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Holistic needs assessment in outpatient cancer care: a randomised controlled trial

Austyn Snowden ![ORCID],[1] Jenny Young,[1] Denis Roberge,[2] Stefano Schipani,[3,4] Esther Murray,[5] Claude Richard,[6] Marie-Therese Lussier,[7] Craig White ![ORCID] [4]

ABSTRACT

Design Analyst blinded, parallel, multi-centre, randomised controlled trial (RCT).

Participants People with confirmed diagnoses of cancer (head and neck, skin or colorectal) attending follow-up consultation 3 months post-treatment between 2015 and 2020.

Intervention Holistic needs assessment (HNA) or care as usual during consultation.

Objective To establish whether incorporating HNA into consultations would increase patient participation, shared decision making and postconsultation self-efficacy.

Outcome measures Patient participation in the consultations examined was measured using (a) dialogue ratio (DR) and (b) the proportion of consultation initiated by patient. Shared decision making was measured with CollaboRATE and self-efficacy with Lorig Scale. Consultations were audio recorded and timed.

Randomisation Block randomisation.

Blinding Audio recording analyst was blinded to study group.

Results 147 patients were randomised: 74 control versus 73 intervention.

Outcome No statistically significant differences were found between groups for DR, patient initiative, self-efficacy or shared decision making. Consultations were on average 1 min 46 s longer in the HNA group (respectively, 17 m 25 s vs 15 min 39 s).

Conclusion HNA did not change the amount of conversation initiated by the patient or the level of dialogue within the consultation. HNA did not change patient sense of collaboration or feelings of self-efficacy afterwards. HNA group raised more concerns and proportionally more emotional concerns, although their consultations took longer than treatment as usual.

Implications for practice This is the first RCT to test HNA in medically led outpatient settings. Results showed no difference in the way the consultations were structured or received. There is wider evidence to support the roll out of HNA as part of a proactive, multidisciplinary process, but this study did not support medical colleagues facilitating it.

Trial registration number NCT02274701.

INTRODUCTION

Patients with cancer experience a wide range of unmet needs including practical, emotional and social concerns, with negative consequences on general well-being.[1] Holistic needs assessment (HNA, figure 1) is a process designed to elicit systematic support of all patient's needs.[2] Systematic reviews on the role and function of HNA broadly agree on the core domains that make up 'holistic' needs in cancer care: physical, practical, emotional, family/relationship, spiritual, information/support.[3] The HNA used in this study was the concerns checklist (figure 1), a list of 48 concerns grouped under the domains described previously. These concerns are rated by the patient at key times in their cancer care to ensure (a) their personally prioritised needs are identified and planned for, and that b) resources are targeted to those in most need.[2]

An HNA helps focus the consultation on the explicit needs of the patient. This person-centred approach should help patients to share decision making within the consultation because, in theory, HNA should support patients to take a more active and participatory role in it. Patient engagement within consultations is associated with self-efficacy, and self-efficacy is associated with better health outcomes.[4 5] Therefore, collaboration within consultations, grounded in patient's personally prioritised needs, should lead

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first study to attempt to establish the impact of a holistic needs assessment (HNA) on the levels of patient participation within the clinical consultation.
⇒ This is also the first study to examine the impact of HNA in a predominantly medical sample of clinical consultations.
⇒ Consultation analysts were blinded to the study group.
⇒ 'Time taken for consultation' should have been a primary outcome.
⇒ The study took 5 years to recruit.

National Cancer Survivorship Initiative – Your Holistic Needs Assessement

Concerns checklist
0001

Living with and beyond cancer – identifying your concerns

Completed by: _____

Date: _____

Designation: _____

Contact details: _____

Patient's name or label

This self assessment is optional, however it will help us understand the concerns and feelings you have. It will also help us identify any information and support you may need in the future.

If any of the problems below have caused you concern in the past week and if you wish to discuss them with a health care professional, please tick the box. Leave the box blank if it doesn't apply to you or you don't want to discuss it now.

☐ I have questions about my diagnosis/treatment that I would like to discuss.

