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ORIGINAL ARTICLE

Effects of home-based specialized palliative care and dyadic psychological intervention on caregiver burden: results from a randomized controlled trial

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ABSTRACT

Background The Domus study, a randomized controlled trial (RCT), evaluated the effect of home-based specialized palliative care (SPC) reinforced with a psychological intervention for the patient-caregiver dyad on increasing advanced cancer patients' time spent at home, as opposed to hospitalized, and the number of home deaths. As palliative care extends to include support for patients' families and may thus assist caregivers and decrease demands on them, in this study we evaluated a secondary outcome, caregiver burden.

Material and Methods Patients with incurable cancer and their caregivers were randomized (1:1) to care as usual or home-based SPC. Caregiver burden was assessed using the Zarit Burden Interview (ZBI) at baseline and 2, 4, 8 weeks and 6 months after randomization. Intervention effects were assessed in mixed effects models.

Results A total of 258 caregivers were enrolled. Eleven per cent of informal caregivers experienced severe caregiver burden at baseline. Caregiver burden increased significantly over time in both groups ($p = 0.0003$), but no significant effect of the intervention was seen on overall caregiver burden ($p = 0.5046$) or burden subscales measuring role and personal strain.

Conclusion In line with the majority of previous RCTs, the Domus intervention was not able to significantly reduce caregiver burden. Future interventions should consider targeting only caregivers reporting the greatest caregiver burden.

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KEYWORDS
Cancer; oncology; family caregiver; palliative care; psychological intervention

Background

Many advanced cancer patients need substantial help from informal caregivers; a complex task, which may be both highly rewarding and burdensome, impacting caregivers' emotional and physical health, social life, and finances [1]. The distress experienced by patient and caregiver is correlated, indicating an interrelated response to cancer [2]. By providing dyadic interventions, clinicians may address this interdependence, with potential beneficial effects on quality of life (QoL) for both [3]. Informal caregiving requires interactions between patient and caregiver, and dyadic interventions might also benefit caregiver burden. Few randomized controlled trials (RCTs) have examined effects of interventions on caregiver burden in advanced cancer, the majority with no or unclear effects [4–11]. Two interventions significantly reduced caregiver burden [12,13]; one targeted the patient-caregiver dyad [12]. More evidence for effective clinical approaches to alleviate caregiver burden, particularly targeting dyads, is needed.

The Domus trial investigated the effect of home-based specialized palliative care (SPC) including a targeted dyadic psychological intervention for advanced cancer patients and caregivers[14]. The intervention had no significant effect on the primary outcomes; patients' time at home, as opposed to hospitalized, and the number of home deaths [14], but improved patients' QoL and caregivers' mental health [14,15]. We hypothesize that the Domus intervention could affect caregiver burden through patients' perceived health or physical symptoms [16–18], caregivers' mental health and coping strategies [19,20], and the intensity and amount of informal care [17,18], all of which are associated with caregiver burden, and some of which were improved by the intervention. Here, we aim to investigate the effects of the Domus

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intervention on caregiver burden, included in the trial as a secondary outcome.

Material and methods

Study design

The Domus study was a parallel group 1:1 RCT. Advanced cancer patients and their caregivers were allocated to home-based SPC and dyadic psychological intervention or care as usual. The study design, including power calculation for the primary outcome, and development of the dyadic psychological intervention are described elsewhere [21,22]. The trial was prospectively registered at clinicaltrials.gov (NCT01885637), and is reported in accordance with the CONSORT statement [23].

Participants and randomization

In- and outpatients at the Department of Oncology at Rigshospitalet, Copenhagen University Hospital, Denmark were systematically screened for inclusion from June 2013 to August 2016 [22]. Eligible patients had incurable cancer, were 18 years or older, lived in the Capital Region of Denmark, had no or limited antineoplastic treatment options or had foregone further treatment [22]. On November 1, 2014, a further inclusion criterion, Eastern Cooperative Oncology Group (ECOG) performance status 2–4, i.e., patients' ability to perform daily activities [24], was dropped to ease recruitment [25]. Patients who were already referred to a specialized palliative care team (SPCT), could not be discharged, spoke insufficient Danish or were unable to cooperate were excluded [22]. Each patient could appoint a caregiver e.g. a partner, adult child or friend aged 18 or above (no other criteria applied) to participate. Participants provided written informed consent, and the study was performed in accordance with the Declaration of Helsinki. Participants completed baseline questionnaires [22] prior to randomization through a computer-generated sequence, generated by an outside statistician, with varying block size, using sealed, opaque envelopes. Nurses recruiting patients and collecting data were blinded to allocation sequence and block size [22]. The nature of the intervention prevented blinding of participants. The trial ended according to protocol, after six months follow-up of the last included patient.[14,22]

