

## CALERIE Phase 2 Schedule of Evaluations

CALERIE Evaluation	Screening	Baseline	Follow-up Month						
			1	3	6	9	12	18	24
Screening Procedures :									
Telephone Screen: Age; Height, Weight ⇒ BMI Inclusion Criteria	X								
Screening Informed Consent and HIPAA Authorization	X								
Demographic Information	X								
Exclusion Criteria									
Medical and Medication History	X								
Abbreviated Medical and Medications History		X							
Screening Questionnaires (Eating Inventory, MAEDS, SCID II, Personality Q're, BDI, GHQ, Body Morph test, IDED-IV)	X								
Serum Pregnancy Test for Women	X								
Barriers to Participation, Diet Preferences, Allergies, Special Conditions	X								
14-day Food Record	X								
Study Informed Consent and HIPAA Authorization		X							
Vital Signs		X	X	X	X	X	X	X	X
Clinic Height		X							
Clinic Weight		X	X	X	X**	X	X**	X**	Mo.17, 18,23,24
Home Diaries, i.e., Weight, Food, Symptoms		X	Daily						
Energy Metabolism:									
TEE by DLW		XX			X*		X	X*	X
RMR		XX			X*		X	X*	X
Core Body Temperature		X			X		X		X

\*CR Intervention only

\*\*Multiple clinic weights during the DLW periods

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Cardiovascular Risk Factors:									
Resting Blood Pressure		X	X	X	X	X	X	X	X
Lipids, Markers of Inflammation, CRP, TGF, etc.		X					X		X
Glucose Tolerance and Insulin:									
OGTT, insulin and C-peptide		X					X		X
Immune Function:									
DTH		X					X		X
Antibody Response to Vaccines		X							Mo.17, 18,23,24
Endocrine Response and Growth Factors:									
Norepinephrine, DHEA, Sex Hormones (for men), Thyroid Hormones, Adipokines, Angiotensin II, Growth Hormone & Growth Factors		X					X		X
QoL, Psychological, Cognitive Function		X			X		X		X
Physical Activity Measurements :									
Stanford 7-day PAR	X	XX			X*		X	X*	X
Maximal Oxygen Uptake (VO <sub>2max</sub> )		X					X		X
Muscular Strength and Endurance		X					X		X
Body Composition:									
Waist Circumference		X	X	X	X	X	X	X	X
DXA, including BMD and BMC		XX			XX*		X	X*	X
Markers of Bone Turnover		X			X		X		X
Nutrient Intake	X	XX			X*		X	X*	X

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Archive Materials:									
Blood		X		X	X		X	X	X
Urine		X					X		X
Muscle and Abdominal Fat Biopsy		X					X		X
Concomitant Medications		X	X	X	X	X	X	X	Mo.17, 23,24
Participant Safety:									
Blood Chemistry, Hematology and Urinalysis	X	X	X	X	X	X	X	X	X
Urine Pregnancy Test for Women		X			X*		X	X*	Mo.17, 23, 24
Adverse Events		X	X	X	X	X	X	X	Mo.17, 23,24
Serious Adverse Events			As they occur with an expedited reporting protocol						
Physical Examination	X	X					X		X
Potassium Screening, ECG, Creatine Phosphokinase	X	X	X	X	X	X	X	X	X
Anemia Screening / Surveillance	X	X	X	X	X	X	X	X	X
Cholesterol Surveillance	X	X					X		X
Eating Disorders Screening / Surveillance	X	X		X	X		X	X	X
BMI Screening / Surveillance	X		X	X*	X*	X*	X*	X*	X*
BDI Screening / Surveillance	X	X	X	X	X	X	X	X	X
DXA scans of hip and spine		X			X*		X		X

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