Physical concerns
☐ Breathing difficulties
☐ Passing urine
☐ Constipation
☐ Diarrhoea
☐ Eating or appetite
☐ Indigestion
☐ Sore or dry mouth
☐ Nausea or vomiting
☐ Sleep problems/nightmares
☐ Tired/exhausted or fatigued
☐ Swollen tummy or limb
☐ High temperature or fever
☐ Getting around (walking)
☐ Tingling in hands/feet
☐ Pain
☐ Hot flushes/sweating
☐ Dry, itchy or sore skin
☐ Wound care after surgery
☐ Memory or concentration
☐ Taste/sight/hearing
☐ Speech problems
☐ My appearance
☐ Sexuality

Practical concerns
☐ Caring responsibilities
☐ Work and education
☐ Money or housing
☐ Insurance and travel
☐ Transport or parking
☐ Contact/communication
   with NHS staff
☐ Housework or shopping
☐ Washing and dressing
☐ Preparing meals/drinks

Family/relationship concerns
☐ Partner
☐ Children
☐ Other relatives/friends

Emotional concerns
☐ Difficulty making plans
☐ Loss of interest/activities
☐ Unable to express feelings
☐ Anger or frustration
☐ Guilt
☐ Hopelessness
☐ Loneliness or isolation
☐ Sadness or depression
☐ Worry, fear or anxiety

Spiritual or religious concerns
☐ Loss of faith or other
   spiritual concern
☐ Loss of meaning
   or purpose of life
☐ Not being at peace with
   or feeling regret about the past

Lifestyle or information needs
☐ Support groups
☐ Complementary therapies
☐ Diet and nutrition
☐ Exercise and activity
☐ Smoking
☐ Alcohol or drugs
☐ Sun protection
☐ Hobbies
☐ Other

Please mark the scale to show the overall level of concern you've felt over the past week.

You may also wish to score the concerns you have ticked from 1 to 10.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
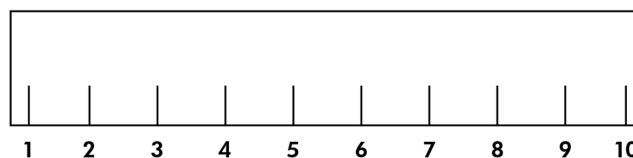
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Figure 1 Holistic needs assessment: the concerns checklist.

to greater patient involvement in decision making and increased likelihood of positive outcomes.[6]

Despite its endorsement in clinical guidelines, outcomes from randomised controlled trials (RCTs) of HNA have been equivocal. A pilot trial of a bespoke HNA tool in a palliative service in the UK found it resulted in worse quality of life outcomes for patients than treatment as usual (TAU).[7] The authors acknowledged that these findings could have been because of the lack of connected follow-up postassessment. Subsequent

researchers[8] therefore integrated care plans into their RCT of HNA as delivered by allied health professionals. Despite the qualitative element of the study pointing to feelings of greater empowerment for those in the intervention group, this study also found no significant differences between groups (HNA and care as usual) in health-related quality of life measures in women with gynaecological cancer at 3 and 6 months from baseline. They concluded that the trend towards improvement seen in some of the quality-of-life subscales was a

function of trained health professionals using person-centred approaches.[8]

Despite these RCT results the consensus in 2020 supported the use of HNA as part of a connected, systematic multidisciplinary process of focused assessment followed by planned action and review.[9 10] It would be helpful to understand if and how HNA works at consultation level because operationalising person centred care is at the heart of current strategic direction in cancer policy in Scotland[11 12] and beyond.[10]

This study was designed to test the impact of HNA on consultation dynamics and patient perceptions of shared decision making and self-efficacy. The aim of the trial was to investigate if and how HNA impacted on patient participation during outpatient oncology consultation and patient perceptions of shared decision-making and self-efficacy afterwards. Objectives were to examine:

1. The impact of HNA on consultation structure and content.
2. The impact of HNA on shared decision-making.
3. The impact of HNA on patient-reported self-efficacy.

To meet these objectives, the study tested the following hypotheses:

1. Use of HNA within clinical consultation will facilitate increased levels of patient participation.
2. Use of HNA within clinical consultation will facilitate increased levels of shared decision making.
3. Use of HNA within clinical consultation will facilitate increased feelings of self-efficacy.

METHOD
Study design
Multi-centre, analyst blinded, RCT conducted across four outpatient oncology clinics in Scotland, UK.[13] A multidisciplinary steering group oversaw the trial.

Participants: clinicians
Nine clinicians (three consultant oncologists, three surgeons, three cancer nurse specialists) based across four outpatient oncology clinics in Glasgow (see table 1). Two clinics were situated in National Health Service

(NHS) general hospitals and two in an NHS specialist cancer centre. None of the oncologists or surgeons had used HNA previously. All attended a training session on HNA and the study protocol, delivered by a consultant psychologist (EM) and the research team. The aim of the training was to familiarise the clinicians with the study process and equip them with the skills and confidence to respond to the patient's needs as identified through the HNA.

Participants: patients
Individuals with head and neck, skin and colorectal cancer were eligible if over the age of 18, had undergone treatment for their diagnosis and were attending post-treatment outpatient clinic with one of the participating clinicians. All patients had previously met their respective clinician. Exclusion criteria included those deemed incapable of consent and any reason in the opinion of the clinician that may interfere with the patient's ability to take part in an audio-recorded consultation, for example, if the patient had received a laryngectomy.

Participants: sample size
Sample size was 156, calculated on G*Power3 based on the following assumptions[11]: power=0.8, alpha=0.0125, d=0.5. Alpha was subjected to Bonferroni correction to account for the additional risk of type 1 error in testing four primary outcomes on the same dataset.

TRIAL PROCEDURE
Patients provided written informed consent to participate before they were randomised. Allocation concealment was maintained through sequentially numbered, opaque, sealed envelopes. Block randomisation (block size of 6 and 4) was used to ensure comparable number of patients within each group. The rationale for using different block sizes was so the sequence could not be predicted. As this was the first RCT to examine HNA on consultation dynamics the decision was made not to stratify by sex or age as we did not have sufficient evidence that these factors were related to the outcome measures. Participants attended their appointment 15 min early, at which point they were informed as to which study group they had been randomised to, so that they could then complete relevant study paperwork preconsultation.

Consultation: intervention arm
Patients completed a demographic questionnaire and the HNA (figure 1) prior to consultation. The patient was then asked to hand their completed HNA to their clinician when they entered the consultation room. The researcher accompanied the patient into the room and switched on the voice recorder.

During the consultation the clinician incorporated the HNA into their discussion.[13] As this was usually the patient's first post-treatment appointment (mean 3 months post-treatment) the clinician had some

Table 1 Study participants by consultant and intervention group

Role	Intervention	Control
Oncologist 1	43	38
Surgeon 1	21	14
Surgeon 2	1	8
Oncologist 2	4	3
Surgeon 3	1	7
CNS 1	3	3
Oncologist 3	1	2
CNS 2		1
CNS 3		1

procedural issues to discuss with the patient first, for example, results from scans, or problems post-treatment. This was usually followed by an examination of the cancer site. The HNA was introduced and discussed after these routine procedures, and any subsequent actions taken by the patient or clinician were recorded in the care plan. The researcher made notes about pauses or non-verbal events throughout to help the team analysing the recordings. At the end of the consultation the recording was stopped. Immediately postconsultation, participants returned to the waiting room with the researcher where they completed two short outcome measures, Collabo-RATE[14] and The Lorig Self-Efficacy scale.[15 16]

Control group: TAU

As with the intervention group, the researcher greeted the patient in the waiting room and re-confirmed consent. The patient completed the demographic questionnaire, and the researcher accompanied the patient into the consultation room, switched on the recorder at the beginning and switched it off at the end, making notes on pauses, details of participants and pertinent events as per intervention group. The control group also completed the postconsultation self-report measures on collaboration and self-efficacy.

OUTCOME MEASURES

Hypothesis 1 tests 'patient participation' within the consultation. Patient participation was obtained by calculating two different primary outcome measures of patient involvement during consultation:

1. *Patient initiative* (PI) represents the proportion of the consultation initiated by the patient as opposed to the clinician.
2. *Dialogue ratio* (DR) measures the degree of collaboration between the speakers during the conversation.

To obtain these aggregate measures consultation audio-recordings were coded by team members blinded to group allocation. Coding was based on the MEDICODE[17] scheme, a coding framework consisting of overarching categories and themes common to medical consultations. The analyst coded sections of the consultation under relevant categories and noted (a) whether the patient or clinician initiated the theme (PI) and (b) whether the conversation around that theme was monologue, dyad or dialogue (DR).

Patient initiative

PI was calculated as the proportion of patient-initiated themes within the consultation. A patient was coded as having initiated conversation when a new theme was introduced by them. The aggregate PI value falls between 0, meaning the patient had no initiative at all, and 1, indicating the patient initiated all themes discussed within the consultation. Any other score represents the balance of initiative between patient and clinician.

Dialogue ratio

The DR is also presented as a value between 0 and 1.[18] A theme coded as monologue was assigned a value of 0, a dyad 0.5 and a dialogue 1. An average score was computed for the same aggregate of themes used for the PI score. An average score of 0 would mean that all the themes were covered in monologue, while a score of 1 would mean that all the themes were discussed in dialogue. As with PI, average DR scores were then compared between groups.

Shared decision-making

The primary outcome for hypothesis 2 was score on CollaboRATE, a validated brief measure of shared decision making.[14] It measures patient perception of how much effort clinicians make to: explain their patients' health issues, listen to the issues that matter most to their patients, and integrate the patients' views and health beliefs.

Self-efficacy

The primary outcome for hypothesis 3 was self-efficacy, as measured by The Lorig Self-Efficacy for Managing Chronic Disease 6-Item Scale. The scale includes items relevant to chronic disease measurement such as symptom control and communicating with physicians. The scale has good internal consistency and construct validity, and it has been extensively used at both clinical and research levels within the cancer patient population.[19]

Time taken in consultation

'Time taken per consultation' had not been part of the original protocol, and previous attempts to time consultations had been quite complex.[20] The focus of this study was on consultation dynamics that required audio recording, and the research assistant also had to ensure consent and preclinic paperwork had been completed as well as postconsultation metrics too. Because we had hoped other teams would participate in the study we wanted to keep the protocol as simple as possible to minimise dropout due to complexity[21] it was decided that timing of the consultations might be a measure too far, and so it was excluded from the original protocol. However, because all the consultations were digitally recorded it was possible to retrospectively record the exact length of time taken in each consultation in a consistent way. This had not been anticipated, hence its absence from the planned hypotheses. It was nevertheless available for exploratory analysis.

ANALYTIC PLAN

All data were checked for input errors, missing data, and means and SD were calculated. Data were then tested for assumptions of normality and homogeneity of variance associated with independent groups analysis. If the assumptions were met for a primary outcome, then independent t-tests were run to test for significant differences between the group means. If the assumptions were not met for a particular outcome, then the optimal non-parametric test

would be selected based on the outcomes of assumption testing.[22] Exploratory analyses were also conducted iteratively. For full plan, refer protocol.[13]

Patient and public involvement

The original idea for this study was conceived in collaboration with patients following a series of presentations of findings from a pilot RCT of the distress thermometer and concerns checklist.[20] Patients from this study had fed back that their consultations had qualitatively improved when clinicians used the concerns checklist. When asked to explain this in more detail they described feeling better listened to and more involved in the consultation. They went on to describe feeling more confident to carry out whatever plan had been discussed in the consultation.

The study protocol focused on exploring these dynamics. DR and PI represented proxy measures of involvement during consultation, CollaboRATE is a valid self-report measure of the degree to which patients felt involved, and self-efficacy was a key element of the improved postconsultation control that patients were describing as a product of this improved involvement. This study was created to replicate and articulate the hypothetical process underpinning the positive experiences reported by patients at feedback events.

RESULTS
Participants

From November 2015 to February 2020, 275 patients appointed to outpatient follow-up were approached by clinicians for participation (see figure 2). Eleven declined and 264 were enrolled. There was an average of 3 months between enrolment and follow-up, and 113 patients were lost to the study in this time. By March 2020, 151 patients had participated when the study was suspended due to COVID-19 restrictions.

All 151 participants were white, Scottish, with mean age of 64.5 (11.5) years. There were 101 men and 50 women. Most were married and the whole sample had a mean Scottish Indicator of Multiple Deprivation quintile category of 4.7 (3.1), five being most deprived. Of those declaring a highest qualification 15 had a degree, 15 A levels/highers, two masters degrees, 25 standard grades and 16 vocational qualifications. Apart from sex, demographics were balanced between the two groups (table 2). The majority were treated for head and neck cancers (n=121), with 23 treated for skin cancers and 7 colorectal. Treatment was chemorad (n=31), radiotherapy (n=37) and surgery (n=43). Patients were predominantly treated by two clinicians, oncologist one (n=86) and surgeon one (n=35), with the other seven clinicians contributing the remaining 35 consultations. Nurses contributed eight consultations, close to 1 in every 20 (table 1).

Use of HNA within clinical consultation will facilitate increased levels of patient participation

Mean scores for PI and DR were computed for each group (table 3). There were no outliers in the data, as assessed by inspection of boxplots. Scores for PI in both groups were normally distributed, as assessed by Shapiro-Wilk's
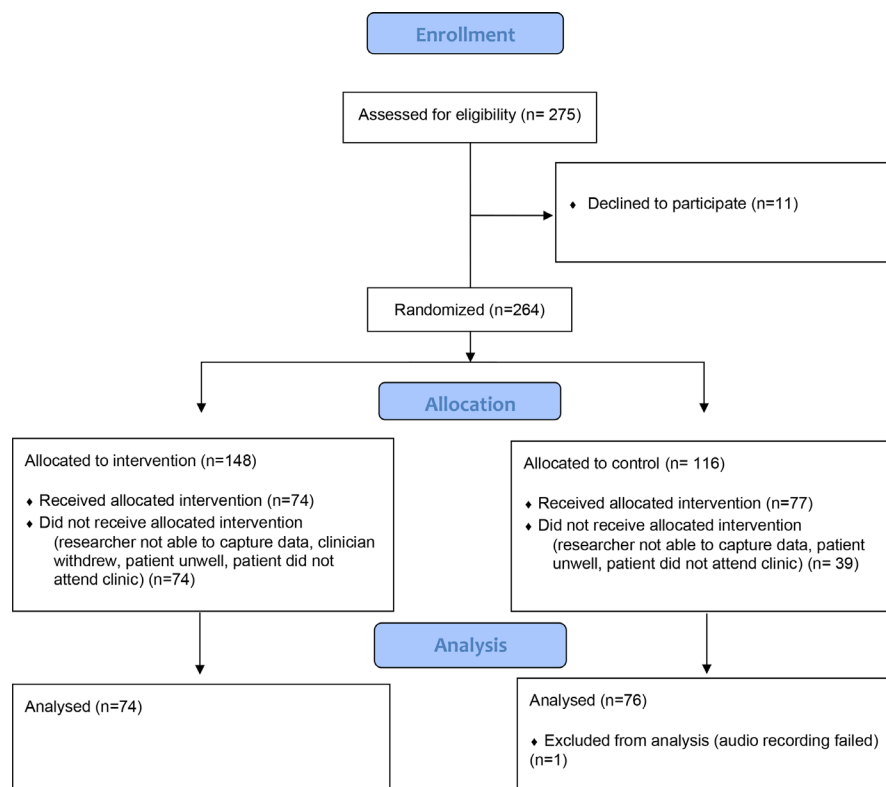
Figure 2 Flow of participants through the trial.

Table 2 Participant demographics

Participant	Intervention (n=74)	Control (n=77)	Descriptive	Intervention (n=74)	Control (n=77)
Age and sex			Cancer		
Male	52	49	Head and neck	60	61
Mean (SD) age	64.9 (10.2) years	60.3 (9.8) years	Colorectal	3	4
Female	22	28	Skin	11	12
Mean (SD) age	66.9 (12.0) years	70 (10.2) years	Treatment		
			ChemoRad	14	17
Status			Radiotherapy	21	16
Single	8	11	Surgery	21	22
Married	55	50	Missing	18	22
Divorced	4	5			
Widow	7	8	Clinician seen		
Missing	0	3	Oncologist	48	43
			Surgeon	23	29
Mean SIMD (SD)	5.21 (3.0)	4.35 (3.1)	Nurse specialist	3	5

SIMD, Scottish Indicator of Multiple Deprivation.

test (p>0.05), and there was homogeneity of variances, as assessed by Levene's test (p=0.055). PI scores were lower for the intervention group (0.25±0.10) than control group (0.26±0.13), a non-significant difference of −0.012 (95% CI −0.06 to 0.04), t(145)=−0.439, p=0.661.

Scores for DR in both groups were normally distributed, as assessed by Shapiro-Wilk's test (p>0.05), and there was homogeneity of variances, as assessed by Levene's test (p=0.051). DR scores were lower for the intervention group (0.38±0.15) than control group (0.40±0.19), a non-significant difference of −0.013 (95% CI −0.05 to 0.02), t(145)=−0.691, p=0.49.

These results did not support hypothesis 1. Use of HNA within clinical consultation did not facilitate increased levels of patient participation.

Use of HNA within clinical consultation will facilitate increased levels of shared decision making

Table 3 shows the mean scores for CollaboRATE were very similar in both groups. There were no outliers in the data, as assessed by inspection of a boxplot. Scores for both groups were normally distributed, as assessed by Shapiro-Wilk's test (p>0.05), and there was homogeneity of variances, as assessed by Levene's test (p=0.649). CollaboRATE scores were higher for the intervention
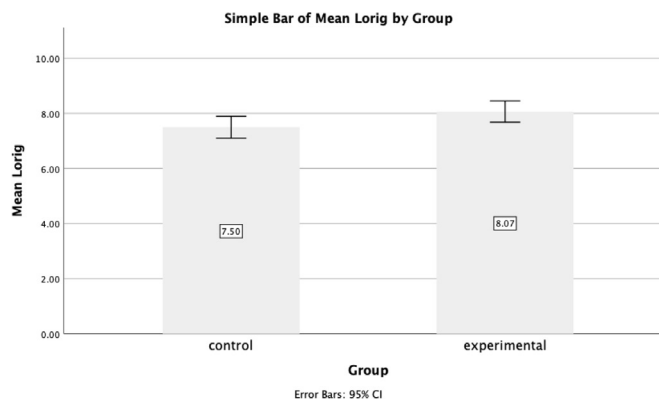
group (25.43±4.1) than control group (25.03±4.4), a non-significant difference of 0.4 (95% CI −1.77 to 0.97), t(149)=−0.58, p=0.562. Hypothesis 2 was not supported: use of HNA did not lead to greater feelings of shared decision making and collaboration.

Use of HNA within clinical consultation will facilitate increased feelings of self-efficacy

The difference in means for the Lorig Self-Efficacy measure were tested using independent samples t-test. There were no outliers in the data, as assessed by inspection of a boxplot. Lorig scores for both groups were normally distributed, as assessed by Shapiro-Wilk's test (p>0.05), and there was homogeneity of variances, as assessed by Levene's test for equality of variances (p=0.809). Lorig scores were higher for the intervention group (8.07±1.7) than control group (7.5±1.7), a non-significant difference of 0.57 (95% CI 0.02 to 1.11),

Table 3 Primary outcome measures

Outcome measure	Intervention (n=74)	Control (n=77)
Mean (SD) dialogue ratio (DR)	0.384 (0.100)	0.398 (0.129)
Mean (SD) patient initiative (PI)	0.253 (0.146)	0.265 (0.185)
Mean (SD) CollaboRATE	25.43 (4.1)	25.03 (4.4)
Mean (SD) Lorig Self-Efficacy	8.1 (1.7)	7.5 (1.7)

Figure 3 Barchart: Mean scores for Lorig Self-Efficacy scale by group, with 95% CIs.

Table 4 Breakdown of consultations according to problems and concerns discussed

Complexity of the discussions	Intervention	Control
Total number of concerns discussed	609	487
Average number of concerns discussed per consultation	8.3	6.6
Proportions of different concerns raised per category		
Cancer (HNA=73; TAU=74)	12.00%	15.20%
Other health problems (HNA=59; TAU=26)	9.70%	5.30%
Physical concerns (HNA=382; TAU=362)	62.70%	74.30%
Emotional concerns (HNA=28; TAU=12)	4.60%	2.50%
Practical concerns (HNA=18; TAU=2)	3.00%	0.40%
Relationship concerns (HNA=5; TAU=2)	0.80%	0.40%
Support needs (HNA=8; TAU=8)	1.30%	1.60%
Spiritual concerns (HNA=1; TAU=0)	0.20%	
HNA level of concerns (HNA=35; TAU=1)	5.70%	0.20%

HNA, holistic needs assessment; TAU, treatment as usual.

t(146)=2.04, p=0.043 (figure 3). Use of HNA within clinical consultation did not facilitate increased levels of self-efficacy postconsultation.

