

Turn sepsis to life!

Submission date 25/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/04/2011	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 05/05/2021	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

Contact name

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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 Relationship 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)

Sponsor details

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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