A supportive group intervention for caregivers to patients diagnosed with a glioblastoma – a protocol for the SUGRI study

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Sara Nordentoft[1] RN, MHSc; Rikke Guldager[2] RN, MScN, PhD; Helle Pappot[3] Professor; Tiit Mathiesen[4] Professor; Anders Tolver[5] MSc, PhD; Karin Piil[6] Associate Professor

[1] Copenhagen University Hospital, Copenhagen, Denmark and Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark. Copenhagen Ø DK
[2] Copenhagen University Hospital, Copenhagen, Denmark. Dept. of People and Technology, Roskilde University, Roskilde, Denmark Copenhagen University Hospital DK
[3] Copenhagen University Hospital and University of Copenhagen, Copenhagen, Denmark and Department of clinical medicine, University of Copenhagen, Copenhagen, Denmark copenhagen DK
[4] Department of Neurosurgery, Copenhagen University Hospital; Department of clinical medicine, University of Copenhagen, Copenhagen, Denmark; Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden Copenhagen Ø DK
[5] Statistics and Data Analysis, Danish Cancer Instititute, Danish Cancer Institute, Copenhagen, Denmark Copenhagen Ø DK
[6] Copenhagen University Hospital, Copenhagen and Department of clinical medicine, University of Copenhagen, Denmark Copenhagen DK

Corresponding Author:
Sara Nordentoft RN, MHSc

Copenhagen University Hospital, Copenhagen, Denmark and Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark.
Inge Lehmanns Vej 8, 2100
Copenhagen
Copenhagen Ø
DK

Abstract

Background: Caregivers to a person diagnosed with a glioblastoma often face significant responsibilities, balancing the demands of care with the complexities of the disease- and treatment trajectory, while also coping with concerns and uncertainty of the future. Caregivers report unmet needs of information and support throughout the patient's disease- and treatment trajectory and they may benefit from targeted supportive care interventions.

Objective: The aim of this study is to develop, test, and evaluate the feasibility of a supportive group intervention among caregivers to patients diagnosed with a glioblastoma.

Methods: The overall study consists of three-phases with ongoing Patient and Public Involvement. In the first phase, a systematic review will be carried out exploring the outcome of supportive group interventions for caregivers to patients diagnosed with a primary brain tumour. In the second phase, the design and development of the intervention will be conducted in cooperation with a panel of caregivers using a Patient and Public Involvement process. The third phase will include the feasibility and evaluation of the intervention. The study will be guided by the British Medical Research Council framework for developing Complex Intervention. Feasibility of the intervention will be tested in reference to relevant parameters. Quantitative data in terms of questionnaires will be analysed using descriptive statistics and qualitative evaluation interviews will be analysed according to Braun and Clarke's thematic analysis.

Results: A national panel of caregivers (n=10) has been successfully established, and the final design of the intervention is currently being developed through an ongoing Patient and Public Involvement process. Three hospitals in Denmark have committed to participating in the recruitment for the feasibility study. Recruitment began in April 2025, and the SUGRI-intervention will be evaluated for feasibility in a multicenter study scheduled for autumn 2025.

Conclusions: The results of feasibility testing of the SUGRI-intervention will guide future potential implementation of the intervention. By offering a supportive group intervention to the caregivers, the intervention may have the potential to address their specific caregiver needs and strengthen their supportive network. This study will provide valuable insights to guide caregiver initiatives, ultimately promoting improved support for caregivers within the neuro-oncology field. Clinical Trial: The

study is registered in ClinicalTrials.gov (NCT06869577) and the systematic review is registered in PROSPERO (CRD42023392222).