Study settings, procedures, and interventions

The control group received standard care, including GP services, hospital treatment, home care, and nursing homes, which are free in the tax-financed Danish healthcare system [22]. The Domus intervention consisted of home-based SPC reinforced with a dyadic psychological intervention. Both intervention components followed standardized procedures [22]. SPCTs were multidisciplinary and provided individually tailored SPC at home to promote QoL and relieve physical, mental, social and spiritual suffering [22]. Approximately five weekdays after randomization, patient and caregiver met with SPCT representatives, a district nurse, if possible, their GP and a project psychologist in their home. The dyadic psychological intervention aimed to decrease patient-caregiver dyads' distress, and was based on Existential Phenomenological Therapy, which supported the dyad in finding alternative ways of living with suffering and uncertainty [21]. Two sessions in the first month focused on needs assessment and establishment of a therapeutic alliance. Subsequently, dyadic or individual sessions were scheduled flexibly, depending on dyads' needs and challenges, and session content was jointly decided [21]. An intervention guide described the theoretical background, organization of the intervention, criteria to determine need for sessions, as well as training and supervision of psychologists [21]. The patient-caregiver dyad continued to be in contact with the SPCT and the psychologist throughout the 6-month intervention. Patients could continue oncological treatment, use home nursing or other treatment options [22].

Measures

Caregivers in the Domus study completed questionnaires at baseline, 2, 4, and 8 weeks, and 6 months after randomization [22], including the 12-item Zarit Burden Interview (ZBI) measuring caregiver burden [26]. Two subscales '*Role strain*' *and* '*Personal strain*' assessed A) caregivers' perceived impairment in areas of life other than caregiving such as work, social life, finances or health, and B) emotional responses to demands of caregiving [27]. The ZBI was administered in Danish (as translated by Mapi-trust, mapi-trust.org). The translation has not yet been formally validated, but the English version of the ZBI has previously demonstrated good validity in cancer caregiver populations [28]. Harms of the intervention were not registered for participating caregivers, and patient-outcomes are reported elsewhere [14,25,29].

Statistical analyses

Sample size was estimated reflecting the primary outcome of the study [22]. To investigate the intervention effect on caregiver burden, a linear mixed effects model of repeated measures was fitted, using restricted maximum likelihood based on the intention to treat principle. Degrees of freedom were calculated with the Kenward-Rogers method. The model included the fixed effects of follow-up time points (2, 4, 8 weeks, and 6 months) and the interaction between randomization group and follow-up time point. From this interaction, intervention effects with 95% confidence intervals (CI) and effect sizes for each follow-up time point were estimated. In a supplementary analysis, the model was adjusted for fixed effects of sex, age and caregiver type (spouse/partner, child, other). Sensitivity analyses were performed based on multiple imputation of missing responses (see Supplementary material).

Results

Of 340 patients recruited, 270 invited an informal caregiver, of whom 258 consented to participate and were randomized (Supplementary Figure 1) to the intervention ($n = 139$) or control group ($n = 119$). The number of dyads in the groups was unequal because the randomization was not stratified according to caregiver participation. Most caregivers in the Domus trial were female spouses or partners, with heterogeneous socioeconomic status (Table 1). Nine caregivers were found ineligible after randomization (Supplementary Figure 1). Of 249 remaining caregivers, 236 completed information on caregiver burden at baseline, and were available for analysis. There was no significant effect of the intervention on overall caregiver burden ($p = 0.5046$) with small effect estimates (ranging from 0.35 to −0.85), or subscales of personal and role strain (Table 2, Supplementary Figure 2). Neither adjusted nor imputed sensitivity analyses changed the findings (data not shown). Only a minority of caregivers (11%) reported high levels of burden (Supplementary Figure 3). Caregiver burden increased significantly over time in both groups ($p = 0.0003$), with significant differences from baseline to 8 weeks (1.66; 95% CI 0.20 to 3.12) and 6 months (3.24; 95% CI 1.41 to5.08) (Table 2).

