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The effects of SmartCare[®] on neuro-oncology family caregivers' distress: a randomized controlled trial

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Running title: SmartCare for neuro-oncology caregivers

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Abstract

Purpose: Patients with primary malignant brain tumors have high symptom burden and commonly rely on family caregivers for practical and emotional support. This can lead to negative mental and physical consequences for caregivers. We investigated effectiveness of an 8-week nurse-led online needs-based support program (SmartCare[®]) with and without online self-guided cognitive behavioral therapy (CBT) for depression compared to enhanced care as usual (ECAU) on depressive symptoms, caregiving-specific distress, anxiety, mastery, and burden.

Methods: Family caregivers scoring ≥ 6 on a depressive symptoms inventory were randomized to three groups: ECAU plus self-guided CBT and SmartCare[®]; ECAU plus SmartCare[®]; ECAU only. Primary outcomes (depressive symptoms; caregiving-specific distress) and secondary outcomes (anxiety, caregiver mastery, and caregiver burden) were assessed online. Intention to treat (ITT) and per protocol (PP) analyses of covariance corrected for baseline scores were performed for outcomes at four months.

Results: In total, 120 family caregivers participated. Accrual and CBT engagement were lower than expected, therefore intervention groups were combined (n=80) and compared to ECAU (n=40). For depressive symptoms, no statistically significant group differences were found. Caregiving-specific distress decreased in the intervention group compared with ECAU (ITT: $p=0.01$, partial $\eta^2=0.08$; PP: $p=0.02$, partial $\eta^2=0.08$). A trend towards improvement in mastery for the intervention group compared with ECAU was identified (ITT: $p=0.08$, partial $\eta^2=0.04$; PP: $p=0.07$, partial $\eta^2=0.05$).

Conclusions: SmartCare[®], with or without self-guided CBT, reduced caregiving-specific distress with a trend towards improving mastery. SmartCare[®] has the potential to improve the lives of families coping with a brain tumor diagnosis.

Trial registration number: NCT02058745; 10 February 2014

Key words: brain tumor; caregiver; online; intervention; mental health; randomized controlled trial.

Introduction

The diagnosis of a primary malignant brain tumor (PMBT) has a devastating effect on patients and their families, with prognosis and treatment options being highly dependent upon tumor type, molecular profile, and grade [1]. Symptom burden is diverse [2] and often leads patients to rely on their family caregivers (e.g. spouses, family members, or close friends; hereafter called caregivers) for practical and emotional support and help to manage their healthcare needs. Neuro-oncology caregiving is particularly difficult as PMBT has a rapid onset and complex treatment regimen (common in cancer), and disease progression that includes neuropsychological symptoms which are highly distressing for caregivers (common in dementia) [3].

Although caregiving can be rewarding, it has been more commonly linked to considerable burden and emotional distress [4, 5]. Our previous biobehavioral descriptive work demonstrated that neuro-oncology caregivers with high baseline depressive symptoms remain at high risk throughout the disease trajectory (capturing 95%, 86%, and 78% of caregivers in the high risk trajectory for depressive symptoms, anxiety, and burden respectively) [4, 6]. Poorer emotional wellbeing in caregivers can lead to poorer self-care, and poorer quality of care provided to patients [7, 8].

Supportive interventions to assist neuro-oncology caregivers have great potential to improve both caregiver and patient outcomes. Yet, our Cochrane systematic review identified only eight small-scale trials (range $N=13-56$), with low overall quality of evidence, rendering it impossible to draw reliable conclusions about intervention effectiveness [9]. This hinders implementation of evidence-based caregiver support in clinical practice. Indeed, neuro-oncology caregivers consistently report difficulty in obtaining acceptable, suitable and effective support [10, 11]. Remote delivery of caregiver support shows promise as it can be effective, can circumvent known practical/physical barriers (e.g., distance and travel) [12, 13], and aligns with caregivers' preferences with support being accessible at any time that is convenient to them [10, 11].

Thus, focusing on caregivers with elevated depressive symptoms, we aimed to evaluate effectiveness of a nurse-led online needs-based caregiver intervention (SmartCare[®]). We further evaluated whether an established self-guided online cognitive behavioural therapy (CBT) depression intervention (Beating the Blues, BtB) would enhance the effectiveness of SmartCare[®]. Our primary aims were to compare the effects of SmartCare[®], with or without BtB, versus enhanced care as usual

(ECAU) on caregivers' depressive symptoms and caregiving-specific distress at four months. Effects on anxiety, mastery, and burden were evaluated as secondary aims.

Methods

Design

This was a three arm parallel-group randomized controlled trial with caregivers allocated to ECAU plus a self-guided version of the 8-week online BtB program [14] followed by the 8-week SmartCare[®] intervention (Arm 1); or 8 weeks of ECAU followed by 8 weeks of SmartCare[®] (Arm 2); or ECAU only (Arm 3). Due to relatively small group sizes and poor uptake of BtB (further details below), intervention Arms 1 and 2 were combined and compared to Arm 3 (ECAU). University of Pittsburgh institutional review board approved the study protocol (registration number PRO11060487). The trial was registered in the ClinicalTrials.gov registry (NCT02058745).

Participants

Between March 2014 and July 2016, caregivers of adult patients (≥ 21 years old) diagnosed with a histologically confirmed PMBT (within four months of initial diagnosis or recurrence; any primary intracranial mass classified as malignant or considered by the neuro-oncologist to be progressive over time) at two NCI designated cancer centers were screened and invited to participate if they met the following criteria: 1) ≥ 21 years of age; 2) identified by patients as the primary, non-professional, non-paid person who provided the majority of emotional, financial and/or physical support; 3) not currently a primary caregiver for anyone else other than children under 21; 4) scoring ≥ 6 on the shortened Center for Epidemiological Studies-Depression scale (CES-D); 5) proficient in English; and 6) have telephone access. Internet access was not a requirement to avoid excluding participants from vulnerable or low-income groups (laptops and internet access were provided as needed). Caregivers were allowed to use pharmacotherapy for depressive symptoms but were excluded if receiving active formal counselling. All participants signed written, informed consent.

Sample size and randomization

A priori sample size calculations yielded 58 dyads per arm based on Cohen's $f = .10$ for CES-D scores. Conservatively assuming up to 20% attrition rate, we aimed to recruit 70 dyads per arm. Following baseline data collection, each dyad was allocated to a study arm (1:1:1) using a web-based random assignment stratified by recruitment site. Due to the nature of the study, neither participants nor researchers were blind to group allocation.

Interventions

SmartCare®

The 8-week SmartCare® program is based on the Representational Approach [15] and aims to teach caregivers effective problem-solving techniques through in-depth reflection of experiences, beliefs, and knowledge (Figure 1A-C, Table 1). Every two weeks, caregivers were invited to complete the Caregiver Needs Screen (CNS) rating the level of distress associated with 32 common caregiving needs/issues and then choose an issue to start or continue working on. Protocolized assignments prompted caregivers to reflect along five dimensions of representations: identity (description of need/issue); cause; timeline; consequences (impact on their lives); controllability; emotions. Examples of common beliefs and concerns that interfere with self-care and asking for help, along with standardized responses to reframe thoughts and behaviors and overcome concerns were presented. Caregivers were then referred to a SmartCare® Guide of evidence-based psychoeducational materials matched to the selected caregiving need/issue (32 Guides available, corresponding to CNS items). Caregivers were asked to compose realistic goals and strategies as part of their draft SmartCare® Plan. This Plan was refined with telephone counseling from the research nurse (within 48 hours, with follow-up to review implemented strategies or goals five days later). Across the intervention period, caregivers were invited to complete the CNS every two weeks and were offered the choice whether to continue with, add, or change the issue they were working on.

Beating the Blues

Beating the Blues (BtB) [14], is an 8-week internet-based CBT program for relieving mild to moderate depressive symptoms. In eight sessions with homework assignments, participants work through cognitive modules such as Automatic Thoughts, Core Beliefs, Challenging Unhelpful Thinking and behavioral modules including Goal-Setting, Problem-Solving, Graded Exposure. BtB (with 80 minutes of nurse guidance) has been found effective [14, 16]. An unguided version of BtB was offered to participants, which is commercially available in several countries including the United States and the United Kingdom.

Enhanced Care as Usual

ECAU included attention-control emails (personalized, friendly messages) every two weeks, and access to an ECAU webpage (with 32 evidence-based SmartCare® Guides, links to web-based resources, basic friends and family page) in addition to care as usual for 16 weeks.

