The effectiveness of a brief motivational nursing intervention to reduce psychoactive substance consumption in entertainment-sector workers: A transversal, observation, and semi-experimental study. Is it a trial and should it have been registered?

Richard GRAY RN PhD¹, Ellie BROWN DCounsPsych²

1. School of Nursing and Midwifery, La Trobe University, Melbourne, Australia, 3084
2. Centre for Youth Mental Health, The University of Melbourne, 35 Poplar Road, Parkville, Victoria 3052, Australia

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PROF. RICHARD GRAY (Orcid ID : 0000-0001-9694-4206)

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Corresponding author mail id: r.gray@latrobe.edu.au

Is it a trial? Should it be registered?

Dear editor,

We read with interest the paper by Almodóvar-Fernandez et al., (2019). The authors state they are reporting “a transversal, observation, and semi-experimental study.” The study is in two parts: the first a survey of 284 entertainment workers, the second a trial of the effect of a brief motivational interviewing intervention on the health-related quality of life of entertainment business workers. Trials should be prospectively registered (before the first participant is enrolled) (De Angelis et al., 2004). The International Journal of Mental Health Nursing author guidelines requires that “clinical trials are prospectively registered in a publicly accessible database.” Almodóvar-Fernandez et al., (2019) do not appear to have registered their trial. It is a standard error to think that only randomised controlled trials need to be registered; this is not correct. The World Health Organisation defines a clinical trial as “...any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes” (WHO, n.d.). In this study, were participants prospectively assigned? Yes, they were. Were they assigned to one or more health-related intervention? Again, yes. And this is the part of the definition of a trial that trips up many investigators (reviewers and editors); a study with one group is still a trial and therefore should be prospectively registered. Prospective trial registration is designed to promote transparent reporting and researcher accountability by minimising publication and selective reporting bias. Because the trial was not prospectively registered we, the readers, have no idea if the authors have amended the order in which they have reported outcomes, or have omitted some outcomes

altogether. It has been mandatory since 2005 for trials submitted to leading medical journals to be prospectively registered (De Angelis et al., 2004). Nurse authors, reviewers, and editors are seemingly either not aware of, or are indifferent to trial registration (Gray et al., 2017); this should make nurse academics extremely uncomfortable. Journal editors are ultimately accountable for the papers they publish. In our opinion, the editors responsible for the Almodóvar-Fernandez et al., (2019) paper should have been aware that the authors were reporting a trial and should have required – before publication – that authors retrospectively register the study and provide an explanation as to why it was not prospectively registered.

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Author/s:

Gray, R;Brown, E

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