

Closeout Data and Resource Sharing Checklist

Data and Resource Sharing Checklist		
1. Study information		
Trial name and acronym: 'Pragmatic trial Of Video Education in Nursing homes' (PROVEN)		
Checklist completed by: Faye Dvorchak, Project Director		
Date: 7/23/2020		
Link to ClinicalTrials.gov registration: https://clinicaltrials.gov/ct2/show/NCT02612688		
Link to study website: https://rethinkingclinicaltrials.org/demonstration-projects/uh3-project-pragmatic-trial-of-video-education-in-nursing-homes-proven/		
2. Resource location		
Item	Provide hyperlink or indicate if item will be stored in the KR	If item will not be shared, please provide a brief explanation for the omission
Publications		
Link to protocol paper	https://pubmed.ncbi.nlm.nih.gov/28068789/	
Link to main outcome paper	https://pubmed.ncbi.nlm.nih.gov/32628258/	
Link to other study-related publications	https://pubmed.ncbi.nlm.nih.gov/29534863/ https://pubmed.ncbi.nlm.nih.gov/30134976/ https://pubmed.ncbi.nlm.nih.gov/30852167/ https://pubmed.ncbi.nlm.nih.gov/31357993/ https://pubmed.ncbi.nlm.nih.gov/31660609/ https://pubmed.ncbi.nlm.nih.gov/31588025/ https://pubmed.ncbi.nlm.nih.gov/31779684/ https://pubmed.ncbi.nlm.nih.gov/31886827/	
Study tools		
Final version of the protocol, including summary of changes	https://clinicaltrials.gov/ProvidedDocs/88/NCT02612688/Prot_SAP_000.pdf	

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Consent documents or consent process	N/A: We received a waiver of informed consent.	
Computable phenotypes for outcome measures	These are enumerated in our Protocol: https://clinicaltrials.gov/ProvidedDocs/88/NCT02612688/Prot_SAP_000.pdf	
Computable phenotypes for the inclusion/exclusion criteria	These are enumerated in our Protocol: https://clinicaltrials.gov/ProvidedDocs/88/NCT02612688/Prot_SAP_000.pdf	
Code for generating variables in the analytic dataset from standard sources	Our study data were obtained through two Data Use Agreements (DUAs): (1) Medicare claims, enrollment, and assessment data from the Centers for Medicare and Medicaid Services (CMS); and (2) electronic health record (EHR) data directly from the study nursing homes, which is not a standard source. We are not able to create a limited file from the EHR received directly from the nursing homes for two reasons. First, none of the "outcome" measures used in any of our primary and/or secondary outcomes were available in the way we had stipulated them in the ClinicalTrials.gov and our Protocol. The only data elements close to the outcome on the data routinely obtained from our partners' EHR was the variable "sent to hospital" from the nursing home. However, based upon considerable analyses cross-walking this variable and the data from CMS (which includes hospital claims for ED visits, Observation stays, and full admissions into the inpatient setting), we find that the nursing home generated hospitalization variable cannot replicate either the composite hospital transfer variable or any of the components very well at the individual level making it impossible to replicate our study results. Second, at least one of our partners is now the largest nursing home company in the country, and we cannot disguise this fact in any individual level data set. It is conceivable that someone could identify a particular facility by comparing the data to external data sources (e.g. bed size, staffing, etc.). This, in turn, would make it possible for individual patients to be identified with relative certainty.	<input type="checkbox"/> <i>In column at left because this column is too narrow.</i>
Datasets and documentation		
Annotated data collection forms	N/A	
Link to public use dataset	N/A: No public use data set. Please see response for "Code for generating variables in the analytic dataset from standard sources" above.	

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Data dictionary (proc contents) for public use dataset	N/A: No public use data set. Please see response for “Code for generating variables in the analytic dataset from standard sources” above.	
Other resources		