Author’s response to reviews

Title: PREDOMOS study. Impact of a social intervention program for socially isolated elderly cancer patients: study protocol for a randomized controlled trial.

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Author’s response to reviews:

Thank you for your review and interesting points, here are precisions we hope will answer your concerns:

1) Given the elderly cancer population it would seem pertinent to use the QLQ-ELD14 as a primary outcome, however this does not seem to be your preferred choice. In the methods there is a suggestion that it is a secondary outcome in the discussion how it will be used is less clear. This could be clarified further.

This is a very good point and QLQ-ELD14 additional module will probably be more sensitive and provide a more significant difference between the two groups. We yet decided to choose the QLQ-C30 as principal endpoint as it is more common in literature for various cancer pathologies (Fiteni, Anota, Westeel, & Bonnetain, 2016; Hao, Wolfram, & Cook, 2016; Jiménez-Fonseca et al., 2015; Roussel et al., 2017; Tarricone, Ricca, Nyanzi-Wakholi, & Medina-Lara, 2016), even in elderly patients (Durá-Ferrandis et al., 2017; Quinten et al., 2015). The QLQ-ELD14 module validation was only in 2013 (Wheelwright et al., 2013) and few studies used it as primary endpoint (Kaufmann et al., 2015; Wrazen et al., 2014). All the more, the normal values provided by the EORTC-QLQ-c30 allowed us to state robust hypothesis for the number of subjects’ calculations.

2) The intervention includes monthly telephone contact from a social worker. Given the age and health status of the population might the use of telephone, rather than face-to-face, lead to missing contacts/follow-up? Might there the option for alternative forms of contact in the event that telephone is unsuccessful?

We added details on the follow up in the protocol to answer this particular concern page 5:

“To avoid follow up missing, the social worker will be provided with the contact informations of every supporting staff caring for the patient (i.e.: nurse, home help, general practitioner…). Furthermore, homes of patient benefiting from social follow up, are connected with remote assistance 24/7; the device isn’t only for the patient to call for help but can remotely be activated to contact him in case of prolonged inactivity of the sensors. Finally, the protocol states the possibility for the social worker to make home visits if necessary”

3) It would be nice to see a rational for the assumption that 20% of patients would be lost to follow-up. This assumption was used in the power calculations.
The assumption that 20% patients would be lost to follow up is now better detailed page 7:

“Because of the severity of these patients’ pathology and the high risk of mortality of metastatic cancer combined with aging population [6] and social isolation [19] [20] [21] [22] [23], we assumed that a potential 20% of patients will be lost to follow-up, these calculations showed that 320 patients are needed (160 per group).”

4) The discussion suggests that patient autonomy is an important outcome/aim of the intervention, how this will be measured could be better described in the methods.

Measure of the patient’s autonomy is stated in page 6:

“Autonomy will be assessed by the Katz and Lawton scales respectively measuring the patient’s ability to perform activities of daily living (ADL Scale) and Instrumental activity of daily living (IADL scale) at 3 and 6 months. Patients unable to perform at least one activity will be considered as dependent either in daily living activities or instrumental activities, except for urinary incontinence. Patients enrolled in the study must present an ADL score higher or equal to 4 (out of 6). Decline in autonomy will be assessed as the number of activities at 3 and 6 months compared to the base line.”

5) The flowchart suggests QoL will be measured as a secondary outcome at the end of first line treatment, which seems appropriate. However the main body of the protocol does not state this, rather it suggests fixed for patients. Small change to ensure consistency.

Indeed the protocol was unclear as to the flexibility of the QoL measure. As several pathology are analyzed the T3 point, when the primary end point is collected, is dependent of the first line of treatment end. As the beginning of the intervention is dependent of the first treatment visit. We tried to clarify this page 5:

“first treatment visit (T0, beginning of the intervention)”

“The primary endpoint is the quality of life assessed at T3 according to the first line of treatment (usually 3 months after T0)”