©Journal of Sports Science and Medicine (2012) **11,** 51-56
http://www.jssm.org

Research article

The effect of tele-monitoring on exercise training adherence, functional capacity, quality of life and glycemic control in patients with type II diabetes

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Abstract
We used tele-monitoring to attempt to improve exercise adherence (number of hours of exercise completed), peak VO_2, HbA1c% and quality of life in an unsupervised, home based exercise program in people with type II diabetes, a cost analysis was also conducted. Thirty-nine patients with type II diabetes were randomized to tele-monitoring (TELE) or control (CON) groups. All patients were asked to complete 6 months exercise training and complete an exercise activity diary. The TELE group was instructed to record their exercise heart rates using a monitor and received weekly telephone calls from an exercise physiologist. Six TELE patients and seven CON patients did not complete the 6 month testing. TELE patients completed a mean weekly volume of 138 minutes, moderate intensity exercise, while CON patients completed 58 minutes weekly ($p < 0.02$). Neither group achieved the American Heart Association statement guideline for weekly exercise volume of 150 minutes. TELE patients improved peak VO_2 (5.5 %), but neither group improved HbA1c% or quality of life. The CON group showed a 4.9% reduction in peak VO_2. While tele-monitored patients completed more hours of exercise and demonstrated improved peak VO_2 compared to controls, the exercise volume completed was insufficient to improve glycemic control. There is the potential via tele-monitoring to enable people with diabetes to meet exercise training guidelines.

Key words: Diabetes mellitus, telemedicine, exercise therapy, outpatient, cost analysis.

Introduction

Exercise training has become an important adjunct therapy for both the prevention and management of type II diabetes mellitus. Meta-analyses of regular, supervised exercise training in type II diabetes mellitus patients concluded that statistically and clinically significant improvements in blood glucose, HbA1c (8-9%), lipid profile and peak VO_2 (12%) are likely, independent of body mass changes (Boule et al., 2003; Yoo and Lee, 2005). Furthermore exercise capacity is a strong predictor of all-cause mortality in type II diabetes (Kokkinos et al., 2009).

It is unfortunate that supervised exercise programs for people with diabetes are often delivered via an outpatient program with a finite duration (Thomas et al., 2006) as outpatient programs of longer duration are cost-prohibitive for most health service providers. Long-term adherence to exercise is required for ongoing effective diabetes management, but the Cochrane systematic review of exercise training studies reports only one included study with a training duration greater than six months (Thomas et al., 2006) and some short duration studies have reported adherence rates insufficient to promote or retain health benefits (Harrison et al., 2005).

Unsupervised exercise training provides a cost-effective alternative to an outpatient program, but is also likely to have poor adherence unless strategies are implemented to keep patients motivated (King et al., 1988). Our group has previously utilised tele-monitoring to maintain exercise training adherence for 12 months in heart failure patients (ACSM, 1993). The provision of telephone-based physical activity counselling has been shown to be effective in increasing physical activity over 12 months in previously low-active older adults (Kolt et al., 2007) and in improving glycemic control in patients with type I diabetes (Gomez et al., 2002), but tele-monitoring of long-term (>3 months) exercise training in patients with type II diabetes is a novel approach (Smart et al., 2005).

The aims of this study were to investigate whether adherence (number of hours of exercise completed and proportion of hours at an appropriate intensity) to a 6 month, unsupervised, home based exercise program would be improved if a tele-monitoring strategy was employed. The secondary aim was to examine if peak VO_2, HbA1c% and quality of life were improved with tele-monitoring and whether any changes were related to aggregate exercise time or mean intensity. Finally, we also wished to examine the cost-effectiveness of exercise training compared to pharmacological therapy in people with type II diabetes.

Methods

A prospective randomized, controlled study was conducted between May 2007 and October 2010 after receiving ethical approval from the Bond University Human Research Ethics Committee. Both external funding organizations had no role in the data collection, analysis or interpretation, nor did the funding bodies approve or disprove the manuscript content. Participants with a diagnosis of type II diabetes mellitus aged between 18 and 80 years, body mass index > 27 $kg \cdot m^{-2}$, based on fasting plasma glucose > 7.0 $mmol \cdot L^{-1}$ and glycosylated haemoglobin (HbA1C%) > 6.5 were included in the study. Individuals with known cardiovascular disease or those unable to complete an exercise program were excluded. Patients were recruited from advertisements placed in an endocrinologist's and general practice office, as well as on the university's website. Following initial patient phone contact, appointments were made with prospective

Received: 17 August 2011 / Accepted: 22 November 2011 / Published (online): 01 March 2012

subjects, who were provided with study details. Prior to entry into the study patients were required to give their consent to participate, and medical clearance was obtained from the patients' general practitioner. Selection was designed in this manner as the exercise program was unsupervised and patients had the potential to develop medical problems when exercising.

All tests started between 0800 and 0900 so circadian variation was eliminated. During pre-exercise screening, patients' body mass and twelve lead electrocardiogram were recorded. Venous blood was taken by the referring physician to establish baseline serum levels for glycosylated haemoglobin (HbA1c%), fasting glucose, high density- and low density-lipoprotein, total cholesterol, triglycerides, albumin and estimated glomerular filtration rate. Patients' general practitioners were asked to provide details of medications used, including doses and frequency. Following informed consent, and prior to the exercise test, patients completed a medical questionnaire, and the twelve-item Assessment of Quality of Life Questionnaire (AQOL), which measures the strength of patient preferences. AQOL data were compared against normal values in Australians (Hawthorne et al., 1999). A physician took the patient's medical and family history, blood pressure and resting heart rate. The physician also assessed suitability of patients for exercise testing against relative and absolute contra-indications to testing as outlined by American Heart Association/American College of Cardiology guidelines (Hunt et al., 2001).

All patients completed an open circuit spirometry graded treadmill test, with continuous 12 lead ECG (Mortara X12+) and blood pressure monitoring. The former was linked in real-time to the open-circuit spirometer. Patients walked on a Vision Fitness Treadmill (model T9800HRT, Wisconsin, USA). Starting at an angle of ten degrees and a speed of 3.2 $km \cdot hr^{-1}$, the gradient of the treadmill was increased by two degrees, and the speed increased by 0.8 $km \cdot hr^{-1}$, every three minutes until volitional exhaustion or the participants met one or more American Heart Association/American College of Cardiology criteria for terminating an exercise test (Hunt , et al. 2001). A Parvo Medics, (TrueOne 2400, East Sandy, Utah) open circuit spirometer of the mixing chamber type was used to determine peak VO_2, respiratory exchange ratio (RER), breathing frequency (BF), tidal volume (V_T), V_E, V_E/VO_2 and V_E/VCO_2. The ventilatory threshold was measured using the V-slope method (Beaver WL 1986). All data were sampled every twenty seconds and maximal or peak oxygen consumption (VO_2) was calculated by taking the mean of the three highest consecutive values. Once maximal or peak VO_2 was established, 55-65% of peak VO_2 was calculated and corresponding heart rates were obtained.

Following baseline testing patients were stratified by gender, and then randomly assigned using computer generated random numbers, to intervention and control groups. A block randomization was employed, where patient numbers assigned to intervention and control groups were balanced after every set of 10 consecutive patients. All subjects, whether in the intervention or the control group, were given a six month individualised walking program. Subjects in both groups were instructed to keep a diary of their exercise schedule**.** Participants in the intervention group were also provided with a heart rate monitor (Polar S625X, Pursuit-performance, Adelaide, Australia). Intervention group patients received weekly phone calls, control patients neither received heart rate monitors or phone calls. Data from the heart rate monitors were downloaded onto a computer so an exercise physiologist could inform patients of their progress during weekly phone calls, which were continued for the duration of the program. Seventy-six patients agreed to participate in the study, although 27 were excluded as they had underlying cardiovascular disease and a further 10 patients did not keep appointments for informed consent or initial testing, leaving 39 patients for randomization.

