

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/08/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Dependence syndrome (except tobacco) 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

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Sponsor information

Organisation

University Hospital Heidelberg Center for Psychotherapy Research

ROR

<https://ror.org/013czdx64>

Funder(s)

Funder type

Not defined

Funder Name

Center for Psychotherapy Research, University Hospital Heidelberg (Germany)

Results and Publications

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