Study Protocol

The Long-Term Effects of Resistance Training and Diet in Elderly Type 2 Diabetics

INVESTIGATORS
Dr David Dunstan (International Diabetes Institute)
Dr Max DeCourten (International Diabetes Institute)
Dr Robin Daly (Deakin University)
Prof. Paul Zimmet (International Diabetes Institute)
Prof. Neville Owen (Deakin University)

Freer CL, *et al. BMJ Open Diab Res Care* 2022; 10:e002950. doi: 10.1136/bmjdrc-2022-002950

1.1 Objectives

The present study plans to assess the efficacy and feasibility of dynamic resistance training involving circuit weight training (CWT) in 60 overweight elderly persons with type 2 diabetes. More specifically, in a parallel study design with 3 phases, including an initial dietary run-in phase, this study will assess (Figure 1):

1. the feasibility of 24 weeks supervised dynamic resistance training within a laboratory-based setting combined with moderate energy-restriction and its effects on strength, glycaemic control, body composition, bone mineral density, lipid profile, blood pressure and general well-being, compared to moderate energy restriction alone (phase 2).
2. the feasibility of an additional 24-week home-based resistance training or resistance training within community/commercial facilities and its impact on muscular strength, glycaemic control, body composition, bone mineral density, lipid profile, blood pressure, general well-being and exercise behaviour (phase 3).

1.2 Background Information

Type 2 diabetes is frequently associated with adverse health outcomes, including hypertension, cardiovascular disease, stroke, and peripheral vascular disease. It is also well documented that poor glycaemic control is associated with the presence or progression of long-term complications such as neuropathy, nephropathy and renal failure, foot ulcers, lower limb amputations and visual disorders.

The importance of regular physical activity in type 2 diabetes is adequately described in several epidemiological studies such as the Da-Qing study in China [1], showing improved glycaemic control in people with diabetes and reduced diabetes risk in physically active individuals with impaired glucose tolerance. Furthermore, its favourable effects on glycaemic control support the role of increased physical activity for the prevention of diabetes complications, since data from the Diabetes Control and Complications Trial (DCCT) [2] have convincingly shown that improving glycaemic control in people with type 1 diabetes can prevent or delay the progression of long-term complications of diabetes. Similar data are accumulating for people with type 2 diabetes [3].

Nevertheless, the promotion of physical activity in type 2 diabetics, particularly older individuals, still remains a challenge. Studies documenting poor patient compliance have led to suggestions that increasing physical activity may not be a feasible means of improving diabetic control in older people with type 2 diabetes [4]. It is probable that aging itself contributes to exercise non-compliance, since it is associated with a host of metabolic and physiological changes that can affect functional capacity and impinge on an individual's ability to perform physical activity. Together these factors result in age-related decreases in muscle strength and aerobic capacity, which contribute to decreases in functional independence and lead to increased frailty and injury risk in the elderly [5, 6]. Furthermore, diabetes and its complications can accentuate the 'normal' age-related deterioration in physical function. Hence, many older type 2 diabetics may miss the benefits of regular physical activity on glycaemic control, cardiovascular disease, weight and psychological health.

Physical activity involving resistance (weight) training may be a logical approach in older individuals because of its positive effects on many of the physiological alterations that accompany aging. Current research indicates that age does not decrease the capacity of the muscle to adapt to resistance training. Indeed, in older individuals, resistance training

interventions employing moderate to high intensities (60 to 90% of maximum strength) have been shown to increase muscle strength and function as well as increase skeletal muscle mass [7, 8]. Favourable alterations in energy expenditure and body composition, including increased fat-free mass and decreased fat mass or body fat, with preferential decreases in the trunk region, have also been observed in some [7, 8], but not all [9], studies following resistance training. Other studies have also shown that resistance training can favourably influence serum lipids and blood pressure [10] and can improve insulin action in middle-aged/older men [11] and post-menopausal women [9]. There is also evidence that resistance training may increase or preserve bone mineral density in post-menopausal women [5, 22] and middle-aged/elderly men [23].

Clearly there is a deficiency in knowledge concerning the efficacy of resistance training in patients with type 2 diabetes. It is believed that previous discouragement for this form of exercise in individuals at risk of heart disease due to the fear of precipitating cardiac or vascular complications, together with its poor impact on aerobic fitness have contributed to this situation. Nevertheless, there is now a considerable body of evidence to indicate that moderate intensity, dynamic, high-volume (moderate to high number of repetitions) resistance training, such as circuit weight training (CWT), can be used effectively and safely in such individuals [12]. Indeed, mild to moderate dynamic resistance training has become an integral component in the physical rehabilitation of patients with cardiac disease [13]. Furthermore, because body weight is supported throughout, dynamic resistance training has the unique potential to overcome the orthopaedic stress commonly associated with endurance exercise involving prolonged periods of weight bearing.

While studies have shown that dynamic resistance training programs can be performed safely in type 2 diabetes patients, the efficacy and feasibility of this type of exercise in older (> 60 years) is not known. Furthermore, the impact of resistance training in combination with moderate energy restriction in type 2 diabetes patients has not been investigated. These issues will be addressed in a three-phase study, whereby the efficacy of dynamic resistance training within a supervised setting for 6 months in elderly type 2 diabetics will be assessed in combination with moderate energy restriction, followed by a 6-month period of non-laboratory-based resistance training performed at home and/or within community facilities.

It is postulated that the combination of resistance exercise training with moderate energy restriction will counterbalance fat-free mass loss often seen with energy restriction alone and may have additive or synergistic benefits in the non-pharmaceutical management of glycaemic control, cardiovascular risk factors and general well-being of elderly type 2 diabetics.

1.3 Description of Project

Eligibility Criteria

60 overweight male and females with type 2 diabetes, age range 60-80 years, will be recruited both from the clinics of the International Diabetes Institute (IDI) and in response to a local media campaign. Inclusion criteria will comprise established (> 6 months) but controlled (diet and/or medication) type 2 diabetes (Hb_{A1c} < 9.0 %), sedentary lifestyle (less than two 30 min sessions of vigorous exercise per week for the preceding 6 months) and a body mass index (BMI) > 29 kg/m^2 but < 40 kg/m^2. All volunteers will undergo further medical examination including medical history, physical examination, and a resting 12-lead ECG to determine suitability for participation.

Exclusion Criteria
Volunteers will be non-smokers or ex-smokers for at least 6 months. Volunteers with a severe orthopaedic, cardiovascular, or respiratory condition that precludes participation in an exercise program will be excluded. Those taking insulin or lipid-lowering medication will not be included. Poorly treated hypertensives (anti-hypertensive medication and BP > 160/90 on at least two occasions) will be excluded.

Withdrawal Criteria
Volunteers who have successfully completed 12 weeks or more of the laboratory-based intervention or who for medical or personal reasons wish to withdraw from the study, will have all endpoints measured and will be considered in the final analysis. Withdrawals prior to this time will whenever possible be replaced.

Sample Size
Based on the experience of an Australian study involving exercise training in older type 2 diabetic patients over a 6-month period [4], 30 participants in each study group will provide at least 80% power to demonstrate a 0.6% decrease in glycated haemoglobin or a 0.1 mmol/l increase in HDL-C. Assuming that a retention rate of at least 80% is achieved, this will require the recruitment of 75 participants. The proposed 24-week duration of resistance training or energy restriction in phase 2 should be sufficient for changes in glycated haemoglobin and body composition.

Study Location
The study will be predominately conducted at Deakin University (Toorak). Existing facilities and resources will be used for the collection of laboratory and clinical measurements and administration of the strength testing and training protocols.

Recruitment
Patients attending the diabetes clinics at the International Diabetes Institute (IDI) will be formally invited to participate in the research project in a document distributed by their supervising physician. This document will outline the aims of the project and the procedures involved and will be similar to the subject information sheet. Subjects will be in a dependent relationship with their supervising physician, however, there shall be no prejudice to further medical care should the individual choose not to participate in the study and may withdraw at any stage. In addition, advertisements for the study will placed on notice boards throughout the clinic. A local media advertising campaign (newspapers, radio) will also be initiated to seek appropriate volunteers.

Screening
The research nurse, in conjunction with the supervising physician, using previous medical records held at IDI initially will identify the suitability of volunteers who wish to participate according to the inclusion and exclusion criteria outlined above. A telephone screening questionnaire will also be used to identify potential volunteers (Appendix A). Those who appear suitable will attend a screening visit at Deakin Toorak. During this visit, $HbA1_c$ and BMI will be determined, and a physician will decide on the suitability of volunteers who wish to participate according to the inclusion and exclusion criteria outlined above. Suitable volunteers will be asked to a complete screening questionnaire to obtain lifestyle information including medical history, medication use, alcohol consumption, past tobacco use and physical activity levels during work, domestic and leisure activities (Appendix A). A resting 12 lead ECG will also be performed. Participants will be required to give informed consent before commencing the study. Eligible participants will be required to provide contact details of their supervising physician who

will be given a description of the study and its requirements and utilised as a point of reference in the event of adverse effects arising during the study.

1.4 Study Design

The study will be completed over 3 phases:

Phase 1: All participants will be instructed and guided by a dietitian for 4 weeks on achieving a standard diabetic diet according to current diabetic dietary guidelines [14]. During this 4-week period all participants will be familiarised with the resistance exercise equipment and their strength determined by measurement of one-repetition maximum (1RM).

Phase 2: After the initial clinical and laboratory measurements, participants will continue with the diet and will be randomly assigned (age/sex/BMI matched) to either:

1. Progressive resistance training (supervised 3 times per week) + Moderate Energy Restriction
2. Placebo exercise (supervised stretching/flexibility exercises 3 times per week) + Moderate Energy Restriction

Supervised training will be performed in a group setting for a period of 24 weeks, during which time participants will be instructed to follow the dietary recommendations. Alterations in medication will be documented. Maximum strength (1RM), clinical and laboratory measurements will be assessed before the intervention, at 12 weeks, and after the 24-week intervention. Participants randomised to resistance training will have strength reassessed monthly to account for strength gains.

Phase 3: At the completion of phase 2, participants will be provided with individualised instruction on how to perform resistance training or flexibility training at home and/or within commercial/community facilities. Questionnaires completed at the end of phase 2 will be utilised to initiate appropriate behavioural strategies based on the Transtheoretical Model (TTM) and social-cognitive theory (SCT) (Questionnaires to be developed). Regular telephone contact will be made during this period. Participants will return to the IDI for the assessment of strength, blood measurements, blood pressure and body composition after 12 weeks and again 12 weeks later during this phase.

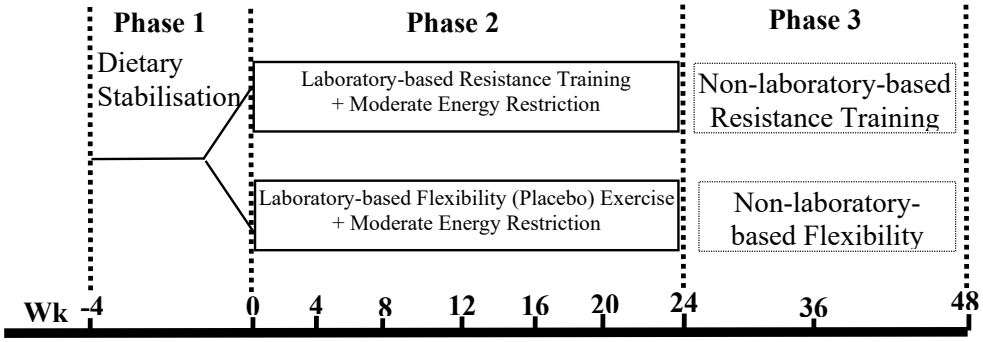

Figure 1: The proposed study design

Diet

During phases 1 and 2, all participants will be guided by a dietitian to follow standard diabetic dietary guidelines [14]. This includes Carbohydrate 55-60%, Protein 0.8 g/kg, Fat < 30%, Cholesterol < 300 mg/day, Fibre 40 g/day and P/S ratio > 1.

Volunteers will be asked to complete 2 weighed, 3-day (two working days, one weekend day) food records during Phase 1 to estimate energy requirements. At the completion of the dietary run-in period, all volunteers will receive dietary counselling about the diet plan at the appropriate energy level to be followed throughout the duration of the study. During phase 2 (intervention), each volunteer will complete four 3-day food records, each representing two weekdays and 1 non-weekday of each week. All analyses of nutritional data will be performed by a dietitian using the Diet 1 V4.22 nutrition analysis computer program.

Moderate Energy Restriction
In addition to the above-mentioned diet, during phase 2 participants will undergo further individualised dietary counselling fortnightly or whenever required to achieve moderate energy restriction. This diet will be tailored on an individual basis to induce approximately 0.25 kg weight loss per week. It is acknowledged that participants involved in CWT may require less energy restriction than controls due the increased energy expenditure of the program. Body mass will be measured for all participants weekly during the intervention. During the final 4 weeks of the 6-month program, all individuals will be instructed to maintain a constant weight on diets similar in composition to the diet advised during phase 1.

Self-Blood Glucose Monitoring (SBGM)
During phase 2, participants will be required to perform self-monitoring of blood glucose using portable monitors on 4 days of the week (2 exercising days, 2 non-exercising days). On these days, they will be required to perform SMBG in the morning prior to breakfast (fasted) and immediately following the exercise session or at the same time on the non-exercising day. The correct procedures required for the use of the blood glucose monitor will be provided by IDI diabetes educators. The participants will be required to document their blood glucose level on a standardised record form and return it at the completion of each week. Dr Dunstan's previous experience with this protocol but with additional measurements performed 2 hours after lunch and the evening meal, shows that persons with type 2 diabetes can successfully achieve the required measurements with adequate instruction and encouragement and are able to comply with the requirements for at least 8 weeks [15, 16].

Maximum Strength Testing
Following initial familiarisation sessions, one-repetition maximum (1RM) strength will be determined for each exercise used in the circuit for all participants under the supervision of a trained instructor. Participants will be given a brief warm-up using a light workload prior to each exercise. Following the successful completion of 3-5 repetitions and after a brief rest (1 min), the workload will be increased incrementally until the participant can perform only one complete repetition (1RM). This weight will be used to determine the appropriate training intensity (60-80% 1RM). Strength testing will be repeated after 3 months and at the end of the laboratory-based intervention for all participants and monthly during the intervention for participants involved in ST program to account for strength improvements. During phase 3, all participants will return to the exercise laboratory after 3 months and at the end of 6 months for strength testing.

Progressive Resistance Training (PRT) Program
Supervised PRT will be performed in an exercise laboratory on 3 non-consecutive days of the week for 24 weeks. Pin-loaded weight machines and free-weights will be used. A warmup and cool down will be performed before and after the exercise session. Participants will perform 8-10 repetitions at the appropriate intensity (60-80% 1RM) in a slow, controlled manner within 30 seconds. They will then rest for 30-60 seconds before proceeding to the next exercise station. Three sets of between 8 and 10 repetitions will be completed during each session. Each exercise session (approximately 45 mins) will be supervised by an experienced instructor to

ensure correct, safe techniques are performed and to monitor the appropriate amount of exercise and rest intervals.

Stretching/Flexibility (Placebo) Program
This program will serve as a control exercise program and is intended to provide participative involvement and to minimise co-intervention bias. Participants will attend the exercise laboratory 3 times per week, during which a series of stretching/flexibility exercises will be performed for 30 minutes. Dr Dunstan's previous experience with this exercise regimen indicates that this program usually does not increase the pulse rate above 100 bpm and does not induce changes in cardiovascular fitness or glycaemic control in middle-aged type 2 diabetic patients [15]. His PhD research experience demonstrated excellent compliance with this placebo exercise regimen performed 3 times per week for 8 weeks in a supervised setting, as shown by having 20 out of 24 participants complete all sessions during this period [15].

