Clinical effectiveness and cost-effectiveness of the Needs Assessment Tool-Cancer in primary care (CANAssess2): a pragmatic, cluster-randomised, controlled trial

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Summary

Background The Needs Assessment Tool-Cancer (NAT-C) is a consultation guide to identify and triage patients' and carers' cancer-related unmet needs, but its effectiveness in primary care is unknown. We aimed to evaluate the clinical effectiveness and cost-effectiveness of the NAT-C in reducing patient unmet needs and reducing carer burden in primary care.

Methods The Cancer Patients' Needs Assessment in Primary Care (CANAssess2) trial was a pragmatic, cluster-randomised, controlled trial of the NAT-C versus usual care in patients aged 18 years and older with active cancer (ie, receiving anticancer treatment with curative or palliative intent; managed with a watch and wait approach; or with recurrent or metastatic disease), conducted across northeast England and Yorkshire. Eligible general practices (clusters) were willing to be trained and deliver the NAT-C for recruited patients if so allocated, were willing to commit to trial procedures, and gave written informed practice-level consent. Practices were randomly assigned (1:1) to deliver the NAT-C intervention or usual care alone by use of minimisation incorporating a random element to ensure treatment groups were well balanced for patient list size, locality, and training centre status. Patients and carers (family or friend nominated by patient) consented to complete follow-up questionnaires at baseline, 1 month, 3 months, and 6 months and attend a NAT-C appointment if registered with an intervention practice. The primary outcome was at least one moderate-to-severe unmet need at 3 months (according to the Supportive Care Needs Survey-Short Form 34 [SCNS-SF34]). Secondary outcomes included at least one moderate-to-severe unmet need at 1 month and 6 months, level of unmet needs (SCNS-SF34 score), symptoms (Revised Edmonton Symptom Assessment System [ESAS-r]), mood and quality of life (EQ-5D-5L and European Organisation for Research and Treatment of Cancer Quality of Life-C15-Palliative questionnaire [EORTC QLQ-C15-PAL]), performance status (Australia-modified Karnofsky Performance Score), carers' ability to care, and carer wellbeing, at all timepoints. Primary effectiveness analyses were done in all participants with at least one post-baseline measurement (at either 1, 3, or 6 months) according to modified intention-to-treat principles. The original sample size target of 1080 participants across 54 practices was reduced in a protocol amendment to 950 across at least 38 practices due to recruitment challenges and improved retention. The trial is registered with ISRCTN, ISRCTN15497400.

Findings Between Oct 21, 2020, and April 12, 2023, of 65 general practices screened, 41 (63%) were randomly assigned: 21 (51%) to NAT-C and 20 (49%) to usual care. Between Dec 1, 2020, and Aug 30, 2023, 788 participants (mean age 66·9 years, SD 10·9; 404 [51%] female and 384 [49%] male) were enrolled: 376 (48%) in the NAT-C group and 412 (52%) in the usual care group. 427 (54%) of 788 participants identified a potentially eligible carer, and a carer was recruited alongside 249 (32%) participants. Follow-up was completed on Jan 19, 2024. For the 3-month primary outcome, 149 (46%) of 321 participants in the NAT-C group and 173 (48%) of 364 participants in the usual care group reported at least one moderate-to-severe unmet need (odds ratio [OR] 0·98 [95% CI 0·63 to 1·53]; p=0·94; intracluster correlation coefficient 0·067). There was no evidence of benefit for any clinical effectiveness outcomes at 1 month or 3 months. However, at 6 months we found evidence that the NAT-C was superior to usual care at reducing the level of unmet need (mean difference –3·57, 95% CI –6·57 to –0·58; p=0·020; predominantly psychological and physical needs). There was also evidence of benefit in the NAT-C group on 6-month symptoms (ESAS-r mean difference –2·98, 95% CI –5·35 to –0·61; p=0·014) and mood and quality of life (mean difference in EORTC QLQ-C15-PAL domains of overall quality of life 3·97, 1·03 to 6·91, p=0·0082; pain –3·81, –7·26 to –0·35, p=0·031; appetite loss –4·02, –7·31 to –0·72, p=0·017; emotional functioning 3·54, 0·21 to 6·87, p=0·037). There was weak evidence of benefit for the 6-month outcome of at least one moderate-to-severe unmet need (OR 0·66, 95% CI 0·42 to 1·04; p=0·075), but no evidence of benefit on performance status (mean difference –0·02, –2·22 to 2·17; p=0·98), carers' ability to care (–0·06, –4·21 to 4·09; p=0·98), or wellbeing (0·00, –1·90 to 1·90; p=0·99).

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Interpretation We found no evidence of benefit of the NAT-C versus usual care at the 3-month primary endpoint timepoint. However, our data suggest potential benefits for patients at 6 months, although future studies with longer follow-up are needed to clarify these findings.

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Introduction

Over 3 million people live with cancer in England, with this number expected to rise to 4 million by 2030.[1] Reported levels of cancer-related unmet need range from 24% to 88%, with higher levels in people who are recently diagnosed, those with metastatic disease, or those approaching the end of life.[2] However, despite policy directives such as the NHS Long Term Plan,[3] which aims to improve cancer care—with a specific role for primary care—this situation remains unchanged.[4] In 2003, cancer care review consultations after cancer diagnosis were introduced into UK primary care. There is a fee payable by the NHS to the general practice for this service[5] and, although most general practices provide cancer care reviews, these vary from a telephone call to a holistic needs assessment (HNA). Despite UK-wide adoption of cancer care reviews, a systematic review (of ten articles, comprising small surveys, service evaluations, and interview studies, but no randomised trials) found little evidence of clinical benefit.[6] Although some qualitative value was observed, interviewed patients generally could not remember having a review or felt it to be of little value, and clinicians felt too time-pressured to complete reviews effectively. Other approaches, such as HNAs and cancer survivorship plans, are mostly used in secondary care (eg, oncology outpatients), with little evidence of clinical benefits, as distinct from process measures (eg, documenting the review had taken place).[7–10]

The Needs Assessment Tool-Cancer (NAT-C) is a clinical consultation guide adapted and validated for UK primary care,[11] which showed a promising reduction in unmet need in our non-controlled feasibility study.[12] We aimed to

Research in context

Evidence before this study

We searched MEDLINE from Jan 1, 2000, to June 30, 2024, for clinical trials using the following terms limited to English language articles: (cancer or neoplasms) and (assessment and needs) and (holistic health or holistic) and (primary care or primary health care or general practice or family medicine [or doctor or practice] or physicians, family). We found no randomised controlled trials evaluating cancer holistic needs assessment (HNA) regarding patient-reported outcomes in primary care. Johnstone and colleagues' systematic review of HNA tools found four secondary care-based randomised controlled trials with patient-reported outcomes. Findings were mixed, but full screening of needs with triage appeared most beneficial. Carey and colleagues' systematic review of interventions to reduce cancer-related unmet need, found three of nine randomised controlled trials or quasi-randomised controlled trials (one in the UK and none in primary care) showed some benefit, mainly in psychological outcomes. The only randomised controlled trial (oncology setting in the UK) of the Macmillan HNA tool showed no difference in outcomes compared with usual care. We adapted and validated a clinician consultation guide (Needs Assessment Tool–Cancer [NAT-C]) for UK primary care. The subsequent non-controlled feasibility study showed a larger trial was feasible and a promising reduction in holistic cancer-related unmet need.

Added value of this study

Patient-reported benefit from HNA interventions has not been shown in randomised trials. To our knowledge, this study is the first phase 3 randomised controlled trial of clinical effectiveness and cost-effectiveness of a validated primary care intervention which, despite finding no difference at 1 month or for our primary 3-month outcome, provides evidence of patient-reported benefits across several physical and psychosocial domains (consistent with a holistic intervention) at 6 months. Given these benefits are seen in secondary outcomes at a single timepoint, these findings should be viewed as suggesting benefit and further research, including longer-term repeated follow-up trials, is needed.

