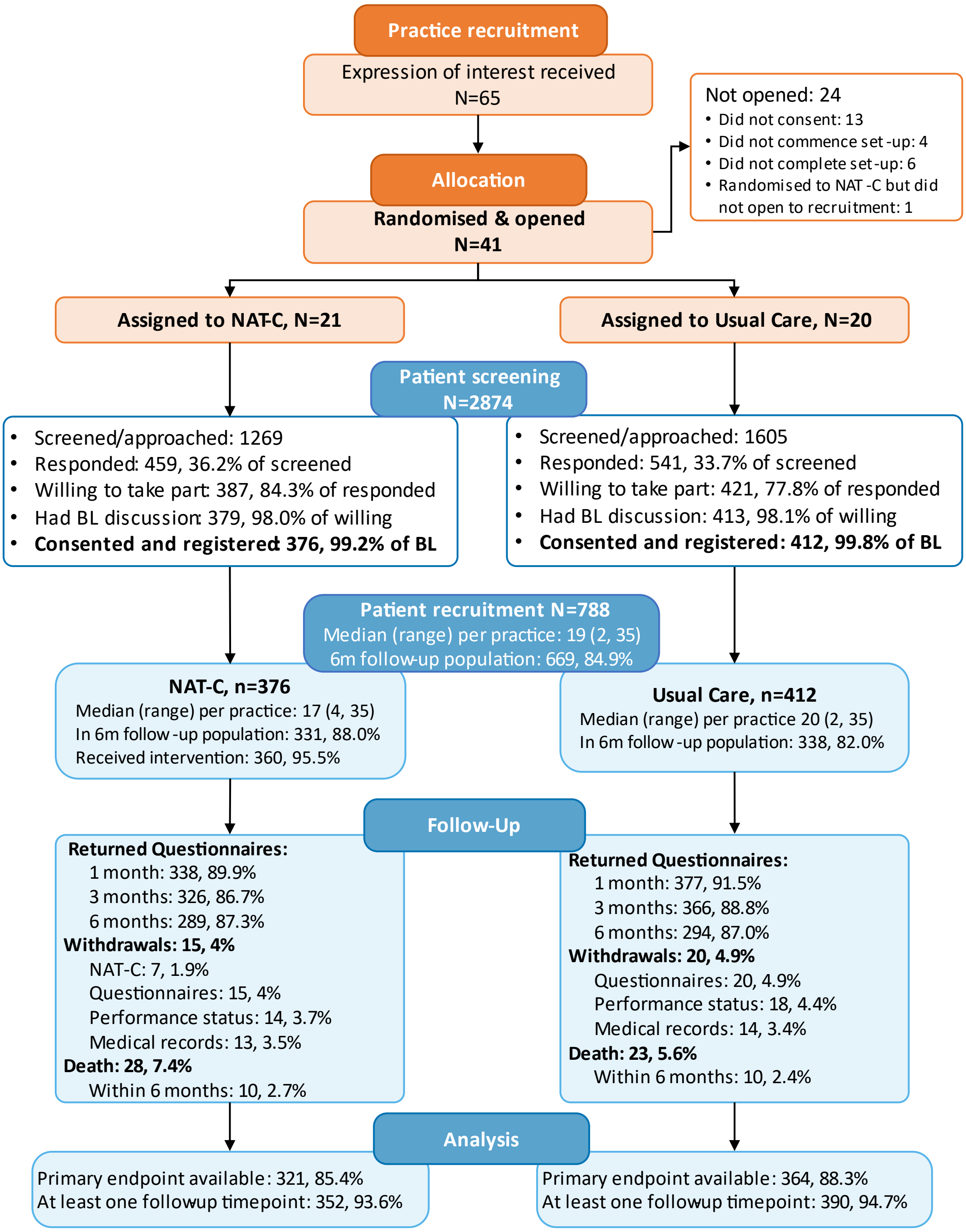
Basic Results Summary

PARTICIPANT FLOW



BASELINE CHARACTERISTICS (1)

