Current Trends in Blood Flow Restriction

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Abstract

Background/Significance: Blood flow restriction (BFR) involves the application of a device to alter blood flow to an extremity. Several types of devices can facilitate blood flow restriction, and safe application can limit adverse effects. **Purpose:** The purpose of the study was to explore how individuals in the United States of America applied BFR/KAATSU devices and administered BFR/KAATSU training. In addition, the study sought to examine safety related to BFR/KAATSU training. **Methods:** The study was completed using survey research. Subjects were recruited through Facebook, email, and word of mouth. The survey was developed, piloted, and finally deployed March 22, 2021-April 21, 2021. **Results:** In total, 148 consented to the research; 108 completed the survey, and of those 108, 70 indicated current use of BFR/KAATSU equipment. Professions represented included athletic training, personal training, physical therapy, and strength and conditioning. The most common devices used were inflatable devices (n=43, 61.4%). Education completed prior to device administration was formal (n= 39, 55.7%) and/or self-directed (n=37, 52.9%). Barriers were faced by 29 (41.4%) when trying to enact training. Techniques and parameters varied during application. Screening processes were used (n=50, 71.4%) prior to training. The devices were used to determine restrictive pressure (n=31, 44.3%), and a supine position was used most when determining initial restrictive pressure (n=33, 47.1%). For subsequent restrictive pressure measurements, respondents repeated the same method used initially (n=38, 54.3%). Workload was often defined as the length of time under tension/load (n=22, 31.4%) and exercise was directly supervised (n=52, 74.3%). Adverse effects including bruising, lightheadedness, and cramping were seen (n=15, 21.4%). The devices have been applied on those with pathology (n=16, 22.9%). **Conclusions:** Those using blood flow restriction/KAATSU training came from a variety of professions and used a variety of devices

for BFR/KAATSU training. Individuals applied devices using a variety of parameters on populations for which efficacy has and has not been well defined.

Keywords: blood flow restriction, KAATSU training

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Current Use of Blood Flow Restriction

Blood flow training was developed in the 1960's by Yoshiaki Sato for his own personal fitness training and rehabilitation (Sato, 2005). Sato termed his methodology KAATSU Training; KA is Japanese for "additional" and ATSU is Japanese for "pressure." KAATSU training devices work by modifying blood flow (KAATSU Training, n.d.a). Since the release of his methodology in the 1980's (Sato, 2005), blood flow training continues to be popularized for its training and therapeutic intervention capabilities (Nakajima et al., 2006; Patterson et al., 2019; Sato, 2005).

Blood flow restriction (BFR) training involves the application of a device to an extremity to alter blood flow and may include brief and partial limitations in blood flow during exercise. Specifically, the pressure applied by the device is intended to limit arterial blood flow to a limb while fully restricting venous outflow in working muscles during exercise (Scott et al., 2015; Patterson et al., 2019). Devices used to alter blood flow (either modify blood flow or restrict blood flow) vary in style. Patterson and Brandner (2018) identified multiple devices including the KAATSU devices as well as inflatable devices, knee wraps, or the use of elastic tourniquets which can all be used to facilitate BFR training. The devices are applied proximally along a limb with minimal pressure to facilitate restriction (McEwen et al., 2019). Restriction pressures can be determined through a variety of means including the use of doppler ultrasound (Masri et al., 2016), the device itself (McEwan et al., 2019), or subjective rating scales (Wilson et al., 2013).

The effects of BFR are believed to facilitate muscle enlargement or hypertrophy through the combination of mechanical tension, or force, and metabolic stress occurring secondary to exercise. The use of low load exercise with BFR creates low force and high stress on muscles producing physiological changes such as cellular swelling, hormone production, and altered fast

twitch muscle recruitment. These changes then produce muscle growth (Pearson & Hussain, 2015).

Blood flow restriction/KAATSU training can be used in conjunction with a variety of exercise techniques on individuals who are healthy or those who have comorbidities. Methods of exercise used with BFR/KAATSU training devices include aerobic exercise and resistance exercise. Aerobic exercise frequently used with BFR/KAATSU training include walking and cycling (Patterson & Brandner, 2018). Implementation of BFR with aerobic exercise in populations across the lifespan yielded improvements in muscle strength and hypertrophy in as little as three to six weeks following implementation (Patterson et al., 2019). When applied with resistance training, BFR in conjunction with low load exercise was also effective at improving muscle strength and hypertrophy in populations across the lifespan, both healthy and unhealthy (Patterson et al., 2019). In a healthy athletic population, the use of BFR with low load resistance exercise was effective when alternated with free flow (no BFR) exercise, specifically high load resistance training for strength gains (Wilk et al, 2018). As an adjunct to therapeutic intervention, BFR with low load resistance training has been used on patients with musculoskeletal weakness to gain muscle strength when high load exercise was contraindicated (Hughes et al., 2017). Furthermore, the use of BFR training post operatively has demonstrated success in those with anterior cruciate ligament (ACL) tears where improvements in leg strength and quadriceps cross sectional area have been seen following the implementation of BFR with low load resistance training (Ohta et al., 2003).

Currently, little is known regarding how individuals are using different types of BFR/KAATSU training devices in the United States of America. The authors of three observational studies looked at experiences with BFR/KAATSU training (Patterson & Brandner,

2018; Nakajima et al., 2006; Yasuda et al., 2017). Researchers assessed how practitioners worldwide administer BFR (Patterson & Brandner, 2018) and conducted epidemiological studies addressing safety concerns specific to KAATSU training (Nakajima et al., 2006; Yasuda et al., 2017).

Purpose

The purpose of this study was to explore how individuals across different professions administered and used various forms of BFR/KAATSU training devices in the United States of America. In addition, the study sought to explore safety related to BFR/KAATSU training with various devices. The follow objectives were addressed to meet the purpose:

Objective 1: Determine how BFR/KAATSU devices were being used across disciplines.

Objective 2: Determine potential safety concerns among users of different forms of BFR/KAATUS devices.

Objective 1 and 2 were quantified using a single setting using a computer-based survey.

Significance of Study

This study adds to the existing body of literature through its exploration of how BFR/KAATSU was being administered. Understanding how different forms of BFR/KAATSU training devices were being used can expose gaps in the literature needing further exploration. In addition, information concerning adverse effects could facilitate additional precautions when using different devices for BFR/KAATSU training.

Literature Review

Blood flow restriction training involves the modification of blood flow (KAATSU Training, n.d.b) which may include the brief and partial occlusion of arterial blood flow into a limb while fully restricting venous outflow in working muscles during exercise (Patterson et al., 2019). Currently, there are several styles of BFR/KAATSU training devices. The devices have been used across multiple age groups in conjunction with aerobic exercises, resistance training, and rehabilitative exercises.

Current Body of Knowledge

Blood flow restriction involves the application of a device to an extremity to alter blood flow. Training with the devices can facilitate blood flow modification as seen with the use of KAATSU equipment (KAATSU Training, n.d.a). Other devices facilitate blood flow restriction through the brief and partial restriction of arterial blood flow into the limb with the full restriction of venous outflow in working muscles during exercise (Patterson et al., 2019). A variety of devices have been used to alter or restrict blood flow. Patterson and Brandner (2018), in part, assessed clinician use of the following forms of devices which have been used to alter or restrict blood flow: knee wraps, KAATSU training device, elastic tourniquets, handheld inflatable devices, and automatic inflatable devices.

Knee Wraps

Knee wraps have been described in the literature by authors as elastic in nature (Head et al., 2015; Wilson et al., 2013) and as wraps used for power lifting purposes (Luebbers et al., 2014; Luebbers et al., 2019). Loenneke and Pujol (2009) described the use of knee wraps as a form of practical occlusion (practical BFR) and suggested when using a knee wrap to facilitate the restriction of blood flow, the wrap should be placed around the proximal targeted muscle

group. Researchers have used wraps approximately 7.6 cm wide (Head et al., 2015; Luebbers et al., 2014; Luebbers et al., 2019; Wilson et al., 2013) but lacked consistency in the length of the wrap ranging from no wrap length identified (Wilson et al., 2013) to 188 cm in wrap length (Head et al., 2015). Practical BFR has been applied to both the upper extremity (Luebbers et al., 2014) and lower extremity (Head et al, 2015; Luebbers et al., 2014; Luebbers et al., 2019; Wilson et al., 2013).

All of the styles of knee wraps currently being used to facilitate BFR are unknown at this time. If, however, the wraps being used are considered straps or tubing and marketed specifically to limit blood circulation when applied to a body part, the devices are considered non pneumatic tourniquet devices by the United States Food and Drug Administration (FDA). The devices are considered a Class 1 device which do not need pre-market approval when used for their intended purpose (FDA, 2020a).

KAATSU Training Device

The KAATSU training device was the original blood flow training device. KAATSU Training received a patent in the 1990's in the United States of America (Sato, 2005), and current KAATSU training devices are marketed as either an air band or an elastic band with pneumatic control (KAATSU Training, n.d.b). The devices are described to facilitate blood flow modification rather than blood flow restriction. The devices have been shown to reduce venous blood flow without occluding arterial blood flow (KAATSU Training, n.d.a; Nakajima et al., 2006), facilitate pooling of venous blood, and decrease cardiac preload (Nakajima et al., 2006).

Elastic Tourniquets

Tourniquets are air powered devices that apply pressure to a limb thereby reducing or occluding circulation to a body part. The devices consist of an inflatable cuff, a unit which

regulates pressure, and tubing which connects the cuff to the regulating unit (FDA, 2020a). Pneumatic tourniquets are described as Class 1 devices by the FDA (2020a) and used for surgery. Because tourniquets used for BFR are not used for surgery, the devices do not meet premarket exemption guidelines and need FDA premarket approval prior to being sold (FDA, 2020a). Tourniquets, when used to facilitate BFR, are recommended for use in conjunction with rehabilitation exercises (McEwan et al., 2019; Patterson et al., 2019).

Inflatable Devices

Inflatable devices are cuffs applied to the limb that can be inflated through an automatic device or handheld pump. Within the literature, terms such as a pressure cuff (Byrk et al., 2016) may be seen as opposed to inflatable devices or inflatable pumps. If the cuff being used to facilitate restriction is a blood pressure cuff, the device is regulated as a Class 2 device by the FDA (2020b).

Device Comparison

Hughes, Rosenblatt, Gissane et al. (2018) compared different types of BFR devices: a device which allowed for automatic rapid inflation (inflatable device), an automatic personalized tourniquet (elastic tourniquet), and a manual handheld device with sphygmometer (inflatable device). Among the results included pressure variations during exercise in the automatic rapid inflation device and the manual handheld device with a sphygmometer (Hughes, Rosenblatt, Gissane et al., 2018). Pressure variations which can be seen in non-tourniquet devices have been noted as a concern particularly during rehabilitation exercise by McEwan et al. (2019).

Restriction Pressure

As noted, several factors have influenced the experience an individual has when using BFR/KAATSU training devices. Essential to the experience; however, is the ability for the

device to alter blood flow and/or occlude venous blood flow resulting from the restriction of arterial blood flow distal to the site of the limb occlusion. The application of a cuff to a site along a limb with a minimal amount of pressure is needed to facilitate the process (McEwen et al., 2019). Factors affecting the process of arterial blood restriction include the cuff's construction and dimensions, restriction pressure, the site of restriction, individual attributes, and individual physiology (McEwen et al., 2019; Patterson et al., 2019). Limb circumference (Jessee et al., 2016; Loenneke et al., 2012; Sieljacks et al., 2018) and diastolic blood pressure (Loenneke et al., 2012; Sieljacks et al., 2018) have also been noted to influence pressure.

There has been wide acceptance in using an individualized approach when determining limb restriction pressure. Individualizing restriction pressure has facilitated consistency and safety. Restriction pressures too high can decrease nerve conduction velocity, promote thrombus development, and minimize outcome effectiveness (McEwen et al., 2019; Wilk et al., 2018). In addition, higher restriction pressures have led to a greater load placed on the cardiovascular system (McEwen et al., 2019), and increased one's discomfort (Patterson et al., 2019).

The application of BFR/KAATSU training is optimally performed at low to moderate restriction pressures. The use of limb occlusion pressure is a method used to determine restriction pressures. One recommendation is to use 40-80% one's limb occlusion pressure when completing exercise (Patterson et al., 2019). Staying at the lower end of the recommended limb occlusion pressures presented by Patterson et al. (2019) will produce lower levels of pain and perceived exertion. Soligon et al. (2018) studied a group of males completing equal total training volume exercise at various BFR limb arterial occlusion pressures or with high intensity exercise and no BFR. Soligon found lower ratings of perceived exertion and pain among the BFR group using lower occlusion pressures, specifically 40% or 50% limb occlusion pressure (Soligon et al.,

2018). Researchers have demonstrated pressure affects blood flow in a nonlinear fashion within the brachial artery (Mouser et al., 2017), and superficial femoral artery perhaps providing reason for more comfortable yet equivalent experience when setting limb occlusion pressure within the range of 40% to 80%, either at rest or at exercise (Crossley et al., 2020).

Lower levels of occlusion pressures over a period of time have also demonstrated improved perceptual response by subjects. Mattocks et al. (2019) found that following an eight-week intervention, ratings of perceived exertion and discomfort were reduced in the upper body when using 40% and 80% occlusion pressures, while ratings of perceived exertion and discomfort in the lower body were reduced when using 40% occlusion pressures. Low load resistance training with BFR also yielded a lower rate of perceived exertion when compared to high load resistance training albeit higher levels of pain. Both forms of exercise yield reductions in both rates of perceived exertion and pain values over an eight-week knee extension training protocol (Teixeira et al., 2020).

Different types of equipment may be used to objectively determine occlusion pressure. Equipment may include an automatic unit or a doppler ultrasound. While doppler ultrasound has shown reproducibility in finding total occlusion pressure of the brachial artery (Bezerra de Morais et al., 2017) and its use has been advocated for when finding limb occlusion pressure (Masri et al., 2016), McEwen et al. (2019) indicated potential limitations due to their manual operation. Other methods, including the use of pulse oximetry, are being explored for their role in determining arterial occlusion pressure (Lima-Soares et al., 2020; Zeng et al., 2019).

When using practical BFR, (use of wraps), objective methods to measure restrictive pressure do not exist. Wilson et al., (2013) subjectively quantified values based on perceived pressure using a 10-point scale with the following criterion: 0 out of 10 was the control, 7 out of

10 was considered moderate pressure, and 10 out of 10 was considered tight pressure. Wilson found a moderate perceived pressure described as a 7 out of 10 on a 0 to 10-point scale repeatedly correlated with venous occlusion but not arterial occlusion (Wilson et al., 2013). Multiple authors have noted a subject's perceived pressure rating of 7 out of 10 when using knee wraps for BFR training research (Formiga et al., 2020; Head et al., 2015; Paton et al., 2017).

