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CONCEPTUALISING THE DESIGN OF CLINICAL TRIALS AND ITS ASSOCIATED SUPPORT SYSTEMS IN INTERPLANETARY MISSIONS

Abstract

On earth, the best available evidence to inform decisions on the effectiveness of treatments are randomised controlled trials. Depending on relevance of the question, availability of resources and willingness of individuals, these trials range from few people to thousands. These trials are usually repeated across the world on different populations which provides further information on the generalisability of the effectiveness of interventions. Only a fraction of individuals on earth participate in clinical trials to provide the evidence basis for the larger population.

In aerospace medicine, the number of astronauts is quite limited so doing large clinical trials is difficult, the evidence in aerospace medicine is primarily relying on simulated studies on earth that can be randomised controlled trials or small case series with astronauts in space. However, the current discussions on long term mission to Mars and other planetary exploration raises the question what is the ideal approach of building an infrastructure to conduct clinical trials for long term interplanetary mission. Long term mission requires the continuous commitment and motivation of participants in the clinical trial – therefore patient involvement in the research process is more important. This paper uses recent empirical evidence on clinical trial methodology and patient and public involvement in research along with suggestion for innovative future methods development to build a conceptual framework on how clinical trial research infrastructure can be innovated in an inter-planetary mission. Some key aspects of the framework includes: (a) the involvement of the target population (astronauts) in all stages of the research process (b)

an integrated system for collecting and ranking uncertainties around health issues both by the members of the mission (astronaut) and responsible health care professional that will be ranked and rated internally to identify which issues are required to be addressed in future clinical trials (c) developing point of care randomisation systems for those highly ranked issue to facilitate conducting high quality randomised controlled trials(d) developing a live-system to design patient (in this case astronauts)-centred outcomes and collect data on them along with surrogate and physiological outcomes that inform these research systems (e) developing an inter-mission approach to conduct randomised clinical trials from one mission to another one to increase the sample size or alternatively design a central framework for a prospective meta-analysis collecting data from clinical trials conducted at each mission. The conceptualisation will inform an art installation experiment to engage with a larger number of individuals.