	NAT-C (n=376)	Usual Care (n=412)	Total (n=788)
Age: mean (sd)	66.6 (10.62)	67.1 (11.12)	66.9 (10.88)
Sex[1]			
Male	177 (47.1%)	207 (50.2%)	384 (48.7%)
Female	199 (52.9%)	205 (49.8%)	404 (51.3%)
Ethnicity			
White	371 (98.9%)	405 (98.3%)	776 (98.6%)
Mixed	2 (0.5%)	2 (0.5%)	4 (0.5%)
Black	2 (0.5%)	2 (0.5%)	4 (0.5%)
Asian	0	2 (0.5%)	2 (0.3%)
Other ethnic group	0	1 (0.2%)	1 (0.1%)
Missing	1	0	1
Registered on Gold Standard Framework/other palliative service: %yes[2]	41 (17.9%)	77 (28.2%)	111 (22.1%)
IMD Quintile[3]			
1 (most deprived)	45 (12.8%)	50 (12.5%)	95 (12.6%)
2	44 (12.5%)	74 (18.5%)	118 (15.7%)
3	41 (11.7%)	68 (17.0%)	109 (14.5%)
4	94 (26.8%)	122 (30.4%)	216 (28.7%)
5 (least deprived)	127 (36.2%)	87 (21.7%)	214 (28.5%)
Relationship status: %married/relationship[4]	266 (70.9%)	318 (77.2%)	584 (74.2%)
Comorbidities			
None	96 (25.5%)	100 (24.3%)	196 (24.9%)
Single	102 (27.1%)	113 (27.4%)	215 (27.3%)
Multiple	178 (47.3%)	199 (48.3%)	377 (47.8%)
Months Between Initial Cancer Diagnosis and Registration: median (IQR)[5]	20.2 (8.6, 43.7)	23.2 (10.3, 45.2)	21.9 (9.7, 44.6)
Active Cancer Managed[6]			
Receiving anti-cancer treatment with curative or palliative intent	233 (62.1%)	238 (57.9%)	471 (59.9%)
Managed with 'watch and wait'	113 (30.1%)	146 (35.5%)	259 (33.0%)
Recurrent or metastatic; or inoperable	29 (7.7%)	25 (6.1%)	54 (6.9%)
Other	0	2 (0.5%)	2 (0.3%)
Stage of malignancy[7]			
Localised disease (early)	201 (54.9%)	210 (60.9%)	411 (57.8%)
Localised disease (advanced) / metastatic disease	165 (45.1%)	135 (39.1%)	300 (42.2%)
Participant has carer: %yes	236 (62.8%)	191 (46.4%)	427 (54.2%)
Carer recruited: %yes	138 (36.7%)	111 (26.9%)	249 (31.6%)

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[1] Data regarding sex was self-reported; the options provided were "male" and "female".
[2] 147 missing in the NAT-C arm and 139 in the usual care arm.
[3] IMD=Index of Multiple Deprivation: 1=neighbourhood in the 20% most deprived neighbourhoods in England, 2=20-40%, 3=40-60%, 4=60-80%, 5= neighbourhood in the 20% least deprived neighbourhoods in England. There were 25 missing in the NAT-C arm and 11 in usual care.
[4] 1 missing in the NAT-C arm
[5] 1 missing in the usual care arm
[6] 1 missing in the NAT-C arm; 1 missing in the usual care arm
[7] 10 missing in the NAT-C arm; 67 missing in the usual care arm

BASELINE CHARACTERISTICS (2)[1]

