B. 3. Data Extraction Form: Lifestyle interventions review- Breast and Prostate Cancer

This study is related to another study yes ☐ ID(s)_____ NO ☐

1. General information and study characteristics

Study author:			Source of funding: industry ☐ government ☐ foundation ☐ other ☐		
Country(ies):	Year of publication:		Recruitment period _____ Source of population Community (volunteers) ☐ Clinic pts ☐ Outpatient ☐ Inpatient ☐ Registry pts ☐ Other (describe) ☐		
Publication type Abstract ☐ Journal article ☐ Thesis/Dissert. ☐					
Trial characteristics			Number of Centers		
RCT ☐	Individual randomization ☐	Cluster randomization ☐	Single centre ☐	Multicentre ☐ # of centres _____	

2. Population – general characteristics/inclusion exclusion

Inclusion Criteria	
Age	Disease(s) stage or description
Other	
Exclusion criteria Not described ☐	

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

k. ↓ risk factors for recurrence or progression of cancer: yes
l. ↓ risk factors for coronary heart/vascular disease: yes
m. Improve measures of metabolic variables (e.g. Pr specific antigen, LNCaP cell growth; ↓ C reactive protein, etc): yes
n. Weight loss: yes
o. Prevent functional decline: yes
p. Improve psychological wellbeing: yes
q. Improve self-sufficiency: yes
r. Increase physical activity and intensity: yes
s. Improve dietary behaviors: yes
t. 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: _____

H. General program description
   e. Participant specific –individually tailored and regularly monitored: yes

f. Self-directed – participants given program to follow at home, have occasional/regular fu: yes
g. Group focused: most of the program delivered to participants in grp format: yes
h. Other: _____

I. Based on a framework: yes NR
f. Transtheoretical model (stages of readiness): yes
g. Social cognitive theory: yes
h. Cognitive behavioral theory: yes
i. Self determination theory; yes
j. Other _____

J. Diet component
f. Weight loss: yes no
g. Follow established guidelines: name _____
h. Specific diet: circle: vegan, lo fat, hi F&V, hi fish, lo glycemic, hi protein, other: name or general description
_____
i. General healthy eating no specific program: yes
j. Other: _____

Delivery mode
f. Individual counseling/education: yes
Who/Frequency/duration
_____
g. Group counseling/education: yes
Who/Frequency/duration
_____
h. Self directed change in eating habits only: yes
i. Materials/food provided: yes _____
j. Follow-up/reinforcement: circle: educational material, log book, workbook, telephone contact, survey completion, newsletter, personal interview, progress reports, other _____

K. Exercise component
e. Aerobic/endurance activities: yes
f. Strength/resistance exercises: yes
g. Stretching: yes
h. General increase in physical activity: yes

Delivery mode
f. Individual counseling/supervision sessions: yes
Who/frequency/duration
_____
g. Group counseling/supervision sessions: yes
Who/ frequency/duration
_____
h. Self directed exercise only: yes
i. Materials/equipment provided: yes _____
j. Follow-up/reinforcement: circle: educational material, log book, workbook, telephone contact, survey, newsletter, personal interview, progress reports, other _____

L. Component(s) in addition to exercise and diet
   i. Stress management: method _____
   j. Behavioral change/modification/motivational guidance: yes
   k. Goal setting and monitoring: Yes
   l. Group discussions/support/education beyond diet and exercise: yes
   m. Scheduled telephone contact/counseling beyond diet and exercise: yes
   n. Other _____

M. Personnel involved: NR
   g. Qualified dietitian: yes
   h. Qualified exercise advisor/consultant/instructor/trainer: yes
   i. Case/nurse manager/counselor: yes
   j. Physician: yes
   k. Behavior therapist: yes
   l. Other _____

5. Characteristics of Control group intervention
   h. Usual/standard care: yes
   i. Attention control (i.e. attention/education/materials in addition to usual care): yes
      Describe _____
   j. Wait list: yes
   k. Diet only
   l. Exercise only
   m. Other _____

