

Rules for suspension of participation

As a rule, any concerns by the dietitian should result in suspension from the study until a physician treating the participant gives written medical clearance.

Criteria for temporary suspension from the study are as follows:

- Hospitalization or evaluation in the Emergency Room for any reason other than for a minor laceration or for a viral infection that has resolved, including but not limited to
 - i. cardiac evaluation for symptoms,
 - ii. syncope or TIA symptoms,
 - iii. adverse reaction to medications,
 - iv. bacterial infection on antibiotics,
 - v. Motor Vehicle Accident,
 - vi. problems with glucose control for patients with diabetes, or
 - vii. dehydration.
- outpatient cardiac evaluation for symptoms (i.e., chest pain or shortness of breath)
- any report of chest pain, shortness of breath or light-headedness when walking
- any injury or impairment that significantly limits ability to walk or increases risk for further injury while walking

As part of each nutritional counseling session, dietitians will ask the participant about any of the above events. For any participant who has experienced one of the above events, the counseling session will be terminated and the participant will be informed that they have been suspended from the study. In order to be reinstated in the study, the participant will need to get written, signed medical clearance from their primary care physician or from a specialist evaluating the problem. The study coordinator at the participant's site will assist the participant in getting the written medical clearance.

Scheduled routine cardiac testing (such as an annual stress-test) for these high risk patients will not constitute grounds for study suspension in the absence of symptoms.