The Leeds Teaching Hospitals NHS
NHS Trust

St James's Institute of Oncology, Level 6, Bexley Wing,
St James's University Hospital, Beckett Street, Leeds, LS9 7TF,
Tel: 0113 20 67967

321GO Trial

Three, Two or One Drug Chemotherapy for Advanced Gastroesophageal Cancer: a Feasibility Study in Frail and/or Elderly Patients

Baseline Comprehensive Health Assessment (CHA)

Notes for Research Nurse/Data Manager:

This baseline health assessment is an indispensable part of the *321GO* trial. It must be completed **after** obtaining the patient's consent, but **before** telephoning the TRIAL CENTRE to register and randomise the patient. The CHA is in two parts, (a) a nurse-administered assessment of physical parameters, mental state and medical history, and (b) a patient-completed questionnaire dealing with various aspects of quality of life. **Randomisation will not be performed until both parts of the CHA have been completed.**

CHA Nurse-Administered Section:

For this section of the CHA, you need a quiet, private environment where the patient can answer questions without feeling pressurised or "on trial". Ensure the patient is comfortable and not hungry, thirsty or in need of the toilet or analgesia. Hearing aids, if used, should be working. The patient may have a carer present, but if so ask them not to answer questions on the patient's behalf. If an interpreter is required, use a professional interpreter in preference to a relative.

You will need: a blank sheet of paper; scales and a measure for height and weight; a tape measure for arm circumference.

Patient initials	**Date form completed**	**Trial Nº. (complete after registering)**

Section P – Physical tests

P.1) **height in cm:**	P.2) **weight in kg:**	P.3) **right arm circumference in cm** (midway between elbow and shoulder):

P.4) **approximate weight change in past 3 months:**

Ask the patient if they are aware of having lost or gained weight:

☐ don't know

☐ weight loss. If so, how much? Approx ……..kg (½ stone = 3 kg)

☐ weight gain If so, how much? Approx ……..kg (½ stone = 3 kg)

Section N (Mini Nutritional Assessment)

Ask the patient the following questions (exact words in **bold**) clearly or make the appropriate assessment and score the patient's answers.

N.1) **"Has your food intake declined over the past 3 months?"** *(may be due to any cause such as loss of appetite, digestive problems, chewing or swallowing difficulties)* 0 = severe decline in food intake 1 = moderate decline in food intake 2 = no loss of appetite	☐ **0**	☐ **1**	☐ **2**	
N.2) **"How much weight loss have you had over the past 3 months?"** 0 = weight loss greater than 3kg (6.6lbs) 1 = does not know 2 = weight loss between 1 and 3kg (2.2 and 6.6lb) 3 = no weight loss	☐ **0**	☐ **1**	☐ **2**	☐ **3**
N.3) **"Is it easy for you to get around in and outside the home?"** 0 = bed or chair bound 1 = able to get out of bed or chair but does not go out 2 = goes out	☐ **0**	☐ **1**	☐ **2**	
N.4) **"Have you suffered stress or a new disease in the past 3 months?"** *(may include a new cancer diagnosis or chemotherapy toxicity)* 0 = yes 1 = no	☐ **0**	☐ **1**		
N.5) Does the patient have current neuropsychological problems 0 = severe dementia or depression 1 = mild dementia 2 = no psychological problems	☐ **0**	☐ **1**	☐ **2**	
N.6) Body Mass Index (BMI) = weight in kg / height in m^2 0 = BMI less than 19 1 = BMI 19 to less than 21 2 = BMI 21 to less than 23 3 = BMI 23 or greater	☐ **0**	☐ **1**	☐ **2**	☐ **3**
N.7) Does the patient live independently *(not in a nursing home or hospital)* 0 = no 1 = yes	☐ **0**	☐ **1**		
N.8) **"Do you take more than 3 different prescription drugs a day"** 0 = yes 1 = no	☐ **0**	☐ **1**		
N.9) Does the patient have pressure sores or skin ulcers? 0 = yes 1= no	☐ **0**	☐ **1**		
N.10) **"How many full meals do you eat daily?''** 0 = 1 meal 1 = 2 meals 3 = 3 meals or more	☐ **0**	☐ **1**	☐ **2**	
N.11) Consumption markers for protein intake. • **"Do you have at least one serving of dairy products (milk, cheese, yoghurt) per day?''**: yes or no • **"Do you have two or more servings of legumes or eggs per week?''**: yes or no • **"Do you have meat, fish or poultry everyday?''**: yes or no 0.0 = if 0 or 1 yes 0.5 = if 2 yes 1.0 = if 3 yes	☐ **0**	☐ **0.5**	☐ **1**	
N.12) **"Do you eat 2 or more servings of fruits or vegetables per day?''** 0 = no 1 = yes	☐ **0**	☐ **1**		

N.13) **"How many cups of fluid do you drink a day?"** 0.0 = less than 3 cups 0.5 = 3 to 5 cups 1.0 = more than 5 cups	☐ **0**	☐ **0.5**	☐ **1**	
N.14) **"Do you have any difficulty with feeding yourself?"** 0 = unable to eat without assistance 1 = self-fed with some difficulty 2 = self-fed without any problem	☐ **0**	☐ **1**	☐ **2**	
N.15) **"Do you feel that you are malnourished"** 0 = views self as being malnourished 1 = is uncertain of nutritional state 2 = views self as having no nutritional problem	☐ **0**	☐ **1**	☐ **2**	
N.16) **"In comparison with other people of the same age do you consider yourself better or less well nourished"** 0.0 = not as good 0.5 = does not know 1.0 = as good 2.0 = better	☐ **0**	☐ **0.5**	☐ **1**	☐ **2**
N.17) Mid-arm circumference (MAC) in cm (girth of the *non-dominant* arm midway between the elbow and the shoulder) 0.0 = MAC less than 21cm 0.5 = MAC between 21 and 22cm 1.0 = MAC 22cm or greater	☐ **0**	☐ **0.5**	☐ **1**	
N.18) Calf circumference (CC) in cm (measure the girth around the *largest* part of the calf) 0 = CC less than 31cm 1 = CC 31cm or greater	☐ **0**	☐ **1**		

Section C (Charlson Co-Morbidity Index)

This section is completed from the medical notes, although it is helpful to do so whilst the patient is still present so that you can clarify any missing data (using lay terms). Record whether there is a past or current history of any of the following medical conditions (if in doubt, consult the doctor responsible):

C.1) Myocardial infarct *History of medically documented myocardial infarction*	☐ present	☐ absent
C.2) Congestive heart failure ***Symptomatic CHF with response to specific treatment***	☐ present	☐ absent
C.3) Peripheral vascular disease *Intermittent claudication, peripheral arterial bypass for insufficiency, gangrene, acute arterial insufficiency, untreated aneurysm (≥6cm)*	☐ present	☐ absent
C.4) Cerebrovascular disease (except hemiplegia) *History of TIA, or CVA with no or minor sequellae*	☐ present	☐ absent
C.5) Dementia *Chronic cognitive deficit*	☐ present	☐ absent
C.6) Chronic pulmonary disease *Symptomatic dyspnoe due to chronic respiratory conditions (including asthma)*	☐ present	☐ absent
C.7) Connective tissue disease *SLE, polymyositis, mixed CTD, polymyalgia rheumatica, moderate to severe RA.*	☐ present	☐ absent
C.8) Ulcer disease *Patients who have required treatment for PUD*	☐ present	☐ absent
C.9) Mild liver disease *Cirrhosis without PHT, chronic hepatitis*	☐ present	☐ absent
C.10) Diabetes (without complications) *Diabetes with medication*	☐ present	☐ absent

C.11) Diabetes with end organ damage *Retinopathy, neuropathy, nephropathy*	☐ present ☐ absent
C.12) Hemiplegia *Hemiplegia or paraplegia*	☐ present ☐ absent
C.13) Moderate or severe renal disease *Creatinine > 265 umol/l, dialysis, transplantation, uraemic syndrome*	☐ present ☐ absent
C.14) 2nd Solid tumour (non metastatic) *Initially treated in the last 5 years. Excl non-melanomatous skin ca, and in situ cervical ca.*	☐ present ☐ absent
C.15) Leukaemia *CML, CLL, AML, ALL, PV*	☐ present ☐ absent
C.16) Lymphoma, Multiple myeloma *Non Hodgkin's Lymphoma (NHL), Hodgkins, Waldenstrom, multiple myeloma*	☐ present ☐ absent
C.17) Moderate or severe liver disease *Cirrhosis with PHT =/- variceal bleeding*	☐ present ☐ absent
C.18) 2nd Metastatic solid tumour	☐ present ☐ absent
C.19) AIDS *AIDS and AIDS related complex*	☐ present ☐ absent

NB Now please go back and check that patient ID and date are completed at the top of this form, then ask the patient to complete the patient questionnaire section of the CHA.

CHA Patient Questionnaire Section:

This section of the CHA is a patient-completed questionnaire. Please ensure the patient has a relaxed, private environment such as a clinic room, **not a public waiting area**. Ensure they are comfortable and not hungry, thirsty or in need of the toilet or analgesia. The patient may have a carer present, but if so ask them not to answer questions on the patient's behalf. If an interpreter is required, use a professional interpreter rather than a relative, if possible.

Some patients will require help reading or interpreting the questions, or ticking the response boxes. The research nurse or data manager should offer to sit with the patient and help if they wish, but if so should not change the patient's initial "gut reaction" responses. **When the patient has finished, the research nurse or data manager should look through the questionnaire before the patient leaves, check that there are no missing or unclear answers and check that the patient ID and date are complete.**

Dear Patient,

As part of our research into finding the best chemotherapy for your condition, we'd like to ask you some questions about your activities, symptoms and feelings. Would you please go through this questionnaire and, for each question, tick the answer that fits most closely, even if it is not exact. If there are questions you cannot answer, please ask the nurse for help (or, if you would prefer, the nurse can sit with you and read out all the questions).

Thank you!

Your initials	**/ / Today's Date**	**Trial Nº. (Nurse to complete)**

First, some questions about what activities you can manage currently:

A.1) Do you walk around outside?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.2) Do you climb stairs?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.3) Do you get in and out of the car?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.4) Do you walk over uneven ground?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.5) Do you cross roads?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.6) Do you travel on public transport?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.8) Do you manage to feed yourself?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.9) Do you manage to make yourself a hot drink?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.10) Do you take hot drinks from one room to another?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.11) Do you do the washing up?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily

A.12) Do you make yourself a hot snack?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.14) Do you manage your own money when you are out?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.15) Do you wash small items of clothing?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.16) Do you do your own shopping?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.17) Do you do a full clothes wash?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.19) Do you read newspapers or books?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.20) Do you use the telephone?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.21) Do you write letters?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.22) Do you go out socially?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.23) Do you manage our own garden?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily
A.24) Do you drive a car?	☐ not at all	☐ with help	☐ alone with difficulty	☐ alone easily

E.1) Over the past **6 weeks** how many times has your GP visited you?	☐ not at all	or: How many times?:……
E.2) Over the past **6 weeks** how many times have you visited your GP?	☐ not at all	or: How many times?:……
E.3) Over the past **6 weeks** how often have you been visited by a district nurse?	☐ not at all	or: How many times?:……
E.4) Over the past **6 weeks,** have you been visited by a MacMillan nurse?	☐ not at all	or: How many times?:……

E.5) Which best describes your mobility **today**?	☐ I have no problems walking about	☐ I have some problems walking about	☐ I am confined to bed
E.6) Which best describes your self-care **today**?	☐ I have no problems with self care	☐ I have some problems washing or dressing	☐ I am unable to wash or dress myself
E.7) Which best describes your activities **today**?	☐ I have no problems performing my usual activities	☐ I have some problems performing my usual activities	☐ I am unable to perform my usual activities
E.8) Do you have any pain **today**?	☐ I have no pain or discomfort	☐ I have some pain or discomfort	☐ I have extreme pain or discomfort
E.9) Which best describes your mood **today**?	☐ I am not anxious or depressed	☐ I am moderately anxious or depressed	☐ I am extremely anxious or depressed

Now some questions about your symptoms over the past week.

Q.1) Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or suitcase?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.2) Do you have any trouble taking a long walk?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.3) Do you have any trouble taking a short walk out of the house?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.4) Do you need to stay in a bed or a chair during the day?	☐ not at all	☐ a little	☐ quite a bit	☐ very much

Q.5) Do you need help with eating, dressing, washing yourself or using the toilet?	☐ not at all	☐ a little	☐ quite a bit	☐ very much

During the past week…

Q.6) …were you limited in doing either your work or other daily activities?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.7) …were you limited in pursuing your hobbies or other leisure activities?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.8) …were you short of breath?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.9) …have you had pain?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.10) …did you need to rest?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.11) …have you had trouble sleeping?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.12) …have you felt weak?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.13) …have you lacked appetite?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.14) …have you felt nauseated?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.15) …have you vomited?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.16) …have you been constipated?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.17) …have you had diarrhoea?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.18) …were you tired?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.19) …did pain interfere with your daily activities?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.20) …have you had difficulty in concentrating on things, like reading a newspaper or watching televesion?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.21) …did you feel tense?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.22) …did you worry?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.23) …did you feel irritable?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.24) …did you feel depressed?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.25) …have you had difficulty remembering things?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.26) …has your physical condition or medical treatment interfered with your family life?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.27) …has your physical condition or medical treatment interfered with your social activities?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.28) …has your physical condition or medical treatment caused you financial difficulties?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.1) … have you had problems eating solid food?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.2) … have you had problems eating liquidised or soft foods?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.3) … have you had problems drinking liquids?	☐ not at all	☐ a little	☐ quite a bit	☐ very much

OG.4) ... have you had trouble enjoying your meals?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.5) ... have you felt full up too quickly after beginning to eat?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.6) ... has it taken you a long time to complete your meals?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.7) ... have you had difficulty eating?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.8) ... have you had acid indigestion of heartburn?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.9) ... has acid or bile coming into your mouth been a problem?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.10) ... have you had discomfort when eating?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.11) ... have you had pain when you eat?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.12) ... have you had pain in your stomach area?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.13) ... have you had discomfort in your stomach area?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.14) ... have you been thinking about your illness?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.15)…have you felt worried about your health in the future?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.16) ... have you had trouble with eating in front of other people?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.17)…have you had a dry mouth?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.18) ... have you had problems with your sense of taste?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.19) ... have you felt physically less attractive as a result of your disease or treatment?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.20) ... have you had difficulty swallowing your saliva?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.21) ... have you choked when swallowing?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.22) ... have you coughed?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.23) ... have you had trouble with talking?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.24) ... have you been worried about your weight being too low?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.25) …were you upset by the loss of your hair? (answer only if you lost any hair)	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.26)…have you had soreness or redness of your hands or feet?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
OG.27) …have you had difficulty handling small objects (eg buttons or zips)?	☐ not at all	☐ a little	☐ quite a bit	☐ very much
Q.29) How was your **overall health** during the past week? *(put a circle around the score)*	**1** Very poor	**2** **3** **4** **5** **6**		**7** Excellent
Q.30) And how was your **overall quality of life** during the past week?	**1** Very poor	**2** **3** **4** **5** **6**		**7** Excellent

Many thanks for helping us by filling in this questionnaire. Please now hand it to the research nurse. You may feel that you wish to discuss some of the issues which it has raised – please feel free to do so.