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Implementation Evaluation of Blood Flow Restriction in the Clinical Setting

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By

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DEDICATION

While God has blessed me by giving me an overwhelmingly long list of supporters to whom I could dedicate this body of work, there is only one person whose love for research stands out above the rest. This thesis is dedicated to my friend, Robert W. Spitz, because "science."

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ABSTRACT

Blood flow restriction (BFR) refers to a relatively new training/rehabilitation method consisting of a tourniquet system applied to a limb to partially inhibit blood flow to the muscles distal to the tourniquet. Though much research has been conducted concerning its use, there is little information addressing why clinicians may or may not implement it. Diffusion of Innovation (DOI) theory explains how a product or idea can spread to specific population groups, ending in adoption of it. The Consolidated Framework for Implementation Research (CFIR) consists of a set of constructs which can be used to determine the specific factors involved in the implementation of an innovation. The current study combined the principles from DOI theory and the CFIR to investigate why clinicians may or may not implement BFR in the clinical setting. To investigate this, an interview addressing twelve implementation constructs was given via teleconference to a total of 10 participants, including five athletic trainers, one occupational therapist, and four physical therapists. Transcripts from the interviews were evaluated to rate each construct as an inhibitor to implementation, neutral to implementation, or facilitative to implementation (-2, -1, 0, +1, +2). The constructs inhibitive to implementation consisted of adaptability, cost, and available resources, while the constructs facilitative of implementation consisted of evidence strength and quality, access to knowledge and information, and knowledge and beliefs about the intervention. Constructs considered neutral or relative to implementation consisted of intervention source, relative advantage, complexity, patient needs and resources, culture, and self-efficacy. An additional two constructs (external policies and incentives, and networks and communications) were noted, but not rated due to lack of investigation. The findings of this research suggest that, while a number of factors contribute to the implementation of BFR, clinicians appear to be most concerned with evidence strength and quality regarding the effectiveness of BFR across different populations, as well as the financial costs associated with BFR. While some clinicians appear to be very receptive to BFR, they may be unable to implement it due to perceived financial restrictions.

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LIST OF ABBREVIATIONS

BFR with aerobic exercise.....BFR-AE

BFR with resistance exercise.....BFR-RE

Blood flow restriction..... BFR

Consolidated Framework of Implementation Research.....CFIR

Cross-sectional area..... CSA

Cutaneous vascular conductance.....CVC

Diffusion of Innovation.....DOI

Flow-mediated dilation.....FMD

Low-load BFR..... LL-BFR

Meters per minute.....m/min

One-repetition maximum.....1-RM

Passive BFR.....P-BFR

BACKGROUND

Blood Flow Restriction

Blood flow restriction (BFR) refers to a training/ rehabilitation method involving the partial restriction of arterial inflow and full restriction of venous outflow, which can be applied alone or coupled with various exercise regimens. Typically, a medical grade tourniquet system is applied on a limb proximally and inflated or tightened to restrict blood flow in the limb. Once BFR occurs, the user can remain still or perform various low-load exercises for a short period of time before removing the tourniquet. By decreasing blood circulation in the targeted limb, tissues underneath and distal to the tourniquet system likely experience hypoxia, or partial oxygen depletion. Several studies have found that BFR, when used in acute doses, can lead to greater muscle strength (Slysz et al., 2016; Luebbers et al., 2014).

Many believe the practice of BFR originated in Japan when Dr. Yoshiaki Sato developed a system called "Kaatsu" training. Using a tourniquet system, he would restrict the blood circulation of those he trained, referring to it as "training with added pressure." The earliest experimental study done on BFR was in 1997, when Shinohara et al. sought to explore the effects of what was then termed tourniquet ischemia. Five untrained males were recruited as subjects and, for four total weeks, performed isometric contractions in both legs, one with an applied tourniquet system to induce ischemia (ischemic leg) and one without (non-ischemic leg). Throughout the study they found that the ischemic leg increased strength significantly more than its non-ischemic counterpart. Despite the limitations of the small study, these results were a breakthrough, unveiling an entirely new innovation to training.

Much research has been done to demonstrate the similar benefits of BFR when compared to standard weight training. A systematic review and meta-analysis conducted by Slysz et al. in 2016 aimed to identify which BFR training methods resulted in the greatest strength and muscle hypertrophy outcomes. The researchers pulled 47 articles for the systematic review, with 28 of those meeting inclusion criteria for the meta-analysis, where participants were male only, female only, both, and all over the age of 18 and considered healthy. They found 15 studies, with a total of 328 subjects, where results indicated that the difference in muscular strength gains between experimental (BFR) groups and control (non-BFR) groups, after following training protocols, was 0.3 kg, where the BFR groups saw a larger increase. Similarly, to speak to muscle size, researchers found 12 studies with 246 participants measuring the cross-sectional area (CSA) of the muscle after resistance exercise combined with BFR training. They found the mean increase in size for BFR groups was 0.41 cm^2, which was greater than that of the control (non-BFR) groups. From this information we can infer that, when following identical training protocols otherwise, the addition of BFR to weight training and resistance exercise can cause the muscle to increase in strength and size.

Another study done by Luebbers et al. (2014) highlighted the difference in a 7-week traditional weight training program versus the same program done with BFR in college athletes.

Sixty-two college football players were divided into four groups: three groups completed a traditional upper and lower body strength training protocol, with two of these groups completing supplemental lifting sessions. During the supplemental lifting sessions, one group used BFR and one group did not. The final group completed a modified, less intense training program, where supplemental BFR lifting sessions were included. At the beginning and end of each week, one-repetition maximum (1-RM) squat, 1-RM bench press, and upper and lower body girths were measured. Researchers found that the group completing the traditional lifting protocol in combination with supplemental BFR lifts had a significantly higher 1-RM squat than other groups. The traditional training with BFR group increased their 1-RM squat by a mean of 24.9 kg, while the traditional training with supplemental non-BFR lifting group increased their 1-RM squat by a mean of 14.1 kg. These results suggest that the addition of BFR to a traditional strength training program can cause significant increases in lower body strength compared to weight training alone.

Not only can blood flow restriction training be used in conjunction with standard weight training to produce increases in muscle size and strength in athletes, but it can also be used in less healthy and elderly populations as a way to limit muscle atrophy. A systematic review and meta-analysis conducted by Hughes et al. (2017) aimed to study the effectiveness of low-load BFR training in those participating in musculoskeletal rehabilitation. Twenty studies were used in the systematic analysis, while 13 articles were used in the meta-analysis. Across the studies, participants experienced rehabilitation for knee osteoarthritis, ligament injuries, muscular disorders, and sarcopenia due to age, as all participants were between the ages of 44 and 72 years-old. BFR was used in conjunction with low-load resistance training, elastic band resistance training, low-to-moderate intensity walking, and body weight exercises. The training load for resistance exercise always ranged from 10% to 30% of the participant's 1RM, and the intensity for aerobic and walking exercises were 45% of heart rate reserve or to 67 m/min if 45% of heart rate reserve could not be achieved. Participants engaged in the studies between 2 and 16 weeks, with between 2 to 6 training sessions weekly. The results of the meta-analysis showed that utilizing low-load resistance training with BFR was more effective than low-load resistance training alone. According to the data, 69% of the entire testing population experienced greater gains in muscular strength than those who did not use BFR. Results also indicated that low-load BFR (LL-BFR) training can be used to lessen the effects of sarcopenia, improve bone health, and be utilized as an early rehabilitation intervention in those battling muscle weakness due to immobilization. Elderly and compromised patients also seemed to view LL-BFR as more tolerable than heavy-load exercises, likely due to the low joint strain and limited stress it produces, which can make it an excellent option for those who may not be able to lift heavy loads.

