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Impact of using a device providing individual feedback on healthcare workers hand hygiene behaviour - phase II

Submission date 08/11/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/11/2019	**Overall study status** Completed	
Last Edited 20/11/2019	**Condition category** Other	

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 about 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 HAIs 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 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 enhancing the quality of their 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 in units) are randomly assigned as to when they receive the intervention. Participants are given a device that is worn on their wrist and a pocket-sized alcohol-based hand rub (ABHR) with a clip that provides personal, automatic and individualized feedback on their hand hygiene quality. This is the second phase of a study performed in 2017 registered with the number ISRCTN25430066.

What are the possible benefits and risks of participating?
Participants may benefit from having personalized and individual feedback regarding their hand hygiene practices and may benefit from the improvement of 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?
November 2019 to October 2020

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

Who is the main contact?
Prof. Didier Pittet
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
32003B_163262 II

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 - phase II

Acronym
SmartRub

Study objectives
The researchers hypothesize a 20% absolute increase in the number of healthcare workers (HCWs) performing at least 60% of correct hand hygiene actions if they receive continuous feedback about their hand hygiene action performance.
A correct hand hygiene action is defined as the use of at least 80% of the customized volume of alcohol-based hand rub and the performance of hand friction for at least 12 seconds.

This is the second phase of a study performed in 2017 registered with the number ISRCTN25430066.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2016, Regional Research Ethics Committee (Commission canonale d'éthique de la recherche [CCER], Rue Adrien-Lachenal 8 1207, Geneva, Switzerland; Tel: +41 (0)54 65 101; Email: ccer@etat.ge.ch), ref: 2016-00714

Study design
Stepped-wedge cluster-randomized (1:1:1:1) controlled open-label clinical trial
Primary outcome will be assessed at the HCW level (closed cohort)

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
The intervention is an electronic device in the form of a wrist band and a cylinder added into a pocket-size individual bottle of alcohol-based hand rub (ABHR) that measures the duration of hand friction and volume of ABHR used in each hand hygiene gesture and provides a personal, automatic and individualised feedback on those parameters.

A stepped wedge trial was designed where clusters (wards) will be randomly and sequentially rolled out from a fixed pre-baseline (no device: 1 month), to the baseline (device without feedback: from 1 to 4 months) followed by the adaptation (1 month) and intervention period (device with feedback: from 1 to 4 months) and finally a post-intervention period (immediate: 1 month and delayed: 1 month). The length of the timepoints is 1 month and the study will have four steps.

At the beginning of the study, none of the wards will be exposed to the intervention (pre-rollout period divided in pre-baseline (no device) and baseline (device without feedback)) and at the end of the study, all wards will be exposed to the intervention (post-rollout period). Additionally, a fixed post-intervention period (no feedback) immediate and delayed (3 months later) was also designated in order to assess the sustainability over time of the intervention (secondary outcome). The time of exposure to the active device will be split into four steps with a longer period of 4 months in step 1, to a shorter period of exposure of 1 month in step 4. Thus, the duration of the trial will be 11 months.

The primary outcome will be assessed at the HCW level; continuous measures will be taken by the device, regarding the volume of ABHR and duration of hand friction, from the same HCWs throughout the study in order to assess the change in HH quality and its relation to the intervention (active device). It will be thus a closed cohort design.

The study periods correspond to:
- Pre-baseline period (no device): this period will last 1 month. HCWs will perform their normal daily activities and will not have the device. HCWs will be directly observed regarding their HH compliance (secondary outcome) once.

- Baseline period (device without feedback): this period will last from 1 to 4 months, depending on the step to which the ward is allocated. HCWs will perform their normal daily activities and will use the device. However, the device will not provide any feedback to the HCW using it. Data will be obtained regarding the volume of ABHR used and duration of hand friction continuously by the device (baseline for the primary outcome).

- Adaptation period: this period will have a fixed duration of 1 month in all steps and it will be immediately before the intervention period and after the baseline period. HCWs will perform their normal daily activities and will continue to use the device. The feedback will be turned on and adjusted progressively to reach the target volume of HCW using it. This will be done by the engineers in the team working in close proximity to the HCWs. Data regarding the volume of ABHR used and duration of hand friction will be not included in the primary outcome in the statistical analysis.

- Intervention period: this period will last from 1 to 4 months, depending on the step to which the ward is allocated. HCWs will continue to use the device introduced during the baseline and adjusted during the adaptation period. There will be no adjustments in this phase. The device will provide immediate feedback after each hand hygiene action performed by the HCW on the volume of ABHR and duration of hand friction.

- Immediate post-intervention period: this period will have a fixed duration of 1 month in all steps and will take place immediately after the end of the intervention period. After the end of the intervention period, HCWs will still wear the device, but the feedback will be deactivated. This period will help to evaluate the post-immediate sustainability of hand hygiene quality improvement (secondary outcome).

- Delayed post-intervention period: this period will have a fixed duration of 1 month in all steps. After the end of the immediate post-intervention period, HCWs will stop wearing the device of the study. Three months after they will be asked to wear the device again without feedback activated. This period will help evaluate the long term sustainability of hand hygiene quality improvement (secondary outcome).

In parallel, HCWs will be directly observed regarding their HH compliance (secondary outcome) once per timepoint (monthly) from the pre-baseline to the delayed post-intervention period (11 months).

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The proportion of HCWs performing correct hand hygiene actions, as defined in the hypothesis, using the device without feedback (baseline for device period) or device with feedback (intervention period). This data will be collected automatically and continuously by the device at baseline and intervention periods (5 months).

Secondary outcome measures
1. Hand hygiene compliance is measured by direct observation by well-trained IPC professionals according to the WHO methodology at the individual HCW level, once per month during the entire study period (11 months)
2. Hand hygiene quality (volume of ABHR, duration of hand friction) and frequency of hand hygiene is measured using the device collecting automatic and continuous data at baseline and intervention (5 months)
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 at baseline and intervention (5 months)
4. Hand hygiene quality (volume of ABHR, duration of hand friction) and frequency of hand hygiene at post-intervention is measured continuously by the device to assess for the sustainability of the intervention the month after and at 3 months after the end of the intervention (2 months)
5. Satisfaction and perception of the usefulness of the device by HCWs is measured using a questionnaire distributed to participants to evaluate their experience with the device at the end of the intervention
6. Adverse events related to the device are measured using a list of open responses (ie., skin irritation, injury to patient, etc) whenever participants have a complaint

Overall study start date
25/11/2019

Completion date
25/10/2020

Eligibility

Key inclusion criteria

1. All wards with inpatient care activities
2. All healthcare workers working in patient care activities in eligible wards

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
Wards:
1. Wards with planned major building works during the study period

HCWs:
1. Healthcare workers who are planning to leave the unit during the study
2. Healthcare workers who have more than three consecutive weeks of vacations during the study

Date of first enrolment
25/11/2019

Date of final enrolment
20/12/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospitals of Geneva
Rue Gabrielle-Perret-Gentil, 4
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Sponsor information

Organisation

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Charity

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, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

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

Location
Switzerland

Funder Name
Fondation Hans Wilsdorf

Alternative Name(s)
Hans-Wildorf-Stiftung

Funding Body Type

Private sector organisation

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

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-review journal. The study protocol and statistical analysis plan are not publicly available.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Didier Pittet (didier.pittet@hcuge.ch). The data can be made available at the end of the study by request and after revision of the purpose of this request.

IPD sharing plan summary
Available on request