original reports abstract

Oncologic Home-Hospitalization Delivers a High-Quality and Patient-Centered Alternative to Standard Ambulatory Care: Results of a Randomized-Controlled Equivalence Trial

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PURPOSE Given the increasing burden of cancer on patients, health care providers, and payers, the shift of certain outpatient procedures to the patients' homes (further indicated as oncologic home-hospitalization [OHH]) might be a high-quality, patient-centered, and cost-effective alternative to standard ambulatory cancer care (SOC).

METHODS A randomized-controlled trial was conducted to evaluate the quality of a locally implemented model for OHH (n = 74) compared with SOC (n = 74). The model for OHH consisted of home administration of certain subcutaneous cancer drugs (full OHH) and home nursing assessments before ambulatory systemic cancer therapy (partial OHH). Quality was evaluated based on patient-reported quality of life (QoL) and related end points; service use and cost data; safety data; patient-reported satisfaction and preferences; and model efficiency. An equivalence design was used for primary end point analysis. Participants were followed during 12 weeks of systemic cancer treatment.

RESULTS This trial demonstrated equivalence of both models (OHH *v* SOC) in terms of patient-reported QoL (95% CI not exceeding the equivalence margin of 10%). Full OHH resulted in significantly less hospital visits (mean of 5.6 ± 3.0 *v* 13.2 ± 4.6; $P = .011$). Partial OHH reduced waiting times for therapy administration at the day care unit with 45% per visit (2 hours 36 minutes ± 1 hour 4 minutes *v* 4 hours ± 1 hour 4 minutes; $P < .001$). No safety issues were detected. Of the intervention group, 88% reported to be highly satisfied with the OHH model, and 77% reported a positive impact on their QoL. At study end, 60% of both study arms preferred OHH above SOC.

CONCLUSION The shift of particular procedures from the outpatient clinic to the patients' homes offers a high-quality and patient-centered alternative for a large proportion of patients with cancer. Further research is needed to evaluate potential cost-efficiency.

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INTRODUCTION

Today, the globally increasing cancer burden has a significant impact on public health. Health care facilities must meet the growing specialized care demand, whereas governments are forced to deal with increasing costs.[1,2]

The exploration and implementation of value-based health care models, offering high-quality personalized care at the most efficient cost, is encouraged.[3,4] According to the Institute of Medicine, health care models should rely on six domains of quality, which are safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitably.[5] A potential patient-centered and cost-effective care model for patients with cancer undergoing systemic treatment is home-hospitalization, defined as a service that provides active treatment by health care professionals in the patient's home, for a condition that otherwise would require acute hospital inpatient care.[6] The possibilities for home-hospitalization within the domain of oncology have been evaluated in different countries and different settings. In general, these initiatives were considered feasible, patient-centered, and safe. However, robust scientific evidence on the overall quality and cost-effectiveness is scarce.[7-9]

This randomized-controlled clinical trial is part of a larger project investigating the feasibility of implementing a model for oncologic home-hospitalization (OHH) in the Belgian health care system. The objective of this randomized-controlled clinical trial was to establish the quality of a locally implemented model for OHH in comparison with the standard ambulatory cancer care (SOC). Quality was evaluated based on (1) patient-reported outcome measures (PROMs) for quality of life (QoL) and related end points, (2) service

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CONTEXT

Key Objective

The shift of certain outpatient procedures to the patients' homes (further indicated as oncologic home-hospitalization [OHH]) might deal with the increasing burden of cancer on patients in need of systemic treatment and ambulatory health care facilities.

Knowledge Generated

A randomized-controlled equivalence trial evaluating the quality of a locally implemented model for OHH compared with standard ambularory cancer care is described. The model for OHH consisted of home administration of certain subcutaneous cancer drugs and home nursing assessments before ambulatory systemic cancer therapy. Quality was evaluated based on patient-reported outcome measures for quality of life and related end points; service use and cost data; safety data; patient-reported satisfaction and preferences; and model efficiency.

Relevance

The results of this trial demonstrated that a shift of particular procedures from the outpatient clinic to the patients' homes offers a high-quality and patient-centered alternative for a large proportion of patients with cancer. Further research is needed to evaluate potential cost-efficiency.

use and cost data, (3) safety data, (4) patient-reported satisfaction and preferences, and (5) model efficiency.

METHODS

This randomized-controlled trial was conducted in the cancer center of the AZ Groeninge general hospital, Kortrijk, Belgium. The study protocol was approved by the local ethics committee (registration number: B396201733129) and was carried out in compliance with good clinical practice guidelines. Written informed consent was obtained from all participants. This trial was registered on the ClinicalTrials.gov database (identifier: NCT03668275).

Patients

Patients eligible for this study had to be age 18 years or older, had a good performance status (Eastern Cooperative Oncology Group ≤ 2), lived within a 30 minutes' drive from the hospital, and were diagnosed with a solid tumor or hematologic malignancy for which they were (re)starting active treatment of curative, palliative (ie, noncurative treatments), or supportive nature (ie, blood transfusions) at the oncology day care unit (DCU). Patients with problematic venous access, known problems with therapy administration, simultaneous radiotherapy treatment, < 12 weeks of planned therapy, language barriers, or communication difficulties were excluded for participation. Participants were randomly assigned to OHH or SOC based on the principle of minimization. Stratification was based on (1) type of treatment (subcutaneous therapy eligible for full home-administration, other therapies not eligible for full home-administration or transfusion), (2) prior systemic cancer drug treatment (yes or no), and (3) age (< 65 or ≥ 65 years).

Study Interventions

OHH, as organized in this study, was implemented to optimize ambulatory care for patients receiving systemic cancer treatment at the oncology DCU. According to the SOC, each hospital visit for administration of cancer therapy starts with a blood collection and intravenous line access provision, after which a nursing review, toxicity scoring, and monitoring of vital signs take place. These are considered the preparatory assessments allowing the oncologist or hematologist to prescribe patient-specific cancer treatment.

The introduced model for OHH was dual. For most patients, the home-intervention comprised all preparatory assessments required before administration of the cancer therapy itself. This included nursing review, toxicity scoring, monitoring of vital signs, blood sampling, and intravenous line access provision. These assessments were performed 1 day before actual therapy administration at the oncology DCU (day –1), enabling the oncologist to prescribe and the pharmacy to prepare cancer therapy before arrival of the patient at the hospital. This part of our home-hospitalization model is further indicated as partial OHH. For those patients receiving subcutaneous injections of bortezomib or azacitidine, all injections were administered at the patients' homes, with the exception of the first administration of each consecutive treatment cycle. This part is further indicated as full OHH as these home visits fully replaced the need of a hospital visit. Home visits were conducted by certified oncology nurses employed by the hospital and in accordance with the standard procedures.

Outcome Measures

Patient-reported health-related QoL was measured using the functional assessment of cancer therapy questionnaire (FACT-G, v4).[10] General QoL and related end points were measured using the EuroQol questionnaire (EQ-5D-3L; consisting of a visual analog scale [VAS] and generic questionnaire [GQ])[11]; the distress barometer (consisting of a distress thermometer [DT] and colored complaint scale

[CCS]),[12] and the hospital anxiety and depression scale (HADS).[13] The choice of this set of PROMs was based on the measurement properties established in the setting of interest during a preceding pilot study.[14] Patients were asked to complete their service use and cost data during the first 12 weeks of cancer therapy in a study-specific costs form. Additional and/or missing data on service use (defined as the number of home and DCU visits, as well as the number of hospitalization days) were collected from the patients' electronic health record. Adverse events related to the home-intervention were recorded by the treating nurses, and patients were asked to complete a questionnaire based on the patient-reported experiences and outcomes of safety in primary care questionnaire (PREOS-PC).[15] In addition, patients were questioned about their feeling of safety at regular time points using a VAS. The homecare nurses had to register safety issues in the hospital's incident reporting system if they felt safety was compromised during their work. Patient satisfaction was measured using the cancer outpatients' satisfaction with care questionnaires (OUT-PATSAT35).[16,17] In addition, a study-specific questionnaire—designed based on the results of a pilot study[14]—was used to question patients' satisfaction and preferences for the explored care model. Besides, this additional questionnaire was used to ask patients directly whether they experienced an effect of the intervention on their QoL. As a measure for model efficiency, the waiting times for therapy administration at the DCU were registered for both groups, as well as the number of avoided hospital visits in case laboratory values on day −1 predicted the need of postponing therapy. Waiting times were calculated as the difference between the time of patient arrival at the DCU and the administration of the anticancer product, which were both collected from the electronic health record.

PROMs were presented to both patient groups at the start of their oncologic treatment and subsequently every 4 weeks up to 3 months later. After 12 weeks of study participation, patients from the control group could opt to cross-over. A final follow-up was planned 20 weeks after the start of the study.

Statistical Analysis

On the basis of a two-sided equivalence sample size calculation, given a noninferiority or superiority margin of 10% on FACT-G and mean, deviation, and dropout rate as calculated in the pilot study,[14] a sample size of 130 patients was considered appropriate to provide 80% power to establish the assumption of equivalence.

Baseline characteristics were compared using exact two-sided chi-square tests and two-sample *t*-tests. Missing data in the primary outcome variable were assessed using a missing data pattern matrix and assumed to be at random. Predictor variables were identified using the MICE package software in R. Linear mixed-effect models were used to evaluate the PROM results over time and between both study groups (the time × group interaction effect). The model was additionally corrected for the predictors of missingness and strata variables. The unstructured covariance structure was selected for the residuals over time. Estimated marginal means for each time point for both groups were calculated, and a post hoc pairwise comparison of the *time* × *group* effect was conducted. The same statistical model was used to evaluate the potential *time* × *group* effect on the secondary end point PROMs: EQ-5D-3L (GQ and VAS), DT, CCS, and HADS.

The data on service use and model efficiency were evaluated using two-sample *t*-tests. Data from those patients who stopped study participation because of the home-intervention (n = 4) were excluded from these analyses. *P* values below .05 were considered statistically significant. All statistical analyses were conducted using SPSS Statistics 25.

RESULTS

Patient Demographics

Between May 2018 and January 2019, all patients (re) starting systemic cancer treatment at the oncology DCU were screened for participation. In total, 103 patients of the 251 meeting the inclusion criteria declined participation (41%). Of those patients eligible for subcutaneous therapy at home, only one out of 12 patients declined. Finally, 148 patients were randomly assigned to OHH (n = 74) or SOC (n = 74; Fig 1). Four patients of the OHH group discontinued study participation prematurely. Two of them felt the intravenous line placed felt uncomfortable at night and two others decided the model did not bring enough patient-benefit. Baseline patient characteristics are presented in Table 1. There were no statistical differences in patient demographics between the intervention and control groups.

Health-Related QoL and Related End Points

Estimated mean QoL scores for both groups over time are presented in Figure 2. The *time* × *group* interaction effect was not found significant ($P = .067$), nor was the effect of the type of treatment and age (all $P > .05$). Significant main effects were found for prior systemic cancer drug treatment (average FACT-G score of 76.19 *v* 72.60 in the benefit of patients who received no prior systemic cancer drug; $P = .039$), baseline scores on EQ-5D VAS (positive association of 0.28; $P < .001$), and baseline scores on CCS (negative association of −0.65; $P < .001$). Post hoc pairwise comparison of the *time* × *group* interaction effect demonstrated equivalence of both groups. Similar to the primary end point, the *time* × *group* interaction effect appeared to be not significant for the secondary PROMs EQ-5D-3L (VAS and GQ), DT, CCS, and HADS, following to the same statistical model.

Service Use and Cost Data

For those patients receiving subcutaneous anticancer drugs at home (full OHH), it was calculated that patients

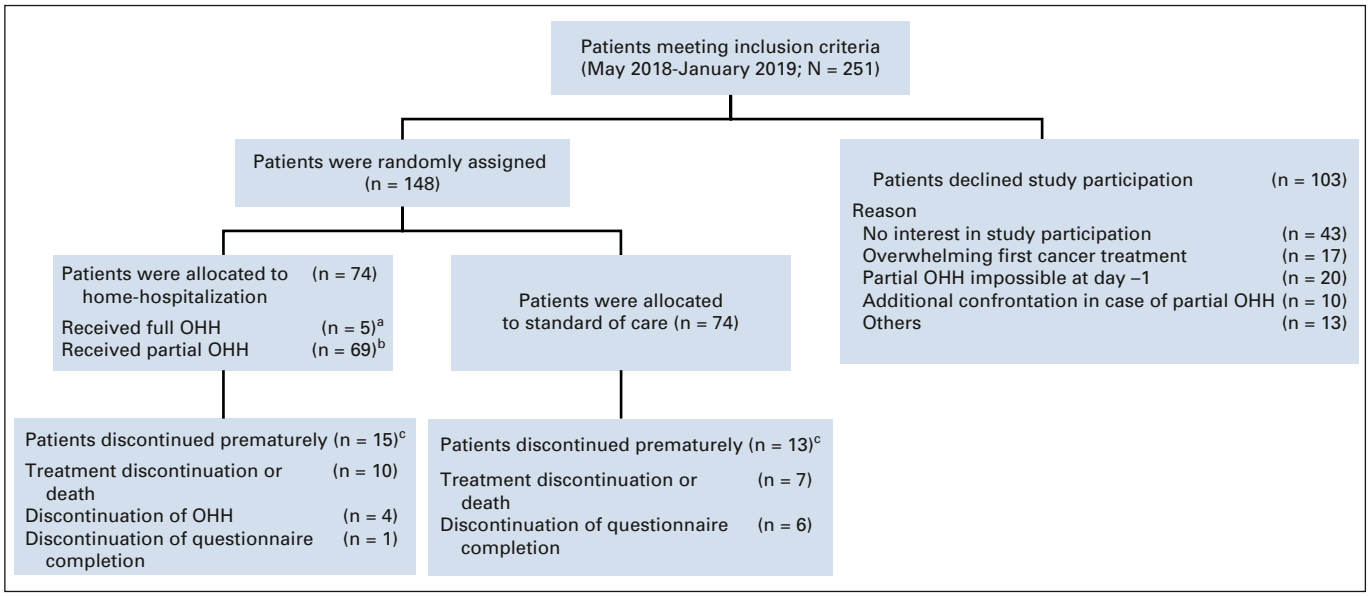

FIG 1. Patient inclusion flowchart. [a]Subcutaneous cancer drug administration at home; [b]preparation for cancer therapy at home; [c]discontinuation within first 12 weeks of study participation. OHH, oncologic home-hospitalization.

from the intervention group had on average 7.6 DCU visits less than the control group during the first 12 weeks of treatment (average of 5.6 ± 3.0 and 13.2 ± 4.6, respectively, $P = .011$). The median number of hospitalization days for the intervention group was 0 (interquartile range = 0; range, 0-0) versus 3.5 (interquartile range = 12; range, 0-12) for the control group.

For those patients being prepared at home for therapy administration at the oncology DCU (partial OHH), the average number of DCU visits did not differ from the control group (6.8 ± 2.5 and 7.5 ± 3.1, respectively, $P > .05$). For the intervention group, on average, 5.3 (±2.6) home visits were performed during study participation. For the group of patients suitable for partial oncologic home-hospitalization, there was no statistical difference in the number of hospitalization days between both groups (average of 3.8 ± 10.6 for the intervention group *v* 2.8 ± 6.8 for the control group, $P > .05$).

Service use and cost data gathered by patients during this clinical trial turned out to be insufficiently consistent for a thorough cost-comparison analysis.

Safety

No adverse events linked to the home-intervention were recorded by the coordinating nurses during the course of the study. The *time* × *group* interaction had no significant effect on the patient's reported feeling of safety on the VAS ($P = .984$). Analysis of the study-specific and PREOS-PC questionnaire demonstrated that of the intervention group, 48 patients reported to feel at home as safe as at the DCU, seven felt more safe at home, whereas one reported to feel more safe at the oncology DCU. Eight patients (two from the intervention group and six from the control group) experienced a medical error during their general cancer treatment, but none of these were related to the intervention examined in this study.

Satisfaction and Preferences

There was no significant effect of the *time* × *group* interaction on the four domains of the OUT-PATSAT35 questionnaire. However, after 12 weeks of home-hospitalization, 43 out of 49 patients of the OHH group that completed the study-specific satisfaction and preferences questionnaire at study end declared to be highly satisfied with the new care model. Three patients registered to be dissatisfied, but they all preferred the intervention model to be continued for the remaining of their therapy. Forty out of 52 patients of the intervention group indicated the intervention had a positive impact on their QoL. In total, 66 out of 110 (60%) patients indicated they preferred OHH above SOC for the remaining of treatment. Seventy-two of 106 (68%) patients declared they would recommend the explored care model to fellow patients (Fig 3).

After 12 weeks of study participation, 16 out of 52 patients allocated to the control group and still in need of cancer therapy chose to continue their treatment with OHH. Of those, 13 of 15 responders declared after 8 weeks to be (highly) satisfied and 11 of 14 responders acknowledged the intervention had a positive impact on their QoL. Eleven of 14 patients would recommend the interventions to fellow patients.

TABLE 1. Patient Demographics

Characteristics	Intervention Group	Control Group	Overall	*P*
No. of patients	74	74	148	NA
Age, avg ± SD	63.8 ± 12.8	63.0 ± 13.0	63.4 ± 12.8	.698
Age category, years, No. (%)				
≤ 65	36 (48.6)	39 (52.7)	75 (50.7)	.742
> 65	38 (51.4)	35 (47.3)	73 (49.3)	
Sex, No. (%)				
Male	29 (39.2)	26 (35.1)	55	.734
Female	45 (60.8)	48 (64.9)	93	
Cancer type, No. (%)				
Breast	24 (32.4)	24 (32.4)	48 (32.4)	.301
Digestive	15 (20.3)	17 (23.0)	32 (21.6)	
Dermatology	2 (2.7)	1 (1.4)	3 (2.0)	
Gynecologic	3 (4.1)	7 (9.5)	10 (6.8)	
Head and neck	2 (2.7)	0 (0.0)	2 (1.4)	
Hematologic	11 (14.9)	14 (19.0)	25 (16.9)	
Lung	13 (17.6)	5 (6.8)	18 (12.2)	
Urologic	4 (5.4)	6 (8.1)	10 (6.8)	
Treatment intent, No. (%)				
Curative	24 (32.4)	27 (36.5)	51 (34.5)	.605
Palliative	39 (52.7)	33 (44.6)	72 (48.6)	
Maintenance	11 (14.9)	14 (18.9)	25 (16.9)	
Previous systemic cancer treatment, No. (%)				
Yes	29 (39.2)	26 (35.1)	55 (37.2)	.734
No	45 (60.8)	48 (64.9)	93 (62.8)	
Type of therapy, No. (%)				
SC drug eligible for OHH	5 (6.8)	6 (8.1)	11 (7.4)	.952
SC or IV not eligible for OHH	68 (91.9)	67 (90.6)	135 (91.2)	
Transfusion	1 (1.4)	1 (1.4)	2 (1.4)	
Social status, No. (%)				
Married or living together	55 (74.3)	51 (68.9)	106 (71.6)	.580
Single	5 (6.8)	4 (5.4)	9 (6.1)	
Divorced	3 (4.1)	4 (5.4)	7 (4.7)	
Widowed	7 (9.5)	13 (16.2)	20 (13.5)	
Missing	4 (5.4)	2 (2.7)	6 (4.1)	
Education level, No. (%)				
Elementary school	2 (2.7)	0 (0)	2 (2.7)	.630
Lower high school (15 years)	21 (28.4)	22 (29.7)	43 (29.1)	
Higher high school (18 years)	26 (35.1)	23 (31.1)	49 (33.1)	
Bachelor degree	14 (18.9)	19 (25.7)	33 (22.3)	
Master degree	5 (6.8)	6 (8.1)	11 (14.9)	
Unknown	6 (8.1)	4 (5.4)	10 (6.8)	
Hospital-distance, km, avg ± SD	9.2 ± 4.3	9.9 ± 5.1	9.6 ± 4.7	.349

Abbreviations: avg, average; NA, not applicable; OHH, oncologic home-hospitalization; SD, standard deviation.

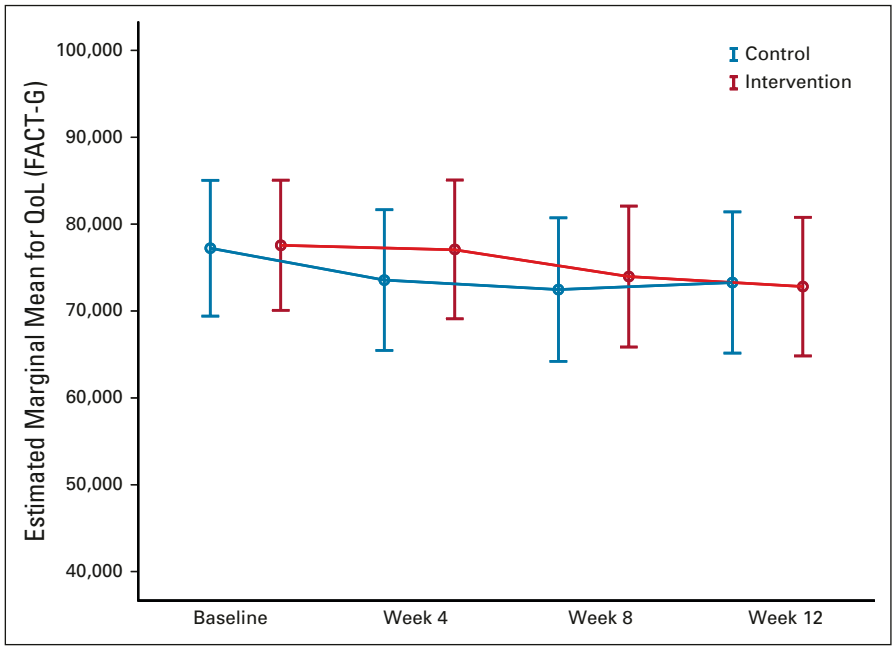

FIG 2. Estimated mean quality of life based on FACT-G for both groups over time, adjusted for baseline characteristics. FACT-G, Functional Assessment of Cancer Therapy–General.

Model Efficiency

In light of this clinical trial, 399 home visits were conducted: 47 for the administration of a subcutaneous anticancer products and 352 to prepare patients for cancer therapy administration at the oncology DCU. In 12 cases of partial OHH, next-day DCU visit was canceled based upon the information gathered during the home visit. Full OHH resulted in disappearance of waiting time before product administration. The average waiting time was calculated at 2 hours and 20 minutes (SD = 1 hour 8 minutes) in the control group. In case of partial OHH, the average waiting time for therapy administration was reduced with 45% compared with SOC (2 hours 36 minutes ± 1 hour 4 minutes *v* 4 hours ± 1 hour 4 minutes; $P < .001$).

