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Assessing the impact of a Carer Support Needs Assessment Tool (CSNAT) intervention in palliative home care: a stepped wedge cluster trial

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ABSTRACT

Objectives To test the impact on family carers of a Carer Support Needs Assessment Tool (CSNAT) intervention to facilitate carer-led assessment and support during end of life care.

Method Mixed method, part-randomised, stepped wedge cluster trial with 6 palliative home care services comparing carers receiving the intervention with those receiving standard care. Postal survey with carers 4–5 months postbereavement measured adequacy of end of life support, current mental and physical health (Short Form 12 Health Survey SF-12), level of grief (Texas Revised Inventory of Grief, TRIG) and distress (Distress Thermometer, DT), place of death and carer satisfaction with place of death.

Results Surveys were sent to 3260 (76%) carers of 4311 deceased patients; 681 (21%) were returned (N=333 control, N=348 intervention). Compared with controls, intervention carers had significantly lower levels of early grief, better psychological and physical health, were more likely to feel the place of death was right, and patients were more likely to die at home. However, differences were small and process measures showed low level of implementation, indicating differences may partially relate to increased awareness of carer issues rather than a direct impact of the intervention.

Conclusions Carers had better outcomes in the intervention condition, albeit modest. If this can be achieved through low level implementation and awareness raising of carers' needs from implementation activities, substantial impact should be possible if the CSNAT intervention can be fully implemented with a majority of carers. The study illustrates challenges of implementing and testing a complex intervention in real-life practice and of achieving comprehensive carer

assessment and support in line with government recommendations.

INTRODUCTION

Family carers are central to enabling patients to remain at home at end of life.^{1 2} However, carers may suffer worse physical and psychological well-being prebereavement and postbereavement from care giving.^{3 4} Better support for carers may promote better bereavement outcomes,^{5–7} improved quality of care for patients⁸ and plausibly, increase likelihood of death at home. To ensure that carers' support needs are assessed and addressed^{9 10} we developed a Carer Support Needs Assessment Tool (CSNAT) in collaboration with the National Association for Hospice at Home to provide an evidence-based carer assessment tool suitable for practice.¹¹

The CSNAT consists of 14 items representing broad domains with which carers require support during care giving at end of life. These include support to help carers support the patient, for example, with knowing what to expect, who to contact, how to manage symptoms and medicines; and support for carers themselves, for example, with feelings and worries, daytime or night time respite. The CSNAT enables carers to identify and prioritise domains where they need more support and then determine, in discussion with a practitioner, what they would find helpful to address needs. This constitutes the CSNAT intervention, a process facilitated by practitioners, but led by carers. Desired support may

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include help practitioners can provide immediately (eg, reassurance, advice, information), help to involve other family members, signposting towards external support or referral for further input. The CSNAT domains were developed from focus groups and interviews with 75 bereaved carers¹¹ and their face and criterion validity tested with 225 current carers.¹² Piloting and feasibility work with practitioners showed perceived benefits of the CSNAT intervention and also some challenges of implementation that informed further CSNAT training and support.^{13 14}

While promising, the CSNAT intervention required further testing to establish whether it improved carer outcomes. However, high demand for an evidence-based carer assessment tool among our service partners and their belief in the benefits of the CSNAT intervention made it difficult to conduct a conventional randomised controlled trial. Randomising individuals within services to the control arm was likely to be seen as unacceptable and also entail risk of cross-contamination between intervention and control arms. Similarly, if services were assigned to a 'control cluster' they were more likely to disengage. Instead a stepped wedge trial design, a variant of the cluster trial, enabled us to build a robust evaluation around a 'controlled' release of the intervention into practice in a situation where providers were keen to start using the CSNAT,¹⁵ and to capitalise on the natural experiment this offered.¹⁶ Stepped wedge cluster designs are recommended where there is strong belief in the benefits of the intervention, its costs are low and side effects unlikely.^{17 18} Further, stepped wedge designs are suited to situations where geographical and pragmatic constraints prevent simultaneous implementation across study settings, and allows all participating sites to eventually use the intervention, thus preventing the disengagement

within control sites which may be a problem in conventional cluster trials.^{17 18}

