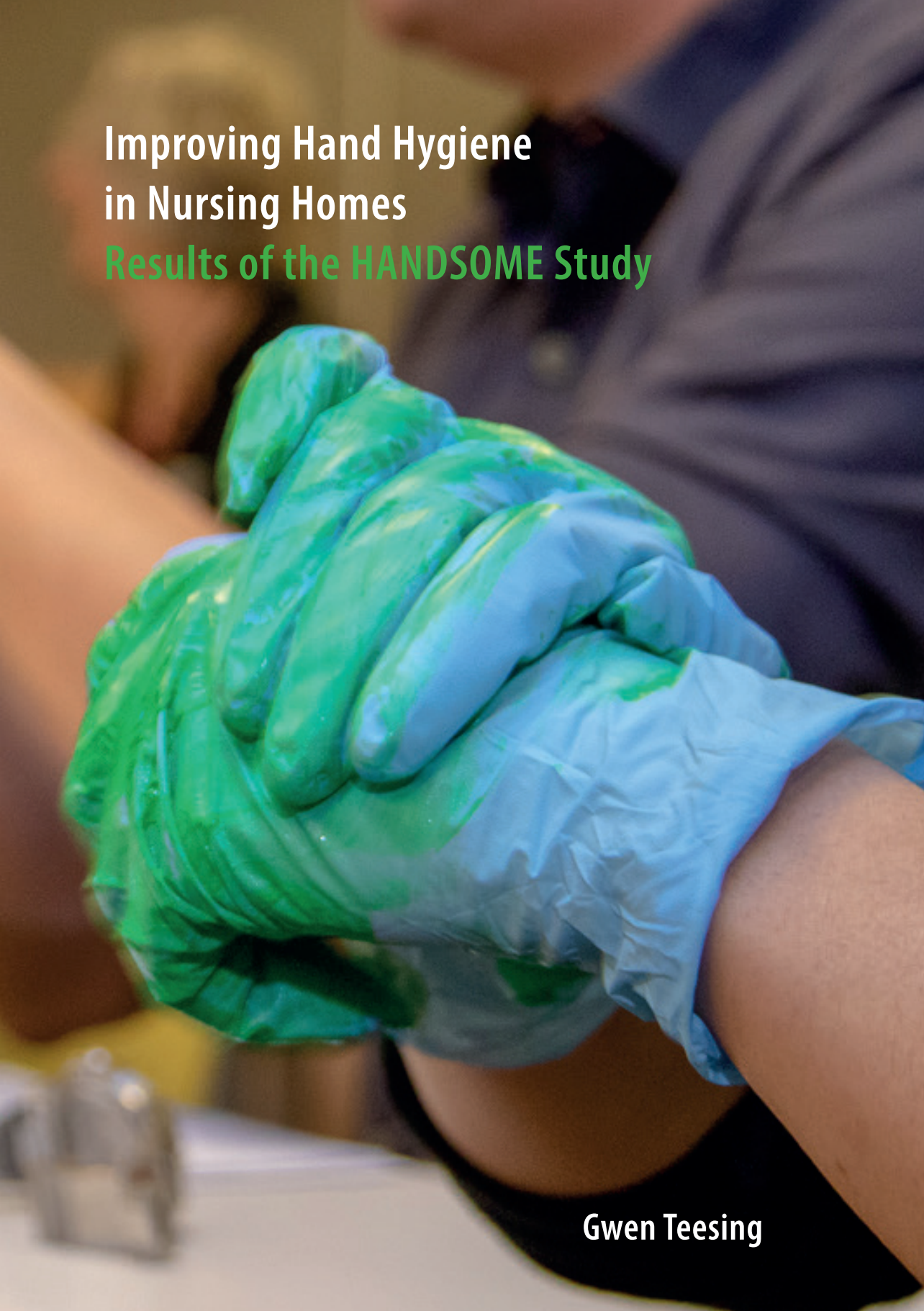

Improving Hand Hygiene in Nursing Homes

Results of the HANDSOME Study

Gwen Teesing

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Improving Hand Hygiene in Nursing Homes

Results of the HANDSOME Study

Handhygiëne verbeteren in verpleeghuizen
Resultaten van de HANDSOME studie

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de rector magnificus

Prof. dr. F.A. van der Duijn Schouten

en volgens het besluit van het College voor Promoties.
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Contents

Abbreviations

ABHR: Alcohol-based hand rub
CDC: Centers for Disease Control and Prevention
CI: Confidence Interval
E. Coli: *Escherichia coli*
ECDC: European Center for Disease Prevention and Control
ESS: Environmental surface sampling
FPC: Filter Penetration Capacity
FU: Follow-up
GGD: Municipal public health service
HAI: Health care–associated infection
HCW: Health care worker
HH: Hand hygiene
HHC: Hand hygiene compliance
ICC: Intraclass correlation
ILI: Influenza-like illness
MRSA: Methicillin-resistant *Staphylococcus aureus*
OR: Odds ratio
RCT: Randomized controlled trial
RT PCR: Real-time polymerase chain reaction
SNIV: Dutch surveillance network for infectious diseases in nursing homes
UTI: Urinary tract infection
WHO: World Health Organization
ZonMw: Netherlands Organization for Health Research Development

Chapter 1

General introduction

Healthcare associated infections (HAIs) remain a major problem in public health to this day. It is estimated that 5.6% of hospital patients and 2.4% of nursing home residents in Europe have at least one healthcare associated infection (HAI) at any given time. [1, 2] HAIs can be avoided through infection control measures, preventing both transmission between a health care worker and the person receiving care, and preventing self-infection. Some common infection control measures are the sterilization of medical instruments and devices, cleaning and disinfecting environmental surfaces, and sharps safety. [3] The most important category of infection control measures is personal protective measures.

Historical context

Some personal protective measures often used in health care are masks, gowns, gloves, hair covers, and hand hygiene. Masks are one of the oldest measures, with people in ancient Roman times wearing a loose-fitting animal bladder to protect themselves against inhaling lead oxide when working in mines. [4] In medieval times, plague doctors donned beak-shaped masks and special clothing to prevent themselves from getting ill. Later, Leonardo da Vinci recommended wearing a wet cloth as mask protection. [4] Nevertheless, it took many centuries before masks became common personal protective equipment. In 1897, surgeons first began wearing cloth masks to keep germs away from the patients. [5] During the Manchurian plague of 1910-1911 and the Spanish influenza pandemic eight years later, face masks were used not just by surgeons, but also by other medical workers, police force, and the population in general. [5, 6] In some cities, such as San Francisco, it was attributed to a decline in Spanish influenza deaths. [5]

Gloves are a more recent public health measure. Reusable rubber gloves were used to protect health care workers starting in the 1870s. [7] It is estimated that (rubber reusable) gloves became standard for surgeries ca. 1937. [8] Disposable latex gloves arrived around the 1960s, and disposable nitrile gloves around the 1990s. [9]

This thesis primarily deals with one of the most prevalent personal protective measures: hand hygiene. We see hand hygiene not only in health care settings, but we wash our hands daily: before we eat, after we use the toilet, when we come in from working in the yard. It may be difficult to imagine a time when it was not standard practice. Yet, hand hygiene has only recently become a standard part of health care.

While hand hygiene has only fairly recently been codified in health care, hand washing has been around since at least the middle ages. Jewish law, for instance, dictates that you wash

your hands before meals, after urinating or defecating, and after touching a part of the body which is dirty, or customarily covered. [10] At the same time, hand hygiene was only first recorded as a health care intervention in 1847. Ignaz Semmelweis introduced hand disinfection in hospitals by requiring all students in a maternal ward to wash their hands in a watery solution of chlorinated lime before entering the maternity ward. This resulted in a decrease in the maternal mortality rate from 10% to 1%. [11] Nevertheless, his ideas about hand hygiene were largely ignored. Between 1865 and 1869, Joseph Lister decreased postamputation mortality rates through preoperative handwashing and the use of disinfectant-soaked wound dressings. [12, 13] Yet, it was only in 1981 that the Centers for Disease Control and Prevention (CDC) in the USA codified hand hygiene practices, one of the first-hand hygiene guidelines. [14] Currently, the World Health Organization (WHO) promotes hand washing with their *SAVE LIVES: Clean Your Hands* campaign (since 2009). [15] The WHO has been instrumental in promoting hand hygiene, publishing supporting documents, toolkits, materials, and by helping coordinate interventions throughout the world. [16] Additionally, there is the related biannual International Consortium for Prevention & Infection Control conference (ICPIC), which places an emphasis on hand hygiene. Most recently, hand hygiene specialists published a book covering a gamut of hand hygiene aspects, from religious issues to surgical hand preparation. [17]

Why perform hand hygiene?

We perform hand hygiene in order to decrease illness. Bacteria and viruses get on hands and are then transferred from one person to the next, or from one part of the body to another part of the body (self-infection), either through direct contact (such as hand shaking) or fomite transmission (with an object as intermediary). Once bacteria or viruses get on someone's hands, they can enter the body when that person touches an eye, mouth, or other bodily cavity. In one study, it was shown that people touch their face 23 times per hour. [18] Of all face touches, 44% (1,024/2,346) involved contact with a mucous membrane (the eyes, mouth, or nose). This demonstrates the importance of hand hygiene in decreasing illness.

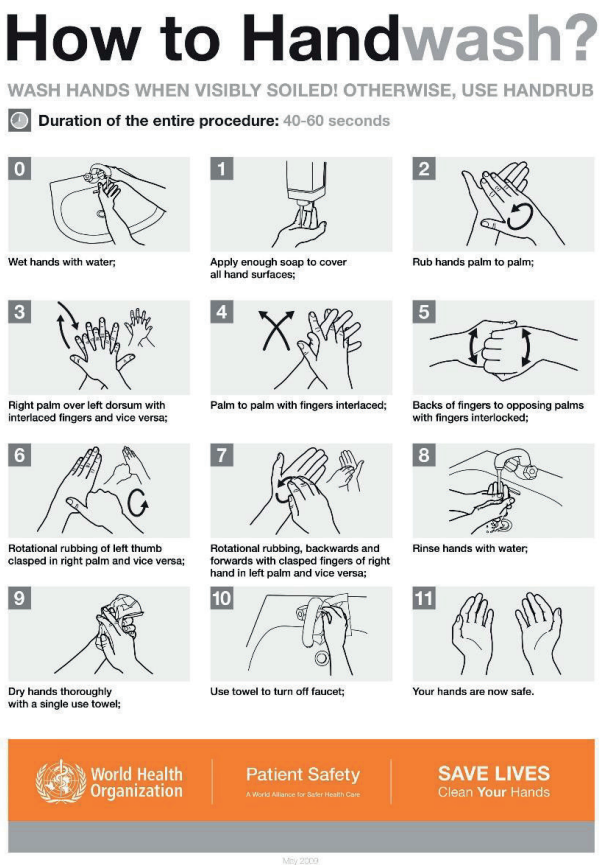
Bacteria and viruses can also travel through the air as droplets or aerosols. These droplets/aerosols can land on hands or be transferred to hands through fomite transmission. If we extrapolate this reasoning to health care, where health care workers are in frequent contact with mucous membranes of the patients/residents, we can conclude that good hand hygiene is essential in thwarting the spread of illness, even when there is no initial direct contact with body fluids.

How to perform hand hygiene

As part of the WHO campaign, how people should perform hand hygiene was codified. This can be done either through handrubbing or handwashing. Figure 1a shows 8 steps, namely: (1) Putting alcohol-based hand rub on your hands, (2) Rubbing hands palm to palm, (3) Rubbing hands placed on top of each other with interlaced fingers (and repeating with the other hand), (4) Rubbing hands palm to palm with interlaced fingers, (5) Rubbing hands while fingers are interlocked, (6) Rotating your thumb in your opposite hand (and repeating with the other hand), (7) Rubbing clasped fingertips in your palm (and repeating with the other hand), and (8) Rubbing hands until dry. [19-21] The handwashing process is quite similar. When handwashing, it is important to use a paper towel to turn off the faucet so that the microorganisms on the faucet do not re-infect your hands (Figure 1b).

While the WHO has created these basic instructions, not everyone agrees that they are optimal. One of the important arguments is that they miss washing or disinfecting the wrists. This is important since people often get microorganisms on wrists when removing gloves. A second issue is that these steps may be experienced as too time-consuming. Tschudin-Sutter, *et al.* developed an alternative 3-step method, which significantly increased both compliance with technique and hand hygiene compliance. [22] Using this method showed no statistical difference in effectivity. The 3 steps are (1) Covering all surfaces of the hands, (2) Rotationally rubbing the fingertips in the palm of the alternate hand, and (3) Rotationally rubbing both thumbs. Both the standard and alternative methods prescribe rubbing or washing for 30 seconds.

Both handrubbing (with alcohol-based hand rub) and handwashing (with water, soap, and a paper towel) are acceptable ways to perform hand hygiene, but this needs to be paired with proper personal hygiene. Bacteria and viruses can nestle in chipped nail polish and behind long (artificial) nails. [23] Rings, bracelets, and watches are also prime breeding grounds for undesired microbial growth. [23] It is also important to have short sleeves, since wet sleeves can act as a reservoir for microorganisms, which could then be transferred to hands. [23] This is why the Dutch guidelines for personal hygiene require health care workers to have short, unpolished nails, not wear any jewelry on their fingers or wrists, and wear short sleeves. [24]



Figures 1a and 1b. How to Handrub and How to Handwash?

Handwashing with soap

Traditionally, hand hygiene is performed with soap and water. In recent years, there has been a proliferation of soaps on the market claiming extra "antibacterial" properties. Yet, these products do not improve soap effectiveness and may cause allergic conditions. [25] There has also been much debate about how to dry your hands. On the one hand, statistically significantly fewer transient and residential bacteria remain on the skin if hands are dried with a jet air dryer than with a paper towel. [26] At the same time, drying hands with either a jet air dryer or a warm dryer causes a statistically significant amount of bacteria (which would otherwise have been wiped off with a paper towel) to spread through the room. [27] These droplets were found at 1 m distance to the dryer, inferring the potential for harmful bacteria and viruses, such as *Escherichia coli* (*E. coli*), to spread through the use of jet air driers and warm air driers.

Handrubbing with alcohol-based hand rub (ABHR)

When using ABHR, you do not need to be concerned with paper towels or air dryers, since you rub your hands until they are dry. What does need to be considered is: how much ABHR should be used, how long it should be used to create efficacy, where to place ABHR, whether it is safe, and whether it is considered acceptable by users. The international norms (NEN) recommend using 3 mL ABHR, and the WHO recommends rubbing for 20-30 seconds. [28, 29] According to one study by Kenters, *et al.*, this is too much ABHR to dry within 30 seconds. [30] This study recommends 1.5-2.25 mL of ABHR. It may even be possible to further reduce the amount of ABHR. According to two studies, hand rubbing for 15 seconds is non-inferior to 30 seconds in reducing bacterial load, irrespective of type of bacteria or contamination concentration. [30, 31]

ABHR comes in different forms, from no-touch sensors to small bottles which fit in pockets. In a study in hospitals, wall-mounted and bed-mounted ABHR dispensers were significantly associated with more ABHR consumption and assumedly a higher hand hygiene compliance. [32] In another study, there was again a statistically significant increase in daily consumption after conspicuous and proximate positioning of dispensers. [33] Interestingly, only increasing the number of dispensers, with disregard to work flow position, did not increase usage.

In practice, health care workers do not always prefer ABHR. For example, if the ABHR is not correctly rubbed until hands are dry, it can sting a patient's eyes when a health care worker gives eyedrops. Similarly, ABHR can be painful if the skin is broken. At the same time, it is

advised that health care workers use a water-resistant bandage on open skin when working, so health care workers can still use ABHR. [34] While eczema is sometimes given as a reason not to use ABHR, it is recommended that health care workers with eczema use ABHR instead of soap and water. [35]

Soap or ABHR

Both soap and ABHR are generally available. When they are not available, guides on how to make soap, handwashing stations and ABHR are available. [36, 37] Some of the benefits of ABHR are that using ABHR is quicker than washing with soap and that it does not disturb communication with a patient by forcing you to face a sink and through the sound of running water. ABHR may also be a better choice in low-resource settings, since it does not require clean water. At the same time, ABHR is not always a good alternative to soap. [38] Soap needs to be used when hands are visibly dirty, sticky, wet, and after using a toilet.

There are also differences in efficacy of ABHR and soap. It has been shown that ABHR was more effective than handwashing with an antiseptic soap in reducing bacterial contamination of healthcare workers' hands and nails during routine patient care. [39, 40] At the same time, there is a large variation in the effectiveness of different formulations of ABHR and soap. [41-43]

There are similar issues regarding viruses. While ABHR is highly effective against enveloped viruses, such as rotavirus (causing diarrhea), SARS CoV-2 (causing covid-19), and influenza virus, it is less effective against non-enveloped viruses, such as rhinovirus (which can lead to pneumonia), Norwalk virus, and norovirus (both causing gastrointestinal illness). [44-48] At the same time, there is evidence that certain ABHR-formulations are effective for reducing the viral load of non-enveloped viruses. [49-51]

The evidence about the effectiveness of ABHR and soap is thus contradictory. This is partly due to the manner in which the ABHRs and soaps are tested, but can also be due to the formulations of the soaps and ABHRs. More research should be done in order to gain a clear picture of the effectiveness of different ABHRs and soaps formulations using various real-world testing methods.

Soap and ABHR may be easy to use, but are they safe? The report 'Careful handling of disinfectants' (*Zorgvuldig omgaan met desinfectanten*) of the Health Council of the Netherlands (*Gezondheidsraad*) led to commotion about the frequent use of disinfectant (antibacterial) agents. [52] The report points out that there are concerns that the frequent

use of disinfectants could lead to resistance of bacteria to the disinfectant (making the agent no longer bactericidal), and resistance to antibiotics. Some of the disinfectants of concern are chlorhexidine, bisphenols, triclosan, and silver. [52] Bisphenols may be present in (the packaging of) certain brands of hand alcohol, and triclosan can sometimes be found in "antibacterial" soap. The Health Council also said that: "In professional sectors, the use of disinfectants should be promoted where they have a clear added value in the prevention or control of infections or damage."

Hand hygiene moments

The WHO recommends 5 moments when health care workers should perform hand hygiene, namely (1) Before touching a patient, (2) Before a clean/aseptic procedure, (3) After body fluid exposure risk, (4) After touching a patient, and (5) After touching a patient's surroundings (Figure 2). [53] Interestingly, they drop the requirement to do hand hygiene after touching a patient's surroundings for health care in a residential home (Figure 3).

Although the WHO recommends 5 moments for hand hygiene, many health care organizations have simplified this to *Room In, Room Out*. Some possible reasons are that it is easier to remember, easier to monitor, and that observations are less conspicuous when observing hand hygiene compliance. [56] At the same time, it misses the moments when the body is most susceptible to infections (Moment 2, before a clean/aseptic procedure) and when body fluids can be transferred (Moment 3, after body fluid exposure risk).

One other common diversion from the 5 moments of hand hygiene is the replacement of hand hygiene with gloves. Gloves are never a replacement for hand hygiene. Firstly, if contaminated hands are used to take gloves, then the outsides of the gloves will be contaminated with transient microorganisms from the health care worker's hands. These microorganisms can also get onto other gloves from the same box. [57] Additionally, when gloves are removed, microorganisms often get on the health care worker's wrists and fingertips, necessitating hand hygiene.

How to promote hand hygiene

The question is not so much: should we do hand hygiene, but: why don't we do hand hygiene? In one study from 2010, it was seen that hand hygiene compliance averages about 39%, assumedly for the hospital setting. [53] There are theories about how we can change behavior to promote healthier choices. Many of these have been laid out by Bartholomew, *et al.* in their Intervention Mapping approach. [58] These theories can be used to target

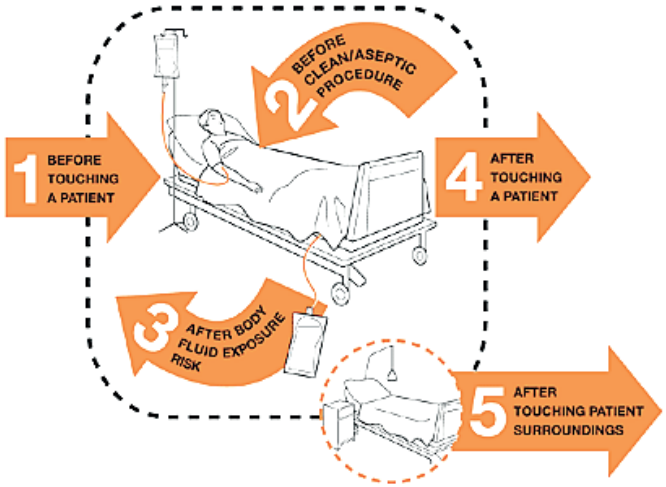


Figure 2. My 5 Moments of Hand Hygiene (WHO) [54]

Figure 3. Your Moments for Hand Hygiene: Health care in a residential home (WHO) [55]

changes on various levels, including the individual, organizational, and interpersonal level. Since we are investigating an action which frequently occurs in a health care setting and often when someone is alone, certain applicable theories are the theory of planned behavior, healthcare environment theory, social cognitive theory, and the theory of habits. [59-61] These theories can be used as such or combined in order to form the right approach and pinpoint which determinants should be addressed for behavioral change.

We know from studies that only providing knowledge about hand hygiene is not enough to change behavior. [61, 62] Multiple determinants need to be addressed. Flottorp, *et al.* developed a systematic overview of 57 potential determinants of behavior, grouped into 7 domains: guideline factors, individual health professional factors, patient factors, professional interactions, incentives and resources, capacity for organizational change, and social, political, and legal factors. [63]

Researchers of various studies, primarily in hospitals, have concluded which determinants they believe are essential for hand hygiene. Løyland believes that adherence to hand hygiene rules is influenced by individuals' knowledge, attitudes, beliefs and work setting. [64] In a study by Erasmus, *et al.*, a lack of positive role models and social norms were the most prevalent determinants. [65] In a similar study of medical students, the most important determinants were attitudes (perceived outcomes of preventive actions), self-efficacy, and habit. In a systematic review from 2012, it was determined that the most highly effective determinants to address in interventions are social influence, attitude, self-efficacy, and intention. [61, 62] The same study determined that interventions which address more than one determinant are more effective.

Not only should the intervention address more than one determinant; when determining strategies, it is necessary to incorporate more than one element/activity, since it is known that multimodal interventions are more effective. [53] Some common strategies are reporting, repetition, consciousness raising, persuasive communication, and cue altering.

Although increasing knowledge about hand hygiene in itself is not enough to change behavior, it has been seen that knowledge of the hand hygiene rules is often lacking. [62] In a review of student nurses' hand hygiene knowledge, it was found in 9 of the 10 studies that student nurses had low-to-moderate hand hygiene knowledge. [66] In a hospital in

Vietnam, 66% (n=120) of the health care workers knew the WHO's 5 moments of hand hygiene. [67] Nurses' and doctors' knowledge of correct HH practice was 41% (n=63) before receiving training sessions in a hospital in Rwanda. [68] In a hospital study in the Netherlands, it was seen that nurses' and doctors' knowledge of HH practices was 74% (n=44) for typical hand hygiene opportunities. [69] These studies show that increasing health care workers' knowledge about hand hygiene is a necessary component of an intervention.

Hand hygiene is often substituted by gloves. Although this seems to be related to knowledge about hand hygiene, this is not the only factor. Acquearulo *et al.*, identified four reasons why health care workers perform substitution: protection and safety of staff and patients, availability of gloves, previous medical training guidance, and barriers to hand hygiene, including the distance from a sink and the use of mobile telephones. [70] On the other hand, Baloh *et al*. characterized the reasons for substitution as workload, type of task, (physical and social) context, and individual factors/beliefs, such as dry hands or the belief that gloves are sufficient. [71]

Structural environmental or protocol changes by themselves are also often not enough to achieve a high hand hygiene compliance rate, but are often necessary to decrease substitution behavior with gloves, and eliminate barriers to hand hygiene. Examples are effective mobile telephone protocols, decreased workload, redesign of the physical environment, and having ABHR that nurses find acceptable. [72]

Hand hygiene determinants can also be culturally and context related. For example, there are large differences between European populations' self-reporting of washing their hands after using the toilet, ranging from 96% of the population in Bosnia & Herzegovina to 50% of the Dutch population, although the actual rates may be lower since this was self-reported data and not observed (Figure 4). [73] Another example is from a recent study in Indonesia, where it was found that major barriers to compliance included longstanding water scarcity, tolerance of dirtiness by the community, and the healthcare organizational culture. [74]

Hand hygiene interventions

Hand hygiene compliance can be influenced through various strategies. Many studies do not employ just one method but are rather multimodal. One of the most common methods

Figure 4. Do Europeans wash their hands after using the toilet?[73]

is teaching, either in person (for groups) or online. Another strategy is to observe health care workers and give them immediate feedback about their hand hygiene activities. Different strategies and components are often addressed in a train-the-trainers model, where health care workers are trained to teach their colleagues about hand hygiene. [16, 75] One other method which organizations use to influence hand hygiene is by giving the responsibility to the patient to tell the health care worker to wash his/her hands. [76]

Another strategy is to make environmental changes. These can be cues to action, such as posters or hanging ABHR at conspicuous locations. Another environmental change involves changing work processes so that less hand hygiene is needed. An example is the order in which you clean a patient. By starting with the cleaner areas and ending with the genital area, a health care worker performs hand hygiene once; by starting with the genital area, the health care worker would need to do hand hygiene twice, since there would be possible contact with body fluids when washing the genital area.

Some of the methods organizations employ are more playful. These can be used to enhance awareness or act as a reminder. Some examples are:

(1) A hand sanitizing relay to see how many people can do hand hygiene within a certain time frame. [77]
(2) Having a health care worker spread a special cream/powder on his/her hands. This cream/powder lights up under a black light. Then, the health care worker tries to wash off the cream/powder using his/her normal technique. He/she then sees which parts of the hands were not rubbed in a light box with a black light.
(3) Using dispensers which measure how many times ABHR is used on a particular day and having this posted on an electronic board. [78]
(4) "Washing" gloved hands with paint with eyes closed, and then seeing which parts of the hands (gloves) are not covered in paint.
(5) Having health care workers participate in a playback or hand hygiene dance routine.

In order to keep continued interest in hand hygiene, the Global Handwashing Partnership initiated Global Handwashing Day (October 15th) and the WHO initiated Hand Hygiene Day (May 5th). [79-81] These two moments prompt infection prevention specialists to give extra attention to hand hygiene.

How to measure hand hygiene compliance

There are different ways to measure hand hygiene compliance. [82] The golden standard is direct observation. This entails an observer following a health care worker for either a period of time or a number of hand hygiene opportunities. This observer marks whether hand hygiene was done, what was used for hand hygiene (soap/ABHR), which hand hygiene moment it is, and whether gloves were used. The hand hygiene can be registered using a standard form, such as the one provided by the WHO, or an app. [83]

Direct observation has three main disadvantages. One is that it can precipitate Hawthorne or observer bias. A second disadvantage is that it is costly and time-consuming to hire observers. A third disadvantage is that observers may not work homogenously, so it can cause variation in how hygiene compliance measurements are registered.

A second way to measure hand hygiene compliance is through indirect observations. The main two methods are by measuring whether hand hygiene is done when someone enters or leaves a room through an automated system, and by measuring soap and ABHR consumption. Neither of these tools is ideal. An automated system does not register

activities in the room, but only at entry and exit. On the other hand, automated systems can give reminders through light and sound cues, acting as an intervention itself.

Measuring the consumption of soap/ABHR is also not ideal. In one article, researchers found no significant correlation between observed hand hygiene adherence and total product used per patient-day. [84] Nevertheless, another researcher was able to gain insight into hand hygiene compliance by seeing how little soap and ABHR was used in nursing homes, making it a useful indicator of (low) hand hygiene compliance. [85] Interestingly, another study saw that the consumption of ABHR increased from 10.1 ml per resident-day to 12.2 ml per resident-day after an intervention. [86]

Some other methods which are used are self-reported hand hygiene questionnaires, video tracking, and sampling hands for microorganisms. [87-89]

Hand hygiene in Dutch nursing homes

While hand hygiene is necessary in all health care settings, this thesis primarily addresses hand hygiene in nursing homes. Although the Dutch average HAIs per 1000 resident-days is lower than the European average (which includes more types of HAIs), namely 2.4 per 1000 resident days vs. 3.2 per 1000 resident-days, higher compliance with prevention measures, such as hand hygiene, can further reduce HAIs in nursing homes. [90-96] (www.sniv.nl)

Nursing homes are different than hospitals or other health care settings in various ways. Here are a few examples that are relevant for hand hygiene interventions:

(1) Nursing homes have mobile residents who are encouraged to interact with each other both in personal rooms/apartments and shared spaces.
(2) It is a home-like environment which provides care and not primarily a medicalized one. Nursing home organizations are often reluctant to create a medicalized environment by placing medical attributes in the resident's room/apartment. The result is that hand hygiene material placement is often not optimal. Specifically, nursing homes are sometimes reluctant to put dispensers for hand hygiene in the residents' rooms. This is different than in a hospital, where ABHR-dispensers can be hung on beds, placed near beds, and hung near doors.

(3) Health care workers are predominantly nurses and nurse's aides, with sporadic doctor visits.
(4) Visitors can have contact with multiple residents. This mobility implies that not only health care workers and residents, but also visitors can more easily spread infections than in a hospital, where patients and their visitors primarily remain in the room of the patient.
(5) Nurses perform more non-nursing duties than in hospitals, such as cooking and eating with residents. Hand hygiene can be cumbersome during such activities, for example if a nurse is eating and helping residents eat simultaneously.
(6) The types of staff/itinerant salespeople who interact with residents is different than in a hospital, such as hairdressers, volunteers who interact with residents, and salespeople who sell clothing or other items to the residents. These non-health care workers are not always schooled in hand hygiene.
(7) Nursing home residents are fragile and extra susceptible to morbidity and mortality from infectious diseases.

Infection prevention measures are essential for curbing morbidity and mortality, but they need to be suited to nursing homes, which have their own context and dynamics. Implementing a hand hygiene intervention which is tailored to nursing homes is one of the most important infection prevention measures, considering that hand hygiene compliance (according to the WHO-moments) in various studies in nursing homes never exceeded 61%, even after an intervention. [64, 92, 97-99]

A new hand hygiene intervention should be based upon the hand hygiene, personal hygiene, and glove use rules in the WHO's guidelines for long term care. [38] These guidelines have been further developed for the Dutch setting. [24, 100, 101] The guidelines include information such as how to wash and disinfect hands, when to perform hand hygiene, what to do if you have a wound on your hand, the use of lotions, and information about dispensers for hand hygiene materials. [34]

For our study (HANDSOME), we developed a new intervention tailored to the nursing home setting. Some determinants which we addressed were: guideline factors (guidelines for hand hygiene and personal hygiene, clinical work process flow, mandate), individual health professional factors (knowledge, self-efficacy, acknowledging importance, motivation,

attitude, professional standards, leadership commitment, sense of ownership), incentives and resources (non-financial incentives, learning facilitation), and capacity for organizational change (assistance with organizational change, systems change).

The intervention included activities for changing NH policy and individual behavior. NH policy changes were achieved through an audit (done with management) including explanations about hand hygiene materials and personal hygiene rules. Nurses and other health care workers were subject to three different live on-site hand hygiene lessons, access to an e-learning, hand hygiene posters on-site, and the opportunity to participate in a hand hygiene photo competition. During the lessons, nurses were taught the 5 moments of the WHO using a novel method, namely *Room In* (Moment 1)*, Room Out* (Moments 4 and 5 combined)*, Before Clean* (Moment 2)*, After Dirty* (Moment 3). This method comprises the same 5 HH moments as the WHO standard, but is more adapted to the nursing home setting, is easy to remember (one slogan), and is easy to visualize (Figure 5).

Scope of this thesis

The goal of the study in this thesis is to increase hand hygiene in nursing homes in order to decrease HAIs. The key research questions are:

(1) How was the tailored hand hygiene intervention received?
(2) Which hand hygiene opportunities should be registered when observing hand hygiene in a nursing home?
(3) Is a tailored hand hygiene intervention for nursing homes successful in increasing hand hygiene compliance?
(4) Does a tailored hand hygiene intervention result in decreased healthcare-associated illness in nursing homes?

We also answered the following research question regarding personal protective measures:

(5) Is there an adequate alternative to commercially manufactured face masks?

To answer these research questions, fieldwork was performed in nursing homes and quantitative methods were employed to analyse the results. This research thereby contributes evidence supporting the effect of infection control measures to prevent direct transmission in nursing homes. The results should inform policymakers how to effectively implement infection control measures.

Figure 5. Room In, Room Out, Before Clean, After Dirty

In **Chapter 2**, we describe the process of developing a multimodal intervention to increase hand hygiene compliance of nurses in nursing homes and evaluate it in a cluster randomized controlled trial (HANDSOME study). Intervention mapping techniques are used to develop the multimodal intervention, using literature, interviews, and pilot observations, and results from past hand hygiene interventions.

For the evaluation, nursing homes are randomly allocated to one of three trial arms: either receiving the intervention at a predetermined date, receiving the identical intervention after an infectious disease outbreak, or serving as a control arm. We define the primary

outcome as hand hygiene compliance of the nurses to the standards of the World Health Organization. The secondary outcome is infectious disease incidence among residents.

Chapter 3 answers the first research question, namely if we can increase hand hygiene compliance of nurses in nursing homes. Hand hygiene compliance is evaluated using direct, unobtrusive observation in nursing homes from the HANDSOME study. Hand hygiene compliance is appraised at baseline (October 2016) and 4, 7, and 12 months after baseline.

Gloves are often used when hand hygiene should be done, regardless that it is not an advisable substitute. We investigate in **Chapter 4** if our hand hygiene intervention decreases substitution of hand hygiene by glove use. We analyse this per WHO-defined hand hygiene moment and for selected sub-moments, assessing: 1) hand hygiene without donning/removing gloves; 2) hand hygiene combined with donning/removing gloves; 3) no hand hygiene, but gloves are donned/removed (substitution); 4) no hand hygiene and gloves are inappropriately not changed; 5) no hand hygiene and no gloves. Baseline and follow-up results are assessed overall, per nurse, and per nursing home unit.

The primary goal of hand hygiene is to reduce infectious diseases. In **Chapter 5**, we examine if residents in nursing home units which receive the hand hygiene intervention have fewer infections when compared to residents in a control group. Five illnesses are investigated: gastroenteritis, influenza, pneumonia, urinary tract infections and MRSA. Infectious disease incidence is registered by a staff member of each nursing home unit. We compare our results to the Dutch surveillance network for infectious diseases in nursing homes (SNIV).

Chapter 6 establishes whether environmental surface sampling can be used as a surrogate indicator for hand hygiene compliance and/or illness monitoring in nursing homes. We collect environmental microbiological samples on three surfaces: a table in a shared living space, a computer keyboard and mouse used by nurses, and a shared toilet for residents. Real-time polymerase chain reaction (RT PCR) techniques are used for the detection of norovirus genogroup I and II, rhinovirus, and *E. coli*. We then compare the environmental surface samples to hand hygiene compliance data and illness registration.

Chapter 7 investigates a different public health care measure, namely face masks. In 2020, there was a worldwide shortage of medical grade face masks. At the same time, donning masks can play an important role in curbing the spread of SARS-CoV-2. We study if there is an adequate alternative for the population to wear in public that could easily be made using readily available materials. Various materials and masks are tested to see if they filtered particles of different sizes, are hydrophobic, seal on the face, are breathable, and can be washed. The outcomes are compared with N95/FFP2/KN95 masks.

Finally, in **chapter 8** we summarize and discuss the findings regarding hand hygiene compliance, glove use, disease surveillance, environmental surface sampling, and mask usage. We formulate conclusions and present recommendations for infection control measures.

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Chapter 2

Improving Hand Hygiene Compliance in Nursing Homes: Protocol for a Cluster Randomized Controlled Trial (HANDSOME Study)

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Abstract

Background: Hand hygiene compliance is considered the most (cost-)effective measure for preventing health care–associated infections. While hand hygiene interventions have frequently been implemented and assessed in hospitals, there is limited knowledge about hand hygiene compliance in other health care settings and which interventions and implementation methods are effective.

Objective: This study aims to evaluate the effect of a multimodal intervention to increase hand hygiene compliance of nurses in nursing homes through a cluster randomized controlled trial (HANDSOME study).

Methods: Nursing homes were randomly allocated to 1 of 3 trial arms: receiving the intervention at a predetermined date, receiving the identical intervention after an infectious disease outbreak, or serving as a control arm. Hand hygiene was evaluated in nursing homes by direct observation at 4 timepoints. We documented compliance with the World Health Organization's 5 moments of hand hygiene, specifically before touching a patient, before a clean/aseptic procedure, after body fluid exposure risk, after touching a patient, and after touching patient surroundings. The primary outcome is hand hygiene compliance of the nurses to the standards of the World Health Organization. The secondary outcome is infectious disease incidence among residents. Infectious disease incidence was documented by a staff member at each nursing home unit. Outcomes will be compared with the presence of norovirus, rhinovirus, and *Escherichia coli* on surfaces in the nursing homes, as measured using quantitative polymerase chain reaction.

Results: The study was funded in September 2015. Data collection started in October 2016 and was completed in October 2017. Data analysis will be completed in 2020.

Conclusions: HANDSOME studies the effectiveness of a hand hygiene intervention specifically for the nursing home environment. Nurses were taught the World Health Organization's 5 moments of hand hygiene guidelines using the slogan "Room In, Room Out, Before Clean, After Dirty," which was developed for nursing staff to better understand and remember the hygiene guidelines. HANDSOME should contribute to improved hand hygiene practice and a reduction in infectious disease rates and related mortality.

Trial Registration: Netherlands Trial Register (NTR6188) NL6049; https://www.trialregister.nl/trial/6049

Introduction

Health care–associated infections (HAI) are a significant source of morbidity in nursing home residents. If we include urinary tract infections, we see on average more than one HAI per resident per year in European nursing homes. [1] Not only do residents become ill from HAI but HAI may also affect staff due to their own illness and increased workload, further disrupting care. Hand hygiene (HH) can play a role in an infection prevention strategy.

Most studies focus on hand hygiene compliance (HHC) in hospitals, ignoring other settings with vulnerable populations, such as nursing homes. [2] The few published studies that recorded HHC in nursing homes according to the World Health Organization (WHO) standards show estimates of 6% to 27% HHC before an intervention. [3-7] There is some evidence that infectious disease rates and mortality rates decrease in nursing homes when HHC increases through HH interventions. [4, 8-10] While most HH intervention studies document HHC rates in hospitals, there are a few published studies showing that interventions can significantly influence HHC in a nursing home. [4, 8, 11] For example, 2 studies in long-term care facilities in Hong Kong showed significant increases in HHC in intervention arms (27% to 61%, $p<0.001$; 22% to 49%, $p<0.001$; and 26% to 33%, $p=0.10$), and no significant changes in control arms after implementing multifaceted HH interventions involving the provision of hand sanitizer, reminder materials, education, and, in one case, performance feedback. [4, 8] In Taiwan, nursing assistants showed significantly better HHC (from 9% to 30%, $p<0.001$) 3 months after participating in a 1-hour class and 30 minutes of hands-on training. [11]

Due to a paucity of HH studies in nursing home settings using the WHO hand hygiene standards, we designed a trial to evaluate the impact of an intervention package tailored to the specific context of nursing homes. HH interventions developed for hospitals are not necessarily appropriate for nursing homes. First, the 5 HH moments of the WHO are difficult to interpret and use in the nursing home setting. The 5 moments of the WHO dictate that HH should be done before touching a patient, before a clean/aseptic procedure, after body fluid exposure risk, after touching a patient, and after touching patient surroundings. At the same time, a patient's surroundings in a nursing home is a fluid concept. Nursing home residents are generally mobile, sharing communal areas. For example, should touching a resident's walking frame in the living room be considered touching a resident's environment (after which HH is indicated)? Is a section of a table in a living room a particular

"resident's environment" because that resident is sitting there at that moment? Second, interventions should minimally disturb the homelike setting. For example, hanging hand sanitizer dispensers on beds could be perceived as transforming the homelike environment to a medicalized one. Another difference is that nurses in nursing homes generally have less education than nurses who work in hospitals. The intervention should therefore be adapted to their educational level by using simple language and hands-on exercises. [12]

The HANDSOME study was developed to evaluate the effectiveness of an intervention to improve HHC in nursing homes. An additional goal of the study is to determine if an intervention is more effective when implemented following an outbreak. In this paper, we describe the study design and protocol details of the HANDSOME study.

Methods

Overview

The HANDSOME intervention is based on our experience with developing HH interventions in hospital and childcare settings. We performed a randomized controlled HH study in 15 hospitals throughout the Netherlands. [13] Underlying determinants for HHC were addressed through various means, including making changes to the physical environment (e.g., adding dispensers), creating new social norms, and implementing an HH e-learning program. While the control and intervention arms did not differ in HHC at baseline, there was a statistically significant difference in HHC during the follow-up between the control arm (24.9% HHC) and intervention arm (35.4% HHC). [14] In childcare settings, we conducted a cluster randomized controlled trial including providing HH products, providing HH training to childcare workers, organizing team sessions to promote goal setting, and providing stickers and posters for caregivers and children as cues to action. This led to a statistically significant increase in HHC in the intervention arm, even 6 months after the intervention. [15] Considering the significant increases in HH in these settings, we adapted these interventions for the current study.