	NAT-C (n=376)	Usual Care (n=412)	Total (n=788)
SCNS-SF34[2]			
Any (%) unmet need[3]	194 (51.6%)	229 (55.9%)	423 (53.7%)
Mean (SD) total level of unmet need	20.3 (17.58)	21.2 (18.92)	20.8 (18.29)
Unmet need (%) by domain			
Psychological	144 (38.3%)	153 (37.4%)	297 (37.7%)
Health Systems	98 (26.1%)	105 (25.6%)	203 (25.8%)
Physical	134 (35.6%)	146 (35.6%)	280 (35.5%)
Care	47 (12.5%)	68 (16.6%)	115 (14.6%)
Sexual	45 (12.0%)	58 (14.1%)	103 (13.1%)
Mean (SD) level of unmet need by domain			
Psychological	25.8 (25.25)	26.2 (25.50)	26.0 (25.37)
Health Systems	17.3 (19.14)	18.6 (20.65)	17.9 (19.94)
Physical	26.3 (27.60)	25.7 (26.20)	26.0 (26.86)
Care	14.0 (16.70)	15.8 (20.30)	14.9 (18.67)
Sexual	13.8 (21.96)	15.7 (24.40)	14.8 (23.27)
Mean (SD) performance status (AKPS)[4]	84.3 (14.37)	85.5 (13.41)	84.9 (13.88)
Mean (SD) severity of symptoms (ESAS-r)[5]	18.2 (16.51)	16.7 (15.07)	17.4 (15.78)
Mean (SD) Mood and Quality of Life (EORTC QLQ-C15-PAL)[6]			
Pain	24.5 (30.52)	22.1 (29.81)	23.3 (30.16)
Dyspnoea	17.6 (26.65)	17.6 (26.99)	17.6 (26.81)
Insomnia	34.3 (36.70)	30.5 (34.84)	32.3 (35.77)
Appetite Loss	12.1 (25.71)	10.5 (24.47)	11.3 (25.07)
Constipation	12.6 (25.23)	13.3 (25.65)	13.0 (25.44)
Quality of Life	72.9 (24.07)	72.5 (23.39)	72.7 (23.71)
Physical Functioning	77.4 (23.97)	78.7 (22.69)	78.1 (23.31)
Fatigue	34.0 (29.45)	31.8 (28.31)	32.9 (28.86)
Nausea/Vomiting	5.6 (16.76)	4.5 (14.62)	5.1 (15.67)
Emotional Functioning	82.5 (24.57)	84.7 (23.61)	83.6 (24.08)
Carer measures, N	138	111	249
Mean (SD) carer experience (CES)[7]	73.4 (12.31)	74.1 (13.08)	73.7 (12.64)
Mean (SD) carer well-being and burden (ZBI-12)[8]	7.2 (7.15)	6.7 (7.27)	7.0 (7.19)

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[1] Higher scores represent worse outcomes with the exception of underlined measures of performance status, quality of life, physical functioning, emotional function, and carer experience.

[2] SCNS-SF34=Supportive Care Needs Survey Short Form 34. Total and domain scores range 0 to 100. Higher scores indicate greater unmet need.

[3] Defined as any moderate to high unmet need in any item on the SCNS-SF34.

[4] AKPS=Australian modified Karnofsky Scale. Values range from 0 (deceased) to 100 (normal physical abilities).

[5] ESAS-r=Revised Edmonton Symptom Assessment System (ESAS-r). Scores range 0 to 90. Higher scores indicate worse symptoms.

[6] EORTC QLQ-C15-PAL= European Organisation for Research and Treatment of Cancer Quality of Life-C15-Palliative questionnaire. Scores range 0 to 100. Higher symptom scores (Pain, Dyspnoea, Insomnia, Appetite Loss, Constipation, Fatigue, Nausea/Vomiting) indicate worse symptoms. Higher Quality of Life, Physical Functioning, and Emotional Functioning scores indicate better outcomes.

[7] CES=Carer Experience Scale. Scores range 0 to 100. Higher scores indicate better experience.

[8] ZBI-12=Zarit Burden Interview. Scores range 0 to 48. Higher scores indicate greater burden.

