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Evaluation of the 'Freedom to Speak Up Local Guardians' in NHS England Acute and Mental Health Trusts

Submission date
28/08/2018

Recruitment status
No longer recruiting

Registration date
13/09/2018

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Employees who "speak-up" or "raise concerns" about problems with healthcare services are often referred to as "whistleblowers". Although "speaking up" makes an important contribution to patient safety in the NHS, whistleblowers have not always been treated well. For example, the Francis Report in 2013 into serious patient care failures at Stafford Hospital identified that whistleblowers were often ignored and mistreated by colleagues. The related Freedom to Speak Up review by Francis in 2015 recommended that raising concerns should become a normal part of the job for anyone working in the NHS.The aim of this study is to better understand the introduction of a new role in NHS England designed to support staff who wish to raise concerns about the quality of patient care. These roles are called "Local Freedom to Speak Up Guardians" (referred to here as "FTSUG"). The introduction of the new FTSUG role is described as potentially making a huge contribution to improving the way "Speak Up" cases are handled. However, there are some important differences in how the FTSUG role is being introduced by organisations across England. More information is needed to fully understand differences in FTSUG roles and what these differences mean for staff raising concerns and how concerns, when raised, are acted upon. The researchers are interested in finding out how FTSUG roles are being introduced in Acute Trusts and Mental Health Trusts and whether FTSUGs are helping staff to "speak up" about their concerns.

Who can participate?
Current FTSUGs, employees who have spoken up via FTSUGs, who have raised concerns through other channels (e.g. a Trade Union) but have not been in contact with FTSUGs, or who may not have spoken up about concerns, and stakeholders who are involved in the oversight and delivery of the FTSUG role and any related speak up initiatives

What does the study involve?
Telephone interviews are carried out with FTSUGs in Acute Hospital and Mental Health Trusts to provide a better understanding of the FTSUG role and what they do within their organisations. Information is also gathered about the number and types of concerns that FTSUGs have dealt with, to show similarities and differences in FTSUG roles and how these influence FTSUGs' work

and how, when and how often staff concerns are raised. The survey results are used to identify case study sites in four Acute Trusts and two Mental Health Trusts. The researchers interview FTSUGs, those working with FTSUGs and employees who have raised concerns and others who have not, and analyse documents (e.g. FTSUG role descriptions, minutes of meetings) and observe the FTSUG working in practice e.g. observe training delivered and meetings attended by the FTSUG.

What are the possible benefits and risks of participating?
Participants will contribute to a better understanding of a new and innovative intervention to enhance patient safety and staff wellbeing. There are no risks of participating.

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

When is the study starting and how long is it expected to run for?
May 2018 to August 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Aled Jones
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
v1

Study information

Scientific Title
Evaluation of the implementation and normalisation of ‘Freedom to Speak Up Local Guardians’ in NHS England Acute and Mental Health Trusts

Acronym
FTSUGproject

Study objectives
The aim of this study is to better understand the introduction of a new role in NHS England designed to support staff who wish to raise concerns about the quality of patient care. These roles are called "Local Freedom to Speak Up Guardians” (referred to here as “FTSUG”). The trialists are interested in finding out how FTSUG roles are being introduced in Acute Trusts and Mental Health Trusts and whether FTSUGs are helping staff to “speak up” about their concerns.

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Healthcare Sciences Research Ethics Committee, Cardiff University, 14/08/2018

Study design
Mixed methods multicentre case study over 27 months

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Patient safety and employee 'speaking-up'

Interventions
The research study is planned over 27 months in 3 discrete but related work packages:

Work Package (WP) 1: A review of literature that investigates different approaches used to encourage staff to speak up in healthcare and other sectors. This will help us develop our survey questions for WP 2. We will also speak to staff in FTSUG roles to help us develop survey questions and gain NHS research ethics/governance approvals at this time.

WP 2: Telephone interviews with FTSUGs in Acute Hospital and Mental Health Trusts will provide a better understanding of the FTSUG role and what they do within their organisations. We will also gather information about the number and types of concerns that FTSUGs have dealt with. Survey results will show similarities and differences in FTSUG roles and how these influence FTSUG's work and how, when and how often staff concerns are raised.

WP 3: Survey results from WP 2 will help identify case study sites in 4 Acute Trusts and 2 Mental Health Trusts. In these case studies we will interview FTSUGs, those working with FTSUGs and

employees who have raised concerns and others who have not. We will also analyse documents (e.g. FTSUG role descriptions, minutes of meetings) and observe the FTSUG working in practice e. g. observe training delivered and meetings attended by the FTSUG. At the end of WP 3 we will better understand whether and how different ways of rolling out the FTSUG role affects staff speaking up.

A respected framework called Normalisation Process Theory (NPT) used by health researchers to collect and analyse data will assist the team to better understand this unique new role in practice. We will analyse the six case study sites separately, before analysing findings across all cases. A project report will then be produced in WP 4 , describing differences in the FTSUG role across England and whether these differences have affected staff speaking up. We will also develop training materials and a 'speak up' guide for managers, clinicians, patients and others.

Intervention Type
Other

Primary outcome(s)
Phase 2 (Oct 2018 -May 2019) – interviews with guardians and national policy leaders (n=110) including respondent demographics, organisation size and CQC rating, examples of barriers /enablers to operationalizing the role and effective response to concerns, numbers, types and severity of concerns raised since FTSUG post created.

Phase 3 (April 2019-December 2019) – interviews in 6 case study sites with various NHS staff (n=120), observations of practice, documentary analysis e.g. observe certain aspects of the FTSUG role e.g. delivering 'speaking up' training and advice to staff, reviewing concerns with colleagues and other FTSUGs within the organisation, attending meetings internally. Documentary analysis of relevant organisational policies, internal communications, reports /investigations undertaken by LGs and reports prepared for the Trust Board on concerns raised by staff and the organisation's cultures.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/08/2020

Eligibility

Key inclusion criteria
In phase 2 (telephone interviews) of the study the participants have to be a current Freedom to Speak Up Guardian (FTSUG). In phase 3 (case studies) purposive sampling will be used to identify key informants, documents and stakeholders who are involved in the oversight and delivery of the FTSUG role and any related speak up initiatives. Snowball sampling will be used to include a sample of those employees who have spoken up via the FTSUG. However, interviewing FTSUGs and those that have engaged with FTSUGs offers only a limited perspective about the LG role, and the culture of speaking up. Therefore, the trialists will also recruit, via snowball sampling, those who may have raised concerns through other channels (e.g. a Trade Union), but have not been in contact with the FTSUG, and/or those who may not have spoken up about concerns, thus providing a better understanding why some may not have yet engaged with the FTSUG role. The views of others involved in employee concerns will offer invaluable insights into coordination, cooperation and commitment to the FTSUG role, as well as other insights, such as whether the

implementation of the FTSUG role has displaced, for better or worse, historically effective ways of informally or formally raising and responding to concerns.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
87

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
School of Healthcare Sciences, Cardiff University
Eastgate House
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Sponsor information

Organisation

Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Due to the nature of the study some of the data, even when anonymised, may contain highly sensitive information about whistleblowing and patient safety in the NHS. As a result the dataset will not be made immediately available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2022	28/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes