Primary outcome reporting in clinical trials for older adults with depression

Additional File C

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Table C1. Framework used to classify outcomes reported in included trials.

Core area [a]	Outcome domain [a]	Outcome subdomain [a]	Outcome term [a]	Definition	Patient-important outcome major domain [b]	Patient-important outcome subdomain [b]	Patient-important outcome term [b]	Outcome type [c]	Number of trials which reported outcome term as single, discernable primary outcome (%)
Physiological/ Clinical	Psychiatric outcomes	Depression outcomes	Depression relapse	The opposite of remission. Assessment of the continual presence of the symptoms of depression. Often a binary measure for meeting a threshold value assessed at the end of the trial.	None	None	None	Patient-reported	1 (3%)
			Depression remission	The extent to which symptoms of depression have been resolved by the intervention/comparator. Often a binary measure for meeting a threshold value assessed at the end of the trial (no threshold specified).	Other	Medication efficacy	Goal of the treatment: recovery	Patient-reported	1 (3%)
			Depression treatment response	The extent to which symptoms of depression have been resolved by the intervention/comparator. Often a difference (continuous measure) comparing baseline and final scores on measures for participants.	Other	Medication efficacy	Goal of the treatment: recovery	Patient-reported	12 (39%)
			Depressive symptom severity	The extent to which symptoms of depression affect the patient, and may range from 'mild' to 'severe'. Often a difference (continuous measure) comparing final scores between arms.	Other	Medication efficacy	Less residual symptoms	Patient-reported	15 (48%)
Life Impact	Delivery of care	N/A	Provider treatment adherence	Compliance of primary care physicians in implementing guideline recommendations for management of older adults with depression (management trial).	None	None	None	Clinician-reported	1 (3%)
Resource Use	Economic	N/A	Cost-effectiveness of study interventions	Economic analysis comparing the relative costs and outcomes of different interventions / comparators used in the trial.	None	None	None	Other	1 (3%)

Notes:

a: Outcome terms were mapped onto three existing frameworks. First, all outcome terms were assigned to the taxonomic classification system proposed by Dodd et al. (2018), which comprise five "core areas": physiological/clinical, life impact, resource use, adverse events, and death, comprised of suggested domains and with the option for the user to add subdomains. We classified outcomes using this framework in our previous study (Rodrigues et al., 2023).

Additional note: Although there are five core areas, no outcomes in our current study fell under the areas of "adverse events" or "death".

b: Second, all outcome terms were mapped to a list of patient-important outcomes identified by a recent global survey (Chevance et al., 2020), which categorized outcome terms into three major domains: symptom-related, improvement of functioning, and other with subdomains.

c: Third, we classified outcome types: clinical (i.e., physical examinations), surrogate markers (i.e., neurobiomarkers), reported by patients, carers or clinicians (i.e., psychometric scales or adherence), or other (i.e., economic analyses) (Papakostas, 2012).

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