

## B.2. Data Extraction Form: Lifestyle interventions: T2D & Metabolic Syndrome

This study is related to another study yes  ID(s) \_\_\_\_\_ NO

### 1. General information and study characteristics

|   |  |  |   |
|---|--|--|---|
| Study author:   |  | Source of funding: industry <input type="checkbox"/> government <input type="checkbox"/><br>NR <input type="checkbox"/><br>Association/Foundation <input type="checkbox"/> other <input type="checkbox"/>                        |   |
| Country(ies):   | Year of publication:                                 | Recruitment period<br>_____  |   |
| Publication type<br>Abstract <input type="checkbox"/> Journal article <input type="checkbox"/> Thesis/Dissert. <input type="checkbox"/> |  | Source of population<br>Community (volunteers) <input type="checkbox"/> Clinic(s) <input type="checkbox"/><br>Inpatients <input type="checkbox"/> Registry <input type="checkbox"/><br>Other (describe) <input type="checkbox"/> |   |
| Trial characteristics   |  | Number of Centers  |   |
| RC<br>T<br><input type="checkbox"/>   | Individual<br>randomization <input type="checkbox"/> | Cluster randomization <input type="checkbox"/>   | Single centre <input type="checkbox"/> Multicentre <input type="checkbox"/> |

### 2. Population

|                    |  |
|--------------------|--|
| Inclusion Criteria |  |
| Age                | Disease(s) stage or description        |
| Other              |  |
| Exclusion criteria | Not described <input type="checkbox"/> |
|                    |  |

### 3. Study objective(s) circle main objective(s)

- a. ↓ risk factors for recurrence or progression of cancer: yes
- b. ↓ risk factors for coronary heart/vascular disease: yes
- c. Improve measures of metabolic variables: yes
- d. Prevent adverse clinical events due to MetS or T2DM: yes
- e. Weight loss: yes
- f. Improve psychological wellbeing: yes
- g. Improve self-sufficiency: yes
- h. Increase physical activity and intensity: yes
- i. Improve dietary behaviors: yes
- j. Other

### 4. Characteristics of lifestyle intervention Circle or check all that apply and fill in blanks where indicated

Length of intervention in months: \_\_\_\_\_

Total Duration of followup in months: \_\_\_\_\_

#### A. General program description

- a. Participant specific –individually tailored and regularly monitored: yes
- b. Self-directed – participant given a program to follow at home, occasional fu: yes
- c. Group focused: yes
- d. Other components: \_\_\_\_\_

- B. Based on a framework:**      yes      NR
- a. Transtheoretical model (stages of readiness): yes
  - b. Social cognitive theory: yes
  - c. Cognitive behavioral theory: yes
  - d. Self determination theory; yes
  - e. Other \_\_\_\_\_

- C. Diet component (intervention 1)**
- a. Weight loss:      yes      no
  - b. Follow established guidelines: yes    name \_\_\_\_\_
  - c. Specific diet: circle. vegan, lo fat, hi F&V, hi fish, lo glycemic, hi protein, other: name or general description  
\_\_\_\_\_
  - d. General healthy eating no specific program: yes
  - e. Other: \_\_\_\_\_

**Delivery mode (intervention 1)**

- a. Individual counseling/education: yes  
Who/Frequency/duration \_\_\_\_\_
- b. Group counseling/education: yes  
Who/Frequency/duration \_\_\_\_\_
- c. Self directed change in eating habits only: yes
- d. Materials/food provided: yes \_\_\_\_\_
- e. Follow-up/reinforcement: circle: educational material, log book, workbook, telephone contact, survey completion, newsletter, personal interview, progress reports, other \_\_\_\_\_

**D. Exercise component (intervention 1)**

- a. Aerobic/endurance activities: yes
- b. Strength/resistance exercises: yes
- c. Stretching: yes
- d. General increase in physical activity only: yes

**Delivery mode (intervention 1)**

- a. Individual counseling/supervision sessions: yes  
Who/frequency/duration \_\_\_\_\_
- b. Group counseling/supervision sessions: yes  
Who/frequency/duration \_\_\_\_\_
- c. Self directed exercise only: yes
- d. Materials/equipment provided: yes \_\_\_\_\_
- e. Follow-up/reinforcement: circle: educational material, log book, workbook, telephone contact, survey, newsletter, personal interview, progress reports, other \_\_\_\_\_

**E. Component(s) in addition to exercise and diet (intervention 1)**

- a. Stress management: yes    method \_\_\_\_\_
- b. Behavioral change/modification/motivational guidance: yes
- c. Goal setting and monitoring: Yes
- d. Smoking cessation: yes    method \_\_\_\_\_



| Variable                        | Group 1<br>Intervention 1 | Group 2<br>(Control grp) | Group 3<br>Intervention 2 | Total |
|---------------------------------|---------------------------|--------------------------|---------------------------|-------|
| Age (mean-SD or SE; median-IQR) |                           |                          |                           |       |
| Gender M/F n (%)                |                           |                          |                           |       |
| Ethnic distribution (%) or NR   |                           |                          |                           |       |
| 1. White                        |                           |                          |                           |       |
| 2. African American             |                           |                          |                           |       |
| 3. Native American              |                           |                          |                           |       |
| 4. Hispanic                     |                           |                          |                           |       |
| 5. Other                        |                           |                          |                           |       |
| SES or NR                       |                           |                          |                           |       |
| 1. Education ≤/≥ hi school (%)  |                           |                          |                           |       |
| 2. Income ≤/≥ \$20,000 US (%)   |                           |                          |                           |       |
| Duration of T2 DM yrs           |                           |                          |                           |       |

Were there more than 2 groups NO

YES  If yes print extra page to extract data

7a. Baseline measures with Outcome measures reported: INTERVENTION GROUP Please enter/circle units reported

Document all times when outcomes are reported but only extract end of trial and last FU for now

| Outcome   | <u>INTERVENTION GROUP</u>  |                    |                              |                  |
|---|----------------------------|--------------------|------------------------------|------------------|
|   | Baseline (mean SD) or n(%) | End trial Time: N= | Mid points data are reported | Last FU Time: N= |
| <b>Primary outcome</b>  |                            |                    |                              |                  |
|   |                            |                    |                              |                  |
| <b>Secondary outcomes</b>   |                            |                    |                              |                  |
| <b>A. Weight related</b>  |                            |                    |                              |                  |
| Weight (kg; lbs)  |                            |                    |                              |                  |
| BMI (kg/m <sup>2</sup> )  |                            |                    |                              |                  |
| Waist (cm; in)  |                            |                    |                              |                  |
| Waist/Hip Ratio   |                            |                    |                              |                  |
| % body fat (how measured)   |                            |                    |                              |                  |
| <b>B. Diet related</b>  |                            |                    |                              |                  |
| Energy intake (kcal/day)  |                            |                    |                              |                  |
| Author's statement on success/maintenance/failure of diet uptake    |                            |                    |                              |                  |
| <b>C. Exercise related (add additional measures if appropriate)</b> |                            |                    |                              |                  |
| Min/day   |                            |                    |                              |                  |

| Outcome  | <u>INTERVENTION GROUP</u>     |                          |                                 |                        |
|--|-------------------------------|--------------------------|---------------------------------|------------------------|
|  | Baseline (mean SD)<br>or n(%) | End trial<br>Time:<br>N= | Mid points data are<br>reported | Last FU<br>Time:<br>N= |
| Times/week   |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
| <b>D. Component 3 related (add additional measures if appropriate)</b> |                               |                          |                                 |                        |
| Current smokers  |                               |                          |                                 |                        |
| QoL  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
| <b>E. T2DM or MetS related</b>   |                               |                          |                                 |                        |
| Progress to<br>T2DM  |                               |                          |                                 |                        |
| Progress to<br>MetS  |                               |                          |                                 |                        |
| HbA1c %  |                               |                          |                                 |                        |
| Fasting glucose  |                               |                          |                                 |                        |
| Insulin<br>resistance  |                               |                          |                                 |                        |
| Blood Pressure:<br>S/D   |                               |                          |                                 |                        |
| Triglycerides  |                               |                          |                                 |                        |
| Total cholesterol  |                               |                          |                                 |                        |
| HDL  |                               |                          |                                 |                        |
| LDL  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
| <b>F. Adverse clinical events</b>                                      |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
| <b>G. Diabetic Drug use</b>  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |
|  |                               |                          |                                 |                        |

**7b. Baseline measures with Outcome measures reported: CONTROL GROUP**

Please enter units reported

Document all times when outcomes are reported but only extract end of trial and last FU for now

| Outcome  | <u>CONTROL GROUP</u>       |                    |                            |                  |
|--|----------------------------|--------------------|----------------------------|------------------|
|  | Baseline (mean SD) or n(%) | End trial Time: N= | Other time points reported | Last FU Time: N= |
| Primary outcome  |                            |                    |                            |                  |
|  |                            |                    |                            |                  |
| Secondary outcomes   |                            |                    |                            |                  |
| A. Weight related  |                            |                    |                            |                  |
| Weight (kg; lbs)   |                            |                    |                            |                  |
| BMI (kg/m <sup>2</sup> )   |                            |                    |                            |                  |
| Waist (cm; in)   |                            |                    |                            |                  |
| Waist/Hip Ratio  |                            |                    |                            |                  |
| % body fat (how measured)  |                            |                    |                            |                  |
| B. Diet related  |                            |                    |                            |                  |
| Energy intake (kcal/day)   |                            |                    |                            |                  |
| Author's statement on success/maintenance/failure of diet uptake |                            |                    |                            |                  |
| C. Exercise related (add additional measures if appropriate)     |                            |                    |                            |                  |
| Min/day  |                            |                    |                            |                  |
| Times/week   |                            |                    |                            |                  |
|  |                            |                    |                            |                  |
|  |                            |                    |                            |                  |
| D. Component 3 related (add additional measures if appropriate)  |                            |                    |                            |                  |
| Current smokers  |                            |                    |                            |                  |
| QoL  |                            |                    |                            |                  |
|  |                            |                    |                            |                  |
|  |                            |                    |                            |                  |
| E. T2DM or MetS related  |                            |                    |                            |                  |
| Progress to T2DM   |                            |                    |                            |                  |
| Progress to MetS   |                            |                    |                            |                  |
| HbA1c  |                            |                    |                            |                  |
| Fasting glucose  |                            |                    |                            |                  |
| Insulin resistance   |                            |                    |                            |                  |
| Blood Pressure: s/d  |                            |                    |                            |                  |
| Triglycerides  |                            |                    |                            |                  |
| Total cholesterol  |                            |                    |                            |                  |
| HDL  |                            |                    |                            |                  |

| Outcome                           | <u>CONTROL GROUP</u>          |                          |                               |                        |
|-----------------------------------|-------------------------------|--------------------------|-------------------------------|------------------------|
|                                   | Baseline (mean SD)<br>or n(%) | End trial<br>Time:<br>N= | Other time points<br>reported | Last FU<br>Time:<br>N= |
| LDL                               |                               |                          |                               |                        |
| <b>F. Adverse clinical events</b> |                               |                          |                               |                        |
|                                   |                               |                          |                               |                        |
|                                   |                               |                          |                               |                        |
|                                   |                               |                          |                               |                        |
| <b>G. Diabetic Drug use</b>       |                               |                          |                               |                        |
|                                   |                               |                          |                               |                        |
|                                   |                               |                          |                               |                        |
|                                   |                               |                          |                               |                        |

### 8. Adverse events

Note: try to report event/person (e.g if a person gets 3 rashes it is only 1 rash/1 person) (not 3 rashes in the group)

| Event | Intervention grp: n/N (%) | Control grp: n/N (%) | Total events |
|-------|---------------------------|----------------------|--------------|
|       |                           |                      |              |
|       |                           |                      |              |
|       |                           |                      |              |

### 9. Study conclusion

### 10. Additional comments / additional information