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Visceral fat mass dynamics in a 2-year randomized STrength versus ENdurance training trial in people with obesity

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Abstract

Aim: To compare the effectiveness of strength versus endurance training on reducing visceral fat in individuals with obesity.

Materials and Methods: For the STrength versus ENdurance (STEN) 24-month randomized clinical trial, we assigned 239 participants with abdominal obesity to either strength or endurance training (two to three times a week, 60 min/training session) in addition to standard nutritional counselling to promote a healthy diet. Changes in abdominal visceral adipose tissue (VAT) area quantified by magnetic resonance imaging after 12 months were defined as a primary endpoint.

Results: Participants (aged 44 years, 74% women, body mass index: 37 kg/m^2, mean VAT volume: 4050 cm^3) had an approximately 50% retention rate and a 30% good training programme adherence at 12 months. There was no difference between strength and endurance training in VAT volume dynamics after 12 and 24 months ($p = .13$). Only in the good adherence group did we find a trend for reduced VAT volume in both training regimens. Independently of the exercise programme, there was a continuous trend for moderate loss of abdominal subcutaneous AT volume, body fat

mass, body mass index and improved parameters of insulin sensitivity. Although parameters of physical fitness improved upon both exercise interventions, the dynamics of resting energy expenditure, glucose and lipid metabolism parameters were not different between the intervention groups and did not significantly improve during the 2-year trial ($p > .05$).

Conclusions: Despite heterogeneous individual training responses, strength and endurance training neither affected VAT volume nor key secondary endpoints differently.

KEYWORDS
body composition, clinical trial, exercise intervention, insulin resistance, randomized trial

1 | INTRODUCTION

Increased central, abdominal, or trunk fat accumulation is a strong determinant for the risk of developing obesity-associated cardiometabolic complications.[1–3] In addition, there is epidemiological evidence that fat distribution impacts all-cause cardiovascular as well as cancer morbidity and mortality more strongly than increased fat mass itself.[1–3]

Reducing visceral fat mass is therefore seen as an important target for the prevention and treatment of obesity-related diseases. It can be achieved by behaviour modifications such as reduced energy intake and increasing physical activity, pharmacotherapies and bariatric surgery.[4] Indeed, both obesity and reduced physical activity are strong and independent predictors of premature mortality.[5] Behaviour interventions aiming at reduced energy intake and higher physical activity have been recently shown to reduce the incidence of type 2 diabetes (T2D), cardiovascular events, microvascular complications, and cardiovascular and all-cause mortality in the 30-year follow-up of the Da Qing Diabetes Prevention Outcome Study.[6] Increased life expectancy in people with regular physical activity and a high fitness level has been a consistent finding in epidemiological studies.[7]

Recommendations for the basic treatment of obesity and cardiometabolic diseases usually focus on aerobic endurance training because of its greater energy expenditure during the exercise session compared with anaerobic resistance training.[8] On the other hand, strength training may represent a strategy to prevent the adverse consequences of reduced muscle mass and could contribute to reduced visceral fat mass.[8,9] However, it is still unclear whether strength training leads to an equivalent or even superior reduction in visceral fat mass compared with endurance training for a given training session duration and frequency. We therefore aimed to test the hypothesis that strength training is more effective than endurance training in reducing visceral mass as well as adiposity and cardiometabolic risk parameters in individuals with obesity. We are aware that many studies have been published that have investigated and/or compared the effects of aerobic endurance and anaerobic, high-intensity resistance training on body composition, cardiometabolic health indicators and physical fitness in different age groups.[9–14] However, previous studies had a shorter duration, and many of the previously tested training protocols are difficult to translate into clinical practice. Considering the benefits of both strength and endurance training, we asked whether general practice recommendations for obesity treatment,[15–17] that is, two to three exercise sessions increasing to 150-300 min/week, result in reduced visceral fat mass and clinically meaningful improvements of obesity-associated risk factors independently of the training strategy.

2 | MATERIALS AND METHODS

2.1 | Study design

The 24-month STrength versus ENdurance (STEN) trial was performed between April 2011 and April 2016 and conducted at the Integrated Research and Treatment Centre for AdiposityDiseases at the University of Leipzig, where all clinical investigations have been performed. The STEN trial was a monocentric, open-label, randomized, controlled study for the dynamics of visceral fat volume and resting energy expenditure in patients with obesity through either strength or endurance training (trial registration number: NCT01435057).

People aged 18-60 years with a body mass index (BMI) ≥35 kg/m^2 and a waist circumference >102 cm (men) and >88 cm (women) were eligible for inclusion. Exclusion criteria are detailed in the methods section of Data S1. The primary outcome measure was abdominal visceral fat as determined by abdominal magnetic resonance imaging (MRI) scans after 12 months of the training intervention, taking the baseline value into account. Secondary outcomes include other measures of fat, quality of life, energy expenditure and glucose metabolism (see the methods section of Data S1 for details).

The trial was approved by the Ethics Committee of the University of Leipzig and performed in accordance with the Declaration of Helsinki. All subjects gave written informed consent to use their data in pseudonymized form for research purposes before taking part in this study.

2.2 | Randomization and intervention

Participants were randomized in a 1:1 ratio electronically to either strength or endurance training (two to three times a week, 60 min/training session) using a minimization method, including a stochastic component, where BMI (<35 kg/m^2), sex and age (>45 years) were used as stratification variables. The algorithm was programmed by the Clinical Trial Centre and accessed by the investigators via a secure web interface. In addition, participants received standard dietary recommendations (every 2-3 months) to promote a healthy diet and achieve a similar intervention intensity without providing specific calorie restriction targets. The exercise programme was designed to meet the World Health Organization recommendations on physical activity for health of a weekly minimum of 150 min of moderate-intensity aerobic physical activity or 75 min of vigorous-intensity aerobic physical activity, or an equivalent combination of both.[17]

Participants were aware of their assigned intervention (open-label protocol). All the participants received free access to the exercise intervention facility for the trial duration and educational sessions to engage in the training programme.

2.3 | Exercise interventions

All exercise interventions were performed at the same sport's centre (Verein Leichter Leben eV).

2.3.1 | Endurance training

For warm-up, participants completed 10 min of either a bicycle ergometer, stepper machine, rowing device or treadmill at approximately 50% of the maximal heart rate determined by the baseline incremental exercise test on a treadmill for time to exhaustion and in the ergospirometry. For cool-down, participants performed 10-15 min of low-intensity stretching exercises. The supervised endurance training consisted of six exercises lasting for 10 min on a treadmill, stepper, cross-trainer, rowing device or bicycle ergometer. The interval between exercise bouts was 1-5 min. Switching between different training machines was allowed, but not mandatory. The heart rate during the exercise was used to prescribe, adjust and control the endurance training. Training intensity recommendations were guided by the individual performance, and training intensity was adjusted to the heart rate. The goal was to achieve a training intensity of approximately 75% of maximal intensity. Protocols were adjusted every 4 weeks or at the discretion of the supervisor based on the individual performance of the study participant.

