

# 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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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

### Participant information sheet

### 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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/08/2004

**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

**Age group**

Senior

**Sex**

Both

**Target number of participants**

277

**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**

England

United Kingdom

## **Study participating centre**

**Consultant Psychiatrist and Hon. Senior Lecturer**

London

United Kingdom

SE13 6LW

## **Sponsor information**

### **Organisation**

South London And Maudsley NHS Trust (UK)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **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

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

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