Author’s response to reviews

Title: PREDOMOS study, Impact of a social intervention program for socially isolated elderly cancer patients: Update to the study protocol for a randomized controlled Trial

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

1) Pg 7, line 48 you use the phrase ‘the interest of PS-DS’ when outlining secondary outcomes. Could you make it clearer if the intent is to assess effectiveness using these outcomes?

To consider this comment, we replaced “interest” by “effect” which is more appropriate (highlighted in yellow in the “Background” section)

“This study will also assess the effect of the PS-DR on treatment compliance, autonomy maintenance, toxicity, time to treatment failure, survival, social isolation, unexpected hospitalizations and QoL at 6 months (secondary endpoints)”

2) There are a few examples of poor phrasing, such as pg8, line 40. Dealing with these would improve readability.

We addressed this concern, the corrections are highlighted in yellow in the “changes and eligibility criteria” section

“To improve patient recruitment, which was difficult from the beginning of the study, the steering committee decided to modify the inclusion criteria. Tumor type restrictions were lifted, allowing patients with locally advanced or metastatic cancer from all organs, including malignant hemopathies, to enter the study. Only patients with acute leukemia will be excluded,
to hope to include patients with a lifespan over 6 months. Furthermore, the treatment conditions selected were expended to patient cared for a second line of oncologic treatment. Due to the inclusion of patients with various cancers, we also specified allowed oncological treatments: new generation hormonotherapy, targeted therapy or immunotherapy with or without, concomitant or not radiotherapy.

Otherwise, to simplify the exclusion criteria, the steering committee added a new inclusion criterion to the protocol “mini mental state examination (MMSE) score strictly over 24” to automatically exclude patients unable to complete the QoL questionnaire without help and patients with dementia. We also decided to delete the exclusion criterion “patient with psychiatric troubles” because in the absence of cognitive impairment these patients are potential candidates like the others.

The inclusion criteria now include 1/ Patient aged 70 years or older…"

3) You state a societal perspective but, unless I missed it, patient and carer costs do not seem to be being included. These would be relevant to the perspective.

To address this concern, we clarified the societal point of view as highlighted in yellow in the “secondary endpoints: adjunction of cost utility analysis” section:

“For example, following an initial cost of implementation and equipment, home care interventions are accompanied by avoided costs of medical care (non-programmed re-hospitalizations, visits, examinations...), as well as costs related to the financial burden for the patient.”

“The perspective will be that of the society and the following type of resources will be included in the cost analysis:

- Techniques of domotic and remote assistance;
- Monthly telephone follow-up of the social worker;
- Non-programmed hospitalizations in both groups (including emergency department visits);
- Prescribed exams, laboratory, and non-programmed medicines;
- Unscheduled visits to the oncologist in both groups (including travel allowances for the patient);
- Costs incurred by the patients (in relation to out-of-pocket charges, extra travel costs). As patients are isolated, we hypothesized that caregiver costs would be negligible.

4) Can you provide some info regarding the timings of data collection for the economic evaluation?

We addressed this concern as highlighted in yellow in the “secondary endpoints: adjunction of cost utility analysis” section

“The time horizon will cover the period during which patients will be exposed to the intervention (i.e. 6 months). This will allow researchers to observe and collect prospectively all health and economic outcomes during the exposed period between the two groups.”

“All resources will be observed, collected though the case report files (CRF), and valorized over the period between baseline and the 6-month follow-up.”