ISRCTN25430066 https://doi.org/10.1186/ISRCTN25430066

Impact of using a device providing individual feedback on healthcare workers' hand hygiene behaviour

Submission date
17/05/2017

Recruitment status
No longer recruiting

Registration date
22/05/2017

Overall study status
Completed

Last Edited
15/06/2023

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Healthcare-associated infections (HAI) are a major public health problem, with an estimated hundreds of millions of new episodes occurring annually worldwide. They affect approximately 7% and 10% of all hospitalised patients in developed and developing countries, respectively, and are responsible for millions of deaths worldwide each year. Around 50-70% of HAI are due to healthcare workers (HCWs)' lack of proper hand hygiene (HH). Proper HH is one of the most efficient methods to prevent HAI. For this reason, the World Health Organization (WHO) recommends a Multimodal Strategy with five elements to improve HH practices in the healthcare setting. In that list, recommendation number three (performing observation of HH practices and providing timely performance feedback) is one of the most challenging because evaluating HH practices by direct observation is a time-consuming and costly task. An electronic device intended to continuously monitor HH practices and to provide a real-time feedback to healthcare workers could be very useful. The aim of this study is to identify the effectiveness of using a new device providing automatic, immediate and personal feedback regarding the quality of hand hygiene gesture in promoting HH compliance amongst HCWs performing patient-care activities, as well as in enhancing the quality of the HH action.

Who can participate?
Health care workers aged 20 to 65 working in patient-care activities

What does the study involve?
Health care workers (grouped as units) are randomly assigned as to when they start the programme. Participants are given a device that is worn on their wrist and an pocket sized alcohol based hand rub (ABHR) with a clip that provides personal, automatic and individualised feedback on their hand hygiene quality. The first part of the study participants use standard methods of hand hygiene (they do not wear the device). The second phase of the study they use the device but do not get feedback on the quality of their hand hygiene. The last phase of the study they use the device and receive feedback about their hand hygiene practices. Throughout the study periods they perform their daily activities and are observed to see if hand hygiene compliance is improved by the use of the device.

What are the possible benefits and risks of participating?
Participants may benefit from having personalised and individual feedback regarding their hand hygiene practices and may benefit from the improvement of hand hygiene compliance and the quality of each hand hygiene action. There are no notable risks with participating.

Where is the study run from?
University of Geneva Hospitals and Faculty of Medicine (Switzerland)

When is the study starting and how long is it expected to run for?
April 2015 to February 2018

Who is funding the study?
Swiss National Science Foundation (Switzerland)

Who is the main contact?
Professor Didier Pittet
Didier.pittet@hcuge.ch

Contact information

Type(s)
Public

Contact name
Prof Didier Pittet

Contact details
Service Prévention et Contrôle de l'Infection
Hôpitaux Universitaires de Genève
Rue Gabrielle-Perret-Gentil 4
Geneva
Switzerland
1211
+41 22 372 9833
didier.pittet@hcuge.ch

Additional identifiers

Protocol serial number
32003B_163262

Study information

Scientific Title
Impact of using a device providing individual feedback on healthcare workers' hand hygiene behaviour: A stepped wedge cluster-randomized clinical trial

Acronym
SmartRub

Study objectives
Study aim:
The aim of this study is to identify the effectiveness of using a new device providing automatic, immediate and personal feedback regarding surrogate markers of hand hygiene (HH) action quality (volume and duration of hand friction) during each hand hygiene gesture in promoting HH compliance amongst healthcare workers (HCWs) performing patient-care activities, as well as in enhancing the quality of HH action.

Hypothesis:
Compliance with HH amongst HCWs may be improved by at least a relative 20%, from baseline to intervention, if they receive a continuous feedback about the quality of their hand hygiene gesture during daily patient care when using the hand hygiene device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Research Ethics Committee (CCER), Geneva, Switzerland, 08/06/2016, ref: (2016-00714).

Study design
Stepped wedge cluster-randomised controlled open-label single-center clinical trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Hand hygiene

Interventions
Participants are given an electronic device in the form of a wrist band, and a pocket-size individual bottle of alcohol based hand rubs (ABHR) with a “clip” inside that provides a personal, automatic and individualised feedback on hand hygiene quality surrogate markers to HCWs. This device was developed at the University of Geneva Hospitals and Faculty of Medicine in cooperation with the School of Engineers of Geneva.

In the designed stepped wedge study, the clusters (units) are randomly and sequentially rolled out from baseline, to a fixed transition period of one month and followed by the intervention period. The length of the time-points is one month and the study has 4 steps.
Random block randomisation of units is done. Hand hygiene observers and participants are blinded regarding allocation of units until the device delivery.

Step 1: This step consists of a baseline period of one month, a transition period of one month and the intervention period of four months.
Step 2: This step consists of a baseline period of two months, a transition period of one month and the intervention period of three months.
Step 3: This step consists of a baseline period of three months, a transition period of one month

and the intervention period of two months.
Step 4: This step consists of a baseline period of four months, a transition period of one month and the intervention period of one month.

The baseline period there is no intervention, as it corresponds to standard of practices (therefore no device is in use). In the transition period HCWs use the device, but they do not receive any feedback about their correct practices. In the intervention period HCWs use the device that provides them with feedback about how well they are doing with their hygiene compliance.

Throughout all the study periods HCWs perform their daily activities and are observed regarding their compliance with hand hygiene. This study will be conducted at the Geriatric Hospital, one of the 8 sites of HUG. In 2018, we aim to perform a larger study to test the device in the acute care hospital sites of HUG.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Hand hygiene compliance is measured by direct observation by well-trained IPC professionals according to the WHO methodology at the individual HCW level at six time-points (once a month) in the three study periods (baseline, transition period and intervention).

Key secondary outcome(s))
1. Hand hygiene quality is assessed using volume of ABHR poured by HCWs and duration of handrubbing in each HH action using the device collecting automatic and continuous data
2. Frequency of hand hygiene is measured using the device collecting automatic and continuous data
3. Adherence to hand hygiene device is measured using how many hours the device is used by HCWS using the device collecting automatic and continuous data
4. Hand hygiene compliance at follow-up is measured by direct observation by well-trained IPC professionals to assess for the sustainability of the intervention at three month follow up
5. Hand hygiene compliance and alcohol-based handrub consumption at a unit level is measured using the HH compliance data is recorded on a regular basis by the IPC professionals and ABHR consumption is provided monthly by the pharmacy
6. Satisfaction and perception of usefulness of the device by HCWs is measured using a questionnaire distributed to participants and some focus group discussions with HCWs participating in the study to evaluate their experience with the device use at the end of the intervention
7. Hand hygiene quality and HH compliance among HCWs working in several units during the study period. This is done as a sub-study with HCWs that are willing to participate but that are excluded from the main study due to working in several units (meaning that they can’t be allocated to a cluster). This group of HCWs receives the device only in the fifth month of the study, when all the units have already started the study intervention, to avoid contamination. These HCWs data does not contribute to the primary outcome analysis.

8. Adverse events related to the device are measured using a list of open responses (ie., skin irritation, injury to patient, etc) asked to participants after each HH session
9. Bloodstream infections (BSI) surveillance are measured using the data routinely and prospectively collected by the IPC program in order to analyse if there is a change in incidence of BSI in the units during the study period

Completion date
28/02/2018

Eligibility

Key inclusion criteria
Units inclusion criteria:
All units are eligible to participate in the study.

HCWS inclusion criteria:
1. All HCWs working in patient-care activities
2. Aged between 20 to 65

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
97

Key exclusion criteria
Units exclusion criteria:
Units without patient-care activities.

HCWs exclusion criteria:
1. Work or will work in several different units during the six months after study start
2. Who will leave the unit in the six months after study start
3. Who have more than three consecutive weeks of vacations in the six months after the study start
4. Who don’t use the standard ABHR at HUG

Date of first enrolment
01/06/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Geneva Hospitals and Faculty of Medicine
Rue Gabrielle-Perret-Gentil 4
Geneva
Switzerland
1211

Sponsor information

Organisation
University of Geneva Hospitals and Faculty of Medicine

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Research council

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	09/02/2021	Yes	No
Basic results		15/11/2019	15/11/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (other)			15/06/2023	No	No