Implications of all the available evidence

Our findings—amalgamated with findings from other randomised controlled trials in secondary care settings, quality improvement evaluations in primary care, and no evidence of harms—suggest the NAT-C could support a systematic and cost-effective needs assessment approach in primary care, standardise the current lottery of practice, and be added to policy recommendations. However, these secondary outcome findings require further research to confirm or refute our observations. We welcome future real-world evaluations or replication featuring a 6-month primary outcome, extended repeated follow-up, and a pragmatic design to strengthen real-world relevance and implementation.

evaluate the clinical effectiveness and cost-effectiveness of the NAT-C in reducing patient unmet need and other outcomes and reducing carer burden in primary care.

Methods

Study design and participants

The Cancer Patients' Needs Assessment in Primary Care (CANAssess2) trial was a pragmatic, cluster-randomised, controlled trial of the NAT-C versus usual care in patients with active cancer (ie, receiving anticancer treatment with curative or palliative intent; managed with a watch and wait approach; or with recurrent or metastatic disease). Our methods, informed by the feasibility trial,[12] are detailed elsewhere.[13] Patient and public involvement representatives were involved throughout, contributing to trial design, documentation, conduct, oversight, and outputs.

CANAssess2 was conducted at general practices across northeast England and Yorkshire. The protocol (appendix pp 92–101)[13] and subsequent amendments (appendix pp 3–4) were approved by London-Surrey Research Ethics Committee (20/LO/0312). The trial was done in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki and registered with ISRCTN, ISRCTN15497400 and is closed to new participants.

Protocol amendments (appendix pp 3–4) were made to allow the trial to be run fully remotely (protocol version 3.0; approved July 24, 2020) and reduce the sample size to 950 participants across a minimum of 38 general practices (protocol version 8.0; approved September 20, 2022) due to the COVID-19 pandemic. A protocol amendment was also made to allow practices to take part regardless of their use of other needs assessment tools (protocol version 7.0; approved Feb 28, 2022).

General practices (clusters) were recruited through the regional Clinical Research Network (now Research Delivery Service). Eligible general practices were willing to be trained and deliver the NAT-C for recruited patients if so allocated, were willing to commit to trial procedures, and gave written informed practice-level consent. Full eligibility criteria are listed in the appendix (p 5).

Eligible patients were adults (aged ≥18 years) with active cancer. Patients were excluded if they were living in an institutional setting, within 1 month of cancer diagnosis, diagnosed with basal cell carcinoma only; or in complete remission. Patients gave informed consent for the trial (written or observed verbal). Eligible carers were patient-nominated adults aged 18 years or older (family or friend), who supported the patient and gave written or verbal informed consent. Patients and carers needed to have sufficient knowledge of English, assessed by study site teams, to contribute to data collection (with an interpreter if needed). Full patient and carer eligibility criteria are in the appendix (p 5) and published elsewhere.[13]

Patients on the practice cancer register were screened by a practice clinician, and eligible patients were sent a trial invitation letter, opportunistically recruited through routine clinical contact, or identified from the Gold Standards Framework practice list (a register of patients considered to be at the end of life).

Randomisation and masking

Practices were randomly assigned (1:1) to deliver the NAT-C intervention or usual care alone. Allocation, via a web randomisation system at the University of Leeds Clinical Trials Research Unit, used minimisation incorporating a random element to ensure treatment groups were well balanced for strata: patient list size (small [<5000] *vs* medium [5000–10 000] *vs* large [>10 000]), locality (urban *vs* rural), and training centre status (yes *vs* no).

General practices and research nurses who recruited participants and provided follow-up support were aware of treatment allocation. Screening logs and baseline characteristics were monitored for selection bias. Before consenting to take part in the trial, patients were not made aware of the intervention details but were aware of practice allocation (ie, they were informed that those registered with intervention practices would be invited to attend an appointment with a clinician and that those registered with a control practice would not). Analysts were unmasked to practice assignment.

See Online for appendix

Procedures

In each intervention practice at least one clinician was trained online (by JC or TM) to use the NAT-C via a 1-h training package piloted during feasibility work. Intervention participants (both patients and carers) were invited by their practice to have an approximately 20-min NAT-C guided consultation with a trained clinician within 2 weeks of study registration at the practice or at home (either in person via a home visit), or remotely (via video or telephone call), according to the clinical judgement of the clinician conducting the NAT-C.

The NAT-C is a one-page psychometrically valid, reliable, and clinically acceptable tool for assessment of patients' and carers' holistic needs.[11] The NAT-C differentiates between need addressable by the usual care team and that requiring referral to other services (eg, palliative care, psychology, or financial advice). The resulting clinical action following the NAT-C consultation was according to individual clinician judgement and patient or carer agreement. Carers were welcome to accompany patients to their consultation; however, the NAT-C allows patient proxy assessment of carer need. The NAT-C was completed using an electronic medical record template or on paper and uploaded to the medical record.

Control practices were asked to continue usual care, defined as the management normally provided in accordance with the general medical services contract.[14] There were no limitations on other treatments received simultaneously.

Participants (patients and carers) completed questionnaires (electronic, postal, phone, or face-to-face, according to participant preference, including validated

outcome measures and health-care resource use) at baseline, 1 month, 3 months, and 6 months after registration. Self-reported data on sex (options provided were male or female) and race and ethnicity (options provided were White, Mixed, Black, Asian, or Other ethnic group) were collected at baseline, following enrolment. Researchers telephoned participants to confirm questionnaire receipt and collect the Australia-modified Karnofsky Performance Score (AKPS[15]) and COVID-19 status (and baseline demographics). Non-responders were sent email or postal reminders after 2 weeks and telephoned by a researcher after 3 weeks.

We documented serious adverse events fulfilling the definition of a related unexpected serious adverse event (identified via researcher contact or direct participant report), and the date and cause of all deaths that occurred during the trial period were collected from medical records.

Data on participant-level usual care and receipt of other holistic reviews were collected across trial groups from health resource use questionnaires and from the medical record. We recorded the use of needs assessment tools at participating practices before recruitment and after follow-up to monitor changes in usual care.

Participants recruited up to June 1, 2023, were followed up at 1 month, 3 months, and 6 months after recruitment. From June 2, 2023, participants were followed up at 1 month and 3 months only. A 12-month internal pilot assessed recruitment, intervention uptake, and follow-up. An economic evaluation of within-study cost-effectiveness is summarised in this Article, but details and an embedded process evaluation exploring issues relating to implementation will be reported elsewhere.

Outcomes

The primary outcome was at least one moderate-to-severe unmet need (according to the Supportive Care Needs Survey-Short Form 34 [SCNS-SF34][16]) at 3 months. The level of unmet need overall across all five domains of the SCNS-SF34 (ie, continuous score) at 3 months was measured as a secondary outcome. All outcomes were assessed centrally.

Other secondary patient outcomes were at least one moderate-to-severe unmet need and the level of unmet needs (SCNS-SF34) at 1 month and 6 months, and the level of domain-specific (psychological, health system and information, physical and daily living, patient care and support, and sexuality needs) unmet needs (SCNS-SF34), performance status (AKPS), severity of symptoms (Revised Edmonton Symptom Assessment System[17]) and mood and quality of life (QOL; European Organisation for Research and Treatment of Cancer Quality of Life-C15-Palliative questionnaire[18] [EORTC QLQ-C15-PAL]) at 1 month, 3 months, and 6 months.

Carer outcomes were the ability to care (Carer Experience Survey[19]) and wellbeing (Zarit Burden Interview[20]) at 1 month, 3 months, and 6 months.

Patient health economic measures included the EQ-5D-5L[21] and EQ-VAS, ICEpop CAPability Supportive Care Measure,[22] and health resource use at 1 month, 3 months, and 6 months.

Additional process outcomes to evaluate intervention delivery, uptake, and fidelity of the NAT-C included: number of NAT-C-trained clinicians in each general practice; completed NAT-C consultations; length of NAT-C consultations; referral patterns; and actions to meet identified unmet need from the completed NAT-C.

