Diabetologia (2012) 55:579–588
DOI 10.1007/s00125-011-2425-9

ARTICLE

Relationship of exercise volume to improvements of quality of life with supervised exercise training in patients with type 2 diabetes in a randomised controlled trial: the Italian Diabetes and Exercise Study (IDES)

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Received: 27 October 2011 / Accepted: 28 November 2011 / Published online: 11 January 2012

Abstract
Aims/hypothesis A positive impact of exercise intervention programmes on quality of life (QoL) may be important for long-term patient compliance to exercise recommendations. We have previously shown that QoL improves significantly with supervised exercise, whereas it worsens with counselling alone, in patients with type 2 diabetes from the Italian Diabetes and Exercise Study (IDES). Here, we report data on the relationship between changes in QoL and volume of physical activity/exercise in these individuals.
Methods This multicentre parallel randomised controlled, open-label, trial enrolled sedentary patients with type 2 diabetes (n=606 of 691 eligible) in 22 outpatient diabetes clinics. Patients were randomised by centre, age and diabetes treatment using a permuted-block design to twice-a-week supervised aerobic and resistance training plus exercise counselling (exercise group) versus counselling alone (control group) for 12 months. Health-related QoL was assessed by the 36-Item Short Form (SF-36) Health Survey.
Results In the exercise group (n=268 of 303 randomised), there was a trend for increasing QoL with increasing

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Electronic supplementary material The online version of this article (doi:10.1007/s00125-011-2425-9) contains a peer-reviewed but unedited complete list of the IDES Investigators; this is available to authorised users.

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exercise volume, with significant improvement of the physical component summary (PCS) measure only above 17.5 metabolic equivalents h^{-1} $week^{-1}$ and a clear volume-relationship for the mental component summary (MCS) measure. A relationship with volume of physical activity also was observed in the control group (n=260 of 303 randomised), despite overall deterioration of all scores. Independent correlates of improvements in both PCS and MCS were exercise volume, study arm and, inversely, baseline score.

Conclusions/interpretation This large trial shows a relationship between changes in physical and mental health-related QoL measures and volume of physical activity/exercise, with supervised exercise training also providing volume-independent benefits.

Trial registration: ISRCTN-04252749

Funding: The study was funded by Lifescan SrL, Novo Nordisk Ltd, Bristol Myers Squibb Italy, Technogym SpA and Cosmed SrL.

Keywords Exercise · Physical activity · Quality of life · Type 2 diabetes

Abbreviations

CON	Control group
EXE	Exercise group
IDES	Italian Diabetes and Exercise Study
IGT	Impaired glucose tolerance
MCS	Mental component summary measure
METs	Metabolic equivalents
PA	Physical activity
PCS	Physical component summary measure
QoL	Quality of life
SF-36	36-Item Short Form Health Survey
$\dot{V}O_{2max}$	Maximal oxygen consumption

Introduction

Lifestyle-modification programmes including physical activity (PA) have been shown to prevent development of type 2 diabetes [1, 2] in patients with impaired glucose tolerance (IGT), to be associated with reduced total and cardiovascular mortality in patients with type 2 diabetes [3, 4] and to improve cardiovascular risk factors in individuals with both IGT [5] and diabetes [6]. More recently, counselling interventions focused on exercise/PA have been designed and tested successfully in clinical settings [7], and a systematic review and meta-analysis showed that structured exercise training, either aerobic, resistance, or both, is associated with HbA_{1c} reduction in patients with type 2 diabetes, especially if >150 min/week and when combined with dietary advice [8].

Despite this large body of evidence on the health benefits provided by PA, and particularly structured exercise, in patients with type 2 diabetes, long-term patient compliance represents a major limitation to successful implementation of exercise recommendations into clinical practice [9]. From a long-term perspective, lifestyle modification might be better maintained if associated with improvement in quality of life (QoL), but results from previous trials investigating the impact of structured exercise counselling or supervised training on physical and mental health and well-being in diabetic patients are inconclusive [10–13].

In the large cohort of sedentary patients with type 2 diabetes from the Italian Diabetes and Exercise Study (IDES), supervised aerobic and resistance training combined with structured exercise counselling was associated with significant improvements in physical and mental health-related QoL measures, whereas all scores worsened in individuals having counselling alone, thus suggesting that type of intervention had a major impact on QoL [14]. In this trial, supervised training was also more effective than counselling alone in promoting PA and improving physical fitness, HbA_{1c} and other modifiable cardiovascular risk factors, and CHD 10-year risk scores [15].

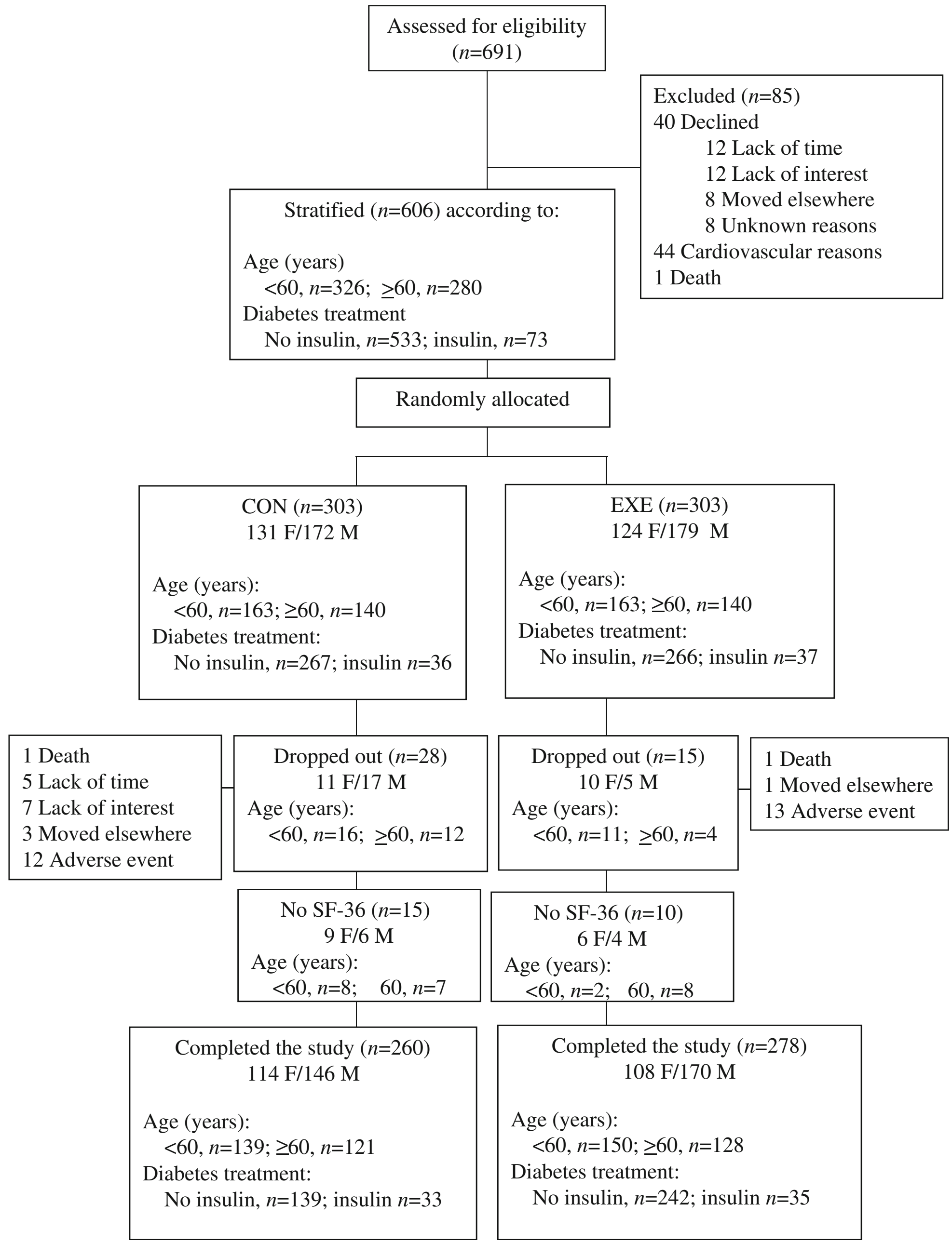
This further analysis of the IDES cohort aimed to assess the relationship between changes in QoL and volume of physical activity/exercise, in type 2 diabetes patients participating in the multicentre randomised controlled trial.

Methods

Design and methods of this multicentre parallel randomised, open-label, controlled trial have been detailed elsewhere [15, 16] and will be briefly reported here. The research protocol was approved by locally appointed ethics committees and participants gave written informed consent.

Setting and participants The IDES involved 22 outpatient diabetes clinics throughout Italy between 1 October 2005 and 31 March 2006. Each centre was connected with a Metabolic Fitness Centre, a dedicated facility where patients trained under the supervision of an exercise professional. Sedentary patients with type 2 diabetes, according to the definition of the American Diabetes Association [17], fulfilling the International Diabetes Federation criteria for the metabolic syndrome [18], were eligible for this study, whereas patients having any condition limiting or contraindicating PA were excluded. Of the 691 eligible patients, 85 were excluded for various reasons and 606 were recruited and randomised to supervised training plus structured exercise counselling (exercise, EXE, group; n=303) versus counselling alone as part of standard care (control, CON, group; n=303) for 12 months (Fig. 1). Randomisation was

Fig. 1 Study flow diagram



stratified by centre, and within each centre, by age (<60 versus ≥60 years) and type of diabetes treatment (no insulin versus insulin, either alone or in combination with oral agents), using a permuted-block randomisation software. Physicians and patients were not blinded to group assignment.

Interventions Subjects from both groups received structured individualised counselling [7], aiming to achieve the currently recommended amount of PA by encouraging any type of commuting, occupational, home and leisure-time PA. Counselling was reinforced every 3 months in individual sessions.