Cuff Properties

When considering the cuff, cuff material has less variability than cuff width on restriction pressure. Both nylon cuffs and elastic cuffs are considered acceptable for use when applying BFR (Patterson et al., 2019). Of greater concern has been limb circumference as well as cuff width when determining restriction pressure for BFR use. Limb circumference was shown to have limited impact when using wider cuffs in cadavers (Crenshaw et al., 1988). The authors of a more recent BFR specific study showed diastolic blood pressure, thigh circumference, and ankle blood pressure influenced the pressure of wider cuffs (13.5 cm) while in smaller width cuffs (5 cm) diastolic blood pressure and thigh circumference influenced cuff pressure in BFR/KAATSU training devices (Loenneke et al., 2012). Thigh circumference has since been demonstrated as a predictor of arterial occlusion pressure in the lower extremity when using BFR (Loenneke et al., 2015).

Adding further variability to restriction pressure determination has been the width of the cuff used. When assessing cuff width and pressure on cadaver-based subjects, Crenshaw et al. (1988) found higher pressure values were needed to eliminate a pulse when using cuffs with narrow widths (4.5 cm). When using cuffs with wider widths (18 cm) lower pressure values were needed to eliminate a pulse (Crenshaw et al., 1988). When using BFR, cuff width has also been noted to influence pressure (Jessee et al., 2016; Loenneke et al., 2012; Scott et al., 2015;

Sieljacks et al., 2018). Like Crenshaw et al. (1988), wider width cuffs (13-14 cm) were found to take a lower pressure value to achieve arterial occlusion pressure while more narrow cuffs (5-6 cm) achieve arterial occlusion pressure at a higher pressure (Loenneke et al., 2012; Sieljacks et al., 2018). When facilitating practical BFR, researchers have used wraps that were approximately 7.6 cm wide (Head et al., 2015; Luebbers et al., 2014; Luebbers et al., 2019; Wilson et al., 2013).

Using cuffs widths both narrow and large pose a risk. Smaller width cuffs need a higher pressure to obtain occlusion risking potential nerve damage (Crenshaw et al., 1988), health risks, and limited exercises benefits (Loenneke et al., 2014; Scott et al., 2015), while wider cuffs can restrict movement, facilitate pain, and increase perceived exertion rates (Scott et al., 2015). To accommodate for the variety in limb size and cuff sizes, one consideration is to use a BFR pressure that is based on limb occlusion pressure while avoiding cuffs which impede movement patterns (Patterson et al., 2019).

Safety

Several researchers have highlighted the importance of correct application and safety in training (Hughes et al., 2017; Loenneke et al., 2011; Patterson et al., 2019; Sato, 2005). Loenneke et al. (2011) found when compared to free flow high load resistance exercise, BFR/KAATSU training produced no change in nerve conduction velocity, muscle damage, and oxidative stress while high load exercise increased all three areas. In addition, these authors reported stroke volume, blood pressure, heart rate, fibrinolytic potential, coagulation activity, and post occlusion blood flow all responded the same as free flow high load resistance exercise in short term studies (Loenneke et al., 2011). While research is needed to identify potential causes of susceptibility to adverse physiologic responses, when BFR is applied and performed

appropriately muscle damage should not occur unless one is otherwise prone to muscle damage (Patterson et al., 2019).

While several concerns surrounding the physiological response to BFR training have been dispelled, adverse effects have been identified. Safety concerns noted by Nakajima et al. (2006) related to the KAATSU training devices included subcutaneous hemorrhage and numbness, while other more serious health concerns including venous thrombus, pulmonary embolism, rhabdomyolysis, and cerebral infarction were noted to have occurred. Yasuda et al. (2017) found symptoms including dizziness, subcutaneous hemorrhage, drowsiness, itchiness, nausea, and numbness among clients who are healthy or may have comorbidities using KAATSU training devices. However, some of the complications are suspected to have occurred secondary to other health concerns or improper use of the device by the device administrator (Yasuda et al., 2017). Errors with BFR application can include incorrect cuff pressure and the width of the cuff used (Patterson et al., 2019).

One condition that has been reported in the literature secondary to BFR/KAATSU training use was rhabdomyolysis. Cases of rhabdomyolysis have been acknowledged (Hughes et al., 2017; Nakajima et al., 2006), including one in an untrained individual with obesity and one in a trained athlete (Hughes et al., 2017). Tabata et al. (2016) likewise described the patients: one patient presented with rhabdomyolysis and bacterial pharyngitis simultaneously following a workout with BFR. While the contents of the workout with BFR were unknown, the authors indicated multiple factors likely contributed to the onset of rhabdomyolysis. The second case of rhabdomyolysis involved a hockey player completing knee extension exercises using a set sustained occlusion pressure of 100 mm Hg (Tabata et al., 2016). No cases of rhabdomyolysis, cerebral hemorrhage, cerebral infarction, or thrombosis were reported by Yasuda et al. (2017)

during use with KAATSU devices. The risk of rhabdomyolysis is thought to be no greater than other forms of exercise (Patterson et al., 2019).

Another area lacking knowledge as it relates to BFR training involves how males and females have experienced BFR. Couts et al. (2018) found research related to BFR training focussed on the male gender with information specific to the female gender lacking. While the menstrual cycle is noted as a potential cause for low representation (Counts et al., 2018), it is unknown if safety concerns vary by gender. Additional safety research pertaining to BFR is needed (Loenneke et al., 2011; Patterson et al., 2019) and ongoing (Patterson et al., 2019).

Blood Flow Restriction and Exercise

The physiological effects of BFR are related to mechanical tension and metabolic stress. Combined they facilitate mechanisms stimulating muscle hypertrophy (Pearson & Hussain, 2015; Wilk et al., 2018). These mechanisms include cell swelling, fast twitch muscle fiber recruitment, and hormone production (Pearson & Hussain, 2015).

Aerobic Exercise

Blood flow restriction has been used in conjunction with aerobic exercise (Patterson et al., 2019). Aerobically, walking and cycling were common forms of exercises used with BFR, while swimming and running were also performed (Patterson & Brandner, 2018). Despite a lack of standardization for the use of BFR with aerobic exercise, it is believed to take approximately three to six weeks to see changes in strength and muscle hypertrophy (Patterson et al., 2019). One recommendation for walking or cycling with BFR has been established by Patterson et al. (2019) and includes exercising two to three times per week at less than 50% heart rate reserve, VO_2 Max, for 5 to 20 minutes at 40-80% arterial occlusion pressure.

Forminga et al. (2020) demonstrated that the use of low to moderate aerobic exercise (running or biking) developed a greater aerobic capacity than low to moderate free flow aerobic exercise. High intensity aerobic exercise with BFR did not improve aerobic capacity more than aerobic capacity in free flow aerobic exercise (Formiga et al., 2020). Chen et al. (2019) assessed the use of BFR in conjunction with running warm up exercises and found no improvement in knee extensor strength or 60-meter sprint performance following a single bout of warm up either with or without BFR followed by either strength testing or a 60-meter sprint. The authors found knee flexor strength was greater when completing warm up running exercises with BFR as was concentric hamstring-quadriceps ratio. In addition, muscle activation of the vastus lateralis and biceps femoris were greater following BFR running exercise warmup; however, no difference was found between warm up groups and tibialis anterior and medial gastrocnemius. Interactions were found between time and warm up in rate of perceived exertion, heart rate, as well as blood lactate (Chen et al., 2019). One barrier to the research by Chen et al. (2019) could have been the length of the study as Patterson et al. (2019) noted three to six weeks is needed to demonstrate muscle strength gains.

When practical BFR has been used with aerobic exercise bilaterally, Paton et al. (2017) found positive effects in a group of healthy subjects. When compared to a free flow group completing 30 second repetitions of running, Paton et al. (2017) found those with practical BFR had increased heart rate, increased peak running velocity, increased incremental test time, and improved time to exhaustion when compared to the free flow group. Both groups saw an improvement in maximal oxygen uptake.

Resistance Training

The use of BFR with resistance training has been researched more than its uses with aerobic exercise. The use of low load resistance exercise with BFR to gain muscle strength and hypertrophy has one of the following suggestions for use: two-four times per week using 75 repetitions (30-15-15-15) or repetitions to failure (Patterson et al., 2019). Each repetition should last 1-2 seconds for the complete movement and 30-60 seconds rest should be allotted between sets for a total of 5-10 minutes restriction at a time. Reperfusion may occur between sets or between single or multiple exercises. When BFR is in use, arterial occlusion pressure should be set at 40-80% (Patterson et al., 2019).

Despite the recommendation, there is data to support not completing exercises with BFR to failure. For instance, when a single bout of low load eccentric exercise was performed with BFR to failure, muscle damage occurred similarly to eccentric exercise with no BFR, and additional bouts of low load eccentric exercise with BFR yielded lower levels of muscle damage (Sieljacks et al., 2016). Additionally, Sieljacks et al. (2019) had 14 male subjects complete 20 to 22 exercise bouts with BFR, one leg to failure and the opposing leg not to failure. Similar changes were seen in muscle size and function between legs. When the exercise was not taken to failure, subjects experienced a lower rate of perceived exertion, a lower discomfort level, and less delayed onset muscle soreness (Sieljacks et al., 2019).

Blood flow restriction with low intensity resistance training has also demonstrated the ability to increase blood pressure, heart rate, and rate-pressure product more than low intensity training alone in reviews of subjects of varied genders (Neto et al., 2017). Blood flow changes were found similar to free flow exercise among unspecified populations (Loenneke et al., 2011).

Another difference between free flow training and BFR training are the mechanisms which produce strength.

Neural changes and mass create strength in free flow exercise particularly high load resistance training, while BFR training allows one to develop muscle strength through muscle hypertrophy (Wilk et al., 2018) secondary to physiological changes occurring with BFR use including cellular swelling, hormone production, and altered fast twitch muscle recruitment (Pearson & Hussain, 2015). As such, strength gains will vary depending on training methods implemented. When compared to BFR with low load resistance training, free flow high load resistance training produced greater strength gains (Cook et al., 2017; Lixandrão et al., 2018). This is contraindicated by Grønfeldt et al. (2020) who found both forms of exercise produced similar muscle strength gains across 16 studies assessing a lone variable in adults across the lifespan. Within an older adult population, strength gains were found to be similar when completing either free flow high load resistance training or low load BFR training (Cook et al., 2017). Compared to low load resistance training alone, strength gains and muscle mass were consistently greater in the group completing BFR with low load resistance training (Slysz et al., 2016). Due to the variability in strength gains, when high load resistance training has been contraindicated, the use of BFR has been recommended to aid in the maintenance and development of strength (Hughes et al., 2017). If BFR training is used among a healthy athletic population, a combination of free flow high load resistance training and BFR with low load resistance training is recommended to accommodate for the difference in strength development (Wilk et al., 2018).

The use of practical BFR as a means to develop strength has been mixed. A randomized control of 12 individuals using either elastic wrap with a perceived 7 out of 10 tightness, or a 0

out of 10 perceived tightness completed single leg body squats until failure twice weekly for six weeks. The authors reported no difference in quadriceps strength, hypertrophy, or function (Head et al., 2015). Luebbers et al. (2014) did see improvements in one repetition maximum squat performance following seven weeks of practical BFR training among collegiate athletes. No improvements, however, were seen in muscle size or the extent of gain in a one repetition max bench press in those completing high intensity workouts, high intensity workouts with low load modification and no practical BFR, or those completing a modified lifting program with practical BFR (Luebbers et al., 2014). A group of high school students completing either a high load training program, a low load training program, or a low load training program with practical BFR saw improvements in a one repetition max on the parallel back squat following the completion of the low load program with practical BFR (Luebbers et al., 2019).

Rehabilitation. Blood flow restriction with and without low load resistance training has been used to help reduce pain, treat atrophy, increase strength, and muscle size in a variety of health conditions. Conditions which BFR has demonstrated effectiveness include post-operative ACL repairs (Barber-Westin, & Noyes, 2019; Hughes et al., 2017; Hughes, Paton, et al., 2018; Hughes, Rosenblatt, Paton, et al., 2018; Ohta et al., 2003); osteoarthritis (Barber-Westin, & Noyes, 2019; Bryk et al., 2016; Ferraz et al., 2018); trauma (Hylden et al., 2015); polymyositis and dermatomyositis (Matter et al., 2014); sarcopenia (Hughes et al., 2017), and other forms of lower extremity pain (Ledlow et al., 2018). In addition, an older population with coronary artery disease saw improved strength and decreased systolic blood pressure following BFR training with low load resistance exercise (Kambič et al., 2019). Researchers have also found fewer cases of adverse knee pain in patients completing BFR training with post-operative ACL repairs (Hughes, Paton, et al., 2018). Similar reductions in adverse knee pain were seen in patients with

osteoarthritis completing BFR training when compared to patients with osteoarthritis completing moderate intensity resistance training (Harper et al., 2019).

One area with mixed results from rehabilitation exercise with BFR includes tendinopathies and the structural change BFR training may facilitate in the tendon. For example, it is believed that the patellar tendon is capable of hypertrophy (Kongsgaard et al., 2007), but research involving an equine population (Abe et al., 2006) and human population (Kubo et al., 2006) found minimal tendon changes following BFR training. Centner et al. (2019) focused on the Achilles tendon demonstrating tendon changes may be capable. These authors assessed the effect of a 14-week intervention on Achilles tendon properties, maximum torque velocity, cross sectional area of the gastrocnemius medialis muscle and Achilles tendon, and tendon stiffness in a sample of untrained males using a control, free flow high load resistance training, or low load resistance training with blood flow restriction. Centner et al. (2019) found improvements in Achilles tendon cross sectional area, Achilles tendon stiffness, gastrocnemius medialis muscle cross sectional area, and maximum torque velocity in both training groups. Pain ratings were not assessed by the authors of the articles pertaining to BFR and tendinopathy (Abe et al., 2006; Centner et al., 2019; Kubo et al., 2006). As with all applicable uses of BFR, many avenues of research are still needed.

Gaps in Knowledge

From the review, several gaps exist in the literature. Gaps include how individuals of various health professions are using various platforms of BFR in practice, and specific adverse effects when using various styles of BFR/KAATSU training devices. In addition, a review of the literature only yielded three observational studies related to BFR/KAATSU training use.

The authors of the observational studies focused on clinician use of BFR (Patterson and Brandner, 2018) and the use of KAATSU training specifically (Nakajima et al., 2006; Yasuda et al., 2017). Patterson and Brandner (2018) assessed the use of BFR training globally by physicians, strength and conditioning specialists, rehabilitation specialists, sport specific scientists, personal trainers and researchers. Patterson and Brandner asked questions related to BFR training devices, BFR training use, safety and methods related to passive BFR training, aerobic BFR training, and BFR resistance exercise training. The authors demonstrated those using BFR training do so in a variety of methods with safe results (Patterson and Brandner, 2018) lending to a position statement by Patterson et al. (2019). In the remaining studies, authors focused on the use and safety related to the KAATSU training (Nakajima et al., 2006; Yasuda et al., 2017). Nakajima et al. (2006) explored how KAATSU training was used and the adverse effects seen. Nakajima demonstrated that KAATSU training was being used for a variety of pathologies with minimal adverse effects. Yasuda et al. (2017) completed a study similar to Nakajima et al. (2006) exploring KAATSU training, how the training methods were being implemented, adverse effects, and what may have changed since the Nakajima article. KAATSU training has been performed on a variety of pathologies, across a variety of demographics with minimal adverse effects (Yasuda et al., 2017).

Prior researchers demonstrated safety in BFR training with inconsistencies in the use of BFR devices (Patterson et al., 2019). Furthermore, KAATSU training methods have demonstrated effectiveness in implementation by trained professionals across demographics for a variety of uses (Nakajima et al., 2006; Yasuda et al., 2017). At this time, it is unknown how individuals of various health related professions specifically in the United States of America are using different styles of BFR/KAATSU training devices. Nor is it known what adverse effects, if

any, have been seen with individual BFR/KAATSU training device use. There is a need to better understand how BFR/KAATSU training is being applied and used in clinical application within the United States of America.

Clinician Relevance

Currently, there are several styles of BFR/KAATSU training devices available on the market. Having an understanding of how styles are being used as compared to the literature can provide those working in health-related fields additional knowledge to make informed decisions regarding the use and applicability of BFR/KAATSU training to one's respected profession.

Method

This was an observational study in which the researcher explored how individuals across different professions in the United States of America used various forms of BFR/KAATSU training devices via survey research. In addition, safety related to BFR/KAATSU training was investigated. The study took place March 22, 2021-April 21, 2021. Prior to starting participant recruitment, the study was approved by the University of Indianapolis' Institutional Review Board.

Participants

Those using BFR/KAATSU training devices were included in the study. To be included in the study, participants met the following criteria: (a) English speaking, (b) older than 18 years old, and (c) use BFR/KAATSU training for aerobic exercise, strength training exercise, or rehabilitation purposes in the United States. Subjects were excluded if (a) BFR/KAATSU training was not being used with patients/clients/athletes.

Sample Size

Sample size was determined using a standardized formula presented by Smith (n.d.): ((z-score)^2 x standard deviation x (1-standard deviation))/(margin of error)^2. The following data will be used: confidence interval of 95%, Z-Score of 1.96, a margin of error of 5% and a standard deviation of .5. A sample size of 384 participants were needed.

Data Collection

Once data collection was completed in Qualtrics (Version XM), the primary investigator exported data for analysis from Qualtrics into Microsoft Excel (Version 2101) then the statistical software management system, IBM SPSS Statistics for Windows (Version 27).

Operationalization of Variables

For this study, blood flow training included any device allowing for modification of blood flow and used in conjunction with aerobic activity, strength training activity, or activities related to rehabilitative exercise.

Instrumentation

The researcher developed the survey. More information regarding the survey itself can be found in the Procedures section. A test pilot of the survey was administered in November 2020. A content expert recruited subjects and served as a liaison between the researcher and the subjects taking the pilot survey to ensure anonymity. The survey was restrictively administered to the group of 10 subjects on two separate occasions, one week apart. All 10 participants completed the survey the first time while eight participants completed the survey the second time. Data was analyzed using IBM SPSS Statistics for Windows (Version 24). Participants were all Caucasian with 60% of subjects identifying as male and 40% identifying as females. All were from the Midwest with a mean age between 31 and 40 years. Participants represented the

professions of athletic training, physical therapy, and strength and conditioning with an average time in their respective fields of less than 10 years.

The survey took participants approximately 13 minutes to complete. The purpose of the test pilot was to assess the content presented in the survey. Individual constructs were both normally and not normally distributed assessing Shapiro Wilkes with $p<.05$. Subsequent Pearson correlation and Spearman Rho correlation showed significance between measures with an alpha value of $p<.05$. Constructs with correlations display moderate correlation to high correlation. Cronbach's alpha on 24 applicable items was $\alpha=.484$. Considering the statistical results in conjunction with subject feedback, the following questions were modified and presented in Appendix A: four questions were modified secondary to the pilot (questions D, E, H, and N), three questions were deleted as the repeated the informed consent (questions A, B, and C), and eight questions were edited to provide more inclusive language (questions F, G, I, J, K, L, M, and O). Further analysis comparing test pilot subjects to the subject pool was completed following the study.

Procedures

Recruitment was completed through convenience and snowball sampling. Several groups were contacted using a similar email template (Appendix B) to help facilitate recruitment. The following groups agreed to be a part of sampling on Facebook: Kansas City Athletic Trainers Society; Women in Athletic Training Group; and the following National Strength and Conditioning Association (NSCA) Special Interest Groups: College Coaches, Personal Trainers, Sport Science and Performance Technology, and Sports Medicine/Rehabilitation. Groups for which the recruitment statement and survey were posted had the following numbers at the time of posting:

- Kansas City Athletic Trainers Society: 445 members
- Women in Athletic Training Group: 9,065 members
- National Strength and Conditioning Association (NSCA) Special Interest Groups
    - College Coaches: 3,596 members
    - Personal Trainers: 2,371 members
    - Sport Science and Performance Technology: 1,752 members
    - Sports Medicine/Rehabilitation: 2,961 members

The following groups agreed to be surveyed through email

- Collegiate Strength and Conditioning Association: membership sent to: 2,601 individuals.

In total, there were potentially 20,190 subjects recruited through Facebook and 2,601 subjects through email. This did not include the effects of snowball recruitment. The recruitment message was posted by the researcher and was uniform across all Facebook group pages (Appendix C). A similar uniform message was emailed out by the Collegiate Strength and Conditioning Association on the researcher's behalf (Appendix C).

The survey was initially available for 14 days beginning and ending at midnight. Following seven days, the same uniform message was re-sent or reposted in all platforms that agreed to take part in sampling (Appendix C). Due to low response rate during the initial two week survey window, the survey was reopened for an additional two weeks and the same uniform message was redistributed through each platform. Following the second period of two weeks the survey was closed and data analysis began.

The survey began with potential participants reviewing an electronic informed consent form and asking if subjects accepted the informed consent form (Appendix D). Following

completion of the informed consent form, the subjects progressed through the survey. All subjects completed the same survey, which was developed, housed, and deployed through Qualtrics. It was anticipated that the survey would take subjects approximately 13 minutes to complete. Participants were asked up to but no more than 37 questions divided into the following sections: Informed Consent, Product Use, Current Use, Safety, Demographics of patients, clients, and athletes, and Demographics of the respondent. The Informed Consent portion of the survey housed the informed consent documentation and participants were asked to consent to the research. The questions within Product Use focussed on the types of BFR/KAATSU training devices both previously and currently being used by the subject. The Current Use section asked questions pertaining to the methods used to apply BFR/KAATSU training. The Safety section assessed safety and adverse effects when using BFR/KAATSU training devices. The final two sets of questions asked about demographics of the patients/clients/athletes for which BFR/KAATSU training was applied and the demographics of the individual completing the survey (Appendix E). A subject could terminate participation in the survey at any given time by closing out of the survey. At the conclusion of the survey, regardless of how much of the survey was completed, all were taken to a separate page also housed through Qualtrics. Participants were offered the opportunity to enroll for a chance to win one of five $10 gift cards. If participants entered the drawing, they were required to provide an email address (Appendix F). Gift cards were sent within one week of the final survey conclusion. Winners were selected using a random selection formula in Microsoft Excel: Formula =INDEX(ColumnCellNumber:ColumnCellNumber, RANDBETWEEN (FirstCellNumber,LastCellNumber)). An example of the formula would be Formula =INDEX(A2:A20, RANDBETWEEN(1, 20)) (Computergaga, 2015). If emails with the gift

cards were returned, new emails were selected using the aforementioned formula and gift cards were sent to new recipients.

Data Management

Following data collection, data was managed accordingly. Acknowledgment and acceptance of the informed consent were asked first within the survey and subsequently housed within Qualtrics. All additional survey data was likewise housed through Qualtrics. At the conclusion of the survey, data was exported to Microsoft Excel then uploaded for analysis into the statistical software management system, IBM SPSS Statistics for Windows.

Data Analysis

Descriptive statistics were used to describe the group. Nominal data was presented as frequencies and percentages while normally distributed interval and ratio data was reported as means and standard deviations and non-normally distributed interval and ratio data as medians and interquartile ranges. Data was analyzed using IBM SPSS Statistics for Windows (Version 27).

Results

Study Validity

The study involved the development of a 37-question survey. To demonstrate face validity, a random sample of 10 responses were compared with the sample of 10 responses from the survey test pilot (test pilot information can be found within the Method section). Data collected from individual questions was either normally distributed (Shapiro-Wilkes $p<.05$) or non-normally distributed (Shapiro Wilkes $p>.05$). No correlations were found between the two groups.

Study Response Rates

The study sought to explore how individuals across a variety of professions within the United States of America were using BFR/KAATSU training devices and to explore safety related to BFR/KAATSU training. Both convenience sampling and snowball sampling were used and the survey was deployed March 22, 2021 through April 21, 2021. During this time 149 responses were collected; 148 individuals consented to participate in the survey research. Of those consenting to the survey research, there were 40 (27%) individuals who did not complete the survey, 38 (25.7%) who were not currently using BFR/KAATSU training, and 70 (47.3%) who at the time of the survey were using BFR/KAATSU training. Through convenience sampling, the survey was made available to 22,791 individuals via Facebook and email for a response rate less than 1%. This excluded those who were made aware of the survey research through other individuals (i.e., snowball sampling) creating a lower response rate than the one reflected.

Previous BFR/KAATSU Training Use

Information regarding those previously using BFR/KAATSU training devices (n=108) and those currently using BFR/KAATSU training devices (n=70) can be found in Table 1. Individuals who were not actively administering BFR/KAATSU training (n=38, 35.2%) were henceforth excluded. Reasons identified for no longer using BFR/KAATSU training include: I previously utilized for injury rehabilitation, is no longer necessary, not allowed per company because I have not taken company's training, I am at a different school where we do not have blood flow restriction devices, and I do not have the resources in my athletic training room to use this form of rehab.

Current BFR/KAATSU Training Use

The remaining respondents (n=70) identified as males (n=41, 58.6%) and females (n=29, 41.4%). Additional information on demographics and professional careers can be found in Table 2. In regards to length of time to complete the survey, one outlier was removed as response time was 193,194 seconds (3,219.9 minutes). For the remaining responses (n=69), the survey took respondents an average of 657.65 seconds (10.96 minutes) to complete; a minimum of 226 seconds (3.76 minutes) and a maximum of 2,937 seconds (48.95 minutes).

Education

Respondents suggested obtaining both formal education (n=39, 55.7%) and self education (n=37, 52.9%) for their respective BFR/KAATSU devices. Of those who received formal training, 29 (74.4%) felt their training promoted a singular device, and 24 (61.5%) indicated their education was tailored toward a specific device. The majority (n=58, 82.9%) felt that some sort of education should take place prior to BFR/KAATSU training implementation, while five felt education prior to implementation was not needed and an additional seven had no opinion on the matter.

Implementation

Barriers. Barriers were faced by 29 (41.4%) when trying to implement BFR/KAATSU training into practice. Barriers noted by those facing barriers included the cost of equipment (n=20, 69%), lack of training (n=10, 34.5%), doubts of effectiveness (n=9, 31%), and a lack of clinical efficacy (n=4, 13.8%). Other barriers noted were: concerns of medical complications (e.g. DVTs), concerns of medical staff, confidence in applying technique and having patient/client understand that BFR training is hard, lack of physician/surgeon buy-in, patient consent, patient fear, patient unwilling to try, and lack of supervisor approval.

Screening. Screening processes facilitated by respondents were comprised of medical screening forms including risk assessments and/or in person physical examinations (n=27, 38.6%), both waiver/release forms and medical screening forms including risk assessments and/or in person physical examinations (n=22, 31.4%), waivers/release forms (n=1, 1.4%), and other screening processes (n=2, 2.9%): assure pt [sic] has no contraindication to BFR per a list and acquire consent from patient after describing treatment, and screening is done based off of recommendations of Owens Recovery Science. Additionally, 57 (81.4%) respondents gave consideration to the psychosocial aspects related to BFR/KAATSU training. Eighteen (25.7%) did not conduct screening. Reasons suggested for a lack of screening were: all participants are screened by medical department prior to contact with us, they are cleared by ATs for physical activity our requisites are met, initial health screening showed not signs of potential adverse interactions, we already know based on the medical history/chart if they are able to use this or not, communication with AT to determine if they are a good candidate for modality of BFR, we ask if they have history of blood clots, verbal consent, elite athletes, it is safe to use on the athletic population and patients I use it on, only self use, I have only used on myself, use only on myself, and we just don't have one outside of the one they sign for therapy.

Application. Survey responses suggested the following methods to determine restrictive pressure: the use of comfort (i.e., "7/10" perceived tightness) (n=13, 18.6%), limb circumference (n=4, 5.7%), standard blood pressure (n=5, 7.1%), doppler ultrasound (n=11, 15.7%), or the device was set to determine restrictive pressure (n=31, 44.3%). The remaining six responses (8.6%) provided other methods to determine restrictive pressures: systolic pressure x 1.5, comfort and blood pressure, skin color, there should be a faint pulse, color should return to skin

when pressed, capillary refill with progressive tightness based on both refill and feedback, device, will often lower pressure for first session, and not able to use any equipment.

The majority (n=67, 95.7%) believed personalizing restrictive pressure would reduce adverse effects, and multiple positions were used to determine restrictive pressure. Restrictive pressure determination was completed with the patient/client/athlete in a supine position (n=33, 47.1%), seated position (n=11, 15.7%), standing position (n=9, 12.9%), and in an exercise dependent position (n=17, 24.3%). For subsequent exercises, restrictive pressure was determined by the same measures as the initial assessment (n=38, 54.3%), a different method from the initial method based on exercise position (n=11, 15.7%), or no additional measurement of restriction pressure was made for subsequent exercises (n=21, 30%). Workload was determined using: heart rate (n=5, 7.1%), percentage of 1 RM (n=18, 25.7%), length of time under tension/load (n=22, 31.4%), work to failure (n=14, 20%), and other methods (n=11, 15.7%). Other methods suggested were using Delfi protocol, adding resistance if not worked to failure by end of protocol at next session, both %1 RM and length of time under tension, load and reps, low weight, high rep, 15-20 minutes, 30/15/15/15, prescribed reps/sets from educational training, reps in deserve [sic], muscle fatigue scale, perceived exertion, RPE, by feel, muscle groups worked, and unknown.

Blood flow restriction and KAATSU devices were applied for various lengths of time. Devices provided restriction for the duration of the workout (n=24, 34.3%), devices were loosened or released between exercises (n=29, 41.4%), devices were loosened or released between sets of an exercise (n=10, 14.3%), or through other methods (n=5, 7.1%); two individuals did not respond to the question. Other methods described by respondents were: as tolerated for prescribed exercise, client dependent- either intermittent or continuous, client

dependent, provide restriction for duration up to 8 minutes max, and unknown. The majority of respondents provided direct supervision to the patient/client/athlete while BFR/KAATSU training was being administered (n=52, 74.3%). Additional respondents provided some supervision to the patient/client/athlete while BFR/KAATSU training was being administered (n=14, 20%), while others provided no supervision to the patient/client/athlete while BFR/KAATSU training was being administered (n=4, 5.7%).