Statistical analysis

We estimated a sample size of 1080 participants from 54 practices would provide 85% power with a two-sided 5% significance level to detect a relative difference of 22% in the proportion of patients with at least one moderate-to-severe unmet need at 3 months (14% absolute difference, from an estimated baseline proportion of patients with unmet need of 64%, to 50% at 3 months).[23] Calculations assumed 20% loss to follow-up, a 0·05 intracluster correlation coefficient (ICC), and a mean cluster size of 20 (range 4–40). Due to COVID-19-related recruitment challenges, but only 10% loss to follow-up, rather than the initial estimate of 20%, we reduced the sample size to 950 participants across a minimum of 38 general practices (increased mean cluster size 25; smaller range 10–40; same ICC of 0·05; appendix pp 3–4) to provide 80% power with a 5% significance level to detect the same 22% relative difference in the proportion of patients with an unmet need. Subsequently, in discussion with the trial steering committee and after recruitment of 41 general practices (exceeding the revised target of 38, and with reduced anticipated mean cluster size 21; smaller range 10–35), we informally re-estimated the sample size requirements to retain 80% power to be 850 participants.

All statistical testing used two-sided 5% significance levels. Analyses were done with SAS version 9.4 or R version 4.4.1 and were prespecified unless indicated. Our single final analysis of outcome data included the internal pilot data. Primary effectiveness analyses were done in all participants with at least one post-baseline measurement (at either 1 month, 3 months, or 6 months) on a modified intention-to-treat basis (ie, according to their practice allocation, regardless of adherence). We assessed selection bias via statistical testing of baseline participant data.

We compared between-group outcome measures using a two-level hierarchical generalised logistic or linear (appropriate to outcome) mixed model with repeated measures and participants nested within practices (participant and practice random effects; AR(1) covariance structure). Prespecified fixed effects included treatment group, time, and treatment-by-time interaction; practice randomisation strata; and participant age, sex, cancer status, baseline measure of the dependent variable (for continuous outcomes), and AKPS. EORTC QLQ-C15-PAL physical subscale was also included as a fixed covariate as it was found to be predictive of missingness (a prespecified approach to exploration and handling of missing data). Results were expressed as adjusted odds ratios (ORs) or

mean differences with 95% CIs, p values, and ICCs for the 3-month primary endpoint and secondary endpoint level of unmet need. Assumptions were checked for all models using Pearson and studentised residual plots.

We explored missing data patterns to identify participant characteristics related to missingness and differential missingness by treatment group (appendix p 15). Primary analyses took a missing at random approach, including all participants with at least one post-baseline measurement.[24] We treated data truncated due to death as missing, adopting a treatment policy estimand strategy.[25] Sensitivity analyses on the primary endpoint and secondary endpoint of level of unmet need used multiple imputation, unadjusted models (excluding covariates), separate analyses per timepoint, analysis restricted to the 6-month follow-up population, and included carer covariates (post-hoc).

We summarised intervention delivery, receipt of usual care, deaths (including Kaplan–Meier survival estimates), and related unexpected serious adverse events descriptively.

Exploratory moderator (subgroup) analyses of the primary endpoint and secondary endpoint of level of unmet need investigated whether the treatment effect varied by practice-level and participant-level variables, using a treatment–moderator interaction in separate analyses at each timepoint. Further exploratory analysis examined the effect of intervention compliance using a complier average causal effect (CACE) and per-protocol analyses (excluding protocol violations and deviations; appendix p 10).

The economic evaluation was a cost utility analysis over the 3-month and 6-month time horizon from a health and personal social services perspective using standard UK national unit costs. Intervention delivery costs, including training costs and time for delivery, were included. Survival was adjusted to create quality-adjusted life-years (QALYs) using the EQ-5D-5L, with utility values derived using the UK crosswalk value set[21] and QALYs via the area under the curve. QALYs and costs were estimated in models using the same covariates as the statistical analysis along with baseline costs and EQ-5D-5L, applying separate linear (QALYs) and generalised linear (costs) models (primary analysis) and linear, seemingly unrelated regression (secondary analysis). We derived incremental cost-effectiveness ratios and incremental net monetary benefit (INMB; incremental QALYs × threshold-incremental costs) to compare the cost-effectiveness of the NAT-C with usual care. We assumed a £20 000 threshold per QALY gain. Complete case primary analysis is provided, supported by exploration of missing data patterns and sensitivity analyses using multiple imputation to assess stability of findings. Cost-effectiveness uncertainty was explored through non-parametric bootstrapping and cost-effectiveness acceptability curves. Full methods and more detailed health economic results will be reported separately.

Given the nature of the intervention, the unmasked data, and the low-risk intervention, the trial steering committee adopted a safety data monitoring role with the agreement of the study sponsor and funder.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Oct 21, 2020, and April 12, 2023, 65 general practices expressed interest in the study and 41 were randomly assigned: 21 (51%) to NAT-C and 20 (49%) to usual care (figure). An additional practice was randomly assigned to NAT-C but withdrew before recruitment (located in a rural area, with a list size of 5000–10 000 and was a training practice). Between Dec 1, 2020, and Aug 30, 2023, 2874 patients were screened (all via practice cancer registry search except for 39 opportunistic approaches; appendix p 6). 788 participants (mean age 66·9 years, SD 10·9; 404 [51%] female patients and 384 [49%] male patients) were enrolled: 376 (48%) in the NAT-C group and 412 (52%) in the usual care group. The median number of participants per practice was 19 (range 2–29; 17 [4–35] in the NAT-C group and 20 [2–35] in the usual care group). 427 (54%) of 788 participants identified a potentially eligible carer, and a carer was recruited alongside 249 (32%) participants (table 1; appendix p 8).

Practice-level strata were well-balanced across groups. Most practices were in urban areas, were training practices, and had a list size of 5000–10 000 people (table 1). Participants were representative of screened patients in terms of age, sex, and registration on the Gold Standard Framework (appendix p 6). Almost all screened and recruited participants were White (table 1). Participants were recruited a median of 21·9 months (range 1–332) after their initial cancer diagnosis. There was no evidence of selection bias, except for increased presence and recruitment of a carer in participants in the NAT-C group (table 1). At baseline, 207 (26%) of 782 participants felt that their cancer care had worsened due to the COVID-19 pandemic; 245 (31%) of 788 patients had tested positive for COVID-19 previously, increasing to 312 (40%) of 788 by the end of follow-up (appendix p 9).

Follow-up was completed on Jan 19, 2024. At least one post-baseline questionnaire was returned for 742 (94%) of 788 participants, and these 742 participants comprised the primary efficacy analysis population. Follow-up questionnaires were mostly completed via paper and post (for 453 [63%] of 715 returns at 1-month follow-up, 440 [64%] of 692 returns at 3-month follow-up, and 377 [65%] of 583 returns at 6-month follow-up), with the remaining completed online. Questionnaires were returned within 1 month of the follow-up timepoint for ≥95% of returns at all timepoints. The 3-month follow-up questionnaire pack was returned by 692 (88%) of 788 participants, of whom 685 had completed the sections relevant to the primary endpoint (figure). The 6-month follow-up questionnaire pack was returned by 583 (87%) of 669 patients in the 6-month follow-up population (ie, those recruited up to June 1, 2023), 581 of whom had completed