METHODS

Study design

A stepped wedge cluster part-randomised trial^{17 18} was used to test the impact of the CSNAT intervention on carer and patient outcomes. The clusters were six palliative home care sites (table 1). Sites started using the intervention one by one at three monthly intervals, the time before the intervention representing their control period (table 2). Site practitioners would start using the CSNAT intervention with all carers of patients on their caseload from their intervention start date. All carers of patients who died before this date would only have received the usual service input and so were part of the control condition. After the intervention start date, all carers should have had the opportunity to receive the CSNAT intervention, so carers of patients who died after this date were part of the intervention condition. This was therefore a repeated cross-section stepped wedge design with different individuals in each cluster in the preintervention and postintervention steps.¹⁷

Pragmatic constraints meant the sequence of sites beginning the intervention was not fully randomised; the sites most and least ready to fit in a practice change at study start were allocated to begin the intervention first (CSNAT intervention only) and last (control only), respectively, in the implementation sequence. The remaining sites were allocated to begin treatment in a randomised sequence in between these two (table 2). Delivery of the CSNAT intervention was recorded to monitor level of implementation, including any transition periods while the intervention was 'bedding in'.

Carer outcomes were obtained through survey of carers postbereavement, to allow assessment of longer

Table 1 Characteristics of trial services

Site	Participating service	Practitioners within teams (outset of study)	Deaths per month (prestudy info)
1	Home care team, two components: Specialist Palliative Care Team Palliative Care Support Team	1 Home care team manager 8 CNSs 7 RGNs 6 HCAs	34
2	Home care team, two components CNS team Hospice at home team	1 CNS team manager 5 CNSs 1 CNS 3 RGNs 9 HCAs	40
3	Hospice at home service—two teams covering different geographical areas	18 CNSs (9 for each geographical area)	50
4	Community Nurse Specialist Team	26 CNSs	100
5	Community Palliative Care Nurse Specialist Team	1 Manager 8 CNSs	25
6	Palliative Home Nursing Service	1 Community team leader 5 CNSs	30

CNS, clinical nurse specialist; HCA, healthcare assistant; RGN, registered general nurse.

Table 2 Stepped wedge trial: deaths (% survey sent/% survey response rate) by trial site, time interval (step) and trial arm (intervention: shaded; control: blank)

Step	1	2	3	4	5	Total	Total control	Total intervention
Site								
1	108 (66/20)	109 (82/25)	127 (69/23)	115 (79/25)	106 (75/15)	565 (74/22)		565 (74/22)
2	91 (65/31)	131 (61/25)	126 (56/30)	127 (54/20)	142 (54/25)	617 (58/26)	91 (65/31)	526 (56/25)
3	98 (74/29)	104 (77/30)	89 (74/30)	97 (85/28)	101 (80/21)	489 (78/27)	202 (76/29)	287 (80/26)
4	305 (82/22)	312 (87/16)	335 (80/18)	301 (81/27)	278 (75/20)	1531 (81/21)	952 (83/19)	579 (78/24)
5	142 (93/23)	115 (88/16)	114 (89/15)	98 (87/11)	86 (77/21)	555 (88/17)	469 (90/17)	86 (77/21)
6	160 (82/12)	146 (67/13)	83 (72/15)	74 (41/13)	91 (60/18)	554 (67/14)	554 (67/14)	
Total	904 (79/21)	917 (78/19)	874 (75/20)	812 (74/23)	804 (71/20)	4311 (76/21)	2268 (79/19)	1478 (72/24)

term impact and measurement of outcomes relative to a common ‘anchor point’, enabling consistent cross-comparison between carers. Earlier psychometric testing of the CSNAT¹² showed predeath outcome measures to be strongly influenced by variations in patients’ stage of illness and proximity to death. Postbereavement measurement furthermore meant outcome data collection proceeded a step behind, and was managed separately from, practice delivery of the intervention, so assessment was fully blinded and intervention and data collection activities did not interfere with each other. Ethics approval was obtained from NRES Committee North West—Greater Manchester East (12/NW/0206).

Implementation of the CSNAT intervention

Implementation required both external facilitation by the research team and internal facilitation by sites, informed by prior pilot and feasibility studies.^{13 14} External facilitation ensured aims and requirements for implementation and the trial were established through documentation and meetings with service managers, lead practitioners and administrators. Training was conducted with all staff involved in the intervention, consisting of two sessions of 2 h 1 week apart. Session 1 covered reflection on current carer assessment, introduction of the CSNAT intervention and how it differed from current practice. Session 2 covered how practitioners could use the intervention during carer contacts and how it would integrate with existing administration, recording and service procedures. A service lead practitioner led the latter component. Each service nominated 1–2 CSNAT Champions to lead the CSNAT implementation. These were supported through regular contacts with the Research Associate (RA), monthly Skype meetings with Champions at other participating sites and two cross-site Champion face-to-face meetings. Research team members met with practitioners involved in the intervention 1–2 months after start of implementation to identify and address any queries. The RA liaised several times per month with core team members to discuss and resolve ongoing issues. A website provided documentation and further means of communication.

Internal facilitation included organisational preparation, formation of a core team (champion, manager, administrator) to steer implementation, adoption of a change management approach and enhancing mutual practitioner support.

Recruitment

Site administrators identified name and contact details of the main carer or next-of-kin (NOK) of all patients who died during the trial period (representing the total sampling frame). Survey packs were sent to carers 4–5 months postbereavement. Previous research indicates 4–6 months may yield the best response rates, while avoiding the period of most intense grieving,¹⁹ but hopefully preserving accuracy of recall. Exclusion criteria were carer age <18 years or being identified by site practitioners as experiencing particularly complicated grief. Administrators recorded surveys sent and reasons for any exclusions.

Survey packs contained an invitation letter from the service, participant information sheet, consent forms, a questionnaire booklet and freepost envelope. Carers sent completed surveys to the RA.

Data from previous cross-sectional hospice home care research⁶ showed a difference of 8.7 (SD 12.6) in postbereavement SF-36 mental health scores between carers who reported sufficient psychological support during end of life care and those who did not, representing a standardised effect size of 0.69. However, cross-sectional designs may inflate effect size. For the trial, we assumed an effect size of half of this would be more realistic (0.345). The need to reduce survey response burden furthermore led to a switch to the shorter SF-12 mental health scale. Based on Monte-Carlo simulation a stepped wedge trial with six clusters (sites) with five time bands (steps) and on average 18 patients per time band per cluster (N=540) should have 80% power to detect a standardised effect of 0.345 assuming an intracluster correlation of 0.05 and a 5% significance level. Early data from participating sites indicated they had N=3600 deaths over 15 months, making the required carer sample of N=540 feasible even with high exclusion (0.20) and low response rates (0.25).

Data collection**Sampling frame information**

Site administrators completed monthly spreadsheets from service records for all patient deaths during the trial to compile the study sampling frame. This included study ID number, patient age, gender, diagnosis, date and place of death; and the name and contact details of main carer or NOK, their gender and relationship to the patient to enable identification of carers for the survey. Anonymised information from the sampling frame was provided for analysis. Data could be linked to individual survey respondents with their consent.

Outcome variables

The survey collected information on carers' age, gender and relationship with the patient.

Primary outcome survey measures comprised adequacy of support provided for the carer during end of life care giving and physical and psychological well-being in bereavement. Perceived adequacy of support was measured using 14 questions based on the CSNAT domains, using the format 'Did you need more support with—' (responses: 1—no; 2—a little more; 3—quite a bit more; 4—very much more). Scores were summarised for the analysis. A further three questions asked whether carers had been asked about their support needs, felt their needs had been listened to, and whether there were concerns they had been unable to discuss (responses: 1—always, 2—usually, 3—sometimes, 4—never). Level of grief in bereavement was measured using the Texas Revised Inventory of Grief (TRIG)²⁰ which covers early (immediately after death) and current grief. Psychological and physical well-being was measured using the SF-12v2,²¹ and distress using the Distress Thermometer (DT).²² General practitioner (GP) contacts postbereavement were collected as a further indicator of physical health.

Secondary outcome survey measures were place of death (home, hospice, hospital, nursing/ residential home, other) and whether the place of death was felt to be the best place (yes, no, mixed feelings, don't know). Information on place of death on all patients was furthermore provided through the sampling frame information on place of death. Place of death was dichotomised into 'home'/'not home'.

Process data on implementation of the intervention

Administrators provided monthly summaries on number of new patients, patients on the caseload and number of CSNAT assessments completed for new patients and total caseload. They also recorded which carers had a CSNAT intervention on the site spreadsheet.

