

Impact of a bundle of hand hygiene-related interventions in nursing homes on the infectious risk.

Submission date 08/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/07/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In nursing homes, the infectious risk for residents is high, making infection control using approaches such as hand hygiene (HH) a major issue. However, the effectiveness of HH to reduce the infectious risk in nursing home settings is not well documented and compliance with HH recommendations often remains low. The objective of this study is to investigate how HH may lower the risk of infections among nursing home residents.

Who can participate?

All residents and staff in the nursing homes participating in the study.

What does the study involve?

The participating nursing homes are randomly allocated to two groups. In the first group, standard infection control practices are used. In the other group, a bundle of interventions related to HH are implemented, including staff education, HH promotion and increased availability of hand-rub solution. Antibiotic prescriptions, as well as glove and hand-rub solution use, are monitored in all participating nursing homes over the study period.

What are the possible benefits and risks of participating?

Nursing homes from the intervention group will benefit from free access to hand-rub solution, as well as material for HH promotion and staff education. There are no risks to participating.

Where is the study run from?

Nursing homes in France run by the Korian group.

When is the study starting and how long is it expected to run for?

January 2014 to March 2015

Who is funding the study?

Funding was provided by Institute of Ageing Well Korian and Korian Medica (France)

Who is the main contact?

Laura Temime

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Contact information

Type(s)

Scientific

Contact name

Prof Laura Temime

Contact details

Laboratoire MESuRS

Conservatoire national des Arts et Métiers

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Paris

France

75003

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Impact of a multifaceted intervention for hand-hygiene in nursing homes: a cluster randomized controlled trial.

Study objectives

It is hypothesised that increasing compliance to hand hygiene recommendations among the staff and residents in nursing homes may lead to a reduction in the infectious risk for residents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval required, as the study did not change patient care, include new drugs or medical devices or add any procedure for patients. In addition, no sensitive data was collected.

Study design

Clustered randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Epidemics of acute respiratory infections and acute gastro-enteritis; hospitalizations; deaths

Interventions

Nursing homes are randomly assigned to the intervention or control arm.

1. Control arm: nursing home use standard infection control practices
2. Intervention arm: a multifaceted hand-hygiene intervention is implemented. The key elements of the multifaceted intervention are the following:
 - 2.1. Increased availability of alcohol-based hand-rub for the staff as well as for residents and visitors
 - 2.2. An educational program for the staff based on e-learning
 - 2.3. The creation of a work group within each nursing home which will propose a list of local recommendations
 - 2.4. A hand hygiene promotion campaign aimed at the staff, as well as at residents and visitors

Intervention Type

Behavioural

Primary outcome measure

1. Total number of cases of acute respiratory infections and acute gastro-enteritis that are reported to regional health agencies (ARS) in the context of clustered cases episodes
2. Episodes of clustered cases are defined as at least 5 cases over 4 days

Secondary outcome measures

1. Number of antibiotic prescriptions for 1000 resident-days (measured at 0, 6 and 12 months)
2. Mortality rate (measured at 0, 6 and 12 months)
3. Hospitalization rate (measured at 0, 6 and 12 months)
4. Hand hygiene compliance assessed by direct observation at 0, 6 and 12 months

Overall study start date

01/01/2014

Completion date

31/03/2015

Eligibility

Key inclusion criteria

1. For the primary outcome: all residents in the participating nursing homes
2. For the secondary outcomes and the intervention: all residents and staff in the participating nursing homes

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

26 nursing homes (13 per arm), with an average of 80 residents per nursing home.

Key exclusion criteria

Anyone not a resident or staff member in any of the participating nursing homes.

Date of first enrolment

01/01/2014

Date of final enrolment

01/03/2014

Locations

Countries of recruitment

France

Study participating centre

Korian Les Jardins d'Alesia

187 bis Avenue du Maine

Paris

France

75014

Study participating centre

Korian Hameau du Roy

16 Boulevard Saint-Antoine

Le Chesnay

France
78150

Study participating centre
Korian L'Age Bleu
7 Grande Rue
Roubaix
France
59100

Study participating centre
Korian La Goélette
34 Rue Surcouf
Équeurdreville-Hainneville
France
50120

Study participating centre
Korian Reine Mathilde
4 Rue des Hauts Vents
Grainville-sur-Odon
France
14120

Study participating centre
Korian Le Castelli
Rue des Lauriers
L'Huisserie
France
53970

Study participating centre
Korian Les Meunières
Place Denfert Rochereau
Lunel
France
34402

Study participating centre

Korian Les Blés d'or
Lieu dit La Mouline
Castelnau-de-Lévis
France
81150

Study participating centre
Korian Mas de Lauze
17 Chemin du Puits de Louiset
Nîmes
France
30900

Study participating centre
Korian Frontenac
Rue Diderot
Bram
France
11150

Study participating centre
Korian Les Annabelles
1 Rue du Diapason
Lyon
France
69003

Study participating centre
Korian L'Astrée
26-28 Rue de Molina
Saint-Etienne
France
42000

Study participating centre
Korian Vill'alizé
2 Rue des Chenevières
Thise
France
25220

Study participating centre
Korian Villa Victoria
Le Clos -Vincent
20 Rue du Dr Jean Vaquier
Noisy-le-Grand
France
93160

Study participating centre
Korian Les Arcades
116 Avenue Daumesnil
Paris
France
75012

Study participating centre
Korian Hauts de Jardy
1 Allée des Lauriers
Vaucluse
France
92420

Study participating centre
Korian Au Fil du Temps
2 Rue de Condé
Meaux
France
77100

Study participating centre
Korian Nymphéas Bleus
15 Avenue Pierre Mendès
Vernon
France
27200

Study participating centre
Korian Le Jardin
121 Avenue des Martyrs de la Résistance

Rouen
France
76100

Study participating centre
Korian Catalogne
18 Cours Lazare Escarguel
Perpignan
France
66000

Study participating centre
Korian Lo Solelh
46 Avenue Enseigne Albertini
Béziers
France
34500

Study participating centre
Korian Les Alpilles
Centre Urbain, Rue Hilaire Touche
Vitrolles
France
13127

Study participating centre
Korian Les Parents
22 Rue Vandiel
Marseille
France
13008

Study participating centre
Korian Sorgentino
52 Rue Auguste Gal
Nice
France
06300

Study participating centre**Korian Villa Janin**

9 Rue du Treyve
Saint-Etienne
France
42000

Study participating centre**Korian L'isle Verte**

50 Rue de Mortillet
Grenoble
France
38000

Study participating centre**Korian Villa d'Albon**

13 Avenue Gambetta
Roanne
France
42300

Sponsor information

Organisation

National Conservatory of Arts and Crafts (Conservatoire National des Arts et Métiers)

Sponsor details

292 rue Saint-Martin
Paris
France
75003

Sponsor type

University/education

Website

<http://www.cnam.fr>

ROR

<https://ror.org/0175hh227>

Funder(s)

Funder type

Industry

Funder Name

Institute of Ageing Well Korian (Institut du bien vieillir Korian)

Funder Name

Korian Medica

Results and Publications

Publication and dissemination plan

We intend to submit for publication at least one paper describing our study and its main results regarding the impact of the hand hygiene intervention that was implemented on hospitalization and mortality rates.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018	24/07/2020	Yes	No