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Title page

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Corresponding Author and first author

Sara, Nordentoft, RN, MHSc, Ph.D.-student, Department of Neurosurgery 7006, Inge Lehmanns Vej 8, 2100 Copenhagen Ø. Copenhagen University Hospital, Denmark, sara.marie.juel.nordentoft@regionh.dk
Orcid: 0000-0001-5600-2644

Authors
First name, last name, preferred title(s), institution, city, country, and email

1. Sara Nordentoft, RN, MHSc, Ph.D.-student, Copenhagen University Hospital, Copenhagen, Denmark and Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark. sara.marie.juel.nordentoft@regionh.dk. Orcid: 0000-0001-5600-2644

2. Rikke Guldager, RN, MScN, PhD, Copenhagen University Hospital, Copenhagen, Denmark. Dept. of People and Technology, Roskilde University, Roskilde, Denmark rikke.guldager.01@regionh.dk. Orcid: 0000-0003-1491-2556

3. Helle Pappot, Professor, Copenhagen University Hospital and University of Copenhagen, Copenhagen, Denmark and Department of clinical medicine, University of Copenhagen, Copenhagen, Denmark Helle.Pappot@regionh.dk. Orcid: 0000-0002-3570-5372

4. Tiit Mathiesen, Professor, Department of Neurosurgery, Copenhagen University Hospital; Department of clinical medicine, University of Copenhagen, Copenhagen, Denmark; Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, tiit.illimar.mathiesen@regionh.dk. Orcid: 0000-0001-9463-1919

5. Anders Tolver, MSc, PhD, Statistics and Data Analysis, Danish Cancer Institute, Danish Cancer Institute, Copenhagen, Denmark, atolve@cancer.dk. Orcid: 0000-0003-1109-9889

6. Karin Piil, Associate Professor, Copenhagen University Hospital, Copenhagen and Department of clinical medicine, University of Copenhagen, Denmark, Karin.Piil@regionh.dk. Orcid: 0000-0001-7972-4674

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Keywords: Caregiver, glioblastoma, group intervention, high-grade glioma, neuro-oncology, supportive care,

Introduction

A primary malignant brain tumour is among the most fatal cancers and present an incident rate internationally of 6.89 per 100,000 and 7.03 per 100,000 in Denmark (1, 2). The most commonly

occurring malignant brain tumour is a glioblastoma (GBM) with 51.5% of all malignant brain tumours and is associated with a poor prognosis of a five-year relative survival of 5% (1). The prognosis of 12 to 15 months includes initial surgical intervention; resection or biopsy, followed by 9-10 months standard treatment plan consisting of concomitant chemo/radiation therapy, with subsequently adjuvant chemotherapy of temozolomide (3). Despite this aggressive treatment tumour progression occurs almost inevitably (4).

The diagnosis of a GBM is usually preceded by symptoms such as an epileptic seizure, focal neurological deficits or cognitive changes that tend to alter the patient's functional status(2). Patients often develop a complex symptom burden across various domains of functioning including physical symptoms: aphasia, hemiparesis and psychological symptoms: cognitive deficits, feelings of anxiety, distress, and depressive symptoms. The symptoms may change as tumour progression occurs (5-7). The combination of the rapid onset of the disease, the intense disease- and treatment trajectories, and the uncertainty of the future affect not only the individual but also the persons being close as the informal caregiver, often demanding great caring responsibilities (8, 9). The caregiver burden is described as multidimensional with components affecting caregivers physically, emotionally, socially, and economically (10). Caregivers express being unprepared for the new role and report symptoms of anxiety and depression (4, 9). Additionally, social isolation is often seen as a consequence of the caregiver role and the invisibility of the patients' symptoms frequently lead to withdrawment of support from family and existing network (4, 11). Caregivers emphasize the importance of meeting other caregivers being in similar situations as they can share experiences, and recognize emotions, and concerns in a peer-to-peer environment (12, 13). Peer support may represent an important access to information, advice and practical help for caregivers and address caregivers' individual support needs (12, 14, 15). Caregivers often struggle with being separated from the patient, as they worry about the risk of seizures or cognitive symptoms that necessitate constant supervision, which further underscores the need for support (16). Online access to peer-support and

information may be a valuable tool for caregivers, ensuring their accessibility while being scalable at a national level. Moreover, online support aligns well with International Council og Nurses' recommendation indicating that digital health can address population health needs, strengthen health systems and in response to shortages in the health workforce (17).

Several authors address the lack of longitudinal studies and advocate for ongoing supportive interventions targeting caregivers to patients diagnosed with a brain tumour (10, 18, 19). This need is echoed in international research agendas (20, 21). A systematic review from 2021 concluded feasibility of interventions for people with a brain tumour and their caregivers (14). Moreover, recommending support groups exclusively for caregivers may help fulfil their need for peer support (14, 22). Therefore, this study aims to develop, test, and evaluate the feasibility of a supportive group intervention among caregivers to patients diagnosed with a GBM.

Methods

Design

This study titled a SUpportive GRoup Intervention for caregivers to patients diagnosed with a glioblastoma (SUGRI) is a three-phase study. The overall framework is guided by the British Medical Research Council framework for developing Complex Intervention. This methodological framework entails four main phases of intervention research: development or identification of the intervention, feasibility, evaluation, and implementation (Figure 1) (23, 24). A Patient and Public Involvement (PPI) plan will be carried out throughout all phases of the SUGRI-study guided by The Workbook to guide the development of a Patient Engagement In Research (PEIR) Plan (25).

Figure 1: Complex intervention for the SUGRI-study

Study population and eligibility criteria

The term “caregivers” is in current study defined according to the criteria provided by The National Cancer Institute (26): "*Informal caregiving is broadly defined as services provided by an unpaid person, such as helping with personal needs and household chores, managing a person's finances, arranging for outside services, or visiting regularly. An informal caregiver is usually a relative or friend who may or may not live in the same household as the person with cancer who requires care*.” Inclusion criteria are Family caregivers (≥18 years) to patients (≥18 years) diagnosed with a GBM grade 4 or diffuse astrocytoma grade 4 receiving chemo-radiotherapy treatment. Despite differential terminology of GBM grade 4 and diffuse astrocytoma grade 4 since 2021 (27), the study will include both categories of grade 4 tumours; both are referred to as “GMB” in the protocol. Participants must be able to understand, read, and speak Danish.

Recruitment procedure

Participants will be recruited from the Department of Neuro-oncology at Copenhagen University Hospital in Denmark. We plan to test the intervention nationally and will invite the three other Departments of Neuro-oncology in Denmark at Odense University Hospital, Aarhus University Hospital, and Aalborg University Hospital to participate in the recruitment process. We will apply a purposive sampling strategy and participants will be recruited face-to-face.

Study phases

The exploratory phase

A systematic review will identify and explore available evidence of outcome(s) of supportive group interventions for caregivers to patients diagnosed with a primary brain tumour. To define the group element of an intervention we decided to include "*any kind of intervention, that sought to facilitate some element of interaction between a minimum of two caregivers*". The search will be applied at the following databases: PubMed, Embase, Web of Science, Emcare, Cochrane Library and PsycINFO. Peer-reviewed studies in English, German, or Scandinavian will be included without any time limits. The software program Covidence will support the process of screening (28). Guidance on the conduct of narrative synthesis in systematic reviews will be used to interpret findings (29). To address the quality of the included studies the Mixed Methods Appraisal Tool will be applied (30). To ensure transparency, the PRISMA guideline for Systematic Reviews and Meta-Analyses will be used (31).

The development phase

Patient and Public Involvement

PPI will be central in the development phase, where a national panel of current and bereaved caregivers to patients with a GBM will be established. A panel consisting of 6-12 members, will allow for deeper interaction and a more trusting environment. Members will be recruited nationally through the Danish Brain Tumour Association. The intervention will be developed and designed in collaboration with a panel of caregivers, utilizing Teams as the meeting platform. Online meetings will be scheduled for every second months and one co-creative workshops requiring physical attendance will be planned. The PPI-process will be evaluated through a focus group interview with

the panel members and quantitatively by applying the Patient Engagement In Research Scale (PEIRS-22) to measure the level of meaningful caregiver engagement in the research process (32, 33).

