Evaluation of Practical Exercise Tools for People with Type 2 Diabetes: Resistance Bands and the MyWellness Key Accelerometer

by

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Abstract

There is a need for practical tools to facilitate exercise, an important component of type 2 diabetes (T2D) management. Thesis objectives included: 1) determine the accuracy of the MyWellness Key (MWK) accelerometer in people with T2D; 2) complete a systematic review and meta-analysis of resistance band training (RBT) in T2D; and 3) propose and initiate a randomized exercise trial utilizing MWK accelerometers and RBT.

The MWK accelerometer was validated against objective treadmill testing and physical activity diaries in people with T2D (n=35). The waist-mounted MWK was quite accurate at determining exercise volume and discriminating between exercise intensities, however the bra MWK consistently underestimated exercise intensity. The meta-analysis of seven trials showed that RBT non-significantly improved glycemic control and significantly increased strength in the lower, but not the upper, extremities in people with T2D.
Preface

Chapter 2 was based on the following scientific manuscript:


Author contributions are as follows: S.M contributed to the conception and design of the project, oversaw all testing and equipment, led data collection and analysis, and drafted, reviewed, and edited the manuscript. M.A and S.Z contributed to the conception, design, and discussion and reviewed and edited the manuscript. F.K contributed to data analysis and reviewed and edited the manuscript. R.S contributed to the conception, design, discussion, data analysis and reviewed and edited the manuscript.

Chapter 3 was based on the following scientific manuscript:


Author contributions are as follows: S.M contributed to the conception and design of the project, contributed to discussion, drafted, reviewed and edited the manuscript, and led data collection and analysis. M.A and R.S contributed to the conception and design, discussion, data analysis, data collection and reviewed and edited the manuscript. N. B contributed to the design, discussion, data analysis, and reviewed and edited the manuscript.
As a portion of this thesis is based on scientific manuscripts, there is some repetition in the introduction and methods sections of Chapter’s 2 and 3.
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<td>RBT</td>
<td>Resistance band training</td>
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<td>Electromyographic</td>
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<td>MET</td>
<td>Metabolic equivalent</td>
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<td>RPE</td>
<td>Rating of perceived exertion</td>
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<td>SD</td>
<td>Standard deviation</td>
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<td>MVPA</td>
<td>Moderate-to-vigorous physical activity</td>
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<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</td>
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<td>Thyroid stimulating hormone</td>
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<tr>
<td>8 RM</td>
<td>Eight-repetition-maximum</td>
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<tr>
<td>OMNI-RES</td>
<td>OMNI perceived exertion scale for resistance exercise</td>
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Chapter One: Introduction

1.1 Type 2 Diabetes Mellitus

Diabetes mellitus is a metabolic disorder characterized by hyperglycemia.\textsuperscript{1} Type 2 diabetes (T2D) is a physiologic condition where there is insufficient insulin secretion to maintain blood glucose levels within the normal range, often accompanied by insulin resistance.\textsuperscript{1} In turn, chronic hyperglycemia can cause damage to organs, vessels, and nerves.\textsuperscript{2}

The prevalence of diabetes in Canada increased by 70\% between 1998-9 and 2008-9, and approximately 90\% of these cases are type 2.\textsuperscript{2} As of 2009, there were an estimated 2.4 million Canadians living with diabetes and this number is projected to grow to 3.7 million by 2019.\textsuperscript{3} The dramatic rise in the prevalence of T2D can be attributed to longer survival, rising obesity rates, an aging population, sedentary lifestyles, and changes in the ethnic makeup of Canada due to immigration (non-Caucasians are at greater risk of T2D than Caucasians).\textsuperscript{4} Diabetes is the leading cause of blindness, end-stage renal failure, and non-traumatic amputation in Canada.\textsuperscript{4} In addition, cardiovascular disease is the leading cause of death for individuals with diabetes, occurring two-to-four times more frequently than in those without diabetes.\textsuperscript{4} The treatment of diabetes and the complications listed above have placed tremendous strain on our publicly funded health care system. In 2010, it was estimated that the total annual economic burden of diabetes in Canada was $12.2 billion dollars.\textsuperscript{4}

Negative health outcomes, and the associated economic burden, can be reduced by managing diabetes well. Aerobic exercise has been shown to help those with T2D achieve a vast array of health benefits.\textsuperscript{5} In addition, aerobic exercise can prevent or delay the development of diabetes in those at high risk.\textsuperscript{6}
1.2 Aerobic Exercise in Type 2 Diabetes Mellitus

1.2.1 Benefits of Aerobic Exercise and Current Guidelines

Aerobic exercise is a type of physical activity (PA) that involves continuous, rhythmic movements of large muscle groups performed in bouts of ten minutes or more. Examples of aerobic exercise include: brisk walking, bicycling or jogging.\(^5\) There is an abundance of research demonstrating the positive impact of aerobic exercise on health outcomes, which is why the Canadian Diabetes Association (CDA) recommends 150 minutes of moderate to vigorous aerobic activity spread out over at least three days of the week.\(^5\)

Large prospective cohort studies have demonstrated the benefit of aerobic exercise in people with T2D. One cohort study\(^7\) prospectively followed 3708 Finnish patients with T2D and found that a moderate or high level of PA was associated with a reduced risk of total and cardiovascular mortality. Reduced risk was found after controlling for body mass index (BMI), blood pressure (BP), total cholesterol, and smoking. Another large cohort study\(^8\) prospectively followed 2896 adults with diabetes and again found that higher levels of walking and total PA were associated with decreased incidence of all-cause mortality and cardiovascular disease mortality. Participants who reported walking at least two hours per week had a 39% lower all-cause mortality rate and a 34% reduced cardiovascular disease mortality risk compared to those participants who reported no walking, after controlling for age, sex, race, BMI, smoking, utilization of health care services, attempts to lose weight, and comorbid conditions.

A sub-study of the Nurses’ Health study\(^9\) prospectively followed 5125 female nurses with diabetes and found that those who engaged in a greater volume of vigorous aerobic activity per week had a lower relative risk of cardiovascular disease. This sub-study found that PA volume was inversely associated with coronary heart disease and ischemic stroke. Lastly, in the Health
Professionals Follow-up Study (HPFS)\textsuperscript{10} 2803 men with T2D were assessed to determine the relationship between PA and risk of cardiovascular disease. Study participants were followed for 14 years and it was determined that PA was associated with a lower risk of cardiovascular disease and total mortality. Furthermore, walking was inversely associated with mortality and a faster walking pace was inversely associated with cardiovascular disease, fatal cardiovascular disease, and total mortality independent of the total amount of time spent walking.

Several systematic reviews and meta-analyses have investigated the effect of structured exercise interventions on glycemic control reflected by hemoglobin A1C (HbA\textsubscript{1c}). HbA\textsubscript{1c} reflects the proportion of hemoglobin that is glycated, which thereby gives an indication of the average blood glucose concentration over the previous two-to-three months. HbA\textsubscript{1c} values are expressed as a percentage. Normal values are between 4 to 6\%, while those with diabetes typically have HbA\textsubscript{1c} values upwards of 6.5\%.\textsuperscript{11} The importance of maintaining low HbA\textsubscript{1c} values was shown by the UK Prospective Diabetes Study (UKPDS).\textsuperscript{12} The UKPDS was designed to determine whether intensive blood-glucose control reduced the risk of microvascular or macrovascular complications in individuals with T2D. Results indicated that with each 1\% absolute reduction in mean HbA\textsubscript{1c} (e.g. from 8\% to 7\%) there was a reduction of risk for microvascular disease by 37\%, any end-point related to diabetes by 21\%, deaths related to diabetes by 21\%, and myocardial infarction by 14\%.\textsuperscript{13} Two separate meta-analyses\textsuperscript{14,15} found that lower HbA\textsubscript{1c} was associated with a decreased risk for macrovascular complications in individuals with T2D.\textsuperscript{14,15} The clinical importance of HbA\textsubscript{1c} has resulted in it being a focus and primary outcome of many research studies.

A meta-analysis\textsuperscript{16} of randomized controlled trials was conducted to assess the effect of structured aerobic exercise training on change in HbA\textsubscript{1c} in people with T2D. Eighteen trials were
pooled in this meta-analysis, which found that HbA$_{1c}$ decreased by 0.73% in the structured aerobic exercise group as compared with control. Other systematic reviews and meta-analyses found that structured aerobic exercise interventions decreased HbA$_{1c}$ by 0.60%$^{17}$ and 0.67%$^{18}$ compared to the control group in people with T2D.

Aerobic exercise is not only helpful in those with T2D, but can reduce the incidence of diabetes in persons at high risk. The Diabetes Prevention Program Research Group conducted a large randomized controlled trial$^{19}$ in persons at high risk of developing diabetes. This trial demonstrated that the incidence of diabetes can be decreased by 58% in people with impaired glucose tolerance through moderate aerobic exercise (mainly brisk walking) and weight loss compared to a control group that did not receive the lifestyle intervention.

**1.2.2 Objective Measurement of Aerobic Exercise**

Objective measurements of PA are utilized in research because measures of self-reported activity such as questionnaires, surveys, and interviews have potential limitations such as recall error and socially desirable responses.$^{20}$ Both accelerometers and pedometers are widely used in research as they can objectively monitor PA. Pedometers are worn on the belt or waistband and record walking behaviour. The main outcome measure of pedometers is steps taken, and these devices may also estimate distance.$^{21}$ The accelerometer, another type of activity monitor, is able to capture the frequency, duration, *and intensity* of physical movement, usually in a time-stamped manner.$^{21}$ Accelerometers measure acceleration of the body (change in velocity per unit time) which allows accelerometers to quantify movement intensity.$^{22}$ Accelerometers can be uni-, bi-, or triaxial and can be sensitive to movements in the vertical, mediolateral, and anterior-posterior planes.$^{22}$
Most accelerometers currently in use are piezoelectric sensors, consisting of a piezoelectric element and a seismic mass, that detect acceleration.\textsuperscript{23} During physical movement, the seismic mass causes the piezoelectric element to experience deformation through either bending, direct tension, or compression.\textsuperscript{23} These changes result in the build-up of charge on one side of the sensor thereby generating an output voltage signal that is proportional to the applied acceleration from the physical movement.\textsuperscript{23} The raw outputs of accelerometers are activity counts, and the period over which the counts are averaged is termed an epoch.\textsuperscript{23}

There are several limitations to the use of accelerometry, the first being the inability to accurately assess non-ambulatory activities such as cycling.\textsuperscript{22} Another limitation to accelerometry is the discrepancy among different accelerometer models, and even among different publications on the same accelerometer, in thresholds between light, moderate and vigorous intensity PA. There is great variability in prediction equations which leads to differences in activity range cut-points. For example, the moderate intensity activity range begins at approximately 200 counts per minute and can range to 2000 counts per minute depending on the reference source.\textsuperscript{21} Despite these limitations, accelerometers are valuable tools as they can monitor PA objectively and capture the intensity, duration, and frequency of human movement. Data collected via accelerometers are useful to monitor the effect of PA interventions and provide information about the effect of different exercise modalities, intensities, and frequencies on health outcomes.

The MyWellness Key\textsuperscript{TM} (MWK) (Technogym, Cesena, Italy) is a uniaxial accelerometer that measures acceleration (ranging in magnitude from 0.06g to 12.0g) at a sampling frequency of 16 Hz. Acceleration is measured in gravitational acceleration units (g), where 1 g = 9.8 m·s\textsuperscript{-2}. The MWK accelerometer has been validated in healthy, normal weight populations and found to
measure walking and running speeds accurately.\textsuperscript{24-26} A small validation study\textsuperscript{25} of 16 participants, average age 40.2±12.6 years, found the MWK to have a high concurrent validity with the ActiGraph accelerometer during treadmill walking (\(r = 0.91\)) and free-living activity (\(r = 0.73-0.76\)). Another study of 30 participants,\textsuperscript{24} average age 24.5±2.6 years, found that the predicted VO\(_2\) from the MWK and oxygen consumption measured via indirect calorimetry was highly correlated during a treadmill protocol (\(r = 0.94\)). Lastly, a study of 25 participants\textsuperscript{26} with an average age of 27.6±4.5 years, found the MWK to be a valid tool using indirect calorimetry during a treadmill protocol (\(r = 0.90\)). The treadmill protocol was 20 minutes in length and consisted of 4 stages, where the treadmill speed ranged from 2.25 KM/H – 7.24 KM/H. The above MWK validation studies were conducted primarily on healthy, non-obese participants. Waist-worn accelerometers have been thought to possibly have reduced accuracy in people who are obese (BMI 30 kg/m\(^2\) or greater) because obesity might alter mechanical efficiency or the orientation of the accelerometer.\textsuperscript{27} Thus, there is a need to validate the MWK in people who are older and overweight. Most people with T2D are older and overweight.

The MWK is valuable in the research setting as the data can be downloaded to a computer via an internal USB attachment. The online portal, the MyWellness Cloud, allows multiple users to be synced to the same portal and followed by a coach (or researcher) who can access all PA information and connect with the participants. All information collected on the portal can be easily exported to a spreadsheet. In \textbf{Chapter 2} the results of the MWK validation study in people with T2D are described. The MWK categorizes all activity into three intensity classifications: light (1.1 – 2.9 metabolic equivalents (METs)], moderate (3.0-5.9 METs), and vigorous (at least 6.0 METs). A MET can be defined as “the quantity of oxygen consumed by the body from inspired air under basal conditions and is equal on average to 3.5ml oxygen/kg per
The MET is considered to be a simple unit for expressing the energy cost of different physical activities as a multiple of the resting metabolic rate. The energy cost associated with different physical activities has been described in the Compendium of Physical Activities as a multiple of the standard resting energy value.

While the Compendium of Physical Activities has received widespread acceptance, there are some limitations with using the MET values described, especially in extrapolating them to people who are overweight or obese. A study of 769 men and women was conducted to determine the resting metabolic rate and the energy cost of walking on a treadmill at 5.6 KM/H, measured via indirect calorimetry. This study found that the resting oxygen consumption in the study population was lower than 3.5ml oxygen/kg per minute (the value used to determine MET values in the Compendium of Physical Activities) and that resting oxygen consumption was strongly predicted by fat mass and fat free mass. The average resting oxygen consumption for the total study population was 2.6±0.4ml oxygen/kg per minute. As a result of the lower resting oxygen consumption found in this study population, the MET value assigned to walking 5.6 KM/H on a treadmill was on average 22% higher than the MET value determined when using the standard resting oxygen consumption of 3.5ml oxygen/kg per minute. This discrepancy demonstrates the limitations of using the standard resting oxygen consumption to determine the metabolic cost of an activity.

Objective measurement of physical activity should be reliable, valid, accurate, and precise. Definitions of these terms are as follows: (1) reliability refers to the extent that the measuring procedure yields the same results on repeated trials; (2) validity refers to the extent that a measuring procedure is measuring what it is intending to measure; (3) accuracy refers to a lack of bias; and (4) precision refers to the degree of closeness that repeated measurements
display and is often measured using the standard deviation. Currently, there are several accelerometer models on the market and some of the most popular models are the Actigraph (Actigraph, Pensacola, FL), the Actical (Phillips Respironics, Bend, OR), and the RT3 (Stayhealthy Inc, Monrovia, CA). A comprehensive study evaluated the validity of nine published and two proprietary energy expenditure prediction equations for these three different accelerometers. This validation study had 277 participants complete both treadmill activity and activities of daily living such as household chores and sporting activities. To describe the magnitude of the difference between the energy expenditure reported by the accelerometers and the energy expenditure measured via indirect calorimetry the root mean squared error (RMSE) was determined, as well as the bias. Actigraph prediction models underestimated energy expenditure 72% of the time and the RMSE ranged from 0.5 METs to 6.2 METs. Bias for the Actigraph prediction models ranged from -5.9 METs to 2.1 METs. Actical prediction models underestimated energy expenditure 79% of the time and the RMSE ranged from 0.5 METs to 5.9 METs. Bias for the Actical prediction models ranged from -5.7 METs to 2.7 METs. Finally, RT3 prediction models underestimated energy expenditure 73% of the time and the RMSE ranged from 1.0 kcal to 7.9 kcal. Bias for the RT3 prediction models ranged from -7.6 kcal to 2.1 kcal.

Figure 1 The MyWellness Key accelerometer with the display screen showing the user’s daily goal has been achieved
1.3 Resistance Exercise in Type 2 Diabetes Mellitus

1.3.1 Benefits of Resistance Exercise and Current Guidelines

There has been a substantial amount of research into the effect of resistance training on people with T2D. The strongest evidence of the value of resistance training in T2D is from trials in which the resistance exercise was performed using free weights or weight machines.\textsuperscript{35-39} In the Diabetes Aerobic and Resistance Exercise (DARE) trial, Sigal et al.\textsuperscript{37} randomized 251 previously-sedentary patients with T2D to aerobic exercise (AER), resistance exercise (RES), aerobic plus resistance exercise (AER+RES) or a sedentary control. Absolute HbA\textsubscript{1c} changes compared to control were a reduction of 0.51\% in the AER group, 0.38\% in the RES group, and 0.97\% in the AER+RES group. The AER+RES intervention resulted in an additional absolute HbA\textsubscript{1c} reduction of 0.46\% when compared to AER and 0.59\% when compared with RES. All of these differences were both statistically and clinically significant. The primary finding of this large, well-designed randomized controlled trial was that the combination of two different exercise modalities (AER+RES) resulted in the most dramatic reduction in HbA\textsubscript{1c}. In addition, an economic analysis\textsuperscript{40} of this trial demonstrated that the AER+RES exercise intervention was highly cost effective. From a societal (single-payer) perspective, the incremental cost per quality-adjusted life-year of the combined aerobic plus resistance exercise program was $37,872, in the scenario where the single payer would cover costs of gym membership and periodic personal trainer sessions for life. This cost would be considered good value for money.\textsuperscript{40}

Another large randomized controlled trial, the Health Benefits of Aerobic and Resistance Training in individuals with T2D (HART-D)\textsuperscript{38} demonstrated similar results as the DARE trial. Church et al. followed a similar group design to the DARE trial by randomizing 262 previously
sedentary men and women with T2D to either AER, RES, AER+RES, or a sedentary control. One of the major differences between the HART-D and the DARE trial was that all groups (minus the control) had the same duration of weekly exercise in the HART-D. All participants trained three times per week for a similar duration, and the total length of the study was nine months. The only group in which a statistically significant decrease in HbA$_1c$ occurred was the AER+RES group (0.34%); the AER only group showed a similar, yet not statistically significant decrease in HbA$_1c$ (0.24%). This study demonstrated that the combination of both aerobic and resistance exercise was most beneficial for greater glycemic control in individuals with T2D. In addition, the HART-D study showed that the combination of aerobic and resistance exercise was the most beneficial for glycemic control even when total exercise time was held constant. HbA$_1c$ changes were smaller in HART-D than in DARE at least in part because the DARE investigators took measures to minimize medication changes while the HART-D investigators did not.

In the Italian Diabetes and Exercise Study (IDES) conducted by Balducci et al.,$^{35}$ 606 previously sedentary individuals with T2D were randomized to either twice weekly gym-based supervised AER+RES plus structured exercise counselling or structured counselling alone for 12 months. Like the DARE and HART-D trials, the IDES trial found that those in the combined AER+RES group had a significant reduction in HbA$_1c$ (0.30%) compared to the counselling-only control group, and also had superior changes in essentially all other variables studied, including: physical fitness; systolic and diastolic BP; high-density lipoprotein; low-density lipoprotein; cholesterol level; waist circumference; BMI; insulin resistance; inflammation; and cardiovascular risk scores. The IDES study demonstrated that those in the AER+RES group reported a better quality of life on the 36-Item Short Form (SF-36) Health Survey.$^{41}$ The IDES study further solidified the notion that the combination of aerobic plus resistance exercise
contributes to an improvement in glycemic control. The DARE, HART-D, IDES and other trials on resistance training have clearly shown that resistance training in those with T2D can lower HbA1c, increase insulin sensitivity, increase strength (assessed via five-to-eight repetition maximum, or peak torque and total work), and improve quality of life.

Several systematic reviews have pooled data from multiple studies to demonstrate the effectiveness of exercise on reducing HbA1c levels. A meta-analysis of 47 trials by Umpierre et al. showed the effects of structured exercise (AER, RES, or AER+RES) on HbA1c levels in individuals with T2D. The AER group showed a decrease in HbA1c of 0.73%, while the combination of AER+RES was shown to reduce HbA1c levels by 0.51%. However the AER only studies, on average, had higher baseline HbA1c levels, greater exercise frequency, and a lower proportion of intention-to-treat analyses, thus a bias was introduced which may have resulted in a relative overestimation of the effect of the AER group. In another meta-analysis of 34 trials by Chudyk and Petrella, the combination of AER+RES reduced HbA1c levels by 0.67%. In addition, this review showed that the combination AER+RES exercise significantly reduced BP, triglycerides, and waist circumference. As a result of the substantial evidence for the benefit of exercise, specifically the combination of aerobic and resistance exercise, the CDA recommends that individuals with diabetes and those at risk for the development of diabetes engage in 150 minutes of moderate-to-vigorous intensity aerobic exercise each week, as well as resistance exercise at least two times per week.

1.3.2 Barriers to Resistance Exercise

The studies mentioned above have demonstrated the wealth of evidence for the role of resistance exercise in the management of T2D. Despite this wealth of evidence, many individuals with diabetes are not meeting the recommended activity levels. Prior to the DARE, HART-D,
and IDES trials Plotnikoff et al.\textsuperscript{49} studied key demographic and health factors associated with participation in PA among those with T2D (n=1614). In this large study it was found that 71.9% of participants were not meeting the PA recommendations of 150 minutes of moderate-to-vigorous activity per week. Further analysis\textsuperscript{50} indicated that the most prevalent mode of PA was walking in which 55% participated, while only 12% engaged in resistance training.

There are many potential barriers which could deter people from participating in traditional resistance training with free weights or weight machines, such as the need to travel to a gym, the cost of a gym membership, and/or the cost and space requirements of home equipment. A systematic review\textsuperscript{51} evaluated the current knowledge on barriers to regular exercise among individuals either at high risk or already diagnosed with T2D. In addition to those mentioned above, some of the barriers to participation in regular exercise were: lack of culturally sensitive facilities, lack of convenient facilities, unwillingness to exercise with people who do not have T2D, not wanting others to know how unfit they are, fear, and shame. Because of the known health benefits of engaging in resistance exercise, research efforts must focus on ways to increase initiation to, and maintenance of resistance exercise programs by reducing barriers to participation that are found with traditional resistance training. Consequently, there is a need to evaluate the efficacy as well as the effectiveness of more user-friendly, inexpensive, and easily accessible forms of resistance exercise in order to increase participation in this important exercise modality.

\textbf{1.4 Resistance Band Exercise}

One potential alternative to traditional resistance training using free weights and/or weight machines (the resistance training methods used in the DARE, HART-D, and IDES trials) is resistance band training (\textbf{RBT}). Thera-Band™ latex bands are a type of resistance band used
for progressive resistance training. The bands are available in eight progressive levels of resistance determined by the thickness of the band. The stepwise increase in resistance is also noted by their color-coded progression: tan, yellow, red, green, blue, black, silver, and gold (Figure 2). The force produced by the bands is directly related to elongation, with greater elongation resulting in greater force. The force produced varies because of band thickness and elongation, and can be as low as 0.5 kg (yellow band, 25% elongation) or as high as 18.2 kg (gold band, 250% elongation). Proper usage of these exercise bands allows for both eccentric and concentric contractions. Resistance bands are relatively inexpensive, portable, safe, and can be used for a variety of different exercises.

The CDA has endorsed the “Physical Activity and Exercise Resource Manual” that was developed by Dr. Jonathon Fowles as a means to help educate diabetes care providers on how best to counsel their patients with diabetes on PA. One component of this resource manual is a home-based RBT program for use in individuals with T2D. Results of a before-after study using the resistance band program are encouraging. In one study, 32 nondiabetic subjects (mean age 66 years) were tested before and after 11 months of supervised home-based RBT. Results indicated that systolic BP decreased from 129 to 123 mmHg, and mean LDL-cholesterol decreased from 3.20 to 3.02 mmol/L. However, a randomized controlled trial evaluating this home-based RBT program in individuals with T2D is still needed. The effect of resistance training using resistance bands has been explored by other researchers but these studies had significant shortcomings. A detailed systematic review and meta-analysis of the effect of RBT on people with T2D is presented in Chapter 3.
1.4.1 Resistance Band Exercise in Other Populations

Resistance bands have been utilized as a method of resistance training in nondiabetic populations as well. In a population of 45 sedentary middle aged women without T2D randomized to RBT, resistance exercise training with weight machines, or control, it was shown that resistance bands and weight machines both produced significant increases in fat-free mass and decreases in fat mass. In addition, both groups (RBT and weight machines) significantly improved their upper body muscle endurance (knee push-up test) and muscle power of the lower extremities (maximum number of squats in one minute). This study found no significant differences between the intervention groups, demonstrating that the use of resistance bands was as beneficial as using weight machines. An eight week study of 42 physically fit women demonstrated resistance bands produced similar strength gains versus weight machines/free weights. In this study, strength gains were assessed by increases in maximal isometric voluntary
contraction via a load cell. Results indicated that both groups (RBT and weight machines/free weights) had significant and equivalent improvements in isometric force.\textsuperscript{57}

Another randomized controlled trial\textsuperscript{58} was conducted in 14 healthy physically active males to determine if two different modes of resistance training (free weights versus RBT) resulted in different manifestations of fatigue. In this study, increases in elastic resistance were achieved by either increasing the thickness of the band or increasing the number of resistance bands placed in parallel. Moreover, authors of this study used resistance bands in a unique manner as they replaced the weights on a weight machine with resistance bands, using as many as 21 resistance bands in parallel to achieve the desired resistance. Results showed that there was no difference in the level of fatigue resulting from the two different modes of resistance training. Lastly, a study investigated the differences in muscle activation [as assessed by electromyographic (EMG) activity] and perceived loading (via the Borg CR10 scale) between RBT and free weights in 16 females. EMG activity was not statistically different between free weights and RBT and perceived loading was moderately to very strongly related to normalized EMG activity (r=0.59-0.92). Authors concluded that comparably high levels of muscle activation were obtained during resistance exercise with free weights and elastic bands. These studies in nondiabetic populations have demonstrated that RBT as a method of resistance training may be comparable to those seen with free weights/weight machines.

\textbf{1.5 Thesis Objectives}

T2D is a serious condition, but glycemic control can be improved significantly by meeting current exercise guidelines established by the CDA. Participation in both aerobic and resistance exercise can result in tremendous benefit in people with T2D, but participation rates
are low. Thus the objective of this thesis was to evaluate two practical exercise tools for people with T2D.

The specific aims of this investigation were:

1. To complete a field validation and examine the accuracy of the MWK accelerometer against objective laboratory treadmill testing and PA diaries in people with T2D
2. To systematically review randomized controlled trials investigating the effects of exercise interventions using RBT on glycemic control (HbA1c), or strength in adults with T2D
3. To propose a pilot randomized controlled exercise intervention trial that utilizes practical exercise tools in people with T2D
Chapter Two: **Assessment of the MyWellness Key Accelerometer in People with Type 2 Diabetes**

### 2.1 ABSTRACT

**BACKGROUND/AIM:** Accelerometers are designed to measure PA objectively. The MyWellness Key (MWK) accelerometer has been validated primarily in younger, normal weight populations. The aims of this study were to examine the accuracy of the MWK against directly measured lab-based exercise and free-living PA in people with T2D, many of whom are older and overweight or obese.