2.3.2 | Strength training

For warm-up, participants completed 10 min of either a bicycle ergometer, stepper machine, rowing device or treadmill at approximately 50% of the maximal heart rate determined by ergospirometry. For cool-down, participants performed 10-15 min of low-intensity stretching exercises. Ten strength training machines and five exercises on dumbbells or therapeutic bands were selected to target the major muscle groups: chest, back, legs, shoulders, biceps, triceps and the trunk. Strength training was supervised and consisted of circuit training for 40-60 min, twice a week. Training sessions were monitored, and participants received recommendations on how to perform exercises. For each exercise, the number of series was eight to 12, with three repetitions. The interval between series was 30 s, and between exercises was 1 min. Monitoring was achieved by supervising each training session. Before the training period, participants performed a 10-repetition maximum test to define the target intensity of approximately 75%-85% for each exercise. The intensity for each exercise was adjusted every week according to the individual performance based on the subjectively reported residual power after the 10th repetition of the exercise. General training protocols, that is, the type of exercise, number of series and repetitions were not changed during the trials, whereas intensities were adjusted according to individual performance.

2.4 | Measurement of main outcome parameters

For MRI, participants were examined at baseline, and after 12 and 24 months of the intervention in a supine position using a standard 1.5T system (Achieva XR; Philips Healthcare) and the integrated whole-body coil for signal reception. Fat-sensitive imaging was based on an axial two-point Dixon sequence with two stacks of 25× 10-mm thick slices (0.5-mm inter-slice gap) covering the whole abdominal cavity. Total visceral adipose tissue (VAT) and abdominal subcutaneous adipose tissue (SAT) volume were quantified between the pelvic floor and diaphragm with custom-made software as described previously.[18,19]

Anthropometric parameters (body weight, waist, hip and neck circumferences), blood pressure, heart rate and blood biomarkers were taken at baseline, after 6, 12, 18 and 24 months of intervention. The assessment of nutritional intake and lifestyle habits was performed using self-reported food frequency questionnaires administered through a computer at baseline, after 6 months and at the end of the trial.

BMI was calculated as weight in kilograms divided by squared height in metres (kg/m^2). The waist circumference was measured at the midpoint between the lower ribs and iliac crest. The percentage body fat was assessed by bioimpedance analysis. Analyses of plasma and serum parameters, including fasting plasma glucose and insulin, glycated haemoglobin, triglycerides, high-density lipoprotein- and low-density lipoprotein-cholesterol, were performed as previously described.[20] Two-hour oral glucose tolerance tests were performed at baseline, after 12 and 24 months of intervention, after an overnight fast with 75 g standardized glucose solution (Accu Chek Dextrose OGT; Roche). At baseline, after 6, 12, 18 and 24 months of

intervention, incremental cycle ergometer tests were performed until exhaustion to assess the maximal power output (P_{max}) and ergospirometry (Aeroman professional; Aerolution) to define aerobic capacity and subsequent individual training intensities.

Resting metabolic rate was to be measured by indirect calorimetry, but technical problems with the calorimeter precluded the analysis of these data.

2.5 | Analysis populations

The confirmatory analysis of the primary and secondary endpoints follows the intent-to-treat (ITT) principle and includes all randomized patients with written informed consent and who provided valid VAT data at baseline.

The good adherence population is defined to be 30% of the ITT population with the largest number of training weeks during the first year and without any violation of inclusion or exclusion criteria.

2.6 | Sample size

In the pilot data, a difference between strength and endurance training in the reduction of VAT of 0.39 ± 0.76 L was observed. Based on these data, we expected an effect size of 0.5 and would require data from 86 patients per group to show this effect size with 90% power. After accounting for an expected 10%-15% dropout rate, we planned to recruit 200 patients in total.

2.7 | Statistical analyses

The primary outcome of the STEN trial was visceral VAT volume at 12 months. Missing values were considered by applying the multiple imputation method 'fully conditional specification' regression with covariates sex, age, BMI at baseline and weeks with training during the first year. Based on the percentage of missing data, 35 imputation steps were used. The confirmatory analysis used the analysis of covariance with VAT volume at 12 months as the dependent variable, the baseline value as covariate and the randomization arm as the independent variable. Seven sensitivity analyses were prespecified in the statistical analysis plan (Supplementary material). SAT volume was analysed as with the primary endpoint and further secondary endpoints were analysed in a repeated measures manner using mixed models with sex, age and BMI at baseline as covariates and patient as the random term. BMI was excluded as a covariate if it was expected to be highly collinear with the dependent variable. Because of the high number of dropouts, only data until 12 months were analysed with this model; the data from month 24 are presented descriptively. Analyses were performed using SAS 9.3 (SAS Institute Inc.) and R 4.2.0 (R Foundation for Statistical Computing) and all tests were two-sided and a significance level of 5% was chosen.

3 | RESULTS

3.1 | Baseline characteristics

Of the 292 volunteers, 239 met the inclusion criteria [age 18-60 years, BMI ≥35 kg/m^2, waist circumference >102 cm (men) and >88 cm (women)], and provided written informed consent. A flow chart of the study is presented in Figure S1. The mean age of the participants was 44 years, 75% were women and the mean BMI was 37 kg/m^2. Baseline characteristics of the two study groups are presented in Table 1. VAT volume ranged from 905 to 11 188 cm^3 (mean = 4041 ± 2049 cm^3) and SAT volume from 4824 to 24 404 cm^3 (mean = 14 544 ± 3993 cm^3). Note that the missing data for SAT result from artefacts rendering images unusable when the region of interest is too close to the MRI wall. As a result, there will be a bias in the SAT estimates, meaning that the true mean is probably somewhat higher. Anthropometric parameters, such as blood pressure, heart rate, resting metabolic rate and maximal power output, in the ergometer test were similarly distributed across the two intervention groups at baseline (Table 1). Table 2 provides baseline data for the good adherence population.

3.2 | Adherence to the intervention

The retention rate was 68% after 6 months, 52% after 12 months and 37% after 24 months and the median (interquartile range) number of training sessions completed in the first year was 39 (13, 77) for the strength group and 41 (14, 72) for the endurance group. For comparison, the median (interquartile range) number of training sessions completed in the first year in the good adherence population was 82 (77, 92) (strength) and 80 (76, 85) (endurance); 51.9% of the participants completed the primary outcome measure, i.e. VAT volume, determined in the abdominal MRI after 12 months of intervention. In total, eight patients from the strength training group and 13 from the training endurance group did not receive the allocated treatment.

The duration of exercise and training frequency was not different between the strength and endurance groups, and both were trained at an intensity of 70%-80% of the maximum heart rate. After 24 months' intervention, 41 (36%) of the participants from the strength group and 41 (40%) from the endurance group had eligible follow-up MRI scans. The main reasons for dropouts included a lack of motivation and medical reasons such as recurrent infections unrelated to the study. Baseline VAT volume, BMI and age were not significantly different between the study completers and participants who withdrew during the trial.

