

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Psychologically optimised hand hygiene promotion (PSYGIENE): a cluster-randomised trial

Trial Acronym

PSYGIENE

URL of the trial

<https://www.mh-hannover.de/medpsycho-projekte.html>

Brief Summary in Lay Language

In the PSYGIENE-study, psychologically optimised interventions to promote hand hygiene of physicians and nurses to prevent nosocomial infections are examined in a situation in which on the 10 intensive care and two hematopoietic stem cell transplantation units at Hannover Medical School (MHH), compliance (i.e. following hand hygiene rules) have decreased after initial successes of the nation- and MHH-wide German "Clear Care is Safer Care"-campaign (ASH), which had been implemented since 2008. In this relapse situation, psychological factors relevant for compliance, such as individual beliefs and action plans, are identified on the aforementioned 12 wards and analysed in terms of strengths and weaknesses on six of the wards. In 2013, on these six wards feedback discussions with ward managers and educational sessions for physicians and nurses are tailored with regard to the wards' strengths and weaknesses, and implemented. On the other six wards, the standard ASH-campaign is implemented. It is assumed that the tailored interventions would lead to higher and more sustainable rebounds in hand hygiene compliance.

Brief Summary in Scientific Language

Hand hygiene (HH) is considered to be the most effective measure to prevent nosocomial infections (NI). At the same time, surveillance data show that even on intensive care units (ICU), which are affected by the highest NI-rates (prevalence in Germany: 19%, at Hannover Medical School [MHH]: 28%), compliance is suboptimal. Also, there is a lack of knowledge on how to deal with relapses such as those experienced on the 10 ICU and two hematopoietic stem cell transplantation units at MHH after initial successes of the German "Clean Care is Safer Care"-campaign (ASH). The PSYGIENE-study, funded by the German Federal Ministry of Health (project-ID: INFEKT-019), analyses whether interventions tailored to wards based on the Health Action Process Approach (HAPA) lead to (more) sustainable rebounds of hand hygiene compliance. In a cluster-randomized controlled trial, problem-focused interviews with responsible ward physicians and head nurses and a written questionnaire survey are conducted and, on the basis of these HAPA-data, education sessions for physicians and nurses and feedback discussions with ward managers tailored to and implemented on six of the

aforementioned wards. In the active control arm with the other six wards, the standard ASH is implemented. Compliance observations adhere to WHO-/ASH-standards. Compliance rates in 2014 and 2015 are the primary endpoints.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00010960**
- Date of Registration in DRKS: **2016/08/19**
- Date of Registration in Partner Registry or other Primary Registry: **2016/08/18**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **1434-2012 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

Health condition or Problem studied

- Free text: **Nosocomial infections**

Interventions/Observational Groups

- Arm 1: **Psychologically tailored feedback discussions with management personnel and education sessions with physicians and nurses of six intensive care/haematopoietic stem cell transplantation units at Hannover Medical School, using behaviour change techniques (tailoring based on empirically assessed factors relevant for hand hygiene compliance according to the Health Action Process Approach).**
- Arm 2: **German "Clean Care is Safer Care"-campaign (educational sessions for physicians and nurses of of six intensive care/haematopoietic stem cell transplantation units at Hannover Medical School)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Ward-specific hand hygiene compliance rates 2014-2015: Hand hygiene compliance with guidelines based on WHO-concept "Five Moments for Hand Hygiene), assessed using the German translation of the respective observation sheet (German Clean Care is Safer Care-campaign) by internally trained nurses and hygiene specialists (in training) during specific time slots in the course of each calendar year.

Secondary Outcome

Changes in ward-specific hand hygiene compliance rates (assessments see above, Primary outcome) over time, and multiresistant pathogens (colonisations and infections), assessed following the procedures defined by the German nosocomial infection surveillance system (KISS).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Hochschule Hannover, Hannover**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/06/08**
- Target Sample Size: **1087**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Employed or working as physician or nurse on one of the study wards.

Exclusion criteria

None

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/02/11**

Trial Publications, Results and other documents

- Paper **von Lengerke T, Lutze B, Krauth C, Lange K, Stahmeyer JT, Chaberny IF. In Reply [Correspondence]. Dtsch Arztebl Int 2017;114(18):329**
- Paper **von Lengerke T, Lutze B, Krauth C, Lange K, Stahmeyer JT, Chaberny IF. Promoting hand hygiene compliance: PSYGIENE—a cluster-randomized controlled trial of tailored interventions. Dtsch Arztebl Int 2017; 114(3):29-36**
- Paper **Stahmeyer JT, Lutze B, von Lengerke T, Chaberny IF, Krauth C. Hand hygiene in intensive care units: a matter of time? J Hosp Infect 2017;95(4):338-43**
- Paper **Lutze B, Chaberny IF, Graf K, Krauth C, Lange K, Schwadtke L, Stahmeyer J, von Lengerke T. Intensive care physicians' and nurses' perception that hand hygiene prevents pathogen transmission: Belief strength and associations with other cognitive factors. J Health Psychol 2017;22(1):89-100**
- Paper **von Lengerke T, Lutze B, Graf K, Krauth C, Lange K, Schwadtke L, Stahmeyer J, Chaberny IF. Psychosocial determinants of self-reported hand hygiene behaviour: a survey comparing physicians and nurses in intensive care units. J Hosp Infect 2015;91(1):59-67**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.