GLP-1 RECEPTOR AGONISTS IN CANCER THERAPY

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EMORY WINSHIP CANCER INSTITUTE

National Cancer Institute-Designated Comprehensive Cancer Center

NCI Designated Comprehensive Cancer Center

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DISCLOSURES

- I have the following financial relationships to disclose:
  - Consultant/Advisor: Pfizer, Novartis, Seattle Genetics, AstraZeneca, Gilead, Boehringer Oncology, Amneal Pharmaceuticals, Arvinas, Daichii-Sankyo, Genentech/Roche, Bayer, SynDevRx, TerSera Therapeutics, BD Life Sciences, Menarini-Stemline, Puma
  - Speaker (Unbranded): MJH Life Sciences, CurioScience, IntrinsiQ Health, Community Health Media, Cardinal Health, DAVA Oncology
  - Editorial Positions: ONCOLOGY (Editor-in-Chief)
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  - Contracted Research (PI): Novartis, SynDevRx

CASES

56yo postmenopausal woman with cT3N1M0 TNBC of R breast

- Planned to start neoadjuvant KEYNOTE522 regimen
- Co-morbidities: BMI 34, diabetes on metformin 1000 bid (Hb A1c 6.2%)

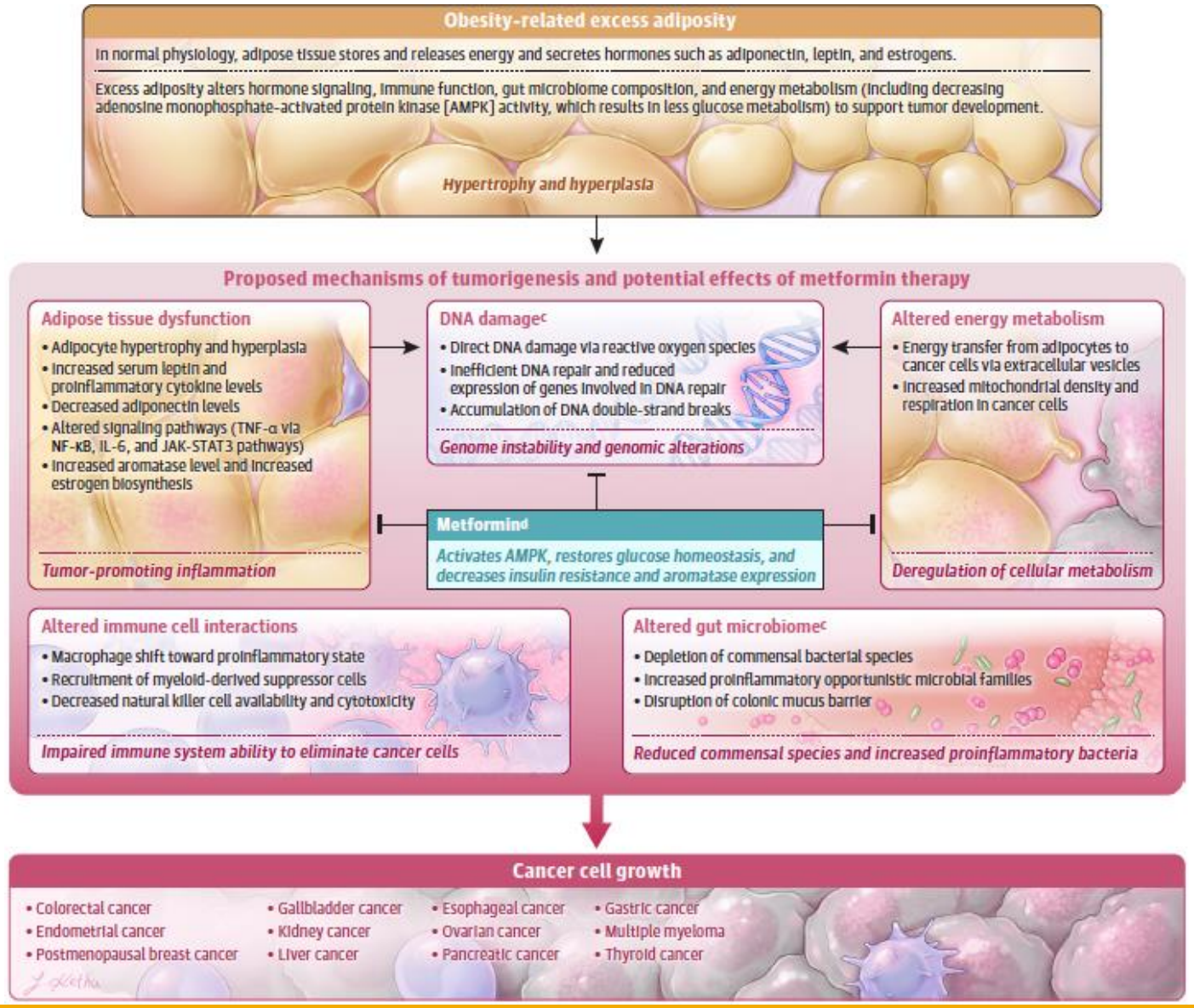
She was planning to start **tirzepatide** prior to TNBC diagnosis and asks if she could start with her breast cancer treatment.

42yo premenopausal woman with pT1cN0M0 HR+/HER2-neg IDC of L breast

- s/p lumpectomy + XRT, OncotypeDX RS 18
- planned to start adjuvant OS + AI
- Co-morbidities: BMI 29 on semaglutide (prior BMI 33)

She asks if she could continue **semaglutide** with adjuvant endocrine therapy.

OBESITY PROMOTES MULTIPLE CANCER HALLMARKS



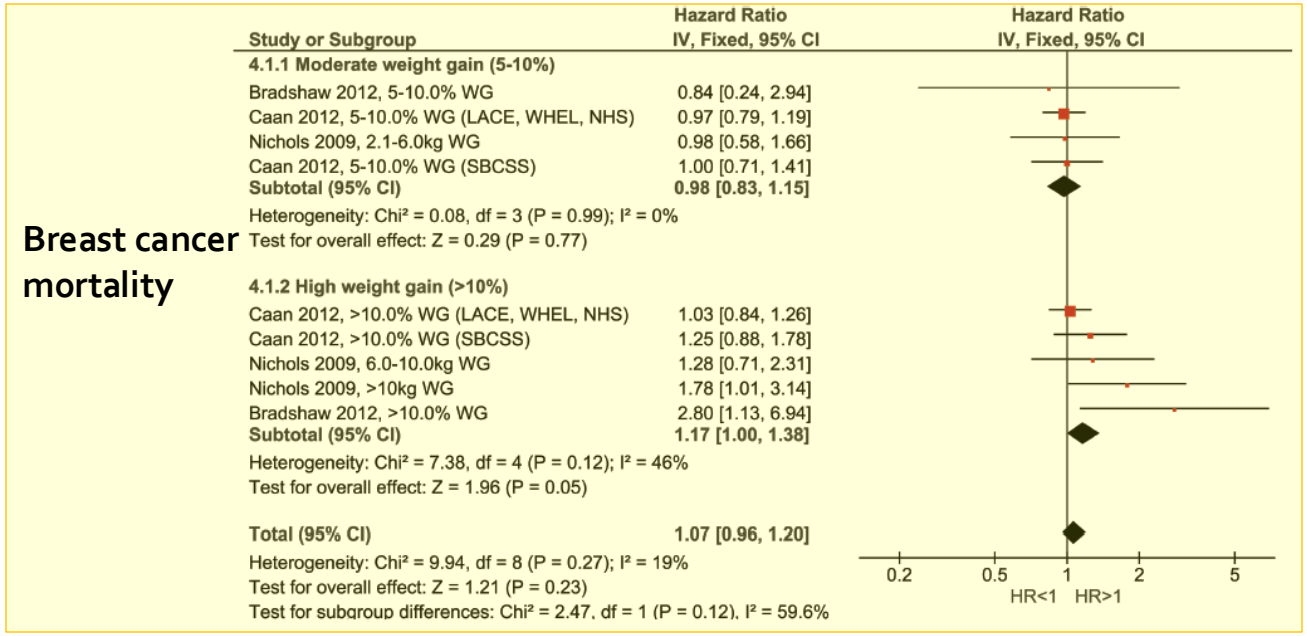
Shen, Brown, Green, Iyengar.
JAMA 2026.

WEIGHT GAIN AFTER DIAGNOSIS

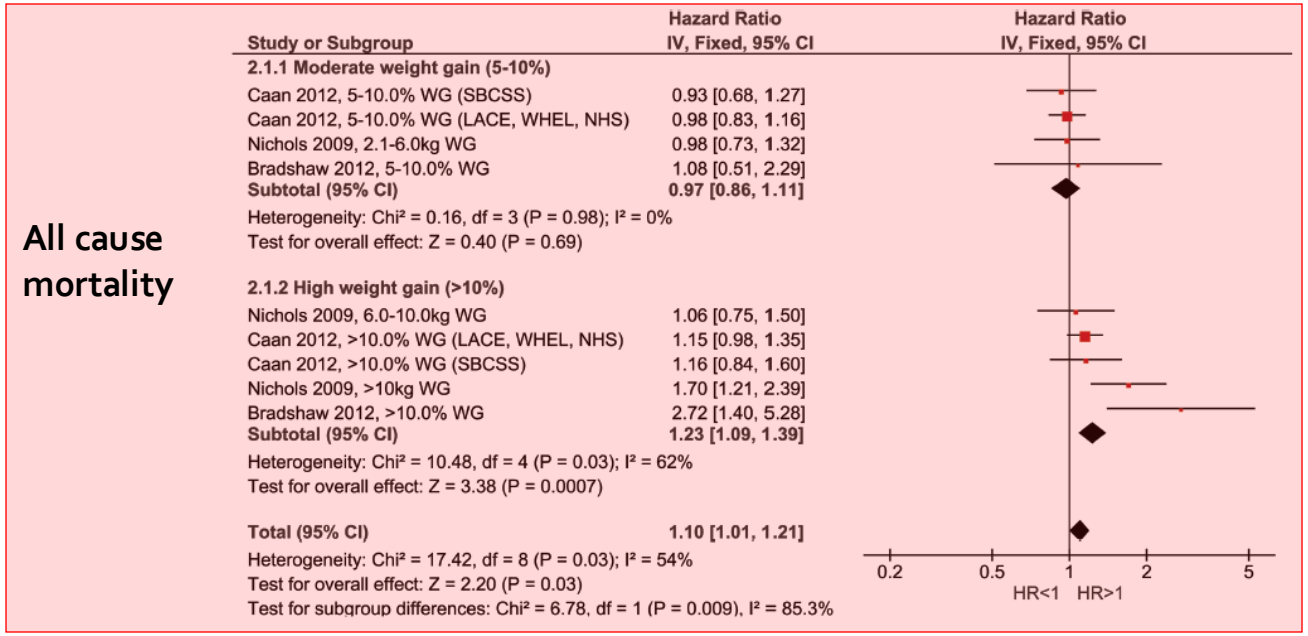
Meta-analysis:
12 studies published up to Dec 2014

Weight gain after diagnosis (over average of 1.5 years) is associated with increased mortality

Breast cancer mortality



All cause mortality



Playdon MC et al. JNCI 2015.

BREAST CANCER WEIGHT LOSS (BWEL) TRIAL

3136 Participants

Key Eligibility*

- Stage II-III Breast Cancer
- HR+/HER-2- or TNBC
- Diagnosed w/in past 14 months
- Completed with surgery and any chemotherapy and/or radiation
- BMI ≥ 27 kg/m2

*Patients planning on taking medications for the purpose of weight loss and/or undergoing a surgical weight loss procedure within 2 years were not eligible

Randomize

- **Health Education + 2-year Telephone-Based Weight Loss Intervention**
- **Health Education Alone**

Standardized Program:

- Telephone-based weight loss program
- Based on Social Cognitive Theory
- Adapted from Diabetes Prevention Program, Look AHEAD, LISA

Centralized Delivery:

- 42 calls over 2 years
- Each patient paired with a weight loss coach, based at Dana-Farber
- Weekly months 1-3
- Biweekly months 3-12
- Monthly months 13-24

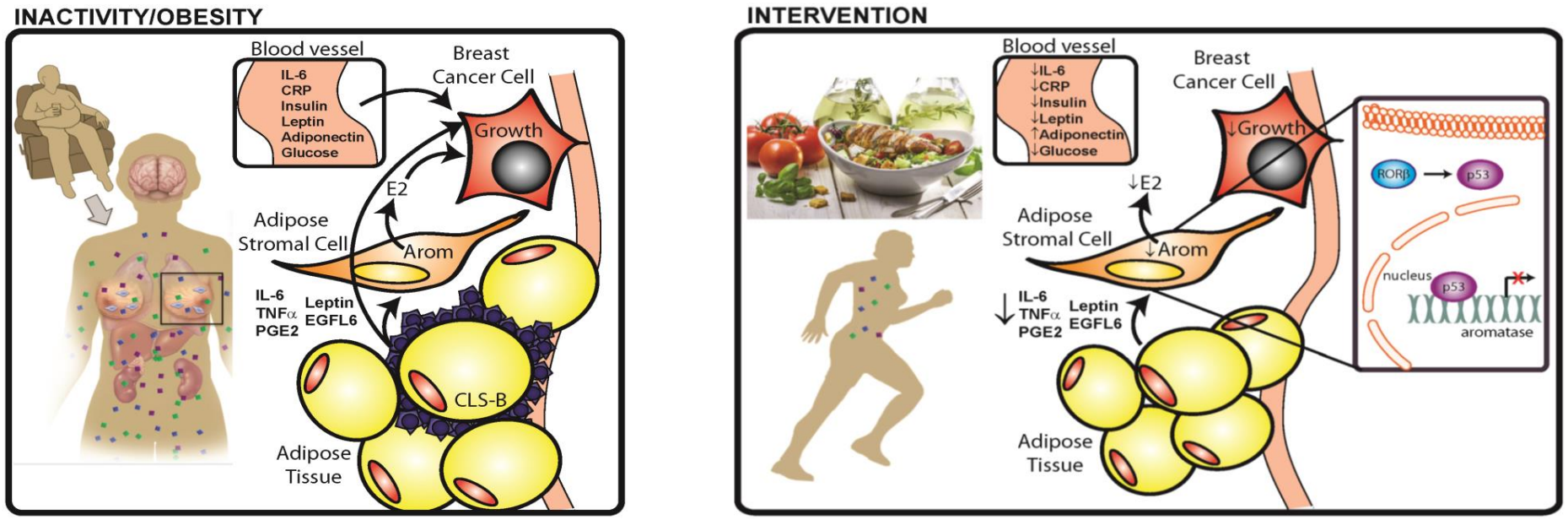
Intervention Goals:

- 10% weight loss
- 500-1000 kcal/day deficit
- Increased physical activity
  150-225 minutes moderate-intensity activity/week

	CONTROL (n=1173)	WLI (n=1222)	P VALUE
Absolute Weight Change at 6-months	+ 0.2 kg	- 4.4 kg	<0.0001
% Weight Change at 6-months	+ 0.3%	- 4.8%	<0.0001
Absolute Weight Change at 12-months	+ 0.7kg	- 4.4kg	<0.0001
% Weight Change at 12-months	+ 0.9%	- 4.8%	<0.0001

Ligibel et al. ASCO 2023.

WEIGHT LOSS TO IMPROVE TISSUE MICROENVIRONMENT AND BIOMARKERS



Iyengar et al. J Clin Oncol 2016

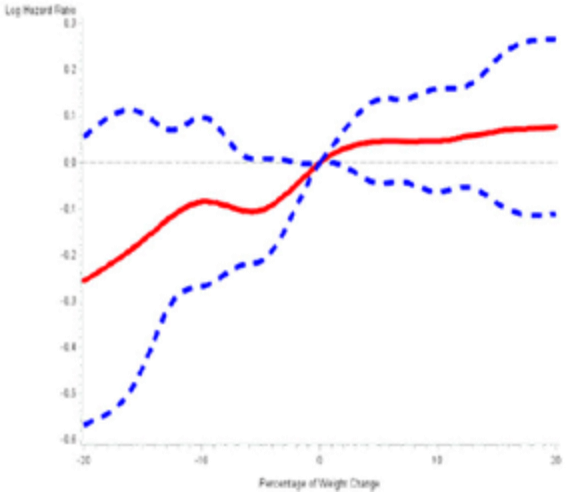
Breast Cancer Research and Treatment. 2013 November; 142:119-132

Favorable Modulation of Benign Breast Tissue and Serum Risk Biomarkers Is Associated with >10% Weight Loss in Postmenopausal Women

Carol J. Fabian, Bruce F. Kimler, Joseph E. Donnelly, Debra K. Sullivan, Jennifer Klemp, Carola Zalles, Gordon B. Mills and Stephen D. Hursting

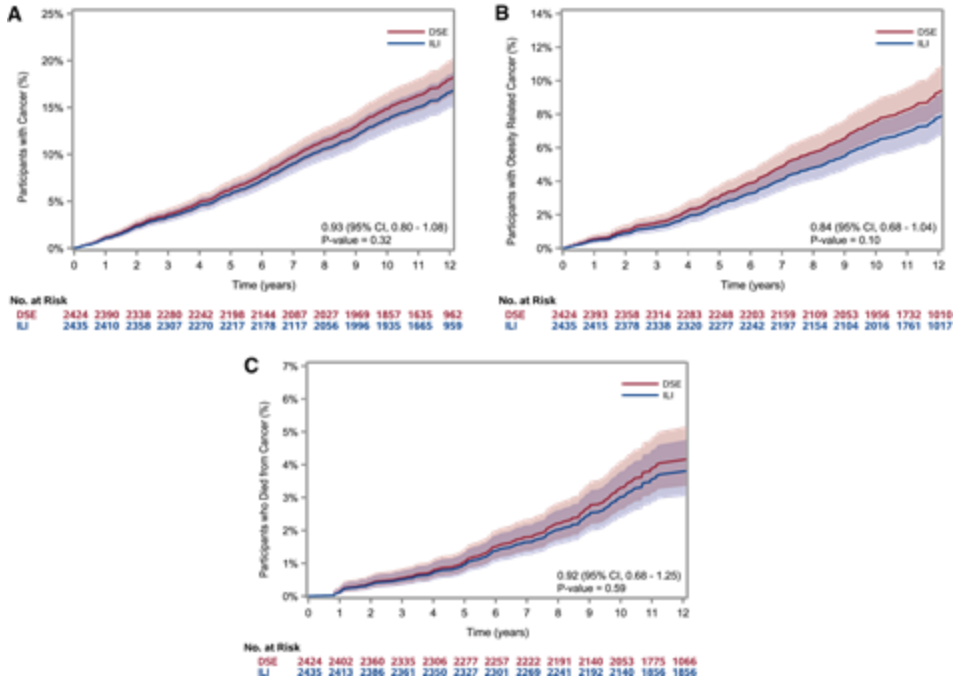
WEIGHT LOSS IS ASSOCIATED WITH REDUCED INCIDENCE OF OBESITY ASSOCIATED CANCERS WITH VARYING EFFECT SIZE

Women's Health Initiative:
- Prospective observational study
- N = 58,667 postmenopausal women
- 12 years median follow-up
- ≥5% weight loss associated with 12% reduction in Obesity Associated Cancers (HR 0.88; 95% CI 0.80 – 0.98)



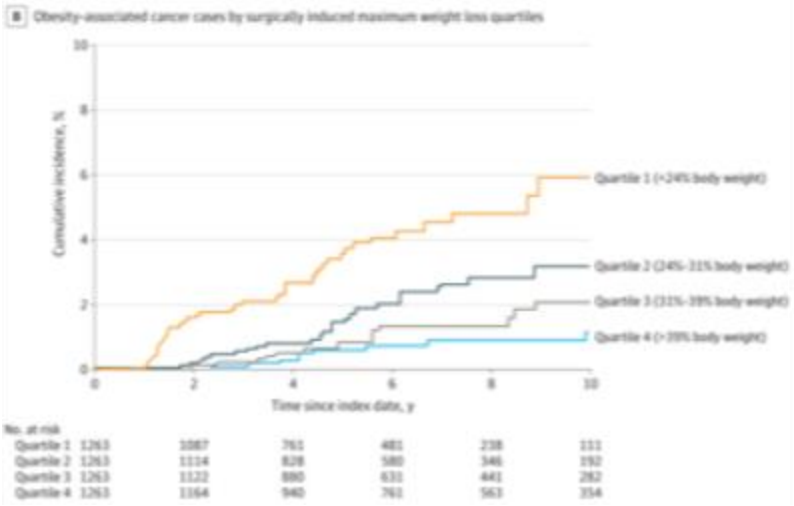
Luo et al. *JNCI Cancer Spectr* 2019

Look AHEAD RCT (post hoc analysis):
- Lifestyle weight loss intervention
- N = 4859 Ow/Ob with T2DM
- 11 years median follow-up
- 16% reduction in Obesity Associated Cancers (HR 0.84; 95% CI 0.68 – 1.04)



Yeh et al. *Obesity* 2020

SPLENDID matched cohort study:
- Bariatric surgery vs no surgery
- N = 30,318 (matched 1:5)
- 6.1 years median follow-up
- 32% reduction in Obesity Associated Cancers (HR 0.68; 95% CI 0.53 – 0.87)



