

SMS study for alcohol dependence

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

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?

Michael Lucht, MD

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2014		Yes	No