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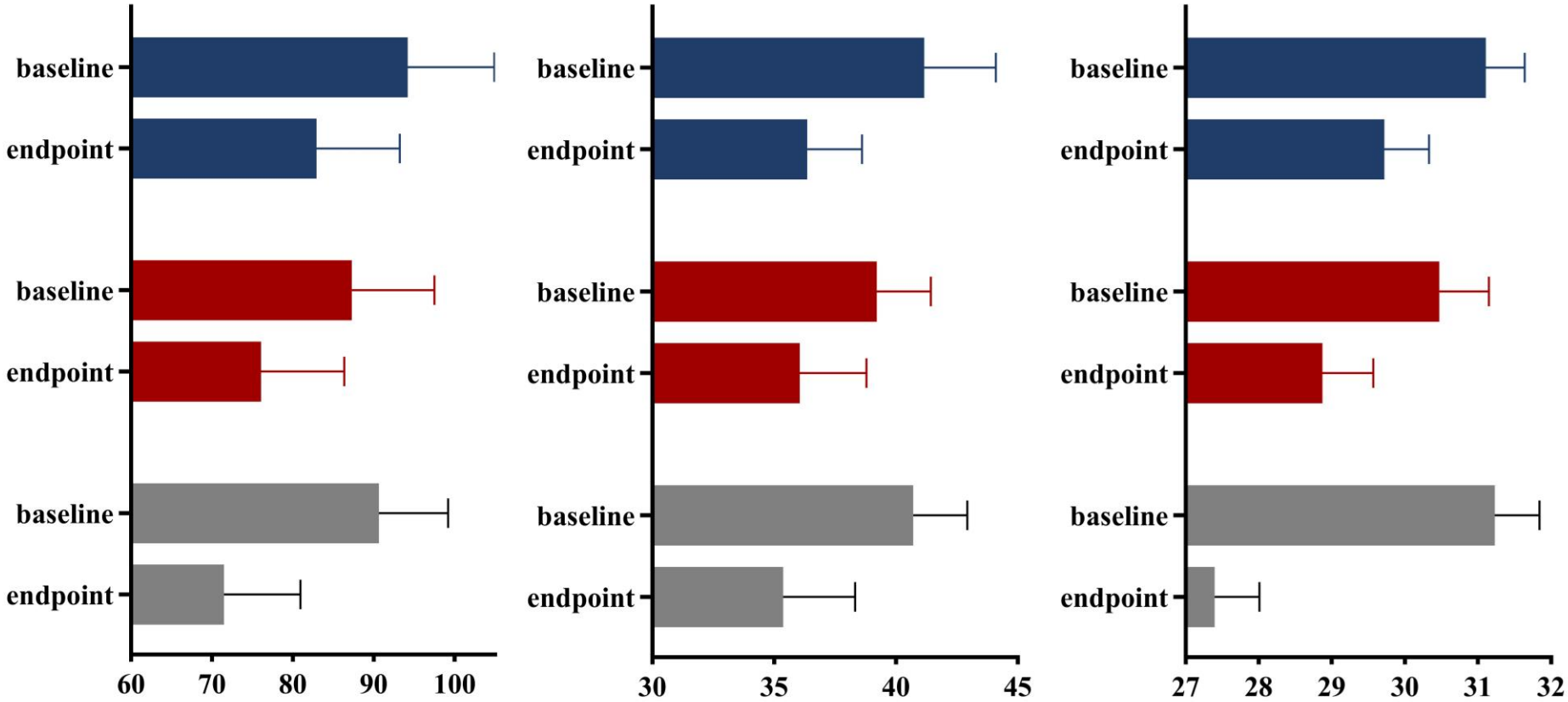
Effects of different dietary interventions on weight loss

High protein diet

Calorie restrict diet

5+2 intermittent fasting



Ma Y, Sun L, Mu Z. Effects of different weight loss dietary interventions on body mass index and glucose and lipid metabolism in obese patients. Medicine (Baltimore). 2023;102(13):e33254.

Study Purpose

To explore The efficacy of plant-based diets combined with calorie restriction on weight management

Study design

Screening Phase

Recruitment
Signed Informed Consent
Baseline Assessment
1:1Randomization

-2 WEEK

0 WEEK

End-of-Study Phase

Compliance Assessment
Final Examinations

- Anthropometric Measurements
- Biochemical Assessments

12 WEEK

14 WEEK

Intervention Phase

Intervention Group

Plant-Based Diet following 5+2 Pattern

Control Group

No specific meal provision Caloric Restriction only, throughout the 12-week period

Duration

12-Week Intervention Period

Ethics & Registration

Ethics Committee: Shanghai Tenth People's Hospital Ethics Committee **(SHYS-IEC-5.0/22K268/P01)**

Clinical Trial Registry: Chinese Clinical Trial Registry **(ChiCTR2400081330)**

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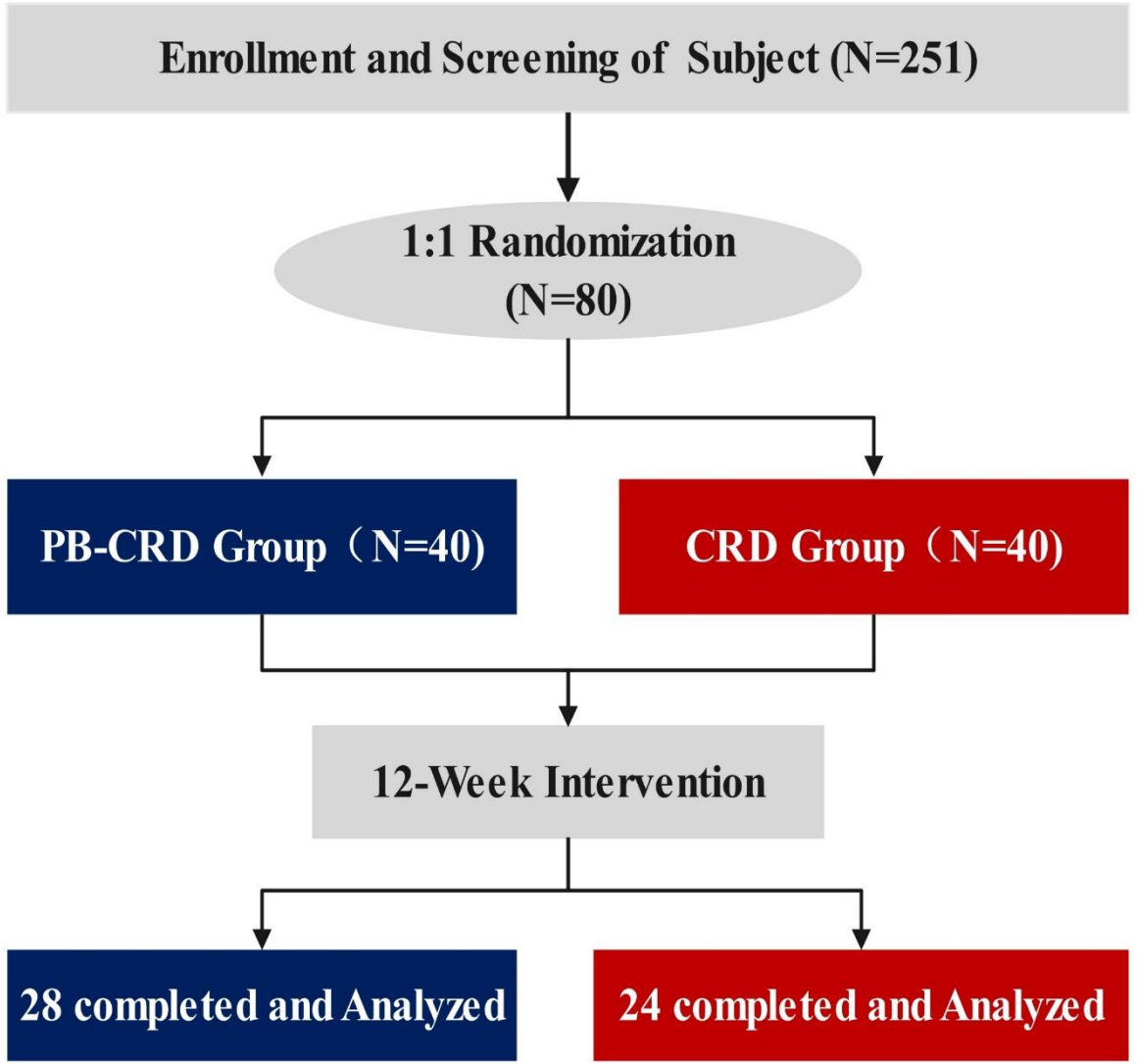
Participant inclusion process

Inclusion Criteria

- Age: 18-45 years
- Gender: Male or Premenopausal Female
- - BMI: 28-40 kg/m²

Exclusion Criteria

- Recent Weight Loss: <3 months
- Weight Meds: <3 months
- Diabetes/Thyroid Issues
- -Antibiotics/Probiotics: <1 month
- Irregular Lifestyle



Recruitment Location

•**Hospital**: Shanghai Tenth People's Hospital

•**Department**: Endocrinology and Metabolis

Intervention methods

Plant-Based Caloric Restriction Diets(PB-CRD)

5 days

+

♂ 1600 kcal

♀ 1300 kcal

kcal

2 days

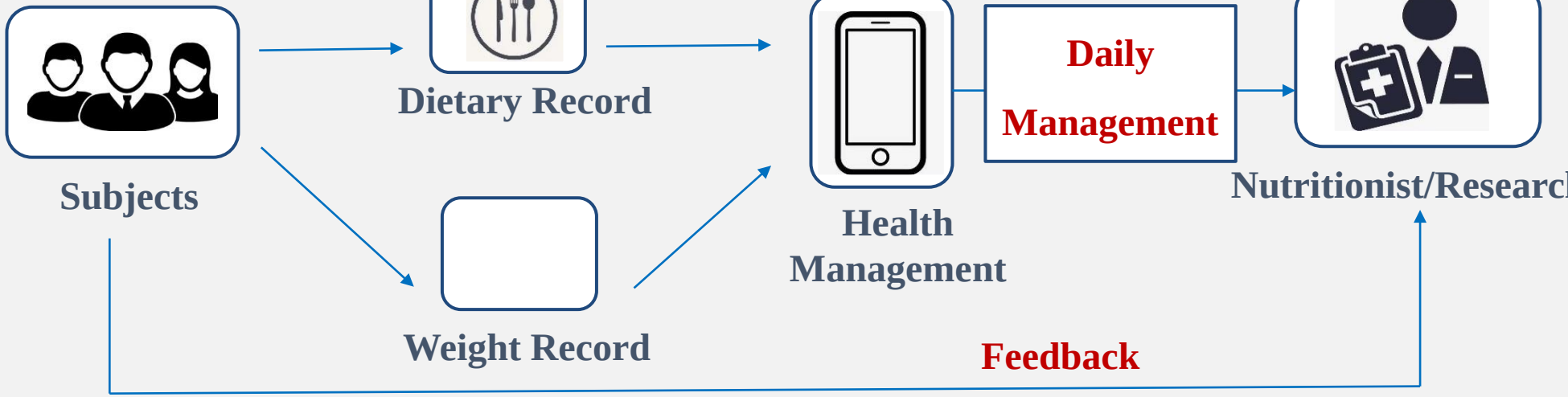
Calorie-Restricted Diet(CRD)

7 days

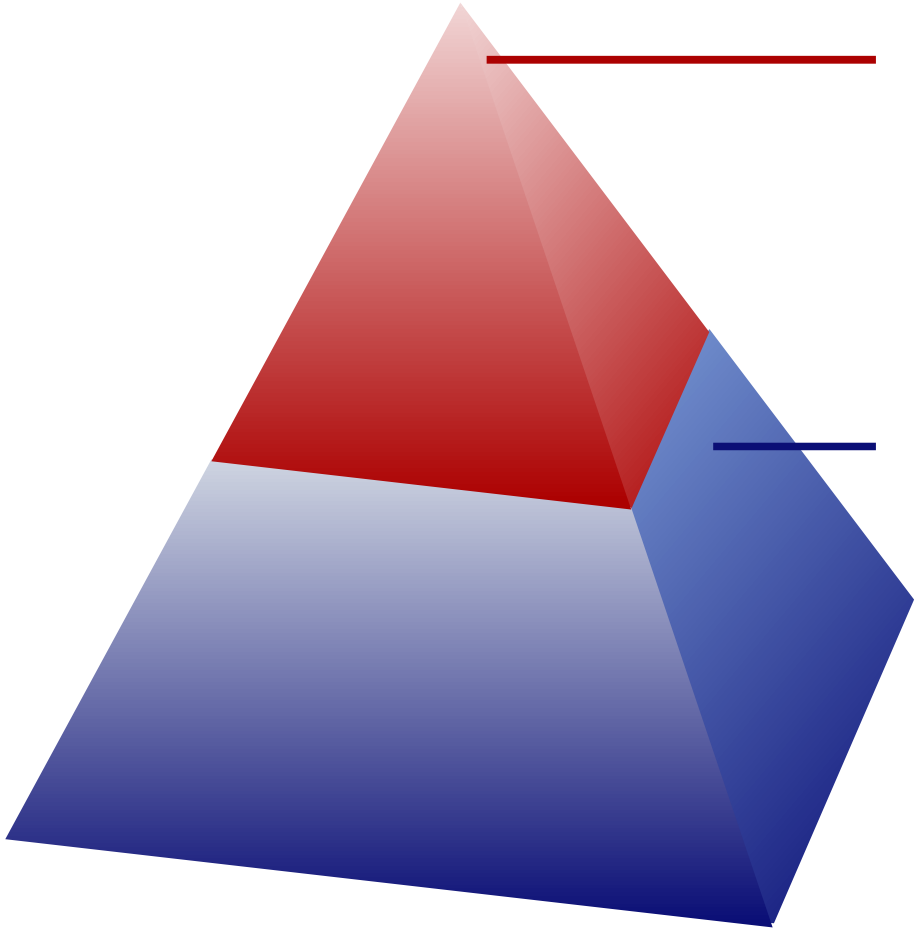
♂ 1600 kcal

♀ 1300 kcal

kcal



Study Endpoints



01 **Primary Endpoint**

Body Weight Changes over 12 Weeks

02 **Secondary Endpoint**

- Fat Distribution Changes over 12 Weeks
- Metabolic Indicators Changes over 12 Weeks
- Liver Steatosis Improvement over 12 Weeks
- Inflammatory Markers Changes over 12 Weeks

Statistical analysis

underwent an 8-week preliminary experiment to assess weight change.

Based on the preliminary experiment results, predict the weight change of both groups over 12 weeks.

Estimate the sample size

Non-inferiority test
Power：0.90 Alpha：0.05
Non - inferiority Margin: 0.5
D(true difference):2
S1=2.5 S2=4

expected number： 80

Randomization

Type: Simple Randomization
Purpose: To eliminate confounding factors
Steps:①Use SPSS to make random numbers.
②Order the numbers from smallest to largest.
③Put the numbers into groups needed for the study.

Allocation Concealment

Purpose: To avoid selection bias.
Details: During diagnosis, eligibility check, patient recruitment, and random allocation, neither the patients, doctors, nor the staff know the random sequence or the groups they correspond to.

Blinding

Type: Open-label trial
Purpose: To reduce bias caused by subjective factors
Details: Subjects are trained before the intervention begins and fully understand the intervention they will receive.

Statistic methods

A **Baseline Comparison**
ITT analysis

B **Pre- and Post-Intervention Comparison**

C **Post-Intervention Difference**

D **Difference Comparison**

EpiData 3.1
PASS 2022
IBM SPSS Statistics 23
GraphPad Prism 9

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Baseline characteristics

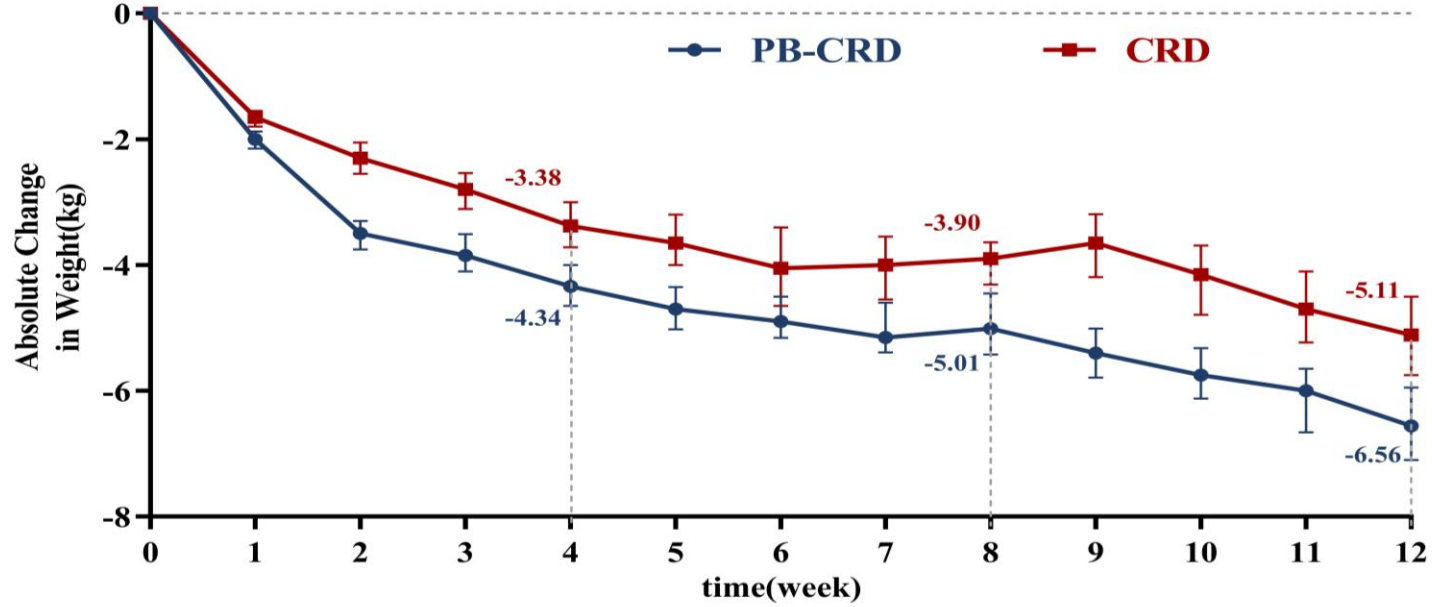
Demographic Characteristics	Total（N=80）	PB-CRD（N=40）	CRD（N=40）	P value
Gender (Male/%)	31/38.8	19/47.5	12/30.0	0.108
Age (Years)	34.78±7.12	35.38±8.01	34.17±6.14	0.454
BMI（kg/m^2）	32.03±3.46	31.91±3.38	32.15±3.58	0.753
Waist Circumference (cm)	100.06±11.64	100.31±10.99	99.81±12.40	0.849
Waist-to-Hip Ratio	0.91±0.08	0.92±0.07	0.90±0.08	0.213
Systolic Blood Pressure (mmHg)	135.08±15.21	134.50±13.96	135.68±16.58	0.740
Diastolic Blood Pressure (mmHg)	88.32±10.70	87.63±11.01	89.03±10.48	0.576
Heart Rate (Beats/Minute)	85.00±6.24	83.61±7.45	86.47±4.25	0.052
Total Body Fat Percentage (%)	42.46±5.29	41.49±4.88	43.48±5.57	0.101
CAP Value（db/m）	342.32±44.12	344.72±40.79	341.92±47.76	0.789
SF-36 Physical Health	48.87±4.98	49.41±4.09	48.30±5.77	0.884
SF-36 Mental Health	47.74±6.62	48.26±6.56	47.19±6.71	0.356
IWQOL-lite CT Score	123.87±22.20	128.08±16.11	119.55±26.60	0.182
Sleep Disturbance Score	8.25±3.84	8.31±3.25	8.19±4.41	0.545
PHQ-9	5.76±4.69	4.64±3.04	6.89±5.75	0.114
BECK Depression Inventory	4(2-7)	4(1.25-5.75)	6(2-8.75)	0.057
Scoring Criteria（N/%）				0.087
No Depression (0-4)	42/52.5	24/60.0	18/45.0	
Mild Depression (5-7)	19/23.8	11/27.5	8/20.0	
Moderate Depression(8-15)	16/20.0	5/12.5	11/27.5	
Severe Depression (≥16)	3/3.8	0/0.0	3/7.5	

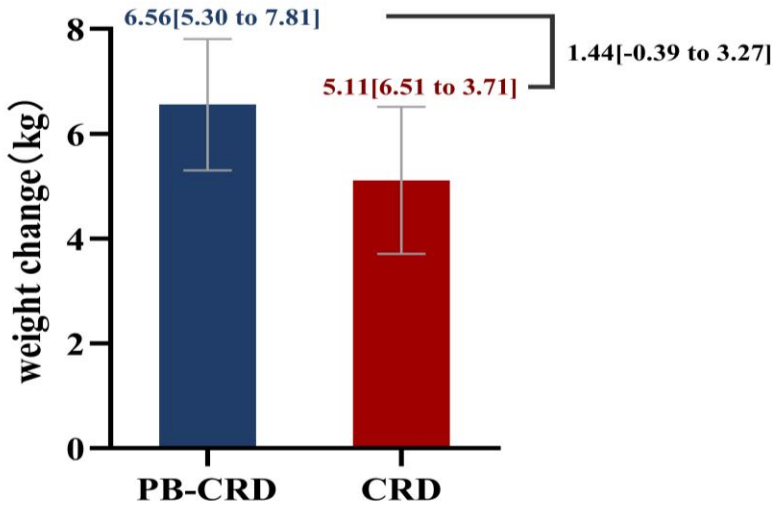
Baseline characteristics

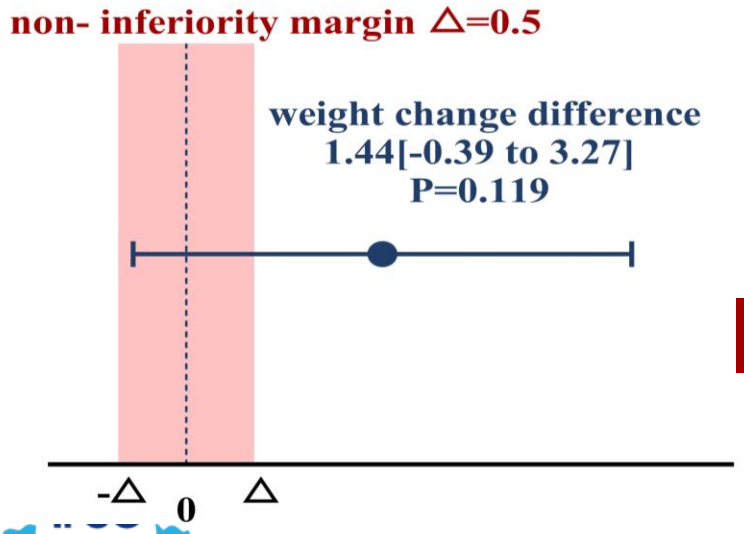
	Total（N=80）	PB-CRD（N=40）	CRD（N=40）	P value
FT3（pmol/L）	5.49±0.62	5.59±0.54	5.39±0.68	0.389
FT4（pmol/L）	16.01±1.97	16.35±1.68	15.65±2.21	0.148
TSH（mU/L）	2.74±1.25	2.59±1.09	2.91±1.40	0.314
hbA1c（%）	5.51±0.37	5.48±0.36	5.5±0.37	0.308
FBG（mmol/l）	4.92±0.48	4.95±0.53	4.88±0.430	0.532
2hBG（mmol/l）	6.89±1.62	6.85±1.34	6.94±1.87	0.471
ALB（g/L）	45.17±2.72	45.52±2.50	44.78±2.93	0.271
ALT（U/L）	31.70(20.20-55.35)	36.70(20.93-67.05)	26.40(19.30-52.25)	0.464
AST（U/L）	21.00(16.80-31.80)	21.65(18.43-34.75)	19.50(16.20-30.05)	0.222
GGT（U/L）	30.65(20.65-56.18)	28.00(21.40-39.90)	31.60(19.70-66.70)	0.581
ALP（U/L）	67.23±18.46	66.25±21.07	68.35±15.15	0.222
Cr（umol/l）	67.20±16.72	68.06±17.15	66.48±16.41	0.573
UA（umol/L）	412.98±109.47	427.66±115.27	395.72±101.18	0.214
TC（mmol/L）	5.01±0.92	5.04±0.86	4.98±1.00	0.932
TG（mmol/L）	1.65±1.01	1.59±0.89	1.72±1.15	0.907
HDL（mmol/L）	1.09±0.22	1.08±0.23	1.10±0.22	0.739
LDL（mmol/L）	3.17±0.80	3.24±0.74	3.10±0.88	0.698
TNF	20.30(11.25-37.95)	19.30(9.03-42.50)	22.35(14.85-30.83)	0.947
IL-6	2.40(2.00-3.62)	2.00(2.00-3.52)	2.00(2.00-3.47)	0.397
IL-8	65.17±82.50	77.78±101.96	52.56±55.65	0.619