Patients in both groups were then asked to complete 180 minutes per week of exercise at the approximate exercise intensity based on the HR range given**.** The weekly exercise program of 180 minutes was selected in the hope it would enhance the chance of achieving 150 minutes as a weekly target. Intervention group patients used heart rate monitors, control group patients were taught how to take their pulse to monitor heart rate.

Telephone calls were always conducted by the same person. Phone calls had standardized content to avoid bias. Three main questions asked were: "How are you going?", "How has your exercise program been?" and "Have you completed the 180 minutes of required exercise?" If the answer to the last question was yes then the exercise physiologist asked if the heart rate monitor was working correctly. Patients were also asked if their mean heart rate for each session had attained the prescribed intensity. If the patient said they were not meeting the required 180 minutes of exercise per week then they were asked why they were not meeting the required time, as well as if and when they might do so. Additionally, the patient was asked whether there were any specific reasons (E.g. muscular injury, ulcer etc.) why they were not meeting the required exercise. The exercise physiologist would speak to the patient about the importance of maintaining the required volume and intensity to effect cardio-respiratory and glycemic changes. The phone calls ranged from five to fifteen minutes and allowed time for patient questions. Patients were encouraged to contact the exercise physiologist if they had any questions. The exercise physiologist met the patients three to four weeks later and their exercise data were downloaded from the heart rate monitors, to prevent the monitor's memory reaching capacity (100 hours). This process was repeated four to eight weeks later. The meetings at these times replaced the phone call allocated for that week. Subjects in the control group did not receive any phone calls during the entire exercise program. At the conclusion of the six month exercise program, all participants in both the intervention and control groups were asked to repeat the testing regimen. Energy expenditure was calculated from the number of hours and mean heart rate (intensity) data that was related to oxygen consumption during baseline testing. Established equations were used (Astrand, 1986).

ANOVA was performed to determine the

Table 1. Baseline participant characteristics. Data are means (±SD).

Baseline Characteristics	TELE Group	Control Group	Withdrawn Group
Number of subjects	15	11	13
Male gender (%)	10 (67%)	4 (36%)	6 (46%)
Age (years)	60.3 (9.41)	65.1 (7.85)	65.6 (8.37)
Mass (kg)	93.3 (18.5)	94.8 (27.8)	91.5 (12.6)
BMI ($kg \cdot m^{-2}$)	32.3 (4.45)	33.0 (8.44)	32.3 (4.24)
HbA1c (%)	7.90 (2.39)	7.53 (1.68)	7.13 (.92)
FBG ($mmol \cdot L^{-1}$)	8.47 (3.03)	8.43 (2.38)	7.32 (1.65)
Peak VO_2 ($ml \cdot kg^{-1} \cdot min^{-1}$)	21.8 (4.99)	20.6 (3.86)	18.7 (4.47)
Insulin use (%)	0	36.4	8.3
Diabetic medication (%)	81.3	72.7	75
eGFR (<59 $mL \cdot min^{-1} \cdot 1.73\ m^{-2}$)	0 (0%)	1 (9%)	0 (0%)

BMI – Body Mass Index, HbA1C% - Glycosylated Hemoglobin, FBG – Fasting Blood Glucose, GFR – Estimated Glomerular Filtration Rate

differences in demographic and clinical variables at baseline, between the intervention group, control group and those who withdrew prematurely from the study. Inter-and intra-group differences between pre-and post-intervention continuous outcome measures, were determined by analysis of variance (ANOVA) with a post-hoc Bonferroni. Pearson correlation coefficients were calculated for changes in peak VO_2 and the number of hours of exercise completed and mean exercise heart rate. The syntax algorithim 4D was run on the AQOL data, followed by the Wilcoxon Rank Sum Test for unevenly distributed data. A P-value of less than 0.05 was considered statistically significant. SPSS software version 18.0 was used to conduct all analyses.

Results

Thirty-nine participants were randomized into the intervention and control groups, and six-month data were collected from twenty-six patients. Patients were well matched at baseline for age, gender, body mass, body mass index, HbA1C%, fasting blood glucose, peak VO_2 and diabetic medication use. Thirteen patients, exactly one third, who were randomized did not complete six month testing, although no demographic differences appeared to predispose patients to withdraw (Table 1).