Aminian et al. *JAMA* 2022

PHASE 2 RCT: NUTRITION + STRUCTURED EXERCISE FOR WEIGHT LOSS

Eligibility
- Stage I-III ER+ breast cancer
- Completed curative surgery, radiation, and cytotoxic treatment
- Current treatment with adjuvant aromatase inhibitor
- BMI ≥ 27
- Sedentary (< 90 min exercise / wk)

- **Breast biopsy**
- **DEXA**
- **Fasting blood**
- **CPET**
- **Stool**

Randomize

6 months

Structured Exercise + Plant-based diet (N=28)

Attention Control Telephone counseling + Treadmill (N=28)

Post-study Visit

- **Breast biopsy**
- **DEXA**
- **Fasting blood**
- **CPET**
- **Stool**

TECHNOGYM

Study Endpoints

Primary: Breast aromatase level
Secondary: Breast tissue gene expression changes, Blood markers, body composition, weight loss, adherence, microbiome, QOL / PROs

Biostatistical Design

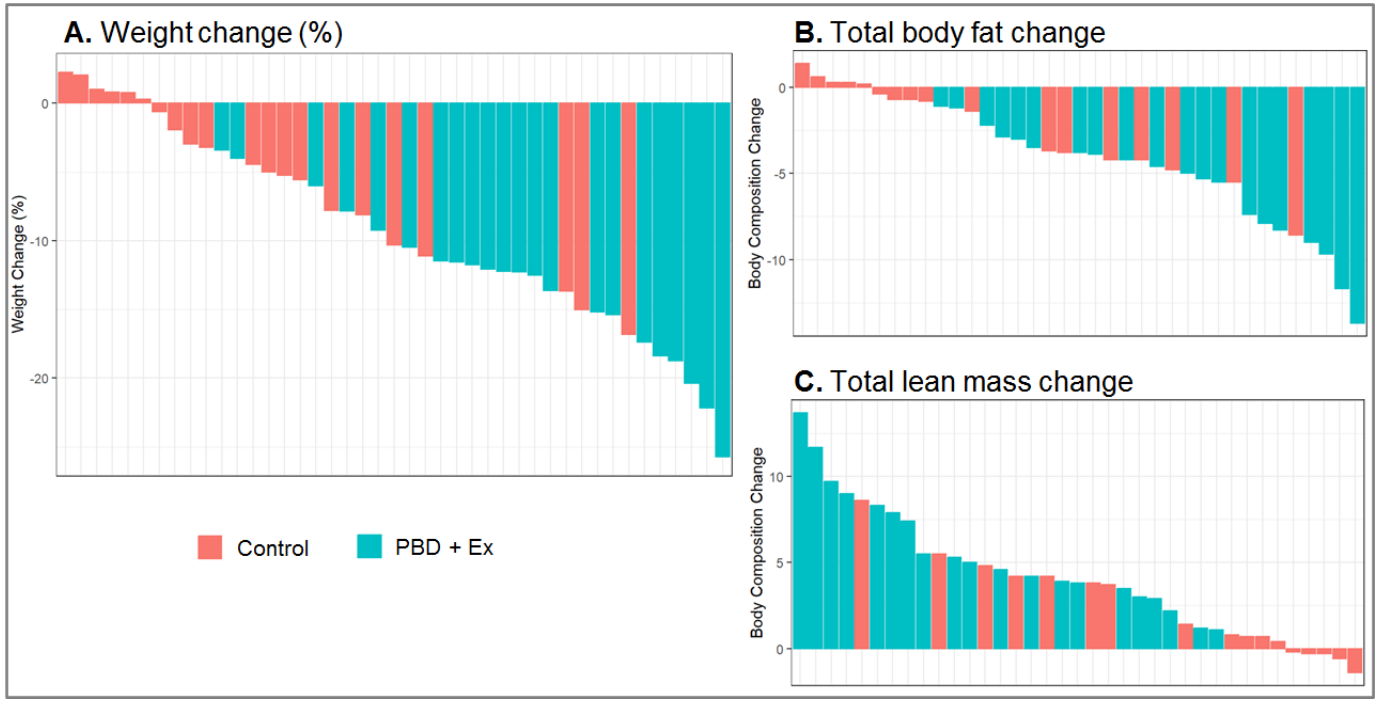
- 1 unit decrease in BMI = 0.06 mean reduction in aromatase (SD 0.81, log scale)
- Goal BMI reduction is 3 kg/m^2

NCT04298086

PHASE 2 RCT: PRECISION NUTRITION + STRUCTURED EXERCISE

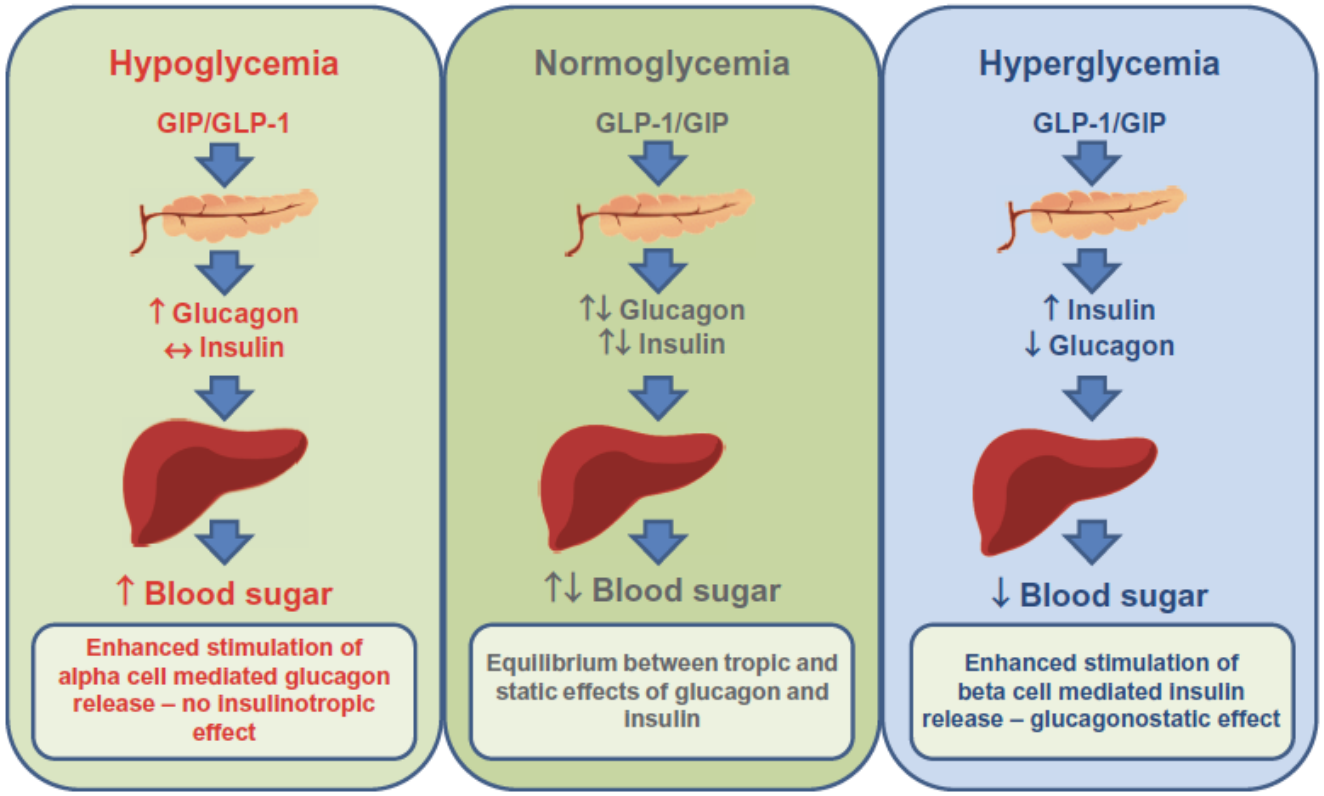
Characteristic	Control (N = 21)	PBD + Ex (N = 22)
Age at consent, mean (SD)	58 (7)	56 (7)
Race, number (%)		
White	16 (76%)	15 (68%)
Black	4 (19%)	3 (14%)
Other	0 (0%)	3 (14%)
Unknown	1 (5%)	1 (5%)
Ethnicity, number (%)		
Non-Hispanic	15 (71%)	18 (82%)
Hispanic	4 (19%)	4 (18%)
Unknown	2 (10%)	0 (0%)
BMI, mean (SD)	34.2 (4)	34.3 (5)
Smoking, number (%)		
Never	13 (62%)	14 (64%)
Prior/quit	8 (38%)	8 (36%)
Alcohol intake, number (%)		
Never	2 (9%)	4 (18%)
Prior/quit	1 (5%)	2 (9%)
Yes	18 (86%)	16 (73%)
Stage, number (%)		
I	11 (52%)	12 (55%)
II	7 (33%)	8 (36%)
III	3 (14%)	2 (9%)
Receptor status, number (%)		
ER+/PR–/HER2–	1 (5%)	1 (4%)
ER+/PR+/HER2–	19 (90%)	18 (82%)
ER+/PR+/HER2+	1 (5%)	3 (14%)
Chemotherapy, number (%)	6 (29%)	8 (36%)
Radiation, number (%)	18 (86%)	17 (77%)
Ovarian suppression, number (%)	5 (24%)	14 (64%)

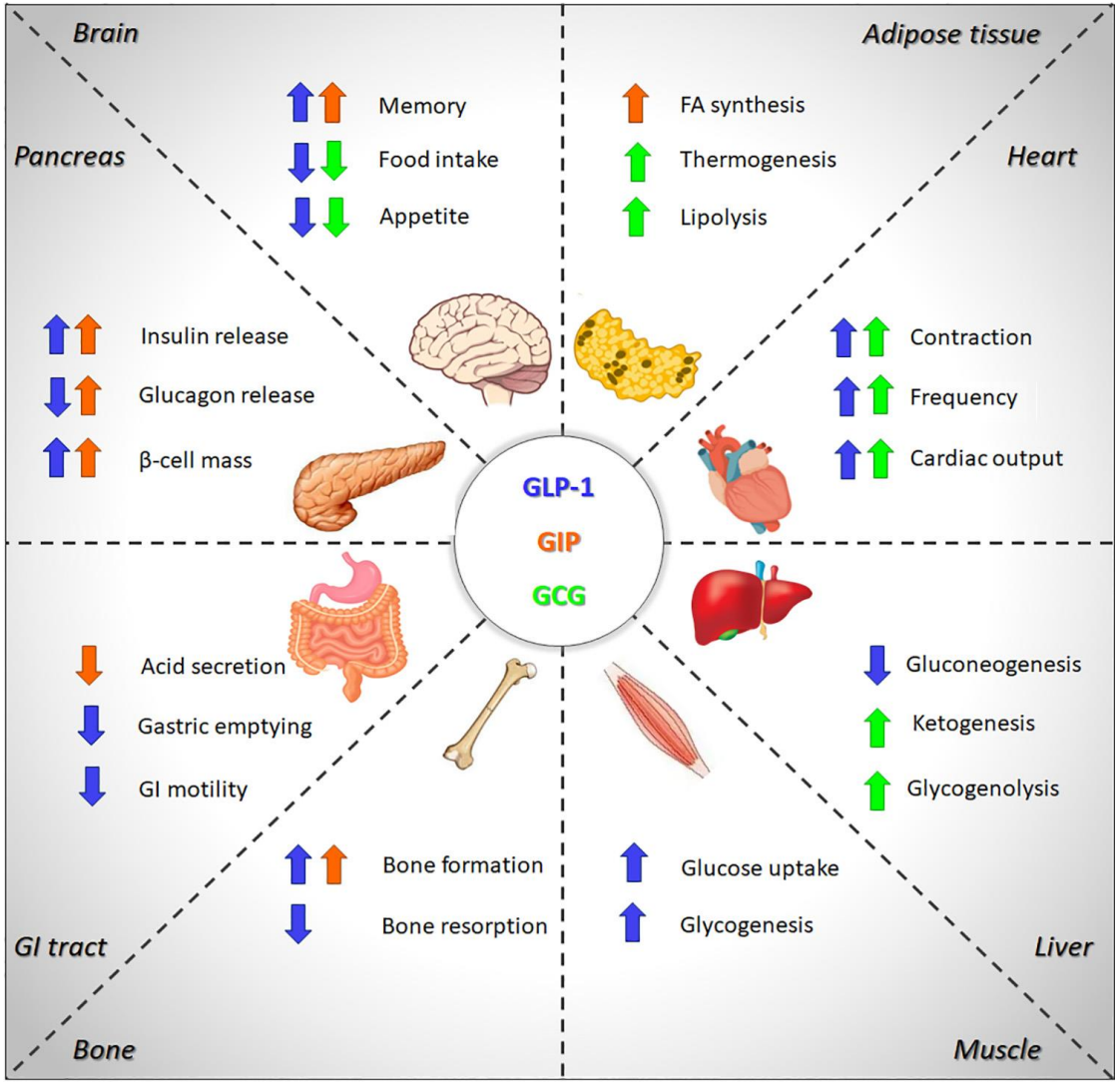
	Control (N=21)	PBD + Ex (N=22)	P
	Change (95% CI)	Change (95% CI)	
Weight (kg)	-4 (-6.6, -2.2)	-12 (-15, -9.4)	<0.001
Total body fat (kg)	-2 (-3.5, -0.71)	-6 (-7.3, -4.1)	<0.001
Trunk fat (kg)	-3 (-4.4, -0.73)	-7 (-8.9, -4.9)	<0.001
Total body lean mass (kg)	2 (0.71, 3.5)	6 (4.1, 7.3)	<0.001
Total body fat to lean mass ratio	-0.01 (-0.02, 0.00)	-0.02 (-0.03, 0.00)	0.4



Iyengar et al. ASCO 2024.

INCRETIN MIMETICS – DUAL- AND TRI-RECEPTOR AGONISTS





Von Websky et al. Vasc Health Risk Manag 2013
Folli et al. Am J Physiol Endocrinol Metab 2023

5 PROPOSED BIOLOGIC MECHANISMS (SUPPORTED BY PRECLINICAL & EPIDEMIOLOGIC DATA)

WEIGHT LOSS	REDUCED ADIPOSE INFLAMMATION	IMPROVED INSULIN RESISTANCE	LOWER HYPERINSULINEMIA	IMMUNE MODULATION	DIRECT GLP-1R SIGNALING	REDUCED HEPATIC STEATOSIS	TUMOR MICROENVIRONMENT
Reduces obesity-related cancer risk factors	Decreases chronic inflammation and cytokine signaling	Enhances metabolic health and insulin sensitivity	Reduces insulin-driven mitogenic signaling	Enhances anti-tumor immunity and T-cell function	GLP-1 receptors expressed on some cancer cells	Improves liver microenvironment and function	May reduce fibrosis, angiogenesis and tumor growth

IMPORTANT LIMITATIONS

- Retrospective observational studies
- Residual confounding
- Selection bias (healthier users)
- Heterogeneity in populations, outcomes, and follow-up
- Misclassification possible
- No randomized trials
- Association ≠ causation

KEY REFERENCES – ASCO 2026 ABSTRACTS)

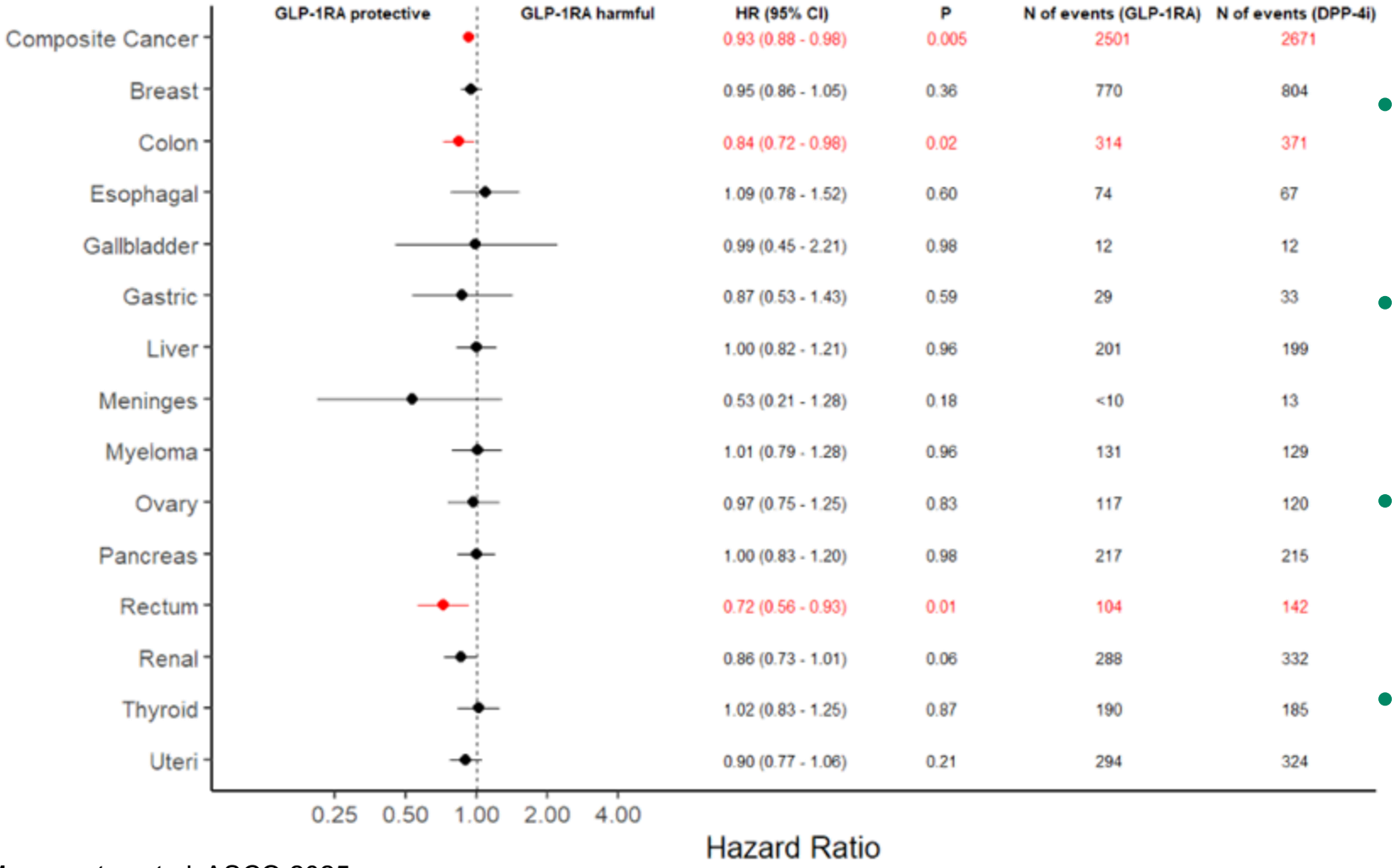
Ref.	Abstract #	First Author (et al.)	Population	Study / Database	Key Finding (GLP-1RA users vs non-users or comparator)
1	10520	McDonald	Women with obesity ± T2DM (no prior cancer)	US real-world database	Breast cancer incidence: HR 0.72 (95% CI, 0.61–0.86)
2	11016	Gotera	General population (T2DM ≥18 yrs)	US real-world database	Overall cancer incidence: HR 0.86 (95% CI, 0.81–0.91); Lower lung, colorectal, liver cancer incidence
3	3143	Orland	Metastatic cancer (lung, breast, colorectal, liver)	US real-world database	Lower risk of metastatic progression: Lung HR 0.69; Breast HR 0.67; Colorectal HR 0.62; Liver HR 0.63 (all 95% CI shown above)
4	11017	Sruti	Multiple cancers	Multiple real-world cohorts	Overall survival: HR 0.63 (95% CI, 0.59–0.68)
5	11018	Zelnick	CKD Stage 3 with T2DM	US claims database (propensity matched)	Overall cancer incidence: RR 0.90 (95% CI, 0.86–0.94); All-cause mortality: HR 0.57 (95% CI, 0.53–0.61)
6	3130	Chang	T2DM (no prior cancer)	US real-world database	GLP-1RA vs DPP-4i: HR 0.87 (0.81–0.94) for overall cancer
7	11019	Tarr	HR+/HER2– early-stage breast cancer on CDK4/6i	US real-world database	Invasive disease-free survival: HR 0.66 (95% CI, 0.48–0.90); Lower risk of recurrence/progression
8	11020	Johnson	Advanced solid tumors receiving immune checkpoint inhibitors	US real-world database	Overall survival: HR 0.71 (95% CI, 0.60–0.85); Higher response rate: 32% vs 24%

All studies presented at the 2026 ASCO Annual Meeting were retrospective observational analyses using real-world data. Results are hypothesis-generating and should not be interpreted as establishing causality.

ABBREVIATIONS: GLP-1RA, GLP-1 receptor agonist; T2DM, type 2 diabetes mellitus; CKD, chronic kidney disease; HR, hazard ratio; RR, risk ratio; CI, confidence interval; ICI, immune checkpoint inhibitor; HR+, hormone receptor positive; HER2–, HER2 negative.

Iyengar. ONCOLOGY 2026.

IN PATIENTS WITH TYPE 2 DIABETES, GLP-1RA USE WAS ASSOCIATED WITH 7% LOWER CANCER INCIDENCE VS DPP4I USE

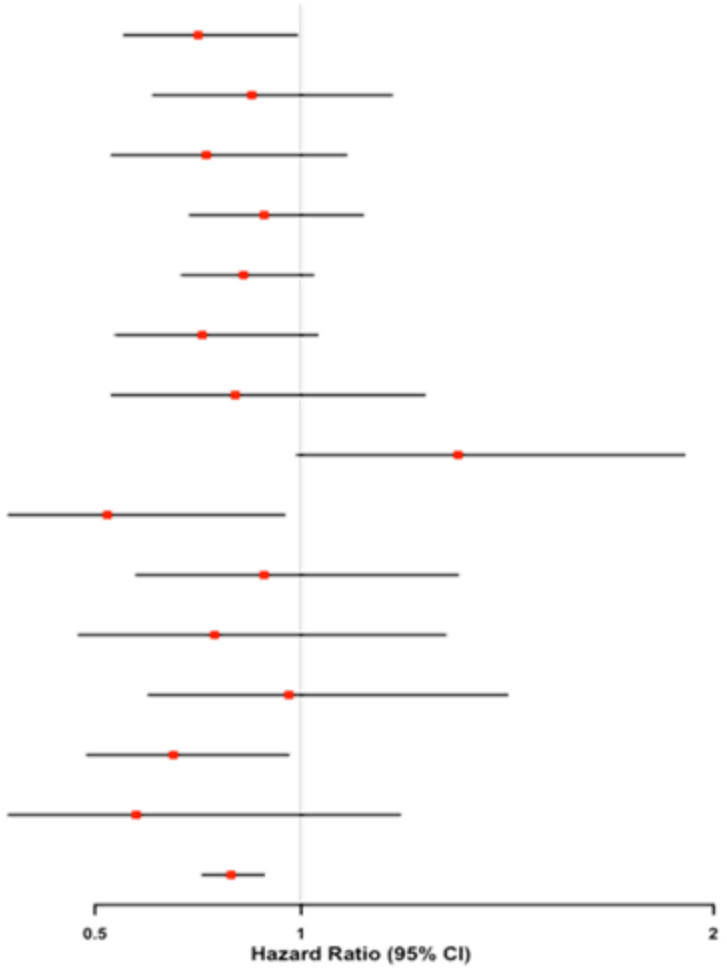


- 7% lower cancer incidence rate HR 0.93 (0.88–0.98)
- 8% lower all cause mortality rate HR 0.92 (0.87–0.97)
- Benefit driven by colorectal cancer risk reduction
- No signal for increase in specific cancers

Mavromatos et al. ASCO 2025.

IN PATIENTS WITH OR WITHOUT DIABETES, GLP1-RA USE WAS ASSOCIATED WITH 17% LOWER CANCER INCIDENCE

Outcome	GLP-1RA, n/N (IR)	non-GLP-1RA, n/N (IR)	Hazard ratio (95% CI)
Endometrial cancer	86/29379 (2.93)	115/29741 (3.87)	0.75 (0.57, 0.99)
Colorectal cancer	70/43317 (1.62)	76/43315 (1.75)	0.88 (0.64, 1.22)
Thyroid cancer	54/43317 (1.25)	67/43315 (1.55)	0.77 (0.54, 1.11)
Prostate cancer	151/13938 (10.91)	145/13561 (10.69)	0.91 (0.73, 1.15)
Breast cancer	200/29379 (6.81)	234/29741 (7.87)	0.86 (0.71, 1.03)
Lung cancer	70/43317 (1.62)	88/43315 (2.03)	0.76 (0.55, 1.04)
Pancreatic cancer	37/43317 (0.85)	42/43315 (0.97)	0.84 (0.54, 1.30)
Kidney cancer	83/43317 (1.92)	58/43315 (1.34)	1.38 (0.99, 1.93)
Ovaries cancer	17/29379 (0.58)	32/29741 (1.08)	0.53 (0.29, 0.96)
Liver cancer	44/43317 (1.02)	46/43315 (1.06)	0.91 (0.60, 1.38)
Multiple myeloma	24/43317 (0.55)	29/43315 (0.67)	0.79 (0.46, 1.35)
Bladder cancer	41/43317 (0.95)	40/43315 (0.92)	0.97 (0.63, 1.50)
Meningioma	55/43317 (1.27)	76/43315 (1.75)	0.69 (0.48, 0.97)
Upper gastrointestinal cancer	12/43317 (0.28)	19/43315 (0.44)	0.60 (0.29, 1.24)
Overall cancer	891/43317 (20.5)	1022/43315 (23.6)	0.83 (0.76, 0.91)



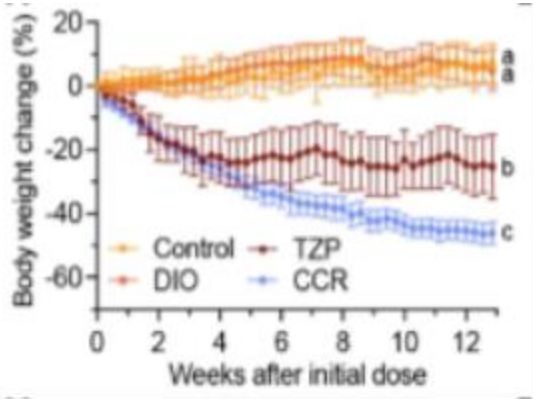
Dai et al. ASCO 2025.

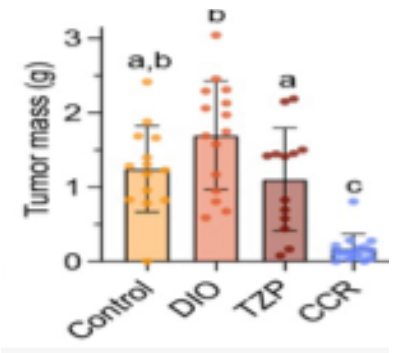
INCRETIN MIMETICS ATTENUATE TUMOR GROWTH: PRECLINICAL EVIDENCE

Tirzepatide attenuates mammary tumor progression in diet-induced obese mice

Elaine M. Glenny, Alyssa N. Ho, Violet A. Kiesel, Fangxin Chen, Claire E. Gates, Evan M. Paules, Ruihan Xu, C. Alex Holt, Michael F. Coleman, Stephen D. Hursting

doi: https://doi.org/10.1101/2024.01.20.576484





Analyte	Control	DIO	TZP	CCR
Adiponectin (µg/ml)	20.0 (7.5)†	23.1 (6.8)†	28.7 (13.4)†	95.0 (40.0)*#
Ghrelin (ng/ml)	15.5 (6.5)†	10.7 (3.0)†	16.2 (5.1)†	27.4 (12.1)*#
GIP (ng/ml)	1.9 (0.4)	1.8 (0.6)	2.0 (0.5)	2.0 (0.3)
GLP-1 (pg/ml)	124.2 (66.2)	108.8 (48.6)	100.8 (48.2)	130.2 (36.7)
Glucose (mg/dl)	127.6 (15.0)†	149.5 (18.5)*†	124.5 (15.5)	107.6 (18.8)#
Glucagon (pg/ml)	847.6 (279.7)	702.0 (185.3)†	696.3 (94.0)†	972.2 (252.7)#
IGF-1 (ng/ml)	30.5 (5.3)	53.8 (18.2)*††	49.0 (10.3)	36.5 (7.9)
Insulin (ng/ml)	2.6 (0.9)	4.5 (1.2)*††	2.6 (0.5)	3.1 (1.6)
Leptin (ng/ml)	0.6 (0.2)†	11.9 (4.4)*††	3.8 (2.5)*†	1.6 (1.2)
PAI-1 (ng/ml)	2.6 (1.4)††	1.7 (0.6)	1.1 (0.5)*	1.9 (0.4)#
Resistin (ng/ml)	89.8 (25.2)	65.5 (15.3)*†	69.0 (17.7)	90.0 (16.5)

Glenny et al. bioRXiv 2024.

INCRETIN MIMETICS IN POST-DIAGNOSIS SETTING

Shen et al:

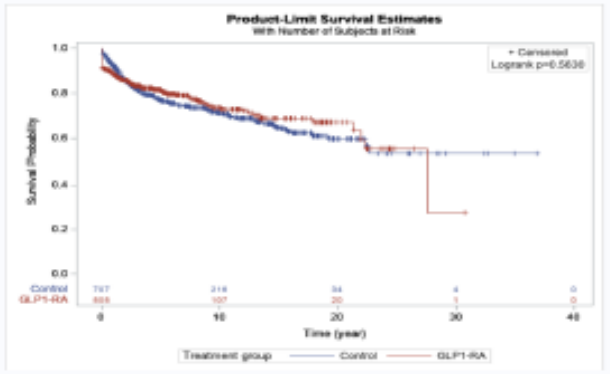
- Retrospective observational study at MSK
- N = 75 women with stage 0-4 breast cancer
- Median GLP-1a duration: 20 months (6 – 111)
- Mean weight change: -6.2 kg (95% CI -6.2 – -2.1)
- Mean relative weight change: -5% (SD 6%)

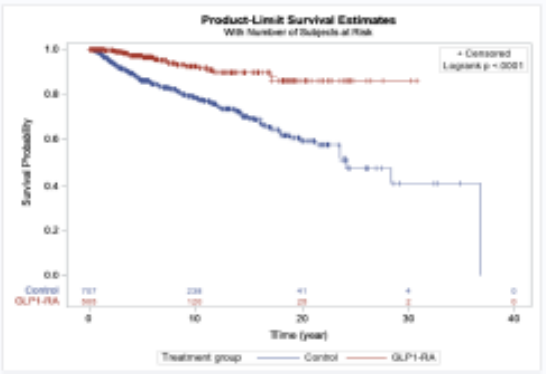
Variable		N	Odds ratio		p
BMI at GLP Start		46		0.95 (0.85, 1.05)	0.30
Race	White	22		Reference	
	Black Or African American	14		0.69 (0.13, 3.58)	0.66
	Asian, Other/No Response	10		0.10 (0.01, 0.90)	0.06
Ethnicity	Not Hispanic	40		Reference	
	Hispanic Or Latino	6		2.17 (0.24, 28.00)	0.50
Stage	0-1	13		Reference	
	2	19		0.92 (0.17, 5.24)	0.92
	3	10		2.45 (0.35, 21.11)	0.38
	4	4		10.20 (0.65, 360.22)	0.13
Receptors	HR-Positive	33		Reference	
	HER2-Positive	9		0.62 (0.09, 3.77)	0.61
	Triple-Negative	4		0.67 (0.02, 11.10)	0.78
Concurrent Endocrine Therapy	No	16		Reference	
	Yes	30		1.65 (0.31, 9.76)	0.56
Menopause	Post	41		Reference	
	Pre	5		0.54 (0.04, 6.04)	0.62

Shen et al. ONCOLOGY 2025.

Sukumar et al:

- Retrospective observational study at MDACC
- N = 1,022 patients with stage 0-3 breast cancer
- Median follow-up 4.7 years (0 – 30.9)
- 38.1% (n=389) received semaglutide or tirzepatide; Median weight loss:
  - 3 months: -2.1% (-13.2%-14.9%)
  - 6 months: -2.9% (-20.2%-19.0%)
  - 12 months: -3.1% (-27.8%-11.5%)
- Tamoxifen or AI use associated with weight gain (+2.3kg; p=0.037)
- DFS: Median 27.53 years (0-30.7) GLP-1RA vs not reached (0-36.08) control
- OS: Median not reached (0-30.7) GLP-1RA vs 24.1 years (0-36.8) control, p<0.0001

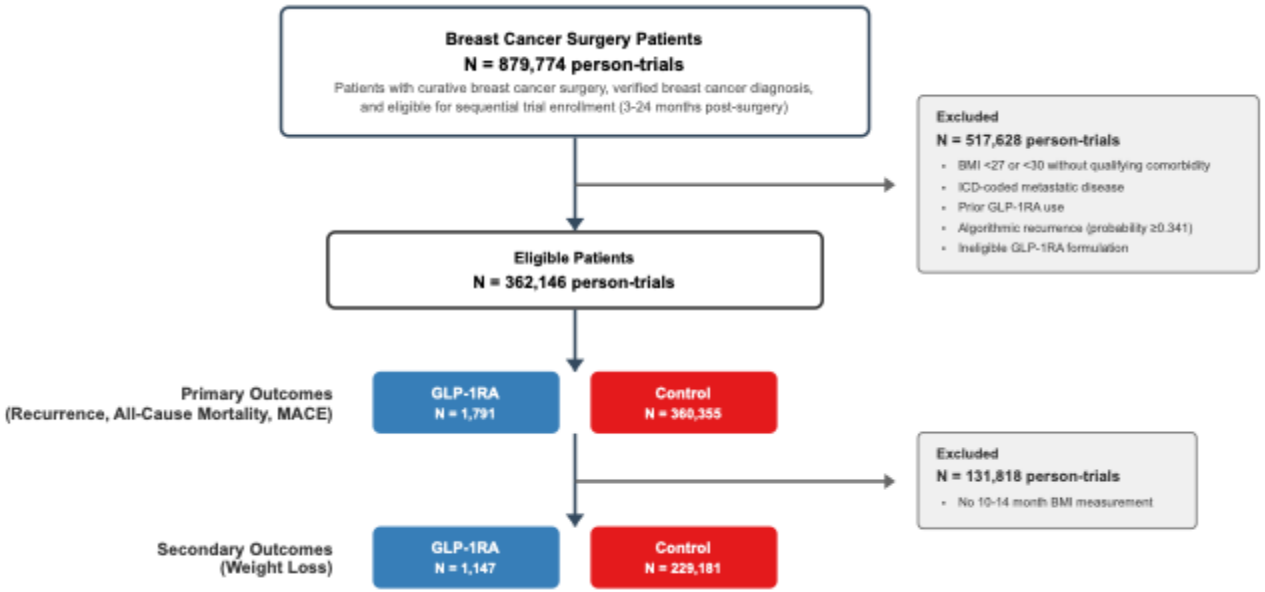


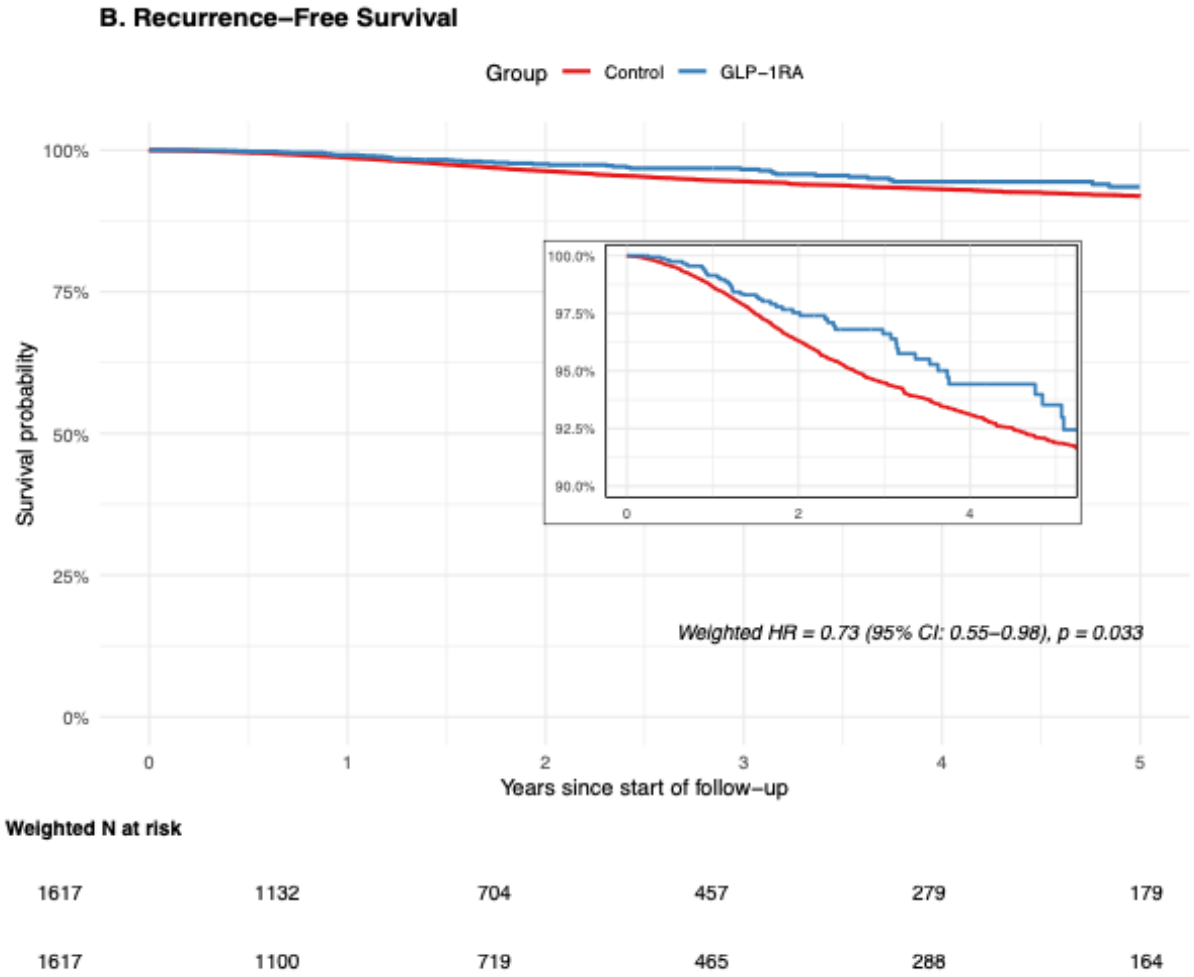


Sukumar et al. SABCS 2024

SAFETY AND EFFECTIVENESS OF GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS IN BREAST CANCER SURVIVORSHIP: A TARGET TRIAL EMULATION STUDY

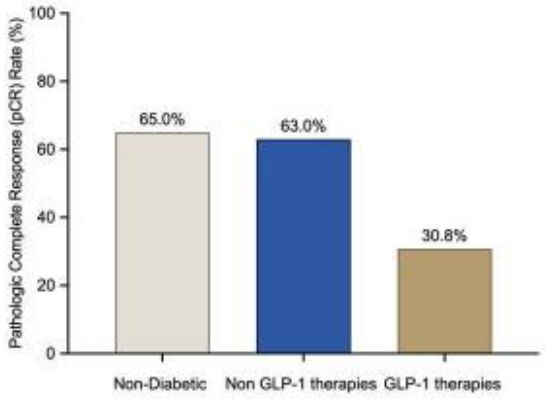
Lucas A. Mavromatis, ScB, Neil M. Iyengar, MD, Elizabeth Comen, MD, Jung-Im Shin, MD, PhD, Morgan E. Grams, MD, PhD

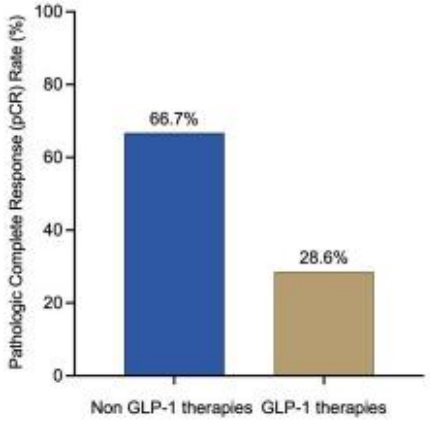


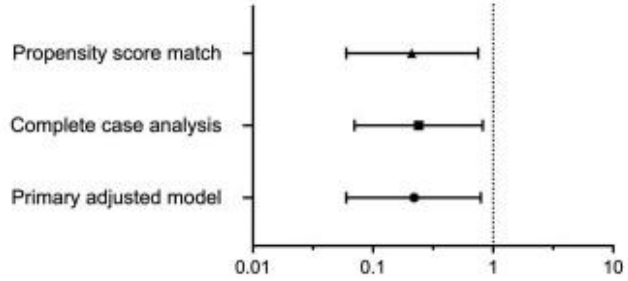


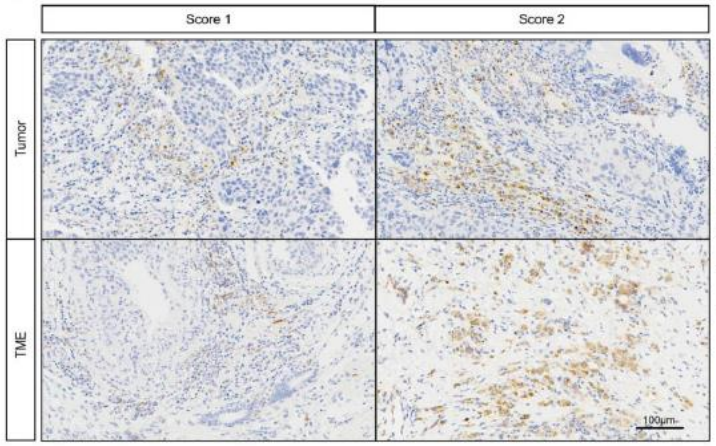
***Do not post**. Under review.*

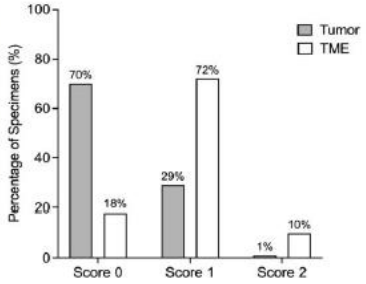
A NOTE OF CAUTION: GLP1-RA USE DURING NEOADJUVANT KEYNOTE522

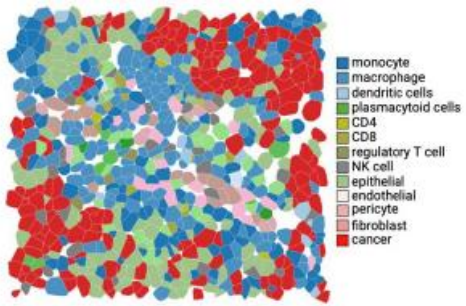


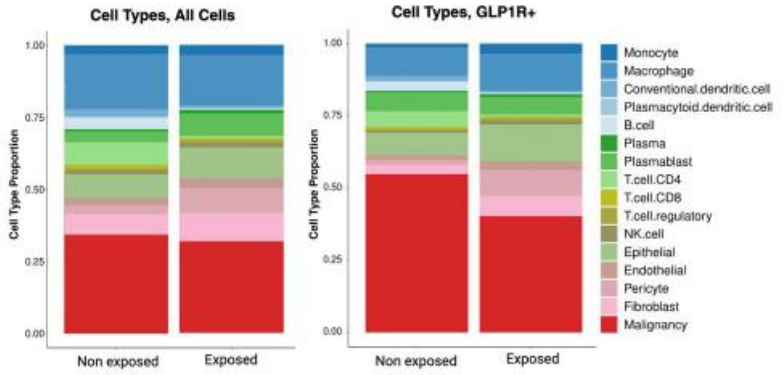






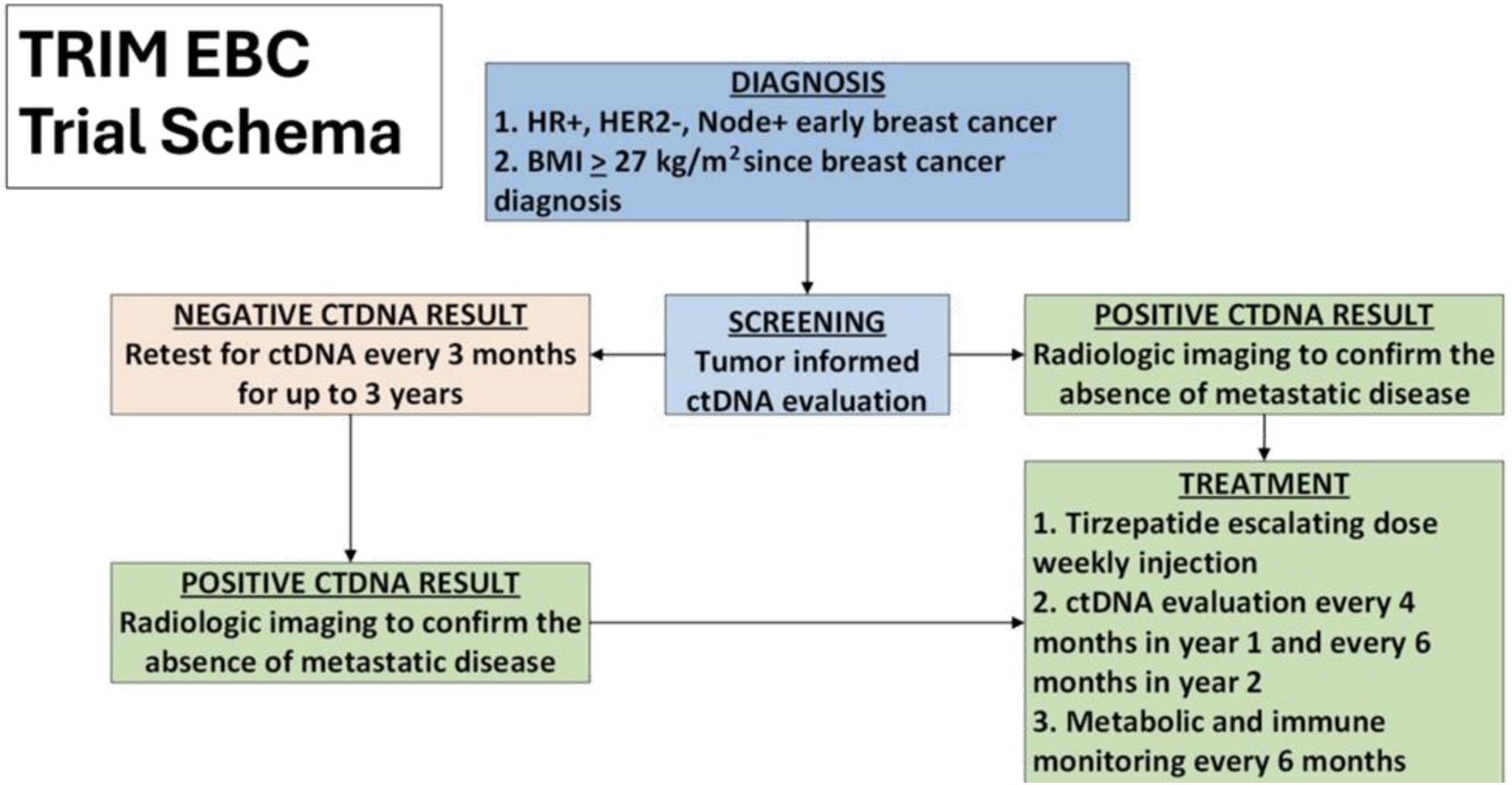






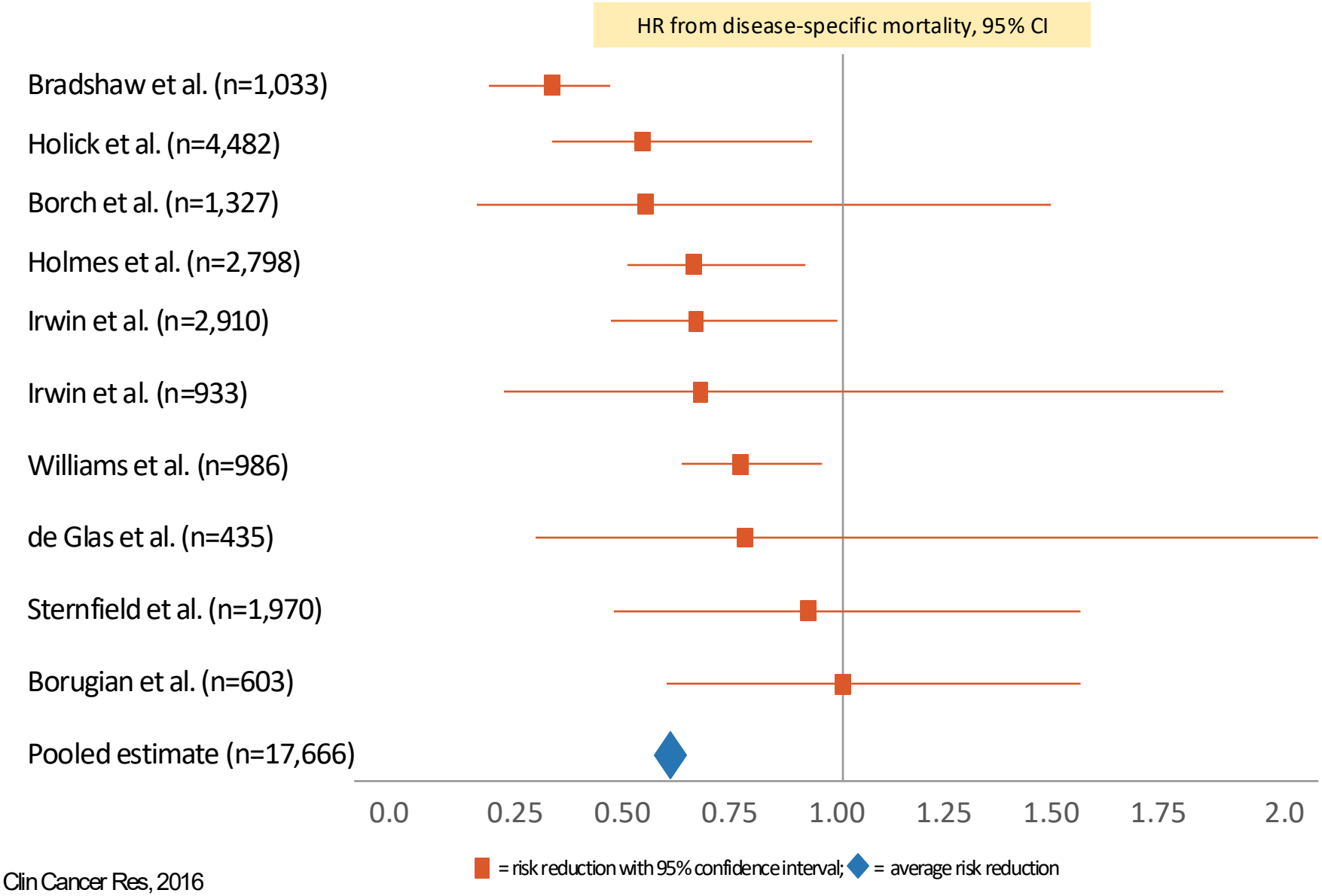
Santos B, *Marção* et al. Preprint. *Research Square.* 2026.

CLINICAL TRIAL - ADJUVANT



O'Shaughnessy et al.

EXERCISE AND BREAST CANCER MORTALITY



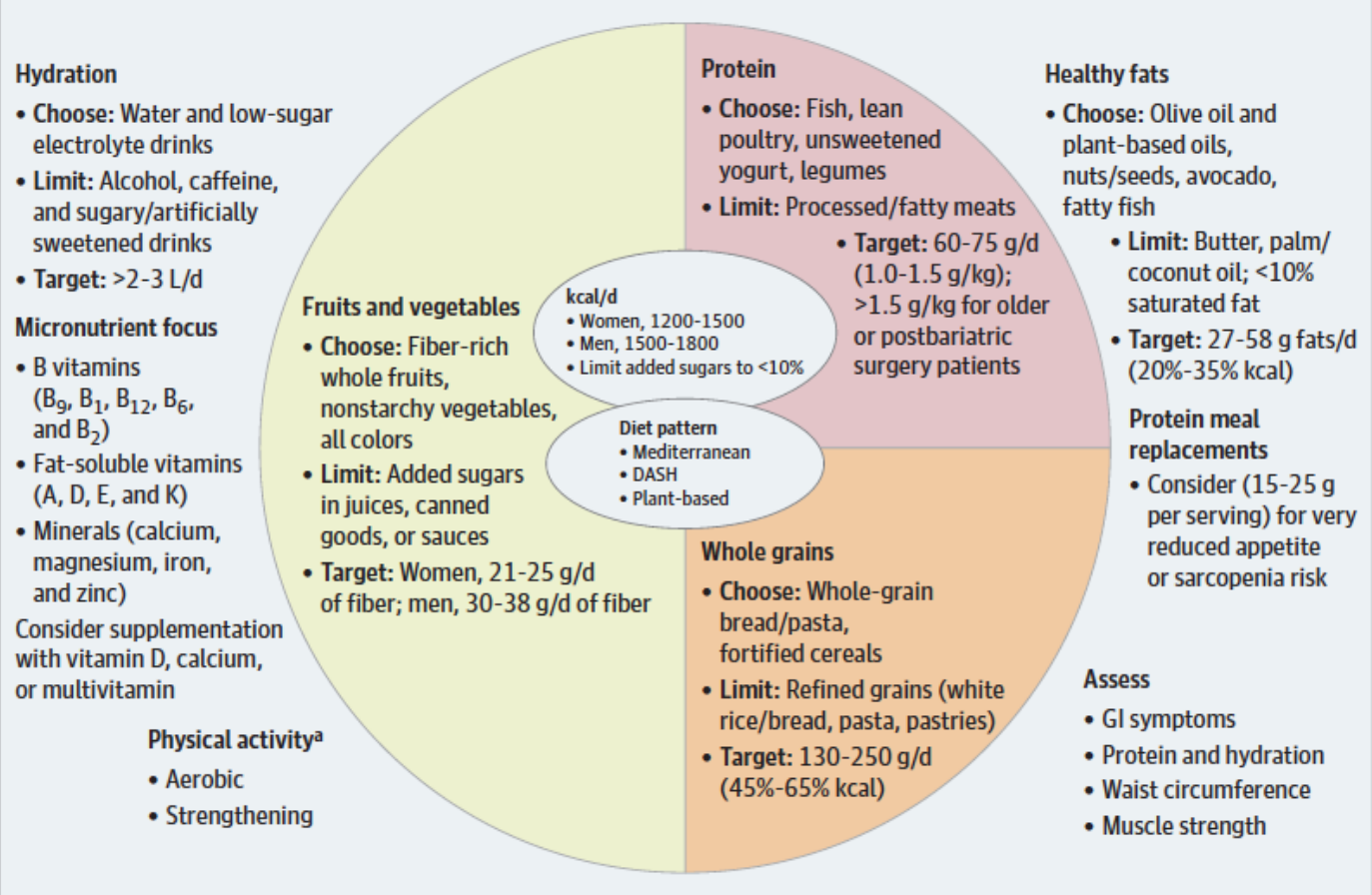
Friedenreich et al. Clin Cancer Res, 2016

Clinical Insights

Integrating Diet and Physical Activity When Prescribing GLP-1s—Lifestyle Factors Remain Crucial

Farhad Mehrtash, MPH; Jody Dushay, MD, MMSc; JoAnn E. Manson, MD, DrPH

JAMA Internal Medicine September 2025 Volume 185, Number 9



- **7-12% weight rebound** after GLP-1RA discontinuation
- Consider dose taper over at least **20 weeks**
- Increase dose or reinitiate if **>5% weight regain**

CASES - REVISTED

56yo postmenopausal woman with cT3N1M0 TNBC of R breast

- Planned to start neoadjuvant KEYNOTE522 regimen
- Co-morbidities: BMI 34, diabetes on metformin 1000 bid (Hb A1c 6.2%)

She was planning to start **tirzepatide** prior to TNBC diagnosis and asks if she could start with her breast cancer treatment.

42yo premenopausal woman with pT1cN0M0 HR+/HER2-neg IDC of L breast

- s/p lumpectomy + XRT, OncotypeDX RS 18
- planned to start adjuvant OS + AI
- Co-morbidities: BMI 29 on semaglutide (prior BMI 33)

She asks if she could continue **semaglutide** with adjuvant endocrine therapy.

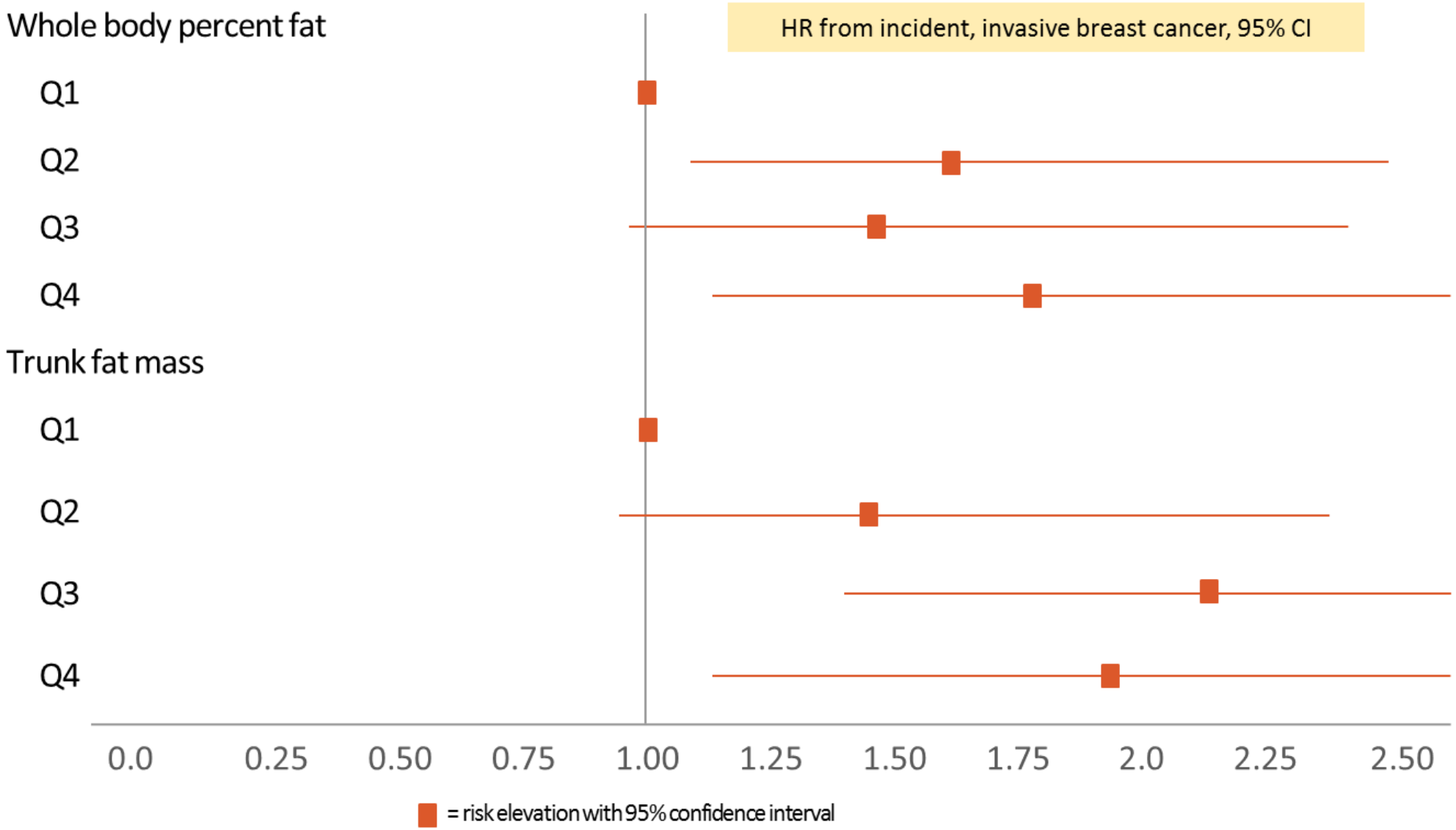
UPCOMING ESMO GUIDELINES STATEMENT

DRAFT STATEMENT:

- GLP-1 RAs may be considered for weight-loss in patients who have completed cancer therapy and may be considered with caution for patients on stable endocrine-based cancer therapies based on limited observational safety data.

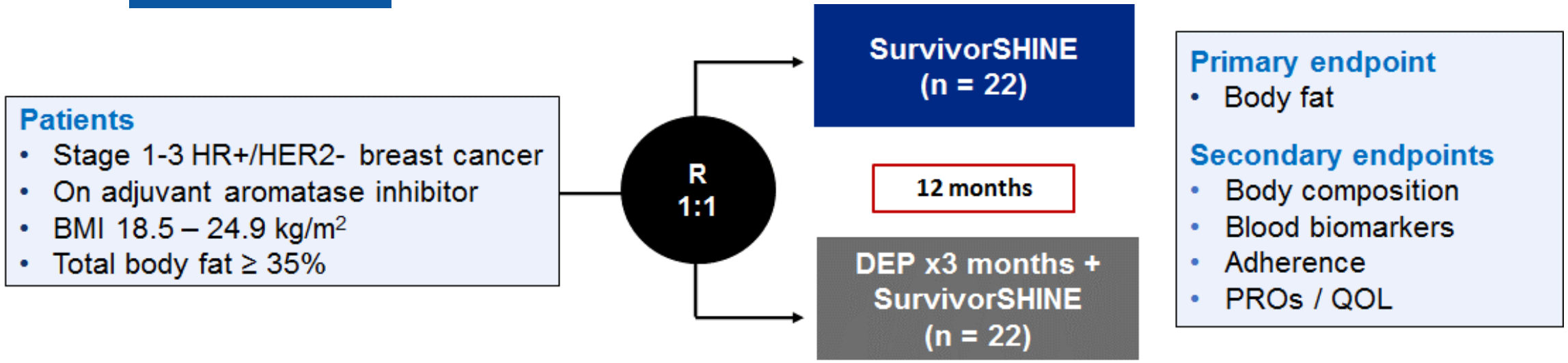
- GLP-1 RAs cannot be recommended currently for patients receiving or initiating chemotherapies and/or immunotherapies due to lack of safety and outcomes data.

Normal Weight Hyperadiposity and Postmenopausal Breast Cancer Risk



Iyengar et al., JAMA Oncol 2018

PHASE 2 RCT IN NORMAL WEIGHT OBESITY AND BREAST CANCER



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Neil M. Iyengar, MD
Co-Director, Breast Oncology Program
Director, Cancer Survivorship Services
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