Trial Design

HANDSOME is a parallel-group, observer-blinded, and observed-blinded cluster randomized controlled trial to increase nurses' HHC. For the purpose of this study, nurses were defined as those who have completed a 3-year or 4-year degree in nursing. The study

has 3 study arms: 2 intervention arms and 1 control arm. Nursing homes were randomized to one of the 3 trial arms: fixed intervention, conditional intervention, and control. The nursing homes in the 2 intervention arms received the same intervention, while the control nursing homes did not receive the intervention. The nursing homes in the fixed intervention arm received the intervention at a predetermined date, while the nursing homes in the conditional intervention arm received the same intervention as the fixed intervention arm, but only after an infectious disease outbreak. The conditional intervention arm was conceived with the idea that an outbreak would cause an increased sense of infection risk and urgency, leading towards a better and/or more sustained HH performance. The control locations were free to implement any other infection prevention intervention, since this is "business as usual" and it is unethical to withhold care improvements from residents. Nursing homes were observed several times for HHC, required to complete illness incidence reports, and subjected to microbiological surface sampling.

Background information about the nursing homes was collected through a structured interview. This was followed by a baseline observation in every nursing home unit. Next, nursing homes were randomized into 1 of the 3 study arms. Randomization was at the level of the nursing home rather than the individual nurse or ward, since the intervention was available to an entire nursing home. The aim was to include a minimum of 55 nursing homes: 15 fixed intervention nursing homes, 25 conditional intervention nursing homes, and 15 control nursing homes (see Sample Size Calculations).

A tablet-based app was used to document compliance. Results from background interviews, pilot observations, and the pilot intervention were used to refine the observation app and intervention. Since we were able to determine which types of HH opportunities (submoments) are the most common, these were added to the app to get more insight into HHC. We also used this extra information to address specific HH issues during the intervention, such as how to handle laundry or use a telephone, tablet, or hand brace. We were also able to specifically incorporate the most common invasive procedures in the intervention lessons. The pilot intervention allowed us to revise the materials so that they were easier to use.

Trial Aim

We aimed to increase compliance with the WHO's 5 moments of HH. [16], which was measured during repeated observations over a period of 12 months.

Study Setting

All data were collected in nursing homes in the Netherlands. To capture diversity, these nursing homes are situated throughout the country in areas with differing degrees of urbanization.

Recruitment

Recruitment of nursing homes began by sending printed flyers with information about the study to large nursing home organizations listed on a website that lists most health care providers in the Netherlands (*ZorgkaartNederland*). Digital flyers were also sent to health care associations so they could inform their members about the study. In addition to the nursing homes recruited for the study, 3 nursing homes from 3 distinct organizations were recruited as pilot locations to train observers and test the intervention. After the distribution of the flyers, organizations were contacted by phone to discuss willingness, eligibility, and conditions for participation. Interested nursing homes were visited personally to further discuss participation. Enrollment began April 25, 2016. Participants are no longer being recruited.

Eligibility Criteria

Eligibility criteria were identified to foster homogeneity between nursing home units. First, only publicly funded organizations willing to commit 3 or 4 nursing homes to the study were eligible. By allocating different nursing homes within the same organization to different study arms, we aimed to minimize variation between the study arms. Each nursing home committed a minimum of 2 eligible units. Nursing home wards were considered eligible as a unit if they had 3 or more nurses working between 8:00 am and 2:00 pm on weekdays so that we could observe a minimum of 3 nurses during one observation session. If there were not enough nurses employed during those hours in one ward, multiple wards were combined and considered 1 unit for purpose of this study. If a nursing home could only supply 1 unit, it was coupled with a unit from another nursing home from the same

organization. All wards primarily provided somatic or psychogeriatric residential care. Nursing homes were allowed to perform other infection prevention improvements, provided they did not simultaneously participate in other HH trials.

Allocation

The randomization process was accomplished through a stepwise procedure after baseline observations. The primary investigator first drew (computer-generated) one nursing home per organization at random for the fixed intervention arm. After this, one nursing home per organization was randomly drawn for the conditional intervention arm. The remaining nursing homes were randomly assigned to the conditional intervention arm or the control arm. This method allowed for random allocation while minimizing the variation between the study arms.

Intervention

Studies have shown that using multiple strategies that address multiple determinants (e.g., a multimodal approach) is the most effective in increasing HHC. [17] Another key determinant for good HHC is repetition. [17-19] These were the cornerstones of our intervention.

For the purpose of the current trial, we scanned literature for determinants that influence HH, in particular for determinants that we had not considered in our earlier interventions. [18, 20, 21] Additionally, 5 interviews were held at nursing homes for a better understanding of obstacles to HH. Next, intervention mapping principles were used to further recognize applicable determinants, methods, and strategies for the development of this intervention. (Table I). [22] The intervention was further refined after informal discussions with members of more than 20 nursing home organizations during the recruitment period. The intervention continued to be adjusted as an iterative process.

The intervention has 4 main components: a meeting with the management, 3 live group lessons, e-learning, and posters. Additionally, there is a photo competition and an arts and crafts project. All components were published on a website after completion of the intervention. [23]

Table I. Intervention mapping for HANDSOME: using determinants and methods to develop the strategy for intervention components.

Intervention element	Determinant	Method/Strategy
Meeting with management		
Present the average hand hygiene compliance (HHC) in nursing homes (NH). Show that there is room for improvement.	Knowledge	Reporting
Talk about costs (time and money) and harm (illness of residents and staff) associated with a MRSA- or norovirus-outbreak.	Perceived threat, acknowledging importance	Consciousness raising, persuasive communication, anticipated regret
Use a form to structurally discuss necessary facilities and facility changes for efficient hand hygiene (HH) practices. Stress that the organization, not the resident, must provide all HH materials. Optimize where HH materials are stored and how and when they are replaced.	Environmental restructuring, rules and regulations, awareness, assistance for organizational change	Organizational diagnosis and feedback/tailoring, systems change, reduce environmental barriers, persuasive communication, participatory problem solving, structural redesign, cue altering/nudging, consciousness raising, goal setting, problem management tool
Talk about the Dutch guidelines for personal hygiene and non-compliance policies at other organizations. Talk about the risk of infection. Use a form to register (new) personal hygiene policy for the organization. Make sure that employees have a safe space for personal belongings. Offer solutions for personnel with rings.	Seeing importance, rules and regulations, professional standards	Systems change, non-financial incentives, mandate, anticipated regret, tailoring, organizational diagnosis tool
Let management know that they can receive a "Good hand hygiene" certification if they achieve a minimum HHC.	Motivation	Non-financial incentives, early commitment
Convince management that their presence at the Lesson 1 will positively influence HHC results. Plan lessons and the personal hygiene presentation.	Capable leadership	Persuasive communication (with management), planning
Lesson 1		
A senior NH manager introduces the intervention and expresses the importance of hand hygiene.	Leadership commitment, framing	Persuasive communication, public commitment, introduce systems change
Show a HH video. Present iatrogenic statistics and explain health risk to self and others. Help employees visualize HH from the perspective of the resident.	Create urgency, framing	Persuasive communication, consciousness raising, anticipated regret, shifting perspective

Intervention element	Determinant	Method/Strategy
Teach using a presentation. Teach *Room In, Room Out, Before Clean, After Dirty.* Teach and discuss how to do HH when handling pills, food, laundry. Teach when to use hand sanitizer or soap and the proper use of gloves.	Knowledge	Chunking, using imagery, personal feedback
Team creates a group HH goal.	Self-efficacy, sense of ownership	Implementation intentions/goal setting, social influence, team commitment
Introduce the e-learning and show the nurse's watch that they can earn by completing the e-learning.	Facilitate learning, non-financial incentives	Structural redesign, beginning of repeated exposure
Show posters and ask where they want to see the posters. Hand out small bottles of hand sanitizer for use in the e-learning.	Non-financial incentives, self-efficacy, sense of ownership	Cue altering
Presentation of the personal hygiene policy		
A senior NH manager presents personal hygiene policy (no long nails, nail polish, rings, bracelets, watches, braces, or long sleeves). Consequences for non-compliance are made known.	Mandate, perceptions of norms, leadership commitment	Punishment, persuasive communication, role models
Lesson 2		
Make an inventory of barriers to good HH.	Attitude, knowledge	Discussion
Think of solutions for barriers.	Systems change	Tailoring, organizational diagnosis, planning coping responses, group discussion, structural redesign, systems change
Lesson 3		
Participants "wash" hands with paint and see where they miss.	Attitude, knowledge	Participation
Participants learn how to disinfect their hands.	Knowledge, self-efficacy	Guided practice
Participants see that they get paint on hands after glove removal and that the paint represents invisible bacteria/ viruses.	Knowledge	Anticipated regret, rationalize risk
Remind participants that they can earn a watch by doing the e-learning.	Non-financial incentives	Persuasive communication
E-learning		
Show playback squelching excuses not to do HH. Show films from the perspective of the resident.	Professional behavior standards, attitude	Using imagery, shifting perspective

Intervention element	Determinant	Method/Strategy
Explain when to use hand sanitizer or soap. Practice using hand sanitizer with participants.	Knowledge, skills, self-efficacy	Advance organizers, modeling, guided practice
Use videos with correct and incorrect behavior to teach HH moments and common HH actions. Teach how to do HH when preparing food and pills.	Knowledge	Chunking, modeling, active learning
Teach how to work efficiently to avoid unnecessary HH using videos with correct and incorrect behavior.	Clinical work process flow	Systems change
Teach the proper use of gloves with still images and videos with correct and incorrect behavior.	Perceived norms, knowledge	Active learning, imagery, modeling, persuasive communication
Show that HH does not inhibit other tasks or social contact with the resident.	Self-efficacy	Modeling
Give a quiz after every module.	Knowledge	Reinforcement through testing, feedback, monitoring
Promise a nurse's watch when the e-learning is completed. Use dripped learning so that the e-learning is done in small modules over 14 weeks. Send reminders.	Curiosity, information system, knowledge, non-financial incentive	Facilitation, anticipated regret, reminders, repetition
Poster		
Multiple copies of a new poster are hung throughout the nursing home monthly.	Social influence, perceived norms	Visuals, repeated exposure, cue to action
Photo competition		
Let NH employees know that they can win a prize for the best photo of hands.	Non-financial incentives	Providing cues
Arts and crafts project		
Residents are informed about HH and the organization's HH goals.	Knowledge	Consciousness raising
Residents do an activity involving hands. NH displays artworks.	Perceived norms	Participation, cues to action

HH: Hand hygiene; HHC: Hand hygiene compliance; NH: nursing home

Meeting with management

A meeting at the nursing home took place 1-2 months after the baseline compliance measurement. A senior nursing home manager, infection prevention specialist, and facilities manager were asked to attend the meeting. The meeting started with consciousness raising about the cost of a methicillin-resistant *Staphylococcus aureus* (MRSA) outbreak so the participants would anticipate regret if they did not implement necessary changes. Next, information about the intervention and necessary facilities for HH were presented. Removing environmental barriers and adding cues to action were discussed,

including the strategic placement of hand sanitizer and posters. Tailored system changes were advised to encourage better HH, such as how to hygienically dispose of dirty laundry.

The Dutch guidelines for (hand-related) personal hygiene dictate that staff members providing care do not wear rings, nail polish, artificial nails, long nails, bracelets, watches, a brace, or long sleeves. [24] Policy changes for personal hygiene noncompliance were discussed, including disciplinary consequences. Management was also asked to give a personal hygiene presentation between the first and second lesson. Although personal hygiene is broader than hand-related personal hygiene, we stressed the need to address hand-related personal hygiene.

Nursing homes were also promised a nonfinancial incentive. If they had a higher than average HHC, they would receive a certificate of good HH. At the end of the meeting, an intervention implementation schedule was discussed. While the compliance measurements were only completed at certain wards, all nurses and nurses' aides from the entire nursing home were welcome to participate in the intervention.

Lessons

A member of the study team provided 3 lessons lasting a half hour each. The lessons were generally given multiple times on one day to a maximum of 18 participants per session.

The first lesson began with an introduction by a senior nursing home manager, showing leadership commitment to systems change. The first goal of the lesson was to create awareness about the necessity of HH. Still images, video, and a persuasive live presentation promoted consciousness raising and anticipated regret. The second goal was to teach the participants when they needed to perform HH. They were taught using a novel description of the 5 HH moments of the WHO. [25], namely "Room In, Room Out, Before Clean, After Dirty" (*Kamer in, Kamer uit, Voor schoon, Na vies*). "Room In" corresponds to the WHO Moment 1 (before touching a patient). "Room Out" corresponds to WHO Moment 4 (after touching a patient) and Moment 5 (after touching patient surroundings). "Before Clean" corresponds to WHO Moment 2 (before a clean/aseptic procedure), and "After Dirty" corresponds to WHO Moment 3 (after body fluid exposure risk). This method comprises the same HH moments as the WHO standard, is more adapted to the nursing home setting, is easier to remember (one slogan), and is easier to visualize.

After explanation of the HH moments and reiteration that the participants are now expected to follow the rules for HH, the participants had time to ask questions. The next step was to ask the participants to pick a HH goal that would receive extra attention. This group goal was a moment that they thought was attainable and immediately implementable. The main reasons for creating a goal were to reflect upon what was just learned, create a sense of ownership, and create team commitment. All goals mentioned during the day's session were printed on a small poster and hung in the nurses' office to act as a reminder.

A larger, colorful poster was presented. Participants were told that different posters would come every month and asked where they would like the posters to hang so that they felt ownership of the project.

To encourage e-learning participation, participants received a nurse's watch (which you can pin on your clothing) after completion of the e-learning. They also left the meeting with an immediate reward, since they left with a small bottle of hand sanitizer to be used during the e-learning. This was done to create a positive association with HH. After Lesson 1, the management-level contact(s) were informed in person and by mail of any pertinent staff comments so that they could consider making system or facility changes.

Between Lesson 1 and Lesson 2, a senior nursing home manager presented the newest rules for personal hygiene to the nurses and nurses' aides. Materials were made available to assist the manager with the presentation, including a picture of an agar with bacterial growth caused by a ring and a poster displaying personal hygiene rules. Nurses and nurses' aides were informed of their organization's disciplinary consequences if they did not adhere to the personal hygiene rules.

Lesson 2 lasted 30 minutes and was usually combined with Lesson 3 to create one lesson of 50 minutes. The main goal of the second lesson was to remove the barriers that nurses experience when trying to perform HH. Each participant was given a sheet with 28 stickers representing 13 different barriers. There were 2 blank stickers, allowing participants to write down any additional barriers. The stickers represented 4 themes, namely facilities, forgetting, choosing not to do HH, and the telephone. The barriers were identified through literature, interviews, and observations.

Sheets of paper were hung on the walls, one sheet for each of the 4 elements of the slogan (Room In, Room Out, Before Clean, After Dirty). Participants were asked to place one sticker on each piece of paper representing the main reason that he or she did not perform HH at that moment. This system facilitates an organizational diagnosis of HH impediments. Once the stickers were placed, the most prevalent barriers were discussed. Group discussions resolved barriers by designing new coping strategies, cues to action, and environmental changes. The barrier analysis with solutions was in turn discussed with the nursing home manager so that any necessary system or facility changes could take place.

During Lesson 3, participants learned the correct execution of HH through active participation. Using gloves and paint, participants saw which parts of their hands they missed when washing them incorrectly and that fluids, bacteria, and viruses can get on hands during glove removal. They also learned the correct HH procedure. Although the WHO promotes a 6-step method, wrist rubbing was added since this area can easily be contaminated when removing gloves. [25] After the third lesson, management was informed of any participant feedback that could influence HHC.

E-learning

The e-learning served two purposes: It allowed nurses and nurses' aides who were unable to attend the live lessons to gain HH knowledge, and it provided reinforcement of these lessons. The e-learning consisted of an introduction and 7 lessons. The themes of the lessons were the resident's perspective, how to wash and disinfect your hands, when to execute HH, HH in combination with sterile activities, time-saving work habits, glove use, and social aspects of HH. Videos modelled knowledge, guided practice, and promoted active learning by encouraging participants to scrutinize videos.

After viewing the introduction, the participant was invited every other week to complete the next lesson. This method provided participants with regular reminders to perform HH. Each lesson lasted 5-10 minutes and ended with a quiz to reinforce the message. After completing the entire e-learning, the participant received a certificate and a nurse's watch.

Posters, Photo Competition, and an Arts and Crafts Project

To reinforce the message, 3 supplementary components were developed, namely posters, a photo competition, and an arts and crafts project. The posters acted as reminders and

included large pictures of hands and the text: "Did you remember to wash your hands?" (*Vergeet je niet je handen te wassen?*). The posters were designed to be visually appealing with a cheery image so that they could be placed in living areas. New posters were distributed monthly over a 10-month period so that the message would repeatedly capture attention. Of these posters, 5 came from the photo competition and the arts and crafts project.

Participants were invited to submit a photo for the photo competition. The idea behind this activity was to get nurses to think about HH in diverse situations, including outside the workplace. The photo submission needed to contain pictures of hands. The winners of the 3 best photos received a gift certificate. Their photos were used for 3 of the monthly posters.

Additionally, nursing homes received a package of information containing instructions on implementing a hand-related arts and crafts project with the residents. This activity had 3 goals: to create a training moment for the residents to learn when to perform HH, to inform residents that the staff is paying more attention to HH, and to again remind staff to perform HH. The 2 most appealing pieces of art were turned into 2 of the monthly posters.

Strategies to Improve and Monitor Adherence to Protocols

While the researcher used persuasive communication to convince nursing home management to allow the entire nursing staff to participate in all 3 lessons, we assumed that not everyone would attend. Intervention adherence was documented. Attendance at the HH lessons and e-learning lessons was recorded. Additionally, attendees were asked in the process evaluation if they received information about personal hygiene policy and if they saw HH posters hanging in the nursing home.

Outcomes

Primary Outcome Measure

HHC is the primary outcome measure. HHC is defined as the number of times that HH is performed at an HH opportunity (according to the WHO's 5 moments of HH), divided by the total number of times that it should be performed, expressed as a percentage. We only documented HH as compliant if hand sanitizer or soap, water, and a paper towel were used. Compliance was measured through live observations, still considered the gold standard,

even though there is a risk of observer bias and the Hawthorne effect. [26, 27] There were 4 registered timepoints (Table II).

Secondary Outcome Measure

The incidence of gastroenteritis, influenza, assumed pneumonia, MRSA, and urinary tract infections in the nursing home residents is the secondary outcome measure. Nursing home staff recorded these infectious diseases on a weekly basis, along with infectious disease outbreaks. The McGeer criteria were used to define the infectious diseases. [28]

Additional Outcome Measures

Additional outcome measures included the presence of norovirus, rhinovirus, and *Escherichia coli* (*E. coli*) on 3 types of surfaces in the nursing home. Norovirus is a common viral gastrointestinal pathogen, rhinovirus is a common respiratory pathogen, and *E. coli* is a common bacterial indicator of fecal contamination of the physical environment. To measure the presence of these pathogens, microbiology samples were taken with wipes and sent to the laboratory for analysis. Samples were taken during the first 3 timepoints for the primary outcome.

Hand-related personal hygiene compliance was also documented as an additional outcome measure. This was measured according to Dutch guidelines. [24] A nurse was considered compliant if he or she did not have long nails, acrylic nails, or polished nails and did not wear a ring, bracelet, wristwatch, brace, or long sleeves. Personal hygiene was noted for every nurse who was observed for HHC. Compliance is defined by the percentage of personal hygiene–compliant nurses, divided by the total number of nurses observed. Hand-related personal hygiene compliance was documented at the same timepoints as the primary outcome measure.

Timeline

The recruitment period lasted from March through September 2016 (Table II). The trial began with baseline measurements of HH, personal hygiene, and environmental sampling in October 2016 (baseline). At this point, nursing homes began submitting a weekly disease incidence report of the illnesses mentioned earlier. After the baseline measurements, nursing homes were allocated to 1 of the 3 study arms. For the fixed intervention nursing

Table II. Timeline of the study.

Timepoint	Study period									
	Recruitment	Baseline	Randomization			Post-allocation				Close-out
	Mar-Sept 2016	Oct 2016	Nov 2016	Dec 2016	Jan 2017	Feb 2017	Mar-Apr 2017	May 2017	Oct 2017	Nov-Dec 2017
Recruitment										
Eligibility screening	X	—[1]	—	—	—	—	—	—	—	—
Signed commitment	X	—	—	—	—	—	—	—	—	—
Randomization	—	—	X	—	—	—	—	—	—	—
Intervention (fixed intervention arm)[2]										
Meeting with management	—	—	—	X	—	—	—	—	—	—
Lesson 1	—	—	—	—	X	—	—	—	—	—
Lessons 2 & 3	—	—	—	—	—	—	X	—	—	—
E-learning[3]	—	—	—	—	X	X	X	X	X	—
Posters[3]	—	—	—	—	X	X	X	X	X	—
Assessments										
Structured interview	X	—	—	—	—	—	—	—	—	—
Compliance observations	—	X	—	—	—	X	—	X	X	—
Illness registry[3]	—	X	X	X	X	X	X	X	X	—
Microbiology samples	—	X	—	—	—	X	—	X	—	—
Process evaluation	—	—	—	—	—	—	—	—	—	X
Close-out questionnaire	—	—	—	—	—	—	—	—	—	X

[1]Not applicable. [2]For the conditional intervention arm, the intervention timeline was dependent upon the month an outbreak occurred. [3]Continuous intervention exposure or measurement

homes, this was followed by a meeting with management, the first lesson, presentation of the e-learning, start of monthly posters, and announcement of the photo competition. After the first lesson, the first follow-up observations occurred at the fixed intervention and control nursing homes 3 months after baseline. This was followed by the second and third HH lessons and the dissemination of information about the arts and crafts project at the fixed intervention nursing homes. Six months after baseline, both the fixed intervention and control nursing homes were observed again. The last observation occurred at the fixed intervention and control nursing homes 12 months after baseline.

After randomization, individual conditional intervention nursing homes followed the same schedule as the fixed intervention nursing homes, but only after an outbreak occurred. Preliminary analyses of the outcome measures were performed after every round of observations. All data were collected by December 2017. This study will be completed in 2020.

Sample Size Calculation

The HH intervention was expected to increase HH compliance from 35% pre-intervention to 50% post-intervention. The sample size was calculated based on 80% power with a two-sided α of .05, taking into account the clustering of observations within nursing homes and assuming a heterogeneity between nursing homes of 0.4. It was determined that a sample size of 45 nursing homes would be sufficient, with 15 nursing homes participating in each arm. Since we could not assume that all nursing homes in the conditional intervention arm would have an outbreak during the study period, the goal was to have a minimum of 25 nursing homes in this arm.

We aimed to evaluate 2 units at each nursing home and to observe 3 nurses in each unit for a maximum of 2 hours each. This equates to 12 hours of observation per nursing home per observation round, in which we expected to observe 75 HH opportunities, equally divided over the 5 moments of the WHO. We therefore expected approximately 1125 opportunities per arm per observation round.

Blinding

Blinding the researcher to the intervention arm was not possible in this trial because the researcher also taught the lessons. The nurses were blinded by giving distinct names to the lessons (The New Way of Working) and the observations (HANDSOME), so that they appeared to be different projects. Furthermore, nurses were told that the observers were registering the frequency of health care activities. HH observers were not informed which nursing homes were receiving the intervention, although they may have noticed HH posters from the intervention while observing.

Data Collection Instruments

Before the first observation, nursing home unit managers were interviewed in person or over the telephone. A baseline questionnaire was used to gain more insight into the background characteristics of each individual unit, such as the number of employees, brand of HH products, and type of care provided by the unit.

We designed a tablet-based observation app to measure HH and hand-related personal hygiene. The registration events were based on the 5 moments of HH, as determined by the WHO, and Dutch guidelines for personal hygiene. [16, 24] Hand-related personal hygiene was recorded once for every observed nurse per observation day.

When documenting HH, a distinction was made between the use of hand sanitizer or combination of water, soap, and paper towel. If neither method was used at an opportunity or if the water-soap-paper towel combination was missing one element, then the HH opportunity was considered "missed." To be considered compliant, HH needed to happen in the same room in which the action occurred. The only exceptions to this rule were if a nurse brought a resident to another room, a nurse carried something soiled, or no door needed to be opened before leaving the room. In these cases, HH should have taken place at the end of the action.

Compliance to the 5 moments of the WHO was broken down into submoments, giving more insight into the frequency of and compliance at submoments (Table III). Three additional activities that potentially facilitate pathogen transmission were registered separately, namely the preparation and serving of food and medication, taking gloves to use for non-resident related activities, and social contact. HHC related to food and

medication activities was documented since this could be considered a clean procedure (Moment 2). HH before taking gloves for non-resident related activities was noted because taking gloves without first performing HH may contaminate other gloves from the same box. [29] According to the WHO guideline for long-term health care, HH is not required during social contact, even though it does involve hand contact and thus potentially facilitates pathogen transmission. [16] We therefore recorded the number of times that this occurred. We defined social contact as patting the shoulder/knee, shaking hands, touching a hand, and hugging.

Once the observations were finished with one nurse, the observer reset the app for the observations with the next nurse. Personal hygiene compliance was only registered one time per nurse.

The residents' infectious disease occurrence was recorded by staff. Each unit received a notebook in which a designated person (nurse, team leader, or geriatrician) recorded the weekly incidence of gastroenteritis, influenza, assumed pneumonia, MRSA, urinary tract infections, and an outbreak. The nursing home was free to decide who was responsible for the reporting. We only collected anonymized patient data. Definitions of the illnesses were given in the notebook to promote homogeneity in reporting. Weekly reports were sent to the researcher via email or WhatsApp.

Microbiology samples were collected at baseline, 3 months after baseline, and 6 months after baseline (Table II). Samples were taken from a communal table, a communal toilet, and the computer mouse and keyboard. The qualitative molecular detection technique quantitative polymerase chain reaction was used to detect viral indicator organisms and *E. coli*. The wipes used in this process do not supply quantitative results, but they make it possible to cover a larger surface area than with swabs, enhancing the sensitivity.

A process evaluation occurred after the intervention. Every nurse who attended at least one live lesson or started the e-learning received an email with a link to a process evaluation questionnaire. They were asked questions to measure fidelity at the unit and their opinion about different aspects of the intervention.

After the intervention was completed, a senior nursing home manager participated in a close-out questionnaire to assess system changes or infection prevention programs that may have affected HHC during the study period.

Table III. Moments and submoments for hand hygiene compliance documentation.

Moment	Submoment
Moment 1 (before touching a patient)	Washing or providing perineal care in own room, providing perineal care at the toilet, other care, and after the use of a mobile phone, tablet, or computer during resident contact (during moment 1 activities)
Moment 2 (before clean/aseptic procedure)	Catheter care, wound care, injection, feeding tube care, colostomy care, pain pump care, eye drops, tracheostomy tube care, mucous suction, other invasive care, and after the use of a mobile phone, tablet, or computer during resident contact (during moment 2 activities)
Moment 3 (after body fluid exposure risk)	Invasive care, removing bedding, washing/cleaning the resident in own room, helping resident at the toilet, other (body fluid of a resident), own body fluid, helping animals, and before the use of a mobile phone, tablet, or computer during resident contact (during moment 3 activities)
Moment 4 (after touching a patient)	Resident care and before the use of a mobile phone, tablet, or computer during resident contact (during moment 4 activities)
Moment 5 (after touching a patient's surroundings)	No submoments
Additional potential moments for pathogen transmission	
Before using gloves (not patient-related)	No submoments
Before food and pills	Preparing or administering medicine, preparing food, serving food, helping with eating, and washing the resident's hands before eating
Social contact	Pat on the shoulder, shaking hands, touching a hand, and hugging

Measuring Compliance: Training and Planning

Independent observers were trained to observe HHC using an adapted training method from an HHC study in Dutch hospitals. [30] Observers were primarily nurses and doctors in training. These observers were trained over a period of 2-3 days using videos, case studies, and live observations at 2 nursing homes. The training ended with an examination using videos from Hand Hygiene Australia. [31] The observers also received training in collecting microbiological samples.

Observers documented nurses' HHC at the nursing home from 8:00 am to 2:00 pm. The objective was to observe a minimum of 3 nurses, each for a maximum of 2 hours.

Promoting Participant Retention

If a nursing home considered stopping the intervention, it was encouraged to continue the program through persuasive communication. If the nursing home refused to follow the protocol, the researcher had the option to withdraw the participant from the program. If the nursing home dropped out of the intervention, management was still asked to answer questions in the close-out questionnaire.

Data Management and Dissemination

Data were collected in different ways. Background information about the nursing homes and information from the close-out questionnaire were collected during interviews and from forms sent from the nursing homes. This information was entered in an Excel (Microsoft Corp, Redmond, WA) document. Weekly infectious disease incidence reports were similarly entered in an Excel document by a dedicated staff member. All compliance data were entered in an app and downloaded into Excel documents. Compliance data will be cleaned in SPSS version 25 (IBM Corp, Armonk, NY). The results of the microbiology samples were entered in an Excel document. Information from the process evaluation was gathered with an online survey and downloaded into SPSS. HHC and protocol adherence results were disseminated to participating nursing homes in personalized reports. The results of the study will be made available to the wider community in scientific publications. Data will be managed and archived according to the Quality Manual of the Department of Public Health, Erasmus MC, University Medical Center Rotterdam. Researchers may request access to the data from the chair of the Department of Public Health, Erasmus MC, University Medical Center Rotterdam.

Statistical Methods

The various outcomes of the trial (primary, secondary, and additional) will be analyzed separately according to the specific research hypotheses (Table IV).

Ethics Approval and Consent to Participate

Ethical approval for the study was waived by the Medical Ethics Review Committee of the Erasmus MC (no.58158). Any significant changes to the study protocol were communicated to the Medical Ethics Review Committee. All changes were communicated to the

Table IV. Statistical methods.

Outcome	Hypothesis	Outcome measure	Methods of analysis
Primary: hand hygiene	Improvement is higher in the intervention arms than the control arm.	Hand hygiene compliance (binary)	Multilevel logistic regression
Secondary: infectious disease incidence	There will be a lower disease incidence in the intervention arms than in the control arm.	Infectious disease incidence (binary)	Multilevel logistic regression
Additional: presence of norovirus, rhinovirus, and *Escherichia coli*	There will be a lower detection rate of microorganisms on surfaces in the intervention arms than in the control arm.	Proportion of samples positive for norovirus (genogroups i and ii), rhinovirus (continuous), and *Escherichia coli*	Multilevel loglinear regression
Additional: personal hygiene	Improvement is higher in the intervention arms than in the control arm.	Personal hygiene compliance (binary)	Multilevel logistic regression

participants, steering committee, and study sponsor. Consent to participate is not relevant in this study, since we did not collect any patient information. No identifying information about the nurses was collected. All collected data will be anonymized before publication to protect the privacy of the nursing home and nursing home staff. Data sets will be anonymized according to our quality manual and data management plan.

Results

The study was funded in September 2015. Medical ethical approval was waived in August 2016. Data collection started in October 2016 and was completed in October 2017. In total, 124 nursing home units were recruited in 62 nursing homes. Of these, 116 units were allocated: 36 to the fixed intervention arm, 50 to the conditional intervention arm, and 30 to the control arm. Data analysis is ongoing, and the first results are expected to be published in 2020.

Discussion

The HANDSOME study was created to increase HHC in nursing homes. We took this opportunity to not only look at HHC but also to investigate a secondary outcome: the incidence of gastroenteritis, influenza, assumed pneumonia, MRSA, and urinary tract

infections in the nursing home residents. The presence of norovirus, rhinovirus, or *E. coli* on nursing home surfaces was also documented, creating the opportunity to triangulate with HHC and infectious disease incidence. We also documented hand-related personal hygiene compliance.

The HANDSOME intervention was developed specifically for the nursing home setting. It used a blended learning model to reach as many nurses as possible. HANDSOME reframes the WHO's HH moments so that they are understandable and easily recalled in a nursing home setting. We created the slogan "Room In, Room Out, Before Clean, After Dirty," which incorporates the WHO framework for HH. It specifically takes into account that most health care actions occur in the residents' bedrooms, social contact is excluded from the HH rules in nursing homes, and it is only feasible to consider the resident's room (or that portion of the room that belongs to him or her) as the resident's surroundings.

"Room In, Room Out" is a concept that has been used before in HH policies, mostly with the terms "Wash In, Wash Out". [32, 33] The "Wash In, Wash Out" method is problematic for various reasons. It inherently neglects HH before an aseptic procedure and after contact with bodily fluids. Additionally, as demonstrated by Sunkesula *et al.*, the health care worker would often be expected to do unnecessary HH when using the "Wash In, Wash Out" method since health care workers often do not touch patients in the patient's room. [34] Furthermore, "Wash In, Wash Out" inherently emphasizes hand washing and ignores the benefits of using hand sanitizer. We address these problems by using the terms "Room In, Room Out, Before Clean, After Dirty" and teaching participants in the lessons and e-learning that they do not need to perform HH in a resident's room if they do not touch the resident or the resident's surroundings and they can omit "Room In" if they only touch the resident's surroundings without touching the resident.

Our observational method should also give more insight into HHC moments. Our study is one of the few that looks specifically at the separate moments and submoments of the 5 WHO moments. This way, we can gain better insight into which health care actions occur most frequently in nursing homes and which moments need the most attention to attain a higher HHC and less illness. We also expect to gain more insight into barriers for each HH moment. During the second lesson, participants were asked to specify barriers experienced during the different HH moments.

This study should add to the body of evidence that HHC is suboptimal in nursing homes and can be significantly improved through an intervention. We also expect to gain insight in personal hygiene compliance in nursing homes. Another strength of this study is that it created an aggregate register of residents' infections. Although there are some data about HAIs in nursing homes, most nursing homes only register illness in individual dossiers. [1] This study collected data about infection incidence using the same definitions as the National Institute for Public Health and the Environment in the Netherlands so that the data can be compared. [35] This could add more insight and help form the agenda to avoid unnecessary illness. We believe that this is also one of the first studies to systematically sample nursing home surfaces for various viruses and bacteria in order to study the potential added value as an alternative method to monitor HHC.

Another novel aspect of our intervention is that we may discover if an intervention is more successful at a random point in time or after an infectious disease outbreak. We should create more insight into when HH interventions should be implemented.

This study also has limitations. Since we used the gold standard of measuring HHC, observers directly observed nurses giving care. This may have caused Hawthorne or observer bias. A second limitation is that nursing homes were not required to send every nurse to the lessons, conceivably causing a significant variation in compliance to the protocol. Another limitation could be that observers were able to guess which nursing homes received the intervention, since these nursing homes had HH posters from the intervention hanging on the walls, which may unconsciously have influenced their observations. Last, we only observed HH at organizations with at least 3 nursing homes. This study therefore does not necessarily reflect HHC at smaller organizations.

Considering that there are few studies that have rigorously investigated the WHO's recommendations for HH, HANDSOME will provide needed insight into HH in nursing homes. The results from this study could help in creating more refined and successful HH interventions in the future. Future interventions can focus on the moments that are more often missed.

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Chapter 3

Increased hand hygiene compliance in nursing homes after a multimodal intervention; a cluster randomized controlled trial (HANDSOME)

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Abstract

Objective: To assess the effect of a multimodal intervention on hand hygiene compliance (HHC) in nursing homes.

Design, setting, and participants: HHC was evaluated using direct, unobtrusive observation in a cluster randomized controlled trial at publicly funded nursing homes in the Netherlands. In total, 103 nursing home organizations were invited to participate; 18 organizations comprising 33 nursing homes (n=66 nursing home units) participated in the study. Nursing homes were randomized into a control group (no intervention, n=30) or an intervention group (multimodal intervention, n=36). The primary outcome measure was HHC of nurses. HHC was appraised at baseline and at 4, 7, and 12 months after baseline. Observers and nurses were blinded.

Intervention: Audits regarding hand hygiene (HH) materials and personal hygiene rules, 3 live lessons, an e-learning program, posters, and a photo contest. We used a new method to teach the nurses the WHO-defined 5 moments of HH: *Room In, Room Out, Before Clean*, and *After Dirty*.

Results: HHC increased in both arms. The increase after 12 months was larger for units in the intervention arm (from 12% to 36%) than for control units (from 13% to 21%) (odds ratio (OR): 2.10; confidence interval (CI): 1.35–3.28). The intervention arm exhibited a statistically significant increase in HHC at 4 of the 5 WHO-defined HH moments. At follow-up, HHC in the intervention arm remained statistically significantly higher (OR: 1.93; 95% CI: 1.59–2.34) for indications after an activity (from 37% to 39%) than for indications before an activity (from 14% to 27%).

Conclusions: The HANDSOME intervention is successful in improving HHC in nursing homes.

Nursing home residents, like patients in hospitals, are at increased risk of developing infections from microorganisms such as norovirus and pneumonia-causing pathogens. [1] To avoid transmission of pathogens, the World Health Organization (WHO) recommends following their hand hygiene (HH) guidelines. [2] We already knew that hand hygiene compliance (HHC) in hospitals and child care centers is often suboptimal, but we did not have much insight into (Dutch) nursing home compliance and what methods could increase compliance. [3, 4]

Only a few rigorous HHC studies have been conducted in nursing homes. [5-9] In a recent Cochrane review on HH interventions, 90 articles were considered for inclusion, and only 5 of these clearly referred to nursing home care, 3 of which had inadequate days of data collection. [6, 10-14] Although these studies showed that HHC could increase after an intervention, none were a large-scale study.

We hypothesized that HHC in Dutch nursing homes (skilled nursing facilities with residential care) could be increased through a multimodal intervention specifically designed for nursing homes. We developed the HANDSOME intervention using literature, interviews at nursing homes, and intervention mapping principles to identify relevant determinants, methods, and strategies. [15]

The effect of this intervention in nursing home units in the Netherlands was assessed in a cluster randomized controlled trial. Here, we report the primary outcome measure of the trial: HHC of nurses to the WHO guidelines. The secondary outcome measure of the HANDSOME study, the incidence of healthcare associated infections in residents, will be reported elsewhere.

Methods

Trial design

The HANDSOME intervention is a cluster randomized controlled trial in Dutch nursing home units, designed to increase nurses' HHC after a multimodal intervention. Nursing homes in the intervention arm received the intervention at a predetermined moment. Nursing homes in the control arm received no intervention. The trial was conducted from October 2016 through October 2017.

HHC was measured through unobtrusive direct observation. Observations took place during weekdays, starting at 8 A.M. and lasting ca. 4.5 hours. Observations started during the mornings because we expected to see the most care activities during this period and to observe the most nurses per unit. All measurements were recorded at the same time of day to foster homogeneity between the observations. At least 3 nurses were observed in every unit, each for a maximum of 1.5 hours. When there were <3 nurses working at the unit, either the observers continued observations at an additional ward (who also received the intervention if in the intervention arm) or they stopped observing. We did not necessarily observe the same nurses at every observation period; the goal was to see an overall behavioral change and not behavioral change per nurse. We also did not collect identifying information about the nurses so they would not be concerned about us reporting their behavior to their supervisors and therefore would exhibit their regular behavior. The turnover rate of nursing staff in the year before intervention commencement was 13% (n=28 nursing home units). Nursing homes were observed at baseline (October 2016), after completion of the first lesson in the intervention units (February 2017), after completion of all lessons in the intervention units (May 2017), and 1 year after the baseline (October 2017) (Figure 1).

All HHC opportunities were registered according to the WHO-defined HH moments (Figure 2). [2] HH was only registered as compliant if the HH occurred immediately before (i.e., moments 1 and 2) or after (i.e., moments 3, 4, and 5) an HH opportunity without touching another object, such as a door handle. HHC, along with at which HH moment it occurred, was registered in an application on a computer tablet. Consecutive opportunities, such as touching a resident (moment 1) and performing an aseptic task (moment 2) without any activity in between, were only registered once and according to a protocol (Figure 2).

Study setting and eligibility criteria

We invited 103 nursing home organizations in 8 provinces in the Netherlands to participate in this study. The nursing homes were required to commit 2 nursing home units to the study. Study participants were nurses working in publicly funded skilled nursing facilities in the Netherlands providing intense psychogeriatric and/or somatic care to geriatric residents. Low-care residential facilities (*verzorgingshuizen*) were excluded from the study. Units were defined as one or multiple wards within a nursing home. When necessary, wards were linked to create units containing the minimum of 3 nurses working during the

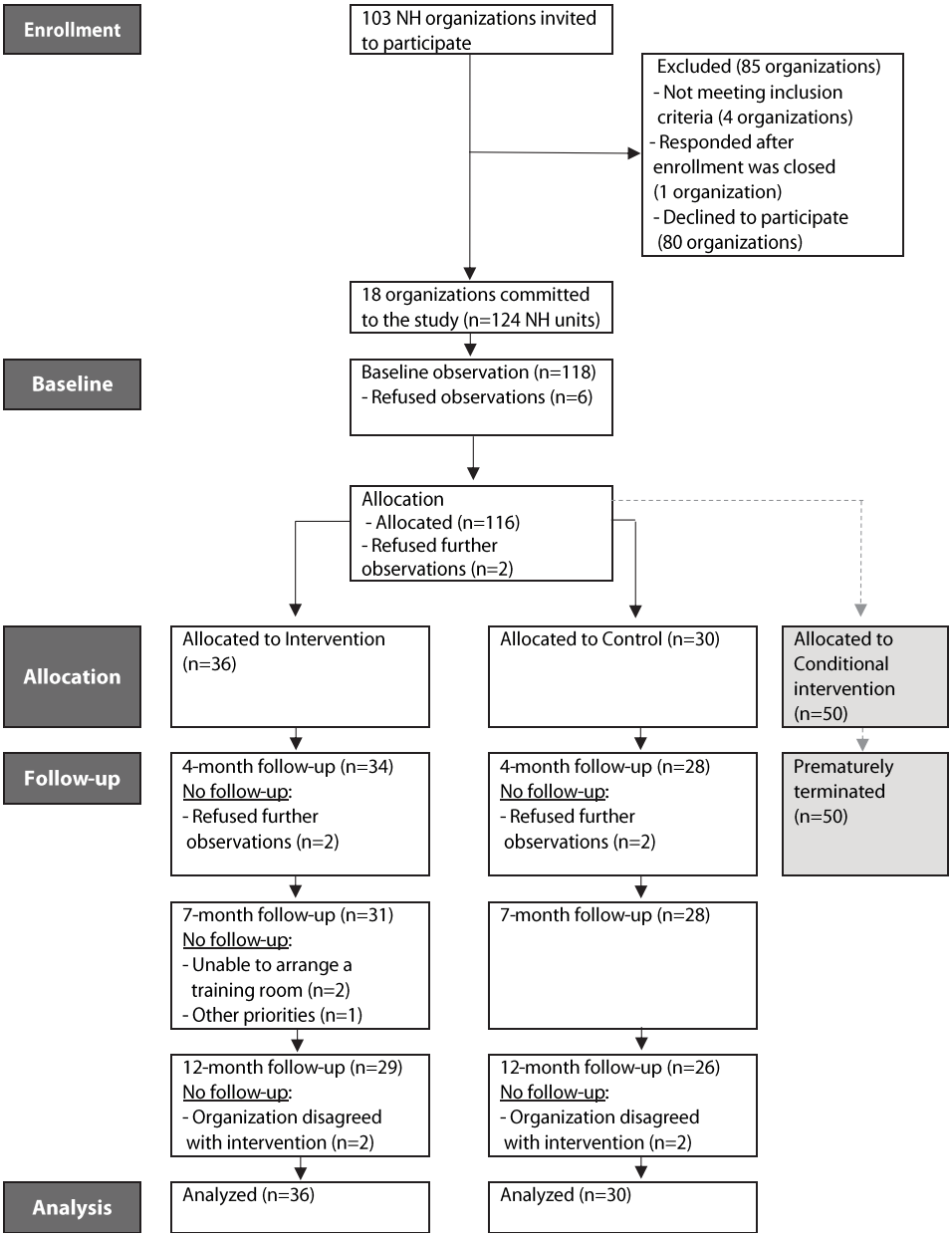
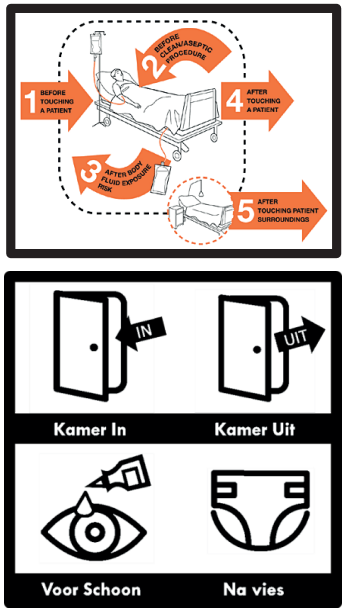


Figure 1. Study design flow diagram.



