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TITLE:

An observational pilot study to evaluate the feasibility and quality of oncological home-hospitalization

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An observational pilot study to evaluate the feasibility and quality of oncological home-hospitalization

ABSTRACT

Purpose The objective of this pilot study was to evaluate the feasibility of oncological home-hospitalization and to compare its quality with standard ambulatory hospital care in terms of patient-reported quality of life and related endpoints by means of a set of validated patient-reported outcome measures (PROMs).

Methods An observational cohort study (clinicaltrials.gov identifier: NCT03073499) was conducted, allocating patients to (partial) home-hospitalisation or standard ambulatory hospital care. PROMs were completed by both cohorts at start of treatment and eight weeks later. An additional study-specific questionnaire was presented to the intervention cohort at study-end assessing their satisfaction with and preferences for the provided homecare.

Results Thirty patients received home-hospitalisation, corresponding to 116 interventions. For twenty-eight patients, this comprised all assessments required prior to administration of treatment, which resulted in a significant reduction of waiting time for treatment administration at the hospital in comparison with the control cohort (n=24) (average reduction of 1:12h, $p<0.001$). Two patients received actual subcutaneous therapy at home. None of the PROM's evaluated revealed significant differences between both cohorts (all $p>0.05$). 29/30 patients of the intervention cohort were satisfied with the provided homecare and preferred to have it continued, 22/25 patients declared to feel at home at least as safe as in the hospital. No serious safety concerns were reported.

Conclusion The results of this pilot study suggest that (partial) oncological home-hospitalisation is feasible, safe and statistically not affecting patient-reported quality of life. Furthermore, this care model was acceptable and preferred by a substantial number of cancer patients.

Keywords: Oncology; Home-hospitalization; Supportive Care; Quality of Care; Patient-satisfaction

INTRODUCTION

The increasing availability of diagnostics and high-effective treatment options have led to an encouraging decrease of mortality for many common cancers (Hashim *et al.*, 2016). However, the increasing prevalence of cancer and the high costs associated with these innovative resources, place a major economic burden on societies (Aiken and Kleinrock, 2016; Luengo-Fernandez *et al.*, 2013; Siddiqui and Rajkumar, 2012). Furthermore, as current (systemic) therapies often require frequent hospital visits over a long period of time, the social burden for patients and increasing workload on healthcare professionals pose critical challenges for the health care system ('The State of Cancer Care in America, 2017: A Report by the American Society of Clinical Oncology,' 2017).

More than ever, policymakers are forced to seek for new healthcare opportunities providing cost-effective care without sacrificing quality. According to the World Health Organization (WHO), new health systems should therefore rely on six domains of quality: Safe, Effective, Patient-centred, Timely, Efficient and Equitable (*Quality of Care - A process for making strategic choices in health systems*, 2016). Recently, the Strategic Advisory Board for Welfare, Health and Family Policy (Strategisch Adviesraad voor Welzijn, Gezondheid en Gezin) of the Flemish Government (Belgium) added two more components: Continuity and Integration of care. A potential cost-effective care model adhering to the requirements of quality is "home-hospitalisation", defined as: "a service that provides active treatment by healthcare professionals in the patient's home, for a condition that otherwise would require acute hospital in-patient care" (Shepperd and Iliffe, 2000). Home-hospitalisation is suggested to be cost-effective by reducing the number and duration of hospital stays, as well as patient-centred by treating patients in a familiar environment (Farfan-Portet *et al.*, 2015; Shepperd and Iliffe, 2000). Introducing home-hospitalization within the domain of oncology might deal with the increasing burden of cancer on healthcare systems, provided that the quality of care is not affected. Several heterogeneous initiatives on oncological home-hospitalisation have been described, and in general these initiatives were considered to be patient-centred and safe. However, robust scientific evidence on the overall quality and cost-effectiveness of this new care model is scarce (Cool *et al.*, 2018; Evans *et al.*, 2016; Corbett *et al.*, 2015).

The present pilot study is part of a larger project in which the feasibility of oncological home-hospitalisation is evaluated within the Belgian context. The primary aim of this pilot study was to evaluate and compare health-related quality of life (QoL) and related endpoints among a cohort of adult cancer patients being (partially) treated at home versus a cohort treated at the oncology day care unit (DCU). Since there is lack of clarity on what patient-reported outcome measures (PROMs) are most sensitive to change within the setting of interest (defined as: responsiveness), a set of validated PROMs was used in order to select, based on the results of this pilot, those questionnaires that are most suitable for use in a subsequently planned randomized-controlled trial (Corbett *et al.*, 2015).

A second objective was to collect an extensive costs inventory for cancer treatment provided as per standard ambulatory hospital care and to make an estimation of the real costs for (partial) oncological home-hospitalization within the Belgian context. The results of the second objective will be published in a separate paper.

METHODS

Patients

Patients eligible for this study had to be 18 years or above, had a good performance status (ECOG ≤ 2) and were diagnosed with a solid tumour or haematological malignancy for which they were (re)starting active treatment of curative, palliative (i.e. non-curative treatments) or supportive nature (i.e. blood transfusions) at the oncology DCU of a general hospital. Patients with important comorbidity (ECOG > 2), problematic venous access, known problems with therapy administration, simultaneous radiotherapy treatment, language barriers or communication difficulties were excluded from participation. A non-randomized design was chosen for this pilot study. Based on patients' preferences, the study population was stratified into an intervention cohort receiving (partial) oncological home-hospitalisation and a control cohort receiving standard ambulatory hospital care. Patients eligible for the intervention cohort had to live within a 30 minutes' drive from the hospital.

The study protocol was approved by the ethical committee of the general hospital in which the trial was performed (registration number: B396201730844) and was carried out in compliance with good clinical practice guidelines. Written informed consent was obtained from all patients recruited to the trial. This trial was registered on the ClinicalTrials.gov database (identifier: NCT03073499).

Study interventions

Oncological home-hospitalization as organized for this study, was implemented in order to optimize the standard of care for patients receiving systemic cancer treatment at the oncology day care unit. According to the standard of care, each hospital visit for cancer treatment administration starts with a blood collection and IV line access provision, after which a nursing review, toxicity scoring and vital signs monitoring takes place. These are considered the preparatory assessments needed in order to allow the oncologist to prescribe patient-specific cancer treatment. Once treatment-continuation is assured, the premedication protecting patients from potential therapy-related side effects, can be applied after which actual therapy can be administrated. (figure 1 – Standard of Care)

The organization of (partial) oncological home-hospitalization was dual. For those patients receiving intravenous cancer medication or blood transfusions, the home-intervention comprised all preparatory assessments required before administration of cancer therapy: nursing review, toxicity scoring, vital signs monitoring, blood sampling and intravenous line access provision. These assessments were performed one day prior to actual therapy administration at the hospital ("day - 1"), enabling the oncologist to prescribe and pharmacy to prepare cancer therapy before arrival of the patient. For those patients receiving subcutaneous cancer therapies (i.e. bortezomib and azacitidine) all injections were administered at the patients' homes, with exception of the first injection of each consecutive treatment cycle (figure 1). Home visits were conducted by certified oncology nurses employed by the hospital and in accordance with the standard procedures. In total, 1.25 full time equivalent (FTE) nurses were deployed for the activities performed at the patients' homes. One FTE was made available from the oncology day care unit, whereas another 0.25 FTE was additionally hired.

Outcome measures

Patient-reported health-related quality of life and related endpoints were measured using a set of validated PROMs. More specifically, the following endpoints and related questionnaires were applied: quality of life [Functional Assessment of Cancer Therapy (FACT-G, v4) (Cella *et al.*, 1993), Euroqol Questionnaire (EQ-5D-3L) ('EuroQol--a new facility for the measurement of health-related quality of life,' 1990), Measure Yourself Concerns and Wellbeing (MYCaW) (Paterson *et al.*, 2007)], satisfaction with care [Cancer Out-Patient Satisfaction with Care Questionnaire (OUT-PATSAT35) (Poinot *et al.*, 2006; Bredart *et al.*, 2005)], depression and anxiety [Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)], distress [Distress Barometer (DB) (Bauwens *et al.*, 2009)] and safety [questionnaire based on Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) (Ricci-Cabello *et al.*, 2016)]. Additional information on the characteristics and scoring methods used of these selected questionnaires is presented in table 1. All PROMs were presented to both patient cohorts (i.e. those receiving (partial) oncological home-hospitalisation as well those receiving standard ambulatory hospital care) at the start of their oncological treatment (i.e. baseline) as well as 8 weeks later (i.e. study-end). An additional study-specific questionnaire was designed to question the intervention cohort about their satisfaction with (using 5-point Likert scale) and preferences for the provided homecare at study-end. Furthermore, this questionnaire included open-ended questions on the perceived advantages and disadvantages of the home-interventions (Appendix 1). All questionnaires were offered on paper. Questionnaire completion at baseline took place at the oncology DCU, during the patient's visit for first treatment administration. At study-end, patients could complete their questionnaire at the DCU or at home, depending upon whether or not they were expected at the hospital for treatment.

Statistical analysis

As this trial was launched as a pilot study, and given the lack of clarity on the ideal sample size for evaluating psychometric properties of PROM's, a sample size of 50 patients (25 per cohort) was considered appropriate (BillinghamWhitehead and Julious, 2013; Hertzog, 2008; Terwee *et al.*, 2007). The continuous outcomes of the PROM's were compared amongst both cohorts by evaluating the mean change in scores between baseline and study-end (score at 8 weeks minus score at baseline) using independent sample t-tests. Normality was assessed by visual evaluation of the histograms and Q-Q plots and considered acceptable for the different outcomes of both cohorts. The sub scores of particular PROMs were examined depending upon their specific design: FACT (physical-, social/family-, emotional- and functional wellbeing); MYCaW (concern 1, concern 2 and wellbeing); EQ-5D-3L (visual analogue scale and descriptive system calculation); HADS (anxiety and depression); OUT-PATSAT35 (doctors, nurses, service and overall); DB (distress barometer and coloured complaint scale). Incomplete data were handled as instructed within the available guidelines for FACT-G and OUT-PATSAT35 CT (Cappelleri *et al.*, 2013; Bredart *et al.*, 2005). For the remaining questionnaires, item-level missing data was prorated per subscale by averaging the available data as long as more than 50% of the items were answered (Cappelleri *et al.*, 2013). Retrospective analysis of the efficiency at the oncology DCU was performed by

calculating the difference in time between arrival of the patient and start of cancer treatment. This was done for all hospital visits planned for administration of cancer treatment during study-participation. An independent sample t-test was used to detect significant differences in waiting times at the DCU between both study-cohorts. In order to assess the comparability of both cohorts, demographic data were compared between both groups. The average age, home-to-hospital distance and number of hospital visits for both cohorts were compared using an independent sample t-test. Exact Chi-Square tests were used to verify if gender, treatment intent, type of cancer malignancy and start vs. restart of treatment was equally distributed between both cohorts. P-values below 0.05 were considered statistically significant (no correction for multiple comparison was done). All statistical analyses were conducted using SPSS Statistics 24. Missing data were deleted pairwise.

Response rates, effect sizes (i.e. difference between the standardized mean change for the treatment and control group), floor-and ceiling effects and item response rates (IRR) for each (sub)scale were analysed in order to pursue selection of the most useful PROMs within this particular research setting. Response rates were calculated based on the number of participating patients who completed the questionnaires at baseline as well as at study-end. Effect sizes were estimated based on the pretest-posttest-control design suggested by Morris (Morris, 2009). Floor-and ceiling effects were verified by analysing the percentage of patients (intervention and control cohort) scoring the most extreme (upper or lower) response categories for each PROM measured at baseline. Proportions of 15% and higher were considered relevant floor- or ceiling effects (Terwee *et al.*, 2007). Finally, item response rates were verified by analysing the average percentage of items completed for each (sub)scale; IRR were calculated for baseline data and study-end data separately.

RESULTS

Patient Demographics

Between January 2017 and April 2017, all patients (re)starting cancer treatment at the oncology day care unit were screened for participation to this pilot study and approached if eligible (n=84). Twenty patients declined participation, with main reason the additional administrative burden. Four patients failed to meet the inclusion criteria. In total, 60 patients agreed upon study-participation, whereof 33 opted for the intervention cohort and 27 for the control cohort. However, only 54 were eligible for analysis due to premature study discontinuation: three patients were no longer treated at the oncology DCU, one patient discontinued due to communication difficulties and two patients withdrew from study participation (Figure 2). There were no statistically significant differences in the average age and home-to-hospital distance of patients assigned to the intervention or control cohort. Furthermore, also gender, cancer types, treatment intent and start vs. restart of treatment were equally distributed between both non-randomized cohorts (Table 2).

Feasibility

In total, 116 home interventions were carried out during this pilot study. For 28 patients, home-hospitalisation comprised the required preparatory assessments prior to intravenous cancer treatment at the oncology DCU. For these patients, the average number of home interventions

during the trial was 3.57 (SD=2.15), corresponding to an average of 5.25 (SD=2.17) visits to the oncology DCU. Home-hospitalisation for those patients resulted in a significant reduction of the waiting time for cancer treatment administration at the oncology DCU compared to the control cohort (average reduction of 1:12h, $p < 0.001$). Two patients of the intervention cohort were visited at home for administration of their subcutaneous cancer therapy. For them, the average number of home- and oncology DCU visits was respectively 8.00 (SD=1.40) and 3.50 (SD=0.70) within the period of eight weeks. Home interventions for these patients fully replaced otherwise required hospital visits. For the control cohort, the average number of visits to the oncology DCU was 5.04 (SD=1.78) during the course of the trial. No serious safety concerns related to the home-interventions were reported and none of the patients allocated to the intervention cohort withdrew home-hospitalisation during the course of the trial.

Patient reported outcomes

There were no significant changes in PROM scores (8 weeks vs. baseline) detected between the intervention and control group, (all $p > 0.05$) (table 3). However, of those patients who opted for (partial) home-hospitalisation, 29 out of 30 patients declared to be (highly) satisfied with the oncological care performed at their homes and preferred to have this type of care continued. One patient was not satisfied nor dissatisfied and preferred standard ambulatory care for the remaining of treatment. The advantages of (partial) oncological home-hospitalisation most often reported by patients were: the time saved at the oncology day care unit, avoidance of (unnecessary) hospital visits and the personal approach of the home nurses. Most patients did not report disadvantages experienced during home-hospitalization. However, two patients for which the home-intervention included the preparatory assessments only, mentioned the fact that they were two times confronted with their disease, instead of once at the hospital, as a burden. One other patient described the nervous feeling about the fact that she could expect a telephone call in case treatment could not be continued as a disadvantage. Of 25 patients, 20 experienced the home-interventions as safe as an intervention at the hospital; 3/25 patients declared to feel more safe at the hospital, 2/25 felt more secure at home. Information of the additional five patients was missing due to incomplete data. Two patients of the home-intervention cohort reported a "medical error" during study-participation, but none of these were related to the home-interventions. One could be traced back to a communication error, the other concerned a medication error.