The intervention

The intervention will be conducted online and will encompass two primary components: an informational element and a group-based element. However, the final design of the intervention and how the two central elements will be incorporated has yet to be determined and will be developed through an iterative PPI-process in cooperation with the panel, existing evidence on caregivers needs and preferences. Results from the systematic review from the exploratory phase will also guide det design of the final intervention. The group element will be designed and inspired by existing knowledge of caregiver preferences of a supportive group interventions (11, 22).

The feasibility and evaluation phase

In the third phase, the online intervention will be tested on a new group of caregivers and feasibility will be analysed and evaluated by integration of qualitative and quantitative methods. A sample size of 30 participants is recommended for feasibility trials (34).

Primary objective and endpoints

The primary objective of this study is to evaluate the feasibility of the intervention. Accurate feasibility parameters are dependent on the final study characteristics and will be defined when the intervention is fully designed. We hypothesize that offering caregivers a supportive group intervention will empower them in their role by boosting their perceived support, strengthen their

family function, and help them to identify strategies to navigate the challenges of caregiving, for ultimate benefit of the caregivers and the patients.

Measurements

Secondary outcomes are patient reported outcome (PRO) data completed by caregivers and patients at baseline, post intervention, and follow-up (Table 1). Caregivers will complete the following three questionnaires: The Caregiver Role and Responsibility Scale (CRRS), to assess broad life impacts for caregivers (35), the Iceland-Family Perceived Support Questionnaire (ICE-FPSQ) to measures families perceived support from nurses and other healthcare professionals (36), and the Hospital Anxiety and Depression Scale (HADS) to measure symptoms of anxiety and depression (37). Patients will complete the following three questionnaires: the Functional Assessment of Cancer Therapy - Brain (FACT-Br) to assess the patients' health related quality of life (38), the MD Anderson Symptom Inventory-Brain Tumor Module (MDASI-BT) to measure patients' symptom prevalence, intensity, and interference with the daily life (39) and HADS (37). The questionnaires are presented in Table 1 and will be collected electronically using REDCap. Demographic data of the participants will be completed at baseline and information on patient histology will be obtained from the patient's medical journal and stored in REDCap.

Table 1: Measurement and time assessment for the feasibility study

To explore experiences and evaluate the intervention, semi-structured individual interviews will be carried out with the participating caregivers at post intervention. A semi-structured interview guide will be applied, and data will be audio-taped and verbatim transcribed.

Analysis

Results of the feasibility of the intervention and attainment to final feasibility parameters will be presented separately. Feasibility parameters and secondary outcomes including subscale scores from PROs will be presented using descriptive statistics. Mean change from baseline to later assessment times will be analysed using appropriate statistical methods. PRO data will provide valuable insight into the impact of the caring responsibilities, perceived support and the caregiver role combined with the patient's wellbeing, with a particular emphasis on their emotional and functional challenges. Qualitative interview data will be analysed according to Braun and Clarke's thematic analysis (40, 41) using the program NVivo (42). The interview data will provide the opportunity to evaluate specific elements of the intervention, contributing to a more comprehensive understanding of how different aspects of the intervention impact caregivers. The qualitative and quantitative data will be collected and analysed separately and then merged. In the overall interpretation of the two datasets will be compared, and we will search for potential common patterns (43-45).

Ethical considerations

The study follows The Helsinki Declaration, and the study is registered with the Danish Data Protection Agency (Jr. P-2022-739) and The Ethical Committee at the Capital Region of Denmark (F-24004933). Participants will be enrolled based on oral and written informed consent, which can be withdrawn at any time.

Results

A national panel of caregivers (n=10) has been successfully established, and the final design of the intervention is currently being developed through an ongoing PPI process. Three hospitals in

Denmark have committed to participating in the recruitment for the feasibility study. Recruitment began in April 2025, and the SUGRI-intervention will be evaluated for feasibility in a multicenter study scheduled for autumn 2025.