3.3 | Changes in visceral fat mass after 12 months' intervention

After 12 months' intervention, VAT volume had not changed significantly (change of −0.12 L, 95% CI: −0.32 to 0.08 L) and the volumes

TABLE 1 Raw data for strength and endurance training in the 2-year randomized STEN trial at baseline, 12 and 24 months.

	Strength training			Endurance training		
Time point	**Baseline**	**12 months**	**24 months**	**Baseline**	**12 months**	**24 months**
Number of patients	114	56	41	102	56	39
Age, years	43.5 ± 10.7 (114)			45.0 ± 11.1 (102)		
Women, %	75.4 (86/114)			73.5 (75/102)		
Height, cm	1.70 ± 0.09 (114)			1.70 ± 0.09 (102)		
Weight, kg[a]	106.8 ± 19.9 (114)	102.7 ± 21.5 (50)	103.4 ± 23.0 (38)	107.6 ± 18.7 (102)	99.8 ± 16.9 (56)	96.8 ± 16.4 (36)
BMI, kg/m^2[a]	37.06 ± 5.22 (114)	35.57 ± 6.08 (50)	35.8 ± 6.74 (38)	37.09 ± 4.83 (102)	34.76 ± 4.2 (56)	34.83 ± 4.96 (36)
WC, cm	113.9 ± 12.8 (111)	112.7 ± 15.6 (49)	112.1 ± 15.4 (38)	114.5 ± 11.6 (97)	110.6 ± 13.0 (53)	110.6 ± 13.4 (36)
HC, cm	125.4 ± 11.3 (111)	119.2 ± 13.9 (49)	119.4 ± 15.7 (38)	126.4 ± 11.9 (97)	119.7 ± 11.5 (53)	119.7 ± 12.9 (36)
WHR	0.91 ± 0.09 (111)	0.95 ± 0.08 (49)	0.94 ± 0.08 (38)	0.91 ± 0.08 (97)	0.93 ± 0.07 (53)	0.93 ± 0.07 (36)
Waist to height ratio	0.67 ± 0.07 (111)	0.66 ± 0.08 (49)	0.66 ± 0.09 (38)	0.68 ± 0.06 (97)	0.66 ± 0.07 (53)	0.67 ± 0.08 (36)
NC, cm	39.9 ± 3.6 (111)	40.2 ± 3.7 (49)	39.9 ± 4.3 (38)	39.6 ± 3.4 (97)	39.1 ± 3.6 (53)	38.2 ± 3.7 (36)
HR, beats/min	87.8 ± 15.7 (110)	71.9 ± 16.6 (49)	72.2 ± 11.5 (38)	87.5 ± 15.5 (91)	67.9 ± 11.2 (55)	68.4 ± 9.5 (37)
BP_{syst}, mmHg	136.9 ± 17.5 (111)	133.9 ± 15.6 (49)	136.3 ± 15.0 (38)	137.8 ± 16.1 (97)	132.2 ± 15.2 (55)	132.9 ± 15.5 (37)
BP_{diast}, mmHg	89.1 ± 12.0 (111)	84.7 ± 10.7 (49)	86.3 ± 9.8 (38)	88.2 ± 10.8 (97)	85.0 ± 9.6 (55)	84.2 ± 9.1 (37)
Body fat mass, %	43.2 ± 5.4 (109)	41.2 ± 6.4 (40)	41.0 ± 6.7 (36)	43.6 ± 6.5 (92)	42.3 ± 6.1 (53)	42.4 ± 7.4 (30)
LBM, %	56.9 ± 5.4 (109)	58.3 ± 5.9 (40)	58.6 ± 6.6 (36)	56.2 ± 6.3 (92)	57.4 ± 6.0 (53)	57.4 ± 7.4 (30)
VAT volume, cm^3	4008 ± 2196 (114)	4132 ± 2389 (56)	4395 ± 2602 (41)	4079 ± 1882 (102)	3703 ± 1910 (56)	3795 ± 2014 (41)
SAT volume, cm^3	14 183 ± 3571 (85)	13 561 ± 3973 (47)	13 031 ± 4052 (34)	14 913 ± 4374 (83)	13 618 ± 4382 (49)	13 473 ± 4634 (37)
P_{max}, W/kg BW	2.09 ± 0.4 (112)	2.47 ± 0.61 (42)	2.40 ± 0.66 (37)	2.02 ± 0.48 (98)	2.48 ± 0.49 (53)	2.45 ± 0.59 (31)
HR_{max}, bpm	160.9 ± 18.1 (111)	160.0 ± 20.3 (40)	160.8 ± 18.8 (37)	159.3 ± 22.2 (95)	159.4 ± 18.6 (49)	158.8 ± 19.8 (31)
BP_{syst_max}, mmHg	187.1 ± 23.9 (111)	186.8 ± 26.4 (40)	185.3 ± 24.8 (37)	185.8 ± 25.9 (98)	186.7 ± 25.5 (50)	186.5 ± 21.2 (31)
BP_{diast_max}, mmHg	90.5 ± 15.0 (111)	85.1 ± 10.6 (40)	91.0 ± 12.1 (37)	89.2 ± 13.2 (98)	88.0 ± 13.3 (50)	90.8 ± 12.3 (31)
Glucose metabolism parameters						
FPG, mmol/L	5.16 ± 0.69 (113)	5.16 ± 0.60 (48)	5.08 ± 0.58 (36)	5.12 ± 0.57 (102)	4.98 ± 0.54 (53)	5.16 ± 0.67 (37)
FPI, pmol/L	107 [75.0-144.7] (106)	84.8 [69.1-129.5] (49)	93.8 [62.7-131.7] (35)	99.8 [72.9-137.2] (92)	79.7 [63.9-111.4] (51)	91.3 [42.3-123.7] (36)
HOMA-IR	3.1 [2.2-4.7] (105)	2.7 [2.1-3.7] (47)	2.8 [1.9-3.9] (34)	3.0 [2.3-4.5] (92)	2.5 [1.9-3.5] (51)	2.9 [1.2-4.1] (35)
2-h OGTT, mmol/L	6.57 ± 1.83 (112)	6.47 ± 1.79 (48)	7.22 ± 1.89 (36)	6.61 ± 1.74 (101)	6.25 ± 1.75 (50)	6.38 ± 1.74 (36)
HbA1c, %	5.21 ± 0.37 (110)	5.25 ± 0.39 (47)	5.33 ± 0.41 (33)	5.25 ± 0.34 (98)	5.28 ± 0.33 (50)	5.47 ± 0.34 (35)
Lipid metabolism parameters						
Triglycerides, mmol/L	1.61 ± 1.04 (108)	1.55 ± 0.80 (49)	1.55 ± 0.93 (36)	1.58 ± 0.72 (98)	1.52 ± 0.85 (52)	1.34 ± 0.57 (38)
LDL-cholesterol, mmol/L	3.47 ± 0.86 (109)	3.26 ± 0.80 (49)	3.36 ± 0.80 (33)	3.56 ± 0.94 (97)	3.64 ± 0.97 (52)	3.52 ± 0.81 (38)
HDL-cholesterol, mmol/L	1.39 ± 0.33 (109)	1.42 ± 0.35 (49)	1.41 ± 0.35 (36)	1.39 ± 0.36 (97)	1.44 ± 0.36 (52)	1.51 ± 0.37 (38)

