A pragmatic, multicentre, double-blind, placebo-controlled randomised trial to assess the safety, clinical and cost-effectiveness of mirtazapine and carbamazepine in people with Alzheimer's disease and agitated behaviours: the HTA-SYMBAD trial

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Plain language summary

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Plain language summary

It is common for people with Alzheimer's disease to experience agitation, for example feeling restless or unsettled. If left untreated, agitation can lead to poorer quality of life and increased hospitalisation and strain for family carers. Often these symptoms are treated with medications that are usually used to manage psychosis (antipsychotic drugs), but such medication has limited effectiveness and can cause serious adverse effects to patients, including risk of increased death. Two medications that are already commonly prescribed for other health issues, mirtazapine (an antidepressant) and carbamazepine (a drug used to treat epilepsy), had been identified as a possible alternative way of treating agitation in Alzheimer's disease that might not have the harms associated with antipsychotic medication.

In this study, we compared the effects of giving mirtazapine or carbamazepine with a dummy drug (placebo) in people with Alzheimer's disease who were experiencing agitation. The results of the study showed that neither medication was any more effective than the placebo in reducing agitation over 12 weeks in terms of improving symptoms, or in economic terms. Mirtazapine may lead to additional carer costs as compared to placebo. The study findings are stronger for mirtazapine than carbamazepine because the carbamazepine arm was stopped when it had recruited less than half the numbers needed. That was done because the study was not recruiting quickly enough to support both the mirtazapine and the carbamazepine arms.

The findings from this study show that mirtazapine should not be recommended to treat agitation in Alzheimer's disease. More work is needed to formulate effective ways and to test new drug and non-drug treatments for agitation in dementia.

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This report

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