

# A randomized, controlled trial to study the effect of exercise consultation on the promotion of physical activity in people with Type 2 diabetes: a pilot study

A. F. Kirk\*, L. A. Higgins\*, A. R. Hughes\*, B. M. Fishert, N. Mutrie\*, S. Hillis\* and P. D. MacIntyre\*

\*Centre for Exercise Science and Medicine, University of Glasgow and †Diabetes Centre, Royal Alexandra Hospital, Paisley, UK

Accepted 21 April 2001

## Abstract

**Aim** To evaluate the effect of exercise consultation on promotion of physical activity in people with Type 2 diabetes.

**Methods** Twenty-six sedentary people with Type 2 diabetes were randomly assigned to receive an exercise consultation and standard exercise information (experimental) or standard exercise information alone (control). Exercise consultation is a one-to-one discussion, based on the transtheoretical model, designed to educate, strengthen motivation and develop realistic strategies to promote physical activity. Changes from baseline at five weeks were assessed in (a) stage of exercise behaviour (b) physical activity levels (7-day recall questionnaire and an accelerometer) (c) quality of life (SF-36 Health Survey and 22-Item Well-Being Questionnaire).

**Results** 82% (9/11) of participants receiving a consultation increased their stage of exercise behaviour compared to 33% (4/12) of controls ( $\chi^2 = 5.4$ ,  $P = 0.02$ ). Physical activity counts/week increased by 4% (1636 067/1696 191) in the experimental group and decreased by 9% (1560 960/1725 510) in controls. A significant difference was recorded for the change in activity counts per week from baseline to follow-up between the experimental and control group (98% CI = 60 673–710 827). The number of participants taking part in sport or leisure activity increased by 55% (6/11) in the experimental group and decreased by 6% (1/12) in controls. Positive changes were evident in the experimental group, compared to controls, in both quality of life questionnaires.

**Conclusion** Exercise consultation is more effective in stimulating exercise behaviour change in the short term than a standard exercise leaflet.

Diabet. Med. 18, 877–882 (2001)

**Keywords** Type 2 diabetes, physical activity, quality of life

**Abbreviations** CSA, Computer Science and applications; SF-36, Short form-36; BMI, body mass index; HbA<sub>1c</sub>, glycosylated haemoglobin

## Introduction

The effectiveness of exercise in the management of Type 2 diabetes is well established [1]. Improvements in glucose homeostasis, cardiovascular risk and quality of life have

Correspondence to: Alison Kirk, Cardiology Department, Level 5 North, Royal Alexandra Hospital, Corsebar Road, Paisley, PA2 9PN, Scotland, UK. E-mail: 9403930k@student.gla.ac.uk

been reported after moderate and vigorous aerobic [2–5] or resistance training [6]. Despite numerous studies supporting the benefits of frequent physical activity for people with Type 2 diabetes, an estimated 60–80% of this population remain sedentary [7,8]. Limited research addressing promotion and maintenance of physical activity in this population is available.

Exercise consultation [9] is a one-to-one discussion, based on the transtheoretical model of behaviour change, designed to educate, strengthen motivation and develop realistic goals and strategies to promote and maintain physical activity behaviour. The transtheoretical model describes five stages which individuals progress through when changing behaviour (precontemplation, contemplation, preparation, action and maintenance). Interventions based on the transtheoretical model incorporate different strategies at each of the five stages to motivate behaviour change.

Exercise consultation tailored to an individual's readiness to change has demonstrated greater changes than traditional educational approaches to physical activity promotion [10]. Hasler *et al.* [11] found exercise consultation compared to standard exercise information was effective at increasing short-term physical activity levels in people with Type 1 diabetes.

This randomized controlled trial describes the short-term effects of exercise consultation on physical activity levels and resultant quality of life in a group of people with Type 2 diabetes. We hypothesized that exercise consultation would increase physical activity levels and improve quality of life.

## Patients and methods

Twenty six sedentary people with Type 2 diabetes were recruited over an eight-week period from a diabetes patient database and from outpatient clinics. Diabetes Mellitus was defined according to the criteria established by the World Health Organization study group [12]. All participants were in either a contemplation or preparation stage of exercise behaviour change, i.e. they were not meeting current physical activity guidelines but had the intention to become more active [13]. Patients with a medical condition contraindicated to exercise or with evidence of ischaemic heart disease by history, resting or exercise electrocardiogram (1 mm ST segment depression) were excluded. The ethical committee of Argyll and Clyde Health Board approved the study and written informed consent was obtained from all participants.

The flow of participants through the trial is shown in Fig. 1. Participants made a total of four visits for study assessment. During the first visit, each participant completed two quality of life questionnaires. Weight, height, recent glycosylated haemoglobin levels and duration of diabetes were recorded. Participants were screened for underlying ischaemic heart disease by performing a maximal exercise tolerance test on a motorized treadmill according to a standard Bruce Protocol

[14]. Participants were then given a Computer Science and Applications accelerometer (CSA Inc).

Exactly seven days later participants attended for visit two. Accelerometers were returned, stage of exercise behaviour change was assessed and participants were asked to complete the Scottish Physical Activity seven-day recall Questionnaire. A blinded research assistant then randomly assigned participants to either the experimental or control group. Randomization was conducted by allocating an identification number to each participant in order to ensure anonymity in this process. The two conditions (experimental and control) were randomly ordered in a list and participants identification numbers then selected by a research assistant and assigned to the next condition on the list. The experimental group received an exercise consultation and standard exercise information and the control group received standard exercise information only.

At five weeks, the outcome measures and procedures carried out at baseline, with the exception of the screening exercise test and both interventions, were repeated.

## Exercise intervention

The exercise consultation [9] involved a one-to-one discussion between a trained research assistant and participant lasting approximately 30 min. The consultation incorporated the following components; past and present physical activity behaviour, benefits and barriers to becoming more active, available facilities, social support, goal setting and relapse prevention. The primary aim of the consultation was to encourage patients to accumulate 30 min of moderate physical activity most days of the week [15]. If the patient was already achieving this level of activity they were encouraged to build in 30 min of vigorous exercise 3 or more days a week [16].

A leaflet entitled 'Exercise and your Diabetes' [17], approved by Diabetes UK, was used as standard exercise information. This was given to both the control and experimental groups.

Equal contact time with the investigator was achieved by conversations with the control group on topics unrelated to exercise.

## Outcome measures

Stage of exercise behaviour change (i.e. readiness to adopt or maintain a physically active lifestyle) was assessed using the five stages described by the transtheoretical model, adapted to exercise behaviour by Marcus [13]. These are precontemplation (not regularly physically active and no intention to change), contemplation (not regularly physically active and intend to change), preparation (doing some physical activity, but not enough to meet current guidelines), action (started to engage in regular physical activity) and maintenance (maintaining regular physical activity). The categories of 'increase'; 'decrease' and 'no change' were used to assess individual movement from baseline to follow-up within the stage of exercise behaviour change model. If an individual increased they progressed to a more active stage of exercise behaviour.

The accelerometer (CSA Inc) was used as an objective measure of dynamic physical activity, measured by bodily acceleration [18]. This accelerometer is small and lightweight

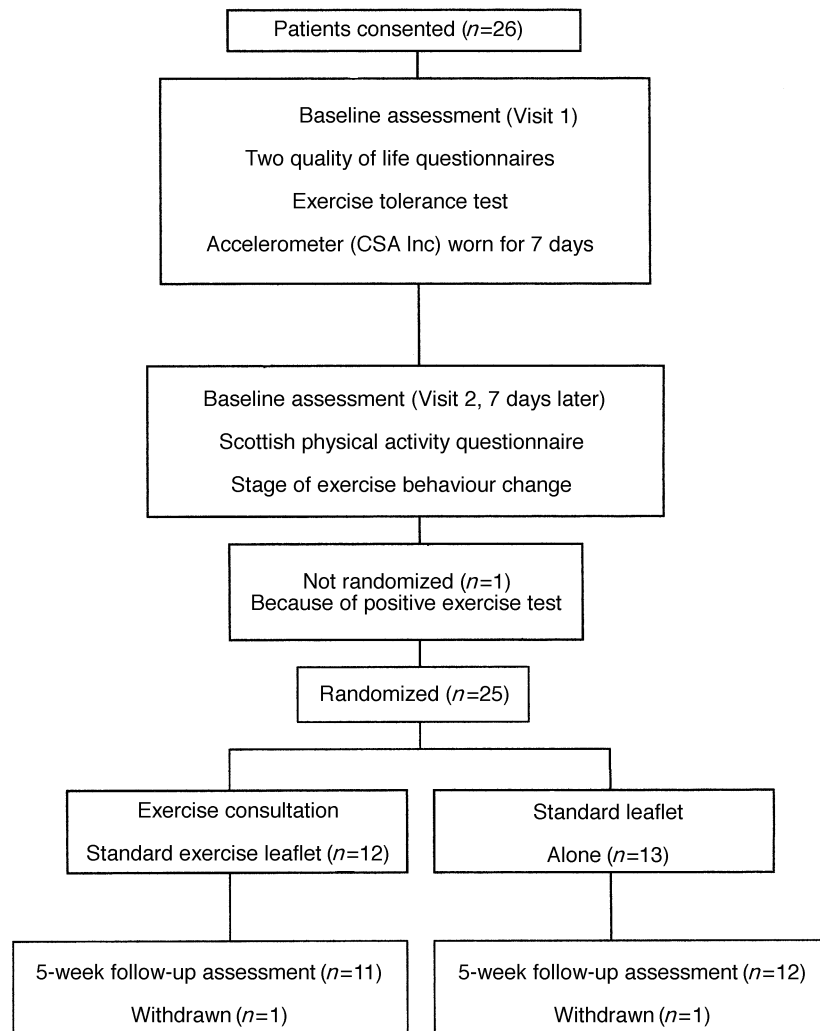


Figure 1 Flow of participants through trial.

and during the study was secured by a belt to the right side of the participant's waist. The activity monitors measure movement using a vertical uniaxial piezoelectric bender which, when displaced, generates a signal proportional to the force acting on it. Generated signals are compiled developing an activity count which is stored over a defined period. Participants were instructed to wear the monitor for seven days during all waking hours except bathing. The activity monitors were programmed to collect activity counts at one-minute intervals for a seven-day period. On return, activity monitors were downloaded and a total weekly physical activity count was calculated for each participant.

Self-reported physical activity was assessed using the previously validated Scottish physical activity questionnaire [19]. This includes questions on mode and duration spent in both work and leisure activities of moderate to vigorous intensity over the previous seven days. A physical activity score was calculated in minutes per week for total, leisure and work related physical activity.

Well-being was assessed by the 22-item self-administered Well-Being Questionnaire [20]. Questionnaire scores were combined to produce a total well-being score and four subscale

scores: depression, anxiety, energy and positive well-being. A higher score indicates greater expression of the individual measured subscale.

The SF-36 Health Survey [21] was used to measure quality of life. The SF-36 evaluates eight functional health status dimensions: physical and social functioning, limitations in usual role activities due to physical or emotional health, bodily pain, general health, vitality and mental health. On all SF-36 subscales a higher score reflects a higher quality of life.

### Statistical analysis

Using subject codes, all data was entered into Minitab (version 12.21) statistical package by a research assistant blinded to group allocation. Data are presented as mean or median. Statistical analyses were performed by paired or 2 sample student *t*-tests or nonparametric equivalent tests. 98% confidence intervals are reported to protect against Type 1 errors. Categorical data were reported as a proportion and analysed using  $\chi^2$  or Fishers exact test.  $P < 0.02$  was considered to be statistically significant.

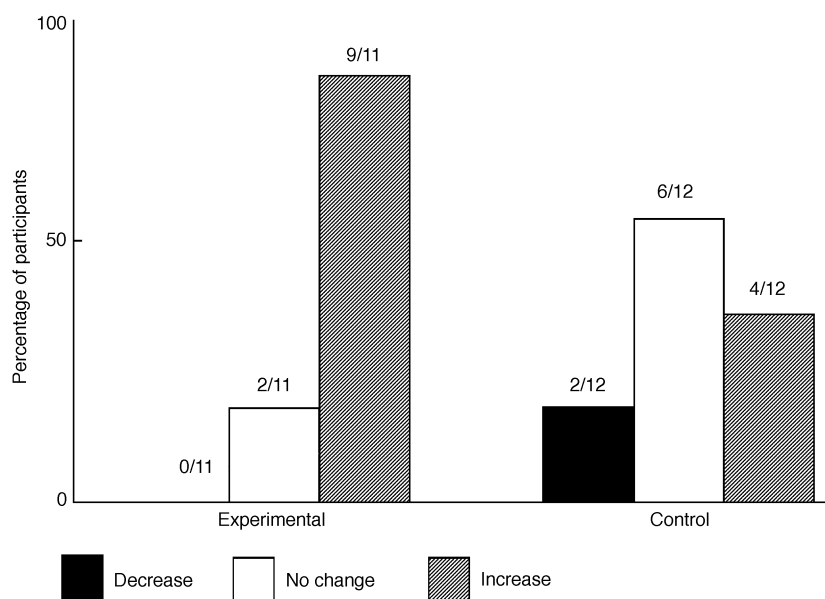


Figure 2 Changes in stage of exercise behaviour.

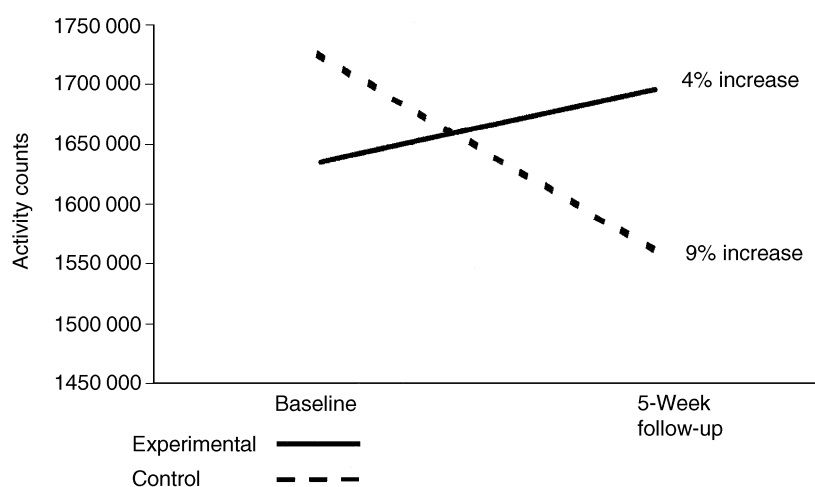


Figure 3 Median change in accelerometer (counts/week).

## Results

Participants in experimental or control groups did not differ in age (mean 48.64 SD 8.51 years), sex (11 men, 14 women), BMI (mean 33.77 SD 5.26 kg/m<sup>2</sup>), HbA<sub>1c</sub> (mean 8.29 SD 1.4%) or duration of diabetes (mean 5.29 SD 3.53 years).

Twenty-three patients completed the study. One participant was excluded after a positive exercise test at screening, implying the presence of ischaemic heart disease, and two participants dropped out due to reasons unrelated to the study.

### Change in physical activity

The proportion of participants who increased their stage of exercise behaviour was significantly higher in the experi-

mental than the control group (82% (9/11) v 33% (4/12),  $\chi^2 = 5.4$ ,  $P = 0.02$ ) (Fig. 2). In addition, at follow-up, 55% (6/11) of the experimental group, compared to 8% (1/12) of controls had progressed to an action stage of exercise behaviour.

A positive change in total physical activity counts per week was recorded from participants receiving a consultation (Fig. 3): Physical activity counts/week increased by 4% (1636 067/1696 191) in the experimental group and decreased by 9% (1560 960/1725 510, 98% CI = 297 420, 234 777) in control. The change in total physical activity counts per week was significantly different between the groups (98% CI = 60 673, 710 827).

The experimental group recorded a trend towards an increase in leisure and total minutes of physical activity per week, as recorded by the Scottish Physical Activity seven-day recall Questionnaire. The control group recorded a

trend towards a decrease in leisure and total minutes of physical activity. However, no significant between or within group changes from baseline were recorded.

Self reported participation in sport, leisure activity or training, a recorded component of leisure physical activity, increased by 55% (6/11) in the experimental group and decreased by 6% (1/12) in the control group.

### Change in quality of life and well-being

At five-week follow-up, a trend towards positive changes in most subscales of both questionnaires was recorded in the experimental group, compared to control. Vitality and mental health subscales on the SF-36 significantly improved in the experimental group from baseline to follow-up (Vitality 98% CI = 0,50, Mental health 98% CI = 0,30) although mental health was the only subscale to record a significant between group difference for change in score from baseline to follow-up (98% CI = -40, -4).

### Discussion

This pilot data suggests that exercise consultation is more effective in stimulating exercise behaviour change in the short term than the standard exercise leaflet, currently used to promote physical activity in people with Type 2 diabetes.

Two out of the three physical activity measures recorded significant changes between groups at five-week follow-up. In stage of exercise behaviour change, the proportion of participants who increased a stage was significantly higher in the experimental than the control group. In addition, output from the CSA accelerometer demonstrated the change in total physical activity counts per week from baseline to follow-up to be significantly different between the groups.

The Scottish Physical Activity seven-day recall Questionnaire was the only physical activity outcome measure with no significant results. An increase in physical activity was recorded in the experimental group compared to the control group and a larger sample would provide greater power to detect a statistically significant difference. Both the Scottish Physical Activity seven-day recall and the CSA accelerometer recorded a decrease from baseline to follow-up in the control group. Possible explanations for this trend could be a lower compliance with wearing the accelerometers during follow-up in the control group or an increase in motivation following recruitment into a physical activity study, followed by a regression to the norm over the five-week follow up period.

Only a few studies have investigated the association between physical activity and psychological well-being in people with diabetes. In a recent randomised controlled trial Ligtenberg [6] assessed the influence of a physical

training program on psychological well-being in 51 elderly people with Type 2 diabetes. After six weeks of training, significant improvements were found in all subscales of the Well-Being questionnaire, except depression. In the present study, Vitality and Mental Health subscales on the SF-36 significantly improved from baseline to follow-up in the experimental group. Change from baseline to follow-up in the Mental Health subscale was the only significant difference between groups. Differences recorded however, were in the expected direction and the small sample size offered limited power in producing a statistically significant difference.

This study is one of the first to assess interventions to promote and maintain physical activity behaviour in people with Type 2 diabetes. In a randomised controlled trial, Hasler *et al.* [11] demonstrated that exercise consultation increased short-term physical activity in people with Type 1 diabetes, measured using stage of exercise behaviour change and a self-report seven day recall questionnaire. Recently, Berlanga *et al.* [22] investigated the impact of focused, individualized advice, compared to routine advice, on physical activity levels over a 1 year period in people with newly diagnosed Type 2 diabetes. The study reported a significant increase in total weekly energy expenditure measured using a modified Paffenbarger physical activity questionnaire. However no objective measurement of physical activity was used.

Given the importance of physical activity in the management of diabetes, the results of the present study have important implications for health care providers regarding the design of effective interventions to increase physical activity in diabetes populations. The exercise consultation does not require to be conducted by an exercise specialist; with minimal training this intervention could be conducted by any one of the multidisciplinary diabetes management team.

The findings of this preliminary study warrant a full-scale trial to evaluate the effectiveness of this intervention on promotion and maintenance of physical activity behaviour in people with Type 2 diabetes. Future investigations could include longer follow-up, larger and more diverse samples and an evaluation of resultant cardiovascular risk, metabolic control and autonomic functioning.

Reference of published abstract Kirk A, Higgins L, Hughes A, Fisher M, Mutrie N, McLean J, MacIntyre P. 2000. The effectiveness of exercise consultation on promotion of physical activity in a group of type 2 diabetic: A, pilot study. (Abstract) *Diabet Med* 17 (1) P19. Presented at *Diabetes UK annual Conference 2000 (Brighton)*.

### References

- 1 American Diabetes Association. Diabetes Mellitus and Exercise. *Diabetes Care* 2000; 23: Suppl. 50: S50-S54.

- 2 Lehmann R, Vokac A, Agosti K, Spinass G. Loss of abdominal fat and improvements of the cardiovascular risk profile by regular moderate exercise training in patients with NIDDM. *Diabetologia* 1995; **38**: 1313–1319.
- 3 Mayer-Davis E, D'Agostino R, Karter A, Haffner S, Rewers M, Mohammed S. Intensity and amount of physical activity in relation to insulin sensitivity. *JAMA* 1998; **279**: 669–674.
- 4 Walker K, Piers L, Putt R, Jones J, O'Dea K. Effects of regular walking on cardiovascular risk factors and body composition in normoglycaemic women and women with Type 2 diabetes. *Diabetes Care* 1999; **22**: 555–561.
- 5 Ligtenberg P, Godaert C, Hillenaar F, Hoekstra J. Influence of a physical training program on psychological well being in elderly Type 2 diabetes patients. *Diabetes Care* 1998; **21**: 2196–2197.
- 6 Honkola A, Forsen T, Eriksson J. Resistance training improves the metabolic profile in individuals with Type 2 diabetes. *Acta Diabetologica* 1997; **34**: 245–248.
- 7 Hays L, Clark D. Correlates of physical activity in a sample of older adults with Type 2 diabetes. *Diabetes Care* 1999; **22**: 706–712.
- 8 Ford E, Herman W. Leisure time physical activity patterns in the US diabetic population: Findings from the 1990 national health interview survey. *Diabetes Care* 1995; **18**: 27–33.
- 9 Loughlan C, Mutrie N. Conducting an exercise consultation: Guidelines for health professionals. *J Inst Health Educ* 1995; **33**: 78–82.
- 10 Lowther M, Mutrie N, Scott M. The long term effect of two physical activity interventions on the physical activity levels of members of the general public who are not regularly active. *J Sports Sci* 2000; **18**: 18–19.
- 11 Hasler T, Fisher M, MacIntyre P, Mutrie N. Exercise consultation and physical activity in patients with Type 1 diabetes. *Pract Diabetes Int* 2000; **17**: 44–48.
- 12 The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 2000; **23**: Suppl 4: S4–S20.
- 13 Marcus B, Simkin L. The transtheoretical model: applications to exercise behaviour. *Med Sci Sports Exerc* 1994; **26**: 1400–1404.
- 14 Bruce R. Exercise testing of patients with coronary artery disease. *Annus Clin Res* 1971; **3**: 323–332.
- 15 Pate RR, Pratt M, Blair SN, Haskell WL, Macera CA, Bouchard C et al. Physical activity and public health. A recommendation for the Centres for Disease Control and Prevention and The American College of Sports Medicine. *JAMA* 1995; **273**: 402–407.
- 16 American College of Sports Medicine. The recommended quantity and quality of exercise for developing and maintaining cardio-respiratory and muscular fitness in healthy adults. *Med Sci Sports Exerc* 1990; **22**: 265–274.
- 17 Boehringer Mannheim UK Exercise and your Diabetes (leaflet). 2000.
- 18 Melanson E, Freedson P. Validity of the Computer Science and Applications Inc (CSA) activity monitor. *Med Sci Sports Exerc* 1995; **27**: 934–940.
- 19 Loughlan C, Mutrie N. Development of a Scottish physical activity questionnaire: a tool for use in physical activity interventions. *Br J Sport Med* 1999; **33**: 244–249.
- 20 Bradely C. Handbook of psychology and diabetes. A Guide to Psychological Measurements in Diabetes Research and Practice. 1st edn. Harwood Academic 1994; 90–98.
- 21 Ware JE, Snow KK, Kosinski M, Gandek B. *SF-36 Health Survey Manual and Interpretation Guide*. Boston: The Health Institute, New England Medical Centre, 1997.
- 22 Berlanga F, Wareham N, Barr W, Nagi D. Does a 'focused' advice to increase physical activity work in patients with newly diagnosed Type 2 diabetes? (Abstract). *Diabetic Med* 1998; **15**: 24–25.