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Connecting callers with minor illness to a pharmacy telephone helpline after consultation with Swedish Healthcare Direct (SHD)

Submission date	**Recruitment status**	[X] Prospectively registered
01/10/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/10/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/10/2015	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

It has been found that around 13% of GP visits and 5% of emergency department (ED) visits are unnecessary, putting needless strain on the healthcare system. Many minor illnesses, such as coughs and colds, could actually be managed by patients themselves (self-care). In many cases, people can easily obtain medicines from pharmacies without the need for prescriptions from a doctor. The Swedish Health Care Direct organization (SHD) is staffed by registered nurses who complete patient consultations over the telephone. This system could help to reduce the amount of unnecessary GP and ED visits, as the nurse is able to advise the patient whether they could pick up what they need from the pharmacy and take care of themselves. In some cases, being given extra advice or assistance can help to make the process of self-care easier. It has been suggested that patients who are satisfied are more likely to recover and less likely to go to the doctor unnecessarily. The aim of this study is to find out whether providing self-care advice through a pharmacy telephone helpline could help patients to feel more satisfied so that they recover quickly and do not need to go to the GP or ED with minor illnesses.

Who can participate?

Adults who have called the pharmacy within opening hours for advice on a minor illness that has been judged suitable for self-treatment by a nurse.

What does the study involve?

Participants are randomly allocated into two groups. Those in the first group (intervention group) are given the option to be connected to a pharmacy telephone helpline after speaking to an SHD nurse. They are then given advice and information about over-the-counter medicines that could make them feel better. Those in the control group are not connected to the pharmacy telephone helpline after speaking with the SHD nurse. One week after the call to the SHD nurse, participants are asked to complete a questionnaire to measure their satisfaction with the service, whether or not their illness has improved and whether they needed to see a GP or go into hospital.

What are the possible benefits and risks of participating?
A possible benefit is that participants will receive improved information about medicines and how to take them. A risk is that participants may become frustrated if they have to go back and forth between the nurse who initially assessed them and the pharmacy.

Where is the study run from?
Healthcare 1177, Luleå (Sweden)

When is the study starting and how long is it expected to run for?
November 2015 to December 2015

Who is funding the study?
Luleå University of Technology (Sweden)

Who is the main contact?
Mrs Siljie Gustafsson

Contact information

Type(s)
Scientific

Contact name
Mrs Silje Gustafsson

ORCID ID
http://orcid.org/0000-0001-8990-752X

Contact details
Odlingsvägen 1
Södra Sunderbyn
Sweden
95442

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DNR 1610-10

Study information

Scientific Title

In careseekers with minor illness, does being connected to a pharmacy telephone helpline after consultation with Swedish Healthcare Direct (SHD) improve patient satisfaction, symtom resolution and/or health care utilization compared to careseekers not being connected?

Acronym
ESCAP

Study objectives
Complementary self-care advice through a pharmacy telephone helpline will improve patient satisfaction and symptom resolution and reduce health care utilization in patients with minor illness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical review board of Umeå University, 07/08/2010, ref: 2010-225-31

Study design
Single-centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Minor illnesses, e.g. conditions that do not need medical treatment

Interventions
The SHD nurses will have a stack of envelopes on their desk containing 1/2 letters saying ”no intervention” and 1/2 letters saying ”offer intervention”. Letters will be placed in the stack in random order using a randomization list and all envelopes will look the same.
1. When a patient matches the criterias for participation in the study, the nurse takes the envelope at the top of the stack and opens it at the end of the call
2. If the letter says ”no intervention” she will end the call as usual
3. If the letter says ”offer intervention” she will give quick oral information about the study and ask the caller if she may connect him/her to the pharmacist:
3.1. If the caller accepts, the nurse will connect the call to the Pharmacy helpline
3.2. If the caller declines the intervention she will end the call as usual
3.3. The nurse will fill in the letter whether the caller accepted or declined the offer

4. Nurses write down the social security number of the caller on the letter, regardless of intervention/no intervention
5. Letters, all containing social security numbers, are to be put it in another stack and collected by researcher.
The duration of the treatment/intervention (e.g. the call lengths with the pharmacy helpline) is estimated to be approximately 5 minutes.
The follow up will be by questionnaire 7 days after the call to the SHD.

Intervention Type
Other

Primary outcome measure
1. Patient satisfaction is measured using a patient satisfaction scale (10-point Likert scale) 7 days after the intervention
2. Symptom resolution is measured by self-reporting on a 6 step scale (from full resolution to symptoms have worsened) comparing their symptoms to how they were at the day of the call to the SHD 7 days after the intervention
3. Health care utilization will be measured through self-reporting 7 days after the intervention

Secondary outcome measures
Experiences of receiving self-care advice when triaged to self-care for minor illness is measured using a questionnaire 7 days after the intervention.

Overall study start date
02/11/2015

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Called is above 18 years of age
2. Person assessed by nurse at the SHD as suitable for practicing self-care for minor illness, for him/herself or for a child (No GP referral)
3. Person calling within the opening hours of the pharmacy telephone helpline (weekdays 4pm to 8pm)

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
1100

Key exclusion criteria
1. Calling for mental illness
2. Calling for suspected or confirmed miscarriage

Date of first enrolment
02/11/2015

Date of final enrolment
27/11/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Healthcare (Sjukvårdsrådgivningen) 1177
Robertsviksgatan 9
Luleå
Sweden
972 41

Sponsor information

Organisation
Lulea University of Technology

Sponsor details
Universitetsalléen
Luleå
Sweden
97187

Sponsor type
University/education

Website
www.ltu.se

ROR
https://ror.org/016st3p78

Funder(s)

Funder type
Government

Funder Name
Luleå University of Technology

Alternative Name(s)
Luleå University of Technology, LTU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
Following data collection and analysis, publication of results in a peer reviewed journal, as well as presentation at national and international conferences are planned. Dissemination of results to interested UK research teams is also planned.

Intention to publish date
30/05/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration