



Research

A multifactorial intervention for frail older people is more than twice as effective among those who are compliant: complier average causal effect analysis of a randomised trial

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KEY WORDS

Compliance
Adherence
Frail elderly
Randomised controlled trial
Exercise



ABSTRACT

Question: What is the effect of a multifactorial intervention on frailty and mobility in frail older people who comply with their allocated treatment? **Design:** Secondary analysis of a randomised, controlled trial to derive an estimate of complier average causal effect (CACE) of treatment. **Participants:** A total of 241 frail community-dwelling people aged ≥ 70 years. **Interventions:** Intervention participants received a 12-month multidisciplinary intervention targeting frailty, with home exercise as an important component. Control participants received usual care. **Outcome measures:** Primary outcomes were frailty, assessed using the Cardiovascular Health Study criteria (range 0 to 5 criteria), and mobility measured using the 12-point Short Physical Performance Battery. Outcomes were assessed 12 months after randomisation. The treating physiotherapist evaluated the amount of treatment received on a 5-point scale. **Results:** 216 participants (90%) completed the study. The median amount of treatment received was 25 to 50% (range 0 to 100). The CACE (ie, the effect of treatment in participants compliant with allocation) was to reduce frailty by 1.0 frailty criteria (95% CI 0.4 to 1.5) and increase mobility by 3.2 points (95% CI 1.8 to 4.6) at 12 months. The mean CACE was substantially larger than the intention-to-treat effect, which was to reduce frailty by 0.4 frailty criteria (95% CI 0.1 to 0.7) and increase mobility by 1.4 points (95% CI 0.8 to 2.1) at 12 months. **Conclusion:** Overall, compliance was low in this group of frail people. The effect of the treatment on participants who comply with allocated treatment was substantially greater than the effect of allocation on all trial participants. **Trial registration:** Australian and New Zealand Trial Registry ANZCTR12608000250336. [Fairhall N, Sherrington C, Cameron ID, Kurrle SE, Lord SR, Lockwood K, Herbert RD (2016) A multifactorial intervention for frail older people is more than twice as effective among those who are compliant: complier average causal effect analysis of a randomised trial. *Journal of Physiotherapy* 63: 40–44]

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Introduction

The number and proportion of older people in the global population are rapidly rising.¹ Frailty and mobility impairment increase the risk of dependence, hospitalisation and death in older people.^{2–3} Interventions that reduce frailty and improve mobility have the potential to benefit older people and society.⁴

The recommended primary approach to analysis of randomised, controlled trials is analysis by intention to treat.⁵ Clinical trials in frail older people are particularly affected by variable compliance to treatment; some people randomised to the intervention group will not undertake the intended treatment and some will undertake part or all of the treatment.⁶ A range of statistical techniques can provide estimates of the average causal treatment effect among compliant participants.^{7,8} The framework and assumptions of these techniques have been described in detail

elsewhere.⁹ Briefly, we assume that at the start of a trial all participants have an unobservable inherent trait that determines whether or not they will comply with the allocated treatment. As randomisation results in the expectation of an equal distribution of compliers and non-compliers to the intervention and control groups, we can observe the proportion of compliers and non-compliers in the treatment group and infer the proportions in the control group. Herein we use the term *complier* to describe a participant who undertakes treatment if allocated to the treatment group and does not undertake treatment if allocated to the control group. The term *treatment received* is used to describe the observed amount of treatment undertaken by trial participants.

In our randomised, controlled trial of 241 frail older people, the intention-to-treat analysis demonstrated that the multifactorial intervention caused worthwhile improvements in frailty and mobility, compared to usual care.⁹ The effect of actually

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