

# Probiotics for antibiotic-associated diarrhoea (including Clostridium difficile) in care homes: providing incidence data on antibiotic-associated diarrhoea in care homes and evaluating care homes as a setting to conduct complex studies/drug trials

<b>Submission date</b> 06/07/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/06/2016	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Taking antibiotics kills off bacteria that cause disease. However, antibiotics also kill the bacteria that help keep the harmful bacteria in check, often causing diarrhoea. Older people, especially those who are frail and have multiple health problems, are particularly prone to getting diarrhoea after taking antibiotics, including diarrhoea caused by the bacterium Clostridium difficile. Many frail elderly people live in care homes and they are often prescribed antibiotics for conditions such as urine or chest infections. Because no one knows exactly how often and what types of antibiotics are prescribed in care homes in the UK, and how often diarrhoea occurs as a consequence and how serious it is, the aim of this study is to provide this information.

### Who can participate?

Residents in nine care homes

### What does the study involve?

Information is collected each time a participating resident is prescribed antibiotics by their GP. If a resident who is prescribed antibiotics develops diarrhoea either during or within 8 weeks of stopping the antibiotic(s), a stool sample is collected and sent for analysis including C. difficile analysis.

### What are the possible benefits and risks of participating?

The results of this study may be useful for guiding future antibiotic treatment decisions and service planning.

Where is the study run from?  
Cardiff University (UK)

When is the study starting and how long is it expected to run for?  
October 2010 to October 2011

Who is funding the study?  
Health Technology Assessment Programme (UK)

Who is the main contact?  
Prof. Christopher Butler

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Christopher Butler

**Contact details**  
Professor of Primary Care Medicine  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HTA 08/13/24; SPON844-10

## Study information

**Scientific Title**  
The PAAD study: Probiotics for Antibiotic-Associated Diarrhoea (including Clostridium difficile) in care homes: establishing the platform

**Acronym**

PAAD

## **Study objectives**

PAAD is a two-stage study:

Stage 1:

There is currently a lack of evidence regarding

1. The frequency of antibiotic prescribing and type of antibiotic prescribed in care homes and,
2. How often diarrhoea occurs associated with taking antibiotics (antibiotic-associated diarrhoea [AAD]), and its severity.

Therefore this study aims to provide data on the incidence of AAD including *C. difficile*-associated diarrhoea in care homes and if there is an issue confirm the estimated sample size for a randomised controlled trial (RCT) in Stage 2.

Stage 2 is a randomised controlled trial to assess whether AAD is prevented or ameliorated in care home service users receiving antibiotics by the administration of a probiotic alongside the antibiotic.

The information supplied here is for Stage 1 only.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/081324>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0011/52211/PRO-08-13-24.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0011/52211/PRO-08-13-24.pdf)

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

South East Wales Ethics Committee Panel B, ref: 10/WSE02/47 – approval pending

## **Study design**

12-month observational cohort study

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Other

## **Study type(s)**

Other

## **Participant information sheet**

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

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

Antibiotic-associated diarrhoea in the elderly, living in care homes

## Interventions

Nine care homes in South Wales and the care home service users (residents) will be recruited for Stage 1. The main part of Stage 1 is a 12-month prospective observational study that aims to collect data (e.g. amount and type of antibiotics prescribed, episodes of antibiotic-associated diarrhoea (AAD) and Clostridium difficile-associated diarrhoea (CDAD) and outcome), in a purposive sample of care homes. Additionally, there will be three sub-studies within Stage 1.

### 1. Main observational study

Data regarding symptoms, indication for prescribing, type of antibiotic, dose, route of administration and duration of antibiotic will be collected each time a participating service user is prescribed antibiotics by their GP. Should a service user who is prescribed antibiotics develop diarrhoea either during or within 8 weeks of stopping the antibiotic(s), a stool sample will be collected and sent to the Public Health Wales Central Microbiology Laboratory for standard microbiological stool analysis including C. difficile analysis. A stool chart will be completed for the duration of antibiotic treatment and for an additional 8 weeks after the antibiotic course is completed.

### 2. Sub-Studies

#### 2.1. Sub Study 1: C. difficile Prevalence

A baseline stool sample will be collected from care home service users to assess C. difficile prevalence in the care homes. Data about previous antibiotic use by the service user for a 3-month period before entry to this sub-study will also be collected.

#### 2.2. Sub Study 2: Probiotic acceptability and feasibility

This sub-study will:

2.2.1. Explore and test the acceptability, procedure and method of delivering a probiotic in conjunction with antibiotics prescribed in the course of routine care in a small number of consenting care home residents in three care homes (up to nine in total). This is to establish the procedures and prove that a probiotic can be given to this population as part of a research study according to a protocol.

2.2.2. This sub-study will also develop and pilot a training package for care home staff in implementing the possible randomised controlled trial in Stage 2.

#### 2.3. Sub Study 3: Qualitative Study

2.3.1. Qualitative interviews will be conducted with service home users capable of consent

2.3.2. Focus groups will be conducted with family members and care home staff discussing issues around consent and assent in care home residents

2.3.3. Additional interviews with GPs regarding these issues will also be conducted.

The focus groups and interviews will also take into account issues from sub study 2 (above).

In summary, Stage 1 will identify the scale of the AAD problem in care homes, provide reliable incidence data and confirm the basis of our sample size calculation for the randomised controlled trial (RCT) in Stage 2. Stage 1 will also allow us to pilot the trial procedures and materials required for a RCT in Stage 2. If Stage 1 indicates that AAD is a rare, unimportant problem, then, based on explicit stopping rules, we will not progress to Stage 2.

## Intervention Type

Other

## Phase

Not Applicable

## **Primary outcome measure**

### **1. Main observational study**

- 1.1. To conduct prospective systematic ascertainment of the incidence of AAD in care homes
- 1.2. To allow an appraisal of the estimated sample size for a randomised controlled trial (RCT) in Stage 2

## **Secondary outcome measures**

### **1. Main observational study**

- 1.1. To conduct prospective systematic ascertainment of antibiotic use in care homes
- 1.2. To estimate the risk of AAD overall and from particular antibiotics in care home settings
- 1.3. To identify barriers and implementation issues in conducting a trial of AAD prevention /amelioration in a care home setting

### **2. Sub-studies**

#### **2.1. Sub Study 1. Prevalence:**

- 1.1.1 To determine the prevalence of asymptomatic *C. difficile* carriage in service users within selected care homes.

#### **2.2 Sub Study 2. Probiotic Feasibility and Acceptability:**

- 2.2.1. To test the acceptability and feasibility of administering probiotics in a small number of service users
- 2.2.2. To pilot and develop trial procedures including modelling consent procedures
- 2.2.3. To develop a training package for nursing home personnel to implement the trial

#### **2.3. Sub Study 3. Qualitative:**

- 2.3.1. To explore the ethical and practical issues of consent and assent, particularly the topic of advanced consent, for elderly residents who may/may not have capacity to consent

## **Overall study start date**

01/10/2010

## **Completion date**

31/10/2011

# **Eligibility**

## **Key inclusion criteria**

1. Service users who are/have been admitted to the care home for >24 hours
2. Planned admission to care home of one month or more (excludes short-term respite care)
3. Written informed consent/assent provided

## **Participant type(s)**

Patient

## **Age group**

Senior

## **Sex**

Both

**Target number of participants**

270

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/10/2010

**Date of final enrolment**

31/10/2011

## **Locations**

**Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

**Cardiff University**

Cardiff

United Kingdom

CF14 4XN

## **Sponsor information**

**Organisation**

Cardiff University (UK)

**Sponsor details**

30-36 Newport Road

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United Kingdom

CF24 0DE

**Sponsor type**

University/education

**ROR**

<https://ror.org/03kk7td41>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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	09/08/2013		Yes	No
<a href="#">Results article</a>	results	01/10/2014		Yes	No