Introduction – DESCANT Trial

As the evidence synthesis in this programme (work stream 1) showed, there is limited evidence for effective approaches to support people with dementia at home, rather than in settings like care homes. In particular, there is little work on home-based cognitive support for people with dementia and their carers following diagnosis; and research on the effectiveness and cost-effectiveness of this approach is sparse. The Dementia Early Stage Cognitive Aids New Trial (DESCANT) evaluated the clinical and cost-effectiveness of a package of memory aids, training and support for people with mild to moderate dementia and their carers at home, compared with treatment as usual (TAU).

For those diagnosed with early-stage dementia, the use of common memory aids like calendars, clocks, whiteboards with electric timers, and "post-it" dispensers is widely recommended; many are already used by people with dementia living at home, often with informal support from their family carers [103]. However, rigorous evaluation is lacking, particularly of what sort of guidance or support for aids is needed or valued. Though a Cochrane review [104] identified several studies reporting the usefulness of memory aids or associated training, they were small, highlighting the need for a larger study [105] [106] [107]. DESCANT aimed to design, implement and evaluate an intervention to support people with early-stage dementia and their carers in the use of memory aids at home. We now summarise the main findings of this trial, unpublished during this programme.

Methods

This was a multi-site, pragmatic randomised trial preceded by internal feasibility and pilot studies. The published trial protocol expounds its aims, methods and measures [48]. We aimed to allocate at random 480 pairs comprising a person with mild to moderate dementia and an identified carer, between the DESCANT intervention and treatment as usual (TAU). Randomisation allocated participants in equal proportions between intervention and comparator arms, stratified by five factors:

- Trust or Health Board (one of 10);
- Time since first attendance at memory clinic (more or less than 90 days);
- Sex (male or female);
- Age (more or less than 75 years); and
- Living with primary carer or not.

We assessed participants at baseline, 13 and 26 weeks. The primary outcome measure was the Bristol Activities of Daily Living Scale (BADLS), rated by carers, at 26 weeks. Secondary outcomes covered cognition, quality of life and social networking of the person with dementia; and mental health, quality of life, and sense of competence of the carer. Analysis followed an explicit statistical plan, approved by the Data Monitoring and Ethics Committee (DMEC) before we accessed any data.

To characterise the effect of the intervention over time, we fitted multi-level mixed-effect models. Analyses by treatment allocated estimated the effect of the intervention on participants by adjusting for baseline differences in the measure under analysis, demographic characteristics (viz. Trust or Health Board, age, gender and ethnicity), time since first attendance at memory clinic or equivalent, whether living with primary carer or not, and the interval until follow up. Secondary outcome measures for people with dementia included: Revised Interview for Deterioration in Daily living activities in Dementia (RIDDD); Control, Autonomy, Self-realisation and Pleasure 19-item (CASP19) measure of quality of life; Clinical Dementia Rating (CDR) of impairment; and Standardised Mini-Mental State Examination (SMMSE) of cognition. Secondary outcomes for carers included: General Health Questionnaire 12-item score (GHQ12); and Short Sense of Competence Questionnaire (SSCQ). To investigate the potential effects of missing data for the primary outcome we performed a multiple Imputation with Markov Chain Monte Carlo (MCMC) procedures. MCMC is the most common parametric approach for multiple imputation, which assumes that all the variables in the imputation model have a joint multivariate normal distribution. Following this, we undertook a sensitivity analysis comparing the outcome with and without imputation. To complement this quantitative evaluation we also conducted a qualitative component and a process evaluation to assess the implementation process and identify contextual factors associated with variation in uptake and acceptability.

The Swansea Trials Unit (STU) adopted the trial, which was conducted according to its standard operating procedures. The Trial Management Group (TMG) comprised staff at STU and the University of Manchester, who monitored compliance with the study protocol and liaised with NHS Trusts to recruit participants. The TMG oversaw and resolved operational issues, and reported to the Data Monitoring and Ethics Committee (DMEC) and NIHR the funder. Only the DMEC had access through the Trial Data Manager to unblinded data before the trial ended in November 2019; the DESCANT analysis team were unblinded only after the DMEC approved the blinded primary analysis late in 2019.

Results

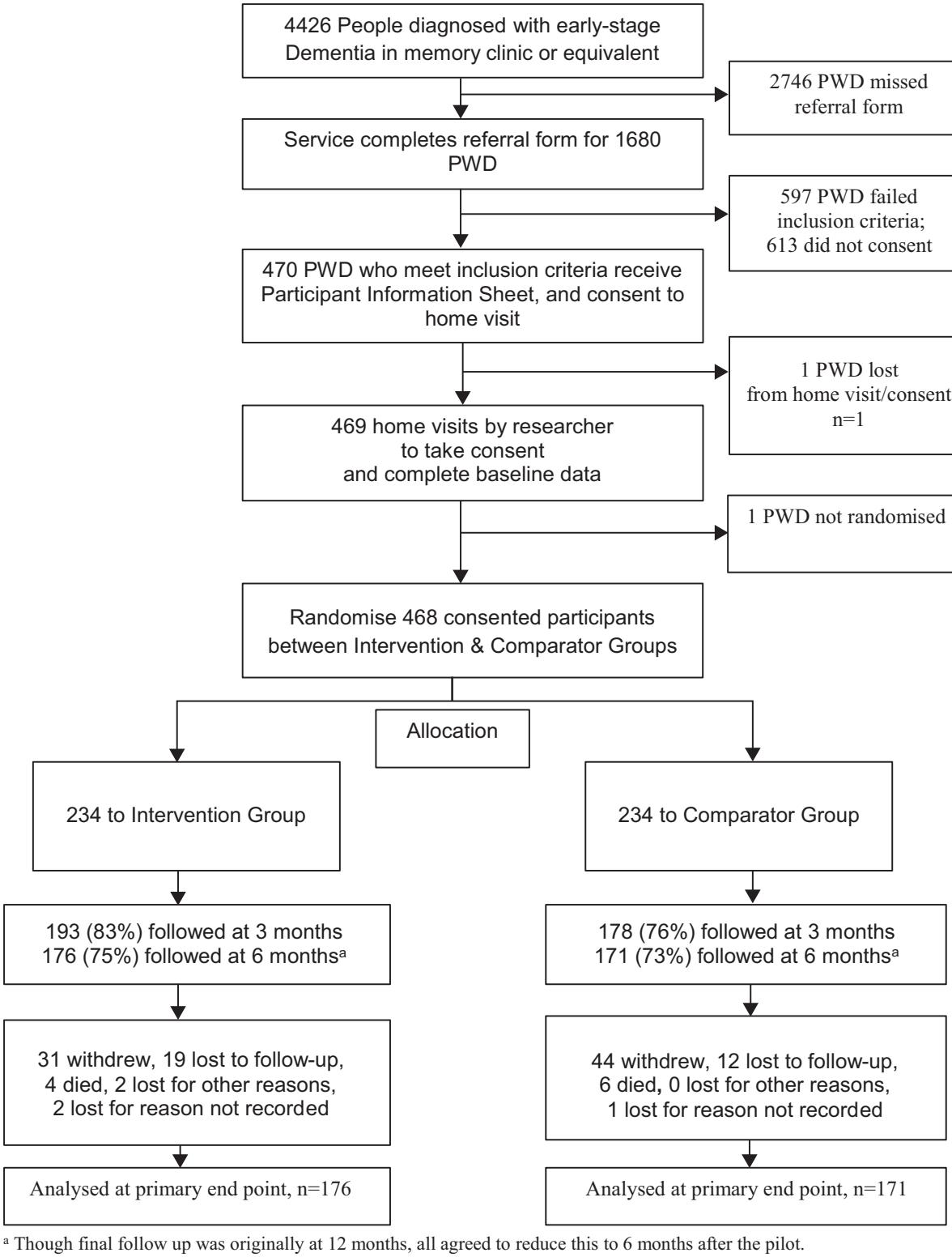
After the feasibility and pilot trials in two NHS Trusts, we extended recruitment to 9 Trusts across England and 1 Health Board in Wales. We recruited 469 participants (people with early-stage dementia and their carers) at baseline. One participant withdrew before randomisation, so we randomised 468. The average age of those with dementia was around 80 years, with slightly more females. Figure 1 is the CONSORT flowchart displaying the progress of participants through the trial, events between screening and completing the trial and Table 1 classifies recruitment by Trust or Health Board. There were 347 participants for primary analysis with data at baseline and 6 months. The baseline data were balanced by group, as one would expect from a validated randomisation algorithm (Table 2). The average age of those with dementia was around 80 years, with slightly more females.

In total 121 participants (58 in the intervention arm and 63 in the comparator arm) were not followed up for a variety of reasons: 75 actively withdrew (31 intervention and 44 controls); 31 were lost to follow up (19 intervention and 12 controls); 1 participant withdrew following a Serious Adverse Event (SAE) unrelated to the trial; and 1 for another reason (both intervention). Ten participants died (4 intervention and 6 controls), and reasons were missing for 3 participants (2 in the intervention group).

We received reports of 43 SAEs in 42 participants (24 intervention and 18 controls). One control experienced 2 SAEs, both falls. Twenty-seven SAEs were adjudged severe (15 in intervention arm and 12 in comparator); 13 moderately severe; and 3 mild. Thirty-six were suffered by the person with dementia. No SAE was definitely, probably or possibly related to the DESCANT intervention. Eight SAEs resulted in death (4 in intervention arm, 4 in comparator); 3 were life threatening (1 intervention, 2 controls); 1 control suffered another medically important condition; 2 caused persistent or significant disability or incapacity (both intervention) and 29 were hospitalised (17 intervention, 12 controls).

Table 3 shows unadjusted primary outcomes: the intervention group starts with higher BADLS scores (indicating more dependency), stays constant at 3 months, but shows a marked increase to significantly higher dependency than the comparator group at 6 months. This increase was partly because BADLS was higher for control people with dementia who were lost to follow-up or died between baseline and 6 months.

FIGURE 1 CONSORT FLOWCHART FOR DESCANT TRIAL



[a] Though final follow up was originally at 12 months, all agreed to reduce this to 6 months after the pilot.

To adjust for this and other potential biases, Table 4 displays the coefficient table for the more reliable multi-level mixed-effect model. After we adjusted BADLS scores for baseline differences in age, gender, ethnicity, time since first attendance at memory clinic, and whether the people with dementia lived with their carers, there was no significant effect on the binary variable comparing intervention and comparator groups at 3 or 6 months. We tested whether there was any effect of cluster (Trust or Health Board) by considering the Trust at level 2 of the multi-level model. The Intra-class Correlation Coefficient (ICC) of 0.01 shows a tendency towards homogeneity of BADLS score within clusters.

Table 5 and Figure 2 present the changes in BADLS our primary outcome over time. Though the change in BADLS is not significant at 3 months, it becomes significant at 6 months. Nevertheless, there is no evidence that the intervention group performs better than the comparator group over time.

TABLE 1 SCREENING AND RECRUITMENT

Trust or Health Board with recruiting memory clinic		**Total number approached**	**Total number eligible (% of approached)**	**Total number consented (% of eligible)**	**Total number randomised (% of consented)**
1	Pennine Care	465	465 (100)	142 (31)	142 (100)
2	NELFT	574	574 (100)	153 (27)	152 (99)
3	CWP	2599	118 (5)	51 (43)	51 (100)
4	Oxford	64	64 (100)	20 (31)	20 (100)
5	Humber	26	26 (100)	21 (81)	21 (100)
6	Cardiff & Vale	400	135 (34)	22 (16)	22 (100)
7	Sheffield	49	49 (100)	19 (39)	19 (100)
8	Lancashire	9	9 (100)	5 (55)	5 (100)
9	Berkshire	200	200 (100)	20 (10)	20 (100)
10	NAViGO	40	40 (100)	16 (40)	16 (100)
	Total	4426	1680 (38)	469 (28)	468 (99)

NELFT = North East London NHS Foundation Trust'; CWP = Cheshire and Wirral Partnership Trust;
NAViGO delivers health and social care across North East Lincolnshire.

TABLE 2 BASELINE CHARACTERISTICS OF PEOPLE WITH DEMENTIA BY ARM

	Intervention (n=234)	Comparator (n=234)	Total
Age (years):			
Mean (Confidence Interval)	79.6 (78.7, 80.4)	79.5 (78.6, 80.4)	79.5 (78.9, 80.1)
Median	80.0	81.0	80.0
Standard Deviation	6.7	7.2	6.9
Minimum	60.0	56.0	56
Maximum	99.0	95.0	99
Gender:			
Male	112 (48%)	108 (46%)	220 (47%)
Female	122 (52%)	126 (54%)	248 (53%)
Ethnicity:			
White	211 (90%)	216 (92%)	427 (91%)
Non-White	23 (10%)	18 (8%)	41 (9%)
Marital Status:			
Single	10 (4%)	4 (2%)	14 (3%)
Married or cohabiting	152 (65%)	150 (64%)	302 (64%)
Separated or divorced	9 (4%)	18 (7%)	27 (6%)
Widowed	62 (26%)	62 (27%)	124 (27%)
Missing	1 (0.4%)	0	1 (0.2%)
Usually living:			
Own home with partner	148 (63%)	144 (61%)	292 (62%)
Own home with carer	12 (5%)	13 (6%)	25 (5%)
Own home alone	60 (26%)	61 (26%)	121 (26%)
Supported accommodation	7 (3%)	6 (3%)	13 (3%)
Other	7 (3%)	10 (4%)	17 (4%)
Accommodation Types			
Owner occupied	195 (83%)	199 (85%)	394 (84%)
Privately rented	13 (6%)	9 (4%)	22 (5%)
Rented from LA or Housing Assoc	23 (10%)	23 (10%)	46 (10%)
Other	3 (1%)	3 (1%)	6 (1%)
Living with Primary Carer	147 (63%)	148 (63%)	295 (63%)
Not living with Primary Carer	87 (37%)	86 (37%)	173 (37%)
<90 days since 1st Memory Clinic	61 (26%)	8 (25%)	19 (25%)
≥ 90 days since 1st Memory Clinic	173 (74%)	176 (75%)	349 (7%)

TABLE 3 UNADJUSTED FINDINGS FOR BADLS (PRIMARY OUTCOME) BY ARM

Time points	Intervention	Comparator	Total	Mean Difference[a] (95% CI)	p
Baseline					
n	234	234	468		
Mean (95% CI)	12.1 (10.9,13.3)	11.5 (10.4,12.6)	11.8 (11.03,12.6)	0.61 (-0.96, 2.19)	0.4
Median	11.0	9.0	10.0		
SD	8.8	8.5	8.7		
Missing (%)	0	0	0		
3 Months					
n	192	178	370		
Mean (95% CI)	12.1 (10.9,13.4)	11.6 (10.1,12.9)	11.9 (10.9,12.8)	0.64 (-1.3, 2.5)	0.5
Median	10.0	10.0	10.0		
SD	8.9	9.7	9.3		
Missing (%)	41 (17.5)	56 (23.9)	98 (20.9)		
6 Months					
n	176	171	347		
Mean (95% CI)	14.6 (13.1,16.2)	12.6 (11.4, 13.8)	13.6 (12.6,14.6)	2.02 (0.06, 3.9)	0.05
Median	12.5	12.0	12.0		
SD	10.4	8.1	9.3		
Missing (%)	58 (24.8)	63 (26.9)	121 (25.9)		

SD = Standard deviation, CI = Confidence Interval;

Bristol Activities of Daily Living Scale (BADLS): scores from 0 to 60; higher scores show greater dependence.

BADLS Score: ranges 0 (totally independent) to 60 (totally dependent); higher scores indicates greater dependency

[a] Mean Difference is based on Intervention-Comparator.

TABLE 4 MULTI-LEVEL MIXED MODEL-FOR BADLS (PRIMARY OUTCOME): COEFFICIENTS

Parameters	Reference Category	Coefficient (B)	95% CI (B)	z	p-value
Treatment arm: Intervention	Comparator	0.70	-0.94, 2.34	0.84	0.40
Age categories					
≤70	81-85 years	-0.54	-3.32, 2.23	-0.38	0.70
71-75		-2.29	-4.68, 0.10	-1.88	0.06
76-80		-2.56	-4.64,-0.47	-2.40	0.02*
86-90		-0.14	-2.56, 2.28	-0.11	0.91
90+		6.76	2.55, 10.97	3.15	0.00*
Gender (Female)	Male	-0.18	-1.77, 1.41	-0.22	0.83
Ethnicity (Non-White)	White	3.50	0.64, 6.38	2.40	0.02*
≥ 90 days since 1st attended Memory Clinic	< 90 days	-0.95	-2.76, 0.87	-1.02	0.31
Living with Primary Carer	No	0.49	-1.25, 2.22	0.55	0.58

Notes: *p < 0.05.

Bristol Activities of Daily Living Scale (BADLS): scores from 0 to 60; higher scores show greater dependence.

Intraclass Correlation Coefficient (ICC) for 'Trust' = 0.01.

We fitted a multi-level mixed-effect model with the variables in the last 5 rows as fixed-effect covariates.

We treated participants as Level 1 and 'Trusts' as Level 2.

TABLE 5 MULTI-LEVEL MIXED-MODEL FOR BADLS (PRIMARY OUTCOME): MEAN CHANGES

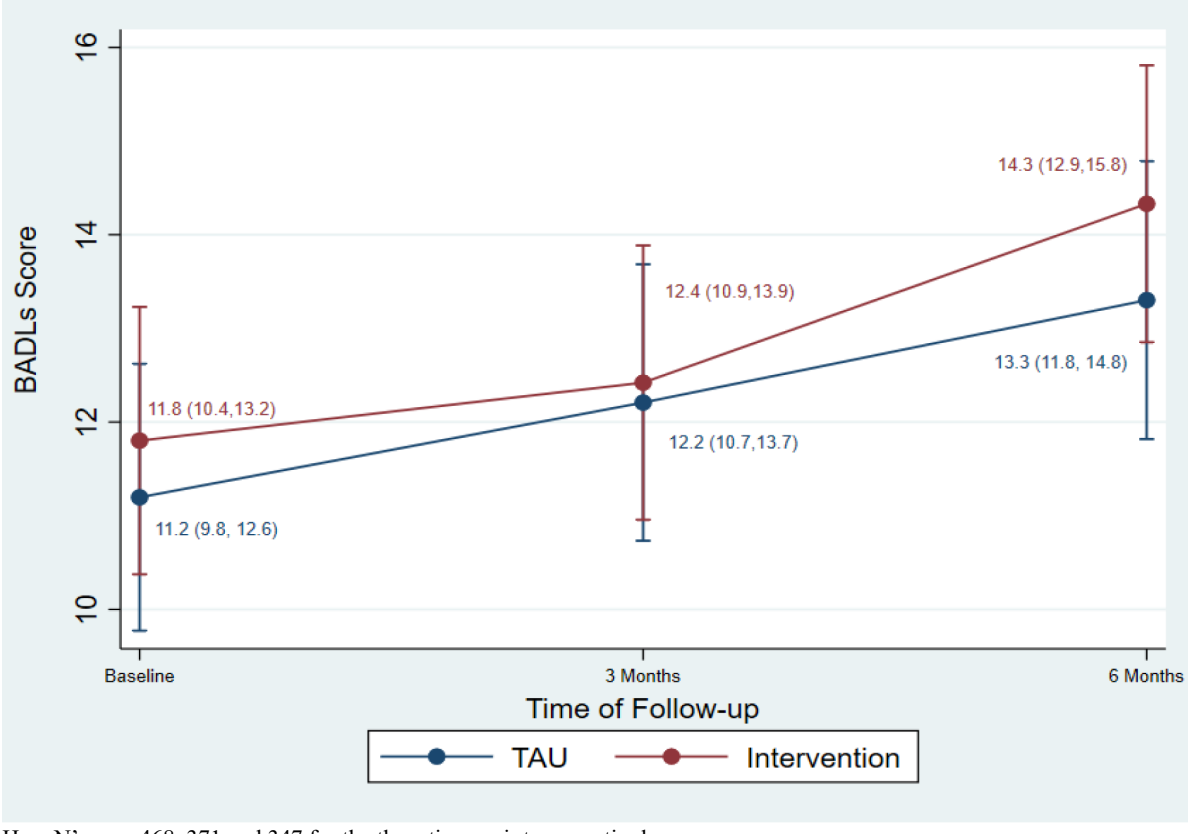
Variable	Mean Baseline BADLS Score (SD)	Mean Change in BADLS from Baseline (95% CI)[a]			
		Month 3	P-Value	Month 6	P-Value
Intervention	12.12 (8.80)	0.72 (-0.14, 1.58)	0.10	2.60 (1.72, 3.51)	0.00*
Comparator	11.52 (8.51)	1.04 (+0.16, 1.94)	0.02	2.23 (1.33, 3.14)	0.00*
Mean difference between groups		-0.33 (-1.56, 0.91)	0.61	0.38 (-0.89, 1.65)	0.56

Notes: * p < 0.05.

Bristol Activities of Daily Living Scale (BADLS): scores from 0 to 60; higher scores show greater dependence.

[a] Estimated from multi-level mixed-effect model reported in Table 4.

FIGURE 2 MEAN (95%CI) BADLS SCORES OVER TIME BY RANDOMLY ASSIGNED GROUP



Here N's are: 468, 371 and 347 for the three time points respectively

Similarly there was no evidence that the DESCANT intervention led to significant change at 3 or 6 months in our comprehensive portfolio of secondary outcome measures for people with dementia, or for carers (Table 6)

TABLE 6 ADJUSTED (MULTI-LEVEL MIXED MODEL) ESTIMATES FOR SECONDARY OUTCOMES: COEFFICIENTS

Outcomes [a]	Coefficient (B)	95% CI (B)	z	p-value
CASP19[b]	-0.04	-1.40, 1.32	-0.06	0.95
CASP19[c]	-0.07	-1.42, 1.28	-0.10	0.92
CDRS	-0.14	-0.82, 0.53	-0.43	0.67
DEMQOL (Person with dementia)	0.13	-2.29, 2.55	0.11	0.92
LSNS-R	-0.89	-2.71, 0.92	-0.96	0.34
RIDDD Initiative	0.89	-2.03, 3.82	0.60	0.55
RIDDD Performance	-0.77	-3.66, 2.11	-0.53	0.60
S-MMSE	-0.20	-1.08, 0.68	-0.45	0.70
GHQ-12	-0.38	-1.32, 0.55	-0.81	0.42
SSCQ	-0.43	-1.46, 0.59	-0.83	0.40

*$p < 0.05$

Ns respectively for T1; T2; T3 are: CASP 19[a] (451; 358; 322); CASP 19[b] (467; 365; 342); CDRS (466; 370; 347; DEMQOL (446; 350; 323; LSNS-R (468; 369; 346); RIDDD Initiative (465; 365; 342); RIDDD Performance (466; 368; 343); S-MMSE (466; 367; 340); GHQ-12 (468; 369; 344); SSCQ (468; 368; 343).

[a] Estimates are for treatment arm with the comparator group as the reference category.

[b]CASP19 by the patients.

[c]CASP19 by the Carer.

Intraclass Correlation Coefficient (ICC) for 'Trust' = CASP19[2](0.000), CASP19[3](0.003), CDRS(0.02), DEMQOL (0.000), LSNS-R(0.000), RIDDD Initiative(0.03), RIDDD performance(0.000), S-MMSE (0.03), GHQ-12(0.000), and SSCQ(0.007).

We fitted a multi-level mixed-effect model with the variables: age, gender, ethnicity, time since 1st attendance at memory clinic and whether living with carer as fixed-effect covariates.

We treated participants as Level 1 and 'Trusts' as Level 2.

Table 7 and Figure 3 show data on the primary outcome, BADLS, after multiple imputation to take account of missing values at follow up. The sensitivity analysis showed that there were no differences in the outcome estimates with and without imputation.

TABLE 7 ADJUSTED (MULTI-LEVEL MIXED MODEL) ESTIMATES FOR PRIMARY OUTCOME, BADLS: COEFFICIENTS (AFTER IMPUTATION)

Parameters	Reference Category	Coefficient (B)	95% CI (B)	z	p-value
Treatment arm: Intervention	Comparator	0.70	-0.92, 2.31	0.85	0.40
Age categories					
≤70	81-85 years	-0.59	-3.32, 2.15	-0.42	0.67
71-75		-2.32	-4.67, 0.03	-1.94	0.05
76-80		-2.46	-4.51, -0.42	-2.36	0.02*
86-90		-0.03	-2.40, 2.34	-0.03	0,98
90+		6.59	2.49, 10.69	3.15	0.002*
Gender (Female)	Male	0.23	-1.79, 1.34	-0.28	0.78
Ethnicity (Non-White)	White	3.56	0.75, 6.36	2.48	0.01*
≥ 90 days since 1st attended Memory Clinic	< 90 days	-0.92	-2.70, 0.87	-1.01	0.31
Living with Primary Carer	No	0.45	-1.25, 2.14	0.52	0.61

*p < 0.05

N =468 at each time point.

