THE IMPACT OF 16-WEEK RESISTANCE TRAINING PERFORMED USING ELASTIC BANDS ALONG WITH DIABETES EDUCATION ON PHYSICAL FUNCTIONS OF OLDER ADULTS WITH TYPE 2 DIABETES MELLITUS AND FRAILTY: THE BAND-FRAIL STUDY

by

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ABSTRACT

Individuals with Type 2 diabetes mellitus (T2DM) or frailty have reduced physical function, however, living simultaneously with both conditions exacerbates an individual's physical function. Research shows that resistance training and diabetes education improve physical function; however, few studies exist on individuals with T2DM and frailty. We hypothesized that performing 16 weeks of elastic band resistance training with diabetes education would increase physical function in individuals with T2DM and frailty. The exposure variable was a 16-week elastic band resistance training program, which consisted of supervised resistance training twice a week and diabetes education once a week. Physical function significantly improved (pre: 8.4 ± 2.1 vs. post: 9.9 ± 2.1; $p<0.01$) following the 16-week intervention, with 73% of participants improving by a minimal clinically important difference of one point on the Short Physical Performance Battery. This suggests that participating in the Band-Frail program enhances physical functions in individuals with T2DM and frailty.

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Table of Contents

List of Symbols, Nomenclature or Abbreviations

Abbreviation	Definition
T2DM	type two diabetes mellitus
ADL	activities of daily living
CFS	Clinical Frailty Scale
BMI	body mass index
ICC	intraclass correlation coefficient
RCT	randomized controlled trial
1RM	one rep max
RPE	rating of perceived exertion
SPPB	Short Physical Performance Battery

Chapter 1: Introduction

As North American societies have become older and more sedentary, regular exercise has been promoted to improve overall health and reduce the risk of developing chronic diseases [1]. Initially, the emphasis was only on aerobic activity until the importance of resistance training was understood. Resistance training is now known to prevent many chronic conditions, increase strength, and promote good health [2].

As we age, we are susceptible to an increased risk of chronic diseases and comorbidities [3], including frailty and type 2 diabetes (T2DM). Frailty is a geriatric syndrome that affects multiple systems and is characterized by a reduction in physiological reserve [4,5]. T2DM is characterized by the ineffective use of insulin and ß cell dysfunction [6,7]. Both frailty and T2DM result in decreased physical function, while T2DM increases the risk of micro-and macrovascular complications. When both frailty and T2DM are present, it exacerbates the financial strain placed on the health care system [8]. Therefore, there is a need to better understand how to manage both frailty and T2DM.

Resistance training is one way of managing these conditions, as it known to improve muscle strength and physical function, even in older adults [9]. Resistance training can also help control T2DM by improving insulin sensitivity [1].

To our knowledge, only one study has investigated the effects of resistance training on frailty and T2DM [10]. The study consisted of 16 weeks of a relatively small amount of exercise twice a week: two to three sets of eight to ten reps of two resistance training exercises using resistance training machines. Even with the relatively small amount of exercise, the study observed an increase in physical function and was cost-

effective. One possible solution to increase the accessibility and cost-effectiveness of resistance training would be to use elastic bands instead of weight machines.

Due to the limited knowledge of the effects of resistance training in those with T2DM and frailty, and the lack of knowledge on the effects of elastic band resistance training in those with T2DM and frailty, the current study aims to provide insight into the effects of an elastic band resistance training intervention in those with frailty and T2DM. We hope this study will add to the body of literature and help guide future randomized controlled trials for those with frailty and T2DM. Therefore, this study aims to investigate the impact of 16-week elastic band resistance training on physical function, HbA1c, and frailty status in older adults with frailty and T2DM.

Chapter 2: Literature Review

2.1 Aging

There are many definitions for aging; however, individuals usually refer to aging as the later stages of life [11]. Senescence is another term that is used when referring to aging. Senescence represents the progressive deterioration of bodily functions over time [12]. These bodily functions include aerobic capacity, muscle strength, balance, and flexibility [13]. Although many definitions of aging exist, most studies agree that aging can be defined as a complex phenomenon characterized by a progressive and gradual impairment of physical and mental functions, resulting in an increased vulnerability to environmental challenges and a growing risk of death and disease [14,15].

Chronological age (number of years since birth) is often used as a metric to quantify the prevalence of aging [16]. Since the beginning of the 21st century, we have observed a significant increase in the worldwide prevalence of older adults [13]. In fact, the prevalence of people aged 65 years or older is the fastest-growing segment of the population [13]. Additionally, by 2050, the proportion of the world's population over 60 will nearly double, going from 12% to 22% [17]. Coincidently, the global population of those aged 65 or older is also expected to double from 703 million to 1.5 billion by 2050 [18]. Canada is no exception to this global trend, with 18.5% of its population aged above 65 years in 2021 [19]. Although the prevalence of older adults is provided using chronological age, aging varies considerably across individuals.

In fact, chronological age is a poor indicator of health and does not accurately reflect biological decline [20]. For example, two individuals could be aged 65, with one

having multiple comorbidities and the other having none. Both individuals are classified the same based on chronological age; however, in terms of health, they are very different. Therefore, a more accurate indicator of health and aging is biological aging. Biological aging is the progressive decline in the physiological ability to meet environmental and intrinsic demands [21]. Chronological and biological age are not always consistent because the speed and decline seen with aging varies between individuals [12,16].

2.1.1 Consequences of Aging

Aging is associated with chronic disease and comorbidities. Comorbidities are the coexistence of multiple chronic diseases. The prevalence of comorbidities in individuals older than 60 can range from 55% to 98% [22]. These comorbidities, along with the aging population will increase the financial strain on the healthcare system [20]. In Canada, the healthcare cost for the average older adult is about $12,700 per year, compared to just $2,700 for younger individuals [23]. In addition, the cost of care in people with three or more chronic conditions is 10 times higher than in those without chronic conditions [24]. Since half of older adults have three or more chronic conditions, the aging problem places enormous financial strain on the healthcare system [25,26]. It is also projected that the rapid aging in Canada will add 93 billion dollars to healthcare costs in the next 10 years [23].

With aging comes a reduction of muscle mass and strength, followed by a decline in physical function [27,28]. Physical function is the ability to perform both basic and instrumental activities of daily living (ADL) [29]. Additionally, physical function is suggested to not only be a marker of musculoskeletal health, but also encapsulate an

individuals' health as a whole [30]. Decline in physical function is almost universal amongst older adults and is exacerbated by chronic conditions [31]. Physical function is also associated with physical and mental health factors that decline with age. Some of these factors include obesity, falls, number of prescribed medications, depression, and quality of life. The decline in both physical function and these health factors increases the risk of morbidity and premature mortality [29].

With aging, individuals' ability to rapidly produce force also decreases. Rapid force production is important because a high rate of force development is essential to maintain physical function and to complete activities of daily life independently [32]. The ability to produce force rapidly is also a vital component in preventing falls in the elderly [33]. Thus, with the decline in rapid force production, the rate of falls increases, contributing to the burden placed on the healthcare system [33].

2.1.2 Aging and elastic band exercise

Due to the decline in strength, physical function, and subsequently the decline in the ability to complete ADL seen with aging, strategies need to be implemented to help manage this decline. These strategies will also aid in the financial burden placed on the health care system by older adults [34].

Many studies have looked at the effectiveness of elastic band resistance training for older adults [35]. The strong for life study was a randomized controlled trial investigating the effects of a six-month elastic band resistance training program in adults aged 60 and above [36]. They found that performing 10 reps of 11 different exercises three

times a week improved lower limb muscle strength by 12%. In addition, the strong for life study was found to significantly reduce disability by up to 18% as measured by the Sickness Impact Profile 68. Recently, an elastic band program of only eight weeks for women over the age of 65 found that 40 minutes of elastic band resistance training twice a week significantly decreased the timed up and go test from 9.04 ± 0.36 to 8.28 ± 0.38 seconds ($p<0.05$) and significantly increased walking speed from 1.19 ± 0.06 m/s to 1.36 ± 0.05 m/s ($p<0.05$) [37]. Other studies found that between six and 12 weeks of elastic band resistance training performed twice a week for 30 to 40 minutes improved physical function, muscle strength, and quality of life in older adults [38,39]. Similarly, these data are supported by a meta-analysis that showed a greater effect size for elastic band resistance training (Cohen's d=0.61) compared to free weights (Cohen's d=0.08) on the physical function of older adults [40].

Together, previous studies on older adults and elastic band resistance training suggest that it improves muscle strength and physical function regardless of the length and duration of these interventions.

2.2 Frailty

There has yet to be an agreed-upon universal definition of frailty; however, the general consensus is that frailty is a geriatric syndrome that affects multiple systems and is characterized by a reduction in physiological reserve, which then increases the risk of disease, disability, and death [4,5]. Thus, frail individuals struggle to deal with minor stressors they could previously overcome [5,41].

2.2.1 Prevalence of Frailty

The prevalence of frailty increases with chronological age [42,43]. The estimation of the prevalence of frailty also changes depending on the definition of frailty used [42,43]. A recent systematic review and meta-analysis of the prevalence of frailty in those 50+ years of age reported the prevalence of frailty being 12% when using Freid's Frailty scale and 24% when using a frailty index. When analyzing data from the Canadian Health Measures Survey, Kehler et al, (2017) found that the prevalence of frailty in adults 18-79 was 8.6% and 6.6% when using a frailty index and Freid's phenotype, respectively. The prevalence of frailty increased with each 15-year increment in age, reaching 20.2% and 7.8% when using a frailty index and Freid's phenotype, for those aged 65+.

2.2.2 Different measures of Frailty

Over the last decades, many measurements of frailty have been proposed [44]. Although no consensus has been established on the best frailty measurement, the most commonly used measure is Fried's Frailty Scale [45]. Other common frailty measurements are Rockwood's Clinical Frailty Scale and The Accumulation of Deficits Model (Frailty Index).

The most widely adopted measurement for frailty was developed by Fried. The Fried frailty scale (also known as the frailty phenotype) identifies five frailty items. The five items are outlined in Table 2 and include: unintentional weight loss of 10kg or 5% of an individuals' weight in the last year, exhaustion (scoring a 2 or 3 on question seven or 20 on the Center for Epidemiologic Studies Depression Scale), low physical activity (<383Kcals/week for males and <270Kcals/week for females), slowness based on sex

and height (20th percentile and lower), and weakness based on sex and body mass index (BMI) (20th percentile and lower) [46]. The Fried model has been used to create a frailty screening tool that scores individuals from 0 to 5: 0 = robust, 1-2 = pre-frail, and 3-5 = frail. The frailty scale provides predictive validity for the prospective association with five adverse health outcomes: incident falls, worsening mobility, decline in ADL function, hospitalization, and death. [47].

The Clinical Frailty Scale (CFS) is based on a clinical evaluation in the domains of mobility, energy, physical activity and function. The scale uses descriptors, icons and figures to stratify older adults according to their level of vulnerability. The CFS uses a physician/clinician's judgement to classify individual's frailty levels on a scale of 1-9, with 1 meaning very well (highly active and healthy), and 9 meaning terminally ill (expected to die in the next 6 months). Individuals are classified as Frail if they score ≥5 [48]. Two recent studies determined a high inter-rater reliability of the clinical frailty scale. A Danish translation of the CFS found that the scale has an intraclass correlation coefficient (ICC) of 0.85 [49], while a French version found the ICC to be 0.87 [50]. Rockwood et al. (2005) determined the clinical frailty scale to have a high predictive validity when compared to other established frailty measures such as a frailty index.

A frailty index has been proposed by Rockwood et al. (2005). In this, it is argued that frailty increases in a dose response manner with the number of deficits accumulated. The Frailty Index quantifies frailty using a continuous variable based on the proportion of deficits present in an individual relative to the number of traits measured.

Usually, the deficit model includes a combination of self-reported and objectively measured deficits, each increasing with age and not prevalent earlier in life. The deficits

are spread through 5 main categories: comorbidities, functions, signs and symptoms, laboratory values, and other self-reported information [51]. The more deficits considered, the higher the validity of the frailty index; however, frailty indexes with 30-40 deficits have shown sufficient accuracy in predicting adverse outcomes. [44]. For each individual, a minimum of at least 80% of the items must be present in the deficit model because if less than 80% of the items are included, the validity of the frailty index becomes compromised [44]. A systematic review by Drubbel et al., (2014) showed that frailty indexes with 30+ items have both a high criterion validity when predicting adverse health outcomes and a high construct validity when compared to comorbidity, disability, and self-rated health.

2.2.3 Risk Factors of Frailty

The pathophysiology of frailty has yet to be completely elucidated. In fact, the development of frailty is complex and multidimensional, stemming from genetic, biological, physical, psychological, social and environmental factors. Although the development of frailty is complex, one often-proposed hypothesis is chronic inflammation [52].

Chronic inflammation may be due to dysregulated immune responses, antigenic stimulation throughout life, and age-associated altered immunological profiles [52]. However, chronic inflammation is pathological and has been proposed as one of the main contributors of frailty. In fact, chronic inflammation is characterized by a chronic release of pro-thrombotic and inflammatory cytokines, which are signaling molecules [53] involved in the alteration of metabolic processes and protein degradation, which can give rise to

frailty [4,54]. Similarly, chronic inflammation is also the main producer of free radicals, which are also involved in skeletal muscle atrophy and protein degradation, which can lead to frailty [55].

Sarcopenia was originally defined as a natural loss of skeletal muscle mass with aging [56]. Recently, research has suggested including the loss in muscle quality in addition to the loss in muscle mass for the definition, as both muscle quality and muscle mass have been reported as a strong predictor of overall health outcomes [57]. Like frailty, sarcopenia is a multifactorial health issue, with endocrine changes, nutritional alterations, physical inactivity and most importantly chronic inflammation, all playing a strong role in sarcopenia [52]. Sarcopenia is also associated with the development of frailty [52,54], and when both sarcopenia and frailty are present, mobility and stability are decreased, leading to an increased risk of falls and a deterioration of daily living [57,58].

Many other factors have been associated with frailty. Some of these factors include sociodemographic influences (poverty and living alone) [59,60], depression [61], malnutrition [60], polypharmacy [59], diseases and their associated complications [59], low physical activity level [59], a low education level [62] and being biologically female [62,63]. However, for this thesis, they will not be discussed in detail.

2.2.4 Consequences of Frailty

The consequences of frailty can take several manifestations. Nevertheless, a common manifestation of frailty is decreased physical function, which results in a decreased quality of life [30,57,64]. As physical function decreases, a deterioration of ADL occur, causing frail individuals to be less independent; therefore, increasing the risk of

admission to an assisted living facility [57]. Frailty also increases the risk of dementia, hospitalization, and death [58]. A systematic review and meta-analysis found a dose-response increase in healthcare costs associated with frailty levels in older adults [65]. Another systematic review concluded that the healthcare cost for an individual with frailty ranged between 7,100 and 70,000 USD per year [66]. Data from the Truven Analytics database showed that the average medical care cost of older adults aged 65+ with frailty was 22,960 USD more per year than those without frailty [67]. Therefore, based on these data, the consequences of frailty are not trivial and are costly for our healthcare system. Due to the severity of the consequences, individuals need strategies to manage the disease and its ramifications.

2.2.5 Management of Frailty with Elastic Band Resistance Training

It has previously been observed that resistance training with weight machines or free weights can improve frailty scores [68,69]. In fact, a systematic review in 2018 concluded that a resistance training program with two to three sets of 6-15 reps at high intensity was shown to promote significant improvements in muscle strength, physical function, and frailty level in frail older adults [68]. In addition, a recent quasi-experimental pilot study supports these data. The study reports that pre-frail females who participated in a 12-week free weight exercise program significantly reduced their frailty scores [70]. More recently, Coelho-Júnior & Uchida, (2021) produced similar results with both high and low-speed resistance training.

As discussed above, resistance training with free weights and weight machines has shown to improve frailty and other measures of health. Despite this, these modes of

resistance training are often inaccessible to older adults with frailty due to financial reasons or a lack of confidence or efficacy. Elastic band programs are an alternative mode of resistance training and has been extensively used amongst frail individuals [68].

A recent systematic review looked at the effect of elastic band resistance training on those who were aged 65 and above and considered frail on Fried's Frailty Scale. Despite the lack of improvement on grip strength, leg strength, or quality of life, elastic band resistance training significantly decreased frailty scores with a standardized mean difference of -0.29 (95% CI: −0.55 to −0.03). Elastic band resistance training also significantly reduced depression with a standardized mean difference of −0.30 (95% CI: −0.52 to −0.09) [71].

Elastic band resistance training has reportedly shown to be beneficial for those with a higher level of frailty, improving ADL [71]. In 2015, an exercise program in Taiwan led by Chen et al, (2016) used elastic band resistance training for those aged over 65 in wheelchairs. The program consisted of two, three-month phases. Each phase consisted of 40 minutes of elastic band resistance training thrice weekly. The second phase added two significantly harder elastic band exercises. ADL were measured using the Brathel index and it was found that over the span of the six month intervention, participants were able to maintain their ability to complete ADL, compared to a decrease in ADL in the control group. Grip strength in the intervention group significantly increased from 13.56 ± 5.8 kg to 14.64 ± 6.43kg; (p=0.004). Lastly, the study concluded that the program increased upper and lower body muscle endurance, leading the authors to conclude that elastic band resistance training is feasible and of meaningful impact with highly frail older adults [72].

In 2019, a randomized controlled trial of an eight-week elastic band resistance training program was performed to investigate its impact on frailty scores in the pre-frail elderly. Sessions were performed three times a week and consisted of two sets of 10-15 reps for eight exercises. The resistance of the elastic band stayed consistent throughout the intervention. They observed significant improvements in Fried's frailty score, having 82% of participants return to a non-frailty state [73]. Grip strength significantly increased from 25.90 ± 3.06kg to 30.76 ± 4.11kg for males (p=0.01), and from 16.73 ± 2.42kg to 21.76 ± 2.84 (p=0.001) for females.

Physical function has also been shown to improve following elastic band resistance training. A recent study took place in Norway on older adults above the age of 70 who were receiving home care due to functional and/or medical disabilities. Participants underwent 8 months of elastic band resistance training and water cane exercise. The exercise program took place twice per week for 30-45 minutes. The chair stand test improved from 18.6s (95% CI: 17.0–20.2s) to 15.2s (95% CI: 13.5–17.2s), 8ft up and go test improved from 14.1s (95% CI: 12.3–16.1s) to 13.0s (95% CI: 11.2–15.0s), and a stair climb test improved from 26.2s (95% CI: 22.2–30.9s) to 23.2s (95% CI: 19.3–27.9). These improvements significantly differed from the control group who received physical activity counselling [74].

A whole body of evidence suggests that resistance training using machines in frail individuals improves frailty level, strength, and physical function [68,69]. However, less research has been conducted on frail individuals with elastic bands. From the limited number of studies available, elastic band resistance training seems to improve frailty levels even after only eight weeks. Significant improvements in physical function are also

achieved as programs increase in duration. Furthermore, the literature shows improvements in physical function not only in pre-frail individuals, but in individuals with high levels of frailty as well.

2.3 Type II Diabetes Mellitus

Diabetes mellitus is defined as a state of "chronic hyperglycemia", which is the result of 1) an ineffective utilization of insulin by the body's cells or 2) a significant decrease in insulin production by the beta cells from the pancreas [75]. There are two main types of diabetes mellitus: Type I diabetes mellitus and T2DM.

T2DM is on the far end continuum of insulin resistance. In fact, insulin resistance precedes the diagnosis of T2DM by 10 to 15 years [7,76]. At first, insulin resistance is the major issue in glucose metabolism. This ineffective utilization of insulin by the cells is compensated by an increase in insulin production by the beta cells. This places the individual in a state of chronic hyperinsulinemia. After prolonged hyperinsulinemia, the beta cells become exhausted and fail, resulting in a reduction of insulin for a given glucose concentration. Thus, resulting in chronic hyperglycemia, at which point T2DM will be diagnosed [7].

2.3.1 Prevalence of diabetes mellitus

In 2013, an estimated 382 million people were living with T2DM worldwide, accounting for 5.3% of the population [77]. In 2017, approximately 462 million individuals were living with T2DM, corresponding to 6.3% of the world's population [78]. This increased number is due in part to the aging population, as T2DM affects more older individuals. Because of this increase, the burden of diabetes is rising globally [78].

In Canada, 5.3 million Canadians had diabetes mellitus in 2022, which represents an overall prevalence of 14% [79]. Of those, 1.2 million were over the age of 65, corresponding to 19% of Canadians over the age of 65 being diagnosed with diabetes mellitus [80]. The prevalence of diabetes in New Brunswick is much higher (20%); however, it equates to significantly less individuals (156,000) [81]. While it could be argued that a province with a larger population and more individuals diagnosed with diabetes poses a greater problem, those provinces also have more financial and healthcare resources when compared to New Brunswick [82]. In 2021, New Brunswick had the lowest spending on public-sector health care per capita, thus creating a greater problem for this population. Diabetes Canada also reported that 11 million Canadians were living with diabetes mellitus or prediabetes in 2019, accounting for almost 1 in every 3 Canadians at the time [83]. While these numbers are the prevalence of diabetes mellitus, T2DM accounts for 90% of all diabetes mellitus cases [6,84].

It is estimated that 37% of all diabetes cases in Canada are undiagnosed [85]. Undiagnosed diabetes is a major threat for our population as it can lead to a faster onset of complications related to diabetes [85].

2.3.2 Risk factors for T2DM

2.3.2.1 Modifiable risk factors

Obesity is an excessive accumulation of adipose tissue that may impair health [86]. Obesity is known as one of the strongest risk factors for T2DM and is associated with several alterations in the metabolic profile, including insulin resistance and T2DM [87]. In fact, the proportion of individuals living with T2DM who are obese is 90% compared to

only 10% for non-obese individuals [88]. It is believed that the cardiometabolic abnormalities associated with excess adipose tissue increases the risk for T2DM in obese individuals. [89]. While this is true, research has shown that high BMI alone increases the risk of developing T2DM, regardless of cardiometabolic abnormalities associated with obesity [89].

Physical inactivity is defined as performing insufficient amounts of physical activity, that is, not meeting the specified physical activity guidelines [90]. Physical inactivity is another risk factor for T2DM. Physical inactivity has been shown to contribute to cardiovascular diseases, dyslipidemia, insulin resistance, and increasing the risk of T2DM [91,92]. Some research suggests that there is an interaction effect between obesity and physical inactivity, exacerbating the risk of developing T2DM [92].

Sedentary behaviour is defined as any waking behaviour characterized by an energy expenditure of ≤1.5 METs while in a sitting or reclining position [90]. It has been shown that sedentary behaviour increases the risk of the development of T2DM. This is supported by a meta-analysis that showed a 91% increased risk of developing T2DM in sedentary individuals compared to individuals with low sedentary behaviour [93].

In 2015, smoking cigarettes was the leading avoidable cause of disease worldwide [94]. While cancer is typically the disease associated with smoking, a systematic review and meta-analysis shows that incidence of T2DM has also been associated with smoking cigarettes. The meta-analysis found that those who currently smoke are 37% more likely to develop T2DM and this increases to 57% for heavy smokers (≥20 cigarettes/day).

Dietary habits can also put someone at an increased risk for T2DM. Large amounts of alcohol in one sitting was associated with an increase in T2DM. Despite this,

consumption of alcohol from wine was associated with a decreased risk of T2DM [95]. Other foods that can increase the risk of T2DM are: excessive amounts of refined grains, sugar-sweetened beverages, desserts and processed meat [96,97]. Foods that have an inverse relationship with T2DM are as follows: vegetables, legumes and whole grains [96,97].

2.3.2.2 Non-modifiable risk factors

Gestational diabetes is defined as glucose intolerance that is first detected during pregnancy [98]. The diagnosis typically occurs during the second or third trimester and affects three to five percent of pregnancies. In most cases of gestational diabetes, the diabetes goes away after birth. Despite this, gestational diabetes will put both the mother and child at an increased risk for developing T2DM [99]. A meta-analysis on T2DM and gestational diabetes reported that one in every three women who experience gestational diabetes during pregnancy developed T2DM within 15 years [100]. Two more meta-analyses further support the increased risk, reporting that women who experience gestational diabetes during pregnancy were 7.4 to 10 times more likely to develop T2DM [98,101].

As we age, the risk for many comorbidities increases, with T2DM being no different. With each increase in age grouping, there is an increase in the prevalence of T2DM, with some studies showing a ceiling effect at age 75 [80,102].

Race/ethnicity has also shown to be a risk factor for T2DM. In fact, in 2011, the age-adjusted prevalence of indigenous people with T2DM was 33% in America, compared to just 7.1% for Hon-Hispanic whites. The prevalence for other ethnicities include: 12.6%, 11.8% and 8.4% for Non-Hispanic blacks, Hispanic Americans, and

Asian Americans, respectively [103]. These populations are at a greater risk for T2DM not only because of their family history and genetics, but also because of environmental factors [102].

A family history of diabetes is a strong risk factor for the development of T2DM. In fact, those with one or more first-degree relatives diagnosed with diabetes have a hazard ratio of 2.72 (95% CI: 2.48, 2.99) [104]. Further, the concordance rates of T2DM seen in identical twins is almost 100% as well [102]. The elevated risk seen from family history likely has to do with genetics and the same shared environment [104].

Genetics also play a role in the development of T2DM [105]. In fact, many genes have been identified as a contributor to the development of T2DM [106]. In addition, genetics often exert their effects after exposure to an obesity conducive environment, consisting of sedentary behaviour, and excess caloric intake.

2.3.3 Consequences of Diabetes mellitus

Those living with T2DM are vulnerable to micro- and macro-vascular complications that occur with T2DM. Microvascular complications are long-term complications that affect small blood vessels and lead to diabetic nephropathy, neuropathy, and retinopathy. Macrovascular complications affect large blood vessels and lead to coronary artery disease, peripheral arterial disease, and stroke [107]. Micro- and macro-vascular complications are not trivial as they can lead to impaired physical function [6]. In 2010, over 22% of those diagnosed with T2DM had heart disease [108]. In fact, individuals diagnosed with T2DM are three times more likely to be hospitalized with cardiovascular disease [108]. Individuals with T2DM are also 20 times more likely to

be hospitalized with a lower leg amputation [105]. In addition, T2DM contributes to 30% of stroke cases, 40% of heart attacks, and is the leading cause of blindness – with over 60% of those with diabetes developing some form of retinopathy within the first 20 years of diagnosis [83,108].

Another important consequence of T2DM is the reduced physical function in individuals with T2DM compared to age- and sex-matched individuals without T2DM. This is accompanied by a loss of mobility in individuals with T2DM, and a reduced quality of life [109]. T2DM complications and diabetes duration are two important factors exacerbating physical function and quality of life [110].

Diabetes mellitus is a major contributor to the economic burden on healthcare systems. Those with T2DM have a healthcare cost of 3.2 times greater than those without T2DM. This cost increases to 9.4 times greater when there is a presence of complications [78]. In the United States, 1 in 4 health care dollars go toward those who have been diagnosed with diabetes mellitus, with the estimated cost in 2017 being $327 billion. Compared to 2012, this is an increase of 26% after adjusting for inflation [111]. In Canada, the cost of diabetes mellitus was 30 billion in 2019, up from just 14 billion in 2008 [83]. With the cost of diabetes mellitus being so high, community programs need to be implemented to help control diabetes and reduce the economic burden it places on the healthcare system.

2.3.4 Management of T2DM

T2DM management includes diabetes education, pharmacological therapies, nutrition, and exercise. Early T2DM management is important as early management of

glycemia helps minimize micro- and macrovascular complications associated with T2DM [105,112]. Optimal T2DM management is a set of lifestyle interventions, including weight reduction (if overweight) [113], increased physical activity [114], eating healthy, cessation of smoking, reduction of alcohol consumption, and drug lowering therapies [105].

According to the American Association of Diabetes Educators and the Canadian Diabetes Association, T2DM management should involve diabetes education [115,116]. In fact, a study assessing the efficacy of diabetes education concluded that diabetes education was associated with increased use of primary and preventive services compared to the use of acute inpatient hospital services for individuals who did not receive diabetes education [117]. Similarly, a systematic review found that 60% of the individuals who received diabetes education significantly improved glycemia and several other cardiometabolic outcomes [118]. Another meta-analysis confirmed that diabetes education improved HbA1c after 6 months and 2 years [119]. Because the efficacy of diabetes education has been shown consistently, research has used diabetes education as a baseline for control groups. Consequently, diabetes education combined with other methods of management have been reported in the literature.

For example, the Diabetes Prevention Program (DPP) reports that those at risk for developing T2DM who participate in a weight loss, physical activity and diabetes education intervention reduces the incidence of T2DM by 58% when compared to the control group (The Diabetes Prevention Program Research Group, 2002). In the Diabetes Remission Clinical Trial (DIRECT), diabetes education prevented an increase in glycemia, while combining diabetes education and diet replacement program reduced

HbA1c by 0.9 ± 1.4% [112]. Diabetes education has even been shown to improve cardiorespiratory fitness in older adults with T2DM [121].

Exercise studies on T2DM investigated the impact of different modes of exercise on glycemia. In 2007, Sigal et al. performed a 22-week randomized control trial comparing aerobic, resistance training, and combined training to a control group. They observed that individuals in the combined group had the greatest reduction in HbA1c [122]. However, in this study, participants were not allowed to change their diabetes medications, and the combined training group performed twice the work compared to the aerobic and resistance training groups, which might explain the observed results. In 2010, church et al. performed a similar trial for 9 months. Similar results were observed, with the combined group displaying the greatest change in glycemia (-0.35 %; p=0.03). However, for this study energy expenditures were matched between exercise groups, reinforcing the idea that combined training is better. These results were confirmed in a systematic review examining combined training and found that seven of the 10 interventions resulted in significant reductions in HbA1c [123].

Nevertheless, resistance training alone has promising benefits. A small study found that 10 weeks of resistance training improved HbA1c values by 17%. However, there were only 10 participants in this intervention [124]. In a population of older Hispanic Americans, resistance training reportedly decreased HbA1c from 8.7 ± 0.3% to 7.6 ± 0.2% (p=0.01). A meta-analysis further confirms this, reporting a reduction of 0.50% in HbA1c and an increase of 37% in strength after a resistance training intervention for an elderly population.

Based on the literature, it seems that while combined training has superior benefits on glycemia, resistance training still shows significant improvements.

2.3.4.1 Management of T2DM with Elastic Band Resistance Training

Resistance training has been widely documented to improve T2DM since the late 2000s. Randomized controlled trials have shown that resistance training improves glycemia in individuals with T2DM [125,126].

Nevertheless, high quality elastic band resistance training studies in individuals with T2DM are very scarce. A meta-analysis in 2014 included seven randomized controlled trials (RCT) that investigated the effects of elastic band resistance training on glycemic control [127]. The meta-analysis found a nonsignificant reduction of 0.18% in HbA1c. However, the RCTs included in this meta-analysis were severely flawed. For example, each RCT stated that they exercised at a percentage of one rep max (1RM). However, none of the RCTs explained how this 1RM was achieved accurately using the elastic bands. In addition, the sample size of these RCTs were very small.

A randomized controlled trial from Sigal et al., in 2018 looked at the differences between an aerobic and elastic band resistance training program and a sole aerobic exercise program in those with T2DM. The trial found that the combined exercise program with the elastic band resistance training increased upper and lower body muscle strength by an average of 65.5% and 61.6%, respectively. They also found that the combined training had a significant but modest improvement in glycemia, decreasing HbA1c by an average of 0.23%. This is further supported by another 12-week

intervention that incorporated elastic band resistance training with aerobic activity in women, reporting a decrease in HbA1c from 7.62 ± 0.19% to 6.64 ± 0.17% [128].

Recently, in Malaysia, a quasi-experimental trial was conducted, and researchers looked at the effects of a 16-week progressive elastic band resistance training program on HbA1c levels in those who were aged 50 and above with T2DM. The exercise program consisted of three sets of eight reps of ten exercises performed at home. The exercise was all completed at a high intensity (Borg scale of 16-18) while focusing on fast concentric phases and slower eccentric phases. The study determined that the intervention significantly improved HbA1c levels, decreasing from 9.40 ± 0.79% to 8.06 ± 0.79% [129]. A similar 12-week at-home study in individuals with T2DM and knee osteoarthritis reported significant improvements in a chair stand test and timed up-and-go test [130].

Altogether these data support that elastic band resistance training enhances glycemia as measured by HbA1c. One study also reports improvements in chair stand and timed up-and-go tests in individuals with T2DM and functional limitations; however, the intervention was unsupervised and more evidence is needed to confirm this.

2.4 Knowledge Gap

Currently, a substantial gap in the literature exists regarding elastic band resistance training in older adults with frailty and T2DM. To date, there has been some research investigating the effect of elastic band resistance training in frail individuals alone, while other studies have investigated elastic band resistance training in individuals living with T2DM alone. However, exercise interventions on individuals with both frailty and T2DM are scarce. To the best of our knowledge, only one study investigated the

impact of a resistance exercise and diabetes education intervention on individuals with frailty and T2DM [10]. The MIDFRAIL study was a cluster-randomized multicenter clinical trial conducted in 74 trial sites across seven European countries. The study was a 16-week exercise and education intervention. The study recruited 964 participants 70 years of age or older with T2DM and frailty or pre-frailty based on Fried's frailty scale. The main result of the study was that a multimodal approach including 16 weeks of resistance training and diabetes education significantly and clinically improved physical function in individuals with frailty and T2DM.

Although the MIDFRAIL study was a large clinical trial, it still has its limitations. First, the study only consisted of two to three sets of eight to ten reps for two exercises – a very small amount of exercise when trying to induce physiological changes. Second, the exercise prescription was only for the lower limb, which could lead to musculoskeletal imbalances and impede the physical function of other tasks unrelated to the lower limb. Third, this study had a dropout rate of 20% following randomization. In addition, 20% of the original sample did not meet a compliance of 70%. This could be potentially explained by individuals deeming the exercise sessions as futile due to the limited volume of exercise, making their commitment unjustifiable. Fourth, the study also bought one leg press and one leg extension machine for each of the 74 sites, which would not be financially practical to implement in other societies such as New Brunswick. Finally, no investigation of changes in glycemia and frailty status was reported, although frailty and T2DM were inclusion criteria for the study.

2.5 Objectives and Hypotheses

Based on the gap and the current literature level about exercise in individuals with frailty and T2DM, this study aims to determine whether 16 weeks of diabetes education and elastic band resistance training influences glycemia and physical function.

Hypothesis: We hypothesize that following a 16-week intervention of diabetes education and elastic band resistance training, glycemia and physical function will improve.

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Chapter 3: Article

The Impact of Elastic Band Resistance Training and Diabetes Education on Physical Functions of Individuals with Frailty and Type II Diabetes Mellitus

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3.1 Abstract

Background: Individuals with Type 2 diabetes mellitus (T2DM) or frailty have reduced physical function compared to healthy individuals. Living simultaneously with both T2DM and Frailty exacerbates an individual's physical function. Nevertheless, research shows that resistance training and diabetes education improve glycemia and physical function. However, no studies have investigated the impact of resistance training using elastic bands along with diabetes education on physical function in individuals with T2DM and frailty. **Objective:** We hypothesized that performing 16 weeks of elastic band resistance training along with diabetes education would increase physical function in individuals with T2DM and frailty. **Methods:** Participants (n=72) were included in the Band-Frail program if they were 1) aged $\geq$ 65 years, 2) living with T2DM (HbA1c $\geq$ 6.5%), and 3) if they were at least pre-frail based on Fried's Frailty Scale. The primary exposure variable was a 16 week elastic band resistance training program, which consisted of 50 minutes of supervised resistance training twice a week and 10-20 minutes of diabetes education with a diabetes educator once a week. The primary outcome was physical function, measured by the Short Physical Performance Battery ((SPPB): Score = 0-12). **Results:** Participants in the Band-Frail program had a 100% attendance rate. Physical function significantly improved (pre: 8.3 ± 2.2 vs. post: 9.9 ± 2.1; $p<0.01$) following the 16 week intervention, with 75% of participants improving by a minimal clinically important difference of one point or more on the SPPB. **Conclusion:** Participating in the Band-Frail program enhances physical functions in individuals with T2DM and frailty.

3.2 Introduction

The prevalence of aging is constantly increasing, with the world's population over the age of 65 expected to double by 2050 [1]. This is not trivial since the prevalence of type two diabetes mellitus (T2DM) and frailty increase with age [2–4]. Frailty is characterized by a decrease in the physiological reserve of multiple organs and systems, which increases vulnerability and compromises the ability of older adults to cope with minor stressors [5,6]. On the other hand, T2DM is characterized by chronic hyperglycemia, increasing the risk of micro and macrovascular complications [7,8]. Unfortunately, the simultaneous presence of T2DM and frailty exacerbate one's physical function [9] and increases the burden on the healthcare system [4,10]. Therefore, there is a need to investigate interventions to help prevent and manage the decline in physical function observed in individuals with T2DM and frailty.

It is well documented that diabetes education, aerobic exercise, and resistance training benefit individuals with T2DM [11,12]. Resistance exercise enhances physical function in older adults with T2DM or frailty [13,14]. However, limited data exist on the effects of resistance exercise in individuals with T2DM and frailty. To the best of our knowledge, only one study investigated the impact of resistance exercise and diabetes education in individuals with T2DM and frailty, which found a significant improvement in physical function [15]. However, despite a strong research design, this study has several limitations that might prevent the extrapolation of the program to a real-world environment or the implementation of the program in a community setting. First, each site was equipped with heavy-duty and costly resistance training equipment. Second, the exercise sessions were performed in a healthcare setting. Third, the exercise program only targeted the lower

limbs instead of whole-body resistance training, and only two exercises were performed at each exercise session. These are serious limitations for this population since resistance training equipment can be inaccessible due to financial reasons, clinical settings can be challenging to access, and finally, an intervention targeting the lower limbs might not create an improvement in physical function for the upper limbs needed to improve the activities of daily living [15,16]. Therefore, more suitable exercise interventions, such as whole-body elastic band resistance training may be needed for this population since studies have shown significant improvements in physical function in older adults with frailty or T2DM [13,17–19]. To the best of our knowledge, no study has investigated the effects of elastic band resistance training along with diabetes education in individuals with both T2DM and frailty while overcoming the previously highlighted limitations. Thus, this study aims to investigate the impact of 16 weeks of elastic band resistance training and diabetes education on the physical function of individuals living with T2DM and frailty. We hypothesized that 16 weeks of elastic band resistance training and diabetes education would significantly improve the physical functions of individuals with T2DM and frailty.

3.3 Methodology

3.3.1 Study Design

The Band-Frail study is a case series study investigating the effects of a 16 week elastic band resistance training and diabetes education intervention on physical function in older adults with T2DM and frailty. The community program was run in 14 locations across the province of New Brunswick. The project was reviewed and approved by the University of New Brunswick Research Ethics Board (REB 2020-029).

3.3.2 Participant Recruitment

Participants from Fredericton, New Brunswick, were recruited between March 2021 and September 2022 using community advertising – radio ads, newspaper/newsletter articles, programmatic displays, flyers, and social media. During January of 2022 there was an interruption in recruitment due to COVID-19. Despite the pause in recruitment, 148 participants contacted us. Thirty-five participants decided they were not interested; therefore, 113 participants completed baseline testing. Twelve participants were excluded because they did not meet any of Fried's frailty characteristics. After baseline testing, three participants decided against participating in the lifestyle intervention due to personal reasons and COVID-19. Twenty participants dropped out during the lifestyle intervention due to the following reasons: health issues, travel, personal reasons, and joining another exercise program. Therefore, 74 participants completed the exercise program in Fredericton and were used in the final analysis (Figure 1).

3.3.3 Inclusion criteria

Participants were 1) aged over 65 years 2) classified as frail or pre-frail based on Freid's frailty scale, and 3) self-reported T2DM or confirmed with an HbA1c reading of ≥ 6.5%.

3.3.4 Overview Protocol

Before beginning the intervention, participants came to the Cardiometabolic Exercise and Lifestyle Laboratory (CELLAB) for baseline testing. Participants performed their baseline testing and started the 16 week intervention within one week of baseline testing. Upon the intervention's completion, participants returned to the CELLAB for follow-up testing. These visits were scheduled one week after the final exercise session. The exercise intervention was performed in small groups spread throughout the day. This strategy was chosen because frail participants required closer supervision from our research staff for safety reasons. Thus, exercise groups were limited to five participants.

3.3.5 Exposure Variable

Exercise intervention

Participants performed 16-weeks of elastic band resistance training and diabetes education, which was developed in collaboration with a diabetes educator using the Diabetes Canada guidelines [20]. The intervention consisted of 12 elastic band resistance training exercises that targeted most major muscle groups. Participants were supervised by a research staff member and completed the exercise twice a week for about 50 minutes. Using Borg's rate of perceived exertion (RPE; 6-20) scale, exercise intensity was quantified by each participant. The initial intensity and workload was set to one set

of eight reps at an RPE of 11 and increased to three sets of ten reps at an RPE of 14 by week 16. When the strength of an elastic band was hindering the participant's form, a weaker elastic band was given to the participant by the research staff, while participants were given a stronger elastic band when they accomplished the total volume of exercise at a lower RPE. If participants needed a stronger elastic band than the study could provide, two elastic bands were used at the same time to achieve higher resistance.

Diabetes education

The diabetes education portion of the intervention was developed with a diabetes educator, certified dietitian, and research staff. A diabetes educator delivered the education pieces for 10-15 minutes once a week before the exercise session. The diabetes education consisted mostly of introductory topics regarding T2DM management. Topics included: proper dieting, recipe substitutions, label reading, physical activity guidelines and strategies, footcare and footwear, blood glucose testing, T2DM medications and solutions and tips on how to help manage the micro- and macrovascular complications that arise with T2DM. During the final session, participants took part in a discussion session where they brought any final questions to the diabetes educator and discussed them with the class [15].

3.3.6 Primary outcome measure – Physical function

Physical function was measured using the Short Physical Performance Battery (SPPB). The SPPB was performed according to the standardized protocol [21]. The three-part test was conducted with shoes on and consisted of three incremental balance tests, a walking speed test, and a sit-to-stand test.

For each balance test, a research staff member demonstrated the standing position and then supported the participant into the standing position. A timer was started once the participant let go of the staff member. The timer stopped when the participant moved their foot, reached out to grasp a staff member or once ten seconds had passed. If the participant completed the 10-second stand, they moved on to the next balance test. For the first balance test, participants had to stand balanced with their feet touching side-by-side. The second test was a semi-tandem stand where participants stood with their feet side-by-side, but with the heel of one foot lined up with the ball of the other foot's big toe. The final test was a tandem stand where participants stood with one foot directly in front of the other foot.

To test walking speed, a three-meter walking course with no obstructions was denoted by two “X” taped on the ground. Participants were asked to walk from one X to just past the second X at their normal walking speed – the speed at which they would walk into a grocery store or through the mall. A staff member would start the test by saying “Ready, GO” and starting a timer. The timer was stopped once the participant crossed the second X. This test was repeated twice and the faster of the two trials was used for scoring and analysis.

