CORRESPONDENCE

Pragmatic trials: how to adjust for the 'Hawthorne effect'?

Hashimoto *et al*[1] have conducted an interesting study to offer a practical and pragmatic insight into steroid-dependent asthma therapeutics in real-world practice. They proposed a strategy based on internet monitoring of objective (spirometry and fraction of exhaled nitric oxide) and subjective (asthma control and asthma-related quality of life questionnaires) measurements to adjust the dose of oral corticosteroids in patients with severe, uncontrolled asthma. However, how 'pragmatic' is a trial in which the patients have to sign an informed consent in order to participate in the study? Signing informed consents or receiving simple verbal instructions has been shown to significantly influence the outcome of interest in simple or more complicated studies.[2 3] This is known as the 'Hawthorne effect' or the unexpected and unexplained reactivity to experimentation in human subjects who are aware of their participation in a study.[4] Specifically in asthma, monitoring for drug intake improves adherence, which consequently is expected to affect treatment outcomes (eg, objective measurements, symptoms, asthma control and quality of life).[5] And indeed, in the study by Hashimoto *et al*,[1] the compliance with measuring forced expiratory volume in one second and fraction of exhaled nitric oxide or completing questionnaires was very high, suggesting a high adherence in asthma medication intake too. It will be of interest to somehow determine compliance with measuring objective and subjective parameters in the internet group outside the context of a study. It can be argued that the 'Hawthorne effect' should have influenced both the internet group and the conventional management group, although it will be very difficult, if not impossible, to measure the amount of the effect this phenomenon has on each experimental arm. However, compliance is of great importance especially for the internet group, since it may affect the parameters on which medication intake is based and thus the effectiveness of this clinical strategy as a corticosteroid sparing approach or even in terms of asthma control and quality of life.

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