

## Advance care planning-family carer psychological distress and involvement in decision making

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# The effect of advance care planning on the family carers' involvement in decision-making, and their psychological distress: results of the ACTION trial

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## Abstract

**Context.** Facilitated advance care planning (ACP) helps family carers' to be aware of patient preferences. It can improve family carers' involvement in decision-making and their overall experiences at the end-of-life, as well as, reduce psychological stress.

**Objectives.** To investigate the effects of the ACTION Respecting Choices (RC) ACP intervention on the family carers' involvement in decision-making in the last three months of the patients' life and on the family carers' psychological distress after three months of bereavement.

**Methods.** Over six European countries a sample of 162 bereaved family carers returned a bereavement questionnaire. Involvement in decision-making was measured with a single item of the VOICES-SF questionnaire. Psychological distress was measured with the impact of event scale (IES).

**Results.** No significant effect was found on family carers involvement in decision-making in the last 3 months of the patients' life (95%-CI=0.449–4.097). However, the probability of involvement in decision-making was slightly higher in the intervention arm of the study (89.6% vs 86.7%; OR=1.357). Overall, no statistical difference was found between intervention and control group regarding the IES (M = 34.1 (1.7) vs. 31.8 (1.5); (95%CI = -2.2–6.8)).

**Conclusion.** The ACTION RC ACP intervention showed no significant effect on family carers' involvement in decision-making or on subsequent psychological distress. More research is needed about 1) how family carers can be actively involved in ACP-conversations, and 2) how to prepare family carers on their role in decision-making.

**Key words:** Advance Care Planning, randomized controlled trial, family carers, involvement in decision-making, psychological distress, advanced cancer

### **What was already known:**

- Family carers' have a prominent role in decision-making
- Facilitated ACP improves the family carers' well-being

### **What are the new findings:**

- No significant effect in family carers' involvement in decision-making
- No significant effect on family carers' level of psychological distress

### **What is the significance:**

#### **Clinical**

- Family carers need to be more empowered and prepared for their role as SDM during ACP

- A whole system-approach is necessary for successful implementation of ACP

**Research**

- Future research should focus on developing a family-focused ACP-model in addition to the current patient-centred ACP models.
- Future ACP research should focus on a consistent way of measuring psychological distress for family carers

# 1 Introduction

2 Cancer is a common life-limiting disease, with about 4 million new diagnoses and 2 million deaths  
3 annually in the European Union<sup>1</sup>. Timely and efficient communication is necessary between  
4 clinicians, patients and their family carers, about future care, including care at the end-of-life in  
5 patients living with cancer <sup>2</sup>. One approach to facilitate this is advance care planning (ACP) which  
6 'enables individuals to define goals and preferences for future medical treatment and care, to  
7 discuss these goals and preferences with family and health care professionals, and to record and  
8 review these preferences if appropriate'<sup>3</sup>. In addition to promoting communication, ACP  
9 facilitates shared decision-making and, above all, aligns end-of-life care with patients'  
10 preferences<sup>4</sup>. This includes the assignment of a surrogate decision-maker (SDM), if the patient  
11 loses decisional capacity<sup>5</sup>. Family carers have a prominent role in the process of decision-making  
12 at the end of life, but making these decisions without knowledge about the patients' preferences  
13 can be extremely stressful<sup>6</sup>. Studies in Australia and the US have found that facilitated ACP  
14 improved the family carer's well-being, satisfaction with hospital care<sup>7</sup> and confidence in making  
15 decisions<sup>8</sup>.

16  
17 The ACTION-study was the first and largest European phase III multicenter cluster randomized  
18 controlled trial, to test the efficacy of an ACP intervention in patients with advanced lung or  
19 colorectal cancer. A systematic review showed that the Respecting Choices (RC) program was one  
20 of the most promising ACP-programs with the best evidence for beneficial effects of ACP<sup>4</sup>. The RC  
21 was developed in the US and successfully trialled in a geriatric setting in Australia<sup>7,9</sup>. In the  
22 ACTION trial, the ACP intervention (ACTION Respecting Choices (RC) ACP intervention), was an  
23 adapted and integrated version of RC program, and consisted of a trained facilitator, using  
24 scripted conversation guides, to assist the person with cancer and their family carer to discuss  
25 goals, values, beliefs and preferences regarding their future treatment and care<sup>9</sup>. However, the  
26 ACTION trial found no significant effects on patients' quality of life, symptoms, satisfaction with  
27 care, coping or shared decision-making<sup>10</sup>. In this paper we report on the secondary outcomes of  
28 the ACTION-study regarding the effect of the ACTION RC ACP intervention on family carer's  
29 involvement in decision-making in the last three months of patients' life, and psychological  
30 distress after three months of bereavement.

## 31 Methods

### 32 Study design

33 We analysed data of the bereavement questionnaire from the ACTION-study which was a  
34 multicentre cluster-randomised controlled trial in six European countries (Belgium, Denmark,  
35 Italy, the Netherlands, Slovenia and the United Kingdom). Detailed information about the  
36 intervention and the trial procedures can be found in the protocol paper<sup>9</sup> or in appendix 1.

37

### 38 Setting and participants

39 In total, 1117 persons with advanced lung or colorectal cancer participated in the ACTION study.  
40 The specific inclusion criteria for patients are described in the protocol paper<sup>9</sup>. The inclusion  
41 criteria for bereaved family carers' were: being older than 18 years, being able to complete the  
42 bereavement questionnaire in the language of each country and not taking part in another study  
43 that is evaluating palliative care services or communication interventions. A bereavement  
44 questionnaire was sent with a cover letter, information sheet and prepaid envelope. A reminder  
45 was sent when the questionnaire was not returned after two weeks. Return and completion of the  
46 questionnaire were considered to indicate that family carers had consented to participate in the  
47 study.

### 48 Outcome measures

49 The main purpose of the bereavement questionnaire was to obtain more information about the  
50 last months and weeks of the patients' life as perceived by a bereaved family carer who lost the  
51 patient during the one year of inclusion in the study. Involvement in decision-making was  
52 measured with a single item of the Views of Informal Carers – Evaluation of Services Short Form  
53 (VOICES-SF) questionnaire, which is a 58-item validated questionnaire about health and social  
54 services completed by bereaved family carers. The item used was: "Looking back over the last  
55 three months of his/her life, were you involved in decisions about his/her care as much as you  
56 would have wanted?". Possible responses were: 1) I was involved as much as I wanted to be, 2) I  
57 would have liked to be more involved, 3) I would have liked to be less involved, 4) Don't know<sup>11</sup>.  
58 Psychological distress was assessed using the impact of event scale (IES) and asked how  
59 frequently each item was experienced during the past week after 3 months of bereavement. The  
60 IES measures psychological responses to stress on two subscales: (1) intrusion and (2) avoidance  
61 and is mostly used to measure post-traumatic stress syndrome. Each item could be rated with  
62 1) not at all, 2) rarely, 3) sometimes and 4) often<sup>12</sup>. During the ACTION-study no baseline  
63 measurement or other follow-up questionnaire was sent to the family carer.

64 Statistical analysis

65 Multilevel analyses were used to determine the effect of ACP on involvement in decision-making  
66 (via multilevel binary logistic regression) and the effect of ACP on psychological distress among  
67 family carers (via multilevel linear regression).

68

69 Ethics

70 Ethical approval has been obtained from research ethics committees and ethical review boards of  
71 all participating hospitals in all countries. Trial registration: International Standard Randomised  
72 Controlled Trial Number (ISRCTN), 17231

73 **Results**

74 Sample characteristics

75 A total of 390 patients died in the year of inclusion, indicating that 390 bereavement  
76 questionnaires were distributed over six European countries. Only 162 returned: 71 for the  
77 intervention group; 91 for the control group (response rate: 41.5%). For 60 out of 71 patients in  
78 the intervention group (84.5%), the family carer had been present during the ACP-conversations.  
79 The majority of family carers were female (71.0%), had an average age of 60 (SD: 11.87) and were  
80 a partner (70.2%) of the deceased patient. The majority of the deceased patients were  
81 approximately 66 years (SD: 9.55), male (64.2%) and died from lung cancer (62,3%). See  
82 Appendix 2 for table: sample characteristics.

83

84 Family carers' involvement in decision-making and psychological distress

85 The probability that family carers had been involved in medical decision making with the patient  
86 during the last three months of life was slightly higher in the intervention group (89.6%) than in  
87 the control group (86.7%), but not statistically significant (OR 1.357, 95%-CI = 0.449 – 4.097).

88 The intervention group had a slightly higher mean score (M = 34.07; SD = 14.61) on the IES,  
89 meaning a higher level of psychological distress, than the control group (M = 31.77, SD= 14.11).  
90 However, this difference was not statistically significant either (t(157)= 1.005, 95%-CI = -2,224 –  
91 6.836) (see Table 1).

92

93 **Table 1: effect of ACP on involvement in decision-making and effect of ACP on psychological**  
94 **distress (measured with IES)**

---

| involvement in decision-making | Psychological distress (IES) <sup>a</sup> |
|--------------------------------|---|
|--------------------------------|---|

---

|   | OR (CI-95%) for I was involved as much as I wanted to be vs. I would have liked to be more involved | T-test (CI-95%)           |
|---|---|---------------------------|
| <b>Condition (Control vs. Intervention group)<sup>b</sup></b> | 1.357<br>(0.449 – 4.097)  | 1.005<br>(-2,224 – 6.836) |

95 Multilevel binary logistic regression analysis was used to measure the involvement in decision-making. Not  
96 included in the analysis were the responses: I would have liked to be less involved N = 0 (0%) and I don't  
97 know N = 4 (2.5%) and missing values N = 1 (0.6%).

98 Multilevel linear regression analysis was used in order to measure psychological distress, measured with  
99 the IES. <sup>a</sup> Possible range impact of events is 0-75. Missing items were replaced by the mean of the other  
100 items for that family carer.

101 Each item was controlled with family carers' age, gender, relationship towards patient; with patients' age,  
102 gender, having children & religion; with cancer type and WHO-status. Because no significant effect was  
103 found we used the basic regression model with dependent variable 'involvement in decision-making' or  
104 'psychological distress' and independent variable 'condition'

105 <sup>b</sup> Control group is the reference category

106

## 107 Discussion and conclusion

108 The ACTION RC ACP intervention did not significantly affect family carers' involvement in  
109 decision-making in the last 3 months of patients' life, nor their level of psychological distress after  
110 three months of bereavement.

111

112 Several hypotheses can explain these results. The ACTION RC ACP intervention was delivered by  
113 a trained external facilitator. These facilitators had no contact with the patients' health care  
114 professionals and were also not allowed to add information about the ACP-conversation to the  
115 medical file of the patient. Participating patients were encouraged by the facilitators to  
116 communicate their preferences themselves to their health care professionals, but only few  
117 patients reported to have done so<sup>13</sup>. Previous studies have already shown that physicians'  
118 awareness of the patients' end-of-life care preferences did not improve when ACP conversations  
119 were conducted by nurses or other facilitators when these were not integrated into routine  
120 services, and it was suggested that a more interdisciplinary collaboration is needed<sup>14</sup>.  
121 Standardization is necessary in a research context in 6 different EU countries. Because of this, the  
122 ACTION RC ACP intervention was not integrated with routine services, and thus it might have  
123 reduced its effects<sup>10</sup> Probably a whole system-approach is necessary for ACP to be successful,  
124 which means that on an individual level, patients and their family carers are provided with the  
125 opportunity to have timely conversations, facilitated by skilled staff. It also means that on the



126 system or health care service level appropriate policies and systems are in place to ensure that  
127 ACP is offered to patients and their family carers, and that previously discussed wishes and  
128 preferences are available to all involved health care professionals<sup>15</sup>. For future research, we would  
129 recommend exploring all options for broader involvement at the institutional level.

130 Moreover, although ACP needs to be patient-centred<sup>15</sup>, family carers also need to be empowered  
131 and prepared for their role as SDM, which was possibly not sufficiently addressed in the ACTION  
132 RC ACP intervention. Little is known about how family carers should be optimally involved in ACP-  
133 conversations. Future research should focus on developing a family-focused ACP-model in  
134 addition to the current patient-centred ACP models.

135 Lastly, increasing literature is questioning whether ACP has the capacity to address goal-  
136 concordant care<sup>16,17</sup>, which leads to a discussion about what the right outcome measures in ACP  
137 research ought to be<sup>18</sup>. Rather than focusing on making binding decisions early on, ACP should be  
138 seen as a process that facilitates patients, families and professionals to prepare for making better  
139 “in-the-moment” decisions. Consequently, outcomes of ACP should concentrate more on its  
140 process<sup>18</sup>, and thus on the relation domain (e.g. patients and family carers discussing preferences,  
141 values and wishes with each other and preparing them for future conversations with  
142 professionals<sup>17,18</sup>). However, this was not assessed in the ACTION trial<sup>10</sup>. As for the results of this  
143 secondary analysis, other studies in ACP have measured well-being and psychological distress  
144 differently and currently, there is no univocal measurement or conclusion on the appropriateness  
145 of these outcome measures<sup>4</sup>. Future research should focus on a consistent way of measuring well-  
146 being and psychological distress of family carers after ACP. More specifically, qualitative research  
147 could enhance our understanding of the well-being and psychological distress of the family carer  
148 when engaging in ACP, as well as identify other relevant outcomes for patients and family carers.

149

150 This study has several strengths. First, the ACTION study is the first and largest RCT on the effects  
151 of ACP for patients with advanced cancer, and their family carers in Europe. Second, to study the  
152 effect of ACP for bereaved family carers, we sent out a bereavement questionnaire using items  
153 from the VOICES-SF and two validated scales measuring psychological distress, anxiety and  
154 depression symptoms.

155 The study has also some limitations. First, the response rate was modest in each of the 6 countries.  
156 As a result, between-country comparisons were not possible due to the low statistical power.  
157 Possible causes of non-response were that bereaved family carers were not interested in  
158 participating in the study anymore; and/or that the questionnaire was sent to the address of the  
159 deceased person, which was not always the address of the family carer. There was no further  
160 follow-up of the non-responders, which makes it difficult to understand family carers reasons for  
161 not responding. Second, a limited number of characteristics of the bereaved family carers were

162 collected in the ACTION study, therefore we do not know whether the family carer who filled out  
163 the bereavement questionnaire was the appointed SDM of the patient.

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## 167 Conflict of interest

168 The authors declare no conflict of interest

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