

# SMS study for alcohol consumption reduction

<b>Submission date</b> 13/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/02/2013	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Alcohol dependence is a common disease with high rates of recovery but also high morbidity and mortality in chronic courses. Recurrent alcohol consumption occurs frequently after inpatient detoxification, and 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. Counselling services may lose track of their patients. Feelings of guilt and shame and physical inability also are barriers to treatment. Outreach services (home visits) are costly and therefore not common. One solution could be a mobile phone based system to maintain contact.

### Who can participate?

Patients (age  $\geq 18$  y) with alcohol dependence after inpatient alcohol detoxification in the psychiatric hospital in Stralsund, who can receive and send SMS and are able to answer questionnaires.

### What does the study involve?

Patients were randomly assigned to one of two groups. In the SMS-group, patients received automatically generated personalized mobile phone SMS twice a week for eight weeks. Patients were requested to answer within 24h with "B" (no help is needed) or "A" (help is needed or relapse has occurred). They also could send an "emergency SMS" anytime. In case of help-need, an e-mail was sent to a therapist who will call the patient by telephone. The therapist would then provide brief telephone counselling and may recommend existing treatments (support, brief interventions, outpatient treatment or readmission). Patients sending "B" received an automatically generated supportive SMS. Outcome parameters were assessed via telephone after 4 and 8 weeks. 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?

Hospital for Psychiatry and Psychotherapy at HELIOS Hansekllinikum, University of Greifswald, Stralsund; Michael Lucht, MD

When is the study starting and how long is it expected to run for?  
The study has already been conducted (Start: May 2009, End: May 2010)  
Approximate duration of the trial: 12 months

Who is funding the study?  
Hospital for Psychiatry and Psychotherapy, Greifswald University Medicine, HELIOS  
Hansekllinikum Stralsund, Germany.

Who is the main contact?  
Michael Lucht, MD  
lucht@uni-greifswald.de

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Michael Lucht

**Contact details**  
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## Additional identifiers

## Study information

**Scientific Title**  
An intervention using mobile phone short message service to reduce alcohol consumption among alcohol dependent patients

**Study objectives**  
Evaluate the efficacy of a 2-month standardized outpatient interactive mobile phone SMS intervention to increase low-risk alcohol consumption rates (males:  $\leq 30$  g alcohol/typical drinking day; females: females:  $\leq 20$  g alcohol/typical drinking day) in alcohol dependent patients after inpatient detoxification.

**Note:**  
We started with the SMS-system as clinical add-on to treatment as usual, to find out, if the system works (pilot-study). All patient signed an informed consent for participation and data

use. There was no randomisation at this stage. We then decided to proceed with a control group and applied for approval of the Ethics Committee. The first patient of the control group was included on November 11th, 2009 (after approval of the Ethics committee).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of the University of Greifswald (Ethikkommission der Ernst-Moritz-Arndt Universitaet Greifswald) Friedrich-Loeffler-Str, 17489 Greifswald, October 1st, 2009, Ref.-Nr. BB71/09

### **Primary study design**

Interventional

### **Study design**

Randomised controlled two-armed single-centre time frame randomisation

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Alcohol dependence

### **Interventions**

Patients will receive automatically generated personalized SMS via mobile phones twice a week for eight weeks. The SMS messages from the study centre are sent to receive information about relapses and need for help as early as possible. Patients are requested to answer within 24h with "B" (no help is needed) or "A" (help is needed or relapse has occurred). They also may send an "emergency-SMS" anytime. In case of sending a "B", 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).

Control group receives treatment as usual (TAU) only.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Level of alcohol consumption: attainment of low-risk alcohol consumption rates (males:  $\leq 30$  g alcohol/typical drinking day; females:  $\leq 20$  g alcohol/typical drinking day) as measured with FORM-90 AQ/AT by telephone in the time interval between four and eight weeks after discharge from hospital.

### **Key secondary outcome(s)**

1. Number of drinking days
2. Standard consumption units per consumption day

3. Number of heavy drinking episodes
4. Utilisation of treatment services

**Completion date**

08/05/2010

## Eligibility

**Key inclusion criteria**

1. Patients with alcohol dependence (ICD-10)
2. Inpatient alcohol detoxification treatment
3. Male or female adult patients aged  $\geq 18$  years, legally competent
4. Able to read and send SMS messages and answer questionnaires
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**

Does not meet inclusion criteria

**Date of first enrolment**

27/05/2009

**Date of final enrolment**

08/05/2010

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

**Hospital for Psychiatry and Psychotherapy**  
Stralsund  
Germany  
18437

## **Sponsor information**

### **Organisation**

University Medicine Greifswald (Germany)

### **ROR**

<https://ror.org/00r1edq15>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Hospital for Psychiatry and Psychotherapy, Greifswald University Medicine, HELIOS  
Hansekllinikum Stralsund (Germany)

## **Results and Publications**

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

### **IPD sharing plan summary**

Not provided at time of registration