Prioritisation of treatment goals among older patients with non-curable cancer: the OPTion randomised controlled trial in Dutch primary care

Abstract

Background
Older patients with cancer often find it difficult to take part in shared decision making.

Aim
To assess the utility of the Outcome Prioritisation Tool (OPT), designed to aid discussion with a patient in regards to their treatment goals, to empower patients with cancer through structured conversations about generic treatment goals with GPs.

Design and setting
A randomised controlled trial of 114 Dutch participants recruited between November 2015 and January 2019, aged ≥60 years with non-curable cancer who had to make a treatment decision with an oncologist. The intervention group used the OPT while the control group received care as usual.

Method
The primary outcome was patient empowerment using the score on the decision self-efficacy (DSE) scale. Secondary outcomes were symptoms measures of fatigue, anxiety, and depression. The experiences of participants were also explored.

Results
No effect was found on patient empowerment between the OPT group (n = 48; DSE 86.8, standard deviation [SD] = 18.2) and the control group (n = 58; DSE 84.2, SD = 17.6; P = 0.47). In the OPT group, although statistically non-significant, fewer patients had low empowerment (18.8%, n = 9 versus 24.1%, n = 14; P = 0.50), but they did have statistically significant lower mean anxiety scores (6.0, SD = 4.4 versus 7.6, SD = 4.4; P = 0.03) and less mild fatigue (58.8%, n = 30 versus 77.2%, n = 44; P = 0.03). Overall, 44.8% (n = 13) of patients indicated that the OPT-facilitated conversations on patient treatment goals facilitated conversation helped them make a treatment decision, and 31.1% (n = 14) of the GPs reported that they gained new insights from the conversation.

Conclusion
An OPT-facilitated conversation about generic treatment goals between patients and their GPs is associated with less anxiety and fatigue, but did not show statistically significant improvements in patient empowerment. Adding the OPT to routine care might ensure more patient-tailored care.

Keywords
aged; decision making; general practice; neoplasms; palliative care; primary health care.

INTRODUCTION

Of the estimated 3.9 million new cases of cancer in Europe in 2018, about 75% were in patients aged ≥60 years. Treatment decisions for such older patients often involve a complex trade-off between risks and benefits. This reflects their limited life expectancy, increased frailty, and greater number of comorbidities, which increase the risk of complications and functional decline after treatment.

Tailored decisions require that a patient’s preferences and goals should be taken into account. Though most patients with cancer consider shared decision making to be important, older patients often find this approach difficult. A perceived barrier is that the expert position of the oncologist leads to a power imbalance in the doctor–patient relationship. This can lead to feelings of low empowerment in the patient, which makes it difficult for doctors to estimate the health goals of a given patient. Consequently, personal preferences may not always be taken into account. Several decision aids have been developed to rectify this problem, with most being designed to clarify the risks and benefits of specific diseases and their associated treatments. The non-specific Outcome Prioritisation Tool (OPT) has been validated for discussing generic treatment goals, such as extending life [Figure 1].

Traditionally, cancer management is provided by oncologists and in the Netherlands most patients also visit their GP during diagnosis and treatment. In countries where the GP functions as a gatekeeper to secondary care, older patients often have a long-term relationship with their GP and consider them a trusted healthcare adviser. This makes the GP well placed to support patients in exploring generic treatment goals and in empowering them for shared decision making with an oncologist.

The authors designed an intervention in which GPs used the OPT to facilitate a conversation with older patients in the period between a diagnosis of non-curable cancer and treatment decisions, focusing on identifying the patients’ generic treatment goals. The primary aim of this study was to analyse the effects of these OPT-facilitated conversations on patient empowerment.