Evaluating the effect sizes of the PROMs based on Cohen's thresholds (Morris, 2009), FACT-G physical wellbeing subscale and HADS depression subscale showed a small respectively negative and positive effect (≥ 0.20). A large effect size was observed for the MYCaW concern 2 subscale (≥ 0.80). All PROMs evaluated reached response rates over 80%; with exception of the MYCaW concern 1 and concern 2 subscale accounting respectively for a response rate of 72% and 24%. A floor effect was observed for the DB colored complaint subscale. Relevant ceiling effects were present for the FACT-G social/family wellbeing subscale; MYCaW concern 1 and concern 2 subscale; EQ-5D-3L index calculation subscale; OUT-PATSAT35 doctors, nurses and overall subscale. High item response rates ($\geq 90\%$) were observed for all questionnaires and subscales. The average item response remained stable between measurement at baseline and study-end

(difference $\leq 1\%$) for all but FACT-G. Item response rates for the physical wellbeing subscale and functional wellbeing subscale were respectively 8.6% and 1.1% higher at study-end. (Table 4)

DISCUSSION

This pilot study was launched within the scope of a larger project in which the feasibility of oncological home-hospitalisation within the Belgian context is evaluated. The primary aim of this study was to explore and compare patient-reported quality of life for patients receiving (partial) oncological home-hospitalization or standard ambulatory hospital treatment. A set of validated patient-reported outcome measures was used, in order to select –based on the results of this pilot study– those questionnaires that are most useful and responsive within this setting for further research. Moreover, the general feasibility of the described model for (partial) oncological home-hospitalization was evaluated during this pilot study.

The results of this pilot study suggest that (partial) oncological home-hospitalization has statistically no effect on patients' quality of life and related endpoints compared to standard ambulatory hospital care. This might be in contrast with the general perception of home-hospitalization being patient-centred and subsequently benefitting patients' quality of life (Farfan-Portet *et al.*, 2015; Tralongo *et al.*, 2011; Chevreul *et al.*, 2004). However, these results are in line with similar studies examining the effect of home-hospitalization on QoL in adult cancer patients (Lal *et al.*, 2015; Corrie *et al.*, 2013; Luthi *et al.*, 2012; Anderson *et al.*, 2003; Borrás *et al.*, 2001; King *et al.*, 2000; Payne, 1992). On the other hand, the high number of patients declaring to be satisfied with and expressing preference for the provided homecare (i.e. 29/30), could suggest that the available validated PROMs may not be sensitive enough to detect changes induced by the intervention (Cool *et al.*, 2018; Corbett *et al.*, 2015). Besides, the impact of the home-intervention on patient-reported quality of life might have been minimal relative to the large physical as well as emotional impact of an oncological treatment on cancer patients' QoL (Calman, 1984). Nevertheless, this study has shown that (partial) oncological home-hospitalization, as described in this paper, is practically feasible, safe and efficient for the oncology day care unit. Reduced duration of stays as well as a reduced number of patients at the oncology DCU may reduce workload on hospital staff, benefitting patients with more complex care needs. Furthermore, increasing efficiency makes hospital beds available that could be deployed elsewhere. Further research should focus on whether the gains in efficiency at the hospital outweighs the use of additional resources in homecare. As waiting times are a crucial source of patient dissatisfaction, the researchers believe it is essential to improve the quality of this care model by optimizing the workflow until an acceptable clinically significant reduction of waiting time is achieved. Ideally, waiting time for cancer treatment administration at the DCU should be reduced to zero (LisRodeghier and Gupta, 2009; Sandoval *et al.*, 2006; King *et al.*, 2000; ThomasGlynn-Jones and Chait, 1997). The idea of analysing blood counts before cancer treatment administration to optimize the clinical patient pathway is a known concept, however, clear evidence on its effects on service quality is scarce (Hall, 2017; Gemmel *et al.*, 2015; Bach, 2014; Scotte *et al.*, 2013).

Another important observation made during this pilot study is the fact that home-hospitalization is not preferred by all patients. Ideally, future research should focus more excessively on the reasons of patients refusing this new care model.