Outcome measures

Outcomes were captured at baseline, two, four, six and ten months. This report focuses on evaluating the efficacy of SmartCare[®] (plus/minus BTB) in improving caregiver mental health from baseline to four months (end of intervention). Other outcomes (e.g., caregiver physical functioning, patient outcomes) and further details on intervention uptake, engagement and use, will be reported on separately. Patient sociodemographic and clinical data and caregiver medication use were collected by a research assistant using a structured interview and medical record review. All questionnaires were selected based on good psychometric properties, and completed online by caregivers.

Primary outcomes

Depressive symptoms were measured with the 10-item version of the CES-D ($\alpha=0.77$; $N=115$) [17]. Higher scores indicate more depressive symptoms (range 0-30), with scores ≥ 8 indicating risk for clinical depression, and ≥ 6 placing caregivers at high risk for poor emotional health [4, 6].

Caregiving-specific distress was measured with the CNS ($\alpha=0.94$; $N=112$) [18]. The CNS assesses distress resulting from 32 common caregiver needs/issues on a 0-10 scale. A higher sum score indicates greater distress; and a total number of distressing needs/issues can be assessed.

Secondary outcomes

Anxiety was measured using the 3-item version of the Profile of Mood States-Anxiety questionnaire ($\alpha=0.86$; $N=116$) [19]. The experience of feeling 'on edge', 'nervous', and 'tense' are evaluated on a 5-point scale, with higher scores indicating more anxiety.

Caregiver mastery, caregivers' perception of control over the care situation, was measured using the 8-item Mastery Scale ($\alpha=0.66$; $N=114$) [20]. Caregivers rated items on a 4-point scale with higher scores indicate higher levels of perceived control.

Caregiver Burden was measured with the Caregiver Reaction Assessment (CRA) [21]: with scales for the impact of providing care on caregivers' self-esteem (higher score meaning lower burden ($\alpha=0.62$; $N=114$)), feelings of abandonment ($\alpha=0.82$; $N=117$) and schedule disruptions ($\alpha=0.73$; $N=119$; higher scores meaning greater burden).

Statistical Analysis

All analyses were performed using SPSS version 26. Due to poor uptake of BtB (17.5% ($n=7$) completed session 5 corresponding to the program's key CBT components) and small group sizes,

the intervention arms were combined to increase statistical power. ANOVAs and Chi Square tests were performed to compare demographic and clinical variables, reasons for dropout, and baseline scores on primary and secondary outcomes between the groups. SmartCare[®] intervention engagement (≥ 1 Plan completed and discussed, meaning caregivers have received the key components of the program) and dosage (total number of Plans completed and discussed) were analyzed descriptively. A detailed account of intervention uptake, use and engagement will be published separately. Observed mean scores were generated for outcome measures at baseline and four months.

ANCOVAs corrected for baseline scores were performed for mean scores of primary outcomes (depressive symptoms; (CES-D); and caregiving-specific distress (CNS)) and secondary outcomes (anxiety (POMS-A); mastery (Mastery Scale); burden (CRA)) at four months. To investigate interaction effects, age (low/high median split), gender (female/male), and relationship (spouse/other) were added as fixed factors only when significantly associated with outcome measures at baseline. Both intention to treat (ITT) and per protocol (PP) analyses (i.e., including those who completed ≥ 1 SmartCare[®] Plan) were run. Due to combining intervention arms, evaluating the effect of reducing depression through BtB before offering SmartCare[®] could not be investigated. Instead, exploratory ANCOVAs corrected for baseline scores comparing CES-D and CNS at four months were calculated for intervention subgroups: 1) not assigned to BtB; 2) completed < 5 BtB sessions; 3) completed ≥ 5 BtB sessions. Effect sizes were calculated as partial η^2 (0.01 small; 0.06 medium; > 0.14 large). Missing data were not imputed, $p < .05$ was considered statistically significant, $p < 0.10$ was considered a trend.

Results

Participants

In total, 120 caregivers completed baseline and were randomized to a treatment arm (see Figure 2). Reasons for non-participation of eligible patient-caregiver dyads ($n=94$) were lack of interest (41.5%), feeling overwhelmed (24.5%), not wanting support (19.2%), or being computer averse (14.8%). Recruitment stopped due to funding restrictions.

Intervention and control arms did not differ in sociodemographic or clinical characteristics (see Table 2), or reasons for attrition ($p > .05$). At baseline, caregivers in the control arm reported higher

anxiety levels ($p=0.032$), no other group differences for primary or secondary outcomes were found ($p>.05$). Observed scores on outcome measures are depicted in Table 3.

SmartCare[®] engagement

Of the 80 participants who received access to SmartCare,[®] 46 (58%) completed ≥ 1 needs assessment (range 1-4). Of these, 41 (89%) selected ≥ 1 need/issue to work on (range 1-3), and discussed ≥ 1 SmartCare[®] Plan with the nurse interventionist (range 1-8).

Effects of the intervention on depressive symptoms and distress from unmet needs

Table 4 shows results from both ITT and PP analyses. For depressive symptom scores (CES-D), no main group effect was found, but a group x age interaction trend was found in ITT analysis ($F(1,80)=3.056$, $p=0.084$, partial $\eta^2=0.037$).

For caregiving-specific distress (CNS total score), both ITT and PP analysis yielded statistically significant group differences with moderate effect size (ITT: $F(1,78)=6.599$, $p=0.012$, partial $\eta^2=0.078$; PP: $F(1,67)=5.598$, $p=0.021$, partial $\eta^2=0.077$), with lower scores in the intervention group, indicating that the intervention reduced caregiving-specific distress compared to ECAU. Results for number of distressing needs/issues were not statistically significant ($p>.10$).

Exploratory analyses showed no significant differences between BtB engagement subgroups for depressive symptoms or caregiving-specific distress ($p>.10$), suggesting that BtB engagement was not associated with intervention effects.

Effects of the intervention on anxiety, caregiver burden and mastery

For mastery, a trend ($p<0.10$) favoring the intervention group with moderate effect size was found (ITT: $F(1,80)=3.058$, $p=0.084$, partial $\eta^2=0.037$; PP: $F(1,68)=3.378$, $p=0.070$, partial $\eta^2=0.047$). No group or interaction effects were found for anxiety or caregiver burden (Table 4).

Discussion

In this randomized controlled trial, we compared neuro-oncology caregivers allocated to receive SmartCare[®] (+/- Beating the Blues) with caregivers allocated to receive enhanced care as usual. The intervention was effective in reducing caregiving-specific distress compared to the control condition. While not directly effective in reducing depressive symptoms, we did find a trend for an age x group interaction indicating that the intervention appeared to be more effective in reducing depressive symptoms in those over 55 years old. Furthermore, we found a trend towards improvement in caregiver mastery favoring the intervention group. The present study provides an

important contribution to the limited evidence base. Our Cochrane systematic review identified eight RCTs that previously assessed any form of support for caregivers of brain and spinal cord tumor patients [9]. Present findings are largely in line with these previous efforts, as six studies evaluated psychological distress (four found improvements after intervention), two studies evaluated mastery (one found improvements), and two evaluated caregiver burden (none found improvements).

Our approach to caregiver support was rooted in a strong theoretical model [22] and based upon the assumption that depressive symptoms would need to be reduced before addressing caregiving-specific distress. Combining intervention arms enhanced statistical power but prevented us from formally comparing SmartCare[®] +/- BtB. Exploratory subgroup analyses of different levels of BtB engagement did not show differences in depressive symptoms or caregiver-specific distress. This could be expected, as despite online CBT being among the National Institute for Health and Clinical Excellence (NICE) recommended treatment strategies for mild to moderate depression, the majority of participants did not use the BtB program. Results align with recent meta-analyses of online CBT programs which indicate guided programs typically have better engagement and outcomes, while unguided programs with their wider access but smaller effect sizes are better suited to large scale population health programs [23]. Our planned qualitative exploration of participant engagement in the interventions may shed light on the relationship between depressive symptoms and caregiving-specific distress.

Study limitations include the relatively small sample size, high attrition rates, and low engagement in BtB and, to a lesser extent, SmartCare[®]. Recruitment difficulties may have been impacted by the setting (caregivers were invited to join during a patient-focused healthcare visit) and timing (within four months of diagnosis or tumor recurrence). Indeed, post-hoc focus groups of participants stated that the intervention was helpful, but that they preferred to have more autonomy when choosing to engage in the intervention. Despite final participant numbers being lower than originally envisioned (120 as opposed to 210, or 57%), it is the largest study in the field with other RCTs reporting between 13-56 neuro-oncology caregivers [9]. Attrition rates were higher in the intervention group (36%) than the control group (13%), although reasons reported for dropout did not differ. The majority of participants who attrited did so due to feeling overwhelmed or because the patient passed away. Noting the additional duties family caregivers assume following the changes in patients' function. The number of participants initiating Smartcare[®] (46; 58%) was lower than