The training programme for the EXE group consisted of 150 min/week in two supervised sessions of progressive mixed (aerobic and resistance) training [15, 16]. Aerobic training was performed using treadmill, step, elliptical, arm or cycle-ergometer. Exercise load for each piece of equipment was calculated to achieve the prescribed exercise intensity, expressed as a percentage of maximal oxygen consumption ($\dot{V}O_{2max}$) using standard equations [19]. Resistance training consisted of four resistance exercises: chest press, lateral pull-down, leg press and abdominal flexion, or equivalent exercises targeting the same muscles. Subjects also did three stretching exercises. Intensity was adjusted according to improvements in $\dot{V}O_{2max}$ and muscle fitness, as recorded throughout the study. In addition, energy expenditure was increased progressively by 0.4184 kJ/kg body weight per session every month.

Standard care consisted of a treatment regimen aimed at achieving optimal glycaemic, lipid, BP and body weight targets, as established by current guidelines, and including diet prescription and glucose-, lipid- and BP-lowering agents as needed. The treatment regimen was adjusted based on results of biochemical tests performed locally at 3-month intervals [15, 16].

Main outcome measures The primary outcome of the IDES was HbA_{1c} reduction, whereas other secondary outcomes included other modifiable risk factors, dosage of glucose-, lipid- and BP-lowering drugs and global CHD 10-year risk. Methods for the assessment of these endpoints, as well as of the volume of PA and variables of physical fitness, have been reported elsewhere [15, 16].

A priori secondary outcomes also included physical and mental health-related QoL [14, 16]. To this end, patients were asked to fill in the Italian version [20] of the 36-Item Short Form Health Survey (SF-36) [21], which yields physical and mental health component scores and has been previously validated in patients with type 2 diabetes [22, 23]. The physical and mental component summary measures (PCS and MCS, respectively) were normalised to a population mean of 50 and SD of 10.

Statistical analysis Estimated marginal mean changes in SF-36 measures (end of study—baseline) were derived from ANCOVA models, with score changes as dependent variables, quintiles of PA/exercise volume as factor (calculated either for each group or for the whole study population) and baseline score, age, sex and BMI as covariates. A test for linear trend was applied.

Independent correlates of PCS and MCS were investigated in the whole study population by multiple linear regression analysis with stepwise variable selection. The following covariates were tested: study arm, age, sex, duration of diabetes, previous CV event, retinopathy, diabetes treatment, PA/exercise volume (as expressed as metabolic equivalents [METs] h^{-1} $week^{-1}$), baseline PCS or MCS score, baseline values of BMI, waist circumference, HbA_{1c}, BP, $\dot{V}O_{2max}$ and their changes at 12 months. Results are reported as beta variables with their associated p value.

Results

Overall, 275 out of 303 (90.8%) patients assigned to the CON group and 288 out of 303 patients (95.0%) assigned to the EXE group completed the study. Among study completers, baseline and end-of-study SF-36 questionnaires were available and fully evaluable for 260 patients in the CON group (94.5%) and 278 patients in the EXE group (96.5%; Fig. 1). Baseline patient characteristics according to study group are reported in electronic supplementary material (ESM) Table 1. No difference was detected between groups in any of these variables.

The main outcomes of the trial have been reported previously [14, 15]. Briefly, compared with counselling alone, supervised exercise produced significant improvements in HbA_{1c} (mean difference −0.30% [−0.49, −0.10] or −20.2 nmol/mol [−18.1, −22.4], $p<0.001$), systolic (−4.2 mmHg [−6.9, −1.6], $p=0.002$) and diastolic (−1.7 mmHg [−3.3, −1.1], $p=0.034$) BP, HDL-cholesterol (0.096 mmol/l [0.057, 0.137], $p<0.001$), LDL-cholesterol (−0.249 mmol/l [−0.412, −0.085], $p=0.003$), waist circumference (−3.6 cm [−4.4, −2.9], $p<0.001$), BMI (−0.78 kg/m^2 [−1.07, −0.49], $p<0.001$), HOMA-insulin resistance index (−0.36 [−0.94, 0.22], $p=0.047$), high sensitivity C-reactive protein (−1.0 mg/l [−1.4, −0. 7], $p<0.001$) and total (−3.1 [−4.2, −2.0], $p<0.001$) and fatal (−2.4 [−3.3, −1.5], $p=0.01$) 10-year CHD risk scores. This was associated with a higher volume of PA (METs h^{-1} $week^{-1}$), which was significantly higher ($p<0.001$) in EXE (both total, 20.0±0.9, and non-supervised, 12.4±7.4) versus CON (10.0±8.7), and with more marked improvement in physical fitness variables. In addition, QoL markedly improved in all the areas investigated except physical functioning in the EXE group, with effect size of 0.90 for PCS and 0.61 for MCS measures, whereas all scores worsened in the CON group, thus resulting in marked between-groups differences for all SF-36 scores. Here, we report the analysis of the relationship of QoL measures with volume of PA/exercise in the two study groups.

