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**Staff training and outreach support for Cognitive Stimulation Therapy and its implementation in practice: a cluster randomised trial.**

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**Keywords.** Cognitive Stimulation Therapy (CST), implementation, staff training, outreach, online support, cluster randomised trial, phase IV trial.

### **Key points**

- The CST and maintenance CST programmes are widely used and considered easy to put into practice.
- Outreach support shows no difference in average number of attendees to the programme.
- Additional support may assist in sustaining the long term implementation of the maintenance CST programme.

## ABSTRACT

**Objective.** There is evidence that Cognitive Stimulation Therapy and maintenance Cognitive Stimulation Therapy are effective in mild to moderate dementia. There is however, little evidence available for its implementation in practice and the impact of outreach support on the sustainability of the programme.

**Methods.** Two hundred and forty-one staff members were randomised from 63 dementia care settings between outreach support including an online forum, email, and telephone support, compared to usual Cognitive Stimulation Therapy control group. The primary outcome was average number of attendees to the Cognitive Stimulation Therapy and maintenance Cognitive Stimulation Therapy programmes.

**Results.** There was no difference in average number of attendees between the intervention and usual Cognitive Stimulation Therapy control groups for the Cognitive Stimulation Therapy ( $p=0.82$ ) or the maintenance Cognitive Stimulation Therapy programme ( $p=0.97$ ).

**Conclusions.** Outreach support does not affect the average number of people with dementia attending the Cognitive Stimulation Therapy or maintenance Cognitive Stimulation Therapy programme. Irrespective of outreach support the programmes remain widely implemented and yield perceived benefits for people with dementia.

## Introduction

There is evidence that Cognitive Stimulation Therapy (CST) achieves positive outcomes for people with mild to moderate dementia (Spector *et al.*, 2003; Orrell *et al.*, 2005; Orrell *et al.*, 2014). There are supportive recommendations in the NICE-SCIE (2006) guidelines and the World Alzheimer Report (2011), namely “cognitive stimulation has the strongest evidence by far” for cognitive benefit for people with dementia.

The Medical Research Council (MRC; Craig *et al.*, 2008) devised a four-phase framework covering their development and evaluation of complex interventions, including consideration of the development, feasibility, evaluation, and long-term implementation of the intervention. More recently the MRC has focussed on process evaluation to understand implementation in practice (Moore, Audrey and Barker., 2014). Failure to implement evidence-based practice can often be attributed to individuals’ lack of, and inability to apply, knowledge or organisational factors that affect the individuals’ ability to implement change in practice (Corrigan, McCracken and Blaser., 2003).

Consequently, it is useful to look at individual and organisational characteristics when considering implementation in practice. CST has adhered to the MRC framework throughout its development and evaluation (Spector *et al.*, 2003, Aguirre *et al.*, 2011, Orrell *et al.*, 2014), and the emphasis is now on the long term benefits and real life implementation of the programme.

CST is a 14-session group-based psychosocial intervention for people with mild to moderate dementia. Maintenance CST is a once weekly 24-session programme leading on from CST. The dissemination strategies for its implementation in practice include two training manuals and DVD (Spector *et al.*, 2006; Aguirre *et al.*, 2011), and a CST training day. The strength of the manuals is the speed in which the therapy can be learned, and high face-validity and fidelity of the intervention (Corrigan, McCracken and Blaser.,

2003). The training day covers the theoretical and research background to dementia and CST, and its practical delivery and implementation in practice. Although this is a comprehensive training package an attempt was made to assess its effectiveness. A training day surveyed staff who had attended, to explore what might help to get the therapy into practice. Respondents identified the main factors as staff support, specialist supervision, online forum, additional training, and regular supervision (Spector, Orrell and Aguirre., 2011). This was a useful in considering the practical delivery of both the CST and maintenance CST programme by healthcare staff. The successful implementation of complex interventions depends on changing behaviour, and therefore requires a scientific understanding of the behaviours that need to change, the factors maintaining current behaviour and barriers and facilitators to change (Michie *et al.*, 2005). Therefore, further CST research is needed when considering implementation. The focus on staff members' beliefs and behaviour, and practical implementation issues are particularly relevant factors due to the CST evidence base and the guidelines supporting the use of CST in dementia. Implementation of CST in practice with outreach support has been previously investigated as part of a service evaluation (Streater *et al.*, 2016) but a more rigorous study design was adopted to evaluate its effectiveness.