Patients/clients/athletes received BFR/KAATSU training on the upper extremity (n=4, 5.7%), lower extremity (n=18, 25.7%), or both the upper extremity and lower extremities (n=48, 68.6%). Activities for which BFR/KAATSU training were administered included strength training exercises (n=47, 67.1%), aerobic exercise (n=15, 21.4%), rehabilitation exercises (n=57, 81.4%), and other activities (n=5, 7.1%). Activities described were: active recovery, effects of BFR on sprint time, healing, I know PT's use it for rapid rehab after surgery, and recovery. Specific forms of exercises performed with BFR/KAATSU can be seen in Table 3. Blood flow restriction and KAATSU training were administered: 1-2 sessions per week (n=51, 72.9%), 3-4 sessions per week (n=18, 25.7%), and 5-6 sessions per week (n=1, 1.4%) but not 7 or more sessions per week (n=0, 0%).

Patient Demographics and Safety

Patient Demographics

Blood flow restriction/KAATSU training was performed on those who were identified as male (n=64, 91.4%), female (n=48, 68.57%), gender non conforming (n=2, 2.9%), transgender (n=3, 4.3%), and unknown (n=1, 1.4%). Patients were of various ethnicities and were identified as white (n=61, 87.1%), black, African American (n=42, 60%), Asian (n=16, 22.9%), Pacific Islander, Hawaiian (n=10, 14.3%), Hispanic/Latino/a (n=27, 38.6%), Native American or

Alaskan Native (n=11, 15.7%), and those of an unknown ethnicity (n=1, 1.4%) or those who were multi-racial (n=1, 1.4%). Patients/clients/athletes were under 20 years old (n=45, 64.3%), 21-30 years old (n=58, 82.9%), 31-40 years old (n=31, 44.3%), 41-50 years old (n=20, 28.6%), 51-60 years old (n=12, 17.1%), and over the age of 60 years old (n=6, 8.6%).

Safety

Blood flow restriction and KAATSU training was administered on patients/clients/athletes with pathology by 16 (22.9%) respondents. Pathologies noted by respondents for which they have applied BFR/KAATSU training were hypertension, diabetes, obesity, EDS [sic], osteopenia, and unspecified cardiac conditions. Adverse effects from the administration of BFR/KAATSU training were seen by 15 (21.4%) respondents. Adverse effects seen can be seen in Table 4. Those who discontinued the use of BFR/KAATSU training did so for a variety of reasons presented in Table 5.

Discussion

To date three survey based research studies have been completed on the administration of BFR (Patterson and Brandner, 2018) and KAATSU training (Nakajima et al., 2006; Yasuda et al., 2017). The present study sought to add to the current body of knowledge through two objectives: the first objective was to better understand how individuals of various professions in the United States of America were using BFR/KAATSU training devices and the second objective was to investigate subsequent safety related concerns. Information was sought from those who have previously used BFR/KAATSU training devices and those using BFR/KAATSU training devices at the time of the study.

A variety of devices have been used in the facilitation of BFR/KAATSU training. The most common type of device applied was the inflatable device (43.5%, n=47) followed by elastic tourniquet based devices (19.4%, n=21). Respondents reported equal use of KAATSU devices and knee wraps. Results of the current study were similar to a previous study by Patterson and Brandner (2018) where the use of inflatable devices, KAATSU devices, and knee wraps were comparable. One area that differed between the present study and Patterson and Bradner (2018) was the use of elastic tourniquet based devices. While the present study found 19.4% of respondents (n=108) have used an elastic tourniquet based device, Patterson and Brandner (2018) found only 3.6% of respondents (n=115) have used an elastic tourniquet based device. It can be hypothesized that the respondents of the present study incorrectly identified the types of devices previously used as they did with the currently used devices which are reflected in Tables 1 and 6, and discussed later within the discussion section. Terminology used to describe the devices was based on Patterson and Brandner (2018) and may not reflect how respondents describe their devices, particularly tourniquet based devices. Other terminology, including

pneumatic tourniquet, has been used when describing tourniquet based devices (McEwen et al., 2019; Patterson et al., 2019). It is unknown if there was confusion surrounding the terms used to describe the devices.

The present study also found 35.18% (n=38) of individuals no longer administering BFR/KAATSU training. Minimal additional data was provided justifying discontinuation. Reasons that were cited included facility resources and facility policy on training prior to use of BFR/KAATSU training. No additional literature pertaining to complete cessation of BFR/KAATSU training secondary to facility or training concerns could be found. However, others have noted side effects or adverse reactions (Nakajima et al., 2006; Patterson and Brandner, 2018; Yasuda et al., 2017) which could lead to temporary or permanent discontinuation of training. Side effects seen among those who were currently using devices can be found later in the discussion section.

At the time of the study, BFR/KAATSU training was being administered by those identifying as male/female genders across the country. Most predominantly, those administering BFR/KAATSU training were from a younger population (18-40 years old and practicing less than 20 years) and represented a variety of professions including athletic training, occupational therapy, physical therapy, personal training, and strength and conditioning. In previous survey based research, authors have likewise noted administration by those of male and female genders (Nakajima et al., 2006; Patterson and Brandner, 2018; Yasuda et al., 2017), and administration by a younger demographic across a variety of professions (Patterson and Brandner, 2018).

Those administering BFR/KAATSU training at the time of the survey research employed a variety of devices. However, the most frequently applied device was the inflatable device likewise noted as the most prevalent previously used device in the current study. This finding

again mirrored Patterson and Brandner (2018) as handheld inflatable devices and automatic inflatable devices were reported as the most commonly used devices. While the majority of those currently using BFR/KAATSU training suggested application of an inflatable device (61.4%, n=43 of 70), there was a discrepancy within the current study in how respondents identified devices used as compared to the type of the device the unit actually represented. Table 1 reflects the device respondents believed he/she were using while Table 6 reflects what type of device the unit actually represented. While terminology used was based on the classification used by Patterson and Brandner (2018), it is unknown if the terminology confused the respondents. For instance, the present study used the term elastic tourniquet (Patterson & Brandner, 2018) while other authors have used pneumatic tourniquet in their writing to describe tourniquet based devices (McEwen et al., 2019; Patterson et al., 2019), perhaps leading respondents to classify devices differently. Additionally, literature could not be found related to some devices used in the present study, including devices intended for flotation, cryo/thermotherapy, and bracing. More information on the types of devices used can be found in Table 6.

It is believed this is the first study to assess barriers implementing BFR/KAATSU training. In the present study, several experienced barriers when implementing BFR/KAATSU training. The most frequently cited barrier was the cost of the apparatuses. While not assessed by the study, it can be noted that the most frequently cited devices (Table 1 and Table 6) have device specific training which can add to the potential cost for the user. In addition to the cost, some faced barriers on the effectiveness of BFR/KAATSU training, as well as concerns by overseeing medical practitioners or supervisors and the patients/clients/athletes for which BFR/KAATSU training was being administered.

The majority of respondents (82.9%, n=58) believe training prior to BFR/KAATSU implementation should take place. While no additional information could be found regarding perceptions of BFR/KAATSU training implementation, respondents of this survey indicated training was necessitated by the BFR/KAATSU device company or the facilities where one is employed. Education received by respondents was both formal and self facilitated but not all training promoted a singular device or was tailored toward a specific device. It is unknown how education was disseminated among the respondents of this survey.

Nearly three-quarters of respondents indicated conducting some sort of screening process and just over 80% gave consideration to the psychosocial aspects of BFR/KAATSU training. The most predominantly facilitated process was a medical screening or a medical screening and a waiver with the patient/client/athlete prior to use. Yasuda et al. (2017) also found most respondents performed interviews or assessments prior to application of KAATSU training either the first time or every time the device was applied. The present study also revealed 25.7% of respondents had no screening process. Upon further examination there were indications a screening process took place at some point. Comments on the open ended question included reference to screenings by other departments and use of initial health screenings.

The same open ended question suggested some screened on a limited basis or not at all. Those that assessed patients/clients/athletes on a limited basis suggested inquiring about blood clot history, while others asked for verbal consent. Also noted in the comments was the perception that no screening was needed when applying BFR/KAATSU training on those who were perceived as healthy. Patterson and Brander (2018) saw similar comments in which respondents felt there were no contraindications in populations of individuals who may be healthy, young, or athletic. In reviews of healthy populations, low intensity exercise with blood

flow restriction has shown effects on hemodynamics within a normal spectrum (Neto et al., 2017) and improved strength gains and muscle mass greater than low intensity exercise alone (Slysz et al., 2016). Furthermore, stroke volume, blood pressure, heart rate, fibrinolytic potential, coagulation activity, and post occlusion blood flow responded the same as free flow high load resistance exercise in short term studies (Loenneke et al., 2011). Additionally, Patterson et al. (2019) suggested when applied and performed appropriately BFR should not produce muscle damage unless other susceptibility to adverse physiologic effects exist. For all populations, correct application and safety in training are important (Hughes et al., 2017; Loenneke et al., 2011; Patterson et al., 2019; Sato, 2005). Regardless, for those wanting to implement a screening tool, Kacin et al. (2015) created a screening questionnaire which can aid a health professional in determining if the treatment is appropriate.

The present study found 95.7% of those administering BFR/KAATSU training believed personalized restrictive pressure was needed to prevent adverse effects. There was variability in the procedures performed to determine restrictive pressure. Techniques used to determine restrictive pressure included the use of doppler ultrasounds, the device themselves, subjective rating scales and the use of capillary refill. When administering BFR/KAATSU training, methods to obtain the pressure vary. For instance, the application of doppler ultrasound has shown reproducibility (Bezerra de Morais et al., 2017) and both the doppler ultrasound (Masri et al., 2016) and devices set to determine limb occlusion pressure (McEwan et al., 2019) have been advocated. For those unable to afford/operate doppler ultrasound, pulse oximeters have shown potential in determining occlusion pressure within the upper extremity (Lima-Soares et al., 2020; Zeng et al., 2019). Subjective rating scales can also be conducted with devices for which pressure cannot be determined through conventional means (Wilson et al., 2013). Additional

procedures performed by respondents of the present study related to the use of skin color, pulse, and capillary refill. Within the current study, 24.3% (n=17) determined restrictive pressure in an exercise dependent position with 15.7% (n=11) determining restrictive pressures for subsequent exercises using methods based on the exercise position. Sieljacks et al. (2018) and Hughes, Jeffries et al. (2018) demonstrated body position does influence arterial occlusion pressure in lower extremity exercise.

In this investigation, responses related to the administration of BFR/KAATSU training both matched and conflicted with previous authors. Frequency of use is one area that was similar. In this study training methods were most applied 1-2 times per week (72.9%, n=51) or 3-4 sessions per week (25.7%, n=18). Authors have suggested BFR/KAATSU training was most administered one to three sessions per week (Nakajima et al., 2006), or one to two sessions and three to four sessions per week (Patterson & Brandner, 2018). Patterson et al. (2019) suggested administering BFR two to three times per week. Types of exercise employed also presented similarly between the current study and research from previous authors. Patterson and Brandner (2018) found cycling and walking were the most frequent aerobic exercises used with BFR which was reflected in the current study. Workload was one area which differed. Patterson and Brandner (2018) found most respondents determined workload using percentage of a one repetition maximum (1RM) with the following repetitions: 30 -15-15-15, or the use of repetitions to failure while the current study found length of time under tension/load was more frequently used than a percentage of 1RM or work for failure. Like Patterson and Brandner (2018), the results of this investigation indicate great variability in administration.

The second objective of the study was to explore safety related to the use of BFR/KAATSU training. The survey explored three areas related to safety. Safety topics

addressed were the use of BFR/KAATSU training on individuals with pathology, adverse effects seen following device use, and reasons for discontinuing BFR/KAATSU training.

In the present study, 22.8% (n=16) of respondents applied BFR/KAATSU training to those with pathology. Respondents indicated BFR/KAATSU training was most applied to individuals with obesity (37.5%, n=6), hypertension (37.5%, n=6), diabetes (25%, n=4), and osteoporosis (12.5%, n=1). Literature related to the use of BFR/KAATSU training with the four identified pathologies was limited. Nakajima et al. (2006) and Yasuda et al., (2017) have found practitioners using KAATSU training among those with obesity, hypertension, and diabetes. Bond et al., (2017) has assessed the effects of BFR on individuals who are both sedentary and obese finding increases in 1 RM and post occlusion blood flow. Nascimento et al. (2019) suggested greater understanding of blood flow restriction's effect on coagulation would be beneficial for those at an increased risk of thrombi development including individuals with obesity, hypertension, and diabetes. Blood flow restriction has; however, shown positive hemodynamic effects (Loenneke et al., 2011; Nascimento et al., 2019; Neto et al., 2017; Yan et al., 2018) including among those with hypertension (Barili et al., 2018).

Specific to those who have diabetes, Kacin et al., (2015) indicated the potential risk of neurological injury caused by ischemia and nerve compression particularly among those with reduced peripheral nerve function. Few studies have explored the effects of administering BFR/KAATSU training on those with osteopenia. Silva et al. (2015) found a small sample of women with osteoporosis were able to improve maximal dynamic strength on knee extension exercise and Yasuda et al. (2017) found practitioners using KAATSU training among individuals with osteoporosis.

For those uncertain how BFR/KAATSU training responds within a population or those with pathologies for which the efficacy of BFR/KAATSU training has not been ascertained, including the pathologies noted by respondents of the present study, some additional recommendations have been made. Nascimento et al. (2019) proposed an alternative exercise regime for resistance training using 50% of the 1 RM. In addition, Kacin et al. (2015) developed a screening tool which may help in the assessment process. Finally, Patterson et al. (2018) suggested the use of clinical prediction rules to assess for additional risk particularly for venous thromboembolism.

Adverse effects were seen by those applying devices marketed for BFR/KAATSU training as well as those applying devices not marketed for BFR/KAATSU training. Details about adverse reactions can be seen in Table 4. With the exception of one adverse effect where prior food consumption was called into question, it is unknown if other personal factors influenced the adverse reaction. The adverse effects described in this investigation matched common reactions presented by other authors (Nakajima et al., 2016; Yasuda et al., 2017).

Individuals discontinued the use of BFR/KAATSU training due to changes to training, facility concerns, monetary issues, as well as safety. Reasons for discontinuation of BFR/KAATSU training (Table 5) directly related to side effects (e.g. lightheadedness and pain) were similar to side effects reported previously (Nakajima et al., 2006; Patterson and Brandner, 2018; Yasuda et al., 2017). Nascimento et al. (2019) recommended further research to quantify side effects to develop clearer parameters for use particularly among patients/clients/athletes who may have pathology or who may be older. Furthermore, quantifying a side effect versus an adverse reaction may limit ambiguity seen in the present study.

Study Limitations

There were limitations in the current study. While a test pilot was completed, Cronbach's alpha was low (α=.484) and correlations were variable. Revisions to the survey were completed but additional test pilots were not performed to ensure internal consistency. Validity was assessed through correlations between the test pilot group and a random sample of ten following the conclusion of the survey. No correlations were found between the groups. The two groups reflected varying professions which could have influenced the results. Additionally, the survey was long at 37 questions taking an average of nearly 11 minutes to complete. Future investigations should explore survey constructs including verbiage for greater clarity.

