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

Submission date
08/06/2018

Recruitment status
No longer recruiting

Registration date
12/06/2018

Overall study status
Completed

Last Edited
01/02/2019

Condition category
Not Applicable

✓ Retrospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
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
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Contact information

Type(s)
Scientific

Contact name
Dr Paul O'Connor

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
N/A

Study information

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

Acronym
SAP-C

Study hypothesis
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

Condition
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

Overall study end date
30/06/2017

Eligibility

Participant 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)

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

Recruitment start date
01/02/2016

Recruitment end date
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
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Sponsor information

Organisation
HRB Primary Care Clinical Trials Network Ireland

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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?
Protocol article	protocol	16/09/2016		Yes	No
Results article	results	30/01/2019	01/02/2019	Yes	No
HRA research summary			28/06/2023	No	No