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SMS study for alcohol dependence

Submission date	Recruitment status	[X] Prospectively registered
18/11/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/01/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/04/2018	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Alcohol dependence is a common disease with high rates of recovery but some patients may have many relapses. Not only is there a high risk of recurrent alcohol consumption after inpatient detoxification, but also many alcohol dependent patients do not respond well to further treatment. Inpatient treatments aiming at staying away from alcohol after discharge do not take into account that alcohol use disorders are chronic diseases and should be treated continuously. German counselling services may lose track of their patients. Feelings of guilt and shame and physical inability also constitute a barrier to treatment. Outreach services (home visits) are costly and therefore not common. One solution could be a mobile phone based system.

Who can participate?
Patients (age >=18 y) with alcohol dependence after inpatient alcohol detoxification in one of the participating hospitals in Rostock, Schwerin, Greifswald and Stralsund. Patients with dementia, acute psychoses and current use of illegal drugs cannot participate.

What does the study involve?
Patients are randomly assigned to one of two groups. In group 1, patients will receive automatically generated personalized mobile phone SMS: in month 1-2 twice a week, in month 3 once a week, and in months 4 to 12 every second week. Patients have to answer within 24h with "N" (no help is needed) or "J" (help is needed or relapse has occurred). They also may send an "emergency SMS" anytime. In this case, an e-mail will be sent to a therapist who will call the patient by telephone. The therapist will then provide brief telephone counselling and may recommend existing treatments (support, brief interventions, outpatient treatment or readmission). Patients sending "N" receive an automatically generated supporting SMS. Outcome parameters are assessed by a telephone studio 4 times during the following year. There is no exchange of information between therapists of the study and collaborators of the telephone studio. Group 2 is the control group and does not receive SMS but treatment as usual.

What are the possible benefits and risks of participating?
Patients in the SMS-group are in close contact with their therapists with a possible positive effect on alcohol consumption. There are no risks for either the SMS or the control group.

Where is the study run from?
Bethanien Hospital for Psychiatry and Psychotherapy, Odebrecht Foundation, Greifswald, Jens Langosch, MD; HELIOS Hospital Schwerin, Hospital for Addictive Disorders, Markus Stuppe, MD; Hospital for Psychiatry and Psychotherapy, University of Rostock, Rostock, Jacqueline Höppner, MD; Hospital for Psychiatry and Psychotherapy, University of Greifswald, Stralsund; Michael Lucht, MD
Lead centre: Hospital for Psychiatry and Psychotherapy, University of Greifswald

When is study starting and how long is it expected to run for?
Anticipated start date: 12/2011. Approximate duration of the trial: 30 months
The trial will be recruiting patients for 18 months

Who is funding the study?
German Research Foundation (Deutsche Forschungsgemeinschaft) (DFG)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
German Research Fund (DFG) Lu 849/2-1

Study information

Scientific Title
Continuity of care among alcohol dependent patients via mobile phone SMS: a randomised controlled trial

Study objectives
Evaluate the efficacy of a 12-months standardized outpatient interactive mobile phone SMS intervention to increase abstinence and non-heavy drinking (according to WHO criteria) rates in month 10-12 after randomisation in alcohol dependent patients after initial routine inpatient detoxification.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the University of Greifswald (Ethikkommission der Ernst-Moritz-Arndt Universität Greifswald) Friedrich-Löffler-Str, 17489 Greifswald approved on July 28th, 2011, Ref.-Nr. BB 79/11
2. Ethics Committee of the University of Rostock (Ethikkommission an der Medizinischen Fakultät der Universität Rostock), St.-Georg-Str. 108,18055 Rostock, Germany approved on August 18th, 2011; Ref.-Nr. A 2011 99

Study design
Randomised controlled two-armed multi-centre (four hospitals) ratio of intervention to control-group of 1:1

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Alcohol dependence; alcohol withdrawal

Interventions
Patients will receive automatically generated personalized SMS over mobile phones with the following regimen: in month 1-2 twice a week, in month 3 once a week, and in months 4 to 12 every second week. The SMS messages from the study centre are sent to receive information about relapses and need for help as early as possible. Patients have to answer within 24h with "N" (no help is needed) or "J" (help is needed or relapse has occurred). They also may send an

"emergency-SMS" anytime. In case of sending J, or in case of not replying, an e mail to a therapist will be generated by the system to call the patient by telephone. The therapist will then provide brief telephone counselling and may recommend routinely existing and available interventions (support, brief interventions, outpatient treatment or readmission).

Therapists of four hospitals in Mecklenburg-Pomerania will receive training for brief telephone counselling. A manual is provided detailing interventions to be recommended to the patient. Patients sending "N" receive an automatically generated supporting SMS.

Control group receives treatment as usual (TAU) only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Level of alcohol consumption with three ordered categories abstinence < non-heavy drinking < heavy drinking, using the WHO criteria of heavy drinking of > 60g/day for males and > 40 g/day for females, in months 10 to 12 after randomization

Secondary outcome measures
1. Cumulative drinking days
2. Standard consumption units
3. Number of heavy drinking episodes
4. Time to first heavy drinking episode
5. Utilisation of treatment services
6. Self-rated health quality
7. Craving
8. Social characteristics such as partnership and housing

Overall study start date
01/01/2012

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Alcohol dependence [Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV)]
2. Inpatient alcohol detoxification treatment
3. Male or female adult patients aged >18 years, legally competent
4. Able to read and send SMS messages
5. Written informed consent of the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
462

Key exclusion criteria
1. Expected noncompliance to the planned assessments
2. Acute withdrawal from illegal drugs within the last 6 months (amphetamines, cannabinoids, morphine, cocaine etc.); nicotine and benzodiazepines are no reason for exclusion
3. Participation in a drug substitution (e.g. methadone) program
4. Severe mental problems, particularly active psychoses and dementia
5. Life expectancy < 12 months due to severe comorbidities
6. Concomitant participation in other clinical trials before inclusion

Date of first enrolment
24/05/2012

Date of final enrolment
27/11/2013

Locations

Countries of recruitment
Germany

Study participating centre
Hospital for Psychiatry and Psychotherapy
Stralsund
Germany
18437

Sponsor information

Organisation
German Research Foundation (Deutsche Forschungsgemeinschaft) (DFG) (Germany)

Sponsor details

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Sponsor type
Government

Website
http://www.dfg.de

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft (Lu 849/2-1)

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	results	01/06/2014		Yes	No