The baseline characteristics between the two groups are balanced and comparable

Primary endpoint： Weight Change





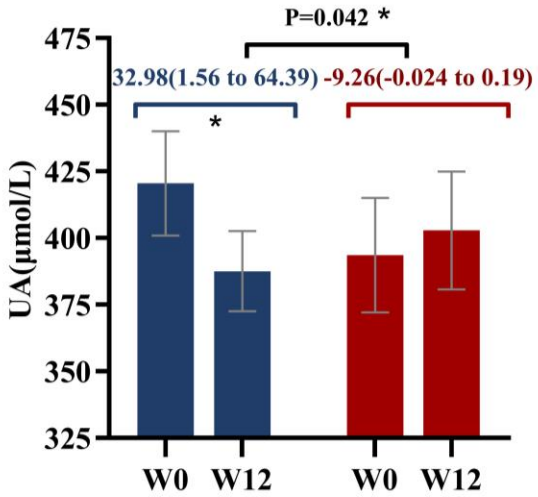


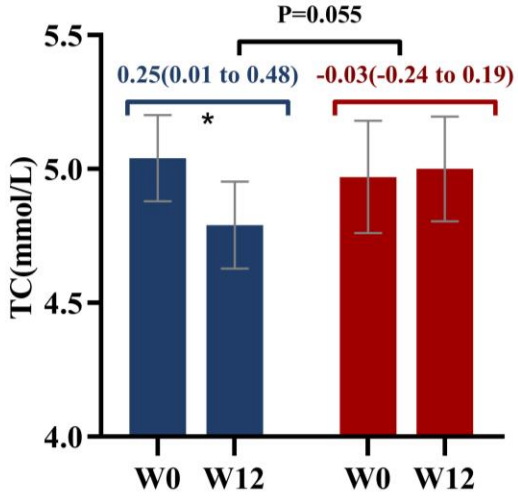
Difference > -△ ， non-inferiority

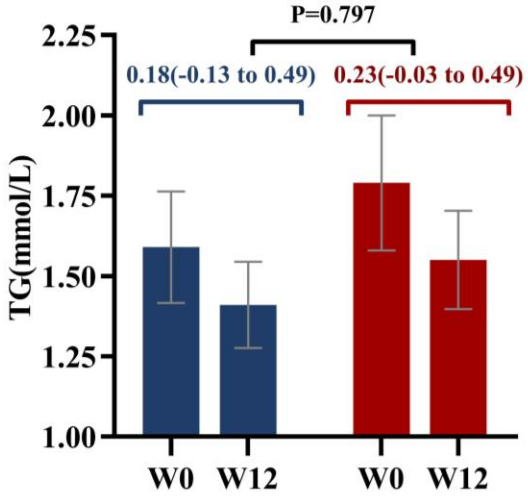
Secondary endpoint： Fat Distribution

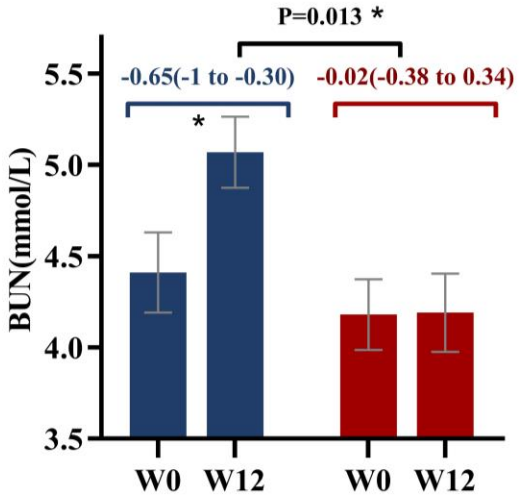
	PB-CRD group（N=28）		CRD group（N=24）		Difference Between Groups		
Index	**Baseline**	**Endpoint**	**Baseline**	**Endpoint**	**PB-CRD Difference (95% CI)**	**CRD Difference (95% CI)**	**P value**
Inbody Body Composition Analysis							
Body Fat Mass(Kg)	32.32±6.08	28.86±7.12	36.75±8.57	32.93±8.65	3.46(1.58-5.34)	3.83（2.48-5.17）	0.741
Visceral Fat Area	151.49±35.04	133.57±38.80	173.51±40.62	156.54±42.85	17.92(8.75-27.09	16.98（9.82-24.13）	0.866
Skeletal Muscle Mass(Kg)	30.94±1.48	30.48±1.33	30.86±7.34	30.03±6.86	0.46(-0.12-1.04)	0.83（-0.53-2.19）	0.587
Inbody Score	66.12±6.85	68.71±6.28	62.69±11.42	66.44±10.77	-2.56(-4.66-5.15)	-3.75（-5.53-1.97）	0.376
DEXA Fat Content Measurement							
Total Body Fat Percentage (%)	**40.79±5.06**	**37.82±5.61**	**43.09±6.30**	**42.28±6.83**	**2.96（1.67-4.25）**	**0.81（-0.68-2.30）**	**0.028**
Fat Mass Index(kg/m²)	12.66±2.24	11.15±2.48	13.71±2.62	12.66±2.50	1.51（0.97-2.05）	1.05（0.51-1.59）	0.217