Selecting the most appropriate questionnaire for measuring quality of life is essential as it determines the presentation of the outcome of interest, and hence also the sample size needed to evaluate the impact on this outcome measure. Given the lack of clarity on what type of questionnaire is most suitable for use in oncology trials evaluating treatment options, several QoL and -related PROMs were examined during this pilot study, as suggested by Corbett, *et al* (Corbett *et al.*, 2015). In this way, both the functional as well as psychological components of health-related QoL were examined. Selection of the PROMs for analysis was based upon their validation and use within a similar population or study-design, their relevance within the setting of interest and the ease of self-completion by patients. Given the particular design of this pilot study and subsequently planned research, the most suitable questionnaires should be highly sensitive as well as responsive in order to detect respectively changes between both cohorts as well as changes over time as a result of the intervention (Terwee *et al.*, 2007; Sprangerste Velde and Aaronson, 1999). In the end, as no significant changes or relevant effect sizes could be observed during this pilot study, it is impossible to judge on the responsiveness of the selected questionnaires within the setting of interest.

Analysing the response rates, floor- and ceiling effects of the MYCaW questionnaire, the usefulness of this PROM within the particular setting is dubious. The observed ceiling effects for OUT-PATSAT 35 CT and EQ-5D-3L descriptive system score are known limitation of these questionnaires (Arraras *et al.*, 2012; Moret *et al.*, 2007). Using EQ-5D with five levels (EQ-5D-5L) should reduce the observed ceiling effects (Pickard *et al.*, 2007a), however a value set to convert EQ-5D-5L states into a single summary index score is currently lacking for the Belgian population. For measuring patient satisfaction, the use of visual analogue scales might be more appropriate (Voutilainen *et al.*, 2016), however according to our knowledge there are currently no such validated questionnaires available. The difference in item response rates at both time measures observed for the FACT-G questionnaire can be ascribed to the difference observed for the physical wellbeing subscale. This difference might be attributed to the cancer therapy specific design of the questionnaire. Within this particular subscale statements on physical wellbeing are presented, which are for patients starting cancer treatment assumed as not applicable yet.

In general, one could conclude that the selection of PROMs used within this pilot study all showed valid measurement properties, with exception of the MYCaW questionnaire.

The results of this pilot study have to be interpreted with caution. First, the sample size used for this trial might have been too small to detect significant changes in the outcomes evaluated between both cohorts. A sample size of at least 50 patients per cohort is recommended by Terwee *et al* in order to evaluate measurement properties of PROM's (Terwee *et al.*, 2007). Secondly, the relatively short observation time with limited number of measurements is a limitation of this study as more frequent measures should reveal more precise data (Vickers, 2006). Finally, as patients could opt for the care model of their preference, an allocation bias was introduced. A randomized design would have been more appropriate. Also the design created for (partial) oncological home-hospitalization and evaluated during this trial implies some shortcomings. Because of practical

issues, only those patients living within a perimeter of 30 minutes' drive from the hospital were considered candidates for oncological home-hospitalization, while those patients living furthest from the hospital could potentially benefit the most. This practical issue could be avoided by transferring these specific tasks to primary healthcare professionals providing subsequently more integrated and continuous care. Another shortcoming of this care model are the limited number of cancer drugs directly administered at the patients' homes. It is assumed that the ideal situation for cancer patients remains a care model in which therapy can be administered directly at the patient's home, in safe conditions and without waiting time or displacement. Extension of the list of cancer treatments considered for home-administration is expected, especially taking into account the efforts of the pharmaceutical industry to seek for more patient-centred modes of treatment administration and cancer drugs with limited toxicity (Cool *et al.*, 2018). Ultimately, this model for (partial) oncological home-hospitalization is new in Belgium. The results of this study inform stakeholders of the potentials and opportunities for oncological home-hospitalization in the future.

Conclusion

This study was the first step in evaluating (partial) oncological home-hospitalization as an equivalent alternative for ambulatory oncological care. Despite the limitations of a pilot study, our results suggest that that oncological home-hospitalization is feasible, safe and not affecting patient-reported quality of life compared to standard ambulatory hospital care. Furthermore, this new care model was acceptable and preferred by a substantial number of cancer patients. The results of this pilot will help to optimize the clinical pathway for home-hospitalization as well as subsequent research in the field.

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APPENDIX 1.**Study-specific questionnaire to question the intervention cohort about their satisfaction with and preferences for the provided homecare at study-end.**

When you received parts of your oncological care at your home (via Onco@Home), then you have here the opportunity to write down your experiences with this type of homecare.

Thank you very much for your feedback.

Advantages (partial) oncological home-hospitalization:

Disadvantages (partial) oncological home-hospitalization:

To what extent are you satisfied with the (oncological) care you received at home?

Very dissatisfied	Rather dissatisfied	Nor dissatisfied, nor satisfied	Rather satisfied	Very satisfied
1	2	3	4	5

What type of care do you prefer?

- ☐ Oncological home-hospitalization, where parts of my oncological care are provided at home.
- ☐ Ambulant hospital care, where all of my oncological care is provided at the oncology day care unit as per standard of care.
- ☐ Neutral, this does not matter to me.

Would you recommend (partial) oncological home-hospitalization to people in the same situation as yours?

- ☐ Yes
- ☐ No
- ☐ I do not know

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Table 1: Characteristics of the patient-reported outcome measures evaluated during the pilot study.

