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Psychosocial support for partners of patients with haemato-oncological disease - a group-based intervention to empower psychosocial health

Submission date
13/02/2019

Recruitment status
No longer recruiting

Registration date
20/03/2019

Overall study status
Completed

Last Edited
10/04/2024

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Suffering from cancer confronts both the patient and their partner with a number of psychosocial challenges in various aspects of their life. These challenges may differentially impact on quality of life, coping ability and compliance to treatment. This especially holds true for haemato-oncological diseases (blood cancer). To date, psychological interventions have predominantly been developed for oncological (cancer) patients but specific interventions for partners of haemato-oncological patients are rare. In this study the aim is to conduct a psycho-oncological group intervention for partners of patients with haemato-oncological diseases. The aim of the intervention is to significantly reduce symptoms of depression and anxiety in the partners and the patient, as well as enhancing dyadic coping.

Who can participate?
Patients with haemato-oncological diseases and their partners, both aged 18 to 70

What does the study involve?
Participants are randomly allocated to the intervention group or to the control group. The intervention group attend the INPART program created specifically for this study. It is a mixed intervention consisting of psychoeducational, cognitive-behavioural and imaginative elements. At the end of the group phase each participant gets the chance for one or two individual psychotherapy sessions in order to face specific problems. Planned topics are: the individual handling of depression and anxiety, stress management, conflict training and managing difficult situations within the dyad (sexuality, communication problems). The program comprises of 5 weekly sessions lasting 1.5 hours and additional home practice assignments. Groups consist of 6 to 8 participants. A presentation via Microsoft PowerPoint supports the structure of the course. In each session the participants receive material supporting the actual topic, a folder containing further information and home practice instructions for the forthcoming week.
The control group receives one structured psycho-oncological consultation (control condition /care as usual), which is regularly conducted by trained psycho-oncologists. The duration of the

consultation is about 30 minutes. Example issues discussed consist of the role of partner within the course of the illness including their own specific burdens and possibility of support. In addition they receive a freely accessible booklet from the German Cancer Aid associated to their specific oncological disease. Depression and anxiety are assessed at the start of the study (before the intervention), and 3 months and 6 months later.

What are the possible benefits and risks of participating?
Depressive and anxiety symptoms may be reduced and dyadic coping (for partner and patients) may improve. No risks of such types of study are known.

Where is the study run from?
It will be conducted at three study centres in Germany: the university medical centres in Leipzig, Hannover and Ulm.

When is the study starting and how long is it expected to run for?
August 2019 to July 2022

Who is funding the study?
José Carreras Leukemia Foundation (Germany)

Who is the main contact?
Dr Jochen Ernst
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DJCLS 23R/

Study information

Scientific Title
Psycho-oncological intervention for partners of patients with haemato-oncological disease

Acronym
INPART

Study objectives
Principal hypothesis: A manualized group psychotherapy to treat clinically significant depressive and anxiety symptoms in partners of cancer patients with haemato-oncological disease will result in a greater reduction of depression and anxiety symptoms than in a control treatment of usual intervention (expected effect size ≥ 0,30) at three (t1) and six months (t2) after commencing intervention. In addition, the INPART program will lead to significant better DC. Secondary hypotheses: The INPART intervention will result in better quality of life, better quality of the relationship and more self-efficacy than the control intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee of the University of Leipzig, Geschaftstelle der Ethik-Kommission an der Medizinischen Fakultat der Universitat Leipzig, Karl-Sudoff-Institut fur Geschichte der Medizin und der Naturwissenschaften, Kathe-Kollwitz-Str. 82, 04109 Leipzig, Tel: +49 (0)341 97 15490, Email: ethik@medizin.uni-leipzig.de, 22/11/2016, ref: NR. 373/16ek

Study design
Randomized controlled multi-centre trial with two parallel groups

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Haemato-oncological diseases

Interventions
Participants will be either assigned to the intervention group (IG) or to the control group (CG). T1 is 3 months after the start of the intervention. Directly after the intervention, before t1, subjects of the intervention group will have the possibility of one additional single session in order to talk about individual topics/problems (i.e. hope, death and loss). Subjects of the control group will be treated as usual (optional unspecific contacts with a psycho-oncologist). At all assessments partners and patients are asked to fill out the questionnaires.

Intervention: The INPART program was created specifically for this study. It is a mixed intervention consisting of psychoeducational, cognitive-behavioural and imaginative elements. The decision, on which contents were to be included in the program, were based on research on the supportive care needs questionnaire for informal caregivers of cancer patients and cancer survivors. At the end of the group phase each participant will get the chance for one or two individual psychotherapy sessions in order to face specific problems. Planned topics are: the individual handling of depression and anxiety, stress management, conflict training and

managing difficult situations within the dyad (sexuality, communication problems). The program comprises of 5 weekly sessions lasting 1.5 hours and additional home practice assignments. Groups consist of 6 to 8 participants. A presentation via Microsoft Powerpoint supports the structure of the course. In each session the participants receive material supporting the actual topic, a folder containing further information and home practice instructions for the forthcoming week.

The control group receives one structured psycho-oncological consultation (control condition /care as usual), which is regularly conducted by trained psycho-oncologists.The duration of the consultation is approximately 30 minutes. Example issues discussed consist of the role of partner within the course of the illness including their own specific burdens and possibility of support. In addition they will receive a freely accessible booklet from the German Cancer Aid associated to their specific oncological disease.

Intervention Type
Other

Primary outcome(s)
1. Depression measured using the PHQ-9 (Patient Health Questionnaire) at Screening, Baseline (prior to intervention), 3 months and 6 months later
2. Anxiety measured using the GAD-7 (Generalization Anxiety Disorder Scale) at Baseline (prior to intervention), 3 months and 6 months later

Key secondary outcome(s))
Measured prior to intervention, 3 months and 6 months later:
1. Quality of life, measured using Health Survey 12 (SF-12)
2. Fatigue, measured using Brief Fatigue Inventory (BFI)
3. Dyadic coping, measured using Dyadic Coping Inventory (DCI)
4. Attachment in close relationship, measured using Experience in close Relationships-Revised (ECR-RD)
5. Locus of control, measured using Internal, Powerful Others, and Chance Scale (IPC)

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Patients who are diagnosed with a confirmed haematological neoplasia: incidences up to one year after diagnose or relapse, ICD-10 diagnoses: C81-C96 and D46, which are: Hodgkin’s lymphoma, Non-Hodgkin’s lymphoma, multiple myeloma, myelodysplastic syndrome, acute or chronic leukaemia
2. Patients who have a partner
3. Patients and partners need to be aged between 18 and 70 years
4. Partners must be mentally and physically able to attend the program
5. Treatment modality and phase of illness is negligible for participation
6. Partners will be assigned to one of two study groups, given that PHQ-9 > 9 (depression) and GAD-7 > 9 (anxiety)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Severe psychiatric disorders
2. Profound cognitive and physical impairment
3. An age limitation of 70 years aimed to minimise possible age-related comorbidities or mobility limitations

Date of first enrolment
01/09/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Germany

Study participating centre
Department of Medical Psychology and Medical Sociology, University Medical Center Leipzig
Philipp-Rosenthal-Straße 55
Leipzig
Germany
04103

Study participating centre
Comprehensive Cancer Center Ulm
Albert-Einstein-Allee 23
Ulm
Germany
89081

Study participating centre

Department of Psychosomatic Medicine and Psychotherapy, Hannover University Medical School
Carl-Neuberg-Straße 1
Hannover
Germany
30625

Sponsor information

Organisation
José Carreras Leukemia Foundation

ROR
https://ror.org/00826gz80

Funder(s)

Funder type
Charity

Funder Name
José Carreras Leukemia Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/09/2019	10/04/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes