1   **Meeting Psychosocial Needs to Improve Health: A Prospective Cohort Study**

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Abstract

Background

Cancer impacts on patients and their families across a range of different domains. For that reason, optimal cancer care has moved away from a disease-centric focus to a more holistic approach in order to proactively support people with their individual needs and concerns. While international policy clearly advocates this agenda, implementation into routine care is limited. Therefore, relevant interventions that measurably improve patient outcomes are essential to understand if this ideal is to become routine multidisciplinary practice. The aim of this study was to analyse the impact of a proactive, holistic, community-based intervention on health-related quality of life in a cohort of people diagnosed with cancer. Secondary aim was to explore the relationship between changes in health status and: cancer type, cancer stage, number of concerns expressed and change in severity of concerns pre and post intervention.

Method

Prospective observational cohort study. A convenience sample of 437 individuals were referred to the service 'Improving the Cancer Journey (ICJ) in the UK. Each completed the Euroqol EQ-5D-3L and visual analogue scale (VAS) and a Holistic Needs Assessment (HNA) during initial visit to the service and again at follow-up review, median 84 days later. Change between scores was tested with paired t-tests and relationships between variables with multiple regression models with heteroscedasticity-consistent standard errors.

Results

Participants were White British with median age between 50-64 years. Cancer type and stage were varied. EQ-5D utility scores improved at follow-up by 0.121 [0.0891-0.153], p<.001, and VAS scores improved by 7.81 [5.88-9.74], p<.001. The strongest predictor of change was a decrease in severity of concerns. Cancer stage 'palliative care' contributed to a reduction in health status.

Conclusion

This study is the first to show that a holistic community intervention dedicated to supporting the individual concerns of participants had both a statistically significant and clinically meaningful impact on participants' health-related quality of life. The mean change in EQ-5D

63 scores was more than the 'minimally important clinical difference' described in the

64 literature. This is important because while quality of life has multiple determinants, this

65 study has shown for the first time that it is possible to capture a clinically meaningful

66 improvement as a function of reducing someone's personally identified concerns.

67

68 **Key words:**

69 Holistic Needs Assessment; health status; EQ-5D; quality of life; community; cancer; support;

70 psychosocial

71

72

73 **Background**

74 Globally, following a cancer diagnosis people report a wide range of needs and concerns [1].

75 The ideal of modern health and social care is therefore to optimise the skills available from a

76 matching range of multidisciplinary professionals to meet these physical, psychological,

77 social, emotional, financial, practical and spiritual needs, whilst at all times keeping the

78 individual at the centre of decisions [2].

79

80 However, evidencing the benefits of holistic approaches to the patient is complex, not least

81 because there are numerous interacting factors that impact on outcomes. For instance,

82 there are different approaches to providing holistic care, including different assessment

83 tools and assessor actions that affect the patient experience [3][4]. Even using the same

84 assessment, individuals respond in different ways according to the professional undertaking

85 the assessment [5], suggesting that there is no such thing as a 'value free' assessment of

86 holistic need. Consequently, while policy has recognised the importance of routine, person-

87 centred, psychosocial care [6], concerns relating to implementation barriers, the lack of

3

88   clarity on the best way to identify needs and poor evidence of impact prevents widespread

89   uptake [7][8]. Nevertheless, successful interventions exist. Therefore, the most appropriate

90   learning at present comes from successful examples of care delivery consistent with this

91   holistic agenda.

92

93   *The intervention – Improving the Cancer Journey*

94   'Improving the Cancer Journey' (ICJ) was commissioned in 2014 in Glasgow, Scotland. It is

95   the first community-based cancer service of its kind in the UK and is unique for three

96   interrelated reasons. First, stakeholders are multi-professional. Led by the city council with

97   partners across health, social care, housing and the third sector. Second, the key

98   intervention (Holistic Needs Assessment (HNA) figure 1) is proactive: people newly

99   diagnosed with cancer are actively sought out and referred to support. Third, the

100   intervention is coordinated by non-clinical 'link officers' rather than health professionals

101   (table 1).