### **Aim**

To evaluate the effectiveness of outreach support options offered to staff members to increase the implementation of the CST and maintenance CST programmes in practice for people with dementia.

### **Methods**

*Design.* This was a single-blind, multicentre, pragmatic randomised controlled trial (RCT) conducted according to the published protocol (Streater *et al.*, 2012). The study was approved by East London Research Ethics Committee (REC) 3 in June 2011 (ethical approval reference number: 11/LO/0059); and its trial registration number is ISRCTN28793457.

*Participants.* Eligible staff members in all 63 participating dementia care centres were required to: (1) have adequate written and spoken English, (2) have adequate knowledge of CST through a training day within this trial or the previous two years, or supervised access to the CST manuals (Spector *et al.*, 2006; Aguirre *et al.*, 2011), (3) have management approval to run the CST and maintenance CST programmes, (4) identify five to eight suitable people with dementia to participate in the groups; and (5) complete online questionnaires at three time-points. The study design accounted for staff members varying levels of CST knowledge and experience: centres new to CST required a minimum of three staff members per centre, whereas centres with previous experience of CST required a minimum of one staff member per centre.

*Intervention.* The outreach support for the duration of the programme provided an online forum, email supervision, and local supervision, based on the results of a pilot study of CST after one day of training (Spector, Orrell and Aguirre., 2011). The local supervision was delivered by a Psychologist, Occupational Therapist, or CST researcher. The researcher provided the remaining outreach support options. Overall, 38 centres had access to the outreach support options.

*Usual CST control.* Centres in this group did not have access to the outreach support. Staff members in the usual CST control group either had no prior experience of CST, had received the CST training day within two years of the recruitment start date, or had access

to the CST manual (Aguirre *et al.*, 2011). Twenty-five centres were randomised in to the usual CST control group.

*Primary outcome.* The primary outcome measure was the average number of attendees (people with dementia) to the CST and maintenance CST programmes (total number of sessions run x average number of people at each) as recorded on the progress monitoring form in the maintenance CST manual (Aguirre *et al.*, 2011). Staff completed attendance records at the end of each session until the CST and maintenance CST groups were completed or discontinued. By calculating the average number of attendees to each session enabled the researcher to cluster the centres together based on ‘successful’ implementation. ‘Successful’ implementation was based on the recommendations of between five to eight group members per session (Spector *et al.*, 2006) thus: (0) unable to run the programme (1) ‘low’ use of CST – fewer than three people per session (2) ‘medium’ use – 3 or 4 people per session (3) ‘high’ use – more than 5 people per session.

*Secondary outcome measures.* Staff members completed a baseline (BL) assessment before randomisation and at six months (FU1) and 12 months (FU2), all online into SurveyMonkey. The data was anonymised and transferred to SPSS version 22. Missing data was imputed within scales according to their published rules. Subject to that we used mean substitution when at most 20% of items were missing; for example, we imputed a five-item score with one missing item by the mean of the other four values. A Mann-Whitney U Test was carried out for average number of attendees to the CST and maintenance CST programme. An ANCOVA model adjusted for baseline for the secondary outcomes was carried out at each follow up individually.

*Job satisfaction.* The Minnesota Satisfaction Questionnaire (MSQ; Weiss, Dawis and England., 1967) determines overall level of job satisfaction. It comprises of 100 questions

with higher scores indicating a higher level of job satisfaction. The measure has adequate internal reliability and validity (Weiss, Dawis and England., 1967).