For the chair stand test, a staff member demonstrated the test first. A flat-backed chair without armrests was placed against the wall. Participants were first asked to cross their arms across their chest, then rise completely from the chair one time. If successful, participants were asked to stand up and sit down five times in a row as fast as they could. A timer began at the start of the first stand and was stopped at the end of the fifth stand.

The test was stopped if the participant used their arms, or took more than one minute to complete five reps.

Results of each domain were rescored according to pre-established cut-points for each section, ranging from 0 (worst performance) to 4 (best performance). The scores were then added to obtain an overall SPPB score that ranges from 0-12. The SPPB has been shown to have very high test-retest reliability with ICCs ranging from 0.88 to 0.92 [22,23]. The test is also reported to have high validity when assessing physical function and activities of daily living [24].

3.3.7 Exploratory measures – Glycemia & Frailty

Glycemia was assessed using hemoglobin A1c (HbA1c), which was measured pre- and post-intervention using the DCA Vantage Analyzer (V 4.4.0.0, Germany). A finger prick was conducted using a Safe-T Pro Plus single-use lancet (Accu-Chek, Roche Diagnostics, Switzerland) to allow for the collection of 1 μL of whole blood. The sample was then loaded into the DCA Vantage Analyzer, where the assessment of HbA1c was conducted. The DCA Vantage Analyzer has been shown to provide accurate, valid measures of HbA1c when compared with laboratory measurements [25,26].

Frailty was measured using Fried's frailty scale. Freid's frailty scale is a five-item frailty scale and includes the following items: I) Self-reported unintentional weight loss of 10lbs OR 5% of their body weight in the past year II) Exhaustion based on the Center for Epidemiologic Studies Depression Scale, III) Lowest 20th percentile in physical activity level based on the Minnesota Leisure Time Activity Questionnaire, IV) Slowest 20th percentile in walking speed based on sex and height, V) Weakest 20th percentile for grip

strength based on sex and body mass index (BMI) [27]. Participants were given a score of one for each criterion they met. The criteria scores were then summed to create a final score. Participants who scored three or higher were considered frail, individuals who scored one or two were considered pre-frail, and those who scored zero were considered robust and excluded from this analysis [27].

Age, sex, ethnicity, smoking, household income, T2DM duration and medications were self-reported. The Caucasian individuals were given a value of one, while other ethnic backgrounds were coded as 0. Household income was stratified into four categories: $0-49,999; $50,000-99,999; ≥ $100,000; didn't know. Additionally, T2DM duration was self-reported in years since the diagnosis, and medications were recorded as a total number of medications for each the following categories: diabetes-related medications, blood pressure medications, and cholesterol medications. Weight was measured using a calibrated column scale (SECA #7000, Hamburg, Germany), and height was measured with a standard stadiometer. Further, BMI was calculated using the following equation: weight (kg)/height (m^2).

3.3.8 Statistical analysis

A power sample calculation was performed to determine the sample size. This calculation was performed using G-power software (version 3.1.9.4, Germany) and an alpha of 0.05, a power of 0.8, and an effect size of 0.34. The effect size of 0.34 was calculated based on the means and standard deviations from the MIDFRAIL study. The MIDFRAIL study reported an average pre and post-intervention SPPB scores of 8.47 ± 2.53 and 9.31 ± 2.40, respectively [15]. A change of 0.34 is smaller than the minimal clinically important

difference (MCID) of 1 point [28], which allows us to detect the MCID. Based on this calculation, an overall sample size of 70 was required. However, we anticipated a drop-out rate of 25.8%, as reported by Rodriguez-Mañas et al. (2019). Therefore, to account for this dropout rate, we recruited 95 participants.

Continuous variables are presented as mean ± SD and categorical variables as N (%). Kolmogorov–Smirnov tests were used to test for normality, and a visual inspection of the data was used to confirm normal distribution. To test the effect of the intervention on physical functions, paired sample t-tests were performed. In addition, the improvement in physical function was reported between sexes and per magnitude of change. Since the MCID for physical function on the SPPB is one point [28], we classified participants as SPPB ≥ 1 point improvement or SPPB < 1 point improvement. Independent sample t-tests were performed to analyze differences in baseline general characteristics between participants above or below the MCID of 1 point improvement. Independent t-tests were also used to determine the difference in physical function improvement between participants above or below the MCID of 1 point. Finally, data management and statistical analyses were performed using SPSS version 16. A p-value less than or equal to 0.05 ($p \leq 0.05$) was considered significant.

3.4 Results

Recruitment opened in March 2021 and closed in September 2022, with an interruption of recruitment in January of 2022 due to COVID-19. Overall, 88 participants completed the program, with 72 participants included in this final analysis. General characteristics of participants are shown in Table 1. The participants' average age was 73.7 ± 5.8 years, and

SPPB score was 8.3 ± 2.1 points. Participants had an average HbA1c reading of 7.6 ± 1.3 percent and diabetes duration of 14.1 ± 10.2 years. The average Freid Frailty score was 1.89 ± 0.96, and 24% of participants were frail. The average adherence rate of participants was 100% in both the diabetes education and elastic band resistance training intervention.

Table 2 shows the impact of the 16-week lifestyle intervention on physical function. Following the intervention, we observed a significant improvement in physical function (SPPB pre: 8.3 ± 2.1 SPPB post: 9.9 ± 2.1; $p<0.001$, Table 2), with 54 (75%) participants improving by at least one point. Each domain score of the SPPB also significantly increased following the intervention, with the greatest improvement seen in the chair stand test (Chair Stand pre: 1.9 ± 1.0 post: 2.9 ± 1.3; $p<0.001$; Balance pre: 3.2 ± 1.1 post: 3.5 ± 0.8; $p=0.004$; Gait Speed pre: 3.3 ± 0.7 post: 3.5 ± 0.7; $p=0.013$). 46 (64%) participants improved by at least one point on the chair stand domain, while 21 (29%) and 23 (32%) participants improved by at least one point on the balance and walking domains, respectively. Both males and females significantly improved their chair stand and total SPPB score (all $p < 0.001$; Table 2), while females also significantly improved their walking ($p=0.013$) and balance scores ($p=0.026$).

The difference in baseline characteristics between participants who improved their SPPB score above or below the MCID is presented in Table 3. Apart from diabetes duration, there were no significant differences in baseline characteristics. Fifty-four (75%) participants improved their SPPB above the MCID of 1-point. Participants who improved by at least 1 point on the SPPB improved their total SPPB score by 31.3 ± 21.0% compared to a reduction of 5.3 ± 8.2% for participants who did not reach a 1-point

improvement ($p< 0.001$; Table 4). Participants who did not reach the MCID significantly declined in the balance domain ($p<0.001$) and non-significantly declined in the walking domain of the SPPB ($p=0.055$). In contrast, participants who reached 1-point improvement on the SPPB significantly improved in both the balance and walking domains ($p<0.001$). Both groups improved their average chair stand score following the intervention (Above MCID: 89.4% ± 104.4 vs. Below MCID: 19.3% ± 58.2; $p=0.004$). As for the secondary outcomes, HbA1c significantly improved after the 16-week intervention. HbA1c scores decreased from 7.6% ± 1.3 to 7.2% ± 1.2, with 31 (43%) participants decreasing their HbA1c by the MCID of 0.3% or more [29].

3.5 Discussion

The main objective of this study was to determine the impact of 16 weeks of elastic band resistance training and diabetes education on physical function and HbA1c of individuals living with T2DM and frailty. The study has several relevant findings for the management of T2DM and frailty. First, this study suggests that individuals living with T2DM and frailty who perform 16 weeks of elastic band resistance training and diabetes education significantly improve their HbA1c and physical function. Second, about 25% of individuals with T2DM and frailty did not improve their physical function above the MCID, reinforcing the concept of heterogeneity in physical function in individuals with T2DM and frailty. Finally, these results provide insight into a practical and accessible approach to managing physical function in individuals living with both T2DM and frailty.

Our study showed a significant improvement in physical function following 16 weeks of elastic band resistance training along with diabetes education. In addition, many participants also improved their physical function above the MCID of 1 point. These results align with other studies that observed improved physical function among individuals with T2DM or frailty following a resistance training intervention [13,15,17]. The Mid-Frail study's effect size of 0.9 points was smaller than our effect size of 1.6 points. A larger workload in our study could explain the greater effect size observed, as we used a whole-body resistance training program, which included 12 exercises, compared to the Mid-Frail study's two exercises and smaller workload. However, this hypothesis should be ruled out since improvements in physical function were not correlated with the total workload completed by participants over the duration of the program (results not shown). Nevertheless, another potential explanation is that we observed a 100% adherence rate in our study, while in the mid-frail study, only 82% of their participants achieved >70% adherence. The difference between our very high attendance rate and the one observed in the Mid-Frail study could be explained by our research staff providing weekly make-up sessions and their strong encouragement toward attendance. Adherence to the intervention strongly predicts exercise intervention efficacy, especially among those with frailty [30]. Taken together, our results suggest that the band-frail study improved physical function above the MCID for the SPPB amongst those with T2DM and frailty.

Finally, we observed a significant reduction in HbA1c of 0.34% ± 0.80 following 16 weeks of elastic band resistance training and diabetes education. Our results align with the findings of Park et al. (2016) who investigated the effects of whole-body elastic band resistance training on HbA1c in females and observed a significant reduction in HbA1c.

However, the effect size observed in the current study (HbA1c reduction -0.34%) was smaller compared to the effect size observed in Park et al.'s study (HbA1c reduction -1.2%). This difference in effect sizes could be explained by the frequency of exercise, which was twice a day for five days a week, while in our study participants trained twice weekly. This is supported by data from the DARE trial that showed a significantly greater reduction in HbA1c following six months of aerobic and resistance exercise (twice the volume when compared to the aerobic exercise or resistance exercise group) in individuals with T2DM [32]. Despite the larger effect size, the long-term sustainability of such an exercise program is questionable when compared to the current study. Contrary to our findings, a meta-analysis of 169 participants, conducted by McGinley et al. (2014) found a nonsignificant reduction in HbA1c of -0.18% in those who completed an elastic band resistance training program when compared to control groups. However, this meta-analysis had several flaws. For example, only randomized controlled trials with small sample sizes were included. Also, they quantified exercise intensity using a percentage of one-repetition maximum. However, the utilization of such a protocol using elastic band resistance training was unclear and not replicable based on their description. In addition, the frailty levels of participants from this meta-analysis were unclear, which could explain the difference in effect size. Together, these results suggest that the Band-Frail program provides similar benefits as traditional resistance training and can improve HbA1c above the MCID in this vulnerable population of frail individuals with T2DM. The current study has limitations that need to be acknowledged. First, the study did not have a non-experimental control group, limiting the conclusions that could be drawn from the present study. Second, the delivery of diabetes education was altered halfway

through the intervention. The diabetes education component transitioned from an in-person delivery to a video-delivered education. Although the content was developed and delivered by the same educator, the alteration in the delivery methods could have changed the participants' perception of diabetes education and impacted the results. Finally, the SPPB test only measures the physical function of the lower limbs. Since our intervention consisted of a mixture of lower and upper body exercises, we might not have captured the improvement in physical function that participants experienced in the upper limbs. Nonetheless, our study is strengthened by our 100% adherence rate, strict control of the exercise intervention, and a high researcher-to-participant ratio during the supervision of the intervention.

3.6 Conclusion

This study suggests that 16 weeks of elastic band resistance training paired with diabetes education improves physical function and HbA1c in older adults with T2DM and frailty. This study provides valuable insight into further understanding the management of T2DM and frailty in individuals living with both chronic conditions. Future studies should confirm these findings using randomized controlled trial designs.

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Table 1: General Characteristics of the study sample.

	Total (n = 72)	Male (n = 37)	Female (n=35)
Age (years)	73.7 ± 5.8	74.9 ± 6.0	72.5 ± 5.6
Male n (%)	37 (51.4)	37 (100)	---
Ethnicity			
White n (%)	70 (97.2)	37 (100)	34 (97.1)
Smoking Status			
Current Smoker n (%)	2 (2.8)	1 (2.7)	1 (97.3)
Household Income n (%)			
Below 50000$	29 (40.3)	15 (40.5)	14 (40.0)
50000$ - 100000$	24 (33.3)	12 (32.5)	12 (34.2)
More than 100000$	9 (12.5)	8 (21.6)	1 (2.9)
Did Not Answer	10 (13.9)	2 (5.4)	8 (22.9)
Body Composition			
Weight (kg)	89.4 ± 19.6	95.0 ± 21.4	83.5 ± 15.8
Body Mass Index (kg/m^2)	31.8 ± 5.8	30.9 ± 6.5	32.7 ± 5.0
Physical Function			
SPPB Score (0-12)	8.3 ± 2.1	8.2 ± 2.3	8.5 ± 2.0
Fried Frailty			
Weight Loss n (%)	3 (4.2)	2 (5.4)	1 (2.9)
Exhaustion n (%)	29 (40.3)	15 (40.5)	14 (40.0)
Physical Activity n (%)	39 (54.2)	21 (56.8)	18 (51.4)
Slowness n (%)	16 (22.2)	8 (21.6)	8 (22.9)
Weakness n (%)	47 (65.3)	23 (62.2)	24 (68.6)
Pre-Frail n (%)	55 (76.4)	27 (73.0)	28 (80.0)
Frail n (%)	17 (23.6)	10 (27.0)	7 (20.0)
Average Score (0-5)	1.89 ± 0.96	1.89 ± 1.05	1.89 ± 0.87
Diabetes Duration			
Average Duration (years)	14.1 ± 10.2	15.4 ± 8.9	12.8 ± 11.5
Hemoglobin A_{1c} (%)	7.6 ± 1.3	7.6 ± 1.3	7.6 ± 1.4
Number of Medications			
Diabetes Medications (#)	1.7 ± 1.0	1.8 ± 0.9	1.7 ± 1.0
Blood Pressure Medications (#)	1.8 ± 1.3	2.0 ± 1.5	1.7 ± 1.1
Cholesterol Medications (#)	0.8 ± 0.4	0.8 ± 0.4	0.8 ± 0.4

Continuous variables are presented as means ± standard deviation. Categorical variables are presented as n (%). SPPB: Short Physical Performance Battery.

Table 2: The impact of the 16-week Band-Frail intervention on SPPB.

	Pre-Test	Post-Test	P-value within group
Total SPPB Score (0-12)			
Male	8.2 ± 2.3	9.5 ± 2.4	0.000
Female	8.5 ± 2.0	10.3 ± 1.8	0.000
Combined	8.3 ± 2.1	9.9 ± 2.1	0.000
Balance Score (0-4)			
Male	3.1 ± 1.1	3.5 ± 0.9	0.062
Female	3.2 ± 1.1	3.6 ± 0.7	0.026
Combined	3.2 ± 1.1	3.5 ± 0.8	0.004
Walking Score (0-4)			
Male	3.3 ± 0.8	3.4 ± 0.8	0.413
Female	3.2 ± 0.7	3.6 ± 0.6	0.013
Combined	3.3 ± 0.7	3.5 ± 0.7	0.013
Chair Stand Score (0-4)			
Male	1.7 ± 1.0	2.7 ± 1.4	0.000
Female	2.0 ± 1.0	3.1 ± 1.1	0.000
Combined	1.9 ± 1.0	2.9 ± 1.3	0.000

Pre-test, post-test and absolute change values are presented as means ± standard deviation. Within group p-values were calculated using paired t-tests. SPPB: Short Physical Performance Battery.

Table 3: General characteristics of the study sample stratified by MCID

	Total (n = 72)	Below MCID (n=18)	Above MCID (n=54)	P-value
Age (years)	73.7 ± 5.8	72.6 ± 5.9	74.1 ± 5.8	0.332
Male n (%)	37 (51.4)	12 (66.7)	25 (46.3)	0.177
Ethnicity				
White n (%)	70 (97.2)	17 (94.4)	53 (98.1)	0.440
Smoking Status				
Current Smoker n (%)	2 (2.8)	1 (5.6)	1 (1.9)	0.440
Household Income n (%)				
Below 50000$	29 (40.3)	9 (50.0)	7 (13.0)	0.934
50000$ - 100000$	24 (33.3)	4 (22.2)	20 (37.0)	
More than 100000$	9 (12.5)	2 (11.1)	20 (37.0)	
Did Not Answer	10 (13.9)	3 (16.7)	7 (13.0)	
Body Composition				
Weight (kg)	89.4 ± 19.4	95.1 ± 26.5	87.6 ± 16.6	0.271
Body Mass Index (kg/m^2)	31.8 ± 5.8	33.3 ± 7.0	31.2 ± 5.3	0.197
Physical Function				
SPPB Score (0-12)	8.3 ± 2.1	9.1 ± 2.4	8.1 ± 2.0	0.098
Fried Frailty				
Weight Loss n (%)	3 (4.2)	1 (5.6)	2 (3.7)	1.000
Exhaustion n (%)	29 (40.3)	9 (50.0)	20 (37.0)	0.409
Physical Activity n (%)	39 (54.2)	11 (61.1)	28 (51.9)	0.590
Slowness n (%)	16 (22.2)	4 (22.2)	12 (22.2)	1.000
Weakness n (%)	47 (65.3)	12 (66.7)	34 (64.8)	1.000
Pre-Frail n (%)	55 (76.4)	11 (61.1)	44 (81.5)	0.109
Frail n (%)	17 (23.6)	7 (38.9)	10 (18.5)	
Average Score (0-5)	1.89 ± 0.96	2.11 ± 1.1	1.8 ± 0.9	0.258
Diabetes Duration				
Average Duration (years)	14.1 ± 10.2	10.7 ± 5.0	15.3 ± 11.2	0.019
Hemoglobin A_{1c} (%)	7.6 ± 1.3	7.5 ± 1.7	7.6 ± 1.2	0.857
Number of Medications				
Diabetes Medications (#)	1.7 ± 1.0	1.9 ± 0.9	1.7 ± 1.0	0.311
Blood Pressure Medications (#)	1.8 ± 1.3	1.4 ± 0.9	2.0 ± 1.4	0.130
Cholesterol Medications (#)	0.8 ± 0.4	0.7 ± 0.5	0.8 ± 0.4	0.367

Continuous variables are presented as means ± standard deviation. Categorical variables are presented as n (%). P-values were calculated with independent t-tests, Fisher's exact tests and chi-square tests. SPPB: Short Physical Performance Battery, MCID: Minimal Clinically Important Difference. Above MCID = ΔSPPB ≥ 1-point, Below MCID = ΔSPPB < 1-point.

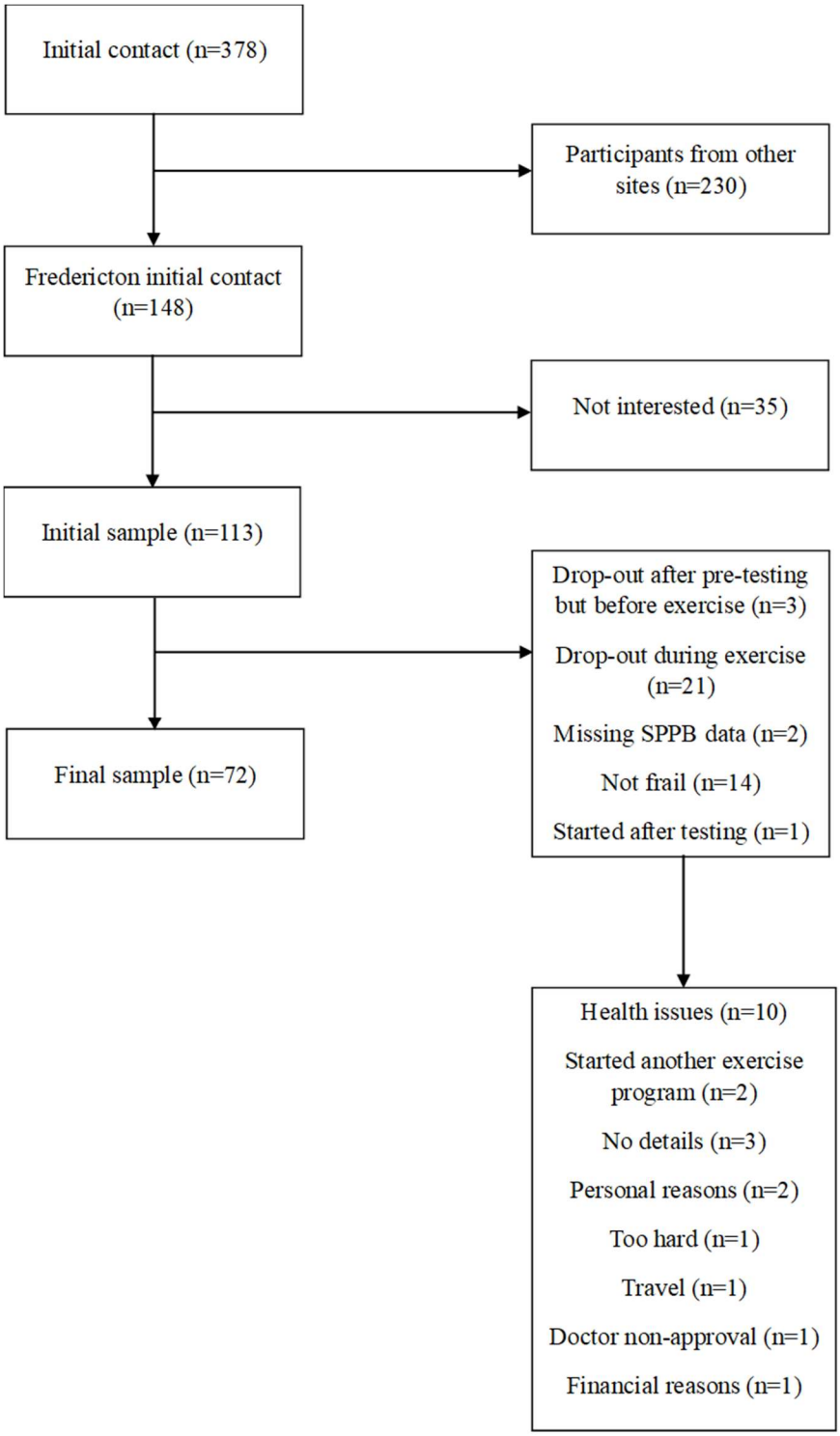
Table 4: The impact of the intervention on SPPB stratified by MCID

	Pre-Test	Post-Test	Absolute Change	P-value within group	P-value between groups
Total SPPB Score (0-12)					
Above MCID	8.1 ± 2.0	10.3 ± 1.8	2.2 ± 1.1	0.000	0.000
Below MCID	9.1 ± 2.4	8.6 ± 2.5	-0.4 ± 0.7	0.016	
Balance Score (0-4)					
Above MCID	3.0 ± 1.1	3.7 ± 0.6	0.6 ± 1.0	0.000	0.000
Below MCID	3.6 ± 0.7	3.1 ± 1.1	-0.4 ± 0.7	0.016	
Walking Score (0-4)					
Above MCID	3.3 ± 0.7	3.7 ± 0.6	0.4 ± 0.7	0.000	0.000
Below MCID	3.3 ± 0.8	3.0 ± 0.8	-0.3 ± 0.7	0.055	
Chair Stand Score (0-4)					
Above MCID	1.8 ± 0.9	3.0 ± 1.2	1.2 ± 1.1	0.000	0.004
Below MCID	2.2 ± 1.4	2.6 ± 1.4	0.4 ± 0.9	0.090	

Pre-test, post-test and absolute change values are presented as means ± standard deviation. Within group p-values were calculated using paired t-tests. Between group p-values were calculated using independent t-tests. SPPB: Short Physical Performance Battery, MCID: Minimal Clinically Important Difference. Above MCID = ΔSPPB $\geq$ 1-point, Below MCID = ΔSPPB < 1-point.

Figures

Figure 1: Participant flowchart



Appendices

Appendix A – Band-Frail Advertisement

UNB EST. 1785 UNIVERSITY OF NEW BRUNSWICK | Cardiometabolic Exercise and Lifestyle Lab

BAND-FRAIL PROGRAM

Are you 65+, living with Type 2 Diabetes, and looking for a way to stay healthy as you age at home?

Benefits:

- **FREE** 16-week supervised exercise and diabetes education program
- Feedback on physical measurements compared to others your age
- Actively work towards staying independent in your home and community

Contact us at CELLAB@UNB.CA or 506-458-7034 for more info!

Curriculum Vitae

Candidate's full name: Isaac Clifford Clark Cull

Universities attended:

- University of New Brunswick, Bachelor of Science in Kinesiology, 2017 - 2021
- University of New Brunswick, Master of Science in Kinesiology, 2021 - Ongoing

Conference Presentations:

- Isaac C Cull, Stephan Dombrowski, (2021). The COVID Binge: A Cross Sectional Survey Examining the perceived effects of COVID-19 on Binge-Watching Behaviour. APES Conference Oral Presentation. (2021 Atlantic Provinces Exercise Scientists and Socio-Culturalists Conference, Fredericton, NB, Canada)
- Isaac C Cull, Stephan Dombrowski, (2021). The COVID Binge: A Cross Sectional Survey Examining the perceived effects of COVID-19 on Binge-Watching Behaviour. AHEAD Collaborative Health Research Conference Poster Presentation. (2021 Atlantic Health Exploration and Discovery Collaborative Health Research Conference, Saint John, NB, Canada)
- Isaac C Cull, Dainel Meister, Danielle Bouchard, Martin Sénéchal, (2022). The impact of 16-week resistance training performed with elastic bands along with diabetes education on physical function, glycemic control, and frailty status in individuals with type 2 diabetes and frailty: Results from the Band-

Frail study. CSEP Poster Presentation. (2022 Canadian Society for Exercise Physiology Conference, Fredericton, NB, Canada)