Because BFR produces similar benefits expected from traditional weight training without having to apply a heavy load on the user, it is often used for rehabilitation training in clinical settings. In a study conducted by Patterson & Brandner, which was published in 2018, survey responses were obtained from 250 practitioners, with 115 total responses stating they had used BFR therapy in the past. In response to the application of BFR in a clinical setting, 32.6% said they used BFR to induce muscle hypertrophy, 24.2% said they used BFR for injury

rehabilitation, and 20.3% said they used BFR to avoid muscle atrophy following injury (Patterson & Brandner, 2018). Thus, it can be said that physical therapists and athletic trainers typically utilize BFR training to not only help healthy patients, but to help rehabilitate the injured. Typically, there are three common types of blood flow restrictive therapy: BFR with resistance exercise (BFR-RE), BFR with aerobic exercise (BFR-AE), and BFR applied alone, also known as passive blood flow restriction (P-BFR).

BFR-RE is useful for eliciting an increase in muscular hypertrophy and strength in patients/participants. A meta-analysis by Loenneke et al. in 2012 found that low intensity BFR-RE, when utilized 2-3 days per week, can maximize training adaptations in both untrained and trained subjects, when compared with traditional resistance training, leading to an increase in both muscular strength and hypertrophy. Another study conducted by Farup et al. in 2015 had 10 healthy teenagers perform 6 weeks of both BFR and non-BFR low-load arm curls on separate, randomized arms to determine whether BFR vs. low-load resistance training alone could equally promote muscle water retention and muscle hypertrophy. They found that BFR and non-BFR training, both at 40% of the participant's 1RM, performed to failure produced almost equal muscle hypertrophy (11.5% vs. 11.6%) and similar acute muscle thickness (35.4mm vs. 34.1mm), and that muscle water content remained almost the same throughout the 6-week period. However, the results were achieved with less than one-third of the exercise repetitions for BFR than for traditional low-load exercise, which suggests that BFR-RE can be more time efficient for muscle hypertrophy than standard low-load resistance training. Because BFR-RE can be more time efficient for growing muscular strength than low load resistance exercise, it can be recommended for injured or vulnerable patients who may not have the ability to utilize high load resistance exercise for training (Patterson et al., 2019). Participants in BFR-RE may only need to lift 20-40% of their 1-RM to see muscular adaptations, making the lifting load much safer for post-surgery patients or the elderly (Patterson et al., 2019).

BFR-AE is commonly used in conjunction with walking or cycling, and helps to increase strength and muscular hypertrophy (Abe et al., 2006; Abe et al., 2010). A study conducted by Abe et al., published in 2006, investigated the effects and benefits of BFR training in conjunction with a walking regimen in healthy young men. The men were split into two groups, one performing walk training with BFR and one walk training without BFR. Both groups performed walk training twice per day, six times per week, for three weeks. Each participant's leg curl and leg press 1RM were taken, their isometric strength was measured, and their muscle-bone cross-sectional area (CSA) were measured both before the start of the program and after the final training session. Upon completion, researchers found that muscle-bone CSA gradually increased over the BFR walking group by about 2% per week, but did not change in the control group. They also found that each participant's 1RM in leg press and leg curl increased by 7.4% and 8.3% in the BFR group, but did not change in the control group. Lastly, they found that the maximum isometric strength for knee extension, but not knee flexion, increased in the BFR group, while neither measurement changed for the control group. From these results, Abe et al. proposed that BFR walk training may be beneficial to those who may not tolerate high-intensity training, such as the elderly. It has also been noted that BFR-AE is typically completed at 45% of the patient's VO2 max, which means it can be utilized safely in patients who may be more

vulnerable, like geriatric populations (Patterson et al., 2019). These outcomes make BFR-AE an effective training method for muscle hypertrophy for those who may not be able to perform resistance exercises, including those who are frail or recovering.

P-BFR is typically used to slow muscular atrophy and strength loss during periods of bed rest or immobility (Patterson et al., 2019). This method can also be utilized to help patients following surgeries (such as the reconstruction of the anterior cruciate ligament) where typical losses in muscular strength may be reduced (Patterson et al., 2019). While muscular growth is not typically seen when using P-BFR, some studies have shown that it can have useful cardiovascular benefits (Patterson et al., 2019). For example, a study conducted by Jones et al. (2004) evaluated the effects of P-BFR on brachial artery endothelial function (using flow-mediated dilation (FMD)) and forearm cutaneous vascular conductance (CVC). Researchers applied BFR to 13 young, healthy males three times for a total of 20 minutes, across a period of seven days, measuring bilateral brachial artery FMD and bilateral CVC responses before and after the 7-day period, as well as eight weeks post-protocol (post+8). They found that significant improvements were made in artery endothelial function (example: FMD, % pre: 5.5 ±2.2; post: 6.1±2.2; post+8: 6.6±2.3), a higher CVC was obtained in the forearm (example: CVC, mV/mmHg pre: 0.12±0.03; post: 0.14±0.04; post+8: 0.16±0.04), and a decline in blood pressure occurred following BFR (example: Mean arterial pressure, mmHg pre: 93±5; post: 90±6; post+8: 88±7). These outcomes are significant, as improvements in endothelial function and blood pressure may prevent future cardiovascular morbidity and mortality. Cardiovascular benefits from P-BFR would be incredibly beneficial to someone experiencing a period of immobilization, due to injury or otherwise, who may not be able to maintain regular physical activity.

When compared with normal exercise, studies have shown that BFR provides a more time efficient method for similar muscular achievements. However, to date, the mechanisms of BFR are not completely understood. It is hypothesized that the reduction in arterial blood flow (hypoxia), and the occlusion of venous blood flow (fluid and metabolite build-up) causes muscle cell swelling and fatigue to occur faster when compared to normal non-BFR exercise. A study recently conducted by Haddock et al. in 2020 gathered 11 trained males to identify the acute changes in skeletal muscle after low-load non-BFR exercise, high-load non-BFR exercise, and low-load BFR exercise. The results indicated that BFR exercise induces a higher degree of cell swelling, acidification, and reduced oxygen uptake in the active muscle than non-BFR exercise, which may explain what happens in the muscle to promote hypertrophy. The findings are useful to understand what happens with BFR training that differs from non-BFR, and why the muscle can grow in similar stride without a high-load. While blood flow restriction training is less cumbersome than its non-BFR counterpart for muscular hypertrophy, it does come with a tradeoff for comfort. A study conducted by Bell et al., published in 2018, observed the acute cardiovascular and perceptual response of BFR and non-BFR low load exercise, compared to those of moderately heavy exercise. To do this, the researchers had 22 participants complete unilateral elbow flexion exercise to failure (or 90 reps) under four different loading conditions: one moderately-heavy load of 70% 1-RM with no arterial occlusion pressure (AOP) (70/0), and three low-loads of 15% 1-RM coupled with 0% (15/0), 40% (15/40), and 80% (15/80) AOP.

Before and after each bout of exercise, ratings of perceived exertion (RPE) and discomfort were taken. Researchers found that, while there were no differences across RPE and discomfort ratings pre-test, the highest ratings for both measures post-test came from low-load BFR exercise, compared to moderately heavy, non-BFR exercise. Overall, participants' ratings of discomfort were highest for BFR exercise (15/80 > 15/40 > 15/0 > 70/0), while the highest rating for RPE was given to the low-load, high pressure (15/80) exercise bout. These findings suggest that the discomfort associated with BFR exercise is higher than that associated with normal, moderately heavy exercise. Some patients/participants, when deciding whether to use BFR, may see discomfort as an inhibition, and opt for regular exercise.