*Approaches to Dementia.* The Approaches to Dementia Questionnaire (ADQ; Lintern and Woods, 1996) is a 19-item questionnaire with high validity and good retest reliability. A higher score indicates good dementia care practice.

*Dementia Knowledge.* The Dementia Knowledge-20 questionnaire (DK-20; Shanahan *et al.*, 2013) measures the staff member's knowledge and approach to caring for people with dementia. The measure has acceptable reliability and validity (Shanahan *et al.*, 2013) and was administered at BL and FU2 only.

*Competence.* The Sense of Competence In Dementia care Staff scale (SCIDS; Schepers *et al.*, 2012) measures perceived sense of competence. The SCIDS comprises of 17 questions with higher scores indicating more sense of competence. The scale has good internal consistency and moderate test-retest reliability (Schepers *et al.*, 2012).

*Learning transfer.* The brief Learning Transfer System Inventory (brief LTSI; Spector, Orrell and Aguirre., 2011) includes one question for each of the 16 constructs identified by the original measure (Holton, Bates and Ruona., 2000). It includes environmental and personal factors that could affect the delivery of CST, but lacks confirmed reliability or validity.

*Barriers to change.* The Barriers to Change Questionnaire (BARCQ; Corrigan, Kwartarini and Pramana., 1992) identifies the person's belief in regards to training being introduced into the workplace. It is a 19-item measure with a lower score indicating less perceived barriers in the workplace.

*Challenging behaviour.* The Controllability Belief Scale (CBS; Dagnan, Grant and McDonnell., 2004) measures the emotional and behavioural responses in relation to challenging behavior and demonstrates good internal reliability. The measure comprises

15-items, with higher scores indicating a greater sense of control.

*Sample size.* The trial sought to recruit 240 staff members across 60 dementia care settings to achieve 80% power of detecting an effect size of 0.4 using a 5% significance level. This includes an adjustment for the cluster design assuming an intra-centre correlation of 0.05 and an assumed attrition rate of 15%. This estimate would provide sufficient numbers to determine the feasibility of the trial.

*Randomisation.* Centres new to CST were randomised on the training day. Paired matching of the centres was done before the training and the two distinct clusters were provided to the clinical trials unit, N.W.O.R.T.H for randomisation on a 1:1 basis. The matching ensured that there was a balance of size within the two clusters. Centres with previous CST experience at denoted time points throughout the recruitment were divided into a matched pair of clusters for randomisation, taking into account size of centre and whether the staff member had received the training day or manual only. As the researcher could not be masked to the resulting allocation, an administrator gave each recruited staff member an identification number, so they could complete online assessments independently of the researcher.

## **Results**

The recruitment period was between August 2011 and September 2012. The final follow-up was completed in September 2013. A total of 241 staff members were recruited across 63 centres. Of these, 175 staff members (73%) received the CST training day, 20 (8%) had previously received CST training, and the remaining 46 (19%) had learned CST only through the use of the CST manual. Of the 241 recruited staff, 168 completed follow up 1 (70% of 241) and 140 at follow up 2 (58% of 241). The CONSORT diagram (Figure 1) records reasons for withdrawal.

[Insert Figure 1 here]

Of the 241 participating staff, 126 (52%) staff members across 35 centres were in receipt of the outreach support intervention and 115 (48%) staff members across 28 centres received usual CST control. The majority were white females with between one and ten years of experience, and qualified to diploma or degree level. The outreach support and usual CST control groups were similar at baseline; subsequent withdrawal rates were also similar. Most centres specialised in dementia; the majority were care homes and most staff were recorded as Care Assistants (Table 1).

[Insert Table 1 here]

The outreach support was accessed on 21 occasions; three times via email, three times via the online forum, and 15 times from local supervisors. These 21 contacts generated 25 separate queries.