Note: Data are presented for the intention-to-treat population. The number of patients with available data are shown in brackets.
Abbreviations: BP, blood pressure; bpm, beats per minute; BMI, body mass index; FPG, fasting plasma glucose; FPI, fasting plasma insulin; HbA1c, glycated haemoglobin; HC, hip circumference, HDL, high density lipoprotein; HOMA-IR, homeostasis model assessment-insulin resistance; HR, heart rate; LBM, lean body mass; LDL, low-density lipoprotein; NC, neck circumference; P_{max}, maximal power; SAT, subcutaneous adipose tissue; VAT, visceral adipose tissue; WC, waist circumference; WHR, waist-to-hip ratio; 2 h OGTT, 2-h oral glucose tolerance test.
[a]Data collection at screening. All data are shown as mean values with standard deviation except FPI and HOMA-IR, which are shown as median and interquartile range.

TABLE 2 Raw data of the good adherence patients in the two study arms at baseline, 12 months and 24 months.

	Strength training			Endurance training		
Time point	**Baseline**	**12 months**	**24 months**	**Baseline**	**12 months**	**24 months**
Number of patients	35	30	24	30	28	24
Age, years	45.3 ± 9.2 (35)			47.0 ± 11.4 (30)		
Women, %	68.96 (24)			83.3 (25)		
Height, cm	169.1 ± 9.6 (35)			168.2 ± 11.0 (30)		
Weight, kg[a]	102.0 ± 16.4 (35)	97.1 ± 19.3 (30)	97.4 ± 20.8 (24)	109.2 ± 22.4 (30)	100.1 ± 19.8 (28)	96.2 ± 18.5 (24)
BMI, kg/m^2[a]	35.37 ± 3.65 (35)	33.70 ± 3.96 (30)	33.36 ± 4.05 (24)	38.18 ± 4.67 (30)	35.77 ± 4.65 (28)	35.37 ± 5.41 (24)
WC, cm	112.5 ± 11.8 (33)	108.2 ± 12.7 (29)	108.3 ± 12.5 (24)	115.0 ± 13.3 (28)	112.1 ± 14.2 (28)	111.4 ± 15.3 (24)
HC, cm	121.6 ± 10.2 (33)	114.7 ± 10.5 (29)	113.1 ± 9.8 (24)	128.8 ± 13.3 (28)	121.8 ± 11.9 (28)	121.4 ± 13.3 (24)
WHR	0.93 ± 0.11 (33)	0.94 ± 0.08 (29)	0.96 ± 0.09 (24)	0.90 ± 0.07 (28)	0.92 ± 0.07 (28)	0.92 ± 0.07 (24)
Waist to height ratio	0.667 ± 0.055 (33)	0.637 ± 0.057 (29)	0.636 ± 0.053 (24)	0.688 ± 0.069 (28)	0.673 ± 0.074 (28)	0.677 ± 0.090 (24)
NC, cm	39.3 ± 3.6 (33)	39.4 ± 3.6 (29)	39.3 ± 4.4 (24)	39.3 ± 3.8 (28)	39.1 ± 4.0 (28)	37.7 ± 3.7 (24)
HR, bpm	85.7 ± 15.0 (32)	69.0 ± 20.1 (29)	71.8 ± 13.9 (24)	87.1 ± 15.4 (28)	65.5 ± 11.2 (27)	69.3 ± 10.2 (24)
BP_{syst}, mmHg	139.1 ± 19.5 (33)	131.7 ± 17.7 (29)	134.3 ± 14.3 (24)	139.2 ± 16.4 (29)	132.3 ± 15.4 (27)	131.2 ± 17.1 (24)
BP_{diast}, mmHg	89.8 ± 10.7 (33)	84.9 ± 12.2 (29)	85.4 ± 10.4 (24)	87.4 ± 12.2 (29)	83.8 ± 10.1 (27)	82.2 ± 8.9 (24)
RMR, kcal/day	1903.4 ± 315.3 (35)	1909.2 ± 412.9 (33)	2015.5 ± 387.1 (24)	1899.9 ± 365.1 (30)	1907.8 ± 320.9 (28)	1849.8 ± 305.0 (25)
BFM, %	42.4 ± 5.8 (34)	39.5 ± 5.6 (26)	39.1 ± 6.0 (23)	45.1 ± 6.1 (27)	44.3 ± 5.4 (26)	43.6 ± 6.3 (20)
LBM, %	57.6 ± 5.7 (34)	59.9 ± 5.3 (26)	60.6 ± 5.9 (23)	54.5 ± 6.0 (27)	55.5 ± 5.4 (26)	56.2 ± 6.4 (20)
VAT, cm^3	4237.6 ± 2672.3 (35)	3760.4 ± 2638.1 (32)	4125.3 ± 2970.9 (26)	4078.2 ± 1772.4 (30)	3526.5 ± 1859.8 (28)	3555.8 ± 2044.1 (25)
SAT, cm^3	13 921 ± 4453.0 (28)	12851.5 ± 4145.4 (29)	12291.3 ± 4145.4 (24)	14864.2 ± 4505.3 (23)	13961.1 ± 3727.9 (24)	13514.2 ± 4768.2 (22)
P_{max}, W/kg BW	2.16 ± 0.38 (35)	2.64 ± 0.51 (28)	2.64 ± 0.59 (24)	1.87 ± 0.45 (30)	2.50 ± 0.42 (28)	2.44 ± 0.55 (22)
HR_{max}, bpm	157.1 ± 14.4 (35)	161.4 ± 18.7 (27)	162.8 ± 15.9 (24)	154.7 ± 27.7 (29)	159.0 ± 21.4 (27)	157.6 ± 21.9 (22)
BP_{syst_max}, mmHg	188.6 ± 28.0 (34)	184.0 ± 29.5 (27)	187.3 ± 26.0 (24)	187.7 ± 28.4 (30)	189.6 ± 27.2 (27)	186.7 ± 22.4 (22)
BP_{diast_max}, mmHg	90.0 ± 14.2 (34)	85.2 ± 11.6 (27)	92.3 ± 14.1 (24)	92.0 ± 16.3 (30)	87.0 ± 13.7 (27)	91.2 ± 11.5 (22)
Glucose metabolism parameters						
FPG, mmol/L	4.85 ± 0.56 (33)	4.79 ± 0.61 (26)	4.88 ± 0.62 (22)	4.86 ± 0.48 (28)	4.91 ± 0.47 (24)	4.93 ± 0.61 (21)
FPI, pmol/L	102.7 [79.7-141.5] (32)	75.1 [65.8-113.6] (29)	83.5 [52.2-118.3] (24)	93.8 [71.9-129.9] (26)	79.3 [62.8-98.8] (26)	82.6 [40.1-133.7] (22)
HOMA-IR	3.1 [2.5-4.4] (32)	2.4 [1.9-3-7] (28)	2.6 [1.5-3.6] (24)	2.9 [2.3-3.9] (26)	2.4 [1.9-3.3] (26)	2.6 [1.2-4.1] (22)
2-h OGTT, mmol/L	6.58 ± 1.54 (35)	6.10 ± 1.76 (29)	7.00 ± 2.09 (24)	6.61 ± 1.36 (29)	5.77 ± 1.09 (26)	6.21 ± 1.65 (24)
HbA1c, %	5.09 ± 0.28 (34)	5.14 ± 0.36 (28)	5.26 ± 0.37 (22)	5.17 ± 0.30 (28)	5.20 ± 0.35 (25)	5.45 ± 0.35 (25)
Lipid metabolism parameters						
Triglycerides, mmol/L	1.77 ± 0.96 (32)	1.62 ± 0.87 (29)	1.53 ± 1.06 (24)	1.57 ± 0.69 (28)	1.41 ± 0.67 (27)	1.30 ± 0.43 (24)
LDL-cholesterol, mmol/L	3.55 ± 0.10 (33)	3.28 ± 0.90 (29)	3.39 ± 0.90 (22)	3.63 ± 0.96 (28)	3.49 ± 0.92 (27)	3.53 ± 0.76 (24)
HDL-cholesterol, mmol/L	1.41 ± 0.36 (33)	1.42 ± 0.34 (29)	1.46 ± 0.35 (24)	1.39 ± 0.37 (28)	1.44 ± 0.34 (27)	1.56 ± 0.37 (24)

