

Effectiveness of a collegial consultation procedure to improve in-patient care - a pragmatic cluster randomized controlled trial

Submission date 16/11/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/07/2022	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Particularly in the course of life-threatening illnesses (e.g. stroke, myocardial infarction, chronic obstructive pulmonary disease) longer ventilation can be necessary. Generally the duration and the amount of ventilation hours has been increasing. With increasing patient age the duration of ventilation procedures rises as well. The aim is to find and prevent potential errors and improve in-hospital quality regarding this high-risk procedure. Due to the association between ventilation, life-threatening illnesses and age of patients there is a risk of a high patient mortality (death rate) while performing ventilation for over 24 hours. The aim of this study is to find out whether the mortality of patients who were ventilated for over 24 hours improves due to an organized collegial consultation ("Peer-Review").

Who can participate?

Hospitals in Germany that are members of the Association Initiative Quality in Medicine and that treated 10 patients in 2016 who were ventilated for over 24 hours

What does the study involve?

Hospitals with the highest in-hospital deaths of patients who were ventilated for over 24 hours are randomly allocated into two groups. The intervention group gets a standardized peer review about ventilation from educated peers from a different hospital in the IQM network. The control group does not get a peer review. Participating hospitals that are not categorized to the highest in-hospital mortality of ventilated patients are allocated to observation only. The in-hospital mortality of patients who receive ventilation for over 24 hours is compared between the groups one year before and one year after the peer-review procedure.

What are the possible benefits and risks of participating?

Benefits include a possible reduction of in-hospital death rates due to better quality of care for the high-risk group of ventilated patients.

Where is the study run from?

Center for Evidence-based Healthcare (Germany)

When is the study starting and how long is it expected to run for?
January 2017 to September 2019 (updated 13/07/2020, previously: June 2019)

Who is funding the study?
Innovation fund of the Joint Federal Committee (Germany)

Who is the main contact?
Mr Felix Walther
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Study website

<https://innovationsfonds.g-ba.de/projekte/versorgungsforschung/impress-effektivitaet-des-iqm-peer-review-verfahrens-zur-verbesserung-der-ergebnisqualitaet-ein.13>

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01VSF16013

Study information

Scientific Title
Effectiveness of the "IQM"-Peer-Review-Procedure to improve in-patient outcome-quality - a pragmatic cluster-randomized controlled trial (IMPRESS)

Acronym

IMPRESS

Study objectives

The IMPRESS Study evaluates a complex quality-intervention on the basis of a cluster-randomized controlled trial. This trial primarily aims to investigate if outcome-quality (mortality) improves due to a (IQM)-peer-review procedure. The "Association Initiative Quality in Medicine" (IQM) is a non-profit-organization with optional membership of German or Swiss acute care hospitals. IQM is an interhospital community which serves as the basis for communication and improvement of inpatient-healthcare quality. The IQM-peer-review-intervention is a standardized, structured collegial case-discussion and consultation of specially trained healthcare professionals. The goal of this intervention is to identify and eradicate error-potentials in structure and/or processes of care and to eventually improve in-house-quality. Observational studies suggest effectiveness of the peer review procedure, but controlled investigations are missing.

Hypothesis: The IQM-Peer-Review Procedure, a standardized collegial consultation procedure, improves in-patient care and decreases in-patient mortality of patients ventilated >24h.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee TU Dresden; registered at institutional review board (IRB): Office for Human Research Protections (OHRP); identification numbers: IRB00001473 and IORG0001076; Date of approval: 24/04/2017

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Primary: ventilation >24h

Secondary: stroke, heart attack, COPD, pneumonia, colorectal resection

Interventions

The IMPRESS study is a two-armed cluster-randomized controlled intervention trial embedded in a prospective hospital-cohort study. 385 IQM-member-hospitals from Germany are invited to participate. 60 hospitals with the highest in-hospital-mortality of patients who were ventilated >24h are randomized into equally sized intervention group (receiving peer review consultation) and control group (standard care). The randomization procedure followed a block-randomization with a constant block-length of 10 clinics per block. The study coordination of the Center for evidence-based healthcare, TU Dresden developed the randomization list. To build balanced groups the participating hospitals will be stratified according to the number of patients/year (median-split) and hospital ownership (public, private, non-profit, university hospital).

Within 4 months after randomization the intervention group gets one standardized peer-review (intervention) regarding ventilation structures and processes through educated peers from a different hospital in the IQM network between the 06/01/2017 and 12/31/2017. The control group will not get any peer-review intervention regarding ventilation procedures between the 06/01/2017 and 12/31/2017. Participating hospitals which are not categorized to the highest in-hospital mortality of patients who were ventilated >24h will not be randomized and will be assigned to the observation group.

To secure high data quality and safety the data-processing and data-analyzing sites are separated. The data analysts are blinded/masked to the allocated group of hospitals. Two analyses are planned. First, in the confirmatory analysis the primary outcome will be evaluated. Second, the explorative analysis will evaluate the secondary outcomes. Every participating hospital of intervention, control or observational group will be analyzed for the years 2016, 2017 and 2018.

Intervention Type

Other

Primary outcome measure

Age- and sex-adjusted mean inpatient mortality rate of hospitals in the intervention or control group within one year before (baseline) and one year follow-up after the peer-review procedure (post-intervention). The primary outcome is measured for patients who receive ventilation >24h

Secondary outcome measures

Age- and sex-adjusted mean inpatient mortality rate of every participating hospital regardless of observation, intervention or control group in 2016, 2017 and 2018. The secondary outcome is measured for patients who receive ventilation >24h and colorectal resection or patients with myocardial infarction, stroke, COPD and pneumonia, respectively. For all analyses the unit of analysis is the hospital, not the individual patient.

Overall study start date

01/04/2017

Completion date

30/09/2019

Eligibility

Key inclusion criteria

Hospital:

1. Member of the Association Initiative Quality in Medicine

2. Located in Germany
3. Treating 10 patients in 2016 who were ventilated > 24h
4. Consented into the study in the written form

Participant type(s)

Other

Age group

Other

Sex

Both

Target number of participants

All IQM member hospitals (N=385) were invited to participate. 237 hospitals applied to participate into the 3-armed study: 1) 30 intervention-hospitals 2) 30 control-hospitals 3) 177 observation arm

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/2017

Date of final enrolment

01/04/2017

Locations**Countries of recruitment**

Germany

Study participating centre

Center for Evidence-based Healthcare

Fetscherstraße 74

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Sponsor information**Organisation**

German Research Centre for Air and Space Travel (DLR)

Sponsor details

Heinrich-Konnen-Str. 1
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Sponsor type

Government

ROR

<https://ror.org/04bwf3e34>

Funder(s)

Funder type

Government

Funder Name

Innovation fund of the Joint Federal Committee

Results and Publications

Publication and dissemination plan

A publication in high impact-peer-reviewed journals is planned. The aim is to fully publish the results of confirmatory and exploratory analysis by 06/01/2020.

Intention to publish date

06/01/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The transfer and use of hospital-accounting data of every hospital underlies the German medical data protection laws due to a patient-relevance and an anonymization and its transfer is strictly bounded to the use of the IMPRESS study due to the patient-relevant details and is guaranteed in the participant (hospital) information sheet. This highly sensitive data is held in a separate position/ organization of trust which will aggregate and anonymize the data. After this process the Center for Evidence-based healthcare will get the data for the realization of the confirmatory and exploratory analysis.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/07/2022	26/07/2022	Yes	No