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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 Union¹. 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 cancer². 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'³. In addition to promoting communication, ACP
9 facilitates shared decision-making and, above all, aligns end-of-life care with patients'
10 preferences⁴. This includes the assignment of a surrogate decision-maker (SDM), if the patient
11 loses decisional capacity⁵. 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 stressful⁶. Studies in Australia and the US have found that facilitated ACP
14 improved the family carer's well-being, satisfaction with hospital care⁷ and confidence in making
15 decisions⁸.

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 ACP⁴. The RC
21 was developed in the US and successfully trialled in a geriatric setting in Australia^{7,9}. 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 care⁹. However, the
26 ACTION trial found no significant effects on patients' quality of life, symptoms, satisfaction with
27 care, coping or shared decision-making¹⁰. 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 paper⁹ 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 paper⁹. 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 know¹¹.
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) often¹². 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) ^a
--------------------------------	---

	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%)
Condition (Control vs. Intervention group)^b	1.357 (0.449 – 4.097)	1.005 (-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. ^a 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 ^b 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 so¹³. 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 needed¹⁴.
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 effects¹⁰ 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 professionals¹⁵. 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-centred¹⁵, 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^{16,17}, which leads to a discussion about what the right outcome measures in ACP
137 research ought to be¹⁸. 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 process¹⁸, 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^{17,18}). However, this was not assessed in the ACTION trial¹⁰. 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 measures⁴. 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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