Note: All data are shown as mean values with standard deviation except FPI and HOMA-IR, which are shown as median and interquartile range. The number of patients with available data is shown in brackets.

Abbreviation: 2-h OGTT, 2 h-oral glucose tolerance test; BFM, body fat mass, BMI, body mass index; BP, blood pressure; bpm, beats per minute; FPG, fasting plasma glucose; FPI, fasting plasma insulin; HbA1c, glycated haemoglobin; HC, hip circumference; HDL, high-density lipoprotein; HOMA-IR, homeostasis model assessment test-insulin resistance; HR, heart rate; LBM, lean body mass; LDL, low-density lipoprotein; NC, neck circumference; P_{max}, maximal power; RMR, resting metabolic rate; SAT, subcutaneous fat volume; VAT, visceral fat volume; WC, waist circumference; WHR, waist-hip ratio.

[a]Data collection at screening.

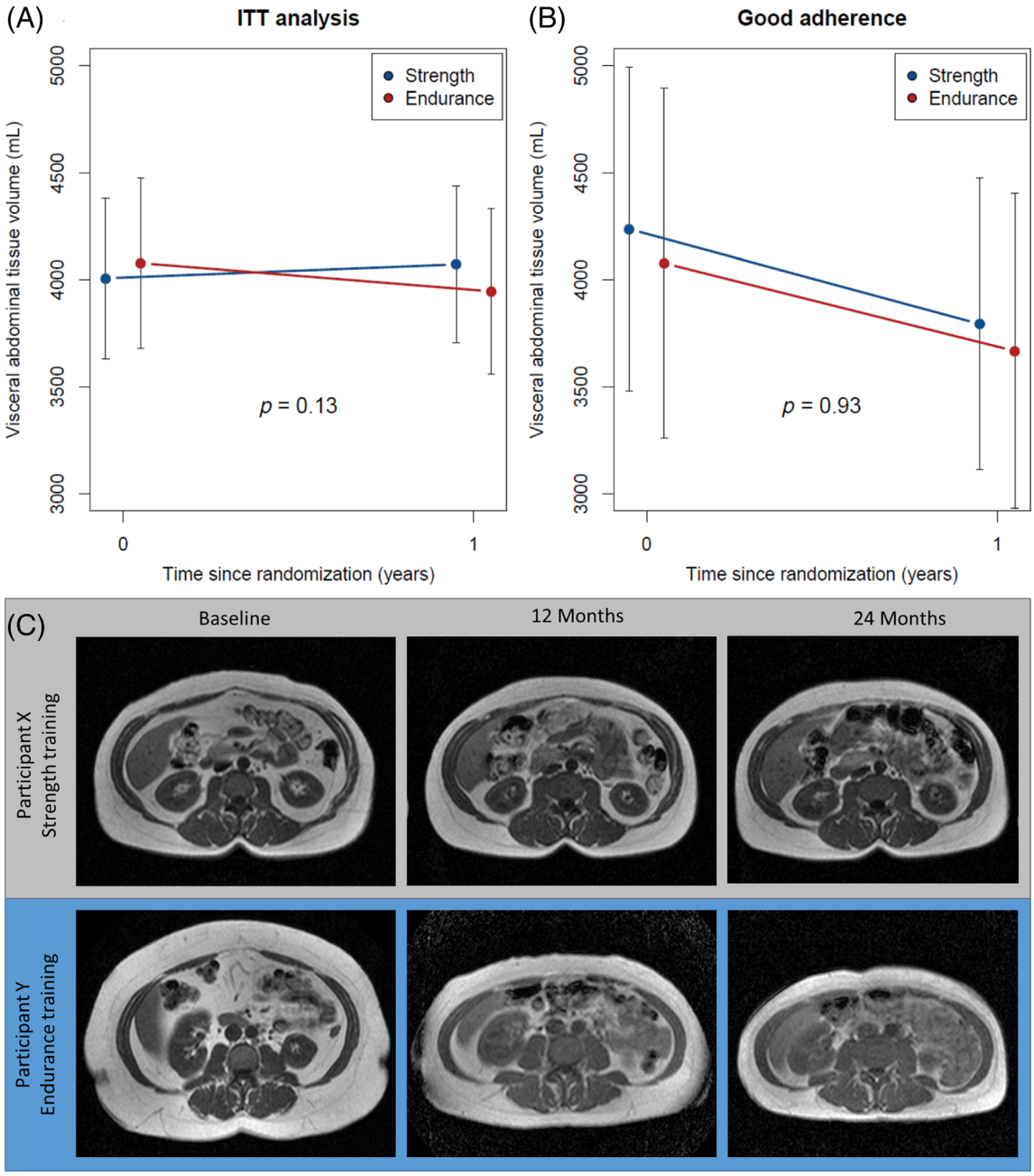

FIGURE 1 Effects of 12 months strength versus endurance training on visceral adipose tissue (VAT) volume. (A) 12 months absolute change in VAT volume between the intervention groups [intention to treat (ITT) analysis, n = 112]. (B) 12 months absolute change in VAT volume in participants with a good adherence to either strength (n = 30) or endurance (n = 30) training intervention. (C) Illustrative example magnetic resonance imaging scans of the abdomen for the best responder to the strength and endurance training intervention. Comparison of two female participants at the age of 47 and 50 years and baseline waist circumference of 130 cm and 110 cm. Participant X was randomly assigned to strength training. Compared with baseline, she reduced body weight by −15.1%, VAT volume by −50% after 12 months (after 24 months: −14.3% body weight, −55% VAT volume). Participant Y was assigned to endurance training. Compared with baseline, she reduced body weight by −26.5%, VAT volume by −68% after 12 months (after 24 months: −39.6% body weight, −84.3% VAT volume).

in the strength training group were 0.19 L (95% CI: −0.06 to 0.45 L, $p = .13$) larger than in the endurance group (Figure 1A). In the subgroup with good adherence, VAT volume did change significantly (change of −0.42 L, 95% CI: −0.68 to −0.17 L) in the pooled groups, but the change was very similar between groups with a difference of −0.02 L (95% CI: −0.38 to 0.35 L, $p = .93$), the negative sign indicating that the reduction in the strength training group was greater (Figure 1B). In both treatment arms, we found participants with a pronounced weight loss and reduction of approximately 50% visceral fat mass (Figure 1C). Individual, participant-level changes in VAT volume were heterogeneous and ranged from −2.6 L to +1.7 L in the strength group and from −2.6 L to +1.1 L in the endurance

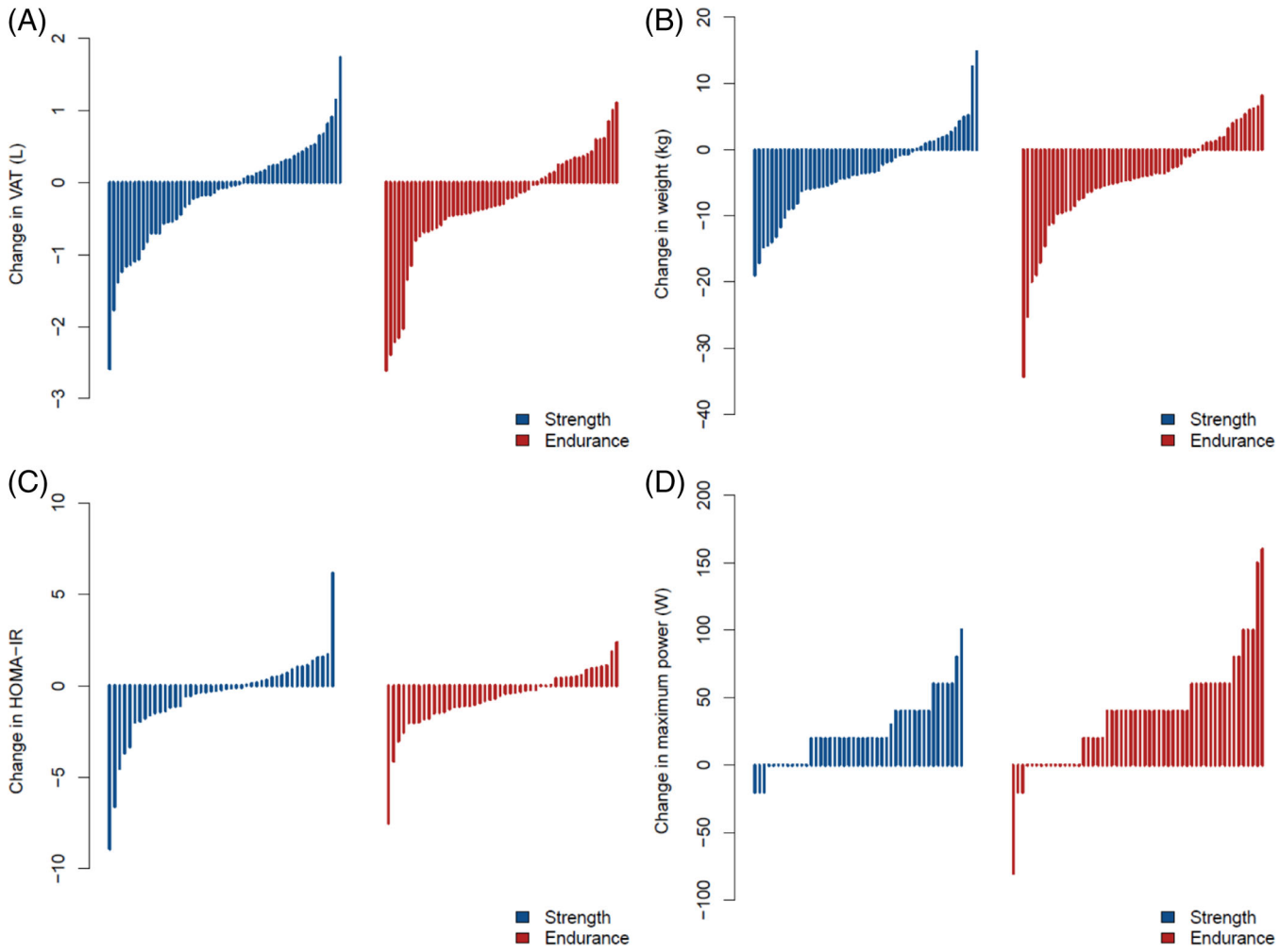

FIGURE 2 Participant-level absolute changes in the primary and secondary outcome parameters of the trial after 12 months of training intervention. Waterfall blots are shown for individual changes in (A) visceral adipose tissue volume, (B) body weight, (C) homeostatic model assessment for insulin resistance (HOMA-IR), and (D) maximum power during the standardized fitness test.

group (Figure 2A). After 12 months' intervention, 26% of participants in the strength group were known to have reduced VAT volume, as were 57% of those who provided data. The corresponding numbers are 34% and 66% in the endurance group. Models that include the number of weeks with training as a covariate suggest that each week is associated with a −0.022 L (−0.030 L to −0.006 L) loss in VAT volume, implying 1.1 L/year. This is also shown in Figure S2, which shows that most patients with few training sessions did not reduce VAT volume by at least 500 ml, and those who did most often attended a considerable number of training sessions. However, many patients who attended many training sessions nonetheless improved substantially regarding the change in VAT.

3.4 | Changes in key secondary study endpoints

In both intervention arms, individual treatment responses varied largely with respect to changes in body weight at 12 months (strength: −19 kg to +15 kg; endurance: −34 kg to +8 kg; Figure 2B), and homeostatic model assessment for insulin resistance (strength: −8.9 to +6.2; endurance: −7.5 to +2.4; Figure 2C). Maximal power in the fitness test increased for most subjects who provided data (Figure 2D).

Some secondary endpoints exhibited slight improvement over the course of the year, namely anthropometric measures such as BMI, metabolic ones such as insulin (Figure 3 and Table 2) and those related to cardiovascular and muscular fitness such as P_{max} and heart rate. A comparison of change in weight with change in fat mass suggests that primarily loss of fat was responsible for weight reduction. There was little evidence for differences between the endurance and strength training groups (Table S1).

Both endurance and strength training led to more pronounced, but statistically not significant trends in the primary endpoint and secondary outcome parameters in participants with good adherence (30% in each intervention arm) (Table 2) compared with those in the ITT analysis (Table 1).

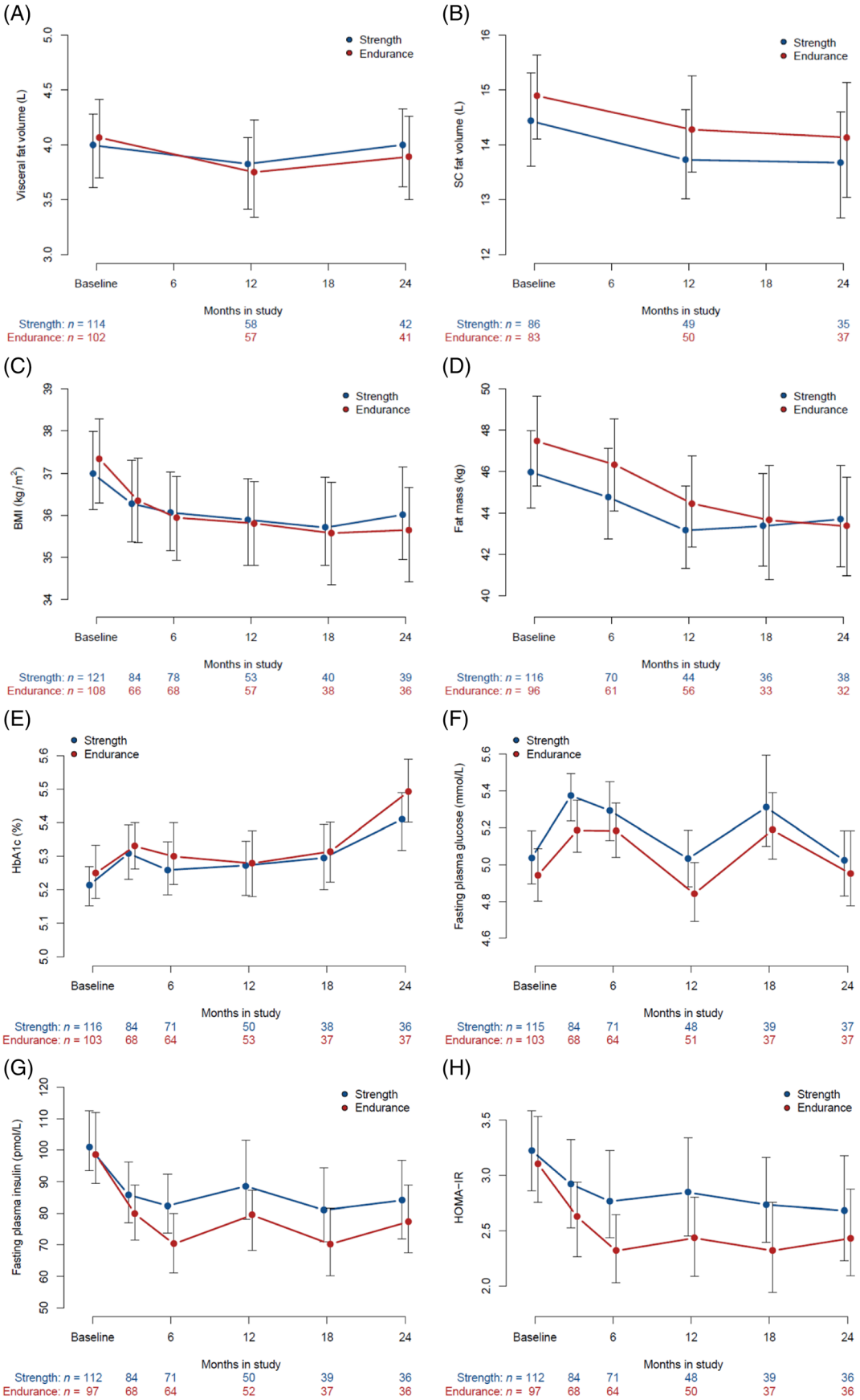

FIGURE 3 Legend on next page.

3.5 | Harms

Adverse events, which were suspected to be related to the exercise intervention, occurred in five participants (recurrent joint or muscle pain). Because of these adverse events, participants changed the treatment arm in the second year of intervention from strength to endurance training (n = 3) or vice versa (n = 2). Based on the ITT principle, these patients were analysed in the arms they were randomly allocated to. Adverse events that occurred in at least 10% of all participants included upper respiratory tract infections, joint and muscle pain, and urinary tract infections. The incidence of adverse events was similar among the training groups, and there was no serious adverse event throughout the study.

4 | DISCUSSION

In the randomized, controlled STEN trial, we tested the hypothesis that strength training is more effective in reducing visceral fat volume compared with endurance training. The background for our study was that practice recommendations for obesity treatment of two to three exercise sessions accumulating to 150-300 min/week[15–17] are frequently not achieved by patients in clinical practice.[21,22] In addition, low adherence and unmet individual preferences for training programmes are further roadblocks to structured exercise programmes that limit the translation of exercise recommendations into clinical practice. We therefore sought to determine whether a feasible, low-threshold, supervised training programme can result in clinically relevant improvements in visceral fat volume, physical fitness level, and other cardiometabolic parameters.

With a median of 40 sessions per year and a retention rate of about 50% of the subjects, we find that supervised moderately intensive training is not sufficient to reduce visceral fat volume, independent of the strength or endurance training strategy. However, in 30% of the participants in each group with the best adherence to our training intervention, the subjects attended a median of about 80 sessions in the first year and there was a significant, albeit modest, reduction in visceral fat volume after 12 months by about 10%, with no difference between strength or endurance training.

Furthermore, we did not find different effects of strength versus endurance training on visceral and abdominal subcutaneous fat volume, body weight, fitness, parameters of body fat distribution, glucose and lipid metabolism. However, our study showed that a low-threshold exercise intervention is sufficient to maintain the health status, defined by the primary and secondary outcome parameters in the STEN study, over 24 months. Maintaining or moderately improving the health status may be considered a beneficial outcome of our study because the deterioration of obesity-related diseases is generally expected, as shown, for instance, from control group data of diabetes prevention studies.[23,24] We have to acknowledge that with our study design, which did not include an untreated control group, we are not able to assess the potential health benefits of the STEN exercise intervention compared with people who remain at a lower physical activity level.

Independent of the exercise programme, there was a moderate loss of body fat mass, BMI and improved parameters of insulin sensitivity. Although parameters of physical fitness improved upon both exercise interventions, the dynamics of resting energy expenditure, glucose and lipid metabolism parameters were not different between the intervention groups and did not significantly improve during the 2-year trial.

Our data highlight an important limitation of lifestyle interventions. Despite several participant retention strategies, such as frequent study visits, regular nutritional advice sessions, reminder calls by the study nurses and exercise trainers, supervised training sessions, feedback on study parameters and adjustments to training intensity, the retention rate was only approximately 50% independent of the intervention arm. Although increasing physical activity is efficacious in the management of obesity and cardiometabolic diseases,[25–27] low adherence to behavioural interventions is a frequent barrier to long-term benefits.[22] There are several factors underlying poor attendance of training sessions in our STEN trial, including previously reported poor motivation, societal and social pressures, lack of time (main reason), health and physical limitations, negative thoughts, gaps in knowledge and awareness, and a lack of enjoyment of exercise.[22] The lower than expected adherence in our study may be mediated by previously described good adherence predictors[22]: a low rate of participants with early weight loss success, a high proportion of women, a younger age and a relatively high baseline BMI.[22] On the other hand, participants with good adherence achieved important recommendations of the American Heart Association, such as a minimum of 20 min of vigorous endurance activity 3 days/week.[28]

The comparison of participants with good adherence versus the ITT cohort and the association between fat reduction and the number of weeks of training suggest strongly that better adherence contributes to more pronounced effects on the primary endpoint of the STEN study, reduction of visceral fat volume after 12 months, and all major secondary outcome parameters.

The STEN trial was designed to directly compare the effects of endurance and strength training with equivalent energy expenditure, duration and intensity levels for each training session. The comparability of endurance versus strength training sessions was ensured by individually designed training protocols, supervision of the exercise and monitoring by exercise physiologists. Therefore, the equal

FIGURE 3 Effects of 24 months strength versus endurance training on key secondary outcome parameters. Changes in (A) visceral adipose tissue volume, (B) abdominal subcutaneous (SC) adipose tissue volume, (C) body mass index (BMI), (D) body fat mass, (E) glycated haemoglobin (HbA1c), (F) fasting plasma glucose, (G) fasting plasma insulin, and (H) homeostatic model assessment for insulin resistance (HOMA-IR) in the intention-to-treat analysis. Data are shown as mean ± standard deviation. Numbers of participants per study arm and time points are given.

efficacy of endurance and strength training on literally all relevant study endpoints may be considered a reflection of the well-balanced training strategy. In addition to adjusting energy expenditure across the two interventions, we did not want to introduce a bias by adding a specific dietary intervention to the study protocol. Instead, participants received standard nutritional counselling to promote a healthy diet and further achieve a similar intervention intensity. It has been shown that exercise interventions are more effective for weight loss in combination with energy-deficit diet interventions.[29–31] In this context, our data support the notion that moderately increased physical activity is not sufficient to cause substantial mean weight loss in clinical trials. On the other hand, the response to the exercise intervention was heterogeneous in both treatment arms, and some individuals achieved a weight loss of >15% and a visceral fat volume reduction of >50% from baseline. However, the distribution of such very good, but also non-responders were equal across the strength and endurance treatment arms (Figure 2).

The main rationale for the STEN trial was to compare the effects of strength versus endurance training, derived from previous studies in patients with T2D showing that strength training may improve glucose metabolism more effectively than endurance training.[32–38] We therefore aimed to extend those findings by including people with obesity without T2D over a longer duration of 24 months. Clinical trials comparing the effects of strength and endurance training on body composition and cardiometabolic risk factors provided inconsistent results.[31]

Previous studies had a shorter study duration,[13,32–39] included patients with T2D,[27] focused on Asian populations[32,34–36] or women,[13] included a calorie-reduced diet treatment or did not assess abdominal visceral fat volume with MRI scans. In a pilot study, including 22 patients with T2D, Cauza et al.[39] showed that strength training was superior to endurance training with regard to improvements in glucose and lipid metabolism parameters. Recently, a randomized 12-week trial among 101 women with abdominal obesity found that both endurance and endurance-strength training decreased total fat and VAT mass without significant differences between the interventions.[13] In agreement with our data, this study showed that neither the endurance training nor endurance-strength training groups showed improvement in glucose and lipid metabolism parameters.[13]

Abdominal visceral and ectopic (e.g. liver, visceral fat depots and pancreas) fat distribution is a strong determinant of metabolic health, as is increased fat mass itself.[3,40] Beyond the associations of BMI, hepatic steatosis and visceral fat accumulation have been shown to predict the risk of developing T2D and atherosclerotic cardiovascular disease, as reviewed in Neeland et al.[3] We therefore defined visceral fat volume as the primary outcome parameter and measured its changes by abdominal MRI. Even with this sophisticated visceral fat volume assessment, we did not find different effects of strength versus endurance training both for the primary endpoint, visceral fat volume change, nor for secondary fat mass, fat distribution and cardiometabolic risk parameters.

Our findings are in accordance with data from a recent meta-analysis that compared the effects of endurance, strength and combined training on people with overweight and obesity from several prospective trials.[41] Although endurance-strength training significantly increased lean body mass compared with endurance training, there were no other differences observed between endurance and strength training.[41] We observed a trend for increased lean body mass in response to both training interventions.

Another recent systematic review and network meta-analysis of 84 randomized controlled trials that included a total of 4836 participants supported the notion that regular exercise can improve VAT in individuals with overweight and obesity.[14] The meta-analysis revealed that aerobic exercise, including at least moderate-intensity resistance training, a combination of both, and high-intensity interval training, was beneficial for reducing visceral fat mass.[14] In individuals with overweight or obesity, aerobic exercise with vigorous intensity and high-intensity interval training appeared to be the most efficacious exercise interventions for improving VAT mass.[14] In conclusion, both strength and endurance training showed a modest reduction of visceral fat volume and improvement in body composition and fitness in those participants with good adherence. However, neither intervention improved parameters of glucose and lipid metabolism or insulin sensitivity over the 24-month study course. The greatest limitation of the study is the uncertainty in ITT estimates as a result of the large number of drop-outs, which cannot be overcome entirely with multiple imputation and mixed models. There have been a number of previous trials investigating the effects of different exercise regimens on body composition and visceral fat mass changes.[10–14,41] However, the majority of the studies had a shorter duration of the intervention, applied other exercise modalities or intensities, and used outcome parameters such as AT or skeletal muscle expression signatures, body fat mass or others.[10–14,41]

Therefore, important strengths of the STEN study are the randomized study design with a relatively large number of women and men over a 2-year duration as well as strict supervision of the type, duration, attendance and intensity of training. We used concise inclusion and exclusion criteria and a state-of-the-art MRI measurement of visceral fat volume, which reduced the impact of potential bias. Our data suggest that both strength and endurance training have the potential to reduce visceral fat volume, body weight and improve parameters of fitness, glucose metabolism and insulin sensitivity and that these changes can be pronounced in a small fraction of participants with abdominal obesity. Future studies should verify with a low-activity control group that these effects are indeed because of the intervention and focus on means for attaining better compliance with training plans, which may include a great reduction in the time and frequency of each session.

AUTHOR CONTRIBUTIONS

SL, UR, AO and RM designed and supervised the training intervention. NL, AS, NG, TK, HB and KS, performed and analysed MRI measurements and researched data. GF, MS and MB researched data and provided clinical investigations. CP, NK-B, DP and ET monitored the trial and performed the data analyses. LS provided dietary advice All authors contributed to the discussion and reviewed/edited the manuscript. SL and MB wrote the manuscript.

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CONFLICT OF INTEREST STATEMENT

MB received honoraria as a consultant and speaker from Amgen, AstraZeneca, Bayer, Boehringer-Ingelheim, Daiichi-Sankyo, Lilly, Novo Nordisk, Novartis, Pfizer and Sanofi. The other authors have no conflicts of interest to declare.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.15767.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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