expected. Our pilot work preceding the present RCT (including walkthroughs, focus groups and a survey) did not warn us of issues with initiation rates. Issues encountered are common in internet-based, or blended care interventions tested in similar populations [24, 25], although a recent systematic review of telehealth for brain tumor patient and caregiver populations shows higher accrual (68%) and adherence (74%) rates [13]. For caregivers, these findings may reflect the difficult trade-off between managing the acute and high demands of caring for a loved one with a PMBT and finding time and headspace to engage in an intervention focused on their own needs. Future efforts could consider utilizing an adaptive trial design to improve efficiency and allow a degree of flexibility (e.g., pre-specified modifications) while maintaining rigor.

Despite its limitations, this is the first RCT to evaluate a nurse-led online program developed specifically for neuro-oncology family caregivers. SmartCare[®], a tailored program allowing individualized goal-setting with real-time interaction with a nurse, had clear and positive effects on caregiving-specific distress with a trend toward improving feelings of mastery. Offering SmartCare[®] at other key transition points in the patients' disease trajectory (e.g., after initial treatment or at start of palliative care) should be evaluated to improve its use in clinical practice. Future research could look at a pragmatic approach to implementation. Minor adaptations could be made to the program to improve fit for caregivers of patients with secondary brain tumors, and caregivers of children with brain tumors. Thus, SmartCare[®] has the potential to reduce caregiving-related distress of many families coping with a brain tumor diagnosis.

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Tables

Table 1. A breakdown of SmartCare® activities for participants in the intervention and ECAU groups.

Study Activities	Self-Directed via SmartCare® web-based system	Individualized through Nurse
Available to caregivers in both groups (ECAU control and SmartCare intervention groups)		
<i>Resource library available throughout study period</i>		
• Links to vetted online cancer and PMBT resources	X	
• Links to caregiving resources	X	
• Evidence-based SmartCare Guides for 32 PMBT Caregiver Needs	X	
• Basic friends and family page	X	
Available to caregivers in SmartCare intervention group only		
<i>Representational Assessment:</i>		
• Every 2-weeks Caregiver Needs Screen	X	
• Prompts to describe needs/issues in care situation	X	
• Clarification and individualized assessment by nurse		X
<i>Create Conditions for Conceptual Change:</i>		
• Assessment of common concerns of PMBT caregivers	X	
• Standardized information to address common concerns	X	
• Discuss concerns and gaps in understanding and individualize to personal consequences		X
<i>Provide New Information</i>		
• Present SmartCare Guide matched to needs/issues	X	
• Guide to personally relevant parts of guide		X
<i>Development of SmartCare Plan</i>		
• Prompt for participant's goal	X	
• CG selects strategies from drop-down menu	X	
• Assist with individualization of goal		X
• Discuss and individualize strategies		X
<i>Goal & strategy review after 2 weeks</i>		
• Review of strategy use & effectiveness		X
• Assistance to refine goals and strategies		X

Table 2. Sociodemographic and clinical characteristics of study sample at baseline.

		SmartCare intervention group N=80	ECAU control group N=40	P-value
Caregiver age M (sd)		53.29 (11.1)	52.00 (12.6)	0.569
Caregiver gender N (%)	Male	27 (33.8%)	9 (22.5%)	0.176
	Female	51 (63.8%)	31 (77.5%)	
Relationship with patient	Spouse	62 (77.5%)	34 (85.0%)	0.395
	Other	17 (21.3%)	6 (15.0%)	
Caregiver medication use (baseline) N (%)	Depression medication	Yes: 14 (17.5%) No: 59 (73.8%)	Yes: 10 (25.0%) No: 26 (65.0%)	0.308
	Anxiety medication	Yes: 7 (8.8%) No: 66 (82.50%)	Yes: 5 (12.5%) No: 31 (77.5%)	0.500
Patient age M (sd)		55.34 (13.6) ^A	53.3 (11.5) ^B	0.447
Patient gender N (%)	Male	50 (63.0%)	28 (70.0%)	0.302
	Female	28 (35.0%)	10 (25.0%)	
Patient diagnosis N (%)	Glioblastoma	47 (58.8%)	23 (57.5%)	0.698
	Astrocytoma	15 (18.8%)	9 (22.5%)	
	Oligodendroglioma	9 (11.3%)	5 (12.5%)	
	Primary CNS lymphoma	4 (5.0%)	0 (0%)	
	Ependymoma	1 (1.3%)	0 (0%)	
	Other	4 (5.0%)	3 (7.5%)	
Patient WHO grade tumour N (%)	Grade 2	16 (20.0%)	9 (22.5%)	0.860
	Grade 3	15 (18.8%)	6 (15.0%)	
	Grade 4	47 (58.8%)	24 (60.0%)	

^AData from 3 patients missing; ^BData from 4 patients missing.

Table 3. Observed scores for outcome measures at baseline and 4 months.

		SmartCare intervention group		ECAU control group	
		Baseline (N=80)	4 months (N=51)	Baseline (N=40)	4 months (N=35)
Depression (CES-D) M (sd)		9.68 (5.74)	7.06 (5.96)	11.68 (5.68)	9.63 (6.71)
Caregiver needs (CNS) M (sd)	Total needs score	82.91 (56.78) ^A	43.80 (34.71) ^A	91.35 (2.56)	70.29 (56.21) ^A
	Number of needs	19.19 (7.59) ^A	14.64 (8.65) ^A	19.35 (6.72)	15.94 (8.64) ^A
Anxiety (POMS-A) M (sd)		8.34 (2.85) ^C	7.33 (2.92)	9.54 (2.77) ^A	8.26 (3.11)
Caregiver mastery (CMS) M (sd)		18.28 (3.59) ^A	19.70 (4.28)	18.12 (4.28)	18.36 (4.34) ^B
Caregiver Burden (CRA) M (sd)	Self-esteem	29.44 (3.33)	29.61 (2.83) ^B	29.23 (3.72)	29.09 (3.55) ^A
	Schedule disruptions	17.56 (5.28)	16.76 (5.55) ^A	18.33 (5.94)	17.32 (6.83) ^A
	Abandonment	9.88 (5.12)	9.84 (4.69) ^A	8.85 (4.20)	9.71 (4.60) ^A

^AData from 1 participant missing; ^BData from 2 participants missing; ^CData from 3 participants missing. Abbreviations: CES-D, Center for Epidemiological Studies - Depression scale; CMS, Caregiver Mastery Scale; CNS, Caregiver Needs Screen; CRA, Caregiver Reaction Assessment; POMS-A, Profile of Mood States - Anxiety; M, mean; sd, standard deviation.

Table 4. Results of analyses comparing the Smartcare intervention group with the ECAU control group at 4 months follow-up.

		Intention to treat			Per protocol		
		Intervention group	Control group	F-value (df), P-value, ES	Intervention group	Control group	F-value (df), P-value, ES
PRIMARY OUTCOMES							
Depression (CES-D) M (sd)	Main effect	N=50 7.02 (6.02)	N=35 9.63 (6.71)	F(1,80)=0.838, $p=0.363$, partial $\eta^2=0.010$	N=38 6.74 (4.85)	N=35 9.63 (6.71)	F(1,68)=2.348, $p=0.130$, partial $\eta^2=0.033$
	Interaction						
	Age low	N=24 8.75 (7.3)	N=20 9.00 (6.4)	F(1,80)=3.056, $p=0.084^*$, partial $\eta^2=0.037$	N=17 8.41 (5.43)	N=20 9.00 (6.43)	F(1,68)=2.536, $p=0.116$, partial $\eta^2=0.036$
	Age high	N=26 5.42 (4.1)	N=15 10.47 (7.2)		N=21 5.38 (3.96)	N=15 10.47 (7.21)	
Caregiver needs (CNS) M (sd)	Total needs score	N=49 44.61 (34.59)	N=34 70.29 (56.21)	F(1,78)=6.599, $p=0.012^{**}$, partial $\eta^2=0.078$	N=38 45.00 (34.71)	N=34 70.29 (56.21)	F(1,67)=5.598, $p=0.021^{**}$, partial $\eta^2=0.077$
	Main effect						
	Interaction effect						
	Age low	N=23 47.74 (34.10)	N=19 68.53 (57.69)	F(1,78)=0.006 $p=0.938$, partial $\eta^2=0.000$	N=17 51.59 (37.62)	N=19 68.53 (57.69)	F(1,67)=0.133, $p=0.716$, partial $\eta^2=0.002$
	Age high	N=26 41.85 (35.45)	N=15 72.53 (56.21)		N=21 39.67 (32.10)	N=15 72.53 (56.21)	
	Number of needs	N=49 14.86 (8.60)	N=34 15.94 (8.64)	F(1,80)=1.194 $p=0.278$, partial $\eta^2=0.015$	N=38 14.21 (8.70)	N=34 15.94 (8.64)	F(1,69)=1.329 $p=0.253$, partial $\eta^2=0.019$
	Main effect						
SECONDARY OUTCOMES							
Anxiety (POMS-A) M (sd)	Main effect	N=49 7.27 (2.96)	N=34 8.35 (3.10)	F(1,78)=0.061, $p=0.805$, partial $\eta^2=0.001$	N=36 7.11 (2.70)	N=34 8.35 (3.10)	F(1,65)=0.570 $p=0.453$, partial $\eta^2=0.009$
	Interaction						
	Age low	N=24 7.83 (3.37)	N=19 8.32 (3.00)	F(1,78)=0.853, $p=0.358$, partial $\eta^2=0.011$	N=17 7.53 (2.81)	N=19 8.32 (3.00)	F(1,65)=0.351, $p=0.556$, partial $\eta^2=0.005$
	Age high	N=25 6.72 (2.44)	N=15 8.40 (3.33)		N=19 6.74 (2.62)	N=15 8.40 (3.33)	