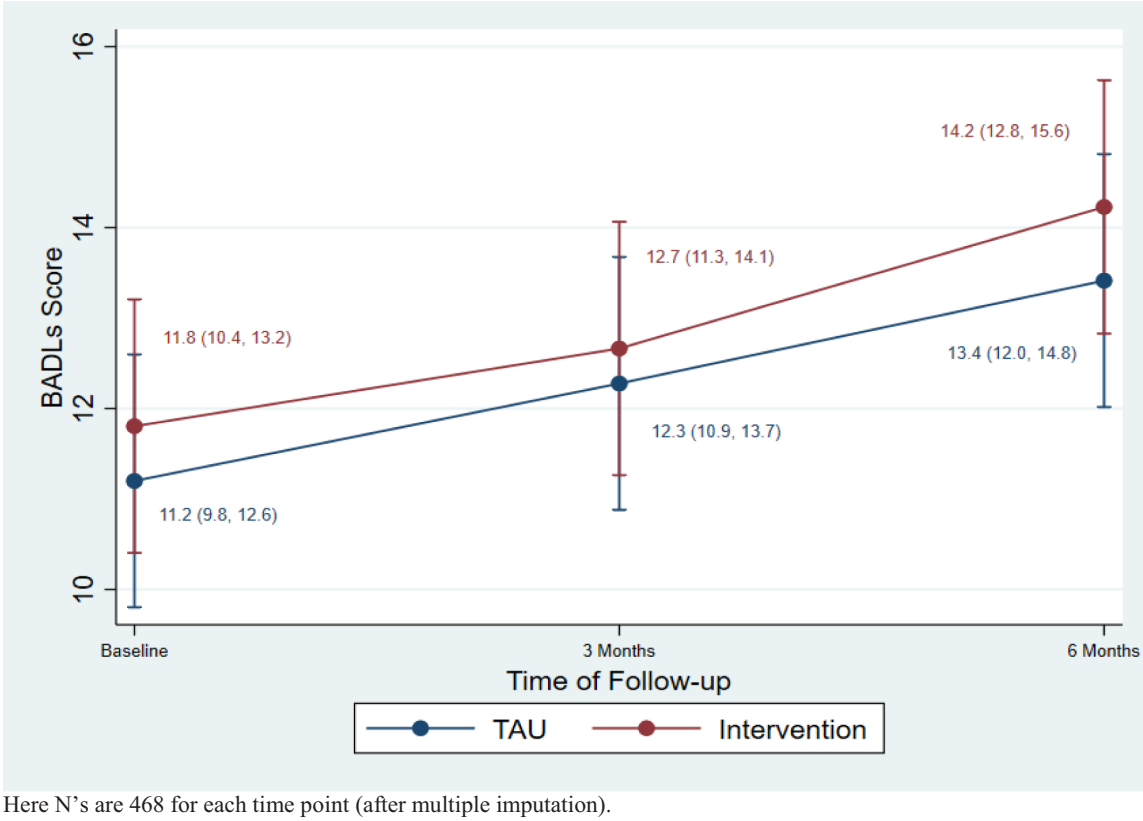
Bristol Activities of Daily Living Scale (BADLS): scores from 0 to 60; higher scores show greater dependence.

Intraclass Correlation Coefficient (ICC) for 'Trust' = 0.01

We fitted a multi-level mixed-effect model with the variables in the last 5 rows as fixed-effect covariates.

We treated participants as Level 1 and 'Trusts' as Level 2.

FIGURE 3 MEAN (95% CI) BADLS SCORES OVER TIME BY RANDOMLY ASSIGNED GROUP (AFTER IMPUTATION)



Here N's are 468 for each time point (after multiple imputation).

Conclusions

We successfully trained Dementia Support Practitioners (DSPs) in the DESCANT intervention and delivered it to most participants in the intervention arm. However, this trial showed no evidence that it improved BADLS the primary outcome or any of our comprehensive portfolio of secondary outcomes for people with dementia or their carers, relative to usual care within memory services in the UK National Health Service.