Qualitative information on implementation was collected from practitioners through face-to-face interviews, focus groups and workshops. In addition, field notes were completed of all RA contacts with participating sites to form a 'diary' of activity relating

to the implementation. Qualitative findings will be reported in detail elsewhere.

Analysis**Response modelling**

Factors affecting survey response rates were investigated using a logistic mixed-effects model. This included a random effect for site and a fixed effect for time (see below). All available patient and carer data from service records were examined as predictors for survey response. These were: carer gender; the relationship of patient to carer; patient age, and patient diagnosis. The intraclass correlation coefficient was also estimated to assess the strength of response clustering between carers of patients from the same site.

Outcomes

Analyses to test for differences in outcomes between control and intervention groups were based on intention to treat (ie, included all intervention participants whether they received the CSNAT intervention or not) and were adjusted for site, patient and carer variables. Outcomes were analysed using mixed-effects models to account for the stepped-wedge cluster-randomised trial design, by including a random effect for site and a fixed effect for time.²³ For quantitative and summary score outcomes, linear mixed effect models were used. To assess the number of carer GP contacts since patients' death, a Poisson mixed-effects model was used; the rate ratio was estimated to evaluate the intervention effect. For questions with ordinal responses, a cumulative logistic mixed-effects model was used, under the proportional odds assumption. For secondary binary outcomes, a logistic mixed-effects model was used. Both logistic and cumulative logistic models provided estimates of the intervention effect via an OR.

All analyses of outcomes included adjustment for carer gender, the relationship of patient to carer (partner/parent/sibling/other), patient age and diagnosis (cancer/other). For variables obtained from both service records and surveys (carer gender, relationship between patient and carer and place of death) unavailable data in service records were imputed from available survey response data and vice-versa. For analyses, any remaining missing categorical covariate values were imputed as a separate 'unknown' category value and missing continuous covariate values were imputed using simple conditional mean imputation.²⁴ The statistical significance of intervention effects was inferred from the likelihood ratio test, and 95% CIs of intervention effect estimates were constructed with normal (Wald) approximations.

RESULTS**Sample**

There were large differences in sample sizes across sites supporting the appropriateness of incorporating

clustering by site in all analyses. There were no obvious imbalances of carer/patient characteristics between control and intervention arms (table 3).

One site initially had two separate, but collaborating services included in the trial. However, the smaller service was withdrawn after some months as coordination procedures were not felt to work well enough to fully guarantee that a carer would not be sent the survey twice. This represented removal of 265 deaths from the initial sampling frame.

There were 4311 deaths in the remaining participating services during the trial (2268 control, 1478 intervention; table 3). Surveys were sent to carers in 3260 (76%) cases. A main recorded reason for not sending a survey was missing or incomplete carer details (439/1051; 42%; as opposed to 'no carer'). Of surveys sent, 681 (21%) were returned. Forty-eight respondents (7%; 22 control, 26 intervention) did not enclose consent to link their survey and service record data, and the data of the latter were imputed for the analysis (see Analysis). Table 2 shows details of patient deaths and surveys sent.

There was a wide range in the unadjusted survey response rates across sites. There was some evidence for difference in response rate by certain predictors. The independent OR estimates (95% CI) for survey

response in (1) the intervention arm compared with control, (2) female carers compared with male carers and (3) carers of patients diagnosed with cancer compared with those with other diseases were 1.30 (0.92 to 1.82) and 1.14 (0.93 to 1.40) and 1.00 (0.75 to 1.34), respectively. There was no statistically significant effect for a difference in response rate across time/phase. Compared with carers who were partners of patients, the OR estimates (95% CI) of carers recorded as being (1) parents, (2) siblings or (3) other of patients were 0.92 (0.73 to 1.15), 0.93 (0.50 to 1.73) and 0.48 (0.27 to 0.85), respectively. Once these predictors were adjusted for, the variation across sites was small; the intraclass correlation coefficient within site was estimated to be 0.017, indicating a low clustering effect of site on the response rate.

Outcomes

Table 4 shows observed, unadjusted primary and secondary outcomes by trial arm. Relative to carer survey reports, services slightly over-reported deaths at home, but this effect appeared similar for control and intervention patients. Table 5 shows adjusted estimates of the effect of the intervention on outcomes.

