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

Submission date	Recruitment status	Prospectively registered
08/07/2015	No longer recruiting	Protocol
Registration date 20/07/2015	Overall study status Completed	Statistical analysis plan
		[X] Results
Last Edited 24/07/2020	Condition category Infections and Infestations	[] Individual participant data
Z 4 /U//ZUZU	IIII ECCIONS AND INTESCACIONS	

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 laura.temime@cnam.fr

Contact information

Type(s)

Scientific

Contact name

Prof Laura Temime

Contact details

Laboratoire MESuRS Conservatoire national des Arts et Métiers 292 rue Saint-Martin Paris France 75003

Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

- 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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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 Vaucresson 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 Vandel 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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type Details
Results article results

Date created Date added Peer reviewed? Patient-facing?

01/02/2018 24/07/2020 Yes