

LETTER

Should persons with autosomal dominant AD be included in clinical trials? Authors' response

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See related review by Szigeti and Doody, <http://alzres.com/content/3/1/4>, and related letter by Grill and Ringman, <http://alzres.com/content/3/3/18>

We would like to thank Grill and Ringman [1] for their thoughtful response to our article [2] in which we made the case that both early-onset sporadic Alzheimer's disease (AD) cases and known or suspected mutation carriers should generally be enrolled in clinical trials. There is consensus between our groups that excluding patients on the basis of age criteria alone is not valid. In regard to enrollment of patients with known or suspected autosomal dominant AD, the authors caution that these subjects may have a different response or different side-effect profile to a given intervention. We considered this possibility in our review; however, there are no human data and only scant preclinical data to support this hypothesis. Available preclinical studies so far are insufficient to support excluding all mutation carriers from all trials. Furthermore, it is likely that sporadic AD populations also contain between-subject differences that could produce differences in the magnitude or likelihood of response to a treatment as well as differences in side effects. Random assignment of subjects in clinical trials is designed to counter such unknown differences. Although it is possible that preclinical development programs may

uncover a rationale for excluding a particular mutation from a particular trial, our conclusion was that, until there are sufficient clinical trials that include mutation carriers alone or as a separate arm, these individuals should have the right to participate and should not be excluded *categorically*.

Abbreviations

AD, Alzheimer's disease.

Competing interests

The authors declare that they have no competing interests.

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References

1. Grill JD, Ringman JM: Should persons with autosomal dominant AD be included in clinical trials? *Alzheimers Res Ther* 2011, **3**:18.
2. Szigeti K, Doody RS: Should EOAD patients be included in clinical trials? *Alzheimers Res Ther* 2011, **3**:4.

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