Figure 2 shows the changes in SF-36 mean scores in the EXE group by quintiles of PA/exercise volume, compared with the mean change in the CON group, whereas Figs 3 and 4 report changes in SF-36 mean scores in the CON and EXE groups, respectively, according to METs quintiles calculated in the whole cohort. Mean changes in the CON group by quintiles of PA/exercise volume are reported in ESM Fig. 1. It is interesting to note that, despite the fact that patients in the CON group had an exercise volume falling between the first and the second quintile of the EXE group, changes in SF-36 scores markedly differ between the two groups. Within the EXE group, a trend of increasing benefit on QoL with increasing PA/exercise volume was documented from the first to the fourth quintiles. Also, within the CON group, a relationship between individual QoL scores and volume of PA changes was observed, with marginal increases from baseline detected for some of the scales only in the highest quintile of PA.

Analysis of the PCS and MCS in the EXE patients by quintiles of PA/exercise volume calculated for the EXE group (Fig. 5) or the whole cohort (Fig. 6), further revealed that a significant improvement in the physical health was present only for a total amount of exercise over 17.5 METs h^{-1} $week^{-1}$, whereas the benefits in mental health were evident at any level of exercise volume. Finally, even within the CON group, a clear relationship existed between PCS

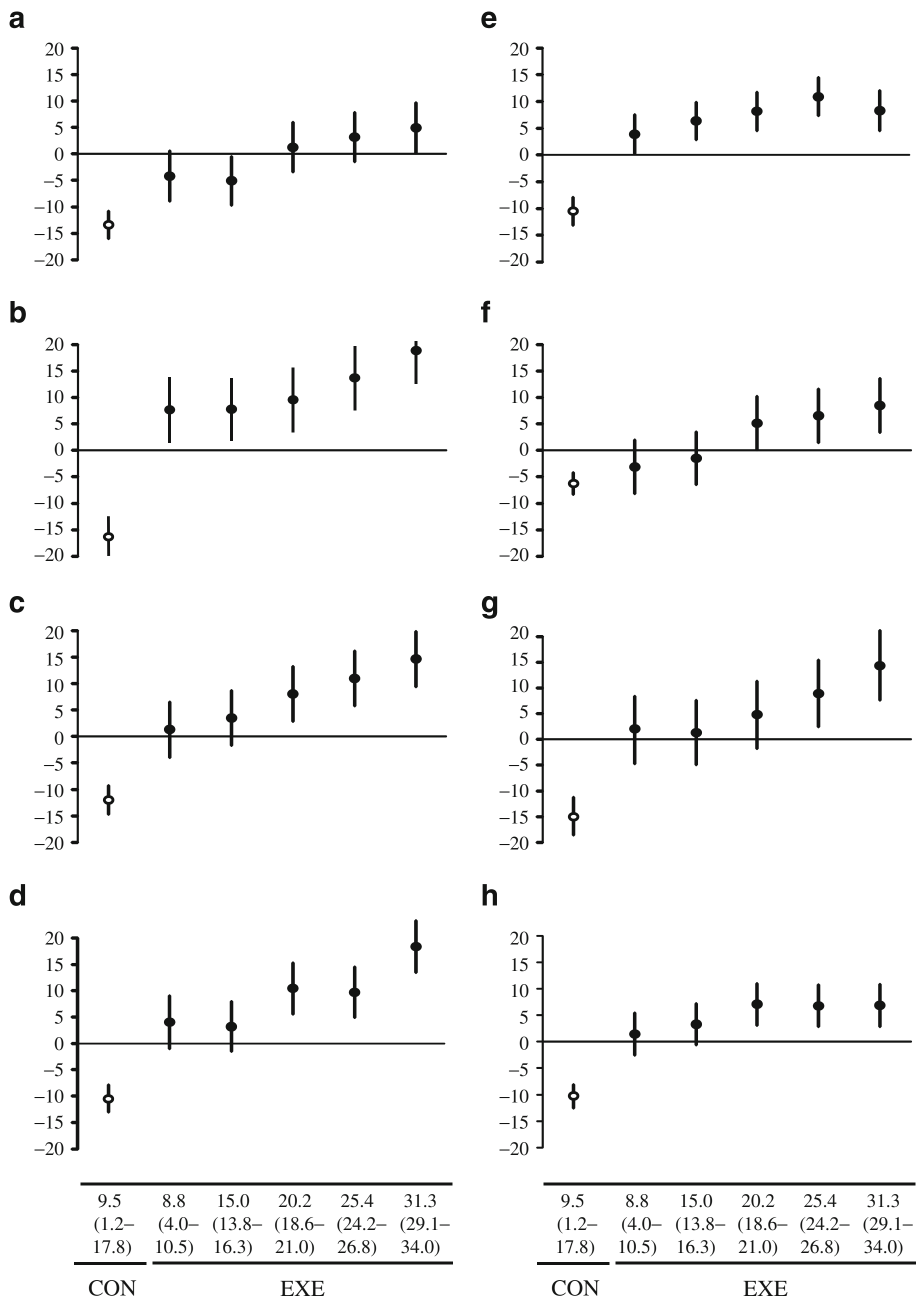


Fig. 2 Mean changes in individual physical and mental components (estimated marginal means ±95% CI) in the EXE group according to quintiles of physical activity/exercise volume (<12, 12–17.5, 17.6–22.2, 22.3–28.4, >28.4 METs h^{-1} $week^{-1}$; black circles) compared with the mean change in the CON group (white circles): physical functioning score (**a**); role physical score (**b**); bodily pain score (**c**); general health perception score (**d**); energy/vitality score (**e**); social functioning score (**f**); role emotional score (**g**); and mental health score (**h**). Median values and interquartile ranges are reported for CON group and EXE group quintiles

and MCS measures and quintiles of PA volume, calculated either for the CON group only (ESM Fig. 2) or for the whole study population (Fig. 6).

At multivariate analysis, independent correlates of improvement in the PCS score were PA/exercise volume (β=0.24; p<0.0001), EXE study arm (β=5.00; p<0.0001) and, inversely, baseline PCS score (β=−0.78; p<0.0001). Independent correlates of improvements in the MCS score were PA/exercise volume (β=0.12; p=0.01), EXE study arm (β=5.00; p<0.0001), reduction in waist circumference during the study (β=0.22; p=0.02) and, inversely, baseline MCS score (β=−0.60; p<0.0001). Baseline PCS and MCS scores did not differ among quintiles of PA/exercise volume (not shown).

Discussion

Even successful intervention such as the supervised mixed exercise programme tested in the IDES can be flawed if compliance to exercise prescription is lost, with consequent return to sedentary habits, regain of body weight and loss of health benefits produced by the lifestyle modification. Our previous findings showing a positive impact of supervised exercise training on QoL [14] indicate that this intervention strategy could be very helpful in supporting long-term maintenance of lifestyle modification and adherence to exercise recommendations. These additional data from the IDES show for the first time that the beneficial effects of lifestyle

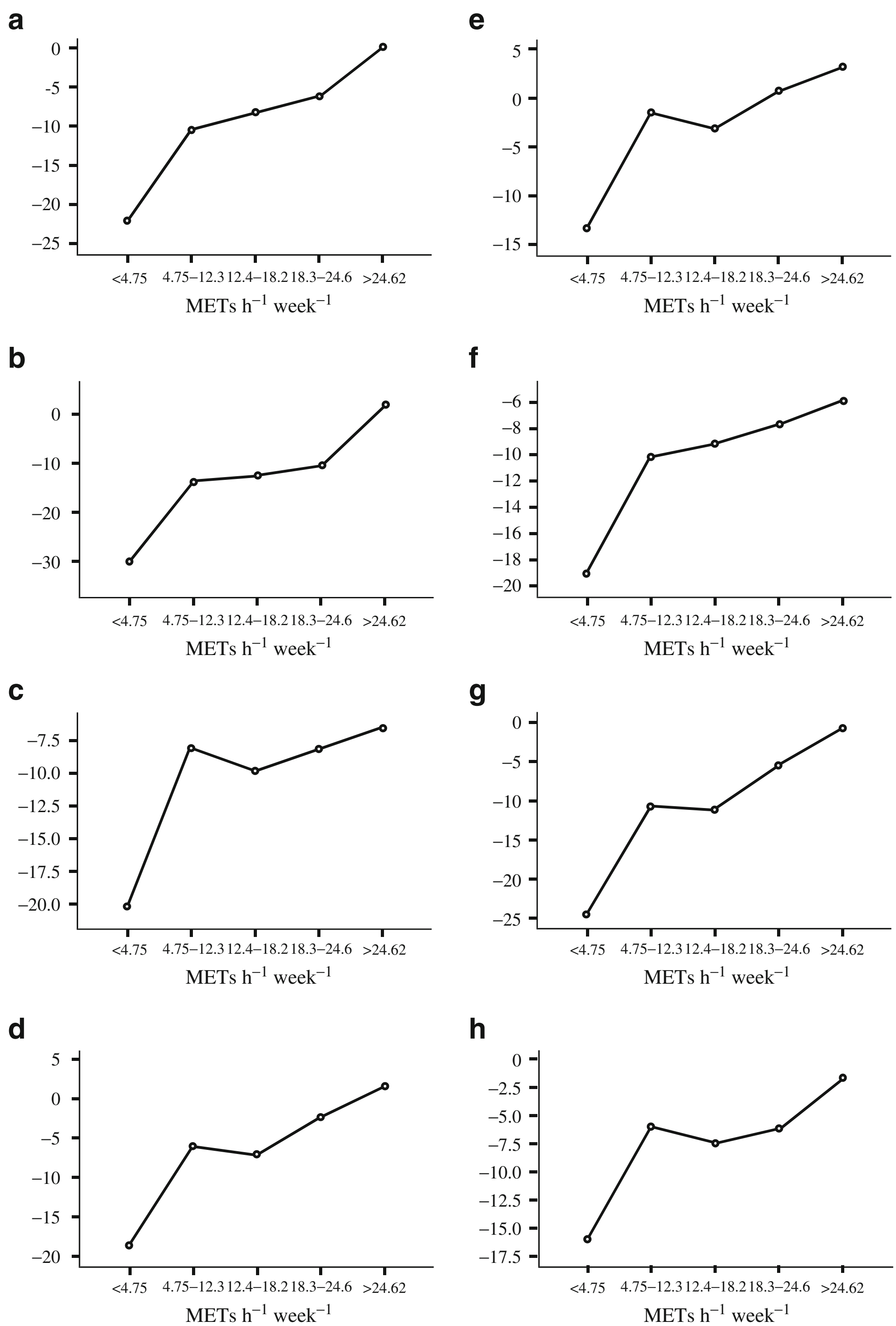


Fig. 3 Mean changes in individual physical and mental components (estimated marginal means) in the CON group according to quintiles of physical activity/exercise volume calculated on the whole study cohort (white circles): physical functioning score (**a**); role physical score (**b**); bodily pain score (**c**); general health perception score (**d**); energy/vitality score (**e**); social functioning score (**f**); role emotional score (**g**); and mental health score (**h**). p for linear trend <0.0001 (**a**, **d**, **e**), p=0.001 (**b**, **g**), p=0.005 (**c**), p=0.008 (**f**), and p=0.003 (**h**)

modification on QoL-related scores are markedly, although not entirely, related to the volume of PA/exercise achieved.

This conclusion is supported by the finding that QoL improved in patients performing supervised exercise with increasing PA/exercise volume, but also individuals on counselling alone showed a relationship with PA volume, despite overall deterioration of all the scores, with a marginal improvement from baseline of few QoL scores in the highest quintile of PA. It is important to note that such a strong relation with volume of PA/exercise also was observed for the primary outcome HbA_{1c} and the other modifiable cardiovascular risk factors and for variables of physical fitness [15].

Supervised training, as opposed to exercise counselling alone, also produced volume-independent incremental benefits on QoL, as previously shown for other clinical endpoints [15]. In fact, being in the EXE group was

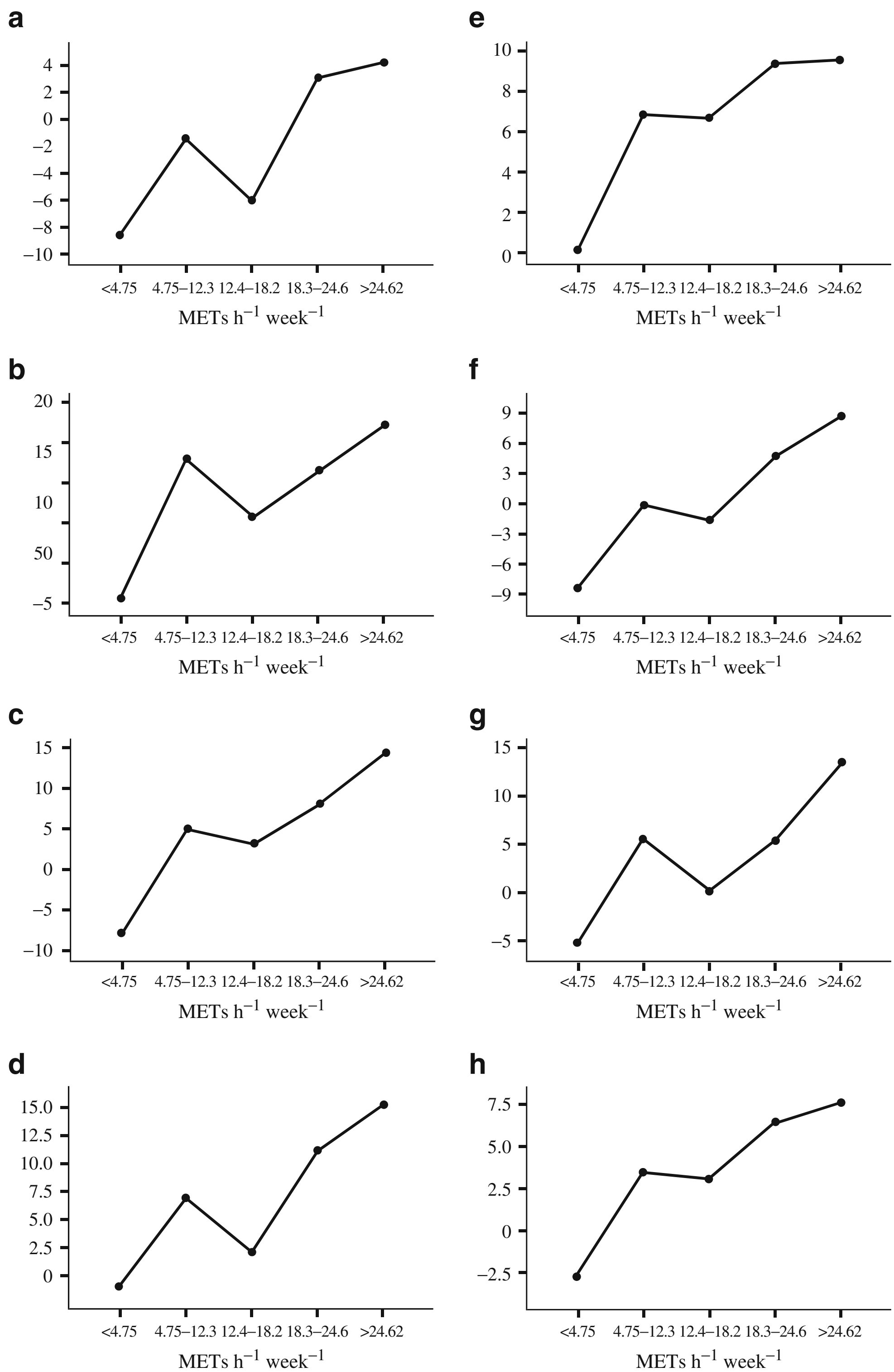


Fig. 4 Mean changes in individual physical and mental components (estimated marginal means) in the EXE group according to quintiles of physical activity/exercise volume calculated on the whole study cohort (black circles): physical functioning score (**a**); role physical score (**b**); bodily pain score (**c**); general health perception score (**d**); energy/vitality score (**e**); social functioning score (**f**); role emotional score (**g**); and mental health score (**h**). p for linear trend =0.001 (**a**), =0.003 (**b**), <0.0001 (**c**,**d**,**f**), =0.005 (**e**), =0.002 (**g**), and =0.008 (**h**)

independently associated with improvement in PCS and MCS scores, compared with the CON group, even after adjustment for PA/exercise volume. This resulted in different thresholds of volume of PA/exercise for detecting QoL improvements between the two groups (see below).

The improvements in QoL with supervised exercise might have been related to the significant health benefits, including reduction or no increment of drug number/dosage [15], provided by exercise training through volume-dependent and independent mechanisms. Patients were

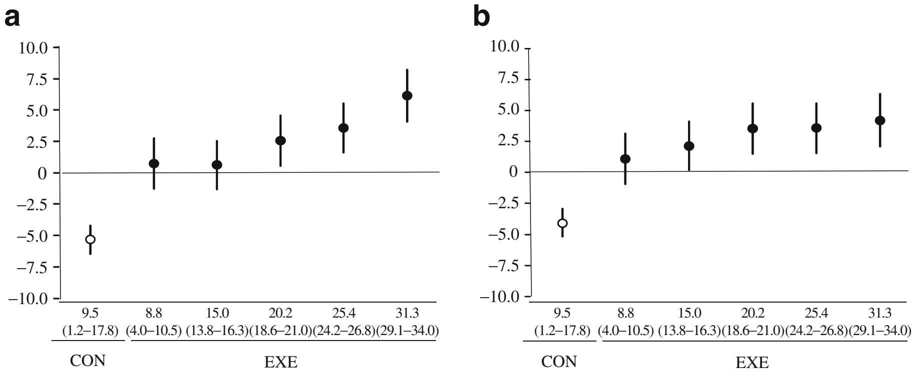
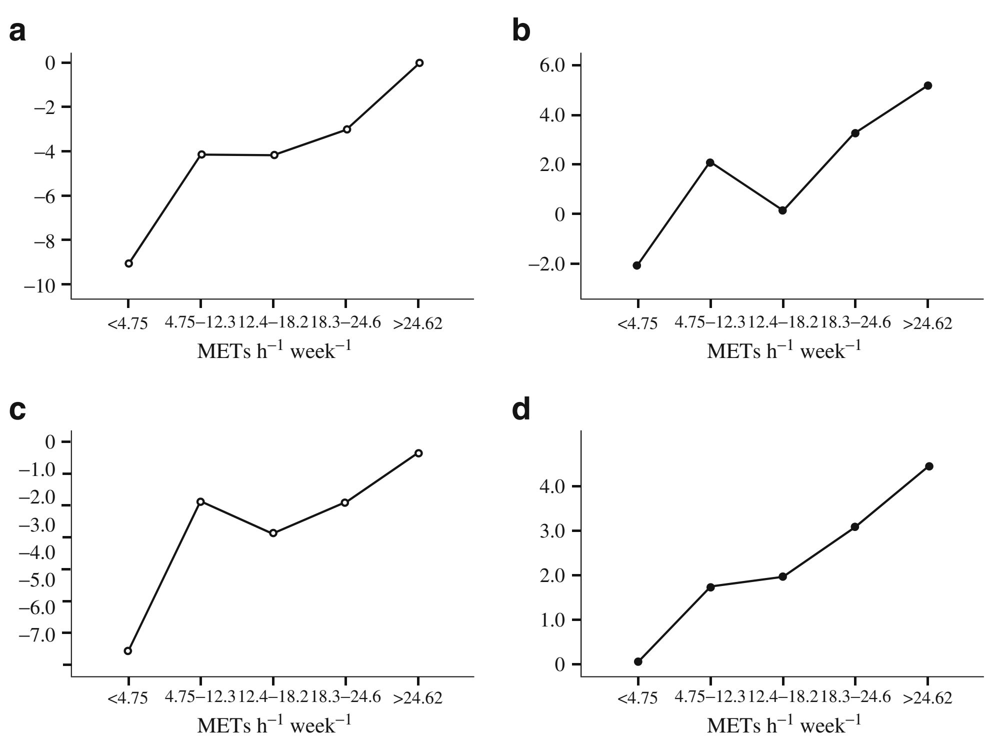


Fig. 5 Mean changes in physical (**a**) and mental (**b**) component summary measures (estimated marginal means ±95% CI) in the EXE group according to quintiles of physical activity/exercise volume (<12, 12–17.5, 17.6–22.2, 22.3–28.4, >28.4 METs h^{-1} $week^{-1}$; black circles) compared with the mean change in the CON group (white circles).

informed during follow-up visits of improvements in clinical and laboratory measurements performed at 3-month intervals [16]. In addition, patients could have felt more comfortable and confident during exercise sessions, due to supervision by trained and qualified exercise professionals, and also when performing unsupervised PA, as, during the first eight sessions of supervised training, they received information about indication and contraindication of PA, type and intensity of exercise, and measurement, interpretation and management of cardiovascular and metabolic variables (BP, heart rate, blood glucose) [16]. Social contacts with exercise professionals and other study participants might also have favoured improvements of several mental components [14]. This is supported by the higher volume of unsupervised PA performed by EXE patients compared with CON participants [16]. This interpretation also is in keeping with the finding that, in the EXE group, the relationship of PA volume with physical and mental health differed somehow, with even small volumes of exercise being associated with improvements in the MCS, whereas significant improvements in PCS became evident only for the quintiles corresponding to a volume of PA, which is higher than that currently recommended, i.e. ≥17.5 versus approximately 11.2 METs h^{-1} $week^{-1}$ [15].

Conversely, overall deterioration of QoL scores during the 12-month period occurred in patients on counselling alone, despite achievement of the currently recommended

Fig. 6 Mean changes in physical (**a**, **b**) and mental (**c**, **d**) component summary measures (estimated marginal means) in the CON (white circles) and EXE (black circles) according to quintiles of physical activity/exercise volume calculated on the whole study cohort. *p* for linear trend <0.0001 (**a**, **b**) and *p*=0.009 (**c**, **d**)



amount of PA [15], indicating a reasonable compliance with recommendations received during counselling sessions. The limited efficacy of unsupervised PA on modifiable cardiovascular risk factors and consequent changes in medication at intermediate visits [15] could have played a role in QoL worsening. Moreover, lack of supervision and insufficient knowledge could have also made patients less confident and safe when performing PA. Finally, as neither patients nor physicians were blinded to group assignment, disappointment and frustration at not being assigned to supervised exercise may have had a negative impact on changes from baseline in physical and, particularly, mental health scores. Under these conditions, PA recommendations may have been felt to be a constraint, requiring too much time and effort and interfering with other important activities in patients' lives. However, the volume-relationship also observed in these individuals suggests that exercise counselling, when effective in promoting behavioural modification, which translates into a large volume of PA (>24.6 METs h^{-1} $week^{-1}$), may not negatively impact on physical and mental health, in keeping with a previous report on the effect of exercise consultation [11]. It remains to be elucidated whether better designed counselling interventions may overcome negative factors on QoL that cancel out benefits associated with increasing PA volume.

The relationship between QoL and PA/exercise volume may also be interpreted in the opposite direction, with increasing QoL favouring increased PA/exercise volume, although this explanation is not mutually exclusive with the positive impact of PA/exercise volume on QoL measures discussed above. The observation that baseline PCS and MCS scores, which did not differ among quintiles of PA/exercise volume, were inversely related to improvements in both measures indicates that better general physical and mental health did not predict QoL and PA/exercise volume outcomes.

A possible limitation of this study, in addition to intrinsic limitation of the SF-36 survey, is the unblinded design, although blinding is not feasible in clinical trials employing behavioural interventions.

Strengths of this study are that it was multicentre, thus less dependent on local factors, and of larger size and longer duration than other exercise intervention trials in patients with type 2 diabetes [24–27], including those assessing QoL and well-being measures [10–13].

In conclusion, this large trial shows that improvements in physical and mental health-related QoL measures are related to volume of PA, with supervised exercise training also providing volume-independent benefits, which lower the threshold of PA volume above which an amelioration of QoL can be detected.

Funding This work was supported by Lifescan SrL, Novo Nordisk Ltd, Bristol Myers Squibb Italy, Technogym SpA and Cosmed SrL.

Duality of interest The authors declare that there is no duality of interest associated with this manuscript. The sponsors had no role in design and conduct of the study; collection, management and interpretation of the data; or preparation, review and approval of the manuscript.

Contribution statement AN was responsible for conception and design, analysis and interpretation of data, drafting the article and final approval of the version; SB was responsible for conception and design, analysis and interpretation of data, revising the article critically for important intellectual content, final approval of the version and acquisition of funding; PC, SC, SF, AB, PS and CI were responsible for analysis and interpretation of data, revising the article critically for important intellectual content and final approval of the version; SZ was responsible for conception and design, analysis and interpretation of data, revising the article critically for important intellectual content and final approval of the version; GP was responsible for conception and design, analysis and interpretation of data, drafting the article, final approval of the version and study supervision.

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