Discussion

This paper describes a study protocol for a supportive group intervention for caregivers to patients diagnosed with a glioblastoma. Caregiver support within the neuro-oncology field remains suboptimal. Given the diverse nature of caregiver needs—shaped by demographic, course of the disease, and patient symptom burden, future research may benefit from moving beyond standardized approaches and explore the potential of multicomponent interventions (14, 22). The feasibility test of the SUGRI intervention aims to address caregivers' supportive needs through the patient's disease- and treatment trajectory. Moreover, we anticipate the SUGRI intervention to inform how a tailored intervention can be both feasible and meaningful within the context of caregivers' daily lives.

Conclusion

The SUGRI-study will develop, test, and evaluate the feasibility of a supportive group intervention. Only few group-interventions targeting the neuro-oncology caregivers has been carried out and results from the intervention may contribute new internationally relevant knowledge that will improve conditions and care for patients with GBM and their caregivers. Within the Danish context, the intervention represents an important step forward in addressing specific caregiver needs. Providing a supportive group intervention for caregivers has the potential to address their unique needs and strengthen their supportive network. This study provides valuable insights to guide caregiver initiatives, ultimately promoting improved support for caregivers within the neuro-oncology field.

Clinical implications

Family to patients diagnosed with a GBM often assume the caregiver role and take on a great responsibility. The SUGRI-study accepts this fact and assumes caregivers to be not only in need of support, but also to comprise an untapped resource. An online intervention may enhance support for caregivers, offering flexibility and helping to reduce the demand on clinical staff. This approach supports the need for labor-saving technologies to address the nurse shortage and improving care (17). A group intervention has to the best of our knowledge not yet been systematically offered to caregivers of patients with a GBM in a Danish context, and the feasibility and outcome are of greatest interest to the field of neuro oncological caregiver research.

Acknowledgments

We would like to acknowledge our caregiver panel for their valuable cooperation in the SUGRI-project. Moreover, we gratefully acknowledge the established collaboration with the national treatment sites.

Conflicts of Interest

None declared

Study registration

The study is registered in ClinicalTrials.gov (NCT06869577) and the systematic review is registered in PROSPERO (CRD42023392222).

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ORCID

Sara Nordentoft: 0000-0001-5600-2644

Rikke Guldager: 0000-0003-1491-2556

Tiit I. Mathiesen: 0000-0001-9463-1919

Helle Pappot: 0000-0002-3570-5372

Anders Tolver: 0000-0003-1109-9889

Karin Piil: 0000-0001-7972-4674

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Figure 1: Complex intervention for the SUGRI-study

