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Turn sepsis to life!

Submission date	Recruitment status	[_] Prospectively registered
25/02/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/05/2021	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01 E0 1002

Study information

Scientific Title
Sepsis survivors monitoring and coordination in outpatient health care: a randomised, multicentre, prospective, two-armed intervention study

Acronym

Smooth

Study objectives
Health-related quality of life of survivors of severe sepsis or septic shock can be improved significantly after six months by application of a specific Disease Management Program

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of Jena University Hospital, approval No. 3001-01/11 - Pending

Primary study design
Interventional

Study design
Randomised multicentre prospective two-armed intervention study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Severe sepsis or septic shock

Interventions
Patients of the intervention group will receive for 12 months in total a specific Disease Management Program, consisting of discharge management, patient monitoring for main sepsis complications and education of patients and treating family physicians in sepsis sequelae.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Health-related quality of life
2. Physical Health Summary Scale (SF-36 Patient survey) after 6 months

Key secondary outcome(s)
1. Health-related quality of life
2. Physical Health Summary Scale (SF-36 Patient survey) after 12 and 24 months
3. Physical activity (XSMFA-D - Patient survey)
4. Patient adherence (Moriskey Patient survey)
5. Process of care (PACIC (Patient Assessment of Care for Chronic Conditions - patient survey)
6. Death for any reason
7. Number of readmissions for any reason
8. Number of hospital days for any reason (GP/post-sepsis-center documentation)
9. Numbers of contacts to GP (GP documentation)
10. Numbers of contacts to specialists (GP documentation)
11. Days on which patient is unfit to work (GP documentation)

12. Medication (PZN and modus Patient survey/GP/post-sepsis-center documentation)
13. Cognitive function (TICS-M (Telephone Interview of Cognitive Status) (Patient survey)
14. Nutritional status (MUST (Malnutrition Universal Screening Tool GP documentation (Patient survey)
15. Chronic pain (GCPS (Graded Chronic Pain Scale) (Patient survey)
16. Neuropathic symptoms (NSS (Neuropathie-Symptom Score) (Patient survey)
17. Post traumatic stress syndrom symptoms (PTSS-10 (Post-Traumatic Stress Syndrome, 10 Questions Inventory (Patient survey)
18. Depressive symptoms (MDI (Major Depression Inventory) (Patient survey)
19. Body perception (DKB (Dresdner Körperfragenbogen) (Patient survey)
20. Attachment pattern (ECR-S (Experiences in Close Relationsship Scale Short form)
21. Insomnia symptoms (RIS (Regensburger Insomniebogen) (Patient survey)
22. ADL (instrumental) activities of daily life (Patient survey)
23. Smelling, hearing, degustation dysfunction (Patient survey)
24. Medication use (KFM (Kurzfragebogen zum Medikamentengebrauch) Patient survey)

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Survivors of severe sepsis or septic shock (ICD-10: A41)
2. At least two systemic inflammatory response syndrome (SIRS) criteria
3. At least one organ dysfunction
4. Adults
5. Sufficient German language skills
6. Patients have primary care provider

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Dementia (TICSM < 27)
2. Guardianship before sepsis
3. Nursing home residents
4. Severe language/speech disorder
5. Deaf or blind patients

Date of first enrolment
28/02/2011

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Jena
Jena
Germany
D-07743

Sponsor information

Organisation
German Federal Ministry of Education and Research (BMBF) (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung (Grant no. 01 E0 1002)

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Center of Sepsis Control & Care (CSCC) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/06/2016		Yes	No
Protocol article	protocol	11/07/2014		Yes	No
Other publications	post hoc analysis of depressive symptoms	29/04/2021	05/05/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes