

Carroll, K.M., Nich, C., McLellan, A.T., McKay, J.R., Rounsaville, B.J., 1999. 'Research' versus 'real-world' patients: representativeness of participants in clinical trials of treatments for cocaine dependence. Drug Alcohol Depend. 54, 171–177.

Rigorous clinical trials have been criticized as having limited external validity, and specifically that subjects participating in clinical trials are not representative of individuals seen in clinical practice. To assess the representativeness of subjects participating in clinical trials, 243 research subjects participating in clinical trials of treatments for cocaine dependence were compared to a sub-sample of 213 individuals being treated for cocaine dependence in outpatient clinical settings from a large national database. The data suggest that research findings are not invariably based on less challenging patients with mild forms of substance dependence and related problems; moreover research patients may be similar to, if not more severe than, individuals with cocaine problems seen in regular clinical settings in the community.

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