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The Feedback Intervention Trial (FIT) - improving hand hygiene compliance in UK healthcare workers

Submission date
07/03/2012

Recruitment status
No longer recruiting

Registration date
05/04/2012

Overall study status
Completed

Last Edited
28/08/2015

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Healthcare-associated infections (HCAI) are infections that are acquired as a result of health care. Studies have shown that in a wide variety of hospital and community settings, hand hygiene significantly reduces the number of HCAI. Despite this evidence, hand hygiene compliance amongst healthcare workers (HCWs) is poor, difficult to change, and any changes are difficult to sustain. Previous studies suggest that giving feedback to HCWs may be the most effective way to improve hand hygiene. In this study we tested whether a hand hygiene intervention would improve rates of hand hygiene compared to standard practice (i.e., the routine use of hand hygiene information).

Who can participate?
16 intensive therapy units (ITUs) & 44 acute care of the elderly (ACE) wards in 16 English/Welsh hospitals were recruited to the study.

What does the study involve?
Trusts were randomly allocated to carry out the hand hygiene intervention in blocks of two to four at five time points. By the end of the study all of the trusts had been allocated to the intervention. The intervention was carried out by an allocated ward coordinator who was generally a junior ward sister or infection control link nurse, and involved a repeating four-week cycle. In week 1 the hand hygiene of an individual Nurse/Health Care Assistant was observed for a 20-minute period. Immediate feedback was given after the period of observation, and where relevant, the person observed was helped to create an action plan to improve their behaviour. Week 2 was the same as week 1 except that a 'non-nurse' (doctor or other health care professional) was observed. In week 3 a ward area was observed for 20 minutes, recording the hand hygiene behaviour of all HCWs entering that area. Poor practice was documented but feedback was not given at the time. In week 4 the week 3 observations were fed back and action plans created at a ward meeting.

What are the possible benefits and risks of participating?
There was no risk involved for the patients on the wards as they all received routine hand

hygiene practice before their ward entered the intervention and all wards were intended to enter the intervention although at different time points.

Where is the study run from?
University College London (UK).

When is the study starting and how long is it expected to run for?
October 2006 to August 2009.

Who is funding the study?
The Patient Safety Research Programme, the Royal Free Hospital Trustees and GOJO industries.

Who is the main contact?
Dr Sheldon Stone
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Study website
http:/www.idrn.org/nosec.php

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
National Research Register N0256159318

Study information

Scientific Title

The Feedback Intervention Trial (FIT) - improving hand hygiene compliance in UK healthcare workers: a stepped wedge cluster randomised controlled trial

Acronym
FIT

Study objectives
Null hypothesis:
Providing feedback to healthcare workers (HCWs) on their hand hygiene using a feedback intervention based on behavioural theory has no effect on hand hygiene compliance compared to standard practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-Centre Research Ethics Committee, Scotland B, January 2005, ref: 05/MRE10/2

Study design
Stepped wedge cluster randomised controlled multi centre trial

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 contact Mr Christopher Fuller, christopher.fuller@ucl.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Healthcare Associated Infection

Interventions
Computer generated stepped wedge randomisation. Hospitals aware only of own allocation. Hand hygiene observer blinded to allocation.

A theory-based, sustainable intervention was designed by two of the study researchers (Health Psychologists) following the MRC framework for complex interventions. The development phase involved identifying an appropriate theoretical framework and associated techniques to inform intervention design. Goal-setting, control and operant learning theories were identified, and the individual and group level behaviour change techniques of feedback, goals, action planning and contingent reward were selected.

The intervention was carried out by an allocated 'ward coordinator' who was generally a junior ward sister or infection control link nurse, and involved a repeating four-week cycle.

Week1: Hand hygiene observation of an individual Nurse/Health Care Assistant for a 20-minute period. Immediate feedback was given after the period of observation, and, for instances of non-compliance with hand hygiene, the person observed was helped to formulate an action plan to improve behaviour.
Week 2: As for week one except that a 'non-nurse' (doctor or other health care professional) was observed.
Week 3: Hand hygiene observation of a ward area for 20 minutes, recording the hand hygiene behaviour of all HCWs entering that area (group compliance). Poor practice was documented but feedback was not given at the time.
Week 4: The week 3 observations (group compliance) were fed back and action plans formulated at a ward meeting.

The effect of this intervention on hand hygiene compliance was compared with that of standard practice.

Standard practice involved implementation of the pragmatically designed national cleanyourhands campaign consisting of:
1. Bedside placement of alcohol hand rub
2. Posters and patient empowerment materials encouraging healthcare workers to clean their hands
3. Audit of hand hygiene compliance

Intervention Type
Behavioural

Primary outcome measure
Hand hygiene compliance measured by covert direct observation by an observer blinded as to ward allocation or randomisation to the intervention.
Observation periods of one hour, every 6 weeks, using a previously tested Hand Hygiene Observation Tool (the HHOT).

Secondary outcome measures
Monthly soap and AHR procurement data (litres per bed day) were collected as a proxy measure of hand hygiene compliance for each of the study wards.
Data were collected either from hospital supplies departments or directly from NHS Supply Chain.

Data routinely collected by trusts for national mandatory reporting on healthcare associated infections (cases per 10,000 bed days) (Methicillin resistant-, and sensitive Staphylococcus aureus bacteraemias and Clostridium difficile infection. Data collected monthly for individual wards from hospital infection control teams).

Overall study start date
01/10/2006

Completion date
31/08/2009

Eligibility

Key inclusion criteria
Acute care of the elderly (ACE) or general medical wards and intensive therapy units (ITUs) in acute NHS trust hospitals across England and Wales. In each hospital, one ITU and a maximum of three acute care of the elderly wards were recruited. Sites recruited by requests posted on the "cleanyourhands campaign" website and by contacting infection control teams directly. Sites were eligible if they still wished to be involved after three or four site visits to gain the support of senior infection control team and management, ward managers, senior nurses and consultants, could offer the ITU and two or three acute care of the elderly wards as the clinical settings for the trial and were implementing the cleanyourhands campaign.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 wards (16 intensive therapy units (ITUs) & 44 acute care of the elderly (ACE) wards in 16 English/Welsh hospitals.

Key exclusion criteria
Wards that do not meet the above inclusion criteria

Date of first enrolment
01/10/2006

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
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NW3 2PF

Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NHS - National Patient Safety Agency - Patient Safety Research Programme (UK) ref: PS-029

Funder Name
Royal Free Hospital Trustees (UK)

Funder Name
GOJO industries (USA)

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?
Results article	results	01/04/2012		Yes	No