WHO		Handsome	Moments which coincided		How moments were registered
Moment 1 (before touching a resident)	→	Room In	Moments 1 & 2	→	Moment 2
Moment 4 (after touching a resident) and Moment 5 (after touching a resident's surroundings)	→	Room Out	Moments 3 & 4; Moments 3 & 5; Moments 3, 4 & 5; Moments 3 & 1; Moments 3 & 2	→	Moment 3
Moment 2 (before a clean/aseptic procedure)	→	Before Clean	Moments 4 & 1; Moments 4 & 2	→	Moment 4
Moment 3 (after body fluid exposure risk)	→	After Dirty	Moments 5 & 1; Moments 5 & 2	→	Moment 5

Figure 2. Comparing the WHO method and the HANDSOME method and protocol for registering combined hand hygiene opportunities. WHO: World Health Organization

observation hours (8 A.M. to 1:30 P.M.). Nurses all attended or were attending a 3- or 4-year nursing program (*verzorgenden* or *verpleegkundigen*). HHC of other healthcare workers, residents, and visitors was not recorded.

Intervention

The HANDSOME intervention included activities for changing nursing home policy and individual behavior. Nursing home policy changes were achieved through an audit with explanations about HH materials and personal hygiene rules. Nurses and other healthcare workers were subject to 3 different live on-site HH lessons, access to an e-learning program, posters for the nursing home wards, and the opportunity to participate in an HH photo competition (Table I). The details and background of this intervention can be found elsewhere. [15] During the lessons, nurses were taught the 5 moments of the WHO recommendations using a novel method, namely *Room In* (moment 1), *Room Out* (moments 4 and 5 combined), *Before Clean* (moment 2), and *After Dirty* (moment 3). [15] This method comprises the same 5 HH moments as the WHO standard, but it is more suitable for the nursing home setting, is easy to remember (i.e., 1 slogan), and is easy to visualize (Figure 2). All intervention units participated in all aspects of the intervention, except those that withdrew from the study.

Outcome measures

The primary outcome measure was HHC of nurses to the WHO guidelines. HHC is defined as the number of times that HH is performed at a WHO-defined HH opportunity, divided by the total number of times that it should be performed, expressed as a percentage. We registered HH as compliant if hand sanitizer was used, or soap, water, and a paper towel.

Sample size

The HH intervention was expected to increase HH compliance from 35% during the preintervention period to 50% in the postintervention period. We made a sample size calculation based on 80% power with a 2-sided α of 0.05, taking into account the clustering of observations within nursing homes, assuming an intraclass correlation of 0.1. We determined that a sample size of 15 participating nursing homes in each arm (30 units per arm) would be sufficient.

Table I. Overview of Most Important HANDSOME Intervention Components.[1]

Component	Description
Meeting with management (45 – 60 minutes)	Discussion of necessary facility and policy changes for efficient hand hygiene (HH) practices. Management is informed that they can receive a "Good hand hygiene" certification if they achieve a minimum HH compliance.
Lesson 1 (20 minutes)	A manager introduces the lesson. Teaching of *Room In, Room Out, Before Clean, After Dirty*. Teaching and discussing how to do HH when handling pills, food, and laundry, when to use hand sanitizer/soap/gloves. Team creates a group HH goal. Showing the nurse's watch that they can earn by completing the e-learning.
Presentation personal hygiene policy (10 minutes)	A senior NH manager presents the personal hygiene policy. Consequences for non-compliance are made known.
Lesson 2 (30 minutes)	Making an inventory and finding solutions to barriers for HH compliance.
Lesson 3 (20 minutes)	Participants "wash" hands with paint and see where they miss. Participants learn how to disinfect their hands. Participants see that they get paint on hands after glove removal and that the paint represents invisible bacteria/viruses.
E-learning (40 minutes)	Videos are used with correct and incorrect behavior to show HH moments, common HH actions, how to work efficiently, and when to use gloves. Teaching how to do HH when preparing food and pills. Dripped learning with quizzes is used, so that the e-learning is done in small modules over 14 weeks.
Poster (10 posters)	Multiple copies of a new poster are hung throughout the nursing home every month.
Photo competition	NH employees are informed that they can win a prize for the best photo of hands.
Arts and crafts project	Residents do an activity involving hands. NH displays artworks.

[1]The full intervention is outlined in: Teesing G, Erasmus V, Petrignani M, *et al.* Improving hand hygiene compliance in nursing homes: Protocol for a cluster randomized controlled trial (HANDSOME study) *JMIR Research Protocols 2020; 9(5):e17419.*

Randomization

The nursing home was the unit of randomization. Each nursing home was assigned an identification number and was then computer randomized to one of the arms by the primary investigator. All nursing homes in the control arm also had a nursing home from the same organization in the intervention arm. We used a cluster-randomized design because certain aspects of the intervention were aimed at the entire nursing home.

Blinding

It was not possible to blind the primary investigator to the intervention arm because this researcher also taught on-site lessons. Nurses were blinded by giving distinct names to the lessons (The New Way of Working) and the observations (HANDSOME), so that they appeared to be different projects. Furthermore, nurses were told that the observers were registering the frequency of health care activities, rather than HHC. HH observers were not informed which nursing homes received the intervention.

Statistical analyses

Background characteristics of all randomized nursing homes were tested for statistically significant differences between the study arms. We computed HHC for each arm for every observation round, as well as for the total follow-up. Analysis was on intention-to-treat basis through multilevel analyses, controlling for statistically significant differences ($p<0.05$) in background characteristics between the study arms and for clustering of observations within nursing homes and nurses. We calculated odds ratios (ORs) for HHC in a multilevel model with 95% CIs, comparing baseline with each follow-up round and the total follow-up in each arm, and comparing the intervention and control arms at each round. Additionally, we calculated overall odds ratios comparing the increase in HHC in the intervention arm with the increase in the control arm. This was calculated for total HHC and per WHO-defined HH moment. HH moments before and after a HH-indicated activity were also statistically compared. We also examined the difference between nurse and student nurse HHC. All calculations were done in SPSS version 25 software (IBM, Armonk, NY).

Adjustments after commencement of the trial

This study originally had an additional "conditional" intervention arm to test a separate hypothesis that implementing a HH intervention following an infectious disease outbreak would have a higher and/or more sustained effect than implementation at a predetermined date, due to an increased sense of infection risk and urgency after an outbreak. The conditional arm was randomized, along with the control and conventional intervention arms, in November 2016, and received the same intervention as the conventional intervention arm, but only after an infectious disease outbreak.

In September 2017, we terminated the conditional intervention arm prematurely for the following reasons: (1) Two nursing homes in this arm were not able to implement the intervention after an outbreak because they had no funds for paying wages for employees to attend the lessons; (2) In 4 cases, the intervention would have taken place during a spring or summer holiday season, during which all available staff was needed at the wards; and (3) observers were not available for some projected observation periods. Due to the premature termination, only half of the nursing home units we aimed to include participated (15 instead of 30 nursing home units), and no 12-month follow-up observations were performed. We did not perform analyses of observations in this arm because we did not achieve the necessary cohort size and because of selection bias.

Ethical considerations

Ethical approval for the study was waived by the Medical Ethics Review Committee of Erasmus MC, University Medical Center Rotterdam (reference no. 58158) because it was not a medical-scientific investigation and because no experiments were conducted on human subjects. A manager at each nursing home approved the study before randomization, including observations. No identifying information was collected about the nurses or residents. We only observed nurses when the residents receiving care did not object to the observations.

Results

Nursing homes were recruited from April through August 2016, and 18 nursing home organizations joined the study, yielding 36 intervention units (938 beds) and 30 control units (865 beds) (Figure 1). Reasons for dropout were refusal to admit observers, inability to

schedule lessons in an appropriate room, other priorities, and disagreement with the intervention content.

We compared background characteristics between the study arms. The only statistically significant difference between the study arms was the size of the nursing home with the control arm having more large nursing homes (p=0.01) (Table II). The size variable was therefore incorporated in all multilevel calculations.

HHC increased over time in both study arms: HHC increased from 12% to 36% in the intervention arm and from 13% to 21% in the control arm (Figure 3). The largest increase in HHC in the intervention arm occurred after the first lesson (at the 4-month follow-up), whereas the control arm steadily increased by 3% at every observation round.

We observed ca.1,000 HH opportunities with 100 nurses per arm per observation round, totaling 8,671 potential HH moments with 782 nurses, of which 17% were nursing students (Table III). We detected no significant difference in HHC at baseline between the study arms. For the intervention arm, HHC was statistically significantly higher during all follow-up measurements than at the baseline, and the OR increased gradually from 3.48 to 4.29. The control arm had a statistically significantly higher HHC during the 7- and 12-month follow-ups than at baseline, but with lower ORs than the intervention arm (ORs, 1.55 and 1.79, respectively). The control arm received no intervention; 60% of the nursing homes in the control arm took their own initiatives to increase HHC (data not shown). Overall, the intervention nursing homes showed a statistically significantly higher increase in HHC during the total follow-up versus the baseline period than the control nursing homes (OR: 2.28; 95% CI: 1.67–3.11).

In the intervention arm, HHC increased for both nurses (from 12% to 34%) and students (from 11% to 32%). Similarly, we saw an increase in the control arm for both nurses (from 14% to 21%) and students (from 11% to 14%, data not shown).

HHC per WHO-defined moment during the 4 observation rounds is depicted in Figure 3. HHC increased more for the intervention arm than for the control arm for each moment, except for moment 2. HHC at moment 2 appeared random and retained a low compliance (with a low sample size).

Table II. Comparison of Baseline Characteristics Between Study Arms (n=66 Nursing Home Units).

Characteristics	Intervention (n=36), %	Control (n=30), %	p-value* (intervention v. control)	n (total)
Organization				
Size of organization			0.50	58
Small (<800 beds)	38	31		
Medium (800 – 1199 beds)	25	23		
Large (1200 or more beds)	38	46		
Nursing Home				
Size of nursing home			0.01	66
Small (<88 beds)	36	27		
Medium (88 – 118 beds)	47	13		
Large (119 or more beds)	17	60		
Urbanization			0.75	66
Extremely, very or somewhat urban	53	57		
Mildly or not urban	47	43		
Management style			0.46	66
Self-organized teams	28	20		
Hierarchical	72	80		
HH reminders hang somewhere			0.35	58
Yes	66	77		
No	34	23		
HH trainings in the past 5 years			0.89	60
Yes	38	36		
No	63	64		
Unit				
Size of unit			0.74	66
Small (<20 beds)	25	27		
Medium (20 – 29 beds)	33	37		
Large (30 or more beds)	42	37		
Number of nurses per bed			0.07	66
Fewer than 1 nurse per bed	72	50		
At least 1 nurse per bed	28	50		
Hand sanitizer available in bedroom			0.86	64
Yes	41	43		
No	59	58		
Faucet in every bedroom			0.30	62
Yes	77	64		
No	24	36		
Type of unit			0.59	66
Psychogeriatric / joint geriatric-psychiatric care	50	43		
Somatic care / combination psychogeriatric & somatic care	50	57		

Characteristics	Intervention (n=36), %	Control (n=30), %	p-value* (intervention v. control)	n (total)
Residents				
Washes him/herself			0.94	60
None	69	68		
Some	31	32		
Goes to the toilet without assistance			0.10	59
Less than 20%	77	57		
20% or more	23	43		
How intense is the care			0.81	66
Only high level of care	89	87		
All levels	11	13		

*Pearson χ^2 test.

Table III. Hand Hygiene Compliance in Nursing Homes per Trial Arm, During Baseline and Follow-Up.

Compliance	Intervention arm		Control arm		OR[1] (95% CI), Intervention vs. Control arm
Baseline	12%	(189/1620)	13%	(166/1254)	0.92 (0.55, 1.55)
4-month FU	33%	(340/1045)	16%	(146/921)	1.79 (0.93, 3.46)
OR* (95% CI) 4-month FU vs. Baseline	3.48 (2.45, 4.93)		1.14 (0.80, 1.62)		2.62 (1.68, 4.08)
Baseline	12%	(189/1620)	13%	(166/1254)	0.92 (0.55, 1.55)
7-month FU	33%	(318/977)	19%	(181/942)	2.37 (1.42, 4.00)
OR* (95% CI) 7-month FU vs. Baseline	3.89 (2.78, 5.44)		1.55 (1.09, 2.21)		2.43 (1.62, 3.67)
Baseline	12%	(189/1620)	13%	(166/1254)	0.92 (0.55, 1.55)
12-month FU	36%	(373/1024)	21%	(187/888)	1.87 (1.12, 3.14)
OR* (95% CI) 12-month FU vs. Baseline	4.29 (2.92, 6.31)		1.79 (1.23, 2.60)		2.10 (1.35, 3.28)
Baseline	12%	(189/1620)	13%	(166/1254)	0.92 (0.55, 1.55)
Total FU	34%	(1031/3046)	19%	(514/2751)	1.98 (1.30, 3.02)
OR* (95% CI) Total FU vs. Baseline	3.81 (2.86, 5.08)		1.45 (1.09, 1.93)		2.28 (1.67, 3.11)

[1]OR was corrected for size of the nursing homes as well as clustering of observations within nurses and nursing homes in a multilevel analysis. The intraclass correlation (ICC) for the level nurse was 0.25 and the ICC for the level nursing home was 0.01. OR: odds ratio; FU: follow-up

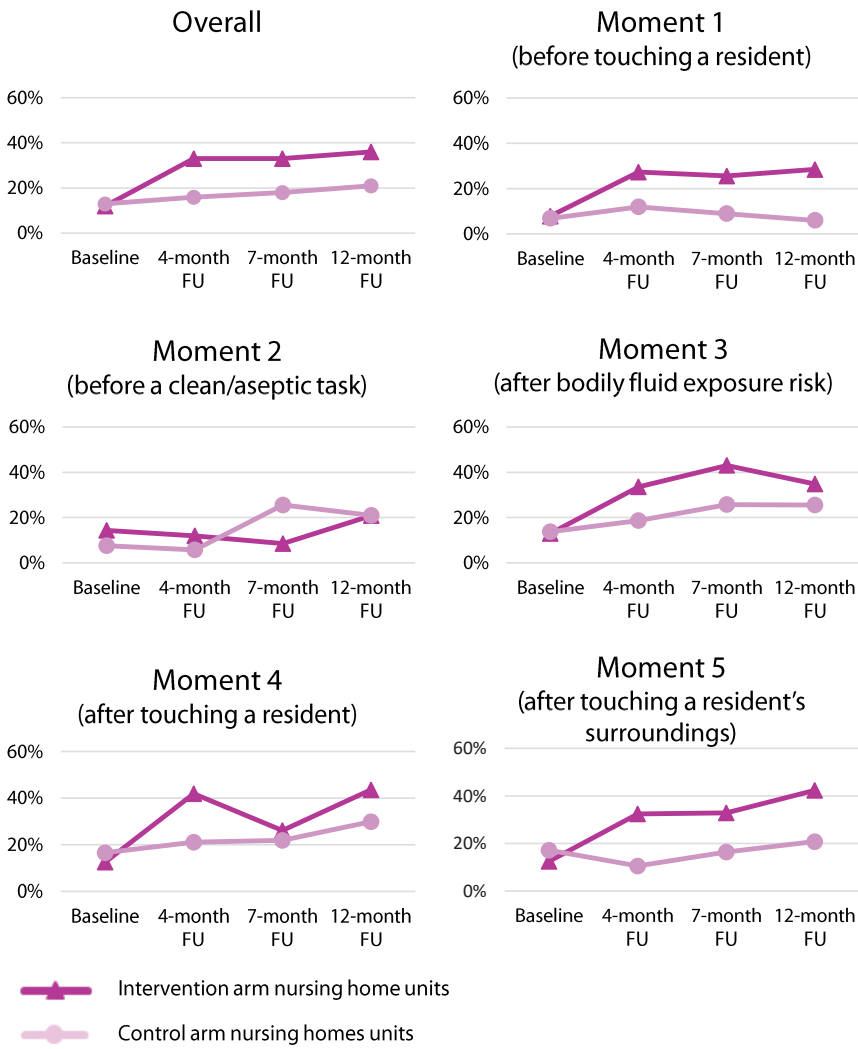


Figure 3. Hand hygiene compliance and in nursing homes per trial arm during baseline and follow-up, overall and per WHO-moment. FU: follow-up; WHO: World Health Organization

For each of the 5 WHO-defined moments, we compared HHC for the total follow-up with the baseline measurement, for both arms (Table IV). HHC per WHO moment ranged from 8% to 14% at baseline, indications before an activity (moments 1 and 2) showing a lower HHC than indications after an activity (moments 3, 4, and 5) (OR: 2.05, 95% CI: 1.63–2.57, data not shown). We detected no statistically significant difference in HHC at baseline between the intervention and the control arms at each WHO moment. For the intervention arm, HHC statistically significantly increased (19%–25%) during follow-up versus baseline at 4 of the 5 WHO moments, except for the sparsely observed moment 2. HHC in the control arm increased significantly at moments 3 and 4. HHC was statistically significantly higher during follow-up at 3 of the 5 WHO moments in the intervention arm compared to the control arm. The largest increases in HHC in the intervention arm compared to the control arm occurred at moment 5 (OR: 3.30; 95% CI: 2.04–5.32) and moment 1 (OR: 3.20; 95% CI: 1.95–5.26). At follow-up, HHC for the intervention arm remained statistically significantly higher (OR: 1.93; 95% CI: 1.59–2.34) for indications after an activity (37% to 39%) than for indications before an activity (14% to 27%) (results not shown).

Discussion

The HANDSOME intervention demonstrates that a multimodal intervention can increase HHC in nursing homes. Adherence to HH guidelines increased significantly during the intervention and remained higher 6 months after the intervention but remained suboptimal. HHC in the intervention arm increased significantly at 3 of the 5 HH moments compared to the control arm, and HHC was better after an HH-indicated activity than before an HH-indicated activity.

This study has several strengths: (1) It is one of the first randomized controlled HH trials in a nursing home; (2) it registers HH moments using direct observation; (3) it is a large-scale study, registering >8,500 HH opportunities; and (4) we studied the long-term effect of an HH intervention. The strengths of the HANDSOME intervention include the following: (1) It involves a minimum time commitment from the nurses for lessons; (2) it provides an audit of the prerequisites for HH at nursing homes; (3) it is tailored to nursing homes; and (4) it includes supplementation with online learning.

Table IV. Hand Hygiene Compliance in Nursing Homes per Trial Arm, During the 5 WHO-Defined Moments (n=8,671 Hand Hygiene Opportunities).

Moment	Compliance	Intervention arm		Control arm		OR[1] (95% CI) Intervention vs. Control arm
1 (Before touching a resident)	Baseline	8%	(30/381)	6%	(19/276)	1.16 (0.62, 2.18)
	Total FU	27%	(207/763)	9%	(62/683)	2.97 (1.67, 5.29)
	OR* (95% CI) FU vs. Baseline	4.67 (2.81, 7.75)		1.32 (0.71, 2.44)		3.20 (1.95, 5.26)
2 (Before a clean/aseptic task)	Baseline	14%	(12/84)	8%	(4/53)	3.02 (0.55, 16.41)
	Total FU	14%	(22/162)	18%	(22/121)	0.64 (0.20, 2.06)
	OR* (95% CI) FU vs. Baseline	0.86 (0.35, 2.08)		2.35 (0.68, 8.08)		0.64 (0.26, 1.59)
3 (After body fluid exposure risk)	Baseline	13%	(70/540)	14%	(52/415)	0.81 (0.47, 1.39)
	Total FU	38%	(356/947)	24%	(203/864)	1.80 (1.17, 2.76)
	OR* (95% CI) FU vs. Baseline	3.90 (2.68, 5.67)		1.88 (1.27, 2.78)		1.82 (1.28, 2.60)
4 (After touching a resident)	Baseline	14%	(40/319)	17%	(49/295)	0.74 (0.37, 1.49)
	Total FU	39%	(263/674)	25%	(152/621)	1.76 (1.00, 3.09)
	OR* (95% CI) FU vs. Baseline	4.10 (2.58, 6.51)		1.56 (1.01, 2.41)		2.03 (1.30, 3.17)
5 (After touching a resident's surroundings)	Baseline	13%	(37/296)	17%	(37/215)	1.06 (0.37, 2.98)
	Total FU	37%	(183/500)	16%	(75/462)	2.78 (1.71, 4.55)
	OR* (95% CI) FU vs. Baseline	4.00 (2.54, 6.31)		0.93 (0.51, 1.67)		3.30 (2.04, 5.32)

[1]OR was corrected for size of the nursing homes as well as clustering of observations within nurses and nursing homes in a multilevel analysis. The intraclass correlation (ICC) for the level nurse was 0.25 and the ICC for the level nursing home was 0.01. WHO: World Health Organization; OR: odds ratio; CI: confidence interval; FU: follow-up

The study also has several limitations. We only observed HH on weekday mornings and early afternoons. HHC in all study arms may have been influenced by a national HH campaign in 2016–2017 for nursing homes. [16-25] There may also have been some contamination from the intervention nursing homes to the control nursing homes, since all control nursing homes had a nursing home from the same organization in the intervention arm. Although the nursing homes in the control arm did not receive any intervention, 60% of nursing homes in the control group took their own action to increase HHC. Nevertheless, we saw better HHC in the intervention arm than in the control arm. Another possible limitation is bias. First, ward managers sometimes refused to keep observations blinded, so some nurses in both trial arms were informed of the purpose of the observations. Secondly, observers could figure out which units received the intervention if they saw the HANDSOME posters, causing potential observer bias. Lastly, the Hawthorne effect may have affected different nurses in different ways, depending upon the number of observation rounds that each nurse experienced. [26] At the same time, because this is an RCT, we believe that the biases were generally equal in both arms, with the possible exception of observer bias.

In this study, HHC increased in the intervention group from 12% to 36%. The highest increase came directly after the first HH lesson. The continuation of the HH intervention (with expanded explanations and repetition) may have been instrumental in capturing a long-term effect and possibly a culture change, considering staff and student turnover.

Although HHC tripled, it remained well below the idealized 100%. At the same time, this is comparable with 3 other Dutch intervention studies in hospitals, which also had a low baseline compliance (20% to 22%) and yielded a 15%–33% increase in HHC. [27, 28]

Studies in nursing homes outside the Netherlands showed a baseline compliance of 6% to 27%. [5-9] Two of these studies also demonstrated the effectiveness of HH interventions (HHC increased from 6% to 46%, 27% to 61%, and 22% to 49%). [5, 6] Studies investigating the long-term effects of one-off HH interventions in nursing homes remain scarce. [6]

The 5 HH moments have distinctive infection prevention goals. Moments 1 and 2 prevent contamination not only from the nurse's topical flora to the resident but also prevent contamination of microorganisms from other residents. Moment 2 is considered a high-risk moment for the resident because the nurse has contact with the resident's open skin or

mucous membranes. [29] Moments 3, 4, and 5 prevent contamination from the resident to the nurse. Moment 3 is also important for the resident because it reduces the chance of microorganisms going from a colonized site on the resident to a noncolonized site. In the literature, primarily regarding hospital care, moment 4 generally has the highest compliance, followed by moment 3. [29-38] These are both moments after an HH-indicated activity. These moments may be prioritized because the healthcare provider wants to protect himself or herself.

In the HANDSOME intervention, the highest compliance at baseline occurred at moment 4, followed by moment 5, two moments that protect the healthcare provider and prevent the spread of disease to other residents. These results are comparable to results from other Dutch studies showing that HHC is better after a HH-indicated activity than before such an activity. [3, 4, 7]

A few other intervention studies distinguished differences in HHC at the different HH moments, although none of these studies had a control arm. [35-38] The HHC in the HANDSOME intervention was consistently low for all moments at baseline, whereas the other studies showed high fluctuations among the different moments. [29, 35-38] The largest gains in other studies were generally at moments 1 and 5. In our study, the largest differences between the control and intervention arms occurred in the follow-up period at moments 1 and 5, but the largest absolute gains in the intervention arm occurred at moments 3, 4, and 5.

In conclusion, the HANDSOME intervention yielded a substantial increase in HHC 4 months after the beginning of the intervention, and this improvement was sustained in the long term. Part of its success may be due to our slogan: *Room In, Room Out, Before Clean, After Dirty*. This slogan is easy to remember, evokes imagery, and contains all the WHO moments. Nursing homes can easily implement the intervention, and it requires little time commitment from the nurses. Because we included a balanced mix of large and small nursing homes and in urban and nonurban settings, we believe that our results could be duplicated in other nursing homes.

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Chapter 4

Hand hygiene and glove use in nursing homes before and after an intervention

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Abstract

We investigated whether an intervention to improve hand hygiene compliance in nursing homes changed glove use. Hand hygiene compliance increased, but substitution of hand hygiene with gloves did not decrease. We observed a reduction of inappropriately unchanged gloves after exposure to body fluids.

Hand hygiene (HH) is a cornerstone of infection prevention programs in nursing homes. Yet, HH is often lacking when gloves are donned or doffed. [1] Although gloves are necessary before a sterile procedure, when a healthcare worker (HCW) expects contact with body fluids, and when using contact precautions, gloves should be used in combination with HH. [2] HH is necessary before donning gloves because micro-organisms on hands can contaminate the outsides of gloves (and other gloves in the same box). HH is also necessary after removing gloves, since microorganisms on gloves can contaminate hands and wrists during glove removal. When an HCW dons or doffs gloves at an HH opportunity without performing HH, we assume that the HCW knows that an infection prevention activity should be done. We therefore consider this replacing HH by glove use (i.e., 'substitution'). Being unaware of the importance of the WHO guidelines and suboptimal availability of HH materials has been shown to cause low compliance with HH and glove protocol. [3]

The primary goal of this paper is to investigate whether the HH intervention in the HANDSOME study decreased substitution of HH by glove use. We also explore other glove use at HH opportunities.

Methods

In this before-and-after study, we used data from a cluster randomized controlled trial to evaluate an HH intervention (HANDSOME study). The protocol and HH compliance outcomes are described elsewhere. [4, 5] The present study analyses glove use in the intervention arm of the trial.

Definitions and data collection

All HH opportunities were registered in accordance with the WHO-defined HH moments. [6] Total HH compliance rates exclude food- and medication-related opportunities. HH was defined as compliant if the nurse used either alcohol-based hand rub (ABHR) or the combination of soap, water, and a paper towel at a WHO-defined HH opportunity, regardless of glove use. HH compliance was measured through unobtrusive direct observation at baseline (October 2016) and follow-up (4 months, 7 months, and 1 year after the baseline observation). We recorded whether HH was performed, which WHO-defined moment it was, which submoment (when applicable), and glove use. Gloves were considered inappropriately unchanged if the nurse was wearing the same gloves as during

a previous activity (moments 1 or 2) or if the nurse did not remove gloves after an activity for which HH was indicated (moments 3, 4, and 5). No distinction was made between sterile and nonsterile gloves.

Analysis

At every HH opportunity, the nurse could do one of the following actions: (1) perform HH and not use gloves, (2) perform HH and don or doff gloves, (3) perform no HH, but don or doff gloves (substitution), (4) perform no HH and inappropriately not change gloves, or (5) perform no HH and not wear gloves. The rate of each category was calculated as the number of times that the action occurred, divided by the total number of WHO-defined HH opportunities, expressed as a percentage. We recorded frequently occurring submoments, specifically (1) before or after washing and/or perineal care in own room, (2) before or after helping at the toilet, (3) after an aseptic procedure, and (4) after removing bedding. Differences in glove-related behavior between baseline and follow-up measurements were statistically tested in multi-level analyses, controlling for clustering of observations within nursing homes and nurses. Because differences are easily statistically significant due to the large number of observed HH opportunities, we considered them to be relevant (and presented the statistical test results) when there was an absolute difference of at least 10%. We also investigated the actions per observed nurse in multilevel analyses, controlling for clustering of observations within nursing homes. Nurses were included if they were observed for 5 or more HH opportunities. Odds ratios (OR) were calculated with 95% confidence intervals (CIs). All data were analyzed using IBM SPSS Statistics for Windows, version 25 (IBM, Armonk, NY).

Ethical approval was waived by the Medical Ethics Review Committee of Erasmus MC, University Medical Center Rotterdam (reference no. 58158).

Results

We observed 4,666 HH opportunities with 476 nurses in 36 nursing home units. Before the intervention, substitution (15% of HH opportunities) was performed more often than HH without gloves (9% of HH opportunities). After the intervention, substitution remained 15%, while HH without gloves increased from 9% to 30% (OR: 3.40; 95% CI: 2.55–4.55). There was

a slight decrease in gloves that were inappropriately unchanged (13% to 9%) and a slight increase in HH with donning and doffing gloves (3% to 9%).

Next, we compared WHO moments at baseline versus follow-up (Figure 1). Substitution varied per moment at baseline (4%–27%). During follow-up, we observed little change in substitution per moment compared to the baseline (0% to −4%). The combination of HH and gloves occurred infrequently at the baseline (0%–4%) and remained infrequent for most moments after the intervention (1%–13%).

Moment 3 showed the largest decrease in inappropriately unchanged gloves (−14%; OR: 0.48; 95% CI: 0.33–0.68). There was little change (−4% to +3%) in substitution between baseline and follow-up for studied submoments. There were relevant changes in inappropriately unchanged gloves for moment 3: after washing or performing perineal care in resident's room (−26%; OR: 0.19; 95% CI: 0.10–0.36) and after residents were helped at the toilet (−20%; OR: 0.18; 95% CI: 0.06–0.50). Correctly performing HH with gloves occurred more frequently at follow-up, specifically after helping the resident at the toilet (+22%; OR: 7.94; 95% CI: 1.72–36.59), after perineal care in the resident's room (+17%; OR: 36.59; 95% CI: 4.87–274.90), and before washing or performing perineal care in the resident's room (+11%; OR: 3.10; 95% CI: 1.40–6.89).

We investigated whether individual nurses' behavior changed at follow-up (345 nurses; mean, 13 opportunities; range, 5–37; standard deviation, 6). The percentage of nurses who performed substitution at least once remained stable (Table I). We detected a 15% increase in nurses who combined HH with glove donning and doffing at least once and a 15% decrease of nurses who inappropriately did not change gloves at least once.

Discussion

We investigated whether an HH intervention in nursing homes changed glove usage. Substitution occurred at 15% of HH opportunities at baseline and did not decrease at follow-up. At moment 3 (i.e., after body fluid exposure risk), there was a marked reduction of inappropriately unchanged gloves (−17%). There were increases in performing HH with donning and doffing gloves at 3 submoments. The percentage of nurses who performed substitution at least once remained stable.

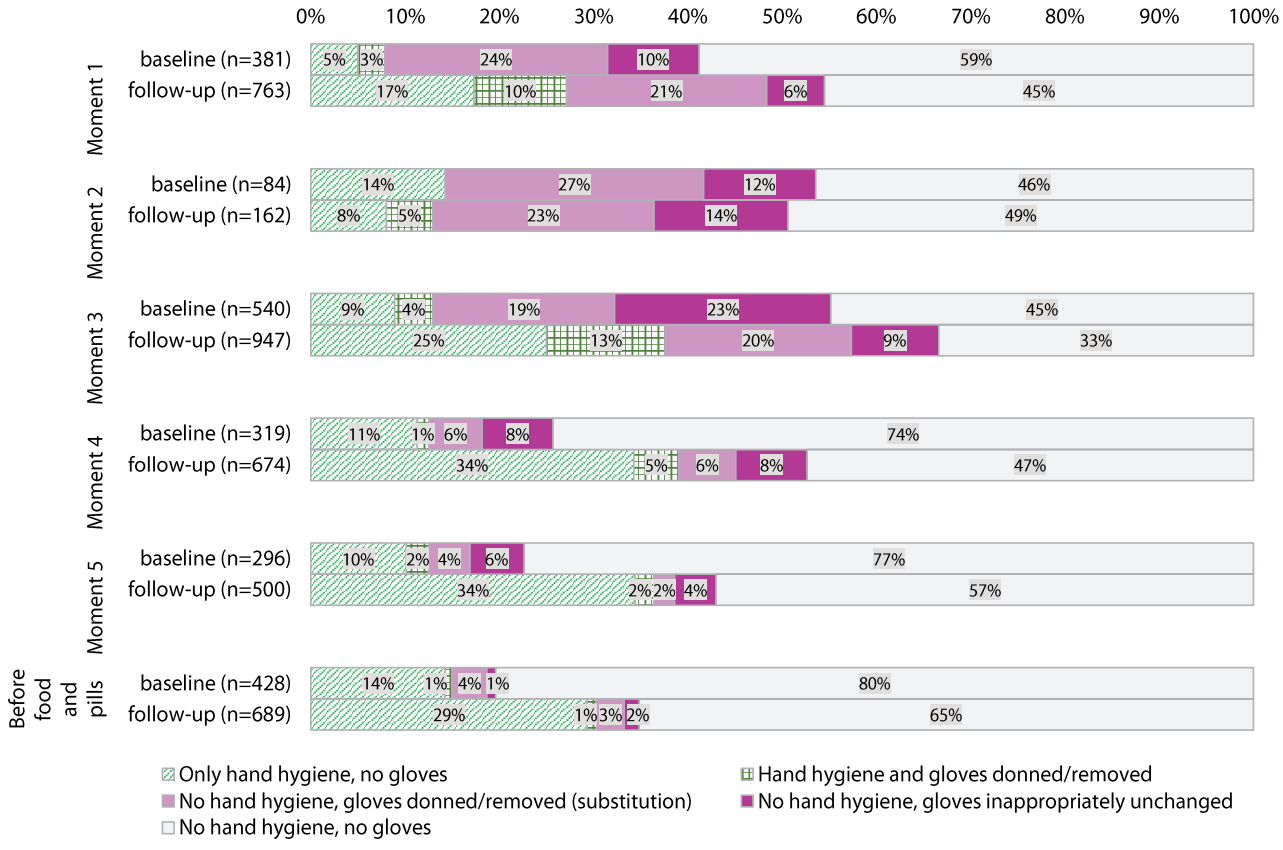

Figure 1. Hand hygiene compliance and glove use at the 5 WHO moments during baseline (n=2,048 hand hygiene opportunities) and follow-up (n=3,735 hand hygiene opportunities.

Table I. Individual nurses' behaviour during the study.[1]

Action	Baseline (n=109), %	Follow-up (n=236), %	Difference, %	Odds ratio (95% confidence interval)[2]
Performed hand hygiene with donning/removing gloves at least once	28	43	+15	1.98 (1.20, 3.28)
Replaced hand hygiene with gloves (substitution) at least once	73	72	-1	0.91 (0.55, 1.53)
Inappropriately unchanged gloves at least once without doing hand hygiene	49	34	-15	0.50 (0.31, 0.82)
Never did hand hygiene, never wore gloves	12	4	-8	0.40 (0.18, 0.90)

[1]345 nurses, of whom 15% were nursing students. [2]Odds ratios were corrected for the clustering of observations within nursing homes in a multilevel analysis.

Other studies have also reported little change in substitution after an HH intervention. [7-10] In our study, facilities for HH were often lacking in the residents' rooms (29% of nursing home units lacked a sink, 54% lacked ABHR), possibly explaining why substitution remained constant. A strength of the study is that not only the WHO Moments but also the frequently occurring submoments were investigated. Furthermore, individual nurse's behavior was analyzed. A limitation is that only nurses were observed, although nurse's aides provide substantial care in nursing homes.

In conclusion, the intervention was not successful in reducing substitution of HH by glove use, even though the training addressed substitution. [5] We observed significant positive changes in HH with donning and doffing gloves as well as a significant decrease in inappropriately unchanged gloves after contact with body fluids. Nurses in nursing homes need dedicated glove-use training.

Acknowledgments

We thank Roel Faber for developing the application to register the observations and Jennifer Bloem for assisting in the organization of the study.

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Chapter 5

The effect of a hand hygiene intervention on infections in residents of nursing homes: a cluster randomized controlled trial

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Abstract

Background: The primary goal of hand hygiene is to reduce infectious disease rates. We examined if a nursing home's participation in a hand hygiene intervention resulted in residents having fewer healthcare associated infections (HAIs) when compared to nursing homes without the hand hygiene intervention.

Methods: This study is a part of a cluster randomized controlled trial in 33 nursing homes to improve hand hygiene (HANDSOME). The incidence of five illnesses was followed over 13 months: gastroenteritis, influenza-like illness, pneumonia, urinary tract infections and infections from methicillin-resistant *Staphylococcus aureus* (MRSA). Incidence rates per study arm were reported for baseline (October – December 2016) and two follow-up periods (January – April 2017, May - October 2017). HAI rates were compared in a Poisson multilevel analysis, correcting for baseline differences (the baseline infection incidence and the size of the nursing home), clustering of observations within nursing homes, and period in the study.

Results: There was statistically significantly more gastroenteritis ($p<0.001$) and statistically significantly less influenza-like illness ($p<0.01$) in the intervention arm when compared to the control arm. There were no statistically significant differences for pneumonia, urinary tract infections, and MRSA infections in the intervention arm when compared to the control arm. In a sensitivity analysis, gastroenteritis was no longer statistically significantly higher in the intervention arm ($p=0.92$).

Conclusions: As in comparable studies, we could not conclusively demonstrate the effectiveness of an HH intervention in reducing HAIs among residents of nursing homes, despite the use of clearly defined outcome measures, a standardized reporting instrument, and directly observed HH in a multicenter cluster RCT.

Introduction

Healthcare associated infections (HAIs) are a major cause of morbidity and mortality in nursing homes. The European Center for Disease Prevention and Control (ECDC) estimated an incidence of 3.2 HAI per 1000 resident days in long term health care in 2013. [1, 2] Infection prevention measures, including improving hand hygiene (HH) compliance, can decrease HAIs. [3] Poor HH compliance by health care workers may result in higher rates of infections through the transmission of microorganisms from a health care worker to a resident and vice versa, and between residents, through either direct contact or fomite transmission.

While increased HH compliance of health care workers has been shown to decrease HAIs in hospitals, nursing homes, and the community setting, study outcomes are inconsistent. [3-6] A systematic review by Hocine, et al. from 2015, included 56 studies in nursing homes, of which 8 studies were randomized controlled trials (RCTs). [6] Thirty-five studies (63%) reported results in favor of the HH intervention regarding infections of residents and/or staff. Of the 8 RCTs, only 2 concluded that increased HH was associated with a reduction of infections. The large variety in infections measured and methodological flaws limited the comparison between studies and the interpretation of the results. The authors concluded that future interventional studies should enhance methodological rigor by using clearly defined outcome measures, standardized reporting, and a relevant HH observation tool.

We evaluated the results of a multimodal HH trial (HANDSOME) tailored for nursing homes. [7] This was a large cluster RCT in 33 nursing homes in the Netherlands. The goal of this intervention was to increase the HH compliance of health care workers. The intervention was successful in increasing HH compliance in the intervention arm compared to the control arm: compliance in the intervention arm increased from 12% to 36% and in the control arm from 13% to 21% (OR: 2.28; CI: 1.67-3.11).

In this paper, we present the secondary outcome of the HANDSOME trial: the incidence of selected HAIs in residents of the nursing homes.

Methods

HANDSOME is a cluster RCT in 66 Dutch nursing home units, designed to evaluate the effect of a multimodal intervention to increase health care workers' HH compliance. Nursing homes in the intervention arm received the intervention while nursing homes in the control arm received no intervention. The trial was conducted from October 2016 through October 2017. The intervention took place from January through April 2017.

The multimodal intervention included a combination of activities for changing hygiene policy and the individual behavior of nurses. Nursing home policy changes were achieved by auditing personal hygiene rules as well as available HH materials. Nursing staff was subject to an e-learning, 3 live lessons, posters, and a photo competition. [7, 8] HH compliance was measured through unobtrusive direct observation according to the WHO-defined HH moments and recorded in a novel app. [7, 8] The nurses were blinded by giving distinct names to the lessons (The New Way of Working) and the observations (HANDSOME), so that they appeared to be different projects. Furthermore, nurses were told that the observers were registering the frequency of health care activities (in general).