A/G Fat Ratio	1.19±0.17	1.16±0.15	1.15±0.17	1.09±0.13	0.02（-0.02-0.07）	0.05（0.01-0.10）	0.324
Trunk/Lower Extremity Fat Ratio	1.13±0.13	1.08±0.15	1.09±0.17	1.05±0.13	0.04（0.01-0.07）	0.04（0.01-0.06）	0.884
Trunk/Quadrants Fat Ratio	1.22±0.18	1.17±0.18	1.13±0.18	1.12±0.19	0.05（-0.02-0.12）	0.01（-0.04-0.05）	0.296
Lean Body Mass Index (kg/m²)	17.23±1.93	17.09±1.79	17.00±2.33	16.12±2.34	0.14（-2.08-0.52）	0.89（0.14-1.63）	0.060
Estimated Visceral Fat Mass(g)	**854.45±145.83**	**731.65±145.36**	882.06±169.27	805.22±240.87	**122.80（53.91-191.69）**	76.83（-11.06-164.73）	0.388
Estimated Visceral Fat Volume(cm³)	**923.75±157.10**	**790.95±157.10**	953.61±183.17	870.50±260.62	**132.80（58.44-207.16）**	83.11（-11.99-178.22）	0.388
Estimated Visceral Fat Area (cm²)	**177.20±30.26**	**151.81±30.13**	182.89±35.14	167.11±50.02	**25.40（11.14-39.66）**	15.78（-2.43-33.98）	0.383
Fat-Free Mass Index (Kg/m²)	7.56±0.94	7.43±0.93	7.84±1.93	7.00±1.46	0.13（-0.14-0.40）	0.83（-0.09-1.77）	0.841

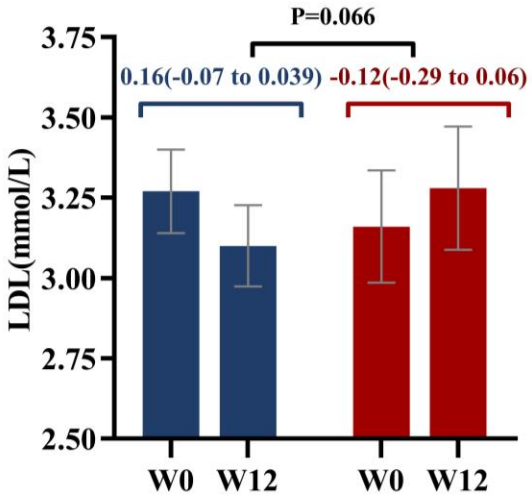
Secondary endpoint： Metabolic Indicators

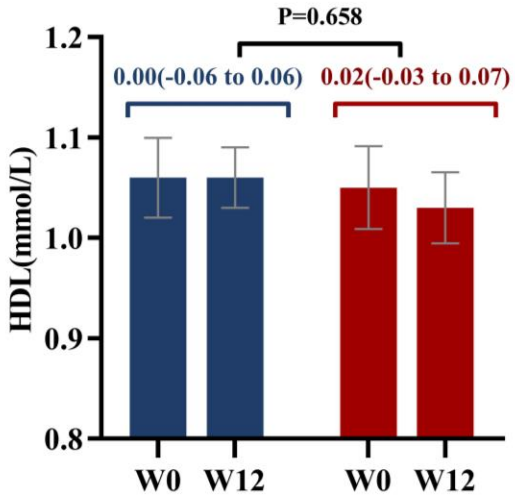












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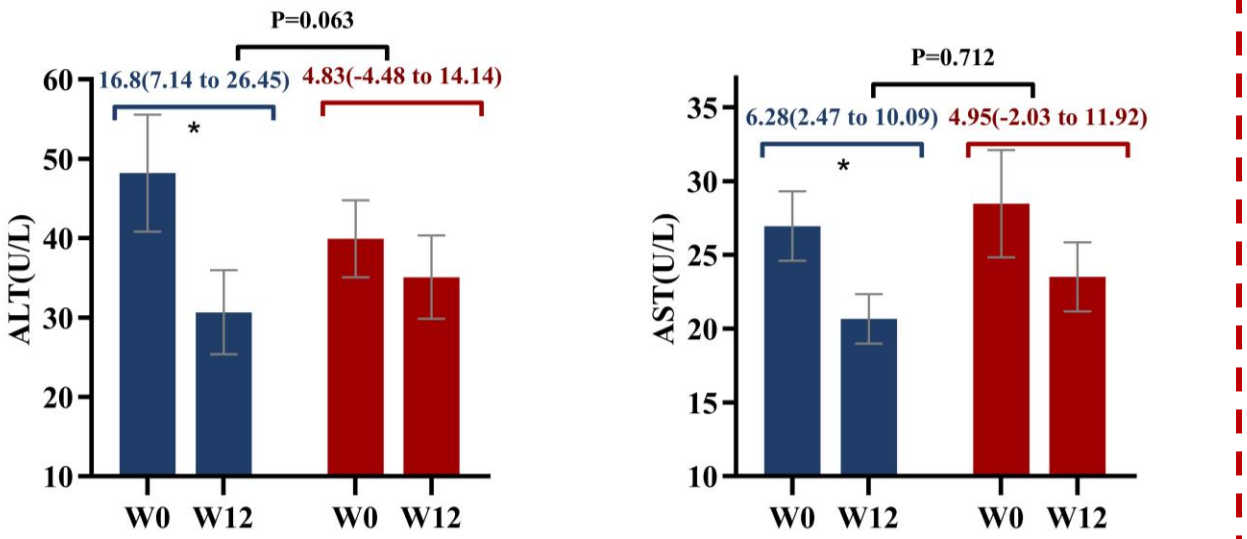
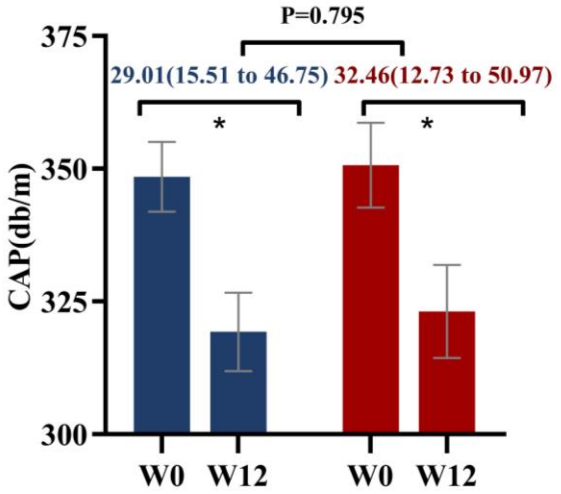
Secondary endpoint： Metabolic Indicators

	PB-CRD group（N=28）		CRD group（N=24）		Difference Between Groups		
Index	Baseline	Endpoint	Baseline	Endpoint	PB-CRD Difference (95% CI)	CRD Difference (95% CI)	P value
HbA1c（%）	5.47±0.38	5.4±0.33	5.52±0.35	5.43±0.27	0.06(-0.04-0.17)	0.09(-0.01-0.18)	0.720
FBG（mmol/l）	4.95±0.51	4.92±0.54	4.85±0.47	4.84±0.63	0.04(-0.23-0.31)	0.01(-0.2-0.23)	0.882
0.5hBG（mmol/l）	9.00±1.78	8.16±1.43	8.66±1.54	8.00±1.46	0.84(0.34-1.34)	0.66(-0.02-1.34)	0.649
1hBG（mmol/l）	8.77±2.31	8.22±2.24	8.78±2.76	8.53±2.03	0.55(-0.06-1.15)	0.24(-0.54-1.03)	0.520
2hBG（mmol/l）							
3hBG（mmol/l）	4.80(3.80-5.50)	3.90(4.30-5.15)	4.74±0.96	5.42±1.21	0.30(-0.17-0.77)	-0.68(-1.2--0.16)	0.006
FINS（mU/L）	19.56(13.43-25.03)	14.55(10.18-25.69)	19.64±9.01	21.7±9.99	-4.92(-21.45-11.6)	2.06(-4.94-0.83)	0.431
0.5hINS（mU/L）	114.90(67.30-146.60)	83.62(49.53-162.60)	130.31±73.07	102.24±50.13	7.01(-11.13-25.16)	28.08(-6.16-62.31)	0.242
1hINS（mU/L）	109.90(55.10-163.50)	94.00(55.23-154.63)	126.80(68.21-194.10)	108.80(73.16-177.20)	16.01(-12.78-44.8)	-13.71(-51.32-23.89)	0.192
2hINS（mU/L）	73.17(49.38-146.80)	52.90(32.69-89.64)	80.83(57.07-151.50)	86.97(49.37-139.10)	22.19(-1.13-45.5)	24.96(-22.65-72.57)	0.909
3hINS（mU/L）	15.02(8.80-33.19)	14.78(8.91-23.37)	17.58(12.65-38.94)	21.87(18.62-54.87)	6.69(-5.84-19.21)	-6.3(-19.53-6.93)	0.146

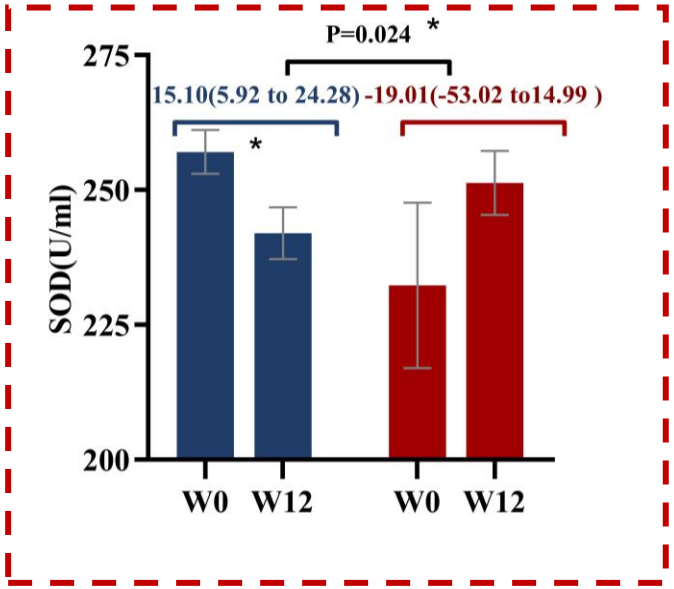
Secondary endpoint: Liver Function and Liver Steatosis

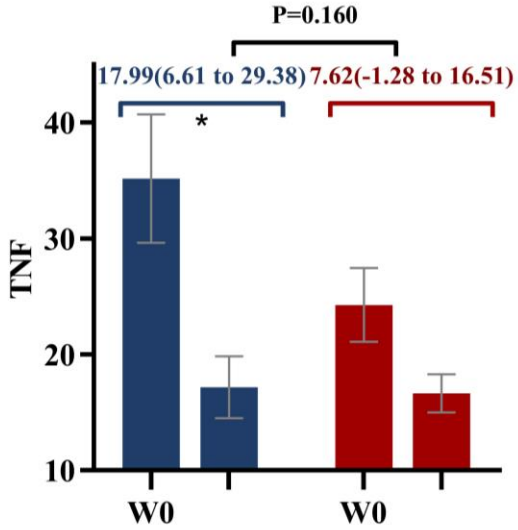


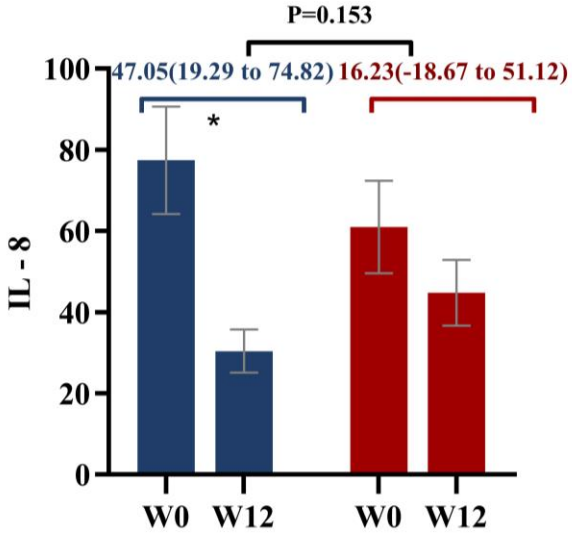


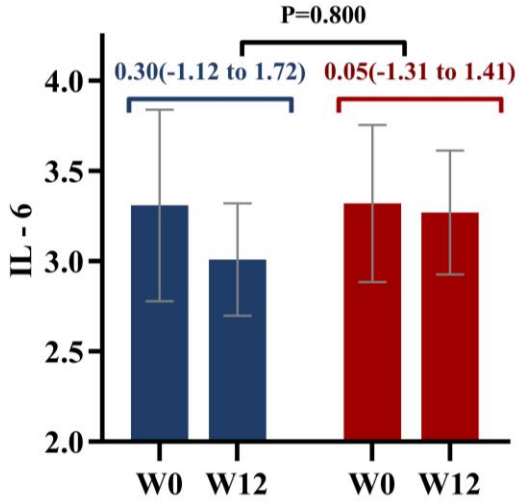
Fibro Scane

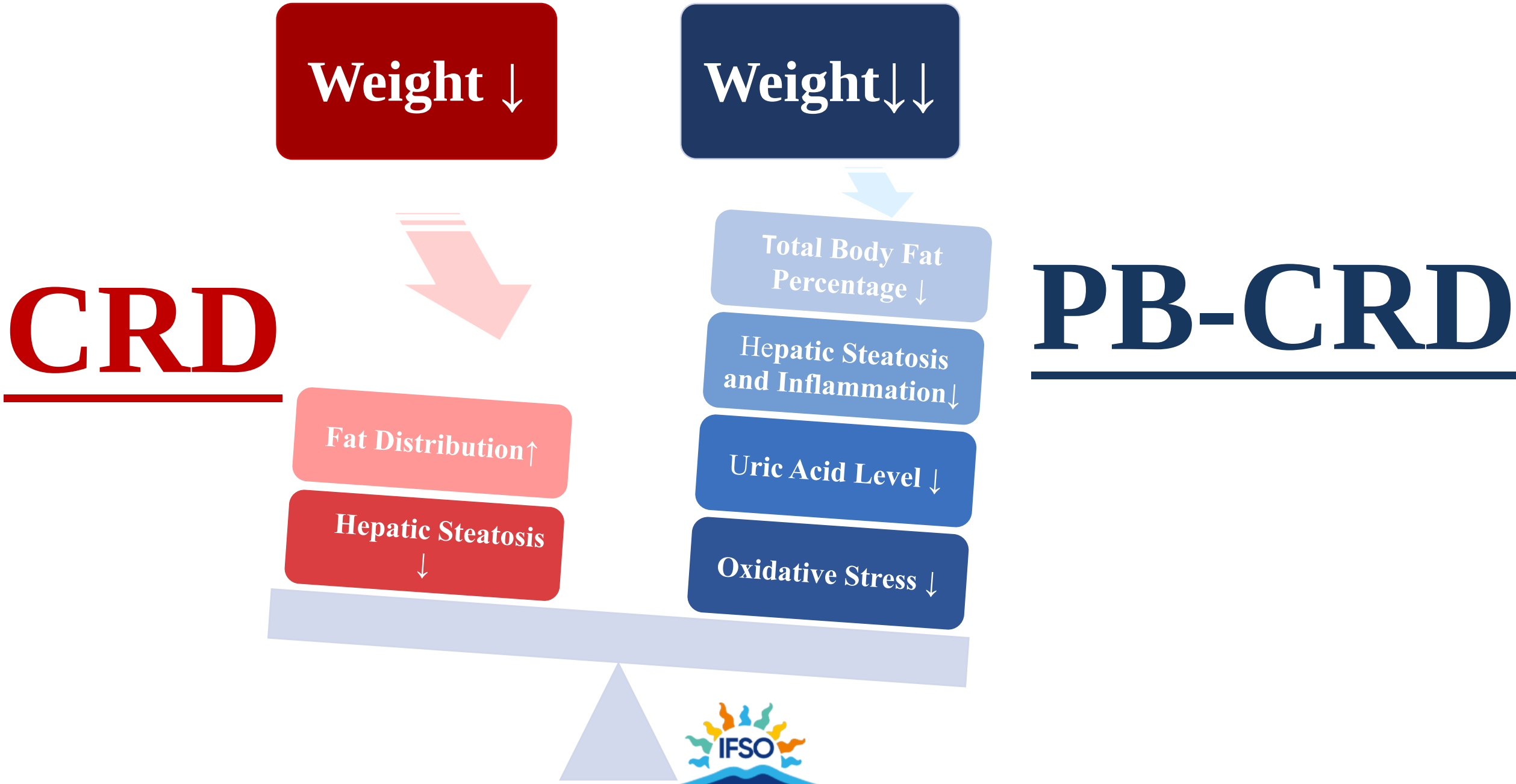
Secondary endpoint： Antioxidant and Inflammatory Markers










Weight ↓
Weight↓↓
CRD
PB-CRD
Total Body Fat Percentage ↓
Hepatic Steatosis and Inflammation↓
Uric Acid Level ↓
Oxidative Stress ↓
Fat Distribution↑
Hepatic Steatosis ↓
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Acknowledge

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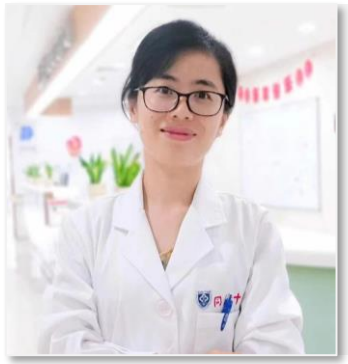

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