NCT02054741-D1 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-D1:

This dataset 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. Data containing the geriatric assessment recommendations by domain in Supplemental Table 2 are located in NCT02054741-D2. 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.

Table of common acronyms in this data:

Acronym	Meaning
CTCAE	Common Terminology Criteria for Adverse Events
PRO	Patient Reported Outcome
GI	Gastrointestinal
GU	Genitourinary
Lymph	Lymphoma
Gyn	Gynaecological
IADL	Instrumental Activities of Daily Living
SPPB	Short Physical Performance Battery
OARS_PH	OARS Physical Health
GDS	Geriatric Depression Scale

The CONTENTS Procedure

Data Set Name	FINDAT.NCT02054741_D1	**Observations**	733
Member Type	DATA	**Variables**	43
Engine	V9	**Indexes**	0
Created		**Observation Length**	416
Last Modified		**Deleted Observations**	0
Protection		**Compressed**	NO
Data Set Type		**Sorted**	NO
Label			

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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	PhysID	Num	8	Physician ID, De-identified/Encrypted.
3	SiteID	Num	8	Site ID, De-identified/Encrypted. This is the clustering unit.
4	StudyArm	Char	7	Study Arm: GA (intervention) or Control (usual care)
5	Patient_718	Char	3	This patient is included in the final 718 patient list: Yes/No
6	PRO_Consort	Char	36	CONSORT flow PRO analysis: PRO data present; Protocol Violation; Withdrew or active with missing data; Patient died
7	Any_Toxicity	Char	3	Patient has any grade 3-5 CTCAE toxic effects over 3 months: Yes/No
8	Haem_Toxicity	Char	3	Patient has a haematological grade 3-5 CTCAE toxic effect over 3 months: Yes/No
9	Non_Haem_Toxicity	Char	3	Patient has a non-haematological grade 3-5 CTCAE toxic effect over 3 months: Yes/No
10	Cycle1_Reduce	Char	3	Patient had reduced dose intensity at cycle 1: Yes/No
11	Month3_Dose_Mod	Char	3	Patient had dose modified at 3 months related to toxicity: Yes/No
12	RDI	Num	8	Patient relative dose intensity (RDI) over 3 months
13	Survival6months	Num	8	Number of days patient survived in first 6 months after enrolling in trial: range 0 - 183 days
14	Survival1year	Num	8	Number of days patient survived in first year after enrolling in trial: range 0 - 366 days
15	Died6months	Char	3	Patient died within 6 months of enrolling: Yes/No
16	Died1year	Char	3	Patient died within 1 year of enrolling: Yes/No
17	Age	Char	3	Patient age in years, continuous: range 70-90+. Within this submission, individual ages of 90 or greater are grouped into a categorical option due to de-identification procedures
18	AgeCat	Char	5	Patient age in years, categorical: 70-79, 80-89, >=90
19	Gender	Char	6	Patient gender, categorical: Male, Female
20	Race	Char	18	Patient race/ethnicity, categorical: Non-Hispanic White, Black, Other
21	Marital	Char	32	Patient marital status, categorical: Single or never married; Married or domestic partnership; Separated, widowed, or divorced
22	Education	Char	21	Patient education, categorical: Less than high school, High school graduate, Some college or above
23	Income	Char	30	Patient income in USD, categorical: Less than or equal to $50,000, More than $50,000, Declined to answer
24	Cancer_Type	Char	16	Patient cancer type, categorical: Breast, Gastrointestinal, Genitourinary, Gynaecological, Lung, Lymphoma, Other
25	Cancer_Stage	Char	9	Patient cancer stage, categorical: Stage III, Stage IV, Other
26	Previous_Chemo	Char	3	Patient has previously received chemotherapy: Yes/No
27	Treatment_Type	Char	29	Patient treatment type, categorical: Single agent chemotherapy, Multiple agents chemotherapy, Chemotherapy and other agents, Non-chemotherapy
28	Number_GA	Num	8	Patient number of impaired GA domains, continuous: range 0-8 (lower is better)
29	Impaired_Physical	Char	3	Patient has impaired physical performance: Yes/No
30	Impaired_Polypharmacy	Char	3	Patient has impaired polypharmacy: Yes/No
31	Impaired_Comorbidity	Char	3	Patient has impaired comorbidity: Yes/No

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Variables in Creation Order				
#	**Variable**	**Type**	**Len**	**Label**
32	Impaired_Function	Char	3	Patient has impaired functional status: Yes/No
33	Impaired_Nutrition	Char	3	Patient has impaired nutrition: Yes/No
34	Impaired_Cognition	Char	3	Patient has impaired cognition: Yes/No
35	Impaired_Support	Char	3	Patient has impaired medical social support: Yes/No
36	Impaired_Psych	Char	3	Patient has impaired psychological status: Yes/No
37	Cancer_Regimen	Char	58	Patient cancer regimen at cycle one, categorical. Missing values indicate that the regimen was not common.
38	RX_Total	Num	8	Total number of prescription medications patient was taking at study enrollment, continuous: range 0-15
39	Rx_Discon	Num	8	Number of prescription medications discontinued before starting cancer treatment regimen, continuous: range 0-11
40	Meds_Total	Num	8	Total number of overall medications (prescription and non-prescription) patient was taking at study enrollment, continuous: range 0-24
41	Meds_Discon	Num	8	Number of overall medications (prescriptions and non-prescription) discontinued before starting cancer treatment regimen, continuous: range 0-13
42	Impaired_Falls	Char	3	Patient has impaired fall history: Yes/No
43	Fall_3m	Char	3	Patient fell at any point over 3 months since start of treatment: Yes/No