The tele-monitored group logged a mean of 59.7± 21 hours of exercise on the heart rate monitors which was 76% of target, equivalent to 138 minutes per week. The control group completed a total of 25.8±21 hours, or 59.8 minutes per patient per week. The patient diaries suggested about 4% or about six minutes per patient per week, was not logged by the tele-monitored group because participants had forgotten, or incorrectly used their heart rate monitors. Moreover the heart rate monitor data suggest that exercise participation was uniform throughout the six month period and not skewed towards the end or the beginning of the study. Mean exercise intensity of each patient ranged from 60-75% peak VO_2 for the intervention group.

Peak VO_2 and exercise (treadmill) test time (minutes) were significantly greater in the tele-monitored compared to control group at six months (Table 2). In the tele-monitored group peak VO_2 increased (5.5%), and treadmill time (18%) and maximum heart rate (3%) were significantly greater at six months. None of the markers of glucose control or lipids were significantly changed at six months (Table 3). Change in peak VO_2 was not correlated with the number of total number of exercise hours ($r = 0.41$, $p = 0.12$) nor was mean exercise intensity ($r = 0.47$, $p = 0.06$).

At baseline, three subjects in the tele-monitored group and five controls exhibited respiratory exchange ratio (RER) values <1.10 at peak exercise (p = NS), at six months three subjects in both groups exhibited RER values <1.10 (p = NS). Mean weekly exercise energy expenditure in the tele-monitoring group was 1392 ± 754 Kcal, loss of body mass in the tele-monitoring group was 1.5 ± 2.4 kg.

Table 2. Baseline and post-intervention metabolic exercise test data. Data are means (±SD).

Variables	TELE Baseline	TELE 6 Months	P-Value TELE	Control Baseline	Control 6 Months	P-Value Control	P-Value Between Groups 6 months
Peak VO_2 ($L \cdot min^{-1}$)	2.06 (.47)	2.18 (.44)	.01	1.96 (.37)	1.86 (.31)	.35	.04
Peak VO_2 ($ml \cdot kg^{-1} \cdot min^{-1}$)	21.8 (5.0)	23.0 (4.6)	.01	20.6 (3.9)	19.6 (3.2)	.35	.04
Body Weight (kg)	93.3 (18.5)	91.9 (17.7)	.08	94.8 (27.8)	92.6 (23.1)	.27	.93
Exercise Time (mins)	8.31 (3.31)	9.87 (3.42)	.01	7.82 (3.07)	7.29 (2.81)	.51	.05
Peak Heart Rate ($beat \cdot min^{-1}$)	150 (14)	156 (18)	.03	147 (10)	145 (16)	.77	.14
Peak Heart Rate as % Maximum Predicted	101 (8)	104 (9)	.87	106 (8)	104 (14)	.91	.82
Respiratory Exchange Ratio	1.11 (.10)	1.10 (.10)	.90	1.08 (.10)	1.09 (.10)	.89	.93
VT ($L \cdot min^{-1}$)	1.29 (.41)	1.35 (.40)	.33	1.29 (.39)	1.21 (.32)	.12	.29
VT ($ml \cdot kg^{-1} \cdot min^{-1}$)	13.8 (2.7)	14.42 (2.67)	.26	13.9 (2.4)	13.6 (1.91)	.64	.27
V_E/VCO_2 at AT	29.9 (2.4)	30.3 (2.4)	.56	29.6 (2.3)	30.7 (3.79)	.55	.49
Peak SBP (mmHg)	207.0 (23.5)	217.0 (24.8)	.07	200.0 (36.8)	217 (24.7)	.42	.38
Peak DBP (mmHg)	94.9 (13.0)	94.0 (13.9)	.32	92.2 (10.6)	89.5 (11.1)	.76	.39

VT – ventilatory Threshold, SBP – Systolic Blood Pressure, DBP - Diastolic Blood Pressure

Table 3. Baseline and post-intervention markers of glucose control and lipids. Data are means (±SD).

Variables	TELE Baseline	TELE 6 Months	P-Value TELE	Control Baseline	Control 6 Months	P-Value Control	P-Value Between Groups 6 months
HbA1c (%)	7.90 (2.39)	7.61 (2.08)	.49	7.53 (1.68)	7.12 (.79)	.34	.46
FBG (mmol·L^{-1})	8.47 (3.03)	8.3 (3.22)	.77	8.43 (2.38)	8.69 (3.24)	.68	.67
Chol (mmol·L^{-1})	4.88 (.19)	4.73 (.73)	.42	3.92 (.56)	4.08 (.78)	.24	.08
HDL (mmol·L^{-1})	1.27 (.31)	1.27 (.36)	1.00	1.15 (.29)	1.14 (.30)	.25	.46
LDL (mmol·L^{-1})	2.60 (.53)	2.45 (.60)	.57	1.95 (.53)	1.91 (.57)	.41	.23
Trigs (mmol·L^{-1})	2.91 (3.93)	3.00 (5.04)	.85	1.43 (.66)	1.36 (.72)	.86	.32

HbA1C% - Glycosylated Hemoglobin, FBG – Fasting Blood Glucose, Chol – Total Cholesterol, HDL – High Density Lipoprotein Cholesterol, LDL – Low Density Lipoprotein Cholesterol ,Trigs – Triglycerides

The assessments of quality of life (AQOL) scores were similar to mean values expected in a healthy 60-69 year old cohort. No significant changes in AQOL score in either group post–intervention were noted, moreover the groups were matched at baseline and six months for AQOL score.

Four people were excluded before randomisation due to positive exercise tests indicating ischaemia. One patient from the tele-monitoring group withdrew due to physician advice after experiencing a non-fatal cardiac arrest, unrelated to exercise or exertion. Seven of the other 12 patients withdrew from the study because of time constraints and 5 withdrew due to non-serious medical conditions unrelated to the exercise program.

The total of cost of administering the tele-monitored exercise program was US $27,300, or US $1,050 per patient who completed the 6 month study. The costs associated with the program were 20 heart rate monitors US$9800, exercise test consumables US$1600, physician supervision of 72 exercise tests US$7200, salary for exercise physiologist US$8700.

Discussion

Our tele-monitoring strategy led to higher exercise adherence compared to the control group participants. Tele-monitored patients completed a mean of seventy-eight minutes more exercise per week, although the mean exercise time was short of the 180 minute weekly target. Moreover the mean number of exercise hours logged per week was constant over the six month period, suggesting improved and sustained exercise adherence in the tele-monitored patients. Patient feedback gave the exercise physiologist the perception that the weekly telephone calls provided the greatest motivation for patient to exercise, although the provision of exercise data to patients via heart rate monitors also appeared to be a motivating factor. Mean exercise intensity would be categorised as moderate (Howley, 2001), moreover exercise intensity was unrelated to change in peak VO_2, although previous meta-analysis has shown higher intensity exercise may proffer additional benefits in terms of cardio-respiratory fitness (Boule et al., 2003). The recent Cochrane systematic review of exercise interventions in people with diabetes does not included a telemonitored exercise training study, so this work is fairly novel (Thomas et al., 2006).

Our tele-monitoring regime was successful in terms of maintaining a regular number of weekly exercise hours over a six month period, albeit 24% below the desired targeted of three hours weekly. Although mean exercise intensity was higher than the prescribed dose, even the upper end of the actual intensity range (75%) would not be classified as vigorous activity. The tele-monitoring regime was modestly effective in increasing peak VO_2 over a six month period. Increasing peak VO_2 is important due to the link with mortality at various peak VO_2 thresholds in chronic disease populations (Mancini et al., 2000; Sietsema et al., 2004). An increase in maximum heart rate at six months in the tele-monitored group suggests that increased peak VO_2 was at least partially attributed to an improved cardiac output, although previous work has shown that people aged 55-65 years also adapt by improving arterio-venous difference (Ades et al., 1996). As actual heart maximum exceeded 100% of predicted in both groups, both pre- and post-intervention, it appears that changes in exercise tolerance were negligible. The TELE group patients moved from an exercise capacity of 6 METS to 7 METS while the CON group fell to 5.6 METS from 6 METS. Previous work has shown, a clinically significant 21-23% reduction in mortality risk for every 1 MET increase in the exercise capacity of people with type II diabetes (Kokkinos et al., 2009).

The majority of our patients were obese and would therefore have a limited exercise capacity relative to body mass, although the TELE group did lose a mean of 1kg. Previous work has shown improved glycemic control (HbA1C%), independent of changes in body mass or composition, following exercise training in people with diabetes (Yoo and Lee, 2005). If energy intake were to be kept constant at baseline levels, the tele-monitored patients completed a sufficient volume of exercise to elicit a potential weight loss of as much as 5 kg. As HbA1C% remained unchanged in both groups one can surmise that more than 1392 Kcal weekly exercise energy expenditure, or more than 138 minutes of exercise per week is needed to elicit improved glycemic control. Indeed our data are consistent with a recently published statement guideline from the American Heart Association suggesting that a minimum weekly exercise volume of 150 minutes moderate intensity or 90 minutes vigorous intensity activity is required to improve glycemic control (Marwick et al., 2009). Previous work has shown that exercise training lasting more than 12 weeks is likely to produce only small changes in glycemic control (Snowling and Hopkins, 2006) and that community based, but not home-based, exercise training has been shown to improve glycemic control in people with type II diabetes (Dunstan , et al. 2005; Dunstan , et al. 2006). Our data confirm that more than 138 minutes of moderate weekly exercise is required. Previous work has suggested patients need to also com-

plement exercise training with a sensible long-term eating plan, designed to effect greater weight loss and elicit control of their type II diabetes (Yoo and Lee, 2005).

Our tele-monitoring program cost about US$1050 per patient to implement, although if cardiovascular disease (CVD) screening had been conducted by referring physicians, costs associated with initial exercise testing would have been reduced. To put the cost into context, US$1050 is similar to the costs that would be borne by the patient for using low dose insulin (US$800) and a blood pressure agent such as an ACE inhibitor (US$ 130) for 6 months (PBS, 2010). Previous work has reported reductions in healthcare costs (less hospitalizations and pharmacological use) associated with exercise training in people with type II diabetes (Brun et al., 2008).

The primary limitation of this study was the sample size. Although not statistically significant, the TEL group was a mean of five years younger, and fewer (0% TELE versus 36% CON) patients used insulin, were male (TELE 76% versus CON 36%) compared to the control group. Previous work has shown peak changes in glycemic control, quality of life and peak VO_2 are often short-term (2-3 months) outcomes. Limited funding prevented three month and longer-term (>6 months), data collection, but this information would have been useful in demonstrating the rate of change in outcome measures and also whether 6 month changes were in fact optimal. In addition, periodic testing would have enabled the exercise training prescription to be titrated upwards in response to initial adaptations. As HbA1C% is a measure of glycemic control over a 120 day period, an oral glucose tolerance test or HOMA index may have been a better indicator of change in glycemic control (Kraus and Levine, 2007).

Conclusion

Telephone calls from health professionals may explain why tele-monitored patients completed significantly more hours of exercise and demonstrated improved peak VO_2 compared to controls, although the exercise volume completed was insufficient to improve glycemic control. There is the potential via tele-monitoring to enable people with diabetes to meet exercise training guidelines.

Acknowledgment

This study was funded by:

a. Novo-Nordisk Regional diabetes Award Scheme 2007.
b. Primary Healthcare Research Evaluation and Development (PHCRED) grant, from the Department of Health and Aging, Commonwealth Government of Australia 2007.
c. This study was also funded internally by a Bond University Vice-Chancellor's Research Grant 2007.

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Key points

- Weekly telephone calls from a health professional providing encouragement, increases the amount of exercise completed by people with diabetes
- Weekly telephone calls will result in improved fitness
- At least 150 minutes weekly exercise is required to improve diabetes control
- The cost of home exercise with telephone monitoring is cheaper (and more convenient for the patient) than delivering an exercise program at the hospital
- Longer term research is needed to examine whether telephone supervised exercise will prevent serious events such as heart attack, strokes and death

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Research interests

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