In the intervention group, there was evidence of reduction in early grief (TRIG-1) and improvements

Table 3 Patient and carer characteristics

Characteristics of patients and carers associated with all deaths at trial sites (n=4311, n _c =2268, n _i =2043)	Characteristics of patients and carers in survey response sample (n=681, n _c =333, n _i =348)					
	All deaths	Missing	Control	Missing	Intervention	Missing
Carer gender (%)						
Male	1322 (34)	440 (12)	101 (33)	24 (8)	90 (29)	35 (11)
Female	2549 (66)		208 (67)		223 (71)	
Patient relationship to carer (%)						
Partner	2248 (56)	302 (7)	208 (67)	22 (7)	222 (69)	26 (8)
Parent	1266 (32)		84 (27)		89 (28)	
Sibling	127 (3)		8 (3)		6 (2)	
Other	368 (9)		11 (4)		5 (2)	
Mean patient age (SD)	73.4 (−12.1)	55 (1)	71.5 (−10.6)	24 (8)	72.2 (−12.2)	26 (8)
Patient gender (%)						
Male	2269 (53)	48 (1)	142 (46)	22 (7)	147 (46)	26 (8)
Female	1994 (47)		169 (54)		175 (54)	
Patient diagnosis (%)						
Cancer	3701 (88)	87 (2)	271 (88)	26 (8)	282 (88)	28 (9)
Other	523 (12)		38 (12)		38 (12)	
Carer gender (%)*						
Male			109 (33)	5 (2)	97 (28)	5 (2)
Female			219 (67)		246 (72)	
Patient relationship to carer (%)*						
Partner			222 (67)	1 (0)	231 (67)	1 (0)
Parent			91 (27)		100 (29)	
Sibling			5 (2)		6 (2)	
Other			14 (4)		10 (3)	

(Note: these summaries are unadjusted for sample sizes at each site and time).

*Data from survey responses, all other data from service records.

Table 4 Observed outcomes in the survey response sample (n=681, n_c=333, n_i=348)

Outcome	Control	Missing (%)	Intervention	Missing (%)
CSNAT total (SD)	20.9 (−7.6)	17 (5)	21 (−7.4)	14 (4)
Asked about support needs (%)				
'Never'	31 (10)	9 (3)	25 (8)	17 (5)
'Sometimes'	53 (18)		78 (26)	
'Usually'	56 (19)		71 (23)	
'Always'	132 (44)		106 (35)	
'Not applicable'	30 (10)		25 (8)	
Listened to (%)				
'Never'	12 (4)	10 (3)	14 (5)	15 (5)
'Sometimes'	24 (8)		25 (8)	
'Usually'	46 (15)		69 (22)	
'Always'	182 (60)		177 (57)	
'Not applicable'	37 (12)		22 (7)	
Unable to discuss concerns (%)				
'Always'	3 (1)	20 (6)	2 (1)	26 (8)
'Usually'	8 (3)		8 (3)	
'Sometimes'	56 (19)		61 (21)	
'No never'	203 (70)		198 (67)	
'Don't know'	21 (7)		27 (9)	
TRIG-1 early grief (SD)	23.3 (−8.2)	17 (5)	21.7 (−7.7)	15 (5)
TRIG-2 present grief (SD)	49.9 (−11.4)	12 (4)	48.4 (−11.2)	6 (2)
SF-12 mental (SD)	39.2 (−11.8)	5 (2)	40.5 (−11.3)	7 (2)
SF-12 physical (SD)	48.5 (−11.7)	5 (2)	51.1 (−10.1)	7 (2)
Distress level (SD)	4.6 (−2.6)	2 (1)	4.4 (−2.7)	10 (3)
Median number of carer GP visits since death (range)	1 (0, 11)	8 (3)	1 (0, 12)	8 (2)
Place of death was best place (%)				
Yes	224 (73)	3 (1)	261 (82)	3 (1)
Other	84 (27)		58 (18)	
Place of death at home (survey) (%)				
Yes	140 (45)	2 (1)	171 (53)	2 (1)
No	169 (55)		149 (47)	
Place of death at home (service—respondents only) (%)				
Yes	148 (48)	0 (0)	180 (56)	0 (0)
No	163 (52)		142 (44)	
Place of death at home (service—all records) (%)				
Yes	1040 (46)	23 (1)	1044 (52)	25 (1)
No	1206 (54)		973 (48)	

Note: these summaries are unadjusted for sample sizes at each site and time and for other covariates.

