# Exclusions from clinical trials in Australia based on proficiency in English

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The exclusion of migrants and members of ethnic minorities from clinical trials is common and can compromise the generalisability of research findings.[1] Reasons for these exclusions are complex, but communication difficulties probably contribute.[1]

We examined inclusion and exclusion criteria for all clinical trials to be conducted in Australia that were registered between 1 June 2015 and 31 August 2015. Data were obtained from the World Health Organization International Clinical Trials Registry Platform (http://www.who.int/ictrp/en/), which combines data from several sources, including the Australian New Zealand Clinical Trials Registry. Trials were deemed to exclude participants with low English proficiency if explicit statements to this effect were included in the inclusion or exclusion criteria.

We found that 71 of 342 trials (21%) specifically stated that participants with low English proficiency would be excluded. Only one trial registered during this period specifically targeted participants with low English proficiency by providing translated material. Documented exclusions of participants with low English proficiency were nearly three times as common in trials of treatments for pain (prevalence ratio [PR], 2.95; 95% confidence interval [CI], 1.87–4.66) and mental health problems (PR, 2.64; 95% CI, 1.72–4.05) as in cancer treatment trials.

Data on the types of outcomes examined in the trials and how likely these outcomes were to require English language proficiency were used to construct an English proficiency impact score (ranging from 1 [no impact] to 4 [outcomes required English proficiency]); types of interventions were categorised by a similar approach. Trials in mental health and pain therapy had high English proficiency impact scores for both the measurement of outcomes, which were often questionnaire-based, and for interventions, which often involved counselling or reading extensive web-based material.

One in five registered clinical trials in Australia documented exclusion of participants with low English proficiency. The proportion is, in practice, probably higher, as trials may exclude participants with low English proficiency during the informed consent process, even when English proficiency was not included in the exclusion criteria.[1]

Our results are important because 28% of the Australian population are migrants.[2] Although being a migrant does necessarily entail being less fluent in English, lower English proficiency is particularly common in older migrants from culturally and linguistically diverse backgrounds (CALD).[3] Older CALD migrants therefore constitute a group at risk of being excluded from clinical research.

Trial exclusions are particularly relevant if there is reason to believe that the effectiveness of interventions may be different in the excluded groups. However, without including migrants with low English proficiency in research trials, it is difficult to establish whether treatment effectiveness varies between populations. The available evidence suggests that the effectiveness of treatments of chronic pain[4] and mental ill health[5] does, in fact, differ for people from different cultural backgrounds. Accordingly, it is particularly important that the participation of CALD migrants in research in these areas is improved. Possible approaches could include recruiting research staff fluent in other languages, and preparing translated and culturally validated versions of commonly used questionnaires.

**Competing interests:** No relevant disclosures. ■

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1 Glickman SW, Ndubuizu A, Weinfurt KP, et al. The case for research justice: inclusion of patients with limited English proficiency in clinical research. *Acad Med* 2011; 86: 389-393.

2 Australian Bureau of Statistics. 3412.0. Migration Australia, 2014–15 [webpage]. Mar 2016. http://www.abs.gov.au/AUSSTATS/abs@.nsf/allprimarymainfeatures/FA3FC34994687B3BCA2580F2000BF1C7?opendocument (accessed July 2016).

3 Federation of Ethnic Communities' Councils of Australia. Review of Australian research on older people from culturally and linguistically diverse backgrounds. Canberra: FECCA, 2015. http://fecca.org.au/wp-content/uploads/2015/06/Review-of-Australian-Research-on-Older-People-from-Culturally-and-Linguistically-Diverse-Backgrounds-March-20151.pdf (accessed July 2016).

4 Brady B, Veljanova I, Chipchase L. Are multidisciplinary interventions multicultural? A topical review of the pain literature as it relates to culturally diverse patient groups. *Pain* 2016; 157: 321-328.

5 Erdal K, Singh N, Tardif A. Attitudes about depression and its treatment among mental health professionals, lay persons and immigrants and refugees in Norway. *J Affect Disord* 2011; 133: 481-488. ■

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