Title:
The Effect of Beliefs Concerning Treatment Allocation on Response to Medication in Clinical Addiction Trials.

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Introduction:
Despite robust evidence for the placebo effect few clinical trials assess the effect of participants’ beliefs about treatment assignment on outcomes. We asked participants enrolled in a randomised controlled trial testing the efficacy of a cannabis agonist (nabiximols) for treating cannabis dependence what treatment (nabiximols versus placebo) they believed they had been assigned to, in order to determine whether these beliefs affected the number of days they used illicit cannabis.

Method
Number of days’ use of illicit cannabis in the previous 28 days and beliefs about treatment allocation were measured once every four weeks during the 12-week trial.

Key Findings
Though the original intention was to conduct a two-factor multiple regression (treatment x guessed treatment) at each of the three time points, the number of participants who received nabiximols but guessed placebo were too low for valid inference. As a result the analysis was restricted to those allocated to the placebo arm only (guessed placebo n=20, guessed nabiximols n=32). In all three periods the mean number of days’ use of illicit cannabis was lower in the group who guessed they received nabiximols than in the group who guessed placebo. This difference was non-significant in the first 4-week period, significant in the second (t35=2.09, p=0.044), and near-significant in the third (t35=2.02, p=0.051).

Discussions and Conclusions:
These results support the theory that a part of pharmacological treatments’ ability to reduce substance use can be ascribed to patients’ belief in the efficacy of these treatments.

Disclosure of Interest Statement:
Study drug (nabiximols and placebo) were provided free of charge by GW Pharmaceuticals, UK.