**METHODS:** Thirty-five participants with T2D completed the protocol, which included a laboratory-based session and a free-living phase. In the laboratory visit, participants completed a structured treadmill protocol wearing MWKs on each hip (all subjects) and bra cup (women only). The speed where each MWK switched from recording light to moderate intensity activity was determined for each MWK worn. In the free-living phase, participants wore the MWK for all waking hours for two weeks, and recorded exercise in PA diaries immediately after each exercise session.

**RESULTS:** The mean cut-points between low (“Free”) and moderate (“Play”) intensity for the right and left waist-worn MWKs were 4.1±0.5 KM/H and 5.0±0.9 KM/H for the bra-mounted MWK; ideal cut-point would be 4.0 KM/H. In the free-living phase, Spearman correlations between PA recorded in diaries and by MWKs were 0.81 (95% CI: 0.76, 0.85; P<0.001) when waist-worn, but only 0.66 (95% CI: 0.53, 0.77; P<0.001) when on the bra.

**CONCLUSION:** The waist-worn MWK measured PA volume accurately, and was acceptably accurate at discriminating between low and moderate intensity PA, in people with T2D. The MWK underestimated PA volume and intensity when worn on a bra.
2.2 INTRODUCTION

The prevalence of T2D is increasing dramatically and is associated with increased morbidity and mortality.\textsuperscript{59,60} Regular participation in PA is important in the management of T2D, as it contributes to improved glycaemic control and reduces many metabolic and cardiovascular risk factors.\textsuperscript{5,61} Unfortunately, many of those with T2D do not regularly engage in PA.\textsuperscript{62} Furthermore, self-selected walking pace in people with T2D is often slower than would be optimal for achievement of health benefits.\textsuperscript{63} As a result, two major concerns have emerged in diabetes therapy: how to increase PA and how to accurately monitor PA levels.

Accurate, objective measurement of PA is valuable in developing intervention strategies. Objective measurement of PA is of importance when examining dose-response relationships to exercise, to specify which aspect of PA is important for a particular health outcome, (e.g. intensity or volume) and to monitor the effect of a particular intervention.\textsuperscript{22} Furthermore, objective measurement of PA can provide insight to temporal patterns of PA, and the way activities are inter-dependent (i.e. how one activity impacts the next). Accelerometers capture the frequency, duration, and intensity of physical movement and can categorize movement into light, moderate, and vigorous intensities.\textsuperscript{21,64} Recent technological advances have allowed reductions in both the size and price of accelerometers, making them an attractive option for objective monitoring of PA for researchers and the general public.\textsuperscript{21} The MWK is a light-weight (18.7 g), uniaxial accelerometer designed to be worn on a belt clip or waistband. The MWK accelerometers’ data can be downloaded to an interactive web-based portal via an internal USB attachment. The MWK device screen gives feedback to the user, including calories burned and time in each exercise intensity.
The MWK has been formally evaluated in healthy, largely younger and non-obese populations and has also been used to monitor PA in clinical studies. However, this device has yet to be tested for accuracy in people with T2D, most of whom are older and overweight or obese. Thus, the main aim of this study was to complete a field validation and examine the accuracy of the MWK accelerometer against objective laboratory treadmill testing and PA diaries in people with T2D.

The MWK is designed to be mounted on a belt or waist band, which many women do not routinely wear. We therefore also evaluated the accuracy of measurements by the MWK mounted on a bra cup.

2.3 MATERIALS AND METHODS

2.3.1 Participants

Thirty-five volunteers, 21 males and 14 females, were recruited through flyers and referrals from Diabetes Educators at the regional Diabetes, Hypertension and Cholesterol Clinic in Calgary, Alberta, Canada. Participants were eligible for inclusion if they had physician-diagnosed T2D, were at least 35 years old, and could walk without impairment on a treadmill at a moderate pace for 20 minutes. The protocol was reviewed and approved by the Conjoint Health Research Ethics Board of the University of Calgary and Alberta Health Services, and all participants provided written, informed consent.

2.3.2 Instruments

2.3.2.1 Anthropometrics and Blood Pressure

Height was taken using a stadiometer with shoes removed. Weight and waist circumference were collected in light clothing without shoes. BMI was calculated as (weight in
kg)/(height in m)^2. Waist circumference was measured midway between the lowest rib and the top of the iliac crest, at the mid-axillary line and measured to the nearest 0.1 cm. Three measures of resting systolic and diastolic BP were taken at one-minute intervals using a digital BP monitor (BPTru, Omron, HEM-907, Vernon Hills, Illinois); the mean of the three measures was taken as the true BP. The mean BP was found for each of three different positions: seated with the back supported, standing, and supine.

2.3.2.2 MyWellness Key Accelerometer

The MWK is a uniaxial accelerometer that measures acceleration (ranging in magnitude from 0.06g to 12.0g) at a sampling frequency of 16 Hz. The MWK uses propriety software to classify PA into three different categories based on the intensity of the movement; light [“Free”; less than 3 METs), moderate (“Play”; 3-5.9 METs), and vigorous (“Run”; at least 6 METs). The MWK data can be downloaded to an online portal and be exported to a spreadsheet.

2.3.2.3 Physical Activity Diary

For the two-week free-living period participants completed a PA diary of their aerobic exercise sessions (walking). Participants recorded the date, time (in minutes) spent exercising, type of exercise (e.g. outdoor walking, treadmill), and their rating of perceived exertion (RPE) according to the modified Borg 1-10 Scale, which was prompted on the PA diary.

2.3.2.4 Heart Rate Monitor

Each participant was fitted with a Polar FT1 heart rate monitor (Polar Electro Oy, Kempele, Finland) during the treadmill protocol to ensure they did not reach greater than 85% of their age predicted maximum heart rate. Participants were loaned a heart rate monitor for the two week free-living phase to wear during their aerobic exercise sessions. Participants were told the heart rate range they achieved when walking between 4.0 and 6.4 KM/H (2.5-4.0 MPH) during
the treadmill protocol and asked to keep their heart rate within those limits for their free-living at home walking sessions.

2.3.3 Procedure

2.3.3.1 Laboratory phase

Each participant was fitted with two MWK accelerometers for the laboratory portion of the trial, one placed at the anterior midline of each hip, as per the manufacturer’s directions. In addition to the hip-mounted MWKs, female participants were fitted with a third MWK for the laboratory portion which was clipped to the superior aspect of the bra cup and angled to be as horizontal as possible. Participants walked on a treadmill calibrated according to the American College of Sport Medicine’s resource manual for guidelines for exercise testing and prescription at speeds beginning at 3.2 KM/H (2.0 MPH), increasing by a small increment every two minutes until they reached 7.2 KM/H (4.5 MPH) (Table 1). The treadmill incline remained flat throughout the treadmill protocol and participants were instructed to avoid grasping the handles on the sides of the treadmill.
Table 1 Treadmill protocol

<table>
<thead>
<tr>
<th>Stage</th>
<th>Speed (KM/H)</th>
<th>Speed (MPH)</th>
<th>METs</th>
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<tr>
<td>1</td>
<td>3.2</td>
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<td>3.7</td>
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<tr>
<td>3</td>
<td>4</td>
<td>2.5</td>
<td>3.0</td>
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<tr>
<td>4</td>
<td>4.3</td>
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<td>5</td>
<td>4.8</td>
<td>3</td>
<td>3.5</td>
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<td>5.6</td>
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</tr>
<tr>
<td>8</td>
<td>7.2</td>
<td>4.5</td>
<td>7.0</td>
</tr>
</tbody>
</table>

MPH, miles per hour; KM/H, kilometers per hour; METs, metabolic equivalents

2.3.3.2 Free-living phase

Following the laboratory session, male participants were loaned one MWK to be worn on the left hip and female participants were loaned two MWKs, one for the left hip and one to be clipped on the left bra cup. All participants were asked to engage in at least 30 minutes of walking or jogging, at least three times per week for a two week period. Participants were asked to wear their MWK accelerometers for all waking hours, except when bathing or swimming, for the two week period and to wear a heart rate monitor while participating in aerobic activity. Participants recorded each exercise session in their PA diary immediately after the session. In addition, participants were asked to record the MWK reading for minutes in light, moderate, and vigorous intensity (found on the MWK screen) before and after their aerobic exercise session to
isolate the time spent in the exercise session. Participants downloaded their MWK information at least once per week.

### 2.3.4 Statistical Analysis

Statistical Analysis was performed using SAS 9.2 (SAS Institute, Cary, North Carolina) and R (R Core Team, Vienna, Austria). Baseline characteristics were summarized with means and SDs. MWK accelerometers’ data were downloaded using the internal USB attachment. Minutes in light, moderate, and vigorous intensity activity were collected directly from the web-based portal and exported to a database. For the treadmill phase, the estimated speed where each MWK switched from recording light intensity to moderate intensity activity was determined by comparing the minutes in moderate intensity captured by the MWK to the known number of minutes spent on the treadmill at a moderate walking pace (4.0-6.4 KM/H; 2.5- 4.0 MPH). The mean difference between the minutes of moderate intensity exercise recorded by the MWK and the known number of minutes spent on the treadmill at a moderate walking pace (4.0-6.4 KM/H) was found.

For the free-living phase, Spearman’s correlations were calculated to assess the association between the minutes of moderate-to-vigorous physical activity (MVPA) recorded by the participants in their PA diaries, and the minutes of MVPA recorded by the MWK. A stratified analysis with pre-set cut-offs for waist circumference and BMI was completed (waist circumference <100 versus ≥100 cm; BMI <30 versus ≥30 kg/m²). Bland-Altman plots with 95% limits of agreement were created to demonstrate the level of agreement between the participants’ logged minutes of MVPA and the minutes of MVPA recorded by the MWK in the free-living phase. The Bland Altman plots were adjusted for repeated measures where applicable.
2.4 RESULTS

Table 2 shows the baseline demographics for the 35 men and women, mean age±SD 62.8±7.8 years who completed the study protocol. Only five of the study participants, one female and four males, reached a vigorous intensity (7.0 KM/H; 4.5 MPH). Figure 3 shows the cut-point speed where each individual MWK switched from recording PA as light intensity to moderate intensity in the laboratory phase. The mean±SD cut-points identified were 4.1±0.5 KM/H (2.6±0.3 MPH) for both the right and the left waist-worn MWKs and 5.0±0.9 KM/H (3.2±0.6 MPH) for the bra-mounted MWK. The mean differences between moderate-intensity minutes on the treadmill and those indicated by the MWKs were 1.14 [median=1.0; interquartile range (IQR)= -1-4], 0.86 (median= 1; IQR= 0-3) for the left and right MWKs respectively. The MWK slightly underestimated PA compared to the treadmill protocol. The mean difference in minutes of moderate intensity exercise versus the treadmill protocol for the bra-mounted MWK was much higher at 3.43 (median= 2; IQR= 2-6) minutes. Again, the MWK underestimated minutes in moderate intensity compared to the treadmill protocol. The Spearman correlation between minutes spent in moderate activity between the left and the right waist-worn MWKs was 0.70 (95% CI: 0.48, 0.84; P<0.001).
Table 2 Descriptive characteristics of study participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Mean (SD)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>14</td>
<td>(40%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>21</td>
<td>(60%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>35</td>
<td>62.8 (7.8)</td>
<td>41</td>
<td>74</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>35</td>
<td>169.5 (8.4)</td>
<td>146.5</td>
<td>186</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>35</td>
<td>89.9 (18.2)</td>
<td>50.2</td>
<td>127.4</td>
</tr>
<tr>
<td>BMI (kg/m^2)</td>
<td>35</td>
<td>31.2 (5.6)</td>
<td>19.4</td>
<td>41.8</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>35</td>
<td>125.7 (13.6)</td>
<td>98</td>
<td>158</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>35</td>
<td>74.5 (10.5)</td>
<td>53</td>
<td>95</td>
</tr>
<tr>
<td>BMI &gt; 30 kg/m^2</td>
<td>18</td>
<td>(51%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WC &gt; 100 cm</td>
<td>18</td>
<td>(51%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BMI, body mass index; BP, blood pressure; WC, waist circumference
Figure 3 Estimated cut-point (KM/H) from low to moderate intensity exercise for the right hip, left hip, and bra MyWellness Key
Figure 4 Spearman correlation coefficient plot between (A) left MyWellness Key and physical activity diary and (B) bra MyWellness Key and physical activity diary during free-living physical activity. *P<0.001

(A)

Left Hip MWK (minutes)

Physical Activity Diary (minutes)

r = 0.81*

(B)

Bra MWK (minutes)

Physical Activity Diary (minutes)

r = 0.66*
As shown in Figure 4, for the free-living phase the Spearman correlation between MVPA minutes according to the PA diary and the waist-worn MWK was 0.81 (95% CI: 0.76, 0.85; P<0.001). The Spearman correlation between MVPA minutes according to the PA diary and the bra MWK was 0.66 (95% CI: 0.53, 0.77; P<0.001). Figure 5 shows the Bland Altman plots for the free-living phase. Moderate intensity minutes recorded by the waist-worn MWK were within five minutes of the PA diary 72.7% of the time, and within 15 minutes of the PA diary 91.3% of the time. For the bra-worn MWK the moderate intensity minutes were within five minutes of the PA diary 34.5% of the time and within 15 minutes of the PA diary 52.9% of the time.

The mean differences between moderate-intensity minutes per session recorded in the PA logs and those indicated by the MWKs were 3.76 [median=1.0; IQR= -1-4], 15.3 (median= 10; IQR= 1-26) for the left and bra MWKs respectively.
Figure 5 Bland-Altman Plots of the free-living phase physical activity showing the differences in minutes of moderate-to-vigorous physical activity recorded between the MyWellness Key and the physical activity log versus the average MyWellness Key and physical activity log values of moderate-to-vigorous physical activity minutes. The mean differences and the ± 95% limits of agreement adjusted for repeated measures are shown.
In analyses stratified by waist circumference, correlations between MVPA minutes captured by the PA diary and the waist-worn MWK were similar for participants with waist circumferences less than 100 cm and greater than or equal to 100 cm with Spearman’s correlations of 0.77 (P<0.001) and 0.83 (P<0.001) respectively (Table 3). The identified cut-point between low and moderate intensity activity during the treadmill protocol was similar between both waist circumference groups, with mean cut-points of 4.1±0.6 KM/H (2.5±0.4 MPH) in participants with a lower waist circumference (<100 cm) and 4.2±0.4 KM/H (2.6±0.3 MPH) in participants with a higher waist circumference (≥100 cm). In stratified analysis by BMI, correlations between MVPA minutes captured by the PA diary and the waist-worn MWK were similar for participants with a BMI less than 30 kg/m² and a BMI greater than or equal to 30 kg/m² with Spearman’s correlations of 0.81 (P<0.001) and 0.80 (P<0.001) respectively (Table 3). The identified cut-points between low and moderate intensity for the left waist-worn MWK during the treadmill protocol were identical in the two BMI groups, with a cut-point of 4.1±0.5 KM/H (2.6±0.3 MPH).
Table 3 Stratified Correlation (p-value) analysis for body mass index and waist circumference

<table>
<thead>
<tr>
<th>MWK Placement</th>
<th>BMI &lt; 30 kg/m²</th>
<th>BMI ≥ 30 kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Hip MWK</td>
<td>0.81 (&lt;0.001)</td>
<td>0.80 (&lt;0.001)</td>
</tr>
<tr>
<td>Bra MWK</td>
<td>0.62 (&lt;0.001)</td>
<td>0.63 (&lt;0.001)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MWK Placement</th>
<th>WC &lt;100 cm</th>
<th>WC ≥ 100 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Hip MWK</td>
<td>0.77 (&lt;0.001)</td>
<td>0.83 (&lt;0.001)</td>
</tr>
<tr>
<td>Bra MWK</td>
<td>0.63 (&lt;0.001)</td>
<td>0.76 (&lt;0.001)</td>
</tr>
</tbody>
</table>

PA, physical activity; MWK, MyWellness Key; BMI, body mass index; WC, waist circumference

2.5 DISCUSSION

The aim of this study was to evaluate the accuracy of the MWK accelerometer to correctly classify varying walking speeds during a laboratory treadmill protocol and unsupervised free-living PA in people with T2D. The waist-worn MWK was shown to differentiate between low and moderate intensity walking speeds in people with T2D at an average speed of 4.1 KM/H for both the left and the right waist-worn MWK’s. The intended cut-point from low to moderate PA according to the MWK is 3.0 METs, with any activity lower than 3.0 METs classified as light intensity and any activity 3.0-5.9 METs classified as moderate.
intensity. The Compendium of Physical Activities quantifies the energy cost associated with a walking speed of 4.0 KM/H (2.5 MPH) as 3.0 METs (Table 1). Thus, the mean MWK cut-point determined in the present trial deviated from the ideal cut-point by 0.1 KM/H. The strong, significant correlation between the time spent in MVPA measured by the waist-worn MWK and recorded in the PA diary \((r=0.81)\), and accuracy in differentiating low from moderate intensity exercise during laboratory testing make the MWK a suitable instrument for objective measurement of walking speed in people with T2D. In addition, the MWK accurately categorized light and moderate PA in those with, and without, increased BMI or central obesity.

The MWK has been previously validated for walking and running in younger, normal weight populations and shown to be a reliable tool to objectively measure PA. A small validation study of 16 participants, average age 40.2±12.6 years, found the MWK to have a high concurrent validity with the gold standard ActiGraph accelerometer during treadmill walking \((r=0.91)\) and free-living activity \((r=0.73-0.76)\). A study of 30 participants, average age 24.5±2.6 years, found that the predicted VO\(_2\) from the MWK and oxygen consumption measured via indirect calorimetry during a treadmill protocol were highly correlated \((r=0.944)\). Lastly, a study of 25 participants with an average age of 27.6±4.5 years used raw counts and VO\(_2\) values from respiratory gas exchange to assess validity and reliability of the MWK accelerometer. Acceptable validity was found as the correlation between VO\(_2\) measured by respiratory gas exchange and that estimated by the MWK was high during a treadmill protocol \((r=0.895-0.902)\). Good overall reliability was found with all intraclass correlations greater than 0.93. The mean BMI of the participants in the previous MWK validation trials was within the normal range of 18-25 kg/m\(^2\).
Objective measurement of PA, by devices such as the MWK accelerometer, are useful in the research setting as these devices can evaluate the effectiveness of interventions aimed at increasing PA levels.\textsuperscript{71} Objective measurement of PA is especially important as measures of self-report such as questionnaires, surveys, and interviews have potential limitations such as recall bias and socially desirable responses.\textsuperscript{20} In the Canadian Community Health Survey,\textsuperscript{72} 53.8\% of adults reported being moderately active in their leisure time; where moderately active was defined as the equivalent to walking at least 30 minutes per day or taking an hour-long exercise class at least three times a week. Objective data collected by accelerometers in the Canadian Health Measures Survey showed that only 15\% of adults accumulated 150 minutes per week of MVPA in ten minute bouts.\textsuperscript{73} In addition, a systematic review\textsuperscript{71} (n=148) that compared self-report and direct measurement of PA in adult populations found an average correlation of r=0.37 between these two measures. Self-report PA estimates were generally higher than direct estimates, however no clear trend emerged demonstrating the variability of self-report measures of PA compared to objective measures. Thus, it is evident that objective measures are a valuable tool to accurately monitor and record PA levels.

The MWK accelerometer could also offer benefit to individuals. Clinical practice guidelines recommend a minimum of 150 minutes of moderate intensity aerobic exercise per week for people with T2D as this volume of aerobic exercise can lead to increased cardiorespiratory fitness, improved glycaemic control, and other benefits.\textsuperscript{5,74} To complete moderate intensity aerobic activity, and attain the associated benefits, a walking pace of at least 4.0 KM/H (2.5 MPH) has been recommended.\textsuperscript{30} When the walking speed of small sample of people with T2D was assessed with an accelerometer,\textsuperscript{75} the median walking speed was 3.4 KM/H (2.1 MPH), which is considered light intensity PA. Feedback provided by the MWK
accelerometer could alert people with T2D if their aerobic exercise was at sufficient intensity and thus provide users motivation to increase their walking pace, leading to enhanced health benefits.

Consumer-based activity monitors are becoming increasingly popular tools to help individuals track their PA. Other activity monitors for consumers are available such as the Fitbit One™ (Fitbit Inc, San Francisco, USA), the Jawbone UP™ (Jawbone, San Francisco, USA), and the Nike+ Fuelband™ (Nike, Beaverton, USA). The Fitbit One is a triaxial accelerometer that has the ability to record step count, stairs climbed, calories burned, and distance travelled, and can upload wirelessly to a website to track activity levels over a longer period of time. The Fitbit One was validated against treadmill walking and no significant difference in step counts between observed values and Fitbit One values was seen. However, significant differences were noted in distance output between the Fitbit One and the treadmill output (P< 0.001), especially at lower walking speeds where the Fitbit One overestimated distance. The Jawbone Up is a wrist-worn tri-axial accelerometer that can record PA patterns such as steps, minutes spent active, and calories burned and syncs with apple and android devices. The Nike+ Fuelband is also a tri-axial accelerometer and records body movement as “Nike Fuel”, steps, distance, and calories burned. The Jawbone Up and the Nike+ Fuelband were assessed for accuracy during a 69 minute semi-structured bout of PA and had correlations with indirect calorimetry of r=0.741 and 0.348 respectively, lower than the correlations between MWK-measured PA and measures by indirect calorimetry.

There are several limitations to this validation study. First, we did not directly measure energy expenditure but instead compared minutes in each exercise intensity. As a result of not measuring energy expenditure, the speed at which walking reaches a moderate intensity had to be estimated from the Compendium of Physical Activities, which may not be accurate,
especially for those who are overweight or obese. The study had a small sample size and all participants were relatively high-functioning because of the inclusion criteria requiring ability to walk 20 minutes at a moderate pace without impairment. The MWK device also has several limitations, one being that it cannot accurately measure forms of aerobic activity other than walking and jogging (i.e. biking, swimming, and elliptical exercise), is not waterproof, and cannot accurately measure resistance training unless connected with Technogym™ brand gym equipment. These limitations are true of other accelerometers as well. Lastly, the MWK does not time-stamp measured activity and is not ideal for measuring sedentary time.

This validation study demonstrated that the MWK accelerometer is acceptably accurate at differentiating between low and moderate intensity walking in people with T2D when worn on the waistband, according to the manufacturer’s instructions. The MWK accelerometer was previously validated in young, normal weight adults and is now shown to be a valid instrument for objective measurement of exercise intensity in people with T2D.
Chapter Three: Effects of Exercise Training Using Resistance Bands on Glycaemic Control and Strength in Type 2 Diabetes Mellitus: a Meta-analysis of Randomised Controlled Trials

3.1 Abstract

AIMS/HYPOTHESIS: Resistance exercise using free weights or weight machines improves glycaemic control and strength in people with T2D. RBT is potentially less expensive and more accessible, but the effects of RBT on glycaemic control and strength in this population are not well understood. This paper aims to systematically review and meta-analyse the effect of RBT on HbA₁c and strength in adults with T2D.

METHODS: Database searches were performed in August 2013 (MEDLINE, SPORTDiscus, EMBASE, and CINAHL). Reference lists of eligible articles were hand searched for additional studies. Randomised trials evaluating the effects of RBT in adults with T2D on HbA₁c or objectively-measured strength were selected. Baseline and post-intervention HbA₁c and strength were extracted for the intervention and control groups. Details of the exercise interventions and methodological quality were collected.

RESULTS: Seven trials met inclusion criteria. Post-intervention weighted mean HbA₁c was nonsignificantly lower in exercise groups compared to control groups [weighted mean difference (WMD)=-0.18 percentage points (-1.91 mmol/mol); P=0.27]. Post-intervention strength was significantly higher in the exercise groups compared to the control groups in the lower extremities (WMD=21.90 kg; P<0.0001), but not in the upper extremities (WMD=2.27 kg; P=0.13) or handgrip (WMD=1.98 kg; P=0.46). All trials were small and had methodological limitations.
CONCLUSIONS/INTERPRETATIONS: RBT did not significantly affect HbA1c, upper extremity, or handgrip strength but significantly increased the strength of the lower extremities in people with T2D.
3.2 Introduction

Resistance training is exercise training that uses muscular strength to move a weight or work against resistance. Randomised controlled trials have shown that resistance training with free weights or weight machines can reduce HbA1c, increase insulin sensitivity, increase insulin sensitivity, increase strength, and improve quality of life in people with T2D. Accordingly, clinical practice guidelines endorse both aerobic and resistance exercise training. However, the proportion of people with T2D who engage in resistance training is far lower than the proportion reporting regular aerobic exercise; in one population-based survey, 55% reported engaging in walking for exercise while only 12% reported engaging in resistance training. Barriers to participation in traditional resistance training with free weights or weight machines include the need to travel to a gym, the cost of a gym membership, and/or the cost and space requirements of home equipment.

One potential alternative to free weights and/or weight machines (the methods used in the majority of resistance training trials to date) is training using resistance bands. Resistance bands are elastic bands used for progressive resistance training. The force produced by resistance bands varies due to band thickness and elongation, with greater thickness and elongation resulting in greater resistance. Resistance bands are vastly less expensive than free weights and weight machines, require very little storage space, and can be used at home or in a group setting. Training with resistance bands is therefore an attractive alternative, as it would allow access to resistance training for people who cannot or choose not to purchase gym memberships and travel to a gym to exercise. If RBT proved to be effective it would allow for greater access to, and potentially increased participation in resistance training. To our knowledge, no previous
literature reviews evaluated effects of this training modality on HbA$_{1c}$ or strength in people with T2D.

The aim of this paper was to systematically review randomised controlled trials investigating the effects of exercise interventions using RBT on glycaemic control (HbA$_{1c}$), or strength in adults with T2D. This systematic review is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.$^{82}$

3.3 Methods

3.3.1 Data Sources and Searches

Our electronic data search aimed to identify studies investigating the effects of RBT on HbA$_{1c}$ (primary outcome) or strength (secondary outcome) in adults with T2D. Electronic searches were performed in August 2013 in the following databases: MEDLINE (1946-2013), SPORTDiscus (1985-2013), EMBASE (1980-2013), and CINAHL (Cumulative Index to Nursing and Allied Health) (1982-2013). In addition, the reference lists of articles selected for the review were hand searched to find any studies that had potential for inclusion. Lastly, experts in the field were asked to determine if any known articles in the area of study were missing. Non-English-language studies were included.

A search strategy was developed and tailored to each database. To ensure that the search strategy was as broad as possible, no filters were used. Medical subject headings, including “type 2 diabetes mellitus” and “diabetes mellitus” were exploded to include several narrower terms (such as type 2 diabetes, diabetes mellitus type II and several others) and combined with the Boolean operator, ‘or’ to map the population of interest. The Boolean operator, ‘and’ was used to include the intervention and the medical subject heading “resistance training” was exploded. To
further the scope of the search common text words were added, including but not limited to: elastic band*, type 2 diabetes*, resistance exercise*, resistance band*, and Thera-band*.

3.3.2 Study Selection

All articles retrieved from the database search were independently reviewed in a two-stage process by two reviewers (S.K.M. and M.J.A.). In the first stage, the titles and abstracts of the articles retrieved from the database search were reviewed. If either reviewer deemed that the study met inclusion criteria, or was uncertain if study inclusion criteria were met, the study was reviewed in full by both reviewers. In the second stage, the full text of each article was read to determine if the study would be included in the review. If the two reviewers could not reach a conclusive decision, ambiguity was resolved by discussion with a third reviewer (R.J.S).

