



Ltf, Lost to follow-up

Figure 1 Participant flow for the Journey through Dementia Trial (JtD) trial

Table 1: Baseline characteristics by randomised group for all randomised participants (n=480)

Characteristic	Intervention (n=241)	Control (n=239)	All (n=480)
Site			
S01	23 (10%)	24 (10%)	47 (10%)
S02	21 (9%)	20 (8%)	41 (9%)
S04	14 (6%)	15 (6%)	29 (6%)
S05	33 (14%)	33 (14%)	66 (14%)
S06	19 (8%)	19 (8%)	38 (8%)
S07	23 (10%)	23 (10%)	46 (10%)
S08	20 (8%)	19 (8%)	39 (8%)
S09	18 (7%)	17 (7%)	35 (7%)
S10	32 (13%)	32 (13%)	64 (13%)
S11	11 (5%)	10 (4%)	21 (4%)
S12	10 (4%)	10 (4%)	20 (4%)
S13	6 (2%)	6 (3%)	12 (3%)
S15	11 (5%)	11 (5%)	22 (5%)
Sex			
Male	136 (56%)	143 (60%)	279 (58%)
Female	105 (44%)	96 (40%)	201 (42%)
Ethnicity			
English / Welsh / Scottish / Northern Irish / British	228 (95%)	230 (96%)	458 (95%)
↓			
Irish	5 (2%)	2 (1%)	7 (1%)
Any other White background	5 (2%)	0 (0%)	5 (1%)
Indian	0 (0%)	3 (1%)	3 (1%)
Any other Asian background	1 (0%)	0 (0%)	1 (0%)
Any other mixed / multiple ethnic background	0 (0%)	2 (1%)	2 (0%)
Caribbean	1 (0%)	1 (0%)	2 (0%)
Any other ethnic group	0 (0%)	1 (0%)	1 (0%)
Prefer not to say	1 (0%)	0 (0%)	1 (0%)
Lives with others*			
No	62 (26%)	63 (26%)	125 (26%)

Characteristic	Intervention (n=241)	Control (n=239)	All (n=480)
Yes	178 (74%)	176 (74%)	354 (74%)
Lives with			
Spouse/partner	156 (65%)	157 (66%)	313 (65%)
Child/children	15 (6%)	6 (3%)	21 (4%)
Both partner and children	5 (2%)	10 (4%)	15 (3%)
Other	2 (1%)	3 (1%)	5 (1%)
Accommodation type			
Sheltered or retirement housing	27 (11%)	16 (7%)	43 (9%)
Own home	207 (86%)	218 (91%)	425 (89%)
Friend / relative's home	7 (3%)	3 (1%)	10 (2%)
Other	0 (0%)	2 (1%)	2 (0%)
Age			
N (%)	241 (100%)	239 (100%)	480 (100%)
Mean (SD)	77 (7.0)	77 (7.7)	77 (7.3)
Median (IQR)	78 (73, 82)	78 (72, 82)	78 (73, 82)
Min., Max.	56, 93	39, 91	39, 93

Max., maximum; Min., minimum. Site ID codes represent JtD sites. See Appendix 3 for information on the Trusts involved in the study.* One response was missing from a participant on the intervention arm.

Table 2: Baseline medical history by randomised group for all randomised participants (n=480)

Characteristic	Intervention (n=241)	Control (n=239)	All (n=480)
Type of dementia diagnosed			
Alzheimer's	142 (59%)	148 (62%)	290 (60%)
Vascular dementia	31 (13%)	19 (8%)	50 (10%)
Mixed Alzheimer's / vascular dementia	51 (21%)	58 (24%)	109 (23%)
Dementia in Parkinson disease	3 (1%)	3 (1%)	6 (1%)
Frontotemporal dementia (FTD)	5 (2%)	2 (1%)	7 (1%)
Lewy body dementia	1 (0%)	3 (1%)	4 (1%)
Unspecified dementia	7 (3%)	5 (2%)	12 (3%)
Other	1 (0%)	1 (0%)	2 (0%)
Length of time since dementia diagnosis (yrs)			
N (%)	241 (100%)	238 (100%)	479 (100%)
Mean (SD)	1.3 (1.5)	1.3 (1.7)	1.3 (1.6)
Median (IQR)	0.7 (0.3, 1.8)	0.8 (0.3, 1.8)	0.7 (0.3, 1.8)
Min., Max.	0.0, 7.9	0.0, 13.0	0.0, 13.0
Medical history			
Stroke	33 (13.7%)	37 (15.5%)	70 (14.6%)
Diabetes	40 (16.6%)	41 (17.2%)	81 (16.9%)
Heart or chest problems	75 (31.1%)	74 (31.0%)	149 (31.0%)
Arthritis/Mobility problems	102 (42.3%)	105 (43.9%)	207 (43.1%)
Falls/dizziness/blackouts	61 (25.3%)	58 (24.3%)	119 (24.8%)
Anxiety/Depression	43 (17.8%)	49 (20.5%)	92 (19.2%)
High blood pressure	82 (34.0%)	72 (30.1%)	154 (32.1%)
Other	91 (37.8%)	117 (49.0%)	208 (43.3%)

Max., maximum; Min., minimum

Table 3: Baseline measurements by randomised group for all randomised participants (n=480)

Participant outcome measure		Intervention (n=241)	Control (n=239)	All (n=480)
MMSE (total score)	Mean (SD)	24.5 (3.1)	24.6 (3.2)	24.6 (3.1)

Participant outcome measure		Intervention (n=241)	Control (n=239)	All (n=480)
	N (%)	241 (100%)	239 (100%)	480 (100%)
MMSE cognitive impairment				
	Mild	92 (38%)	87 (36%)	179 (37%)
	Normal	149 (62%)	152 (64%)	301 (63%)
DEMQOL (total score)				
	Mean (SD)	90.8 (13.0)	90.3 (13.2)	90.6 (13.1)
	N (%)	241 (100%)	239 (100%)	480 (100%)
DEMQOL quality of life overall (Q29)				
	Poor	5 (2%)	5 (2%)	10 (2%)
	Fair	43 (18%)	45 (19%)	88 (18%)
	Good	123 (51%)	109 (46%)	232 (48%)
	Very good	70 (29%)	80 (33%)	150 (31%)
PHQ-9 (total score)				
	Mean (SD)	4.2 (4.4)	4.0 (4.4)	4.1 (4.4)
	N (%)	241 (100%)	239 (100%)	480 (100%)
PHQ-9 Depression severity				
	None (0 to 4)	156 (65%)	152 (64%)	308 (64%)
	Mild (5 to 9)	52 (22%)	58 (24%)	110 (23%)
	Moderate (10 to 14)	25 (10%)	23 (10%)	48 (10%)
	Moderately severe (15 to 19)	6 (2%)	3 (1%)	9 (2%)
	Severe (20 to 27)	2 (1%)	3 (1%)	5 (1%)
GAD-7 (total score)				
	Mean (SD)	2.8 (3.6)	2.8 (3.5)	2.8 (3.5)
	N (%)	241 (100%)	238 (100%)	479 (100%)
GAD-7 anxiety severity				
	Mean (SD)	0.77 (0.21)	0.78 (0.19)	0.77 (0.20)

Participant outcome measure		Intervention (n=241)	Control (n=239)	All (n=480)
EQ-5D-5I (crosswalk value index)	N (%)	241 (100%)	239 (100%)	480 (100%)
EQ-5D VAS	Mean (SD)	75.6 (16.7)	73.8 (17.8)	74.7 (17.3)
	N (%)	241 (100%)	238 (100%)	479 (100%)
GSE (total score)	Mean (SD)	30.4 (5.5)	30.9 (5.4)	30.6 (5.5)
	N (%)	239 (99%)	238 (100%)	477 (99%)
Diener's Flourishing scale	Mean (SD)	45.3 (6.7)	45.6 (7.2)	45.5 (6.9)
	N (%)	240 (100%)	233 (97%)	473 (99%)
SMA	Mean (SD)	124.6 (20.7)	125.6 (19.5)	125.1 (20.1)
	N (%)	235 (98%)	236 (99%)	471 (98%)
IADL (total score)	Mean (SD)	5.7 (1.8)	5.8 (1.9)	5.7 (1.8)
	N (%)	237 (98%)	234 (98%)	471 (98%)

Max., maximum; Min., minimum

MMSE is measured on a scale from 0-30, higher scores indicate better cognitive function; we used the cut-off scores of 21-26 for mild dementia to identify the trial population

DEMQOL is measured on a scale from 28 to 112, higher scores represent higher health-related Quality of Life.

PHQ-9 is measured on a scale from 0 to 27, with higher scores indicating more severe depressive symptoms.

GAD-7 is measured on a scale from 0 to 21, higher scores represent increasing severity of anxiety.

EQ-5D-5L score is measured on a scale from -0.224 to 1.00 (full health).

EQ-5D VAS is measured on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state).

GSE is measured on a scale from 10 to 40, higher scores indicate more self-efficacy.

Diener's Flourishing scale is measured from 0 to 56, higher scores represent more psychological resources and strengths.

SMAS is measured on a scale from 30 to 175, higher score indicates greater self-management ability

IADL is measured on a scale from 0 to 8, higher scores represent lower level of dependence.

Table 4: Comparison of mean 8-month patient reported quality of life outcomes by treatment group (n=388)

Outcome	Treatment group			
	Intervention		Control	
	n	Mean (SD)	n	Mean (SD)
DEMQOL score	191	93.3 (13.0)	197	91.9 (14.6)
PHQ-9 (total score)	186	3.4 (4.2)	193	3.6 (4.8)
GAD-7 (total score)	185	2.4 (3.5)	192	2.4 (3.8)
EQ-5D-5L (crosswalk value index)	190	0.78 (0.21)	195	0.78 (0.22)
EQ-5D VAS	188	74.6 (18.3)	193	72.1 (18.0)
GSE (total score)	178	30.1 (5.5)	185	29.5 (5.8)
Diener's Flourishing scale	169	46.0 (6.3)	177	45.1 (7.1)
SMAS	171	124.8 (20.2)	176	123.7 (18.1)
IADL (total score)	181	5.2 (1.8)	190	5.2 (1.9)

DEMQOL is measured on a scale from 28 to 112, higher scores represent higher health related QoL.

PHQ-9 is measured on a scale from 0 to 27, with higher scores indicating more severe depressive symptoms. GAD-7 is measured on a scale from 0 to 21, higher scores represent increasing severity of anxiety. EQ-5D-5L score is measured on a scale from -0.224 to 1.00 (full health). EQ-5D VAS is measured on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state). GSE is measured on a scale from 10 to 40, higher scores indicate more self-efficacy. Diener's Flourishing scale is measured from 0 to 56, higher scores represent more psychological resources and strengths. SMAS is measured on a scale from 30 to 175, higher score indicates greater self-management ability. IADL is measured on a scale from 0 to 8, higher scores represent lower level of dependence.

Table 5: Comparison of mean 12-month secondary participant quality of life outcomes by treatment group (n=356)

Outcome	Treatment group			
	Intervention		Control	
	n	Mean (SD)	n	Mean (SD)
DEMQOL (total score)	172	92.3 (14.3)	180	91.7 (13.9)
EQ-5D-5L (crosswalk value index)	170	0.79 (0.22)	178	0.78 (0.22)
EQ-5D VAS	173	70.8 (19.1)	177	70.9 (19.1)

DEMQOL is measured on a scale from 28 to 112, higher scores represent higher health-related quality of life. EQ-5D-5L score is measured on a scale from -0.224 to 1.00 (full health). EQ-5D VAS is measured on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state). A positive mean difference implies the intervention group had the better health-related quality of life.

Table 6: Serious adverse events by treatment group (n=480)

Serious Adverse Events	Intervention (n=241)	Control (n=239)	All (n=480)
Number of participants who experienced ≥ 1 SAE	40	35	75
Number of all SAEs (including repeated events)	61	39	100
Occurred			
Before randomisation	3 (5%)	1 (3%)	4 (4%)
After randomisation	58 (95%)	38 (97%)	96 (96%)
Seriousness			
Death	10 (16%)	5 (13%)	15 (15%)
Life threatening	3 (5%)	2 (5%)	5 (5%)
Inpatient hospitalisation	45 (74%)	31 (79%)	76 (76%)
Prolongs hospitalisation	1 (2%)	0 (0%)	1 (1%)
Persistent or significant disability/incapacity	2 (3%)	1 (3%)	3 (3%)
Intensity*			
Mild	6 (10%)	5 (13%)	11 (11%)
Moderate	35 (57%)	25 (64%)	60 (60%)
Severe	17 (28%)	9 (23%)	26 (26%)
Relationship to intervention			
Unlikely	13 (21%)	5 (13%)	18 (18%)
Unrelated	48 (79%)	34 (87%)	82 (82%)

Two SAEs were recorded on participants who withdrew before randomisation and are not included in the table. * Information on the intensity of three SAEs was not available due to: 1) inability to access patient medical records after withdrawal, 2) PI not being able to assess intensity based on available data, 3) data being missing.