Were there more than 2 groups NO ☐ YES ☐ If yes print an outcomes page to extract data

6. Demographic characteristics

Variable	Group 1 Intervention 1	Group 2 (Control grp)	Group 3 Intervention 2	Total
Number of participants randomized				
Number of participants analyzed				
Number of dropouts/withdrawals				
Reasons for dropouts/withdrawal				
Age (*mean-SD or SE; median-IQR)*				
Gender M/F n (%)				
Ethnic distribution (%) or NR				
6. White				
7. African American				

Variable	Group 1 Intervention 1	Group 2 (Control grp)	Group 3 Intervention 2	Total
8. Native American				
9. Hispanic				
10. Other				
SES				
3. Education ≤/> hi school (%)				
4. Income ≤/> $20,000 US (%)				
Time since Dx /completed Tx with Ca				

7a. Baseline measures with Outcome measures reported: INTERVENTION GROUP

Please enter or circle units reported

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

Outcome	INTERVENTION GROUP			
	Baseline N=	End trial Time: N=	Other time points reported	Last FU Time: N=
Primary outcome: mean; median; SD; SE; IQR; range; n(%); other				
Secondary outcomes				
H. Weight related				
Weight (kg; lbs)				
BMI (kg/m^2)				
Waist (cm; in)				
Waist/Hip Ratio				
% body fat (how measured)				
I. Diet related				
Energy intake				
Author's statement on success/maintenance/failure of diet uptake				
J. Exercise related (add additional measures if appropriate)				
Min/day				

Outcome	INTERVENTION GROUP			
	Baseline N=	End trial Time: N=	Other time points reported	Last FU Time: N=
Times/week				
K. Component 3 related (add additional measures if appropriate)				
Current smokers				
QoL				
L. Breast or prostate cancer related				
Recurrence of Ca				
Additional tx for original or metastatic Ca				
New primary Ca				
Pr specific antigen				
LNcaP cell growth				

b. 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	CONTROL GROUP			
	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;				

Outcome	CONTROL GROUP			
	Baseline (mean SD) or n(%)	End trial Time: N=	Other time points reported	Last FU Time: N=
lbs)				
BMI (kg/m^2)				
Waist (cm; in)				
Waist/Hip Ratio				
% body fat (how measured)				
B. Diet related				
Energy intake				
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. Breast or prostate cancer related				
Recurrence of Ca				
Additional tx for original or metastatic Ca				
New primary Ca				
Pr specific antigen				
LNcaP cell growth				

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

B.3. Risk of Bias: Lifestyle interventions review

Cochrane Collaboration's tool for assessing risk of bias: Lifestyle Interventions

Reviewer's initials: _____ Study ID: _____ Date (dd/mm/yy): _____

Domain	Description	Review authors' judgment	Consensus (circle)
Sequence generation		Was the allocation sequence adequately generated? YES / NO / UNCLEAR	YES NO UNCLEAR
Allocation concealment		Was allocation adequately concealed? YES / NO / UNCLEAR	YES NO UNCLEAR
Blinding of participants, personnel and outcome assessors,	Objective outcomes: Self-reported outcomes:	Was knowledge of the allocated intervention adequately prevented during the study? Objective: YES / NO / UNCLEAR Self-reported: YES / NO / UNCLEAR	Objective: YES NO UNCLEAR Self-reported: YES NO UNCLEAR
Incomplete outcome data, *Outcome:*	Objective outcomes: Self-reported outcomes:	Were incomplete outcome data adequately addressed? Objective: YES / NO / UNCLEAR Self-reported: YES / NO / UNCLEAR	Objective: YES NO UNCLEAR Self-reported: YES NO UNCLEAR
Selective outcome reporting		Are reports of the study free of suggestion of selective outcome reporting? YES / NO / UNCLEAR	YES NO UNCLEAR
Other sources of bias	Baseline imbalance: Funding:	Was the study apparently free of other problems that could put it at a high risk of bias? Baseline: YES / NO / UNCLEAR Funding: YES / NO / UNCLEAR	Baseline: YES NO UNCLEAR Funding: YES NO UNCLEAR
Overall risk of bias	Objective outcomes	HIGH / LOW / UNCLEAR	HIGH/ LOW/ UNCLEAR
	Self-reported outcomes	HIGH / LOW / UNCLEAR	HIGH/ LOW/ UNCLEAR

