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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

Study website
http://www.allgemeinmedizin.uni-jena.de/content/research/smooth/index_eng.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised multicentre prospective two-armed intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
28/02/2011

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

Age group
Adult

Sex
Both

Target number of participants
290

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)

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Friedrichstraße 130 B
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Sponsor type
Government

Website
http://www.bmbf.de/en/index.php

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 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	11/07/2014		Yes	No
Results article	results	28/06/2016		Yes	No
Other publications	post hoc analysis of depressive symptoms	29/04/2021	05/05/2021	Yes	No