Inclusion criteria consisted of: (i) study population (adults diagnosed with T2D); (ii) intervention (resistance exercise program using resistance bands for eight weeks or more); (iii) comparison (standard care, no treatment); (iv) outcome (HbA_1c or strength) and (v) study design (randomised controlled trial only).

Studies were excluded if the resistance training utilised free weights or weight machines, or if the population included children, adolescents, or participants with type 1 diabetes or prediabetes. Studies were also excluded if they did not report on the outcomes HbA_1c or strength, and if the resistance training was used in combination with another form of resistance exercise (such as free weights).

3.3.3 Data Extraction and Quality Assessment

A data extraction form was used. Details of the RBT program extracted were: setting, frequency, supervision, duration, intensity, and length of the intervention. Other extracted data included mean age, percent female, duration of diabetes, baseline characteristics, and any control
of diet or medication (Table 4). If necessary, authors of potentially eligible articles were contacted to resolve any ambiguities regarding the protocol or results.

Baseline and post-intervention means and SDs were collected for both the intervention and control groups for the primary and secondary outcomes. Whenever possible, the means ± SDs of the absolute change from baseline to post-intervention were also collected for secondary analysis. The absolute changes in HbA$_{1c}$ and handgrip strength were not reported in the majority of the articles$^{83-87}$ allowing for meta-analysis of just the pre- and post-intervention values for these variables.

In one of the selected studies$^{88}$ the post-intervention SD for HbA$_{1c}$ and handgrip strength were not provided. In this case, we used the baseline SD as the imputed post-intervention SD. The imputed post-intervention SD was assumed to be appropriate as on average, the baseline SD of the other trials included in the meta-analysis was very similar to the post-intervention SD. For strength of the upper and lower extremities, baseline and post-intervention means ± SDs were collected, as well as absolute changes in strength from baseline to the end of the intervention for secondary analysis. The change in strength was not reported for one of the control groups$^{83}$ but was obtained from the baseline and post-intervention values. To find the mean change in strength, the mean baseline strength was subtracted from the mean post-intervention strength (for both the upper and lower extremities). The SD of the difference between means was obtained from the p-value as described in the Cochrane handbook.$^{89}$ HbA$_{1c}$ values were converted from percentage points to mmol/mol using NGSP’s HbA$_{1c}$ converter.$^{90}$

The methodological quality of the included articles was assessed using the validated 5-point scale by Jadad et al.$^{91}$ The Jadad scale assigns methodological quality by assigning point values to the following study characteristics: randomisation, blinding, and description of any
participant withdrawals. Allocation concealment was assessed as another dimension of methodological quality.

3.3.4 Data Synthesis and Analysis

Statistical Analysis was performed using Review Manager Software (RevMan 5.2, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration), PASW Statistics 18.0 (SPSS Inc., Quarry Bay, Hong Kong), and Stata, version 11.0 (Stata Corp., College Station, TX, USA). For all variables, the mean difference was calculated by the difference between means of the exercise and control groups at the end of the intervention for each study. For variables where mean change ± SD was reported (upper and lower extremity strength), secondary analysis was carried out, and the mean difference was calculated by the change in strength (in kilograms) from baseline to the end of the intervention and compared between groups. This secondary analysis allowed us to quantify the amount by which RBT changed strength on average compared with the control group. Each mean difference, for all outcomes, was weighted by the inverse of its variance and the average was taken. As there was limited heterogeneity between trials, the WMD for each analysis was pooled according to the fixed-effects model.

To assess heterogeneity (the presence of variation in the mean difference of included studies), forest plots were visually inspected for the overlap of confidence intervals. In addition to inspecting the confidence intervals, both the p-value for the Q statistic and the $I^2$ statistics were calculated. The $I^2$ statistic is a function of the Q statistic which quantifies the percentage of variability that is attributed to between trial heterogeneity. Publication bias was assessed through Begg and Mazumdar’s rank correlation test for asymmetry and Egger et al.’s weighted regression test. A significant statistical test (P <0.05) suggests potential publication bias.
In addition there were 5 supervised sessions spread out over the 16 week intervention

Table 4 Description of Exercise Interventions

<table>
<thead>
<tr>
<th>Reference (first author and year)</th>
<th>Sample size, weeks</th>
<th>Duration, weeks</th>
<th>Age (SD)</th>
<th>Female, %</th>
<th>Frequency /week</th>
<th>Intensity</th>
<th>Length, min</th>
<th>Exercises</th>
<th>Sets</th>
<th>Reps</th>
<th>Setting</th>
<th>Jadad Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>An(^{86},) 2005</td>
<td>17</td>
<td>12</td>
<td>56.4 (9.0)</td>
<td>100</td>
<td>10</td>
<td>60% 1RM</td>
<td>60</td>
<td>10</td>
<td>2-3</td>
<td>15-20</td>
<td>NR</td>
<td>1</td>
</tr>
<tr>
<td>Cheung(^{88},) 2009</td>
<td>37</td>
<td>16</td>
<td>60.0 (7.9)</td>
<td>68</td>
<td>5*</td>
<td>3 METs</td>
<td>40</td>
<td>7</td>
<td>2</td>
<td>12</td>
<td>facility and home-based</td>
<td>1</td>
</tr>
<tr>
<td>Kim(^{87},) 2004</td>
<td>20</td>
<td>12</td>
<td>65.6 (5.2)</td>
<td>100</td>
<td>3</td>
<td>50% 1RM</td>
<td>65</td>
<td>11</td>
<td>2</td>
<td>8-15</td>
<td>NR</td>
<td>1</td>
</tr>
<tr>
<td>Ku(^{85},) 2010</td>
<td>29</td>
<td>12</td>
<td>56.9 (7.3)</td>
<td>100</td>
<td>5</td>
<td>40-50% 1RM</td>
<td>NR</td>
<td>10</td>
<td>3</td>
<td>15-20</td>
<td>facility-based</td>
<td>1</td>
</tr>
<tr>
<td>Kwon(^{83},) 2010</td>
<td>28</td>
<td>12</td>
<td>56.4 (7.1)</td>
<td>100</td>
<td>3</td>
<td>40-50% 1RM</td>
<td>60</td>
<td>11</td>
<td>3</td>
<td>10-15</td>
<td>facility-based</td>
<td>2</td>
</tr>
<tr>
<td>Kwon(^{84},) 2011</td>
<td>27</td>
<td>12</td>
<td>55.9 (7.3)</td>
<td>100</td>
<td>3</td>
<td>40-50% 1RM</td>
<td>60</td>
<td>10</td>
<td>3</td>
<td>10-15</td>
<td>facility-based</td>
<td>1</td>
</tr>
<tr>
<td>Sun(^{85},) 2010</td>
<td>21</td>
<td>12</td>
<td>58.9 (7.0)</td>
<td>59</td>
<td>3</td>
<td>NR</td>
<td>30(b)</td>
<td>12</td>
<td>2</td>
<td>8-12</td>
<td>facility and home-based</td>
<td>2</td>
</tr>
</tbody>
</table>

*a*In addition there were 5 supervised sessions spread out over the 16 week intervention

*b*Two 30 minute sessions per week plus one 60 minute session

NR, not reported; Reps, repetitions
3.4 Results

The progression through the systematic review process is summarised in Figure 6. The initial database search yielded 815 citations after duplicates were removed. During stage one, the title and abstract review, 679 citations were excluded ($\kappa = 0.73$). The most common reasons for exclusion were use of free weights/weight machines rather than resistance bands, combining treatments (e.g. free weights and resistance bands), inappropriate population, and ineligible study design (e.g. not a randomised controlled trial). In stage two, the full texts of the remaining 136 articles were assessed for eligibility. We excluded 129 articles ($\kappa = 0.82$); the main reason for exclusion was the use of free weights/weight machines rather than resistance bands. The seven remaining articles were included in the review. Six articles were included in meta-analyses of HbA\textsubscript{1c}, two articles were included in meta-analyses of strength of the major muscle groups, and two articles were included in meta-analyses of handgrip strength.

Several of the included studies had a third group, either an aerobic exercise group, or a Qigong exercise group. In order to evaluate the effect of resistance bands alone, neither the aerobic intervention groups nor the Qigong exercise group were included in the meta-analysis, and the mean values for each study (e.g. mean age) along with the SDs were adjusted after removing the third group according to the formulae provided by the Cochrane Handbook.

3.4.1 Study Characteristics

Methodological details of each study meeting inclusion criteria are shown in Table 4. Publication years ranged from 2004 to 2011 and percentages of women in each study ranged from 59% to 100%. In several other studies, the mode of resistance training (i.e. free weights, weight machines, body weight, or resistance bands) could not be determined by full text review or author contact, therefore these articles were excluded from the review. Several articles
that used resistance bands in conjunction with other forms of training such as resistance exercise with free weights or aerobic exercise were excluded from the review as the effect of the resistance bands could not be isolated. A total of 179 subjects participated in the seven included trials. The weighted mean age of the included participants was 58.7 years and the mean ages of participants in the individual studies ranged from 56.4 years to 65.6 years. The weighted mean duration of diabetes, for the studies where it was available, was 6.0 years and individual study means ranged from 4.8 years to 7.3 years.

**Figure 6 Search Strategy and Article Selection Flow Sheet**

- Citations identified through other sources \( (n=3) \)
- Citations identified through database searching \( (n=1215) \)
- Citations after duplicates removed \( (n=815) \)
- Citations screened \( (n=815) \)
- Citations excluded based on inclusion/exclusion criteria \( (n=679) \)
- Full-text articles excluded \( (n=129) \)
  - Did not use exercise bands \( (n=105) \)
  - Not original data \( (n=6) \)
  - Ineligible study design \( (n=6) \)
  - Wrong population \( (n=4) \)
  - Combination intervention \( (n=4) \)
  - Could not contact author to clarify method of resistance training \( (n=3) \)
  - No data on HbA1c or strength \( (n=1) \)
- Studies included in qualitative synthesis \( (n=7) \)
- Studies included in quantitative synthesis (meta-analysis) \( (n=7) \)
According to the 5-point scale by Jadad et al. the quality of the included studies was low-to-moderate. The mean score ± SD of the included articles on the 5-point Jadad scale was 1.3±0.5 (Table 4). The maximum Jadad score for trials in this meta-analysis was three, since it is not feasible to blind participants to their allocation in an exercise trial. All of the included studies were described as randomised, however neither the method of randomisation, nor allocation concealment, were described. None of the included articles were double-blinded or used intention-to-treat analysis. Only two of the seven studies had an adequate description of withdrawals.

In all but two of the included studies, participants were told not to change their medications over the duration of the study. In four of the seven studies, participants were told that diet should remain constant during the study, and three of the studies had participants complete three-day food logs. The mean frequency ± SD of the RBT in the included studies was 5±3 times per week (median 3 times per week, range 3-10), and the time ± SD allotted to each session was 54±11 minutes, including a warm-up and a cool-down. The mean duration ± SD of the RBT intervention was 13±2 weeks. For each intervention there were between 7-11 exercises, 2-3 sets, and 8-20 repetitions. The prescribed intensity of the RBT was said to be based on a percentage of the one-repetition-maximum (1 RM) in five of the seven included studies, and ranged from 40-60 percent of the 1 RM. It is not clear how the percent of the 1 RM determined on a weight machine was extrapolated to resistance bands, as the exact intensity of resistance band exercise is difficult to determine. One study used the Compendium of Physical Activities to estimate the MET count of the resistance band exercise: it was estimated at 3 METs. Another study did not report the prescribed intensity of the RBT.
3.4.2 Effect of Resistance Band Exercise on Glycaemic Control

A total of 159 participants were included in the six studies reporting post-intervention HbA$_{1c}$ values, including 79 participants who performed resistance band exercise and 80 in the comparator control. Post-intervention differences in HbA$_{1c}$ between the exercise and control groups for the six trials were pooled to assess the effect estimate. For the six comparisons between the exercise and control groups there were no significant baseline differences in HbA$_{1c}$ [WMD= 0.01 percentage points (0.03 mmol/mol); P=0.94; Figure 7]. As shown in Figure 7, when the post-intervention mean differences in HbA$_{1c}$ were pooled using a fixed-effects model, HbA$_{1c}$ was not significantly different in the exercise group compared to the control group [WMD= -0.18 percentage points (-1.91 mmol/mol); P=0.27; Figure 7]. Significant heterogeneity was not observed ($I^2=0\%$; P=0.96). There was no evidence of publication bias with Begg and Mazumdar’s test (P=0.35) or Egger et al.’s test (P=0.45).
**Figure 7 Differences in HbA1c (%) between resistance band training and control**

<table>
<thead>
<tr>
<th>Source, y</th>
<th>Period</th>
<th>Exercise Group</th>
<th>Control Group</th>
<th>Weight %</th>
<th>WMD, fixed (95% CI)</th>
<th>Favours treatment</th>
<th>Favours control</th>
</tr>
</thead>
<tbody>
<tr>
<td>An et al.</td>
<td>Baseline</td>
<td>10/7.1 (0.9)</td>
<td>7.78 (1.1)</td>
<td>8.8</td>
<td>-0.70 (-1.69 to 0.29)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2005</td>
<td>Post</td>
<td>10/6.4 (0.9)</td>
<td>7.67 (0.8)</td>
<td>14.9</td>
<td>-0.30 (-1.11 to 0.51)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chen et al.</td>
<td>Baseline</td>
<td>20/7.2 (1.6)</td>
<td>17.74 (1.0)</td>
<td>12.0</td>
<td>-0.60 (-1.05 to 0.65)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2009</td>
<td>Post</td>
<td>20/7.5 (1.6)</td>
<td>17.73 (1.0)</td>
<td>13.8</td>
<td>0.20 (-0.65 to 1.65)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ku et al.</td>
<td>Baseline</td>
<td>13/7.3 (0.9)</td>
<td>16.73 (0.7)</td>
<td>24.0</td>
<td>0.60 (-0.56 to 0.60)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2010</td>
<td>Post</td>
<td>13/7.0 (0.9)</td>
<td>16.72 (0.9)</td>
<td>22.8</td>
<td>-0.20 (-0.86 to 0.46)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kwon et al.</td>
<td>Baseline</td>
<td>13/7.3 (0.9)</td>
<td>15.74 (0.7)</td>
<td>23.5</td>
<td>-0.10 (-0.70 to 0.50)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2010</td>
<td>Post</td>
<td>13/7.0 (0.9)</td>
<td>15.73 (0.9)</td>
<td>22.1</td>
<td>-0.30 (-0.97 to 0.37)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kwon et al.</td>
<td>Baseline</td>
<td>12/7.4 (0.9)</td>
<td>15.72 (0.8)</td>
<td>20.3</td>
<td>0.20 (-0.41 to 0.85)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2011</td>
<td>Post</td>
<td>12/7.0 (0.9)</td>
<td>15.72 (0.8)</td>
<td>23.3</td>
<td>-0.20 (-0.85 to 0.43)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sun et al.</td>
<td>Baseline</td>
<td>11/8.6 (1.2)</td>
<td>10/7.9 (0.8)</td>
<td>11.5</td>
<td>0.70 (-0.17 to 1.57)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2010</td>
<td>Post</td>
<td>5/7.9 (1.6)</td>
<td>8/7.9 (1.6)</td>
<td>3.1</td>
<td>0.00 (-1.79 to 1.79)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Overall</td>
<td>Baseline</td>
<td>79</td>
<td>80</td>
<td>100.0</td>
<td>0.61 (-0.28 to 0.30)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Post</td>
<td></td>
<td>73</td>
<td>78</td>
<td>100.0</td>
<td>-0.18 (-0.49 to 0.14)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

WMD, weighted mean difference; CI, confidence interval. Studies are placed in alphabetical order and represent the mean difference and the 95% CI for baseline and post-intervention measurements. Weights are from a fixed-effects analysis.
3.4.3 Effect of Resistance Band Exercise on Strength

A total of 57 participants were included in the two studies reporting on strength of the upper and lower extremities, including 26 in resistance band exercise groups and 31 in the control groups. Post-intervention differences in strength between the exercise and control groups for the two trials were pooled to assess the effect estimate. Meta-analyses were completed to assess the effect of resistance band exercise on strength of the upper extremities, assessed by chest press 1 RM (in kilograms), and of the lower extremities, assessed by leg press 1 RM (in kilograms). For the two comparisons between the exercise and control groups there were no significant baseline differences in upper body strength (WMD=-1.27 kg; P=0.36; Figure 8) or lower body strength (WMD=0.54 kg; P=0.94; Figure 8). For the upper extremities, post-intervention strength was not significantly different in the exercise groups compared to control (WMD=2.27 kg; P=0.13; Figure 8). Significant heterogeneity was not observed ($I^2=0\%$; $P=0.61$). For the lower extremities, weighted mean post-intervention strength was significantly different in the exercise group compared to the control (WMD=21.90 kg; $P<0.0001$; Figure 8). Significant heterogeneity was not observed ($I^2=0\%$; $P=0.98$).

In secondary analyses, studies reporting means and SDs of change in strength were pooled to assess the effect estimate. These analyses allowed for greater statistical power as smaller SDs were observed. Weighted mean absolute change in strength for the upper extremities was significantly higher in the exercise groups compared to control groups (WMD=3.53 kg; $P<0.00001$). The absolute change in strength for the lower extremities was also significantly higher in the exercise group compared to the control (WMD=21.21 kg; $P<0.00001$).

A total of 57 participants were included in the two studies reporting on handgrip strength, including 30 who performed resistance band exercise and 27 in the control groups. There were
no significant baseline differences in handgrip strength between the exercise and the control groups (WMD=0.07 kg; P=0.98; Figure 8). When post-intervention mean differences in handgrip strength were pooled using a fixed-effects model, handgrip strength was not significantly different in the exercise group compared to the control group (WMD=1.98 kg; P=0.46; Figure 8). Significant heterogeneity was not observed ($I^2=0\%$; $P=0.64$).
**Figure 8 Differences in strength (kilograms) between resistance band training and control**

<table>
<thead>
<tr>
<th>Source, y</th>
<th>Period</th>
<th>Exercise Group</th>
<th>Control Group</th>
<th>Weight %</th>
<th>WMD, fixed (95% CI)</th>
<th>Favours</th>
<th>Favours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Upper Extremities</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ku et al.</td>
<td>Baseline</td>
<td>13/17.0 (4.0)</td>
<td>16/18.0 (5.0)</td>
<td>55.4</td>
<td>-1.00 (-4.66 to 2.66)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>2010 Post</td>
<td>13/19.0 (4.0)</td>
<td>16/16.0 (7.0)</td>
<td>31.1</td>
<td>3.00 (-1.06 to 7.06)</td>
<td></td>
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</tr>
<tr>
<td>Kwon et al.</td>
<td>Baseline</td>
<td>13/16.5 (4.3)</td>
<td>15/18.1 (5.6)</td>
<td>44.6</td>
<td>-1.60 (-5.68 to 2.48)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>2010 Post</td>
<td>13/18.5 (4.4)</td>
<td>15/17.0 (6.7)</td>
<td>48.9</td>
<td>1.50 (-2.65 to 5.65)</td>
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</tr>
<tr>
<td><strong>Overall</strong></td>
<td>Baseline</td>
<td>26</td>
<td>31</td>
<td>100.0</td>
<td>-1.27 (-3.99 to 1.45)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>Post</td>
<td>26</td>
<td>31</td>
<td>100.0</td>
<td>2.27 (-0.64 to 5.17)</td>
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<tr>
<td><strong>Lower Extremities</strong></td>
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</tr>
<tr>
<td>Ku et al.</td>
<td>Baseline</td>
<td>13/87.0 (25.0)</td>
<td>16/87.0 (33.0)</td>
<td>50.9</td>
<td>0.00 (-21.12 to 21.12)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>2010 Post</td>
<td>13/97.0 (15.0)</td>
<td>16/75.0 (24.0)</td>
<td>51.3</td>
<td>22.00 (7.59 to 36.31)</td>
<td></td>
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<tr>
<td>Kwon et al.</td>
<td>Baseline</td>
<td>13/86.8 (24.5)</td>
<td>15/85.7 (33.1)</td>
<td>49.1</td>
<td>1.10 (-20.40 to 22.60)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>2010 Post</td>
<td>13/96.9 (15.1)</td>
<td>15/75.1 (24.1)</td>
<td>48.7</td>
<td>21.80 (7.10 to 36.50)</td>
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<td></td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>Baseline</td>
<td>26</td>
<td>31</td>
<td>100.0</td>
<td>0.54 (-14.53 to 15.61)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>Post</td>
<td>26</td>
<td>31</td>
<td>100.0</td>
<td>21.90 (11.65 to 32.16)</td>
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<td><strong>Handgrip</strong></td>
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</tr>
<tr>
<td>Cheung et al.</td>
<td>Baseline</td>
<td>20/25.3 (10.3)</td>
<td>17/25.7 (9.8)</td>
<td>64.0</td>
<td>-0.40 (-5.89 to 6.09)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>2009 Post</td>
<td>20/26.3 (10.2)</td>
<td>17/25.2 (9.8)</td>
<td>67.3</td>
<td>1.10 (-5.39 to 7.59)</td>
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<td></td>
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<tr>
<td>Kim</td>
<td>Baseline</td>
<td>10/21.1 (11.7)</td>
<td>10/20.2 (7.6)</td>
<td>26.0</td>
<td>0.00 (-7.75 to 9.55)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>2004 Post</td>
<td>10/22.7 (11.1)</td>
<td>10/18.9 (10.1)</td>
<td>32.7</td>
<td>3.80 (-5.50 to 13.10)</td>
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<td></td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>Baseline</td>
<td>30</td>
<td>27</td>
<td>100.0</td>
<td>0.07 (-5.12 to 5.26)</td>
<td>Control</td>
<td>Treatment</td>
</tr>
<tr>
<td>Post</td>
<td>30</td>
<td>27</td>
<td>100.0</td>
<td>1.98 (-3.34 to 7.30)</td>
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</tr>
</tbody>
</table>

WMD, weighted mean difference; CI, confidence interval. Studies are placed in alphabetical order and represent the mean difference and the 95% CI for baseline and post-intervention measurements. Weights are from a fixed-effects analysis.
3.5 Discussion

We identified seven randomised controlled trials examining the effects of RBT on glycaemic control (as reflected by HbA1c) or strength in people with T2D. In the six trials that were pooled and meta-analysed, we found a nonsignificant overall -0.18 percentage points (-1.91 mmol/mol) lower post-intervention HbA1c in the RBT groups compared to the control groups. In the two trials that were meta-analysed there was no significant difference in post-intervention strength of the upper extremities between the RBT groups and the control groups. Meta-analyses of trials assessing post-intervention lower extremity strength found a significant difference of 21.90 kg in favour of the exercise group compared to the control. As the baseline values for the lower extremities showed no significant difference between groups, this strength difference represents a significant increase in lower extremity strength in the exercise group compared to the control. Meta-analysis of trials with handgrip strength showed no statistically significant difference in post-intervention handgrip strength in the exercise groups compared to the control groups. However, secondary analyses comparing within-group changes showed a significantly greater increase in strength for both the upper and lower extremities in the RBT compared to the control.

The nonsignificant -0.18 percentage points (-1.91 mmol/mol) difference in post intervention HbA1c in the resistance band groups versus control groups suggests a smaller effect on HbA1c than was found in meta-analyses looking at free weights/weight machines in participants with T2D; these found overall reductions in HbA1c of -0.25 (2.7 mmol/mol),103 -0.33 (3.6 mmol/mol),48 -0.57 (6.2 mmol/mol)16 and -0.64 (7.0 mmol/mol)18 percentage points in resistance training versus control groups. It is possible that RBT is simply not an effective method to reduce HbA1c. However, there were a number of key differences in studies using free
weights or weight machines and those using resistance bands that may have contributed to this lesser reduction in HbA\textsubscript{1c} in the latter.

First, the duration of training in the resistance bands studies may have been too short to see the full benefits of resistance training. The resistance band studies were all between 12-16 weeks in duration, with a mean duration ± SD of 13±2 weeks, while the mean duration ± SD of studies\textsuperscript{37,38,42,43,104} using free weights/weight machines was 22±10 weeks. Previous trials examining resistance training with free weights/weight machines that had data at both three and six months showed that exercise-induced reductions in HbA\textsubscript{1c} were significantly greater at six months than at three months.\textsuperscript{37,38,42} Another difference was that with RBT it was not possible to assess resistance precisely to ensure optimal progression to higher loads. In contrast, with free weights or weight machines, exact quantities of weight were assessed, and were increased by fixed, small amounts (e.g. 5 pounds at a time), allowing the participant or trainer to assess and ensure progressive strength increases. Resistance can be progressed to a higher intensity by switching to a higher level of resistance band. In addition, resistance could potentially be increased by using more than one elastic band at a time, but none of the included papers reported doubling the bands.

RBT has shown promise in other populations. For instance, in an 8-week RBT intervention in young women (average age 21.8 years), strength gains in the RBT group were comparable to those in the free weight/weight machine training group.\textsuperscript{57} In a 10-week resistance band intervention in middle aged women (average age 53.1 years), muscle power and strength of the upper and lower extremities increased significantly in both the weight machine group and the resistance band group.\textsuperscript{105} Both of these studies utilised the OMNI-Resistance scale for the active muscle\textsuperscript{106} and a targeted number of repetitions to ensure intensity was equivalent between both
groups. Utilizing the OMNI-Resistance scale for the active muscle may be a more practical, effective strategy to ensure adequate strength progression than attempting to set band resistance at a percentage of the 1RM (the strategy in five out of the seven studies included in this review). Studies in young adults demonstrated that resistance bands produced similar manifestations of muscle fatigue\textsuperscript{58} and muscle activation\textsuperscript{107} when compared to weight machines and dumbbells respectively.

In our secondary analysis we found that upper and lower body strength increased significantly with RBT. This strength increase is an important finding, as muscle strength and quality decrease more rapidly in older adults with diabetes than in older adults without diabetes, especially in the lower extremities.\textsuperscript{108,109} Diabetes is an independent risk factor for lower muscular strength, especially in those with poor glycaemic control,\textsuperscript{108,110} and is associated with two to three times increased odds of disability.\textsuperscript{111} Lower limb strength is essential for maintaining function and performing the activities of daily living.

