

The personality structure of ‘normal’ volunteers

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The personality structure of 65 volunteers for a Phase 1 drug trial was examined using the Eysenck Personality Questionnaire. It revealed a common pattern of high extroversion, low neuroticism and psychoticism. The reasons why the study might attract such people are examined and the structure compared with those that take drugs that might have ‘strange or dangerous effects’. The likely forms of bias that this personality structure may bring to the trial are explored.

Keywords volunteers drug trial personality extroversion

Introduction

The development of any new drug requires assessment at a number of different levels. Phase 1 studies involve normal volunteers to determine whether the drug can be given to humans without serious side effects or toxicity whilst still producing the desired pharmacological effects. Volunteers for these studies must be fully informed as to the implications of the tests and give consent freely [1].

In the case of drugs working on the central nervous system (CNS) the subjective effects of the compounds may be important for both therapy and compliance. The assessment of these effects relies to a large extent on the self-report of the participant. Whilst placebo controlled studies help in identifying consistent effects of the drugs it is likely that particular personality types will influence the reporting of subjective symptoms. Trials of this nature rely on volunteers and not on random cross sections of the population and may therefore produce skewed results although Lasagna & von Felsinger [2] have suggested that drug effects are able to cut across any psychological distortions induced by the selection procedure.

To investigate this issue further Eysenck Personality Questionnaires (EPQ) [3] were given to all the participants in a Phase 1 trial of a centrally acting drug.

Method

All participants in a Phase I trial of a centrally acting drug were asked to fill in an EPQ following their introduction to the study by the responsible physicians. The possible risks, tests to be completed and the time over which these would be performed were explained and

participants could withdraw at this point. Informed consent to the trial was then obtained. The participants were also interviewed in an unstructured manner by two investigators (CJB and PMM) to identify the presence of psychiatric illness or major psychological distress. The interview included the broad categories of history and mental state covered in a routine clinical interview [4]. These included the use of illicit drugs and alcohol as well as brief personal histories. These details were not recorded formally, merely the suitability of the individual for the trial. The participant’s attitude to drug taking was more formally investigated by looking at their response to the question of the EPQ asking if they would take drugs that may have ‘strange or dangerous effects’. Participants were financially rewarded for their participation in the trial.

Results

Sixty-six males took part in the study for which 65 complete EPQs were available. The mean age of the participants was 24.23 years. The EPQ scores are reported in Table 1.

Thirteen (20%) participants indicated they would take drugs which may have ‘strange or dangerous effects’. The participants divided fairly evenly into two groups; the first were British and undertaking some

Table 1 Eysenck personality questionnaire scores

Neuroticism	Mean score 5.8	s.d. 2.5
Psychoticism	Mean score 3.8	s.d. 3.3
Extroversion	Mean score 17.95	s.d. 1.2

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form of higher education and the second were from South Africa and the Antipodes travelling around Europe. None was alcohol dependent but many drank often and at times heavily. None was addicted to illicit drugs and although many had experimented with various substances they found using alcohol a more pleasant experience. Many participated in sporting activities and the associated social functions. There were no cases of overt mental illness in the group.

Discussion

Opinion is divided as to the effects that volunteers bring to clinical trials [e.g. 2, 5]. No study has previously used a standardised instrument to look at the personality of normal volunteers, although they have been used to look for psychopathology and personality disorder in symptomatic volunteers [6]. From the EPQ results a clear pattern can be discerned. The pattern is one of low neuroticism and psychoticism with a high degree of extroversion. Eysenck & Eysenck [3] report a similar structure for their group of normal males age 20–29 years (extroversion 13.72, neuroticism 9.81 and psychoticism 4.19) but the extroversion score in our sample is more pronounced and the neuroticism score lower. This suggests that the volunteers are a group with little tendency to anxiety and who seek diversions from their routine [7]. Ayd [8] has suggested a number of reasons why volunteers participate in drug studies. The major impetus is financial. However it may represent an indirect way of getting medical help. This is of more importance when symptomatic volunteers are required [5, 9]. Escape from loneliness and stimulus seeking are also felt to be important [8]. It has been suggested that where payments are made for participation then the level of psychopathology of the volunteers is increased [2, 10]. Pollin & Perlin [11] found 52% of their sample show 'significant psychopathology' but this varied with a number of socio-cultural variables that underlay the motivations for volunteering and money was not a factor. Where money is a factor Ayd [8] suggested that an excess of obsessive and schizoid personality types were found. This is at odds with the findings above where the participants score at low levels on the psychoticism and the neuroticism scales.

This may suggest that risk taking or increasing the range of experience may be of importance for this group. Whilst the commonest overtly stated reason for involvement in the trial was financial, people with personality structures such as the one found above have been shown to seek new experiences. Gale [12] found that extroverts did more to relieve mild sensory deprivation than introverts and Judivinh & Happ [13] reported an association between the active seeking of new sensations and extroversion. Extroverts have been shown to 'increase the entropy of responsiveness' when performing tasks of a boring nature [14]. Eysenck [7] has described them as seeking diversion from their routine. This is in line with our observation that many of the participants were travelling around Europe far from their country of origin.

Thirteen (20%) participants replied yes to the EPQ item asking if they would take drugs that may have strange or dangerous effects. The personality structure

of users of drugs that may have strange or dangerous effects has been studied [15, 16]. Users of heroin were not distinguished by their extroversion scores [16] but are reported to have high neuroticism and psychoticism [17]. Cannabis users are also not distinguished by extroversion but it has been associated with a high neuroticism score [18]. Coan [15] suggests that its depressant effects are not welcomed by the extrovert but by the more neurotic. Many of the participants had used cannabis at some time but few were habitual users. Very few admitted to the use of other psychoactive drugs. This impression is in line with the personality profile of the group. The relationship between alcohol and extroversion is debatable with some investigators finding no clear relationship whilst others suggest that it is associated with drinking in men (see 19 for a review). Extroversion is also associated with social entertainments and talking with friends [7, 20]. In view of this the drinking may be a secondary phenomena. Many participants drank regularly and at times to excess. Their personality structure is suggestive of Type II alcoholics [21] who seek high novelty without concern for the harm it may engender (low harm avoidance). Whilst money is the most important motivation for this group, the structure of their personality attracts them to these trials. The trial provides a change from the usual regime, invokes a degree of camaraderie [11] and also entails a degree of uncertainty and risk. These are aspects of experience which are consistently sought by the extrovert.

The personality structure may also have the some influence on the effects that are likely to be reported by this group. They are low on neuroticism and unlikely to be prone to anxiety related symptoms be they of a somatic or psychological nature. Subjects with high extroversion scores do well in tests of immediate recall but less well on longer term tasks. The relatively low levels of arousal they experience are thought to lead to a failure of the consolidating processes required for such tasks [22, 23]. There may also be differences in vigilance tasks dependent upon the extroversion score [12, 14].

Conclusions

Young male volunteers for Phase 1 trials have a personality structure that is high in extroversion, low in neuroticism and psychoticism. It is important to have a 'normal' population for the assessment of drugs at this stage of their development. It is likely that aspects of the trials are likely to attract people with a personality structure high in extroversion who are in need of money and this is borne out in the study. The group are nonetheless very close to norms of Eysenck & Eysenck [3] and it is unlikely that those with personalities high in neuroticism or psychoticism, found in the community at large, will volunteer. The structure is different from those who take drugs that may have strange or dangerous effects outside of medical supervision.

The personality structure may have effects upon the frequency of reported side effects especially the somatic and psychic correlates of anxiety and also upon tasks of memory and vigilance.

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