

# Influenza vaccine in nursing homes - why doesn't it work?

**Submission date**  
26/07/2004

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
05/10/2004

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
14/09/2009

**Condition category**  
Infections and Infestations

☐ Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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**Contact details**  
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London  
United Kingdom  
SE13 6LW

## Additional identifiers

**Protocol serial number**  
SL&M Research Ethics Committee 04/045

## Study information

**Scientific Title**

**Study objectives**

Primary Objectives: To determine whether assessing antibody response to the influenza vaccine, and administering a booster vaccination if the antibody response is inadequate, is more effective in reducing hospitalisation and death rates than current standard practice.

Secondary Objectives: To estimate the overall antibody response rate to the influenza vaccine in the trial population; To investigate whether non-response to the influenza vaccine is associated with HLA type, psychiatric diagnosis, Cornell score or MMSE score; To investigate whether assessing antibody response to the influenza vaccine, and administering a booster vaccination if the antibody response is inadequate, increases antibody response rates relative to current standard practice; To investigate what baseline factors predict clinical response (hospitalisation and death rates) and antibody response across intervention groups (including Cornell score, MMSE score, psychiatric diagnosis, and HI titres); To investigate whether Cornell score, MMSE score and HLA type differentially predict clinical response (hospitalisation and death rates) and antibody response to the intervention versus control.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Received from South London And Maudsley Research Ethics Committee (ref: 04/045)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Influenza

**Interventions**

Randomised into immediate assay of 21-day haemagglutination inhibition (HAI) antibody response to flu vaccine, and administration of booster if antibody response inadequate, as compared to treatment as usual.

**Intervention Type**

Biological/Vaccine

**Phase**

Not Specified

**Primary outcome(s)**

Hospitalisation (Yes/No) between randomisation and 30th April 2005.

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/07/2005

## Eligibility

### Key inclusion criteria

All consenting/assenting individuals in care homes with nursing care who receive their primary care from Lambeth and Southwark primary care trusts (PCTs), who would ordinarily receive the influenza vaccine are eligible for inclusion in the trial.

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Senior

### Sex

All

### Key exclusion criteria

If an individual has had a reaction to the initial flu vaccine or if the flu vaccine is contra-indicated in that individual, then they will be excluded from the trial.

### Date of first enrolment

01/08/2004

### Date of final enrolment

31/07/2005

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

Consultant Psychiatrist and Hon. Senior Lecturer

London

United Kingdom

SE13 6LW

## Sponsor information

**Organisation**

South London And Maudsley NHS Trust (UK)

**ROR**

<https://ror.org/015803449>

**Funder(s)****Funder type**

Charity

**Funder Name**

Charitable Foundation of Guy's and St. Thomas' (UK) (R031166)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2007		Yes	No