The survey response rate was low at less than 1% creating the potential for bias, and a lack of generalization. The low sample size and parsing data into those that have previously used and were currently using BFR/KAATSU training devices also contributed to the low sample size. Furthermore, of the 148 consenting to participate in the research 27% did not complete the survey. The percentage of those not completing the survey raises concerns with the survey itself and length of time needed to complete the survey.

The majority of the survey were selection based questions. The questions potentially prevented respondents from elaborating or required a best fit answer which may not reflect what was actually being done. Participants were; however, given the opportunity to provide written responses on several constructs. The written work likewise posed limitations. Some of the written work presented incomplete thoughts and typographical errors limiting the ability to interpret what was written.

Real World Implications

The data represented a very small subset of the population who may be applying BFR/KAATSU training devices. Notable takeaways from the present study include the

variability in the devices used, training received, screening applied, and the overall administration of BFR. Devices being used for BFR that have not been scientifically explored, should be avoided until their safety and efficacy can be demonstrated. Training is encouraged prior to use and is a shared viewpoint with many who participated in the survey research. While screening processes vary, tools do exist for those needing a process. The versatility presented in the current study makes the generalization of consideration based documents (Patterson et al., 2018) difficult but these documents may provide a general framework for use. Finally, additional considerations should be given to those with pathology and those who experience side effects and/or adverse reactions to BFR/KAATSU training as these areas lack complete understanding.

Future Directions

From the current study, several gaps have been highlighted for which research should continue. Data from the present study failed to demonstrate reasons why individuals may no longer be using BFR/KAATSU training and warrants additional attention. Additionally, barriers described within the study deserve further exploration. The types of devices used, device associated training and education, and the application of devices administered also lacks detail. Finally, research is still lacking on safety and efficacy related to BFR/KAATSU training particularly among those with pathology.

Conclusion

The current study sought to explore how individuals of various professions were using BFR/KAATSU training within the United States of America as well as to seek a better understanding of the safety related to BFR/KAATSU training. Through survey research it was discovered that BFR/KAATSU training was applied by a variety of professions in a variety of settings. Devices varied in style and brand including those marketed and not marketed for

BFR/KAATSU specific use. Those administering BFR/KAATSU training have done so on a variety of individuals with and without health complications. Adverse reactions and side effects have been seen and likewise noted by other authors (Nakajima et al., 2016; Yasuda et al., 2017). Overall, the study demonstrated diversity in the devices used, training received, screening applied, and the overall administration of BFR.

References

Abe, T., Kearns, C. F., Manso Filho, H. C., Sato, Y., & McKeever, K. H. (2006). Muscle, tendon, and somatotropin responses to the restriction of muscle blood flow induced by KAATSU-walk training. *Equine Veterinary Journal, 7*(S36), 345-348. https://doi.org/10.1111/j.2042-3306.2006.tb05566.x

Baker, B. S., Stannard, M. S., Duren, D. L., Cook, J. L., & Stannard, J. P. (2020). Does blood flow restriction therapy in patients older than age 50 result in muscle hypertrophy, increased strength, or greater physical function? A systematic review. *Clinical Orthopaedics and Related Research 478*(3), 593-606. https://doi.org/10.1097/CORR.0000000000001090

Barber-Westin, S., & Noyes, F. R. (2019). Blood flow-restriction training for lower extremity muscle weakness due to knee pathology: A systematic review. *Sports Health, 11*(1), 69-83. https://doi.org/10.1177/1941738118811337

Barili, A., Corralo, V. dS., Cardoso, A. M., Mânica, A., Bonadiman, B. dS. R., Bagatini, M. D., Silva-Grigoletto, M. E. D., de Oliveira, G. G., & Sá, C. A. D. (2018). Acute responses of hemodynamic and oxidative stress parameters to aerobic exercise with blood flow restriction in hypertensive elderly women. *Molecular Biology Reports 45*, 1099-1109 https://doi.org/10.1007/s11033-018-4261-1

Beckwée, D., Delaere, A., Aelbrecht, S., Baert, V., Beaudart, C., Bruyere, O., de Saint-Hubert, M., & Bautmans, I. (2019). Exercise interventions for the prevention and treatment of sarcopenia. A systematic umbrella review. *Journal of Nutrition, Health, and Aging 23*(6), 494-502. https://doi.org/10.1007/s12603-019-1196-8

Bezerra de Morais, A. T., Santos Cerqueira, M., Moreira Sales, R., Rocha, T., & Galvão de

Moura Filho, A. (2017). Upper limbs total occlusion pressure assessment: Doppler ultrasound reproducibility and determination of predictive variables. *Clinical Physiology and Functional Imaging 37*(4): 437–441. https://doi.org/10.1111/cpf.12330

Bond, V., Curry, B. H., Kumar, K., Pemminati, S., Gorantla, V. R., Kadur, K., & Millis, R. M. (2017). Restricted blood flow exercise in sedentary, overweight African-American females may increase muscle strength and decrease endothelial function and vascular autoregulation. *Journal of Pharmacopuncture, 20*(1). 23-28. http://doi.org/10.3831/KPI.2017.20.002

Bryk, F. F., dos Reis, A. C., Fingerhut, D., Araujo, T., Schutzer, M., Cury, R. P., Duarte Jr. A., & Fukuda, T. Y. (2016). Exercises with partial vascular occlusion in patients with knee osteoarthritis: A randomized clinical trial. *Knee Surgery, Sports Traumatology, Arthroscopy, 24*(5), 1580-1586. https://doi.org/10.1007/s00167-016-4064-7

Centner, C., Lauber, B., Seynnes, O. R., Jerger, S., Sohnius, T., Gollhofer, A., & König, D. (2019). Low-load blood flow restriction training induces similar morphological and mechanical Achilles tendon adaptations compared with high-load resistance training. *Journal of Applied Physiology, 127*(6), 1660-1667. https://doi.org/10.1152/japplphysiol.00602.2019

Chen, Y.T., Hsieh, Y. Y., Ho, J.Y., & Lin, J.C. (2019). Effects of running exercise combine with blood flow restriction on strength and sprint performance. *Journal of Strength and Conditioning Research, 00*(00), 1-7. https://doi.org/10.1519/JSC.0000000000003313

Computergaga (2015, December 16). Pick a name at random-Excel formula. [Video file]. Retrieved from https://www.youtube.com/watch?v=Wrsnolpfej8&t=178s

Cook, S. B, LaRoche, D. P., Villa, M. R., Barile, H., & Manini, T. M. (2017). Blood flow

restricted resistance training in older adults at risk of mobility limitations. *Experimental Gerontology, 99*(1), 138-145. https://doi.org/10.1016/j.exger.2017.10.004.

Counts, B. R., Rossow, L., M., Mattocks, K. C., Mouser, J. G., Jessee, M. B., Buckner, S. L., Denkel, S. J., & Loenneke, J. P. (2018). Let's talk about sex: Where are the young females in blood flow restriction research? *Clinical Physiological and Functional Imaging, 38*(1), 1-3. https://doi.org/10.1111/cpf.12394

Crenshaw, A. G., Hargens, A. R., Gershuni, D. H., & Rydevik, B. (1988). Wide tourniquet cuffs more effective at lower inflation pressures. *Acta Orthopaedica Scandinavica, 59*(4), 447-451. http://dx.doi.org/10.3109/17453678809149401

Crossley, K. W., Porter, D. A., Ellsworth, J., Caldwell, T., Feland, J. B., Mitchell, U., Johnson, A. W., Egget, D., & Gifford, J. R. (2020). Effect of cuff pressure on blood flow during blood flow-restricted rest and exercise. *Medicine and Science in Sports and Exercise, 52*(3), 746-753 . https://doi.org/10.1249/MSS.0000000000002156

Ferraz, R. B., Gualano, B., Rodrigues, R., Kurimori, C., Fuller, R., Lima F., Sá-Pinto, A. L., & Roschel, H.(2018). Benefits of resistance training with blood flow restriction in knee osteoarthritis. *Medicine and Science in Sports and Exercise, 50*(5), 897-905. https://doi.org/10.1249/MSS.0000000000001530

Formiga, M. F., Fay, R., Hutchinson, S., Locandro, N., Ceballos, A., Lesh, A., Buscheck, J., Meanor, J., Owens, J. G., & Cahalin, L. P. (2020). Effect of aerobic exercise training with and without blood flow restriction on aerobic capacity in healthy young adults: A systematic review with meta-analysis. *International Journal of Sports Physical Therapy, 15*(2), 175-187. https://doi.org/10.26603/ijspt20200175

Grønfeldt, B. M., Nielsen, J. L., Mieriz, R. M., Lund, H., & Aagaard, P. (2020). Effect of

blood-flow restricted vs heavy-load strength training on muscle gains: Systematic review and meta-analysis. *Scandinavian Journal of Medical and Science in Sports, 30*(5), 837-848. https://doi.org/10.1111/sms.13632

Harper, S. A., Roberts, L. M., Layne, A. S., Jaeger, B. C., Gardner, A. K., Sibille, K. T., Wu. S. S., Vincent, K. R., Fillingim, R. B., Manini, T. M., & Buford, T. W. (2019). Blood-flow restriction resistance exercise for older adults with knee osteoarthritis: A pilot randomized clinical trial. *Journal of Clinical Medicine,8*(2),265-277. https://doi.org/10.3390/jcm8020265

Head, P., Austen, B., Browne, D., Campkin, T., & Barcellona, M. (2015). Effect of practical blood flow restriction training during bodyweight exercise on muscular strength, hypertrophy, and function in adults: A randomised controlled trial. *International Journal of Therapy and Rehabilitation, 22*(6), 263-271. https://doi.org/10.12968/ijtr.2015.22.6.263

Hughes, L., Jeffries, O., Waldorn, M., Rosenblatt, C. G., Paton, B., & Patterson, S. D. (2018). Influence and reliability of lower-limb arterial occlusion pressure at different body positions. *PeerJ e4697.* https://doi.org/10.7717/peerj.4697

Hughes, L., Paton, B., Haddad, F., Rosenblatt, B., Gissane, C., & Patterson, S. D. (2018). Comparison of the acute perceptual and blood pressure response to heavy load and light load blood flow restriction resistance exercise in anterior cruciate ligament reconstruction patients and non-injured population. *Physical Therapy in Sport, 33*, 54-61. https://doi.org/10.1016/j.ptsp.2018.07.002

Hughes, L., Paton, B., Rosenblatt, B., Gissane, C., & Patterson, S. D. (2017). Blood flow restriction training in clinical musculoskeletal rehabilitation: A systematic review and

meta-analysis. *British Journal of Sport Medicine, 51*(13), 1003-1011. https://doi.org/10.1136/bjsports-2016-097071

Hughes, L., Rosenblat, B., Gissane, C., Paton, B., & Patterson, S. D. (2018). Interface pressure, perceptual, and mean arterial pressure responses to different blood flow restriction systems. *Scandnavian Journal of Medicine and Science in Sports, 28*(7) 1757-1765 https://doi.org/10.1111/sms.13092

Hughes, L., Rosenblatt, B., Paton, B., & Patterson, S. D. (2018). Blood flow restriction training in rehabilitation following anterior cruciate ligament reconstructive surgery: A review. *Techniques in Orthopedics, 33*(2), 106-113. https://doi.org/10.1097/BTO.0000000000000265

Hylden, C., Burns, T., Stinner, D., & Owens, J. (2015). Blood flow restriction rehabilitation for extremity weakness: A case series. *Journal of Special Operations Medicine, 15*(1), 48-54. https://www.owensrecoveryscience.com/files/Hylden_RS_1.pdf

Jesse, M. B., Buckner, S. L., Dankel, S. J., Counts, B. R., Abe, T., & Loenneke, J. P. (2016). The influence of cuff widths, sex, and race on arterial occlusion: Implications for blood flow restriction research. *Sports Medicine 46*, 913-921. https://doi.org/10.1007/s40279-016-0473-5

KAATSU Training (n.d.a). Science behind KAATSU. Retrieved from https://www.kaatsu.com/index.cfm?Action=About.scienceBehindKAATSU

KAATSU Training (n.d.b). KAATSU Store. Retrieved from https://www.kaatsu.com/?Action=Store.Home

Kacin, A., Rosenblatt, B., Grapar Žargi, T., & Biswa, A. (2015). Safety considerations with

blood flow restricted resistance training. *Annales of Kinesiologiae 6*(1), 3-26. https://www.researchgate.net/publication/293767736_SAFETY_CONSIDERATIONS_WITH_BLOOD_FLOW_RESTRICTED_RESISTANCE_TRAINING

Kambič, T., Novaković, M., Tomažin, K., Strojnik, V., & Jug, B. (2019). Blood flow restriction resistance exercise improves muscle strength and hemodynamics, but not vascular function in coronary artery disease patients: A pilot randomized controlled trial. *Frontiers in Physiology, 10*(656), 1-11. https://doi.org/10.3389/fphys.2019.00656

Kongsgaard, M., Reitelseder, S., Pedersen, T. G., Holm, L., Aagaard, P., Kjaer, M., & Magnusson, S. P. (2007). Region specific patellar tendon hypertrophy in humans following resistance training. *Acta Physiologica, 191*(2), 111-121. https://doi.org/10.1111/j.1748-1716.2007.01714.x

Kubo, K., Komuro, T., Ishiguro, N., Tsunodo, N., Sato, Y., Ishii, N., Kanehisa, H., & Fukunaga, T. (2006). Effects of low load resistance training with vascular occlusion on the mechanical properties of muscle and tenon. *Journal of Applied Biomechanics, 22*(2), 112-119. https://doi.org/10.1123/jab.22.2.112

Ledlow, P., Coppack, R. J., Dharm-Datta, S., Conway, D., Sellon, E., Patterson, S. D., & Bennett, A. N. (2018). Low load resistance training with blood flow restriction improves clinical outcomes in musculoskeletal rehabilitation: A single blind randomized controlled trial. *Frontiers in Physiology, 9*(1269), 1-14. https://doi.org/10.3389/fphys.2018.01269

Lima-Soares, F., Pessoa, K. A., Cabido, C. E. T., Lauver, J., Cholewa, J., Rossi, F., & Zanchi, N. (2020). Determining the arterial occlusion pressure for blood flow restriction: Pulse oximeter as a new method compared with a handheld doppler. *The Journal of Strength*

and Conditioning Research, Publish Ahead of Print. https://doi.org/10.1519/JSC.0000000000003628

Lixandrão, M. E., Ugrinowitsch, C., Berton, R., Vechin, F. C., Conceicão, M. S., Damas, F., Cleiton, A. L., & Roschel, H. (2018). Magnitude of muscle strength and mass adaptations between high-load resistance training versus low-load resistance training associated with blood-flow restriction: A systematic review and meta-analysis. *Sports Medicine, 48*(2), 361-378. https://doi.org/10.1007/s40279-017-0795-y

Loenneke, J. P., Allen, K. M., Mouser, J. G., Thiebaud, R. S., Kim, D., Abe, T., & Bemben, M. G. (2015). Blood flow restriction in the upper and lower limbs is predicted by limb circumference and systolic blood pressure. *European Journal of Applied Physiology,115*, 397-405. https://doi.org/10.1007/s00421-014-3030-7