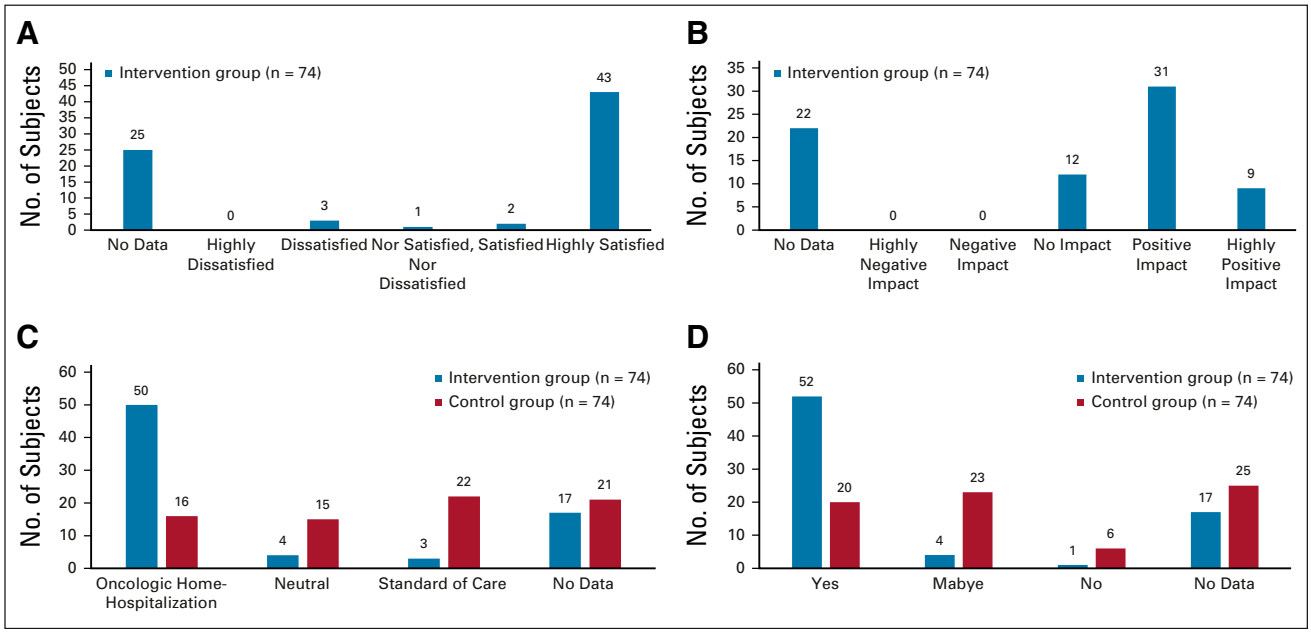

FIG 3. Patient-reported satisfaction and preferences for oncologic home-hospitalization compared with standard ambulatory care after 12 weeks of study participation: (A) satisfaction with home-hospitalization, (B) impact of home-hospitalization on quality of life, (C) care model of preference after 12 weeks of study, and (D) recommendation of home-hospitalization to fellow sufferers.

DISCUSSION

In this study, the quality of a model for OHH was compared with SOC. From the inclusion number, we learned that about 60% of the target population is in favor of our model for OHH. The intervention had an equivalent effect on patient-reported QoL and related end points as compared to SOC. Nevertheless, large majority of patients allocated to the intervention group reported to be highly satisfied with the new care model and preferred it above SOC. In addition, a large proportion of the intervention group declared that the home-intervention had a positive impact on their QoL. The contradictory results of the quantitative and qualitative evaluations suggest that the effect of the intervention could not be detected by the generic validated PROMs. New outcome measures focusing on the burden of cancer treatment instead of on the burden of the disease itself should be developed.[9]

In terms of service use and efficiency, this trial showed that for patients eligible for subcutaneous administration at home, an average of 7.6 DCU visits were avoided within a period of 3 months. Unfortunately, this subgroup was too small to evaluate the potential effects on PROMs of this obvious patient comfort. For those patients allocated to partial OHH, the waiting times for therapy administration at the oncology DCU were reduced with an average of 45%. At last, this trial demonstrated that such innovative care model can be performed with the same level of safety as standard ambulatory cancer care, which is similar to previous observations.[7]

When applying these results to the quality principle of the Institute of Medicine, we can conclude that evidence of quality was provided for all domains, with the exception of cost-efficiency. As result of the poor quality of patient-reported cost data, a planned cost comparison from patients' perspective could not be conducted. An evaluation from perspective of the health care provider and/or payer might be of greater value to evaluate the financial feasibility of the model and should be subject of further research. Another important limitation of this study is the proportional difference of patients being allocated to partial versus full OHH (92% *v* 8%, respectively). Albeit the small number of patients included in the full OHH model, the authors are truly convinced of the importance of evaluating this opportunity. The aim of this study was to explore the possibilities of OHH and in this first evaluation, only azacitidine and bortezomib were selected as suitable candidates for home-administration. This selection was based on clinical experience, their favorable toxicity profile, and their logistical benefit. The positive results and experiences of this trial allow further exploration of the full OHH model with new candidates for home-administration. In addition, this trial demonstrated that partial OHH can also have a large impact on the patients' experiences and DCU efficiency. This intermediate step might favor the perception toward home-hospitalization of a lot of stakeholders and is believed to be a crucial preparatory step toward further expansion of full oncologic home-hospitalization. According to our knowledge, this is the first documented study exploring the effects of partial oncologic home-hospitalization. Similar initiatives focused on the day-1 principle to reduce patient waiting times, but did not involve specialized home-interventions.[18,19] At last, this study was prone to selection bias as result of the impossibility of blinding the intervention. A cross-over design might partially address this issue, albeit patients will always have preference for one of the two care models.

The strengths of this randomized trial compared with others available in the known literature are the large sample size, the limited number of inclusion criteria leading to a representative study-population, and the evaluation of a large set of quality-indicators. In addition, this was the first trial, to our knowledge, evaluating the effects of partial OHH.

In conclusion, given the increasing number of patients with cancer in need of systemic treatment and the evolution toward safer treatment options, (partial) oncologic home-hospitalization offers a high-quality and patient-centered alternative to the current ambulatory cancer care for a large proportion of patients with cancer. Authorities should encourage such initiatives and provide health care providers with suitable legal and financial frameworks allowing implementation of such innovative transmural care models in daily practice. Nevertheless, further research is needed to investigate the financial impact of such models.

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DISCLAIMER

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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