

NCT02054741-D2 Data Dictionary

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Brief description of Study NCT02054741 (PMID 34741815):

Evaluation of geriatric assessment and management on the toxic effects of cancer treatment (GAP70+) is a cluster-randomized study conducted within the National Cancer Institute Community Oncology Research Program. The study primary objective was to examine whether a geriatric assessment intervention can reduce serious toxic effects in older patients with advanced cancer who are receiving high-risk treatment (e.g., chemotherapy). Eligible patients were aged 70 years or older, had incurable solid tumors or lymphoma, had at least 1 impaired geriatric assessment domain, and were starting a new treatment regimen. Practices were randomized to geriatric assessment intervention vs. usual care. Key results: In this cluster-randomized clinical trial of 40 community oncology practices and 718 eligible older patients with advanced cancer, providing a geriatric assessment summary with recommendations to oncologists reduced serious toxic effects from cancer treatment. Geriatric assessment with management should be integrated into the clinical care of older patients with advanced cancer and ageing-related conditions.

Brief description of dataset NCT02054741-D2:

This dataset provides the geriatric assessment recommendations by domain located in Supplemental Table 2. NCT02054741-D1 provides CONSORT, prevalence of toxicity, treatment intensity, survival, patient baseline characteristic, and treatment regimen data, as well as some of the effect of intervention variables. The longitudinal effect of intervention variables located in Table 3 can be found in NCT02054741-D3. Common haematological and non-haematological toxic effects identified in the results section are contained in NCT02054741-D4.

Unless otherwise specified, blank values indicate missing data.

The CONTENTS Procedure

Data Set Name	FINDAT.NCT02054741_D2	Observations	1606
Member Type	DATA	Variables	60
Engine	V9	Indexes	0
Created		Observation Length	208
Last Modified		Deleted Observations	0
Protection		Compressed	NO
Data Set Type		Sorted	NO
Label			
Data Representation	WINDOWS_64		
Encoding	wlatin1 Western (Windows)		

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Variables in Creation Order				
#	Variable	Type	Len	Label
1	PtID	Num	8	Patient ID, De-identified/Encrypted
2	Domain	Char	20	Corresponds to domain categories in Supplemental Table 2: Physical Performance, Functional Status, Comorbidity, Cognition, Nutrition, Social Support, Polypharmacy, Psychological Status
3	ToxCheck	Char	3	Conduct frequent toxicity checks: Yes/No
4	Fall	Char	3	Provide fall counseling hand-out: Yes/No
5	Exercise	Char	3	Provide information on exercise and exercise prescription: Yes/No
6	Energy	Char	3	Provide energy conservation hand-out: Yes/No
7	PsychoMeds	Char	3	Minimize psychoactive meds including those used for supportive care: Yes/No
8	DupMeds	Char	3	Minimize duplicative medications: Yes/No
9	SingleAgent	Char	3	Consider single agent rather than doublet therapy if appropriate: Yes/No
10	ModDose	Char	3	Modify dosage (e.g., 20% dose reduction with escalation as tolerated): Yes/No
11	ModTx	Char	3	Modify treatment regimen (e.g., use an option with demonstrated safety and efficacy in older and/or frail adults): Yes/No
12	PhysTherapy	Char	3	Refer to physical therapy (outpatient or home-based depending on eligibility for home care): Yes/No
13	OccTherapy	Char	3	Refer to occupational therapy: Yes/No
14	AideServ	Char	3	Refer to aide services: Yes/No
15	PERS	Char	3	Refer to Personal Emergency Response information (PERS): Yes/No
16	Vision	Char	3	Vision specialist if difficulties: Yes/No
17	OrthoBP	Char	3	Check orthostatic blood pressure: Yes/No
18	BPMeds	Char	3	Decrease or eliminate blood pressure meds if blood pressure is low or low normal: Yes/No
19	DirectComm	Char	3	Initiate direct communication (written, electronic, or phone) with patient's primary care physician about the plan for the patient's cancer: Yes/No
20	Diabetes	Char	3	Modify treatment choices if patient has history of diabetes - avoid neurotoxic agents if another option is equivalent: Yes/No
21	HeartFail	Char	3	Modify treatment choices if patient has history of heart failure - minimize volume of agents and/or administer treatments at a slower infusion rate: Yes/No
22	RenalImpair	Char	3	Modify treatment choices if patient has history of renal impairment - adjust as appropriate: Yes/No
23	ModSchedule	Char	3	Modify dosage or schedule if there is concern about how the patient will tolerate therapy or if there is a concern about worsening of comorbidities: Yes/No
24	Smoking	Char	3	Provide smoking cessation counseling if the patient currently smokes: Yes/No
25	Instructions	Char	3	Provide explicit and written instructions for appointments, medications, and treatment: Yes/No
26	MedReview	Char	3	Medication review - minimize psychoactive and high-risk medications: Yes/No
27	DecisionMaking	Char	3	Assess decision-making capacity and elicit health care proxy information and input if the patient lacks decision-making capacity: Yes/No
28	ModTxChoice	Char	3	Modify treatment choice (consider starting with single agent with escalation to doublet if standard at second cycle depending on tolerance): Yes/No
29	DeliriumRisk	Char	3	Give patient/family member hand-out on delirium risk counseling: Yes/No
30	CogEval	Char	3	Refer to clinician experienced in memory care: Yes/No
31	Nutrition	Char	3	Give nutrition hand-out: Yes/No

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Variables in Creation Order				
#	Variable	Type	Len	Label
32	Mucositis	Char	3	Give mucositis hand-out: Yes/No
33	Caution	Char	3	Use caution with highly emetogenic regimens and use another option if appropriate: Yes/No
34	Antiemetic	Char	3	Utilize aggressive anti-emetic therapy: Yes/No
35	Dietician	Char	3	Refer to nutritionist/clinical dietician: Yes/No
36	Dentist	Char	3	Refer to dentist if poor dentition or denture issues: Yes/No
37	Swallow	Char	3	Refer to speech and swallow if difficulty with swallowing: Yes/No
38	Proxy	Char	3	Confirm documented health care proxy is in medical record: Yes/No
39	ModTxDose	Char	3	Modify treatment choice and/or dosage: Yes/No
40	OnSite	Char	3	Provide referral/information on social work via on-site or visiting nurse services: Yes/No
41	HomeHealth	Char	3	Provide referral/information on visiting nurse service or home health aide (if meets criteria): Yes/No
42	RideProgram	Char	3	Provide referral/information on transportation or ride services: Yes/No
43	MedAdvise	Char	3	Provide referral/information on medical insurance advising, advocacy, and negotiation: Yes/No
44	Legal	Char	3	Provide referral/information on legal assistance for economic or social needs: Yes/No
45	Community	Char	3	Provide referral/information on community resource mobilization: Yes/No
46	BroughtMeds	Char	3	Ask patient to bring in prescribed, over-the-counter medication, and supplements to review at the next visit: Yes/No
47	PCPContact	Char	3	Contact primary care provider to help reduce regimen complexity: Yes/No
48	ReduceMeds	Char	3	Reduce medicines solely used for hypertension or diabetes if appropriate (including dose and number of medications): Yes/No
49	MedRefills	Char	3	Consult the pharmacist who fills the patient's scripts to synchronize medication refills whenever possible: Yes/No
50	EvalDrugs	Char	3	Have the pharmacist meet with the patient to evaluate drug interactions and medication counseling: Yes/No
51	MedCalendar	Char	3	Recommend pillbox and/or medication calendar: Yes/No
52	PolyHandOut	Char	3	Provide hand-out on polypharmacy: Yes/No
53	Comm	Char	3	Provide written or verbal communication with primary care physician: Yes/No
54	Counseling	Char	3	Refer to counseling or psychotherapy: Yes/No
55	SocialWork	Char	3	Refer to social work: Yes/No
56	Chaplaincy	Char	3	Refer to spiritual counseling or Chaplaincy services: Yes/No
57	Psychiatry	Char	3	Refer to psychiatry if severe symptoms or if already on medications which are not adequate: Yes/No
58	PallCare	Char	3	Refer to palliative care if other physical and/or cancer symptoms are present: Yes/No
59	PharmTherapy	Char	3	Initiate pharmacologic therapy if appropriate in conjunction with primary care provider: Yes/No
60	SupportGroup	Char	3	Provide linkage to community resources (such as support groups and local/national buddy or volunteer programs): Yes/No