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SMS study for alcohol consumption reduction

Submission date
13/01/2013

Recruitment status
No longer recruiting

Registration date
25/02/2013

Overall study status
Completed

Last Edited
25/02/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 Hanseklinikum Stralsund, Germany.

Who is the main contact?
Michael Lucht, MD
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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
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)

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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