Importance of identifying factors that limit participation in genetic studies

For studies involving human research subjects it is, in general, crucial to keep up participation rates in order to reduce the risk of sample bias, that is, the systematic under-representation of certain groups in the study sample, which can potentially bias the research results. So far, genetic research has often faced greater difficulties than non-genetic research in recruiting participants, although participation rates can vary widely [1]. Recent discussions suggest that research subjects can experience 'research fatigue' after being over-researched, making them less prone to consent to further participation, indicating that there might be increasing difficulties in recruiting subjects in the future. This could be especially problematic for genetic studies that are added on to a plethora of existing non-genetic studies. In order to reduce non-participation, which may be due to a variety of factors, it is crucial for researchers to find out why different patient groups, and healthy individuals, choose not to participate in genetic research. While some factors may be strongly tied to specific patient categories, others may be of more general relevance [1].

A study by Lanfear and colleagues [1], published in this issue of Genome Medicine, addresses this important issue by examining a large number of factors potentially influencing recruitment to a genetic study of patients with myocardial infarction (MI). This work fills a gap in the literature regarding participation in genetic research among patients with acute illnesses, but the results of Lanfear and colleagues are also of general interest to anyone doing genetic research involving patient material. They identify one factor, the site of enrollment, as particularly important for successful recruitment, while their results indicate that most others are of limited relevance.

Significance of the enrollment site

Taking TRIUMPH (Translational Research Investigating Underlying disparities in recovery from acute Myocardial infarction: Patients’ Health status), a prospective multi-center registry of patients with MI, as their starting point, Lanfear et al. examined factors associated with participation or non-participation of registered patients with MI in a genetic sub-study [1]. Data for all patients included in the study, enrolled in the 24 hospitals involved in TRIUMPH, were collected. Using trained data collectors at each site, a broad spectrum of information was obtained, including data on health status, medical history, sociodemographic data, socioeconomic status and social support. Standardized sets of questions were used to quantify psychosocial and health status characteristics for each patient.

The overall consent rate to donate genetic material as part of the TRIUMPH sub-study was 80%, but Lanfear et al. observed considerable variations between the different enrollment sites. Rates of consent ranged from 100% of the patients enrolled in TRIUMPH to as low as 40%,
Optimal or ethical recruitment - or both?

Success in recruiting participants may, in principle, come at the price of side-stepping ethical requirements for research involving human subjects, such as providing appropriate information about relevant aspects of participation. This means that proven success in recruiting patients to genetic studies does not automatically imply that the recruitment process is to be recommended. Enrollment centers may at times prioritize satisfying the urge of researchers for a large amount of patient material over concern for patient autonomy and privacy. If trust relationships are to be maintained, which seems necessary for success in recruitment in the long run [8], disregarding patient interests would be the wrong way to proceed. The concerns and worries of actual and potential research subjects need to be dealt with thoughtfully. Confidentiality and proper data protection, and respect for privacy and autonomy, are themes that have been pointed out as particularly important by participants in genetic research [9,10].

Lanfear et al. touch upon ethical issues in the discussion of their article, where they underline the importance of close collaboration between researchers, coordinators and institutional review boards, among others, in order to guarantee that the interests of research subjects are well protected. Indeed, an underlying idea, shared by others [3,8], seems to be that good research ethics, in the sense of proper and respectful protection of the interests of actual and potential research subjects, is conducive to successful recruitment and thereby to high research quality.

Abbreviations

BMI, body mass index; MI, myocardial infarction.
Competing interests
The author declares that he has no competing interests.

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