very good ○ Fairly good ○ Fairly bad ○ Very bad

Do you suffer from snoring or sleep apnoea?

○ Yes ○ No ○ I do not know

Over the past two weeks, how often have you felt lethargic first thing in the morning?

○ Everyday ○ Frequently ○ Occasionally ○ Rarely ○ Never

Over the past two weeks, how often has your energy or motivation dipped in the afternoon/evening?

○ Everyday ○ Frequently ○ Occasionally ○ Rarely ○ Never

Do you currently suffer from any joint pain or discomfort?

○ Yes ○ No

If yes, please briefly specify.

Do you currently suffer from any medical conditions?

○ Yes ○ No

If yes, please briefly specify.

In general, do you participate in physical activity more than twice a week?

○ Yes ○ No

If yes, please briefly specify.

Following physical activity, do you suffer from muscle soreness?

○ Never ○ Rarely ○ Occasionally ○ Frequently ○ Always

Do you currently have any impact injuries or bruising from physical activity or otherwise?

○ Yes ○ No

Do you have any prior knowledge of the Ionic Balance Band and its effects?

○ Yes ○ No

If yes, please briefly specify.

What is your main motivation for participating in this study?

Please briefly specify.

What are your expectations on the effect that wearing the Ionic Balance Band will have on test results?

○ Improve them ○ No effect ○ Worsen them ◉ Unsure

Appendix F

Questionnaire delivered on post-test date

How would you rate your quality of sleep over the past two weeks?

○ Very good ○ Fairly good ○ Fairly bad ○ Very bad

Since wearing the wristband, has your sleep quality improved?

○ Yes ○ No

If you suffer from snoring or sleep apnoea, has there been an improvement since wearing the wristband?

○ Yes ○ No ○ Not applicable

Over the past two weeks, how often have you felt lethargic first thing in the morning?

○ Everyday ○ Frequently ○ Occasionally ○ Rarely ◉ Never

Since wearing the wristband, have you noticed an improvement in feelings of lethargy first thing in the morning?

○ Yes ○ No

Over the past two weeks, how often has your energy or motivation dipped in the afternoon/evening?

○ Everyday ○ Frequently ○ Occasionally ○ Rarely ○ Never

Since wearing the wristband, have you noticed an improvement in your energy levels during the afternoon/evening?

○ Yes ○ No

Do you currently suffer from any joint pain or discomfort?

◉ Yes ○ No

If yes, please briefly specify.

Has there been a decrease in joint pain or discomfort since wearing the wristband?

○ Yes ○ No ○ Not applicable

Do you currently suffer from any medical conditions?

○ Yes ○ No

If yes, please briefly specify.

Has there been an improvement to any condition since wearing the wristband?

○ Yes ○ No ○ Not applicable

If yes, please briefly specify.

In general, do you participate in physical activity more than twice a week?

○ Yes ○ No

If yes, please briefly specify.

Following physical activity, do you suffer from muscle soreness?

○ Never ○ Rarely ○ Occasionally ○ Frequently ○ Always

Since wearing the wristband, have you noticed an improvement in recovery following exercise?

○ Yes ○ No

Do you currently have any impact injuries or bruising from physical activity or otherwise?

○ Yes ○ No

Since wearing the wristband, have you noticed improved recovery or healing related to these injuries?

○ Yes ○ No ○ Not applicable

Do you think you have been wearing an Ionic Balance Band or a control band over the last two weeks?

○ Ionic Balance Band ○ Control band