The Body Composition Signature of Switching to BIC/FTC/TAF or DTG/3TC Over 96 Weeks

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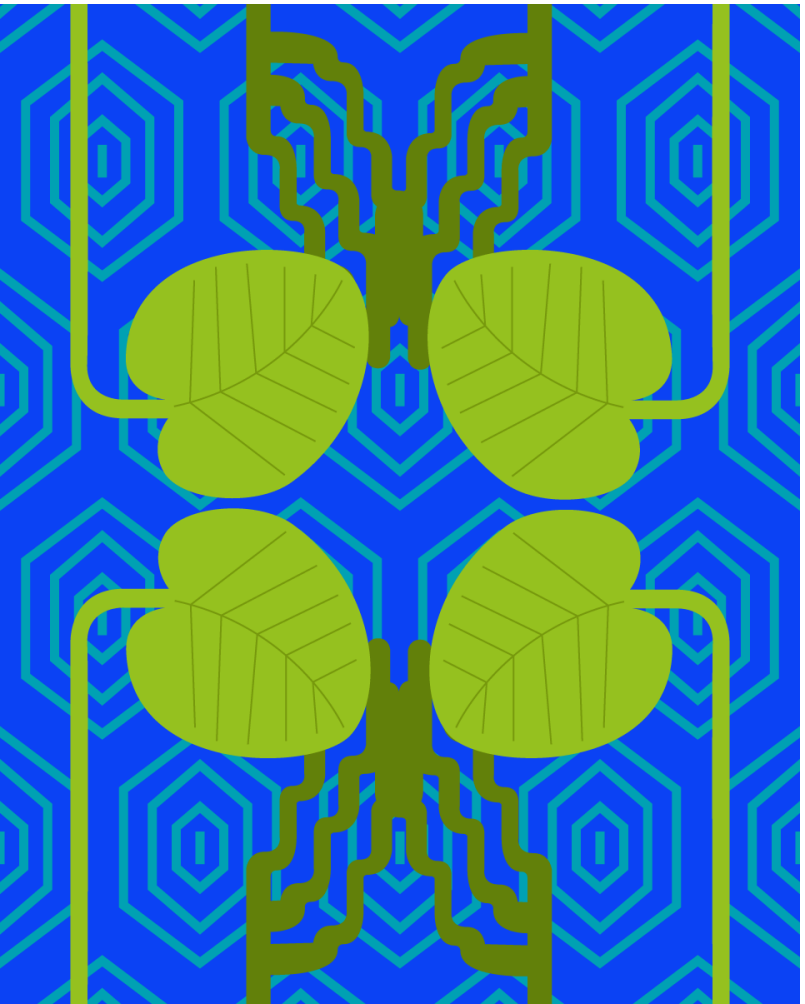
Disclosures



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Summary

Week 96 body-composition substudy of PASO DOBLE

What is your main question?

What body composition changes explain weight gain after switching to DTG/3TC or BIC/FTC/TAF?

What did you find?

Switching to either regimen was associated with fat gain and lean-mass loss, but adiposity increased more with BIC/FTC/TAF.

Why is it important?

Body weight underestimated fat gain and missed continued central fat accumulation through Week 96.

3TC, lamivudine; **BIC,** bictegravir; **DTG,** dolutegravir; **FTC,** emtricitabine
TAF, tenofovir alafenamide

PASO DOBLE study design

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Phase IV, open-label, multicentre, randomised clinical trial[1,2]

Screening

- HIV-1 RNA <50 c/mL for ≥24 weeks
- Current ART containing >1 pill/day, cobi booster, EFV or TDF
- No prior VF or known/suspected resistance
- No prior DTG or BIC
- No chronic hepatitis B

Randomised 1:1

Stratified by BL TAF use and sex at birth

- **DTG/3TC (N=277)**
- **BIC/FTC/TAF (N=276)**

BL — **Week 48** — **Week 96**

Primary endpoint: Participants with plasma HIV-1 RNA ≥50 c/mL at Week 48 (FDA Snapshot; non-inferiority margin 4%)
Key secondary endpoint: Weight change (study was powered to assess differences)

Other secondary endpoints include body composition assessments:

- Full-body **DXA** and abdominal **CT** at BL, Week 48 and Week 96
- Metabolic laboratory parameters were assessed longitudinally through Week 96

30 sites across Spain

Collaborative study between **Fundación SEIMC-GESIDA** and ViiV Healthcare

Key findings at Week 96[3]

- DTG/3TC was **non-inferior** to BIC/FTC/TAF in maintaining **virologic suppression**
- DTG/3TC was associated with less **weight gain*** and
- lower odds of **clinically meaningful**† weight gain versus BIC/FTC/TAF

***Mean adjusted difference from BL to Week 48: 0.92 kg (95% CI: 0.17, 1.66), p=0.016;
†Weight gain >5% from BL to Week 48 (>5% is a widely recognized metric for clinically meaningful weight change in adults).[4–11]
CT, computed tomography; **DXA,** dual-energy x-ray absorptiometry

1. Ryan P, et al. Lancet HIV 2025;12:e473–84; **2.** PASO DOBLE. Available at: https://clinicaltrials.gov/ct2/show/NCT04884139. Accessed February 2026; **3.** Martinez E, et al. EACS 2025. Oral RO3.8.LB;
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8. Brown JD, et al. Transl Behav Med 2016;6:339–46; **9.** Ryan DH and Yockey SR. Curr Obes Rep 2017;6:187–94; **10.** Milic J, et al. AIDS 2022;36:1643–53; **11.** Verkouter I, et al. J Clin Med 2019;8:1559

Body composition substudy

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Analysis population with DXA + abdominal CT:
At baseline: 498/553 (90.1%)
DTG/3TC n=250; BIC/FTC/TAF n=248
Included in the Week-96 analyses: 446/553 (80.7%)
DTG/3TC n=224; BIC/FTC/TAF n=222

Only participants with paired body-composition data included in longitudinal analyses

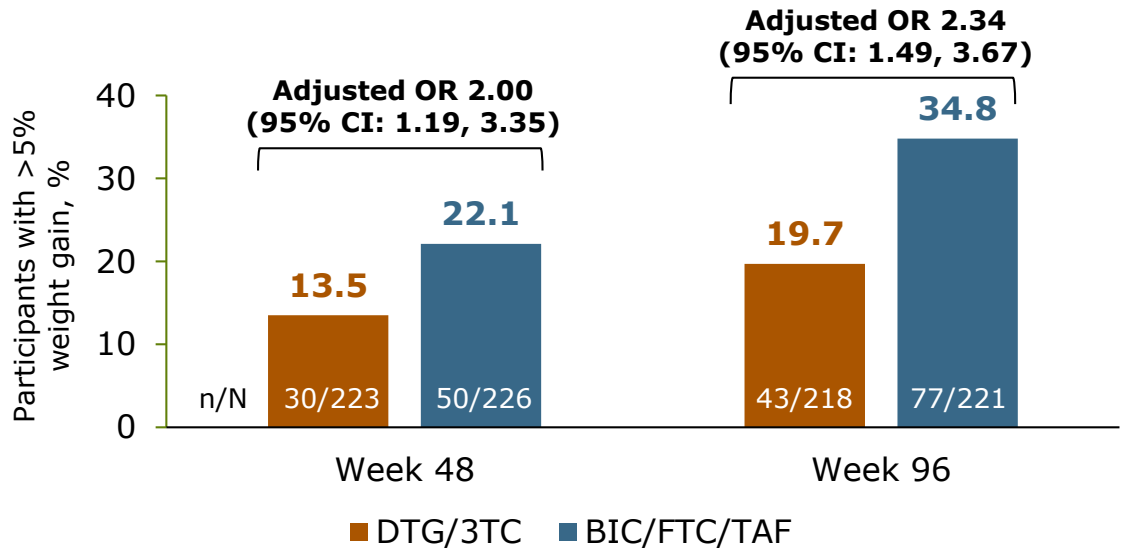
Adjusted by sex, age, race, baseline weight and baseline TAF use

Baseline characteristics
Median (IQR) or n (%)

Characteristic	DTG/3TC (N=250)	BIC/FTC/TAF (N=248)
Age (years)	**49.1 (40.7–57.0)**	**50.8 (39.0–57.7)**
Male sex at birth, n (%)	**184 (73.6)**	**185 (74.6)**
Weight (kg)	**73.0 (64.0–84.0)**	**72.8 (63.0–82.0)**
BMI (kg/m^2)	**25.2 (22.4–28.4)**	**24.8 (22.1–28.0)**
Obesity (≥30), n (%)	**45 (18.0)**	**39 (15.7)**
CD4 count (cells/mm^3)	**716.8 (522.0–918.4)**	**677.2 (479.5–856.5)**

Baseline characteristics balanced between arms

>5% weight gain in the body-composition substudy



BMI, body mass index; **OR,** odds ratio

Adiposity increased more with BIC/FTC/TAF than DTG/3TC

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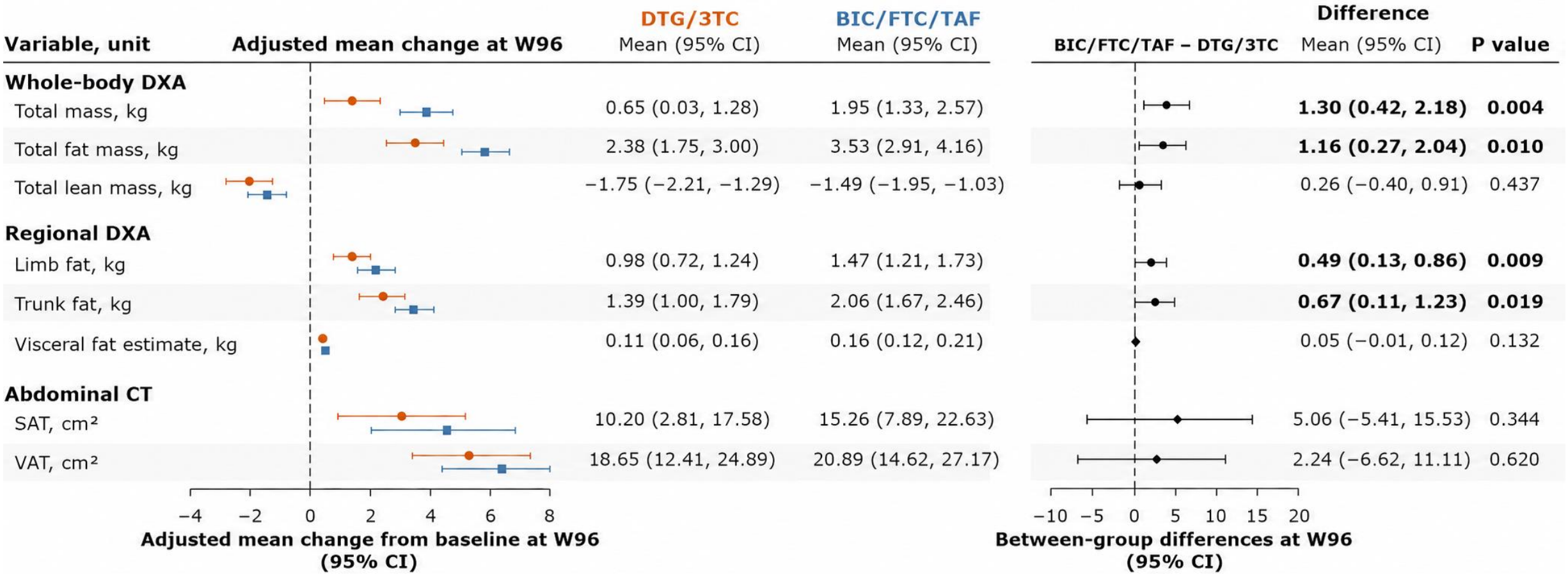

Fat mass increased and lean mass declined;
between-arm differences were driven mainly by greater adipose gain with BIC/FTC/TAF

Fat accumulation differed by compartment

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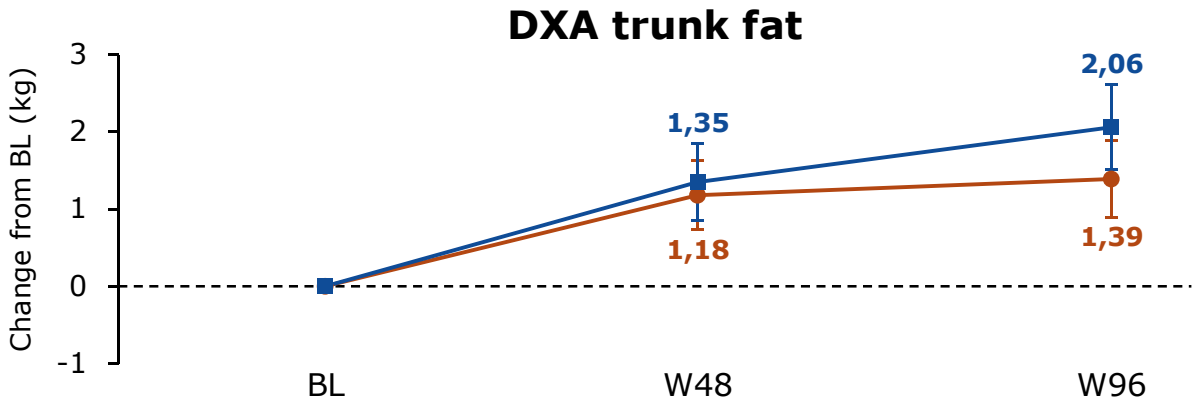

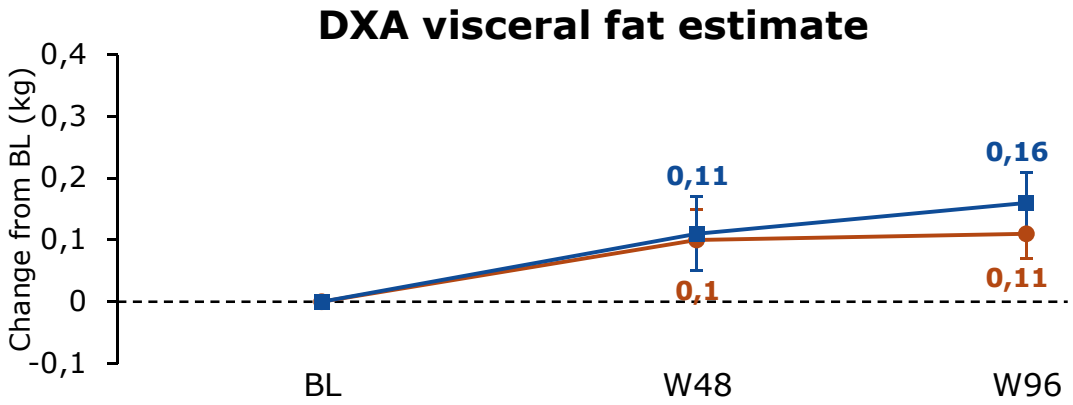

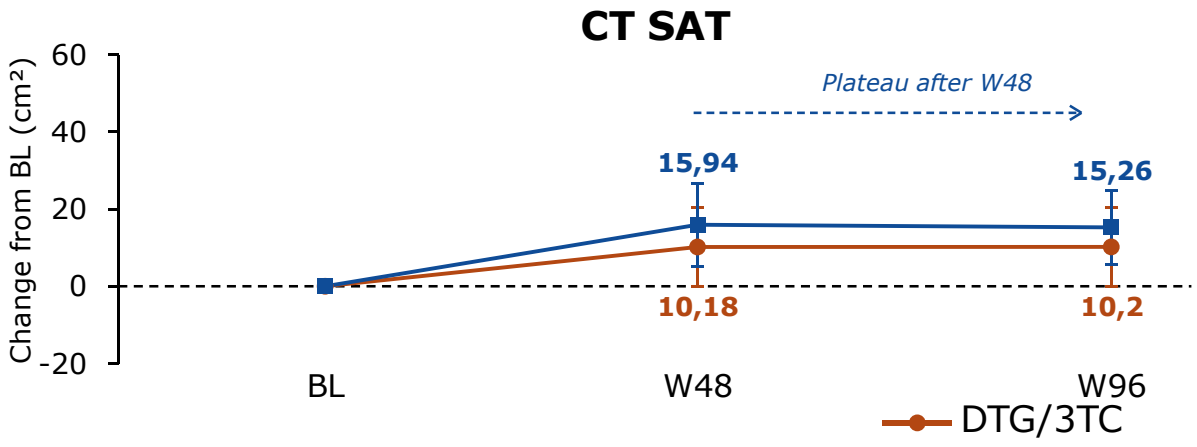

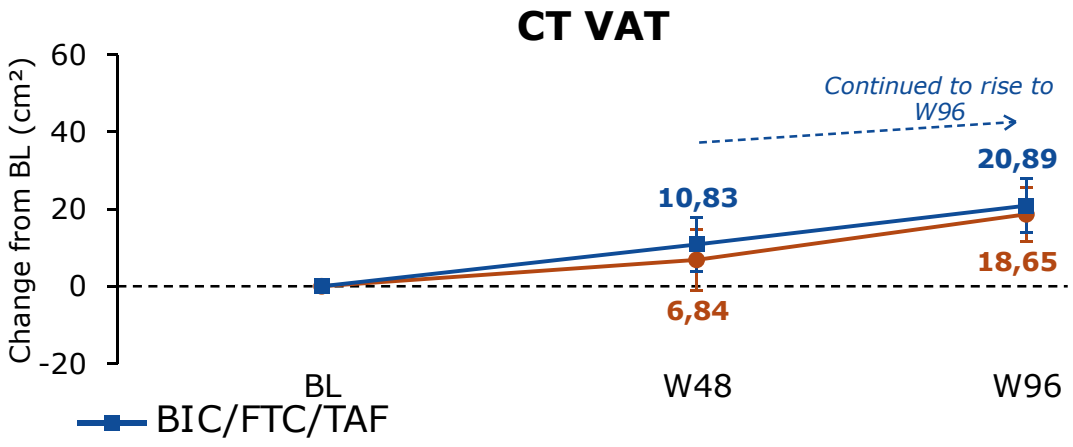

Central fat accrued with both regimens; subcutaneous expansion attenuated after Week 48, while central fat measures continued to increase through Week 96

BL, baseline, **W48,** week 48, **W96,** Weeek 96

Metabolic changes at Week 96

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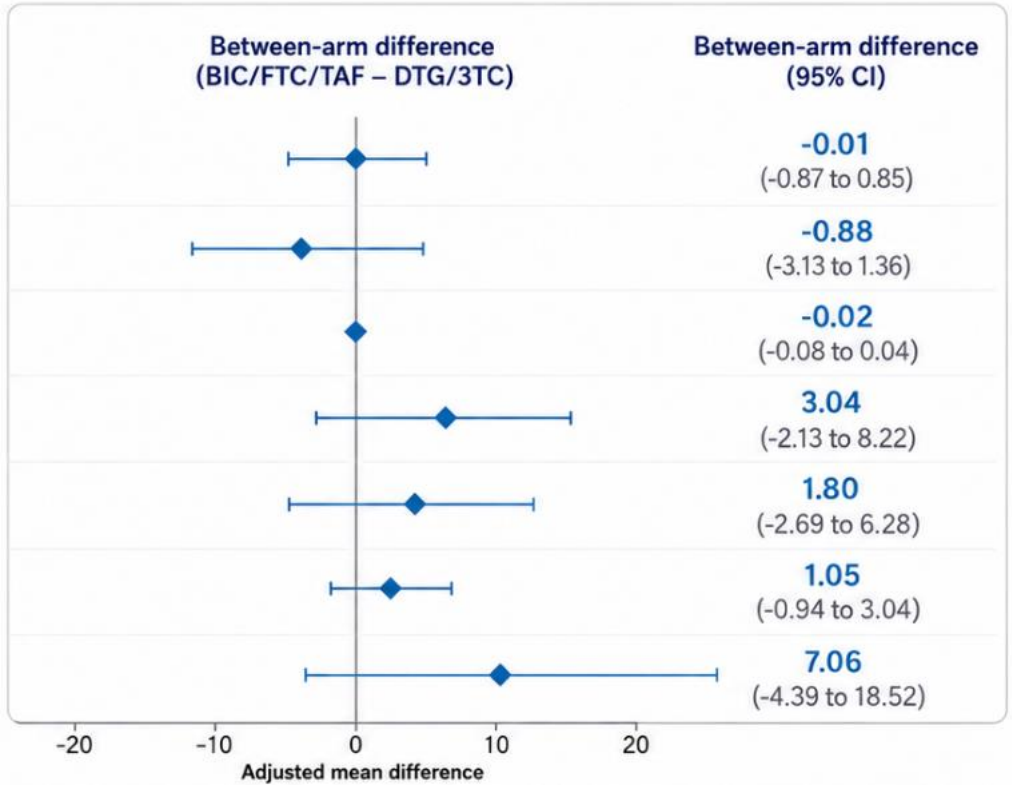
Parameter	DTG/3TC Adjusted mean change (95% CI)	BIC/FTC/TAF Adjusted mean change (95% CI)
HOMA-IR	**–0.55** (–1.15, 0.06)	**–0.56** (–1.17, 0.06)
Glucose (mg/dL)	**–0.10** (–1.67, 1.47)	**–0.98** (–2.59, 0.62)
HbA1c (%)	**0.14** (0.09, 0.18)	**0.12** (0.07, 0.16)
Total cholesterol (mg/dL)	**–6.47** (–10.05, –2.89)	**–3.43** (–7.16, 0.30)
LDL (mg/dL)	**–2.29** (–5.38, 0.80)	**–0.49** (–3.75, 2.76)
HDL (mg/dL)	**–1.50** (–2.87, –0.13)	**–0.45** (–1.89, 1.00)
Triglycerides (mg/dL)	**–20.85** (–28.76, –12.95)	**–13.79** (–22.05, –5.53)



Despite differences in adiposity, metabolic laboratory changes remained modest through Week 96, with no clear between-arm differences

HbA1c, haemoglobin A1c; **HDL,** high-density lipoprotein; **HOMA-IR,** homeostatic model assessment for insulin resistance **LDL,** low-density lipoprotein

Predictors of DXA total fat mass change

Week-96 multivariable model

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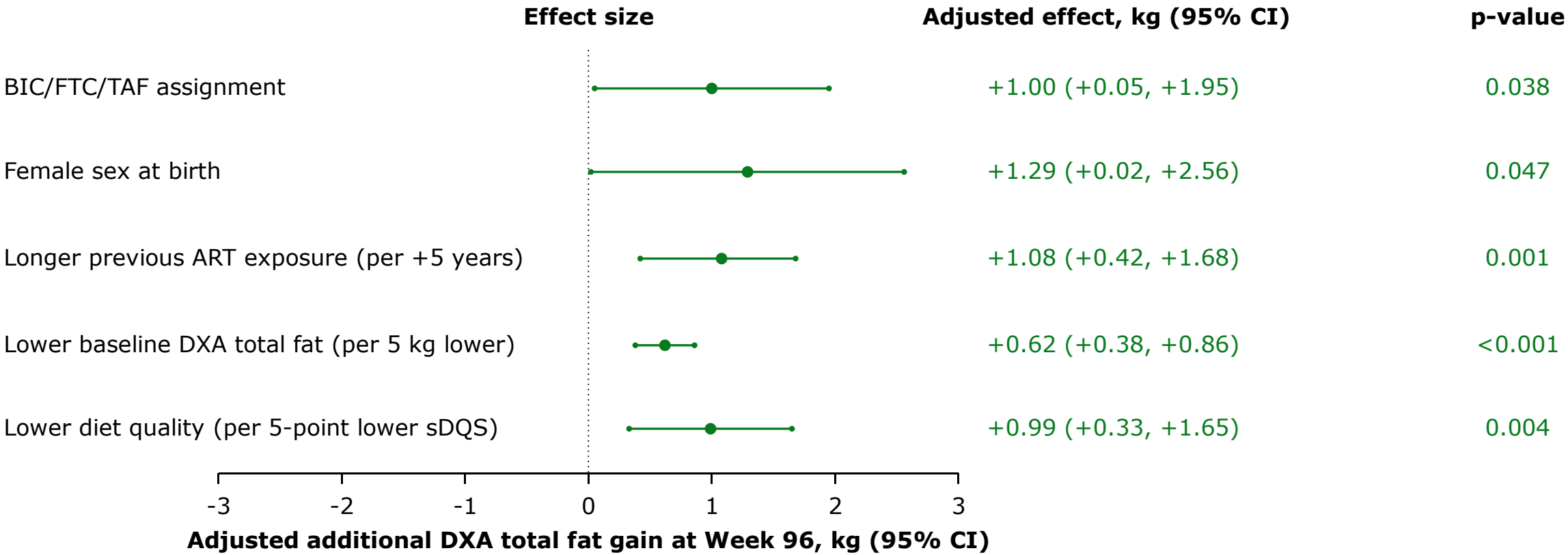

Greater fat gain reflected treatment assignment plus host, ART-history, and lifestyle factors

Outcome: DXA total fat mass change from baseline to Week 96
sDQS, Short Diet Quality Screener score
sDQS (range 0–36); higher scores indicate better diet quality

Predictors of CT VAT change

Week-96 multivariable model

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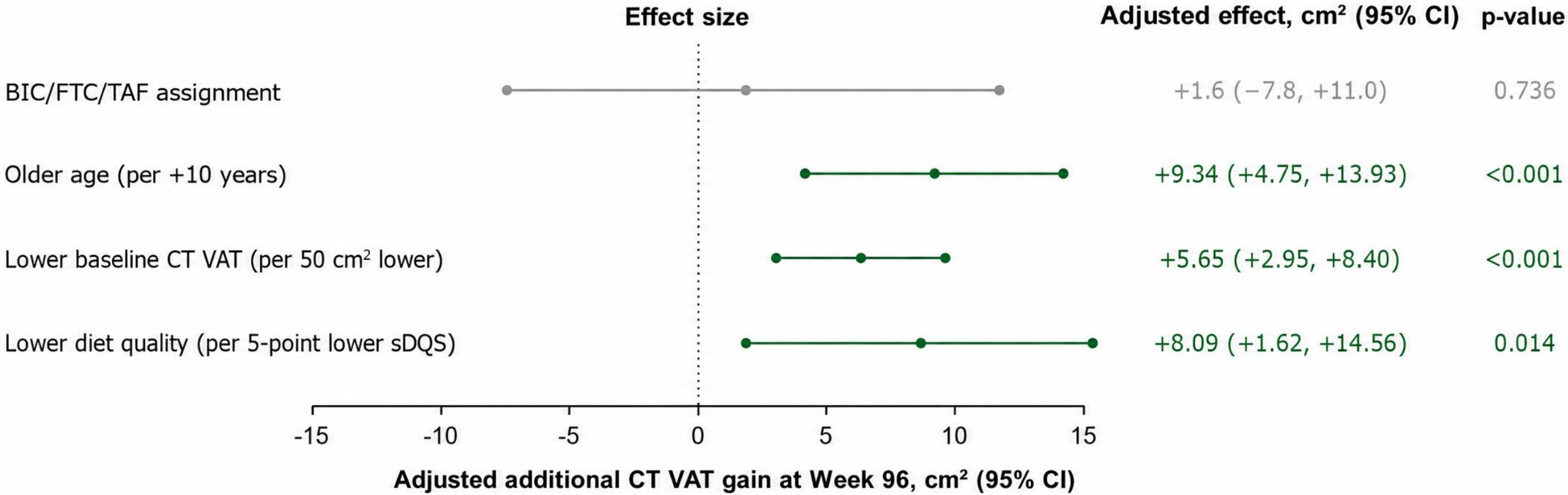

Greater CT VAT gain was independently associated with older age, lower baseline VAT, and lower diet quality; no independent treatment effect was observed

Outcome: CT VAT change from baseline to Week 96
sDQS (range 0–36); higher scores indicate better diet quality
sDQS, Short Diet Quality Screener score

Conclusions

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1. BIC/FTC/TAF showed greater adipose gain than DTG/3TC

Mainly involving trunk and limb fat, resulting in greater total fat gain.

2. Both regimens showed tissue remodeling

Fat mass increased while lean mass declined.

3. Central fat compartments behaved differently

SAT accumulation stabilized after Week 48, whereas VAT continued to increase similarly in both arms.

4. Weight alone underestimated the signal

Fat distribution and lean mass provide relevant information beyond weight when comparing ART switches.

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