Non-Laboratory-Based Training
This encompasses a 24-week period where participants will be required to follow an individualised resistance training or flexibility training program at home and/or within community/commercial facilities. Participants will be individually guided and provided with written information on the selection of exercise equipment and training facilities at the end of the laboratory-based intervention. Provisions will be made for the use of IDI weight equipment during this period for participants who do not wish to purchase their own equipment. Questionnaires based on TTM and SCT described earlier will be utilised to implement and analyse exercise behavioural change (To be developed). Initially, participants will be telephoned by a staff member every week for the first 4 weeks to check his or her progress. Thereafter, telephone contact will be made fortnightly. This will be used to administer questionnaires, monitor progress, answer questions, and provide individualised feedback. Participants will also be required to complete weekly activity logs.

Non-Intervention Controls
Volunteers fulfilling the eligibility criteria but excluded on the basis of having a previous history or physical signs suggestive of ischaemic heart disease only will be invited to serve as comparison group of participants (non-intervention controls) for bone mineral density and body composition measurements. This group will not receive diet or exercise intervention and will undergo body composition assessment (anthropometry, BIA & DEXA) and have glycated haemoglobin, 24-hour urine and questionnaires measured once at baseline (end of phase 1) and again after 6 months (end of phase 2) and 12 months (end of phase 3). This group will be instructed to maintain their usual dietary and physical activity patterns throughout the 12-month period. Participants in this group will be required to give informed consent to participate.

Compliance with Study Requirements
Compliance with the diets will be assessed by weekly food checklists and monthly 3-day food records. A seven-day physical activity recall questionnaire [17] will be administered fortnightly during phases 2 and 3 to monitor habitual activity levels (Appendix A). This questionnaire takes approximately 10 minutes to complete. Compliance with the exercise training regimens during phase 2 will be assessed by attendance to the supervised exercise sessions. Dr Dunstan's previous experience with exercise training shows that excellent exercise compliance can be achieved in type 2 diabetic patients in such studies. In the previously mentioned study involving CWT, participants were required to attend exercise sessions held on campus at UWA 3 times per week for a period of 8 weeks. As already indicated, all participants completed at least 22 of the 24 exercise sessions required, with 9 of the 11 participants completing all 24 sessions over this period. His other PhD research study required all participants to attend 3 exercise sessions per week for 8 weeks at Royal Perth Hospital, located in the CBD of Perth. In this study, half

were assigned to moderate aerobic exercise training involving stationary cycling for 30 mins, while the remainder performed light exercise involving stretching/flexibility exercises for 30 minutes. Briefly, of the 52 participants who commenced the intervention, only 3 were excluded from the final analysis. Despite the intensive nature of the study, all participants were able to successfully complete at least 21 of a possible 24 exercise sessions during this period (88% adherence), with 45 participants (92%) completing all sessions. Dr Dunstan has identified several helpful initiatives to improve compliance with study requirements. In particular, conducting group exercise sessions proved to be highly beneficial because it enabled social interaction among participants with similar medical concerns within a friendly atmosphere. Also, in recognition of work and family commitments, he gave participants the choice of early morning or evening exercise times. In the event of a missed session, participants were telephoned and a supplementary catch-up session (usually a Saturday morning) was organised. It is envisaged that the recruitment of elderly participants, many of whom will be retired, will enable even greater flexibility in exercise session scheduling in the proposed study. Questionnaires administered at the completion of laboratory-based intervention will be used to identify each individual's stage of readiness for change and the appropriate intervention strategy based on TTM and SCT administered to enhance exercise compliance during phase 3. In addition, participants will be telephoned fortnightly and will be instructed to complete logs describing the exercise frequency, duration and rating of perceived exercise for each training session. These will be returned monthly via mail.

1.5 Data Collection

Blood and Urine Measurements

A small blood sample (2.5 ml) will be collected during screening for the measurement of glycated haemoglobin levels. A 25 ml fasting blood sample will be collected before, during (12 weeks) and after the laboratory-based intervention. Samples will be assayed for: routine biochemical and haematological profile, glucose, insulin, C-peptide, serum lipids (triglycerides, total cholesterol, HDL-C and LDL-C), glycated haemoglobin, testosterone, estrogen, insulin-like growth factor (IGF-I), intact parathyroid hormone and markers of bone formation (procollagen type I propeptide, osteocalcin). A 24hr urine collection will be performed at these time points for measurement of urinary sodium, potassium, calcium, creatinine and albumin excretion and markers of bone resorption (pyridinoline cross-links). Measurements will be assessed again following 12 weeks and 24 weeks of non-laboratory-based training.

Laboratory Measurements

All blood samples will be centrifuged immediately at IDI and then sent by courier to an off-site testing laboratory for analysis. Serum for insulin assays will be frozen at - 70 degrees and measured in a single assay to minimise inter assay variability.

Body Composition and Bone Mineral Density

Anthropometric measurements, including body mass, height, skinfold and circumference measurements will be assessed using standardised protocols by the International Society of the Advancement of Kinanthropometry and administered by a Anthropometry-certified graduate officer. Dual energy X-ray absorptiometry (DEXA) will be performed under the guidance of a trained technician once at baseline and once at the end of the respective six-month interventions to assess total body, lumbar spine and proximal femur bone mineral density, fat-free mass and lean mass. In addition, Bioelectrical Impedence Analysis (BIA) will be performed once during baseline and once at the end of the end of the respective interventions. Fat mass, fat-free mass and total body water will be estimated, based on BIA. This technique of body composition measurement was recently assessed by a panel of experts in the US [18], who concluded that BIA provides a reliable estimate of total body water under most conditions and is a useful technique for body composition in healthy individuals and those with mild-to-moderate

obesity, including diabetes mellitus. These procedures will be used collectively to assess body composition changes resulting from the respective interventions.

Blood Pressure
Resting blood pressure will be measured at the beginning, mid-way (3 months) and at the end of each respective intervention period. Systolic and diastolic blood pressure will be determined manually by a trained assessor using a conventional mercury sphygmomanometer with participants having rested (5 mins) in a seated position. The mean of 3 separate readings (30 secs apart) will be recorded.

Physical Function Tests
A collection of simple tests will be used to measure changes in physical function. These include: a timed backward tandem walk test over a 6-metre course (dynamic balance); standing balance, measured with semi-tandem, tandem, and one leg stands in sequence and timed; chair stand (no. of stands in 60 seconds); reaching down and returning to standing position (seconds); 3 metre walk (lengths in 60 seconds); 360° turn (steps to complete); and manual dexterity (seconds required to turn a coin five times).

General Health and Well-Being
A self-reported, generic measure of health status that has been validated for adult age groups in Australia, the US and the UK called the SF36 questionnaire will be used to assess general health and well being at baseline and after 24 weeks of both laboratory-based and non-laboratory-based training (Appendix A). This questionnaire measures 8 important health concepts including, physical function, the impact of both physical health and emotional health on role performance, bodily pain, social functioning, general mental health, vitality and general health perceptions. This questionnaire was recently used in the 1995 ABS National Health Survey.

Exercise Behaviour
As indicated, questionnaires administered at baseline and at the end of each respective intervention period will be utilised for the initiation of individualised intervention strategies based on the Trans-Theoretical (stages of change) model [19] and social-cognitive theory [20]. These questionnaires will be used to analyse the implementation and maintenance of exercise behaviour change. Pre-testing on specific measures and items will be used to determine whether paper and pencil or personal interview formats, or a combination of these, are most appropriate. Self-efficacy and stage of change items have been developed through earlier studies and can be adapted and expanded for elderly type 2 diabetic patients.

1.6 Statistical Analysis
Data will be analysed using the Statistical Package for the Social Sciences (SPSS Inc., USA) for Windows. Independent t-tests will be used to assess between-group comparisons for the changes during the respective interventions. A pooled time-series regression analysis using a random effects model [21] will be used to evaluate changes in self-monitored blood glucose readings during the laboratory-based intervention period.

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