ISRCTN38405571 https://doi.org/10.1186/ISRCTN38405571

Improving fundamental care in hospitals

Submission date	Recruitment status	[_] Prospectively registered
04/03/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2022	Other	

Plain English summary of protocol

Background and study aims
Hospital patients receive care and support to meet personal care needs (taking on enough fluids, skin care, toileting, keeping active and eating healthily). This is called 'fundamental care'. Sometimes patients feel this care doesn't take their needs into account and they don't feel involved. When the researchers asked a range of patients, carers and members of the public about fundamental care, they said that making it more personalised and involving patients was crucial. However, research into making care more personalised shows patients can worry about seeming 'difficult' when asking for what they want.

Who can participate?
Patients aged 18 and over and nurses and care assistants working on participating wards

What does the study involve?
The study uses three things together that have worked separately in previous research to see if they can improve the personal care people receive in hospital: training for teams of nurses on hospital wards, a feedback card for patients to record what is important about their care, a tool to help patients understand and choose the care that is best for them. The study focuses on bedsores as a proxy for meeting a range of fundamental care needs. Care is compared between wards where this work is done (intervention wards) with wards where this work is not done (control wards). To test what difference these ideas make to patient care in the hospital wards, the researchers:
1. Ask patients and staff on the wards to complete surveys and participate in interviews
2. Watch how staff support patients and take notes
3. Collect documents like meeting notes and forms
4. Use information already collected by the ward about patient care
The researchers collect the following information before and after they use the new tools and way of working:
1. Quality of staff support for patients
2. Whether care is thought to be personalised
3. Patient and carer satisfaction with care, bedsore development, and development of other complications like falls and infections where good records are available.

What are the possible benefits and risks of participating?
The results from this study will be used to help plan a larger test of working in this way.

Where is the study run from?
1. Southampton General Hospital (lead site) (UK)
2. Queen Alexander Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2017 to August 2018

Who is funding the study?
National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Health Research and Care (CLAHRC) Wessex (UK)

Who is the main contact?
Dr Jo Hope
j.l.hope@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Lisa Gould

ORCID ID
https://orcid.org/0000-0002-4334-8061

Contact details
Office 3029
Building 67
Highfield Campus
University of Southampton
Southampton
United Kingdom
SO17 1BJ
+44 (0)2380 597590
l.j.gould@soton.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
33268

Study information

Scientific Title
Assessing the feasibility and acceptability of a combined intervention to increase the delivery of patient-centred multiple fundamental care activities on adult wards in acute hospitals, specifically those related to pressure ulcer prevention (hydration, nutrition, mobility, continence and skin care)

Acronym
IFCH

Study objectives
This study aims to assess the feasibility and acceptability of a combined intervention to increase the delivery of patient-centred multiple fundamental care activities, specifically those related to pressure ulcer prevention (hydration, nutrition, mobility, continence and skin care). The combined intervention includes a patient feedback card and the Creating Learning Environments for Compassionate Care (CLECC) nursing staff intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/04/2017, London - Harrow Research Ethics Committee, Education Centre, Northwick Park Hospital, HA1 3UJ, Tel: +44 (0)207 104 8057, Email: nrescommittee.london-harrow@nhs.net, ref: 17/LO/0365

Study design
Randomised; Both; Design type: Process of Care, Complementary Therapy, Complex Intervention, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Health Services Research, Primary sub-specialty: Health Services Research; Health Category: Generic health relevance

Interventions
This study combines two existing interventions.
1. The Creating Learning Environments in Compassionate Care (CLECC) intervention - this been designed for use by ward nursing teams in inpatient settings for older people. The implementation programme takes place over a 4 month period but it is designed to lead to a longer-term period of service improvement. The behavioural intervention in this study aims to improve compassionate care by delivering an intervention which involves improving the workplace environment and the work team.
2. A modified version of the 'Tell Us' card, a patient card to elicit care preferences.

In each of two hospitals this intervention is run in two wards, with one ward serving as a control (no intervention as described above).

Intervention Type
Behavioural

Primary outcome(s)
Pre- and post-intervention surveys and observations will be taken:
1. Patient-centredness of care measured using the patient version of the Individualised Care Scale (ICS) and the Person-centred Climate Questionnaire (PCCQ)
2. Nurses' perceptions of patient-centredness of care measured using the staff versions of the Individualised Care Scale (ICS) and the Person-centred Climate Questionnaire (PCCQ)
3. Quality of staff-patient interactions measured using the QUIS, a time sampling tool that gives a measure of both the volume and quality of interactions. Interactions between staff and patients are observed by independent raters and coded as positive social, positive care, neutral, negative protective and negative restrictive. Observations will be divided into ten 2 hour periods (per ward at each assessment period) to ensure representation of a range of patients, times of day, nurses and days of week.

Key secondary outcome(s))
Timepoint(s): Pre- and post-intervention surveys:
1. Carer experiences of care; all eligible carers/visitors on each ward over a six week period will be invited to complete a Carer Experiences of Care (CEC) questionnaire
2. Feasibility of study design to inform a future definitive trial, capturing levels of recruitment, recruitment difficulties and feasibility of intervention (through interviews with staff)
3. Pressure ulcer prevalence (as a proxy for fundamental care activities being carried out satisfactorily) measured using audit data

Completion date
01/05/2019

Eligibility

Key inclusion criteria
Staff (interviews, surveys):
1. All nurses and care assistants (CAs) (Health care assistants, assistant practitioner, nursing auxiliaries) working on participating wards during any data collection period will be invited to be interviewed and eligible to complete the nursing questionnaires.
2. Age: 18+
3. Gender: Both

Patients (interviews, surveys):
1. Age: 18+
2. Gender: Both
3. Only people who speak English and who have the cognitive and communicative capacity to participate in a research interview (as assessed by the researcher and/or ward staff) will be invited to take part

Care interactions (patients and staff):
1. Age: 18+
2. Gender: both
3. Patients who are able to consent OR if lacking mental capacity, advice will be taken from an appropriate consultee in deciding whether or not to include someone

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Staff:
1. Nursing students, bank and agency staff will not be eligible to be interviewed nor to complete the nursing questionnaires

Patients
1. Reverse-barrier nursed, receiving palliative care or are critically ill (research team will be advised by the nurse-in-charge when coming onto the ward)
2. Lacking capacity to decide about taking part in the research and/or unable to communicate their choices about taking part in the research AND a consultee (as defined by the Mental Capacity Act) cannot be consulted (NB patients who lack capacity will be included in care interaction observations if a consultee advises this is appropriate and the patient does not show signs of dissent)
3. Indicate either verbally or non verbally that they do not wish to take part
4. Unconscious or where there are clinical concerns that may preclude them from being approached (we will check with the nurse-in-charge on arrival on the ward whom we should not approach)
5. Receiving continual clinical care that would impair their capacity to make a decision about taking part
6. Communication difficulties, including e.g. language differences, auditory impairments, impair the recruiter's ability to communicate about the research or the patient's ability to communicate their choice about taking part
7. Unable to complete a questionnaire in English with interviewer help
8. Qualitative interviews - lacking the cognitive and communicative capacity to be interviewed

Date of first enrolment
06/09/2017

Date of final enrolment
30/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital (lead site)
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Queen Alexander Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR CLAHRC Wessex

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the nature of the consent obtained from participants.

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		25/01/2022	15/02/2022	Yes	No
Results article		01/11/2019	15/02/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results			15/02/2022	No	No