Exploratory analyses

You will recall that 'time in consultation' was not a primary outcome, but the digital audio-recordings provided accurate timings of consultation, nonetheless. These times were on average nearly 2 min longer for the intervention group (17 min 25 s) than control group (15 min 39 s). Using HNA within these clinical consultations took longer than not using HNA. The content of the consultations also differed (table 4), with more concerns discussed overall in the intervention group, and a shift away from discussing physical concerns towards emotional, practical and other health problems.

DISCUSSION

Use of HNA within post-treatment, outpatient consultation did not facilitate increased levels of PI, did not change the consultations in terms of overall monologue-dialogue, did not facilitate any greater sense of collaboration and did not increase feelings of self-efficacy immediately post-consultation. HNA took up more consultation time than TAU. This lack of support for HNA is consistent with other RCTs designed to establish its impact.[7 23] It is inconsistent with the wider literature showing that undertaken as part of a proactive and well connected multidisciplinary process, HNA has improved outcomes from both patients and clinicians.[10 24] It may be that the outcome measures used were not sensitive enough, or that the impact of HNA may have been more nuanced, given there were observable differences between the groups.

For example, a higher number of concerns were discussed in the intervention group (8.3 vs 6.6) (table 4). It is possible this increase could be a function of the extra time taken in the intervention groups, but this would not explain the changes seen in the *content* of these consultations. Focus tended to remain on cancer and physical health in TAU group whereas 'other health problems', 'practical' and 'emotional concerns' were more prevalent in the intervention group (table 4). HNA apparently facilitated a more *complex* consultation, giving patients 'permission' to discuss difficult problems they may otherwise not have raised. If HNA could become integral rather than additional, then it seems HNA could facilitate a more holistic, patient targeted consultation. However, the study did not show that this would be the best use of consultation time.

Since this trial started, research into HNA has grown considerably.[25] A systematic review in 2019 found mixed outcomes from the included trials, with some finding improvement in quality of life but most not. A similar picture emerged from a 2022 scoping review of 'Cancer Care Reviews' that included HNAs.[26] These reviews concluded, like Ahmed *et al*[7] that it is the way in which these discussions are integrated that is key. If they are disconnected from other services they are seen as a tick box exercise or not remembered at all.[27] The setting needs to be conducive to confidential discussions, personnel need to be trained, confident and skilled in delivering HNA as part of a connected multidisciplinary process.[10 24]

Conditions in this study broadly met those facilitative criteria, so it may be that oncologists and surgeons are not the best members of the multidisciplinary team to be facilitating HNA. This study showed oncologists generated mainly physical needs (table 4). This is consistent with their specialism. When psychologists conduct HNA, patients tend to prioritise mainly emotional concerns, non-clinical social colleagues facilitate mainly money and housing needs.[28 29] Allied health professionals and nurses generate the broadest range of needs.[23 30] In other words, patient expectations of the consultation, including the role of any assessment in it, are largely consistent with their interpretations of what the consultation is for.[27] If generalisable, then the best way to articulate the widest range of holistic needs is to have the assessment facilitated by *non*-specialists.

The Western policy push for care to be personalised and holistic has been widely accepted in principle but remains difficult to operationalise, which is why studies like this are useful. HNA makes sense to patients when they know what it is for, it appears at optimal times as part of an ongoing process, making the best use of multidisciplinary specialists to support them with their evolving

concerns.[27] This study has shown that these optimal times and places should not include outpatient follow-up care conducted by oncologists and surgeons.

Limitations

The main weakness of the study was that it only examined a snapshot in time. Given HNA is ideally used at various points on the patient journey this was problematic. The focus of the study was on the mechanism of action during consultation, and no study had previously examined the HNA consultation in this depth. Nevertheless, some follow-up would have helped further contextualise the results. Another weakness was the study sample. It was all white, which was unexpected as 17.3% of the local population identified as an ethnic minority in the 2011 census, and this is known to have subsequently increased.