Loenneke, J. P., Fahs, C. A., Rossow, L. M., Sherk, V. D., Thiebaud, R. S., Abe, T., Bemben, D. A., & Bemben, M. G. (2012). Effects of cuff width on arterial occlusion: Implications for blood flow restriction exercise. *European Journal of Applied Physiology, 112*(8), 2903-2912. https://doi.org/10.1007/s00421-011-2266-8

Loenneke, J. P., & Pujol, T. J. (2009). The use of occlusion training to produce muscle hypertrophy. *Strength and Conditioning Journal, 31*(3), 77-84. https://doi.org/10.1519/SSC.0b013e3181a5a352

Loenneke, J. P., Thiebaud, R. S., Abe, T., & Bemben, M. G. (2014). Blood flow restriction recommendations: The hormesis hypothesis. *Medical Hypotheses, 82*(5), 623-626. http://dx.doi.org/10.1016/j.mehy.2014.02.023

Loenneke, J. P., Wilson, J. M., Wilson, G. J., Pujol, T. J., & Bemben, M. G. (2011). Potential safety issues with blood flow restriction training. *Scandinavian Journal of Medicine &*

Science in Sports, 21(4), 510-518. https://doi.org/10.1111/j.1600-0838.2010.01290.x

Luebbers, P.E., Fry, A. C., Kriley, L. M., & Butler, M. S. (2014). The effects of a 7-week practical blood flow program on well trained athletes. *The Journal of Strength and Conditioning Research, 28*(8), 2270-2280. https://doi.org/10.1519/JSC.0000000000000385

Luebbers, P.E., Witte, E. V., Oshel, J. Q., & Butler, M. S. (2019). Effects of practical blood flow restriction training on adolescent lower-body strength. *The Journal of Strength and Conditioning Research, 33*(10), 2674-2683. https://doi.org/10.1519/JSC.0000000000002302

Masri, B. A., Day, B., Younger, A. S. E., & Jeyasurya, J. (2016). Technique for measuring limb occlusion pressure that facilitates personalized tourniquet systems: A randomized trial. *Journal of Medical and Biological Engineering 36*(5): 644–650. https://doi.org/10.1007/s40846-016-0173-5

Mattar, M. A., Gualano, B., Perandini, L. A., Shinjo, S. K., Lima, F. R., Sá-Pinto, A. L., & Roschel, H. (2014). Safety and possible effects of low-intensity resistance training associated with partial blood flow restriction in polymyositis and dermatomyositis. *Arthritis Research and Therapy, 16*(5), 473. https://doi.org/10.1186/s13075-014-0473-5

Mattocks, K. T., Mouser, J. G., Jessee, M. B., Buckner, S. L., Dankel, S. J., Bell, Z. W., Abe, T., Bentley, J. P., & Loenneke, J. P. (2019). Perceptual changes to progressive resistance training with and without blood flow restriction. *Journal of Sports Science, 37*(16), 1857-1864. https://doi.org/10.1080/02640414.2019.1599315

McEwen, J. A., Owens, J. G., & Jeyasurya, J. (2019). Why is it crucial to use personalized occlusion pressures in blood flow restriction (BFR) rehabilitation? *Journal of Medical*

and Biological Engineering, 39, 173-177. https://doi.org/10.1007/s40846-018-0397-7

Mouser, J. G., Dankel, S. J., Jessee, M. B., Mattocks, K. T., Buckner, S. L., Counts, B. R. & Loenneke, J. P. (2017). A tale of three cuffs: The hemodynamics of blood flow restriction. *European Journal of Applied Physiology, 117*, 1493-1499. https://doi.org/10.1007/s00421-017-3644-7

Nakajima, T., Kurano, M., Lida, H., Takano, H., Oonuma,, H., Morita, T., Meguro, K., Sato, Y., Nagata, T., & KAATSU Training Group. (2006). Use and safety of KAATSU training: Results of a national survey. *International Journal of KAATSU Training Research* 2, 5-13. https://doi.org/10.3806/ijktr.2.5

Nascimento, D. D. C., Petriz, B., Oliviera, S. D. C., Vieira, D. C. L., Funghetto, S. S., Silva, A. O., & Prestes, J. (2019). Effects of blood flow restriction exercise on hemostasis: A systematic review of randomized and non-randomized trials. *International Journal of General Medicine 2019*(12), 91-100. https://doi.org//10.2147/IJGM.S194883

Neto, G. R., Novaes, J. S., Dias, I., Brown, A., Vianna, J., & Cirilo-Sousa, M. S. (2017). Effects of resistance training with blood flow restriction on haemodynamics: A systematic review. *Clinical Physiology and Functional Imaging, 37*(6), 567-574. https://doi.org/10.1111/cpf.12368

Ohta, H., Kurosawa, H., Ikeda, H., Iwase, Y., Satou, N., & Nakamura, S. (2003). Low-load Resistance muscular training with moderate restriction of blood flow after anterior cruciate ligament reconstruction. *Acta Orthopaedica Scandinavica 74*(1), 62-68. https://doi.org/10.1080/00016470310013680

Paton, C. D., Addis, S. M., & Taylor, L. (2017). The effects of muscle blood flow restriction

during running training on measures of aerobic capacity and run to exhaustion. *European Journal of Applied Physiology. 117*(12), 2579-2585. https://doi.org/10.1007/s00421-017-3745-3

Patterson, S. D., & Brandner, C. R. (2018). The role of blood flow restriction training for applied practitioners: A questionnaire-based survey. *Journal of Sports Sciences, 36*(2), 123-130. https://doi.org/10.1080/02640414.2017.1284341

Patterson, S. D., Hughes, L., Warmington, S., Burr, J., Scott, B. R., Owens, J., Abe, T., Nielsen, J. L., Cleiton, A L., Laurentino, G., Neto, G. R., Brandner, C., Martin-Hernandez, J., & Loenneke, J. (2019). Blood flow restriction exercise position stand: Considerations of methodology, application, and safety. *Frontiers in Physiology, 10*(533), 1-15. https://doi.org/10.3389/fphys.2019.00533

Pearson, S. J., & Hussain, S. R. (2015). A review on the mechanisms of blood-flow restriction resistance training-induced muscle hypertrophy. *Sports Medicine, 45*(2), 187-200. https://doi.org/10.1007/s40279-014-0264-9

Sato, Y. (2005). The history and future of KAATSU training. *International Journal of Kaatsu Training Research, 1*(1), 1-5. Retrieved from https://www.jstage.jst.go.jp/article/ijktr/1/1/1_1_1/_pdf

Scott, B. R., Loenneke, J. P., Slattery, K. M., & Dascombe, B. J. (2015). Exercise with blood flow restriction: An updated evidenced-based approach for enhanced muscular development. *Sports Medicine, 45*(3), 313-325. https://doi.org/10.1007/s40279-014-0288-1

Sieljacks, P., Degn, R., Hollaender, K., Wernbom, M., & Vissing, K. (2019). Non-failure blood flow restricted exercise induces similar muscle adaptations and less discomfort than

failure protocols. *Scandinavian Journal of Medicine and Science in Sport, 29*(3), 336-347. https://doi.org/10.1111/sms.13346

Sieljacks, P., Knudson, L., Wernbom, M., & Vissing, K. (2018). Body position influences arterial occlusion pressure:Implications for standardization of pressure during blood flow restricted exercise. *European Journal of Applied Physiology, 118*, 303-312. https://doi.org/10.1007/s00421-017-3770-2

Sieljacks, P., Matzon, A., Wernbom, M., Ringgaard, S., Vissing, K., & Overgaard, K. (2016). Muscle damage and repeated bout effect following blood flow restricted exercise. *European Journal of Applied Physiology, 116*(3), 513-525. https://doi.org/10.1007/s00421-015-3304-8\

Silva, J., Neto, G. R., Freitas, E., Neto, E., Batista, G., Torres, M., & Sousa, M. D. S. (2015). Chronic effect of strength training with blood flow restriction on muscular strength among women with osteoporosis. *Journal of Exercise Physiology Online 18*(4), 33-41. ISSN: 1097-9

Slysz, J., Stultz, J., & Burr, J. F. (2016). The efficacy of blood flow restricted exercise: A systematic review and meta-analysis. *Journal of Science and Medicine in Sport, 19*(8), 669-675. https://doi.org/10.1016/j.jsams.2015.09.005

Smith, S. M. (n.d.). Determining sample size: How to ensure you get the correct sample size. Qualtrics. https://uncw.edu/irp/ie/resources/documents/qualtrics/determining-sample-size-2.pdf

Soligon, S. D., Lixandrão, M. E., Biazon, T. M. P. C., Angleri, V., Roschel, H., & Libardi, C. A. (2018). Lower occlusion pressure during resistance exercise with blood-flow restriction promotes lower pain and perception of exercise compared to higher occlusion pressure

when the total training volume is equalized. *Physiology International, 105*(3), 276-284. https://doi.org/10.1556/2060.105.2018.3.18

Tabata, S., Suzuki, Y., Azuma, K., & Matsumoto, H. (2016). Rhabdomyolysis after performing blood flow restriction training: A case report. *The Journal of Strength and Conditioning Research. 30*(7), 2064-2068. https://doi.org/10.1519/JSC.0000000000001295

Teixeira, E. L., Painelli, V. dS., Scoenfeld, B. J., Silva-Batista, C., Longo, A. R., Aihara, A. Y., Cardos, F. N., Peres, B. dA., & Tricoli, V. (2020). Perceptual and neuromuscular responses adapt similarly between high load resistance training and low load resistance training with blood flow restriction. *Journal of Strength and Conditioning, 0*(00), 1-7. https://doi.org/10.1519/JSC.0000000000003879

U.S. Food and Drug Administration. (2020a). *Electronic code of federal regulations*. https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=4eaa752058f2df963cb395dbd8a65d81&mc=true&n=pt21.8.878&r=PART&ty=HTML#se21.8.878_19

U.S. Food and Drug Administration. (2020b). *Product description*. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=840

Wilk, M., Krzysztofik, M., Gepfert, M., Poprzecki, S., Golas, A., & Maszczyk, A. (2018). Technical and training related aspects of resistance training using blood flow restriction in competitive sport-A review. *Journal of Human Kinetics, 65*(1), 249-260, https://doi.org/10.2478/hukin-2018-0101

Wilson, J. M., Lowery, R. P., Joy, J. M., Loenneke, J. P. & Naimo, M. A. (2013). Practical blood flow restriction training increases acute determinants of hypertrophy without increasing indices of muscle damage. *Journal of Strength and Conditioning Research, 27*(11), 3068-3075. https://doi.org/10.1519/JSC.0b013e31828a1ffa

Yan, Z., Aicui, L., Andong, C., & Beibei, L. (2018). Effect of cardiovascular function to resistance exercise training with blood flow restriction. *Annals of Physical and Rehabilitation Medicine, 61*(Supplement), e275 https://doi.org/10.1016/j.rehab.2018.05.640

Yasuda, T., Loenneke, J. P., Ogasawara, R., & Abe, T. (2013). Influence of continuous or intermittent blood flow restriction on muscle activation during low-intensity multiple sets of resistance exercise. *Acta Physiologica Hungarica, 100*(4), 419-426.

Yasuda, T., Meguro, M., Sato, Y., & Nakajima, T. (2017). Use and safety of KAATSU training: Results of a national survey in 2016. *International Journal of KAATSU Training Research, 13*(1), 1-9. https://doi.org/10.3806/ijktr.13.1

Zeng, Z., Centner, C., Gollhofer, A., & König, D. (2019). Blood-flow restriction training: Validity of pulse oximeter to assess arterial occlusion pressure. *International Journal of Sports Physiology and Performance*, *14*(10), 1408-1414. https://doi.org/10.1123/ijspp.2019-0043

Table 1

Previously and Currently Used Devices as Indicated by Respondents

Type of device	Previously used	Currently used	Currently used devices identified
Elastic tourniquet device	n=21	n=9	3M (n=1) BFR Bands (n=1) Generic brand (n=1) HMKL (n=1) Koala Bands (n=1) Konmed/OBM (n=1) Defi PTS-PBFR (n=1)
Inflatable device	n=47	n=43	Air Bands (n=4) Mad-Up (n=2) Occlusion Cuffs (n=1) Edge Rehab Cuffs (n=2) Smart Cuffs (n=10) B Strong (n=7) Defi PTS-PBFR (n=16) Fitcuffs (n=2) H+ Cuffs (n=2) BFR Signature Series (n=1) BFR Occlude (n=1) Throwraft original TD 2401 (Note: this is a personal floatation device) (n=1) VALD (n=2) Unknown name (n=2)
KAATSU training device	n=11	n=9	Air Cuffs (n=1) Dumbbell pressure exercise (n=1) Inflatable Cuffs (n=1) KAASTU Cycle Pro (n=1) Nano (n=2)
Knee wraps	n=11	n=2	LP Sports Protector (n=1)
Other	n=8 BFR Bands (n=1) KELVI BFR (n=1) RockCuff (n=1) DELFI-PTS-PBFR (n=5)	n=7	Ace bandages (n=1) Delfi PTS-PBFR (n=3) KELVI (n=1) Rock Cuff (n=1)

Table 2

Demographics

Demographics of respondents	
Gender	Male (n=41)
	Female (n=29)
Age (in years)	18-30 (n=36)
	31-40 (n=27)
	41-50 (n=5)
	51-60 (n=1)
	61 and older (n=1)
Ethnicity	White (n=57)
	Black, African American (n=3)
	Asian (n=1)
	White/Black, African American (n=1)
	American Indian or Alaskan Native (n=4)
	Asian/Native Hawaiian or Pacific Islander (n=1)
	Hispanic or Latino/a (n=1)
	White/Hispanic or Latino/a (n=1)
	All race (n=1)
Location	Northeast (n=11)
	Southeast (n=17)
	Midwest (n=27)
	West (n=7)
	Southwest (n=7)
	Unanswered (n=1)

Profession	Athletic Training (n=33)	
	Personal Training (n=6)	
	Physical Therapy (n=19)	
	Physical Therapy Aide (n=3)	
	Strength and Conditioning (n=20)	
	Other	
		Athletic Training Student (n=1)
		Lecturer of Exercise Science (n=1)
		Occupational Therapy (n=1)
		Semi-retired Consultant (n=1)
Years in Profession	1-10 years (n=50)	
	11-20 years (n=18)	
	21-30 years (n=1)	
	31 or more years (n=1)	

Table 3

Exercise Employed with BFR/KAATSU Training

Types of exercises used with BFR/KAATSU training	Number of respondents using this form of exercise (n=)
Single Joint Exercise	51
Single Joint Machine Based Exercise	37
Single Joint Free Weight Exercise	47
Multi Joint Exercise	57
Multi Joint Machine Based Exercise	32
Multi Joint Free Weight Exercise	49
Cycling	29
Walking	15
Jogging	10
Swimming	4
Rowing	1
Other	1
Recumbent stepper	
Sport Specific	