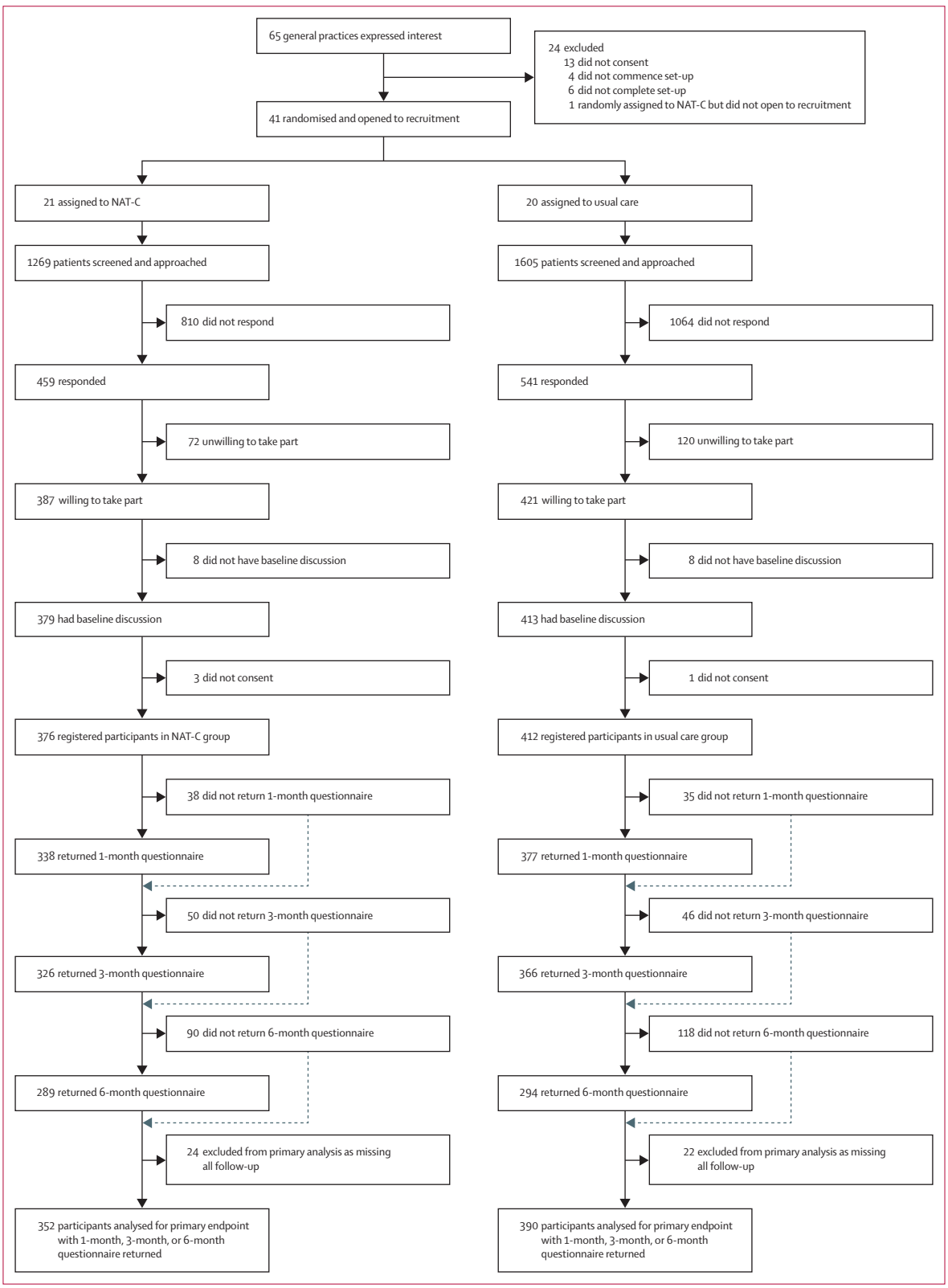

Figure: **Trial profile**
NAT-C=Needs Assessment Tool-Cancer.

the relevant questions, with similar rates of return across study groups. Participants recruited with follow-up limited to 3 months (n=119) had higher baseline levels of unmet need than those in the 6-month follow-up population (appendix p 19). Participants missing 3-month primary outcome data had less favourable characteristics across multiple baseline measures than those with 3-month primary outcome data, predominantly physical functioning (thereby included as an analysis covariate; appendix pp 15–18). We found no evidence of differential patterns by study group baseline characteristics, apart from practice locality (appendix p 16).

Consent was withdrawn for at least one trial process from 35 (4%) of 788 participants (in the NAT-C group: seven [2%] participants withdrew from receipt of the intervention, 15 [4%] from questionnaires, 14 [4%] from telephone contact to complete performance status, and 13 [3%] from data collection via medical records; in the usual care group: 20 [5%] participants withdrew from questionnaires, 18 [4%] from performance status, and 14 [3%] from medical records). 16 (6%) of 249 carers also withdrew from questionnaires, and 51 (6%) of 788 patients died (28 [7%] of 376 in the NAT-C group and 23 [6%] of 412 in the usual care group, and 20 within 6 months [ten participants in each group]; appendix pp 10–11). Major protocol violations occurred in five (<1%) participants (appendix p 10). There were no related unexpected serious adverse events.

We trained 54 clinicians to use the NAT-C, which was delivered to 360 (96%) of 376 participants in the NAT-C group (appendix p 12). Most consultations were completed within 1 month of recruitment (median 13 days, IQR 7–22), by telephone (229 [66%] of 347 consultations for which data on method of contact were available), and without a carer present (279 [88%] of 316 consultations for which data on method of carer presence were available). Consultations took a median of 24 min (IQR 20–30) and led to external referrals for 50 (14%) of 360 participants, mostly to specialist palliative care or psychology services (appendix p 13). Action (ie, a response to the identified need) was taken for 258 (72%) of 360 participants, with direct management of at least one need for 232 (64%) and management by another team member for 61 (17%) participants (appendix p 13).

Receipt of other cancer care reviews or HNAs within usual care were identified for 221 (28%) of 788 participants since their diagnosis and up to 6 months after registration (84 [22%] of 376 participants in the NAT-C group; 137 [33%] of 412 participants in the usual care group); most were other primary care reviews, and some used other electronic health record templates (appendix p 14).[26,27] 47 (6%) of 788 participants had such assessment during the 6-month trial period (26 [7%] of 376 participants in the NAT-C group; 21 [5%] of 412 participants in the usual care group; appendix p 14).

For the 3-month primary outcome, 149 (46%) of 321 participants in the NAT-C group and 173 (48%) of 364 participants in the usual care group reported at least one moderate-to-severe unmet need (OR 0·98, 95% CI

	NAT-C group	Usual care group	p value*
Patient-level data			
Patients	376	412	NA
Age, years	66·6 (10·6)	67·1 (11·1)	0·95
Sex			0·45
Male	177 (47%)	207 (50%)	··
Female	199 (53%)	205 (50%)	··
Ethnicity‡			0·67†
White	371/375 (99%)	405 (98%)	··
Mixed	2/375 (1%)	2 (<1%)	··
Black	2/375 (1%)	2 (<1%)	··
Asian	0	2 (<1%)	··
Other ethnic group	0	1 (<1%)	··
Registered on Gold Standard Framework or other palliative service	41/229 (18%)	77/273 (28%)	0·98†
Index of Multiple Deprivation Quintile§			0·12†
1 (most deprived)	45/351 (13%)	50/401 (12%)	··
2	44/351 (13%)	74/401 (18%)	··
3	41/351 (12%)	68/401 (17%)	··
4	94/351 (27%)	122/401 (30%)	··
5 (least deprived)	127/351 (36%)	87/401 (22%)	··
Married or in a relationship	266/375 (71%)	318 (77%)	0·095†
Comorbidities			0·66†
None	96 (26%)	100 (24%)	··
Single	102 (27%)	113 (27%)	··
Multiple	178 (47%)	199 (48%)	··
Time between initial cancer diagnosis and registration, months¶	20·2 (8·6–43·7)	23·2 (10·3–45·2)	0·28†
Active cancer managed‖			0·50†
Receiving anticancer treatment with curative or palliative intent	233/375 (62%)	238/411 (58%)	··
Managed with watch and wait	113/375 (30%)	146/411 (36%)	··
Recurrent or metastatic, or inoperable	29/375 (8%)	25/411 (6%)	··
Other	0	2/411 (<1%)	··
Stage of malignancy			0·38
Localised disease (early)	201 (53%)	210 (51%)	··
Localised disease (advanced) or metastatic disease	165 (44%)	135 (33%)	··
Missing	10 (3%)	67 (16%)	··
Participant has carer	236 (63%)	191 (46%)	0·0041†
Carer recruited	138 (37%)	111 (27%)	0·024†
Cluster-level data			
Practices (clusters)**	21	20	NA
Locality			··
Urban	16 (76%)	14 (70%)	··
Rural	5 (24%)	6 (30%)	··
Training practice			··
Yes	16 (76%)	19 (95%)	··
No	5 (24%)	1 (5%)	··
List size			··
<5000	3 (14%)	1 (5%)	··
5000–10 000	10 (48%)	11 (55%)	··
>10 000	8 (38%)	8 (40%)	··

Data are n, mean (SD), n (%), n/N (%), or median (IQR). Percentages are calculated with a denominator of the total enrolled participants, unless otherwise indicated. NA=not applicable. NAT-C=Needs Assessment Tool-Cancer. *Group differences compared using mixed linear or logistic model incorporating a random effect of practice. †p values included post-hoc for completeness. ‡p value estimated based on ethnicity grouped into two categories: White versus non-White (mixed, Black, Asian, other, and missing). §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. ¶Data missing for one participant in the usual care group. ‖To compute the p value, other is considered missing. **p values were not computed as randomisation was at the practice (cluster) level with stratification according to presented practice characteristics.

Table 1: **Demographics of registered participants and cluster characteristics**

0·63 to 1·53; p=0·94; ICC 0·067; table 2; appendix pp 19, 21). Similarly, at 3 months, we found no evidence that NAT-C was superior to usual care in reducing the level of unmet need (mean difference –0·51, 95% CI –3·36 to 2·35; p=0·73; ICC 0·043; table 2; appendix pp 20, 22).

At 6 months, we found weak evidence that the NAT-C was superior to usual care at reducing the proportion of individuals with at least one moderate-to-severe unmet need (OR 0·66, 95% CI 0·42 to 1·04, p=0·075) and good evidence of a reduction in the level of unmet need (mean difference –3·57, 95% CI –6·57 to –0·58, p=0·020). No differences were found at 1 month (table 2).

The sensitivity and exploratory analyses had similar conclusions to the main analysis regarding the primary endpoint at 3 months (appendix pp 21–22). At 6 months, the CACE and sensitivity analyses using multiple imputation and separate analysis at each timepoint resulted in more precise confidence intervals than the main analysis at 6 months, providing good evidence of a beneficial 6-month effect. The per-protocol analysis also had very similar results to the main 6-month analysis. Additional sensitivity analyses of the primary outcome and secondary outcome of level of unmet need at 3 months are shown in the appendix (pp 23, 29).

Other secondary outcomes were largely similar, with no evidence of a difference in outcomes at 1 month or 3 months, but some evidence in favour of NAT-C at 6 months on unmet psychological, and physical and daily living needs, severity of symptoms, and QOL (specifically domains of overall QOL, emotional functioning, pain, and appetite loss; table 3; appendix pp 24–29). We found no evidence of a difference on other patient or carer secondary outcomes at 6 months.

Exploratory subgroup analyses of 3-month and 6-month primary and key secondary outcomes are shown in the appendix (pp 30–33).

Complete case economic analyses included 644 participants with available relevant data (appendix p 34), and found that the estimated mean incremental QALYs and costs (INMB) for NAT-C versus usual care at 3 months were 0·006 (95% CI –0·013 to 0·025) and –£212 (–1213 to 789 [£332]), respectively, and 0·015 (–0·027 to 0·058) and –£283 (–1607 to 1040 [£583]) at 6 months, respectively. At both timepoints, estimates indicated that NAT-C was both cost saving and provided QALY gains compared with usual care. However, the wide confidence intervals crossing zero for both costs and QALYs mean that we cannot draw firm conclusions about cost-effectiveness. For the complete case sample, using linear, seemingly unrelated models, the chance that NAT-C was cost-effective was more than 80% at 3 months and 6 months. This figure was sensitive to the analytical approach (data not shown). In multiple imputation analysis, 3-month mean QALY differences were 0·001 or 0·004 (depending on the model), and mean cost differences were –£168 or £322 (INMB –£302 to £248). At 6 months, mean QALY differences were 0·001 or 0·05, and mean cost differences were –£194 or £308 [INMB £206 to £692]. Thus, NAT-C was either dominant (cheaper and more effective) or more effective but more expensive (but cost-effective) compared with usual care depending on the modelling approach (data not shown).

Discussion

We found no evidence of benefit of the NAT-C versus usual care for the primary endpoint at 3 months, or for any secondary outcomes at 1 month. However, for the first time to our knowledge, we found evidence of patient-relevant benefit at 6 months for the secondary outcomes of overall level of unmet need, psychological, and physical and daily living unmet need, symptom severity, QOL (including overall QOL domain, emotional functioning, pain, and appetite domains). Although point estimates favoured NAT-C in terms of QALYs and costs, imputed analyses showed greater variability, with cost-effectiveness conclusions sensitive to the model used. There was high intervention compliance, with consultations lasting, on average, approximately twice the length of a routine appointment. Although we did not reach our target sample size, the negligible difference observed at 1 month and 3 months suggests that increased statistical power would not have altered our conclusions. However, increased power would have reinforced the strength of evidence for the beneficial effect observed at 6 months.

Despite the prevalence and impact of unmet need in people with cancer, clinical effectiveness evidence for interventions is lacking,[4] particularly in primary care settings. Holistic assessment approaches are recommended in the UK (eg, HNA and cancer care reviews) and other high-income countries (eg, survivorship care plans). The challenges of showing clinical benefit have been highlighted in a systematic review of survivorship care plans.[10] Only so-called proximal outcomes (directly resulting from the care plan[10]), such as patient satisfaction, showed benefit. The more distal (requiring a chain of actions) patient-reported outcomes take longer to show benefit (eg, from changing medications or referrals). This finding is consistent with our observation of benefit with the NAT-C but not until 6 months.

Another potential explanation for the delayed effect we observed relates to systematic holistic enquiry and the message to the patient that their concerns are legitimate issues to raise with their primary care team.[28] To volunteer concerns, a patient needs health literacy and agency to recognise their concern as something potentially remediable and that a clinician is the right person to tell. Given the relationship between social determinants of health and health literacy,[29] relying on patients to volunteer concerns builds in inequity. Furthermore, patients consider doctors to have little time, and a perception that only one problem can be raised per appointment, which forces patients to prioritise their most pressing issue—at least in the UK standard 10-min appointment.[30] More unmet needs are identified using systematic enquiry. A palliative care study showed that patients, on average, volunteered one concern

	Baseline			1 month			3 months*			6 months		
	NAT-C group	Usual care group	p value†	NAT-C group	Usual care group	Effect size (95% CI); p value	NAT-C group	Usual care group	Effect size (95% CI), p value	NAT-C group	Usual care group	Effect size (95% CI); p value
Questionnaire pack returned‡	376/376 (100%)	412/412 (100%)	..	338/376 (90%)	377/412 (92%)	..	326/376 (87%)	366/412 (89%)	..	289/331 (87%)	294/338 (87%)	..
At least one moderate-to-severe unmet need (primary endpoint at 3 months)§	194/376 (52%)	229/410 (56%)	0·37	169/338 (50%)	190/376 (51%)	1·00 (0·65 to 1·54); 0·99	149/321 (46%)	173/364 (48%)	0·98 (0·63 to 1·53); 0·94	125/287 (44%)	145/294 (49%)	0·66 (0·42 to 1·04); 0·075
Total level of unmet need	20·3 (17·6)	21·2 (18·9)	0·51	23·0 (20·5)	23·4 (19·8)	–0·91 (–3·73 to 1·91); 0·53	21·4 (19·3)	21·6 (19·5)	–0·51 (–3·36 to 2·35); 0·73	20·5 (19·3)	23·1 (19·9)	–3·57 (–6·57 to –0·58); 0·020
At least one moderate-to-severe unmet need by domain												
Psychological	144/376 (38%)	153/409 (37%)	0·97	137/337 (41%)	132/376 (35%)	1·18 (0·75 to 1·85); 0·48	106/321 (33%)	122/364 (34%)	0·85 (0·54 to 1·36); 0·50	86/287 (30%)	99/294 (34%)	0·59 (0·37 to 0·96); 0·034
Health system and information	98/375 (26%)	105/410 (26%)	0·79	90/336 (27%)	105/376 (28%)	0·84 (0·56 to 1·28); 0·42	71/321 (22%)	69/365 (19%)	1·14 (0·72 to 1·80); 0·57	60/287 (21%)	71/294 (24%)	0·69 (0·44 to 1·09); 0·12
Physical and daily living	134/376 (36%)	146/410 (36%)	0·97	113/338 (33%)	129/376 (34%)	0·87 (0·52 to 1·43); 0·58	99/321 (31%)	115/364 (32%)	0·90 (0·54 to 1·50); 0·67	78/286 (27%)	96/294 (33%)	0·57 (0·33 to 0·98); 0·043
Patient care and support	47/376 (13%)	68/409 (17%)	0·25	52/338 (15%)	61/376 (16%)	0·88 (0·55 to 1·41); 0·60	47/320 (15%)	48/364 (13%)	1·08 (0·66 to 1·77); 0·77	33/286 (12%)	40/294 (14%)	0·78 (0·46 to 1·32); 0·35
Sexuality	45/376 (12%)	58/410 (14%)	0·47	51/333 (15%)	59/376 (16%)	0·90 (0·54 to 1·50); 0·69	35/319 (11%)	50/363 (14%)	0·67 (0·39 to 1·17); 0·16	29/285 (10%)	34/294 (12%)	0·66 (0·37 to 1·18); 0·16
Level of unmet need by domain												
Psychological	25·8 (25·3)	26·2 (25·5)	0·76	28·8 (25·8)	28·8 (25·0)	–1·43 (–4·98 to 2·12); 0·43	27·8 (25·1)	26·8 (24·8)	–0·03 (–3·73 to 3·66); 0·99	26·1 (24·9)	29·3 (26·0)	–5·02 (–8·96 to –1·08); 0·013
Health system and information	17·3 (19·1)	18·6 (20·7)	0·36	20·2 (21·4)	21·2 (21·8)	–1·10 (–4·36 to 2·17); 0·51	17·9 (19·4)	19·0 (20·9)	–1·08 (–4·23 to 2·07); 0·50	17·9 (19·8)	20·1 (21·3)	–2·79 (–6·08 to 0·49); 0·095
Physical and daily living	26·3 (27·6)	25·7 (26·2)	0·86	26·0 (26·4)	26·8 (26·6)	–2·71 (–6·16 to 0·74); 0·12	25·2 (26·9)	25·9 (27·5)	–2·05 (–5·74 to 1·64); 0·28	22·9 (25·5)	27·9 (27·0)	–7·00 (–10·85 to –3·16); 0·0004
Patient care and support	14·0 (16·7)	15·8 (20·3)	0·33	17·9 (20·9)	17·2 (20·3)	0·50 (–2·43 to 3·43); 0·74	15·6 (18·5)	16·3 (19·0)	–0·95 (–3·78 to 1·89); 0·51	15·2 (18·7)	17·1 (20·0)	–2·33 (–5·40 to 0·74); 0·14
Sexuality	13·8 (22·0)	15·7 (24·4)	0·44	17·6 (24·8)	18·3 (25·6)	–1·55 (–4·82 to 1·73); 0·35	15·6 (23·4)	15·7 (23·1)	–0·93 (–4·11 to 2·25); 0·57	16·2 (23·1)	16·1 (23·3)	–2·30 (–5·74 to 1·15); 0·19

Data are n/N (%) or mean (SD), unless otherwise indicated. SCNS-SF34 total and domain scores range from 0 to 100, with higher scores indicating greater unmet need. The table presents raw data by group alongside the treatment effect estimate, representing the adjusted mean difference between treatment groups for continuous outcomes (level of unmet need) and adjusted ORs for binary outcomes (moderate or high unmet need) estimated using linear and logistic mixed models with repeated measures, adjusted for covariates. NAT-C=Needs Assessment Tool-Cancer. OR=odds ratio. SCNS-SF34=Supportive Care Needs Survey Short Form 34. *Primary endpoint timepoint. †p values for group differences at baseline were estimated separately using mixed linear or logistic model incorporating a random effect of practice. ‡Represents the number of participants who returned their questionnaire packs; the denominator for some endpoints is slightly lower than the number who returned the questionnaire pack in some cases due to missing responses within the relevant questionnaires. §In any item on the SCNS-SF34.