CSNAT, Carer Support Needs Assessment Tool; GP, general practitioner; TRIG, Texas Revised Inventory of Grief.

in mental and physical health (SF-12) compared with the control group, although improvements were at most moderate. Most intervention effect estimates on primary outcomes (7/10) were in a favourable direction even if not always statistically significant. However, there was no indication that the intervention group felt their needs had been met (CSNAT total), or their support needs probed or listened to, to a greater extent than the control group.

For survey respondents, there was evidence of a favourable intervention effect on probability of death at home and seeing the place of death as the best place, with an OR of approximately 2 for each.

Although survey records for all deaths also indicate a favourable effect on the probability of dying at home, the adjusted analysis did not support this.

Implementation of the intervention

Monthly summaries of CSNAT assessments were obtained from four of the five sites that began the intervention during the trial, but to varying levels of completeness. Three provided monthly data on number of new patients, and CSNATs handed out and completed for carers of new patients. Two of these services also provided data on total numbers on case-load, and total CSNATs handed out and completed

Table 5 Estimate of effect of intervention with ICC on site

Outcome	Intervention effect	95% CI	p Value	Favourable result	ICC
Estimate of effect of intervention on quantitative or summary score outcomes (*Rate ratio from Poisson mixed-effects model, all other estimates from linear mixed-effects models)					
CSNAT total (n=646)	-0.36	(-2.17, 1.44)	0.684	<0	0.108
TRIG-1 early (n=645)	-1.96	(-3.83, -0.09)	0.038	<0	0.106
TRIG-2 present (n=659)	-1.24	(-3.95, 1.47)	0.322	<0	0.204
SF-12 mental (n=666)	2.58	(0.00, 5.15)	0.049	>0	0.073
SF-12 physical (n=666)	3.09	(0.64, 5.53)	0.011	>0	0.105
Distress level (n=665)	-0.18	(-0.79, 0.44)	0.508	<0	0.029
Number of GP visits since patient death (n=662)	1.02*	(0.86, 1.20)	0.833	<1	0.000
Estimate of effect of intervention (proportional OR) on ordinal response outcomes (ICC calculated on latent scale)					
Asked about support needs (n=595)	0.77	(0.47, 1.26)	0.38	>1	0.013
Listened to (n=591)	0.87	(0.51, 1.46)	0.600	>1	0.016
Unable to discuss concerns (n=577)	1.05	(0.55, 2.00)	0.890	>1	0.026
Estimate of effect of intervention (OR) on secondary binary outcomes (ICC calculated on latent scale)					
Place of death was best place (n=673)	1.94	(1.06, 3.56)	0.033	>1	0.032
Place of death at home (survey), (n=675)	2.13	(1.25, 3.61)	0.006	>1	0.036
Place of death at home (service), (n=4263)‡	0.957	(0.76, 1.20)	0.698	>1	0.029

‡Model fitted to all carer/patient records, not just survey respondents.

CSNAT, Carer Support Needs Assessment Tool; GP, general practitioner; ICC, intraclass correlation; TRIG, Texas Revised Inventory of Grief.

for total caseload. One provided information on CSNATs handed out and completed, but not on the denominators.

Based on available summary data, 985 CSNATs were reported to have been handed out to carers, but CSNAT assessments were completed in only 209 (21.2%) of these cases (range of completion across sites: 13.7–56.3%). CSNATs were reportedly handed out to 685 (41.6%) carers of 1645 new patients, and completed for 113 of these (completion rate 16.5%). Where total caseload numbers are available, CSNATs was handed out to 789 (32.1%) of 2461 on total caseload (completion rate 20.0%).

DISCUSSION

Results show that compared with the control group the intervention group had small but significant reductions in levels of early grief and improvements in psychological and physical health.

Correspondingly, results from Australia indicate that CSNAT use may benefit carers and reduce carer strain.^{25 26} Furthermore, among our survey respondents, the intervention carers were significantly more likely to feel the place of death was right and patients more likely to die at home. However, the latter result was not significant when considering service records for all deaths (respondents, non-respondents and those not surveyed). This may reflect underlying differences between survey respondents and non-respondents, the latter being a much larger group. Although not evident by table 3, there may be differences in unrecorded characteristics that, for example, may make home death both more likely and more responsive to the intervention condition in the survey group.

Overall, there appears to be favourable effects of the intervention, but differences were small, and intervention carers were not more likely to feel their needs had been met. However, the process data indicate that implementation of the CSNAT intervention was limited, both in terms of numbers of carers affected and the extent to which the intervention was delivered as intended. Available data indicate that the CSNAT was only handed out to carers of a third of patients in total. Furthermore, while a reasonable proportion of carers may have seen the CSNAT, potentially alongside other paperwork, CSNAT assessment was only completed in a minority of cases. Completion in itself may not mean there was subsequent discussion about carers' needs, priorities and preferred solutions and follow-up action plans. This low level of implementation means the CSNAT intervention would have limited opportunity to make a strong direct impact.

Improvements in the intervention group may therefore in part result from awareness raising regarding carers' needs through activities surrounding the implementation of the intervention, including training, champions' efforts, regular RA contacts, keeping CSNAT on staff meeting agendas and encouragement by managers. However, if significant improvements, albeit small, may be produced by low level implementation and general awareness raising, it is plausible that more substantial improvements can be achieved if the CSNAT intervention can be delivered to the majority of carers in its intended form, that is, an assessment and support process based on carers' self-identified needs, priorities and solutions.

While there was no doubt about efforts expended by sites participating in the trial, implementation of

the CSNAT intervention presented greater challenges than expected. Qualitative data collection helped identify main factors that affected implementation, illustrating the value of a mixed-methods approach to trials.²⁷ While these factors will be reported in detail elsewhere, in brief outline they encompassed practitioner perceptions and engagement, service context factors, external and internal facilitation: the CSNAT intervention represented a step change in practice, but practitioners may not perceive its value over existing practice and/or have concerns over workload impact. Services differed in the extent to which existing administrative systems and working practices enabled the CSNAT intervention to be easily integrated and carers to be accommodated as clients in their own right. This included existing opportunities for carer identification, contact and recording of support needs and actions. Internal facilitation was affected by time and availability of management leads, champions' opportunities for leverage and organisational resources to support implementation in the face of competing demands and staffing levels. External facilitation did not fully address the step change that the intervention represented. Our findings correspond with the components of the Promoting Action on Research Implementation in Health Services (PARIHS) framework for implementation where implementation of a complex intervention depends on the perceived value of the intervention, service context and facilitation.^{28 29}

The research was also affected by some of the service factors. Missing information on main carers or NOK increased administrator workloads in chasing information, reduced numbers of surveys sent and left less time for supplying process data. Lack of procedures for routine recording of CSNAT assessments and follow-up actions also hampered further collection and analysis of process information. Service support costs for recruitment were fully covered, but this was only helpful if services could appoint additional staff. Services' ability to fit in a practice change at the time furthermore meant that (constrained) randomisation only occurred in four of six participating sites; therefore, some selection biases and imbalances between the control and intervention samples are possible.

CONCLUSION

The trial highlights the importance of investing effort in understanding implementation of complex interventions as recommended by the MORECare guidance for palliative care³⁰ and the MRC Framework for evaluations.³¹ Our trial furthermore illustrates the value of mixed methods and process measures to understand how complex interventions behave in a practice context.^{27 31}

Furthermore, the trial highlights the challenges in implementing comprehensive carer assessment and support: our qualitative data indicate that carers are

not 'visible' on administrative systems in that often carer details are not recorded and there are commonly no consistent means of documenting their needs as separate from patients; that practice procedures often do not afford opportunity for regular carer contact, assessment and follow-up; and that engagement with assessment of carers' needs separately from the patient and with carer-led assessment represents a significant step change for practitioners. These challenges need to be recognised and addressed before guidelines and government recommendations that carer needs should be assessed and addressed^{9 10} can have meaningful impact. We have used trial findings to develop a training and implementation package to improve external facilitation and encourage better internal facilitation of the CSNAT intervention and are testing this in an implementation study with improved results.

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The survey used the question wording, answer categories and order of questions identical to SF-12v2, but their appearance was changed to make a more user-friendly bereavement survey booklet. They were therefore not in a format approved by OptumInsight Life Sciences (QualityMetric), and due to these modifications, scores may not necessarily be reliable or valid.

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