There are several limitations to this systematic review. The studies included were conducted primarily on middle-aged women. Thus, the results from this meta-analysis are not necessarily generalizable to men of any age, or to young or elderly women. Also, while no statistically significant heterogeneity was found, there were differences in the frequency, exercise prescription, and setting of the included studies. Additionally, the majority of articles did not present the change data for HbA\textsubscript{1c}. As a result, statistical analysis was run with post-intervention values which reduced the statistical power of the meta-analysis. Lastly, the studies included in this review had small samples sizes and the number of studies included in the meta-analysis was small, especially for each measure of strength. Despite these limitations, this meta-analysis includes recently published studies on the effect of RBT on glycaemic control and
strength in those with T2D, is the only meta-analysis in this area, and uses the PRISMA guidelines for systematic reviews. This meta-analysis found that in participants with T2D, training using resistance bands had no significant effect on HbA1c. However, all included trials had significant limitations. It remains possible that a RBT program of longer duration, including measures to ensure progressive increases in load, might have results more similar to those achieved with free weights or weight machines. RBT resulted in no change in handgrip strength or strength of the upper extremities, but resulted in significant increases in strength of the lower extremities. Given the limitations in the evidence for RBT, the current widespread adoption of RBT in exercise programs designed for people with chronic disease may be premature. However, the low cost and easy accessibility of resistance band exercise make it attractive, if it is indeed effective. There is therefore a need for additional, higher-quality research evaluating resistance band exercise training. Future research should include studies with longer duration (at least six months), and with well-defined, reproducible protocols to ensure appropriate progression to higher resistance loads.
Chapter Four: **Putting it All Together – Background Summary, Summary of Findings, a Proposed Trial, and Significance of Work**

4.1 **Background Summary**

T2D is a metabolic disorder in which hyperglycemia results from insufficient insulin secretion, usually combined with insulin resistance.\(^1\) The prevalence of diabetes in Canada is rising and can be attributed to many factors, such as sedentary lifestyles and rising obesity rates. Aerobic exercise has been shown to help those with T2D manage their condition and decrease all-cause mortality and cardiovascular disease mortality. In addition, resistance exercise can improve blood glucose control, increase insulin sensitivity, increase strength, and improve quality of life. As a result of these positive outcomes, the CDA recommends that those with T2D engage in at least 150 minutes of moderate-to-vigorous intensity aerobic exercise each week, as well as resistance exercise at least twice per week.\(^5\)

Unfortunately, a large proportion of those with T2D do not meet current exercise recommendations, especially those for resistance exercise, because of the barriers described earlier.\(^51\) Thus, there is a need to evaluate practical exercise tools for people with T2D to increase adherence to exercise routines, and to increase the proportion of those with T2D meeting current exercise guidelines. The first practical exercise tool assessed in this thesis was the MWK accelerometer which objectively measures PA volume and intensity. A validation study was conducted to examine the accuracy of the MWK accelerometer against objective laboratory treadmill testing and PA diaries in people with T2D. Resistance bands were also examined in this thesis by completing a systematic review and meta-analysis, which aimed to determine the effect of exercise training using resistance bands on glycemic control and strength in T2D.
4.2 Summary of Findings

The overall aim of this thesis work was to evaluate two practical exercise tools for people with T2D. The major findings were:

1. The waist-worn MWK measured PA volume accurately, and was acceptably accurate at discriminating between low and moderate intensity PA in people with T2D. The mean cut-point between low (“Free”) and moderate (“Play”) intensity for the right and left waist-worn MWKs was 4.1 KM/H (close to the ideal cut-point of 4.0 KM/H) and the Spearman correlation between free-living PA recorded in a diary and by the waist-worn MWK was 0.81 (95% CI: 0.76, 0.85; P<0.001).

2. The bra-mounted MWK was less accurate at measuring PA volume and discriminating between low and moderate intensity PA in people with T2D. The mean cut-point between low (“Free”) and moderate (“Play”) intensity for the bra MWK was 5.0 KM/H and the Spearman correlation between free-living PA recorded in a diary and by the bra-mounted MWK was 0.66 (95% CI: 0.53, 0.77; P<0.001).

3. Meta-analysis of seven trials evaluating the effect of RBT on people with T2D found that the post-intervention weighted mean HbA1c was nonsignificantly lower in exercise groups compared to control groups [WMD= -0.18 percentage points (-1.91 mmol/mol); P=0.27].

4. Meta-analysis of seven trials evaluating the effect of RBT on people with T2D found that the post-intervention weighted mean strength was significantly higher in the exercise groups compared to the control groups in the lower extremities (WMD= 21.90 kg; P<0.0001), but not in the upper extremities (WMD=2.27 kg; P=0.13) or handgrip (WMD=1.98 kg; P=0.46).
4.3 Future Directions: Proposed Trial

Based on the findings of this thesis, we propose a trial utilizing the practical exercise tools discussed throughout the body of this thesis: resistance bands and the MWK accelerometer. In Chapter 2, the MWK was shown to accurately measure the intensity and volume of exercise, therefore this device would be an appropriate tool to monitor PA objectively in a clinical trial. We systematically reviewed the clinical trial evidence on RBT, a potentially attractive option because of the much lower costs and greater feasibility of home-based training, compared to training with free weights or weight machines. We found that many of the previous studies using RBT in people with T2D had serious limitations as discussed in Chapter 3, and the evidence currently available is insufficient to assess the efficacy of RBT. As a result, there is a need for a high-quality randomized trial to evaluate RBT in people with T2D. The proposed trial, the Diabetes Aerobic and Resistance Bands Exercise (DARE-Bands) Trial, utilizes two practical exercise tools in an exercise intervention to assess the effect on strength and glycemic control in people with T2D. The RBT program for the trial is based on the CDA endorsed “Physical Activity and Exercise Resource Manual” which was created due to a large demand for PA related resources from diabetes care providers.

4.3.1 Research Question

What are the effects of 24 weeks of aerobic training plus RBT in either a primarily group based, supervised class setting (RBT-G) or a primarily home-based setting (RBT-H) compared to aerobic training only (ATO) on strength (primary outcome), HbA1c (principal secondary outcome), anthropometric measures, body composition, satisfaction with the program, and quality of life measures on previously sedentary men and women with T2D, age greater than 35 years?
4.3.2 Hypotheses

Based on the results of studies using free weights/weight machines and the few studies using RBT we hypothesize that those randomized to 24 weeks of RBT plus aerobic training in both the primarily supervised group setting and the primarily home-based setting, will experience greater strength gains than those randomized to the ATO group. Secondly, glycemic control, anthropometric measures, satisfaction with the program, and quality of life measures will have a more significant improvement in both RBT plus aerobic training intervention groups (RBT-G and RBT-H) compared to those in the ATO group. Lastly, there will be no significant differences between the RBT-G and RBT-H intervention groups in the primary and secondary outcomes.

4.3.3 Subjects

We have initiated a pilot study, in which we aim to randomize 30 subjects (10 per group). Inclusion criteria include: 1) aged at least 35 years; 2) T2D as defined by the CDA expert committee;¹ and 3) HbA1c levels between 6.6%-9.9%. To account for potential dropouts we hope to initially recruit 36 participants. Participants must be willing to follow all study procedures, including: wearing and downloading the accelerometer, completing exercise logs, attending resistance training group sessions, and performing home-based or class-based RBT. Exclusion criteria include: 1) participation in 150 minutes or more of aerobic exercise per week, during the six months prior to enrolment; 2) participation in any form of resistance training in the previous six months; 3) requirement for insulin therapy currently or in the previous three months; 4) uncontrolled hypertension (systolic BP greater than 160 mmHg or diastolic BP greater than 100 mmHg) measured in the seated position; 5) hypoglycemia unawareness, or severe hypoglycaemia requiring assistance from another person within the previous three months; 6)
restrictions to PA because of disease; 7) inability to comply with or understand instructions, because of a language barrier or other reasons; 8) pregnancy at the start of the study, or intention to become pregnant in the next six months; 9) unwillingness to sign informed consent.

4.3.4 Methodology

The pilot study is a 3 arm, parallel groups randomized controlled trial. Since this study is an exercise trial, blinding of participants is not feasible. However, most study outcomes are analyzed by personnel who will be blinded to group assignment.

4.3.4.1 Baseline assessment

At the initial visit, potential participants are assessed by the Research Coordinator to ensure they meet inclusion and exclusion criteria, and to obtain signed informed consent. The Research Coordinator takes a complete medical, drug and exercise history, administers the Rose Angina Questionnaire, completes a structured physical examination, and consults a study physician if uncertain or concerned about any finding. Anthropometric measures are taken, including height, weight, and waist and hip circumferences. All subjects complete three quality of life questionnaires: two generic quality of life questionnaires, the SF-36 and the EQ-5D, and one disease-specific, the Diabetes Distress Scale (DDS). A resting electrocardiogram (ECG) is obtained. If symptoms suggesting angina are reported, or the resting ECG is abnormal, subjects are referred for further medical evaluation and require medical clearance from an internist or cardiologist prior to entering the trial.

4.3.4.2 Laboratory measurements

Blood is drawn at baseline for serum creatinine, complete blood count, alanine transaminase (ALT), and thyroid stimulating hormone (TSH), and urine is obtained for albumin/creatinine ratio. These tests are performed periodically in routine care for people with
diabetes, and will identify anemia, renal insufficiency, liver or thyroid dysfunction meriting investigation and, if appropriate, treatment prior to entry in the trial. Blood for other outcomes, including HbA\textsubscript{1c}, glucose, lipids, ApoA1, ApoB, and HSCRP are drawn at baseline, 12 and 24 weeks post-randomization. A report from a dilated retinal exam or retinal photographs by an optometrist or ophthalmologist within the previous year is requested, as further assurance that macular edema or proliferative retinopathy is not overlooked. An eye exam must be arranged if not done in the past year.

4.3.4.3 Testing of strength

The maximum weight that can be lifted 8 times while maintaining proper form (8 RM) is determined for chest press (upper body), leg press (lower body).

4.3.4.4 Orientation to accelerometer and exercise logs

Each subject is issued a MWK single-axis downloadable accelerometer which is worn on a belt clip or waist band. Participants are instructed how to wear, charge, and download the device. For the few without internet access at home to download the accelerometer (<10% of our clinic population), alternative arrangements are made, such as: using a computer at a friend’s home, at work, at a community facility, or at our research office. Subjects are instructed on completion of exercise logs to track RBT.

During the two week run-in period study subjects are asked to attend two sessions per week of supervised RBT at a centrally located community facility. RBT classes are led by an exercise specialist. Resistance bands are distributed at the beginning of each RBT session and collected at the end of each session; participants do not take them home. Only those subjects who attend all four supervised resistance band sessions, successfully download the accelerometer at least twice, and complete their exercise logs during the run-in period are eligible for
randomization. Participants are randomized in equal numbers into three groups: RBT-G, RBT-H, or ATO. Allocation to intervention group is conducted using a central randomization system, with allocation concealment. After randomization, participants are contacted by phone weekly for the first four weeks, every two weeks in weeks 5-8, and every four weeks in weeks 9-24 to troubleshoot any problems the participant is having with the demands of the trial, including the exercises, the MWK, and record keeping.

4.3.4.5 Aerobic Training

The aerobic training is common to all three groups (RBT-G, RBT-H and ATO) and is home-based and unsupervised. Aerobic training is included in all three groups because we suspect that, if we did not specify and measure aerobic training for both groups, the subjects randomized to the control group (no RBT) will complete more aerobic exercise than the intervention group, potentially washing out true benefits of RBT. Given the established benefits of aerobic exercise (e.g. walking) it is not be ethical to ask control subjects to avoid all exercise. All subjects participate in a 10-week ramp-in period with the goal of achieving 150 minutes of MVPA per week. Walking and jogging (for the few with sufficient fitness), are the primary modes of achieving the prescribed aerobic activity as these are the modes of aerobic exercise that are most accurately recorded by an accelerometer. Subjects use their RPE to guide aerobic exercise intensity.116

Aerobic activity is monitored by the MWK accelerometer. The MWK has a USB connector which when plugged into a computer allows for the exchange of data between the key and the web-based interface, the MyWellness portal. The MyWellness portal stores all collected individual data which is easily exported to Microsoft Excel. Participants are contacted if the MyWellness portal shows activity either less than 150 minutes per week or more than 200
minutes per week of moderate-vigorous aerobic exercise. By guiding participants to target at least 150 minutes per week but not more than 200 minutes per week of aerobic exercise, we aim to ensure that the average amounts of aerobic training will be similar among groups.

4.3.4.6 Resistance Band Training

The RBT intervention follows the resistance bands protocol outlined by the CDA-endorsed “Physical Activity and Exercise Resource Manual”. The RBT-G and RBT-H groups engage in RBT three times per week, progressing to three sets of 10 repetitions of the 12 exercise outlined in the resource manual. The exercises included are: chair squat, sitting chest press, seated rear fly, seated row, overhead press, lateral raise, biceps curl, triceps extension, leg extension, hamstring curl, gluteal extension, and abdominals (Figure 9). The resistance band exercise sessions are between 25-60 minutes depending on how advanced the participant is in the program. Free videos demonstrating proper form for each exercise can be found online at http://www.youtube.com/watch?v=-6D6fpQLh3s.

The RBT program is delivered in a circuit. Delivering the RBT program through a circuit is the preferred method for several reasons. First, a circuit approach requires less time to complete due to reduced time resting. Moreover, a circuit approach is more strenuous which may result in the RBT program having a greater effect on the study outcomes. Participants complete the first set of each exercise with a brief 30 second rest in between exercises. After the completion of the first set of each of the 12 exercises, participants take a two or three minute rest before beginning the next set.
Figure 9 Resistance Bands Exercises

1. Hips & Thighs
   - Start: Sit at the front of the chair, chest up, and feet hip width apart. Slowly lift out of the chair with your knees directly over your toes. Keep your back straight and arms out.
   - Finish: Hold the top position with knees bent. Slowly bend knees to lower yourself to the chair. Don’t drop to the chair.

2. Chest
   - Start: Place the band around your upper back. Grab the ends of the band with elbows bent and palms facing down or inward.
   - Finish: Press out, extending your elbows forward to shoulder level. Slowly return to starting position.

3. Upper Back
   - Start: Grasp the band with both hands in front of your chest with the elbows slightly bent and shoulders down.
   - Finish: Keep elbows slightly bent and pull band outward until the band reaches across your middle chest. Hold the end position briefly, squeezing the shoulder blades together. Slowly return to starting position.

4. Middle Back
   - Start: Wrap the middle of the band around an extended foot. Grasp both ends of the band at the outside of your knee with your outside hand. Pause. Slowly lower to starting position.