METHOD

This randomised controlled trial was registered in the Dutch trial register (ref: NTR5419), and the study design is published in detail elsewhere.
Participants were recruited from nine locations in six hospitals (one academic) between November 2015 and January 2019. Patients were eligible if they were aged ≥ 60 years, had cancer that had no curative treatment options, and had to make a treatment decision with an oncologist. Patients were excluded if they had a life expectancy of < 3 months or were unable to complete the questionnaires. Patients with haematological cancers were also excluded because they are known to have a different disease course.18

After providing informed consent, patients were randomised to an intervention group (OPT-facilitated conversation) or control group (care as usual) on a one-to-one basis, stratified by hospital. Allocation was determined by a web-based application (ALEA) that used random permuted blocks with randomly varying block sizes.

Intervention
The intervention consisted of a conversation with the GP during which treatment goals were explored with the aid of the OPT.11,12 The OPT is a decision aid with four visual analogue scales, each representing a generic treatment goal: extending life, maintaining independence, reducing pain, and reducing other symptoms (Figure 1). The tool was developed in the US and designed to discuss, with patients, which (treatment) goal was most important to them.11,12 GPs were contacted via telephone by the research team. After their consent, the OPT was sent to them with a short user manual that also contained a hyperlink with a video example of an OPT-facilitated conversation. GPs invited patients to value and rank the different goals according to the trade-off principle that the goals cannot be equally important. Patients received no instructions about what to tell their oncologist. The control group received care as usual and could consult their GP at their own discretion. Blinding was not possible owing to the nature of the intervention. Immediately after their follow-up consultations with oncologists, during which the treatment decision was made, patients from both groups completed questionnaires (Figure 2). Oncologists did not receive any training as they played no role in the intervention.

Outcomes
Patient-reported age, sex, education level, and social network data were recorded. Data on the tumour type, performance score (Eastern Cooperative Oncology Group classification19), and comorbidities (Charlson score20) were extracted from hospital records.

The primary outcome was patient empowerment, as measured by the decision self-efficacy (DSE) scale. The DSE scale comprises 11 items that are scored 0-4.21 The scores were transformed to a
scale ranging from 0 (no self-efficacy) to 100 (high self-efficacy). No cut-off value is described in the literature, but a score of <75 was defined as low empowerment and <50 defined as very low empowerment, based on consensus in the research group.

Secondary outcomes focused on symptoms of fatigue, anxiety, and depression. These outcomes were chosen based on their high prevalence in patients with cancer and their major impact on their lives. It has also been suggested that these outcomes are associated with patient empowerment. Fatigue was measured using the multidimensional fatigue inventory (MFI-20), which ranges from 0 to 80. Based on earlier research in older populations, the authors defined cut-off scores of 58 and 73 to represent mild and severe fatigue, respectively. Symptoms of anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS-A and HADS-D). These subscales each include seven questions, resulting in a total score that ranges from 0 to 21. Subscale cut-off scores of ≥8 and ≥11 represent mild and severe symptoms, respectively. Finally, the experiences of patients and GPs with the OPT were explored using questions based on former evaluations of this instrument.

**Sample size**

The authors aimed to include 80 patients in each group based on a difference of at least four points on the DSE (effect size or Cohen’s $d = 0.44$), two-sided testing, an $\alpha$ of 0.05, and a $\beta$ of 0.20 ($P = 0.80$). A low rate of loss to follow up was expected because comparison between groups was performed immediately after consultations. Therefore, the authors aimed to include 84 patients per group to allow for a 5% loss.

**Statistical methods**

All data were entered in a secured digital data management system, pseudonymised, and extracted to IBM SPSS Statistics (version 25) and STATA/SE (version 15). Descriptive statistics were used to describe the participants and to compare groups at baseline. The effects of the intervention on the DSE, MFI-20, and HADS scores were tested by linear regression for continuous measures, and by logistic regression for dichotomous measures. Odds ratios (ORs) and 95% confidence intervals (CIs) are reported. If scores showed a ceiling effect with censoring from above, that is ≥100, a Tobit model was used. In all models, adjustments were made where necessary for baseline differences between the groups. A $P$-value ≤0.05 was considered statistically significant for all analyses. Finally, the experiences of GPs and patients were reported descriptively.

**RESULTS**

**Participants**

During the study period, the contact details of 268 patients were sent to the research team by oncologists and were screened for eligibility. Of these, 223 were eligible and 145 (54%) agreed to participate. Finally, 53 and 61 patients completed the assessment in the OPT and control groups, respectively (Figure 3). The mean age of participants was 74.0 years (standard deviation [SD] = 6.4 years), 70.2% ($n = 80$) were male, and 71.9% ($n = 82$) had lung cancer (Table 1). In the intervention group, both the OPT scores and/or a GP evaluation were available for 47 patients (88.7%). There were no apparent differences in the baseline characteristics between groups (Table 1).

**Patient empowerment**

Continuous scores. For both groups, high DSE scores were observed (ceiling effect). Correcting for this, the adjusted mean scores were 86.8 (SD = 18.2) for the OPT
Dichotomised scores. Between the two groups, 18.8% of patients in the OPT group had low empowerment compared with 24.1% in the control group, but the difference was not statistically significant (OR 0.73; 95% CI = 0.28 to 1.86; P = 0.50). Two patients scored very low empowerment in the control group and no patients scored very low empowerment in the OPT group.

Symptoms of fatigue, anxiety, and depression
Continuous scores. The mean fatigue scores were 62.9 (SD = 21.2) in the OPT group and 67.1 (SD = 18.6) in the control group (95% CI = –11.28 to 3.8; P = 0.33). The mean anxiety score was 6.0 (SD = 4.6) in the OPT group and 7.6 (SD = 4.4) in the control group, a statistically significant difference of –1.67 (95% CI = –3.33 to –0.01; P < 0.05). The mean depression score was 5.9 (SD = 4.8) in the OPT group and 6.4 (SD = 4.1) in the control group (95% CI = –2.02 to 1.28; P = 0.66).

Dichotomised scores. The proportion of patients with mild fatigue was statistically significantly lower in the OPT group than in the control group (58.8%; n = 30 versus 77.2%; n = 44; P = 0.05), while this was not the case for the proportion of patients with severe fatigue (33.3%; n = 17 versus 40.4%; n = 23; P = 0.32). Fewer patients in the OPT group had either mild anxiety (30.6%; n = 15 versus 40.7%; n = 24; P = 0.28) or severe anxiety (12.2%; n = 6 versus 20.3%; n = 12; P = 0.55). In the OPT group, there were fewer patients with mild depression (28.6%; n = 14 versus 37.3%; n = 22; P = 0.34) or severe depression (16.3%; n = 8 versus 18.6%; n = 11; P = 0.75) (see Table 2).

Patients’ goals and experiences of GPs and patients
Of the 38 patients who noted their favoured goal, most rated either maintaining

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Table 1. Baseline characteristics of the OPT and the control group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>OPT, N=53</th>
<th>Control, N=61</th>
<th>Total, N=114</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>75.3 (6.8)</td>
<td>72.9 (5.9)</td>
<td>74.0 (6.4)</td>
</tr>
<tr>
<td>Sex, male</td>
<td>38 (71.7)</td>
<td>42 (66.9)</td>
<td>80 (70.2)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school/GCSE</td>
<td>29 (56.9)</td>
<td>40 (69.0)</td>
<td>69 (63.3)</td>
</tr>
<tr>
<td>A-levels</td>
<td>16 (31.4)</td>
<td>10 (17.2)</td>
<td>26 (23.9)</td>
</tr>
<tr>
<td>College/university</td>
<td>6 (11.8)</td>
<td>8 (13.8)</td>
<td>14 (12.8)</td>
</tr>
<tr>
<td>Social support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>0 (0.0)</td>
<td>1 (1.7)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Some</td>
<td>4 (7.8)</td>
<td>4 (6.9)</td>
<td>8 (7.3)</td>
</tr>
<tr>
<td>Much</td>
<td>34 (66.7)</td>
<td>41 (70.7)</td>
<td>75 (68.8)</td>
</tr>
<tr>
<td>Very much</td>
<td>13 (25.5)</td>
<td>12 (20.7)</td>
<td>25 (22.9)</td>
</tr>
<tr>
<td>Localisation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>34 (64.2)</td>
<td>48 (78.7)</td>
<td>82 (71.9)</td>
</tr>
<tr>
<td>Urogenital</td>
<td>8 (15.1)</td>
<td>5 (8.2)</td>
<td>13 (11.4)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>9 (17.0)</td>
<td>5 (8.2)</td>
<td>14 (12.3)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (3.8)</td>
<td>3 (4.9)</td>
<td>5 (4.4)</td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>22 (43.1)</td>
<td>24 (41.4)</td>
<td>46 (41.8)</td>
</tr>
<tr>
<td>Other symptoms</td>
<td>25 (49.0)</td>
<td>24 (41.4)</td>
<td>49 (44.5)</td>
</tr>
<tr>
<td>CCI, mean (SD)</td>
<td>10.3 (14.1)</td>
<td>9.8 (14.4)</td>
<td>10.0 (14.4)</td>
</tr>
<tr>
<td>ECOG performance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>22 (41.5)</td>
<td>29 (47.5)</td>
<td>51 (44.7)</td>
</tr>
<tr>
<td>1</td>
<td>24 (45.3)</td>
<td>24 (39.3)</td>
<td>48 (42.1)</td>
</tr>
<tr>
<td>2</td>
<td>7 (13.2)</td>
<td>8 (13.1)</td>
<td>15 (13.2)</td>
</tr>
</tbody>
</table>

*Unless otherwise stated. a This variable was not complete for all cases: N = 51, 58, and 109, respectively. b CCI, ranging from 0 (healthy) to 37 (all possible comorbidities). c ECOG performance score, ranging from 0 (fit) to 5 (death). d CCI = Charlson Comorbidity Index. ECOG = Eastern Cooperative Oncology Group. GCSE = General Certificate of Secondary Education. OPT = Outcome Prioritisation Tool. SD = standard deviation.
Table 2. Comparison of outcomes between intervention group and control group

<table>
<thead>
<tr>
<th>Continuous outcomes</th>
<th>OPT, N = 53</th>
<th>Control, N = 61</th>
<th>OPT versus control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient empowerment, mean (SD): DSE</td>
<td>86.8 (18.2)</td>
<td>84.2 (17.6)</td>
<td>2.54 (4.46 to 9.54)</td>
</tr>
<tr>
<td>Fatigue: MFI</td>
<td>62.9 (21.2)</td>
<td>67.1 (18.6)</td>
<td>–3.72 (–11.28 to 3.83)</td>
</tr>
<tr>
<td>Anxiety: HADS-A</td>
<td>6.0 (4.6)</td>
<td>7.6 (4.4)</td>
<td>–1.67 (–3.33 to 0.01)</td>
</tr>
<tr>
<td>Depression: HADS-D</td>
<td>5.9 (4.8)</td>
<td>6.4 (4.1)</td>
<td>–0.37 (–2.02 to 1.28)</td>
</tr>
</tbody>
</table>

Table 3. Patients’ goals and GPs’ and patients’ experiences of the OPT-facilitated conversation

<table>
<thead>
<tr>
<th>Goals and experiences</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most important goal, N = 38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extending life</td>
<td>11</td>
<td>28.9</td>
</tr>
<tr>
<td>Maintaining independence</td>
<td>12</td>
<td>31.6</td>
</tr>
<tr>
<td>Reducing pain</td>
<td>8</td>
<td>21.1</td>
</tr>
<tr>
<td>Reducing other symptoms</td>
<td>1</td>
<td>2.6</td>
</tr>
<tr>
<td>Chose ≥2 goals as most important</td>
<td>6</td>
<td>15.8</td>
</tr>
</tbody>
</table>

Patient evaluations, N = 29
- I discussed my OPT score with my oncologist | 14 | 48.2 |
- The OPT conversation: is time-consuming | 2 | 6.9 |
- helped me to prepare for the conversation in the hospital | 8 | 27.6 |
- helped me to make a treatment decision | 13 | 44.8 |
- helped me to improve the relationship with my GP | 15 | 51.7 |
- made me contemplate | 9 | 31.0 |
- I would recommend the OPT conversation to others | 18 | 62.1 |

GP evaluations, N = 45
- I was able to explain: extending life | 42 | 93.3 |
- maintaining independence | 40 | 88.9 |
- reducing pain | 43 | 95.6 |
- reducing other symptoms | 36 | 80.0 |
- I was able to explain the concept of prioritising | 32 | 71.1 |
- The patient could easily prioritise the goals | 29 | 64.4 |
- I gained new insights | 14 | 31.1 |

OPT = Outcome Prioritisation Tool.
Funding
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Ethical approval
The trial was assessed by the Medical Ethics Committee of the University Medical Centre Groningen [ref: 2015/275].

Provenance
Freely submitted; externally peer reviewed.

Competing interests
The authors have declared no competing interests.

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difficult to include in studies, making these data informative and useful in an otherwise scarce research landscape.

The main limitation of the present study was the failure to meet the pre-specified sample size requirements; including older patients with non-curable cancer appeared to be difficult for various reasons. Oncologists did not ask all eligible patients whether they could be contacted by the researchers because they forgot or because they thought it too difficult to combine delivering ‘bad news’ with a request to participate in a study. The interval between diagnosis and treatment decision was often surprisingly short [1–2 days]. Sometimes the decision had already been made when the researchers contacted the patient or the interval was too short a time for the intervention to take place. The short interval appears to be a frequently encountered phenomenon, which is exemplified by the current discussion in the Netherlands that patients should be given multiple treatment options and a ‘time-out’ interval to allow non-rushed decision making. Further, dropout rates were higher than expected. Despite requiring that patients should have a life expectancy of >3 months, many patients died or became too ill before they could complete questionnaires. Various methods were employed, such as weekly personal contact between researchers and oncologists, to improve accrual and the changing of the original inclusion criterion from age ≥70 years to ≥60 years.

Finally, it is important to realise that the effects of an OPT-facilitated conversation can be partly determined by other topics of a conversation with the GP, such as attention to symptoms, and words of reassurance and support. Though the authors have no information about the conversations in the usual care group, earlier research showed that many patients have contact with their doctor immediately after a cancer diagnosis.13

Comparison with existing literature
Other studies using the same questionnaire have described comparably high mean scores, indicating that patients might generally be confident in their ability to participate in shared decision making. It may also be that the outcome measure is not robust enough. Finding robust outcome measures has proven to be a problem in research on improving health care.65

Any healthcare provider can use the OPT, but the authors deliberately chose the GP because of their often longstanding relationship with older patients. Interestingly, one-third of the GPs reported that they still gained new insights about the treatment goals of their patients during the conversations, consistent with earlier research showing that healthcare providers often incorrectly assume their patients’ priorities.6 GPs also reported that the OPT helped them to start a conversation about advance care planning. This is particularly important because research indicates that most patients would not only like to talk with their GP about this topic but also that they would like GPs to take the initiative.61

It has been argued that GPs lack the expertise to discuss different treatment options and could increase confusion and anxiety.66 However, treatment options are irrelevant to the OPT-facilitated conversation, which only considers the generic goals of patients. Moreover, in the present study sample, the OPT-facilitated conversation was associated with statistically significant lower anxiety compared with care as usual.

Implications for research and practice
In conclusion, the results presented here indicate that an OPT-facilitated conversation with a GP about generic treatment goals may lead to less anxiety and fatigue. This conversation might affect empowerment for subgroups of patients with low baseline empowerment scores, yet the present results remain inconclusive. Further research is needed into the effect of these conversations, but in view of the positive evaluations, healthcare providers might consider adding the OPT to facilitate conversations that seek to improve patient-tailored care.
REFERENCES