Questionnaire	Description	Domains (Number of items)	Response mode	Min – Max Score	Scoring method (*)	Reliability statistics (Cronbach's Alpha)
FACT-G	Health-related quality of life scale for patients undergoing cancer therapy.	<ul style="list-style-type: none"> - Physical wellbeing (7) - Social/Family wellbeing (7) - Emotional wellbeing (6) - Functional wellbeing (7) <p>Total score = sum of sub scores (27).</p>	5-point Likert scale (range 0 – 4)	<ul style="list-style-type: none"> - Physical wellbeing: 0 – 28 - Social/Family wellbeing: 0 – 28 - Emotional wellbeing: 0 – 24 - Functional wellbeing: 0 – 28 <p>Total score: 0 – 108</p>	Fact-G Scoring Guideline (Version 4) (FACIT.org)	0.88 (Victorson <i>et al.</i> , 2008)
EQ-5D-3L	Generic preference-based measure for health status.	<ul style="list-style-type: none"> - EQ-5D descriptive system (5) - EQ Visual analogue scale (VAS) (1) 	EQ-5D : 3-level scale EQ VAS: VAS (range 0 – 100)	EQ-5D: 0 – 1 EQ VAS: 0 – 100	EQ-5D-3L User Guide (Version 5.1) ; using the Belgian value set for societal preference. (euroqol.org)	EQ-5D: 0.71 ((Pickard <i>et al.</i> , 2007b)
MYCaW	Questionnaire designed for evaluating complementary therapies in cancer support care.	<ul style="list-style-type: none"> - Self-reported problem or concern, determined at first use of the questionnaire, which should be scored again afterwards (1) - Second self-reported problem or concern determined at first use of the questionnaire, which should be scored again afterwards (1) - General wellbeing (1) 	7-point Likert scale (range 0 – 6)	0 – 6	MYCaW user notes. (www.bris.ac.uk)	Not applicable
OUT-PATSAT35	Questionnaire designed for evaluating satisfaction with care expressed by cancer outpatients receiving chemotherapy and modified from the EORTC IN-PATSAT32.	<ul style="list-style-type: none"> - Doctors (11) - Nurses (11) - Services and care organisation (12) - General satisfaction (1) 	5-point Likert scale (range 1 – 5)	For each domain separately; 0 – 100	Scoring Procedure for the OUT-PATSAT35. (Poinso <i>et al.</i> , 2006)	> 0.70 for all subscales with exception of 'doctors availability' (2 items) and 'environment' (3 items) (Arraras <i>et al.</i> , 2012).
HADS	Questionnaire to determine the levels of anxiety and depression a person is experiencing.	<ul style="list-style-type: none"> - Depression (7) - Anxiety (7) <p>Total score = sum of sub scores (17).</p>	4-level scale for each item.	Total score: 0 – 42	H.A.D. Scoring manual. (Zigmond and Snaith, 1983)	0.87 (Villoria and Lara, 2018)

DB	Screening tool developed to evaluate the intensity of distress in ambulatory cancer patients.	<ul style="list-style-type: none"> - Distress thermometer (DT) (1) - Colored complaint scale (CCS) (10) 	DT: VAS (range 0 - 10) CCS: 5-point Likert scale	DT: 0 - 10 CCS: 0 - 50	DB user guide. (Bauwens <i>et al.</i> , 2009)	CCS: 0.80 (Bauwens <i>et al.</i> , 2009)
PREOS-PC, modified to the setting of this trial.	Instrument developed for measuring experiences and outcomes related to patient safety in primary care.	<ul style="list-style-type: none"> - General perception on patient safety (1) - Patient experiences (14) - Impact of malpractices (4) - Solutions (1) 	Combination of Likert scales (varying range), VAS and open ended questions. (Ricci-Cabello <i>et al.</i> , 2016)	For this study, only the VAS on safety feeling and descriptive statistics were used to analyse the responses.	For this study, only the VAS on safety feeling and descriptive statistics were used to analyse the responses.	> 0.70 for all domains ((Ricci-Cabello <i>et al.</i> , 2016)

*: Scoring method used in this trial.

Abbreviations: FACT-G: Functional Assessment of Cancer Therapy - General; EQ-5D-3L: Euroqol Questionnaire; MYCaW: Measure Yourself Concerns and Wellbeing; OUT-PATSAT35: Cancer Out-Patient Satisfaction with Care Questionnaire; HADS: Hospital Anxiety and Depression Scale; DB: Distress Barometer; PREOS-PC Patient Reported Experiences and Outcomes of Safety in Primary Care; DT: Distress Thermometer; CCS: Colored Complaint Scale; VAS: visual analogue scale.

Table 1: Patient Demographics

Characteristics	Intervention cohort	Control cohort	Significance
Number of patients	30	24	NA
Age (avg $\pm$ SD)	64 $\pm$ 13	60 $\pm$ 9	$p = 0.19$
Hospital-distance (km) (avg $\pm$ SD)	9 $\pm$ 4	13 $\pm$ 12	$p = 0.18$
Gender (n)			
Male	7 (23.3%)	7 (29.2%)	$p = 0.76$
Female	23 (76.7%)	17 (70.8%)	
Cancer type (n)			
Breast	14 (46.7%)	10 (41.7%)	$p = 0.33$
Digestive	1 (3.30%)	4 (16.7%)	
Gynaecologic	4 (13.3%)	3 (12.5%)	
Head & Neck	0 (0%)	1 (4.2%)	
Hematologic	7 (23.3%)	2 (8.3%)	
Urologic	4 (13.3%)	4 (16.7%)	
Treatment intent (n)			
Curative	14 (46.7%)	9 (37.5%)	$p = 0.15$
Palliative	9 (30%)	13 (54.2%)	
Maintenance	7 (23.3%)	2 (8.2%)	
First systemic cancer treatment			
Yes	19	15	$p = 1.00$
No	11	9	

Abbreviations: avg = average; SD = standard deviation.

Table 2: Difference in Patient Reported Outcomes for both study cohorts (study-end vs. baseline)

Questionnaire	Cohort	Mean (SD)	95% CI	Effect of mean % change (study-end vs. baseline)	p-value (between-group comparison)
FACT-G total score	C	-0,25 (10.91)	-5.21 to 4.72	No change in QoL	$p = 0.449$
	I	-2,62 (10.47)	-6.76 to 1.53	2% decrease of QoL	
FACT-G physical wellbeing	C	-1,14 (3.68)	-2.77 to 0.49	1% decrease of physical wellbeing	$p = 0.123$
	I	-3,17 (5.08)	-5.17 to -1.16	2% decrease of physical wellbeing	
FACT-G social/family wellbeing	C	-0,79 (4.54)	-2.75 to 1.17	1% decrease of social/family wellbeing	$p = 0.780$
	I	-0,50 (2.78)	-1.58 to 0.58	No change in social/family wellbeing	
FACT-G emotional wellbeing	C	1,89 (4.19)	0.08 to 3.70	2% increase of emotional wellbeing	$p = 0.638$
	I	1,43 (2.67)	0.39 to 2.46	1% increase of emotional wellbeing	
FACT-G functional wellbeing	C	0,19 (4.53)	-1.77 to 2.15	No change in functional wellbeing	$p = 0.622$
	I	-0,51 (5.30)	-2.56 to 1.55	No change in functional wellbeing	
MYCaW concern 1	C	-0,71 (1.16)	-1.30 to -0.11	12% decrease of concerns	$p = 0.892$
	I	-0,77 (1.74)	-1.55 to 0.00	13% decrease of concerns	
MYCaW concern 2	C	0,29 (1.11)	-0.74 to 1.31	5% increase of concerns	$p = 0.185$
	I	-0,83 (1.72)	-2.64 to 0.97	14 % decrease of concerns	
MYCaW wellbeing	C	-0,10 (1.17)	-0.65 to 0.45	2% increase of wellbeing	$p = 0.885$
	I	-0,04 (1.51)	-0.66 to 0.58	1% increase of wellbeing	
HADS total score	C	-1,61 (4.82)	-3.69 to 0.48	4% decrease of hospital anxiety and depression	$p = 0.515$
	I	-0,75 (4.61)	-2.50 to 1.01	2% decrease of hospital anxiety and depression	
HADS anxiety	C	-1,43 (3.41)	-2.91 to 0.04	7% decrease of hospital anxiety	$p = 0.988$
	I	-1,42 (2.87)	-2.51 to -0.33	7% decrease of hospital anxiety	
HADS depression	C	-0,17 (1.95)	-1.02 to 0.67	1% decrease of hospital depression	$p = 0.200$

	I	0,68 (2.61)	-0.32 to 1.67	3% increase of hospital depression	
EQ-5D-3L vas	C	4,48 (22.13)	-5.09 to 14.05	4% increase of QoL	$p = 0.688$
	I	1,89 (22.94)	-7.19 to 10.96	2% increase of QoL	
EQ-5D-3L index	C	0,10 (0.18)	0.03 to 0.18	10% increase of QoL	$p = 0.357$
	I	0,05 (0.19)	-0.02 to 0.13	5% increase of QoL	
OUT-PATSAT 35CT doctors	C	0,31 (16.12)	-6.67 to 7.28	No change in satisfaction with doctors	$p = 0.840$
	I	-0,64 (17.14)	-7.16 to 5.88	1% decrease of satisfaction with doctors	
OUT-PATSAT 35CT nurses	C	-4,15 (13.87)	-10.15 to 1.85	4% decrease of satisfaction with nurses	$p = 0.455$
	I	-6,90 (12.43)	-11.62 to -2.17	7% decrease of satisfaction with nurses	
OUT-PATSAT 35CT service	C	-0,76 (14.11)	-6.86 to 5.35	1% decrease of satisfaction with service	$p = 0.711$
	I	-2,16 (12.13)	-7.05 to 2.74	2% decrease of satisfaction with service	
OUT-PATSAT 35CT overall	C	-3,41 (14.01)	-9.62 to 2.80	3% decrease of overall satisfaction	$p = 0.878$
	I	-2,78 (14.43)	-8.49 to 2.93	3% decrease of overall satisfaction	
DB thermometer	C	-0,93 (3.33)	-2.48 to 0.63	9% decrease of distress	$p = 0.596$
	I	-0,44 (2.91)	-1.59 to 0.71	4% decrease of distress	
DB colored complaint scale	C	-2,37 (6.07)	-4.99 to 0.26	5% decrease of distress	$p = 0.559$
	I	-3,33 (5.49)	-5.50 to -1.16	7% decrease of distress	
PREOS-PC Safety feeling	C	2,74 (27.72)	-9.25 to 14.73	3% increase of safety feeling	$p = 0.734$
	I	0,34 (22.74)	-8.31 to 9.00	No change in safety feeling	

