

SMS study for alcohol consumption reduction

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Registration date 25/02/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/02/2013	Condition category 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 ≥ 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 Hanseklinikum, 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
Hospital for Psychiatry and Psychotherapy
University Medicine Greifswald at HELIOS Hansekllinikum Stralsund
Rostocker Chaussee 70
Haus 30
Stralsund
Germany
18437
+49 38381 452143
lucht@uni-greifswald.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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: ≤ 30 g alcohol/typical drinking day; females: females: ≤ 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

Study design

Randomised controlled two-armed single-centre time frame randomisation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

Level of alcohol consumption: attainment of low-risk alcohol consumption rates (males: ≤ 30 g alcohol/typical drinking day; females: ≤ 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.

Secondary outcome measures

1. Number of drinking days
2. Standard consumption units per consumption day
3. Number of heavy drinking episodes
4. Utilisation of treatment services

Overall study start date

27/05/2009

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 ≥ 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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)

Sponsor details

c/o Michael Lucht, MD

Hospital for Psychiatry and Psychotherapy,

University Medicine Greifswald at HELIOS Hanseklinikum Stralsund

Rostocker Chaussee 70

Haus 30

Stralsund

Germany

18437

+49 3831 452143

lucht@uni-greifswald.de

Sponsor type

University/education

Website

<http://www.uni-greifswald.de>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital for Psychiatry and Psychotherapy, Greifswald University Medicine, HELIOS Hanseklinikum Stralsund (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