Thirty-three nursing homes each committed 2 nursing home units to the study. Randomization was done per nursing home so that both units within one nursing home were always randomized to the same study arm. All nursing homes provided intense psychogeriatric and/or somatic care to geriatric residents. Units were defined as one to three wards within a nursing home. NH wards were considered eligible as a unit if they had three or more nurses working during observation hours (8 am to 1:30 pm on weekdays), so that we could observe a minimum of three nurses during one observation session. If there were not enough nurses employed during those hours in one ward, multiple wards were combined and considered one unit for purpose of this study. A nurse was defined as someone trained in nursing skills with either a 3-year nursing degree (*verzorgende*) or 4-year nursing degree (*verpleegkundige*). Nursing assistants (*helpenden*) were excluded. Nursing homes were computer randomized after baseline hand hygiene measurements to either the intervention arm or the control arm. Differences between the study arms were investigated, such as the level of care, type of care, the number of nurses per bed, and the availability of HH materials in the residents' rooms. Size of the nursing homes was the only statistically significant background variable after randomization: the intervention arm had more small and

medium-sized nursing homes (<88 beds, 88-118 beds) while the control arm had more large nursing homes (>118 beds). The study protocol, background information, and other results of the trial can be found elsewhere. [7-10]

The outcome measures of this paper are the incidence of gastroenteritis, influenza-like illness (ILI), assumed pneumonia, urinary tract infections (UTIs), and infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in nursing home residents. We investigated these HAIs based on the four most prevalent HAIs reported in nursing homes in Europe (respiratory disease, urinary tract infections, skin infections and gastroenteritis). [1] We did not investigate skin infections since the incidence is low. We included MRSA since the incidence of MRSA in nursing homes in the Netherlands is of growing concern.

Residents' infections in each unit were recorded weekly. Each nursing home unit had a staff member (nurse, team leader, or geriatrician) who recorded the incidence (per week) of gastroenteritis, ILI, pneumonia, UTI, and MRSA, in a notebook using the McGeer criteria. [11] MRSA is not defined by the McGeer criteria. It is generally tested in nursing homes with nasopharyngeal and oropharyngeal swabs and is per definition laboratory confirmed. Every infection per resident was recorded once in the study; multiple unique infections per resident could be recorded. All infection data were registered anonymously. Weekly illness incidence reports were sent to the researcher via email or WhatsApp. When the illness incidence report was not sent, the dedicated staff member at the nursing home unit received weekly reminders by email and/or phone until all illness incidence reports were collected. Units commenced their illness incidence reporting the same week that HH was first observed. The first observation of HH occurred over a period of 4 weeks in October 2016.

We compared our data to data from SNIV, a national surveillance network (www.sniv.nl). The SNIV routinely collects data from 34 nursing homes, representing approximately 4060 residents. No nursing homes participated simultaneously in this study and the SNIV surveillance program. At our request, SNIV provided infection incidence data corresponding with the weeks of the HANDSOME trial. This study and the SNIV both (1) use the McGeer illness definitions and (2) represent a geographically diverse sample of nursing homes throughout the Netherlands.

All nursing home units were included in the analyses in an intention-to-treat model. To calculate resident days, all beds in a unit were included, regardless of occupancy, since beds were generally all occupied during the study period. [12] Units were included for a particular week if the HAI-incidence was recorded for that week. Illness per 1000 resident days was calculated as (total recorded incidence per arm* 1000) / (total number of recorded resident-weeks per arm*7).

Differences in illness incidence between the intervention and control arms were explored per period: Baseline (October – December 2016); during the intervention (Follow-up 1: January-April 2017); and post-intervention (Follow-up 2: May – October 2017). Infection incidence rates in the intervention arm were compared to the control arm in a Poisson multilevel analysis to account for the clustering of observations within a nursing home. This model corrected for baseline differences (baseline infection incidence and the size of the nursing home, the only statistically significantly different background variable after randomization) as well as study period (baseline, during the intervention, follow-up). (7) Since exceptionally high HAI incidence rates per unit per week could unduly affect the analyses, we performed a sensitivity analysis by rerunning the analyses after removing the highest 1% incident rates per HAI per week. We also tested if there was variation of treatment effect over time. We did this by replacing the variable "period" with "months" and adding an interaction term to the model (month * study arm).

Data from the control and intervention arms were combined to calculate yearly infection incidence rates per 1000 resident days (range, mean, and interquartile range) for the individual nursing home units over the period November 2016 – October 2017, in order to ease comparison of our data to other datasets in the future. Data were analyzed using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA), and R version 4.0.2.

Results

Of the 66 nursing home units in the HANDSOME trial, 36 (976 beds, median 25 per unit) were in the intervention arm, and 30 (886 beds, median 28 per unit) in the control arm. During the baseline measurements, the intervention and control arm units sent in their illness incidence reports on average 81% and 73% of the twelve weeks, respectively (Supplementary table S1). Eight units (12%) left the study during the follow-up for various reasons: six intervention units (four during Follow-up 1 and two

during Follow-up 2) and two control units (both during Follow-up 2). [7] There was on average 99%-100% reporting per week for both arms during the follow-up, excluding the weeks after units discontinued the study.

Figure 1 shows the incidence of episodes of gastroenteritis, ILI, pneumonia, UTI, and MRSA by study arm per month, covering 640,486 resident days. The infection incidence registered by SNIV is included for comparison. Our data showed similar trends to the SNIV data. Since MRSA was not a common cause of disease (16 cases of MRSA were reported, with one unit in the intervention arm reporting 8 cases in Follow-up 2), we excluded it from further analyses. The two arms in the study had similar rates of infection per month. There was evidence of variation of treatment effect over time for ILI (April $p=0.01$, May $p=0.03$, and August $p=0.02$), pneumonia (April $p=0.01$), and UTI (April $p<0.001$).

Figure 2 shows the same incidences, but now per study period, again including infection incidence registered by SNIV. There was more ILI in the intervention arm in the Baseline and more UTI in the intervention arm during Follow-up 1. In general, our study showed more reported infections than the SNIV, most notably for ILI.

Incidence fluctuated per intervention arm, HAI type, and period (Table I). UTI was the most common infection reported (n=941), approximately triple the number of cases of pneumonia (n=392), ILI (n=346), or gastroenteritis (n=331). When analyzing the data in a multilevel Poisson analysis, the intervention arm had statistically significantly more gastroenteritis ($p<0.001$) and statistically significantly less ILI ($p<0.01$), when compared to the control arm. There were no statistically significant differences between the study arms with regards to pneumonia and UTI incidence. In the sensitivity analysis, there was no statistically significant difference between the study arms with regards to gastroenteritis ($p=0.92$).

We explored how often nursing home units reported HAIs (i.e., reported a number other than zero). Other than UTI, each HAI type was reported in <10% of the weekly reports (Supplementary table S2). UTI was reported in 23% of the weekly reports. Incidence of any HAI in any week was ≤16 per unit (79 per 1000 resident days).

There was a marked difference between the study arms in April 2017 (Follow-up 1) for gastroenteritis. This was largely caused by a gastroenteritis outbreak in one

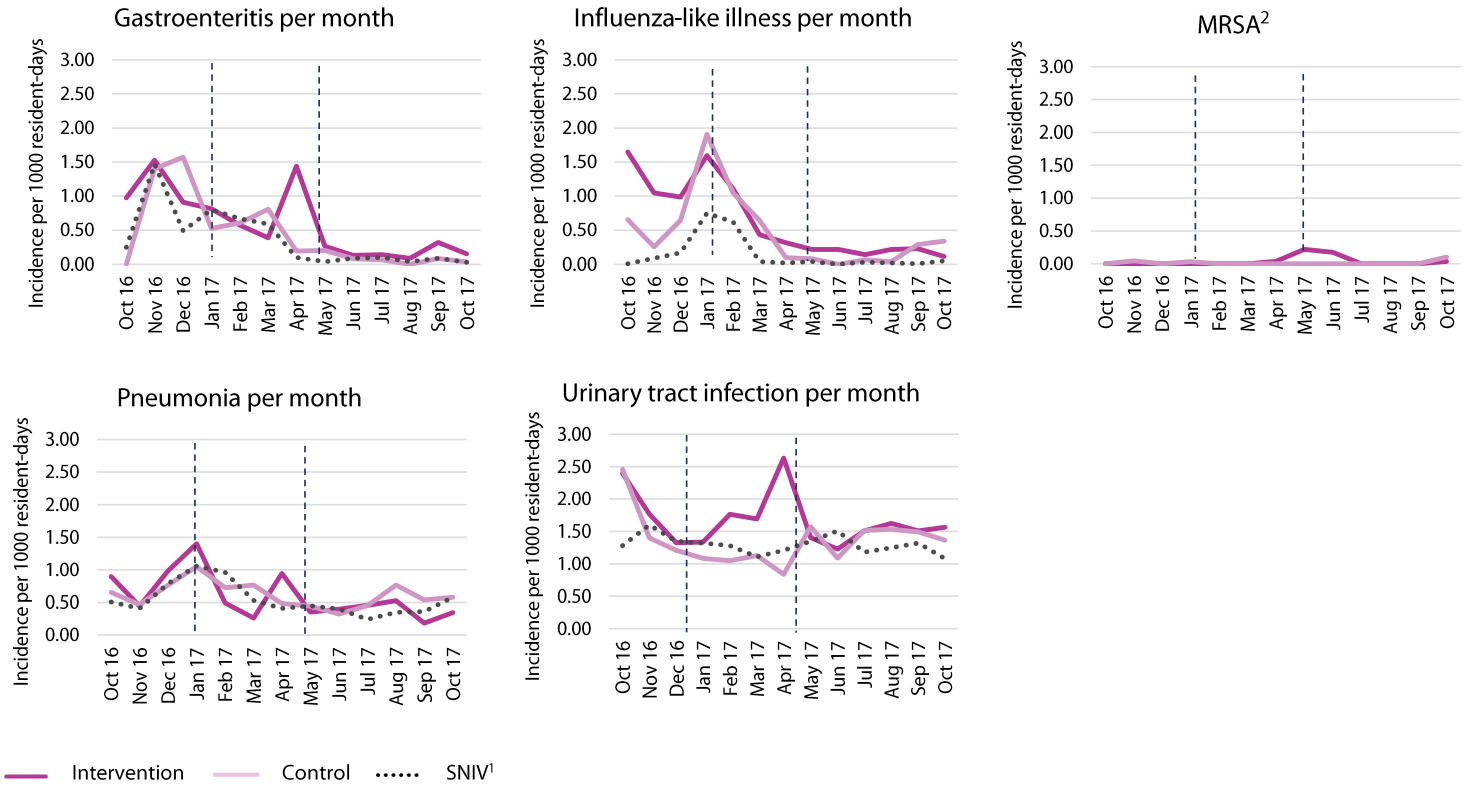

Figure 1. Infection incidence per 1000 resident-days in nursing homes by month[1] (n=640,486 resident days). [1]For comparison, incidence registered by the Dutch surveillance network for infectious diseases in nursing homes (SNIV) is also depicted (black dotted line). The dashed vertical lines indicate the three study periods (Baseline, Follow-up 1, and Follow-up 2). [2]SNIV did not provide data for MRSA.

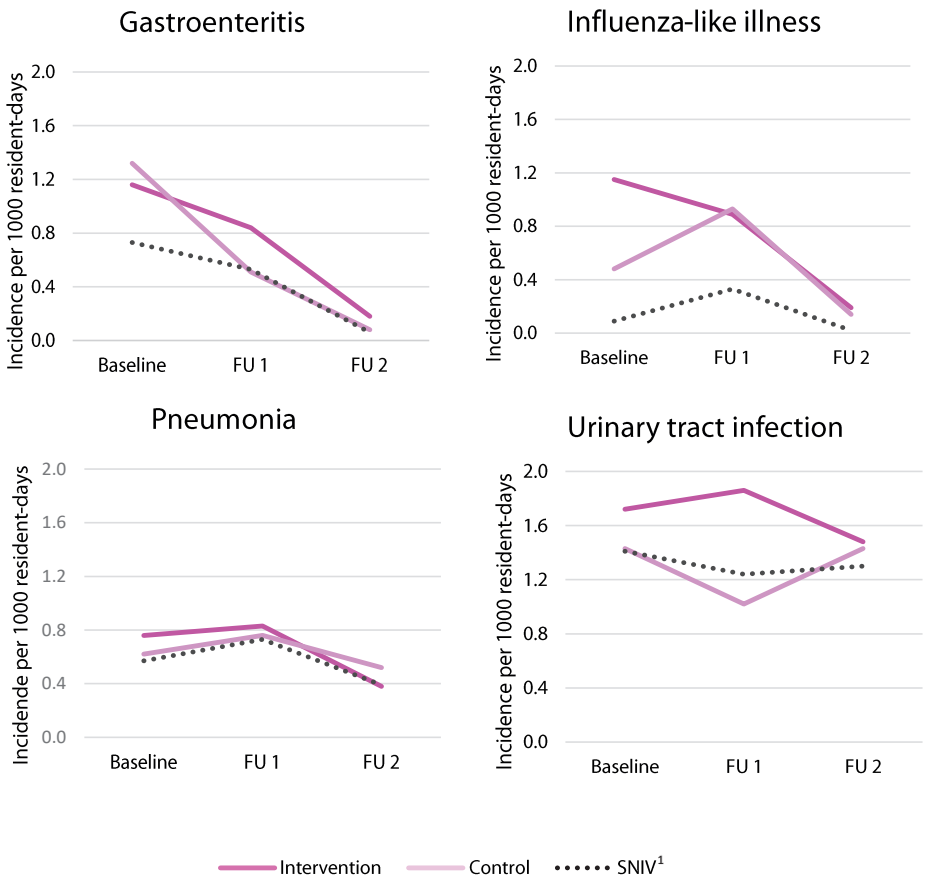

Figure 2: Infection incidence per 1000 resident-days in nursing homes by study period (n=640,486 resident days). Baseline: October 2016 – January 2017, Follow-up 1: February 2017 – April 2017, Follow-up 2: May 2017 – October 2017. FU: Follow-up. [1]For comparison, incidence registered by the Dutch surveillance network for infectious diseases in nursing homes (SNIV) is also depicted (black dotted line). FU: Follow-up

intervention unit in April 2017 (31 cases of gastroenteritis over 2 weeks (76 cases per 1000 resident days)), the most prominent outlier in the data. This is an outlier in our data since all other records of gastroenteritis per unit per month showed less than 17 cases per 1000 resident days. This increase in gastroenteritis coincided with a notable increase in UTIs in the same nursing home unit in the same 2-week period (27 cases of UTI per 1000 resident days).

Lastly, the yearly mean infection incidence rate (November 2016 – October 2017) per 1000 resident days per unit was: 0.64 for gastroenteritis, 0.70 for ILI, 0.64 for pneumonia, and

Table I. Healthcare-associated infection incidence per 1000 resident days in nursing homes: intervention versus control arm.[1]

Illness and period[1]	Intervention arm		Control arm		Full dataset[2]		Sensitivity analysis[2,3]	
	per 1000 resident days	number of cases	per 1000 resident days	number of cases	Incidence rate ratio (95% CI)	p-value	Incidence rate ratio (95% CI)	p-value
Gastroenteritis								
Baseline	1.16	(75/64617)	1.32	(72/54453)				
Follow-up 1	0.84	(89/106554)	0.51	(57/111048)				
Follow-up 2	0.18	(26/144914)	0.08	(12/158900)				
					2.32 (1.49, 3.61)	<0.001	1.03 (0.56, 1.90)	0.92
Influenza-like illness								
Baseline	1.15	(74/64617)	0.48	(26/54453)				
Follow-up 1	0.89	(95/106554)	0.93	(103/111048)				
Follow-up 2	0.19	(27/144914)	0.14	(22/158900)				
					0.51 (0.31, 0.82)	<0.01	-[4]	-
Pneumonia								
Baseline	0.76	(49/64617)	0.62	(34/54453)				
Follow-up 1	0.83	(88/106554)	0.76	(84/111048)				
Follow-up 2	0.38	(55/144914)	0.52	(82/158900)				
					0.87 (0.60, 1.26)	0.47	0.79 (0.52, 1.21)	0.28
Urinary Tract Infection								
Baseline	1.72	(111/64617)	1.43	(78/54453)				
Follow-up 1	1.86	(198/106554)	1.02	(113/111048)				
Follow-up 2	1.48	(214/144914)	1.43	(227/158900)				
					1.05 (0.78, 1.42)	0.75	1.15 (0.83, 1.59)	0.39

[1]Baseline: October 2016 – December 2016, Follow-up 1: January 2017 – April 2017, Follow-up 2: May 2017 – October 2017. [2]The results were corrected for the clustering of infection registrations within nursing homes, baseline differences and period in the study, in a multilevel Poisson regression. [3]The sensitivity analysis excluded the highest 1% incident rates per HAI per week. [4]Could not fit model due to convergence issues. CI: Confidence Interval

1.63 for UTI (Table II). By comparing the range and the interquartile range, we see that the data is skewed towards zero.

Table II. Healthcare-associated infection rates per unit per 1000 resident days (November 2016 – October 2017, n=66 units).

HAI	Range	Mean	Interquartile range		
			25%	50% (Median)	75%
Gastroenteritis	0 - 5.56	0.64	0.00	0.25	0.78
Influenza-like illness	0 - 5.72	0.70	0.00	0.30	0.92
Pneumonia	0 - 1.65	0.64	0.34	0.43	0.86
Urinary tract infection	0 - 6.28	1.63	0.72	1.26	2.18

Discussion

We investigated the impact of an HH intervention for nursing homes staff on HAI in residents. Five illnesses were investigated: gastroenteritis, ILI, pneumonia, UTI, and MRSA. There was statistically significantly more gastroenteritis ($p<0.001$) and less ILI ($p<0.01$) in the intervention arm when compared to the control arm when taking baseline data into account and controlling for the clustering of observations in nursing homes, baseline differences, and the period in the study. For pneumonia and UTI, there were no differences between study arms. Sensitivity analysis did not confirm that there was statistically significantly more gastroenteritis in the intervention arm ($p=0.92$).

Other studies have also looked at the effect of an HH intervention on HAI reduction. The results of the systematic review cited in the introduction suggest that HH interventions may help control the infectious risk in nursing home settings, but that the precise impact remains poorly documented. [6] Many studies in the review were limited by methodological flaws; only 8 of 56 studies were RCTs, 6 of which were published over the last 5 years before the review (in the period 2010-2015). Also, most studies were in single-site nursing homes and provided a limited array of data. Finally, a low proportion of the studies in the review included direct observations of HH compliance, and the authors recommend strongly that future studies should include direct observation of HH compliance. Our current study complies with the recommendations from this review in that it is a large multicenter trial with extensive data collection on many possible determinants for HH compliance and risk factors for infection. Additionally, HH

compliance was established through direct observation. Nevertheless, our study produced rather paradoxical results of which the interpretation is challenging.

After baseline, nursing homes were randomly assigned to either the control or intervention arm, ensuring that nursing homes from the same organization were in different study arms. Despite randomization, there were marked differences in the distribution of HAIs at baseline. This could possibly be explained by the fact that the introduction of infectious disease is a highly random phenomenon, especially when observed over a short period. Baseline differences between the two arms of the trial were particularly notable for ILIs and to lesser extent for gastroenteritis.

Many infectious diseases are seasonal. We addressed this through our RCT-design, assuming the seasonal changes to be the same in both arms. Yet, our implementation of the RCT may not have been ideal for two reasons: (1) It was possibly difficult to see a statistically significant difference between the study arms, because the follow-up period was primarily after the winter season when one would expect lower rates of gastroenteritis and ILI (February – October 2017); and (2) because of the generally low HAI incidence, observation is ideally performed over multiple years.

A hand hygiene intervention is not always the most important hygiene intervention to reduce HAIs, which can have both endogenous and exogenous sources. Hand hygiene compliance should primarily decrease HAIs that spread through person-to-person contact, with a secondary effect of lower contamination of surfaces. When the most prevalent transmission route is via droplet or aerosols, mask usage can be the most important hygiene intervention. We would therefore expect the effect of increased hand hygiene on gastroenteritis to be high and on pneumonia or UTI to be low, considering the disease pathways. At the same time, hand hygiene is necessary when handling a catheter and approximately 12% of nursing home residents have a catheter. [13] The results of our study are rather paradoxical (there was a statistically significant increase of gastroenteritis in the intervention arm) and emphasize that it is difficult to establish the effect of improved hand hygiene when using HAI as an outcome indicator.

To place the outcomes of the HANDSOME study into perspective, we compared these with a Dutch national surveillance program (SNIV) and European data from the ECDC. The nursing homes in HANDSOME (both intervention and control arms of the study) followed the SNIV data closely (except for ILIs); the control arm followed the SNIV trends more closely. A possible

explanation that the nursing homes in the intervention arm registered more infections could be that the nursing homes in the intervention arm were extra alert to infections among residents because of the intervention and thus more motivated to provide diligent illness incident reports than nursing homes in the control arm. Comparing our data to the infection rates provided by the ECDC, we had slightly more reporting of HAI (4.2 per 1000 resident days vs. 3.2 per 1000 resident days), even though the ECDC has a broader definition of HAI, including, for instance, skin/soft tissue infections, eye/ear/mouth/nose infections and bloodstream infections. [1]

We used the McGeer criteria in this study to define infectious diseases for two reasons: (1) the SNIV uses the McGeer criteria, and we wanted to compare our data to another dataset; and (2) it is hard to justify (invasive) diagnostic testing in nursing home residents when the goal of the study is not to find suspected HAIs but to understand the effect of hand hygiene on HAIs. At the same time, the diagnosis of HAIs is often uncertain and may be based on subjective criteria. Additionally, the McGeer criteria have been updated by diverse researchers and organizations; newer insights could lead towards more accurate identification of HAIs. (14-15) Future studies could perform diagnostics for more definitive results or use updated versions of the McGeer criteria.

The effect of HH on HAIs may be dependent on various infection prevention measures, such as cleaning methods and schedules. It is also assumedly dependent on the HH compliance level. Although the HANDSOME intervention was successful in tripling the HH compliance in the intervention arm, it only reached a 36% compliance rate. [7] The hand hygiene compliance in the intervention arm may not have crossed a critical threshold to lower infection rates. Some (primarily single-site or small-scale) studies in nursing homes have shown a correlation between HH compliance and infection rates, although larger studies generally show no relationship, making it difficult to determine a threshold value. [6] The compliance rate after the intervention might have been higher if more nurses had attended the lessons; the estimated attendance of health care workers at *at least one* of the lessons varied per unit: 23% units had <50% of the unit's health care workers attending at least one lesson, 18% had 50-74% attendance at *at least one* lesson and 59% had >75% attendance at *at least one* lesson (n=22).

Understanding the pathways of HAIs during social interactions in nursing homes is also important when evaluating the results of interventions on HAIs. In contrast to hospital settings,

nursing homes promote the socialization of residents. Residents may practice poor hygiene, and hence infect each other. The HANDSOME intervention did not target residents. Therefore, it cannot be expected that the direct resident-to-resident infection rate decreased. There are also social interactions in a nursing home between residents and staff for which HH is not prescribed by the WHO, such as a handshake or patting a hand. [16] This is different than in a hospital, where all hand interactions are considered HH opportunities. [17]

A strength of the study is that it is based on data from a large multicenter cluster RCT. There are also limitations. Firstly, there may have been factors that influenced the reliability of the HAI data. Illness was recorded weekly by hand, which could elicit recall bias. Although the nursing home staff was accustomed to reporting infections in individual dossiers, they were not accustomed to reporting weekly infections for the unit as a whole. Since this type of illness incident reporting was new, it may have taken time until the illness incident reporting was consistent. Secondly, consistency between units may also have been a problem, since the function of the staff member who registered illnesses (nurse, team manager, or geriatrician) varied per unit. The staff member's knowledge of HAIs present in the unit may also have differed. At the same time, this study used stratified randomization; for every nursing home in the intervention arm (2 units), there was generally one nursing home from the same organization in the control arm (2 units), thereby minimizing differences between study arms. The nursing homes in the two study arms were also not statistically significantly different for various variables, including management style, number of nurses per resident, and the intensity of care. [7] Therefore, we expect the illness incident reporting errors to be similar in the two arms of the study.

Conclusion

This study, similarly to comparable studies, could not conclusively demonstrate the effectiveness of an HH intervention in reducing HAIs among residents of nursing homes, despite the use of clearly defined outcome measures, a standardized illness incident reporting instrument, and directly observed HH in a multicenter cluster RCT. This could be due to an insufficient increase in HH compliance and/or other factors in the nursing home environment that need to be addressed concurrently in order to decrease illness rates.

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Supplementary table S1: Number of received illness incident reports from nursing home units per study week

Week, Year	Intervention arm	Control arm
41, 2016	3	0
42, 2016	15	1
43, 2016	26	8
44, 2016	33	19
45, 2016	34	27
46, 2016	33	29
47, 2016	33	29
48, 2016	33	30
49, 2016	35	30
50, 2016	35	30
51, 2016	35	30
52, 2016	35	30
1, 2017	34	29
2, 2017	34	29
3, 2017	34	30
4, 2017	34	30
5, 2017	34	30
6, 2017	33	30
7, 2017	34	30
8, 2017	34	30
9, 2017	34	30
10, 2017	33	30
11, 2017	32	30
12, 2017	32	30
13, 2017	32	30
14, 2017	32	30
15, 2017	32	30
16, 2017	32	30
17, 2017	32	30
18, 2017	32	30
19, 2017	32	30
20, 2017	32	30
21, 2017	32	30
22, 2017	32	30
23, 2017	32	30
24, 2017	32	30
25, 2017	32	30
26, 2017	32	30
27, 2017	32	30
28, 2017	32	30
29, 2017	32	30
30, 2017	32	30
31, 2017	32	30
32, 2017	32	30
33, 2017	32	30
34, 2017	32	30
35, 2017	32	30
36, 2017	32	30
37, 2017	32	30
38, 2017	30	28
39, 2017	30	28
40, 2017	30	28
41, 2017	30	28
42, 2017	30	28
43, 2017	30	28
44, 2017	30	28

Supplementary Table S2: Number of cases (incidence) of a HAI per unit per week (intervention n=1612 weeks, control n=1477 weeks)

Number of incidences per week per unit	Gastroenteritis		Influenza-like illness		Pneumonia		Urinary tract infection		MRSA	
	Int.	Control	Int.	Control	Int.	Control	Int.	Control	Int.	Control
0	1494	1413	1495	1395	1458	1323	1227	1151	1607	1472
1	93	35	82	52	139	130	303	269	3	5
2	12	13	18	17	7	21	63	46	0	0
3	8	8	11	6	6	3	14	9	0	0
4	2	2	2	3	0	0	4	1	2	0
5	0	1	2	2	1	0	0	0	0	0
6	0	2	1	1	1	0	0	0	0	0
7	1	0	1	0	0	0	0	1	0	0
8	0	1	0	1	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0
10	0	1	0	0	0	0	0	0	0	0
11	0	1	0	0	0	0	1	0	0	0
12	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0
15	1	0	0	0	0	0	0	0	0	0
16	1	0	0	0	0	0	0	0	0	0
Percentage of weeks with zero HAI incidence	93%	96%	93%	94%	90%	90%	76%	78%	100%	100%
Range of incidence per week per 1000 resident days	0-79	0-52	0-57	0-38	0-24	0-18	0-54	0-71	0-16	0-10

Int.: Intervention

Chapter 6

The association of environmental surface contamination with hand hygiene and infections in nursing homes: a prospective cohort study

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Abstract

Background: Little is known about the presence of infections in nursing home residents, the causative microorganisms, how hand hygiene (HH) influences this presence, and to what extent environmental contamination is associated with the incidence of residents' infections.

Aim: To establish (1) whether environmental contamination can be used as an indicator for HH compliance, and (2) whether environmental contamination is associated with the incidence of infections.

Methods: Collection of environmental surface samples in an exploratory study as part of a HH intervention in 60 nursing homes. E environmental surface sample results on three distinct surfaces (nurse's station, communal toilet, and residents' shared living area) were compared to nurses' HH compliance and to residents' infection incidence. Real-time polymerase chain reaction assays were used for the detection of norovirus genogroup I and II, rhinovirus and *E. coli*. HH compliance was measured by direct observation. Infection incidence was registered weekly.

Findings: We detected rhinovirus (nurse's station: 41%; toilet: 14%; living area: 29%), norovirus (nurse's station: 18%; toilet: 12%; living area: 16%), and *E. coli* (nurse's station: 14%; toilet: 58%; living area: 54%). There were no statistically significant ($p<0.05$) associations between HH compliance and the presence of microorganisms. There was an association of *E. coli* contamination and disease incidence in general ($p=0.04$). There were no other associations between microorganisms and illness incidence.

Conclusion: We detected rhinovirus, norovirus and *E. coli* on surfaces in NHs. There were no convincing associations between environmental contamination with HH compliance or illness incidence. This study does provide reference data about surface contamination.

Introduction

Healthcare-associated infections (HAIs) are a major cause of morbidity and mortality in nursing homes (NHs). The European Centre for Disease Prevention and Control estimates a prevalence of 38 HAIs per 1000 resident-days in long-term health care, with the most prevalent being respiratory infection, urinary tract infection (UTI) and skin/soft tissue infection. [1, 2] Infections can be endogenous or exogenous, and increased compliance with hand hygiene (HH) can decrease the exogenous infection rate. [3] Poor HH compliance by healthcare workers can result in higher rates of infection through the transmission of micro-organisms from an infected resident or healthcare worker to another resident through either direct contact or fomite transmission. HAI has also been shown to be associated with the complexity of care, resident characteristics, duration of contact, number of contacts, and type of contact. [4, 5]

The evaluation of HH compliance is challenging. Direct observation is costly and can be affected by the Hawthorne effect or observer bias, and automated HH monitoring systems do not register all HH opportunities. [6, 7]

Disease monitoring can also be challenging in NHs. In the Netherlands, few NH organizations perform disease surveillance. This is contrary to hospitals, where infection surveillance is part of a quality system with dedicated staff to register illness and perform sampling, and diagnostics are used to determine causative micro-organisms.

Environmental surface sampling (ESS) is commonly used in the control of food safety or veterinary infections to detect environmental contamination after an outbreak, but this method has not, to the authors' knowledge, been used to monitor HH compliance of nurses or as a proxy for infections among residents in NHs. [8] ESS is an objective measurement tool that is not dependent on the observations of either nurses or observers. [9, 10] The challenges in evaluating HH compliance and disease surveillance mentioned led the authors to execute exploratory research to establish if environmental contamination can be used as an indicator for HH compliance; and if environmental contamination is associated with the incidence of infection.

Methods

Study design

This cohort study explored the presence of indicator micro-organisms in the environment, and associations with HH compliance of nurses and the incidence of infection among residents (as measured prospectively in the HANDSOME study). [11] HANDSOME, a cluster randomized controlled trial in publicly funded Dutch NHs, determined the increase in HH compliance among nurses after a multi-modal HH intervention. The NHs in the intervention arm received the intervention and those in the control arm did not receive any intervention. The multi-modal intervention targeted NH policy changes by auditing personal hygiene rules as well as available HH materials, and targeted behaviour of nurses through e-learning, three live lessons, posters, and a photo competition. Data were collected between October 2016 and October 2017. Eighteen NH organizations committed three or four NHs to the study. All NHs provided psychogeriatric and/or somatic care to geriatric residents. The protocol and HH compliance results are described elsewhere. [11, 12] The study population was diverse in terms of the size of the organization, urbanization, type of care, and staff-to-resident ratio. Ethical approval for the study was waived by the Medical Ethics Review Committee of Erasmus MC (Ref. 58158) as the residents were not subjected to sampling, treatment, or behaviour rules.

Hand hygiene compliance

HH compliance was measured through unobtrusive direct observation. HH compliance was defined as the use of alcohol-based hand rub or soap, water and a paper towel. NHs were observed from 8 am to 1:30 pm in October 2016 (baseline), February 2017 (during the intervention) and May 2017 (after the intervention). There was originally a third arm in the study, but this was discontinued because six NHs in this arm were not able to implement the intervention and observers were not available for certain observation periods. As there were concurrent baseline measurements from this third arm, these were included in the present study. HH opportunities were defined according to the World Health Organization's 'Five Moments', namely: before touching a resident, before a clean/aseptic task, after body fluid exposure, after touching a resident, and after touching a resident's surroundings. [13] As this study was performed in NHs, the surroundings were defined as the resident's room or that portion of the room that belonged to the resident. HH was registered by trained research assistants in a novel app. [11] In total, 426 nurse observations and 5200 HH opportunities were included in this study. Sixty NHs were included in the trial, representing a total of 3284 beds. Of these, 85% participated through May 2017 (51/60 NHs) and 15% left

the study prematurely for various reasons. Aggregated HH compliance at baseline was 11% (range 1–26%). This increased to 27% (range 7–53%) in May 2017. [12]

Environmental sampling in nursing homes

The presence of rhinovirus (a common respiratory virus), norovirus (a common cause of non-bacterial gastroenteritis) and *Escherichia coli* (*E. coli*) (an indicator of faecal contamination and general hygiene) were examined. [9, 14-16] Rhinovirus was chosen as this is one of the most common (9%) causes of respiratory infection in institutionalized elderly people. [10] Norovirus was chosen based on studies in healthcare facilities which found that norovirus is frequently detected and a leading cause of HAI-associated death in individuals aged >65 years. [17]

Environmental swab samples were collected by trained research assistants at the end of each HH observation session. Sterile, ready-to-use wipes, prewetted with 10 mL of Ringer's solution (Sodibox, Névez, France), were used for swabbing following the protocol of the Food Safety Authority. [18] Three high-contact surfaces for HH were targeted to determine circulation of the targeted micro-organisms in the facility: the computer keyboard and mouse at the nurse's station (used solely by staff), a table in a communal living area (used primarily by residents), and the toilet flushing knob and toilet seat of a communal toilet (used primarily by residents). It was assumed that the keyboard and mouse would give an indication of micro-organism contamination by nurses, and that the table in the living room would primarily give an indication of micro-organism contamination by residents.

Processing of swab samples

Wipes were placed in a 50-mL tube with sterile forceps for each sample, after which 15 mL of lysis buffer was added to each tube. Nucleic acid was isolated using the Boom method. [18] Real-time polymerase chain reaction assays were used for the detection of norovirus genogroup I and II, rhinovirus and *E. coli*. The viral micro-organisms were detected by primers and probes used in the routine molecular viral diagnostics setting of Erasmus Medical Centre, as described previously. [19-21] *E. coli* was detected using primers and probes as described by Pavlovic *et al.* [22] Most samples were positive for *E. coli* to some extent, and in some cases had very high cycle threshold (Ct) values; for these analyses, samples with an arbitrary cut-off of Ct >35 for *E. coli* were considered negative.

Incidence of infection

Infections of residents over a 7-week period were considered: 3 weeks before ESS, the week of ESS, and 3 weeks after ESS. This study therefore considered the incubation period (1–3 days), at least one serial interval (1–3 days) and the shedding period (rhinovirus: 1–2 weeks, norovirus: 3 weeks) of the included micro-organisms to detect circulation. [23-25] This study also considered that norovirus survives and remains detectable on hard surfaces for days or weeks. [26] Infection registration started during or after the first round of ESS; the baseline had a maximum registration period of 4 weeks.

Each NH unit had a self-designated staff member (nurse, team leader, or geriatrician) who recorded the weekly incidence of gastroenteritis, influenza-like illness (ILI), suspected pneumonia, UTI, and meticillin-resistant *Staphylococcus aureus* (MRSA) on a uniform form. The McGeer criteria were used to define illnesses, and MRSA was laboratory confirmed. [27] Data on the incidence of infection were anonymized and aggregated.

Analysis

The presence of rhinovirus, norovirus, and *E. coli* was noted and expressed as a percentage of NHs that had the micro-organism per observation round. HH compliance was calculated by dividing the number of compliant HH opportunities by the total number of HH opportunities, and expressed as a percentage. [12] A multi-level analysis was performed subsequently to determine if the presence of a micro-organism in one of the three sampling locations (nurse's station, toilet or living area) was an inverse predictor of HH compliance. All multi-level analyses in this paper controlled for: (1) the clustering of observations within NHs; (2) period; and (3) whether the NH received the intervention.

Next, the association between the incidence of HAI and positive environmental samples was examined. The 7-week period of HAI registration per NH per round was aggregated, and multi-level analyses were used to investigate if the presence of each individual micro-organism was a predictor of infection in general, and whether the presence of norovirus was associated with gastroenteritis.

Next, the association between background variables and surface contamination was explored using a multi-level model. Background variables were included if data were available from at least 75% of the NHs. The following background variables were included: number of beds in the unit; complexity of care as determined by a care indication ('*zorgzwaartepakket*'); number of residents per bathroom; presence of a faucet in every

bedroom; presence of a faucet in every shared living area; whether the healthcare workers worked on one or multiple wards; whether it is standard practice that residents are informed about HH; the percentage of residents that wash themselves; how often the residents' rooms are cleaned; how often the bathrooms/toilets are cleaned; whether HH reminders were hung somewhere; the number of nurses per beds in the NH; whether alcohol-based hand rub is available in all bedrooms; and the percentage of residents that were able to go to the toilet without assistance. Association of these background variables with any surface contamination (either norovirus, rhinovirus and/or *E. coli*) at any of the locations (living room, toilet and/or nurse's station) was examined. All analyses were performed using SPSS Version 25 (IBM Corp, Armonk, NY, USA).

Results

Detection of environmental contamination

Positive samples were detected (n=121 per surface) for rhinovirus (nurse's station: 41%; toilet: 14%; living area: 29%), norovirus (nurse's station: 18%; toilet: 12%; living area: 16%) and *E. coli* (nurse's station: 14%; toilet: 58%; living area: 54%) (Figure 1). Generally, more positive rhinovirus samples were found at the nurse's station and in the general living area compared with the toilet. In contrast, there were no clear differences in the presence of norovirus RNA in all three sampling areas, although the average level of virus contamination per positive sample was highest for the toilet (data not shown). The percentage of positive *E. coli* samples was lowest for the nurse's station. Only rhinovirus presented a clear pattern over time, with a reduction in total positive samples at the second and third timepoints.

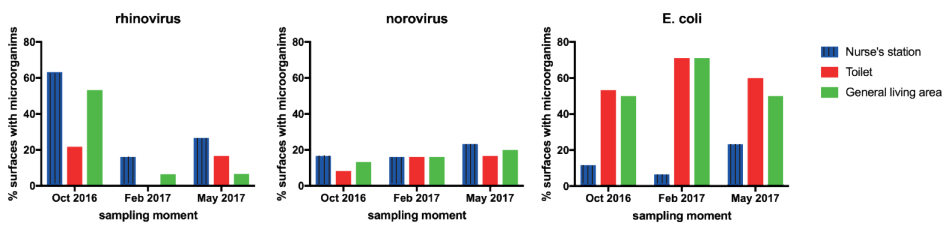

Figure 1. Percentage of nursing homes where selected micro-organisms were found on environmental surfaces over three periods (n=60, 31 and 30 nursing homes per sampling moment, respectively). E. coli: *Escherichia coli*

Association between environmental contamination and hand hygiene compliance

In order to assess the association between HH compliance and environmental contamination, the authors tested for significant differences in average HH compliance between NHs where micro-organisms were present and NHs where micro-organisms were not present. Average HH compliance ranged from 12% to 20% when a micro-organism was present and from 16% to 21% when a micro-organism was not present (Table I). In the multi-level regression model, no significant ($p<0.05$) associations between HH compliance and the presence of a micro-organism were found, although there was a weak association ($p=0.07$) between rhinovirus in the living area and HH.

Association between environmental contamination and incidence of infection

First, the incidence rates of gastroenteritis, ILI, pneumonia, UTI, MRSA and a combination of gastroenteritis, ILI and pneumonia, per 1000 resident-days in each period, were examined (Table II). Average incidence rates per period were low; the highest mean incidence was for UTI (1.40–2.07 per 1000 resident-days). The lowest incidence was for MRSA, with 0–0.07 incidents per 1000 resident-days per round. When gastroenteritis, ILI and pneumonia-like illnesses were combined, the range was 0–11.90 cases per 1000 resident-days per NH for all periods, with an overall average per period ranging from 1.27 to 2.71 per 1000 resident-days. Considerable differences were evident between NHs regarding numbers of HAIs reported. For the periods observed, 7% of the NHs reported no infections.

Next, the authors investigated whether the indicator micro-organisms were associated with infectious disease. When all variables were tested in the multi-level model, only *E. coli* contamination of the toilet was significantly associated with the incidence of disease in general ($p=0.04$) (Table III). A weak association ($p=0.06$) was found between norovirus at the toilet and gastroenteritis. None of the other micro-organisms on any of the three surfaces were associated with the incidence of disease.

Relation between environmental contamination and background variables

Finally, significant associations between surface contamination and background variables of NHs were investigated. After Bonferroni's correction to account for testing 79 possible associations ($\alpha=0.0006$), none of the variables were significantly associated with ESS (Table S1).

Table I. Average hand hygiene compliance per nursing home (NH), comparing NHs where micro-organisms were present on surfaces and NHs where micro-organisms were not present on surfaces, to test the association between environmental contamination and hand hygiene compliance (n=121 NH observation-days in 60 NHs, n=8928 hand hygiene observations).

Tested micro-organism	Sampling location	Microorganism present		Microorganism not present		p-value[1]
		Average hand hygiene compliance (%)	(Percentage of nursing homes with micro-organism)	Average hand hygiene compliance (%)	(Percentage of nursing homes without microorganism)	
Rhinovirus	Nurse's station	14	(43)	20	(58)	0.79
	Toilet	16	(15)	18	(85)	0.26
	Living area	12	(30)	21	(70)	0.07
Norovirus	Nurse's station	16	(18)	18	(82)	0.82
	Toilet	18	(13)	17	(88)	0.66
	Living area	20	(15)	17	(85)	0.87
E. coli	Nurse's station	18	(13)	17	(87)	0.87
	Toilet	18	(60)	16	(40)	0.58
	Living area	18	(56)	17	(44)	0.80

[1]Controlled for the clustering of observations within NHs, period, and whether the NH received the intervention in a multi-level regression model.