An anticipated weakness was the potential for crossover learning, given the same clinicians delivered both intervention and TAU (table 2). As stated in the protocol, crossover learning would not improve the likelihood of clinicians establishing patient's specific holistic needs,[13] but it is feasible that a consistently person-centred approach could account for the equivalent scoring in consultation participation. The levels of PI and DR seen in both groups implied inclusive levels of patient centredness, and this is likely to have been the case before the study. The original plan had been to conduct some prestudy interviews to benchmark the baseline 'treatment as usual' levels of all study metrics,[13] but this proved impractical when it became clear we were going to struggle to recruit to power. We therefore had to use all data for the study, and while this is a weakness of the study, it is evidence of good practice from all the clinicians.

Patient participation within the consultation was quantified using MEDICODE, a method of parsing conversations according to two simple metrics. However, aggregating values of DR and PI to account for the whole consultation had not been done previously. Studies using MEDICODE that have showed variations between consultations have shown variation in specific themes as opposed to the whole consultation.[31 32] This appeared to be the case again here. The intervention group discussed emotional issues 28 times as opposed to the TAU group's 12. This suggests that HNA did change consultation content, and that MEDICODE is of more use at this granular level. There may be better metrics to summarise participation in consultations at a more general level.

It would have been interesting to see if a change in dynamics would have been seen had HNA been introduced at the beginning of the consultation in the intervention group. While developing the protocol, participating clinicians were keen to maintain focus on the primary purpose of their consultations, namely: disseminating test results, organising further tests and examinations, discussing prognosis and treatment. The research team agreed that the study should not disturb these discussions but rather follow them. It is therefore unsurprising that HNA took longer, because it was conducted in addition to TAU. Further, the only opportunity for HNA facilitated variation in consultation style happened at the end of the traditional consultation. These extra 1 min and 46 s would likely have had to be completely patient led to impact on the overall consultation metrics. It is much more likely that the balance of the consultation continued as before the introduction of the HNA, and this is born out in the results for DR and PI.

CONCLUSION

The importance of being able to talk about holistic concerns in cancer care is well understood, as is the importance of clinicians systematically supporting people to meet their individual health and social care needs. HNA is known to facilitate this process, so this RCT aimed to understand the mechanism of action of HNA by finding out whether and how it changed consultation dynamics in outpatient follow-up consultation. Results showed there was no change. Both groups were equivalently person-centred. There was no impact on patient involvement during the consultation, or sense of collaboration or self-efficacy just after. While there was evidence of more emotional concerns being discussed in the intervention group, these consultations were also nearly 2 min longer.

The wider evidence supports the integration of HNA into a multidisciplinary process of proactive, patient-led health and social cancer care, and the results of this study are best interpreted from that perspective. Oncologists and surgeons are expensive, highly specialist members of the multidisciplinary team. Results of this study suggest that health and social care colleagues other than they are best placed to facilitate HNA.

Author affiliations
[1]Edinburgh Napier University, School of Nursing Midwifery and Social Care, Edinburgh, UK
[2]Département de médecine de famille et de médecine d'urgence, University of Quebec in Montreal, Montreal, Quebec, Canada
[3]Clinical Oncology, Beatson West of Scotland Cancer Centre, Glasgow, UK
[4]School of Cancer Sciences, University of Glasgow, Glasgow, UK
[5]Psychology, Beatson West of Scotland Cancer Centre, Glasgow, UK
[6]MEDICODE, University of Quebec in Montreal, Montreal, Quebec, Canada
[7]Faculté de médecine - Département de médecine de famille et de médecine d'urgence, University of Montreal, Montreal, Quebec, Canada

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by West of Scotland Research Ethics Committee (14/WS/0126) and also approved by the Clinical Trials Executive Committee within the Beatson West of Scotland Cancer Centre on 13 June 2014. NHS Research & Development approval followed on 26 August 2014. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Anonymised summary data are available on reasonable request. No audio recordings are available.

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ORCID iDs
Austyn Snowden http://orcid.org/0000-0001-9321-622X
Craig White http://orcid.org/0000-0001-8695-8014

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