QxQ updated: 06/24/2004

HALT-C Trial Q x Q

Physical Activity - Risk Factors AS

Form # 140 Version B: 12/03/2001

<u>Purpose of Form #140:</u> The Physical Activity form records the patient's current recreational and non-recreational activity levels, at work or at home using a brief, self-administered questionnaire.

When to complete Form #140: This form should be completed for all patients at the following study visits:

- Lead-in patients: Baseline (W00).
- Express patients: Baseline (R00).
- Randomization phase: Month 12 (M12), Month 24 (M24), and Month 54 (M54).

Form #140 will be data entered at each clinical site.

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date of the visit in MM/DD/YYYY format.
- A5. Enter the initials of the person completing Section A of the form.

General Instructions for Sections B and C:

- The patient should complete sections B and C of Form #140 by following the directions written on the form.
- If the patient is not able to complete Form #140 by her/himself, the interviewer may read the questions and answers to the patient and record the answers given by the patient on the form. If the interviewer completes the form in this manner, please note so in the margins of the form by writing "form completed by interviewer" with the initials of the interviewer.
- It is important that the patient complete all of the items on Form #140.
 - Review the form for any missing items.
 - Make sure that each item has only a single answer selected.
 - Please ask the patient to complete any missing or doubly marked items.

SECTION B: NON-RECREATIONAL ACTIVITY (WORK-RELATED)

B1. The description for each activity is in parentheses on Form #140. The patient should circle the activity level that best describes his/her usual non-recreational activity. The patient should circle only one option.

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B2. The patient should record the average amount of time per day in hours spent at this level of activity.

B3. The patient should record the average amount of time per day in hours spent sitting down.

SECTION C: RECREATIONAL ACTIVITY

For each activity listed in Section C, the patient should consider whether s/he participates in the activity for at least 15 minutes a week. For each activity that s/he participates in for at least 15 minutes per week, the patient should circle that activity and write the number of hours or minutes that s/he does that activity per week in the spaces to the right. The patient does not need to make any marks for activities in which s/he does not participate. The patient may skip those activities.

Additional instructions for data entry:

Data entry personnel should note that there is an additional question in the electronic version of the form in the Data Management System that does not appear on the paper copy of the form. For each activity listed on the paper form, an additional question appears in the DMS asking the data enterer to record whether or not the patient replied that s/he participates in that activity. For each activity, the questions is "C#a" (where # is replaced by the number corresponding to the listed activity). The options for this question are YES (code of 1) and NO (code of 2).

- If the patient has recorded hours and/or minutes in the spaces provided, then answer YES (code of 1) in question C#a, to indicate that the patient participates in this activity.
- If the patient has circled or otherwise marked an activity to indicate that s/he participates in this activity, then answer YES (code of 1) in question C#a. If, in addition to marking that activity, the patient did not record hours and/or minutes that s/he participates in the activity, then record the hours (question C#b) and minutes (question C#c) as "Missing" (code of –9).
- If the patient has not recorded hours and/or minutes and has not otherwise marked an activity, then answer NO (code of 2) in question C#a, to indicate that the patient does not participate in this activity.

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