Dietary Randomized Controlled Trials

Diet and cardio-metabolic risk: mechanism and clinical implications; evidence based medicine

Iris Shai, BGU
n=322, Retention rate: 1st year: 96%, 2nd year: 85%

Med and low-carbohydrate diets may be effective alternatives to low-fat diets
Two-year weight loss diets can induce a significant regression of measurable carotid VWV.
Four-Year Follow-up after Two-Year Dietary Interventions

2-year intensive intervention trial has long-lasting, favorable post-intervention effects, particularly in Med and low-carb diet & despite weight regain.
The 2-year CaRdiovaSCulAr Diabetes and Ethanol (CASCADE) RCT

Glycemic control

Cardiovascular system

Blood biomarkers

Clinical measurements

MRI fat depots

Symptoms

Genetics

Adherence

Continuous Glucose Monitoring System (CGMS)

Carotid plaque

Heart holter

Holter BP

224 participants with T2D 2 years

BGU/NRCN/Soroka, Israel

Collaborators:

Harvard U, USA
Leipzig U, Germany
Robarts Institute, Canada
Karolinska Institute, Sweden
Haddash Ein Karem, Israel

Retention rate:

1st year: 94%
2nd year: 87%

NCT00784433
Initiation conference
A day before the randomization

- T2D risk
- 2-year plans
- Win-win situation
- Randomization
- Individual final medical report
The 2-year CArdiovaSCuLAr Diabetes and Ethanol (CASCADE) RCT

- Glycemic control
- Cardiovascular system
- Carotid plaque
- Heart holter
- Continuous Glucose Monitoring System (CGMS)
- Blood biomarkers
- MRI fat depots

224 participants with T2D

Initiating moderate wine intake, especially red wine, in T2D: apparently safe and modestly decreases cardiometabolic risk.

Collaborators:
- Harvard U, USA
- Leipzig U, Germany
- Robarts Institute, Canada
- Karolinska Institute, Sweden
- Haddash Ein Karem, Israel

Retention rate:
- 1st year: 94%
- 2nd year: 87%
- NCT00784433
Abdominal superficial subcutaneous fat: a putative distinct protective fat subdepot in T2D

- Superficial subcutaneous AT
- Deep subcutaneous AT
The CENTRAL Whole-body MRI RCT

- Abdominal fat Compartments
- Hepatic fat
- Pericardial fat (Intrapericardial & Extrapericardial)
- Cervical fat

Retention rate:
- 1st year: 93%
- 1.5 year: 86%

Total Energy expenditure (7-days accelerometer)

Blood & Urine biomarkers
Epigenetics
Clinical measurements
Electronic questionnaires

Visceral adipose tissue
Superficial subcutaneous AT
Deep subcutaneous AT

Blood & Urine biomarkers
Pericardial fat
(Extrapericardial & Intrapericardial)

Abdominal fat Compartments

Visceral adipose tissue
Superficial subcutaneous AT
Deep subcutaneous AT

Hepatic fat

Renal fat
Muscular fat
Pancreatic fat

NRCN- BGU/, Israel
Collaborators:
Harvard U, USA
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Hadassaha Ein Karem, Israel

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Resting Metabolic Rate, DIT, RQ

Total Energy expenditure (7-days accelerometer)

Clinical measurements
Electronic questionnaires
Vision
International leading center of dietary RCTs

Challenges
• Funding of long-term non-pharmacological trials
• The “Middle east” challenge