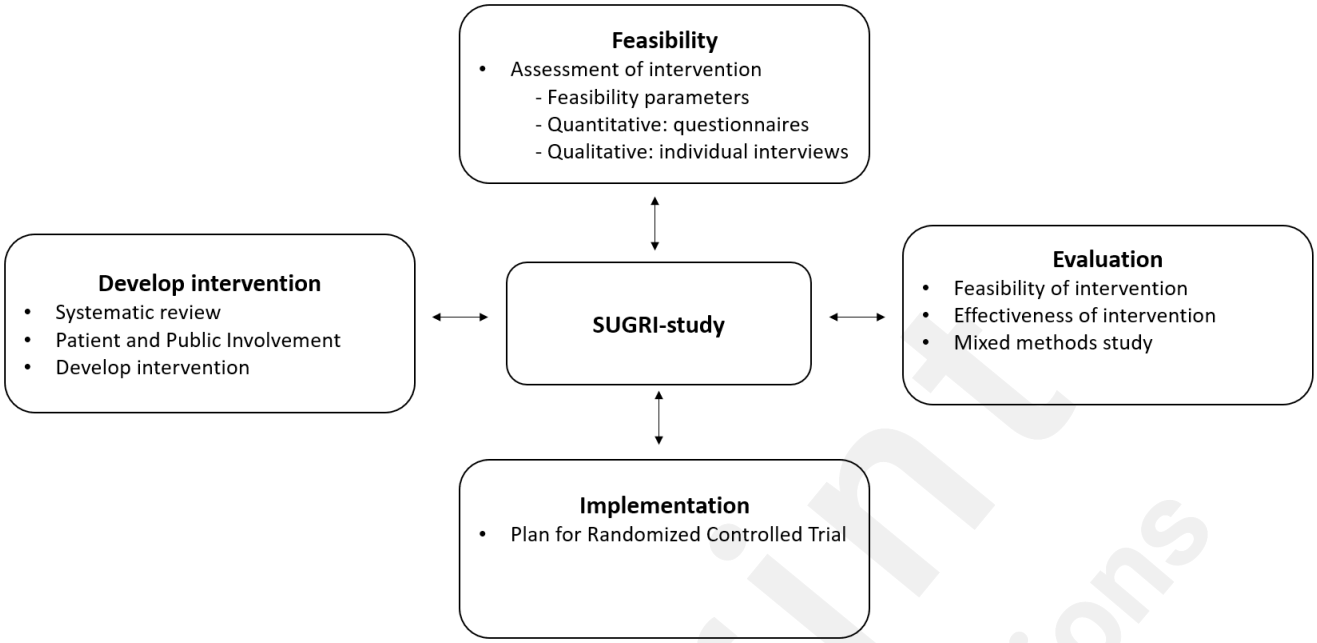


Table 1: Measurement and time assessment for the feasibility study

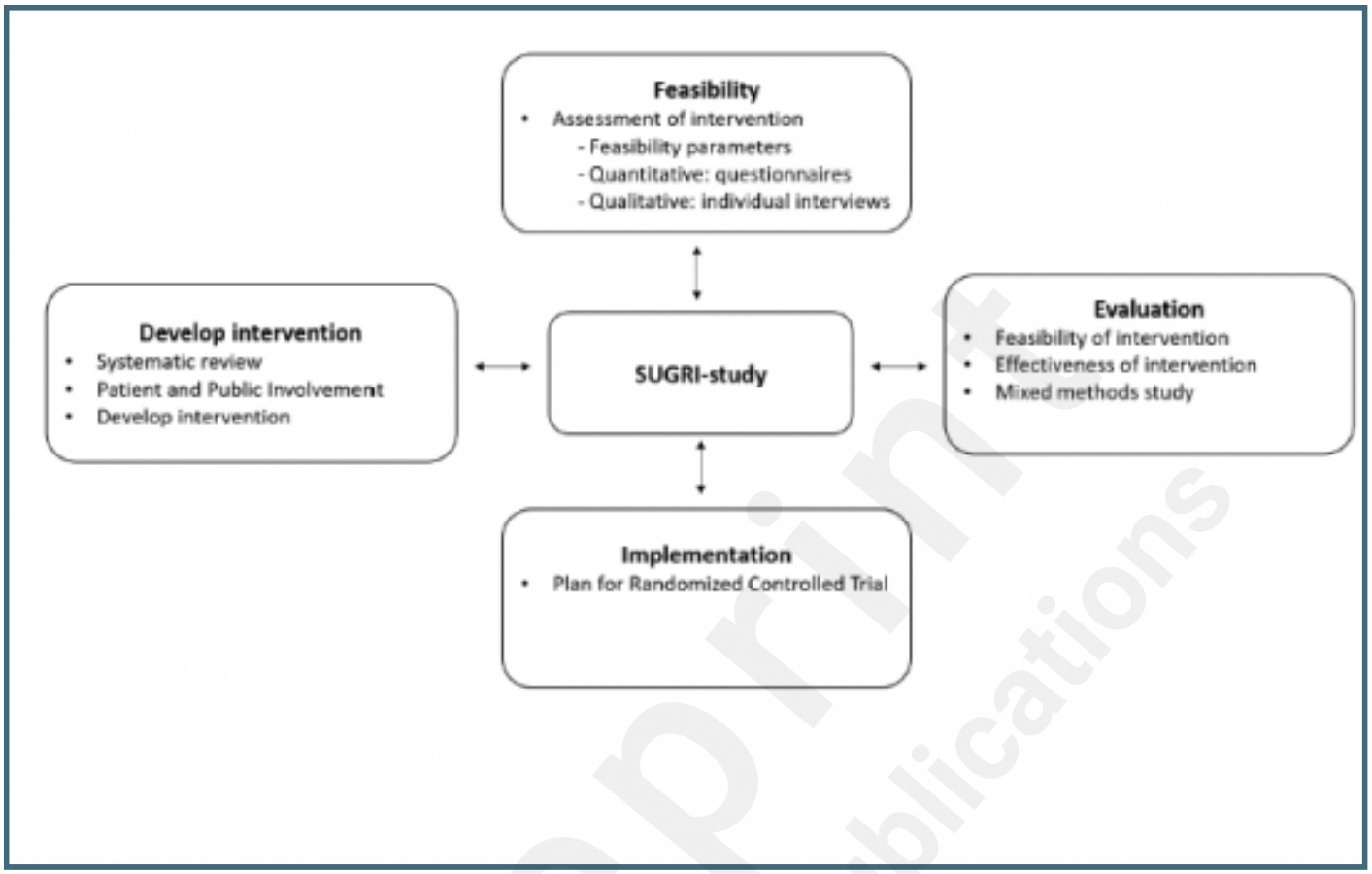
OUTCOME MEASUREMENTS	CAREGIVER			PATIENT		
	T0[1]	T1[2]	T2[3]	T0	T1	T2
QUANTITATIVE						
INFORMED CONSENT	•	•	•	•	•	•
DEMOGRAPHIC DATA	•	•	•	•	•	•
CRRS[4] 41 ITEMS (0-164 POINTS)	•	•	•			
ICE-FPSQ[5] 14 ITEMS (14-70 POINTS)	•	•	•			
HADS[6] 14 ITEMS (0-21 POINTS)	•	•	•	•	•	•
FACT-BR[7] 50 ITEMS (0-200 POINTS)				•	•	•
MDASI-BT[8] 13 CORE CANCER-RELATED SYMPTOMS AND 9 BRAIN TUMOR–SPECIFIC SYMPTOMS (0-220 POINTS)				•	•	•
QUALITATIVE						
SEMI-STRUCTURED INTERVIEW		•				

[1] T0 = Baseline [2] T1 = Post intervention [3] T2 = Follow-up [4] CRRS = The Caregiver Roles and Responsibilities Scale [5] ICE-FPSQ = Iceland-Family Perceived Support Questionnaire [6] HADS = Hospital Anxiety and Depression Scale [7] FACT-Br/EORTC = Functional Assessment of Cancer Therapy – Brain [8] MDASI-BT = MD Anderson Symptom Inventory-Brain Tumor Module • = Assessment of outcome measure

Supplementary Files

Figures

Complex intervention for the SUGRI-study.



Measurement and time assessment for the feasibility study.

OUTCOME MEASUREMENTS	CAREGIVER			PATIENT		
	T0[1]	T1[2]	T2[3]	T0	T1	T2
QUANTITATIVE						
INFORMED CONSENT	•	•	•	•	•	•
DEMOGRAPHIC DATA	•	•	•	•	•	•
CRRS[4] 41 ITEMS (0-164 POINTS)	•	•	•			
ICE-FPSQ[5] 14 ITEMS (14-70 POINTS)	•	•	•			
HADS[6] 14 ITEMS (0-21 POINTS)	•	•	•	•	•	•
FACT-BR[7] 50 ITEMS (0-200 POINTS)				•	•	•
MDASI-BT[8] 13 CORE CANCER-RELATED SYMPTOMS AND 9 BRAIN TUMOR–SPECIFIC SYMPTOMS (0-220 POINTS)				•	•	•
QUALITATIVE						
SEMI-STRUCTURED INTERVIEW		•				

[1] T0 = Baseline
[2] T1 = Post intervention
[3] T2 = Follow-up
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[5] ICE-FPSQ = Iceland-Family Perceived Support Questionnaire
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