

A3.26 Randomisation Request Form: HTA-SADD Trial

To register a participant in the HTA-SADD Trial, please first complete this form and then email, fax or telephone the Mental Health & Neurology Clinical Trials Unit (MH&N CTU) at the Institute of Psychiatry.

The office is open for randomisations 9am to 5pm, Monday to Fridays, not Bank Holidays.

Email: randomization_request@iop.kcl.ac.uk **Telephone No.:** 0207 848 5282 **Fax No.:** 0207 848 5229

NB: It is important to identify the HTA-SADD Trial – this telephone line is used for randomisations for a number of trials. There may be delay in response of up to 24 hours from request.

Request from:			Date of Request: _ / _ / _ _ _ (dd/mm/yyyy)	
Centre <i>(Circle which centre request is for)</i>	Birmingham	01	Newcastle	06
	Cambridge	02	North London	07
	Leicester	03	Southampton	08
	Liverpool	04	South London & Kent	09
	Manchester	05		

PARTICIPANT DETAILS:

PIN		PIN Initials	
Gender	Male / Female	Date of Birth (dd/mm/yyyy)	_ / _ / _ _ _
CIN		CIN Initials	

INCLUSION CRITERIA – All answers must be **YES** for the participant to be eligible

	YES	NO
1 Participant has a clinical diagnosis of mild to moderate probable or possible Alzheimer's Disease		
2 Participant has a co-existing depressive illness likely to need treatment with antidepressants		
3 Depression duration more than four weeks at referral		

EXCLUSION CRITERIA – All answers must be **NO** for the participant to be eligible

	YES	NO
1. Participant is currently taking antidepressants		
2. Dementia too severe to complete baseline CSDD		
3. The case is considered too critical to be randomised (eg because of suicide risk)		
4. Participant displays absolute contraindications to one or more of the trial treatments		
5. Participant is entered on another trial		
6. There is no identifiable family carer or other informant to give collateral information		
7. Participant has a baseline CSDD score of 7 or under		

BASELINE DATA:

CSDD Available & Ratable	Score: _____
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I confirm that the above is complete and correct and that all vital baseline data is available:

Signature:	Date:
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