Caregiver mastery (CMS)	Main effect		N=50 19.70 (4.28)	N=33 18.36 (4.34)	F(1,80)=3.058, $p=0.084^*$, partial $\eta^2=0.037$	N=38 19.87 (4.36)	N=33 18.36 (4.34)	F(1,68)=3.378, $p=0.070^*$, partial $\eta^2=0.047$
Caregiver Burden (CRA)	Self-esteem Main effect		N=49 29.61 (2.83)	N=34 29.09 (3.55)	F(1,77)=1.119, $p=0.293$, partial $\eta^2=0.014$	N=38 29.29 (2.94)	N=34 29.09 (3.55)	F(1,67)=0.877, $p=0.352$, partial $\eta^2=0.013$
M (sd)	Interaction	Gender (M)	N=14 29.93 (2.56)	N=8 29.25 (2.43)	F(1,77)=0.002, $p=0.964$, partial $\eta^2<0.001$	N=10 30.00 (2.36)	N=8 29.25 (2.43)	F(1,67)=0.097, $p=0.757$, partial $\eta^2=0.001$
		Gender (F)	N=34 29.41 (2.97)	N=26 29.04 (3.86)		N=28 29.04 (3.13)	N=26 29.04 (3.86)	
	Schedule disruptions Main effect		N=50 16.76 (5.55)	N=34 17.32 (6.83)	F(1,81)=0.051 $p=0.822$, partial $\eta^2=0.001$	N=38 16.84 (5.38)	N=34 17.32 (6.83)	F(1,69)=0.015 $p=0.904$, partial $\eta^2<0.001$
	Abandonment Main effect		N=50 9.84 (4.70)	N=34 9.71 (4.60)	F(1,81)=0.534 $p=0.467$, partial $\eta^2=0.007$	N=38 10.08 (4.42)	N=34 9.71 (4.60)	F(1,69)=0.687 $p=0.410$, partial $\eta^2=0.010$

*p-value<0.10; **p-value<0.05. Partial η^2 effect sizes: 0.01 small; 0.06 medium; >0.14 large. Abbreviations: CES-D: Center for Epidemiological Studies – Depression Scale; CNS: Caregiver Needs Screen; POMS-A: Profile of Mood States - Anxiety; CMS: Caregiver Mastery Scale; CRA: Caregiver Reaction Assessment; ES: Effect size; ITT: Intention to treat (all randomized to arm); PP: per protocol (those who completed ≥ 1 SmartCare[®] Plan, M, mean; sd, standard deviation; df, degrees of freedom.

Figure legends

Figure 1a. Screenshot of SmartCare© program: homepage.

Figure 1b. Screenshot of SmartCare© program: understanding your issue.

Figure 1c. Screenshot of SmartCare© program: creating a care plan.

Figure 2. Consort flow diagram.