Table 4

Adverse Reactions Described by Respondents

Described demographics	Adverse Outcome	Other noted factors	Device used	Screening procedure
Elderly Age: 70's	Bruising, petechiae		Not enough info to determine device used; several devices indicated for current use	Waiver/Release and medical screening
Bodybuilding athlete Age: 40's	Bruising, petechiae		Not enough info to determine device used; several devices indicated for current use	Waiver/Release and medical screening
Male Age: 18-25	Giddy		Not enough info to determine device used; several devices indicated for current use	Medical screening
Caucasian female Age: 18-21	Lightheaded, increased body temperature		KELVI	Medical Screening
Athlete Age: college	Dizzy, lightheaded	Did not eat prior	Ace Bandage	No Screening
Caucasian female Age: mid 60's	Elevated heart rate, sweating, shortness of breath		Smart Cuffs	Waiver/Release and medical screening
Male Age: 40's	Increased pain with cuff occlusion		Delfi PTS-PBFR	Consent, ask contraindications
Unknown	Lightheadedness, muscle cramping		Delfi PTS-PBFR	Waiver/Release and medical screening
Hispanic Female Age: 21	Nausea, vomiting		Delfi PTS-PBFR	Waiver/Release and medical screening
Athletes High school, college Varied gender and race	Moderate cramping, lightheadedness, or did not tolerate sensation		Delfi PTS-PBFR	ORS specified

Table 5

Reasons Respondents Discontinued BFR/KAATSU Training

Non safety related	Safety related	Other
Heavy load strength training is able to be performed consistently	Client was found to have developed a blood clot issue	Dangerous actions for people with poor health
It is used with our Physical Therapists and Sports Medicine Staffs in our settings. We have not incorporated in team/individual training, only utilize for personal use.	Discomfort, Fatigue Some tired, occasionally need a short rest	Over time, a blood clot can develop that can lead to a fatal pulmonary embolism
I want to do it another way	Discomfort, had a patient who had fear of blood pressure cuffs but never told therapist, increased paraesthesia in the limb	
Money	Excessive pain, discomfort, or noticeable swelling Pain due to too much restriction	
N/A	Exercise pursor [sic] reflex symptoms	
Progression to higher intensities due to rehab progress	Extreme discomfort and loss of touch sensation	
Time restrictions	Failure or too uncomfortable for patient	
Time under pressure was reached	Feeling much discomfort while exercising. Only use for 10-15 min.	
Wasn't anything special	If athlete complains of severe and unusual discomfort.	
When the patient reaches 15-20 minutes time of BFR cuff placed on leg or arm	If the person cannot handle the pressure or repeatedly cannot hit target range	
Work reasons	Improper operation caused by bump	
	Patient discomfort	
	Patient discomfort, significant DOMS	
	Perceived exertion gets too high or significant fatigue or muscle failure	
	Prescreen, but if I find later that the person has a history of clotting I will discontinue	
	Unable to tolerate the cuff, fatigue, inability to complete repetition range without severe compensatory patterns of movement	
	Vomiting, lightheadedness	

Table 6

Actual Device Type

Type of device	Device name
Tourniquet device	Delfi PTS-PBFR
Inflatable device	AirBands BFR Bands-Signature Series B Strong Fit Cuffs H+ Cuffs MAD- UP Occlusion Cuff Smart Cuffs The EDGE Restriction Systems VALD
KAATSU Training device	KAATSU Cycle 2.0 KAATSU Nano
Wraps	BFR Bands Koala Bands Rock Cuff
Other	3M ACE bandage Conmed/OBM HMKL KELVI (Cryo/Thermotherapy Device) LP Sports Protector Throwraft Original TD2401 (Personal Flotation Device)

Appendix A

Changes Made to Survey Following Survey Test Pilot

Previous Question	Revised Question
A. Are you 18 years or older? ● Yes ● No	Deleted
B. Are you currently or have (in the past) used blood flow restriction/KAATSU Training in patient, client care? ● I am currently using blood flow restriction/KAATSU Training in patient, client care. ● I have previously used blood flow restriction/KAATSU Training in patient, client care. Please indicate why blood flow restriction/KAATSU training is no longer being used by you for patient, client care. ● I am not currently using blood flow restriction/KAATSU training.	Deleted
C. Have you either previously or are you currently using blood flow restriction/KAATSU training for strength training, aerobic exercise, or rehabilitative purposes? ● Yes ● No	Deleted

D. What device are you currently using to apply restriction?	What device are you currently using to apply restriction?
● Elastic tourniquet. Please identify brand/style of device. ● Inflatable device. Please identify brand/style of device. ● KAATSU training device. Please identify brand/style of device. ● Knee wraps. Please identify brand/style of device. ● Other-please identify. ● I am not currently using blood flow restriction/KAATSU training.	● Elastic tourniquet. Please identify brand/style of device. ● Inflatable device. Please identify brand/style of device. ● KAATSU training device. Please identify brand/style of device. ● Knee wraps. Please identify brand/style of device. ● Other-please identify. ● I do not know what type of device I am using to apply restriction. Please identify brand/style of device. ● I am not currently using blood flow restriction/KAATSU training. Please indicate why blood flow restriction/KAATSU training is no longer being used by you for patient, client, or athlete care.
E. Which body parts are you applying strength training exercises with blood flow restriction/KAATSU training?	Which body parts are you applying exercise with blood flow restriction/KAATSU training?
F. On average, how often will you have a patient/client completing exercises with blood flow restriction/KAATSU training?	On average, how often will you have a patient/client/athlete complete exercises with blood flow restriction/KAATSU training?

G. What position is the patient/client when initially taking personalize restrictive pressure?	What position is the patient/client/athlete when initially taking personalize restrictive pressure?
H. If you determine personalized restrictive pressure, do you always take restrictive pressure in supine for any subsequent exercise (ie. Straight leg raise, seated leg extensions, squats) • Yes • No • Not applicable	Do you use the ${position restr pr/ChoiceGroup/SelectedChoices} position to determine restrictive pressure for subsequent exercises which vary in position (ie. supine straight leg raise, seated leg extensions, squats)? • Yes, I repeat the same method to determine restrictive pressure on subsequent exercises regardless of exercise position • No, I use different methods to determine restrictive pressure on subsequent exercises which vary in exercise position • I do not retake personalized restrictive pressure on subsequent exercises
I. Generally, how long is the device providing restriction to a patient/client completing strength training exercises?	Generally, how long is the device providing restriction to a patient/client/athlete completing exercise?
J. What systematic screening process is used to determine eligibility of blood flow restriction/KAATSU training in patients/clients?	What systematic screening process is used to determine eligibility of blood flow restriction/KAATSU training in patients/clients/athletes?

K. Do you consider the psychosocial aspects surrounding the application of blood flow restriction/KAATSU training (eg. attitude/beliefs about exercise, the degree of exercise-induced discomfort, patient/client adherence) when determining its use with a patient/client?	Do you consider the psychosocial aspects surrounding the application of blood flow restriction/KAATSU training (eg. attitude/beliefs about exercise, the degree of exercise-induced discomfort, patient/client/athlete adherence) when determining its use with a patient/client/athlete?
L. How much supervision is provided when a patient/client is completing exercise with blood flow restriction/KAATSU training? ● Patient/client performing exercises with blood flow restriction/KAATSU training has no supervision for the duration of blood flow restriction/KAATSU training use ● Patient/client performing exercises with blood flow restriction/KAATSU training has some supervision for the duration of blood flow restriction/KAATSU training use ● Patient/client performing exercises with blood flow restriction/KAATSU training is directly supervised for the duration of blood flow restriction/KAATSU training use	How much supervision is provided when a patient/client/athlete is completing exercise with blood flow restriction/KAATSU training? ● Patient/client/athlete performing exercises with blood flow restriction/KAATSU training has no supervision for the duration of blood flow restriction/KAATSU training use ● Patient/client/athlete performing exercises with blood flow restriction/KAATSU training has some supervision for the duration of blood flow restriction/KAATSU training use ● Patient/client/athlete performing exercises with blood flow restriction/KAATSU training is directly supervised for the duration of blood flow restriction/KAATSU training use
M. Identify the genders of the patients/clients completing exercise with blood flow restriction/KAATSU training? (please select all that apply)	Identify the genders of the patients/clients/athletes completing exercise with blood flow restriction/KAATSU training? (please select all that apply)

N. What were the ethnicities (races) of the patients/clients completing exercise with blood flow restriction/KAATSU training? (Select all that apply)

- White
- Black or African American
- American Indian or Alaskan Native
- Hispanic or Latino/a
- Asian
- Native Hawaiian or Pacific Islander
- Multiple Races
- Other-Please identify

What were the ethnicities (races) of the patients/clients/athletes completing exercise with blood flow restriction/KAATSU training? (Select all that apply)

- White
- Black or African American
- American Indian or Alaskan Native
- Hispanic or Latino/a
- Asian
- Native Hawaiian or Pacific Islander
- Other-Please identify

O. What were the age groups of the patients/clients completing exercise with blood flow restriction/KAATSU training?

What were the age groups of the patients/clients/athletes completing exercise with blood flow restriction/KAATSU training?

Appendix B

Letter to Prospective Subject Groups

Hello,

I am currently working on my doctoral degree through the University of Indianapolis pursuing a Doctor of Health Sciences degree. For my doctoral project I am hoping to explore how health professionals are using various blood flow restriction devices through the use of survey research. Once the project has been approved through the institutional review process, can I post the survey within your respective social media platform?

Thank you.

Sincerely,

Molly Cuffe MA, ATC, LAT

Appendix C

Hello!

For Facebook Groups: I have received permission to post by (Insert name).
For Email Group: Permission from the Collegiate Strength and Conditioning Coaches Association has been granted for this email

My name is Molly Cuffe. I am an athletic trainer and currently a doctoral student at the University of Indianapolis pursuing a Doctor of Health Sciences degree. For my doctoral research project-Current Trends in Blood Flow Restriction- I am hoping to explore how health professionals are using various blood flow restriction devices using survey research. If you currently or have previously used any form of blood flow restriction device, you are invited to participate in the survey research using the link below. Participation in the research will take approximately 13 minutes. The link will be active from midnight on March 22, 2021 to midnight April 21, 2021. After participating in the survey research, you will have the opportunity to enter a drawing for one of five $10 gift cards.

This research has been approved as exempt status by the University of Indianapolis Institutional Review Board (IRB). Date of approval: 03/12/2021 Study number: 01390.

Thank you!

https://uindy.co1.qualtrics.com/jfe/form/SV_9oYpHk0qHKWbtGd

Appendix D

Informed Consent

CONSENT TO PARTICIPATE IN RESEARCH STUDY

Current Trends in Blood Flow Restriction

Study Principal Investigator (PI): Emily Slaven

Co-Investigator: Molly Cuffe

UIndy Email: slavene@uindy.edu

UIndy Telephone: 317-788-3305 or 800-232-8634 X3305

This research is being done by Molly Cuffe, an athletic trainer and a student in the Interprofessional Health and Aging Studies: Doctor of Health Sciences Program at the University of Indianapolis. The study is to fulfil the requirements of a doctoral project through the University of Indianapolis. The Doctoral Committee Chair is Emily Slaven, PT, PhD Associate Professor at the University of Indianapolis.

Why is this study being done?

The purpose of this study is to explore how individuals across different professions are administering and using various forms of blood flow restriction (BFR)/KAATSU training devices in the United States of America. In addition, this study seeks to explore the safety concerns seen by individuals of different professions administering BFR/KAATSU training devices with various devices.

- Inclusions:

  To be included in the study, participants must meet the following criteria: (a) English speaking, (b) older than 18 years old, and (c) use BFR/KAATSU training devices for aerobic exercise, resistance exercise, or rehabilitation purposes in the United States.

- Exclusions:

  The following exclusion criterion exists: (a) BFR/KAATSU training is not being used with patients/clients/athletes.

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to do the following:

Participation in the research study is voluntary and involves the completion of the survey. The survey will ask you questions about the BFR/KAATSU training devices you have used and are using, the methods used, safety related concerns and demographic related questions. The survey can be completed on any device which the internet can be accessed.

How long will I be in the research study?

The survey will take approximately 13 minutes to complete.

Are there any potential risks or discomforts that I can expect from this study?

Risks associated with participation in the survey can include mental stress from recalling past experiences with BFR/KAATSU training devices. Compensation for adverse effects will not be provided by the researcher.

Are there any potential benefits if I participate?

Completing the study may increase one's knowledge of the research process.

What other choices do I have if I do not wish to participate?

Your participation is voluntary. If you decide not to participate, to withdraw yourself at any point during completion of the survey, or withdraw your data following the completion of the survey, you may do so without penalty. To withdraw from the study, please close out of the survey.

Will I be paid for participating?

At the conclusion of the survey you will have the opportunity to enter your email address into a drawing for the chance to win one of five $10 gift cards.

Will information about me and my participation be kept confidential?

The results of this study may be published in a scholarly book or journal, presented at professional conferences or used for teaching purposes. However, only aggregate data will be used. Personal identifiers will not be used in any publication, presentation or teaching materials.

All information collected in this survey will be anonymous. I will not record your name in this survey. De-identified data from this survey will be transferred to a statistical analysis platform. Furthermore, this survey is web based. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

Will the data from my study be used in the future for other studies?

It is possible that de-identified data from this study could be used for future research or shared with other researchers for use in studies, without additional informed consent. De-identified means that any codes and personal information that could identify you will be removed before the data is shared.

What are my rights if I take part in this study?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any question/s that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

- The Research Team:

  If you have any questions, comments, or concerns about the research, you can talk to one of the researchers. Please contact:

  Emily Slaven, PT, PhD Associate Professor at the University of Indianapolis at 317-788-3305 or 800-232-8634 X3305 or via email at slavene@uindy.edu.

  The Director of the Human Research Protections Program (HRPP):

  If you have questions about your rights as a research participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact

the Director of the Human Research Protections Program, by either emailing hrpp@uindy.edu or calling 1 (317) 781-5774 or 1 (800) 232-8634 ext. 5774.

How do I indicate my informed consent to participate in this study?

If you consent to participate in this study, then you affirm that you satisfy the inclusion criteria, and your consent is voluntary. To indicate your voluntary consent and proceed with the questionnaire, select one of the following options:

I voluntarily consent to participate in this study.

I do NOT consent to participate in this study.

Appendix E

Survey

Current Use of Blood Flow Restriction

Start of Block: Proposed Consent Form

CONSENT TO PARTICIPATE IN RESEARCH STUDY

Current Trends in Blood Flow Restriction

Study Principal Investigator (PI): Emily Slaven
Co-Investigator: Molly Cuffe
UIndy Email: slavene@uindy.edu
UIndy Telephone: 317-788-3305 or 800-232-8634 X3305

This research is being done by Molly Cuffe, an athletic trainer and a student in the Interprofessional Health and Aging Studies: Doctor of Health Sciences Program at the University of Indianapolis. The study is to fulfil the requirements of a doctoral project through the University of Indianapolis. The Doctoral Committee Chair is Emily Slaven, PT, PhD Associate Professor at the University of Indianapolis.