102

The link officer

ICJ link officers are city council employees, not health care professionals. The council

currently employ seven link officers. When they first join the service, link-officers have a 3-

month induction period where each officer becomes familiar with their role and

completes a range of training. Currently all officers are, or are working towards, being

accredited with a Level 3 Scottish Vocational Qualification (SVQ) in healthcare support to

reflect their competencies in this area. Level 3 SVQ is a vocational qualification

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academically equivalent to graduate diploma level, or second year of baccalaureate degree.

103

104 *Table 1 The link officer*

105

106 In more detail, ICJ writes to every person with a confirmed cancer diagnosis in Glasgow and

107 invites them to access the support, if they wish. At a pre-arranged appointment the link

108 officer meets with their client at a location of their choice. This may be their home, a

109 community venue such as a library or their local hospital (both inpatient and outpatient).

110 During this appointment a HNA (figure 1) is carried out, whereby clients are asked to score

111 each of their identified concerns from zero to 10, reflecting the severity of the concern for

112 that person. Based on mutually agreed priorities between the patient and link officer, a care-

113 plan is then co-constructed which details any actions that will be carried out to support the

114 identified concerns. For example, the link officer may provide written information or make a

115 referral to an appropriate agency. The link officer revisits each case; the timing dependant

116 on the clients' circumstances, severity of concerns raised, care plan details and prognosis. At

117 this review, a second HNA is carried out to identify if the client's concerns have reduced

118 and/or there are any new concerns. This process continues until the client and the link

119 officer are satisfied that no further support is required.

120

121 The service has supported approximately 4000 people since 2014 across a range of cancer

122 types and stages and sociodemographic backgrounds [9]. However, the most common use of

123 the service is from individuals with lung cancer, who are aged between 55-64 years and who

124 live in areas of high deprivation, as measured by the Scottish Index of Multiple Deprivation

125   (SIMD). Thirty per cent of ICJ clients were receiving treatment at the time of their first HNA.

126   Most (over 50%) have at least one co-morbidity. The top three concerns for all users of ICJ

127   are financial, fatigue and worry/anxiety. Actions taken by the service include referral to

128   organisations for financial support (including payment of state benefits), referral to other

129   charities for services such as counselling and complementary therapies and referral to social

130   care for assistance with daily living.

131

132   There is quantitative and qualitative evidence that this service generates positive outcomes

133   for individuals [9, 10]. Demonstrating a national commitment to this model of care in 2019,

134   Macmillan Cancer Support (a UK charity) and the Scottish Government each pledged £9

135   million to ensure everyone diagnosed with cancer has a dedicated support worker.

136   According to the Scottish Government [11] this will make Scotland the first country in the UK

137   to offer cancer patients guaranteed emotional, practical and financial advice .

138

139   However, despite this public support it remains unclear what, if any, relationship there is

140   between identifying and meeting someone's personally identified needs and any subsequent

141   impact on self-reported health status. This is important as it would provide currently lacking

142   evidence of effectiveness using standardised measures. In turn, this will improve the ability

143   to generalise findings to other geographical and cancer care settings and lay the foundation

144   for future research to develop a conceptual theory on the relationship between 'need'

145   (which may cover a number of domains) and health related quality of life [12].

146

147

148

149 **Aim**

150 The overarching aim was to analyse the impact of ICJ on self-reported health status using the

151 EQ-5D - 3L utility measure and visual analogue scale (VAS) [13]. Secondary aim was to

152 explore the relationships between change in health status and cancer type, cancer stage,

153 number of HNA concerns expressed, severity of concerns and change in severity of concerns

154 between pre and post intervention.

155

156 *Hypotheses*

157 Primary:

158 1. There will be a statistically significant difference between EQ-5D scores at baseline

159 and EQ-5D scores post intervention.

160 Secondary:

161 2. There will be a relationship between changes in health status and: cancer type,

162 cancer stage, number of concerns expressed and change in severity of concerns pre

163 and post intervention.

164

165 **Method**

166 *Design*

167 Prospective observational cohort study.

168

169 *Analytic variables*

170 Sociodemographic data included age range, sex, and Scottish Index of Multiple Deprivation

171 (SIMD). These data were collected with consent from the participants who had accessed the

172 intervention at baseline. The following data were collected at baseline and also post

173   intervention: cancer type, cancer stage, and data relating to the HNA process (figure 1)

174   including number and mean severity rating of concerns identified. To measure self-reported

175   health status, participants completed the EQ-5D-3L and Visual Analogue Scale (VAS) at

176   baseline and post intervention. A utility score was computed from the EQ-5D ratings using

177   an algorithm and value sets produced in a UK population study [14] of societal preferences

178   using the Time Trade-off (TTO) method. A utility score of 1 is interpreted as the best possible

179   health, 0 as death, and values of <0 as being worse than death.

180

181   *Participants*

182   In 2018/19 a consecutive, convenience sample of 437 ICJ clients completed the EQ-5D-3L

183   and VAS on paper versions during their initial visit and again at their follow-up review. Initial

184   assessments were face to face so individuals completed the surveys themselves. Reviews

185   usually occurred over the telephone so the link officer, through conversation, completed it

186   on the participants' behalf.

187

188   *Analytic plan*

189   All data were imported into R (version 3.5.0, using 'tidyverse' package version 1.3.0 [15]) and

190   SPSS package for statistics version 23, cleaned and checked for outliers. For the main

191   hypothesis, a paired t-test was run to ascertain the difference in EQ-5D-3L scores between

192   initial visit and post intervention, and the same for the VAS. For the secondary aim, EQ-5D-3L

193   and VAS change scores post intervention were tested for associations using univariate linear

194   regressions with sociodemographic, clinical and HNA-related variables, with those found

195   associated entered into two multiple linear regression models to identify likely predictors of

196   change in EQ-5D scores and VAS between assessments. For descriptive statistics, means and

197   confidence intervals were computed for approximately normally distributed variables,

198   proportions for categorical variables, and median and minima and maxima for non-normally

199   distributed variables. Only pairwise complete observations were used in analysis.

200

201   Regarding interpretation, the concept of 'minimally important clinical difference' (MICD) has

202   been used to explain the amount of change required in a particular test score that

203   represents a clinically meaningful change for the individual taking that test. For example, it

204   has been used to interpret change in measures of asthma control [16] and wellbeing [17],

205   including the EQ5D [18], and so this concept was also applied here.

206

207

208   Figure 2. *Sample inclusions and exclusions.*

209

Results

HNA data *and* EQ-5D results at baseline and follow-up were obtained for 349 individuals as not every client opts to have a HNA or has a Review (as of August 2019, approximately 6800 clients were referred to ICJ, with approx. 4100 or 60% of referrals completing a HNA, and approx. 1800 or 43% of HNAs also receiving a follow-up HNA). As detailed in Figure 2, twelve participants were excluded for not having had any concerns recorded at HNA or review, four participants were removed for having baseline and follow-up scores recorded less than 14 days apart, one participant was removed for reporting an unusually large number of concerns in their HNA, and one participant was removed for having an incomplete EQ5D. A total of 331 individuals were analysed. The time between assessments ranged from 14 to 456 days, averaging 117 days (median 84). Between baseline and follow up, self reported severity of concern dropped, in line with previous findings [9]. Figure 3 shows the mean change in the different domains of the HNA. There is further detail in supplementary file 1.

Figure 3 Baseline, Follow-up and Change score for Mean concern severity across domains. Error bars depict 95% CI. The negative change scores correspond to an improvement.

236

237 Table 2 shows patient characteristics. In summary, the majority of participants were aged

238 between 50-64 years, 59% were female, most resided in areas of high deprivation and

239 cancer type and stage were varied. ==The variable 'Palliative care' denotes individuals who==

240 ==identified as receiving palliative care at baseline or follow-up.==

241

Characteristic	Statistic	N
Age, N (%):		330
25 to 49 years	32 (9.70%)	
50 to 64 years	127 (38.5%)	
65 to 74 years	112 (33.9%)	
75 years and over	59 (17.9%)	
Sex, N (%):		325
Female	192 (59.1%)	
Male	133 (40.9%)	
Cancer type, N (%):		331
Bowel	29 (8.76%)	
Breast	71 (21.5%)	
Lung	72 (21.8%)	
Pther	131 (39.6%)	
Prostate	28 (8.46%)	
Cancer stage at baseline, N (%):		273
Living with condition	55 (20.1%)	
Receiving palliative care	26 (9.52%)	
Recently completed treatment (within 1 month)	17 (6.23%)	
Recently diagnosed (1 month)	35 (12.8%)	
Undergoing tests	18 (6.59%)	
Undergoing treatment	122 (44.7%)	
Cancer stage at follow-up, N (%):		322
Living with condition	144 (44.7%)	
Receiving palliative care	55 (17.1%)	
Recently completed treatment (within 1 month)	28 (8.70%)	
Recently diagnosed (1 month)	1 (0.31%)	
Recurrence	1 (0.31%)	
Undergoing tests	9 (2.80%)	
Undergoing treatment	84 (26.1%)	
Palliative care, N (%):		276
Yes	59 (21.4%)	
No	217 (78.6%)	
Deprivation (1=most deprived), Median [min-max]	3 [1-20]	331

242 *Table 2. Patient characteristics*

243

245 *Primary Hypothesis*

246   1. There will be a statistically significant difference between EQ-5D scores at baseline

247   and EQ-5D scores post intervention.

248 Table 3 presents the descriptives of the EQ-5D-3L Utility score and Visual Analogues Scale

249 (VAS) at baseline and follow-up. Figure 4 shows the same data but for each individual

250 participant in spaghetti plots. Both EQ-5D measures increased, indicating an improvement in

251 health status. The distributions of change scores for EQ-5D utility scores and VAS were

252 approximately normal with heavier tails on the positive side, and a large proportion of 0

253 values. However, because the sample size was sufficiently large, the t-test was assumed to

254 be sufficiently robust to non-normality (Lund & Lund, 2019).

Outcome	Mean [95% CI]
Follow-up time (days)	117 [107;126]
Concern severity at baseline	6.47 [6.23;6.71]
Concern severity at follow-up	2.90 [2.66;3.13]
Concern severity difference at follow-up	-3.57 [-3.84;-3.30]
VAS at baseline	49.1 [47.1;51.1]
VAS at follow-up	56.9 [54.9;58.9]
VAS difference at follow-up	7.81 [5.88;9.74]
Utility score at baseline	0.45 [0.42;0.49]
Utility score at follow-up	0.58 [0.55;0.60]
Utility score difference at follow-up	0.12 [0.09;0.15]

255 *Table 3. Descriptive summary of outcomes. The negative difference in concern severity is*
256 *interpreted as an improvement.*
257

258 Using a paired t-test, the increase in EQ-5D utility scores of 0.121 [0.0891-0.153] at follow-up

259 was found to be statistically significant (p<.001), as was the increase in VAS of 7.81 [5.88-

260 9.74] (p<.001). Cohen's d effect sizes were 0.43 [0.27-0.58] for Utility score difference, and

261 0.42 [0.27-0.58] for VAS, both of which are considered small to moderate. The hypothesis of

262 a significant difference between baseline and follow-up on EQ-5D scores was supported. The

263 mean changes in EQ-5D scores fell within previously published Minimal Clinically Important

264 Difference (MCID) estimates for oncological patients: 0.07 to 0.12 for utility scores[20], and 7

265 to 12 for VAS [21]. Table 3 shows the estimated proportion of individuals who had a clinically

266 important improvement or decline using the reported MCID values as lower and upper

267 bounds.

Measure	Declined	Improved
Utility score	12.7 - 17.5%	41.7 - 48.6%
VAS	6.3 - 13.6%	30.5 - 48.0%

268 *Table 3. Proportion of individuals whose EQ5D scores improved or declined above the MCID*

269 *threshold, using published lower and upper bound estimates.*

280 Figure 4. *Spaghetti plots showing change of EQ5D Utility scores and VAS from baseline to*

281 *follow-up for each participant. Each partly transparent line segment denotes one participant,*

282 *with darker lines indicating overlapping trajectories. The follow-up score is marked with a*

283 *circle for clarity.*

13

Secondary hypothesis

285   2. There will be a relationship between changes in self-reported health related quality

286   of life and: cancer type, cancer stage, number of concerns expressed, and change in

287   severity of concerns pre and post intervention.

288

289   Univariate regressions of EQ-5D scores on age group, gender, cancer type, cancer stage,

290   palliative care, deprivation level, number of concerns reported, follow-up time, and mean

291   change in concerns between assessments can be found in Table 4. Variables that were

292   statistically significantly (p < .05) associated with EQ-5D scores were entered into multiple

293   regression models (Table 5). The variables used were: time elapsed between EQ-5D

294   assessments, mean change in concerns between assessments, and palliative care, with the

295   EQ-5D utility score model also using number of concerns as predictor. Utility score

296   differences were only significantly different between 25-49 years, and 75 years and over, so

297   Age was not included in the multiple regression.

298

Variable	N	Utility score			VAS		
		Beta	95% CI	p-value	Beta	95% CI	p-value
Age	330						
25 to 49 years		—	—		—	—	
50 to 64 years		-0.11	-0.22, 0.01	0.068	-4.7	-12, 2.2	0.2
65 to 74 years		-0.11	-0.22, 0.01	0.067	-5.9	-13, 1.1	0.1
75 years and over		-0.15	-0.28, -0.03	**0.019**	-5.7	-13, 2.0	0.15
Sex	325						
Female		—	—		—	—	
Male		0.01	-0.05, 0.08	0.7	0.33	-3.6, 4.2	0.9
Cancer type	331						
Bowel		—	—		—	—	

	N						
Breast		0	-0.13, 0.12	>0.9	-0.99	-8.7, 6.8	0.8
Lung		-0.02	-0.15, 0.11	0.7	-3.5	-11, 4.2	0.4
Other		0.03	-0.08, 0.15	0.6	0.07	-7.1, 7.3	>0.9
Prostate		0.08	-0.07, 0.23	0.3	1.6	-7.7, 11	0.7
Cancer stage at baseline	273						
Living with condition		—	—		—	—	
Receiving palliative care		-0.08	-0.21, 0.06	0.3	-3.3	-11, 4.9	0.4
Recently completed treatment (within 1 month)		0.04	-0.12, 0.19	0.7	1.3	-8.2, 11	0.8
Recently diagnosed (1 month)		0.08	-0.04, 0.20	0.2	-0.32	-7.7, 7.0	>0.9
Undergoing tests		0.21	0.05, 0.36	**0.008**	0.76	-8.5, 10	0.9
Undergoing treatment		0.06	-0.04, 0.15	0.2	3	-2.6, 8.5	0.3
Cancer stage at follow-up	322						
Living with condition		—	—		—	—	
Receiving palliative care		-0.08	-0.18, 0.01	0.075	-9	-15, -3.5	**0.001**
Recently completed treatment (within 1 month)		-0.03	-0.15, 0.09	0.6	2.2	-4.9, 9.4	0.5
Recently diagnosed (1 month)		-0.13	-0.72, 0.45	0.6	-9.9	-45, 25	0.6
Recurrence		0.45	-0.13, 1.0	0.13	-4.9	-40, 30	0.8
Undergoing tests		0.05	-0.15, 0.25	0.6	-11	-23, 1.2	0.077
Undergoing treatment		-0.01	-0.09, 0.07	0.8	-2.8	-7.5, 2.0	0.3
Palliative care	276						
Yes		—	—		—	—	
No		0.09	0.01, 0.18	**0.029**	6.6	1.7, 12	**0.008**
Deprivation (1=most deprived)	331	0	-0.01, 0.00	0.2	0.06	-0.34, 0.45	0.8
Number of concerns at baseline	331	0.02	0.00, 0.03	**0.025**	0.46	-0.37, 1.3	0.3
Mean change in concern severity at follow-up	331	-0.03	-0.04, -0.02	**<0.001**	-1.2	-1.9, -0.39	**0.003**
Follow-up time (30 day increments)	331	0.02	0.01, 0.03	**0.003**	1.2	0.56, 1.9	**<0.001**

Table 4. Univariate regressions of patient characteristics and outcomes on EQ-5D scores; p-values significant at α<.05 shown in bold. Follow-up time in multiples of 30 day increments was defined as the number of days divided by 30 to approximate number of months.

303 Both the EQ-5D utility score and VAS models were heteroscedastic so White's

304 heteroscedasticity-consistent standard errors were used (HC0, using R 'sandwich' package

305 version 2.5-1) [22][23]. Following assumption testing [19], the omnibus test of the EQ-5D

306 utility score model was significant at $F_{(4,271)} = 13.9$, $p < .001$, adj. $R^2 = .158$, with regression

307 terms *Mean change in concern severity between assessments* significant at $p < .001$,

308 *Palliative care* significant at $p < .01$, and *Number of concerns* significant at $p < .05$. *Time*

309 *elapsed between assessments* was not a significant predictor. The omnibus test of the VAS

310 score model was significant at $F_{(3,272)} = 8.6$, $p < .001$, adj. $R^2 = .076$, with regression terms

311 *Time elapsed between assessments*, *Mean change in concern severity between assessments*

312 significant at $p<.001$, and *Palliative care* statistically significant at $p < .0001$. Regression

313 coefficients, robust standard errors and confidence intervals for both models can be found in

314 Table 5.

315

316 HNA average score decreased, indicating a reduction in severity of concerns (figure 3). The

317 mean concern severity was 6.47 [6.23-6.71] at baseline, dropping to 2.90 [2.66-3.13] post

318 intervention. Only three individuals (<1%) showed increase in severity of concern post

319 intervention. Mean concern severity was independent of the number of concerns

320 (Spearman's $\rho=.076$, $p=.17$). In the EQ-5D utility score change model, the strongest predictor

321 was *Mean concern change* ($\beta=-0.34$), meaning that a one standard deviation (1SD) decrease

322 in concern severity at follow-up corresponded to a 0.34SD increase in utility score. Next

323 strongest predictor was *Palliative care*, which contributed -0.408SD to the EQ-5D utility

324 score change. Finally, when the *number of concerns* increased by 1SD, the utility score

325 increased by 0.13SD. The time elapsed between EQ-5D assessments was not a significant

326 predictor in the model.

327

In the VAS model, the strongest predictor was *Palliative care*, which contributed

approximately -8 points on the VAS scale, followed by *Mean concern change*, where a 1SD

decrease in concerns corresponded to a 0.17SD increase in VAS. *Time elapsed between*

assessments was a significant predictor of VAS change in the model, corresponding to a

0.16SD increase in VAS in a 1SD time increase.

Predictors	EQ5D-3L Utility value change					EQ5D VAS change				
	Estimates	std. Beta	CI	standardized CI	p	Estimates	std. Beta	CI	standardized CI	p
Intercept	-0.109		-0.195 – -0.022		**0.014**	0.459		-3.370 – 4.287		0.814
Time elapsed (30 day increment)	0.012	0.102	-0.007 – 0.030	-0.011 – 0.216	0.207	1.076	0.157	0.122 – 2.030	0.040 – 0.274	**0.027**
Mean concern change	-0.04	-0.343	-0.055 – -0.024	-0.456 – -0.230	**<0.001**	-1.132	-0.166	-2.155 – -0.109	-0.284 – -0.048	**0.03**
Number of concerns at baseline	0.016	0.129	0.001 – 0.032	0.014 – 0.244	**0.036**					
Palliative care	-0.12	-0.408	-0.206 – -0.033	-0.283 – -0.052	**0.007**	-8.636	-0.501	-14.178 – -3.095	-0.322 – -0.090	**0.002**
Observations	276					276				
R² / R² adjusted	0.170 / 0.158					0.087 / 0.077				

Table 5. *Linear multiple regression with White's heteroscedasticity-consistent standard errors for Utility score change and VAS change at follow-up; p-values significant at α<.05 shown in bold*

338

Discussion

This study has described a significant association between change in HNA score and self-reported health status. Following intervention from ICJ, mean HNA concern severity reduced from 6.4 [6.23-6.71] to 2.9 [2.66-3.13], consistent with the decrease seen in the wider ICJ population [9]. Concurrently, EQ-5D score increased from 0.45 [0.422-0.488] to 0.57 [0.547-0.604], while VAS scores increased from 49 [47.1-51.1] to 57 [54.9-58.9]. This EQ-5D utility score difference of 0.12 [0.0891-0.153] and VAS difference of 7.81 [5.88-9.74] are considered to be above the 'minimally important clinical difference' (MICD) in EQ-5D scores described by Coretti et al., [20], and Pickard et al [24]. In other words, this level of improvement has been described as an important and meaningful improvement for patients [25]. This is also consistent with qualitative evidence [10] on the perceived benefits of using ICJ.

To further contextualise the scores in this study, supplementary file 2 presents mean baseline and post intervention EQ-5D utility scores from participants in this study, according to cancer type. The same table also contains a reference range of the highest and lowest mean EQ-5D utility scores for the same cancer types, obtained from international studies specifically designed to ascertain EQ-5D population norms. These values show that the ICJ cohort recorded some of the lowest quality of life scores published in the cancer literature. The intervention is therefore not just clinically meaningful but also successfully reaching the population that requires it the most.

360

361 Overall, the models explained a moderate to small amount of variance (approximately 16%

362 for utility scores, and 8% for VAS). The strongest predictor was 'mean concern change'. Over

363 the same period of time that the EQ-5D scores increased, the HNA mean level of concern

364 severity decreased. Receiving palliative care and the number of concerns were also

365 significant predictors, along with time between assessments on the VAS scores, but not the

366 index scores. However, a proportion of the improvement remains unexplained. There is a

367 missing explanatory variable, consistent with the interpretation that the *process of ICJ* is also

368 contributing to the change in health status. For example, identifying a larger number of

369 concerns at baseline was associated with increased health status at follow up. This also

370 points to the process of ICJ being a determinant of improvement: identifying more concerns

371 leads to more engagement with the services on offer, resulting in better outcomes.

372 However, this remains unknown at present because there is no measure of impact of specific

373 services. This hypothesis will be explored in future research by recording attendance and

374 satisfaction ratings of all the services provided and signposted by ICJ.

375

376 Previous research investigating the association between needs assessment and improved

377 outcomes has predominantly focused on measuring impact through a range of measurable

378 outcomes such as distress, anxiety, depression and pain using specific tools such as the

379 Distress Thermometer (DT) [26–28]. Qualitative evidence on the use of HNA has shown that

380 it can improve communication between patients and clinicians, providing an opportunity to

381 discuss non-clinical concerns and signpost patients to a variety of different services [29, 30].

382 However, assessment alone does not always lead to improved outcomes. Sandsund et al.,

383 [29] did not find a statistically significant difference in quality of life after using the HNA in

384 124 women diagnosed with gynaecological cancer. Hollingworth et al. [31] found no

385 evidence of an effect on distress or quality of life, and concluded that the timing of the

386 assessment and the profession of the assessor can impact on outcomes.

387

388 The HNA assessor in ICJ was a *non-clinical* expert. Link officers come to this role with

389 backgrounds in financial inclusion and city council processes, and then undertake a three-

390 month training programme to become specialists. They are therefore equipped with a range

391 of skills and knowledge to help navigate people affected by cancer through the complex

392 systems within health but especially through social care and the third sector. In other studies

393 only limited training was provided to the assessors [7]. This is likely to impact on the quality

394 of the HNA interaction and the knowledge and confidence required to make referrals across

395 different services and sectors. Further, it is rational to suggest that people tailor responses

396 to what they perceive to be the expertise of the person conducting the consultation [32].

397 Accordingly, in this study participants commonly identified non-clinical concerns such as

398 finances and worry/anxiety. These concerns have been identified as being a substantial

399 burden with individuals much more likely to rate their physical health, mental health, and

400 satisfaction with social activities and relationships as poor compared to those with no

401 financial hardship [33]. For that reason, relieving financial burden is likely to have had a

402 substantially positive impact on other areas of concern, which may also add to the

403 interpretation of the findings in this study.

404

405 Identifying and assessing individual concerns [34–36] is unarguably beneficial as it can help,

406 amongst other things, with resource allocation. However, to our knowledge, this is the first

407 study to quantify what this means to individuals' health related quality of life. This is

408 important because while quality of life has multiple determinants this study has reported

409   that it is possible to capture a meaningful improvement in quality of life as a function of

410   reducing someone's personally identified concerns.

411

412

413

414   *Strengths and limitations*

415   The current study has several strengths. This is the first examination of health status over

416   time in a large and heterogeneous sample of cancer patients who have all been supported

417   through the HNA process. The primary limitation is that the sample was not random, and the

418   time between EQ-5D assessments was not standardized. Some degree of improvement over

419   time was anticipated. The way ICJ functions is that assessments are followed by referrals and

420   then followed by further ICJ contact. Therefore, over this time period it is likely that

421   individuals may, for example, finish their treatment and report a higher health status.

422   However, the time elapsed between assessments was only a significant predictor of

423   improvement in VAS but *not* utility scores. Nevertheless, as stated, most of the improvement

424   was unexplained. While a broad array of variables were considered for the model we

425   acknowledge that other variables may have influenced the findings. For example,

426   information on comorbidities and more detailed information on participant's use of other

427   services and interactions with other professionals would have been beneficial. Future

428   research should identify a broader array of variables including sociodemographic,

429   interpersonal (patient and assessor interaction) and clinical to explore the relationship

430   between needs assessment and health related outcomes.

431

432

Conclusion

The primary aim of this research was to document any changes in self-reported health status

following intervention from a cancer service. Health status significantly increased following

intervention from ICJ. This is noteworthy because at a time where the cancer workforce is

stretched and patient numbers are increasing there is an urgent need to rethink how to use

resources efficiently without negatively impacting on patient care. The fact that the

assessors in this study were non-health based could well be a model to follow – primarily

due to their expertise and the types of concerns they tended to elicit and manage. This

sample had complex needs with a large proportion residing in areas of high deprivation, with

a poor cancer prognosis and with baseline levels of health status that were considerably

lower than other cancer populations. That they can be helped in a clinically meaningful way

bodes well for those needing similarly targeted support in the future. These results

encourage wide application of HNA and supportive care planning combined with approaches

like ICJ that tailor support based on need.

Abbreviations

Holistic Needs Assessment (HNA)

Improving the Cancer Journey (ICJ)

EQ-5D (EuroQol 5 Dimension)

VAS (Visual Analogue Scale)

Declarations

Ethics approval and consent to participate

455 The study was reviewed and approved by the West of Scotland Research Ethics Committee

456 (WS/15/0166) and Edinburgh Napier University School of Health and Social Care Ethics

457 Committee.

458 *Consent for publication*

459 Informed consent was obtained from all participants

460 *Availability of data and materials*

461 The datasets used and/or analysed during the current study are available from the

462 corresponding author on reasonable request.

463 *Competing interests*

464 The authors declare that they have no competing interests

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466 This study is funded by Macmillan Cancer Support, UK. The funders had no role in the

467 conception of the study design. They provided comment on data collection, analysis and

468 interpretation.

469 *Authors contributions*

470 AS conceived the study design, wrote the manuscript and oversees all aspects of the study.

471 JY conceived the study design, wrote the manuscript and contributed to the analysis. JS

472 wrote the manuscript and carried out data analysis. All authors have read and approved the

473 manuscript.

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