Table 1. Baseline characteristics of informal caregivers in the Domus trial, $n = 249$.

Baseline characteristics of caregivers	Intervention group $n = 134$	Control group $n = 115$
Age, years		
Mean (SD)	61 (12)	62 (13)
Sex *n* (%)[a]		
Male	49 (37)	40 (39)
Female	85 (63)	75 (65)
Marital status *n* (%)		
Married/cohabiting	123 (92)	103 (90)
Single	7 (5)	7 (6)
Divorced/widow(er)	1 (2)	5 (5)
Missing information	3 (2)	–
Children *n* (%)		
Children	110 (82)	97 (84)
- living at home[b]	*27 (20)*	*24 (21)*
- not living at home[b]	*86 (64)*	*78 (68)*
No children	19 (14)	17 (15)
Missing information	5 (3)	1 (1)
Highest achieved education *n* (%)		
Elementary/middle school (9 years)	14 (10)	14 (12)
Vocational	35 (26)	31 (27)
High school	2 (2)	2 (2)
Further education (-4½ years)	48 (36)	47 (41)
Higher education (5-years)	27 (20)	16 (14)
Missing information	8 (6)	5 (4)
Relationship to patient *n* (%)		
Spouse/partner	103 (77)	92 (80)
Son/daughter	24 (18)	10 (9)
Other	7 (5)	13 (11)
Patient's cancer diagnosis *n* (%)		
Lung	28 (21)	25 (22)
Central nervous system	16 (12)	21 (18)
Female genitalia	18 (13)	13 (11)
Lower gastrointestinal	15 (11)	13 (11)
Upper gastrointestinal	13 (10)	13 (11)
Prostate	17 (13)	5 (4)
Head and neck	6 (5)	9 (8)
Connective tissue	5 (4)	8 (7)
Breast	5 (4)	7 (6)
Other	11 (8)	1 (1)
Performance Status *n* (%)		
0–1[c]	68 (51)	59 (51)
2–3	66 (49)	56 (49)

[a]Some percentages do not add up to 100 due to rounding; [b]Categories not exclusive [c]Eastern Cooperative Oncology Group (ECOG).

Discussion

The Domus trial is the first RCT to evaluate effects of home-based SPC reinforced with a dyadic psychological intervention. In line with the majority (8 out of 10) of RCTs examining effects of interventions in informal caregivers of advanced cancer patients [4–11], no effect was found on caregiver burden. Two previous RCTs targeting caregivers of advanced cancer patients found significant effects on caregiver burden [12,13]. In both interventions, only one of which was published when the present study was planned [13], caregivers were taught skills related to caregiving and coping with caregiving, including problem-solving skills, symptom management, and self-care strategies [12,13]. One effective intervention targeted the patient-caregiver dyad [12], yet the dyadic focus in the present intervention had no effects, suggesting that the content rather than the dyadic format may be the necessary component. The individually tailored Domus intervention included the possibility to teach symptom management skills and address coping and self-care related to caregiving, yet neither was mandatory. An enhanced and systematic focus on skills training, coping and

Table 2. Estimated differences with 95% confidence intervals (CI) in caregiver burden for caregivers in the intervention compared to the control group in the Domus trial, $n = 236$.

