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# Improving the continuity of care in schizophrenia through an intervention delivered via mobile phones and internet: a pilot study

**Submission date**
03/07/2015

**Recruitment status**
No longer recruiting

**Registration date**
12/07/2015

**Overall study status**
Completed

**Last Edited**
18/08/2023

**Condition category**
Mental and Behavioural Disorders

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

**Plain English summary of protocol**

Background and study aims

Schizophrenia is a severe mental illness with a high risk of relapse. Following discharge from inpatient or day hospital psychiatric treatment, patients are confronted with the challenges of daily life and the management of their illness. Continuous support is important during this period, yet challenging to implement as part of routine mental healthcare. The aftercare intervention HEINS is delivered via mobile phones and internet and provides continuous low-threshold support to patients following their discharge from inpatient or day hospital treatment. In case of symptoms becoming worse, more intense professional support is offered to participants. It is expected that participation in the aftercare intervention has positive effects on patients' well-being and on their utilization of mental healthcare services following their discharge from the hospital. Overall, the study's findings should help to improve the continuity of care for patients with schizophrenia.

Who can participate?

Adult patients discharged from treatment for schizophrenia, schizotypal, or delusional disorder at the Department of General Psychiatry, University Hospital Heidelberg, Germany. Participation in the study requires that patients undergo treatment as usual following their discharge from the hospital (i.e., they have to have an outpatient mental healthcare provider). Furthermore, participation requires that patients have access to the Internet, possess a mobile phone, and have sufficient knowledge of the German language.

What does the study involve?

Participants are randomly assigned to one of two groups, i.e. either they receive treatment as usual or they receive treatment as usual plus participation in the aftercare intervention HEINS which is delivered via Internet and mobile phone for six months. HEINS is made up of several modules, i.e., psychoeducation, an individualized crises plan, and counselling via chat and/or telephone. The central module is a monitoring and feedback system. Once a week, participants answer a short questionnaire on their adherence to medication, sleep, anxiety, social contacts,

and well-being via their mobile phone. Participants receive an automated feedback message referring to their current status and changes. In case of severe impairment participants are contacted by the hospital in order to evaluate the situation and provide further support if necessary.

What are the possible benefits and risks of participating?
The intervention aims at strengthening self-management competencies, and the detection of early warning signs in order to prevent relapses and counteract deteriorations as early as possible. There are no known risks associated with participation.

Where is the study run from?
Center for Psychotherapy Research and the Department of General Psychiatry at the University Hospital Heidelberg (Germany).

When is the study starting and how long is it expected to run for?
July 2015 to April 2016

Who is funding the study?
Center for Psychotherapy Research, University Hospital Heidelberg (Germany)

Who is the main contact?
Dr Stephanie Bauer
stephanie.bauer@med.uni-heidelberg.de

# Contact information

### Type(s)
Scientific

### Contact name
Dr Stephanie Bauer

### Contact details
Center for Psychotherapy Research
University Hospital Heidelberg
Bergheimer Str. 54
Heidelberg
Germany
69115
00496221567345
stephanie.bauer@med.uni-heidelberg.de

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

N/A

# Study information

### Scientific Title
Is an aftercare intervention delivered via mobile phones and internet a feasible add-on to treatment as usual for patients with schizophrenia?

### Acronym
HEINS

### Study objectives
1. The intervention HEINS is well-accepted by the target population
2. The assessments and procedures prove to be feasible
3. Participation in HEINS yields to improved well-being six months after discharge from inpatient treatment compared to TAU
4. Participation in HEINS yields to improved service utilization in case of crisis within six months after discharge from inpatient treatment compared to TAU

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethikkommission der Medizinischen Fakultät Heidelberg [Ethics Committee of the Faculty of Medicine, University of Heidelberg], 01/06/2015, ref: S-147/2015

### Study design
Prospective single center randomized controlled trial; Pilot study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Other

### 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
Schizophrenia, schizotypal, and delusional disorders; ICD-10 Categories F20-F29

### Interventions

All patients undergo treatment at the Department of General Psychiatry at the University Hospital Heidelberg. Prior to discharge patients are randomized to one of two arms:
1. TAU (Treatment as usual): Patients in the TAU condition undergo the standard outpatient follow-up treatment, provided by an outpatient psychiatrist or the outpatient unit of the Department of General Psychiatry.
2. TAU plus HEINS (“Heidelberger Nachsorgeprogramm fuer Schizophrenie / Heidelberg aftercare program for schizophrenia”): HEINS is an aftercare program based on mobile phone and Internet technology. The intervention comprises several modules, i.e., psychoeducation, an individualized crises plan, and counselling via chat and/or telephone. The central module is a monitoring and feedback system. Once a week, participants answer a short questionnaire on their adherence to medication, sleep, anxiety, social contacts, and well-being via their mobile phone. Participants receive an automated feedback message referring to their current status and changes. In case of severe impairment participants are contacted by the hospital in order to evaluate the situation and provide further support if necessary. The duration of participation in HEINS is six months.

### Intervention Type
Behavioural

### Primary outcome measure
1. Willingness to participate: The proportion of the target population willing to participate in the study
2. Adherence: Utilization of HEINS modules and rate of drop-out from the intervention
3. Attitudes, expectations, and satisfaction: Attitudes and expectations towards Internet-based interventions at the beginning of participation and satisfaction with HEINS at the end of participation

### Secondary outcome measures
1. Feasibility of assessment instruments (questionnaires and interviews)
2. Feasibility of procedures and external randomization
3. Intervention effects on well-being six months after discharge from hospital (measured with the Positive and Negative Syndrome Scale; PANSS)
4. Intervention effects on service utilization within six months after discharge from hospital (measured with the Longitudinal Follow-up Evaluation; LIFE)

### Overall study start date
01/01/2015

### Completion date
31/12/2016

## Eligibility

### Key inclusion criteria
1. ICD-10 Diagnosis Categories F20-F29 (Schizophrenia, schizotypal and delusional disorders)
2. Inpatient or day hospital treatment at the University Hospital Heidelberg, Department of General Psychiatry
3. Outpatient follow-up treatment provided by an outpatient provider or the outpatient unit of the Department of General Psychiatry
4. Age: at least 18 years old

5. Sufficient German language skills
6. Mobile phone
7. Access to the Internet
8. Capability to give informed consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
50

### Key exclusion criteria
1. Dependence syndrome (except tacacco) in the last 2 years
2. Severe craniocerebral injury
3. Acute psychotic disorder with a duration of less than 4 weeks

### Date of first enrolment
15/07/2015

### Date of final enrolment
15/04/2016

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Department of General Psychiatry**
University Hospital Heidelberg
Voßstr. 2
Heidelberg
Germany
69115

## Sponsor information

**Organisation**
University Hospital Heidelberg Center for Psychotherapy Research

**Sponsor details**
Bergheimer Str. 54
Heidelberg
Germany
69115

**Sponsor type**
University/education

**Website**
www.psyres.de

**ROR**
https://ror.org/013czdx64

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Center for Psychotherapy Research, University Hospital Heidelberg (Germany)

# Results and Publications

**Publication and dissemination plan**
To be confirmed at a later date

**Intention to publish date**
31/12/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 25/11/2021 | 18/08/2023 | Yes | No |