Change in patient reported outcomes for the different scores was calculated by subtracting the scores at study-end with the scores at baseline. Effect of avg % change describes the effect of the average change, based on the design of the specific PROM.

Abbreviations: SD = standard deviation; CI = confidence interval; QoL = quality of life; C = control cohort; I : intervention cohort

Table 4: Measurement properties of the selected PROMs

Questionnaire	Response rate (%)	Effect size	Floor effect at baseline (%)	Ceiling effect at baseline (%)	Item response rate (%) at BL and SE
FACT-G total score	94.4%	-0.16	0%	0%	89.7% - 98.2%
FACT-G physical wellbeing	90.7%	-0.34	0%	12.2%	91.4% - 100%
FACT-G social/family wellbeing	90.7%	0.06	0%	15.7%	93.0% - 92.9%
FACT-G emotional wellbeing	90.7%	-0.08	0%	0%	99.0% - 100%
FACT-G functional wellbeing	90.7%	-0.12	0%	0%	98.9% - 100%
MYCaW concern 1	72.2%	-0.05	2.3%	20.9%	NA
MYCaW concern 2	24.1%	-1.09	0%	25%	NA
MYCaW wellbeing	83.3%	0.04	6%	4%	NA
HADS total score	96.3%	0.11	0%	0%	99.5% - 99.6%
HADS anxiety	96.3%	0.00	1.9%	0%	99.2% - 99.7%
HADS depression	96.3%	0.22	7.7%	0%	99.7% - 99.5%
EQ-5D-3L vas	92.6%	-0.11	2.0%	2.0%	NA
EQ-5D-3L index	96.3%	-0.17	0%	21.2%	100% - 100%
OUT-PATSAT 35CT doctors	96.3%	-0.05	0%	25%	99.5% - 100%
OUT-PATSAT 35CT nurses	96.3%	-0.16	0%	25%	100% - 100%
OUT-PATSAT 35CT service	90.7%	-0.09	0%	0%	98.5% - 99.4%
OUT-PATSAT 35CT overall	90.7%	0.04	0%	34.7%	NA
DB thermometer	87%	0.16	12.5%	6.3%	NA
DB colored complaint scale	92.6%	-0.10	15.7%	0%	93.7% - 93.7
PREOS-PC Safety feeling	96.3%	-0.11	0%	0%	NA

Response rates were calculated by analysing the percentage of participating patients who completed questionnaires both at baseline as well as at study-end.

Effect sizes were calculated based upon the pretest-posttest-control design suggested by Morris (Morris, 2009).

Floor- and ceiling effects were verified by analysing the percentage of patients scoring the most extreme (upper or lower) response categories at baseline.

Item response rates were calculated by calculating the average number of items completed by the study-participants for each scale, at baseline and at study-end (only if minimally one item was scores).

NA: (Not applicable) accounts for those questionnaires or subscales existing of only one item or visual analogue scale; BL: Baseline; SE: study-end.

Figure 1: Standard of care for ambulatory cancer patients versus (partial) oncological home-hospitalization.

*This includes: nursing review, toxicity scoring, vital signs monitoring, blood collection and IV line access provision (if applicable).

**Within this study, administration of subcutaneous cancer drugs at the patients' homes was limited to the drugs bortezomib and azacitidine.

The home symbol indicates those specific parts of the care model that are performed at the patients' homes, parts without symbol are performed at the hospital. Abbreviations: IV = intravenous; SC = subcutaneous.

Figure 2: Patient inclusion flowchart. Abbreviations: DCU = day care unit.

An observational pilot study to evaluate the feasibility and quality of oncological home-hospitalization

HIGHLIGHTS

- * (Partial) Oncological home-hospitalization is feasible, safe and statistically not affecting patient-reported quality of life.
- * (Partial) Oncological home-hospitalization reduces patient waiting times at the hospital significantly.
- * An important proportion of the ambulatory treated cancer population is in favour of (partial) home-hospitalization.
- * Larger randomized-controlled trials should be organized to evaluate the overall quality and cost of this care model in comparison with the standard ambulatory hospital care.