SCNS-SF34 OUTCOME MEASURES[1]

	One Month			Three Months[2]			Six Months		
	NAT-C	**Usual Care**	**Effect (95% CI), p-value**	**NAT-C**	**Usual Care**	**Effect (95% CI), p-value**	**NAT-C**	**Usual Care**	**Effect (95% CI), p-value**
Questionnaire pack completed[3]	338 (89.9%)	377 (91.5%)		326 (86.7%)	366 (88.8%)		289 (87.3%)	294 (87.0%)	
Primary endpoint (SCNS-SF34[4]): Any (%) unmet need[5]	169 (50.0%)	190 (50.5%)	1.00 (0.65, 1.54), p=0.9967	149 (46.4%)	173 (47.5%)	0.98 (0.63, 1.53), p=0.9428	125 (43.6%)	145 (49.3%)	0.66 (0.42, 1.04), p=0.0749
Key-secondary endpoint (SCNS-SF34): Mean (SD) total level of unmet need	23.0 (20.51)	23.4 (19.80)	-0.91 (-3.73, 1.91), p=0.5274	21.4 (19.27)	21.6 (19.46)	-0.51 (-3.36, 2.35), p=0.7265	20.5 (19.31)	23.1 (19.91)	-3.57 (-6.57, -0.58), p=0.0195
Unmet need (%) by domain (SCNS-SF34)									
Psychological	137 (40.7%)	132 (35.1%)	1.18 (0.75, 1.85), p=0.4815	106 (33.0%)	122 (33.5%)	0.85 (0.54, 1.36), p=0.4988	86(30.0%)	99(33.7%)	0.59 (0.37, 0.96), p=0.0344
Health Systems	90 (26.8%)	105 (27.9%)	0.84 (0.56, 1.28), p=0.4240	71 (22.1%)	69 (18.9%)	1.14 (0.72, 1.80), p=0.5683	60(20.9%)	71(24.1%)	0.69 (0.44, 1.09), p=0.1153
Physical	113 (33.4%)	129 (34.3%)	0.87 (0.52, 1.43), p=0.5781	99 (30.8%)	115 (31.6%)	0.90 (0.54, 1.50), p=0.6749	78(27.3%)	96(32.7%)	0.57 (0.33, 0.98), p=0.0434
Care	52 (15.4%)	61 (16.2%)	0.88 (0.55, 1.41), p=0.5951	47 (14.7%)	48 (13.2%)	1.08 (0.66, 1.77), p=0.7666	33(11.5%)	40(13.6%)	0.78 (0.46, 1.32), p=0.3523
Sexual	51 (15.3%)	59 (15.7%)	0.90 (0.54, 1.50), p=0.6910	35 (11.0%)	50 (13.8%)	0.67 (0.39, 1.17), p=0.1578	29(10.2%)	34(11.6%)	0.66 (0.37, 1.18), p=0.1625
Mean (SD) level of unmet need by domain (SCNS-SF34)									
Psychological	28.8 (25.79)	28.8 (25.04)	-1.43 (-4.98, 2.12), p=0.4304	27.8 (25.08)	26.8 (24.81)	-0.03 (-3.73, 3.66), p=0.9853	26.1 (24.88)	29.3 (26.00)	-5.02 (-8.96, -1.08), p=0.0126
Health Systems	20.2 (21.39)	21.2 (21.80)	-1.10 (-4.36, 2.17), p=0.5100	17.9 (19.40)	19.0 (20.92)	-1.08 (-4.23, 2.07), p=0.5007	17.9 (19.80)	20.1 (21.26)	-2.79 (-6.08, 0.49), p=0.0954
Physical	26.0 (26.42)	26.8 (26.56)	-2.71 (-6.16, 0.74), p=0.1233	25.2 (26.90)	25.9 (27.49)	-2.05 (-5.74, 1.64), p=0.2759	22.9 (25.46)	27.9 (26.98)	-7.00 (-10.85, -3.16), p=0.0004
Care	17.9 (20.93)	17.2 (20.31)	0.50 (-2.43, 3.43), p=0.7363	15.6 (18.45)	16.3 (19.03)	-0.95 (-3.78, 1.89), p=0.5125	15.2 (18.65)	17.1 (19.95)	-2.33 (-5.40, 0.74), p=0.1366
Sexual	17.6 (24.8))	18.3 (25.55)	-1.55 (-4.82, 1.73), p=0.3540	15.6 (23.40)	15.7 (23.10)	-0.93 (-4.11, 2.25), p=0.5669	16.2 (23.08)	16.1 (23.31)	-2.30 (-5.74, 1.15), p=0.1910

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[1] The following table presents raw data by arm alongside the treatment effect estimate, representing the adjusted mean difference between treatment groups for continuous outcomes (level of unmet need) and adjusted odds ratios for binary outcomes (moderate or high unmet need) estimated using linear and logistic mixed models with repeated measures, adjusted for covariates.

[2] Primary endpoint timepoint; ICC at 3 months estimated as 6.7% and 4.3% for the primary and key secondary endpoint respectively.

[3] Represented the number of questionnaire packs completed and retuned, number with available endpoints is slightly lower in some cases due to missing responses within questionnaires. Follow-up questionnaires were mostly completed via paper and post (for 63.4%, 63.6%, 64.7% returns at 1-, 3- and 6-month follow-up), with the remaining completed online. Questionnaires were completed within 1 month of the follow-up timepoint for ≥95% of returns at all timepoints.

[4] SCNS-SF34=Supportive Care Needs Survey Short Form 34, total and domain scores range 0 to 100 with higher scores indicating greater unmet need.

[5] Defined as any moderate to high unmet need in any item on the SCNS-SF34.

SECONDARY OUTCOME MEASURES[1]

	One Month			Three Months			Six Months		
	NAT-C	Usual Care	Mean Difference (95% CI), p-value	NAT-C	Usual Care	Mean Difference (95% CI), p-value	NAT-C	Usual Care	Mean Difference (95% CI), p-value
Participant questionnaire pack completed	338 (89.9%)	377 (91.5%)		326 (86.7%)	366 (88.8%)		289 (87.3%)	294 (87.0%)	
Mean (SD) performance status (AKPS)[2]	84.4 (14.41)	86.0 (13.90)	-0.05 (-2.00, 1.89), p=0.9591	85.5 (14.72)	85.7 (14.31)	1.64 (-0.44, 3.73), p=0.1229	84.5 (14.43)	86.7 (13.50)	-0.02 (-2.22, 2.17), p=0.9828
Mean (SD) severity of symptoms (ESAS-r)[3]	19.0 (17.79)	18.0 (16.36)	-0.86 (-3.07, 1.35), p=0.4462	18.0 (16.99)	17.4 (16.19)	-0.81 (-3.09, 1.46), p=0.4842	17.2 (16.58)	18.2 (16.80)	-2.98 (-5.35, -0.61), p=0.0137
Mean (SD) Mood and Quality of Life (EORTC QLQ-C15-PAL)[4]									
Pain	22.8 (28.94)	21.5 (27.43)	-0.45 (-3.71, 2.81), p=0.7869	21.0 (27.77)	22.1 (27.99)	-2.79 (-6.07, 0.49), p=0.0955	19.6 (26.16)	22.5 (28.34)	-3.81 (-7.26, -0.35), p=0.0307
Dyspnoea	19.5 (27.60)	19.7 (26.65)	-1.07 (-3.95, 1.81), p=0.4656	19.5 (26.38)	18.8 (25.80)	0.64 (-2.26, 3.55), p=0.6649	19.4 (26.23)	19.6 (25.78)	0.32 (-2.84, 3.48), p=0.8427