Guidelines and Decision Rules for Risk of Bias Assessments: Lifestyle Interventions

Sequence generation:
If computer-generated, random number list, flipping coins, randomly picking envelopes, etc. is specified → YES
If the description only includes 'random', 'randomly generated', 'randomized', etc, do not assume additional details → UNCLEAR
If the description is quasi-randomized (e.g. alternate randomization, day of the year, day of the month, birth date, birth month, beginning letter of last name, availability of investigator or specialist, etc) → NO
Allocation concealment:
If the assignment is conducted by central telephone, pharmacy, etc → YES
If dark (or opaque), sealed, sequentially-numbered envelopes are used → YES
If the envelopes are not stated to dark and sealed, or sequentially-numbered → UNCLEAR
Note: sequential numbering of the envelopes is only required for adequate allocation concealment if the method of randomization was anything other than randomly picking envelopes (i.e. the envelopes were only used for allocation concealment and not as part of the randomization process).

Blinding: Objective outcomes
No blinding, but outcome measures are not likely to be influenced by lack of blinding → YES
Blinding: Self-reported outcomes
If the study was stated to be blinded (masked) and the blinding is considered to be possible (i.e., participants and key personnel blinded to study hypothesis), and not likely to be broken → YES
If the study is only stated to be blinded, double-blinded, etc. without any further details → UNCLEAR
If the study states the use of a placebo (dummy) but with no further details → UNCLEAR
If no mention of blinding → NO

Incomplete outcome data (all outcomes):
Look for intention-to-treat analysis (all randomized pts. are analyzed) → YES
If all participants were accounted for (i.e. no drop-outs or censored analysis conducted) → YES
If the numbers and reasons for withdrawal/drop-outs were described and comparable across groups (and ≤ approximately 10%) → YES
If there is between 10% - 30% drop-out and no ITT analysis → UNCLEAR
If there is greater 30% drop-out and no ITT analysis → NO

Selective outcome reporting:
If the study protocol is available (referenced in the manuscript), compare the outcomes reported in the publication to those specified in the protocol. If they match → YES
If the study protocol is available (referenced in the manuscript), compare the outcomes reported in the publication to those specified in the protocol. If they do not match, but there is reference to another publication with this information presented → YES
If the study protocol is not available, compare the outcomes reported in the Methods and Results sections. If they match → YES

Other sources of bias:
Assess for baseline imbalances that could have biased the results (or were not accounted for).
Assess for inappropriate influence of funders that could have biased the results:
If industry sponsor is acknowledged and there is a clear statement regarding no involvement of sponsor in trial conduct or data management/analysis, or co-authorship → YES
If industry sponsor is acknowledged with no further information provided or (co)author works for industry → NO
If there is no mention of funding source → UNCLEAR

Overall assessment of ROB:
Low risk of bias → if reviewer said YES for all domains
Unclear risk of bias → if reviewer said UNCLEAR for one or more key domain
High risk of bias → if reviewer said NO for one or more key domain

Table 8.5.c: Criteria for judging risk of bias in the 'Risk of bias' assessment tool

SEQUENCE GENERATION Was the allocation sequence adequately generated? [Short form: Adequate sequence generation?]	
Criteria for a judgment of 'YES' (i.e. low risk of bias).	The investigators describe a random component in the sequence generation process such as: Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgment of 'NO' (i.e. high risk of bias).	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: Sequence generated by odd or even date of birth; Sequence generated by some rule based on date (or day) of admission; Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgment or some method of non-random categorization of participants, for example: Allocation by judgment of the clinician; Allocation by preference of the participant; Allocation based on the results of a laboratory test or a series of tests; Allocation by availability of the intervention.
Criteria for the judgment of 'UNCLEAR' (uncertain risk of bias).	Insufficient information about the sequence generation process to permit judgment of 'Yes' or 'No'.
ALLOCATION CONCEALMENT Was allocation adequately concealed? [Short form: Allocation concealment?]	
Criteria for a judgment of 'YES' (i.e. low risk of bias).	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: Central allocation (including telephone, web-based, and pharmacy-controlled, randomization); Sequentially numbered drug containers of identical appearance; Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgment of 'NO' (i.e. high risk of bias).	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: Using an open random allocation schedule (e.g. a list of random numbers); Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); Alternation or rotation; Date of birth; Case record number; Any other explicitly unconcealed procedure.
Criteria for the judgment of 'UNCLEAR' (uncertain risk of bias).	Insufficient information to permit judgment of 'Yes' or 'No'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgment – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
BLINDING OF PARTICIPANTS, PERSONNEL AND OUTCOME ASSESSORS Was knowledge of the allocated interventions adequately prevented during the study? [Short form: Blinding?]	
Criteria for a judgment of 'YES' (i.e. low risk of bias).	Any one of the following: No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding; Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken; Either participants or some key study personnel were not blinded, but outcome

	assessment was blinded and the non-blinding of others unlikely to introduce bias.
Criteria for the judgment of 'NO' (i.e. high risk of bias).	Any one of the following: No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding; Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken; Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.
Criteria for the judgment of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: Insufficient information to permit judgment of 'Yes' or 'No'; The study did not address this outcome.
INCOMPLETE OUTCOME DATA Were incomplete outcome data adequately addressed? [Short form: Incomplete outcome data addressed?]	
Criteria for a judgment of 'YES' (i.e. low risk of bias).	Any one of the following: No missing outcome data; Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; Missing data have been imputed using appropriate methods.
Criteria for the judgment of 'NO' (i.e. high risk of bias).	Any one of the following: Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; Potentially inappropriate application of simple imputation.
Criteria for the judgment of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: Insufficient reporting of attrition/exclusions to permit judgment of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided); The study did not address this outcome.
SELECTIVE OUTCOME REPORTING Are reports of the study free of suggestion of selective outcome reporting? [Short form: Free of selective reporting?]	
Criteria for a judgment of 'YES' (i.e. low risk of bias).	Any of the following: The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgment of 'NO' (i.e. high risk of bias).	Any one of the following: Not all of the study's pre-specified primary outcomes have been reported; One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); One or more outcomes of interest in the review are reported incompletely so that

	they cannot be entered in a meta-analysis; The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgment of 'UNCLEAR' (uncertain risk of bias).	Insufficient information to permit judgment of 'Yes' or 'No'. It is likely that the majority of studies will fall into this category.
OTHER POTENTIAL THREATS TO VALIDITY Was the study apparently free of other problems that could put it at a risk of bias? [Short form: Free of other bias?]	
Criteria for a judgment of 'YES' (i.e. low risk of bias).	The study appears to be free of other sources of bias.
Criteria for the judgment of 'NO' (i.e. high risk of bias).	There is at least one important risk of bias. For example, the study: Had a potential source of bias related to the specific study design used; or Stopped early due to some data-dependent process (including a formal-stopping rule); or Had extreme baseline imbalance; or Has been claimed to have been fraudulent; or Had some other problem.
Criteria for the judgment of 'UNCLEAR' (uncertain risk of bias).	There may be a risk of bias, but there is either: Insufficient information to assess whether an important risk of bias exists; or Insufficient rationale or evidence that an identified problem will introduce bias.