Table 2: **SCNS-SF34 primary and secondary unmet need endpoints**

	Baseline			1 month			3 months			6 months		
	NAT-C group	Usual care group	p value*	NAT-C group	Usual care group	Mean difference (95% CI); p value	NAT-C group	Usual care group	Mean difference (95% CI); p value	NAT-C group	Usual care group	Mean difference (95% CI); p value
Participant questionnaire pack returned	376/376 (100%)	412/412 (100%)	..	338/376 (90%)	377/412 (92%)	..	326/376 (87%)	366/412 (89%)	..	289/331 (87%)	294/338 (87%)	..
Performance status (AKPS)†	84·3 (14·4)	85·5 (13·41	0·72	84·4 (14·4)	86·0 (13·9)	−0·05 (−2·00 to 1·89); 0·96	85·5 (14·7)	85·7 (14·3)	1·64 (−0·44 to 3·73); 0·12	84·5 (14·4)	86·7 (13·5)	−0·02 (−2·22 to 2·17); 0·98
Severity of symptoms (ESAS-r)‡	18·2 (16·5)	16·7 (15·1)	0·53	19·0 (17·8)	18·0 (16·4)	−0·86 (−3·07 to 1·35); 0·45	18·0 (17·0)	17·4 (16·2)	−0·81 (−3·09 to 1·46); 0·48	17·2 (16·6)	18·2 (16·8)	−2·98 (−5·35 to −0·61); 0·014
Mood and quality of life (EORTC QLQ-C15-PAL)§												
Overall quality of life	72·9 (24·1)	72·5 (23·4)	0·80	70·7 (23·1)	71·8 (21·5)	0·34 (−2·31 to 2·99); 0·80	71·9 (22·8)	71·4 (21·0)	1·61 (−0·94 to 4·16); 0·21	73·3 (20·9)	70·3 (21·6)	3·97 (1·03 to 6·91); 0·0082
Pain	24·5 (30·5)	22·1 (29·8)	0·36	22·8 (28·9)	21·5 (27·4)	−0·45 (−3·71 to 2·81); 0·79	21·0 (27·8)	22·1 (28·0)	−2·79 (−6·07 to 0·49); 0·096	19·6 (26·2)	22·5 (28·3)	−3·81 (−7·26 to −0·35); 0·031
Dyspnoea	17·6 (26·7)	17·6 (27·0)	0·85	19·5 (27·6)	19·7 (26·7)	−1·07 (−3·95 to 1·81); 0·47	19·5 (26·4)	18·8 (25·8)	0·64 (−2·26 to 3·55); 0·66	19·4 (26·2)	19·6 (25·8)	0·32 (−2·84 to 3·48); 0·84
Insomnia	34·3 (36·7)	30·5 (34·8)	0·27	34·9 (33·2)	32·8 (32·2)	−0·98 (−4·75 to 2·78); 0·61	33·2 (31·4)	31·8 (34·0)	−0·68 (−4·77 to 3·41); 0·75	29·8 (30·6)	32·9 (32·2)	−3·61 (−7·69 to 0·48); 0·084
Appetite loss	12·1 (25·7)	10·5 (24·5)	0·53	13·4 (25·6)	11·7 (22·9)	0·26 (−2·56 to 3·09); 0·85	12·4 (23·8)	11·2 (22·9)	0·29 (−2·68 to 3·26); 0·85	10·2 (21·8)	13·7 (25·2)	−4·02 (−7·31 to −0·72); 0·017
Constipation	12·6 (25·2)	13·3 (25·7)	0·71	15·6 (25·7)	16·2 (26·0)	0·18 (−3·02 to 3·38); 0·91	13·3 (23·4)	14·9 (25·3)	−0·87 (−4·06 to 2·33); 0·59	14·0 (24·3)	16·6 (25·9)	−1·27 (−4·80 to 2·26); 0·48
Physical functioning	77·4 (24·0)	78·7 (22·7)	0·79	76·7 (24·3)	78·2 (22·4)	0·32 (−2·49 to 3·13); 0·82	76·8 (23·2)	77·9 (23·5)	0·14 (−2·76 to 3·05); 0·92	76·7 (23·3)	76·9 (23·3)	2·61 (−0·59 to 5·81); 0·11
Fatigue	34·0 (29·5)	31·8 (28·3)	0·29	35·2 (27·6)	35·8 (26·4)	−2·17 (−4·98 to 0·65); 0·13	32·6 (26·4)	33·9 (25·7)	−2·45 (−5·30 to 0·40); 0·091	32·0 (25·4)	33·5 (26·0)	−2·06 (−5·10 to 0·97); 0·18
Nausea or vomiting	5·6 (16·8)	4·5 (14·6)	0·45	6·4 (17·3)	5·3 (13·8)	0·23 (−1·69 to 2·16); 0·81	6·2 (17·2)	4·6 (12·5)	0·82 (−1·20 to 2·84); 0·43	4·5 (13·5)	5·2 (14·0)	−0·98 (−2·95 to 1·00); 0·33
Emotional functioning	82·5 (24·6)	84·7 (23·6)	0·36	80·0 (23·9)	81·1 (23·4)	1·93 (−0·86 to 4·72); 0·18	80·2 (24·8)	82·3 (22·5)	0·54 (−2·50 to 3·58); 0·73	81·5 (24·9)	80·7 (24·8)	3·54 (0·21 to 6·87); 0·037
Carer questionnaire pack returned	138/138 (100%)	111/111 (100%)	..	122/138 (88%)	105/111 (95%)	..	121/138 (88%)	99/111 (89%)	..	103/128 (80%)	81/93 (87%)	..
Carer experience (Carer Experience Scale)¶	73·4 (12·3)	74·1 (13·1)	0·84	71·9 (13·2)	73·8 (13·4)	−2·53 (−5·92 to 0·85); 0·14	71·1 (13·2)	71·4 (13·2)	0·54 (−2·93 to 4·01); 0·76	70·7 (15·0)	71·2 (14·9)	−0·06 (−4·21 to 4·09); 0·98
Carer wellbeing and burden (Zarit Burden Interview-12)||	7·2 (7·2)	6·7 (7·3)	0·74	8·9 (7·8)	9·1 (7·8)	0·09 (−1·47 to 1·64); 0·91	9·4 (8·5)	9·6 (8·6)	−0·54 (−2·40 to 1·32); 0·57	9·5 (8·4)	8·8 (7·7)	0·00 (−1·90 to 1·90); 0·99

Data are n/N (%) or mean (SD), unless otherwise indicated. The table presents raw data by group 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 poorer outcomes for all endpoints with the exception of performance status, overall quality of life, physical functioning, emotional function, and carer experience endpoints. AKPS=Australia-modified Karnofsky Performance Score. ESAS-r=Revised Edmonton Symptom Assessment System. EORTC QLQ-C15-PAL=European Organisation for Research and Treatment of Cancer Quality of Life-C15-Palliative questionnaire. NAT-C=Needs Assessment Tool-Cancer. *p values for group differences at baseline were estimated separately using a mixed linear or logistic model incorporating a random effect of practice. †Values range from 0 (deceased) to 100 (normal physical abilities). ‡Scores range from 0 to 90. §Scores range from 0 to 100. ¶Scores range from 0 to 100. ||Scores range from 0 to 48.

Table 3: **Secondary endpoints**

but disclosed ten with systematic enquiry, all of which were considered serious by the patient. In another study of women with breast cancer, the number of concerns extracted by use of a patient-completed holistic needs tool was greater than those extracted from clinical case records.[31] In our feasibility study, clinicians interviewed were concerned that a systematic approach would identify needs that they could not address.[5] However, patient interviews identified that the NAT-C-guided consultation made them feel seen and heard; they did not expect resolution of all issues, but acknowledgement was helpful.[5] Potential concerns that increased primary care input would risk further fragmentation of care were not supported; rather, patients felt reassured that their primary care team was aware of their situation.[5]

The CANAssess2 study has strengths and limitations. The trial took place across a wide area of northern England with diverse populations, increasing the generalisability of our findings. Participants represented different cancer types and stages and had different comorbidities. However, we did not collect data on race, and minoritised ethnic communities were under-represented, a group who might have higher levels of unmet need, limiting generalisability. Our patient population was healthier than in our feasibility study.[12] Recruitment of a population with more unmet needs might have provided greater scope for benefit. This hypothesis is supported by our exploratory subgroup findings at 6 months, which generally showed stronger beneficial treatment effects in participants with a greater baseline level of unmet need; however, the absence of a difference in the primary outcome and secondary outcome of level of unmet need at 3 months was consistent across all baseline levels of unmet need.

Participant recruitment occurred after practice randomisation, but we found no evidence of selection bias, except for a higher proportion of participants in the NAT-C group having a carer compared with usual care. However, this factor did not affect the primary results. Inevitably, participants were unmasked to allocation. We minimised the potential risk of self-selection bias and in outcome measurement by masking potential participants to the details of the intervention at trial enrolment; ensuring clinical care providers were not involved in data collection; and using standardised outcome assessment methods and follow-up processes across trial groups, the success of which is illustrated via similar recruitment and follow-up rates across trial groups. Questionnaire completion might have triggered help-seeking behaviour. There appeared to be more access to community-based or outpatient hospital services in the usual care group than in the NAT-C group (appendix p 34), which might indicate help-seeking behaviour. Given previous work indicating that patients have the perception that the health services are overwhelmed—especially during the COVID-19 pandemic—we suspect an increase in help-seeking behaviour is unlikely. However, if help-seeking behaviours did increase after questionnaire completion, such a Hawthorne effect could have underestimated any benefit seen from our intervention. Receipt of a cancer review of some sort within usual care might have diluted any potential benefit of the NAT-C intervention. In our sensitivity analyses, at 6 months we found a similar (non-significant) effect in per-protocol analyses to our main analysis results at 6 months, and good evidence for a smaller benefit of the NAT-C compared with usual care in CACE analyses.

Although data were missing for just over 10% of participating patients for the primary 3-month outcome, and those with missing data had less favourable baseline characteristics, our analysis approach effectively reduced the proportion of patients with missing data to around 6%. The sensitivity analysis using multiple imputation found consistent and more precise treatment effects at 6 months compared with the main analysis. There was evidence of QALY gains and the potential for cost-effectiveness at 3 months and 6 months, but substantial uncertainty around these values, highlighting the uncertainty introduced by missing data in economic analysis and a need for cautious interpretation.

Challenges in recruiting practices and participants led to a reduced target sample size, which was ultimately not met. However, given the negligible treatment effect across 3-month outcomes, it is unlikely that increasing statistical power by meeting our sample size would have changed our conclusions. Our primary outcome was binary rather than continuous, due to its use in previous trials to inform sample size assumptions.[23] This approach reduces statistical power, consistent with our findings of stronger evidence of a treatment effect at 6 months in analysis of the level of unmet need compared with the presence of any unmet need.

We restricted follow-up for participants enrolled after June, 2023, to 3 months (primary endpoint) to reduce trial costs, which reduced the available 6-month data sample, adding complexity to analyses and interpretation. We observed some differences, particularly in baseline unmet need, between participants recruited with 3 months of follow-up versus those recruited with 6 months of follow-up. Participants with restricted 3-month follow-up had higher levels of baseline unmet need compared with those with 6 months of follow-up. Exploratory subgroup analyses found no evidence of a differential treatment effect between these groups, but a larger 3-month benefit was observed in the cohort with 3 months of follow-up versus the cohort with 6 months of follow-up (appendix pp 30, 32).

Although we found no differences in carer outcomes between those receiving the NAT-C and those receiving usual care, most consultations assessed carer's needs using a patient proxy, which might have underestimated concerns and limited opportunities for action. Adapting the NAT-C to focus on patient need only and combining its administration with carer-faced assessments (eg, the Carer Supportive Needs Assessment Tool[32]) might be more effective.

The clinical importance of the findings at 6 months should be interpreted alongside available data on the

minimal clinically important difference (MCID) for each outcome. However, the SCNS measure has no published MCID, and although MCIDs are estimated to be at least a 1-point change for individual Edmonton Symptom Assessment Scale symptoms, this measure has no MCID for its summary score.[17] Similarly, there is no published MCID for the EORTC QLQ-C15-PAL (which was chosen for the study because of the small number of items to reduce participant burden) in such a heterogeneous cancer population in the primary care setting. Although these factors are limitations, we propose that the beneficial effects observed across multiple domains, and potential translation into increased QALYs in the intervention group, provides a rationale for further research to clarify the MCID and enable improved judgement of clinical relevance.

A review of systematic reviews of models of cancer survivorship care indicated that primary care-based models have equivalent patient outcomes, but are heterogenous, poorly adopted, face implementation barriers, and do not include people undergoing primary cancer treatment or end-of-life care.[33] The authors of that review call for implementation guidance and highlight gaps in knowledge regarding the effectiveness of interventions across domains of care, understudied outcomes, and differing patient populations. Although a detailed discussion regarding implementation issues is beyond the scope of this Article, 1 h of training and a single consultation lasting just over twice a standard 10-min appointment appears to provide patient-relevant benefit over time in a population that included people with all stages of active cancer. The validated NAT-C guide could be embedded into routine cancer care reviews in UK primary care, helping to standardise the current lottery of practice, and added to policy recommendations regarding which template to use. The NAT-C could also be useful at other stages of cancer care (eg, end of primary treatment, recurrence, advanced disease, and end of life).

The NAT-C approach could have relevance beyond cancer. Many unmet needs identified were comorbidity-related, including those related to COVID-19 infection. A generically adapted NAT could be useful in primary care in chronic disease management. However, similar to the cancer literature, a primary care study of holistic assessment for people with multiple long-term conditions did not show benefit.[34] However, the primary outcome of that study focused on QOL rather than unmet need. A quasi-experimental study of a community-based holistic assessment and management of older adults with frailty showed benefits at 3 months using a level-of-concern outcome (Integrated Palliative care Outcome Score[35]), which measures the impact of the problem as perceived by the patient, rather than the severity of the problem; a problem that has a plan of action, with perceived control, represents a met need, even if the problem is still present. Future adaptation of the NAT-C for generic use and testing in combination with the Carer Supportive Needs Assessment Tool would be a good next step.

In conclusion, we found no evidence of benefit at the 3-month timepoint with the systematic use of a holistic cancer needs assessment tool. However, we found, for the first time to our knowledge, evidence of patient-relevant clinical benefit at 6 months for many outcomes, and potential cost-effectiveness. However, the evidence of benefit seen in our secondary outcomes requires cautious interpretation and further research is needed to support or refute our findings. We welcome replication featuring a 6-month primary outcome, extended repeated follow-up, and a pragmatic design to strengthen real-world relevance and implantability, alongside future real-world evaluation.

Contributors

MJJ co-conceived and designed the trial, contributed to practice and participant enrolment and data acquisition, and had overall responsibility in their role as chief investigator. AW-H co-designed the trial and provided statistical input into the implementation and statistical analysis plan. EM contributed to the protocol development, implemented the trial, and contributed to the coordination of data acquisition and trial reporting. AH provided statistical input into the implementation and statistical analysis plan. JC co-conceived and designed the trial, contributed to the acquisition of qualitative data, and implemented the nested qualitative study. TM, JMD, RF, and SW co-designed the trial and contributed to practice and participant enrolment and data acquisition. JC and TM trained intervention practices. DMM co-designed the trial and designed, implemented, and supervised the health economic evaluation. JLO implemented the health economic evaluation. SB provided patient and public input in the implementation and trial reporting. DCC co-conceived and designed the trial. FS contributed to the acquisition of qualitative data and conducted and analysed the nested qualitative study. FD undertook operational delivery of the trial. AJF co-conceived and designed the trial, was responsible for its overall implementation across Leeds Clinical Trials Research Unit, and supervised the statistical analysis. AW-H and AH had full access to, and verified, all the data in the study. EM and FD had access to accumulating data to support trial conduct. DMM and JLO accessed data relevant to health economic analysis. JC and FS accessed data relevant to the qualitative analysis. Other trial management group members did not require access to study data but could request it under the collaboration agreements. Broader access required formal data sharing agreements. AJF is guarantor. MJJ, AW-H, AH, DMM, and JLO drafted the manuscript. All authors contributed to interpretation of data, commented on drafts of the paper, and approved the final draft of the manuscript. MJJ, AW-H, and AJF had final responsibility for the decision to submit for publication. Further contributions of authors and collaborative members are detailed in the appendix (pp 35–36), according to the CRediT Taxonomy.

Declaration of interests

MJJ, AW-H, JC, TM, JMD, RF, SW, DMM, and AJF report payments via their institution as co-applicants on the Yorkshire Cancer Research grant supporting the present manuscript. MJJ reports payments via their institution for grant funding from the National Institute for Health and Social Care Research (NIHR) and unpaid contributions as independent chair of a trial steering committee for the ChelSEA II trial (NIHR) and the PIPS2 study (NIHR). AW-H reports payments via their institution for grant funding from the NIHR; unpaid contributions for independent participation on a data monitoring and ethics committee and trial steering committees and as a statistical and trial design expert committee member for the Yorkshire and North East Regional Advisory Committee for NIHR Research for Patient Benefit (August, 2022, to present). JC reports payments via their institution for grant funding from the Medical Research Council. TM reports payments via their practice for the following grants or contracts: primary care associate research lead, Yorkshire and Humber Clinical Research Network; primary care regional research settings co-lead for the Yorkshire and Humber Regional Research Delivery Network. RF reports payments via their institution for grant funding from the NIHR, consulting fees for

the National Cancer Audit Collaborating Centre and THIS Institute; and unpaid contributions for independent participation as chair on the independent study oversight committees for NIHR-funded studies: Implementing improved asthma self-management as routine (IMP2ART); Acne Care Online (ACO); Evaluating the impact of artificial intelligence triage in online consultations to reduce delays in urgent and emergency primary care; and At-Risk Registers Integrated into primary care to Stop Asthma crises (ARRISA-UK). SW reports payments via their institution for grant funding from the NIHR. AJF reports payments via their institution for grant funding from the NIHR, including an NIHR senior investigator award from 2021, and unpaid contributions for independent participation on a data monitoring and ethics committee for the NIHR HTA phase 3 trial STADIA, trial steering committee for the British Heart Foundation phase 3 trial OPTIMAS, and as a programme committee independent statistician for the NIHR Programme Grants for Applied Research-funded study RENAL-HF. All other authors declare no competing interests.

Data sharing

All data requests should be submitted to ctru-dataaccess@leeds.ac.uk and the corresponding author for consideration. Requests are subject to review by a subgroup of the trial team, which will include the data guarantor, Amanda J Farrin, and chief investigator, Miriam Johnson. Access to anonymised data can be granted following this review. All data sharing activities require a data sharing agreement.

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