*Primary outcome.*

*CST only.* The distribution of the average number of attendees was assessed before applying the independent sample t-test and due to the large number of centres that did not run any sessions this was not normally distributed ( $W(69)=0.817, p<.001$ ). Therefore, a Mann Whitney U-Test was applied. A Mann-Whitney U Test revealed no significant difference in the average number of attendees in receipt of the CST programme across outreach support ( $Md = 3.57, n = 38$ ) and no outreach support ( $Md = 0, n = 31$ ),  $U = 571, z = -.231, p = .81, r = .03$  (Table 2).

*Maintenance CST.* Similarly a large number of maintenance CST sessions were not run and this was not normally distributed ( $W(69)=0.650$ ,  $p<.001$ ). A Mann-Whitney U Test showed no significant difference in the average number of attendees in receipt of the maintenance CST programme across outreach support ( $Md = 0$ ,  $n = 38$ ) and no outreach support ( $Md = 0$ ,  $n = 31$ ),  $U = 586$ ,  $z = -.043$ ,  $p = .97$ ,  $r = .05$  (Table 2).

[Insert Table 2 here]

A Chi-square test for independence indicated no significant association between number of CST groups run and intervention group,  $\chi^2 (1, n = 69) = .95$ ,  $p = 0.59$  or for the number of maintenance CST groups run and the intervention group,  $\chi^2 (1, n = 69) = .02$ ,  $p = 1.0$ . However, it was possible to group together CST and maintenance CST groups that had been run at a low, medium or high level dependent on number of group members. All groups were run at a medium (three to four group members) to high (five to eight group members) level across both programmes irrespective of outreach support or not.

[Insert Table 3 here]

*Secondary outcome measures.* There were no significant differences between groups in any secondary outcome measures at six or 12 months (Table 4). Table 4 adjusts the means and standard errors at both time points for the planned covariate.

[Insert Table 4 here]

## **Discussion**

There was no difference between the outreach support group and the usual CST control group in the average number of people attending the number of CST groups run.

However, irrespective of outreach support all groups run were being delivered at a medium or high level. This is a positive finding as it indicates that when groups are being delivered in practice this is being carried out with a satisfactory number of participants.

Although this provides us with limited information this is the first piece of research looking at how well groups are being implemented in practice.

There was no statistically significant difference in secondary outcome measures at either six or 12 months. However, this was not wholly unexpected as these were not directly targeted by the outreach support. Furthermore, staff varied in both their uptake of outreach support and their contributions to both programmes. So, it would be difficult to detect change in these outcomes.

The trial was designed to test for an increase in the number of people with dementia attending CST programmes receiving outreach support. Thus, the absence of differences between the two groups could be due to the large target effect size and the unexpected loss of staff members at follow up, resulting in a type II error.

The trial delivered a low level intervention and the outreach support options were suggested by previous CST research (Spector, Orrell and Aguirre., 2011) and considered feasible in a clinical setting. So relying on staff to access outreach support options may have contributed to the lack of uptake. In contrast, a more proactive approach may have increased the use of the outreach support. It was expected that the staff members with previous experience of CST might be less likely to access outreach support and may have increased confidence or patterns of CST implementation already established in their workplace. There was likely to be variability in the delivery of the programme that was not accounted for in the analysis of the data. However, as this was considered a pragmatic

trial the intention was for centres to demonstrate the variability in the delivery of the programme as a reflection of real life practice. In addition, there was a higher than expected dropout rate so potentially the trial was not powered to a high enough level. The primary outcome of average number of attendees to the programmes was a pragmatic decision taken to determine if outreach support impacted on the delivery of the sessions. However, this could not account for the wider factors that may impact on CST and maintenance CST delivery.

*Clinical implications.* This study saw 47% of centres go on to successfully deliver the CST programme in practice. A recent audit estimated 66% of memory clinics had access to CST (Hodge and Hailey, 2013), confirming that access to evidence-based CST for people with dementia is improving, which is a promising outcome. The outreach support does not impact on number of attendees to the programmes or number of sessions run and this might indicate that the current training package is sufficient to run groups in practice.

### **Conclusions**

This is a unique and innovative pragmatic trial looking at the implementation of CST and maintenance CST across a variety of care settings. Outreach support does not appear to impact on the average number of attendees to the CST or maintenance CST programmes. However, a localised service evaluation of CST in care homes including outreach support in the form of 'spot visits', telephone support and local supervision was encouraging (Streater *et al.*, 2016). Nevertheless, further research is required to understand how CST programmes might be adapted in everyday practice whilst maintaining the nature and fidelity of the therapy.

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Figure 1: Consort diagram of staff members progress through the STANDOUT & MONOU trials

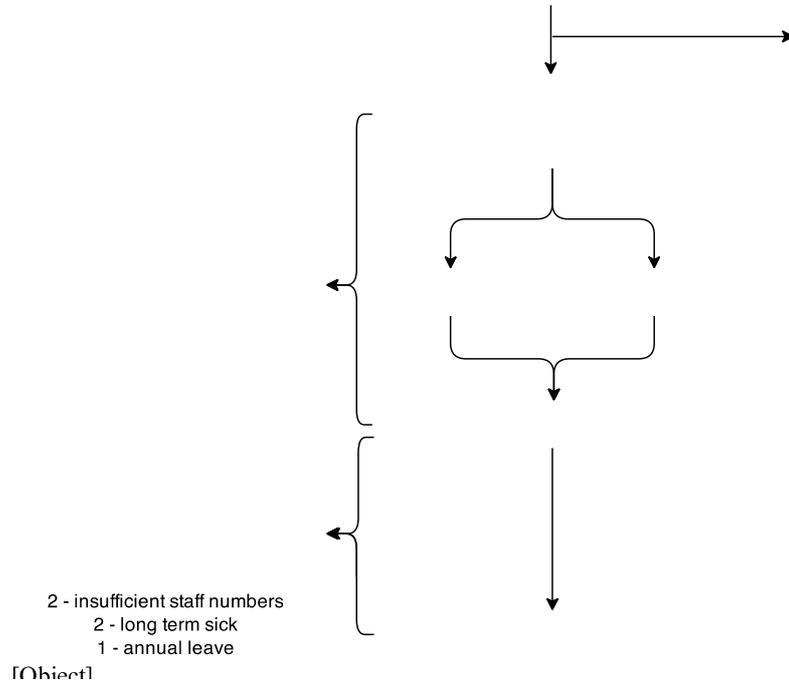


Table 1: Baseline characteristics of staff members (n = 241)

	<b>Outreach support (n = 126)</b>	<b>Treatment as usual group (n = 115)</b>
<b>Characteristics</b>	<b>n (%)</b>	<b>n (%)</b>
Female	110 (87)	102 (89)
Ethnicity: White	98 (78)	90 (78)
Age, years range (45-54 years)	42 (33)	28 (24)
Experience: 1 < 10 years	50 (40)	42 (37)
Qualification: Degree / Diploma	42 (37)	45 (36)
Specialist dementia setting: Yes	73 (58)	82 (71)
Setting: Care home	36 (28)	44 (38)
Job title: Care assistant	38 (30)	41 (36)
<b>Measures</b>	<b>Mean (s.d)</b>	<b>Mean (s.d)</b>
Approaches to Dementia Questionnaire	49.9 (4.6)	48.6 (5.3)
Minnesota Satisfaction Questionnaire	373.9 (52.7)	371.3 (49.3)
Controllability Belief Scale	53.8 (7.6)	53.4 (7.0)
Sense of Competence in Dementia - Staff	54.5 (7.8)	55.4 (7.9)
Brief Learning Transfer System Inventory	56.0 (7.2)	55.7 (6.7)
Barriers to Change Questionnaire	34 (17.3)	35.5 (17.3)
Dementia Knowledge - 20	3.3 (1.4)	3.2 (1.2)

Table 2: Mann-Whitney test on outreach support or usual CST control group for CST and maintenance CST programme.

Outcome	Intervention	N	Mean rank	Mann Whitney U	<i>P</i> value
Average number of attendees to CST	No outreach	31	34.42	571	0.82
	Usual CST control group	38	35.47		
Average number of attendees to maintenance CST	No outreach	31	34.90	586	0.97
	Usual CST control group	38	35.08		

Table 3: Chi-square test on receipt of intervention and the delivery rating of CST and maintenance CST programme.

Programme	Intervention	No groups (%)	Low level (%)	Medium level (%)	High level (%)	Total (%)
Cognitive Stimulation Therapy	Outreach support	16 (42)	0 (0)	7 (18)	15 (40)	38 (100)
	Usual CST control group	16 (52)	0 (0)	1 (3)	14 (45)	31 (100)
	Total	32 (46)	0 (0)	8 (12)	29 (42)	69* (100)
Maintenance Cognitive Stimulation Therapy	Outreach support	25 (66)	0 (0)	5 (13)	8 (21)	38 (100)
	Usual CST control group	21 (68)	0 (0)	3 (10)	7 (23)	31 (100)
	Total	46 (67)	0 (0)	8 (11)	15 (22)	69 (100)

Chi-square test with 2 degrees of freedom for CST:  $p = 0.15$

Chi-square test with 2 degrees of freedom for maintenance CST:  $p = 0.90$

\*Higher number due to multiple groups run per centre

Table 4: Effects on secondary outcome measures at primary and secondary endpoints.

Measure	Primary end point FU2 (12 months)				Secondary end point FU1 (6 months)			
	Intervention Mean (SE)	Control Mean (SE)	Group difference. Mean (SE)	Between group difference	Intervention mean (SE)	Control Mean (SE)	Group difference. Mean (SE)	Between group difference
ADQ	50.22 (0.54)	49.62 (0.55)	0.60 (0.77)	$F_{1,136}=0.61,$ $p=0.44$	50.66 (0.55)	49.74 (0.60)	0.92 (0.81)	$F_{1,163}=1.29, p=0.26$
MSQ	367.72 (6.21)	366.16 (6.71)	1.56 (9.14)	$F_{1,86}=0.03, p=0.87$	383.26 (4.97)	376.88 (4.97)	6.37 (7.04)	$F_{1,113}=0.82, p=0.37$
CBS	41.33 (0.44)	41.33 (0.45)	0.002 (0.64)	$F_{1,131}=0.00.$ $p=0.99$	54.90 (0.79)	55.30 (0.87)	-0.41 (1.18)	$F_{1,160}=0.12, p=0.73$
SCIDS	57.62 (0.65)	58.37 (0.67)	-0.74 (0.93)	$F_{1,133}=0.64,$ $p=0.43$	57.22 (0.61)	57.88 (0.66)	-0.66 (0.90)	$F_{1,160}=0.54, p=0.46$
Brief LTSI	55.50 (0.80)	56.58 (0.82)	-1.08 (1.15)	$F_{1,127}=0.88,$ $p=0.35$	56.87 (0.68)	55.57 (0.75)	1.30 (1.01)	$F_{1,155}=1.672,$ $p=0.20$
BARCQ	32.44 (1.83)	33.55 (1.87)	-1.11 (2.61)	$F_{1,130}=0.18,$ $p=0.67$	28.80 (1.23)	29.77 (1.35)	-0.98 (1.83)	$F_{1,155}=0.29, p=0.59$
DK-20	2.96 (0.24)	2.91 (0.25)	0.05 (0.34)	$F_{1,133}=0.024,$ $p=0.88$				