Overall Caregiver Burden	Estimate	95% CI	*p*Value
Intercept	25.42	24.35; 26.48	
Follow-up time			
Week 2	0.00	−1.03; 1.03	0.0003
Week 4	0.35	−0.89; 1.60	
Week 8	1.66	0.20; 3.12	
Month 6	3.24	1.41; 5.08	
Intervention effect			
Week 2 Intervention vs. control	0.35	−0.98; 1.67	0.5046
Week 4 Intervention vs. control	0.10	−1.51; 1.71	
Week 8 Intervention vs. control	−1.17	−3.06; 0.73	
Month 6 Intervention vs. control	−0.85	−3.20; 1.50	
Personal strain sub-scale	**Estimate**	**95% CI**	***p*Value**
Intercept			
Follow-up time			
Week 2	−0.03	−0.86; 0.79	<.0001
Week 4	0.61	−0.33; 1.56	
Week 8	1.62	0.54; 2.69	
Month 6	2.29	0.98; 3.61	
Intervention effect			
Week 2 Intervention vs. control	0.51	−0.55; 1.57	0.5623
Week 4 Intervention vs. control	0.00	−1.22; 1.22	
Week 8 Intervention vs. control	−0.62	−2.01; 0.77	
Month 6 Intervention vs. control	−0.11	−1.81; 1.58	
Role strain sub-scale	**Estimate**	**95% CI**	***p*Value**
Intercept			
Follow-up time			
Week 2	−0.01	−0.46; 0.43	0.0039
Week 4	−0.42	−0.93; 0.08	
Week 8	−0.07	−0.63; 0.48	
Month 6	0.82	0.09; 1.56	
Intervention effect			
Week 2 Intervention vs. control	−0.27	−0.82; 0.29	0.2268
Week 4 Intervention vs. control	0.14	−0.50; 0.78	
Week 8 Intervention vs. control	−0.52	−1.22; 0.19	
Month 6 Intervention vs. control	−0.75	−1.68; 0.18	

self-care could have improved effects on caregiver burden in the Domus trial.

The lack of intervention effect on caregiver burden could be understood in relation to the hypothesized mechanisms. First, caregiver burden could be decreased if patients' symptoms were alleviated, and their perceived health increased. The Domus trial found some effects on patients' overall QoL, social- and emotional functioning, but no effects on physical symptoms [30]. These effects may not have been sufficient to translate into lower caregiving demands. Second, the intervention could enhance caregivers' mental health and coping strategies, thus reducing caregiver burden. While benefiting mental health, the intervention did not systematically target caregiving-related coping strategies. Third, SPCT could reduce caregiver burden by limiting caregivers' tasks. The Domus intervention took place in the Danish health care system, which provides free access to high levels of medical care and practical assistance. Consequently, the potential for the intervention to benefit caregivers beyond what is already available in Danish standard care may be limited. Additionally, few caregivers (11%) consistently reported having problems nearly always or frequently on the ZBI. A recent Danish cohort study found similar levels of caregiver burden [1], which could indicate that, while caregiver burden may be linked to adverse caregiver outcomes, such as worse mental health in bereavement [27] and sleep problems [31], only a sub-group may need interventions targeting caregiver burden in a setting with high levels of existing healthcare– and caregiving support. Researchers performing future studies could consider screening caregivers and targeting only those with greater experienced burden.

Strengths and limitations

The primary limitation of this study is that caregiver burden was not the primary outcome of the Domus trial, and the trial may not have been sufficiently powered to investigate effects in the subgroup of caregivers with high burden. Second, the measure of caregiver burden has been validated in English in a cancer population, but not in a Danish population. Further, the content of the provided SPC was not recorded, thereby limiting knowledge about mechanisms. However, an intervention guide was developed for the psychological sessions. Nonetheless, our study had several strengths. Informal caregivers were actively included in the intervention and the psychological sessions focused on the patient-caregiver dyad as the unit of care. Nine different SPCTs provided the intervention, which limited bias of the single recruitment site on generalizability. The generalizability of the study was enhanced by the high participation rate among caregivers (96%), their socioeconomic heterogeneity, and the systematic screening of patients, ensuring that all eligible patients were approached [22].

Conclusions

The Domus intervention of home-based SPC reinforced with dyadic psychological sessions did not significantly improve caregiver burden in informal caregivers of advanced cancer patients.

Addressing caregiver burden remains a challenge, and future interventions should consider targeting caregivers with the highest levels of burden. Successfully addressing and alleviating caregiver burden may also contribute to reducing other negative effects, such as increased health care use and work-related impairments in caregivers.

Ethics approval

Regional Committee on Health Research Ethics (37237) and the Danish Data Protection Agency (2007-58-0015) approved the study.

Disclosure statement

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Data Availability statement

The data from this study are available in aggregated form on reasonable request to the first author (AvH). The data are not available at the individual level or publicly due to participant privacy and consent, and applicable national law.

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