

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	☐ Prospectively registered ☐ Protocol
Registration date 14/12/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/08/2019	Condition category Other	☐ 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 There are no risks for participating physicians and participation can be withdrawn at any time throughout the study.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

Contact information

Type(s)
Scientific

Contact name
Dr Kayvan Bozorgmehr

Contact details
Dept. of General Practice & Health Services Research
University Hospital Heidelberg
INF 130.3
Heidelberg
Germany
69120 Heidelberg

Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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-Württemberg. 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

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 Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes