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A patient-held health-record for asylum-seekers in reception centres to improve continuity of care

Submission date
24/11/2016

Recruitment status
No longer recruiting

Registration date
14/12/2016

Overall study status
Completed

Last Edited
21/08/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Newly arriving asylum-seekers are often dispersed between and within federal states, districts and communities. At each location many people are involved in providing health care, leading to a fragmentation of care and challenges for continuity of care. A patient-held health-record (PHR) for asylum-seekers has been developed and tested in a routine care setting in a reception centre. As this was successful, the regional authorities have decided to introduce the PHR in all reception centres of the administrative area. The aim of this study is to assess the effectiveness of the introduction of the PHR on continuity of care.

Who can participate?
Physicians and asylum-seekers at reception centres with on-site health care clinics

What does the study involve?
The PHR is introduced into the participating reception centres in a random order at 3-week intervals, so that by the end of the study period the PHR has been introduced into all of the reception centres. Physicians at the reception centres are asked to complete questionnaires to assess health-related information, missing essential information, and their satisfaction with the quality of the information for each patient-physician encounter. Interviews are also conducted with physicians, health workers and asylum-seekers using the PHR to gain insights into its applicability, acceptance, and the perceived benefits and risks.

What are the possible benefits and risks of participating?
Participating will help assess the effectiveness of the PHR in a complex healthcare setting for a vulnerable patient group. Physicians participating in the study are asked to complete a one-page questionnaire for each patient they treat which takes 1-2 minutes. There are no risks for participating physicians and participation can be withdrawn at any time throughout the study. Asylum-seekers will be interviewed to gain insights into their experiences of using the PHR. This may require talking about personal histories of illness, which may in turn create emotional distress for the participants. The interviewers will be informed about this possibility and instructed to contact local psychosocial support centres if needed.

When is the study starting and how long is it expected to run for?
August to December 2016

Who is funding the study?
The study receives no specific funding. The principal investigator is funded by the German Federal Ministry for Education and Research (BMBF).

Who is the main contact?
Dr Kayvan Bozorgmehr

Study website
https://www.gesundheitsheft.info/public/evaluation.jsp

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
S-438/2016

Study information

Scientific Title
Effectiveness of a patient-held health-record for asylum-seekers in reception centres to improve continuity of care: a cluster-randomised stepped wedge trial in a German federal state

Acronym
PHRASYL

Study objectives
The hypothesis of this intervention study is that a patient-held health record for asylum-seekers in reception centres improves the transfer of health-related information between providers and health care sectors and thereby improves continuity of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Medical Faculty of Heidelberg University, 29/08/2016, ref: S-438/2016

Study design
Cluster-randomised stepped wedge trial (including qualitative methods in form of a parallel mixed-methods design)

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
The study does not focus on specific conditions

Interventions
The intervention consists of the introduction and routine use of a patient-held health-record (PHR) for asylum-seekers in reception centres. The PHR is a paper-based structured document (DIN A5) consisting of: a cover page with information for asylum-seekers in 10 languages; information for the treating physicians; a flap to insert other documents (e.g. vaccination cards); a form for pre-existing conditions; a medication plan; a form for reasons of encounter, assessment results, diagnoses and therapies; a form for vital parameters; and a personal schedule for appointments. Once the PHR is introduced, it is used continuously in the respective health care setting.

The PHR will be introduced by cluster-randomisation in a stepped wedge design in all reception centres in a large administrative area of the federal state of Baden-Würrtemberg. The sequence of introducing the PHR is randomly determined at level of the reception centres (a total of five clusters). Allocation of clusters to the intervention remains concealed towards the authorities in charge of implementing the PHR. To allow for local preparations to introduce the PHR, authorities will be informed about the allocation of the randomly chosen reception centre towards the intervention 10 days in advance. The PHR will be introduced in 3-week intervals, so

that at the end of the study period the PHR will be introduced in all reception centres. Data will be collected for primary and secondary outcomes at the level of each patient-physician encounter on specific dates of the week (+/- 2 days) determined by a random procedure. Due to the stepped wedge design, the number of follow-ups in the post-intervention period (i.e. after the PHR has been introduced) differs between reception centres, ranging from 12 weeks (reception centre in which the PHR was first introduced) to 3 weeks (last reception centre in which the PHR was introduced).

Quantitative evaluation: Based on the turnover of patients in the reception centres, a total of 4,230 patient-physician encounters is anticipated to be assessed quantitatively in 15 weeks. Due to the heterogeneous care settings, the number of participating physicians cannot be determined in advance. Furthermore, it is anticipated that about 80 sentinel practices will be recruited in the three cities.

Intervention Type
Device

Primary outcome measure
Prevalence of health-related information in patient-physician encounters, assessed by physician questionnaire throughout the whole evaluation period twice per week at randomly determined days (Monday to Friday +/- 2 days). Measurement occasions are chosen randomly using a simple random procedure. Time-points for each measurement occasion remain concealed until the randomly chosen day and health care providers are not informed in advance of all measurement points. Sentinel practices are asked to measure the primary outcomes for each patient-physician encounter with an asylum-seeker during the 15 weeks.

Secondary outcome measures
1. Prevalence of "missing essential health-related information"
2. Physician satisfaction with the prevalence of health-related information

Secondary outcomes will be measured throughout the whole evaluation period twice per week at randomly determined days (Monday to Friday +/- 2 days). Measurement occasions are chosen randomly using a simple random procedure. Secondary outcomes are measured at the level of patient-physician encounters (physician-rated measurement). Time-points for each measurement occasion remain concealed until the randomly chosen day and health care providers are not informed in advance of all measurement points. Sentinel practices are asked to measure the secondary outcomes for each patient-physician encounter with an asylum-seeker during the 15 weeks.

Overall study start date
22/08/2016

Completion date
05/12/2016

Eligibility

Key inclusion criteria
Inclusion criteria for reception centres:
The centres must provide health care services

Inclusion criteria for physicians:
Working in the reception centres

Qualitative evaluation:
Health professionals and asylum-seekers (aged over 18) using the PHR

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4,230 patient-physician encounters

Total final enrolment
2308

Key exclusion criteria
Exclusion criteria for reception-centres:
The centres do not provide health care services on spot

Exclusion criteria for physicians:
Not working in the reception centres

Date of first enrolment
22/08/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Germany

Study participating centre
State Reception Centre Karlsruhe
Germany
76137

Study participating centre
State Reception Centre Mannheim
Germany
68159

Study participating centre
Reception Centre Heidelberg
Germany
69124

Sponsor information

Organisation
University Hospital Heidelberg

Sponsor details
Dept. of General Practice & Health Services Research
INF 130.3
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Government

Funder Name
University Hospital Heidelberg

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
The protocol of the trial will be published (manuscript in preparation at time of registration). The trial results will be disseminated to local authorities mandating the reception centres and healthcare providers working in the reception centres through personal communication and via workshops. The trial results will be published in a scientific journal (preferably open access). Results will also be made publicly available via the website of the PHR (in German): https://www.gesundheitsheft.info/. Final results will also be presented in national and international conferences.

Intention to publish date
05/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Kayvan Bozorgmehr

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/08/2019	21/08/2019	Yes	No