Diffusion of Innovation Theory

Blood flow restriction for therapeutic exercise serves to help a number of cases in the clinical realm. Although it has been studied since 1997, it is relatively new compared to the study of traditional exercises with which it is often combined. The newness of BFR therapy and the understanding of who might use it can be related back to diffusion of innovation theory, or DOI theory. Developed by E.M. Rogers in 1962, DOI theory explains how, over time, a product or idea can spread to specific population groups, with the end result being that people accept and adopt something new. Adoption of an innovation demonstrates that the innovation was more beneficial to them than their previous way of solving the same issues. This is important, because it means that the group or system decided to give up the way they had been doing things. In a medical system, innovation does not come easily. Often, it must be used by peers, reputable, effective, and supported by substantial scientific research (Damschroder & Lowery, 2009). Because of implementation complexity, it is important to evaluate why certain groups may be drawn to certain innovations over others.

In order to understand DOI theory, one must understand the different types of adopters for the theory. There are five different types, including innovators, early adopters, early majority, late majority, and laggards. Each of the different kinds of adopters are necessary to understand how to target certain populations, and how to address their specific interests. Innovators are the first to try a new process or idea- typically, very little convincing is needed for this population to try something new (Kaminski, 2011). Early adopters are usually leaders who appreciate change and are willing to adopt it when given a manual and ideas for implementation of the innovation (Kaminski, 2011). The early majority consists of people who are willing to adopt change if given evidence that the innovation works through things like research or testimonials. While they do not accept the innovation immediately, they do not require much convincing to adopt it (LaMorte, 2019). The late majority, on the other hand, is typically resistant to change and will only adopt it after the early majority. People and systems in this category usually require proof of how many people have adopted the innovation and seen real results from using it (Kaminski, 2011). Finally, laggards consist of people who maintain strict, cookie-cutter methodology. People in this group will resist change unless pressured or persuaded by outside sources (LaMorte, 2019). Different groups of people accept innovation at different times, so it is important to target each population by addressing their direct concern.

To target each group of adopters, researchers must educate themselves on the motivations behind innovation adoption. DOI proposes five notable factors which influence people to adopt innovations: relative advantage, compatibility, complexity, trialability, and observability (LaMorte, 2019). Relative advantage of innovation refers to the perception of the benefits versus both the financial and non-financial costs of changing from a previously used method (Sanson-Fisher, 2004). If the rewards of adopting a new product or method outweigh the risks of switching, people are more likely to adopt it. Compatibility consists of the extent to which a new product or development fits within the system or people group adopting it (Kaminski, 2011). For example, a clinic dealing largely with geriatrics would likely not be drawn to an innovation largely dealing with athletes, unless they have substantial evidence that the innovation can be used to benefit the elderly in a substantial capacity. Likewise, a system run by a laggard, or someone resistant to change, would probably not be compatible with many brand-new innovations. Complexity of an innovation deals with the ability to understand and apply the innovation itself (Kaminski, 2011). If the adoption being pushed is difficult to comprehend, not easily picked up, or only able to be handled after extensive training, the likelihood of its widespread acceptance is slim. On the other hand, if an innovation is easily understood and able to be used by a large number of people, it is more likely to be adopted. Trialability denotes the extent to which a system, group, or person can try or practice the innovation before completely adopting it (LaMorte, 2019). For example, if a clinic is able to use an inventive apparatus for a period of time before committing to purchasing it, they are more likely to adopt it. Also, if they are able to use the apparatus on a few patients and receive positive feedback regarding the effects of the new treatment, they will be even more likely to switch to the innovation. This leads into observability, where a person or group is more likely to adopt an innovation if they are able to see tangible results from the innovation itself (Sanson-Fisher, 2004). When a system or clinic has proof of an innovation doing well, the possibility of its adoption increases greatly. These five factors are important influences to consider in the understanding of innovation adoption.

According to DOI, an individual progresses through a series of predictable stages of decision processing until an innovation is adopted or rejected. The stages of decision making as they pertain to diffusion of innovation are necessary to understand the extent to which adoption of something new is accomplished. These stages include the awareness of the need for innovation, the decision to adopt innovation, the initial trial of innovation use, and further use of the innovation (LaMorte, 2019). The initial stage is the awareness of the need for innovation. In this stage, a system or group has become aware that the old and/or traditional way of accomplishing certain things is no longer working; they realize that a new method or machine is necessary in order to continue effectively (Van de Ven, 1991). At this stage, innovation adoption becomes much more likely, and the group becomes more willing to hear about, look at, and experiment with innovative products and methods. Once an innovation is recognized or valued within the system, it moves into the second stage, which is the decision to adopt innovation (Van de Ven, 1991). At this point, the innovation has been prepared for via training, research, or monetary funds, and the group has figured out a way to implement it into their program. Once an innovation is adopted, it is much more likely to be continually used, which is the final stage of diffusion of innovation (Van de Ven, 1991).

Innovation Implementation

Developing successful innovation in the healthcare realm can be difficult. Often, research and testing must be done for years to provide enough evidence for the accuracy and usefulness of the idea or device to influence health care professionals to utilize it. To help understand how innovation is implemented in different settings, the Consolidated Framework for Implementation Research (CFIR) is a set of 39 constructs across five major domains which interact to influence the implementation of innovations (Damschroder et al., 2009). The domains include Intervention, Outer Setting, Inner Setting, Characteristics of Individuals, and Process.

Intervention characteristics can be related back to the qualities of the innovation itself. Characteristics include the innovation source, the evidence strength and quality, the relative advantage of the innovation, adaptability, trialability, complexity, design quality and packaging, and the cost of the innovation. All of these aspects discuss the innovation itself, and provide a measure of how valuable or useful it might be. Without positive perceptions about the innovation in each of these categories, an innovation or idea may be less appealing, and therefore less likely to be adopted.

The outer setting includes patient's needs and resources, cosmopolitanism, peer pressure, and external policies and incentives. The outer setting greatly involves external influence to adopt an innovation, and, without strong external influence from peers or advisors, some innovations may never be implemented.

The inner setting includes qualities like structural characteristics, networks and communications, culture, implementation climate, tension for change, compatibility, relative priority, organizational incentives and rewards, goals and feedback, learning climate, readiness for implementation, leadership engagement, available resources, and access to knowledge and information. While this list is incredibly daunting, it all comes back to the preparedness for different settings to implement an innovation. When a group or system is well-versed in the innovation and able to adapt to the changes adopting it will encompass, the implementation of it occurs much more quickly.

The characteristics of individuals include knowledge and beliefs, self-efficacy, individual stage of change, identification with organization, and other attributes. When individuals find that their knowledge, beliefs, and general confidence in their abilities match those required by an innovation, adoption is much more likely to happen. If an individual relates less to the innovation or doubts their abilities to use it successfully, there is less likelihood of it being implemented.

Finally, the process of implementation involves planning, engaging, executing, and reflecting and evaluating the innovation. Continued use of an innovation occurs when those utilizing it develop strategies, methods, and conditions by which they plan to implement the innovation. Frequent evaluation of the benefits of the new device or method, as well as the outcomes when it is chosen, help users to gauge whether the innovation meets a need in the setting. If it does, then it will continually be used- if it does not, then the implementation of the innovation will likely not succeed.

Innovation in the Health Care Setting

Innovation in a health care setting can be particularly different from that of other settings. While evidence-based practice, where clinical evidence of an innovation's usability is translated into the clinical environment, plays a large role in the adoption of new methods, health care reform can also be a largely social process- especially in the physical therapy realm. A study conducted by Sabus & Spake in 2016 evaluated DOI theory in combination with the CFIR to determine the deciding factors in innovation adoption for outpatient physical therapy settings. Fourteen physical therapists, two clinic owners, and two clinic managers were interviewed to evaluate conceptual frameworks in physical therapy practice on multiple levels.

Overall, Sabus & Spake found that the keys to innovation adoption in outpatient physical therapy settings are patient-centered care and collaborative learning. Despite developers' attempts to integrate new and exciting practices into the health care realm, innovation adoption largely depends on what the patient wants. It is also noted that, in order for innovation to occur within a practice, disruption must be accepted, strong leadership and effective relationships between staff must be present, and innovation must be embedded in the culture of the organization.

While one study has been conducted regarding influences behind why users may want to adopt BFR based on expected outcomes (Patterson & Brandner, 2018), and one study has been conducted regarding the constructs associated with innovation in outpatient care practice in physical therapy (Sabus & Spake, 2016), there are no known studies done regarding the adoption of BFR in relation to CFIR constructs and DOI theory. The aim of this study is to utilize DOI theory and CFIR to determine why health care professionals in rehabilitation settings may or may not adopt BFR as an innovation.

INTRODUCTION

Clinical settings are often faced with the issue of treating clients/patients who may suffer from illnesses or injuries that limit them from exercising to either increase or maintain muscular strength and size. Muscular atrophy is often experienced by those recovering from a surgery or those who are immobilized, due to injury or otherwise, leading to increased recovery time to return to a normal state. To prevent muscular atrophy, clinicians often prescribe low-load exercise to train the body and maintain strength. However, there is often a limit to how much growth a patient can experience doing normal, low-load exercises.

Blood flow restriction (BFR) refers to the partial restriction of arterial blood flow and full restriction of venous blood flow that can be used in conjunction with resistance exercise, aerobic exercise, or by itself to produce significant muscular strength and size outcomes in participants (Slysz et al., 2016; Abe et al., 2006; Jones et al., 2004). Much research has been conducted regarding the use of BFR to both increase muscular size and strength, as well as prevent muscular atrophy when muscles cannot be externally loaded (Hughes et al., 2017). This intervention can be especially applicable in rehabilitation settings, where the process of getting an athlete back from surgery, or keeping a geriatrics patient strong without overloading them, is a daily goal.

While there is much research regarding the clinical uses of BFR, there is no known study regarding why clinicians may choose to implement it. To evaluate the factors involving the spread of an innovation across specific populations and its subsequent adoption, the Diffusion of Innovation (DOI) theory was developed by E.M. Rogers in 1962. DOI theory discusses different types of adopters and their characteristics, as well as intervention characteristics that adopters may consider before implementing something new. The Consolidated Framework for Implementation Research, developed by Damschroder et al. in 2009, takes principles from DOI theory to create constructs for implementation. The constructs can be categorized to Intervention Characteristics, Outer Setting, Inner Setting, and Characteristics of Individuals. When researching implementation, these constructs can be scored to determine whether they influence implementation positively, negatively, or neutrally. Prior research has been conducted using the CFIR to determine intervention implementation in a physical therapy setting (Sabus & Spake, 2016), but no research has been done regarding the implementation of BFR in the clinical setting.

To understand why someone may choose to adopt BFR, there must first be understanding of the constructs relating to its implementation. The purpose of this study is to use DOI theory in conjunction with the CFIR to investigate why a clinician may or may not implement BFR in rehabilitation settings. Once the factors related to implementation are identified as inhibitors or facilitators to implementation, implications for improved BFR marketing, educational interventions, or research can be made.

METHODS

Interview Development

In order to determine why clinicians might implement blood flow restriction in the rehabilitation setting, we developed a semi-structured interview based on several of the CFIR constructs. Initially, thirty interview questions were developed to investigate intervention characteristics, the outer setting, the inner setting, and the characteristics of individuals. We excluded questions regarding process because we were looking to determine why clinicians may initially decide to implement the innovation, not why they would continue to implement it. It was determined that questions regarding the process of implementation did not contribute a significant amount to the research question, and therefore excluded them from investigation.

Following the initial development of the interview, a panel of experts comprised of BFR researchers and two field clinicians evaluated the interview to increase validity. After evaluation by the panel, specific questions were refined based on feedback provided. Specifically, ten of the questions were omitted to decrease interview time and prevent redundancy. Following omission of ten questions, the constructs of innovation trialability and individual stage of change were eliminated from the research. Pursuits were not made to reinsert these constructs anywhere because they were not necessary to achieve the study aims.

The result was a twenty-question, semi-structured interview script (see Appendix), with additional probing questions, which covered a total of twelve constructs. These constructs were chosen to determine which considerations were most important to clinicians' decision to implement BFR.

Participants

Because our aim was to discover the implementation of BFR in the rehabilitation setting, participants were required to be licensed physical therapists, occupational therapists, or athletic trainers. Interviewees were not required to have experience utilizing BFR, but they were required to have some knowledge regarding its use. If clinicians were unable to answer the question of what BFR is and what it is used for, they were excluded. However, we wanted to discover the opinions of those who have not implemented BFR in order to determine why they have not. Therefore, interviewing both those who have used it and those who have not helps us to better understand the constructs surrounding the decision.

In total, five physical therapists, one occupational therapist, and four athletic trainers were interviewed. The clinicians worked in outpatient, inpatient, and collegiate settings in Alabama, Indiana, Mississippi, Tennessee, and Texas. They were contacted via email where an information sheet about the study was provided, and their participation in the study was done without incentive. This study was approved by the University of Mississippi's Institutional Review Board.

Data Collection and Analysis

All interviews were conducted by the same investigator through a recorded teleconference where an audio transcript was taken. During the interview, participants were asked each of the open-ended questions. Participants were not sent the questions ahead of time to prevent possible discussion of the questions among others, thereby rendering their opinions salient. Following the interview, transcripts were inspected and checked for accuracy with the recording and then evaluated for any of the twelve constructs the interview was designed to measure. Upon review, despite not explicitly being targeted with specific questions, two additional constructs were found to be relevant to the clinicians' implementation of BFR. These constructs are highlighted to provide clarification. The constructs and their general definitions can be found in Table 1.

Intervention Characteristics			
Intervention Source	Participants' perceptions of the source of the intervention (validity, legitimacy, etc.)	Adaptability	Participants' perceptions of the extent to which the innovation can be altered to meet the needs of different clients
Evidence Strength and Quality	Participants' perceptions of the quality and integrity of the evidence surrounding the innovation's effectiveness	Complexity	Participants' perceptions of the difficulty associated with implementing the innovation
Relative Advantage	Participants' perceptions of the advantage/disadvantage of using the innovation compared to pre-existing protocols/methods	Cost	Participants' perceptions of the financial costs associated with implementing the innovation, and the extent to which the benefits outweigh them
Outer Setting			
Patient Needs and Resources	Participants' perceptions of the extent to which an innovation meets the needs of their patients, as well as the barriers faced by the patient (such as perception, finances, etc.)	External Policies and Incentives	The extent to which external influence contributes to implementation (via incentives, collaborations, mandates, etc.)
Inner Setting			
Networks and Communications	The extent to which outside communication or networking, formal or informal, influences implementation	Available Resources	Participants' perceptions of their access to non-financial resources, such as time and space, that may affect implementation
Culture	Hierarchy of implementation in a setting, and the extent to which an individual has the ability to implement any protocol they deem necessary	Access to Knowledge and Information	Participants' perceptions of their access to knowledge and information regarding the innovation, and the extent to which it affects their perception of the innovation
Characteristics of Individuals			
Knowledge and Beliefs about Intervention	Patients' knowledge about and perceptions of the innovation; the extent to which they believe in its effectiveness	Self-efficacy	Participants' beliefs in their own abilities to safely and effectively implement the innovation

Table 1: Definitions adapted from Damschroder et al. (2009)

Once the constructs were identified within each participants' responses to the interview questions, they were scored to determine their relevance. The criteria for scoring was adapted from implementation research using the CFIR by Damschroder and Lowery (2013). The criteria is explained in Table 2.

Construct Rating	Criteria
+2	The construct is considered a positive influence on the majority of participants and has facilitated implementation efforts with necessary evidence exemplifying its manifestation.
+1	The construct is considered a positive influence on the majority of participants and has facilitated implementation efforts, but lacks concrete evidence exhibiting its manifestation.
0	The construct is considered neutral if it is mentioned only generically or without example of either positive or negative influence. It could also be considered neutral if participant views contradict each other considerably.
-1	The construct is considered a negative influence on the majority of participants and has inhibited implementation efforts, but lacks concrete evidence exhibiting its manifestation.
-2	The construct is considered a negative influence on the majority of participants and has inhibited implementation efforts with necessary evidence exemplifying its manifestation.

Table 2: Construct rating criteria adapted from Damschroder & Lowery (2013)

RESULTS

Following data analysis, scores were produced for each construct. The constructs and their associated ratings can be found in Table 3.

Intervention Characteristics			
Intervention Source	0	Adaptability	-1
Evidence Strength and Quality	+2	Complexity	0
Relative Advantage	0	Cost	-2
Outer Setting			
Patient Needs and Resources	0	External Policies and Incentives	N/A
Inner Setting			
Networks and Communications	N/A	Available Resources	-2
Culture	0	Access to Knowledge and Information	+2
Characteristics of Individuals			
Knowledge and Beliefs about Intervention	+2	Self-efficacy	0

Table 3: Constructs and associated ratings

Innovation Characteristics

Intervention Source

Intervention source was given a rating of 0, as its influence was considered neutral to implementation. Of the ten participants interviewed, only four had knowledge of the source of the intervention. Likewise, each of those four attributed the original source of BFR to be Johnny Owens, citing the work he had done with injured service members. Three of the four people who cited Owens Recovery Science as the intervention source actively implement BFR in their respective settings, while the other does not. Two other participants who currently use BFR did not state an intervention source when prompted, and the remaining three participants neither use BFR nor know its source. When asked about the intervention source, one athletic trainer who currently implements BFR responded:

> "I do not know how it was developed- I've never heard that. […] I think it was probably developed because you can [mimic that] the body's having the effect that it's doing a lot of weight when in reality it's not. […] I think [BFR] is very beneficial. I personally have had very good results with it."

This particular participant admittedly did not know the intervention source, but still thought very highly of the intervention itself. For these reasons, intervention source did not seem to be a contributing factor as to why someone would implement BFR as a rehabilitation treatment. Knowledge, or perceived knowledge of the source, did not seem to alter the clinicians' perspective of the validity of the intervention. However, it should be noted that education about the intervention can contribute to implementation, so that is considered in further constructs.

Evidence Strength and Quality

Evidence strength and quality was given a rating of +2. Aside from cost and patient needs and resources, evidence strength and quality appeared to be one of the most strongly considered factors when it comes to a clinicians' implementation of BFR. Of the five clinicians currently utilizing it, each cited strong research as a reason as to why they have decided to implement it. One clinician, an athletic trainer who was certified in BFR through Owens Recovery Science, stated:

> "There's good research behind it as well. […] we want to do things that have the research behind it and we know it works. […] I wanted a little bit more information on, you know, occlusion- does it work, how long can we leave it occluded, you know, all that kind of stuff... So, I think the research that they presented in our course, to be honest, kind of gave me what I was looking for to really kind of get on the bandwagon."

Similarly, those who do not currently implement BFR stated that the research behind it has influenced their thinking to make it more of a possibility in their setting. One physical therapist said, "looking at some of those articles and things I've looked at, it just you know, […] makes you go that is something to think about." Both those who do and do not implement BFR also said that word of mouth and personal, anecdotal evidence of the effectiveness of BFR has shaped their perceptions of BFR for rehabilitation. One athletic trainer stated that seeing its success with his own patients made him significantly more apt to utilize it, and several other clinicians echoed his sentiments.

The quality of scientific articles and similar research does significantly affect clinicians' perceptions of the intervention. However, eight of the ten clinicians, presented research gaps that made them less likely to use BFR, especially in consideration of their clientele. Some ideas for further research, according to each clinician, are listed as follows:

- "I think it just needs to still a little bit more science behind it- Just implementing it more and more with just kind of smaller injuries, I think, could help out as well."
- "I think that it would be really interesting to try it amongst different groups in different settings so that we can actually see the effectiveness throughout different populations. […] I think it would be interesting to see BFR use in pediatrics amongst patients who have some amount of like cognitive involvement. […] It'd be interesting to know if it could, I don't know, help with strength to where [the patients are] able to stand at the sink longer and wash their face for a longer amount of time."
- "You know, not just showing [BFR] in athletic populations, but in populations that I primarily work with, which is, for the most part, more on the geriatric side. […] kind of showing […] inpatient hospital settings and results with those patient populations to carry forward using BFR."
- "I would say research that showed that it did better than typical rehab without it."
- "I would like to see more research with how it would be applicable to those […] that may be obese or that may have diabetes and [if it's] safe with them."
- "I'm not sure... I haven't seen too much research on [exercise repetition] range."

- “I would be intrigued to see just more research across the board, you know, are there ways that we can use it that we don't realize we can use it.”

The most cited research gap was that of BFR use with diverse populations. Especially concerned were the occupational therapist and inpatient and outpatient physical therapists, saying that they would like more research that BFR would be safe to use, not only on young, healthy populations, but on the people they see on a daily basis. One especially concerned physical therapist stated, “We in Mississippi […] unfortunately see a lot of folks with co-morbidities. We see a lot of folks that have obesity, diabetes, heart disease and that kind of thing. […] I would like to see more research with how it could be applicable to those [populations].” Those who do not currently implement BFR were the most concerned about its safety with the general population, and one physical therapist who does currently implement it said that she would be hesitant to utilize it with geriatric patients, due to lack of research regarding its safety.

While several clinicians stated concerns with the lack of research regarding BFR’s application across a more diverse population, future research filling that research gap could positively influence those clinicians to implement BFR in their settings. Therefore, evidence strength and quality should still be noted as a positive construct for the implementation of BFR in the healthcare setting.

Relative Advantage

Relative advantage was given a rating of 0, as different participants reported conflicting views on the construct. Almost every clinician had strong viewpoints on the advantages of implementing BFR in their respective rehabilitation settings. Two athletic trainers stated that they believe blood flow restriction is the most advantageous modality to have in a training room, while admittedly stating that it is not the “end-all, be-all" of rehabilitation. When asked how BFR compares to existing protocols and therapies, one stated:

> “I think it's superior to the existing modalities. I would say that stem unit, ultrasound, they have their purpose but I'm not going to get […] a guy back from an ACL surgery just using stem and ultrasound. […] I could get a guy completely back, without even touching those devices, with BFR.”

However, while some sang its praises, others reported that the relative advantage of BFR is not incredibly outstanding. One athletic trainer who currently implements it in a collegiate setting said, “You know, the majority of the country is not using BFR and [is] getting people back to playing just fine.” Many clinicians said that, while BFR is advantageous, they could not describe it as being better than existing protocols- only different than them. Because of the mixed response regarding advantages of BFR, it cannot be regarded as the most influential construct for implementation.

Advantages of BFR

Each clinician was asked about his or her perception of the advantages of BFR compared to other modalities. The most commonly stated advantage of using BFR was shorter recovery time, and ability to get results of loading a joint without actually having to load it.

Disadvantages of BFR

Similarly, each clinician was asked about the disadvantages of BFR for therapy. The most frequently listed disadvantages were time to set-up, cost, and patient intolerance. One clinician said that the mobility of the machine can also be a disadvantage, as the cords can be limiting for exercise protocols, and one physical therapist said they were unsure if BFR can benefit patients in an inpatient setting, as they are usually only treated for a couple days before returning home. Nine out of ten clinicians said that standard weight lifting and exercise protocols would be the only therapy people may rather implement than BFR to achieve similar results, simply because of the cost of the machine, the time to set it up, patient discomfort, and actual availability of the machine (if other clinicians in the clinic are utilizing it).

Adaptability

Adaptability was given a construct rating of –1, as the majority of participants had no concrete evidence of BFR's alterability, but reported negative perceptions on its flexible application. When asked about the adaptability of BFR, and whether it can be altered to work in different settings, the majority agreed that it could be adaptable to some extent; however, some interpreted the question as it referred to machine/protocol adaptability, while others interpreted it as referring to adaptability to different populations. Because we did not specify which response we were looking for, the question was open to interpretation. Of those who said the machine/protocol could be adapted to an extent, they specifically mentioned the type of exercises done with BFR, the number of exercise sets and repetitions a participant completed, and arterial occlusion pressure percentage. Each stated that it would be best to stay within the guidelines provided by journal articles and other evidence, but that the numbers could possibly be adapted to fit the patients' needs and goals. None of the participants gave concrete evidence regarding their adaptation of BFR when using it.

Those who mentioned the adaptability of BFR across different populations were slightly more hesitant to call it alterable. An athletic trainer who currently implements BFR with an athletic population stated, "I feel like it'd be […] more effective and beneficial in the athletic training […] setting compared to physical therapy." Similarly, a physical therapist currently working in an inpatient hospital setting said, "You just maybe get a preconceived notion of like, 'Oh [BFR is], for you know, athletes […] versus […] little old ladies and little grandpas. […] It sounds like it [is alterable], especially with patient populations that […] maybe physically can handle [it]." These statements show the extent to which some clinicians believe that BFR is only adapted for athletic or young, healthy populations. Based on these statements, adaptability can be considered an inhibiting construct for implementation, especially across settings that see older, objectively unhealthy populations.

Complexity

Complexity was given a construct rating of 0, as its influence on implementation could be considered neutral to the majority of participants. Nine out of ten participants stated that BFR use in the clinical setting is not complicated, especially after receiving training. An occupational therapist disagreed, stating, "[It's] complicated because […] it's not widely used. In many […] settings, it would be complicated just because you'd have to explain, not only to the patient, but to other therapists [what BFR is] because so many people don't know anything about it." This clinician does not currently use BFR, and is also not persuaded that it can be incredibly beneficial across all populations. Her concern was not complexity with the application of BFR, but complexity associated with persuading patients and other therapists in the clinical setting to buy into it and support it. In summary, the majority of clinicians did not see the complexity of BFR as being an inhibiting factor to its implementation in the healthcare setting. However, depending upon the interpretation of the question, it could be considered complicated to explain to patients and other clinicians what BFR is, what it can be used for, and its associated benefits. Nonetheless, complexity is not viewed by a majority of participants as having either a positive or negative effect on implementation of BFR.

Cost

Cost was given a rating of –2. Cost associated with BFR implementation was the single most cited concern when considering its implementation across every setting. Two clinicians in different states stated that the only reason their clinics had not yet implemented BFR was because they were not yet able to afford it. While a majority of participants stated that the benefits of BFR could outweigh the costs if they were able to utilize it on enough patients, several people, especially outside of the athletic setting, had concerns about the number of patients who would be able to use it, provided the gap in research of BFR use across variable populations. One clinician said it plainly:

> "I've always been part of organizations that were involved in [BFR research] or athletic organizations that were, you know, power five schools [where] money was not a factor... The issue you have is when you get in a smaller clinic or a smaller school, who are presenting this financial thing to the board... [They] say, 'Okay, this machine is going to cost X amount of dollars' and then their response is, 'Can you get your patient better without the machine?' The answer to that question is yes, but it's going to take a whole lot longer."

She went on to say that, in colleges where sports are integral to financial gain, they will spend any money they need to in order to have their top athletes on the field as fast as possible so that they can win games and advance their profits. However, in an outpatient PT setting, where a majority of patients are geriatric with a number of co-morbidities, clinics will make sure to have the equipment necessary in order to help the patient, but they may not overspend to get better results faster. The difference is the patient need and timeline- small clinics may not be able to afford BFR, but they are still able to treat patients without it. Another participant said, "I definitely think for smaller […] places or places with not as many funds... They just may never

have the opportunity to even go and get [BFR equipment] or use [it]. I think that's the main barrier for them." Therefore, it can be noted that cost is an inhibitive factor in clinicians' implementation of BFR.

Outer Setting

Patient Needs and Resources

Patient needs and resources was given a construct rating of 0, as the clinicians' perspectives of BFR to meet their patients' needs differed considerably. Some clinicians stated that BFR was able to meet the needs of their patients incredibly thoroughly, with one even claiming it "exceeds [patients' needs]." Other clinicians stated that it was or could be incredibly beneficial to their patients, citing the athletic populations they currently treat. For example, one physical therapist who does not currently use BFR said:

> "It's definitely geared towards a more athletic-type crowd versus some geriatric-type patients. […] We cover sports medicine for three local high schools at our clinic, and so we see a [large] variety of athletic injuries, and, now, we're actually seeing a lot of Navy patients who are mostly young and fit. […] I think it would be really good for a lot of them as well."

Another physical therapist who is also not currently implementing it said, "Right now I treat a pretty healthy, young population [and] a lot of athletes, so I think that it could have a really positive impact for our young athletes and our folks that have had surgeries, so I'm all about it."

Those more skeptical stated that, while BFR could meet the needs of some of their younger patients, they were unsure as to whether it could meet the needs of the older, less healthy patients. One clinician said, "If you've got a seventy-year-old woman, you know, she's probably not going to tolerate it as well as a nineteen-year-old collegiate football player will." A majority of the clinicians said that they believed it could meet their patients' needs, but they were unsure of whether it could be as effective in older populations, giving the construct conflicting scores.

Patient Perceptions of BFR

When asked about their patients' perceptions of BFR, or what they thought they would be, each clinician said roughly the same thing. A majority of clinicians reported what one athletic trainer answered, claiming patients' perceptions are/would be "skeptical, then uncomfortable, then love it or hate it." Most also said that, once the clinician explained to them what BFR is and how it works, they would be more open to trying it. For example, one physical therapist said, "They look at us as, you know, the expert; so once they're educated, most patients are pretty open to anything we recommend."

One athletic trainer who works in a collegiate football setting remarked that some athletes think of BFR positively, because it challenges them, not just physically, but also mentally:

> "You know, it can be a depressing time, or a really dark time when you have a long-term injury and you're in the training room for a long time. You know, these guys are bred to want competition and to want challenge. I think […] sometimes the rehab process can be boring and sometimes easy for guys, depending on what their injury is and where they are. I think BFR gives them a challenge and something to look forward to. […] You can do things like make competitions out of it, and really […] tap into a different part of these guys that […] you don't get to see on a normal day."

Still, an occupational therapist said that, within her patient population, perceptions of BFR may be much more negative:

> "Geriatrics would probably be mad and uncomfortable [when using BFR]. Inpatient [clients] would be uncomfortable. […] I think that [in] pediatrics, the families would be really uncomfortable with it being used initially because [they would be] watching their kid […] have an uncomfortable experience, [and] I think that would be enough for them to not want to do [BFR]."

Patient Barriers

When asked about possible barriers a patient may face if participating in BFR, there were two clear responses: pain and payment. Five of the nine participants who identified patient barriers stated that physical discomfort could greatly limit a participant from utilizing blood flow restriction for therapy. Three of the clinicians, including the occupational therapist and two physical therapists said that they were unsure whether insurance providers, such as Medicare, would reimburse patients for BFR therapy. One participant stated, "If there is minimal funding and reimbursement for it then patients could have to pay for it out of pocket, and if they are paying out of pocket, then that obviously leads to barriers." One other participant said that availability of the machine in the clinic could also be a barrier to patient use of BFR.

External Policies and Incentives

External policies and incentives was not a construct we originally aimed to investigate. However, two participants working at the same clinic cited it as being relevant to their implementation of BFR. The two clinicians stated, respectively:

- "We don't work for the hospital system, but we work with a hospital system that does a good amount of research, and they're researching BFR. So, to be honest with you, we have it and we're trying to implement it for that reason. And, don't get me wrong, I love the fact that we have it, but that that's kind of the base reason why we have it and why we've implemented it."
- "[Our head trainer] got a deal with [a local hospital], and we were able to get a few units [for free], while also helping them conduct research."

Because only two clinicians cited external policies and incentives being integral to their implementation of BFR, we cannot accurately give it a construct rating. However, their

involvement with a local hospital could be an innovative idea for further BFR research, and may cause other clinics to implement BFR if they had the same opportunity.

Inner Setting

Networks and Communications

Networks and communications was another construct that was not initially considered when designing the interview. However, one participant mentioned his communication with others in his field as a positive influence on his implementation of blood flow restriction:

> "As athletic trainers... You know, athletic training is kind of a small field in the grand scheme of things. So, you know, we talk with each other, and when we find something we really like and get good results with, we recommend it to other people, and so they buy it as well."

Because only one participant mentioned influence of networks and communications, we could not accurately rate its effect on implementation of BFR. However, it could be something to consider for future research, as communication across a specific field could greatly affect innovation implementation.

Culture

Culture was assigned a rating of 0, as its influence on implementation was considered neutral. Each participant was asked about their ability to implement what they deem necessary with each patient, where every participant said they had free range to use any modalities or therapies within their setting. This construct was explored to determine whether any clinicians were limited to protocols or therapies assigned by a supervisor or director, which could inhibit implementation of blood flow restriction in their setting. However, no participants reported implementation culture as being influential to their individual rehabilitation practice, so the construct was not considered influential in a positive or negative way.

Available Resources

Available resources was given a construct rating of –2, as the majority of clinicians said that time with patients or available space could be a factor in implementation. One clinician said that the time it takes to set up BFR with a patient does not always make it her first choice for therapy:

> "Sometimes [BFR equipment] does take time to set up, and, if I've got a guy that has 15 minutes max for exercises that day, I'm not necessarily going to put them on BFR and spend five to seven minutes […] setting it up."

Other clinicians reported similar problems with available time being an inhibition to using BFR over other modalities or therapies. One athletic trainer even speculated, "I think time is definitely a factor. You know, if you're a one man show at a PT clinic and you've got four patients at the same time, it's going to be really difficult to do BFR with one of them."

Another clinician mentioned available space being a possible inhibiting factor when deciding to use BFR. She mentioned capacity restrictions in her setting's gym space due to the COVID-19 pandemic, saying that she may not always have the ability to take a patient into the gym to perform exercises with blood flow restriction. Because of these statements, lack of available resources can be considered a negative influence on implementation of BFR in the clinical setting.

Access to Knowledge and Information

Access to knowledge and information was given a score of +2, as it played a positive role in the implementation of blood flow restriction. When participants were asked about their awareness of information available to them to help them implement blood flow restriction, those who do implement it cited several sources of information. Even those who do not currently implement BFR with their clients said that their access to information significantly impacted their perception of BFR. When asked how his access to knowledge and information affects his perception of blood flow restriction, one participant stated:

> "I would say that it directly affects it. I mean, all [of] the evidence that I've read showing that it's got promise and that it's, you know, helping individual patients in case studies […] has correlated to me having a good perception of it and wanting […] to use it more in my own practice in our own clinics."

Other participants stated that they wished there were more readily-available information about blood flow restriction specifically:

> "I know there are articles out there that exist. But, you know, again, […] sometimes we get set in our ways and just, you know, [think] 'I know how to get patients better doing you know X, Y, and Z.' […] You know I guess the overall marketing [needs to be changed]."

Three participants mentioned their desire for better marketing of blood flow restriction so that clinicians could have more knowledge about their access to information. If the marketing were altered to present BFR to more people in the clinical setting, several participants said that they believed it would be implemented more. Still, those aware of their access to knowledge and information said that it directly, positively influences their perception of BFR, making it a facilitator of BFR implementation.

Characteristics of Individuals

Knowledge and Beliefs about Intervention

Knowledge and beliefs about the intervention was scored 0, as it greatly affected a clinicians' desire to implement blood flow restriction with his or her patients, either positively or negatively. One athletic trainer, who mentioned that he uses BFR nearly every day with his athletes, said, "I'd say, [in] my general opinion, I think it is probably the most important and best modality that we have in our training room. I think it is something that needs to be integrated

into rehab protocol." His belief that blood flow restriction is the best modality in the training room directly relates to the frequency with which he utilizes it.

On the other hand, one physical therapist who works with mostly geriatric patients in an inpatient hospital setting, believed that the intervention was specifically for an athletic population, which negatively affects his decision to implement it in his setting. Another physical therapist who works in an outpatient setting and does not currently implement BFR said that he would mostly use it post-surgery, as he believes "it's just used to increase muscle hypertrophy after an injury." Because his beliefs are that BFR is really only used following an injury, his patient population is automatically limited, preventing him from wanting to implement BFR with other groups.

It appears that those who currently implement blood flow restriction with their patients have greater knowledge of it and better beliefs about it, which likely comes with time and familiarization. Overall, a clinicians' knowledge and beliefs about BFR does significantly impact their decision to implement BFR, whether its negatively or positively.

Self-efficacy

Self-efficacy was given an overall rating of 0, as it did not affect a clinician's decision to implement blood flow restriction positively or negatively. Those who currently implement BFR said that they were confident in their ability to apply it safely. Their justifications for their self-efficacy related to familiarization with the protocol, education about BFR, and reliable equipment. Those who do not currently implement BFR said that, though they are not currently confident in their ability to apply it safely, they would be confident if given training or researching the protocols for it themselves. Because no one said that it affected their decision to implement it, it can be considered a neutral construct.

DISCUSSION

The aim of this study was to utilize the Diffusion of Innovation theory in combination with the Consolidated Framework of Implementation Research to determine why health care professionals in rehabilitation settings may or may not adopt blood flow restriction as an innovation. Upon evaluation of the data, several constructs proved to be more relevant to implementation than others. In relation to the characteristics of the intervention, evidence strength and quality, relative advantage, and cost were rated in a way that demonstrated their significance in implementation. Clinicians were concerned with the reliability of evidence proving the effectiveness of blood flow restriction in their setting. Many voiced their concerns with the lack of evidence showing its effectiveness across diverse population, specifically geriatric, obese, diabetic, or other co-morbid people groups. Still, several stated that the presence of strong evidence citing BFR's usefulness was one of the main reasons why they decided to implement it in the first place. If further research could be conducted showing safety implications of BFR use in older, co-morbid patients then BFR may continue to be implemented in more settings. Similarly, clinicians' perceptions of the relative advantage of BFR affected their decision to implement it either positively or negatively. Those who believed BFR was significantly more advantageous than other protocols and modalities were much more likely to implement it. However, those who believed they could achieve similar results using other methods were less likely to use BFR. Cost proved to be one of the most negatively influential constructs related to BFR's implementation. While some believed that the cost to benefit ratio was good, others felt that small schools and clinics may never acquire enough funds to invest in all of the necessary blood flow restriction equipment needed to see these benefits. Cost also related to patient needs, where some clinicians were concerned that, while BFR may be worth the cost in athletic settings, it would not be worth it in settings with mainly geriatric or co-morbid patients.

In relation to the outer setting, patient needs and resources was the most highly-considered construct. Clinicians are greatly concerned with purchasing and investing in innovations that will serve their patient populations. It was evident that those serving athletic populations felt that BFR went above and beyond to meet patient needs, while those serving more diverse patients were unsure of the ability of BFR to meet their patients' needs, recalling the lack of evidence surrounding BFR's safety and effectiveness across diverse populations. Clinicians were also concerned with patients' ability to fund the treatment, as they were unsure whether insurance companies would fund it or if patients would have to pay out of pocket, which would be considered a barrier to implementation. Overall, patient perceptions were not a problem for implementation, as the clinicians felt that, once they were able to explain to their clients what blood flow restriction is and how it could help them, the patients would be on board with it. One clinician also noted that some athletes perceive BFR as a challenge, motivating them to accomplish their exercises and move forward in their rehabilitation.

The constructs found to be significant in the inner setting were available resources and access to knowledge and information. Clinicians felt that a lack of available resources, such as time and space, could negatively impact their ability to implement blood flow restriction in the clinical setting. Several participants reported the lack of time in their treatment windows being an inhibiting factor, while one stated that a lack of gym space for the patient to perform exercises with BFR could prevent them from being able to use it. Access to knowledge and information was also important for the clinician to feel able to implement BFR in his or her setting. While several participants felt that they had ample access to knowledge and information regarding the use of BFR, others felt that BFR itself could be marketed more to clinicians so that they would be more aware of its implications in the rehabilitation setting. As one participant said, "You don't know what you don't know."

Finally, when determining the significant constructs related to characteristics of individuals, only clinicians' knowledge and beliefs about the intervention seemed facilitative of or inhibitive of BFR implementation. The way in which a participant viewed blood flow restriction directly affected their use of it. Those who believed in its effectiveness and had more knowledge of its usefulness appeared to use it more in their setting, while those who do not currently implement it seemed to have fewer positive beliefs about it, and significantly less knowledge about it.

Implications

This research could be used to determine better ways to market BFR so that more people are aware of its usefulness in the clinical setting. It could also be used to promote funding of research determining the effectiveness of BFR across diverse populations, which would in turn increase adoption of BFR. It could also be used to promote educational interventions explaining whether insurance providers cover BFR treatments, or, interventions advocating for providers to cover it. Further research should be done to understand the constructs related to the outer and inner settings, and the characteristics of the innovation and individuals that may also be relevant to the implementation of BFR in the clinical setting.

Limitations

This study was limited in a number of ways. First, the participant population was small and limited. There was only one representative of occupation therapy, which would limit generalizability of results, and all of the athletic trainers worked in Division I collegiate settings, which traditionally have more access to funding than small colleges or high schools. Secondly, time restraints limited the extent to which the different constructs could be explored. Further research could replicate this study to determine the generalizability of the results across different athletic trainer, physical therapist, and occupational therapist participants. Lastly, we did not specify what kind of response we were looking for when asking certain questions, so specific constructs were left to the clinicians' interpretation.

CONCLUSION

In conclusion, the CFIR in conjunction with DOI theory can be used to infer the constructs that facilitate and inhibit the implementation of BFR in the clinical setting. Of the 14 constructs investigated in this study, clinicians seem to be most concerned with available evidence and information regarding the effectiveness of BFR across their specific patient population. If provided with this information, it appears that financial costs associated with BFR can completely hinder adoption of the intervention. For example, some clinicians are aware of the research showing the benefits of BFR and believe it could benefit their patients, but do not implement it because their clinic cannot currently afford it. These findings suggest that the adoption of BFR in the clinical setting is influenced by a number of factors, with cost being the overarching construct that can inhibit its implementation entirely. Still, future research and educational interventions should address BFR use on diverse populations to increase adoption of BFR in the clinical setting.

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APPENDIX

Interview Questions

1. Based on your knowledge could you describe BFR and its implementation in the healthcare setting?

2. Based on your knowledge could you describe how and/or why BFR was developed?
    a. What is your general opinion of it?

3. Do you or your colleagues (or anyone you know) implement BFR with clients/patients?
    b. Why or why not?

4. Do you think BFR is/would be effective in your setting?
    c. Why or why not?

5. Why do you think BFR is/is not being implemented in your setting?
    d. Who decides whether or not to implement BFR?
    e. Within your practice, do individual practitioners have the ability to personally decide what treatment techniques are utilized?

6. What kind of information or evidence are you aware of that shows whether or not BFR will/does work in your setting?
    f. What evidence have you heard about from your own investigation into the topic? Are there practice guidelines? Published literature? Co-workers? Others?
    g. How does this knowledge affect your perception of BFR?

7. What kind of supporting evidence or proof about the effectiveness of BFR do you think is/was needed for yourself or your colleagues to decide to use it?

8. What support, such as education, online resources, education materials, are available to help you implement and use BFR?
    h. How do you access these materials?

9. How does BFR compare to other existing protocols/therapies in your setting?
    i. What advantages does BFR have compared to existing protocols/therapies?
    j. What disadvantages does BFR have compared to existing protocols/therapies?

10. What other interventions would practitioners rather implement instead of BFR that would produce similar results?
    k. Can you describe that intervention?
    l. Why would people prefer that intervention compared to BFR?

11. How do/would you feel about BFR being used in your setting?
    m. Positive? Negative?
12. How confident are you in your ability to apply BFR safely?
    n. What gives you that level of confidence?

13. How confident do you think your colleagues feel in their ability to apply BFR?
    o. What do you think gives them that level of confidence?

14. How well do you think BFR will/does meet the needs of the individuals/patients served by your organization?
    p. In what ways does/will BFR meet their needs? E.g. improved outcomes? Reduced recovery times? Health/quality of life?
    q. Can you describe specific examples?
    r. Is/can BFR be altered to meet their needs and preferences?
    s. Are there components of BFR that should not be altered? If so, which components should not be altered?

15. How do you think the individuals/patients served by your organization respond/would respond to BFR? I.e., physical responses, adherence to treatment, etc.

16. What barriers might individuals/patients served by your organization face if participating in BFR?

17. What are patients' perceptions of BFR, or what do you think they would be?
    t. Can you describe a specific example if you have one?

18. What kinds of changes or alterations do you think need to be made to BFR so it will work effectively in the healthcare setting?
    u. Do you think you are be able to make these changes? Why or why not?

19. In your opinion how complicated is the use of BFR in the healthcare setting?

20. Could you discuss the associated financial costs of implementing BFR relative to the benefits one might get in return?
    v. What about any non-financial costs, could you discuss those if there are any?