Insomnia	34.9 (33.24)	32.8 (32.15)	-0.98 (-4.75, 2.78), p=0.6079	33.2 (31.37)	31.8 (34.02)	-0.68 (-4.77, 3.41), p=0.7454	29.8 (30.64)	32.9 (32.23)	-3.61 (-7.69, 0.48), p=0.0838
Appetite Loss	13.4 (25.63)	11.7 (22.94)	0.26 (-2.56, 3.09), p=0.8546	12.4 (23.83)	11.2 (22.93)	0.29 (-2.68, 3.26), p=0.8471	10.2 (21.83)	13.7 (25.20)	-4.02 (-7.31, -0.72), p=0.0169
Constipation	15.6 (25.72)	16.2 (26.01)	0.18 (-3.02, 3.38), p=0.9110	13.3 (23.42)	14.9 (25.29)	-0.87 (-4.06, 2.33), p=0.5948	14.0 (24.34)	16.6 (25.90)	-1.27 (-4.80, 2.26), p=0.4795
Quality of Life	70.7 (23.12)	71.8 (21.48)	0.34 (-2.31, 2.99), p=0.8001	71.9 (22.76)	71.4 (20.96)	1.61 (-0.94, 4.16), p=0.2149	73.3 (20.94)	70.3 (21.60)	3.97 (1.03, 6.91), p=0.0082
Physical Functioning	76.7 (24.26)	78.2 (22.41)	0.32 (-2.49, 3.13), p=0.8243	76.8 (23.23)	77.9 (23.51)	0.14 (-2.76, 3.05), p=0.9221	76.7 (23.33)	76.9 (23.27)	2.61 (-0.59, 5.81), p=0.1093
Fatigue	35.2 (27.59)	35.8 (26.41)	-2.17 (-4.98, 0.65), p=0.1312	32.6 (26.40)	33.9 (25.66)	-2.45 (-5.30, 0.40), p=0.0914	32.0 (25.43)	33.5 (25.98)	-2.06 (-5.10, 0.97), p=0.1826
Nausea/Vomiting	6.4 (17.29)	5.3 (13.77)	0.23 (-1.69, 2.16), p=0.8110	6.2 (17.20)	4.6 (12.54)	0.82 (-1.20, 2.84), p=0.4259	4.5 (13.54)	5.2 (14.04)	-0.98 (-2.95, 1.00), p=0.3314
Emotional Functioning	80.0 (23.92)	81.1 (23.44)	1.93 (-0.86, 4.72), p=0.1752	80.2 (24.80)	82.3 (22.47)	0.54 (-2.50, 3.58), p=0.7279	81.5 (24.90)	80.7 (24.79)	3.54 (0.21, 6.87), p=0.0374
Carer questionnaire pack completed	122 (88.4%)	105 (94.6%)		121 (87.7%)	99 (89.2%)		103 (80.5%)	81 (87.1%)	
Mean (SD) carer experience (CES)[5]	71.9 (13.13)	73.8 (13.41)	-2.53 (-5.92, 0.85), p=0.1423	71.1 (13.20)	71.4 (13.18)	0.54 (-2.93, 4.01), p=0.7599	70.7 (15.04)	71.2 (14.85)	-0.06 (-4.21, 4.09), p=0.9774
Mean (SD) carer well-being and burden (ZBI-12)[6]	8.9 (7.78)	9.1 (7.75)	0.09 (-1.47, 1.64), p=0.9145	9.4 (8.53)	9.6 (8.63)	-0.54 (-2.40, 1.32), p=0.5697	9.5 (8.35)	8.8 (7.70)	0.00 (-1.90, 1.90), p=0.9980

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[1] The following table presents raw data by arm alongside the treatment effect estimate, representing the adjusted mean difference between treatment groups estimated using linear mixed models with repeated measures, adjusted for covariates. Higher scores represent worse outcomes for all endpoints with the exception of performance status, quality of life, physical functioning, emotional function, and carer experience endpoints.

[2] AKPS=Australian modified Karnofsky Scale. Values range from 0 (deceased) to 100 (normal physical abilities).

[3] ESAS-r=Revised Edmonton Symptom Assessment System (ESAS-r). Scores range 0 to 90.

[4] EORTC QLQ-C15-PAL= European Organisation for Research and Treatment of Cancer Quality of Life-C15-Palliative questionnaire. Scores range 0 to 100.

[5] CES=Carer Experience Scale. Scores range 0 to 100.

[6] ZBI-12=Zarit Burden Interview. Scores range 0 to 48.

PROCESS EVALUATION OUTCOME MEASURES (1): CLINICIANS TRAINED

	Total Practices (n=21)
Frequency Count	
Total Clinicians trained	53
Mean (SD)	2.5 (1.36)
Median (Range)	2.0 (1.0, 6.0)
IQR	(2.0, 3.0)
Missing	0
Of those trained	**Total Trained (n=53)**
How was training done[1]?	
Face to face: teleconference	43 (81.13%)
Face to face: webinar	7 (13.21%)
Web training	3 (5.66%)
Days between training and first NAT-C Appointment	
Mean (SD)	105.68 (47.93)
Median (Range)	97.00 (46.00, 230.00)
IQR	(67.00, 134.00)
Missing	22[2]

PROCESS EVALUATION OUTCOME MEASURES (2): NAT-C INTERVENTION RECEIPT BY HUB

	Hull (n=99)	**Leeds (n=91)**	**Sheffield (n=133)**	**Sunderland (n=53)**	**Total NAT-C (n=376)[3]**
NAT-C Intervention delivered					
Yes	96 (97.0%)	85 (93.4%)	126 (94.7%)	53 (100.0%)	360 (95.7%)
No	3 (3.0%)	6 (6.6%)	7 (5.3%)	0	16 (4.3%)
Of those delivered	**Hull (n=96)**	**Leeds (n=85)**	**Sheffield (n=126)**	**Sunderland (n=53)**	**Total Delivered NAT-C (n=360)**
Length of consultation (minutes)					
Mean (SD)	25.7 (11.21)	24.5 (8.69)	26.5 (7.22)	17.5 (6.59)	24.4 (9.18)
Median (Range)	20.0 (10.0, 60.0)	20.0 (16.0, 40.0)	27.5 (8.0, 60.0)	17.0 (8.0, 35.0)	24.0 (8.0, 60.0)
IQR	(20.0, 30.0)	(20.0, 32.0)	(22.0, 30.0)	(12.0, 23.0)	(20.0, 30.0)
Missing	15	74	0	0	89

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[1] There were no refresher training sessions

[2] Reasons for missing: clinician completed training but no appointments. There were some NATs where the name was unclear (i.e. two doctors with the same surname)

[3] Only showing participants randomised to the NAT-C group (i.e. ignoring the one protocol violation where a participant in the usual care group received a NAT-C session)

PROCESS EVALUATION OUTCOME MEASURES (3): REFERRALS

	NAT-C (n=360)
Referred?	
No	310 (86.1%)
Yes	50 (13.9%)
Of Those Referred	**NAT-C (n=50**)
Referral speciality	
Social worker	1 (2.2%)
Psychologist	7 (15.2%)
Specialist palliative care service[1]	10 (21.7%)
Medical oncologist	1 (2.2%)
Other	10 (21.7%)
No speciality given	17 (37.0%)
Missing	4
Assessment priority (of referred)	
Semi-Urgent (2-7 days)	3 (6.7%)
Non-Urgent (next available)	42 (93.3%)
Missing	5

ADVERSE EVENTS

There were no adverse events associated with this study.

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[1] Of those ten participants referred to SPCS, one indicated this in section 2 only, three in section 1 only, three in both sections 1 and 2, and three in no sections at all.