Table II. Infections during three sampling rounds. For every round, 7 weeks from the infection registry were included (3 weeks before sampling, the week of sampling and 3 weeks after sampling). In October 2016, registered infections started the week of environmental sampling (n=116 nursing home observation-days[1] in 60 nursing homes with n=5200/1852/1876 observations per round).

Sampling round	Infections per 1000 resident-days	Mean	Median	Standard deviation	Minimum	Maximum
October 2016 (n=55)	Gastroenteritis	1.20	0.00	2.20	0.00	10.27
	Influenza-like illness (ILI)	0.84	0.00	1.71	0.00	8.93
	Pneumonia	0.66	0.51	0.76	0.00	2.93
	Urinary tract infection	2.07	1.59	2.09	0.00	10.20
	MRSA	0.02	0.00	0.11	0.00	0.64
	Combination gastroenteritis, ILI or pneumonia	2.71	1.76	2.90	0.00	11.90
February 2017 (n=31)	Gastroenteritis	0.95	0.00	1.80	0.00	7.02
	ILI	1.15	0.00	1.95	0.00	8.63
	Pneumonia	0.50	0.42	0.52	0.00	1.83
	Urinary tract infection	1.40	1.12	1.34	0.00	5.44
	MRSA	0.00	0.00	0.00	0.00	0.00
	Combination gastroenteritis, ILI or pneumonia	2.60	1.24	2.82	0.00	11.38
May 2017 (n=30)	Gastroenteritis	0.45	0.00	1.07	0.00	4.25
	ILI	0.30	0.00	0.99	0.00	5.10
	Pneumonia	0.51	0.45	0.59	0.00	2.63
	Urinary tract infection	1.59	1.34	1.28	0.00	5.10
	MRSA	0.07	0.00	0.33	0.00	1.81
	Combination gastroenteritis, ILI or pneumonia	1.27	0.72	1.86	0.00	8.50

[1]Five nursing homes started their infection registry ≥4 weeks after the first observation.

Table III. Association between the presence of surface micro-organisms in nursing homes (NHs) and the incidence of disease (n=116 NH observation-days in 60 NHs, 7-week illness registration per period for three periods).

Micro-organism	Place found	Infection[1]	Microorganism present		Microorganism not present		p-value[2]
			Illness incidence per 1000 resident-days	(Percentage of nursing homes with micro-organism)	Illness incidence per 1000 resident-days	(Percentage of nursing homes with micro-organism)	
Rhinovirus	Nurse's station	I/G/P	2.35	(41)	2.27	(59)	0.88
	Toilet	I/G/P	1.92	(15)	2.37	(85)	0.47
	Living area	I/G/P	2.49	(29)	2.23	(71)	0.70
Norovirus	Nurse's station	I/G/P	2.78	(19)	2.19	(81)	0.65
	Toilet	I/G/P	2.75	(13)	2.24	(87)	0.44
	Living area	I/G/P	1.67	(16)	2.43	(84)	0.41
E. coli	Nurse's station	I/G/P	1.92	(14)	2.36	(86)	0.48
	Toilet	I/G/P	2.74	(59)	1.68	(41)	0.04
	Living area	I/G/P	2.55	(55)	2.01	(45)	0.82
Norovirus	Nurse's station	Gastroenteritis	1.63	(19)	0.78	(81)	0.17
	Toilet	Gastroenteritis	1.71	(13)	0.83	(87)	0.06
	Living area	Gastroenteritis	0.28	(16)	1.07	(84)	0.11

[1]I/G/P: either influenza-like illness, gastroenteritis or pneumonia. [2]We controlled for (1) the clustering of observations within NHs, (2) period, and (3) if the NH received the intervention in a multilevel analysis. *E. coli: Escherichia coli*

Discussion

This exploratory study in NHs detected rhinovirus (41% at the nurse's station, 14% in the toilet and 29% in the living area), norovirus (18% at the nurse's station, 12% in the toilet and 16% in the living area) and *E. coli* (14% at the nurse's station, 58% in the toilet and 54% in the living area). No significant ($p<0.05$) associations were found between HH compliance and the presence of a micro-organism, although there was a weak association ($p=0.07$) between rhinovirus in the living area and HH. With regard to environmental contamination and HAI occurrence, there was an association between *E. coli* contamination and the incidence of disease in general ($p=0.04$), and a weak association ($p=0.06$) between norovirus and gastroenteritis. None of the other micro-organisms on any of the three surfaces were associated with the incidence of disease.

Other studies have also detected the micro-organisms selected in this study on different types of surfaces. Shortly after or during outbreaks, levels of norovirus contamination on surfaces in catering companies were up to 40%, while in non-outbreak-related establishments, only 2% of the surfaces tested gave positive results for norovirus. [8] Similar observations were reported in other settings such as military garrisons, cruise ships and long-term care facilities. [28, 29] Besides *E. coli*, faecal contamination on surfaces has also been studied by testing CrAssphage. [29]

Several reasons could explain why little to no relationship was found between ESS results and HH compliance. Firstly, the differences in HH compliance levels between NHs were small, impacting the power of the analyses. Secondly, norovirus and *E. coli* may be more difficult to eliminate when using alcohol-based hand rub than other micro-organisms. [30, 31] In this study, 51% of HH compliance was achieved with alcohol-based hand rub (data not shown). There is evidence that alcohol-based hand rub is effective for eliminating rhinovirus. [32, 33] This may explain why there was some evidence of a reduction in rhinovirus when HH compliance was higher. Thirdly, viruses can also spread through droplets and aerosols (i.e., through coughing and vomiting). These droplets and aerosols would fall on surfaces and thus be detectable but unrelated to HH. This is particularly the case for rhinovirus, and could occur for norovirus but not for *E. coli.* [34, 35] Fourthly, contamination of a surface, such as a computer keyboard, implies that at least one person had poor HH, but does not indicate average HH compliance. Finally, other unstudied factors which were not taken into account may also influence the association between ESS and HH compliance levels, such as how many hours/days there were between cleaning surfaces and

taking environmental samples, the quality of cleaning of the different surfaces, HH of nursing assistants, and HH of residents.

Recognizing disease can be challenging in NH residents as their symptoms can be more subtle and differ from those in younger populations. Taking samples for diagnostic tests can also be more challenging in an elderly population with psychogeriatric disorders, and therefore difficult to justify ethically when research is the main goal. ESS may help to gain insight into which diseases are circulating in the environment. However, the relationship between ESS results and HAI (per 1000 resident-days) is complicated for various reasons. For example, a single ill or infectious person could cause positive ESS results. It may therefore be better to use a dichotomous variable (some/no illness in the NH) to understand the association between the presence of infections and positive samples, rather than the number of infections per 1000 resident-days. Also, if surfaces were cleaned immediately before the samples were taken, this may have eliminated potential positive samples and therefore weakened the relationship between HAI and positive ESS. A third issue is that this study included a standard instrument for HAI reporting in NHs which did not include the common cold. Consequently, a potential association between HAI and rhinovirus was missed. There was a significant association between *E. coli* and HAI. One possible explanation for this is that less hygienic NHs are more likely to experience HAIs. [36]

The detection of micro-organisms was also assumed to be affected by seasonal differences in the prevalence of viruses. For example, rhinovirus circulates throughout the year, but generally has slightly more infections in the autumn and fewer infections in the summer. [37] Norovirus also presents seasonal differences, with most outbreaks occurring in the winter. [38] Thus, during the third period (May 2007), the prevalence of the indicator viruses could be lower than in the first two periods, potentially affecting the outcomes.

Conclusions and recommendations

Further exploration of ESS is recommended, where detection in the environment is followed by sampling residents to further validate this method. Any future study including rhinovirus should incorporate surveillance of the common cold to enable better association of the observed illness and the target micro-organism. Another suggestion is that similar studies should be performed within a limited time frame when the illnesses caused by these micro-organisms are most prevalent.

To conclude, the authors were able to detect rhinovirus, norovirus, and *E coli* on surfaces in NHs. No convincing associations were found between environmental contamination and HH compliance or the incidence of disease. This study provides reference data on surface contamination.

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Supplementary table S1. Background variables and surface contamination[1]

Background variable	Percentage of nursing homes (n=60)	Rhinovirus, norovirus or *E. coli* in living room, p-value (n=93/121)	Rhinovirus or norovirus at toilet, p-value (n=28/121)	Rhinovirus, norovirus or *E. coli* nurse's station, p-value (n=69/121)	Norovirus anywhere, p-value (n= 38/121)	Rhinovirus anywhere, p-value (n=66/121)	*E. coli* in living room or nurse's station, p-value (n=71/121)
Number of beds in units		0.65	0.70	0.45	0.35	0.38	0.78
<45	32%						
45-59	23%						
≥60	45%						
How complex is the care		0.79	0.02	0.80	0.75	0.91	0.98
Only high complexity of care	73%						
All levels	25%						
Missing	2%						
Number of residents per bathroom			0.08		0.92	0.65	
2 or more/bathroom	70%						
1/bathroom	30%						
Faucet is in every bedroom		0.33	0.93	0.26	0.07	0.73	0.45
Yes	63%						
No	32%						
Missing	5%						
Faucet is in every shared living area		0.47			0.69	0.26	0.66
Yes	85%						
No	10%						
Missing	5%						
Health care workers work in one unit or multiple units		0.85	0.66	0.10	0.70	0.46	0.52
One unit	88%						
Multiple units	10%						
Missing	2%						
Standard practice is that residents are informed about good hand hygiene		0.36	0.67	0.76	0.27	0.71	0.66
Yes	17%						
No	82%						
Missing	2%						

Background variable	Percentage of nursing homes (n=60)	Rhinovirus, norovirus or *E. coli* in living room, p-value (n=93/121)	Rhinovirus or norovirus at toilet, p-value (n=28/121)	Rhinovirus, norovirus or *E. coli* nurse's station, p-value (n=69/121)	Norovirus anywhere, p-value (n= 38/121)	Rhinovirus anywhere, p-value (n=66/121)	*E. coli* in living room or nurse's station, p-value (n=71/121)
Percentage residents that washes him/herself		0.21	0.18	0.27	0.77	0.90	0.23
10% or less	85%						
>10% to 25%	15%						
How often residents' rooms are cleaned					0.85	0.13	0.68
> 1x/week	25%						
Weekly	53%						
Missing	22%						
How often bathrooms and toilets are cleaned			0.52		0.86	0.57	0.68
>1x/week	47%						
Weekly	33%						
Missing	20%						
HH reminders hang somewhere		0.70	0.62	0.71	0.64	0.87	0.21
Yes	55%						
No	25%						
Missing	20%						
Number of nurses per resident		0.33	0.04	0.83	0.56	0.96	0.55
< 1 nurse/resident	67%						
> 1 nurse/resident	33%						
Hand sanitizer is available in all bedrooms		0.67	0.89	0.38	0.03	0.71	0.60
Yes	40%						
No	53%						
Missing	7%						
Percentage that goes to the toilet without assistance		0.65	0.93	0.41	0.33	0.89	0.18
<20%	55%						
20% or more	45%						

[1]We controlled for (1) the clustering of observations within NHs, (2) period, and (3) if the NH received the intervention in a multilevel regression model. We used a Bonferroni correction to account for 79 possible correlations. Therefore, the p-value should be below 0.0006 in order to consider an association to be significant.

Chapter 7

Is there an adequate alternative to commercially manufactured face masks? A comparison of various materials and forms

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Abstract

Background: There is a worldwide shortage of medical-grade face masks. Donning masks can play an important role in curbing the spread of SARS-CoV-2.

Aim: To conclude whether there is an effective mask for the population to wear in public that could easily be made during a medical face mask shortage using readily available materials.

Methods: We determined the effectiveness of readily available materials and models for making a face mask. The outcomes were compared with N95/FFP2/KN95 masks that entered the Netherlands in April–May 2020. Masks were tested to determine whether they filtered a minimum of 35% of 0.3-µm particles, are hydrophobic, seal on the face, are breathable, and can be washed.

Findings: Fourteen of the 25 (combinations of) materials filtered at least 35% of 0.3-µm particles. Four of the materials proved hydrophobic, all commercially manufactured filters. Two models sealed the face. Twenty-two of the 25 materials were breathable at <0.7 mbar. None of the hydrophobic materials stayed intact after washing.

Conclusions: It would be possible to reduce the reproduction rate of SARS-CoV-2 from 2.4 to below one if 39% of the population would wear a mask made from ePM_1 85% commercially manufactured filter fabric and in a duckbill form. This mask performs better than 80% of the imported N95/FFP2/KN95 masks and provides a better fit than a surgical mask. Two layers of quilt fabric with a household paper towel as filter is also a viable choice for protecting the user and the environment.

Introduction

The current SARS-CoV-2 crisis caused a worldwide shortage of medical-grade personal protective equipment, including face masks. Nevertheless, some governments, such as in Austria, Israel, Singapore, and the Czech Republic, require(d) the population to wear a mask when outdoors, while other governments suggest the use of face masks in public. [1, 2] This contradiction has led to the improvisation of face masks out of readily available materials.

Some governmental organizations provide instructions on how to make an alternative to a medical-grade face mask, such as in the Netherlands, Belgium, the USA and India. [3-6] These are all fabric-based masks. The American and Belgian models optionally hold a filter, either a coffee filter (USA) or not specified (Belgium). There are no published data available describing the protection these masks provide to the wearer and/or the environment.

Although there is contradictory evidence about the protective effect of masks, meta-analysis concludes that surgical and FFP2/N95 masks reduce the risk of SARS by approximately 80%. [7] We investigated the production of an alternative, effective mask for the population to wear in public that can easily be made during a crisis using readily available materials. We define effectiveness as the ability of the mask to reduce the reproduction rate (R_0) of the virus to under 1.

There are few published studies investigating the efficacy of readily available materials for face masks. One such article describes various commonly available fabrics for masks but omits information about the form of the mask and the use of additional filters. [8] The authors tested the filtration efficiencies and pressure drops for a surgical mask, vacuum cleaner bag, cotton t-shirt, scarf, tea towel, pillowcase, cotton mix, linen and silk. The two micro-organisms used for the filter efficiency tests were 0.023 µm and 0.95–1.25 µm. These tests showed that the fabrics filtered 49–90% of the micro-organisms at 0.023 µm. Quesnel described the benefits of a particular cotton mask from four-ply cotton muslin. [9] This mask showed an efficiency of 77% for particles of 0–3.3 µm. We aimed to find a mask material with an effective filtration value, that can be washed for reuse, and has the potential to reduce the R_0.

According to Tian, *et al.* widespread mask usage in the population can halt the spread of the virus in the population. [10] They calculated the reduction factor of R_0 as:

$$(1 - (efficiency\ of\ the\ mask) * (percentage\ of\ the\ population\ which\ wears\ the\ mask))^2$$

According to their theory, a partially effective mask can halt the spread of SARS-CoV-2 if a minimum population wears the mask. If we assume $R_0 = 2.4$, the minimum percentage of the population who would have to wear a mask in order to reduce R_0 to less than 1 can be calculated as 0.352 divided by mask efficiency.

There is some debate whether SARS-CoV-2 spreads through aerosols, because SARS-CoV-2 RNA has been detected in aerosols; we assumed that viable SARS-CoV-2 could travel on aerosols. [11, 12] We also assumed that there is airborne transmission of this virus through breathing and talking, because this has been documented for influenza. [13] We would additionally suggest that the population wearing the mask not be limited to people who are symptomatic and coughing, as there are signs of SARS-CoV-2 transmission from pre-symptomatic patients. [14, 15] Accordingly, assuming that SARS-CoV-2 travels on aerosols (or droplets) that are 0.3 µm or larger, the spread of COVID-19 can be halted if 100% of the population wears a mask that provides a minimum of 35% protection of 0.3-µm particles.

We intended to develop a mask prototype for the general population which meets the following requirements: (1) can be produced at home from widely available fabrics, including commercial air filters and materials which are available at a fabric or grocery store; (2) filters a minimum of 35% of particles at 0.3 µm; (3) has a seal on the face (at the level of an FFP2-mask); (4) is breathable; (5) is hydrophobic; (6) can be washed.

For direct comparison, we used two commonly used masks as references: an FFP2/N95 mask and an RII-surgical mask which were made conform to European standards. [16, 17] FFP2 masks are recommended for aerosol-forming procedures such as open suctioning of the respiratory tract, intubation, bronchoscopy and cardiopulmonary resuscitation. [18, 19] RII-surgical masks are considered sufficient for the majority of regular care for COVID-19 patients, although this is debated and there is mixed evidence. [7, 18] We aimed to create a mask with a better fit than a surgical mask, because surgical masks do not seal on the face. The filtration capability of our best mask was then compared with N95/FFP2/KN95 masks that were imported during the COVID-19 crisis.

Materials and methods

We chose filters based on a literature search, on which fabrics are promoted as filters by governments, and by searching for readily available non-woven fabrics, although we are

aware that woven fabrics can possibly be effective. [3-5, 8, 20, 21] Commercial air filter fabric, made for heating, ventilation and air conditioning (HVAC) systems, were considered a viable option, because they are built to filter out particles ranging from 0.3 to 10 µm in diameter. We hypothesized that filter material of ePM_1 85% (ISO 16890) or F9 (EN 779:2012), similar to the American MERV 16 filter standards, could approach the filter capacity of an FFP2 mask. [22, 23] Materials which are generally used in healthcare were avoided, since this could cause new shortages in the health care system. We hypothesized that materials could be used to make a mask as such or as an inlay filter. Materials were therefore tested by themselves and between two pieces of cotton quilt fabric. Masks were made with and without a metal nose strip.

Procedure

Step 1: Particle test

A calibrated particle counter (Solair 3100 Lighthouse, San Francisco, www.golighthouse.com, Supplementary Figure S1) counted the number of free-flowing airborne particles in a 1-min cycle with a flow rate of 1.0 cfm. The measurement was conducted on particles of sizes 0.3, 0.5, 1.0 and 5.0 µm. The closed particle chamber was specifically built to conduct these tests.

A baseline measurement was performed before every material test, during which free-flowing air was drawn into a particle chamber. The particle chamber was connected through a silicone tube to the particle counter. Material was then clamped to the top of the particle chamber and we repeated the test three times. The last measurement reflects total number of particles drawn into the particle counter through the fabric. This test was repeated three times to ensure that loose particles on the fabrics would not affect the filtration measurement. We calculated the ratio of particles that passed through the material to the baseline measurement. This is an effective method for precise and fast measurements. [24]

Step 2: Fit test

Mask safety depends not only on the filtration, but also on the fit on the face. [16, 17] It is important that air does not enter or exit from the top, side or bottom of the mask to guarantee that the air always passes through the filter. We used an AccuFIT 9000 Respirator Fit Test apparatus (https://accutec-ihs.com/accufit-9000; Supplementary Figure S2). This machine counts the number of particles in the face mask during a series of movements,

creating stress on the seal of the mask, which is compared with the ambient particulate concentration.

After validation of the device, the face mask was equipped with an inlet to a tube. A flow is created through the tube and the number of particles in the mask is counted. The fit test includes cycles for normal breathing, deep breathing, moving your head from side to side, moving your head up and down, talking out loud, and bending over. [25] The fit factor confirms the level of leakage and is calculated as a ratio of the particles inside the mask relative to the ambient concentration outside the mask. A fit factor of 100 or higher represents a good fit. All tests were carried out on one woman to ensure homogeneity in the results.

The mask prototypes were from either filter fabric only (ePM_1 85%) or filter fabric (ePM_1 85%) with cotton quilt fabric. Different models were tested, such as folded, pleated, round, flat, and duckbill.

Step 3: Pressure test

The pressure drop over the fabric was measured to ensure that the wearer of the mask could breathe easily through the mask. A differential pressure sensor, type SDP2000-L, was attached to the particle chamber (Supplementary Figure S1). The analogue differential pressure sensor is temperature compensated, calibrated, and has a resolution of 11 Pa with a repeatability of 0.3% and accuracy of 1%. We calculated the pressure as follows:

$$\Delta P_{mask} = \left(\frac{\Delta P_{fabric}}{100}\right) \times \left(\frac{Area_{fabric\_sample}}{Area_{best\_mask}}\right)$$

ΔP_{mask} = pressure delta over full mask area [mbar]

ΔP_{mask} = measured pressure in particle chamber [Pa]

$Area_{fabric\_sample}$ = the surface area of the tested fabric sample [m^2]

$Area_{best\_mask}$ = the surface area of the best performing design [m^2]

Step 4: Hydrophobic test

The hydrophobic test compared the capacity of different fabrics to resist the penetration of fluids. Measuring wet particles can be seen as cross-validation of the dry particle testing.
All fabrics deemed breathable by the researcher were tested. A solution of 0.5 MacFarland *Staphylococcus epidermidis* (ATCC 12228) was sprayed on the fabrics.

Subsequently, by means of a vacuum pump, air was drawn through the fabrics a rate of 1.2 L/min per cm^2 for 20 s. Culture membranes positioned underneath the fabrics were transferred onto blood agar plates. After incubation for 24 h at 37°C, results were read by two independent readers as the number of colony forming units. An ordinary laboratory paper towel was used as a control; an IIR-surgical mask served as a reference. The amount of fluid applied was unrealistically high as compared with exposure in a real-life setting.

Step 5: Wash test

We tested the commercial filters for usability after washing at 90°C.

Step 6: Determination of needed population compliance

We determined which percentage of the population would need to wear the mask for the rate of growth of disease to fall below 1. This was calculated as 0.352 divided by mask efficiency, assuming $R_0 = 2.4$. Only breathable materials were included.

Results

Step 1: Particle test

Particle tests were performed on potential mask materials and imported N95/FFP2/KN95 masks (Table I, Supplementary Table S1). The best-performing commercially manufactured material was the ePM_1 85%, either alone or between quilt fabric. Of the more readily available fabrics, leather performed the best, followed by a folded coffee filter between quilt fabric, a folded household paper towel between quilt fabric, and microfibre fabric.

Figure 1 indicates how our best-performing self-made mask performed with respect to the 244 imported N95/FFP2/KN95 masks that we measured in April–May 2020. [26] This figure shows the particle filtration efficiency for 0.3, 0.5, 1 and 5 µm from lowest to highest. The X indicates the filtration of the ePM_1 85% commercially manufactured filter.

Step 2: Fit test

Both the duckbill model with the seams on the inside and with the seams on the outside passed the fit test (Table II, Supplementary Table S2, Supplementary Figure S4). None of the models with an inserted filter into a cotton mask provided a satisfactory fit.

Step 3: Pressure test

We used the best mask from the fit test as the reference, the duckbill with the seam inside, for calculating the pressure (Supplementary Figure S3). Of the manufactured filters, the F7, F9 and M5 showed equal or less pressure than the 3M reference mask (Table I). Both the single and folded tea towels showed equal or less pressure than the 3M reference mask.

Step 4: Hydrophobic test

Results showed considerable differences between fabrics. Four of the five commercially manufactured air filters outperformed the IIR-surgical mask (Table III). None of the other readily available fabrics performed as well as the reference mask.

Step 5: Wash test

We tested all materials that we expected could be malformed from being washed at 90°C. The manufactured filters, cleaning cloth, leather, static dust cloth and felt were all malformed after washing.

Step 6: Determination of needed population compliance

The best mask from the fit test was used as the reference, the duckbill with the seam inside. In Table I, we only included fabrics which were breathable. The percentage of the population which would have to wear a mask in order to halt the spread of SARS-CoV-2 ranges from 37% to 88%, depending upon the fabric. From the masks made from manufactured filters, the percentage of the population which would need to wear a mask ranges from 39% to 88%. If people made masks from easily available fabrics from the fabric store and/or grocery store, the reproduction rate could go below 1 if 85% of the population would wear a mask from quilt fabric with a single layer household paper towel. These masks are relatively inexpensive to manufacture. We estimate the cost of the materials of a mask at approximately €0.50 (quilting cloth) to €0.60 (ePM_1 85%).

Discussion

From the above measurements, we conclude that it would be possible to reduce the R_0 of SARS-CoV-2 from 2.4 to below 1 if a minimum of 39% of the population wears a mask from ePM_1 85% fabric in a duckbill form. Other commercially manufactured filters could be used, but then a greater portion of the population would need to wear them in order to achieve the desired reduction in the spread of the virus. This mask provides nearly as much

Table I. Particle filtration test, pressure test, and estimation of the population which needs to wear a mask of this material in order to achieve R_0<1.

Description	Filtration value (%)					Pressure (maximum acceptable value set at 0.7)	Population which would need to wear a mask of this material to achieve R_0<1 (%)[4]
	0.3µm	0.5µm	1µm	3µm	5µm	(mbar)[3]	
IIR-surgical mask[1]	59	75	84	100	100	0.15	n/a
3M 1862+[1]	96	98	99	99	100	0.20	37
ePM_1 60%[2]	40	60	73	99	95	0.23	88
ePM_1 60%[2] between quilt fabric	56	78	87	97	99	0.47	63
ePM_1 85%[2]	90	96	98	100	100	0.31	39
ePM_1 85%[2] between quilt fabric	94	98	99	97	97	0.72	n/a
F7[2]	41	55	65	99	100	0.07	85
F7[2] between quilt fabric	55	72	82	97	97	0.43	64
F9[2]	78	88	92	100	99	0.15	45
F9[2] between quilt fabric	77	89	94	97	97	0.50	46
M5[2]	3	6	11	90	96	0.05	>100
M5[2] between quilt fabric	19	38	54	96	97	0.39	>100
Cleaning cloth between quilt fabric	21	40	54	92	93	0.39	>100
Coffee filter (double) between quilt fabric	90	99	99	98	98	2.18	n/a
Felt 155g between quilt fabric	20	39	55	96	97	0.36	>100
Leather	100	100	100	99	99	2.92	n/a
Microfiber	59	88	95	99	99	1.50	n/a
Household paper towel (1 layer) between quilt fabric	42	70	82	95	94	0.64	85

Description	Filtration value (%)					Pressure (maximum acceptable value set at 0.7)	Population which would need to wear a mask of this material to achieve R_0<1 (%)[4]
	0.3μm	0.5μm	1μm	3μm	5μm	(mbar)[3]	
Household paper towel (2 layers) between Quilt fabric	65	90	96	98	98	1.01	n/a
Polypropelene fabric 1	10	27	41	65	75	0.41	>100
Polypropelene fabric 2	5	18	28	55	61	0.18	>100
Quilt fabric (2 layers)	16	37	55	94	95	0.31	>100
Quilt fabric (4 layers)	34	59	69	63	71	0.66	>100
Quilt fabric (6 layers)	46	74	88	98	98	0.97	n/a
Static dust cloth between quilt fabric	21	40	57	94	96	0.35	>100
Tea towel (1 layer)	5	15	14	35	36	0.05	>100
Tea towel (2 layers)	5	13	23	84	88	0.10	>100

[1]Reference. [2]Commercially manufactured filter. [3]Pressure is calculated assuming the duckbill form with the seams on the inside. [4]Only materials which passed the pressure test.

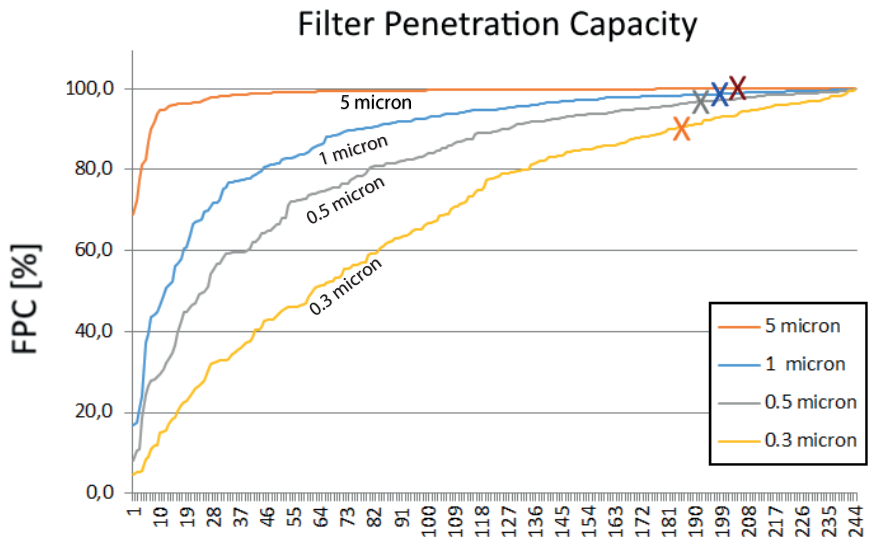

Figure 1. Filter penetration capacity (FPC) for different particle sizes of 244 different imported N95/FFP2/KN95 masks that entered the Dutch market in April and May 2020. The 'X' indicates the FPC of our best-performing model for each particle size.

Table II. Fit quality of model (≥100 represents a good fit).

Fabric	Form	Overall fit factor
IIR-surgical mask[1]	Surgical mask	4
3M 1862+[1]	FFP2	134
ePM$_1$ 85%	American model (flat)[2] with nose strip	22
ePM$_1$ 85%	American model (flat) with nose strip and foam	57
ePM$_1$ 85%	Belgian model (pleated)[2]	15
ePM$_1$ 85%	Belgian model (pleated) with nose strip and foam[2]	18
ePM$_1$ 85%	Duckbill with seam on inside with nose strip and foam	130
ePM$_1$ 85%	Duckbill with seam on outside with nose strip and foam	120
ePM$_1$ 85%	Flat (folded) (with quilt cloth) with nose strip and foam	56
ePM$_1$ 85%	Indian model (pleated) (with quilt cloth) with nose strip	8
ePM$_1$ 85%	Indian model (pleated) with nose strip	67
ePM$_1$ 85%	Other model (pleated)[2] with nose strip	36
ePM$_1$ 85%	Round with nose strip	79

[1]Reference. [2]The filter was inserted.

Table III. Hydrophobic qualities of filter fabrics (Colony Forming Units).

Mask Fabric	Tester 1	Independent tester
IIR-surgical mask[1]	150	174
ePM_1 60%[2]	120	95
ePM_1 85%[2]	21	34
F7[2]	44	35
F9[2]	15	14
M5[2]	300	180
Felt (155g)	>1000	>1000
Quilt fabric	>1000	>1000
Tea towel	800	800
Laboratory paper towel	>1000	>1000

[1]Reference. [2]Commercially manufactured filter.

protection as an FFP2 mask and would provide more protection to both the user and the environment than a surgical mask. We saw that the mask according to the specifications in our study is better than approximately 80% of all commercially manufactured N95/FFP2/KN95 face masks now entering the Netherlands. This mask is hydrophobic and not washable.

We also found that the two layers of quilt fabric with a household paper towel as filter can be a viable and sustainable choice for protecting the population as it is widely available and cleanable. Unfortunately, none of the mask designs in which a filter could be placed passed the fit test due to leakage, although the duckbill form could be made with quilt fabric and a paper towel. Masks made from quilt fabric and paper towel are not hydrophobic and therefore likely to be less effective. Thus 85% of the population wearing this type of mask may still be inferior to 39% wearing the ePM_1 85% fabric mask.

Few tests have been published proving the efficacy of masks made from readily available materials. In a time when people are wearing improvised masks in public in order to keep themselves and others healthy, it is of utmost importance to know their effects. Our findings indicate that the omnipresent cotton mask without a filter will not achieve the necessary reduction in reproduction of the virus.

For our calculations, we used a formula to give an estimate of R_0 if mask-wearing was the only intervention. Eikenberry *et al.* created a more advanced model, dependent upon insight into when COVID-19 antibodies provide protection against COVID-19, which

populations are at risk, and the infectiousness of symptomatic, pre-symptomatic and asymptomatic COVID-19 carriers. [27] Ngonghala *et al.* presented another model which additionally takes public health interventions into account, such as social distancing and quarantining. [28] By combining data presented in our study about the characteristics of specific face masks with local/regional data and estimates regarding the spreading of the disease, the formulas presented by Ngonghala *et al.* or Eikenberry *et al.* may provide more precise mask efficacy estimates for specific populations.

Our tests are more specific than the European standards. For testing the filtering requirements, the EN 149+A1 (FFP masks) states that material should be tested with a particle size distribution with a 0.02- to 2-µm equivalent aerodynamic diameter with a mass median diameter of 0.6 µm. [17] The EN 14683:2014 (surgical masks) requires testing with an aerosol of *Staphylococcus aureus*, which is approximately 1 µm in size. [16] At the same time, if we looked at tests used in manufactured surgical masks, we see that it is not always clear which particles sizes are used for the bacterial filtration efficiency test. The particulate filtration efficiency test, when listed, was carried out on particles from 0.1 to 5 µm. [29-31] Our tests detected particles from 0.3 µm.

European standards may not be optimal for SARS-CoV-2, which can be carried by aerosol or droplet. The WHO considers the minimum droplet size to be 0.5 µm. [32] Two size ranges of SARS-CoV-2 aerosols have been found, one from 0.25 to 1.0 µm, and another with a diameter >2.5 µm. [12] It could thus be advisable to perform filtration tests for 0.25 µm particles. This is close to our measurement of 0.3 µm.

Only the duckbill shape passed the fit test, both with the seams on the inside as on the outside. This could be partly due to the fact that the duckbill design had few seams and thus fewer places where air could enter or escape. Hypothetically some of the other models would work well if they had been glued instead of/along with sewn.

The breathability requirements for respiratory protective devices are clear in the European standards. [17] The maximum permitted resistance (mbar) differs for FFP1, FFP2, and FFP3 masks, ranging from 0.6 to 1.0 for inhalation at 30 L/min, 2.1–3.0 for 95 L/min and 3.0 for exhalation at 160 L/m. The norm for an FFP2-mask at 30 L/min is 0.7 mbar. Our test was able to measure at 28 L/min and indicated that most masks showed a pressure drop below 0.7 mbar.

Our study has some limitations. The filters used may not be representative of all filters in these classes, in particular regarding the hydrophobic characteristics. We also performed new 'state of the art' tests, rather than the tests described in the European standards. Furthermore, we were not able to test the filtration value at 0.25 µm, which is the assumed smallest particle size with SARS-CoV-2. Nevertheless, we consider the filtration value at 0.3 µm relevant. We also were only able to perform the pressure test at one value, whereas the European standards suggest testing the resistance at three different values.

This research should give more insight into the next steps in developing a mask for the general population. It would be prudent to repeat the tests of the masks from commercially manufactured filters after various sterilization processes. Similarly, it would be advisable to repeat the tests on the quilt fabric mask with a single layer of household paper towel, both before and after it has been washed, because there is evidence that the pores of the cotton fabric widen after washing. [33] We would also suggest fit tests with quilt cloth and a paper towel using other mask designs.

Our study strongly supports the use of commercially manufactured filters as the fabric for an alternative face mask, specifically ePM_1 85% in a duckbill form. We conclude that it is possible to halt the growth of the spread of SARS-CoV-2 if 39% of the population wore a mask from this material. This material performs better than 80% of the N95/FFP2/KN95 masks entering the Netherlands.

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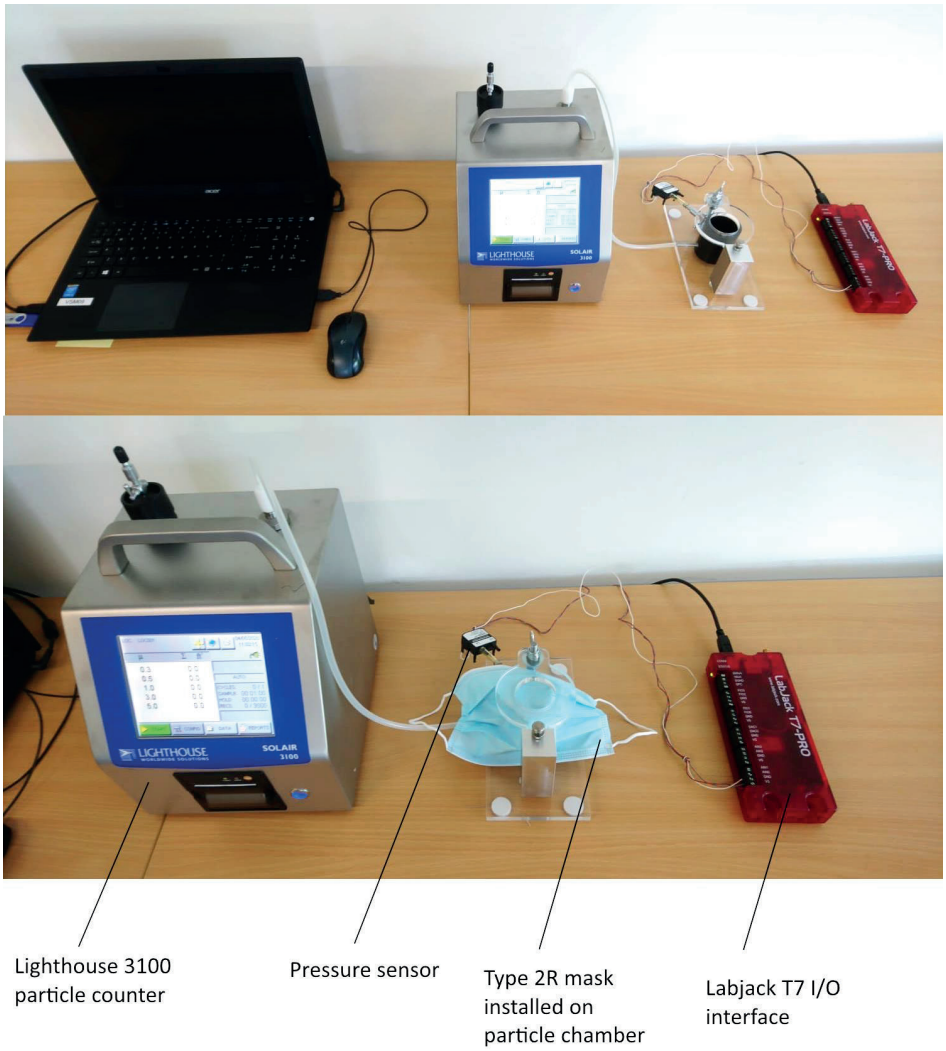


Supplementary figure S1. Particle counter with custom-made particle chamber.

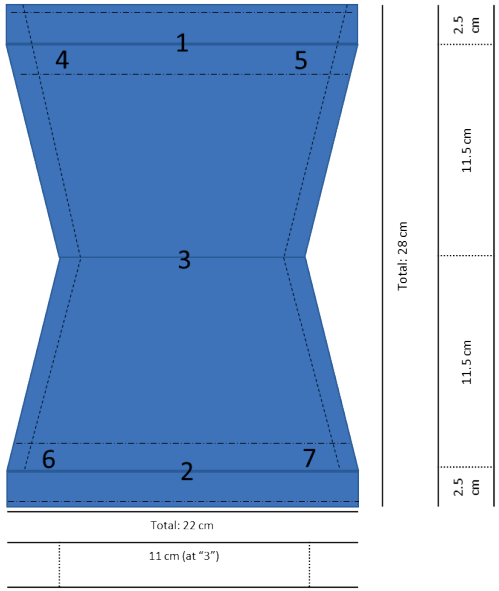
Supplementary figure S3. Masks with duckbill form.

Supplementary figure S2. Fit test.

Supplementary figure S4. Instructions for making a mask.

Instructions for making a mask

Cloth material



Other material

A wire/folded wire placed in electrical tape to that it does not hurt the wearer or a pipe cleaner, folded double. Either should be approximately 14 cm long when folded.
Elastic straps. Length depends on how strong the elastic is. For our model, we used 21.5 cm and 32 cm.
You can optionally add a narrow strip of foam (2 mm width) to the inside of the mask on the side with the metal wire in case of concerns of the metal wire causing irritation.

Instructions

Cut the material as directed. Fold the material along "1" and "2". Sew the material so that the fold stays in place (along the lines with the dot-dash). This will create two tubes. Insert the metal wire into tube 1. Place it in the middle. Sew around each side of the metal wire/pipe cleaner to keep it in place or use a zigzag stitch to sew it in place. Fold the material at 3. Sew along the dotted lines (0.8 cm from the edge). Sew the longer elastic at 4 and 5 (4.5 cm from the edge). Sew a shorter elastic at 6 and 7 (4.5 cm from the edge). Trim edges and threads. Turn inside out.

Note

This model was made for an adult woman's face. This model would need to be adjusted and retested for significantly larger or smaller faces.

Supplementary table S1: Raw data from particle measurements.

		Baseline					1st measurement					2nd measurement					3rd measurement				
mask	material	0.3	0.5	1	3	5	0.3	0.5	1	3	5	0.3	0.5	1	3	5	0.3	0.5	1	3	5
1	Tea towel (2 layers)	987569	160998	32727	1645	956	931366	138360	24869	528	315	929767	138573	24667	245	100	934799	140024	25199	263	113
2	F9	970818	157925	32214	1206	703	219708	19657	2398	5	5	215577	19459	2337	6	4	216995	19658	2463	4	4
3	Cleaning cloth between cloth	952939	155413	31485	1429	857	751534	96237	17154	1496	971	748024	91704	14130	174	103	750838	92709	14330	116	57
4	Felt 155g between cloth	936712	152502	31254	1232	700	753888	93700	14694	276	171	757399	93691	14289	62	32	748997	92283	14019	53	18
5	Paper towel (1 layer) between cloth	787575	140748	29112	808	376	458332	43541	6253	582	364	456151	41896	5194	57	36	459738	41816	5133	37	24
6	Static dust cloth between cloth	780157	140381	30824	1798	1037	619128	85099	14599	561	317	623058	84133	13413	135	60	619138	83605	13211	99	43
7	ePM1 85%	965482	157124	31583	1073	665	94302	5364	497	1	0	95451	5395	521	2	2	96831	5595	562	0	0
8	ePM1 60%	778142	136505	28417	1125	522	463449	52709	7585	11	6	467809	53540	7397	6	1	465336	54317	7569	9	3
9	ePM1 60% between cloth	769638	131391	26449	803	399	333459	30581	5139	973	615	337330	29087	3501	93	60	336798	28881	3517	27	20
10	M5 between cloth	941709	152666	31816	1708	1107	767184	97374	16027	627	366	764616	95677	14587	94	40	759170	95164	14736	70	31
11	F7 between cloth	973408	152177	30535	1287	716	435965	43618	6681	538	352	433392	41985	5356	70	44	439195	43282	5646	33	20
12	cloth (2 layers)	757385	133729	29299	2043	1186	621314	83883	14315	997	619	630374	83900	13105	183	83	635024	84439	13323	128	55
13	F7	952521	152286	30472	1114	615	555734	68776	10643	12	3	555825	69703	10961	12	4	557736	68711	10567	9	3
14	F9 between cloth	833181	154313	32016	1021	526	190615	17311	2118	145	98	191615	16968	1872	32	25	194623	17324	2019	26	14
15	cloth (6 layers)	847272	170350	42307	3695	2080	452800	45303	6744	797	475	454905	43394	5139	101	49	459345	43614	5198	65	40
16	ePM1 85% between cloth	975850	136749	26526	1512	873	68059	6476	2681	932	471	59635	2890	559	154	97	58290	2530	319	49	24
17	Coffee filter (double) between cloth	999024	159041	31925	1373	821	113096	5156	2276	928	533	105794	2186	360	77	48	102012	1947	211	27	13
18	Cloth (4 layers)	900974	145372	30177	1484	847	650267	103088	35222	9244	4454	600798	63687	11094	1056	466	596356	59887	9241	548	247
19	Paper towel (2 layers) between cloth	955118	139652	28660	2070	1309	336088	15031	1994	436	290	319945	12975	1147	44	27	337408	13959	1201	38	24
20	Tea towel (1 layer)	1001506	161678	32283	1146	628	957815	148692	28547	954	584	965418	149215	28299	572	323	953128	136824	27702	746	403

		Baseline					1st measurement					2nd measurement					3rd measurement				
mask	**material**	**0.3**	**0.5**	**1**	**3**	**5**	**0.3**	**0.5**	**1**	**3**	**5**	**0.3**	**0.5**	**1**	**3**	**5**	**0.3**	**0.5**	**1**	**3**	**5**
21	Leather	973685	157164	31643	1199	713	4731	222	178	118	101	4855	71	52	35	27	4722	36	19	9	5
22	M5	773727	135297	27639	1014	512	744058	125303	24000	100	21	746998	125081	24150	103	28	746688	126584	24556	100	18
23	Polypropelene cloth 1	797458	143482	30276	923	451	719982	105438	18581	409	213	722758	104885	17753	278	115	719382	104412	17718	321	114
24	Polypropelene cloth 2	804902	145987	30582	893	415	753887	119558	22500	752	423	756956	119299	21804	353	133	761135	119934	21942	402	160
25	Microfiber	807900	148462	31809	1044	510	324493	17593	1586	12	5	327702	177368	1621	7	3	328827	17338	1494	6	5
26	Surgical mask type IIR	1033475	158604	31114	1313	747	448842	43136	5528	4	4	442099	42531	5419	2	2	419202	39444	5019	1	0
27	3M 1862+	991012	162303	32431	1039	645	145882	12309	1503	1	1	147162	12625	1493	2	1	143921	12273	1488	0	0

Supplementary table S2: Raw data from fit test.

Fabric	Form	With cotton cloth	Normal breathing	Deep breathing	Head side to side	Head up and down	Talk out loud	Bending over	Normal breathing	Overall fit factor
ePM$_1$ 85%	Flat (folded)	Yes	115	67	27	33	59	129	112	56
ePM$_1$ 85%	Duckbill with seam on inside	No	151	146	116	142	81	176	158	130
ePM$_1$ 85%	Belgian model (pleated)*	No	13	14	14	16	14	18	16	15
ePM$_1$ 85%	Belgian model (pleated) with nose strip and foam*	No	13	17	11	30	17	30	29	18
ePM$_1$ 85%	American model (flat)*	No	17	15	23	30	29	35	18	22
ePM$_1$ 85%	American model (flat) with nose strip	No	64	38	73	90	37	91	55	57
ePM$_1$ 85%	Round	No	156	109	88	48	58	69	103	79
ePM$_1$ 85%	Indian model (pleated)	Yes	5	6	15	7	17	15	5	8
ePM$_1$ 85%	Other model (pleated)*	No	38	21	34	30	39	64	41	36
ePM$_1$ 85%	Duckbill with seam on outside	No	103	96	108	126	98	259	140	120
ePM$_1$ 85%	Indian model (pleated)	No	163	87	28	93	43	117	112	67
Surgical Mask	Surgical mask	No	10	7	3	4	5	3	3	4
3M 1862+	FFP2	No	245	80	281	138	79	142	189	134

Chapter 8

Discussion

This dissertation reports mainly on the findings of the HANDSOME study, which had the primary aim to establish the effect of a hand hygiene intervention in nursing homes on nurses' hand hygiene. The effectiveness was studied in a cluster randomized controlled trial (HANDSOME) in 60 nursing homes (120 nursing home units). Our primary outcome was hand hygiene compliance of the nurses to the standards of the World Health Organization. The goal of hand hygiene is to decrease illness. Therefore, the secondary outcome of this study was healthcare-acquired infections (HAI) in nursing homes. Related research was executed simultaneously, such as looking at the use of gloves in nursing homes. A separate study was about commercially manufactured face masks, which was instigated by the Covid-19 pandemic.

In this chapter we address the research questions posed in chapter 1 and conclude the dissertation with recommendations based on the results presented. The research questions are:

(1) How was the tailored hand hygiene intervention received?
(2) Which hand hygiene opportunities should be registered when observing hand hygiene in a nursing home?
(3) Is a tailored hand hygiene intervention for nursing homes successful in increasing hand hygiene compliance?
(4) Does a tailored hand hygiene intervention result in decreased healthcare-associated illness in nursing homes?
(5) Is there an adequate alternative to commercially manufactured face masks?

Research question 1: How was the tailored hand hygiene intervention received?

The HANDSOME intervention was broadly accepted and appreciated. It was possible to implement in nearly all situations and was accepted by not only the nursing home staff, but also by national organizations dealing with care for the elderly and infection prevention. It has been actively used, even after conclusion of the study.

HANDSOME had an intervention arm which received the intervention, while the control arm received no intervention. The intervention in the nursing homes included 3 lessons, an e-learning, posters, a photo competition, and an arts and crafts project for the residents. Here we will focus on experiences with the 3 lessons and the e-learning.

Lesson 1: When to perform hand hygiene

During the first lesson, participants were taught the importance of hand hygiene and when to perform hand hygiene. When to perform hand hygiene ("hand hygiene opportunities") was taught using our novel translation of the 5 hand hygiene moments of the WHO: "Room In, Room Out, Before Clean, After Dirty" (*Kamer in, Kamer uit, Voor schoon, Na vies*). [1, 2] "Room In" corresponds with the WHO's Moment 1 (before touching a patient); "Room Out" corresponds with the WHO's Moment 4 (after touching a patient) and Moment 5 (after touching patient surroundings); "Before Clean" corresponds with the WHO's Moment 2 (before a clean/aseptic procedure); and "After Dirty" corresponds with the WHO's Moment 3 (after body fluid exposure risk) (Table I).

Table I. New explanation of the hand hygiene moments.

Handsome	World Health Organization (WHO)
Room In	Before touching a patient (Moment 1)
Room Out	After touching a patient (Moment 4), After touching patient surroundings (Moment 5)
Before Clean	Before a clean/aseptic procedure (Moment 2)
After Dirty	After body fluid exposure risk (Moment 3)

This method comprises the same hand hygiene moments as the WHO standard, is more adapted to the nursing home setting, is easier to remember (one slogan), and is easier to visualize. Additionally, it specifically takes into account that most health care actions occur in the residents' bedrooms, that social contact between caregivers and residents is excluded from the hand hygiene rules in nursing homes, and that it is only feasible to consider the resident's room (or that portion of the room that belongs to the resident) as the resident's surroundings. [3] This translation of the WHO's 5 moments of hand hygiene has not only proved useful for this study, but has also been accepted by the field and is now a part of (national) hand hygiene guidelines and protocols, both for nursing homes and home-based care. [4, 5]

When we presented the first lesson during pre-testing and during the intervention, it became clear that health care workers knew that they needed to perform hand hygiene, but either did not remember the WHO hand hygiene moments, or never learned them. The WHO only defined these moments in 2009, so this could partly explain their lack of knowledge.

That the nurses could not state the WHO's 5 moments of hand hygiene implied that a new method was needed that nurses could remember. It was easy to implement a new slogan for hand hygiene opportunities, since it did not appear to contradict any previous (remembered) schooling. That this new method was easy to remember was evidenced by the fact that health care workers remembered the slogan 2-3 months later when they received their second lesson in hand hygiene.

Lesson 2: Barriers for performing hand hygiene

The main goal of the second lesson was to remove the barriers that nurses experience at hand hygiene opportunities. Each participant was given a sheet of paper with 28 stickers representing 13 different barriers that were previously identified through literature, interviews, and observations. There were 2 blank stickers, allowing participants to write down any additional barrier. The stickers represented 4 themes, namely facilities, forgetting, choosing not to do hand hygiene, and the telephone.

Four sheets of paper were hung on the wall, one sheet for each part of the slogan (Room In, Room Out, Before Clean, After Dirty). Participants were asked to place one sticker on each piece of paper representing the main reason that he or she did not perform hand hygiene at that moment. Once the stickers were placed, the most prevalent barriers were discussed. Group discussions resolved barriers by designing new coping strategies, cues to action, and environmental changes. The barrier analysis with solutions was in turn discussed with the nursing home manager so that necessary system or facility changes could take place. After the lessons, 98% of the survey respondents (n=489) stated that they were able to implement coping strategies.

The main reasons for non-compliance were forgetting (22%), that the telephone rang (19%), and that the dispenser was empty (14%) (Figure 1). There were clear differences per moment, particularly for forgetting hand hygiene: 46% of the nurses stated that the main reason for not doing hand hygiene at 'Room In' was forgetting to do hand hygiene vs. 4% who stated that they forgot to do hand hygiene at 'After Dirty'. This shows that different strategies are necessary to address different behaviors, based on what action is about to or has just taken place.

The fewest reactions were at 'Before Clean' and 'After Dirty'. The reason that there were fewer reactions at 'Before Clean' was that not all health care workers at the training performed activities which would have been classified as 'Before Clean', namely before a

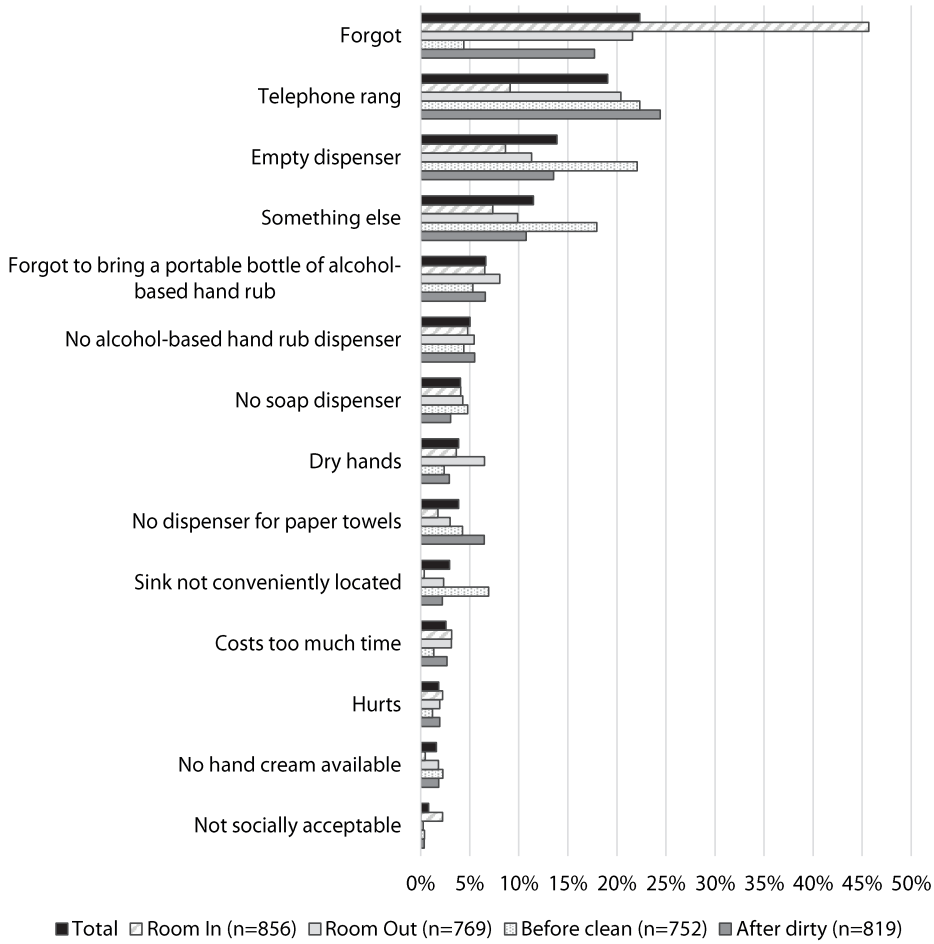


Figure 1. Barriers for hand hygiene, total and per hand hygiene moment

clean/aseptic procedure. All health care workers would have had experience with 'After Dirty' (after body fluid exposure risk). They often declared that "something else" was the reason for not doing hand hygiene at this moment, since they could not fathom any reason. Many stated that they always did hand hygiene at 'After Dirty'. This is doubtful if we look at the compliance figures (Moment 3: 38% compliance in the follow-up in the intervention arm, n=947) and shows discordance between self-perception and actual activity. When health care workers did state a cause for not doing hand hygiene at 'After Dirty', it was generally a cause for which they felt that they had little control, such as the telephone ringing or empty dispensers. They often also placed blank stickers for 'After Dirty', since they could not think of a reason for omitting HH at that time, even though the blank stickers were meant to represent a barrier not on the other stickers.

Habits cannot be changed if the materials are not available where needed. Many nurses (30% of all reactions) stated that they could not do hand hygiene because materials were not available/dispensers were empty/the sink was in an inconvenient place. Infection prevention workers can take this barrier, as well as the other barriers mentioned, into account when trying to optimize hand hygiene by changing policies and routines. Similarly, interior architects can take these barriers into account when trying to nudge nurses to perform infection prevention practices as part of an evidence-based design methodology. In our study, we facilitated positive changes by bringing barriers to the attention of the management. This was not only observed, but survey results also showed that hand hygiene materials were available when needed at the end of the study period (according to 96% of the respondents, n=447).

Lesson 3: Learning about hand hygiene through active participation

During Lesson 3, participants learned how to perform hand hygiene through active participation. Using gloves and paint, participants saw which parts of their hands they missed when washing them incorrectly and that fluids, bacteria, and viruses can get on hands during glove removal. They also learned the correct hand hygiene procedure. Although the WHO recommends 20-30 seconds for hand disinfection, we taught participants that 15 seconds was sufficient for hand disinfection, since this has been proven elsewhere. [3, 6] The WHO promotes a 6-step method, but this misses wrist rubbing. [7] We added wrist rubbing to the procedure since this area can easily be contaminated when removing gloves. After the third lesson, management was informed of any suggestions for management from the participants that could influence hand hygiene. Some examples are: setting disinfection materials next to the telephones, training new colleagues and temporary staff about hand hygiene, ordering alcohol-based hand rub which is better for people with eczema, hanging dispensers for alcohol-based hand rub instead of having to carry small bottles since the pockets in the uniform are too small, and instructing the custodial staff to check and fill dispensers.

Lesson 3 required that nurses sit at a table and use gloves and paint. While this was possible at most nursing homes, not all nursing homes had an available space where this could be done. The result is that one nursing home stopped with the trial, since there was no available space.

After the trial, we evaluated the acceptance of the different aspects of the study. Every individual aspect received a score of 7 or higher out of 10 by 81-88% of the survey

respondents (n=448). The highest average scores were for using gloves and paint to see that fluids, bacteria, and viruses can get on hands during glove removal (8.0/10), and for using gloves and paint to see which parts of their hands they missed when washing them incorrectly (7.9/10). We also saw that 94% of the survey respondents stated that the nursing home where he or she works changed some aspect of their infection prevention policy and/or materials after the start of the intervention. Additionally, 96% of the respondents stated that they would recommend HANDSOME for other nursing homes. This led us to create a train-the-trainer program. This program was promoted by national and local organizations dedicated to quality improvement of elderly care or infection prevention, including university networks for elderly care, municipal health care centers, and antibiotic resistance networks. We trained 200 health care workers in 12 sessions to implement the intervention independently. We also made the intervention instructions and tools publicly available on a website dedicated to care for the elderly (https://www.zorgvoorbeter.nl/hygiene/handhygiene-verbeteren-verpleeghuis) so that other nursing homes could implement the intervention as well. These tools were downloaded more than 1700 times within 6 months after making them available.

E-learning

The e-learning served two purposes: a) it allowed nurses and nurses' aides who were unable to attend the live lessons to gain HH knowledge; and b) it provided reinforcement of the live lessons. The e-learning contained an introduction and seven lessons. The themes of the lessons were: the resident's perspective, how to wash and disinfect your hands, when to execute HH, HH in combination with sterile activities, time-saving work habits, glove use, and social aspects of HH. Videos modelled knowledge, guided practice, and promoted active learning by encouraging participants to scrutinize videos.

After viewing the introduction, the participant was invited every other week to complete the next lesson (dripped learning). This method provided participants with fortnightly reminders to perform HH. Each lesson lasted 5 to 10 minutes and ended with a quiz to reinforce the message. After completing the entire e-learning, the participant received a certificate and a nurse's watch which he or she could pin to clothing as an incentive.

We realized during the intervention that nurses did not like having to wait to complete the e-learning. We were also not satisfied with the number of people who completed the e-learning, since only 310 of the potential 1397 nurses and nurse's aides completed the e-learning (22%). This led us to rewrite the e-learning so that it could be completed in one sitting. The new version was also made freely available on a website dedicated to lessons

for nurses. (www.freelearning.nl/handhygiene) Within the first 6 months of going live, 3000 people successfully finished the e-learning. As per January 2021, 8200 people completed the e-learning successfully.

Conclusion

We conclude that the HANDSOME intervention was broadly accepted and appreciated. We can base this on a number of outcomes: (1) reactions from nursing home staff in our survey to questions about the lessons and the e-learning; (2) national organizations have incorporated it into protocols and promoted it; (3) the instructions on how to perform the intervention have been extensively downloaded; and (4) the e-learning has been widely used.

During this study, we inventoried the most frequently named reasons why people do not perform hand hygiene, and at what points they did not perform hand hygiene. Infection prevention workers can take these reasons into account when trying to optimize hand hygiene by changing policies and routines. Similarly, interior architects can take these reasons into account as part of an evidence-based design methodology for infection prevention.

Research question 2: Which hand hygiene opportunities should be registered when observing hand hygiene in a nursing home?

We made a thorough inventory of activities for which it was unclear (1) whether hand hygiene needed to be performed, and/or (2) how they were to be registered. This inventory of 103 moments demonstrates that the WHO definitions are difficult to interpret in many situations. Using expert opinion, we determined whether hand hygiene should be done at these moments.

In 2009, the WHO presented the 5 moments of hand hygiene, with a graphic depicting hand hygiene opportunities. These hand hygiene rules became standard throughout the world. In our study, we realized it was necessary to understand how these general terms should be applied in nursing homes.

To begin with, Moment 5 (after touching patient surroundings) is difficult to define in a nursing home, since residents are mobile and share communal spaces, such as living rooms and toilets. Their personal items also travel with them, such as walking frames or purses. In its specification for long term care, the WHO omits Moment 5. [3] We chose to use an

adapted definition of Moment 5, namely the resident's room or that portion of the room belonging to the resident.

Another debated issue in the 5 Moments of the WHO is Moment 2. This moment is defined as "before a clean/aseptic procedure", but also can include preparing food or medication, as specified by the WHO (Table I). [1] At the same time, not all hand hygiene studies include preparing or serving food and medications in their compliance measurements. We resolved this issue by separately registering the preparing and serving of pills and food (as Moment 6).

Thirdly, it is not always clear if an activity requires hand hygiene. Some examples are:

- Should hand hygiene take place between giving perineal care at the toilet (Moment 3) and putting trousers on the resident (Moment 1)?
- If the health care worker sneezes into his / her elbow, should hand hygiene be performed?
- Is hand hygiene necessary after using pens or keys belonging to the staff member?

The WHO mentions some unclear moments and whether hand hygiene should take place, but this does not cover all unclear moments (Table II). It also does not define the specific social interactions involving hands which can be ignored in a nursing home. In order to ensure that all hand hygiene opportunities were registered in the same manner, we created a list of frequently asked questions: a total of 103 moments which were unclear to our observers (Appendix). We used research and expert opinion to decide whether it was a hand hygiene opportunity and which Moment should be registered. During the last two observation rounds, there were no new unclear moments, implying that we saturated the unclear hand hygiene moments in nursing homes. One reason that we were able to create a complete list is that we had 16,730 observations of nurses. Another reason that we were able to create a complete list was that nursing homes have a limited number of different activities when compared to hospitals.

Conclusion

We made an inventory of 103 moments for which it is unclear whether nurses in nursing homes need to perform hand hygiene, and how they are to be registered. The size of the inventory demonstrates that the WHO definitions are difficult to interpret in many situations. We determined whether hand hygiene should be done at these moments, using

expert opinion. In the future, it would be wise to allow a larger group of experts to determine if hand hygiene should be done at these unclear moments, using, for example, the Delphi-method to create consensus.

This inventory can have far-reaching implications, making studies more comparable in the future. Also, by knowing which activities occur, it is possible to not only tally which activities occur most frequently, but also to better tailor interventions to address these activities. This inventory can further be used and expanded for other staff types and contexts.

Table II. Specific hand hygiene opportunities mentioned by the WHO as found in: The World Health Organization's Guidelines on Hand Hygiene in Health Care. Geneva: World Health Organization; 2009.

Hand hygiene moment	Hand hygiene indications mentioned by the WHO (selection)
Moment 1: Before touching a patient	Helping a patient to move around, washing a patient, taking a pulse, taking blood pressure, chest auscultation, abdominal palpation
Moment 2: Before clean/ aseptic procedure	Oral/dental care; secretion aspiration; skin lesion care; wound dressing; subcutaneous injection; catheter insertion; open a vascular access system; preparing food, medication, dressing sets; handling an invasive device for patient care; moving from a contaminated body site to a clean body site during patient care
Moment 3: After body fluid exposure risk	Oral/dental care; secretion aspiration; skin lesion care; wound dressing; subcutaneous injection; drawing and manipulating any fluid sample; opening draining system; endotracheal tube insertion and removal; clear up urine, feces or vomit; handling waste (bandages, napkin, incontinence pads); cleaning contaminated and visibly soiled material or areas (lavatories, medical instruments); removing gloves; contact with body fluids, excretions, mucous membranes, non-intact skin, or wound dressings; moving from a contaminated body site to a clean body site during patient care
Moment 4: After touching a patient	Helping a patient move around; wash; taking a pulse; taking blood pressure; chest auscultation; abdominal palpation
Moment 5: After touching patient surroundings	Changing bed linen; adjusting perfusion speed; monitoring an alarm; holding a bed rail; clearing the bedside table; contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient

Research question 4: Does a tailored hand hygiene intervention result in decreased healthcare-associated infections in nursing homes?

No, the intervention did not result in a reduction of illnesses in nursing homes. A higher hand hygiene compliance rate may have been necessary to see a difference in healthcare-associated infections. It may also be necessary to simultaneously implement other infection prevention measures in order to decrease illness.

The primary goal of hand hygiene is to reduce infectious disease rates. We examined if nursing homes in the intervention arm had fewer healthcare associated infections (HAIs) when compared to the control arm. [23] Five illnesses were investigated: gastroenteritis, influenza-like illness, pneumonia, urinary tract infection, and MRSA. There was significantly more gastroenteritis ($p<0.001$) and significantly less influenza-like illness ($p<0.01$) in the intervention arm when compared to the control arm when correcting for baseline differences, the clustering of observations within nursing homes, and period in the study. There were no statistically significant differences for pneumonia, urinary tract infections, and MRSA infections in the intervention arm when compared to the control arm. In a sensitivity analysis gastroenteritis was no longer statistically significantly higher in the intervention arm ($p=0.92$). As in comparable studies, we could not conclusively demonstrate the effectiveness of a HH intervention in reducing HAIs among residents of nursing homes, despite the use of clearly defined outcome measures, a standardized reporting instrument, and directly observed HH in a multicenter cluster randomized controlled trial.

Other studies have also looked at the effect of a hand hygiene intervention on HAI reduction. The results of a systematic review suggest that hand hygiene interventions may help control the infectious risk in nursing home settings, but the precise impact is difficult to ascertain. [24] Many studies in the review were limited by methodological flaws; only 8 of 56 studies were RCTs, and most studies were in single-site nursing homes and provided a limited array of data. Finally, a low proportion of the studies in the review included direct observations of hand hygiene compliance. Our current study complies with the recommendations from this review in that it is a large multicenter trial with extensive data collection on many possible determinants for hand hygiene compliance and risk factors for infection. Additionally, hand hygiene compliance was established through direct observation. At the same time, nursing home units generally did not achieve a high hand hygiene compliance, even in the intervention arm, with only a few nursing home units achieving a compliance of 50% or more at any given time.

Despite randomization, there were marked differences in the distribution of HAIs at baseline. This could possibly be explained by the fact that the introduction of disease is a highly random phenomenon, especially when observed over a short period. Baseline differences between the two arms of the trial were particularly notable for influenza-like illness and to lesser extent for gastroenteritis. The differences at baseline could be attributed to a small number of nursing home units with higher levels of illness.

To place the outcomes of the HANDSOME study into perspective, we compared these with a Dutch national surveillance program (SNIV) and European data from the European Centre for Disease Prevention and Control. The nursing homes in HANDSOME (both intervention and control arms of the study) followed the SNIV data closely (with the exception of ILIs); the control arm followed the SNIV trends more closely, both having lower rates of infections than the intervention arm. A possible explanation that the nursing homes in the intervention arm registered more infections could be that the nursing homes in the intervention arm were extra alert to infections among residents because of the intervention and thus more motivated to provide diligent reports than nursing homes in the control arm. Comparing our data to the infection rates provided by the ECDC, we had slightly more reporting of HAI (4.2 per 1000 resident days vs. 3.2 per 1000 resident days), even though the ECDC has a broader definition of HAI, including, for instance, skin/soft tissue infections, eye/ear/mouth/nose infections and bloodstream infections. [25]

In our study, we did not see a correlation between participation in the intervention and illness. When we additionally look at the correlation between hand hygiene compliance and illness, using the average illness per unit from the 7-week registration surrounding the week of the observation, we again see no correlation (Figure 6). Other studies also investigated the correlation between hand hygiene compliance and illness. Some (primarily single-site or small-scale) studies in nursing homes have shown a correlation between hand hygiene compliance and infection rates, although larger studies generally show no relationship. [24] This is different than studies done in hospitals, where there is evidence that higher hand hygiene compliance is associated with lower illness rates. [26]

Understanding the pathways of HAIs in nursing homes is therefore important to consider. In contrast to hospital settings, nursing homes promote the socialization of residents. Residents may practice poor hygiene themselves, and hence infect each other. There are also social interactions in a nursing home between residents and staff for which hand hygiene is not prescribed by the WHO, such as a handshake or patting a hand. [3] This is different than in a hospital, where all social interactions are considered hand hygiene opportunities. [1]

Research question 3: Is a tailored hand hygiene intervention for nursing homes successful in increasing hand hygiene compliance?

Yes, the intervention in the HANDSOME study was successful in increasing hand hygiene in the intervention arm of the study when compared to the control arm. It was equally successful in a Train the Trainer model. Hand hygiene was significantly better at 4 of the 5 WHO-defined hand hygiene moments.

Observed hand hygiene compliance

We observed hand hygiene four times throughout the study: at baseline (October 2016), after the first hygiene lesson (February 2017), after completion of the intervention (May 2017) and one year after baseline measurements (October 2017) (Figure 2). Though hand hygiene compliance increased in both arms, the increase after 12 months was larger for units in the intervention arm (12% to 36%) than for control units (13% to 21%); odds ratio (OR): 2.10, confidence interval (CI): 1.35-3.28. The intervention arm had a statistically significant higher increase in hand hygiene compliance at 4 of the 5 WHO-defined hand hygiene moments when compared to the control arm.

HANDSOME originally included a third study arm, the conditional intervention arm (n=50 units). This arm was created to test a separate hypothesis that implementing a HH intervention following an infectious disease outbreak would have a higher and/or more sustained effect than implementation at a pre-determined date, due to an increased sense of infection risk and urgency after an outbreak. Hand hygiene compliance was measured at all nursing home units at baseline concurrently with the two other study arms (October 2016). Nursing homes in the conditional intervention arm were further included if they had an outbreak in one of the nursing home units from that nursing home. Hand hygiene compliance was then measured after they received the first (n=15) and third (n=13) lessons, i.e., in the same schedule as the conventional intervention arm. This did not necessarily happen concurrently with the hand hygiene observations in the control and conventional intervention arms. The conditional intervention arm was aborted before we could reach the desired inclusion since (1) not all nursing homes had the finances to pay employees to attend the (unplanned) lessons; (2) the intervention was to take place during a period when nursing homes were understaffed and therefore nurses could not be spared for lessons; and (3) trained hand hygiene observers were not consistently available outside the planned observation periods. We did not perform analyses of observations in this arm since we did

not achieve the necessary inclusion and because of selection bias. Regardless, the conditional intervention arm had a similar increase in hand hygiene compliance as the conventional intervention arm (11% to 35% versus 12% to 36%) (Figure 2).

Although we were generally successful at achieving a higher hand hygiene compliance rate, we were not successful at Moment 2 (before a clean/aseptic procedure). After the final observations, we asked 26 different nurses why he or she did not perform hand hygiene at Moment 2 activities, specifically before giving eyedrops (n=9), wound care (n=7), catheter care (n=5), and injections (n=5). Fifteen (58%) of these nurses had received the hand hygiene intervention. The most stated reason was that he or she did not think about it (n=13), that his/her hands were still clean (n=6), that he or she didn't know it was necessary (n=4), that it takes too much time (n=3), and that it was sufficient to use gloves (n=3). Other comments were that it was difficult to put on gloves after doing hand hygiene, that he or she does not perform hand hygiene at this point, that the alcohol-based hand rub takes too long to dry, that the garbage bins are inconvenient so there was no place to put dirty gloves, and that there was no alcohol-based hand rub available.

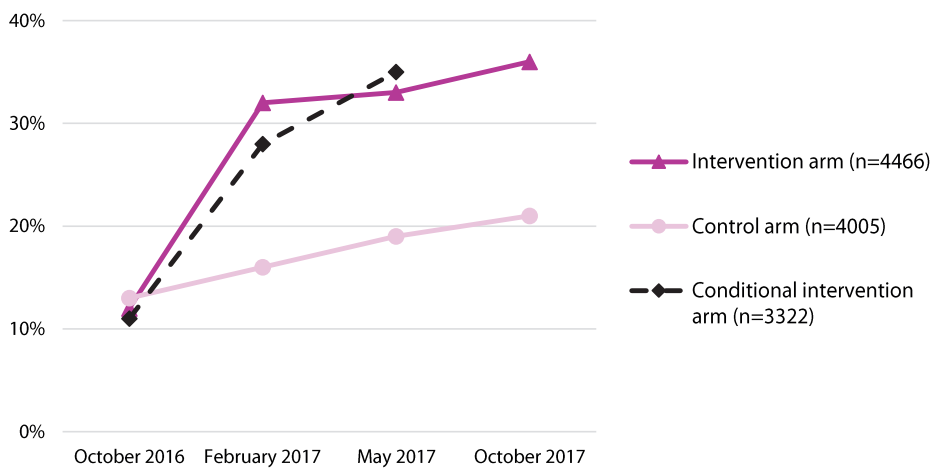


Figure 2. Hand hygiene compliance per study arm

Compliance per nursing degree

We also compared the results of the intervention per nurse type, making a distinction between a 3-year degree (*verzorgenden*) and a 4-year degree (*verpleegkundigen*) (Table III). This was done by averaging the mean hand hygiene compliance *per nurse*. We saw that

nurses with a higher degree had a higher hand hygiene compliance. Other studies also saw differences in hand hygiene compliance between professions, primarily nurses and doctors. In large studies, nurses had higher hand hygiene than doctors, with a gap of 15-20 percentage points in a large study in Australia over 9 years. [8-10] Both categories of nurses in our study showed similar increases in hand hygiene compliance (22-23%), which is also similar to the Australian study. [10] Nurses showed a slight decrease (1-3%) in hand hygiene compliance 6 months after completion of the intervention, implying that reminders are necessary. Students tended to have their best hand hygiene in October 2017, but the reasons for this are unknown.

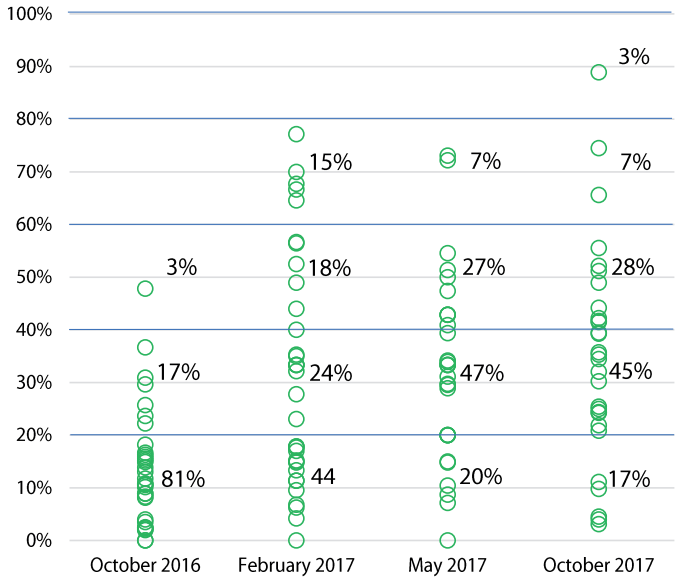
Table III. Average hand hygiene compliance per nurse in the intervention arm.

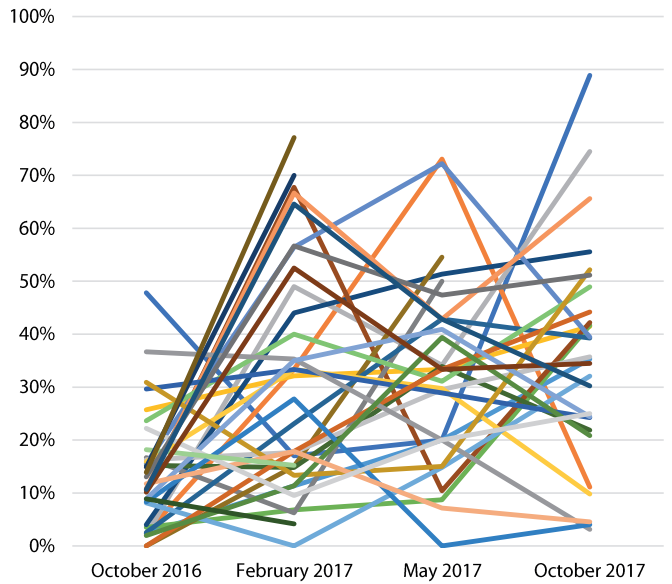
Degree type	October 2016		February 2017		May 2017		October 2017	
	HHC	n	HHC	n	HHC	n	HHC	n
4-year degree (587 observations)	28%	(20)	43%	(18)	51%	(8)	48%	(14)
3-year degree (3266 observations)	13%	(106)	31%	(97)	35%	(70)	34%	(64)
Student 4-year degree (275 observations)	14%	(20)	26%	(3)	36%	(9)	48%	(5)
Student 3-year degree (374 observations)	15%	(7)	23%	(12)	21%	(11)	44%	(10)

HHC: Average hand hygiene compliance per nurse per nursing degree type, n=number of nurses observed.

Compliance per nursing home

Another interesting observation from the intervention arm is that while hand hygiene compliance was generally homogenously low at baseline, with 81% of the nursing home units having less than 20% hand hygiene compliance, there was more diversity in hand hygiene compliance after the start of the intervention. After the intervention, hand hygiene compliance ranged from 0% to 89% per nursing home unit (Figure 3a). The number of nursing home units scoring <20% hand hygiene compliance went from 81% to 17% and the number of nursing home units scoring >40% hand hygiene compliance went from 3% to 38% (40-60%: 28%, 60-80%: 7%, 60-80%: 3%). Nursing home units were not consistently high or low scorers (Figure 3b). This is perplexing and would need further investigation. One reason could be that some organizations have a high turnover and/or rely heavily on external nurses who would not have followed the course, highlighting one of the main problems with using non-staff members as nurses. A more consistent and permanent staff would make it possible to ensure that all staff receive necessary training.





Figures 3a and 3b. Hand hygiene compliance per nursing home unit per observation round in the intervention arm. Figure 3a depicts the compliance per unit with the number of units in each compliance quintile; Figure 3b depicts each individual unit connected over time.

Perceived vs. actual compliance

After completion of the intervention, we asked attendees of the intervention what they thought their hand hygiene compliance was (Figure 4). On average, they thought that they achieved 73% hand hygiene compliance. This is more than twice as high (37 percentage points) than the actual compliance (36%). Again, we see a discordance between perception and reality at hand hygiene opportunities. One possible intervention which could be used in order for perceived hand hygiene compliance to be closer to reality, is to use (immediate) performance feedback. Performance feedback can be automated or done by hand hygiene observers and is a known instrument to increase hand hygiene compliance, although the precise impact of immediate feedback is difficult to measure since it is often one of many tools used within an intervention. [11, 12]

Discordance between perceived hand hygiene and actual hand hygiene was observed in other studies as well. Some studies which registered this discordance took place in hospitals in Spain and India, where the difference between perceived hand hygiene and actual hand hygiene was 16 and 35 percentage points, respectively. [13, 14]

Train the trainer

Since we were successful at achieving a statistically significant increase in hand hygiene in the intervention arm when compared to the control arm, and the participants of the original study stated that they would recommend this intervention to other nursing homes, we subsequently taught staff from other nursing homes how to implement the intervention themselves (i.e., teach the 3 lessons themselves) in a Train the Trainer model. After giving the trainers a few months to implement the intervention, we observed hand hygiene compliance in the participating nursing home units in the same manner as in the main study. We did not carry out baseline measurements in these nursing home units and assumed that their baseline compliance would be comparable to our baseline hand hygiene compliance level in the main study (12%). The average hand hygiene compliance after the training was 34% (range 0%-68% per nursing home unit, n=38 nursing home units at 19 nursing homes). This compliance level was the same as the total average hand hygiene compliance in the intervention arm of the study during follow-up (34%), implying that this initiative was successful.

Obstacles to performing hand hygiene

A number of issues may have caused the compliance increase in our HANDSOME trial to be lower than ideal. First of all, attendance at the lessons and e-learning was not optimal, with some nursing home units having a much higher turnout than others. A similar issue is that the first lesson (20 minutes) and second and third lessons (50 minutes) were given on two different days. Some nursing homes are required to pay nurses for a minimum of 2 hours if they report to work. This may have caused nursing homes to choose to only send nurses to the lessons who were on duty that day.

There are also characteristics of nursing home care which are difficult to change. For example, although we convinced some nursing homes to change their products (like alcohol-based hand rub), product placement, or policies, there are many variables which were impossible to change, such as shared bathrooms and shared bedrooms. Another issue is that many of the managers, and some health inspectors, did not always adhere to personal hygiene rules and therefore did not serve as role models. Thirdly, educational institutions do not give sufficient attention to hand hygiene. Lastly, hand hygiene sometimes needs to be performed extremely frequently. We researched the mean hand hygiene opportunities per nurse (*verzorgende,* n=9) at psychogeriatric wards in nursing homes (n=3) over a period of 24 hours (Figure 5). [15] This varied considerably, from 0 to 25 opportunities per half hour (data not shown). At the mean maximum of 13 opportunities per hour, this would mean that the nurse had to perform hand hygiene nearly every 4 minutes, totaling approximately 4 minutes per hour. It may be necessary to take a closer look at the definition of hand hygiene opportunities in order to make it more feasible.

Notwithstanding these obstacles, we facilitated a tripling of the hand hygiene compliance. While the absolute increase in hand hygiene in the intervention arm (24 percentage points) may not seem particularly high, these results are comparable with three other Dutch intervention studies in hospitals, which also had a low baseline compliance (20% to 22%) and saw a 15 to 33 percentage point increase in hand hygiene compliance. [16, 17]

There are only a few rigorous hand hygiene compliance studies in nursing homes, of which very few are randomized controlled trials and/or record hand hygiene compliance rates. [18-22] Two examples of hand hygiene trials in nursing homes (which were not RCTs) demonstrated the effectiveness of hand hygiene interventions (hand hygiene compliance increased from 6% to 46%, 27% to 61% and 22% to 49%). [18, 19]

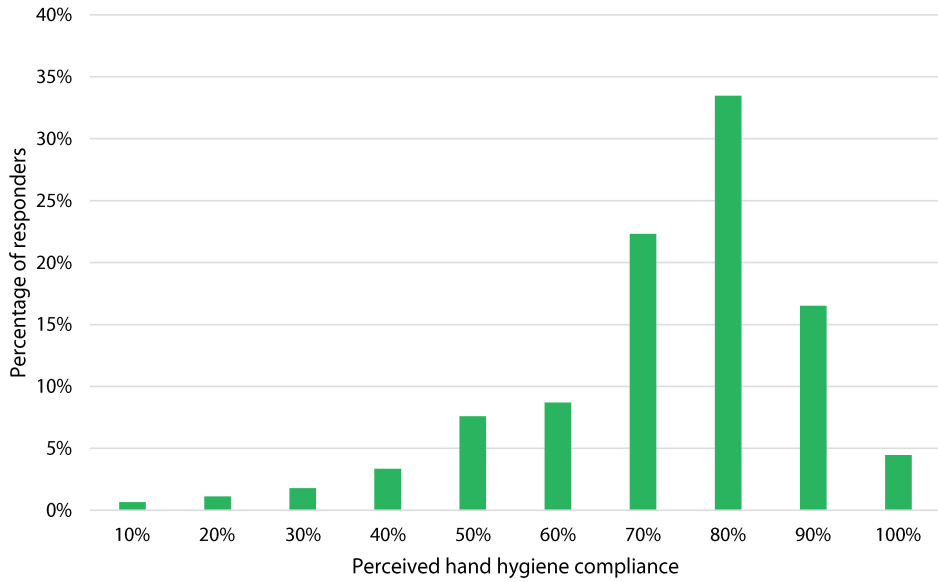


Figure 4. Health care workers' self-perception of their hand hygiene compliance (n=448).

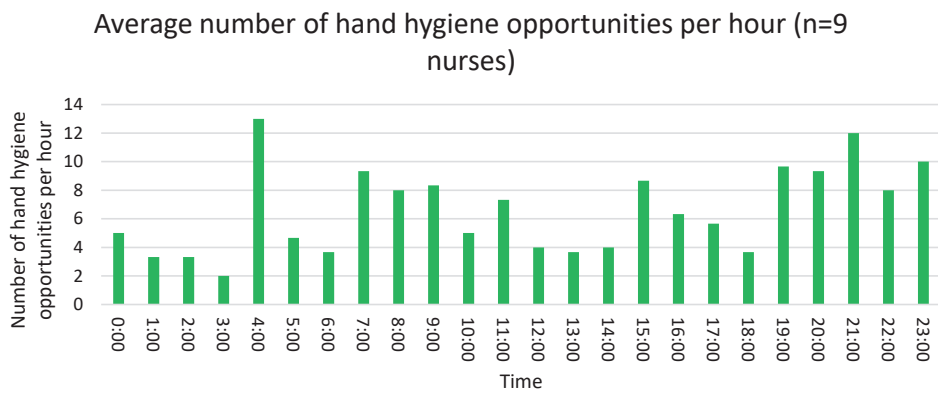


Figure 5. Average hand hygiene opportunities per hour per nurse in a nursing home (n=3 psychogeriatric wards).

Conclusion

The intervention in the HANDSOME study was successful in increasing hand hygiene in the intervention arm of the study when compared to the control arm. It was equally successful in the conditional intervention arm and in a Train the Trainer model. We would expect a higher hand hygiene compliance if underlying barriers were addressed, such as creating a workflow which minimizes hand hygiene opportunities, providing materials for hand hygiene at the necessary places, and having a consistent workforce. Hand hygiene compliance would assumedly also increase if nurses received immediate feedback about their hand hygiene so that their perception of their compliance and their actual compliance converge. Knowing their actual compliance may help in motivating them to pay more attention to hand hygiene.

At the same time, it seems unrealistic that nurses would perform hand hygiene at every opportunity, not only because of work flow issues or other obstacles, but also because it is not realistic that someone would perform hand hygiene as frequently as our maximum average measurement of 13 opportunities per hour. In the future, decisions should be made about which hand hygiene moments to prioritize in order to create more realistic guidelines.

Conclusion

The intervention did not result in a reduction of illnesses in nursing homes. In order to understand the differences in effectiveness of hand hygiene compliance between hospitals and nursing homes, it would be prudent to examine the differences in transmission pathways and other infection control measures between hospitals and nursing homes. It may be necessary to have a higher hand hygiene compliance rate in order for hand hygiene compliance to have an impact on illness rates.

Other observations from the hand hygiene study

During the execution of the HANDSOME study, we investigated other aspects of infection prevention as well. This includes surface contamination, glove use, personal hygiene, and hand hygiene at hairdressers in nursing homes.

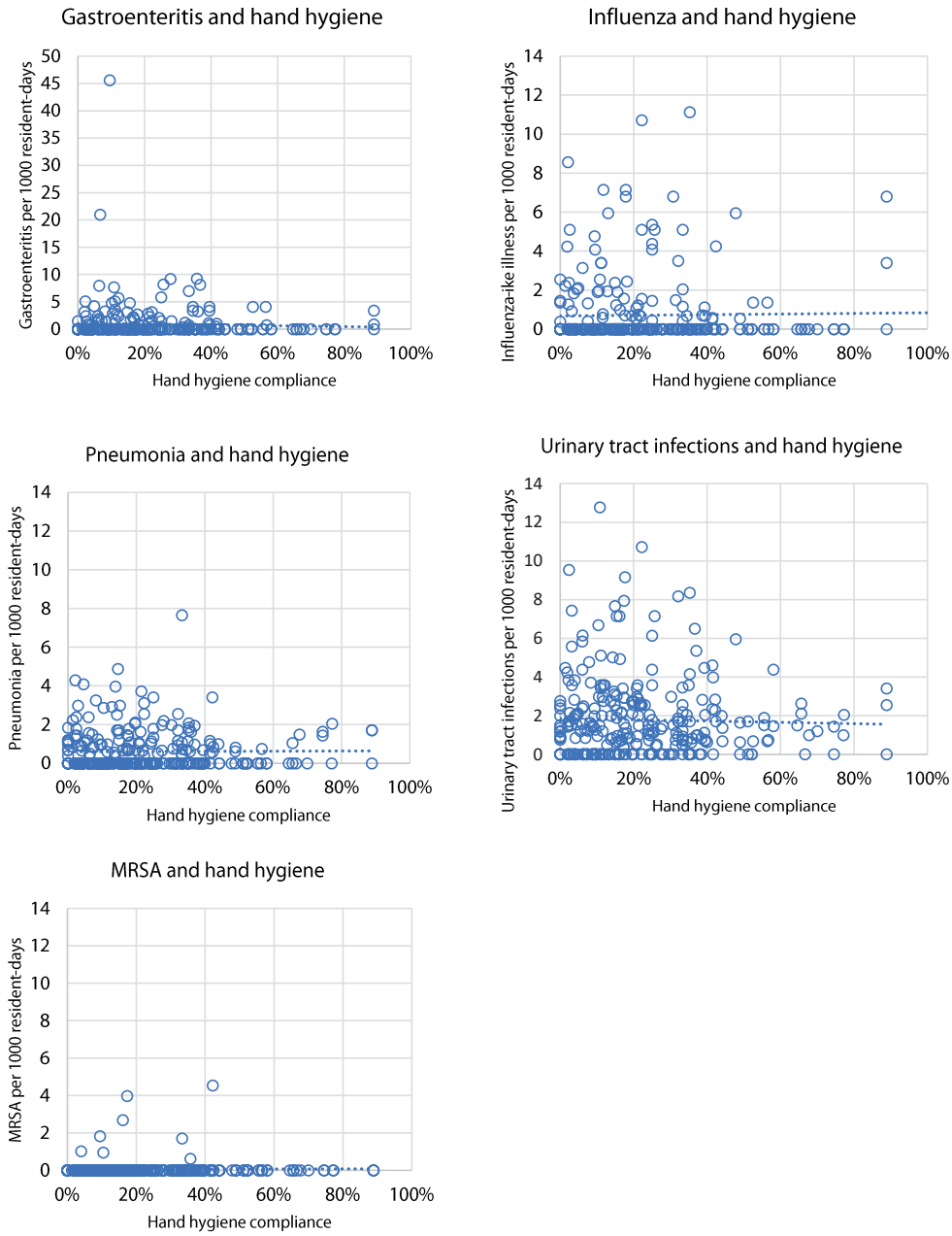


Figure 6. Relationship hand hygiene and illness per nursing home unit, using the 7-week period surrounding the observation (n=293)

Surface contamination

Positive samples were detected (n=121 per surface) for rhinovirus (nurse's station: 41%; toilet: 14%; living area: 29%), norovirus (nurse's station: 18%; toilet: 12%; living area: 16%), and *E. coli* (nurse's station: 14%; toilet: 58%; living area: 54%). [27] There were no convincing associations between environmental contamination with hand hygiene compliance or illness incidence. There were also no convincing differences between the intervention arm and the control arm of the study.

We recommend further exploration of environmental surface sampling in a new study where detection in the environment is followed by sampling of residents to further validate this method. Any future study including rhinovirus should incorporate the common cold to enable a better association of observed illness and the target microorganism. Similar studies should also be performed within a limited time frame when the illnesses caused by these microorganisms are more prevalent.

Glove use

The intervention was not successful in reducing substitution of hand hygiene by glove use, even though the training addressed substitution. [28] After the intervention, there was a significant increase in hand hygiene combined with donning/removing gloves and a significant decrease in nurses inappropriately not changing gloves after contact with body fluids. Nurses in nursing homes need dedicated glove use training. While glove substitution is a problem, and wider availability of gloves may lead towards more substitution, gloves do need to be available for nurses wherever they could be expected to need them so that they do not use dirty gloves from their pockets. These gloves should be available in different sizes.

Personal hygiene

The Dutch guidelines for (hand-related) personal hygiene dictate that staff providing care does not wear nail polish/artificial nails/long nails, rings, bracelets, watches, a brace, or long sleeves. [2] This is to ensure that bacteria and virusses do not nestle in crevices and to ensure that hands and wrists can be washed or disinfected. During the intervention, nursing home directors presented the hand hygiene rules to staff and stated the consequences for not following personal hygiene policy. Of the staff surveyed (n=515), 63% stated that he or she received this training. Total compliance with the personal hygiene measures was high, with the lowest being for long sleeves (95%), rings (96%), and nails (97%). This generally did not change over the course of the study in either study arm. All nursing homes individually had at least 75% compliance for each personal hygiene variable for each observation period.

We can conclude that nurses' hand-related personal hygiene is generally good at nursing homes. The most improvement can be gained by eliminating long sleeves. While some nursing homes had uniforms, others did not. By introducing appropriate uniforms, that are warm enough in the winter (so that health care workers do not wear long sleeves under their uniforms), nursing home staff would be more compliant with the guidelines.

Hairdressers

We looked at the hand hygiene of hairdressers who work in nursing homes, since 79% of the nursing homes surveyed (n=28) had hairdressers. [29] We also knew that MRSA was transmitted to 6 residents via a hairdresser located in a nursing home prior to study commencement. Out of the 82 hand hygiene opportunities at 5 hairdresser salons located in the nursing homes, hand hygiene was never done. It is conceivable that hairdressers feel clean, since they are constantly washing hair with shampoo.

Research question 5: Is there an adequate alternative to commercially manufactured face masks?

Yes, we found an adequate alternative to commercially manufactured face masks. The best outcome was with ePM$_1$ 85% commercially manufactured filter fabric in a duckbill form. Two layers of quilt fabric with a single household paper towel as filter was also a viable choice for protecting the user and the general population.

Due to the shortage of masks during the SARS CoV-2 pandemic, we investigated if there is an adequate alternative to medical grade face masks, since donning masks can play an important role in curbing the spread of SARS-CoV-2. This should be an effective mask for the population to wear in public that could easily be made during a medical face mask shortage using readily available materials.

We determined the effectiveness of readily available materials and models. [30] The outcomes were compared with N95/FFP2/KN95 masks that entered the Netherlands in April-May 2020. Twenty-five masks were tested to see if they filter a minimum of 35% of 0.3μm particles, are hydrophobic, seal on the face, are breathable, and can be washed. We concluded that it would be possible to reduce the reproduction rate of SARS CoV-2 from 2.4 to below one if 39% of the population would wear a mask made from ePM$_1$ 85% commercially manufactured filter fabric and in a duckbill form. This mask performs better than 80% of the imported N95/FFP2/KN95 masks and provides a better fit than a surgical mask. Two layers of quilt fabric with a single household paper towel as filter is also a viable

choice for protecting the user and the environment. While the commercially manufactured filter fabric is cheap and easy to sew, it is not readily available for consumers. The mask from quilt fabric with a paper towel seems at present to be the most ideal solution. All materials (commercially manufactured filter fabric, quilting cloth, and paper towels) should be checked for safety, particularly lung and skin protection.

Recommendations

During our study, we learned from our successes, our failures, comments from people working with and in nursing homes, and comments by editors of peer-reviewed journals. This has led to the recommendations for teaching hand hygiene, system changes that promote hand hygiene, observing hand hygiene, and new hand hygiene studies.

Recommendations for teaching hand hygiene

- Explain the "Room In, Room Out, Before Clean, After Dirty" slogan to caregivers in nursing homes. This new method is easier to remember than the 5 moments of the WHO and is tailored to the nursing home setting.
- Use hand hygiene training materials that have already been developed and tested, such as our hand hygiene handbook (https://www.zorgvoorbeter.nl/hygiene/handhygiene-verbeteren-verpleeghuis). [31]
- Employ a train the trainer method in order to increase outreach.
- Address and demonstrate the most frequently occurring hand hygiene opportunities, as well as those which are most frequently missed, as shown in this study.
- Use immediate feedback to decrease the discordance between self-perception of hand hygiene compliance and actual hand hygiene compliance. This involves observing a nurse while that nurse provides care for a resident. Observations are followed by providing feedback about which hand hygiene opportunities were missed. Feedback should be given tactfully so that the nurse does not feel reprimanded in front of a resident.
- Include wrist rubbing in the hand hygiene procedure since this area can easily be contaminated when removing gloves.
- Ensure that all staff is trained through careful planning of lessons so that both present staff and staff not on duty can attend.
- Develop e-learnings which can be completed in one sitting.
- Provide nurses with dedicated glove use training.
- Volunteers and (external) staff, such as hairdressers, housekeepers, and kitchen staff, should receive tailored hand hygiene training.

- Ensure that the nursing home has a room that is suitable to giving hand hygiene lessons.
- Provide incentives for nurses to do the training, such as nurse's watches or hand cream.

Recommendations for system changes that promote hand hygiene

- Adjust the environment to make it easier to perform hand hygiene. This does not just involve hanging alcohol-based hand rub dispensers inside of the resident's apartment at the entrance, but also providing appropriate uniforms with short sleeves and pockets which can carry small bottles of alcohol-based hand rub as well as other commonly carried attributes. These uniforms should be appropriately different for the summer and the winter, so that nurses do not wear long sleeves under their uniforms because they feel cold in winter.
- Address underlying (external) barriers. For instance, create a workflow which minimizes hand hygiene opportunities, provide necessary materials for hand hygiene at points of care, minimize telephone use, and have a consistent workforce.
- Make gloves widely available in different sizes so that nurses do not carry gloves in their pockets, since they could then get contaminated.
- Create a policy that nurses either eat with the residents or help the residents with eating, but not both at the same time, since this hampers hand hygiene.

Recommendations for observing hand hygiene

- Consider a 'Room Out' hand hygiene opportunity as compliant if it takes place right before a nurse leaves the resident's room or right after a nurse leaves a resident's room and has not yet touched anything or anyone. In this study, we only considered hand hygiene opportunities to be compliant if the hand hygiene took place in the room of the resident and after the nurse entered the room or before the nurse left the room. This was done because we wanted to copy what is considered best practice in hospitals; nevertheless, this is not necessarily best practice for a nursing home. It would be better to perform hand hygiene after leaving the room, since the doorknob is used by other caregivers and the resident.
- Specifically register which hand hygiene opportunity (sub-moment) takes place. This can be done for nursing homes based on the hand of the findings in this study. The results from this can be used to further refine hand hygiene lessons.
- Use and expand our inventory of hand hygiene sub-moments for other staff types and contexts.
- Observe hand hygiene throughout the day. Our study took place in the morning and early afternoon. Because of this, we missed certain behaviors which may take place more

often at other times, such as handshakes, hugs and patting a hand/shoulder/knee. While these are considered hand hygiene opportunities in hospitals, the WHO specifically states that social interaction (such as these) can be ignored in a nursing home. At the same time, they are moments when pathogen transmission can take place. It would therefore be good to also observe at different times of the day when there is less general daily care such as bathing, toothbrushing and giving medication, in order see more social interactions which do not prescribe hand hygiene in nursing homes.

Recommendations for new hand hygiene studies

- Test the effectiveness of the "Room In, House Out, Before Clean, After Dirty" method in the home care setting. The effectiveness of this method should be tested by comparing it to a control group who learns the 5 Moments of the WHO.
- Research the most effective way to teach volunteers and visitors the "Room In, Room Out, Before Clean, After Dirty" method.
- Determine what nurses should do at unclear hand hygiene opportunities in a Delphi study.
- Experts should reexamine what is considered hand hygiene opportunity. At the mean maximum of 13 opportunities per hour, a nurse would perform hand hygiene nearly every 4 minutes, totaling approximately 4 minutes per hour.
- Examine the differences between hospitals and nursing homes in population, transmission pathways, and infection control measures, in order to understand why the relationship between hand hygiene and illness is clearer in hospitals than it is in nursing homes.
- Make an inventory of the frequency and quality of hand hygiene and infection prevention lessons in educational settings for health care workers in order to create new policies at these institutions.

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Appendix

How to score hand hygiene in nursing homes for regular care (inventory)

During the observations of the HANDSOME trial, it was not always obvious whether hand hygiene needed to be done. The WHO mentions some unclear moments and whether hand hygiene should take place, but this does not cover all unclear moments. [1] We made a thorough inventory of activities and situations (103 unclear moments, formulated as "Questions" in the following table) for which it was unclear (1) whether hand hygiene needed to be performed, and/or (2) how it was to be registered. These 103 unclear moments were encountered while observing 16730 hand hygiene opportunities of nurses in the HANDSOME study. During the last two observation rounds, there were no new unclear activities, implying that we saturated the unclear hand hygiene opportunities in nursing homes.

Research and expert opinion were used to decide whether it was a hand hygiene opportunity and which moment should be registered. In the future, it would be wise to use a larger expert panel to decide whether hand hygiene is necessary at these moments and what should be registered.

In this study, necessary hand hygiene before activities involving food and pills were registered separately. Although this is considered a hand hygiene opportunity by the WHO, not all hand hygiene studies include preparing or serving food and medications in their compliance measurements. [1] We resolved this issue by separately registering the preparing and serving of pills and food. In the overview presented here, these moments are indicated as "Moment 2/score separately for food and pills".

This inventory is divided into sections, namely:

- general principles
- adult diaper
- aids (wheelchair/ walker/hoist)
- alcohol-based hand rub
- bathroom/toilet
- body fluids
- catheter
- cleaning/tidying up
- doors
- dressing
- food and pills
- general care
- gloves
- hand wounds on the health care worker
- invasive actions
- linen/bedding
- medication
- mouth
- own body fluids
- pen and keys
- resident's surroundings
- shared rooms
- social contacts
- telephone
- washing
- washing hands
- wound care

When unclear moments were relevant to multiple sections, we repeated the question.
For inquiries about this overview, contact Gwen Teesing, gwenteesing@gmail.com.

Category	Question	Answer	Extra explanation
General principles	Do I have to score both an AFTER Moment (Moments 3, 4, 5) and a BEFORE Moment (Moment 1, 2), even if they follow each other?	No. AFTER takes precedence in most cases. Do not score a "before" moment (Moment 1 or 2) if hand hygiene was already done after an action and the health care worker continues to work in the same room. BUT: there are exceptions (see below).	
General principles	If the care is interrupted, can I get two BEFORE-Moments in a row (Moments 1 and 2)?	Yes. Example: The health care worker does hand hygiene (Moment 1). The health care worker washes a resident. The health care worker bumps into a teacup and has to clean it up. The health care worker thus touches the floor (which is outside the resident's surroundings). Then the health care worker has to do hand hygiene (Moment 1) before continuing to wash the resident.	
General principles	If I am asked whether I can, for example, close a door or help with something, how should I deal with it?	During the observation, you are **not allowed to** help. It is best to say that you are not authorized to help and that it interferes with your research. **You can only watch.**	
General principles	Should hand hygiene always be done before touching a door when leaving a room?	The health care worker must always do hand hygiene before leaving the resident's room (Moment 3, 4, or 5). An exception is if the health care worker is accompanying the resident somewhere.	
General principles	Two residents in the ward were **MRSA positive**. A protective apron and gloves were put on. These gloves were then kept on throughout contact. With gloves on, no hand alcohol can be used after contact with body fluids. What should be scored?	This guide only covers **"regular" care** and not special situations, such as for **norovirus, MRSA, and COVID-19**. Do not observe hand hygiene in this case.	
General principles	A health care worker takes gloves out of his/her pocket to use. What should be scored?	In case of an invasive operation, this is scored as hand hygiene missed, because the gloves are not clean. It is allowed for a non-resident related task (such as removing bedding or cleaning toilets).	
General principles	Blood pressure was measured in the living room, whereby every resident was touched. What should be scored?	The health care worker has to do hand hygiene between the residents, because these are medical procedures (score: Moment 4).	

Category	Question	Answer	Extra explanation
Adult diaper	What should I score after a health care worker **touches** (not changes) a diaper?	Assume that diapers do not leak (Moment 4), unless it is clearly visible that this has happened. If it has leaked, then score Moment 3.	
Aids (Wheelchair / walker / hoist)	What should I score if a resident is rolled from one room to another in a wheelchair?	If the health care worker leaves the resident's surroundings, score it as 'after touching the resident's surroundings' (Moment 5). Hand hygiene can occur after bringing the resident somewhere in the wheelchair.	
Aids (Wheelchair / walker / hoist)	What should I score after a health care worker touches an aid (wheelchair/walker/hoist)?	If the aid is located in the resident's surroundings, score this as after touching the resident's surroundings (Moment 5). Do not score if these aids are touched outside the resident's surroundings.	
Alcohol-based hand rub	If the health care worker **wears gloves** and **then uses alcohol-based hand rub** (on the gloves), what do I score?	If it is a hand hygiene moment, then score it as missed; otherwise score nothing.	
Alcohol-based hand rub	If **both soap and alcohol** are used, should both be checked?	Check both as done.	
Bathroom/toilet	If a resident's diaper has just been changed, does hand hygiene take place before **trousers** are put on?	No, but there is an exception. Hand hygiene should only take place before putting on trousers if the health care worker's hands are **visibly dirty**.	If a diaper is changed and then trousers are put on, this is seen as one action. This action is not finished until the trousers are put on. After that, hand hygiene must take place (Moment 3).
Bathroom/toilet	What should be scored if a resident is washed or dressed in a **WC / bathroom**?	Moment 3.	
Bathroom /toilet	What should be scored if a resident is only helped with dressing at the toilet?	Moment 3.	There is some chance of having contact with bodily fluids.
Bathroom/toilet	What should be scored if **while changing a diaper / going to the toilet** a wound is detected and cleaned?	Cleaning a wound is a clean operation. Before it is cleaned, hand hygiene must first take place (Moment 2). Hand hygiene should take place again after cleaning the wound (Moment 3).	
Bathroom/toilet	What should be scored when urine is tested with a **urine strip**?	As 'before touching the resident' (Moment 1) and 'after possible contact with body fluid' (Moment 3).	

Category	Question	Answer	Extra explanation
Body fluids	What is considered a body fluid?	Vomit, snot, spit, urine, blood, tears, etc. Sweat is not considered a body fluid unless it is excessive.	
Body fluids	What should be scored when urine is tested with a **urine strip**?	Score it as before touching the resident (Moment 1) and after possible contact with body fluid (Moment 3).	
Body fluids	What should be scored if gunk (**rheum**) is also wiped from the resident's eyes while washing the resident's face?	This is equivalent to eye drops: this is therefore seen as an invasive action (Moment 2).	
Body fluids	What should be scored after **eye drops** are given?	When tears are wiped, there is contact with body fluids (Moment 3). Otherwise, this is Moment 4.	
Body fluids	What should be scored when there is possible contact with body fluids when not in contact with the resident (such as cleaning toilets)?	Moment 3.	
Catheter	If only the **catheter drainage bag** is changed, is this an invasive procedure?	No. Since there is possible contact with body fluids, there is a hand hygiene opportunity after touching a catheter drainage bag (Moment 3).	If only the bag is changed, **no skin barrier is** breached and therefore no invasive operation is involved.
Catheter	If the health care worker moves the **catheter drainage bag** while washing the resident, does hand hygiene have to take place before continuing to wash the patient?	No.	In this case, moving the catheter drainage bag is part of the washing procedure. That is why this is not seen as a separate moment. After washing, score for possible contact with body fluids (Moment 3).
Catheter	What should be scored when urine is tested with a **urine strip**?	Score as before touching the resident (Moment 1) and after possible contact with body fluid (Moment 3).	
Catheter	When **catheter care** and **washing** are done simultaneously, what do I score?	Hand hygiene always needs to occur directly before an invasive action (Moment 2). After an invasive procedure, assess whether hand hygiene should be applied immediately, depending on whether there has been possible contact with body fluids.	

Category	Question	Answer	Extra explanation
Cleaning / tidying up	If dirty **cutlery** is put in the dishwasher by the health care worker, should it be scored?	Yes. However, the health care worker is allowed to clean up cutlery from several residents first, as 1 action. After that, hand hygiene must take place because of possible contact with body fluids (Moment 3).	
Cleaning/ tidying up	What do I score what **bed linen is straightened**, without changing it?	Moment 5.	
Cleaning/ tidying up	What do I score after a **garbage bag** is touched?	Score it as touching the **resident's surroundings** (Moment 5).	
Doors	If a health care worker (with clean hands) uses **knuckles** to knock on the door, is hand hygiene necessary before touching the resident?	Yes.	
Doors	If the **door handle of the medicine cabinet** is touched, must hand hygiene take place again before touching medication?	No. Touching the door handle of the medicine cabinet is part of the **entire act** of giving medicine (Moment 1). This is an exception to the rule, just like touching the refrigerator door when distributing food.	However, hand hygiene must take place after giving medicine (Moment 4 or Moment 5).
Doors	A health care worker helped a resident off the bedpan and walked out the door with the bedpan, which she opened with her **elbow**. Does this count as missed? After putting the bedpan in the flushing machine without touching anything else, she did hand hygiene.	This is fine. The health care worker may first complete this action and then apply hand hygiene (Moment 3).	
Doors	The health care workers use **badges** to open doors. Before touching the badge, they apply hand hygiene and open the door with their hands. What should be scored?	Hand hygiene must always take place on the inside of the room: When entering the room: Badge -> door handle -> hand hygiene (Moment 1 or 2). When leaving the room: Hand hygiene -> badge -> door handle (Moment 3, 4, or 5).	

Category	Question	Answer	Extra explanation
Doors	If I am asked whether I can, for example, close a door or help with something, how should I deal with it?	During the observation, you are **not allowed to** help. It is best to say that you are not authorized to help and that it interferes with your research. **You can only watch.**	
Doors	From the inside of the room, the door opened with a button. Because of this the health care worker did not touch the door. What should be scored?	Treat the button as a door handle.	The button is touched by various people.
Doors	Should hand hygiene always be done before touching a door when leaving a room?	The health care worker must always do hand hygiene before leaving the resident's room (Moment 3, 4, or 5). An exception is if the health care worker is accompanying the resident somewhere or is carrying something such as a bed pan. Then hand hygiene should be done after accompanying the resident or completing the action (Moment 3, 4, or 5).	This point is debatable. When entering a resident's room, hand hygiene should always occur in the room, not before entering the room. Since alcohol-based hand rub is generally only placed either inside the room or outside the room, to keep the door handle as clean as possible, and to avoid the health care worker forgetting to do hand hygiene once having left the room, we suggest that hand hygiene should happen before the health care worker leaves the resident's room.
Dressing	Should hand hygiene be done between **washing** and **dressing**?	No.	In practice, clothing is often put on to prevent the resident from getting (too) cold. Hand hygiene between washing and dressing is therefore not necessary. After washing (and dressing) hand hygiene is required (Moment 4).

Category	Question	Answer	Extra explanation
Dressing	If a resident needs a change of clothing, does the health care worker have possible contact with body fluids because the clothing is possibly soiled? Is this Moment 3 or Moment 4?	Assume that adult diapers do not leak and that there is no body fluid on the clothing (Moment 4).	If the clothes are visibly dirty with body fluids (may also be vomit or saliva), score Moment 3.
Dressing	If a resident's diaper has just been changed, does hand hygiene take place before **trousers** are put on?	No, but there is an exception. Hand hygiene should only take place before putting on trousers if the health care worker's hands are **visibly dirty**.	If a diaper is changed and then trousers are put on, this is considered one action. This action is not finished until the trousers are put on. After that, hand hygiene must take place (Moment 3).
Dressing	What should I score after putting on the resident's **shoes**?	Only the door, the floor itself and the **bottom of the shoe** are outside the resident's surroundings. If the floor is not touched, and neither are the bottom of the shoes, then the action remains within the resident's surroundings and you do not need perform hand hygiene when continuing care. If putting on shoes is the last action before the health care worker leaves the room, score it as a Moment 4.	However, the bottoms of the shoes are dirty. Touching the bottom of the shoes is a break in care. If care is continued after touching the bottom of the shoes, then hand hygiene should be done beforehand (Moment 1).
Food and pills	Should hand hygiene take place in between touching the **common refrigerator** and preparing food?	No. Touching the refrigerator is part of the act of preparing food.	
Food and pills	Should hand hygiene be done between **touching** the resident and helping with or preparing **food in the resident's room**?	It is not necessary because it is contact between the resident and the surroundings. At the **beginning and the end of the total action** hand hygiene must take place.	
Food and pills	Should hand hygiene be done between **touching** the resident and preparing **food in the communal kitchen**?	Yes (Moment 4).	
Food and pills	If a bib is taken off, what should be scored?	As possible contact with body fluids (Moment 3).	

Category	Question	Answer	Extra explanation
Food and pills	Does hand hygiene need to be done every time that coffee is served/pills are distributed/soup is served in a resident's room?	When a health care worker is bringing food/pills/coffee to different rooms, an exception is made. The health care worker should start by doing hand hygiene (Moment 2/score separately for food and pills). If the health care worker goes to each room and uses the residents' cups for coffee (a coffee round, just like a pill round or a soup round), do not register it as contact with a resident's surroundings. This is because hand hygiene is not feasible at that point (i.e., 20 times in 30 minutes).	
Food and pills	If dirty cutlery is put in the dishwasher by the health care worker, should it be scored?	Yes. However, the health care worker is allowed to clean up cutlery from several residents first, as 1 action. After that, hand hygiene must take place because of possible contact with body fluids (Moment 3).	
Food and pills	If the observed health care worker also occasionally takes a bite of something while feeding a resident, is this a hand hygiene opportunity?	If the health care worker is eating something himself/herself, he/she must do hand hygiene before continuing to feed the resident.	
Food and pills	If cutlery falls to the floor, is picked up and returned to the resident's plate, is this a Moment?	No, but there is an exception. If the health care worker touches the ground, then the health care worker has to do hand hygiene before helping the resident again (Moment 1).	Preferably, the fork would be put aside and a new fork would be taken.
Food and pills	If the health care worker continues to prepare / distribute food after a social Moment, is this a Moment?	Yes. This is before preparing food and should be a clean activity (Moment 2/score separately for food and pills).	
Food and pills	When something goes wrong again and again, do I have to **score it every time**?	Yes.	
Food and pills	Every resident has his/her own medication cabinet in the room. Should hand hygiene also take place before giving pills?	The health care worker has to do hand hygiene before handling food and pills (Moment 2/score separately for food and pills).	

Category	Question	Answer	Extra explanation
Food and pills	The health care worker is preparing food and the **phone** rings. The health care worker picks up the phone and then continues to prepare food. What do I then score?	Missed (Moment 2/score separately for food and pills).	
General care	If the resident is **rubbed** with oil, cream, petroleum jelly, etc., is this considered possible contact with body fluids?	No, although there is an exception. There is possible contact with body fluids if the resident is rubbed in the **pubic area**.	Sweat is not considered a body fluid unless it is excessive.
General care	What do I score when attributes such as **razor, toothbrush, comb, etc.** are touched**?**	This is part of a resident's surroundings, provided the attributes are also located in the resident's surroundings (Moment 5).	
General care	What do I score when **lipstick** is applied on the resident?	As **food and pills** (Moment 2/score separately for food and pills), and then as possible contact with body fluids (Moment 3).	
Gloves	When are gloves a substitute for hand hygiene?	Gloves are **never** a substitute for hand hygiene. Gloves are used when there will be possible contact with body fluids. Hand hygiene should be done before putting on gloves and after removing gloves. The only exception is if the action is not with a patient, such as cleaning the toilet. Then, hand hygiene does not need to be done before donning gloves, but it does need to be done after removing gloves.	
Gloves	If **1 glove** is taken off, but the hand that is being used is still has a glove on, what should be scored?	Score that gloves are on.	
Gloves	If the health care worker **wears gloves** and **then uses alcohol-based hand rub** (on the gloves), what do I score?	If it is a hand hygiene moment, then score it as missed; otherwise score nothing.	
Hand wounds on the health care worker	If the **health care worker has a bandage** on his/her hand, does this change anything about the hand hygiene?	No. However, at the start of the day, the health care worker should apply a **water-repellent bandage.** This must be removed at the end of the shift. The hand hygiene remains the same.	

Category	Question	Answer	Extra explanation
Invasive actions	Do I always have to score a Moment 3 (after contact with body fluids) after a Moment 2 (before invasive action)?	This is almost always true, although there are exceptions.	Incidentally, Moment 2 does not always take place before Moment 3. There can also be contact with body fluids without invasive action. Consider, for example, emptying a catheter drainage bag or changing a diaper.
Invasive actions	Should the health care worker do hand hygiene right after **stoma** care?	After possible contact with body fluids, hand hygiene is necessary (Moment 3).	
Invasive actions	Does inserting an **enema** count as an invasive procedure?	It is an invasive act/aseptic procedure (Moment 2).	
Invasive actions	Is taking a temperature with a **thermometer** an invasive practice?	No. This is not scored as an invasive act/aseptic procedure (Moment 1).	However, there is generally possible contact with body fluid (Moment 3). This depends on where the temperature is measured.
Invasive actions	Is inserting a **suppository** an invasive procedure?	No. This is not scored as an invasive act/aseptic procedure (Moment 1).	However, by inserting a suppository there is possible contact with body fluid (Moment 3).
Invasive actions	If only the **catheter drainage bag** is changed, is it invasive?	No. Since there is possible contact with body fluids, there is a hand hygiene opportunity after touching a catheter drainage bag (Moment 3).	If only the bag is changed, **no skin barrier is** breached and therefore no invasive operation is involved.
Invasive actions	Is using an **insulin pen** an invasive procedure?	Yes. All injections are considered invasive procedures (Moment 2), followed by possible contact with body fluids (Moment 3).	
Invasive actions	Is inserting an **IV** an invasive procedure?	Yes (Moment 2). This is followed by possible contact with body fluids (Moment 3).	

Category	Question	Answer	Extra explanation
Invasive actions	If other things are touched during an invasive act, should I score for Moment 2 again?	This depends on **what exactly is being touched.** If what is being touched is related to the invasive act, then no hand hygiene needs to be done. If anything else is touched, hand hygiene must take place before continuing with the invasive procedure (Moment 3, 4 or 5).	
Invasive actions	What should be scored if an **IV** bag is replaced?	When an IV bag is replaced, score it as an invasive action (Moment 2), and subsequently as contact with the resident's surroundings (Moment 5). This applies **only to replacement** and not to insertion / removal. Then there is a chance of exposure to body fluids (Moment 3).	
Invasive actions	If **blood sugar** is tested, does this fall under invasive treatments?	Yes (Moment 2).	
Invasive actions	What should be scored if gunk (**rheum**) is also wiped from the resident's eyes while washing the resident's face?	This as equivalent to eye drops: this is therefore seen as an invasive action (Moment 2).	
Invasive actions	If something has been administered via a **feeding tube which was already present**, is this scored as a Moment 3?	No. Before administering something via a feeding tube it is a Moment 2. Since there is **no** possible contact with body fluids, at the end of the action score it as Moment 4 or 5, depending on whether there is physical contact with the resident.	
Invasive actions	When **catheter care** and **washing** are done simultaneously, what do I score?	Hand hygiene always needs to occur directly before an invasive action (Moment 2). You can continue care unless there has been clear contact with body fluids, in which case hand hygiene needs to be immediately done.	
Invasive actions	What do I score after a health care worker touches a **wound**?	If the wound is clearly closed, then there is no possible contact with body fluids (Moment 4). If the wound is clearly still open, score it as possible contact with body fluids (Moment 3).	If it is unclear whether the wound is open or closed, do not score anything. However, if the health care worker says something such as: the mouth has healed nicely, use that as a guide whether the wound is open or closed.

Category	Question	Answer	Extra explanation
Linnen/bedding	What do I score after **dirty laundry or bedding** is picked up?	Moment 3.	
Medication	Should hand hygiene occur in between touching the **medicine cabinet / medicine cart / mixing machine** and administration of **medicine**?	No, the medicine cabinet is part of the act of preparing or administering medicine.	
Medication	During the **medication round**, the health care workers were often disturbed by a telephone call or someone talking to him/her. The telephone or a person was touched. Should hand hygiene be done again before continuing with the medication round?	If care is disrupted, then the health care worker needs to do hand hygiene again (Moment 2/score separately for food and pills).	
Medication	Does hand hygiene have to be repeated after every time **medication** is given to a resident?	If the resident or resident's surroundings is touched or a resident is helped with taking medicine, hand hygiene must take place before continuing the medicine round. If medications are placed (on a table) for the resident to take without the health care worker touching anything, then hand hygiene is not necessary.	
Medication	If the **door handle of the medicine cabinet** is touched, must hand hygiene take place again before touching medication?	No. Touching the door handle of the medicine cabinet is part of the **entire act** of giving medicine (Moment 1). This is an exception to the rule, just like touching the refrigerator door when distributing food.	However, hand hygiene must take place after giving medicine (Moment 4 or Moment 5).
Mouth	What do I score after **dentures** are cleaned and placed in the mouth of the resident?	As **food and pills** (Moment 2/score separately for food and pills), and then as possible contact with body fluids (Moment 3).	
Mouth	What should be scored before and after **toothbrushing**?	As **food and pills** (Moment 2/score separately for food and pills) and then as possible contact with body fluids (Moment 3).	
Mouth	What should be scored if a cigarette is given / put in the mouth of the resident/ lit?	As **food and pills** (Moment 2/score separately for food and pills), and then as possible contact with body fluids (Moment 3).	

Category	Question	Answer	Extra explanation
Mouth	When a health care worker **wipes the nose/mouth** of a resident with a napkin, what should be scored?	There is possible contact with body fluids (saliva / mucous), so score it as Moment 3.	
Mouth	What should be scored when **lipstick** is applied on the resident?	As **food and pills** (Moment 2/score separately for food and pills), and then as possible contact with body fluids (Moment 3).	
Mouth	If dirty **cutlery** is put in the dishwasher by the health care worker, should it be scored?	Yes. However, the health care worker is allowed to clean up cutlery from several residents first, as 1 action. After that, hand hygiene must take place because of possible contact with body fluids (Moment 3).	
Own body fluids	If the health care worker sneezes into his / her elbow, should hand hygiene be applied?	Yes. This is possible contact with the health care worker's own body fluids (Moment 3).	
Own body fluids	If the observed health care worker also occasionally takes a bite of something while feeding a resident, is this a hand hygiene opportunity?	If the health care worker is eating something himself/herself, he/she must do hand hygiene before continuing to feed the resident.	
Own body fluids	If the health care worker has a bandage on his/her hand, does this change anything about the hand hygiene?	No. However, at the start of the day, the health care worker should apply a **water-repellent bandage**. This must be removed at the end of the shift. The hand hygiene remains the same!	
Pen and keys	What should I score when the health care worker uses **keys or pens**?	In general, ignore keys and pens. Exception 1: It is not allowed to use a key or pen after hand hygiene but before an invasive procedure (Moment 2). Exception 2: It is not allowed to use a key or pen immediately following contact with body fluids and before hand hygiene (Moment 3).	

Category	Question	Answer	Extra explanation
Resident's surroundings	What are the resident's surroundings?	The resident's surroundings is everything in the resident's room. If it concerns a couple in 1 room, then the entire room is seen as the resident's surroundings for both residents. If it concerns 2 people in 1 room who are not a couple, then each resident has his/her own resident surroundings. 'The resident's surroundings' is then that portion of the room which belongs to him/her. **The communal areas are not considered the resident's surroundings**. Exceptions: the floor, door to leave the room/apartment, and curtains are considered outside the resident's surroundings.	
Resident's surroundings	If activities happen with a resident and the resident's surroundings are touched, what do I score?	'After touching the resident' (Moment 4) always **precedes** 'after touching resident surroundings' (Moment 5). In this case, score Moment 4.	
Resident's surroundings	Should hand hygiene be done before an invasive procedure if the health care worker is already touching the resident's surroundings?	Yes. Hand hygiene should always be applied before an invasive procedure (Moment 2).	If the items touched are necessary for the invasive procedure, then no new hand hygiene is needed before the invasive action.
Resident's surroundings	If the health care worker alternates between the resident and resident's surroundings, must hand hygiene be applied between touching the resident and the resident's surroundings?	No, unless there has been possible contact with body fluids in between.	Of course, hand hygiene must be applied before the resident is touched for the first time (Moment 1 or 2).
Resident's surroundings	What do I score after a **garbage bag** is touched?	Consider this touching the **residents' surroundings** (Moment 5).	
Resident's surroundings	What do I score when attributes such as **razor, toothbrush, comb, etc.** are touched**?**	Score this as a resident's surroundings, provided the attributes are also located in the resident's surroundings (Moment 5).	

Category	Question	Answer	Extra explanation
Resident's surroundings	What should be scored when aids (wheelchair / walker / hoist) are touched?	If the aid is located in the resident's surroundings, score this as after touching the resident's surroundings (Moment 5). Do not score if these aids are touched outside the resident's surroundings.	
Resident's surroundings	If the health care worker touches the resident's surroundings, but **not a resident,** and then leaves the resident's surroundings, must hand hygiene take place?	Yes. If the resident's surroundings is touched, hand hygiene must then take place (Moment 5).	
Resident's surroundings	If the **bathroom is not in the residents' room** and the resident is escorted from his or her room to the bathroom with a walker, when should hand hygiene be done?	As long as the health care worker walks with the resident, he or she does not need to do hand hygiene. Hand hygiene should occur after the resident has been escorted to the other room/bathroom and before other care occurs (Moment 4).	
Shared rooms	What do I score when a **bedroom is shared**?	A resident's surroundings is the part of the room belonging to that resident, such as the bed, nightstand, and cabinet.	
Shared rooms	Should hand hygiene be applied between contact with different residents in a **shared bedroom**?	Yes. Hand hygiene must be applied every time another resident is helped.	If it concerns a couple in 1 bedroom, then the entire room is seen as one resident's surroundings for both residents. If it concerns two people in one bedroom who are not a couple, then each resident has his or her own resident's surroundings.
Shared rooms	Is a **curtain** considered the equivalent of a door when it is used as a divider in a shared room?	Yes. Hand hygiene should be done before touching the curtain and after touching the curtain.	
Social contacts	If a health care worker has **social contact** with one or more residents and then prepares medication, should hand hygiene be done?	Yes. Hand hygiene should always be done before preparing medication/a medicine round (Moment 2/score separately for food and pills).	

Category	Question	Answer	Extra explanation
Social contacts	For which **social contacts** is hand hygiene not necessary?	**In nursing homes**, hand hygiene is not necessary before a pat on the hand/back/knee, handshake, or a hug. This is different than in a hospital, where these exceptions do not apply.	
Social contacts	If the health care worker continues to prepare / distribute **food** after a social moment, is this a Moment?	Yes. The care is interrupted. Hand hygiene needs to be done again (Moment 2/score separately for food and pills).	
Telephone	If a health care worker answers a **telephone** while tidying up a room, did she/he miss a hand hygiene moment?	Yes (Moment 5).	
Telephone	If the **telephone** is answered during the resident's care, is this a separate action?	Yes. Hand hygiene needs to be done before picking up the phone (Moment 3 or 4). It then needs to be done again before returning to care for the resident (Moment 1 or 2).	
Telephone	If a **telephone is used as an instrument**, for example for measuring heart rate, what should be scored?	In this case, the phone is a material used to provide care. Do not score using the telephone as a disruption of the care.	
Telephone	If the **telephone** is only **touched with 1 finger** to look at or delete a message, do I have to score this every time?	Yes. The care was disrupted. Hand hygiene is necessary before touching the phone (Moment 3, 4, or 5) and before resuming care (Moment 1 or 2).	
Washing	When is there possible contact with body fluid (Moment 3) after **washing** a resident?	If the pubic area is washed, then it is a Moment 3. If the pubic area is not washed, then it is a Moment 4.	Sweat is not considered a body fluid unless it is excessive.
Washing	Should hand hygiene be done between **washing** and **changing a diaper**?	If the diaper was changed as the end, then the health care worker only needs to do hand hygiene once. If the diaper was changed before or while washing the resident, then hand hygiene needs to be done before continuing to wash the resident.	In practice, while washing the resident, some clothing is often put on to prevent the resident from getting (too) cold. Hand hygiene between washing and dressing is therefore not necessary. After washing (and dressing), hand hygiene should be done (score Moment 3 or 4).

Category	Question	Answer	Extra explanation
Washing	What should be scored if gunk (**rheum**) is wiped from the resident's eyes while washing the resident's face?	This is equivalent to eye drops: this is invasive action (Moment 2).	
Washing	When **catheter care** and **washing** the resident are done simultaneously, what do I score?	Hand hygiene always needs to occur directly before an invasive action (Moment 2). If there has been contact with body fluids, then hand hygiene needs to be done immediately (Moment 3).	
Washing	If the health care worker **washes** the resident, including the **pubic area**, and then takes clothing out of the cabinet, does hand hygiene need to be done in between?	In practice, while washing the resident, some clothing is often put on to prevent the resident from getting (too) cold. Hand hygiene between washing and changing/dressing is therefore not necessary. After washing (and dressing) hand hygiene is necessary (score Moment 4).	It is better if the clothing is taken out of the cabinet before washing the resident.
Washing hands	If there are no **paper** towels and the hands are dried on a regular **towel**, is hand washing still correct?	No. This is missed unless it is a fresh towel.	
Washing hands	If hands are washed **without soap**, is hand washing still correct?	No. This is missed.	
Washing hands	If the hand hygiene technique is incorrect, will this count as missed?	No.	
Washing hands	If **both soap and alcohol-based hand rub** are used, should both be checked?	Check both.	
Washing hands	If the health care worker washes his/her hands in the resident's bathroom, then opens the bathroom door and walks out of the resident's room, should hand hygiene take place again?	Yes. The door of the bathroom falls under the resident's surroundings. Hand hygiene needs to be done after touching the resident's surroundings (Moment 5).	
Wound care	How should **wound** care be done?	Hand hygiene (Moment 2) -> Prepare everything for wound care -> Put on gloves -> Remove old dressing and clean the wound-> Remove gloves -> Hand hygiene (Moment 3) -> Put on gloves -> Put on fresh dressing -> Remove gloves -> Hand hygiene (Moment 3)	

Category	Question	Answer	Extra explanation
Wound care	What do I score after a **wound** is touched?	If the wound is clearly closed, then there is no possible contact with body fluids (Moment 4). If the wound is clearly still open, score Moment 3.	If it is unclear whether the wound is open or closed, do not score anything. However, if the health care worker says something such as: the mouth has healed nicely, use that as a guide whether the wound is open or closed.
Wound care	What should be scored if **during changing / going to the toilet** a **wound** is detected and cleaned?	Cleaning a wound is a clean operation. Before it is cleaned, hand hygiene must first take place (Moment 2). Hand hygiene should take place again after cleaning the wound (Moment 3).	

Reference:

1. World Health Organization. WHO Guidelines on Hand Hygiene in Health Care. World Health Organization; 2009.

Summary

Nursing home residents, like patients in hospitals, are at an increased risk of developing healthcare-associated infections. To avoid transmission of microorganisms, and likewise decrease morbidity and mortality, the World Health Organization (WHO) recommends following their hand hygiene guidelines. This dissertation reports the findings of the HANDSOME study, a randomized controlled trial in 60 nursing homes (120 nursing home units), with the primary aim to establish the effect of a hand hygiene intervention in nursing homes. Our primary outcome was hand hygiene compliance of the nurses to the standards of the WHO. The goal of hand hygiene is to decrease illness. Therefore, the secondary outcome of this study was healthcare-associated infections in nursing homes. This dissertation also analyses the use of gloves in nursing homes and alternatives for commercially manufactured face masks, which was instigated by the Covid-19 pandemic.

The key research questions are:

(1) How was the tailored hand hygiene intervention received?
(2) Which hand hygiene opportunities should be registered when observing hand hygiene in a nursing home?
(3) Is a tailored hand hygiene intervention for nursing homes successful in increasing hand hygiene compliance?
(4) Does a tailored hand hygiene intervention result in decreased healthcare-associated illness in nursing homes?
(5) Is there an adequate alternative to commercially manufactured face masks?

The introduction, **chapter 1**, provides a general overview of personal protective measures in health care. The principle of hand washing has been around for centuries, but was only considered a health care intervention since 1847. Hand hygiene rules were first codified in 1981. Hand hygiene is important to prevent infective disease transmission. Hand hygiene should be performed in health care settings at the 5 hand hygiene moments prescribed by the World Health Organizaion (WHO). In order to succesfully promote hand hygiene, the literature shows that multiple strategies should be used (i.e. a multimodal intervention) to address multiple determinants of hand hygiene compliance. Some common strategies are teaching, environmental changes and changing work processes. For better insight into hand hygiene compliance, organizations primarily use direct or indirect observation. Nursing homes are a home-like setting for medically fragile residents who receive care. Nursing homes also vary from hospitals insofar as the main caregivers are nurses and nurse's aides. Interventions for the nursing home setting should take these and other factors into account when developing interventions to increase hand hygiene compliance.

Chapter 2 introduces our multimodal intervention to increase hand hygiene compliance of nurses in nursing homes, our methodology to evaluate it, and our study design, namely a cluster randomized controlled trial (HANDSOME). The HANDSOME intervention included activities for changing nursing home policy and individual behavior. Nursing home policy changes were achieved through (1) an audit with explanations about hand hygiene materials; and (2) audit of personal hygiene policy. Nurses and other health care workers were subject to 3 different live on-site hand hygiene lessons, access to an e-learning, posters for the nursing home wards, and the opportunity to participate in a hand hygiene-photo competition. Hand hygiene moments were taught using the slogan: ***Room In, Room Out, Before Clean, After Dirty***, which was developed for (lower-educated) nursing staff to better understand and remember hygiene guidelines. The primary outcome was hand hygiene compliance of the nurses to the standards of the WHO, namely before touching a patient, before a clean/aseptic procedure, after body fluid exposure risk, after touching a patient, and after touching patient surroundings. Nursing homes were randomized into one of three study arms: receiving the intervention at a predetermined date, receiving the identical intervention after an infectious disease outbreak (conditional intervention arm), or the control arm. Hand hygiene was evaluated in nursing homes by direct, unobtrusive observation at baseline (October 2016) and 4, 7 and 12 months after baseline. The secondary outcome was infectious disease incidence among residents. Associations were studied between infectious disease reports and the presence of norovirus, rhinovirus and *Escherichia coli* on surfaces in the nursing homes, which was measured using real-time quantitative polymerase chain reaction (RT PCR).

Chapter 3 describes the successful results of our primary outcome: increased hand hygiene compliance of nurses in nursing homes. Eighteen organizations participated in the study, resulting in 33 nursing homes (n=66 nursing home units) for this study. The conditional intervention arm was not included in this chapter, since this was prematurely discontinued. Hand hygiene compliance increased in the intervention and control arms. The increase after 12 months was significantly larger for units in the intervention arm (12% to 36%) than for control units (13% to 21%). The intervention arm had a statistically significant increase in hand hygiene compliance at 4 of the 5 WHO-defined hand hygiene moments. At follow-up, hand hygiene compliance in the intervention arm remained statistically significantly higher for indications after an activity (37% to 39%) than for indications before an activity (14% to 27%).

Although gloves are often used when hand hygiene is necessary, they cannot be considered an alternative to hand hygiene since (1) dirty hands contaminate gloves and (2) hands often

get contaminated during glove removal. **Chapter 4** investigates whether our intervention decreased the substitution of hand hygiene by glove use, since this was addressed during the hand hygiene lessons. We analysed compliance with WHO-defined hand hygiene opportunities, assessing: 1) hand hygiene without donning/doffing gloves; 2) hand hygiene combined with donning/doffing gloves; 3) no hand hygiene, but gloves were donned/doffed (substitution); 4) no hand hygiene and gloves were inappropriately not changed; 5) no hand hygiene and no gloves.
We assessed baseline and follow-up results overall (n=4666 hand hygiene opportunities), per nurse (n=345), and per nursing home unit (n=36) in the intervention arm of the study. The HANDSOME intervention was unsuccessful in reducing substitution of hand hygiene by glove use. There was a reduction in nurses not removing their gloves after exposure to body fluids (from 26% to 9%) and an increase in the use of gloves with hand hygiene (3% to 9%).

Chapter 5 investigates our secondary outcome: whether our hand hygiene intervention resulted in lower infection rates when compared to the control arm. Five illnesses were investigated: gastroenteritis, influenza, pneumonia, UTI and MRSA. The incidence of these infections was recorded weekly. We compared our results to the Dutch surveillance network for infectious diseases in nursing homes (SNIV). Infection incidence rates were compared in a Poisson multilevel analysis, correcting for baseline differences, clustering of observations within nursing homes, and period in the study. As in comparable studies, we could not conclusively demonstrate the effectiveness of a HH intervention in reducing health care-associated infections among residents of nursing homes, despite the use of clearly defined outcome measures, a standardized reporting instrument, and directly observed HH in a multicenter cluster randomized controlled trial. The HANDSOME intervention did not result in reduced illness incidence. Illness incidence in the HANDSOME study showed the same trends as the national surveillance network, although the nursing home units in our study generally reported higher incidences.

Our next step was to establish whether environmental surface sampling can be used as a surrogate indicator for hand hygiene compliance and/or illness monitoring in nursing homes. **Chapter 6** presents the results from environmental surface samples on three surfaces: a shared living room table, a toilet which was shared by residents, and a computer keyboard and mouse used by nurses. We compared the samples to the aforementioned hand hygiene compliance data and illness registration. RT PCR techniques were used for the detection of norovirus genogroup I and II, rhinovirus and *Escherichia coli*. We found positive samples for *Escherichia coli* (43%), rhinovirus (29%), and norovirus (15%). There were no statistically significant associations between the microorganisms and hand hygiene

compliance. There was also no evident association between any registered illness and the detection of surface microorganisms. Thus, environmental surface sampling cannot be used as an indicator of hand hygiene compliance or illness in residents. However, our study does provide insight into surface contamination in nursing homes.

Lastly, **chapter 7** studies whether there is an effective mask for the population to wear in public that could be made using readily available materials. We compared the effectiveness of masks made from readily available materials to N95/FFP2/KN95 masks that entered the Netherlands in April-May 2020. Masks were tested to see if they filtered different sized particles, were hydrophobic, sealed on the face, were breathable, and could be washed. We concluded that it would be possible to reduce the reproduction rate of SARS CoV-2 from 2.4 to below one if 39% of the population would wear a mask made from ePM_1 85% commercially manufactured filter fabric and in a duckbill form. This mask performs better than 80% of the imported N95/FFP2/KN95 masks and provides a better fit than a surgical mask. Two layers of quilt fabric with a household paper towel as filter is also a viable choice for protecting the user and the general public.

In **chapter 8**, we answer the research questions, discuss the results of the study, and present results which further clarify the findings. This chapter ends with recommendations for teaching hand hygiene, system changes that promote hand hygiene, observing hand hygiene, and new hand hygiene studies.

The answers to the research questions can be summarized as follows:

(1) How was the tailored hand hygiene intervention received?

The HANDSOME intervention was broadly accepted and appreciated. We can base this on a number of outcomes: (1) reactions from nursing home staff in our survey to questions about the lessons and the e-learning; (2) national organizations have incorporated aspects of the intervention into protocols and promoted it; (3) the instructions on how to perform the intervention have been extensively downloaded; and (4) the e-learning has been widely used.

(2) Which hand hygiene opportunities should be registered when observing hand hygiene in a nursing home?

We made inventory of 103 moments for which it is unclear whether nurses in nursing homes need to perform hand hygiene, and how they were to be registered. The size of

the inventory demonstrates that the WHO definitions are difficult to interpret in many situations. We determined whether hand hygiene should be done at these moments, using expert opinion. In the future, it would be wise to allow a larger group of experts to determine if hand hygiene should be done at these unclear moments, using, for example, the Delphi-method to create consensus.

(3) Is a tailored hand hygiene intervention for nursing homes successful in increasing hand hygiene compliance?

The intervention in the HANDSOME study was successful in increasing hand hygiene in the intervention arm of the study when compared to the control arm. It was equally successful in the conditional intervention arm and in a Train the Trainer model. We would expect a higher hand hygiene compliance if more barriers were addressed, such as creating a workflow which minimizes hand hygiene opportunities, providing the necessary materials for hand hygiene at the necessary places, and having a consistent workforce. Hand hygiene compliance would assumedly also increase if nurses received immediate feedback about their hand hygiene so that their perception of their compliance and their actual compliance converge. Knowing their actual compliance may help in motivating them to pay more attention to hand hygiene.

(4) Does a tailored hand hygiene intervention result in decreased healthcare-associated illness in nursing homes?

The intervention did not result in a reduction of illness incidence in nursing homes. In order to understand the differences between hospitals and nursing homes in the effect of hand hygiene compliance on healthcare associated infections, it would be prudent to examine the differences in transmission pathways and other infection control measures between hospitals and nursing homes. It may be necessary to have a higher hand hygiene compliance rate in order for hand hygiene compliance to have an impact on illness rates.

(5) Is there an adequate alternative to commercially manufactured face masks?

There are adequate alternatives to commercially manufactured face masks. While the best outcome was with ePM_1 85% commercially manufactured filter fabric in a duckbill form, two layers of quilt fabric with a single household paper towel as filter was also a viable choice for protecting the user and the public.

Samenvatting
(Dutch summary)

Bewoners van verpleeghuizen hebben, net als patiënten in ziekenhuizen, een verhoogd risico op het ontwikkelen van zorggerelateerde infecties. Om de overdracht van micro-organismen te voorkomen en eveneens de morbiditeit en mortaliteit te verminderen, raadt de Wereldgezondheidsorganisatie (WHO) aan om hun richtlijnen voor handhygiëne te volgen. Dit proefschrift rapporteert de bevindingen van de HANDSOME-studie, een gerandomiseerd gecontroleerd onderzoek in 60 verpleeghuizen (120 verpleeghuis-units). De studie had als primair doel het effect te meten van een handhygiëne-interventie in verpleeghuizen. De primaire uitkomstmaat was de naleving (compliance) van de handhygiënerichtlijnen van de WHO door verpleegkundigen en verzorgenden. Het doel van handhygiëne is om ziekte te verminderen. Daarom was de secundaire uitkomstmaat van deze studie zorggerelateerde infecties in verpleeghuizen. Dit proefschrift analyseert ook het gebruik van handschoenen in verpleeghuizen en – geïnspireerd door de COVID-19-pandemie - alternatieven voor commercieel gereproduceerde gezichtsmaskers.

De onderzoeksvragen zijn:

(1) Hoe werd de op maatgemaakte handhygiëneinterventie ontvangen?
(2) Welke handhygiënesituaties moeten worden geregistreerd bij het observeren van handhygiëne in een verpleeghuis?
(3) Is een op maatgemaakte handhygiëneinterventie voor verpleeghuizen succesvol in het verbeteren van de handhygiënecompliance?
(4) Leidt een op maatgemaakte handhygiëneinterventie in verpleeghuizen tot een afname van zorggerelateerde infecties?
(5) Is er een geschikt alternatief voor commercieel gereproduceerde medische gezichtsmaskers?

De inleiding, **hoofdstuk 1**, geeft een algemeen overzicht van persoonlijke beschermingsmiddelen in de zorg. Het principe van handenwassen bestaat al eeuwen, maar werd pas sinds 1847 beschouwd als een interventie in de gezondheidszorg. De regels voor handhygiëne werden voor het eerst gecodificeerd in 1981. Handhygiëne is belangrijk om overdracht van infectieziekten te voorkomen. Handhygiëne moet worden uitgevoerd in zorginstellingen op de 5 handhygiënemomenten die zijn voorgeschreven door de WHO. Om handhygiëne met succes te promoten, moeten volgens de literatuur meerdere strategieën worden gebruikt (d.w.z. een multimodale interventie) om zo meerdere determinanten aan te pakken. Enkele veel voorkomende strategieën zijn lessen, veranderingen in de omgeving en veranderende werkprocessen. Organisaties gebruiken

voornamelijk directe of indirecte observatiemethodes om een beter inzicht te krijgen in handhygiënecompliance. Anders dan ziekenhuizen bieden verpleeghuizen een huiselijke omgeving voor medisch kwetsbare bewoners die zorg ontvangen. Verpleeghuizen verschillen ook van ziekenhuizen qua personeel: de zorgverleners zijn voornamelijk verpleegkundigen, verzorgenden en helpenden. Interventies voor verpleeghuizen moeten met deze en andere factoren rekening houden bij het ontwikkelen van interventies om de handhygiënecompliance te verbeteren.

Hoofdstuk 2 beschrijft onze multimodale interventie om de handhygiënecompliance van verpleegkundigen in verpleeghuizen te verbeteren, onze methodologie om deze te evalueren en onze onderzoeksopzet, namelijk een cluster gerandomiseerd gecontroleerd onderzoek (HANDSOME). De HANDSOME-interventie omvatte activiteiten om het verpleeghuisbeleid en individueel gedrag te veranderen. Veranderingen in het verpleeghuisbeleid werden bereikt door (1) een audit met uitleg over handhygiënematerialen; en (2) een audit van het beleid ten aanzien van persoonlijke hygiëne. Verpleegkundigen, verzorgenden en overig zorgpersoneel kregen 3 verschillende live lessen over handhygiëne, toegang tot een e-learning, posters voor de verpleeghuisafdelingen en de mogelijkheid om deel te nemen aan een handhygiëne-fotowedstrijd. Handhygiënemomenten werden aangeleerd met de slogan: ***Kamer In, Kamer Uit, Voor Schoon, Na Vies***, ontwikkeld voor (lager opgeleid) personeel, om zo de hygiënerichtlijnen beter te begrijpen en te onthouden. De primaire uitkomstmaat van de studie was de compliance van verpleegkundigen en verzorgenden op de door de WHO vastgestelde handhygiënemomenten, namelijk vóór het contact met de cliënt, voor schone/steriele handelingen, na contact met lichaamsvloeistoffen, na contact met de cliënt en na aanraken van de omgeving van de cliënt. Verpleeghuizen werden gerandomiseerd in een van de drie studie-armen: de klassieke interventiearm, die de interventie ontving op een vooraf bepaalde datum; de voorwaardelijke interventiearm, die de identieke interventie ontving na een uitbraak van een infectieziekte; of de controlearm, die geen interventie ontving. Handhygiëne werd gemeten in verpleeghuizen door directe, onopvallende observatie bij de nulmeting (oktober 2016) en 4, 7 en 12 maanden na de nulmeting. De secundaire uitkomstmaat was de incidentie van infectieziekten onder bewoners. De associatie werd onderzocht tussen de geregistreerde infectieziekten en de aanwezigheid van norovirus, rhinovirus en *Escherichia coli* op oppervlakken in verpleeghuizen, welk werd vastgesteld met behulp van real-time kwantitatieve polymerasekettingreactie (RT PCR).

Hoofdstuk 3 beschrijft de succesvolle resultaten van onze primaire uitkomstmaat: de verhoogde handhygiënecompliance door verpleegkundigen en verzorgenden in verpleeghuizen. Achttien organisaties namen deel aan het onderzoek, wat resulteerde in 33 verpleeghuizen (n=66 verpleeghuisunits) voor dit onderzoek. De voorwaardelijke interventiearm is in dit hoofdstuk niet meegenomen, aangezien deze voortijdig is stopgezet. De handhygiënecompliance nam toe in de interventiearm en controlearm. De toename na 12 maanden was significant hoger in de interventiearm (van 12% naar 36%) dan in de controlearm (van 13% naar 21%). De interventiearm had een statistisch significante toename in handhygiënecompliance op 4 van de 5 WHO-gedefinieerde handhygiënemomenten. Bij de follow-up bleef de handhygiëne in de interventiearm statistisch significant hoger voor indicaties na een activiteit (37% tot 39% compliance) dan voor indicaties voor een activiteit (14% tot 27% compliance).

Hoewel handschoenen vaak worden gebruikt wanneer handhygiëne noodzakelijk is, kunnen ze niet worden beschouwd als een alternatief voor handhygiëne, aangezien (1) vuile handen handschoenen besmetten en (2) handen vaak besmet raken tijdens het verwijderen van handschoenen. **hoofdstuk 4** onderzoekt of onze interventie de substitutie van handhygiëne door handschoengebruik heeft verminderd, aangezien dit behandeld werd tijdens de lessen over handhygiëne. We analyseerden de compliance met de WHO-gedefinieerde handhygiënemomenten en keken naar: 1) handhygiëne zonder handschoenen aan/uit te doen; 2) handhygiëne gecombineerd met het aan- en uittrekken van handschoenen; 3) geen handhygiëne, maar handschoenen werden aangetrokken/uitgetrokken (substitutie); 4) geen handhygiëne en handschoenen waren onterecht niet verwisseld; 5) geen handhygiëne en geen handschoenen.
We analyseerden de baseline- en follow-upresultaten in het algemeen (n=4666 handhygiënemomenten), per zorgmedewerker (n=345) en per verpleeghuisafdeling (n=36) in de interventiearm van het onderzoek. De HANDSOME-interventie was niet succesvol in het verminderen van de substitutie van handhygiëne door handschoenen. Er was een afname van verpleegkundigen/verzorgenden die hun handschoenen niet uitdeden na blootstelling aan lichaamsvloeistoffen (van 26% naar 9%) en een toename van het gebruik van handschoenen met handhygiëne (van 3% naar 9%).

Hoofdstuk 5 onderzoekt onze secundaire uitkomstmaat: of de handhygiëne-interventie resulteerde in minder infecties in vergelijking met de controlearm. Er werden vijf ziekten onderzocht: gastro-enteritis, influenza, longontsteking, urineweginfectie en MRSA. De incidentie van deze infecties werd wekelijks geregistreerd. We hebben de resultaten vergeleken met gegevens van het Nederlandse surveillancenetwerk voor infectieziekten

in verpleeghuizen (SNIV). Infectie-incidentiecijfers werden vergeleken in een Poisson-multilevel-analyse, waarbij werd gecorrigeerd voor verschillen in baseline, clustering van observaties binnen verpleeghuizen en de periode in het onderzoek. Net als in vergelijkbare onderzoeken konden we de effectiviteit van een HH-interventie bij het verminderen van zorggerelateerde infecties bij bewoners van verpleeghuizen niet overtuigend aantonen, ondanks het gebruik van duidelijk gedefinieerde uitkomstmaten, een gestandaardiseerd rapportage-instrument en direct geobserveerde HH in een multicenter cluster gerandomiseerd gecontroleerd onderzoek. De HANDSOME-interventie resulteerde niet in een verminderde ziekte-incidentie. De incidentie van ziekten in de HANDSOME-studie vertoonde dezelfde trends als het landelijke surveillancenetwerk, hoewel de verpleeghuisafdelingen in onze studie over het algemeen hogere incidentie rapporteerden.

Onze volgende stap was om vast te stellen of bemonstering van oppervlakken kan worden gebruikt als een surrogaatindicator voor handhygiënecompliance en/of ziektemonitoring in verpleeghuizen. **Hoofdstuk 6** presenteert de resultaten van omgevingsbemonstering van drie oppervlakken: een gemeenschappelijke eettafel, een toilet dat door bewoners werd gedeeld en een computertoetsenbord en muis die door zorgmedewerkers werden gebruikt. We hebben de monsters vergeleken met de eerdergenoemde gegevens over handhygiëne en met de ziekteregistratie. RT PCR-technieken werden gebruikt voor de detectie van norovirus genogroep I en II, rhinovirus en *Escherichia coli*. We vonden positieve monsters voor *Escherichia coli* (43%), rhinovirus (29%) en norovirus (15%). Er waren geen statistisch significante associaties tussen de micro-organismen en handhygiënecompliance. Er was ook geen duidelijk verband tussen de geregistreerde ziekte en de detectie van micro-organismen op oppervlakken. Bemonstering van oppervlakken in de omgeving kan dus niet worden gebruikt als een indicator van handhygiënecompliance of ziekte bij bewoners. Ons onderzoek geeft echter wel inzicht in oppervlakcontaminatie in verpleeghuizen.

Ten slotte onderzoeken we in **hoofdstuk 7** of er een effectief masker is dat de bevolking in het openbaar kan dragen en dat gemaakt kan worden met gemakkelijk verkrijgbare materialen. We vergeleken de effectiviteit van maskers gemaakt van gemakkelijk verkrijgbare materialen met N95/FFP2/KN95-maskers die in april-mei 2020 Nederland binnenkwamen. Maskers werden getest op filterkwaliteit, of ze waterafstotend waren, of ze goed aansloten op het gezicht, of ze voldoende ademend waren en of ze konden worden gewassen. We concludeerden dat het mogelijk zou zijn om het reproductiegetal van SARS CoV-2 te verminderen van 2,4 naar minder dan 1 als 39% van de bevolking een masker zou

dragen dat is gemaakt van ePM$_1$ 85% commercieel vervaardigd filterdoek en in de vorm van een eendenbek. Dit masker presteert beter dan 80% van de geïmporteerde N95/FFP2/KN95-maskers en zorgt voor een betere pasvorm dan een chirurgisch masker. Twee lagen quiltstof (van katoen) met een vel keukenrol als filter is ook een goede keuze om de gebruiker en het publiek te beschermen.

In **hoofdstuk 8** beantwoorden we de onderzoeksvragen, bediscussiëren we de resultaten van het onderzoek en presenteren we resultaten die de bevindingen verder verduidelijken. Dit hoofdstuk eindigt met aanbevelingen voor het onderwijzen van handhygiëne, voor veranderingen in beleid en de omgeving om handhygiëne te bevorderen, voor het observeren van handhygiëne en voor nieuwe onderzoek naar handhygiëne.

De antwoorden op de onderzoeksvragen kunnen als volgt worden samengevat:

(1) Hoe werd de op maatgemaakte handhygiëneinterventie ontvangen?

De HANDSOME-interventie werd breed geaccepteerd en gewaardeerd. Dit kunnen we baseren op een aantal uitkomsten: (1) reacties van verpleeghuispersoneel in een enquête op vragen over de lessen en de e-learning; (2) nationale organisaties hebben (delen van) de interventie in protocollen opgenomen en gepromoot; (3) de handleidingen voor het uitvoeren van de interventie zijn vaak gedownload; en (4) de e-learning is op grote schaal gebruikt.

(2) Welke handhygiënesituaties moeten worden geregistreerd bij het observeren van handhygiëne in een verpleeghuis?

(3) We hebben een inventarisatie gemaakt van 103 situaties waarvoor het onduidelijk was of verpleegkundigen/verzorgenden in verpleeghuizen handhygiëne moesten doen en hoe ze geregistreerd moesten worden. De omvang van de inventarisatie toont aan dat de WHO-definities in veel situaties moeilijk te interpreteren zijn. Met behulp van advies van deskundigen hebben we bepaald of handhygiëne op deze situaties gedaan moest worden. In de toekomst zou het verstandig zijn om een grotere groep experts te laten bepalen of handhygiëne op deze onduidelijke situaties gedaan moet worden, bijvoorbeeld met de Delphi-methode om consensus te creëren.

(4) Is een op maatgemaakte handhygiëneinterventie voor verpleeghuizen succesvol in het verbeteren van de handhygiënecompliance?

(5) De interventie in de HANDSOME-studie was succesvol in het verbeteren van de handhygiëne in de interventiearm van de studie, in vergelijking met de controlearm. Het was even succesvol in de voorwaardelijke interventiearm en in een Train de Trainer-model. We zouden een hogere handhygiënecompliance verwachten als er meer belemmeringen zouden worden aangepakt, zoals het creëren van een werkvolgorde die de handhygiënemomenten minimaliseert, het plaatsen van de handhygiënematerialen op handige plaatsen en het hebben van continuïteit in personeel. Handhygiënecompliance zou vermoedelijk ook toenemen als verpleegkundigen onmiddellijk feedback zouden krijgen over hun handhygiëne, zodat hun perceptie van hun compliance en hun feitelijke compliance meer in overeenstemming zijn. Het kennen van hun daadwerkelijke compliance kan hen mogelijk motiveren om meer aandacht te besteden aan handhygiëne.

(6) Leidt een op maatgemaakte handhygiëne-interventie in verpleeghuizen tot een afname van zorggerelateerde infecties?

(7) De interventie heeft niet geleid tot een afname van ziekteincidentie in verpleeghuizen. Om de verschillen te begrijpen tussen ziekenhuizen en verpleeghuizen in het effect van handhygiënecompliance op ziekteincidentie, zou het verstandig zijn om de verschillen in transmissieroutes en infectiepreventiemaatregelen tussen ziekenhuizen en verpleeghuizen te onderzoeken. Een hogere handhygiënecompliance is misschien nodig om een effect te zien op ziekteincidentie.

(8) Is er een geschikt alternatief voor commercieel gereproduceerde medische gezichtsmaskers?

(9) Er zijn geschikte alternatieven voor commercieel gereproduceerde gezichtsmaskers. Hoewel het beste resultaat was met ePM$_1$ 85% commercieel vervaardigde filterstof in de vorm van een eendenbek, is twee lagen quiltstof met een enkel vel keukenrol als filter ook een goede keus om de gebruiker en het publiek te beschermen.

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Officemates can be wonderful when writing a thesis. You support one another, laugh together and generally go through life together. It was lovely sharing a room with Denise Twisk, Maaike Honsbeek, Nikki Elzehery-Francis, Emina Omerigić, Rianne Vriend, Corine Swaan, Naomi van der Linde, and Dominique Lescure. An extra thanks to Denise for supporting me as paranymph and for pushing us to do desk chair yoga. A very special

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Manuela, Johanneke, Lisa – three friends that have always been there for me, even when we've been oceans apart. Manuela – an extra thanks for being my paranymph during my defence. We've studied together, worked together, and crossed paths so many times in so many ways, I couldn't picture having this day without you there. Johanneke –you have kept me sane through these crazy times with our conversations, long walks and of course, recaps of Grey's. Lisa – Thanks for inspiring me to write. Looking forward to our next trips together!

Gloria, Cindy, Zarah – you have been wonderful in picking up the slack at home when I wasn't around and listening to me kvetch when I was exhausted. I'm honoured to call you my family. I would like to thank my parents as well, who taught me the importance of education and hard work. Jos – what can I say, especially without the use of emojis. You've been more than a wonderful, caring, involved partner. Always there to cheer me on and cheer me up. You're my sunshine!

Curriculum Vitae

C

Gwen Teesing was born in Queens, New York. She obtained her bachelor's degree in Music at Binghamton University (United States, 1993) and her master's degree in Musicology at the University of Utrecht (The Netherlands, 2004). This was followed by a career organizing chamber music concerts, primarily at the Concertgebouw (Amsterdam), but also at other locations in the Netherlands and the United States.

After achieving her dream of organizing world-class chamber music concerts, Ms. Teesing decided to try a new challenge. This resulted in a master's in Health Economics, Policy, and Law at Erasmus University (Erasmus School of Health Policy & Management, 2015) and a master's in Health Sciences, specialization Epidemiology, at Erasmus University (Netherlands Institute for Health Sciences, 2020). While Ms. Teesing found her work interesting as a cultural economist and as a project manager combining arts and health care research, she has thoroughly enjoyed focusing on her Ph.D. research about hand hygiene in nursing homes, which she started in 2016 jointly at the Municipal Public Health Service (GGD) in Rotterdam and the Department of Public Health of Erasmus MC. This served to increase her passion for and knowledge about the fields of infection prevention and elderly care. She recently worked at the GGD Rotterdam-Rijnmond researching large-scale SARS CoV-2 testing. Teesing is presently working as a senior program manager at The Netherlands Organisation for Health Research and Development (ZonMw) and as a policy advisor and researcher at Kennemerhart.

Ph.D. portfolio

P

Sum of registered credits (EC): 37.20

Year	Name	EC
Courses	**MSc, Netherlands Institute of Health Sciences (NIHES)**	**31.50**
2016	Principles of Research in Medicine and Epidemiology (ESP01)	0.70
2016	Introduction to Global Public Health (ESP41)	0.70
2016	Methods of Public Health Research (ESP11)	0.70
2016	Primary and Secondary Prevention Research (ESP45)	0.70
2017	Logistic Regression (ESP66)	1.40
2017	Fundamentals of Medical Decision Making (ESP70)	0.70
2017	Joint Models for Longitudinal and Survival Data (ESP72)	0.70
2017	Social Epidemiology (ESP61)	0.70
2017	The Practice of Epidemiologic Analysis (ESP65)	0.70
2018	Causal Inference (ESP48)	1.40
2018	Case-control Studies (ESP40)	0.70
2018	Methods of Health Services Research (ESP42)	0.70
2018	Causal Mediation Analysis (ESP69)	1.40
2018	Biostatistical Methods I: Basic Principles (CC02)	5.70
2018	Public Health Research: Analysis of Population Health (HS02a)	1.90
2018	Public Health Research: Analysis of Determinants (HS02b)	1.90
2018	Public Health Research: Intervention Development and Evaluation (HS02c)	1.90
2019	Quality of Life Measurement (HS11)	0.90
2019	Planning and Evaluation of Screening (HS05)	1.40
2019	Epidemiology of Infectious Diseases ((CE05)	1.40
2019	From Problem to Solution in Public Health (HS18)	0.90
2019	Study Design (CC01)	4.30
Other course		
2017	Research integrity (Erasmus MC)	0.30
Conferences and Seminars		
2016-2021	Infectious Diseases Section – Research meetings	2.40
2017	Netwerken in ABR-surveillance	0.20
2017	International Conference on Prevention and Infection Control	1.00
2018	Antibioticaresistentie in de ouderenzorg	0.20
2018, 2020	RODIN seminars	0.40
2019	ABR Kennis- en Netwerkdag	0.20

2019	Thuis in het Verpleeghuis	0.20
2019	CEPHIR seminars	0.20
2020	Congres thuiswonende ouderen	0.20
2020	VSO-congres: Meer doen met Kennis	0.20

Publications

Publications in peer-reviewed journals

Teesing GR, Erasmus V, Petrignani M, Koopmans MPG, de Graaf M, Vos MC, *et al*. Improving Hand Hygiene Compliance in Nursing Homes: Protocol for a Cluster Randomized Controlled Trial (HANDSOME Study). JMIR Research Protocols 2020; 9(5):e17419. (https://www.researchprotocols.org/2020/5/e17419/)

Teesing GR, Erasmus V, Nieboer D, Petrignani M, Koopmans MPG, Vos MC, *et al*. Increased hand hygiene compliance in nursing homes after a multimodal intervention: A cluster randomized controlled trial (HANDSOME). Infection Control & Hospital Epidemiology. 2020;41(10):1169-77. (https://doi.org/10.1017/ice.2020.319)

Teesing GR, van Straten B, de Man P, Horeman-Franse T. Is there an adequate alternative to commercially manufactured face masks? A comparison of various materials and forms. Journal of Hospital Infection 2020; 106(2):246-253. (https://doi.org/10.1016/j.jhin.2020.07.024)

Teesing GR, Richardus JH, Erasmus V, Petrignani M, Koopmans MPG, Vos MC, *et al*. Hand hygiene and glove use in nursing homes before and after an intervention. Infection Control & Hospital Epidemiology 2021; 1-3. (https://doi.org/10.1017/ice.2020/1415)

Teesing GR, de Graaf M, Petrignani M, Erasmus V, Klaassen CHW, Schapendonk CME, *et al*. The association of environmental surface contamination with hand hygiene and infections in nursing homes: a prospective cohort study. Infection Prevention in Practice 2021; 3(2):100129. (https://doi.org/10.1016/j.infpip.2021.100129)

Teesing GR, Richardus JH, Nieboer D, Petrignani M, Erasmus V, Verduijn-Leenman A, *et al*. The effect of a hand hygiene intervention on infections in residents of nursing homes: a cluster randomized controlled trial. Antimicrobial Resistance & Infection Control. 10(80) (2021). (https://doi.org/10.1186/s13756-021-00946-3)

Other publications

Teesing G. HANDSOME: Handhygiëne in verpleeghuizen, handbook. [*Hand hygiene in nursing homes*] (https://www.zorgvoorbeter.nl/zorgvoorbeter/media/documents/thema/hygiene/handsome-handleiding-handhygiene-verpleeghuizen.pdf)

Handhygiëne in verpleeghuizen, e-learning [*Hand hygiene in nursing homes*] (https://www.free-learning.nl/modules/handhygiene/start.html)

Presentations

Cliniclowns (2020)
Department of Public Health, Erasmus MC (2018, 2019, 2020)
GGD Rotterdam-Rijnmond [*The Municipal Public Health Service Rotterdam-Rijnmond*] (2017, 2018)
GGD Rotterdam-Rijnmond (visiting students from Erasmus MC) (2018)
Hogeschool Rotterdam (Guest lecturer for nursing students) (2020)
Inspectie voor gezondheidszorg en Jeugd [*Health and youth care inspectorate*] (2018)
Landelijk Centrum Hygiëne en Veiligheid [*National center for hygiene and safety*] (2016)
Onderzoek & Business Intelligence [*Research and business intelligence*] (2018)
Rijksinstituut voor Volksgezondheid en Milieu [*National institute for public health and the environment*] (2018, 2020)
Verenso [*Dutch Association of Elderly Care Physicians*] (2018, 2020)
Vereniging voor Hygiëne & Infectiepreventie in de Gezondheidszorg [*Society for hygiene and infection prevention in health care*] (2018)
Vilans [Centre of Expertise for Long-term care in the Netherlands] (2018)
Werkgroep Infectiepreventie [*Workgroup infection prevention*] (2016)

Workshops

'Train de trainers: HANDSOME-training om handhygiëne in jouw verpleeghuis te verbeteren', [*Train the trainers: HANDSOME training to learn how to better hand hygiene in your nursing home*] 12 6-hour sessions, 2018-2019.
'Van Slecht naar Beter: Handhygiëne in Verpleeghuizen' [*From bad to better: Hand hygiene in nursing homes*], Aanpak Antiobiotica Resistentie in de Ouderenzorg, 2018.
HANDSOME lessons, ca. 25 days with multiple sessions of lessons from 25-60 minutes, 2016-2017.

'Naleving handhygiëne: Van slecht naar beter' [*Hand hygiene compliance: from bad to better*], ABR Zorgnetwerk Zuidwest Nederland, 2019.

Supervision

Seven medical students, Erasmus MC (2016-2021)
Eight nursing students, Hogeschool Leiden and Hogeschool Rotterdam (2016-2018)
Twenty-eight research assistants (2016-2018)

Media

Radio: BNR (2020), Radio Rijnmond (2020)
Television: RTL4 (2020)
Print (general public): Het Parool (2020), Algemeen Dagblad (2020), Libelle (2020)
Print (specific for health care): Zorg voor beter (2019), Actiz (2019), Tijdschrijft voor verzorgenden (2020)