

# The safety in primary care study: a randomised, controlled feasibility study

<b>Submission date</b> 08/06/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/06/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/02/2019	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Research on patient safety has focused largely on hospital settings, and there is limited knowledge about patient safety in primary care. This study aims to assess the effectiveness of an intervention to improve patient safety in primary care. The purpose of this study is to evaluate whether a future larger study of the patient safety intervention should be carried out.

### Who can participate?

Staff working in general practices in the Republic of Ireland and in Northern Ireland

### What does the study involve?

Participating practices are randomly allocated to one of two groups to either receive the intervention over a 9-month period or to continue care as usual. The interventions include repeated completion of a safety questionnaire and feedback on these findings, and the review of patient records to identify any patients who may have been harmed as part of their care.

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

The findings from the study may increase knowledge of how often patients are harmed in primary care, contribute to improved patient safety practices in primary care, and inform future research on patient safety improvement. The benefits of participating are that there will be an increased awareness of patient safety in the practice that may lead to improved patient care. The risks are that participants may become distressed if they realise they contributed to a patient safety incident.

### Where is the study run from?

1. NUI Galway (Ireland)
2. Queen's University Belfast (UK)

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

September 2015 to June 2017

Who is funding the study?  
Health Research Board (Ireland)

Who is the main contact?  
Dr Paul O'Connor  
paul.oconnor@nuigalway.ie

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Paul O'Connor

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
The safety in primary care study: a randomised, controlled feasibility study

**Acronym**  
SAP-C

**Study objectives**  
The purpose of this feasibility study is to evaluate the:

1. Willingness of practices to participate in the study
2. Retention of control and intervention practices
3. Response rates to questionnaires
4. Feedback from the intervention group on the feasibility, usefulness, and sustainability of the

intervention

5. Effects of the intervention on safety climate

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Irish College of General Practitioners' Research Ethics Committee, 14/01/2016
2. Office for Research Ethics Committees of Northern Ireland, 23/02/2016, ref: 16/NI/0008

### **Study design**

Cluster randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Other

### **Participant information sheet**

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

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

General practice

### **Interventions**

Simple randomisation was employed, whereby participating practices were assigned to either the intervention or control group.

Five practices received the intervention over a 9-month period. The intervention consisted of: 1) repeated safety climate (SC) measurement (using GP-SafeQuest questionnaire) and feedback, and 2) patient record reviews using a specialised trigger tool to identify instances of undetected patient harm.

The five practices in the control group continued care as usual.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

The evaluation of the study's implementation process was the primary outcome. Outcomes of interest were:

1. Willingness of practices to participate in the study, measured during the recruitment phase prior to the intervention

2. Response rates to safety climate questionnaire, measure at baseline and month 9
3. Feasibility questionnaire at month 9
4. Retention of control and intervention practices, measured at month 9
5. interviews on the feasibility, usefulness, and sustainability of the intervention at month 9

**Secondary outcome measures**

None

**Overall study start date**

01/09/2015

**Completion date**

30/06/2017

## Eligibility

**Key inclusion criteria**

Staff working in general practices in the Republic of Ireland or Northern Ireland that have expressed a willingness to be involved in the study

**Participant type(s)**

Health professional

**Age group**

Adult

**Sex**

Both

**Target number of participants**

This is a randomised controlled feasibility study, so the target was 10 general practices (8 from the Republic of Ireland and two from Northern Ireland)

**Key exclusion criteria**

People who do not work in a general practice that agreed to participate in the study

**Date of first enrolment**

01/02/2016

**Date of final enrolment**

21/03/2016

## Locations

**Countries of recruitment**

Ireland

Northern Ireland

United Kingdom

**Study participating centre**  
**Discipline of General Practice**  
NUI Galway  
Galway  
Ireland  
H91 TK33

**Study participating centre**  
**Department of General Practice and Primary Care**  
Queen's University Belfast  
Belfast  
United Kingdom  
BT9 7HR

## **Sponsor information**

**Organisation**  
HRB Primary Care Clinical Trials Network Ireland

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Discipline of General Practice, School of Medicine, NUI Galway  
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**Sponsor type**  
Research organisation

**ROR**  
<https://ror.org/003hb2249>

## **Funder(s)**

**Funder type**  
Research organisation

**Funder Name**  
Health Research Board

**Alternative Name(s)**

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Ireland

## Results and Publications

**Publication and dissemination plan**

The manuscript describing the trial is under review in a primary care journal, expected publication in winter 2018.

**Intention to publish date**

31/12/2018

**Individual participant data (IPD) sharing plan**

Requests for access to data should be made to Dr Paul O'Connor (paul.oconnor@nuigalway.ie). The data will be available from December 2018. Data that could be made available is anonymous safety climate data, and the feasibility questionnaire data. Sharing data was not explicitly mentioned in the consent form. Therefore, requests for data sharing will have to be considered on a case-by-case basis by the members of the trial steering committee.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	16/09/2016		Yes	No
<a href="#">Results article</a>	results	30/01/2019	01/02/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No