5. Shoulders
   - Start: One foot and band anchor one end of the band. The other hand is beside the shoulder grasping the band, hand level with the chin, and arm straight up from the floor.
   - Finish: Extend the arm overhead until directly over the shoulder. Try not to lean to one side. Pause. Slowly lower to starting position.

6. Upper Arm – Front
   - Start: Anchor as per #5 with slightly shorter band. Grasp the band at position just outside the knee. Can have palm down or palm forward (faster on the shoulders).
   - Finish: Lift arm to side with elbow slightly bent. Lift to shoulder height or slightly below shoulder height if you have shoulder problems. Pause. Slowly lower to starting position.

7. Upper Arm – Back
   - Start: Keep same anchor position as #6, except slightly shorter band length. Grasp band with palm facing up.
   - Finish: Curl band to shoulder keeping your elbow at your side at the lower ribs. Pause. Slowly lower to starting position.

8. Lower Back
   - Start: Seated at the front edge of the chair and chest up. Place the band around your knees, anchoring the band with one hand on the opposite thigh and holding the other end of the band down at your side with your elbow bent.
   - Finish: Extend your elbow until your arm is straight down by your side. Pause. Slowly return to starting position.

9. Legs – Front
   - Start: Tie the band in a knot and wrap around your feet, or tie the band around one leg of the chair with your foot through the loop.
   - Finish: Extend one leg out, keeping your knee in the same position. Keep your posture. Pause. Slowly return to starting position.

10. Legs – Back
    - Start: Stand behind the chair holding the back for support. Wrap the tie band around your ankles, or tie the band around a leg of the chair with your foot through the loop.
    - Finish: Curl one ankle up. Keep the knee in the same position and your back stable. Pause. Slowly return to starting position.

11. Lower Back
    - Start: Stand behind the chair holding the back for support, with knees slightly bent, and leaning forward with back straight. You can wrap a band around your ankles, or do the exercise without a band.
    - Finish: Extend one leg out so that it is in line with your body. Don’t over-extend the leg or arch in the low back. Pause. Slowly return to starting position.

12. Abdominals
    - Start: Seated comfortably in the chair, chest up, and both knees bent with the feet on the ground in front of you.
    - Finish: Lift one knee so that it is higher than the opposite knee, or slightly rock back with both feet on the ground. Tighten your abdominals. Keep your chest up. Pause. Slowly return to starting position.

Figure 9 Resistance Bands Exercises
The following instructional guidelines, taken from the Physical Activity and Exercise Resource Manual, are emphasized: (1) maintain a stable posture, ensure that the spine remains neutral and that there is no bending or twisting; (2) keep each movement slow and controlled, strive for three seconds of forceful contraction and three seconds to return to the starting position; (3) do not hold breath, exhale with effort and inhale on the return to the starting position; (4) keep a comfortable range of motion to reduce injury; (5) use an appropriate resistance, pick a Thera-band that allows participants to perform the required number of repetitions while achieving the prescribed level of fatigue. When necessary to achieve the required degree of resistance, two or more bands are used together.

Participants in the primarily supervised RBT-G intervention group attend group sessions supervised by a Kinesiologist twice per week for the 24 week program and also complete one additional RBT session at home on their own time every week. A greater amount of supervision ensures that participants are adhering to the program and that participants are utilizing proper form and technique, as well as the proper progression of Thera-band resistance as they increase strength. Having this weekly at-home session is intended to facilitate long-term adherence and, if desired, later transition to in-home training after the end of the intervention period.

The primarily home-based RBT-H intervention group attends a supervised group RBT class twice per week in weeks 1-2, once per week in weeks 3-6, and once every two weeks thereafter. Participants in this group are responsible to complete all remaining sessions (a total of three per week, including supervised sessions) at home on their own time. Participants attend the supervised classes to ensure that they are executing the exercises safely with proper form, to ensure participants use the right band colour as they gain strength, and to increase adherence through group support.
All RBT-G and RBT-H participants are informed that if they are not feeling the prescribed level of fatigue after the prescribed number of repetitions, they should switch to the next colour of resistance band.\textsuperscript{81} Participants are responsible for assessing their own level of fatigue at home by determining where their exertion falls on the OMNI perceived exertion scale for resistance exercise (OMNI-RES) and are helped by the researcher when they attend supervised classes. The OMNI-RES scale has been validated for use with Thera-band resistance bands against EMG signals and heart rate.\textsuperscript{117} This scale measures the RPE for the active muscle on a ten point scale that ranges from 0-10. The scale has both verbal and pictorial cues (Figure 10). The 12 exercises target all major muscle groups and the intensity progresses from “somewhat easy” to “hard”. The OMNI-RES scale is a tool for participants, as they know to switch to the next resistance level when their fatigue falls low on the scale (Figure 11). All participants in the RBT-G and RBT-H groups are asked to record all resistance band exercise sessions in a detailed exercise log.

To ensure adequate supervision, each class has a maximum of eight participants. Supervised sessions are offered four times per week, two daytime classes and two evening classes. Adherence is monitored by direct verification of supervised classes and review of exercise logs.
Figure 10 The OMNI perceived exertion scale for resistance exercise\textsuperscript{117}
Figure 11 Resistance band progression guide

<table>
<thead>
<tr>
<th>Band 1</th>
<th>Band 2</th>
<th>Pounds resistance (at 100% elongation)</th>
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<tbody>
<tr>
<td>Red</td>
<td></td>
<td>3.7</td>
</tr>
<tr>
<td>Green</td>
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<td>4.6</td>
</tr>
<tr>
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<tr>
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<td>7.3</td>
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<tr>
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<td>Green</td>
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<tr>
<td>Silver</td>
<td></td>
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<tr>
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4.3.5 Outcomes/Measurements

4.3.5.1 Primary Outcomes

4.3.5.1.1 Strength testing

The 8 RM is determined for chest press (upper body), and leg press (lower body) using a Torque TQ5 Universal Gym for chest press and the Body Solid Leg Press/Hack Squat (GLPH 1100) for leg press testing. Strength testing is done at baseline, 12 and 24 weeks post randomization.

4.3.5.2 Secondary Outcomes

4.3.5.2.1 HbA₁c

Blood is drawn for HbA₁c at baseline, 12 and 24 weeks post randomization. As HbA₁c analysis every 12-13 weeks is part of standard care for those with T2D, the costs of these measurements are not attributable to the study. Lab testing is run by Calgary Laboratory Services whose lab technicians are blinded to randomized assignment.

4.3.5.2.2 Anthropometrics

Height is measured at baseline using a stadiometer with shoes removed. Weight, waist and hip circumferences are collected in light clothing without shoes at baseline, 12 and 24 weeks post randomization. Waist circumference is measured midway between the lowest rib and the top of the iliac crest, at the mid-axillary line. Hip circumference is taken around the widest portion of the buttocks. Both waist and hip circumference are measured to the nearest 0.1 cm. BMI is also calculated at baseline, 12 and 24 weeks post randomization as (weight in kg)/(height in m)².

4.3.5.2.3 Blood pressure
Three measures of systolic and diastolic BP are taken at 1-minute intervals using a digital BP monitor HEM-907 (Omron, Vernon Hills, Illinois, United States) with the subject sitting with back supported; the mean of the lower two measures will be taken as the true BP.

4.3.5.2.4 Moderate-to-vigorous aerobic exercise

Weekly time spent in MVPA (i.e. at least 3 METs) as measured by the MWK accelerometer is collected via the web-based interface.

4.3.5.2.5 Questionnaires

The SF-36\textsuperscript{113} is the most widely-used and extensively-validated generic measure of health-related quality of life. It consists of 36 questions and can be administered in five minutes. The validity of the SF-36 is demonstrated in studies of diabetic subjects by differences in mean scores in the expected directions according to several variables (age, sex, treatment with insulin vs. oral medication).\textsuperscript{118} The EuroQOL EQ-5D questionnaire is also be administered. This questionnaire includes questions for five core domains of quality of life (mobility, self-care, ability to conduct usual activities, pain and discomfort, and anxiety and depression) and also uses a simple visual analogue scale.\textsuperscript{114} It has been extensively validated and has proven reliable.\textsuperscript{119-121}

For this study we use the enhanced EQ-5D-5L questionnaire which will have greater sensitivity in determining differences in quality of life.\textsuperscript{122} Lastly, the DDS\textsuperscript{115} is a 17-item questionnaire assessing emotional distress and functioning specific to living with diabetes. Responses are on a six-point scale from one (no problem) to six (serious problem). Scores can range from 17-102 with higher scores indicating poorer diabetes-related quality of life. This instrument has high internal reliability, with a Cronbach’s alpha of 0.93. DDS scores were positively associated with depressive symptomatology, and had convergent validity with the Center for Epidemiology Studies Depression Scale ($r=0.56$). In addition, DDS scores were positively associated with
decreased adherence to meal planning recommendations ($r=0.30$), and lower levels of PA ($r=0.13$). All quality of life assessments are done at baseline, 12 and 24 weeks post randomization.

4.3.5.2.6 Medications

Medications are assessed at baseline, 12 and 24 weeks post-randomization. After study subjects are randomized, we fax letters to their physicians informing them of their patients involvement in the study. Physicians are told that changes in medication for glycemia, lipids and BP should be avoided between study entry date and the end of the intervention period unless deemed medically necessary. If physicians feel that medication changes are necessary, we ask that these changes be discussed with Dr. Ronald Sigal or study staff. In addition, smoking, traditional lipids, Apolipoproteins, and HSCRP will be analyzed for the larger DARE-Bands Trial.

4.3.5.3 Feasibility

All aspects of the study are monitored and assessed to ensure that the future larger study runs as well as possible and that any unforeseen problems are addressed. Areas of focus include: recruitment, participant training, adherence, data collection, contamination, adverse outcomes, time demands (for study staff and participants) and participant satisfaction. Feasibility of the study cost, design and data collection methods are assessed throughout the trial by research staff and participants. Information regarding the methods being used and any changes that would be required to ensure the feasibility and ease of conduct for the larger subsequent trial are recorded. Detailed logs are maintained in which any unforeseen costs and problems with the study will be noted and discussed at regular research team meetings. In addition, any barriers to successful recruitment will be noted as well as time taken to recruit.
Several methods of recruitment are used in this pilot trial such as posters, referrals from Diabetes Educators, and Kijiji/Craigslist advertisements. These different methods of recruitment will be assessed to see which strategies are the most useful. These observations will lead to a successful recruitment strategy for the larger DARE-Bands trial as well as an indication of the staff needed to handle recruitment.

To assess contamination (ie. participants in the ATO group participating in RBT), adverse outcomes, adherence, and participant satisfaction, detailed questionnaires and participant monitoring are utilized. We record the occurrence of contamination, adverse outcomes, and adherence as well as the reasoning for these events. These problems will be addressed with the goal of decreasing contamination and adverse outcomes and increasing adherence in the future. Adherence is monitored by the completion of exercise logs which are to be handed in at every supervised resistance band exercise session. Participants are also asked to scan or take a digital photo of their RBT log after each home-based session and email or fax it to the study coordinator. If participants fail to attend the supervised classes they are contacted via telephone, email or text messaging until contact is achieved.

4.3.6 Limitations

This study has several limitations that have been taken into consideration but deemed appropriate based on the objectives. First, the study has a small sample size (n=30) which will limit the ability to detect small intergroup differences (high type II error). In addition, because of the sampling method participants may be more motivated than the target population since they are volunteering for this study, so our results could not be generalizable to people with no interest in exercise. Lastly, there is no sedentary control group. However, the inclusion of moderate aerobic exercise in all three groups is of importance since aerobic exercise is
recommended for all people with diabetes, and the combination of aerobic plus resistance exercise has shown to be the most beneficial for reduction in HbA1c. Furthermore, inclusion of aerobic exercise in all three groups allows us to control for the effect of aerobic exercise, and take measures to equalize its volume among groups. Otherwise, it is likely that participants randomized to the control group would achieve more aerobic exercise than those in RBT-G or RBT-H, potentially washing out the effects of RBT.

4.3.7 Significance

With the completion of the proposed pilot study, and the subsequent larger trial, knowledge will be gained regarding a novel approach to resistance training in those with T2D through the use of resistance bands. If home-based exercise training with resistance bands improves strength, glycemic control and other vascular risk factors it could be beneficial to the large numbers of patients who prefer not to have to travel to a gym or cannot afford a gym membership. If home-based training is shown to be effective, many of the most common barriers to participation in resistance training (e.g. lack of access to exercise facilities, cost of gym memberships, cost of home equipment, time to travel to and from gym) will be greatly reduced. With less barriers to resistance exercise it is likely that this modality of training will then be adopted by more patients, and that the morbidity associated with T2D will be decreased. This is particularly true if such training also improves quality of life, and more people are thus inclined to continue exercising in the long term.

If only the fully-supervised group-based program improves strength and other study outcomes, this would underscore the importance of supervision for resistance training and would temper enthusiasm for home-based RBT. If neither group-based nor home-based RBT improves primary or secondary outcomes compared to the aerobic training-only group, it will be clear that
RBT is not useful for people with T2D and that for the positive effects of resistance training to be seen, free weights and weight machines must be used. Using resistance bands could make resistance training available to many people for whom cost and convenience are obstacles to traditional gym-based training with weight machines or free weights.

4.4 Overall Thesis Conclusion

The global burden of T2D is increasing, and complications of the illness occur primarily in those whose glycemic control is fair or poor. Fortunately, T2D can be managed and a pillar of this care is PA. There is a wealth of research demonstrating the beneficial effects of aerobic, resistance, and combination (aerobic plus resistance) exercise; however, there are still many barriers that diminish exercise participation in people with T2D. Practical exercise tools, such as the MWK accelerometer and resistance bands, can potentially increase participation and long term adherence to PA by providing important information and decreasing barriers to exercise. Increased participation among those with T2D will likely result in decreased morbidity associated with T2D, especially with long term adherence to exercise. In addition, increased PA participation in people with T2D could reduce health-care burden and expenditure.
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