Why is this study being done?
The purpose of this study is to explore how individuals across different professions are administering and using various forms of blood flow restriction (BFR)/KAATSU training devices in the United States of America. In addition, this study seeks to explore the safety concerns seen by individuals of different professions administering BFR/KAATSU training devices with various devices.

· Inclusions:

To be included in the study, participants

must meet the following criteria: (a) English speaking, (b) older than 18 years

old, and (c) use BFR/KAATSU training devices for aerobic exercise, resistance exercise, or rehabilitation purposes in the United States.

·Exclusions:

The following exclusion criterion exists:
(a) BFR/KAATSU training is not being used with patients/clients/athletes.

What will happen if I take part in this research study?
If you volunteer to participate in this study, the researcher will ask you to do the following:

Participation in the research study is voluntary and involves the completion of the survey. The survey will ask you questions about the BFR/KAATSU training devices you have used and are using, the methods used, safety related concerns and demographic related questions. The survey can be completed on any device which the internet can be accessed.

How long will I be in the research study?
The survey will take approximately 13 minutes to complete.

Are there any potential risks or discomforts that I can expect from this study?
Risks associated with participation in the survey can include mental stress from recalling past experiences with BFR/KAATSU training devices. Compensation for adverse effects will not be provided by the researcher.

Are there any potential benefits if I participate?
Completing the study may increase one's knowledge of the research process.
What other choices do I have if I do not wish to participate?
Your participation is voluntary. If you decide not to participate, to withdraw yourself at any point during completion of the survey, or withdraw your data following the completion of the survey, you may do so without penalty. To withdraw from the study, please close out of the survey.

Will I be paid for participating?
At the conclusion of the survey you will have the opportunity to enter your email address into a drawing for the chance to win one of five $10 gift cards.

Will information about me and my participation be kept confidential?
The results of this study may be published in a scholarly book or journal, presented at professional conferences or used for teaching purposes. However, only aggregate data will be used. Personal identifiers will not be used in any publication, presentation or teaching materials.

All information collected in this survey will be anonymous. I will not record your name in this survey. De-identified data from this survey will be transferred to a statistical analysis platform. Furthermore, this survey is web based. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

Will the data from my study be used in the future for other studies?
It is possible that de-identified data from this study could be used for future research or shared with other researchers for use in studies, without additional informed consent. De-identified means that any codes and personal information that could identify you will be removed before the data is shared.

What are my rights if I take part in this study?
· You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
· Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
· You may refuse to answer any question/s that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?
· The Research Team:
If you have any questions, comments or concerns about the research, you can talk to one of the researchers. Please contact:
Emily Slaven, PT, PhD Associate Professor at the University of Indianapolis at 317-788-3305 or 800-232-8634 X3305 or via email at slavene@uindy.edu.

· The Director of the Human Research Protections Program (HRPP):
If you have questions about your rights as a research participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the Director of the Human Research Protections Program, by either emailing hrpp@uindy.edu or calling 1 (317) 781-5774 or 1 (800) 232-8634 ext. 5774.

How do I indicate my informed consent to participate in this study?
If you consent to participate in this study, then you affirm that you satisfy the inclusion criteria and your consent is voluntary. To indicate your voluntary consent and proceed with the questionnaire, select one of the following options:

I voluntarily consent to participate in this study.

I do NOT consent to participate in this study.

Skip To: End of Block If Informed Consent: Please review the following prior to starting the survey. Identification of R... = I voluntary consent to participate in this study.

Skip To: End of Survey If Informed Consent: Please review the following prior to starting the survey. Identification of R... = I do NOT consent to participate in this study

End of Block: Proposed Consent Form

Start of Block: Product Use

Product Use: The following set of questions relate to the blood flow restriction/KAATSU training products which you have or are currently using.

Which of the following types of devices have you used previously to apply restriction? (please select all that apply.)

- ▢ Elastic tourniquet (1)
- ▢ Inflatable device (2)
- ▢ KAATSU training device (3)
- ▢ Knee wraps (4)
- ▢ Other-Please specify (5) _____

What device are you currently using to apply restriction?

- o Elastic tourniquet. Please identify brand/style of device. (1) _____
- o Inflatable device. Please identify brand/style of device. (2) _____
- o KAATSU training device. Please identify style of device. (3) _____
- o Knee wraps. Please identify brand/style of wrap. (4) _____
- o Other- Please specify (5) _____
- o I do know what type of device I am using to apply restriction. Please identify brand/style of device. (7) _____

- o I am not currently using blood flow restriction/KAATSU training. Please indicate why blood flow restriction/KAATSU training is no longer being used by you for patient, client, or athlete care. (6) _____

Skip To: End of Survey If What device are you currently using to apply restriction? = I am not currently using blood flow restriction/KAATSU training. Please indicate why blood flow restriction/KAATSU training is no longer being used by you for patient, client, or athlete care.

Years device used Please answer all remaining questions as they apply to the device you are currently using.

How many years have you used this device?

- o 0-1 years (1)
- o 2-5 years (2)
- o 6-10 years (3)
- o 11-15 years (4)
- o 16-20 years (5)
- o 20+ years (6)

For what reasons are you using this device? (please select all that apply)

- ▢ Strength training (1)
- ▢ Rehabilitation (2)
- ▢ Aerobic training (3)
- ▢ Other-Please specify (4) _____

What training did you complete prior to utilizing this blood flow restriction/KAATSU training device? (please select all that apply).

- ▢ Self educated (1)
- ▢ Formal course work (2)

Display This Question:

If What training did you complete prior to utilizing this blood flow restriction/KAATSU training dev... = Formal course work

In the formal course work you received, was the education paired with promoting a specific device?

- o Yes (1)
- o No (2)

Display This Question:

If In the formal course work you received, was the education paired with promoting a specific device... = Yes

Do you feel that the education you received was tailored towards the use of that device?

- o Yes (1)
- o No (2)

Do you believe there should be formal education on blood flow restriction/KAATSU training before being allowed to use it with patients/clients/athletes?

- o Yes (4)
- o No (5)
- o No opinion (6)

Did you face any barriers implementing blood flow restriction/KAATSU training into practice?

- o Yes (1)
- o No (2)

Display This Question:

If Did you face any barriers implementing blood flow restriction/KAATSU training into practice? = Yes

What barriers did you face when integrating blood flow restriction/KAATSU training into practice? (please select all that apply)

- ▢ Lack of training (1)
- ▢ Equipment cost (2)
- ▢ Doubts of effectiveness (3)
- ▢ Lack of clinical efficacy (4)

- ▢ Other-Please explain (5) _____

End of Block: Product Use

Start of Block: Current Use

Current Uses: The following set of questions relate to your current use of blood flow restriction/KAATSU training.

Which body parts are you applying exercise with blood flow restriction/KAATSU training?

- o Upper Extremity (1)
- o Lower Extremity (2)
- o Both Upper and Lower Extremity (3)

Which types of exercises are being performed with blood flow restriction/KAATSU training? (please select all that apply)

- ▢ Single joint exercise (1)
- ▢ Single joint machine based exercise (2)
- ▢ Single joint free weight based exercise (3)
- ▢ Multi joint exercise (4)
- ▢ Multi joint machine based exercise (5)
- ▢ Multi joint free weight based exercise (6)
- ▢ Cycling (7)
- ▢ Jogging (8)
- ▢ Swimming (9)
- ▢ Rowing (10)
- ▢ Walking (11)
- ▢ Other types of exercise-Please specify (12)

_____

On average, how often will you have a patient/client/athlete complete exercises with blood flow restriction/KAATSU training?

- o 1-2 sessions per week (1)
- o 3-4 sessions per week (2)

- o 5-6 sessions per week (3)
- o 7+ sessions per week (4)

What method are you using to determine the restrictive pressure of your blood flow restriction/KAATSU training device?

- o Comfort (ie “7/10” perceived tightness) (1)
- o Limb circumference (2)
- o Standard blood pressure (3)
- o Doppler ultrasound (4)
- o The device is set to determine restrictive pressure (5)
- o Other-Please specify (6) _____

What position is the patient/client/athlete when initially taking personalize restrictive pressure?

- o Supine (1)
- o Seated (2)
- o Standing (3)
- o Exercise dependent (4)

Do you use the ${position restr pr/ChoiceGroup/SelectedChoices} position to determine restrictive pressure for subsequent exercises which vary in position (ie. supine straight leg raise, seated leg extensions, squats)?

- o Yes, I repeat the same method to determine restrictive pressure on subsequent exercises regardless of exercise position (1)
- o No, I use different methods to determine restrictive pressure on subsequent exercises which vary in exercise position (3)
- o I do not retake personalized restrictive pressure on subsequent exercises (2)

Do you feel that personalizing the pressure to the individual reduces the risk of adverse events during blood flow restriction/KAATSU training exercise?

- o Yes (4)
- o No (5)

When applying blood flow restriction/KAATSU training what are you using to consider work load?

- o Heart rate (1)
- o Percentage of 1 RM (2)
- o Length of time under tension/load (3)
- o Work to failure (4)
- o Other-Please describe (5) _____

Generally, how long is the device providing restriction to a patient/client/athlete completing exercise?

- o The device provides restriction for the duration of the workout (1)
- o The device is loosened or released between exercises (continuous application) (2)
- o The device is loosened or released between sets of an exercise (intermittent application) (3)
- o Other-Please describe (4) _____

End of Block: Current Use

Start of Block: Safety

The following set of questions relate to safety during blood flow restriction/KAATSU training with your current device.

What systematic screening process is used to determine eligibility of blood flow restriction/KAATSU training in patients/clients/athletes?

- o Waiver/Release forms (4)
- o Medical screening forms including risk assessments and or in person physical examinations (5)
- o Both waiver/release forms and medical screening forms including risk assessments and or in person physical examinations (8)
- o Other-Please describe systemic screening process being used. (6)

_____

- o No screening process is used to determine eligibility. Please explain the reason for no screening process. (7) _____

Do you consider the psychosocial aspects surrounding the application of blood flow restriction/KAATSU training (eg. attitude/beliefs about exercise, the degree of exercise-induced

discomfort, patient/client/athlete adherence) when determining its use with a patient/client/athlete?

- o Yes (4)
- o No (5)

How much supervision is provided when a patient/client/athlete is completing exercise with blood flow restriction/KAATSU training?

- o Patient/client/athlete performing exercises with blood flow restriction/KAATSU training has no supervision for the duration of blood flow restriction/KAATSU training use (1)
- o Patient/client/athlete performing exercises with blood flow restriction/KAATSU training has some supervision for the duration of blood flow restriction/KAATSU training use (2)
- o Patient/client/athlete performing exercises with blood flow restriction/KAATSU training is directly supervised for the duration of blood flow restriction/KAATSU training use (3)

Have you performed blood flow restriction/KAATSU training in individuals with medical comorbidities (ie diabetes, hypertension, obesity etc)?

- o Yes-Please indicated comorbidities seen. (1)

_____

- o No (2)

Have you seen any adverse effects in patients/clients/athletes either during a session or following a session using your current device?

- o Yes (1)
- o No (2)

Display This Question:

If Have you seen any adverse effects in patients/clients/athletes either during a session or followi... = Yes

What adverse effects have you seen in patients/clients/athletes completing exercise with restricted blood flow, either during a session or following a session using your current device? (If possible please include gender, race, approximate age range, and adverse effect).

_____

_____

_____

_____

_____

For what reasons have you discontinued use of exercise with blood flow restriction/KAATSU training while exercise is being performed?

_____

_____

_____

_____

_____

End of Block: Safety

Start of Block: Demographics of patients, clients, and athletes

Patient/Client/Athlete Demographics: The following questions relate to the demographics of the patients/clients/athletes for which blood flow restriction/KAATSU training has been applied.

Identify the genders of the patients/clients/athletes completing exercise with blood flow restriction/KAATSU training? (please select all that apply)

- ▢ Male (1)
- ▢ Female (2)
- ▢ Gender Nonconforming (3)
- ▢ Transgender (4)
- ▢ Unknown (5)
- ▢ Other-Please identify (6) _____

What were the ethnicities (races) of the patients/clients/athletes completing exercise with blood flow restriction/KAATSU training? (Select all that apply)

- ▢ White (1)
- ▢ Black or African American (2)
- ▢ American Indian or Alaskan Native (3)
- ▢ Hispanic or Latino/a (4)
- ▢ Asian (5)
- ▢ Native Hawaiian or Pacific Islander (6)
- ▢ Other-Please identify (8) _____

What were the age groups of the patients/clients/athletes completing exercise with blood flow restriction/KAATSU training?

- ▢ <21 years old(1)
- ▢ 21-30 years old (2)
- ▢ 31-40 years old (3)
- ▢ 41-50 years old (4)
- ▢ 51-60 years old (5)
- ▢ 61+ years old (6)

End of Block: Demographics of patients, clients and athletes

Start of Block: Demographics

Your Demographics: The following questions relate to your demographics.

Please select the gender you identify.

- o Male (1)
- o Female (2)
- o Gender Nonconforming (3)
- o Transgender (4)
- o Other-Please identify (5) _____

Please select your age group.

- o 18-30 years old (1)
- o 31-40 years old (2)
- o 41-50 years old (3)
- o 51-60 years old (4)
- o 61+ years old (5)

Please identify your ethnicity (race). Select all that apply

- ▢ White (1)
- ▢ Black or African American (2)
- ▢ American Indian or Alaska Native (3)
- ▢ Asian (4)
- ▢ Native Hawaiian or Pacific Islander (5)
- ▢ Hispanic or Latino/a (6)
- ▢ Other-Please identify (7) _____

Which region of the United States do you currently reside?

- o Northeast (1)
- o Southeast (2)
- o Midwest (3)
- o West (4)
- o Northwest (5)
- o Southwest (6)

What is your current profession? (Select all that apply)

- ▢ Athletic Trainer (41)
- ▢ Chiropractor (42)
- ▢ Physical Therapist (43)
- ▢ Physical Therapist Assistant (48)
- ▢ Personal Trainer (44)
- ▢ Strength and Conditioning Specialist (45)
- ▢ Other-Please identify (47) _____

How many years have you been in your current profession?

- o 0-10 years (1)
- o 11-20 years (2)
- o 21-30 years (3)
- o 31+ years (4)

End of Block: Demographics

Survey Termination:

Redirect to a full URL, ex. "https://www.qualtrics.com" : https://uindy.co1.qualtrics.com/jfe/form/SV_1ZYlv7HDWDEt4pv

Survey Drawing

Start of Block: Default Question Block

Q1 Thank you for completing the survey titled Current Trends in Blood Flow Restriction. If you would like to be entered to win one of five $10 gift cards, please provide your email address in the box below. Winners will be notified within one week of the conclusion of the survey. If you do not wish to be entered for a chance to win a gift card, please close out of the survey at this time. Thank you again!

_____

End of Block: Default Question Block

Appendix F

Gift Card Entry

Thank you for completing the survey titled Current Trends in Blood Flow Restriction. If you would like to be entered to win one of five $10 gift cards, please provide your email address in the box below. Winners will be notified within one week of the conclusion of the survey. If you do not wish to be entered for a chance to win a gift card, please close out of the survey at this time. Thank you again!